# **GEMPACS**

# **Radiological PACS software**

# **Operation Manual**

#### **DRGEM Corporation**



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## **REVISION HISTORY**

Revision Number	Date	Description
0	JUN 28, 2024	First Release
1	SEP 10, 2024	Change of U.S. Entity Customer Service Contact Information
2	JAN 22, 2025	Delete PACS Alarm, PACS Order Content

#### ABOUT THESE INSTRUCTIONS FOR USE

The following advisory symbols are used throughout this manual.

Their application and meaning are described below.

<u>"Bold"</u>	Is used for Product's Name.		
<italic></italic>	Is used for references and for table or figure titles.		
'Button'	Is used for Button's Name.		
•	Indicates a list item.		
*	Indicates additional explanations.		
1. 1) a. i .	Indicates steps within operating sequences.		
WARNING	Warning symbol is used to indicate a potential hazard for operators and service personnel that can lead to serious injury, death or radiation exposure.		
CAUTION	Caution symbol is used to indicate a potential hazard for operators and service personnel that can lead to injury or damage of equipment.		
NOTE	Note symbol is used to indicate important information needed for proper use and correct operation of equipment.		

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#### **NOTE**

Keep this Manual with the equipment at all times, and review the important information whenever required.

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1. INTRODUCTION GEMPACS

#### 1. INTRODUCTION

This manual contains the necessary instructions for proper operation of <u>"GEMPACS"</u>. All persons operating this equipment need to have read this manual beforehand.

You must have a thorough understanding in the proper use of this product before you use this S/W.

#### 1.1 USE OF THE PRODUCT

Radiology can refer to two sub –field, diagnostic radiology and therapeutic radiology. Diagnostic radiology is concerned with the use of various imaging modalities to aid in the diagnosis of disease. Therapeutic radiology or, as it is now called, radiation oncology uses radiation to treat diseases such as cancer using a form of treat diseases such as cancer using a form of treatment called radiation therapy.

Commonly used techniques for diagnostic radiology includes.

- Computed tomography (CT)
- Magnetic resonance imaging (MRI)
- Ultrasound
- X-ray
- Nuclear imaging techniques.

#### 1.1.1 INTENDED USE

The <u>"GEMPACS"</u> is intended for use in obtaining, storing, communicating, displaying and diagnosis assisting in of human anatomic images for medical diagnosis.

DRGEM Corporation 1. INTRODUCTION

#### 1.1.2 INTENDED PATIENT POPULATION

The intended patient population can be divided into general adults and pediatric except for pregnant. Normal adult patient population is below.

Item	Content
Age	Everyone can use it, except for pediatric only.
Weight	Normal adult weight (weight above pediatric standard)
Height	Normal adult size height (height above pediatric standard)
Healthy	People suspected of injury or disease inside the human body, which cannot be identified
state	by appearance, take x-rays.
Nationality	The whole world

Normal pediatric patient population is below.

Item	Content			
Age	Description	Weight group	Age group based on weight-for-age charts	Most common age groups used for the NDRLs (or equivalent)
	Neonate	< 5 kg	< 1 m	0 y
Weight	Infant, toddler and early childhood	5 - < 15 kg	1 m - < 4 y	1 y
	Middle childhood	15 - < 30 kg	4 - < 10 y	5 y
	Early adolescence	30 - < 50 kg	10 - < 14 y	10 y
	Late adolescence	50 - < 80 kg	14 - < 18 y	15 y
Healthy	People suspected of injury or disease inside the human body, which cannot be			
state	identified by appearance, take x-rays.			
Nationality	The whole world			

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1. INTRODUCTION GEMPACS

#### 1.1.3 INTENDED USER PROFILE

The <u>"GEMPACS"</u> is intended for use by suitably trained and experienced personnel who have received specific training in the operation and use of the equipment. Medical staff must be suitably qualified to comply with applicable country-specific regulations for the use of x-ray equipment. This requires operating personnel to be familiar with the Operation Manual. This manual must be studied thoroughly prior to starting up the system. Special attention must be paid to general safety information.

The intended users are:

- Radiologists
- Radiographers (Technicians)
- Qualified trained nurses or doctors

#### **NOTE**

The user holds licenses as a nurse, radiographer, and doctor, and is required to undergo education on equipment usage methods. However, according to local regulations, they must also possess the qualification to operate X-ray systems.

#### NOTE

It is the responsibility of the system operator to ensure that operating personnel are professionally and properly instructed. Instruction is to be repeated at appropriate intervals. We recommend simulating emergency conditions during training so that appropriate conduct can be taught.

#### **CAUTION**

Federal law (USA) restricts this device for sale or use by or on order of a physician or properly licensed practitioner. Failure to do so may result in software malfunction and PC damage.

DRGEM Corporation 1. INTRODUCTION

#### 1.1.4 CONTRAINDICATION AND PRECAUTION

#### Contraindication

- 1. Only trained individuals should operate the GEMPACS.
- 2. Always log in using the designated username and password.

#### Precaution

- 1. Before using the GEMPACS, take note of the following:
  - Check if the disk capacity of the image storage device is sufficient.
  - Ensure that the power is turned on for each device.
- 2. During the use of the GEMPACS, observe the following precautions:
  - Do not save or delete medical images of patients being reviewed arbitrarily.
  - Refrain from using features that are not thoroughly understood.
  - Do not shut down the power or forcefully terminate the program during use.
- 3. After using the GEMPACS, observe the following precautions:
  - Close all viewed medical images upon completion of use.
  - Always log off from the program after use.
  - Never turn off the power to the image storage device after use.
  - Store the device in a dry environment at room temperature at all times.

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1. INTRODUCTION GEMPACS

#### 1.1.5 CLINICAL BENEFITS

The introduction of PACS into general radiography promises to eliminate some of the vexing problems associated with the management of large-volume imaging operations. Images can be made available simultaneously at local and remote sites within minutes of being obtained; images are rarely loss, and prior examinations are readily accessible. It is hoped that the ability to view the image itself promptly will also improve patient care. In fact, the use of a PACS system in a radiology department can significantly reduce the time to complete an X-ray examination by 35% to 52%, which can lead to an increase in the number of examinations per year, overall costs, and reduced time to results. Taken together, patients clinical benefit from faster x-ray imaging, which can help with diagnosis, clinical monitoring and treatment decisions.

#### 1.1.6 SIDE EFFECTS

Storage and retrieval of digital images is an integral component of any digital imaging system. A picture archiving and communication system (PACS) includes hardware and software that allows for display, storage, retrieval, and communication functions. PACS software allows for manipulation of the images to enhance interpretation by way of changes in contrast, brightness, magnification, and measurements, among others. Digital images for medical imaging should be in the digital imaging communications in medicine file format. This specified format allows for interconnectivity between imaging systems from different vendors and is important to ensure appropriate security. Related to above, Cybersecurity issues have been on the rise for years, increasingly affecting the healthcare sector. The import of patient data from storage media containing malware, a compromise of the hospital network, malware embedded in digital imaging and communications in medicine images or reports, a malicious manipulation of medical images and a network infiltration of malicious health level seven messages. This can result in leakage of patient image information, and can cause disruption in the event of a total system shutdown or network failure, such as a prolonged power outage.

#### 1.1.7 RESIDUAL RISKS

The overall residual risk was reviewed and assessed. And Despite the overall acceptable residual risk, we have provided information such as NOTE, CAUTION and WARNING in the operating to reduce the risk of patients and operators.

DRGEM Corporation 1. INTRODUCTION

#### 1.2 CUSTOMER SUPPORT

Address any questions regarding "GEMPACS" to:

#### **DRGEM Corporation**

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#### In USA,

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TEL: +1 (972) 924-9554

E-mail: service@drgemamerica.com



#### Obelis s.a.,

Bd.Général Wahis 53,1030 Brussels, Belgium Tel) +32.2.732.59.54, Fax) +32.2.732.60.03

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2 SAFETY INFORMATION GEMPACS

#### 2 SAFETY INFORMATION

The policy of DRGEM Corporation is to manufacture X-ray equipment that meets high standards of performance and reliability. We enforce strict quality control techniques to eliminate the potential for defects and hazards in our products. The intended use of this device is to obtaining, storing, communicating, displaying and diagnosis assisting in of human anatomic images for medical diagnosis.

The safety guidelines provided in this section of the manual are intended to educate the operator on all safety issues in order to operate and maintain "GEMPACS" in a safe manner.

The following warnings and cautions are specific to "GEMPACS".

Read them carefully - some of them are not obvious to typical use.

#### **NOTE**

According to Medical Devices Regulation (EU) 2017/745, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established. Contact our official dealer or DRGEM Representative. (Refer to the section 1.2)

#### **NOTE**

This manual contains important safety information.

An understanding of this information is critical to the safe operation of your equipment.

Please ensure that you read the warning notices before using the equipment.

#### 2.1 SYMBOL DEFINITIONS

The table below defines the meaning of various symbols used on labels on the software.



Consult accompanying documents (Required to consult for Safety)



Indicates the medical device manufacturer



Indicates the authorized representative in the European Community / European Union.



Indicates the manufacturer's catalogue number so that the medical device can be identified.



Indicates the manufacturer's serial number so that a specific medical device can be identified.



To identify the country of manufacture of products



Indicates the item is a medical device



(01)08800011170028

(11)

(21)

Indicates a carrier that contains Unique Device Identifier information.

2 SAFETY INFORMATION GEMPACS



A manufacturer declares that the product meets all the legal requirements for CE marking and can be sold throughout the EEA. This also applies to products made in other countries that are sold in the EEA.

This subsection defines the safety labels used inside and outside the "GEMPACS" cover or packaging.

#### **NOTE**

These labels and warnings are provided to alert service personnel that serious injury or damaged equipment will result if the hazard identified is ignored.

This information is provided to help you establish safe operating conditions for both you and your <u>"GEMPACS"</u>. Do not operate <u>"GEMPACS"</u> except in accordance with these instructions, and any additional information provided by the <u>"GEMPACS"</u> manufacturer and / or competent safety authorities.

#### 2.2 LIABILITY

#### 2.2.1 STATEMENT OF LIABILITY

While this <u>"GEMPACS"</u> has been designed for safe operation, improper operation or carelessness may result in damage to device. The manufacturer or its agents and representatives assume no responsibility for the following:

- Danger from improper use of the function.
- Problems or hazards resulting from failure to maintain the device as specified in the Installation chapter
- Device which has been tampered with or modified. DRGEM Corporation is not liable for any damage
  arising from failure to follow the instructions and procedures provided within the manuals or associated
  informational material, or from user failure to use caution when installing, operating, adjusting, or servicing
  this device. DRGEM Corporation is not liable for damage arising from the use of this product for any other
  use than that intended by the manufacturer.

#### 2.2.3 MANUFACTURER'S RESPONSIBILITY

Allow only authorized, properly trained personnel to operate this device.

No responsibility is assumed for any unit that has not been serviced and maintained in accordance with the Manual, or which has been modified or tampered with in any way.

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2 SAFETY INFORMATION GEMPACS

#### 2.3 IT NETWORK CHARACTERISTICS

"GEMPACS" may only be run in an environment approved or authorized by the manufacturer.

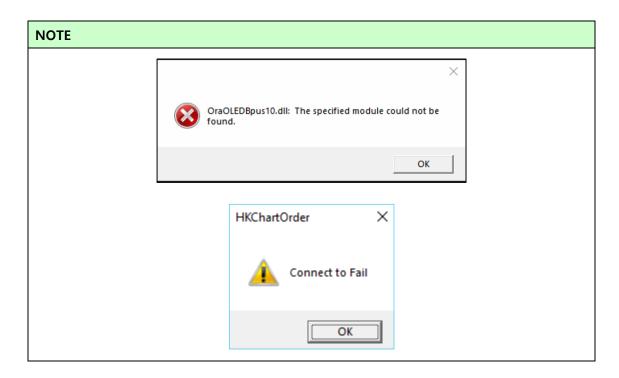
The manufacturer requests a firewall and an antivirus program preinstalled in user's workstation according to the institution's regulation.

"GEMPACS" provides the user interface for user access that the user can be authorized by entering valid User Name and/or Password.

DICOM communication for receiving/ sending data is made through the Ethernet port on a workstation. Optionally WIFI network can be used.

#### 2.4 WARNING & ERROR MESSAGES AND STATUS INDICATORS

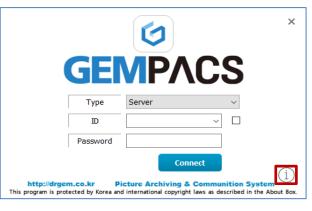
The software displays warnings, error and status messages as pop-up messages on the interface.



#### 2.5 LABEL LOCATION



This label is displayed GemPACS viewer.



The Label is displayed when you click the i-shaped icon in the GemPACS viewer..

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3. SYSTEM OVERVIEW GEMPACS

#### 3. SYSTEM OVERVIEW

#### 3.1 PRODUCT FEATURES

"GEMPACS" is software that manages, stores, retrieves, and transmits medical image data.

#### Image Viewing:

- Capable of viewing various types of medical images such as CT, MRI, and X-ray.
- Provides basic image manipulation functions like zoom, pan, and rotate.

#### Image Management:

- Organizes and manages images by patient, date, etc.
- Allows adding tags or notes to easily search for specific images.

#### Image Analysis:

- Includes basic measurement tools (e.g., length, angle measurement) to aid in accurate diagnosis.
- May feature advanced analysis tools such as density analysis and histograms.

#### Compatibility:

- Complies with the DICOM (Digital Imaging and Communications in Medicine) standard, ensuring compatibility with various medical devices.
- Supports data exchange with other PACS systems for an integrated healthcare environment.

DRGEM Corporation 3. SYSTEM OVERVIEW

#### 3.2 SPECIFICATION

The software specified for use with the <u>"GEMPACS"</u> has been selected, tested, and verified by DRGEM Corporation to meet the intended applications. All specified software meets applicable regulatory agency requirements for those countries where it is offered for sale with respect to its intended applications. It indicates a standard to refer to APPECNDIX C. APPLICABLE STANDARDS for details.

#### **WARNING**

Do not operate this system except in accordance with information included in this section, and any additional information provided by the manufacturer and / or competent safety authorities. Failure to do so may result in software malfunction and PC damage.

#### **NOTE**

GEMPACS is a software and has non-physical characteristics, and because it is unrelated to hardware, there is no separate product life.

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3. SYSTEM OVERVIEW GEMPACS

#### 3.2.1 GEMPACS CONFIGURATION PART

Part	Configuration
Software	GEMPACS

#### • Available Workstation

The minimum PC specifications are as follows.

CPU	Intel Core i5 10th or higher
Memory	8GB (1x8GB) DDR4 2400Mhz or higher
Display	Intel® HD Graphics 630 or Higher
Storage	256GB SSD, 1TB 7200RPM SATA HDD
OS	Windows 10 or 11
Monitor	23 inch Color LED or Higher, Display resolution: 1920 x 1080 pixels (16:9)

<sup>\*</sup> We recommend configuring backup storage to prevent data loss.

Please refer to <page 36> of the <GEMPACS Service Manual> document.

#### 3.2.2 SOFTWARE INFORMATION

#### • Software Version

Software/	Version	Description
GemPACS Server	4.0	"GEMPACS" is software that manages, stores, retrieves, and transmits
GemPACS Viewer	4.0	medical image data.

DRGEM Corporation 3. SYSTEM OVERVIEW

#### 3.3 ENVIRONMENT OF USE

#### **OPERATING ENVIRONMENT**

Ambient temperature range 10 °C to 45°C (50 °F to 113 °F)

Relative humidity range 20% to 80%, non-condensing

Altitude Limit This product is rated to operate at an altitude ≤3048m

#### TRANSPORT AND STORAGE ENVIRONMENT

Ambient temperature range -40 °C to 60°C (-40 °F to 140 °F)

Relative humidity range 20% to 80%, non-condensing

Altitude Limit This product is rated to operate at an altitude ≤10668m

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4. SYSTEM OPERATION GEMPACS

### 4. SYSTEM OPERATION

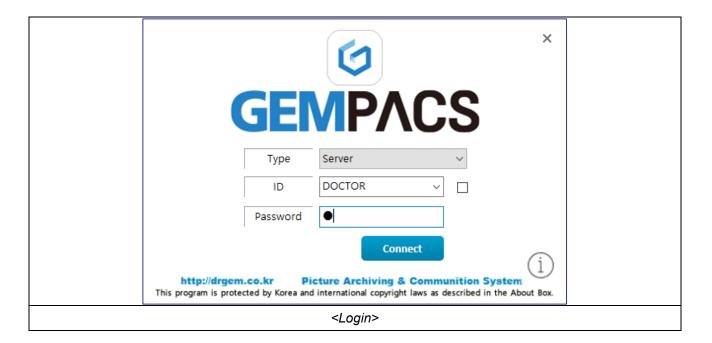
#### 4.1 SOFTWARE

#### **4.1.1 VIEWER**

#### 4.1.1.1 LOGIN

When you start this GEMPACS program, you will see the user login screen.

User selects a predefined server and enters their own ID and password to access the program.



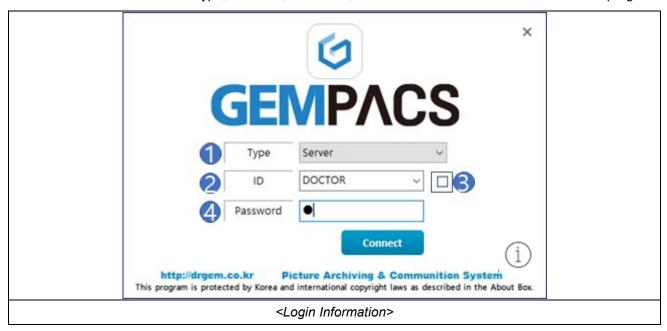
#### **NOTE**

If you do not see the login screen, you can use the Alt+Tab button to locate the login screen.

DRGEM Corporation 4. SYSTEM OPERATION

#### 4.1.1.1.1 LOGIN INFORMATION

The user selects the connection type, enters ID, Password, and click the Connect Button to access the program.



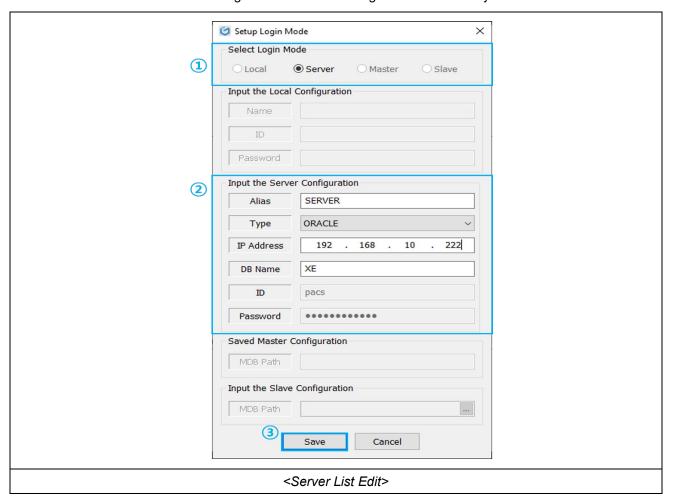
		- Select "Server" to access the server's database.
Type	Type	- When you select "Setup Login Mode", the Server Setting window
1	туре	appears where you can save the information of the server you want
		to connect to in advance.
	ID	- Enter your ID.
2	lD	- Click "▼" to display a list of previously used IDs.
	ID Save check box	If checked, the entered ID is saved and automatically entered when the
(3)	③ ID Save check box	program is restarted.
	Daggward	- Enter your password.
4 Pas	Password	- The entered password is displayed as "●●●●" to ensure user privacy.

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4. SYSTEM OPERATION GEMPACS

#### 4.1.1.1.2 LOGIN MODE CONFIGURATION

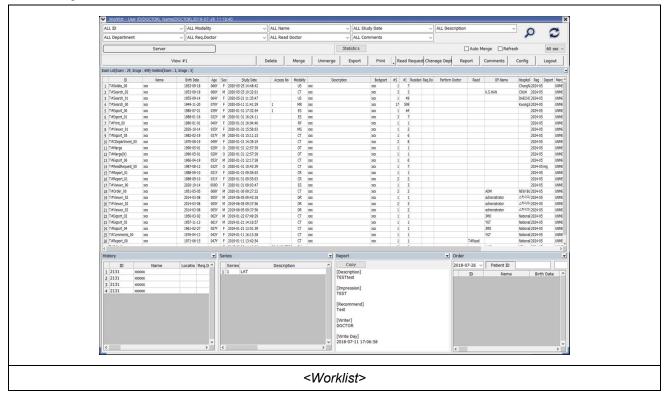
This is a window where user can configure the detailed settings of the server they want to use.



1	Select Login Mode	- You can select the database you want to configure.
	Input the	- Enter the information of the server you want to connect to.
2	Server Configuration	- For the type, you can select either Oracle or MSSQL, and configure it
	according to the installed server environment.	
	3 Save	After selecting/inputting the information, be sure to click "Save" button to
(3)		store the settings

#### **4.1.1.2 WORKLIST**

This is a window in the GEMPACS program where you can perform functions such as searching, editing, and transmitting related to the database.

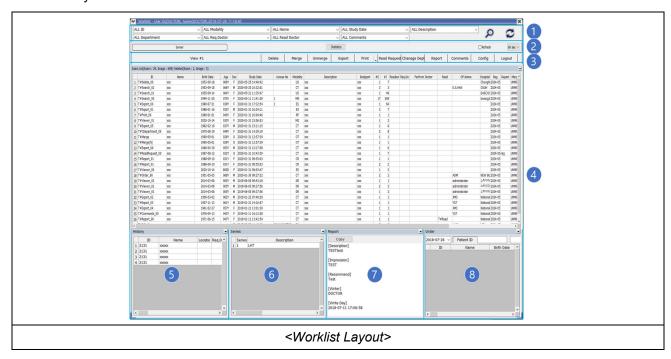


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4. SYSTEM OPERATION GEMPACS

#### 4.1.1.2.1 LAYOUT

The basic layout of the Worklist.



1	Search Condition Combo Box	You can set search conditions for each field.
2	Setting Tab	You can modify search functions such as auto-refresh and calculate examination statistics.
3	Toolbar	Buttons that perform various functions.
4	Exam List	Displays the search results for the server or local as a list
(5)	History List	Displays the history information for the exam selected in ④.
6	Series List	Displays the series information for the exam selected in ④.
7	Report Preview	Displays the report information for the exam selected in ④.
8	Order	Displays the order information of the PACS.

#### 4.1.1.2.2 **SEARCH**

This function searches for images stored in the database. It retrieves the relevant exam list information based on the set search conditions.



- Each search condition is represented by a combo box, allowing selection and direct input of each search criterion.
- The desired search conditions can be configured in the environment settings.
- After configuring the search conditions, clicking the ""> button initiates the search, and the results are displayed in the Exam List
- Clicking the "C" button resets the search conditions.

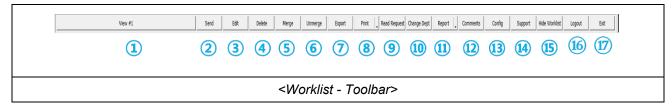
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4. SYSTEM OPERATION GEMPACS

#### 4.1.1.2.3 TOOLBAR

This is where the functions used in the Worklist are gathered.

There are also functions that call external programs for execution among the various functions.



( <u>1</u> )	View	This function transfers selected items from each list (Exam, History,
		Series List) to the View.
	Send	This function calls the Dicom Send program to transmit the selected
2		examination images from the list.
		This function modifies patient information for the selected examination
(3)	Edit	·
		images from the list.
<b>(4)</b>	Delete	This function deletes selected items from the Exam list.
( <del>5</del> )	Merge	This function merges selected items from the Exam list into a single Exam.
	Worgo	This furnished the first the Exam list line a single Exam.
		This function separates merged (Merge) Exams back into their original
6	Unmerge	Exams from the Exam list.
		This function saves selected items from the Exam list to a CD or a desired
7	Export	
		folder.
<b>(8)</b>	Print	This function prints selected items from the Exam list to a standard printer.
0	11110	The farious prints selected from the Exam list to a standard printer.
		This function changes the Read Doctor for selected items from the Exam
(9)	Read Request	list.
10	Change Department	This function changes the department for selected items from the Exam list.
( <u>11</u> )	Report	This function displays a reading window for selected items from the Exam
•••		list.
	0	This formation adds assume that a select of the second of Freeze P. C.
12	Comments	This function adds comments to selected items from the Exam list.
13	Config	This function configures the environment settings for the current program.
<u>(14)</u>	Support	This function calls remote-related programs (or websites).
•••		

15)	Hide Worklist	This minimizes the Worklist window to hide it.
16	Logout	This logs out, returning to the login window.
17)	Exit	This exits the program.

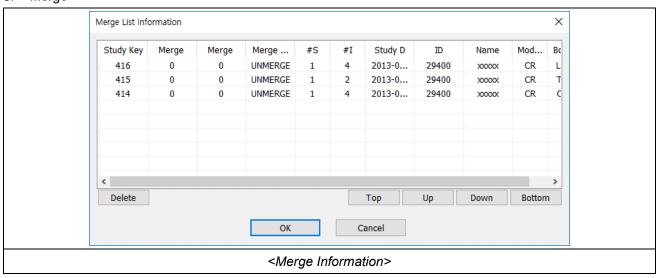
#### 1. View

- This function transfers selected items from the lists to the View.
- Items can also be transferred to the View by double-clicking them in each list (Exam List, History List, Series List).

#### 2. Delete

- This function deletes selected Exams from the Exam list.
- When one or more Exams are selected in the Exam list and the "Delete" button is clicked, a confirmation window appears to confirm the deletion. Clicking "OK" button proceeds with the deletion, while clicking "Cancel" button cancels it.
- Deleted Exams are moved to a designated storage location, and if restoration is needed, users should contact the administrator.

#### 3. Merge



- This function merges two or more Exams into one.
- If already merged Exams are selected and the Merge function is executed, an error message appears, and the operation is canceled.
- When two or more Exams are selected in the Exam list and the "Merge" button is clicked, the Merge window appears

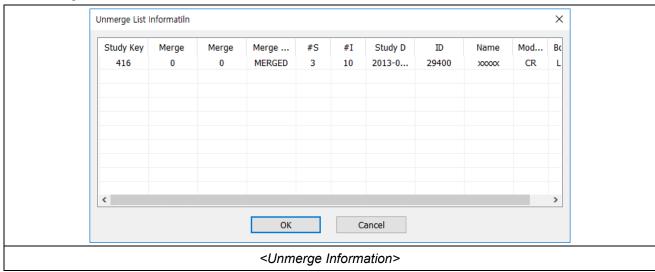
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4. SYSTEM OPERATION GEMPACS

- In the Merge window, the order of Exams can be adjusted using the up and down buttons. Clicking "OK" button executes the Merge.

- Pressing the "Delete" button removes the selected items from the Merge list.
- After merging, only the top-level Exam appears in the list, and the Merge field in the Exam list changes to 'Merged'.
- The Merge status field can be configured in the environment settings and viewed in the Exam List.

#### 4. Unmerge



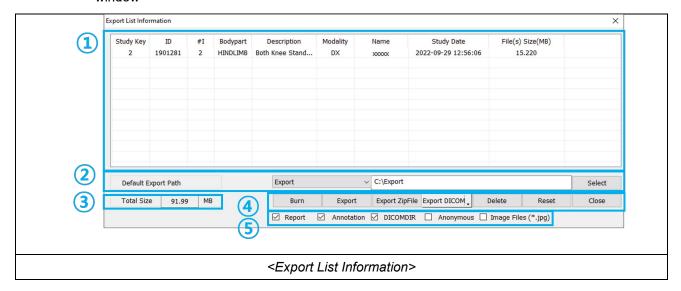
- This function restores a merged Exam back to its original individual Exams.
- If an Exam that has not been merged or two or more merged Exams are selected and the Unmerge function is executed, an error message appears, and the operation is canceled.
- When a merged Exam is selected in the Exam list and the "Unmerge" button is clicked, the Unmerge window appears
- Clicking the "OK" button, restores the merged Exams back to their original state.
- The Merge field value of the restored merged Exams changes to 'Unmerged'.
- The Merge status field can be configured in the environment settings and viewed in the Exam List.

#### 5. Export

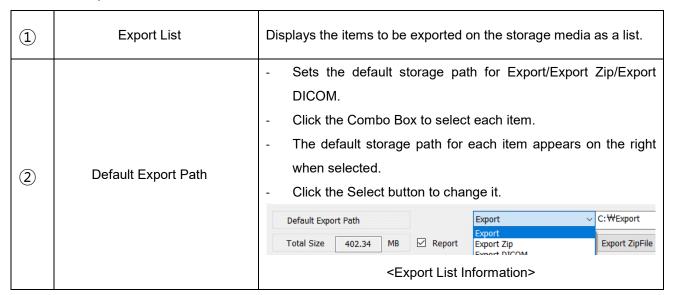
- The Export function allows the selected Exams in the Exam list to be saved to a CD or desired folder.
- However, if the CD burning program is not present or damaged within the same folder, the Export button may not appear.

#### 1) CD Export

Select one or more Exams in the Exam list and click the "Export" button to display the Export List window



- a) The Export List Information window displays the selected Exam list.
- b) If you close the Export List Information window and then select items to export again from the Exam List and click the Export button, both previously selected items and currently selected items are added to the list.
- c) To reset the list, click the Reset button.



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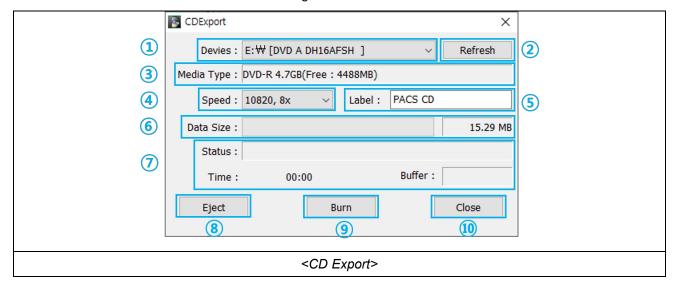
4. SYSTEM OPERATION GEMPACS

			<u></u>
3	Total Size		<ul> <li>Displays the total size of the images set in the Exam List.</li> <li>Users need to adjust the size according to the capacity of the CD when copying to a CD.</li> </ul>
4	Toolbar	Burn	<ul> <li>Clicking the "Burn" button in the CD Burn Queue launches an external program called CD Burning</li> <li>The CD contains the CD Viewer and the selected Exam images.</li> </ul>
		Export	<ul> <li>CD Viewer and selected Exam images are saved to the user-specified folder.</li> <li>When Export is executed, a screen for selecting the folder appears. Once the desired folder is selected and confirmed, the saving process begins in that folder.</li> </ul>
		Export Zip File	<ul> <li>CD Viewer and selected Exam images are saved in compressed format to the user-specified folder.</li> <li>Executing Export Zip File saves the compressed file to the Export Zip path.</li> <li>The compressed folder needs to be extracted using a compression program before it can be used.</li> </ul>
		Export DICOM	<ul> <li>Only the DICOM (DCM) files of the selected Exam images are saved to the user-specified folder.</li> <li>Executing Export DICOM saves the folder to the Export DICOM path.</li> </ul>
		Delete	Deletes the selected items from the Exam List.
		Reset	Clears all contents of the Exam List.
		Close	Closes the Exam List Information window.
	Option	Report	If checked, the report content is exported along with the images.
		Annotation	If checked, the annotations of the images are exported along with them.
(5)		DICOMDIR	If checked, a DICOMDIR file is created for the images and exported along with them.
		Anonymous	If checked, the images are exported in an anonymized form.
		Image File (*.jpg)	If checked, jpeg image files of the exam images are exported along with them.

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#### 2) CD Export

This is the actual window for burning CDs

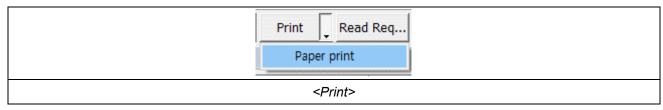


1	Devices	Select the device for burning from the list of devices attached to the PC.	
2	Refresh button	Re-scans information about the CD/DVD drive.	
3	Media Type	Displays the type of media (CD/DVD) present in the CD/DVD drive.	
4	Speed	Sets the burning speed when burning a CD.	
(5)	Label	Sets the label name of the storage media.	
6	Data Size	Displays the total size including the CD Viewer program file.	
7	Status	Displays status messages during CD/DVD burning.	
8	Eject button	Ejects the CD from the CD/DVD drive set in Devices.	
9	Burn button	<ul> <li>When you click the Burn button, the button's label changes to 'Cancel' and the operation begins.</li> <li>If a storage medium that does not exist or cannot be burned is inserted, burning does not start, and an error message appears.</li> <li>Clicking the Cancel button cancels the operation.</li> </ul>	
10	Close button	Closes the window.	

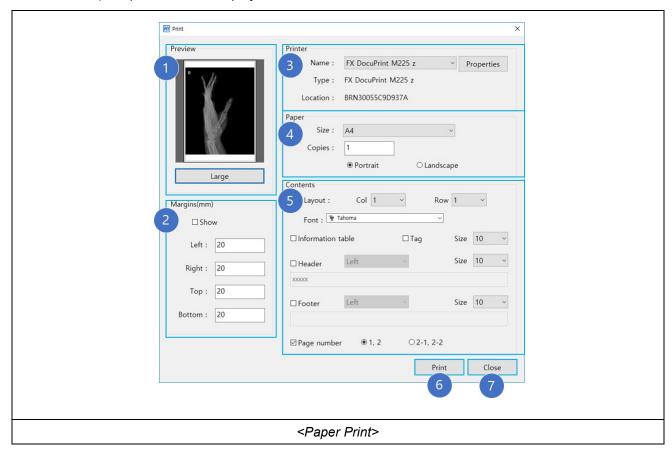
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#### 6. Print



- This function allows printing DICOM images of selected Exams on a regular printer.
- Select one or more Exams from the Exam List and click the Print button or the expanded button to the right of the Print button, then click the Paper Print button.
- Selecting Paper Print displays a screen
  - 1) Paper Print
    - a) This feature enables printing images of selected Exams on a regular printer.
    - b) A print windows displayed.

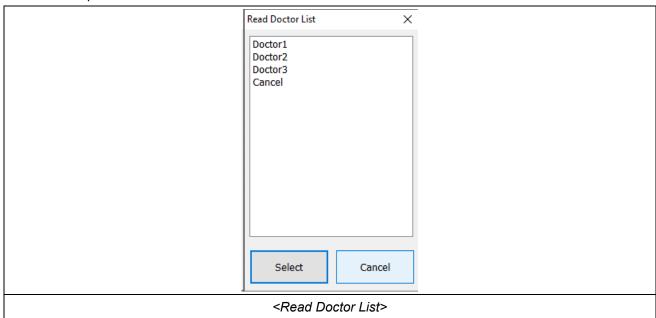


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	<u> </u>		
	PreView		- Displays a preview image to be printed.
			- Clicking the "Large" button allows for a larger view
1			R I I I I I I I I I I I I I I I I I I I
			<large preview=""></large>
2	Margin		<ul><li>Sets the margins of the printed paper.</li><li>Show: Displays the border of the margin.</li></ul>
_			
3	Printer		Selects the printer for printing.
4	Paper		Selects the paper type/quantity/printing paper direction.
	Content	Layout	Sets the layout of the images to be printed.
		Font	Sets the font
		Information Table	Selects to display patient information and examination details.
(5)		Tag	Checks the image information to be printed together
		Size	Selects the font size of the left item in the Size combo box.
		Header /Footer	Adds header and footer.
		Page Number	Displays page number and format.
6	Print button		Starts printing.
7	Close button		Cancels the operation and closes the window.

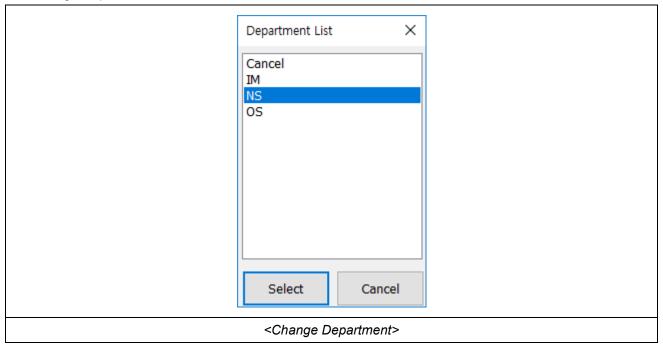
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## 7. Read Request



- This function requests reading for the selected items in the Exam List.
- To use it, there must be a "Read Doctor" item in the search criteria, and at least one doctor must be registered via Custom Add.
- To add "Read Doctor" to the search criteria, refer to Config.
- Select the doctor to whom you want to assign the reading then click the Select button.
- The Read column value in the Worklist will change to the selected value.
- To cancel a previously selected request, choose the "Cancel" in the list and click the Select button.

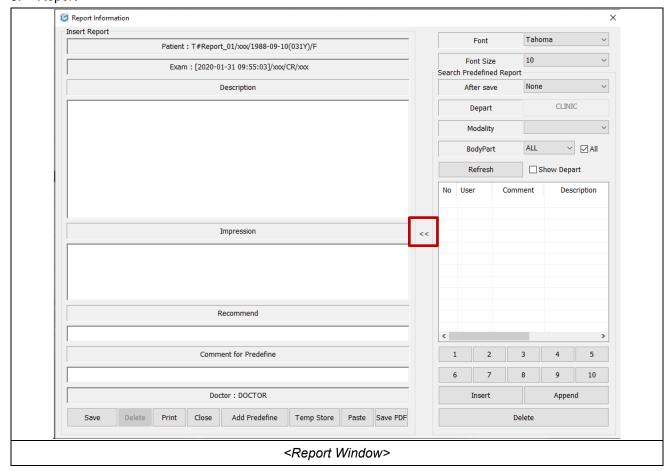
## 8. Change Department



- This function changes the department for the selected items in the Exam List.
- To use it, there must be a "Department" item in the search criteria, and at least one department must be registered via Custom Add.
- To add "Department" to the search criteria, refer to Config.
- Select the department to which you want to assign the examination, then click the Select button.
- The Department column value in the Worklist will change to the selected value.
- To cancel a previously selected assignment, choose the Cancel option in the list and click the Select button.

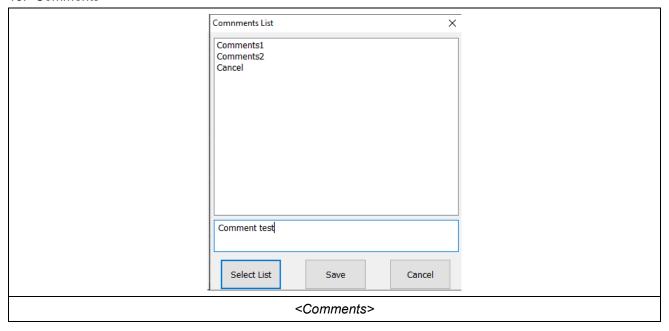
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### 9. Report



- This function displays a reading window for the selected items in the Exam List.
- Only users with authorization to write reports can enter content.
- The font of the current Report window can be modified using the Font and Font Size options on the right.
- The '<<' button can be used to hide or show the UI to the right of the button.

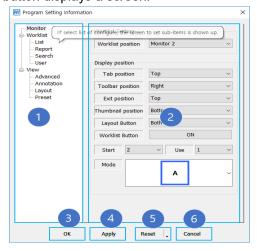
#### 10. Comments



- This feature allows adding comments to the selected items in the Exam List.
- If the search criteria include the Comments item, previously registered comments can be selected for use; otherwise, comments can be directly entered for addition.
- To add Comments to the search criteria, refer to Config.
- Upon selecting the item to input and clicking the Select button, it appears in the input field below. After addition (or modification), clicking the Save button will store the comment. Alternatively, it will be saved directly upon double-clicking from the list.
- The Comments column value in the Worklist changes to the selected value.
- To cancel, select the Cancel item from the list and click the Select button.

#### 11. Config

- Config is a feature that allows configuring all aspects related to the program.
- Clicking the "Config" button displays a screen.

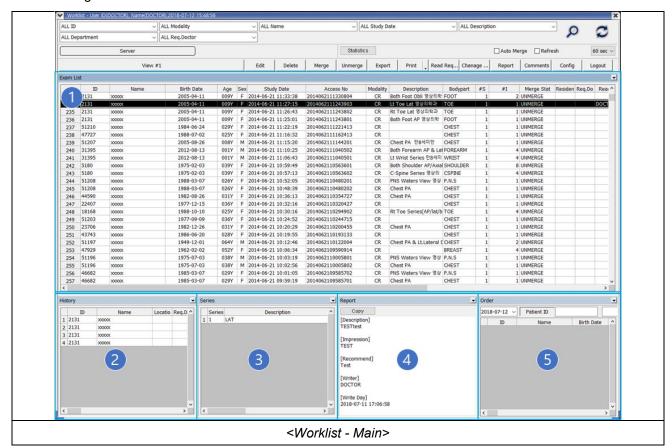


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#### 4.1.1.2.4 MAIN

Main is the primary screen that displays Exam List, History List, Series List, Report List, and Order List from the Worklist.

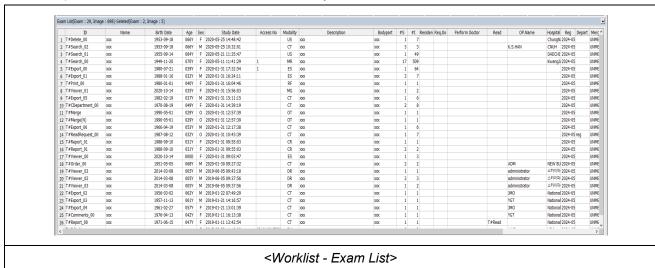
From the Main screen, users can select items from the lists and perform various functions. Additionally, they can transmit images to the View.



1	Exam List	This is the default list provided by the Worklist, offering various				
		functionalities.				
	History List	Displays the history related to the selected item(s) from the Exam List in				
2	Tilstory List	the Worklist.				
	Coming Lint	Shows the Series list included in the selected item(s) from the Exam List				
3	Series List	in the Worklist.				
		Displays the reports included in the selected item(s) from the Exam List				
4	Report List	in the Worklist.				
(5)	Order List	Shows the Order information from the PACS.				

#### 1. Exam List

The list displays Exams. Users can select one or more items from the list, enabling various functionalities to be performed on the selected items. Additionally, selected items can be transmitted to View.

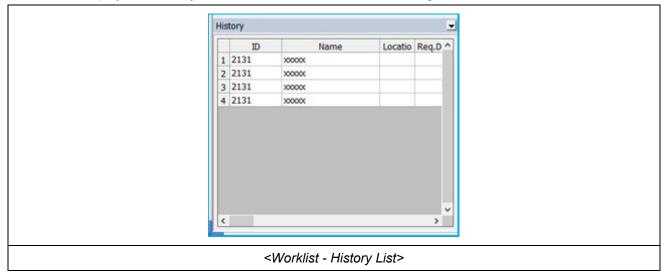


- The list displays the Exam items retrieved from the Server DB using the specified search criteria.
- Users can customize the fields displayed in the Exam list, as well as adjust font and boldness settings,
   through the configuration options available in the Worklist-List section.
- Exams can be selected using the mouse, allowing for single or multiple selections via mouse drag.
- Users can double-click on an Exam item or click the "View" button in List 4.1.1.2.3 (Tool Bar) to transmit the images to View for examination.
- Upon selecting an Exam, the list presents information about its associated History, Series, and Report in separate lists.
- Double-clicking on an Exam item directly transmits its image list to View.
- When the "View" button is clicked, all selected items are transmitted to View.
- Users can utilize the right-click context menu for additional actions:
  - Search with Same PatientID
  - Search with Same Modality
  - Search with Same StudyDate
  - Search with Same StudyDescription
  - Reset Search Condition
  - Whole Search Again
  - Report Window
  - Report (Normal)
  - Export to Exam List
  - Change Use Status (UnRead -> Read, Read -> UnRead)

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### 2. History List

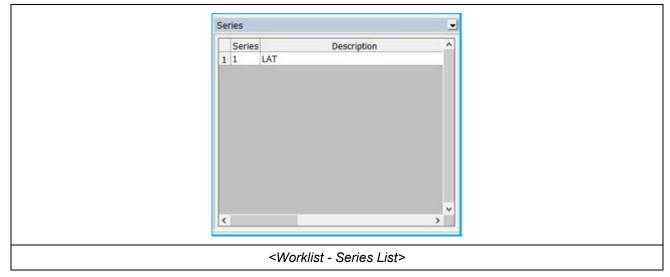
The list displays the History information related to the selected images in the Exam list.



- The list displays the History information related to the currently selected Exam's patient history.
- Field selection for the History list can be configured in the Worklist-List section of the environment settings
- You can double-click or select an item in the History list and then click the "View" button in List 4.1.1.2.3 to transmit the images to the viewer.

#### Series List

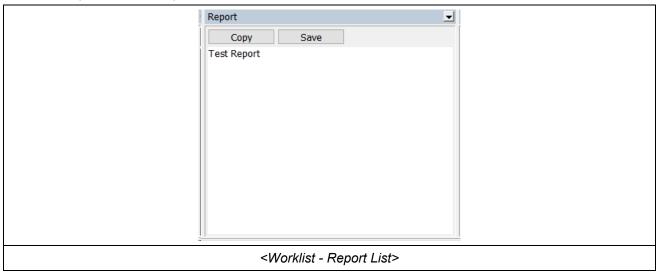
This list presents the Series information of the selected images from the Exam list.



- This list displays the Series of the currently selected Exam.
- You can customize the fields displayed in the Series list through the settings in Worklist-List
- To view the images associated with a Series, double-click on the corresponding item or click the "View" button in List 4.1.1.2.3

### 4. Report List

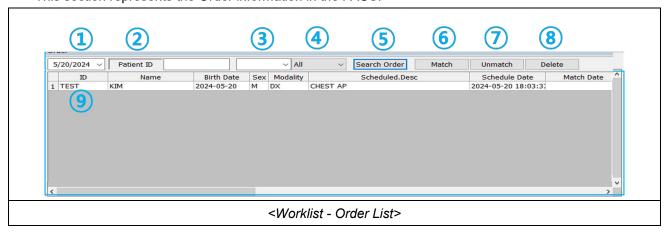
This list presents the Report information associated with the exam in the Exam list.



- It shows the list of reports belonging to the currently selected Exam.
- Accounts with writing permissions can create and modify reports. However, during the initial creation, only the Description can be filled out. The changes can be applied by clicking the "Save" button.

### 5. Order List

This section represents the Order information in the PACS.



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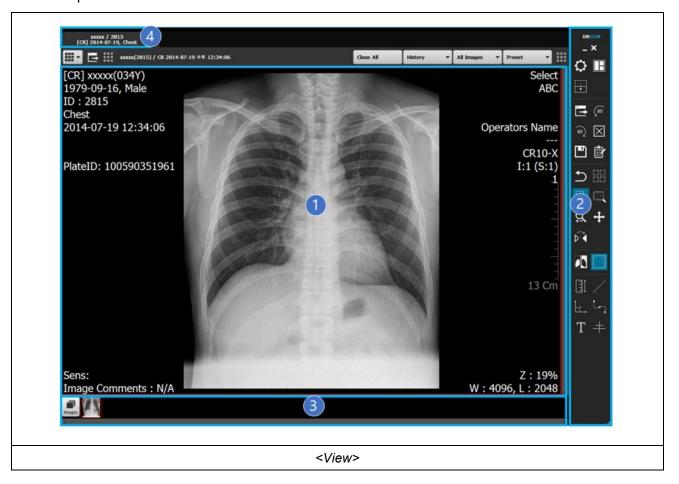
1	Date	Sets the date of the order being searched.	
2	Patient ID	Inputs the patient ID for the search.	
3	Modality	Selects the modality for the search.	
4	Order Status	Opens a dropdown menu where the status of the order to be queried can be set.  All Search Order Scheduled.Desc Matched	
(5)	Search Order	Displays search results in the Order List (9) based on the input conditions in 1234.	
6	Match	Matches the selected order from the Order List (⑨) with the selected exam from the Exam List.	
7	Unmatch	Cancels the matching of the order selected in the Exam List.	
8	Delete	Deletes the selected order from the Order List (⑨).	
9	Order List	Displays the search results.	

## 4.1.1.3 VIEW

The screen displays and allows control of DICOM images received from the Worklist, and it consists of four main components, as follows:

- Main Display
- Tool Bar
- Thumbnail
- Exam Tab

These components are structured.

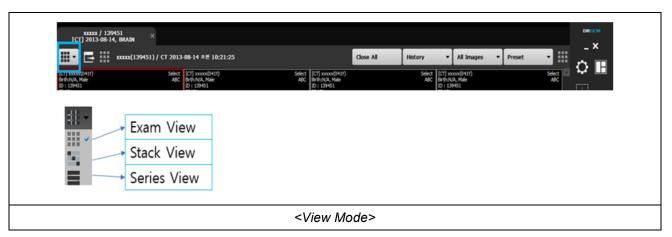


1	Main Display	This area is designated for displaying images.	
2	Tool Bar	It provides functions used in the viewer.	
3	Thumbnail	It displays the entire image set for the selected examination in small images.	
4	Exam Tab	It displays one exam in one tab.	

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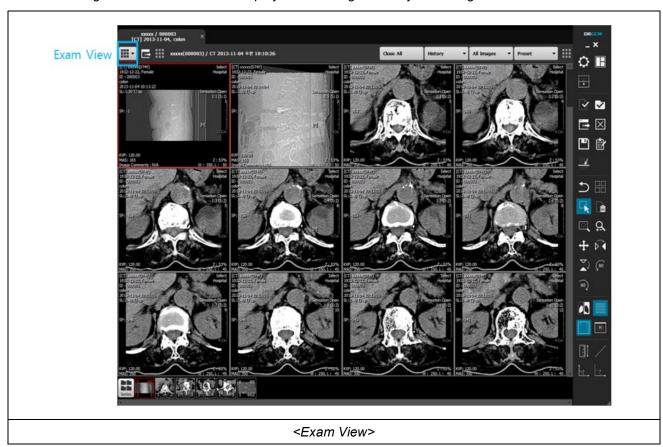
# 4.1.1.3.1 VIEW MODE

The DICOM images received from the Worklist are displayed in various ways by selecting Exam/Stack/Series Mode.



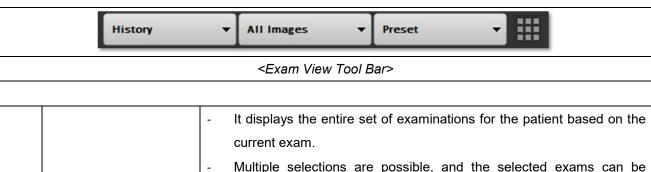
### 4.1.1.3.2 EXAM VIEW

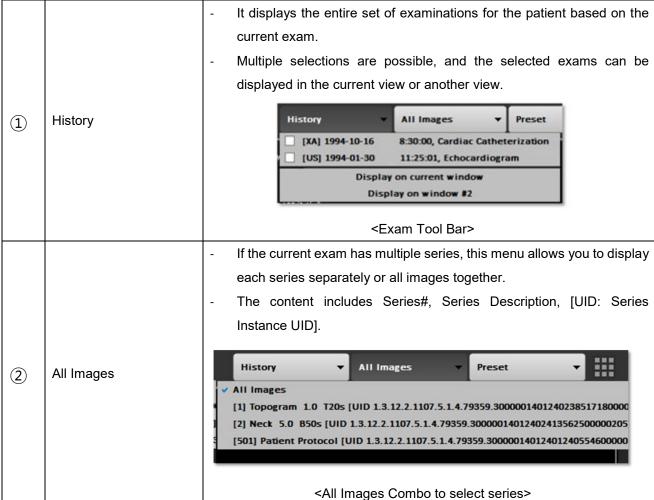
The entire image of the examination is displayed according to the layout settings.



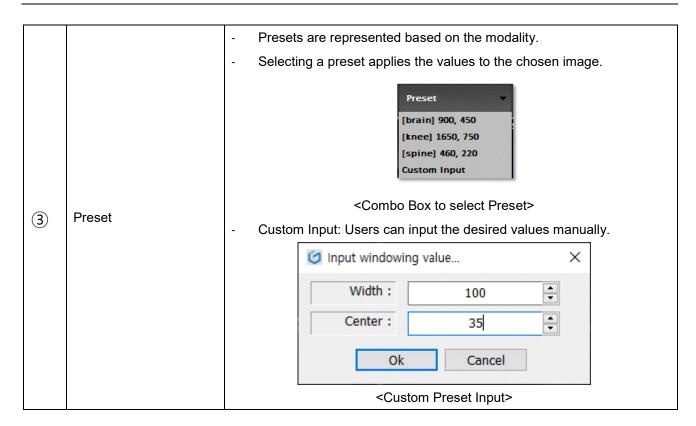
### 4.1.1.3.3 EXAM VIEW TOOL BAR

In Exam View Mode, you can directly access past images without going through the Worklist screen using the "History" function. Additionally, you can view and display images of the series part of the examination using the "All Images" feature. Furthermore, you can load preset values for "Window Width / Center" using the "Preset" function.





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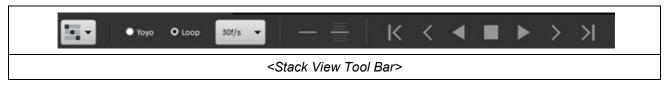
## 4.1.1.3.4 STACK VIEW

Display the entire set of images for the examination in accordance with the layout settings on a series-by-series basis.



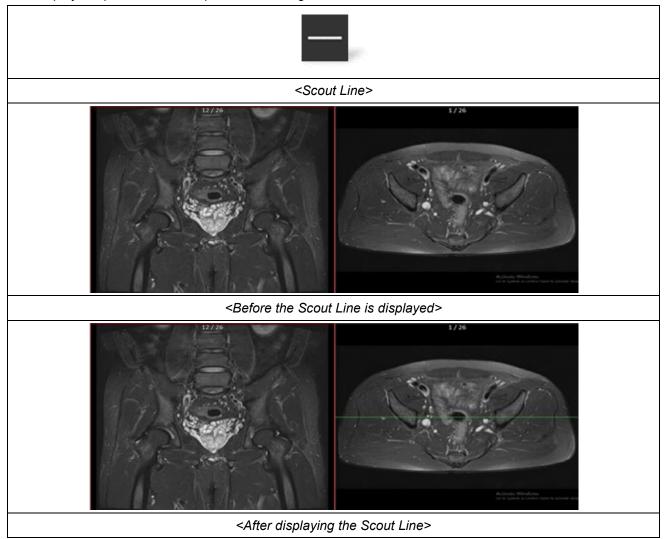
### Stack Tool Bar

In Stack View Mode, the examination is displayed on a series-by-series basis. It includes features such as the "Scout Line" to indicate the position of slices captured in CT or MR scans, "3D" for three-dimensional rendering, and the ability to play multiframe images as videos.



## 1. Scout Line

Display the position of the captured slice images.



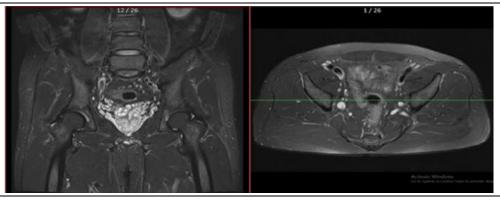
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# 2. All Scout Line

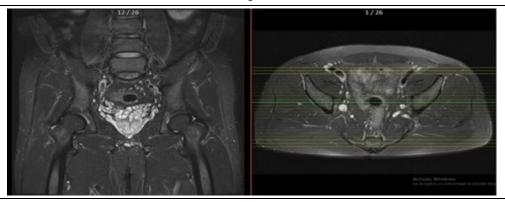
Display the positions of all captured slice images.



<Scout Line>



<Before showing All Scout Line>



<After displaying All Scout Line>

# 3. Video

This is a function that allows you to view multiple images in one series like a video.



1	First Image View	K	It shows the first frame of the series.
2	Previous Image View	<	It shows the previous frame of the currently displayed image.
3	Reverse Play View	<b>▼</b>	Reverse play of the series' images.
4	Stop		Pauses the playback of the series' images.
(5)	Play View		Plays the series' images in forward direction.
6	Next Image View	>	Shows the next frame of the currently displayed image.
7	Last Image View	X	Shows the last frame of the current series.



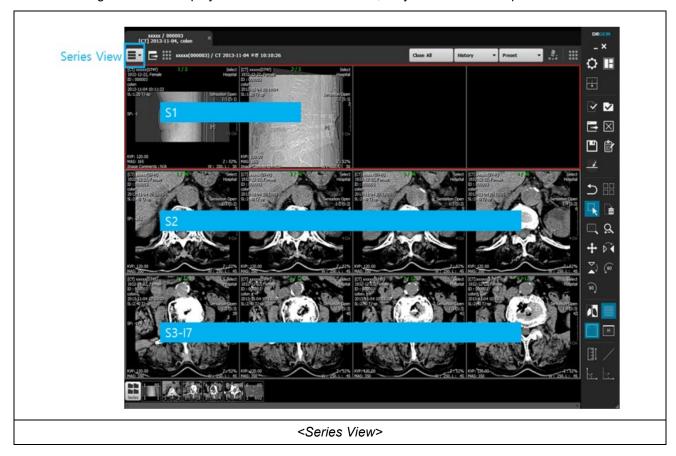
	Yoyo		Changes the direction of video playback
1		Yoyo	from forward to reverse or from reverse to
			forward.
	Loop	O Loop	The video plays repeatedly in one
2	Loop	Coop	direction only.
	Dlay Speed		Sets the number of frames per second that
3	Play Speed	30f/s ▼	can be played.
4	Clear	4	Clears the series displayed on the screen.

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# **4.1.1.3.5 SERIES VIEW**

Display the entire set of images for the examination in accordance with the layout settings, arranged horizontally by series.

When selecting a series to display from the Thumbnail screen, they are shown in sequence.

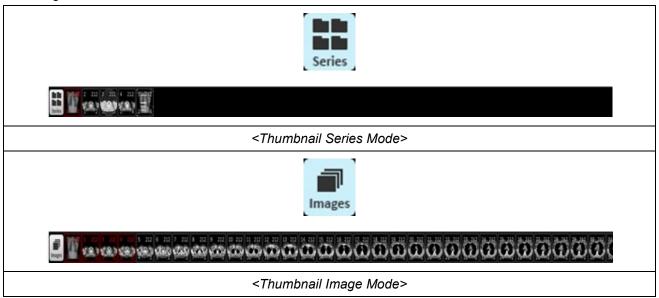


## **4.1.1.3.6 THUMBNAIL**

Display images for the examination as thumbnails and display the first image of the series.

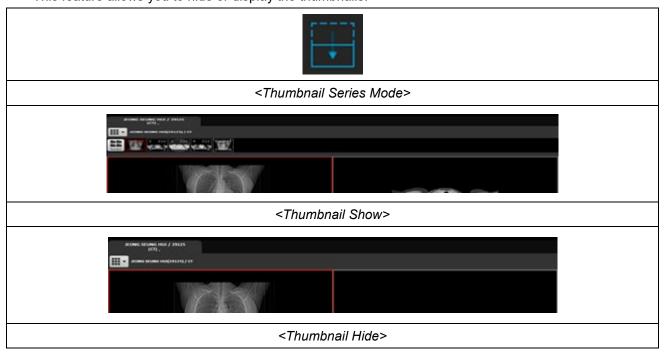
## 1. Thumbnail Series / Images

Thumbnails are displayed at the series level when Series Mode is selected and at the image level when Image Mode is selected.



## 2. Thumbnail Hide / Show

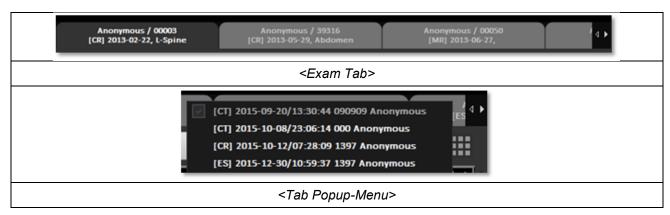
This feature allows you to hide or display the thumbnails.



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### 4.1.1.3.7 EXAM TAB

Tabs are created on an exam-by-exam basis, allowing you to display the desired exam in the "Main View" using the Exam Tab.



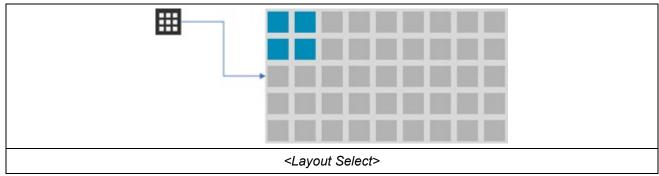
- The currently active (selected) exam tab is displayed in bold, while inactive tabs are shown in gray.
- Clicking on an inactive tab activates it, displaying the images of the corresponding exam on the screen.
- If all tabs are not visible, you can select the desired exam from the popup menu that appears when you right-click, or navigate through tabs using the left and right arrows to activate them.

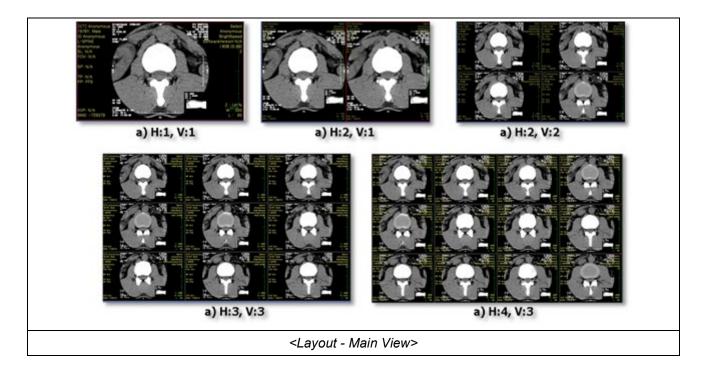
#### 4.1.1.3.8 LAYOUT

This is where various layout features used in the View are consolidated.

### 1. Layout Select

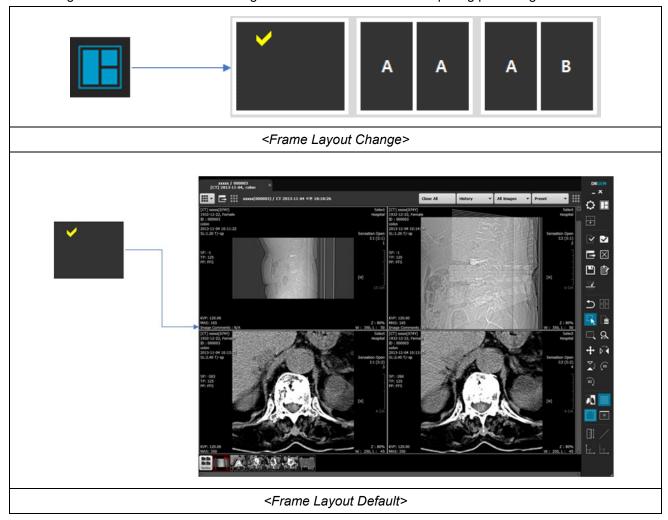
This function allows you to set the number of rows and columns for displaying images horizontally and vertically. The configuration of the Layout Combo Box can be adjusted in the Layout section of the environment settings.



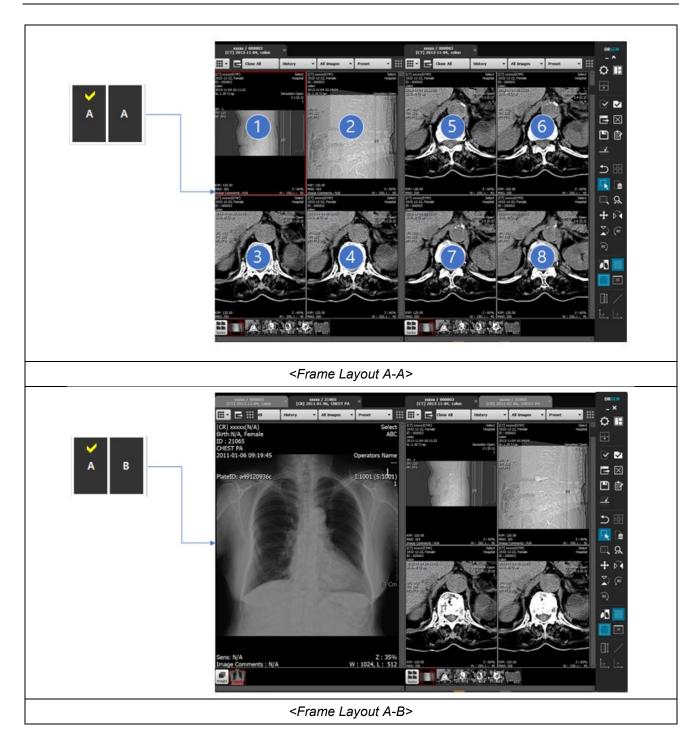


# 2. Frame Layout Change

Configure the Exam to simulate using one monitor as two or for comparing past images.



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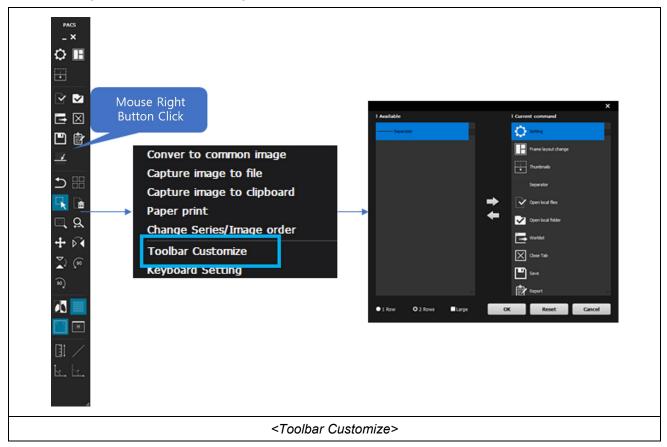
- Set the Frame Layout Default screen as the default when calling images from the Worklist.
- Display the examination, resembling an open book, using the Frame Layout A-A screen.
- Display the examination as recognized for a different test, using the Frame Layout A-B screen as depicted.

### 4.1.1.3.9 VIEWER TOOL BAR

Describes the icon customization in the View function, the View shortcut function, and the Context Menu.

### 1. Toolbar Customize

Right-clicking within the Tool Bar area brings up the "Context Menu", as shown below. Click on the "Toolbar Customize" menu in this "Context Menu".

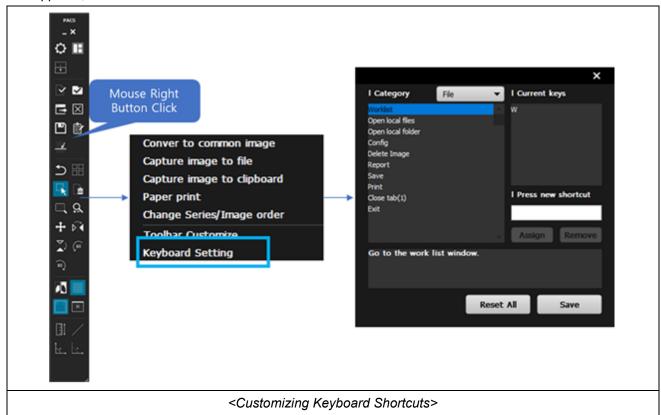


- Available: A list of Toolbars that can be added to the Toolbar.
- Current command: Toolbar list currently displayed in the Toolbar.
- 1 Row: Displays Toolbar icons in a single row.
- 2 Rows: Displays Toolbar icons in two rows.
- Large: Displays Toolbars with large icons.

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### 2. Customizing Keyboard Shortcuts

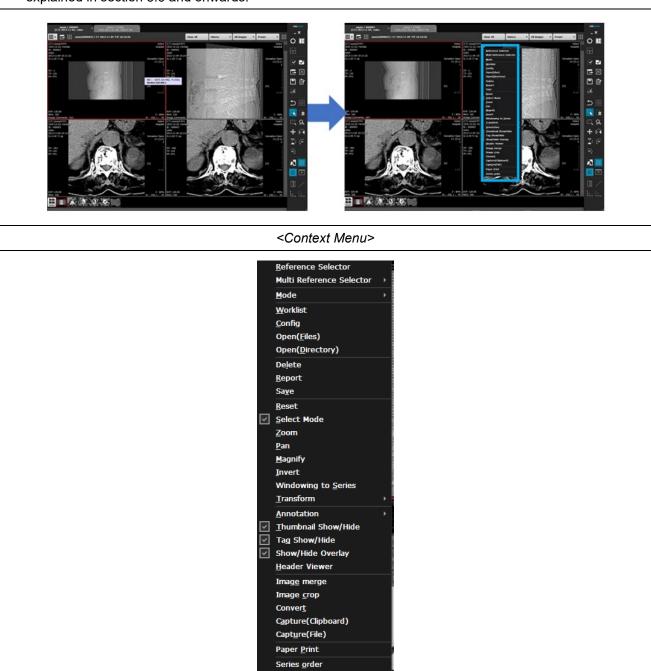
Right-click in the Tool Bar area and select the Keyboard Setting menu from the Context Menu that appears, as shown in the illustration below.



- Category: Group of each function
- Current Keys: Shortcut keys assigned to the currently selected function
- Press new shortcut: Field to input a new shortcut key to be assigned
- Assign: Button to assign the shortcut key entered in <Press new shortcut> to the function
- Remove: Button to delete the shortcut key selected in <Current Keys>

## 3. Context Menu

You can access the Context Menu by right-clicking on the main screen. The details of this feature are explained in section 3.6 and onwards.

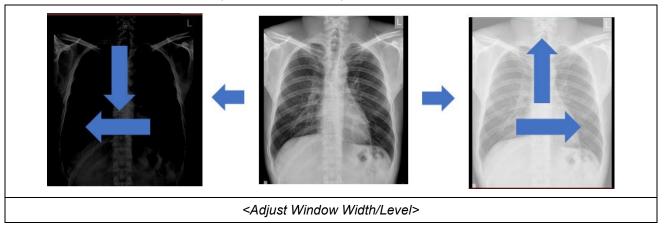


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<Context Menu>

## 4. Adjust Window Width/Level

By right-clicking and holding the mouse over the image, moving it left/right will adjust the *Window Width* value: left to right increases it, and right to left decreases it. Similarly, moving it up/down will adjust the *Window Level* value: down to up increases it, and up to down decreases it.



# 4.1.1.3.10 TOOL BAR

A collection of functions related to opening images, viewing, and writing reports used in the *View*.

			Minimize button
1	Minimize / Close	×	Close button
2	Setting	$\Diamond$	Configuration function: provides the same functionality as the <i>Config</i> in the <i>Worklist</i> .
	Frame	$\blacksquare$	Configure the Exam to simulate using one monitor as two
3	Layout Change		of for comparing past images.
4	Thumbnails		Toggle the On/Off setting for the thumbnail window.
			This function loads DICOM files.
(5)	Open Local Files		

			This feature loads DICOM files directly from the selected
			folder without searching through subfolders within the
			chosen directory.
6	Open Local Folder	N	Standard   Standard
7	Worklist		Display the Worklist screen.
			The currently active Exam Tab is closed, and if there is
8	Close Tab	$\boxtimes$	only one tab remaining, the screen switches to the
			Worklist screen.
			The feature saves all the changed information (Annotation,
	Save		WWL, Flip, Rotate, Inverse) for the selected image in the
9	Gave		Main View, and when reopening the same examination, it
			loads the image in the previously saved state.
			This is a function that allows you to read while taking the
		È	exam. The worklist has the same function as the report in
10	Report		the tool bar. This feature allows only authorized users to
			create readings. Unauthorized users can only view the
			reading results.
			When you select a specific image in the Main View and click
			on this feature, a popup window is activated and if you
			select another image, the overlay of the popup window
			image is displayed.
11)	Reference Line	_≠	

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	T	T	
			Reset the image with changes made by WWL, Zoom, Pan,
			Flip, Rotate, Inverse to its original state as it was initially
			displayed.
12	Reset	<b>↑</b>	
			The button to select all images in the current Exam, when
			all are selected, borders are visible around all images.
13	Select All		
			This is the button to change the current mouse operation
			mode to Select mode.
			- When in Select Mode, the background of the icon
			becomes darker.
			- Selected images are outlined with a color and this color
<u>14</u> )	Select Mode		can be customized in the settings.
			- Multiple images can be selected using the Ctrl or Shift
			key + Mouse Left Click on the keyboard.
			- Clicking only selects the clicked image.
			- Pressing the ESC key on the keyboard after using
			another function activates Select Mode.
			Delete the selected images.
			The deleted images will display the text 'Deleted' in the
			center of the image until the viewer is closed.
15)	Delete Image		Delete Function Message X Deleted roomally Delete Function Message X Deleted roomally Delet

			This is a feature that allows you to prove in an analysis
<b>16</b> )	Magnify Glass		This is a feature that allows you to zoom in on a specific part of the image.    Comparison
(17)	Zoom Mode	Q	You can use it by holding down the left mouse button on the image and dragging in the direction (→ or ↑ (zoom in) / ↓ or ← (zoom out)).  - When zooming with Ctrl or Shift pressed, the zoom level is larger than the default zoom level.  - If you change the Mouse Wheel Zoom option in Config(Advanced) to On, you can also use the mouse wheel to zoom in (↑) or out (↓).
(18)	Pan Mode	<b>+</b>	When you press and drag the left mouse button on the image, the image will move to the corresponding position.  [CT] xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
<b>(19)</b>	Flip Horizontal		This function flips the selected image horizontally in the Main View.  CT monoton flips the selected image horizontally in the Main View.  CT monoton flips the selected image horizontally in the Main View.  CT monoton flips the selected image horizontally in the Main View.  CT monoton flips the selected image horizontally in the Main View.  CT monoton flips the selected image horizontally in the Main View.  CT monoton flips the selected image horizontally in the Main View.  Act Main View.  CT monoton flips the selected image horizontally in the Main View.  Act Main View.  CT monoton flips the selected image horizontally in the Main View.  Act Main View.  CT monoton flips the selected image horizontally in the Main View.  Act Main View.  CT monoton flips the selected image horizontally in the Main View.  Act Main View.  CT monoton flips the Selected image horizontally in the Main View.  Act Main View.  CT monoton flips the Selected image horizontally in the Main View.  Act Main View.  CT monoton flips the Selected image horizontally in the Main View.  Act

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			This function flips the selected image vertically in the Main
			View.
20	Flip Vertical		(CT) associatory (CT) a
			This function rotates the selected image counterclockwise
			by 90 degrees in the Main View.
2	Rotate counter-clockwize	90	(CT) energic(417)   Solid   ST   Solid   Solid   ST   Solid   Solid   ST   Solid   Solid   Solid   ST   Solid   So
			This function rotates the selected image clockwise by 90
			degrees in the Main View.
22	Rotate clockwize	90)	CT   Section   CT
			This function inverts the colors of the selected image in the
			Main View.
23	Inverse		CT mmo(MHz)   Select   March 1944   March
			This function allows you to show or hide the overlay
			information displayed on the image.
<b>2</b>	Show / Hide Overlay		(CT) anodCHY)  (CT) a

25)	Show / Hide DICOM tags		This function allows you to show or hide the DICOM tag information displayed on the image.
26	View all dicom tags	Н	This feature allows you to display the DICOM header information window when you select the examination image and click "View all DICOM tags".  * There is additional information on the 73 page  CDICOM Tag Viewer>
7	Ruler	Trriii (Trriii)	<ul> <li>When you click and drag with the left mouse button on the displayed image, a ruler is drawn, and releasing the left mouse button creates the ruler and displays the length information.</li> <li>After switching to Select Mode, you can select the created ruler to move and adjust its length.</li> </ul>
28)	Line		<ul> <li>When you click and drag with the left mouse button on the displayed image, a line is drawn, and releasing the left mouse button creates the line. After switching to Select Mode, you can select the created line to move and adjust its length.</li> <li>This functions the same as the ruler but does not display length information.</li> </ul>

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29	Angle	E.	<ul> <li>When you click once with the left mouse button on the displayed image, the center point is created. With the second and third clicks, a protractor is completed centered on the initial point, displaying the angle information.</li> <li>After switching to Select Mode, you can select the created angle to move and adjust its angle.</li> </ul>
30	Cobb's Angle		<ul> <li>When you click and drag the left mouse button on the displayed image, a line is drawn, and releasing the left mouse button displays the line. Repeating this process once more displays the angle information.</li> <li>After switching to Select Mode, you can select the created Cobb's Angle to move and adjust its angle.</li> </ul>
3	Freeline	<b>ن</b> م	- When you click and drag the left mouse button on the displayed image, a Freeline is drawn. Releasing the left mouse button creates the Freeline with points appearing intermittently along the mouse's path.  - After switching to Select Mode, you can select the created Freeline to move it.

32	Text	Т	<ul> <li>When you click and drag the left mouse button on the displayed image, a space for writing text appears with the default text ("AaBbYyZz"), and the text is created in an editable state.</li> <li>After switching to Select Mode, you can select the created text to move it, and double-clicking the text allows you to edit it.</li> </ul>
33)	Rectangle ROI		<ul> <li>When you click and drag the left mouse button on the displayed image, a rectangle is drawn, and releasing the left mouse button completes the rectangle.</li> <li>In Select Mode, you can select the created Rectangle ROI to move and resize it.</li> <li>Right-clicking the created Rectangle ROI allows you to view its information.</li> </ul>
<b>34</b> )	Ellipse ROI		<ul> <li>When you click and drag the left mouse button on the displayed image, a circle is drawn, and releasing the left mouse button completes the circle.</li> <li>In Select Mode, you can select the created Ellipse ROI to move and resize it.</li> <li>Right-clicking the created Ellipse ROI allows you to view its information.</li> </ul>

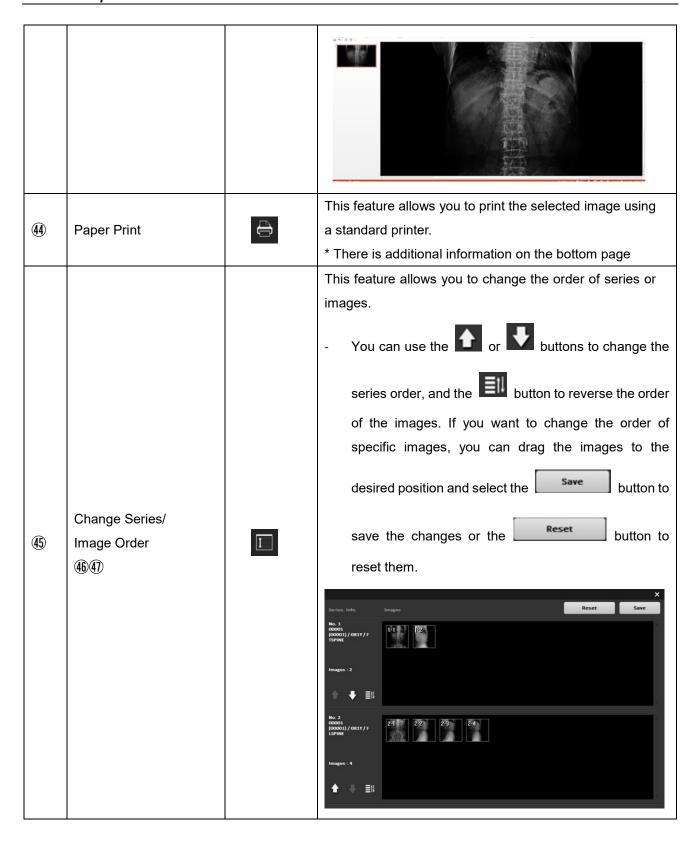
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This button allows you to measure the ratio of the heart area. Click and drag the left mouse button on the displayed image to draw a vertical line, and releasing the left mouse button completes the Heart Ratio. You can adjust the position and length by moving all vertices up/down or left/right. **35**) **Heart Ratio** The Heart Ratio 2 feature provides the same functionality as described above for measuring the ratio of the heart area. Similar to the Heart Ratio tool, Heart Ratio 2 generates an annotation with a similar appearance, but with separate lines at the top that can be individually adjusted for the left and right sides.

36)	Delete last selected annotation	* <u>*</u>	Select one of the annotations you want to delete, then click on the corresponding function, and it will be deleted.
3	Delete all on last clicked image	/ ×	It deletes all annotations on the last clicked image.
38	Delete all annotation of selected files	*	When you select multiple desired images and then click on this function, all annotations on the selected images are deleted.
39)	Image merge		It is a function to merge two images into one, where you can choose to export the result as JPG or DCM files, or append it to the end of the current examination.  - When you select two images and click the "Image Merge" button, a window will appear. In this window, you can edit the images, and after making your adjustments, click the ▶ button to select the desired

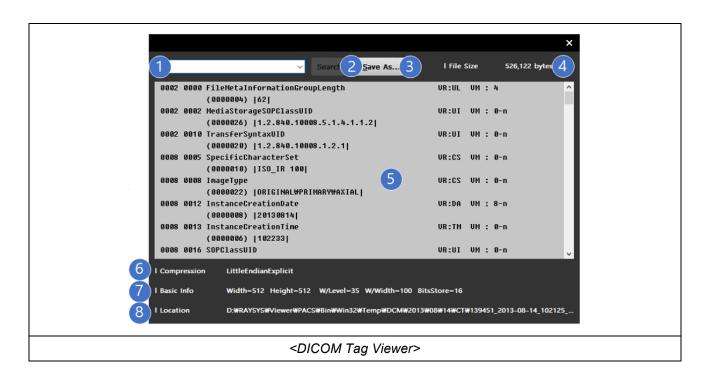
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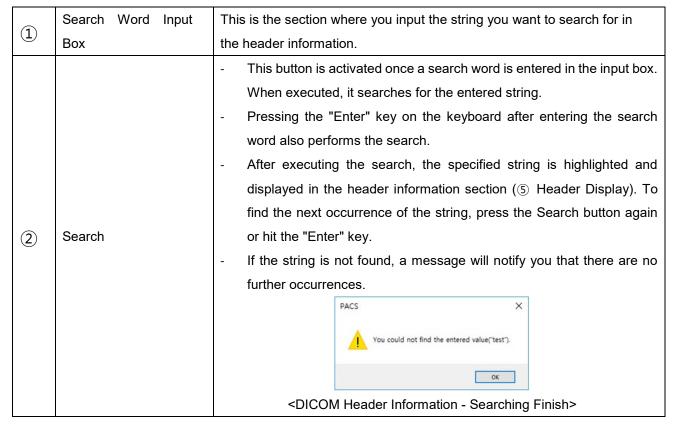
			<u>,                                      </u>
			portion to save separately by clicking either  or Save dicom. Alternatively, you can click the button to save the merged images as the last series of the current examination.
40	Image Crop	#	This feature allows you to crop a specific region of a DICOM image and add it back as a DICOM image. By clicking or separately. Clicking the cropped region separately. Clicking the saves the cropped region as part of the current examination. Additionally, after performing a crop and setting the Recovery option via Replace, clicking the Send button restores the original image of the examination where the crop was made.
41)	Convert to common image		<ul> <li>This is a feature for converting Multiframe, MPGE2, and DICOM images to BMP, PNG, JPEG formats and saving them.</li> <li>After selecting the desired images for saving, choosing Convert will save them all as Common images.</li> <li>* There is additional information on the bottom page</li> </ul>
42	Capture image to file	r <sub>lw8</sub> J	You can save the selected image as a separate file in JPG, PNG, or BMP format.    Save As
43)	Capture image to clipboard	<b>⊛</b>	You can copy the selected image and paste it into applications such as Microsoft Word, Excel, or other software that supports image pasting.



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· View all dicom tags





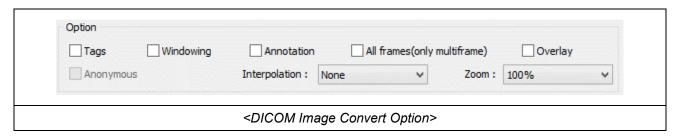
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3	Save As	<ul> <li>This feature allows you to save the currently displayed header information as a text file.</li> <li>When executed, a file save dialog appears, allowing you to choose the path and enter a file name for saving.</li> <li>The default file name entered is the same as the image file name.</li> <li>The file is saved in a text format that can be opened with a text editor like Notepad.</li> </ul>
		Save As  A This PC > Desktop  Organize  New folder  Date modified  Sype  Size  Quick access  Desktop  Out  Source Styles  Downloads  Downloads  Downloads  Downloads  Syze Zozd4 1:39 AM  File folder  File folder  File rout  Save as type:  File name:  Save as type:  File name:  Fi
4	File Size	Displays the size of the current image file in bytes.
(5)	Header Display	<ul> <li>This section displays the header information.</li> <li>You can scroll up and down using the scroll bar on the right.</li> <li>You can select text by dragging with the mouse and copy it using the "Ctrl+C" key on the keyboard.</li> </ul>
6	Compression	Indicates whether the pixel data of the current image is compressed and the compression method used.
7	Basic Info	Displays the basic information of the current image, including its width and height, Window Width/Level, and the number of bits per pixel.
8	Location	Shows the location of the current image.

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• Convert to common image

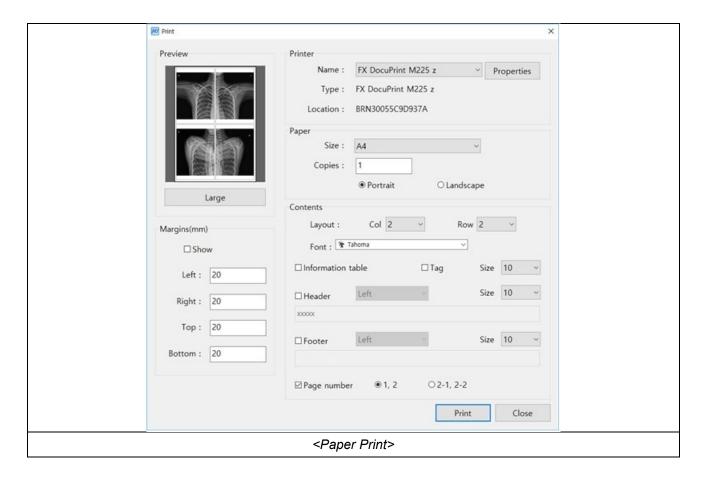
Below are the basic settings and information.



1	Tage	This option determines whether DICOM Tags information will be
1	Tags	displayed when saving the file.
		When saving the file, this option allows you to choose whether to save
2	Windowing	the image with the original value or with the changed Width/Center
		information.
		When saving the file, this option allows you to choose whether to save the
3	Annotation	image with the original annotation or with the changed annotation
		information.
	All Frames	For multi-frame examinations, this option allows you to choose whether to
4	(only multiframe)	save all frames or only the selected frames.
	O	This option determines whether overlay information will be displayed in the
(5)	Overlay	saved image.
		This feature, activated when Tags are selected, displays patient information
		anonymously.
		When selecting Multi-frame & MPEG2 images and clicking Convert, the
	Anonymous	screen displayed is as follows. Below are the basic settings and
		information.
6		And Bernow 1/ 100112000 00000000000000000000000000000
		<multi &="" convert="" frame="" mpeg2="" option=""></multi>

	Add	After selecting the desired image location, click the Add button to add
7		the image.
	Remove	This button allows you to remove images that have been added using
8		the Add button.
	Tags	Determines whether DICOM Tags information will be displayed when
9		saving the file.
10	Anonymous	Displays patient information anonymously.

# Paper Print



1	Preview	Displays the print preview screen.
2	Large	Enlarges the print preview screen for better visibility.
3	Margins	Sets the margins of the paper and toggles the display of margin lines.
4	Printer	Shows information about the printers installed on the computer. You can select the printer for output and view printer properties.

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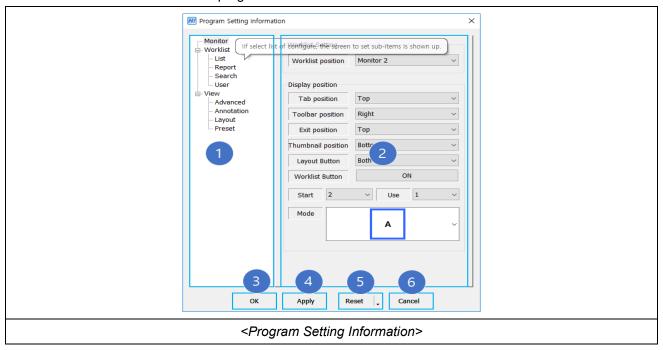
(5)	Paper	Allows selection of the output paper, as well as setting the number of copies and paper orientation (landscape/portrait).
6	Layout Col	Sets the number of images to be printed horizontally.
7	Layout Row	Sets the number of images to be printed vertically.
8	Font	Sets the font for the displayed text.
9	Information table	Sets whether to print the basic information of the examination at the top of the paper.
10	Header	Set whether or not to print the header.
11)	Header Align	Set the alignment position of the header.
12	Header Size	Set the font size of the header.
13	Header Text	This is where you enter the content to be printed in the header.
14)	Footer	Set whether or not to print the footer.
15)	Footer Align	Set the alignment position of the footer.
16	Footer Size	Set the font size of the footer.
17)	Footer Text	This is where you enter the content to be printed in the footer.
18	Page number	Set whether to print page numbers and the number format.
19	Print	This is the button to print to the printer.
20	Close	This button cancels printing and closes the window.

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# 4.1.1.4 PROGRAM SETTING

This screen allows you to save and modify all the settings required for the program's execution.

All values within the program settings screen are stored in a designated location, and you can initialize them back to the default values set in the program.

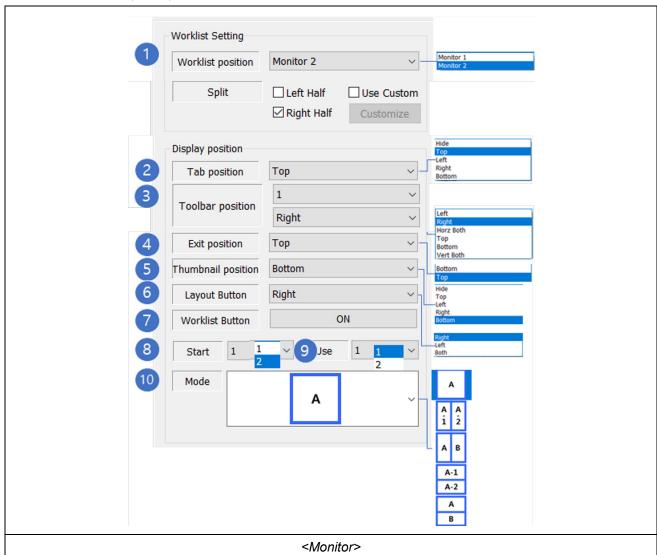


1	Config Item	Select the item you want to change, and the settings screen will appear on the right side.
2	Config Settings Screen	Displays the options available for each item.
3	OK button	Applies the changes and closes the window.
4	Apply button	Applies the changes and saves them to the designated location.
(5)	Reset button	Resets to the default values set in the program.  Clicking the Reset button will display submenus:  - Current Page Reset: Resets only the items shown on the Config Settings Screen.  - All Page Reset: Resets all settings screens.
6	Cancel button	Exits without saving any changes.

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# 4.1.1.4.1 MONITOR

This window allows you to set the positions of the Viewer and Worklist in the program, as well as the positions of the Viewer Toolbar, Tabs, and Thumbnails.



1	Worklist position	If there is only one monitor, "1" will be displayed for the Worklist screen.
		If there are multiple monitors, the leftmost monitor will be designated as
		"1".
	Tab position	You can specify the position of the View Tab by clicking the arrow in the
2		Combo Box.
	Toolbar position	- In the Toolbar position top option, you can set the Viewer Index to
		which the Toolbar will be applied (1, 2).
3		- In the Toolbar position bottom option, you can specify the Toolbar
		position for the currently configured Viewer Index.

4	Exit position	By clicking the arrow in the Combo Box, you can specify the position of the Viewer's exit button.
(5)	Thumbnail position	By clicking the arrow in the Combo Box, you can specify the position of the View Thumbnail.
6	Layout Button	By clicking the arrow in the Combo Box, you can specify the position of the Display Layout button.  Display Layout  Close All Industry All Brooks Proof.
7	Worklist Button	By clicking the arrow on the button, you can toggle the Worklist button on or off.
8	Start	If there are more than two monitors, you can set the starting position of the Viewer. It starts from 1 based on the leftmost monitor.
9	Use	You can select the number of monitors to display the View screen.
10	Mode	By clicking the arrow in the Combo Box, you can select the display method for the View Layout.

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# 4.1.1.4.2 WORK LIST

This is the window where you can configure the default items in the Worklist.

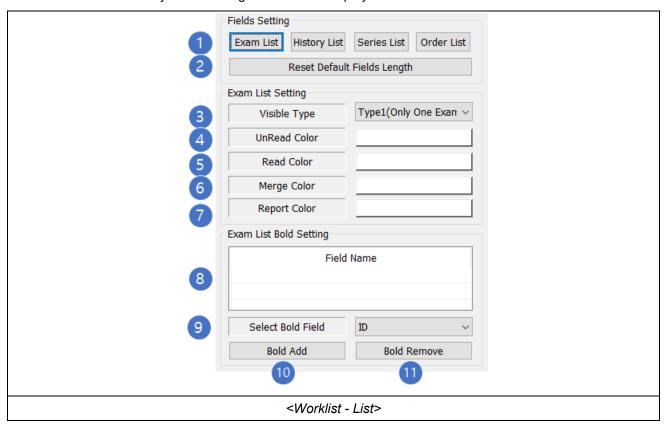


1	Worklist Auto Hide	Determines whether the Worklist automatically hides when the viewer is clicked.
2	History List	Configures whether to display the History List in the Worklist window.
3	Series List	Specifies whether to show the Series List in the Worklist window.
4	Report List	Controls the visibility of the Report List in the Worklist window. Unlike items ②, ③, and ④, the Exam List is always displayed.
(5)	Order List	Sets whether to display the Order List in the Worklist window.
6	List Theme	Defines the theme for the Worklist.
7	List Layout Save	Specifies whether to save the position information of Exam List, History List, Series List, and Report List. If set to ON, the program saves the

		position information of all lists upon exit, so they appear in the same position when the program is restarted.
8	Font Name	Allows you to choose the font for the Worklist.
9	Font Size	Adjusts the font size for various areas of the Worklist, including the Search Field, Grid, and Config sections.

List

This is the window where you can configure the items displayed in the Worklist.



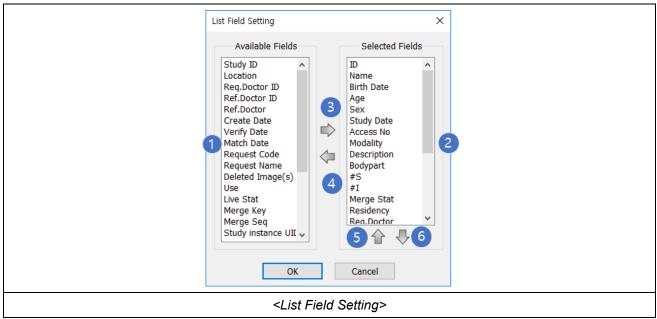
1	Exam/History/Series	Configure the field items in the Exam/History/Series List in the Worklist
	List	,
	List Field Length	Reset the width between all fields in the list.
2	Reset	
	Visible Type	- Set whether to distinguish Read/UnRead status of Exams in the Exam
		List of the Worklist.
3		- Type1 (Only One Exam): Display search results in a single Exam List.
		- Type2 (UnRead & Read): Display UnRead List and Read List
		separately

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		Exam Uniked
		D   Nome   Birth Date   Apr   Set   Study Date   Access No   Modelly   Description   Bodypart   S   Z1   Mergy Star (Beech Req.)   Read   Access No   No.   No.
		<unread &="" list="" read=""></unread>
4	Read Color	<ul> <li>Set the color for Exams that have been read by the physician in the Exam List.</li> <li>Upon execution, a window for selecting the color will appear.</li> </ul>
(5)	UnRead Color	<ul> <li>Set the color for Exams that have not yet been read by the physician in the Exam List.</li> <li>Upon execution, a window for selecting the color will appear.</li> </ul>
6	Merge Color	Set the color for merged items in the Exam List.  Upon execution, a window for selecting the color will appear.
7	Report Color	Set the color for items that include reports in the Exam List.  Upon execution, a window for selecting the color will appear.
8	Bold List	Display the list of fields in the Exam List that are displayed in bold.
9	Bold Field	Display the list of all fields that can be added to the Bold List.
10	Bold Add	Select fields from the Bold Field (⑨) and add them to the Bold List (⑧).  If a field has already been added, it will not be added again.
11)	Bold Remove	Select fields from the Bold List (®) and remove them from the list.

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# 1. List Field

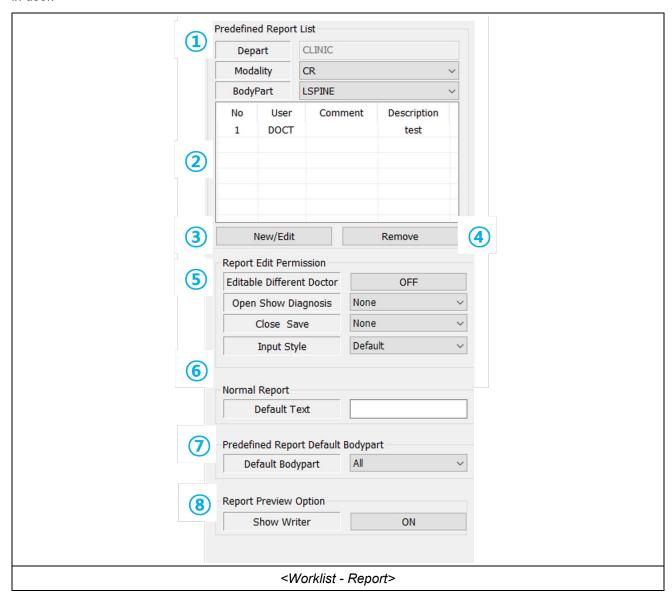


	Available Fields	- This section contains the available fields that can be selected for the List Field.	
1		- To add a desired field from the Available Fields, select it and click the	
		3 Add button, which will move it to the Selected Fields section.	
		- Once a field is added, it will be removed from the Available Fields.	
		- This section displays the fields that have been selected for the List	
		Field.	
	Selected Fields	- To remove a field from the Selected Fields, select it and click the ④	
2		Remove button, which will move it back to the Available Fields section.	
		- Once a field is removed, it will be added back to the Available Fields.	
		- The Selected Fields section must have at least one field selected and	
		can have a maximum of fifteen fields.	
(a)	Dight (Add)	This button adds a field from the Available Fields to the Selected Fields	
3	Right (Add)	section.	
	Loft (Pamaya)	This button removes a field from the Selected Fields section and adds it	
4	Left (Remove)	back to the Available Fields section.	
(5)	Up	This button moves the selected field up by one position.	
6	Down	This button moves the selected field down by one position.	

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#### Report

This is the window where you can search for and edit reports based on the items configured in the Report List. Reports can only be searched for or edited within the list corresponding to the department of the currently logged-in user.



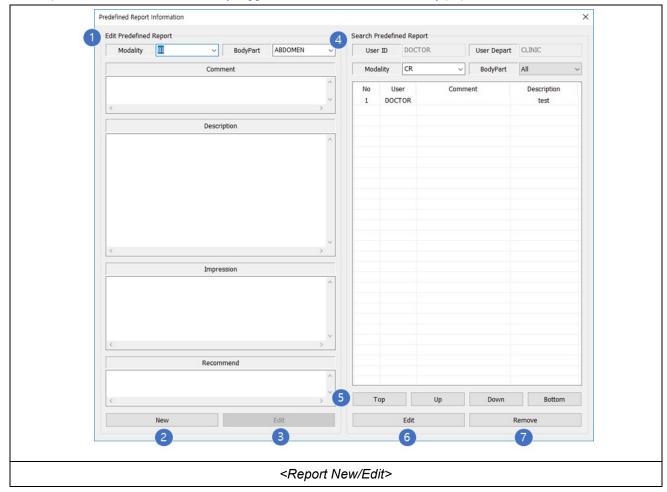
			Sets the conditions for searching reports.
	Predefined Report Search Condition	-	"Depart" refers to the department name of the currently logged-
1			in user and is automatically populated.
		-	Only the Modality and BodyPart of the saved Predefined
			Reports can be selected.
		-	Displays the searched lists.
2	Predefined Report List		Double-click an item or select an item and click "③Edit" to
			modify the report information.

			- Select an item and click "④Remove" to delete it.
3	New/Edit		<ul> <li>Function to add or modify report information.</li> <li>Clicking the button opens a window where report information can be entered.</li> <li>Added report information can be viewed by searching in "2 Report List".</li> </ul>
4	Remove		<ul> <li>Deletes the selected item in "②Report List".</li> <li>Pressing the Delete button on the keyboard also deletes the item.</li> </ul>
(5)	Report Edit Permission	Editable Different Doctor Open Show Diagnosis Close save	Configures warning messages when attempting to edit reports authored by other users. Enabling this option triggers a warning message when attempting to edit reports authored by others.  When enabled, opens the report window along with the examination images.  None: No action is taken.  Close Tab: Closes the currently read examination tab.  Close Tab & Open Worklist: Closes the current examination tab and opens the Worklist window.  Configures the user interface of the report window.  Default: Provides the default UI.  Description + Impression: Provides only the Description and Impression writing fields.  Description+Recommendation: Provides only the Description and Recommendation writing fields.
6	Normal Report	Default Text	Specifies the Description to be included in the report when processing Normal Reports.
7	Predefined Report Default Bodypart		Specifies whether the default value for BodyPart in the "Search Predefined Report" section on the right side of the Report window should be "All" or the BodyPart of the currently selected examination.
8	Report Preview Option	Show Write	Configures whether the author of the reading should be displayed in the Report Preview window in the Worklist

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# 2. Report New/Edit

This is the window where you can set up report information by executing the "3New/Edit" function. After saving the configured values, you can view them as a list through a search. "Depart" refers to the department name of the currently logged-in user and is automatically populated.



		- Allows adding or modifying a report.
1	Edit Report	- Select Modality and BodyPart, then input information into Comment,
		Description, Impression, and Recommendation fields.
2	New	Adds the information entered in ① (Edit Report) to the report.
		- After selecting a report from ④ (Search Report) and clicking ⑥
	Edit	(Edit), the information of the selected report appears in ① (Report
3		List), and the ③ (Edit) button is enabled.
		- After making modifications, clicking the ③ (Edit) button updates the
		selected report.

4	Search Report	<ul> <li>Displays previously saved reports.</li> <li>Selecting Modality and BodyPart lists reports that meet those criteria.</li> <li>Only Modality and BodyPart options from previously saved reports are available for selection.</li> </ul>		
(5)	Top/Up/Down/Bottom	Allows moving the selected item's position in ④ (Search Report).		
6	Edit	After selecting an item to modify from ④ (Search Report) and clicking ⑥ (Edit), the content of the selected item appears in ① (Edit Report).		
7	Remove	Selecting an item to delete from ④ (Search Report) and clicking ⑦ (Remove) removes the selected item from the report.		

#### Search

This is the window where you can configure the search criteria to retrieve lists from the database in the Worklist.



1	Search Field Setting	Configure the search criteria for retrieving lists from the database. This window displays the available fields for selection, and the chosen fields will appear in the Worklist's search window.
2	Duration	Set the search period for the Study Date field. Selecting "0" represents all durations, and you can select up to a maximum of -365 days. Use the button on the far right to select the duration.

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		Set the date for the Study Date (date of examination) search condition.	
		Options include various predefined date ranges like "Today," "Within Last	
3	Date		
		1 Day," "Within Last 3 Days," and so on. The selected value applies to	
		the initial search condition in the Worklist.	
	Donartment	Configure the Department search condition. Choose from custom-added	
4	Department	items in the Department search condition	
(E	Request Doctor	Set the Request Doctor search condition. Choose from custom-added	
(5)	Nequest Doctor	items in the Request Doctor search condition.	
		Specify the total number of digits for the Patient ID. If the entered value for	
6	Auto Fill Patient ID	the Patient ID in the search condition has fewer digits than this value, the	
		remaining digits will be automatically filled with zeros.	
	01.0	Arrange the search results based on the currently selected Sort By	
7	Sort By	condition.	
	01.01	Choose the sorting order for the selected Sort By condition, either	
8	Sort Order	ascending (Asc) or descending (Desc)	
	Use Refresh Auto		
9	Searching	Enable automatic searching of the Worklist upon program execution.	
	D.C. L.F.	Set the interval for automatically refreshing the search results based on the	
(10)	Refresh Timer	current search criteria.	
	A 11	Choose the time unit for the automatic refresh timer, such as seconds or	
11)	Auto Timer Unit	minutes.	
10	Searching  Refresh Timer  Auto Timer Unit	Set the interval for automatically refreshing the search results based on t current search criteria.  Choose the time unit for the automatic refresh timer, such as seconds	

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User

This window allows you to configure settings related to user passwords.

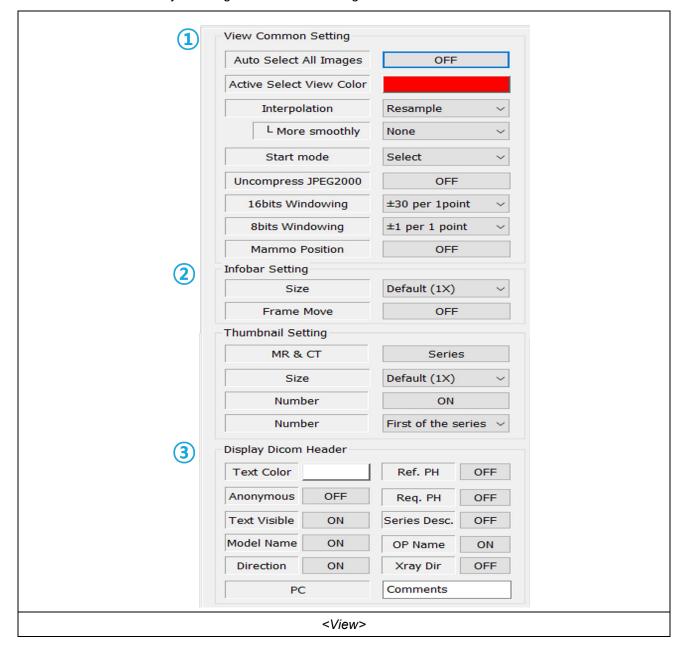


1	Current Password	<ul> <li>Enter your current password.</li> <li>If the entered password does not match the current password, the password change will not proceed.</li> </ul>	
2	New Password	Enter the new password you want to set.	
3	Confirm Password	Re-enter the new password for confirmation.	
4	Confirm	Change the password to the new one.	

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# 4.1.1.4.3 VIEW

This is the window where you configure the default settings for the 2D View.



		Auto Select	When opening an image from local or worklist, all images are
		All Images	selected by default.
		Active	Colocida by doldari.
		Select View	Set the color of the border of the pane when selected.
		Color	Set the color of the porter of the parte when selected.
		Coloi	Set the interpolation method for reducing staircasing effects when
			zooming images None: No interpolation; staircasing effects remain visible.
			- Resample: Some reduction in staircasing effects.
		Interpolation	- Cubic: More reduction in staircasing effects, but may slow
			down and cause blurriness in original image.
	View		- Sharpen: Enhances staircasing effects. Used for correcting bl
1	Common		urry images.
	Setting		Define the initial mouse function when opening an image.
			- Select: Selection mode.
		Start Mode	- Zoom: Zoom in/out mode.
			- Pan: Image panning mode.
		Uncompres	
		s PEG2000	Toggle decompression of JPEG2000 images when loading.
		16bits	Set the value change per mouse point for brightness adjustment in
		Windowing	images with 16-bit or higher values.
		8bits	Set the value change per mouse point for brightness adjustment in
		Windowing	images with 8-bit or higher values.
		Mammo	Conton monare image
		Position	Center mammo images.
		Size	Adjust the size of the infobar. (Default(1X), Larger(1.5X),
	Infobar	JIZE	Largest(2X))
(2)	Setting	Frame	Set the Viewer window to move by dragging the infobar with the
		Move	mouse. (By default, only possible through tab)
		MR & CT	Choose how thumbnails are displayed when opening MR & CT
		IVIIX & CT	images: display only the first image of the series or all images.
		Size	Adjust the size of the thumbnails. (Default(1X), Larger(1.5X),
3	Thumbnail		Largest(2X))
3	Setting	Number	Toggle the display of numbers on thumbnails
		Number	
		Format	Set the format for the numbers displayed on thumbnails.
	I .	1	

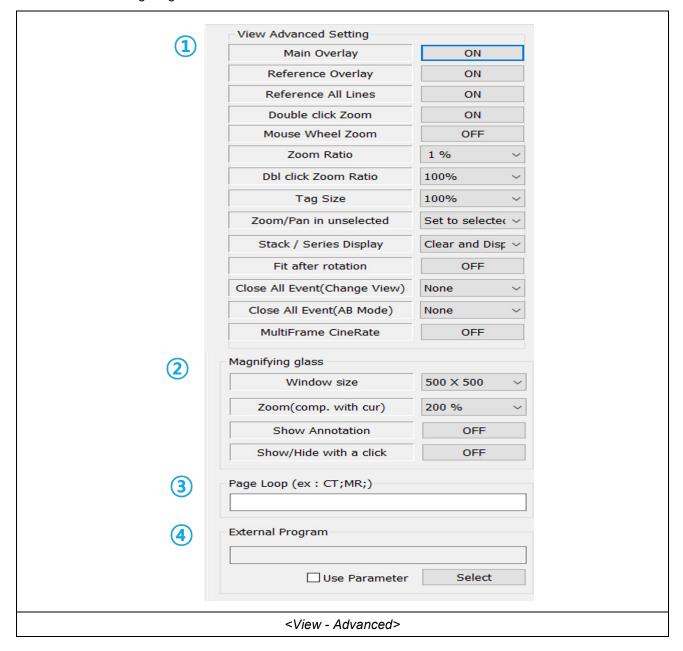
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		Text Color	Set the color of text displaying image information on the screen.
		Ref. PH	Toggle display of Referring Physician header information.
		Anonymous	Set anonymity for important patient and hospital-related information in image details.
		Req. PH	Toggle display of Requesting Physician header information
	Display DICOM Header	Text Visible	Set visibility of image information (DICOM Header) on the screen.
4		Series Desc.	Toggle display of series description in header information.
		Model Name	Toggle display of Manufacturer Model Name.
		OP Name	Toggle display of Operator's Name.
		Direction	Toggle display of Direction in the viewer.
		Xray Dir	Toggle display of Xray Direction in the viewer.
		PC	Set the header prefix for Patient Comments.

DRGEM Corporation 4. SYSTEM OPERATION

Advanced

The window for configuring additional features in the View.



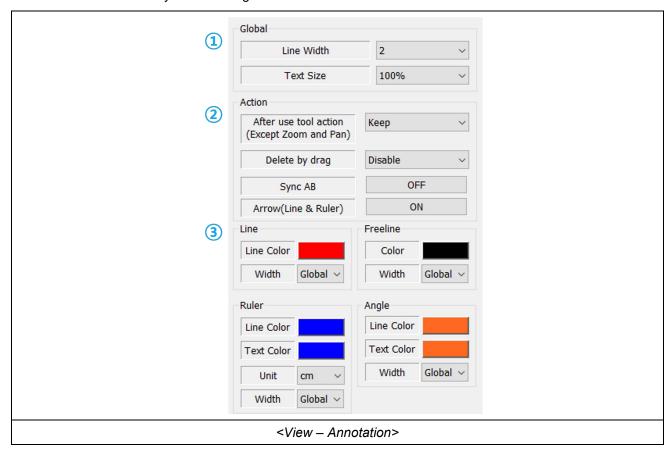
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		Main Overlay	Specifies the display status of overlay images in the viewer.
		Reference Overlay	Specifies the display status of overlay images in reference images.
		Reference All Lines	Specifies the display status of all image positions of the same series in reference images.
		Double-click Zoom	Determines whether to display the image in full screen when double-clicking on CR/DX images.
		Mouse Wheel Zoom	Specifies whether zooming with the mouse wheel is enabled.
		Zoom Ratio	Sets the default zoom ratio to be used in zoom mode.
		Dbl click Zoom Ratio	Sets the default zoom ratio to be used in double-click zoom mode.
		Tag Size	Sets the size of the header information displayed in the viewer.
1	View Advanced Setting	Zoom/Pan in Unselected	Specifies whether the actions on unselected images also affect the selected images.
		Stack / Series Display	<ul> <li>Determines the behavior when opening a new study in stack mode.</li> <li>None: No action is taken.</li> <li>Clear and Display: Clears the stack window and displays images in series order.</li> <li>Close and Display: Closes all study tabs, opens a new study, and displays it in the stack window.</li> </ul>
		Fit after rotation	Specifies whether to fit the image after rotation.
		Close All Event(Chan ge View)	Specifies whether to switch to Exam View when closing all tabs in stack/series mode.
		Close All Event(AB Mode)	Specifies whether to switch to A Mode when closing all tabs in AB mode.
		MultiFrame CineRate	Specifies whether to adjust the playback speed of MultiFrame images based on the CineRate value.  Turn on this option if the playback speed of MultiFrame images is not appropriate.

		Magnifying Window	Sets the size of the magnifying glass window in pixels.
		size	guest wild the magnifying guest will act in pixels.
2	Magnifying glass	Magnifying Zoom Ratio	Sets the zoom ratio to be used in the magnifying glass.
		Show	Specifies whether to display annotations in the magnifying glass
		Annotation	area.
		Show/Hide	Sets the behavior of the magnifying glass.
		with a click	Gets the behavior of the magnifying glass.
	Page Loop		Sets the modality of the study images to which the page loop will
3	rage Loop		be applied.
	External Progra		Sets the path and parameters of the external program to be called
4	External Program		when using the external program calling feature.

# Annotation

This is the window where you can configure the colors related to annotations used in the View.



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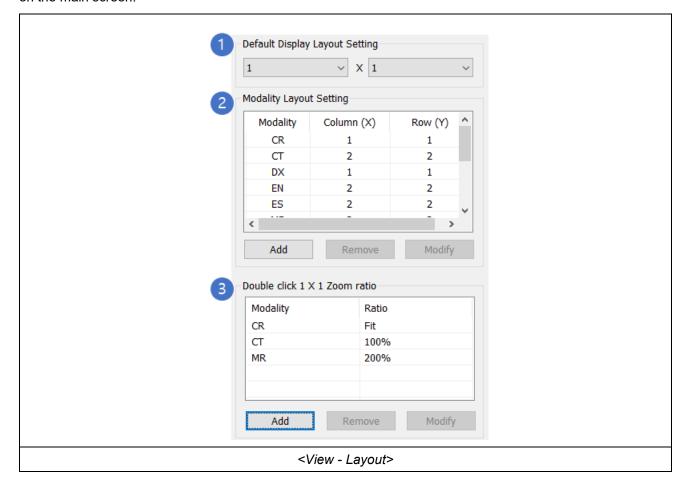
1	Global	Line width	Select the default thickness for all lines drawn in annotations.	
		Text Size	Choose the default size for text in annotations.	
2	Action	After using a tool action	Set the Toolbar Mode after performing an annotation action.	
		Delete by drag	<ul> <li>Determine whether annotations can be deleted by dragging.</li> <li>Out of region (mouse): Delete the annotation if it goes outside the pane.</li> <li>Invisible: Delete the annotation if it's not visible.</li> <li>Disable: Deactivate this feature.</li> </ul>	
		Sync AB	If an annotation is deleted on screen A (or B), it will be updated and reflected immediately on screen B (or A).	
3	Annotation Settings		Configure units, colors, line thickness, text size, and other properties for annotations provided by the program.	

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#### Layout

This is the window where you can configure the arrangement of images in the View.

It consists of Default Layout, Modality Layout, and Control Layout. The Default Layout determines the arrangement when the current Modality is not listed in the Modality List. If the Modality is listed, the arrangement follows the corresponding Modality Layout. The Control Layout refers to the list of layouts available in the toolbar on the main screen.



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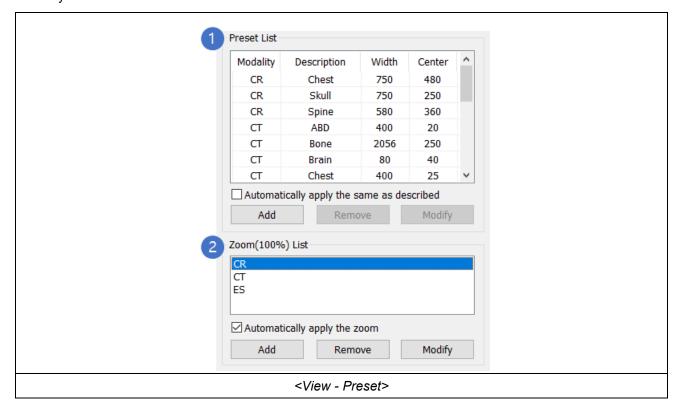
		- Sets the basic layout for images.				
1		- When opening images for the first time and the Modality isn't listed in				
	Default Layout	② Modality Layout List, they will be arranged according to the Default				
		Layout.				
2	Modality Layout List	- Lists the user-defined Modality Layouts.				
		- Each Modality has its own layout. Use the Add/Remove/Modify buttons				
		to add, remove, or modify layouts.				
		Modality Layout Add Information X Modality Layout Modify Information X				
		Current Layout State				
		Modality BI V Modality DX				
		Column (X) 1				
		Row (Y) 1				
		OK Cancel OK Cancel				
		<modality add="" layout="" modify=""></modality>				
3	Double click 1X1 ratio	- Sets the default image scale when double-clicking on images other				
		than X-Ray (CR, DX, etc.) to view them in a 1x1 ratio.				
		- Use the Add/Remove/Modify buttons to add, remove, or modify				
		settings.				
		1 X 1 Zoom Ratio X 1 X 1 Zoom Ratio X				
		Modality Modality MR				
		Ratio Fit V Ratio 200% V				
		OK Cancel OK Cancel				
		<1 X1 Zoom Ratio Add/Modify>				
ļ		1				

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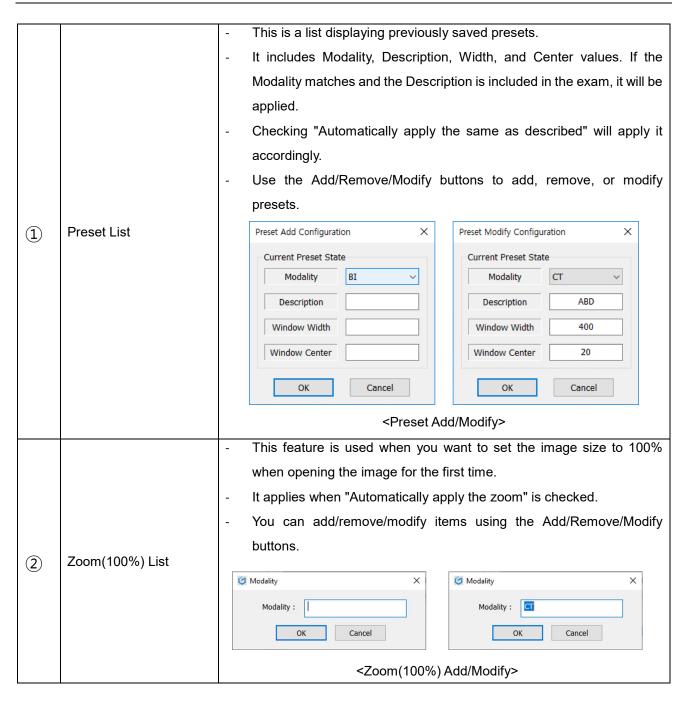
#### Preset

This is the window where you can set the Window Width and Window Center values for images.

The Preset List allows multiple preset configurations for each Modality. Configured Preset Lists will appear in the Preset combo box in the toolbar on the main screen when opening images or exams, corresponding to the Modality.



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5. MAINTENANCE GEMPACS

# 5. MAINTENANCE

The user must routinely check the software for apparent defects or damage. Report any apparent defects or irregular operation of any software to service personnel immediately, and discontinue use of the suspected faulty software until repairs are made. Continuing operation with faulty software may present various safety hazards, including software malfunctions.

#### **WARNING**

Maintenance should only be carried out by competent and trained personnel who are well aware of the potential risks associated with this equipment. Failure to do so may result in software malfunction and PC damage.

#### **NOTE**

Maintenance schedule frequency may be dictated by certain regulatory requirements of the country or state in which the installation is located. Always check the local codes and regulations when setting the maintenance schedule.

#### NOTE

Due to varying operating conditions, the maintenance may have to be performed at greater or lesser intervals.

It may adjust intervals according to system's performance.

DRGEM Corporation 5. MAINTENANCE

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# APPENDIX A. APPLICABLE STANDARDS

The main components of <u>"GEMPACS"</u> comply with the regulatory requirements and design standards in this section as follows:

## 1) CLINICAL EVALUATION

#### ■ MDCG2020-1

Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software

#### ■ MDCG2020-5

Clinical Evaluation – Equivalence. A guide for manufacturers and notified bodies

#### ■ MDCG2020-6

Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies

#### ■ MDCG2020-13

Clinical evaluation assessment report template

#### ■ MEDDEV 2.7/1, Rev.4

EVALUATION OF CLINICAL DATA: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

#### 2) OTHERS

## ■ (EU) MDR 2017/745

Medical Devices Regulation

#### ■ MDCG2019-16, R1

Guidance on cybersecurity for medical devices

#### ■ ENISO13485:2016/A11:2021

Medical devices - Quality management systems - Requirements for regulatory purposes ISO 13485:2016

#### ENISO14971:2019/A11:2021

Medical devices - Application of risk management to medical devices ISO 14971:2019

#### ENISO15223-1:2021

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

ISO 15223-1:2021

#### ■ EN62366-1:2015+A1:2020

Medical devices - Application of usability engineering to medical devices IEC 62366-1:2015+A1:2020

#### ■ EN62304:2006+A1:2015

Medical device software — Software lifecycle processes IEC 62304:2006+A1:2015

#### ■ IEC/TR80001-2-2:2012

Application of risk management for IT-networks incorporating medical devices – Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls

# ■ ISO20417

Information supplied by the manufacturer with medical devices ISO 20417:2021

#### ■ DICOM 3.0

Digital Imaging and Communication in Medicine

# APPENDIX B. INDEX OF PACS FEATURES

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lmage <i>I</i>	Analysis Operation	Manual	4.1.1.3.10
Compat	tibilityOperation	Manual	4.1.1.2.3

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