



Operation Manual



VOYANCE

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1. Information

This section gives basic information of this manual and the product.

Cautions

Document Guide

Document Convention

Version Information Revision History



1.1 Cautions

If the user is not fully acquainted with this manual, the system can be malfunctioned or unsuspected problem can be happened due to carelessness. To prevent any medical accidents, the user should fully understand the instructions of this manual before operating the program.

When the user operates this software, take the following precautions. Otherwise, problems may occur or the product may not function correctly.

1 Roentgenography, image processing, reading of image, and data storage must be performed in accordance with the law of each country where the program is being used. Also, the user is responsible for protecting the privacy of image data.

2 In no event will Voyance llc. be liable for direct or indirect consequential damage arising out of the use of this program. Voyance llc. will not be liable for loss of image data due to any reason.

3 Before using this software, be sure to read this manual thoroughly. Also, read the manuals of relevant instruments in the system. Keep this manual where it is easily accessible.

4 Other systems and product names in this manual are the trademarks from their manufacturer.



- The user is responsible for ensuring whether the detector calibration is performed right after the software installation. Do not try to use the software if the detector calibration has not been performed.



1.2 Document Guide

This section describes about the information of this document.

Contents This document is the operation manual for **Voyance** users. You can install **Voyance** and acquire / manage images from the detector. It is also available to improve the image quality by using various image management and adjustment tools.

Target This manual is intended for the end users who use the **Voyance Software**.

Contact Department

For any comments or inquiries regarding this document, contact the customer support team in Voyance.



1.3 Document Convention

This section describes the rules about symbols and notations in this document.

1.3.1 Symbols

Caution and Warning



WARNING: Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other Person or can lead to a mistreatment.

Information



This symbol is used for indicating the product-related references and complementary information.

1.3.2 Notations

Bold Types

We applied bold font style to the words indicated GUI (Graphic User Interface) of the program or needed to transmit clear meaning to the customers. This helps you to easily distinguish GUI from other technical ones for explaining functions and the emphasis content.



1.4 Patient data security

It is the responsibility of the hospital to ensure that the patients' legal requirements are met and that the security of the patient records is:

- maintained and tested,
- audited,
- administered locally to cover risks from third party access and
- How the availability of the services is to be maintained in the event of disaster.

1.5 High security: HIPAA & Cyber Security

Within the healthcare industry, several standardization efforts are ongoing as a response to Privacy and Security legislation and regulations. The purpose of this standardization for hospitals and vendors is to enable information sharing, interoperability and to support the workflow of hospitals in a multiple vendor environment.

In order to allow hospitals to comply with HIPAA regulations (Health Insurance Portability and Accountability Act) and meet the IHE standards (Integrated Healthcare Enterprise) security features are included in Voyance:

- User authentication. The administrator can configure different user accounts. Each account consists of a user name and a password. Refer to "Patient data security" in **Appendix I** the system login is used for user authentication and identification is required.
- Node authentication, using certificates. Working with SSL (Secure Sockets Layer) allows secure communications on an insecure network. SSL is the security layer on top of TCP/IP.
- Administrator logging. This implies logging to a setting and configurations of specific VOYANCE 'Areas', e.g. users privileges, Hardware configuration , Dicom Configurationsetc.
-



1.6 Revision History

| Ver. | Date | Revision History |
|---------|------------|-------------------------|
| 1.0.0.1 | 06-27-2016 | Revised newly |
| 1.0.0.2 | 08-13-2018 | Revised additionally |
| 1.0.0.3 | 01-19-2019 | (Updated) New features |
| 1.0.0.4 | 09-16-2021 | (Updated) More features |



2. Instruction

This section provides basic concept and recommended specifications of

Voyance. Overview Recommended Specifications



2.1 Overview

Voyance is the image Acquisition/Viewer program for **Digital Flat panels** only that acquiring, adjusting and managing images generated from the detectors.

Voyance is organized with several specialized modules. This system provides high quality medical images to users through various advanced functions and quick image processing between the modules.

2.2 Main Features

- Acquire and search images exposed from the DR detector.
- Implement high-quality image by applying Voyance image processing algorithm developed by Voyance.
- Skins for various GUI (Graphic User Interface) suitable for both ordinary and touch screens.
- Store and manage images in the database.
- Adjust images using various processing tools.
- Export images using various media.
- Check the detector condition and change the settings.
- Chase and search the system status.
- Voyance conforms to the standard of DICOM 3.0.



2.3 Minimum System Requirement

- OS: Microsoft Windows 10 Pro, 64 bits or Higher
- CPU : Intel core i5
- RAM : 4GB
- HDD : 128 GB free space
- NIC : Ethernet Network Card
- Display : 1280 x 1024 Resolution, 24



3. Installation

This chapter provides information about installing Voyance



3.1 Installation Guide

Follow the instructions for safe and correct installation of Voyance. Failure to comply with the instructions under will result critical errors of its installation or operation.

- You should be fully aware of this manual before / after installing Voyance.
- Do not install Voyance to USB HDD, USB memory or a network drive.
- Be sure to install Voyance to the local drive. (C or D drive)
- Do not install Voyance to the root folder of C drive. It is recommended to install the program to the setup path guided by Voyance.
- Check the free space of storage media before installing Voyance. If the Storage space is limited, the software cannot be operated normally.
- You should secure enough space of the drive for storing the images and Data.
- Log on to Voyance by the Windows account with administrative rights when installing or removing Voyance.
- Set the Windows date and time precisely in advance.
- Check the virus infection of your PC by using virus test software before / after installing Voyance.
 - Voyance complies with the UAC (User Account Control) policy of Microsoft Windows. Therefore, the user should install and log on to Voyance by Windows account with the administrative rights. You can use Voyance with the general user account after the installation.
 - The computer name and the user account name should be set differently to install the database in Windows normally.
 - Before you install the Voyance program, make sure to change the computer name if it is same as that of the user account. If not, the program cannot be installed properly.
 - Check the computer name as follows.
 - Check the user account name as follows.



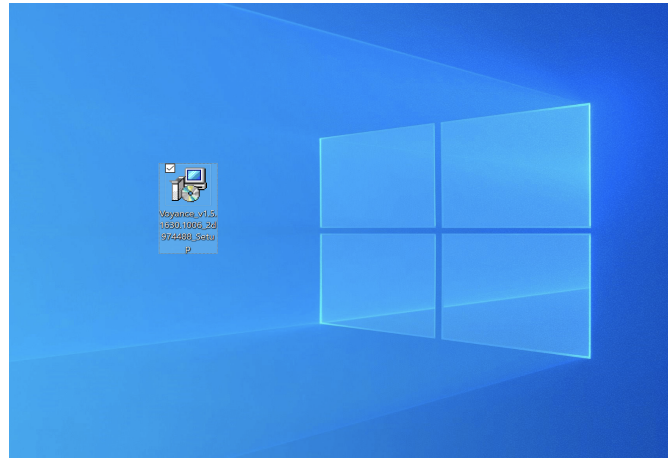


3.2 Start installation

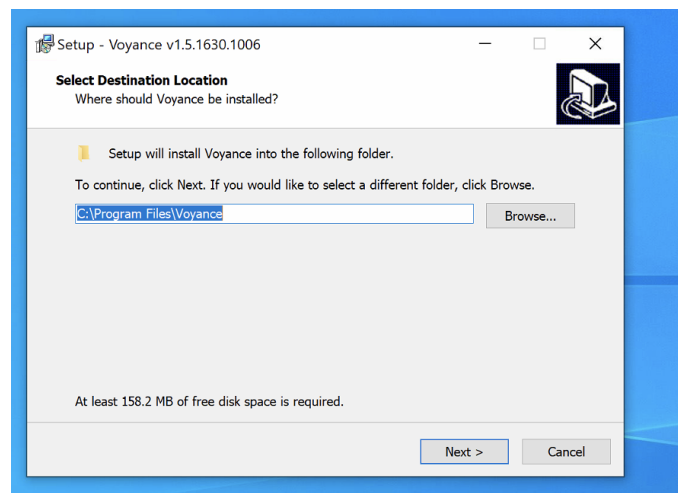
- a) Double-Click on Voyance setup file to Start the installation.



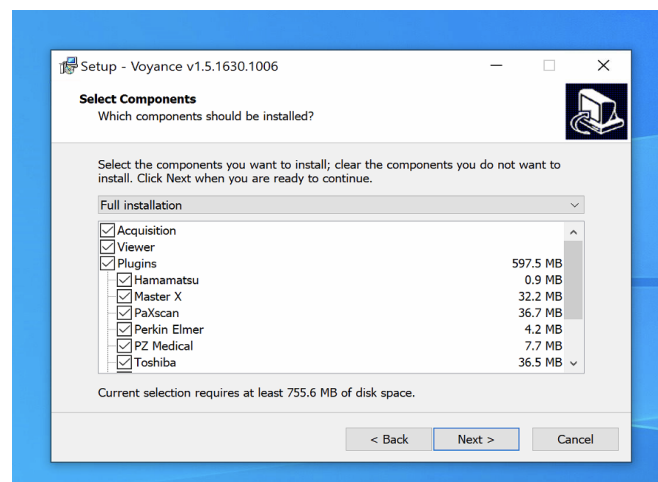
Note: The installation wizard will guide you through the installation



- c) Click "Next" to continue the installation , Change the Voyance installation destination if needed

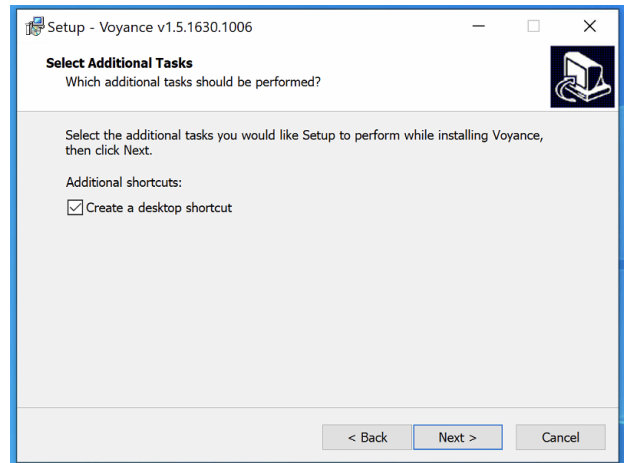


- b) Choose Which Detector then Click "Next" to continue the installation

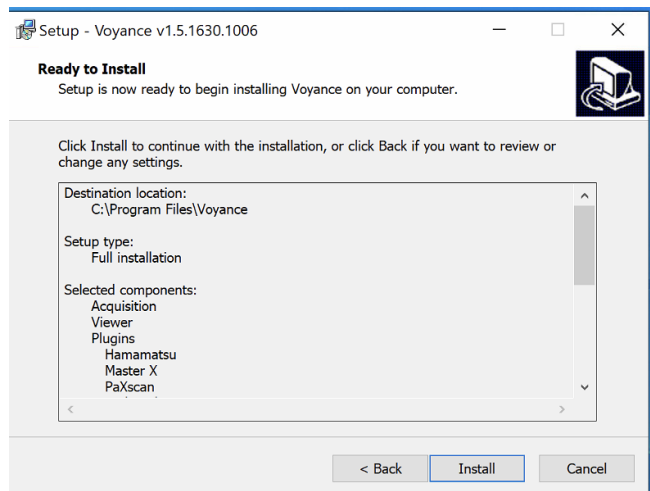




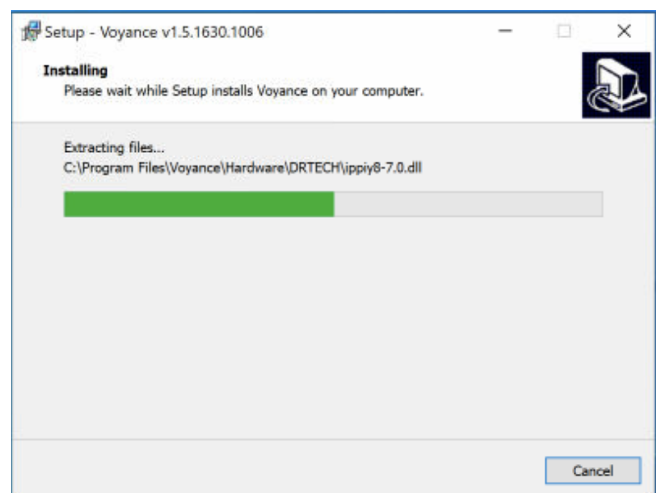
- f) Click "Next" to continue the installation , check create desktop shortcut option if you want to have Voyance shortcut on the desktop



- d) Confirm the installation destination folders and Click "Next" to continue the installation



- e) Wait for installation to be completed.

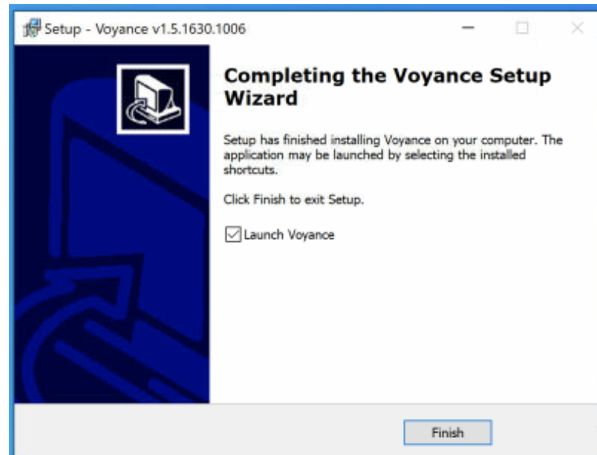




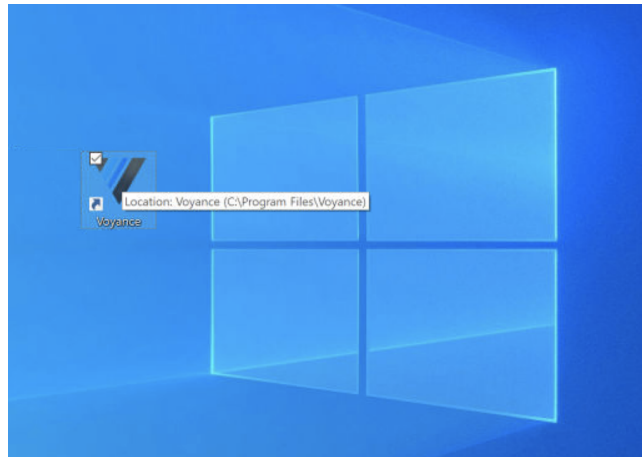
- i) Click "Finish" to complete the installation



Some computers may need to be restarted to finish installation

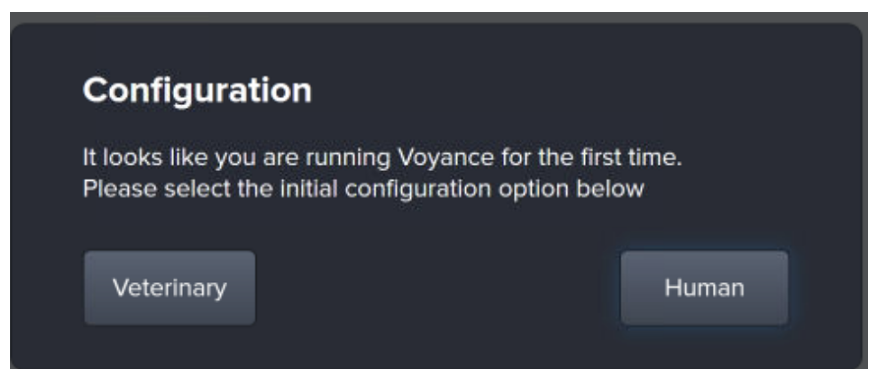


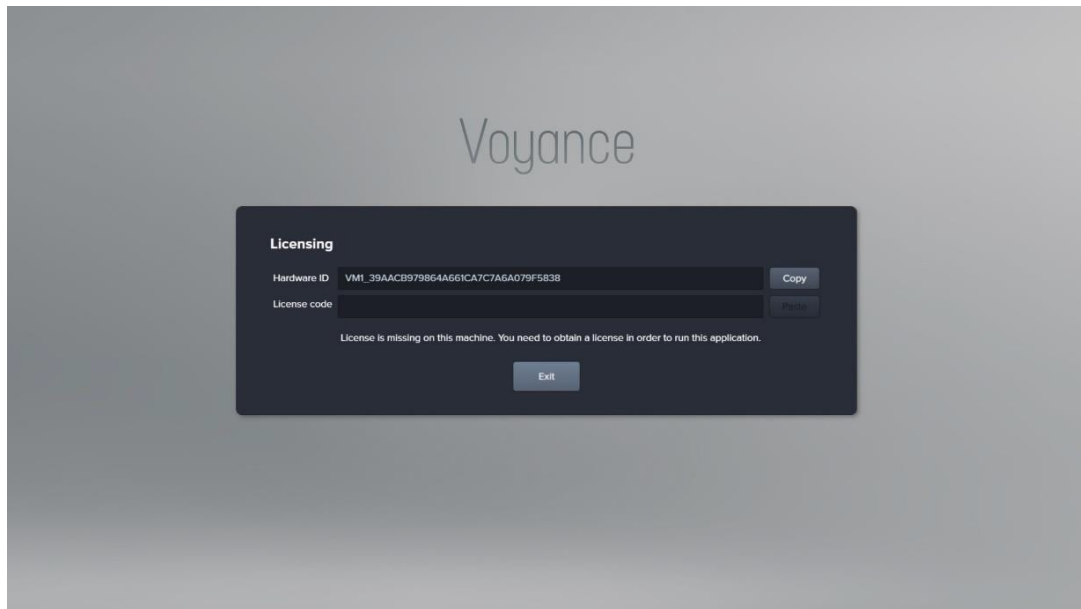
- h) Double Click on "Voyance "shortcut on the Desktop to launch the software for the first time.



- g) Confirmation on what applications will be used will be requested.

Select Human or Vet





- Get a license by using the **Hardware ID** indicated on the License window. This window is not displayed again after the license is registered successfully.
- A new license window can be displayed if you change specifications of the PC where **Voyance** is installed. Contact Voyance Support for providing a software license for activation of the software.



4. Browse Around

This section gives instruction on how to start and close Voyance and its basic components.

Starting Up

Basic Composition

Registration Area

Exposure Mode

Layout

Viewer Area

Tools

Pop up menu

4.1 Starting Up

4.1.1 Running Voyance

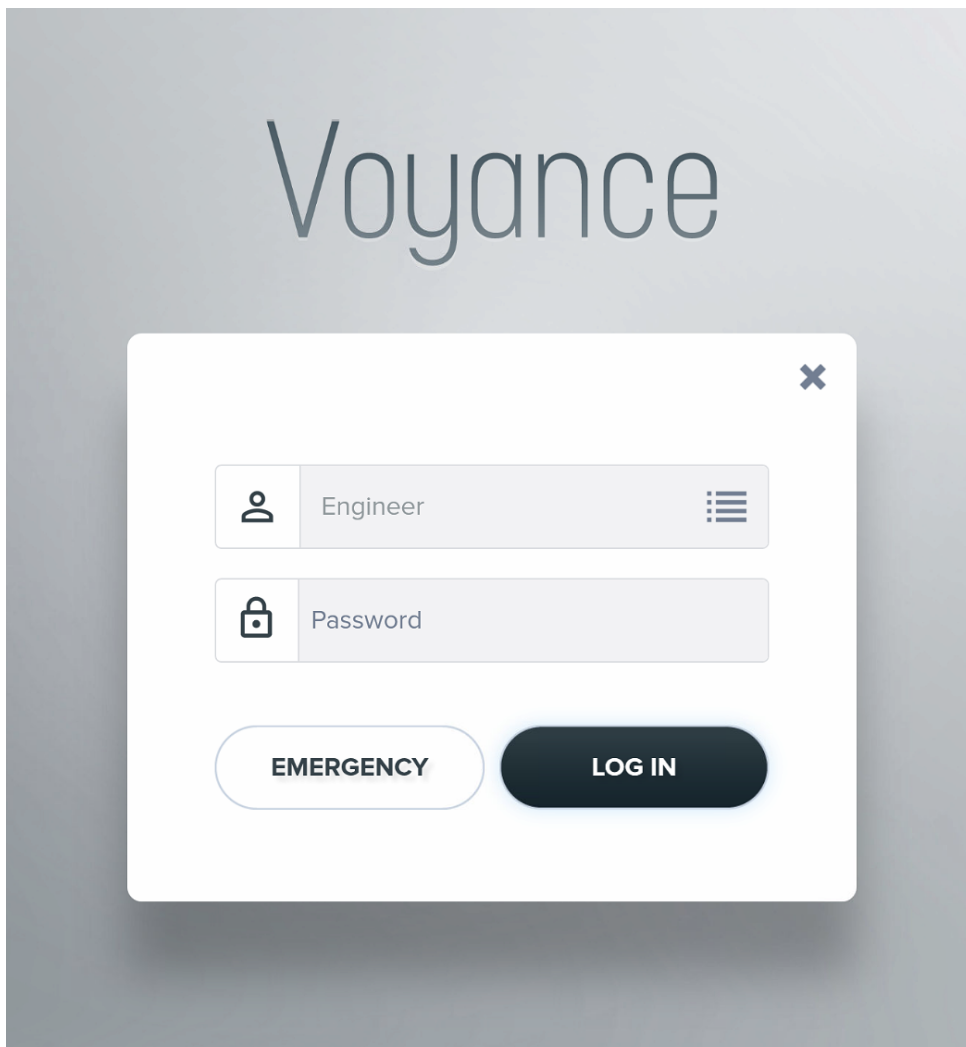
Start

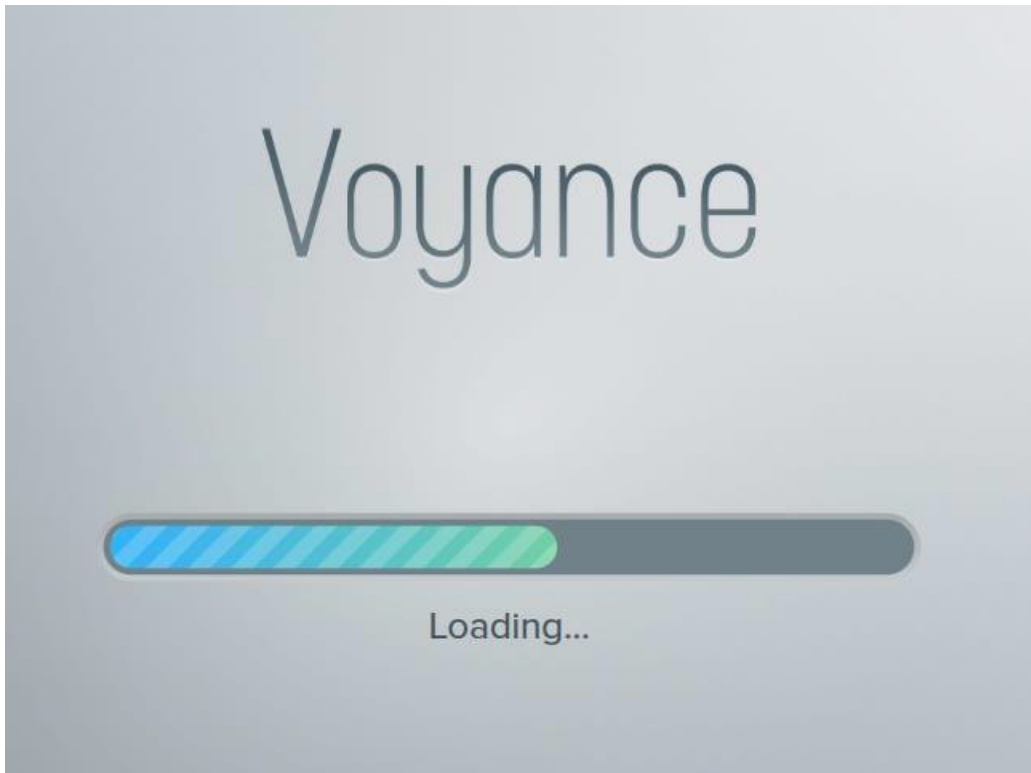
- **Login**



Start the program.

1. Double click **Voyance** icon on desktop to start click on login.





2. Wait until **Voyance** loads completely.

While running **Voyance**, the following points are processed.

- Connecting to database.
- Checking license registration status
- Checking detector connection status
- Checking detector calibration status
- Checking resolution.
- Initializing UI (User Interface)



1. Use the provided user name and password to login then click login.

4.2 Registering License

The screenshot shows a dark-themed window titled "License". It contains two text input fields. The first field is labeled "Hardware ID" and contains the text "R90L2RNF_53B3B227AA1F646EA54F662331F8BECC". To the right of this field is a "Copy" button. The second field is labeled "License code" and contains the text "FB385B26D7A7ADBF8E99CFF600081846A3DD9F605EAE0414119DC84A817508C45946313373084026F906". To the right of this field is a "Paste" button.

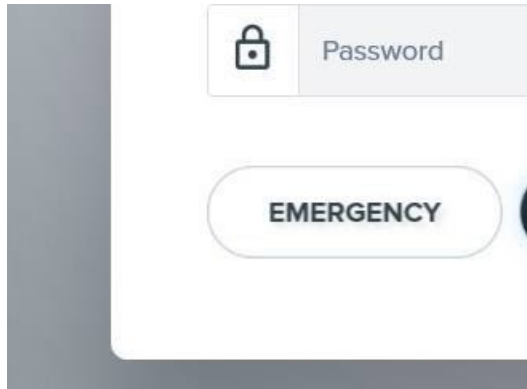
- Get a license by using the **Hardware ID** indicated on the License window. This window is not displayed again after the license is registered successfully.



- A new license window can be displayed if you change specifications of the PC where **Voyance** is installed.
- Contact the Voyance Support for the license issue and input.



4.3 Log on to (Emergency Room) Mode



Click on the **EMERGENCY** button to log on to the **EMERGENCY** mode.

- This mode can be used for the emergency circumstances such as emergency exposure without entering ID and Password.



4.4 Registration Area

The **Registration** Area provides functions for registering and managing the patient information.

1 Searched list area

You can check the searched result on the list after searching patient information.

2 Tool button area

The bottom area show active device information plus some more menu including setting through Voyance pop- up menu.



3 Search tool area

You can use the search tools for searching the patient information.

4 Patient Information Area divided into three Tabs (**Worklist**, **Add** and **Completed**) according to the registration method of patient information. You can choose the desired tab and register patient information.



4.5 How to Register Patient Information

This section provides information about registering the patient information.

Retrieve Patient information through the Worklist in the Worklist Tab and Input patient information through Add Tab.

4.5.1 Worklist Tab

You can retrieve the scheduled patient information in the Worklist tab using DICOM Worklist configuration.

1. Input or choose the search conditions to start searching for patients.
2. Check the searched **Worklist** and choose the desired item.
3. Double click on the requested patient to start study.

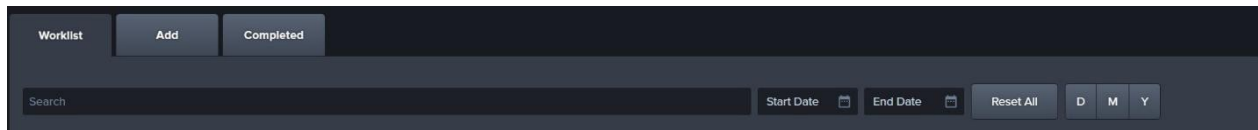


- Ask DICOM compatibility guide (**DICOM Conformance Statement**) to the DICOM server company for checking the operation of the SCP server and for its correct connection.

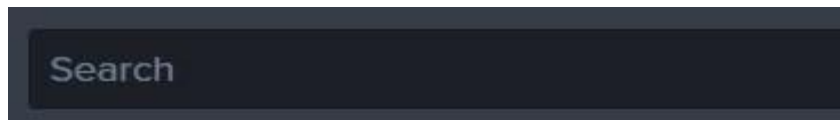


4.5.2 Tools

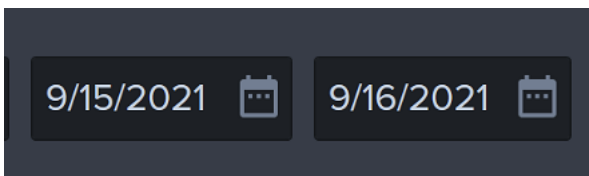
Worklist search tools you can get the patient information list by using the search tools in **Worklist tab**.



4.5.3 Tool buttons of Worklist



Patient information search area



Date Search period



Clear to reset all search

D search for one day

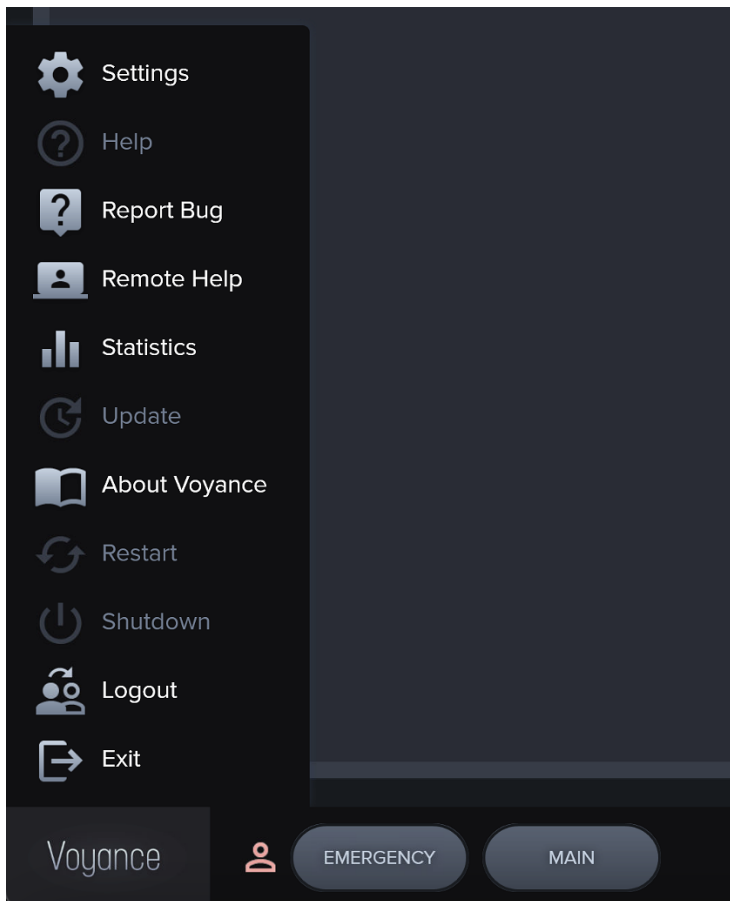
M search for one month

Y search for one year

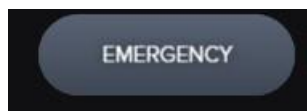
Worklist Item Search field for scheduled patient's studies, Search Studies by dates, Reset All and Also Search for a period of time by Press the period selection buttons (**Today, Week, Month**).



4.6 Voyance common Tools bar / Pops-up Setting Menu



4.6.1 Start emergency exposure

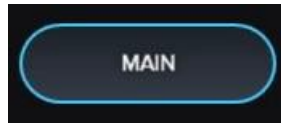


Click on the Emergency button to start the emergency exposure irrespective of the Scheduled item.

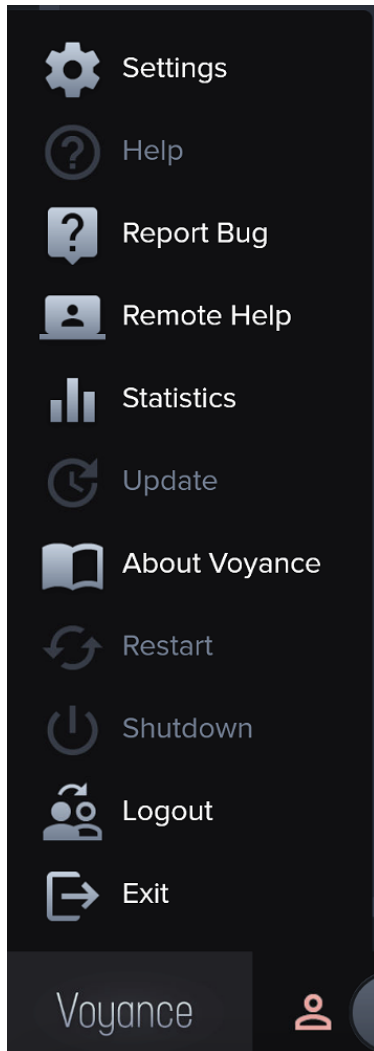
The screen is switched to the Exposure mode automatically.

The ID and name of the emergency patient is input automatically based on the present date and time. The ID form is Emergency Number.

| | |
|--|-----------------------------------------------------------------------------------------------------------------------|
| | <ul style="list-style-type: none">You can update the patient information after completing the exposure. |
|--|-----------------------------------------------------------------------------------------------------------------------|



Click on the Main button to access the Registration Tabs any time during using the Voyance software.



Click on the Voyance button to access the pops-up menu any time during using the Voyance software.



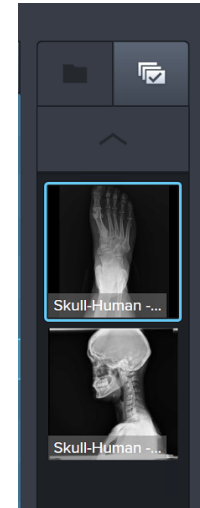
4.6.2 Detector information

- Wi-Fi Strength
- Temperature
- Battery level
- Virtual Keyboard



4.6.3 Images Thumbnail display

It shows thumbnails for images included in the selected study.



Completed Study List - Shows studies filtered by Date, Name and PID

| Worklist Add Completed | | | | | | | | | | | | | |
|------------------------|---------------------|-------------|-----------|------------|---------------|-----------------|------------|------------------------|-------------|-------|---------------------|-------------|--------------|
| Patient Name | | Patient UID | | Start Date | End Date | Default | Clear | D | M | Y | SEARCH | + | Delete |
| State | Created | Scheduled | Accession | Physician | Patient ID | Patient name | Birth date | Age (years and months) | Sex | Count | Exposure date | Description | Last Sending |
| Completed | 7/16/2021 9:26 AM | | | | Emergency 191 | Emergency 7/16/ | | | Unspecified | 4 | 7/16/2021 9:28 AM | | .. |
| Completed | 7/13/2021 9:16 AM | | | | Owner Name | Emergency 7/13/ | | | Unspecified | 3 | 7/13/2021 9:17 AM | | 7/13/2021 |
| Completed | 4/16/2021 1:21 PM | | | | Emergency 179 | Emergency 4/16/ | | | Unspecified | 1 | 4/16/2021 1:21 PM | test | 6/3/2021 |
| Completed | 3/12/2021 5:42 PM | | | | Emergency 165 | Emergency 3/12/ | | | Unspecified | 6 | 9/15/2021 10:55 AM | | .. |
| Completed | 3/12/2021 5:18 PM | | | | Emergency 164 | Emergency 3/12/ | | | Unspecified | 6 | 3/12/2021 5:32 PM | | .. |
| Completed | 3/4/2021 1:57 PM | | | | Emergency 150 | Emergency 3/4/ | | | Unspecified | 4 | 3/4/2021 2:08 PM | | .. |
| Completed | 2/16/2021 2:09 PM | | | | Emergency 136 | Emergency 2/16/ | | | Unspecified | 2 | 2/16/2021 2:09 PM | | 4/16/2021 |
| Completed | 1/15/2021 3:38 PM | | | | Emergency 85 | Emergency 1/15/ | | | Unspecified | 1 | 1/15/2021 3:39 PM | | .. |
| Completed | 12/9/2020 1:42 PM | 12/9/2020 | | | 09271976 | Mina Henry | 9/27/1976 | 44y 11m | Unspecified | 3 | 12/9/2020 1:46 PM | | .. |
| Completed | 12/4/2020 9:43 AM | | | | Emergency 71 | Emergency 12/4/ | | | Unspecified | 4 | 12/4/2020 9:48 AM | | .. |
| Completed | 12/4/2020 9:25 AM | | | | Emergency 70 | Emergency 12/4/ | | | Unspecified | 1 | 12/4/2020 9:25 AM | | 4/16/2021 |
| Completed | 12/4/2020 8:25 AM | | | | Emergency 68 | Emergency 12/4/ | | | Unspecified | 3 | 12/4/2020 9:14 AM | | 4/16/2021 |
| Completed | 11/2/2020 2:46 PM | | | | Emergency 67 | Emergency 11/2/ | | | Unspecified | 4 | 11/2/2020 3:27 PM | | .. |
| Completed | 10/30/2020 11:16 AM | | | | Emergency 56 | Emergency 10/31 | | | Unspecified | 2 | 10/30/2020 11:16 AM | | 10/30/2020 |
| Completed | 10/30/2020 11:00 AM | | | | Emergency 52 | Emergency 10/31 | | | Unspecified | 8 | 10/30/2020 11:20 AM | | 10/30/2020 |
| Completed | 10/30/2020 8:18 AM | | | | Emergency 50 | Emergency 10/31 | | | Unspecified | 3 | 10/30/2020 9:12 AM | | 10/30/2020 |
| Completed | 10/28/2020 4:23 PM | | | | Emergency 46 | Emergency 10/21 | 10/28/2015 | 5y 10m | Male | 3 | 10/28/2020 4:25 PM | | .. |
| Completed | 10/26/2020 9:28 AM | | | | Emergency 43 | Emergency 10/21 | | | Unspecified | 2 | | | .. |
| Completed | 10/21/2020 3:52 PM | | | | Emergency 37 | Emergency 10/21 | | | Unspecified | 2 | | | .. |
| Completed | 10/21/2020 2:45 PM | 10/21/2020 | 1234567 | | 12345 | Test Testing | 10/21/2006 | 14y 10m | Unspecified | 7 | 10/21/2020 3:05 PM | | 10/21/2020 |
| Completed | 10/21/2020 10:55 AM | | | | Emergency 30 | Emergency 10/21 | | | Unspecified | 3 | 10/21/2020 11:25 AM | | 4/16/2021 |
| Completed | 7/31/2020 10:26 AM | | | | Emergency 24 | Emergency 7/31/ | | | Unspecified | 3 | 7/31/2020 10:29 AM | | 9/23/2020 |
| Completed | 2/27/2020 11:18 AM | | | | Emergency 23 | Emergency 2/27 | | | Unspecified | 4 | 2/27/2020 11:19 AM | | 4/16/2021 |
| Completed | 2/26/2020 9:34 AM | | | | Emergency 21 | Emergency 2/26 | | | Unspecified | 8 | 2/26/2020 9:34 AM | | 4/16/2021 |



4.7 Add Tab

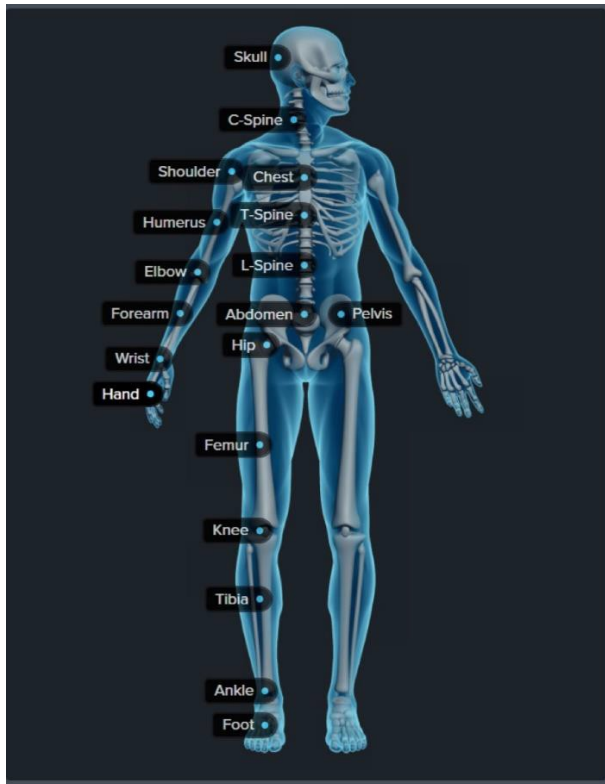
You can manually input the patient information from the add tab.

- The patient information can be stored to the local database.
- You can make an exposure after inputting the patient information.
- You can start an emergency exposure without inputting the patient information.
- You can start exposure mode once you input the required information.

* Required fields



- Input the required patient information
- Select the body part on the showing Skelton
- Add the requested views





Worklist

Add

Completed

Schedule new study

Patient ID*

Patient Name*

First Name

M.I

Last Name

Age

Date of Birth

DOB

Species

Human

Sex

Unspecified

Please fill all the required fields

Accession number

Performing physician

Scheduled date

Study notes

Positions

Reset All

Save

Start

Click Reset All to reset all patient information fields.

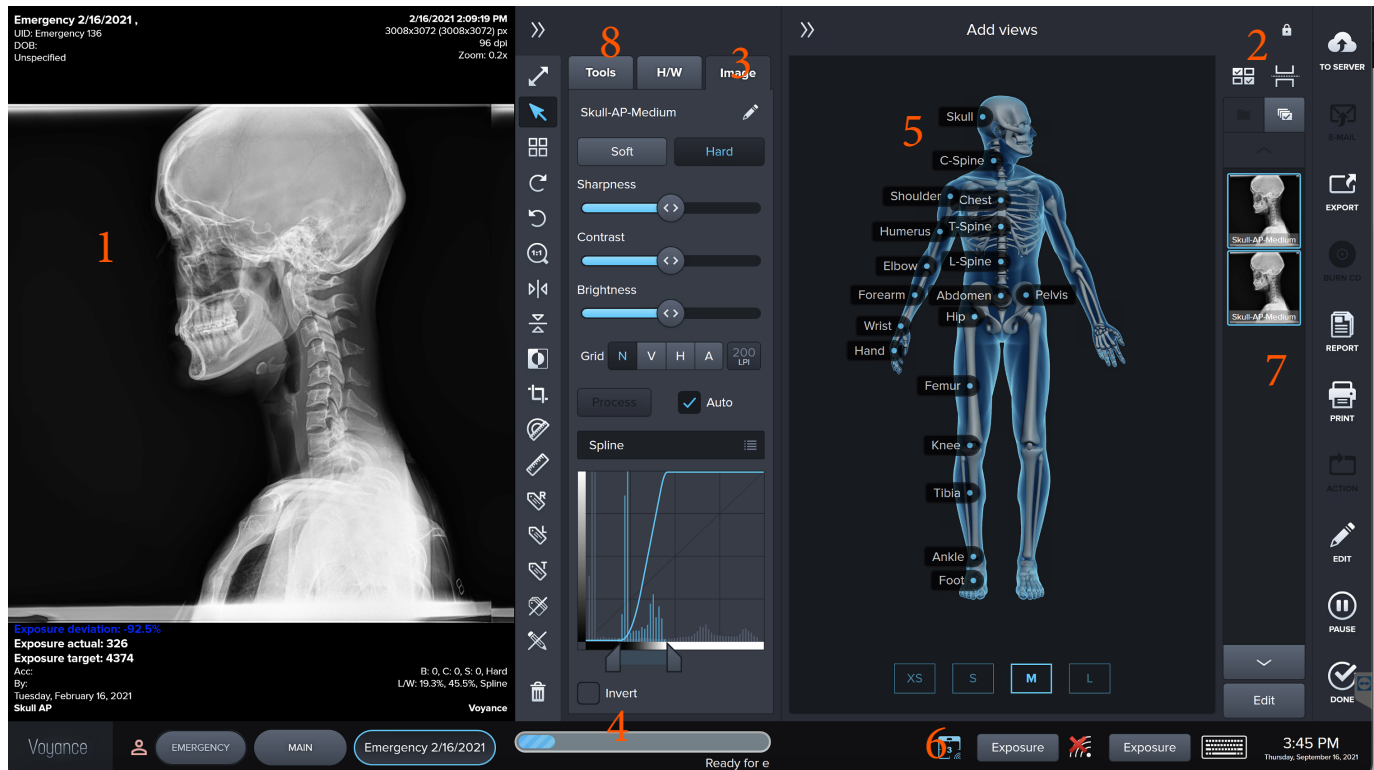
Click Save to the save patient information to the

Click Start to start study in exposure mode.



4.8 Exposure Mode

The displaying layout of **Exposure** mode is changed automatically depending on the screen choice (Fold / unfold).



- 1 Exposure Area (Acquired Image Area)
- 2 Screen Options / Tools / Stitching Icon
- 3 Image Tools
- 4 Status Bar
- 5 Body Parts
- 6 Active Sensors
- 7 Views Thumbnails
- 8 Study Tools
- 9 CPI Integration Interface





4.9 Default Layout (Unexpanded)

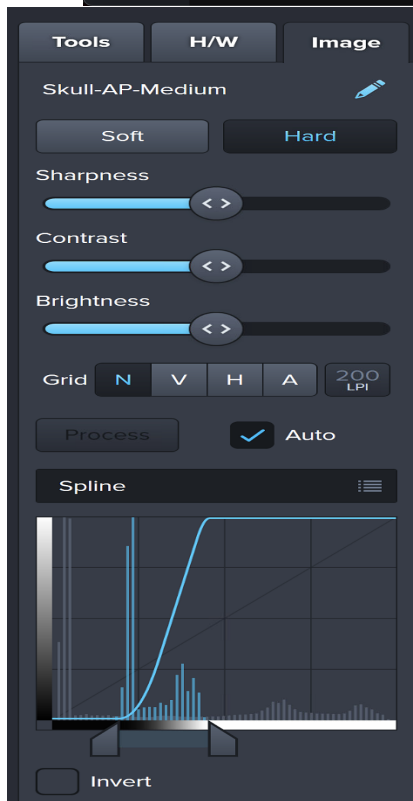
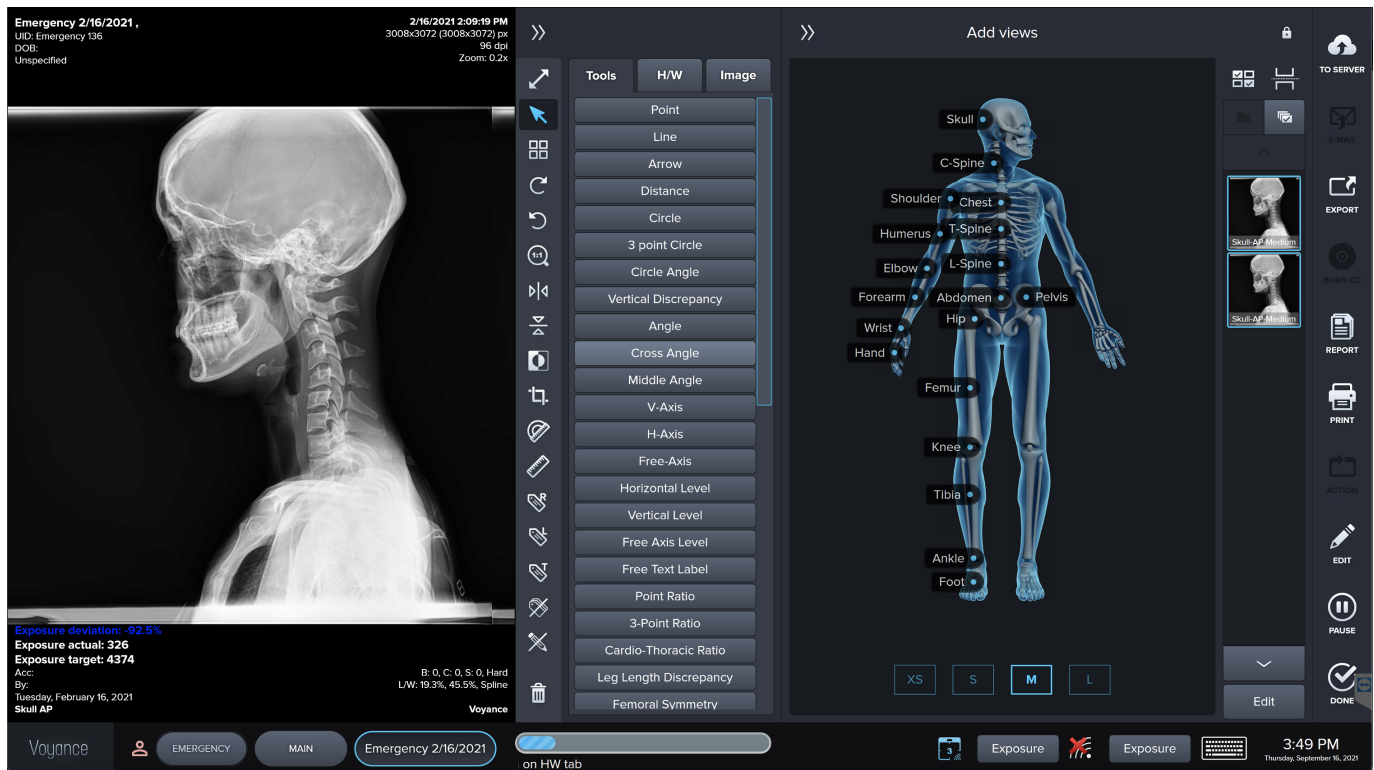
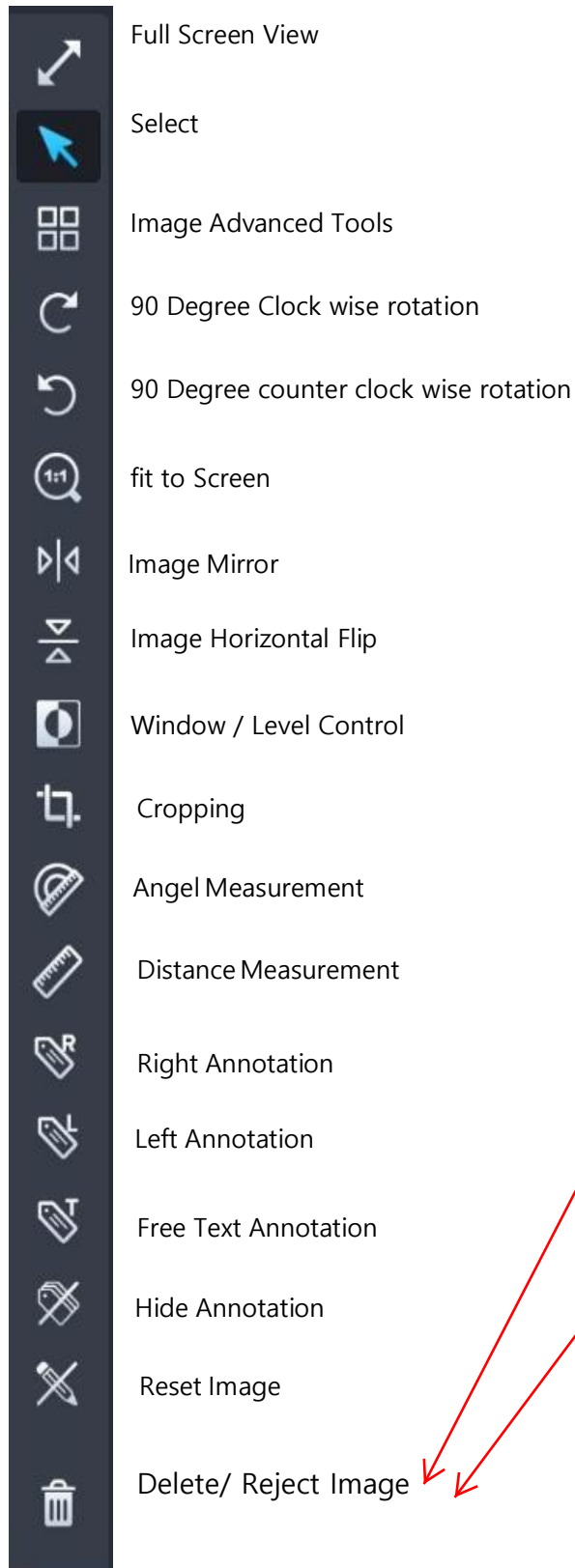


Image Processing Tab

- Soft Preset Image Processing Algorithm Showing soft tissues.
- Hard Preset Image Processing Algorithm showing more bone details and less Soft tissues.
- Sharpness / Contrast and Brightness Manual Adjustment for the Acquired images.
- Grid Suppression (Vertical & Horizontal) and grid Lines selection
- Invert: if checked the image will be inverted.



4.10 Image Tools:



Full Screen View

Select

Image Advanced Tools

90 Degree Clock wise rotation

90 Degree counter clock wise rotation

fit to Screen

Image Mirror

Image Horizontal Flip

Window / Level Control

Cropping

Angel Measurement

Distance Measurement

Right Annotation

Left Annotation

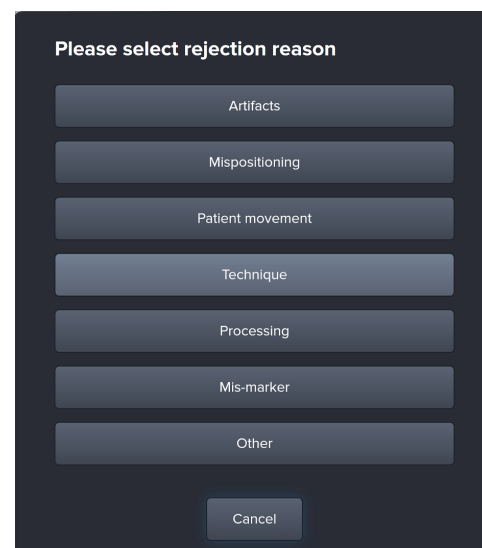
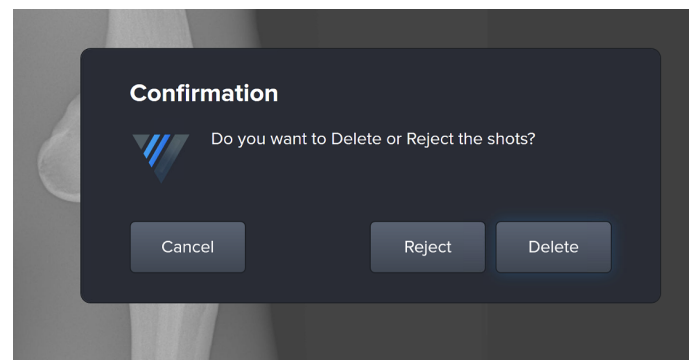
Free Text Annotation

Hide Annotation

Reset Image

Delete/ Reject Image

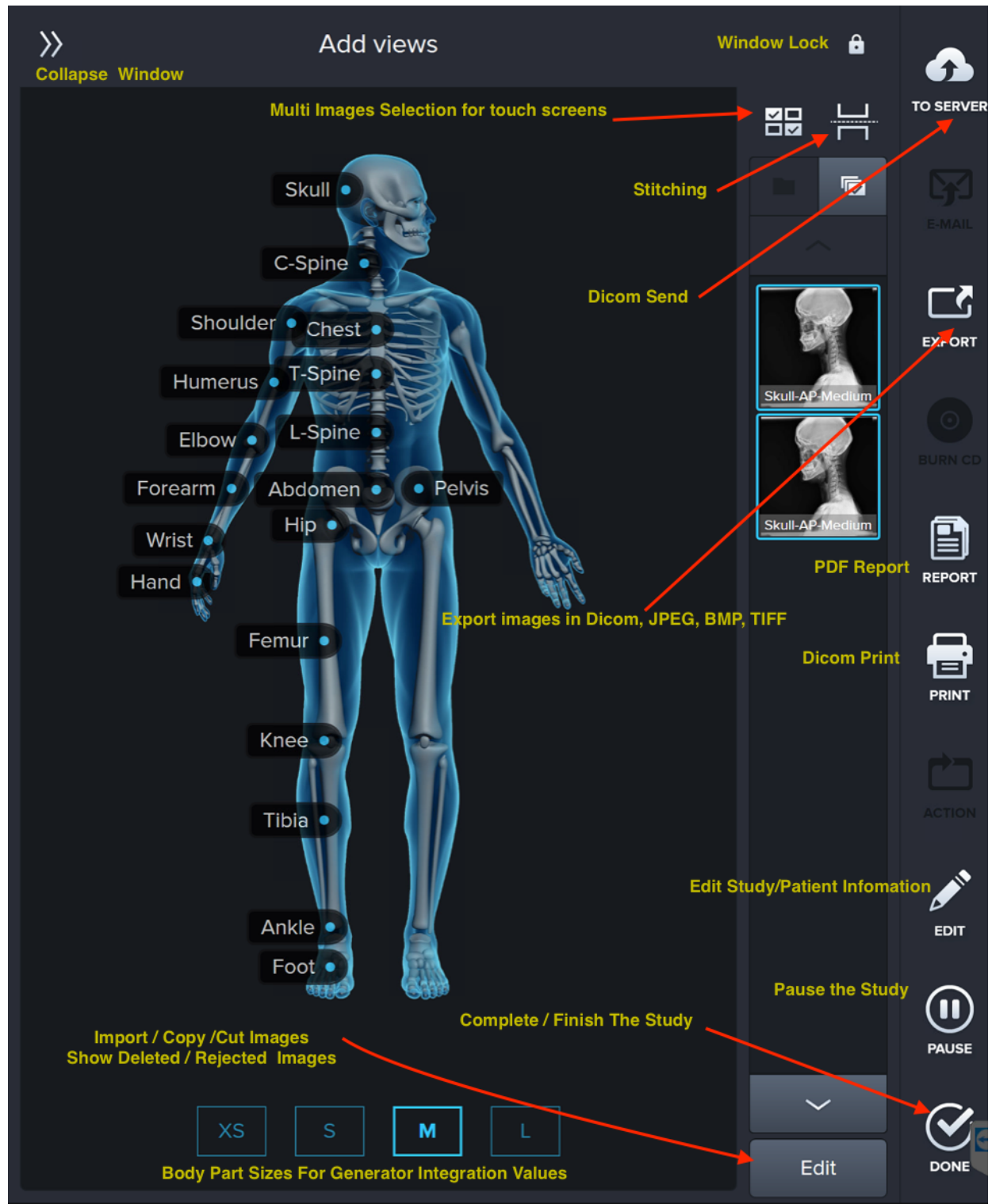
To use the reject option, choose the reason, and software will repeat the images that was rejected





4.11

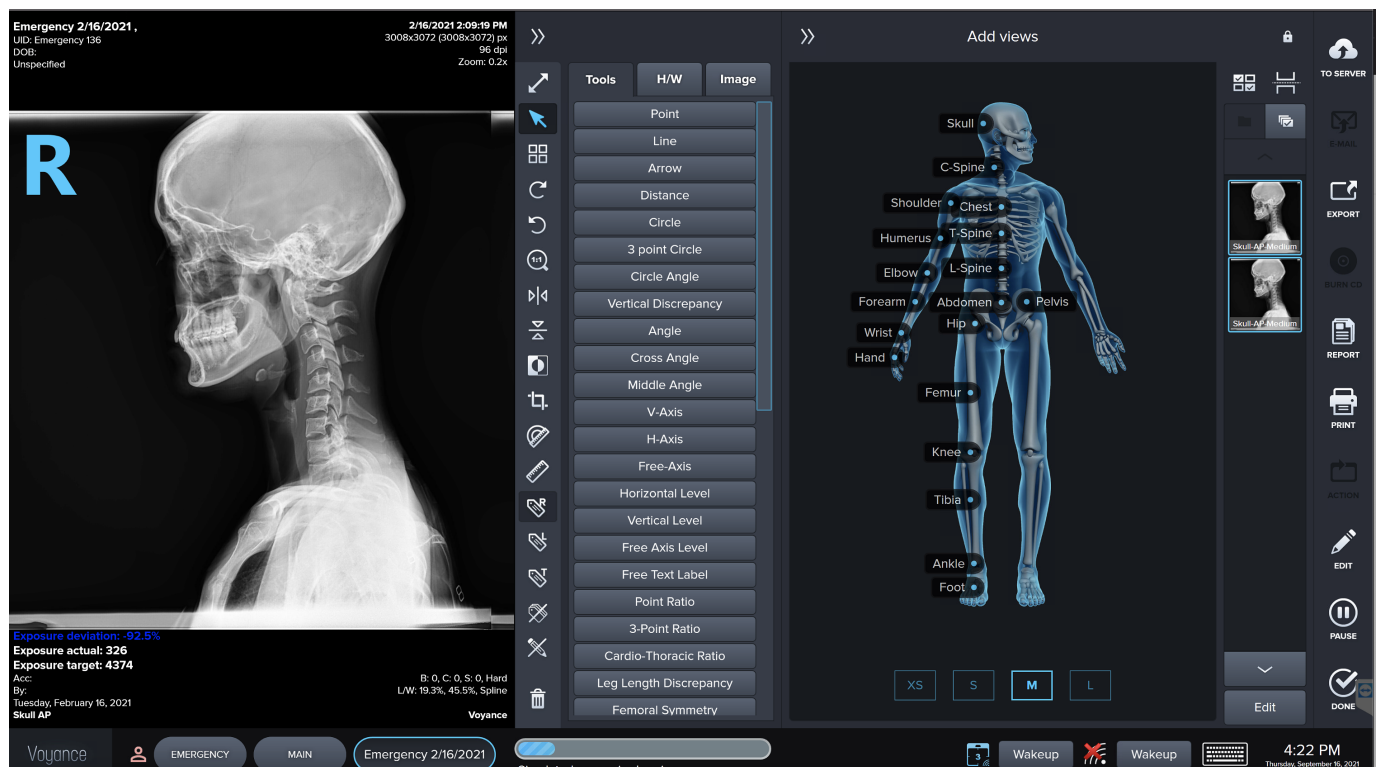
Screen Options /Tools On Open Study Functions :





4.12 Unexpanded Layout

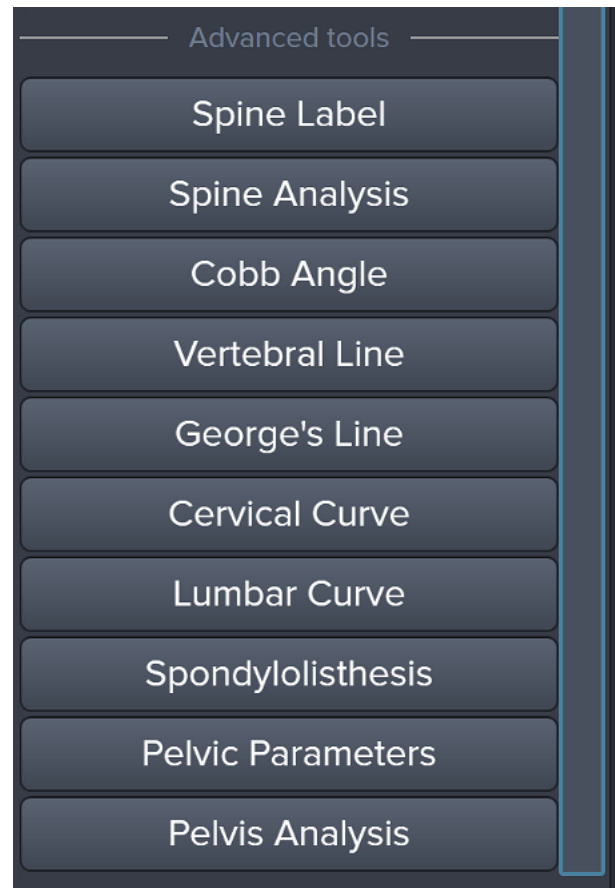
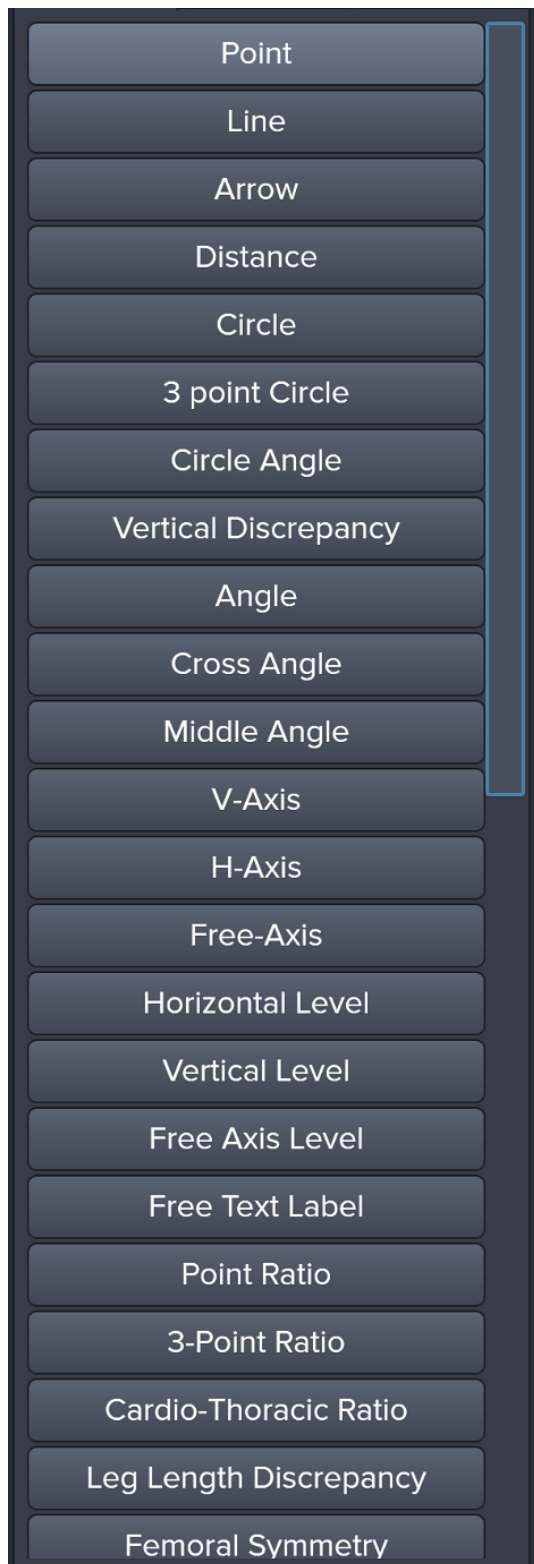
- The minimum display resolution is 600 x 800 however we 1280x800 or higher is recommended.
- The Exam area is switched to the expanded area when you make an exposure after setting the study.
- After making the exposure you can go back to unexpanded screen by clicking of touching collapse window arrows.
- You can keep the current view by selecting the lock icon.



*Imported file formats could be all image file formats (Bmp, Tiff, Jpeg.....etc.) or Dicom format



4.13 Main Image Tools and Advanced Tools



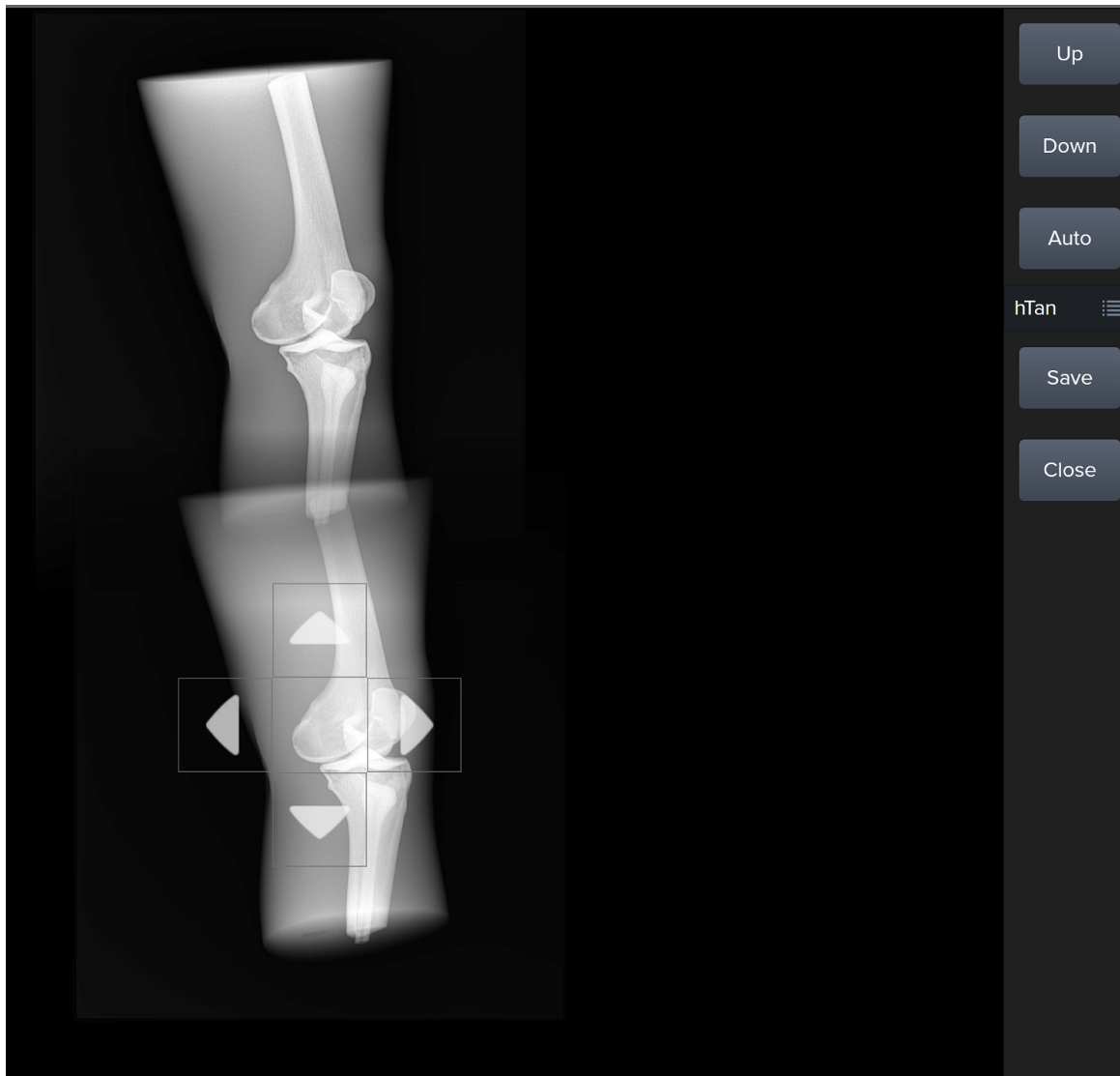


How To Use Stitching Tool

Select two or more images to be able to use the stitching

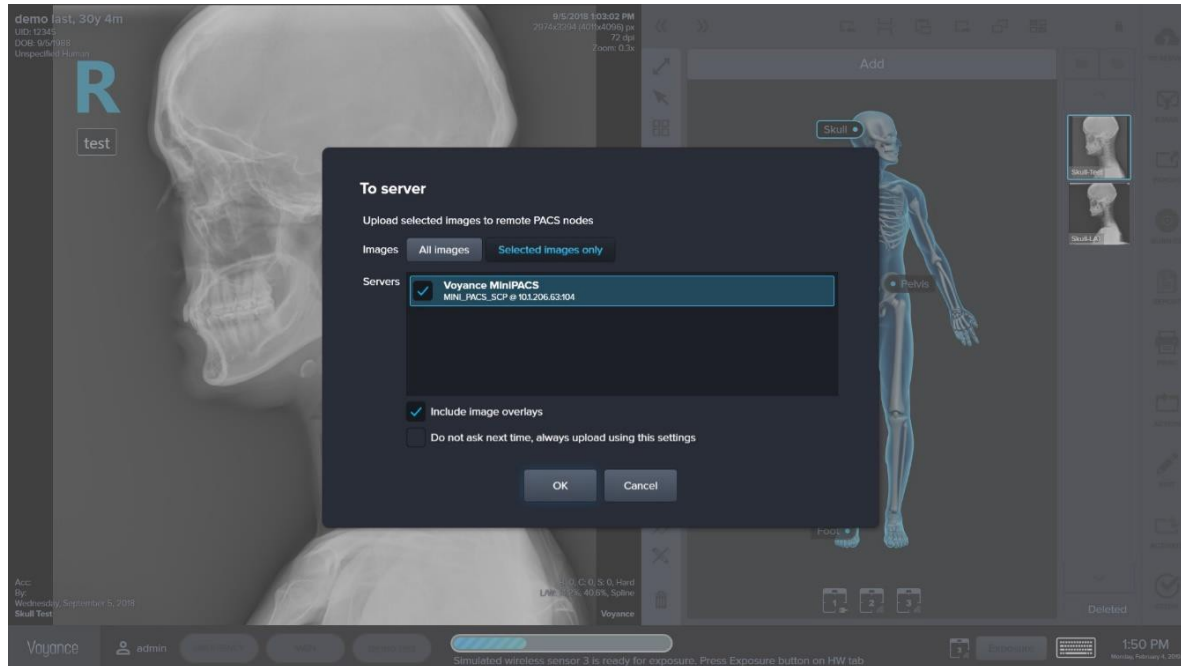
Stitching Window below shows auto stitch or you can click and hold then move the bottom image to match and align with the top image.

Click on Save to get a new Image with the stitched view





4.14 Send to the PACS server



For Manual send to the PACS

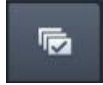
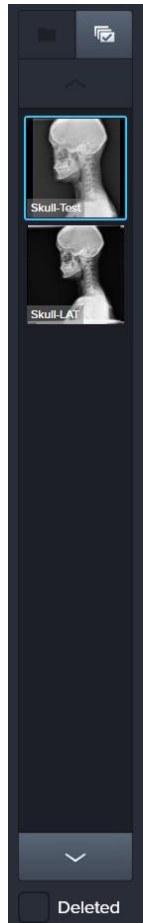
- Click To Server Icon
- Make sure to select the requested PACS destination
- Select all images or selected images
- Click ok



PACS Destination must be previously configured through setting



4.15 Thumbnail Area Tools



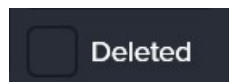
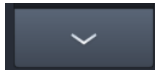
Multi images select when using touch Screen



Group selected images



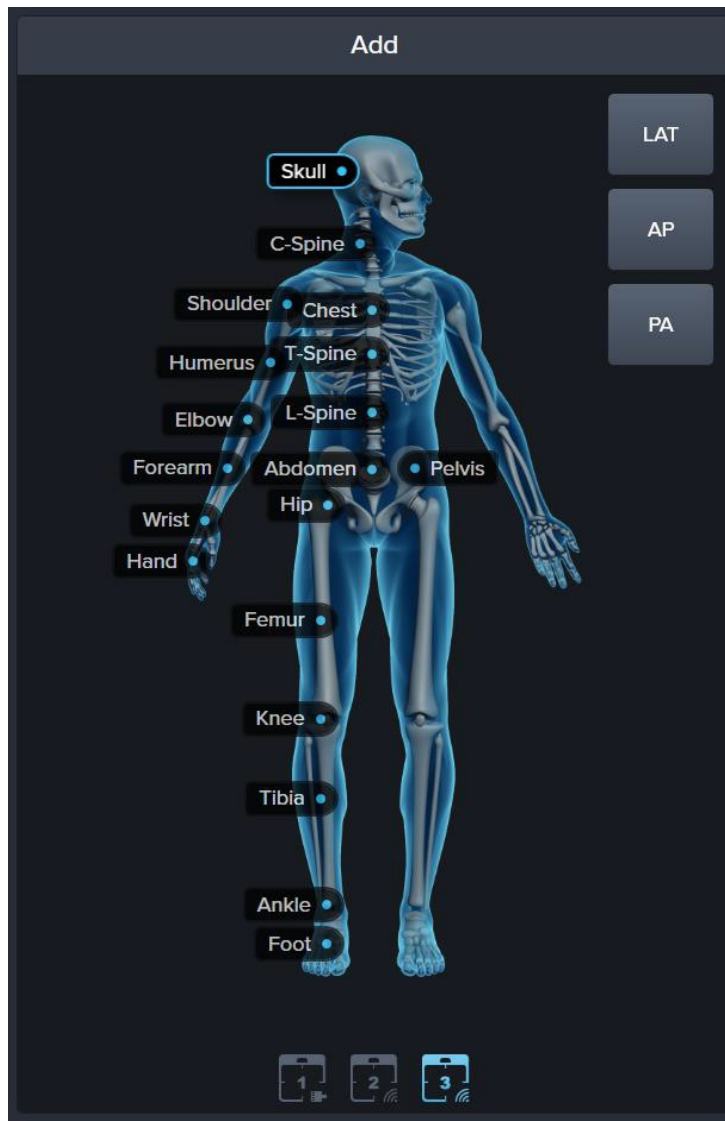
Moving Image View Selection up/down



Show Deleted Images when checked



4.16 Body part / Views Selection



Selection of the scheduled views



Manual Selection of the Active Sensor



Failing on selecting the active Sensor might lead to failure in the image acquisition .



4.17 Voyance Pop up Menu

| | | |
|--|---------------|----------------------------|
| | Settings | Access Setting |
| | Help | Access Interactive Help |
| | Report Bug | Report a Software Bug |
| | Remote Help | Request Remote Support |
| | Statistics | Studies Statistics |
| | Update | Check for Software update |
| | About Voyance | About the Software version |
| | Restart | Restart the Workstation |
| | Shutdown | Shutdown the Workstation |
| | Logout | Logout the Current User |
| | Exit | Exit the Software |

Create a PDF Statistics Report

Statistics Shows The Number of Exposed , Rejected , Deleted , Sent and Printed Images

Voyance Analysis Exposures

Users Filter Per Account From date To date Export

Engineer 2/1/2019 9/16/2021 PDF

Total Analysis

| User | Period | Patients | Exposed | Rejected | Deleted | Sent | Printed |
|----------|------------|----------|---------|----------|---------|------|---------|
| Engineer | 2/1/2019 | 2 | 0 | 0 | 0 | 6 | 0 |
| Engineer | 11/15/2019 | 1 | 0 | 0 | 0 | 0 | 0 |
| Engineer | 11/19/2019 | 1 | 0 | 0 | 0 | 2 | 0 |
| Engineer | 11/23/2019 | 1 | 0 | 0 | 0 | 7 | 0 |
| Engineer | 11/26/2019 | 1 | 0 | 0 | 0 | 3 | 0 |
| Engineer | 11/29/2019 | 1 | 0 | 0 | 0 | 6 | 0 |
| Engineer | 11/30/2019 | 1 | 0 | 0 | 0 | 2 | 0 |
| Engineer | 2/16/2020 | 1 | 1 | 0 | 0 | 0 | 0 |
| Engineer | 2/17/2020 | 6 | 6 | 0 | 0 | 1 | 0 |
| Engineer | 2/18/2020 | 2 | 3 | 0 | 0 | 0 | 0 |
| Engineer | 2/19/2020 | 2 | 4 | 0 | 0 | 0 | 0 |
| Engineer | 2/21/2020 | 1 | 3 | 0 | 1 | 0 | 0 |
| Engineer | 2/26/2020 | 3 | 14 | 0 | 2 | 7 | 0 |
| Engineer | 2/27/2020 | 1 | 3 | 0 | 0 | 2 | 0 |
| Engineer | 7/31/2020 | 1 | 3 | 0 | 0 | 3 | 0 |
| Engineer | 11/8/2020 | 2 | 9 | 0 | 0 | 0 | 0 |

Rejected Shots

| User | Artifacts | Mispositioning | Patient movement | Technique | Processing | Mis-marker | Other |
|----------|-----------|----------------|------------------|-----------|------------|------------|-------|
| Engineer | 0 | 0 | 1 | 0 | 0 | 0 | 0 |

Projection Analysis

| Projection | Position | Count |
|------------|----------|-------|
| Abdomen | DV | 2 |
| Abdomen | LAT | 12 |
| Abdomen | PA | 6 |
| Abdomen | VD | 10 |

Close

Statistics

Voyance Analysis Exposures

From date To date Export

1/1/2021 9/30/2021 PDF

| State | Exposure | User | Patient | Physician | Shots |
|-----------|-----------------------|-----------|---------------------|-----------|-------|
| Completed | 9/16/2021 4:32:07 PM | Engineer | Emergency 2/27/2020 | | 1 |
| Scheduled | 9/12/2021 12:58:36 PM | Engineer | Emergency 1/12/2021 | | 3 |
| Completed | 9/16/2021 3:39:41 PM | Engineer | Emergency 8/5/2021 | | 1 |
| Paused | 2/3/2021 12:00:21 PM | Engineer | Emergency 2/3/2021 | | 1 |
| Scheduled | 2/15/2021 8:58:47 AM | Emergency | Emergency 2/15/2021 | | 2 |
| Scheduled | 2/15/2021 3:58:07 PM | Emergency | Emergency 2/15/2021 | | 3 |
| Paused | 2/16/2021 2:09:16 PM | Emergency | Emergency 2/16/2021 | | 2 |
| Scheduled | 2/24/2021 1:15:15 PM | Emergency | Emergency 2/24/2021 | | 1 |
| Completed | 3/4/2021 2:06:10 PM | Emergency | Emergency 3/4/2021 | | 4 |
| Paused | 3/12/2021 4:12:44 PM | Emergency | Emergency 3/11/2021 | | 4 |
| Scheduled | 3/12/2021 4:39:10 PM | Emergency | Emergency 3/12/2021 | | 2 |
| Scheduled | 3/12/2021 5:10:05 PM | Emergency | Emergency 3/12/2021 | | 1 |
| Completed | 3/12/2021 5:19:15 PM | Emergency | Emergency 3/12/2021 | | 6 |
| Completed | 3/12/2021 5:42:47 PM | Emergency | Emergency 3/12/2021 | | 6 |
| Scheduled | 3/12/2021 5:59:02 PM | Emergency | Emergency 3/12/2021 | | 1 |
| Scheduled | 3/12/2021 6:02:24 PM | Emergency | Emergency 3/12/2021 | | 4 |
| Scheduled | 3/16/2021 10:47:39 AM | Emergency | Emergency 3/16/2021 | | 4 |
| Completed | 4/16/2021 1:21:14 PM | Emergency | Emergency 4/16/2021 | | 1 |
| Completed | 7/13/2021 9:17:02 AM | Emergency | Emergency 7/13/2021 | | 1 |
| Scheduled | 7/13/2021 3:22:08 PM | Emergency | Emergency 7/13/2021 | | 1 |
| Completed | 7/16/2021 9:28:36 AM | Emergency | Emergency 7/16/2021 | | 2 |
| Paused | 3/12/2021 5:37:51 PM | Engineer | Same Test | | 1 |
| Paused | 7/14/2021 5:53:01 AM | Engineer | Test Testing | | 3 |

Close



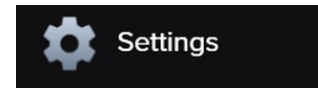
5. Setting

This chapter provide information on how
Configure the different features in Voyance

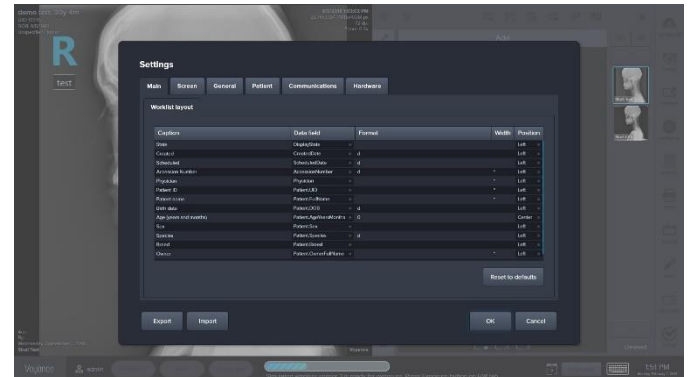


5.1 Getting Access

Select setting tab from pop up menu to access the system setting



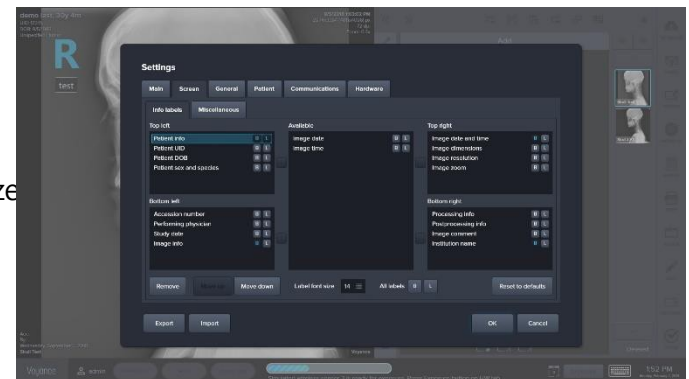
Only Admin users can access this menu



5.1.1 Main tab (Worklist layout): used to customize the main worklist layout in the software



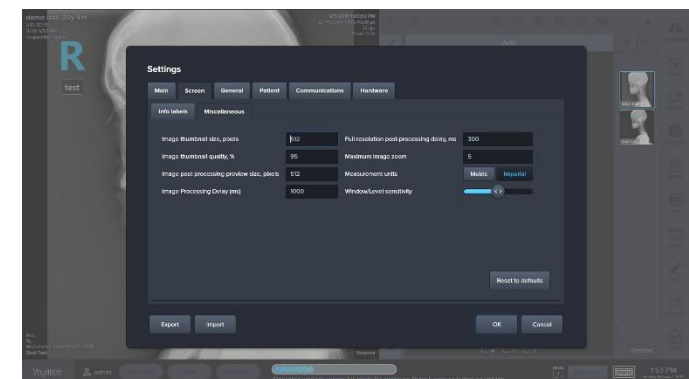
Export / import is used to export or import setting



5.1.2 Screen /info labels tab: use to customize What information to show in the different 4 corners of the image Screen. Labels font size and information order Could be customized as well.

5.1.3 Miscellaneous tab: used to control

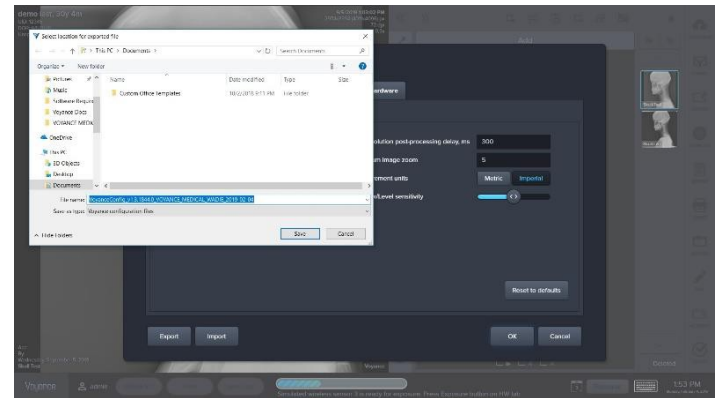
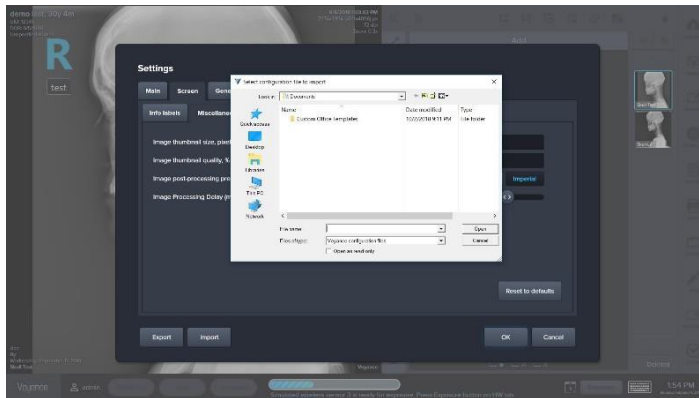
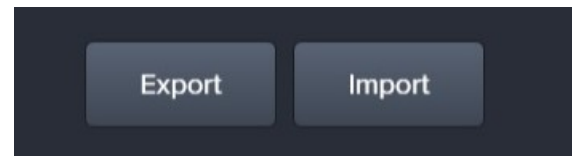
- Image thumbnail size
- Image thumbnail resolution
- Image post processing preview size
- Image delay
- Max. image zoom
- Setup the software measurement unit
- Window/level sensitivity





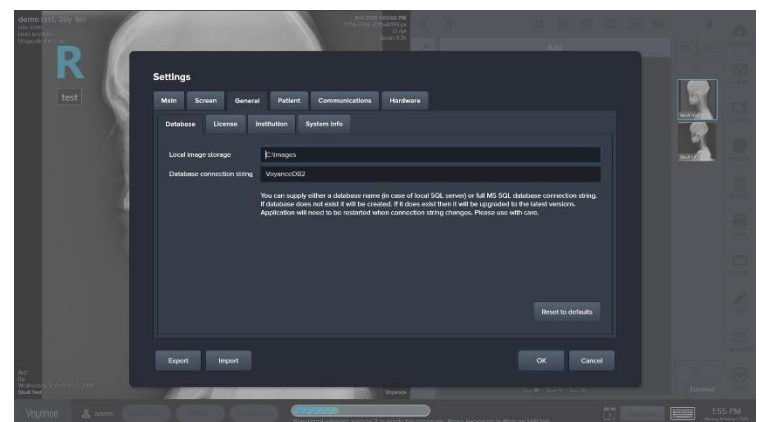
5.1.4 Export / Import:

- use the export icon to Export Setting of the software
- use the import icon to import Setting form a setting file



5.1.5 Database:

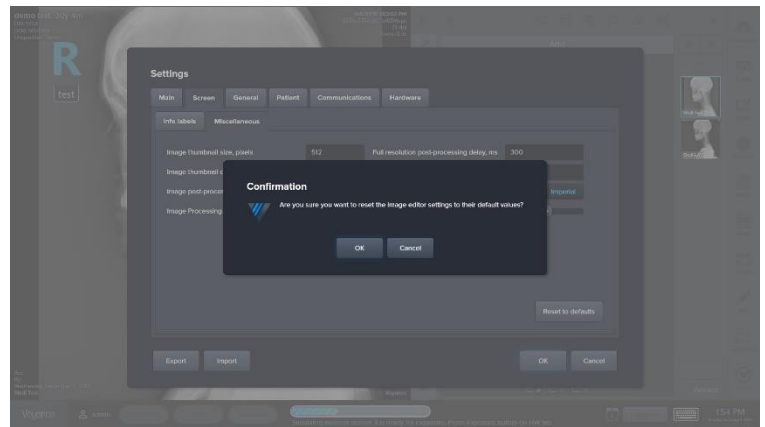
- Use Database tab to change the Storage images location.
- Connect with a new database



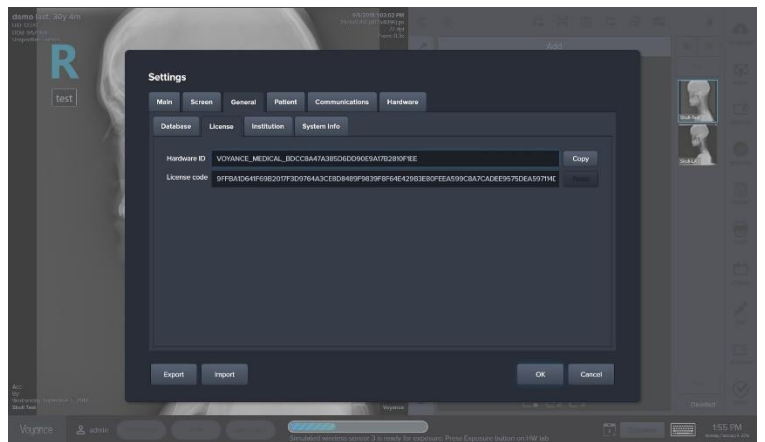
Make sure to click ok to save new setting.



Rest all will discard all changes set back software default setting.



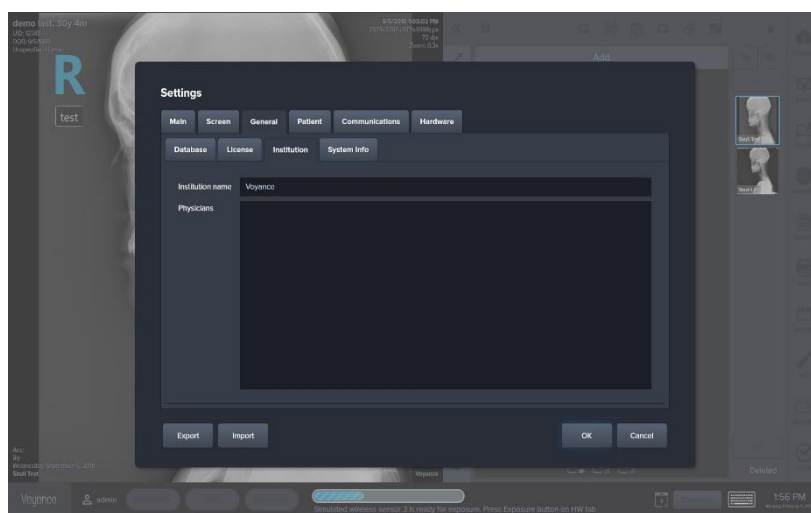
5.1.6 License Tab: provide information on The Hardware ID as well as changing the Software license.



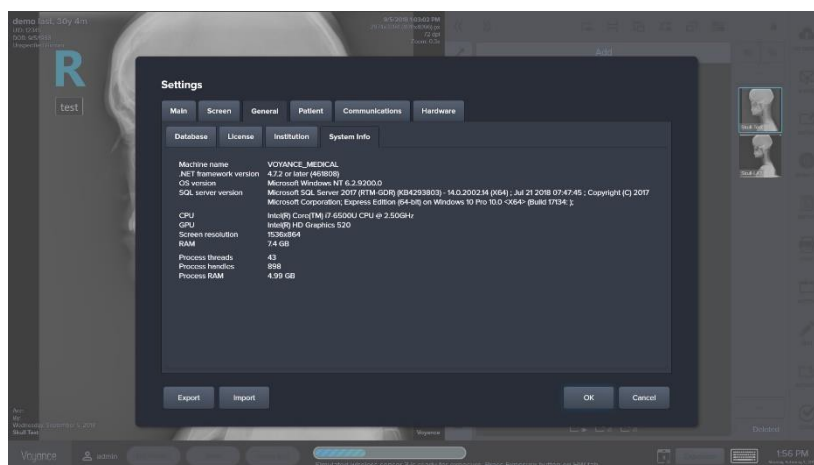
Changing the software license might lead to failure launching Voyance



5.1.7 Institution Tab: used to add institution name as well as the physician names



5.1.8 System information Tab: used to provide the workstation information as well as the voyance software version





5.1.9 Patient Tab: used to add patient body part and different views

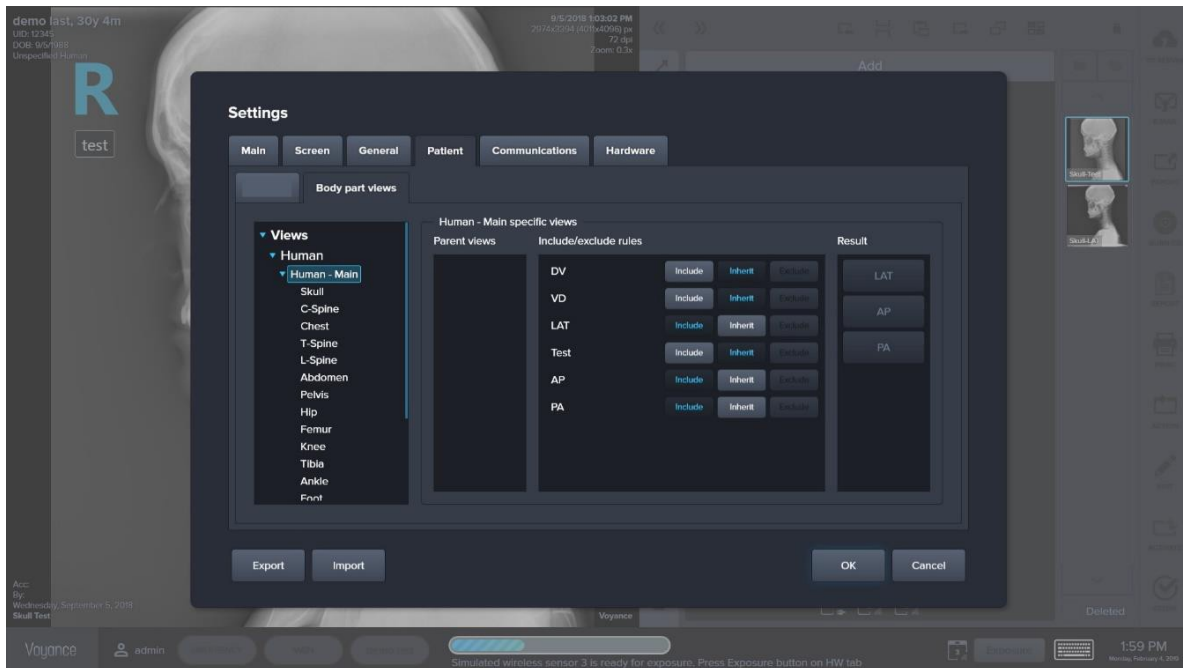
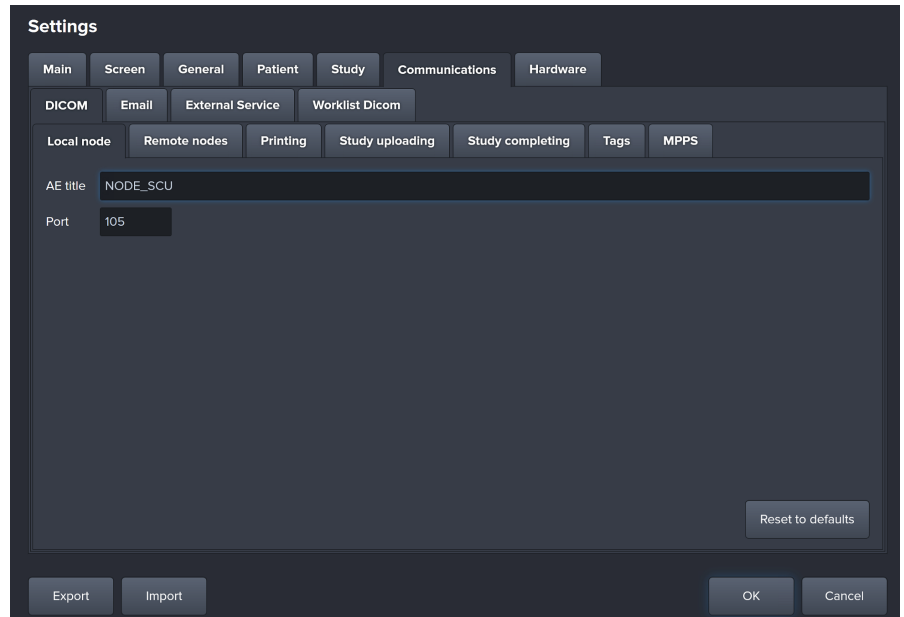


Image processing of the desired bodypart / view will assigned automatically



5.1.10 Communication / Dicom / Local Tab:

used to configure the local AE Title and Port number of the Acquisition workstation

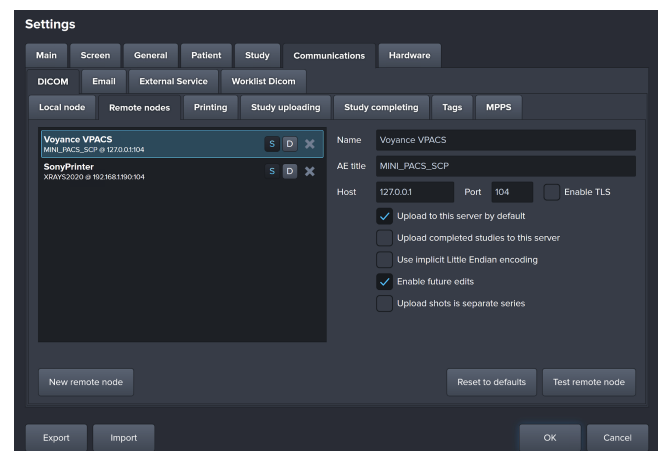


5.1.11 Communication / Dicom / Remote node Tab:

used to add the different Dicom destination nodes or Dicom Printers, for Dicom printers you need to go to printing tab to select the default dicom printer



AE Title, IP address and Port number of the Dicom node are required To be added

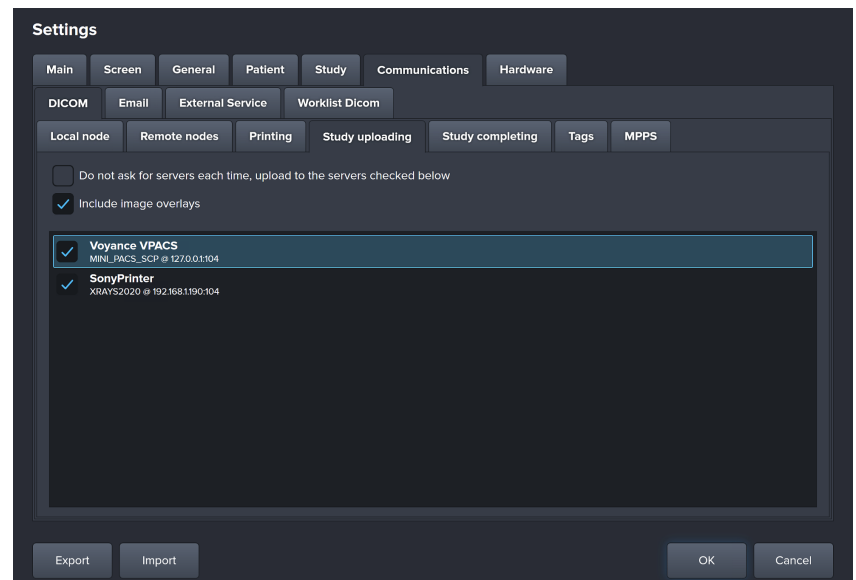


Multiple Dicom Node destination can be added
Multiple Dicom Printers can be added



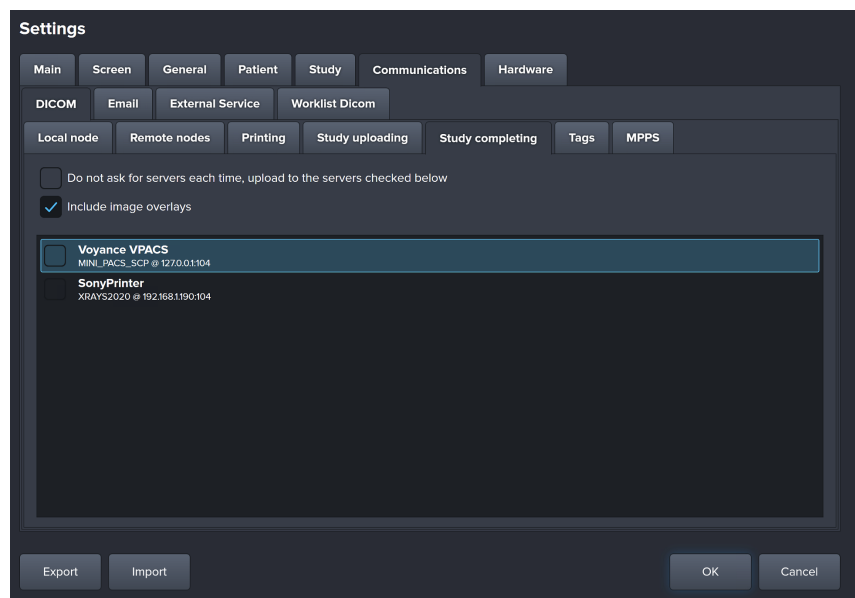
5.1.12 Communication / Dicom / Study

Uploading Tab: used to configure the Auto send to the Dicom Destination And image overlay information for suspended studies



5.1.13 Communication / Dicom / Study

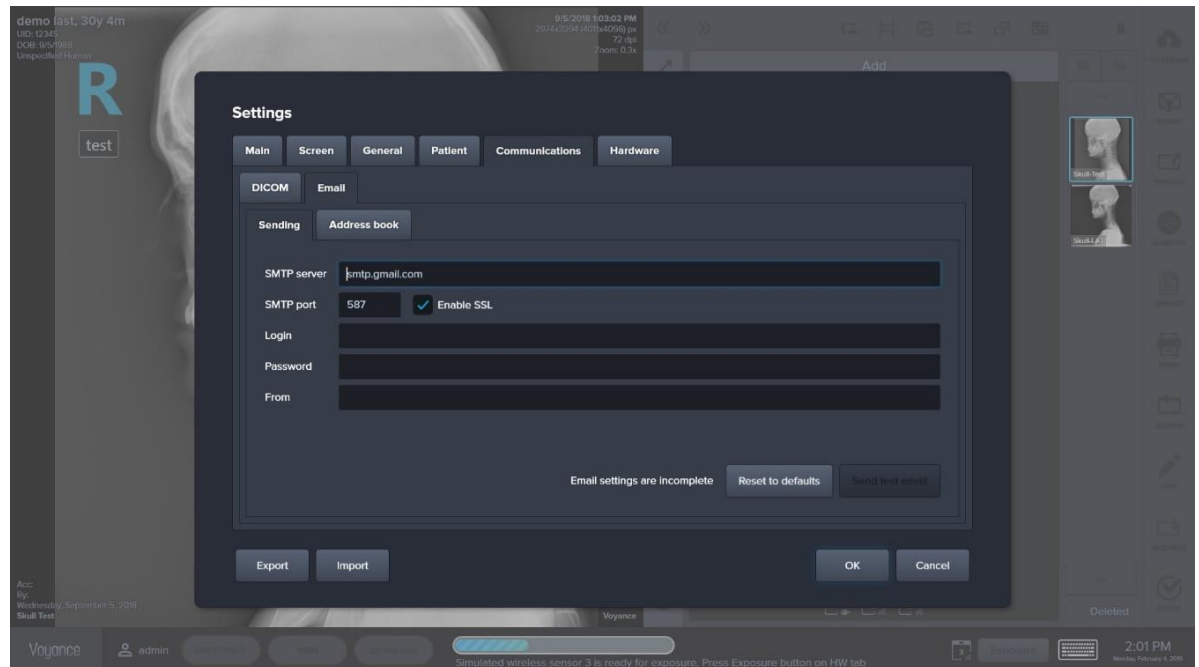
Completing Tab: used to configure the Auto send to the Dicom Destination And image overlay information for Completed studies





5.1.14 Communication / Dicom Email

Tab: used to configure sending through emails.

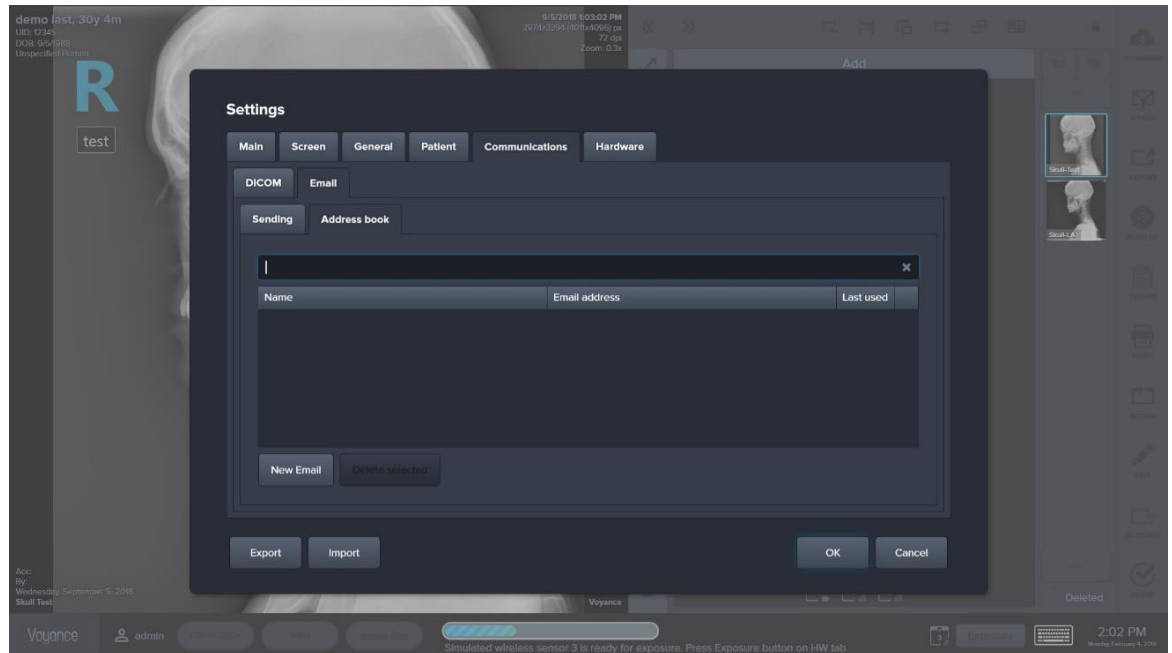


Emailed studies will be sent with anonymous information



5.1.15 Communication / Dicom

Address Book Tab: used to setup your email sending list

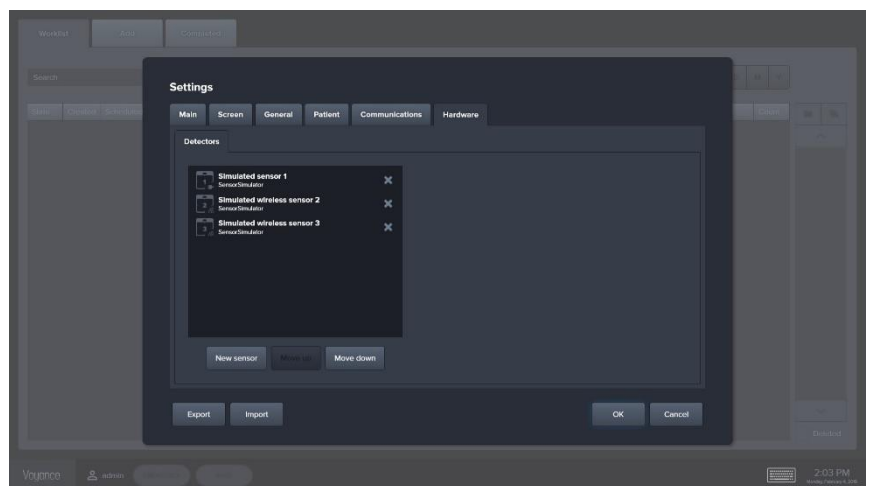


5.1.16 Communication / Hardware Tab:

used to add a new image acquisition sensors



Use the Hardware manual for hardware configuration



Failing on setting up the hardware sensor may lead to system malfunctioned



6. Glossary

| Term | Explanation |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEC | Automatic Exposure Control |
| CR | Computed Radiography, using a phosphor plate to capture the X-Ray image and a digitizer to read it and send it to the workstation. |
| Collimation | Collimation is performed during exposure using the tube collimator, to expose only part of the full exposure field. The collimation area is used by the software to apply black borders. DR images are automatically cropped at the collimation borders. |
| Cropping | Selecting a rectangular area on an image and displaying only the contents of this area. |
| Dicom Destination | A destination is a device to which the studies are routed after they have been digitized. |
| DICOM | Digital Imaging and Communication in Medicine. |
| DR | Direct Radiography, using a digital image sensor to capture the X-Ray image and send it directly to the workstation. |
| EI | Exposure Index: measure of the detector response (on a linear scale) in a relevant image region of an image. |



7. Terms & Explanations

| Term | Explanation |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Exposure type | An Exposure type is a set of parameters (concerning image processing, exposure options such as view position and cassette orientation, and collimation) which are by default used for a defined type of exposure. A number of Exposure types make up an Exam group. |
| HIPAA | Acronym for the Health Insurance Portability and Accountability Act of 1996. It is a set of rules to be followed by health plans, doctors, hospitals and other health care providers. It took effect on April 14, 2003. |
| License | A digital permit containing descriptions of rights that can be applied to one or more pieces of content. |
| Local database | Database stored on the hard disk of a workstation. |
| Marker | A marker behaves differently as compared to an annotation. It is always burnt onto the image when it is sent out by DICOM, even when GSPS is used. |
| Protocol code | A code that completely defines and identifies a specific exposure type. Protocol codes are imported from the RIS, and can be linked to exposure groups, exposures and exams that are displayed in the user interface. This way, an incoming protocol code can be "resolved" and the operator receives immediate feedback on the examination he needs to perform. |
| RIS | Radiology Information System. |



APPENDIX 1



Patient data security

- It is the responsibility of the hospital to ensure that the patients' legal requirements are met and that the security of the patient records is:
 - ☐ maintained and tested,
 - ☐ audited,
 - ☐ Administered locally to cover risks from third party access and how the availability of the services is to be maintained in the event of disaster.

- Voyance software provided with different ways of access and privileges control in the software.
 - ☐ User authentication. The administrator can configure different user accounts. Each account consists of a user name and a password to access the system, login is used for user authentication and identification is required.
 - ☐ Node authentication, using certificates. Working with SSL (Secure Sockets Layer) allows secure communications on an insecure network. SSL is the security layer on top of TCP/IP.
 - ☐ Administrator logging. This implies logging to a setting and configurations of specific VOYANCE 'Areas', e.g. users privileges, Hardware configuration , Dicom Configurationsetc.
 - ☐ Software will log off automatically to the log in page if not used for few minutes (configured through the setting).
 - ☐ It is recommended to you use recommended Antivirus / Malware software using the workstation in a network environment (please contact voyance support for a list of recommended antivirus software)



Compliance

Voyance has been designed in accordance with the MEDDEV Guidelines relating to the application of Medical Devices and has been tested as part of the conformity assessment procedures required by 93/42/EEC MDD (European Council Directive 93/42/EEC on Medical Devices).

Voyance has been designed in accordance with the IEC 60601-1,

The workstation console is comply with the following safety standards:

- UL 1950, Third Edition.
- CAN/CSA 22.2 No. 950-95, Third Edition (cUL).

Voyance fully complies with the CE Directive 89/336/EEC and with the federal code of the United States, bearing on:

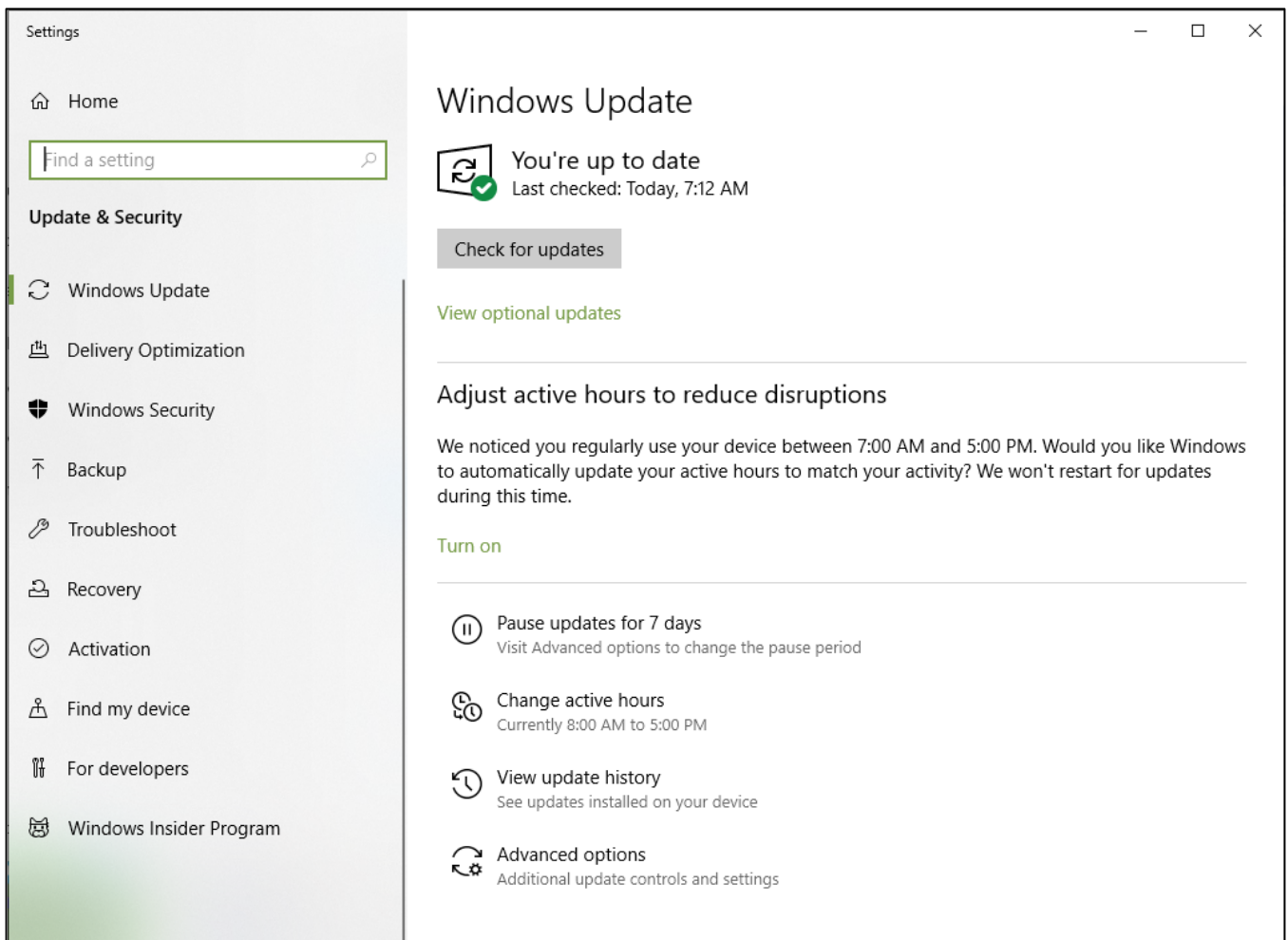
- Emission and immunity according to EN 60601-1-2, for emissions the equipment complies with EN 55011 class A (CISPR 11). This is a Class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.
- Emissions according to 47 CFR part 15 subpart B, Class A. This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

USER MANUAL SUPPLEMENT

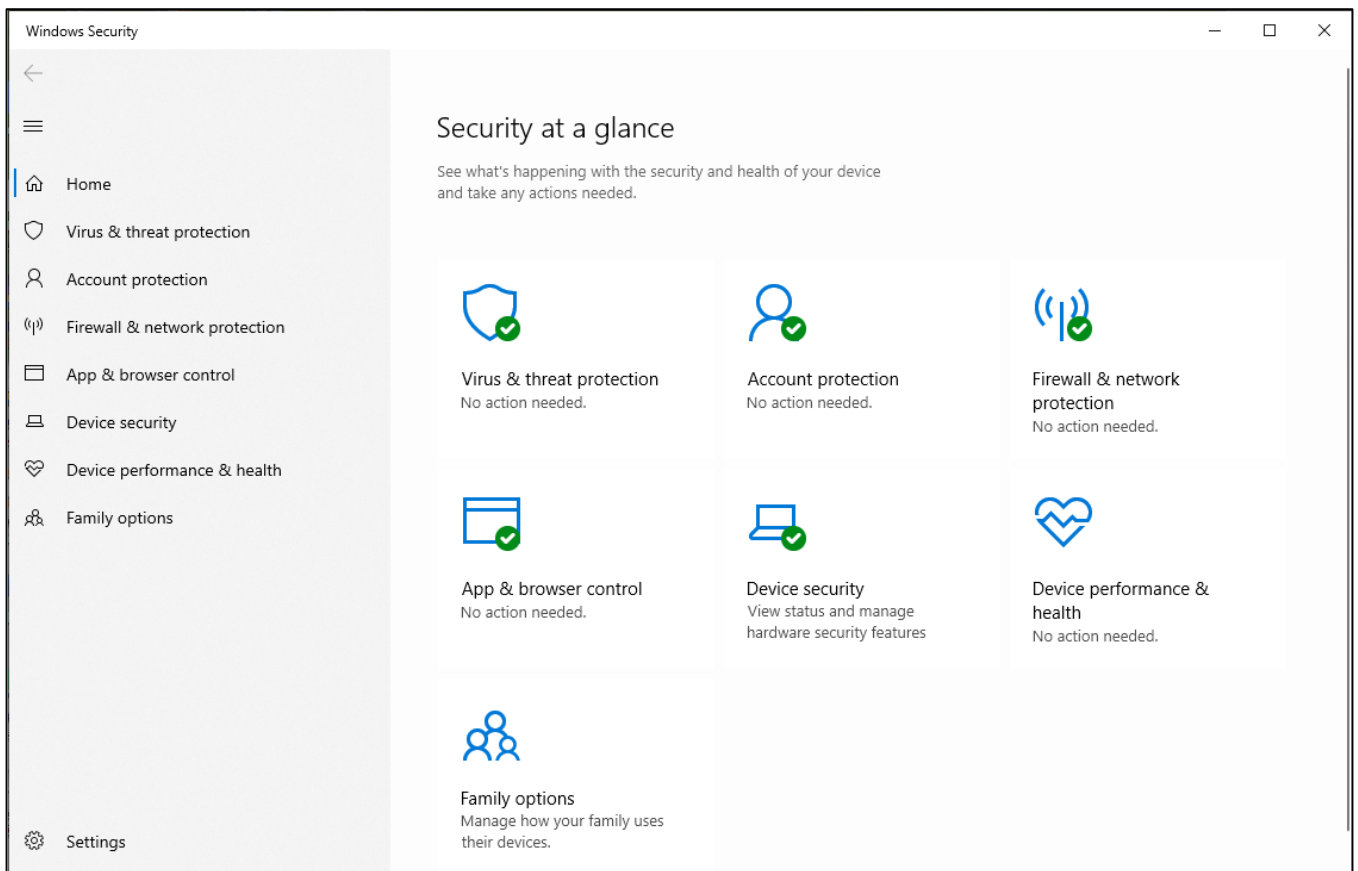
PROTECTING YOUR SYSTEM FROM CYBERSECURITY THREATS

INTRODUCTION

Because the imaging computer may connect by Wi-Fi or Ethernet to the Internet or via a hospital information system, cybersecurity may become an issue for you. Here are some tips to keep your system and your medical images secure. If your imaging system came with a Windows based computer system, it has had an anti-virus program installed on it. We request that you keep the operating system up to date with the operating system and anti-virus updates. You can view the status by typing Windows Update in the search box:



Also you can check the status of the anti-virus program by typing “Windows Security” in the search box:



REQUIRED STRATEGIES: Your Responsibilities

Use antivirus programs such as:

- Microsoft Defender
- TotalAV
- ScanGuard Security Suite
- Norton by Symantec
- PCProtect
- McAfee Antivirus Plus

Keep these products UP TO DATE.

Identify and Protect:

- Limit Access to Trusted Users Only: Limit access to devices through the authentication of users (e.g. user ID and password.)

Ensure Trusted Content:

- Restrict software or firmware updates to authenticated code. **USE ONLY MATERIALS SUPPLIED BY US FOR YOUR IMAGE MANAGEMENT SOFTWARE UPDATES.**
- Use systematic procedures for authorized users to download version-identifiable software and firmware from the manufacturer.

Detect, Respond, Recover:

- Watch for on-screen warnings of possible virus infections
- Respond by scanning for and removing possible virus infections
- Recover from possible virus infections by having up to date BACKUPS of your host computer.

REQUIRED STRATEGIES: Our Responsibilities

We affirm our commitment to providing you with validated software updates and patches as needed throughout the lifecycle of the medical device to continue to assure its continued safety and effectiveness. Please promptly apply software updates and patches provided by us and never use image management software supplied by anyone else. Our development process utilizes the Microsoft Malware Defense Guide which can be found at: <https://technet.microsoft.com/library/cc162791#E1F> We are constantly scanning our development computers for malware. We hope you are doing the same.

A SUMMARY OF OUR INTEGRITY CONTROLS

- Our development computers are constantly being scanned for malware, and our supplier for anti-virus software automatically updates the software continuously as new threats are revealed.
- We perform daily backups to our external hard drives. These drives are then disconnected from the system after the backups.
- During software development we disconnect from the Internet to prevent external attacks.
- Our development process utilizes the Microsoft Malware Defense Guide.
- Copies of software updates we will be sending you are individually scanned for malware. USE ONLY MATERIALS SUPPLIED BY US FOR YOUR UPDATES.

CONCLUSION

It is our JOINT responsibility to ensure your medical image software and image collection is safe and secure. We must both do our parts.



Voyance llc.

50 Maxwell, Irvine, CA 92618