Instruction For Use

RUS

CE MDR assessment is currently in progress.

hutom

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Revision History			
No.	**Revision no.**	**Summary of Changes**	**Date**
1	Rev 0	First prepared	2023.03.22

Table of Contents

Chapter 1. Introduction

This instruction for use describes the functions and operation of 'RUS' device. To ensure safety of the patients, RUS software must be used its intended use. Please read this manual thoroughly before use.

	Please read these instructions carefully before use for proper usage.

1.1 Indication for use

RUS is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning for adult patients. RUS accepts DICOM compliant medical images acquired from a variety of imaging devices, including CT.

Chapter 2. How to use

As this product is a device that manages medical data, the user should give attention to the matters described in this chapter.

2.1 Preparation before use

1) Read the manual before use and should be used only by the person having medical knowledge about the correct use of the device.

2) Allow this product to be used only for authorized users.

2.2 How to use

	Please read these instructions carefully before use for proper usage.

2.2.1 h-Server

h-Server is software that helps create and manage hu3D files that can be used through RUS.

2.2.2 h-Space

h-Space reconstructs the CT image into a 3D model to create hu3D data.

2.2.3 RUS Stomach Planning

(1) Software setup

(2) Log In

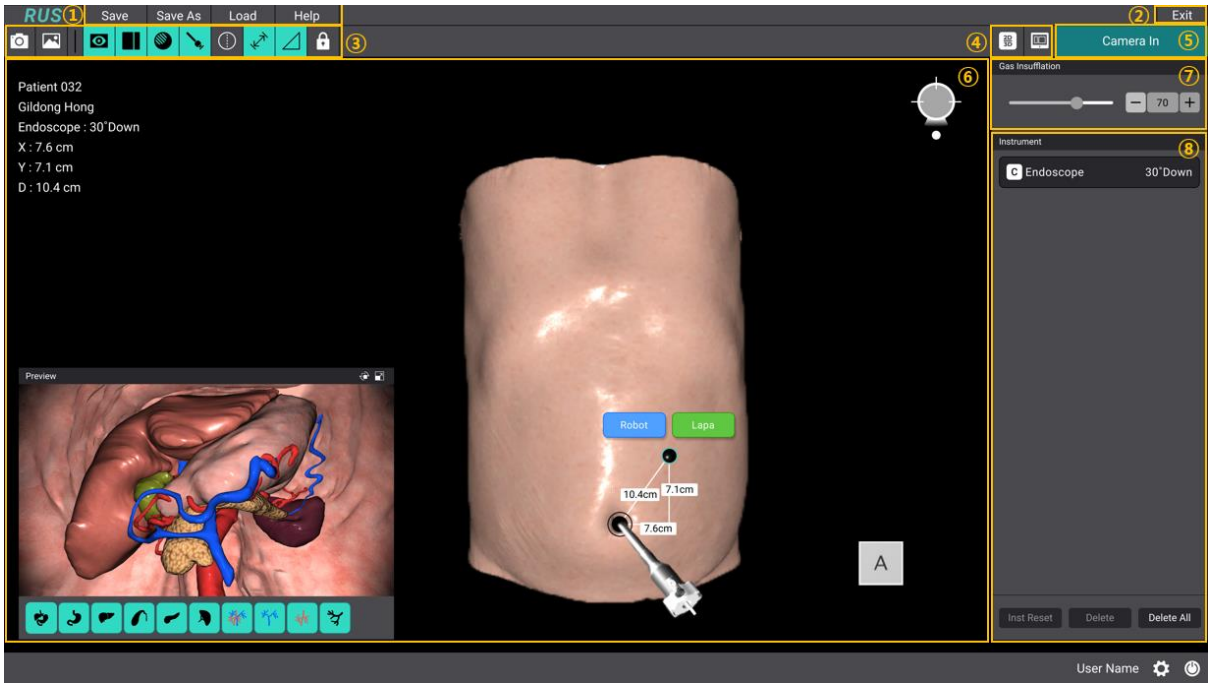
Enter your ID and Password to log in.

(3) Patient list

Confirm the patient ID and name.

(4) Port placement

Provide Port Placement view.

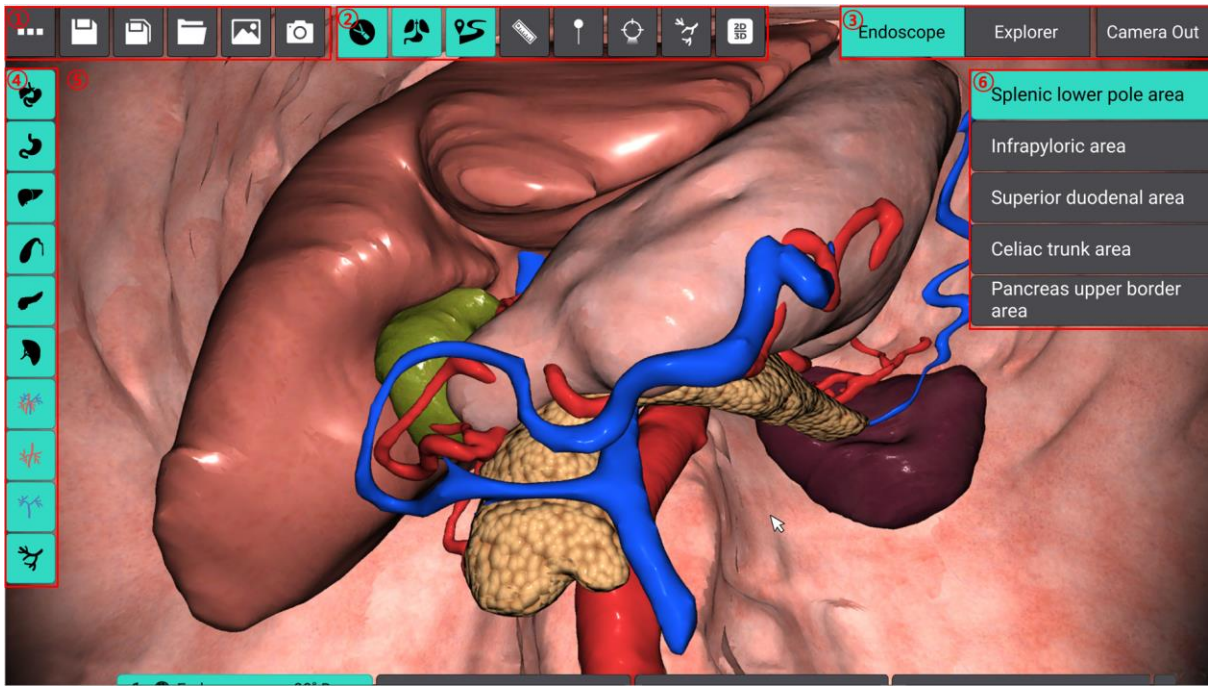


⚠	- This software is for reference only and the user is responsible for the final

	operation. - You must check and secure the saved Data, snapshot storage space, and hu3D data storage space of RUS Application in advance for smooth use.

(5) Endoscope view

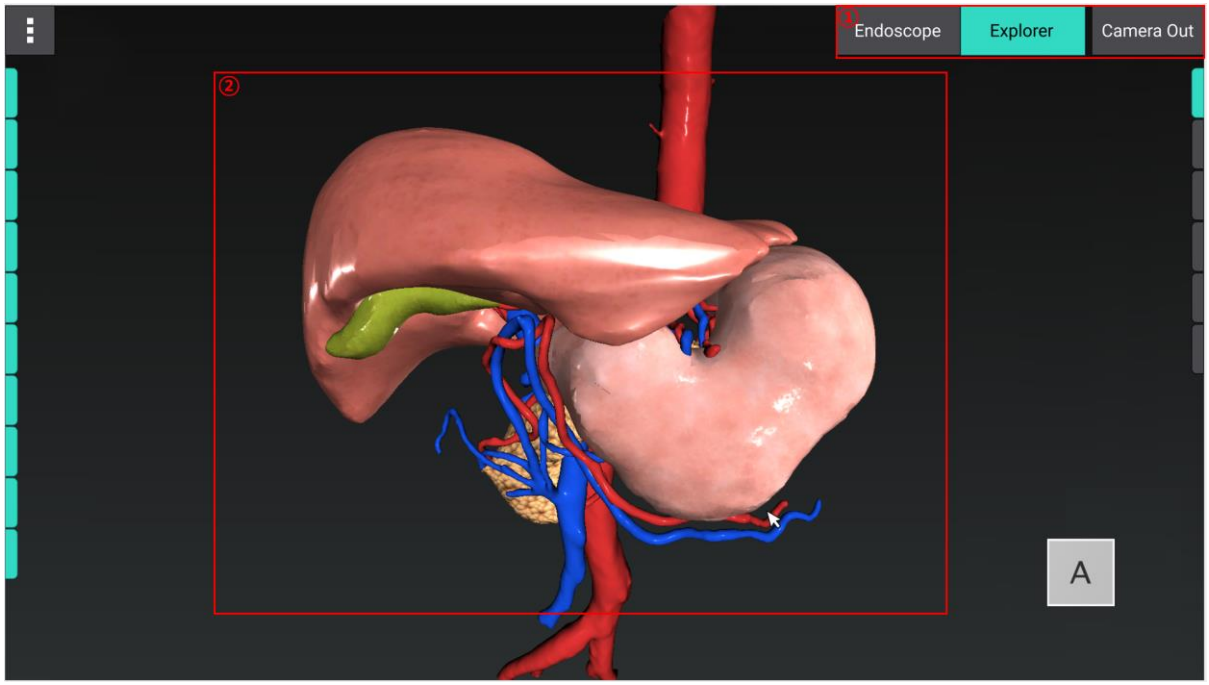
Provide the Endoscope view.



⚠	- This software is for reference only and the user is responsible for the final operation. - You must check and secure the saved Data, snapshot storage space, and hu3D data storage space of RUS Application in advance for smooth use.

(6) Explorer view

Provide the Explorer view.



⚠	- This software is for reference only and the user is responsible for the final operation. - You must check and secure the saved Data, snapshot storage space, and hu3D data storage space of RUS Application in advance for smooth use.

Chapter 3. Warning, Precaution, Limitation

3.1 Warning

1) If there is a risk of malicious code intrusion into the PC network where this software is installed, and if a security solution is not installed and used on the PC, the PC may be exposed to the risk of malicious software.

2) If the PC on which this software is installed is infected with malicious software, normal software may not be available, and the integrity of stored data may be affected.

3) Since there may be a difference between software and the actual surgical environment, it should be used by a skilled person (doctor) who is well trained medically for the patient's anatomy.

4) This software is for reference only and the user is responsible for the final operation.

3.2 Precaution

1) When using this software, you must comply with the Medical Act and Personal Information Protection Act.

2) It may take a lot of time while Download and Import the patient’s 3D model.

3) If the network connection is disconnected, only the patient’s 3D model that has already been downloaded and imported can be checked.

4) Depending on the user's network condition, the download speed of the patient's 3D model may be slow.

5) If you run other software on your PC at the same time, it may slow down your PC's normal operating performance.

6) Rendering speed may vary depending on the performance of the graphics card of the PC where this software is installed.

7) In the case of a hu3D model that does not include hu3D metadata, which is an essential data format required by the RUS Application, the data may not be loaded properly regardless of the import fails or the import succeeds in the RUS Application.

8) You must check and secure the saved Data, snapshot storage space, and hu3D data storage space of RUS Application in advance for smooth use.

9) Be sure to turn off the PC after the software is completely shut down; otherwise, data loss may occur.

10) When connected to PACS, you can use the Query/Retrieve function through PACS CT Load.

Chapter 4. Safety

4.1 Symbols

No.	Symbol	Description	Location	Symbol location
1		Manufacturer	IFU, Label	ISO 15223-1, 5.1.1
2		Authorized representative in the European Community	IFU, Label	ISO 15223-1, 5.1.2
3		Date of manufacturer (Date of releasing software)	IFU, Label	ISO 15223-1, 5.1.3
4		Warning	IFU	ISO 7010, W001
5		Refer to instruction for use	Label, Software	ISO 15223-1, 5.4.3
6		Caution	IFU, Label, Software	ISO 15223-1, 5.4.4
7		Prescription use only	Label	FDA-3013-N-0125

4.2 Label

The indication of labeling is provided in the 'Software info' button of the software.

Chapter 5. Product specifications

5.1 Operating environment

System specification	Note
• CPU: 11th-Gen Intel Core i7 Processor • RAM: 16GB • GPU: Intel Iris Xe • HDD: 250GB • O/S: Windows 10 • Ethernet-based intranet/internet connection • Wi-Fi	Recommended specs

The operating environment of h-Server, h-Space and RUS Stomach Planning is the same.