



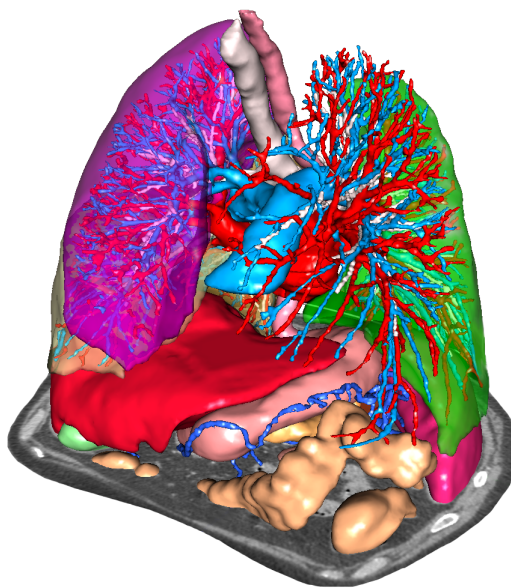
VISIBLE PATIENT

Visible Patient Sender

Version: 1.0.15

November 2020

User Documentation



Unique Device Identifier (UDI)

+B373VPS10150/\$\$71.0.15I



Software instructions for use (in english and other available languages) can be downloaded at <https://www.visiblepatient.com/en/go/sender-vps/user-manual>.

Software instructions for use in english are available in the “Help” menu of the software. Hard copy of instructions for use can be requested at no additional cost and delivered to the customer within 7 working days.



Prescription use only

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Indications for use

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

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

The software provides several categories of tools. It includes basic imaging tools for general images, including 2D viewing, volume rendering and 3D volume viewing, orthogonal Multi-Planar Reconstructions (MPR), image fusion, surface rendering, measurements, reporting, storing, general image management and administration tools, etc.

It includes a basic image processing workflow and a custom UI to segment anatomical structures, which are visible in the image data (bones, organs, vascular/airway structures, etc.), including interactive segmentation tools, basic image filters, etc.

It also includes detection and labeling tools of organ segments (liver, lungs and kidneys), including path definition through vascular/airway, approximation of vascular/airway territories from tubular structures and interactive labeling.

The software is designed to be used by trained professionals (including physicians, surgeons and technicians) and is intended to assist the clinician who is solely responsible for making all final patient management decisions.

Approvals



This medical device software is **CE marked** and **FDA cleared**. It can therefore be used in clinical routine and/or for patient care in member states of the European Union where national regulations are respected and the USA (complete list of countries available at <https://www.visiblepatient.com/en/go/sender-vps/countries>).

Use of this software is not allowed in countries not mentioned in the list above.

In these countries, the software is considered as a prototype software and *its use is limited to demonstration, research, or educational purposes*. Any other use is strictly prohibited, clinical use on humans in particular.



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CHAPTER 2

Contraindication

None known.

3.1 General caution

This software is designed to be used by trained medical professionals and is intended to assist the clinician who is solely responsible for making all final decisions.

3.2 Secure computing environment

Visible Patient requires the software to be installed on a secure workstation, compliant with FDA's guidance about cybersecurity. All images or resulting 3D models should be transferred via a user facility's secured network file transfer system.

3.3 Visible Patient data transfer

Visible Patient requires all transferred images to be anonymized and provided to and from the company via a user facility's secured network file transfer system. Visible Patient will not accept images in any other format or transferred in any other manner.

4.1 System requirements and characteristics

Visible Patient Suite is designed to run on a standard standalone platform, through the installed operating system (Windows or Mac). The hardware of such platform consists of an “off-the-shelf”, standard PC computer. Furthermore, all software included in the suite (explained in detail below) can be installed on different computers and they are not required to be interconnected through a network.

4.1.1 PC - Minimal System Requirements

- **Operating System:** Windows 7 x64
- **Processor:** Intel Core i3
- **Video:** Dedicated graphics card (since 2012)
- **Memory:** 4 GB RAM
- **Storage:** 10 GB available HD space
- **Internet:** Broadband Internet connection
- **Media:** Not required
- **Resolution:** 1024x768 or higher

4.1.2 PC - Recommended System Requirements

- **Operating System:** Windows 7 x64
- **Processor:** Intel Core i7 – 2.5 GHz
- **Video:** Nvidia GeForce GTX 760 or better
- **Memory:** 16 GB RAM

- **Storage:** 300 GB available HD space
- **Internet:** Broadband Internet connection
- **Media:** Not required
- **Resolution:** 1920x1080 minimum display resolution

4.1.3 Mac - Minimal System Requirements

- **Operating System:** Mac OS 10.12
- **Video:** Dedicated graphics card

4.1.4 Mac - Recommended System Requirements

- **Operating System:** Mac OS 10.12. Any Apple computer since late 2013 release
- **Video:** Dedicated graphics card

4.2 Software overview

4.2.1 Visible Patient Sender

Visible Patient Sender includes only modules dedicated to data management. The software is a simple tool to anonymize multidimensional digital images acquired from a variety of medical imaging modalities (DICOM images). This software is used by trained medical professionals (usually radiologists or radiologist technicians) to share anonymous data between trained medical professionals. Visible Patient Sender allows users to load and visualize DICOM images to automatically anonymize them. Anonymous data is saved in a zip file with a unique anonymous ID. Moreover, a pdf report is generated, summarizing data such as date, ID number, referring physician, comments, etc. There is no 3D data volume interpretation in this software. Each of the modules present in the software component are discussed in more detail below.

4.3 Software modules

The modules of Visible Patient Suite can be grouped by categories:

Category	Functionality	Visible Patient Sender
Data management	DICOM files anonymization	X

The table above groups each software module into: data management, image and surface analysis and image and surface processing. In addition, each individual software module is discussed in more detail below.

4.3.1 DICOM files anonymization

This software module is a simple tool to anonymize multidimensional digital images acquired from a variety of medical imaging modalities (DICOM images) and allows users to load and visualize DICOM images to automatically anonymize them. Anonymous data is saved in a zip file with a unique anonymous ID. Moreover, a pdf report is generated to keep a link between the anonymous ID and the patient's information. There is no 3D data volume interpretation in this module.

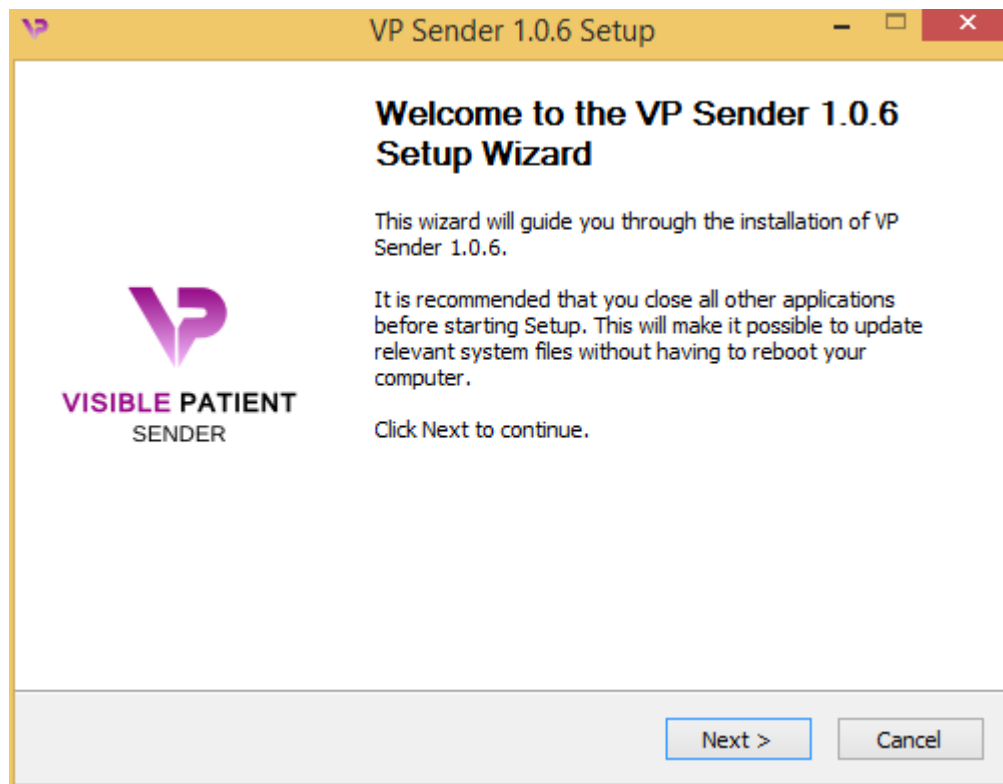
5.1 Install Visible Patient Sender software

Visible Patient Sender installation can be started from an executable file.

5.1.1 How to install Visible Patient Sender on Windows

Start the installation

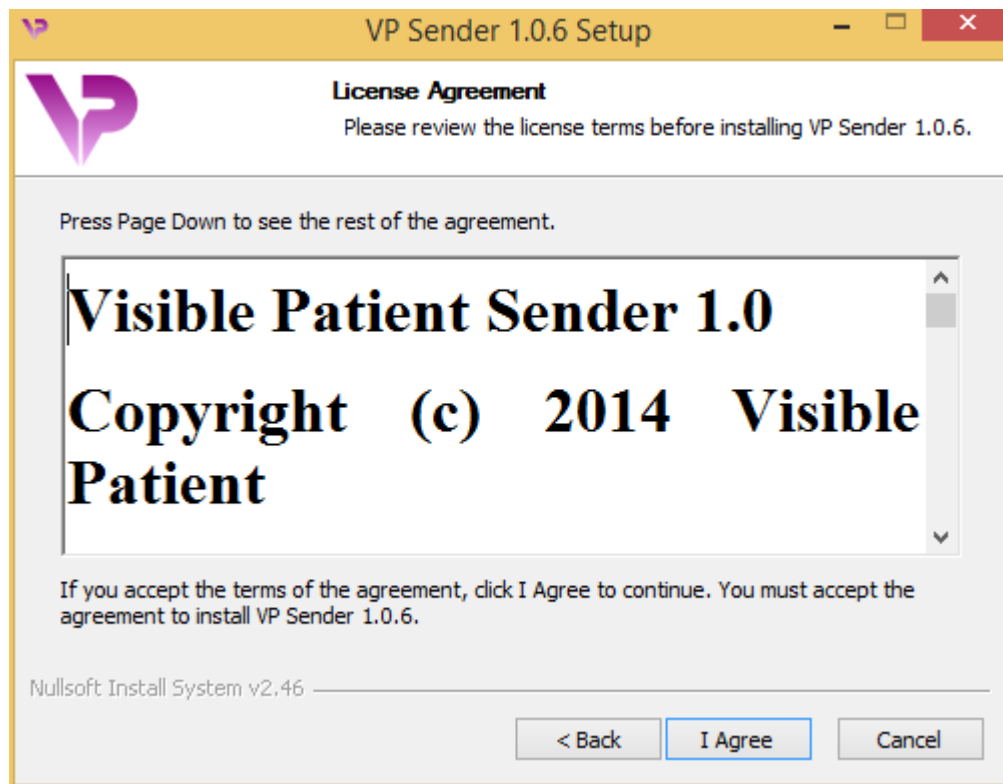
Double click the installation file provided by Visible Patient: the following installation welcome dialog will be displayed.



Click "Next".

Accept the license

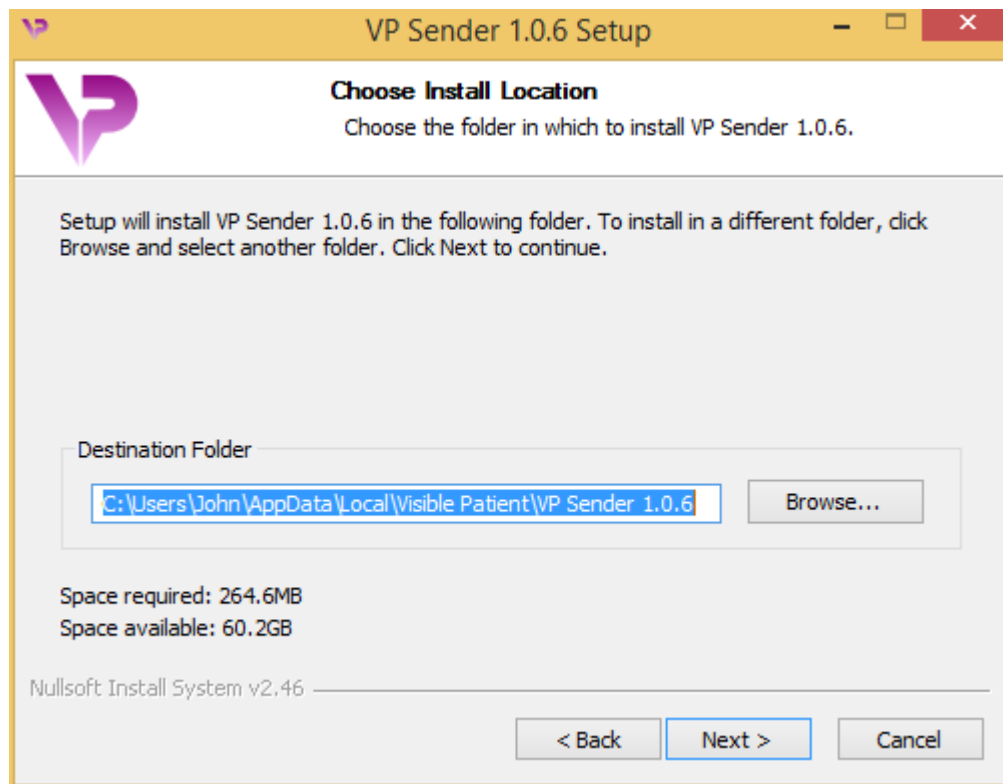
License agreement is displayed.



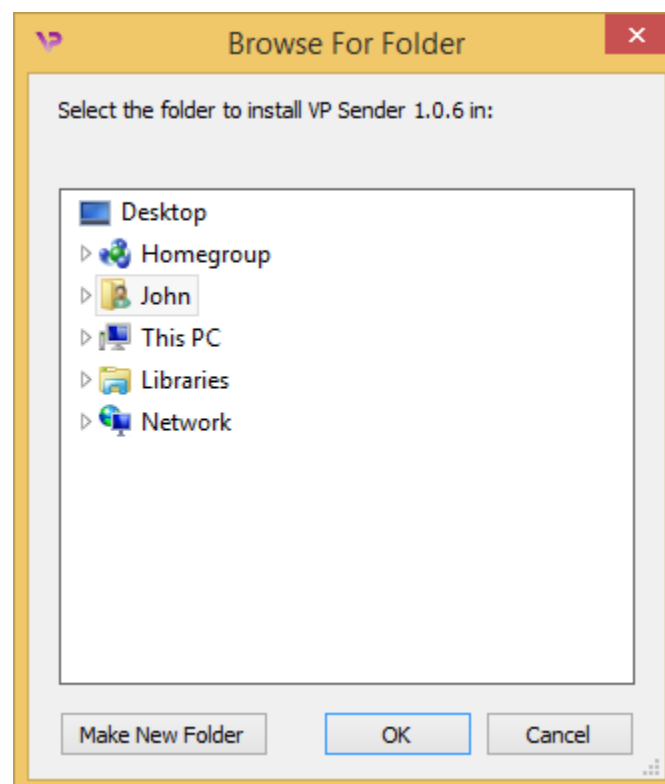
Read the license agreement and click “I agree” to continue the installation. (If you do not agree, click “Cancel” to cancel the installation.)

Select the destination folder

The destination folder where the software will be installed is displayed.



You can change this destination folder by clicking “Browse” and selecting a new destination folder. You can also create a new one by clicking “Make New Folder”.

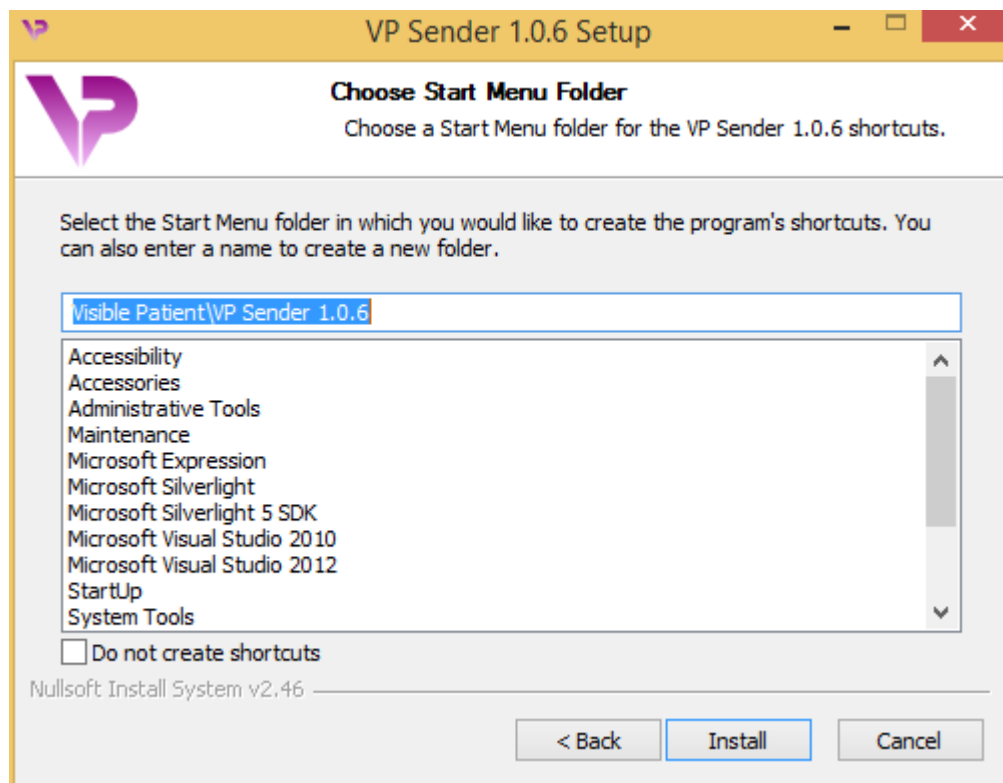


Select your destination folder and click “Ok”.

To continue the installation, click “Next”.

Create a shortcut

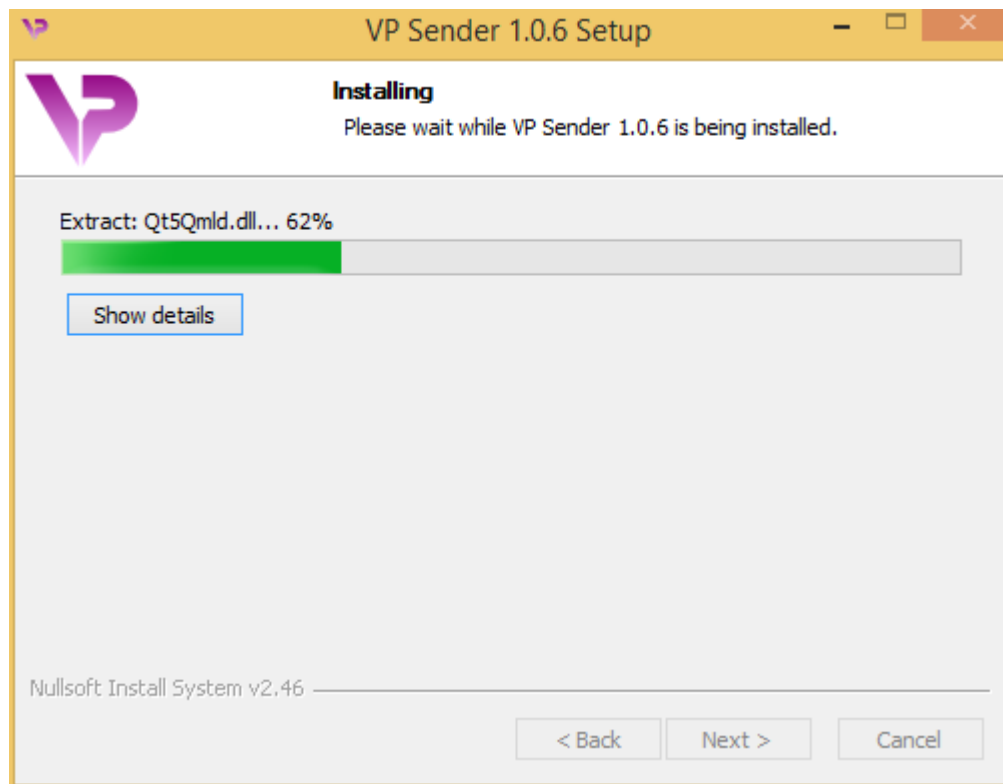
You can then decide to create a shortcut for easier access to the software. By default, a shortcut will be created on your computer desktop but you can choose another location. You can also enter a name to create a new start menu folder or decide to not create a shortcut.



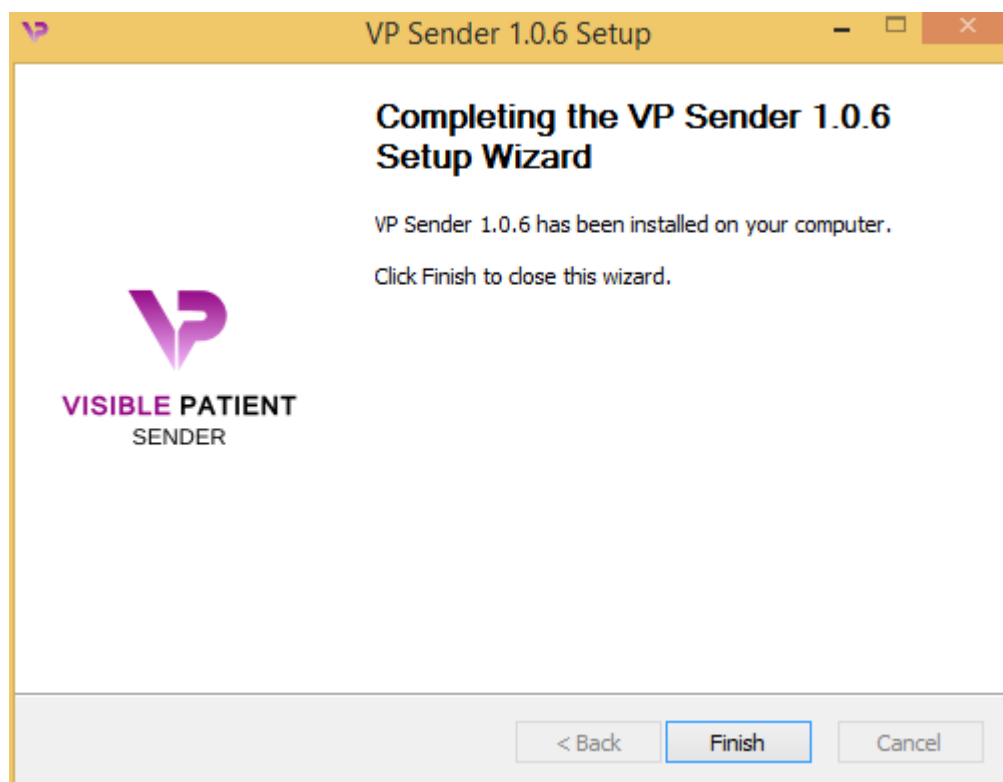
Finish the installation

To continue the installation, click “Install”.

The installation process starts.



The installation takes a few seconds to proceed. When it is done, a message indicates that the installation is over. Click “Finish” to close the setup window.



Visible Patient Sender is now installed on your computer in the chosen destination folder.

Launch the software

You can start Visible Patient Sender by clicking the shortcut created during installation (by default on the computer desktop).

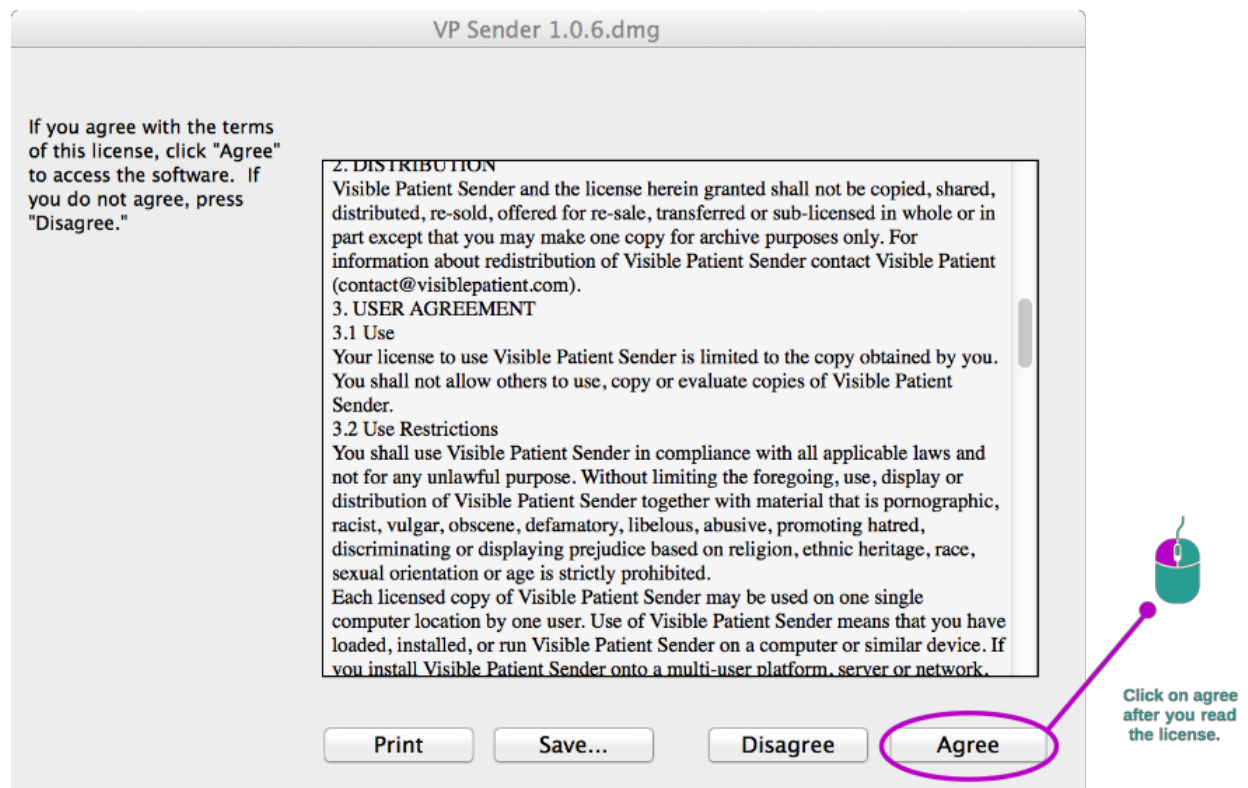
If you encounter any issue with the software installation, please contact Visible Patient at support@visiblepatient.com.

5.1.2 How to install Visible Patient Sender on Mac

Start the installation

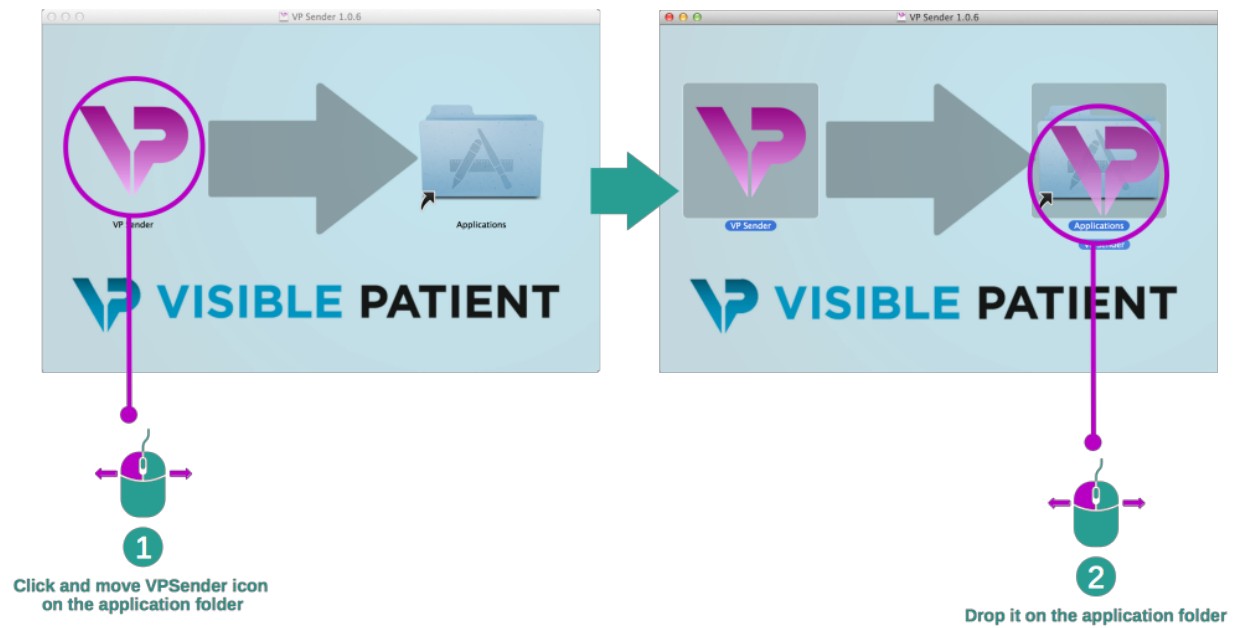
Double click the installation file provided by Visible Patient.

A license agreement window is displayed. Click “Agree” to continue the installation.



Install the application

Drag the Visible Patient Sender app into the application shortcut and drop it.



Visible Patient Sender is now installed.

Launch the software

Visible Patient Sender can be started from the application folder by double clicking the Visible Patient Sender icon.

If you encounter any issue with the software installation, please contact Visible Patient at support@visiblepatient.com.

6.1 How to anonymize an image

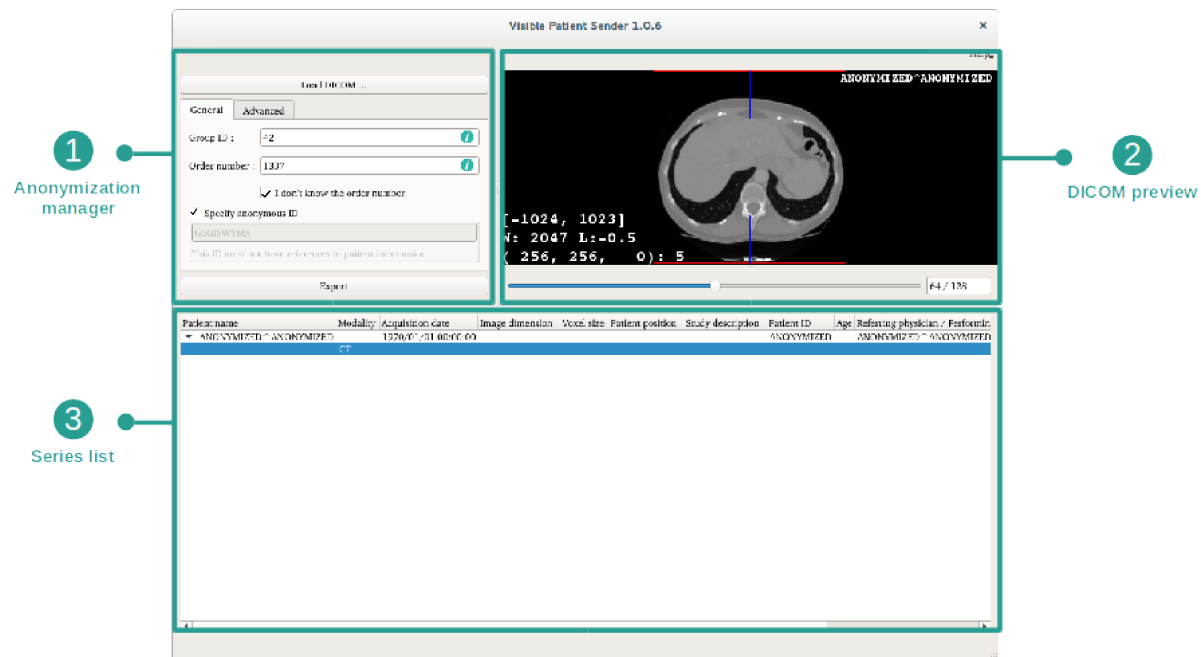
The Visible Patient Sender software is dedicated to the anonymization of DICOM data. An anonymization report will also be generated in order to keep a link between the anonymization number and the patient's information.

6.1.1 Prerequisites

In order to anonymize an image, the Visible Patient Sender software must be used.

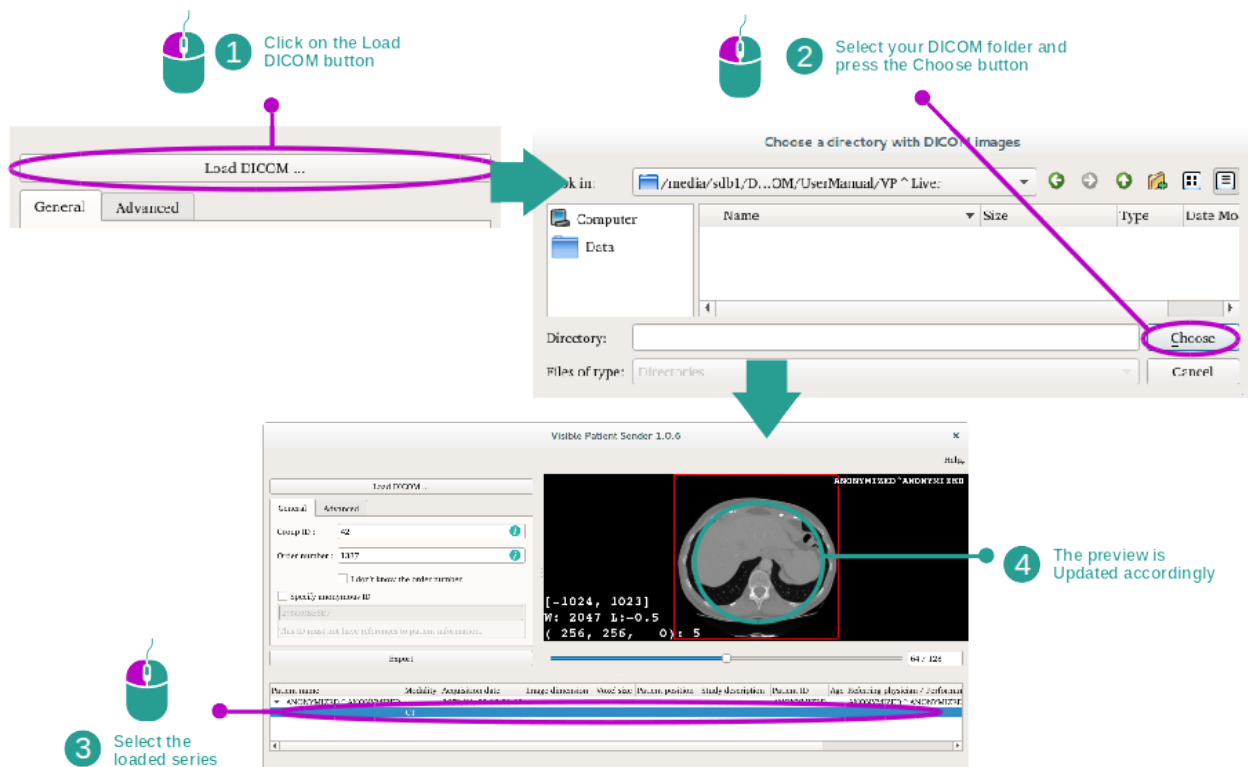
6.1.2 Anonymise a DICOM series

Let's get started with a short description of the Visible Patient Sender layout.



This software is composed of three main parts. The first one on the upper left corner is dedicated to the management of the anonymization process. The second one on the right side is a preview of the loaded DICOM files. The final one on the bottom is the list of the loaded series.

Step 1 : Open a DICOM series



The first step to anonymize DICOM data is to load it into the Sender software. To do so, click “Load DICOM”. Once loaded, the series is displayed on the list at the bottom of the view. You can then preview the series by selecting it in the list.

Step 2 : Update the anonymization information and export an anonymized series

1 Fill your VP Group ID

2 Fill your Order ID

2 If you don't know your Order ID Check this box

3 If you have series that you do not want to send, select them and press the delete key

4 Press the export button to export your data and generate an anonymization report

Once the series is selected, you have to complete mandatory fields for the anonymization process.

Once the information provided, the anonymized DICOM file can be exported using the Export button. A ZIP file containing the series will be generated. A PDF will also be generated. This PDF contains the information that link the anonymous ID to your patient's private information.

No maintenance is required for Visible Patient Suite. To control software distribution, a license system is used in each software of Visible Patient Suite.

7.1 Sender

Sender software comes with integrated license which are granted for 6 months.

7.2 License update

60 days before license expiration, a popup with information about expiration date appears each a software is started.

It is recommended to check for a new software version if the expiration date is less than 30 days away. If there is no new version, please contact the support for a new license.

8.1 General troubleshooting

There is no troubleshooting in Sender.