



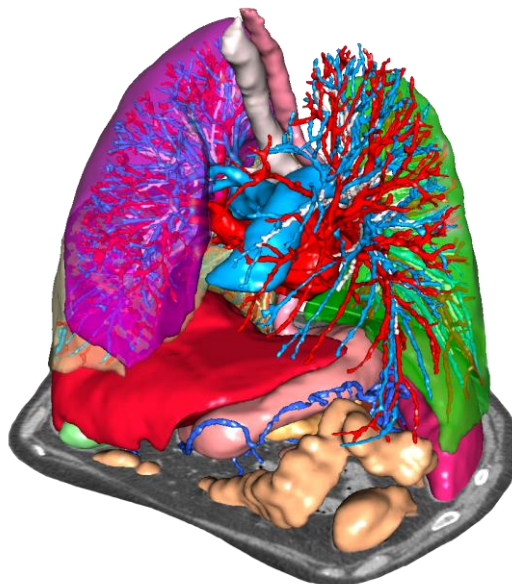
VISIBLE PATIENT

Visible Patient Sender

Version: 1.0.19

November 2023

User documentation



Unique device identifier (UDI)

+B373VPS0/\$\$71.0.19F



Software instructions for use (in English and other available languages) can be downloaded at <https://www.visiblepatient.com/en/go/planning-vps/1.0.19/user-manual>. Hard copy of instructions for use can be requested at contact@visiblepatient.com at no additional cost and delivered to the customer within 7 calendar days.

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 for both pediatric and adult patients. 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.

Rx Prescription use only

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

Note 1: Any serious incident in relation to the device should be reported to Visible Patient and the local Competent Authority.

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/planning-vps/1.0.19/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.

First date of CE marking: 2014

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1 Indications for use

1.1 General

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 for both pediatric and adult patients¹. 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.

(1) See section "Intended patient population" for details.

1.2 Intended patient population

Intended patients of VP Suite can be all patients whose physician needs a specific 3D model of their anatomical and pathological structures to optimize their therapy definition.

The Visible Patient Suite can be used regardless of the patient's age.

- | |
|---|
| <ul style="list-style-type: none"><input checked="" type="checkbox"/> Neonate/Newborn (birth through 28 days)<input checked="" type="checkbox"/> Infant (from 29 days to 2 years of age)<input checked="" type="checkbox"/> Child (from 2 years to 12 years of age)<input checked="" type="checkbox"/> Adolescent (from 12 years to 18 years of age) |
|---|

☒ Transitional Adolescent (18 through 21 years of age)

☒ Adults (greater than 21 years of age)

The patient is not the user of VP Suite software.

1.3 Intended users

For Visible Patient Sender software, not knowledge is required to use this software module.

The software is intended to assist the physician who is solely responsible for making all final patient management decisions.

2 Contraindication

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

3 Intended performances and claims

3.1 Clinical performances

- The Visible Patient Suite does not claim any clinical performance.

3.2 Safety claims

VP Sender v1.0.19 is a stand-alone software. Any direct clinical risk to neither user nor patient is identified. Thus, there is no expected undesirable side-effects in the use of VP Sender version 1.0.19.

However, some indirect Adverse Device Effects have been identified and could occur:

1. Minor injuries to patients due to longer operating time or unnecessary incisions during surgery when the wrong patient (=another patient) is analyzed.
 - A wrong patient may be selected to perform an action and result in wrong patient analysis (pay attention to the displayed patient information).
 - A wrong patient may be analyzed when several patients are open in the software and result in wrong patient analysis (pay attention to the displayed patient information).
 - A study of another patient may be selected when some results are exported and result in wrong patient analysis (pay attention to the displayed patient information).
 - Software issue may occur with patient information management and result in wrong patient analysis.
 - A hacker may find and exploit a software or a environment vulnerability to modify the device or the medical records to alter medical information.

3.3 Security claims

Protected Health Information (PHI) are not exposed with the use of this medical device. The device is not designed to allows private data transfer nor private data storage.

The document informs users of the precautions to be taken regarding the security of the IT environment and the transfer of personal data (see Cautions).

3.4 Technical performances

The Visible Patient Suite allows medical team to:

- Anonymize DICOM medical images (supported modalities: CT, MR)

All functionalities of the Visible Patient Suite were tested during the test phase of the development. Each feature can be used for pediatric or adult patients

In addition, a literature study and post-market assessment were conducted to support the device performance and intended use.

4 Cautions

4.1 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.

4.2 Secure computing environment caution

The device shall be installed on a secure environment, compliant with cybersecurity rules. These rules or guidelines may differ from country to country. The section IT security requirements presents the general security recommendations.

4.3 Medical records management caution

The device produces or uses medical records that can be stored by health professionals or transferred between them to perform device intended uses. The medical record management (transfer, storage, etc) shall comply with the rules for the protection of personal health information. The section IT security requirements presents the general security recommendations.

5 Technological characteristics

5.1 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.

5.1.1 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
- **Resolution:** 1024x768 or higher

5.1.2 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
- **Resolution:** 1920x1080 minimum display resolution

5.1.3 Mac – Minimal System Requirements

- **Operating System:** Mac OS 10.12. Any Apple computer released since 2010
- **Video:** Dedicated graphics card

5.1.4 Mac – Recommended System Requirements

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

5.2 Application overview

5.2.1 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 im- ages). 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 DI- COM 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.

5.3 Application modules

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

| Category | | Functionality | VP 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.

5.3.1 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.

6 Installation instructions

Visible Patient Suite installation can be started from a software executable file.

6.1 IT security requirements

6.1.1 Secure environment

The device shall be installed on a secure environment, compliant with cybersecurity rules. Moreover, the device produces or uses medical records that can be stored by health professionals or transferred between them to perform device intended uses. The medical record management (transfer, storage, etc) shall comply with the rules for the protection of personal health information.

These rules or guidelines may differ from country to country. Below are the general security recommendations to follow to manage the environment security:

- Thanks to the operating system's authentication mechanism, the environments (the software environment and the data storage environment) shall be restricted to authorized users to limit access to the device.
- A layered authorization model shall be employed for the management of the environments by differentiating privileges based on the user role (e.g., system administrator, health professional).
- The environments shall lock when the user is inactive thanks to the operating system's auto-lock mechanism.
- The remote access to the environments shall be controlled and authorized only for trusted user thanks to operating system tools, firewall configurations or infrastructure rules.
- An anti-virus software shall be installed and shall control the environments. The device is designed to allow routine security and antivirus scanning such that the safety and essential performance of the device is not impacted.
- Medical records shall be provided to and from health professionals via a secured network file transfer system which guarantees the appropriate security level of personal health information.

6.1.2 Package verification

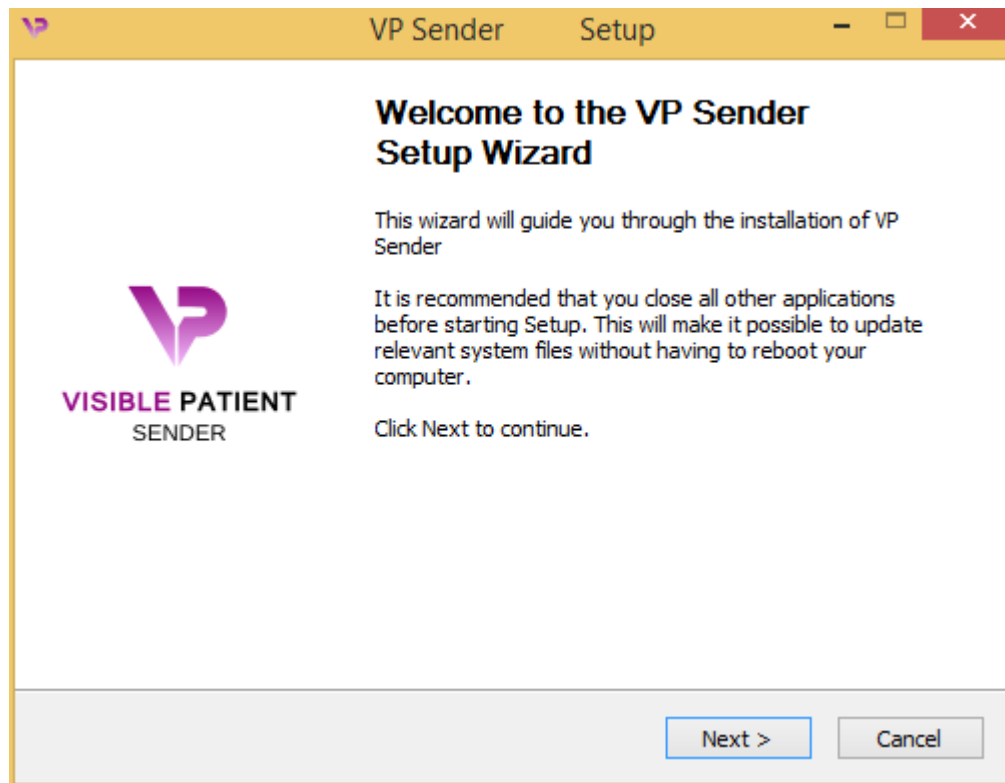
Below are general recommendations to follow before installing the device.

- The package integrity shall be verified after its download (the package hash is provided on the company website).
- The software authenticity shall be controlled before the installation. Visible Patient company signed all these packages.
- The device shall be installed by a system administrator in a location where standard user cannot write to protect the device.

6.2 How to install Visible Patient Sender on Windows

6.2.1 Start the installation

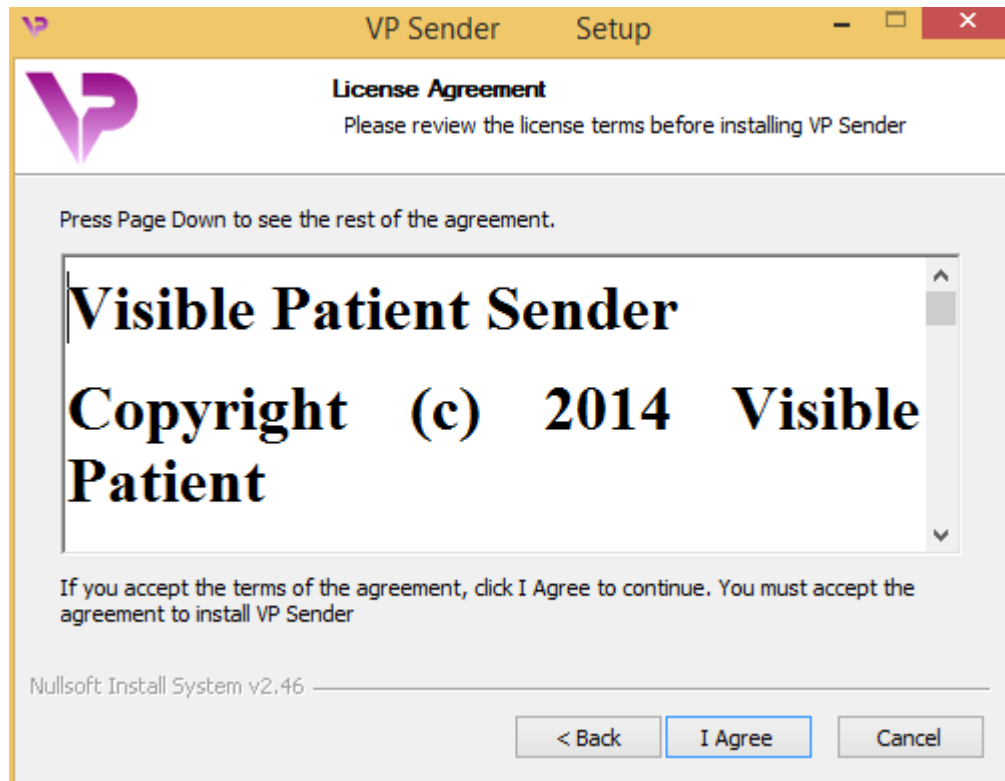
Double click the installation file provided by Visible Patient: the following installation welcome dialog will be displayed.



Click “Next”.

6.2.2 Accept the license

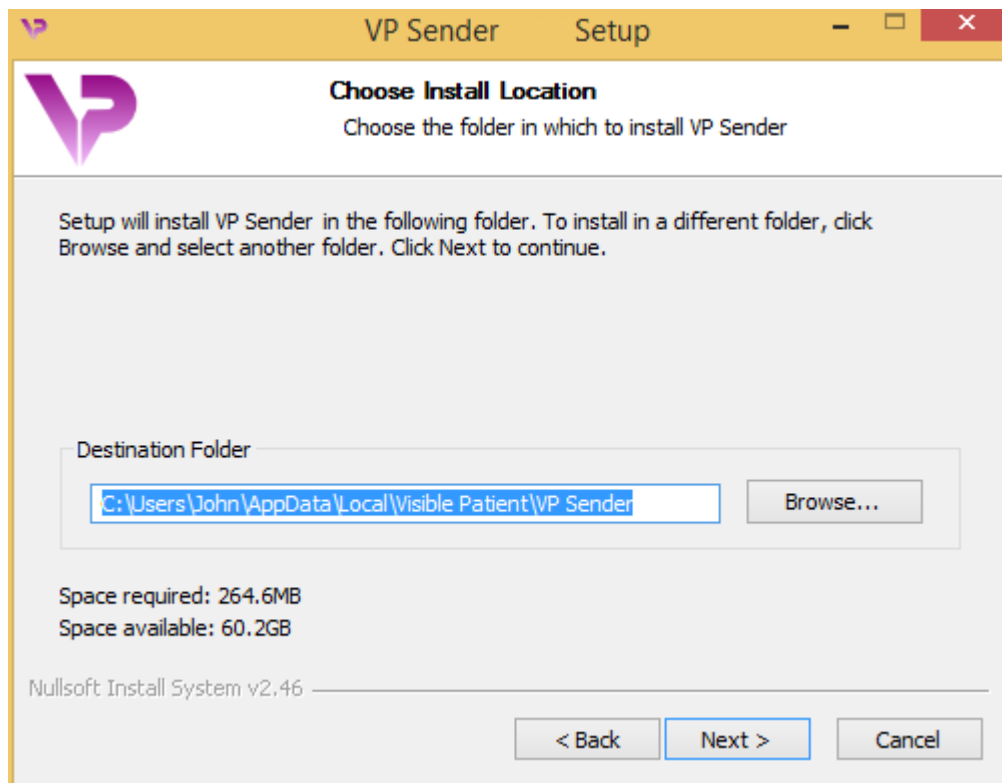
License agreement is displayed.



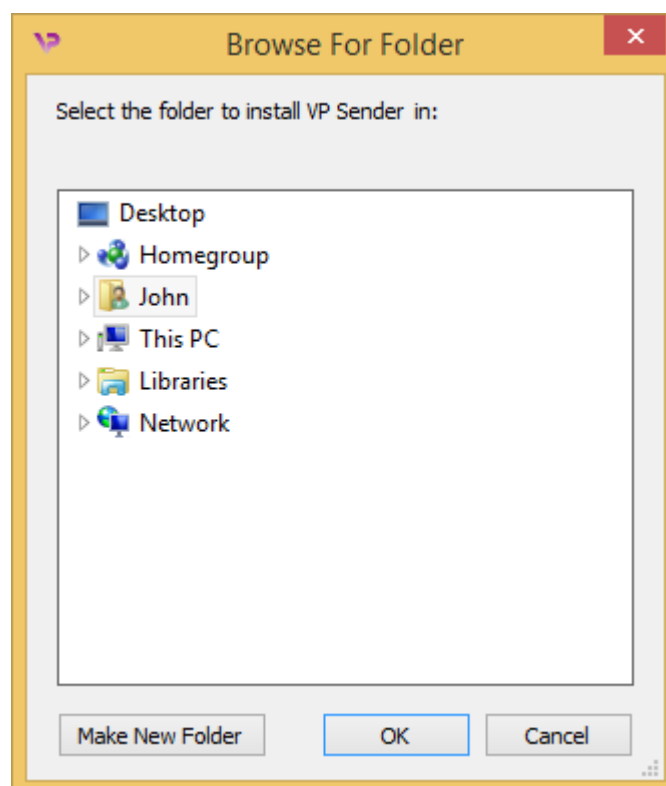
Read the license agreement and click “I agree” to continue the installation. (If you do not agree, click “Cancel” to cancel the installation.)

6.2.3 Select the destination folder

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



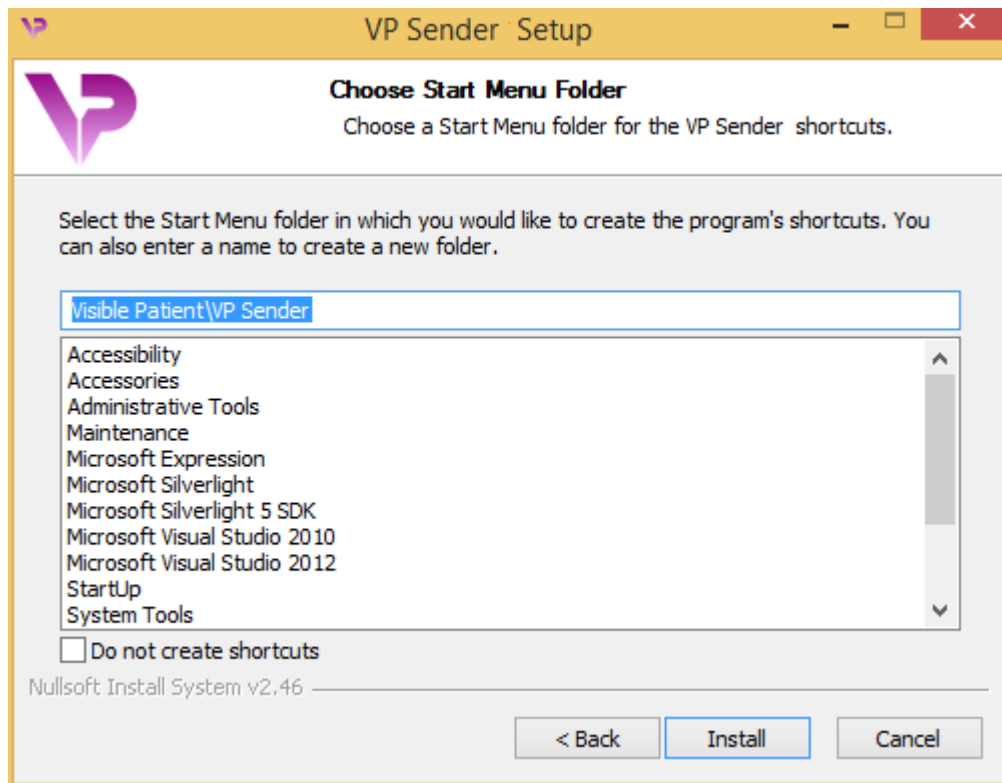
You can change this destination folder by clicking “Browse” and selecting a new destination folder. You can also create a new one by clicking “Make New Folder”.



Select your destination folder and click “Ok”. To continue the installation, click “Next”.

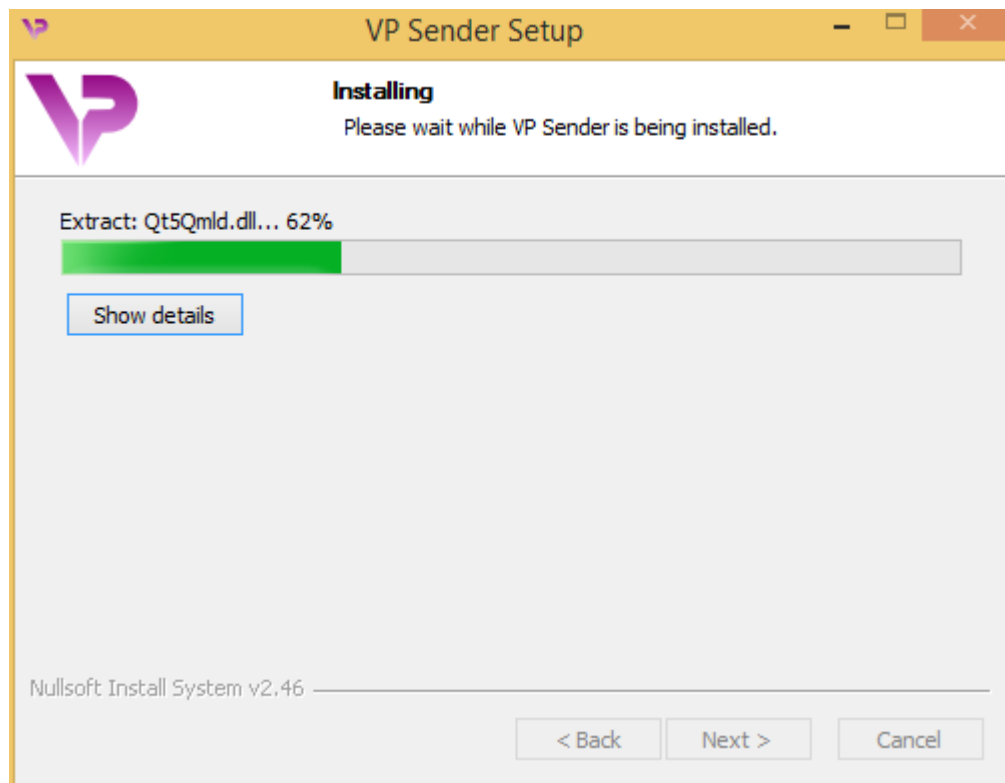
6.2.4 Create a shortcut

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.

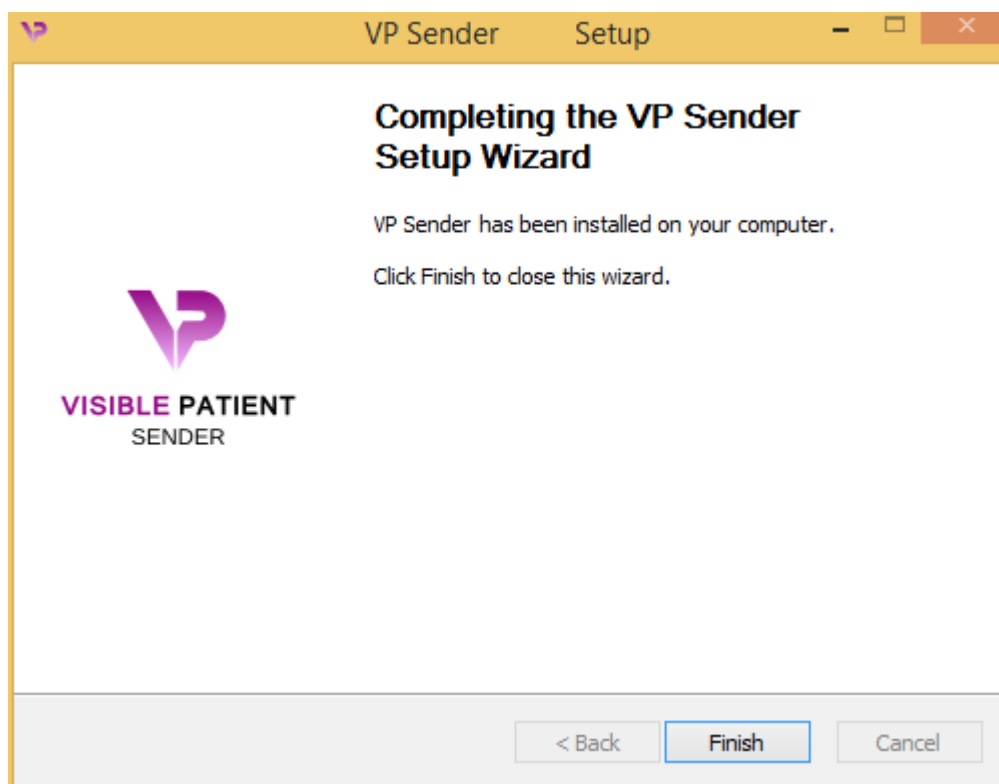


6.2.5 Finish the installation

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.

6.2.6 Launch the software

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

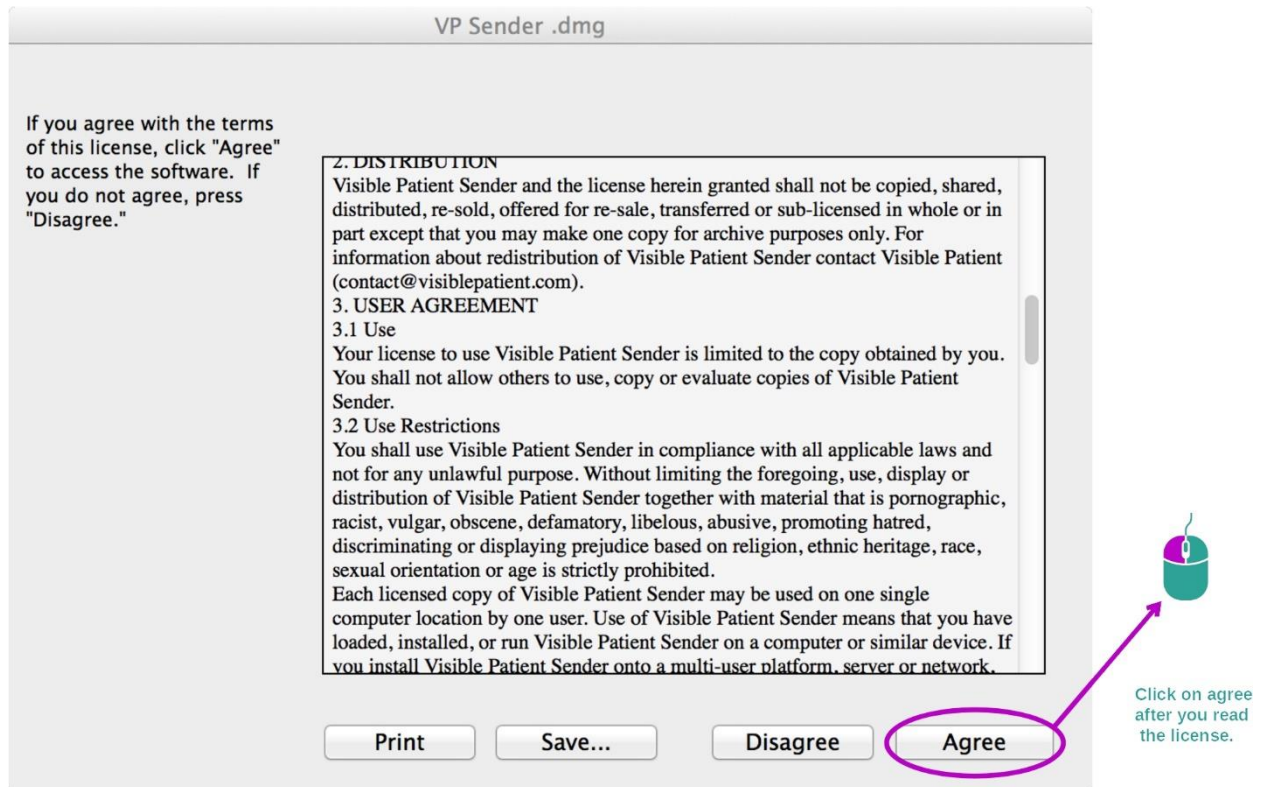
If you encounter any issue with the software installation, please contact Visible Patient at support@visiblepatient.com.

6.3 How to install Visible Patient Sender on Mac

6.3.1 Start the installation

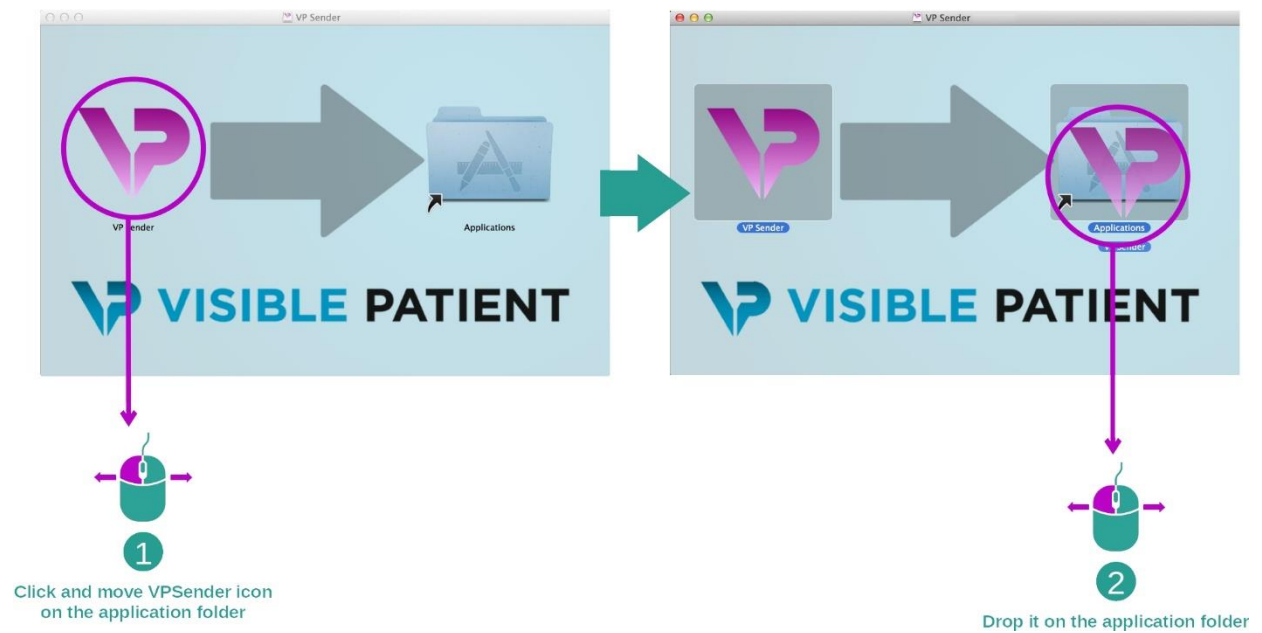
Double click the installation file provided by Visible Patient.

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



6.3.2 Install the application

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



Visible Patient Sender is now installed.

6.3.3 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.

7 Instructions for use

7.1 How to anonymize an image

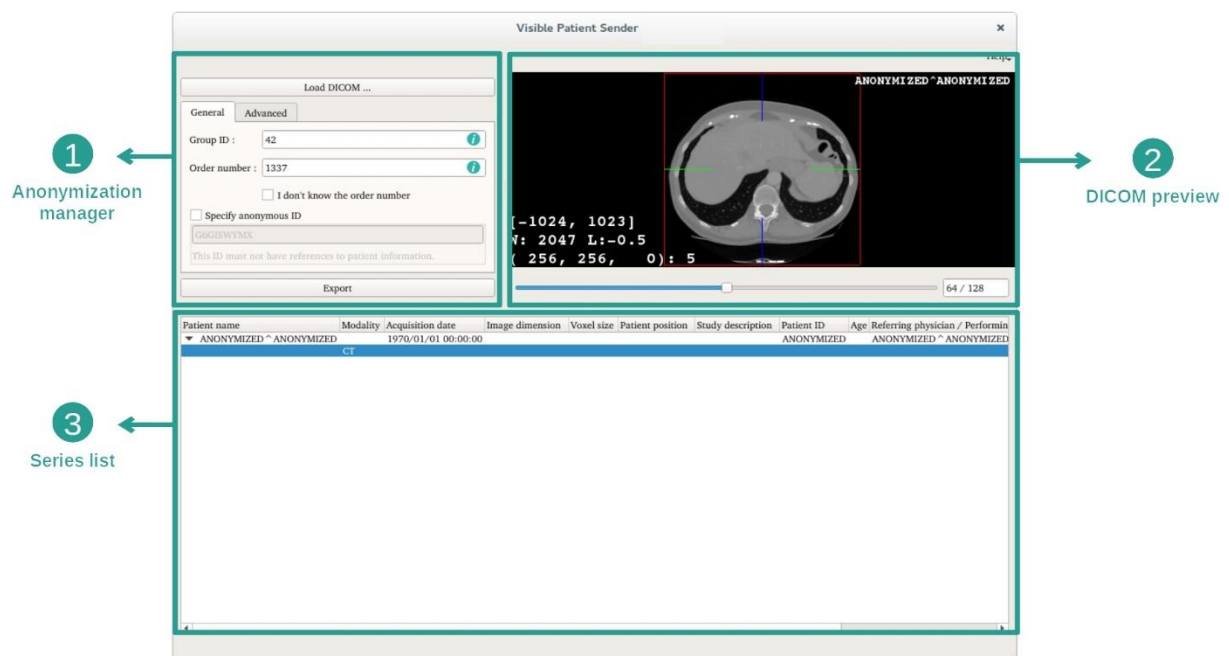
The Visible Patient Sender software is dedicated to the anonymization of DICOM data. An anonymization report will also be generated in order to keep a link between the anonymization number and the patient's information.

7.1.1 Prerequisites

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

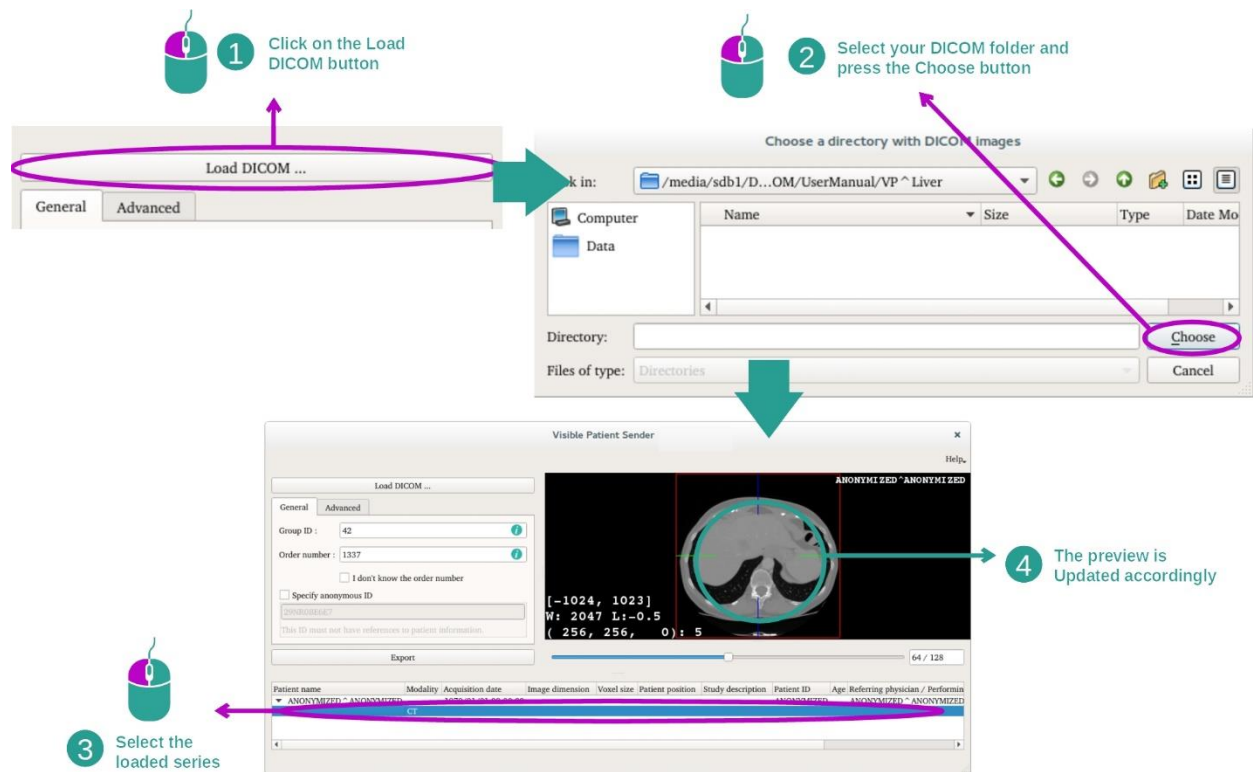
7.1.2 Anonymize a DICOM series

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



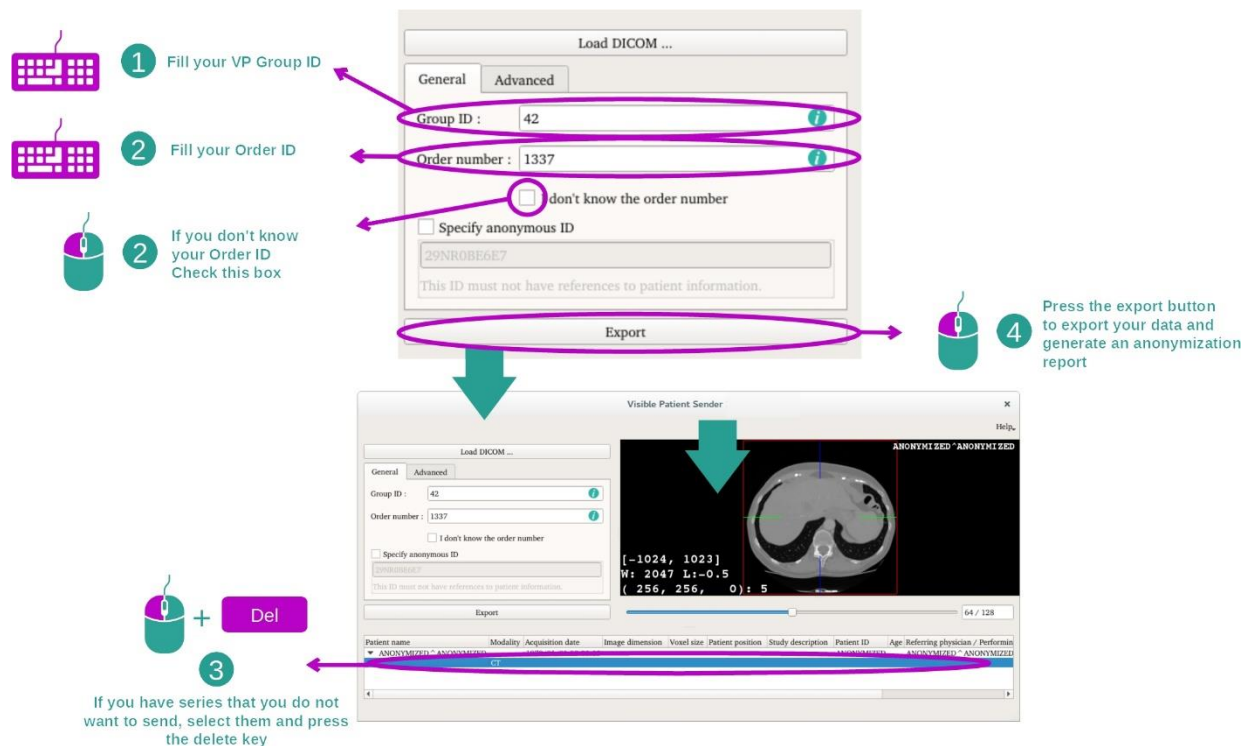
This software is composed of three main parts. The first one on the upper left corner is dedicated to the management of the anonymization process. The second one on the right side is a preview of the loaded DICOM files. The final one on the bottom is the list of the loaded series.

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



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.

8 Maintenance

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

8.1 Visible Patient Sender

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

8.2 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.

9 Troubleshooting

There is no troubleshooting with VP Sender.