User Manual

PRAEVAorta® Web

Software as a Medical Device

Version: v1.2.X[1]

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[1] X correspond to the number of patches. X is varying.

TABLE OF CONTENT

1 HISTORY

Revision	Modifications	Date
0	Creation	21/04/2022
1	Update functionalities	20/10/2023
2	Change figure 8 and 9 ,label add drag and drop folders and DICOMDIR management CC-2024-03	09/02/2024
3	Change the label, Add two section in the Upload button: anonymization and hospital information configuration according to CC-2024-13	29/11/2024

Writer	Reviewer	Approved by

2 PRODUCT

General information

Product Name	PRAEVAorta® Web
Trending name	PRAEVAorta® Web
Product Model / Version	v1.2.X
Classification	I (Regulation 2017/745)
UDI-DI	0377002375009
Product Lifetime	2 years
Manufacturer's Name	Nurea
Manufacturer's headquarters	213 cours Victor Hugo 33130 Bègles, FRANCE
Manufacturing Address	213 cours Victor Hugo 33130 Bègles, FRANCE
Web site	www.nurea-soft.com
Contact e-mail	*support@nurea-soft.com*

Description of the medical device:

PRAEVAorta Web is a web client providing a user interface for communication between users and cloud-based servers. It is intended for transmission, reception, storage, post-process, and display of medical data.

The platform:

- allows the user to send CT scan images for analysis to Nurea's server;
- displays the main indicators (arteries maximum diameter, volume), highlighting ones above a given value, for better patient monitoring;
- download various computation results (report, segmentation, csv measurements, etc.)

Intended purpose:

PRAEVAorta® Web is a web client providing a user interface for communication between users and computation servers. It is intended for transmission, reception, storage, post-process, and display of medical data.

Foreseen users and patients:

- Vascular surgeons
- Radiologists
- Clinical specialists

Use environment:

The software is intended to be used on CT scan images.

Indications for use:

- Analysis management
- Communication with computation server
- Display of analysis report and results
- DICOM transmission to computation server for analysis

Precautions for use:

PRAEVAorta® Web should only be used by a health care professional who has been trained in the proper use of PRAEVAorta® Web. The images sent must be in DICOM format. The PRAEVAorta® Web software is intended to supplement, not replace, conventional diagnostic examination of medical image data. No diagnostic or treatment decision should be made solely based on the use of PRAEVAorta® Web.

Contraindications:

Not suitable for other use than CT scan images of the human body containing the aorta.

Product constitutes:

This product is a software as a medical device.

Environment execution:

Recommended web browsers:

- Google Chrome, version 118.0.5993.71
- Mozilla Firefox, version 118.0.2
- Microsoft Edge, version 118.0.288.46
- Safari, version 16.1

Optional accessories:

PRAEVAorta® Web requires PRAEVAorta DB to operates. PRAEVAorta DB is a database, which is not a medical device.

3   USER GUIDE

Preamble

- *PRAEVAorta® Web software is intended to supplement, not replace, conventional diagnostic examination of medical image data. No diagnostic or treatment decision should be made solely based on the use of PRAEVAorta® Web.*
- *PRAEVAorta® Web is advanced medical imaging software and should only be used by qualified and trained persons. Users should be aware of the inherent limitations of digital imaging and familiarize themselves with the software using the user documentation and training materials provided.*
- *The user is responsible for the interpretation of the measurements and other calculations and the use of these results in the findings, regardless of their form (printed, stored, emailed, etc.). The user must effectively communicate the limitations inherent in these findings to untrained or uninformed recipients.*
- *It is the responsibility of the user to ensure that all available DICOM image data for a particular study/series is available and fully loaded into the software before reviewing the data for its intended use.*
- *Nothing in this material diminishes the user's responsibility for good clinical judgment and best clinical practice.*
- *Although PRAEVAorta® Web has been extensively tested for functionality, it cannot be guaranteed to be completely free of defects. It is therefore possible that the software contains defects. Users should be aware of the possibility of errors in areas such as measurements, be aware of alignment marks, etc.*
- *PRAEVAorta® Web has access to confidential patient information. Therefore, access to the system or to patient data must be controlled to prevent unauthorized users from viewing this data.*
- *Do not use PRAEVAorta® Web or the hardware on which it runs if it is damaged or compromised, or if you suspect in any way that its security may be compromised.*
- *PRAEVAorta® Web is not intended to be used as a primary archive for medical imaging data. This means that a secure copy of any data should be maintained in a location separate from the software, for example, in the scanner, in a PACS archive, or on archive media. Please do not rely on PRAEVAorta® Web as your primary archive.*
- *It is imperative that the user has an up-to-date paper version of the user manual at his disposal.*
- *Users shall have been trained to use PRAEVAorta® Web. For PRAEVAorta® Web to work properly, the uploaded images must be CT scans containing the aorta*

General functions

PRAEVAorta® Web is a client software that provides a user interface.
PRAEVAorta® Web allows a simple access to CT scan analysis for vascular disease.

Working principle

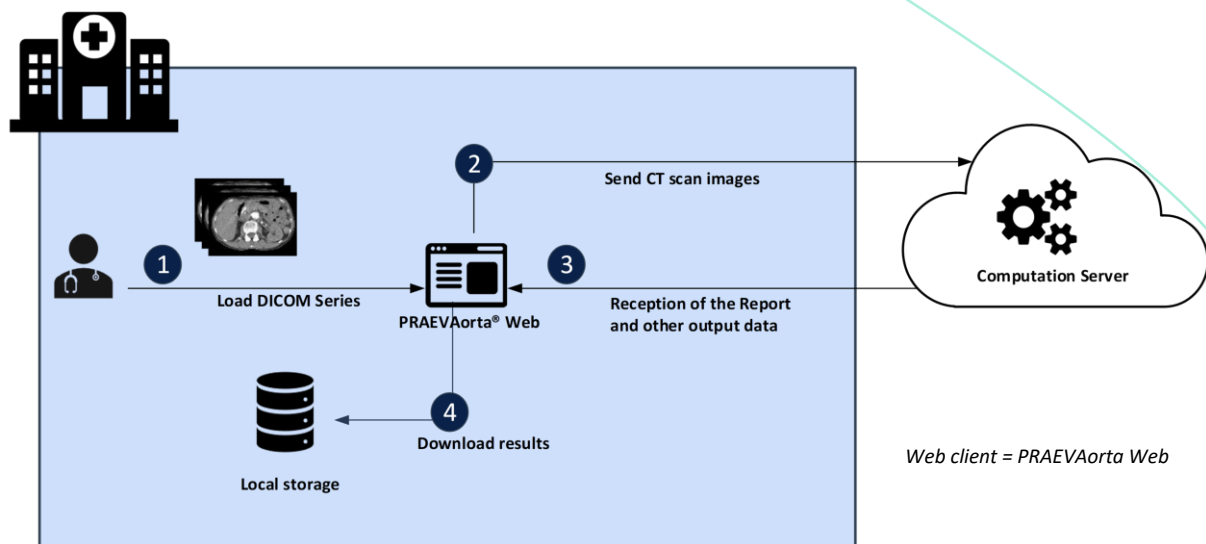PRAEVAorta® Web operates under the following principle:

Figure 1: System worksheet

3.1   Authentication page

To access PRAEVAorta® Web, please use the link communicated to you when signing the contract.

You will be redirected to the login page.

This is the first page that opens once you have launched the application. It is mainly composed of a form that will allow you to login to the platform.
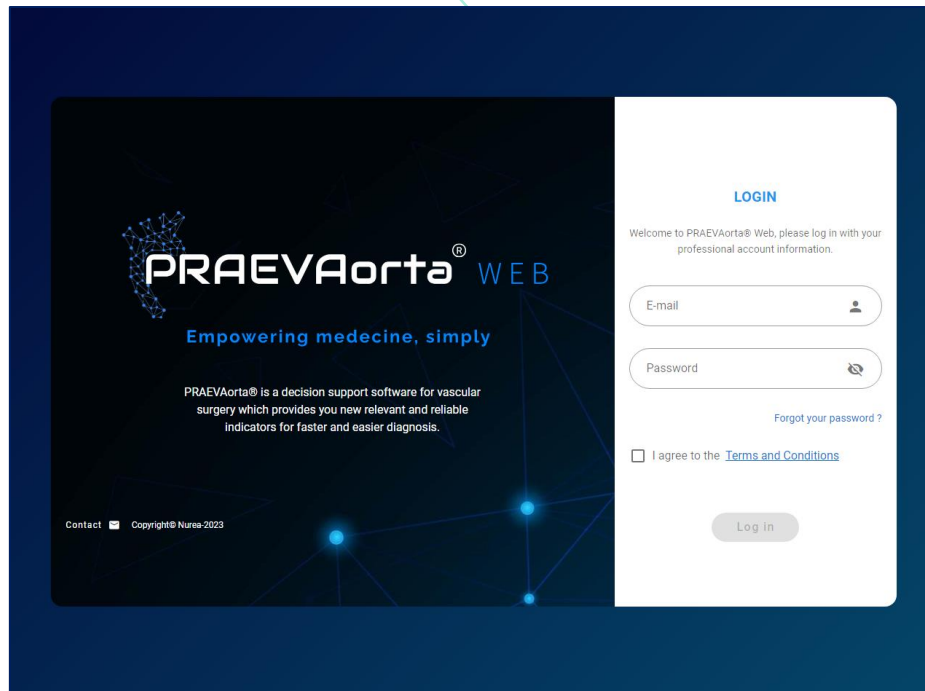
Figure 2: Login page

"Login" information

To log into PRAEVAorta® Web, you will need your username and password. The username is your e-mail, and the password has been given to you when signing the contract.

Enter these login identifiers in the appropriate fields and accept the "Terms and Conditions" by ticking the checkbox to log into the software. Then press the "login" button.

The password must be kept secret and memorized.

If you have forgotten your password or username, please contact us using the "contact" button on the page or the "Forgot your password?" button so that our team can help you as soon as possible. Forgetting your password or username will cause a delay in accessing PRAEVAorta® Web, this could delay the patient care of a potential critical patient.

"Contact" button

The "contact" button will redirect you to Nurea's website on a page containing a form. This form will allow you to contact Nurea's team in order to solve the problem you are experiencing. You can also contact us using the following address support@nurea-soft.com.

"Terms and conditions" button

The "Terms and Conditions" link (terms in blue and underlined) will display on your screen the terms and conditions that you must respect when using PRAEVAorta® Web.

3.2   Home page

After logging into the platform with your Nurea credentials, you will be redirected to the home page, as shown in the following screenshot.
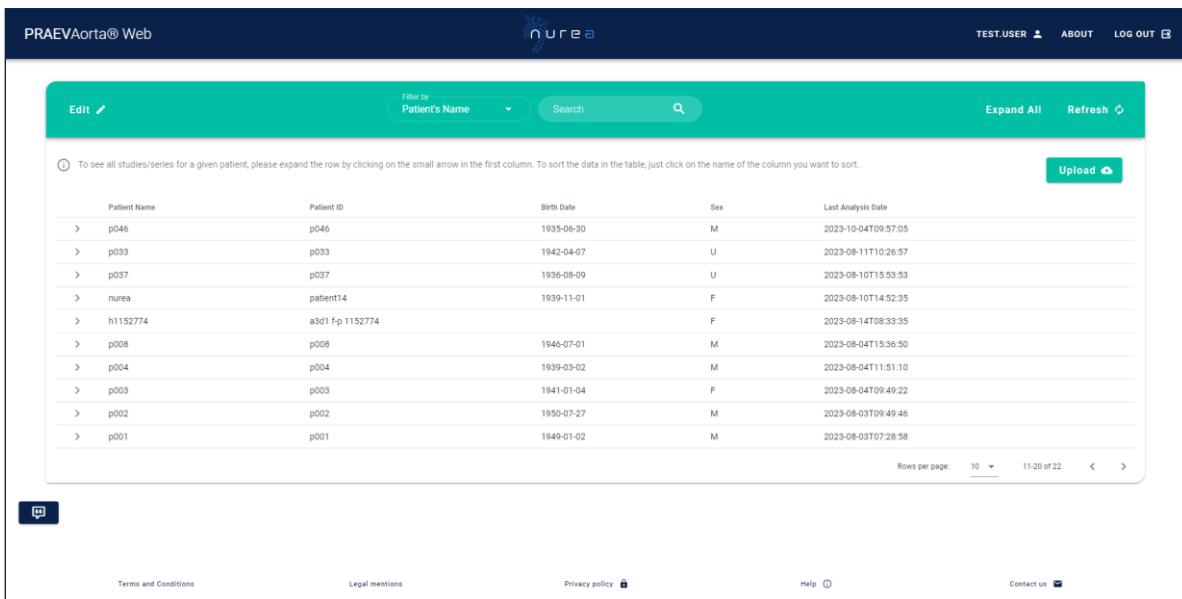
The home page is the main page of the platform, it includes a main view, constituting a table with all the patients and their series that have been treated.

It will allow you to manage patients and their series and associated reports. If you stay inactive for too long your session will expired and you will have to retry your operation. You will not have to inter your identifiers again so please logout when not using the software.

Please logout after using the software to guarantee data security and mitigate the risk of access to the medical data by a malicious person.

After logging in, the user has access to an intuitive interface. He will find a simple management of the registered patient and their analysis results (if the database option has been subscribed, if not, the patient list will be empty at logging). For each patient, the maximum diameter and the volume of the abdominal aorta are displayed with an access to the associated report.
Sending DICOM images series has never been easier with our drag and drop function. Finally, the navigation through the platform is very simple thanks to a system of pagination, search, and filter.

Figure 3: Home page

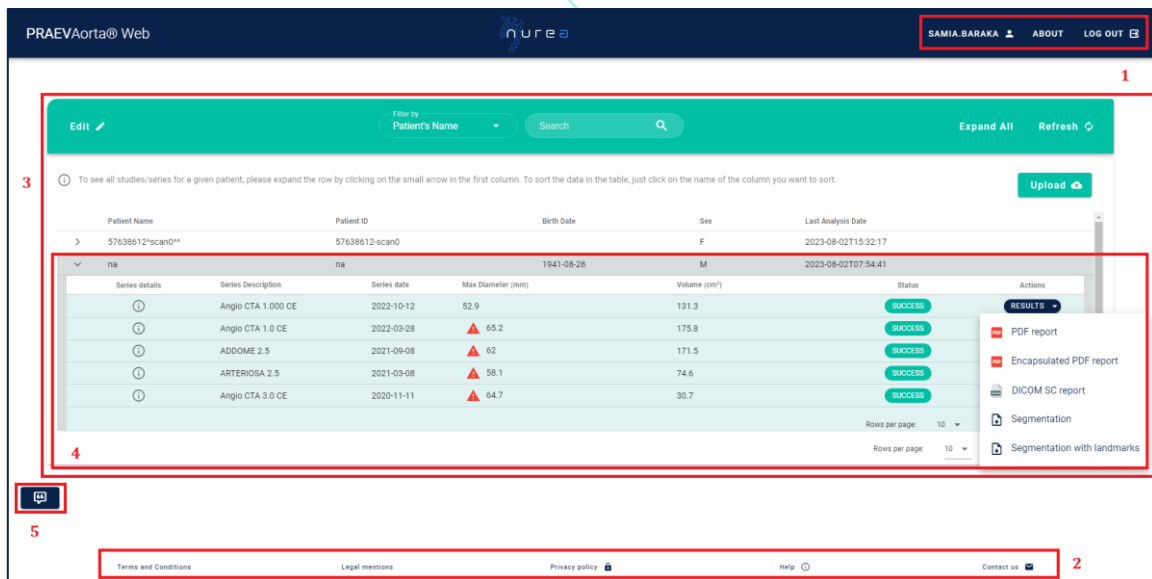The operation of this page will be explained in the following sections.

Figure 2: Different areas of the main page – PRAEVAorta® Web with database

3.2.1   Zone 1

Top banner

The top banner, in zone 1, contains your username, the "about" button and the "Logout" button. The "about" button displays information about PRAEVAorta® Web and Nurea Server. The "Logout" button allows the logged user to logout.

By clicking on your username in the navigation bar on the main page, you will have a modal page composed of two main sections.

Dashboard

It aggregates various relevant data allowing to have a general and detailed view on the use of PRAEVAorta®Web. It shows the total number of analyses performed, total patients with error , total number of critical patient cases as well as the total number of patients treated.
There is also a stats widget that details the number of segmentations, centerline and report performed by each user, group and customer, as shown in the following screenshot (Figure4).

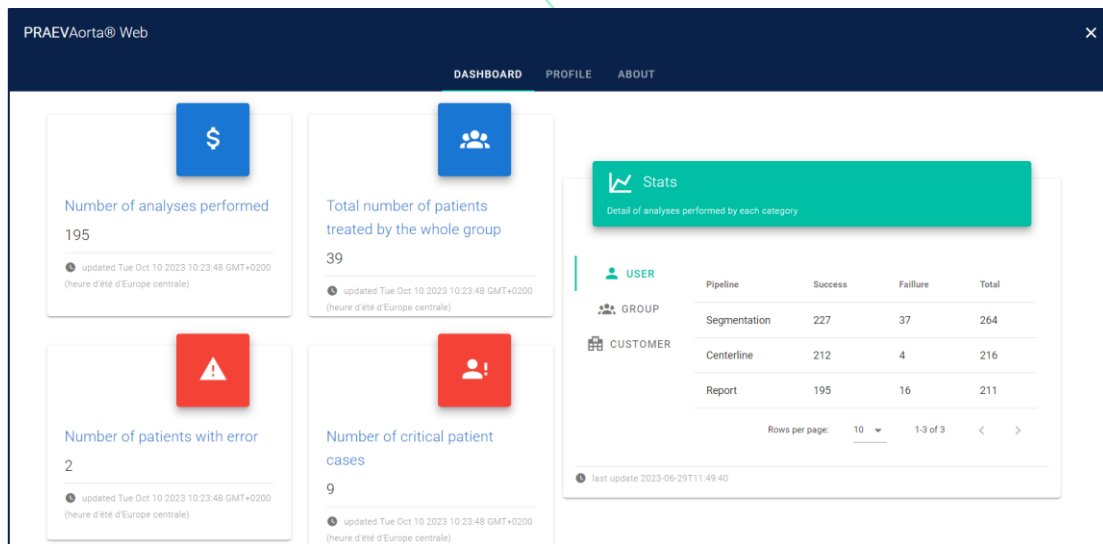 Note: these data are updated regularly to allow you to follow your use in a synchronous way.

Figure 4: Dashboard

Profile

The user section shows all the information about the user such as the email, the group he belongs to and the customer, as shown in the following screenshot.

Other functions are also available in the personal space: password reset, logout from the platform and activation of two-factor authentication. Users can change their password and/or log out directly from their personal space.

Two-factor authentication enables users to reinforce the security of their account by requiring a third identification element, in addition to the username and password, to validate each connection.
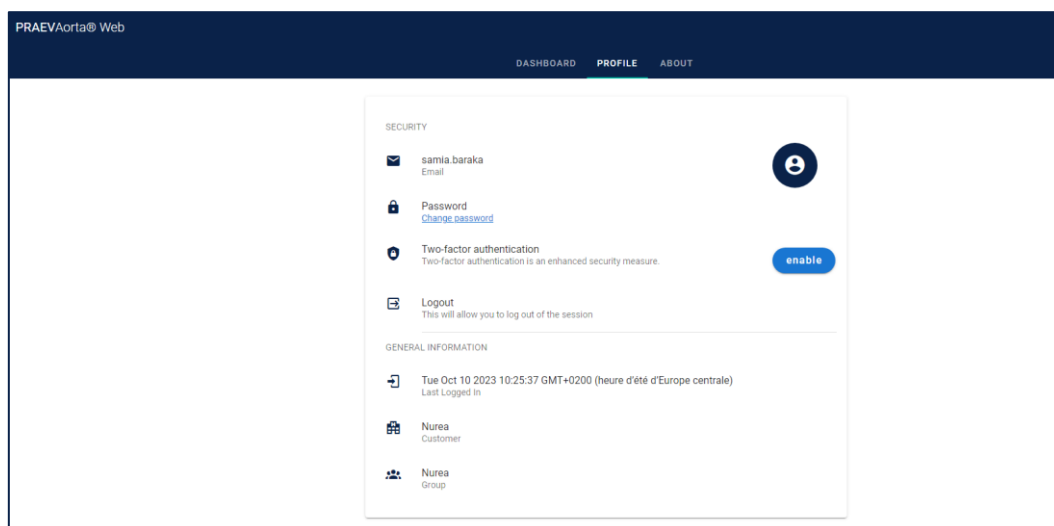

Figure 5: User profile page

To activate two-factor authentication, simply click on "enable" button, and the following dialog box will be opened:
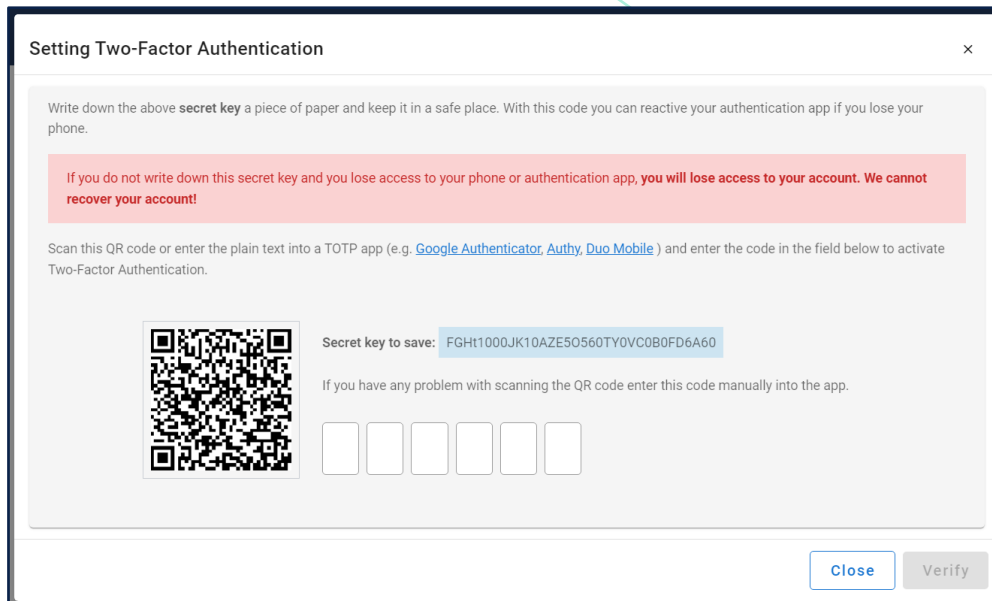

Figure 6 Setting Two-Factor Authentication window

You will need to scan this QR code or enter the plain text into a TOTP app (e.g. Google Authenticator, Authy, Duo Mobile) and enter the code in the field shown in Figure 6.

3.2.2   Zone 2

"Terms and conditions" button

The "Terms and Conditions" button, in zone 2, will display on your screen the terms and conditions you are committing to using PRAEVAorta® Web.

"Legal mentions" button and "privacy policy" button

The "Legal Mention" button, in zone 2, displays the mandatory legal mentions of Nurea. The "Privacy policy" button 🔒 in the zone 2 displays the privacy policy of Nurea.

"Help" button

The "help" button i , in zone 2, displays the help tab. This tab is a succinct explanation of how to use PRAEVAorta® Web but does not substitute the user manual. You can go through the few slides to easily understand the use of PRAEVAorta® Web.

"Contact" button

The "contact" button ✉ ,in zone 2, will redirect you to Nurea's website on a page containing a form. This form will allow you to contact Nurea's team in order to solve the problem you are experiencing.

3.2.3   Zone 3

List of patients

This is the set of patients that have been added and/or processed by the computation servers. Each user has appropriate access to the patients.

Each line corresponds to a patient. It contains the patient's ID number, name, date of birth, gender and the date of the last series treated.

You can easily browse the patient list by clicking on the "arrow" button at the bottom right of the table.

To show or hide all the series treated for each patient, simply click on the "down arrow" button in the first column.

You can sort the list of patients by date of birth, gender, name, etc... Simply click on the arrow icon next to each column name.
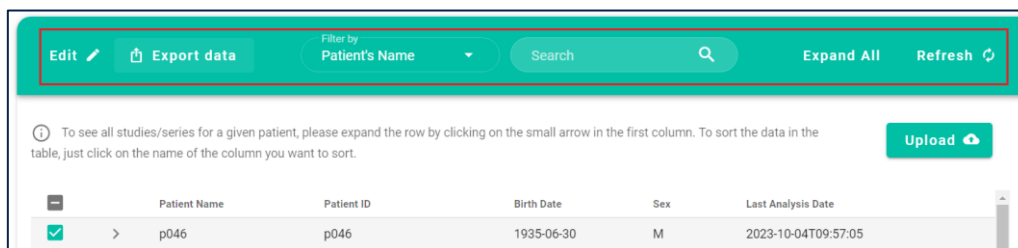
Tool bar

Figure 7: Tool bar screenshot

🔍 **Search**

It allows you to search for a patient more quickly with different filters to refine your search, for example, find all patients at risk or find patients whose name contains or begins with "PATIENTX".

✏ **Edit**

By clicking on the "Edit" button and then on the small icon in front of each patient/series, you can delete patients/series from the table list.

↩ **Export measurement data**

you can export all the measurements of the patient/series that have been performed in csv format, by simply selecting the concerned patient(s)and series and confirming the data export;

 You can only perform this task when the patient series has already been processed by the server.

🔄 **Refresh**

To refresh the patient/series records, you can click on the "Refresh" button and the data table will be updated*.*

Expand all

To view the complete series information for all patients and display all patient rows, simply click on the "Expand all" button.

"Upload" button

The "upload" button, in zone 3, above the patient list, allows you to open the upload window to import and upload CT scan for analysis:
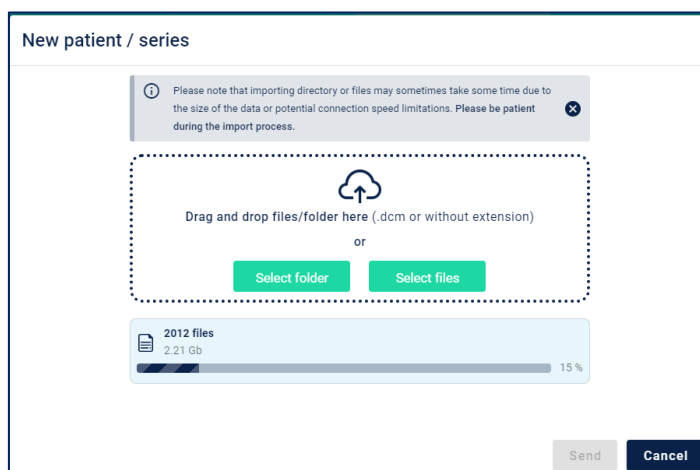

Figure 8: Upload window

To add a new patient or a new series of patients, simply drag and drop CT-scan images or folder into the input area or click on the buttons select folder or select to open a browse window and select the CT-scan series files (or folder).

If there are several series in the same file or series is related with DICOMDIR file, you will see the following arrangements:
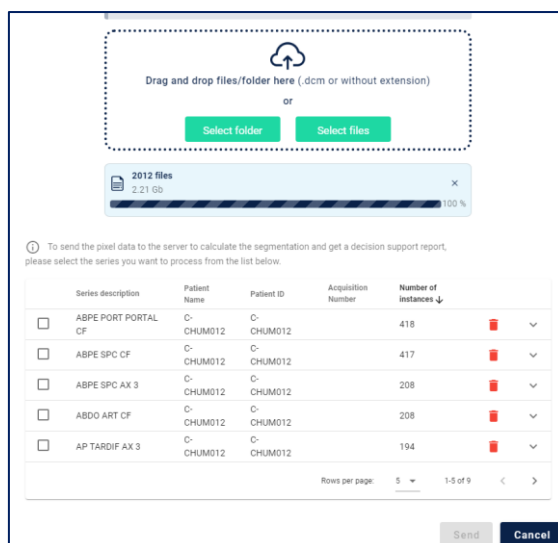

Figure 9 example of PRAEVAorta® Web upload window with several series

Select the one or several series you want to process by checking the boxes.

Once the CT-scan series is uploaded, it appears in the list of series, a "trash" button 🗑 to delete the series and an "arrow" button ⌄ to open an information window about the series. You can easily navigate in the list of series with the "arrow" button ⟩ of the pagination. If you click on the "cancel" button it will cancel all you have done on the window, and you will be sent back to the patient management page.

Warning! only DICOM files are supported.

Optional Features

The following features, **anonymization** and **hospital information configuration**, are optional. You can send the patient or series data as-is without anonymizing it or associating it with a hospital. These features are available to enhance data privacy and organization but are not mandatory for sending data to the computation server.

Anonymization

The anonymization function ensures patient data confidentiality by replacing or obfuscating sensitive information. This feature allows you to anonymize data for a selected patient or an entire series before further processing.

To anonymize data for a patient or a series, follow these steps:

1. Select the patient or series you wish to anonymize by clicking the checkbox next to the record.

2. Click the "Anonymize" button at the bottom of the table. A dialog box will appear, prompting you to enter a new patient ID and name.

3. Click "Submit" to finalize the anonymization process.

4. View and download results, after anonymization, a mapping table will display, showing the DICOM tags that have been modified or replaced. You can use the "Download anonymization results" button to download all images in the series with the updated anonymized information.

5. Check the anonymized status : once the data is anonymized, the patient/series will have a visible tag **anonymized**. You can use this tag to verify which records have already been anonymized.

The screenshots below illustrate the anonymization section, with the "Anonymize" button at the bottom of the table and the dialog box that appears when anonymization details are entered.
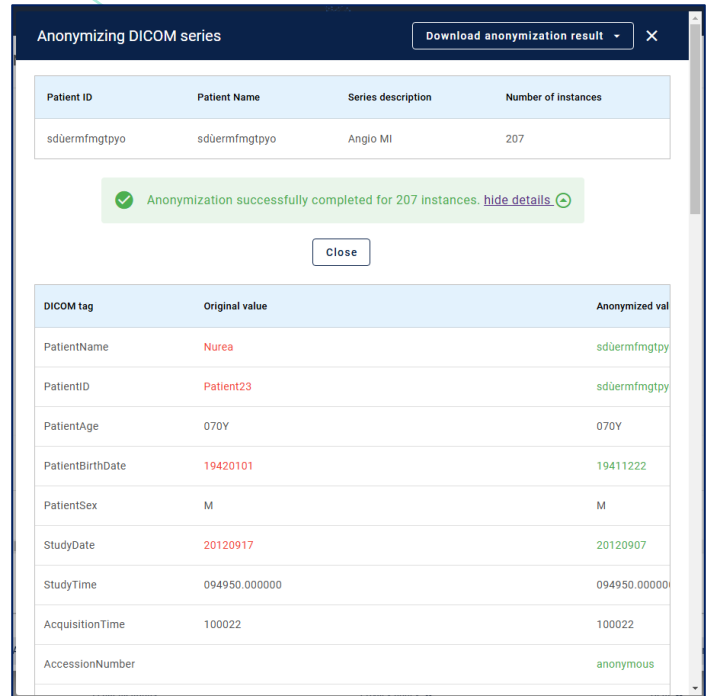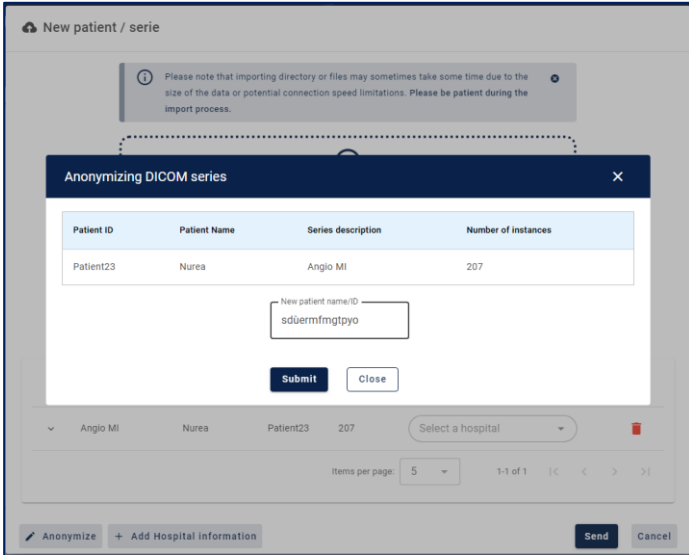

Figure 10: Anonymization window showing the anonymization section

Hospital information configuration

The hospital information configuration feature allows you to associate a patient/series with a hospital. This can be done via:

- Adding a new hospital using the "Add new hospital information" button.

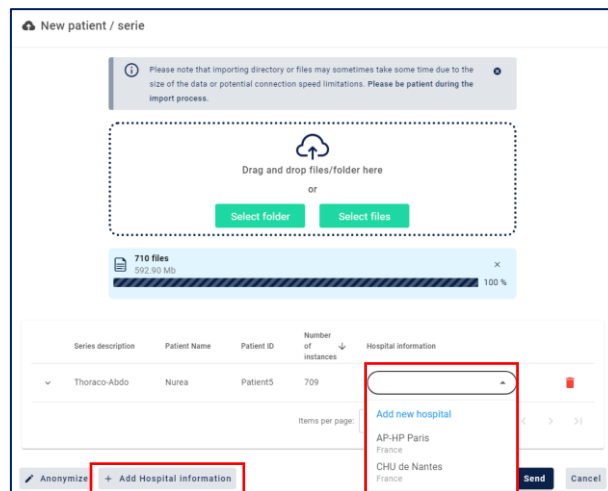- Quickly selecting an existing hospital from the dropdown in the table for each patient as shown in figure 11.

Figure 11 Upload window with hospital configuration elements

Option 1: Add hospital information

1. Click the "Add hospital information" Button: clicking it opens a dialog to add a new hospital with hospital name and country text fields.

2. Save the hospital information: once all details are filled, click "Submit". The new hospital information will automatically appear in the list of selectable hospitals.

Option 2: Quickly select a hospital

1. Locate the "Hospital Information" Column: in the patient table, find the column labeled Hospital Information (figure 11).

2. Open the dropdown for a record:

   - For the desired patient or series, click the dropdown in the "Hospital Information" column.

   - A list of existing hospitals will appear.

3. Select an existing hospital:

   - Choose a hospital from the list.

4. Clear the Selection: use the "Clear" icon in the dropdown to remove the hospital association for that patient.

Best Practices

- Always verify hospital information before saving or linking to a patient/series to avoid incorrect associations.

- Use the **Anonymization** feature before processing data to comply with privacy and data protection regulations.

Don't worry, if you upload a series that has already been uploaded, a message will be displayed.
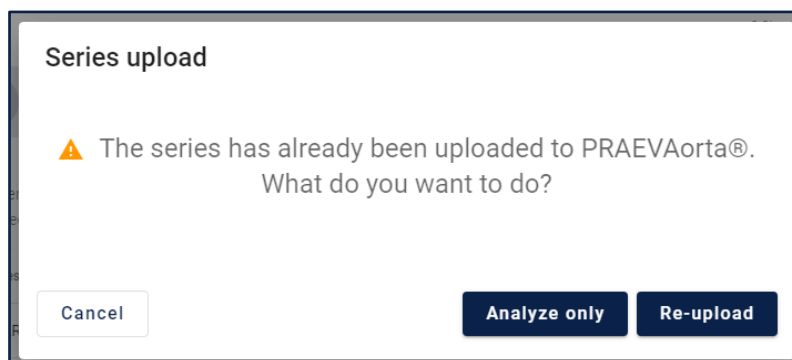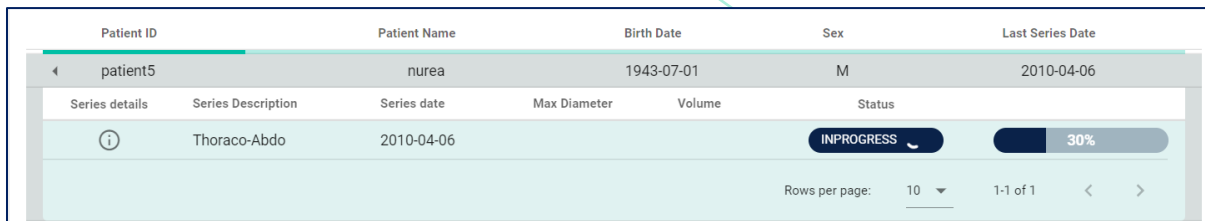

Figure 12: Warning message for Re-uploaded series

You can click on the "Re-upload" button if you would like to re-send the series. If you only need to recompute the series, click on the "Analyze only" button. To cancel the entire operation, click on "Cancel".

Once the upload is done, the patient/series will be displayed in the table where you can follow the progress of the computation.

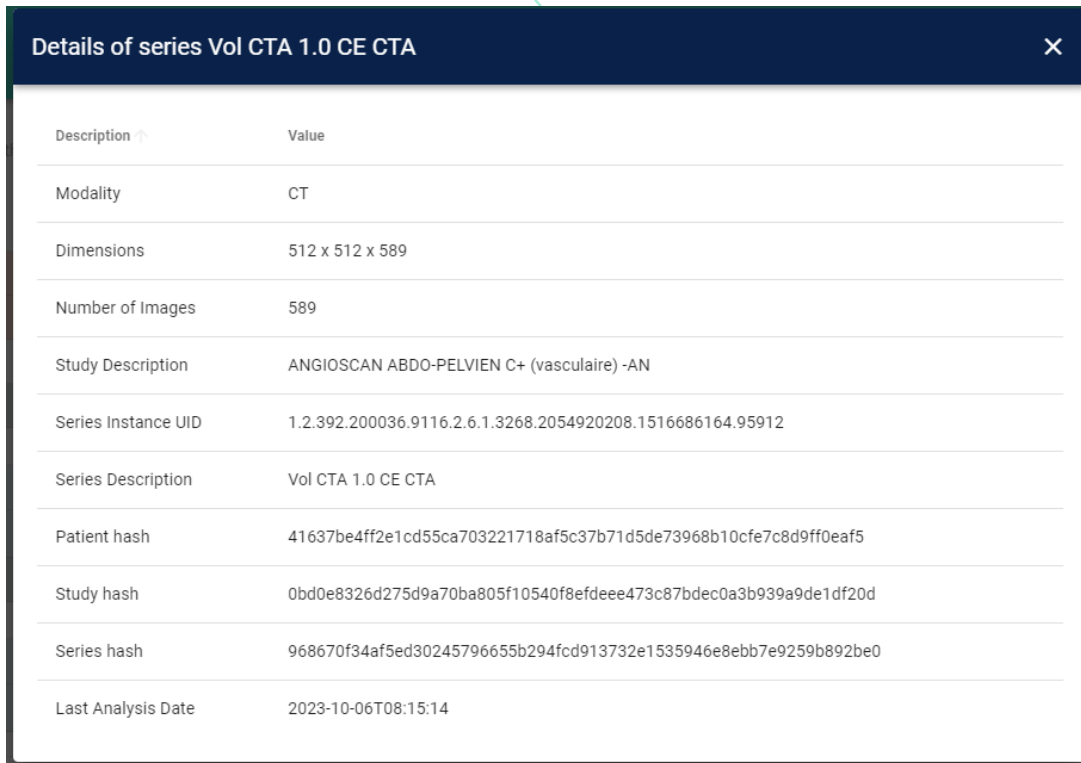*Figure 13: Compute progress*

List of patients

In Zone 3, the patient list represents the patients that the user has either added or been granted access to. Each record in this list corresponds to a patient and includes their identification number, name, date of birth, gender, and the date of their last analysis date. You can easily move through the list and increase the number of patients displayed with the "arrow" button ❯ below the list. To show or hide the series and reports and other explanations just click on the "arrow" button ⌄ in the first column.

3.2.4 Zone 4

List of series

The series list, in zone 4, is a list of all the patient's series. On each row, there's a button to view information about the series ⌄ (see figure 4), the series description, the series date, the maximum diameter measured on the series, the aneurysm volume, the calculation progress status, the button to download the results, i.e. the PDF report, the encapsulated PDF report, the report in DICOM format, the segmentation file with and without landmarks. Another button ⓘ is also available for displaying some series tags.

If the button for downloading results is not displayed and the status is not "in progress" or "pending", reload the page, if the problem persists try downloading the series again, if the problem is still not solved contact support: support@nurea-soft.com.

Figure 14: Serie information example

3.2.5   Zone 5

User Feedback

In the main page, you will find at the bottom left a widget with an icon like this ⬚ .

Which allows you to display a dialog as shown in the screenshot.

This dialog allows you to select an option according to your need, either there was a bug while using the platform, or you have an idea or a suggestion to make that allows us to improve the application. The last option is to write any complaint you want to make, ask a question or anything else.

To send feedback, you just have to select an option, write your message in the text box and send it by clicking on the Send button. You will be redirected to your email box to complete the process and send your email securely.

You can edit your message directly in the modal or on your email before sending it.
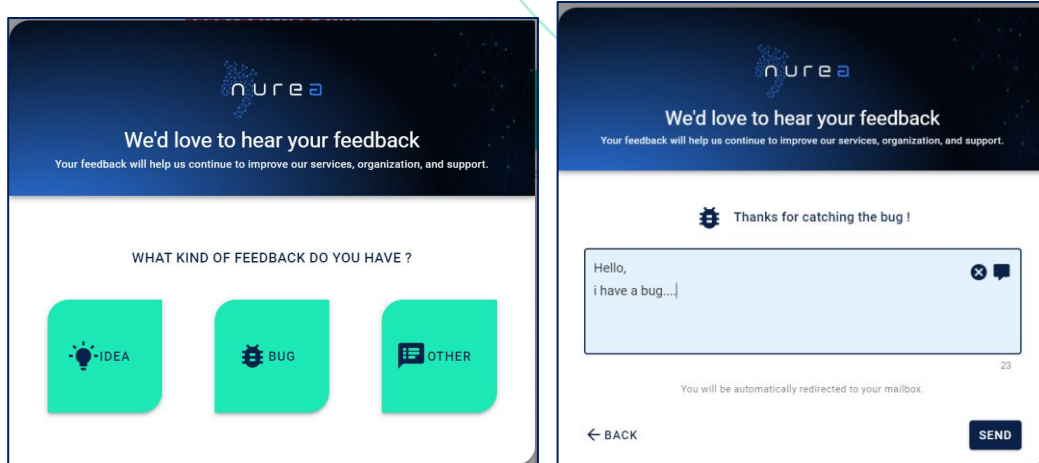
Figure 15: Feedbag window on the left and an example for a bug problem on the right

4   TECHNICAL SPECIFICATIONS

Operating Compatibilities:

PRAEVAorta® Web runs on a web browser.

Guaranteed operation on the following popular web browsers: Google Chrome, Mozilla Firefox, Safari, Microsoft Edge (refers to section "environment execution" page 6, to have functional versions).

A good internet connection with a high-speed transfer (download and upload) is recommended.

PRAEVAorta® Web can be used with PRAEVAorta® 2.

System Input:

Input data necessary for PRAEVAorta® Web are:
- Login credentials
- CT scans in DICOM format

System output:

The output data from PRAEVAorta® Web are:
- Analysis results files (segmentation, reports, measurements, etc.)
- Usage statistics.
- Error, success and warning messages

5   WARNINGS AND PRECAUTIONS

Notes on safety:

Any information other than that required by PRAEVAorta® Web sent to PRAEVAorta®2 will not be processed and invalid and will result in the invalidation of the input data and the non-creation of the series or patient.

If you have administrator status, you can cause permanent loss of patient data by deleting series or patients. Please be careful.

It is very risky to leave your PRAEVAorta® Web session unsupervised, as this would allow a malicious individual to gain access to the patients' health data.

Warnings:

PRAEVAorta® Web cannot be held responsible for any decision made with the information provided. We encourage users to systematically check the report.

The maximum diameter and indicators provided are indicative, the user must control its position, the other diameter measurements, and the report.

Information posted by PRAEVAorta® Web must be checked and verified.

Only DICOM series are supported by the software.

Residual risk:

- Research function returns the wrong patient data.

6   TROUBLESHOUTING

PRAEVAorta® Web			
N°	Problem	Possible cause	Resolution
1	*Unable to connect to PRAEVAorta® Web*	*The platform is stopped/Error* *Authentication* *Network error*	*reload the page* *Check the identifiers used* *Contact customer support* <u>*support@nurea-soft.com*</u> *with mentioning "authentication error".*
2	*Results (report, segmentation, etc.) not available*	*Input data corrupted/Bad image type image type/Network error*	*Check the compatibility of the input data (scanner images with contrast medium).*

			Verify the proper functioning of the computer network and the connection to the platform. Check the correct functioning of the internet connection in case of cloud use. Contact customer support at support@nurea-soft.com with describing: - The use cases - The error message obtained
3	*A button or function is not available*	Display bug/refresh error	*reload the page* Contact customer support support@nurea-soft.com with mentioning " error/non-display of function".

Before reporting any bugs or problems, please check the correct use of the product in accordance with this user manual (intended use, minimum system requirements, compatibility, ...). If the problem persists, please report it by sending an email to the following address: support@nurea-soft.com.

7   ERROR MESSAGES

List of possible messages and errors:

PRAEVAorta® Web			
Code	Error message	Causes possible	Resolution
200	Operation successfully completed	you used *PRAEVAorta® Web* correctly	N/A
208	Patient / series already exist	the element you want to add already exists	The user must check if the element already exists, if it does not already exist, please contact Nurea on: support@nurea-soft.com.
403	Warning, your session has expired, please try your operation again	Expired session or you don't have	Try to reconnect, if fail, contact Nurea's

	You do not have access to the platform.	permissions to access the software	support team at *support@nurea-soft.com*.
404	Reports not found or segmentations not found or patient not found	the element you wanted to search for was not found	reload the page and check that the element exists
409	The series has already been uploaded and processed by the computation servers	the request could not be processed	check that the request is possible

8   UPDATES AND MAINTENANCE

The maintenance of the software is handled by Nurea. Please contact us in case of any issue.

Any problems, bugs, incidents, incidents of material vigilance, must be reported to Nurea by email at the following address: support@nurea-soft.com.

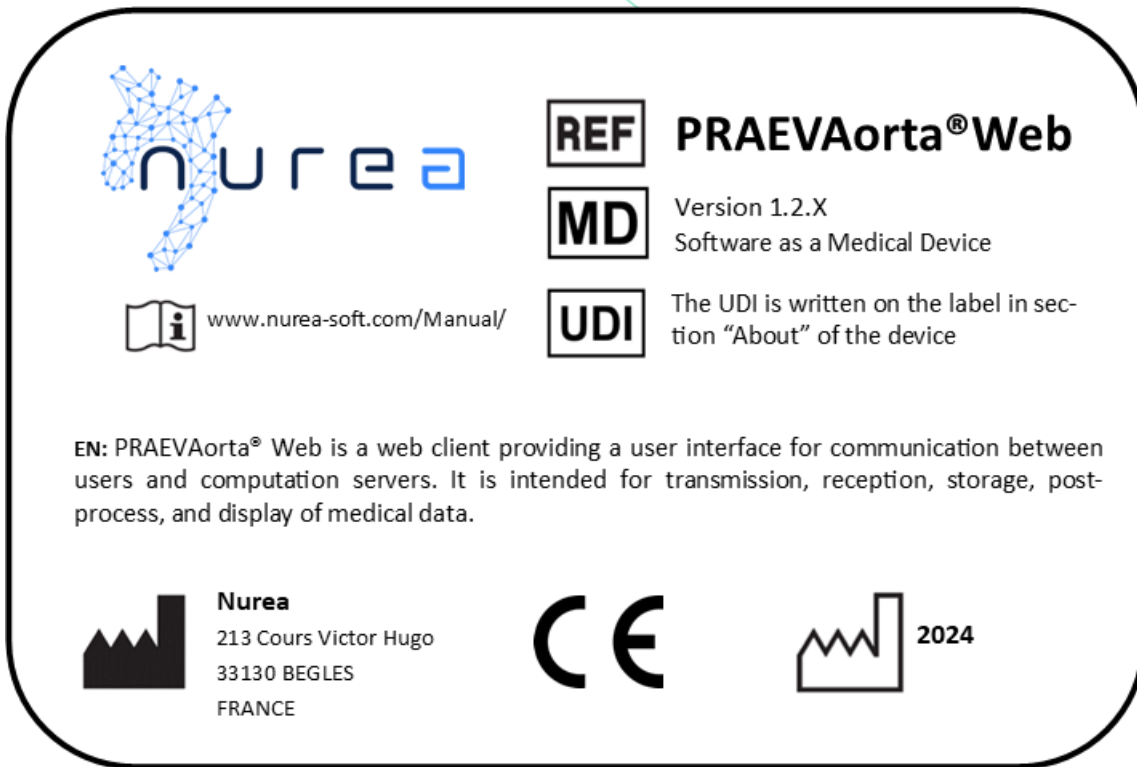*The software is continuously updated by our services when deemed necessary and with an acceptable an acceptable risk.*

9 LABEL

Figure 16: Example of PRAEVAorta® Web label

Symbol	definition
	Manufacturer Mail address of the manufacturer's headquarters
	Date of production of the software YYYY
	It is important to consult the user manual www.nurea-soft.com/Manual/
	CE Marking
	Software reference, here its commercial name and its version The X indicates a variable number. In fact, this number corresponds to the most minor modifications for which the user manual does not need to be updated.
	MD means medical device

MD	
UDI	Unique Device Identifier. It is composed of the product identifier, the date of manufacture in yymmdd and the version of the software. This Identifier is linked to the company, the software, and the version. It is to be communicated to Nurea and competent authority when reporting an incident or bug.

10 TRAINING

A training will be done at the purchase, before the first use. For further training please contact Nurea.