User Manual
PRAEVAorta® 2

Software as a Medical Device

Version: v1.2.X[1]

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

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1 HISTORY

Revision	Modifications	Date
0	Creation	20/01/2023
1	Modifications according to CC-2022-07	03/02/2023
2	Modifications following MDR certification review, ROUND 2	28/04/2023
3	Adding performances on non-contrasted CT scans, update the example of the first age of an analysis report, update the version	01/12/2023
4	Modification of the version of the software according to CC-2024-02 and update of the performances	05/07/2024

Writer	Reviewer	Approved by

2 PRODUCT

General information

Product Name	PRAEVAorta®2
Product trade name	PRAEVAorta®2
Product Model / Version	v1.2.X
Classification	IIb (Regulation 2017/745)
Notify Body	2797
UDI-DI	03770023750004
Product Lifetime	2 years
Manufacturer's Name	Nurea
Manufacturer's Headquarter	213 Cours Victor Hugo 33130 Bègles, FRANCE
Manufacturing Address	213 Cours Victor Hugo 33130 Bègles, FRANCE
Website	www.nurea-soft.com

Contact e-mail	support@nurea-soft.com

Product description

PRAEVAorta®2 is a decision-making support software for diagnosis and follow-up of vascular diseases. It is intended for automatic segmentation and geometric analysis of vessels.

It is a companion software whose purpose is to accompany the doctor in the first assessment of several indicators from CT scan images.

The software is able to reconstruct automatically the vascular structures from CT (Computerized Tomography) scans images. As current solutions only reconstruct the lumen, Nurea's software also automatically segments aneurysms and associated thrombus.

With this reconstruction, the software provides diameters, volumes, angles and distances between anatomic points.

It is the first solution automatically extracting geometric measurements and allowing comparative evaluation of the evolution of the disease during follow-up, providing personalized diagnostic support to improve therapeutic strategies.

This software is cloud based or can be installed on premises. PRAEVAorta®2 is a server software usable through APIs. However, it is hardly recommended to use it via a client software. The client aims to provide a user interface to send images and receive the analysis results. It can either be a web client, a gateway / PACS client, an integrating solution, or a marketplace.

Intended use

PRAEVAorta® 2 is a decision-making support software for diagnosis and follow-up of vascular diseases. It is intended for automatic segmentation and geometric analysis of vessels

Intended users

Intended users are healthcare professionals:

- Vascular surgeons
- Radiologists
- Clinical specialist

Intended target group:

Adults patients with a CT scan.

Indications for use:

- Aneurysm and stenosis assessment
- presence of vascular diseases on CT (Computed Tomography) modality
- suspicion of vascular diseases

- any need for vessels geographic analysis
- vessels segmentation

Precautions for use

It is recommended to use PRAEVAorta®2 through a software client.
The CT scan series to be analysed shall be send in DICOM format only.

In case of unusual patient morphologies, a very "noisy" image, or the presence of implants (protheses, screws, implants of embolization …) providing metal artefacts, results may be altered.

Contraindications

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

Not suitable for scanner series with several acquisition number or too many noises.

Product constitutes

The product is a standalone software. It is a medical device.

Environment execution

PRAEVAorta®2 is executed on a production server equipped with
- Linux,
- an X86 compatible processor
- a Nvidia graphics card
- 32 Gb RAM

Optional accessories

There are no accessories.

Clinical benefits

The patient benefit is related to medical time saving in clinical routine, accurate and reproductible measurements, and a medical follow-up improvement.

Particularly, this software facilitates the taking of measurements through their automation and standardisation.

Performance characteristics

PRAEVAorta®2 performance characteristics, based on the results of Nurea clinical investigation, are identified as follows:

- Improvement of evaluation time (up to 95% of time saving).
- Improvement of reproducibility. A 5 mm graduation diameter measurement had been observed between healthcare professionals (intra and inter variation) while PRAEVAorta®2 had returned the same results.

- Improvement of inter and intra-observer variability by standardizing the measurements.
- Improvement of blood vessels representation (3D representation).

Degrees of accuracy of PRAEVAorta®2

Measurements accuracy with manual measurements:

On contrasted CT scans:

- Maximum diameter: 94.5%
- Diameters: 94.9%
- Volumes: 80.7%
- Lengths: 61.2%
- Angles: 98%

On non-contrasted CT scans:

- Maximum diameter: 95.4%
- Diameters: 96.7%
- Volumes: 45.6%
- Lengths: 62.9%
- Angles: 98.1%

Segmentation accuracy:

- Dice similarity coefficient (DSC): 0.95
- Sensitivity: 0.94
- Specificity: 0.98

Segmentation time per CT scan: from 27 seconds to 4 minutes.

3 USER GUIDE

Preamble

- *PRAEVAorta®2 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®2.*
- *PRAEVAorta®2 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®2 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® 2 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®2 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® 2 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® 2 as your primary archive.*
- *The uploaded images must be human CT scans containing the aorta.*

General functions

The general function of the product is the 3D reconstruction of the arterial system from which a geometrical analysis is realized such as diameters, volumes, length, and angles. The results are provided through a report allowing a quick identification of the principal clinical indicators such as the maximum volumes.
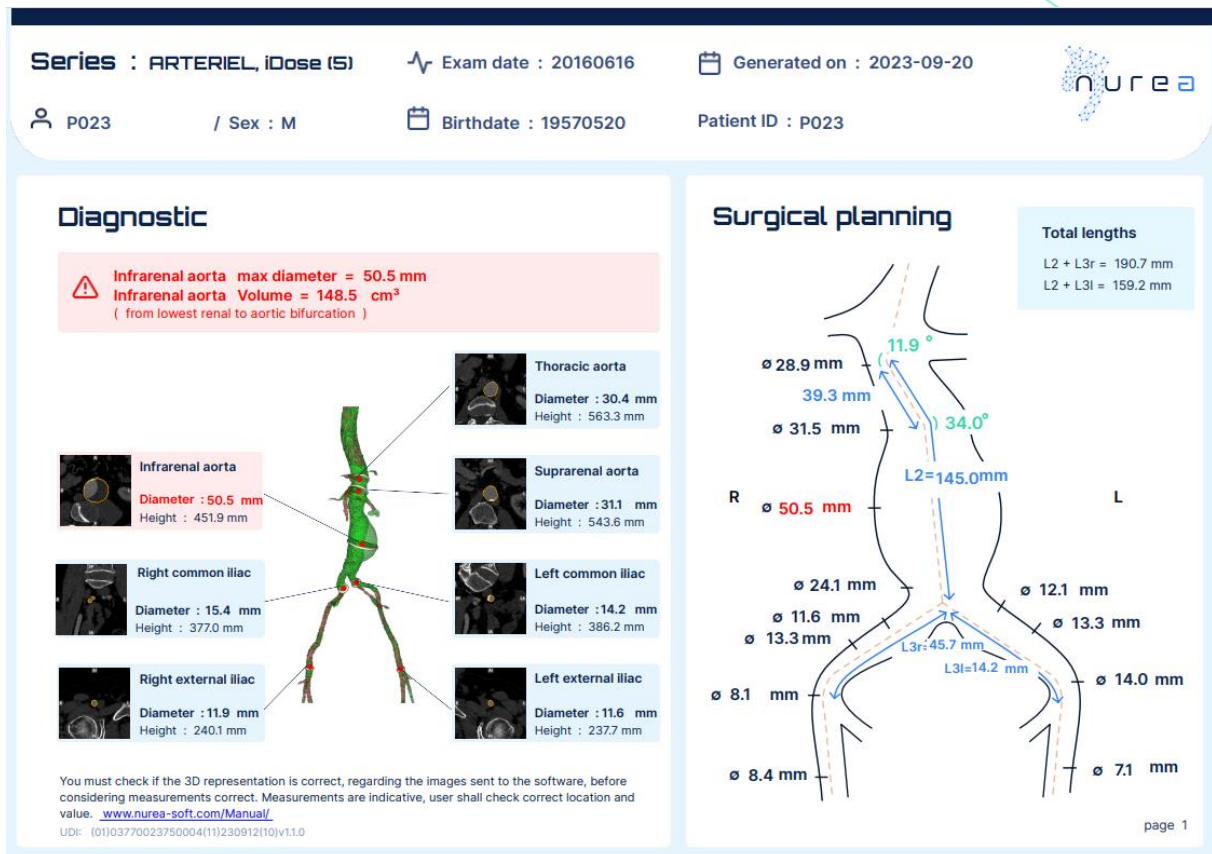

Figure 1: Example of the front page of the report

Working principle

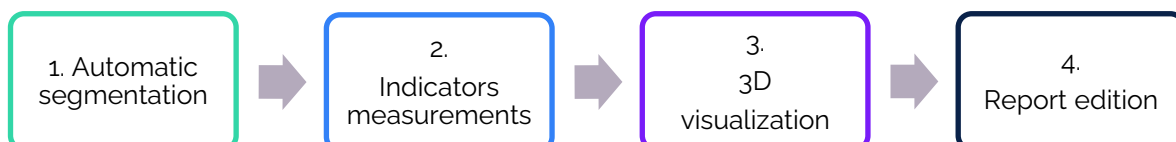The software works according to the following workflow:

Figure 2: Software PRAEVAorta® 2 workflow

The sending of the CT scan series to analysed and the reception of the report is realized through the web client:
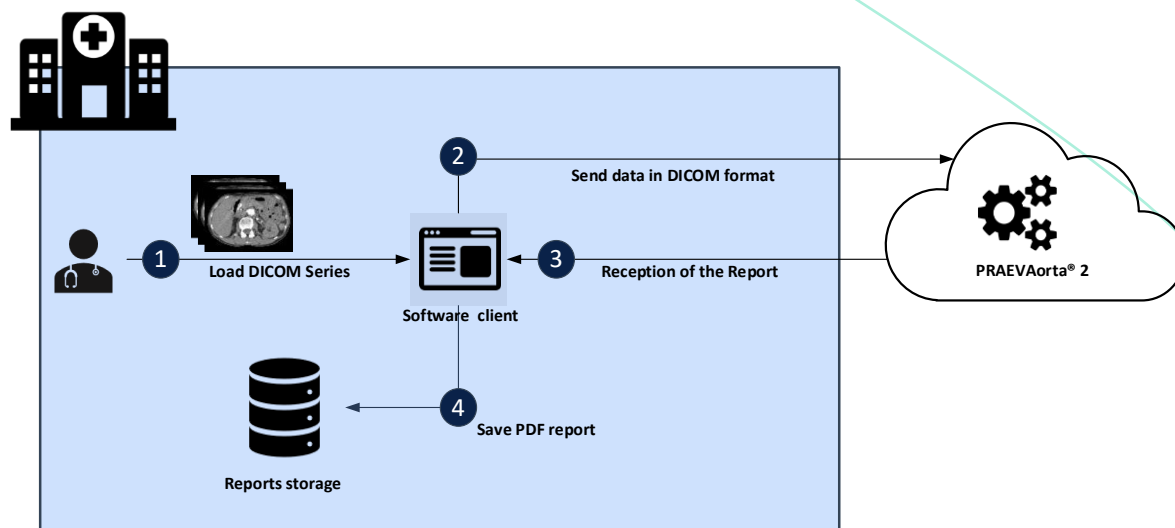

Figure 3: Use diagram

4   TECHNICAL SPECIFICATIONS

Operating Compatibilities

PRAEVAorta®2 is compatible with a system equipped with Linux, an X86 compatible processor and a Nvidia graphics card.
A good internet connection with a high-speed transfer (download and upload) is recommended.

Security measures taken are the followings:
- On premise: Data are stored directly inside hospital server
- On cloud: Data are stored in a HIPAA-compliant and HDH-certified (Health data host) cloud storage.
- An encrypted secure workflow is used to ensure a secure transmission of sensitive data (HTTPS/TLS 1.2/ AES 256)

Performances

For example: when using PRAEVAorta®2 with a CT scan of an axial resolution of 512x512 and 895 slices, on a Ubuntu 20.04 64-bits Core i7 8750H 32Gb RAM RTX2080-MaxQ machine, the treatment time was 232 seconds. This time does not take into account the data transfer steps to and from PRAEVAorta®2, which depend on the software client used and the network between that client and the software.

System input:

Input data necessary for PRAEVAorta®2 are:
- An Authorization token in JWT format delivered by a secure Identity and Access Management (IAM) software
- CT scans in either:
  - JSON format with:
    - a list of pixels of a DICOM series
    - the origin of a DICOM series

- the spacing of a DICOM series
- the orientation of a DICOM series
  - o or DICOM format

System output:

The output data from PRAEVAorta®2 is:
- an analysis report
- Vessel's segmentation
- Geometric measurements
- Error messages (when applicable)

5   WARNINGS AND PRECAUTIONS

Notes on safety

The data must be sent by the software client in a secure manner. Any information sent to the device, that does not fill requirements, will not be processed and will result in the invalidity of the input data.

⚠️ Any serious incident that has occurred in relation to the device should be reported to Nurea via the email address vigilance@nurea-soft.com and to the competent authority (ex: BfArm for Germany, ANSM for France…).

Warnings

The information is provided for guidance only and must be systematically checked by the user. PRAEVAorta®2 cannot be held responsible for any decision made with the information provided. In particular, we encourage users to systematically check the segmentation before considering the geometric measurements as being correct.

The user must check if the 3D representation is correct, regarding the images sent to the software, before considering measurements corrects. There might be segmented part that do not belong to the vessels or part of the vessels that have not been taken under consideration.

The maximum diameter provided is indicative, the user should check its position. The same applies to all the measurements.

Residual risk

Two residual risks have been identified:

- Wrong maximum diameter
- Wrong segmentation

A wrong diameter is usually linked to the segmentation. Please take a look at the 3D reconstruction and the scan screenshots (under each results' tables) to identify a possible wrong segmentation or wrong maximum diameter.

6   TROUBLESHOOTING

N°	Problem	Possible cause	Resolution
		Product name	
1	*Impossible connection to PRAEVAorta®2*	*The platform is stopped/Authentication Error*	*Verify the ID and password used. Contact Nurea's customer support using the following email address:* *support@nurea-soft.com by mentioning "authentication error"*
2	*No result*	*Input data corrupted/ Wrong image type/network mistake*	*Verify the input data compatibility (scan images)* *Verify the proper functioning of the informatic network, the web connection and the connection to the platform.* *If the problem hasn't been solved, please contact Nurea's customer support for help by using the following email address:* *support@nurea-soft.com and describe:* - *The usage case* - *The error message obtain*
3	*Bad segmentation / measurements*	*To many noises on the CT scan / wrong acquisition timing / Wrong part of the body / Software limits reached*	*Verify the acquisition timing* *Verify the sharpness of the images*

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

7   ALARMS AND MESSAGES

List of the possible error and messages: Messages are sent to and displayed through the software client. Please refer to the user manual of the software client for more details.

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 risk.

9 LABEL

Please note: information specific to the version of the software used is only available through the Application Program Interface (API). With the exception of the UDI, the unique identifier of the device, which is also available in the footer of the analysis report returned by the software.
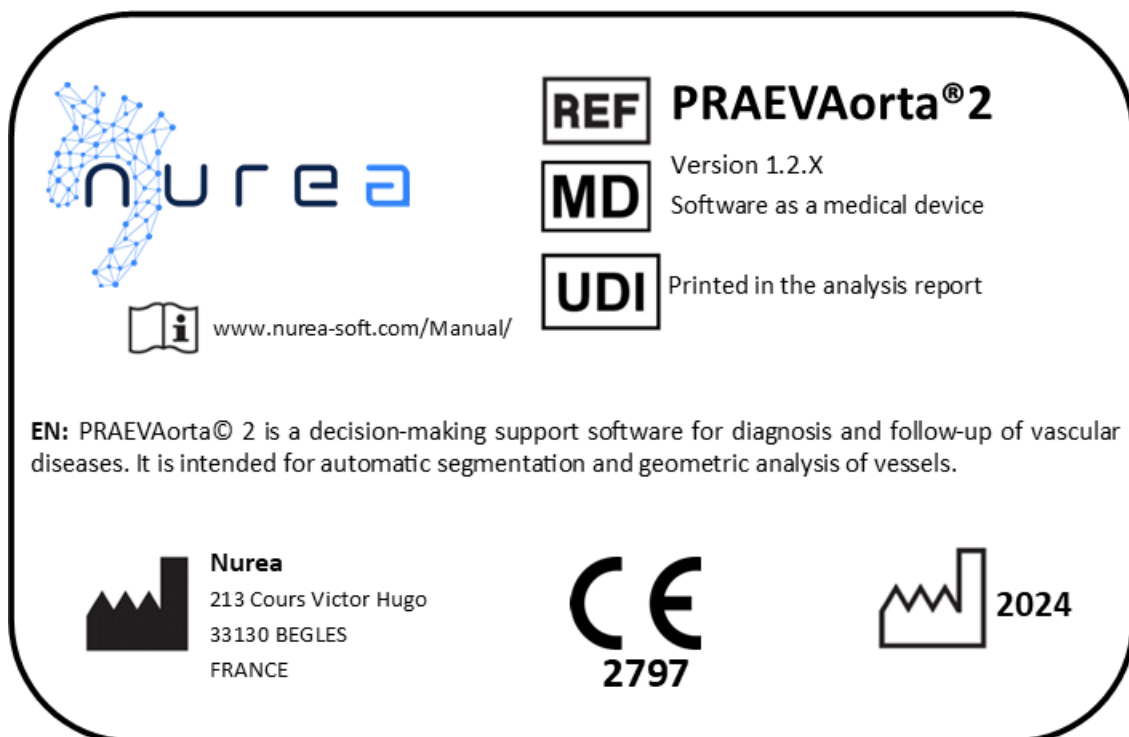
Figure 4: Label of the device PRAEVAorta® 2

Symbol	definition
	Manufacturer Mail address of the manufacturer's headquarters
	Year of production of the software aaaa
	It is important to consult the user manual www.nurea-soft.com/Manual/
REF	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	MD means Medical Device
UDI	Unique Device Identifier. It is composed of the product identifier, the date of manufacture in yymmdd format and the version of the software. This unique identifier is available at the bottom of the analysis report returned by the software. It is also available in the Application Program Interface (API).
CE 2797	CE Marking 2797 is the identification code of the notified body that issued the CE marking certificate. Here it is the BSI.

10 TRAINING

No training is planned for this device. A training maybe provided for the client software (which is not covered by this manual).