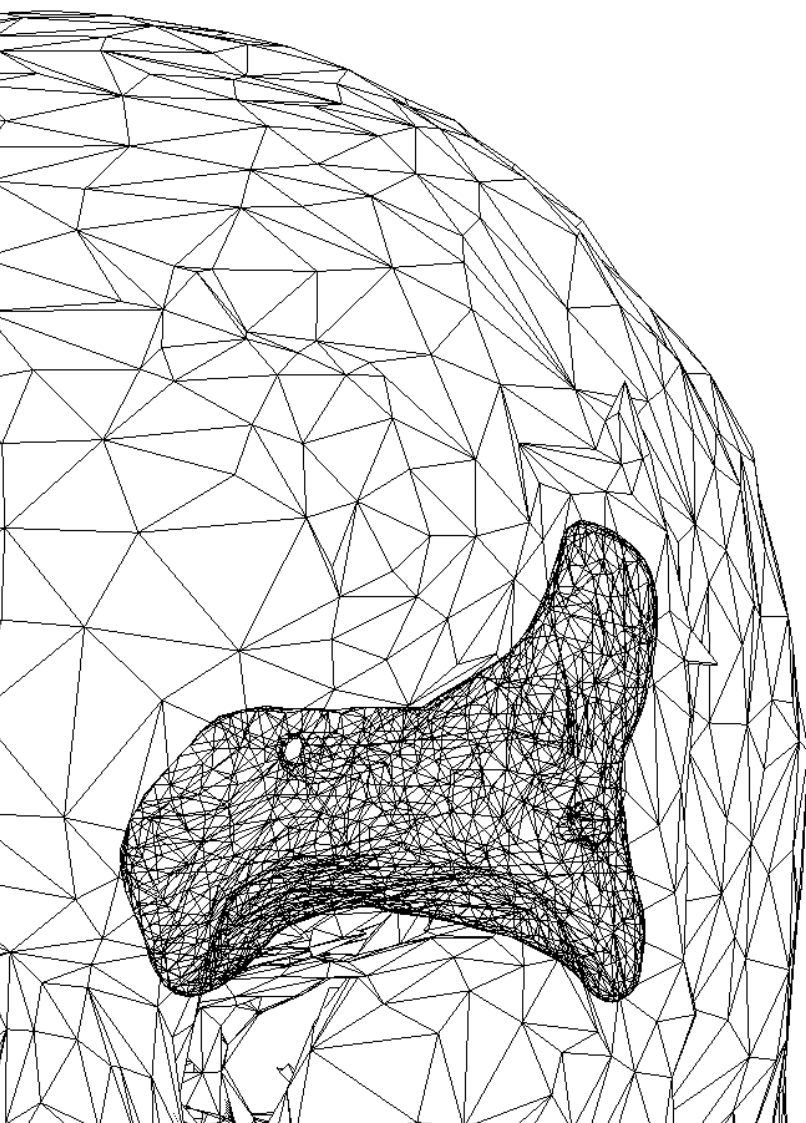


Customy Vision

Instructions for Use

Version CV-IFU-2022.01-EN

Release date 2022.06.03



This document is an electronic copy of the *Instructions for Use* of Customy Vision Software. Detailed instructions can be found in the User Software Manual of Customy Vision.

Used Symbols



Manufacturer



Date of manufacture



Consult instructions for use



Cautions and Warnings

Manufacturer Contact Details

Customy Vision 1.1.0 Software manufactured in June 2022 by



Smart Labs Sp. z o.o.
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Description of Customy Vision

Customy Vision is software for visualizing and processing medical images from a medical scanner, such as a CT scanner or an MRI scanner, to an output file. The software allows the user to import, visualize, and segment medical images, check and correct the segmentations, and create digital 3D models. Digital 3D models serve as the basis for advanced visualization of the patient's anatomy, fabrication of anatomical models, or design of patient-specific implants and surgical guides.

The output files can be used to produce anatomic physical 3D models (using traditional or additive manufacturing methods), used in physician-patient communication and for preoperative planning of surgical treatment for orthopedic and craniomaxillofacial applications.

Indications for Use

Customy Vision is intended for use as software for importing, visualizing, segmenting, processing medical data, and creating 3D digital anatomical models. 3D. Customy Vision can also be used as preoperative software for virtual planning of surgical or prosthetic treatment and evaluating surgical treatment options

Recommendations



Customy Vision should only be used in conjunction with other diagnostic tools and expert clinical judgment by a physician.



An intended user of the software is a professional user having high competencies and professional experience: a doctor or a biomedical engineer:

- having an appropriate experience in anatomical analysis and inference - diagnostics, carried out based on diagnostic medical imaging such as computed tomography, magnetic resonance imaging, ultrasound, and other imaging methods in radiology;
- fluent in English at work (the software interface is only available in English).



Customy Vision Software can be used after the detailed reading of the Instructions for Use and User Software Manual of Customy Vision.

Warnings



Scanning protocols are left to the user's discretion; however, the manufacturer recommends referencing and adhering to industry standards.



Only images obtained less than 6 months earlier should be used to simulate and/or evaluate surgical treatment options.



For preoperative surgical planning or 3D printing, it is recommended that the inter-slice distance and pixel size be less than 1mm in medical imaging for reconstruction.



Outputs intended for treatment or diagnosis of patients must be checked by a responsible clinician who can compare 3D reconstructions with cross-sectional images to verify quality. The clinician's ultimate responsibility is to make a professional assessment as to whether the planned treatment using Customy Vision software should be carried out.



Medical image data in DICOM format have tags in their structure, among other things, containing sensitive data about the patient and the medical unit where the examination took place. In order to preserve the security of sensitive data, it is recommended to convert the way the data is saved to an anonymized study - without sensitive information allowing to identify the patient and the study performed. The anonymization tool available in the Import Module is designed to remove this data.

Accuracy



The model's accuracy depends on the image resolution and the quality of the original scan.



The resolution of the image file limits the measurement.

Contraindications



Customy Vision Software is not intended to process mammography imaging due to the imaging method of this study.

Best practice tips and precautions

Combining the basic segmentation algorithms with the Smart segmentation algorithms is recommended for the best results.

The quality of medical images directly impacts the precision with which the software creates the spatial mesh output file. Medical devices have their own protocols, and it is recommended to adhere to the reference standards set by the manufacturer.

The precision with which Customy Vision creates output files is listed as 1 mm for images. The accuracy of the measurements is specified as 0.1 mm for both: medical images and spatial mesh. The resolution of medical images limits measurements.

It is recommended to use the latest medical images no more than six months old. Older ones can be used as reference images in patients with long-term diseases.



Customy Vision Software requires constant access to the Internet to function properly. Please note that its operation may be interfered with by the antivirus or firewall installed on the device, which may block or restrict the software's access to the Internet.

Instructions for Use

Installation – Start the installation by running the downloaded installation file (*.dmg format). If the User Account Control asks for permission to make changes to the device, express your consent. The Installation Wizard will guide you through the installation process. In each Installation Wizard step, select your preferred options and click *Next* to continue. After successfully installing the software, a dialog box will appear informing you that the installation is complete.

Using the software – After installing the software, launch the application by selecting Customy Vision in *Start Menu* > *All Programs* or double-click an existing Customy Vision project. Once the application is launched, the user is required to log in with their login and password. Only users with active license can use Customy Vision software. The validity of the license is checked during using the software. An Internet connection is required for the software to function properly.



The detailed process of installing Customy Vision Software is described in the Software Installation Instructions.

Minimal Recommended System Requirements

Operating Systems:

- Microsoft Windows 10
- Apple macOS Big Sur 11

Hardware:

- Processor: 3GHz Multicore
- Memory (RAM): 8 GB*
- Graphic card: GeForce 1050
- Screen resolution: 1920 x 1080
- Free disc space: 1 GB

* The memory required depends heavily on the size and complexity of the image data and results model to be processed. It is recommended to use better hardware specifications when working with large data packages.

It is recommended to use Customy Vision within a hardware and/or network environment in which cyber security controls have been implemented including anti-virus and use of a firewall.

Paper IFU

End-users of Customy Vision Software can request a free paper copy of this document by emailing support@customy.eu. The paper version will be provided within 7 working days.

Reporting of serious medical incidents



Any serious incident related to Customy Vision Software must be reported to the manufacturer at contact@customy.eu and to the competent authority where the user or patient resides.

Serious incident - means an incident that directly or indirectly led, may have led or may lead to any of the following: death of a patient, user or other person; temporary or permanent serious deterioration of the health of a patient, user or other person; serious threat to public health.

Incident - means any malfunction or deterioration of the characteristics or performance, including a usability error due to ergonomic features, of a product made available on the market, any inaccuracy in the information provided by the manufacturer, and any adverse reaction.