Cysware® 4H
Surgiverse® Web-Planning

UDI-DI: 3760365550004
REF: H001-WEB001

UDI	UDI
📖ℹ	Consult instructions for use: www.abys-medical.com/ifu
REF	Catalogue number
MD	Medical Device
⚠	Caution
℞ only	Federal law restricts this device to sale by or on the order of a physician
🏭	Manufacturer

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1- General

Note: in the following document, Abys® Medical Cysware® 4H is also called Surgiverse® Web-Planning. Both denominations refer to the same product.

Abys® Medical Cysware® 4H web platform is a web-based medical device designed and intended for use prior to surgery to gather in one place the information needed by the surgeon to make a surgical planning. As a result, a planning assistance file is created and contains medical imaging, 3D models, documents, and notes. The Abys® Medical Cysware® 4H web platform is used to export the planning assistance file to the Abys® Medical Cysart® 4H mixed reality application, another medical software.
The planning assistance file can only be generated if the following rules are respected. The user of Abys® Medical Cysware® 4H must have read those instructions for use.

2- Product description

Abys® Medical Cysware® 4H allows the user to log in to a secure space to centralize the documents that are useful for planning an operation. On this space he(she) can register each patient who needs a surgical act. A patient file is automatically created with patient's data. One patient may have one or more planning assistance files (PAF). Each planning assistance file is specific to a patient surgery and allows the information necessary to perform the surgical procedure to be centralized, while at the same time meeting the patient's anatomical specificities.
A planning assistance file can be remotely shared and completed with other surgeons, at a distance, simultaneously or not.

Abys® Medical Cysware® 4H is compatible with Abys® Medical Cysart® 4H. The Abys® Medical Cysart® 4H application allows you to view PAF documents and information in stereoscopic 3D images by means of Microsoft® HoloLens 2 (see specific instructions for use of Abys® Medical Cysart® 4H).

The expected benefits for the user are indirect, but use of Abys® Medical Cysware® 4H allows for:
- 3D display of computed tomodensitometry (CT) images for a better understanding of anatomical structures.
- Viewing and comparison before and after the operation, making the post-operative controls more reliable.
- Unique file centralizing all patient information necessary for the future operation, saving time for the medical staff.
- Constitution of the assistance file in collaboration and consultation with surgeons and interns.
- Annotations and measurements based on medical imaging and 3D views marking key points and/or steps of the planned surgery.
- Review of the planning assistance file by peers who can be remote.

3- Indications

Abys® Medical Cysware® 4H is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. Abys® Medical Cysware® 4H is also intended as pre-operative software for surgical planning assistance. Abys® Medical Cysware® 4H is intended to be used by clinician with appropriate clinical judgement.

Abys® Medical Cysart® 4H is a medical display intended for 3D image visualization and image interaction. The stereoscopic 3D images are generated from 3D volumetric data acquired from CT scan source. The device is intended to provide visual information to be used by clinician with appropriate clinical judgement for analysis of surgical options, and the intraoperative display of the images. Abys® Medical Cysart® 4H is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. Abys® Medical Cysart® 4H is intended to be used as a reference display for consultation to assist the clinician with appropriate clinical judgement who is responsible for making all final patient management decisions.

4- Contraindications

Abys® Medical Cysware® 4H is not intended for use without adequate training or for any surgery using a medical imaging format that is not supported by Cysware® 4H. Abys® Medical Cysware® 4H is only an adjunct tool for planning with indirect clinical benefits, facilitating but not replacing or altering medical information-based users decision making.

5- Types of users

Abys® Medical Cysware® 4H can be used by a clinician with appropriate clinical judgement as well as by an Abys® Medical practitioner as part of a user support. Abys® Medical Cysware® 4H should be used autonomously under the user's control.

6- Residual risks and associated recommendations

- Risk of inappropriate treatment: user must make sure to open the right planning assistance folder for his(her) patient on Abys® Medical Cysware® 4H. (double check patient's identity and surgery type).
- Risk of inappropriate treatment: user may check appropriateness of dimensions between original CT scan and file displayed on Abys® Medical Cysware® 4H by means of integrated measurement tool and must systematically verify the right side of the limb that is going to be operated.
- Risk of inappropriate treatment: when planning assistance files are used in clinical collaboration user should monitor the modifications made by his(her) peers before surgery.
- Risk of data loss: for data security, the

user is responsible for letting other people accessing device with his/her QR code. Abys® Medical declines all responsibility in case of use of the Abys® Medical Cysware® 4H web platform by a person other than the one who was provided his(her) with credentials at registration.

▪ Risk of data loss: user must ensure that he(she) logs out of Abys® Medical Cysware® 4H when he(she) no longer uses it to avoid abusive use by a third and related issues.

7- Residual Anomalies

▪ The labels are displayed for all users, it is recommended to refer to the label management panel to hide or show the points of interest.

8- Precautions of use

▪ Abys® Medical Cysware® 4H should only be used in the following up-to-date browsers: Chrome, Firefox, Safari or Edge.
▪ Abys® Medical Cysware® 4H should only be used in full screen window.
▪ The user's workstation must meet the following minimum requirements: Windows 10 (32/64 bits) and 4 GB of RAM.
▪ Abys® Medical Cysware® 4H must not be used from a mobile device to create or modify a PAF.
▪ Abys® Medical Cysware® 4H must be used on devices authorized for the user by his(her) institution's security policy. The security policy of his(her) institution must guarantee that his(her) computer network and workstation are secure. Workstations should have timely security patches and updates, necessary anti-virus software, firewalls and other protection.
▪ The user must ensure that he(she) has a good quality internet connection with a speed of at least 50 Mbit/s before connecting to Abys® Medical Cysware®

4H webpage and throughout his(her) use of the platform.
▪ The user must carefully read all the warnings and errors that appear on the software. **Caution**: Most alerts are blocking.
▪ The use of weblinks is only intended as support prior to surgery. Therefore, the weblinks are only available in Cysware® 4H and not in Cysart® 4H.
▪ When working collaboratively on the same series, the following parameters can affect other users: MPR axes, window width, window level and segmentation manipulation.
▪ A DICOM can only be uploaded if it meets the following criteria:
  • Be a file in ZIP format ending in ".zip", or a directory containing DICOM images
  • Images must be CT modality only
  • Contain the information of only one patient
  • Have a maximum size of 2GB
  • Be complete with no missing slice
▪ It is necessary for the recipient to have a Cysware 4H account to perform the sharing.

9- Essential information
Data safety and cybersecurity
Abys® Medical Cysware® 4H complies with the best practices in terms of security and data protection.
Abys® Medical Cysware® 4H complies with the EN 12251 standard on healthcare user identification security.
The user must choose a unique password for the Abys® Medical Cysware® 4H and not save the password in the browser.
The user shall not disclose his(her) login details to any third party.
The user must ensure privacy/confidentiality during registration to avoid password theft.
All personal and sensitive data in the databases are anonymized.
Abys® Medical Cysware® 4H does not store personal data and documents containing

personal data after logging out of the web platform.
Logging in to Abys® Medical Cysware® 4H without action cannot exceed 15 minutes, after which time the user is automatically logged out of his(her) account.
The user should not connect to a public Wi-Fi network without using a virtual private network (VPN).
To protect the critical functionalities of Abys® Medical Cysware® 4H, databases are stored on a web host HIPAA compliant. The databases are saved for a minimum period of 7 days and up to 1 year on the web host and can be restored during this timelapse in case of deterioration or malfunction.

Documents supported by Abys® Medical Cysware® 4H
The documents that can be included in a PAF are
▪ CT scans and their metadata
▪ Annotations
▪ Points of interest related to the CT scan
▪ Documents of type: *png, jpg, pdf or gif*
▪ Multiplanar reconstructions (MPR)
▪ Web links (URL)
Abys® Medical Cysware® 4H must not be used for documents other than those supported by the platform.

Documents display
Abys® Medical Cysware® 4H allows the user to visualize one or more CT scans as MPR views and as a 3D view. To facilitate this visualization, the user can change the brightness of the 3D model and the contrast of the MPR views.

CT metadata is accessible from Abys® Medical Cysware® 4H.

Abys® Medical Cysware® 4H allows the user to manipulate the MPR views and the 3D view. It is also possible to segment bone tissue from a CT scan.

Documents edition

The user can add a point of interest on the 3D model and take a screenshot of the views they have. Taking measurements, editing the screenshot, editing checklists and adding annotations are also integrated features on Abys® Medical Cysware® 4H.
The user can delete a document from the planning assistance file.

Transmission of information to the mixed reality application
Abys® Medical Cysware® 4H is used to transmit planning assistance information to Abys® Medical Cysart® 4H. The user can use dedicated tools to check and validate elements before transmitting them. Refer to the specific instructions for use of the Abys® Medical Cysart® 4H application.

Collaborative work
Abys® Medical Cysware® 4H allows the user to share his (her) PAF with others through their email addresses.

The author of the patient record can decide if his (her) peers can view and modify the PAF and set an end date for sharing the record.

It is necessary that these people possess an Abys® Medical Cysware® 4H account to be able to access the shared PAF.
Up to three people can work simultaneously on the same patient record and fifteen people can connect to Abys® Medical Cysware® 4H simultaneously.
Communication tools are available for calling other Cysware® 4H or Cysart® 4H users.

Cautions
▪ Only patients who meet the criteria detailed in section "Indications" may be selected.
▪ Patients meeting the criteria detailed in section "Contraindications" should not be selected.
▪ Abys® Medical Cysware® 4H does not replace the user's medical decision.
▪ The user must ensure that the elements

imported on Cysware® 4H are secure (pdf, images).

- The user must ensure that the added weblinks are secure.
- Measurements taken from the Abys® Medical Cysware® 4H web platform are indicative with an accuracy of 1.25mm for distance measurements and 3° for angle measurements.
- Extraction tools are for informational purposes only and not intended for diagnostic use.

Complaint about the medical device

Any healthcare professional with a complaint regarding the quality of this medical device, its identity, reliability, safety, efficacy, or performance should notify Abys® Medical.

Any malfunction of this medical device, and/or any malfunction that may have caused or contributed to serious injury to a patient, must be notified immediately to Abys® Medical.

For any claim on this medical device, please provide the name, part number and version of the medical device, your name and address, and a detailed description of the claim.

Install, maintenance/updates and decommissioning

No install maintenance or decommissioning procedures are needed for users. Cysware® 4H is a web platform under responsibility of Abys Medical ensuring all operations. Users will be noticed for updates and related timelapses of unavailability of platform if needed.

Additional Information

For more information on this medical device, or to obtain free printed instructions for use within 7 days, please contact Abys® Medical's customer service department at support@abys-medical.com.

Abys® Medical engages to maintain this medical device in service for a minimum period of 2 years and provides security patches or software updates during this period.

Warnings

Abys® Medical's liability is limited exclusively to the applications and uses indicated in these instructions for use.

10- Instructions revision date

Reference and version: IFU-004 V9
Revision date: 2023-09-15