USA: Instructions for use

Cysart® 4H

Surgical strategy assistance application in Mixed Reality

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

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1. General

The Abys® Medical Cysart® 4H mixed reality application is a medical device designed and intended for use in office room and in operating room to display and manipulate all documents in the planning assistance file generated from the Abys® Medical Cysware® 4H web platform. The consultation of a planning assistance file can be correctly done only if the following rules are respected. The clinician with appropriate clinical judgement intended to use the Abys® Medical Cysart® 4H mixed reality application must be qualified, familiar with the surgical technique and have read these instructions for use.

2. Product description

Abys® Medical Cysart® 4H is used on the Microsoft® HoloLens 2 mixed reality headset. It allows the user to log in to their account with the same credentials as on Abys® Medical Cysware® 4H web platform. On his or her account, the user can find each patient file as well as the planning assistance files (PAF) created on Abys® Medical Cysware® 4H. The user can view and manipulate all the documents in the planning assistance folder in the form of stereoscopic 3D images.

The expected benefits for the user are indirect, but use of Abys® Medical Cysart® 4H allows for:

- Better visibility and manipulation of 3D data in mixed reality than in 2D, making the surgical procedure more reliable
- Accessibility and manipulation of planning assistance file data without leaving the sterile field, reducing the gap between the planning and the actual operation, and reducing user workload
- Accessibility to online data if needed improving decision making during the operation

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 Cysart® 4H is not intended for use with data not coming from the associate planification tool specified in the instruction for use.

5. Types of users

Abys® Medical Cysart® 4H should be used by a clinician with appropriate clinical judgement. For intraoperative assistance, the operating room nurse may install and initiate display for surgeon to avoid sterility disruptions. In case of clinical collaboration, the device may be used by medical practitioners from other specialties. Device can also be used by an Abys® Medical employee, member of the user support team.

The software must be used independently under the control of the user.

6. Side effect

The use of Microsoft® HoloLens 2 may obstruct user's view and may cause distraction. Transparency or moving occluding objects may easily solve this inconvenience.
Use of the Microsoft® HoloLens 2 may cause kinetosis to the user, especially in prolonged use and in case of loss of fluidity in the application.
Usability tests showed that a short time lapse (5-10 minutes) may be needed to accustom for some new users.
Prolonged use or neighborhood with a heat source may increase the temperature of the Microsoft® HoloLens 2 and disturb the user. Caution: for temperature above proper functioning, Microsoft® HoloLens 2 automatically switches off.

7. Residual risks and associated recommendations

- Risk of inappropriate treatment: in cases of clinical collaboration, the user should monitor and validate changes made by peers on the shared PAFs prior to surgery. The user should not open a PAF that was not validated
- Risk of data loss: for data security, surgeon is responsible for the Microsoft® HoloLens 2 and those who have access to it
- Risk of contamination: the user should not touch the Microsoft® HoloLens 2 once the sterile gloves have been put on. Installation and removal of the Microsoft® HoloLens 2 by an assistant or an operating room nurse who is out of the sterile field should be done without touching any sterile part of the user. This operation should not be performed in proximity of the patient in order to avoid any risk of contact of Microsoft® HoloLens 2 or its parts with the operating field or the patient
- Risk of inappropriate treatment: the user must ensure that the correct patient's planning folder is opened on Abys® Medical Cysart® 4H. The user should check his/her PAF data just prior to using Abys® Medical Cysart® 4H
- Risk of inappropriate treatment: the virtual objects might mask the elements in the background and the surgical acts carried out. The user must ensure that proper visibility is established and maintained by positioning virtual objects over a clear background that does not contain the patient, or any medical imaging display
- Risk of overheating: the user should avoid exposing the Microsoft® HoloLens 2 to heat while using Abys® Medical Cysart® 4H; If the Microsoft® HoloLens 2 overheats, it may automatically switch off, in which case the user should allow the Microsoft® HoloLens

2 to cool down before use

- Risk of data loss: the user must make sure to systematically disconnect from Abys® Medical Cysart® 4H at the end of a use session
- Risk of discomfort in use: during the selection phase of patient files or PAFs, in the case of a number of files greater than 6, the application may slow down. The framerate can go down to 30 frames per second at a minimum which may cause kinetosis in prolonged use. To ensure fluidity and avoid discomfort, it is recommended that the user select a PAF from a patient file menu
- Risk of eye fatigue or dizziness of the user: the user must use the device for a maximum duration of 40 minutes at a time
- Risk of inconvenience in use: in bright environment, documents, images, and 3D objects may be less visible or readable. The user should adjust objects brightness according to ambient environment lighting. For better visibility and readability, all virtual objects should not be placed and consulted under the scialytic
- Risk of perception of color separation effect in some virtual objects displayed close to the user. To avoid this effect, the user must place the virtual object further from him/her
- Risk of distraction during the surgical act. The user must not use Cysart® 4H when he/she actively operates on the patient
- Risk of inconvenience in use: Microsoft® HoloLens 2 display presents significant luminance nonuniformity over the field of view. For better comfort of use when consulting documents, it is recommended to put documents and images in the upper-middle part of the field of view
- Risk of inconvenience in use: Microsoft® HoloLens 2 display presents significant geometrical distortion over the field of view. For better comfort of use when consulting documents, it is recommended to put documents and images in the upper-middle part of the field of view

8. Precautions of use

8.1. Prior to sterile scrubbing

- Before each use, and prior to sterile scrubbing the user must fit the device to his/her head using straps and adjustment wheel. From that point on, all fitting and adjustment must be done by a non-sterile surgical team member
- Before each use, and prior to sterile scrubbing the user must adjust the device to his/her vision, following the calibration procedure bellow:
  1. Open the Start menu of the Microsoft® HoloLens 2
  2. Select All Apps
  3. Select Settings, and then select System > Calibration > Run eye calibration

Note: The user can keep his/her corrective glasses or contact lenses during use

8.2. In the sterile field

- Before each use, the user should follow the following procedure for preparing his/her session in Cysart® 4H:

  Before starting the surgery and preparing virtual objects from Cysart® 4H, the user must open the display quality test pattern available in the user menu of Cysart® 4H and check the visibility points:
  - "You should be able to read the mention "QUALITY CONTROL" inside the 3 bottom rectangles."
  - "You should be able to distinguish the grayscale in the sidebands, without artifacts."
  - "You should be able to distinguish the 19 grayscale squares around the perimeter of the central part of the pattern"
- The user should follow the following procedure for preparing and positioning the virtual objects from Cysart® 4H:

  Before starting the surgery, the virtual objects must be

positioned at a point in the operating room where they will not distract the surgeon during the surgery. The virtual objects can be positioned similar to a secondary surgical rack usually available for the surgeon, surrounding him/her (where surgical instruments are placed for instance).

When the surgeon deems it necessary to consult 3D objects, he/she can only consult it when he/she doesn't actively operate on the patient

- Intraoperatively, the user should ensure that proper visibility is established and maintained by positioning virtual objects over a clear background that does not contain a light source
- Intraoperatively, the user should ensure that proper visibility is established and maintained by positioning virtual objects over a clear background that does not contain any medical imaging display
- Intraoperatively, the user should ensure that proper visibility is established and maintained by positioning virtual objects over a clear background that does not contain the patient

8.3. General use

- The Microsoft® HoloLens 2 must be used in accordance with the Microsoft® instructions. These instructions supplied with the Microsoft® HoloLens 2 should be consulted before the first use of the Cysart® 4H
- The Microsoft® HoloLens 2 must be cleaned in accordance with the Microsoft® HoloLens 2 instructions for use (use only a 70% isopropyl alcohol solution). They must not be subjected to a sterilization process.
- Microsoft® HoloLens 2 should be used according to Microsoft® precautions of use described in Microsoft® HoloLens 2 instructions for use
- Abys® Medical Cysart® 4H must not be installed on any device other than the Microsoft® HoloLens 2
- No other application should be opened on Microsoft® HoloLens 2 at the same time as Abys® Medical Cysart® 4H
- The user must ensure that he/she has a good quality internet connection with a speed of at least 50 Mbp/s before connecting to Abys® Medical Cysart® 4H and during the whole use of the platform to ensure fluidity and prevent from latency
- The user must carefully read all the warnings and errors that appear on the Microsoft® HoloLens 2, some may be blocking without user action
- The user should make sure the Microsoft® HoloLens 2 battery is charged before use and should monitor the battery level of the Microsoft® HoloLens 2 during use
- The user must ensure that the date and time are correctly set on the Microsoft® HoloLens 2
- The vocal control is intended to be used in an environment with moderate noise. The use of voice commands is effective in a noise environment up to 60dB, and therefore voice commands should not be used when surgical instruments with higher noise levels are in operation.

9. Essential information

Data safety and cybersecurity

Abys® Medical Cysart® 4H complies with the best practices in terms of security and data protection.

Abys® Medical Cysart® 4H complies with the EN 12251 standard on the security of healthcare user identification.

- The user shall not disclose his/her login details to any third party
- The user must ensure privacy during login to avoid password theft

All personal and sensitive data in the databases are anonymized.

Abys® Medical Cysart® 4H does not store personal data and documents containing personal data after logging out of the application.

- Logging in to Abys® Medical Cysart® 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 and Cysart® 4H, databases are stored on a web host with Healthcare Data Hosting (HDS) certification. 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.

Offline mode.

Abys® Medical Cysart® 4H allows the user to view and interact with data if needed, without internet connection: once the application is loaded, the Microsoft® HoloLens 2 can go into offline mode.

However, modifications made on Abys® Medical Cysware® 4H web platform since the device was disconnected from the internet are not available in offline mode.

Displaying data from a PAF

Abys® Medical Cysart® 4H provides access to all data prepared on the Abys® Medical Cysware® 4H web platform. This data includes:

- DICOMs and their metadata
- Annotations
- Labels attached to the DICOM
- Documents of type: png, jpg or pdf

Abys® Medical Cysart® 4H allows to display stereoscopic 3D images corresponding to 3D data at 1:1 scale.

Note: Stereoscopic images of CT scan are designated by the terms "3D" or "3D Objects" in the application and in the product documentation.

Autonomy of Microsoft® **HoloLens 2**

The autonomy of Microsoft® HoloLens 2 is not guaranteed for a use lasting more than 1h30 without sharing the video stream and 45 minutes with sharing the video stream to a workstation connected to the same network. These durations are valid for Microsoft® HoloLens 2 charged to 100% for new batteries at the start of the application.

Cautions

- Abys® Medical Cysart® 4H is not intended for superimposition or registration of the medical image information to the live patient
- Abys® Medical Cysart® 4H is not intended for use in the operating room during a surgical gesture implying patient's anatomy manipulation, surgical instruments manipulation, implantable medical device positioning or fixing or any other surgical operation involving direct or indirect contact with the patient lying on the operating table
- The user must not place the virtual objects displayed in Abys® Medical Cysart® 4H between him/her and the patient to not obstruct the surgical field
- Abys® Medical Cysart® 4H is not a primary viewing system**,** is not a substitute for the use of other monitors already present in the operating room for procedure purpose or diagnostic, and must not interfere with their use
- The user should not use vocal commands when a surgical instrument is operating (noise level of 60dB or more)
- The user must not use Microsoft® HoloLens 2 if they are partially or totally damaged and/or if all moving parts are not properly fixed
- Only patients who meet the criteria detailed in section 3 "Indications" may be selected. Patients meeting the criteria detailed in section 4 "Contraindications" should not be selected
- The device should be kept at least 15 cm away from a pacemaker to avoid any potential risk of interference with the pacemaker. When using with a medical device other than a pacemaker, consult the device manufacturer or your physician about the use of other electronic devices near your medical device
- Microsoft® HoloLens 2 should not be used in contact with

another device or heating areas
- Abys® Medical Cysart® 4H does not replace user's medical decision
- Abys® Medical Cysart® 4H should not be used if any of the test pattern quality control points are not met

Complaints about the medical device

Any healthcare professional who has a complaint regarding the quality of this medical device, its identity, reliability, safety, efficacy, or performance must 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.

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 contact@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.

Install, maintenance/updates and decommissioning:

No install maintenance or decommissioning procedures are needed for users.

Cysart® 4H is a software under responsibility of Abys® Medical ensuring all operations. Users will be noticed for updates and related timelapses of unavailability of platform if needed.

Warnings

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

10. Instructions for use revision date

Reference and version:
IFU-005 V8
Date of revision: 2022-12-29