SURGIVERSE

Digital Cockpit

User Guide Surgiverse®

Digital Cockpit / CYSART 4H

English version for USA only

www.surgiverse.ai

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The user should consult the instructions for use before using the Abys® Medical Surgiverse® Digital Cockpit mixed reality application (referred to below as Surgiverse® Digital Cockpit).

In the following document, Abys® Medical Cysart® 4H is also called Surgiverse® Digital Cockpit. Both denominations refer to the same product

1 Description

Surgiverse platform

Surgiverse® is a collaborative platform gathering all the elements used to prepare an operation in a Planning Assistance Files (PAF) and making them available in augmented reality glasses through Surgiverse® Digital Cockpit. A PAF is related to a patient. It contains the analysis details performed on 3D models generated from DICOM files (CTScan) and other documents.

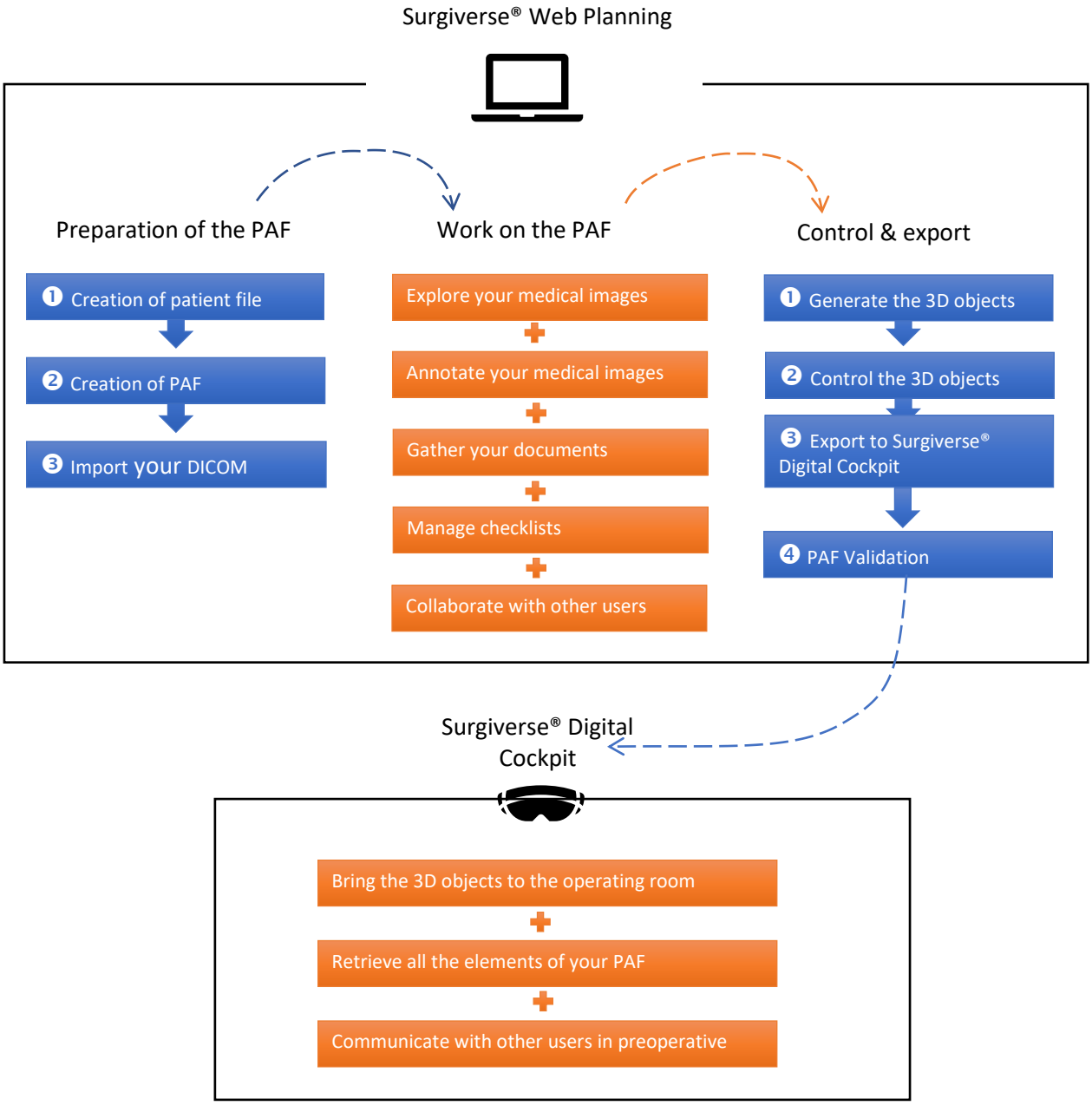


Figure 1: Surgiverse platform

Surgiverse® Digital Cockpit

The Abys® Medical Surgiverse® Digital Cockpit mixed reality application is a medical device designed and intended for use in office room and in operating room to display and manipulate all the documents and 3D images of a planning assistance file (PAF) generated from the Abys® Medical Surgiverse® Web Planning web platform (referred to below as Surgiverse® Web Planning), and to communicate with Surgiverse® Web Planning users. To be viewed and manipulated in Surgiverse® Digital Cockpit, documents must have been loaded into a Planning Assistance File (PAF). The 3D images of the DICOMs must have been loaded in a PAF and exported from Surgiverse® Web Planning (see Surgiverse® Web Planning User Guide).

2 Read before use

Surgiverse® Digital Cockpit has been designed to run on the Microsoft® HoloLens® 2 display device.

When the Microsoft® HoloLens® 2 are not in use, the flip-up display front panel can be raised by an operating room nurse (who is outside the sterile field) to completely clear the surgeon's vision. The Microsoft® HoloLens® 2 can also be completely removed from the surgeon's head under the same conditions.

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

Precautions of use

⚠ Precaution of use: Abys® Medical Surgiverse® Digital Cockpit must not be installed on any device other than the Microsoft® HoloLens® 2.

⚠ Precaution of 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 Surgiverse® Digital Cockpit.

⚠ Precaution of use: No other application should be opened on Microsoft® HoloLens® 2 at the same time as Surgiverse® Digital Cockpit.

⚠ Precaution of use: 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 Surgiverse® Digital Cockpit and during the whole use of the platform to ensure fluidity and prevent from latency.

⚠ Precaution of use: 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.

⚠ Precaution of use: The user must carefully read all the warnings and errors that appear on the Microsoft® HoloLens® 2, some may be blocking without user action.

⚠ Precaution of use: 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.

⚠ Precaution of use: 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.

⚠ Precaution of use: The user must ensure that the date and time are correctly set on the Microsoft® HoloLens® 2.

⚠ Precaution of use: Before each use, and prior to sterile scrubbing the user must run mandatory calibration and verification test features available in the Microsoft® HoloLens® 2 settings menu or in the application launcher:

- Eye-calibration (available in the Microsoft® HoloLens® 2 settings menu)
- Display quality test pattern, check the visibility points:
  - "You should be able to read the mention "QUALITY CONTROL" inside the 3 bottom rectangles." (see 1 in Figure 2)
  - "You should be able to distinguish the grayscale in the sidebands, without artifacts." (see 2 in Figure 2)
  - "You should be able to distinguish the 19 grayscale squares around the perimeter of the central part of the pattern" (see 3 in Figure 2)

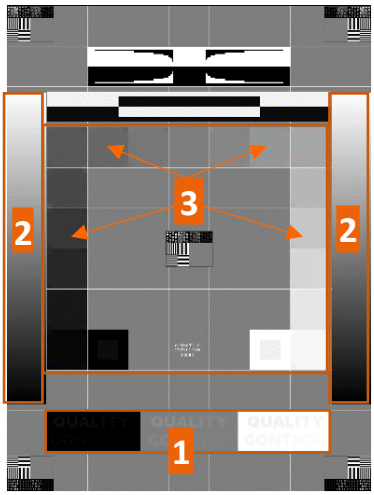


Figure 2: Display Quality Test Pattern

- Sound calibration test (sound quality test and microphone test)

⚠ Precaution of use: The user shall not disclose his/her login details to any third party.

⚠ Precaution of use: The user must ensure privacy during login to avoid password theft.

⚠ Precaution of use: For security reasons, the user is automatically logged out of his/her account if it is not used during 15 minutes.

⚠ The user should not connect to a public Wi-Fi network without using a virtual private network (VPN).

⚠ Precaution of use: The user should follow the following procedure for preparing and positioning the virtual objects from Surgiverse® Digital Cockpit:
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).

⚠ Precaution of use: When the surgeon deems it necessary to consult 3D object, he/she can only consult it when he/she doesn't actively operate on the patient.

⚠ Precaution of use: 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.

⚠ Precaution of use: 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.

⚠ Precaution of use: 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.

⚠ Precaution of use: When starting communication, the user should ensure that all attendees to the call are expected to participate.

Caution

⚠ Caution: 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.

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit should not be used if any of the test pattern quality control points are not met.

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit 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.

⚠ Caution: The user must not place the virtual objects displayed in Abys® Medical Surgiverse® Digital Cockpit between him/her and the patient to not obstruct the surgical field.

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit is not intended for superimposition or registration of the medical image information to the live patient.

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit 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.

⚠ Caution: 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.

⚠ Caution: Microsoft® HoloLens® 2 should not be used in contact with another device or heating areas.

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit does not replace user's medical decision.

⚠ Caution: For temperature above proper functioning, Microsoft® HoloLens® 2 automatically switches off.

⚠ Caution: During communication with Abys® Medical Surgiverse® Web Planning users, the Abys® Medical Surgiverse® Digital Cockpit user point of view including virtual objects may be shared and visible for all attendees to the call.

⚠ Caution: During communication with Abys® Medical Surgiverse® Web Planning users, captures of the shared Abys® Medical Surgiverse® Digital Cockpit user point of view including virtual objects may be saved by any attendee to the call.

⚠ Caution: During communication with Abys® Medical Surgiverse® Web Planning users, the call may be recorded, including the Abys® Medical Surgiverse® Digital Cockpit user point of view including virtual objects and the conversations.

⚠ Caution: The communication with Abys® Medical Surgiverse® Web Planning users is for preoperative use only.

⚠ Caution: The user should always check the scale and orientation of the used 3D objects. Opening several 3D objects may deteriorate the fluidity of the display.

3 Before starting the application

3.1 Mandatory calibration and tests

As mentioned in the precautions of use, mandatory calibration and test features should be run before starting a session in Surgiverse® Digital Cockpit. Calibration and test features are available either in the Microsoft® HoloLens® 2 settings menu or in the launcher menu.

Eye-calibration is available in the Microsoft® HoloLens® 2 settings menu : use the start gesture according to Microsoft® instructions to access the Microsoft® HoloLens® 2 settings menu.

Calibration application is available at the following location: System > Calibration > Eye Calibration > Run eye calibration

Note: when Surgiverse® Digital Cockpit is launched by default, if eye-calibration has not been completed by a new user, the Microsoft® HoloLens® 2 shall detect it automatically and a popup shall be displayed proposing to launch the calibration. In this case, it is mandatory to complete calibration or some Surgiverse® Digital Cockpit features may not run properly.

3.2 Optional settings features

In addition to mandatory calibration and test features, the launcher menu provides access to optional settings features.

For users who never used Microsoft® HoloLens® 2, the *HoloLens Tips* discovery application is available in the Microsoft® HoloLens® 2 start menu: use the start gesture according to Microsoft® instructions to access the Microsoft® HoloLens® 2 start menu.

The launcher menu provides access to following settings features:

- Wi-Fi settings

3.3 Subscription

To access the features of Surgiverse® Digital Cockpit, the user must have a valid and active subscription on Surgiverse®.

4 Overview of the Surgiverse® Digital Cockpit interface

4.1 Launcher menu

The launcher menu is divided into two parts:

- Mandatory calibration and test features:
  - Display quality test (1 in Figure 3)
  - Sound calibration test (2 in Figure 3)
- Optional features:
  - Wi-Fi settings (3 in Figure 3)
  - Access to user guide (7 in Figure 3)
  - Access to terms of use and legal notice (8 in Figure 3)

Figure 4: Launcher menu

Figure 3: Launcher menu

The user can choose preferred language by clicking on corresponding button (4 in Figure 3).

To start using Surgiverse ® Digital Cockpit, click on “Start Surgiverse Digital Cockpit” (5 in Figure 3).

To exit the application, click on “Exit” (6 in Figure 3).

4.2 Connection menu

The tab “Credentials” (1 in Figure 4) enables the user to connect to Surgiverse® Digital Cockpit with the credentials used on Surgiverse® Web Planning (2 in Figure 4).

The show/hide characters button (3 in Figure 4) enables to display or hide password characters entered.

The checkbox “Remember me” (4 in Figure 4) enables the user to save his username in text input field.

The “Login” button (5 in Figure 4) sends the login request and checks credentials validity.

Software version in indicated on the bottom of the connection menu (6 in Figure 4).

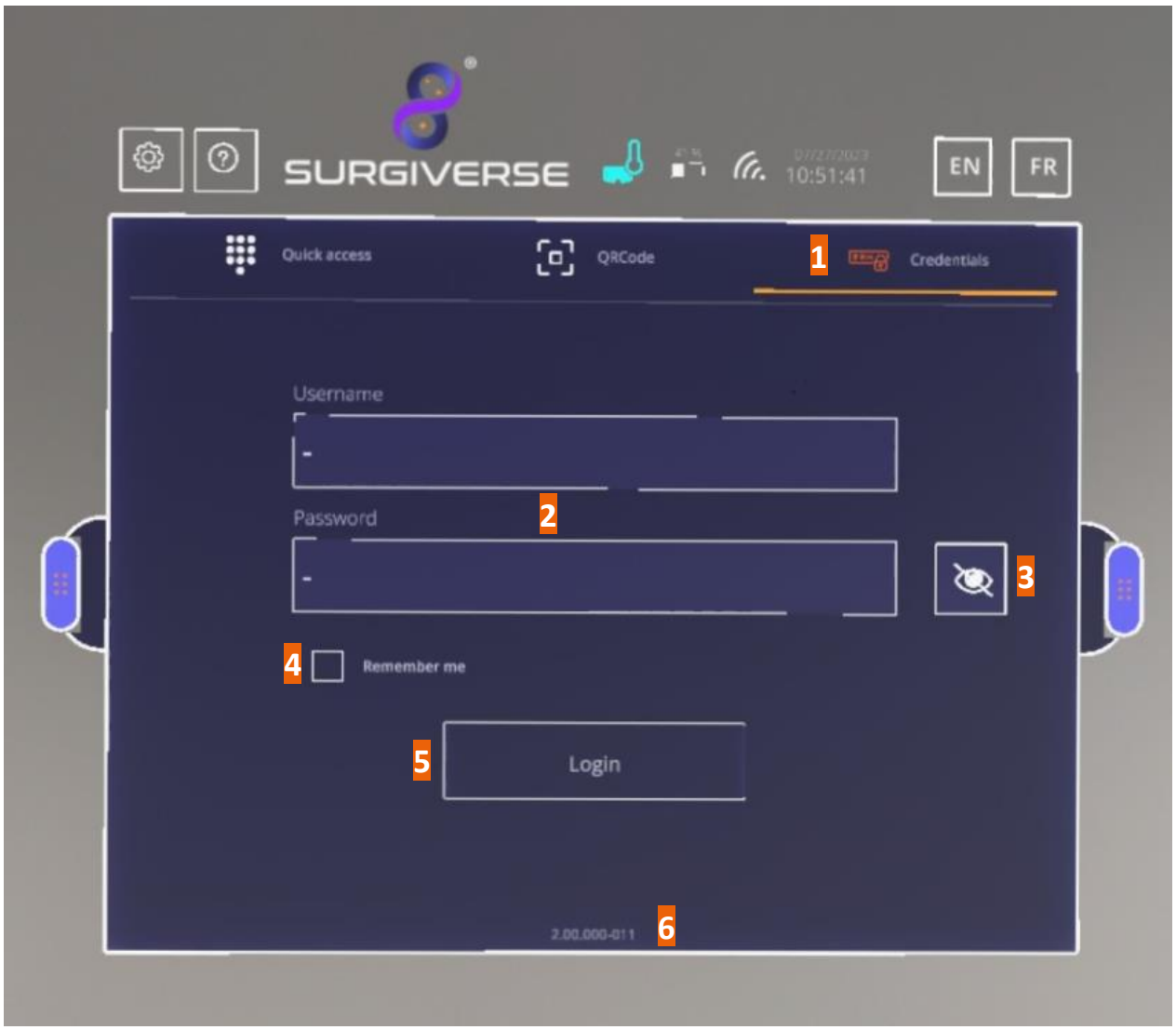


Figure 5: Connection menu - connect with login & password

The tab “Connect with QRCode” (1 in Figure 5) enables the user to automatically connect to Surgiverse® Digital Cockpit by flashing an appropriate QR code provided on Surgiverse® Web Planning.

A crosshair (2 in Figure 5) is displayed in user’s field of view to aim the QR code displayed on Surgiverse® Web Planning.

Figure 6: Connection menu - connect with QR code

The tab “Connect with Quick access” (1 in Figure 6) enables the user to connect to Surgiverse® Digital Cockpit with a PIN code created during the first connection on this HoloLens2 device.

A tab (2 in Figure 6) lists the IDs of users who have set up PIN codes on this HoloLens2 device.

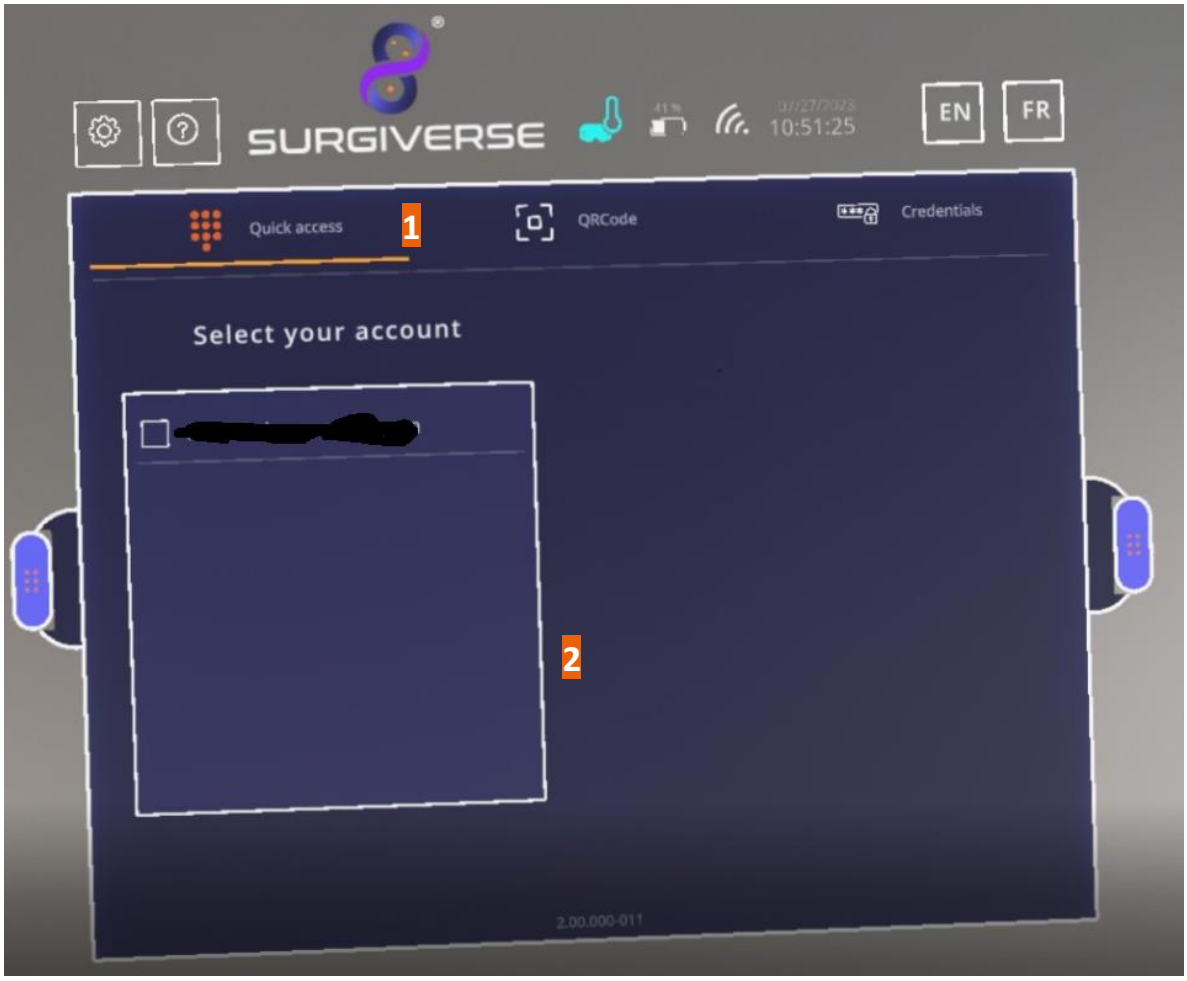


Figure 7: Connection menu - connect with PIN code.

Creation of Pin Code:

To skip this step, click on “Skip” (1 In Figure 7).

To create a PIN code, enter and confirm your 6-digits code in fields (2 In Figure 7).

Figure 7: Connection menu – creating a PIN code

4.3 Information banner

On the top part of the interface, an information banner provides information about the current session.

Figure 8: Information banner

Settings button (1 in Figure 8) enables to open Settings menu.

About button (2 in Figure 8) enables to open About menu.

Notification button (3 in Figure 8) enables to open Notification menu.

Account reminder (4 in Figure 8) indicates the user account connected in the current session.

Temperature indicator (5 in Figure 6) displays the Microsoft® HoloLens® 2 temperature level: four levels of temperature are rated in the application. When the temperature reaches the highest level, corresponding to the critical operating temperature, the icon is displayed in red color, and a notification is sent to the user.

⚠ Caution: For temperature above proper functioning, Microsoft® HoloLens® 2 automatically switches off.

Battery level indicator (6 in Figure 8) displays the Microsoft® HoloLens® 2 battery level (in %). When the level drops to 25% or less, the icon is displayed in red color. With a full battery level, Surgiverse® Digital Cockpit should work during at least 1h30.

Network connection indicator (7 in Figure 8) indicates if the current session is connected to the network. In case of disconnection, icon appears crossed out.

Date and time indicator (8 in Figure 8) displays the time and date adjusted to the time zone set in the Microsoft® HoloLens® 2.

4.4 Home menu

Once connected to Surgiverse® Digital Cockpit, the user can reach the home menu and access to Planning Assistance Files (PAF) and to patients' files.

Information banner is still present.

The Files tab (1 in Figure 9) provides access to a list of PAFs created by or shared with the user (2 in Figure 9).

A text input field (3 in Figure 9) enables to enter searching criterion in the list and automatically opens virtual keyboard to enter characters.

In the list, PAFs can be sorted by each table entry.

The "Show my files only" button (4 in Figure 9) enable to filter PAFs created by the user only.

PAFs status indicates:

Validated PAFs		(5 in Figure 9).
PAFs in edition		(6 in Figure 9).

Note: only validated PAFs can be opened from this list.

If the list covers several pages, the arrow buttons on the side of the panel (7 in Figure 9) enable to scroll the pages.

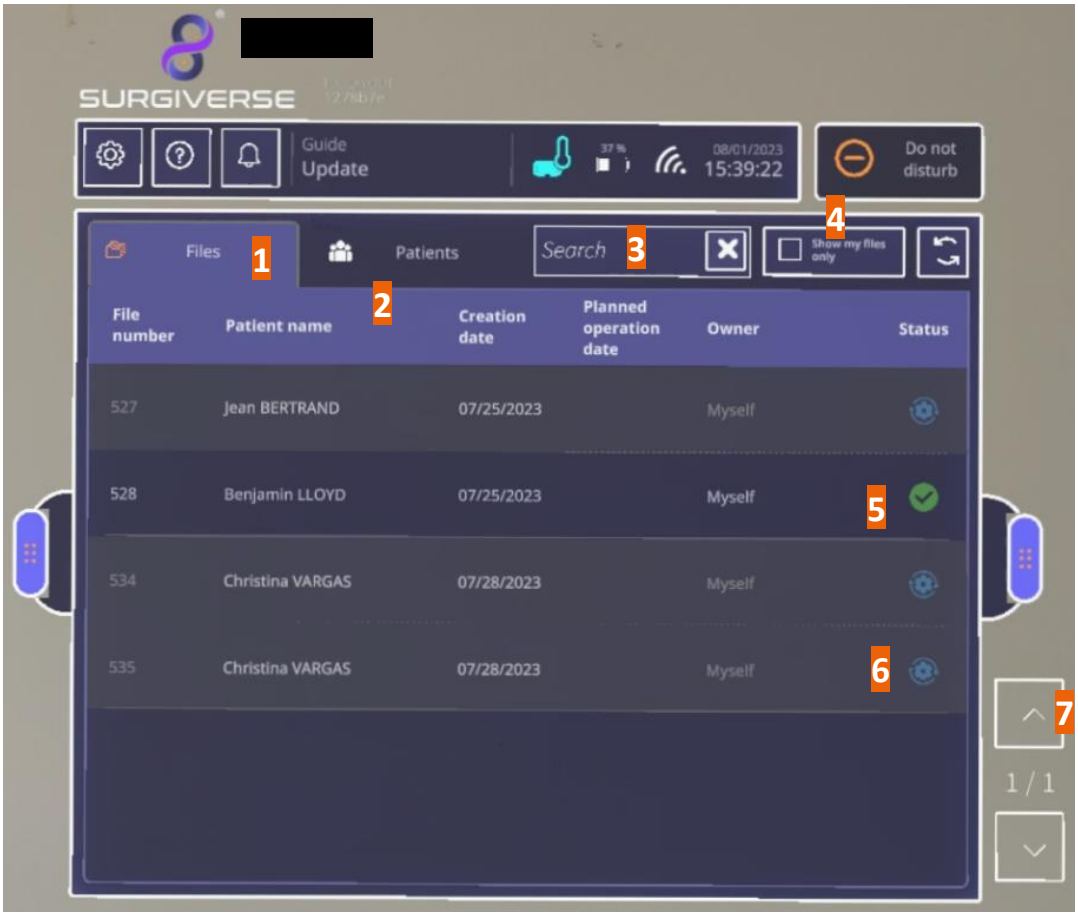


Figure 9: Home menu - PAFs tab

The Patients tab (1 in Figure 10) provides access to a list of patient files created by the user. Once a patient is selected, the user accesses to the PAFs related to this patient.

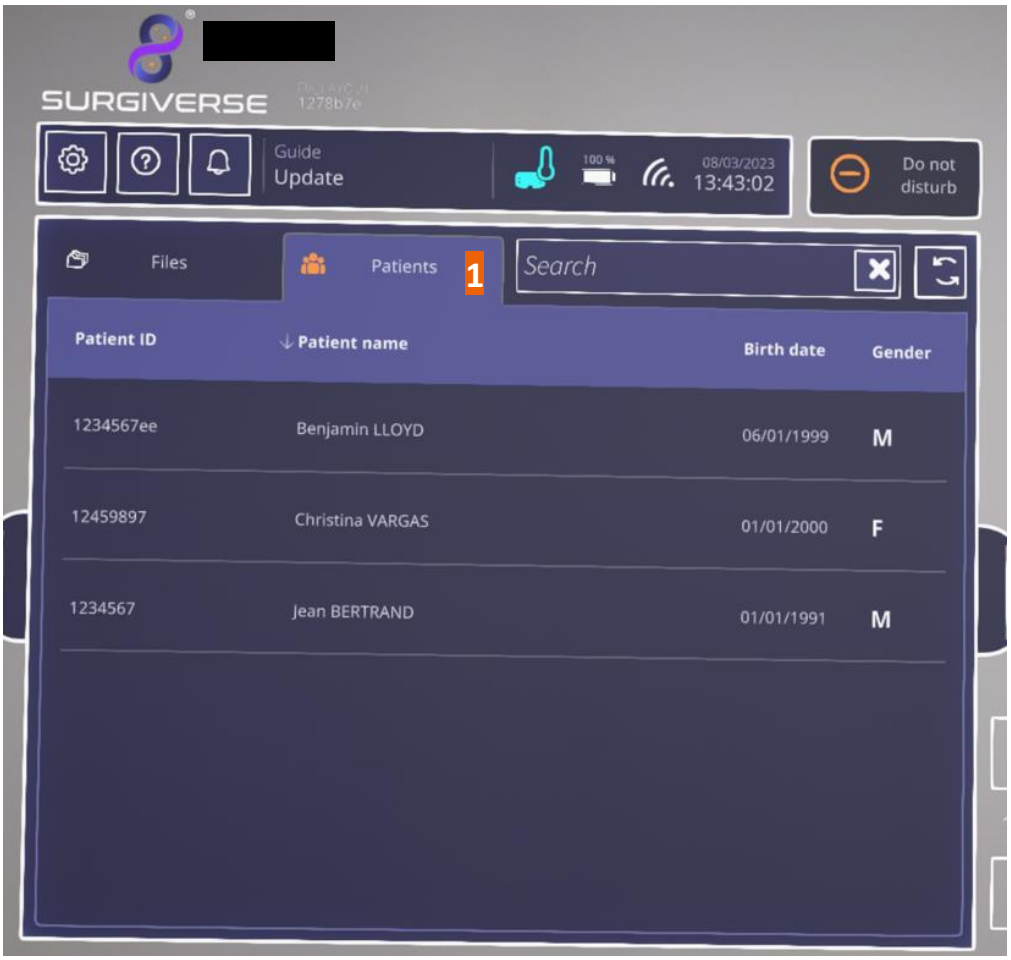


Figure 10: Home menu - Patients tab

4.5 Main menu

Once a PAF is opened, the Main menu is displayed.

Information banner is still present.

On the bread crumb on the top of the panel, the current opened PAF is indicated with its ID (1 in Figure 11). The home button (2 in Figure 11) enables to exit the current PAF and go back to the home menu and PAFs and patients lists.

On the sides of the panel. Two handles (3 in Figure 11) enable to grab and move the panel. They can be caught directly with thumb and index or with the lasso.

Attached to the panel (as long as they are wired to the panel, they should move with it), two spawn points (4 in Figure 11) materialize respectively the appearance areas of documents and

3D objects when they are opened. Each spawn point can be grabbed and moved independently from the panel (the wire then disappears)

On the left side of the panel, several tabs (5 in Figure 11) provide access to contents of the PAF and specific features:

- Information: displays main data of the current PAF when filled on Surgiverse® Web Planning form (6 in Figure 11)
- Notes: displays notepad created on Surgiverse® Web Planning
- Checklists: displays clickable/checkable checklists created on Surgiverse® Web Planning
- Measurements: displays measurements taken on Surgiverse® Web Planning
- Documents: provides access to the list of documents uploaded on Surgiverse® Web Planning
- 3D: provides access to the meshes exported from the series on Surgiverse® Web Planning
- Communication: provides access to the communication feature.

On the bottom of the panel, “Open all” button (7 in Figure 11) enables to open all contents of the PAF (Documents, 3D) on their respective spawn points.

“Reset all” button (8 in Figure 11) enables to reset all opened contents of the PAF (in position, orientation, and scale) on their respective spawn points when they have been moved, or rescaled.

Capture buttons (9 in Figure 11) enable to activate respectively audio recording, snapshot mode, and video recording features.

“Do not disturb” button (10 in Figure 11) enables to activate the “Do not disturb” mode.

Figure 11: Main menu

4.6 Documents tab

The documents tab displays a list of documents uploaded to the PAF on Surgiverse® Web Planning.

Documents can be of several types (1 in Figure 12): images, pdf documents, sounds (audio records), video (video records).

Note: as Surgiverse® Digital Cockpit does not provide any audio or video player, sounds and videos cannot be opened in Surgiverse® Digital Cockpit and appear in the list only as an indication. Buttons are not clickables for these types of documents.

The "Hide unavailable documents" button (2 in Figure 12) enables to display available documents only in the list.

Searching tool (3 in Figure 12) is also available in the documents list.

Clicking on an element in the list (4 in Figure 12) opens it on the Documents spawn point. Clicking again on the element in the list closes the document.

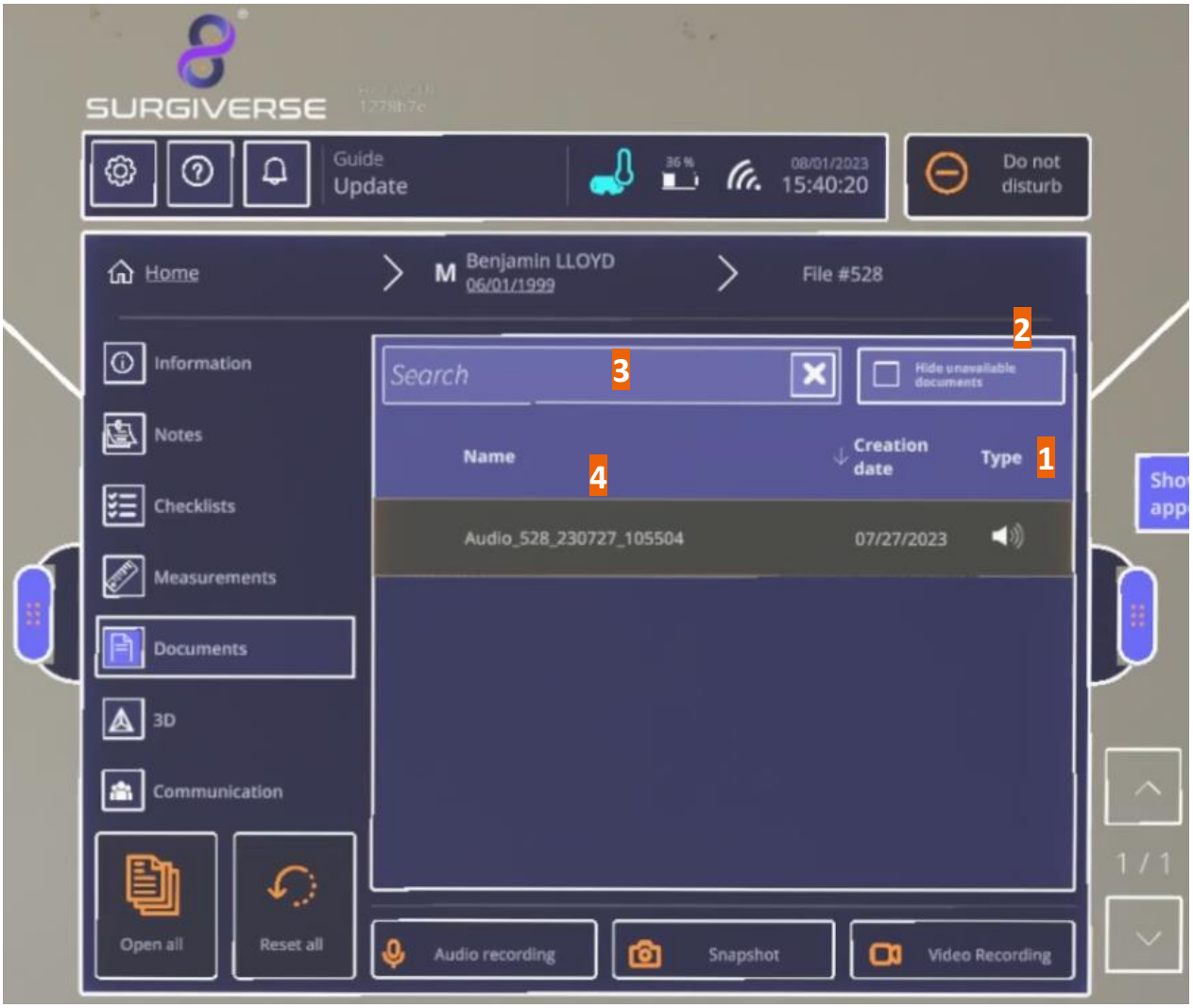


Figure 12: Documents tab

4.7 3D tab

The 3D tab displays a list of 3D objects exported from the series on Surgiverse® Web Planning.

Clicking on an element in the list (1 in Figure 13) opens it on the 3D spawn point. Clicking again on the element in the list closes the 3D object.

A brightness adjustment slider (2 in Figure 13) enables to adjust the brightness of all 3D objects in the scene.

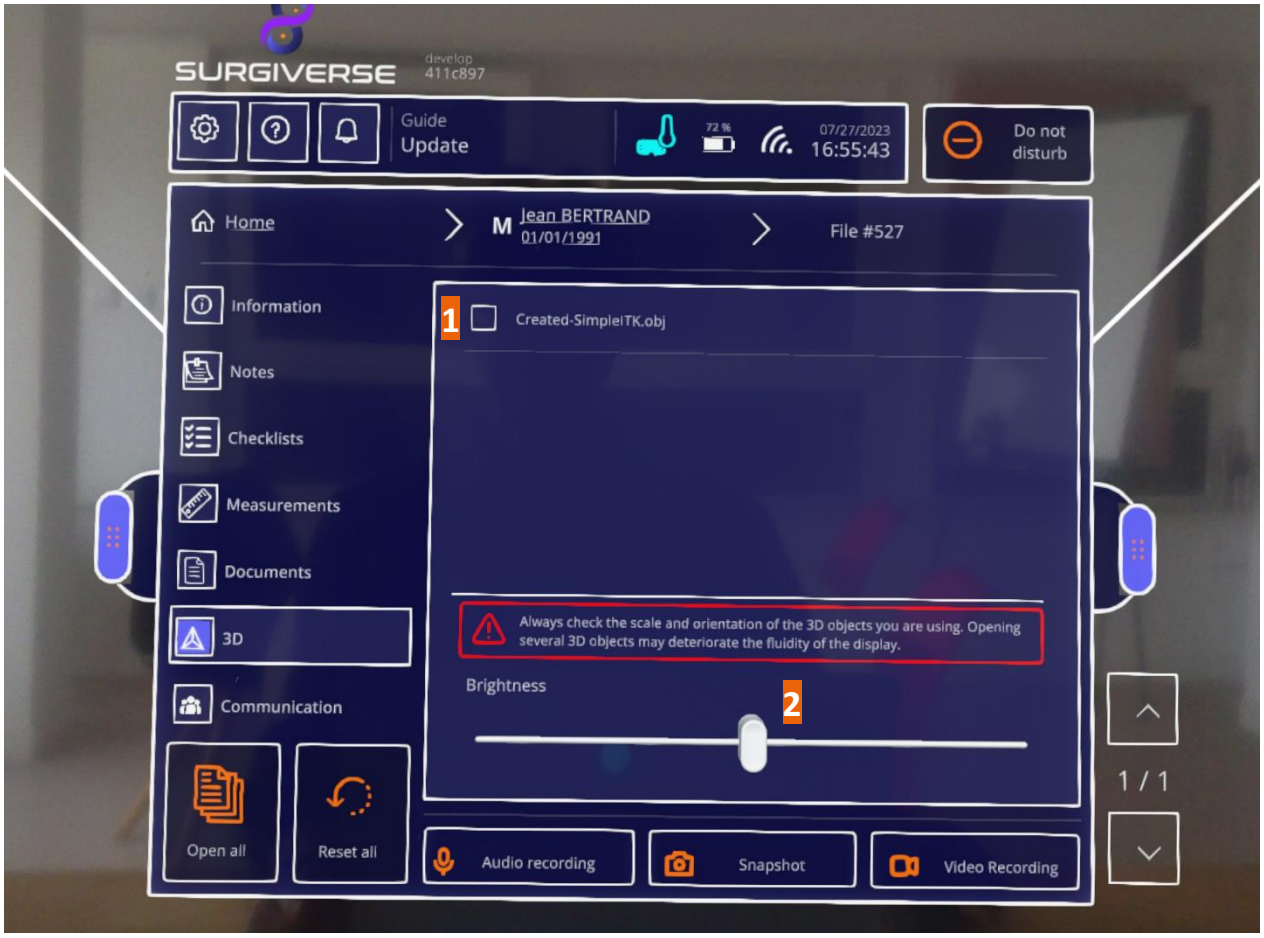


Figure 13: 3D tab

4.8 Settings menu

Clicking on the settings button (1 in Figure 14) always available in the information banner opens the Settings menu.

The following settings and features are available:

- Display quality test (2 in Figure 14) also available in the launcher menu
- Sound calibration test (3 in Figure 14) also available in the launcher menu
- Reset appearance zones button (4 in Figure 14) enables to reset spawn points position on either side of the panel and wired to it, when they have been moved by the user
- Language setting buttons (5 in Figure 14) also available in the launcher menu, enable to choose preferred language
- "Lay-out mode activation" toggle (6 in Figure 14) activates Lay-out mode
- Lay-out settings button (7 in Figure 14) opens layouts menu, enabling to delete existing layouts saved in memory
- "First use mode" toggle (8 in Figure 14) activates First use mode
- When First use mode is activated, "Always visible" toggle (9 in Figure 14) displays all available tooltips of each current opened menu
- "Display virtual hands" toggle (10 in Figure 14) displays or hide virtual hands as detected by the Microsoft HoloLens® 2
- "Send statistics" toggle (11 in Figure 14) activates log recording for support and maintenance purposes
- "Logout" button (12 in Figure 14) also available in the launcher menu, enables to logout session
- "Exit" button (13 in Figure 14) also available in the launcher menu, enables to exit Surgiverse® Digital Cockpit

Figure 14 : Settings menu

4.9 About menu

Clicking on the settings button (1 in Figure 15) always available in the information banner opens the About menu and provides access to product documentation.

Product labeling (2 in Figure 15) is permanently displayed in the menu.

Dedicated buttons enable to open respectively:

- The Instructions for use (IFU) (3 in Figure 15)

Figure 15: About menu

4.10 3D contextual menu

When a 3D object is opened, clicking on the 3D settings button (1 in Figure 16) displays a contextual menu dedicated to the 3D object.

This menu provides access to:

- Display mode setting (2 in Figure 16) enabling to display 3D object with a standard or transparent material

- Measurements display/hide in 3D on the object (3 in Figure 16), provided some measurements have been made on the corresponding series and exported in Surgiverse® Web Planning, they should appear in a list
- Labels display/hide in 3D on the object (4 in Figure 16), provided some labels have been created on the corresponding series and exported in Surgiverse® Web Planning, they should appear in a list
- Scale modification or lock at 1:1 (5 in Figure 16)

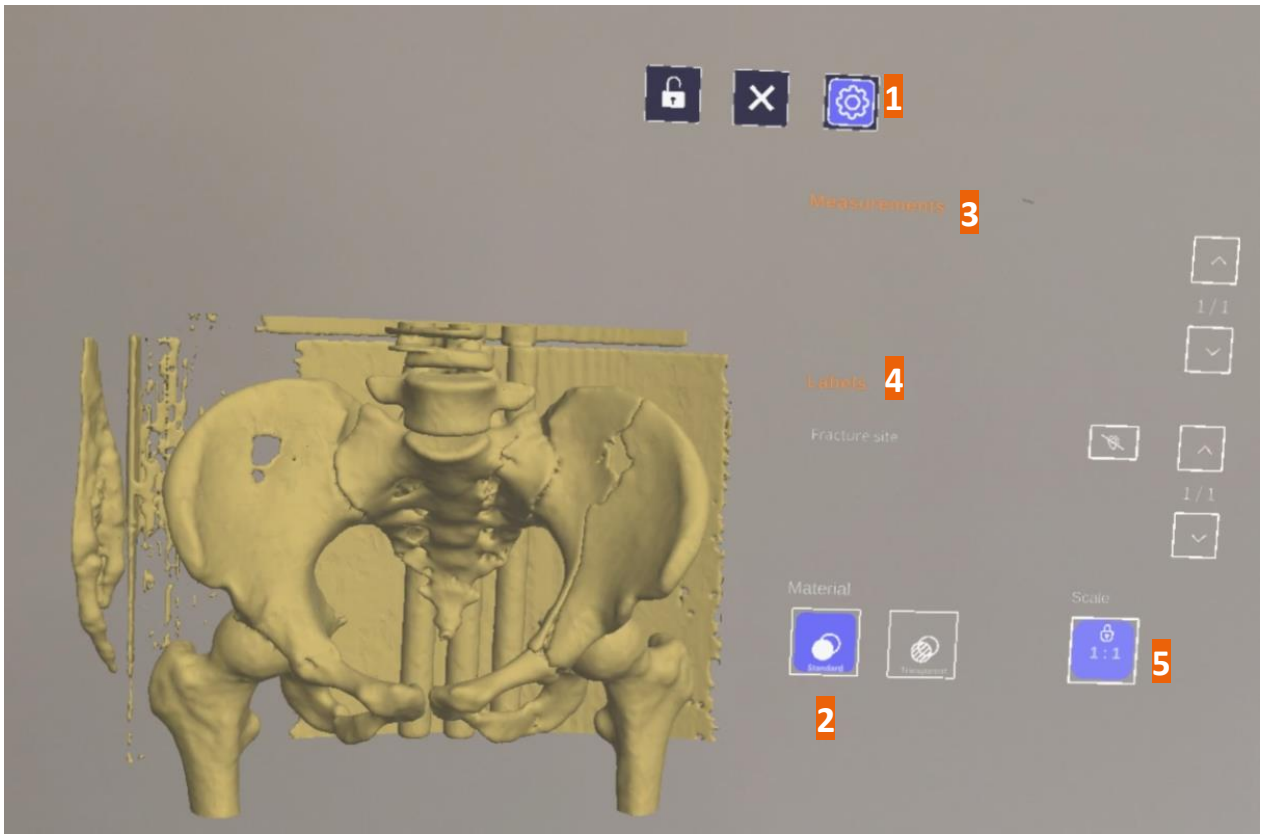


Figure 16: 3D contextual menu

4.11 Communication tab

Communication tab provides access to communication and sharing features with contacts who can be members of the user's team, or other users with a shared on the current PAF.

A list of contacts (1 in Figure 17) shows contacts ID, rights on the current PAF, and communication status:

- = Connected/Available

- = In communication
- = Not available
- = Disconnected

Clicking on one or several available contacts enable to select them and to initiate a call.

Clicking on the start call button (2 in Figure 17) enables to start a call.

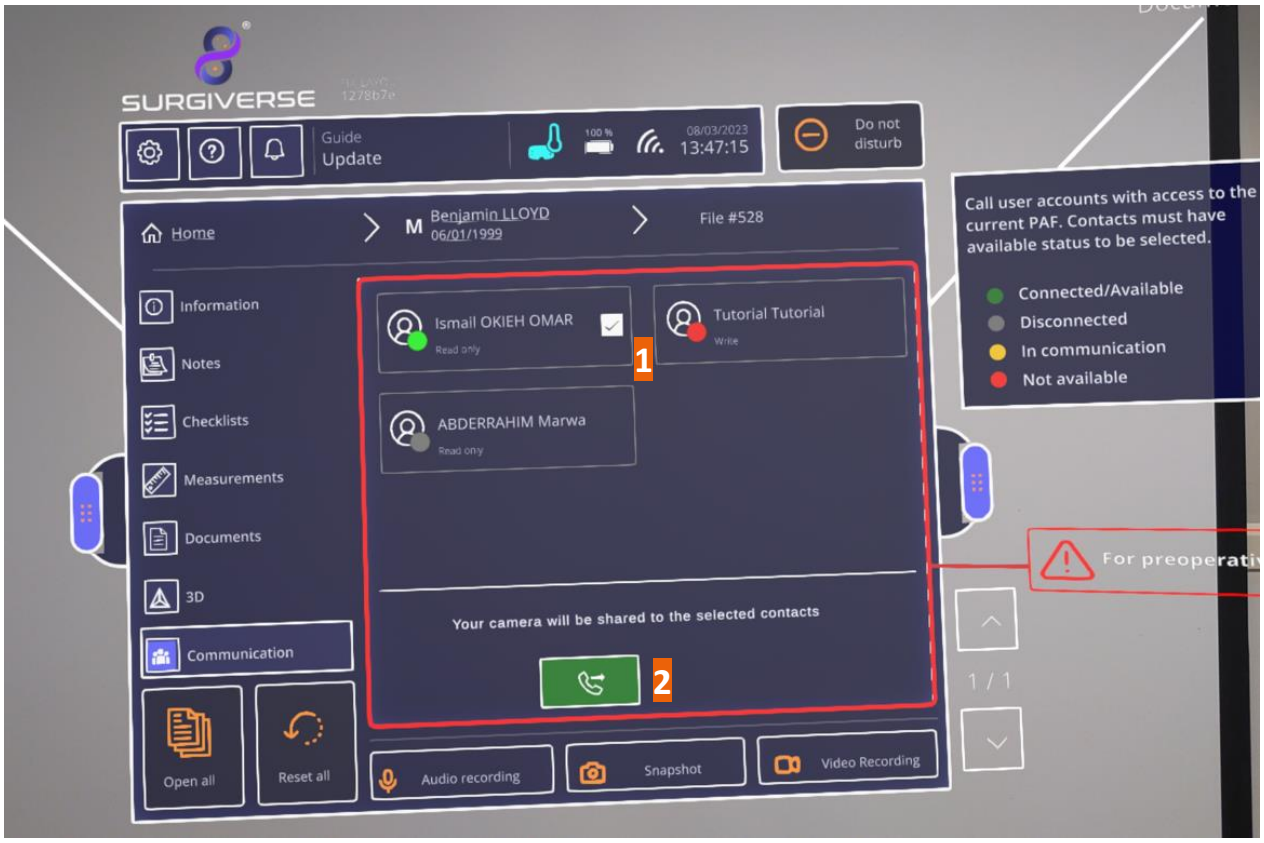


Figure 17: Communication tab - Initiating a call

During the communication, a communication toolbar is available:

- Mute/unmute button (1 in Figure 18) enables to activate or deactivate user's microphone.
- End call button (2 in Figure 18) enables to hang up the call.
- Share Point of View button (3 in Figure 18) enables to activate or deactivate the display of user's point to contacts in communication.
- A timer (4 in Figure 18) is launched at the start of the communication and indicates the duration of the in progress call.

When the call is in progress and sharing mode is active:
The  to indicate a call in progress, and the  icon to indicate active sharing mode.
Both stay visible in the up-right corner of the user's field of view.

⚠ Caution: During communication with Abys® Medical Surgiverse® Web Planning users, the Abys® Medical Surgiverse® Digital Cockpit user point of view including virtual objects may be shared and visible for all attendees to the call.

⚠ Caution: During communication with Abys® Medical Surgiverse® Web Planning users, captures of the shared Abys® Medical Surgiverse® Digital Cockpit user point of view including virtual objects may be saved by any attendee to the call.

⚠ Caution: During communication with Abys® Medical Surgiverse® Web Planning users, the call may be recorded, including the Abys® Medical Surgiverse® Digital Cockpit user point of view including virtual objects and the conversations.

⚠ Caution: The communication with Abys® Medical Surgiverse® Web Planning users is for preoperative use only.

Note: according to the settings of the entity of the Surgiverse® Digital Cockpit user, communication may be automatically recorded and stored in the PAF documents. The recordings are available in Surgiverse® Web Planning only.

Note: by default, sharing mode is activated, and during a call, all participants may see to the user's point of view.

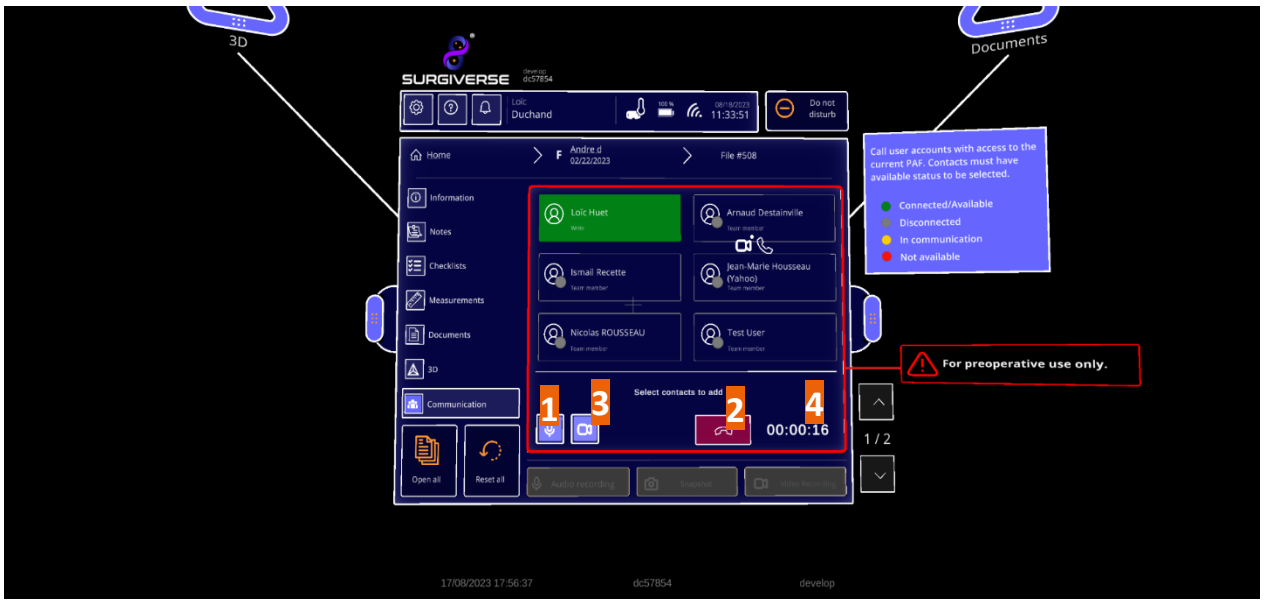


Figure 18: Communication tab - During a call

4.12 Preparation of Surgiverse® Digital Cockpit and display in operating room

When the user wishes to use the software in the operating room, the following precautions must be respected.

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit 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

⚠ Caution: The user must not place the virtual objects displayed in Abys® Medical Surgiverse® Digital Cockpit between him/her and the patient to not obstruct the surgical field

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit is not intended for superimposition or registration of the medical image information to the live patient

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit 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

⚠ Precaution of use: Before each use, and prior to sterile scrubbing the user must run mandatory calibration and verification test features available in the Microsoft® HoloLens® 2 settings menu or in the application launcher:

- Eye-calibration (available in the Microsoft® HoloLens® 2 settings menu)
- Display quality test pattern, check the visibility points:
  - "You should be able to read the mention "QUALITY CONTROL" inside the 3 bottom rectangles." (see 1 in Figure 19)
  - "You should be able to distinguish the grayscale in the sidebands, without artifacts." (see 2 in Figure 19)
  - "You should be able to distinguish the 19 grayscale squares around the perimeter of the central part of the pattern" (see 3 in Figure 19)

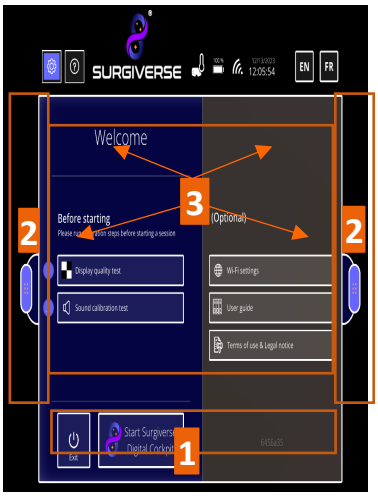


Figure 19: Display Quality Test Pattern

- Sound calibration test (sound quality test and microphone test).

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit should not be used if any of the test pattern quality control points are not met

⚠ Precaution of use: The user should follow the following procedure for preparing and positioning the virtual objects from Surgiverse® Digital Cockpit:

- 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 object, he/she can only

consult it when he/she doesn't actively operate on the patient.

⚠ Precaution of use: 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.

⚠ Precaution of use: 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.

⚠ Precaution of use: 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.

⚠ Caution: 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.

⚠ Caution: Microsoft® HoloLens 2 should not be used in contact with another device or heating areas.

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit does not replace user's medical decision.

While the surgeon can have the flip-up display front panel in place during surgery he/she can still ask the operating room nurse to raise the flip-up display front panel and/or to remove Surgiverse® Digital Cockpit from his head at will.

5 Index of Surgiverse® Digital Cockpit features

Before starting, connect the Microsoft® HoloLens® 2 to the Internet

⚠ Caution: 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.

Once the application is launched. Launcher menu is opened. If needed, it is possible to set up the Wi-Fi to connect to the internet.

① Click on 

to open the network settings menu.

② Select the desired Wi-Fi network.

③ Enter the Wi-Fi network password.

Before starting, display quality pattern test

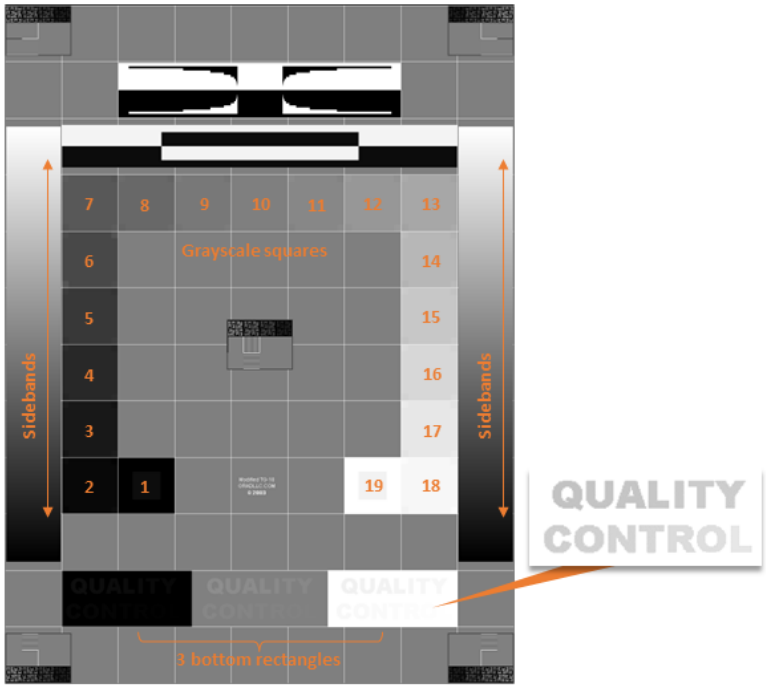
Once the application is launched, the launcher menu is opened. Before starting Surgiverse® Digital Cockpit and opening a session, it is mandatory to complete display quality test.

① Click on 

to open the display quality test.

② Check the visibility points on the pattern displayed:

- 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.



③ Click on  or "Back" button on the breadcrumb to go back to the Launcher menu.

⚠ Caution: Abys® Medical Surgiverse® Digital Cockpit should not be used if any of the test pattern quality control points are not met.

Before starting, sound level and microphone test

Once the application is launched. Launcher menu is opened. Before starting Surgiverse® Digital Cockpit and opening a session, it is mandatory to complete sound level and microphone test.

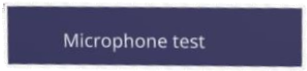
① Click on 

to open the sound level and microphone test.

② Click on 

to start the sound test.

You should distinctly ear the sound played. If not, consider increasing sound volume with the buttons on the side of the visor.

③ Click on 

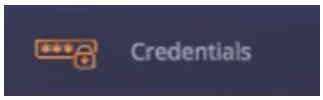
to start the microphone test.

④ Speak normally. You should see the dynamic sound level meter react to the sound. If not, microphone may be deactivated and communication feature of Surgiverse® Digital Cockpit will not work normally.

⑤ Click on  or “Back” button on the breadcrumb to go back to the Launcher menu.

Connection with login and password

After launching Surgiverse® Digital Cockpit, connection menu enables to log in to the application.
You can use your credentials from Surgiverse® Web Planning with an ID and a password.

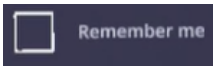
① Click on 

tab to use login and password connection.

② Click on the *Username* text input field to open the virtual keyboard

③ Enter your login with the virtual keyboard. Use your index for typing and favor slow gestures. A sound is emitted when a key on the virtual keyboard is pressed.

④ Close the virtual keyboard by clicking on the little cross button in the up-right corner of the keyboard.

⑤ If needed you can click on 

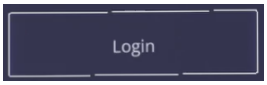
checkbox to store your login for a next connection.

⑥ Click on the *Password* text input field to open the virtual keyboard

⑦ Enter your password with the virtual keyboard.

⑧ If needed you can click on  to display the password. Click again to hide it.

⑨ Close the virtual keyboard by clicking on the little cross button in the up-right corner of the keyboard.

⑩ Click on 

to connect to Surgiverse® Digital Cockpit.

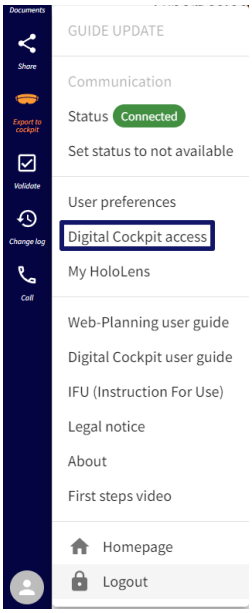
Connection with QR code

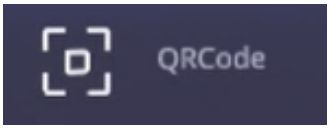
After launching Surgiverse® Digital Cockpit, connection menu enables to log in to the application. You can use QR code automatic connection.

To get QR code, you need to connect to Surgiverse® Web Planning and access your profile:

① In Surgiverse® Web Planning, click on the avatar at the top right of the navigation bar to open user menu.

② Click on “Surgiverse® Digital Cockpit Access” to display QR code.



③ In Surgiverse® Digital Cockpit, click on 

tab to use QR code connection.

④ A virtual pattern is displayed. Align the pattern on the frame of the QR code to optimize its scanning.

A confirmation check is briefly displayed when QR code is recognized, and when connection succeeds.

Note: For safety reasons, the QR code changes every 30 sec.
Note: You may need to reduce the brightness of your screen to optimize QR code scanning.

Handling main menu

It is possible to grab the main menu to move it in space.

① Grab  handle on one side of the main menu by pinching it between thumb and index.

It is also possible to grab it with the lasso.

About menu: access to product documentation

About menu enables to access to product documentation:

- Labeling
- User guide
- Terms of use and legal notice
- Instructions for use

Labeling:

① Click on  In the information banner to open about menu.

Labeling is displayed in the panel.

User guide:

① Click on  In the information banner to open about menu.

② Click on 

to display user guide as a pdf file next to the panel.

Terms of use and legal notice:

① Click on  In the information banner to open the information menu.

② Click on 

to display terms of use.

Instructions for use:

① Click on  In the information banner to open about menu.

② Click on 

to display IFU as a pdf file next to the panel.

Note: When opening a product documentation, if another one is already opened, it shall be automatically closed and replaced by the new one.

Setting language

① Click on  to open Settings menu.

② Click on 

to select language.

Filtering validated PAF in a list / Filtering my PAF in a list

In the PAF list, all PAFs are displayed in the list by default. It is possible to filter PAF created by the user only.

① Click on 

to filter PAF created by the user in the list.

② Click on the button again to display all PAF in the list.

Searching in a list

In Documents tab or PAF and patients lists, it is possible to search an element in the list.

① Click on 

text input field.

The virtual keyboard is automatically opened.

② Enter the first characters of your research in the virtual keyboard.

List is filtered and updated with searching criterion.

③ Close the keyboard.

④ Click on the cross button if needed to clear the text input field.

Sorting elements in a list

① In a list, click on the header of the column you want to sort.

② The order is represented by an arrow up or down.

First use mode: activation/deactivation

To assist the user during the first uses of Surgiverse® Digital Cockpit, a first use mode identifies the commands and features available in each menu displayed. Based on eye-tracking and hand tracking, this mode displays a tooltip with some explanations next to each button or area of interest in the user interface that:

- You look at during at least 1 second
- You approach with your finger

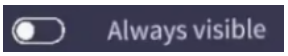
If needed, it is possible to display all tooltips available for a given menu displayed at a time.

① Click on  to open Settings menu.

② Click on 

toggle to activate first use mode.

③ Look at buttons or area of interest in the user interface you wish to have information about.

④ Click on 

toggle to display all tooltips at a time. Click again to deactivate.

Note: First use mode is activated by default for the first use. Afterward, it keeps its last state.

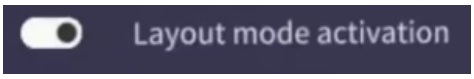
Layout mode: activation/deactivation

The layout mode allows you to set up a specific spatial configuration and organize the virtual dashboard of the session relative to a physical point of reference. The point of reference used is a QR code which must be positioned and fixed in space (on a wall of the operating room for example). The positions of the main menu and spawn points are saved relative to the position of this QR code and linked to it, all saved in the user profile. Several QR codes can be edited to save several configurations.

When activated, layout mode can scan and recognize eligible QR codes to store layout information.

Eligible QR codes contain the following data: “AbysMedical_layout_[char]” with [char] from 1 to 8 characters.

① Click on  to open Settings menu.

② Click on 

toggle to activate Lay-out mode.

③ Click on toggle again to deactivate Lay-out mode.

Note: Layout QR code are provided with Surgiverse® Digital Cockpit.

Layout mode: saving a layout

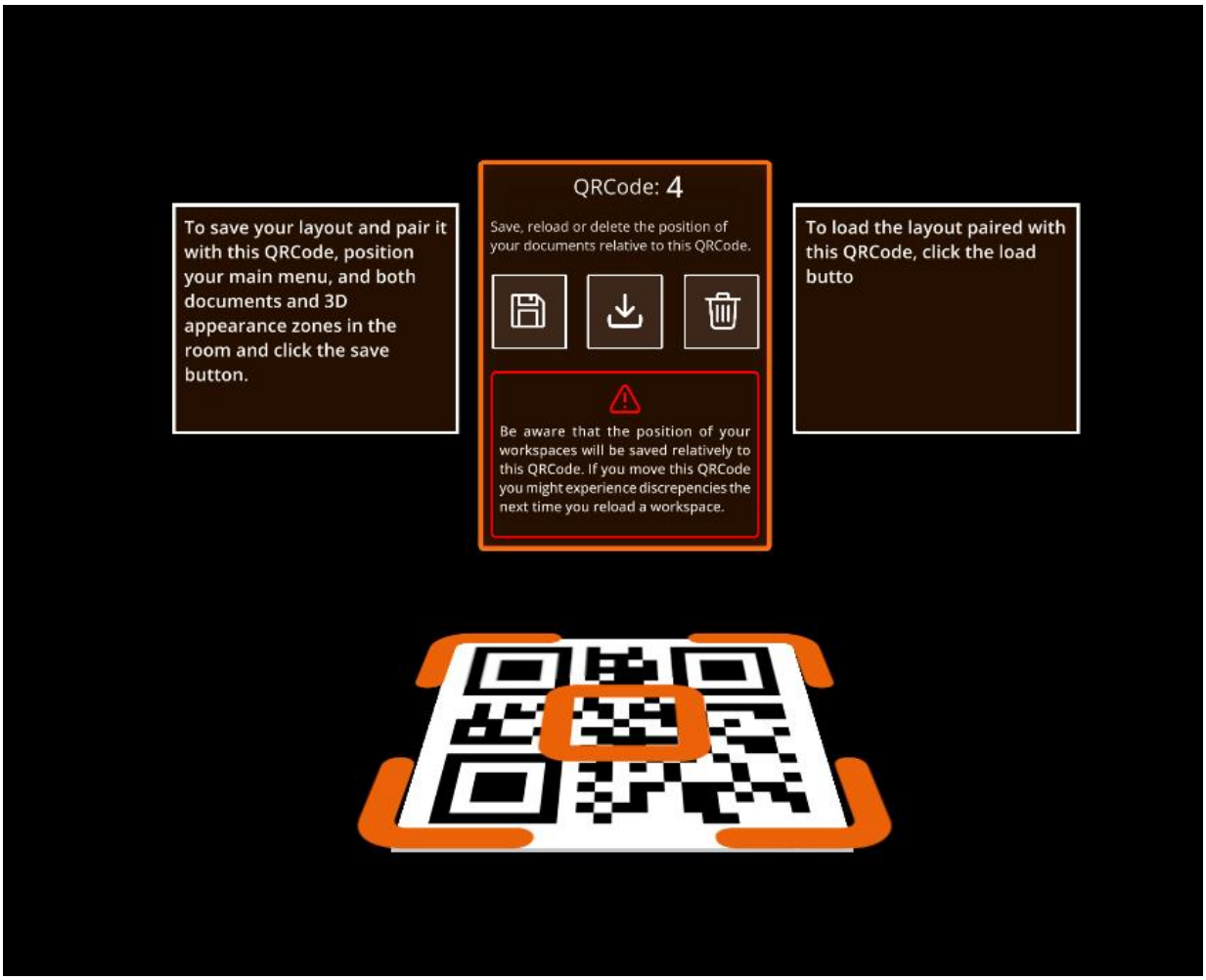
Once lay-out mode is active, it is possible to save a layout.

① Place the main menu and the spawn points as you wish.

② Scan a valid QR code. A menu is displayed on the QR code. If no layout is saved:

③ Click on  to save the layout and attach it to the QR code.

If a layout is already saved in memory:



④ Click on  to save the layout and attach it to the QR code.

A confirmation is required to save the layout.

⑤ Click on  to confirm the choice.

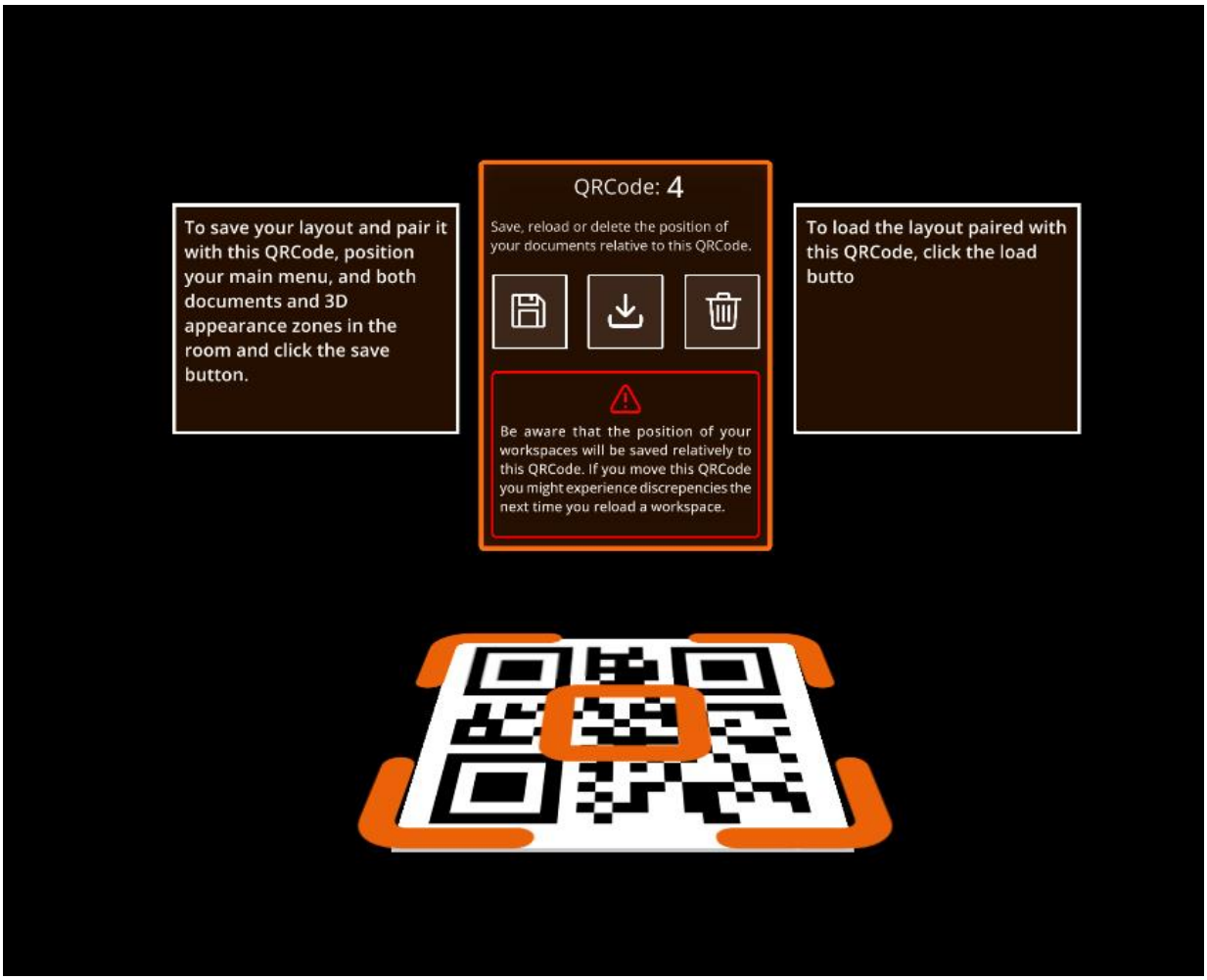
Layout is saved. Main menu and spawn points positions are saved and attached to the QR code, and can be loaded later.

Note: Be aware that the position of your workspace is saved relatively to the QR code. If you move the QR code, you might experience discrepancies in workspace position.

Layout mode: loading a layout

Once lay-out mode is active, it is possible to load a previously saved layout.

① Scan a valid QR code. A menu is displayed on the QR code.



② Click on  to load a layout attached to this QR code.

A confirmation is required to load the layout.

③ Click on  to confirm the choice.

Layout is loaded. Main menu and spawn points are automatically positioned relative to the QR code.

Note: Be aware that the position of your workspace is saved relatively to the QR code. If you move the QR code, you might experience discrepancies in workspace position.

Layout mode: delete a layout

When a layout is stored in the user profile, it is possible to delete it.

① Click on  to open Settings menu.

② Click on  to open layouts list.

③ Click on  next to a layout in the list to delete it.

④ Confirm choice to validate the action

Autosave

PAF are autosaving at regular intervals. Autosave considers PAF contents opened, as well as their position and orientation relative to the spawn points. This enables to retrieve a session state when disconnected or when the application has been quitted.

When reopening a PAF that has already been opened and then closed, or after disconnecting from the session, a window is displayed asking whether you want to open last session on this file.

① Click on  to open the PAF with last autosave configuration.

② Click on  to open the PAF with a reset configuration.

Reset spawn areas positions

If needed, it is possible to reset position of spawn points. Once reset, spawn points shall be attached and wired to the main menu.

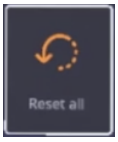
① Click on  to open Settings menu.

② Click on 

to reset spawn points.

Reset all positions

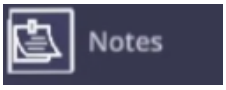
If needed, it is possible to reset position of all opened contents of a PAF. They shall return to their respective spawn points.

① Click on 

to reset all opened contents.

Display notepad

If notes from Surgiverse® Web Planning, they can be retrieved in Surgiverse® Digital Cockpit.

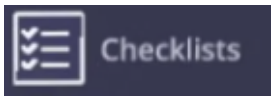
① Click on 

to open the Notes tab and display the notepad inside the panel.

Note: Personal notes cannot be edited from Surgiverse® Digital Cockpit.

Checklists

Checklists created in Surgiverse® Web Planning are available in Surgiverse® Digital Cockpit in a dedicated tab on the main menu.

① Click on 

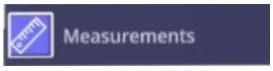
to open the checklists tab. A list of available checklists is displayed.

② Click on the checklist you want to work on.

③ Click on each item you want to check/uncheck in the current checklist.

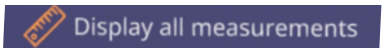
Measurements

If measurements have been taken on Surgiverse® Web Planning on a series exported to Surgiverse® Digital Cockpit, it is possible to display them in a list with their respective values.

① Click on 

tab to display measurements list.

All measurements are displayed with names and values.

② Click on 

to display all measurements in 3D on opened 3D objects.

Filtering available documents in a list

In the documents tab, all documents are displayed in the list by default. It is possible to filter available documents in order to hide non available documents such as video or audio files.

① Click on 

to filter available documents in the list.

② Click on the button again to display all documents in the list.

Free or constrained mode for documents

When opened in the scene, for better readability and visibility, documents are always oriented toward the user. If moved, they will automatically turn to face the user when released. Yet it is possible to disengage this constrained mode. When free mode is activated, documents stay in their last position and orientation when released by the user.

① Click on  button in the upper banner above the concerned document to activate free mode.

② Click on the button again to activate constrained mode.

Note: the document handling mode is active on the concerned document only.

3D: brightness adjustment

Display brightness of all 3D objects opened can be adjusted for better comfort and visibility.

① Click on 

to open the 3D tab on the main menu.

② Grab the slider cursor by pinching it between the index and thumb

③ Move the cursor to the left to decrease brightness, and to the right to increase it.

3D: change objects scale

3D objects are displayed at 1:1 scale by default when opened. By default, 1:1 scale is locked, and 3D objects cannot be enlarged or diminished. Yet it is possible to unlock scale and allow upscaling up to x2.5 and downscaling down to x0.5.

When unlocked, current scale of the 3D object is displayed on the button.

Note: the scale value is displayed with one decimal place and is rounded down or to the upper 1/10.

Note: when unlocked, a warning informs the user that object may not be at scale.

① Click on  next to the 3D object concerned, to open contextual 3D object settings menu.

② Click on 

to unlock 3D object scale.

③ Grab the object with both hands, pinching the thumb and index finger of each hand, then spread the hands apart to enlarge the object, or bring the hands together to decrease it.

④ Click on the scale button again to scale the 3D object back to 1:1 and lock it.

Note: the scale 1:1 is the size of 3D object as exported from Surgiverse® Web Planning. Moreover, the size of the 3D object is inherent to the medical images and cannot be edited on Surgiverse® Web Planning.

⚠ Caution: The user should always check the scale and orientation of the used 3D objects. Opening several 3D objects may deteriorate the fluidity of the display.

3D: display mode

3D objects can be displayed with standard opaque material or with transparency if needed.

① Click on  next to the 3D object concerned, to open contextual 3D object settings menu.

② Click on 

to display 3D object with transparency.

③ Click on 

to display 3D object with standard opaque material.

3D: display/hide measurements

If measurements have been taken on Surgiverse® Web Planning on a given series exported to Surgiverse® Digital Cockpit, it is possible to display them in 3D on the corresponding 3D object when it is opened. Several measurements can be attached to a single 3D object.

① Click on  next to the 3D object concerned, to open contextual 3D object settings menu.

② Click on  In the list attached to the 3D object, to display the corresponding measurement.

③ Click on the button again to hide the corresponding measurement.

Note: button appearance changes to show current state (displayed/hidden).

3D: display/hide labels

Labels created with Surgiverse® Web Planning on a series exported to Surgiverse® Digital Cockpit, can be displayed in 3D on the 3D object. Several labels can be attached to a single 3D object.

① Click on  next to the 3D object concerned, to open contextual 3D object settings menu.

② Click on  In the list of labels attached to the 3D object, to display the corresponding label.

③ Click on the button again to hide the corresponding label.

Note: button appearance changes to show current state (displayed/hidden).

Communication: add a participant to a call

While a call is in progress with one or several contacts, it is possible to add another contact to the call if his status is available.

① Click on the contact in the list you wish to add to the call.

① Click on  in the communication toolbar to add the contact. Dialing starts.

If the contact accepts the call, he is added to the call.

The small icon  next to the contact in the list indicates that he participates to the call.

Note: Contacts who are not available cannot be added to a call.

Communication: start a call

If communication feature is available, it is possible to start a call if at least one contact is present in the contacts list (with a share on the PAF, or member of your team), and has the status available.

① Click on the contact in the list you wish to add to the call.

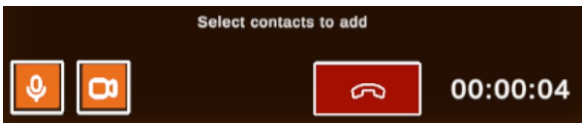
② Click on  to start the call. Dialing is launched.

 small icon next to the contact in the list indicates that dialing is in progress with this contact.

 small icon is visible in the up-right corner of the field of view, indicating that dialing is in progress.

If the concerned contact accepts the call, he is successfully added to the conversation.

 small icon next to the contact in the list indicates that he participates to the call.



The communication toolbar is displayed, and a timer is launched at the start of the communication to indicate the duration of the call in progress.

Communication: activate/deactivate video sharing

While a call is in progress with one or several contacts, it is possible to activate or deactivate sharing mode. When activated, the sharing mode enables to share with participants to the call, the user's augmented point of view, including real scene filmed by Microsoft® HoloLens® 2 cameras, and all virtual objects present in the field of view.

① Click on  in the communication toolbar to activate or deactivate sharing mode.

 A small icon is visible in the up-right corner of the field of view, indicating that sharing mode is activated.

Note: Sharing mode is activated by default.

Note: The button appearance changes and indicates the current state.

Communication: mute/unmute microphone

While a call is in progress, it is possible to mute/unmute your microphone.

① Click on  in the communication toolbar to mute or unmute your microphone.

Note: By default, when a call starts, your micro is unmuted.

Note: The button's appearance changes and indicates current state.

Communication: hang up a call

While a call is in progress, it is possible to hang up and terminate the call. Sharing mode and automatic call recording of the Surgiverse® Digital Cockpit session will be terminated.

① Click on  to hang up the call. A popup is displayed to ask for confirmation/cancellation.

② Click on  on the displayed popup to confirm or cancel the action.

The call is terminated.

 small icons disappear from the up-right corner of the field of view.

Captures: take a snapshot

If the user has the right to edit the PAF, it is possible to make some captures of the session and to store it in the PAF. If needed, snapshot can be taken from the user's augmented point of view, including real scene as captured by Microsoft® HoloLens® 2 cameras, and all virtual objects present in the field of view.

① Click on 

to activate snapshot mode.

 small icon is visible in the up-right corner of the field of view, indicating that snapshot mode is activated.

② Pinch your thumb and index to take a snapshot. Snapshot mode is automatically exited after capture.

Note: You get a notification once the snapshot is uploaded to the PAF. The file appears as a picture in the documents list of the PAF.

Note: Snapshot mode is not available if the user does not have the rights to edit the PAF.

Note: Snapshot mode is not available in the case of network disconnection.

Captures: record an audio

If the user has the right to edit the PAF, it is possible to make captures of the session and to store it in the PAF data. If needed, audio capture can record a voice report during the session.

① Click on 

to start audio recording.


A small icon is visible in the up-right corner of the field of view, indicating that record is in progress.

② Click on the button again to stop recording. A progression bar indicates uploading progression.

Note: You get a notification once the audio record is uploaded to the PAF. The audio file appears in the documents list of the PAF.

Note: Audio records cannot be read in Surgiverse® Digital Cockpit.

Note: Audio recording is not available if the user do not have the rights to edit the PAF.

Note: Audio recording is not available in the case of network disconnection.

Captures: record a video

If the user has the right to edit the PAF, it is possible to make captures of the session and to store it in the PAF data. If needed, video capture can record session from the user's augmented point of view, including real scene filmed by Microsoft® HoloLens® 2 cameras, and all virtual objects present in the field of view.

① Click on 

to start video recording.


A small icon is visible in the up-right corner of the field of view, indicating that record is in progress.

② Click on the button again to stop recording. A progression bar indicates uploading progression.

Note: You get a notification once the video record is uploaded to the PAF. The video appears in the documents list of the PAF.

Note: Video records cannot be read in Surgiverse® Digital Cockpit.

Note: Video recording is not available if the user does not have the rights to edit the PAF.

Note: Video recording is not available in the case of network disconnection.

Notifications: receiving and reading notifications

Two kinds can be received by the user: information and warnings.

Warning notifications can be critical and are mandatory. A long sound is emitted, and a permanent icon with the following text "Warning, check your notification panel" is displayed in the field of view.

The notifications are sent when:

- A network error occurred (warning notification)
- A PAF has been unvalidated and/or modified (warning notification)
- Microsoft® HoloLens® 2 temperature has reached critical value (warning notification)
- Microsoft® HoloLens® 2 battery level is low (warning notification)
- A content has been added to the PAF (information notification)

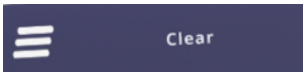
① Click on  button to open notifications.

② Click on a notification in the list or look at it during at least 1 second to mark it as read.

Notifications: clear notifications

Once notifications are read, it is possible to clear them from the list.

① Click on  button to open notifications.

② Click on 

to clear read notifications.

Note: Clearing notifications shall also clear unread information notifications.

"Do not disturb" mode

This mode enables the user not to be distracted nor disturbed by Surgiverse Digital Cockpit.

Once activated:

- Main menu panel is reduced
- Information banner (Figure 20) is always visible at the top of the user's field of vision. Next to the banner, a button (1 in Figure 20) indicating the current opened PAF enables to deactivate the mode
- All virtual objects in the scene are locked in position and orientation, avoiding wrong or unexpected handling
- All information notifications are disabled
- Warning notifications are still activated

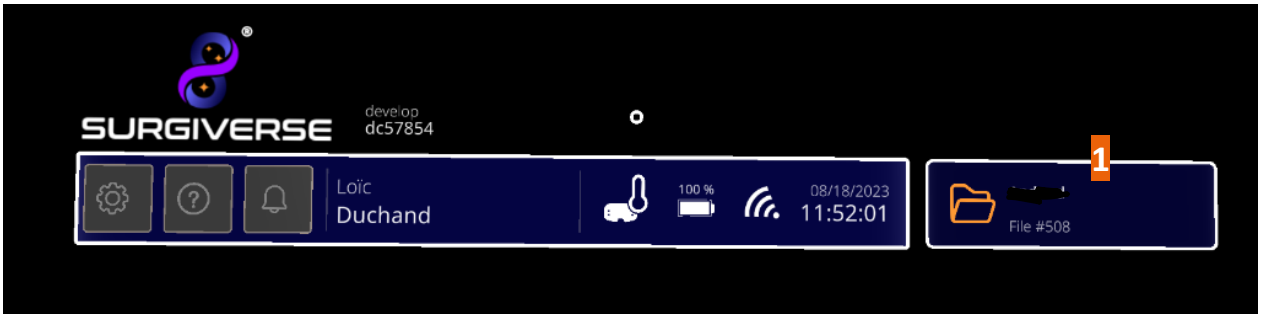
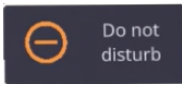


Figure 20: Information banner

① Click on  to activate the «Do not disturb» mode.

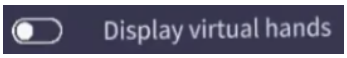
② Click on  located next to the information banner to deactivate the mode

Display/hide virtual hands

During communication with sharing mode, or video recording, it may be useful for the user to point a specific area on a 3D object with the finger.

3D objects are perceived to be localized in space, but the 3D image is projected onto the visor of the HoloLens. This can induce an obfuscation of the finger/hand by the 3D object when both occupy the same space. To avoid it and to ensure both hand/finger and 3D object are visible, it is possible to display user's virtual hands as they are detected by Microsoft® HoloLens® 2 sensors.

① Click on  to open Settings menu.

② Click on 

toggle to display virtual hands.

③ Click on the toggle again to hide virtual hands.

Offline mode

If the internet connection is lost, the Surgiverse® Digital Cockpit application remains opened. If a file has been opened before the loss of the connection, 3D objects, images and documents remain available for consultation and manipulation.

It is not possible to login to the Surgiverse® Digital Cockpit application or open a new PAF without internet connection.

Logout from Surgiverse® Digital Cockpit

① Click on  to open Settings menu.

② Click on 

to log out.

③ Click on  to confirm choice.

Exit Surgiverse® Digital Cockpit

① Click on  to open Settings menu.

② Click on 

to exit Surgiverse® Digital Cockpit.

③ Click on  to confirm choice.

6 Residual risks, and associated recommendations

⚠ Risk of inappropriate treatment: in cases of clinical collaboration, 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 HoloLens 2 once the sterile gloves have been put on. Installation and removal of the 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 Surgiverse® Digital Cockpit. The user should check his/her PAF data just prior to using Abys® Medical Surgiverse® Digital Cockpit.

⚠ 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 HoloLens 2 to heat while using Abys® Medical Surgiverse® Digital Cockpit; If the HoloLens 2 overheats, it may automatically switch off, in which case the user should allow the HoloLens 2 to cool down before use.

⚠ Risk of data loss: the user must make sure to systematically disconnect from Abys® Medical Surgiverse® Digital Cockpit at the end of a session.

⚠ 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. 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 Surgiverse® Digital Cockpit when he/she actively operate 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

7 Software installation / maintenance / decommissioning

No installation, maintenance or decommissioning procedures are needed for users. Surgiverse® Digital Cockpit 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.

In the event of a major modification of Surgiverse® Digital Cockpit that could have an impact on the clinical or technical performance of Surgiverse® Digital Cockpit, a new validation will be performed. If applicable, the new performance parameters will be communicated to users if they are modified.

8 Complaints

Any healthcare professional with a complaint regarding the quality of this medical device, its identity, reliability, safety, efficiency, or performance should notify Abys® Medical. Any malfunction of this medical device, and/or any malfunction that may have caused or contributed to a patient's death or severe injury, must be notified immediately to Abys® Medical and to the concerned competent authority. 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. For additional information on this medical device, or to obtain free hard copy instructions for use within 7 days, please contact Abys® Medical Customer Service at support@abys-medical.com .

9 Troubleshooting

If you have any problems with hand or wall motion detection or graphics display, please turn off the Microsoft® HoloLens® 2 and turn it back on using the following procedure: https://docs.microsoft.com/fr-fr/hololens/hololens2-setup .

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