



Instructions for Use
Fiagon Navigation Software
Version 3.7

Model ENT

Revision 171113-E

Introduction

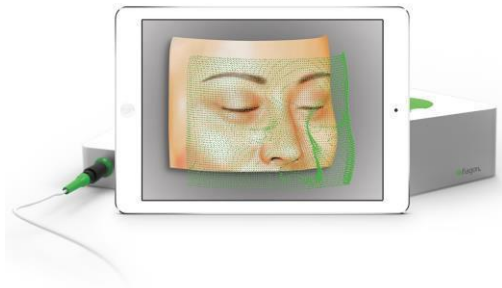
The Fiagon Navigation software is component of the Fiagon Navigation System

Trade Name: Fiagon Navigation System
Fiagon Tracey Navigation System

Common Name of Device: Image guided surgery system

This User Manual provides instructions on the use of the Fiagon Navigation Software for image-guided surgery.

It contains helpful information on frequently used functions and safety features of the software. The Fiagon Software is installed on the Fiagon navigation unit.



Explanation of symbols



Refer to documentation

For the required information and contraindications, please refer to the instruction for Use supplied with Fiagon Navigation system. For detailed instructions and the required safety information related to the components and accessories (e.g. head rest, patient localizer and instruments) refer to the corresponding Instructions for Use.

i

Marks an information message



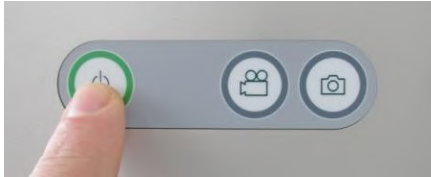
This is the general warning sign. It is used to alert the user to potential hazards. All safety messages that follow this sign shall be obeyed to avoid possible harm.

Contents

1.	Set up system and logon	4
2.	Load image sets	6
3.	Views of the software	12
4.	Verify and adjust image set	17
5.	Preparing patient registration	19
6.	Improve Registration	21
7.	Marking sensitive structures	21
8.	Shift – local registration refinement	24
9.	Length measuring tool	25
10.	Fusion of 3D Data Sets	26
11.	Enabling navigation	27
12.	Modes of operation	30
13.	Patient registration	31
14.	Display of the navigation information	33
15.	Repeated checking of the navigation information	35
16.	Screenshot and video recording	36
17.	Export of the documentation	37

1. Set up system and logon

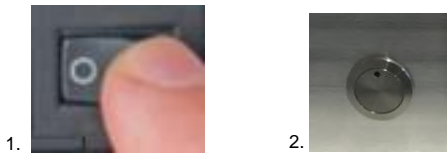
Push the main switch of the system tower according to the instruction manual on the backside of the module and press the On/Off button on the front panel to start the system.



The system will start up. And the logon page will appear. Use the mouse and the displayed ON-Screen keyboard to enter the logon key.

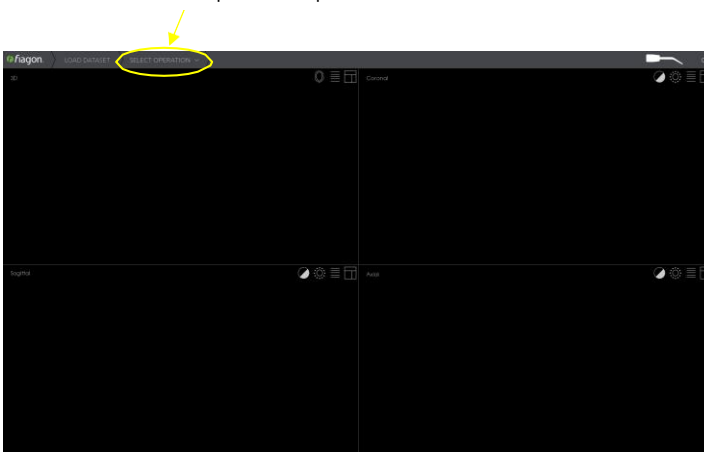
After entering the Logon information, the main screen appears.

For the Fiagon Tracey Navigation System push the main switch of Tracey Navigation Hub on its back. Then start the Tracey Monitor by pushing the On/Off Button on the fronted panel of the Tracey Monitor Unit. The Fiagon Navigation Software will start automatically after the Tracey Monitor Unit found the connection to the Tracey Navigation Hub.



Make sure the Tracey Navigation Hub is switched on before starting the Tracey Monitor Unit.

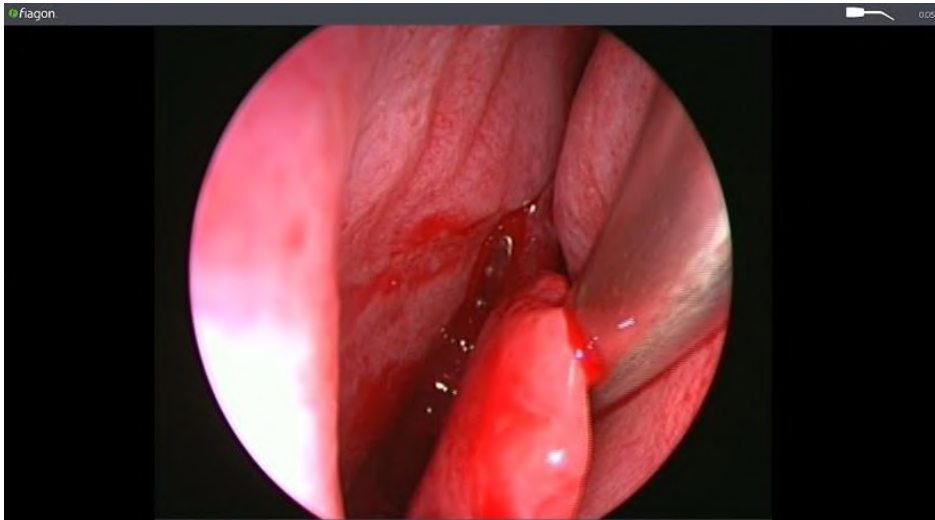
Operation dropdown menu



Fullscreen mode

In case the navigation system is used with an medical video source (video endoscope,microscope) the software is configured to display the video information as a fullscreen image in case of no activity in respect to the navigation.

This fullscreen mode is activated automatically after starting up and when the mouse has been inactive for 5 seconds



The user automatically gets the available video information in optimized full screen display. The mouse cursor and any interaction button are blinded out in this mode.

Interaction mode

In this mode the user can interact with the functions of navigation software by using the iPad Remote Control (mouse optional). The mode can be entered at any time by tapping the iPad Remote Control (or clicking once on any of the mouse buttons).

With optional usage of mouse: The interaction buttons and the mouse cursor are faded in. The mouse cursor has the focus and operation by mouse is possible.

The interaction mode automatically returns to navigation mode or Full screen video mode after a 5 second of inactivity of the mouse.

- i NOTE:** If you want to operate the system with the mouse (interaction mode), click once to leave the full-screen mode or navigation mode and to display the cursor. You can operate the software now with the mouse. The system will exit the automatically 5 seconds after you stopped using the mouse.

2. Load image sets

Fiagon Navigation software requires an image set as a basis for navigation.

With the Fiagon Navigation software, the following medical image types (in DICOM format) are supported:

- CT
- MRI
- Cone beam CT (CBCT)



To ensure efficient and accurate navigation, follow the recommendations for image acquisition as depicted in the Fiagon respective scan protocols.



CAUTION: You can only select DICOM image data. If you encounter any problems when loading the DICOM data sets, contact the radiologist who has carried out the scan or a service representative.



NOTE: Before using the navigation system on patients, ask your radiologist to provide a CD-ROM containing a test data set. Check that the exported data set and the navigation software are compatible.

There are two options for importing images: importing images from media and from the network.

Import images from media

- Insert the media (CD-R/DVD and USB) with the patient image data into CD slot resp. USB port of the navigation unit
- Click the button "LOAD DATASET" or patient info (if a patient is already loaded) to open the patient manager and to display the list of patients on the external source.



- Choose a patient data set from the menu:
 - The image data sets of the inserted external source (CD-ROM, USB) are displayed on the right list denoted as "On External Sources"
 - The data sets that have already been imported into the system are displayed on the left list "On System".

Following information are displayed in the list:

Select a dataset

Search

On System	On External Sources
Demo Ear #1 Phantom 01/10/2009	Demo Brain #1 Phantom Plast 01/10/2009
Demo Face #1 CT 01/10/2009	Demo Brain #2 Phantom MR 01/10/2009
Demo Fusion #2 MR 01/10/2009	Demo Common #1 MR 01/10/2009
Demo Fusion #1 CT 01/10/2009	Demo Common #2 DVT 01/10/2009

pictogram indicating axial, sagittal or coronal data set

patient's name

No. of slices in the image data set

patient's date of birth

- Select image data set by clicking onto the list entry. The entry will be highlighted.
- Additional information about the selected data set and a larger scan preview will also be displayed on the very right.

Select a dataset

Search

On System	On External Sources
Demo Ear #1 Phantom 01/10/2009	Demo Brain #1 Phantom Plast 01/10/2009
Demo Face #1 CT 01/10/2009	Demo Brain #2 Phantom MR 01/10/2009
Demo Fusion #2 MR 01/10/2009	Demo Common #1 MR 01/10/2009
Demo Fusion #1 CT 01/10/2009	Demo Common #2 DVT 01/10/2009
Demo Brain #2 Phantom MR 01/10/2009	Demo Common #3 DVT 01/10/2009
Demo Brain #1 Phantom Plast 01/10/2009	Demo Ear #1 Phantom 01/10/2009
Demo Common #1 MR 01/10/2009	Demo Face #1 CT 01/10/2009
Demo Common #3 DVT 01/10/2009	Demo Fusion #1 CT 01/10/2009
Demo Common #2 DVT 01/10/2009	Demo Fusion #2 MR 01/10/2009
Demo Sinus #3 Phantom CT 01/10/2009	Demo Sinus #1 Phantom Skin 01/10/2009
Demo Spine #1 Phantom CT 01/10/2009	Demo Sinus #2 Phantom Skin 01/10/2009
Demo Sinus #1 Phantom Skin 01/10/2009	Demo Sinus #1 Phantom Skin 01/10/2009
Demo Sinus #2 Phantom Plast 01/10/2009	Demo Sinus #2 Phantom Plast 01/10/2009
	Demo Sinus #2 Phantom Plast 01/10/2009
	Demo Sinus #3 Phantom CT 01/10/2009
	Demo Sinus #3 Phantom CT 01/10/2009
	Demo Spine #1 Phantom CT 01/10/2009

patient ID: 0

patient's date of birth: 01/10/2009

Study description: MR_T1p1 Routine

Study date: 10/05/2010

Study ID: 0132451176

Series description: T1_mpr_cor sag_30_30_30

Series date: 10/05/2010

Modality: MR

Slice thickness: 1.00

Post spacing: 1.00 1.00

Number of post columns: 256

Number of post rows: 256

Referring physician's name: NR-NC 2B

Institution name: Neuroimaging

SINUS EAR

DVD USB DELETE

Select Procedure / Application

Select one of the preset procedures. Depending on which application is available you can choose one of the following buttons: "Sinus", "Ear".



The image data will be imported and displayed on the screen. Furthermore, the configuration of the selected procedure will be loaded and the views will be rearranged accordingly.



i **NOTE:** To accommodate individual needs and preferences, features can be added or hidden to the default procedure workflows. Ask your Fiagon representative for more information.



NOTE: It is also possible to import patient image datasets by using the iPad Remote Control. Please check the instructions for use for iPad Remote Control.

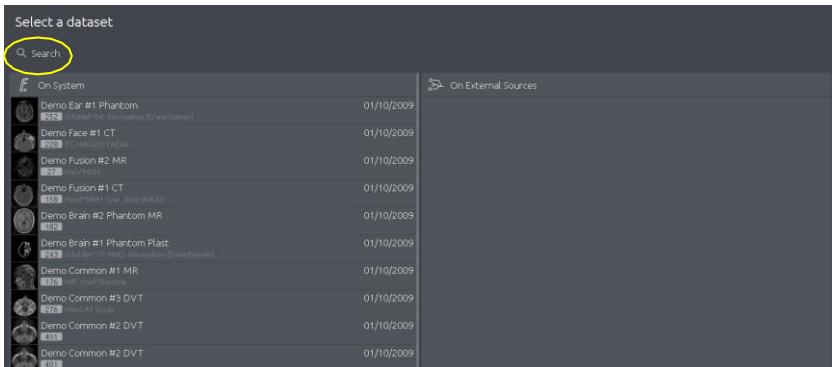
Import images from PACS Network (optional)

NOTE: Fiagon navigation unit needs to be connected to the network and the navigation system needs to be registered in the facility's PACS network in order to send queries to the PACS sever. Ask your Fiagon representative for more information.

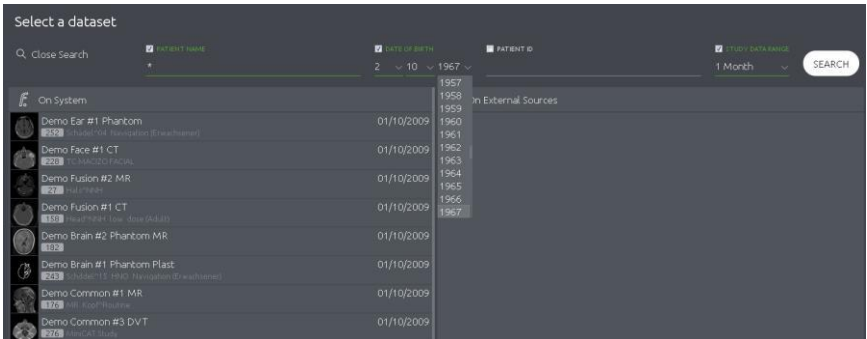
- Click the button "LOAD DATASET" or patient info (if a patient is already loaded) to open the patient manager and to display the list of patients on the external source.



- Click on "Search"



- Select the patient's date of birth with the dropdown menus (Day - Month - Year)

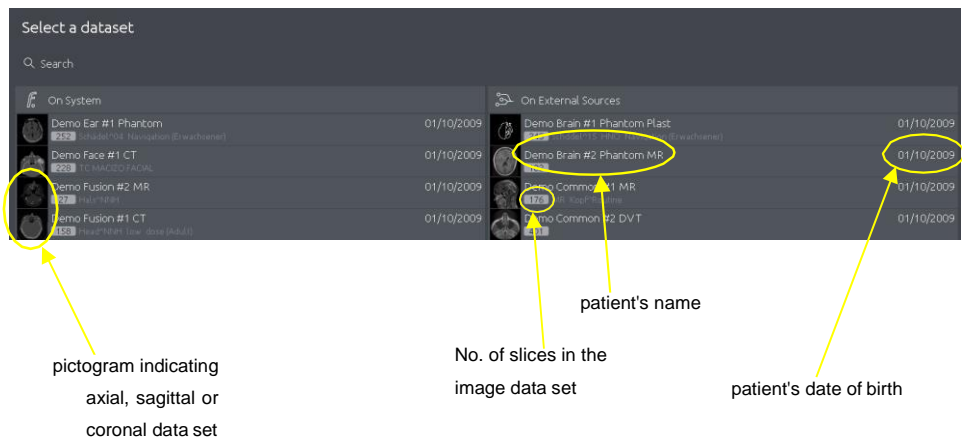


- If necessary filter the query with the dropdown menu for the Series date range. The time interval set in this menu will filter data set recorded in the last day, week, month...etc.



- The query will be sent by pressing **SEARCH** and the list of data sets is generated on the right side

Following information are displayed in the list:



- Select image data set by clicking onto the list entry. The entry will be highlighted and the pictogram indicating axial, sagittal or coronal will be displayed.

Select Procedure / Application

Select one of the preset procedures. Depending on which application is available you can choose one of the following buttons: "Sinus", "Ear".



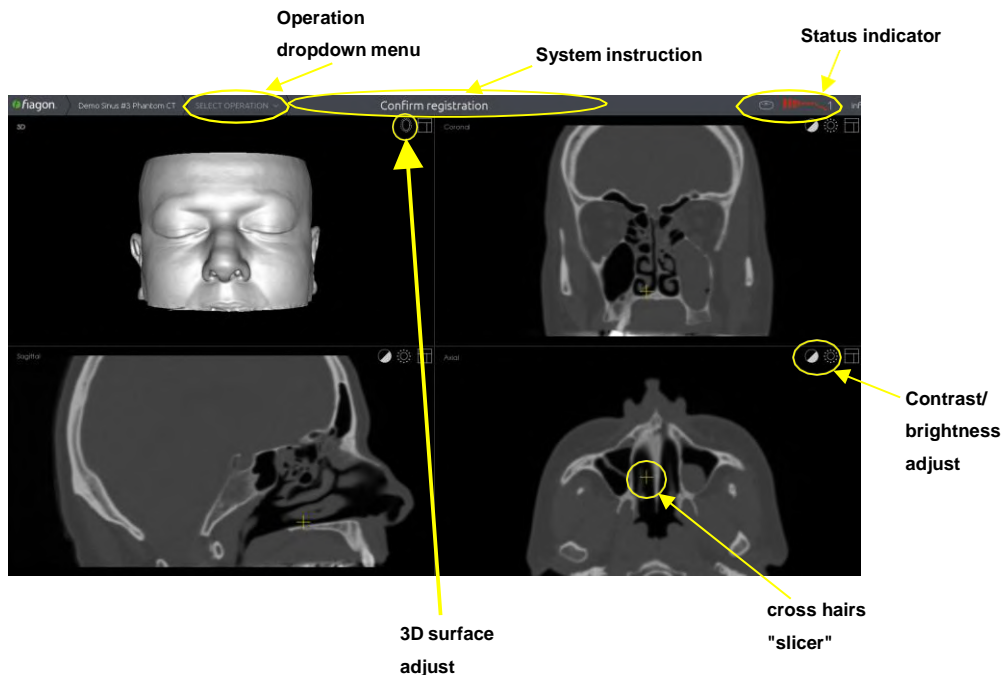
The image data will be imported and displayed on the screen. Furthermore the configuration of the selected procedure will be loaded and the views will be arranged accordingly.



- i** **NOTE:** To accommodate individual needs and preferences, features can be added or hidden to the default procedure workflows. Ask your Fiagon representative for more information.

3. Views of the software

There are four windows displaying different views of the patient image data. By default, there is one 3-D surface model and there are three 2-D orthogonal images (axial, coronal, and sagittal). The system status and procedure messages are displayed on top.



The four different views and the adjustment buttons of the screen will be described below.

In all 2-D views, cross hairs are displayed to display a position. The horizontal resp. the vertical lines of the cross hairs represent the layers displayed in the two remaining 2-D views. You can move the cross hairs with the mouse to scroll through the views.

Display Layouts

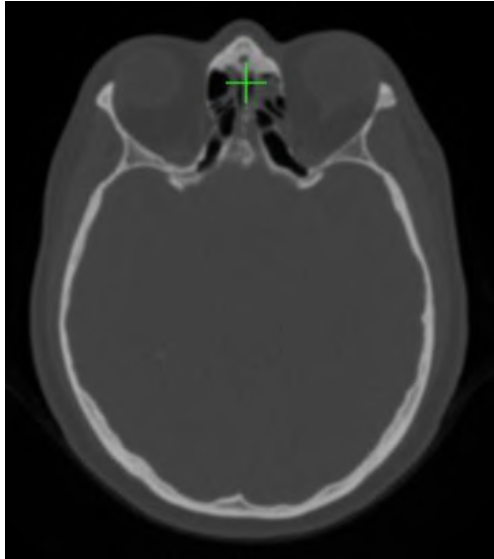
It is possible to set up two layouts of the four views on the patient data in the navigation software. The four views are set up with the Configurator. It is possible to switch between the layouts by click on the button below.



Axial view

In axial view, one of the captured axial slice images is displayed. By moving the cross hairs you can scroll through different slice images in the other views.

- moving crosshairs up or down = scrolling through coronal slices
- moving crosshairs left or right = scrolling through sagittal slices
- right mouse button + scroll wheel = scrolling through axial slices



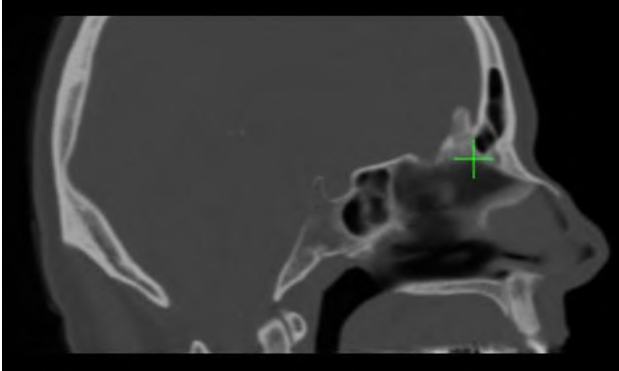
You can zoom in or out by using the scroll wheel.

Use the right mouse button to move a slice in the view. (Only possible when the slice is zoomed in).

Sagittal view

In sagittal view, one of the captured sagittal slice images is displayed. By moving the cross hairs you can scroll through different slice images in the other views.

- moving crosshairs up or down = scrolling through axial slices
- moving crosshairs left or right = scrolling through coronal slices
- right mouse button + scroll wheel = scrolling through sagittal slices



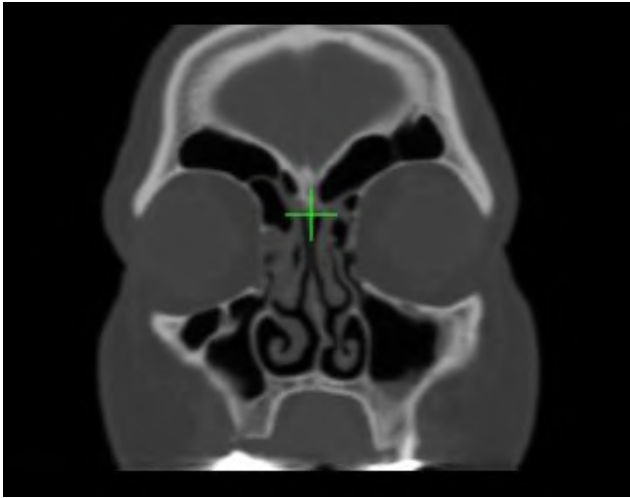
You can zoom in or out by using the scroll wheel.

Use the right mouse button to move a slice in the view. (Only possible when the slice is zoomed in).

Coronal view

In coronal view, one of the captured coronal slice images is displayed. By moving the cross hairs you can scroll through different slice images in the other views.

- moving crosshairs up or down = scrolling through axial slices
- moving crosshairs left or right = scrolling through sagittal slices
- right mouse button + scroll wheel = scrolling through coronal slices



You can zoom in or out by using the scroll wheel.

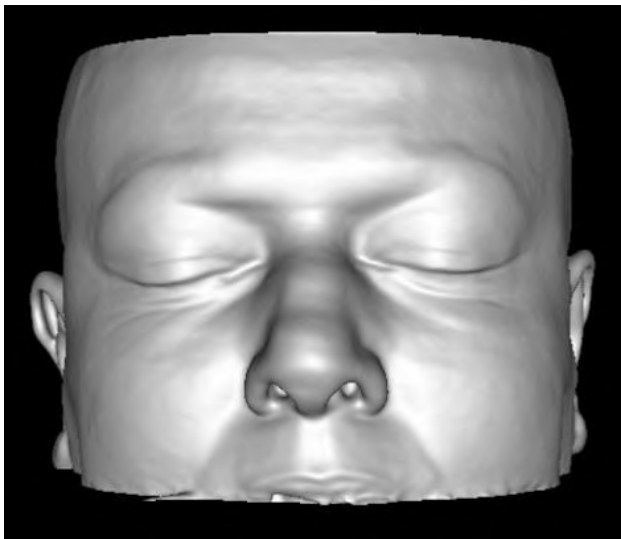
Use the right mouse button to move a slice in the view. (Only possible when the slice is zoomed in).



NOTE: Please check the instructions for use for iPad Remote Control to learn how to interact with the navigation views here.

3D view

The display of the 3-D surface model of the patient can be moved and rotated.



You can move the 3-D surface model with the cursor as desired.

Moving - The model can be moved by holding the left mouse button (right/left, up/down)

Rotating - The model can be rotated by holding the right mouse button

Zooming - Zoom in or out of the model by using the scroll wheel

During the setting of the registration markers, the model cannot be rotated with the mouse.

4. Verify and adjust image set

Verify correctness of images by scrolling through the slices.

Any of the views can be displayed in full screen. To do so, move the mouse to the view you want to enlarge and click onto the scroll wheel of the mouse.

Only the selected view will be displayed on the screen. You can use the scrolling wheel of the mouse (scrolling up and down) for scrolling through the slices of the images

Return to the 4 -view split screen by clicking the scroll wheel once more.

If necessary, adjust

- contrast/brightness of the 2D images
- surface level of the 3D model

Adjust of Contrast / Brightness

By using the contrast and brightness dropdown buttons on the upper right hand corner in all 2-D views, you can change the contrast and brightness settings of the image data.



Once the settings are changed, they will be saved for the respective data set.

By switching the "Reset" button, you can change the settings to the default settings of the data set.



NOTE: Please check the instructions for use for iPad Remote Control to learn how to change contrast and brightness here.

Adjust of 3-D view

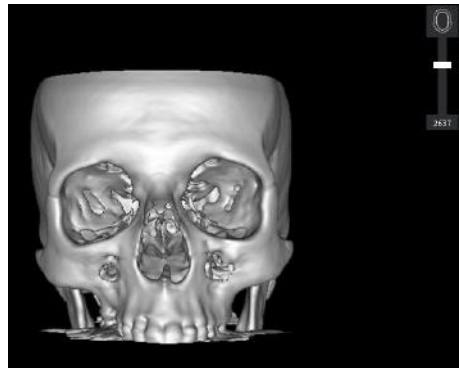
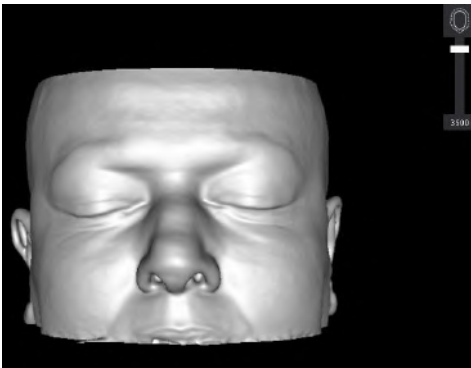
If you select an MRI or cone-beam CT use the slider to optimize the skin surface of the 3D view.

- i** **NOTE:** Patient registration procedure requires the skin surface adjusted in the 3D model.
For CT images skin level is at 3500. For MRI and CBCT it can differ.



Once the settings are changed, they will be saved for the respective data set.

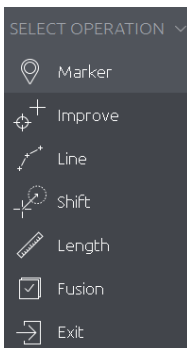
- i** **NOTE:** You can use the slider to display the bone model of the data set.



5. Preparing patient registration

Setting registration markers

For the registration of the patient, you need to set markers in the patient model. The button "Marker" to set the markers is activated automatically after patient images have been loaded.



Follow these instructions for setting the markers

- Select the markers in areas where the bone is located directly underneath the skin and where the skin is relatively inflexible.
- Make sure to avoid sensitive structures such as the eyes when positioning the markers.
- The markers must not touch surface areas with traumata, loose skin (cheeks, former craniotomy areas) or movable parts (lower jaw).
- You should select anatomically distinct positions for the registration markers that can be easily touched with the pointer.
- The distance between those markers should be at least 4 cm.
- The markers should be close to the area of surgical intervention.

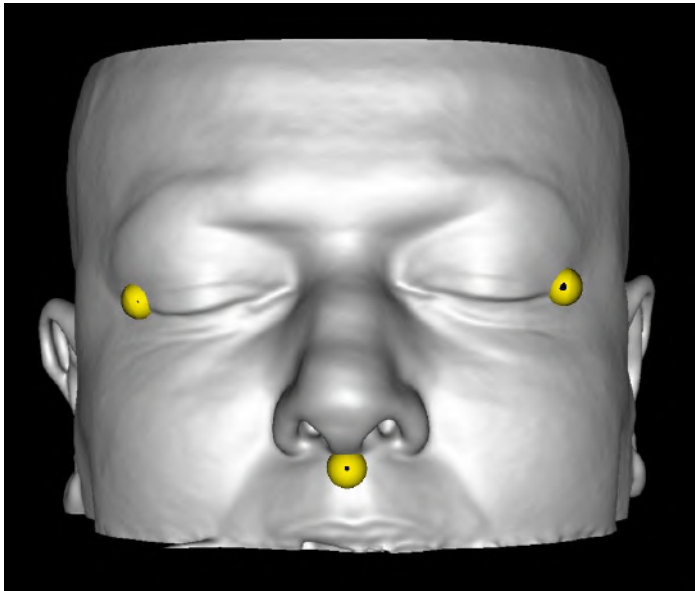


NOTE: If the Automatic Registration Feature is installed on the navigation system no registration markers are necessary to perform the Automatic Patient Registration.

Setting registration markers in 3-D surface model

You can add registration markers to the 3-D surface model.

- Left-click at the location where you want to place the marker.
- The new marker that has been selected and added is displayed as a yellow sphere.



CAUTION: Pay attention to the notes regarding the placement of registration markers.



NOTE: When using cone beam CT or MRI image data, you first need to use the slider to choose the surface of the skin

Positioning registration markers

You can change the position of the markers in all views. To do this, you need to select the marker with the left mouse button and pull it to the new position (while holding the mouse button).



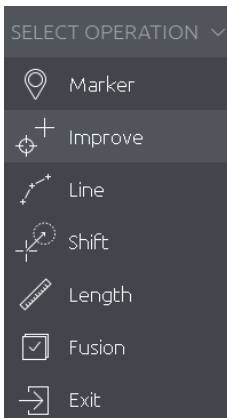
NOTE: Use the zoom function to place the markers in the various views as accurately as possible.

Deleting registration markers

- To select and delete markers, double-click the marker with the left mouse button.
- Once a marker has been deleted, you can add a new marker.

6. Improve Registration

The function IMPROVE enables the functionality to record additional points to enhance the existing patient registration. For detailed information please refer to the application note "Fiagon Navigation Improve Registration".

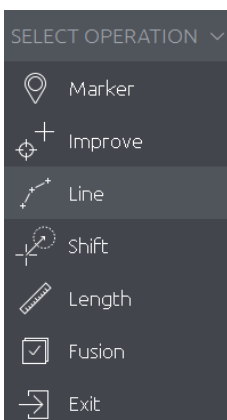


7. Marking sensitive structures

You can create a line segment to visualize anatomical structures of interest for operative planning or navigation and enable collision warnings.

i **NOTE:** During navigation collision warning displays proximity of the navigation instrument to the planned line structure by color change of the navigation display and optionally by acoustic signal. It is possible to mark more than one structure with solitary lines.

- Select "Line" from the operation dropdown menu



- Use the cross hairs in the views to display to the region of interest.
- Click with the mouse at the starting point of the structure you want to mark.

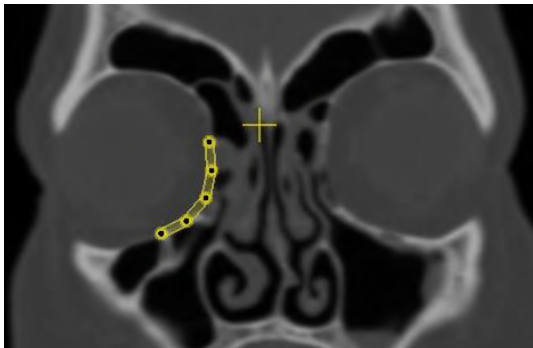


- Select the next point of the line structure with the mouse and click. The marked points will be connected by a line segment.

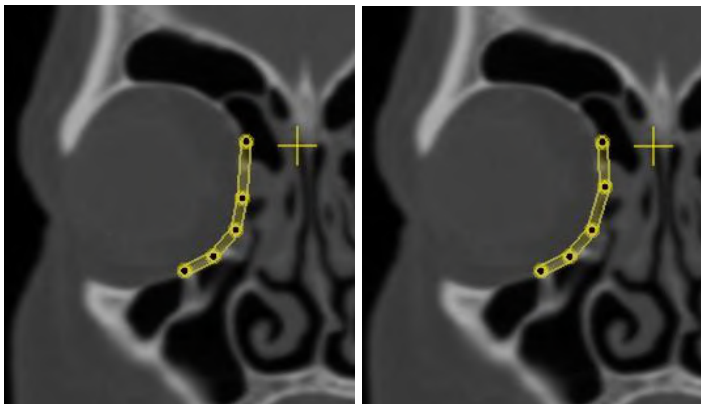


- Proceed along the path of the structure you want to mark.

- Markers can be set between markers to refine the contour of the line



- Set markers can be moved in order to adjust the path of the line. Click on a marker and move it (while holding the mouse button)



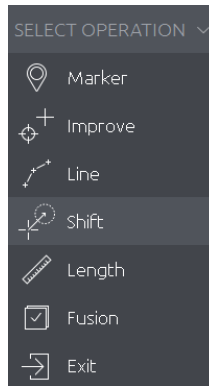
- To select and delete markers, double-click the marker with the left mouse button.

The structure is saved instantly to the patient data on the system. It will be reloaded when the patient file is loaded again.

8. Shift – local registration refinement

In case the initial registration needs to be refined because of a slight deviation between the real instrument position and the position shown in the navigation screen the function SHIFT can be used. The function enhances the registration quality in a locally restricted working area of 2 cm x 2 cm x 2 cm.

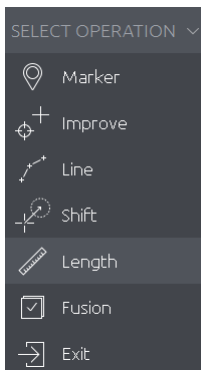
For detailed information please refer to the "Fiagon Application Note SHIFT".



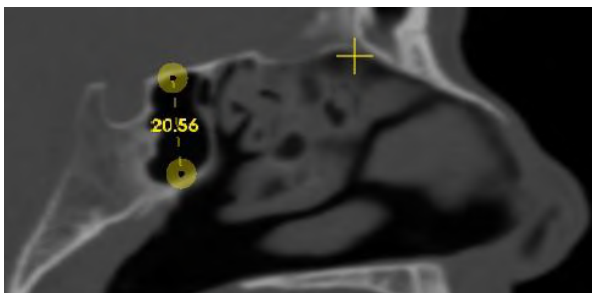
9. Length measuring tool

You can use the length display for the display of an absolute length.

- Select "Length" from the operation dropdown menu



- Select a view and click on two points, for which the distance shall be displayed.
- The selected points will be marked with yellow spheres and the distance between them will now be displayed.



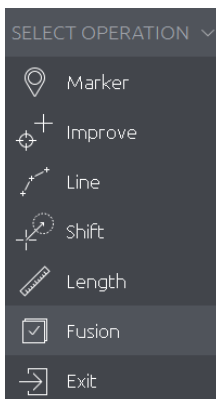
- The marker spheres can be moved. The display of the distance will be updated accordingly.



WARNING: The accuracy of the displayed length is based on the quality of the image data. Take this information into account when measuring the length.

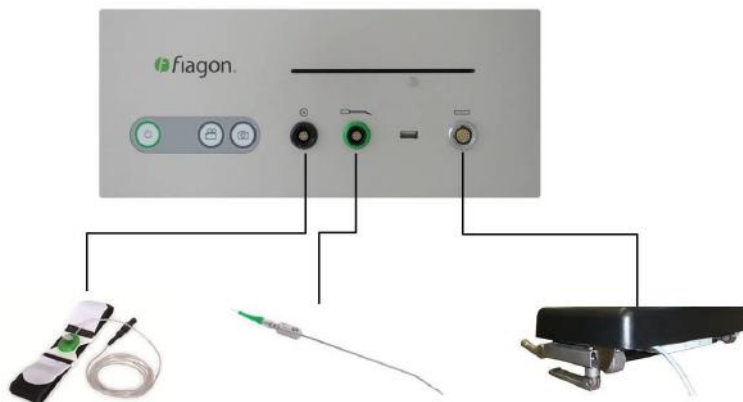
10. Fusion of 3D Data Sets

The function FUSION enables the user to match 3D data sets from various imaging sources, e.g. CT and MRI, automatically. For detailed information please refer to the "**Fiagon Application Note FUSION**".



11. Enabling navigation

Navigation is automatically enabled after connecting the Navigation sensor, the patient localizer and the Instrument to the navigation unit.



NOTE: Refer to the Instructions for use of the navigation unit for details.

Once the navigation sensor is connected to the navigation unit the status indicator of the instrument and the patient localizer will be displayed in the right upper corner of the screen.



Status indicator Navigation sensor

The status indicator of the navigation sensor indicates if the sensor is disabled, or not attached. In rare occasions, it can happen, that the sensor is attached, but not recognized by the system. In that clicking on the white sensor symbol will result in a restart of the field generator, after five seconds it will be recognized.

The navigation sensor can be disabled manually by foot switch operation "Sensor".

By disabling the sensor, the navigation information is paused and in case a video source is connected, the full screen video will be displayed.



The Navigation sensor is not plugged.

Check if the sensor is plugged properly.

or

The Navigation sensor is not recognized by the system.

Click on the white sensor symbol to restart the sensor.

The Navigation sensor is plugged and working properly.



The Navigation sensor is subject to interference.

Please check if there are any heavy metal objects close to the Navigation sensor.

or

Turned off manually by the foot switch.

To turn the sensor on again hit the button "Sensor" on the foot switch once.



NOTE: The foot switch is an optional accessory of the Fiagon navigation system



NOTE: Please check the instructions for use for iPad Remote Control to learn how to turn off the sensor here.

Status indicator Instrument

The status indicator is located on the right side of the status bar. It indicates the status of the instrument. The status of the instrument is shown with the instrument icon.



The instrument is not plugged.

Please check connection to the system, if necessary, plug in again.



The instrument is in the navigation area.

The navigation screen is displayed.



Normal Case: The instrument is out of the navigation area.

The full video image is displayed.



The number of uses of the instrument is used up.

The symbol is red and indicates that no more uses are left. The status bar displays the message: „Change the tool“.

or

The number of uses is displayed here: In this case, 1 out of 10 uses left.

Distortion:

The instrument is in the patient and stays red. A fault is detected. Eliminate source of disturbance.

Status indicator Localizer

The status of the localizer is shown with the localizer icon in the status bar.

The icon is not displayed when the localizer is working correctly.



The localizer is not plugged.
Please check connection to the system, if necessary, plug in again.

The localizer is plugged and well positioned in the navigation area



The localizer is not optimally positioned in the navigation area.

Check the location.

or

The localizer detects a disturbance.

Eliminate possible sources of interference:

- An instrument on the localizer
- Instrument table on/under the plate

Status indicator iPad Remote Control

In case of use of the iPad Remote Control the connection is shown with the Remote Control Icon in the status bar.

The icon is not displayed when the iPad Remote Control is not connected.



Status indicator of connected
iPad Remote Control



Status indicator of connected
iPad Remote Control during data exchange

Status bar

The status bar is located on the top of the navigation screen. System instructions are displayed here. The instructions on the screen provide the steps to be carried out during patient registration. Follow these instructions to prepare the system for navigation.

12. Modes of operation

The Fiagon Navigation System has three modes of operation that are automatically switched dependent on the situation and user interaction.

- Navigation Mode (for navigation interaction)
- Mouse mode (for software operation interaction)
- Full screen video mode

Navigation mode

In this mode the navigation information in of the instrument is displayed in the image data. The mode is entered automatically when the instrument is being guided in the measurement field of the navigation sensor.



The status indicator turns green

The display is optimized for displaying the navigation information. All software interaction buttons and the mouse cursor are blinded out. The navigation instrument has the focus.

Full screen Video mode

This mode is configured in the applications (modules) offered by Fiagon that utilize a video signal of a medical video device (endoscope or microscope).

In this mode the connected video signal is displayed in full screen on the display. The mode is entered when no navigation information is available for 3 seconds. That is when the navigation instrument is currently not used and is guided out of the measurement field of the navigation sensor



The status indicator is red

The user automatically gets the available video information in optimized full screen display.

Interaction mode

In this mode the user can interact with the functions of navigation software by using the iPad Remote Control (mouse optional). The mode can be entered at any time by tapping the iPad Remote Control (or clicking once on any of the mouse buttons).

With optional usage of mouse: The interaction buttons and the mouse cursor are faded in. The mouse cursor has the focus and operation by mouse is possible.

The interaction mode automatically returns to navigation mode or Full screen video mode after a 5 second of inactivity (of the mouse).

13. Patient registration

The patient registration as part of the procedure for enabling navigation is described in the respectively application note for the chosen procedure.



Refer to the application notes for detailed guidance for performing the patient registration for your procedure.

The following steps are performed during Automatic Registration process:

1. Move the MapperFrame around the patient's face.
2. Take 3 pictures with the iPad Remote Control.
3. Verify the navigation information. Confirm or restart the registration.

The following steps are performed during the registration process:

1. Use the navigation instrument to touch the three defined registration markers.
2. Use the navigation instrument to scan the skin surface of the patient.
3. Verify the navigation information. Confirm or restart the registration.

The system will prompt instructions in the status bar for each step.

i **NOTE:** No interactions others than with the navigation instrument are necessary. Holding the instrument still at one point will be detected as interaction to record a point or verification/rejection.

NOTE: For the registration process, a minimum number of markers is required on the surface. If this number is not reached, e.g., because the pointer has been lifted repeatedly, you will be prompted to repeat the registration process.

NOTE: For the Automatic Registration process, the markers of the MapperFrame are required to be in the pictures. If this is not fulfilled, you will be prompted to repeat the registration process.

Verify patient registration

Evaluate the system accuracy after patient registration.

The status bar displays the following requirement: "Confirm Registration"

The 3D-model on the screen is now replaced by the video view. You can now use the endoscope or microscope along with the navigation in order to confirm the registration.

Do the following:

- Using the instrument and touch several anatomically distinct positions on the patient (e.g., tip of the nose, wrinkles) and in the sinus anatomy. Make sure that the tip of the pointer in the image data corresponds to the actual position on the patient with sufficient accuracy.
- If you are satisfied with the accuracy, you can activate the navigation process. To do this, keep the instrument in one position until the progress bar is displayed and completed. If the activation is approved, you will hear a confirmation tone.



WARNING: Check the displayed position of the instrument on several anatomical structures. If the deviation is significant, the patient registration process must be rejected and repeated.

WARNING: Do not start an operation before the registration has been confirmed.

i **NOTE:** You can reject a patient registration that has not yet been completed at any time by touching the screw of the patient localizer.

Restart patient registration

If you are not satisfied with the displayed positions you should restart the patient registration and carry it out once more

- To restart, place the instrument onto the little hole of the patient localizer
- You will hear a confirmation tone, a pop-up window with “Resetting Registration” appears
- If you place the instrument onto the patient localizer within 3 seconds, the registration will be restart automatically (this conformation step makes sure that you don’t restart the registration if you don’t want to)
- If you are sure to restart the registration you can also keep holding the instrument onto the patient localizer, the registration will be restart automatically as well
- Repeat the patient registration.



NOTE: Please check the instructions for use for iPad Remote Control to learn how to restart the patient registration here.

14. Display of the navigation information

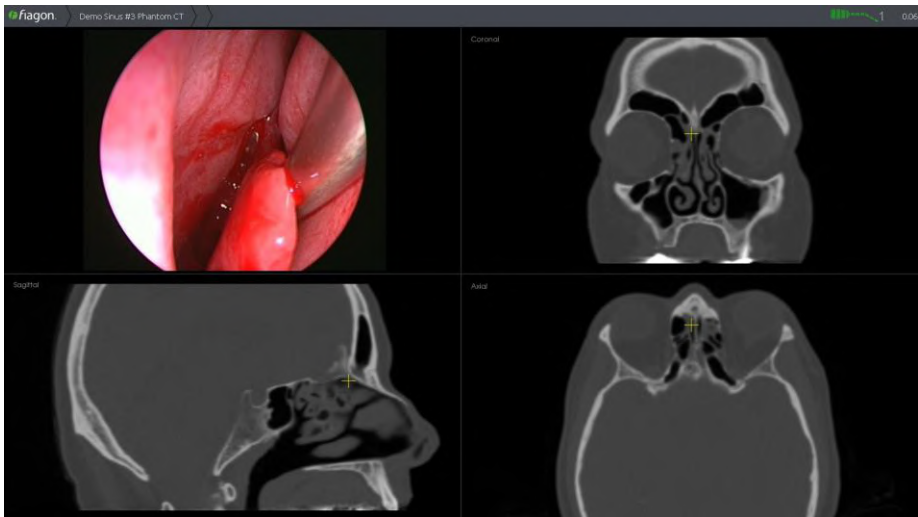
Once the patient registration has been completed, you can use the navigated instrument for treatment.

Navigation display

By moving the instrument into the operating range, the orthogonal layers are displayed along with the navigation information and the video image is displayed in the split screen.

The position of tip of the instrument is indicated by the cross hairs in the orthogonal layers (axial, sagittal and coronal). The cross-sectional images follow the current position of the tip of the pointer.

Planned structures in the data set will be displayed in the slice image that is intersecting the line or parts of it. If collision warning is enabled the cross hair will turn red if the displayed cross hair is closer than 2 mm to the structure line planned in the images.

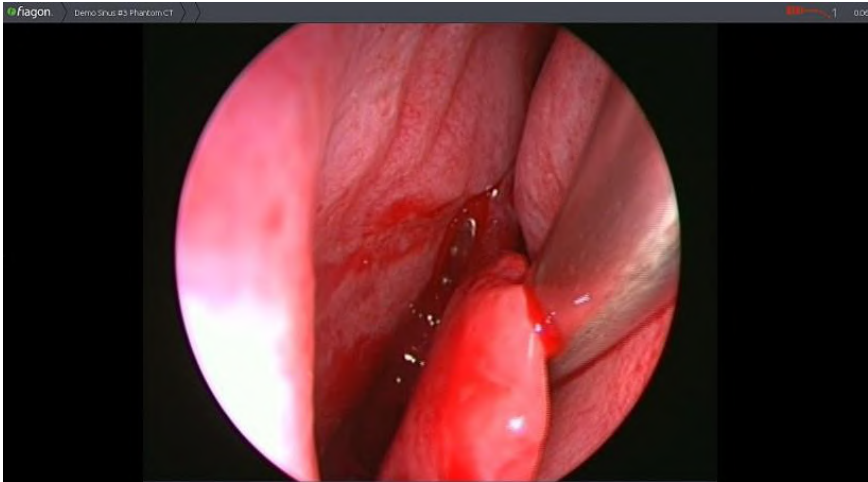


If the patient localizer and/or the surgical instrument cannot be detected by the navigation sensor or if an interference occurs, the status indicator "Localizer" and/or "Pointer" are indicated red.

If the navigated instrument is moved outside of the operating range, the position that was last detected by the navigation sensor is displayed. This last position typically lies outside of the patient anatomy.

Display of the endoscopic image

If the navigation information is not needed, the endoscopic video image is displayed on the navigation screen in full size (Full screen mode).



If the navigated instrument is outside of the operating range (e.g. on the instrument table), the endoscopic image will be automatically displayed on the screen in full size.

If the instrument is moved back into the operating range, the split screen with the navigation information is shown automatically.

i NOTE: If the surgical instrument cannot be detected due to an interference in the operating range, the display also switches to the full-size endoscopic image as long as the interference is present. The status display is also visible in the full-size endoscopic image.

Changing the instrument

During an operation, you can use different Fiagon navigation instruments.

Insert the plug of the surgical instrument into the appropriate socket ("Instrument") on the navigation module.

The instrument can be used after the confirmation tone. The registration will not be rejected.

15. Repeated checking of the navigation information

Repeatedly check the accuracy of the navigation information when using the device by holding the surgical instrument in one distinct anatomical position that can be easily identified. Compare this position with the position on the display.

An integrated timer makes a determination of time distance possible which are used for displaying verification reminders. The system standards value is 15 minutes. Other options can be defined in the configurations.



NOTE: There will not be displayed any verification reminder message at the defined time interval if the option “disabled” is selected.



WARNING: Fiagon advises strongly against the deactivation of the timer.

Despite of the frequent check of the anatomic landmarks the verifications during the operation should be performed at the following times:

- before critical decisions
- after changing instruments
- after force effects at the localizer
- at defined time distance, which are displayed the verification timer
- after every major change of the anatomy

The signal “confirm registration” is displayed when:

- after restart and re-establishment the registration
- if the patient localizer connected again



WARNING: The verification step is necessary for ensuring the accuracy of the navigation system. Disregarding this step can lead to an increased safety risk.

Safety notes

If you suspect that the position displayed on the screen does not correspond to the actual position, repeat the patient registration.

Do not use the navigation system if the data still do not correspond to each other after several registrations.

The navigation system is intended as guidance for the surgeon. Note that its accuracy can be influenced by operating errors, errors during the scanning process or other internal errors. Most important for the proceedings during an operation is the evaluation of the operating range based on direct vision.



WARNING: Make sure that the patient localizer does not slip during the operation. Otherwise, the navigation information is incorrect. As a result, the registration must be repeated.

CAUTION: During the operation, check if the display of the surgical instrument is correctly displayed in the radiological data by regularly touching a landmark that is clearly visible. If you detect an error in the display, carry out the patient registration once again.

16. Screenshot and video recording

During the procedure, you can take screenshots and record video sequences for a documentation of the operation.

- To take a screenshot, press the photo button on the navigation module. Once the screenshots has been taken, you will hear a confirmation tone.



- To record a video sequence, press the video button on the navigation module.



- You will hear a confirmation tone. The video recording will be displayed by a green dot in the status bar and at the video button.



- To stop the recording, press the video button once more.
- A yellow triangle is displayed if the available disc saving capacity is less than 2h video (each minute of video generates 62MB of data).



- A red triangle is displayed when no more video data can be recorded.



NOTE: Please check the instructions for use for iPad Remote Control to learn how to record screenshots or videos [here](#).

17. Export of the documentation

You can export the documentation after the operation and save it on a CD-R, a DVD or a USB stick.



All images and videos of the operation are saved in the patient data. Use the patient manager to export these images and save them on a CD /DVD or a USB stick to view them on a PC

- Select "LOAD DATASET" or patient info (if a patient is already loaded).



- Patient manager will open.
- Select a patient from the list on the left (system) whose data and documentation you want to export.
- Click the button "DVD" to burn the patient data onto a CD/DVD.
- Click the button "USB" to save the patient data onto the plugged-in USB stick



Content of the export

After the export, the following files will be saved on the external source:

- -Radiological image data (DICOM) in the dicom directory
- -Images and video sequence of the operation in the [patientencode]/images directory



WARNING: The content of the exported data might contain sensitive healthcare information. Prevent unauthorized access

You can open the documented image and video data in a graphic or media program by clicking them.

Deleting patient data from the system

- Select a patient from the list on the left (system) whose data and documentation you want to export.
- Click the button "Delete."
- The patient data set will be deleted from the system.