

1 Instructions for Use

Product

E 01 1430 VirtuEye

Manufacturer:

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For US market only. This document is intended to provide information to an audience of the US.

Explanation of symbols



Manufacturer / Manufacturing date



Reference number/Order number



Serial number



To ensure safety, follow the instructions for use



Marks an information message indicated as a note



Refers to documentation indicated as a note. Consult instructions for use. Follow the supporting documentation



Indicates the temperature limits to which the medical device can be safely exposed



Indicates the range of humidity to which the medical device can be safely exposed



Indicates the range of atmospheric pressure to which the medical device can be safely exposed



Fragile, handle with care (symbol on transport box)



Keep dry (symbol on transport box)



Keep away from sunlight/heat (symbol on transport box)



Applied part type BF



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



Federal law (USA) restricts this device to sale by or on order of a physician

1. General information

The product VirtuEye supports the registration process for image guided surgery procedures with the Cube Navigation System for ENT interventions.

The device VirtuEye is a component of the Cube Navigation System produced by Fiagon GmbH.



DANGER: Devices emitting electromagnetic radiation to a high degree can influence the proper operation of the device. Turn off or remove cellular phones or similar devices close to the device.



CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.



CAUTION: Read the instructions for use carefully and follow the instructions before using the device.

CAUTION: Before using the device, the VirtuEye must be treated according to the treatment instructions. The VirtuEye is delivered in NON-STERILE conditions.

CAUTION: Do not open or alter the device! In the event of unauthorized intervention, any warranty and product liability become null and void. This can result in damage to the device. If the device is altered, it may result in reduced interference resistance of the device.

CAUTION: Make sure not to use the device without a valid instruction for use.

NOTE: In case the Navigation System is not able to recognize VirtuEye, the device cannot be used.

2. Indications for Use

The Cube Navigation System and its components are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Cube Navigation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to:

- ENT Procedures;
- Transsphenoidal access procedures.
- Intranasal procedures.
- Sinus procedures, such as Maxillary antrastomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.
- ENT related anterior skull base procedures

3. Intended use



CAUTION: The application of the VirtuEye is limited to the intended use described here.

VirtuEye is designed for use as part of the Cube Navigation System for navigated ENT interventions in combination with the Navigation Unit Cube4D and the Navigation Software ENT with the feature Photo Registration activated.

VirtuEye is intended to support the process of patient registration. It is intended to deliver stereo images and an RGB image of a face of a lying patient to the Navigation Unit / Navigation Software via an USB3 cable connection and to deliver a position information to the Navigation Unit via an instrument connection for further processing

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on the Navigation Unit by the Navigation Software. The software will use the information to calculate a 3D surface grid for the patient registration process.



NOTE: Refer to the instructions for use of the Cube Navigation System as well as the Navigation Software. VirtuEye may only be used if the safety instructions of the Navigation System have been followed.

The Cube Navigation System and its components are intended for use by healthcare professionals (physicians) only. An operator is anyone who uses the Navigation System.

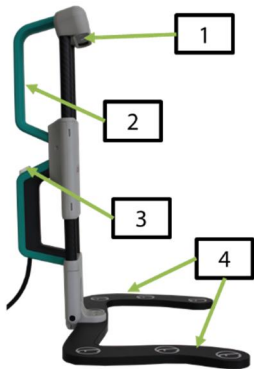
The instructions for use of the Cube Navigation System describe the proper use of the entire Navigation System in detail.

4. Compatible devices

VirtuEye may only be used as an accessory of the Navigation System of Fiagon GmbH. The VirtuEye is intended and compatible for use with the following devices/components groups of the Cube Navigation Systems.

Group	Compatible Devices
Navigation Unit	E 01 1106 - HD/8 Navigation Unit Cube 4D E 01 1106 – 4K/8 4K Navigation Unit Cube 4D
Navigation Software	Software Version 4430 and higher Application: Sinus
Navigation Sensor/ Headrest	ALL
Navigation Instruments	ALL
Patient Localizer	ALL

5. Device description



1. Registration Camera for acquiring the patient registration images.
2. Stabilizing Grip for secure hand holding position.
3. Registration Trigger Button for triggering the capture of the registration images and for resetting registration.
4. MapperFrame: Part of VirtuEye to deliver reference position information for the registration calculation. Aid to position the device to the patient's head.

6. Set up device for patient registration

Prepare the Navigation System as described in the instructions for use of the Navigation System: Loading patient data, mounting Navigation Sensor, preparing the patient with a Patient Localizer.



CAUTION: If the Navigation System setup is altered by a person not authorized to do so, this may result in reduced interference resistance of the Navigation System.



CAUTION: Prior to each use, the user must check the proper condition of the device. Check for loose components and damage. **DO NOT** use if these conditions exist. If service is required, contact your Service Representative immediately.



NOTE: Before use check that the VirtuEye has been properly cleaned. Do not use it before properly cleaned. It is recommended to disinfect the MapperFrame part and hand parts of the device with a disinfectant towelette. (see also section 9).

Additionally, for preparing the patient registration with VirtuEye do the following:

6.1 Connection of the VirtuEye Instrument Cable

Insert the plug of the VirtuEye Instrument Cable into any available instrument green socket on the Navigation Unit or VirtuLink.

Once the VirtuEye Instrument Cable is connected, you will hear a confirmation tone.



i NOTE: If the VirtuEye Instrument Cable does not register at the Navigation System, VirtuEye cannot be used for the patient registration.

6.2 Connection of the VirtuEye USB Cable

Insert the USB plug of the VirtuEye into any available USB port on the Navigation Unit. Note that there are (2x) USB ports on the front of the Navigation Unit Cube4D and (4x) USB ports on the back of the Navigation Unit.

Once VirtuEye is connected the registration camera video streaming is displayed on the navigation screen, if a CT data of a patient is loaded.



6.3 Prepare patient for registration

- Position the patient in a vertical or horizontal orientation.
- Make sure the Navigation Sensor and Patient Localizer are connected to the Navigation Unit.



WARNING The registration can be performed on non-sterile draped and sterile draped patients, but it is recommended to perform the registration prior to draping the patient.



NOTE: If performing the registration on a draped patient ensure the eyes, nose, and checks are not covered as shown below.


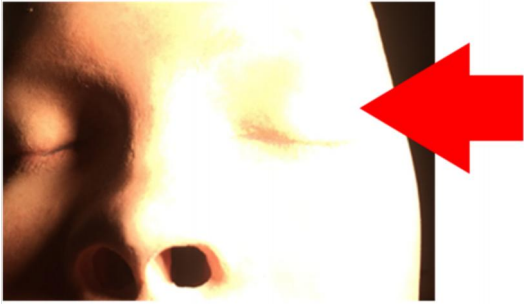


NOTE: The VirtuEye should not be used on patients who are draped completely in the face (only showing the nose). The registration will not be calculated or will be rejected.

NOTE: The VirtuEye should not be used if other equipment is covering the face (above the mouth and below the brows) of the patient. The registration will not be calculated or will be rejected.

6.4 Adjust the Lighting

- Bright and non-point light is ideal for Photo Registration.
- Turn on all the ceiling lights.
- Do not use spotlighting as they affect the camera (Example – surgical spotlighting directly on the patient's face). It might cause rejections of the patient registration by the Navigation System or during confirmation step and repetition of the registration).

Best practice	Incorrect / to avoid
	



CAUTION: In case you need to perform tactile registration instead of using VirtuEye, plan for availability of a navigation instrument that can be used for registration (i.e. RegistrationPointer, FlexPointer).

7. Patient registration

When performing the registration with VirtuEye be aware of the following:



WARNING: While using the device, please be careful not to accidentally drop the device on the patient.

WARNING: The VirtuEye is not sterile. Do not touch the sterile area with the VirtuEye.



CAUTION: Please ensure that there is no movement of the patient during the photo registration; otherwise this process must be repeated.

CAUTION: Follow the instruction to position VirtuEye in a correct manner.



NOTE: If the camera lens is dirty, it can disturb the picture quality and thus influence the Photo Registration result. Check that the camera lens is free of dirt and fingerprints.

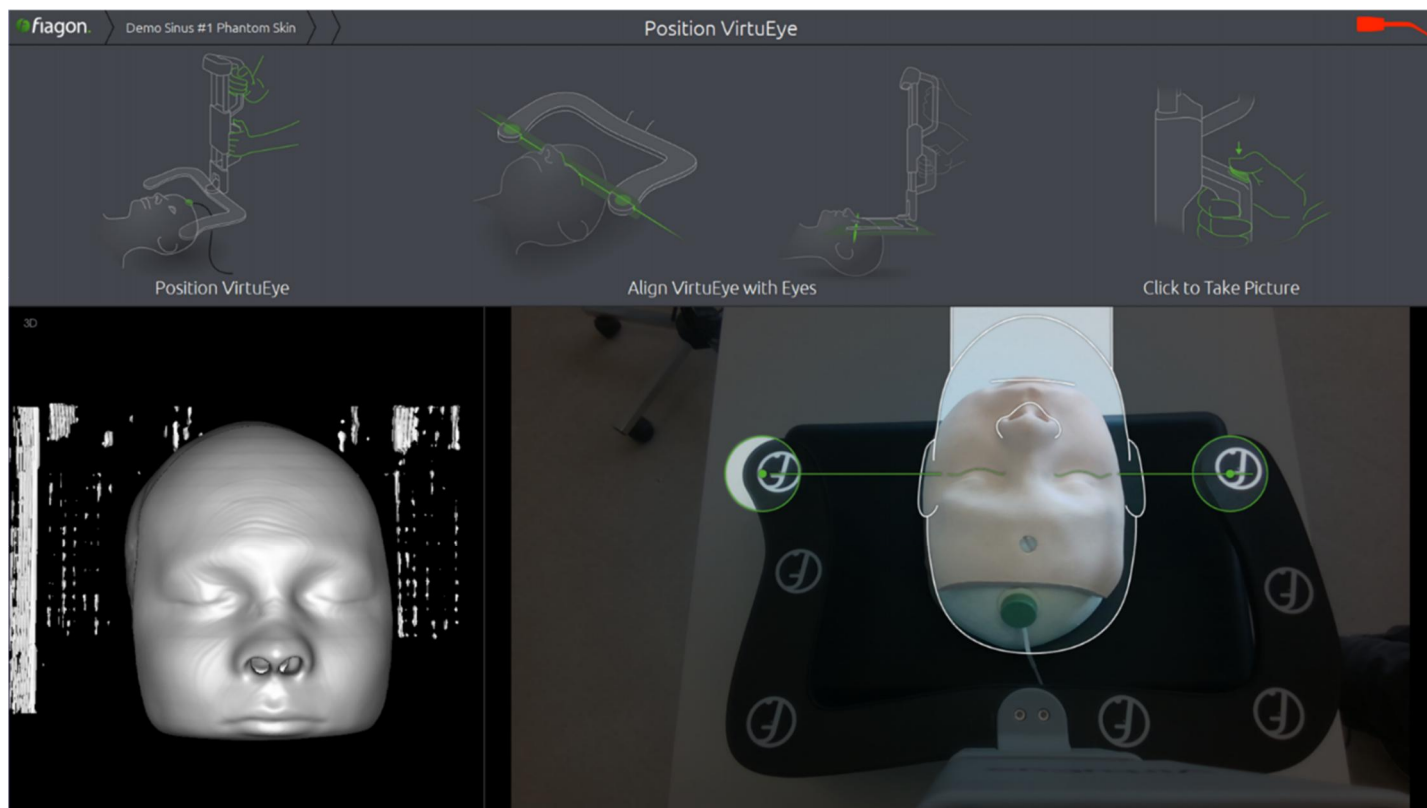
NOTE: The registration can be performed handheld.

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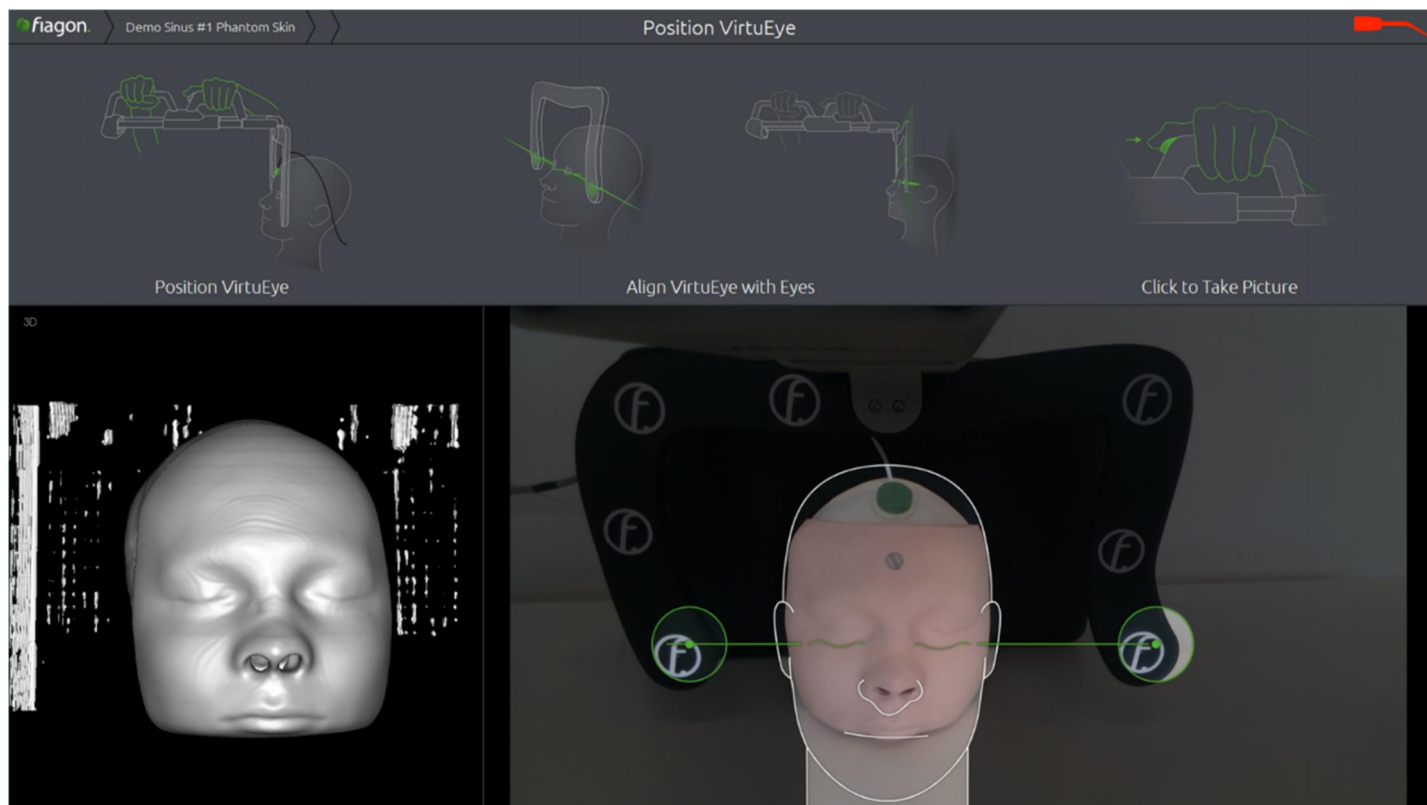
7.1 Position the VirtuEye

While securely holding the VirtuEye with two hands, place the MapperFrame around the patient's head. The MapperFrame must be in the EM field of the Navigation System.

Instructions for OR procedure:



Instructions for Office procedure:



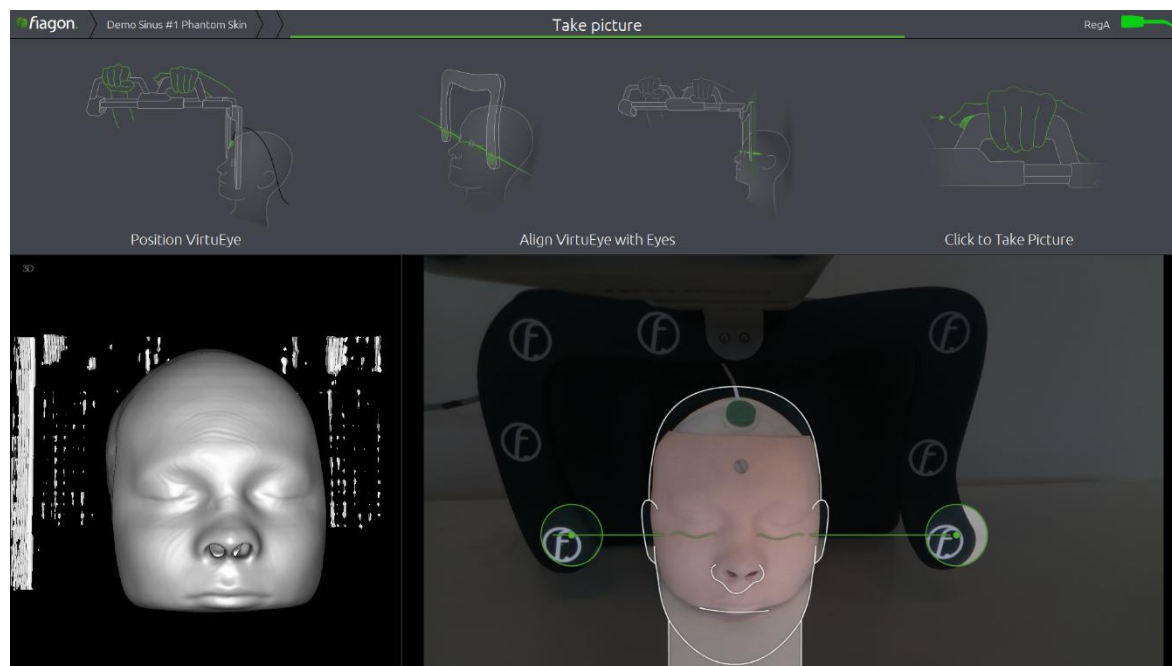
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The green instrument indicator at the top right of the screen should be solid green, confirming the VirtuEye is inside the EM-Field.



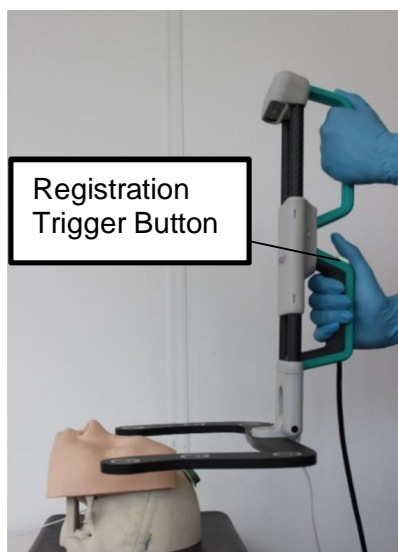
7.2 Align VirtuEye with Eyes

Once VirtuEye enters the EM field, see that the “Take picture” prompt is visible in the status bar. The camera view contains a MapperFrame and head template, which must match the MapperFrame and patient head. Ensure that the green line is aligned with the patient’s eyes.



7.3 Take Picture

When the VirtuEye is positioned correctly, hold it still and click the registration trigger button once to capture the picture.



Positioning for OR procedure

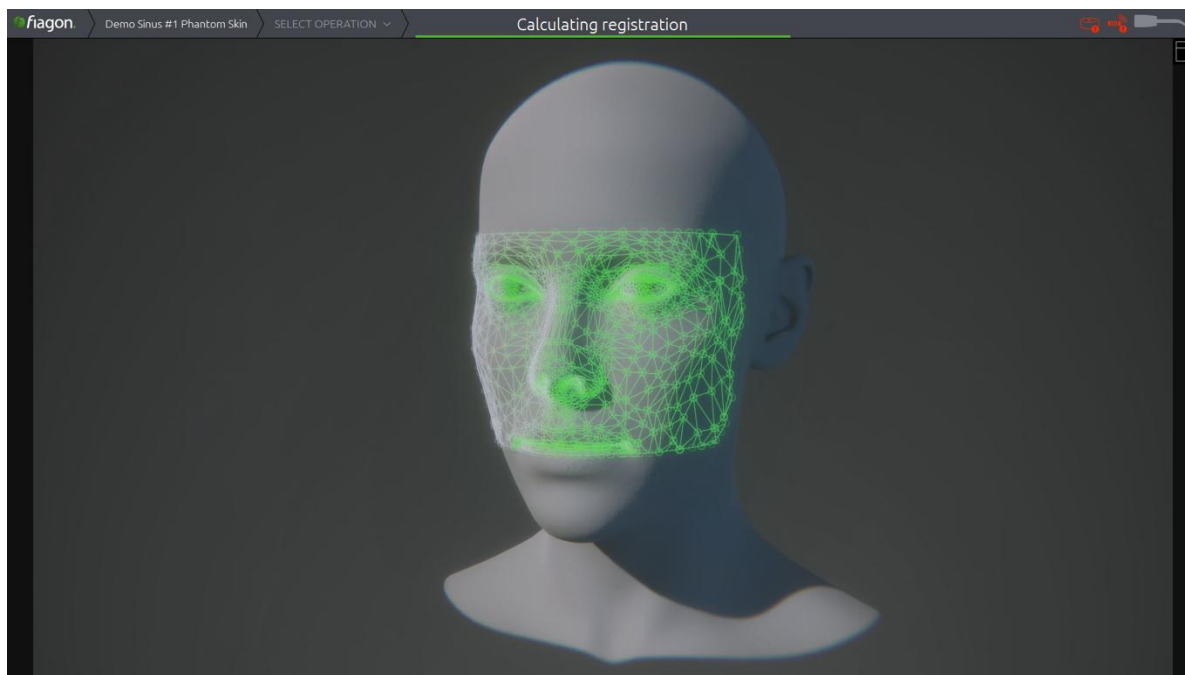


Positioning for Office procedure

The images are captured and transferred automatically to the Navigation System.

7.4 Calculating Registration

The Navigation System begins calculating registration indicated in the status bar message “Calculating registration” and the VirtuEye can be removed.



i NOTE: If the images are not acquired successfully for registration, the status bar will prompt the user to “Take pictures” again.

7.5 Confirm Registration

After registration calculation is completed, the prompt “Confirm registration” appears in the status bar and the patient registration needs to be verified.



1. Verify Patient Registration

Evaluate the Navigation System accuracy after patient registration in the same way as for the tactile registration and as described in the instructions for use of the Navigation Software ENT.

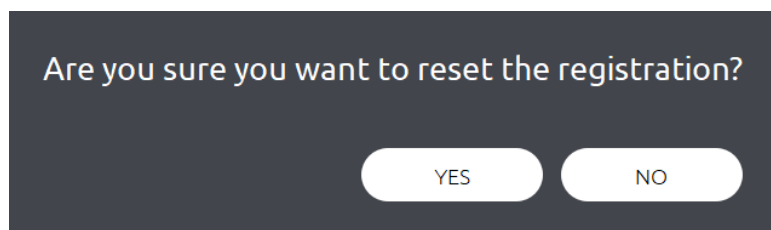
The status bar displays the following requirement: "Confirm Registration".



CAUTION: In case of significant deviation after registration remember to reset the registration and to start again.

2. Resetting Registration

If you are not satisfied with the accuracy, the registration can be reset by pressing and holding the Registration Trigger Button until the resetting registration message appears and then will automatically disappear.



3. Start New Registration



Once registration is reset, go back to step one of “patient registration” to perform another Photo Registration.

8. Specifications

REF	E 01 1430
Device name	VirtuEye
Description	<ul style="list-style-type: none"> · Registration Device · Component of Cube Navigation System · Group: Navigation accessory · Nonsterile · Reusable
Dimensions	450 mm (h) x 220 mm (w) x 145 mm (d)
Weight	1.45 Kg
Packaging	Protective Case with foam inlay
Operating conditions	Temperature: +15°C to + 35°C, Humidity: 30% to 75% without condensation Air pressure: 700 hPa to 1060 hPa
Transport conditions	Temperature: -10°C to + 50°C, Humidity: 10% to 90% non condensing Recommended Air pressure: 700 hPa to 1060 hPa
Storage conditions	Protected against dust, moisture and recontamination. Storage temperature: -10° to +50°C Storage humidity: 10% to 90% non condensing Recommended air pressure: 700 hPa to 1060 hPa

9. Cleaning and Storage

After the registration, the VirtuEye can be disconnected from the Navigation Unit by pulling the plug directly. Do not pull the cable or the bend protection as this may damage the cable of the device.

Instructions for manual cleaning of VirtuEye	
Disconnecting	Perform cleaning only if the device is disconnected from the Navigation Unit.
Manual Cleaning and disinfection	<p>Materials:</p> <ul style="list-style-type: none"> - CaviWipes™ (intermediate-level disinfectant towelettes, aldehydes free) or equivalent disinfectant towelettes <p>Method:</p> <ol style="list-style-type: none"> 1. Clean exterior surfaces of case, cable, screw, and outer face of connector, with a first towelette. 2. Disinfect surface of all above mentioned parts with a second new/unused towelette. Leave surface wet for three (3) minutes, discard used towelette <p> CAUTION: Inflammable and explosive disinfection sprays must be handled with great care since their vapors are highly flammable.</p> <p>CAUTION: Prevent liquids from getting into the camera housing or bottom housing of the VirtuEye.</p> <p>CAUTION: Do not immerse any part of the device in a disinfectant or cleaning agent. Do not rinse any part of the device.</p> <p>CAUTION: Never spray or pour cleaning solution or disinfectant directly onto the surfaces or camera, because there is a risk that the cleaning agent comes into direct contact with the components within the device and causes irreparable damage to the electrical components. Spilling liquids on any electrical device attached to the VirtuEye should warrant inspection by an authorized service representative.</p>
Cleaning inspection	Examine surfaces for visible soil/detergent/debris. If residual soil or debris are still visible on the instrument after reprocessing, all cleaning and disinfection steps should be repeated.
Inspection	The instrument should be inspected after cleaning and before use for surgery. Visually inspect the instrument for damage or wear. Visually inspect the cable and connectors.
Storage, Point of Use / Protective Wraps:	<p>After cleaning and disinfection, fold the MapperFrame up in a vertical position. For safe storage. Place the device in a protective wrapping.</p> <p> CAUTION: Use the provided storage box to prevent damage to the VirtuEye during storage</p>



CAUTION: In case the device cannot be cleaned effectively, please make sure that it is not been used.

