

Product

E 01 1420 VirtuEye V1

Manufacturer:

Fiagon GmbH
 Neuendorfstraße 23b
 16761 Hennigsdorf, Germany
 Tel: +49 3302 20121 10
 Fax: +49 3302 20121 15
 info@fiagon.de



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



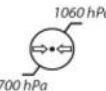
Consult instructions for use. Follow the supporting documentation



Recommended storage temperature +15°C to +35°C



Recommended storage humidity 30% to 75% without condensation



Recommended storage air pressure 700 hPa to 1060 hPa



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 V1 supports the registration process for image guided surgery procedures with the Fiagon Navigation System for ENT interventions.

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



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 before using the device.

CAUTION: Before using it, 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: 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.

2. Indications for Use / Field of application



The application of the VirtuEye is limited to the intended purpose for use described here.

VirtuEye is designed for use as part of the Fiagon Navigation System for navigated ENT interventions in combination with the Navigation Unit Cube^{4D} 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 / Fiagon Navigation Software via an USB3 cable connection and to deliver a position information to the Navigation Unit via a Navigation sensor connection for further processing on the Navigation Unit by the Fiagon Navigation Software. The software will use the information to calculate a 3D surface grid for the patient registration process.



Refer to the instructions for use of the Fiagon Cube Navigation System as well as the Navigation Software ENT.

VirtuEye may only be used if the safety instructions of the Navigation System have been followed.

The Fiagon Navigation System and its components are intended for use by healthcare professionals (physicians) only. In addition, the users must receive a training. The operator, i.e. the person or facility that is responsible for the use and service of the Navigation System, must ensure that all users of the Navigation System receive an adequate briefing in accordance with valid laws and regulations. An operator is anyone who uses the Navigation System.

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

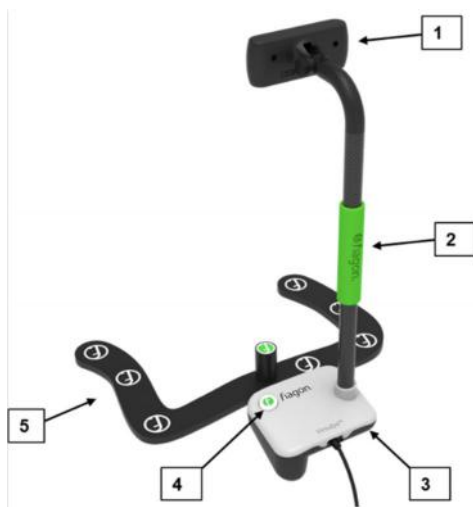
3. Compatible devices

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 Fiagon Navigation Systems.

Group	Compatible Devices
Navigation Unit	E 01 1106 -HD/8 Navigation Unit Cube 4D

Navigation Software	Software Version 4333 and higher Application: Sinus
Navigation Sensor/ Headrest	ALL
Navigation Instruments	ALL
Patient Localizer	ALL
Other Accessories for this device	Tripod Mount

4. Device description



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

5. 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 localizer.

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



CAUTION: 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 8).

CAUTION: Before use check that the VirtuEye is in proper conditions. Do not use it otherwise.

Connection of the MapperFrame

Insert the plug of the VirtuEye - MapperFrame into any available instrument green socket on the Navigation Unit or VirtuLink. Note that the white marking at the plug is at 12 o'clock position.

Once the MapperFrame is connected, you will hear a confirmation tone.



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

Connection of the Registration Camera

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 Cube^{4D} (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.



USB port (2x)



USB port (4x)

Prepare patient for registration

- Position the patient in lying down orientation.
- Make sure the navigation sensor and patient localizer are connected to the Navigation Unit.

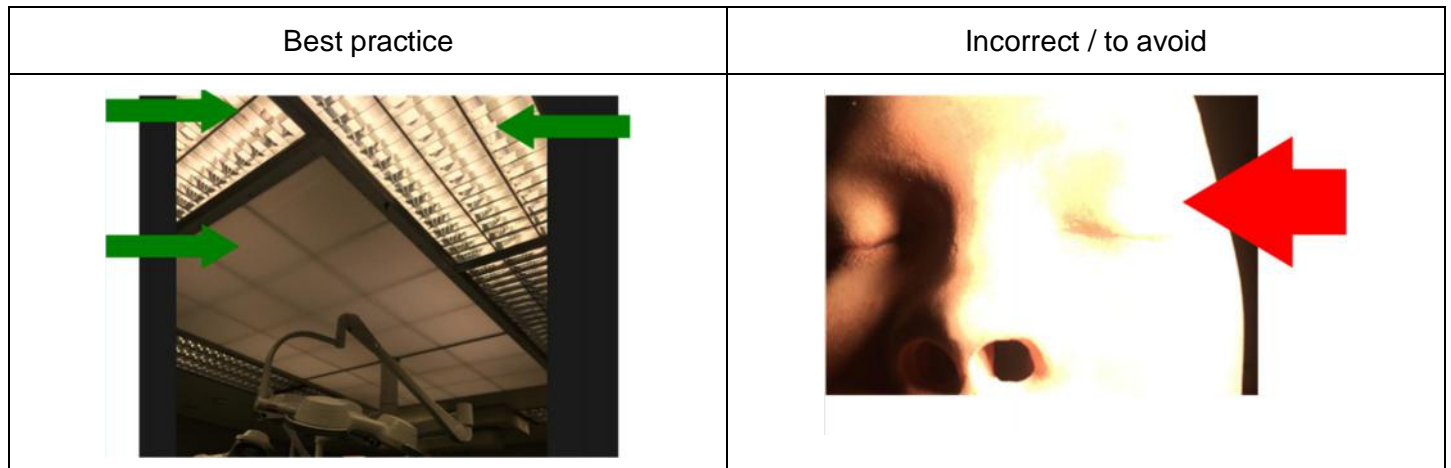
i **NOTE:** The registration can be performed on non-sterile draped and sterile draped patients, but it is recommended to perform the registration prior to draping the patient.

NOTE: 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.

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).



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

6. Patient registration

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



WARNING: When positioning the MapperFrame, securely hold the VirtuEye to prevent dropping the device on the patient or hitting the patient with MapperFrame.

WARNING: The VirtuEye and MapperFrame are not sterile. Do not touch the sterile area with the VirtuEye or MapperFrame.

CAUTION: The patient should not move during the registration. If the patient does move, reset and repeat the registration.



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 or using the tripod accessory for holding VirtuEye.

Sequence:

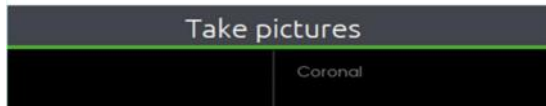
1. Position the MapperFrame.

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.

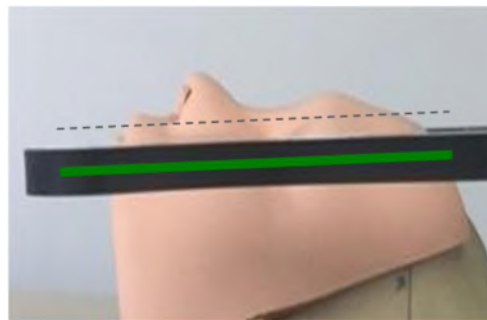
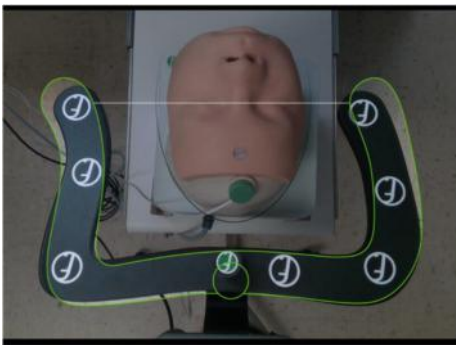
Note: The green instrument indicator at the top right of the screen should be solid green, confirming the MapperFrame is inside the EM-Field.



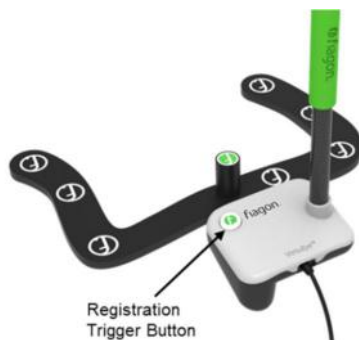
- Once MapperFrame enters the EM field, see that the “Take pictures” prompt is visible in the status bar.



- The camera view contains a MapperFrame and head template, which must match the MapperFrame and patient head. Ensure that the white line is aligned with the patient’s eyes.



- When the MapperFrame and camera are positioned correctly, hold it still and click the registration trigger button once to capture the picture.



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

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

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

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

7. 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".

The following **safety notes of the Navigation Software ENT** for the verification of the registration need to be respected for a registration supported by VirtuEye as well:



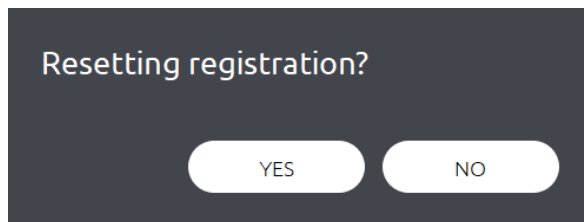
CAUTION: Check the displayed position of the instrument on several anatomical structures. If the deviation is significant, the patient registration process must be rejected and repeated.

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



NOTE: You can reject a patient registration that has not yet been completed at any time by touching the patient's localizer.

8. 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.






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

7. Specifications

REF	E 01 1420
Device name	VirtuEye V1
Description	<ul style="list-style-type: none"> · Registration Mapper Device · Component of Fiagon Navigation System · Group: Navigation accessory · Nonsterile · Reusable
Dimensions	240 mm (h) x 169.5 mm (w) x 7.5 mm (d)
Weight	0.469 Kg
Packaging	Protective Case with foam inlay

8. Cleaning and Storage

After the registration, the MapperFrame and Registration Camera 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 V1	
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</p> <p>Do not immerse any part of the device in a disinfectant or cleaning agent.</p> <p>Do not rinse any part of the device.</p> <p>Prevent liquids from getting into the camera housing or bottom housing of the VirtuEye.</p> <p>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 Fiagon service representative.</p> <p>To prevent damage, Inflammable or explosive disinfection sprays must not be used.</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> <div style="text-align: center;">  </div> <p> CAUTION: Use the provided Fiagon storage case to prevent damage to the VirtuEye V1 during storage</p>