MICS MKR simulator	**REF: ZYX-1**		
Annulus and mitral valve dummies	**REF: ZYX-2**	**Training instruments:**	
Suture ring dummy	**REF: ZYX-3**	**HCR atraumatic forceps**	**REF: ZYY-1**
Papillary muscle dummies	**REF: ZYX-4**	**HCR valve scissors**	**REF: ZYY-2**
Suture fixation	**REF: ZYX-5**	**HCR nerve hook**	**REF: ZYY-3**
		HCR knot slider	**REF: ZYY-4**
LifeLike Mitral valve dummy	**REF: ZYX-7**	**TC HCR needle holder**	**REF: ZYY-5**
LifeLike Mitral valve dummy with Papillary muscle and Chordae	**REF: ZYX-8**		

Intended use:

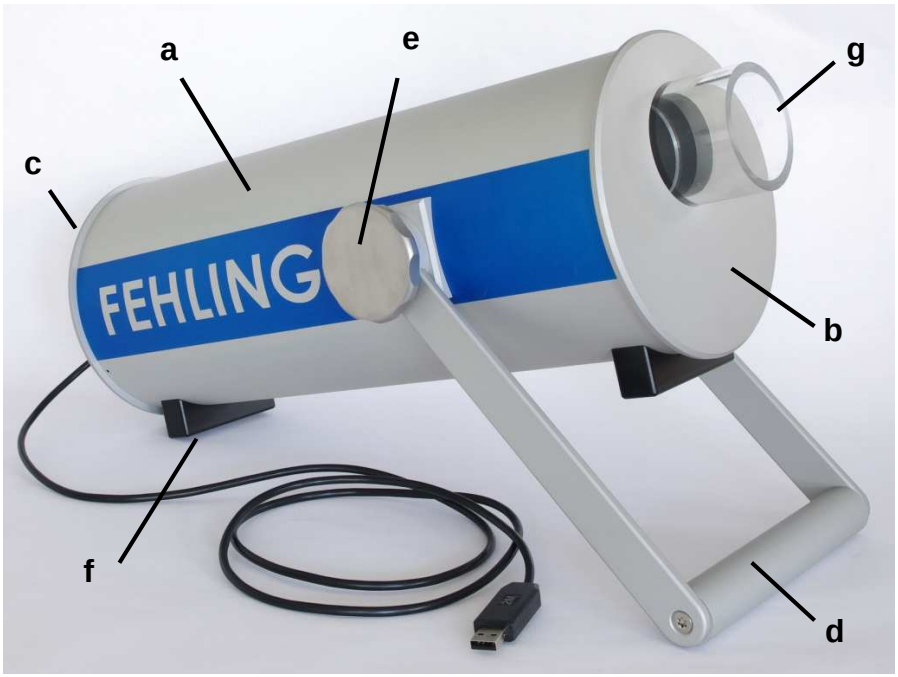
The simulator serves to develop and refine manual/tactile skills of surgeons on a dummy instead of 'learning by doing' in a stable and during the operation of a patient. The simulator was especially designed for operation techniques of the minimum invasive cardiac surgery. The fields of application include e.g. annuloplasty, chord replacement, triangular resection of the posterior cusp, or the implantation of a synthetic mitral valve.

Caution: The simulator and the training instruments are intended exclusively for use in the wetlab. Using the instruments in the operating room is a non-intended use.

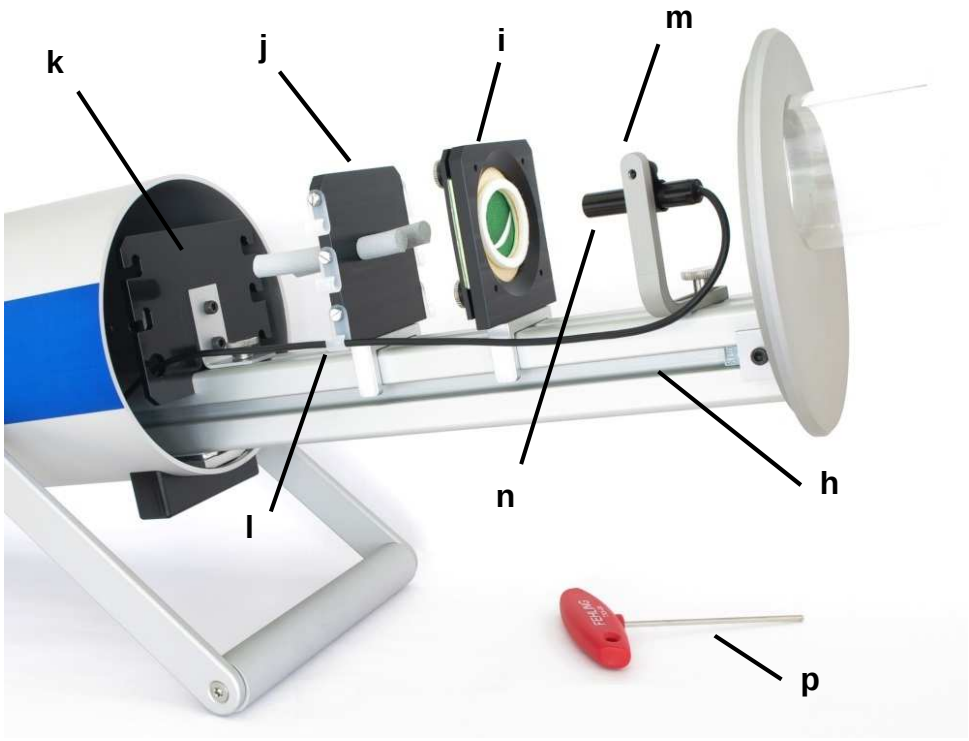
Components of the simulator:

The simulator consists of the following components

a) Simulator housing
b) Front panel
c) Rear panel
d) Carrying handle
e) Locking screw
f) Stands
g) "Skill enhancer" in two lengths



h) Drawer
i) Object seat for annulus and mitral valve dummies
j) Object seat for papillary muscle dummies
k) Instrument seat
l) Clamping clips
m) Camera seat
n) USB endoscope camera
o) Software CD for camera
p) Hexagon screwdriver 3mm (Item No. TXX-0X)



The components can be divided into external elements (a-g) and internal components (h-p).
Additional complementary products especially designed for the simulator are:

1 Annulus dummy (yellow)
2 Mitral valve dummy (green)
3 Suture ring dummy
4 Papillary muscle dummy (grey)
5 Training instruments
6 Suture fixation

During use:

Positioning and opening the simulator

For an optimum footing the simulator is placed on the two stands on an even ground. To open the simulator the drawer that is attached to the front panel, is pulled out of the tube. To do so, the carrying handle must be folded up or down.

Closing the simulator

To close the simulator push the drawer in slowly and carefully. When closing in the angular/inclined position avoid to push shut in a jerky manner and too strong. The instruments might fall out of the brackets or bump against the rear panel what may cause damage to the distal instrument end. In addition there is danger of pinching the fingers and/or the camera cable.

Caution: When opening and closing the simulator care must be taken not to pinch the camera cable. When closing it is advisable to pull the cable carefully with one hand through the rear panel out of the simulator housing at the same time.

Adjusting the carrying handle

The carrying handle can be locked in any position by loosening and tightening the locking screws on both sides of the simulator. The angle (28° maximum) and the height are simultaneously adjusted by changing the position of the carrying handle. Thus the working position can be adapted perfectly to the different postures of the operator (standing or sitting). Always support the simulator housing with the free hand when repositioning it.

Note: It is recommended to lubricate the locking screw regularly. Apply a small amount of lubricant to the thread of the screw only.

Application of suture retainers

The hook tape (item No. ZYX-5) is assigned to retain sutures as used when implanting annuloplasty-rings. We recommend to cut ca. 1.5 – 2.0 cm long pieces. They are self-adhesive. Apply these pieces (after removing protection foil) as shown in the below image or according to your individual preference. Fix the sutures coming out of the simulator properly on the hook tape elements. That can be done in both closed and open position of the drawer and with or without the "skill enhancer".

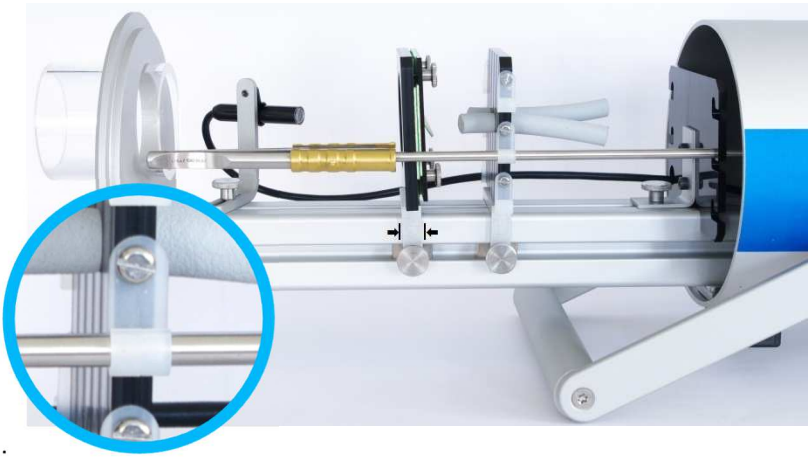
Adjusting the "skill enhancer"

The "skill enhancer" serves to simulate different anatomies. For that the "skill enhancer" can be pushed into the provided hole of the front panel in different depths. To further increase the level of difficulty, soft tissue retractors with a smaller diameter can be inserted into the "skill enhancer" as well.

In the initial stage we recommend to work without or (to avoid scratching the front panel) with the small "skill enhancer": This will ease the approach.

Installing and removing the instruments

Up to five tube-shaft instruments can be stored inside the simulator, like e.g. the training instruments made specially for the simulator (see p. 1, par. 1). To do so, first pass the distal working ends of the instruments through the angular oblong holes of the instrument seat and then click them into the clamping clips that are attached to the object seat for the papillary muscle dummies. To be able to place the handle grips of the instruments between the front panel and the object seat it might be necessary to change the position of the object seats and the camera bracket. The Objectseat for the annulus and mitral valve dummies has to be moved to the “Park position” – marked with the →| P |← sticker on the guiderail. The instruments have to be removed before the simulator is used for training purposes. The removal of the instruments is done in reverse order by analogy with the installation steps.



Displacing and removing the object seats

The object seats can be displaced along the profiles. To do so, loosen the knurled screw on the right side a little. Now it is possible to reposition the object seat by moving the knurled screw and the element guided in the groove. To remove the object seat the knurled screw on the right side must be loosened so much that the slide can be pulled out vertically upward.

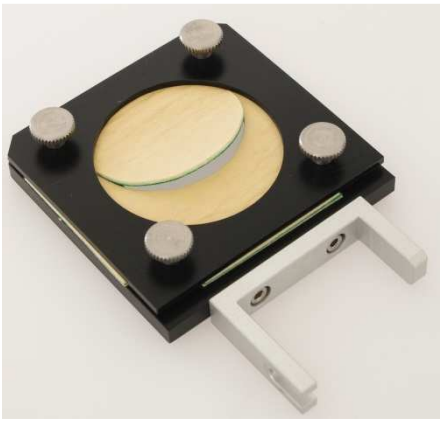
Caution: Never unscrew the knurled screw completely out of the guided element.
Hold the object seat on both sides during the displacement.

Installing the papillary muscle dummies

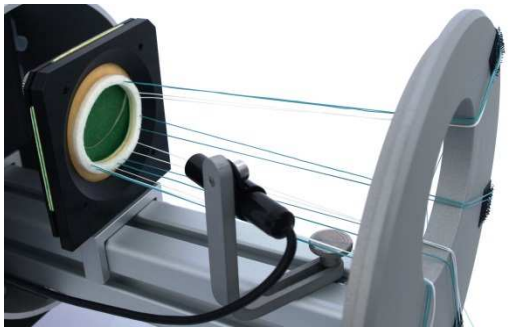
The available papillary muscle dummies (article number ZYX-4) are always used in pairs as well. The dummies are provided as stings of 75 mm. Before they are used in the simulator they can be cut to measure using a pair of household scissors for example. We recommend a length of 25 mm per papillary muscle. Depending on the use, other lengths might be helpful. Alternatively, the papillary muscle dummies can also be installed in one piece. After use the dummies are just pulled through the mounting hole and the used ends are cut off. To install the dummies it is recommended to remove the entire object seat. To do so, the knurled screw on the right side must be loosened so much that the slide can be pulled out vertically upward. Outside the simulator the two dummies can be inserted into the two holes of the object seat. Depending on the tolerance of the dummies, the installation is easier if they are pressed together between index finger and thumb first and then pushed forward by slightly turning them.

Installing the annulus and mitral valve dummy

The available annulus and mitral valve dummies (article number ZYX-2) are always used in pairs. To install the dummies it is recommended to remove the entire object seat. Outside the simulator the four knurled screws on the rear of the object seat can now be unscrewed and the attachment disk removed. First the annulus dummy (green), then the mitral valve dummy (yellow) and last the attachment disk are placed on the object support. The object support must be oriented such that the longer leg of the U-shaped guide element shows to the left. The edges of the dummies must finish flush with the upper edge and the lateral edges so that the threaded holes are not covered. Now the knurled screws are screwed in again, by which the dummies are firmly clamped between the object support and the attachment disk. Both types of dummies are two-colored (front and back) and can be combined at will, by which the level of difficulty can be increased or decreased.



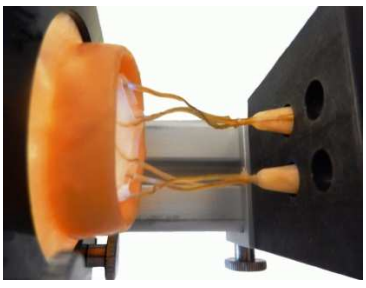
Use of the annuloplasty-rings (dummies)



These dummies (item No. ZYX-3) made of felt are designed to simulate the suture ring of a mitral valve prosthesis. Shape and size are according to the annulus dummy ZYX-2.

Further attachments

Synthetic Mitral valve dummies without (ZYX-7) or with (ZYX-8) Papillary muscle and Chordae can be also used in the simulator. The installation is performed in the same manner as the procedure described above.



During use spray dummy with regular tap water every 30 minutes to prevent dummy from drying-out and loosing shape. The synthetic dummies are reusable. Rinse dummy after use and store with some drops tap water in a zip lock bag. To ensure longtime reusability store dummy in a plastic container filled with tap water.

Adjusting the camera bracket

The camera is already attached to the clamp of the camera bracket. Guide the cable of the camera through the hole on the instrument seat and through the lowest clamp of the fixation bracket for the papillary muscle dummies

The USB endoscope camera installed in the simulator must be adjusted such that the complete situs is visible and sharp. The distance between camera and object support should be 4-6 cm. The camera bracket provides several adjustment options to position the camera in the best way. On the one hand, the camera can be rotated inside the clamping clip by 360°, on the other hand, the clamping clip can be inclined in different angles. For this purpose, loosen and tighten the screw of the clamp, utilizing the hexagonal screwdriver TXX-0X.

The distance between front panel and camera bracket can be varied by loosening the knurled screw and displacing the sliding block that is guided in the groove. In addition, the angle section has an oblong hole that allows to laterally displace and to rotate the camera bracket.

Using the endoscope camera

The endoscope camera must be connected to an external imaging system, for example a laptop computer.

The following specifications are required:

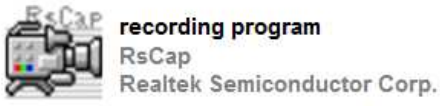
- CD-Drive
- USB 2.0- interface
- Internal memory: 64 MB or higher
- CPU: Pentiums 300 or higher
- Hard disk serviceable space: 12 MB or above

The camera is provided with a so called plug-and-play function. To use it, the USB plug of the camera is connected to a free USB port on the PC.

The camera has four integrated LEDs of which the intensity can be adjusted using the rotary control at the switch. If the LEDs do not light after connecting, please reconnect the USB endoscope camera with the PC and, where applicable, use another USB port.

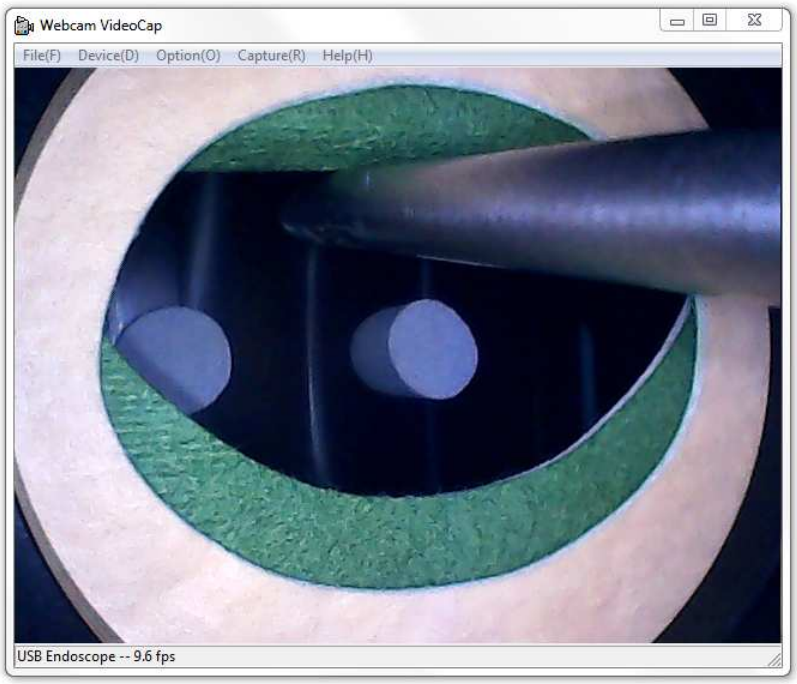
Use with Windows operating system

To visualize and to record videos and photos we recommend using the application "recording program" included on the enclosed CD.



The software should be copied to the hard disk of the device used.
Use the right mouse button to click on the camera-Icon and choose → “copy“ (Ctrl +C); then insert the file in the appropriate directory on the hard drive or on the desktop by right-click → "paste" (Ctrl + V)

The application is easy to use and well-structured and offers several setting option that can be saved for repeated applications.



At the beginning a folder to save recorded files to has to be selected in the *File (F)* menu.

Make sure that the USB endoscope camera is selected in *Device (D)*.

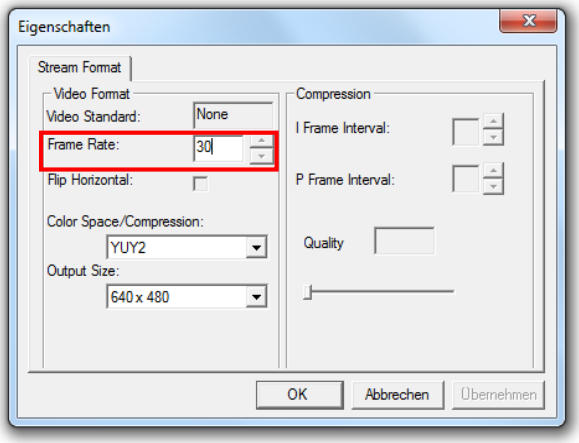
If the check mark is set at *Preview* in the *Option (O)* menu the live picture of the camera is shown (similar to figure on the left).

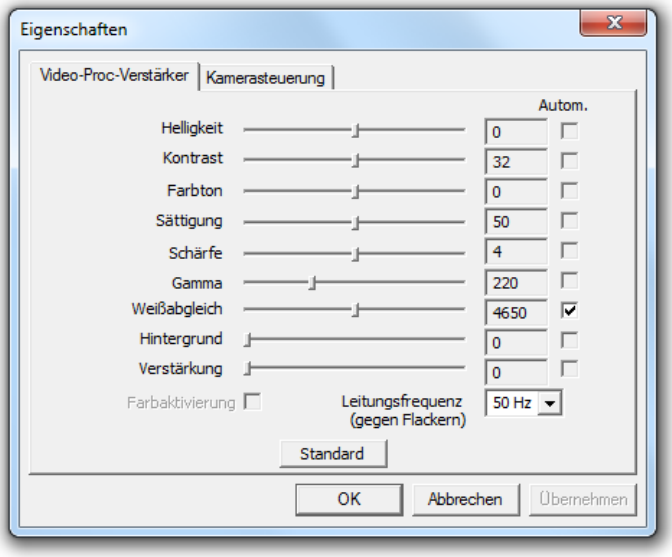
If no image is shown, please close the application and restart it. Try removing the USB camera and reconnect, if applicable, to another available USB port

All functions and settings for the recording of videos (*Start Capture (S)*) and photos (*Snap Shot (P)*) can be found under the menu item *Capture (R)*.

Ensure that the frame rate "*Frame Rate*" in the *Video Capture Pin... (I)* submenu is set to the maximum value of 30 fps (red box).

Other options available in the *Video Capture Filter... (C)* submenu are brightness, contrast, hue, saturation, resolution and gamma correction, etc.





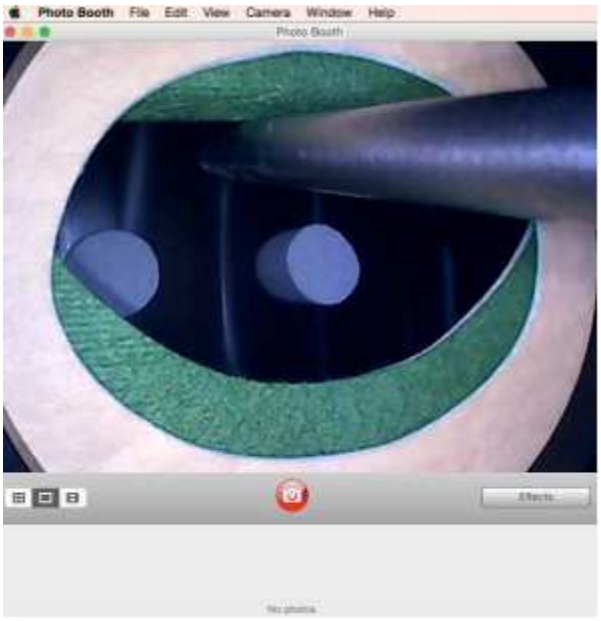
Note: The software included on the enclosed CD does not work with Mac operating systems.

Use with Mac operating system

It is possible to use the pre-installed program Photo Booth. Photo Booth is a software application for taking photos and videos with a (internal or external) camera or a webcam from other manufacturers.

After connecting the camera, the "Photo Booth" icon (similar to picture on the left) in the Dock must be selected (double-click) to open the application.

If the USB endoscope camera is selected in the *camera* menu, the live picture of the camera is shown (similar to figure on the right).



If no image is shown, please close the application and restart it. Try removing the USB camera and reconnect, if applicable, to another available USB port

Further settings and options, as well as detailed instructions on using the software, can be found in the software help file.

Cleaning	
	Caution: To clean dirt and dust off the simulator only a damp, lintless and soft cloth without addition of cleansing agent may be used. The inside of the simulator can be cleaned with a household vacuum cleaner, if required. If the instruments are dirty they can be cleaned under running water with a soft brush and subsequent wipe disinfection.

Storage / Symbols

- Store in cool, dry place (5-30 °C); do not expose to direct sunlight.
- Relative humidity: 30% - 70%, non condensing.

Protect from excessive heat!	Store in dry place! Do not store under +5 °C and over +40 °C for prolonged periods!	Observe instructions for use	Article number	Attention

Manufacturer::	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein/Germany Phone: 06188-957440 Fax: 06188-957445 www.fehling-instruments.de