

AESCULAP®



Powered by **TRUE**
DIGITAL
SURGERY

USA **Instructions for use/Technical description**
Aesculap Aeos – Digital Surgical Microscope

Aesculap, Inc. - Document No.: TA015615 - Version: 6.0 - Document ID: SOP-AIC-5001887 - Effective Date: 2022-10-06 - Status: Effective



Aesculap Aeos – Digital Surgical Microscope

Legend

- 1 3D surgical screen
- 2 Control screen
- 3 Robotic arm
- 4 Camera
- 5 Base
- 6 Footswitch
- 7 Warranty seal

The illustrations in these instructions for use (especially illustrations of the software) may deviate from the actual device.

Contents

1.	About this document	3	2.6.10	Shutdown procedure	15
1.1	Scope	3	2.6.11	Putting out of operation	15
1.2	Safety messages	3	2.6.12	Changing footswitch batteries	16
2.	Clinical use	3	3.	Software	16
2.1	Product description	3	3.1	Home screen	16
2.1.1	Robotic arm	3	3.2	Setup	16
2.1.2	Camera	4	3.2.1	Preset positions	16
2.1.3	Base	4	3.2.2	Rebalance scope	17
2.1.4	3D display (optional)	6	3.2.3	Robot Recovery	17
2.1.5	3D display stand (optional)	6	3.3	Live screen	17
2.1.6	Footswitch PV014	6	3.4	Control panel	18
2.1.7	Keyboard	7	3.4.1	Camera	18
2.1.8	Polarized 3D glasses	7	3.4.2	Robot	19
2.1.9	Additional components	7	3.4.3	Setup	20
2.2	Areas of use and limitations of use	7	3.4.4	Waypoints	20
2.2.1	Intended use	7	3.5	Quick Access Bar (QAB)	20
2.2.2	Indications for use	7	3.5.1	Autofocus	20
2.2.3	Contraindications	7	3.5.2	Image modes	21
2.2.4	Warnings	7	3.6	Software settings	21
2.2.5	Essential performance	7	3.6.1	Camera settings	21
2.3	Safety information	8	3.6.2	Screen Layout	21
2.3.1	Clinical user	8	3.6.3	Digital Aperture	22
2.3.2	Product	8	3.6.4	DUV 400 (Fluorescence)	22
2.3.3	Sterility	9	3.6.5	Color	22
2.4	System set-up	9	3.6.6	Recording	22
2.4.1	3D display and robotic arm workspace	10	3.6.7	Display	23
2.4.2	Connecting the power supply	11	3.6.8	Input Source	24
2.5	Functional test	11	3.6.9	DICOM	24
2.6	Application	11	3.6.10	Handles	24
2.6.1	Positioning the 3D display	11	3.6.11	Footswitch	25
2.6.2	Turning the system on	12	3.6.12	About	26
2.6.3	Enable footswitch	12	3.7	Robotic arm state indicators	27
2.6.4	Setting up the robotic arm and the camera	12	3.8	Robot malfunction	28
2.6.5	Starting a case	14	4.	Troubleshooting	28
2.6.6	Taking videos and snapshots of live view	14	4.1	Malfunctions	28
2.6.7	Ending a case	14	4.2	Error messages in the software	29
2.6.8	Saving case media	14	5.	Reprocessing procedure	30
2.6.9	Removing the drape	15	5.1	Single-use products	30
			5.2	Reusable products	30
			5.3	Preparation before cleaning	30
			5.4	Product-specific safety instructions for the reprocessing procedure	30
			5.5	Wipe disinfection	31
			5.6	Inspection	31
			5.6.1	Visual inspection	31
			5.6.2	Functional test	31
			5.7	Packaging	31
			5.8	Storage and transport	31
			6.	Security	32
			7.	Maintenance and service	32
			7.1	Maintenance	32
			7.2	Technical Service	32

8.	Disposal	32
9.	Technical data	33
9.1	Classification acc. to Directive 93/42/EEC and Regulation (EU) 2017/745	33
9.2	Performance data, information about standards	33
9.3	Voltage selector setting	33
9.4	Safe working load	33
10.	Symbols on product and packaging	33
11.	Distributor in the US/Contact in Canada for product information and complaints	34

1. About this document

Note

General risk factors associated with surgical procedures are not described in these instructions for use.

1.1 Scope

These instructions for use apply for the following products:

Art. no.	Designation
PV008	26" Full HD 3D Monitor
PV010	Aesculap Aeos (Digital Surgical Microscope)
PV011	Upgrade kit for the integration of a 3D monitor
PV014	Aesculap Aeos foot switch wireless (including batteries)
PV022	Software module DUV 400
PV023	Software module DIR 800
PV024	Software module DICOM
PV030	White balance card
PV031	Keyboard
PV032SU	DUV 400 reference card
PV033SU	DIR 800 reference card
PV012SU	Aesculap Aeos sterile drape

1.2 Safety messages

Safety messages make clear the dangers to patient, user and/or product that could arise during the use of the product. Safety messages are labeled as follows:

⚠ DANGER

Indicates a possible threat of danger. If not avoided, death or serious injury may result.

⚠ WARNING

Indicates a possible threat of danger. If not avoided, minor or moderate injury may result.

⚠ CAUTION

Indicates a possible threat of material damage. If not avoided, the product may be damaged.

2. Clinical use

2.1 Product description

The Aesculap Aeos is a freestanding, digital surgical microscope in a look-over configuration. The Aesculap Aeos does not utilize traditional microscope binoculars within the field of use and is intended to be an alternative to traditional optical microscopes. The Aesculap Aeos software is a component of the medical device.

The main components of the Aesculap Aeos system are:

- 3D surgical screen 1 – live surgical view
- Control screen 2 – control interface
- Robotic arm 3
- Camera 4 – 3D camera, illumination, and handle controls
- Base 5 with embedded computers
- Footswitch 6
- Visualization software
- Sterile drape

Note

The essential performance feature is defined by the "robotic arm" specifications.

2.1.1 Robotic arm

The robotic arm is a six-jointed arm that supports the camera. Its touch-guided movement allows the user to manipulate it through the workspace. The robotic arm may be controlled via the handles, footswitch, or control screen. On the 3D display, the robot state indicator shows the current state of the robotic arm. The robotic arm workspace is illustrated below.

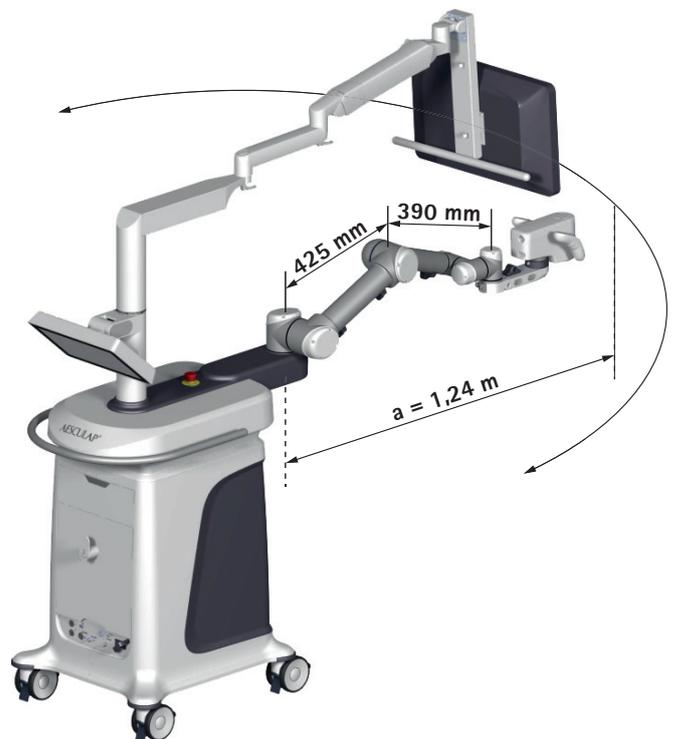


Fig. 1

Legend

a Max. radius

2.1.2 Camera

The camera contains two sets of optics and two high-resolution sensors to convert the analog signal to a digital video stream.

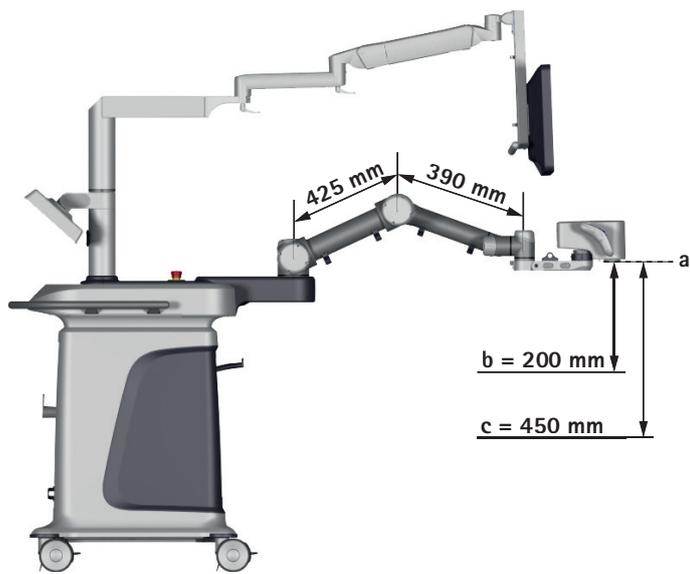


Fig. 2

Legend

- a Bottom of camera
- b Min. working distance
- c Max. working distance

Camera LED indicator

The camera has an LED indicator on the back panel. The indicator colors are explained below.

Indicator	Description
Blinking blue	The camera is starting up
Solid green	The camera is ready for use
Solid yellow	A minor error has occurred. See software message for details.
Solid red	A major error has occurred. User should switch to a backup system immediately

Handle buttons (default setting)

The Aesculap Aeos is designed to be controlled primarily through the buttons on the handles of the sides of the camera. The default layout of the handles is shown below. In the software Handles settings, the handle button commands can be customized.

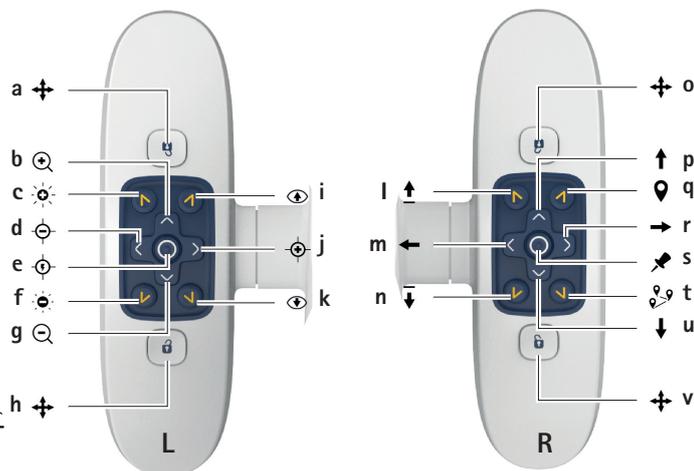


Fig. 3

Legend

- a Assisted drive
- b Zoom +
- c White light +
- d Focus -
- e Auto focus
- f White light -
- g Zoom -
- h Assisted drive
- i Image Mode (Next)
- j Focus +
- k Image Mode (Previous)
- l Move up
- m Move left
- n Move down
- o Assisted drive
- p Move forward
- q Way point save/delete
- r Move right
- s Lock-on mode
- t Waypoint select/move
- u Move backward
- v Assisted drive

2.1.3 Base

Emergency stop

The robotic arm emergency stop is located at the top of the base. The robotic arm movement is always under the control of the operator.

- ▶ If there is a malfunction and the robotic arm moves in an unintended way, first attempt to press the soft stop button on the control screen.
- ▶ If the control screen does not respond, use the emergency stop to remove power from the arm and cease all movement.

Note

When the emergency stop is pressed, the camera may move up to 3 cm (depending on position) due to mechanical brakes locking into place.

Base LED indicators

There are three LED indicators near the bottom of the base that display the status of the camera, system computer (EPU), and robotic arm components. The indicator colors are explained below.

Indicator	Description
Camera:	
Green	The camera is powered on.
Red	The camera is powered off / power failure.
Off	The system is powered off.
System computer (EPU):	
Green	The EPU is powered on.
Red	The EPU is powered off / power failure.
Off	The system is powered off.
Robotic arm:	
Green	The robotic arm is functional.
Orange	The robotic arm is booting.
Red	The robotic arm is powered off / power failure.
Off	The system is powered off.

Control screen

The system can be controlled by using the control screen. The control screen is 2D only and not sterile.

- ▶ Position the control screen for quick and convenient access.

Isolation transformer

The system contains a medical-grade isolation transformer to ensure patient and product safety. The transformer is configured by a service technician to accept the required voltage from the alternating current supply mains.

Uninterruptible Power Supply (UPS)

The system contains an uninterruptible power supply (UPS) which is connected to the isolation transformer. By that means, components such as the Aesculap Aeos computers, robotic arm, 3D display and control screen are safely powered.

The UPS is able to buffer the Aesculap Aeos system for at least 5 seconds in the case of an external power interruption.

If no case is started, the system will shut down after 2 minutes without mains power. If a case is started the system will be provided with power until the batteries are empty, which depends on factors like the charging state of the batteries.

The UPS is not designed to be used as a replacement for a mains power connection.

- ▶ While in use, do not deliberately disconnect system from mains power.

Base connections

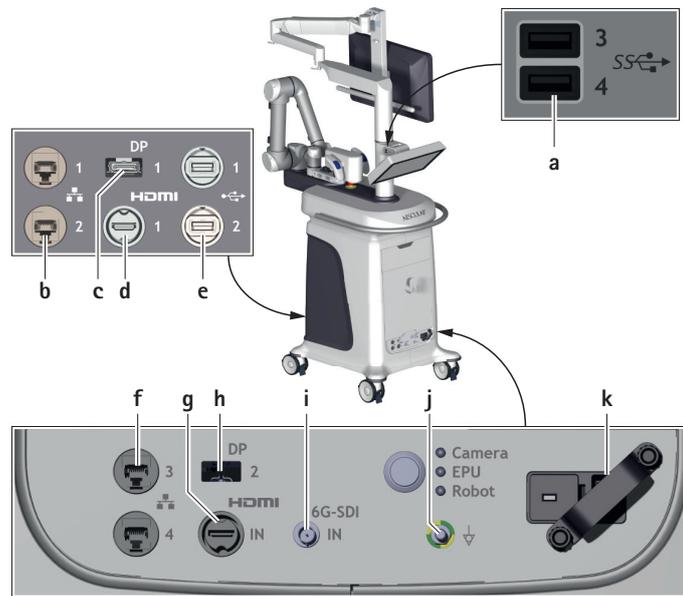


Fig. 4

On the control screen arm, there are the following connections:

Reference	Port	Connect to
a	USB 3.0	Keyboard, storage device
b, f	Ethernet	Clinical network
c, h	Display Port	External monitor
d	HDMI (output)	External monitor
e	USB 2.0	Storage device
g	HDMI (input)	(not used)
i	SDI	Video source
j	6 mm potential equalization pin	Potential equalization system
k	Mains power cord connection	Mains socket outlet

Note

Depending on the system configuration it could be that only one of the DP Ports (c/h) can be used and the other one is covered by a blind cover. The service technician will check with the operator during system installation to determine which one to use.

⚠ DANGER

Risk of injury due to unapproved configuration using additional components!

- ▶ Make sure that all configurations comply with basic standard IEC/DIN EN 60601-1 requirements for ME-systems. Any individual connecting devices with one another is responsible for such configuration and must ensure compliance with basic standard IEC/DIN EN 60601-1 or applicable national standards.

Combinations of accessories that are not mentioned in the present instructions for use may only be employed if they are specifically intended for the respective application, and if they do not compromise the performance and safety characteristics of the products.

Also note that any equipment connected at the connections must demonstrably meet the respective IEC standards (e.g. IEC 60950 for data processing equipment, IEC/DIN EN 60601-1 for electromedical devices).

- ▶ Please address the B. Braun/Aesculap partner or Aesculap Technical Service with any inquiries in this respect; for a contact address, see Chapter 7.2
- ▶ Every time a new piece of equipment is added and cables are connected to the Aesculap Aeos system, power down the system prior to connecting cables, then power it back up once the cables are connected.

Connecting a video stream from another device (input)

Video streams from other devices may be connected to facilitate display in conjunction with the 3D image from the camera.

The following device is approved for providing video input:

Art. no.	Designation	Connection Cable
PV480	2D camera platform	BNC Cable

- ▶ Connect the device to the SDI input port i at the front of the base, see Fig. 4.
- ▶ Configure the video input in the Aesculap Aeos software "Input Source" settings panel, see Chapter 3.6.8.

Connecting to a potential equalization system

Directly above the main power cord connection j, the Aesculap Aeos system is equipped with a 6 mm potential equalization pin j that can be connected to the healthcare facility potential equalization system.

- ▶ Connect the healthcare facility potential equalization system to the potential equalization pin j at the front of the base, see Fig. 4.

Connecting to a PACS/RIS server

There are two Ethernet ports on the both the front and back panels of the base.

- ▶ Ensure that the Ethernet cable and connector comply with at least Cat-5e EIA/TIA-568A-5, preferably Class D values from ISO/IEC 11801:2002 or EN 50173-1:2002.

Note

Power over Ethernet (PoE) is not allowed.

- ▶ Connect an Ethernet cable to one of the Ethernet ports b or e to link the system with the facility PACS server, see Fig. 4.
- ▶ Configure the connection in the software DICOM settings. See TA015615-DCS for the complete DICOM Conformance Statement.

2.1.4 3D display (optional)

The 3D display has a circularly-polarized, micro-polarizing filter that displays the right and left image alternately. Circularly-polarized glasses are worn to ensure that the left eye only sees the left image and the right eye only sees the right image. The display is set up by your Aesculap representative for optimal visualization.

- ▶ If the display settings are causing inadequate visualization, please contact customer support for assistance.

Connecting a secondary display (output)

The system can support simultaneously displaying the live view on multiple displays.

The following 3D displays are recommended for use with the Aesculap Aeos:

Art. no.	Designation	Connection cable
PV008	26" display	DisplayPort to DVI
PV644	31" 4K display	HDMI / DP-HDMI
PV648	32" display	DisplayPort to DVI
PV015	55" 4K display	HDMI / DP-HDMI

- ▶ Connect the display to the DisplayPort output port c respectively to HDMI d at the back of the base or h at the front of the base, see Fig. 4.
- ▶ Configure the additional displays in the Aesculap Aeos software "Display" settings panel, see Chapter 3.6.7.

The individual display settings are specially configured at the factory. When this function is activated, the power indicator flashes in amber. It is not recommended to drape the displays.

- ▶ If two external displays in addition to the central 3D monitor PV008 should be connected, contact Aesculap Technical Service, see Chapter 7.2.

2.1.5 3D display stand (optional)

The system can support remote 3D displays on a display stand approved by Aesculap. If the default 26" 3D display does not come with the system, an optional display can be the primary display.

The following display stands are approved for use with the Aesculap Aeos:

Art. no.	Designation
PV016	Mobile monitor stand for 55" monitor
PV818	Mobile monitor stand for 26" to 32" monitors

2.1.6 Footswitch PV014

The system can be controlled by using the wireless footswitch. The footswitch is uniquely paired with the Aesculap Aeos system in the Aesculap Aeos software "Footswitch" settings panel, see Chapter 3.6.11.

Default footswitch button functionality

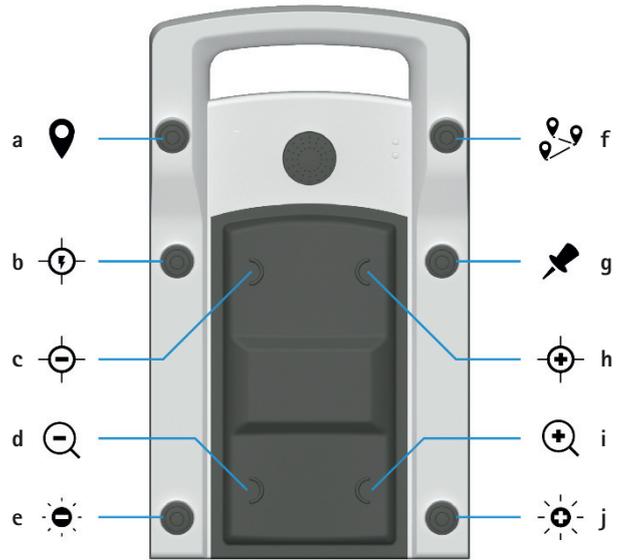


Fig. 5

Legend

- a Waypoint save/delete
- b Auto focus
- c Focus -
- d Zoom -
- e White light -
- f Waypoint select/move
- g Lock-on mode toggle
- h Focus +
- i Zoom +
- j White light +

The footswitch button commands can be customized in the Aesculap Aeos software "Footswitch" settings panel, see Chapter 3.6.11.

Footswitch status LEDs

Symbol	State	Designation
↔ Connection	Solid green	Radio connection established, footswitch engaged
	Blinking green	No radio connection, e.g. radio range error or receiver not online
	Blinking red	Warning: possible loss of connectivity Pairing mode active for ≈ 30 s; user action required Follow pairing instructions, see Chapter 3.6.11.
🔋 Battery	Off	Footswitch in power save mode
	Solid orange	Warning 1: "Battery low" Battery voltage = 3.3 V to 3.2 V (± 10 %)
	Blinking orange	Warning 2: "Battery low" Battery voltage ≤ 3.2 V (± 10 %)
	Fast blinking orange	Battery is empty: No further operation is possible. Battery voltage < 3.0 V (± 10 %)
	Off	Depending on Connect LED: Connect LED ON: Battery voltage > 3.55 V Connect LED OFF: Footswitch in sleep mode

2.1.7 Keyboard

The system includes a keyboard with an integrated touchpad.

The keyboard is intended to be connected to the system via an USB interface.

- ▶ Preferably connect the keyboard via the mast USB interface
- ▶ Only use the enclosed keyboard PV031 (US english layout), as the input of country-specific character sets is not supported by the software.

2.1.8 Polarized 3D glasses

Passively, circularly-polarized glasses are needed to see the display in 3D. The glasses may be worn over prescription glasses. Keep the glasses clean and free of scratches. To ensure optimal image quality, the system should only be used with Aesculap-supplied 3D glasses. Polarized prescription glasses will distort the 3D effect and should not be used.

- ▶ Contact Aesculap if additional pairs are required.

The following 3D glasses are approved for use with the Aesculap Aeos:

Art. no.	Designation
PV621	3D polarization glasses
PV622	3D anti-fog glasses
PV623	3D polarization glasses with clip
PV624	3D eye shield glasses kit

2.1.9 Additional components

The Aesculap Aeos system comes with additional components to help configure the system to work best in the operating room.

Art. no.	Designation	Function
FS095	Mains cord orange angled	Switzerland
FS096		Europe
FS097		Great Britain and Ireland
FS098	Mains cord black angled	Japan, USA, Canada
GK537	Equipotential bonding lead 5 m	Connecting the device to the potential equalization system of the room
PV030	White balance card	White-balancing the camera image sensors. The reverse side of the card is used by the technical service.
PV032SU	DUV 400 reference card	For checking the functionality of the DUV 400 imaging module (optional). Single use only for accuracy check
PV033SU	DIR 800 reference card	For checking the functionality of the DIR 800 imaging module (optional). Single use only for accuracy check
PV034	HDMI cable 5 m	Cable for connecting an external monitor
PV035	HDMI cable 10m	Cable for connecting an external monitor
PV052	DP-HDMI cable 5m	Cable for connecting an external monitor
PV053	DP-HDMI cable 10m	Cable for connecting an external monitor
PV057	BNC cable 5 m	Cable for connecting an endoscope video input device

Art. no.	Designation	Function
PV056	DisplayPort - DVI cable 5 m	Cable for connecting an external monitor
TA015635	Lens cap	Protecting the lens of the camera when it is being stored

Aesculap doesn't provide a sterile drape for the base. If required, the sterile drape should meet the following recommendations:

Minimum height	30 cm
Maximum height	75 cm
Minimum width	70 cm
Maximum width	115 cm
Additional recommendations	<ul style="list-style-type: none"> ■ Must not hang over the castors ■ Must not cover the base vents

2.2 Areas of use and limitations of use

2.2.1 Intended use

This device is for use with patients undergoing microsurgery within its indications for use. The fluorescence functions of the Aesculap Aeos are intended only for patients undergoing a procedure where the appropriate fluorescent dyes and treatments are being used.

There is no patient contact intended with this device.

2.2.2 Indications for use

Note

The manufacturer is not responsible for any use of the product against the specified indications and/or the described applications.

The Aesculap Aeos (Digital Surgical Microscope) generates a magnified 3D view of the surgical field.

Software module DUV 400 PV022

The DUV 400 is an accessory for the Aesculap Aeos and is used for viewing fluorescence of fluorophores, comprising:

- An excitation filter for blue spectral range between 390 nm and 420 nm
- An observation filter for visible light with spectral range greater than 510 nm

Software module DIR 800 PV023

The DIR 800 is an accessory for the Aesculap Aeos and is used in viewing intra-operative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency in neurosurgery. It also aids in the visual assessment of intraoperative blood flow and vessel patency in bypass surgical procedures in neurosurgery.

2.2.3 Contraindications

The Aesculap Aeos system must not be used for ophthalmology.

2.2.4 Warnings

Warnings include, but are not limited to, medical and/or surgical conditions that could prevent the success of the procedure.

In the presence of warnings, the user decides individually regarding the use of the product.

2.2.5 Essential performance

Prevent unintended and unprecise movement of robot arm while robot is in movement.

2.3 Safety information

2.3.1 Clinical user

General safety information

CAUTION

Federal law restricts this device to sale by or on order of a physician!

To prevent damage caused by improper setup or operation, and to not compromise the manufacturer warranty and liability:

- ▶ Use the product only according to these instructions for use.
- ▶ Follow the safety and maintenance instructions.
- ▶ Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge and experience.
- ▶ Store any new or unused products in a dry, clean, and safe place.
- ▶ Prior to use, check that the product is in good working order.
- ▶ Keep the instructions for use accessible for the user.

Note

The user is obligated to report all severe events in connection with the product to the manufacturer and the responsible authorities of the state in which the user is located.

Notes on surgical procedures

It is the user's responsibility to ensure that the surgical procedure is performed correctly.

Appropriate clinical training as well as a theoretical and practical proficiency of all the required operating techniques, including the use of this product, are prerequisites for the successful use of this product.

The user is required to obtain information from the manufacturer if there is an unclear preoperative situation regarding the use of the product.

2.3.2 Product

Product-specific safety information

Risk of fatal injury from electric shock!

- ▶ Do not open the product.
- ▶ To avoid the risk of electric shock, only connect this equipment to a supply mains with protective earth.
- ▶ Never connect the product using a multiple socket-outlet.
- ▶ Observe "Notes on electromagnetic compatibility (EMC) for the Aesculap Aeos (Digital Surgical Microscope) PV010" TA015615-EMV, see B.Braun eIFU at eifu.bbraun.com.
- ▶ To prevent damage caused by improper setup or operation, and in order not to compromise warranty and manufacturer liability:
 - Use the product only according to these instructions for use.
 - Follow the safety and maintenance instructions.
 - Only combine Aesculap products with each other.
- ▶ Always adhere to applicable standards.
- ▶ Set up and connect any external video input or output before the system is turned on.
- ▶ Ensure that exposed cables for the footswitch, camera, any external displays, and power supply are laid flat on the ground and out of high-traffic areas to minimize potential tripping hazards.
- ▶ Do not use the robotic arm as an armrest or to support any unapproved accessories. Do not place other equipment on the system.
- ▶ Do not place objects around or on top of the E-stop or on the camera and arm.
- ▶ Prior to starting a case, unplug any USB devices (i. e. keyboard, external hard drives) from external USB ports.
- ▶ Ensure the E-stop is not locked prior to surgery.
- ▶ Use the soft stop on the control screen if there is unintended robot arm movement.
- ▶ Use the E-Stop only if the soft stop malfunctions.

- ▶ Check fluorescence functionality prior to surgery using the provided reference card.
- ▶ Ensure that the camera working distance is between 20 cm and 45 cm.
- ▶ The fluorescence reference card and the control screen are not sterile. Perform fluorescence functional tests before surgery.
- ▶ Take precautions to avoid touching any system components and the patient at the same time.
- ▶ Do not push or pull the product by the display, camera, or power cable.
- ▶ To ensure optimal image quality, only use product with 3D glasses supplied by Aesculap. Contact Aesculap if additional pairs are required.
- ▶ Do not use polarized prescription glasses as they will distort the 3D effect.
- ▶ Always return the robot to storage position before shutdown.
- ▶ Store the camera with the lens cap covering the main objective when it is not in use.
- ▶ Do not cover the air vents of the system, control screen, or 3D display.
- ▶ Make sure that in case of a system failure or other malfunctions that prevents further use of the system, the user is able to finish the procedure using a reserve system (e.g. traditional optical microscope).

Note

When the emergency stop is pressed, the camera may move up to 3 cm (depending on position) due to mechanical brakes locking into place.

Light emission risks

Retinal blue light and Near-UV emission risk.

- ▶ Do not stare at the lamp emission area during operation.
- ▶ Minimize exposure to eyes and skin.
- ▶ Use appropriate shielding.
- ▶ Make sure that no light from the Aesculap Aeos enters the patient's eyes.

Fluorescent surgery

- ▶ Only use fluorescent agents that are approved for the planned application.
- ▶ Danger of injury to the eyes due to possibly hazardous infrared and UV light. Do not look at the Aesculap Aeos illumination, minimize exposure to eyes or skin, and use appropriate shielding.
- ▶ Use the lowest comfortable light intensity.
- ▶ Ensure that no tissue damage is caused by excessive illumination intensity.
- ▶ The room lighting impairs the visualization of fluorescence. For surgeries using the Aesculap Aeos fluorescence modules, operate in a darkened room, if possible.
- ▶ Always perform a functional test before using the fluorescence modules, see Chapter 3.4.1. Use the reference cards to check whether the fluorescence medium can be excited for the Aesculap Aeos wavelength range and whether it emits fluorescent light of sufficient intensity.

Note

As in almost all diagnostic procedures, false-positive and false-negative results can occur in the fluorescence-based digital overlay. Evaluation by the user based on other methods may be necessary.

Place of use

This system is not suitable for use in the presence of flammable anesthetics mixture with air or with oxygen.

- ▶ Do not use system in explosive atmospheres.
- ▶ To prevent fire or shock hazard, do not expose system to rain or moisture.

Footswitch PV014

- ▶ Always carry and lift the footswitch using the carrying handle.
- ▶ Place footswitch on hanger at the base of the Aesculap Aeos when not in use.
- ▶ Switch off Aesculap Aeos before cleaning or maintenance work on the footswitch.
- ▶ Keep footswitch within a range of max. 10 m to the receiver.
- ▶ Do not place the footswitch in or near strong magnetic fields.
- ▶ Do not use more than four wireless systems in the same area.

The footswitch is regularly powered by three alkaline batteries of type C "Baby" (IEC-LR 14; included in delivery), which are placed behind the backside battery cover.

- ▶ If they need changing, the terminal must be switched off first in order to rule out any unintended triggering of functionality.
- ▶ Only use footswitch with the specified batteries.
- ▶ To prevent the footswitch from battery leakage, remove battery from the case during long periods of non-use.
- ▶ Never touch the battery contacts and the patient at the same time.

The maximum mechanical load which the operating elements may be subjected to is max. 1350 N.

The integrated accelerometer prevents an accidental actuation of switching element if the inclination passes 35°.

- ▶ Only use footswitch on a firm, even (horizontal) surface.
- ▶ During use, do not tilt (> 35°) or move the footswitch because this can lead to immediate cancellation of signals and functionality.

Ambient conditions

The following environmental conditions apply to the use of the product:

Aesculap Aeos (Digital Surgical Microscope) PV010	
Temperature	10 °C to 30 °C
Relative humidity	30 % to 90 %; non-condensing
Atmospheric pressure	700 hPa to 1 060 hPa

Aesculap Aeos foot switch wireless PV014	
Temperature	10 °C to 40 °C
Relative humidity	30 % to 90 %; non-condensing
Atmospheric pressure	800 hPa to 1 060 hPa

2.3.3 Sterility**Non-sterile packaged products**

Art. no.	Designation
PV008	26" Full HD 3D Monitor
PV010	Aesculap Aeos (Digital Surgical Microscope)
PV011	Upgrade kit for the integration of a 3D monitor
PV014	Aesculap Aeos foot switch wireless
PV022	Software module DUV 400
PV023	Software module DIR 800
PV024	Software module DICOM
PV030	White balance card

The product is supplied non-sterile and must be used under non-sterile conditions.

- ▶ Inspect the new product after removing its transport packaging and prior to first use to ensure it is in good working order.

Sterile products

Art. no.	Designation
PV012SU	Aesculap Aeos sterile drape

The product is the only sterile component of the system.

- ▶ Place an Aesculap Aeos sterile drape prior to surgery.
- ▶ Do not use the product if it is damaged or defective.
- ▶ In case of intraoperative damage of the drape: remove the system from the operating table and replace the drape.

The product has been EO-sterilized and is supplied in sterile packaging.

- ▶ Do not use products from open or damaged sterile packaging.
- ▶ Do not use the product after its use-by date.
- ▶ Do not reuse the product.

The reprocessing of the product affects its functionality. Risk of injury, illness or death due to soiling and/or impaired functionality of the product.

- ▶ Do not reprocess the product.

2.4 System set-up

Non-compliance with the following instructions will preclude all responsibility and liability in this respect on the part of Aesculap.

- ▶ When setting up and operating the product, adhere to
 - national regulations for installation and operation,
 - national regulations on fire and explosion protection.
- ▶ Make certain that the control elements, mains power switch and power socket are freely accessible for the user.
- ▶ Set up the product in such a way that it can be easily disconnected from the mains.
- ▶ Lay non-system cables and cords separately. RF cables in particular can cause strong interference.
- ▶ If interference from external devices is suspected, immediately deactivate those devices, if possible, until the source of interference is found. If necessary, consult a specialist in medical electrical devices to remedy the interference.
- ▶ Make certain that the ventilation slots at the back of the housing are not covered, e.g. by an OR cloth.

Note

For the safety of patients and users it is essential that the mains power cord and, especially, the protective earth connection are intact. In many cases defective or missing protective earth connections are not registered immediately.

- ▶ Connect the device via the potential equalization pin j at the front of the base to the potential equalization system of the room used for medical purposes, see Fig. 4.

Note

Installation and initial commissioning may only be performed by Aesculap representatives.

2.4.1 3D display and robotic arm workspace

To help with positioning the Aesculap Aeos in the operating room, the base dimensions, the minimum and maximum extensions of the 3D display arm, and the height and maximum extension of the robotic arm are shown below.

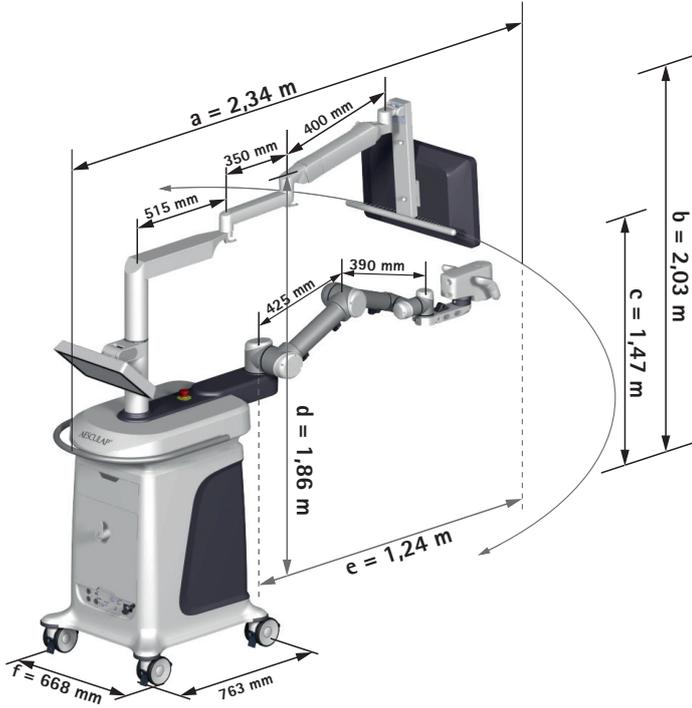


Fig. 6

Legend

- a Max. length (arm fully extended)
- b Max. monitor height
- c Min. monitor height
- d Highest point (roll through doors)
- e Radius
- f Minimum width to roll through doors

There are three recommended layouts for the operating room.

Note

For additional operating room layout examples, please contact your local B.Braun/Aesculap representative

Neurosurgery operating room layout (example)

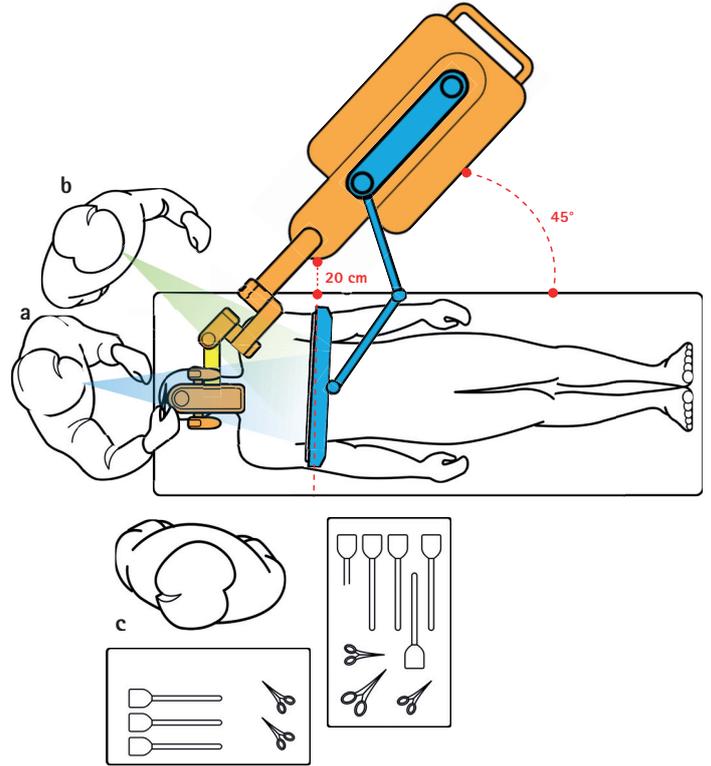


Fig. 7

Legend

- a Surgeon
- b Assistant
- c Scrub nurse

Spinal surgery operating room layout (example)

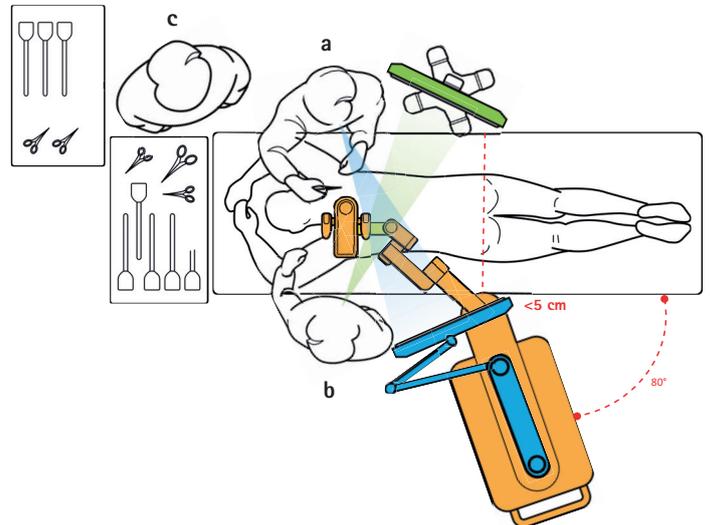


Fig. 8

Legend

- a Surgeon
- b Assistant
- c Scrub nurse

Semi-sitting operating room layout

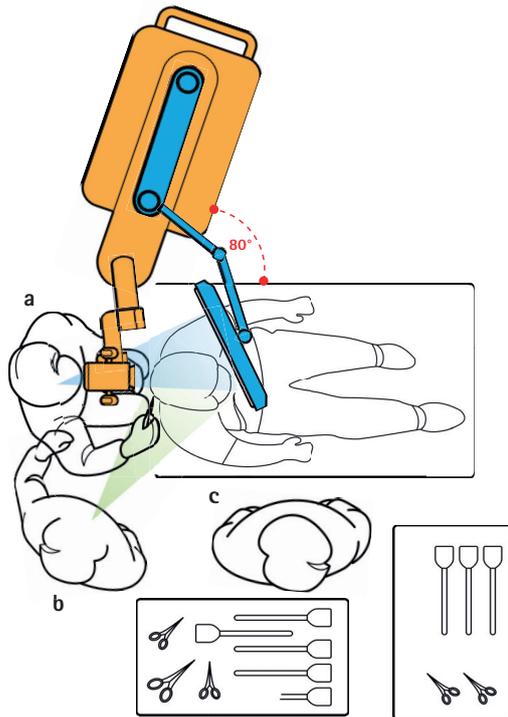


Fig. 9

Legend

- a Surgeon
- b Assistant
- c Scrub nurse

2.4.2 Connecting the power supply

⚠ DANGER

Risk of fatal injury from electric shock!

- ▶ Connect this equipment only to a supply mains with protective earth.
- ▶ Connect the main power cable directly to a power outlet. Do not use un-approved extension cords or multiple socket-outlets. Use uninterruptible power source when loss of power would result in an unacceptable risk.
- ▶ Lay the power cable in areas with minimal foot traffic.
- ▶ Place power cable on hanger at the base of the Aesculap Aeos when not in use.

2.5 Functional test

Before turning the Aesculap Aeos system on

- ▶ Check that the castors are locked once the base is in the desired location. Make sure the base is stable and cannot roll in any direction.
- ▶ Connect the main power cable, see Chapter 2.4.2.
- ▶ Connect any external input or output video or Ethernet cables, see Chapter 2.1.3.
- ▶ Check that there are no unnecessary objects or people within the range of the robotic arm workspace.
- ▶ Check that the camera optical path is clean and free from dust.
- ▶ Ensure that exposed cables for the footswitch, any external displays, and power supply are laid flat on the ground and out of high-traffic areas to minimize potential tripping hazards.

After turning the system on and before starting the surgery

- ▶ Position the universal coupler as desired, see Chapter 3.2.1.
- ▶ Move the robotic arm from "Storage" to "Drape" position, see Chapter 3.2.1.
- ▶ Follow the instructions printed on the drape packaging to correctly apply the drape to the camera and robotic arm.
- ▶ Position Aesculap Aeos at the OR table.
- ▶ Position the 3D display for the surgeon's viewing preference.
- ▶ Check that the "Zoom", "Focus", and "White Light Level" handle buttons are functioning properly.
- ▶ Check that the 3D image colors, focus, and alignment look correct.
- ▶ Check that the robotic arm assisted drive is moving smoothly and predictably.
- ▶ Check that the footswitch is paired with the system and the buttons are working properly.
- ▶ If using fluorescence visualization (DIR 800 or DUV 400), check the fluorescence module using a reference card to ensure proper working order.

2.6 Application

2.6.1 Positioning the 3D display

- ▶ For ideal viewing, position the 3D display next to the patient table, between 4 and 6 feet (1 to 2 meters) away from the surgeon.
- ▶ Position the screen perpendicular to and at the same height as the surgeon's eyes when he or she is seated at the operating table.

The 3D display arm's maximum extension and height are shown below:

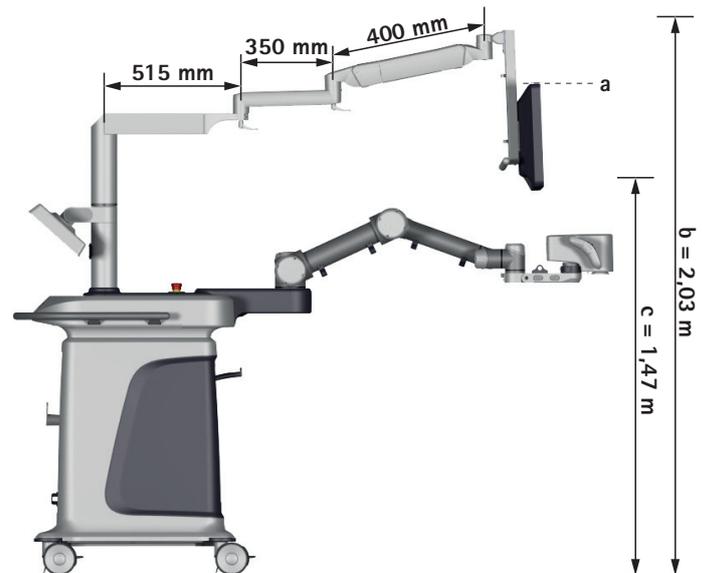


Fig. 10

Legend

- a Top of the screen
- b Max. monitor height (top of the screen)
- c Min. monitor height (top of the screen)

2.6.2 Turning the system on

- ▶ Perform the relevant items of the function checks, see Chapter 2.5.

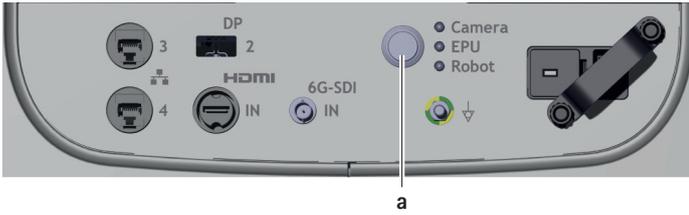


Fig. 11

Legend

a Main power button

- ▶ Press the main power button **a** located on the front panel of the base, next to the power cable connection and LED indicators. The LED ring around the main power button lights up green. The displays, camera, computers, robotic arm, and software are set to automatically start when the system is turned on.
- ▶ Wait for the system to initialize (about 90 seconds). The system will be ready for use once the Aesculap Aeos software has opened and the notification "Aesculap Aeos initializing, please wait..." is no longer displayed.

2.6.3 Enable footswitch

After every restart of the Aesculap Aeos software, the first time a button on a paired footswitch is pressed a message will appear on the screen to confirm footswitch usage.



Fig. 12

- ▶ Press "Confirm" button to confirm the usage of the footswitch.
- ▶ Press "Cancel" button if the footswitch is not needed and confirm the second message with "Yes" button. The footswitch is deactivated until the next start of the Aesculap Aeos software.

2.6.4 Setting up the robotic arm and the camera

Rotating the Aesculap Aeos using the universal coupler

Depending on the surgical approach and operating room layout, it may be advantageous to rotate the camera 90° to the left or right.

Note

For semi-sitting approaches it may be necessary to flip down the universal coupler (camera NOT rotated).

- ▶ Only flip down the universal coupler before draping, using the proper "Reconfigure Coupler" workflow. Do not flip down the universal coupler during surgery.

CAUTION

When the coupler is set to the semi-sitting position, there are 3 known possible contact points.

- ▶ Use caution to avoid the following positions:

- When set to Semi Sitting Elbow Down, it is possible to contact the elbow joint with the arm base of the cart. Observe patient and avoid contact.
- When moving from positions Semi Sitting Left Elbow Up to Semi Sitting Right Elbow Up, move to the drape position first instead of moving directly from one position to the next. This will prevent the camera from contacting the elbow to wrist joint.
- When moving from positions Semi Sitting Right Elbow Up to Semi Sitting Left Elbow Up, move to the drape position first instead of moving directly from one position to the next. This will prevent the camera from contacting the elbow to wrist joint

Note

To flip down the universal coupler it is recommended to slightly lift the camera to avoid potential sticking of the slider.

- ▶ Once the system has fully started up, go to the "Robot" tab in the Aesculap Aeos home screen, see Fig. 31.
- ▶ Under "Coupler", press the "Reconfigure Coupler" button.
- ▶ Press and hold the "Hold or Reconfigure position" button until the arm is fully extended.

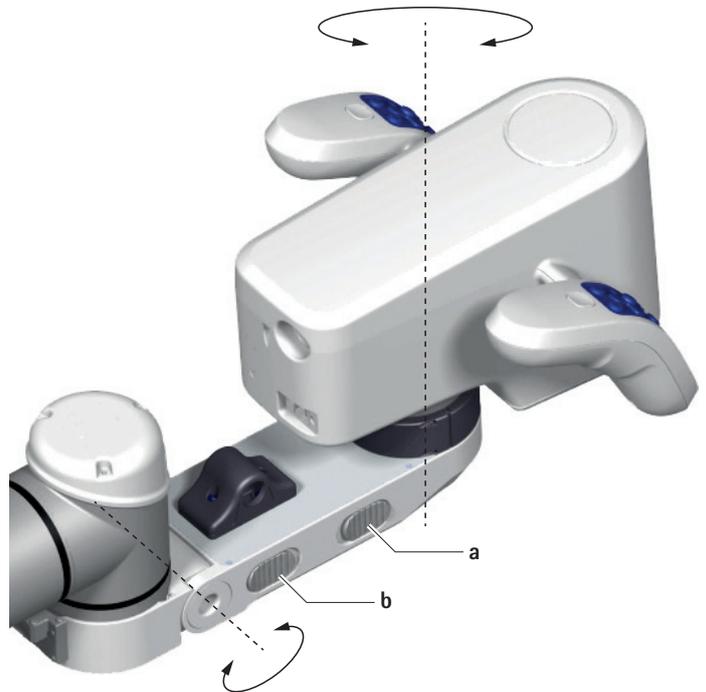


Fig. 13

Legend

a Sliders to rotate camera
b Sliders to flip down camera

- ▶ Unlock the sliders **a/b** and rotate the Aesculap Aeos manually into the desired position.

For available coupler positions, see Fig. 14. The geometry limits of the robotic arm will change based on the coupler position.

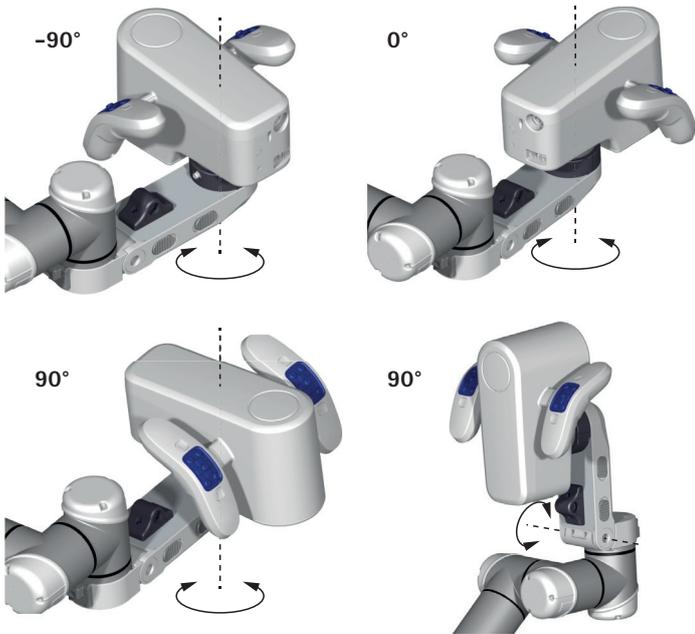


Fig. 14

- ▶ Press the "Hold for Drape position" button in the Aesculap Aeos software until the movement is finished.

Moving the robotic arm out of storage position and draping the robotic arm

The camera and distal portion of the robotic arm must be draped using the provided Aesculap Aeos sterile drape PV012SU prior to surgery.

- ▶ Only use sterile drape PV012SU, as sterile covers from other manufacturers can impair system performance as well as image quality.

Note

Additionally, the base may be draped at the user's discretion (base drape not provided by Aesculap). For drape dimensions, see Chapter 2.1.9.

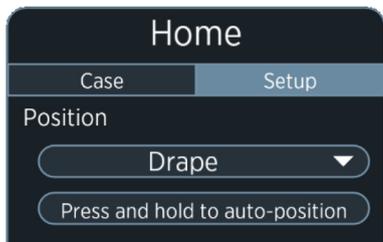


Fig. 15

- ▶ Once the system has fully started up, move the robotic arm into the "Drape" position, see Fig. 15.
- ▶ Move the universal coupler into the position used during the procedure.

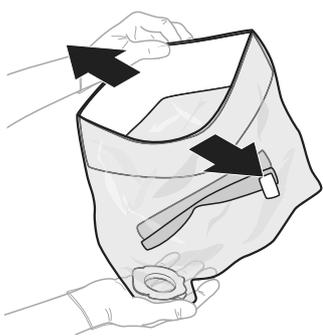


Fig. 16

- ▶ Remove drape from sterile packaging and unfold, see Fig. 16.

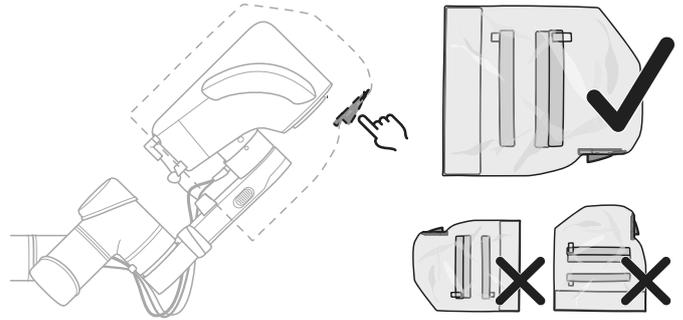


Fig. 17

- ▶ Notice the correct position of the drape lens, see Fig. 17.

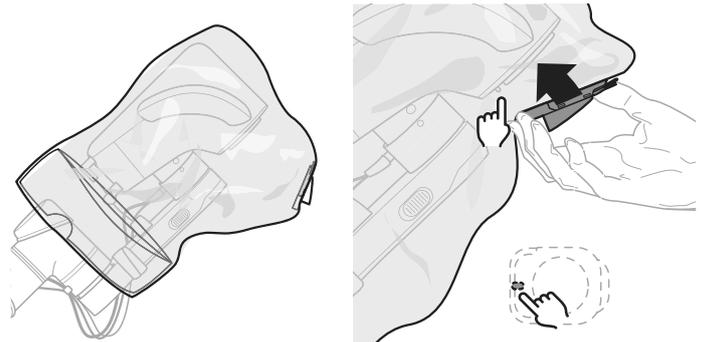


Fig. 18

- ▶ Put the drape over the camera, align the lens using the locking pin and attach the lens housing to the ocular ring using snap elements on the side, see Fig. 18.

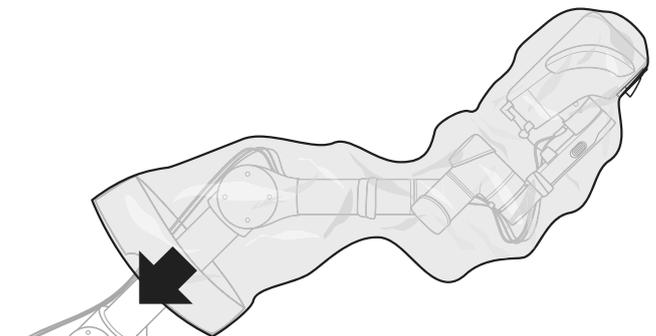


Fig. 19

- ▶ Pull the drape bag completely over the robot arm, see Fig. 19.

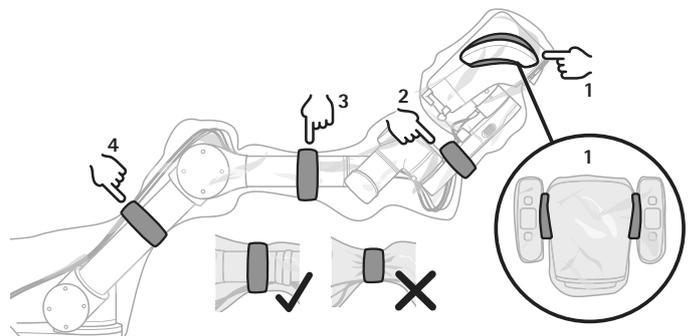


Fig. 20

- ▶ Attach the adhesive tape as follows, see Fig. 20:
 - Attach tape 1.
 - Attach tape 2. Ensure that it fits loosely and that the cables are not squeezed (force on sensor between camera and universal coupler).
 - Attach tapes 3 and 4.

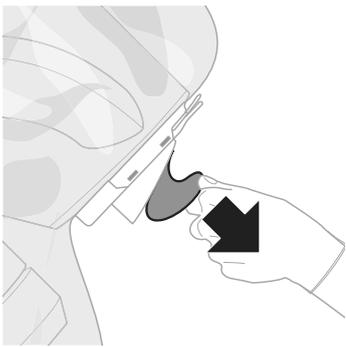


Fig. 21

- ▶ Remove the protective lens film, see Fig. 21.

Note

It is recommended to rebalance the Aesculap Aeos after draping, see Chapter 3.2.2.

- ▶ Perform all the remaining items of the function checks before starting the surgery, see Chapter 2.5.

Note

If the universal coupler has to be rotated during the procedure, the adhesive tapes must be loosened beforehand in order to avoid tension on the sensor.

Tension on the sensor may cause the balancing process to fail.

2.6.5 Starting a case

Once the Aesculap Aeos arm has been draped and all pre-operative checks are complete, a new case can be started.



Fig. 22

- ▶ Select a surgeon profile and a patient in the "Case" tab.
 - or -
- ▶ Add a new Surgeon profile or Patient by using the Add (+) button. Aesculap Aeos settings and preferences are saved for each Surgeon profile. The Delete (-) button is disabled when the "Default Surgeon" or "Default Patient" is selected, but it can be used to delete custom profiles.
- ▶ When the DICOM settings are configured to a networked database, select the "DICOM" toggle and search for a patient. To search all listed patients in the database, enter an asterisk (*) in the first and last name search fields.
- ▶ Once the desired surgeon and patient have been chosen, press "Start Case" to advance to the live screen, see Chapter 3.3.

2.6.6 Taking videos and snapshots of live view

Snapshots and videos of the current live image can be taken with the two buttons in the upper left corner.

Button	Description
	Start/stop video recording of current live view.
	Take image snapshot of current live view.

2.6.7 Ending a case

- ▶ Select the End Case (E) button to end the current case.

If settings have been changed during the case, a message window will appear with options to discard changes, overwrite current profile or create a new surgeon profile.

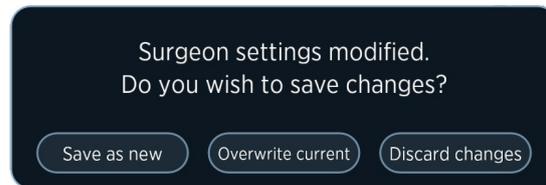


Fig. 23

- ▶ Press the corresponding option and confirm selection.

If recordings or snapshots were taken during the case, there will be options to save and/or upload the case media for both DICOM and non-DICOM patients to the DICOM server (if applicable), local drives, or connected external drives.

2.6.8 Saving case media

If snapshots and/or images were recorded, ending the current case will prompt users to save the media. The patient information can also be updated at this time, even if the case was started with previously saved information.

Save to default location

After selecting to end the case:



Fig. 24

- ▶ Press "Yes" to continue saving the media information.
 - or -
- ▶ Press "No" to permanently delete all case media (this will require confirmation).
 - or -
- ▶ Press "Cancel" to return to the case.

Selecting "Yes" will allow the patient's information to be added or updated. Patient information saved prior to starting the case will be retained at the end of the case.

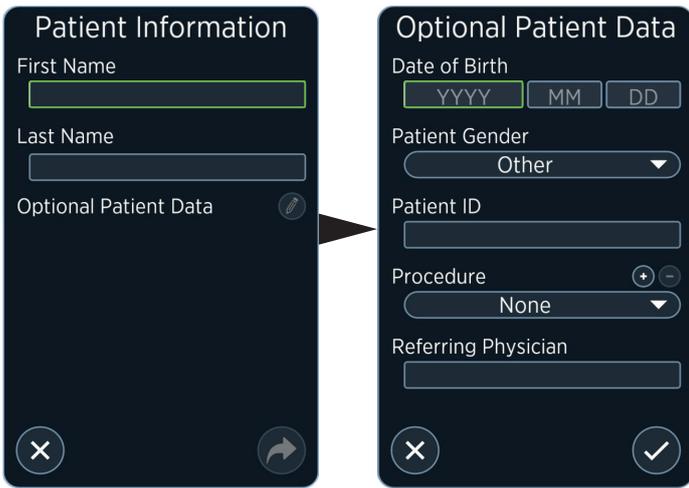


Fig. 25

- ▶ Enter a first and last name, then press Next button to continue, or Cancel button to return to the "Save Recorded Media?" message.
- ▶ Press the pencil button to add or update "Optional Patient Data". This option is enabled once a first and last name have been entered.
- ▶ Press OK button when done editing to proceed.

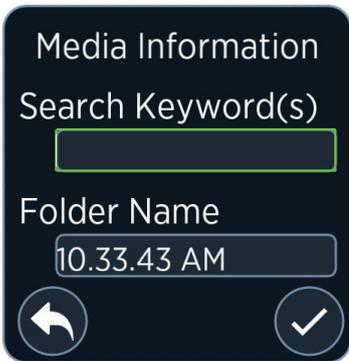


Fig. 26

From the "Media Information" screen, optionally keyword(s) can be entered or the folder name changed.

- ▶ Press Back button to return to the previous screen or press OK button to proceed.

Copy media to drive

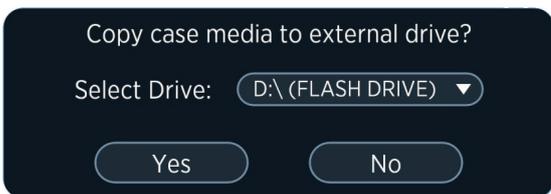


Fig. 27

- ▶ To copy case media to an available local or externally connected drive, select the drive letter from the drop-down list, then press "Yes" – or –
 - ▶ Press "No" to save to the default location only.
- The save media screens will close and the application returns to the home screen.
- There will be progress messages for the copy in progress, as well as confirmation once it completes.

Note

The location where case media will be saved is F:\TVS\TrueVision\Surgeons\<<SurgeonName>. Selecting an additional drive to copy to will be in addition to the default location.

2.6.9 Removing the drape

At the end of the case or when the robotic arm drape needs to be removed:

- ▶ Ensure the area is clear of objects or people and move the robotic arm into the "Drape" position, see Chapter 3.2.1.
- ▶ Release the adhesive tape on the drape bag.
- ▶ Remove the lens housing of the sterile cover from the camera using the buttons on the side.
- ▶ Invert and remove the drape along the robotic arm.
- ▶ Dispose the sterile drape in compliance with medical waste regulations.

2.6.10 Shutdown procedure

For safety, it is important to follow proper shutdown procedure when the Aesculap Aeos system is not in use.

- ▶ After the drape has been removed from the robotic arm, press the Exit button.
 - ▶ Once the 3D display is cleared from the robotic arm movement path, move the robotic arm to "Storage" position, see Chapter 3.2.1 or press "Cancel" button (return to the application).
- Once the robotic arm is fully in "Storage" position, the software will automatically provide further options to "Shut Down", or press "Cancel" button (return to the application).



Fig. 28

- ▶ Press "Shut Down" button.
- The system shut down sequence starts.
- After the EPU shuts down, the LED at the front panel (Camera, Robot, EPU) and also the system fans will turn off.

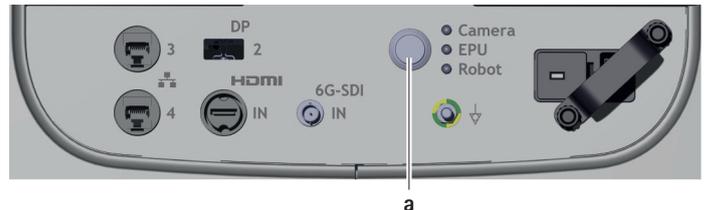


Fig. 29

Legend

- a Main power button
- ▶ Once the system is shut down turn off the system power with the main power button a.

2.6.11 Putting out of operation

Note

The safe and all-pole disconnection of the Aesculap Aeos system from the supply mains is only guaranteed when the power supply cord is unplugged.

- ▶ Shut down the Aesculap Aeos system, see Chapter 2.6.10.
- ▶ Unplug the power supply cord from the supply mains.

2.6.12 Changing footswitch batteries

- ▶ Shut down Aesculap Aeos, see Chapter 2.6.10.
- ▶ Open battery housing: Rotate both lockers near battery housing by 90°. While doing so, lightly press down the battery cover.
- ▶ Lift the empty batteries by the ejector belt and remove them.
- ▶ Insert new batteries. Keep attention to the right polarity (see marking on battery compartment bottom).
- ▶ Only use alkaline batteries. The use of rechargeable batteries is not allowed.
- ▶ Never mix used and new batteries.
- ▶ Close battery housing: rotate both lockers back to original position.
- ▶ To protect the footswitch from battery leakage during long periods of non-use, remove the batteries from the battery compartment.

3. Software

3.1 Home screen

The Aesculap Aeos software starts on the home screen on the control screen.

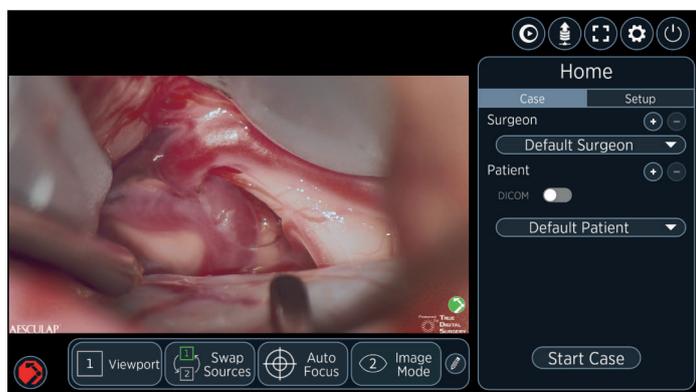


Fig. 30

Symbols

- Soft stop**
As a risk control, the software has a soft stop button in the unlikely scenario that the robotic arm moves in an unpredictable way. The soft stop button halts all robotic arm movement when pressed. The button is available in both the home and live screens. The button will change color from red to gray when engaged. Press the button again to remove the soft stop and allow the robotic arm to move again. The button will change back to red.
- Eject drive**
When an external USB drive is connected to the system, select the Eject button to properly eject the drive. The software will confirm the drive has been ejected and can be physically removed.
- Media Upload Queue**
Here the queued DICOM uploads can be seen and the upload process can be started.
- Software settings**
see Chapter 3.6
- TrueMedia application**
Select the TrueMedia application playback button to view or edit surgical content. The Aesculap Aeos software will need to close in order to open TrueMedia.



Fullscreen view

Select the fullscreen button to enter fullscreen mode, which displays the surgery view and contains active status messages and the buttons for emergency stop, settings, and exit fullscreen mode. The fullscreen view button is available in both the home and live screens. Select the close fullscreen button to exit fullscreen mode.



System shutdown

see Chapter 2.6.10

3.2 Setup

The "Setup" panel in the home screen provides the following functions:

- Move the robotic arm to a preset position
- Rebalance the Aesculap Aeos
- Enter recovery state
- Reconfigure the coupler.

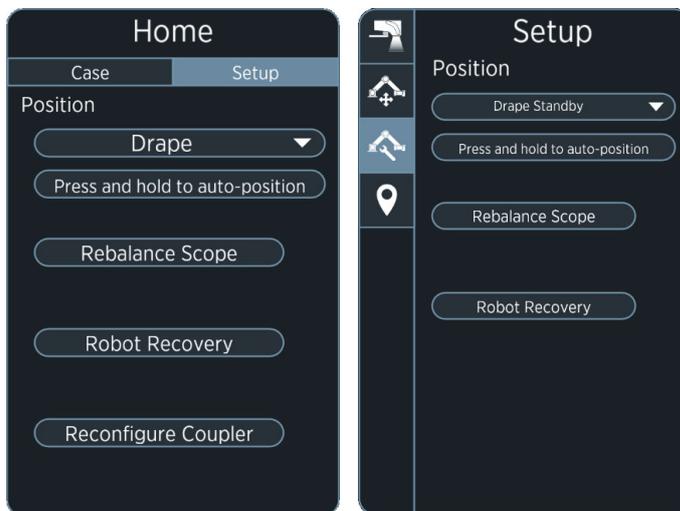


Fig. 31

3.2.1 Preset positions

The available preset positions are:

- Drape
- Drape Standby
- Semi-Sitting Left (Elbow Down)
- Semi-Sitting Left (Elbow Up)
- Semi-Sitting Right (Elbow Down)
- Semi-Sitting Right (Elbow Up)
- Storage

Note

Semi-Sitting presets are only available in Semi-Sitting coupler configuration.

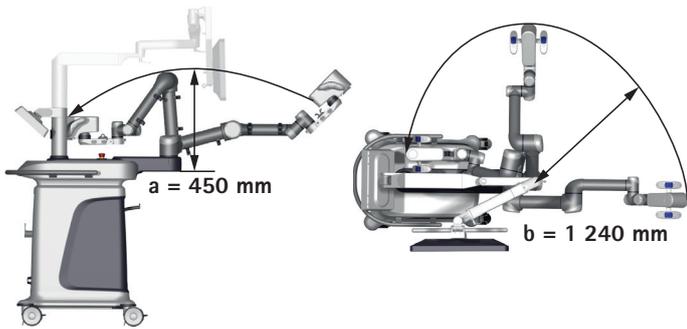


Fig. 32

Legend

- a Keep this area clear vertically during position change
- b Keep this area clear horizontally during position change

WARNING

Risk of injury due to unintended movement of the robotic arm!

- ▶ Make sure the area surrounding the robotic arm is clear of objects or people.
- ▶ Watch the robotic arm while it is moving.
- ▶ Select a pre-configured position for the robotic arm in the "Position" drop-down list.
- ▶ Press the "Press and Hold to auto-position" button until the robotic arm movement fully stops in position.

3.2.2 Rebalance scope

Moving the robotic arm to its limits can affect the Aesculap Aeos' balance. To correct the presence of any drift, the Aesculap Aeos can be rebalanced.

The Aesculap Aeos robotic arm is factory-calibrated. It is recommended to rebalance the robotic arm once annually or as needed, especially if the robotic arm feels unbalanced during movement with the handle brake-release buttons.

- ▶ Ensure the area of the robotic arm is clear.
- ▶ Press "Rebalance Scope" in the "Setup" tab.

In rare instances, some configurations can cause the robotic arm to lock up when reaching the joint limits.

- ▶ If this occurs, move the robotic arm to a preset position.

Note

If proper rebalancing of the Aesculap Aeos still results in unsatisfactory balance, contact Aesculap Technical Service for assistance, see Chapter 7.2

3.2.3 Robot Recovery

CAUTION

Robot Recovery can damage the system or its cables by moving the robot outside its defined limits.

- ▶ Only use Robot Recovery in emergencies.
- ▶ First try the following steps before using Robot Recovery:
 - Position the robot via handle / foot switch.
 - Position the robot via preset positions (e.g. Draped Position, Standby Position, see Fig. 31) on the touch screen.

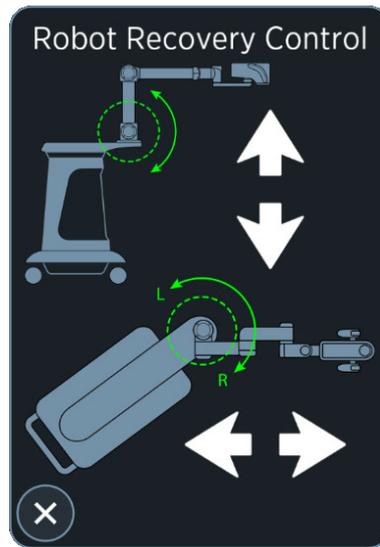


Fig. 33

- ▶ Press and hold the white arrow buttons to move the robot.
- ▶ Avoid collisions of the robot or jamming of the cables.

3.3 Live screen

Selecting "Start Case" in the "Case" tab advances to the live screen, intended for live surgery. The Live Screen shows controls for the camera, robotic arm, recording, fluorescence, and access to settings.



Fig. 34

Legend

- 1 Settings bar
- 2 Control panel
- 3 Live image
- 4 Quick Access Bar (QAB)

3.4 Control panel



Fig. 35

Legend

- 1 "Camera" tab
- 2 "Robot" tab
- 3 "Setup" tab
- 4 "Waypoints" tab

3.4.1 Camera

The "Camera" tab within the control panel shows controls for zoom, focus, white light levels, and fluorescence light levels (if licensed). The control values can be adjusted by using the handles, footswitch, or the control screen.

- ▶ Press anywhere on the value bar or press and drag the slider to change the values.
- ▶ Select the **+** or **-** buttons for fine tuning.

Setting	Range
Zoom	1.00 x to 10.00 x
Focus	200 mm to 450 mm
White Light	0 % to 100 %
Fluorescence Light (DUV)	0 % to 100 %
Fluorescence Light (DIR)	75 % to 100 %

Fluorescence controls

Note

Fluorescence modules (DUV 400 and DIR 800) require a license for use with the Aesculap Aeos system.

DUV 400: The integrated DUV 400 fluorescence module of the Aesculap Aeos is used to visualize near-UV fluorescent areas in the surgical field. The module has been designed for excitation in the wavelength range from 390 nm to 420 nm and for fluorescence visualization in the wavelength range greater than 510 nm. The module enables the surgeon to switch between white light and blue-violet excitation light for fluorescence. In addition to visualization, users can record fluorescent and auto-fluorescent light emitted by tissue by enabling the "Overlay" feature.

DIR 800: The integrated DIR 800 fluorescence module of the Aesculap Aeos is used to visualize infrared fluorescent areas in the surgical field and includes features to record and play back a video clip of the area of focus where fluorescent light is emitted. The module has been designed for excitation in the wavelength range from 740 nm to 800 nm and for fluorescence visualization in the wavelength range from 820 nm to 900 nm. The fluorescence feature generates an image in the infrared spectrum, which means it cannot be seen by the naked eye.

Fluorescence controls can be adjusted by using the handles, footswitch, or control screen.

Note

The "Autofocus" feature is disabled while fluorescence functions DUV 400 or DIR 800 are enabled. Use the control screen, handles, or footswitch to manually refocus the target image.

Function checks

⚠ WARNING

The fluorescence reference card and the control screen are not sterile!

▶ Perform fluorescence functional tests before surgery.

- ▶ Before starting fluorescence visualization, always check the functionality of the integrated fluorescence module.
- ▶ Ensure that the Aesculap Aeos system is in a dark room, with no other illumination other than the Aesculap Aeos integrated lighting and the system displays.
- ▶ Place the reference card on a level surface.
- ▶ Set the focus to 325 mm and the zoom to 5 x on the control screen.
- ▶ Refocus the image by moving the camera upwards or downwards using assisted drive.
- ▶ Activate the fluorescence function by selecting the "DUV 400 On" or "DIR 800 On" button on the control screen or the corresponding handle or footswitch button.
- ▶ In the live image, check the following:
 - **DUV 400:** There is distinct contrast (orange/pink) between the DUV 400 reactive compound and the reference card (green/white).
 - **DIR 800:** There is distinct contrast (black/white) between the DIR 800 reactive compound and the reference card.
 - The reactive compound must be clearly distinguishable and the live image should not be washed out. Slight deviations in color and brightness are acceptable.

DUV 400 imaging

The following factors influence the visualization of the fluorescence signal:

- Fluorescence medium and its concentration in the tissue
- Transmission of the optical system
- Working distance and the illuminated field diameter
- Selected white light level
- Selected fluorescence light level

▶ Ensure that no navigation systems are directed at the surgical field during the DUV 400 application and turn off the ambient lights or any lamp that can illuminate the field of view.

▶ Activate the fluorescence function by selecting the "DUV 400 On" button on the control screen or the corresponding handle or footswitch button.

The white light level can be increased to allow for better visualization of the surrounding area.

The "Aesculap Aeos Control" panel will still be available and – additionally – the "Fluorescence Light Level" value bar can be adjusted while DUV 400 is on (default value: 100 %).

- ▶ Select "Overlay" to show an overlay of captured fluorescence in the live view.
- ▶ Select "FL Off" to turn off near-ultraviolet light and return to white light only.

DIR 800 imaging

Optimum illumination in DIR 800 fluorescence module is achieved if the illuminated field of focus diameter on the Aesculap Aeos is set to the middle position of the live image, i.e. a small depth of field is set, as well as the smallest acceptable working distance.

The following factors influence the visualization of the fluorescence signal:

- Fluorescence medium and its concentration in the tissue
- Transmission of the optical system
- Working distance and the illuminated field diameter
- Selected white light level
- Selected fluorescence light level
- Working distance

⚠ CAUTION

The light output of the LED decreases as they heat up (for example, with increased operating time of the light source) and, as a result, the brightness of fluorescence decreases.

- ▶ When using DIR 800, do not exceed a working distance of 300 mm as indicated by the Focus slider.
- ▶ Ensure that no navigation systems are directed at the surgical field during the DIR 800 application and turn off the ambient lights or any lamp that can illuminate the field of view.
- ▶ Activate the fluorescence function by selecting the "DIR 800 On" button on the control screen or the corresponding handle or footswitch button.

The "Aesculap Aeos Control" panel will still be available and – additionally – the "Fluorescence Light Level" value bar can be adjusted between 75 % and 100 % while DIR 800 is on (default value: 100 %). The software will begin a recording with a 01:40.00 (MM:SS.MS) countdown timer that will continue until either the "Playback" or "FL Off" button is selected or the timer reaches 00:00.00. If the timer is allowed to reach 00:00.00, DIR 800 will automatically advance to "Playback" mode.

The white light level can be increased to allow for better visualization of the surrounding area.

Once in "Playback" mode, the captured DIR 800 recording will loop playback in "Picture in Picture (PiP)" view, until "FL Off" is selected.
- ▶ Take multiple DIR 800 recordings by selecting "DIR 800 On" again.

Selecting "Playback" will continue to loop through all recordings, starting with the most recent. All DIR 800 recordings taken within a case will be available for playback during the case and will be saved as separate recordings, if select to do so when ending the case.
- ▶ Navigate through DIR 800 recordings using the dedicated buttons in the "PiP" view on the control screen or by using configured control buttons on the handles or footswitch.
- ▶ Select "FL Off" to stop playback and return to white light only.

Changing DIR 800 recording quality



Fig. 36

- ▶ Select the Settings button to open system settings panels.
- ▶ Select the Recording button.
- ▶ In the "Recording" panel, press the "Advanced" tab.

The recording quality can be adjusted using the "DIR 800 Quality" slider.

The recording quality and the corresponding file size can be increased from left to right.
- ▶ Save changes and close panel using the OK button.

3.4.2 Robot

"Control" tab

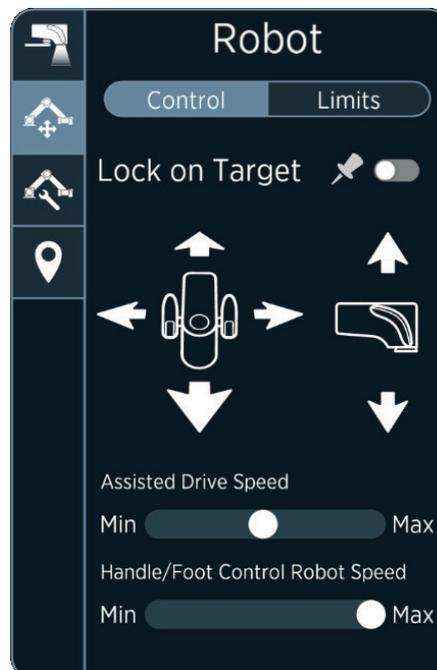


Fig. 37

The robotic arm pan and rotation movements can be controlled from the "Robot" tab in the control panel in precise, single-axis movements. Each arrow (Forward, Back, Left, Right, Up, and Down) corresponds to a directional movement in relation to the camera.

Holding down one of the directional arrow buttons moves the robotic arm until a joint limit is reached. Directional movements can also be employed by configuring the corresponding commands to the handle buttons (see Chapter 3.6.10) or footswitch buttons (see Chapter 3.6.11).

The "Lock On Target" function locks the Aesculap Aeos onto a selected focal target in the live image. When enabled, directional movement will rotate around the focal target instead of moving linearly. Up and Down directional movement remains unchanged while "Lock On Target" is enabled.

"Lock On Target" can be used via the button on the control screen in "Robot" tab or the corresponding handle or footswitch button.

- ▶ Press the "Lock On Target" button to activate/deactivate the function. If the slider position is closer to "Min" (minimum), the robotic arm movement will be slower, and if the slider position is closer to "Max" (maximum), the robotic arm movement will be faster.
- ▶ Change the speed of the robotic arm movement by clicking anywhere on the "Robot Speed" bar or by clicking and dragging the slider.

"Limits" tab

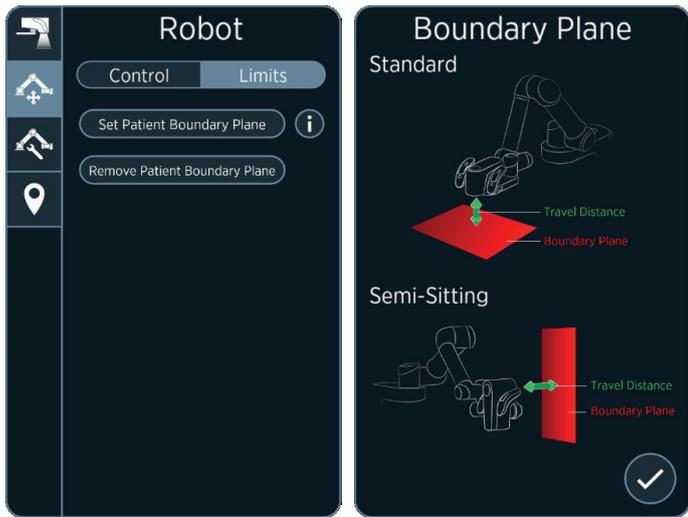


Fig. 38

The patient boundary plane can be set to prevent potential collisions. If a patient boundary plane is set it will prevent the system to go below the defined limit/plane.

- ▶ To set or remove the patient boundary plane, press the corresponding button.

3.4.3 Setup
see Chapter 3.2

3.4.4 Waypoints

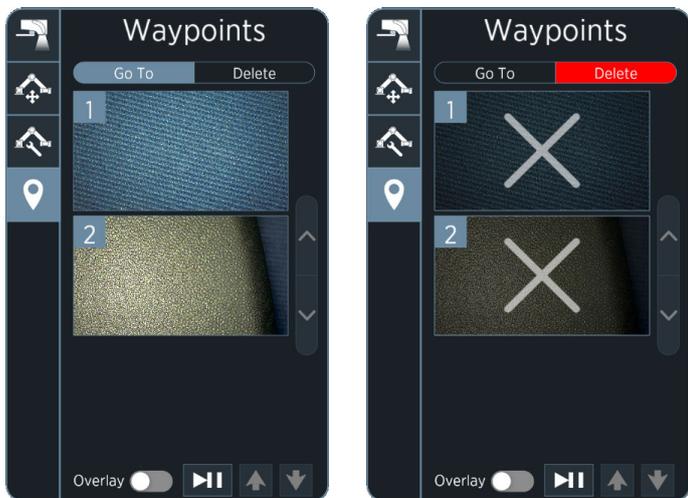


Fig. 39

- ▶ To set a new waypoint, press the corresponding button on the handles / foot switch or the corresponding function in the Quick Access Bar (QAB).
- ▶ To navigate to a previously set waypoint: Press the corresponding button on the handles / foot switch or select the waypoint in the "Go To" menu.
The robot arm moves back to the previously saved waypoint. If the overlay function is active the image of the waypoint is overlaid with the live image. The transparency of the overlay can be adjusted using the arrows.
- ▶ To delete a waypoint: Press the corresponding button on the handles / foot switch or select the waypoint in the "Delete" menu.

3.5 Quick Access Bar (QAB)

The Quick Access Bar (QAB) can be configured to show the top four most-used available functions in the home and live screens, as well as while in fullscreen.



Fig. 40

- ▶ Edit the QAB by selecting the pencil button and toggling on or off the available functions.
Selected QAB functions are highlighted in green and are added to the bar by order of selection.

The following QAB functions are available:

Function	Description
Viewport	Configure the format for multiple inputs on screen. Select between primary input, secondary input, split screen, or picture-in-picture. Configure a second video source in the input settings.
Swap Sources	Switch between the primary and secondary input in the main view.
Autofocus	Initiation of the autofocus function
Digital Aperture	Toggle a digital aperture that blocks out the periphery of the image. Adjust the size and transparency in the "Digital Aperture" settings, see Chapter 3.6.3.
Rebalance Scope	see Chapter 3.2.2
Save Waypoint	Press button once to save current location and configuration as a waypoint.
Image mode	Switch between the five predefined image modes

3.5.1 Autofocus

Select this option to automatically focus the subject in the center of the Aesculap Aeos image.

- ▶ Do not initiate the autofocus function when the robot arm is being moved.
- ▶ Start the autofocus as follows:
 - Press the configured key on the handles, see Chapter 3.6.10
 - Press the configured key on the foot switch, see Chapter 3.6.11.

Note

If "Autofocus After Move" in the "Camera" settings panel is disabled, the focal target will not be reassessed after manual movement while "Lock On Target" is enabled. To refocus image manually, use the control screen, handles, or footswitch.

Note

If the autofocus function cannot be selected, the camera must be repositioned to enable the functionality.

3.5.2 Image modes

The Image Modes allow to adjust the image to the preference of the user respectively to adjust the image to a specific scene or need. The system is always booting up in Image Mode 2.

Mode	Vividness	Brightness
Mode 1	■ ■ ■ □	■ □ □ □
Mode 2	■ ■ □ □	■ ■ □ □
Mode 3	■ □ □ □	■ ■ ■ □
Mode 4	■ □ □ □	■ ■ ■ ■
Mode 5	Artificial	■ ■ ■ □

3.6 Software settings



Fig. 41

- ▶ Select the Settings button to open system settings panels. The "Camera" settings panel will open by default the first time the settings are accessed. After that, the last used panel will be opened in subsequent accesses. Selecting a different Settings button will automatically save any changes made and switch panel.
- Selecting the More Settings button reveals additional settings panels. Commonly found buttons in the settings panels include:

Icon	Description
	Exit panel without saving changes made to current panel.
	Reset the current panel to its default settings. (Not present for DICOM or Input panels.)
	Save changes and close panel.

3.6.1 Camera settings



Fig. 42

In the Camera settings panel the following settings of the camera can be selected.

Auto Focus modes

Mode	Description
Continuous	When Aesculap Aeos is moved by any method or the image is zoomed in or out, the software will continuously and automatically refocus on the center of the image. To initially start "Continuous" a manual auto focus using handles, footswitch or control screen must be performed once. "Continuous" is the default mode.
After move	After Aesculap Aeos has been moved by any method, the software will automatically refocus on the center of the image.
None	The Aesculap Aeos will not refocus automatically. Manual focus or manual auto focus using handles, footswitch or control screen must be performed to achieve ideal focus.

Focus Indicator

If "Focus Indicator" is enabled the focus indicator will appear when manual focus or auto focus is performed. It will also appear when Aesculap Aeos is moved via any method. The focus indicator disappears when movement and focussing are completed.

This setting is enabled by default.

3.6.2 Screen Layout

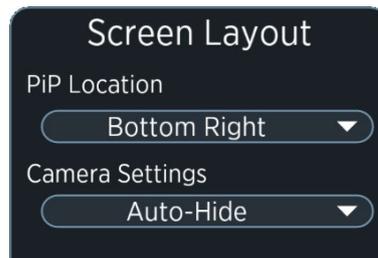


Fig. 43

In the Screen Layout settings panel the following settings of the camera can be modified:

- Picture in Picture (PiP) Location
- Camera Settings

Picture in Picture (PiP) Location

The "PiP Location" drop-down menu has the following options:

- Bottom Right (default)
- Top Left
- Top Right
- Bottom Left

Camera Settings

The "Camera Settings" drop-down list has the following options:

Option	Description
Auto-Hide (default)	The Aesculap Aeos control values (Zoom, Focus, and White Light) will be displayed over the live surgery screen for ~5 seconds and then hidden after adjusting the values.
Show	The Aesculap Aeos control values will always been shown on the surgery screen(s).
Hide	The Aesculap Aeos control values will never be shown on the surgery screen(s).

3.6.3 Digital Aperture

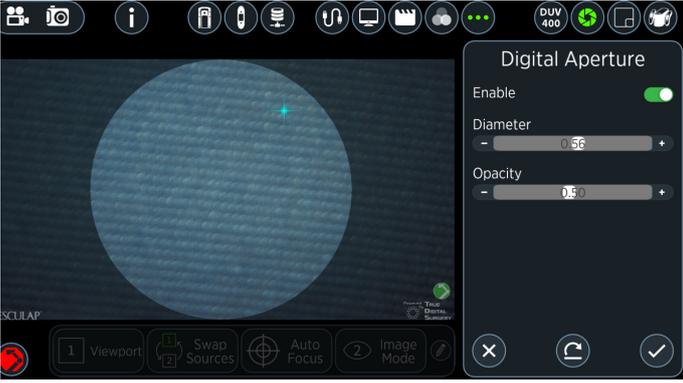


Fig. 44

The Digital Aperture feature enables a digital overlay where the live image can be restricted to a circle in the center of the screen, with a dark mask covering the rest of the image.

- ▶ Press the toggle button to disable (default) or enable the feature.

Diameter

- ▶ Use the "Diameter" bar to select or slide the value anywhere between 0.05 (smallest diameter) and 1.00 (largest diameter). The default diameter is 0.56.

Opacity

- ▶ Use the "Opacity" bar to select or slide the value anywhere between 0.05 (most transparent mask) and 1.00 (most opaque mask). The default Opacity is 0.50.

3.6.4 DUV 400 (Fluorescence)

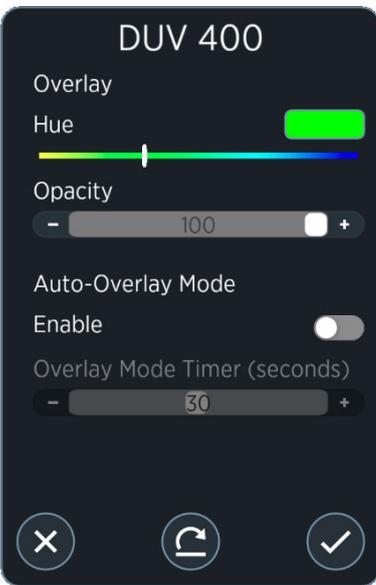


Fig. 45

In the DUV 400 panel the following settings for the DUV 400's overlay can be modified:

- Hue: can be adjusted on a range of yellow to blue (default: green)
- Opacity: can be adjusted from 0 to 100 (default: 100)
- "Auto-Overlay"

"Auto-Overlay", when enabled, transitions from DUV 400 to Overlay after a set amount of time. "Overlay Mode Timer" can be adjusted from 1 to 60 seconds. By default, "Auto-Overlay" is disabled and "Overlay Mode Timer" is set to 30 seconds.

3.6.5 Color



Fig. 46

In the Color panel the following settings can be modified:

- Gain: can be adjusted from 0 to 80 (default: 0)
- White Balance

White Balance

Every Aesculap Aeos is shipped with pre-configured white balance settings. For standard lighting conditions it is recommended to use factory white balance settings.

- ▶ To reset the white balance to the factory settings, press "Reset to Factory WB" button.

Under specific lighting conditions a manual white balance may improve the image quality:

- ▶ Set the Aesculap Aeos light to the surgeon's normal working conditions.
- ▶ Place the white balance card PV030 under the light. Ensure that the entirety of the live view is filled by the card. Never use gauze, tape, sheets, or other fabrics which may have been bleached.
- ▶ Tilt the card and move it either closer or farther from the light as the software instructs.
- ▶ Select "White Balance" to perform white balance and follow the on-screen instructions to complete the white balance process.
- ▶ Test the colors by viewing your hand under the Aesculap Aeos. Repeat the process if the colors look incorrect.

3.6.6 Recording



Fig. 47

In the Recording  panel the following settings can be modified:

- Movie or snapshot file formats
- Auto-record
- Fullscreen recording
- Frame rate
- Movie quality
- DICOM 3D recording

Note

Recording settings cannot be changed while recording a case.

Basic settings

Note

Fullscreen recording is not recommended due to possible delays in the image.

► Select the desired recording settings:

- Movie format: Press the radial button of either "AVI" or "MOV" (default: AVI).
- Auto-Record: check the checkbox to have the software start recording as soon as "Start Case" is selected (default: unchecked).
- Fullscreen: Check the checkbox to record the surgery screen with all annotations and overlays. If unchecked, the software will only record the raw Aesculap Aeos input (default: unchecked).
- Snapshot format: Press the radial button of either "JPEG" or "PNG" (default: PNG).

Advanced settings

Note

Increases or decreases to frame rate and quality can be expected to have relative increases or decreases to file size.

► Select the desired advanced recording settings:

- Frame Rate: frames per second that will be captured during a recording. Select the desired frame rate by pressing or pressing and dragging the slider from any value between 30 fps and 58 fps (default: 45 fps).
- Quality: can be adjusted from 0 to 10, resulting in respective changes to recording quality. Notably, minimizing the slider can introduce compression elements such as haloing or blurry frames to the recording with the benefit of reducing file size. Select the desired quality setting by pressing or pressing and dragging the slider from any value between 1 and 10 to change the quality for non-DIR 800 recordings (default: 7).
- DIR 800 Quality: similar to the quality setting above, set the desired quality setting for DIR 800 recordings (default: 8).
- Squeezed SxS (side by side): checking the checkbox reduces resolution of saved media to 1920 × 1080 (default: unchecked). Select this option when smaller file sizes and/or the ability to edit with 3rd party editing software are required.
- DICOM Record 3D: when a DICOM patient is selected at the start of a case, all media recordings will be in 2D by default. Check the checkbox to record all DICOM case media in 3D. Uncheck the checkbox to record in 2D again.

Note

Non-DICOM patient case media are in 3D by default, therefore the "DICOM Record 3D" feature is disabled when a non-DICOM patient is selected.

3.6.7 Display



Fig. 48

In the Display  panel certain display settings can be modified, including the view type, 3D format, and polarity of connected monitors (see Chapter 2.1.3 for a list of compatible displays).

Identification information (numeric identifier, model number, 3D format, polarity, resolution, and view type) will automatically appear on the live image of each connected monitor while the Display settings panel is open.

Note

For displays intended for use (see Chapter 2.1.3), the 3D format and polarity ("Swap 3D") are automatically detected and set to their ideal pre-configurations, as long as "Detect" remains enabled with the default panel settings.

► To return to the ideal pre-configuration after making changes, select "return to defaults" button, then ensure "Detect" is enabled.

Detect

► Press the "Detect" button to turn this feature on or off. Detect is set to "Off" by default to allow the software to automatically configure the connected displays to their saved settings.

Display List

► To view or manually modify settings for a specific display, select the corresponding numeric identifier for that display from the "Display" drop-down list.

View

► Press the "View" drop-down list to assign a view type to the selected display.

The available view types are:

- Control
- Surgery
- Assistant 180
- Assistant 90 CW
- Assistant 90 CCW

"Surgery" view is a non-interactive secondary view with the primary function of displaying the live image. "Surgery" view will display relevant notifications as they appear on the "Control" view.

"Assistant 180", "Assistant 90 CW" (clockwise), and "Assistant 90 CCW" (counter-clockwise), are "Surgery" views that are rotated as indicated.

Note

At least one display must be assigned a "Control" view type. The control screen display is assigned as the "Control" view by default.

3D Format

- ▶ When "Detect" is set to "Off", press the "3D Format" drop-down list to change the 3D format for the selected display from the following available options:
 - Monoscopic
 - Row-Interleaved
 - Side-By-Side
 - Top-Bottom
 - LL-RR-Interleaved

Swap 3D

- "Swap 3D" switches the left and right eye polarity and can be used to help determine if the monitor is using the correct 3D polarity setting.
- ▶ To check the polarity, close the right and left eye alternatively while wearing 3D glasses and ensure the on-screen "Left" and "Right" text matches the eye opened.

3.6.8 Input Source



Fig. 49

In the Input Source panel external display devices, such as an endoscope, can be configured to the correct input type. The available input source types are:

- SDI
- HDMI

"Viewport 1" is set to the 3D live image from the camera. "Viewport 2" can be configured to display either SDI or HDMI input from connected external devices. Both SDI and HDMI devices can be connected simultaneously, however only one type can be displayed at a time.

- ▶ Press the corresponding radial button of the desired input type.
- The following Aesculap camera system is supported by the Aesculap Aeos:

Art. no.	Supported settings
PV480	50 Hz or 60 Hz signal, SDI output on PV480, SDI input on Aesculap Aeos

3.6.9 DICOM

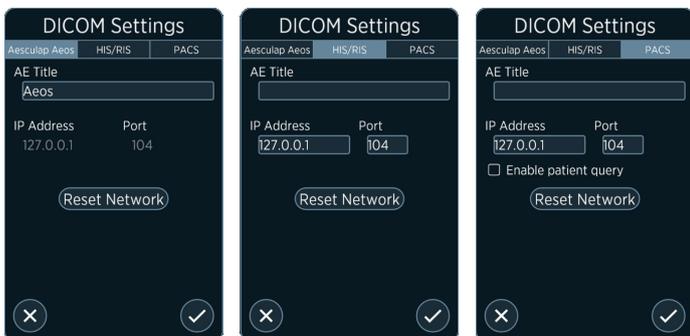


Fig. 50

In the DICOM panel the networking for uploading and downloading media to and from a configured server database can be set up.

Note

The DICOM module requires a license for use with the Aesculap Aeos system.

See DICOM Conformance Statement TA015615-DCS for information related to the use of DICOM data exchange.

- Network and DICOM addresses must be provided by the IT administrator responsible
- AE titles are case-sensitive
- A connection test is automatically run prior to each DICOM upload to verify both servers are running and accepting the data type being sent
- The information on the "Aesculap Aeos" tab except the AE-Title is static. The settings in "HIS/RIS" and "PACS" tabs are editable and can be updated at any time.

Setting up network connection

- ▶ To set up the initial connection with the hospital network, consult with local B. Braun/Aesculap representative.

3.6.10 Handles



Fig. 51

In the Handles panel the layout and functions of the camera handles using can be customized.

- ▶ Press the "Left-Right" toggle to switch between handles.
- ▶ See below for a list and description of each button's function.

Dual Mode

- ▶ Press the "Dual Mode" checkbox to enable/disable this function. When Dual mode is enabled, both handles share the same configuration. Two Dual mode setups can be configured, A and B, and toggled between. The A-B toggle is only accessible when "Dual Mode" is enabled.

Available handle button functions

The following functions can be mapped to the blue buttons.

Button description	Functionality
None	No Function
Autofocus	Microscope will automatically focus on the center of the field of view.
Button Layout Toggle	Displays the current button layout.
Cycle DIR 800	Toggle near infrared light mode to enable intraoperative visual assessment of blood flow after an ICG injection.
Cycle DUV 400	Toggle to a blue-light filter to intraoperatively differentiate between diseased and healthy tissue after a 5-ALA injection.
DIR On/Off	Turns the DIR light on and off.
FL Light Down	Reduce the amount of light while DUV 400 mode is on.
FL Light Up	Increase the amount of light while DUV 400 mode is on.
DUV On/Off	Turns the DUV light on and off.
Digital Aperture Toggle	Toggle digital aperture overlay. Diameter and Opacity can be changed in settings.
Focus (+)	Move the objective lens closer.
Focus (-)	Move the objective lens farther away.
Image Mode (Next)	Skips to next image mode.
Image Mode (Previous)	Skips to previous image mode.
Level Scope	Positions the camera so that it is level scoped.
Lock-On Mode Toggle	Toggles Lock-on target mode
Move (Backward)	Move the camera backward.
Move (Down)	Move the camera down.
Move (Forward)	Move the camera forward.
Move (Left)	Move the camera left.
Move (Right)	Move the camera right.
Move (Up)	Move the camera up.
Orbit Target CCW	Move the camera around the target counter-clockwise.
Orbit Target CW	Move the camera around the target clockwise.
Pause/Play	Pause/Play current DIR 800 recording.
Record	Start/stop video recording.
Recording (Next)	Skips to the next recorded DIR 800 video.
Recording (Previous)	Skips to the previous recorded DIR 800 video.
Show Button Layout Hold	Shows the button layout of the handle on the surgeon screen while button is held.
Show Button Layout Toggle	Toggles showing the button layout of the handle on the surgeon screen.
Show Foot Pedal Layout Toggle	Toggles showing the foot pedal layout on the surgeon screen.
Snapshot	Take a snapshot.

Button description	Functionality
Swap Sources	Toggle between input sources. Can be configured to either SDI or HDMI.
Toggle Secondary Image	Toggles waypoint overlay picture.
Viewport Layout Cycle	Cycle through available viewport settings. Can be configured to "Source 2", "Picture in Picture", or "Side by Side" view.
Waypoint Save/Delete	Press button once to save current location and configuration as a waypoint. Hold down button to delete selected waypoint.
Waypoint Select/Move	Press button to toggle through saved waypoints. Hold down button to move to selected waypoint.
White Light (+)	Increase white light.
White Light (-)	Decrease white light.
Zoom (+)	Increase zoom.
Zoom (-)	Decrease zoom.

The following functions can only be mapped to the white buttons with .

Button description	Functionality
Assisted Drive	Free movement of the robotic arm.
Turbo Assisted Drive	The Turbo Assisted Drive enables the user to quickly remove the robotic arm from the surgical field.

Note

If the robot arm is moved without pressing the assisted drive button this causes a protective stop state.

3.6.11 Footswitch

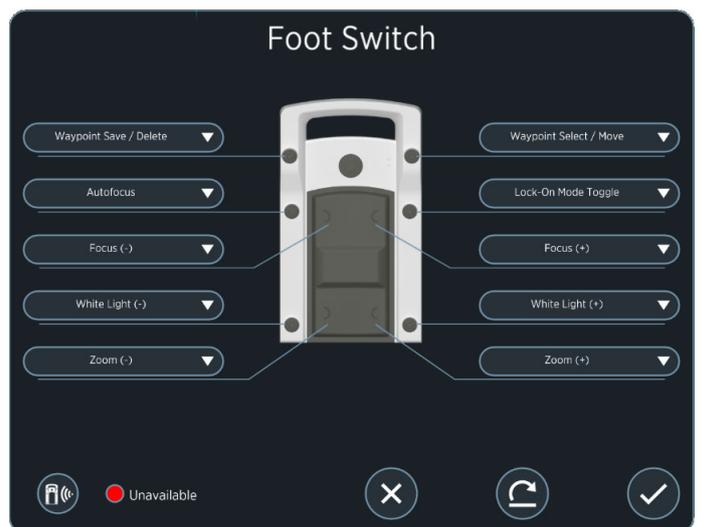


Fig. 52

In the Footswitch  panel the footswitch can be paired with the Aesculap Aeos and the layout and function of the footswitch can be configured.

See below for a list and description of each button's function.

Note

The footswitch has a red colored status indicator when unpaired.

Pairing the footswitch

- ▶ Make sure that the footswitch is in sleep mode and there is no active radio connection:
 - Do not press switches for at least 2.5 seconds.
 - Ensure that all LEDs on the footswitch are off.
- ▶ Simultaneously press and hold buttons 1 and 2 on footswitch until the LED slowly blinks red, then select the Pair  button in the Aesculap Aeos software.

The footswitch is ready for pairing. The footswitch LED will blink red until a new dongle is found or until pairing mode times out after ~30 seconds.
- ▶ To stop the pairing process, press "Cancel".

Once successfully paired, the status indicator in the software will be green and the footswitch will have a green LED when commands are sent to the software.

A yellow status indicator in the Aesculap Aeos software means the footswitch is paired but inactive (no current command is being sent to the software).

A green status indicator in the Aesculap Aeos software means the footswitch is paired and in use (a current command is being sent to the software).

By pressing any of the control components the footswitch changes into active mode and tries to establish a radio connection with the receiver. If there is no pressed button or switch for more than 2.5 seconds, the footswitch falls back to sleep mode. In this mode all indication LEDs are turned off.

Enabling the footswitch

After every restart of the Aesculap Aeos software, the footswitch must be enabled, see Chapter 2.6.3.

Available footswitch button functions

The same button functions as for the handle are also available for the footswitch, see Chapter 3.6.10

3.6.12 About

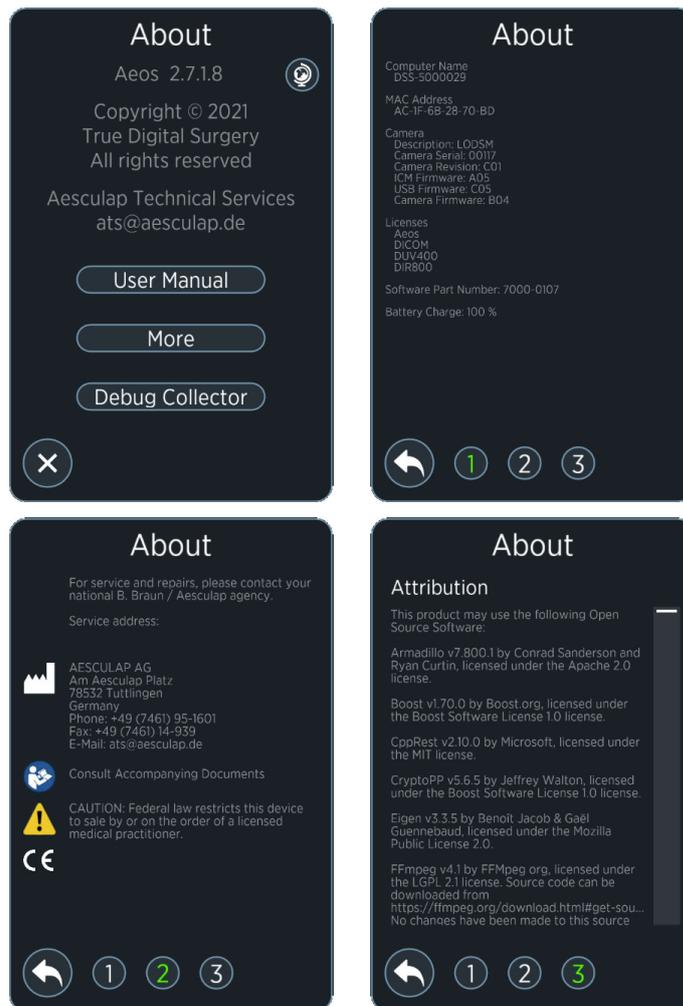


Fig. 53

In the About  panel the following system information is shown:

- Software version
- Technical support contact information
- Language selection
- Link to the user manual
- Link to download system log files (Debug Collector)
- Other software and regulatory information
- ▶ Press "More" button to view information about the product.
- ▶ Press  button to change the software language.

Language selection

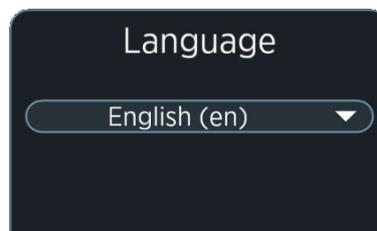


Fig. 54

- ▶ From the drop-down list, select the desired language, then select OK  button to confirm.

The Aesculap Aeos application will need to restart after changing the language.
- ▶ Select Cancel  button to keep the current language.

Note

Patient data saved in a language other than the current language will not be displayed.

Debug Collector

The Debug Collector is used to download system log files to a USB storage device.

- ▶ Insert a USB storage device into one of the USB ports of the Aesculap Aeos, e.g. at the mast.
- ▶ Select "Debug Collector" button.
System log files will be copied onto the USB storage device.

Note

The log files can only be saved onto an external medium.

User manual

- ▶ Press "User Manual" to open the user manual folder found on the desktop.
- ▶ Double-click on the Aesculap Aeos user manual to open the PDF version.

Note

The Aesculap Aeos application does not need to be closed in order to view the user manual.

More

- ▶ Press "More" to open a separate panel with two pages.
Page 1 contains system information, including Computer Name, Mac Address, Camera, Licenses, and Software Part Number.
Page 2 contains regulatory information.
- ▶ Press Back  button to return to the main "About" panel.

3.7 Robotic arm state indicators

The robotic arm has defined force, speed, and geometric limits for safety. As the arm approaches a limit, the indicator shown in the lower right of the live screen will change its icon and color.

The Indicator states are pictured and described in the table below:

State	Icon	Description
Initializing State		Displayed during initial power ON, or when arm is initializing
Ready State		Displayed when arm is ready for movement
Emergency Stop State		Displayed when Emergency Stop button is engaged
Protective Stop State		Displayed when the robot is in a protective stop state after the arm movement is interrupted
Soft Stop State		Displayed when soft stop state is selected
Footswitch Directional Move with No Restrictions		Displayed when moving the arm with the footswitch and there are no movement restrictions
Footswitch Directional Move Approaching Restrictions		Displayed when moving the arm with the footswitch and arm approaches a directional limit
Footswitch Directional Move with Restrictions		Displayed when moving the arm with the footswitch and arm reaches a directional limit

State	Icon	Description
Handle Directional Move with No Restrictions		Displayed when moving the arm with the handle buttons and there are no movement restrictions
Handle Directional Move Approaching Restrictions		Displayed when moving the arm with the handle buttons and arm approaches directional limit
Pre-Programmed Position Move		Displayed when arm is moving to a pre-programmed position
Assisted Drive Move with No Restrictions		Displayed when moving the arm with the handles and there are no movement restrictions
Assisted Drive Move Approaching Restrictions		Displayed when moving the arm with the handles and arm approaches directional limit
Assisted Drive Move with Restrictions		Displayed when moving the arm with the handles and arm reaches a directional limit
Uncalibrated State		Displayed when arm hasn't been calibrated
Handle Directional Move with Restrictions		Displayed when moving the arm with the handles buttons and arm reaches a directional limit
GUI Directional Move with No Restrictions		Displayed when moving the arm from the user interface and there are no movement restrictions
GUI Directional Move Approaching Restrictions		Displayed when moving the arm from the user interface and arm approaches a directional limit
GUI Directional Move with Restrictions		Displayed when moving the arm from the user interface and arm reaches a directional limit
Failure State		Displayed during a hardware malfunction
Coupler in Unlocked Position		Displayed when coupler in Unlocked position and while changing coupler orientation

Note

In the unlikely event that the robotic arm becomes difficult to move near a geometric limit, it is recommended to move the robotic arm back to a pre-set position (e.g. Drape).

Note

If the system is running but not used for more than 12 h, the robot will automatically be turned off and following message will appear on the screen:

"Robotic arm powered off for safety. Please power on and place in storage to exit Aesculap Aeos."

3.8 Robot malfunction

Note

If the robot arm can no longer be moved, e.g. after a Protective Stop, the complete system must be shut down.

Important: For resetting the robot arm, the system must be switched off since a reboot of the operating system is not sufficient.



Fig. 55

- ▶ Press the Exit button.
- ▶ Press the grey text "Shutdown without following recommended procedure" in the message box to shut down the system independent of the robot position.

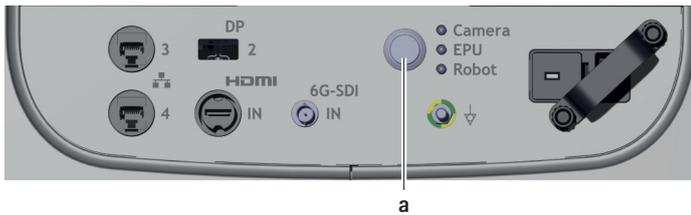


Fig. 56

Legend

- a Main power button
- ▶ Press main power button a to turn off system.
- ▶ Wait for 10 seconds, then press main power button a to turn on system.
- ▶ If the system still cannot be moved, please contact Aesculap Technical Service.

4. Troubleshooting

4.1 Malfunctions

Malfunction	Remedy
System computer (EPU) not working	Shut down and reboot system if the LED indicator is red. If issues remain, contact Aesculap Technical Service, see Chapter 7.2
Colors look wrong	Perform a white balance of the camera in the software settings.
3D looks inverted	Switch the 3D polarity in the software settings.
Image is upside-down	Rotate the camera orientation in the software settings.
Hard to see 3D	Position the display so that it is directly in front of the surgeon. Some displays have a small ideal viewing angle. Adjust the height and tilt of the display for the best view.
Camera not detected	If the software reports that the camera is not connected, check the camera cable connection at the camera. Unplug the cable connection at the camera and plug it back in to check if the software is operating correctly now. Shut down and reboot the system if system is not running after cable connection check. Reboot the system if the indicator LED is red. If issues remain, contact Aesculap Technical Service, see Chapter 7.2
Light, zoom, or focus not working	Check that the camera power cable is connected. Ensure that the camera indicator is green. Shut down and reboot the system. If issues remain, contact Aesculap Technical Service, see Chapter 7.2
Autofocus cannot be selected	If the autofocus function cannot be selected, the camera must be repositioned to enable the functionality.
Display not recognized	If a display is turned on after the EPU has started, it may not recognize the display. Check that the display cable is securely plugged into the back of the display. Restart the EPU.
Spots on the display	If the displayed image develops spots that do not move as the viewing target is moved, the camera optics may have dust on the viewing surfaces. Clean the optics and screen. If the spots remain, the dust may be inside the camera. Contact Aesculap Technical Service, see Chapter 7.2
Robotic arm not working	Follow the error message on the display. If this does not work, switch off the system completely and disconnect it from the power for 10 seconds. Then restart the system. If issues remain, contact Aesculap Technical Service, see Chapter 7.2
Control screen not working	Use keyboard to shut down and reboot the Aesculap Aeos.
Keyboard not working	Disconnect and reconnect USB plug.

Malfunction	Remedy
Image errors during high frequency surgical applications	Observe "Notes on electromagnetic compatibility (EMC) for the Aesculap Aeos (Digital Surgical Microscope) PV010" TA015615-EMV
Disturbance when DIR / DUV is used by other infrared light-based devices, e.g. IR remote controls, pulse oximeters, video-optical localizer systems (navigation), etc.	Change the spatial position of the devices in relation to one another, cover or deactivate external sources.
Low DIR 800 fluorescence intensity	Move the camera closer to the object. Ensure the working distance is set within the range of 200 mm to 300 mm as indicated by the Focus slider.
No live image	Restart Aesculap Aeos software by double clicking the Aesculap Aeos icon.
Software unresponsive	Follow the error message on the display. If this does not work, switch off the system completely and disconnect it from the power for 10 seconds.
Windows desktop visible	Then restart the system.

4.2 Error messages in the software

Startup errors

Error message	Remedy
Error message when operating the universal coupler	Due to the software, an error message may be displayed when the coupler is turned quickly, but this must immediately disappear. Contact Aesculap Technical Service, see Chapter 7.2 if the error does not disappear within 5 seconds.
Protective Stop error message (robot)	Follow the error message on the display. If this does not work, switch off the system completely and disconnect it from the power for 10 seconds. Then restart the system. If that does not help, contact the local Aesculap representative or Aesculap Technical Service, see Chapter 7.2
Rebalancing message	It is recommended to rebalance the system after draping. It is important to ensure that the attachment of the drape does not generate any tension between the camera and the universal coupler. Pulling on the sensor can mean that the balancing process of the system cannot be carried out successfully. If the universal coupler has to be rotated during the procedure, the adhesive tapes must be loosened beforehand in order to avoid tension.

Error message	Remedy
Already initialized	Restart the system.
Aesculap Aeos Head Manager failed	If that does not help, contact the local Aesculap representative or Aesculap Technical Service, see Chapter 7.2
Cursor Manager failed	
Aesculap Aeos failed	
Event Manager failed	
Message System failed	
Core functions failed	
Patient Manager failed	
Playback Manager failed	
Procedure Manager failed	
Recording Manager failed	
Storage Manager failed	
Surgeon Manager failed	
QAB settings failed	
Video Capture Manager failed	
Widget Manager failed	
Invalid init parameters	
Failed to run	

License error

Error message	Remedy
Aesculap Aeos license not found. Please contact Aesculap for support.	Contact the local Aesculap representative or Aesculap Technical Service, see Chapter 7.2

Recording errors

Error message	Remedy
Recording failed. Not enough disk space available.	Download any videos from the system that should be kept and delete any extra files to free up space on the computer.
Erasing recordings less than [3] seconds.	Any recordings shorter than three seconds are automatically deleted. Create a longer recording.
Insufficient space on external drive. Internal drive has approx. [time] remaining.	Download any videos from the system that should be kept and delete any extra files to free up space on the connected drive. Recordings will only save locally.
[Drive volume name] drive connected. Insufficient recording space.	Download any videos from the system that should be kept and delete any extra files to free up space on the connected drive.

Camera errors

Error message	Remedy
Aesculap Aeos head is too hot. Maximum white light reduced to 50%.	The camera is overheating. The maximum white light setting has been capped at 50%. Turn the system off and allow it to cool when safe.
Connect Aesculap Aeos head.	The system is not connected to the camera. Connect the camera while the system is off. Wait 30 seconds and restart. If the connection is failing, contact Aesculap Technical Service, see Chapter 7.2
Possible image degradation detected.	Frame rate from the camera is not acceptable. Check camera cable connections. Contact Aesculap Technical Service, see Chapter 7.2
Lens is dirty / Dust particles on the image	Clean lens with a lint free cloth and water. Contact Aesculap Technical Service, see Chapter 7.2

Power supply errors

Symbol	Error message / Description	Remedy
	No power supply Aesculap Aeos runs on backup battery.	Check power supply connection.
	Battery failure Battery lifetime has expired	Contact Aesculap Technical Service, see Chapter 7.2
	Temperature sensor error Thermocouple sensor failure Hardware malfunction	Contact Aesculap Technical Service, see Chapter 7.2
	Intake fan failure Exhaust fan failure Hardware malfunction	Contact Aesculap Technical Service, see Chapter 7.2

Other hardware errors (robot arm, cart and EPU)

Error message	Description	Remedy
Hardware malfunction detected, 120 seconds time till shutdown. Contact Technical support immediately.	Temperature inside cart too high or hardware malfunction leading to a safety shutdown.	Contact Aesculap Technical Service, see Chapter 7.2

5. Reprocessing procedure

5.1 Single-use products

Art. no.	Designation
PV012SU	Aesculap Aeos sterile drape

- ▶ Do not reuse the product.

The reprocessing of the product affects its functionality. Risk of injury, illness or death due to soiling and/or impaired functionality of the product.

- ▶ Do not reprocess the product.

5.2 Reusable products

For the Aesculap Aeos there is no set maximum number of uses and reprocessing cycles.

A careful visual and functional inspection before the next use is the best opportunity to recognize a product that is no longer functional, see Chapter 5.6.

5.3 Preparation before cleaning

- ▶ Remove any visible surgical residues as much as possible with a damp, lint-free cloth.

5.4 Product-specific safety instructions for the reprocessing procedure

Risk of electric shock and fire hazard!

- ▶ Unplug the device before cleaning.
- ▶ Do not use flammable or explosive cleaning or disinfecting solutions.
- ▶ Ensure that no fluids will penetrate the product.

Damage to, or destruction of the product caused by mechanical cleaning/disinfection!

- ▶ Only clean and disinfect the product manually.
- ▶ Do not sterilize the product under any circumstances.

Damage to the product due to inappropriate cleaning/disinfecting agents!

- ▶ Only use cleaning/disinfecting agents approved for surface cleaning. Follow the manufacturer's instructions for the respective cleaning/disinfecting agent.

Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- ▶ Use cleaning and disinfecting agents according to the manufacturer's instructions which
 - are approved for plastic material and high-grade steel,
 - do not attack softeners (e.g. in silicone).
- ▶ Observe specifications regarding concentration, temperature and exposure time.

5.5 Wipe disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Cleaning	RT	1	-	-	Alcohol(s), quaternary compound(s) *
II	Wipe disinfection	RT	≥1	-	-	Alcohol(s), quaternary compound(s) *

RT: Room temperature

* Recommended: Meliseptol® wipes sensitive (B. Braun)

Phase I

- ▶ Remove any visible residues with a disposable disinfectant wipe.

Phase II

- ▶ Wipe all surfaces of the optically clean product with a fresh, disposable disinfectant wipe.
- ▶ Observe the application time (1 min minimum).

5.6 Inspection

- ▶ Dry the product if it is wet or damp.

5.6.1 Visual inspection

- ▶ Make certain that all soiling has been removed. In particular, pay attention to mating surfaces, hinges, shafts, recessed areas, drill grooves and the sides of the teeth on rasps.
- ▶ If the product is dirty: repeat the cleaning and disinfection process.
- ▶ Check the product for damage, e.g. insulation or corroded, loose, bent, broken, cracked, worn or severely scratched and fractured components.
- ▶ Check the product for missing or faded labels.
- ▶ Check the surfaces for rough spots.
- ▶ Check the product for burrs that could damage tissue or surgical gloves.
- ▶ Check the product for loose or missing parts.
- ▶ Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Chapter 7.2.

5.6.2 Functional test

- ▶ Check that the product functions correctly.
- ▶ Check that all moving parts are working properly (e.g. hinges, locks/latches, sliding parts etc.).
- ▶ Check the product for any atypical running noise, overheating or excessive vibration.
- ▶ Check for compatibility with associated products.
- ▶ Periodically download and delete video files on the system computer to avoid filling up the storage drive.
The Aesculap Aeos system will not allow the user to make new recordings if the storage drive is filled up.
- ▶ Immediately put aside inoperative products and send them to Aesculap Technical Service, see Chapter 7.2.

5.7 Packaging

- ▶ Ensure that the packaging will prevent a recontamination of the product.

5.8 Storage and transport



Fig. 57

- ▶ Ensure that the robotic arm is in "Storage" position before moving the base, see Chapter 3.2.1.
- ▶ Wrap the power cable around its wrapping post and hang the wireless footswitch from its on the front of the base. Release the brakes on each of the four casters and move the 3D display into the position illustrated above.
- ▶ Twist the arm joint handles to lock the arm in place.
- ▶ Do not push the product while transporting. Only pull the product, especially over elevator and door thresholds.
- ▶ Lock the base castors after moving the system.
- ▶ Use handle at base to pull the Aesculap Aeos for transport.

Note

The system includes a UPS with batteries. To avoid deep discharge of the batteries, the system must be connected to the mains supply for at least one hour after being not in use for two months at the latest.

Ambient conditions

The following environmental conditions apply to the transport and storage of the product:

Aesculap Aeos (Digital Surgical Microscope) PV010

Temperature	-10 °C to 50 °C
Relative humidity	10 % to 90 % non-condensing
Atmospheric pressure	500 hPa to 1 060 hPa

Aesculap Aeos foot switch wireless PV014

Temperature	-18 °C to 55 °C
Relative humidity	10 % to 90 %; non-condensing
Atmospheric pressure	500 hPa to 1 120 hPa

6. Security

Aesculap Aeos does not support any specific security measures.

It is assumed that Aesculap Aeos is used within a secured environment. It is assumed that a secured environment includes at a minimum:

- Firewall or router protections to ensure that only approved external hosts have network access to Aesculap Aeos.
- Firewall or router protections to ensure that Aesculap Aeos only has network access to approved external hosts and services.
- Any communication with external hosts and services outside the locally secured environment use appropriate secure network channels (e.g., such as a Virtual Private Network (VPN)).
- ▶ If using a keyboard, verify that no external device (e.g. keystroke recorder) is attached to the USB cable connection.
- ▶ If you are using DICOM connection, verify that no external device is attached between device and the IT network to avoid any manipulation of data.
- ▶ Do not install and/or use third-party software, such as word processors or games.
- ▶ Delete patient data that is no longer needed and especially before the system is shipped.
- ▶ Store patient data on a regular base to avoid data loss.
- ▶ Stop using the device and contact technical support if a cyber security event is detected.

7. Maintenance and service

7.1 Maintenance

Maintenance of the system according to the maintenance protocol in an interval of 12 month is mandatory.

Maintenance has also to be carried out after each kind of repair, if the device or one component was dropped or damaged or if the medical device was not used according to its intended use.

Maintenance includes the following activities:

- Visual inspection
- Updating software and firmware
- Function check of all components
- Carrying out safety measurements
- Documentation of the test results

Maintenance may only be performed by a person specially trained and authorized by Aesculap.

- ▶ For corresponding services, contact your national B. Braun / Aesculap representative, see Chapter 7.2.

7.2 Technical Service

⚠ DANGER

Danger to life of patients and users if the product malfunctions and/or protective measures fail or are not used!

- ▶ Do not perform any servicing or maintenance work under any circumstances while the product is being used on a patient.

⚠ CAUTION

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights, system liability and forfeiture of applicable licenses.

- ▶ Do not modify the product.
- ▶ Do not break warranty seal (attached to front and rear cover).
- ▶ For service and repairs, please contact your national B. Braun/Aesculap agency.

Service addresses

Aesculap Inc.

Attn. Aesculap Technical Services

615 Lambert Pointe Drive

Hazelwood

MO, 63042 USA

Aesculap Repair Hotline

Phone: +1 (800) 214 -3392

Fax: +1 (314) 895 -4420

Other service addresses can be obtained from the address indicated above.

8. Disposal

⚠ WARNING

Risk of infection due to contaminated products!

- ▶ Adhere to national regulations when disposing of or recycling the product, its components and its packaging.

Note

The user institution is obliged to reprocess the product before its disposal, see Chapter 5..



The recycling pass can be downloaded from the Extranet as a PDF document under the respective article number. (The recycling pass includes disassembling instructions for the product, as well as information for proper disposal of components harmful to the environment.)

Products carrying this symbol are subject to separate collection of electrical and electronic devices. Within the European Union, disposal is taken care of by the manufacturer as a free-of-charge service.

- ▶ Detailed information concerning the disposal of the product is available through your national B. Braun/Aesculap agency, see Chapter 7.2.

9. Technical data

9.1 Classification acc. to Directive 93/42/EEC and Regulation (EU) 2017/745

Art. no.	Designation	Class
PV010	Aesculap Aeos (Digital Surgical Microscope)	Ila

9.2 Performance data, information about standards

Weight (basic hardware configuration including system's safe working load)	300 kg / 661 lbs.
Dimensions (unpacked, L x W x H)	32.5" x 48.3" x 76.3" / 826 mm x 1 227 mm x 1 938 mm
Power input (max. values)	100 V~/110-120 V~/220 V~/230-240 V~/9.6 A / 8.7-7.5 A / 4.1 A / 4.0-3.7 A 50 Hz / 60 Hz
Footswitch battery type	3 x IEC- LR14 (Type C - "Baby")
Basic hardware configuration conforming to standards:	IEC/DIN EN 60601-1 IEC/DIN EN 60601-1-2
	<ul style="list-style-type: none"> ■ PV008 ■ PV010 ■ PV011 ■ PV031
Wireless characteristics (in combination with footswitch PV014)	<ul style="list-style-type: none"> ■ Power output: -6 dBm e.i.r.p. (0 dBm at 50 Ω) ■ Frequency range: 2.400 MHz to 2.483,5 MHz

9.3 Voltage selector setting

Nominal mains voltage (V~)	Voltage selector setting
230-240	240
220	220
110-120	120
100	100

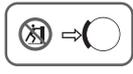
Note

- Check nominal mains voltage and set voltage selector accordingly.

9.4 Safe working load

PV011 monitor arm	8.5 kg / 18.7 lbs.
Robotic arm	5 kg / 11 lbs.
Drawer	2 kg / 4.4 lbs.

10. Symbols on product and packaging

Symbol	Location	Description
	Base	Main power switch. Press to turn the system ON. Press again to turn the system OFF
	Base	Fuse
	Product label	AC input
	Camera	DC input
	Base	Warning: Only to be operated by trained personnel
	Base Robotic arm	Risk of electric shock! Do not open.
	Robotic arm Support arms	Take care to avoid injury when in the vicinity of the display arm or robotic arm.
	Base	Warning: Retinal blue light and Near-UV emission risk. Do not stare at the lamp emission area during operation. Minimize exposure to eyes and skin. Use appropriate shielding.
	Base mast arm	Do not move system with extended arms
	Support arms and drawer	Do not exceed load ratings for support arms and drawer.
	Base and footswitch	Follow instructions for use.
	Base top cover emergency stop	Emergency stop control device
	Base mast	Do not move the cart if one or more parking brakes are activated.
	Product label	System mass
	Packaging label and footswitch product label	Caution Observe important safety information such as warnings and precautions in the instructions for use.
	Product label and packaging label	Manufacturer
	Packaging label	Date of manufacture
	Product label	CSA NRTL Mark
	Product label and packaging label	CE marking acc. to Regulation (EU) 2017/745
	Product label	Medical device

Symbol	Location	Description
	Control screen mount label	USB 3.0 port
	Base interface	USB 2.0 port
	Base interface	DisplayPort
	Base interface	HDMI port
	Base interface	Ethernet port
	Coupler label	Unlocking of coupler Yaw adjustment slider
	Coupler label	Unlocking of coupler Flip down adjustment slider
	Base potential equalization conductor	Connection point for potential equalization conductor
	Product label	Marking of electric and electronic devices according to directive 2012/19/EU (WEEE), see Chapter 8.
	Product label	Catalog number
	Packaging label	Manufacturer's batch designation
	Product label	Serial number
	Product label	Revision
	Packaging label	Delivery quantity
	Packaging label	Temperature limits during transport and storage
	Packaging label	Air humidity limits during transport and storage
	Packaging label	Atmospheric pressure limits during transport and storage
	Packaging label	Non sterile medical device
	Packaging label	USA: Federal law restricts to sale by or on the order of a physician
	Packaging label	See instruction for use
	Packaging	Packaging is recyclable and will be disposed of and recycled by the partners of the RESY organization for Wertstoffsorgung GmbH.

Symbol	Location	Description
	Packaging	Keep dry
	Packaging	This side up
	Packaging	Fragile, handle with care
	Packaging	Do not stack

11. Distributor in the US/Contact in Canada for product information and complaints

Aesculap Inc.
3773 Corporate Parkway
Center Valley, PA, 18034,
USA

