

KINEVO 900

Software Release 1.6

Instructions for use



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Brands

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1 Notes on Instructions for Use

1.1 Product name

KINEVO 900 is referred to as "Device" in these Instructions for Use.

1.2 Scope of application

The present Instructions for Use apply to KINEVO 900 with Software Release 1.6 and the following identification:

- Reference number: 6640

1.3 Purpose and storage of the documentation

These Instructions for Use explain the safety features, functions and performance parameters of the device. They contain instructions on the safe use of the device and identify measures for its care and maintenance.

Correct operation of the device is imperative for its safe and successful function.

- ▶ Read these Instructions for Use before setting up and using the device the first time.
- ▶ Keep the Instructions for Use accessible for all users at all times.
- ▶ Pass the Instructions for Use to future owners of the device.

1.4 Questions and comments

- ▶ If you have questions or comments regarding these instructions for use or about the device, contact ZEISS Service.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

1.5 Conventions in this document

Certain types of information are specially marked in this document for better recognition.

1.5.1 Conventions in all text areas

- This is a list.
 - This is a second level list.

This is a cross-reference: Questions and comments [▶ 11].

This is **bold type**.

This is `software code or program text`.

Names of software dialogs, fields or menus, and software messages are marked by quotation marks:

- "View" menu.
- "Do you want to save the settings?"

The steps in menu and file paths are separated by slashes:

- "File / Save as"
- "My documents / Documents"

Keys, buttons, knobs, levers and other operating controls are marked by square brackets:

- [START] key
- [Next] button

1.5.2 Conventions in a course of action

WARNING!

This is warning information about hazards that can cause death or severe injuries if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

CAUTION!

This is warning information about hazards that can cause injuries if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

NOTE

This is warning information about hazards that can cause property damages if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

- This is a requirement that must be met before the start of a sequence of actions.

1. This is a command.
2. **CAUTION! This is a warning message about hazards that can occur during a single action.** This is a command.
 - ⇒ This is the result of a sequence of actions.

1.6 Other applicable documents

Document type	Document title	Document number
Training record	Briefing report for newly installed systems	G-30-1714
Instructions for use	INFRARED 800 with FLOW 800 Option	G-30-1956
Instructions for use	Mouth switch (option)	G-30-1469
Instructions for use	14-function foot control panel, wired (FCP) or wireless (FCP WL) (option)	G-30-1706
Instructions for use	QEVO and QEVO ECU (option)	G-30-1976
Reprocessing instructions	QEVO	G-30-1989
Instructions for use	Loupe EyeMag Pro S	G-30-1688
Instructions for use	SMARTDRAPE	G-30-1996
Product Overview	ZEISS Video Accessories	G-30-1888
Conformance statement	DICOM Declaration of Conformity	G-30-1952
MICROSOFT SOFTWARE LICENSE TERMS	WINDOWS EMBEDDED STANDARD 7	As an annex to the present Instructions for Use
Release Notes	Release Notes for KINEVO 900 SW 1.6	RN-30-9059

Empty page, for your notes

2 Safety notes

2.1 Target group

CAUTION!

Only to be operated by trained personnel!

These Instructions for Use are intended for physicians, nurses and other medical and technical staff who prepare, operate or maintain the device after appropriate training. It is the duty of the device owner/operator to train and brief all the operating personnel.

- ▶ Initial instruction in preparation, operation, warnings/hazards, emergency operation and transport of the device shall be provided according to Training record G-30-1714 in connection with the present Instructions for Use.
- ▶ Any further training and instruction of planned operating personnel shall be performed by the operator of the device based on these Instructions for Use.

2.2 Area of use

2.2.1 Intended use

The KINEVO 900 is a surgical microscope intended for the illumination and magnification of the surgical area and for the support of visualization in surgical procedures.

CAUTION!

Injury to the patient's eye!

The device must not be used for ophthalmological procedures.

- ▶ Make sure that no xenon light and no laser radiation enters the patient's eyes.

Optional functionalities

The BLUE 400 option is designed for a surgical microscope and can be used in tumor surgery to visualize tumor tissue marked with fluorescence dyes.

The YELLOW 560 option is an accessory for the intraoperative illumination of the surgical area with light in the wavelength range from 460 nm to 500 nm. Light in the wavelength range between 540 and 690 nm is particularly highlighted.

2.2.2 Indications

Information on the indication of use, contraindications and the target patient group is set out in the following table.

Indication of use	
Discipline:	<ul style="list-style-type: none"> ■ Neurosurgery and spine surgery ■ Orthopaedic surgery ■ Oral and maxillofacial micro-surgery ■ P&R procedure ■ Not applicable for ophthalmology
Indication:	The KINEVO 900 is a surgical microscope intended to illuminate and magnify the surgical area and to support visualization in surgical procedures.
Contraindication:	Provided that KINEVO 900 is used within its indication of use, there are no known contraindications.
Patient target group:	No restriction
Age:	No restriction
Gender:	All

2.2.3 Normal use

The complete system comprises a surgical microscope with a highly flexible floor stand containing the electronics, the light source, a graphic touchscreen with video display and an optional second monitor (2D or 3D). The stand supports the operation of the system in the following combinations:

- as an optical system
- as a digital system
- as a combined optical-digital ("hybrid"), robotic visualization system

The visualization system can use mono or stereo video functionalities combined with or without optical observation (tubes/ eyepieces). KINEVO 900 is ideally suited for cranial and spinal applications in neurosurgery as well as ENT applications in the area of the auditory nerve and the base of the skull. Further fields of application include P&R procedures and oral and maxillo-facial surgery. The system is also ideally suited to multidisciplinary use in microsurgery.

It is also designed for surgical interventions in which an endoscope and a surgical microscope are used at the same time, particularly with its microvisualization tool which can be added as an optional extra and simply plugged into the system so that the surgeon can detect hidden details or "see around the corner".

The system is equipped for the connection of navigation systems, intraoperative neuromonitoring systems and for the data communication with external network systems. Optional fluorescence modules enable a better visualization of tumor and healthy tissue as well as better vascular visualization.

The system is intended for use in hospitals, clinics or other medical facilities.

The functions of the surgical microscope (OPMI) and the stand are controlled via the central control unit in the console. The interactive graphic touchscreen enables the user to configure all necessary settings. The user may trigger these functions using the buttons on the handgrips or on an optional foot control panel.

The system may be operated only by physicians, nurses and other medically trained OR staff who have received appropriate training and observe the instructions for use.

The installation conditions and the use of the system must meet microsurgical requirements:

- Low vibration
- Dust-free environment
- Level, horizontal positioning

- Avoidance of extreme mechanical stress
- EMC-specific environment based on a professional healthcare facility (use of RF surgical devices in combination with the microscope)

2.2.4 Possible damage/injury from burns due to the high light intensity

CAUTION!

Tissue damage and burns at high light intensity!

A high light intensity over a longer period of time can damage tissue and cause burns in the area of the illuminated surgical field.

- ▶ Read and observe the factors which can increase the risk of burns described below.
- ▶ Read and observe the recommendations on how you can reduce the risk of burns.
- ▶ Make sure that the "Focus Light Link" function is always switched on.

⇒ The "Focus Light Link" function limits the maximum adjustable light intensity in the focal plane depending on the working distance. Possible tissue damage due to an unintentional high light intensity can thus be avoided. This function should only be deactivated if a higher light intensity is required for the current application.

General

- The device is equipped with a powerful xenon illumination.
- If used improperly, excessive illumination intensities may lead to third-degree burns.
- A device with light source switched on must never be left unattended.

Various factors contribute to the risk of burn injuries:

System-related factors

- If a high magnification is used, the diameter of the field of view and the light intensity at the surgeon's eye and on the integrated cameras both decrease whereas the light intensity in the surgical field remains the same. This effect is increased by the use of certain components, such as e.g. eyepieces with higher magnification or the foldable tube f170/f260 with tube magnification (PROMAG function). When working at maximum magnification, you should therefore pay particular attention to the set light intensity to prevent burns, especially of the surrounding tissue.

Surgery-related factors

- The size of the luminous field influences the risk of injury in two respects: With a large luminous field diameter, areas of the skin are illuminated which are not monitored as strictly by the surgeon and which are not moistened sufficiently. These areas are particularly at risk of injury. These injuries can be prevented by adjusting the illuminated-field diameter to the smallest size required for the relevant operation.
- If the luminous field is reduced in size, the intensity increases because the light is focused more. So, if possible, the intensity should be lowered as soon as the size of the illuminated field is reduced. The device can optionally be equipped with Automatic Light Field Limitation.
- A long surgical procedure increases the risk of injury, in particular if a standard procedure takes considerably longer than usual.
- Injuries in the peripheral area can be prevented by covering this area with moist, sterile gauze. Moisten the gauze at regular intervals to prevent the area from drying out or heating up. The risk is increased if dry drapes are used to cover such areas.
- Some areas of the patient's body may be more sensitive than others.
- Certain preparations of the surgical field, local vasoconstrictive medications and drapes at the wound edge may also result in a higher risk of injury (drapes may heat up to varying degrees depending on their color and moisture content).
- When working in deep channels, the working distance from the illuminated wound edges is shorter than the distance from the actual surgical field. If you increase the light intensity to better illuminate a deeper surgical field, the risk of burns increases for the wound edges.

Patient-related factors

- The general condition of a patient's health may contribute to the risk of injury.
- The skin type may be decisive for the risk of burns or injuries caused by light.
- Certain medications (e.g. light sensitizing substances) also affect the sensitivity to light.
- The interaction of heat and antimicrobial substances in incision foils may lead to an increased reaction of the patient to these substances.

Recommendations

- Make sure that the "Focus Light Link" function is switched on. The "Focus Light Link" function limits the maximum adjustable light intensity in the focal plane depending on the working distance. Possible tissue damage due to an unintentional high light intensity can thus be avoided. This function should be deactivated temporarily at most and only if a higher light intensity is required for the current application. Therefore, please note the recommendations for preventing burns.
- The initial illumination intensity should be preset to a low value.
- If used, drapes should also be remoistened at regular intervals in order to prevent heat from accumulating underneath the drape.
- The risk of burns can be reduced by constantly irrigating the illuminated surgical field and by keeping it moist.
- Using the buttons on the hand grip or foot control panel, the surgeon can set the illumination intensity to the value required for the procedure. Please note that the intensity increases with decreasing luminous field size if the spot function is used. For this reason, the intensity should be set only after the size of the illuminated field has been changed.
- The device features an "Automatic Light Field Limitation" which should not be turned off.
- Reduce the luminous field diameter when working in deep channels, so that the wound edges are not illuminated at a high light intensity wherever possible.
- If the magnification factor is increased during surgery, the light intensity on the observer's side decreases. For balancing, the illumination intensity must be increased. This loss in image brightness is automatically compensated if the "Auto Brightness" function is activated.
- Never leave a device unattended when its light source is switched on.
- Switch off the light when the microscope is not being used, and ensure it is not directed at unprotected bare skin.

2.2.5 Electromagnetic compatibility

The device is subject to specific requirements with regard to electromagnetic compatibility (EMC).

Take the following precautionary measures to avoid EMC malfunctions:

Procedure

- ▶ Observe the Instructions for Use.
- ▶ Observe the EMC guidelines in the section "Technical specifications".
- ▶ Only use accessories, cables and spare parts which have been approved by ZEISS for this device.
- ▶ If you use radio equipment or wireless transmission components: Maintain a minimum distance of 30 cm from all components of the device.
- ▶ If you install the device in the vicinity of other devices or stack it with other devices: Check whether normal operation is possible in this arrangement.

2.3 Responsibilities and duties of the operator

Operating personnel

Only personnel who have undergone training and instruction are allowed to use this instrument.

- ▶ Make sure that the operating personnel are appropriately trained and instructed.
- ▶ Make sure that the operating personnel have read and understood the Instructions for Use.
- ▶ Keep the Instructions for Use available at all times for the operating personnel.
- ▶ To simplify access for all operating personnel, order additional copies of the Instructions for Use from ZEISS as required.
- ▶ Specify the competencies for handling the device and state who is authorized for what tasks.
- ▶ Determine the reporting obligations for faults and damages and make them known. Notification to manufacturers and authorities [▶ 26]
- ▶ Provide the necessary protective clothing.
- ▶ Regularly check that the generally applicable legal regulations regarding accident prevention and health and safety at work in your country are being complied with.

Technical Safety Tests

- ▶ In order to prevent a reduction of the device's safety due to aging and wear, have safety inspections performed regularly as specified for this device by the applicable national regulations.

The technical safety checks must only be performed by the manufacturer or qualified personnel.

- ▶ Comply with the specified time limits.
- ▶ Carry out checks according to the extent specified.

The technical safety checks of the device should at least comprise the following points:

- Availability of the Instructions for Use
- Visual inspection of system and accessories for damage and legibility of labels
- Leakage current test
- Test of protective ground conductor
- Function and wear test of the brakes
- Function test of all switches, buttons, sockets and indicator LED of the system

Maintenance and inspection

- ▶ To ensure safe operation of the device and reach the expected service life: Observe the maintenance and inspection intervals that are specified in these instructions for use.

Changes to the product

- ▶ **WARNING:** This device must not be modified without the manufacturer's permission. If the device is modified, suitable inspections and tests must be performed to ensure that the device can still be used safely.

Accessories and additional equipment

- ▶ If you want to connect accessories or additional equipment to the device: Contact your ZEISS contact person [▶ 11].

Any additional equipment connected to medical electrical devices must demonstrably comply with the applicable IEC or ISO standards (e.g. IEC 60950 for data processing equipment).

In addition, all configurations must meet the normative requirements for medical systems (see IEC 60601-1-1 or Clause 16 of the 3rd edition of IEC 60601-1 respectively).

Anyone connecting additional equipment to medical electrical devices is a system configurer and as such responsible for compliance of the system with the standards for systems.

Local legislation has priority over the above normative requirements.

Dangers arising from connection to a network

Before connecting the device to a network, observe the following safety measures to prevent injury or damage:

- ▶ The user (or IT manager) is responsible for ensuring that no computer viruses are transmitted to the device via the network connection.
- ▶ Ensure a data transmission rate of 1 Gbit/s (Fast Ethernet) and the conformity of your network configuration with internet protocol IPv4 so that patient data can be exported to your network reliably, safely and error-free.

Changes to the network

The following subsequent changes to the network may result in new risks:

- Changes to the network configuration
- Connecting additional devices to the network
- Disconnecting devices from the network
- Updates of devices connected to the network
- Upgrades of devices connected to the network
- ▶ Analyze and eliminate any risk factors newly incurred by such changes to the network.

2.3.1 Requirements for the network connection

The following requirements apply to the network in which the KINEVO 900 is integrated:

LAN

Name	Value
Ethernet protocol IPv4	TCP/IP
Video Streaming	RTP via UDP
Gigabit Ethernet	1000BASE-T, IEEE 802.3 Paragraph 40
Assignment of IP addresses	Static IP or DHCP (configurable within the device)
LAN connection to the navigation system	
Latency	< 3 ms
Data transmission rate	> 1 Mbit/s
Parallel video recording for release in the network	
Data transmission rate (without SmartRecording)	> 40 Mbit/s
Data transmission rate (with SmartRecording)	> 80 Mbit/s
Live streaming of camera image	
Data transmission rate	> 40 Mbit/s

WLAN

Name	Value
Security standard	WPA2/PSK
WLAN standard	802.11 a/b/g/n
Ethernet protocol IPv4	TCP/IP
Video Streaming	RTP via UDP
Assignment of IP addresses	Static IP or DHCP (configurable within the device)
Parallel video recording for release in the network	
Data transmission rate (without SmartRecording)	> 40 Mbit/s
Data transmission rate (with SmartRecording)	> 80 Mbit/s
Live streaming of camera image	
Data transmission rate	> 40 Mbit/s

WLAN hotspot

Name	Value
Security standard	WPA2/PSK
WLAN standard	802.11 a/b/g/n
Ethernet protocol IPv4	TCP/IP
Video Streaming	RTP via UDP
Assignment of IP addresses	DHCP
Live streaming of camera image	
Data transmission rate	> 40 Mbit/s

Network configuration

Name	Value
Assignment of IP addresses	Static IP or DHCP (configurable within the device)
Shared network drive	SMB protocol (Server Message Block), also known as CIFS (Common Internet File System)
Streaming client (via LAN, WLAN, WLAN hotspot)	
Log	RTSP (RTP via UDP)
2D video codec	<ul style="list-style-type: none"> ■ Encoding: H.264/MPEG-4 AVC / High Profile / Level 4.2 ■ HD resolution: 1920x1080p50/60 ■ LowRes resolution: 960x540p25/30
3D video codec	<ul style="list-style-type: none"> ■ Encoding: H.264/MPEG-4 AVC / High Profile / Level 4.2 ■ Resolution: 1920x1080p50/60 TopBottom

2.3.2 Messages to manufacturer and authorities

If a serious incident occurs in connection with this medical device affecting the operator or another person, the operator (or person responsible) must report this serious incident to the manufacturer of the medical product. In the European Union, the operator must report this serious incident to the competent authority in his/her country.

2.4 Measures and duties of the operator

Electrical safety

- ▶ Always switch off the device before connecting it to or disconnecting it from the power supply, for cleaning its surface, or if it will not be used for a prolonged period of time.
- ▶ Only connect the device to a power supply that complies with the values specified on the rating label.
- ▶ Do not use multiple sockets!
- ▶ Do not use extension cables!
- ▶ Do not touch the device if your body is electrostatically charged and the device is not grounded.
- ▶ Connect the device via the potential equalization connection (according to IEC 60601-1) to other active devices with the same ground potential or connect it to a protective ground connection.
- ▶ Please observe the information on electromagnetic compatibility (EMC).

The device contains freely accessible live components. If you remove the housing, you run the risk of electric shock.

- ▶ Never open the device!

Environmental conditions

- ▶ Make sure that the installation conditions and the operation of the device comply with the surgical requirements:
 - Low vibration
 - Clean environment
 - Avoid extreme mechanical stress
- ▶ Do not use power-operated devices included in the delivery package
 - in explosive atmospheres,
 - at a distance of less than 25 cm from flammable anesthetics or volatile solvents such as alcohol, benzine or similar substances.
- ▶ Do not use or store the device in damp rooms. Do not expose the device to water splashes, dripping water or sprayed water.
- ▶ Ensure that fluids cannot enter the device.

Symbols and labels

- ▶ Note the symbols and labels attached to the device!

Transport

- ▶ Only transport the device over long distances (e.g. relocation, return for repair) in its original packaging or special return packaging.
- ▶ Please contact your dealer or ZEISS Service for this purpose.

2.5 Liability and warranty

The warranty and liability depend on the contractually specified conditions.

Do not modify the device without permission.

- This device must not be modified without the manufacturer's approval. If the device is modified, suitable inspections and testing must be completed to ensure that it can still be used safely.
- The manufacturer is not liable for damage caused by unauthorized use of the device. Furthermore, this will forfeit any rights to claim under warranty.

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3 Device description

3.1 General

KINEVO 900 is a robotic visualization device for demanding neuro-surgical applications. A modular hard and software concept enables the successive expansion of the system with additional options such as co-observation lenses, fluorescence modules or the preparation for the connection of navigation systems.

The fully digital configuration enables exclusively digital operation with an external 3D video monitor. Optical co-observation cannot be used in this configuration.

Only options that have been installed and activated with a corresponding license are displayed on the touchscreen.

3.2 Innovative functionalities

3.2.1 Kinematic and robot-assisted positioning functions

KINEVO 900 offers the user new and innovative movement and positioning functions for simplified and more precise pre- and intra-operative microscope positioning.

- Manual "PointLock" movement mode

The [SB] (Selected Brakes) buttons can be assigned using the PointLock function. This function enables the microscope to be moved around a constant visual field centre and repositioned. The focus is at the same time automatically adjusted from 200 to 625 mm within the available focal length range.

- Motorized "PointLock" XY movement mode

This new motorized XY movement function enables the adjustment of the microscope while maintaining the image centre and the working distance. The motor control can be triggered via the XY joystick on the handgrip or hands-free with the FCP.

- Position Memory

The current position of the microscope as well as the working distance and the magnification can be saved at any time. Via the handgrip and the FCP or the user interface on the touchscreen, these stored positions can be called up again and moved to with high accuracy. Important intraoperative landmarks or anatomical details can be called up again and set in this way.

- Motorized "Microscope" XY movement mode
The microscope can be moved by motor in the three axes of its suspension, 4, 5 and 6. This enables motorized tilting and swiveling of the focal point in the XY direction with a fixed working distance. The stand does not move in the process.
- Motorized "Stand" XY movement mode
The microscope can be moved by motor in the three axes 1, 2 and 3 in the XY focal plane without tilting or swiveling; the alignment of the eyepieces always remains the same (e.g. horizontal). This enables precise motorized XY movement of the focal point at a fixed working distance. Only the axes of the stand move in the process.
- Motorized movement to the system park position
The device can be automatically moved to its park position.
- Motorized movement to a drape position
A drape position is saved as a factory setting, however, can be changed arbitrarily. This drape position can be redefined and saved by the user in order to enable more efficient draping always performed in the same position.

3.2.2 QEVO handheld Micro-Inspection Tool (option)

QEVO (option, see Instructions for Use G-30-1776) is a new type of hand-held, digital and completely sterilizable exploration tool for the display of anatomic details not accessible with the microscope (e.g. a view behind an aneurysm to be clipped). It can be plugged into the console of the KINEVO 900 easily and quickly as required, thus replacing an additional endoscope system which would require both time and effort to prepare. The clear high-resolution HD video image of QEVO is displayed on the system monitor or an externally connected video monitor by pressing a button on the handgrip or the FCP.

3.2.3 Integrated 3D video system for observation without eyepieces (option)

KINEVO 900 can be used with a fully integrated stereo video camera as a purely digital visualization system. The observation is carried out in this case using stereo glasses via an external 3D video monitor or an additional 3D video monitor (component of the stereo option), which is installed directly on the console instead of the second HD system monitor. If configured accordingly - depending on the surgical situation at hand and individual preference - the system can also be used with a tube and eyepieces and/or stereo glasses and monitor.

NOTE

Application of BLUE 400 only with eyepiece-based optical observation!

Tubes and eyepieces must be used when the BLUE 400 option is applied.

3.2.4 Data management

- Data storage in a shared network (option)

The KINEVO 900 can be connected to the clinic network via a LAN connection (and optionally via WLAN, see below). A correspondingly configured server directory enables fast and easy data transfer of images and videos to this network drive for central data storage and fast accessing of this data from every PC/laptop connected to the network for editing and processing (e.g. with a video editor). This option also enables parallel video recording (option) on this network drive and prevents e.g. time-consuming data transfer using USB media.

- Wireless WLAN data transfer (option)

An optional WLAN module with a WiFi hotspot function simplifies the management of images and videos stored with the KINEVO 900 enormously. With this option, a wireless connection to the clinic network or server directory can be configured instead of a LAN connection for time-saving data transfer. A WiFi hotspot for connections to mobile devices (e.g. tablets or smartphones) can be additionally activated and used, thus enabling users to access the patient data directory in the KINEVO 900 and download the desired images and video clips quickly and easily. All network, WLAN and WiFi connections are password-protected.

3.2.5 Navigation functionality

The KINEVO 900 is prepared for the display of navigation information and the connection of external navigation systems (factory-integrated standard navigation interface and MultiVision system). In connection with an extended navigation license, the new robotic positioning capabilities featuring motors in all system axes permit automatic alignment of the microscope to a trajectory predefined in the navigation planning software, provided that the connected navigation system supports this function.

3.2.6 Video recording functionality (option)

The KINEVO 900 offers the user a considerably more effective video recording functionality. When using a stereo video camera, the user can choose between a 2D or a 3D recording of the surgical procedure. In addition to the normal HD video recording (activated via hand grip, FCP or touchscreen user interface), a disk space optimized recording with a reduced resolution also can be activated, e.g. in order to record and save daily surgical procedures in their full length. An intuitive video editor with a cut & merge function enables fast and easy video editing on the system prior to downloading. A video streaming option can be activated if the system is connected to the clinic network. This option makes it possible to transmit the surgical procedure via LAN/WLAN e.g. to a remote auditorium with any accessible IP address or to a connected mobile device via WiFi.

Note:

If mobile systems are to be used for the display of the video stream, ZEISS recommends using the VLC media player (VideoLAN) for Apple IOS and Windows.

3.3 Device marking

3.3.1 Labeling on the microscope

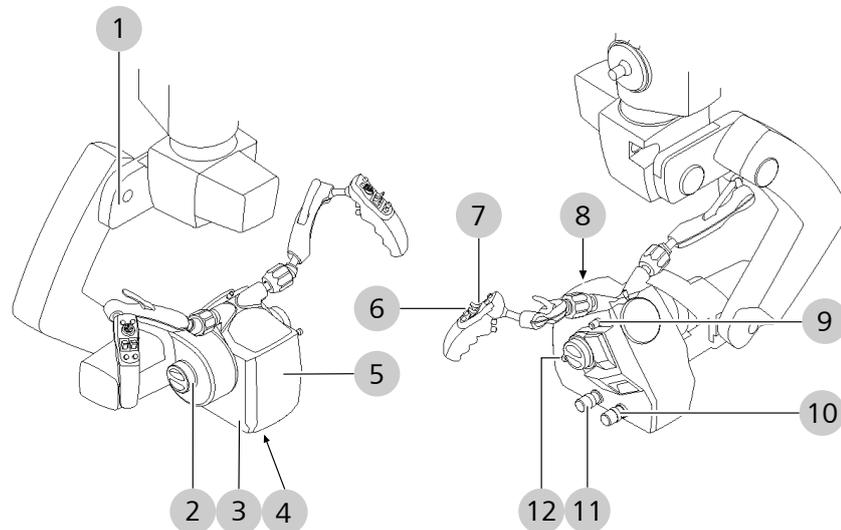


Figure 1: Labeling on the microscope

Pos.	Symbol	Explanation
1		Max. load: 6 kg
2		Open, right/left co-observation port

Pos.	Symbol	Explanation
3		Warning of laser beam (labeling for autofocus option)
4	Varioskop	Brand name
5		Brand / ZEISS logo
6	Z	Zoom
7	F	Focus
8	302584-9000-888 XXXXXXXXXX	Microscope identification label (inside)
9		Switch over, right/left co-observation port
10		Luminous-field diaphragm
11		Focus/working distance
12		Adjust zoom magnification manually

3.3.2 Approval label / UDI label

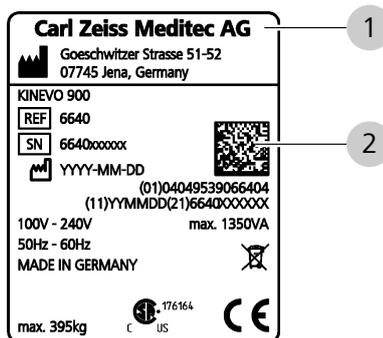


Figure 2: Approval label / UDI label

Pos.	Explanation
1	<p>Approval label</p> <ul style="list-style-type: none"> ■ Manufacturer: Carl Zeiss Meditec AG ■ Manufacturer's address ■ Manufacturer symbol:  ■ Device name: KINEVO 900 ■ Reference and serial number ■ Date of manufacture ■ Rated voltage: 100V - 240V ■ Max. connected load: 1350VA ■ Line frequency range: 50Hz - 60 Hz ■ Designation of origin for industrial products: MADE IN GERMANY ■ WEEE mark:  ■ CSA mark:  ■ CE labeling: This medical device is labeled according to Medical Device Ordinance (EU) 2017/745. ■ Maximum total mass: Max. 395 kg
2	<p>UDI label</p> <ul style="list-style-type: none"> ■ Machine-readable label (barcode) ■ Date of manufacture, year-month-day ■ UDI Device Identifier (UDI-DI) ■ UDI Production Identifier (UDI-PI)

3.3.3 Labeling on stand, Part 1



Figure 3: Labeling on stand

Item	Symbol	Explanation
1	KINEVO 900	Device name
2		Brand / Logo
3		Seal for drape suction
4		Risk of crushing!
5		Transport position: <ul style="list-style-type: none"> ■ Observe the Instructions for Use ■ Pushing position ■ General warning

3.3.4 Labeling on stand, Part 2

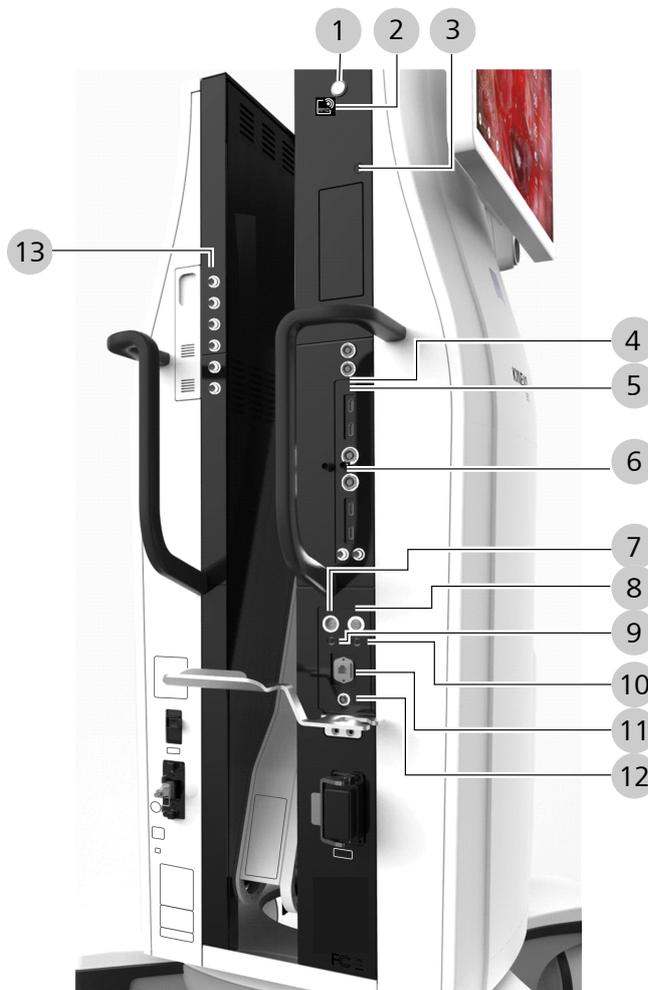


Figure 4: Labeling on stand, Part 2

Pos.	Symbol	Explanation
1		Standby/ON-OFF switch
2		RFID capture or reading device
3	USB OPEN	Open USB cover
4		Video output 4K <ul style="list-style-type: none"> ■ Number 1: 4K HDMI output ■ Number 2: 4K HDMI output
5		Video input <ul style="list-style-type: none"> ■ Number 3: Display port input ■ Number 4: Display port input ■ Number 5: HDMI/DVI input

Pos.	Symbol	Explanation
6		Video output <ul style="list-style-type: none"> ■ Number 6: HDMI/DVI output ■ Number 7: Display port output ■ Number 8: Display port output ■ Number 9: HD-SDI / 3G-SDI output ■ Number 10: HD-SDI / 3G-SDI output
7		Remote connector
8		Foot control panel, 14 functions
9		Audio out
10		Audio in
11	LAN	Ethernet port (LAN)
12		Rocker foot switch
13		4K video output (present only for 4K option, not yet available) <ul style="list-style-type: none"> ■ Number 11: 3G-SDI output, left (2D/3D) ■ Number 12: 3G-SDI output, left (2D/3D) ■ Number 13: 3G-SDI output, left (2D) ■ Number 14: 3G-SDI output, left (2D) ■ Number 15: 3G-SDI output, right (3D) ■ Number 16: 3G-SDI output, right (3D)

3.3.5 Labeling on stand, Part 3



Figure 5: Labeling on stand, Part 3

Pos.	Symbol	Explanation
1		Risk of crushing!
2		Approval label for INFRARED 800 (option) provides information on: <ul style="list-style-type: none"> ■ Manufacturer ■ License data ■ UDI labeling ■ Safety Agency Approval
3		Fuse display F1
4		Read and observe the Instructions for Use.
5		Non-ionizing electromagnetic radiation

Pos.	Symbol	Explanation
6		Potential equalization
7		Approval label for KINEVO 900 provides information on: <ul style="list-style-type: none"> ■ Manufacturer ■ System data ■ Power data ■ UDI labeling ■ Type of disposal ■ total weight ■ CSA label ■ Safety Agency Approval
8		SIP label, specifying: <ul style="list-style-type: none"> ■ Manufacturer ■ Manufacturer's contact information ■ SIP number of device (SIP = Service Identification Program)
9	6640xxxxxx	Serial number of device
10		MD labeling (Medical Device)* * Depending on the respective country-specific registration status
11		Port for navigation system
12	<ul style="list-style-type: none"> Pure Digital <input type="checkbox"/> Video Recording <input type="checkbox"/> 3D Video <input type="checkbox"/> 4K Camera <input type="checkbox"/> QEVO ECU <input type="checkbox"/> BLUE 400 <input type="checkbox"/> YELLOW 560 <input type="checkbox"/> INFRARED 800 (Compact) <input type="checkbox"/> INFRARED 800 <input type="checkbox"/> FLOW 800 <input type="checkbox"/> DICOM <input type="checkbox"/> Shared Network Interface <input type="checkbox"/> Wireless LAN Interface <input type="checkbox"/> PositionMemory <input type="checkbox"/> PointLock <input type="checkbox"/> Navigation <input type="checkbox"/> Multivision <input type="checkbox"/> Autofocus <input type="checkbox"/> FCP WL <input type="checkbox"/> FCP <input type="checkbox"/> 	Identification label, options
		Identification for installed options

3.3.6 Labeling on stand base

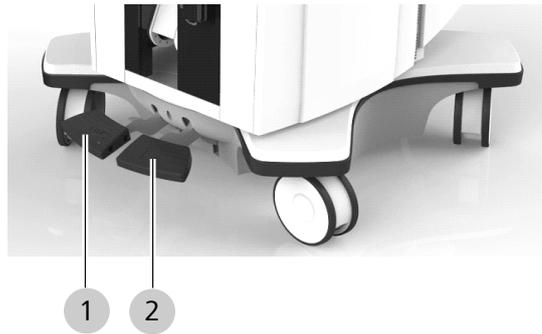


Figure 6:

Item	Symbol	Explanation
1		Pedal locking tabs
2		Straight-ahead travel pedal

3.3.7 Labeling on light source

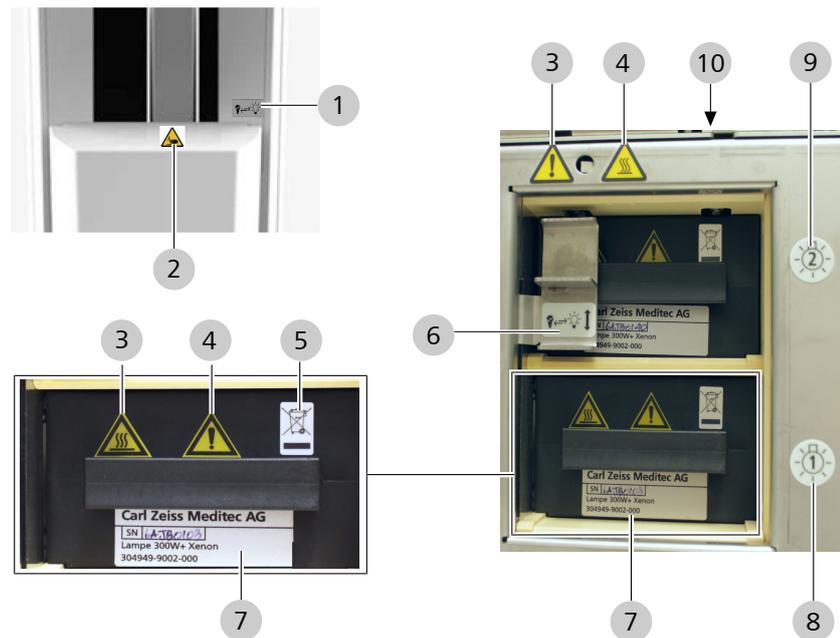
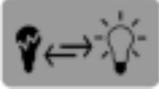
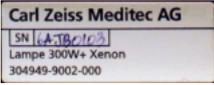
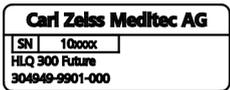


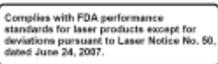
Figure 7: Labeling on light source

Pos.	Symbol	Explanation
1		Lamp replacement/manual lamp replacement (removal of light source cover)
2		Risk of crushing!
3		Hot surface
4		General Warning
5		"Observe disposal regulations" label Do not dispose of electrical or electronic devices along with normal domestic waste.
6		Manual lamp change
7		Identification label, lamp 300 W+ xenon
8		Light 1
9		Light 2
10		Identification label, "HLQ 300 Future" light source

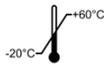
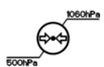
3.3.8 Labeling for autofocus option



Figure 8: Labeling for autofocus option

Item	Symbol	Explanation
1		Warning of laser beam
Country-specific labels: Class 2 laser - laser radiation - Do not look into the beam or view directly with optical instruments		
2		German label: Class 2 laser
3		Spanish label: Class 2 laser
4		English label: Class 2 laser
5		French label: Class 2 laser
6		US label: Class 2 laser

3.3.9 Labeling on packaging

Symbol	Symbol	Explanation
	Indication of direction "This side up"	Indicates the correct upright position of the package.
	Fragile	Handle with care
	Keep dry	Protect packaging and packaged contents from wetness.
	Do not stack	Stacking of the packages is not permitted. No load should be placed on the package.
	Permissible temperature	The product may only be transported and stored at a temperature range of min. -20°C to max. +60°C.
	Packing unit	Specification of the number of packing units
	Permissible relative humidity	The product may only be transported and stored at an humidity of min. 10% and max. 90% RH.
	Permissible atmospheric pressure	The product may only be transported and stored at an atmospheric pressure of min. 500 hPa and max. 1060 hPa.
KINEVO 900		Device name
		Brand / Logo
		Min. 1.2 m forklift length
	Center of gravity	Indicates the package's center of gravity.
		Shockwatch

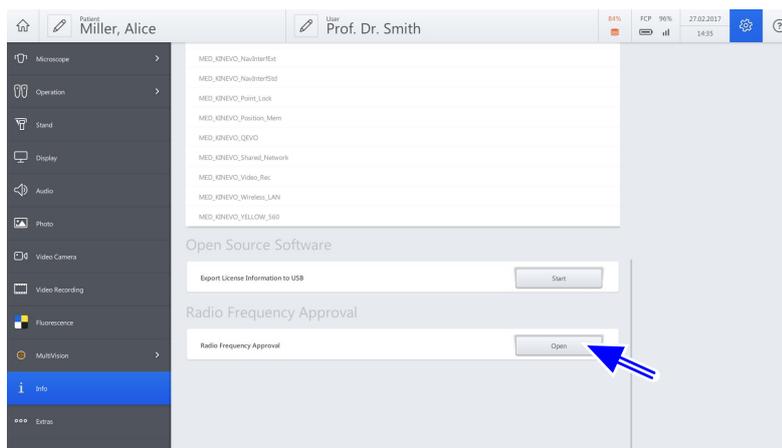
Symbol	Symbol	Explanation
		Tiltwatch

Table 1: Symbols for transport and storage

3.3.10 Displaying radio frequency approvals on the monitor

Action

1. Tap on  Settings →  Info.



2. Scroll down in the “Info menu”: Open → Radio Frequency Approval.
 - ⇒ The markings of the existing radio frequency approval are displayed.
3. Scroll down in the “Radio Frequency Approval” display.
4. Close the “Radio Frequency Approval” display by tapping on the black surface next to the display.

3.4 Structure of the device

3.4.1 Device overview



Figure 9: Overview of device

1	Main monitor (touchscreen):	2	Vertical arm
3	Horizontal arm	4	Microscope suspension
5	Microscope	6	Console
7	Lamp housing	8	Stand base
9	Connector panel	10	Transport handle, 2x
11	Second monitor (option)		

3.4.2 Overview of connector panel

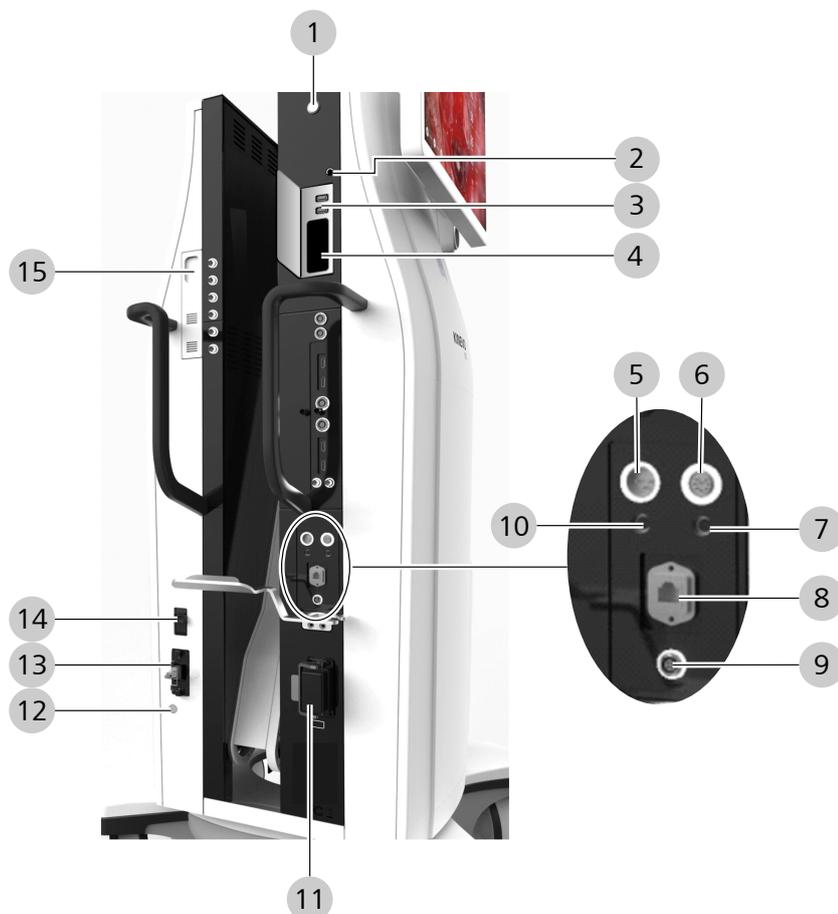


Figure 10: Overview of connector panel

Pos.	Symbol	Name
1	I/O	Switching a device
2	USB OPEN	Open USB cover
3	2 x USB 3.0	USB port (3.0) (2x)
4		Shelf for external USB mini HDD
5		Remote port (AUX) for external signal, max. 24 V / 0.5 A, galvanically decoupled as per IEC 60601-1
6		Connector 14-function foot control panel
7		Audio in
8	LAN	Ethernet port (LAN), galvanically decoupled as per IEC 60601-1
9		Rocker foot switch connector
10		Audio out

Pos.	Symbol	Name
11		Port for navigation system
12		Potential equalization: For connecting the system to the potential equalization system in compliance with IEC 60601-1.
13		Power input socket
14		Automatic circuit breaker
15		Connection socket for hand-held, digital exploration tool QEVO

3.4.3 Overview of video connector panel

The video ports are consecutively numbered from 1 to 10 on the device.



Figure 11: Overview of video connector panel

Pos.	Symbol	Type	Use
1	4K 	Video output	4K: HDMI video output, left Output signal: HDMI 2.0 3840x2160p50/60 (ODU)
2	4K 	Video output	4K: HDMI video output, right Output signal: HDMI 2.0 3840x2160p50/60 (ODU)
3		Video input: Display port	Connection of navigation video source for MultiVision overlay
4		Video input: Display port	
5		Video input: HDMI/DVI	Video input for external video source Input signal: HDMI 1920x1080p50/60, 1280x720p50/60 (Lemo)

Pos.	Symbol	Type	Use
6		Video output: DVI	<ul style="list-style-type: none"> ■ 2D/3D for stereo option ■ Live full screen/Endo/PIP ■ Touchscreen imaging Output signal: DVI-D 1920x1080p50/60 (Lemo)
7		Video output: Display port (stereo)	Camera signal video output, e.g. also for external monitor (option) Output signal: 1920x1080p50/60 (DP)
8		Video output: Display port (mono)	2D live image touchscreen, mono left Output signal: 1920x1080p50/60 (DP)
9		Video output: HD-SDI / 3G-SDI	Live camera image (corresponds to eyepiece view) with MultiVision overlay (option) Mono camera (HD): video output, left Stereo camera (3DHD): video output, left Output signal: 3G-SDI or HD-SDI 1920x1080p50/60 ("Interlace" or "Progressive", selectable), 1xBNC
10		Video output: HD-SDI / 3G-SDI	Live camera image (corresponds to eyepiece view) with MultiVision overlay (option) HD-SDI (1080i) 3G-SDI (1080p) Stereo camera (3DHD): video output, right Output signal: 3G-SDI or HD-SDI 1920x1080p50/60 ("Interlace" or "Progressive", selectable), 1xBNC

KINEVO 900 does not support any active DP systems on DisplayPort outputs 7 and 8.

3.4.4 Overview of video connector panel (4K 2D/3D option)*

If your device is equipped with the 4K 2D/3D option, you can connect an external 4K monitor. The ports for the 4K 2D/3D option are located on the left side of the connector panel and consecutively numbered from 11 to 16.

* These ports are not yet available at this time.



Figure 12: Overview of video connector panel (4K 2D/3D option)*

Pos.	Symbol	Use	Output signal
11		3G-SDI video output, left (2D/3D)	QuadSDI 3840x2160 50/60p (4xBNC)
12		3G-SDI video output, left (2D/3D)	
13		3G-SDI video output, left (2D)	
14		3G-SDI video output, left (2D)	
15		3G-SDI video output, right (3D)	
16		3G-SDI video output, right (3D)	