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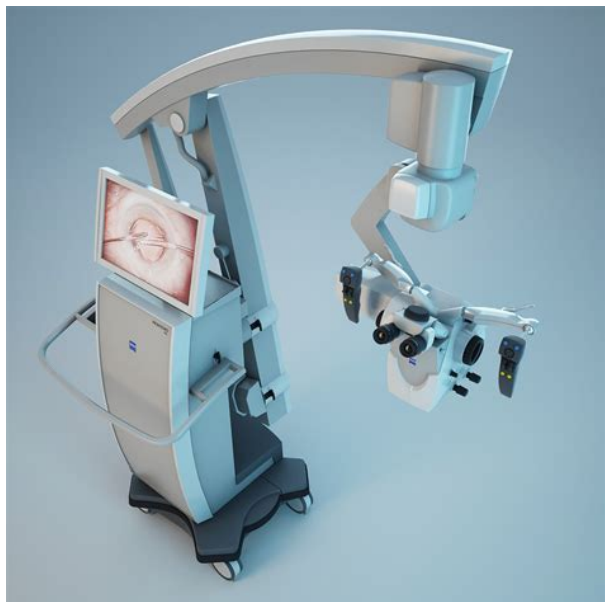
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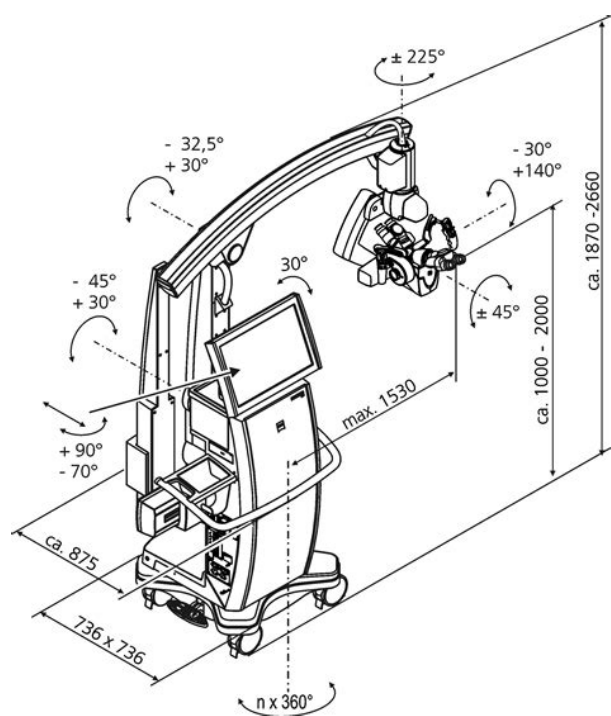
Prices are indicative only and may vary by country, with changes to the cost of raw materials and exchange rates. Building on the innovations of OPMI Pentero introduced in 2004, OPMI PENTERO 900 combines awardwinning design concepts and new functionalities in a proven, fully integrated platform. Key functions have been enhanced and new visualization methods integrated, raising OPMI PENTERO 900 to a high level of performance. Brilliant Visualization Fully integrated camera systems with factoryaligned optics ensure reliable and consistent performance. Enjoy the esthetic and ergonomic advantages of the surgical microscope without any impairment by cables or bulky video adapters. The integrated control allows management of both the video solution and the surgical microscope, which provides a streamlined surgical workflow. They can also be transferred directly to a USB storage media Videos can be easily and quickly edited through the touchscreen With the wide viewing angle and the flexible suspension arm, the OR team can observe the procedure comfortably Optionally available in HD quality. Completely integrated module with no external components or cables. Optionally available in HD quality. This is particularly well suited for sterile assistants or for training. The intelligent power management function ensures longlasting operability. Whether it is a highend surgical microscope, an ophthalmic laser, diagnostic equipment, or radiotherapy system, we provide timely, responsive services through a national network of highly skilled technicians. For country specific product information, see the appropriate country website. Product specifications are subject to change in design and scope of delivery as a result of ongoing technical development. The page you have requested is not part of the ZEISS US Medical Technology website and may contain information on products or uses that are not approved in your country of residence. <http://pataibicaj.hu/userfiles/easycap-manual.xml>



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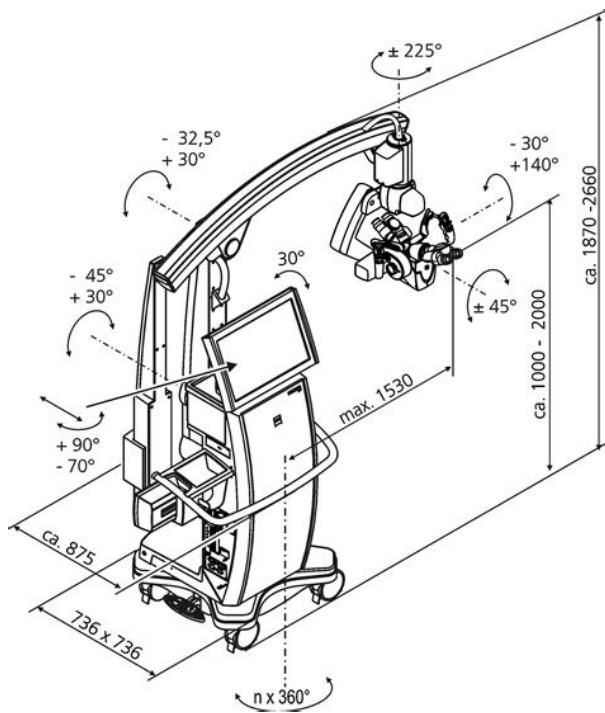
Further trainings of the staff operating the system is performed by the operator according to this user manual. Rx only OPMI Pentero 900 with INFRARED 800 and the option FLOW 800 may only be used by physicians or and qualified medical staff authorized by said physicians. Range of application Intended use OPMI PENTERO 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 patients eye. The OPMI PENTERO 900 is intended for cranial and spinal procedures in neurosurgery as well as for ENT treatments of auditory nerves and the base of the skull. It is furthermore used for reconstructing and plastic emergency surgery, plastic and reconstructive surgery and MCG surgery. The OPMI PENTERO 900 may be used for multidisciplinary use in microsurgery. It is designed for surgical operations that use endoscope and surgical microscope simultaneously. The system is equipped with a plug for a navigation system and data exchange with external network systems and intended for use in hospitals, medical centers and other institutions for human medicine. The functions of the surgical microscope and the floor stand

are controlled via the central control unit in the panel. All settings are configured via an interactive graphic touchscreen display. It is possible to open the functions using the keys in the handle or via a foot panel. We recommend you take adequate precautions, depending on the application, to enable the surgical procedure or treatment to be finished without using this microscope for example in case of a system error. Therefore, please thoroughly familiarize yourself with the content of these Instructions for Use before starting up the device. Please also observe the Instructions for Use of additional instrument equipment. Further information is available from our service department or from authorized representatives.



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If the system is modified, suitable inspections and tests must be performed to ensure that it can still be used safely. The manufacturer is not liable for damage caused by unauthorized persons tampering with the device. Secure network! The user IT specialist is responsible for suitable security measures e.g. firewall against unauthorized access from outside to the network the system is linked to. The device contains freely accessible live components. Please make sure that the following requirements continue to be met for further operation. The connecting components have been properly connected. The screw connections have been firmly tightened. All cables and plugs are in perfect condition. The voltage set on the system corresponds to the rated line voltage on the site of installation. The power cord has been plugged into a power outlet which has a properly connected protective ground contact. The power cord being used is the one designed for use with this system. When connecting the device to any network, please ensure the network is free of dangerous voltages. If a plug cannot be connected easily, check again whether the plug and socket are made to fit. If the plug connection is damaged, please call our service department. Never connect defective or unidentifiable accessories. Please replace the xenon lamp in due time. Do not use the system until it has been repaired by the Carl Zeiss service team. Warranty and liability Warranty and liability depend on the applicable contractual stipulations. **WARNING** Device must not be modified without manufacturers approval. This system must not be modified without the manufacturers approval. If the system is modified, suitable inspections and testing must be completed to ensure that it can still be used safely. Furthermore, this will forfeit any rights to claim under warranty. General The OPMI PENTERO 900 features a powerful xenon lamp.



Once the lamp operating time of 500h is elapsed, the user is prompted by a message on the touchscreen to replace the lamp. When working at maximum magnification, you should therefore pay particular attention to the set light intensity to prevent burns, especially of the surrounding tissue. These areas represent a particular injury risk. The gauze must be moistened at regular intervals to avoid that the area dries out or heats up. Recommendations Due to the large number of different factors involved and the lack of scientific publications on this topic, Carl Zeiss cannot provide guidance on acceptable intensities and exposure durations. However, the OPMI PENTERO 900 has several features that can help the user to reduce the risk of burn injuries. Please note that the intensity increases with decreasing luminous field size if the Spot function is used. This darkens the image so that the illumination intensity must be increased. Please note that most burns affected the skin around the incision. The most important measure for prevention of burn injuries are reduction of the size of the illuminated field by the spot function and the coverage of peripheral areas by sterile, wet gauze. The area of the incision should be constantly irrigated. The lighting intensity is factory adjusted to show a warning on the touchscreen when the threshold value of 25% is reached. Transport locks¹ please refer to the illustration on the next page. Safety switch The brakes will be activated if a spring or cable breaks. You can nevertheless finish surgery, as you can still move the surgical microscope by applying slight force. Uninterruptible power supply UPS The device is ready for operation after it has been switched on. The UPS is then charged automatically. In the event of power failure, the uninterruptible power supply UPS automatically starts to operate. It ensures for a short period of time that no data will be lost. This process may take a few seconds.



NOTE Discharging of UPS A continuous beep indicates extreme discharging of the UPS. As long as the power cable is connected, the USP is being charged. The system automatically tries to remedy problems in the control software. After several unsuccessful attempts, the system executes a PC reset to restart the application. This restart runs automatically in the background and restores the full functionality of the system within approx. 2 minutes. NOTE Function handling All major basic functions of the device remain fully available to the user during this time operation of focus, zoom, light, brakes, motorized XY movement. Backup illumination The lamp module contains two identical lamps. If lamp 1 fails, a quickaction changer ensures that the light guide is supplied by lamp 2. The lamp change does not impair the surgeon in his work. The focuslight control adjusts the lighting intensity in relation to the working distance. The minimal working distance of 200 mm means that the lighting intensity is limited to a maximum of 25%. As the working distance increases, the user gradually has more light to use. The actually available maximum lighting intensity that is dependent on the work distance is shown in the light control display as a blue bar 1. The lighting intensity can be modified within the limits marked in blue, but cannot be adjusted to exceed those limits. The focuslight control is preset as active reactivated at every start of the device. By pressing the focuslight key 2, you can switch off the function after confirming the warning 4 with. Do you really want to switch off the automatic focuslight control. This maude entry was filed from a foreign,health professional,u report with the FDA on 20161027 for OPMI PENTERO 900 3025829902000 manufactured by Carl Zeiss Meditec Ag oberkochen.The manufacturer level 2 support engineer confirmed fses finding and repair action after reviewing the error log of the microscope.

The manufacturer evaluated the function deterioration of the microscope during surgery. The essential functions with light, focus, zoom and brakes are still working in such a situation. The hcp decided to use a doppler system for monitoring the blood flow in the vessels, when the ir800 function of the opmi pentero 900 did not start. The hcp confirms that there are other factors not related to opmi pentero 900 malfunction, which can lead or contribute to the reported patient outcome of a paralysis ater an aneurysm emergency surgery. Patient Sequence No 1, Text Type N, H10 When trying to start the ir800 mode during surgery for monitoring the blood flow in the vessels, the ir800 function did not work. The hcp decided to use a doppler system ultrasonic instead and which was available in order to monitor the blood flow. The surgery was completed and no significant delay was reported. No other issues were reported. The hcp informed after surgery that the patient has a paralysis. No details about severity and body area were provided. There were no further details provided about patient outcome and the surgery during the followup with the doctor. Patient Sequence No 1, Text Type D, B5. I need the service manual for the Zeiss Pentero 900! AnyoneCan you send the manual to my emailI need the Service Manual for RX Philips Compacto Plus

600. Did you found Best regards,. Click here to read more I need the service manual of Polymobil Plus also!!!Sign up now. These symbols are explained in the following. Warning!The warning triangle indicates potential sources of danger which mayconstitute a risk of injury for the user or a health hazard. CautionThe square indicates situations which may lead to malfunction, defects,collision or damage of the system. NoteThe hand indicates hints on the use of the system or other tips for theuser. Read the user manual. OPMI and Pentero are registered trademarks of Carl Zeiss SurgicalGmbH.

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Josephs Hospital and Medical Center, Phoenix, USA Find articles by Evgenii G Belykh Xiaochun Zhao Josephs Hospital and Medical Center, Phoenix, USA Find articles by Xiaochun Zhao Claudio Cavallo Josephs Hospital and Medical Center, Phoenix, USA Find articles by Claudio Cavallo Michael A Bohl Josephs Hospital and Medical Center, Phoenix, USA Find articles by Michael A Bohl Kaan Yagmurlu Josephs Hospital and Medical Center, Phoenix, USA Find articles by Kaan Yagmurlu Joseph L Aklinski Josephs Hospital and Medical Center, Phoenix, USA Josephs Hospital and Medical Center, Phoenix, USA This is an open access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited. This article has been cited by other articles in PMC. Abstract Background We assessed a new robotic visualization platform with novel usercontrol features and compared its performance to the previous model of operative microscope. Methods In a neurosurgery research laboratory, we performed anatomical dissections and assessed robotic, exoscopic, endoscopic, fluorescence functionality. Usability and functionality were tested in the operating room over 1 year. PpIX visualization was comparable to the previous microscope. Nearinfrared indocyanine green imaging 3step replay allowed for more convenient accurate assessment of blood flow. Point lock and pivot point functions were used in dissections to create 3D virtual reality microsurgical anatomy demonstrations. Pivot point control was particularly useful in deep surgical corridors with dynamic retraction. 3D exoscopic function was successfully used in brain tumor and spine cases. Endoscopic assistance was used for aroundthecorner views in minimally invasive approaches. We present illustrative cases highlighting utility and new ways to control the operative microscope.

Conclusion Improvements of the robotic visualization platform include intraoperative fluorescence visualization using FNa, integrated microinspection tool, improved ocular imaging clarity, and exoscopic mode. New robotic movements positively assist the surgeon and provide improved ergonomics and a greater level of intraoperative comfort, with the potential to increase the viewing quality. New operational modes also allow significant impact for anatomy instruction. With the

increasing number and complexity of functions, surgeons should receive additional training in order to avail themselves of the advantages of the numerous novel features. Keywords microscope, exoscope, endoscope, visualization, fluorescence, fluorescein sodium, 5ala, indocyanine green, robotics, virtual reality Introduction Operative microscopes are an integral part of the surgical armamentarium. They have become so fundamental to the success of modern neurosurgical and other surgical specialty procedures that they nearly define the advent of modern technology-assisted surgery and certainly are requisite for a modern standard of care. These advances have led to a terminology evolution towards appraisal beyond microscope and to “visualization platform”, as these developments provide significantly more functions than previous operative microscopes. The goal of this study was to perform a comprehensive assessment of a new robotic visualization platform with novel user-control features and to compare its performance to the previous model of operative microscope. Our laboratory and clinical investigations were focused primarily around four main areas 1 control, robotic features and handling; 2 video recording and educational value; 3 hybrid visualization functionality; 4 intraoperative fluorescence visualization modules. Several of the new microscope platforms are incorporating some or many of the functions of the microscope platform we have assessed, evolving into more than mere operative microscopes.

We did not have access to other brands of operative microscopes to assess previous and new model platforms. This technology evaluation serves only to compare the performance of a significant new operative visualization platform development with a previous version of a neurosurgical microscope in widespread use and is not an endorsement of operative microscopes from Carl Zeiss AG. Further refinements are projected for the newer microscope system e.g., with surgical navigation system optimization as greater widespread use is encountered and with surgeon feedback. Thus, we aimed this investigation to be an evaluation in terms of functions, rather than an individual brand or system. The utility of control and robotic functions were subjectively assessed. We also assessed an exoscope option when viewing an image on a three-dimensional display through polarizing glasses 55" screen size, 3D, 4K, model LMDX550MT, Sony Corp., Tokyo, Japan. 3D projection employed passive linear light polarization technology that provided a perception of depth. In addition, we evaluated the QEVO, a 45-degrees viewing endoscopic microinspection tool integrated into the Kinevo designed to assist microsurgical procedures. Open in a separate window Figure 1 The robotic visualization system Illustration of the robotic visualization system ZEISS KINEVO 900 Carl Zeiss AG, Oberkochen, Germany Used with permission from Barrow Neurological Institute, Phoenix, Arizona Interactive 3D virtual reality Images acquired with the Kinevo were generated into interactive 3D virtual reality 3DVR images using Object2VR software Garden Gnome Software e.U., Vienna, Austria. 3DVR images were created for the cadaveric specimens to demonstrate and review anatomical landmarks within surgical approaches. The steps for creating 3DVR images are summarized in Table 1. Step The number of images could be as many as 60 per second, but a higher number of images would increase the final 3DVR file size and slow the presenting speed.

Use the resulting images from step 10 as an input. The grid size should correspond to the number of images used. The output file format can be .swf, .html5 or .mov files. Joseph's Hospital and Medical Center Institutional Animal Care and Use Committee. Surgeries were performed under ketamine and xylazine anesthesia for mice and a ketamine, xylazine, and acepromazine cocktail for rats. Fluorescence was visualized using appropriate filters intraoperatively after craniotomy. Microvascular Anastomosis Model Rat groin and cervical regions were dissected to expose carotid and femoral arteries and to perform microvascular anastomoses. The surgery was performed under the exoscope viewing at the 3D monitor positioned in front of the surgeon. Louis, MO, USA solutions Eu were used ex vivo to compare the sensitivity of the platforms to the red fluorescence. Eu has an excitation maximum at 355 nm and emission maximum at 615 nm, which is similar to protoporphyrin IX PpIX, but Eu is more photostable. Fluorescence visualization Appropriate filters were used for intraoperative fluorescence visualization YELLOW 560 for FNa, BLUE 400 for PpIX or Eu, and

INFRARED 800 for ICG. Settings were similar values for focal distance, magnification, tube length, light intensity and diaphragm diameter to ensure correct and unbiased comparison. Image acquisition and analysis Images were acquired by the internal cameras of the Kinevo and Pentero. In order to approximate and compare fluorescence visualization by an unaided surgeon's eye through the oculars, we also acquired images with an iPhone 6s Apple, Cupertino, CA, USA through the oculars and microscopemounted digital singlelens reflex camera Canon USA, Inc., Melville, NY, USA. Images were processed for green, blue and red channels separation and intensities were analyzed in ImageJ NIH after drawing regions of interest over the fluorescent areas.

A t test was used for comparisons between groups with P Clinical assessment The usability and functionality of Kinevo with the QEVO endoscopic microinspection tool was tested in the operating room over nearly one year 2017. A patient study protocol was approved by the Institutional Review Board of the Barrow Neurological Institute. Patients signed a voluntaryinformed consent form to participate in this study. Results Robotic features Possible means to operate and move the Kinevo system during surgery are systematized in Figure 2. There are essentially 2 ways to operate the microscope manual mode via brake buttons on the handgrips or mouthpiece and motorized robotic mode via a joystick on handgrips or foot control panel. Open in a separate window Figure 2 Manipulations and Movements Schematic representation of the possible ways to operate and move the Kinevo system. The movements can be generated by motors and by manual movements holding the handgrips. When the Kinevo moved to the desired location, it overlaid a semitransparent image from the previous position that assisted with image alignment. Such near perfect alignment during or after repositioning was not possible during dissection or surgery with the Pentero. Open in a separate window Figure 3 Position Memory Illustration of the "Position Memory" concept that allows the microscope to return to a preset position based on multiple spatial coordinates previously recorded during the surgical procedure. Used with permission from Barrow Neurological Institute, Phoenix, Arizona Motorized movements of the Kinevo could be selected in three options "PointLock", "Stand Breaks", movements parallel to surface or "Microscope Breaks" swiveling movements of the microscope head. When "PointLock" function was selected for the upper button of the handgrip, it released the brakes, allowing the manual movements of the microscope head while remaining in automatically adjustable focus and angle towards targeted point.

Open in a separate window Figure 4 Point Lock Illustration of the "Point Lock" concept that allows pointing at a region of interest and locking the target while moving the microscope to different spatial positions. Used with permission from Barrow Neurological Institute, Phoenix, Arizona Open in a separate window Figure 5 Point Lock for a Keyhole Illustration of the "PointLock" concept for a keyhole application. Visualization of the maxillary artery through a maxillary sinus by pivoting around previously selected superficial point on the bone window. Used with permission from Barrow Neurological Institute, Phoenix, Arizona 3D exoscope The maximal measured working distance was significantly longer for the Kinevo 657 mm at 0.95.2x range magnification, compared to the Pentero 513 mm at 1.26.6x magnification. A 144mm increase in working distance allowed exoscopic head positioning above the surgeon's line of view to the monitor. We performed endtoside anastomoses on five rat carotid arteries confirming the feasibility of the 3D exoscope to visualize fine surgical details. The Kinevo was used as an exoscope in 10 clinical cases. It was noted during these cases that a significant learning curve exists for becoming accustomed to operating with exoscope visualization. Most neurosurgeons today are accustomed to operating through an operative microscope, although, the exoscope provides a very different feel than a standard microscope and thus requires accommodation and practice. However, once the surgeon has become accustomed to operating while looking at a 3D projection of the surgical site away from the actual surgical site, the exoscope provided additional freedom of movement, easy positioning and target finding, and greater degrees of surgical freedom. This was especially prominent during imaging of murine brains with and without gliomas after FNa injection.

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