

Admn/Prop/106/2021-AIIMS.JDH

Dated: 24th February 2022

Subject: Purchase of Operating Microscope for the department of Neurosurgery at AIIMS, Jodhpur

on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Operating Microscope for the department of Neurosurgery

at AIIMS, Jodhpur from M/s Carl Zeiss Meditec AG, Oberkochen Site, Rudolf-Eber-Str. 11 73447

Oberkochen, Germany on proprietary basis. The proposal submitted by M/s Carl Zeiss Meditec AG,

Germany and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection,

comments, if any from any manufacturer regarding proprietary nature of the equipment within

21days of issue giving reference Admn/Prop/106/2021-AIIMS.JDH. The comments should be

received by office of Deputy Director (Admin), Medical College at AIIMS, Jodhpur on or before

17th March 2022 upto 03:00 PM failing which it will be presumed that any other vendor is having

no comment to offer and case will be decided on merits.

Yours faithfully,

Deputy Director (Admin)

Enclosed: Related documents enclosed.





Carl Zeiss Meditec AG 73446 Oberkochen

To The HOD Neurosurgery Department All India Institute of Medical Science (AIIMS) Jodhpur, Rajasthan (342005) India

Division/Dept.:

Your contact: Alexander Partsch

MED-MSS

Carl Zeiss Meditec AG

Oberkochen location Rudolf-Eber-Str. 11 73447 Oberkochen Germany

Phone: +49 (0) 7364/ 20 2928 e-mail: alexander.partsch@zeiss.com

Date: 08.02.2022

Property certificate for ZEISS KINEVO 900 robotic visualisation system for neurosurgery

Dear Sir,

We hereby certify that the Zeiss KINEVO 900 robotic visualisation system for Neurosurgery is the proprietary product of Carl Zeiss Meditec AG, Germany.

The KINEVO® 900 from ZEISS is designed to deliver more functionalities than any surgical microscope to-day. It is a combines digital and optical visualization modality, offers a unique Micro-Inspection Tool and will impress you with its Surgeon-Controlled Robotics. The new navigation interface of ZEISS KINEVO 900 is designed to work in concert with your navigation device. When you require precise repositioning to re-examine previously visualized structures or when you need to align with a pre-mapped trajectory, making use of all six axes, the Robotic Visualization System™ delivers precise positioning at the push of a button. Putting you exactly where you need to be — when you need to be there. The following features and benefits of KINEVO 900 are:

The high-speed robotic system, when treating complex vascular conditions, you typically work at high magnification. Even the slightest vibrations can cause disruptions. And constant manual repositioning to better visualize structures or precisely approach deep-seated lesions can become extremely tedious. Not anymore! ZEISS KINEVO 900 delivers a lot more positioning precision with a lot less effort. The large focusing range from 200 mm to 625 mm almost convenient working distances for all procedures observation done through Visualise Screen or oculus lens.

Basni Phase-2, Jodhpur, Rajasthan-342005. Phone: 0291-2740741 Email: procurement@aiimsjodhpur.edu.in Website: www.aiimsjodhpur.edu.in

Address of Record: Goeschwitzer Strasse 51 - 52 07745 Jena, Germany

Address for Delivery: Carl Zeiss Meditec AG Rudolf-Eber-Strasse 11 73447 Oberkochen, Germany Banks: Deutsche Bank Jena Account: 624536900 (BLZ 820 700 00) IBAN: DE90 8207 0000 0624 5369 00 BIC/ SWIFT: DEUT DE 8EXXX

Commerzbank Jena Account: 258072800 (BLZ 820 400 00) IBAN: DE31 8204 0000 0258 0728 00 BIC/ SWIFT: COBADEFFXXX Commercial Register: Local Court Jena HRB 205623

VAT-ID No.: DE 811 922 737 WEEE-Reg.-No.: DE55298748 Chairman of the Supervisory Board: Dr. Karl Lamprecht

Board of Management: Dr.Markus Weber (President & CEO) Justus Felix Wehmer Jan Willem de Cler

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Point Lock

Surgeon-Controlled Robotics adds a completely new level of ease to precise positioning. Imagine being able to focus and move around a structure to visualize the targeted anatomy – reducing any manual hassle. In addition, Point Lock enables you to do a Keyhole movement to observe a larger area inside a cavity- a particular benefit in areas with narrow access. The movement is 360°.

Active vibration dampening

You know the problems that can be created by the tiniest vibrations. The active dampening provided by ZEISS KINEVO 900 minimizes collateral system vibrations, ensuring rock-solid stability. Enabling you to completely, and steadily, focus on what matters most: your treatment.

Position Memory

When working on a tumor case, you may already have identified regions of concern where you want to protect the functional structure. After storing these in Position Memory, you can come back and visualize them at the exact same magnification, working distance and focus – without losing time for manual repositioning.

ZEISS QEVO - The Micro-Inspection Tool

The unique, proprietary Micro-Inspection Tool from ZEISS complements intraoperative microsurgical visualization, enabling you to discover unexplored areas during the surgical intervention without additional footprint. It helps to look around corners and eliminate blind spots. And most importantly, it gives a gain greater insight – for better clinical decisions.

To support the surgical workflow, ZEISS QEVO is truly integrated & engineered with an angled design – keeping your hands out of the line of sight during insertion in the surgical field. And it allows for an easy fit between the ZEISS KINEVO 900 and the situs, eliminating the need to reposition the head of the device. For a seamless surgical workflow and to easily switch back and forth between views.

ZEISS QEVO is fully autoclavable and enables to inspect the perforator or examine the distal neck of the aneurysm to ensure the clip blades are fully extended.

Direction of View: 45° upwards; Shaft Diameter: 3.6 mm; Shaft Length: 120.0 ± 1.0 mm; Total Diameter: 13.0 mm; Field of View: $100^{\circ} \pm 5^{\circ}$ wide angle view; Illumination: 20 - 35 lumen LED; Weight (without cable): 250 g; Sterilization: Autoclavable; Image Resolution: 1920×1080 pixel full HD; Length of Cable: 5000 mm; Operation Temperature: +10 to +40 °C (500/1000 s intermittent use).

Fully integrated 4K Digital Hybrid Visualization

During lateral lumbar or thoracic spine and posterior fossa approaches, ZEISS KINEVO 900's integrated 4K visualization can be essential. It provides with multimodal visualization capabilities – the flexibility to decouple from the classic optical approach and to work with outstanding 4K picture quality and clarity. Even when magnifying tiny details.









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Now, relief and revolutionary dimensions in visualization are in sight. The Digital Hybrid Visualization with integrated 4K technology of ZEISS KINEVO 900 offers a world of heads-up ocular-free surgery, giving you freedom of movement. And freedom of choice to use an optical setup, depending on the application need.

Working through oculars at extreme angles can sometimes be a pain in the neck. Literally. With no way out, you might have to contend with uncomfortable working positions causing fatigue.

ICG INFRARED 800 - HD resolution

Intraoperative visual assessment of blood flow and vessel patency during aneurysm, bypass and AVM surgery is critical to your treatment. During such complex vascular procedures, the new high-definition visual quality of ZEISS INFRARED 800 enables visualization of sub-millimeter blood vessels – for deeper insights into the blood flow dynamics.

ZEISS FLOW 800

FLOW® 800 from ZEISS is a unique analysis tool generating blood flow dynamics data by identifying detailed vessel blood flow from INFRARED 800 video sequences - intraoperatively. The newly transformed ZEISS FLOW 800 delivers a more convenient visual assessment of the increase in the fluorescence intensity during the procedure.

The Diagram Function outlines assessment of fluorescence intensity variation over time and fast access to the key indicators for further analysis.

The new optimized view option enables you to generate summaries from a selected sequence of the INFRARED 800 video. For instance, removing video sequences with movement artefact, you can now generate a summary map without compromises. So, you can get the most vivid and helpful representation of your procedure – for the right decisions and convincing podium talks.

ZEISS SMARTDRAPE

A special focus to the OR preparation process in the development of ZEISS KINEVO 900. Being an integral part of the optical path, the SMARTDRAPE® with Vision Guard® from ZEISS is designed together with ZEISS KINEVO 900 so you and your team can have the benefits of a vivid view, uninterrupted movement and effective patient protection. At the same time – the new innovations make the draping process simply simple. Innovative folding: to eliminate guesswork and complexity. Intuitive attachment: for an effortless and simple self-locking mechanism. Integrated RFID chip: for easy activation of Auto Drape®.

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FOLDABLE BINOCULARS 170f/260f

Rotate the tube easily without moving the microscope head using the integrated 360-degree rotation

Work ergonomically-by reducing or increasing the distance to the required treatment field.

Easily compensate for eye level differences between the surgeon and the assistant when operating in a face-to-face configuration by simply rotating the tube. Instantly yield a 50% magnification gain for delicate and detailed procedures with the integrated func-

Best regards

Carl Zeiss Meditec AG i.V.

Alexander Partsch

Senior Business Manager Microsurgery

Barbara Schmid

Carl Zeiss Meditec Microsurgery Standort: Oberkochen
Standort: Oberkochen - Germany

ZEIZZ



Carl Zeiss Meditec AG 73446 Oberkochen

To whom it may concern

Carl Zeiss Meditec AG Oberkochen Site Rudolf-Eber-Str. 11 73447 Oberkochen

Date: December 15, 2021

ZEISS KINEVO 900

Enclosed a list of representative granted patents. The maximum validity term is listed in brackets. Further patents are under examination.

Please note that the listed patent status might change (e.g. due to patent lapse). If necessary, please request an updated letter from your sales representative.

Der Vorsitzende des Aufsichts-

Dr. Michael Kaschke

Sitz der Gesellschaft:

Göschwitzer Str. 51-52 07745 Jena, Deutschland Tel.: +49 36 41 220-0

Der Vorstand: Dr. Ludwin Monz (Vorsitzender) Dr. Christian Müller

Lieferanschrift: Carl Zeiss Meditec AG

Rudolf-Eber-Str.11 73447 Oberkochen Banken:

Deutsche Bank Jena Konto: 624536900 (BLZ 820 700 00) S.W.I.F.T.-Code: DEUT DE 8EXXX IBAN: DE90820700000624536900

Commerzbank Jena

Konto: 258072800 (BLZ 820 400 00) S.W.I.F.T.- Code: COBADEFFXXX IBAN: DE31820400000258072800

UST-ID. Nr. DE 811 922 737 WEEE-Reg.-Nr. DE55298748

Amtsgericht Jena HRB 205623



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Surgeon-Controlled Robotics
DE102004008381 B4 (20.02.2024)
US7109678 B2 (10.11.2024)
JP4532188 B2 (30.06.2024)
DE10353961 B4 (19.11.2023)
US7110173 B2 (12.01.2025)
US7515334 B2 (18.11.2024)
US10092368 B2 (05.04.2037)
JP6789790 B2 (13.12.2036)
US10386010 B2 (19.04.2037)
JP6881983 B2 (11.01.2037)
DE102016200214 B4 (11.01.2036)
CH712020 B1 (14.12.2036)

<u>AutoDrape®</u> US7846086 B2 (07.12.2022)

Fluorescence Options (e.g. INFRARED 800)
EP1772726 B1 (06.10.2026)
US7369073 B2 (09.03.2027)
JP5218881 B2 (06.10.2026)
DE102006004232 C5 (30.01.2026)
EP1979780 B1 (30.01.2027)
US8040599 B2 (04.05.2028)
JP5245832 B2 (30.01.2027)
US8810907 B2 (10.01.2024)
DE10339784 B4 (28.08.2023)

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ZEISS FLOW® 800
DE102008040807 B4 (28.07.2028)
DE102008040801 B8 (28.07.2028)
DE102008040802 B4 (28.07.2028)
US8144958 B2 (12.09.2030)

US9129366 B2 (20.12.2030) US9351644 B2 (10.12.2028) US9320438 B2 (10.12.2028)

US9357931 B2 (10.12.2028)

ZEISS YELLOW 560 US8730601 B2 (09.08.2031)

<u>Optical System</u> DE10336476 B4 (08.08.2023) DE102005003437 B4 (25.01.2025)

<u>User Interface</u> DE102004004616 B4 (29.01.2024) US7594188 B2 (23.08.2024) US7924307 B2 (16.08.2024)

Foldable Tube
DE102009037921 B4 (19.08.2029)
US8514488 B2 (24.07.2031)
JP5620746 B2 (18.08.2030)

ZEISS QEVO US10842347 B2 (04.11.2038) US10859804 B2 (11.09.2038)

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Particularly notable are the following features:

- DE102004008381 B4, US7109678 B2, JP4532188 B2 address the feature to use the autobalance of the microscope body and accessories independently from the direction of the optical axis.
- DE10353961 B4, US7110173 B2, US7515334 B2 refer to the function "PointLock" representing hands-free pivoting in relation to a selected focus point.
- US10092368 B2 refers to the usage of robotic axis in order to ensure high stability at standstill (position control) and ease of movement during positioning (force control).
- US10386010 B2 refers to smooth and effortless positioning of the stand during hand-guided mode (force controlled stand by means of torque sensors).
- US7846086 B2 refers to the AutoDrape® function. This function facilitates the draping process of the sterile surgical microscope by automatically evacuating the air inside the drape at the microscope. The drape is tightened perfectly even without securing bands and thus enabling optimal usability and positioning of the microscope during surgery.
- US10842347 B2 and US10859804 B2 refer to the Micro-Inspection Tool ZEISS QEVO®. The
 color impression of the QEVO integrated illumination is automatically adjusted to the illumination properties of the surgical microscope, thus providing optimal and enhanced visualisation to the surgeon.

For saving energy the tool automatically switches off after setting aside for non-use after a defined time period.

DE10336476 B4 refers to the feature to automatically adapt the angle of the integrated auxiliary illumination in relation to the working distance.

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- DE102004004616 B4 refers to the feature to rotate the handgrips without a fixed stop using integrated sliding contacts.
- US7924307 B2 refers to the feature to visualize previously acquired superimposed data in correct colours (e.g. data injection of navigation information).
- DE102009037921 B4 refers to the ergonomic insight view based on specific zoom optics using two tilting axis.
- DE102006004232 C5 refers to the feature to switch between the fluorescence options BLUE 400 und INFRARED 800 by means of a simple button press.
- US7369073 B2 refers to the computer-aided compensation of relevant contrast differences in the INFRARED 800 fluorescence image (display of images without overexposure of bright image sectors).
- US8810907 B2 refers to the option to change between white light and INFRARED 800 mode.
- DE102008040802 B4 refers to the optimal representation of blood flow and anatomical structures in FLOW 800 mode.
- DE102008040807 B4 refers to motion correction during visualization of blood flow in vessels in FLOW 800 mode.
- DE102008040801 B8 refers to quantitative evaluation of angiography images in FLOW 800 mode.
- US8144958 B2 refers to the visualization of sequences of fluorescence recordings summarized within one image (Intensity based Map) in FLOW 800 mode.
- US9320438 B2 refers to quality control of applied clips during aneurysm surgery in FLOW 800 mode.

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Carl Zeiss Meditec AG US8730601 B2 refers to the display of images in ZEISS YELLOW 560: Vascular structures are highlighted in fluorescence while the surrounding tissue is visualized in nearly natural colors. Dr. Patricia Welz Intellectual Property Manager MED-MODA MM 5B



Technical Specifications of Operating Microscope (KINEVO 900 Digital hybrid visualization system) for Neurosurgery

Optics:

- 1. The maximal working distance must be at least 625 mm.
- 2. The Minimal working distance must be 200 mm.
- The Total working distance range must be at least 425 mm without changing or adding lenses.

Focus:

- 1. System should have 2 dot laser auto focus and have point lock focus, focus of the system should not disturb while moving the head of the system,
- 2. Parking position: system should have auto parked function, system should park in its parking position commanding from user interface
- 3. Camera: system should have integrated 3D 4K camera without any external attachment and wire (not visible from outside), the quality of 3D camera should be good enough to operate with the help of 3D monitor itself
- 4. Maneuverability of the system: When tilting the system head laterally the co-observer tube must not move in order to reduce intraoperative rebalancing.
- 5. System should have anti-damping mechanism to reduce the damping effect of the system

Illumination:

- 1. The system must offer an electronically controllable second light beam path to brighten up shadowed areas in the field of view.
- 2. In order to protect tissue from inadvertent light exposure the system must offer respective safety mechanisms:
- 3. System information when exceeding individual light threshold

Stand:

- 1. The system must be able to automatically move to a parking position.
- 2. The system must be able to automatically move into a draping position, which can be adapted/changed by the end user, to assist the draping of the system.
- 3. The system must offer an electronic dampening system to increase stability of the microscopic view.
- Surgeon and assistant must be able to see commonly used system parameters, such as working distance, magnification and light intensity, within the field of view in the oculars.
- 5. The system must provide an automatic balancing of all system axes without any manual interaction or axis adjustments.
- 6. The automatic balancing of the system must be possible in any position within the system head tilt and swivel movement range.
- 7. Draping of the system must be facilitated by an automatic air vacuum.
- 8. Tubes must be available that can be stretched & folded, providing a comfortable working position during surgery.
- 9. Tubes must be available, providing an integrated magnification changer facilitating procedures where high magnifications are needed.

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10. The system must be able to operate without counterweights that increase the required floor space opposite of the system.

System kinematics and Robotic movements:

- 1. The system must be able to offer a manual movement function, allowing for positioning the system freely within the entire working distance range while keeping the focal point in the center of the field of view ("Manual Point Lock").
- 2. The system must offer a motorized positioning function from the handgrip and Foot Control Panel (FCP) to change the viewing angle to the focal point in the center of the field of view. ("Motorized Point Lock").
- 3. The system must offer a function to memorize focal point positions.

Data management / Networking / Connectivity:

- 1. The system must offer a function to wirelessly upload demo licenses to activate specific product functionality.
- The system must feature a Wireless LAN Access Point to access patient data files as well as video/photo files.
- The system must be able to connect to a network storage and upload/download pictures and videos.
- The system must be able to connect to a network storage and offer parallel recording to this destination.
- 5. The system must offer live video streaming to a wireless device or a network IP address.
- 6. The system must provide an interface and a function for fast internet remote diagnosis to be operated via the central touchscreen user interface.
- The system must provide a blood flow assessment tool supporting objective analysis of ICG based video angiography data.
- 8. The assessment tool must be fully integrated into the host system not requiring additional hardware components.
- The assessment tool must provide an objective summary of the ICG fluorescence distribution in the recorded field of view supported by color encodings.
- 10. The assessment tool must provide a summary to objectively assess the sequence of the fluorescence appearance in the recorded vessels.
- 11. The analysis tool must provide a summary supporting the interpretation of blood flow speed.
- 12. The system must offer an option for fluorescence-based video angiography detecting with Full-HD resolution.
- 13. An optional setup phase for Indo-Cyanine Green (ICG) video angiography guiding in optimal adjustment for blood flow assessment must be available.
- 14. The system must provide automatic fluorescence detection in order to skip blank recording sequences when replaying the fluorescence video.
- 15. The system must provide a functionality to automatically adjust the brightness of the ICG video to avoid overexposure.
- 16. The system must be able to show an overlay of the ICG fluorescence signal on the white light image both in the oculars as well as on the monitor.

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- 17. The system must offer Picture-in-Picture functionality for the infrared and white-light image.
- 18. The fluorescence-based video angiography system must support parfocal recording of white light and near Infrared fluorescence detection for all working distances and zoom settings without requiring manual adjustments.
- 19. The system must provide a blood flow assessment tool supporting objective analysis of ICG based video angiography data.
- 20. The assessment tool must be fully integrated into the host system not requiring additional hardware components.
- 21. The assessment tool must provide an objective summary of the ICG fluorescence distribution in the recorded field of view supported by color encodings.
- 22. The assessment tool must provide a summary to objectively assess the sequence of the fluorescence appearance in the recorded vessels.
- The analysis tool must provide a summary supporting the interpretation of blood flow speed.

Integrated Micro-Inspection Tool

- 1. The system must include a stand integrated Micro-Inspection Tool for endogenous visualization of tissue out of the line of sight of the system
- 2. The integrated Micro-Inspection Tool must simultaneously provide a straight look and a 90° view without changing optics.
- 3. The integrated Micro-Inspection Tool must feature a HD resolution.
- 4. The integrated Micro-Inspection Tool must not require additional footprint in the OR.
- 5. The Central Computing Unit, Recorder, User Interface and Monitor of the integrated Micro-Inspection Tool must be integrated into the system.
- 6. The recording system must be able to capture the microscopic and integrated Micro-Inspection Tool view into a single stream.
- 7. The integrated Micro-Inspection Tool must be fully autoclavable and machine washable.
- 8. The integrated Micro-Inspection Tool must use an angled design to ensure a free line of sight through the system in to the surgical field.
- 9. The integrated Micro-Inspection Tool must use a working distance between 5 mm and 30 mm for Neuro and Spine applications without the need to refocus.
- 10. The integrated Micro-Inspection Tool must feature an automatic off mode.
- 11. The system software must provide a function to digitally align the viewing direction of the integrated Micro-Inspection Tool to the system.

Fluorescence:

ICG-I.R 800 with Flow 800

- The System must offer an option for fluorescence-based video angiography detecting with Full-HD resolution.
- 2. An Optional setup phase for indocyanine green (ICG) video-angiography guiding in optimal adjustment for blood flow assessment must be available.
- 3. The system must provide automatic fluorescence detection in order to skip blank recording sequence when replaying the fluorescence video.

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- 4. The system must provide a functionally to automatically adjust the brightness of the ICG video to avoid overexposure.
- 5. The system must be able to show an overlay of the ICG fluorescence signal on the white light images both in the oculars as well as on the monitor.
- The system must offer Picture-in-Picture functionality for the infrared and white-light image.
- 7. The fluorescence-based video angiography system must support parfocal recording of white light and near infrared fluorescence detection for all working distance and zoom setting without requiring manual adjustment.

Yellow 560

- 1. The system must offer an option which can be used to visualize fluorescent areas with excitation in the wavelength range from 460 to 500 nm and observation in the wavelength range from 540 to 690 nm.
- 2. The module must allow to simultaneously see fluorescence signals and non-fluorescent areas in almost natural –like colors

*Warranty, CMC, AMC as per institutional rules.

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