

ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER

LOT 1: VIDEO COLONOSCOPY EQUIPMENT

Publication reference: EuropeAid/135215/DH/SUP/RS

**Columns 1-2 are completed by the Contracting Authority
Columns 3-4 to be completed by the tenderer
Column 5 is reserved for the evaluation committee**

Annex III - the Tenderers technical offer

The tenderers are requested to complete the template on the next following pages:

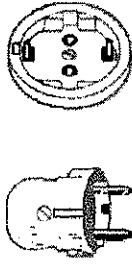
- Column 2 is completed by the Contracting Authority and shows the specifications of the goods required (any modification applied by the tenderer may lead to the disqualification of the Lot so modified).
- Column 3 to be filled in by the tenderer and must detail what exactly is offered and name of manufacturer (for example the words "compliant" or "yes" are not sufficient).
- Column 4 allows the tenderer to make comments on his proposed goods and also to make reference to his documentation

The tenderers are required to demonstrate that specifications of the items that they offer are responsive to the requirement set out in the tender dossier and to identify model and manufacturer of each individual item in their technical offer and to provide necessary documentation such as catalogues, brochures, booklets that inform of details of technical specifications that sufficiently define the equipments being offered, and thus should enable the contracting authority to check the information provided in the technical offer. Offers that do not permit to identify precisely the models and the specifications quoted may be rejected during evaluation.

MANDATORY REQUIREMENTS FOR LOT 1

Main supplies Electricity 220-230 Volt single phase, 380 Volt three phase, Frequency 50 Hertz.

All equipment connected to an electrical outlet shall be provided with a solid "Schuko" Plug.



Ambient temperature: 40°C (hot zone)

Humidity: 70-80%

Altitude: Sea level

All equipment shall be delivered complete with all accessories, cables, plugs and sockets, required for operation including any software driver and manuals.

WARRANTY:

During the 1 year warranty, the tenderer must ensure the technical support locally, capable of solving any problem on site with a response time of less than 24 hours.

COMMERCIAL WARRANTY:

All items supplied in this Lot shall include full **manufacturer's commercial warranty** granted for a minimum of two (2) years from **provisional acceptance**. The commercial warranty provided shall be described in detail in the tender.

STANDARDS:

All equipment should be from a branded source with a certified quality assurance system and have the following certifications:

- International Standard Organization (ISO);

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- CE marking

The Tenderer shall include in his offer official proof/documents proving conformity of the offered equipment with all applicable Serbian (Medicines and Medical Devices Agency) and EU technical regulations.

All equipment shall fully comply with international safety measures and regulations.

TRAINING:

The tenderer has to organize appropriate user training in Serbian language for effective and problem-free use of the equipment included in this LOT in each of the location mentioned in the distribution list below.

A **training proposal** for the operation of the equipment will be submitted by the tenderer in the tender.

This proposal shall include at least:

- Schedule and duration
- Description of training materials

MARKING AND LABELING

All equipment shall be marked with labels in English bearing the EU logo as per EU visibility Guidelines. See special conditions for additional details.

VISIBILITY

The contractor must be familiar and comply with the objectives and priorities, as well as guarantee the visibility of EU financing (see the Communication and Visibility Manual for EU external actions specified and published by the European Commission at http://ec.europa.eu/europeaid/work/visibility/index_en.htm). In addition to the these standard visibility provisions, the consultant should install a commemorative metal plaque on the entrance to the institution where the equipment is to be placed, providing information on the EU donation. The Contractor shall produce a draft of the layout and submit it for approval to the Contracting Authority prior to production/delivery. The Contracting Authority shall also advise the successful bidder on the exact dimension, layout, colour regime and wording/symbols of self-adhesive stickers marking each piece of equipment and the commemorative plaque upon contract signature.

DOCUMENTS:

The following documents shall be delivered for all equipment:

- Service and operation manuals in English language. The operation manual also translated into Serbian.
- Execution guidance / installation drawings.
- Certificates of compliance to safety norms and standards and/or trial test results at the manufacturer's facility.

TECHNICAL SPECIFICATIONS:

| 1. Item Number | 2. Specifications | 3. Specifications Offered | 4. Notes, re- marks, ref to docu- mentation | 5. Evaluation Committee's notes |
|----------------------|---|---------------------------------|---|--|
| 1.1 | Video Colonoscope system | | | |
| | Video Colonoscope Quantity: 20 (twenty) | | | |
| | Field of view: min. 140° | | | |
| | Depth of view: 3-100 mm | | | |
| | Insertion tube outer dia.: < 13 mm | | | |
| | Instrument channel inner dia.: $\geq 3,7$ mm (equal or larger then) | | | |
| | Working length: min 1600 mm (long type) | | | |
| | Bending up/down 180°/180°, left/right 160°/160° | | | |
| | Standard set to include: - Biopsy forceps - Biopsy valves - Channel cleaning brush - Cleaning adapters and system for cleaning and disinfecting | | | |
| | Light source Quantity: 10 (ten) | | | |
| | 300 W Xenon lamp, 500 hrs. life time | | | |
| | Emergency halogen lamp | | | |
| | Automatic and manual light intensity adjustment | | | |
| | Air feeding minimum 3 level | | | |

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|----------------------|---|---------------------------------|---|--|
| | Video system unit Quantity: 10 (ten) | | | |
| | Color CCD system | | | |
| | Automatic white balance adjustment | | | |
| | Minimum 3 step image size selection | | | |
| | Minimum 4 level image enhancement settings, structural and edge enhancement | | | |
| | Automatic gain control | | | |
| | Memory card storage | | | |
| | Digital outputs (IEEE, Fire-wire, DV etc) | | | |
| | Iris control, 2 modes (peak and auto) | | | |
| | Freeze image control | | | |
| | Patient data, scope identification | | | |
| | Function scope switches | | | |
| | Color adjustment (red, blue etc) | | | |
| | Cart Quantity: 10 (ten) | | | |
| | Mobile cart on antistatic casters, 2 of which brakeable, incl. appropriate shelving and cable conduits, sliding keyboard tray, LCD monitor arm etc. | | | |

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|----------------------|--|---------------------------------|---|--|
| | Color LCD monitor | Quantity: 10 (ten) | | |
| | 26" | | | |
| | Resolution: 1920x1200 (WUXGA) | | | |
| | Medical device certification | | | |
| | Input: 2x RGB (4xBNC connectors) 1 x Y/C (4-pin mini-DIN), 1 x Composite (BNC connectors) | | | |
| | Output: 1 x RGB (4xPNC connectors), 1 x Y/C (4-pin mini- DIN) 1 x video-out (BNC connector) | | | |
| | Suction pump | Quantity: 10 (ten) | | |
| | Nominal vacuum: approx. 0.85 bar | | | |
| | Nominal free air flow rate: approx. 20 l/Min. | | | |
| | Variable suction | | | |
| | Suction bottle approx. 2 litres | | | |
| | System for capturing image and video documentation with the possibility of DICOM and HL 7 interface for integration in the hospital information system (HIS) and hospital net- work | Quantity: 10 (ten) | | |
| | Imaging documentation system with touch screen-operated | | | |
| | All-in-one solution for video and still image documentation and reporting | | | |
| | Recording of still images and video either via the touch screen or directly from buttons on endoscope | | | |

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| | Patient-related archiving and documentation of still images and videos | | | |
| | Patient and examination data are documented together with the respective image data | | | |
| | Real-time display of live image -- touch screen (LCD-TFT 17" (1280 x 1024) can be used as 2nd monitor | | | |
| | Hardware certified according to the Medical Device Directive | | | |
| | System to be ready to use with an integrated DVD/CD recorder and hard disk. No additional hardware or software is needed | | | |
| | Possibility system to be installed on side of endoscopy trolley | | | |
| | Possibility for CRC program and statistic data for analyses | | | |
| | Controlling of recording via buttons on endoscopes | | | |
| | Writing standard reports with option of structured terminology | | | |
| | Possibility for integration with reprocessing machines, tracking of procedures of reprocessing | | | |
| | Tracking of material consumption | | | |
| | Can be operated as stand-alone or network solution | | | |
| | Language: English and Serbian if available | | | |
| | General inclusions: | | | |
| | User Manual English and Serbian (if available) | | | |
| | All required software installed plus on CD | | | |

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| | | | | |
| | Commercial Warranty (minimum two years) | | | |
| | Training | | | |

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LOT 1 Delivery, installation and training list:

| No. | Items to be delivered and installed | Location | Institution |
|-----|-------------------------------------|------------|---|
| 1 | Video colonoscopy system | Loznica | General Hospital Loznica |
| 2 | Video colonoscopy system | Kragujevac | Clinical Centre Kragujevac |
| 3 | Video colonoscopy system | Nis | Clinical Centre Niš |
| 4 | Video colonoscopy system | Pancevo | General Hospital Pančevo |
| 5 | Video colonoscopy system | Prokuplje | General Hospital Prokuplje |
| 6 | Video colonoscopy system | Bor | General Hospital Bor |
| 7 | Video colonoscopy system | Pirot | General Hospital Pirot |
| 8 | Video colonoscopy system | Belgrade | Clinical Hospital Center "Dr Dragisa Misovic" |
| 9 | Video colonoscopy system | Belgrade | Clinical Hospital Center "Zvezdara" |
| 10 | Video colonoscopy system | Belgrade | General Hospital Kraljevo |