**Procurement of Equipment for The Obstetrics and Gynaecology Clinic Narodni Front, Belgrade, Serbia**

**IOP/29-2019/RD**

**Clarification No.2**

**Issued on 29.11.2019.**

**LOT 3**

1. Concerning procurement BR ИОП/29-2019/РД  LOT 3, Position 3.6 , item  3.6.6, we would appreciate the clarification.

Is it obligatory for the microscope to be equipped with its own diascopic light, as stated in the technical specification, or an existing lightening of the laminar chamber is used ?

In case of using laminar chamber light, the item of diascopic light of the microscope is not needed.

* Light source for microscope will be provided along with laminar chamber, therefore it is not necessary to provide diascopic light with microscope

1. Is it acceptable to offer microscope stand with LED illumination, since most producers do not offer halogen illumination (including Olympus) any more

* It is acceptable.

1. Regarding public procurement IOP/29-2019/RD, please give us following clarification

1. for position 3.12.10 it is stated that “Pressure given in mm Hg or kPa."

we have following question:

Is it acceptable to offer aspiration pump with pressure given only in mm Hg, since this is widely used in all IVF centers?

In this way you would enable participation to more than one supplier.

* No, it isn't acceptable. To both parameters are important for procedures.

2. for position 3.12.1 it is stated that "High Vacum, Low Flow ( ISO 10079-1), digital aspiration pump”

Is it acceptable to offer aspiration pump High Vacum, Low Flow, digital aspiration pump without ISO 10079-1 certificate?

In this way you would enable participation to more than one supplier.

* No, it isn’t acceptable. This standard ensures safety and performance of device.

1. 3.13.3 Is it acceptable to offer instrument which has 14 places for test tubes?

* No, it isn’t acceptable.

1. 3.13.7 Is it acceptable to offer instrument with internal power supply?

* No, it isn’t acceptable. We need device that ensures more safety, and required specification provides that.

1. 3.13.8 Is it acceptable to offer instrument which could be programmable from ambient to 50 C?

* No, it isn’t acceptable. Required temperature is important, as we stated in specification, device must maintain ambient temperature of 36.9. We are not sure from your question that stated functionality is possible.

1. 3.13.9 Is it acceptable to offer instrument with led display which shows that instrument is ON?

* Yes, it is acceptable

1. 3.13.10 Is it acceptable to offer instrument with led display which shows temperature value?

* No, it isn't acceptable.

1. 3.13.11 Is it acceptable to offer instrument without temperature alarm?

* No, it isn't acceptable. Temperature alarm ensures safety and monitoring of process.

1. 3.13.13 Is it acceptable to offer instrument with max power consumption 40W (average 10W)?

* Yes, it is acceptable

1. Considering that cytogenetic CGH protocols for processing of slides with content recommended by the ISCA consortium and used in reference centers in the country and region do not ask for extremely low or high resolution, would it be acceptable to offer an instrument with the following specification: scanning resolution: adjustable 2, 3, 5 or 10?

* Yes, it is acceptable

1. It is required that dynamic range is „105 or better”. Is this a typing error, is the dynamic range referred to „105 or better”?

* This is typing error, dynamic range should be 105 or better

1. Taking into consideration that manual focus can introduce user-related errors into the protocol, would it be acceptable to offer an instrument with dynamic autofocus that continually adjusts scanner’s focus, keeping features in focus at all times?

* Yes, it is acceptable

1. In order to allow for a wider array of competitive bids, would you accept an open system instrument that has a maximum scanning window of 74 mm (+/- 10%) x 22 mm (+/- 10%) and scans standard microscopic slides?

* Yes, it is acceptable

1. Considering that CGH protocols of all leading manufacturers state that slides are hybridized at temperatures of 60-70oC constant temperature, would you accept a hybridization oven with temperature control: + 5° to 70°C?

* Yes, it is acceptable

**LOT 6**

6.7.1 Question 1:

Is it acceptable to the Purchaser to offer fully automatic washer disinfector with two manual hinged glass doors?

* It is not acceptable according to space availability

6.7.5 Question 2:

Will the Purchase allow offering of the machine that has fast cycle configuration that allows a complete pre-washing, washing and drying cycle time 37 minutes?

* It is acceptable.

6.7.11 Question 3:

Is it acceptable to the Purchaser to offer the machine with two levels of water filtering system (Gross and fine) to prevent recirculation of residues?

* It is not acceptable.

6.7.12 Question 4:

Is it acceptable to the Purchaser to offer machine with two full glass doors, manually operated, with the possibility to use them as tables for racks

* It is not acceptable according to space availability and safety reasons.

6.7.15 Question 5:

Is it acceptable to offer the machine with storage for 2 canisters of 10 lt?

* It is acceptable.

6.7.16 Question 6:

Is it acceptable to the Purchaser to offer the machine with 2 tanks: One for washing and rinsing and a pre-heating tank for thermal disinfection used for fast cycle?

* It is acceptable.

6.7.19 Question 7:

Is it acceptable to the Purchaser to offer the machine with operating display, dimensions of 20x120mm, membrane keypad and additional process status display?

* It is not acceptable. Display with mentioned characteristics is needed for complete visualization and real time following of the machine status and complete cycle.

6.7.21 Question 8:

Is it acceptable to offer the machine that has the following interfaces: RS323 for printer, RS485 for PC cycle documentation and RS 232 for barcode reader?

* It is acceptable.

6.7.22 Question 9:

Will the Purchaser allow participation with the machine that has 12 pre set programs that are in accordance with A0 value and ISO 15883?

* It is acceptable.

6.7.23 Question 10:

Is it acceptable to offer the machine with external dimensions including DI-Tank and condenser: (HxWxD) 2210 x 680 x 710 mm?

* It is acceptable.

6.7.24 Question 11:

Is it acceptable to the Purchaser to offer the machine with the chamber dimensions: 625x 575 x 628 mm (HxWxD)?

* It is acceptable.

6.7.29 Question 13:

As the validation or efficacy control of the machine is not stated as necessary, we are urging you to delete this standard form technical specification in order to enable grater competitiveness.

* It is not acceptable.

6.7.31 Question 14:

As the machine is already in accordance with the ISO 15883 1 and 2, we suggest the Health technical memorandum 2030 to be deleted from technical specifications, as it is applicable in the UK. In this way the grater competitiveness would be provided.

* It is acceptable to offer machine without this standard.

"6.9.4 Question 1.

Will the Purchaser allow offering of the sterilizer with the frame and external panels made of steel sheets covered with the paint resistant to disinfectants?

* It is acceptable.

6.9.6 Question 2.

Is it acceptable to the Purchaser to offer the machine with the chamber made of high grade AISI 304 stainless steel?

* It is acceptable.

6.9.10 Question 3.

Is it allowed to offer the sterilizer that uses H2O2 sterilant cartridge/bottle that is intended for several (more than one) sterilizing cycles?

* It is acceptable.

6.9.11 Question 4.

Is it acceptable to the Purchaser to offer the sterilant cartridges/bottles that are equipped with barcode identifiers?

* It is acceptable.

6.9.13 Question 5.

Is it acceptable to the Purchaser to offer the sterilizer with the doors made of high grade AISI 304 stainless steel?

* It is acceptable.

6.9.16 Question 6.

Is it acceptable to offer the machine without air compressor if it is not necessary for the machine functioning?

* It is acceptable.

6.9.18 Question 7.

Is it allowed to offer the device that has 4 cycles?

* It is acceptable.

6.9.19 Question 8.

Is it acceptable to offer the sterilizer with dot printer?

* It is acceptable.

6.9.20 Question 9.

Is it acceptable to offer the machine with Electrical Power Supply: 200/230/240VAC, 50Hz

* It is acceptable.

**LOT 6**

ID 6.5 Sterilization organizers

6.5.1 Is it acceptable to the Purchaser to offer ALUMINIUM BOTTOM FOR 1/1 CONTAINER HEIGHT:100MM ?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment

6.5.2 Is it acceptable to the Purchaser to offer ALUMINIUM BOTTOM FOR 1/1 CONTAINER HEIGHT:138MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.3 Is it acceptable to the Purchaser to offer ALUMINIUM BOTTOM FOR 1/1 CONTAINER HEIGHT:116 MM

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.4 Is it acceptable to the Purchaser to offer ALUMINIUM BOTTOM FOR 3/4 CONTAINER HEIGHT:116 MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.5 Is it acceptable to the Purchaser to offer ALUMINIUM BOTTOM FOR 1/2 CONTAINER HEIGHT:116 MM ?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.6 Is it acceptable to the Purchaser to offer ALUMINIUM BOTTOM FOR 1/2 CONTAINER HEIGHT:100MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.7 Is it acceptable to the Purchaser to offer ALUMINIUM BOTTOM FOR 1/1 CONTAINER HEIGHT:190MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.8 Is it acceptable to the Purchaser to offer ALUMINIUM BOTTOM FOR 3/4 CONTAINER HEIGHT:100MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.9 Is it acceptable to the Purchaser to offer ALUMINIUM 1/1 LID RED WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.10 Is it acceptable to the Purchaser to offer ALUMINIUM 1/1 LID BLUE WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.11 Is it acceptable to the Purchaser to offer ALUMINIUM 1/1 LID GREEN WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.12 Is it acceptable to the Purchaser to offer ALUMINIUM 1/2 LID GREEN WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.13 Is it acceptable to the Purchaser to offer ALUMINIUM 1/2 LID RED WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.14 Is it acceptable to the Purchaser to offer ALUMINIUM 1/2 LID GOLD WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.15 Is it acceptable to the Purchaser to offer ALUMINIUM 1/2 LID BLUE WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.16 Is it acceptable to the Purchaser to offer ALUMINIUM 3/4 LID GOLD WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.17 Is it acceptable to the Purchaser to offer ALUMINIUM 3/4 LID BLUE WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.18 Is it acceptable to the Purchaser to offer ALUMINIUM 3/4 LID GREEN WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.19 Is it acceptable to the Purchaser to offer ALUMINIUM 3/4 LID SILVER WITH INTEGRATED PTFE FILTER FOR 2000 CYCLES?

* It is not acceptable.

6.5.20 Is it acceptable to the Purchaser to offer BOTTOM F/MINI CONTAINER HEIGHT:58MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.26 Is it acceptable to the Purchaser to offer MINI-SIZE WIRE BASKETW/LID47MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.27 Is it acceptable to the Purchaser to offer 3/4 BASKET W/ STACK.FEET 411x259x84MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.28 Is it acceptable to the Purchaser to offer 1/1 BASKET W/ STACK.FEET 491X259X84MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.29 Is it acceptable to the Purchaser to offer 1/2 BASKET W/ STACK.FEET 250X259X84MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.30 Is it acceptable to the Purchaser to offer 1/1 SIZE PERF BASKET 546X259X84MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.31 Is it acceptable to the Purchaser to offer 1/1 SIZE PERF BASKET 491X259X84MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.32 Is it acceptable to the Purchaser to offer 1/2 SIZE PERF BASKET 250X259X84MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.33 Is it acceptable to the Purchaser to offer 3/4 SIZE PERF BASKET 411X259X84MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.42 Is it acceptable to the Purchaser to offer SILICONE CUSHIONING PAD 275X125MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.44 Is it acceptable to the Purchaser to offer SILICONE CUSHIONING PAD 250X235MM

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.47 Is it acceptable to the Purchaser to offer INSTRUMENT FIXATION SYSTEM 238X45MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.48 Is it acceptable to the Purchaser to offer INSTRUMENT FIXATION SYSTEM158X45MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.49 Is it acceptable to the Purchaser to offer CABINET CART SLD SHLVS 1260X680X1280MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.50 Is it acceptable to the Purchaser to offer STORAGE CART OPEN 1070X700X1340MM?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

6.5.52 Is it acceptable to the Purchaser to offer the set without SCREW DRIVER HEXAGON SOCKET 3MM, if the manufacturer‘s solution for fixation system (6.5.47) does not need it (the fixation system can be mounted/dismounted by hand)?

* It is not acceptable. The requirements of the contracting authority are conditioned by the existing equipment.

**Lot 1**

"Dear All, By analyzing the tender documentation Procurement of Equipment for The Obstetrics and Gynecology Clinic Narodni Front, Belgrade, Serbia IOP /29-2019/RD, we determined that we need clarification of bidding documents.

– Lot 1 Radiology - PACS

1)In item 2.7.5. of the technical specification of the PACS system you specify the following: ""Medical Monitor, its graphic card and calibration software must be from the same producer;""

Please change this requirement to read ""Medical Monitor and calibration software must be from the same producer and graphic card must be recommended by medical monitor manufacturer;"", bearing in mind that medical monitor manufacturers are almost never graphic card manufacturers and that for use with their medical monitors, they recommend graphics cards from well-known brands, such as Nvidia.

* It is acceptable.

2) In item 2.7.6. of the technical specification of the PACS system you specify the following: Response time maximum 10ms.

Please clarify what response time is meant, ""black to white or black to white to black or gray to gray""? If it is ""Response time black to white to black"" please change the request to read ""Response time maximum 12ms. ""

* It is acceptable.

3) In item 3.1 of the technical specification of the PACS system you specify the following ""Work on the"" Microsoft Windows ""platform (supported 32-bit and 64-bit versions of operating systems: Minimum MS Windows 7""

Considering that 32-bit operating systems can address i.e. use only 4GB RAM, since the tender documentation itself in item 2.2 specifies ""At least 8GB RAM"" and considering

that PACS client applications are very demanding in terms of the use of computer resources (including RAM storage) please exclude the requirement regarding 32-bit OS. Please change this requirement to read ""Work on the Microsoft Windows platform (supported 64-bit versions of operating systems: Minimum MS Windows 7)""

* It is acceptable.

4) In item 3.16. of the technical specification of the PACS system you specify the following ""Support for at least English and Serbian language;""

Since most manufacturers use English as their base language when developing their software, and it is very rare that the software is localized in Serbian by almost all internationally renowned manufacturers, please modify the request to ""Support for at least English or Serbian language;""

* It is not acceptable.

It is very important that PACS system supports Serbian as mother language. Not all personnel are familiar with English and in such cases user interface in Serbian language significantly improve workflow and make the system easy and comfortable to use. It is known that many PACS vendors adopt software and user interfaces to local languages.

5) In item 6.7.2. of the technical specification of the PACS system you specify the following "Making curved section"" tennis specifications of the PACS system

Please exclude this requirement from the tender documentation, since there is no need for clinicians who are primary users of the zero footprint Viewer to use this complex tool and given that it is the task of the radiologist to describe the exam and provide all necessary information for the clinician through the radiological report and/or through annotations/notes on the image.

* It is acceptable to provide PACS systems without functionality of making curved section.

"– Lot 1 Radiology- SYSTEM FOR DIGITALIZATION

1) In item 6.7.6. of the technical specification of the PACS system you specify the following ""Automatic removal of the patient table""

Please exclude this requirement from the tender documentation, since there is no need for clinicians who are primary users of the zero footprint Viewer to use this complex tool and given that it is the task of the radiologist to describe the exam and provide all necessary information for the clinician through the radiological report and/or through annotations/notes on the image.

* It is acceptable to provide system without this functionality.

2) In item 6.7.7. of the technical specification of the PACS system you specify the following "Segmentation""

Please exclude this requirement from the tender documentation, since there is no need for clinicians who are primary users of the zero footprint Viewer to use this complex tool and given that it is the task of the radiologist to describe the exam and provide all necessary information for the clinician through the radiological report and/or through annotations/notes on the image.

* It is acceptable to provide system without this functionality.

3) In items 6.1.1 and 6.2.1 of the technical specification of the X-ray equipment digitization system, you specify the following: Charge capability: min. 6h / 1000 images

 Is it acceptable for the Contracting Authority to change this requirement to Charge capability: min. 6h / 320 images. As the detector's charging time is only a couple of hours, the practice is to charge the detectors every day and 320 images a day means that one image could be taken every 4 and a half minutes.

* It is not acceptable. Charge capability of min 6h/1000 images enables imaging in one hospital shift without disturbing the workflow by exchanging batteries. One battery needs to have such a capacity that it can be replaced and put into the charger only after one hospital shift finishes its work. Therefore, capacity of 320 images might not be sufficient in case of heavy workflow.

 4) In item 6.3.1 of the technical specification for a dry laser printer you requested the following: Different printing formats: 35x43cm; 35x35cm; 26x36cm; 25x30cm; 20x25cm

 Is it acceptable for the Contracting Authority to change the request to: Different printing formats: 35x43cm (14x17in); 35x35cm (14x14in); 26x36cm (11x14in); 25x30cm (10x12in); 20x25cm (8x10in) because different manufacturers use different units of measure.

* It is acceptable

 5) In item 6.4.2 of the technical specification for the monitor you requested the following: Luminance: min 1900 cd / m2. Is it acceptable for the Contracting Authority to change the request to: Luminance: min 1200 cd / m2. By changing this requirement you would not lose out on the functionality of the device while allowing more bidders to submit correct bids.

* It is not acceptable. Higher luminance is characteristic of better monitors. Luminance is a measure of quantity of light emitted by a part of display area. As the radiologists describe, the diagnostic image directly from the monitor is characteristic of vital importance, and it can directly influence the accuracy of diagnostic finding. Luminance of 1900 cd/m2 is industry standard, and it doesn’t exceed the usual parameter of similar equipment present in the market.

6)In item 6.1.2 of the digitization technical specification you requested the following:

Acquisition and imaging console

- PC workstation: new generation, multi-core PC min i5 or equivalent

- RAM: min 4 GB

- HDD: min 500 GB

- Archive system: DVD RW

- Monitor: High luminance LCD monitor min 21""

- Resolution: full HD 1920 x 1080 or higher

- Operating system: Windows

Software characteristics:

- Acquisition, processing and visualization of radiographic images

- Local archive of high resolution images

- DICOM 3.0 interface with the support of service classes: send and print, worklist / MPPS, storage, storage commitment

- Image post-processing: annotations, contrast and brightness, noise reduction, edge enhancement, image reversal, grayscale optimization, zoom, measurements

Is it acceptable for the Contracting Authority to change the request to: Acquisition and imaging console (hardware and software validated by manufacturer). Different manufacturers define their products differently. For this reason, some manufacturers require stronger hardware, while others may get the same functionality with weaker hardware.

* Not acceptable we defined minimum technical request. However better offered functionality will be accepted. Contemporary software has high requirements regarding hardware characteristics, especially in terms of processor speed and memory capacity. The requested hardware specification is an industry standard, and it can be satisfied by products of a number of manufacturers.

Requested minimal characteristics of acquisition software are standard part of most (if not all) of the products present in the market. Only generic, non-specific software features are requested. None of the requested characteristics exceeds usual.

The aim of digitalization of existing X-ray equipment is to enjoy the benefits of digital image acquisition, processing and archival using the contemporary software products, with minimal features given in requested specification. The requested hardware is minimal and necessary to enable normal function of such acquisition software.

"Lot 1 Radiology- SYSTEM FOR DIGITALIZATION

7) In item 6.2.2 of the digitization system technical specification you requested the following:

Acquisition and imaging console

- PC workstation: new generation, multi-core Notebook PC min i5 or equivalent

- RAM: min 4 GB

- HDD: min 500 GB

- LCD display: min 15""

- Resolution: full HD 1920 x 1080 or higher

- Operating system: Windows

Software characteristics:

- Acquisition, processing and visualization of radiographic images

- Local archive of high-resolution images

- DICOM 3.0 interface with the support of service classes: send and print, worklist / MPPS, storage, storage commitment

- Image post-processing: annotations, contrast and brightness, noise reduction, edge enhancement, image reversal, grayscale optimization, zoom, measurements

Is it acceptable for the Contracting Authority to change the request to: Acquisition and imaging console (hardware and software validated by manufacturer). Different manufacturers define their products differently. For this reason, some manufacturers require high-profile hardware, while others may get the same functionality with low-profile hardware."

* Not acceptable we defined minimum technical request. However better offered functionality will be accepted. Contemporary software has high requirements regarding hardware characteristics, especially in terms of processor speed and memory capacity. The requested hardware specification is an industry standard, and it can be satisfied by products of a number of manufacturers.

Requested minimal characteristics of acquisition software are standard part of most (if not all) of the products present in the market. Only generic, non-specific software features are requested. None of the requested characteristics exceeds usual.

The aim of digitalization of existing X-ray equipment is to enjoy the benefits of digital image acquisition, processing and archival using the contemporary software products, with minimal features given in requested specification. The requested hardware is minimal and necessary to enable normal function of such acquisition software.

" Lot 1 Radiology - 4D Gynecological ultrasound system with two transducers

Question 1.

Item 4, the following is required: Full HD OLED monitor, at least 22 ”diagonal, resolution of minimum 1920x1080 pixels, tilt / rotate adjustable

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Full HD OLED or LCD monitor, at least 22 ”diagonal, resolution of minimum 1920x1080 pixels, tilt / rotate adjustable

We propose to the Contracting Authority this minor modification, because the technology of production of the monitor (OLED, HD LCD or similar) will not affect the clinical quality of the obtained image of the device. This minimal change increases the competitiveness of the public procurement process, while the technical specification remains at premium performances of the device.

* Not acceptable- OLED and LCD are different technologies. OLED technology is the latest monitor technology and has better image quality compared to LCD monitors which means better contrast, higher brightness and wider viewing angle, much faster refresh rates (no ghost effect) which provide to operator easy work and reliable diagnostics. Taking into consideration this is Premium ultrasound system which will be used for advanced diagnostics procedures and visualization of tiny structures, it is required that system has high performance monitor (OLED). Also, several vendors have ultrasound systems with OLED monitors

Question 2.

Item 6, the following is required: Rotatable and electrically height adjustable floating operator keyboard with full-sized backlit alphanumeric keyboard.

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Rotatable and height adjustable floating operator keyboard with full-sized backlit alphanumeric keyboard.

We are of opinion that every device should have the adjustment of the control panel by height, rotation and depth, in order for the user who uses the device all day long has the most optimal position at the device. Highlighting a solution in terms of electrical / mechanical / hydraulic etc ... is just a restriction of competition for the same / similar solutions.

* It is accepted.

Question 3.

Item 9, the following is required: Maximum depth range in B-mode not less than 40 cm - probe dependent

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Maximum depth range in B-mode not less than 30 cm - probe dependent

Procurement subject matter is a 4D gynecologic ultrasound device - and thus a depth required of 40 cm (and, at the same time, it is not required that at least one transducer offered should support such depth) is eliminatory in nature, since the exam of the fetus is performed at a depth of 15 to 25 cm, depending on different factors, but not at the required depth of 40 cm.

* Not acceptable. For the examination of very obese OB/GYN patients with high BMI, that are more common, it is necessary that the system has depth range much greater than standard. More manufacturers can fulfil this request.

Question 4.

Item 10, the following is required: Maximum frame rate not less than 3000 f / sec.

Is a minimum change to this item acceptable to the Contracting Authority as follows: Maximum frame rate 3000 f / sec. (+/- 200 f / sec.)

Depending on the transducer, setting and application (2D / 4D), the frame rate differs, too- and therefore, the required minimum of 3000 f / sec does not mean that it will be for the duration of the entire exam, for this reason we consider that the required feature is only of eliminatory character and limits competition. Third-party manufacturer premium devices also have other technical features, not mentioned here, that lead to premium image in the required modes / applications. Accordingly, the proposed amendment is minimal and allows for a tolerance that allows the participation of more interested bidders.

* It is acceptable.

Question 5.

Item 21, the following is required: Write Zoom up to 5x and read zoom with HD-Zoom functionality up to 20x

Is a minimum change to this item acceptable to the Contracting Authority as follows: Zoom functionality up to 15x

For the user of the device, the function of the Zoom itself is more than clear so it is not necessary to explain specifically that an original way in which the item is defined is only of an eliminatory character."

* It is acceptable.

"Lot 1 Radiology - 4D Gynecological ultrasound system with two transducers

Question 6.

Item 22, the following is required: Automated standardized measurements for Nuchal Translucency and Intracranial Translucency.

Is it acceptable for the Contracting Authority to remove point 22?

The rationale is that the required automatic measurement determines the further progression, treatment or, ultimately, termination of pregnancy. This automatic measurement is not recommended by any world guide, as it is considered an individual measurement from user to user (from doctor to doctor) who, based on the placement of the cursor (calipers), decide the further course of pregnancy - too important to be allowed to be done by the computer (ultrasonic device) automatically.

* Not acceptable- Customer is experienced university clinic with everyday routine NT exams. The required option that provides automatic Nuchal Translucency and Intracranial Translucency measurements is very important because with automatic measurement we get standardized, accurate, quantifiable, reproducible and operator-independent results. Minor inaccuracies in NT measurement can have very significant negative impacts on abnormality detection. Semi-automated method is more reliable than manual (<https://www.ncbi.nlm.nih.gov/pubmed/20617517>). Having such an option would significantly improve workflow- especially in situations with huge patient throughput on our clinic. A few vendors have this option on their ultrasound systems.

Question 7.

Item 23.10, the following is required: Volume 4D Matrix Convex

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Volume 4D Matrix Convex or Single Crystal

We propose to the Contracting Authority this minimal change, for the reason that different manufacturers have different technologies that have the same result, which is the user to be satisfied with the quality of the diagnostic image, no matter what technology is used.

* Matrix and Single Crystal technologies are not equivalent and comparable. More manufacturers of ultrasound systems use matrix technology because of its advantages.

Question 8.

Item 24.9, the following is required: Method for showing hemodynamics direct in B-Mode (without use of doppler technology) which is based on reflection of blood cells.

Is the minimum modification to this item acceptable to the Contracting Authority as follows: Special technology for slow flow visualization (is not acceptable Power Doppler technology)

In this way, the user receives equally valuable technology as originally required, which requires advanced technology - aimed at visualizing slow flows in tissue and blood vessels.

* It is not acceptable. The requested technique has great clinical benefit because a visualization of hemodynamics directly in B mode overcoming the limitations that Doppler techniques have.

- direct, not indirect technique,

- enables simultaneous visualization of both slow and fast flows,

- no aliasing

- not only displays hemodynamics in a limited region but in the entire field of view

- shows real hemodynamics, without overflowing beyond the edges of the blood vessel

- gives better spatial and temporal resolution of the flow

- does not depend on the angle

Question 9.

Item 25.1. the following is required: The method which during 3D / 4D acquisition automatically determines the position and shape of the render start line and optimally adjusts it for the best adaptation to the render object.

Is it acceptable for the Contracting Authority to delete item 25.1?

The reason for this item to be deleted is that the required method is not recognized as a recommendation in any world guide to ultrasound diagnostics. Another reason is that it is not possible to use a method that automatically sets the start line and performs optimization for rendering - and it is well known that there are no 2 equal pregnant women and babies, and therefore any automation is not sufficient without the use of correction by a doctor - which is not the required automated method any longer.

* Not acceptable- This technology provides faster and accurate 3D/4D imaging avoiding manual definition of start line. The requested technique is very useful in everyday workflow because saves time and simplifies 3D / 4D acquisition. A few vendors have this option on their ultrasound systems.

Question 10.

Item 25.4, the following is required: Mode for rendering anechogenic structures.

Is it acceptable for the Contracting Authority to delete item 25.4?

The reason for the deletion is that the proposed method was developed by only one manufacturer of ultrasonic devices - which this represents the violation of the Law on Public Procurement. This mode is also not clinically demonstrable, because if the structures are anechogenic - this means that there is no signal (the signal that the transducer needs to receive to process such signal at a later point) and that nothing can be rendered.

* It is acceptable to provide device without this functionality.

"Question 11.

Item 25.6, the following is required: Technology that provides more natural tissue presentation in a 3D / 4D mode with three virtual light sources that can be independently adjusted, intensifying impression of depth and highlighting the anatomical structure of the interest.

Is a minimum modification to this item acceptable to The Contracting Authority as follows: Technology that provides more natural tissue presentation in 3D / 4D mode with virtual light source that can be independently adjusted, intensifying impression of depth and highlighting the anatomical structure of interest

* It is acceptable

The requirement defined in this way enables competitiveness in the public procurement process - it will not clinically diminish the importance of the technology required. The light source itself, be it 3 or 1, which can be moved to an unlimited number of places, is an acceptable solution for the user.

Question 12.

Item 26.2, the following is required: 6 USB ports

Is a minimum modification to this item acceptable to the Contracting Authority as follows: USB ports

The device should be equipped with a USB port, but restricting it with the number of USB connectors is only a violation of the Law on Public Procurement, because if a device has 2 or 12 USB ports, it will not affect the clinical work of doctors on such device.

* It is acceptable

Question 13.

Item 26.3, the following is required: Export of the data in the following formats: BMP, TIFF, JPEG, AVI, MP4, DICOM, Raw files (2D, VOL, 4DVOL), 3D Raw (Cartesian format possible), Surface formats (STL, OBJ , PLY, 3MF, XYZ)

Is a minimum modification to this item acceptable to the contracting authority as follows: Export of the data in some of the PC formats

In this way, the user gets the necessary technique - to export the data from the ultrasound device in one of the formats that can be displayed on a PC. Restricting competition by listing the formats that are not harmonized by all world manufacturers of US devices, is not in accordance with the Law on Public Procurement.

* Not acceptable. BMP, TIFF, JPEG, AVI, MP4 are standard PC formats and other listed formats are standardized formats which enable further image evaluation and postprocessing on another medical devices (e.g. other ultrasound systems or workstations…). Every manufacturer of ultrasound system has possibility to export data in some kind of raw format. Since two systems are requested, it is important to have a possibility to transfer data in the original (raw) format from one system to another.

Question 14.

Item 27.1, the following is required: 4D Volume convex, abdominal probe with active matrix array: Frequency range: 1 - 7 MHz (+/- 0.5 MHz), Number of elements: minimum 900, Field of view (FOV): 90 °

Is a minimum modification to this item acceptable to the Contracting Authority as follows: 4D Volume convex, abdominal probe with active matrix array or single crystal technology: Frequency range: 2 - 7 MHz or wider, Number of elements: minimum 192, Field of view (FOV): 90 °

The transducer, its fabrication technology, the number of frequency crystals ... are not the only things that determine whether the device / transducer is premium or not, and therefore it is not necessary to restrict competition if they have equally valuable transducer fabrication technology, rather than the required matrix technology, for example. All this causes the clinical image that produced by the device to be at the premium level, as requested by the user, only with the possibility that other interested bidders also offer their premium ultrasound device solution.

* Partially acceptable. The numbers of elements determine quality of probe and there is no reason to fully accept request from prospective bidder bearing in mind the number and complexity of exams that our institution have. The specification will be modified to:

4D Volume convex, abdominal probe with active matrix array: Frequency range: 2 - 7 MHz or wider, Number of elements: minimum 900, Field of view (FOV): 90 °

Question 15.

Item 27.2, the following is required: 4D Volume endocavity probe: Frequency range: 4 - 9 MHz (+/- 0.5 MHz), Number of elements: minimum 192, Field of view (FOV): 180°

Is a minimum modification to this item acceptable to the Contracting Authority as follows: 4D Volume endocavity probe: Frequency range: 4 - 9 MHz or wider, Number of elements: minimum 128, Field of view (FOV): 160°

Minimal changes in the required technical specification of the transducer, the number of crystals, the frequency ... are not the only things that determine whether the device /transducer is premium or not, and thus it is not necessary to restrict competition, but allow more interested bidders to participate in the public procurement process.

* Not acceptable. The numbers of elements determine quality of probe and there is no reason to mitigate that request. The endocavitary probe is used for examination of female reproductive organs, primarily the uterus, and therefore FOV is very important. More manufacturers of ultrasound systems can fulfill this request.

"Question 16.

Item 20, the following is required: Automatic fetal biometry for BPD, AC, HC, HL, FL.

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Automatic fetal biometry measurements for most commonly used fetal biometry parameters min. 5

In this way, the user defined in a precise manner that he/she wants automated measurements for fetal biometrics, but without restricting competition - because it varies from manufacturer to manufacturer in 1 to 2 measures. The characteristic defined in this way allows more bidders to participate in the public procurement process.

* Partially acceptable. It is necessary to provide at least 5 fetal biometry parameters, mandatory: BPD, AC, HC, FL.

Question 17.

Is it acceptable for the Contracting Authority to add a new item, e.g. 6.1 to read as follows: The possibility of rotating the control panel of the device min. 180° from the center, without moving the device?

This allows the user, the doctor, who spends the whole day at the device, to adjust the work on the device in a way that suits him/her.

* Not acceptable- Customer already defined minimal technical specification of the ultrasound system which should be offered according to their needs and clinical requirements. It is requested a possibility to rotate the control panel horizontally without specifying min. angle, as this parameter doesn't have significant clinical benefit.

Question 18.

Is it acceptable for the Contracting Authority to add a new item, e.g. 2.1 to read as follows: Number of digital processing channels min. 4,700,000

In this way, the user will get a high-quality ultrasound device, which is also owned by other manufacturers of ultrasound devices."

* Not acceptable- The contracting authority has already defined with other parameters the technical characteristics that premium system must to have, so there is no need to add this additional parameter, especially because the premium systems of leading manufacturers have even 100 times more process channels than the proposed value.

" Lot 1 Radiology - 2D Gynecological ultrasound system with two probes

Question 1.

Item 4, the following is required: LCD LED monitor with DVI interface, at least 23 ""diagonal, resolution of minimum 1920x1080 pixels, tilt / rotate adjustable, digital backlight and color temperature adjustment. Minimum 10 default monitor settings available.

Is a minimum modification to this item acceptable to the Contracting Authority as follows: LCD LED monitor with DVI interface, at least 23 ""(+/- 2 '') diagonal, resolution of minimum 1920x1080 pixels, tilt / rotate adjustable, digital backlight and color temperature adjustment Minimum 10 default monitor settings available.

Acceptable deviation of only 2'' in monitor size will not affect the clinical picture of the device and is only an eliminating feature in the public procurement procedure.

* Not acceptable- Bigger monitor provides better overview during examination, especially in situations where it is necessary to display several images, complete system menu and all available functionalities for particular exam. There is no reason to mitigate request for monitor size. More manufacturers of ultrasound systems can fulfill this request.

Question 2.

Item 11, the following is required: Maximum depth range in B-mode not less than 35 cm - probe dependent

Is the minimum modification to this item acceptable to the Contracting Authority as follows: Maximum depth range in B-mode 35 cm (+/- 5 cm) - probe dependent

The procurement subject matter is a 2D gynecologic ultrasound device - and thus required depth of 35 cm (and, at the same time, it is not required that at least one transducer offered should support that depth) is of an eliminatory nature, since the exam of the fetus is performed at a depth of 15 to 25 cm , depending on different factors, but not at the required depth of 35 cm.

* Not acceptable. For the examination of very obese OB/GYN patients with high BMI, that are more common, it is necessary that the system has depth range much greater than standard. More manufacturers can fulfil this request.

Question 3.

Item 12, the following is required: Write Zoom up to 5x and read zoom with HD-Zoom functionality up to 20x

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Zoom functionality up to 15x

For the user of the device, the function of the Zoom itself is more than clear so it is not necessary to explain specifically that an original way in which the item is defined is only of an eliminatory character.

* It is acceptable.

Question 4.

Item 13, the following is required: Automatic fetal biometry for BPD, AC, HC, HL, FL.

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Automatic fetal biometry measurements for most commonly used fetal biometry parameters min. 5

In this way, the user defined in a precise manner that he/she wanted automated measurements for fetal biometrics, but without the restriction of competition - because it varies from manufacturer to manufacturer in 1 to 2 measures. The characteristic defined in this way allows more bidders to participate in the public procurement process.

* Partially acceptable. It is necessary to provide at least 5 fetal biometry parameters, mandatory: BPD, AC, HC, FL.

Question 5.

Point 14, the following is required: Integrated uplink for cloud-based data storage.

Is it acceptable for the Contracting Authority to delete item 14?

The reason for this is that it is not known whether and what kind of computer network the user owns, which is necessary for the realization of this request. Also, to condition at present anyone with this option which does not affect the clinical operation of the device, is contrary to the Law on Public Procurement."

* It is acceptable to provide system without this functionality.

" Lot 1 Radiology - 2D Gynecological ultrasound system with two probes

Question 6.

Item 16, the following is required: Image size: standard and extra large (XL) format.

Is it acceptable for the Contracting Authority to correct the item to read as follows: Image size: standard and extra large (XL) format or simultaneously display the image from the monitor on the touch screen

Equally valuable technology, which leads to the user being able to display an image on the screen of the US device and on the touch screen, which is not even requested, but as a responsible bidder we want to offer better than minimum specification. We believe that the required and proposed technology is not intended to affect the quality of the clinical image, but the comfort of the user is concerned.

* The request will remain unchanged and bidders can offer the system with better characteristics than requested.

Question 7.

Item 20.2, the following is required: Method which during 3D/4D acquisition automatically determines the position and shape of the render start line and optimally adjusts it for the best adaptation to the render object.

Is it acceptable for the Contracting Authority to delete item 20.2?

The reason for the deletion of this item is that the required method is not recognized as a recommendation in any world guide to ultrasound diagnostics. Another reason is that it is not possible to use a method that automatically sets the start line and performs optimization for rendering - and it is well known that there are no 2 same pregnant women and babies, and therefore any automation is not sufficient without the use of correction by a doctor - which is not the required automated method any longer.

* Not acceptable- This technology provides faster and accurate 3D/4D imaging avoiding manual definition of start line. The requested technique is very useful in everyday workflow because saves time and simplifies 3D / 4D acquisition.

Question 8.

Item 20.3, the following is required: Method for showing hemodynamics direct in B-Mode (without use of Doppler technology) which is based on reflection of blood cells.

Is the minimum modification to this item acceptable to the Contracting Authority as follows: Special technology for slow flow visualization

In this way, the user receives equally valuable technology as originally requested, which requires advanced technology - aimed at visualizing slow flow in tissue and blood vessels.

* Not acceptable. The requested technique has great clinical benefit because a visualization of hemodynamics directly in B mode overcoming the limitations that Doppler techniques have.

- direct, not indirect technique,

- enables simultaneous visualization of both slow and fast flows,

- no aliasing

- not only displays hemodynamics in a limited region but in the entire field of view

- shows real hemodynamics, without overflowing beyond the edges of the blood vessel

- gives better spatial and temporal resolution of the flow

- does not depend on the angle

Question 9.

Item 21.1; 22.2; 22.3; 22.4; 22.5, the following is required: Bitmap files: BMP, TIFF, JPEG; Raw files: RAW (2D), VOL (Volume data), 4DV (RAW, VOL incl. Patient data); Sequence of Bitmaps: BMP, MP4; DICOM Files: DCM, DICOM Files with DICOM DIR; 3D Raw Data: conversion to Cartesian format possible.

Is it acceptable for the Contracting Authority to make a minimum modification to the above items into a single item, 21, as follows: PC Formats and DICOM

In this way, the user gets the necessary technique - to export the data from the ultrasound device in one of the formats that can be displayed on PC and DICOM workstations. Restricting competition by picking up formats that are not harmonized by all world manufacturers of US devices, is not in compliance with the Law on Public Procurement.

* Not acceptable. BMP, TIFF, JPEG, AVI, MP4 are standard PC formats and other listed formats are standardized formats which enable further image evaluation and postprocessing on another medical devices (e.g. other ultrasound systems or workstations…). Every manufacturer of ultrasound system has possibility to export data in some kind of raw format. Since that more than one system are requested, it is important to have a possibility to transfer data in the original (raw) format from one system to another.

Question 10.

Item 23.1, the following is required: 2D Wideband Convex probe. Frequency range: 2-5 MHz (+/- 0.5MHz), Number of elements: minimum 128, Scan angle in wide mode: minimum 80°

Is a minimum modification to this item acceptable to the Contracting Authority as follows: 2D Wideband Convex probe: Frequency range: 2-5 MHz or wider, Number of elements: minimum 128, Scan angle in wide mode: minimum 80°

Minimal modification in the frequency range will not lead to a change in the clinical quality of the image, but aims to allow more bidders to participate in the public procurement procedure.

* It is acceptable.

" Lot 1 Radiology - 2D Gynecological ultrasound system with two probes

Question 11.

Item 23.2, the following is required: 2D Endocavity probe: Frequency range: 2.5 - 10 MHz (+/- 0.5MHz), Number of elements: minimum 192, Scan angle in wide mode: minimum180°

Is a minimum modification to this item acceptable to the Contracting Authority as follows: 2D Endocavity probe: Frequency range: 4 - 9 MHz or wider, Number of elements: minimum 128, Scan angle in wide mode: minimum 180 °

Minimal modification in the frequency range will not lead to a change in the clinical quality of the image, but aims to allow more bidders to participate in the public procurement procedure.

* It is acceptable.

Question 12.

Is it acceptable for the Contracting Authority to add a new item, e.g. 4.1 to read as follows: The possibility of rotating the control panel of the device min. 180° from center, without moving the device?

This allows the user, the doctor, who spends the whole day at the device, to adjust the work on the device in a way that suits him/her.

* Not acceptable- Customer already defined minimal technical specification of the ultrasound system which should be offered according to their needs and clinical requirements. It is requested a possibility to rotate the control panel horizontally without specifying min. angle, as this parameter doesn't have significant clinical benefit.

Offered System which exceeds defined minimal technical specification will be accepted.

Question 13.

Is it acceptable for the Contracting Authority to add a new item, e.g. 2.1 to read as follows: Number of digital processing channels min. 4,700,000

In this way, the user will get a high-quality ultrasound device, which is also owned by other manufacturers of ultrasound devices."

* Not acceptable. The contracting authority has already defined with other parameters the technical characteristics that premium system must to have, so there is no need to add this additional parameter, especially because the premium systems of leading manufacturers have even 100 times more process channels than the proposed value.

"– Lot 1 Radiology - 2D Gynecological ultrasound system with two probes

Question 1.

Item 4, the following is required: LCD LED monitor with DVI interface, at least 23 ""diagonal, resolution of minimum 1920x1080 pixels, tilt / rotate adjustable, digital backlight and color temperature adjustment. Minimum 10 default monitor settings available.

Is a minimum modification to this item acceptable to the Contracting Authority as follows: LCD LED monitor with DVI interface, at least 23"" (+/- 2'') diagonal, resolution of minimum 1920x1080 pixels, tilt / rotate adjustable, digital backlight and color temperature adjustment. Minimum 10 default monitor settings available.

An allowed deviation of only 2'' in monitor size will not affect the clinical image of the device, and is only an eliminating feature in the public procurement procedure.

* Not acceptable- Bigger monitor provides better overview during examination, especially in situations where it is necessary to display several images, complete system menu and all available functionalities for particular exam. There is no reason to mitigate request for monitor size. A few vendors have this option on their ultrasound systems

Question 2.

Item 5, the following is required: Maximum depth range in B-mode not less than 40 cm - probe dependent

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Maximum depth range in B-mode not less than 30 cm

The subject matter of the procurement is a 2D gynecological ultrasound device - and thus required depth of 40 cm (and, at the same time, it is not required that at least one transducer offered should support such depth) is of an eliminatory nature, as the examination of the fetus is performed at a depth of 15 to 25 cm , depending on different factors, but not at the required depth of 40 cm.

* Not acceptable. For the examination of very obese OB/GYN patients with high BMI, that are more common, it is necessary that the system has depth range much greater than standard. More manufacturers can fulfil this request.

Question 3.

Item 12, the following is required: Automated standardized measurements for Nuchal Translucency and Intracranial Translucency.

Is it acceptable for the Contracting Authority to delete item 12?

The rationale is that the required automatic measurement determines the further progression, treatment, or, ultimately, termination of pregnancy. This automatic measurement is not recommended by any world guide, as it is considered an individual measurement from user to user (from doctor to doctor) who, based on the placement of the cursor (calipers), decide the further course of pregnancy - too important to be allowed to be performed by a computer (ultrasound device) automatically.

 •Not acceptable. Translucency measurements is very important because with automatic measurement we get standardized, accurate, quantifiable, reproducible and operator-independent results. Minor inaccuracies in NT measurement can have very significant negative impacts on abnormality detection. Semi-automated method is more reliable than manual (https://www.ncbi.nlm.nih.gov/pubmed/20617517).

Having such an option would significantly improve workflow- especially in situations with huge patient throughput on our clinic. A few vendors have this option on their ultrasound systems.

Question 4.

Item 15, the following is required: Write Zoom up to 5x and read zoom with HD-Zoom functionality up to 20x

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Zoom functionality up to 15x

For the user of the device, the function of the Zoom itself is more than clear so it is not necessary to explain specifically that an original way in which the item is defined is only of an eliminatory character."

* It is acceptable.

"Lot 1 Radiology - 2D Gynecological ultrasound system with two probes

Question 5.

Item 16, the following is required: Automatic Fetal Biometry for BPD, AC, HC, HL, FL.

Is a minimum modification to this item acceptable to the Contracting Authority as follows: Automatic fetal biometry measurements for most commonly used fetal biometry parameters min. 5

In this way, the user defined in a precise manner that he wanted automated measurements for fetal biometrics, but without restricting the competition - because it varies from manufacturer to manufacturer in 1 to 2 measures. The characteristic defined in this way allows more bidders to participate in the public procurement process.

* Partially acceptable. It is necessary to provide at least 5 fetal biometry parameters, mandatory: BPD, AC, HC, FL.

Question 6.

Item 17, the following is required: Integrated uplink for cloud-based data storage.

Is it acceptable for the Contracting Authority to delete item 17?

The reason for this is that it is not known whether and what kind of computer network the user mentions, which is necessary for the realization of this request. Also, to condition anyone now with this option, which does not affect the clinical operation of the device, is contrary to the Law on Public Procurement.

* It is acceptable to provide device without this functionality.

Question 7.

Item 19, the following is required: Image size: standard and extra large (XL) format.

Is it acceptable for the Contracting Authority to correct the item to read as follows: Image size: standard and extra large (XL) format or at the same time display the image from the monitor on the touch screen

Equally valuable technology, which leads to the user being able to display an image on the screen of the US device and on the touch screen, which is not even demanded, but as a responsible bidder we want to offer better than minimum specification. We believe that the required and proposed technology is not intended to affect the quality of the clinical image, but the comfort of the user is concerned.

* The request will remain unchanged and bidders can offer the system with better characteristics than requested.

Question 8.

Item 21.5, the following is required: Matrix linear

Is it acceptable for the Contracting Authority to delete item 10?

The subject of the procurement is a 2D gynecologist ultrasound device, which in its min. technical specifications do not contain any linear transducer, which comes with the device or as an upgrade option for future exams. Therefore, this transducer / option is of eliminatory character.

* It is acceptable

Question 9.

Item 22.8, the following is required: Real Time triplex mode: B + CFM + PW; B + PD + PW; B + M + MCFM; B / HD-Flow / PW;

Is it acceptable for the Contracting Authority to correct the item to read as follows: Real Time triplex mode

In this way, the item is defined in accordance with the Law on Public Procurement, because it does not prioritize any particular manufacturer of ultrasound device or technology names thereof, and it is a clinically acceptable technology.

* Partially acceptable. The required specifications will be modificated to :

Real Time triplex mode: B + CFM + PW; B + PD + PW;

Question 10.

Item 23.2, the following is required: Method which during 3D / 4D acquisition automatically determines the position and shape of the render start line and optimally adjusts it to the best adaptation to the render object.

Is it acceptable for the Contracting Authority to delete item 23.2?

The reason for this item to be deleted is that the required method is not recognized as a recommendation in any world guide to ultrasound diagnostics. Another reason is that it is not possible to use a method that automatically sets the start line and performs optimization for rendering - and it is well known that there are no 2 same pregnant women and babies, and therefore any automation is not sufficient without the use of correction by a doctor - which is not the required automated method any longer."

* Not acceptable- This technology provides faster and accurate 3D/4D imaging avoiding manual definition of start line. The requested technique is very useful in everyday workflow because saves time and simplifies 3D / 4D acquisition.

A few vendors have this option on their ultrasound systems.

"Question 11.

Item 23.3, the following is required: Method for showing hemodynamics direct in B-Mode (without use of doppler technology) which is based on reflection of blood cells.

Is the minimum modification to this item acceptable to the Contracting Authority as follows: Special technology for slow flow visualization

In this way, the user receives equally valuable technology as originally required, which requires advanced technology - aimed at visualizing slow flow in tissue and blood vessels.

* Not acceptable. The requested technique has great clinical benefit because a visualization of hemodynamics directly in B mode overcoming the limitations that Doppler techniques have.
  + direct, not indirect technique,
  + enables simultaneous visualization of both slow and fast flows,
  + no aliasing
  + not only displays hemodynamics in a limited region but in the entire field of view
  + shows real hemodynamics, without overflowing beyond the edges of the blood vessel
  + gives better spatial and temporal resolution of the flow
  + does not depend on the angle

Question 12.

Item 24.3, the following is required: 5 USB ports

Is a minimum modification to this item acceptable to the Contracting Authority as follows: USB ports

The device should have a USB port, but limitation with the number of USB connectors represents only the violation of the Law on Public Procurement, because having a device with 2 or 12 USB ports will not affect the clinical operation of doctors on such device.

* It is acceptable.

Question 13.

Item 24.4; 24.5, the following is required: Export of the data in the following formats: BMP, TIFF, JPEG; AVI, MP4, DICOM Files; 3D Raw Data: conversion to Cartesian format possible

Is a minimum modification to this item acceptable to the Contracting Authority so that it reads as follows: Export of the data in some of the PC formats and DICOM

In this way, the user gets the necessary technique - to export the data from the ultrasound device in one of the formats that can be displayed on a PC. Restricting competition by picking up formats that are not harmonized by all world manufacturers of US devices, is not compliant with the Law on Public Procurement.

* Not acceptable. BMP, TIFF, JPEG, AVI, MP4 are standard PC formats and other listed formats are standardized formats which enable further image evaluation and postprocessing on another medical devices (e.g. other ultrasound systems or workstations…). Every manufacturer of ultrasound system has possibility to export data in some kind of raw format. Since that more than one system are requested, it is important to have a possibility to transfer data in the original (raw) format from one system to another.

Question 14.

Item 25, the following is required: 2D Wideband Convex probe: Frequency range: 2-5 MHz (+/- 0.5MHz), Number of elements: minimum 192, Scan angle in wide mode minimum: 113°

Is a minimum modification to this item acceptable to the Contracting Authority as follows: 2D Wideband Convex probe: Frequency range: 2-5 MHz or wider, Number of elements: minimum 128, Scan angle in wide mode: minimum 80°

Minimal change in the frequency range and number of crystals will not lead to a change in the clinical quality of the image, but aims to allow more bidders to participate in the public procurement procedure. The number of crystals itself and the technology of transducer production is one component of quality image, while the other one is the device itself - which processes all the data obtained from the transducer, and thus it is not necessary to keep the technical specification of the device at a high level. The device we would like to offer is far better in technical specifications than required ones."

" Lot 1 Radiology - 2D Gynecological ultrasound system with two probes

* Partially acceptable- The specification would be modified to:

2D Wideband Convex probe: Frequency range: 2-5 MHz or wider, Number of elements: minimum 192, Scan angle in wide mode: minimum 80°

Question 15.

Item 25.2, the following is required: 2D Endocavity probe: Frequency range: 2.5 - 10 MHz (+/- 0.5MHz), Number of elements: minimum 192, Scan angle in wide mode: minimum 180°

Is a minimum modification to this item acceptable to the Contracting Authority as follows: 2D Endocavity probe: Frequency range: 4 - 9 MHz or wider, Number of elements: minimum 128, Scan angle in wide mode: minimum 180°

Minimal change in the frequency range will not lead to a change in the clinical quality of the image, but aims to allow more bidders to participate in the public procurement procedure.

* Partially acceptable- The specification would be modified to:

2D Endocavity probe: Frequency range: 4 - 9 MHz or wider, Number of elements: minimum 192, Scan angle in wide mode: minimum 180°

Question 16.

Is it acceptable for the Contracting Authority to add a new item, e.g. 4.1 to read as follows: The possibility of rotating the control panel of the device min. 180° from center, without moving the device?

This allows the user, the doctor, who spends the whole day at the device, to adjust the operation on the device in a way that suits him/her.

* Not acceptable- Customer already defined minimal technical specification of the ultrasound system which should be offered according to their needs and clinical requirements. It is requested a possibility to rotate the control panel horizontally without specifying min. angle, as this parameter doesn't have significant clinical benefit.

Offered system which exceeds defined minimal technical specification will be accepted.

Question 17.

Is it acceptable for the Contracting Authority to add a new item, e.g. 2.1 to read as follows: Number of digital processing channels min. 4,700,000

In this way, the user will get a high-quality ultrasound device, which is also owned by other manufacturers of ultrasound devices."

* Not acceptable- The contracting authority has already defined with other parameters the technical characteristics that premium system must to have, so there is no need to add this additional parameter, especially because the premium systems of leading manufacturers have even 100 times more process channels than the proposed value.

Public procurement Commission

.