Procurement of Medical Devices for University Children Hospital "Tiršova"

IOP/11-2017/RD

Clarification no. 7

Issued on December 1, 2017

LOT 4 Radiology

ID 4.1

1) In your bidding documentation, you have defined the following for lot 4,1 under points 4, 5 and 6:

-The system shall provide at least 512 lines of density

-The system shall have minimum 192 hardware channels

-The system shall provide up to 67,000 channels.

As manufacturers of ultrasound devices in their specifications of units in different ways describe the strength and quality of their units, is it acceptable for the Contracting Authority for points 4,5 and 6 the following to be offered: Powerful distributed multi-core processing architecture capable of achieving 225 x 109 40-bit Multiply- Accumulates/second with min. 4.700.000 digital channels?

Answer 1: There are many features of the ultrasound system which can describe strength and quality of the system. If offered system who has your proposed features/values also meets requirements defined under points 4, 5, 6, it will be acceptable for Purchaser.

2)In your bidding documentation, you have defined the following for lot 4,1 under points 12 and 13:

-The system shall have integrated gel warmer for convenience which is integrated into the system cart and controlled from the system control panel

Is it acceptable for the Contracting Authority an external gel heater to be delivered with the ultrasound unit to reduce the risk of possible bacteriological infections?

Answer 2: Not acceptable. Integrated gel warmer provides to operator and patient big comfort during examination. Integrated gel warmer is particularly important when system is moving from one to another examination room. In such cases we want to ensure that gel have always optimally predefined temperature (defined on the ultrasound system) for every patient and exam. Also, several leading ultrasound systems producers have this feature on their systems.

3)In your bidding documentation, you have defined the following for lot 4,1 under point 14:

-The system shall provide height adjustment of control panel of minimum 250 mm.

We think that the characteristic is eliminatory and that greater competitiveness should be provided to enable the participation of more bidders, and clinically there is no implication. Is it acceptable for the Contracting Authority to change this point so that it reads as follows: The system shall provide height adjustment of control panel of minimum 200 mm? Please keep in mind that competition should not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

Answer 3: Acceptable.

4)In your bidding documentation, you have defined the following for lot 4,1 under point 15:

-Wheels:

The system shall have four independent swivel wheels to allow for positioning in tight spaces, yet allow the locking of two wheels for ease in transporting.- 2- and 4-wheel braking- 2- and 4-wheel steering.

We think that it is necessary for the system to be manageable, but it is eliminatory in the way it is defined, we suggest an amendment for this to read as follows: The system shall have four independent swivel wheels to allow for positioning in tight spaces, yet allow the locking of two wheels for ease in transporting.

Answer 4: Acceptable.

5)In your bidding documentation, you have defined the following for lot 4,1 under point 31:

-The system shall provide image steering left/right and trapezoid up to 60º on linear transducers.

The Contracting Authority's request is eliminatory. We suggest an amendment, so the point reads like this: The system shall provide image trapezoid up to 20º on linear transducers. Please keep in mind that competition should not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

Answer 5: Not acceptable. Purchaser defined this request according to customer clinical needs. Steering angle for Trapezoid imaging defines field of view on linear probe. For customer it is very important to get as much as possible diagnostic information during exam. Angle of 60º enables gathering more information from region of interest. Maximum angle of 20º is not acceptable in this case.

6)In your bidding documentation, you have defined the following for lot 4,1 under point 37:

-The system shall have scale range: 0.004 – 450 cm/sec.

On the premium device that we want to offer our range is defined from 1.3 - 308 cm/s, is this range acceptable for the Contracting Authority?

Answer 6: Acceptable.

7)In your bidding documentation, you have defined the following for lot 4,1 under point 40:

-Power Doppler Maps: The system shall have up to 8 maps.

Is it acceptable for the Contracting Authority this request to be supplemented by: Color Doppler or Power Doppler Maps: The system shall have up to 8 maps?

Answer 7: Not acceptable. Purchaser already defined number of color Doppler maps under point 36. Number of maps requested under Point 40 is related only with Power Doppler

8)In your bidding documentation, you have defined the following for lot 4,1 under point 41:

-Power Doppler Line Density: The system shall have 6 selections for Power Doppler line density.

The request is eliminatory, please exclude it.

Answer 8: Not acceptable. This features defines sensitivity of power Doppler and such it is very important from clinical perspective and power Doppler signal quality

9)In your bidding documentation, you have defined the following for lot 4,1 under point 43:

-The system shall have scale range: 0.12 – 2000 cm/sec with 0° angle correction (with HPRF).

Is it acceptable for the Contracting Authority the range of 4,6 - 830 cm/sec in PW to be offered?

Answer 9: Acceptable.

10)In your bidding documentation, you have defined the following for lot 4,1 under point 44:

-The system shall have gate size correction of 1.0 – 40 mm

Is it acceptable for the Contracting Authority to modify the range to 1-20mm?

Answer 10: Not acceptable. Sometimes during clinical examinations, it is necessary to cover whole diameter of the vessel. In such cases gate size of 20 mm is not sufficient.

11)In your bidding documentation, you have defined the following for lot 4,1 under point 49:

-The system shall have full screen, Split, Quad and Dual Select screen formats as well as Dual, Dual seamless, Dual select and Dual from Freeze

Is a modification acceptable for the Contracting Authority so the request reads as follows: The system shall have full screen and Dual imaging with 2D/2D, 2D/color, color/color, color/CPA?

Answer 11: If offered system who has your proposed features/screen formats also meets requirements defined under point 49, it will be acceptable for Purchaser.

12)In your bidding documentation, you have defined the following for lot 4,1 under point 71:

-The system shall provide an image-based assessment using a color-coded quantitative scale for shear wave velocity.

Is it acceptable for the Contracting Authority to offer: Configurable analysis for Shear Wave: Pressure (kPa) and velocity (m/s) options and IQR (interquartile range) calculation?

Answer 12: Not acceptable. Quantitative value/parameters measured for share wave elastography are already requested under point 70. Under point 71, it is requested image-based assessment.

13)In your bidding documentation, you have defined the following for lot 4,1 under point 75:

-The system shall provide continuous slice thickness focusing without segmentation of transducer elements rows.

The request is unclear. Is the following definition acceptable for the Contracting Authority: Multiple technologies for one-button approach to automatically and immediately adjust system performance for different patient sizes, flow states and clinical requests.

Answer 13: Partially acceptable. Request under point 75 is changed to: The system shall provide continuous slice thickness focusing without segmentation of transducer elements rows or system shall provide multiple technologies for one-button approach to automatically and immediately adjust system performance for different patient sizes, flow states and clinical requests

14)In your bidding documentation, you have defined the following for lot 4,1 under point 81:

-Number of crystal elements min. 192

Is it acceptable for the Contracting Authority to modify this point so that it reads: number of crystal elements min. 160

Answer 14: Not acceptable. Higher number of elements enables better spatial resolution and image quality. Number of elements is one of the criteria which defines transducers quality. Several leading producers of ultrasound systems have convex transducers with number of elements which is 192 or higher on their ultrasound machines.

15)In your bidding documentation, you have defined the following for lot 4,1 under point 79:

-Frequency range: 1.5 – 6 MHz

Is an abdominal probe with range from 1-5 MHz acceptable for the Contracting Authority?

Answer 15: Not acceptable. Taking into consideration that big majority of the patients are small children, upper frequency of 5 MHz is not sufficient for such patients exams. Higher upper frequencies provide better image quality with higher spatial resolution enabling confident diagnostics. If you offer probe with wider frequency range then requested, it will be acceptable

16)In your bidding documentation, you have defined the following for lot 4,1 under point 89:

-Frequency range: 3 – 8 MHz

Is an abdominal probe with range from 2-9MHz acceptable for the Contracting Authority?

Answer 16: Acceptable. This frequency range of the probe which is wider then requested under point 89 is acceptable. Also, offered probe to be acceptable has to meet other requirements for this probe defined in technical specification

17)In your bidding documentation, you have defined the following for lot 4,1 under point 91:

-Number of crystal elements min. 384

Is it acceptable for the Contracting Authority to modify this point so that it reads: Number of crystal elements min. 190

Answer 17: Not acceptable. Higher number of elements enables better spatial resolution and image quality. Number of elements is one of the criteria which defines transducers quality. Several leading producers of ultrasound systems have new generation of convex transducers with number of elements which is 384 or higher on their ultrasound machines.

18)In your bidding documentation, you have defined the following for lot 4,1 under point 31:

-Frequency range: 4 – 9 MHz

Is a probe with range from 4-18MHz acceptable for the Contracting Authority?

Answer 18: Acceptable. This frequency range of the probe which is wider then requested under point 96 is acceptable. Also, offered probe to be acceptable has to meet other requirements for this probe defined in technical specification

19)In your bidding documentation, you have defined the following for lot 4,1 under point 105:

-Frequency Range: 4 – 12 MHz

Is a probe with range from 5-12MHz acceptable for the Contracting Authority?

Answer 19: Acceptable.

20)In your bidding documentation, you have defined the following for lot 4,1 under point 109:

-Max field of view min. 150mm

Is a probe L12-5 with Scanplane aperture 50mm acceptable for the Contracting Authority?

Answer 20: Under point 108, it is defined footprint of min. 50mm. Under point 109, it is defined max field of view for this probe. If offered probe with scan plane aperture also meets requirements of max field of view requested under point 109, it will be acceptable for Purchaser

21)In your bidding documentation, you have defined the following for lot 4,1 under point 124:

-(power down within 10 seconds; complete boot up within 30 seconds).

We think that time of powering down of the system is not significant, but only the speed of its booting up, so we suggest that you modify this point to read like this: Complete boot up within 30 seconds.

Answer 21: Acceptable.

22)In your bidding documentation, you have defined the following for lot 4,1 under point 131:

-The system shall include at least 2 TB of dedicated hard drive for large local storage capacity allowing over 600.000 B&W and color images.

Is it acceptable for the Contracting Authority that the device supports HDD of 500GB and additional 1.5TB to be delivered by an external HDD?

Answer 22: Not acceptable. External HDD is not acceptable for customer. Information and patient data security is crucial for Purchaser (Virus protection solution defined under point 155). Several leading producers of ultrasound systems have new generation systems with integrated hard drive with storage space of 2TB or higher.

23) In your bidding documentation, you have defined the following for lot 4,1 under point 136:

-DICOM Storage Class User (SCU)

Is DICOM SR (Structural report) acceptable for the Contracting Authority?

Answer 23: Not acceptable. DICOM Structured Reporting is already requested under point 149

4.2

24)In your bidding documentation, you have defined the following for lot 4,2 under point 2:

Power min. 40kW

Having analyzed the market, we have found that a large number of manufacturers do not have 40 kW generators, but with lower power. We are specifically thinking of Shimadzu DaRt Evolution, Siemens Mira, Siemens Mobilett, CSH DRX Revolution, GE Optima XR220... To enable greater competition in the public procurement procedure, we suggest that you modify your request so that it reads:

“Power min. 30kW”

Answer 24: Not acceptable. Requested power is clinical request for pediatric and adult patients. Many Producer offering requetsed power, e.g. Agfa, Philips, Samsung, Canon.

25) In your bidding documentation, you have defined the following for lot 4,2 under point 4:

Maximum current value, min 450 mA

In accordance with the previous question, the generators of 30kW generally have a lower range of current (up to 400mA), and taking into account that with the current of 400 mA, the generator power of 30 kW and the voltage of max 133kV all of the radiographic procedures may be covered, we propose that you modify your request in the bidding documentation so that it reads as follows:

"Maximum current value, min 400 mA"

Answer 25: Not acceptable. See answer 24).

26) In your bidding documentation, you have defined the following for lot 4,2 under point 6:

Minimum exposure time 1 ms

Since the difference between the 1 ms and 2 ms time interval is completely negligible, and by increasing this parameter, you would enable participation to more bidders, we kindly ask you to modify your request in the bidding documentation so that it reads as follows:

"Minimum exposure time 2 ms"

Answer 26: Not acceptable. Increasing exposure time (ms) value from 1ms to 2ms means double dose (mAs) for patient for same current values (mA)

27) In your bidding documentation, you have defined the following for lot 4,2 under points 24 and 25:

Big detector weight: max 3 kg

Small detector weight: max 2 kg

There are manufacturers whose detectors are only a few grams heavier than the requested weight. In order to allow them to participate, and without significantly modifying your request, we suggest that you modify these items to:

Big detector weight: max 3 kg ± 10%

Small detector weight: max 2 kg± 10%

Answer 27: Yes, it is acceptable. Difference of detectors weights ± 10% in kg is not substantial neither for clinical use nor for technical manipulation by operator.

28) In your bidding documentation, you have defined the following for lot 4,2 under point 30

Image preview in max 3 seconds after exposure (for both detectors)

Do you think that the difference between 3 and 5 seconds is so important, since after the exposure, the technician will have to review such image for some time measured in minutes? Is it acceptable for the Contracting Authority, in order to allow greater competition, to modify the request so it reads as follows:

"Image preview in max 5 seconds after exposure (for both detectors)"

Answer 28: Yes, it is acceptable. Difference in 2 sec will not damage operators workflow.

29) In your bidding documentation, you have defined the following for lot 4,2 under point 44:

Distance from focal spot to floor in vertical direction, in range of min. 500-2100 mn

Is it acceptable for the Contracting Authority to modify point 44 in order to enable greater competition without loss of functionality of the unit, so that it reads as follows:

Distance from focal spot to floor in vertical direction, in range of min. 685-2020 mn

Answer 29: Yes, it is acceptable, difference between range min. 500 -2100mm and range 685-2020 mm is not substantial for clinical use.

30) In your bidding documentation, you have defined the following for lot 4,2 under point 46:

X-Ray tube rotation around arm min. +/- 150 °

Some manufacturers have the range of the mentioned rotation greater than the requested one, only it is not the same in both directions. Is it acceptable for the Contracting Authority to modify the request without loss on the total range of tube rotation around the arm so that it reads as follows:

X-Ray tube rotation around arm min. 300 °

Answer 30: Not acceptable, due to clinical needs to access patient from both sides.

31) In your bidding documentation, you have defined the following for lot 4,2 under point 47:

X-Ray tube rotation around vertical axis min. 90 °/-20 °

Since this is a mobile, easy-to-move device on which positioning is simple, and in order to allow a greater number of bidders in the public procurement procedure, please modify the request to the following:

X-Ray tube rotation around vertical axis min. 90 °/-10 °

Answer 31: Not acceptable, due to clinical needs to access patient exposures in bed, e.g. head examinations.

32) Under point 14 for lot 4,2 in your bidding documentation, you have defined the following:

Manual and automatic collimation

As each patient positioning can be performed both manually and automatically, while the vertical stand can be positioned more quickly by manual shift, please modify your request to:

"Manual or automatic collimation"

Answer 32: Not acceptable, there is no need for examinations in vertical stand.

33) Under point 29 for lot 4,2 in your bidding documentation, you have defined the following:

Disk storage capacity of min. 10.000 images

Since the device has the ability to export images to external media, there is no need for such a disk capacity, and in order to provide greater competition in the procedure, we suggest that you modify your request in the bidding documentation so that it reads as follows:

"Disk storage capacity of min. 4000 images"

Also, this request is irrelevant given that the children's university clinic has its own archiving system.

Answer 33: Not acceptable. Decreasing this feature will decrease unit autonomy (capacity) to save images (studies) before storing on archiving system.

34) Under point 48 for lot 4,2 in your bidding documentation, you have defined the following:

System weight max 400 kg

We think that weight does not play any role, since the device has the possibility of motorized movement. Regardless of the weight of the device, the user will not feel it because the device is powered by a battery engine. By this request you only limit competition which is maybe able to offer a device that is better in every respect, but it has a greater weight than the requested one. Accordingly, we suggest that you modify the request to:

“System weight max 600 kg”

Answer 34: Not acceptable. Increasing weight of unit will damage operator workflow especially in cases when movement w/o motor support is needed , e.g.. batteries are empty.

35) Under point 49 for lot 4,2 in your bidding documentation, you have defined the following:

System width max 600 mm

The narrowest space through which the device is to pass is certainly the door, and even the room doors are made in standard dimensions of 80cm or 70cm while the door in medical institutions should be even wider. Bearing in mind that greater width of the device does not imply any loss of quality and functionality and at the same time allows more bidders to participate in the procedure, we suggest that you modify your request in the bidding documentation so that it reads as follows:

"System width max 700 mm"

Answer 35: Yes, it is acceptable. On site narrowest space in intensive care and elevators can afford unit width of max. 700mm.

4.3

36) In your bidding documentation, under point 4 for lot 4,3 you have defined the following:

Angulation min. ±220°

Is it acceptable for the Contracting Authority to modify point 4 in order to enable greater competition and without loss of functionality of the unit, so that it reads as follows:

Angulation min. 140°

Answer 36: Not acceptable. More angulation provides more freedom in C arm positioning and many manufacturers can fulfil this request.

37) In your bidding documentation, under point 8 for lot 4,3 you have defined the following:

Free space along vertical axis min. 80cm

Is it acceptable for the Contracting Authority to modify point 8, in order to enable greater competition and without loss of functionality of the unit, so that it reads as follows:

Free space along vertical axis min. 80 ±5%cm

Answer 37: Acceptable. Point 8. for ID 4.3 C-arm will be changed to following: Free space along vertical axis min. 80 ±5%cm

38) In your bidding documentation, under point 14 for lot 4,3 you have defined the following:

Single-tank generator with output power min. 20 kW

Is it acceptable for the Contracting Authority to modify point 14, in order to enable greater competition and without loss of functionality of the unit, so that it reads as follows:

Single-tank generator with output power min. 15 kW

Answer 38: Not acceptable. More power provides better image quality and possibility to do complex cardiovascular procedures, many manufacturers can fulfil this request.

39) In your bidding documentation, under points 24 and 25 for lot 4,3 you have defined the following:

Pulsed fluoroscopy with pulse rate in range min. 0.5 to 15 fps

Is it acceptable for the Contracting Authority to modify points 24 and 25, in order to enable greater competition and without loss of functionality of the unit, so that they read as follows:

Pulsed fluoroscopy with pulse rate in range min. 4-15 fps

Answer 39: Not acceptable. Low frame rates provides low dose during orthopedics, trauma and spine procedures which is very important for children and staff, many manufacturers can fulfil this request.

40) In your bidding documentation, under point 28 for lot 4,3 you have defined the following:

Flat Panel Detector dimension min. 30x30 cm

Is it acceptable for the Contracting Authority to modify point 28, in order to enable greater competition and without loss of functionality of the unit, so that it reads as follows:

Flat Panel Detector dimension min. 30x30cm ± 4cm

Answer 40: Not acceptable. Requested flat panel dimensions of min. 30x30cm fullfil all surgical procedures especially for vascular surgery, many manufacturers can fullfil this request.

4.4

41) In your bidding documentation, under point 7 for lot 4,4 you have defined the following:

kV range for pulsed fluoroscopy: 50-110 kV or more

mA range for pulsed fluoroscopy: 0,5-20 mA or more

Is it acceptable for the Contracting Authority to modify point 7, in order to enable greater competition and without loss of functionality of the unit, so that it reads as follows:

kV range for pulsed fluoroscopy: 50-110 kV or more

mA range for pulsed fluoroscopy: 0,5-10 mA or more

Answer41: Not acceptable. Higher mA values during pulsed fluoroscopy enables use of lower kV values which gives lower overall dose to children. Also higher mA values gives better image quality for obese children. There are manufacturers that can fulfil this request.

42)In your bidding documentation, under point 43 for lot 4,4 you have defined the following:

Digital pulsed fluoroscopy: min. 1024x1024, 12 bits with min. 30 fps with ability of fps selection

Is it acceptable for the Contracting Authority to modify point 28, in order to enable greater competition and without loss of functionality of the unit, so that it reads as follows:

Digital pulsed fluoroscopy: min. 1024x1024, 12 bits with min. 15 fps with ability of fps selection

Answer 42: Acceptable. Point 43. for ID 4.4 will be changed to following: Digital pulsed fluoroscopy: min. 1024x1024, 12 bits with min. 15 fps with ability of fps selection

Public Procurement Committee