Procurement of Medical Devices for University Children Hospital "Tiršova"

IOP/11-2017/RD

Clarification no. 9

Issued on December 6, 2017

LOT 2

ID 2.10.

1. In your bidding documentation, under point 4 for lot 2.10 you have requested the following

- 22"wide screen High-Definition (HD) flicker-free OLED display or LCD-LED display with monitor translation (independent of console):horizontal bidirectional and vertical height adjustment and swivel to any viewing direction

Is there a possibility of offering a premium US unit with a 21.5" panel size (which is by about 1 cm smaller, so that no requested functionality of the device you request would be disabled)? Please allow offering monitors with panel size of 21.5" .

1. **Accepted, point 4 for lot 2.10 is: - panel size minimum 21"**

2. In your bidding documentation, under point 8 for lot 2.10 you have requested the following

-Maximum depth range not less than 45 cm – probe specific

Please allow a tolerance, i.e. allowed deviation of +/- 5 cm referring to this request, because it does not affect any clinical application in the field of pediatrics.

2. **Accepted, point 4 for lot 2.10 is: - -Maximum depth range not less than 45 cm (+/- 5cm) – probe specific**

3. In your bidding documentation, under point 26 for lot 2.10 you have requested the following:

-4D tissue mode; Tissue Harmonic Imaging (Coded harmonic imaging);4D tissue mode

The 4D tissue mode is of eliminatory character, which is owned by only one manufacturer of ultrasound devices. This method is not recognized in the recommendations of AHA/ASE, and therefore not all the manufacturers possess the requested technology. We suggest point 26 be modified so that it reads: 2D tissue mode; Tissue Harmonic Imaging (Coded harmonic imaging) . Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

3. **The request is not acceptable.**
   In the lot 2.10, Tender request is 4D color dopler cardiac ultrasound system, and therefore is demand for 4D Tissue mode

4. In your bidding documentation, under point 27 for lot 2.10 you have requested the following

- M-Mode; Anatomical M-mode; Curved anatomical M-mode; Color M-mode; Tissue M-mode

Curved anatomical M-mode is of eliminatory character, owned by only one manufacturer and not recognized by the recommendations of AHA/ASE. We suggest that this point is modified so that it reads: M-Mode; Anatomical M-mode; Color M-mode; Tissue M-mode. Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

4. **The request is not acceptable. More than one manufactures produce these kind of technology.**
   Curved M-mode is significant parameter as display format in which functional information (such as velocities, strain, strain rate) concerning different segments of the heart (such as the 4-chamber view) are displayed along an M-mode line which follows the myocardial walls. The M-mode line "curves" around the myocardium. Starting at the basal inferior segment it moves to the apex and back to the basal lateral wall.

5. In your bidding documentation, under point 31 for lot 2.10 you have requested the following

- CW Doppler Triplex mode (simultaneous display of 2D, Color Flow and CW Doppler image in real time)

Mentioned triplex mode is owned by only one manufacturer, we suggest a modification, to allow for greater competitiveness in the procurement procedure, so that it reads: Doppler Triplex mode (simultaneous display of 2D, Color Flow and CW Doppler or 2D, Color I PW Doppler image in real time). Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

5. **The request is not acceptable.**

More than one manufactures produce these kind of technology. Real time 2D-CFM-CW Facilitates the operation of operator, especially in the diagnostics of fine flows (MR. AR, Coronary flow), not necessary to update frozen images.

6. In your bidding documentation, under point 38 for lot 2.10 you have requested the following

- Multi-dimensional (bi-plane/tri-plane) color acquisition.

Mentioned acquisition is eliminatory, because it is owned by only one manufacturer. Please change the point to enable participation to other bidders with a premium model so that it reads: Multi-dimensional (bi-plane) color acquisition. Please keep in mind that competition must not be

restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

6. **The request is acceptable. The request under point 38: - Multi-dimensional (bi-plane) color acquisition.**

7. In your bidding documentation, under point 40 for lot 2.10 you have requested the following

- Simultaneous display of minimum 12 slices extracted from the 4D volume data (tissue and/or color) with combination of short-axis and long-axis standard views

Display of min. 12 is an eliminatory request. We suggest that this point is modified so that it reads: Simultaneous display of minimum 9 slices extracted from the 4D volume data (tissue and/or color) with combination of short-axis and long-axis standard views. Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

7. **The request is not acceptable. More slices gives better observance of myocardial kinetics which results in better quantification of myocardial chambers.**

8. In your bidding documentation, under point 43 for lot 2.10 you have requested the following

- Storage and transfer formats: JPEG, MPEG, AVI, DICOM, Raw DICOM and VolDicom

Manufacturers of ultrasound devices have different names and capabilities to export images from the device, and the most important are two of them, and this is DICOM and non-DICOM formats which can be displayed on each computer, so we suggest modifying this point to read: Storage and transfer formats: DICOM and nonDICOM

8. **The request is not acceptable. This is very precise request, the types of storage and transfers which are standard formats.**

9. In your bidding documentation, under point 47 for lot 2.10 you have requested the following

- 2D Sector matrix cardiac probe with Single Crystal technology

* matrix technology provides probe elements in several rows in matrix order

- Frequency range of 1.4 to 4.6 MHz (+/- 0,5 MHz).

- Depth of field: minimum 30 cm

- Sector width: minimum120 °

Due to the greater competitiveness in the public procurement procedure, we consider that the request is eliminatory, which can be fulfilled by only one manufacturer. We suggest that the matrix be excluded from the formulation, which will not affect the quality of the transducer itself, and thus you allow for greater competition. The angle of scanning on the offered transducer is also eliminatory; we suggest that the minimum is 90° to allow for greater competitiveness. We suggest that the point should read:

2D Sector cardiac probe with Single Crystal technology

- Frequency range of 1.4 to 4.6 MHz (+/- 0,5 MHz).

- Depth of field: minimum 30 cm

- Sector width: minimum 90 °

Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

9. **The request is not acceptable. More than one manufactures produce the probes with requested sector width. For the diagnostics benefit, wider angle is better for accurate results.**

10. In your bidding documentation, under point 48 for lot 2.10 you have requested the following

- 2D Sector Phased Array pediatric transducer Frequency range from 2.5 MHz to 8 MHz (+/- 0,5 MHz)

- Sector width: minimum115 °

The angle of scanning on the required transducer is eliminatory, we suggest that the minimum is 90 °, in order to allow greater competitiveness and that the point finally reads

-2D Sector Phased Array pediatric transducer Frequency range from 2.5 MHz to 8 MHz (+/- 0,5 MHz)

-Sector width: minimum 90 °

Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

10. **The request is not acceptable.More than one manufactures produce the probes with requested sector width. For the diagnostics benefit, wider angle is better for accurate results.**

11. In your bidding documentation, under point 49 for lot 2.10 you have requested the following:

- 4D Volume Transesophageal (TEE) matrix array probe transducer for real-time three-dimensional imaging. *matrix technology provides probe elements in severel rows in matrix order, Frequency range from 3 MHz to 8 MHz (+/- 0,5 MHz)

The frequency range of the transducer is eliminatory, we suggest modifying the possibility of deviation to +/- 1MHz and that the point finally reads: 4D Volume Transesophageal (TEE) matrix array probe transducer for real-time three-dimensional imaging. *matrix technology provides probe elements in severel rows in matrix order, Frequency range from 3 MHz to 8 MHz (+/- 1 MHz)

Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

11. The request is not acceptable More than one manufactures produce the probes with requested frequency range. Your demand for modify may lead to the probe with very narrow frequency range which is non acceptable.

2.7

12. In your bidding documentation, under point 2 for lot 2.7 you have requested the following

- less than 55 cm

We think that the point is eliminatory and that it does not allow equal participation in the procurement procedure, because a mobile device with a battery is not requested, and we suggest that it is modified and reads: less than 58 cm. The specified deviation does not in any way affect the functionality of the device.

Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

12. Accepted, point 2 for lot 2.7 is: - less then 58cm

13. In your bidding documentation, under point 3 for lot 2.7 you have requested the following

- less than 75kg

We think that the point is eliminatory and that it does not allow equal participation in the procurement procedure because a mobile device with a battery is not requested, therefore we suggest that it is modified and reads:

- less than 85kg

Also, we kindly ask you to explain the difference between weight of 75kg and 85 kg because it does not in any way affect the functionality of the device.

13. Accepted, point 3 for lot 2.7 is: - less then 85kg

14. In your bidding documentation, under point 23 for lot 2.7 you have requested the following

- M-Mode; AnatomicalM-mode; Curved anatomicalM-mode

Curved anatomical M-mode is an item of eliminatory character, owned by only one manufacturer, which is not recognized in the recommendations of AHA/ASE. We suggest that this point is modified so that it reads: M-Mode; Anatomical M-mode; Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

14. The request is not acceptable. More than one manufactures produce these kind of technology.

Curved M-mode is significant parameter as display format in which functional information (such as velocities, strain, strain rate) concerning different segments of the heart (such as the 4-chamber view) are displayed along an M-mode line which follows the myocardial walls. The M-mode line "curves" around the myocardium. Starting at the basal inferior segment it moves to the apex and back to the basal lateral wall. The functional information is color encoded.

15. In your bidding documentation, under point 26 for lot 2.7 you have requested the following

- CW Doppler Triplex mode (simultaneous display of 2D, Color Flow and CW Doppler image in real time

Mentioned triplex mode is owned by only one manufacturer, we suggest a modification, to allow for greater competitiveness in the procurement procedure, so that it reads: Doppler Triplex mode (simultaneous display of 2D, Color Flow and CW Doppler or 2D, Color I PW Doppler image in real time).Please keep in mind that competition must not be restricted by using exclusive specifications and names of technologies owned by only one manufacturer.

15. The request is not acceptable. More than one manufactures produce these kind of technology. Real time 2D-CFM-CW Facilitates the operation of operator, especially in the diagnostics of fine flows (MR. AR, Coronary flow), not necessary to update frozen images.

16. In your bidding documentation, under point 32 for lot 2.7 you have requested the following

- Storage and transfer formats: JPEG, MPEG, AVI, DICOM, Raw DICOM and VolDicom

Manufacturers of ultrasound devices have different names and capabilities to export images from the device, and the most important are two of them, and this is DICOM and non-DICOM formats

which can be displayed on each computer, so we suggest modifying this point to read: Storage and transfer formats: DICOM and Non DICOM formats

16. **The request is not acceptable. This is very precise request, the types of storage and transfers which are standard formats.**

17. **In your bidding documentation, under point 36 for lot 2.7 you have requested the following:**

- 2D Sector Phased Array pediatric transducer

- Frequency range from 2.5 MHz to 8 MHz (+/- 0,5 MHz)

- Sector width: minimum115 °

Please modify the angle of scanning to allow greater competition in the procurement process of the device so that it reads:

-2D Sector Phased Array pediatric transducer

-Frequency range from 2.5 MHz to 8 MHz (+/- 0,5 MHz)

-Sector width: minimum 90 °

17. **The request is not acceptable. More than one manufactures produce the probes with requested sector width. For the diagnostics benefit, wider angle is better for accurate results.**

18. **In your bidding documentation, under point 37 for lot 2.7 you have requested the following:**

- 2D Sector Phased Array pediatric/neonatal transducer

- Frequency range from 4.0 MHz to 12.0 MHz (+/- 0,5 MHz)

- Sector width: minimum105 °

Please modify the angle of scanning to allow greater competition in the procurement process of the device so that it reads:

- 2D Sector Phased Array pediatric/neonatal transducer

- Frequency range from 4.0 MHz to 12.0 MHz (+/- 0,5 MHz)

- Sector width: minimum 90 °

18. **The request is not acceptable. More than one manufactures produce the probes with requested sector width. For the diagnostics benefit, wider angle is better for accurate results.**

19. In your bidding documentation, under point 38 for lot 2.7 you have requested the following

- 2D Transesophageal (TEE) pediatric transducer

- Frequency range from 3,5 MHz to 10.0 MHz (+/- 0,5 MHz)

Please modify the frequency range of the transducer, as manufacturers of ultrasound devices have different transducers designed for TEE pediatric examinations, so we suggest that the point reads

- 2D Transesophageal (TEE) pediatric transducer

- Frequency range from 3,5 MHz to 10.0 MHz (+/- 3MHz)

19. The request is not acceptable. More than one manufactures produce the probes with requested frequency range. Your demand for modify may lead to the probe with very narrow frequency range which is non acceptable.

2.2

20. In your bidding documentation, in lot 2. CARDIOLOGY, lot 2.2 Monitor for vital functions of patient - 4 pieces

In point 7. the Contracting Authority requested a 'monitor with a cooling system'. All monitors have a cooling system. Cooling through a fan is a common system. Since these are monitors that will be installed in the Intensive Care Unit, do the monitors have to have a passive cooling system without a fan so that the dust and bacteria are not spread through the intensive care unit?

20. Yes. Monitors must have passive cooling system without a fan.

2.8

21. In your bidding documentation, for lot 2,8 - angiography, under point 24. you have defined the following:

-Continuous display of remaining free tube capacity

Bearing in mind that different manufacturers have different solutions issuing alerts about the remaining tube capacity, is it acceptable to offer a solution that meets the same functionality as an indicator that informs that a critical level of tube capacity has been reached, which fulfills the requested functionality?

21. Yes, it is acceptable.

22. In your bidding documentation, for lot 2,8 - angiography, under point 34. you have defined the following:

-System must have effective way to control skin dose. If the accumulated reference air kerma exceeds a configures threshold, a warning sound is given and pop-up displays on the system, so operator must change existing C-arm position

As increasing number of manufacturers use light indicators instead of warning sounds for intervention procedures (which at the same time do not interfere with the execution of emergency procedures), is it acceptable for the Contracting Authority to offer light indicator instead of warning sound?

22. Yes, it is acceptable.

23. In your bidding documentation, for lot 2,8 - angiography, under point 41. you have defined the following:

-Removable grid for preventing scattered radiation

Besides this request, does the system have to possess technology which includes management of the X-ray beam, less radiation-on time and more dose information for the operator. This management provides automatic customization of the X-ray beam spectrum, shape, and pulse frequency. This kind of technology provides grid switching of the X-ray beam in the X-ray tube instead of the traditional generator switching method. In the examination of pediatric patients, this technology has been scientifically documented to significantly reduce radiation dose in regard to traditional continuous fluoroscopy systems. Since all leading manufacturers worldwide possess this technology (Siemens Gigalix tube with grid switch technology, Philips grid switch tube technology, Toshiba Grid Pulsed Fluoro with grid switching technology), and it would be very important to you, we suggest that you include it in the request either, to get the best solution both for your needs, and your budget.

23. There are several dose reduction technologies depending on manufacturer which provides low dose protocols. However, point 26 will be changed to following: X-ray tube with any kind of dose reduction technology (grid switch technology, flat emitter technology or equivalent) and collimator

<u>Lot 2</u>

24.Item 8. Digital angiography

Specification no. 6 Longitudinal and transversal motorized movement of C-arm which enables imaging without moving the patient table

This is not applicable for a standard interventional Cathlab. It is only important in case of surgery, but this is definitely not the case here. This specification is eliminate us from this tender, reducing fair competition. Therefore, we kindly ask you to remove this specification.

24. Not acceptable. This system will be the only one at Children university hospital and will be used not only for cardiac procedures, also for peripheral and vascular procedures. In cardiac procedures will be treated also complex cases like Structural and congenital heart disseases combined with minimal surgery approach (hybrid

procedures) where we need fully freedom of C arm motorized movement in longitudinal and transversal direction. We have small patient – newborn where procedures are done under general anesthesia and during such procedures movement of table cause lot of problems to stuff and safety of procedure, so longitudinal and transversal motorized movement of C-arm which enables imaging without moving the patient table is MUST. Many manufacturers have this function, some of them on floor, some on ceiling mounted system, both options can be offered.

LOT 1

1.22

25. In your bidding documentation, under point 7 for lot 1.22 you have requested the following:

- Easy maneuverable system on wheels. System weight max 75kg

We think that by the description a portable device with a battery is not requested, but a stationary one, so the request is of an eliminatory character and we kindly ask you to modify it and enable the participation to the bidders. We suggest that the request be: Easy maneuverable system on wheels. System weight 75kg (+/- 10 kg)

25. Not acceptable. Light weight system with easy maneuverability is very important because it is very often moved from one to another room. Also, big majority of modern ultrasound systems built in new technology produced by leading producers of ultrasound systems has weight less then requested.

26. In your bidding documentation, under point 18 for lot 1.22 you have requested the following:

-2D convex multifrequency probe with frequency range of min 2-5 MHz, equipped with needle guide set

We think that the frequency range is eliminatory, we suggest that the request be modified to 2D convex multifrequency probe with frequency range of min 2-5 MHz (+/- 1MHz), equipped with needle guide set

26. Not acceptable. Frequency range of the probe is defined in accordance with customer clinical needs. It is defined minimal frequency range and all offered probes which has higher frequency range then requested will be accepted as well.

27.In your bidding documentation, under point 19 for lot 1.22 you have requested the following:

- 2D linear multifrequency probe with frequency range of min 4-12 MHz, equipped with needle guide set. Array length of transducer should be min 5 cm

We think that the frequency range is eliminatory, we suggest that the request be modified to 2D linear multifrequency probe with frequency range of min 4-12 MHz (+/- 1MHz), equipped with needle guide set. Array length of transducer should be min 5 cm

27. Not acceptable. Frequency range of the probe is defined in accordance with customer clinical needs. It is defined minimal frequency range and all offered probes which has higher frequency range then requested will be accepted as well.

28. In your bidding documentation, under point 21 for lot 1.22 you have requested the following:
- Integrated gel warmer on the system
Is it acceptable for the Contracting Authority to deliver an external gel warmer with the device?

28. 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. Customer defined this request in accordance with objective clinical needs.

29.**Technical Specification Requested ID1,12LED operting light with satelite,**

under 14-20,22 HD camera with medical monitor is requested. Due to low space on Customer site and no need for HD camera and monitor, is it acceptable to offer "shadow management" instead positions 14-20,22 ?

29. Yes, it is acceptable and ultimately necessary that operating light with satellite possesses the ''shadow management'' even instead HD camera and monitor in this case.

Procurement Committee