

**Procurement of equipment for General Hospital in Loznica
NO. IOP/61-2021/UHI**

**Clarification No. 5
Issued on 28th of October 2022**

Question 1:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.19 requested: Column rotation range min. $\pm 180^\circ$.

Question 1: Do you accept to offer system with rotation of X-ray tube along the vertical axis in range $-154/+180^\circ$, because such range is enough for providing all necessary examinations? If your answer is - no, with "general" explanation that column rotation range of min. $\pm 180^\circ$, we are kindly asking you to describe which position cannot be reached with such column rotation, or which examination cannot be done with discrepancy of $- 26^\circ$ in rotation range? Accepting such minor deviation will allow more competition and wider spectrum of digital X ray machine to be offered.

Answer: ID 1.19. It is not acceptable to offer system without Column rotation range min. $\pm 180^\circ$. System will be used in challenging environment like it is trauma and emergency and patients who are not conscious and best maneuverability of the system is required. Column rotation of full 360° enables positioning of column rotation to reach any possible projection without the need to move patient itself. Many vendors fulfill required technical feature.

Question 2:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.22 requested: User Interface: Display of SID, Tube Angle, Column Rotation, Patient Name and Date of Birth.

Question 2: Do you accept to offer system with display of SID, Tube Rotation Angle, Patient Name, Patient ID.?

Answer: ID 1.22. It is acceptable to offer: User Interface: Display of SID, tube rotation angle and Patient Name and Patient ID or Date of Birth.

Question 3:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.28 requested: Vertical travel range min. 145 cm.

Question 3: Do you accept to offer system with vertical travel range min. 140 cm. Accepting our suggestion with such minor deviation, you still will be able to manage all requested X-ray procedures but allow other possible bidders to participate on this procurement.

Answer: ID 1.28. It is acceptable to offer: Vertical travel range min. 140 cm.

Question 4:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.31 requested: Compatible with 43x43cm and 43x35cm detectors

Question 4: Could you please confirm whether potential bidder correctly understand your request – Bucky wall stand must be compatible with both detectors, but not at the same time, one or the other- 43 x 43cm, or 35x43cm?

Answer: ID 1.31. Bucky stand must be compatible with both requested detectors, but not at the same time.

Question 5:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.34 requested: Vertical motion control by foot switch.

Question 5: Do you accept possibility to control Bucky Wall Stand via buttons directly on BWS or via Wireless Remote Control? Controlling it via foot switch or wireless remote control provides the same comfort for the operator and system functionality.

Answer: ID 1.34. **It will be amended in the Amendment no. 3.** - Vertical motion control by foot switch or via buttons directly on BWS or via wireless remote control.

Question 6:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.41 requested: Predefined APR.

Question 6: Could you, please explain what does it mean – APR? Do you mean – Organ Program?

Answer: ID 1.41. Yes, APR is synonym for Organ programs.

Question 7:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.50 requested: Collimator blades are set manually and automatic by APR

Question 7: Do you accept that initial collimation is defined in the organ program (as automatic option) and can be adjusted via the collimator knobs manually?

Answer: ID 1.50. We confirm that suggested collimation solution will be evaluated as valid offer.

Question 8:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.54 requested: Detector sizes first: min 35x43 cm, second min. 43x43 cm
Question 8: Please confirm that is acceptable to offer system with detector active area, for the first one 34,8 x 42,4 cm and for the second one 42,3 x 42,5 cm?

Answer: ID 1.54. We confirm that suggested active detector sizes will be evaluated as valid offer.

Question 9:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.58 requested: Pixel size max. 125 µm.
Question 9: Do you accept to offer system with Pixel size 148 µm, but with much higher DQE than requested? This will allow practical the same image quality because detector efficiency is higher. Also, smaller pixel size does not necessarily mean better image quality, because signal noise is higher. Some of the producer compromised pixel size with signal to noise ratio.

Answer: ID 1.58. It is acceptable to offer: Pixel size max. 150µm.

Question 10:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.65 requested: Ingress protection min IPX4.
Question 10: Could you, please explain what you mentioned under IPX4? Did you mean possibility to configure IP address in IPv4 format?

Answer: ID 1.65. Ingress Protection rating (or just IP rating) is an international standard (IEC 60529) used to rate the degree of protection or sealing effectiveness in electrical enclosures against intrusion of objects, water, dust or accidental contact. It corresponds to the European standard EN 60529.

Question 11:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.67 requested: Image storage capacity min. 15.000 images.
Question 11: Do you accept to offer system with image storage capacity of 10.000 images, because in all hospitals is mainly used external storage and archiving for images from different modalities.

Answer: ID 1.67. It is acceptable to offer: Image storage capacity min. 10.000 images.

Question 12:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.68 requested: Image preview times max. 2 sec

Question 12: Do you accept to offer system with image preview time < 3 sec? This minor and unsubstantial discrepancies cannot be visible in daily workflow.

Answer: ID 1.68. It is acceptable to offer: Image preview times max. 3 sec.

Question 13:

Lot 5: Radiology_Imaging, Line item nr. 1 – Ceiling mounted x-ray device

ID 1.71 requested: Monitor size min 24"

Question 13: Please confirm that monitor diagonal size of 23.8" is acceptable.

Answer: ID 1.71. It is acceptable to offer: Monitor size min 23.8".

Question 14:

Lot 5: Radiology_Imaging, Line item nr. 2 – Mobile x-ray device

ID 2.6 requested: Colum rotation min. $\pm 180^\circ$

Question 14: This request is fully restrictive for different technology and solution of products which are mobile and have no movement restrictions in any direction and operability but doesn't have Column. Due to different technology of the products, some mobile x ray device of other producers doesn't need to be able to rotate through 180 degrees like a column does (so they can fold it away when moving the system). Please see attached image for rotating and moving of the system.

So, we are suggesting changing this request in a way: Colum rotation min. $\pm 180^\circ$ or counterbalance arm rotation min $\pm 90^\circ$ depending on producer's technology.

Answer: ID 2.6. It is not acceptable to offer system without Column rotation min. $\pm 180^\circ$. System will be used in challenging crowded environment like it is ICU and OP rooms and best maneuverability of the system is required. Column rotation of full 360° enables only positioning of column rotation of already parked system to reach any possible projection without need from operator to go again in front of the system and move complete system to new position. Many vendors fulfill required technical feature.

Question 15:

Lot 5: Radiology_Imaging, Line item nr. 2 – Mobile x-ray device

ID 2.10 requested: High frequency generator min. 60 kHz

Question 15: Do you accept to offer system with High frequency generator with 50 kHz? High frequency x-ray generators are better as compared to conventional single-phase generators due to efficient generation and control of high voltage power required to drive the x-ray tube.

50kHz is also referred as a High Frequency generator and will provide all requested as generator of 60kHz. Please refer to article <https://www.primedeq.com/blog/difference-between-high-frequency-x-ray-unit-and-conventional-x-ray-machine/>

Answer: ID 2.10. It is acceptable to offer: High frequency generator min. 50 kHz

Question 16:

Lot 5: Radiology_Imaging, Line item nr. 2 – Mobile x-ray device

ID 2.16 requested: Two focal spots: max. 0.7 and min. 1.2 mm
Question 16: Do you accept to offer system with one focal spot of 0.8mm, keeping in mind the usage purpose of the requested Mobile X ray system? The difference between the two focal spots is just a matter of geometry. The longer the filament is, the fuzzier or wider the shadow (also called penumbra) around the x-ray image can be. It works just like light and shadows. A shadow formed from a pinpoint-like light source will be really sharp and crisp, and a shadow formed from a large fluorescent tube will be much fuzzier. Having the small and large focal spots provides versatility to image something as small as a finger and something as large as the side of the lumbar spine. In practice, this means that the smaller focal spot size should be used for more detailed imaging procedures like looking for hairline fractures in the hand or foot, and the larger focal spot size should be used for when you are looking at larger anatomical structures like the curvature of the spine. One focal spot middle size can practically cover all mentioned examination, compromised with penumbra size. The mobile x ray system is used for laying patients for imaging of the lung, abdomen and MSK exams but generally bigger anatomical regions, so one mid-size focal spot is sufficient.

Answer: ID 2.16. It is not acceptable to offer system without two focal spots. Mobile radiography system will be used for chest and abdominal imaging where big focal spot will be used for bariatric patients, but system will be also used for orthopedics trauma patients for imaging of wrist, hand, knee where small focal spot will be used. Also, system will be used as back-up system in case of failure of fixed X-ray system, so two focal spots are required to cover all possible radiography examinations. Many vendors fulfill required technical feature.

Question 17:

Lot 5: Radiology_Imaging, Line item nr. 2 – Mobile x-ray device

ID 2.23 requested: Detector size min 35 x 43 cm.

Question 17: Please confirm that active size of the detector 34,8 x 42,4cm is acceptable.

Answer: ID 2.23. We confirm that suggested active detector size will be evaluated as valid offer.

Question 18:

Lot 5: Radiology_Imaging, Line item nr. 2 – Mobile x-ray device

ID 2.25 requested: Removable snap-on anti scatter grid 6:1.

Question 18: Please confirm that Grid ratio 5:1 with 85 lines/cm is acceptable.

Answer: ID 2.25. Request has been already changed to: Removable snap-on anti scatter grid or virtual grid.

Question 19:

Lot 5: Radiology_Imaging, Line item nr.3 - Digital mammography system

ID 3.4 requested: kV range min. 25-45 kV, with 1 kV steps

Question 19: Kv range from 25-35kV is used for standard 2D and 3D imaging. Higher kV ranges from 45kV and above are used for CEM imaging. Producers have different technology and dedicate selectable ranges for different procedures. Please confirm that minimal requested kV is max 25kV and maximal requested kV is min. 45kV?

Answer: ID 3.4. We confirm that system with minimal requested kV is max. 25kV and maximal requested kV is min. 45kV will be evaluated as valid offer.

Question 20:

Lot 5: Radiology_Imaging, Line item nr.3 - Digital mammography system

ID 3.8 requested: Anode heat capacity min. 300 kHU

Question 20: Do you accept to offer mammography system with anode heat capacity of 162 kHU? If you refer to research article from National Library of Medicine, National Center for Biotechnology Information, link: <https://pubmed.ncbi.nlm.nih.gov/3306772/> Mammography equipment: principles, features, selection, you may find: “A mammographic unit with an anode heat capacity of 90,000 heat units or more should be adequate for most practices. A mammography unit with a heat capacity of 20,000 heat units or less may require waiting time between exposures or studies in a high-volume mammography practice.” If 90 kHU is (according to research) adequate for most practice, then 162 kHU will be more than adequate for all requested procedures and examinations.

Answer: ID 3.8. It is not acceptable to offer system with Anode heat capacity of 162kHU. Potential bidder is referring to the abstract made 1987. Which is totally absolute technology. At that time, screening mammography was not established on today level of massive screening and 3D technology (Tomosynthesis) was not developed. It is known fact that higher anode heat capacity means higher number of patients in short time, without the need to wait for cooling down the system. As proposed value is almost 50% less than required one, it means less comfort and security for the operator to image more patients overall. Many vendors fulfill required technical feature.

Question 21:

Lot 5: Radiology_Imaging, Line item nr.3 - Digital mammography system

ID 3.11 requested: Automatic exposure mode KV, mAs, filter
Question 21: Is it acceptable for end user to offer high end technology where beam parameters are set via the program (Brand name of program will not be mentioned here)? In this program end user can preset exposure factors (kV, target/filter, dose level). Such program is activated by the compression and is very accurate and automatic. By the exposure the AEC cuts the radiation when the entrance dose for a desired pixel value is reached.

Answer: ID 3.11. We confirm that suggested AEC solution will be evaluated as valid offer.

Question 22:

Lot 5: Radiology_Imaging, Line item nr.3 - Digital mammography system

ID 3.42 requested: Scan time max 10 sec
Question 22: Requested scan time of max 10 sec is related with scan tomo angle of 25°. Some of producers have wider scan tomo angle e.g. 50° which is clinically proven higher sensitivity method, specially for smaller lesions and early phase diagnosis. Such wider scan angle logically requires longer scan time. Is it acceptable to offer system with scan time max 10 sec for tomo angle 25° or scan time max 25 sec for tomo angle 50°?

Answer: ID 3.42. It is not acceptable to offer system with Scan time max. 25 sec. During 3D tomosynthesis scan patient breast is compressed all the time and it is inconvenient experience for the patients. From the other side, such long scan time leads to possible movement of the tissue and blurry images. Many vendors fulfill required technical feature.

Question 23:

Lot 5: Radiology_Imaging, Line item nr.3 - Digital mammography system

ID 3.49 requested: Dedicated tools to review tomosynthesis data sets: cine-loop, bookmarks, breast localizer, breast height ruler
Question 23: Could you please explain what do you mean by breast localizer” and bookmarks?

Answer: ID 3.49. The breast localizer tool provides a schematic drawing of the breast image as seen from the front. It provides an indication of the acquisition angle, which helps the user navigate through 3D (tomosynthesis) volume breast images. Bookmarks in 3D (tomosynthesis) allows the user to mark images while going through the slices, even when no annotation is created.

Question 24:

Lot 5: Radiology_Imaging, Line item nr.3 - Digital mammography system

ID 3.60 requested: Displays plane of point selected in corresponding image view.
Question 24: Could you please explain what do you mean by this requirement? Do you mean display of CT/MR images for comparison?

Answer: ID 3.60. It enables operator to select a point in a CC or MLO image and software automatically displays the corresponding region in the MLO or CC view defined by two vertical bars or similar.

Question 25:

Lot 5: Radiology_Imaging, Line item nr.4 - Mobile digital X-ray with C-arm

ID 4.17 requested: Generator power min 2.4 kW

Question 25: Do you accept generator with power of 2.3kW as minor deviation of 0.1 kW does not represents substantial deviation for all requested procedures?

Answer: ID 4.17. It is acceptable to offer: Generator power min. 2.3kW.

Question 26:

Lot 5: Radiology_Imaging, Line item nr.4 - Mobile digital X-ray with C-arm

ID 4.23 requested: Anode heat capacity min. 70 kHU.

Question 26: Do you accept anode heat capacity of 61,1 kHU as minor deviation of less than 9 kHU does not represents substantial deviation for all requested procedures?

Answer: ID 4.23. It is acceptable to offer: Anode heat capacity min. 61kHU.

Question 27:

Lot 5: Radiology_Imaging, Line item nr.4 - Mobile digital X-ray with C-arm

ID 4.33 requested: Pixel size max. 140 microns

Question 27: Do you accept to offer system with Pixel size 152 μm , but with much higher DQE than requested? This will allow practical the same image quality because detector efficiency is higher. Also, potential bidder compromised pixel size with signal to noise ratio. Smaller pixel size can also lead to leakage of the input signal and vice versa.

Answer: ID 4.33. It is acceptable to offer: Pixel size max. 152 microns.

Question 28:

Lot 5: Radiology_Imaging, Line item nr.4 - Mobile digital X-ray with C-arm

ID 4.35-4.36 requested: Monitor(s) integrated on C-arm: High resolution LCD touch screen monitor size min. 27" with dual screen view or two LCD touch screen monitors min. 19" inch each.

Question 28: Request for touch screen monitor(s) integrated in C arm has not any objective neither clinical base, but just intention for tender to exclude almost all vendors except one. Having such touch screen monitors or one touch screen monitor integrated in C arm, is not really recommended by the customer as practical value especially keeping in mind sterile condition in Op room. Further, but even more important, image on touch screen will not have the quality and resolution as image on "normal" monitor.

Therefore, we are kindly asking you to change request as following: Monitor(s) integrated on C-arm: High resolution LCD monitor size min. 27" with dual screen view or two LCD monitors min. 19" inch each

Accepting all suggestion of potential bidder will unlock this procurement, provide competitiveness. Purchaser will have more opportunity, more potential bidders, and products with different price range.

Answer: ID 4.36. It is not acceptable to offer monitor(s) which is/are not touch screen, because required solution is to have mobile C-arm system with integrated monitor(s) and therefore there is no need to have additional keyboard or appropriate commands for data entry or image processing.

Public Procurement Committee

