**PROCUREMENT OF RADIOTHERAPY AND DIAGNOSTIC EQUIPMENT, BELGRADE**

**(PROCUREMENT NO. IOP/36-2019/RD)**

**CLARIFICATION NO. 2**

Issued on April 13, 2020

Regarding the list of questions that the Purchaser, Public Investment Management Office Belgrade, No. 11 Nemanjina street, have received from the potential bidders, concerning the procurement procedure: Procurement of Radiotherapy and Diagnostic equipment, Belgrade no. IOP/36-2019/RD, we give you the following answers:

**1. Item 2, CT scanner - Item 2- Multislices CT scanner for diagnostics and RT procedures with CT Simulation Laser System,** under the Point 6.2. the following is mentioned: Spatial resolution in all three directions x/y/z for 2% MTF min. 14,5 lp/cm.

Question: Please confirm that you mentioned: Spatial, High -Contrast resolution in all three directions x/y/z for 2% MTF min. 14,5 lp/cm.?

**Answer:** Yes. We confirm.

2. **Item 4 - Item 4 - 3D Digital Mammography System with Thomosynthesis, Mammography Contrast Software (CE2D), with addition for stereotactic and tomosynthesis-guided breast biopsy**

Point 1.1 requested: High frequency generator of a constant potential of minimum power of 7kW.

Question: Is it acceptable to offer high frequency generator of a constant potential of minimum power of 5kW, keeping in mind that power of generator is not important in digital mammography where low dose procedures are performed with no matter regarding obesity of patient like in radiography?

**Answer:** This is not acceptable

It is true that mammography is low dose procedure but only in comparison to common X-ray procedures for lungs or abdomen. Mammography is an X-ray imaging diagnostic procedure that will achieve better diagnostics result with higher energy of X-ray beam like any other X-ray procedure. The limitation here is not the procedure itself (mammography), but the maximum allowed dose that patient may receive. As most of modern 3D digital mammography units are giving patient doses well below the allowed limits, the unit running with higher energy will certainly achieve better diagnostic results.

In clinical practice, there is a undoubtful need for higher energy to penetrate bigger breasts, for example - to improve the visualization of the margins of subcentimeter mass lesions. Also, for contrast imaging, having in mind the fact that it is performed with low and high energy of X-rays, being subtracted in order to provide functional imaging, there is a need for usage of higher kV than for common 2D mammography.

Also, having extra power capability, the system works relaxely in the necessary range being optimally loaded, and not under pressure in peaks, especially if there is higher throughput of patients which is expected by experience in the diagnostic department of IORS.

Consecutively, many manufacturers raised the nominal power of the generators for their new mammo units for the new ways of application.

3. Point 2.2 requested: Anode heat storage capacity: min. 300.000 HU.

Question: Is it acceptable to offer Anode heat storage capacity: min. 162.000 HU keeping in mind that each manufacturer uses different technologies in combination with tube cooling in order to make stable system for massive mammo screening? There is no evidence in practice that any of Siemens premium digital mammography systems was overheated, even with proved system effectiveness with more than 15 patients per hour in screening.

**Answer:** This is not acceptable.

IORS is not doing mammography screening procedures, but diagnostic, and the reliability and speed are necessary for the workload of high patient throughput common for IORS, not for a screening. It is assumed we are evaluating the 3D mammography with 2D synthetic mammogram.

Hence, the higher the heat capacity of the tube – the heavier workload might be applied, and, at least, the tube will work under less stress and live longer expectedly.

4. Point 2.4 requested: Filter: Rhodium (Rh) and Aluminum (Al).

Question: Is it acceptable to offer Filter: Rhodium (Rh) and (Aluminum (Al) or Titanium (Ti) keeping in mind that each manufacturer use different technologies in combination with different filter materials in order to make mest image quality with lowest possible dose, especially for contrast enhanced mammography where Ti filter is one of best filter materials.

**Answer:** This is acceptable.

It is common sense looking to this parameter particularly that more is better. The more different filters one device has, the more adaptable it is going to be to a different clinical situations/specific cases. So, it is acceptable to offer Rhodium (Rh) and Aluminum (Al) or Titanium (Ti).

5. Point 2.5 requested: Anode rotation speed min. 9500 r.p.m.

Question: Is it acceptable to offer Anode rotation speed min. 9300 r.p.m. keeping in mind that this is nonessential deviation?

**Answer:** This is acceptable

6. Point 3.16 requested: Compression paddle for small breast has automatic motorized shift in the X axis for correct collimation in MLO projections

Question: Is it acceptable to offer Compression paddle for small breast has automatic motorized or manual shift in the X axis for correct collimation in MLO projections keeping in mind that technican is standing beside patient and it is not important if shifting of paddle is manual or motorized, because it is easy to operate on both ways.

**Answer:**This is not acceptable

The motorized function of the shifting paddle is introduced on the modern digital mammography systems for improved system speed, elimination of possible operator’s errors and ease of use for the operators. The microprocessor of the mammo system triggers the automatic setup of the whole system according to particular projection and used compression paddle. If the operator choose LMLO projection on the acquisition station and the “small” paddle is installed, the system automatically shifts the paddle to the left side, and vice versa (RMLO-right side), in order to achieve the appropriate position. One unnecessary positioning step is eliminated.

7. Point 4.2 requested: The pixel size max. 70µm.

Question: Is it acceptable to offer The pixel size max. 85 µm keeping in mind that this is more than enough to get excellent image details, less microns bring more noise to the image and required more dose, so optimal balance of image quality/dose is reached with this pixel size.

**Answer:** This is not acceptable

As there are four types (manufacturers) of Full Field Digital Detectors available today according to applied pixel size, 50 µm, 70 µm, 83 µm and 100 µm, we simply decided for the better half of the range. The complexity of each of them is undoubtful, but technology has its advantages and disadvantages, and we decided to keep it simple.

It is an accepted fact that the smaller the pixel size, the images have higher resolution. Higher resolution gives better visualization of fine detail, as is required for detecting microcalcifications and spiculations.

The microcalcifications are approximatelly 140-150 µm in size, and in order to show one undoubtfully on the diagnostic screen in 1 pixel on detector = 1 pixel on the screen resolution, you need at least two pixels. That was the rule we have applied on this characteristic.

8. Point 5.9 requested: Speed of Tomosynthesis scan less than 5 seconds

Question: Is it acceptable to offer Speed of Tomosynthesis scan less than 25 seconds keeping in mind that our unique wide angle tomosynthesis provides best resolution on the market which required much more time, but reason for tomosynthesis in 95% of examinations is diagnostic purpose, not screening, so resolution and more details are of most importance.

**Answer:** This is not acceptable

As tomosynthesis is introduced into clinical usage more than ten years ago, in the meantime a speed of acquisition is recognised as one of the most important factors in breast 3D imaging. The speed of tomosynthesis scan appeared to be The Most Important factor.

Scan times must be short for two key reasons: to support a reasonable patient throughput and more importantly, to reduce blurring caused by patient motion. Currently, no tomosynthesis system is capable of matching the very short total exposure times associated with conventional mammography. Even mammography has occasional cases of patient motion; therefore, it is expected that patient motion will be present in some tomosynthesis cases. Analogously to conventional mammography, this problem is expected to be greater the longer the total tomosynthesis scan time.

The faster the scan, the chances for patient movement artifact to appear are less. Even point one millimeter (0.1mm) of patient movement during tomosynthesis scan would make image of fine microcalcifications or spiculations blurred. That might cause the need for repeating the scan.

9. For item 4, Point 8.3 requested: Two diagnostic medical TFT monitors, min. 21 inch, resolution min. 5MP with technology which enable to render 15 mega sub-pixel image, max. luminance min. 1000 cd/m² dicom calibrated, contarst ration min. 1:1400 or one dual screen 12MP diagnostic monitor, max. luminance 2100, min. 1000 cd/m² dicom calibrated.

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**Answer:** This is not acceptable

Taking into consideration that procurement is for premium mammography unit, diagnostic monitor has also essential importance for image quality. End customer wants to buy best available, latest technology solution.

**Item 5 - 3D Digital Mammography System with Thomosynthesis and addition for stereotactic and tomosynthesis-guided breast biopsy**

1. Point 1.1 requested: High frequency generator of a constant potential of minimum power of 7kW.

Question: Is it acceptable to offer high frequency generator of a constant potential of minimum power of 5kW, keeping in mind that power of generator is not important in digital mammography where low dose procedures are performed with no matter regarding obesity of patient like in radiography?

**Answer:** This is not acceptable

High power generator allows setup of various system conditions and use of advanced applications. See answer for Item 4 - 3D Digital Mammography System with Thomosynthesis, Mammography Contrast Software (CE2D), with addition for stereotactic and tomosynthesis-guided breast biopsy for Point 1.1

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**Answer:** This is not acceptable

Higher anode heat storage capacities means larger number of exams, and longer life of X-ray tube. See answer for Item 4 - 3D Digital Mammography System with Thomosynthesis, Mammography Contrast Software (CE2D), with addition for stereotactic and tomosynthesis-guided breast biopsy for Point 2.2

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**Answer:** This is not acceptable

It is not acceptable. Latest technology allows choosing pixel size depending of procedure and necessary level of details, by so optimizing dose. Maximum pixel size is set on optimal level.

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