**Procurement of Medical Imaging Equipment**

**no. IOP/5-2017/RD**

**Clarification no. 10**

**Issued on 17.10.2017.**

Question No. 1

In the technical specification for Premium Cardiovascular ultrasound system for Clinical Hospital Center „Zemun" the bidders are required to offer under **2.11** - 2D analysis functionality requested in point 2.10. is suitable for other ventricle and atriums.

The majority of ultrasound manufactures have developed functionality of this technique in atriums offline, through an external workstation for analyzing echocardiography data.

We kindly request to expand the specification, allowing for broader participation to the tender, and more favorable bids to the end user. Please accept following modification:

**Specification 2.11** – 2D analysis functionality requested in point 2.10. is suitable for other ventricle and atriums, on board technique or offline through an external workstation.

**Answer 1: We accept, specification 2.11 is amended: "2D analysis functionality requested in point 2.10. is suitable for other ventricle and atriums, on board technique or offline through external workstation (in this case external workstation must be offered with system)"**

Question No. 2

In the technical specification for Premium Cardiovascular ultrasound system for Clinical Hospital Center „Zemun" the bidders are required to offer under **2.15** - Ultrasound system can be upgraded with fusion imaging which enables display of the same anatomical section on ultrasound live image as well as on last exam image performed on CT or MR systems. Image Fusion functionality should be available on 2D transthoracic matrix cardiac probe.

The fusion functionality of cardiac ultrasound imaging with images from CT or MR systems is a new application that has not been fully integrated yet in the high-end echocardiography by the majority of ultrasound manufactures. In addition other manufactures have developed fusion of the ultrasound cardiac image with an x-ray image e.g. from angiography and in particular with Transesophageal probe, for increased accuracy and efficiency in cath labs during structural heart procedures e.g. Mitral Valve Replacement (Mitral clip) and Transcatheter Aortic Valve Implantation (TAVI). Moreover the specification does not specify the exact application of the technique (clinical value). Given that the technique is requested only as a future upgrade possibility and it`s not a current crucial operating

functionality of the system, we kindly suggest that every company should be allowed to offer the fusion technology available from each manufacturer.

We kindly request either to remove this specification or accept the following modification allowing for broader participation to the tender, and more favorable bids to the end user:

**Specification 2.15** - Ultrasound system can be upgraded with fusion imaging which enables display of the ultrasound cardiac live image as well as on last exam image.

**Answer 2: We accept, specification 2.15 amended: "Ultrasound system can be upgraded with fusion imaging for cardiology: US with cardiac CT using transthoracic probe, or US with cardiac MR using transthoracic probe, or US with Angio X-ray using transesophageal probe."**

**Question 3:**

1. Molim vas za sledeća pojašnjenja: Za IOP/5-2017/RD **Nabavka medicinske dijagnostičke opreme (Procurement of Medical Imaging Equipment)**, partija br. 2 - **Digitalni angiografski sistem za kardiovaskularnu dijagnostiku i interventne procedure (**Digital angiography system for cardio-vascular diagnostic and interventional procedures) za IKVB "Dedinje"
   Kao dokaz za postkvalifikovanje za Tehnički kapacitet zahtevate:
   1. Proizvođači su dužni da obezbede postprodajni servis od strane kompanije koja je registrovana Na teritoriji Republike Srbije.
   2. Minimalni broj kvalifikovanih osoba zaposlenih od strane serivisera, sertifikovanh za servisiranje od strane proizvođača – 1 (jedan)
      Potrebno je da serviser poseduje sertifikat ISO 9001

Proizvođač dobra koje nudimo u partiji br. 2 ima nešto drugačiji organizovan servis.
Zbog specifičnosti opreme proizvođač poseduje Servisni centar u Briselu u kojem je zaposleno 5 eksperata servisera koji su obučeni za podešavanje, instalaciju i servisiranje dobra koje nudimo na predmetnom tender.

Ponuđač bi po prijavi kvara od strane korisnika kontaktirao Servisni centar i Sertifikavani serviser bi došao u najkraćem vremenu do mesta gde se dobro nalazi i dijagnostikovao kvar.
Rok za popravku ili zamenu dobra je maksimalno 15 dana.

Naše pitanje je, da li bi kao dokaz o ispunjavanju Tehničkog kapaciteta prihvatili Izjavu proizvođača o navedenim činjenicama?

Takođe, obzirom da fizičko lice ne može da poseduje ISO 9001, molim vas za pojašnjenje da li pod tim uslovom podrazumevate dostavljanje ISO 9001 proizvođača ?

Please for following clarification: IOP/5-2017/RD, **Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"**

As evidence for postqualification for Technical capacity you required:
1. Manufacturers - shall provide after sales service for equipment by the service company registered in the Republic of Serbia.

2. Service company shall employ minimum number of qualified persons – certified by the manufacturer of equipment for servicing - 1 (one).

Service company shall have a professional certificate ISO 9001

Manufactures of goods which we could offer in lot 2 has a different organized service.

Due to the specifics of the equipment, the manufacturer service center is in Brussels, with 5 five certified employees qualified for setup, installation, and service of goods we offer on this tender.

Bidder should, after the beneficiary's notification of failure, contact the Service center and in shortest period of time came and troubleshoot the problem. Maximum period for repair and replacement from the moment of declaring would be 15 days.
Is it acceptable for the Purchaser Manufacturer's statement about the mentioned facts?

Also, the person could not be certified witrh ISO9001, we ask you if you mean under this requirement submitting ISO 9001 for manufacturers?

**Answer 3: It is not acceptable. Our requirement is service company registered in the Republic of Serbia.**

**ISO 9001 is required for service company, not for staff.**

**Question 4:**

LOT 1

2.3.: Our solution has the rails needed to attach Control modules and TSM on the side of the table. These are needed to control the system and are at a good location to avoid staff to go back and forth, so also to improve workflow in the room as that equipment is needed to operate the system.

Clinically longer metal free area (in our case rails free area) has no relevance, as it is used for peripheral procedures. This procedures are done in 2 ways as AP view or 30° Left/Right. In both ways the rails are not visible on the image and don`t have any effect on IQ. Rails in our solution are not placed on the surface or above surface of table, nor in the table itsself, but positioned around the table. Length of the table without rails on sides is 125 cm. "

Is it possible to offer the table which has "metal free" length 125 cm without rails on side, not 200 cm and it fits to all other requirements set for table.

**Answer 4: Not acceptable. The purpose of willed angio-theatre is to provide conditions for complex procedures that includes approach site on upper extremities and target region on lower extremities.**

**Question 5:**

LOT 1

In your tender documentation you request for LOT 1 - Multislice CT Scanner for cardiovascular procedures for Institute for cardiovascular diseases "Dedinje" following:

"Reconstruction speed 40 images/ second, or more, and 20 images/ second, or more, in reduction dose options"

Is it possible to offer reconstruction speed without dose reduction - 33 images/second ( 20 % less) and

reconstruction speed with dose reduction - 24 images/second (20 % more)

**Answer 5: It will be accepted.**

**Question 6:** 2.7.: In tender requirements under point 2.7. it is written: " Management of functions from diagnostic workstation". Did you meant by this that diagnostic workstation functions can be managed by the table side, because management of functions under 2.7. can`t be performed from diagnostic workstation. Please change your request in Management of functions from table side control". Otherwise there is no manufacturer who can fulfill your request.

**Answer 6: . Last item regards on ability to create own protocol on table side panel**

**Question 7:**
5.3.: Detective quantum efficiency (DQE) is one of the fundamental physical variables related to image quality in radiography and refers to the efficiency of a detector in converting incident x-ray energy into an image signal.

High DQE values indicate that less radiation is needed to achieve identical image quality; increasing the DQE and leaving radiation exposure constant will improve image quality. The ideal detector would have a DQE of 1 (DQE 100% at all spatial frequencies), meaning that all the radiation energy is absorbed and converted into image information.Specification written in the tender requirements is DQE 70% or less, which is contradictory to the specification. We believe that it was the writing mistake and that DQE should be 70 % or more. Please change your request to:"DQE should be 70% or more."

**Answer 7: It will be accepted.**

**Question 8:**

**Partija 1, pozicija 9, tačka 9.1:**

- Naručilac je naveo sledeće: ***" opportunity for mixture of contrast and "***

**Pitanje**: S obzirom na to da je očigledno došlo do štamparske greške, da li Naručilac pod ponuđenom tehničkom karakteristikom podrazumeva "opportunity for mixture of contrast and saline" što predstvalja standardnu karakteristiku CT injektora?

Lot 1, point 9.1, The purchaser stated: "opportunity for mixture of contrast and"

It is obvious that it is a typo error, does Purchaser under this technical characteristic means "opportunity for mixture of contrast and and saline" which is standard charactesristic of CT injector.

**Answer 8 : Yes, point 9.1 reads as follows:**

**Double Syringe Contrast Injector:**

- **opportunity for mixture of contrast and saline**
- **workstation**
- **two pistons**

**RIS/ PACS compatible.**

**Question9:**

*Respectable Commision, we kindly ask you for the following clarification: For IOP/5-2017/RD Procurement of Medical Imaging Equipment, lot no 1 item no. 2 – Digital angiography system for cardio-vascular diagnostic and inteventional procedures at Institute for cardiovascular diseases »Dedinje«*

*Folllowing the Adendum No. 2 to the tender documents for procurement of medical imaging equipment, IOP/5-2017/RD, issued on 06.10.2017, the ne line 8.6. reads as follows:*
*8.6. Integrated FFR plus OCT or FFR plus IVUS. Integrated in angio patient table in angio-suite. Real time coregistration with angiography image.*
*Our questions are:*

a. *Is iFR considered following your answer in Clarification 5 issued on 9.10.2017?*
b. *Shall we interpretate FFR as funtional measurements in general, because coregistration is possible only with hyperemia free measurements?*
c. *Is the coregistration intended between »angiography and functional measurements« and »angiography and intravascular imaging«?*

**Answer9:**

**a. Yes, iFR is also requirement, see Addendum 4.**

**b. Requirement for coregistration will be deleted, see Addendum 4**

**c. Requirement for coregistration will be deleted, see Addendum 4**

**Question 10:**

**U skladu sa tačkom 7.1 konkursne dokumentacije ya nabavku medicinske dijagnostičke oprem, IOP-5'2017-RD, molimo Vas za pojašnjenje konkursne dokumentacije.**

**Naime, po pitanju tačke 8.6 tehničke specifikacije, da li je prihvatljivo da se zahtev ya koregistraciju odnosi samo na OCT, a ne i na IVUS, kako je bilo predviđeno prvobitnom konkurnsom dokumentacijom?**

**Smatramo da bi pozitivan odgvor omogućio većem broju potencijalnih ponuđača da učestvuje u nabavci.**

In accordance with Tender documentation for procurement of medical devices IOP/5-2017/RD, point 7.1, we ask you for clarification.

Naimely, considering the point 8.6 of technical specification, is it acceptable requirement for coregistration just for OCT, not for IVUS, as per originally tender documents?

We think that positive answer would enable greater number of bidders to participate in procurement.

**Answer 10: The requirement for coregistration will be deleted from technical specification, see Addendum 4.**

**Public Procurement Commission**