**DIAGNOSTIC AND INTERVENTION IMAGING EQUIPMENT FOR CLINICAL CENTER ZEMUN**

**(PROCUREMENT NO. IOP/37-2019/UHI)**

**CLARIFICATION NO. 3**

Issued on February 28, 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 Diagnostic and Intervention Imaging Equipment for Clinical Center Zemun no. IOP/37-2019/UHI, we give you the following answers:

**Question 1:**

5 All movements of the system, including C-arm, patient table and system for image acquisition, have control at the patient table side. Joysticks at command panel are above panel plane

Please accept the amendment of this technical requirement as follows “All movements of the system, including C-arm, patient table and system for image acquisition, have control at the patient table side. Joysticks or equivalent solution at command panel”

Please note that this requirement completely restricts the access at the procedure for all Philips Medical Systems angiography systems, as one of the most established manufacturers of devices of this kind cannot meet this requirement with any of the systems in its portfolio.

The system we would like to offer introduces a new concept for workflow. It integrates advanced viewing solutions, new and optimized control modules for ease-of-use as a smartphone, parallel working technologies in the control room, as well as single-motion selectable digital cards, which contain predefined settings of the procedure. All of this was designed to help communication within the team of doctors, and to increase the efficiency of procedures and reduce complications. For objective testing of the platform, a study with 61 clinical users from Europe and the United States of America was conducted in 2015-2016 before its launch. The study was conducted in a simulated laboratory environment and was designed and supervised by Use-Lab GmbH, an independent and objective consulting company in engineering and assessment of user interface design and usage. Use-Lab analyzed the results of the study and documented the following conclusions on the new workflow approach implemented by Philips in this system’s platform:

•100% of users consider that the ability to access and control multiple applications from the patient’s table will remove the paths between the exam room and the control room, ensuring greater workplace sterility and faster procedures

•91% of users consider using digital cards with predefined settings to help standardize workflow

•87% of users believe that the ability to access and control multiple applications from the table side will reduce team communication failures during the procedure

•91% of users believe that the system will reduce the duration of the intervention procedures

•93% of users consider that the system can help them make better use of their time in the examination room.

Consequently, due to the fact that we do consider the workflow as being very important, and our workflow being one of the best in the industry, even without the joystick and in order to allow more operators to access this procurement procedure,please accept the amendment of this technical requirement as follows “All movements of the system, including C-arm, patient table and system for image acquisition, have control at the patient table side. Joysticks or equivalent solution at command panel”"

**Answer 1:**

It is acceptable to offer the system with following specification : All movements of the system, including bi-plane C-arm, patient table and system for image acquisition, have control at the patient table side. **Joysticks or equivalent solution** at command panel.

**Question 2:**

Automatic stand positioning depending on the reference image selected

Please accept the amendment of this technical requirement by accepting an equivalent solution, as follows “Automatic C-arm/stand positioning depending on the reference image selected”,while maintaining the required performance level and the desired outcome.

**Answer 2:**

It is acceptable to offer Automatic C-arm/stand positioning depending on the reference image selected.

**Question 3:**

Software collision protection to prevent collision between C-arm and patient

Please confirm, for good practice, common reference and similar understanding for all manufacturers, in order to avoid confusion, that by “software collision protection” you expect collision protection governed by physical sensors, whose response is indeed integrated into a software which provides the user warnings and protection.

**Answer 3:**

We confirm.

**Question 4:**

 Control panel, at the patient table side comprises:

a) Motorized vertical table movement

b) Blockage and release of the tabletop

c) Motorized movement of the C-arm for reaching of the desired position.

Please accept the amendment of this technical requirementas follows:

“Control panel OR Touch screen control panel, at the patient table side comprises:

a) Motorized vertical table movement

b) Blockage and release of the tabletop

c) Motorized movement of the C-arm for reaching of the desired position”,

while maintaining the required performance level and the desired outcome.

We would like to mention that, indeed, the table panning handle is on the control panel; The pan handle controls the table (blocking/unblocking for floating). With regard to the possibility to completely block the table’s movements, or block just its transversal or longitudinal, the system we would like to offer can do this from the touch screen module.

Each manufacturer has its own way of configuring and optimizing the system, and according to studies conducted by Philips Medical Systems, for an optimal workflow, patient table breaks have been positioned at table-side, as the contracting authority requests, only controlled from the touch screen module, not from the control panel.

Consequently, in order to allow more operators to access this procurement procedure,please also accept a solution in which patient table breaks are controlled from the table-side, from the touch screen module, respectively the amendment of this technical requirement as follows

“Control panel OR Touch screen control panel, at the patient table side comprises:

a) Motorized vertical table movement

b) Blockage and release of the tabletop

c) Motorized movement of the C-arm for reaching of the desired position”,"

**Answer 4:**

It is acceptable to offer touch screen control panel as control panel.

**Question 5:**

Generators enables continuous display of actual anode heat (HU status), with display of free capacity left to reach maximum anode heat content

Please accept the amendment of the this technical requirement in „Generators enables continuous display of actual anode heat (HU status), with display of free capacity left to reach maximum anode heat content OR an equivalent solution, only when there is a warning involved”, without altering the required performance level.

Please accept as equivalent the possibility to display the generator load, only not continuously, but only when there is a warning involved. For example, depending on the level of generator load, the operator will be instructed on whether only fluoroscopy will be possibile, or neither exposure/fluoroscopy will be possible.

We believe this solution is more effective, taking into consideration the fact that the operators should not be overloaded with unnecessary information on the screen, leaving space for more important parameters, such as dose display.

Moreover, Philips Medical systems has always been known for building reliable systems and x-ray tubes alike. The system we would like to offer has the biggest heat storing capacity in the industry, as well as the fastest cooling rate. Such a situation in which the user should be aware of the remaining free tube capacity and modulate and adjust the remaining of the procedure according to it, is a burden and a huge inconvenience which the Philips engineers didn’t even project.

Hence, each manufacturer has its own way of configuring and optimizing the system, therefore please kindly accept other solutions for this technical request, such as:

“Generators enables continuous display of actual anode heat (HU status), with display of free capacity left to reach maximum anode heat content OR an equivalent solution, only when there is a warning involved”

**Answer 5:**

It is acceptable to offer Generators enables continuous display of actual anode heat (HU status), with display of free capacity left to reach maximum anode heat content OR an equivalent solution, only when there is a warning involved.

**Question 6:**

With your Tender Documents, under item 56, you defined the following:

56. Synchronized rotation of detector and collimator in all C-arm positions in order to get always upright live image, usefull with radial approac

The requested technical characteristic with all other parameters represents an eliminatory functionality that does not allow competition in the subject procedure. Please also accept the possibility of offering a monoplar premium floor-mounted intervention solution that has an equivalent solution. With respect to the standards applicable to angiography devices, the value of ± 90 degrees for motorized rotation of the floor-mounted C-arm, part of monoplanar angiography systems, provides sufficient positioning flexibility to perform all angiographic procedures, fully covering the therapeutic needs of the Contracting Authority as well as minimally invasive procedures for diagnostic and therapeutic procedures of cardiac catheterization in all its forms, as well as interventional and radiological procedures. To achieve all the necessary projections in cardiac and vascular interventional procedures, in the conditions of safety and comfort both for the patient and the medical staff, the C-arm is constructed in such a way that it can undergo linear and rotational movements to achieve any required projection at any angle against the patient. Therefore, this system with motorized 90-degree rotation of the C-arm stand can easily perform the positioning of the most demanding procedures. In addition, this rotation describes an 180-degree circle arc, which fully meets all the Contracting Authority's requirements for positioning of the C-arm above the patient's head, as well as to the left of the patient's table. The system we would like to offer allows 3 predefined positions, which are most useful and effective in cardiovascular interventional procedures, as follows: frontal (at the patient's head), lateral (+90 degrees, the so-called ""nurse"") and lateral (-90 degrees, the so-called ""physician side""). In these positions, the image orientation is automatically adjusted-rotated to synchronize with the actual physical position of the C-arm. This is especially useful for 3D rotary scans that can be performed in any of these predefined positions, with all C-arm systems, whether floor- or ceiling-mounted. Automatic image rotation (± 90°) in these positions is a modern solution that allows the the display of an upright image, regardless of the C-arm position, just as required by the Contracting Authority and represents an equivalent solution that we propose. Accordingly, in order to allow more than one bidder to compete in the subject procedure, and given the fact that each manufacturer has its own way of system configuration and optimization, please accept the modification of requirement to read as follows:

“56. „ Synchronized rotation of detector and collimator in all C-arm positions in order to get always upright live image or equivalent solution“"

**Answer 6:**

It is accepted.

**Question 7:**

66 System must be delivered with all available features provided by manufacturer for offered model for dose reduction with improved image quality at the same time (ClarityIQ, Care+Clear and equivalent)

In your Bidding Documents, you defined under item 66 that the system needs to have all possibilities for dose-reduction by mentioning Philips trademarks.

As the official and sole authorized distributor of Philips products in the Republic of Serbia, we point out that you incorrectly labeled and requested two different products, namely the common dose reduction function and image enhancement, as well as an additional incorrectly named product from a potential bidder offered by Philips. DoseWise & Clarity IQ does not exist as a product but the following already exists:

- Common dose reduction and image quality enhancement feature - Dose & Wise which is similar to or the same as the common dose reduction features from other manufacturers such as requested. Care&Clear. These common features are found in the system CoreBlock and form an integral part thereof. As such, they are comparable and give approximately the same results.

- Clarity IQ - a separate product, that is, technology that does not have an equivalent on the market of the Republic of Serbia

In this case, you defined that the potential bidder offering Philips products, in addition to its common dose reduction feature (Dose & Wise), needs to offer Clarity IQ technology that is not a radiation dose reduction function without loss in image quality. We herewith highlight that by your requirement you defined Clarity IQ technology. Clarity IQ technology is a registered name of the manufacturer whose we are sole agents and distributors in the Republic of Serbia. As such, we emphasize that Clarity IQ technology is a unique technology that significantly reduces dose per patient while maintaining the same or better image quality in the field of diagnostic coronary angiography for PCI, or other radiology interventions. The results and effectiveness of Clarity IQ technology have been proven by multiple independent clinical studies with live patients as well as in the field of pediatric cardiology.

Please find attached the manufacturer's statement.

Clarity IQ is a complex technology incorporating software and hardware components that allows for dose reduction and image processing on a larger scale. The hardware component provides the much greater computing power required to maintain compound and complex real-time image processing.

In its Bidding Documents, the Contracting Authority predicted that there was an equivalent to Clarity IQ technology with the common dose reduction feature - Dose&Wise, more precisely defined common dose reduction features of other manufacturer (Care+Clear) as equivalent to the product we represent. Clarity IQ technology is a registered name of the manufacturer whose we are sole agent and distributor in the Republic of Serbia. As such, we emphasize that Clarity IQ technology is a unique technology that significantly reduces dose per patient while maintaining the same or better image quality in the field of diagnostic coronary angiography for PCI, or other radiology interventions. The results and effectiveness of Clarity IQ technology have been proven by multiple independent clinical studies with live patients. On the other hand, our manufacturer has common dose reduction features also possessed by other angiographic device manufacturers - Dose&Wise. Attached please find a study showing a comparison chart of common dose reduction features from different manufacturers - common features are Dose&Wise for the manufacturer we represent, Care+Clear for another manufacturer. We emphasize that our manufacturer on all their products i.e. angiographic rooms has common dose reduction functions with the same or better image quality as other angiographic room manufacturers - in our manufacturer's products this segment, more precisely common available dose reduction functions with retention of the same or better image quality is called Dose&Wise. Common options such as Dose&Wise or Care+Clear from another manufacturer are integral to the angiographic devices that different manufacturers have in their portfolio, they are integral to the ""core block"" or more precisely of devices, and they are delivered independently of other options that are possible, such C-arch, patient station, or acquisition station are supplied. Therefore, it is not possible to deliver an angiography device without common dose reduction features, as for the products of our manufacturer it is not possible to deliver Azurion angiography room without Dose&Wise dose reduction feature with the retention of the same or better image quality. In other words, your definition - Clarity IQ, Care + Clear, or equivalent third-party technology - discriminates against our manufacturer to offer an additional Clarity IQ product, while giving other manufacturers the ability to offer common dose reduction features. Also, in your definition you specify equivalent third-party technologies, and on this occasion we emphasize that Dose&Wise is equivalent to Care+Clear defined technology or a common technology of other manufacturer. In order to specify your request and the possibility of offering an adequate, i.e. required equivalent technology that you defined by your request, please specify your requirement as follows:

66. The system needs to have all available manufacturer's radiation dose reduction features without losing image quality or at the same time enhancing image quality for a device model that meets the Contracting Authority's minimum technical specification (Care+Clear or Dose&Wise or equivalent technology of other manufacturer). Bidders need to clearly state and indicate what features have been offered and included in the bid, as well as provide evidence of fulfillment of the above requirements in the manner stipulated by the Contracting Authority in the Bidding Documents.""

Otherwise, you are discriminating against potential bidders because you are equating common dose reduction features with advanced Philips-Clarity IQ technology that does not have an equivalent solution among other manufacturers. The discrimination in this case is performed in a way that we are the only one, as official distributors of a particular manufacturer, forced to offer an additional product with the required common dose reduction features and maintain the same level of image quality (Dose & Wise), while other bidders have no obligation to offer an additional product. We believe that this is destroying equality between potential participants and preventing the offering of an equivalent solution to indicated technologies of other manufacturers. In case you do not accept our request, please answer the following question: Can we, as representatives of Philips exclusively distributing Clarity IQ technology, offer equivalent radiation dose reduction features without losing image quality while improving image quality for a device model that fulfills the Contracting Authority's minimum technical specification to the requested Care+Clear system, with the submission of appropriate studies proving this?"

**Answer 7:**

 It is not acceptable.

Description of the specification no. 66 is clear, precise and not eliminatory among the products made by different manufacturers. Therefore, every bidder can prepare a valid offer.

The end customer is very aware that both ClarityIQ and Care+Clear are the unique technology software for dose reduction, produced by two different manufacturers. Both softwares fully meet user’s need in dose reduction and improving of image quality. This is the reason that both names of those softwares are existed in the description of the specification.

In accordance to this mentioned above, the bidder who offers Philips’ system should include the software ClarityIQ in the offer and the bidder who offers the system in which Care + Clear dose reduction software could be run should include that software in the offer.

**Question 8:**

Image storage capacity min. 50.000 images, 1024 x 1024 pixels, 12 bits

Please also accept angiography system having the possibility to store a minimum of 50.000 images at size of 1024 x 1024 , at 10 bits.

We appreciate that the difference between the requested value and the value offered by the system we are proposing is technically and clinically irrelevant. An image stored at a 1024 x 1024 matrix at 10 bits will not at all alter the image information and the diagnostic quality. Anyway, CHC Zemun has existing PACS system witch can store XA images.

Consequently, in order to allow more operators to access this procurement procedure, please kindly accept the amendment of this technical requirement in „Image storage capacity min. 50.000 images, 1024 x 1024 pixels, 10 bits” without altering the required performance level.

**Answer 8**:

It is acceptable to offer Image storage capacity min. 50.000 images, 1024 x 1024 pixels, 10 bits.

**Question 9:**

 Interface to connect with bidirectional communication to existing hemodynamic system Sensis, Siemens (software version VC12) or if not possible new hemodynamic system with following speciification:

Please note that the technical specification defined in this way discriminate against all potential manufacturers and give undue advantage to Siemens. Also, the subject procurement is defined as the procurement of new supplies and not as an upgrade or utilization of an existing System. Please define the subject specification in terms of the procurement of a new hemodynamic system and define your requirement as follows:

New hemodynamic system fully integrated with angiography room with the following minimum specification:

**Answer 9:**

It is acceptable and specification is now reads as: “New hemodynamic system fully integrated with angiography room with the following minimum specification:…”

**Question 10:**

 (2) two monitors min. 19`` in control room and display provided on Large monitor in examination room

Please consider to allow following definition:

One monitor min. 19`` in control room and display provided on Large monitor in examination room

For hemodynamic parameters in control room its more that enough one monitor. If you do not accept our proposal please explain why you insist on two monitors in control room?"

**Answer 10:**

It is acceptable to offer One monitor min. 19`` in control room and display provided on Large monitor in examination room.

**Question 11:**

 o Fully integrated FFR measurement with FFR display on hemodynamic monitor and arhiving in patient folder together with other hemodynamic paparameters, supporting and fully comaptible with FFR systems from minimum 2 manufacturers: Abbott (St. Jude Medical), Volcano, Boston Scientific and ACIST

With your subject item of minimum technical specification, you ruled out the possibility of offering a Philips angiography system because there is no compatibility you request with all manufacturers. The item defined in this way is eliminatory and, together with all other defined parameters, favors the manufacturer Siemens. Therefore, we ask the following question - is it acceptable to the Contracting Authority a device to be offered that is compatible with at least 1 of the 4 listed manufacturers? By accepting our suggestion you will not lose out on the quality of the device while you will allow more bidders to submit correct and appropriate bids. Otherwise, only one manufacturer may submit a correct bid, which is not in accordance with CEB and EU instructions and guides. Also, each of these manufacturers has all the types of catheters you need for your work.

**Answer 11:**

It is acceptable.

**Question 12:**

 Mobile x-ray protective shield MAVIG WD304 or eqv., Pb 1.0 mm with lateral lead rubber strips. Steel construction with lead inlay Pb value 1.0 mm, Upper part transparent lead acrylic shield, Pb 0.5 mm, Additional lateral lead rubber curtain in Pb 0.5 mm

Please consider modifying the item defined above as it may only be completed by the manufacturer MAVIG, whose solution is completely described and as such represents a restrictive parameter of the subject procurement. Please define your requirement as follows in order to allow more competition:

X-ray protective shield MAVIG WD304., Pb 1.0 mm with lateral lead rubber strips. Steel construction with lead inlay Pb value 1.0 mm, Upper part transparent lead acrylic shield, Pb 0.5 mm, Additional lateral lead rubber curtain in Pb 0.5 mm or eqv. solution which protect operator.

**Answer 12:**

It is already stated that it is allowed to offer eqvivalent equipment to Mavig WD304.

Non significant deviation is acceptable.

This specification describes accessory for angiography system and because of that cannot be eliminatory for any manufacturer of angiography system.

**Question 13:**

 Supplier is obliged to dismantle and remove existing angiography system Axiom Artis dFA, Siemens and take care of it according to applicable laws

Please exclude the subject requirement from the subject specification. Namely, the existing Siemens Axiom Artis dFA angiography room is the exclusive property of CHC Zemun and accordingly, the Public Investment Office as the Contracting Authority is not competent to order the institution, or potential bidders to alienate someone else's property. Also, the subject description discriminates against all other potential manufacturers, except Siemens, which may account for the added value of the existing angiography room against the other potential bidders."

**Answer 13:**

It is not acceptable.

The existing Axiom Artis dFA, Siemens system is already end of service support system and its dismounting and removal should be executed within the budget of this procurement. There is no grant or any bonus or added value to any bidder for such work. The contracting authority mentioned the name of the system just to inform the bidders which that system is. It was not requested to be done by authorized service dealer.

**Question 14:**

 o Installation of the offered system- “Turn key” project (preparation of facilities- technical room, examination room and control room - all typical civil works -floor, walls, ceiling, HVAC, electrical, enviroment ionizing protection including new Pb shielding doors, The Executive Design (PZI), in conformity with the previously prepared designs of measures of radiation safety and security, Designs/drawings of as built space (PIO),). The future selected bidder will have to engage institutions authorized for:

1) preparing the Design of measures of radiation safety and security for trial commissioning/use of scanner requiring the preparation of the said Design).

Taking into account your existing requirement, please provide the following information, which will also be an integral part of the Tender Documents in order to be able to make an acceptable and appropriate bid:

1)Detailed layout of the premises designated for the placement and installation of the angiography room

2)Please clarify which scanner is the subject of your requirement that reads as follows: preparing the Design of measures of radiation safety and security for trial commissioning/use of scanner requiring the preparation of the said Design

3)Please clarify whether the access roads to the projected site of installation allow the smooth transportation and installation of the offered device?"

**Answer 14:**

Any potential bidder can make the visit of the site for inspection and to do all needed measurements in order to prepare the offer.

The access route to the site of installation should be defined by the bidder. All the costs regarding eventual adaptation of access route for equipment transportation are born by the bidder and should be included in offered price. For site visit, please contact administration of CHC Zemun, Radiology department of CHC Zemun or Public Investment Management Office.

2) Please See Notice issued on PIMO portal on 27/02/2020

**Question 15 Part1:**

Your Tender Documents defined the eliminatory scoring parameters. Moreover, you defined your criterion of the most economically advantageous bid in a disproportionate ratio of 50 ponders for price and 50 ponders for quality (more precisely the technical and technological specification of the offered model). It is important to point out that you defined quality ponders in proportion to favoring one manufacturer whose solution (at a given weighting ratio for quality) is favored, thereby making it directly impossible to offer premium angiographic solutions of other manufacturers, which is not in line with CEB and EU instructions and guides. We therefore kindly ask you that your best price criteria be aligned with genuine performances and clinical requirements, as giving 50 ponders based on the technical and technological specifics of the model (more specifically, the technical specifics that do not individually bring clinical and operational advantage to the end user) of one manufacturer's angiography room is a discriminatory requirement that restricts competition in any public procurement.

Please note that in the procurements of capital medical equipment so far, ponders for technical and technological advantages have ranged mainly from 5 to a maximum of 10 ponders, therefore your defined requirements indisputably prevent competition and have a highly discriminatory character.

Please note that the technical parameters carrying the highest number of ponders in the subject procurement are related solely to technical specification and not to clinical performances and are absolutely disproportionate in terms of the number of ponders to be allocated.

In order to indicate to the Contracting Authority a clear violation of EU and CEB guidelines, we provide the following example:

3 P3 3D perfusion functional imaging acquisition protocols on workstation (syngo DynaPBV Neuro or eqv.) that provide physiological information of distribution of blood in lesions and surrounding tissue by means of color-coded cross-sectional blood volume maps. Furthermore, it allows for quantitative measurement of parenchymal blood volume in brain and abdomen in order to assess changes in perfusion caused by treatment 10

6 P6 Number of selectable pulse rates during pulsed fluoroscopy which are less than 7.5 fps 10

7 P7 X ray tube with 3 physical focal spots 10

**Answer 15 Part1:**

The scoring parameters by definition cannot be eliminatory. The purpose of an evaluation process, using quality requirements is to get the best value for money. In the evaluation process applied in the tender it is implemented weighted scoring method, because it is necessary to make a more complex evaluation of the bids, combining a compliance rating with a weighting for the clinical and functional importance of each selected technical parameter/characteristic.

Taking into account that this procurement is not simple and the price is not the most important factor, requested distribution of the offer price and quality as evaluation criteria with equal weighting of 50% to 50% is based on the requirement of the end customer that quality is very important factor and the price is not a key driving factor.

There is no any violation in accordance with CEB Procurement Guidelines, 2011. and also other EU procurement guidelines rules.

Selection for the scoring technical parameters/characteristics and way of their scoring are made by end user professional team. Selected parameters/characteristics reflect and represent clinical and functional advantages, i.e. better quality and the newer technology of the system which best meet the needs of the hospital and right balance of the scoring in ponders assigned to the price of the system and to the quality and technology of the system.

**Question 15 Part 2:**

These three criteria carry a total of 30 ponders that disproportionately (as much as 60% of the price and other required parameters) affect competition and are highly discriminatory.

By your description of the P3 criterion, you define the commercial name of only one manufacturer i.e. Siemens without giving a commercial description of any other manufacturer. In doing so, the manufacturer Siemens needs to offer only the neuro option, more precisely syngoDynaPBV Neuro, while you ask from other potential bidders to offer an equivalent option which is intended and include options for abdominal procedures, as well. In doing so, you have directly discriminated against all manufacturers except Siemens whose commercial speicification is the only one you defined.

**Answer 15 Part 2:**

The answer to this question partly is given above in the previous answer.

The specification P3 is not defined by the commercial name of only one manufacturer. The specification is clearly and precisely described. In order to be more precise and clear the commercial name of one manufacturer with added “or equivalent” is put in the brackets. The reason of mentioning the commercial name of one manufacturer is just because such information has been accessible in the product data sheet of that manufacturer. Knowing that also other manufacturer in their products can provide the same technique the wording “or eqv.” was put in the description of this specification.

Regarding your request to include the option also for abdominal procedures, the request is acceptable and the specification is now read as: „3D perfusion functional imaging acquisition protocols on workstation (syngo DynaPBV Neuro and Body or eqvivalent) that provide physiological information of distribution of blood in lesions and surrounding tissue by means of color-coded cross-sectional blood volume maps. Furthermore, it allows for quantitative measurement of parenchymal blood volume in brain and abdomen in order to assess changes in perfusion caused by treatment.“

**Question 15 Part 3:**

With your P6 criterion description, you directly describe and promote the solution and technology of the manufacturer Siemens with a percentage share against the price of even up to 20%, because only Siemens technology solutions have more than one selective pulse rate selectable programs at pulse fluoroscopy than other manufacturers. The clinical justification for such a requirement is out of place since, even with premium solutions of other manufacturers, all procedures are generally performed at 7.5 frames or more, while the existence of one program below the required 7.5 fps is sufficient for any required clinical procedure. All this is disproportionate to the set requirement and discriminatory against all manufacturers except Siemens.

**Answer 15 Part 3:**

Beside mentioned manufacturer, there are also other manufacturers, such as Canon, GE, Shimadzu who produce the systems with lower pulse rate than 7.5 fps.

More pulse rate choices means more flexibility and dose reduction both for operator and stuff and for the patient. Depending on the type of procedure, the length of the procedure, the technical characteristics, the dose reduction and image quality , the ability to choose pulse rates as much as possible is very important criteria for the end user.

There are many of evidences in scientific and standard literature of radiology and cardiology societies, mentioning that the rate below 7.5 frame per second is very important.

In perihpheral procedures where there is no high speed dynamic movements like in coronary, less pulse rate is possible and makes huge dose reduction. Dose reduction is growing lineary with pulse rate reduction.

Finally, if the offer cannot be evaluated with maximum points (ponders) for one parameter, it does not mean that this offer is eliminated. All formulas and description of the scoring parameters are in logic connection with the subject of the procurement and justified the clinical and functional advantages of the system, which are the most important for the user.

**Question 15 Part 4:**

Your description of the P7 criterion as well as the scoring method (YES/NO) whereby each solution that does not have 3 physical focuses receives 0 points (representing 20% of the price) is another example of discriminatory scoring conditions. Namely, the vast majority of angiography room models have two focuses that are pretty sufficient to accomplish any clinical task that would be placed before any angiography room solution. Here we particularly emphasize the disproportionality of scoring - a 3-focus solution not being technologically superior to a 2-focus solution receives 20% for the price only on the basis of its conceptual design."

**Answer 15 Part 4:**

The answer to this question partly is given above in one of the previous answers.

Beside mentioned manufacturer, there are also other manufacturers, such as Canon, GE who produce the systems with the tube with three focal spots.

Depending on the type of procedure regarding the dose delivery and image quality, ability to have a choice to select one of three focal spots instead of two is one of the most important criteria for end user.

In addition to this, the advantage of the tube with three focal spots in relationship with the tube with two focal spots is that in a case of failure of one or two focal spots, the tube can be still used.

If all bidders don’t get maximum points on certain criteria, it doesn’t mean they are discriminated. All formulas and description of criteria is in logic connection with procurement subject and correlated to clinical and functional advantages that are most important for end user.

**Question 16 Part 1:**

Among the other requested criteria, we also highlight the disproportionate and discriminatory character of the following specifications:

2 P2 System has 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 2

4 P4 Maximum mA value for pulsed fluoroscopy 5

5 P5 Number of Cu pre-filtration levels, maximum 2

 P10 Digital subtraction angiography (DSA) with high resolution 2K 3

8 P11 2D/3D fusion which enables that only two fluoro projections are required to easily fuse 3D volumes from other imaging modalities for live image guidance 2

Criterion P2

Please accept the amendment of this technical requirementas follows “System must have effective way to control skin dose. If the accumulated reference air kerma exceeds a configured threshold, a warning sound is given OR pop-up displays on the system, so operator must change existing C-arm position”, without altering the required performance level.

Please note that this requirement completely restricts the access at the procedure for all Philips Medical Systems angiography systems, as one of the most established manufacturers of devices of this kind cannot meet this requirement with any of the systems in its portfolio.

The system we would like to offer enables visible and audible signals, which are configurable by application specialist or field service engineer, depending on the requests of the customer. The angiography system has a comprehensive and clear workflow for dose awareness. In case the accumulated air kerma exceeds a threshold, a visible warning is given, which is displayed on the monitor in the examination room and in the control room. This warning consists of coloring the Air Kerma value with an orange-red color, which makes the message visible and clear to the operators, or to the nurses in the control room.

Consequently, in order to allow more operators to access this procurement procedure and taking into consideration the fact that each manufacturer has its own way of configuring and optimizing the system, therefore please kindly accept other solutions for this technical request, such as:

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

**Answer 16 Part 1:**

It is not acceptable.

In order to have better control of the complete procedure, both pop-up display as visible and warning sound as audible signal at the same time bring to operator to be fully concerned and informed, especially during long lasting procedures that certain dose threshold is reached and operator must change existing C-arm position. High dose can make big risk for patient skin burning in case that operator is not aware of warning visual and audible signals.

This is why the system which provides both warning sound and visible (pop-up display on the system) is treated as better quality system.

**Question 16 Part 2:**

Criterion P5

We appreciate that X-ray filtering is very important for dose reduction and image quality enhancement, but it’s not only about the number of Copper filters, but how they are used.

As such, we are proposing the Contracting authority a solution in which the maximum score is awarded to the manufacturer who enables the biggest number of Cu filters, but also to the one who maintains the filters throughout the whole examination, regardless of the patient size, of the selected protocol or of the projection used or fluoroscopy time.

**Answer 16 Part 2:**

It is not acceptable.

Al filter serves for inherent filtration and it is always in the X-ray beam. Purpose of Cu additional prefilters in the X-ray beam is to filter out low energy radiation which does not have any influence on image quality, but have huge impact on patient dose. Furthermore, it is clinical and operator objective to have selection of variable Cu filtration according to the angulation and patient´s thickness always to maximize image quality while minimizing patient entrance dose. For example, if, during examination, the direction of projection is changed from oblique to antero-posterior, the filter thickness should be increased since the volume of the area of examination is decreasing and thus the distance of the X-ray, penetrating the patient's tissue is decreased during the change of the angulation. The increased filter thickness will lead to lower patient dose. The thinner the patient, the more copper is inserted into the beam ‒ resulting in a lower patient entrance dose by filtering out low energy radiation.

This is why the system with more Cu pre-filter levels is treated as better quality system than the system with lower number of Cu pre-filter levels.

**Question 16 Part 3:**

Criterion P7

We appreciate that even mentioning the table weight load as part of the scored criteria, and moreover, awarding this technical requirement with such a high score is strictly done just to offer an economical advantage to this manufacturer, but not for clinical or technical reasons.

Rewarding with additional points a higher table weight load does not say anything about the system’s performance and capabilities. A sturdy and robust patient table able to support at least 250 kg (as mentioned in the minimal mandatory technical requirements) is more than enough to ensure not having to be selective about certain overweight patients, ensures smooth maneuvering and manipulation, as well as precise positioning reproducibility.

Taking into consideration all of the above, we appreciate the Contracting Authority should remove this criteria altogether from the scored technical specification, taking into consideration its lack of clinical relevance."

**Answer 16 Part 3:**

It is not acceptable.

Maximum table load is very important criteria, because of running the procedures with obese patients. Many time it is happened that during procedures with big, obese patient, when a lot of accessories are on the table, in the case of emergency in order to do reanimation, the stuff need to be on the table.

In such cases robust table capable to handle huge weights is needed . CHC Zemun is working as emergency care center for heart and brain stroke 24/7 and handle all kind of patients and procedures, treating all patients no matter of weight and health conditions.

**Question 17:**

1.In your Tender Documents, for lot2, under item 2you defined the following: Gentry aperture at least 78 cm

Considering the fact that gentries of 78 cm or more are used exclusively in radiotherapy, as well as the fact that such a restrictive definition completely excludes the devices of the newer generation of reputable manufacturers, please redefine your request as follows and make the process competitive:

Gentry aperture at least 78 cm (tolerance +/- 8%)

If you do not accept our proposal, please explain to us the clinical justification for your need of Gentry aperture of exactly 78 cm

**Answer 17:**

Not acceptable.

78 cm gantry aperture is now standard for most manufacturers of CT scanners and it is not used only for radiotherapy purposes. Bigger aperture means more space for patient, especially for obese patients.

**Question 18:**

In your Tender Documents, for lot2, under item5you defined the following: Vertical movement of patient couch in range of at least 50 cm with the lowest height maximum 50 cm

Is it acceptable for the Contracting Authorityto modify the requirement to: Vertical movement of patient couch in range of at least 40 cm with the lowest height maximum 50 cm (+/-3cm). By allowing minimal deviation in this way, the Contracting Authority will certainly not lose out on the functionality or quality of the device itself.If you do not accept our proposal, please explain to us the clinical justification for your need for vertical movement of patient couch in range of at least 50 cm with the lowest height maximum 50 cm

**Answer 18:**

It is acceptable, please See Amendment No.1 to Tender Documents

**Question 19:**

In your Tender Documents, for lot2, under item7you defined the following: Scanning range in horizontal direction with extensions at least 200 cm

Is it acceptable for the Contracting Authorityto modify the requirement to: Scanning range in horizontal direction with extensions at least 185 cm? Changing this requirement would still allow all necessary procedures to be performed, whereas the submission of the adequate bids would be made possible for reputable manufacturers.If you do not accept our proposal, please explain to us the clinical justification for your need for scanning range in horizontal direction with extensions of200 cm

**Answer 19:**

Not acceptable. Minimum 200 cm scanning range gives much more flexibility and comfort for the patient and operator during the scanning comparing with lower range and it is standard for all CT manufacturers.

**Question 20:**

Does your minimum requirement under item 14 for maximum anode capacity refer to a nominal or effective (software-enhanced) value?

**Answer 20:**

It refers to a nominal capacity value.

**Question 21:**

In your Tender Documents, for lot2, under item8you defined the following: Patient couch maximum load capacity at least 300 kg

Is it acceptable for the Contracting Authority to modify the requirement to: Patient couch maximum load capacity at least 200 kg.It is possible to carry out examinations on all patients on a table with a capacity of up to 200 kg. If you do not accept our proposal, please explain to us how many patients weighing over 200 kg are examined annually via the computed tomography system and what is clinical justification for Your need for patient couch with maximum load capacity of 300 kg

**Answer 21:**

It is not acceptable. Hospital already has CT with patient couch loading apacity of 200 kg. All major vendors offer patient couch loading capacity of 300 kg

Many time it is happened that during the scanning with big, obese patient, when a lot of accessories are on the table, in the case of emergency in order to do reanimation, the stuff need to be on the table.

In such cases robust table capable to handle huge weights is needed. CHC Zemun is working as emergency care center for heart and brain stroke 24/7 and handle all kind of patients and procedures, treating all patients no matter of weight and health conditions.

**Question 23:**

"7.In your Tender Documents, for lot 2, under item17you defined the following: Number of detector elements in one detector row excluding reference detector elements at least 800. With all other required elements this requirement is an eliminatory parameter especially for Philips systems. Our computed tomography systems have 672 detector elements in the detector array, but also more detector arrays compared to the same systems in the class. Also the composition of the detectors themselves as image receptors differ from manufacturer to manufacturer. The technology of our detectors enables better signal utilization and thus achieves the same or better image quality, even with fewer detector elements in the detector array. Please modify your requirement to:

* Number of detector elements in one detector row at least 672

If you do not accept our proposal, please explain to us the clinical justification for your need for exactly 800 detector elements in one row. Also, please answer how you can compare different detector technology trough numbers?

**Answer 23:**

It is not accepted. The higher number of detectors (detector elements) allows obtaining of more acquired data, which is important to create better slice and have better image resolution.

**Question 24:**

In your Tender Documents, for lot 2, under item 18you defined the following eliminatory parameter in favor of one manufacturer which reads as follows: Total active detector length

(coverage and collimation), in submillimeter mode, in “Z” direction and in iso-center in axial mode without patient couch moving at least 160 mm

Please note that collimation and coverage is not only achieved in the Z direction, but that different manufacturers have different solutions that achieve coverage and collimation in other ways. Please remove this parameter from your Tender Documents.

**Answer 24:**

More than one manufacturer and more than one model meets required specification. The axial scanning mode has been taken here, in this specification only for defining the detector coverage in simple and clear way.

**Question 25:**

In your Tender Documents, for lot2, under item34you defined the following: Fastest image reconstruction time at least 50 images per second with usage of iterative reconstruction technology

Is it acceptable for the Contracting Authorityto modify the requirement to: Fastest image reconstruction time at least 18 images per second with usage of iterative reconstruction technology?If you do not accept our proposal, please explain to us the clinical justification for your need for image reconstruction of 18 images per second with usage of iterative reconstruction technology? We would also like to highlight that you also included the above request in the scoring system under P9: Image reconstruction speed, including iterative reconstruction. Since only one manufacturer can currently fulfill the requirement under item 34 with all other requirements, please lower the requirement according to our proposal, as bidders who offer a higher rate of reconstruction will in any case get more ponders."

**Answer 25:**

It is not accepted.

Reconstruction time is one of the most important parameters of computer system of the CT scanner. CT scanner with higher reconstruction speed, produced by any of CT scanner producers is ranging as better quality system in relation to CT scanner of the same producer with lower image reconstruction speed.

Higher image reconstruction speed does not mean only higher number of examinations in time, but also it is very important feature which is needed for running of new advanced software applications.

**Question 26:**

In your Tender Documents, for lot 2, under item 35 you defined the following: Advance reconstruction algorithm for reduction of artifacts caused by metal presence in patient’s body (not Dual Energy)

Advanced reconstruction algorithm for reduction of artifacts caused by metal implants has different commercial names with different manufacturers (O-MAR, SEMAR, iMAR, MAR etc.) For precision purposes, please define your requirement as follows:

Advance reconstruction algorithm for reduction of artifacts caused by metal presence in patient’s body ( O-MAR, SEMAR, iMAR, MAR or ""appropriate"")

Also, kindly note that Dual Energy is an advanced premium option primarily of cardiology computed tomography systems. With this acquisition technique, dual energy sequences that can assist with advanced diagnostic studies are obtained and reconstructed:

-weighted average images (simulating single energy spectra)

-virtual monoenergetic images (attenuation at a single photon energy rather than a spectrum)

-material decomposition images (mapping or removing substances of known attenuation characteristics, such as iodine, calcium, or uric acid)

-virtual non-contrast images (iodine removed)

-iodine concentration (iodine maps)

-calcium suppression (calcium removed)

-uric acid suppression (uric acid removed)

-electron density maps

-effective atomic number (Zeff) maps

We kindly ask you to specify whether or not a Dual Energy option needs to be offered in order to precise which class of device you require.

**Answer 26:**

It is not accepted. The specification is clearly described and defined and therefore there is no need to add commercial names of some manufacturers. The requested application tool should not be based on Dual Energy scanning. Dual Energy scanning is not required.

**Question 27:**

"10.In your Tender Documents, for lot 2, under item 50 you defined the following: 4D CT Brain Perfusion with display of blood flow, blood volume and Mean Transit Time (MTT), to define presence of acute cerebral infarcts. System has automatic correction of artefacts from patient movement. Software package makes calculation in all three orthogonal planes of volume on any slice. Ability to display 4D DSA contrast flow through blood vessels.

The requirement defined in this way is eliminatory and can only be met by one manufacturer. Different manufacturers define their solutions differently even though they have the same purpose and functionality. All other manufacturers are not able to offer their solution for brain perfusion since the requirement contains the description of brain perfusion of only one manufacturer. In order to enable other world renowned manufacturers to participate in the subject procedure, please generalize your requirement so that it reads:

-Brain Perfusion with display of blood flow, blood volume and Mean Transit Time (MTT), to define presence of acute cerebral infarcts.

If you do not accept our proposal, please explain to us the clinical justification for your need for brain perfusion defined on this specific way."

**Answer 27:**

It is not accepted.

CHC Zemun is on call every second, dayly in a year. So half of a year hospital is on call for almost million patients, who significant number of the have a stroke. Advanced stroke analysis is needed to be provided, which, by the way, most of major manufacturers has such CT products.

**Question 28:**

"11.In your Tender Documents, for lot 2, under item 61 you defined the following: CT Perfusion 4D body. Package for calculation of perfusion of other organs in any axis. Special calculation method of perfusion of the organs that are fed with one blood vessel and different method for those organs that are fed with two blood vessels

The requirement defined in this way is eliminatory and can only be met by one manufacturer. Different manufacturers define their solutions differently even though they have the same purpose and functionality. All other manufacturers are not able to offer their solution for body perfusion since the requirement contains the description of body perfusion of only one manufacturer. In order to enable other world renowned manufacturers to participate in the subject procedure, please generalize your requirement so that it reads:

-CT Body Perfusion. Package for calculation of perfusion of other organs.

If you do not accept our proposal, please explain to us the clinical justification for your need for CT Body Perfusion defined on this specific way.

**Answer 28:**

It is not accepted.

CHC Zemun has developed oncology department, treating a significant number of oncology patients with different diagnosis. Advanced body perfusion analysis is needed, both for new diagnosis and for follow-up. This requested feature exists in the products of the most of major CT manufacturers.

**Question 29:**

In your Tender Documents, for lot 2 in the scoring system you defined item P2 as follows: Gantry

tilt ±30⁰ (physical, non-digital).

We kindly ask you to allow a minimum deviation of +/- 6⁰ so that the bidders could offer a device with a physical gantry tilt of -24⁰/+30⁰ or -30⁰/+24⁰, since there is no difference in clinical usability, and there are no procedures that can be done with a ± 30⁰ tilt, and cannot be done with a physical tilt of -24⁰/+30⁰ ili -30⁰/+24⁰.

Answer 30:

It is accepted.

Definition of scoring parameter “Gantry tilt ±30⁰ (physical, non digital)” is changed and now is stated as:

“Gantry tilt ±30⁰±6⁰ (physical, non digital)”

The number of ponders to be awarded based on whether offered system has gantry tilt ±(30⁰±6⁰) (physical, non-digital) shall be calculated based on the following:

YES (included in offer), 5 ponders

NO (not included in offer), 0 ponders”

**Question 31:**

In your Tender Documents, for lot 2 in the scoring system you defined item P3 as follows: Variable Pitch Technology-Software package that enables possibility to acquire image of three body regions in one run with different pitch settings, where one body part is possibly scanned with ECG triggering, to obtain image without artefact related to movement of heart and attached structures

We kindly ask the Contracting Authority to delete this requirement from the Tender Documents. Different manufacturers define their technologies in different ways. The requirement describes the technology of only one manufacturer. The requirement defined in this way is eliminatory, while manufacturers who may offer the same clinical functionality in some other way are at a disadvantage.

**Answer 31:**

It is not accepted.

The requirement is not mandatory. It is scoring parameter and therefore is not eliminatory.

**Question 32:**

In your Tender Documents, for lot 2 in the scoring system you defined item P4 as follows: Lowest Patient Table Height

 We kindly ask the Contracting Authority to delete this requirement from the Tender Documents. The height of the table on a computed tomography device does not in any way affect its functionality or quality. Also, a difference of a few centimeters will certainly not make a difference in the daily work, in preparing patients for imaging, or in getting them off the patient table.

**Answer 32:**

It is not accepted.

It is not accepted. Lowering of patient couch influences patient comfort. For pediatric or small patients this is beneficial.

**Question 33:**

In your Tender Documents, for lot 2 in the scoring system you defined item P10 as follows: X-ray Tube heat capacity

 We kindly ask the Contracting Authority to define whether this requirement refers to the nominal or effective tube capacity, since it is impossible to compare the two mentioned. "

**Answer 33:**

Requirement refers to nominal anode heat storage capacity.

**Question 34:**

In technical specification for LOT 1 - Digital angiography system for cardiovascular diagnostic and interventional procedures, ID 67 - is required „Mobile OCT with FFR system, connected and compatible with angiography system“.

Since OCT and IVUS (Intravascular Ultrasound) are both imaging methods and both present in everyday practice just with different blood vessel contour imaging technology, is it acceptable to offer a Mobile IVUS with iFR/FFR system, connected and compatible with the angiography system.

**Answer 34:**

It is not acceptable.

Public Procurement Committee