Procurement of Medical Imaging Equipment

no. IOP/5-2017/RD

Clarification no. 4

Issued on 09.10.2017.

Item 1 – Multislice CT Scanner for cardiovascular procedures for Institute for cardiovascular diseases "Dedinje"

1. Specification No.6.6. "Adaptive 'pitch' with ECG triggering combination during arteriography and coronography"

   Thanks to its innovative design, the Revolution CT delivers breakthrough clinical applications for cardiac exams:

   i) 1-Beat High definition, motion free coronary images at any heart rate with intelligent motion correction
   ii) 1-Beat, comprehensive cardiac assessment for every patient at low dose - coronaries, rest / stress perfusion & function
   iii) 4D imaging capabilities for all anatomies enabled by whole organ acquisition to visualize vascular flow, organ motion or kinetic properties

   [redacted] Dynamic, low dose perfusion studies up to 16cm for cardiac, neuro or body applications with no table motion, personalized coverage & sampling,
   v) Ability to acquire Perfusion and CTA data from a single exam
   vi) Dedicated HD cardiovascular and head / neck angio in a single low dose exam for comprehensive stroke workup.

   The aforementioned advanced applications enable high quality imaging and fluid workflow with the lowest possible radiation dose per patient, therefore providing clinical benefits. In this respect, we kindly ask you to remove this specification point as it limits the competition. Enabling more manufacturers to participate will reflect in more favorable bids for the end user.

Answer 1:

If bidder can offer protocol that provides ECG triggered coronary artery examination and aortography with adequate pitch in one session, it will be accepted regardless of title. There are a lot of urgent patient treated in our institution that should be diagnosed in mentioned protocol ASAP with the lowest X ray beam radiation and contrast media exposure.

- All features you mentioned are not dedicated to that goal.

Question 2:

2. Specification No 7.13 "Ultra high spatial resolution-min 24lp/cm or more"

The Gemstone Clarity detector enables high definition CT imaging with a revolutionary, extremely fast scintillator. The relative speed of the scintillator enables High Definition technologies such as High Resolution imaging capability, with less noise and the ability to perform fast kV switching that may enable applications such as spectral acquisitions. Revolution CT provides best in class spatial resolution at 18.2lp/cm in z-direction and 14.8lp/cm in X-Y direction (measured at 2% MTF). This spatial resolution provides clear images to help the physician with tasks such as accurately quantifying stenosis in coronary and other vascular structures. Also the Revolution CT detector provides best in class high contrast spatial resolution of 0.23mm. [redacted] Revolution CT is a breakthrough that delivers uncompromised image quality & clinical capabilities through the convergence of coverage, spatial resolution, temporal resolution & dose performance – all in one.

Therefore, in order for [redacted] to be able to participate in the tender, we kindly ask you to change the specification to "Ultra high spatial resolution-min 21lp/cm or more"

Answer 2:

Spatial resolution is, by temporal resolution, one of the most important feature for cardiac MDCT. The suggestion will be accepted and point 7.13 will be exchange into "**Ultra-high spatial resolution – to be minimal 20 line pairs / cm or more."**

Question 3:

Item 3. Magnetic resonance system 1.5 T equipped and suitable for whole body examination "Zemun"

3. Specification No 1.5 - Magnet length from cover to cover 150 cm ± 10%

We kindly request that the magnet length is increased to 160cm ± 10%. With this small increase, [redacted] will be able to offer a system of increased magnet homogeneity that guarantees higher quality large Field of View and off-center imaging.

Answer 3:

According to performed market survey all major vendors have in their portfolio MR unit conforming to this request. Tender specification already enables 10% deviation form requested 150 cm which enables

longer Gantry by 15 cm from requested. Shorter gantry enables less patient anxiety due to less claustrophobic effect. Therefore we cannot accept change in specification No 1.5.

Question 4:

4. Specification No 1.6 - Field of view - not less than 55x55x50 cm (XxYxZ)

We kindly request that the maximum Field of View is specified to not less than 50 x 50 x 45cm as the requested 55x55x50cm specification does not allow us to participate in this tender, limiting the competition without enhancing the clinical capabilities of the offered system since the guaranteed magnet homogeneity in such a large FOV is so poor that reliable imaging is not possible and such large Field of Views are offered just for locator scans by specific manufacturers. Finally, this change will enable more manufacturers to participate, thereby enhancing competition, which will reflect in more favorable bids for the end user.

Answer 4:

We accept request specification No 1.6 is amended: "Field of view - not less than 50x50x45 cm (XxYxZ)"

Question 5:

5. Specification No 2.3 - Gradient power at least 20 kW

Please clarify if this specification refers to the RF Amplifier or the Gradient Amplifier. The maximum gradient power normally greatly exceeds the specified value which is closer to RF amplifier power. In the case that specification 2.3 was meant to refer to the RF amplifier power we request that this is specified to 16KW in order to enable [redacted] to participate in this tender as the 20KW specification restricts the competition without offering any clinical benefit to the MR system.

Suggested addition to the Gradient specifications

The gradient system plays a significant role in image quality and imaging speed. Its performance is clinically manifested by the minimum achievable sequence timing parameters as Echo Time (TE), Echo Spacing (ESP) and Repetition Time (TR) for specific imaging techniques. The most demanding techniques for the gradient system are 3D GRE, EPI, and FSE/TSE pulse sequences. In these sequences the smaller the Echo time/ESP the better the image quality due to inherent artifacts reduction (off-resonance artifacts, SNR drop, image distortion, image blurring etc) or scan time (breath-hold time and patient conformance). These parameters are measured and stated in the product datasheets of all major MR manufacturers and can serve as criteria of the clinical capabilities of a gradient system.
The gradient system was typically specified by its maximum Amplitude in mT/m and Slew Rate in T/m/s at each axis. Newer technologies though do not allow these criteria to fully describe its performance.

In most of the recent MR tender books a combination of minimum timing parameters and gradient Amplitude and Slew rate criteria is introduced which allows for a more precise evaluation of this MR subsystem.

We suggest that in order to secure a high performance of the gradient system of the offered scanners at least the maximum values of the minimum Echo Spacing of 2D FSE/TSE and 2D EPI pulse sequences for a specific scan matrix (128 or 256) is specified. For 128 scan matrix values that describe systems of higher gradient performance are 1.7ms for 2D FSE/TSE and 0.49ms for 2D EPI.

Answer 5:

Specification No 2.3 is amended: "RF Amplifier power at least 20 kW"

Question 6:

6. Specification No 3.1 RF system with 16 channels for simultaneous A/D conversion

In the wide bore 1.5T segment, a typical independent channel performance can exceed 32 independent channels with 32 independent A/D converters. Additionally, the majority of the recent MR systems of this segment offer a digital RF architecture which enables A/D conversion to be performed either on the magnet bore or the RF coil itself. Then the signal is optically transferred to reconstruction engine enhancing considerably the achieved SNR compared to the older analogue transfer architectures by minimizing the noise that is

introduced during the analogue signal transfer. This technology is currently offered by all major manufacturers and is one of the basic characteristics that defines up to date MR technology. Therefore, we kindly request that specification 3.1 which describes the RF receive architecture is amended to request 32 channels with 32 A/D converters and an optical-digital RF architecture.

Answer 6:

Specification No 3.1 clearly defines requirement form user. If 32 channel system is offered it conforms to Specification No 3.1.

Question 7:

7. **Specification No 4.3 - Separate, dedicated, head-neck coil with minimum of 16 coil elements**

Current technology commonly offers superior to the requested number of channels for the head – neck coils, and is offered by most major manufacturers. Therefore, we kindly request and suggest that specification 4.3 is amended to request a separate, dedicated head – neck coil with a minimum of 20 coil elements.

As MR is a technology that has breakthroughs every 5 to 6 years, we believe this change will ensure the use up-to-date technology, which will be able to perform on a high standard over the following 10 years or more. Specification in this point favors an already obsolete technology.

Answer 7:

It is common belief that increase in number of coil elements dramatically increases image quality. Unfortunately MRI physics is clear increase of number of elements on same surface means smaller elements. That consequently leads to less penetration as penetration depends on element size. If offered system has Head coil with 20 elements it will conform to specification No 4.3 so there is no need to change it.

Question 8:

8. **Specification No 4.4 - Spine coil with minimum of 32 coil elements, with coverage of minimum 100cm and with possibility of axial movements inside the patient table**

Please clarify the movement that is described in specification 4.4. Typically, the spine (posterior) coils that are embedded in the patient table and reach 100cm in coverage do not allow for any coil movement since this is not needed in any clinical scenario.

Answer 8:

It is required spine coil to be movable in patient table along the longitudinal axis so it can be positioned more to the head end or more to the feet end of the table. This is indeed much needed as it enables patients to be scanned feet first for several types of exams, and not necessarily be put into gantry which unmovable spine coils require.

Question 9:

9. Specification No - 5.1 Minimal height position of patient table - 45 cm or less

The minimal height position of the patient table of 45cm or less allows for only one MR vendor to participate in this tender. Therefore, we kindly request that the minimal height position is increased to 52cm to broaden competition and to allow more companies and [redacted] to participate. This increase is expected to have minimal impact to the workflow as the minimal height remains short and the patient table will be easily accessible by the patients. Finally, as this change will enable more manufacturers to participate, it will enhance the competition, which will finally reflect in more favorable bids.

Answer 9:

Although Patient table lowering height is important and enables easier approach specification 5.1 is amended and now states: "Minimal height position of patient table- 52 cm or less", to further enable competition.

Question 10:

10. Specification No – 6.1. Wireless Signal Transfer

We kindly request that specification 6.1 is removed as it is limiting the competition. This characteristic has a minimal impact in workflow. Additionally, wired physiologic measurement sensors offer more robust and reliable signal and consequently more robust acquisition triggering and image quality.

Answer 10:

Almost all vendors have in their offering both wired and wireless gating units, and all of them describe wireless one as superior, as wires are shorter and less interference is caught especially on ECG, also signal is digitized almost directly on patient and then wirelessly transferred further. There will be no change in specification.

Question 11:

11. Specification No - 7.15 Automatic setting of scanning plane and position of slices for exams of intervertebral spaces

Scan locations planning in spine exams is always requested to be reviewed by the user as the pathologies vary and the scan coverage is not the same for all patients. Automatic planning software adds little benefit in some exams and could even create problems for novice radiographers who would rely on the software's suggestion with a possibility to scan either more, or less than the required area. [redacted] offers the possibility to the user to plan only the first acquisition in each scan plane and then the system automatically propagates the setup to the remaining acquisitions. In this way both workflow and scan quality is secured. Therefore, we kindly request that specification 7.15 is removed as it limits the competition in this tender, and does not offer any significant advantage to the offered system. Finally, this change will enable more manufacturers to participate, thereby enhancing competition, which will reflect in more favorable bids for the end user.

Answer 11:

Automatic setting of scan plane is offered by several major vendors, and enables novice radiographers to gain more confidence and steeper learning curve, this is a tool that even for experienced radiographers accelerates workflow. There will be no change in specification.

Question 12:

12. Specification No 7.16 - Automatic setting of scanning plane and position of slices for cardiology exams in six (6) typical scanning planes

Cardiac scanning is a demanding application with respect to system (gradient coil performance) and user (clinical knowledge). Cardiac anatomy is severely altered due to pathology and automatic plan software require careful review. This results to minimal benefits in workflow from such software. [redacted] offers the possibility to the user to plan only the first acquisition in each scan plane and then the system automatically propagates the setup to the remaining acquisitions. In this way both workflow and scan quality is secured. Therefore, we kindly request that specification 7.15 is removed as it limits the competition in this tender, and does not offer any significant advantage to the offered system. Finally, this change will enable more manufacturers to participate, thereby enhancing competition, which will reflect in more favorable bids for the end user.

Answer 12:

Automatic setting of scan plane is offered by several major vendors, and enables novice radiographers to gain more confidence and steeper learning curve, this is a tool that even for experienced radiographers accelerates workflow. There will be no change in specification.

Question 13:

13. Specification No - 8.3 Advanced fast scanning techniques: FASE (fast advanced spin echo), hybrid EPI, multi-shot EPI, single-shot EPI, SSFP (steady state free precision), FSE/FASE T2 Plus or equivalent

Please clarify if for any of the described scanning techniques an equivalent technique that can cover the same clinical needs can be offered.

As one of the most prominent and largest medical equipment manufacturers, [redacted] does not offer in its imaging portfolio a hybrid EPI sequence as these sequences suffer from image distortions, and current imaging coils and acceleration techniques can offer ultra-fast T2 weighted imaging based on standard FSE pulse sequences.

Answer 13:

On the end of specification it is clearly stated “or equivalent”, so equivalent scanning techniques can be offered.

Question 14:

14. Specification No 8.6 - Non contrast angiography with following acquisition techniques: FSBB, FBI, Time-SLIP

The imaging techniques listed in specification 8.6 refer to vendor specific techniques and entirely exclude competition. Therefore, we kindly request that specification 8.6 is amended to allow for equivalent techniques to be offered, or specify the clinical need these imaging techniques need to cover. We underline that this change will enable more manufacturers to participate, thereby enabling competition, which will reflect in more favorable bids for the end user.

Answer 14:

As it is very well known there is no consensus between vendors of MRI units on naming scanning sequences. In specification 8.6 there is "or equivalent" missing at the end. You are allowed to offer equivalent scanning techniques to those named in specification 8.6.

Question 15:

15. Specification No - 8.14 Techiques for cardiac acquisition (cine with and without gating, Black Blood, retrospective acquisition of whole heart cycle, perfusion imaging)

A cardiac exam is commonly not limited to the mentioned applications but also includes a myocardial viability study based on GRE IR technique. To facilitate this study additional multiple IR scans are performed to identify the correct TI time for normal myocardial signal nulling in order to be able to identify pathology of delayed enhancement with the optimal contrast. Having in mind the aforementioned, we suggest that specification 8.14 is amended with the addition of these techniques to offer a comprehensive cardiac study.

Answer 15:

There will be no change in specification 8.15

Question 16:

16. Specification No - 8.15 Multislice scanning techniques: from beginning to the end, from end to beginning and from central position to end positions

We kindly request that the requirement of multi-slice scanning technique from central position to end positions is removed from specification 8.15 as it limits the competition in this tender, and describes an insignificant feature of an MR system. Having in mind the aforementioned, this change will enable more manufacturers to participate, thereby enhancing competition, which will reflect in more favorable bids for the end user.

Answer 16:

Although these scanning techniques enable less crosstalk and interference between slices, Specification 8.15 is amended and now states: Multislice scanning techniques: from beginning to the end and from end to beginning.

Question 17:

17. Specification No - 8.22 Diffusion techniques: EPI Diffusion, FASE Diffusion

We request that specification 8.22 is amended to allow for equivalent imaging techniques to be offered as FASE diffusion is a vendor specific technique and excludes any and all competition. Fair competition is the principal postulate of public tenders, and ensures most favorable bids for the end user.

Answer 17:

As it is very well known there is no consensus between vendors of MRI units on naming scanning sequences. In specification 8.22. there is "or equivalent" missing at the end. You are allowed to offer equivalent scanning techniques to those named in specification 8.22. Specification 8.22. is amended: "Diffusion techniques: EPI Diffuion, FASE Diffusion or equivalent"

Question 18:

Item 6 - Premium Cardiovascular ultrasound system for Clinical Hospital Center „Zemun" -

18. Specification no. 1.2 - LCD monitor size min 23" Full HD on articulating arm

The premium Cardiovascular ultrasound system of [redacted] has an LCD monitor with size 22" High-Definition (HD) flicker-free of the latest technology OLED display, providing excellent spatial and dynamic resolution.

We kindly request to amend the specification, as this minor deviation in the monitor size does not affect clinical efficiency of our system. In addition, such change will enhance competition in the tender and ensure more favorable bids for the end user. Having in mind the aforementioned, please accept the following modification:

Specification no 1.2 - LCD monitor size min **22" Full HD** on articulating arm

Answer 18:

We accept request specification No 1.2 is amended: “LCD monitor size min 22“ Full HD on articulating arm”**Question19:** **19:**

19. Specification no 1.9. - TGC equilizers for lateral gain control on LCD touch - screen panel

The premium Cardiovascular ultrasound system of [redacted] has an automatic calculation and adjustment of the lateral gain.

We kindly request to expand the specification, allowing for broader participation to the tender and more favorable bids for the end user. Please accept the following modification:
Specification no 1.9. - TGC equilizers for lateral gain control on LCD touch - screen panel **or automatic lateral gain control.**

Answer 19:

Specification 1.9 is amended: “TGC equilizers for lateral gain control on LCD touch - screen panel or automatic lateral gain control”

Question 20:

20. Specification no 2.11. - 2D analysis functionality requested in point 2.10. is suitable for other ventricle and atriums

The majority of ultrasound manufacturers, including [redacted] 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 for the end user. Please accept the following modification:
Specification no 2.11. - 2D analysis functionality requested in point 2.10. is suitable for other ventricle and atriums, **on-board technique or offline through external workstation.**

Answer 20:

We cannot accept this as it totally changes workflow. If such functionality is on system itself that accelerates diagnosis process.

Question 21:

21. **Specification no 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 systems by the majority of the manufacturers. In addition other manufacturers 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 for the end user: **Specification 2.15. –** The 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 21:

We cannot accept this request. KBC Zemun already has CT and is to receive MRI unit, fusion with these modalities enables continuous fusion during scanning, while fusion with X-ray enables only fusion on single image.