Procurement of Medical Imaging Equipment

no. IOP/5-2017/RD

Clarification no. 6

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U dokumentu Technical_Specifications_IOP5-2017RD na strani 1 od 32 tačka 1.1. zahteva se: „Aperture, minimum 70 cm“.
Ovakav zahtev je bio tipičan za CT skenere prethodne generacije. Savremeni CT skeneri imaju standardno otvor gentrija od 78 cm. Ovo inače omogućuje skeniranje barijatrijskih pacijenata, jer pacijenti od 204 kg (koliko je zahtevano tačkom 2.2 na istoj strani istog dokumenta) ne mogu da stanu u gentri otvora 70 cm, a većina pacijenata IKVB „Dedinje“ i jesu barijatrijski pacijenti. Takođe, IKVB „Dedinje“ već poseduje skener prethodne generacije (star skoro ili 10 godina) sa otvorom gentrija od 70 cm pa ima smisla da novonabavljeni aparat ipak pruža malo više mogućnosti.
Pitanje 1: Da li se prihvata izmena ovog zahteva tako da glasi: „Aperture, minimum 70 cm“
In the document Technical_Specifications_IOP5-2017RD on page 1 of 32 line number 1.1 the following requirement is listed: “Aperture, minimum 70 cm”.
This kind of requirement was typical for the CT scanners of the previous generation. Modern CT scanners have the standard gantry aperture of 78cm. By the way, this prevents scanning of bariatric patients, because patients weighing up from 204 kg (which is required in line number 2.2 on the same page of the same document) cannot fit into the gantry aperture of 70 cm, and most of the patients of the Institute for Cardiovascular Diseases “Dedinje” are precisely bariatric patients. Also, the Institute for Cardiovascular Diseases “Dedinje” already has a scanner of the previous generation (10 or almost 10 years old) with the gantry aperture of 70 cm so it makes sense for the newly purchased piece of equipment to provide some more possibilities.
Question 1: Do you accept to change this requirement so that it says: “Aperture, minimum 70 cm”
Answer 1: It is already requested min 70cm.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 1 od 32 tačka 1.2. zahteva se: „Full rotation shortest time (3600), no longer than 0.28 sec“.
Ovaj zahtev je sasvim opravdan za standardne CT skenere koji preglede srca rade u zastarelom spiralnom ili „scan and scan“ modu. Aparat koji bi smo ponudili proizvođača Toshiba Medical Systems Corporation poseduje „Wide Area Detector“ tehnologiju, odnosno detektor širine 16 cm koji pokriva celo srce u jednoj rotaciji pa mu nije neophodna velika brzina rotacije za postizanje istog efekta kao kod spiralnih skenera.
Pitanje 2: Da li se prihvata izmena ovog zahteva tako da glasi: „Full rotation shortest time (3600), no longer than 0.28 sec, or 0,35 sec if detector width of offered CT Scanner is 16 cm or more“
In the document Technical_Specifications_IOP5-2017RD on page 1 of 32 line number 1.2 the following requirement is listed: “Full rotation shortest time (360°), no longer than 0.28 sec”.
This requirement is completely justified for the standard CT scanners that do heart examinations in the spiral or “scan and scan” mode. The device we would offer is made by the Toshiba Medical Systems Corporation and has the “Wide Area Detector” technology, i.e. the 16 cm detector width which covers the entire heart in one rotation so it doesn't need a high speed of rotation for achieving the same effect as the spiral scanners.
Question 2: Do you accept to change this requirement so that it says: “Full rotation shortest time (360°), no longer than 0.28 sec, or 0.35 sec if detector width of offered CT Scanner is 16 cm or more”

Answer 2: Not accepted. There is also spiral exam of the heart that requires more than one rotation. It is dedicated for those that are not just coronary exam.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 1 od 32 tačka 3.2. zahteva se: „Maximum intensity of current - 740 mA or more“.
Ovaj zahtev je sasvim opravdan za standardne CT skenere koji preglede srca rade u zastarelom spiralnom ili „scan and scan“ modu. Aparat koji bi smo ponudili proizvođača Toshiba Medical Systems Corporation poseduje „Wide Area Detector“ tehnologiju, odnosno detektor širine 16 cm koji pokriva celo srce u jednoj rotaciji pa mu nije neophodna velika brzina rotacije a samim tim ni ekstremno velike struje ekspozicije za postizanje istog efekta kao kod spiralnih skenera.
Pitanje 3: Da li se prihvata izmena ovog zahteva tako da glasi: „Maximum intensity of current - 740 mA or more, or 600 mA or more if detector width of offered CT Scanner is 16 cm or more“
In the document Technical_Specifications_IOP5-2017RD on page 1 of 32 line number 3.2 the following requirement is listed: “Maximum intensity of current - 740 mA or more”.
This requirement is completely justified for the standard CT scanners that do heart examinations in the spiral or “scan and scan” mode. The device we would offer is made by the Toshiba Medical Systems Corporation and has the “Wide Area Detector” technology, i.e. the 16 cm detector width which covers the entire heart in one rotation so it doesn't need a high speed of rotation, and therefore doesn’t need extremely high exposure current for achieving the same effect as the spiral scanners.
Question 3: Do you accept to change this requirement so that it says: “Maximum intensity of current - 740 mA or more, or 600 mA or more if detector width of offered CT Scanner is 16 cm or more”
Answer 3: Not accepted. Current intensity is in relation with number of photons that improve visualization of submilimetar changes on coronary vessels (for instance).

U dokumentu Technical_Specifications_IOP5-2017RD na strani 2 od 32 tačka 6.4. zahteva se: „Full rotation time, (360 degrees), 0,28 second or faster“.
Ovaj zahtev je identičan zahtevu pod tačkom, 1.2. te važe isti zaključci kao za zahtev 1.2.
Pitanje 4: Da li se prihvata ili izbacivanje ovog zahtev,a obzirom da je već naveden pod tačkom 1.2, ili izmena ovog zahteva tako da glasi: „Maximum intensity of current - 740 mA or more, or 600 mA or more if detector width of offered CT Scanner is 16 cm or more“
In the document Technical_Specifications_IOP5-2017RD on page 2 of 32 line number 6.4 the following requirement is listed: “Full rotation time, (360 degrees), 0.28 second or faster”.
This requirement is identical to the one from 1.2. so the same conclusions apply as for the requirement 1.2.
Question 4: Do you accept to either remove this requirement since it is already listed under the line number 1.2, or to change this requirement so that it says: “Maximum intensity of current - 740 mA or more, or 600 mA or more if detector width of offered CT Scanner is 16 cm or more”
Answer 4: Not accepted. Current intensity is in relation with number of photons that improve visualization of submilimetar changes on coronary vessels (for instance).

U dokumentu Technical_Specifications_IOP5-2017RD na strani 3 od 32 tačka 7.13. zahteva se: „Ultra High Spatial resolution - min. 24 lp/cm or more“.
Ovaj zahtev je kategorija koja je nemerljiva posebno u standardnim uslovima isporuke, instalacije opreme i kvalitativnog prijema. Svi proizvođači ovaj parametar definišu pri različitim uslovima te nije moguće izvršiti adekvatno poređenje i evaluaciju ponuda.
Pitanje 5: Da li se iz navedenih razloga prihvata izbacivanje ovog zahteva iz tehničke specifikacije?
In the document Technical_Specifications_IOP5-2017RD on page 3 of 32 line number 7.13 the following requirement is listed: “Ultra High Spatial resolution - min. 24 lp/cm or more”.
This requirement is a category that is immeasurable particularly in the standard conditions of delivery, installation of equipment and qualitative receipt. All manufacturers define this parameter in different conditions so it is not possible to have adequate comparison and evaluations of bids.
Question 5: Due to the reasons above, do you accept to remove this requirement from the technical specifications?

Answer 5: See Addendum 2, point 5.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 3 od 32 tačka 8.1. zahteva se između ostalog: „- with flow of processing of at least 15000 images/sec, or more“.
Ovaj zahtev je kategorija koja je nemerljiva posebno u standardnim uslovima isporuke, instalacije opreme i kvalitativnog prijema. Svakako svaki respektabilni proizvođač isporučuje sisteme koji rade tako da imaju dovoljan protok informacija.
Pitanje 6: Da li se iz navedenih razloga prihvata izbacivanje ovog zahteva iz tehničke specifikacije?
In the document Technical_Specifications_IOP5-2017RD on page 3 of 32 line number 8.1 the following requirement is listed among others: “- with flow of processing of at least 15000 images/sec or more”.
This requirement is a category that is immeasurable particularly in the standard conditions of delivery, installation of equipment and qualitative receipt. Certainly every respectable manufacturer delivers systems that work in a way that they have a sufficient information flow.
Question 6: Due to the reasons above, do you accept to remove this requirement from the technical specifications?
Answer 6:
Not accepted. We have to provide some threshold for the flow of and operation with the acquired data in the same time.
U dokumentu Technical_Specifications_IOP5-2017RD na strani 3 od 32 tačka 8.3. zahteva se između ostalog: „2 (two) diagnostic DICOM compatible monitors, minimum 2 Mp resolution, or more and screen diagonal minimum 21,3 inch, or more“.
Različiti proizvođači imaju različita softverska rešenja. Rešenje koje nudimo podržava rad sa jednim monitorom veće rezolucije.
Pitanje 7: Da li se prihvata izmena ovog zahteva tako da glasi: „2 (two) DICOM compatible monitors, minimum 2 Mp resolution, or one DICOM compatible monitor diagonal minimum 26,5 inch“?
In the document Technical_Specifications_IOP5-2017RD on page 3 of 32 line number 8.3 the following requirement is listed among others: “2 (two) diagnostic DICOM compatible monitors, minimum 2 Mp resolution, or more and screen diagonal minimum 21.3 inch, or more”.
Different manufacturers have different software solutions. The solution we offer supports working with one higher resolution monitor.
Question 7: Do you accept to change this requirement so that it says: “2 (two) DICOM compatible monitors, minimum 2 Mp resolution, or one DICOM compatible monitor diagonal minimum 26.5 inch”?
Answer 7: Not accepted. It is more comfortable work with two monitors especially when two sessions are opened.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 4 od 32 tačka 8.12. zahteva se između ostalog: „DICOM Get work list (HIS/RIS)“.
Radne liste su potrebne na modalitetu da bi tehničar video kog pacijenta sledeće pregleda, a ne na dijagnostičkoj radnoj te po našim saznanjima ne postoji sredstvo za pregled dijagnostičkih snimaka koje poseduje ovu funkcionalnost.
Pitanje 8: Da li se iz navedenih razloga prihvata izbacivanje ovog zahteva iz tehničke specifikacije?
In the document Technical_Specifications_IOP5-2017RD on page 4 of 32 line number 8.12 the following requirement is listed among others: “DICOM Get work list (HIS/RIS)”.
Work lists are needed on the modality so that the technician could see which the next patient to be examined is, and not on the diagnostic workstation, so according to our knowledge there is no means for viewing the diagnostic images that has this functionality.
Question 8: Due to the reasons above, do you accept to remove this requirement from the technical specifications?
Answer 8: Not accepted. It is basic request.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 4 od 32 tačka 9.1. zahteva se između ostalog: „Workstation“ i „RIS/ PACS compatible“.
Samo jedan svetski proizvođač ima u ponudi ovakav uređaj.
Pitanje 9: Da li se iz navedenih razloga prihvata izbacivanje ovog dela zahteva iz tehničke specifikacije?

In the document Technical_Specifications_IOP5-2017RD on page 4 of 32 line number 9.1 the following requirement is listed among others: “Workstation” and “RIS/ PACS compatible”.
Only one manufacturer in the world offers such a device.
Question 9: Due to the reasons above, do you accept to remove this part of the requirement from the technical specifications?
Answer 9: Not accepted. It is basic request.
U dokumentu Technical_Specifications_IOP5-2017RD na strani 4 od 32 tačka 9.2. zahteva se: „DICOM color printer on photo paper or X-ray gray scale film “.
Samo jedan svetski proizvođač ima u ponudi ovakav uređaj.
Pitanje 10: Da li se prihvata izmena ovog zahteva tako da glasi: „DICOM X-ray gray scale film printer“?
In the document Technical_Specifications_IOP5-2017RD on page 4 of 32 line number 9.2 the following requirement is listed: “DICOM color printer on photo paper or X-ray gray scale film”.
Only one manufacturer in the world offers such a device.
Question 10: Do you accept to change this requirement so that it says: “DICOM X-ray gray scale film printer”?

Answer 10: Not accepted. Both features are necessary.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 6 od 32 tačka 2.3. zahteva se: „Floating tabletop of radio transparent material, length of table 260 cm or more, width of table 50 cm or more but not to wide in order to avoid collision with C- arm lateral angulations. To provide stepping DSA table movement. „Metal free“ area of table to be 200 cm or more, in length. There must be cranial-caudal tilt“.
Sistem koji nudimo ima širinu stola od 45 cm. Takođe, pacijent sto koji ima samo kranio-kaudalni tilt nije pogodan za hitne hirurške intervencije na pacijentu (ako do toga dođe) već lateralni tilt u levu i desnu stranu.

Pitanje 11: Da li se prihvata izmena ovog zahteva tako da glasi: „Floating tabletop of radio transparent material, length of table 260 cm or more, width of table 45 cm or more but not too wide in order to avoid collision with C- arm lateral angulations. To provide stepping DSA table movement. „Metal free“ area of table to be 200 cm or more, in length. There must be cranial-caudal and lateral left/right tilt“?
In the document Technical_Specifications_IOP5-2017RD on page 6 of 32 line number 2.3 the following requirement is listed: “Floating tabletop of radio transparent material, length of table 260 cm or more, width of table 50 cm or more but not too wide in order to avoid collision with C- arm lateral angulations. To provide stepping DSA table movement. “Metal free” area of table to be 200 cm or more, in length. There must be cranial-caudal tilt”.
The system we offer has the width of table of 45 cm. Also, the patient table that has only the cranial-caudal tilt is not suitable for urgent surgical interventions on the patient (if it comes to that), but the lateral left/right tilt is.
Question 11: Do you accept to change this requirement so that it says: “Floating tabletop of radio transparent material, length of table 260 cm or more, width of table 45 cm or more but not too wide in order to avoid collision with C- arm lateral angulations. To provide stepping DSA table movement. “Metal free” area of table to be 200 cm or more, in length. There must be cranial-caudal and lateral left/right tilt“?
Answer 11: Partially accepted. The only change could be about width of table that can be 45 cm or more. All other requests stay the same.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 8 od 32 tačka 5.7. zahteva se: „Acquisition matrix 2000x1500 (approximately), with highest acquisition speed of 30 fps“.
zahtev je nejasan da li je potrebno da detektor oba zahteva zadovoljava pojedinačno ili u kombinaciji što smatramo da nema proizvođača koji ga zadovoljava.

Pitanje 12: Da li se prihvata izmena ovog zahteva tako da glasi:
„5.7.1.: Acquisition matrix 2000x1500 (approximately), with highest acquisition speed of 30 fps“
„5.7.2.: with highest acquisition speed of 30 fps“?
In the document Technical_Specifications_IOP5-2017RD on page 8 of 32 line number 5.7 the following requirement is listed: “Acquisition matrix 2000x1500 (approximately), with highest acquisition speed of 30 fps”.

The requirement is unclear on whether it is necessary for the detector to meet both of the requirements individually or combined, because we believe there is no manufacturer who could meet this requirement.
Question 12: Do you accept to change this requirement so that it says:
"5.7.1.: Acquisition matrix 2000x1500 (approximately), with highest acquisition speed of 30 fps"
"5.7.2.: with highest acquisition speed of 30 fps"?
Answer 12: Not accepted. It is just about capacity space of acquired data.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 9 od 32 tačka 6.14. zahteva se: „System capacity to be 50 000 (or more) images in 2000x1500 (approximately) matrix; 12 bits; with antivirus integrated system protection and data protection".
Kapacitet sistema se obično definiše za matricu veličine 1024x1024, i tako je i bilo definisano na svim tenderima za angio-salu u Srbiji bez obzira na naručioca.

Pitanje 13: Da li se prihvata izmena ovog zahteva tako da glasi: „System capacity to be 50 000 (or more) images in 1024x1024 matrix; 12 bits; with antivirus integrated system protection and data protection"?
In the document Technical_Specifications_IOP5-2017RD on page 9 of 32 line number 6.14 the following requirement is listed: "System capacity to be 50 000 (or more) images in 2000x1500 (approximately) matrix; 12 bits; with antivirus integrated system protection and data protection".
The system capacity is usually defined for the 1024x1024 matrix size and this is the way it was defined in all tenders for angio-suites in Serbia regardless of the Contracting Authority.

Question 13: Do you accept to change this requirement so that it says: "System capacity to be 50 000 (or more) images in 1024x1024 matrix; 12 bits; with antivirus integrated system protection and data protection"?
Answer 13: Not accepted. Pixel matrix must be in proportion with acquired image that can be 40x30 cm (approx.).

U dokumentu Technical_Specifications_IOP5-2017RD na strani 11 od 32 tačka 7.8. između ostalog zahteva se: „DICOM Modality Worklist, DICOM Radiation Dose Structured Report".
Kako se ovaj zahtev odnosi na dijagnostičku radnu, ona je deo sistema i učitava slike koje su već nastale na sistemu (angio-Sali) dakle pacijent ne dolazi na pregled na dodatnu radnu stanicu jer ona sama za sebe nije dijagnostičko sredstvo a radne liste postoje samo na dijagnostičkim sredstvu, već se na njoj dodatno obrađuje slika. Takođe sama radna stanica ne vrši zračenje pacijenta nego angio-sala pa su dva navedena zahteva nesuvisla.

Pitanje 14: Zbog svega navedenog da li se prihvata da se dva sporna zahteva izbace iz tačke 7.8 na strani 11 od 32 tehničke specifikacije?
In the document Technical_Specifications_IOP5-2017RD on page 11 of 32 line number 7.8 the following requirement is listed among others: "DICOM Modality Worklist, DICOM Radiation Dose Structured Report".
As this requirement relates to the diagnostic workstation, which is a part of the system and loads the images already created in the system (in the angio-suite) so the patient does not come for examination to the additional workstation because by itself it is not a diagnostics tool and work lists exist only on the diagnostics tools, but it is used for additional processing of the image. Also the workstation itself does not have any radiation on the patient but the angio-suite does so the two mentioned requirements are unclear.
Question 14: Due to all of the above, do you accept to remove the two disputable requirements from line number 7.8 on page 11 of 32 of the technical specifications?
Answer 14: Not accepted. It is basic request.
U dokumentu Technical_Specifications_IOP5-2017RD na strani 11 od 32 tačka 8.4. zahteva se: „Contrast injector; volume of syringe 150 ml or more, with air detection and transducer compatible; mounted on patient table".
Na ovaj zahtev može da odgovori samo jedan proizvođač injektora na svetu.

Pitanje 15: Da li se prihvata izmena ovog zahteva tako da glasi: „Contrast injector with changeable flow real time control; volume of syringe 150 ml or more; mounted on patient table or separate trolley" kako bi se omogućila veća konkurencija ponuđača?
In the document Technical_Specifications_IOP5-2017RD on page 11 of 32 line number 8.4 the following requirement is listed: "Contrast injector; volume of syringe 150 ml or more, with air detection and transducer compatible; mounted on patient table".
Only one injector manufacturer in the world can meet this requirement.

Question 15: Do you accept to change this requirement so that it says: "Contrast injector with changeable flow real time control; volume of syringe 150 ml or more; mounted on patient table or separate trolley" in order to allow for greater competition among the bidders?
Answer 15: Not accepted. Mentioned features make easier working process in high flow surrounding.

U dokumentu Technical_Specifications_IOP5-2017RD na strani 12 od 32 tačka 8.5.7. zahteva se: „FFR, iFR (or equivalent) enabled image on control room monitor, compatible with FFR catheters of all producers (St.Jude, VOLCANO,ACIST…)".
Ovakvi zahtevi su nezahvalni za davanje ponude, da li iko na svetu zna koji su sve proizvođači FFR katetera, možda se baš u trenutku pisanja ovog dokumenta pojavio neki novi, možda će se pojaviti dva dana pred otvaranje ponuda. Smatramo da bi bilo poželjno da svakako korisnik ima mogućnost izbora FFR katetera.

Pitanje 16: Da li se prihvata izmena ovog zahteva tako da bude precizniji i glasi: „FFR, iFR (or equivalent) enabled image on control room monitor, compatible with FFR catheters of at least 2 producers?
In the document Technical_Specifications_IOP5-2017RD on page 12 of 32 line number 8.5.7. the following requirement is listed: "FFR, iFR (or equivalent) enabled image on control room monitor, compatible with FFR catheters of all producers (St. Jude, VOLCANO, ACIST…)".
Such requirements are tricky for bidding, does anyone in the world know all the manufacturers of FFR catheters, maybe just as we are writing this documents a new one has emerged, maybe they will emerge two days before the opening of bids. We believe it would be desirable for every beneficiary to have to possibility of choice of the FFR catheter.
Question 16: Do you accept to change this requirement to make it more precise so that it says: "FFR, iFR (or equivalent) enabled image on control room monitor, compatible with FFR catheters of at least 2 producers?"
Answer 16:
Not accepted.
Pitanje 17: U dokumentu Technical_Specifications_IOP5-2017RD na strani 12 od 32 tačkama 8.6 i 8.7 definisana su posebna medicinska sredstva koja normalno niti proizvode niti isporučuju proizvođači angio-sala. Obzirom na nepoznato stanje tržišta u Srbiji ovih sistema, u skorije vreme nije bilo nabavki prema javno dostupnim podacima, da li se prihvata da se tačke 8.6 i 8.7 na strani 12 od 32 dokumenta Technical_Specifications_IOP5-2017RD izbace?
Question 17: In the document Technical_Specifications_IOP5-2017RD on page 12 of 32 in line numbers 8.6 and 8.7 there are special medical devices listed which are usually not manufactured or distributed by manufacturers of angio-suites. Due to the unknown situation on the market in Serbia for such systems, there were no procurements lately with publicly available information, do you accept to remove line numbers 8.6 and 8.7 on page 12 of 32 of the document Technical_Specifications_IOP5-2017RD?
Answer 17:
Partially accepted. Points 8.6 and 8.7 are merged in one. Integrated FFR plus OCT or FFR plus IVUS. Integrated in angio patient table in angio-suite. Real time coregistration with angiography image.

Public Procurement Commission