Procurement of Medical Imaging Equipment

no. IOP/5-2017/RD

Clarification no. 8

Issued on 16.10.2017.

Question1:

Item 4: Digital angiography X-ray system for diagnostic cardiac and interventional procedures for Clinical Hospital Center „Zemun“

Specifications changes (with bold):

*Specification no 1.1: Monoplane ceiling **or floor** mounted C-arm which enables to the operators free access to the patient from all sides during intervention, without patient moving*

Please confirm if it is sufficient to offer floor angio equipment as well as ceiling mounted. Ceiling mounted gantry technology has several disadvantages:

- one of them is sterility (since ceiling mounted rails collect dust and may cause sterility concerns in the lab),
- the other is the added cost for the cathlab construction (reinforcing/strengthening the ceiling due to heavy equipment weight). [redacted] company has decided and proven over time, that all cardiac procedures (from simple PCI to complex structural heart interventions) can be done with the same efficiency with floor mounted gantries as with ceiling mounted gantries (see the referenced testimonials).

Answer 1: Ceiling mounted C-arm is in standard offering of most vendors. In angio suite ceiling rails are mounted anyway for monitor mount so ceiling suspended C-arm does not increase sterility issue, in fact it reduces it, as no foreign matter can collect around and under C-arm mount as it is possible with floor mounted systems. Also in case of KBC Zemun there will be no influence on cost of construction as floor has special construction so whether floor or ceiling will be reinforced is pricewise same. There will be no change in specification.

Question2:

*Specification no 1.3: Possibility of continuous C-arm movement **or table panning** in longitudinal direction for peripheral anatomy coverage, without patient moving and coverage of at least 200cm, from left and right patient table side*

Please confirm the above modification of the specification regarding movement. The combination of the table and the gantry must ensure the access, and the x-ray coverage of the patient regardless of the actual mechanical solution. Therefore, moving a c-arm longitudinally, or panning with the table longitudinally provides the same x-ray coverage.

Answer 2: While moving of C-arm or panning the table is same regarding coverage, it is far from same regarding workflow in cathlab. If only C-arm is moved this means staff does not move, it is less risky

for patient to detach ECG cables, IBP transducers or even worse pull some wires as there is no patient table movement There will be no change in specification.

Question3:

Specification no 1.4: Possibility of hand examination (for creating shunt, venography, also during PCI with radial/brachial access) ~~***with only C-arm positioning, without patient table rotation***~~

Please confirm the above modification of the specification regarding hand exams. The combination of the table and the gantry must ensure the access, and the x-ray coverage of the patient regardless of the actual mechanical solution. Therefore, if table rotation is used for better patient access, it should be allowed as it is specified in the datasheet of the offered equipment.

Answer 3: Similar to previous answer. Patient table is not preferred in cathlab. If same requirement can be met only by moving C-arm then this is far better solution. This requirement is met by most vendors. There will be no change in specification.

Question4:

Specification no 1.6: SID range at least 90-119 cm
CRA angulations at least 50° - CAU angulations at least 45°
LAO rotation at least ***105°*** ~~***120°***~~ *- RAO rotation at least* ***105°*** ~~***120°***~~

Please confirm the above modification of the specification regarding gantry rotation. The referenced clinical proofs show that the [redacted] systems can ensure state of the art clinical performance (dose/image quality/clinical outcomes), independently from a slightly smaller LAO/RAO rotation range.

LAO/RAO +/- 105° is a sufficient range to visualize the cardiac vessel structures from all clinically relevant angulations (which is +/- 90°).

Answer 4:Steep RAO/LAO angulations enable better side access and smaller SID in that position. Most vendors offer requested angulations. There will be no change in specification

Question 5:

Specification no 1.11: Possibility of C-arm rotation around vertical axis, which pass through detector center and X-ray tube center, at ***±100°*** ~~***±135°***~~

Please confirm the above modification of the specification regarding gantry rotation. The referenced clinical proofs show that the [redacted] systems can ensure state of the art clinical performance (dose/image quality/clinical outcomes), independently from a slightly smaller vertical C-arm rotation range.
L-arm rotation (or vertical C-arm rotation) +/- 100° is a sufficient range to visualize the cardiac vessel structures from all clinically relevant angulations (which is +/- 90°).

Answer 5: Vertical C-arm rotation in requested range enables free head access as well as more room during ICD, Pacemaker implantations. There will be no change in specification.

Question6:

Specification no 2.2: Tabletop movement in longitudinal direction at least 100 cm and in lateral direction at least ***±14*** ~~***±17,5***~~ *cm*

Please confirm the above modification of the specification regarding table lateral movement.

The referenced clinical proofs show that the [redacted] systems can ensure state of the art clinical performance (dose/image quality/clinical outcomes), independently from a slightly smaller table lateral movement range.
+/- 14 cm is a sufficient range to cover the full anatomy of the patient (since the [redacted] detector is 20.5 cm in width, the patient abdominal coverage is 48.5 cm which is sufficient to visualize all the cardiac vessel structures.

Answer 6: Specification 2.2 is amended and now states: "Tabletop movement in longitudinal direction at least 100 cm and in lateral direction at least ±14 cm"

Question7:

Specification no 3.5: Generator has at least double inverter ***or the angiograph has a fluoro UPS (uninterruptable power supply)*** *and in case of malfunction* ***the backup system can*** ~~***of one inverter, second must***~~ *insensibly take over operation* ***to provide x-ray imaging***

Please confirm the above modification of the specification regarding generator.

The purpose of this requirement is to ensure continuous operation even in case of a power failure. However, the original requirement is unique to a single vendor (Toshiba) therefore limits competition. The new requirement allows other vendors' equipment to be offered as well. As this change will enable more manufacturers to participate, it will enhance the competition, which will finally reflect in more favorable bids.

Answer 7:

Specification 3.5 is amended: "Generator has at least double inverter or angiograph has a fluoro UPS (uninterruptable power supply) and in case of malfunction the backup system can insensibly take over operation to provide x-ray imaging or other equivalent technology for inverter protection.

Question8:

Specification no 4.7: Automatically synchronized detector and collimator for providing of correct image on the display ~~***rotation independent of C-arm position***~~*, rotation range min. ±70°*

Please confirm the above modification of the specification regarding detector and collimator.

The referenced clinical proofs show that the [redacted] systems can ensure state of the art clinical performance (dose/image quality/clinical outcomes), independently from the image position. The image of the Innova systems are being adjusted to the nearest 45 degrees (therefore may be slightly rotated on the screen within +/-45 degrees range). However, they are synchronized with the collimator as the modified requirement requests.

Answer 8: According to information's available to general population more than one vendor has this feature. There will be no change in specification.

Question9:

Specification no 5.8: Maximum allowed size of the flat panel housing with collision protection is ***350 x 350 mm*** ~~***325 x 300 mm***~~

Please confirm the above modification of the specification regarding housing dimensions.

The referenced clinical proofs show that the [redacted] systems can ensure state of the art clinical performance (dose/image quality/clinical outcomes), independently from size of the detector housing.

The size of the flat detector housing implicitly determines the achievable gantry angulations, which are already specified ion requirement 1.5.

Since these 2 technical characteristics that are tightly correlated, there is no need for requirement 5.8 – so instead of modification, it can also be omitted.

Answer 9:

Smaller size of detector housing enables not only steeper angulations but also smaller SID for same angulation compared to system with larger detector housing and same angulation. This leads to sharper image and dose reduction for patient. There will be no change in specification.

Question10:

Specification no 7.5: ~~***Anatomically***~~ *image zoom without x-ray dose increasing "Digital Acquisition Zoom" which can be applied on all available field of views with possibility of selection at least 4 different zoom factors in acquisition programs in following operating modes: Fluoroscopy, "Roadmap Fluoro", Digital angiography, Digital Subtraction angiography.*

Please confirm the above modification of the specification regarding zooming.

A well-known image processing principle is that when *anatomical (or physical) zoom* (or so called "Field of View" change, or magnification) happens, the dose levels are changed accordingly. When such anatomical zoom is applied, the dose is increased slightly (although not in a linear fashion).

When *digital zoom* is applied the dose levels do not change.

The requirement mixes up the 2 zoom methods. Therefore, the correction above is necessary to avoid a technically conflicting requirement.

Answer 10: Specification 7.5 is amended: “Image zoom without x-ray dose increasing “Digital Acquisition Zoom” which can be applied on all available field of views with possibility of selection at least 4 different zoom factors in acquisition programs in following operating modes: Fluoroscopy, “Roadmap Fluoro”, Digital angiography, Digital Subtraction angiography.”

Question11:

Specification no 7.6: System of data protection with at least 1 redundancy disc (RAID 5) ***or by image storage in parallel on postprocessing workstation.***

Please confirm the above modification of the specification regarding data protection.
The original requirement is unique to a single vendor (Toshiba) therefore limits competition. The new requirement allows other vendors' equipment to be offered as well. As this change will enable fair competition, it will reflect in more favorable bids.

Answer 11: According to information’s available to general population more than one vendor has this feature. Still, we are amending specification no 7.6: “System of data protection with at least 1 redundancy disc (RAID 5) or by image storage in parallel on postprocessing workstation

Question12:

Specification no 7.7: Possibility of display at least ***1*** ~~***2***~~ *physiological signal which are taking over during appropriate image acquisition. Physiological signals are stored together with appropriate images and sent together with appropriate DICOM data.*

Please confirm the above modification of the specification regarding displayed physiological signals on the image.
The specification asks for a Hemodynamic recording system as a sophisticated way to store ECG data (physiological signals) in section 9 (*System for hemodynamic measurements*).
The Hemodynamic recording system stores a 12 lead ECG, which is *much more* than the 2 ECG signals requested in requirement 7.7.
Showing 2 ECG signals on the displayed image are therefore unnecessary, and a single ECG signal is enough to give indication on top of the visible and stored hemodynamics data.

Answer 12: Specification 7.7 is amended: “Possibility of display at least 1 physiological signal which are taking over during appropriate image acquisition. Physiological signals are stored together with appropriate images and sent together with appropriate DICOM data”.

Question 13:

LOT 1, Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"

Suggested Specifications changes (with bold):

Specification 2.3: Floating tabletop of radio transparent material, length of table 260 cm or more, width of table ***46 cm*** ~~***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

Specification no 5.1: Detector size 295 mm (or more up to ***410 mm*** ~~***305 mm***~~*) x 395 mm or more,* ~~***rotatable***~~

Specification no 5.4: Number of field of views – ***4 or more*** ~~***5 or more***~~

Specification no 5.8: ***In case of rectangular detector,*** *synchronized rotation of detector and collimation regardless C-arm position*

Specification no.6.9: Road mapping (RM) with automatic "pixel shift" correction and superimposition of live fluoroscopic image and reference image ~~***in real time***~~*. LIH RM and DSA RM with changeable superimposition and tableside command.*

Specification no 6.15: System capacity to be 50 000 (or more) images in 2000x1500 (approximately) matrix; 12 bits; ~~***with antivirus integrated system protection and***~~ *data protection*

Please confirm the above modification of the specifications regarding equipment.
The referenced clinical proofs show that the [redacted] systems can ensure the requested state of the art clinical performance (dose/image quality/clinical outcomes), independently from the above specification changes.

Specification 2.3: It is acceptable regarding tabletop to be width of 46 cm or more.

Specification 5.1: Not acceptable. It is already explained.

Specification 5.4: It is acceptable if 4 fields of view can provide magnification necessary for coronarography.

Specification 5.8 Not acceptable. It must be rectangular flat panel detector with synchronized rotation and collimation regardless C-arm position.

Specification 6.9: Not acceptable. Road mapping must be in real time.

Specification 6.15: Not acceptable. Vendor must provide preferable antivirus protection in case of warranty rights.