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IOP/6-2017/RD
Clarification no. 11
Issued on 26.09.2017.

Position 7.12 Volume CT scanner

Q1:

1. Specification no.3 : "Physical gantry tilt at least ±20°"

New technology CT may have digital tilt rather than physical, without any compromise to dose that the patients receive, due to very low dose examinations they are able to perform due to latest technology iterative reconstruction techniques, such as ASIR-V that enables up to 82% dose reduction. On top of that, Revolution CT has preset protocols that can be selected prospectively, which allows images to be reconstructed at a specified tilt angle. This capability, combined with organ dose modulation and tilted head holder accessory for the patient allows for reducing the dose to sensitive organs such as the eyes while also reducing dental artifacts. Therefore, in order for [redacted] to be able to participate, we kindly ask you to accept also digital tilt at least ±20? Enabling more manufacturers to participate will reflect in more favorable bids for the end user.

Answer Q1: Specification no.3 will not be changed. Gantry tilt is a feature that has been present on CTs form early models up to contemporary systems. Real tilt rather than digital provides more flexibility, and no need to reposition patient for exam due to usage of right tiltable head holder.

Q2:

2. Specification No. 5 : "Vertical movement of patient couch in range of at least 60 cm with the lowest height maximum 40 cm"

GE's Revolution CT has table that features a next generation table capable of 300 mm/s travel speed. This enables fast scanning for longer range anatomies. The table has also been designed with 10 x more stiffness to reduce deflection under heavy load and provide the best possible images even under heavy load conditions. Also, controls on gantry for elevation and cradle movement. Foot pedals on both sides of table for fast elevation. Cradle position controlled from OC for prescribed scans. The table goes down to 56 cm without any problem to patient positioning.

Since this specification limits the competition, without significant clinical value, in order for [redacted] to be able to participate, we kindly ask you to accept vertical movement of patient couch in range of at least 80 cm with the lowest height maximum 60 cm.

Answer Q2: Specification no.5 is changed and now states: "Vertical movement of patient couch in a range of at least 37 cm with the lowest height maximum 60 cm". Although patient access is very important to us and lowest height of 40 cm enables much more access to older and children we accept and change specification no.5.

Q3:

3. Specification No.17 "Number of detector elements in one detector row excluding reference detector elements at least 890"

The scanner Revolution CT features next generation "Gemstone Clarity" detector which is a state of the art technology, with ground breaking technology and also features Gemstone scintillator with the industry's best primary speed & afterglow specifications.
The Gemstone Clarity detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems. Combined with Volume HD (VHD) reconstruction technology, the system delivers excellent image quality at full 160mm coverage to enable whole organ imaging. Further, the 3D Collimator reduces scatter to primary ratio by more than 50% compared to a 160mm system with a 1D post patient collimator. The Gemstone Clarity detector enables high definition CT imaging with a revolutionary, extremely fast scintillator. The scintillator material is an isotropic ceramic with cubic structure highly uniform and translucent. (Cubic structures offer better transparency to that of Gadolinium Oxysulfide (GOS) which has a hexagonal lattice). 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.
- Scintillator speed : 0.03 µs (100 times faster than GOS)
- Afterglow: 0.001% - 4 times lower than GOS
- Radiation damage: 0.03% - 20 times less than GOS
The Gemstone Clarity Data Acquisition Subsystem (DAS) features 3 times faster trigger rates capable of supporting features such as High definition imaging up to 2496 views per rotation and fast kV switching mode with 1968 views per rotation even at 0.2s rotation speed. The detector elements are 832 per detector row. Therefore, in order for [redacted] to be able to participate we kindly ask you to accept number of detector elements in one detector row excluding reference detector elements at least 800?

Answer Q3: Specification no.17 will not be changed. Higher number of detector elements enables more data per view, which in turn creates sharper images with higher resolution.
Q4:

4. Specification No. 36. "Software to predict movement during image acquisition triggered with ECG signal in cardiac CT studies in volumetric image acquisition and use of anatomically correct reconstruction in order to minimize artifacts caused by movement"

[redacted] Revolution CT due to the novel technology and the technical characteristics of the whole system cardiac exams are done with only axial mode in one rotation and heartbeat, and we comply with the software to predict movement during image acquisition triggered with ECG signal in cardiac CT studies and use of anatomically correct reconstruction in order to minimize artifacts caused by movement. Therefore, we kindly ask you to remove the term 'volumetric image acquisition" in order for [redacted] to be able to participate.

Answer Q4: Specification no.36 will not be changed. Whole point of purchasing volumetric scanner is to have Volumetric acquisitions in sensitive imaging areas like heart due to its movement or brain due to brain perfusion or body perfusion. Axial heart acquisition on such a scanner is technological step back and cannot be accepted.

Q5:

Item No. 7.6 - MR system 1.5 T with open bore

Magnet 1.5T

5. Specification no 6, 7

The Magnet is the most critical component of an MR system. It is the most expensive component to build and its quality offers specific advantages to the clinical capabilities of the system like signal uniformity and consistent fat saturation especially over larger FOV and off-center imaging (ie Body, MSK). The specification that determines the performance of a magnet is its homogeneity as this is described at various Diameters of Spherical Volumes (DSV) from the isocenter in ppm measured with standardized procedures.

- **We suggest** that the DSV for 1ppm guaranteed homogeneity measurement does not exceed 40cm which is a routine FOV for body and off-center imaging *(with reference to specification 6)*.
- **We suggest** that the magnet length is limited to 175cm as shorter magnets typically cannot exhibit a high homogeneity performance. A length of 175cm especially for a wide bore system does not have significant impact to the openness perception of the patient. This will allow systems with better magnet homogeneity to be offered *(with reference to specification 7)*

Answer Q5. Customer has defined specification according to its clinical needs. Positions 6 and 7 of Item no. 7.6- MR system 1.5T with open bore are defined with respect to provide participation of several vendors of MR system. With such requirements all vendors should offer the latest generation MR systems. In new technologies of MR systems, homogeneity is not the only criteria for performance of

MR system. Also, all leading producers of MR systems have new generation magnets designed in so called short geometry (150cm or less).

Q6:

Gradient System

6. Specification no. 12, 13

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 tenderbooks 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.

Based on the current technological MR advancements:

- **We suggest** that the minimum timing parameters TE/ESP/TR of 2D FSE/TSE and 2D EPI acquisitions and minimum TE and minimum TR of 3D GRE acquisitions are requested and evaluated *(suggestion for additional specification).*
- **We suggest** that the maximum amplitude per axis at maximum FOV is specified as not less than 34mT/m *(with reference to specification 12)*

We suggest that the maximum slew rate per axis at maximum FOV is not specified as not less than 150T/m/s *(with reference to specification 13)*

These specifications will mandate a level of equipment that can perform adequately in the demanding clinical applications that are currently requested to diagnose specific conditions.

Answer Q6:

6. We agree not all parameters has been taken into account, like e.g. timing parameters you proposed and many others you didn't mention, but technical specification for MR system is defined based on evaluation of most clinically relevant parameters. We cannot accept suggestions for positions 12 and 13. In these positions we defined minimum values so bidders who are going to offer MR systems with maximum amplitude per axis at maximum FOV of 34 mT/m and maximum slew rate per axis at maximum FOV of 150 T/m/s, will meet minimum requirements.

Q7:

RF System

7. Specification no 15, 19, 21, 22, 23, 24, 25, 26, 27, 28

The RF system comprises of the transmission and reception subsystems. In 1.5T transmission architecture is basically common among manufacturers with differences in the power of the RF amplifier. This is adequately specified at 16kW.

The RF reception subsystem combined with the RF coils is another decisive factor of the image quality and scan time capabilities of an MR scanner. Optical digital RF architecture is a technology currently used by the leading MR manufacturers. With this technology, the digitization of the signal is performed earlier, either in the RF coil itself or the system bore, inside the magnetic field. This technology offers a significant increase in SNR with all used coils in the case that the signal is digitized on the bore or the compatible coils in the case that the digitization is performed in the coil. This SNR increase which can exceed 25% compared to the previously used analogue architecture, offers a combination of scan time decrease and image quality improvement (SNR, resolution).

A second significant characteristic of the RF receive subsystem is its independent channels capacity. With more independent channels the system can offer improvements in image quality (SNR) and imaging speed (parallel imaging acceleration factors). The number of independent RF channels is to be considered with respect to the number of channels of the offered RF coils or combinations of coils in a single imaging FOV with relevance to any valid clinical scenario (ie max FOV body imaging, max FOV neurovascular imaging, MSK imaging, pelvic imaging, etc). A system that offers equal number of channels in the imaging coils with another system but a higher number of independent RF channels has no clinical benefit over the other system. The number of used independent channels per clinical scenario is what determines the imaging capabilities of the MR system.

- **We suggest** that the architecture of the RF receive system is specified as of optical-digital technology, to secure a purchase of a system of current (up-to-date) technology *(suggestion for additional specification)*.
- **We suggest** that the number of simultaneous RF channels is increased to minimum 32 channels which is currently a common capability of all major manufacturers for the wide bore segment of 1.5T MR systems, and can secure up-to-date imaging results. *(with reference to specification 15)*
- **We suggest** that the requested coil technology is described as integrated with the posterior coil embedded in the patient table as this is a common capability among all major manufacturers and considerably enhances the workflow *(with reference to specification 19)*.
- **We suggest** that the separate dedicated body coil is specified to offer a minimum of 50cm scan range (upper abdominal area and pelvis) as this is the commonly used clinical scenario. For the majority of the manufacturers a request for a coverage that exceeds 50cm will force them to offer coils that are able to cover an area considerably larger than 100cm which will not add any clinical benefit to the offered system. **We also suggest** that this coil is specified

with minimum 16 coil elements as this is a common capability of all major manufacturers *(with reference to specification 21)*.

We suggest that the number of elements of the head and neck coil is specified at minimum 20 *(with reference to specification 22)*.

We suggest that the number of elements of the Spine coil is specified at minimum 32 *(with reference to specification 23)*.

We suggest that for MSK coils both Flexible and Rigid coils can be accepted and the minimum number of channels is specified at minimum 16. Additionally, since an advantage of the flexible coils is that they can be used for various anatomies or "difficult" imaging scenario's **we suggest** that these coils should not be requested to be dedicated as this offers no clinical advantage *(with reference to specification 24)*.

We suggest that the number of elements of the Breast coil is specified at minimum 8 with a biopsy compatibility *(with reference to specification 25)*.

We suggest that the multichannel coils for imaging of small Field of Views and small structures are not described as dedicated as these coils are commonly used for various applications including MSK imaging (TMJ, wrist, etc) *(with reference to specification 26)*.

We suggest that a flexible or rigid coil is accepted for shoulder imaging as flexible coils offer better conformance with the anatomy, more positioning capabilities (ABER position) and at least equal image quality capabilities with rigid coils of equal number of channels *(with reference to specification 27)*.

We suggest that the number of channels of the dedicated Knee coil is increased to minimum 15 channels as this is a common capability of all major manufacturers and enhances the image quality at an optimal scan time for knee exams *(with reference to specification 28)*.

Answer Q7: Suggestion for Position 15 is partially acceptable and changed to: "Digital radio-frequency system (built in optical digital technology) with simultaneous signal recipient of minimum 24 independent channels."

In position 15, it is defined minimum number of channels of 24, so bidders who are going to offer systems with 32 channels will meet minimum requirements.

Under position 19 customer defined latest generation of integrated coil technology with commercial names of leading MR producers. Request is defined precisely and there is no changes in this position.

Customer defined position 21 according to its clinical needs. Imaging of anatomy area from neck to pelvis requires coverage of min 65cm. For such cases, 50cm is not sufficient.

Coils specification under positions 20, 21, 22, 23, 24, 25, 26, 27 and 28 are defined according to customer clinical needs and with respect to provide participation of several vendors.

Q8:

Sequences and Imaging techniques

8. Specification no 76

The sequences and imaging techniques are the tools that enable physicians to perform all required diagnostic procedures. These are on the first line of technological development and are continuously updated to meet current standards. New imaging techniques emerge that enable physicians to improve their diagnostic confidence or address pathologies that exceeded the imaging capabilities of MR in the past (non-contrast angiographies, multi-arterial liver studies, poly-parametric prostate studies, perfusion quantification, cartilage mapping, fat-fraction quantification, etc).

- **We suggest** that a soft tissue dynamic imaging technique implementing view-sharing for fast dynamic studies with fat saturation for liver multi-arterial studies is requested *(suggestion for additional specification)*.
- **We suggest** that an imaging technique that corrects for the distortion induced by MR compatible implants in joints both in plane and through plane is requested *(suggestion for additional specification)*.
- **We suggest** that a technique that offers high resolution small Field of View diffusion imaging is requested *(suggestion for additional specification)*.

Silent scanning is a generic reference to a variety of imaging techniques that differ from each other in terms of achievable noise reduction, compatible sequences and exams coverage. The sequences that can offer silent scanning at a noise level that approaches ambient noise levels are zero TE or UltraShort TE techniques (like Silenz, Petra or equivalent).

- **We suggest** that a zTE or UTE silent technique is requested *(with reference to specification 76)*.
- **We suggest** that the silent scanning compatibility with Neuro, Spine and MSK exams is requested *(with reference to specification 76)*.
- **We suggest** that the silent scanning compatibility with FSE/TSE and DWI techniques is requested *(with reference to specification 76)*.

Answer Q8: 8. Sequences and imaging techniques are defined according to customer clinical needs. Position 76 is precisely defined and with respect to provide participation of several vendors

Q9:

Item 7.5 - Mobile Ultrasound color doppler device with 2 probes - 1 pc

***Spec. 1**: Integrated color LCD or TFT high resolution display minimal diagonal 19" on artificial arm and handle on display for easier guidance to desired position*

The request for handle on the display monitor, limits competition significantly and does not allow big manufacturers with high performance ultrasound systems (such Philips, GE etc) to participate to the tender.

We kindly request to **remove the request for handle on display** and expand the specification, allowing for broader participation to the tender, and please accept the following modification:

Spec. 1 - Integrated color LCD or TFT high resolution display minimal diagonal 19" on artificial arm.

Answer Q9 (S1): Specification 1 is changed and states: "Integrated color LCD or TFT high resolution display minimal diagonal 19" on artificial arm". Although many vendors now have this kind of handle and we have several systems with such a feature and it is clearly easier to use them we accept request and change specification.

Q10:

***Spec. 11 :** Maximum scanning depth in B mode at least 40 cm*

The majority of the ultrasound systems in the market, have a maximum scanning depth up to 30 cm which is adequate for difficult to scan patients, in depth structures and for performing all the required examinations according to the international standards. The request for 40 cm scanning depth limits competition and does not allow [redacted] to participate to the tender with a high performance radiology ultrasound system that has a scanning depth of 33 cm.

We kindly request to expand the specification, as this minor deviation in scanning depth does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification :

Spec. 11 : Maximum scanning depth in B mode at least **33 cm**

Answer Q10 (S11): Specification no.11 will not be changed. Imaging depth of 40 cm has become standard in ultrasound. Most vendors have systems that are in line with this request.

Q11:

***Spec. 21 :** Possibility to display diagnostic image over entire area of the screen (Full Screen Display)*

The ultrasound system of [redacted] has a wide screen monitor 21.5" (bigger than the requested in the specs) that allows for multiple sizes of ultrasound image and capability for the user to increase display diagnostic image size. Given that the monitor has an already bigger size and the image size can be increased the manufacturer has not featured a full screen display.

We kindly request to expand the specification, given that every manufacturer has developed a different way to provide the user with images of the highest clinical diagnostic confidence, allowing for broader participation to the tender, and please accept the following modification:

Spec. 21 : Possibility to **increase** display diagnostic image over the screen.

Answer Q11 (S21): Specification no.21 will not be changed. Wide display of 21.5 inch still has lower height of 19 standard (4:3) display and therefore image is smaller.

Q12:

Spec. 41 : *Linear probe with operating frequencies in range from 7 till 12 MHz or more, with FOV not less than 56 mm.*

The request for FOV not less than 56 mm limits competition and does not allow [redacted] to participate to the tender with a high performance radiology ultrasound system that has a linear probe with FOV of 50 mm. This FOV combined with a high frequency range and matrix technology offers great spatial resolution and image uniformity from near to far field with high diagnostic confidence.

We kindly request to expand the specification, given that this minor deviation in FOV does not affect system's clinical diagnostic confidence, allowing for broader participation to the tender, and please accept the following modification:

Spec. 41 : Linear probe with operating frequencies in range from 7 till 12 MHz or more, with FOV not less than **50 mm.**

Answer Q12 (S41): Specification no.41 will not be changed. As this probe is mostly for soft tissue exams requested FOV enables coverage of entire thyroid and good coverage for breast exams. May vendors have in their offer such a probe.

Q13:

Item 7.7 - Ultrasound for Radiology with 4 probes - 1 pc

Spec. 1 : *Stationary ultrasound system on wheels with central brake, not portable by concept*

The majority of ultrasound systems in the market have locking mechanism on each wheel that provides rolling lock and caster swivel lock. The central brake does not offer any addition value to the system, however limits competition significantly.

We kindly request to expand the specification, allowing for broader participation to the tender, and please accept the following modification:

Spec. 1 : Stationary ultrasound system on wheels **with brakes**, not portable by concept

Answer Q13 (S1): Specification 1 will not be changed. Central Brake enables faster positioning of the systems. Many vendors offer this on their system.

Q14:

Spec. 3 : *High resolution LCD display minimum diagonal 23" on artificial arm*

The premium radiology ultrasound system of [redacted] has a LCD monitor with size 22" High-Resolution of the latest technology OLED display, providing excellent spatial and dynamic resolution.

We kindly request to expand the specification, as this minor deviation in the monitor size does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification :

Spec. 3 - High resolution LCD display minimum diagonal **22"** on artificial arm

Answer Q14 (S3): Specification 3 will not be changed. Most major vendors on their high end system for radiology offer 23" display.

Q15:

Spec 6 : *LCD touch - screen panel minimum 12" diagonal*

The request for 12" touch screen panel limits competition and does not allow [redacted] to participate to the tender with a premium radiology ultrasound system that has a LCD touch screen panel with size 10.1".
We kindly request to expand the specification, as this minor deviation in the touch screen size does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification :
Spec 6 : LCD touch - screen panel minimum **10.1"** diagonal

Answer Q15 (S6): Specification 6 will not be changed. Most major vendors on their high end system for radiology offer 12" touch screen LCD display.

Q16:

Spec. 9 : *- Maximum scanning depth in B mode of at least 50 cm*

The majority of the ultrasound systems in the market have a maximum scanning depth up to 30 cm which is adequate for performing all the required examinations. The request for 50 cm scanning depth limits competition and does not allow [redacted] to participate to the tender with a premium radiology ultrasound system that has a scanning depth of 33 cm.

We kindly request to expand the specification, as this minor deviation in scanning depth does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification :
Spec. 9 : - Maximum scanning depth in B mode of at least **33 cm**

Answer Q16 (S9): Specification 9 will not be changed. This is a specification for high end radiology system and such scanning depth is needed for bariatric patients.

Q17:

Spec. 26 : *Cine memory minimum 800 MB*

The request for 800 MB cine loop limits competition and does not allow [redacted] to participate to the tender with a premium radiology ultrasound system that has a cine memory of 776 MB.
We kindly request to expand the specification, since this minor deviation does not affect clinical efficiency of the system, allowing for broader participation to the tender, and please accept the following modification :
Spec. 26 : Cine memory minimum **770 MB**

Answer Q17 (S26): Specification 26 is changed and now states: "Cine memory minimum 700 MB"

Q18:

Spec. 34 : Convex matrix transducer
The request for matrix technology limits competition. [redacted] has developed advanced probe technologies such as XDclear that provides extreme image resolution and uniformity at extended depth.
We kindly request to expand the specification, so that every manufacturer can offer probe of the latest technology, allowing for broader participation to the tender, and please accept the following modification :
Spec. 34 : Convex matrix or other advanced technology transducer

Answer Q18 (S34): Specification 34 will not be changed. Matrix technology is nowdays recognized as superior technology in ultrasound imaging. Most major vendors on their high end systems offer matrix convex probes including GE M6C-D convex matrix probe.

Q19:

Spec. 36 : *Linear matrix superficial transducer with operating frequencies up to 24 MHz*

The request for matrix technology and for 24 MHz upper frequency of the linear probe limits competition and does not allow [redacted] to participate to the tender with a premium radiology ultrasound system that has a high frequency linear probe for superficial structures imaging with upper frequency of 18 MHz.
We kindly request to expand the specification, since this deviation does not affect clinical efficiency of the system, allowing for broader participation to the tender, and please accept the following modification :
Spec. 36 : Linear superficial transducer with operating frequencies up to **18 MHz**

Answer Q19 (S36): Specification 36 will not be changed. It is very well known about physics of ultrasound that higher frequency enables higher resolution with penalty o penetration. Obviously with this probe high resolution is needed and decrease of specification by 25% is not acceptable.

Item 7.4: RADIOGRAPHY SYSTEM WITH TWO FIXED PLAT PANEL DETECTORS FOR UNIVERSAL RADIOGRAPHIC PROCEDURES WITH HIGH PATIENT THROUGHPUT, WITH CEILING MOUNTED TUBE SUPPORT AND HORIZONTAL AND ERTICAL BUCKIES

Q20:

Specification no. 4: Highest height of patient table top: at least 950 mm

There is no any radiography procedure which needs 95cm table top height. Since this is non interventional table it has no clinical relevance. The 85cm table is more than convenient to manage any exam on the table. We suggest to accept 85cm as min. criteria.

Answer Q20: Specification no.4 will not be changed. Many Vendors offer systems with such table travel.

Q21:

Specification no. 15: Effective radiographic size of Flat Panel Detector: at least 420x420 mm

The 420x420mm detector has no advantage compared to 404x404 mm since in 404mm even chest exam can fit which usually used to be performed on the walstand. We suggest to accept 404x404mm as a min. criteria.

Answer Q21: Specification no.15 will not be changed. Detector size of 420x420 is now standard in offering of most vendors.

Q22:

Specification no. 16: Effective number of detector pixels: at least 3000x3000

International studies are proving that detector with 200 micron pixel size has equivalent (even better) image quality as smaller ones. If you accept the 404x404mm detector size and 200micron pixel size the matrix would be 2022x2022.We suggest to accept 2022x2022 as min. criteria for effective number of pixels.

Answer Q22: Specification no.16 will not be changed. Higher number of elements enables higher resolution image.

Q24:

Specification no. 19: Ceiling mounted tube support with liquid crystals touch sensitive panel with at least following functions: display of patient information (name and identification number), system status display, X-ray conditions (technique, tube voltage, tube current, radiography time, AEC, beam hardening filter, patient size, radiography size), anatomic program setting and display of acquired image. Panel orientation aquatically changes between horizontal and vertical depending on tube rotation angle, SID display, system malfunction display

The most important parameters to be displayed and selected: patient name, kV, mAs, rotation angle SID display. All other requested parameters are non relevant and not indispensable to perform a radiography exam. We suggest to accept as min criteria, the above mentioned parameters.

Answer Q24: Specification no.19 will not be changed. Requested data is exposition and patient data which is relevant to the exam.

Q25:

Specification no. 20: Tube rotation around tube support column ±180° with fixed positions at 0°, ±90° и ±180°

There is no any examination which would need 360 degree rotation of the column. With ±135° it is possible perform all exams without restriction. Therefore, we suggest to accept ±135° as min. criteria.

Answer Q25: Specification no.20 will not be changed. Requested change creates blind spot in the room where patients can not be imaged.

Q26:

Specification no. 21: Tube rotation around horizontal axis (angulation) ±180° with fixed positions at 0°, ±90° и ±180°

Because of the same reason above we suggest to accept '+135/'-180° as min. criteria with 0, ±90° detents.

Answer Q26: Specification no.21 will not be changed. Requested change creates blind spot in the room and does not eneble for urgent angulations often needed with trauma patients.

Q27:

Specification no.28: Vertical bucky stand to be used only with fixed Flat Panel Detector

The use in Vertical Bucky fix detector is a restriction. In case of hand or elbow exam, exposure without grid, -the anatomy in contact with the detector -is recommended. In this case mobile detector is more useful, because it can be taken out and used for this purpose. We suggest to accept mobile detector as an equivalent solution.

Answer 27: Specification no.28 will not be changed. System is purchased with high patient troughput in mind. All studies show that for such system fixed detectors are the best solution. Wireless or Wired mobile detectors are subject to dropping and expensive for repair.

Q28:

Specification no. 29: Effective radiographic size of Flat Panel Detector: at least 420x420 mm

The 420x420mm detector has no advantage compared to 404x404mm since in 404mm even chest exam can be performed without limitation. We suggest to accept 404x404mm as a min. criteria

Answer Q28: Specification no.29 will not be changed. Detector size of 420x420 is now standard in offering of most vendors.

Q29:

Specification no. 34: Local control unit

Local control unit is a company specific feature. We suggest to eliminate this requirement.

Answer Q29: Specification no.34 will not be changed. This is not company specific requrement almost every vendor has local controls on vertical BUCKY stand if it is motorized.

Q30:

Specification no. 35: Information display on vertical bucky stand with display of patient information (name, age, gender and identification number)

This is company specific requirement: we suggest to eliminate it.

Answer Q30: Specification no.36 will not be changed. This is not company specific requrement. furthermore it enables one more step towards error free imaging as whereever patient is imaged his patient data is clearly visible to radiographer.

Q31:

Specification no. 38: Effective number of detector pixels: at least 3000x3000

International studies are proving that detector with 200-micron pixel size has equivalent (even better) image quality as smaller ones. If you accept the 404x404mm detector size and 200 micron pixel size the matrix would be 2022x2022.We suggest to accept 2022x2022 as min. criteria for effective number of pixels.

Answer Q31: Specification no.38 will not be changed. Higher number of elements enables higher resolution image.

Q32:

Specification no. 34: Motorized filet selection: automatic (by selecting of anatomic program) or manual

Please clarify what is "filet" here?

Answer Q32: Fillet means leaf of collimator.

Q33:

Specification no. 55: Radiography time range: at least 1-9 seconds

Certainly, this requirement is 1ms-9sec. Regarding 1ms shortest exposure time we consider it is non recommended, because at the beggining of the x-Ray beam there is present a "wrong" spectrum which does not contribute to image creation. With longer exposure time (2ms for istance) with really settled kV there are less ineffective X-Rays.On the other hand ,too long exposure time is increasing the patient dose.We suggest to accept 2ms-2sec range as min. Criteria

Answer Q33: Specification is as written 1-9 seconds.

Q34:

Specification no. 57: Ability to connect at least 2 different tubes

This feature is useful only in case of Radiography and Fluroscopy system with a remote control table and with a ceiling mounted OTS..We suggest to eliminate this requirement.

Answer Q34: Specification no.57 is deleted from technical requirements.

Q35:

Specification no. 62: At least dual focus tube 0,6/1,2 mm

In case of focal spot size the tolerance in international standards is 50%. We suggest to accept for a large focal spot 10% tolerance,ie. 1.3mm as min criteria.

Answer Q35: Offers with 20% tolerance on both focal spets will be accepted.

Q36:

Specification no. 64: Bigger focus power: at least 100 kW

In radiography, there are not performed long lasting procedures, they do not need so high power tube as in case of interventional systems. We suggest to accept 80kW as a min criteria for large focal spot.

Answer Q36: Specification no.64 is changed and states: „Bigger focus power: at lest 80 KW"

Q37:

Specification no. 65: Smaller focus power: at least 40 kW

In radiography, there are not performed long lasting procedures, they do not need so high power tube as in case of interventional systems. We suggest to accept 32kW as a min criteria for small focal spot.

Answer Q38: Specification no.65 is changed and states: „Smaller focus power: at least 32 KW"

Q39:

Specification no. 72: Touch sensitive display size: at least 19" (1280x1024 pixels)

We suggest to accept as equivalent solution the non touchsensitive dispaly

Answer Q39: Specification no.72 will not be changed. Touch sensitive display is something all vendors offer.

Q40:

Specification no. 73: Control: mouse and touch sensitive display

We sugest to accept for contol the mouse as alternative solution.

Answer Q40: In regard with answer to previous question specification no.73 will not be changed.

Q41:

Specifications changes (with bold):

*Specification no 7: Setting of following parameters in C-arm memory positions: cranio-caudal angulations, RAO/LAO, SID, **~~patient table height~~***

Please confirm if it is sufficient to offer angio equipment without table height memorization.
During most interventional cardiac and interventional radiology procedures, the table height is modified only when the patient is being put on or off the tabletop. During the rest of the procedure the only table panning is used (lateral and longitudinal movements) rather than lowering the table up/down. The table height is mainly determined by the height of the operator (his hands require a standard, comfortable working height). But it is unchanged during the procedure and only need to change when a different operator or patient comes to the table. Therefore, the memorization of table height position is clinically negligible compared with memorized gantry positions.

AnswerQ41:
Specification no 7:
It is sufficient to offer angiography system withou patient table height memorization, so specification no 7 is changed to:
Setting of following minimum parameters in C-arm memory positions: cranio-caudal angulations, RAO/LAO, SID

Q42:

Specification no 35: ~~***Wireless***~~ *footswitch for fluoroscopy and acquisition*

Please confirm the above modification of the specification regarding footswitch. A wireless footswitch is a comfort feature, not something which is clinically relevant. It also *needs maintenance* (keeping its battery charged), and may pose a *safety risk* (by interfering wifi signals that may trigger unwanted X-ray radiation). Therefore, [redacted] decided not to employ wireless X-ray triggering mechanisms in their devices, due to the above 2 main concerns.

AnswerQ42:
Specification no 35:
Technical specification will remain unchanged, as it is defined according to customer needs to have comfort and hygienic feature which for sure enables wireless technology with less cables on floor in busy angioenviorement. It is precisely defined and with respect to provide participation of several vendors.

Q43:

Specification no 41: Maximum mA value in pulsed fluoro mode ***min. 140 mA*** ~~***min. 200 mA with small focus***~~

Please confirm the above modification of the specification regarding maximum pulsed fluoroscopy current. Fluoroscopy is *the low dose imaging mode*, used for navigation of anatomy and device positioning. Therefore, a higher current value may simply *increase* the patient dose *unless the x-ray impulse width is defined* within the same specification. [redacted] latest generation of angiographic devices introduced *High Contrast Fluoroscopy*, where the maximum fluoro current is 140 mA to keep patient dose to a minimum.
Any higher mA value falls into the category of *radiographic X-ray* modes (where current goes up to 1000 mA) and should only be used to record images sequences that will be archived.
To provide proof of GE's dose efficiency and leadership in actual clinical practice, please read the attached pdf of "*Minimizing radiation exposure during Interventional Cardiology procedures. Multicenter experience from Innova IGS 520 users*".

Answer43:
Specification no 41:
Technical specification will be changed to following:
Maximum mA value in pulsed fluoro mode min. 140 mA with small focus
Customer needs to have requested min. value on small focus, as resolution is on of the important factors for image quality during pulsed fluoro.

Q44:

Specification no 52: Detector size ***min. 30x30 cm*** ~~***30x40 cm***~~ *with rotation in landscape/portrait position,* ***or without rotation for square detectors***

Please confirm the above modification of the specification regarding minimum detector size. GE is manufacturing all its *square size* detectors, which do *not* need rotation, because they are symmetrical.
The selectable sizes are 20x20, 30x30, and 40x40. For mixed use cathlabs (both for Cardio and Radiology) the best size is 30x30 cm since it is an anatomical compromise.

Answer 44:
Specification no 52:
Technical specification will remain unchanged, as it is defined according to customer clinical needs. Suggested min. 30x30 cm is sufficient only for cardiology procedures, customer as clinical teaching hospital needs to have 40 cm in portrait position during EVAR and TEVAR procedures and 40 cm in landscape position for abdominal and peripheral vascular procedures where both legs have to be shown. It is precisely defined and with respect to provide participation of several vendors with 30x40 cm detector.

Q45:

Specification no. 55. Input fields ***min 4*** ~~***min. 5***~~

Please confirm the above modification of the specification regarding input fields.
Input fields (or Field of View, or optical zoom) are necessary to achieve the right level of magnification of the region of interest. However, with the introduction of the *Large Display Monitors* (56" diagonal screen size) a *new digital zoom function* became available, where users can increase the magnification up *to 500%* digitally, without increasing the dose, selecting any magnification level by the tableside joystick. Given such digital feature the resulting input fields basically became infinite.

AnswerQ45:
Specification no 55:
Technical specification will be changed to following:
Input fields min. 4

Q46:

Specification. no 66: Digital subtraction angiography (DSA) with highest frame rate min. 6 fps in high resolution ***min. 1K*** ~~***min. 2K***~~

Please confirm the above modification/contradiction of the specification regarding resolution.
As written earlier, the best system for combined use (Intv'l Cardiology and Radiology) is the 30x30 detector size (it has an acquisition matrix of 1536x1536).
Since *Requirement 58* asks for "Acquisition matrix size 1024 x 1024 with highest speed of 30 fps", *Requirement 66* is contradicting this.
Req 66 2K = 2000 x 2000 ←→ **Req 58** 1024x1024
To resolve the contradiction please modify Requirement 66 to *"Digital subtraction angiography (DSA) with highest frame rate min. 6 fps in high resolution min. 1K"*

AnswerQ46:
Specification no 66:
Technical specification will remain unchanged, as it is defined according to customer clinical needs. Customer has requested under specification no 52 detector 30x40 cm and according to that fact customer needs highest resolution in DSA mode which gives systems with 2K matrix in order to see smallest vessels during peripheral procedures. It is precisely defined and with respect to provide participation of several vendors. Specification no 58 refers to standard fluoro mode, not to DSA mode.

Q47:

Specification no. 67: Roadmapping with automatic pixel shift ~~***in real time***~~

Please confirm the above modification regarding automatic pixel shift.
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 "real time" automatic pixel shift.
Manual pixel shift, and Automatic pixel shift are *both available* on [redacted] Angiographs, although they are not "real-time". (Pixel shifting is considered a post-processing step in the imaging).

AnswerQ47:
Specification no 67:
Technical specification will be changed to following:
Roadmapping with automatic pixel shift