# Technical Specification amendment/Clarification No.6 (Part 2)

#### The angiography system

• Touch sensors should be on the tube, detector, C-arm and stand: The inclusion of touch sensors, as well as requiring sensors to be on the stand, locks out Philips, among others, from submitting a responsive bid and is clinically inappropriate. Several manufacturers prefer contactless sensors over touch sensors to ensure equipment sterility. Moreover, including sensors directly on the stand inhibits the C-arm from functioning properly. Opening this specification to permit contactless sensors in addition to touch sensors, and removing the obsolete requirement to include sensors on the stand, will uphold the critical functionality of this solution.

Answer: The specification Touch sensors should be on the tube, detector, C-arm and stand: amended to Touch sensors should be on the tube, detector and C-arm

• The height adjustment range of the patient tabletop should be at least in the range of 75 to 105 cm: Philips and other manufacturers' tabletop range extends to 74.5 cm. We request that this specification be modified to permit a range of 74.5 to 105 cm. This minor adjustment will permit Philips to participate and it will have no impact on the equipment's performance.

Answer: This deviation is considered minor deviation and will be accepted.

• Nominal power (cold tube) for small focus at least 40 kW and 100 kW at least for the large focus: This is a competition limiting specification. Philips and other manufacturers' tube power setting are 30 kW and 65 kW for the small and large focal spots, respectively. As image quality is a factor of multiple items, including focal spots and heat management functions, modifying these parameters alone will not reduce image quality.

Answer: The specification Nominal power (cold tube) for small focus at least 40 kW and 100 kW at least for the large focus amended to Nominal power (cold tube) for small focus at least 30 kW and 65 kW at least for the large focus

• *Output impedance should be less than lOOfl:* This is a lock-out competition limiting specification. Philips, among other global manufacturers, produce angiography systems with an output impedance of exactly 100'Q. This minor modification will have no material impact on the equipment's critical functionality.

Answer: This is a small deviation

• *IECG leads should be IECG bipolar or unipolar:* We request the removal of this competition limiting specification. Requiring inter-cardiac ECG Leads is a fundamental part

of a dual hemodynamic electrophysiology solution, an extremely specialized device which only a few manufacturers in the world are capable of supplying. Removing this specification will uphold the critical functionality of the interventional hemodynamic software while allowing Philips and others to submit a responsive bid.

- Stimulator interface: We request the removal of this competition limiting specification. The requested stimulator is a fundamental part of the dual hemodynamic-electrophysiology solution, an extremely specialized device which only a few manufacturers in the world are capable of supplying. There is no clinical difference in separately channeling the Stimulator interface to the hemodynamic system and ECG channel, as the Stimulation interface's peak detection and removal capabilities function by means of the device's internal software.
- Chanel Stimulation System for Stimulation: We request the removal of this competition limiting specification. As currently written, this specification would limit competition and unnecessarily raise equipment costs. The requested stimulation system is a fundamental part of the dual hemodynamic electrophysiology solution, an extremely specialized device which only a few manufacturers in the world are capable of supplying. There is no clinical difference in separately channeling the Stimulator to the hemodynamic system and ECG channel, as the Stimulation's peak detection and removal capabilities function by means of the device's internal software.

Answer: The specifications IECG leads should be IECG bipolar or unipolar, Stimulator interface, Chanel Stimulation System for Stimulation are removed.

**Regarding the MRI, Item 9,** RF cage for the system offered and the adequate cooling system

Please confirm what adequate cooling should cover. There are various areas that could relate to cooling such as:

- 1) chiller for the magnet,
- 2) the air conditioning for the examination room,
- 3) the air conditioning for the technical room,
- **4)** the air conditioning for the control

Answer: Please note that the cooling system provided should include the chiller for the magnet. The air conditioning for the examination room, technical room and control room will be provided by the hospital during the site preparation.

## Annex

Procurement of Equipment for Regional Hospitals: ICU Equipment, Ultrasounds, X-Rays, MRIs, and Angiography Systems

ICB No: HSIP/ICB/01-2016

IBRD Loan No. 8466 AL

Spec No.	Actual Text in Tender	Requested Modifications	Rationale
Lot 1: Intensiv			
Item 1.1: Defil	orillator		
2.2	12V rechargeable battery	Rechargeable battery between 12V and 14.5V	As currently written, this specification would limit competition and unnecessarily raise equipment costs. Batteries are in some cases slightly above 12V in order to drive 12V internal circuitry. Permitting voltage up to 14.5V would in fact permit the intended 12V functionality of the defibrillator and would allow Philips and other manufacturers to submit a fully responsive bid.
2.5	Charges from 0 to 200 joules in less than 5 seconds wth a new fully charged battery	Charges from 0 to 200 joules in less than 6 seconds wth a new fully charged battery	As currently written, this specification would limit competition and unnecessarily raise equipment costs. Permitting an additional one second in charching time would uphold defibrillator' critical functionality.
3.1	Reusable hard paddles for external defibrillation —1 pair adult and 1 pair pediatric	Reusable hard paddles for external defibrillation - 1 pair adult and 1 pair pediatric or paddles that can accommodate both adult and	paddle adapters that can accommodate both adult and pediatric patients. Permitting hard paddles with

		pediatric patients.	and maintain the defibrillator's critical functionality.
	Single use pads for 20	Single use pads for 20	Please specify patient type: adult or pediatric. It is
	applications compatible	applications compatible with	unclear how many of the 20 sets of pads should be
3.6	with	Emergency defibrillator	for adult use and how many for pediatric use.
	Emergency defibrillator	including 10 sets for adult	
		patients and 10 ets for	
		pediatric patients.	

Lot 2: Ultrasonograj	ohy		Lot 2: Ultrasonography			
Item 2.1: Cardic Ultrasound	Sector phased array transducer 1.5 to 4.0 MHz	1	As currently written, this specification would limit competition and unnecessarily raise equipment costs. Permitting a MHz range of 2.0 to 4.0 MHz is the industry standard and would yield a materially equivalent level of analysis as the 1.5 MHz minimum threshold. Thus, making this modification would permit the broadest possible competition while upholding the Ultrasound's critical functionality.			
Item 2.2: Abdominal Ultrasound	M-mode or D-mode dynamic memory mm. 60 sec	M-mode or D-mode dynamic memory mm. 48 sec	As currently written, this specification would limit competition and unnecessarily raise equipment costs. The industry standard for M-Mode and D-mode dynamic memory is 10-15 seconds; 60 seconds is very excessive and would not yield a materially superior clinical outcome. Permitting a minimum of 48 seconds would open up this specification to allow for the broadest possible competition while upholding its critical functionality.			

Item 2.3: Obstetrics and Gynecology Ultrasound	The control panel with height adjustable, equipped with display LCD touch, for command	The control panel with height adjustable, equipped with display LCD touch and/or with soft keysand with rotating and pushing functionality for command	competition and unnecessarily raise equipment costs. Permitting "soft keys", or keys that can be programmed to have multiple functions, would yield the same or a superior clinical outcome as the LCD touch screen. Soft keys can also be supplied by many
Item 2.4: General Endoscopic Surgery Lot 3.: Radiologji	Compatible with HDTV videoscopes; videolaparoscopes, videocolonoscopes, videogastroscopes etc	Remove specification.	As currently written, this is a lock-out specification that only one manufacturer can comply with: Karl Storz. Moreover, it would not be clinically appropriate or safe to require the HDTV videoscope be compatible with either videocolonoscopes or videogastroscopes. Videocolonscopes and videogastroscopes are designed for non-sterile environments, whereas the HDTV videoscope is designed for the (sterile) operating theater. Removing this specification would permit additional manufacturers to bid clinically appropriate HDTV videoscope solutions that uphold this devices critical functionality.

Item 3.1: X-Ray Machine			
	Tables with removable upper uppers  Table range movement that table: 115cm longitudinal, transverse 25cm	Table with removable upper uppers or fixed uppers that can be cleaned,  Table range movement that has maximum table dimension range: 42-115 cm longitudinal, transverse 25cm	As currently written, is an obsolete specification that would limit competition. Permitting fixed uppers that can be cleaned in addition to removable uppers would have no material clinical impact and would permit many more suppliers to participate in this lot.  As currently written, this specification would limit competition and unnecessarily raise equipment costs. Philips table range is 42 cm longitudinal and 25 cm transverse, dimensions which fully permit imaging coverage of the entire body while exhibiting the same functionalities.
	Manual and motorized collimation	Manual or motorized collimation	As currently written, this is an obsolete specification which would limit competition and unnecessarily raise equipment costs. For an analog x-ray machine, motorized collimation would not have any impact on the x-rays performance or functionality. Permitting either manual or motorized collimation will allow many suppliers to bid while upholding the x-ray's critical performance and functionality. The industry standard for analogue X-ray is manual collimation, motorized collimation is a feature more commonly found in digital x-ray solutions.
Item 3.2: X-Ray Mobile			

Lot_5_Magnetic_Reso	2500x3000	Number of pixels mm. 2476x3000	As currently written, this specification would limit competition and unnecessarily raise equipment costs. Alternatively, permitting minimum pixels of min 2476x3000 would promote broad competition while upholding the mobile x-ray's critical functionality. There is no material difference between a minimum resolution of 2476 and 2500 pixels.
Lot_5_Magnetic_Rest	mance_(MM)		
Item 9	RF cage for the system offered and the adequate cooling system		Please confirm what adequate cooling should cover. There are various areas that could relate to cooling such as:  1) chiller for the magnet, 2) the airconditioning for the examination room, 3) the airconditioning for the technical room, 4) the airconditioning for the control room

7			
Lot 6: Angiograph Item 6: Angiograph			
nem o. Angrogi apii	Touch sensors should be on the tube, detector, C-arm and stand	Touch or contactless sensors should be on the tube, detector and C-arm and stand	As currently written, this specification would limit competition, unnecessarily raise equipment costs and is clinically inappropriate. In a patient setting, contactiess sensors provide superior performance reliability and sterility than touch sensor solutions. Using contactless sensors also helps avoid collisions between equipment components, and using electromechanical protection prevents damages to the lab area. Requiring that sensors be included on the stand prevents the C-arm from properly

		functioning and is an obsolete specification, and thus should be removed.
The height adjustment range of the patient tabletop should be at least in the range of 75 to 105 cm	The height adjustment range of the patient tabletop should be at least in the range of 74.5 to 105 cm	As currently written, this specification would limit competition and unnecessarily raise equipment costs. Philips and several other manufacturers height adjustment range extends down to 74.5 cm. This is a minor deviation that still upholds the critical functionality of the overall angiography system.
Nominal power (cold tube) for small focus at least 40 kW and 100 kW at least for the large focus	Nominal power (cold tube) for small focus at least 30 kW and 65 kW at least for the large focus	As currently written, this specification would limit competition, unnecessarily raise equipment costs and has the potential to sacrifice patient safety. Larger kW levels do not necessarily translate to superior image quality. Even more important is the overall X-Ray tubes performance and heat management capabilities, including its cooling system, which dictates the ability for the tube to generate X-Rays with a given amount of power. Moreover, using the overall image chain more effectively reduces the radiation dose exposure for patients and staff independent of the tube power. The requested modification of 30 kW for small focus and 65kw for large focus is clinically sufficient to maintain the X-rays image quality, ensures patient

		safety and would permit a broader range of suppliers to submit a responsive bid.
Output impedance should be less than 1000	Output impedance should be less than or equal to 1000	As currently written, this specification would limit competition and unnecessarily raise equipment costs as several manufacturers can supply an output impedance of 100'O, however without this modification Philips and others cannot submit a responsive bid. This is a minor deviation that would still uphold the critical functionality of the Angiography system.
IECG leads should be IECG bipolar or unipolar	Remove specification	As currently written, this specification would limit competition and unnecessarily raise equipment costs. Requiring inter-cardiac ECG Leads is a fundamental part of a dual hemodynamic-electrophysiology solution, an extremely specialized device which only a few manufacturers in the world are capable of supplying. Removing this specification will uphold the critical functionality of the interventional hemodynamic software while allowing Philips and others to submit a responsive bid.

Stimulator interface	Remove specification	As currently written, this specification would limit competition and unnecessarily raise equipment costs. The requested stimulator is a fundamental part of the dual hemodynamic-electrophysiology solution, an extremely specialized device which only a few manufacturers in the world are capable of supplying. There is no clinical difference in separately channelling the Stimulator interface to the hemodynamic system and ECG channel, as the Stimulation interface's peak detection and removal capabilities function by means of the device's internal software. Removing this specification will uphold the critical functionality of the interventional hemodynamic solution while allowing Philips and others to submit a responsive bid.
Chanel Stimulation System for Stimulation	Remove specification	As currently written, this specification would limit competition and unnecessarily raise equipment costs. The requested stimulation system is a fundamental part of the dual hemodynamic-electrophysiology solution, an extremely specialized device which only a few manufacturers in the world are capable of supplying. There is no clinical difference in separately channelling the Stimulator to the hemodynamic system and ECG channel, as the Stimulation's peak detection and removal capabilities function by means of the devices internal software. Removing this specification will uphold the critical functionality of the interventional hemodynamic solution while allowing Philips and

	others to submit a responsive bid.

## Lot 5: Magnetic Resonance (MRI) - 1 pc

#### 1. Requirement is:

## the magnet: Areas with high magnetic intensity (1G radial axial x) (fringe field) $<5.5m \times <3.5 m$

The requested radial fringe field for 1G (5.5m) is less than what we can offer with Signa Creator/Explorer (5.7m). The limitations regarding proximity to the magnetic field extend to the 5Gauss line with which we comply.

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

Specification : Areas with high magnetic intensity (1G radial axial x) (fringe field)  $<5.7m \times <3.5 m$ 

## Answer: The variation of the above mentioned specification is considered minor deviation

## **2.** Requirement is: **The length of the magnet (without lids) < 1.60m**

The length of the magnet is specified as less than 1.60m. The overall length of our systems is 1.95m (with the covers). Although considered to be a feature that enhances the acceptance of the technique smart design characteristics as large flairs at the edges of the magnet offer similar results. Furthermore, a "longer" magnet favors the homogeneity of the magnetic field which enables high quality imaging.

We kindly ask the Committee to accept the following

modification: Specification The length of the magnet

<1.95m with the covers.

Answer: The specification is requested without lids, **The length of the magnet** < 1.95m with the covers will be accepted.

## 3. Requirement is: The number of shim positions for correct thickness of the magnetic field >32 trays

There is a requirement that specifies the number of shim positions. On our systems shim is done using 18 superconducting coils included in the magnet. This is active shimming at installation and on request during PM. Also, a gradient shim is available using the 3 gradients coils to correct on request the shim. Passive shim is performed during manufacturing on 12x49 = 588 positions.

We kindly ask the Committee to accept the following modification:

Specification the number of shim positions for correct thickness of the magnetic field to be mentioned.

Answer: The specification amended from The number of shim positions for correct thickness of the magnetic field >32 trays to Specification the number of shim positions for correct thickness of the magnetic field to be mentioned.

## **4.** Requirement is

Homogeneity (V- RMS) guaranteed ppm)	VMRS / guaranteed
50 x 50 x 45 cm	<1
40 x 40 x 40 cm	<0.35
30 x 30 x 30 cm	<0.18
20 x 20 x 20 cm	<0.09
10 x 10 x 10 cm	0.03

The requested value is not available in our official product datasheets. GE traditionally sets the industry standards regarding magnet homogeneity characteristics. We request that the largest specified volume is limited to the one stated for a spherical volume diameter of 40cm. We kindly ask the Committee to accept to expand the specification, as this minor deviation does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please

#### **Specification**

Homogeneity (V- RMS) guaranteed ppm)	VMRS / guaranteed
40 x 40 x 40 cm	<0.35
30 x 30x 30 cm	<0.18
20 x 20 x 20 cm	<0.09
10 x 10 x 10 cm	<0.03

accept the following modification:

Answer: Specification **Homogeneity (V- RMS) guaranteed ppm) VMRS / guaranteed, 50 x 50 x 45** cm <1 is removed.

#### **5.** Requirement is

<b>1</b>	
Spatial linearity 20 cm DSV	<0.4%
Spatial linearity 50 cm DSV	<1.5%

The spatial linearity for 20cm DSV is specified at 99.95% and for 50cm DSV at 97.5%, values that exhibit strong linearity and exquisite gradient performance at large FOVs.

We kindly ask the Committee to accept the following modification:

## **Specification**

Spatial linearity 20 cm DSV	99.95
	%
	97.5%,

Answer: The specification **Spatial linearity 50 cm DSV <1.5% is amended to Spatial linearity 50 cm DSV <2.5%** 

6. Requirement is:

Minimum of visibility

(FOV)

At 1.5T field strength imaging at a FOV of less than one cm is clinically impossible as this would request a very long scan time that cannot be acceptable in a clinical setting. The only technique that could potentially use such a small FOV (although again with extreme time penalties) could be spectroscopic acquisitions that are not requested.

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

## **Specification**

Minimum of visibility 1 cm (FOV)

Answer: The specification Minimum of visibility (FOV) 0.5 amended to Minimum of visibility (FOV) 1 cm

## 7. Requirement is:

Maximum slice >300 thickness mm

The specified maximum slice thickness of >300 mm offers no clinical value as extreme partial volume effects and would offer no clinical information with such a scan.

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

#### **Specification Maximum slice thickness > 100mm**

Answer: The specification Maximum slice thickness >300mm amended to

Maximum slice thickness > 100mm

## **8.** Requirement is

Highest resolution plan

This is an extreme specification that is calculated by the ratio of two extreme values of minimum FOV and maximum resolution. As suggested also in the previous argument a scan FOV of 0.5cm is clinically impossible rendering the specified in plane resolution a number that adds no clinical value to the system.

<u><</u>5μM

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

## **Specification**

 $\begin{array}{ll} \text{Highest} & & \leq \! 10 \mu \\ \text{resolution plan} & & m \end{array}$ 

## Answer: The specification Highest resolution plan is removed

## **9.** Requirement is:

Minimum slice/ thickness of the partition	<u>&lt;</u> 0.05mm
(3D)	

A clinically relevant slice thickness in 3D is normally at the range of 1mm and in specific indications could be lowered to 0.6 - 0.8mm (inner acoustic canal studies). Prescribing a scan area of adequate SNR in a scan time that could be acceptable in a clinical study does not allow for such small slice thickness.

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

Specificatio	Minimum slice / thickness of the partition ≤ 0.1mm	
	(3D)	

Answer: The specification: Minimum slice/ thickness of the partition (3D)  $\leq 0.05$ mm amended to  $\leq 0.1$ mm

## 10. Requirement is:

Maximum slice / thickness of the partition (D) >60mm

3D scan techniques are developed to offer enhanced resolution and these large slice thickness offers no clinical value. Even 10mm is larger than any possible clinical need.

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

## **Specification**

Maximum slice / thickness of the >10m partition (3D) m

Answer: The specification Maximum slice / thickness of the partition (D) amended to

Maximum slice / thickness of the partition (3D) > 10mm

#### **11.** Requirement is:

shortes TE/TR	(2D gradient echo, 128	<1.10/<0.50 ms

matrix)	
,	

These increased values are not indicative of the clinical outcome that the gradient system can provide. 2D Gradient echo acquisitions are typically not affected by this difference as 3D gradient echo techniques which are demanding with respect to gradient performance where smaller min TE/TR should be specified. We kindly ask the Committee to accept to expand the specification, as this minor deviation does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification:

## **Specification:**

shortest TE / TR (2D gradient echo, 128 ma <u>tr</u> ix	<2.3 / <0.8 ms
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Answer: Specification Shortest TE/TR (2D gradient echo, 128 matrix) <1.10/<0.50 ms is amended to shortest TE / TR (2D gradient echo, 128 matrix <2.3 / <0.8 ms

## **12.** Requirement is :

shortest 3D Echo Spacing TSE (ms, 128 matrix)	<5.50 ms
shortest TSE TR / TE 3D (ms, 128 matrix)	<31.50/<5.50 ms

The shortest TE/TR and Echo Spacing values for 3D TSE acquisitions are not available in our official product datasheets. We request.

We kindly ask the Committee to **remove these specifications**.

Answer: The specifications shortest 3D Echo Spacing TSE (ms, 128 matrix) <5.50 ms, shortest TSE TR / TE 3D (ms, 128 matrix) <31.50/<5.50 ms are removed

13. Requirement is:

shortest 3D Echo Spacing EPI (ms, 128	<0.650 ms
matrix)	
shortest SE EPI 3D TR (ms, 128 matrix)	<17 ms
shortest SE EPI 3D TE (ms, 128 matrix)	<7 ms

The requested Echo Spacing and shortest TE/TR for 3D SE EPI ore not available in our official product data sheets and no such technique is available in the market to our knowledge.

We kindly ask the Committee to **remove these specifications.** 

Answer: The specifications shortest 3D Echo Spacing EPI (ms, 128 matrix) <0.650 ms, shortest SE EPI 3D TR (ms, 128 matrix) <17 ms, shortest SE EPI 3D TE (ms, 128 matrix) <7 ms, are removed.

#### **14.** Requirement is

Min TE DW1 (b = 1000, 128 matrix)	<65 ms

The min TE DWI (b=1000,128 matrix) value is not available in our official product datasheets. The overall performance of a system in EPI acquisitions could serve as a general criterion for also DWI acquisitions.

We kindly ask the Committee to **remove these specifications**.

Answer: The specification Min TE DW1 (b = 1000, 128 matrix) <65 ms is removed

## 4. RF system:

#### **15.** Requirement is :

Output Power	>15kW

New technologies that aim to reduce the energy consumption and the heat that is deposited on the patient have emerged.

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

## **Specification**

Output Power	>=10kW
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Answer: The specification Output Power>15kW is amended to Output Power >= 10kW

#### **16.** Requirement is:

The number of independent receiver	16
channels	

The number of independent receiver channels of GE Healthcare proposed system is limited to 8. This number matches the number of channels in a single scan FOV provided by the majority of the RF coils that are offered in this system category. Furthermore, no coils of a number of channels higher than 8 in a single FOV are requested.

We believe that the request of the existence of an option to update to a higher number of channels should not be a mandatory capability as upgrade paths for new systems in the market are not readily defined at the early stage of the life of the systems but later when possible technology advances create value to such update capabilities.

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

## **Specification:**

The number of independent receiver	8
channels	

Answer: The specification **The number of independent receiver channels is** amended to The number of independent receiver channels 8.

#### 4. Patient environment.

## **17.** Requirement is:

Maximum weight capacity for vertical and horizontal movement	>200 kg

GE Healthcare system is limited to 160 Kgr. This is a mechanical limit and exceeds the body weight of a patient that could fit in a 60cm bore. As such it does not add any value to the system.

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

## **Specification:**

Maximum weight capacity for vertical and horizontal movement	>=160 kg

Answer: The specification Maximum weight capacity for vertical and horizontal movement >200 kg is amended to Maximum weight capacity for vertical and horizontal movement >=160 kg

## **18.** Requirement is

Patient table horizontal speed	3 speed. > 175 mm / sec

We believe that the demand for a 3speed horizontal table movement with a maximum velocity of 175mm/s does not add any clinical or workflow advantage to the system. A two-speed drive for normal and detailed positioning is adequate for clinical use. A lO0mm/s velocity is adequate to ensure fast workflow with limited discomfort to the patient especially in the cases that motion halts are triggered.

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

#### **Specification:**

Patient table horizontal speed	2 speed > 100mm/s

We request that the weight holder for the transport of the patient before and after the examination matches the weight value we suggest for the examination table of 160Kg maximum.

Answer: The specification Patient table horizontal speed 3 speed. > 175 mm / sec is amended to Patient table horizontal speed 2 speed > 100mm/s

## 5 Requirements for the preparation of place of installation

18. Requirement is:

Heat release in the technical room (standby)	<3kW
Escaping the heat in technical room (during the examination)	<10kW
Heat release in the examination room	l3kW
Heat release in the control room	<lkw< td=""></lkw<>

The heat release in the technical room should be specified during examination since this is the greater value that should be taken into consideration for the installation We kindly ask the Committee the heat release in the technical room at standby to be removed from the requirements and that the heat escaping in the technical room during the examination to be specified at maximum 16KW. This value should be considered as the maximum possible that the system can generate during scanning. We request that the heat release in the Examination room to be specified at maximum 3.6kW. This value should be considered as the maximum the system can generate and it is very close to the initially requested of 3kW. We request that the heat release in the control room to be specified at maximum 1.5kW which describes the the maximum heat release of a host PC of the requested specifications. we kindly ask the Committee to accept the following modification:

#### Specification:

Escaping the heat in technical room (during the examination)	<16k W
Heat release in the examination room	<3,6kW
Heat release in the control room	<1,5 kW

Answer: The specifications Heat release in the technical room (standby), Escaping the heat in technical room (during the examination), Heat release in the examination room, Heat release in the control room are removed

#### 6. A computer system

#### 19. Requirement is:

•				
Type of processor	Intel	Quad	Core	or
	better			
The clock frequency	>2.6 GI	Hz		
	>4,000		image/	sec,
Reconstruction speed (100% FOV, reconstruction		recon	ıs/sec (	256
/ sec)	FFT, 10	)0% FC	OV)	

We kindly ask the Committee to accept the following

modification: Specification:

Type of processor	Dual Core
The clock frequency	>2.4 GHz
Reconstruction speed (100% FOV, reconstruction	>6,000 recons/sec (256
	FFT, 100% FOV)

The specification that shows the overall reconstruction capacity of a reconstruction engine is the number of recons at a specified matrix (typically 256x256) at full FOV per second.

We request that the requested processor type to be changed to Dual core or better and the clock frequency to 2.4GHz or better as these specifications have the ability to provide more than the requested reconstruction speed of 6,000 recons/sec (256FFT, 100%FOV).

We kindly ask the Committee to clarify or remove the requirement for "server reconstruction divided". The requirement is not clear to us and we do not see how it could enhance the reconstruction performance of the system. An MR system, in order to secure high workflow should offer the possibility of fast reconstruction at the same time with scanning and post-processing. We believe that this should be the context of a reconstruction engine related specification on top of a high reconstruction speed.

Answer: The specifications Type of processor Intel Quad Core or better amended to Type of processor Dual Core, The clock frequency >2.6 GHz amended to The clock frequency >2.4 GHz,

#### 7. Coils

#### **20.** Requirement is:

For integrated coil solutions state maximum parallel imaging factor	≥4
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Parallel imaging acceleration has the potential to generate multiple artifacts when high accelerator factors are prescribed. In practice acceleration factors of more than 3 are rarely clinically used due to severe SNR loss and related artifacts generation. A maximum acceleration factor of 3.A is adequate for fast imaging in challenging applications and patients. For ultra fast imaging other techniques have been developed that provide the needed scan speed (temporal resolution) without compromising the image quality, like view sharing techniques.

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

Specification:

For integrated coil solutions maximum parallel imaging factor	state	>3,4

Answer: The specification For integrated coil solutions state maximum parallel imaging factor ≥4 amended to For integrated coil solutions state maximum parallel imaging factor >3,4.

#### 8.The software

## **18.** Requirement is:

Fast imaging techniques for some patients based on the patient type turbo / fast Spin Echo with under 300 ms temporal resolution in any direction and be able to combine with	
Tl, T2 and DWI	

We kindly ask the Committee to clarify what is described in the requirement "Fast imaging techniques for some patients based on the patient type turbo / fast Spin Echo with under 300 ms temporal resolution in any direction and be able to combine with Tl, T2 and DWI". As it is we cannot define the context of the requirement.

Answer: This should remain as initially requested. No modification will be applied.

#### **19.** Requirement is:

Fat suppressing with adiabatic adipose	It must be included. State details

The requirement for "Fat suppressing with adiabatic adipose" is a fat suppression technique that aims to uniform fat suppression. Other fat suppression techniques like Dixon offer even more uniform fat suppression even at areas that spectral fat suppression regardless of the type of the used pulse are prone to failure. We kindly ask the Committee to accept to expand the specification, as this minor deviation does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification:

#### Specification:

Fat suppressing	It must be included. State details.
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Answer: The specification Fat suppressing with adiabatic adipose is amended to Fat suppressing with adiabatic adipose or other techniques

#### **23** Requirement is:

Interleaved IR / SE for calculating mapping combined Tl & T2	It must be included. State details

The requirement for a technique for Tl and T2 maps calculations via an interleaved IR/SE acquisition is a generalized requirement that fails to identify the actual techniques that offer clinical value in MSK studies. In MSK the relaxometry maps that add clinical information are basically T2.

Answer: The specification Interleaved IR / SE for calculating mapping combined Tl & T2 is removed

## **24.** Requirement is:

Multi-Echo T2 measurements for T2 mapping	It must be included. >32 echoes. State details.

We kindly ask the Committee to accept the removal of specifications "Multi-Echo T2 measurements for T2 mapping" technique as is also separately specified.

All suggested changes in the specifications listed in this tender book are requested in an effort to increase competition and allow the participation of systems of established value of the latest technology.

Answer: The specification: Multi-Echo T2 measurements for T2 mapping is removed.

## Lot 6: ANGIOGRAPH - 1 pc

#### **Generator**

1. Specification requests Technical data for the generator: acquisition kV and mA range not less than 40kV and not more than 125kV, continuous fluoroscopy kV and mA range not less than 40kV not more than 125kV

Our fine-tuned dose protocols that provide the highest quality digital images in the industry (DQE 84% in acquisition) do not require lower kV range to achieve this.

Our fine-tuned dose protocols that provide the highest quality fluoroscopic images in the industry (DQE 73% in low dose fluoroscopy) do not require lower kV range to achieve this.

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

## **Specification**

Technical data for the generator

Acquisition kV and mA range to be not less than 50kV and not more than 125kV. the Fluoroscopy kV and mA range to be not less than 60kV and not more than 125kV.

Answer: The specification ranges... not less than 50kV and ... not less than 60kV, fulfill the range requested. No need for change

## The patient table

2. Specification requests

The height adjustment range of the patient tabletop should be at least in the range of 75 to 105 cm

The original requirement request for 75cm to 105 cm (20 cm range) and the GE tables are 78-108 cm (also 20 cm range). The two ranges are clinically equivalent, but the new wording is not limiting our participation.

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

## **Specification**

"The height adjustment range of the patient tabletop should be at least in the range of 20 cm

Answer: The variation of this specification is considered minor deviation and will be accepted.

**3.** Specification requests

## The patient tabletop width should be approx. 50 cm

A wider tabletop may cause more collisions with the x-ray tube or the detector when the gantry is in lateral position, therefore can slow down the intervention, which can result in excess dose to the patient.

We kindly ask the Committee to accept to expand the specification, as this minor deviation does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification: **Specification** 

## The patient tabletop width should be approx.46 cm

Answer: The above **tabletop width** will be considered minor deviation and will be accepted.

## ECG acquisition and storage

**4.** Specification requests

## ECG waveform should be recorded, stored and displayed on the monitor together with the image information

With our solution the ECG waveforms are constantly displayed on the Hemodynamics Recording systems monitor (in real-time), and can be archived and displayed on an archiving system monitor if required.

We kindly ask the Committee to accept to expand the specification, as this minor deviation does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification: **Specification** 

ECG waveform should be recorded, stored and displayed on the monitor or Archiving system (PACS) together with the image information.

Answer: ECG waveform should be recorded, stored and displayed on the monitor or any archiving media together with the image information.

## LV analysis

- **5.** Specification requests **It should be** 
  - with automatic and manual ventricular wall and contour recognition

The features of an LV analysis software package vary vendor by vendor, and automatic wall contour recognition is not yet implemented in most vendor's software package (basically only one equipment vendor claims to have this feature). Since the clinical outcome is the same and manual measurements are still the clinical standard today, we ask to modify this specification. We kindly ask the Committee to accept to expand the specification, as this minor deviation does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification:

Specification

#### It should be

- with manual ventricular wall and contour recognition

Answer: Specification: With automatic and manual ventricular wall and contour recognition amended to With manual or automatic ventricular wall and contour recognition.

## **Storage of Fluoroscopy scenes**

- **6.** Specification requests
  - The number of fluoroscopy images, which are saved automatically to replace potential exposures scenes at a higher dose should be the last 1000 images

Storing 450 images can last as long as 2 minutes (120 seconds) with 3.75 fps fluoro mode. This length of the stored sequence is more than enough to substitute for a high dose cine acquisition, which is performed at 15 frames per sec and do last not more than maximum 20-30 seconds. We kindly ask the Committee to accept to expand the specification, as this minor deviation does not affect clinical efficiency of our system, allowing for broader participation to the tender, and please accept the following modification:

Specification

The number of fluoroscopy images, which are saved automatically to replace potential exposures scenes at a higher dose should be the last 450 images

Answer: The specification - The number of fluoroscopy images, which are saved automatically to replace potential exposures scenes at a higher dose should be the last 1000 images amended to The number of fluoroscopy images, which are saved automatically to replace potential exposures scenes at a higher dose should be the last 450 images

7. Specification requests

## Measuring range at least -50 to 400 mm Hg

The requested measuring range is available in GE official product datasheets for hemodynamic measurements system. The range of measuring is typical for all patient population on the world and is in accordance with the guidelines of the European Society of Hypertension.

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

## Measuring range at least -25 to 249 mmHg

Answer: The specification Measuring range at least -50 to 400 mm Hg amended to Measuring range at least -25 to 249 mmHg

**8.** Specification requests

## Oxygen saturation range 0 to 100 %

The requested range is available in GE official product datasheets for hemodynamic measurements system and is in the range of measuring deviation -1%.

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

#### **Specification**

Oxygen saturation range 1 to 100 %.

Answer: This variation is considered minor deviation

**9.** Specification requests

## Signal input box and catheter input box

We kindly ask the Committee for resignation from the condition Signal input box and catheter input box. The requested feature is not typical for hemodynamic registration and information system for the heart catheterization laboratory. This feature it can be useful as part of specialized electrophysiology recording system forep diagnostics.

Answer: Specification Signal input box and catheter input box is removed.

**10.** Specification requests

IECG leads should be IECG bipolar or unipolar

We kindly ask the Committee for resignation with the parameter IECG leads should be IECG bipolar or unipolar. The requested feature is not typical for hemodynamic registration and information system for the heart catheterization laboratory. This feature it can be useful as part of specialized electrophysiology recording system for ep diagnostics.

## Answer: The specification IECG leads should be IECG bipolar or unipolar is removed

## 11. Specification requests **Stimulator interface**

We kindly ask the Committee for resignation with the parameter Stimulator interface. The requested feature is not typical for hemodynamic registration and information system for the heart catheterization laboratory. This feature it can be useful as part of specialized electrophysiology recording system for ep diagnostics.

## Answer: The specification Stimulator interface is removed

#### **12.** Specification requests

#### 2- Chanel Stimulation System for Stimulation

We kindly ask the Committee for resignation with the parameter 2 - Chanel Stimulation System for Stimulation. The requested feature is not typical for hemodynamic registration and information system for the heart catheterization laboratory. This feature it can be useful as part of specialized electrophysiology recording system for ep diagnostics.

Answer: The specification Chanel Stimulation System for Stimulation is removed