Clarification document Dated March 31, 2017

REGARDING THE TECHNICAL SPECIFICATIONS:

For LOT 1:

1.DEFIBRILLATOR
1.11 Optional Sp02 and C02 upgrade possible

We kindly ask you to cancel it since it is optional, or to be modified
Optional Sp02 and C02 upgrade possible in delivery time
Answer: These specifications are optional. They are not mandatory

1.5Syringe Pump
Syringe to be used with 2-5-10-20-30-50ml syringes
Since we are considering it as lock out specification we kindly ask you **to modify** as following:

Syringe to be used with 5-10-20-30-50/60ml syringes

Most of well-known companies are using above mentioned syringe volumes
Answer: Specification amended to: **5-10-20-30-50/60ml syringes**

ELECTRO SURGERY
-The instrument connected identified by Rfid radio frequency

It is lock out specification for ERBE and EMED sp manufacturers and excluding all other manufacturers
We kindly ask you to cancel this request in order to allow a wider participation to the tender in compliance with the international fair competition rules and principles.

Answer: The specification: **The instrument connected identified by Rfid radio frequency is removed**

1.8 MONITOR
4.5 ST segment analysis for all 12 ECG leads, with diagnosis with all measurement points, and graphic representation of th ST Modifications
Since it is not clear can you please, modify as following in order to avoid any misinterpretation:
4.5 ST segment analysis for all 12 ECG leads, with diagnosis with all measurement points

Answer: This is a standard requirement regarding the ST segment analysis and the graphic representation of the modifications. It remains as initially requested

12.13 No more than 20 seconds for warm up time and calibration to full accuracy It is lock out specification with not any clinical value.

Please, **modify** as following:

12.13 No more than 1 min for warm up time and calibration to full accuracy

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

1.10 VENTILATORS
-Modes of ventilation:

Please, be so kind to modify them in general, in order to avoid any misinterpretation -02 measurement with maintenance-free electrochemical **dual probe fuel cell**
A new oxygen measurement technology that apply in the medical ventilators today is based in the Paramagnetic 02 Cell which offers excellent linearity, accuracy, repeatability, stability in time and environment conditions and wide range in measurement
with a very short time of measurement response compared with existing other methods and sensors such as galvanic fuel cell that have been used in this devices until today. This sensors are non consumable parts and because of their features they maintains the same stability all the time, thus reducing periodic maintenance and calibrations from operators which has been all the time significant subject of troubles and device synchronization for treatments

Please, **modify** the request as following at least **-02 measurement with maintenance-free**

Answer: The specification **O2 measurements with maintenance-free electrochemical dual probe fuel cell** amended to: **O2 measurements with maintenance-free cell**

Lot 3
The technical specifications in question include lock-out and competition limiting specifications for Items 3.4 (DIGITAL MAMMOGRAPHY).

The specific clarifications which we are addressing:

Items with technical specifications which only one manufacturer can fulfill

Specifications Lot 3: Radiology, item 3.4 DIGITAL MAMMOGRAPHY is requested: "Prone stereotactic table Mammography prone breast biopsy table, for biopsy procedures. Height adjustment by food pedal, with antistatic revolving and lockable wheels"

Technical specification for this item are a lock-out in favor of GIOTTO and Hologic . The bid documents call for a prone breast biopsy table with antistatic revolving and locable wheels which is a feature exclusive to GIOTTO. The stereotactic biopsy can be performed without the need of pron table. The required specification for prone table except it is a lock out specification in favor of a company and excluding the well

known companies and leader worldwide like FUJIFILM, SIEMENS etc, will increase significantly the cost of system (almost double). The experience of more development countries , like Turkey, is that there are only around 10 prone table installed for more the 400 digital mamographies installations
We kindly request you to CANCEL the technical specification for PRONE TABLE or to be modified as following :.

REQUESTED MODIFICATIONS
"Prone stereotactic table or motorized mammography chair and stereotactic biopsy for biopsy studies
Mammography prone breast biopsy table or stereotactic biopsy chair, for biopsy procedures. Height adjustment by food pedal, with antistatic revolving and lockable wheels or motorized mammography chair for biopsy procedures"

Answer: The specification:
Prone stereotactic table

Mammography prone breast biopsy table, for biopsy procedures. Height adjustment by food pedal, with antistatic revolving and lockable wheels

is amended to:

Table/Chair suitable for stereotactic biopsy procedures:

height adjustment by foot pedal or motorized control, with antistatic revolving and lockable wheels

Question

Lot.6

1. high pressure contrast injector for angiography lot 6

a. Do you need a single head or double head injector?

b. If you need a single head injector, please tell me if it must be wireless (with battery) or cable version

c. Please specify with remote control or with interface for the brand of angiography (Siemens, Philips, Toshiba etc...)

d. Please specify if the disposable for starting work are need, if yes please specify the quantity.

Answer

Lot.6

a) Single head injector
b) According the respective technology
c) According the respective technology

Question N.13

Lot.6

Uninterruptible power supply at angiography lot 6

"Uninterruptible power supply for whole should be with at least 5 min operating time for full loaded system."

Please clarify/specify if it is requested a UPS for Hemodynamic system only (since it is at the hemodynamic system technical requirements) or for the whole angiography system

Answer

Lot.6

A UPS is requested for the whole Angiography system not just for the Hemodynamic system

Request for Clarifications for Section VII. Schedule of Requirements Part 2. Technical Specifications

Lot 1: Intensive Care

Item 1.8 - Patient monitors - 21 pcs

1. Requirement is :

2.1. Minimum: LCD or TFT, min 17", color screen 1024 x 768 pixel

Question:

In the requirement the Committee requires patient monitor that has a display of 17". This requirement locks out many market leader patient monitor providers from offering their high end solution which could bring additional functions to the patients that are not specified in the specification. So we kindly ask the Committee to accept a solution that can provide 15" built in color touch display with the option on request to provide a secondary screen that can be 17" or 19" inches in diameter.

Answer: The specification: Minimum: LCD or TFT, min 17" is amended to: Minimum: LCD or TFT, min 15"

2. Requirement is

4.3. Heart Rate measurement range: 20 - 290 bpm

Question:

In the heart rate measurement requirement the Committee is asking a solution that has as a minimum heart rate 20 bpm which is excluding the market leader companies to make competitive offer. We kindly ask the Committee to accept minor deviation from the minimum requirement and accept a solution that can provide measurement range from 30-300 bpm as there is no clinical relevancy to measure 20 bpm.

Answer: The variation of the parameter in the above mentioned range is considered minor deviation.

3. Requirement is :

8.3. Adjustable time ranges in automatic mode from 1 min to 480 minutes

Question

The requirement refers to non-invasive blood pressure measurement automatic time range and from the other requirement it is clear that the device will be used for high acute patient that need frequent check in NIBP measurement.

We kindly ask the Committee to accept a solution that time interval can be from 1-240 minutes as the severe patient needs to have frequent check in NIBP max. 15-30 minutes interval.

Answer: The variation of the parameter in the above mentioned range is considered minor deviation.

Item 1.9 - ANESTHESIA MACHINE - 5 pcs

1. Specification requests:

Emergency oxygen flush 25 - 75 L/min bypassing the vaporizers

Question:

We kindly ask the Committee to accept the **Emergency oxygen flush range 35-75 L/min,** as this over-protects the patient and in case of emergency the anesthesiologist must deliver emergency oxygen with a high flow.

Answer: **The variation of the parameter in the above mentioned range is considered minor deviation.**

2. Specification requests:

Electronically controlled, gas driven ventilator - No consumption of driving gas

Question:

We kindly ask the Committee to **accept a small consumption in the driving gas,** as this is necessary in the gas driven ventilator that it is requested. The small consumption of the driving gas for gas driven ventilators are necessary for patient safety and device protection as well as this provides that no contamination can go into the ventilator through the patient tube or exhaust line.

Answer: The specification: Electronically controlled, gas driven ventilator - No consumption of driving gas is amended to: Electronically controlled, gas driven ventilator

3. Specification requests: **I:E ratio 3 : 1 to 1 : 8**

Question:

We kindly ask the Committee to accept **the l:E range 2:1 to 1:8,** as this is suitable even for Inverse Ratio Ventilation, which is the clinical scope of a setting > 1:1.

Answer: **The variation of the parameter in the above mentioned range is**

considered minor deviation.

4. Specification requests:

Battery min 45 minutes

Question:

We kindly ask the Committee to **increase the battery autonomy to 70 min,** as this is also a requirement at the patient monitors. This could provide the same autonomy and continuous operation for the anesthesia and patient monitors as well.

Answer: This specification fulfills the need for autonomy and remain as initially requested: **Battery min 45 minutes**

Item 1.10-VENTILATOR/RESPIRATOR - 4 pcs

1. Requirement is :

Modes of Ventilation: PPV (CMV), SIMV, SIMVASB (SIMV/PS) CPAP, CPAPASB (CPAP/PS), IPPVAssist (CMVAssist), BIPAP/PCV+

Question:

We kindly ask the Committee to **include also Non Invasive Ventilation, Pressure Control with Volume Guarantee and Pressure Support with Volume Guarantee.** All modern types of Ventilators offer these Modes of ventilation in order to support as many different pathologic cases as possible.

Answer: Bidders are allowed to offer additional ventilation modes, besides the ones already included in the technical specifications

2. Requirement is: **Automatic and manual in slope/ rise**

Question:

We kindly ask the Committee to clarify **if an automatic preset according to the Patient type and weight will be accepted.**

Answer: This solution will be accepted for the above required specification

3. Requirement is: **Use of the ventilator without additional proximal or distal filters possible**

Question:

We kindly ask the Committee to clarify if it is required the possibility to use the ventilator without a proximal flow sensor.

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

4. Requirement is:
Volume constant ventilation with free patient breathing during both inspiratory and expiratory phase

Question: We kindly ask the Committee to clarify if it is required the ventilator to have an active Exhalation valve in order the patient to be free to get additional flow in both inspiratory and expiratory phases.

Answer: **Specification: Volume constant ventilation with free patient breathing during both inspiratory and expiratory phase is amended to: Synchronized ventilation with minimal tidal volume target**

5. Requirement is: **Tidal volume 10-2000 ml**

Question:

We kindly ask the Committee to change the minimum Tidal Volume setting to 20 ml as this is a setting suitable even for Infant patients. A setting less than 20 ml would be considered suitable for Premature Neonates and would be combined with a Frequency setting more than 100 b/min which is the requirement for this type of Ventilator.

Answer: **The variation of the parameter in the above mentioned range is considered minor deviation.**

6. Requirement is: **With inspiratory trigger**

Question:

We kindly ask the Committee to clarify the required method of triggering; is it Flow triggering and Pressure Triggering (very useful also in Non-Invasive Ventilation)?

Answer: The specification: **With inspiratory trigger** is amended to**: Flow and/or Pressure inspiratory triggering**

7. Requirement is: **02 measurements with maintenance-free electrochemical**

Question: We kindly ask the Committee to clarify if the required sensor is the traditional chemical sensor or cell that needs to be replaced every 6-8 months or new technology sensor that is maintenance free and does not require replacement?

8. Requirement is: **dual probe fuel cell**

Question: We kindly ask the Committee to clarify the exact requirement.

Answer (7. and 8.): The specification **O2 measurements with maintenance-free electrochemical dual probe fuel cell** amended to: **O2 measurements with maintenance-free cell**

9. Requirement is: **Built-in trolley**

Question:

We kindly ask the Committee to clarify the requirement for additional crucial usability components of the ventilator. These components to be added in your requirements would be: Rotatable Touch Screen 15" with four waveforms, loops, alarm records, patient trends, patient support arm and patient circuit, brakes for the trolley.

Answer: The specifications: Touch Screen 12" monitor with four waveforms, loops, alarm records, patient trends, patient support arm and patient circuit, brakes for the trolley are added.

10. Requirement is : **Internal battery for min 45 min, Power supply 220V, 50 Hz**

Question:

We kindly ask the Committee to clarify if together with the electric requirements there are or should be added pneumatic requirements for 02 and Air supplies.

Answer: **The requested specification is sufficient. No other requirements will be added.**

Lot **2** : Ultrasonography and Endoscopy

According to **Section II Bid Data Sheet (BDS),** it is provided that ***"the number and identification of lots (contracts) comprising this ICB includes ".....Lot 2: Ultrasonography and Endoscopy.....".***

The way this lot is structured, includes equipment of two **(2) different categories** (U**/S** and Endoscopy), and does not allow for a bidder to bid for only one out of the two categories. Given that the accelerating technological evolution in the field of medical equipment has led the majority of medical equipment providers to be specialized in specific categories of equipment, in both sale as well as provision of after sales services, and given that in this way the Purchaser will not have the option to select for each category of products the best one from technology perspective or the one that has the better price, we consider that **separating Lot 2 in two different lots, one for Ultrasonography and one for Endoscopy, will expand competition by allowing a bigger participation of widely accepted leading technologies** in this Tender.

Therefore, we kindly request the **amendment** of the tender book in this respect, by **separating Lot 2 in two different lots, one for Ultrasonography and one for Endoscopy.**

Answer: No amendment of the lot composition will be applied

ITEM 2.1 - CARDIAC ULTRASOUND - 2 pes

1. Requirement is: **Contrast Imaging**

Given that the requested ultrasound system is for Cardiac applications the only contrast technique with a clinical value would be contrast imaging for cardiac evaluation.

In order to ensure that the offered system will have the proper features that would add clinical value to the system for the intended purpose, we kindly request to specify the usage of the technique and please accept the following modification:

Specification: **Contrast imaging for cardiology**

Answer: The specification **Contrast Imaging** is amended to: **Contrast imaging for cardiology**

2. Requirement is: **Alphanumeric keyboard up-down mobility of console**

Given that the requested ultrasound system is for Cardiac applications, the examination is always performed with the patient in lying position, therefore the up-down mobility of the console does not add any special value to the clinical efficiency of the system, however limits the competition.

We kindly request to expand the specification, omitting the request for up-down mobility of console, allowing for broader participation to the tender, and please accept the following modification :

Specification : **Alphanumeric keyboard**

Answer: The specification: **Alphanumeric keyboard up-down mobility of console is amended to**

Alphanumeric keyboard

ITEM 2.2 - ABDOMINAL ULTRASOUND - 6 pcs

1. Requirement is: **B-mode FRAME RATE: min. 1500 images/sec.**

The ultrasound system to be offered by our company has a combination of latest technologies and an agile beamformer providing extremely high speed image acquisition and ultrasound images of high resolution and uniformity. Our system has a frame rate in B-Mode of 1449, slightly lower than the requested.

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

Specification : B-mode FRAME RATE: min. 1440 images/sec.

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

2. Requirement is: **Min. 4 second harmonic bands**

Different ultrasound systems manufacturers have different ways of displaying harmonic signals -either in harmonic bands or harmonic frequencies.

In order to avoid confusion we kindly request to expand the specification, allowing for broader participation to the tender, and please accept the following modification:

Specification Min. 4 second harmonic bands or frequencies

Answer: The specification Min. 4 second harmonic bands amended to: Min. 4 second harmonic bands or frequencies

3. Requirement is:

Continuous Wave Doppler (CWD) velocity range min.: +/- 16 m/sec (at 0 degree sample volume angle correction)

Given that the system purpose is for abdominal examinations and the requested configuration does not include cardiac sector probe, the request for such a specific velocity range in CW Doppler, limits competition significantly, without adding any clinical value to the system for the intended purpose.

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

Either **delete** the phrase: "velocity range min.: +/- 16 m/sec (at 0 degree sample volume angle correction
or

Modify specification : **Continuous Wave Doppler (CWD) velocity range min.: +/- 10 m/sec (at 0 degree sample volume angle correction)**

Answer: **The specification: Continuous Wave Doppler (CWD) velocity range min.: +/- 16 m/sec (at 0 degree sample volume angle correction) is amended to**: **Continuous Wave Doppler (CWD)**

4. Requirement is: **Real-time anatomical M-mode imaging with at least 3 straight line cursors**

The request for "at least 3 straight line cursors" in Anatomical M-mode limits competition significantly - since only one or two manufacturers may have this feature - without adding any clinical value to the system for the intended purpose (abdominal applications), since Anatomical M-Mode is mainly a technique for cardiology applications.

We kindly request to expand the specification, deleting the phrase **"with at least 3 straight line cursors"** allowing for broader participation to the tender, and please accept the following modification:

Specification: **Real-time anatomical M-mode imaging**

Answer**: The specification Real-time anatomical M-mode imaging with at least 3 straight line cursors amended to: Real-time anatomical M-mode imaging**

5. Requirement is: **Doppler sample volume size range: min. from 0,5 mm to 20 mm**

Ultrasound manufacturers are developing ultrasound platforms combining technologies and parameters to achieve optimal clinical efficiency. The request for the specific Doppler sample volume size range limits competition significantly without

adding any clinical value to the system for the intended purpose. The ultrasound systems of Our company have a high sensitive Doppler technique with sample volume size ranging from 1 to 16 mm.

We kindly request 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 : **Doppler sample volume size range: min. from 1 mm to 16 mm**

Answer: **The variations of the above mentioned specifications are considered minor deviations**

6. Requirement is: **Real Time 3D**

This technique operates only with specialized volumetric probes. In the standard system configuration there is no request for such probes. In addition, in a following paragraph the same technique (3D/4D) for OB/GYN is requested to be offered as optional.
Since the technique is the same, in order to avoid confusion as per the standard configuration, we kindly request this technique to be offered as optional and please accept the following modification:

Specification: **Real Time 3D (optional)**

Answer: **The specification: Real Time 3D is amended to: Real Time 3D (optional)**

7. Requirement is: **Automatic Volume Measurement - Multi slice**

The above are very specialized volume imaging techniques, mostly used in obstetrics and gynecology and might limit competition.

Since there is no request for specialized volumetric probe in the standard configuration, we kindly request to **delete this specification,** as this will not affect clinical efficiency of the system for the intended purpose, allowing for broader participation to the tender.

Answer: The specification: Automatic Volume Measurement - Multi slice is removed.

8. Requirement is: **Number of measurements displayed simultaneously on the screen: Minimum 10**

The ultrasound systems of our company have 9 measurements displayed simultaneously on the screen, which is sufficient for the intended purpose.

We kindly request 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: **Number of measurements displayed simultaneously on the screen: Minimum 9**

Answer: The specification: **Number of measurements displayed simultaneously on the screen: Minimum 10 is amended to: Number of measurements displayed simultaneously on the screen: Minimum 9**

9. Requirement is: **TDI/Strain Analysis**
Advanced Cardiac Calculation Package with kinetic imaging, wall thickness or adequate, Optional

The above techniques are advanced cardiology techniques used only in cardiological departments by trained and certified personnel.

Our company has developed different series of ultrasound systems equipped with the most advanced techniques to address the needs and requirements of each different medical specialty.

The request of such techniques in a system intended for abdominal examination does not add any additional clinical value to the system, however limits competition and does not allow Our company to participate to the tender with a latest technology ultrasound system, suitable for abdominal applications.

In addition, we noticed that the specifications request advanced cardiology techniques for a system intended for abdominal use. On the other hand techniques such as Elastography imaging, that would definitely add clinical value to the system for the intended purpose, for the evaluation of structures suspicious for malignancy, are not requested at all.

We kindly request to **delete the specification,** as the absence of the above techniques does not affect clinical efficiency of the system for the intended purpose, allowing for broader participation to the tender.

Answer: The specifications: **TDI/Strain Analysis, Advanced Cardiac Calculation Package with kinetic imaging, wall thickness or adequate, Optional** are optional. These specifications are not mandatory.

10. Requirement is: **3D/4D in Cardiology (optional)**

As previously explained, Our company has developed different series of ultrasound systems equipped with the most advanced techniques to address the needs and requirements of each different medical specialty.

The 3D/4D is the most specialized cardiology technique performed only by trained cardiologists with specialized probes and does not have any usability in a radiology dept. Not only Our company, but also other manufactures such as Toshiba and Siemens have developed special ultrasound systems equipped with the 3D/4D cardiology feature and respective probes, while they have other models for radiology use.

The request for this feature does not allow the participation of Our company with a high technology ultrasound system suitable for abdominal examinations.

We kindly request to **delete the specification,** as the absence of the above technique does not affect clinical efficiency of the system for the intended purpose, allowing for broader participation to the tender.

Answer: The specifications: **3D/4D in Cardiology (optional) are optional. These specifications are not mandatory.**

ITEM 2.3 - OBSTETRICS AND GYNECOLOGY ULTRASOUND - 8 pcs

1. Requirement is:

The control panel with height adjustable, equipped with display LCD touch, for command

Given that the requested ultrasound system is for obstetrics and gynecology applications, the examination is always performed with the patient in lying position, therefore a control panel with height adjustable does not add any special value to the clinical efficiency of the system, however limits the competition.

We kindly request to omit the request for height adjustable control panel, allowing for broader participation to the tender and please accept the following modification :

Specification: **The control panel, equipped with display LCD touch, for command**

Answer: **Specification amended from: The control panel with height adjustable, equipped with display LCD touch, for command to: The control panel, equipped with display LCD touch, for command**

2. Requirement is: **The minimum number of elements: 192**

Our company has a specialized 4D Convex probe with 128 elements that in combination with the latest technology agile beamformer performs high quality examinations.

We kindly request 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 minimum number of elements: 128.

Answer: Specification amended from: **The minimum number of elements: 192**
to: **The minimum number of elements: 128 or higher**

Lot **3:** Radiology

Item 3.4 DIGITAL MAMMOGRAPHY

1. Requirement is:

Rotating anode preferably with a Tungsten anode to reduce the dose with focuses approx. 0.1-0.3 mm and filtration in Al material and in Rh or W material

Our company has Molybden/Rhodium anode combinations it is the most appropriate for mammography examination because, Molybdenum can create the optimal X-ray spectrum for thin and non-dense breast penetrating adequately without loss of information, and Rhodium is creating the optimal spectrum of X-Ray for thick and dens breast which need photons for higher energy (19-21keV) which are the adequate to penetrate in this anatomy.

The W anode can create only high spectrum.

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: **Rotating anode, specify for evaluation the anode material, preferable the ones which reduce dose, focuses approx. 0.1-0.3 mm and mention filter material.**

Answer: **The specification states "preferably with a Tungsten anode", the Molybden/Rhodium anode is also accepted.**

2. Requirement is: **Pixel size, maximum 90 um.**

Our company has a 100 um. Too small pixel size is not recommended because small pixel collects lot of noise and deteriorates the image quality decreasing the signal to noise ratio. Too big pixel size decreases the resolution consequently the small submillimetrical objects like microcalcifications in the breast cannot be detected which can lead to miss the cancer. The optimal pixel size in mammography is around 100 microns. With lOO micron pixel size is not necessary to join pixels(binning) in case of Tomoshhyntesis.With binning the resolution will be lower which can also lead to miss the cancer in tomo.

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 Pixel size, maximum 100 um.

Answer: Specification amended from: **Pixel size, maximum 90 um Pixel size to Pixel size, maximum 100 um**

3. Requirement is: **Prone stereotactic table**

Our company hasn't such solution; Prone table is exclusive solution of very two only companies

On the other hand the disadvantage of the prone table, is that the biopsy needle cannot be inserted parallel to the chest wall, which can lead to cause pneumothorax.
- in case of multifocal lesion if one of the lessions is in the upper outer quadrant, it cannot be reached, the patient should be removed and rotated, which is extremely inconvenient for 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: table suitable for stereotactic

Answer: The specification:
Prone stereotactic table

Mammography prone breast biopsy table, for biopsy procedures. Height adjustment by food pedal, with antistatic revolving and lockable wheels

is amended to:

Table/Chair suitable for stereotactic biopsy procedures:

height adjustment by foot pedal or motorized control, with antistatic revolving and lockable wheels

Question/Comment

Lot 2 **(ultrasonography and endoscopy)** related to **endoscopy** is a lock-out for Karl Storz, and unless the specifications are opened up, this will effectively be a sole source for that manufacturer. We request that the below 4 specifications be modified to broaden competition, permitting responsive and competitively-priced bids, in line with industry best practices. This lot also contains a specification that is clinically inappropriate, which we request be removed.

General comments for Lot 2 **(ultrasonography and endoscopy)** related to **Ultra-Sound** as per points below:

• ***Sector phased array transducer 1.5 to 4.0 MHz:*** Very few manufacturers can supply a device below 2 MHz. Allowing a range of 2.0 - 4.0 MHz would permit significantly broader competition while upholding the ultrasound's critical functionality.

• ***M-mode or D-mode dynamic memory mm. 6Osec:*** The industry standard for M-Mode and D-Mode dynamic memory is 10-15 seconds. A 60 second minimum is excessive and does not yield a superior clinical outcome. Permitting a 48 second minimum would allow for broader competition while upholding the ultrasound's critical functionality.

• ***Control panel with height adjustable, equipped with display LCD touch, for command:*** Permitting soft keys in lieu of an LCD touch would yield the same or a superior outcome for the ultrasound, while broadening competition. LCD touch screens are excessively expensive yet have the same functionality as soft keys.

• ***Compatible with HDTV videoscopes; videolaparoscopes, videocolonoscopes, videogastroscopes etc.:*** Only Karl Storz can fulfill this specification. If left unchanged, it will lock out all competition. Moreover, it is also clinically inappropriate, as these solutions combine devices designed for both sterile and non-sterile environments. Unless this specification is removed, Philips' solutions will be precluded from participating in this lot.

Answer:

The specifications:

- Sector phased array transducer 1.5 to 4.0 MHz amended to ***Sector phased array transducer*** **2.0 - 4.0 MHz;**

- M-mode or D-mode dynamic memory mm. 6Osec amended to **M-mode or D-mode dynamic memory min 45 sec;**

- Control panel with height adjustable, equipped with display LCD touch, for command amended to **Control panel with height adjustable, equipped with soft key LCD display, for command**

The specification **-Compatible with HDTV videoscopes; videolaparoscopes, videocolonoscopes, videogastroscopes etc.,** is removed

Lots 3 & 6 Include Competition Limiting Specifications Which Should Be Opened Up

Lot 3 contains 4 specifications which are excessively restrictive and offer no additional clinical or safety advantages. As currently written, these specifications preclude [company name] from participating; however, minor adjustments to them will broaden competition while upholding the desired functionality of the equipment being procured

• ***Tables with removable upper uppers:*** This is a competition limiting and obsolete specification. Allowing for fixed uppers that can be cleaned without removal, in addition to removable uppers, would have no material impact on the X-ray equipment yet would broaden competition. The industry is evolving towards using fixed uppers which can be cleaned as this is considered more practical and user friendly by equipment operators.

Answer: Specification **Tables with removable upper uppers is removed**

• **Table range movement that table: 115cm longitudinal, transverse 25cm:** This is a competition limiting specification. It provides no material benefit to the X-ray equipment, yet it will preclude [company name] from participating. Permitting a maximum range of 42-115 cm longitudinal, 25 cm transverse would still permit full imaging of the body and other functionalities.

Answer**:** Specification **Table range movement that table: 115cm longitudinal, transverse 25cm** amended to: **Table range movement: approx. 100 longitudinal, transverse 25cm.**

• **Manual and motorized collimation:** This is a competition limiting specification. While some manufacturers' x-rays include motorized collimators, the industry standard for analog systems is manual collimation. Motorized collimation is a feature which was designed for digital x-ray solutions. Opening this specification to permit both manual and motorized collimation will not reduce the performance of the x-ray systems, and it will broaden competition.

Answer: The **specification: Manual and motorized collimation is amended to: Manual or motorized collimation**

• **Number of pixels mm. 2500x3000:** This specification limits competition. [company name] analog x-ray systems offer high quality images with 2476x3042 pixels. This resolution is considered clinically sufficient for accurate x ray diagnosis. Permitting solutions with a minimum of 2476x3DOO constitutes a minor modification, yet this will broaden competition and without reducing the equipment's performance.

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

Minor Modifications to Lot 1 Will Permit [company name] to Bid Appropriate Solutions

Lot 1 contains 3 excessively narrow specifications that severely limit the number of

vendors that can submit a competitively-priced bid. The specifications are written in a way which force several companies to offer their higher-end solutions which will not be price-competitive. Minor adjustments will permit [company name] to bid its appropriate solutions which will be competitive with those of all other manufactures for this market segment. There is also a vague specification that must be clarified.

• **12V rechargeable battery voltage:** It can be beneficial for batteries to range up to 14.5V in order to drive 12V of internal circuitry. Adjusting the upper threshold to 14.5V would uphold this device's critical functionality while permitting [company name] and other global manufacturers to submit a competitively-priced bid.

Answer: The rechargeable battery could be 12V or higher

• **Charges from 0 to 200joules in less than 5 seconds with a new fully charged battery:** Capping charge time at 5 seconds would significant increase the price of this equipment while adding no clinical benefit. Rather, permitting a charge time of less than 6 seconds would uphold this device's critical functionality while resulting in a more competitive procurement.

Answer**: The reason why this technical specification is required is related to the vital importance of the quick response with enough power to proceed with the next shock. Quicker the response better for the patient. However, a defibrillator providing a 6s response of the required power is accepted.**

• **Reusable hard paddles for external defibrillation:** This is an obsolete specification as many global manufacturers now produce paddles that can accommodate both adult and pediatric patients. Permitting paddle adapters with dual functionality would broaden competition while upholding the defibrillator's critical functionality.

Answer: This solution will be accepted.

• **Single use pads for 20 applications:** Please specify how many pads be designed for adult versus pediatric use.

Answer: **Single use pads for 20 applications – 10 adults and 10 pediatrics**