(Part 1)Technical Clarification No.6- Question and Answer

Question 1

Regarding the Technical Specification of Lot N. 3, Section VII of the Schedule of Requirements, pages 117-122, many of the technical features listed in this document appear to be strict.
Could you please clarify whether the Technical Specifications should be intended as exclusion criteria? Otherwise, are the Companies allowed to produce documents to demonstrate the equivalence of the offered goods, from a technical and clinical point of view?

Answer 1: Technical specifications describe the minimum requested to fulfill the need for that device. Higher technology will be accepted.

Question 2

Loti 1: Intensive Care , Item 1.6 – Electro surgery unit

The specifications of this item can comply to only one product Valleylab LS10, manufactured by the company Medtronic.

The specifications are locked-out for other products and manufacturers, therefore we would ask you either to change specifications in order to be open for other products and manufacturers, or to separate this item from the package of equipment of Lot 1.

Answer 2: **The specifications amended as per Answer 6**

Question 3

Angiography

On page Nr.138 of the technical specification of Angiography it is requested: XVIII)Display for the Control room Two 19“diagonal color flat-screen display incl. console in the control room. The resolution of the display should be at least 1,280 x 1,024 (Pixel). While on page 140 it is requested ▪ Monitors in control room In the control room should be available 2 displays Size not less than 20" Please kindly clarify this discrepancy between different monitor sizes.

Answer 3. P**lease refer to the 138 ,** XVIII)Display for the Control room Two 19“diagonal color flat-screen display incl. console in the control room. The resolution of the display

should be at least 1,280 x 1,024 (Pixel). The specification **Monitors in control room In the control room should be available 2 displays Size not less than 20"** is removed.

Question 4

As a prospective bidder in the above-referenced tender for the procurement of medical equipment, here attached we are submitting this clarification letter in accordance to Section 7.1 of the World Bank Standard Bidding Documents and Bidding Data Sheet of the tender.
One additional request for revising the technical specification of

Lot 1., item **1.6 ELECTRO SURGERY**
Required
- Blood vessels to be sealed with sinusoidal signal approx. 400kHz without interruptions

Since this specification is clearly lockout specification we kindly ask you to modify as following
Blood vessels to be sealed with sinusoidal signal approx. 300kHz without interruptions

The way it is specified is clearly only for Valleylab (part of Medronic group) model FT 10
We hope you will consider our request for clarifications and complaints in order to allow a wider participation to the tender in compliance with the international fair competition rules and principles

Answer 4: **The specifications amended as per Answer 6**

Question 5

Dears,

After careful study of the technical/product specifications, we have identified several points that will kindly ask you modifications to technical specifications for items under Lot 1, Lot 3. As currently written, a number of technical specifications can only be fulfilled by certain manufacturers only, while other specifications are overly restrictive or outdated, seriously limiting competition and effectively blocking other manufactures from participating in this tender.

REGARDING THE TECHNICAL SPECIFICATIONS:
For LOT 1:
1.DEFIBRILLATOR
1.11 Optional SpO2 and CO2 upgrade possible

We kindly ask you to cancel it since it is optional , or to be modified
Optional SpO2 and CO2 upgrade possible in delivery time , or to be cancelled as request

1.5 Syringe 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 wellknown companies are using above mentioned syringe volumes

1.6 ELECTRO SURGERY

-The instrument connected identified by Rfid radio frequency

It is lock out specification for ERBE and MEDTRONIC (Valelab) 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: For Lot 1 item 1.11

REGARDING THE TECHNICAL SPECIFICATIONS:
For LOT 1:

1.DEFIBRILLATOR
1.11 Optional Sp02 and C02 upgrade possible
Answer: These specifications are optional. They are not mandatory

1.5Syringe Pump
Answer: Specification amended to: **5-10-20-30-50/60ml syringes**

ELECTRO SURGERY

Answer : **The specifications amended as per Answer 6**

Question 6

Subject: Request for modifications regarding the tender for the procurement of Medical Equipment for Regional Hospitals
Request for Clarifications for Section VII. Schedule of Requirements

Part 2. Technical Specifications

Loti 1: Intensive Care

Item 1.6 – Electro surgery unit

The specifications of this item can comply to only one product Valleylab LS10, manufactured by the company Medtronic.

The specifications are locked-out for other products and manufacturers, therefore we would ask you either to change specifications in order to be open for other products and manufacturers, or to separate this item from the package of equipment of Lot 1.

Answer 6: Specifications Suitable for use with different instruments for open surgery and laparoscopy interventions amended to Suitable for use with different instruments for saline bipolar cut, resection and sealing in open surgery and laparoscopy interventions.

No less than 10 levels is removed, Acoustic signaling amended to Acoustic and /or visual signaling, Specific acoustic signals for each showing message, remote audio signals amended to Specific acoustic/visual signals for each showing message, remote audio / visual signals

The instrument connected identified by Rfid radio frequency amended to The instrument connected identified automatically.

Sealing and cutting should be independent amended to Sealing and cutting can be independent from each other or simultaneously.

Blood vessels to be sealed with sinusoidal signal approx. 300-500 kHz without interruptions
The maximum peak voltage not less than 250V is removed.

When the input voltage ranges from 210-260V the output power should change no more than 20% is removed.

Clamp haemostatic re-usable with a curved top 10 pcs amended to Clamp/forceps haemostatic re-usable 3 pcs.

Electrodes for sealing blood vessels, with integrated knife, single use, possible to integrate in the above clamp - 3 pcs amended to Single use electrodes for sealing blood vessels and knife for cutting, possible to integrate to the above clamp - 10 pcs/each
Pedal footswitch included

Question 7

Question N1
Item 1.8: Monitor
"ST segment analysis for all 12 ECG leads, with diagnosis with all measurement points, and graphic representation of the ST Modifications."

The requirement of the graphic representation of the ST Modifications, limits the number of possible Bidders introducing a strong raise of the performance range of prospective models. We therefore ask you to consider not mandatory the graphic representation of the ST Modifications.
Answer 7: This is a standard requirement regarding the ST segment analysis and the graphic representation of the modifications. It remains as initially requested

Question N2
Item 1.8: Monitor
"No more than 20 seconds for warm up time and calibration to full accuracy".

This requirement relates to small portable fingertips capnometers. In case of a ICU monitor, being required the display of the C02 waveform in real time, alarms setting and integrated menu and longer self-checking procedure, longer warm-up time is required to operate the monitor. We therefore ask to substitute the sentence "no more than 20 seconds" to "no more than 60 seconds". This slowing doesn't cause any disadvantages for the efficiency or security of the device.

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

Question N3
Item 2.1: Cardiac Ultrasound
"Cine loop with for B/W and Color images and scrolling memory (M-Mode and Doppler) 2000 frames"

Being this specification restrictive for some reputable manufacturers, we kindly ask you to consider this requirement as not mandatory.

Answer: This is a standard requirement. It remains as initially requested

Question N4
ITEM 2.2: Abdominal Ultrasound
"Number of dynamic memory images (so-called Cineloop): min. 2 000 frames. Provide"

Being this specification restrictive for some reputable manufacturers, we kindly ask you to consider this requirement as not mandatory.

Answer: This is a standard requirement. It remains as initially requested

Question N5
ITEM 2.3: Obstetrics and Gynecology Ultrasound
"4D Convex broadband multifrequence 2-6 MHz. The minimum number of elements: 192. Advanced technology for maximum penetration and resolution."

Being this specification restrictive for some reputable manufacturers, we kindly ask you to change it to " 4D Convex broadband multifrequence 2-6 MHz. The minimum number of elements: 128. Advanced technology for maximum penetration and resolution.". We underline that this change has not only no negative effects on the use and efficiency of the equipment for any type of exam, but this changing would increase the competitiveness of the bid.

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

Question N6:
Item 1.1: Defibrillator
"Optional Sp02 and C02 upgrade possible"

This requirement states that it must be possible to connect the optional modules for SpO2 and CO2. If this interpretation of the requirement is correct, since requiring the CO2 measurement module for a defibrillator implies a substantial raise of the performance

range for the defibrillator, we ask you to kindly consider as optional the possibility to connect the CO2 module.

Answer: These specifications are optional. They are not mandatory

Question N.8
Item 1.5: Syringe Pump
"Syringe to be used disposable 2- 5- 10- 20-30 -50 ml syringe"

This requirement limits the number of prospective manufacturers that can provide this item, as there are few manufacturers that produce pumps that can support 2mL syringes. Moreover not all manufacturers of infusion disposables can produce syringe of this capacity thus limiting the competitiveness and the availability of such disposables. In order to allow many quality manufacturers to participate we ask you to change this request in "Syringe to be used disposable 5-10-20-30-50 ml Syringe", removing the 2ml syringe.

Answer: Specification amended from "Syringe to be used disposable 2- 5- 10- 20-30 -50 ml syringe" to "Syringe to be used disposable **5-10-20-30-50/60ml syringes**

Question N.14
LOT 5 -MRI
The echo times requested are not very important, because they have not so much clinical value. The more important is all homogeneity and signal to noise ratio not ms. We recommend to make a wider range of ms for echo times in order to make tender more competitive

Answer: please refer to the amendments in MRI specifications

Question N.15. For all Lots
There are some cases of specific technical request that leads to a certain Brand. In this way other Brands seems to excluded by this especially in big equipment like MRI, X-Ray Ultrasound, etc.
I suggest to consider all these deviations as minor ones.

Answer: The evaluation will be done according the World Bank Guidelines

Question N.18

Item 3.1 – X Ray Machine

- "Tables with removable upper uppers": Please clarify the meaning of this requirement.
- "Table range movement that table: 115cm longitudinal, transverse 25cm": accept longitudinal range movement of approx. 100 cm. We underline that this change has no negative effects on the use and efficiency of the equipment for any type of exam.
- "Accessories: Volume 1 35x43 cm, Volume 1:35x35, Volume 1 30x40 cm, Volume 1 18x24": Please clarify;

Answer:

- Specification ***Tables with removable upper uppers is removed***
- Specification ***Table range movement that table: 115cm longitudinal, transverse 25cm*** amended to: **Table range movement: approx. 100 longitudinal, transverse 25cm.**
- ***Volume*** is referring to the ***Cassettes***

Question N.19

Item 3.2 – X-RAY MOBILE

- "mAs range: 0.1 to 100 mAs": please modify the lower limit to 0.5. We underline that this change has not only no negative effects on the use and efficiency of the equipment for any type of exam, but this changing would increase the competitiveness of the bid.
- "Tube rotation around support arm: +/- 180°": please modify this request in +/- 90°. We underline that this change has not only no negative effects on the use and efficiency of the equipment for any type of exam, but this changing would increase the competitiveness of the bid.
- "Number of pixels min. 2500x3000": This number is too high, it's not coherent with pixel pitch. Please modify.
- "Integrated workstation with HDD capacity of min. 500 GB": Please modify this request in capacity of min 300GB. This change has no negative effects on the use and efficiency of the equipment.

Answer: These specifications are largely produced by the different producers.
Specification Integrated workstation with HDD capacity of min. 500 GB amended to Integrated workstation with HDD capacity of min. 300 GB

Question N.20

Item 3.3 - RADIOGRAPHY AND FLUOROSCOPY

- The column and arm rotation ± 90 °: please delete this request. We underline that this change has not only no negative effects on the use and efficiency of the equipment for any type of exam, but this changing would increase the competitiveness of the bid.

- "Movement lamp (focal center)": Please clarify the meaning of this requirement.
- " Ore audio-video alarm in case of high temperature anode mud": Please clarify the meaning of this requirement.
- "Tube Movement (focal center)": Please clarify the meaning of this requirement (it's similar to Movement lamp (focal center)";
- "Table height of approximately 110 cm": Please confirm that a table height of 100 is acceptable.
- "The area of movement of the spot: longitudinal, transverse, vertical": Please clarify the meaning of "spot". Could you also clarify the purpose of transverse movement, should it be considered as optional?

Question: Lot 1 Item 1.7 NEBULIZER

Answer: the specification Aerosol heating unit for the nebuliser is removed

Question N.21- Complain provided from the firm

The answer of this complain is already provided to the bidder

As a prospective bidder in the above-referenced tender for the procurement of medical equipment, we are submitting this clarification letter in accordance to Section 7.1 of the World Bank Standard Bidding Documents and Bidding Data Sheet of the tender.

We are witness that our Ministry of Health is continuing strongly the effort to modernize the Healthcare equipment in the public sector in Albania. We feel that the intention of the Ministry is to encourage the participation of the leading manufacturers that develop the expected quality and technology and at the same time, create an open and fair competitive environment, which does not exclude well known manufacturers

We respectfully request your consideration and urge your agreement with our suggested modifications to technical specifications for items under Lots 3. As currently written, a number of technical specifications can only be fulfilled by certain manufacturers, while other specifications are overly restrictive or outdated, seriously limiting competition and effectively blocking other manufactures from participating in this tender.

We Albaphoto sh.p.k located in Tirana – Albania in the adress : Rr.Frederik Shiroka,Nd. 18 H.9Njesia Bashkiake has a distribution agreement with Fujifilm Europe B.V in Netherlands and his affiliate office FUJIFILM Dis Ticaret A.S. in Turkey. As FUJIFILM, we would like to participate in this tender but we kindly ask you to consider to change some points as below:

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

1. Specification Lot 3: Radiology, item 3.1. X-RAY MACHINE is requested:

Table range movement that table: 115 longitudinal, transverse 25cm

This point means that the table movement must be 57,5cm for both side and it looks so hard and almost all the manufacturers produce products as 100 cm (50 cm/50cm).

REQUESTED MODIFICATIONS:

Table range movement that table: 100 longitudinal, transverse 25cm

In order to participate with FUJIFILM FDR Smart f, we need to change one point as above.

Specification Lot 3: Radiology, item 3.2.X-RAY MOBILE is requested:

Small focus min.0.8mm, large focus min. 1.3mm

Number of pixels min. 2500x3000

Resolution min.3,0lp/mm

LCD Color touch screen of at least 19”

REQUESTED MODIFICATIONS:

Small focus min.0.7mm, large focus min. 1.3mm

Number of pixels min. 2300x2880

Resolution min.3,3lp/mm

LCD Color touch screen of at least 19”

The reasons of these requests as below.

Focus numbers depend on the tube type what the company use so some companies get the tube from Varian some companies get from Toshiba. Therefore those changes can be useful for each companies to participate.

Pixels pitch point is matching by FUJIFILM so this point and resolution must be the same mathematically. It means 3,0lp/mm must be changed as 3,3lp/mm. The screen must be changed as 17 inch to offer FUJIFILM FDR GO mobile digital x-ray.

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 pron table except it is a lock out specification in favour 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. Additionally, the cost of prone table is more than 5 times more than motorized mammography chair and stereotactic biopsy unit together. On the other hand, prone table needs to get another room to install cause of having own x-ray system. We FUJIFILM has 158 digital mammography installation only in Turkey so according to technical specification if we make comparison, FUJIFILM Amulet Innovality has much more qualified specification for each point. As an example; even we have 7 kW generator power and 50 microns detector quality, we do not much the specification due to one point shown below. The Amulet Innovality is upgradable to tomosynthesis and the other master features as main competitors. Consequently, even you delete the prone table point, cause of having stereotactic biopsy for FUJIFILM, Hologic, GE, Siemens, Giotto companies, nobody would be out of the tender.

We kindkly 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 unit** for biopsy procedures. Height adjustment by food pedal, with antistatic revolving and lockable wheels **or motorized mammography chair for biopsy procdures**"