Chapter B :

Technical specifications

Topic 1.

Defibrillator (item 1.1 Lot 1)

- Requirement on the technical specifications point 2.5: Charges from 0 to 200 joules in less than 5 seconds with a new fully charged battery. We would require revision of this technical requirement from 5 seconds to 6 seconds which does not impact at all the clinical performance and benefit of the equipment and at the same time allow higher number of the bidders to offer for this item. We do believe that scope of the requirements is to assure best performance but also assure good practice in the procurement process and all reputable manufacturers can quote their products in order also to save budget of the tax payers.

Answer Topic 1. : 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.

Topic 2. Incubator (Item 1.2Lot 1)

- Requirements on the technical specifications as below are strictly build up adopting specific manufacturers technical data and combination of those technical specifications make it impossible to offer for other reputable manufacturers. We strongly agree to keep the best performance and quality of the medical equipment procured but also there must be a fair competition. We will list below arguments that widening technical specifications will not impact their performance and will help in open procurement process and high quality equipment.

a) Weighing in at a screen resolution of 1gr.

b) Weighing Accuracy 10 kg + 1gr

What is the clinical benefit of screen resolution and accuracy 5 gram compared to 1 gram? From the clinical point of view is nothing and requirement is just a number which does not allow reputable manufactures to offer their solution. The weight accuracy of + 1gr is not usual for newborn patients. In regular use, for the patient's weight the difference of 5 grams is perfectly acceptable. In addition, we would like to emphasize that the environment and conditions inside the incubator offer a large number of factors that will influence the patient's weighing, much more than the weighting accuracy requested in the tender. Please kindly clarify if deviations from above requirement will be considered minor or requirement will be changed.

Answer Topic 2 a) and b)

The baby incubator is a highly sensitive devices directly related to the baby survival. The technical specifications required aim to guarantee the quality of the product. The variations of the parameters in the above mentioned range are considered minor deviations.

c) Air curtain to keep the temperature during the patient treatment

This requirement is clearly adopted from specific manufacturer and is a locked up. Every manufacturer has its own technology which guarantees the temperature stability inside the equipment. The technical performance of the equipment has to be ensured by the IEC standard certification, which is accepted worldwide. Please kindly clarify if deviations from above requirement will be considered minor or requirement will be removed.

Answer Topic 2 c) This is a common technology to keep the temperature during the patient treatment. Any other technology that proves to ensure the same performance will be accepted.

d) Humidity check range: 21-95 %

Please kindly note that this requirement is again adopted from specific manufacturer and clinically speaking there is no need to check for humidity below 40 %. We require this range to be modified since is just a requirement which does not allow fair participation.

Answer Topic 2, d): This specification is amended to 40-95%

e) All parameters in one screen

What if a certain manufacturer provides display of all parameters but in two different screens? Which is the clinical benefit from this requirement? This is a technological solution of each manufacturer and must be considered a minor deviation or removed. Please clarify.

f) Movable bed + / - 12 °

What is the clinical benefit of tilting + / - 10 ° compared to + - 12°? From the clinical point of view is not relevant and requirement is just a number which does not allow reputable manufactures to offer their solution. Please kindly clarify if deviations from above requirement will be considered minor or requirement will be changed. Many prestigious manufacturers offer only + / - 10 ° which from the clinical point of view is the same and have no difference with + / - 12 °. Please kindly consider to change this requirement.

g) Noise level inside incubator less than 45db

What is the clinical benefit of noise level 50 db compared to 45 db°? From the clinical point of view is not relevant and requirement is just a number which does not allow reputable manufactures to offer their solution. Please kindly clarify if deviations from above requirement will be considered minor or requirement will be changed. Many prestigious manufacturers offer their products with 50 db noise level which is widely accepted clinically also from international guidelines including from WHO guidelines. This is obviously adopted from specific manufacturer datasheet and we strongly require

revision of it. You can easily check that only one or max two manufacturers may comply with this requirement meanwhile that from the technical point of view 5 db are nothing and will not impact clinical benefits. Please kindly consider to change this requirement.

Answer Topic 2, e), f), g) The variations of the parameters in the above mentioned range are considered minor deviations.

Topic 3.

Transport Incubator (item 1.3 Lot 1)

Some of the technical requirements for this item are just taken from specific manufacturers and will not allow fair competition. We will list below our concerns regarding some requirements.

a) Power mode light: AC, DC, or external DC

This is not a clear requirement. Usage of AC or DC or external DC is a technological solution of every manufacturer and has nothing to do with clinical benefits or performance of the required equipment. We kindly demand to be instructed of what is precisely required as a power mode and leave the technology solution to the manufacturers.

Answer Topic 3. a): To further clarify this specification: this requirement covers any of the power sources needed to keep the transport incubator working.

b) Rechargeable battery 12 VDC, 24 AH

We do understand 12 VDC as an standard but clearly the capacity of fixed 24 AH is adopted from specific manufacturer and again has nothing to do with the quality or performance of the equipment itself. We kindly ask you to be less specific in such technical details and remove or include a certain range.

Answer Topic 3. b): This is a common specification of rechargeable batteries, however minor variations of AH will be accepted.

c) Min 200 complete charge/discharge cycles

This is a requirement not relevant at all and we do not understand the need .Is adopted from specific manufacturers.

d) Charge time 10 hours per battery from full discharge

- Requirement adopted from specific manufacturer. We kindly demand to be removed or be widened in certain range.

e) Safety Alarms High temperature; if incubator air temp. >39 ± 0.5 °C Low DC

Low DC <10.5 vDC, or external 28 Vdc falls down

Requirement adopted from specific manufacturer. Again this is technology solution. we agree with the requirement of the alarm but not to specify exact numbers which are adopted from a specific manufacturer or to be widened the range for a fait competition. all above requirements and combination of these are driving in specific manufacturer products we require revision as above detailed.

Answer Topic 3. c), d) e): The technical specifications required aim to avoid performance failure however the variations of the parameters in the above mentioned ranges are considered minor deviations.

Topic 4.

Syringe pump (item 1.5 Lot 1)

Please kindly note that the below requirement:

Syringe to be used disposable 2 - 5- 10 - 20 -30 -50 ml syringe

discriminates most of the manufacturers since the requirement for a 2 ml syringe does not make sense for such equipment. This requirement is also clinically useless sine no infusion of such low volume is required in the ICU. The lower level generally start with 5 ml and in cases 2 ml is required to infuse, the 5 ml syringe can be used. Please advice is this will be considered as minor deviation or the requirement will be removed for the 2 ml syringe.

Answer Topic 3. This will be considered minor deviation

Topic 4.

Nebulizer (item 1.7 Lot 1)

Technical specifications for this equipment are build up is such way that no manufacturer beside one can comply with all technical specifications. Generally speaking compressor nebulizers does not offer heating unit and this is mostly feature of ultrasonic nebulizers and this can be easy proved. Please consider to remove this request or change specifications is such a way that also ultrasonic nebulizers can be offered. Ultrasonic technology is a proven technology and nebulizers with such technology are durable, robust and perfect for hospital use. Technical requirements like for instance:

a) Aerosol heating unit for the nebulizer

b) Manometer

c) Operating pressure: 0-130 kPa

d) Strong compressor for continuous use makes impossible to offer a compliant product. Please kindly let us know if you will allow to be offered a ultrasonic nebulizer with same performance by removing technical specifications which describe a compressor nebulizer. Financial impact of this item is not even comparable with the LOT and only this item will damage the fair competition. By the way Ultrasonic

nebulizers are far more expensive than such level compressor nebulizer specified. This again shows that performance wise and clinically wise they are far better.

Answer Topic 4. a), b), c) d): The one requested is a common technology. Any other technology that proves to ensure the same performance will be accepted.

Topic 5.

Anesthesia machine (item 1.9 Lot 1)

Technical requirement for this unit as below:

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

We find this requirement "no consumption of driving gas" in conflict with a gas driven ventilator. Ventilator in general are electronically controlled gas driven ventilators, but it is of course consuming drive gas (which naturally can be configured to AIR so it does not consume the more expensive O2). Please let us know how this requirement will be considered.

Answer Topic 5. : The specifications electronically controlled, gas driven ventilator - No consumption of driving gas is amended to electronically controlled, gas driven ventilator

Topic 6 . General Endoscopic Surgery (item 2.4 Lot 2)

Specification require on page 112 of the tender documentation:

- Compatible with HDTV videoscopes; videolaparoscopes, videocolonoscopes, videogastroscopes etc..
We would like to kindly draw your attention to the fact that laparoscopy is a procedure which is carried out in sterile operating theatres while videocolonoscopy and videogastroscopy is not carried out in operating theatres. Hence, there is absolutely no logic to ask for a unit which must be connectable for videolaparoscopes and videocolonoscopes + videogastroscopes because it does not bring at all any specific clinical benefit as these are complete different procedures carried out in different areas. Unfortunately these specifications lead to specific manufacturer, more in detail to Karl Storz and the way these specifications are drawn makes other prestigious manufacturers fail in complying this specification.

Answer Topic 6. : The specification -Compatible with HDTV videoscopes; videolaparoscopes, videocolonoscopes, videogastroscopes etc.. is removed

Topic 7.

X-Ray machine (item 3.1 Lot 3)

- On page 118, technical specifications ask for

Pockets for hands

We would like to know what is meant with this requirement.

Answer Topic 7. : Clarification on the above specification: meaning – Hand holders