Procurement of Medical Devices for University Children Hospital "Tiršova"

IOP/11-2017/RD

Clarification no. 10

Issued on December 6, 2017

LOT 3

Question 1. for Lot 3, item 3,4 HFO Ventilator

In Technical specification given in Excel for Lot 3 – Equipment for General pediatric departments, Pediatric and neonatal Intensive care, Item 3, 4 HFO ventilator, there are contradictory and not enough precise requirements in requrements 1, 2 and 3. According to requirement 1 the ventilator is intended for ventilation premature, newborns and children, but considering requirements in 2 ("In standard ventilation modes ventilates for pediatric and neonatal patients") and 3 ("In HFO ventilation mode ventilates for neonatal patients") it is obvious the device does not cover all category of patients that is intended for per requirement in position 1.

To avoid free interpretations of mentioned requirements, we recommend requirements 1, 2 and 3 to be replaced with more precise definition as follows:

"1. Ventilator intended for ventilation of neonatal and pediatric patients"

"2. In standard ventilation modes ventilates patients minimum from 300g up to 30 kg of body weight"

"3. In HFO mode ventilates patients up to 10 kg of body weight or more"

On this way the ventilator performance capabilities are precisely defined with regard to patient categories.

Answer to question 1

Suggestion is accepted. Technical specification for Lot 3, Item 3, 4 HFO ventilator will be changed in requirement 1, 2 and 3. These requirements are now:

1. Ventilator intended for ventilation of neonatal and pediatric patients

2. In standard ventilation modes ventilates patients minimum from 300g up to 30 kg of body weight

3. In HFO mode ventilates patients up to 10 kg of body weight or more

Question 2. for Lot 3, item 3,4 HFO Ventilator

In position 13 of technical specification for Item 3, 4 HFO ventilator, upper PEEP value in range is excessively higher then real clinical need for declared patient categories. Therefore we recommend current requirement 13, to be replaced with:

”13. PEEP 1 - 30 cm H2O”

On this way, more specific ventilator models with regard to patient category can be offered on tender.

Answer to question 2

Suggestion is accepted. Requirement under 13. is now

”PEEP 1 - 30 cm H2O”

Question 3. for Lot 3, item 3,4 HFO Ventilator

Considering request in position 17 of technical specification for Item 3, 4 HFO ventilator, that ventilator should have possibility of pressure or volume (flow) triggering. It is clinically accepted the flow (or volume) triggering is more convenient and commonly used required for declared patient categories and in no way reduces the quality level of ventilator. Therefore we recommend current requirement 17, to be replaced with:

” 17. Flow (or volume) triggering”

On this way, more specific ventilator models with regard to patient category can be offered on tender.

Answer to question No.3

Suggestion is accepted. Requirement under 17. is now

” Flow (or volume) triggering”

Question 4. for Lot 3, item 3,4 HFO Ventilator

Considering request in position 24 of technical specification for Item 3, 4 HFO ventilator, it is quite enough having one information of Resistivity value that is commonly clinically used. Therefore we recommend partial change of current text in requirement 24. Text “inspiratory and expiratory resistivity“ is now replaced with “resistivity“

On this way, more specific ventilator models with regard to patient category can be offered on tender.

Answer to question 4

Suggestion is accepted. Requirement under 24. is now

”Frequency, pressures (peak, mean, PEEP), tidal volume, minute volume, leak, compliance, resistivity battery status;”

LOT 5

Question 5. for Lot 5, item 5,3 Modular monitoring system for OR

In position 25 of technical specification for item 5.3 Modular monitoring system for OR, you have requested the following: " 25. Recorder 4-channel "

Since the mentioned request is an additional option, and the item hasn't primary medical importance , can you change it to reads: " Recorder min 3 channel. " ?

Answer to question 5

Suggestion is accepted.

Requirement under 25. is now : " Recorder min 3 channel."

Question 6. for Lot 5, item 5,1 Anesthesia

In req.no.5 it is required device must have the battery with operating time of minimum 90 minute. Commonly minimum of working time for internal battery is 30 min. Can you change this request to be

minimum 30 minute for internal battery?

Answer to question 6

It is not accepted. Required minimum of 90 min gives more comfort to overcome power supply problem during procedure.

Question 7. for Lot 5, item 5,1 Anesthesia

In req.no.6 it is described display as LED. We think more correct description would be LCD instead, can you replace it?

Answer to question 7

It is not accepted.

Question 8 for Lot 5, item 5,1 Anesthesia

We think there is no real need for 6 waveforms on display as required in no.7. The anesthesiologist should simply focus on data which is much easier with 3 waveforms (pressure/flow/EtCO2 or anesthetic) and this is also common design and use of anesthesia machines.Can you reduce this request to 3 waveforms or more?

Answer to question 8

It is not accepted. All described parameters are important for procedure. More manufacturers have models with such display characteristics.

Question 9 for Lot 5, item 5,1 Anesthesia

In req.no.15 it is required that vaporizer must be with electronic injection. Can you change this request that "vaporizer should be electronically controlled"? It allows more models to be offered from different manufacturers.

Answer to question 9

It is not accepted. Electronic injection technology of vaporizer is more advanced and precise solution. More manufacturers have models with required vaporizer characteristics.

Question 10 for Lot 5, item 5,1 Anesthesia

Can you change req.no.28 to be ”Fresh gas flow range minimum 1 l/min to 15 l/min”?

Answer to question 10

It is not accepted. The machine need to have flow range as required or better.

Question 11 for Lot 5, item 5,1 Anesthesia

Can you reduce Tidal volume setting range request to be from 20 ml to 1500 ml (req.no 29)

Answer to question 11

It is not accepted. The machine need to have Tidal volume range as required or better.

Question 12 for Lot 5, item 5,1 Anesthesia

Instead of setting range requirements:

In req.no.32 I:E min. 1:10 to 4:1

In req.no.33 PEEP : minimum 0-50 cmH2O

In req.no.34 Trigger : Flow/Pressure

can you accept following changes that allows more models to be offered from different manufacturers

In req.no.32 I:E min. 1:8 to 2:1

In req.no.33 PEEP : minimum 4- 30cmH2O

In req.no.34 Trigger : Flow

Answer to question 12

It is not accepted. More manufacturers have models that fulfill these requirements.

Question 13. for Lot 5, item 5,10 Ventilator

In req.no.2 it is required minimum 3 hours for internal battery. We think this is excessive demand, can you exclude it or reduce to common value od minimum 30 minutes.

Answer to question 13

It is not accepted. 3 hours battery capacity gives more comfort during ventialted patient transport.

Question 14. for Lot 5, item 5,10 Ventilator

According to req.no.12 Device must have possibility to upgrade with set for using in MR field. Since this is optional feature and not the subject of current procurement. Can you exclude it from specification.

Answer to question 14

It is not accepted. For purchaser it is important the ventilator has such possibility, because it allows ventilated patient can get MRI diagnostics in the future.

Question 15. for Lot 5, item 5,10 Ventilator

Can you please exclude following requirements:

In req.no 33 Neuro assisted ventilation

In req.no 34 Non invasive neuro assisted ventilation

Answer to question 15

It is not accepted. Neuro assisted ventilation is important feature because it helps significantly patient weaning.

Question 16. for Lot 5, item 5,10 Ventilator

Instead of setting range in req.no 35 Inspiratory tidal volume : 2-4000 ml can you accept following changes that allows more models to be offered from different manufacturers

”Inspiratory tidal volume : 2-2000 ml”

Answer to question 16

It is not accepted. More manufacturers have models that fulfill these requirements.

Public Procurement Committee