

Procurement of Medical Devices for University Children Hospital “Tiršova”

IOP/11-2017/RD

Clarification no. 12

Issued on December 7, 2017

LOT 1

Item 1.22

1. Is it possible to change systems weight from 75kg to 83 kg under number 7. on the list?

Answer1: Not acceptable.

Light weight system with easy maneuverability is very important because it is very often moved from one to another room. Also, big majority of modern ultrasound systems built in new technology produced by leading producers of ultrasound systems has weight less than requested.

2. Is it possible to replace image archiving .tiff format with .wmv (MPEG 4) format under number 15. on the list?

Answer2: Not acceptable.

.Tiff format is related with images archiving and .wmv (MPEG 4) is related with video archiving.

3. Could you define what you mean by CINE memory under number 14. on the list?

Answer3: It means that system has ability of storing and displays ultrasound information (images and clips) frame by frame

LOT 3

3.1 Incubator

Question no. 1.

The tender documentation requires:

4. Integrated humidity servo control 30 – 99%

Please modify this require into:

4. Integrated humidity servo control 30 – 95%

The required moisture value does not fulfill any incubator model that can be found on the market.

Proposed values can satisfy a larger number of bidders, i.e. a greater number of equipment manufacturers.

Answer to question No.1

Suggestion is accepted. Requirement under 4. is now:

4. Integrated humidity servo control 30 – 95%

Question no. 2.

The tender documentation requires:

14. Incubator has selfcleaning option

Please remove this item because no incubator on the market can satisfy this requirement.

Answer to question No.2

Suggestion is accepted.

Question no. 3.

The tender documentation requires:

16. Trend scale to 7 days

Please modify this require into:

16. Trends 24h, weight trend 7 days

Because most incubators offered on the market can fulfill this requirement.

Answer to question No.3

Suggestion is accepted. Requirement under 16. is now:

16. Trends 24h, weight trend 7 days.

Question no. 4.

The tender documentation requires:

17. Simultaneous display of two temperature curves

Please modify this require into:

17. Temperature graphical display

To enable all bidders to participate equally in procurement

Answer to question No.4

Suggestion is accepted. Requirement under 17. is now:

17. Temperature graphical display.

Question no. 5.

The tender documentation requires:

11.

O2 concentration: 21% - 75%

humidity: 30% - 99%

temperature: 20° - 39°C with confirmation for temp. set. over 37°C

Please modify this require into:

11.

O2 concentration: 21% - 65%

humidity: 30% - 95%

temperature: 20° - 39°C with confirmation for temp. set. over 37°C

The required value of these characteristics does not fulfill any incubator model that can be found on the market.

Proposed values can fulfill larger number of bidders, i.e. a greater number of equipment manufacturers.

Answer to question No.5

Suggestion is accepted. These requirements are now:

11. O2 concentration: 21% - 65%

humidity: 30% - 95%

temperature: 20° - 39°C with confirmation for temp. set. over 37°C

Question no. 6.

Please remove this item: 18. Display can be positioned on every side of the incubator since the incubator which meets the required characteristic can not be found on our market. For most incubators with any manufacturer, the display is centrally located on one of the incubator sites, where the baby's access ports are located, and thus always access the display, as in practice the incubator positions it to open up for access to the baby be available.

Answer to question No.6

Suggestion is accepted.

Question no. 7.

The tender documentation requires: 21. Integrated weight scale, range 0,3kg to 10kg, with graphical display for last 30 measurements Please modify this require into: 21. Integrated weight scale, range 0,3kg to 7kg, with 7 days trend

Because these limits are standard for incubators of the leading manufacturers of this equipment. Also, in practice, there is almost no need to store babies weighing more than 7kg into the incubator, because babies with these weight are capable of thermoregulation by themself.

Answer to question No.7

Suggestion is accepted. Requirement under 21. is now:

21. Integrated weight scale, range 0,3kg to 7kg, with 7 days trend

LOT 5

5.3

Question no. 1.

The tender documentation requires:

9. ECG monitoring including additional options for patients up to 18 years:

- Simultaneous arrhythmia monitoring in 3 or more leads
- ST segment monitoring of 12 leads and ST trend views to detect changes
- 12-leads diagnostic ECG, age and gender specific algorithm with interpretation with max. 6-leads cable (interpolated)

Please modify this require into:

9. ECG monitoring with

- arrhythmia monitoring
- ST segment monitoring of 12 leads
- 12-leads diagnostic ECG with interpretation with max. 6-leads cable (interpolated)

In order to ensure competitiveness when procuring equipment, since only one bidder can fulfill required characteristic.

Answer 1.

The Purchaser retains the request as formulated.

More manufacturers have these functions, even on lower class of monitoring equipment than requested. The characteristic determines the class and quality of the equipment . The Purchaser has provided the column "Technical Specification Offered" in table, where all bidders have opportunity to describe in detail and prove on which way their offered model fulfill required characteristics. **Considering the fact that more manufacturers meet this**

characteristic, the specifications required do no limit the competitiveness and assure fair competition.

Question no. 2.

The tender documentation requires:

18. PICCO monitoring including : CCO,CO, SV,CI,CCI,SVI, GEDV,GEDI,ITBV,ITBI,PPV,GEF,CFI,dPmax,SVR,SVRI,EVLW,ELWI,CPO,CPI,PVPI,IBP, Pulse rate, Temperature

Please modify this require into:

18. PICCO monitoring including : CCO,CO, SV,CCI,SVI, GEDV,GEDI,ITBV,PPV,GEF,CFI,dPmax,SVR,SVRI,EVLW,ELWI,PVPI,IBP, Pulse rate, Temperature

In order to allow other bidders to offer their equipment, because the requested characteristic can be fulfilled by only one bidder in the market of Serbia.

Answer 2.

The Purchaser retains the request as formulated.

PiCCO and mentioned monitoring parameters is patented technology and different patient monitor manufacturers bought right to implement this technology on their monitors. The bidder have opportunity to describe in detail the offered solution in the column "Technical Specification Offered" and prove on which way it is equal or equivalent to requested one. Considering the fact that more manufacturers meet this characteristic, the specifications required do no limit the competitiveness and assure fair competition.

Question no. 3.

The tender documentation requires:

23. SPI monitoring - patient response to surgical stimulus and analgesic medication during general anesthesia (level of analgesia in OR)

Please remove this item because it favors one manufacturer and disables other bidders from participating in the procurement process equally.

Answer 3.

The suggestion can not be accepted.

The level of analgesia component during anaesthesia procedure is undoubtedly one of the main factor that can't be omitted. The bidder have opportunity to describe offered equal or

equivalent solution that gives information about level of analgesia during procedure. **Our request is to provide device with solution which ensure monitoring of responses to administration of analgesic agents no matter how the manufacturers name it.** The analgesia level information helps clinician to adequately maintain therapy (rationally), as well as make easier postoperative patient recovery. **Considering the fact that more manufacturers meet this characteristic, the specifications required do no limit the competitiveness and assure fair competition.**

Question no. 4.

The tender documentation requires:

24. Possibility to detect changes in patient's metabolic status caused by septic reactions or injuries etc. and measurement of parameter that helps in determination of nutritive support in patient therapy

Please remove this item because it favors one manufacturer and disables other bidders from participating in the procurement process equally. Removing this feature will allow other bidders to submit an appropriate offer.

Answer 4.

After surgery the monitoring of the postoperative status of patients is crucial in the first 24 - 48 hours. The detection of metabolic changes allows a timely reaction in terms of therapeutic support to the patient needs in order to achieve stability / avoid complications. This option represents objective needs and is in line with the way of work and care of children. There are more manufacturers that have monitors with measurement of VO₂ consumption and VCO₂ production, on which metabolic monitoring is based. The bidder have opportunity to describe in detail the offered solution in the column "Technical Specification Offered" and prove on which way it is equal or equivalent to requested one.

The Purchaser retains the request as it is formulated. **Considering the fact that more manufacturers meet this characteristic, the specifications required do no limit the competitiveness and assure fair competition.**

Question no. 5.

The tender documentation requires:

25. Recorder 4-channels

Please modify this require into:

25. Recorder 2-channels

Most monitor manufacturers offer the option of connecting or installing 2-channel printers, and in practice it is shown that there is no need to print multiple channels directly from the monitor. If there is a need for a more detailed examination, in practice, an independent ECG apparatus is used, and not a monitor for monitoring vital patient parameters.

Answer 5.

The Purchaser has changed this feature, so it is now: "Recorder min 3-channel." 3-channel recorder is common feature on patient monitoring equipment of many different manufacturers.

Question no. 6.

The tender documentation requires:

27. Barcode reader

Please remove this item in order to enable all bidders to participate equally in the procurement process. This option of a patient monitor does not represent a technological advantage in terms of monitoring the patient's vital parameters, and therefore can not be an excluding condition for the procurement.

Answer 6.

The Purchaser retains the request as it is formulated. Barcode reader is common feature of the last generation patient monitors of different manufacturers.

5.9

5.9. Modular monitoring system

Question no. 1.

The tender documentation requires:

2. Integrated Hi-resolution colour display (1024 x 768 pixels XGA) of size: min.15inch (diagonal)

Please modify this requirement into:

2. Integrated colour display (800 x 600 pixels XGA) of size: min.12inch (diagonal)

To display all the required parameters, the size of the 12-inch screen is quite enough for a preview. Also, most manufacturers can offer a monitor with exactly the same screen size.

Answer 1.

**The Purchaser retains the request as it is formulated.
The characteristic determines the class and quality of the equipment that is chosen.
It is common feature of the last generation patient monitors of different manufacturers.**

Question no. 2.

The tender documentation requires:

3. User interface: touchscreen and rotating navigation knob

Please modify this require into:

3. User interface: rotating navigation knob and fixed dedicated buttons

The touch screen monitor is significantly more sensitive and less robust than non-touch screen. With a non-touch screen monitor there is less possibility of incorrect selection of the function or value, since they are not selected by touching the screen, but by placing the marker on the exact desired field. Most of the parameters monitored on the monitor's screen are pre-configured, and there is no often need to change the look of the display, and the dedicated buttons allow you to quickly access the most needed settings, or review the parameters. The most important thing with The patient monitors are possibilities and options for measuring certain parameters, while the touchscreen represents only a small contribution to the comfort, and only in certain situations, while selecting with the rotary knob remains the most reliable working principle with the monitor.

Answer 2.

**The Purchaser retains the request as it is formulated.
It is common feature on many 15 inch display patient monitors of different manufacturers.**

Question no. 3.

The tender documentation requires:

5. Displays simultaneous 12 lead ecg

Please modify this require into:

5. 12 lead ECG

Because this option has the majority of monitors that can be found on the market.

Answer 3.

**The Purchaser retains the request as it is formulated.
It is common feature on many 15 inch display patient monitors of different manufacturers.**

Question no. 4.

The tender documentation requires:

7. 72 hours of trend data

Please modify this require into:

7. 24 hours of trend data

For a monitor that is used in postoperative intensive care, monitoring of patients within 24 hours is sufficient. Patients that are placed there have permanent supervision, so there is no need for a longer memory of data. Most monitors intended for this purpose have the ability to monitor trends within 24 hours.

Answer 4.

The Purchaser remains on the request as it is formulated. This requirement is a common feature.

72h trend of data is needed because it cover period during when the number of working experts is reduced (e.g. during weekend). In this way, the intensivist who started the therapy on Friday, and did not work for the weekend, on Monday has the opportunity to quickly review the values of the measured parameters and the patient's response to the therapy.

Question no. 5.

The tender documentation requires:

10. ECG monitoring including:

- simultaneous arrhythmia monitoring in 2 or more leads
- ST segment monitoring of 12 leads and ST trend views to detect changes
- Continous QT/QTc monitoring , including mesurement , trending and alarming for early identification of Torsades de pointes events
- Algorithm for acute coronary ischemia predictibility
- 12-leads diagnostic ECG, age and gender specific algorithm with interepretation with max. 6-leads cable (interpolated)

Please modify this require into:

10. ECG monitoring including additional options for patients up to 18 years

- simultaneous arrhythmia monitoring in 3 or more leads
- ST segment monitoring of 12 leads
- 12-leads diagnostic ECG, with max. 6-leads cable (interpolated)

Most monitors from leading manufacturers of medical equipment can offer monitoring of these parameters. By changing this item, you will allow more bidders to offer their equipment.

Answer 5.

The Purchaser retains the request as formulated.

More manufacturers have models with these functions. The characteristic determines the class and quality of the equipment that is chosen .

The Purchaser has provided the column "Technical Specification Offered" in table, where all bidders have opportunity to describe in detail and prove on which way their offered model fulfill required characteristic.

Question no. 6.

The tender documentation requires:

12. CRG –cardiorespirogram - beat-to beat evaluation of bradycardia and apnea events (High-resolution trends)

Please modify this require into:

12. CRG or OxyCRG - beat-to beat HR or beat-to beat HR and SpO2 trends

not to be favored only one bidder. Required characteristics are required so only one bidder can offer adequate equipment.

Answer 6.

The Purchaser retains the request as formulated.

CRG monitoring shows a correlation between cardiac and respiratory activity, and most of manufacturers have as the standard feature CRG, with beat-to beat monitoring of parameters and trends . The bidder have opportunity to describe in detail the offered solution in the column "Technical Specification Offered" and prove on which way it is equal or equivalent to requested one.

Question no. 7.

The tender documentation requires:

19. Patient spirometry

Please remove this item because this is not an essential parameter for the department for which the monitor is intended. This also limits the number of bidders that can offer the appropriate monitor.

Answer 7.

The Purchaser retains the request as formulated.

More manufacturers have these functions. The characteristic determines the class and quality of the equipment that is chosen. The bidder have opportunity to describe in detail the offered solution in the column "Technical Specification Offered" and prove on which way it is equal or equivalent to requested one.

Question no. 8.

The tender documentation requires:

19. SPI monitoring - patient response to surgical stimulus and analgesic medication during general anesthesia (level of analgesia in OR)

Please remove this item because this limits the number of bidders that can offer the appropriate monitor. By requiring this feature, only one bidder for the required equipment is favored.

Answer 8.

The suggestion can not be accepted.

The level of analgesia component during anaesthesia procedure is undoubtedly one of the main factor that can't be omitted. The bidders have opportunity to describe their equivalent solutions that gives information about level of analgesia during procedure. The analgesia level information helps clinician to adequately maintain therapy (rationally), as well as make easier postoperative patient recovery.

Question no. 9.

The tender documentation requires:

19. Possibility to detect changes in patient's metabolic status caused by septic reactions or injuries etc. and measurement of parameter that helps in determination of nutritive support in patient therapy

Please remove this item because this limits the number of bidders that can offer the appropriate monitor. By requiring this feature, only one bidder for the required equipment is favored.

Answer 9.

After surgery the monitoring of the postoperative status of patients is crucial in the first 24 - 48 hours. The detection of metabolic changes allows a timely reaction in terms of therapeutic support to the patient needs in order to achieve stability / avoid complications. The option represents objective need and is in line with the way of work and care of children. There are more manufacturers that have monitors with measurement of VO₂ consumption and VCO₂ production, on which metabolic monitoring is based. The bidders have opportunity to describe in detail in the column "Technical Specification Offered" their offered solution and on which way it is equal or equivalent to requested one.

The Purchaser retains the request as it is formulated.

Question no. 10.

The tender documentation requires:

27. Recorder 4-channels

Please modify this require into:

27. Recorder 2-channels

Most monitor manufacturers offer the option of connecting or installing 2-channel printers, and in practice it is shown that there is no need to print multiple channels directly from the monitor. If there is a need for a more detailed examination, in practice, an independent ECG device is used, and not a monitor for monitoring vital patient parameters.

Answer 10.

**The Purchaser has changed this feature, so it is now: ” Recorder min 3-channel.”
3-channel recorder is common feature for many different manufacturers of patient monitoring equipment.**

Question no. 11.

The tender documentation requires:

29. Barcode reader

Please remove this item in order to enable all bidders to participate equally in the procurement process. This option of a patient monitor does not represent a technological advantage in terms of monitoring the patient's vital parameters, and therefore can not be excluded as a condition for the procurement of equipment.

Answer 11.

**The Purchaser retains the request as it is formulated.
Barcode reader is common feature of the last generation patient monitors of different manufacturers.**

Public Procurement Committee