

Procurement of Medical Devices for Clinical Centre Dr Dragiša Mišović

IOP/6-2017/RD

Clarification no. 10

Issued on 26.09.2017.

LOT 5, ID 5.1 Anesthesia system with monitoring

Question 1.

In the Tender Documentation, the following technical characteristic is stated:

1. System console must be wide maximum 80 cm and has depth maximum 80 cm.

We kindly ask you to alter this item so that it reads:

System console must be wide maximum 120 cm and has depth maximum 80 cm.

By doing this, you would enable a larger number of bidders to participate in the equipment procurement in question, without limiting it to one bidder only.

Answer 1:

Suggestion is not acceptable. The dimensions are determined according to the working conditions and working methods. The purchaser maintains its requirement as formulated.

Question 2.

In the Tender Documentation, the following technical characteristic is stated:

14. Must have procedure for a mechanical breath delivery with predefined pressure and time (e.g. for maneuver of quick lung recruitment after intubation);

We kindly ask that you remove this item from the technical specification in order to enable a larger number of interested bidders to participate in the equipment procurement. This characteristic significantly raises the price of the procurement, and also limits the number of bidders able to participate in it.

Answer 2:

Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. The described procedure is more accurate compared to the classic maneuver performed by an anesthetist with a resuscitation bag. The purchaser maintains its requirement as formulated.

Question 3.

In the Tender Documentation, the following technical characteristic is stated:

15. Must have the routine for a programming and delivery of several consecutive mechanical breaths that have different parameter settings (e.g. P_{insp}, PEEP, I:E, rate)

We kindly ask that you remove this item from the technical specification in order to enable a larger number of interested bidders to participate in the equipment procurement. This characteristic significantly raises the price of the procurement, and also limits the number of bidders able to participate in it.

Answer 3:

Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. It replaces a separate manual set-up of parameters for each subsequent mechanical inspiration, which makes handling simpler. The purchaser maintains its requirement as formulated.

Question 4.

In the Tender Documentation, the following technical characteristic is stated:

18. It has ability of flow measurement with proximally placed sensor (right in front of airway tube);

We kindly ask you to alter this item so that it reads:

It has ability of flow measurement with proximally placed sensor or with sensors placed at the beginning of inspiratory hose and the end of patient expiratory hose.

This way, it would be possible for a larger number of interested bidders to participate, without decreasing the precision rate of flow measurement.

Answer 4:

Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. For the beneficiary, it is a more favorable solution where only one proximal sensor is in position in front of the tube, but the two sensors proposed, in which there is a large

empty space between the patient and the sensor. It is better to detect the trigger when the sensor is in front of the tube itself. The purchaser maintains its requirement as formulated.

Question 5.

In the Tender Documentation, the following technical characteristic is stated:

19. It has inspiratory and expiratory conc. O₂, CO₂, N₂O and agent via movable gas module, compatible with accompanying patient monitor

We kindly ask you to alter this item so that it reads:

It has inspiratory and expiratory conc. O₂, CO₂, N₂O and agent via gas module, compatible with accompanying patient monitor

By using a gas module which is integrated in the anesthetic device, an entirely equivalent functionality of the device is achieved, and it is not clinically justifiable to request that the gas module be movable ("movable gas module")

Answer 5:

Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. A more favorable solution for the purchase is that the gas module is portable and compatible with the monitor, as this allows for greater functionality in work. The purchaser maintains its requirement as formulated.

Question 6.

In the Tender Documentation, the following technical characteristic is stated:

20. System has its own color display on mobile arm, of size minimum 15", with resolution of 1024x768 or higher, touchscreen. The display must have a rotary command for menu selection and settings

We kindly ask you to alter this item so that it reads:

System has its own color display that can be tilted, of size minimum 15", with resolution of 1024x768 or higher, touchscreen. The display must have a rotary command for menu selection and settings

Anesthetic devices are constructed so that they enable a comfortable work experience to the anesthesiologist, and the device screen itself is positioned so that it is simultaneously accessible with the other device commands, which are separated in relation to the screen (e.g. O2 flush command, or APL vent for controlling the pressure in the airways in manual vent mode). In practice, it is shown that it is the most practical for the anesthesiologist that all the device commands are in close proximity to the anesthesiologist or anesthetician so that they are available at any time, and that is exactly the position of the screen and other commands on every anesthetic device.

Answer 6:

Suggestion is not acceptable. The mobile carrier is a more convenient ergonomic solution for the beneficiary, because it allows rotation and positioning the screen as needed. The solution is in use on many anesthetic devices. The purchaser maintains its requirement as formulated.

Question 7.

In the Tender Documentation, the following technical characteristic is stated:

21. Display must show following measured data: three parametric curves at the same time (pressure, flow, CO2), respiratory mechanic curve (pressure-volume or flow-volume), airway pressure, breathing rate, tidal and minute volume, compliance, bargraf of flowmeters, digitally showed pipeline pressures, measured conc. of O2, CO2, N2O and anesthetic agent in inspirium and expirium, MAC value

We kindly ask you to alter this item so that it reads:

Display must show following measured data: three parametric curves at the same time (pressure, flow, CO2), respiratory mechanic curve (pressure-volume or flow-volume), airway pressure, breathing rate, tidal and minute volume, compliance, bargraf of flowmeters, digitally showed pipeline pressures (this can also be displayed on separate display), measured conc. of O2, CO2, N2O and anesthetic agent in inspirium and expirium, MAC value

This way, a larger number of bidders would be able to participate, without affecting the functionality of the anesthetic device.

Answer 7:

The beneficiary will accept the digital display of pressure from the central gas distribution on a separate display, if it is part of the same anesthetic system. The purchaser remains at the request as formulated.

Question 8.

27. Patient monitor has color LCD display of size minimum 15", touchscreen

We kindly ask you to alter this item so that it reads:

Patient monitor has color LCD display of size minimum 12"

Doing this would enable a larger number of bidders to participate in the procurement, with a financially justifiable price for the buyer. The characteristics stated in the technical specification require the bidder to offer significantly more expensive equipment than they would have been able to offer should this proposition be accepted.

Answer 8:

Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. The purchaser maintains its requirement as formulated.

Question 9.

29. Active measuring parameters: ECG, saturation (SpO2), non invasive pressure, temperatura, invasive pressure x 2, measurement of sensitivity on surgical stimuli during general anesthesia (level of analgesia), status of CNS during anesthesia (anesthesia depth)

We kindly ask you to alter this item so that it reads:

Active measuring parameters: ECG, saturation (SpO2), non invasive pressure, temperatura, invasive pressure x 2, NMT, BIS (anesthesia depth)

Clinical practice has proven that measuring these parameters is enough to safely conduct anesthesia, and doing this would enable bidders to offer financially favorable equipment with equivalent functionality.

Answer 9:

The adequate analgo therapy is one of the key components of the anaesthesia procedure. It ensures that the therapy is in line with the individual needs of every patient. This monitoring ensures more rational use of medicines, and reduces the number of postoperative side effects, patients recover more easily and faster, i.e. have a shorter stay in the hospital. We as the institution managed to secure with the Republic Health Insurance Fund a separate code for the

TIVA TCI anaesthesia, as well as for all the accompanying aspects by which we ensure its high quality performance. The ability to monitor the parameter that provides insight into the adequacy of analgesia and control of the autonomous system is an extremely important component of anaesthesia. The Contracting Authority maintains its requirement as formulated, because it significantly contributes to the overall work economy and patient safety.

Question 10.

The adequate analgo therapy is one of the key components of the anaesthesia procedure. It ensures that the therapy is in line with the individual needs of every patient. This monitoring ensures more rational use of medicines, and reduces the number of postoperative side effects, patients recover more easily and faster, i.e. have a shorter stay in the hospital. We as the institution managed to secure with the Republic Health Insurance Fund a separate code for the TIVA TCI anaesthesia, as well as for all the accompanying aspects by which we ensure its high quality performance. The ability to monitor the parameter that provides insight into the adequacy of analgesia and control of the autonomous system is an extremely important component of anaesthesia. The Contracting Authority maintains its requirement as formulated, because it significantly contributes to the overall work economy and patient safety.

30. It has trend of 72 h

We kindly ask you to alter this item so that it reads:

It has trend of 24 h

The monitor being an integral part of the anesthesiology work station, there is no need to follow trends for longer than 24h. By following trends during 24h, even the most complex operations can be covered, so it is not necessary to track vital parameters during 72h, thus a trend of 24h is enough to cover at least each individual case, i.e. a minimum of one patient.

Answer 10:

Suggestion is accepted.

Question 11.

33. Minimum integrated 2 USB ports for periferal devices connection (keyboard, mouse, barcod reader, remote control etc)

We kindly ask you to remove this item

The monitor being an integral part of the anesthesiology work station, it is enough to access it directly via commands on the monitor itself. Given that it is required that the monitor has LAN

connectivity, external devices can be connected that way. Also, the primary function of the accompanying monitor is to display parameters during procedures, and it is necessary for it to be compact and to reduce the number of peripheral devices to achieve comfortable work experience.

Answer 11:

The suggestion is not acceptable. The purchaser procures new generation equipment. USB ports belong to standard connectors. The purchaser maintains its requirement as formulated.

LOT 5, ID 5.4.1 Advance Monitoring system (ICU 2)

Question 12.

In the Tender Documentation, the following technical characteristic is stated:

2. Integrated colour display 15 inch with resolution min. 1024 x 768 pixels

We kindly ask you to alter this item so that it reads

Integrated colour display 12 inch

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, procuring monitors with the suggested characteristics is financially justifiable. Touchscreen monitors 15 inches in size, made by almost all renowned manufacturers of patient monitors, belong to a higher price range, while the functionality of 12-inch monitors is at the same level as the 15-inch ones. Absence of touchscreen brings an advantage in terms of robustness and damage resistance, and also significantly reduces the possibility of accidental activation by non-qualified staff.

Answer 12:

Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. The purchaser maintains its requirement as formulated.

Question 13:

In the Tender Documentation, the following technical characteristic is stated:

3. Controls: touchscreen and rotary control button

We kindly ask you to alter this item so that it reads

3. Controls: rotary control button

See explanation for Question 1.

Answer 13:

The combination of a touchscreen and a rotary control is a standard functional solution for most monitors. Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. The purchaser maintains its requirement as formulated.

Question 14.

In the Tender Documentation, the following technical characteristic is stated:

4. Number of traces : individual min. 8 or up to 14 with overlays and insets

We kindly ask you to alter this item so that it reads

4. Number of traces : individual min. 8

Displaying 8 traces on the display is enough to track the most relevant patient parameters. This would enable greater competition in the equipment procurement procedure, not favorizing any manufacturer, given that the majority of world-renowned manufacturers can display 8 traces on the display.

Answer 14:

The request says that the minimal number of traces is 8.

Question 15:

In the Tender Documentation, the following technical characteristic is stated:

8. 72-hour parameter trends

We kindly ask you to alter this item so that it reads

8. 24-hour parameter trends

Parameter tracking during 72h is not necessary on the monitor itself, given that it is possible to access the monitor via LAN. Most manufacturers can offer monitors with a 24h trend, so this would enable everyone to participate in the procurement.

Answer 15:

The monitor must have an autonomous function of the vital parameters trend for several days, in the case that patients stay longer in the intensive unit. The request is standard for most monitors regardless of the class of equipment. Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment.

Question 16.

In the Tender Documentation, the following technical characteristic is stated:

13. Arrhythmia monitoring in four simultaneous leads , including atrial fibrillation detection and trending

We kindly ask you to alter this item so that it reads

13. Arrhythmia monitoring

The majority of patient monitor manufacturers have the ability of arrhythmia monitoring. The required technical characteristics favor certain medical equipment manufacturers.

Answer 16:

Simultaneous arrhythmia monitoring in more leads are acceptable for beneficiary. The purchaser maintains its request as formulated.

Question 17:

In the Tender Documentation, the following technical characteristic is stated:

30. Remote controler

We kindly ask you to alter this item so that it reads

Remote controler or keyboard

This way, monitor access and equivalent functionality is enabled.

Answer 17:

Remote control is a more acceptable solution for the because it is easier to operate than the keyboard. Suggestion is not acceptable. The purchaser maintains its requirement as formulated.

Question 18:

In the Tender Documentation, the following technical characteristics are stated:

10. Integrated 2 USB ports
15. Continuous Qt/QTc monitoring , including measurements, trending and alarming , to support in early identification of Torsades de pointes events.
25. Measuring the expiratory concentrations of CO₂, through a portable module that is compatible with the ventilator device;
26. Monitoring of Gas exchange and metabolics –continuous non-invasive measurement of oxygen consumption (VO₂), carbon dioxide production (VCO₂) , and calculation of respiratory quotient (RQ) and energy expenditure (EE)
27. Patient spirometry

We kindly ask you to remove these items to enable the necessary competition in the procurement process, thus enabling a larger number of bidders to submit an appropriate offer.

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, it is financially justifiable to procure monitors with suggested characteristics. Monitors with required technical characteristics, made by almost all renowned manufacturers of patient monitors, belong to the higher price range. Removing these technical characteristics would make it possible to procure significantly affordable equipment, and the functions required are not very often used in clinical practice, so it is justifiable to procure monitors without the required characteristics. Also, a significantly higher number of bidders can offer equipment without the characteristics stated in items 10, 15, 25, 26, 27.

Answer 18:

The suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. Certain characteristics allow for better functionality, diagnostics, assessment of the nutritional status of the patient and accordingly selection of adequate therapy, which leads to faster recovery of the patient. When defining technical specifications, Beneficiary was not guided by the economic interests of potential bidders, but with its needs and functional and clinical solutions that enable total economic savings in the exploitation of equipment. The purchaser maintains its requirement as formulated.

LOT 5, ID 5.4.2 Advance Monitoring system (ICU 3)

Question 19.

In the Tender Documentation, the following technical characteristic is stated:

2. Integrated colour display 15 inch with resolution min. 1024 x 768 pixels

We kindly ask you to alter this item so that it reads

Integrated colour display 12 inch

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, procuring monitors with the suggested characteristics is financially justifiable.

Touchscreen monitors 15 inches in size, made by almost all renowned manufacturers of patient monitors, belong to a higher price range, while the functionality of 12-inch monitors is at the same level as the 15-inch ones. Absence of touchscreen brings an advantage in terms of robustness and damage resistance, and also significantly reduces the possibility of accidental activation by non-qualified staff.

Answer 19:

The suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. The purchaser maintains its requirement as formulated.

Question 20.

In the Tender Documentation, the following technical characteristic is stated:

3. Controls: touchscreen and rotary control button

We kindly ask you to alter this item so that it reads

3. Controls: rotary control button

See explanation for Question 1.

Answer 20:

The combination of a touchscreen and a rotary control is a standard functional solution for most monitors. Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. The purchaser maintains its requirement as formulated.

Question 21.

In the Tender Documentation, the following technical characteristic is stated:

4. Number of traces : individual min. 8 or up to 14 with overlays and insets

We kindly ask you to alter this item so that it reads

4. Number of traces : individual min. 8

Displaying 8 traces on the display is enough to track the most relevant patient parameters. This would enable greater competition in the equipment procurement procedure, not favorizing any manufacturer, given that most world-renowned manufacturers can display 8 traces on the display.

Answer 21:

The request says that the minimal number of traces is 8.

Question 22.

In the Tender Documentation, the following technical characteristic is stated:

8. 72-hour parameter trends

We kindly ask you to alter this item so that it reads

8. 24-hour parameter trends

Parameter tracking during 72h is not necessary on the monitor itself, given that it is possible to access the monitor via LAN. Most manufacturers can offer monitors with a 24h trend, so this would enable everyone to participate in the procurement.

Answer 22:

The monitor must have an autonomous function of the vital parameters trend for several days, in the case that patients stay longer in the intense unit. The request is standard for most monitors regardless of the class of equipment. Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment.

Question 23.

In the Tender Documentation, the following technical characteristic is stated:

13. Arrhythmia monitoring in four simultaneous leads , including atrial fibrillation detection and trending

We kindly ask you to alter this item so that it reads

13. Arrhythmia monitoring

The majority of patient monitor manufacturers have the ability of arrhythmia monitoring. The required technical characteristics favor certain medical equipment manufacturers.

Answer 23:

Simultaneous arrhythmia monitoring in more leads are acceptable for beneficiary. The purchaser maintains its request as formulated.

Question 24:.

In the Tender Documentation, the following technical characteristic is stated:

30. Remote controler

We kindly ask you to alter this item so that it reads

Remote controler or keyboard

This way, monitor access and equivalent functionality is enabled, and almost all manufacturers can offer a monitor with this characteristic.

Answer 24:

Remote control is a more acceptable solution for the because it is easier to operate than the keyboard. Suggestion is not acceptable. The purchaser maintains its requirement as formulated.

Question 25.

In the Tender Documentation, the following technical characteristics are stated:

10. Integrated 2 USB ports

24. Measuring the expiratory concentrations of CO₂, through a portable module that is compatible with the ventilator device;

25. Monitoring of Gas exchange and metabolics –continuous non-invasive measurement of oxygen

consumption (VO₂), carbon dioxide production (VCO₂) , and calculation of respiratory quotient (RQ) and

energy expenditure (EE)

26. Patient spirometry

We kindly ask you to remove these items to enable the necessary competition in the procurement process, thus enabling a larger number of interested bidders to submit an appropriate offer.

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, it is financially justifiable to procure monitors with suggested characteristics. Monitors with required technical characteristics, made by almost all renowned manufacturers of patient monitors, belong to the higher price range. Removing these technical characteristics would make it possible to procure significantly affordable equipment, and the functions required are not very often used in clinical practice, so it is justifiable to procure monitors without the required characteristics. Also, a significantly higher number of bidders can offer equipment without the characteristics stated in items 10, 15, 25, 26, 27.

Answer 25:

The suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. Certain characteristics allow for better functionality, diagnostics, assessment of the nutritional status of the patient and accordingly selection of adequate therapy, which leads to faster recovery of the patient. When defining technical specifications, beneficiary was not guided by the economic interests of potential bidders, but with its needs and functional and clinical solutions that enable total economic savings in the exploitation of equipment. The purchaser maintains its requirement as formulated.

LOT 5, ID 5.4.3 Advance Monitoring system - CCU /Coronary Care Unit

Question 26.

In the Tender Documentation, the following technical characteristic is stated:

2. Integrated colour display 15 inch with resolution min. 1024 x 768 pixels

We kindly ask you to alter this item so that it reads

Integrated colour display 12 inch

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, procuring monitors with the suggested characteristics is financially justifiable. Touchscreen monitors 15 inches in size, made by almost all renowned manufacturers of patient monitors, belong to a higher price range, while the functionality of 12-inch monitors is at the same level as the 15-inch ones. Absence of touchscreen brings an advantage in terms of robustness and damage resistance, and also significantly reduces the possibility of accidental activation by non-qualified staff.

Answer 26:

The suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. The purchaser maintains its requirement as formulated.

Question 27.

In the Tender Documentation, the following technical characteristic is stated:

3. Controls: touchscreen and rotary control button

We kindly ask you to alter this item so that it reads

3. Controls: rotary control button

See explanation for Question 1.

Answer 27:

The combination of a touchscreen and a rotary control is a standard functional solution for most monitors. Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. The purchaser maintains its requirement as formulated.

Question 28.

In the Tender Documentation, the following technical characteristic is stated:

4. Number of traces : individual min. 8 or up to 14 with overlays and insets

We kindly ask you to alter this item so that it reads

4. Number of traces : individual min. 8

Displaying 8 traces on the display is enough to track the most relevant patient parameters. This would enable greater competition in the equipment procurement procedure, not favorizing any manufacturer, given that most world-renowned manufacturers can display 8 traces on the display.

Answer 28:

The request says that the minimal number of traces is 8. Suggestion is not acceptable.

Question 29.

In the Tender Documentation, the following technical characteristic is stated:

7. 72-hour parameter trends

We kindly ask you to alter this item so that it reads

7. 24-hour parameter trends

Parameter tracking during 72h is not necessary on the monitor itself, given that it is possible to access the monitor via LAN. Most manufacturers can offer monitors with a 24h trend, so this would enable everyone to participate in the procurement.

Answer 29:

The monitor must have an autonomous function of the vital parameters trend for several days, in the case that patients stay longer in the coronary unit. The request is standard for most monitors regardless of the class of equipment. Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment.

Question 30.

In the Tender Documentation, the following technical characteristic is stated:

12. Arrhythmia monitoring in four simultaneous leads , including atrial fibrillation detection and trending

We kindly ask you to alter this item so that it reads

12. Arrhythmia monitoring

The majority of patient monitor manufacturers have the ability of arrhythmia monitoring. The required technical characteristics favor certain medical equipment manufacturers.

Answer 30:

Simultaneous arrhythmia monitoring in more leads are acceptable for beneficiary. The purchaser maintains its request as formulated.

Question 31.

In the Tender Documentation, the following technical characteristic is stated:

30. Integrated thermal recorder (min 3 channel)

We kindly ask you to alter this item so that it reads

12. Integrated thermal recorder

The majority of renowned monitor manufacturers can offer a monitor with this characteristic.

Answer 31:

Most monitors have a 3-channel printer. The suggestion is not acceptable. The purchaser maintains its requirement as formulated.

Question 32.

In the Tender Documentation, the following technical characteristic is stated:

31. Remote controler

We kindly ask you to alter this item so that it reads

31. Remote controler or keyboard

This way, monitor access and equivalent functionality is enabled, and almost all manufacturers can offer a monitor with this characteristic.

Answer 32:

Remote control is a more acceptable solution for the because it is easier to operate than the keyboard. Suggestion is not acceptable. The purchaser maintains its requirement as formulated.

Question 33.

In the Tender Documentation, the following technical characteristics are stated:

9. Integrated 2 USB ports

14. Continuous Qt/QTc monitoring , including measuremets, trending and alarming , to support in early

identification of Torsades de pointes events.

15. 12 channel ECG gender-specific algorithm for interpretation

16. Algorithm for acute cardiac ischemia- triage of chest-pain patients with numeric score of probabilityof

acute cardiac ischemia (%)

26. Measuring the expiratory concentrations of CO₂, through a portable module that is compatible with

the ventilator device;

27. Monitoring of Gas exchange and metabolics –continuous non-invasive measurement of oxygen

consumption (VO₂), carbon dioxide production (VCO₂) , and calculation of respirtory quotient (RQ) and

energy expenditure (EE)

28. Patient spirometry

We kindly ask you to remove these items to enable the necessary competition in the procurement process, thus enabling a larger number of interested bidders to submit an appropriate offer.

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, it is financially justifiable to procure monitors with suggested characteristics. Monitors with required technical characteristics, made by almost all renowned manufacturers of patient monitors, belong to the higher price range. Removing these technical characteristics would make it possible to procure significantly affordable equipment, and the functions required are not very often used in clinical practice, so it is justifiable to procure monitors without the required characteristics. Also, a significantly higher number of bidders can offer equipment without the characteristics stated in items 9, 14, 15, 16, 27, 28.

Answer 33:

The suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. Certain characteristics allow for better functionality, cardio diagnostics, assessment of the nutritional status of the patient and accordingly selection of adequate therapy, which leads to faster recovery of the patient. When defining technical specification, Beneficiary was not guided by the economic interests of potential bidders, but with its needs and functional and clinical solutions that enable total economic savings in the exploitation of equipment. The purchaser maintains its requirement as formulated.

LOT 5, ID 5.5 – Ventilator with metabolic monitoring

Question 34.

In the Tender Documentation, the following technical characteristic is stated:

8. It has integrated or modular EtCO₂ measurement

We kindly ask you to alter this item so that it reads

It has integrated volumetric EtCO₂ measurement

Most mechanical ventilator manufacturers can offer this characteristic, which would achieve competition in the equipment procurement process.

Answer 34:

The suggestion is not accepted. The Purchaser will also accept the integrated volumetric EtCO₂ measurement. The purchaser maintains its requirement as formulated.

Question 35.

In the Tender Documentation, the following technical characteristic is stated:

9. Ventilation modes: VCV, PCV, PRVC, Bi Level (or BiPAP or DuoPAP), APRV, SIMV-VC, SIMV-PC, SIMVPRVC, VS, CPAP/PSV, NIV;

We kindly ask you to alter this item so that it reads:

Ventilation modes: VCV, PCV, PRVC or autoflow, Bi Level (or BiPAP or DuoPAP), APRV, SIMV-VC, SIMV-PC, SIMV-PRVC/autoflow, VS, CPAP/PSV, NIV;

PRVC is just one of the names for a certain mode of ventilation, so it necessary to make possible to offer a ventilator with equivalent mode of ventilation, in order not to favor any one manufacturer.

Answer 35:

The purchaser will accept a specifically equivalent solution, autoflow instead of the above PRVC ventilation modes.

Therefore, the purchaser maintains its requirement as formulated.

Question 36.

In the Tender Documentation, the following technical characteristic is stated:

13. It has adjustable compensations for tube resistance, leakage, trigger;

We kindly ask you to alter this item so that it reads:

It has compensations for tube resistance, leakage, trigger;

Most world manufacturers can offer equipment with these characteristics. In order to make participation possible for as many bidders as possible, we kindly ask you to alter this characteristic.

Answer 36:

Suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of equipment. Adjustable compensations for tube resistance means that the user can enter data on the type and diameter of the tubes used. Adjustment of leakage and trigger compensation means that the user can activate or deactivate these functions as needed. The purchaser maintains its requirement as formulated.

Question 37.

In the Tender Documentation, the following technical characteristic is stated:

14. It has flow and pressure triggering;

We kindly ask you to alter this item so that it reads:

It has flow or pressure triggering;

By asking that a ventilator possess flow and pressure triggering ability, a certain ventilator manufacturer is being favored. Most manufacturers have in their portfolio ventilators that have flow or pressure triggering ability.

Answer 37:

The suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of the equipment. The beneficiary has chosen the most up-to-date technology that suits the planned mode of work, which does not mean that all manufacturers of respirators have the required characteristics. Since several manufacturers can fulfill the above requirement, the purchaser maintains its requirement as formulated.

Question 38.

In the Tender Documentation, the following technical characteristic is stated:

25. P support: 0 - 50 cm H₂O;

We kindly ask you to alter this item so that it reads:

P support: 0 - 80 cm H₂O;

Certain patients require P support higher than 50 cm H₂O in treatment (e.g. COPD patients). Such patients have very high PEEP value, so in certain situations P support of 50 cm H₂O is not sufficient.

Answer 38:

The minimum range of the parameter is given, which means it is acceptable for the bidders to offer goods that have a higher range than the requested one.

Question 39.

In the Tender Documentation, the following technical characteristic is stated:

28. Bias flow: 2 -10 lit

We kindly ask you to alter this item so that it reads:

Bias flow: 6 lit

Most mechanical ventilator manufacturers can offer a device that satisfies this technical requirement.

Answer 39:

The existence of the range of passive continuous flow rate control during the expiration phase (bias flow) is a better solution for the beneficiary, because it allows the adjustment of this parameter in accordance with the requirements of the procedure (more efficient washing of CO₂, auxiliary pressure measurement, nebulization, etc.).

Question 40:.

In the Tender Documentation, the following technical characteristic is stated:

30. Color LCD display of minimal size 15 '' (diagonal), touchscreen, with adjustable height and tilt;

We kindly ask you to alter this item so that it reads:

Color LCD display of minimal size 15 '' (diagonal), touchscreen, with adjustable tilt;

By adjusting the tilt it is possible to adjust the ventilator for comfortable work. Also, modern display manufacturing technology enables a high viewing angle, and the largest number of commercially available ventilators has tilt adjustment, so it is sufficient that the ventilator only has tilt adjustment ability.

Answer 40:

It is acceptable if the offered respirator has height adjustment or tilt adjustment or if it has both of these functions.

Question 41.

In the Tender Documentation, the following technical characteristic is stated:

30. Ventilation monitoring on display consisting of: 4 breathing curves showed at the same time, respiratory mechanic (pressure-volume or pressure-flow or flow-volume), pressure (peak,mean,plato),

PEEP_e, PEEP_i, tidal and minute volume (inspiratory and expiratory), compliance, resistance, FiO₂, EtCO₂;

We kindly ask you to alter this item so that it reads:

Ventilation monitoring on display consisting of: 4 breathing curves showed at the same time, respiratory mechanic (pressure-volume or pressure-flow or flow-volume), pressure (peak, mean, plateau), PEEP, PEEP_i, tidal and minute volume, compliance, resistance, FiO₂, EtCO₂

Most manufacturers can offer a ventilator with these technical characteristics, so this should be changed to achieve bigger competition.

Answer 41:

The suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. It allows better detection of the cause of the problem (e.g., leakage) based on the difference between the inspiratory and expiratory fraction of the respiratory volume. The purchaser maintains its request as formulated.

Question 42.

In the Tender Documentation, the following technical characteristic is stated:

33. It measures/calculates parameters: P_{0.1}, RSBI, vital capacity, NIF;

We kindly ask you to alter this item so that it reads:

It measures/calculates parameters: P_{0.1}, RSBI, NIF;

Suggested characteristics are the most commonly applied procedures in patient testing, and also are the standard procedures which all ventilators made by renowned medical equipment manufacturers have.

Answer 42:

The suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of the equipment. The beneficiary procure the latest technology devices. A vital capacity test is an important indication of the functionality of the patient's lungs. Several manufacturers have models that can meet the requirements. The purchaser maintains its request as formulated.

Question 43.

In the Tender Documentation, the following technical characteristic is stated:

3. Possibility of work with one gas supply source;

7. It has a port for optional auxiliary pressure measurement (tracheal);
17. Besides ventilator flow sensors it has ability for alternative precise flow measurement with sensors placed right behind the airway tube;
18. It has PEEP titration routine to achieve targeted functional residual capacity and faster patient recovery;
19. It has monitoring of patient metabolic status (e.g. hypermetabolic changes due to infection or nutrition status information) expressed as calculated energy expenditure in kCal during ventilation therapy and as respiratory coefficient;
20. Besides ventilator flow sensors it has ability for alternative precise flow measurement with sensors placed right behind the airway tube;

We kindly ask you to remove these items

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, it is financially justifiable to procure ventilators with suggested characteristics. Ventilators with required technical characteristics, made by almost all renowned manufacturers, belong to the higher price range. Also, the required characteristics are not commonly applied in clinical practice, so the additional investment is not justifiable. Removing these technical characteristics would make it possible to procure more affordable equipment, and a significantly higher number of bidders can offer equipment without the characteristics stated in items 3, 7, 17, 18, 19, 20.

Answer 43:

The suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of the equipment. The beneficiary has chosen for the latest technology in equipping. When defining technical specifications, Beneficiary was not guided by the economic interests of potential bidders, but with its needs and functional and clinical solutions that enable total economic savings in the exploitation of equipment.

LOT 5, ID 5.6 – Ventilator with standard capnography

Question 44.

In the Tender Documentation, the following technical characteristic is stated:

8. It has integrated or modular EtCO₂ measurement

We kindly ask you to alter this item so that it reads

It has integrated volumetric EtCO₂ measurement

Most mechanical ventilator manufacturers can offer this characteristic, which would achieve competition in the equipment procurement process.

Answer 44:

The suggestion is not accepted. The Purchaser will also accept the integrated volumetric EtCO₂ measurement

The purchaser maintains its requirement as formulated.

Question 45.

In the Tender Documentation, the following technical characteristic is stated:

9. Ventilation modes: VCV, PCV, PRVC, Bi Level (or BiPAP or DuoPAP), APRV, SIMV-VC, SIMV-PC, SIMVPRVC, VS, CPAP/PSV, NIV;

We kindly ask you to alter this item so that it reads:

Ventilation modes: VCV, PCV, PRVC or autoflow, Bi Level (or BiPAP or DuoPAP), APRV, SIMV-VC, SIMV-PC, SIMV-PRVC/autoflow, VS, CPAP/PSV, NIV;

PRVC is just one of the names for a certain mode of ventilation, so it necessary to make possible to offer a ventilator with equivalent mode of ventilation, in order not to favor any one manufacturer.

Answer 45:

The purchaser will accept a specifically equivalent solution, autoflow instead of the above PRVC ventilation modes.

Therefore, the purchaser maintains its requirement as formulated.

Question 46.

In the Tender Documentation, the following technical characteristic is stated:

13. It has adjustable compensations for tube resistance, leakage, trigger;

We kindly ask you to alter this item so that it reads:

It has compensations for tube resistance, leakage, trigger;

Most world manufacturers can offer equipment with these characteristics. In order to make participation possible for as many bidders as possible, we kindly ask you to alter this characteristic.

Answer 46:

Suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of equipment. Adjustable compensations for tube resistance means that the user can enter

data on the type and diameter of the tubes used. Adjustment of leakage and trigger compensation means that the user can activate or deactivate these functions as needed. The purchaser maintains its requirement as formulated.

Question 47.

In the Tender Documentation, the following technical characteristic is stated:

14. It has flow and pressure triggering;

We kindly ask you to alter this item so that it reads:

It has flow or pressure triggering;

By asking that a ventilator possess flow and pressure triggering ability, a certain ventilator manufacturer is being favored. Most manufacturers have in their portfolio ventilators that have flow or pressure triggering ability.

Answer 47:

The suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of the equipment. The beneficiary has chosen the most up-to-date technology that suits the planned mode of work, which does not mean that all manufacturers of respirators have the required characteristics. Since several manufacturers can fulfill the above requirement, the purchaser maintains its requirement as formulated.

Question 48.

In the Tender Documentation, the following technical characteristic is stated:

25. P support: 0 - 50 cm H₂O;

We kindly ask you to alter this item so that it reads:

P support: 0 - 80 cm H₂O;

Certain patients require P support higher than 50 cm H₂O in treatment (e.g. COPD patients). Such patients have very high PEEP value, so in certain situations P support of 50 cm H₂O is not sufficient.

Answer 48:

The minimum range of the parameter is given, which means it is acceptable for the bidders to offer goods that have a higher range than the requested one.

Question 49.

In the Tender Documentation, the following technical characteristic is stated:

23. PEEP:

We kindly ask you to alter this item so that it reads:

PEEP:1- 50 cm H₂O

No value for PEEP is given in the documentation, while the suggested PEEP range is standard for most manufacturers.

Answer 49:

Due to technical error the parameters for PEEP are not entered. The suggestion is accepted.

Question 50.

In the Tender Documentation, the following technical characteristic is stated:

24. Insp T:1- 50 cm H₂O;

We kindly ask you to alter this item so that it reads:

Insp T:0,5-10 sec

The value required in the equipment specification is not relevant.

Answer 50:

Due to technical error the correct value and units are not entered. The correction is accepted

Question 51.

In the Tender Documentation, the following technical characteristic is stated:

28. Bias flow: 2 -10 lit

We kindly ask you to alter this item so that it reads:

Bias flow: 6 lit

Most mechanical ventilator manufacturers can offer a device that satisfies this technical requirement.

Answer 51:

The existence of the range of passive continuous flow rate control during the expiration phase (bias flow) is a better solution for the beneficiary, because it allows the adjustment of this parameter in accordance with the requirements of the procedure (more efficient washing of CO₂, auxiliary pressure measurement, nebulization, etc.).

Question 52.

In the Tender Documentation, the following technical characteristic is stated:

30. Color LCD display of minimal size 15 " (diagonal), touchscreen, with adjustable height and tilt;

We kindly ask you to alter this item so that it reads:

Color LCD display of minimal size 15 " (diagonal), touchscreen, with adjustable tilt;

By adjusting the tilt it is possible to adjust the ventilator for comfortable work. Also, modern display manufacturing technology enables a high viewing angle, and the largest number of commercially available ventilators has tilt adjustment, so it is sufficient that the ventilator only has tilt adjustment ability.

Answer 52:

It is acceptable if the offered respirator has height adjustment or tilt adjustment or if it has both of these functions.

Question 53.

In the Tender Documentation, the following technical characteristic is stated:

30. It measures/calculates parameters: P0.1, RSBI, vital capacity, NIF;

We kindly ask you to alter this item so that it reads:

It measures/calculates parameters: P0.1, RSBI, NIF;

Suggested characteristics are the most commonly applied procedures in patient testing, and also are the standard procedures which all ventilators made by renowned medical equipment manufacturers have.

Answer 53:

The suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of the equipment. The beneficiary procure the latest technology devices. A vital capacity test is an important indication of the functionality of the patient's lungs. Several manufacturers have models that can meet the requirements. The purchaser maintains its request as formulated.

Question 54.

In the Tender Documentation, the following technical characteristic is stated:

32. It has ability to take and memorize snapshot, including: 15 sec of all actual curves, active alarm

messages, all measured parameters, all ventilation settings;

We kindly ask you to alter this item so that it reads:

It has ability to take and memorize snapshot, freeze waveforms and analyze them with cursor

Most mechanical ventilator manufacturers satisfy this characteristic, so we kindly ask you to accept the change so everyone would be able to participate in the procurement.

Answer 54:

The suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of the equipment. The purchaser maintains its request as formulated

Question 55.

In the Tender Documentation, the following technical characteristic is stated:

32. It has 72 h trend of settings and measured parameters

We kindly ask you to alter this item so that it reads:

It has 72 h trend

All mechanical ventilator manufacturers can offer a model with this technical characteristic.

Answer 55:

The suggestion is not acceptable. The request clearly indicates which parameters are trend-based. The purchaser maintains its request as formulated

Question 56.

In the Tender Documentation, the following technical characteristic is stated:

3. Possibility of work with one gas supply source;

7. It has a port for optional auxiliary pressure measurement (tracheal);

17. Besides ventilator flow sensors it has ability for alternative precise flow measurement with sensors

placed right behind the airway tube;

We kindly ask you to remove these items

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, it is financially justifiable to procure ventilators with suggested characteristics. Ventilators with required technical characteristics, made by almost all renowned manufacturers, belong to the higher price range. Also, the required characteristics are not commonly applied in clinical practice, so the additional investment is not justifiable. Removing these technical characteristics would make it possible to procure more affordable equipment, and a significantly higher number of bidders can offer equipment without the characteristics stated in items 3, 7, 17.

Answer 56:

The suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of the equipment. The purchaser maintains its request as formulated

LOT 5, ID 5.8 - Central station with WEB remote access to patients' clinical information

Question 57.

In the Tender Documentation, the following technical characteristic is stated:

8. Single viewer display format: min 8 waveforms per patient. Multy viewer display format: min. 4 waveforms per patient and 1-16 individual patient in standard display form

We kindly ask you to remove this item to make possible for more than one bidder to participate in the equipment procurement.

Answer 57:

The suggestion is not acceptable. Most central stations of the new generation can satisfy the required characteristics.

Question 58.

In the Tender Documentation, the following technical characteristic is stated:

4. Display information : Access to patient demographic information , arrhythmias, ST-limit violations,and ECG samples in event review, parametar data in graphic and numeric trends, full disclosure data 24 h , parameter numerics and waveforms available in a live view presentation.

We kindly ask you to alter this item so that it reads:

Display information : Access to patient demographic information , arrhythmias, ST-limit violations,and ECG , , full disclosure data 24 h , Clinical tools to support advanced analysis: ST segment review, Full and Event Disclosure with ECG calipers and trend display, and 12-lead rest ECG analysis

Suggested technical characteristics are standard for most central monitoring stations on the market, so it is necessary to alter the characteristic to enable competition.

Answer 58:

The suggestion is not acceptable. Most central stations of the new generation can satisfy the required characteristics.

Question 59.

In the Tender Documentation, the following technical characteristic is stated:

5. Central station must provide monitor control: remote control of admit/discharge settings, parameter priority, alarm and patient monitor settings.

We kindly ask you to alter this item so that it reads:

Central station must provide monitor control

All patient monitoring medical equipment manufacturers can satisfy these technical characteristics.

Answer 59:

The suggestion is not acceptable.

The request represents the standard characteristics of the bi-directional communication of the monitor and the central station. Most central stations of the new generation can satisfy the required characteristics.

Question 60.

In the Tender Documentation, the following technical characteristic is stated:

6. Alarm notification: audible, visual
Patient alarms-4 configurable levels complies with IEC standard

We kindly ask you to alter this item so that it reads:

Alarm notification: audible, visual
Patient alarms complies with IEC standard

Required technical characteristic limits the number of bidder able to participate in the procurement, while the change of the characteristic would enable a significantly larger number of equipment manufacturers to participate.

Answer 60:

The audio/visual alarms that complies with IEC standard are acceptable. The purchaser maintains its request as formulated

Question 61.

In the Tender Documentation, the following technical characteristic is stated:

Additional Options and features: Full Disclosure and ST review records min. 6 days

We kindly ask you to alter this item so that it reads:

Additional Options and features: Full Disclosure min. 5 days

All monitoring equipment manufacturers can offer a central unit with suggested characteristics, so acknowledging them would enable greater competition in the equipment procurement process.

Answer 61:

The suggestion is not acceptable. Most central stations of the new generation can satisfy the required characteristics.

LOT 5, ID 5.10 - Monitoring system with advance cardio function – (ICU 1, Post-CCU)

Question 62.

In the Tender Documentation, the following technical characteristic is stated:

2. Integrated colour display 15 inch with resolution min. 1024 x 768 pixels

We kindly ask you to alter this item so that it reads

Integrated colour display 12 inch

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, procuring monitors with the suggested characteristics is financially justifiable.

Touchscreen monitors 15 inches in size, made by almost all renowned manufacturers of patient monitors, belong to a higher price range, while the functionality of 12-inch monitors is at the same level as the 15-inch ones. Absence of touchscreen brings an advantage in terms of robustness and damage resistance, and also significantly reduces the possibility of accidental activation by non-qualified staff.

Answer 62:

The suggestion for modification is not acceptable. Characteristics essentially determine the class and quality of the equipment. The purchaser maintains its request as formulated

Question 63.

In the Tender Documentation, the following technical characteristic is stated:

3. Controls: touchscreen and rotary control button

We kindly ask you to alter this item so that it reads

3. Controls: rotary control button

See explanation for Question 1.

Answer 63:

The combination of a touchscreen and a rotary control is a standard functional solution for most monitors. Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment which is the subject of procurement. The purchaser maintains its requirement as formulated.

Question 64.

In the Tender Documentation, the following technical characteristic is stated:

7. 72-hour parameter trends

We kindly ask you to alter this item so that it reads

7. 24-hour parameter trends

Parameter tracking during 72h is not necessary on the monitor itself, given that it is possible to access the monitor via LAN. Most manufacturers can offer monitors with a 24h trend, so this would enable everyone to participate in the procurement.

Answer 64:

The monitor must have an autonomous function of the vital parameters trend for several days, in the case that patients stay longer in the intense unit. The request is standard for most monitors regardless of the class of equipment. Suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment.

Question 65.

In the Tender Documentation, the following technical characteristic is stated:

12. Arrhythmia monitoring in four simultaneous leads , including atrial fibrillation detection and trending

We kindly ask you to alter this item so that it reads

12. Arrhythmia monitoring

The majority of patient monitor manufacturers have the ability of arrhythmia monitoring. The required technical characteristics favor certain medical equipment manufacturers.

Answer 65:

Simultaneous arrhythmia monitoring in more leads are acceptable for beneficiary. The purchaser maintains its request as formulated.

Question 66.

In the Tender Documentation, the following technical characteristic is stated:

15. 12 channel ECC gender-specific algorithm for interpretation

We kindly ask you to alter this item so that it reads:

12 channel ECG

Answer 66:

The suggestion is not acceptable. The purchaser maintains its request as formulated.

Question 67.

In the Tender Documentation, the following technical characteristic is stated:

26. Measuring the expiratory concentrations of CO₂, through a portable module that is compatible with the ventilator device;

We kindly ask you to alter this item so that it reads:

Measuring the expiratory concentrations of CO₂

Most manufacturers can offer a monitor model with this characteristic. Besides, there is a large number of ventilators able to measure CO₂ concentration, so it is enough that the monitor has its own module for measuring CO₂ concentration.

Answer 67:

The suggestion is not acceptable. Characteristics essentially determine the class and quality of the equipment. Certain features allow for better functionality. The purchaser maintains its request as formulated.

Question 68.

In the Tender Documentation, the following technical characteristic is stated:

27. Monitoring of Gas exchange and metabolics –continuous non-invasive measurement of oxygen

consumption (VO₂), carbon dioxide production (VCO₂) , and calculation of respiratory quotient (RQ) and energy expenditure (EE)

We kindly ask you to alter this item so that it reads:

continuous noninvasive arterial pressure

Most manufacturers possess models with this characteristic, so it is necessary to enable everyone to participate in the procurement.

Answer 68:

The suggestion is not acceptable. The monitor already has an active invasive pressure function, with a free choice of the type of pressure to be measured. The purchaser maintains its request as formulated.

Question 69.

In the Tender Documentation, the following technical characteristic is stated:

30. Integrated thermal recorder (min 3 channel)

We kindly ask you to alter this item so that it reads:

Integrated thermal recorder

Most renowned monitor manufacturers can offer a monitor with this characteristic.

Answer 70: 69

The majority of renowned monitor manufacturers can offer a monitor with this characteristic.

Question 70.

In the Tender Documentation, the following technical characteristic is stated:

31. Remote controller

We kindly ask you to alter this item so that it reads:

Remote controller or keypad

This way, monitor access and equivalent functionality is enabled, and almost all manufacturers can offer a monitor with this characteristic.

Answer 70:

Remote control is a more acceptable solution for the because it is easier to operate than the keyboard. Suggestion is not acceptable. The purchaser maintains its requirement as formulated.

Question 71

U konkursnoj dokumentaciji su navedene tehničke karakteristike:

9. Integrated 2 USB ports

14. Continuous Qt/QTc monitoring , including measurements, trending and alarming , to support in early

identification of Torsades de pointes events.

interests of potential bidders cardiac ischemia (%)

28. Patient spirometry

We kindly ask you to remove these items.

Doing this would enable a larger number of bidders to participate in the equipment procurement. Also, it is financially justifiable to procure monitors with suggested characteristics. Monitors with required technical characteristics, made by almost all renowned manufacturers, belong to the higher price range. Removing these technical characteristics would make it possible to procure more affordable equipment, and the functions stated are not very commonly applied in clinical practice, so it is justified to procure monitors without stated characteristics. Furthermore, a significantly higher number of bidders can offer equipment without the characteristics stated in items 9, 14, 28.

Answer 71:

The suggestion is not acceptable. The characteristic essentially determines the class and quality of the equipment. Certain characteristics allow for better functionality, diagnostics, assessment of the nutritional status of the patient and accordingly selection of adequate therapy, which leads to faster recovery of the patient. When defining technical specifications, Beneficiary was not guided by the economic interests of potential bidders, but with its needs and functional and clinical solutions that enable total economic savings in the exploitation of equipment. The purchaser maintains its requirement as formulated.

Ustavski