Procurement of Medical Devices for Clinical Centre Dr Dragiša Mišović

IOP/6-2017/RD

Clarification no. 8

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2. System console must be wide maximum 80 cm and has depth maximum 80 cm
Q1: Nije nam jasno da li se ovde podrazumevaju dimenzije radne površine, ili celog aparata? Ukoliko su u pitanju dimenzije celog aparata, onda ovu karakteristiku može da ispuni samo jedan ponuđač, pa Vas molimo da je izbacite iz tehničkih specifikacija. Pored toga, smatramo da dimenzije sofisticirane mašine kao što je aparat za anesteziju ne trebaju da budu parametar odlučivanja pri nabavci, budući da nemaju apsolutno nikakav klinički značaj.

Q1: It is not clear to us whether this implies the dimensions of the work area or the entire device? If it is the dimensions of the entire device, then only one manufacturer can meet this requirement, so we kindly ask you to remove it from the technical specifications. In addition, we believe that the dimensions of a sophisticated device such as such as an anaesthesia device should not be the decisive parameter in procurement, since they have absolutely no clinical significance.

ANSWER Q1:
The dimensions relate to the entire anaesthesia device. They are defined within the range which corresponds to the conditions in the operating rooms where the equipment will be used. In addition to the clinical and ergonomic, the physical characteristics of the equipment, such as dimensions, are also important in procurement of big equipment such as an anaesthesia device. Several manufacturers meet this requirement. The Contracting Authority maintains its requirement as formulated.

19. It has ability of flow measurement with proximally placed sensor (right in front of airway tube);
Q2: Da li je prihvatljivo da se ova mogućnost nalazi na pratećem pacijent monitoru umesto na aparatu za anesteziju?

Q2: Is it acceptable for this ability to be found on the accompanying patent monitor instead of the anaesthesia device?

ANSWER Q2:
It's a better ergonomic solution for the Contracting Authority, and more precise measurement results are obtained when the mentioned data is measured from the anaesthesia device because it is the same system, and they are displayed in a centralized manner with the other ventilation parameters on the display of the anaesthesia device. The Contracting Authority maintains its requirement as formulated.

21. System has its own color display on mobile arm, of size mininum 15", with resolution of 1024x768 or higher, touchscreen. The display must have a rotary command for menu selection and settings;
Q3: Da li je prihvatljivo da sistem za anesteziju umesto rotirajuće komande poseduje dodatni touch-pad?

Q3: Is it acceptable for the anaesthesia system to have an additional touch pad instead of a rotary command?

ANSWER Q3:
It's a better ergonomic solution for the Contracting Authority for functions management for the display to also have the rotary command, since it is nearby, on the display itself. The Contracting Authority maintains its requirement as formulated.

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), NMT;

Q4: Da li je prihvatljivo da se deo „measurement of sensitivity on surgical stimuli during general anesthesia (level of analgesia)" izbaci iz tehničkih specifikacija, budući da je to stavka koju može da ispuni samo jedan ponudač?

Q4: It is acceptable to remove the entire part "measurement of sensitivity on surgical stimuli during general anaesthesia (level of analgesia)" from the technical specifications, since only one manufacturer can meet this requirement?

ANSWER Q4:
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.

5.2.2 DEFIBRILLATOR for HOSPITAL USE – ADVANCED

3. Upgradeable capability with an extra battery with capacity of autonomy for a minimum 4h monitoring
Q5: Ukoliko ponuđeni aparat već poseduje bateriju koja ima kapacitet od 5 h monitoringa, da li je u tom slučaju moguće ponuditi aparat koji ne poseduje ovu vrstu nadogradnje?

Q5: If the offered device already has a battery with the capacity for 5h of monitoring, is it in this case possible to offer a device without this type of upgradeability?

ANSWER Q5:

The requirement for the possibility of upgrading the device with an additional battery is intended to enable the user, if necessary, to easily increase the autonomy of the defibrillator

from 2 to 4 hours. If the offered defibrillator model already has a standard battery life of 5 h, it is not it necessary for it to have the option of upgrading with an additional battery.

6. The pedals for defibrillation have to have integrated buttons to select energy, charge, shock delivery and start / stop function for integrated thermal printer
Q6: Da li je moguće ponuditi defibrilator koji na papučicama ima sve navedene funkcije osim: „start / stop function for integrated thermal printer"?

Q6: Is it possible to offer a defibrillator that has all the listed functions on the pedals except for the "start / stop function for integrated thermal printer" function?

ANSWER Q6:

The start / stop function for printing of reports integrated on the pedals is intended to provide the maximum operator functionality during an intervention. The Contracting Authority maintains its requirement as formulated.

8. Integrated color LCD monitor with diagonal minimum 10"
Q7: S obzirom da defibrilator treba da prikazuje samo EKG, SpO2 i NIBP, smatramo da nema potrebe da dijagonala ekrana bude 10". Da li je prihvatljivo da se ponudi defibrilator dijagonale ekrana od 7" ?

Q7: Since the defibrillator should only show the ECG, SpO2 and NIBP, we believe that there is no need for the screen diagonal to be minimum 10". Is it acceptable to offer a 7" screen?

ANSWER Q7:

The device should have the options of simultaneous display of the 12-lead ECG, SpO2 and NIBP, so the function of clear and unambiguous monitoring is one of the most important functions in the process of reanimation. The Contracting Authority maintains its requirement as formulated.

10. Monitor must have the possibility of simultaneous display of 12 ECG leads
Q8: Da li se ovde podrazumeva da monitor treba da poseduje priključak i pribor (kablove) za praćenje 12-kanalnog EKG?

Q8: Is it implied here that the monitor should have the connector and accessories (cables) for monitoring the 12-lead ECG?

ANSWER Q8:

Yes, it is implied.

15. The complete menu of user interface software must be in Serbian language
Q9: Da li je za korisnika prihvatljivo da korisnički softver bude na engleskom jeziku?

Q9: Is it acceptable for the beneficiary if the user software is in English.

ANSWER Q9:

Defibrillator must have user software in Serbian, and in addition to Serbian, it may also have user software in other languages. The Contracting Authority maintains its requirement as formulated.

16. Device must have a minimum of integrated following interfaces: 1 x USB, 1 x QRS trigger and 1 x RS 232
Q10: Da li je za korisnika prihvatljivo da se izbaci eksterni QRS trigger, budući da većina defibrilatora poseduje ovu funkciju integrisanu unutar samog aparata, kao i da se izbaci RS 232 kao zastareli način komunikacije koji se gotovo nigde više i ne koristi?

Q10: Is it acceptable for the beneficiary to remove the external QRS trigger, since most defibrillators have this function integrated within the device, and also to remove RS 232 as an outdated mode of communication which is practically no longer used any more.

ANSWER Q10:

The Contracting Authority clearly defined that integrated QRS system is required, and not external. The other required interfaces represent minimum conditions. The Contracting Authority maintains its requirement as formulated.

24. Weight max. 6 kg with batteries and pedals
Q11: Da li je prihvatljivo da se ponudi defibrilator težine 8 kg sa baterijom i papučicama?

Q11: Is it acceptable to offer a defibrillator weighing 8 kg with the battery and pedals?

ANSWER Q11

The weight of the device is an important feature that achieves conformity and functionality at work, which is especially prominent in the usual transport or moving of a patient connected to the device. The Contracting Authority maintains its requirement as formulated.

5,2,2 DEFIBRILLATOR for HOSPITAL USE – ADVANCED

3. Battery capacity of min. 150 shocks with a maximum energy or 3.5 h of ECG monitoring
Q12: Da li je prihvatljivo da se ponudi defibrilator sa kapacitetom baterije od 100 šokova?

Q12: Is it acceptable to offer a defibrillator with the battery capacity of 100 shocks?

ANSWER Q12

The battery capacity that allows 30% more shocks with the maximum energy compared to the requested change allows for greater functionality of equipment. The Contracting Authority maintains its requirement as formulated.

10. Thermo printer uses paper width minimum 70 mm width
Q13: Da li je prihvatljiv printer koji koristi papir širine 50 mm?

Q13: Is a printer using paper width of 50 mm acceptable?

ANSWER Q13

The paper width enables better visibility of the printed measurements and findings, thus achieving greater functionality of the equipment. The Contracting Authority maintains its requirement as formulated.

12. Device must have a minimum of integrated following interfaces: 1 x USB and 1 x RS 232
Q14: Da li je za korisnika prihvatljivo da se izbaci RS 232 kao zastareli način komunikacije koji se gotovo nigde više i ne koristi?

Q14: Is it acceptable for the beneficiary to remove RS 232 as an outdated mode of communication which is practically no longer used any more.

ANSWER Q14

The required interfaces are the minimum conditions the devices must meet.
The Contracting Authority maintains its requirement as formulated.

14. The complete menu of user interface software must be in Serbian language
Q15: Da li je za korisnika prihvatljivo da korisnički softver bude na engleskom jeziku?

Q15: Is it acceptable for the beneficiary if the user software is in English.

ANSWER Q15:

Defibrillator must have user software in Serbian, and in addition to Serbian, it may also have user software in other languages. The Contracting Authority maintains its requirement as formulated.

18. Maximum gross weight of defibrillator including battery and pedals 5.5 kg
Q16: Da li je prihvatljivo da se ponudi defibrilator težine 6 kg sa baterijom i papučicama?

Q16: Is it acceptable to offer a defibrillator weighing 6 kg including the battery and pedals?

ANSWER Q16:

The weight of the device is an important feature that achieves conformity and functionality at work, which is especially prominent in the usual transport or moving of a patient connected to the device. The Contracting Authority maintains its requirement as formulated.

19. Device must have minimum IP 53 protection standard
Q17: Da li je prihvatljivo da se ponudi standard IP 44, budući da su u pitanju bolnički uslovi gde je nepotrebno da standard zaštite od prašine bude klase 5?

Q17: Is it acceptable to offer the IP 44 standard, since we are talking about the hospital environment where the class 5 dust protection standard is unnecessary?

The defibrillators in question are intended for optimal working conditions at Clinical Centre Dr Dragisa Misovic, i.e. in addition to the standard intra-hospital use, they are also used for patient support during the transport within and outside the institution. Due to the layout and the great space that the department covers and the exposure of equipment to changes in ambient conditions during transport, it needs to have the required protection standard. The Contracting Authority maintains its requirement as formulated.

Public Procurement Commission