# Procurement of Medical Devices for Clinical Centre Dr Dragiša Mišović

## IOP/6-2017/RD

## Clarification no.14

## Issued on 29.09.2017.

**1. 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;**

Analgesia level is characteristics of just one world manufacturer GE, so we kindly ask you to delte this techical characterstics so other world manufacturers like Maquet, Draeger, Mindray etc could participate. Or if this characteristic is specially important for you can score it like special technological advantage.

Answer 1:

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.

Odgovor1 :
Adekvatna analgo terapija je jedna od ključnih komponenti anestezijske procedure. Njom se postiže da terapija bude u skladu individualnim potrebama svakog pacijenta. Ovim praćenjem se omogućava racionalnija primena lekova, time smanjuje broj postoperativnih neželjenih efekata, pacijenti lakše i brže oporavljaju, odnosno kraće borave u bolnici. Mi smo kao ustanova uspeli da u RFZO obezbedimo posebnu šifru za TIVA TCI anesteziju, kao i za sve prateće aspekte kojima obezbedjujemo njeno kvalitetno izvodjenje. Mogućnost praćenja parametra koji pruža uvid u adekvatnost analgezije i kontrole autonomnog sistema je izuzetno važna komponenta anestezije. Naručilac ostaje pri zahtevu kako je formulisan, jer on značajno doprinosi ukupnoj ekonomičnosti rada i bezbednosti pacijenata.

Question 2:

**2.**

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| 22 | Additional Options and Features: |
| 23 | SvO2 module |
| 24 | EEG module |
| 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 respirtory quotient (RQ) and energy expenditure (EE) |
| 27 | Patient spirometry |
| 28 | PICCO module |

You just describe just additional options, which you will not get in delivery, but are only used to decrease competition and enable price manipulation.

For example, Picco modules in Serbia are in work practice just in two instutions, IKVB Sremska Kamenica and sometimes KC Srbija. You, like Clinical hospital center do not have such patients on whom PiCCO monitoring could be done, neither educated staff for that. We kindly ask you to adjust your description to your real needs not needs of bidder GE, so they could remove their competitors.

Answer 2:

BC "Dr Dragisa Misovic-Dedinje" is a tertiary level health care institution, which includes the Clinics for Surgery and Anesthesia that handle a large number of high risk surgical patients. Such patients require a proposed level of monitoring, and therefore remain with the requested tender requirement.

Odgovor 2:

KBC "Dr Dragisa Misovic- Dedinje" je ustanova tercijarnog nivoa zdravstvene zastite, koja u svom sastavu ima Klinike za hirurgiju i anesteziju koje zbrinjavaju veliki broj visoko rizicnih hirurskih pacijenata. Takvi pacijenti zahtevaju predlozeni nivo monitoringa, te stoga ostajemo pri trazenom tenderskom zahtevu.

Question 3:

**3. Device must have the ability to be upgraded with software option thrombolysis (gives a recommendation to users regarding thrombolytic therapy)**

We put your attention, in order to get recomendation for thrombolytic therapy(it is not clear why beneficiary as tertiary health care institution, which means that have patients with lots of diagnostics documents and examniation done before come to KBC, more precisely to Surgery of KBC, beacuse the equipment which is the subject of procurement is for new surgery department, should have RECOMENDATION for thrombolytic therapy) before ECG, beneficiary must enter in ECG exact amount and name of drugs which patient use and do that by generic of used medicines, and after that to enter the hight od patient, weight, years... After all the medication entered and ecg measured, ecg will be print whether patient is recomended to start for thrombolytic therapyor not(but in anyway doctor must determine and decide). Anyway, the taking of ecg, which usually lasts 5 minutes, if all of these is entered into the system means that the ecg will takes a minimum 30 min. That means that in one shift which lasts 8 hours it could be possible to take 16 ECGs, if working without pause. If all of this is really beneficiary's need and if beneficiary really has time to spend half hour for one ecg, we kindly ask you that this technical characteristics score like technological advantag, and if not, to remove it in order to enable other manufacturers participating, not just manufacturer Schiller.

Answer 3:
From the letter sent to us, it is quite clear that the complainant does not recognize what is required by the technical specification and how the ECG with thrombolysis works.
Reperfusion strategy for the treatment of acute myocardial infarction is determined depending on: duration of symptoms to the first medical contact (ie diagnosis on the ECG, no finding of biohumoral markers of myocardial necrosis!); age of the patient; infarct size; body weight of the patient; tendencies to hemorrhagic complications; as well as the availability of pPCI within 90-120 minutes (National Guidance for Good Clinical Practice for the Diagnosis and Treatment of Ischemic Heart Disease, Republic Commission for the Development and Implementation of Good Clinical Practice Guides, Ministry of Health of the Republic of Serbia).
The ECG apparatus should enable physicians to obtain advanced software analysis, in routine way, standardly recorded ECG (without a bunch of accompanying activities of the hospital staff which is state in this question) and help the physician in a faster and more accurate assessment of whether the patient needs or does not thrombolytic therapy .This method does not require a little more time than what is required for classical ECG recording.
About the claims that only the SCHILLER manufacturer fulfills the required characteristic, we note that such a claim is not entirely in line with the fact that there are still manufacturers on the market who can offer ECG appliances with thrombolysis software.

Odgovor 3:
Iz dopisa koji nam je dostavljen je u potpunosti jasno da podnosilac primedbe ne prepoznaje šta je tehničkom specifikacijom traženo i kako EKG sa tromboliza softverom funkcioniše.

Reperfuziona strategija lečenja akutnog infarkta miokarda određuje se zavisno od: trajanja simptoma do prvog medicinskog kontakta (**odnosno postavljanja dijagnoze na EKG-u**, ne čeka se nalaz biohumoralnih markera miokardne nekroze!); starosti bolesnika; veličine infarkta; telesne težine bolesnika; sklonosti ka hemoragičnim komplikacijama; kao i dostupnosti da se uradi pPCI u roku 90–120 minuta (Nacionalni vodič dobre kliničke prakse za dijagnostikovanje i lečenje ishemijske bolesti srca. Republička stručna komisija za izradu i implementaciju vodiča dobre kliničke prakse, Ministarstvo zdravlja Republike Srbije).

Predmetni EKG aparati treba da omoguće lekarima da iz rutinski, standardno snimljenog EKG-a (bez gomile pratecih aktivnosti osoblja bolnice koje podnosilac zahteva navodi) dobiju naprednu softversku analizu i pomognu lekaru u bržoj i tačnijoj proceni da li je pacijentu potrebno ili ne davanje trombolitičke terapije. Ova metoda pri tome ne zahteva ni malo vise vremena od onoga koje je potrebno za klasicno snimanje EKG-a.

Sto se tice tvrdnje podnosioca zahteva da samo proizvodjac SCHILLER ispunjava predmetnu karakteristiku napominjemo da takva tvrdnja u potpunosti ne stoji obzirom da na tržištu postoji jos proizvodjača koji mogu da ponude EKG aparate sa tromboliza softverom.

**Question 4:**

LOT 3, position 3.5

Please accept the participation of the appliance whose consumption is 22- 26 liters per cycle, as the difference in relation to the required characteristic (water consumption up to 25 liters per cycle) is less than 5%.

Please accept the participation of the device dimension (HxLxW) 1042 (+ - 3) x600x500 mm, since the difference in relation to the required dimension, (HxLxW) 947x607x432 is insignificant.

**Answer 4:**

It is acceptable.

**Question 5:**

LOT 1, position 1.11

Please accept the CE certificate instead of ISO 9001 for this position, since most manufacturers of shoe wrappers do not have ISO 9001.

**Answer 5:**

It is acceptable