



Republic of Serbia

MINISTRY OF FINANCE

Department for Contracting and Financing of EU Funded Programmes (CFCU)

Belgrade, 3 March 2022

CONTRACTING AUTHORITY'S CLARIFICATIONS no.1

Supply of equipment for relevant institutions within the SoHo System in Serbia

Publication ref: NEAR/BEG/2021/EA-OP/0180

Disclaimer: All requests for additional information must be made in writing through the TED eTendering website accessible from the F&T portal. Contracting Authority shall not accept any responsibility or liability in case of requests for additional information which are not submitted fully in line with applicable provisions for submission of the request for additional information.

| No. | Question | Answer |
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| 1 | Please be informed that the tender documents mention the amount for the tender guarantees for lot 1, 2, 3 and 5 only. Does this mean that for lot 4 no tender guarantee is required? Please confirm and if not, please inform us about the required tender guarantee amount for lot 4. | <i>Please note that in accordance with Section 23 of Instructions to Tenderers, tender guarantee must be provided for Lots 1, 2, 3 and 5. For Lot 4 no tender guarantee is required.</i> |
| 2 | a) Engine: diesel, 2.2, 140 HP We kindly ask you revise the engine volume as Engine: diesel, 2.0 since manufacturers decrease engine volumes by keeping the same power. On the other hand there is shortage on vehicle supply, and there are limited manufacturers as well. Therefore, this revision will also enable more options to offer. b) Vehicle layout: 5 doors, 6 seats The definition of 5 doors is usually used for estate type vehicles. Since requested vehicle is Van type, they have one back | <i>a) and b) This issue will be remedied by means of corrigendum no.2 to Tender Dossier. Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet. c) Offered air-conditioning solution for driving and passenger space must assure appropriate thermal comfort, involving heating, ventilation and cooling.</i> |

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| | <p>door, one sliding door, left and right front doors meaning that total is 4 doors. Do 6 doors stand for (5 passenger + 1 driver seat)? Please revise this specification as 4 doors, 5+1 seats.</p> <p>c) Manual air conditioning for driving space and passenger compartment Cooling for driving space and passenger compartment. Please clarify whether if this specification is meant to be for heating purpose, since air conditioning is requested in the above specification as well.</p> | |
| 3 | <p>Lot 4 item 4.2: FREEZER FOR BLOOD PLASMA STORAGE (-40 ° C).</p> <p>Description: Requirement “Audio-visual alarms for: temperature, disappearance of the electricity, equipment failure, low battery voltage, open doors, all powered with rechargeable battery, condenser dirt, anti-freezing evaporator”.</p> <p>Could you please clarify this requirement? Does it mean that all the alarms should be active in case of power failure and be powered with a battery? Should the requirement “anti-freezing evaporator” be a separate requirement since it has nothing to do with any alarms?</p> | <p><i>In case of power failure, a corresponding power failure audio-visual alert must be activated. Alert functions described in the technical specifications must be powered via separate, rechargeable battery.</i></p> <p><i>A requirement „anti-freezing evaporator “is to be considered as may be a separate, requirement, not linked to requested alarms.</i></p> <p><i>It is not necessary that all alarms have a battery. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 4 | <p>Lot 4 item 4.2: FREEZER FOR BLOOD PLASMA STORAGE (-40 ° C). Requirement “Additional Monitor”.</p> <p>Description: Could you please clarify this requirement? What is the purpose of the requested additional monitor? Conventional freezers are equipped with a display and require no additional monitors.</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| 5 | <p>Lot 4 item 4.3: pH METER. Requirement "mV measuring range: -2.000 – 20.000".</p> <p>Description: Most pH/mV-meters have a measuring range of ± 2000 mV. The requested value is excessive. Will the offer of a pH-meter with a measuring range of ± 2000 mV be considered as meeting minimal requirements of technical specification?</p> | <p><i>Most of the parameters in the measurement are in range of ± 2000 mV. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 6 | <p>Question concerning item 3.1: Automatic blood component extractor</p> <p>Description:</p> <p>1) How many whole blood bags need to be processed per year?</p> <p>2) What kind of Whole blood bags are used? a. Bottom and top? b. Top and top? c. Whole blood filtration bags?</p> <p>3) How many platelets coming from whole blood are produced per year?</p> <p>4) How many production sites are there? 1 or several? If several how many are there?</p> <p>5) How would the 12 AUTOMATIC BLOOD COMPONENT EXTRACTOR be spread over the production site.</p> | <p><i>1) About 200.000-220.000 units per year.</i></p> <p><i>2) Quadruple bags Top and top are in use and quadruple and quintuple Bottom and top. There are all listed types of bags including Top and Top.</i></p> <p><i>3) 120.000-145.000 approximately 60% of platelets coming from whole blood are produced per year.</i></p> <p><i>4) There are eight (8) production sites.</i></p> <p><i>5) According to the number of collected units. 12 Automatic blood component extractor will be spread over the production site:</i></p> <p><i>1. Institut za transfuziju krvi Srbije, Svetog Save 39, 11000 Beograd</i></p> <p><i>2. Zavod za transfuziju krvi Niš, Bulevar Dr Zorana Đinđića 48, 18000 Niš</i></p> <p><i>3. Zavod za transfuziju krvi Vojvodine, Hajduk Veljka 9a, 21000 Novi Sad;</i></p> <p><i>4. Zavod za transfuziju krvi Kragujevac, Zmaj Jovina 30, 34000 Kragujevac;</i></p> <p><i>5. Opšta bolnica Uzice, Miloša Obrenovića 17, 31000 Užice;</i></p> <p><i>6. Opšta bolnica Subotica; Izvorska 3, 24000 Subotica;</i></p> <p><i>7. KBC Zemun, Vukova 9, 11080 Zemun;</i></p> |

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| | | 8. Vojnomedicinska Akademija, Crnotravska 17, 11000 Beograd |
| 7 | <p>TECHNICAL CLARIFICATIONS Lot 3 – MVTC TOOLS & ELECTRICAL MATERIALS</p> <p>Description: Please kindly let us receive additional information and pictures relative to the following items: 4-5-9-10-14-24-30-31-36-37-38-39-40-41-42-45 Best regards</p> | <p><i>There are no images available. It is important to note that all the necessary additional information is already listed in the text of the amended Technical Specifications and through the answers to the questions. Please refer to the Corrigendum no.2 to the Tender Dossier.</i></p> |
| 8 | <p>TECHNICAL CLARIFICATIONS Lot Two – MOBILE LABORATORY</p> <p>Description: Please kindly let us have more details relative to the vehicle: Overall external and internal dimensions Dimensions of the working area Number of front seats And the following information relative to laboratory onsite: Which a environmental parameters will be analysed? How many operators will be using the equipment? / How many working stations are needed onsite?</p> | <p><i>In the Technical Specification published in the Tender Dossier there is no Lot Two MOBILE LABORATORY. The list of equipment that is purchased does not mention Mobile laboratory.</i></p> |
| 9 | <p>LOT 5</p> <p>Description: We made an additional verification of the technical specification and wish to clarify some elements as they are contradictory or need more precisions:</p> <p>a) Vehicle size o while, also FIAT dimensions differ slightly, an L2H2 size would be 5413 / 2522 mms L/H vs. 5400 and 2500 mms, so formally not conform, but very much the same. Volume in this size is 11,5 m3 which is OK. o an L1H1 size (4963 / 2254 mms) would be conform in sizes, but in that case the volume is only 8 m3, not OK. o an L2H1 size would also result in 10 m3</p> | <p><i>a) Please refer to the existing Technical Specifications. Unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> |

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| | <p>volume, not OK. o so currently there is no vehicle to comply with all requirements. Please confirm you will accept the L2H2 sizing.</p> <p>b) Blood refrigerator o portable and 80 liter capacity are contradictional o we might include an inverter to produce 230V instead of 12V (required), this could help to find the right model o would it be possible to preview a separate blood refrigerators for portability? • Oxygen o do we talk here a kind of special portable bag with two liter bottle? • Pictures & internals o can we have some pictures of existing model/patient compartment expected, current use etc? o portable tables and chairs: any feedback / preferences on their type? no fixing points for them within the patient compartment? which standard must be met for them?</p> <p>c) Doors & windows o exact number of doors: 5. Driver cabin: 2x. Patient compartment: 3x. Does this count the back doors as 2? or do we need a left door too? do we need window on the right door? do we need window on the left door, if any door? do we need window on the back doors? do we need windows all around?</p> | <p><i>b) Refrigerator needs to have possibility of working in vehicle, power supply 230/12 as in stated in the existing Technical Specifications.</i></p> <p><i>Basic set of oxygen.</i></p> <p><i>Table and chairs should be flooding so they can fit in small places, and high quality for long-term and everyday use.</i></p> <p><i>c) Yes, this counts back door as second door and we need left door; we do not need window on left door, we need window on back door. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 10 | <p>Engine: diesel, 2.2 140 HP With the development of more efficient engines and in meeting new EURO6 Emission Regulations many manufacturers have reduced engine sizes to 2.0 whilst still meeting or exceeding power requirements. In consideration of improvement to the engine efficiency as well as environmental impact we would ask for confirmation that engine from 2.0 would be deemed acceptable. Front Wheel Drive Currently many major manufacturers are</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> |

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| | <p>now give preference to rear wheel drive since weight is more equally distributed across the vehicle improving overall handling without reducing carrying capacity. We would therefore ask for confirmation that either Front Wheel Drive or Rear Wheel Drive would be acceptable. We thank you for your consideration of our questions.</p> | |
| 11 | <p>Lot 4 item 4.2: FREEZER FOR BLOOD PLASMA STORAGE (-40°C).</p> <p>Description: Requirement “Permissible room temperature: max + 32°C”. According to international regulations, room temperature for blood storage facilities should be kept in the range of 20-25°C. Higher ambient temperature may result in blood shelf-life reduction and will require additional equipment such as a blood transport box or isolator carriers to transport blood even inside the blood storage facility. Will the offer of a blood plasma freezer with maximum permissible room temperature up to 25°C be considered as meeting minimal requirements of technical specification?</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> |
| 12 | <p>Lot 4 item 4.2: FREEZER FOR BLOOD PLASMA STORAGE (-40 ° C).</p> <p>Description: Requirement “Insulation material: polyurethane foam 70 mm thick”.</p> <p>Insulation material may be applied with different density. High density polyurethane with a thickness of 50 mm is sufficient for excellent insulation. Will the offer of a blood plasma freezer with 50 mm thick high density polyurethane foam be</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> |

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| | considered as meeting minimal requirements of technical specification? | |
| 13 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.4 HANDHELD TUBE SEALER</p> <p>Description: 4. Specification: "PVC carrying case for complete sealer (head, battery and charger) with connection for charging the battery without taking it out of the carrying case" Question: Will the tender authority accept other materials such as leather, synthetic leather, plasticizer with polyurethane? Defining the material of the carrying case as PVC only limits the competition.</p> | <p><i>Please note that this issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 14 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.4 HANDHELD TUBE SEALER</p> <p>Description: 3. Specification: "The maximum weight of the welding head 300g" Question: Will the tender authority accept maximum weight of the welding head 400g?</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 15 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.4 HANDHELD TUBE SEALER</p> <p>Description: 2. Specification: " The sealing process indicator on the battery and on the sealing head " Question: Will the tender authority accept indicator on sealing head only? Modern devices do not display sensor on battery pack since experience show it is not visible for the operator. Since this is what operator sees in reality</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| 16 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.4 HANDHELD TUBE SEALER</p> <p>Description: 1. Specification: "Battery and charger: Lithium Polymer Battery 12V DC, rechargeable and compatible charger" Question: Will the tender authority accept new generation of battery and voltage standards such as Li-ion, 29.6V? that will allow to offer state of art newest technology with higher autonomy and capacity (more sealings on single charge)?</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 17 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.3 BLOOD COLLECTION SCALE/MIXER</p> <p>Description: 5. Specification: "Weight of appliance up to 4 kg (with battery)" Question: Will the tender authority allow weight of appliance up to 4,5 kg (with battery) that will allow to offer best range of devices?</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 18 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.3 BLOOD COLLECTION SCALE/MIXER</p> <p>Description: 4. Specification: "Data input and data display: possibility to enter the data of the donor in blood scale/mixer internal memory via a computer and displaying on the LCD screen of the blood scale/mixer" Question: Will the tender authority accept also newer generations of screens like TFT touch screen?</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 19 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.3 BLOOD COLLECTION SCALE/MIXER</p> | <p><i>Yes, it means to tare empty bag weight before collection.</i></p> |

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| | <p>Description: 3. Specification: "Weight calibration: possibility to tare empty memory bags" Question: How the tender authority defines "memory bags". Did you mean to tare empty bags weight before collection?</p> | |
| 20 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.3 BLOOD COLLECTION SCALE/MIXER</p> <p>Description: 2. Specification: "LCD display with blood weight, donation time and blood flow, date, time and battery status" Question: Will the tender authority accept also newer generations of screens like TFT touch screen?</p> | <p><i>Please refer to the answer to the question no.18.</i></p> |
| 21 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.3 BLOOD COLLECTION SCALE/MIXER</p> <p>Description: 1. Specification: "In case of insufficient rapid flow so that the user adjusts the speed of the flow " Question: Will the tender authority accept the offer for device that alert and stop the flow in case of insufficient flow from the donor vein? There is no possibility to adjust speed of flow with the device. Device can alert (and stop) in case of too low or too high flow.</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 22 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.2 BLOOD CENTRIFUGE WITH COMPUTER DATA SYSTEM</p> <p>Description: 2. Specification: " Double blood pack bucket 2x 300-900 ml" Question: Will the tender authority accept Double blood pack bucket 2 x 450 -750 ml? Standard of blood bags is 450 ml in collection and up 750ml is</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> |

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| | <p>enough for all procedures based on actual EDQM guidance.</p> | |
| 23 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.2 BLOOD CENTRIFUGE WITH COMPUTER DATA SYSTEM</p> <p>Description: 1. Specification: " Swing-out rotor with wind shield, 6 places</p> <p>" Question: Will the tender authority accept Swing-out rotor without wind shield? Without wind shield temperature in centrifuge is more homogeneous and faster to achieve. Wind shield is in a way during loading and unloading device and makes it less convenient for operator. Also, if blood bag spill occurs during centrifugation wind shield makes it much more difficult to clean and rotor itself is much heavier.</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 24 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR</p> <p>Description: 6. Specification: "Weight of equipment: maximum 30 kg"</p> <p>Question: Will the tender authority accept the device of weight up to 55 kg? Devices available in the market equipped with all above mentioned requirement have more weight than 30 kg. Change of specification to "Weight of equipment: maximum 55 kg" will allow to place valid offers.</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| 25 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR</p> <p>Description: 5. Specification: "Color LCD screen" Question: Will the tender authority accept also newer generations of screens such as TFT touch screen?</p> | <p><i>Please refer to answer to the question no.18.</i></p> |
| 26 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR</p> <p>Description: 4. Specification: "Three integrated systems for the automatic opening of the "brake way" cannulas (for full blood on the front panel, on the Red Cell extraction line to the Red Cell bag and on the top plate for adding the SAG-M solution)" Question: Will the tender authority require the offer for a device that is equipped with automatic opening for "break away" cannulas for most blood bags configurations on market (eg. Terumo BCT, Macopharma, Fresenius, JMS, Kawasumi...)?</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> |
| 27 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR</p> <p>Description: 3. Specification: "Propulsion headboard with embedded optical sensor" Question: Please explain this specification, what is the function/device outcome?</p> | <p><i>Automatic blood component extractors have numerous high sensitivity optical sensors, and one of them is on Propulsion headboard. The function of propulsion headboard with embedded sensors refers to the main press with optical sensors that pushes the bag.</i></p> <p><i>The quality of automatic blood components extractors differs in the numbers of optical sensors that exist for different processes of production of blood components. (more sensors-better quality of extractors)</i></p> <p><i>It is not entirely clear why this sensor is particularly distinguished from the others,</i></p> |

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| | | <i>but is certainly affects the better quality of the process of obtaining blood components and can be part of technical specification.</i> |
| 28 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR</p> <p>Description: 2. Specification: "The time of separation of blood components below 2 minutes" Question: Will the purchasing authority accept the equipment with adjustable time duration of separation? Is 2 min time referring to time of extraction during Top& Bottom process or Top& Top? Speed can be adjusted on device according to customer request (variable speed extraction). Time of separation is proportional with product quality (less time, lower quality product). Allowing adjustable time on the equipment will allow to offer better quality processing device.</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 29 | <p>Request for clarification LOT 3 - Support Equipment for Transfusion and Transplantation Establishment 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR</p> <p>Description: 1. Specification: "Parallel separation of Red Cells, Plasma and Platelets" Question: Will the purchasing authority accept the offer for a device that performs sequential separation of blood components? No device on market can do parallel separation of all components, way of blood component production is in a way that platelet production is always part of second centrifugation; therefore, second</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| | expression. Plasma and RBC production is done in first separation. | |
| 30 | <p>Clarification Request for Lot 5- Mobile Oxygen Unit</p> <p>Description: Could you please provide more details for the required mobile oxygen unit? *Is it such a oxygen system with ventilator to be mounted on the vehicle like an ambulance * Is it such an unit for emergency oxygen system with ventilation? *Is it just an oxygen cylinder with valve and face mask without ventilator? *What is the required oxygen cylinder capacity and quantity?</p> | <p><i>Mobile Oxygen Unit is just an oxygen cylinder with valve and face mask without ventilator and must be mounted on the vehicle like in ambulance.</i></p> |
| 31 | <p>Lot 3 Support Equipment for Transfusion and Transplantation Establishment</p> <p>Description: 3.1 Questions and comments for Separators</p> <p>1. Would a single device with two separation places, with the equivalent or better performance, with possibility of space saving and weight reduction, be acceptable in quantity of 6 pieces instead of 12 devices with one place for separation?</p> <p>2. Propulsion headboard with embedded optical sensor Please clarify this request in more details and explanation.</p> <p>3. The top plate with a sensor for controlling the Leukocyte filter filling and adding the SAG-M solution into a bag with Red Cells Would a solution with location of the pressing plate on a different place, with completely the same functionality and performance, in the sense of automatic valve breaking and balance sensor on the RBC scale and controlled filling of Leucocyte filter, be acceptable?</p> | <p><i>1. Technical Specifications will remain unchanged with regards to this issue. In case of breakdown from the one single device with the two separation places, the loss of the one press will immediately be the loss of two separator places which can't be used anymore. To secure the daily process, it has to be a single press device.</i></p> <p><i>2. Automatic blood component extractors have numerous high sensitivity optical sensors, and one of them is on Propulsion headboard. The function of propulsion headboard with embedded sensors refers to the main press with optical sensors that pushes the bag. The quality of automatic blood components extractors differs in the numbers of optical sensors that exist for different processes of production of blood components. (more sensors-better quality of extractors). It is not entirely clear why this sensor is particularly distinguished from the others, but is certainly affects the better quality of the process of obtaining blood components and can be part of technical specification.</i></p> |

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| | <p>4. Magnetic Holder for Red Cells Leukocyte filter</p> <p>Is it mandatory to have the magnetic holder for RC leukocyte filter or another firmer solution would be acceptable?</p> | <p><i>3. The most important thing is that the system has the ability to control transfer of SAG-M into a bag with Red Cells and the Leukocyte filling which certainly affects the better quality of the process of obtaining blood components. In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>4. Please note this issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 32 | <p>Lot 3 Support Equipment for Transfusion and Transplantation Establishment</p> <p>Description: 3.3 Questions and comments for Blood collection scale/mixer 1. Please clarify this request by explaining how would a user change speed of flow, because it is not allowed to adjust any parameters during donation. Additionally, the speed of flow doesn't depend on any device, but on the donor. The minimum and maximum flow can be adjusted and changed any time by the user, with the alarm in case of exceeding pre-set parameters.</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 33 | <p>Lot 3 Support Equipment for Transfusion and Transplantation Establishment</p> <p>Description: 3.4 Questions for handheld tube sealer 1. Battery and charger:</p> <p>Lithium Polymer Battery 12 V DC, rechargeable and compatible charger Is Lithium-Ion Battery Acceptable Instead of Required Lithium-Polymer Battery? Li-Ion comparing vs Li-Polymer</p> <p>The most significant difference between li-ion and li-polymer batteries is the chemical electrolyte between the negative electrodes. Li-Ion</p> | <p><i>Please note that this issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| | <p>batteries use liquid electrolyte, and Li-Po batteries use gel-like, dry or a porous chemical compound as an electrolyte. Most lithium-ion batteries also include controller board, which regulates power and discharge flows to protect it from over0charge or over-heating. Li-Ion batteries – Features & Characteristics:</p> <ul style="list-style-type: none"> • Offer higher capacity at lower price • Offer higher capacity density • Relatively more mature technology with more developed safety mechanism • Offer higher lifespan • No-memory effect <p>Li-Polymer batteries – Features & Characteristics:</p> <ul style="list-style-type: none"> • Very low self-discharge level • Offer lower capacity density • Higher price per same capacity • Electrolyte inside is not liquid (usually dry or gel type) • Can be molded and shaped in different ways (more flexible casing) | |
| 34 | <p>Lot 3 Support Equipment for Transfusion and Transplantation Establishment</p> <p>Description: 3.6 Questions for Donor chair stationary</p> <p>1. All visible metal parts are chromed for easy cleaning and maintenance Is it acceptable if the offered stationary donor lounge is made of epoxy painted metal?</p> <p>The same cleaning agents are used for cleaning both, Chrome and epoxy painted metal, water and soap or water and alcohol, so this metal meets the required specification, too.</p> <p>2. Linear actuator that can be located on either side of the bearing head to control the positioning engine Please clarify the question.</p> | <p><i>1. In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification. This issue will be remedied by means of corrigendum no.2 to Tender Dossier</i></p> <p><i>2. This request is necessary for controlling donor chair position.</i></p> |
| 35 | <p>LOT 2 Support Laboratory Equipment for Transfusion and Transplantation Establishment</p> <p>Description: 2.3 PLATELET INCUBATOR WITH AGITATOR 1. Table Top</p> | <p><i>Please note that this issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

| No. | Question | Answer |
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| | Incubator A device for required number of bags and subsequently its dimensions, cannot be table top. Kindly clarify this request. | |
| 36 | <p>LOT 2 - Support Laboratory Equipment for Transfusion and Transplantation Establishment</p> <p>Description: 2. Capacity for 192 pooling platelet bags Please 2 platelet agitators with minimum capacity of 96 platelet bags each, cannot store 192 pooling platelet bags. Do you think of storing 192 platelet bags, not pooling ones? If pooling, please advice the size of the pooling bags used and storage capacity.</p> | <p><i>Yes, we thought about storing 192 platelet bags, not pooling platelets bags once.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 37 | <p>LOT 2 - Support Laboratory Equipment for Transfusion and Transplantation Establishment</p> <p>Description: 3. 7-Days thermal temperature graphic recorder Would a more suitable solution, in order to secure all data collected in an incubator, such as temperature changes and alarms, which includes data transfer to the local PC with USB stick and possibility of organizing daily, weekly, monthly, yearly tables and printing them, in case hard copy is required, be acceptable?</p> | <p><i>Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> |
| 38 | <p>LOT 2 - Support Laboratory Equipment for Transfusion and Transplantation Establishment</p> <p>Description: 4. Removable perforated drawers Would a solution with grids, for better air circulation be acceptable, as per the below explanation? The surface area of the bag exposed for gaseous exchange is significantly increased with grid shelves (351cm² per bag) vs perforated sheet shelves (234.95cm² per bag) representing a breaking (reduction) factor in exchange time of 2.5% for grid shelves vs 34.7%</p> | <p><i>Please note that this issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

| No. | Question | Answer |
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| | for perforated sheet shelves, thus significantly increasing the potential for optimal gaseous exchange. | |
| 39 | <p>Location for installation and training</p> <p>Description: Dear Sirs, please confirm that the only location for delivery, installation and training is at the Directorate of Biomedicine in Belgrade. If not, please inform us about the exact number of locations as well as their addresses. Thank you!</p> | <p><i>Delivery, installation and training location will be on site.</i></p> <p><i>For the Transfusion Establishment, exact number of locations is 8:</i></p> <ol style="list-style-type: none"> <i>1. Institut za transfuziju krvi Srbije, Svetog Save 39, 11000 Beograd</i> <i>2. Zavod za transfuziju krvi Niš, Bulevar Dr Zorana Đinđića 48, 18000 Niš</i> <i>3. Zavod za transfuziju krvi Vojvodine, Hajduk Veljka 9a, 21000 Novi Sad;</i> <i>4. Zavod za transfuziju krvi Kragujevac, Zmaj Jovina 30, 34000 Kragujevac;</i> <i>5. Opšta bolnica Uzice, Miloša Obrenovića 17, 31000 Užice;</i> <i>6. Opšta bolnica Subotica; Izvorska 3, 24000 Subotica;</i> <i>7. KBC Zemun, Vukova 9, 11080 Zemun;</i> <i>8. Vojnomedicinska Akademija, Crnotravska 17, 11000 Beograd</i> <p><i>For the Transplantation Establishment, exact number of locations is 5:</i></p> <ol style="list-style-type: none"> <i>1. Univerzitetski klinički centar Srbije, Pasterova 2, 11000 Beograd;</i> <i>2. Univerzitetski klinički centar Niš, Bulevar Dr Zorana Đinđića 48, 18000 Niš</i> <i>3. Klinički centar Vojvodine, Hajduk Veljkova 1-9, 21000 Novi Sad;</i> <i>4. Univerzitetska dečja klinika, Tiršova 10, 11000 Beograd;</i> <i>5. Vojnomedicinska Akademija, Crnotravska 17, 11000 Beograd</i> |

| No. | Question | Answer |
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| 40 | <p>3.6 DONOR CHAIR, STATIONARY Specification: Seating material: vinyl (artificial leather) cover that can be disinfected with standard disinfectants and with antibacterial coating to prevent growth and reproduction of bacteria</p> <p>Description: Question: Material used for donor chairs are designed in a way that they can be disinfected, but antibacterial coating is additional option. Would tender authority accept basic seating material without antibacterial coating?</p> | <p><i>Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> |
| 41 | <p>3.6 DONOR CHAIR, STATIONARY Specification: Bearing length min 150 cm, width armrest (with armrests) of 90-100 cm</p> <p>Description: Please explain what is meant by "Bearing length"? Would tender authority accept armrest width of 48 cm since this is standard in this type of chairs. Width of 90-100 cm way to wide for comfortable of approach to donor arm.</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>Bearing length is total length of the stationary donor chair.</i></p> |
| 42 | <p>3.6 DONOR CHAIR, STATIONARY Specification: All visible metal parts are chromed for easy cleaning and maintenance</p> <p>Description: Would tender authority accept coating of all visible metal parts with different materials like Epoxy resin which is newer technology with same functionality as chrome?</p> | <p><i>Please refer to answer to question no.34.</i></p> |
| 43 | <p>3.6 DONOR CHAIR, STATIONARY Specification: Possibility to install flexible arm holder for the computer with the LCD screen.</p> <p>Description: Would tender authority accept donor chair without this option since in blood donation settings usually LCD screen is wall mounted due to better access of personnel to donor in case or</p> | <p><i>Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by</i></p> |

| No. | Question | Answer |
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| | urgent intervention needed where this bulky holder and LCD screen together would be in a way or efficient and quick intervention. | <i>the Contracting Authority in reply to a question or a request for clarification.</i> |
| 44 | Request for clarification Description: Annex II+III, Item 4.1 WHOLE BLOOD COOLING, TRANSPORT AND STORAGE SYSTEM: The following specification is requested: Maximum time required for cooling of refrigeration elements at +4° C. Please clarify this request. What is the maximum time required for cooling? | <i>Maximum time required for cooling of refrigeration elements at +4° C should be shorter as possible for adequate maintenance of temperature.</i> |
| 45 | Request for clarification Description: Annex II+III, Item 4.2 FREEZER FOR BLOOD PLASMA STORAGE (-40 ° C): Additional Monitor is requested. Please clarify this request. Does it refer to some external data logger or additional temperature sensor? | <i>It is enough for the freezer for blood plasma storage to be equipped with a display without additional monitors.</i> <i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i> |
| 46 | Request for clarification Description: Annex II+III, Item 4.3 Ph METER mV, measuring range: -2.000 – 20.000 is requested. Please confirm that this is a typo error and that the requested range should be: mV, measuring range: -2.000 – 2.000. Electrodes for Ph Meter are optional equipment and their price can be higher than the price of Ph Meter. Please clarify the exact type of measurement or type of electrodes that should be delivered with Ph Meter | <i>Most of the parameters in the measurement are in range of ± 2000 mV.</i> <i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i> |
| 47 | REQUEST FOR CLARIFICATION LOT3-SUPPORT EQUIPMENT FOR TRANSFUSION AND TRANSPLANTATION ESTABLISHMENT Item 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR | <i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i> <i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i> |

| No. | Question | Answer |
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| | <p>Description: 1.) In the tender specification is specified “Internal memory for 2,000 blood component separation processes”. Q: Does the contracting authority allow the offer of a machine with 1000 memory locations for storing separation data, which is also connected to the data collecting software? This software allows you to save an unlimited number of records in the memory of an external computer. At the same time, we would like to point out that assuming that one separation lasts three minutes, we are able to perform a maximum of 480 separation each day, working 24 hours a day. The memory of 1000 separation is therefore sufficient for work and data storage, in case of failure of the connection with the LIS system, for about 3 days. Best regards,</p> | |
| 48 | <p>REQUEST FOR CLARIFICATION LOT3-SUPPORT EQUIPMENT FOR TRANSFUSION AND TRANSPLATATION ESTABLISHMENT Item 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR</p> <p>Description: In the tender specification is specified “The top plate with a sensor for controlling the Leukocyte filter filling and adding the SAG-M solution into a bag with Red Cells”. Q: Will the tender authority accept a machine that do not have a sensor that allows to control the filling of the red blood cell filter, but instead of sensor, controls this process by accurately measuring the weight of the product from the transfer bag, additionally the device checks the weight of the target bag with Leukoreduced Red Blood Cells and automatically mixes SAGM</p> | <p><i>The most important thing is that the system has the ability to control transfer of SAG-M into a bag with Red Cells and the Leukocyte filling which certainly affects the better quality of the process of obtaining blood components.</i></p> <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

| No. | Question | Answer |
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| | solution with Red Blood Cells? Best regards, | |
| 49 | <p>REQUEST FOR CLARIFICATION LOT3-SUPPORT EQUIPMENT FOR TRANSFUSION AND TRANSPLANTATION ESTABLISHMENT Item 3.1 AUTOMATIC BLOOD COMPONENT EXTRACTOR</p> <p>Description: In the tender specification is specified: Weight of equipment: maximum 30 kg Q: Will the tender authority accept a device with a curb weight of 42 kg equipped with automatic break-away cannulas breakers and a side weighing device with a break-away cannulas breaker intended for the Red Blood Cell Concentrate bag? At the same time, we would like to point out that the greater weight of the machine does not have a negative impact on the quality of the end products, but can only improve the stability of the entire system, which may have a positive effect on the separation process. Furthermore, all the new extractors of the last generation with all above mentioned accessories, available on the market, weigh more than 30 kg. Best regards</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |
| 50 | <p>Request for clarification</p> <p>Description: Annex II+III, Item 1.2 MOBILE DIGITAL TCD DEVICE FOR MONITORING AND DETECTION OF EMBOLY: In the requested technical specifications for this item, all hardware and software modules which are available for this type of product are specified. These modules are configured and delivered in accordance with the application of the device. Please</p> | <p><i>All necessary hardware and software modules are precise defined in technical specification and could be delivered.</i></p> |

| No. | Question | Answer |
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| | clarify which hardware and software modules should be delivered and which are optional. Please take in mind that the delivery of all modules can seriously affect the total budget for this item | |
| 51 | <p>REQUEST FOR CLARIFICATION LOT1- SUPPORT EQUIPMENT FOR BLOOD SAFETY AND ORGAN ESTABLISHMENT Item 1.3 AUTOMATIC SYSTEM FOR BLOOD GROUP SEROLOGY TESTING (throughput min. 150 mandatory tests/hour)</p> <p>Description: In the tender is specified the "Irregular antibody screening)". In Serbia we need to detect all clinically significant antibodies (Liss/Coombs / Solidphase method) in donor samples. Will the tender authority accept (Liss/Coombs / Solidphase method)? Please find below further explanations and scientific references:</p> <p>Saline & Enzyme methods do not fulfill this necessity: - Saline method only detects cold antibodies (not clinically significant) - Enzyme methods enhanced detecting some clinical antibodies and at the same time it destroys important antibodies which only can be detected in Liss/Coombs testing. References: - The British guidelines, see attached "UK Final version of 2012 Tx Testing BCSH guidelines", see section 5.2 on page 19. - The German guideline "Richtlinie_Haemotherapie_2017 ...", see page 56, A comment is added showing the English translation and the meaning of detection of irregular antibodies. Best regards,</p> | <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> |

| No. | Question | Answer |
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| 52 | <p>REQUEST FOR CLARIFICATION LOT1- SUPPORT EQUIPMENT FOR BLOOD SAFETY AND ORGAN ESTABLISHMENT Item 1.3 AUTOMATIC SYSTEM FOR BLOOD GROUP SEROLOGY TESTING (throughput min. 150 mandatory tests/hour)</p> <p>Description: 1.)Will the tender authority require the offer for an analyzer who uses a wash step in the irregular antibody screening to reduce interference with icteric, hemolyzed or lipemic samples and to remove fibrin? 2.)To reduce refrigerator storage capacity, will the tender authority require the offer for an analyzer which uses microplates for groups and screening tests that are stored at room temperature? Best regards,</p> | <p><i>This questions don't refer on technical specification.</i></p> |
| 53 | <p>REQUEST FOR CLARIFICATION LOT3-SUPPORT EQUIPMENT FOR TRANSFUSION AND TRANSPLATATION ESTABLISHMENT Item 3.5 RESIDUAL WHITE BLOOD CELL COUNTER IN BLOOD COMPONENTS</p> <p>Description: We would like to point out that in Lot3, item 3.5 you requested product that is produced only by one manufacturer which is blocking all the offers of the distributors which don't have possibility to deliver mentioned product. We truly believe that blocking a tender in this way is not good for the buyer because is limiting amount of offers for rest LOT points. Will the tender authority allow to separate the LOT3, item 3.5 product in a separate LOT, not bundled with other products to ensure that more companies can offer and with this to guaranty the most lowers competitive prices and best quality in the tender? Best regards,</p> | <p><i>Technical Specifications are prepared in accordance with the detailed market analysis that has been previously conducted, therefore Technical Specifications will remain unchanged with regards to this issue.</i></p> |

| No. | Question | Answer |
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| 54 | <p>Questions and clarifications for tender Supply of equipment for relevant institutions within the SoHo System in Serbia, reference: NEAR/BEG/2021/EA-OP/0180</p> <p>Description: Dear Sirs,</p> <p>1. In your tender's specification, the values of tender guarantee have been given: • The original, signed tender guarantee, for: Lot 1: 8700.00 EUR Lot 2: 8360.00 EUR Lot 3: 19,344.00 EUR Lot 5: 10,780.00 EUR We just want to check, if the tender guarantee isn't necessary for Lot 4?</p> <p>2. LOT 4 Whole Blood Cooling, Transport and Storage System (boxes a 6) - CompoCool WB 32 pcs. Question 1 For a tender PUBLICATION REF: NEAR/BEG/2021/EA-OP/0180 Lot 2 : Support Laboratory Equipment for Transfusion and Transplantation Establishment under 4.1. Is stated: Transport trolley for transporting at least 5 cooling boxes We propose to change to: Transport trolley at least 4 cooling boxes The reason: Fresenius KABI is the only producer of these medical device and the newest version of product have capacity of 4 cooling boxes which better prevent accidentally dropping of loaded boxes (with blood bags) and easier handling of operators in the field. However, Fresenius KABI older product version have capacity that you ask (5 cooling boxes) but is started to be phased-out globally</p> | <p><i>1. Please note that in accordance with Section 23 of Instructions to Tenderers, tender guarantee must be provided for Lots 1, 2, 3 and 5. For Lot 4 no tender guarantee is required.</i></p> <p><i>2. In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification. This issue will be remedied by means of Corrigendum no.2 to Tender Dossier.</i></p> <p><i>3. In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification. This issue will be remedied by means of Corrigendum no.2 to Tender Dossier.</i></p> <p><i>4. Technical Specifications are prepared in accordance with the detailed market analysis that has been previously conducted, therefore Technical Specifications will remain unchanged with regards to this issue.</i></p> |

| No. | Question | Answer |
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| | <p>3. For item 4.2: Is it possible to offer freezer with compressor under the chamber, since there ' s no significant technical difference if the compressor is under or above the chamber?</p> <p>4. For item 4.3: The technical specification for this item is totally written according to the manufacturer from Swiss Confederation. Since this country isn't in EU, and the changing specification of the item would be almost total in order to offer some product from EU and appropriate countries, is it acceptable to offer the product which is originally from Swiss Confederation, in order to satisfy the needs of end users?</p> | |
| 55 | <p>Questions and clarifications for tender Supply of equipment for relevant institutions within the SoHo System in Serbia</p> <p>Description: 6. Question For a tender PUBLICATION REF.: NEAR/BEG/2021/EA-OP/0180</p> <p>Lot 2 : Support Laboratory Equipment for Transfusion and Transplantation Establishment under 2.2 Portable rapid hemoglobin screening device for blood donour regarding technical specification stated: "Measurement time: maximum 1 second" "Measurement time: maximum 2 seconds "</p> <p>we propose to change to: " Measurement time: maximum 2 seconds " This change has no impact on device performance and has minimal impact to operator speed and comfort if we take in consideration that whole process of finger disinfection, skin perforation, blood drop sampling and measuring of hemoglobin level on device takes more than 30 seconds</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| | <p>in total. This change will also allow that you are in line with Article 18 of DIRECTIVE 2014/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL issued on 26th February 2014. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1415180510261&uri=CELEX:32014L0024 This Article states: “The design of the procurement shall not be made with the intention of excluding it from the scope of this Directive or of artificially narrowing competition. Competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favouring or disadvantaging certain economic operators.”.</p> | |
| 56 | <p>Questions and clarifications for tender Supply of equipment for relevant institutions within the SoHo System in Serbia - 2</p> <p>Description: LOT 2 Rapid Haemoglobin screening device 15 pcs. 5.</p> <p>Question For a tender PUBLICATION REF: NEAR/BEG/2021/EA-OP/0180 Lot 2 : Support Laboratory Equipment for Transfusion and Transplantation Establishment under 2.2 Portable rapid hemoglobin screening device for blood donor regarding technical specification stated: “Measurement range: 1.0–25.6 g/dL (10–256 g/L, 0.62–15.9 mmol/L)” we propose to change to: “Measurement range: 1.0-25.5 g/dl (10-255g/l, 0,62-15,9mmol/L) or better” This minimal change has no impact on device performance if we take in consideration that normal hemoglobin level range is for Male: 14,0–18,0 g/dL Female: 12,0–16,0 g/dL. This change will also allow being in line with Article 18 of</p> | <p><i>Tenderers should strictly adhere to existing technical specifications.</i></p> |

| No. | Question | Answer |
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| | <p>DIRECTIVE 2014/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL issued on 26th February 2014.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1415180510261&uri=CELEX:32014L0024</p> <p>This Article states: “The design of the procurement shall not be made with the intention of excluding it from the scope of this Directive or of artificially narrowing competition. Competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favoring or disadvantaging certain economic operators.”.</p> | |
| 57 | <p>1. Question For a tender PUBLICATION REF.: NEAR/BEG/2021/EA-OP/0180 Lot 2 : Support Laboratory Equipment for Transfusion and Transplantation Establishment under 2.2 Portable rapid hemoglobin screening device for blood donor regarding technical specification stated: “Storage temperature of microscope and work: 0 – 50°C” Could you please explain or rephrase this question? Is there accidentally put word microscope in it?</p> <p>2. “Determination of hemoglobin by full-blood absorbance method at the isochoric point Hb / HbO2” – would it be acceptable to offer an instrument based on Vanzetti’s azide methemoglobin method, which correlates to the HiCN reference method?</p> <p>3. Would you consider an instrument with measurement time of 25-60 seconds, since this time does not significantly change the time of donor examination?</p> | <p><i>1. The word microscope is a spelling mistake.</i></p> <p><i>2. Tenderers should strictly adhere to existing technical specifications.</i></p> <p><i>3. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>4. Technical Specifications will remain unchanged with regards to this issue.</i></p> |

| No. | Question | Answer |
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| | <p>4. Is it acceptable to offer the instrument slightly different in operating and storage temperature requirements NE: 15 – 40°C, since it does not significantly change the donor examination conditions?</p> | |
| 58 | <p>1. Would you consider an instrument that weights 700 g, since it is not significantly heavier than requested 600 g?</p> <p>2. For item 2.3. Platelet incubator with incubator: The technical specification for this item is totally written according to the manufacturer from USA, Helmer. Since this country isn't in EU, and the changing specification of the item would be almost total in order to offer some product from EU and appropriate countries, is it acceptable to offer the product which is originally from USA, in order to satisfy the needs of end users?</p> | <p><i>1. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>2. Technical Specifications are prepared in accordance with the detailed market analysis that has been previously conducted, therefore Technical Specifications will remain unchanged with regards to this issue.</i></p> |
| 59 | <p>For item 2.3. Platelet incubator with agitator (with EU origin):</p> <p>a) Is floor model acceptable?</p> <p>b) Is fixed temperature 22 °C acceptable?</p> <p>c) Are doors with magnetic seal acceptable?</p> <p>d) Are stainless steel interior, exterior and door handles acceptable?</p> <p>e) Are four-pane tempered glass doors acceptable (two doors for each incubator)?</p> <p>f) Is LCD display with LED indicators acceptable?</p> | <p><i>a) In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification. This issue will be remedied by means of Corrigendum no.2 to the Tender Dossier.</i></p> <p><i>b) In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>c) Please refer to the answer provided under bullet point b).</i></p> <p><i>d) Please refer to the answer provided under bullet point a).</i></p> <p><i>e) Please refer to the answer provided under bullet point a).</i></p> |

| No. | Question | Answer |
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| | <p>g) Is alarm test by manually choosing alarm triggering settings acceptable?</p> <p>h) Is start-up function with alarms off after initial incubator start until temperature reaches 22°C acceptable?</p> <p>i) Is connection for external alarm monitoring acceptable?</p> <p>j) Is power failure alarm on external uninterrupted power supply (included) acceptable?</p> <p>k) Is battery backup as external uninterrupted power supply with battery acceptable?</p> <p>l) Is data recorder with LCD screen for 3 days and reading of additional data on PC acceptable (necessary software and USB memory stick included)?</p> <p>m) Is stainless steel interior acceptable?</p> <p>n) Is stainless steel front surface on drawers for self-adhesive labels acceptable?</p> | <p><i>f) Please refer to the answer provided under bullet point a).</i></p> <p><i>g) Manual alarm test include alarm test by manually choosing alarm triggering settings.</i></p> <p><i>h) and i) These two question not refer on required specification.</i></p> <p><i>j) Power failure alarm include external uninterrupted power supply.</i></p> <p><i>k) Please refer to the answer provided under bullet point j).</i></p> <p><i>l) Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> <p><i>m) Please refer to the answer provided under bullet point a).</i></p> <p><i>n) Please refer to the answer provided under bullet point a).</i></p> |
| 60 | <p>1. Should the instrument have “ blood bank mode option”, which allows analyzing blood products?</p> <p>2. For item 1.3 Automated blood grouping system for serology testing:</p> <p>a) Regarding the request for the irregular antibody screening method to be saline and enzyme method, would you accept an instrument using indirect antiglobuline test, considering that the enzyme method has proved to detect cold antibodies and benign autoantibodies, which makes it less than ideal method for irregular antibodies screening?</p> | <p><i>1. The question do not refer on required specification.</i></p> <p><i>2.</i></p> <p><i>a) In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>b) Crossmatch testing do not refer on required specification.</i></p> <p><i>c) We consider that availability for working with user-defined reagents</i></p> |

| No. | Question | Answer |
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| | <p>b) Should the instrument offer the possibility of crossmatch testing?</p> <p>c) "Availability for working with user-defined reagents" – to our knowledge no instruments registered in Serbian Agency for drugs and medical devices, that is suitable to the rest of the technical specification, can accommodate this request – would you consider an instrument that uses microplates with pre-dispensed antibodies?</p> <p>d) Would you consider an instrument without pipetting and dispensing liquid system pressure sensors, as there are machines that have different system of liquid handling that doesn't require the sensors?</p> <p>e) Throughput: is it acceptable to offer an instrument capable of performing 110 blood groupings per hour and 240 Ab screenings per hour?</p> | <p><i>include all commercial reagents (like microplates with pre-dispensed antibodies) according to manufacture recommendation.</i></p> <p><i>d) In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>e) Throughput defined minimum 150 mandatory test per hours include instruments capable performing 240 Ab screenings per hour.</i></p> |
| 61 | <p>Questions and clarifications for tender Supply of equipment for relevant institutions within the SoHo System in Serbia</p> <p>Description: 14. For item 2.4 Blood cell counter:</p> <p>a) Is it acceptable to offer the instrument with speed 100 tests/h instead of 120/h since this difference in speed won't have significant impact on obzirom da ova razlika u brzini nece znacajno uticati na vreme do izdavanja rezultata?</p> <p>b) Is it acceptable to offer the instrument without CHCM I HDW parameters, since the instrument which we want to offer (specifications below) has different parameters for estimation of</p> | <p><i>a) Technical Specifications will remain unchanged.</i></p> <p><i>b) This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

| No. | Question | Answer |
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| | <p>cells in erythropoiesis, which have higher diagnostic significance than requested parameters ?</p> <ul style="list-style-type: none"> Automated hematology analyzer Flow/fluorescent cytometry technology Leukocyte differential count, reticulocyte count and body fluids analysis for IVD use in clinical laboratories Sample volume in manual mode: $\leq 120\mu\text{L}$ Body Fluid results: WBC-BF, RBC-BF, MN#/%, PMN #/% <p>Results: WBC, RBC, HGB, HCT, MCV, MCHC, RDW, PLT</p> <p>Differential results (No and %): NEUT, LYMPH, MONO, EOS, BASO</p> <p>Platelet results: PLT, MPV, PDW, PCT</p> <p>Reticulocyte results: 4 parameters, morphology differentiation of NRBC within RBC population</p> <p>Throughput: CBC/DIFF 100 samples/hour</p> <p>PC: Ethernet connection</p> <p>Software: MS Windows or equivalent compatible operational system</p> <p>LCD display, screen 19"</p> <p>Data management capacity for archiving 10 000 samples (including scatter gram and histogram)</p> <p>Printer: ink jet color printer with networking option</p> <p>Bar code reader option, equipped with compatible software</p> | |
| 62 | <p>17. For a tender PUBLICATION REF.: NEAR/BEG/2021/EA-OP/0180 LOT 3 - Support Equipment for Transfusion and Transplantation Establishment under 3.1 Automatic Blood Component Extractor regarding technical specification stated: "Weight of equipment: maximum 30 kg" We propose to change to: "Weight of equipment: maximum 50 kg" This change has no impact on device performance or to operator speed and comfort. Please take in consideration that Automatic component extractors are not portable but benchtop devices. This</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| | change will allow more bidders to apply. | |
| 63 | <p>19. For item 3.2: Blood centrifuge with computer data system</p> <p>a) You asked for centrifuge with windshield rotor. Is it acceptable to offer the centrifuge without windshield rotor, since it has advantages: One advantage of the windshield-less rotor system is that all parts of the centrifuge chamber can be easily viewed and accessed without removing the entire rotor assembly. Should liquid or frost build up, the centrifuge chamber can be wiped with paper towel to absorb the excess liquid. If there is excessive liquid or frost formed in the chamber, please check to ensure that the motor cover seal (at the bottom of the chamber) as well as the standard lid seal are properly fitted and showing no damage. Some other brands of floor standing blood centrifuges have drain ports and hoses for drain water from the chamber. Hettich has not used this design feature as we feel it is not hygienic. The drain port and output hose can become clogged and it is very difficult to properly clean and disinfect. Therefore, we recommend at the end of the day/period of use that the excess liquid be wiped clean and lid be left open to allow any extra moisture to evaporate naturally. If large deposits of frost are forming on the sides of the chamber (where the cooling coils are located) this is not an interference to the normal function of the machine. Should the end user wish to 'melt' this frost, they can simply run the machine</p> | <p><i>a) In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>b) This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>c) Defined range from 300-900mL include 750mL.</i></p> |

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| | <p>without cooling (temperature set to 30°C or so.) The normal heat generated from the centrifuge without the cooling system running will increase the temperature enough to melt any frost and the liquid can be removed as described above.</p> <p>b) You asked for PC with Windows XP. How it is possible, since Windows XP isn't operational for several years?</p> <p>c) You asked for double buckets 300-900ml. Is it acceptable to offer buckets up to 750ml, since most of the blood bags have the volume up to 750 ml?</p> | |
| 64 | <p>1. Is it necessary to have Manual lateral connection of the sealer for bloodlines ?</p> <p>2. For a tender PUBLICATION REF.: NEAR/BEG/2021/EA-OP/0180 LOT 3 - Support Equipment for Transfusion and Transplantation Establishment under 3.4 Hand tube sealer regarding technical specification stated: "Battery and charger: Lithium Polymer Battery 12 V DC, rechargeable and compatible charger" We propose to change to: "Battery and charger: Lithium Polymer Battery, rechargeable and compatible charger" Limiting Lithium Polymer Battery to 12V DC is unnecessary restriction and has no any impact on device properties. If you are setting this limit in concern of operator safety then we propose that you at least take in consideration setting up Lithium Polymer Battery range of 12V DC to 24V DC.</p> <p>3. For a tender PUBLICATION REF.: NEAR/BEG/2021/EA-OP/0180 LOT 3 - Support Equipment for Transfusion and Transplantation Establishment under 3.4 Hand tube sealer regarding technical specification stated: "PVC carrying case for</p> | <p>1. Manual lateral connection of the sealer for bloodlines is not necessary for handheld tube sealer.</p> <p>2. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</p> <p>3. This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</p> |

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| | <p>complete sealer (head, battery and charger) with connection for charging the battery without taking it out of the carrying case” We propose to change to: “Carrying case for complete sealer (head, battery and charger) with connection for charging the battery without taking it out of the carrying case” Limiting carrying case only to PVC material we consider as unnecessary restriction. This change has no impact on device performance or to operator speed and comfort.</p> | |
| 65 | <p>23. For item 3.4: HANDHELD TUBE SEALER Quantity: 31 COMPOSEAL Indicated Composeal Mobiliea II Specification Possible questions in order to adopt specification • Mobile sealer for blood line on blood bags • Power supply: 220 V / 50 Hz • Material of exterior: metal housing with rubber edges as a protection against falling Designed for portable use: Low weight power pack of just 760g, robust metal housing, rubber pads for shock absorption • Battery and charger: Lithium Polymer Battery 12 V DC, rechargeable and compatible charger We have Li-ion, 29.6V Please accept new generation of battery and voltage standards • Number of welding's with full battery 1.000 sealing Modern Lithium Polymer battery provides a capacity of up to 1000 seals per full charge on standard blood bag tubes • Weight: Maximum 2,5 kg (handle and battery) CompoSeal Mobilea II set 1) 395 mm x 106 mm x 295 mm, 2364 g • Ergonomically designed welding handle for holding in hand • Cord length up to 150cm CompoSeal Mobilea II handsealer cable 1,470 mm x 5 mm x 5 mm 3) • The sealing</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| | <p>process indicator on the battery and on the sealing head We have only on sealing head Please accept indicator on sealing head only since this is what operator sees in reality • Automatically adjust the sealing time depending on the thickness of the bloodline Automatic adjustment of sealing time depending on tube thickness</p> <ul style="list-style-type: none"> • Possibility of sealing when the patient is attached to the bloodline (without danger to the patient) Approved for bedside sealing while donor is connected • The sealing head is detachable from the welding handle for easier maintenance | |
| 66 | <p>24. For item 3.5: This item could be offered only by one bidder only. We are kindly asking you to put this item into separate lot , in order to provide competition. This change will also allow being in line with Article 18 of DIRECTIVE 2014/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL issued on 26th February 2014.</p> <p>https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1415180510261&uri=CELEX:32014L0024</p> <p>This Article states: “The design of the procurement shall not be made with the intention of excluding it from the scope of this Directive or of artificially narrowing competition. Competition shall be considered to be artificially narrowed where the design of the procurement is made with the intention of unduly favoring or disadvantaging certain economic operators.”.</p> | <p><i>Technical Specifications are prepared in accordance with the detailed market analysis that has been previously conducted, therefore Technical Specifications will remain unchanged with regards to this issue.</i></p> |

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| 67 | <p>For item 4.3:</p> <p>1. Do you need only pH meters?</p> <p>2. If you need electrodes, which kind do you need-pH, ORP or some ion selective? In which medium will you measure pH?</p> <p>3. Which buffers do you need? (2,4,7 ili 9?)</p> <p>4. On which locations would pH meters be delivered</p> | <p><i>Please note that unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.</i></p> <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> |
| 68 | <p>18. Regarding item 3.1 Automatic blood component extractor: AUTOMATIC BLOOD COMPONENT EXTRACTOR Quantity: 12 COMPOMAT G5 (OLD version, Launched 2007, have to be checked additionally) Lockout specification Possible question in order to adopt specification</p> <ul style="list-style-type: none"> Automatic blood component separation Parallel separation of Red Cells, Plasma and Platelets Shortened separation time by simultaneous processing of program steps No device on market can do parallel separation of all components, way of blood component production, platelet production is always part of second centrifugation; therefore, second expression. Plasma and RBC production is done in first separation. Please remove this request. Buffy Coat pooling program The time of separation of blood components below 2 minutes <p>Advantages of wide bore tubing Average separation time with Top and Bottom system typically 2 min Please clarify for which procedure this timing is valid for. For Top&Bottom or Top&Top. Also speed can be adjusted on device according to customer request (variable speed extraction). Time of separation is proportional with product quality (less time, lower quality product). Please</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>Automatic blood component extractors have numerous high sensitivity optical sensors, and one of them is on Propulsion headboard. The function of propulsion headboard with embedded sensors refers to the main press with optical sensors that pushes the bag. The quality of automatic blood components extractors differs in the numbers of optical sensors that exist for different processes of production of blood components. (more sensors-better quality of extractors). It is not entirely clear why this sensor is particularly distinguished from the others, but is certainly affects the better quality of the process of obtaining blood components and can be part of technical specification.</i></p> |

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| | <p>either allow variable speed defined by user or remove this request. • Motor drive 220 V / 50 Hz, electric • Propulsion headboard with embedded optical sensor Please explain • Front full-blood pressure plate with front-mounted weighing pan and optical sensor, and automatic opening system for 'brake way' cannulas • The top plate with a sensor for controlling the Leukocyte filter filling and adding the SAG-M solution into a bag with Red Cells Sensor controlled priming of in-line filters for optimal standardization The re-designed top press primes the in-line filter fully automatic and sensor controlled. What does here mention sensor controls? Does it control if tube is placed correctly or something else? Amount of SAG-M added to Red Cells bag is controlled by scale.</p> | |
| 69 | <p>18. Regarding item 3.1 Automatic blood component extractor • Red Cells scale with automatic calibration • Plasma scale calibration: automatic • Plasma bag air removal system and integrated lines welding heads at completion of blood air removal • Three integrated systems for the automatic opening of the "brake way" cannulas (for full blood on the front panel, on the Red Cell extraction line to the Red Cell bag and on the top plate for adding the SAG-M solution) Please add specification "automatic opening of "brake way" cannulas must be suitable/universal for most blood bags configurations on market" • Magnetic Holder for Red Cells Leukocyte filter • Colour LCD screen 10 Pantalla a color Please accept also newer generations of screens like TFT touch</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> |

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| | <p>screen • Internal memory for 2,000 blood component separation processes Internal back-up storage of 1.000-2.000 preparation data Internal storage of the last 1.000 process data sets (???) • Network interface: LAN and/or WLAN interface • Bar Code Reader • Weight of equipment: maximum 30 kg Weight 30kg Weight 30 kg (device), 2.8 kg (PL Unit), 1.4 kg (RCC unit) Device equipped with all above mentioned requirement have more weight that 30 kg. Please change specification to “Weight of equipment: maximum 55 kg</p> | |
| 70 | <p>20. For item 3.3: BLOOD COLLECTION SCALE/MIXER Quantity: 37 Fresenius Compoguard – Launched 2002 • Possible question in order to adopt specification • A scale for controlling blood collection by blood donors • • Power supply: 220 V / 50 Hz • • Backup power supply: ability to work on an integrated rechargeable battery, with a minimum of 70 donations with full battery capacity • • Flow switch integrated into the blood scale/mixer body • • Automatic switch off: Automatically interrupt blood flow when reaching the set amount • • Audio-visual alarm (indicator): • • - upon completion of the collection of the donor blood, • • - upon too long donation time and • • - in case of device failure •</p> | <p><i>Technical Specifications will remain unchanged with regards to this issue.</i></p> |
| 71 | <p>20. For item 3.3: • In case of insufficient rapid flow so that the user adjusts the speed of the flow There is no possibility to adjust speed of flow on device. Device can alert (and stop in case of high flow) in case of too low or too high flow. • LCD display with blood weight, donation time and blood flow, date, time and battery status Please accept also</p> | <p><i>This issue will be remedied by means of corrigendum no.2 to Tender Dossier.</i></p> <p><i>In line with Section 4.3.4 of the PRAG, please note that no prior opinion on the assessment of the tender can be given by the Contracting Authority in reply to a question or a request for clarification.</i></p> <p><i>With regards to memory bags, please note</i></p> |

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| | <p>newer generations of screens like TFT touch screen • Weight calibration: possibility to tare empty memory bags Please define “memory bags”. Did you mean to tare the memory of previous used bags weight? • Blood mixer/agitator • • Blood bag holder large enough for a system with a built-in leukocyte filter • • Position of control panel and visual alarm: upward control panel with holder for "Bar Code Reader" and visual alarm at the top of the control panel • Data transfer: USB data-transferring slot for data transfer to computer with USB portable memory • Data input and data display: possibility to enter the data of the donor in blood scale/mixer internal memory via a computer and displaying on the LCD screen of the blood scale/mixer Please accept also newer generations of screens like TFT touch screen • Connectivity: ability to connect to any standard Blood Bank Program and LAN and/or W-LAN communication with the computer • Transport case for transportation and as a blood scale/mixer shelf • Manual lateral connection of the sealer for bloodlines • Weight of appliance up to 4 kg (with battery) Please allow weight of appliance up to 4,5 kg (with battery)</p> | <p><i>that it means to tare the memory of previous used empty bags weight.</i></p> |