Procurement of equipment for General Hospital in Loznica
NO. IOP/61-2021/UHI

Clarification No. 7
Issued on 04th of November 2022

Question 1:

- **In technical specification for LOT 10 - Sterilization, Item 20 – Steam sterilizer (autoclave), ID 20.15** it says "Outer dimensions: 470 x 400x 630 cm ± 5%""

  As this is small, tabletop autoclave, with capacity of 18 l, the dimensions should probably be in mm, not in cm.

  Please, confirm if this ID should be: ""Outer dimensions: 470 x 400x 630 mm ± 5%""

Answer: ID 20.15. will be change and read as: Outer dimensions: 470 x 400x 630 mm ± 5%

Question 2:

- **For Lot 3 – Anesthesia and ICU, Item 1 – Anesthesia machine with patient monitor, line 1.57**, "Volume of breathing system in mechanical ventilation not bigger than 3L, including CO2 canister":

  Requested volume of 3L limits competition and eliminates leading anaesthesia machine manufacturer. Does purchaser agree to change request to: "Volume of breathing system in mechanical ventilation not bigger than 3,1L, including CO2 canister".

Answer: ID 1.57. It is acceptable to offer: Volume of breathing system in mechanical ventilation not bigger than 3,1L, including CO2 canister.

- **For Lot 3 – Anesthesia and ICU, Item 6 – Intensive Care monitoring**, line 6.9, "Thermal recorder that can be connected to any of the monitors":

  Please confirm that purchaser requires the bidder to provide: "Total of one thermal recorder that can be connected to any of the monitors"?

Answer: ID 6.9. will be change and read as: One thermal recorder in total that can be connected to any of the monitors.

Question 3:

- **For Lot 7 – Mobile diagnostics equipment, Item 9 – Channel ECG, line 9.1,** "It must be a 6 channel device and have the ability to record all the ECG's 12 leads. It must provide

different print types for the 12 leads and furthermore it must have the ability to record the leads rhythm":

If the device is recording all 12 ECG leads, difference in channel numbers between 3 and 6 is negligible from clinical perspective. It also limits the competition by eliminating leading ECG manufacturer. Does purchaser agree to change request to:

"It must be a 3 channel device and have the ability to record all the ECG's 12 leads. It must provide different print types for the 12 leads and furthermore it must have the ability to record the leads rhythm"

Answer: ID 9.1. It is acceptable to offer: It must be a min. 3 channel device and have the ability to record all the ECG's 12 leads. It must provide different print types for the 12 leads and furthermore it must have the ability to record the leads rhythm.

- **For Lot 7 - Mobile diagnostics equipment, Item 9 - Channel ECG, line 9.2,** "It must provide at least a 6 inches monitor of simultaneously representation of the whole leads. It must have an alphanumeric full keybord, waterproof to insert the patients details and more data in the fascia of the device":

  Requested monitor of 6 inches and full keyboard is from a practical side unnecessary large, takes more space and increases size and weight of the device.

  Does purchaser agree to change request to:

  "It must provide at least a 4 inches monitor of simultaneously representation of the whole leads. It must have tactile membrane keyboard, waterproof to insert the patients details and more data in the fascia of the device"

Answer: ID 9.2. It is acceptable to offer: It must provide at least a 4 inches monitor of simultaneously representation of the whole leads. It must have keyboard, waterproof to insert the patients details and more data in the fascia of the device.

- **For Lot 7 - Mobile diagnostics equipment, Item 9 - Channel ECG, line 9.7**, "It must have a frequency range from 0.05 to 150 Hz. It must provide at least 3 print speeds of 5, 25, and 50mm/sec. It must also have minimum 4 sensitivity scales of 5, 10, 20, 40 mm/mV":

  Requested sensitivity of 40mm/mV is high in value and has limited clinical use in lower channel ECG. It also limits the competition by eliminating leading ECG manufacturer.

  Does purchaser agree to change request to:

  "It must have a frequency range from 0.05 to 150 Hz. It must provide at least 3 print speeds of 5, 25, and 50mm/sec. It must also have minimum 3 sensitivity scales of 5, 10, 20 mm/mV"

Answer: ID 9.7. It is acceptable to offer: It must have a frequency range from 0.05 to 150 Hz. It must provide at least 3 print speeds of 5, 25, and 50mm/sec. It must also have minimum 3 sensitivity scales of 5, 10, 20 mm/mV.

- For Lot 7 - Mobile diagnostics equipment, Item 9 - Channel ECG, line 9.8, "It must have a digital print recorder in thermosensitive paper of 140X110mm size in roll shape or package":

  For a lower channel ECG, large thermosensitive paper is unnecessary, takes more space and increases size and weight of the device.

  Does purchaser agree to change request to:

  "It must have a digital print recorder in thermosensitive paper of 80mm size in roll shape or package"

Answer: ID 9.8. It is acceptable to offer: It must have a digital print recorder in thermosensitive paper of at least 80mm size in roll shape or package.

- For Lot 7 - Mobile diagnostics equipment, Item 9 - Channel ECG, line 9.9, "It must have automatic and manual facility. The transition from the one function to another happens with one click of the mouse. It must be given in the basic composition the ability of continuous monitoring and the printing of reports in case of arrhythmia":

  Request for one click of the mouse is presumably a technical error as ECG devices have no peripherals. Also, solution to perform continuous monitoring of ECG via the continuous manual printing is acceptable.

  Does purchaser agree to change request to:

  "It must have automatic and manual facility. The transition from the one function to another happens with one click of a button. It must perform continuous monitoring of ECG via the continuous manual printing in case of arrhythmia"

Answer: ID 9.9. It It is acceptable to offer: It must have automatic and manual facility. The transition from the one function to another happens with one click of a button. It must perform continuous monitoring of ECG via the continuous manual printing in case of arrhythmia.

- For Lot 7 - Mobile diagnostics equipment, Item 9 - Channel ECG, line 9.10, "ECG must have a USB port or RS232 port and also an PDF Format Output Option. It must be given as a choice. Moreover it must be able to be connected in a net in the hospital and it must also be given the prospective of being upgraded to WIFI. It must be given as a choice.":

  As there is request for USB or RS232 and also PDF output, request for network limits the competition by eliminating leading ECG manufacturer.

Does purchaser agree to change request to:

"ECG must have a USB port or RS232 port and also an PDF Format Output Option."

Answer: ID 9.10. It is acceptable to offer: ECG must have a USB port or RS232 port and also an PDF Format Output Option.

Question 4:

For Lot 7 - Mobile diagnostics equipment, Item 9 - Channel ECG, line 9.11, "Connection with outer laser print for 12 lead printing in paper of A4 size. It must be given as a choice.":

Does purchaser accept the solution export to PDF and printing of the report and change a request to:

"Export to PDF and printing of the report in an external laser printer."

Answer: ID 9.11. It is acceptable to offer: Export to PDF and printing of the report in an external laser printer.

- For Lot 7 – Mobile Diagnostic equipment, Item 9 - Channel ECG, line 9.16, "It must be constructed with the EU safety standards (class CF according to the guidance IEC 60601-2-25:2011) and have a CE mark qualification.":

  IEC 60601-2-25:2011 is an outdated standard. CE mark qualification is requested in procurement documents, (e) Certifications, standards and licences, thru ALIMS or CE certificate.

  Does purchaser agree to change request to:

  "It must be constructed with the EU safety standards (class CF according to the guidance IEC 60601-2-25)"

Answer: ID 9.16. will be change and read as: It must be constructed with the EU safety standards (class CF according to the guidance IEC 60601-2-25).

- For Lot 7 – Mobile Diagnostic equipment, Item 9 - Channel ECG, line 9.17, "It must be constructed with the EU safety standards (class CF according to the guidance IEC 60601-2-25:2011) and have a CE mark qualification.":

  Please remove this line as this is an exact copy of line 9.16

Answer: Request will be removed.

For Lot 7 – Mobile Diagnostic equipment, Item 10 – 12 Channel ECG Analyses programm with measurement, interpretation and rolling stand, line 10.1, "Appropriate for hospital use to

newborns, infants and kids. It must provide the "CE" mark and comply with the international safety standards, in particular by the EN 60601-1-25:2015 for ECG.":

EN 60601-1-25:2015 standard does not exist, purchaser is presumably referring to standard IEC 60601-2-25 for ECG. CE mark qualification is requested in procurement documents, (e) Certifications, standards and licences, thru ALIMS or CE certificate.

Does purchaser agree to change request to:

Appropriate for hospital use to newborns, infants and kids. It must comply with the international safety standards, in particular by the EN 60601-2-25: for ECG."

Answer: ID 10.1. will be change and read as: Appropriate for hospital use to newborns, infants and kids. It must comply with the international safety standards, in particular by the EN 60601-2-25: for ECG.

Public Procurement Committee