



MINISTRY OF HEALTH
PROJECTS MANAGEMENT UNIT

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Our ref.no: **11922**/24.02.2017

To: All prospective bidders that received the Bidding Documents

Ref: Health Sector Reform - Improving Health System Quality and Efficiency Project - Loan No. 8362-RO. Procurement of equipment for emergency room - ICB No. G/C1/1.2

Dear Mrs. /Mr.

Please find attached the following documents:

1. Addendum no. 3 to the Bidding Documents for Procurement of equipment for emergency room – ICB No. G/C1/1.2, consisting of 7 pages that include the amended clause/technical specifications as a result of the responses given to the requests for clarifications received and other changes;
2. The responses to the clarification requests related to the provisions of the bidding documents – Clarification no. 2 (4 pages).
3. Section IV Bidding forms and Section VII Schedule of Requirements in editable version.
4. Section VI of the Bidding Documents, Schedule of requirements – Technical Specifications, scanned copy and editable pdf. format, including the revised Technical Specification in accordance with the provisions of Addendum no. 3 to the Bidding Documents and the answers to the clarification requests (31 pages).

All changes related to the technical specifications that are subject of Addendum no. 2 are highlighted in green and the ones that are subject of Addendum no. 3 are highlighted in yellow.

Due to the size, all the documents mentioned above will be sent only by e-mail to the address provided by your company.

Please confirm the receipt of the documents above and that you will take into account the clarifications no. 2 and the provisions of Addendum no. 3 to the Bidding Documents in preparing your bid.

Considering the provisions of addendum no. 3 and the clarifications no. 2, we are kindly inform you that the deadline for bids submission will be **March 6th, 2017, 12:00 hour's local time**. Other requests for clarification will not be taken into consideration.

Yours sincerely,

Ministry of Health – Project Management Unit
Mircea-Sorin Zaharcu, PMU Interim Director



ROMANIA

Ministry of Health – Project Management Unit

Health Sector Reform - Improving Health System Quality and Efficiency Project (HSRIHSQEP) -
IBRD Loan No. 8362-RO

ADDENDUM NO. 3 TO THE BIDDING DOCUMENTS FOR PROCUREMENT OF EQUIPMENT
FOR EMERGENCY ROOM - ICB NO. G/C1/1.2

Under this addendum it is agreed that the provisions of the Bidding Documents shall be amended as follows:

Article 1:

Technical specification for Lot II - Item II.1- ECG.

Shall read: “Display min 7”, Touchscreen or Physical alphanumeric keyboard for entering patient data”

Instead of: “Display min 10”, Touchscreen or Physical alphanumeric keyboard for entering patient data”

Article 2:

Technical specification for Lot I - Item I.3 Standard radiotransparent examination/transfer hydraulic trolley for bariatric patient

Shall read: “Height maximum position at least 85 cm (not includes the mattress height)”

Instead of: “Height maximum position at least 90 cm (not includes the mattress height)”

Article 3:

Technical specification for Lot II - Item II.1- ECG.

Shall read: “Graphic display with high definition. The required minimum resolution starting with 800 x 480 pixels for LCD or the minimum resolution starting with 640 x 480 pixels for TFT”

Instead of: “Graphic display with high definition. The required minimum resolution is 800 x 480 pixels”

Article 4:

Technical specification for Lot II - Item II.1- ECG.

Shall read: “Recording speeds: minim 25 mm/sec”

Instead of: “Recording speeds: minim 25/50 mm/sec”

Article 5:

Technical specification for Lot II - Item II.1- ECG.

Shall read: “Common Mode rejection: min 99 dB or according with ANSI/AAMI EC 11”

Instead of: “Common Mode rejection: min 100 dB or according with ANSI/AAMI EC 11”

Article 6:

Technical specification for Lot II - Item II.1- ECG.

Shall read: “Low weight, device including incl. battery: max 10 kg (excluding transport trolley). If the weight is above 6 kg the cart / trolley with the ECG will have the centre of gravity at a maximum height of 1 meter above the ground level”

Instead of: “Low weight, device including incl. battery: max. 6 kg (excluding transport trolley)”

Article 7:

Technical specification for Lot II - Item II.1- ECG – “Maximum time constant 5 s.” will be deleted.

Article 8:

Lot II - Item II.1 ECG: The quantity will be increased from 150 pcs. to 235 pcs. The additional quantity (85 pcs.) will be delivered and installed in the Intensive Care Units from 63 hospitals from all over Romania. The list of final destinations will be provided at the contract signing stage.

Article 9:

Lot III - Item III.1 Defibrillator with monitor: The quantity will be increased from 105 pcs. to 275 pcs. The additional quantity (170 pcs.) will be delivered and installed in the Intensive Care Units from 63 hospitals from all over Romania. The list of final destinations will be provided at the contract signing stage.



Article 10:

Section II. Bid data sheet (BDS) – A. General - ITB 1.1

Shall read:

“The name of the ICB is: **Procurement of equipment for emergency room.**

The identification number of the ICB is: **G/C1/1.2**

The number and identification of lots (contracts) comprising this ICB is:

LOT I: Intrahospital transportation equipment

- I.1. Resuscitation, intensive care, transfer radiotransparent trolley
- I.2. Standard radiotransparent examination/transfer hydraulic trolley
- I.3. Standard radiotransparent examination/transfer hydraulic trolley for bariatric patient
- I.4. Trolley for instruments and drugs
- I.5. Patient wheel chairs for inhospital transport

LOT II: ECG equipment

- II.1. ECG

LOT III: Defibrillation equipment

- III.1 Defibrillator with monitor

LOT IV: Immobilization equipment

- IV.1. Scoop stretcher
- IV.2. Vacuum mattress
- IV.3. Vacuum splints set
- IV.4. Cervical collars set
- IV.5. Pelvic belt set
- IV.6. Traction splint
- IV.7. Backboard with head restraint and belts
- IV.8. Transfer device (roll) for bariatric patient
- IV.9. Transfer mattress for bariatric patient

LOT V: Ventilation and spirometry equipment

- V.1. Neo-nate portable ventilator
- V.2. Nebulizer
- V.3. Spirometry measurement device

LOT VI: Neonatology and patient heating device equipment

- VI.1. Incubator for neo-nate transport
- VI.2. Warm air heating blanket system for adult / paediatric

LOT VII: Video laryngoscope devices

- VII.1. Video laryngoscope

LOT VIII: Bronchoscope devices

- VIII.1. Bronchoscope for foreign body extraction in pediatric cases (rigide)

LOT IX: Resuscitation and airway management equipment

- IX.1. Resuscitators set
- IX.2. Laryngoscope with blades set

LOT X: Portable suction devices

- X.1. Portable suction device

LOT XI: Volumetric perfusion devices

- XI.1. Volumetric perfusion devices (Infusion Pump Syringe)

LOT XII: Fast perfusion transfusion devices

- XII.1. Fast perfusion transfusion device

Bidders are invited to bid for all or any of the lots.

Evaluation will be done on a lot-by-lot basis. Incomplete lots will be rejected.”

Instead of:

“The name of the ICB is: **Procurement of equipment for emergency room.**

The identification number of the ICB is: **G/C1/1.2**

The number and identification of lots (contracts) comprising this ICB is:

LOT I: Intrahospital transportation equipment

- I.1. Resuscitation, intensive care, transfer radiotransparent trolley
- I.2. Standard radiotransparent examination/transfer hydraulic trolley
- I.3. Standard radiotransparent examination/transfer hydraulic trolley for bariatric patient
- I.4. Trolley for instruments and drugs



I.5. Patient wheel chairs for in-hospital transport

LOT II: ECG equipment

II.1. ECG

LOT III: Defibrillation equipment

III.1. Defibrillator with monitor

LOT IV: Immobilization equipment

IV.1. Scoop stretcher

IV.2. Vacuum mattress

IV.3. Vacuum splints set

IV.4. Cervical collars set

IV.5. Pelvic belt set

IV.6. Traction splint

IV.7. Backboard with head restraint and belts

IV.8. Transfer device (roll) for bariatric patient

IV.9. Transfer mattress for bariatric patient

LOT V: Ventilation and spirometry equipment

V.1. Neo-nate portable ventilator

V.2. Nebulizer

V.3. Spirometry measurement device

LOT VI: Neonatology and patient heating device equipment

VI.1. Incubator for neo-nate transport

VI.2. Warm air heating blanket system for adult / paediatric

LOT VII: Video laryngoscope devices

VII.1. Video laryngoscope

LOT VIII: Bronchoscope devices

VIII.1. Bronchoscope for foreign body extraction in pediatric cases (rigide)

LOT IX: Resuscitation and airway management equipment

IX.1. Resuscitators set

IX.2. Laryngoscope with blades set

IX.3. Portable suction device

LOT X: Volumetric perfusion devices

X.1. Volumetric perfusion devices (Infusion Pump Syringe)

LOT XI: Fast perfusion transfusion devices

XI.1. Fast perfusion transfusion device

Bidders are invited to bid for all or any of the lots.

Evaluation will be done on a lot-by-lot basis. Incomplete lots will be rejected."

Article 11:

Section II. Bid data sheet (BDS) – A. General - ITB 19.1

Shall read:

"A Bid-Securing Declaration is not accepted

A Bid Security is required.

Bid shall include a Bid Security (issued by bank) in the form of a Bank Guarantee using the form included in Section IV Bidding Forms.

The amount and currency of the Bid Security for each lot shall be:

- **EUR 29,500** (twenty-nine thousand and five hundred Euros) *or* **RON 135,000** (one hundred thirty-five thousand RON) for **Lot no. I**
- **EUR 9,500** (nine thousand and five hundred Euros) *or* **RON 44,000** (forty-four thousand RON) for **Lot no. II**
- **EUR 34,000** (thirty-four thousand Euros) *or* **RON 160,000** (one hundred and sixty thousand RON) for **Lot no. III**
- **EUR 3,900** (three thousand and nine hundred Euros) *or* **RON 18,000.00** (eighteen thousand RON) for **Lot no. IV**
- **EUR 8,300** (eight thousand and three hundred Euros) *or* **RON 38,000** (thirty-eight thousand RON) for **Lot no. V**
- **EUR 22,000** (twenty-two thousand Euros) *or* **RON 100,500.00** (one hundred thousand and five hundred RON) for **Lot no. VI**



- **EUR 2,700** (two thousand and seven hundred Euros) *or* **RON 12,500** (twelve thousand and five hundred RON) for **Lot no. VII**
- **EUR 5,600** (five thousand and six hundred Euros) *or* **RON 25,700** (twenty-five thousand and five hundred RON) for **Lot no. VIII**
- **EUR 3,000** (three thousand Euros) *or* **RON 14,000.00** (fourteen thousand RON) for **Lot no. IX**
- **EUR 3,000** (three thousand Euros) *or* **RON 14,000.00** (fourteen thousand RON) for **Lot no. X**
- **EUR 12,500** (twelve thousand and five hundred Euros) *or* **RON 57,500.00** (fifty-seven thousand and five hundred RON) for **Lot no. XI**
- **EUR 2,000** (two thousand Euros) *or* **RON 9,200.00** (nine thousand and two hundred RON) for **Lot no. XII**

In the case of a bid covering multiple lots the bid security amount must be not less than the total of the required bid security amounts per each lot, as covered by the bid.”

Instead of:

“A Bid-Securing Declaration **is not accepted**

A Bid Security **is required.**

Bid shall include a Bid Security (issued by bank) in the form of a Bank Guarantee using the form included in Section IV Bidding Forms.

The amount and currency of the Bid Security for each lot shall be:

- **EUR 29,500** (twenty-nine thousand and five hundred Euros) *or* **RON 135,000** (one hundred thirty-five thousand RON) for **Lot no. I**
- **EUR 6,000** (six thousand Euros) *or* **RON 27,500** (twenty-seven thousand and six hundred RON) for **Lot no. II**
- **EUR 13,000** (thirteen thousand Euros) *or* **RON 60,000** (sixty thousand hundred RON) for **Lot no. III**
- **EUR 3,900** (three thousand and nine hundred Euros) *or* **RON 18,000.00** (eighteen thousand RON) for **Lot no. IV**
- **EUR 8,300** (eight thousand and three hundred Euros) *or* **RON 38,000** (thirty-eight thousand RON) for **Lot no. V**
- **EUR 22,000** (twenty-two thousand Euros) *or* **RON 100,500.00** (one hundred thousand and five hundred RON) for **Lot no. VI**
- **EUR 2,700** (two thousand and seven hundred Euros) *or* **RON 12,500** (twelve thousand and five hundred RON) for **Lot no. VII**
- **EUR 5,600** (five thousand and six hundred Euros) *or* **RON 25,700** (twenty-five thousand and five hundred RON) for **Lot no. VIII**
- **EUR 6,500** (six thousand and five hundred Euros) *or* **RON 30,000.00** (thirty thousand RON) for **Lot no. IX**
- **EUR 12,500** (twelve thousand and five hundred Euros) *or* **RON 57,500.00** (fifty-seven thousand and five hundred RON) for **Lot no. X**
- **EUR 2,000** (two thousand Euros) *or* **RON 9,200.00** (nine thousand and two hundred RON) for **Lot no. XI**

In the case of a bid covering multiple lots the bid security amount must be not less than the total of the required bid security amounts per each lot, as covered by the bid.”

Article 12:

Section III. Evaluation and Qualification Criteria – 3. Qualification requirements (ITB 36) – point d)

Shall read:

“d) The Bidder must have the financial capability to assume the responsibility for the proposed contract as evidenced by an annual average turnover of not less than: EUR 3,000,000 for Lot no. I; EUR 950,000 for Lot no. II; EUR 3,400,000 for Lot no. III; EUR 400,000 for Lot no. IV; EUR 850,000 for Lot no. V; EUR 2,200,000 for Lot no. VI; EUR 270,000 for Lot no. VII; EUR 550,000 for Lot no. VIII; EUR 350,000 for Lot no. IX; EUR 350,000 for Lot no. X; 1,300,000 for Lot no. XI; 200,000 for Lot no. XII or its equivalent over the past three (3) years (i.e. 2013, 2014, 2015).

In the case of a bid covering multiple lots the annual average turnover of the Bidder over the past three years must be no less than the total of the required annual average turnover amounts per each lot, as covered by the bid. The Bidder shall furnish, as part of its bid, such documentary evidence, in the form



of audited financial statement or balance sheet endorsed by authorized accountant, demonstrating the annual turnover for each of the last three (3) years.“

Instead of:

“d) The Bidder must have the financial capability to assume the responsibility for the proposed contract as evidenced by an annual average turnover of not less than: EUR 3,000,000 for Lot no. I; EUR 600,000 for Lot no. II; EUR 1,400,000 for Lot no. III; EUR 400,000 for Lot no. IV; EUR 850,000 for Lot no. V; EUR 2,200,000 for Lot no. VI; EUR 270,000 for Lot no. VII; EUR 550,000 for Lot no. VIII; EUR 700,000 for Lot no. IX; 1,300,000 for Lot no. X; 200,000 for Lot no. XI or its equivalent over the past three (3) years (i.e. 2013, 2014, 2015).

In the case of a bid covering multiple lots the annual average turnover of the Bidder over the past three years must be no less than the total of the required annual average turnover amounts per each lot, as covered by the bid. The Bidder shall furnish, as part of its bid, such documentary evidence, in the form of audited financial statement or balance sheet endorsed by authorized accountant, demonstrating the annual turnover for each of the last three (3) years.“

Article 13:

Invitation for Bids (IFB) – para no. 2:

Shall read:

“The Ministry of Health - ***Project Management Unit*** now invites sealed bids from eligible bidders for procurement of the following goods: LOT I: Intrahospital transportation equipment; LOT II: ECG equipment; LOT III: Defibrillation equipment; LOT IV: Immobilization equipment; LOT V: Ventilation and spirometry equipment; LOT VI: Neonatology and patient heating device equipment; LOT VII: Video – laryngoscope devices; LOT VIII: Bronchoscope devices; LOT IX: Resuscitation and airway management equipment; LOT X: Portable suction devices; LOT XI: Volumetric perfusion devices; LOT XII: Fast perfusion transfusion devices“

Instead of:

“The Ministry of Health - ***Project Management Unit*** now invites sealed bids from eligible bidders for procurement of the following goods: LOT I: Intrahospital transportation equipment; LOT II: ECG equipment; LOT III: Defibrillation equipment; LOT IV: Immobilization equipment; LOT V: Ventilation and spirometry equipment; LOT VI: Neonatology and patient heating device equipment; LOT VII: Video – laryngoscope devices; LOT VIII: Bronchoscope devices; LOT IX: Resuscitation and airway management equipment; LOT X: Volumetric perfusion devices; LOT XI: Fast perfusion transfusion devices“

Article 14:

Invitation for Bids (IFB) – para no. 7:

Shall read:

“All bids must be accompanied by a *Bid Security* in amount of:

- **EUR 29,500** (twenty-nine thousand and five hundred Euros) or **RON 135,000** (one hundred thirty-five thousand RON) for **Lot no. I**
- **EUR 9,500** (nine thousand and five hundred Euros) or **RON 44,000** (forty-four thousand RON) for **Lot no. II**
- **EUR 34,000** (thirty-four thousand Euros) or **RON 160,000** (one hundred and sixty thousand RON) for **Lot no. III**
- **EUR 3,900** (three thousand and nine hundred Euros) or **RON 18,000.00** (eighteen thousand RON) for **Lot no. IV**
- **EUR 8,300** (eight thousand and three hundred Euros) or **RON 38,000** (thirty-eight thousand RON) for **Lot no. V**
- **EUR 22,000** (twenty-two thousand Euros) or **RON 100,500.00** (one hundred thousand and five hundred RON) for **Lot no. VI**
- **EUR 2,700** (two thousand and seven hundred Euros) or **RON 12,500** (twelve thousand and five hundred RON) for **Lot no. VII**
- **EUR 5,600** (five thousand and six hundred Euros) or **RON 25,700** (twenty-five thousand and five hundred RON) for **Lot no. VIII**
- **EUR 3,000** (three thousand Euros) or **RON 14,000.00** (fourteen thousand RON) for **Lot no. IX**
- **EUR 3,000** (three thousand Euros) or **RON 14,000.00** (fourteen thousand RON) for **Lot no. X**



The deadline for bid submission is:

Date: **February 28th, 2017**

Time: **12:00 hour's local time**

Bidders **shall not** have the option of submitting their bids electronically.”

Article 16:

Section II. Bid Data Sheet (BDS) - ITB 25.1.

Shall read:

“The bid opening shall take place at:

Ministry of Health - Project Management Unit

Address: 1-3, Cristian Popișteanu St., 2nd floor, room 225A (Conference room), Sector 1

City: Bucharest

ZIP Code: 010024

Country: Romania

Date: **March 6th, 2017**

Time: **12:00 hour's local time”**

Instead of:

“The bid opening shall take place at:

Ministry of Health - Project Management Unit

Address: 1-3, Cristian Popișteanu St., 2nd floor, room 225A (Conference room), Sector 1

City: Bucharest

ZIP Code: 010024

Country: Romania

Date: **February 28th, 2017**

Time: **12:00 hour's local time”**

Article 17:

Invitation for Bids – para. 6.

Shall read:

“Bids must be delivered to the address below at or before: **12:00 hour's local time on March 6th, 2017.**

Electronic bidding will not be permitted. Late bids will be rejected. Bids will be publicly opened in the presence of the bidders' designated representatives and anyone who choose to attend at the address (2) below at **12:00 hour's local time on March 6th, 2017”**

Instead of:

“Bids must be delivered to the address below at or before: **12:00 hour's local time on February 28th, 2017.**

Electronic bidding will not be permitted. Late bids will be rejected. Bids will be publicly opened in the presence of the bidders' designated representatives and anyone who choose to attend at the address (2) below at **12:00 hour's local time on February 28th, 2017”**

All other parts, clauses and provisions of the original Bidding Documents and Addendum no. 2 to the bidding documents that are not amended as per the articles above shall remain valid and unchanged.

-----**END OF DOCUMENT**-----



CLARIFICATIONS NO. 2

Bidding Documents ICB No. G/C1/1.2 “Procurement of equipment for emergency room” – dated December 8th, 2016.

Questions regarding provisions of the bidding documents - Part I and Part. III

1. **Q.** Addendum no. 2 to the bidding documents – Article 1 – Section III – Evaluation and Qualification Criteria – point 3. Qualification requirements (ITB 36).

Taking into consideration the final version of the qualification criteria according to Addendum no. 2 and on the other hand to not limit competition in favour of a small number of bidders, we propose, that “supply of medical equipment similar to that offered in the bid”, to be accepted not only equipment’s of the same type with the requested machines/lots, but other high-tech medical equipment’s (E.g.: heart lung machines and other machines for cardiac surgery or for interventional cardiology, high technology laboratory analysers like DNA sequencers, real time PCR devices, etc.) too, attesting the technical capacity and the experience of respectively bidder.

This could allow for more potential integrators, with good reliability, financial capacity and experience to participate in many more lots.

A: We propose that the word similar will mean: equipment that are used for similar functionalities, technical or operational features or are used on similar human body structures (systems or body parts). By that if any pump is requested similar means ECMO or mechanical ventilator (these device have similar technological features even if designed for different body parts), for example, but not a DNA sequencer. The expertise we want to prove is not the quantity that the provider is able to provide but also the ability to have a well organised maintenance network and expertise after the purchase of the equipment will be finished.

2. **Q.** Section IV – Bidding forms – Price schedule: Goods Manufactured outside the Purchaser Country, already imported.

For this product category, please be clearly, if the total bid price must include VAT or not.

A. All prices will be expressed without VAT.

3. **Q.** Regarding the qualification criteria ITB 36 : During the past 5 years the Bidder must have at least three (3) contracts that cumulated to be equal to the value of the bid price offered involving supply of medical equipment similar to that offered in the bid and provision of either directly or through an authorized local Agent – After Sales services for medical equipment for which this Invitation for Bids is issued and covered by the Bid” please confirm reformulation you will accept contracts to be cumulated dated since 2011;

A. Will be accepted just the contracts signed between February 28th, 2012 – February 28th, 2017.

Questions regarding provisions of the bidding documents (Part II Schedule of Requirements)

1. **Q.** LOT IV Immobilization equipment – Item IV.5 Pelvic belt set

In the table with technical characteristics, it is mentioned the following:

Available as set of three different sizes individually packed with clearly identifiable labels for size and rules for use

- a. Small ...
- b. Medium
- c. Large

The required number of pieces is stated as 156 pcs. But the item is called “Pelvic belt set”

Please explain if we need to quote either 156 pcs of 3 different size (which means 52 pcs of each size) or 156 sets consisting of 3 belts of different size (which means 156 pcs of each size and consequently a total number of 468 pcs).



A: As stated in the requirements one set consists of **THREE DIFFERENT SIZES (S, M, L)**. So we will need 156 sets x 3 sizes means 468 belts (156 S + 156 M + 156 L)

2. Q. LOT II.1 ECG

As for your answer related to the dimension of the screen “display min 10”, we are sorry to iterate our request so that this requirement may be modified to “display not less than 7” or considered not mandatory.

The requirements for the ECG and the size of the display lead the Bidder to a very limited number of products. Since other Bidders have raised the question, you cannot disregard that this strong limitation to open concurrency is caused by a combination of the technical requirements that, in their totality, do not introduce any significant advantage in terms of diagnostic efficacy of the device and can't therefore justify this serious restriction of competition due to the exclusion of many reputable Manufacturers.

You can't, on the other hand, ignore that ECRI HPCS is one of the most complete and accurate market observation sources of medical devices world market.

For your convenience, we have attached the results of the queries based on your technical requirements so as to demonstrate the very low number of compliant ECGs which seems not appropriate for an International Competitive Bid.

Table A: all ECG from the ECRI database

Table B: all ECG with CE mark and integral printer

Table C: all ECG with CE mark and integral printer, A4 format, screen more than 10 inch and store of 100ECGs

Table D: all ECG with CE mark and integral printer, A4 format, screen more than 10, store of 100ECGs and battery with 4h's operativity

A: Accepted.

The requirement will be changed as follows: Display min 7”, Touchscreen or Physical alphanumeric keyboard for entering patient data.

Please see article no. 1 of Addendum no. 3 to the bidding documents.

3. Q. LOT I - ITEM I.3 Standard radiotransparent examination/transfer hydraulic trolley for bariatric patient
Technical Specifications: Item I.3 Standard radiotransparent examination/transfer hydraulic trolley for bariatric patient

Initial Criteria: Height maximum position at least 90 cm (not includes the mattress height)

Reformulation proposal: Height maximum position at least 85 cm (not includes the mattress height)

Comment: Common trolleys have an height range of 30-35 cm between the lower and the higher position, due to the capacity of the hydraulic pump. According to the Article n.18 of Addendum No.2 the new lower limit is 50 cm however, if the higher limit will not be modified, this modification will be useless to include devices with a lower limit of 50 cm (assuming a range of 35 it can reach 85 cm, not 90 cm).

Since in bariatric application it is important to have trolleys with a lower height, we find correct the minimum value of 50 cm, and we kindly ask you to modify consequently the higher value in “at least 85 cm”.

A: Accepted.

The requirement will be changed as follows: Height maximum position at least 85 cm (not includes the mattress height)

Please see article no. 2 of Addendum no. 3 to the bidding documents.

4. Q. LOT II ECG

Because in the Technical Specification (Connectivity and communication), it is required to install the software programs, please to confirm the obligation of the final beneficiaries to assure the necessities standard PC.

A: The PCs will be available and provided by the Emergency Departments.

5. Q. LOT II ECG

According to addendum no. 2/13.02.2017 to the technical requirements it has been added “The required minimum resolution is 800 x 480 pixels.” To the request “Graphic display with high definition” By conditioning the minimum resolution with above minim limit you restrict the participation in the bid of the other models/brands of ECG. For example if the offered ECG has a display fulfilling the dimension



requirement of minimum 10” and the display is higher technology – as is TFT (superior to LCD by improving the LCD resolution via transistor attached to each pixel, which provides more control over the color and images it can render) – then the current limitation will restrict. Please accept and allow formulation “the minimum resolution starting with 800 x 480 pixels for LCD or the minimum resolution starting with 640 x 480 pixels for TFT”.

A: Accepted.

The requirement will be changed as follows: Graphic display with high definition. The required minimum resolution starting with 800 x 480 pixels for LCD or the minimum resolution starting with 640 x 480 pixels for TFT.

Please see article no. 3 of Addendum no. 3 to the bidding documents.

6. Q. Regarding the technical specification for lot X.1 Volumetric perfusion devices: Flow rate: min range 0.1 ml – 999.9 ml/h (max 0.1 ml increments)

We propose to accept an increment of maximum 0.1 ml/h in the range 0.1 ml -99.9 ml and an increment of maximum 1 ml/h in the range 100 ml-999.9 ml/h in order to not unduly restrict access to this procedure and implicitly restrict competition between economic operators, please consider consistent and electric syringes that provides for the 1.0-99.9 mL increment 0.1 ml / h, 1ml increment for the 100-999.9 ml / h. We mention that there is no other national or international standard that limit an electric syringe in the range from this point of view.

A: Not accepted. The standard is related to the dose administered by this device.

7. Q. Regarding LOT VII. ITEM. VII.3 Portable suction device.

Please consider a separate lot for Portable suction devices in order to offer the possibility to the respected manufacturers for suction devices but not for laryngoscopes and resuscitation sets to submit the bid.

A: Accepted.

Please see article no. 10 - 14 of Addendum no. 3 to the bidding documents.

8. Q. LOT II ECG

Recording speeds: minim 25/50 mm/sec: Printing at speeds beyond 25 mm/sec offers no clinical benefit and could even compromise the quality of the printout. ECGs manufactured by, as well as many of those made by other global manufacturers, print at 25 mm/sec which is the industry standard and considered clinically sufficient for emergency room doctors to reach critical vital signs. We request that this specification be modified to permit a printing speed of 25 mm/sec.

A: The clinical relevance has already discussed as it is related to interpreting high frequency heart rhythms in an environment where there are no other options to analyse such rhythms (holters, etc). Although the 50 mm/s speed can be excluded from the requirements.

The requirement will be changed as follows: “Recording speeds: minim 25 mm/sec.”

Please see article no. 4 of Addendum no. 3 to the bidding documents.

9. Q. LOT II ECG

Common mode rejection: min 100 dB or according with ANSI/AAMI EC11:ECG is designed to have a common mode rejection of 99 dB, which is considered clinically sufficient to ensure diagnostic performance. We request that this specification be adjusted accordingly, pointing out that such a minor modification would not have material impact on the equipment s critical performance.

A: There are several standards that ensure the security of the recorded data. We don’t understand why a device can not comply with at least one of these. Ultimately as suggested the threshold can be reduced to 99 dB.

The requirement will be changed as follows: “Common Mode rejection: min 99 dB or according with ANSI/AAMI EC 11”

Please see article no. 5 of Addendum no. 3 to the bidding documents.

10.Q. LOT II ECG

Low weight, device including battery: max 6 kg (excluding transport trolley): Given design differences, each manufacturers ECG has a different weight. weighs 9 kg. As the ECG will be placed on a transport trolley, its weight will not influence the mobility, ease of use, or critical performance of the equipment. We requested that a max weight of 9 kg be allowed.



A: Accepted but as it will be used in emergency departments where different obstacles could be found on the ground (wires, steps, etc.) so the ECG cart has to have a good stability (which depends on the height of the centre of gravity of the cart + device).

The requirement will be modified as follows: “Low weight, device including incl. battery: max 10 kg (excluding transport trolley). If the weight is above 6 kg the cart / trolley with the ECG will have the centre of gravity at a maximum height of 1 meter above the ground level”

Please see article no. 6 of Addendum no. 3 to the bidding documents.

11.Q. LOT II ECG

Maximum time constant 5s: This parameter is not used byor other ECG manufacturers. It is not clinically relevant and must either be further clarified or removed.

A: Accepted.

Please see article no. 7 of Addendum no. 3 to the bidding documents.

12.Q. LOT II ECG – Lot I

Item I.4 you requested CE mark for trolley for instruments and drugs according to the directive 93/42/EEC. Regarding to the directive 93/42/EEC the trolley for instruments and drugs cannot be marked with the CE mark because it does not comply the definition of “Medical device” in this directive. Can the bidder offer product with the declaration of conformity without CE mark?

A: Accepted.

