MINISTRY OF HEALTH
PROJECTS MANAGEMENT UNIT

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Our ref.no: 51814/September 19th, 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/C1/1.3

Dear Mrs. /Mr.

Please find attached the following documents:

1. Amendment no. 2 to the Bidding Documents for Procurement of equipment for emergency room – ICB No. G/C1/1.3, consisting of 3 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. 1 (14 pages).
3. 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 Amendment no. 2 to the Bidding Documents and the answers to the clarification requests (11 pages).

All changes related to the technical specifications that are subject of Amendment no. 2 are highlighted in yellow.

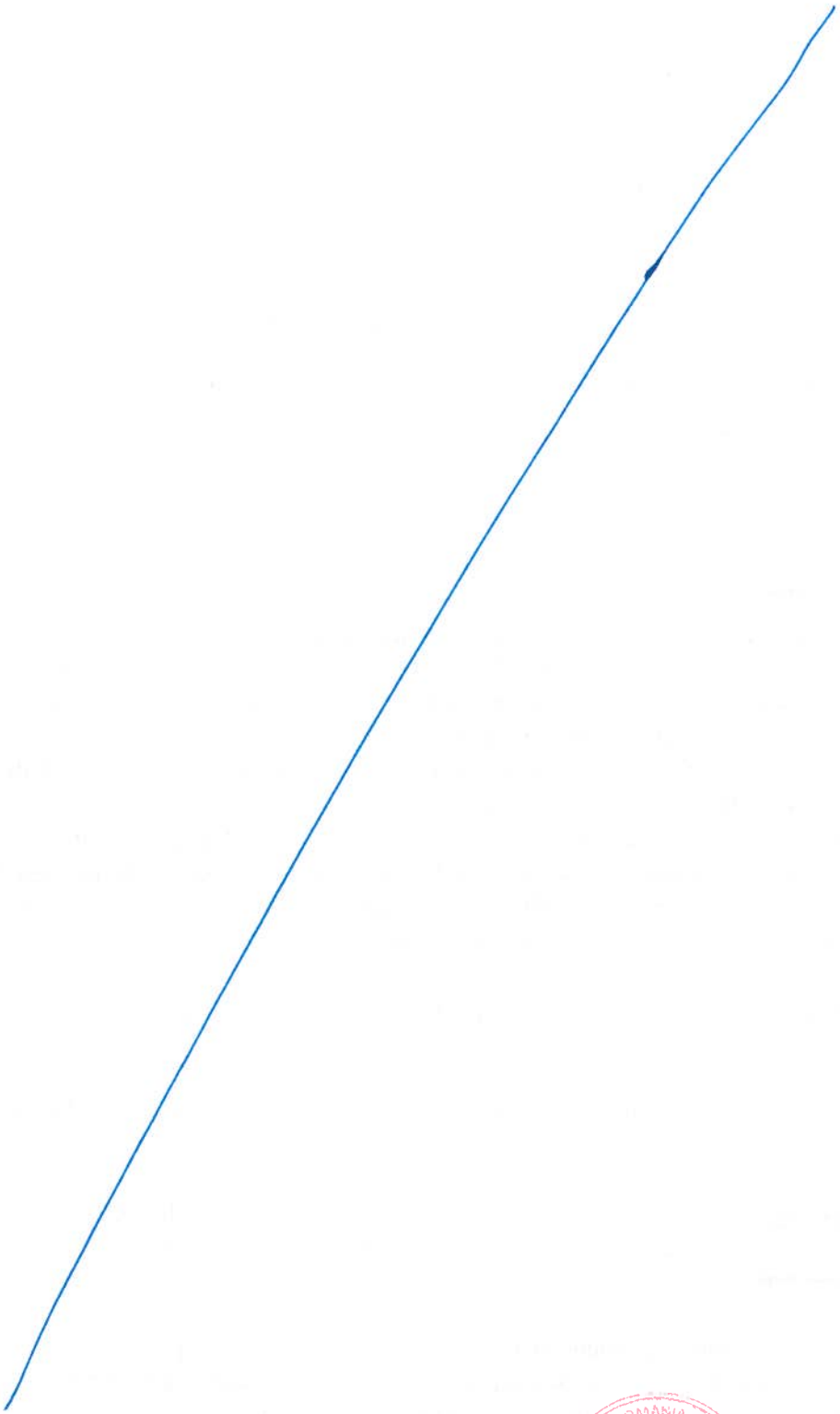
Due to the size, all the documents mentioned above will be sent only by e-mail to the address provided by your company.

Please confirm the receipt of the documents above and that you will take into account the clarifications address no. 1 and the provisions of Amendment no. 2 to the Bidding Documents in preparing your bid.

Considering the provisions of amendment no. 2 and the clarifications no. 1, we are kindly inform you that the deadline for bids submission will be **September 29th, 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

AMENDMENT NO. 2 TO THE BIDDING DOCUMENTS FOR PROCUREMENT OF EQUIPMENT FOR EMERGENCY ROOM - ICB NO. G/C1/1.3

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

Article 1: **Section III point 3. Qualification requirements (ITB 36)**

***Shall read*:** "a) During the past 5 years the Bidder must have completed at least three (3) contracts that cumulated to be equal to the value of the bid price offered or in the last 2 years succeed to deliver and install the same amount of equipment offered, involving supply of medical equipment similar to that offered in the bid (e.g.: Monitoring equipment for Lot. V) 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. In order to demonstrate it meets the experience requirement the Bidder shall furnish detailed information regarding contracts completed: purchaser name and address, country, name and object of the contract, date of contract completion, equipment supplied, contract amount, contract role (prime supplier, subcontractor, partner in Joint Venture) and percent of the contract value undertaken by subcontract.
Sub-contractors experience will not be considered during the evaluation process. The bidder should meet the qualification requirements for similar experience on its own."

***Instead of*:** "a) During the past 5 years the Bidder must have completed at least two (2) contracts, each one equal to the value of the bid price offered, involving supply of medical equipment similar to that offered in the bid (e.g.: Monitoring equipment for Lot. V) 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. In order to demonstrate it meets the experience requirement the Bidder shall furnish detailed information regarding contracts completed: purchaser name and address, country, name and object of the contract, date of contract completion, equipment supplied, contract amount, contract role (prime supplier, subcontractor, partner in Joint Venture) and percent of the contract value undertaken by subcontract.
Sub-contractors experience will not be considered during the evaluation process. The bidder should meet the qualification requirements for similar experience on its own"

Article 2:
Section II. Bid Data Sheet (BDS) - ITB 22.1.

***Shall read*:**
"For **bid submission purposes** only, the Purchaser's address is:
Attention: Mr. Sorin Zaharcu, PMU Interim Director
Ministry of Health - Project Management Unit
Street Address: 1-3, Cristian Popișteanu Ent. Sector 1
Floor/Room number: 2nd floor, room 236
City: Bucharest
Postal Code: 010024
Country: Romania
The deadline for bid submission is:
Date: **September 29th, 2017**
Time: **12:00 hour's local time**
Bidders **shall not** have the option of submitting their bids electronically."

***Instead of*:**
"For **bid submission purposes** only, the Purchaser's address is:
Attention: Mr. Sorin Zaharcu, PMU Interim Director
Ministry of Health - Project Management Unit
Street Address: 1-3, Cristian Popișteanu Ent. Sector 1

Floor/Room number: 2nd floor, room 236
City: Bucharest
Postal Code: 010024
Country: Romania
The deadline for bid submission is:
Date: **September 25th, 2017**
Time: **12:00 hour's local time**
Bidders **shall not** have the option of submitting their bids electronically."

Article 3:
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 Popişteanu St., 2nd floor, room 225A (Conference room), Sector 1
City: Bucharest
ZIP Code: 010024
Country: Romania
Date: **September 29th, 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 Popişteanu St., 2nd floor, room 225A (Conference room), Sector 1
City: Bucharest
ZIP Code: 010024
Country: Romania
Date: **September 25th, 2017**
Time: **12:00 hour's local time**"

Article 4:
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 September 29th, 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 September 29th, 2017**"

Instead of:
"Bids must be delivered to the address below at or before: **12:00 hour's local time on September 25th, 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 September 25th, 2017**"

Article 5:
Technical specification for Lot no. VI - Item VI.1 Ultrasound Doppler.
***Shall read*:** "Turn-on system in up to 50 sec"
***Instead of*:** "Turn-on system in up to 40 sec"

Article 6:
Technical specification for LOT V: Monitor (ECG, Respiration, SpO2, NIBP): "Compatible with the central station for monitoring (item 2.4)" and "Network Hardware with the central station for monitoring (item II.4)" ***will be deleted***.

Article 7:
Technical specification for Lot no. VI - Item VI.1 Ultrasound Doppler: "Minimum 3 user-selectable transmit frequency in Harmonic Mode"; "Minimum 3 user-selectable transmit frequency in Doppler mode; "Minimum

2 user-selectable transmit frequency in Harmonic Mode" and "Minimum 2 user-selectable transmit frequency in Doppler mode" ***will be deleted***.

Article 8:
Technical specification for Lot no. VI - Item VI.1 Ultrasound Doppler: "Multiple frequencies transmitted in Harmonic and Doppler mode suitable to the frequency range of each transducer" ***will be added***.

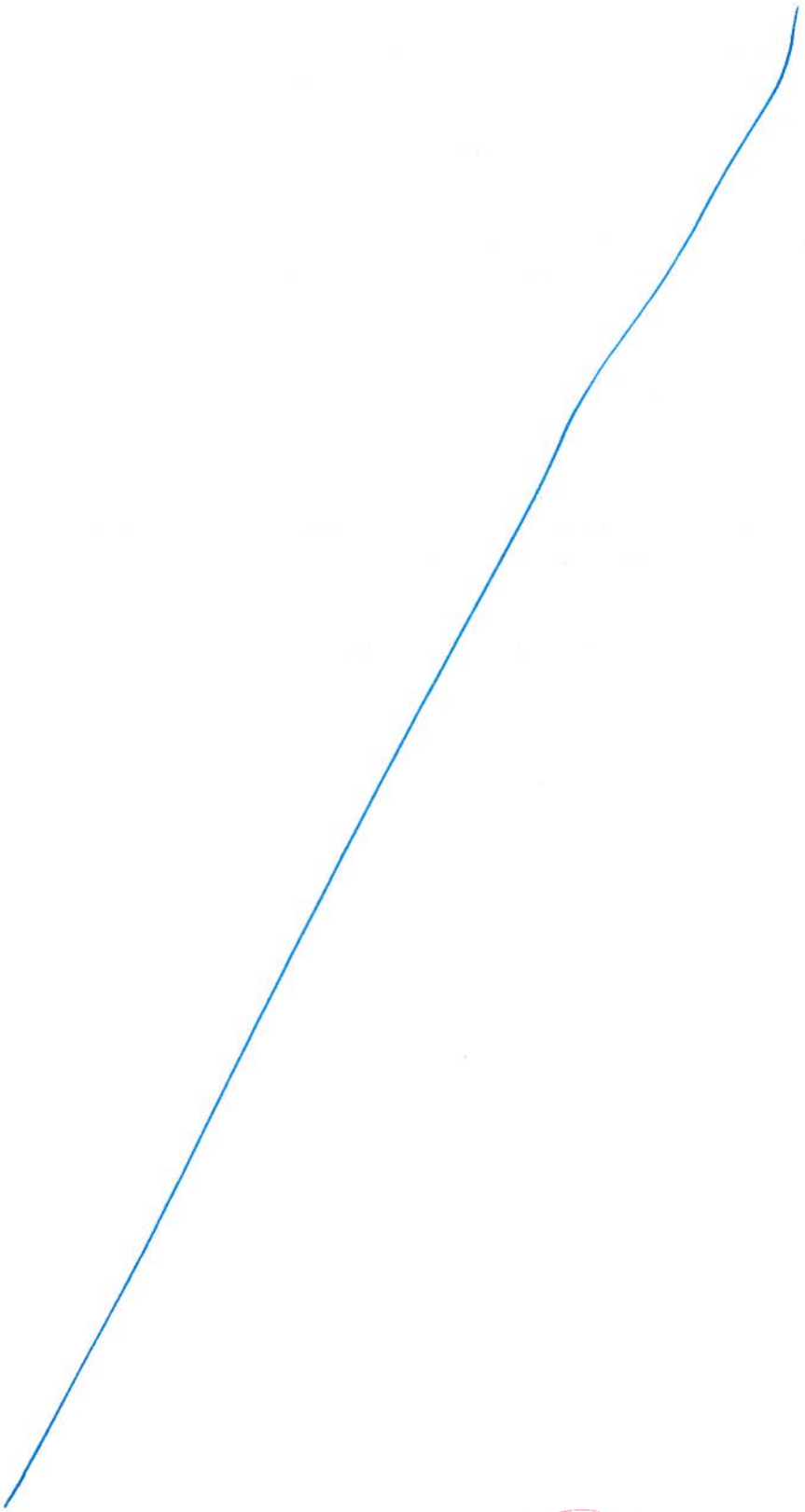
Article 9:
Technical specification for Lot no. VI - Item VI.1 Ultrasound Doppler.
Shall read: "Doppler function - For all transducers - Color, Spectral, Power, and for phased array transducer: Continuous Doppler"
Instead of: "Doppler function - For all transducers - Color, Continuous, Spectral and Power"

Article 10:
Technical specification for LOT IV Portable Ventilation Equipment.
Shall read: "Response pressure of demand valve: - 1 mbar or other similar-in-effect triggers"
Instead of: "Response pressure of demand valve: - 1 mbar"

Article 11:
Technical specification for LOT IV Portable Ventilation Equipment.
Shall read: "Maximum flow delivered: max 200 l/min"
Instead of: "Maximum flow delivered: max 100 l/min"

All other parts, clauses and provisions of the original Bidding Documents that are not amended as per the articles above shall remain valid and unchanged.

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

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MINISTERUL SĂNĂTĂȚII
REFORMA SECTORULUI SANITAR
UNITATEA DE MANAGEMENT A PROIECTULUI
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CLARIFICATIONS NO. 1

Bidding Documents ICB No. G/C1/1.3 "Procurement of equipment for Emergency Room" – dated August 4th, 2017.

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

1. Q. Regarding Section III - Qualification Requirements (ITB 36) – you request: "During the past 5 years the Bidder must have completed at least two (2) contracts, each one equal to the value of the bid price offered, involving supply of medical equipment similar to that offered in the bid (e.g.: Monitoring equipment for Lot. V)"
Being the fact that the bidder may not be the exclusive or single distributor of a manufacturer division of products, this requirement is too restrictive taking into consideration that the bidder may meet this requirement by presenting several contracts for similar products (Eg: medical equipment). We consider that providing proof of several contracts to various different clients/beneficiaries on different medical equipment, shows that the bidder can work with more than 1 client/beneficiary especially that this bid has a list of 71 final beneficiaries and can comply on the complexity of this contract. Furthermore, you request that the similar experience to be double than the offer the bidder shall submit.

Do you accept that the Bidder to meet the requirement by presenting various contracts for medical equipment equal to value of it's bid?
A. The request will be changed. Please see article no. 1 of the amendment no. 2 to the bidding documents

2. Q. Regarding Section II – Bid Data Sheet - ITB 20.2 – It is requested that the written confirmation of authorization to sign on behalf of the Bidder shall consist of:

- Notarized Power of Attorney signed by the firm's Board of Directors or notarized shareholder's general meeting decision or notarized Power of Attorney signed by the firm's Administrator
- Notarized copy of firm statute

In case of a local bidder or Joint Venture, we kindly ask to accept as sufficient the original of power of attorney or shareholder's general meeting decision, accompanied by the legalized copy of firm statute or Register of Commerce providing the name of the company administrator/ legal representative
A. Accepted.

3. Q. Please be so kind and clarify the following qualification requirements (ITB 36) from point 3 a) of Section III. Evaluation and Qualification Criteria:

„During the past 5 years the Bidder must have completed at least two (2) contracts, each one equal to the value of the bid price offered, involving supply of medical equipment similar to that offered in the bid (e.g.: Monitoring equipment for Lot V) 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. In order to demonstrate it meets the experience requirement the Bidder shall furnish detailed information regarding contracts completed".

Considering the fact that we want to apply for Lot VI – Ultrasound Doppler, we kindly ask you to accept as sufficient qualification criteria also that the Bidder has succeeded in the last 2 years to deliver and install the same amount of equipment offered, involving supply of medical equipment similar to the that offered in the bid.

The tender book request would become as follows:
"During the past 5 years the Bidder must have completed at least two (2) contracts, each one equal to the value of the bid price offered or in the last 2 years succeed to deliver and install the same amount of equipment offered, involving supply of medical equipment similar to that offered in the bid (e.g.: Monitoring equipment for Lot V) 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. In order to demonstrate

it meets the experience requirement the Bidder shall furnish detailed information regarding contracts completed."
A. Please see answer to Q. 1.

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

1. Q. LOT V: Monitor (ECG, Respiration, SpO2, NIBP)
Do you require CENTRAL STATION OPTION for the monitor or not?
A: No.

2. Q. LOT V: Monitor (ECG, Respiration, SpO2, NIBP)
Regarding the LOT V: VITAL SIGNS MONITOR, we need to know patient monitor brand name and series model number to know what ecg cable will work for the patient monitor. I attached 1 picture for the specifications that we need to know patient monitor brand name and series model number illustrated by red in the annex to be more crystal clear. Considering the specifications in the picture could you inform us which brand names and model number do you require?

MONITOR (ECG, Respiration, SpO2, NIBP)	Yes/No
01. TECHNICAL CHARACTERISTICS	
Adult/ Paediatric portable monitor	
Adult / paediatric respiration	
SpO2 multisensor	
NIBP paediatric and NIBP adult	
Compatible with the central station for monitoring (item 2.4)	
Cables and disposables: — for what brand and what model number patient monitor?	
ECG patient cable 3-lead shielded – 1 pc	YES
Cuff set reusable, all dimensions adult / paediatric – 2 set	YES
Extra cuff reusable adult normal size – 1 pc	YES
ECG electrodes – 100 pcs	YES
ECG electrodes paediatric – 100 pcs — for what brand and what model number?	YES
SpO2 (multisensor) sensor adult – 2 pcs — (for example: Masimo P5)	YES
Disposable SpO2 infant sensor – 50 pcs.	

A: A monitor is a device that, through various sensors, records or displays different parameter data. In our case we requested a monitor that displays and records as parameters those related to patient's vital signs. That means: cardiac electrical activities (ecg), spo2, NIBP, heart rate, respiratory etc. So the cables that are used for the connection between the device and the patient are part of the monitoring device. The brand and all other requested identification numbers for the monitor are issues that are the subject of this tender. The cables will be provided by the provider who will win the tender

3. Q. LOT III Portable Ventilation Equipment
Regarding the Lot 3: Portable Ventilation Equipment, ''Power supply: 220 VAC, 50 Hz; vehicle battery (12 VDC); internal battery (min 6 hours)'' is demanded in the specifications. We offer a machine with internal battery support about 2 hours. Generally our machine battery can support for 2 hours. Actually for portable ventilator, it is mainly used for emergency, so 2 hours is enough for daily use. One more reasons is that if the battery can support over 6 hours, the battery shall be larger and heavier, which will cause inconvenience for carrying. Do you insist on 6 hours or 2 hours is also acceptable?
A: Not accepted. The required 6 hours are mandatory as ventilation has to be performed in all situations implied by an emergency department even if external power source is not available

4. Q. LOT III Portable Ventilation Equipment
Regarding the Lot 3: Portable Ventilation Equipment, ''Minute volume: min range 0.5-45 1/min'' is demanded in the specifications. We offer a machine with 2-30L/min. and 0.5-45 range is usual for ICU ventilator, for portable ventilator, 2-30L/min is common for most suppliers. Can our offer (2-30L/min) be acceptable?
A: Not accepted. The requested ventilator as it will be used in emergency situations, has to provide respiratory support to patients with less and higher weight than the one with 2-30 l/min range of minute volume.

5. Q. LOT V: Monitor (ECG, Respiration, SpO2, NIBP)
'Device for bed rail hanging'' is demanded in the specifications. Is it trolly for patient monitor?
A: It is not a trolley. It is a clamp that allows the device to be mounted on patient's bed during the transport.

6. Q. LOT V: Monitor (ECG, Respiration, SpO2, NIBP)
''Rapid exhaust mode'' is demanded in the specifications. We consider offering a machine with USA standard. Is it acceptable?
A: Rapid exhaust mode, in our perspective mean the possibility to deflate quickly the cuff, So any solution that fits in this description is acceptable.

7. Q. LOT VI: Ultrasound Doppler - Turn-on system in up to 40 sec.
Please accept the start in 50 sec., as it has no impact on normal work schedule
A: Accepted. Please see article no. 5 of the amendment no. 2 to the bidding documents.

8. Q. LOT VI: Ultrasound Doppler - Screen appearance of system data simple with direct visualization of measurement application and image enhancement.
To clarify this requirement, please explain in more detail and possibly an example
A: The main screen of the device will allow an easy access to all software subcomponents and menus not only to the operating system but also to the modules required for measurements, image enhancement applications. These features could be available through a well-organized menu system but any other solution could be analysed.

9. Q. LOT VI: Ultrasound Doppler - The unit can be mobile or compact portable with Li-Ion battery (2 hours minimum autonomy) integrated for in hospital transport.
Typically, most units of this kind are designed with a maximum of 30 minutes of battery life, since during this time any type of investigation can be terminated in the event of a power outage.
Please also accept a 30 minute autonomous unit on your internal battery or additional UPS that can be installed on your mobile unit to reach these 2 hours
A: Not accepted. Inside hospitals there are situations when the ultrasound is needed in places where there are no plug-in possibilities. An UPS is not acceptable because one which will allow to keep the device longer than 30 minutes have unacceptable size and weight. The requirement remains for 2 hours.

10. Q. LOT V: Monitor (ECG, Respiration, SpO2, NIBP) - you request twice that the monitor to be
-"compatible with the central station for monitoring (item 2.4)
- network hardware with the central station for monitoring (item II.4)
Could you please provide more details regarding the central station for monitoring like model/code/manufacturer.
A: Both requirements "Compatible with the central station for monitoring (item 2.4)" and "Network Hardware with the central station for monitoring (item II.4)" will be deleted. Please see article no. 6 of the amendment no. 2 to the bidding documents.

11. Q. LOT VI – ULTRASOUND DOPPLER - you request that it has "1024 minimum processing channels"
Do you accept that this request to be met by adding to the physical channels, the virtual channels?
A: Not accepted

12. Q. LOT VI – ULTRASOUND DOPPLER - you request:
- Minimum 3 user-selectable transmit frequency in Harmonic Mode

- Minimum 3 user-selectable transmit frequency in Doppler mode
- Minimum 2 user-selectable transmit frequency in Harmonic Mode
- Minimum 2 user-selectable transmit frequency in Doppler mode

Do you accept that these requests to be met by a Doppler that has automatic frequency selection, meaning that the equipment transmits multiple frequencies simultaneously, not a single frequency as required?
A: Accepted. The requirements will be changed as follows for all the transducers: "Multiple frequencies transmitted in Harmonic and Doppler mode suitable to the frequency range of each transducer". Please see article no. 7 and 8 of the amendment no. 2 to the bidding documents.

13. Q. LOT VI – ULTRASOUND DOPPLER - you request – "RS 232 port or similar":
The request is obsolete nowadays. Can you please reformulate or eliminate the request?
A: Similar means that any other port for data export/import, forwarding, etc. is acceptable.

14. Q. LOT VI – ULTRASOUND DOPPLER - you request that the transducer for cardiac (phased array) to allow the following applications: "transthoracic cardiac use for adult and paediatric".
Transthoracic application require a special probe TEE probe, which is not required in the technical specs – as included in the configuration.
Please specify that you want this kind of application for future purchasing option of a TEE probe, taking into consideration that this application will not be usable through a phased array probe?
We can provide this application but it will not be functional without the TEE probe.
A: All applications required have to be functional.

15. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request: "System permit software upgrade of the main system and transducer data base - during the warranty period it will be free of charge''
Please accept the following change request:
System permit software upgrade of the main system and transducer data base - During the warranty period software updates without adding additional options or Hardware will be free of charge.
A: Not accepted as not only main but all software components may require updates so this requirements has to be applicable for all of them

16. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request: "The unit can be mobile or compact portable with Li-Ion battery (2 hours minimum autonomy) integrated for inhospital transport"
Usually any exam does not exceed 45-60 minutes therefore we ask to reduce System autonomy time to 1hour.
Please accept the following change request:
The unit can be mobile or compact portable with Li-Ion battery (1 hour minimum autonomy) integrated for inhospital transport.
A: Not accepted. Inside hospitals there are situations when the ultrasound is needed in places where there are no plug-in possibilities. The requirement remains for 2 hours.

17. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request:"b. emergency for lung, transcranial Doppler (TCD)"
Since TCD is not a standard emergency application we ask to remove this point and please accept the following change request:
b. emergency for lung
A: Not accepted. Transcranial Doppler has applications in the emergency departments.

18. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request: "Software package for image auto optimization during processing (auto gain button; eventually tissue and border optimization technology) and post processing image"
Since Image Optimization should be done during Image acquisition, we ask you to remove Auto Optimization for Post processing and please accept the following change request:

Software package for image auto optimization during processing (auto gain button; eventually tissue and border optimization technology).
A: Not accepted. Image optimization has to be available during acquisition, during processing but also after processing the acquired image.

19. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request: "CD/DVD RW and USB ports for transfer patient data (images and reports)"
It is sufficient to deliver either USB or CD/DVD capability since CD/DVD is only rarely used.
Please accept the following change request:
CD/DVD RW or USB ports for transfer patient data (images and reports)
A: Not accepted. USB is not similar to CD-DVD. Their use is different in different situations. Both are required in order to export or import data in most of the situations.

20. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request: "Transmit of images in TIFF format or JPEG, or loop (40-120 sec) on AVI or MPEG4 or DICOM format - package with stock and review DICOM format on PC"
Please confirm that for a portable device 40 sec are sufficient, considering the HDD capacity
Requirements:
"Minimum 100 GB HDD for images and loops storage in case of compact unit or memory card in case of portable device with at least 8GB and possibility to storage 40 patients exams with 20-50 images JPEG or AVI/MPEG4/DICOM with 40 sec. loop"
A: Yes.

21. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request: "Integrated software for patient database with storage of images, measurements and reports. Images review and post processing in B-Mode and Doppler Mode (gain, zoom, image rotation, gray maps, colorize maps, Doppler Automatic Calculations)"
Post processing of saved images is usually time consuming and therefore very rarely done in Emergency Rooms, furthermore it would allow to manipulate already diagnosed images. Since images are saved in DICOM format we ask you to remove the possibility of changing Gain, Zoom, Image Rotation, Grey maps, colorize maps in order to preserve the original stored image and to do not manipulate already diagnosed images.
Please accept the following change request:
Integrated software for patient database with storage of images, measurements and reports.
A: Not accepted. There are several reasons or situations when the post-processing as well as the processing is required

22. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request: "Applications: transthoracic cardiac use for adult and pediatric; also with application soft for abdominal and TCD examination"
Since TCD is not a standard emergency application we ask to remove this point and please accept the following change request:
Applications: transthoracic cardiac use for adult and pediatric; also with application soft for abdominal.
A: Not accepted. Please see the answer to Q. 17

23. Q. LOT VI – ULTRASOUND DOPPLER
Linear steer angle minimum +/- 20°
Please accept as conform also +/- 15°. The 5^0 difference has no major clinical relevance.
A: Reducing the linear steer angle will narrow the providing company's number so it will be limitative without any significant benefits in the quality of the image. The +/- 15 degrees are included when the requirements are for +/- 20 degrees.

24. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request:
"Doppler function
Color, Continuous, Spectral and Power"
Continuous Wave Doppler is used to measure high Blood Flow Velocities which occur in Cardiac Exams, therefore CW Doppler for Phased Array Probes should be sufficient for all exams.
Please accept the following change request:
Doppler function
Color, Continuous for minimum Phased Array Probes, Spectral and Power
A: Accepted

25. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request:
„Storage and Documentation Devices:
CD/DVD – RW Drive"
Since CD/DVD is very rarely used, please accept to make this request optional and accept the following change request:
Storage and Documentation Devices:
CD/DVD – RW Drive – optional
A: Not accepted. CD and DVD are the most common ways for sending the data to other physician, or professionals which are involved in the treatment and assessment of the patient.

26. Q. LOT VI – ULTRASOUND DOPPLER
Referring to the tender request: "System permit software upgrade of the main system and transducer data base - during the warranty period it will be free of charge''
In our understanding the aim is to keep the configuration acquired at the last level of performance.
Since the upgrades are major changes/extensions which allow the customer to install new options, hardware or new licenses, with the possibility of unlimited extensions to the existing configuration and the updates are improvements as well as safety and patch-software improvements to the purchased configuration, we kindly ask you to accept the following change request:
System permit software upgrade of the main system and transducer data base - During the warranty period the Performance Related Updates, Safety Related Updates and Refinement (System improvements) Updates will be free of charge
A: Please see the answer to Q. 15.

27. Q. LOT IV – PORTABLE VENTILATION EQUIPMENT
Regarding the requirement: "Communication via Ethernet or similar";
Please consider USB as a similar type of communication.
USB is a more commonly used type of communication interface for latest generation ventilation equipments, which benefits of a protocol that can identify errors during the data transfer process and notify the transmitter to retransmit the data. Thus, USB ensure an error-free data communication.
A: Accepted.

28. Q. LOT IV – PORTABLE VENTILATION EQUIPMENT
Regarding the requirement: "Complete configuration with patient hoses (one reusable patient hoses for each type of hoses)"
Please accept also ventilators in complete configuration with single use patient hoses for each type of hoses.
The reason for this request is ensuring that the risk of cross-contamination is minimized or completely eliminated while using disposable hoses (circuits). Since the circuit come in direct contact with the patient's respiratory system, multiple airborne bacteria can adhere to it, resulting in circuit contamination. If reused, there is a high risk of transporting the respective infectious microorganisms to another patient, which may lead to the development of ventilation-associated diseases.

Aditionally, there is a significant difference between the reusable hoses and the disposable ones, in terms of price and technical characteristics.

1. The first aspect to mention is that the reusable hoses require sterilization, which implies a higher expense (including the necessity of filters sterilisation) and time invested in this type of circuit.
2. The second issue and most important from clinical point of view is regarding the dead space. In a reusable patient circuit, the dead space represents approximately 25% of the minimal tidal volume, compared to an average of 4% (3.41% for pediatric/infant circuits and 4.72% for adult circuits) for single use circuits.

A: Not accepted. 1. The sterilisation of the reusable hose does not imply higher costs. All emergency department nurses have the competencies and the ability to perform this procedure and also the materials are available. The single use hoses available are so expensive that most of emergency departments in Romania are using reusable hoses in many situations. A single use hose for the emergency department ventilator is approximately 150 lei, as average, and a sterilization procedures costs are around 50 lei or less. The dead space generated by the hose has to be compensated by the device as the hose is dedicated for the device and is not a generic one (but even in this case the compensation has to be available).

29. Q. LOT IV – PORTABLE VENTILATION EQUIPMENT

Regarding the requirement: "Response pressure of demand valve: -1 mbar"

A demand valve is a mechanism which functions based on the negative pressure generated when the patient inspires. This valve releases a corresponding amount of oxygen from the cylinder and delivers it to the patient via circuit, similar as the Spontaneous/Assisted Breath Trigger is doing.

Please consider as similar solution, the Spontaneous/Assisted Breath Trigger: - 1mbar. When the pressure drop is detected (generated when inhaling), an assisted breath is delivered. The trigger value can be adjusted by user from -5.8mbar to - 0.5mbar.

A: Accepted.

30. Q. LOT III – NEO-NATE PORTABLE VENTILATOR

Regarding the requirement: "Portable, with built-in O2 mixer 21-100%";

Please inform us if in order to fulfill the requirement "portable ventilator" ventilator will include a trolley in the configuration or the ventilator will be placed on a ceiling-anchored console available in emergency rooms since majority of the medical devices are kept plugged-in, to guarantee the patient's safety. This means that not all of them have a solution which assures portability.

A: The device will have the necessary features to be mounted on the standard rails that are available in the ED's but also on the incubators rails.

31. Q. LOT III – NEO-NATE PORTABLE VENTILATOR

Regarding the requirement: "The life of the internal battery - minimum 6 hours" and "Maximum Weight: 8 kg"

In order to allow a wider bidder participation to the procurement procedure, please accept "Maximum Weight: 25kg and minium 1 hour internal battery life", since the ventilator is used on a trolley or ceilling anchored console in emergency room, in a intra hospital transport enviroment and not in the EMS service.

According to a brief analysis of the market, only one ventilator, Hamilton T1 (http://medidyne.dk/wp-content/uploads/ENG-HAMILTON-T1-Specs.pdf) meets the specified technical characteristics, having a weight of 6.5kg and a battery life more than 9 hours. This model is used mainly for ambulance.

A: As it is a portable device its role is to provide respiration support for new-borns in the ED but also during transport of the new-borns in incubator to other departments. So the weight and autonomy are very important features. The trolley does not always solve the transportability because it is difficult to move around a hospital two independent devices (incubator and ventilator). The best solution is a ventilator that can be mounted on the incubator's rails. But to achieve the weight of the ventilator has to be also lower than the one suggested. The power autonomy is also required as there are many situations during which the ventilator has no external power source.

32. Q. LOT VI – ULTRASOUND DOPPLER

For the request "Turn-on system in up to 40 sec".

Is it not specified in which condition systems need to perform this request "Considering that for an emergency department it's important to have patient and doctor access to ultrasound exam immediately, ultrasound system should be turned on and connected the AC continuously. When is not connected to the AC power, system runs on battery mode, in stand-by. When fast exam is needed, the system turn-on from stand-by and it is ready to scan with real time image available in less than 40 seconds. Therefore, please confirm that request refers to turn-on from standby mode in up to 40 seconds.
A: See answer for Q7. The requested time is between the start time after a complete shut down and the moment in which real time images are available. This is important in emergency department when as during longer evaluations the device loses battery power or restarting the device is required (as some examples).

33. Q. LOT VI – ULTRASOUND DOPPLER
For the request: "The unit can be mobile or compact portable with Li-Ion battery (2 hours minimum autonomy) integrated for inhospital transport"
Please consider in accordance also a system that can have totally 2 hours minimum functional autonomy in stand-by mode with minimum 30 minutes autonomy for continue scanning examination.
A: Not accepted as the operation time is the one which has to be considered in an emergency department where ultrasound assessment has to be performed sometimes in places where external power sources are not available.

34. Q. LOT VI – ULTRASOUND DOPPLER
For the request: "Minimum 3 transducer ports in case of compact unit with mobile trolley and interchangeable mobile port for portable unit which can be used outside around the department (1)."
Please consider in accordance also a system with minimum 2 active transducer ports in case of compact unit, since usually, in fast scan practice are used maximum 2 transducers for the same patient examinations. This allows doctors to work everywhere in the department, inside or outside with one system with 2 permanent active probes without necessary using a mobile trolley or cart.
A: Not accepted. For a compact device 3 transducer ports are required as there are several situations when all three transducers are used (in an ED not only fast scans are performed).

35. Q. LOT VI – ULTRASOUND DOPPLER
For the request: "For the phased array transducer the penetration will be in the range of 2cm and at least 30 cm".
Usually for phased array transducers on cardiac application, penetration is between 1 cm – 16 cm.
By introducing as a superior limit of 2 cm to at least 30 cm, all vendors will not be able to offer a system.
In order to be able to participate to the tender, please consider as conform also:
"For the phased array transducer the penetration will be in the range of 1 cm and at least 16 cm"
A: During an emergency evaluation of a patient we need the possibility to see a depth from the subcutaneous area to the retro peritoneum even in children or obese adults. The in-depth visualization of the different layers depends on the axial resolution and on the waves frequency. Also the penetration establishes the possibility to visually distinguish the different layers which are passed through by the ultrasound waves, otherwise the structures situated in an area which is not included in the penetration range are not seen as independent structures. So we need a transducer that allows us to visualize structural elements which are anatomically situated in the range of a penetration of 2 - 30 cm because these structural elements are clinically significant for the emergency medicine practice (nerves, vessels). There is no use to see these elements as blocks and not as independent structures especially during specific procedures (vascular access, nerve blocks, etc).

36. Q. LOT VI – ULTRASOUND DOPPLER
For the request:
"Doppler function
For all transducer
Color, Continuous, Spectral and Power"
Continuous Doppler is a dedicated mode only for phased array probe. For this reason please modify your request or please accept also:
„Doppler function
For all transducers: Color, Spectral, Power, and for phased array transducer: Continuous Doppler

A: Accepted. Please see article no. 9 of the amendment no. 2 to the bidding documents.

37. Q. LOT VI – ULTRASOUND DOPPLER

For the request: "RS 232 port or similar". Our latest technology system incorporates USB and we kindly ask you to consider in accordance an USB port instead of RS 232 port. Please note that USB communication mode is a superior technology that provides up to 480 MBps speed since RS232 port provides only 0,02 MBps speed and its old technology.

Please accept systems with RS232 port or USB port.

A: Accepted. Similar includes USB

38. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Latest generation system. The proposed model must be registered with no more than 3 years before the date of the submission of the bidding documents"

Please note that for medical device/system, regardless of the year, in which a model is launched, software and hardware revisions are performed periodically. Following these revisions a new version of the EC Declaration of Conformity it is issued in compliance with the specific EU Directives.

Therefore please confirm that a system which incorporates the latest software and hardware revisions and updates and has a EC Declaration of Conformity issued with no more than 3 years before the date of the submission of the bidding documents is compliant with the requirements of the Bid Data Sheet.

A: Not accepted. The issue is to have an updated system from no more than 3 years not as certification but as software and hardware (a device if is produced 5 years ago and is up to date as no other updates were issued, even it was certified 3 years ago is not acceptable).

39. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Turn-on system in up to 40 sec"

We would like to draw your attention to the fact that modern ultrasound systems have a sleeping mode available that enables quick activation of the system in less than 40 sec. We acknowledge the fact that for emergency units, an ultrasound system must have a short time for turning on, but it is essential for the good performance and functioning of the system to be kept in sleep mode and to be activated when needed, rather than turning it on and off all the time.

Thus please confirm that an ultrasound system which allows to be turned on from sleep mode in less than 40 sec is compliant with the requirements of the Bid Data Sheet. Accepting the proposed reformulation it will ensure a non-discriminatory regime, transparent and equal for all participants.

A: See answer to Q7. In order to ensure a non-discriminatory regime, transparent and equal for all participants we inform you that the requested time is between the start time after a complete shut down and the moment in which real time images are available. This is important in emergency department when as during longer evaluations the device loses battery power or restarting the device is required (as some examples)

40. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "The unit can be mobile or compact portable with Li-Ion battery (2 hours minimum autonomy) integrated for in hospital transport."

We kindly ask you to accept the following reformulation: "The unit can be mobile or compact with Li-ion battery (1.5 hours minimum autonomy) integrated for in hospital transport".

Please note that in emergency units the maximum duration for an ultrasound examination is usually not longer than 1.5 hours.

Thus by accepting our proposed reformulation it will ensure a non-discriminatory regime, transparent and equal for all participants.

A: Not accepted. See answer to Q. 16.

41. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Application programs:

a) abdominal, obstetrics, gynecology, urology
b) emergency for lung, transcranial Doppler (TCD)
d) pediatric and neonatal – transfontanelar
e) vascular, nerve, small parts: muscle, skeleton, joint, thyroid"

We would like to point out that all modern ultrasound systems have the possibility to save and customize more than 40 presets excluding the standard presets. These presets can be modify as needed for one specific examination and customize by an application specialist to meet the user's clinical requirements.

Thus we kindly ask you to confirm that an ultrasound system which allows setting up more than 40 customizable presets, including presets for abdominal, obstetrics, gynecology, urology, pediatric and neonatal – transfontanelar, vascular, nerve and small parts: muscle, skeleton, joint, thyroid is compliant with the requirements of the Bid Data Sheet.

A: Not accepted. The presets are generally fixed settings and factory generated as the applications are more dynamic covering a wider range of situations.

42. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Minimum 4 selectable transmit focus."

Since transmit focusing is static on beam former based systems (a single focus per transmit pulse), the resulting echoes which are being produced display good lateral resolution around the single point of focus. However lateral resolution degrades away from that focal point. This limitation can always be reduced if one is willing to sacrifice other image performance characteristics such as temporal resolution. With the purpose to acquire the best image detail at various depths, ultrasound manufacturers, have different values for this parameter.

Thus we kindly ask you to accept the following reformulation: "Selectable transmit focus: please specify."

A: Not accepted. During the evaluation of a critically ill patient it is necessary to change the position of the focus according to the suspected level of the lesion, this is the reason why we need this selectable focus and not an adjusted one (near/far).

43. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Software package for image auto optimization during processing (auto gain button; eventually tissue and border optimization technology) and post processing image."

We kindly ask you to accept the following reformulation: "Software package for image auto optimization during processing (auto gain button; eventually tissue and border optimization technology)."

Please note that auto optimization of stored images it's a time consuming process and useless, as it will not improve much the poor quality images which have already been acquired. Moreover modern ultrasound systems provide controls and automatic optimization that can be manipulated during the examination, ensuring a very good image quality for an optimum diagnostic and also reducing the examination and analysis time.

Thus please accept our request for the reformulation of this technical specification.

A: See answer to Q18.

44. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Image depth from 2 cm to a minimum of 30 cm 1 cm step transducer and frequencies dependent."

We kindly ask you to accept the following reformulation: "Image depth from 2 cm to a minimum of 28 cm 1 cm step transducer and frequencies dependent"

Please note that at a higher depth, the transducer needs to cover a longer distance, therefore the frame rate and the resolution are equally lower. Furthermore there is a very small difference, between the value requested in

the technical specifications of the Bid Data Sheet, and the value ensured by the ultrasound system we intend to offer, that does not introduce any kind of clinical limitations.
Thus please accept our request for the reformulation of this technical specification.
A: See answer to Q. 35.

45. Q. LOT VI – ULTRASOUND DOPPLER
Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "CD/DVD RW and USB ports for transfer data – images and reports."
We kindly ask you to accept the following reformulation: "CD/DVD RW or USB ports for transfer data – images and reports"
Since many modern ultrasound systems (especially portable ones, laptop-like) don't have DVD drives, the DICOM data is often distributed on a USB flash drive. USB flash drives allow users to save and import data much faster compared with average hard-disk drive and offer increased power efficiency. Hence USB flash drives offer distinct advantages over hard-disk drives when it comes to storing data.
Thus we kindly ask you to accept our proposed reformulation: "CD/DVD RW or USB ports for transfer data – images and reports".
A: See answer to Q. 19.

46. Q. LOT VI – ULTRASOUND DOPPLER
Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Distance – 3 simultaneous measurements."
We kindly ask you to confirm that through "simultaneous measurements" it is meant that more than 3 distance measurements are made on the same image.
A: Yes.

47. Q. LOT VI – ULTRASOUND DOPPLER
Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Linear array transducer – linear steer angle minimum +/- 20 degree."
We kindly ask you to accept the following reformulation: "Linear array transducer – linear steer angle minimum +/- 15 degree"
Please note that there is an insignificant difference of only 5 degrees between the value requested in the technical specifications of the Bid Data Sheet, and the value ensured by the ultrasound system we intend to offer. Moreover this difference does not introduce limitations in terms of the quality of images acquired and does not affect the examination from a clinical point of view. Furthermore, the aperture and the size of the Field of View (FOV) of the linear transducers, compatible with the ultrasound system we intend to offer, provide full coverage over the region of interest.
We want to point out that such a specification limits the competition by locking out Philips ultrasound systems, without showing any clear clinical benefit.
Thus please accept our request for the reformulation of this technical specification.
A: Reducing the linear steer angle will narrow the providing company's number so it will be limitative without any significant benefits in the quality of the image. The +/- 15 degrees is an arch that is included in the +/- 20 degrees requirement.

48. Q. LOT VI – ULTRASOUND DOPPLER
Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "For the phased array transducer the penetration will be in the range of 2 cm and at least 30 cm."
We kindly ask you to accept the following reformulation: "For the phased array transducer the penetration will be in the range of 2 cm and at least 28 cm"
Please note that at a higher depth, the transducer needs to cover a longer distance, therefore the frame rate and the resolution are equally lower. Furthermore there is a very small difference, between the value requested in the technical specifications of the Bid Data Sheet, and the value ensured by the ultrasound system we intend to offer, that does not introduce any kind of clinical limitations.
Thus please accept our request for the reformulation of this technical specification.

A: See answer to Q. 35.

49. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "Curved array transducer, multiple selectable transmit frequency approx. range 2-5 MHz – penetration at least 25 cm up to 30."

We kindly ask you to accept the following reformulation: "Curved array transducer, multiple selectable transmit frequency approx. range 2-5 MHz – penetration at least 25 cm up to 28"

Please note that at a higher depth, the transducer needs to cover a longer distance, therefore the frame rate and the resolution are equally lower. Furthermore there is a very small difference, between the value requested in the technical specifications of the Bid Data Sheet, and the value ensured by the ultrasound system we intend to offer, that does not introduce any kind of clinical limitations.

Thus please accept our request for the reformulation of this technical specification.

A: The penetration establishes the possibility to visually distinguish the different layers which are passed through by the ultrasound waves, otherwise the structures situated in an area which is not included in the penetration range are not seen as independent structures. By limiting the range higher limit will reduce the range of tissue layers which are clearly identified and this is unacceptable for obese patients or during more in-depth examinations.

50. Q. LOT VI – ULTRASOUND DOPPLER

Technical specification requirement from chapter "01. TECHNICAL CHARACTERISTICS - Basic unit:": "RS 232 port or similar."

We kindly ask you to confirm that an USB port is considered a similar RS 232 port.

A: USB is similar.

51. Q. LOT VI – ULTRASOUND DOPPLER

"The unit can be mobile or compact portable with Li-Ion battery (2 hours minimum autonomy) integrated for in hospital transport"

In order not to restrain participation of certain bidders, please reformulate the request as follows:

"The unit can be mobile or compact portable with Li-Ion battery (1 hour and 20 minutes minimum autonomy) integrated for in hospital transport"

The portable ultrasound we want to propose, with reduced dimensions and weight, has an internal battery with extremely fast recharging time. This autonomy is more than enough to insure the use of the ultrasound for scanning several patients.

A: See answer for Q. 16.

52. Q. LOT VI – ULTRASOUND DOPPLER

"High Resolution (non-interlaced) LCD minimum 15 inch monitor"

In order not to restrain participation of certain bidders, please consider qualified also equipment with a high resolution LCD monitor, of at least 13 inches.

The portable ultrasound we would like to offer in this tender has a color LCD display with a 15/9 ratio and high resolution. The resulting images will have higher resolution and enhanced contrast, a guarantee for high level clinical examination. More, the effective ultrasound image on the 13" monitor fills the entire monitor, resulting in the same size as the image displayed on the 15" monitor (which usually is just part of the entire 15" area). In this way, our solution offers the advantage of higher resolution images with same effective size and the smaller size of the display will not affect the equipment performances.

A: Not accepted as the monitor size establishes the size of the image not as pixels but as width and height. A smaller monitor reduces the area in which the image is displayed and as during an emergency evaluation we don't have an examination room with default position of the device so we are not able to have a fixed optimal distance between the screen and the doctor's eyes.

53. Q. LOT VI – ULTRASOUND DOPPLER

"Transducer for cardiac (phase array) use: Minimum 3 user-selectable transmit frequency in Doppler mode"

In order not to restrain participation of certain bidders, please reformulate the request as follows:

"Transducer for cardiac (phase array) use: Minimum 2 user-selectable transmit frequency in Doppler mode"

We consider that availability of two Doppler mode frequencies for the "phased array" probe is enough. We are proposing a probe with high number of elements, high frame rate and scanning depth, parameters which are more important for the quality of the ultrasound scan then the number of frequencies selectable in Doppler mode.

A: Accepted.

54. Q. LOT IV – PORTABLE VENTILATION EQUIPMENT

Technical characteristics according to tender book:

"Display of the following parameters: expired volume, minute volume"

Request for clarification:

Minute volume derives from tidal volume and respiratory rate and can be calculated multiplying these two parameters. Expired volume is typically monitored by end-tidal capnography devices and in the technical characteristics you don't ask for a device that can monitor end-tidal CO2. Therefore, please remove your request of expired volume, minute volume to be displayed and/or change it with minute volume and respiratory rate to be displayed.

A: The expired volume as parameter is measured by the flow sensor and is not calculated. The request remains as it was stated.

55. Q. LOT V: Monitor (ECG, Respiration, SpO2, NIBP)

Regarding the technical request "Monitor automatically displays all physiological parameters available and has a capacity of min 3 waveform traces", please accept the alternative of "2 or 12 waveform". Considering the fact that it has a capacity of 12 waveform traces, the device can be considered superior

A: Not accepted. Our request means three simultaneous waveforms displayed. This is not similar with displaying 2 even if the waveforms could be selected from 12.

56. Q. LOT V: Monitor (ECG, Respiration, SpO2, NIBP)

Regarding the technical request "Automatically set patients alarm limits based on pre-defined user selections or the individual patient. User changeable settings", please accept the alternative of "manual alarm settings". This does not affect the performance of the device. For every patient we must have custom alarm limits that are manually set by the medical staff

A: Not accepted. The automatization allows certain default values which makes easier to set up the device when changing the monitored patient. To set manually for each patient all alarm limits is practically impossible in an emergency department where the turn-over of the patients is higher than in a regular department.

57. Q. LOT V: Monitor (ECG, Respiration, SpO2, NIBP)

Regarding the technical request "Automatically set patient's alarm limits based on default settings. User changeable settings if necessary to reflect pre-defined user selections or the individual patient", please accept the alternative of "manual alarm settings". This does not affect the performance of the device. For every patient we must have custom alarm limits that are manually set by the medical staff.

A: See answer for Q. 56.

58. Q. LOT IV Portable Ventilation Equipment - In the chapter "Technical Characteristics" is required "Volume controlled ventilation with fixed mandatory minute."

Please accept similar ventilations mode, such as VCV with fixed tidal volume. As we could demonstrate below, there is no difference between the ventilation modes.

VT x f = MV

MV : f = VT

A: Accepted as compliant

59.Q. LOT IV Portable Ventilation Equipment - In the chapter "Technical Characteristics" is required "Inspiratory pressure limit: min range 20 - 60 mbar."
Please accept as compliant a portable ventilator featuring the Inspiratory pressure upper limit up to 55 mbar, but with the much lower limit of 5 mbar, which may be more useful for the specialized personnel.
A: Accepted as compliant

60. Q. LOT IV Portable Ventilation Equipment - In the chapter "Minute volume: min range 0,5 – 45 l/min."
Please accept as compliant a portable ventilator featuring a upper threshold of 42 l/min, but with a much lower threshold starting point of 0,2 l/min., which may be more useful for the specialized personnel.
A: Accepted.

61. Q. LOT IV Portable Ventilation Equipment - In the chapter "Response pressure of demand valve: - 1 mbar."
Please remove this requirement as it is a feature of a particular portable ventilator manufacturer and restricts access to the procedure and free competition.
A demand valve is used for resuscitation to deliver a manual triggered gas flow (e.g. oxygen) via mask or mouthpiece.
It is also used for diving.
With our high-class ICU ventilator the operator can select a real ventilation or an oxygen therapy, which is not comparable with such a simple "finger-tip flow valve" for connection to a gas cylinder.
A: As several other uses are defined for the demand valve different than diving and bag-mask ventilation we will keep this requirement with an accepted change as follows: Response pressure of demand valve: -1 mbar or other similar-in-effect triggers. Please see article no. 10 of the amendment no. 2 to the bidding documents.

62. Q. LOT IV Portable Ventilation Equipment - In the chapter "Maximum flow delivered: max 100 l/min."
Please accept as compliant a portable ventilator featuring a maximum settable flow delivered up to 200 l/min.
A: Accepted. Please see article no. 11 of the amendment no. 2 to the bidding documents.