MINISTRY OF HEALTH
PROJECTS MANAGEMENT UNIT

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Our ref.no: 6350/02.02.2017

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 anesthesia workstations for the anesthesia and intensive care units - ICB No. G/C1/5.1

Dear Mrs. /Mr.

Please find attached the following documents:

1. Addendum no. 3 to the Bidding Documents for Procurement of anesthesia workstations for the anesthesia and intensive care units – ICB No. G/C1/5.1, consisting of 2 pages that include the amended clause/technical specifications as a result of the responses given to the requests for clarifications received;
2. The responses to the clarification requests related to the provisions of the bidding documents – Clarification no. 1 (11 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 Addendum no. 3 to the Bidding Documents and the answers to the clarification requests (21 pages).

All changes related to the technical specifications 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 and the provisions of Addendum no. 3 to the Bidding Documents in preparing your bid.

Considering the above information please to take into consideration the *deadline for bids submission* that was establish through Addendum no. 2 dated January 19th, 2017 for *February 14th, 2017, 12:00 hour's local time*.

Yours sincerely,

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 ANESTHESIA WORKSTATIONS FOR THE ANESTHESIA AND INTENSIVE CARE UNITS - ICB NO. G/C1/5.1

Under this addendum it is agreed that the provisions of the Bidding Documents, including the provisions of Addendum no. 1 dated December 30th, 2016 and Addendum no. 2 dated January 19th, 2017, shall be amended as follows:

Article no. 1:
Technical specification for Lot no. I, characteristic will be changed as follows:
Shall read: "integrated writing surface that does not use extra space outside the floor projection of the main chassis of the anesthesia machine."
Instead of: "integrated writing desk, concealable"

Article no. 2:
Technical specification for Lot no. II and Lot no. III, monitor characteristics (incl. art. 23 and 24 of Addendum no. 2) will be updated and
Shall read: "Parameter placing on screen configurable by the user: Selectable position of each parameter monitored on screen, Selectable color of waveforms, the operator can save different configurations of the screen (curve position on screen, curve type etc.) to be subsequently loaded, the operator can choose from display of parameter boxes instead of waveform at the screen base the operator can choose display of minitrend boxes near the waveforms displayed in real time"
Instead of: "Parameter placing on screen configurable by the user: Selectable position of each parameter monitored on screen, Selectable color of waveforms, Optional display of parameter boxes instead of waveform at the screen base, Optional display of minitrend boxes near the waveforms displayed in real time"

Article no. 3:
Technical specification for all 3 lots – 8. Detailed requirement; will be changed as follows:
Shall read: "Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 4-20 mbar (cmH2O) in increments of 1 mbar, with the possibility of no PEEP (0 mbar), frequency 5- 60 bpm, I:E ratio 1:4 – 2:1, inspiratory flow 0 – 120 L/min"
Instead of: "Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 0 -20 mbar (cmH2O), that can be increased by a minimum of 5 mbar (cmH2O), frequency 5 -60 bpm, I:E ratio 1:4-2:1, inspiratory flow 0-120 L/min"

Article no. 4:
Technical specification for all 3 lots – 13. Other components; will be changed as follows:
Shall read: "The monitor will have the possibility of selection of alarm levels"
Instead of: "Single key on the front panel of the monitor which can be used to select alarm levels"

Article no. 5:
Technical specification for all 3 lots – 13. Other components, Electrocardiogram – EKG will be changed as follows:
Shall read: "Simultaneous monitoring, including the ST segment, in 12 leads"
Instead of: "simultaneous monitoring, including the ST segment, in 12 leads using a cable with maximum 6 wires"

Article no. 6:
Technical specification for all 3 lots – 13. Other components, Electrocardiogram – EKG will be changed as follows:
Shall read: "simultaneous display of any 2 of the 12 leads on the main screen"
Instead of: "simultaneous display of any 3 of the 12 leads on the main screen"

Article no. 7:
Technical specification for Lot no. II and Lot no. III – 8. Detailed requirement: "(n) Automatic, pressure and time controlled, allowing the patient's spontaneous breathing with rapid and sudden discharge of pressure, within a preset time" **will be deleted.**

Article no. 8:
Technical specification for Lot no. II and Lot no. III – 9. Displayed and measured parameters, will be changed as follows:
Shall read: "Monitor allowing the display of trends (tabular of graphic) simultaneously with the three waveforms displayed in real time"
Instead of: "Monitor allowing the display of its minitrends simultaneously with the three waveforms displayed in real time"

Article no. 9:
Technical specification for Lot no. II and Lot no. III – 9. Displayed and measured parameters: "Display of vaporizer setting and its filling level" **will be deleted.**

Article no. 10:
Technical specification for Lot no. II and Lot no. III – 10. Safety requirements and alarms: "Display of alarm message when the vaporizer is empty" **will be deleted.**

All other parts, clauses and provisions of the original Bidding Documents that are not amended as per the articles above and the Addendum no. 1 provisions shall remain valid and unchanged.

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

CLARIFICATIONS NO. 2 – Bidding Documents ICB No. G/C1/5.1 "Procurement of anesthesia workstations for the Anesthesia and Intensive Care Units" – dated November 25th, 2016.

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

1. Q. "as company interested in participating with a bid in the Project, WHEREAS
   1) According to ITB 7.1 from Section I of the Bidding Procedure – Instructions to Bidders, a Bidder may require clarification of the Bidding Documents by contacting the Purchaser in writing. Where clarifications result in changes to the essential elements of the Bidding Documents, the Purchaser shall amend the Bidding Documents following the procedure under ITB 8 and ITB 22.2;
   2) According to ITB 8.3 from Section I of the Bidding Procedure – Instructions to Bidders, to give prospective Bidders reasonable time in which to take an addendum into account in preparing their bids, the Purchaser may, at its discretion, extend the deadline for the submission of bids, pursuant to ITB 22.2;

we hereby submit to your attention a request for extension of the deadline for the submission of the bids in the Awarding Procedure with minimum fifteen (15) working days from the date the answer of clarifications will be received, by amending the Bidding Documents in accordance with ITB 8.

In fact, our aim is to participate in the Awarding Procedure and commenced preparation of our bid. As we felt the need for more clarity on certain technical and legal aspects of the Bid, on December 20, 2016 we have submitted a clarification request letter to the Ministry of Health – the Project Management Unit. While:

- It is a requirement under ITB 7.1 of Section II – Bid Data Sheet that the Purchaser responds in writing to any request for clarification received no later than twenty-one (21) days prior to the deadline for submission of bids;
- Our clarification request letter has been sent on December 20, 2016 therefore observing the timeline provided in the Bid Data Sheet;
- By the time of sending this request, we have not received any response to our letter, and answers expected to our clarification requests are essential in preparing our bid, both from technical specifications and legal perspective;
- The current deadline for submission of the Bids is January 25, 2017, making it impossible for us to prepare our bid in less than eight (8) working days prior to submission deadline as we need to obtain complete answers to our clarifications first in order to be able to assess whether or not the Bid requirements are clear and sufficient enough and finalize our bid in such a manner to achieve the technical specifications and your other requirements in the Bid;

  we kindly ask you to issue an addendum to be part of the Bidding Documents, in which you extend the submission date of the Bids to at least fifteen (15) working days from the date the answer of clarifications will be received.

A: The request was received by the PMU prior to the issuance of Addendum no. 2 to the Bidding documents. The deadline for bid submission was extended through Addendum no. 2 with 20 days from January 25th, 2017 to February 14th, 2017.

2. **"3. Qualification requirements (ITB 36)**

a) During the past 5 years the Bidder must have completed at least two (2) contracts, together cumulating the value of the bid price offered, involving supply of anesthesia equipment provision of - either directly or through an authorized local Agent"

- Please clarify if there is a limit for the maximum number of contracts completed during the past 5 years that can be cumulated. Our understanding is that "At least two (2) contracts" means that it is allowed to cumulate more than 2 contracts.

A: The bidder must present at least two (2) contracts, ***together cumulating the value of the bid price offered***, involving supply of anesthesia equipment 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. It is not allowed to cumulate more than 2 contracts in order to comply with the qualification requirement.

- Please also clarify if "the past 5 years" are calculated from the bid submission date (February 14 2017) or from the issue date of the bid (November 25, 2016).

A: The past 5 years are calculated from the bid submission date (February 14th, 2017).

3. **"3. Qualification requirements (ITB 36)**

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 11,000,000 for Lot no. I;
- EUR 8,000,000 for Lot no. II;
- EUR 6,000,000 for Lot no. III;

or its equivalent over the past three (3) years (i.e. 2013, 2014, 2015).

- Please clarify if the annual average turnover can be calculated starting from year 2014 (years 2014, 2015 and 2016).

A: Yes. "Over the past three (3) years" can be considered 2014, 2015, 2016 if the bidder has the financial statement audited or the balance sheet registered at the relevant authorities.

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

1. Q. ItemI 1. Standard Anesthesia Machine (For all 3 lots)
Initial Criteria: Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 0 -20 mbar (cmH2O), that can be increased by a minimum of 5 mbar (cmH2O)
Requirements: The request "PEEP 0 -20 mbar (cmH2O)" is restrictive for many producers on the market and indicates a certain one (Draeger's Fabius series and Primus Anesthesia machine). Please accept to other solutions such as PEEP 3-20 mbar (cmH2O).

A: Accepted for all 3 lots. Recent studies (Severgnini et al. Anesthesiology 2013; 118(6)) have demonstrated that the use of PEEP during general anesthesia is associated with better patient outcome, early extubation and decreased incidence of postoperative pulmonary complications. Moreover the recently presented results of the LAS VEGAS trial conducted by the European Society of Anaesthesiology (http://www.esahq.org/research/clinical-trial-network/completed-trials/las-vegas) have demonstrated the same results in over 10.000 patients in 147 European hospitals. When the results of this very large trial will be published in the following months the use of PEEP during surgery that requires mechanical ventilation of the lungs will become standard of care beyond a doubt. On the other hand we have to remember that there are some special circumstances, especially in the hemodynamically instable patient and thoracic surgery when we have to ventilate the patient's lungs for short periods of time without applying PEEP. Although these clinical situations are not that often, these patients must benefit from the most up-to-date and evidence-based management as any patient. So the possibility of mechanically ventilating the patient's lungs using no PEEP is mandatory. We also consider that if PEEP is applied a minimum of 4 mbar is necessary in order for a clinical benefit to be observed. Our criteria "PEEP 0 -20 mbar (cmH2O),that can be increased by a minimum of 5 mbar (cmH2O)" referred to this two clinical situations: the machine should be able to ventilate both with 0 mbar PEEP or using PEEP range 4 mbar to 20 mbar. Because we are not native English speakers we consider that this is only a misunderstanding of what we wanted to state.
In order to make things cleared we rephrase this criteria as follows:
"Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 4-20 mbar (cmH2O) in increments of 1 mbar, with the possibility of no PEEP (0 mbar), frequency 5- 60 bpm, I:E ratio 1:4 – 2:1, inspiratory flow 0 – 120 L/min"
Please see article no. 3 of Addendum no. 3 to the bidding documents.

2. Q. Item I 1. Standard Anesthesia Machine (For all 3 lots)
Initial Criteria: Multi-parameter monitor
- Single key on the front panel of the monitor which can be used to select alarm levels
Reformulation Proposal/Requirements: This request clearly indicates one producer (Draeger), should read "monitor allows user to select alarm levels" which would be applicable to most of the major producers.

A: Accepted for all 3 lots. This requirement will be changed as follows:"**The monitor will have the possibility of selection of alarm levels**".
Please see article no. 4 of Addendum no. 3 to the bidding documents.

3. Q. ItemI 1. Standard Anesthesia Machine (For all 3 lots)
Initial Criteria: Electrocardiogram – EKG

- Simultaneous monitoring, including the ST segment, in 12 leads using a cable with maximum 6 wires.
Reformulation Proposal/Requirements:
This request clearly indicates certain producers, please accept other solutions such as "Simultaneous monitoring, including the ST segment, in 12 leads using a cable with maximum 6 wires as optional."

A: Perioperative myocardial ischemia is one of the most feared complications in patients undergoing surgery under general anesthesia with a high incidence of mortality and morbidity (Landesberg et al. Circulation 2009; 119). This topic has been a "hot topic" for anesthesiologists in the last decade. To these date two specific guidelines have been published by ACC/AHA and endorsed by ASA and by ESC/ESA. To quote this guidelines: "Continuous ECG monitoring is recommended for all patients undergoing anaesthesia. The patient should be connected to the ECG monitor before induction of anaesthesia or institution of a regional block. The *duration of ST-segment changes correlates positively with the incidence of perioperative myocardial infarction*; (...) It was also shown that ECG monitoring *with fewer leads (as few as three) has lower sensitivity than monitoring with 12 leads and there is a statistically significant association*, independent of perioperative troponin values, between perioperative ischemia on a 12-lead ECG and long-term mortality. **Thus, 12-lead ECG monitoring is recommended especially in high-risk patients**". We are willing to accept that the number of maximum EKG wires is not fundamental **BUT the multiparameter monitor should have the possibility of monitoring all 12 EKG leads.**
The technical specification will be changed as follows: "**Simultaneous monitoring, including the ST segment, in 12 leads.**"
Please see article no. 5 of Addendum no. 3 to the bidding documents.

4. Q. Item I 1. Standard Anesthesia Machine (For all 3 lots)
Initial Criteria: Electrocardiogram – EKG
- Simultaneous display of any 3 of the 12 leads on the main screen
Reformulation Proposal/Requirements:
Due to the fact that clinically display of 2 leads is enough, please accept to rephrase as "Simultaneous display of any 2 of the 12 leads on the main screen."

A: Accepted for all 3 lots. The technical specification will be changed as follows: "Simultaneous display of any 2 of the 12 leads on the main screen"
Please see article no. 6 of Addendum no. 3 to the bidding documents.

5. Q. Item I 1. Standard Anesthesia Machine
Initial Criteria: requires support C.O and BIS for 10" display monitor
Requirement: Please accept as a solution for display monitor "requires support C.O and optional BIS for 10" display monitor"
A: Not accepted. Intraoperative monitoring has been the subject of many international and national guidelines including ASA, GB, Austria etc. All these guidelines state that in the case of high risk surgical patients advanced cardiovascular and anesthesia depth monitoring should be applied in order to improve patient outcome: "Depth of anaesthesia monitoring is recommended during transfer of patients receiving TIVA and neuromuscular blockade" (Anaesthesia 2016; 71). Having this in mind we do not consider that either CO monitoring or BIS should be optional.
Moreover we would like to remind you that the multiparameter monitor should be able to display on at least 5 channels either one of the 8 monitoring parameters. We do not state that ALL these should be displayed at the same time. The anaesthesiologist should have the possibility to choose from any one of

these. On the second hand the monitor is not to have 10" but at least and not 5 channels but at least 5 channels. All bidders can present an offer with a larger monitor and a higher number of channels.

6. Q. Item : II.1 High performance anesthesia machine type I with advanced cardiovascular-monitoring (Lot II & LOT III)

Initial Criteria: Ventilation/breathing modes:
(n) Automatic, pressure and time controlled, allowing the patient's spontaneous breathing with rapid and sudden discharge of pressure, within a preset time
Requirement: This request clearly indicates one producer (Draeger Perseus A500). Taking into consideration that APRV is not commonly used in anesthesia machine but in ICU, this request is restrictive to most of the producers. In order to not limit the possibility of different companies to participate in the bidding, please accept the deletion of this technical requirement or adopt other solutions.

A: Accepted. The technical specification"Automatic, pressure and time controlled, allowing the patient's spontaneous breathing with rapid and sudden discharge of pressure, within a preset time" of Lot no. II and Lot no. III will be deleted.
Please see article no. 7 of Addendum no. 3 to the bidding documents.

7. Q. Item : II.1 High performance anesthesia machine type I with advanced cardiovascular-monitoring **(Lot II & LOT III)**

Initial Criteria: Monitor allowing the display of its minitrends simultaneously with the three waveforms displayed in real time
Requirements: This request indicates clearly to one producer (Draeger Perseus A500). Taking into consideration that minitrends are not commonly used for anesthesia machines, please accept to other solutions such as "Monitor allowing the display of its tabular or graphic trends"

A: ACCEPTED. This is clearly a misunderstanding due to the fact that we are not native english speakers. The possibility of displaying trends is crucial for safe anaesthesia care when anaesthesia records must be consulted later during surgery or even after surgery so that trends offer a better view of the registered parameters. The technical specification will be changed as follows: "**Monitor allowing the display of trends (tabular of graphic) simultaneously with the three waveforms displayed in real time.**"
Please see article no. 8 of Addendum no. 3 to the bidding documents.

8. Q. Item : II.1 High performance anesthesia machine type I with advanced cardiovascular-monitoring (Lot II & LOT III)

Initial Criteria: Display of vaporizer setting and its filling level
Initial Criteria: Display of alarm message when the vaporizer is empty
Requirement: As per our knowledge, there is no other producer can fulfill these requests except one (Draeger Perseus A500). Please accept other solutions or eliminate these two requirements.

A: Accepted for Lot no. II and Lot no. III. To our knowledge there are at least two providers that offer this technical solution but in order to offer the possibility of all bidders to take part, these technical specifications will be deleted.
Please see article no. 9 and no. 10 of Addendum no. 3 to the bidding documents.

9. Q. Item : II.1 High performance anesthesia machine type I with advanced cardiovascular-monitoring (Lot II & LOT III)

Initial Criteria: Monitored parameters, included and/or modular

Reformulation Proposal/Requirements: The requests of including "oxygenation calculation (DO2, VO2), Transpulmonarythermodilution cardiac output, anesthesia depth morning (BIS) for one monitor" is obviously good for Draeger and excludes all other manufacturers from submitting competitive offer. Please put these request as optional.

A: Not accepted. Since more than 10 years (2005) monitoring of cardiac output and anaesthesia depth are considered standard of care in high risk patients. International guidelines state that in the case of high risk surgical patients advanced cardiovascular and anesthesia depth monitoring should be applied in order to improve patient outcome: "Depth of anaesthesia monitoring is recommended during transfer of patients receiving TIVA and neuromuscular blockade" (Anaesthesia 2016; 71). Oxygenation calculation (DO2, VO2) are derived from invasive cardiac output monitoring and do not required other special techniques or hardware but only a dedicated software. **To our knowledge there are at least 3 manufacturers that offer this parameters.**

10.Q. **Lot I: Standard anesthesia machine**

"- Measured parameters: Cardiac Output – CO, Cardiac Index – CI, Stroke Volume - SV and SVi"
- Calculated parameters:….."

- Regarding the cardiac output measurement using the thermodilution method we consider that the only measured parameter is the Cardiac Output – CO. The other parameters, Cardiac Index – CI, Stroke Volume - SV and Svi are calculated and should be diplayed in the Calculated parameters menu. Please clarify if it is allowed to display Cardiac Index – CI, Stroke Volume - SV and Svi in the Calculated parameters table.

A: Accepted for all 3 lots. According to the laws of physics and haemodynamics cardiac output and cardiovascular pressures (right atrium, pulmonary artery etc) are the only measured parameters by thermodilution and all the rest are measured. We accept and CI, SV and SVI may be displayed in the calculated parameters table.

11.Q. **Lot II: High performance anesthesia machine type I with advanced cardiovascular -monitoring**

"- Measured parameters: Cardiac Output – CO, Cardiac Index – CI, Stroke Volume - SV and SVi"
- Calculated parameters:….."

- Regarding the cardiac output measurement using the thermodilution method we consider that the only measured parameter is the Cardiac Output – CO. The other parameters, Cardiac Index – CI, Stroke Volume - SV and Svi are calculated and should be diplayed in the Calculated parameters menu. Please clarify if it is allowed to display Cardiac Index – CI, Stroke Volume - SV and Svi in the Calculated parameters table.

A: See the answer to question no. 10.

12.Q. **Lot III: High performance anesthesia machine type II with advanced neuro-monitoring**

"- Measured parameters: Cardiac Output – CO, Cardiac Index – CI, Stroke Volume - SV and SVi"
- Calculated parameters:….."

- Regarding the cardiac output measurement using the thermodilution method we consider that the only measured parameter is the Cardiac Output – CO. The other parameters, Cardiac Index – CI, Stroke Volume - SV and Svi are calculated and should be diplayed in the Calculated parameters menu. Please clarify if it is allowed to display Cardiac Index – CI, Stroke Volume - SV and Svi in the Calculated parameters table.

A: See the answer to question no. 10.

13. **Regarding the amendment for PEEP values** adopted by Article 28 of Addendum No. 2 related to - ventilation parameter settings, respectively "Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 0 -20 mbar (cmH2O), that can be increased by a minimum of 5 mbar (cmH2O), frequency 5- 60 bpm, I:E ratio 1:4 – 2:1, inspiratory flow 0 – 120 L/min"

We would like to draw your attention that the change of the technical requirement regarding PEEP from 4-20 mbar to PEEP 0-20 mbar could limit the fair and transparent participation of multiple bidders in this tender.

During anesthesia procedure it is important to use a minimum PEEP of 4 mbar (cmH2O) to ensure that the anesthetic agents will reach into the lungs, at the alveoli level and the gas exchange will be done. As an example, the Sevoflurane molecule is heavier than oxygen molecule and it requires a driven pressure to allow this process to be more efficient.

According to your answer to clarification request no. 55 from "Clarifications no. 1" document, you refer to the fact that: "in Romania, premature newborns are taken care of in designated center and surgical interventions in this group are not routinely performed. **In rare and urgent cases these patients may be ventilated using neonatal intensive care unit ventilator and receive intravenous anesthesia**".

This means that there is not a common practice during majority of operating procedures to use a PEEP of 0, as it refers to very rare situations which can be addressed through different therapeutically methods, like the use of a patient ventilator.

Based on the above facts, we kindly ask you to keep the **initial** technical requirement regarding PEEP range **for all 3 lots**: "**Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 4 -20 mbar (cmH2O), that can be increased by a minimum of 5 mbar (cmH2O), frequency 5- 60 bpm, I:E ratio 1:4 – 2:1, inspiratory flow 0 – 120 L/min".**

Also, according to tender procedures, the answers to clarification requests should give access to increased number of participants and not limit the competition.
The initial technical specification was enabling fair competition while the new technical request could limit the fair and transparent participation of multiple bidders in this tender, by introducing this PEEP value request which is very rare used in the common medical practice.

A: See the answer to question no. 1.
In regard to our previous answer" Premature newborns are taken care of in designated centers in Romania and surgical interventions in this group are not routinely performed. In rare and urgent cases these

patients may be ventilated using a neonatal intensive care unit ventilator and receive intravenous anesthesia." This was referred to the request of very small tidal volumes not to PEEP!! As previously measured there are sufficient surgical procedures that require that PEEP should not be used for small periods of time.
In regard to your comment: „During anesthesia procedure it is important to use a minimum PEEP of 4 mbar (cmH2O) to ensure that the anesthetic agents will reach into the lungs, at the alveoli level and the gas exchange will be done. As an example, the Sevoflurane molecule is heavier than oxygen molecule and it requires a driven pressure to allow this process to be more efficient." We would like to assure you that in Romania the driving pressure for the delivery of anaesthetic agent is achieved during inspiration and not at end expiration, although the use of PEEP aids in this process.

14. Regarding **"Clarification no. 1"** document, **question 51, point (n):** "Automatic, pressure and time controlled, allowing the patient's spontaneous breathing with rapid and sudden discharge of pressure, within a preset time" - Please clarify if this ventilation mode is similar with APRV (Airway Pressure Release Ventilation), your answer was: 'Yes, … is similar to APRV".
We kindly ask you to take into consideration and accept to remove this technical specification "Automatic, pressure and time controlled, allowing the patient's spontaneous breathing with rapid and sudden discharge of pressure, within a preset time" from LOT 2 and LOT 3.
We would like to draw your attention that the APRV mode is characteristic for only one manufacturer (Draeger) and a similar mode with this one is not common for other anesthesia machine manufacturers. Such a technical specification will eliminate the fair competition for these lots as only one manufacturer can fulfill it.
The APRV mode and other similar ventilation modes are mainly used in the ICU environment.
Please allow us to highlight that the APRV mode or a similar one is not used in common practice, there are very rare situations when this mode or a similar one can be used.
Use of APRV mode or similar one during the surgical procedure may cause changes in hemodynamic stability of the patient, especially for those with lungs problems.
For LOT 2 and LOT 3, we kindly ask you to remove this technical requirement, as it is specific to only one manufacturer and will not allow multiple bidders' participation to the tender.

A: See the answer to question no. 6.

15. Furthermore, we reached the conclusion that there are some inconsistencies in between these two documents. Please allow us to present them for assuring a clear view of all details:

- Regarding "Addendum no. 2", please note that there is an inconsistency between the answer from Article no. 11 and document "Clarification no. 1" answer to Q. 21.

In "Clarification no. 1", Q. 21 (page 8) are amended all 3 lots while Article no.11 of "Addendum no. 2" is referring only to LOT 1.
Please confirm that your answer is amending all 3 lots.

A: Yes. The answer to the clarification no. Q. 21 is amending all 3 lots. The technical specification grid was amended in accordance with the answer.

- Regarding "Addendum no. 2", please note that there is an inconsistency between the answer from Article no. 13 and document "Clarification no. 1" answer to Q. 23.

In "Clarification no. 1", Q. 23 (page 8) are amended all 3 lots while Article no.13 of "Addendum no. 2" is referring only to LOT 1.

Please confirm that your answer is amending all 3 lots.

A: Yes. The answer to the clarification no. Q. 23 is amending all 3 lots. The technical specification grid was amended in accordance with the answer.

- Regarding "Addendum no. 2", please note that there is an inconsistency between the answer from Article no. 34 and document "Clarification no. 1" answer to Q. 65.
In "Clarification no. 1", Q. 65 (page 23) are amended all 3 lots while Article no.34 of "Addendum no. 2" is referring only to LOT 2 and LOT 3.
Please confirm that your answer provided in Q.65 is amending all 3 lots.

A: Yes. The answer to the clarification no. Q. 65 is amending all 3 lots.
Please see article no. 1 of Addendum no. 3 to the bidding documents.

- Regarding "Clarification no. 1", your answer to Q.50 (page 15) refers to LOT 3 and the answer is the same as for Q. 45: "The operator can save different configuration of the screen (curve positions on the screen, curve type etc.) to be subsequently loaded".

Please note that the above modification related to Q.50 it is not included in ADDENDUM No 2. Also, this amended technical requirement from Q.45 & Q.50 is not modified in the technical specifications for LOT 2 and LOT 3.

A: Yes. The error has been corrected.
Please see article no. 2 of Addendum no. 3 to the bidding documents

16. Item I.1 Standard anesthesia machine - c. Anesthesia machine ventilator
Subsection 8. Detailed requirement: Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 0 -20 mbar (cmH2O), that can be increased by a minimum of 5 mbar (cmH2O)
There is no clinical relevance for PEEP 0.please accept also a PEEP: Off, 3 to 30 cmH2O (increments of 1 cmH2O).

A: See the answer to question no. 1.

17. Item I.1 Standard anesthesia machine - c. Anesthesia machine ventilator
Subsection 13. Physical characteristics: Multi-parameter monitor - Single key on the front panel of the monitor which can be used to select alarm levels.
So as not to restrain competition please also accept other modalities to select alarm levels such as touch screen.

A: See the answer to question no. 2.

18.<u>High performance anesthesia machine type I with advanced cardiovascular-monitoring.</u> Technical Characteristics
Subsection 8. Detailed requirement: c. Anesthesia machine ventilator Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 0 -20 mbar (cmH2O), that can be increased by a minimum of 5 mbar (cmH2O),

There is no clinical relevance for PEEP 0. please accept also a PEEP: Off, 3 to 30 cmH2O (increments of 1 cmH2O).

A: See the answer to question no. 1.

19. High performance anesthesia machine type I with advanced cardiovascular-monitoring. Technical Characteristics

Subsection 9. Displayed and measured parameters

- Display of vaporizer setting and its filling level
- Display of alarm message when the vaporizer is empty

As per our knowledge, there is only one producer that can fulfill this request. Please accept to eliminate these requests or accept visual display of the level of filling of the vaporizer.

A: See the answer to question no. 8.

20. High performance anesthesia machine type I with advanced cardiovascular-monitoring. Technical Characteristics

Subsection 13. Physical characteristics

- Multi-parameter monitor
  Single key on the front panel of the monitor which can be used to select alarm levels

So as not to restrain competition please also accept other modalities to select alarm levels such as touch screen.

A: See the answer to question no. 2.

21. High performance anesthesia machine type II with advanced neuro-monitoring - Technical Characteristics:

Subsection 8. Detailed requirement

- c. Anesthesia machine ventilator
  Equipment allowing adjustment of the ventilation parameters (minimum intervals): tidal volume 20 – 1400 ml, PEEP 0 -20 mbar (cmH2O), that can be increased by a minimum of 5 mbar (cmH2O),

There is no clinical relevance for PEEP 0. please accept also a PEEP: Off, 3 to 30 cmH2O (increments of 1 cmH2O).

A: See the answer to question no. 1.

22. High performance anesthesia machine type II with advanced neuro-monitoring - Technical Characteristics:

Subsection 9. Displayed and measured parameters

- Display of vaporizer setting and its filling level
- Display of alarm message when the vaporizer is empty

As per our knowledge, there is only one producer that can fulfill this request. Please accept to eliminate these requests or accept visual display of the level of filling of the vaporizer.

A: See the answer to question no. 8.

23. High performance anesthesia machine type II with advanced neuro-monitoring - Technical Characteristics:

Subsection13. Physical characteristics

- Multi-parameter monitor

  Single key on the front panel of the monitor which can be used to select alarm levels

So as not to restrain competition please also accept other modalities to select alarm levels such as touch screen.

A: See the answer to question no. 2.

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