International Organization for Migration (IOM)
The UN Migration Agency

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Addendum No 6

IFB No.: 2021/MED/03/IC

This Addendum No. 6 is issued to amend information provided in the Revised Bidding Document – Medical Equipment for ICU units for the **"Supply and delivery of Medical Equipment for ICU units"** issued to the prospective bidders. In detail:

Section III. Technical Specifications

The Technical Specifications in the Revised Bidding Document – Medical Equipment for ICU units have been replaced for Item No.2 - **MECHANICAL VENTILATOR (ICU)** and for Item No.3 - **MONITOR (ICU).** You are kindly requested to take into consideration the **"Section III – Technical Specifications (Revision 21/04/2021)"** prior of submission of your bid. Hence the second revised **"Section III – Technical Specifications (Revision 21/04/2021)"** should be submitted with your quotation. Interested bidders should regularly follow the IOM website https://greece.iom.int/el/tenders for any possible addenda and clarifications.

PROJECT TITLE : Supply and delivery of Medical Equipment for ICU units Item Code : 2 Item Description : **MECHANICAL VENTILATOR (ICU) – Second Revision of specifications dated 21/04/2021**	
Manufacturer : _____ Origin : _____ Model : _____	
PURCHASER'S SPECIFICATIONS	**BIDDER'S SPECIFICATIONS**
2. MECHANICAL VENTILATOR (ICU) 1. Respirator with volume and pressure ventilation suitable for adults and children for use in Intensive Care Unit. Should consist of: • Basic unit • Wheeled cart with braking system, of the same construction company with the basic unit and humidifier support socket. • Structured patient tube suspension arm 2. Operates under mains voltage (230V / 50Hz) and is equipped with a built-in rechargeable battery that provides a range of at least 60 minutes.	

3. Should operate powered by a central oxygen supply (with a pressure of about 2.5 - 6 bar) as well as with compressed air either from a central supply (with a pressure of about 2.5 - 6 bar) or by a built-in turbocharger. 4. It shall have a color touch screen of at least 15 ", which can be rotated in all directions and detached from the main body of the ventilator. Also be able to display at least: • Four (4) waveforms simultaneously (pressure, flow, volume and CO2 (if selected) over time) • Loops (volume-pressure, flow-volume and flow-pressure) • Prices and trends of the operator's choice. 5. Should be able to configure different screen displays according to the needs of the users which are easily and quickly eligible, depending on the treatment. 6. It is necessary to perform the following models of mandatory and automatic ventilation: • Compulsory controlled and controlled ventilation, volume and pressure (VCV, VCV-AC, PCV, PCV-AC) • Synchronous intermittent forced volume and pressure ventilation (VC-SIMV, PC-SIMV) • Two-phase pressure ventilation (BIPAP) • Continuous positive pressure ventilation with or without pressure support (CPAP / PS) • Continuous positive pressure ventilation with or without tumor support (CPAP / VS) • Guaranteed volume ventilation with the lowest possible pressure with or without synchronization and support pressure. • Ventilation to control the volume per minute, allowing the number of mechanical breaths to be adjusted automatically based on the patient's automatic breaths. 7. Airway pressure relief ventilation (PC-APRV). It is necessary to be able to upgrade for the following: • Monitoring of smoking, • Automatic weaning program. Should be offered for selection. 8. Have software to perform non-invasive ventilation with automatic leak compensation. It is desirable for the system to reduce the flow in case of removal of the mask or tube so that there is no contamination of the medical staff. 9. Have a high-flow type oxygen therapy function, at least 50 L / min, during which the operator will adjust the oxygen percentage and the total flow. 10. In case of apnea, apnea ventilation should be activated automatically, with user-defined ventilation parameter settings, with automatic return when the patient's respiratory capacity is restored. 11. Should be able to adjust the following ventilation parameters: At least 20 - 2000 ml of administered volume • Breathing at least up to 100 BPM • Inhalation time of at least 0,1s to 10s, with the ability to achieve I-E ratios in a wide range • Inhalation flow up to 120 LPM at least • FiO2 from 21% to 100% • PEEP / CPAP from 0 to 50 mbar at least • Inhalation pressure 5 - 90 mbar at least • Pressure Support from 0-60 mbar at least • Slip from 0-500 sec	

• Sensitivity of onset of expiration from 5 to 70% of the maximum inspiratory flow. • Flow Trigger from 1-9 l / min 12. Should be able to measure and indicate at least the following parameters: • Respiratory volume (Vt) • Total expiratory volume per minute (MV) and automatic breathing (MVspont) • Inhaled volume • Maximum, middle, end-expiratory and plateau pressure • Total respiratory rate (f) • Inhaled oxygen density (FiO2) • Time of inhalation-expiration and of reason I: E • Resistance (R) and Dynamic Survival (Cdyn) 13. Should have the possibility of direct supply of 100% oxygen with a special program to facilitate the process of aspiration with an automatic program of pre-oxygenation, aspiration, post-oxygenation. 14. Should have the following special functions: • Manual inspiration Hold • Manual expiration Hold • Intrinsic PEEP • Occlusion pressure P0.1 • Rapid Swallow Breathing Index (RSBi) • Possibility of manual breathing and sigh addition will be assessed. 15. Should have a maneuvering function to determine the static properties of the lungs by recording the PV loops, analysis with a cursor, automatic detection of inflection points. Should be described for evaluation. 16. Should have a graphic representation / projection of lung characteristics and in particular the endurance, lung resistance as well as the ratio between spontaneous breathing and mechanical ventilation in real time which helps the treating physician in assessing the patient's pulmonary function. 17. Should have an automatic compensation function of the endotracheal tube resistance and reduction of the patient's breathing work. 18. Should have alarms (Alarms) for at least the following cases: • High and low ventilation pressure • Apnea • Low and high expiratory volume per minute • Low and high concentration of inhaled oxygen • High respiratory rate • Falling supply to the main air-oxygen network • Low battery charge level • Device failure 19. Should have trends of at least 24 hours for all respiratory parameters as well as memory of events, settings and alarms of the last patient, to inform users. 20. Should have freeze-free capability, reference function for loops with the ability to measure values. 21. Should be able to lock the touch screen and securely adjust settings to avoid the risk of accidentally disabling them. 22. Should have a pulsating throttle technology nebulizer 23. The parts of the ventilator which come in contact with the expired gases shall be sterile.	

24. Each ventilator should be delivered with: • Two (2) sets of sections that pass expired gases (such as exhaust valves, flow sensors, any necessary filters, etc.) to ensure the smooth operation of the ventilator. • One (1) multi-purpose nebulization container set • One (1) trial bag • At least one (1) mask, oral, non-invasive (NIV) multi-purpose ventilation • O2 and air tubes (if not turbine operated) 25. Should have a paramagnetic oxygen monitoring system and not to require the use of consumable sensors. 26. It must have Greek operating menu software. The existence of an electronic user manual integrated in the ventilator menu will be positively assessed for direct user information. 27. Have a USB port for data extraction and exchange of settings between the same ventilators. General Characteristics 1. Should be manufactured in accordance with international European safety standards and to be marked CE. Should be made available by a representative who has ISO 9001 and ISO 13485 certification in accordance with Y.A. DY8d / 1348/04 concerning the movement and technical support of medical devices. 2. Provide a warranty of good performance for at least two (2) years including all maintenance kits provided by the manufacturer. Indicate the replacement frequency of all the above mentioned by the manufacturer. 3. Certify in writing by the construction company the availability of spare parts for one decade. 4. The participants must have a permanently organized technical support and service department and the response in case of failure must be immediate. The appropriately trained staff must have a training certificate from the construction company for the maintenance of the offered items. 5. Submit a detailed sheet of compliance with references and a detailed response to the requested specifications with corresponding documentation in official documents of the construction company.	

PROJECT TITLE	: Supply and delivery of Medical Equipment for ICU units
Item Code	: 3
Item Description	: **MONITOR (ICU) – Second Revision of specifications dated 21/04/2021**
Manufacturer	: _____
Origin	: _____
Model	: _____

PURCHASER'S SPECIFICATIONS	BIDDER'S SPECIFICATIONS
3. MONITOR (ICU) I. Generally 1. Be state-of-the-art (at least last 10 years - report first release year for evaluation), suitable for use in Intensive Care Unit, to monitor the vital parameters of seriously ill patients. 2. Have a built-in power supply to operate at 220V / 50Hz and be quiet without a fan. 3. Should cover medical-related products, international safety standards and to have the necessary CE marking certificate. Should be made available by a representative who has ISO 9001 certification and / or ISO 13485 as well as a certificate from a competent authority or a notified body which shows that it complies with the requirements of Ministerial Decision ΔΥ8δ / Γ.Π. (1348 / 07.01.2004) ("Principles and guidelines for the proper distribution of medical devices" - Government Gazette B '32 / 16.01.2004). 4. Participants must have a permanently organized technical support department (indicate the city where they are based). 5. Should be easy to handle via touch screen and to have software and operating menu in Greek. Otherwise, a written statement of the manufacturer must be submitted that the monitors will have an operating menu in the Greek language upon delivery. 6. The monitor must necessarily carry the appropriate amplifiers - capabilities, programs, electrodes, cables, etc. and general parts for operation and full use in the unit, without any further financial burden for the Hospital. 7. Should communicate, by connecting to a common ETHERNET digital network, both with the Central Station and with the other side monitors (bed to bed communication). When communicating bed to bed, display the information of the monitored monitor at the same time as the monitor received. 8. Should have a color touch screen, TFT technology, Medical Grade, at least 15 inches, high resolution at least 1024x768, twelve (12) channels. 9. The suspension of each monitor will be at the responsibility and expense of the supplier either with a broken arm from the wall, rail or roof console of the ICU or on a shelf depending on the infrastructure of each ICU. 10. Should be fully plugged type (modular) with multi-parameter or separate amplifiers with the possibility of switching between monitors, so that it is possible to	

configure the composition according to the patient but also to better address technical problems in case of failure. 11. Should wear network parasite filters, protection against defibrillation and diathermy currents. Be able to detect pacing pulses. 12. Should have waveform scanning speeds of 6,25 - 12,5 - 25 - 50mm / sec depending on the parameter and the ability to freeze the waveforms and perform measurements with cursor. II. General Characteristics 1. Should have for all parameters, audio-visual alarms (alarms) with adjustable upper and lower limits as well as alarm for technical problem. Should have at least three different alarm levels depending on its criticality and to be able to archive alarm events with the possibility of recall (separately from the Central Station). Should be able to automatically adjust the alarm limits for all parameters at the same time. 2. The limits of the alarms of the side monitors for the various parameters shall be easily adjusted by the operator, both by the monitor and by the Central Station, and shall be continuously displayed on the monitor screen. 3. In case of ECG electrode detachment, the monitor automatically switches to another abduction so that the patient's ECG is not lost from the screen and the user is notified. 4. Have a trend memory of at least 72 hours, all parameters in graphs and tables with a high sampling rate of at least 20 sec. The graphs should be displayed on the screen at the same time as all real-time waveforms and measurements, so as not to alter the patient's monitoring. 5. Be able to detect arrhythmias and classify them automatically (at least twenty), including atrial fibrillation, by analyzing at least two leads at the same time, and store the arrhythmias in their memory. 6. Should perform ST analysis on 12 leads and give the corresponding change on the screen for both leads at the same time. Should give the corresponding change to the screen in the form of a graph for all 12 abductions at the same time, to facilitate the staff in its interpretation and to be able to adjust the J points manually. 7. The monitor shall be capable of receiving and displaying a complete 12-lead electrocardiogram with a five-pole or six-pole cable and simultaneously displaying them on the screen. In addition, using a 10-pole cable to receive a complete cardiogram of 12 leads with the ability to automatically diagnose and print through the Central Station on a laser printer. 8. Have a hemodynamic and oxygenation program as well as a drug dosing program. III. Parameters 1. Respiratory cardiogram scale A) The cardiogram is obtained by means of flexible, resistant to mechanical stresses of cable with 3/5/6 and 10 electrodes. Accompanied by a patient's five-pole cable.	

B) Heart rate 30-300 bpm and diagnostic heart rate 0.05-150Hz. C) The heart rate should be taken as an alternative to the population curve or blood pressure. D) Show the value and display the breathing waveform from the same as the ECG cable, the sensitivity of which is adjusted both manually and automatically. E) Breathing frequency range 0-150 bpm. F) Should regulate apnea time 2. Hemoglobin saturation scale A) Display the waveform (peripheral pulse wave) and display the O2 saturation value (SpO2). B) Pulse measuring range 30-300bpm and saturation 0% - 100% C) Should have a special system for the disposal of parasites due to low perspiration and in the movement of the patient and the accuracy provided in conditions of continuous movement and low perspiration in the range 70-100% to be ≤3%. D) Should be accompanied by a multi-purpose finger sensor and to accept single-use sensors. 3. Non-invasive pressure scale A) Should measure the non-invasive pressure with the oscilloscopic method manually and manually with adjustable intervals from every 1 minute to 8 hours and display on the screen the corresponding values of systolic, diastolic and mean pressure. B) Should be able to accommodate different sizes of cuffs and be accompanied by two cuffs (normal and large adult). C) Have high accuracy in patient movement conditions. 4. Temperature scale A) Should be able to measure the temperature in one and optionally two independent channels (T1 and T2) and to display their value and the difference (CB). B) Accompanied by a rectal / esophageal sensor. 5. Blood pressure scale A) Should have at least 2 blood pressure amplifiers that display the waveforms and simultaneously display the systolic, diastolic and mean pressure values. B) Should be able to display the waveforms in overlapping (over lapping with common 0). C) Calculate Pulse Pressure Variation and have a specific program for measuring pulmonary artery stenosis and cerebral arterial pressure (CPP) in intracranial pressure. Additional parameters D) Should be able to monitor additional blood pressure by adding corresponding plugged amplifiers. 6. Continuous cardiac output scale to monitor the patient's haemodynamic image using PiCCO technology catheters. Accompanied by a multi-purpose catheter connection cable (One (1) step for sharing with all monitors). 7. Smoking scale A) Show the waveform and numerically the value of the ultra-expiratory carbon dioxide (EtCO2). B) Mainstream or sidestream measurement method for use in intubated and non-intubated patients. (One (1) step for sharing with all monitors).	

8. Should be capable of upgrading with plugged reinforcing steps and of course mixed oxygen saturation step of mixed venous blood (SvO2) and venous blood (ScVO2), electroencephalography step of at least four channels with BSR imaging, intermediate independent step from the reservoir and baseline level two-phase indicator (BIS). Should be offered at a separate price. 9. Should be able to connect to a ventilator, desirable for injection pumps and other bedside devices to transfer data from them to its screen. Make a list of compatible machines and models. 10. Should have a flexible transport solution for the patient, so that during the transport there is no need to disconnect it from the cables and the modifiers for receiving the vital signs and there is no loss of data, or to be accompanied by a special transport monitor, which accepts the same plugged units of the side monitor with a screen greater than 6 '' and battery time of at least 3 hours (1 piece per ICU). GENERAL 1. The devices must be new, untapped, of modern technology, durable construction suitable for use in the premises of the Hospital and must include all the necessary accessories for its proper operation. 2. The Supplier is obliged to fully perform the installation of the equipment under supply and to deliver it in operation, with its own specialized and insured personnel and its own full responsibility, in accordance with the technical and scientific rules, the regulations of the Greek State, the instructions and the plans of the construction company and the assistance of the competent services of the organization in the space available 3. Medical equipment to enable interconnection with other hospital information systems (e.g. electronic patient file) through internationally recognized communication standards (e.g. HL7, ASTM). The Contractor undertakes that even after the completion of the project, it will provide the organization with the technical support (configuration parameters and information) that may be required in order to achieve the interconnection with third information systems 4. Should submit a compliance sheet which clearly states the agreement or not to the technical specifications, referring, for the documentation, to the attachments to the prospectus offer, or other brochures of the company, with the same numbering of the technical specifications 5. Provide a warranty of good performance for two years which will include all spare parts for any repairs and required periodic checks of safe operation. 6. The financial offer will also include a full technical coverage of all side monitors and modules, including all types of spare parts for preventive and repair maintenance as well as the regular settings-controls of good performance, after the end of the warranty period. The relevant annual price shall remain unchanged at least until the completion of ten (10) years from the commencement of the operation of the machinery, which may not be	

adjusted, except for the index. 7. The contractor must have an adequate Technical Personnel, trained and certified by the Manufacturer Company, (for the specific devices offered), which will report in detail and will provide all the evidence regarding their training and certification on exclusion penalty 8. The tenderer is obliged to co-pay with a penalty of exclusion after his offer: • Complete manual for use and operation of the construction company with a detailed description of the respective protocols and functions for all the respective applications, necessarily translated into Greek at the time of delivery of the assembly, while the initial offer (in the individual technical tender dossier) can be given in English and by preference also in Greek. 9. Training program for users: structure and completeness of training, offered aids, proposed duration of training and number of persons proposed to be trained, possible proposal for more than one training in staff (users) of the HOSPITAL within the time period from the end of the proposed warranty period good performance until the end of the period of ten years from the final acceptance of the complex. 10. The contractor will undertake to train the personnel of the Biomedical Technology department regarding the use and maintenance of the machinery. During the warranty and within the decade it will also provide a similar training at the request of the organization without paying any additional fee for any repetition of the training to be carried out later for the training of new staff. After the end of the training, the appropriate certificate will be given by a certified trainer or by the construction company. A complete maintenance manual of the construction company (SERVICE MANUAL) in Greek or English in printed and electronic form will be delivered to the Department of Biomedical Technology. 11. For reasons of quality assurance, the following must be submitted: • EN ISO 9001 Certificate: 2008 or EN ISO 13485: 2003 with a certification field for the movement of medical devices (translated into Greek and legally validated) • Certificate EN ISO 13485. 2003 on technical support for medical devices (translated into Greek and legally validated) • CE marking certificates for the equipment offered	

All other terms and conditions of Section III. Technical Specifications remain unchanged.