# *ANNEX II + III:* TECHNICAL SPECIFICATIONS + TECHNICAL OFFER

**Contract title: Supply of** Medical Equipment **p 1 /…**

**Publication reference:** RORS00008/GHZr/TD6

**Columns 1-2 should be completed by the contracting authority**

**Columns 3-4 should be completed by the tenderer**

**Column 5 is reserved for the evaluation committee**

Annex III - the contractor's technical offer

The tenderers are requested to complete the template on the next pages:

* Column 2 is completed by the contracting authority shows the required specifications (not to be modified by the tenderer),
* Column 3 is to be filled in by the tenderer and must detail what is offered (for example the words ‘compliant’ or ‘yes’ are not sufficient)
* Column 4 allows the tenderer to make comments on its proposed supply and to make eventual references to the documentation

The eventual documentation supplied should clearly indicate (highlight, mark) the models offered and the options included, if any, so that the evaluators can see the exact configuration. Offers that do not permit to identify precisely the models and the specifications may be rejected by the evaluation committee.

The offer must be clear enough to allow the evaluators to make an easy comparison between the requested specifications and the offered specifications.

| **1.**  **Item number** | **2.**  **Specifications required** | **3.**  **Specifications offered** | **4.**  **Notes, remarks,  ref to documentation** | **5.**  **Evaluation committee’s notes** |
| --- | --- | --- | --- | --- |
|  | **Cardiac 4D high-class ultrasound device – 1pc**  1.1 Ultrasound device equipped with software and calculations for cardiac 2D and live 3D (4D) exams  1.2 Min. 4 "pinless" equal active connectors for transducers, not counting "pencil" connectors  1.3 Monitor with panel size min. 21" on a movable artificial arm, with the resolution min. 1920x1080 pixels. Display of the ultrasound image allowed over the entire ultrasound screen in 16:9 format in high resolution.  1.4 Integrated color "Touch-screen" panel size min. 12"  1.5 Simultaneous real-time image display of the ultrasound image from the ultrasound monitor on the "Touch-screen" panel  1.6 Control panel with keyboard (on the touch screen or on the control panel) and interactive background lighting, heigh-adjustable (up and down min. 20 cm), with a rotating control panel (min. 170° from the center)  1.7 Max. scanning depth in 2D mode min. 30 cm  1.8 Frequency range of the device from 1 to 22 MHz or wider  1.9 2D "Frame rate" min. 1,900 f/sec  1.10 The system has the ability to adjust the SV (''Sample Volume'') size in the range of 1.0 - 19 mm or wider (depending on the transducer)  1.11 The system has the ability to detect speed in CW Doppler min. 25 m/s  1.12 The device has a dynamic system range min. 280 db, as well as the number of digital processing channels min. 4,500,000  1.13 Continuous automatic image optimization in 2D, color Doppler and spectral display in Doppler mode, by pressing a button  1.14 2D image obtained by the modern method of tissue harmonic imaging (Tissue Harmonic Imaging)  1.15 Speckle" artifact reduction (or other appropriate name for the same technology), available in B mode. Minimum 4 levels of optimization.  1.16 Spatial compounding technique - combining images obtained from different angles into one image in real time, Compound Imaging" or appropriate  1.17 TGC control on the touch screen and on the control panel (min.8); LGC on the touch screen  1.18 Quick waking-up of the device for operation (max. 120 seconds) - from completely switched off. Integrated battery for transport mode; in transport mode, it provides a source of energy for min. 40 minutes  1.19 Ultrasound system, stationary (max. weight 85 kg), on wheels.  1.20 Device noise max. 50 dB  1.21 The system supports the following transducers:  1.21.1 Sector (phased array) transducers  1.21.2 4D TTE matrix transducers  1.21.3 Sector (phased array) matrix transducers and/or "single crystal" transducers  1.21.4 4D TEE matrix transducers  1.21.5 Convex and microconvex transducers  1.21.6 Linear transducers (supports high-frequency linear transducers >20 MHz)  1.21.7 Intraoperative linear transducers  1.22 Operating modes:  1.22.1 2D-Mode (B-Mode);  1.22.2 Live 3D (4D) mode  1.22.3 "M-Mode"; Anatomical "M-Mode";  1.22.4 Software for Stress echo exams  1.22.5 "PW Doppler", "PW with HPRF doppler", "CW Doppler", Tissue doppler  1.22.6 "Color Doppler";  1.22.7 Automatic optimization of Doppler flow in real time:  1.22.8 - automatic adjustment of the position and angle of the region of interest ("color box"),  1.22.9 - automatic adjustment of the angle and position of the sampling window ("SV"),  1.22.10 - automatic scale and baseline adjustment in PW mode  1.22.11 "Power Doppler and directional Power Doppler" or appropriate  1.22.12 Fully automatic cardiac software, AI-based, for automatic measurement in 2D and Doppler exams. Supports min. following 2D automatic measurements: IVSD, LVIDD, LVPWD, LVIDS, Aortic diameter, Asc AO Diam, Ao Sinus Diam, Ao STJ Diam, LVOT diameter, RV base, RV mid, RV length, RV annulus. Supports min. following Doppler measurements: MV Peak E Vel, MV Peak A Vel, LVOT VTI, LVOT Vmax, AV VTI, AV Vmax, PV VTI, TR Vmax  1.22.13 Simultaneous visualization in min. two planes of section in real time, with the use of Color Doppler allowed, with lateral and elevation rotation  1.22.14 Fully automatic AI-based software performing the following functions:  1.22.15 - Calculation of the GLS (''Global Longitudinal Strain'') value of the left ventricle, by pressing a button without any manual definition of cardiac structures required. Automatic recognition of common sections (AP4, AP3 and AP2) with the manual correction allowed. Automatic detection of left ventricular contour. The analysis of sections allowed with and without ECG recording. Display of the 18th seg. "peak-systolic" and "end-systolic" strain in the form of a "bull's-eye" diagram. Ability Display of "endo" and "mid" strain values allowed  1.22.16 - Fully automatic calculation of EF, using the same images/sections already processed for LV strain analysis.  1.22.17 - Complete automatic assessment of the segmental wall motion of the LV (''segmental wall motion''). Display of values of each segment in apical sections. Display of the 17th "Bull's-eye", manual change allowed of the values in the apical views and to "Bull's-eye". "Wall motion score index", export of data to a report allowed  1.22.18 Fully automatic software for evaluating right ventricular (RV) deformation by tracking reference points (speckle tracking). Calculation of global longitudinal strain (GLS) values without any manual labeling of cardiac structures allowed  1.22.19 Fully automatic software for the evaluation of deformation of the left atrium (LA) by tracking reference points (speckle tracking). Calculation of global longitudinal strain (GLS) values without any manual labeling of cardiac structures allowed.  1.22.20 Fully automatic advanced software, AI-based, which automatically detects the segments and quantifies the left ventricle and left atrium of the heart during a full cycle, based on the 3D acquisition of the heart. The analysis allowed of multiple heart cycles as well as display of mean values in one analysis. The aim is to speed up the exam of patients with chronic diseases and as a result automatically yields the following measurements:  1.22.21 - Measurements and volumes of the left ventricle at the end of systole and at the end of diastole,  1.22.22 - The volume of the left atrium at the end of systole  1.22.23 - Ejection fraction of the left ventricle  1.22.24 - Heart rate  1.22.25 - Cardiac output  1.23 Integrated "ECG modules"  1.24 Archiving and connectivity  1.24.1 "Storage" and transfer formats: "PC formats and DICOM"  1.24.2 "Ethernet network" connection  1.24.3 CD/DVD, USB  1.25 Transducers with the device:  1.25.1 Matrix transthoracic cardiac transducer 1 - 5MHz or wider, which enables 2D and 4D display of the heart on the device, with min. 3,000 crystal elements; supporting technology that enables rotation of the ultrasound beam, without moving the transducer (from 0 to 360°) in real time on the device.  1.25.2 Linear transducer, frequency range from 3 to 12 MHz or wider, intended for vascular exams, FoV transducers min. 37mm ( +/-5mm)  1.26 Thermal B/W printer  1.27 The device is upgradeable with the following hardware and software options:  1.27.1 Program for estimating the left atrium (LAA) from three-dimensional TEE volume data. Automatic measurements after confirming the projection are min. following: min. and max. axis, range and area. Global or local measurement correction allowed.  1.27.2 3D quantification Live 3D, 3D Zoom; offers viewing, cropping, cutting and quantification, including distance measurements and calculation of area, left ventricular volume in min. two planes, ejection fraction (EF) and LV left ventricular mass,  1.27.3 Software for mitral valve analysis from real-time volume data. Recognition and labeling of the topology of the mitral valve without any manual labeling of the annulus, leaflets and coaptation required. Visualization of mitral valve anatomy in the form of a static and dynamic model.  1.27.4 Doppler view/mode with the features of a 3D view for better visualization of vascular structures while reducing artifacts, which uses and combines information from color and power doppler views/mode. Available in min. 5 display levels  1.27.5 Also available in combination with high-sensitivity Doppler display/mode for the visualization of microvascular structures  1.27.6 TEE transducer from 2 to 8 MHz or wider, intended for 2D and live 3D (4D) TEE exams, in single crystal technology and matrix technology, with min. 2,500 crystal elements,  1.27.7 Linear transducer with a frequency range of 2 – 22 MHz or wider, in single crystal and matrix technology, transducer width FOV min. 50mm, with the number of crystals min. 1,900  2.28 - 1x User manual in Serbian |  |  |  |
|  | **External chest compression device -1pc**  2.1 Portable device for chest compressions during patient resuscitation  2.2 The device shall allow multidirectional compressions (3D) on the patient's chest (thoracic and cardiac compression).  2.3 The device shall have two compression modes: continuous mode (100/min) and ventilation mode (30:2)  2.4 The device shall be equipped with a user-friendly keyboard  2.5 The weight of the device together with the battery max. up to 4 kg  2.6 Power and battery operation of the device  2.7 The device shall have integrated power supply connections from the network 100-240 VAC and direct power supply from the vehicle 12-48 VDC  2.8 The device shall also have the ability to operate via the associated batteries  2.9 Batteries shall have integrated led indicators that show the charge level, that is, the remaining capacity independent of the device.  2.10 The autonomous operation of one battery shall be min. 45 minutes of chest compressions  2.11 With the device it is necessary to deliver an independent charger for fast charging of min. 2 batteries at the same time, with integrated led indicators that show the charging features and the functionality of batteries.  2.12 The battery charger shall be capable of fast charging / for only one battery, max. 60 minutes / for two batteries at the same time, max. 150 minutes.  2.13 The device shall have an integrated USB interface.  2.14 The device shall have at least IP33 protection class and min. following standards: EN1789 and RTCA/DO-160G or equivalent  2.15 The device shall allow operation at temperature values in min. range from -20°C to 40°C  2.16 The device is supplied with operating accessories: 2 rechargeable batteries, a charger for simultaneous charging of min. 2 batteries, mains cable and transport bag for the device and accessories  2.17 - 1x User manual in Serbian |  |  |  |
|  | **Biphasic defibrillator - 1pc**  3.1 Biphasic, synchronous/asynchronous defibrillator with an integrated AED function  3.2 Maximum defibrillation energy 200J in steps of: 1-2-3-4-5-6-7-8-9-10-11-12-13-14-15-30-50-70-90-120-150- 170-200 J.  3.3 Integrated defibrillator power/battery operation  3.4 Defibrillator battery capacity 250 shocks with max. energy or 8 hours of ECG monitoring.  3.5 Without power supply, the defibrillator shall have an integrated feature of showing on the display the remaining capacity of the battery, that is, the expected autonomy in hours and minutes and the expected number of shocks to be delivered.  3.6 The defibrillator features multi-functional defibrillation paddles with integrated LED indicators for checking patient resistance, energy selection buttons, charge and shock delivery buttons, and a print and event registration button  3.7 The defibrillation paddles have the option of removing the large defibrillation plate for adult resuscitation, which frees up the area of the pediatric defibrillation pedal for children and automatically activates the pediatric mode.  3.8 The defibrillator has the ability to work with self-adhesive defibrillation electrodes  3.9 The defibrillator has an integrated automatic external defibrillation feature with textual and graphic instructions to the operator.  3.10 The defibrillator has an integrated color screen, sensitive to touch, panel size min. 7" protected by tempered glass  3.11 The defibrillator has the ability to select several different screen configurations  3.12 The defibrillator has the ability to operate the screen in color and black and white "high contrast" mode for operation under direct sunlight.  3.13 In monitoring mode, the display enables min. 6-channel ECG signal with the detection of disconnected electrodes.  3.14 The defibrillator has an integrated 3-channel thermal printer, with printing of graphic and numerical reports automatically and manually, on thermal paper 80 mm wide.  3.15 The defibrillator has a "screenshot" feature in all operating modes  3.16 The defibrillator has an integrated Wi-Fi module for communication with the information system.  3.17 The defibrillator has the possibility of automatic self-testing of functionality with automatic report printing  3.18 The defibrillator also has the ability to automatically send a report on the performed self-test of functionality to the information system via the integrated Wi-Fi module.  3.19 The defibrillator has an integrated hook on the back side for hanging the defibrillator on the bed when transporting the patient  3.20 Integrated defibrillator memory for min. 24 hours of recorded data.  3.21 Weight of the device without defibrillation paddles max. 5 kg  3.22 The defibrillator has an min. IP 33 protection standard  3.23 The defibrillator is supplied with min. the following common operating accessories:  3.23.1 - 1x paddle for defibrillation  3.23.2 - 1x Defibrillation Gel  3.23.3 - 1x Self-adhesive electrodes for adult defibrillation  3.23.4 - 1x 4-wire ECG patient cable  3.23.5 - 1x Power cable  3.23.6 - 1x Thermal paper  3.23.7 - 1x User manual in Serbian |  |  |  |
|  | **Ergometric workplace with treadmill - 1pc**  4.1. Ergometric workstation for 12-channel ECG acquisition at rest and under stress  4.1.1. Ergometric workstation shall enable the following tests:  4.1.2. simultaneous recording of 12-channel ECG at rest  4.1.2.1. • continuous recording of 12-channel ECG rhythm with the full disclosure display allowed  4.1.2.2. • measurement and analysis of QT segment/dispersion  4.1.2.3. • conducting a cardiological physical stress test with complete software processing  4.1.3. The ergometric workstation shall be a compact system consisting of:  4.1.3.1. • intuitive cardiac diagnostic software with a complete database of patients and performed tests  4.1.3.2. • associated ECG recorder  4.1.3.3. • PC system with associated infrastructure, LCD screen with panel size greater than 21 inches and a laser printer  4.1.04 The ECG recorder shall have high-resolution ECG recording technology with the following specification  4.1.4.1. • sampling frequency min. 8000Hz  4.1.4.2. • CMRR greater than 110dB  4.1.5. The system is upgradeable with a wireless ECG recorder with an integrated OLED/LCD/TFT screen for displaying min. 1-channel ECG signal, weight with batteries max. 140 grams, with battery capacity min. 36 operating hours and integrated protection standard min IP53  4.1.6. The ergometric workstation shall operate under the MS WINDOWS operating system  4.1.7. The ergometric workstation shall be fully compatible with the associated treadmill to perform the stress test  4.1.8. The ergometric workstation shall have the ability to select min. following leads: Standard, standard with C4r, right precordial, left posterior, Nehb and pediatric,  4.1.9. The ergometric workstation shall enable the possibility of correcting the QT interval according to the Bazett, Fredericia, Fremingham and Hodges formulas, or equivalent.  4.1.10. The ergometric workstation shall have software for complete measurement, serial comparison and interpretation of ECG findings in adults and children.  4.1.11. The ergometric workstation shall have software for the interpretation of ECG findings in athletes in accordance with the SEATLLE criteria or or equivalent  4.1.12. The ergometric workstation shall have the ability to print the recorded ECG on a laser printer that should be delivered as an integral part of the system.  4.1.13. The ergometric workstation shall have the ability to continuously record a 12-channel ECG for min. 60 minutes.  4.1.14. The ergometric workstation shall be upgradeable with software options for 3D vector cardiography and pharmacological stress testing.  4.1.15. The ergometric workstation shall be upgradeable with a sensor/module for performing spirometry tests  4.1.16. The ergometric workstation shall have the possibility of two-way communication and easy integration into "EMR", "PACS" and "HIS".  4.1.17. The ergometric workstation is supplied with common, associated work accessories  4.2. Associated treadmill for carrying out the load test  4.2.1. The treadmill shall be absolutely compatible with the ergometric workstation  4.2.2. The treadmill shall meet the medical device risk classification of min. class IIb, in accordance with the medical device classification directives  4.2.3. Control of treadmill operation via ergometric workstation  4.2.4. The treadmill shall have an instant stop button  4.2.5. Min. dimensions of the treadmill 150x50mm  4.2.6. Treadmill speed adjustable in a range of no less than 0-22 km/h with an adjustment accuracy of max. 0.1 km/h  4.2.7. Treadmill incline adjustable in the range of 0-25%  4.2.8. The maximum allowed weight of the patient on the treadmill not less than 200 kg  4.2.9. The treadmill is supplied with a cable for direct connection to the ergometric workstation  4.3. - 1x User manual in Serbian |  |  |  |
|  | **Holter system for continuous recording and analysis of ECG and blood pressure - 1pc**  5.1. Software for long-term analysis of recorded ECG and blood pressure  5.1.1. complete diagnostic software that has a module for the analysis of ECG holter recordings and a module for the analysis of measured blood pressure values  5.1.2. the software shall have a unique patient database  5.1.3. complete automatic analysis of a 3-channel ECG recording  5.1.4. automatic analysis shall enable accurate definition of the QRS complex with a precision of min. 99% (recognition precision shall be scientifically or clinically proven)  5.1.5. complete analysis of the ST segment in all three channels  5.1.6. complete analysis of the QT segment with min. 4 formulas for QT correction: Bazzet, Fridericia, Pfeufer, Sagie or equivalent  5.1.7. software for manual reanalysis/reclassification of each QRS complex  5.1.8. PM signal detection software  5.1.9. integrated HRV software (Time domain)  5.1.10. optional upgradeability to "Echo view" or equivalent software for advanced analysis of arrhythmias with "color coded" display of rhythm disturbances  5.1.11. optionally upgradeable of software module for atrial analysis with rapid detection of AV blocks, atrial flutter and atrial fibrillation / software operates on the basis of genuine, realistic detection of P-waves  5.1.12. optional upgradeability to »sleep apnea« software module for registering breathing disorders with simultaneous display of SpO2 saturation  5.1.13. graphic and numerical display of measured blood pressure values when the patient is awake and sleeping  5.1.14. comments allowed and deletion of certain measurements  5.1.15. trend analysis and histogram display of measured blood pressure values  5.1.16. the definition allowed of limits on the basis of which deviations from the set blood pressure values will be analyzed  5.1.17. display of systolic, diastolic and mean blood pressure, heart rate.  5.1.18. Software analysis allowed of the recording with the following options:  5.1.18.1. • recognition of hidden hypertension  5.1.18.2. • recognition of "white coat" hypertension  5.1.19. comments for selected video segments allowed  5.1.20. free definition of the working environment allowed - the appearance of the screen  5.1.21. the report format freely selectable  5.1.22. report packing in PDF format allowed  5.2. ECG holter recorder  5.2.1. high-resolution, 3-channel ECG recorder  5.2.2. the recorder shall have an integrated dual power supply. via an internal rechargeable battery and via an external AA or AAA battery  5.2.3. when working only with an internal battery, the capacity of continuous operation of the recorder min. 7 days  5.2.4. when working with an internal rechargeable battery and an external AA or AAA battery, the capacity of continuous operation of the recorder min. 14 days  5.2.5. recording data on a memory card with the capacity of min. 14-day ECG  5.2.6. the recorder shall have an integrated OLED/LC/TFT display to display min. 1-channel "on-line" ECG signal  5.2.7. the recorder shall have an ECG signal sampling frequency (sampling rate) min. 30,000 Hz with min. 15-bit resolution  5.2.8. the recorder shall have real P wave detection  5.2.9. the recorder shallallow the connection of a 5- and 7-wire patient cable with automatic detection of the connected patient cable  5.2.10. the recorder shall have an integrated USB port  5.2.11. the recorder shall enable the transfer of recorded data with a transmission speed of up to 3 minutes for 24 hours of recording  5.2.12. the recorder shall have an integrated Bluetooth interface for connecting to the SpO2 sensor and connecting to a PC workstation for wireless quality control of the ECG signal when connecting the recorder with the patient  5.2.13. the recorder shallallow respiratory monitoring via ECG signals (without additional electrodes for monitoring pauses in breathing)  5.2.14. the recorder shall have an integrated "Event" button for registering possible events by the patient  5.2.15. the recorder shall have an integrated voice recorder for saving voice messages  5.2.16. recorder weight, max. 130 grams without external battery  5.2.17. the recorder should be supplied with a complete set of common operating accessories  5.3. Recorder for registering blood pressure values  5.3.1. 24/48 hour blood pressure measurement, at the user's discretion  5.3.2. the recorder shall allow auscultatory (Korotkoff/Riva-Rocci) and oscillometric blood pressure measurement methods  5.3.3. the definition the speed of the cuff deflation allowed in the min. range of 2-9 mmhg/sec  5.3.4. definition of several different protocols for pressure measurement with different time intervals  5.3.5. min. pressure measurement range: 25-300 mmHg  5.3.6. memory capacity min: 350 measurements and 30 sec. of voice messages  5.3.7. the recorder has an integrated high-resolution color display for displaying currently measured values  5.3.8. the recorder has an integrated USB interface for connection to a computer and data transfer  5.3.9. the recorder has an integrated button for pressure measurement by the patient, independent of the defined protocol  5.3.10. recorder may be initiated independently of the PC software  5.3.11. the recorder should be supplied with common operating accessories  5.3.12. recorder weight, max. 200 g with batteries  5.4. PC system  5.4.1. Along with the software and associated recorders, it is necessary to deliver a PC with an appropriate specification with two OLED/LCD/TFT screens with panel size for the simultaneous presentation of software tools for the analysis of holter recordings, with a laser printer and a WINDOWS license.  5.5. - 1x User manual in Serbian |  |  |  |
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**Important Note:**

All equipment dimensions and or other characteristics which are set to be fixed in technical specifications will be acceptable if offered with 5% difference than requested.