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MEDICAL DEVICE SPECIFICATION		
ITEM No.		**1**
NAME		**Class II A2 Biosafety Cabinet**
TECHNICAL CHARACTERISTICS		
1	Detailed requirements	Biosafety Cabinet Class II A2 with base stand for handling microbiological specimen. The manufactures shall have a local, Iraq, technical support network and availability of spare parts and accessories. **Protection**: It shall provide protection to the operator and the environment from exposure to biohazards, and also protects products from contaminated room air and cross-contamination. **Recirculation:** Shall has a common plenum from which 30% of air is exhausted, and 70% is re-circulated to the work area as the downflow. **Filtration:** HEPA filters: 99,99% efficiency (EN 1822 (H14)) **Airflow rate**: Inflow velocity: ≥ 100 FPM (NSF 49) ≥ 0.40 m/s (EN12469). Downflow velocity: 0.25–0.50 m/s (EN12469) **Monitoring and Alarms:** Real-time airflow alarms. Independent sensors detect pressure changes across the exhaust and downflow plenums. Alarm signals when a approx. 20% change in inflow/exhaust or downflow occurs. **Other features:** • UV irradiation for decontamination • Timed UV irradiation • Safety interlock to prevent UV illumination when window is open • Integrated monitoring of airflow • Adjustable airflow rates • Integrated lights for containment area • Tempered safety glass sash (fully) • Work surface: 304 stainless steel or better material. • Puncture-resistant metal plenum. • Antimicrobial powder coating • Gas tubing connection in working area. Up to two pre-plumbed penetrations per side. • Automatic airflow balancing. • Night Mode. To reduce airflow to about 30% of normal operation during low-usage periods. **Dimensions and weight.** External dimensions (WxHxD), approx: 90 x 160 x 80 cm Weight, approx. max. 250 Kg.
2	Displayed parameters	
3	User adjustable settings	
UTILITY REQUIREMENTS		
4	Electrical, water and/or gas supply (if relevant)	Gas tubing connection in working area. Up to two pre-plumbed penetrations per side. 220 / 240 V, 50 Hz
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
5	Accessories (if relevant)	
6		
7	Spare parts (if relevant)	
ENVIRONMENTAL REQUIREMENTS		
8	Context-dependent requirements	

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TRAINING, INSTALLATION AND UTILISATION		
9	Pre-installation requirements(if relevant)	Withing 10 days after awarding the suplier shall provide detailed imformation, inclusive of drawings of any pre-installation requirement.
10	Requirements for commissioning (if relevant)	The supliyer is required to do the installation and commisioning. A certificate is to be produced.
11	Training of user/s (if relevant)	The supliyer is required to provide trainning to end users on operation, preventive mantenence, calibration and safe use. A training certificate is to be produced.
12	User care(if relevant)	
WARRANTY AND MAINTENANCE		
13	Warranty	2 years
14	Software / Hardware upgrade availability	
DOCUMENTATION		
15	Documentation requirements	Full set of operational instructions, trouble shooting and maintenance manuals in Arabic and English.
SAFETY AND STANDARDS		
16	International standards	EN 12469:2001 / NSF/ANSI 49 / Performance criteria for microbiological safety cabinets. Certified EN 14175-2:2003. Fume cupboards. Part 2: Safety and performance requirements. ISO 15190:2020(en) Medical laboratories — Requirements for safety EC Mark

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ITEM No.		**2**
NAME		**Blood Gas Analyzer**
TECHNICAL CHARACTERISTICS		
1	Detailed requirements	It shall be a heavy duty machine with state of the art technology and manufactured by international well known and reputed brands with local, Iraq, after sales services and reagent availability. Suitable for clinical hospital laboratories and point of care services with high workloads and where fast analysis results is required such as ED, ICU, NICU, Delivery Rooms, etc. **Other features:** Automatic quality control and short calibration times. Intuitive Color Touch Screen User Interface Samples Volume-all parameters: 60µL to 65µL Automatic sample mixing in 5 to 7 sec. Fast Self-cleaning inlet Measuring time-all parameters: ≤ 40 seconds on about 19 parameters from a syringe, capillary tube or test tube. Maximum Cycle time: ≤ 60 sec Throughput 40 to 50 samples/hour Average uptime more than 22 hours/day Startup time ≤ 1 hour Inbuilt printer **Interface** Built-in barcode reader for patient data entry and sampler ID Serial interface RS232 with power for external barcode reader Minimun 2 USB connections
2	Parameters Displayed/Measured	Minimun parameters measured, about 19. Blood gases: pH; pCO2; pO2 Metabolites: cGlu; cLac; cCrea; cUrea Electrolytes: cCa2+; cCl-; cK+; cNa+ Oximetry: FCOHb; ctBil; ctHb; FHbF; FHHb; FMetHb; sO2; FO2Hb
3	User adjustable settings	
UTILITY REQUIREMENTS		
4	Electrical, water and/or gas supply (if relevant)	220/240 V , 50 Hz Inbuilt battery
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
5	Accessories (if relevant)	Rolling stand
6	Consumables / reagents (if relevant)	BG / LYT / MET / OXI with QC for about 1.000 tests Solution pack for about 1.000 tests
7	Spare parts (if relevant)	
ENVIRONMENTAL REQUIREMENTS		
8	Context-dependent requirements	Operating environment 15°C–32°C

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TRAINING, INSTALLATION AND UTILISATION		
9	Pre-installation requirements(if relevant)	
10	Requirements for commissioning (if relevant)	The supliyer is required to do installation and commisioning. A certificate is to be produced.
11	Training of user/s (if relevant)	The supliyer is required to provide trainning to end users on operation, preventive mantenence, calibration and safe use. A training certificate is to be produced.
12	User care(if relevant)	
WARRANTY AND MAINTENANCE		
13	Warranty	2 years warranty
14	Software / Hardware upgrade availability	Yes, as per manufacturer product policy
DOCUMENTATION		
15	Documentation requirements	Operation and service manuals in English and Arabic language.
DECOMMISSIONING		
16	Estimated Life Span	
SAFETY AND STANDARDS		
17	International standards	ISO 13485, IEC 60601 EC Mark

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MEDICAL DEVICE SPECIFICATION		
ITEM No.		**3**
NAME		**Color Doppler Cardio Echo Unit**
TECHNICAL CHARACTERISTICS		
1	Detailed requirements	High end Color Doppler Cardio Echo Unit, Fully Digital, latest generation and state of the art with powerful cardiologic capabilities. Manufactured by first level and well reputed international brands. Application Software: Software for cardio imaging analysis, measurements and annotations. • Automated Function Imaging. • Advanced Tissue Synchronization. Ports: 2 Transducer Ports minimum. Transducers: Multi-frequency Transducers (Minimum 3 frequencies on each transducer). Data Acquisition • Cardiac, cardiovascular, abdominal, OB/GYN, peripheral vascular and OR application presets • High-precision data acquisition • Digital data acquisition Data Processing. • High speed data bus for pre and post-processing. • Upgradable capabilities, for future updates. • Data compression options. • Secure data managment Display. • Minimum 17” high resolution non-interlaced color monitor, swivel and tillable. • Instant review screen capable of display about min 8 to 12 simultaneous images. • Scan plane position indicator. • Selectable configuration of duplex and triplex modes. • Full range of display annotations possibilities. Tissue imaging. • Variable transmit frequencies. • Zoom, general and higher resolution for ROI. • Countor filtering. • Modes: 2D, M, Anatomical M, as minimum. • Zoom, general and higher resolution for ROI.
		General. • Approximate dimensions (mm). Height; min. 1200 - max. 1500. Width; Min. 500 - max 700. Depth min 75 - max 950. • Weight Kg (including monitor): About 160 Kg to 200 Kg. Fully DICOM compliant for HIS, PACS, etc.
2	Displayed parameters	
3	User adjustable settings	
UTILITY REQUIREMENTS		
4	Electrical, water and/or gas supply (if relevant)	Should work on 220-240 VAC , 50 Hz .
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
5		**Probes:** Standards probes. Plus (if not in the standar set) 1 (one) Adult probe and 1 (one) Pediatric probe. Minimum frequency range. 2,7 Mhz to 4 Mhz for this ones. • DVD writer built in • Printer, built in • Color laser printer. • USB interface • UPS

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6	Consumables / reagents (if relevant)	• Paper rolls for built in printer, Qty. 100 units
7	Spare parts (if relevant)	
ENVIRONMENTAL REQUIREMENTS		
8	Context-dependent requirements	
TRAINING, INSTALLATION AND UTILISATION		
9	Pre-installation requirements(if relevant)	
10	Requirements for commissioning (if relevant)	
11	Training of user/s (if relevant)	YES
12	User care(if relevant)	
WARRANTY AND MAINTENANCE		
13	Warranty	2 years warranty
14	Software / Hardware upgrade availability	
DOCUMENTATION		
15	Documentation requirements	Full set of manuals and technical documents in English and Arabic. Soft set of operating instructions and technical documents in English and Arabic,.
DECOMMISSIONING		
16	Estimated Life Span	7 years
SAFETY AND STANDARDS		
17	International standards	21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. UL 60601 -1, Safety Requirements for Medical Equipment IEG 60601-2-37 Diagnostic Ultrasound Safety Standards GSA C22.2 No. 601-1, Safety Requirements for Medical Equipment AIUM/NEMA UD-3. Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment AIUM/NEMA UD-2. Acoustic Output Measurement Standard for Diagnostic Ultrasound 93/42/EEC Medical Devices Directive Safety and EMC Requirements for Medical Equipment EN/IEG 60601-1 EN/IEC 60601-1-1 EN/IEG 60601-1-2 EG 1157 Declaration of Acoustic Power ISO 10993-1 Biocompatibility CE certified. Any other aplicable.

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MEDICAL DEVICE SPECIFICATION		
	ITEM No.	**4**
	NAME	**Radiofrequency Generator, Pain and Neurosurgical**
TECHNICAL CHARACTERISTICS		
1	Detailed requirements	The state of the art brand new radiofrequency generator for Pain Management and Neurosurgical treatments device shall, both independently and automatically, control up to four electrodes at once, in monopolar or bipolar mode, with thermal RF or pulsed RF (PRF) output. Compose of: 1. Radiofrequency generator device 2. Medical Grade Power Cord 3. RFG-TP Generator Output Test Plug 4. CB112-TC Connection Cable for Reusable Electrodes 5. Minimum 12-inch color touch screen Features: • Number of independent controlled electrodes: Four (4) electrodes • Start times with temperature ramp • Monopolar, bipolar of pulsed RF to ensure procedural versatility • Saved procedure settings. • Graphical and numerical display modes • Automatic and manual stimulation features. • Smooth automatic temperature control for large and small electrodes. • Thermal RF: □ About 480 kHz □ Minimum range of temperature settings 37-95 °C □ Intradiscal stepped temperature in built programs □ Timer range, minimum : 5 sec – 30 min □ Auto Stepped: Start, Step, Final Temps and Times □ Power range: 0–50 Watts • Pulsed RF □ Pulse settings: Rate 1-10 Hz, Width 2-30 msec, □ About 480 kHz □ Control of pulse settings: Automatic □ Low and high-temperature PRF: minimum range 37-95 °C • Pulse Width Stimulation (Biphasic Square Pulses) □ Rates: 2, 5, 50, 75, 100, 150, 180, 200 Hz □ Widths/Durations: 0.1, 0.5, 1, 2, 3 msec □ Voltage Control: 0-3 Volts □ Current Control: 0-10 mA • Sensory and motor stimulation □ Audible impedance tone for cordotomy and intradiscal □ Support for both spinal and neurosurgical procedure: Rate 2-200 Hz, Width 0.1-3 msec, voltage or current control features.
2	Displayed parameters	· Displays of all crucial RF readings: Volts, Milliamps, Watts, and Ohms · Settings and alarms
3	User adjustable settings	User settings and alarms
UTILITY REQUIREMENTS		
4	Electrical, water and/or gas supply (if relevant)	Should work on 220-240 VAC , 50 Hz .
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
5	Accessories (if relevant)	Set of: RF Injection Temperature-Control Electrode (CU) RF Injection Electrode (CR) Stimulation Injection Electrode (CP) Block Injection Needle (CN)
6	Consumables / reagents (if relevant)	
7	Spare parts (if relevant)	
ENVIRONMENTAL REQUIREMENTS		
8	Context-dependent requirements	The Unit shall be capable of being stored continuously in ambient tempreture of (-5 to 70) deg C nd relative humidity of 10 - 95%

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TRAINING, INSTALLATION AND UTILISATION		
9	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover
10	Requirements for commissioning (if relevant)	Local clinical staff to affirm completion of installation
11	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
12	User care(if relevant)	The case is to be cleanable with alcohol or chlorine wipes Unit layout to enable easy cleaning and sterilization of all surfaces.
WARRANTY AND MAINTENANCE		
13	Warranty	Two years
14	Software / Hardware upgrade availability	Yes, if aplicable.
DOCUMENTATION		
15	Documentation requirements	User, technical and maintenance manuals to be supplied in English language. Certificate of inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost.
SAFETY AND STANDARDS		
17	Regulatory Approval / Certification	EC Mark.
18	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-2-2 Ed. 5.0:2009 (b) Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

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MEDICAL DEVICE SPECIFICATION		
ITEM No.		**5**
NAME		**ENT Station**
TECHNICAL CHARACTERISTICS		
1	Detailed requirements	ENT workstation with the following modules Servant module • Ear irrigation / thermal nystagmus stimulation • Light source: LED • Light intensity, minimum: 240.000 Lux • Infection control: Strict separation of clean and contaminated area. • Endoscope management with control of disinfection time • Suction equipment with suction auto start function • Compressed air nebulization of medications • Heating module for instruments • Mirror fast heating • Diagnosis software • Instrument drawers Vision module •• Light modules • ENT camera • Stroboscope, LED • Ergonomic LED light handle, suitable for direct connection to the endoscope avoiding cabling; • LED headlights • Halogen cold light. Lamp service time, about 300 hours • Integrated ENT camara • Integrated LED stroboscope • Quiver for clean endoscopes • Swab area for endoscope • Area for bottles and instrument trays. • With monitors, visualization systems and diagnosis software
	Detailed requirements	• Area for bottles and instrument trays Instruments • Waste bin • Storage for used instruments • Drawers • Instrument management area • Extractable writing surface Patient chair • Foot operate Microscope • Integrated in the ENT station Other features • Patient chair backrest: Variable from approx. 5° forward to the horizontal position. The height adjustment is variable from lower, approx. 50 cm, to higher position, approx. 70 cm. • Electrical/pneumatic adjustment. • Patient weight: Up to approx. 150 Kg • Doctor stool: Shall match the ENT station and the patient chair.
2	Displayed parameters	
3	User adjustable settings	
UTILITY REQUIREMENTS		

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4	Electrical, water and/or gas supply (if relevant)	Should work on 220-240 VAC , 50 Hz .
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
5	Accessories (if relevant)	Doctor stool Patien chair Complete set of instruments for standard procedures
6	Consumables / reagents (if relevant)	
7	Spare parts (if relevant)	
ENVIRONMENTAL REQUIREMENTS		
8	Context-dependent requirements	The Unit shall be capable of being stored continuously in ambient tempreture of (-5 to 70) deg C nd relative humidity of 10 - 95%
TRAINING, INSTALLATION AND UTILISATION		
9	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover
10	Requirements for commissioning (if relevant)	Local clinical staff to affirm completion of installation
11	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
12	User care(if relevant)	The case is to be cleanable with alcohol or chlorine wipes Unit layout to enable easy cleaning and sterilization of all surfaces.
WARRANTY AND MAINTENANCE		
13	Warranty	Two years
14	Software / Hardware upgrade availability	Yes, if aplicable.
DOCUMENTATION		
15	Documentation requirements	User, technical and maintenance manuals to be supplied in English language. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost.
SAFETY AND STANDARDS		
16	International standards	
17	Regulatory Approval / Certification	
18	International standards	EC Mark

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ITEM No.		**6**
NAME		**Portable Ventilator**
TECHNICAL CHARACTERISTICS		
1	Detailed requirements	Portable ventilator with carring system for transporting patient. Ventiletory Modes; IPPV, PCV, PSV, SIMV, CPAP, PEEP, APNEA BACK-UP and MANUAL BREATH, with all accessories for adult and pediatric with portable oxygen flowmeter and cylinder size fit to recovery trolley and can be connected easily to trolley, Weight Approximately 5.8 kg (including internal battery) Gas supply From a pipeline system or from an O2 cylinder O2 service pressure 270 kPa to 600 kPa at 100 L/min Gas consumption for internal control Average 0.5 L/min Operating data Ventilation Modes VC-CMV, VC-AC, VC-SIMV, SpnCPAP, PC-BIPAP Additional settings for ventilation – Pressure support: in the ventilation modes VCSIMV, PC-BIPAP* and SpnCPAP – Apnoea ventilation: in the ventilation mode SpnCPAP – AutoFlow (optional): in the ventilation modes VC-CMV, VC-AC and VC-SIMV – NIV: in the ventilation modes: SpnCPAP (/PS), PC-BIPAP (/PS), VC-CMV /AF, VC-AC /AF and VC-SIMV/AF Ventilation Respiratory Rate 2 to 60/min (VC-SIMV, PC-BIPAP) 5 to 60/min (VC-CMV, VC-AC) 12 to 60/min for apnoea ventilation Tidal volume VT 0.05 to 2.0 L; BTPS**** Ti / I:E I:E or Ti configurable, for all ventilation modes Ventilation time ratio I:E 1:100 to 50:1 Inspiration time Ti 0.2 to 10 s Inspiratory pressure Pinsp PEEP +3 to +55 mbar O2 concentration 40 to 100 Vol.%****
2	Displayed parameters	
3	User adjustable settings	User-resettable time elapsed indicator to be incorporated.
UTILITY REQUIREMENTS		
4	Electrical, water and/or gas supply (if relevant)	Should work on 220-240 VAC , 50 Hz .
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
5	Accessories (if relevant)	Including two O2 cilinder with suitable regulator and fittings.
6	Consumables / reagents (if relevant)	Disposable Mask for Ambu Bag qty. 100. Catheter Disposable qty. 100. Filter Antibacterial qty. 200. Breathing circuit qty. 100.
7	Spare parts (if relevant)	
ENVIRONMENTAL REQUIREMENTS		
8	Context-dependent requirements	The Unit shall be capable of being stored continuously in ambient tempreture of (-5 to 70) deg C nd relative humidity of 10 - 95%
TRAINING, INSTALLATION AND UTILISATION		
9	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover
10	Requirements for commissioning (if relevant)	Local clinical staff to affirm completion of installation
11	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided

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12	User care(if relevant)	The case is to be cleanable with alcohol or chlorine wipes. Interior chamber to be accessible for easy cleaning
WARRANTY AND MAINTENANCE		
13	Warranty	Two years
14	Software / Hardware upgrade availability	Yes, if aplicable.
DOCUMENTATION		
15	Documentation requirements	User, technical and maintenance manuals to be supplied in English language. Certificate of inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost.
SAFETY AND STANDARDS		
16	International standards	
17	Regulatory Approval / Certification	
18	International standards	ISO 13485:2003 Medical devices -- Quality management systems. ISO 14971:2007 Medical devices -- Application of risk management to medical devices Electromagnetic compatibility (EMC): IEC/EN 60601,1-2-2007; EN 794-3 and ISO 10651-3 Airworthiness: RTCA DO-160F Mechanical strength: MIL STD 81F method 514.5 EC Mark
19	Equivalent to the reference image	

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	ITEM No.	**7**
	NAME	**Defibrillator (DC Shock)**
TECHNICAL CHARACTERISTICS		
1	Detailed requirements	DC- Defibrillator for adult and pediatric paddles-biphasic, with manual and AED functions Type: Manual, External, Biphasic wave form. AED (Automated External Defibrillation): this function is required Should operate on mains power as well as rechargable built in battery. A fully charged battery should operate for at least 2 hrs. of monitoring of at least 50 shocks of 270 J. A minimum size 8.5 inches color LCD display. Should have wide range of energy selection from 0-270 J with low energy selection from 1-30 J in increment of 1-2 joule each. Difibrillator should be able to monitor ECG and deliver shock of maximum energy (on main power) even if battery is fully deplated or disconnected. It should display the energy selected. Fast charging: Approx. 3 seconds for 200J, 5 seconds for 270J charging in AC operation. Noninvasive pacing.
2	Displayed parameters	Should have in -built service mode for easy maintenance and setting operational parameters like: records, frequency response, alarms, ECG leads.
3	User adjustable settings	Maintenance and Service menus .
UTILITY REQUIREMENTS		
4	Electrical, water and/or gas supply (if relevant)	Should work on 220-240 VAC , 50 Hz .
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
5	Accessories (if relevant)	Disposable defibrillation pads sets for semiautomated defibrilation: Qty 5 pads Complete SPO2 Cable , ECG, NIBP Cables
6	Consumables / reagents (if relevant)	
7	Spare parts (if relevant)	Disposable pad adaptor cable and disposable pads for AED funtion. Qty:10
ENVIRONMENTAL REQUIREMENTS		
8	Context-dependent requirements	The Unit shall be capable of being stored continuously in ambient tempreture of (-5 to 70) deg C nd relative humidity of 10 - 95%
TRAINING, INSTALLATION AND UTILISATION		
9	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover
10	Requirements for commissioning (if relevant)	Local clinical staff to affirm completion of installation
11	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
12	User care(if relevant)	The case is to be cleanable with alcohol or chlorine wipes. Interior chamber to be accessible for easy cleaning
WARRANTY AND MAINTENANCE		
13	Warranty	Two years
14	Software / Hardware upgrade availability	Yes, if aplicable.

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DOCUMENTATION		
15	Documentation requirements	User, technical and maintenance manuals to be supplied in English language.
SAFETY AND STANDARDS		
16	Risk Classification	
17	Regulatory Approval / Certification	
18	International standards	ISO 13485:2003 Medical devices -- Quality management systems. ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601 EC Mark