

Section II: Schedule of Requirements- Lot 3

eSourcing reference: ITB/2023/49547- **Rev 3**

A. Summary of Requirements

Lot 3: Patient Monitoring Equipment

B. Technical specifications for Goods and Comparative Data Table

All changes made in Rev 3 will be in RED

Item No	Description	Quantity
1	NeuroMuscular Transmission Monitor	6
2	Monitoring system with 8 patients monitors	2
3	Non-invasive cardiac output monitor	3
4	Monitor for the Depth of anesthesia	6
5	Transport monitor with invasive blood pressure module	5
6	NIRS Monitor	3

General requirements for :

- The manufacturer of **all** the equipment must be ISO 13485
- Each device shall be CE marked,
- Conforms to the requirements as per MDR 745/2017 or MDD 93/42 or Provide a Regulatory approval and marketing authorization issued by FDA
- Copy of the above mentioned certifications shall be included in the offer.
- The supplier must provide Installation, User and technical manual in French preferably or English hard copy for the medical system during delivery on site.
- The supplier should provide the contact of the official representative in Tunisia for each of the equipment offered. The Official representative or distributor of the brand should be in charge of the after sales services during the warranty period.
- The supplier must provide with his/her offer the corresponding Price List of accessories, consumables and most significant spare parts for the items.

➤ Associated services per site

C: DELIVERY AND INSTALLATION

The supplier is responsible and in charge of supplying and installing goods following the below listed minimal conditions:

- 1) DAP at the final user site for each equipment including unloading.

- 2) The bidder must request and include a **waiver of demurrage charges** at the port in Tunisia of at least 30 days.
- 3) The transportation must be done following the manufacturer guidelines (storage conditions , temperature, humidity, movemementation requirements, battery management...) on how to handle the equipment, accessories, consumables and reagents when applicable:
- 4) Every single box delivered must be labeled as follow

3.a- Label on the boxes

The supplier has to ensure that the boxes are labeled as per requirements and with reference to the "principles of Labeling for Medical Devices and IVD Medical Devices", IMDRF/GRRP WG/N52 FINAL:2019 <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf>

Region A Color code Region: A	Ministry of Health, TUNISIA UNOPS Office Xxxxx , TUNIS, TUNISIA		
Beneficiary Hospital Data:	Tender: xxx	Lot xxx	Item xxx
Box	2	of	5
Box Weight kg	Length cm	Width	Height
xxx	xxx	xxx	xxx

3.b- Detailed Packing list of the box contents

The supplier has to ensure that the boxes are labeled as per requirements and with reference to the "principles of Labeling for Medical Devices and IVD Medical Devices", IMDRF/GRRP WG/N52 FINAL:2019 <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf>

- 5) The boxes will be opened for contents check before starting the installation and a Report will be signed by the supplier and/or UNOPS:
- 6) All responsibility on the goods are transferred to the beneficiary Hospital once the installation, testing, training and commissioning is done and provisional acceptance documentation duly signed by Beneficiaries, UNOPS and Supplier representatives.
- 7) All the tools, instruments, products, solutions, simulators needed for the Transportation, Installation and testing as per manufacturer guidelines and country reglementation must be provided by the supplier during those activities.
- 8) Prior to shipment, the following documents should be sent to UNOPS:
 - · Bill of Lading
 - · Invoice
 - · Packing List

- Once UNOPS confirms that the information is correct, then you may proceed with the shipment.
- 9) UNOPS reserves the right to perform Pre-Inspection (virtual or physic) checks before packaging of goods for delivery.
 - 10) After the goods are shipped, the supplier must provide to UNOPS an updated delivery plan/schedule at least 2 weeks before DAP delivery on the final beneficiaries sites. UNOPS will facilitate the necessary authorizations and coordinate & confirm delivery dates with the beneficiary hospitals.
 - 11) The supplier must be flexible enough to accommodate variations in the deliveries and installation schedule,

E: TESTING AND COMMISSIONING

For all the following list of equipment and system , The supplier is responsible and in charge of providing appropriate training for users and biomedical technicians.

- The Training documentation (Operating manual, Technical manual, Training presentation, diagrams, schematics etc.) and training schedule/agenda in French must be provided to the UNOPS team at the latest 90 calendar days after contract signature. UNOPS reserves the right to provide suggestions or recommendations with regards to the training contents.
- The training must be held in French or translated in French
- The trainer(s) must perform the training Onsite (anti-covid prevention / medical insurance /appropriate vaccinations must have been be done by the trainers)

E.1 Training Group 1: Technical Training

Item	Description	Number of participants	Minimum duration
01	NeuroMuscular Transmission Monitor	6	1 day
02	Monitoring system with 8 patients monitors	4	3 days
03	Non-invasive cardiac output monitor	6	1 day
04	Monitor for the Depth of anesthesia	6	1 day
05	Transport monitor with invasive blood pressure module	9	2 days
06	NIRS Monitor	8	2 days

- Training location: Local Distributor Facilities
- Starting: On demo Equipment before Installation of equipment in beneficiary sites
- Theoretical and practical training sessions on the same model in the distributor's premises by the manufacturer's engineers or equipment specialists.
- Trained technicians will receive a manufacturer's training certificate (equivalent to field service engineer level).

E.2 Training Group 2: Medical users on the use and operation of equipment.

Item	Description	Number of participants	Minimum duration
01	NeuroMuscular Transmission Monitor	5	1 day
02	Monitoring system with 8 patients monitors	5	2 days
03	Non-invasive cardiac output monitor	5	1 day
04	Monitor for the Depth of anesthesia	5	1 day
05	Transport monitor with invasive blood pressure module	5	1 day
06	NIRS Monitor	5	1 day

- Training location: Beneficiary sites
 - Starting: After Equipment Installation
 - Theoretical session / practical sessions
 - Trained Users will receive a manufacturer's training certificate
 - Technical Assistance by clinical application engineers might be requested to enable users to fully familiarize themselves with the equipment (the expected assistance requested during operations is: answering users questions in relation to the technologies installed, clarifications on how to find specific features on the equipment, users guidance during the use of the technologies...)
 - The Trainers must be a manufacturer's product specialist or field application engineer
 - Credentials (certificates, cv,...) must be sent to UNOPS at least 7 days before the start of training.
- 1) Each trainee documentation in French, training accessories (pen, pencil, notepad) must be provided by the suppliers.
 - 2) All the video projectors, Parts, the tools, instruments, products, solutions, simulators, calibrators, internet needed for the training as per manufacturer guidelines and tender requirements must be provided by the supplier during those activities.
 - 3) A training report and attendance list must be produced to MoH & Unops
 - 4) Waste management: The supplier is in charge of the safe removal and disposal of all the waste produced during his interventions.
 - 5) The supplier must be flexible enough to accommodate perturbation or delays due to the medical activities in some sites during his intervention.

E.3 The training minimum objectives to achieve are:

a) Users

Theoretical session

- Introduction to the equipment (general presentation, description, functionalities)
- Presentation of the equipment parts and system components (Knobs, Display...) + accessories + Installation
- Presentation of accessories and their installation/integration

- Risks or conditions leading to incorrect operations of the medical system
- Functionalities, Parameters
- Reporting
- Safe start and stop for the medical system
- How to set up the parameters How to configure the equipment or system
- How to interpret/understand messages/warnings
- Mastering of the equipment use with reference to the expected clinical uses in the hospital
- Visual inspection, testing and cleaning

Demo - Hands On - Practical session

- Demonstration, hands-on work
- Demonstration and hands-on use of all relevant safety devices, accessories and consumables.

b) Biomedical Technicians

Theoretical session

- Users training + scope of equipment, machine parameters, operating environment
- Equipment principles of operation
- Study of Circuits, block diagrams, circuit diagrams, electronic board, hydraulic circuit, pneumatic circuit
- Device units, Boards and electronics testing
- Common fault / Failures & Solutions
- Troubleshooting
- Routine Testing & Preventive Maintenance (planning of operations: frequency, tools required, overhaul kit and consumables or supplies).
- QC norms and standards

Demo - Hand On - Practical session

- Preventive and corrective maintenance (with fault simulation and correction): case studies.
- Quality control (control procedures, measuring equipment, standards, etc.).
- Parts replacements: Disassembly and assembly of machine units.
- Practical description of machine parameters (operating mode /programs).
- Describe the machine's technical parameters in practice (technical mode).

F: MAINTENANCE AND TECHNICAL SUPPORT REQUIREMENTS

For all the equipment and system provided, The supplier is responsible and in charge of

- Preventive maintenance
- Corrective Maintenance / Repairs
- Technical support (remote/onsite) to the Hospital

These activities must be performed following the below listed minimal conditions:

- 1) All the Parts, the tools, instruments, products, solutions, simulators needed for the preventive maintenance, repairs as per manufacturer guidelines and country reglementation must be provided by the supplier during those activities.
- 2) After the Maintenances a general Testing of all the essential functions of the equipment or system complete with accessories with the appropriate tools, measurement equipment, simulators and

Testing of all the technical and clinical data according to manufacturer testing guidelines must be performed. In conformity with IEC 62353 or IEC 60601

- 3) An Intervention report must be produced to MoH & Unops after each intervention with indications of parts used code, tools, instruments, cost of the replacement parts or maintenance kits.
- 4) All the fees requested for providing the maintenance and technical support are supported by the supplier.
- 5) Waste management: The supplier is in charge of the safe removal and disposal of all the waste produced during his interventions.
- 6) The supplier must be flexible enough to accommodate perturbation or delays due to the medical activities in some sites during his intervention.
- 7) The supplier or local representative response delay in case of notification should be less than 2hrs
- 8) The time between the issue notification and the start of the intervention on site must be less than 48hrs .
- 9) The out of order time due to fault monthly should be less than 72 hours / 3 days
- 10) A Minimum of four (4) preventive maintenance visits (1 per quarter) during the warranty year must be included in the package
- 11) The provisional acceptance will be done after the full commissioning of the medical system and the final acceptance will be done with the beneficiary representative after the warranty year following the evaluation of the performance of the equipment and after sales services provided by the local or regional representative.

G: WASTE MANAGEMENT, HYGIENE, SECURITY AND SAFETY

The sites are functional hospitals with medical and logistical activities involving several categories of people, equipment and vulnerable infrastructures.

The supplier is responsible for the removal and safe disposal of all waste generated during its operations. Waste disposal must not be integrated into the beneficiary hospitals' waste processing chain.

- A preliminary waste management plan will be provided with the technical offer for evaluation. UNOPS reserves the right to request adjustments to the waste management plan in line with best practice in the country.
- A methodology or preliminary plan for the prevention of incidents and accidents involving materials, equipment and people during the supplier interventions (from delivery till commissioning) must be provided with the bid. UNOPS reserves the right to request adjustments to the plan in accordance with good safety and environmental management practices in force in the country.

The successful supplier will be required to take out an insurance policy covering accidents or incidents involving damage to persons or property in the beneficiary hospitals.


The supplier is responsible for the security of the materials, tools, equipment used to provide the requested services.

H: REQUIRED ADDITIONAL DOCUMENTATION

- The supplier must provide with his/her offer the corresponding Price List of accessories, consumables, annual maintenance kits and most significant spare parts for the items or medical system.

Item 1- NeuroMuscular Transmission Monitor

Item No	UNOPS minimum technical requirements	Quantity
1. NeuroMuscular Transmission Monitor	<i>NeuroMuscular Transmission Monitor using either thumb adductor contractions data following ulnar nerve stimulation and eyebrow muscle contraction data following facial nerve stimulation</i>	6
	Requirements: Electrical, Electromagnetic, Dimensions, documentation...	
	Each device shall be CE marked, conforms to the requirements as per MDR 745/2017 or MDD 93/42 or Provide a Regulatory approval and marketing authorization issued by FDA	
	Power supply requirements: 230VAC +/- 10% , 50Hz single-phase	
	Internal protection against overvoltage and overcurrent.	
	Battery autonomy at least 1h	
	Type Electrical Class 2 (Double Insulated)	
	All system components must have FRENCH or ENGLISH as interface language	
	The medical system will be supplied with: User manual in French or English- electronic and hard copy as well as all user passwords	
	The medical system will be supplied with: Technical manual in French or English - electronic and hard copy as well as all technical / access passwords	
	OPERATIONAL FEATURES	
	Brand & Model	
	Provide detailed data sheet	
	A triaxial accelerometer that provides feedback from the curars and enables different stimulation patterns to be tracked.	
	3D - acceleromyography Techonology	
	3D curar monitoring on the display.	
	Multiple functions: Localization and control of curares.	
	Current stimulation up to 60 mA	
	On-screen digital and graphic display.	
	Automatic self-test.	
	Automatic cable detection.	
	Battery indicators	
	Low battery alarm.	
	Neuromuscular stimulation model :	
	-Double burst (DBS)	
	-Train of four TOF	
	-Automatic TOF	
	-Post Titanic count (PTC)	
	-Single Twitch (TWI) ; 0.1 Hz and 1 Hz or equivalent	
	-Tetanus (TET) 50 Hz or equivalent	

	Production of 3D accelerometer measurements from induced muscle responses:	
	TOF % : T4/T1 or equivalent	
	TOF % : T4/TRef or equivalent	
	TOF Count : Number of responses detected	
	Post Titanic count (PTC) : Number of responses detected	
	INCLUDED ACCESSORIES AND CONSUMABLES	
	Supply of complete overhaul / preventive maintenance kit for the warranty year	
	Qty 1: Sensor Extension Cable	
	Qty 2: Thumb Sensor / Hand Sensor reusable	
	Qty 2: Eyebrow Sensor reusable	
	Qty 5: Single-use 3D-AMG hand sensor with stimulation electrodes	
	Clamps for mounting the device to a pole or bedrail	
	To be delivered with all accessories required for proper operation	
	ANCILLARY SERVICES INCLUDED	
	On-site delivery, installation , See Associated Services	
	Testing & Commissioning, See Associated Services	
	Preventive maintenance, repairs and technical assistance during the warranty year, See associated Services	
	Training of medical staff, See Associated Services	
	Training of technical personnel, See Associated Services	
	<i>The images below are intended solely as a guiding support and should be considered as purely indicative and not restrictive of the expected item characteristics:</i>	
		

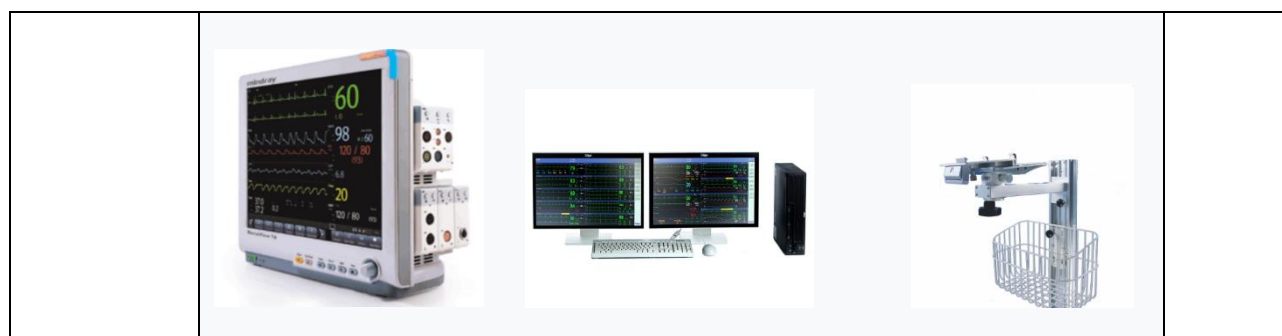
Item 2- Monitoring system with 8 patients monitors

Item No	UNOPS minimum technical requirements	Quantity
2. Monitoring system with 8 patients monitors	<p><i>The medical system is made of a monitoring central screen and 8 multiparametrics patients monitors. It enables you to centrally monitor the vital signs of a minimum of 8 patients monitors connected to the central unit. This medical system streamlines workflow for clinicians, while dramatically increasing patient safety.</i></p> <p>Requirements: Electrical, Electromagnetic, Dimensions, documentation...</p>	2

	Each device shall be CE marked, Conforms to the requirements as per MDR 745/2017 or MDD 93/42 or Provide a Regulatory approval and marketing authorization issued by FDA	
	Power supply requirements: 230VAC +/- 10% , 50Hz single-phase	
	Internal protection against overvoltage and overcurrent.	
	All system components must have FRENCH or ENGLISH as interface language	
	The medical system will be supplied with : User manual in French or English- electronic and hard copy as well as all user passwords	
	The medical system will be supplied with : Technical manual in French or English - electronic and hard copy as well as all technical / access passwords	
	OPERATIONAL FEATURES	
	Central monitoring Station Brand & Model	
	Multiparametric Monitors Brand and Model	
	Provide detailed data sheets	
	A- The central monitoring station: Qty 1	
	CPU complete with all software and accessories (Mouse, Keyboard, dedicated UPS minimum 1000VA)	
	Equipped with 1 medical screen, size 22" or larger	
	Print data or reports directly from the central unit to a network printer	
	Downloading and storage of patient data	
	High-speed network ports for access to PACS and networked devices	
	Integrated WLAN for wireless data transfer	
	LAN connectivity: HDMI; RJ45	
	DICOM 3.0 connectivity for the medical system (sending, archiving, retrieval, printing, importing...) all full licences included	
	Simplified display for content management and intuitive system control	
	View any number of monitors from the central unit.	
	Display of all monitor events for all beds.	
	Arrhythmia detection and review of arrhythmia events.	
	Printout of various patient parameters and recording times.	
	Bi-directional control: allows clinicians to configure and display alarm parameters for each patient monitor from the central station.	
	Network security: the central station operates on a dedicated network and does not communicate with the external network	
	Flexible report export: patient monitoring reports can be sent to network printers or saved as PDF documents for review	
	Three levels of audible and visual alarms	
	Presence of patient protocols	
	Configuration of selected data reports	
	Record and store patient monitoring parameters for a minimum of 72 hours	
	Stores at least the last 100 alarm events per monitor	
	Physiological waveforms displayed on central screen: ECG, RESP, SPO2, IBP, TEMP, CO2, N2O, AA	
	Values - Physiological parameters displayed HR, RESP, ST, NIBP	
	SpO2 and Pulse	


	NIBP: SYS, MAP and DIA	
	IBP: SYS, MAP and DIA	
	Two temperatures	
	B- Multiparametric patient monitor: Qty 8	
	Downloading and storage of patient data	
	High-speed network ports for access to PACS and networked devices	
	Integrated WLAN for wireless data transfer	
	LAN connectivity: HDMI; RJ45	
	DICOM 3.0 connectivity for the medical system (sending, archiving, retrieval, printing, importing...) all full licences included	
	Modular design for trend management and physiological parameter monitoring for adults, children and newborns.	
	Integrated protections against overvoltage and overcurrent line conditions.	
	Built-in rechargeable back-up battery with at least 2 hours autonomy	
	Type Electrical Class 2 (Double Insulated)	
	Simultaneous visualization of a minimum of 8 traces and digital display of physiological data on screen	
	Active-matrix color display (wide viewing angle) minimum size 15"	
	Minimum screen resolution (in pixels) 1024 X 768	
	Trace freeze	
	Selection of minimum scan speeds 12.5 , 25 and 50mm/s	
	Minimum 24-hour trend display (for at least one value for all monitored parameters every 10 min or less)	
	Numerical and graphical trend with scrolling cursor.	
	Patient data transfer to other compatible monitors.	
	Monitoring parameters : IBP , Respiration, ECG , HR, Oxygen saturation, NIBP, Temperature , CO2, AA, N2O	
	Programmed adult and pediatric settings	
	Touch screen and button controls	
	Clear display of measured values and alarms (visual and audible).	
	Simultaneous display of all parameters: ECG curves, respiration curve, SpO2 curve, NIBP measurements and measurements of temperature, Co2, IBP, AA,	
	Selection by the user of the parameters and curves to be displayed	
	Data trends for event reminders	
	Modular monitor: CO2 Module, SPo2 Module, NIBP Module, ECG/RESP Module, IBP Module, AA,N2O Module...	
	Sensors, probes protected against defibrillation shocks	
	SPO2: Oxygen saturation (SpO2) Nellcor or Massimo technology with parameters and alarm adjustments.	
	Non-invasive blood pressure (NIBP) - single-tube cuff type - automatic and manual measurements, with parameters and alarm adjustments. SYS, MAP and DIA	
	ECG module: standard 5-lead ECG with 12-lead capability, ST-segment analysis for arrhythmia detection and recognition, with alarm settings and adjustments; pacemaker detection	
	Respiration: via standard ECG electrode impedance, with alarm settings and adjustments.	

	<p>Temperature: 2-channel temperature measurement (Skin and endocavitary) with alarm settings and adjustments.</p>	
	<p>CO2 measurement: Module designed to acquire a CO2 curve, displaying numerical values for P_{Et}CO₂(exhaled) , min CO₂(inspired) and respiratory rate.</p> <p>Audible and visual apnea alarm.</p>	
	<p>IBP measurement: 2-channel IBP blood pressure measurement. SYS, MAP and DIA</p> <p>Systolic, diastolic and mean pressure values displayed. High and low audible and visual pressure alarms.</p>	
	<p>INCLUDED ACCESSORIES AND CONSUMABLES</p>	
	<p>Supply of complete overhaul / preventive maintenance kit for the warranty year</p>	
	<p>Accessories and consumables for the set</p>	
	<p>Qty: 16 ECG cable 5-leads</p>	
	<p>Qty: 800 disposable adhesive electrodes (expires after March 2025)</p>	
	<p>Qty: 16 reusable temperature probes (skin and endocavitary types).</p>	
	<p>Qty: 16 reusable non-invasive pressure cuffs for adults</p>	
	<p>Qty: 16 reusable non-invasive pediatric pressure cuffs</p>	
	<p>Qty: 16 reusable non-invasive infant pressure cuffs</p>	
	<p>Qty: 16 reusable NIBP tubes and metal connectors</p>	
	<p>Qty: 16 IBP reusable Cables</p>	
	<p>Qty: 80 complete accessories/consumables kit for IBP measurement</p>	
	<p>Qty: 16 reusable adult oxygen saturation (SpO₂) sensors</p>	
	<p>Qty: 16 reusable pediatric oxygen saturation sensors</p>	
	<p>Qty: 16 oxygen saturation (SpO₂) sensor extensions if applicable</p>	
	<p>Qty 80: disposable adult SPO₂ sensors</p>	
	<p>Qty 80: disposable SPO₂ sensors for children</p>	
	<p>Qty 40: single-use CO₂ line accessory/consumable kits including lines and 40 water traps</p>	
	<p>Qty 4: AA and N₂O accessories /consumable kits</p>	
	<p>All wires, cables, hardware or software components necessary for the medical system connectivity</p>	
	<p>Qty 1: Genuine, adjustable wall-mounting or ceiling mounting kit with bracket for horizontal rotation and vertical movement of the central screen</p>	
	<p>Qty 8: Genuine, adjustable wall-mounting kit with bracket for horizontal rotation and vertical movement of multiparameter monitor</p>	
	<p>Qty 8: Multiparametric monitor , Wall-mounted basket for monitor accessories, adjustable height</p>	
	<p>ANCILLARY SERVICES INCLUDED</p>	
	<p>On-site delivery, installation and system wiring , See Associated Services</p>	
	<p>Testing & Commissioning, See Associated Services</p>	
	<p>Preventive maintenance, repairs and technical assistance during the warranty year, See associated Services</p>	
	<p>Training of medical staff, See Associated Services</p>	
	<p>Training of technical personnel, See Associated Services</p>	
	<p><i>The images below are intended solely as a guiding support and should be considered as purely indicative and not restrictive of the expected item characteristics:</i></p>	



Item 3- Non-invasive cardiac output monitor

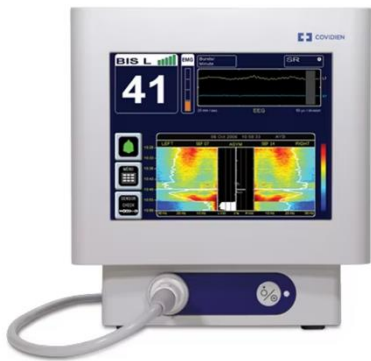
Item No	UNOPS minimum technical requirements	Quantity
3. Non-invasive cardiac output monitor	<i>Non-invasive hemodynamic monitoring system provides advanced, beat-by-beat monitoring for informed decision-making in critical care environments</i>	3
	Requirements: Electrical, Electromagnetic, Dimensions, documentation...	
	Each device shall be CE marked, Conforms to the requirements as per MDR 745/2017 or MDD 93/42 or Provide a Regulatory approval and marketing authorization issued by FDA	
	Power supply requirements: 230VAC +/- 10% , 50Hz single-phase	
	Internal protection against overvoltage and overcurrent.	
	Battery autonomy at least 1h	
	All system components must have FRENCH or ENGLISH as interface language	
	The medical system will be supplied with : User manual in French or English-electronic and hard copy as well as all user passwords	
	The medical system will be supplied with : Technical manual in French or English - electronic and hard copy as well as all technical / access passwords	
	OPERATIONAL FEATURES	
	Brand & Model	
	Provide detailed data sheet	
	Battery charge level indicator	
	Color Touch screen and button controls	
	Artifact and interference safety features	
	Displays measured values and alarms (visual and audible).	
	The monitor must be able to measure :	
	Blood flow	
	- systolic ejection volume / systolic ejection index	
	- change in systolic ejection volume	
	- Heart rate	
	- Cardiac output / Cardiac index	
	Vascular system	
	-Systemic vascular resistance	
	-Indexed systemic vascular resistance	
	- Total arterial compliance	
	Blood Pressure	
	Systolic blood pressure	

	Diastolic blood pressure	
	Mean arterial pressure	
	Oxygen status	
	Oxygen supply / Oxygen supply index	
	Minimum 12" color display	
	Screen resolution (in pixels) 800x 600 minimum	
	Three levels of audible and visual alarms	
	Recording and storage of parameters for a minimum of 24hours	
	Stores at least the last 50 alarm events	
	To be delivered with all accessories required for proper operation.	
	INCLUDED ACCESSORIES AND CONSUMABLES	
	Supply of complete overhaul / preventive maintenance kit for the warranty year	
	Qty 2: module cable if applicable	
	Qty 2: reusable non-invasive electrodes if applicable	
	Qty 40: accessories/consumables set for non-invasive cardiac output monitoring	
	Genuine cart	
	ANCILLARY SERVICES INCLUDED	
	On-site delivery, installation , See Associated Services	
	Testing & Commissioning, See Associated Services	
	Preventive maintenance, repairs and technical assistance during the warranty year, See associated Services	
	Training of medical staff, See Associated Services	
	Training of technical personnel, See Associated Services	
	<i>The images below are intended solely as a guiding support and should be considered as purely indicative and not restrictive of the expected item characteristics:</i>	
		

Item 4- Monitor for the Depth of Anesthesia

Item No	UNOPS minimum technical requirements	Quantity
4. Monitor for the Depth of	<i>Monitoring medical system designed to monitor the hypnotic state of the brain by acquiring and analyzing EEG signals. The system must process the raw EEG signals in such a way as to generate a single value correlated with the patient's level of hypnosis.</i>	6
	Requirements: Electrical, Electromagnetic, Dimensions, documentation...	

Anesthesia	Each device shall be CE marked, Conforms to the requirements as per MDR 745/2017 or MDD 93/42 or Provide a Regulatory approval and marketing authorization issued by FDA	
	Power supply requirements: 230VAC +/- 10% , 50Hz single-phase	
	Internal protection against overvoltage and overcurrent.	
	Battery autonomy at least 2h	
	All system components must have FRENCH or ENGLISH as interface language	
	The medical system will be supplied with : User manual in French or English-electronic and hard copy as well as all user passwords	
	The medical system will be supplied with : Technical manual in French or English - electronic and hard copy as well as all technical / access passwords	
	OPERATIONAL FEATURES	
	Brand & Model	
	Provide detailed data sheet	
	Battery charge level indicator	
	Color Touch screen and button controls	
	Artifact and interference safety features	
	Displays measured values and alarms (visual and audible).	
	Electro disconnection detection.	
	Protection against defibrillator shock and H.F.	
	Programmed adult and pediatric settings	
	Multiple levels of audible and visual alarms	
	Stores at least the last 50 alarm events	
	Display of instantaneous anesthesia depth value.	
	Display of raw EEG tracings in real time.	
	Display of EMG value.	
	Display of Suppression Ratio	
	Bilateral sensor	
	Artifact rejection: automatic.	
	User-selectable event markers.	
	Audible and visual alarm	
	Adjustable alarm limits.	
	Mandatory measured parameters: State of anesthesia EEG, BS%, CSI, EMG or equivalent	
	Other Non mandatory additional parameters (ECG, NIBP, SpO2 Nellcor or massimo, RR, TEMP)	
	INCLUDED ACCESSORIES AND CONSUMABLES	
	Qty: 2 reusable module with cables for state of anesthesia sensors	
	Qty: 25 adult sensors	
	Qty: 25 pediatric sensors	
	To be delivered with all accessories required for proper operation(Including all accessories or consumables for additional non-mandatory parameters if applicable)	
	Genuine Kit for wall-mounting (original brand support) allowing movement on two axis	
	ANCILLARY SERVICES INCLUDED	
	On-site delivery, installation , See Associated Services	

	Testing & Commissioning, See Associated Services	
	Preventive maintenance, repairs and technical assistance during the warranty year, See associated Services	
	Training of medical staff, See Associated Services	
	Training of technical personnel, See Associated Services	
	The images below are intended solely as a guiding support and should be considered as purely indicative and not restrictive of the expected item characteristics:	
		

Item 5- Transport monitor with invasive blood pressure module

Item No	UNOPS minimum technical requirements	Quantity
5. Transp ort monitor with invasive blood pressur e module	<i>Medical device used for physiological parameters monitoring during transport (ECG, NIBP and SpO2, PI) of a patient to be used for Adult and Pediatrics patients</i>	5
	Requirements: Electrical, Electromagnetic, Dimensions, documentation...	
	Each device shall be CE marked, Conforms to the requirements as per MDR 745/2017 or MDD 93/42 or Provide a Regulatory approval and marketing authorization issued by FDA	
	Power supply requirements: 230VAC +/- 10% , 50Hz single-phase	
	Internal protection against overvoltage and overcurrent.	
	Battery autonomy at least 4h	
	Type Electrical Class 2 (Double Insulated)	
	All system components must have FRENCH or ENGLISH as interface language	
	The medical system will be supplied with : User manual in French or English- electronic and hard copy as well as all user passwords	
	The medical system will be supplied with : Technical manual in French or English - electronic and hard copy as well as all technical / access passwords	
	OPERATIONAL FEATURES	
	Brand & Model	
	Provide detailed data sheet	
	12" minimum color display	
	Battery charge level indicator	
	Touch screen and button controls	
	Artifact and interference safety features	

	Displays measured values and alarms (visual and audible).	
	Electrode disconnection detection.	
	Protection against defibrillator shock and H.F.	
	Programmed adult and pediatric settings	
	Displays measured values and alarms (visual and audible).	
	Modular monitor: SPO2 Module, NIBP Module, ECG/RESP Module, IBP Module, Temperature module...	
	Monitored parameters: IBP , Respiration, ECG , HR, Oxygen saturation, NIBP, Temperature	
	Simultaneous display of all parameters: ECG curves, breathing curve, SpO2 curve, NIBP measurements and measurements of temperature, IBP	
	Capacity for the user to select the data and curves to be displayed	
	Data Trend for events	
	Sensors, probes protected against defibrillation shocks	
	SpO2 Module	
	Oxygen saturation (SpO2) with parameters and alarm adjustments.	
	Digital display of:	
	- Arterial O2 saturation	
	- Pulse rate.	
	- High and low alarms	
	SpO2 parameter with Nellcor or Masimo technology	
	Real-time plethysmography curve acquisition.	
	NIBP Module	
	Non-invasive blood pressure (NIBP) - single-tube cuff type	
	Systolic, diastolic and mean pressure values displayed	
	Automatic and Manual measurements, with parameters and alarm settings.	
	NIBP overpressure detection	
	HR	
	ECG Module	
	5 standard ECG leads with the option of 12 leads, ST segment analysis for arrhythmia detection and recognition, with alarm settings and adjustments.	
	Respiration Rate: via standard ECG electrode impedance, with alarm settings and adjustments.	
	Temperature Module	
	Temperature measurement with alarm settings and adjustments.	
	IBP Module	
	2-channel IBP blood pressure measurement.	
	Systolic, diastolic and mean pressure values displayed. High and low audible and visual pressure alarms.	
	INCLUDED ACCESSORIES AND CONSUMABLES	
	Supply of complete overhaul / preventive maintenance kit for the warranty year	
	Qty: 2 ECG cable 5-leads	
	Qty: 100 disposable adhesive electrodes (expires after March 2025)	
	Qty: 2 reusable non-invasive pressure cuffs for adults	
	Qty: 2 reusable non-invasive pediatric pressure cuffs	
	Qty: 2 reusable non-invasive infant pressure cuffs	
	Qty: 2 reusable NIBP tubes and metal connectors	
	Qty: 2 reusable adult oxygen saturation (SpO2) sensors	


	Qty: 2 reusable pediatric oxygen saturation sensors	
	Qty: 2 oxygen saturation (SpO2) sensor extensions if applicable	
	Qty: 2 reusable temperature probes (skin and endocavity types).	
	Qty 2: IBP reusable Cables	
	Qty: 10 accessories/consumables for IBP measurement on 10 patients	
	Original carrying bag	
	Qty: 2 genuine battery pack	
	Anchoring system on bed or vertical support during transport	
	ANCILLARY SERVICES INCLUDED	
	On-site delivery, Installation, See Associated Services	
	Testing & Commissioning, See Associated Services	
	Preventive maintenance, repairs and technical assistance during the warranty year, See associated Services	
	Training of medical staff, See Associated Services	
	Training of technical personnel, See Associated Services	
	The images below are intended solely as a guiding support and should be considered as purely indicative and not restrictive of the expected item characteristics:	



Item 6- NIRS Monitor

Item No	UNOPS minimum technical requirements	Quantity
6. NIRS Monitor	<i>Non-invasive, real-time, simultaneous monitoring of cerebral and somatic oximetry using NIRS near-infrared spectroscopy. Determines the quality of local tissue perfusion and provides regional oxygen saturation (rSO2). Enables continuous, non-invasive observation of patients with reduced blood flow or no flow.</i>	3
	Recommended brand and model: Masimo, Somanetics, Edwards (NIRS) or equivalent	
	REQUIREMENTS: ELECTRICAL, ELECTROMAGNETIC, DIMENSIONS, DOCUMENTATION...	
	Each device shall be CE marked, Conforms to the requirements as per MDR 745/2017 or MDD 93/42 or Provide a Regulatory approval and marketing authorization issued by FDA	
	Power supply requirements: 230VAC +/- 10% , 50Hz single-phase	
	Internal protection against overvoltage and overcurrent.	
	Battery autonomy at least 2h	

	All system components must have FRENCH or ENGLISH as interface language	
	The medical system will be supplied with : User manual in French or English- electronic and hard copy as well as all user passwords	
	The medical system will be supplied with : Technical manual in French or English - electronic and hard copy as well as all technical / access passwords	
	OPERATIONAL FEATURES	
	Brand & Model	
	Provide detailed data sheet	
	Real-time measurement of cerebral oxygen saturation in the frontal cortex.	
	measurement of parameters at brain or tissue level.	
	Digital display of regional oxygen saturation	
	Real-time graphic display of the patient's cerebral or tissue status.	
	Non-invasive system.	
	Graphic and digital display.	
	Automatic self-test.	
	Color touch screen.	
	Screen size $\geq 10"$	
	Screen resolution (in pixels) 800 X 600 or better	
	Audible and visual alarm	
	Variable levels of audible and visual alarms	
	Adjustable alarm limits.	
	Patient data download via data ports (LAN or USB ...)	
	Network ports	
	Recording and storage of parameters for a minimum of 48 hours	
	Stores at least the last 50 alarm events	
	Data module with 2 sensors or 2 channels	
	Accuracy of adult sensor	
	Accuracy of regional oxygen saturation (rSO2) $\leq 5\%$	
	Accuracy of pediatric sensor	
	Accuracy of regional oxygen saturation (rSO2) $\leq 5\%$	
	ADDITIONNAL CONSUMABLES AND ACCESSORIES INCLUDED	
	Supply of complete overhaul / preventive maintenance kit for the warranty year	
	Qty 2 : rSO2 extension modules with cables	
	Qty 25 : adult tissue saturation sensors	
	Qty 25 : pediatric tissue saturation sensors.	
	To be delivered with all accessories required for proper operation.	
	Mounting kit for vertical support (e.g. serum holder)	
	Genuine Wall-mounting kit, rotation or movement on both axes or genuine cart	
	ANCILLARY SERVICES INCLUDED	
	On-site delivery, installation , See Associated Services	
	Testing & Commissioning, See Associated Services	
	Preventive maintenance, repairs and technical assistance during the warranty year, See associated Services	
	Training of medical staff, See Associated Services	
	Training of technical personnel, See Associated Services	

	<p>The images below are intended solely as a guiding support and should be considered as purely indicative and not restrictive of the expected item characteristics:</p> 	
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H. Delivery requirements and Comparative Data Table

UNOPS Requirements	
Delivery time	Bidder shall deliver the goods 20 weeks after Contract signature.
Delivery place and Incoterms rules	Tunisia DPU (Consignee-wise quantity distribution list) UNOPS and/or the consignee will submit all tax exemption documentation to the selected supplier- The bidder must submit all shipment documents to UNOPS before departure of the shipment from the FCA point.
Consignee details	Ministry of Health in Tunisia
UNOPS Right to vary requirements	At the time the Contract is awarded, UNOPS reserves the right to vary the quantity of the goods and associated services specified above, provided this does not exceed +/- 20, without any change in the unit prices or other terms and conditions of the ITB.

Consignee-wise quantity distribution

Beneficiaries:

Tunis	Hop La Marsa	ANESTH REAN	Neuromuscular Transmission Monitor	1
Tunis	La Rabta	ANESTH REAN	Neuromuscular Transmission Monitor	1
Tunis	Hop Charles Nicolle	ANESTH REAN	Neuromuscular Transmission Monitor	1
Sousse	Hop Sahloul	ANESTH REAN	Neuromuscular Transmission Monitor	1
Sfax	Hop H Bourguiba	ANESTH REAN	Neuromuscular Transmission Monitor	1
Monastir	Hop F Bourguiba	ANESTH REAN	Neuromuscular Transmission Monitor	1
Tunis	Cngmo		Monitoring System With 8 Patients Monitors	2

Tunis	La Rabta	CCVT	Non-Invasive Cardiac Output Monitor	1
Sousse	Hop Sahloul	CCVT	Non-Invasive Cardiac Output Monitor	1
Sfax	Hop H Bourguiba	CCVT	Non-Invasive Cardiac Output Monitor	1

Tunis	La Rabta	Anesth Rean	Monitor For the Depth of Anesthesia	1
Tunis	Hop La Marsa	Anesth Rean	Monitor For the Depth of Anesthesia	1
Tunis	Hop Charles Nicolle	Anesth Rean	Monitor For the Depth of Anesthesia	1
Sousse	Hop Sahloul	Anesth Rean	Monitor For the Depth of Anesthesia	1
Sfax	Hop H Bourguiba	Anesth Rean	Monitor For the Depth of Anesthesia	1
Monastir	Hop F Bourguiba	Anesth Rean	Monitor For the Depth of Anesthesia	1

Tunis	Hop Charles Nicolle	ANESTH REAN	Transport Monitor with Invasive Blood Pressure Module	1
Sousse	Hop Sahloul	CCVT	Transport Monitor with Invasive Blood Pressure Module	1
Tunis	Hop La Marsa	ANESTH REAN	Transport Monitor with Invasive Blood Pressure Module	1
Mahdia	Hop T Sfar	ANESTH REAN	Transport Monitor with Invasive Blood Pressure Module	1
Sfax	Hop H Bourguiba	SAMU	Transport Monitor with Invasive Blood Pressure Module	1

Tunis	La Rabta	CCVT	Nirs Monitor	1
Sfax	Hop H Bourguiba	CCVT	Nirs Monitor	1
Sousse	Hop Sahloul	CCVT	Nirs Monitor	1

Related services requirements

Service	UNOPS minimum requirements for services	Place where services will be performed	Final completion date(s) of services
1.	Delivery as per Distribution list	Tunisia (As per the distribution list)	Delivery should be made in fully as follows: - The Bidder shall deliver all the equipment no later than 20 weeks after contract signature.
2.	Installation		- The Bidder shall complete the installation for the units no later than 4

			weeks after the delivery (24 weeks after the contract signature).
3.	Testing and Commissioning		Should be done at the end of the installation
4.	Preventive Maintenance, Corrective/Repair and technical assistance contract for users, IEC 62353		Must be valid for the warranty period of each item
5.	Training Group 1: Technical Training		During the installation phase of the equipment (Section E: TRAINING REQUIREMENTS)
6.	Training Group 2: Medical users on the use and operation of equipment.		Should be done at the end of each installation (Section E: TRAINING REQUIREMENTS)

I. Additional Inspections and tests

The following inspections and tests shall be performed:

The vendor must have the goods inspected in the manufacturer's works by a competent authority and submit a test certificate and also a guarantee/warranty certificate that the goods conform to written specifications.

UNOPS and/or its beneficiary representatives reserve the rights to conduct visits to the individual manufacturers' production premises to ensure and track the timely completion of their orders as per the defined quantities attributed to each scheduled deliveries. Those visits will be planned and coordinated with the manufacturers and constitute an important quality assurance step.

UNOPS or its representative reserve the rights to inspect and/or test any or all items of the goods to confirm their conformity to the contract, prior to dispatch from the manufacturer's premises. Such inspection and clearance will not prejudice the right of the consignee to inspect and test the goods on receipt at destination.

If the goods fail to meet the laid down specifications, the supplier shall take immediate steps to remedy the deficiency or replace the defective goods to the satisfaction of the purchaser.