**Section II: Schedule of Requirements**

**eSourcing reference:** ITB/2021/28945

* **Summary of Requirements**

UNOPS requirements are comprised of the 9 items listed below. Quantities are undefined. UNOPS will not be committed to purchase any minimum quantity of the Goods, and purchases will be made only if and when there is an actual demand.

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| **Item No** | **Item description** | **Is bid compliant?** Bidder to complete |
| **1** | **Oxygen concentrator 5 LPM** | ☐ Yes ☐ No |
| **2** | **Oxygen concentrator 8 LPM** | ☐ Yes ☐ No |
| **3** | **Oxygen concentrator 10 LPM** | ☐ Yes ☐ No |
| **4** | **Flow splitter** | ☐ Yes ☐ No |
| **5** | **ICU Patient monitor multiparametric, advanced** | ☐ Yes ☐ No |
| **6** | **Transport monitor** | ☐ Yes ☐ No |
| **7** | **Pulse oxymeter, handheld** | ☐ Yes ☐ No |
| **8** | **Pulse oxymeter, tabletop** | ☐ Yes ☐ No |
| **9** | **Pulse oxymeter, fingertip** | ☐ Yes ☐ No |
|  |  |  |

**General disclaimer**

All medical equipment must be provided with:

* User care instructions and protocols, including guidance for replacement of accessories and consumables and safe decontamination of reusable parts, indicating if they are generic or brand related;
* Technical maintenance protocols;
* Warranty (including software updates) specifying date of commencement, duration period, exclusions/inclusions and other conditions as relevant.

**Other requirements that shall be confirmed during the call-off order issuance:**

* All electrical connections according to the destination Country standards.
* In the event of termination of production of the spare parts:   
  Advance notification to the Purchaser of the pending termination, in sufficient time to permit the Purchaser to procure needed requirements; and following such termination, furnishing at no cost to the Purchaser, the blueprints, drawings and specifications of the spare parts, if requested.

**Section II: Schedule of Requirements**

**Technical specifications for Goods and Comparative Data Table**

Bidders are NOT allowed to make any change in the “UNOPS requirements” columns of the Comparative Data Tables. Such changes might disqualify your bid.

**Items 01 -03: Oxygen concentrators**

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| --- | --- | --- | --- | --- |
| **Item No** | **UNOPS minimum technical requirements** | **Quantity** | **Is Bid compliant?** Bidder to complete | **Details of goods offered.** Bidder to complete |
| 01; 02; 03 | An electrically powered medical device designed to concentrate oxygen from ambient air. Used to deliver oxygen at the bedside, typically through an attached nasal cannula (or prongs), to a patient requiring oxygen therapy. The intended use or clinical purpose is the delivery of low-flow, continuous, clean and concentrated oxygen (> 82%) from room air (21%). | Unlimited | ☐ Yes ☐ No | Insert details of goods offered, including specifications and brand/model offered if applicable |

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| --- | --- | --- |
| **1. General technical requirements:**   * Provides a continuous flow of concentrated oxygen (> 82%) from room air through one oxygen outlet. * Continuous flow up to 5 L/min (item 01) or 8 L/min (item 02) or 10 L/min (item 03)   The below technical specifications are applicable to all three oxygen concentrators.   * Contains oxygen monitor to verify concentration. * Requires continuous AC power source to operate. * Power efficiency ≤ 70 W/L/min * User interface to be easy to operate; numbers and displays clearly visible and easily readable in low ambient light and sunlight. * Digital or analogue meter that displays cumulative hours of device operation. * Oxygen outlet(s) with 6 mm (1/4 inch) barbed fitting or equivalent. * Oxygen outlet to be securely mounted and sheltered to reduce risk of being broken or bent. * Flowmeter minimum flow rate of 0.5 L/min or less. Flowmeter adjustable, within minimum gradation intervals of 0.5 L/min for 5 L/min models, and 1 L/min for larger models. * Noise level < 60 dB(A). * Capable to be disinfected with hospital grade detergents. * At least IP11 degree of protection to the harmful ingress of water (fluid spill resistance). * Mechanical shock resistance, mechanical vibration, electromagnetic compatibility and electrical safety testing. * Capable of supplying the specified oxygen concentration continuously in ambient temperature from 10–40 °C, relative humidity from 15–85%, and elevation from 0 to at least 2000 m. For operation at elevations higher than 2000 m, environmental requirements are less stringent; performance characteristics at such altitudes must be stated. | 1.☐ Yes ☐No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes ☐ No  12.☐ Yes ☐ No  13.☐ Yes ☐ No  14.☐ Yes ☐ No  15.☐ Yes ☐ No |  |
| **2. Displayed parameters**   * Oxygen flow rate (on flowmeter). * Cumulative hours of operation. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No |  |
| **3. User adjustable settings**  Oxygen flow rate | ☐ Yes ☐ No |  |
| **4. Alarms**  Audible and/or visual alarms for:   * Low oxygen concentration (< 82%). * Power supply failure. * High temperature. * Low/high output pressure. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No |  |
| **5. Accessories (included and mentioned in a disaggregated list)**   * DISS and 6 mm barbed adaptor for each outlet (interchangeable between devices of different brands and models) (if applicable): 1 package of 20 per equipment. * Humidifier included, bubble, non-heated, single use or Reusable with appropriate disinfection protocols. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No |  |
| **6. Spare parts (included and mentioned in a disaggregated list)**  1-year spare parts kit as per preventive maintenance programme, including:   * Internal and external mounted filters for cleaning the air intake. * Spare battery set for alarm system (if applicable). * Spare mains power cable length ≥ 2.5 m. * Replacement sets of spare fuses (if non-resettable fuses are used). * Sieve beds. * Bidder must give a complete list of the specific spare parts included in their bid. * Other spares that may be needed: circuit breaker, printed circuit board, compressor service kit, valves, wheels, motor capacitor, flowmeters and fan. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No |  |
| **7. Mobility, portability**   * Whole unit to be movable with wheels on at least two castors. * Unit weight to be < 27 kg. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No |  |
| **8. Power supply, voltage, frequency and plug vary across countries**   * Operates from AC power electric line: 100–240 V/50–60 Hz. * Main power cable and plug adapted for various countries. * Mains power cable length ≥ 2.5 m. * Electrical protection by resettable circuit breakers or replaceable fuses, fitted in both neutral and live lines or single fuse in live line. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No |  |
| **9. Documentation requirements (English language mandatory)**   * Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages. * Certificate of calibration and inspection. * Troubleshooting, calibration and routine maintenance. * List of all spare parts and accessories, with part numbers and contact details for parts supply. * Document with contact details of manufacturer, supplier and local service agent | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No |  |
| **10. Primary packaging label**   * Name and/or trademark of the manufacturer. * Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). * Model or product reference. * Information for particular storage conditions (temperature, pressure, light, humidity). | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No |  |
| **11. Standards, for the manufacturer**   * Certified quality management system for medical devices ( ISO 13485). * General quality management (e.g. ISO 9001). * Application of risk management to medical devices (e.g. ISO 14971). | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | Bidder to specify |
| **12. Regulatory approval/certification**   * Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.   2. Proof of regulatory approval and marketing authorisation issued by one of the GHTF Founding Members: European Union, United States, Canada, Australia or Japan. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | Bidder to specify |
| **13. Standards, for product performance**  Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for:   * ISO 80601-2-69:2020 Medical electrical equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment. * IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. * IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests. * IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability. * IEC 60601-1-8:2012 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. * IEC 60601-1-9:2013 Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design. * IEC 60601-1-11:2010 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home health-care environment. * Compliance with ISO 8359 may be considered. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No |  |
| **14. Warranty**   * Not less than 2 years. * Availability of accessories, consumables and spare parts for at least 2 years. * Contact details of manufacturer, supplier and local service agent to be provided. | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No |  |
| **15. Maintenance**   * Maintenance tasks:List of procedures required for local routine maintenance should be provided. * Spare parts availability post-warranty:Availability of accessories, consumables and spare parts to be specified (in years) * List of countries where the bidder has capacity either directly or through authorised agent to provide support in installation, training and preventive maintenance | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | Bidder to specify and provide list of countries |
| **16. Estimated lifespan:**  Not less than 7 years depending on the use | ☐ Yes ☐ No | Bidder to specify |
| 17. Name and address of the manufacturer and manufacturing site |  |  |
| 18. Lead time |  |  |
| 19. Weight and volume in kg and m3 per UOM (1 device) |  |  |
| 20.Brand and model number |  |  |
| 21. Unique Device Identification Number |  |  |

*Any variation to be indicated in the offer.*

**Item 04: Flow splitter**

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| --- | --- | --- | --- | --- | --- | --- |
| **Item No** | **UNOPS minimum technical requirements** | **Qty** | **Is quotation compliant?** Bidder to complete | | **Details of goods offered.** Bidder to complete | |
| 04 | Tabletop or wall-mounted device composed of an inlet valve that delivers oxygen to multiple independent flowmeters, each one providing an outlet. Up to five independent Thorpe tube pressure-compensated flowmeters, that can be calibrated to multiple flow ranges, are installed in the flowmeter stand housing. It can be connected to concentrators or to any standard pressure oxygen source, like cylinders and central system, according to device version. | **Unlimited** | ☐ Yes ☐ No | |  | |
| **1. General technical requirements:**   * Flow splitter from a single or double oxygen supply. * Equipped with four or five independent, pressure-compensated, Thorpe tube flowmeters, to regulate the flow of medical gas. * Suitable for tabletop and/or wall mount. * Flowmeters capacity: 0.125–2 L/min. * Accuracy: ± 10%. * Inlet port to be compatible with all the international standards for oxygen fittings, including DISS, threaded and non-threaded, 6 mm barbed – availability of different ports and/or adapters to be stated. * 6 mm barbed outlet as standard – availability of adapters and outlet options to match all the * international standards for oxygen fittings to be stated. * Transparent, clearly readable and graduated (metric system) column, shatter-resistant polymer certified for medical use. * Needle valve and body constructed of brass or aluminium. * Adjustment knobs to have rough surface to prevent slipping. * Flowmeter stand hard plastic or metal epoxy painted. * Capable to be disinfected with hospital grade detergents. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes ☐ No  12.☐ Yes ☐ No  13.☐ Yes ☐ No | |  | |
| **2. Primary packaging label**   * Name and/or trademark of the manufacturer. * Model or product reference. * Information for particular storage conditions (temperature, pressure, light, humidity). * Gas type, calibration temperature and pressure should be specified on the label. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No | |  | |
| **3. Standards, for the manufacturer**   * Certified quality management system for medical devices ( ISO 13485) * General quality management (e.g. ISO 9001). * Application of risk management to medical devices (e.g. ISO 14971). | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  | |
| **4. Regulatory approval/certification**   * Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. * Proof of regulatory approval and marketing authorisation issued by one of the GHTF Founding Members: European Union, United States, Canada, Australia or Japan. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | | Bidder to specify | |
| **5. Standards, for product performance**  Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for:   * Colour coding ISO or ANSI for medical gases. * Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved. * ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen. * ISO 15002 Flow-metering devices for connection to terminal units of medical gas pipeline systems. * ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications. * ISO 10524 Pressure regulators for use with medical gases. * ISO 18082 Anaesthetic and respiratory equipment – Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases. * ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. * ISO 5359 Low-pressure hose assemblies for use with medical gases. * ISO 32 Colour coding for medical gases. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No | |  | |
| **6. Warranty**   * Not less than 2 years. * Availability of accessories, consumables and spare parts for at least 2 years. * Contact details of manufacturer, supplier and local service agent to be provided | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | | Bidder to specify | |
| **7. Maintenance**   * Maintenance tasks:List of procedures required for local routine maintenance should be provided. * Spare parts availability post-warranty:Availability of accessories, consumables and spare parts to be specified (in years). * List of countries where the bidder has capacity either directly or through authorised agent to provide support in installation, training and preventive maintenance | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  | |
| **8. Estimated lifespan:**  Not less than 7 years | | | | ☐ Yes ☐ No | | Bidder to specify | |
| 9. Name and address of the manufacturer and manufacturing site | | | |  | |  | |
| 10. Lead time | | | |  | |  | |
| 11. Weight and volume in kg and m3 per UOM (1 device) | | | |  | |  | |
| 12.Brand and model number | | | |  | |  | |
| 13. Unique Device Identification Number | | | |  | |  | |

*Any variation to be indicated in the offer.*

**Item 05: ICU Patient monitor multiparametric: advanced**

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| --- | --- | --- | --- | --- | --- |
| **Item No** | **UNOPS minimum technical requirements** | **Qty** | **Is quotation compliant?** Bidder to complete | | **Details of goods offered.** Bidder to complete |
| 05 | Medical device that continuously measure, calculate and display physiological parameters (ECG, CO2, invasive blood pressure (IBP), non-invasive blood pressure (NIBP), oxygen saturation (SpO2), respiratory rate (RR) and temperature (TEMP) designed to monitor patients, (with accessories). | **Unlimited** | ☐ Yes ☐ No | |  |
| **1. General technical requirements:**   * Continuous display on screen of patient ECG, respiration rate and heart rate, invasive and non-invasive blood pressure, body temperature, SpO2 and CO2 mainstream or side stream. * Dynamic digital display that can show all active parameters. * Unwanted parameters can be deselected from display. * Operator can set audio-visual alarm levels for low or high levels of each parameter independently. * Operates from mains voltage or from internal rechargeable battery. * ECG patient connectors sterilizable and reusable or disposable. * Hard copy printout of traces will not be required. * Multichannel (up to 12 leads) ECG measurement and selectable display; * Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. * SpO2 measurement range at least 70–99%, with accuracy better than ± 3% and minimum gradation 1%. * Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg. Cuff sizes neonatal/paediatric and adult. User selectable measurement intervals. * Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection. * Temperature probe to be reusable, external skin contact type, but consumable to protect between patients or disinfection method explained. * Temperature range at least 30–40 °C, minimum gradation 0.1 °C. * Respiration rate measurement range at least 0–100 bpm, minimum gradation 1 bpm. * CO2 monitoring capabilities. * Invasive blood pressure (IBP) monitoring capabilities. * Automatic and programmable memory. * Storage of continuous monitoring data. * Trace signal velocity of at least 25 mm/s. * LCD or TFT screen with: a. analogue shape signals and numerical values visualization; b. settable limits for the measured variables;  c. not less than 10” wide. * Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests. * Protections of all the functions against defibrillator discharges and electrosurgical units. * Pace-maker detection. * Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%. * Enclosure to have ingress protection level IPX1 or better | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes ☐ No  12.☐ Yes ☐ No  13.☐ Yes ☐ No  14.☐ Yes ☐ No  15.☐ Yes ☐ No  16.☐ Yes ☐ No  17.☐ Yes ☐ No  18.☐ Yes ☐ No  19.☐ Yes ☐ No  20.☐ Yes ☐ No  21.☐ Yes ☐ No  a.☐ Yes ☐ No  b.☐ Yes ☐ No  c.☐ Yes ☐ No  22.☐ Yes ☐ No  23.☐ Yes ☐ No  24.☐ Yes ☐ No  25.☐ Yes ☐ No  26.☐ Yes ☐ No |  | | |
| **2. Displayed parameters**  Trend display of each parameter | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No |  | | |
| **3. User adjustable settings**  1. Alarm override and temporary silence facility to be included.  2. Audio-visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No |  | | |
| **4. Alarms**   * Alarm override and temporary silence facility to be included. * Audio-visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery, cuff leak, cuff disconnect, hose leak, inflation/deflation errors, failure to take successful reading, low battery notice. * Power failure. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No |  | | |
| **5. Consumables**  ECG electrodes (if applicable): 100 sets | | | ☐ Yes ☐ No |  | | |
| **6. Accessories (included and mentioned in a disaggregated list)**   * All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid. * Lead ECG cable: 2 per equipment. * Lead ECG cable (if option offered): 2 per equipment. * Sets of ECG connection electrodes (if reusable type): 5 sets. * Tubes electrode gel (if required): 5 tubes. * Reusable SpO2 probes adult: 2 probes. * Reusable SpO2 probes paediatric use: 2 probes. * Blood pressure – non-invasive: 3 paediatric reusable cuffs; 3 adult reusable cuffs. * Blood pressure – invasive: 1 sensor for each channel offered. * External skin temperature probes: 2 probes. * If CO2 mainstream technology: tube adapter: 3 per equipment; sensor: 3 per equipment. * If CO2 side stream technology: sample lines: 100 lines; water traps: 10 per equipment. * Battery: 1 set. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes ☐ No  12.☐ Yes ☐ No  13.☐ Yes ☐ No |  | | |
| **7. Spare parts (included and mentioned in a disaggregated list)**  1-year spare parts kit as per preventive maintenance programme including but not exclusively, sets of spare fuses (if non-resettable fuses used) and battery. | | | ☐ Yes ☐ No |  | | |
| **8. Power supply, voltage, frequency and plug vary across countries**   * Operated by line electrical power supply with internal replaceable rechargeable battery backup allows operation for at least 1 hour in the event of power failure. * Operates from AC power electric line: 100–240 V~/50–60 Hz. * Main power cable and plug adapted for various countries. * Mains power cable length ≥ 2.5 m. * Protections against over-voltage and over-current line conditions. * Protection against defibrillator discharges and electrosurgical units. * Automatic switch between battery and mains powered modes, when recharging or in mains power failure. * The display shall show which power source is in use. * Compliance with electrical standards and regulations. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No |  | | |
| **9. Documentation requirements (English language mandatory)**   * Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages. * Certificate of calibration and inspection. * Troubleshooting, calibration and routine maintenance. * List of all spare parts and accessories, with part numbers and contact details for parts supply. * Document with contact details of manufacturer, supplier and local service agent. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No |  | | |
| **10. Primary packaging label**   * Name and/or trademark of the manufacturer. * Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). * Model or product reference. * Information for particular storage conditions (temperature, pressure, light, humidity). | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No |  | | |
| **11. Standards, for the manufacturer**  1.Certified quality management system for medical devices (ISO 13485).  2. General quality management (e.g. ISO 9001).  3. Application of risk management to medical devices (e.g. ISO 14971). | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No |  | | |
| **12. Regulatory approval/certification**   * Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. * Proof of regulatory approval and marketing authorisation issued by one of the GHTF Founding Members: European Union, United States, Canada, Australia or Japan. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | Bidder to specify | | |
| **13. Standards, for product performance**  Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for:   * IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. * IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. * IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. * IEC 60601-1-8 General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems). * IEC 80601-2-49 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment. * IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometer. * IEC 60601-2-34 Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment). * ISO 80601-2-55 Particular requirements for the basic safety and essential performance of respiratory gas monitors). * ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. * IEC 60601-2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No |  | | |
| **14. Warranty**   * 5 years with regards efficiency and quality of the product. * Availability of accessories, consumables and spare parts for at least 2 years. * Contact details of manufacturer, supplier and local service agent to be provided. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No |  | | |
| **15. Maintenance**   * Maintenance tasks:List of procedures required for local routine maintenance should be provided. * Spare parts availability post-warranty:Availability of accessories, consumables and spare parts to be specified. * List of countries where the bidder has capacity either directly or through authorised agent to provide support in installation, training and preventive maintenance. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | Bidder to specify and provide list of countries | | |
| **16. Estimated lifespan:**  Not less than 7 years | | | ☐ Yes ☐ No |  | | |
| 17. Name and address of the manufacturer and manufacturing site | | |  |  | | |
| 18. Lead time | | |  |  | | |
| 19. Weight and volume in kg and m3 per UOM (1 device) | | |  |  | | |
| 20.Brand and model number | | |  |  | | |
| 21. Unique Device Identification Number | | |  |  | | |

*Any variation to be indicated in the offer.*

**Item No 06 Transport Monitor**

|  |  |  |  |  |  |  |  |
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| **Item No** | **UNOPS minimum technical requirements** | **Qty** | | **Is quotation compliant?** Bidder to complete | | **Details of goods offered**. Bidder to complete | |
| **06** | Vital signs monitoring system used for transport and emergency situations. For adult and pediatric patients | **Unlimited** | | ☐ Yes ☐ No | |  | |
| **1. General technical requirements**  1. 120-240V, 50/60Hz mono-phase electrical source.  2. Protections against over-voltage and over-current line conditions.  3. Rechargeable battery back-up with at least 3 hours of autonomy.  4. 12Vdc input for ambulance use.  5. Protections against defibrillator discharges and electrosurgical units.  6. Monitoring modules: Respiration, ECG, Oxygen Saturation, Non-Invasive Blood Pressure, Temperature.  7. For adults and pediatric patients.  8. Storage of at least 24 hours of continuous monitoring data.  9. Trace signal velocity of at least 25mm/sec.  10. 10” LCD or TFT display with curves and numerical values visualization  11. At least 5 simultaneous curves visualization.  12. Pace-maker detection.  13. Visual, audible and adjustable alarms for all the parameters measured.  14. Built-in handle.  15. Lightweight monitor, no more than 3kg.  Respiration module:  16. frequency respiration of at least 0-140 bpm;  17. precision no greater than 2%.  ECG module  18. 12 standard leads and simultaneous visualization of 3 ECG signals.  19. Alarms for at least: cardiac arrest, ventricular fibrillation, tachycardia, bradycardia, arrhythmia, lead connection interruption.  20. QRS detection range of at least 0.5-5 mV.  21. Cardiac frequency range of at least 30-250 beats/min, precision no greater than 2%.  22. Software: Arrhythmias detection and analysis; ventricular fibrillation detection and analysis; ventricular tachycardia detection and analysis.  Oxygen Saturation module:  23. Range of at least of 70 to 90% SpO2;  24. Precision no greater than 2%.  Non-invasive Blood Pressure module (NIBP)  25. Diastolic, Systolic, and mean pressure measurement.  26.Measurement range of at least 50-240mmHg, precision no greater than 5%.  27. Total measurement time no greater than 30 sec.  Temperature module  28. Measurement range at least 30–40 °C, minimum gradation 0.1 °C. | | | 1.☐ Yes☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes☐No  12.☐ Yes☐ No  13.☐ Yes ☐ No  14.☐ Yes ☐ No  15.☐ Yes ☐ No  16.☐ Yes ☐ No  17.☐ Yes ☐ No  18.☐ Yes ☐ No  19.☐ Yes ☐ No  20.☐ Yes ☐ No  21.☐ Yes☐ No  22.☐ Yes ☐ No  23.☐ Yes ☐ No  24.☐ Yes ☐ No  25.☐ Yes ☐ No  26.☐ Yes ☐ No  27.☐ Yes ☐ No  28.☐ Yes ☐ No | |  | |
| **2. Accessories (included and mentioned in a disaggregated list)**  1. Software licenses and user and maintenance manuals.  2. All the cables, sensors and connectors needed for full monitor functionality.  3. Reusable respiratory sensor and connector set.  4. 200 Disposable adult ECG Electrodes.  5. 100 Disposable pediatric ECG Electrodes.  6. Two (2) set of reusable electrodes and connectors included.  7. Two (2) ECG lead cables.  8. Two (2) Reusable adult oxygen saturation sensor and connector set.  9. Two (2) Reusable pediatric oxygen saturation sensor and connector set.  10. Two sets of adult reusable cuffs different sizes: pediatric, small, medium, large and extra-large.  11. Two (2) Reusable temperature transducer and connector set. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes ☐ No | |  | |
| **3. Documentation requirements (English language mandatory)**  1. Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages.  2. Certificate of calibration and inspection.  3. Troubleshooting, calibration and routine maintenance.  4. List of all spare parts and accessories, with part numbers and contact details for parts supply.  5. Document with contact details of manufacturer, supplier and local service agent | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No | |  | |
| **4. Primary packaging label**  1. Name and/or trademark of the manufacturer.  2. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames).  3. Model or product reference.  4. Information for particular storage conditions (temperature, pressure, light, humidity). | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No | |  | |
| **5. Standards, for the manufacturer**  1. Certified quality management system for medical devices ( ISO 13485).  2. General quality management (e.g. ISO 9001).  3. Application of risk management to medical devices (e.g. ISO 14971) | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  | |
| **6 . Regulatory approval/certification**  1. Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country.  2. Proof of regulatory approval and marketing authorisation issued by one of the GHTF Founding Members: European Union, United States, Canada, Australia or Japan. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | |  | |
| **7. Standards, for product performance**  Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for:  1. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.  2. IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.  3. IEC 60601-1-8 General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems).  4. IEC 80601-2-49 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.  5. IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometer.  6. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.  7. IEC 60601-2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment. | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No | | Bidder to specify | |
| **8. Warranty**  1. 5 years with regards efficiency and quality of the product.  2. Availability of accessories, consumables and spare parts for at least 2 years.  3. Contact details of manufacturer, supplier and local service agent to be provided | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  | |
| **9. Maintenance**  1. Maintenance tasks: List of procedures required for local routine maintenance should be provided.  2. Spare parts availability post-warranty: Availability of accessories, consumables and spare parts to be specified (years).  3. List of countries where the bidder has capacity either directly or through authorised agent to provide support in installation, training and preventive maintenance | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  | |
| **10. Estimated lifespan**  Not less than 7 years | | | ☐ Yes ☐ No | |  | |
| 11. Name and address of the manufacturer and manufacturing site | | |  | |  | |
| 12. Lead time | | |  | |  | |
| 13. Weight and volume in kg and m3 per UOM (1 device) | | |  | |  | |
| 14.Brand and model number | | |  | |  | |
| 15. Unique Device Identification Number | | |  | |  | |

*Any variation to be indicated in the offer.*

**Item 07:** Pulse oximeter: handheld

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| **Item No** | **UNOPS minimum technical requirements** | **Qty** | **Is quotation compliant?** Bidder to complete | | **Details of goods offered.** Bidder to complete | |
| 07 | Medical device designed to monitor the haemoglobin oxygen saturation (SpO2) through transcutaneous measurements using plethysmography, displays the SpO2 value and pulse rate. Handheld**:** portable, battery-powered. | **Unlimited** | ☐ Yes ☐ No | |  | |
| **1. General technical requirements:**   * SpO2 and pulse rate monitor, for adults, children, for all skin pigmentations. * SpO2 detection to include the range: 70–100%. * SpO2 resolution: 1% or less. * SpO2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions. * If equipment capable of a wider SpO2 detection range, accuracy over that wider range shall be stated. * Pulse rate detection to include the range: 30–240 bpm. * Pulse rate resolution: 1 bpm or less. * Pulse rate accuracy within ± 3 bpm. * Data update period for valid data displayed ≤ 10 s. * Display with main parameters: % SpO2, pulse rate, alarm messages, battery state indication. * Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). * Automatic correction for movement and ambient light artefacts (as per ISO 80601-2-61, test method must be described). * Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests in ISO 80601-2-61. * Capable of working with adult, paediatric and neonatal reusable probes. * Enclosure to have ingress protection level IPX2 or better. * Overall device and probe weight < 400 g. * Any aspects of usability as per IEC 62366-1 must be described. * Suitable for cleaning and disinfection. * Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–85% non-condensing * Function for continuous monitoring. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes ☐ No  12.☐ Yes ☐ No  13.☐ Yes ☐ No  14.☐ Yes ☐ No  15.☐ Yes ☐ No  16.☐ Yes ☐ No  17.☐ Yes ☐ No  18.☐ Yes ☐ No  19.☐ Yes ☐ No  20.☐ Yes ☐ No | |  | |
| **2. Displayed parameters**   * Display with main parameters: % SpO2, pulse rate, , alarm messages, battery state indication. * Display must allow easy viewing in all ambient light levels. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | |  | |
| **3. User adjustable settings**   * Audio-visual adjustable alarms: high/low SpO2 and high/low pulse rate (operator variable settings). * Alarm override and temporary silencing. | | | | ☐ Yes ☐ No | |  | |
| **4. Alarms**   * Audible and visual alarms for low/high saturation and pulse rate, threshold set by user. * Audible and visual alarms for sensor error or disconnected, system errors, low battery. * Alarm temporary silencing function | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  | |
| **5. Accessories (included and mentioned in a disaggregated list)**   * Carry case: 1 per equipment. * Reusable probes, adult (finger clip): 2 per equipment. * Reusable probes, paediatric: 2 per equipment. * Extender cable to achieve probe cable length > 1 m (if applicable): 3 per equipment. * Battery charger (if applicable): 1 per equipment | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No | |  | |
| **6. Spare parts (included and mentioned in a disaggregated list)**  1-year spare parts kit as per preventive maintenance programme | | | | ☐ Yes ☐ No | |  | |
| **7. Portability**  Portable handheld | | | | ☐ Yes ☐ No | |  | |
| **8. Power supply, voltage, frequency and plug vary across countries**   * Operated by replaceable battery power supply, either rechargeable or single use. * External or built-in AC battery charger, if rechargeable type. Power connection requirements as per local power supply. * Charger, if used, to have protection against over-voltage and over-current line conditions (specify if IEC 60601-1 certified) * Protection against defibrillator discharges and electrosurgical units. * The display shall show which power source is in use. * Running time on battery only ≥ 12 hours. * Operates from AC power electric line: 100–240 V~/50–60 Hz. * Main power cable and plug adapted for various countries | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No | |  | |
| **9. Documentation requirements (English language mandatory)**   * Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages. * Certificate of calibration and inspection (other means of assurance may be considered). * Troubleshooting, calibration and routine maintenance. * List of all spare parts and accessories, with part numbers and contact details for parts supply. * Document with contact details of manufacturer, supplier and local service agent. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No | |  | |
| **10. Primary packaging label**   * Name and/or trademark of the manufacturer. * Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). * Model or product reference. * Information for particular storage conditions (temperature, pressure, light, humidity). | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No | |  | |
| **11. Standards, for the manufacturer**   * Certified quality management system for medical devices (ISO 13485). * General quality management (e.g. ISO 9001). * Application of risk management to medical devices (e.g. ISO 14971). | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | | Bidder to specify | |
| **12. Regulatory approval/certification**   * Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. * Proof of regulatory approval and marketing authorisation issued by one of the GHTF Founding Members: European Union, United States, Canada, Australia or Japan. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | | Bidder to specify | |
| **13. Standards, for product performance**  Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for:   * IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. * IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. * IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. * ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. * ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No | |  | |
| **14. Warranty**   * 2 years with regards efficiency and quality of the product. * Availability of accessories and spare parts for at least 2 years. * Contact details of manufacturer, supplier and local service agent to be provided | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  | |
| **15. Maintenance**   * Maintenance tasks:List of procedures required for local routine maintenance should be provided. * Spare parts availability post-warranty:Availability of accessories, consumables and spare parts to be specified (years). * List of countries where the bidder has capacity either directly or through authorised agent to provide support in installation, training and preventive maintenance. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | | Bidder to specify and provide list of countries | |
| **16. Estimated lifespan:**  Not less than 7 years | | | | ☐ Yes ☐ No | | Bidder to specify | |
| 17. Name and address of the manufacturer and manufacturing site | | | |  | |  | |
| 18. Lead time | | | |  | |  | |
| 19. Weight and volume in kg and m3 per UOM (1 device) | | | |  | |  | |
| 20.Brand and model number | | | |  | |  | |
| 21. Unique Device Identification Number | | | |  | |  | |

*Any variation to be indicated in the offer.*

**Item 08:** Pulse oximeter: tabletop

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| **Item No** | **UNOPS minimum technical requirements** | **Qty** | **Is quotation compliant?** Bidder to complete | | **Details of goods offered.** Bidder to complete | |
| 08 | Medical device designed to monitor the haemoglobin oxygen saturation (SpO2) through transcutaneous measurements using plethysmography, displays the SpO2 value, pulse rate, and may detect, calculate and display other parameters.  Tabletop, electrically powered. | **Unlimited** | ☐ Yes ☐ No | |  | |
| **1. General technical requirements:**   * Continuously monitors SpO2, plethysmography waveform and pulse rate for adults and children. * SpO2 detection to include the range: 70–100%. * SpO2 resolution: 1% or less. * SpO2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions. * If equipment is capable of a wider SpO2 detection range, the accuracy over that wider range shall be stated. * Pulse rate detection to include the range: 30–240 bpm. * Pulse rate resolution: 1 bpm or less. * Pulse rate accuracy within ± 3 bpm. * Data update period for valid data displayed ≤ 10 s. * Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). * Automatic correction for movement and ambient light artefacts (as per ISO 80601-2-61, test method must be described). * Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests in ISO 80601-2-61. * Internal data storage for patient data and trends and for event log. * Capable of working with adult, paediatric and neonatal reusable probes. * Enclosure to have ingress protection level IPX2 or better. * Any aspects of usability as per IEC 62366-1 must be described. * Disinfectable with hospital grade detergents. * Continuous operation within specification in ambient temperature of at least 5–40 °C, relative humidity of at least 10–85% non-condensing. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes ☐ No  12.☐ Yes ☐ No  13.☐ Yes ☐ No  14.☐ Yes ☐ No  15.☐ Yes ☐ No  16.☐ Yes ☐ No  17.☐ Yes ☐ No  18.☐ Yes ☐ No | |  | |
| **2. Displayed parameters**   * Display with main parameters: % SpO2, pulse rate, plethysmography waveform (and possibly other indicators of signal quality), alarm messages, battery and system messages/state indication. * Display must allow easy viewing in all ambient light levels | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | |  | |
| **3. User adjustable settings**   * Audio-visual adjustable alarms: high/low SpO2 and high/low pulse rate (operator variable settings). * Alarm override and temporary silencing | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | |  | |
| **4. Alarms**   * Audible and visual alarms for low/high saturation and pulse rate, threshold set by user. * Audible and visual alarms for sensor error or disconnected, system errors, low battery. * Alarm override and temporary silencing function. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  | |
| **5. Accessories (included and mentioned in a disaggregated list)**   * Reusable probes, adult (finger clip): 2 per equipment. * Reusable probes, paediatric: 2 per equipment. * Extender cable to achieve probe cable length > 1 m: 3 per equipment. * Battery charger (if applicable): 1 per equipment | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No | |  | |
| **6. Spare parts (included and mentioned in a disaggregated list)**  1-year spare parts kit as per preventive maintenance programme | | | | ☐ Yes ☐ No | |  | |
| **7. Portability**  Tabletop | | | | ☐ Yes ☐ No | |  | |
| **8. Power supply, voltage, frequency and plug vary across countries**   * Operated by line electrical power supply with internal replaceable rechargeable battery backup. * Protection against defibrillator discharges and electrosurgical units. * Battery charger integrated in the main unit. * Automatic switch between battery and mains powered modes, when recharging or in mains power failure. * The display shall show which power source is in use. * Running time on battery only ≥ 6 hours. * Operates from AC power electric line: 100–240 V~/50–60 Hz. * Main power cable and plug adapted for various countries. * Mains power cable length ≥ 2.5 m. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No | |  | |
| **9. Documentation requirements (English language mandatory)**   * Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages. * Certificate of calibration and inspection (other means of assurance may be considered). * Troubleshooting, calibration and routine maintenance. * List of all spare parts and accessories, with part numbers and contact details for parts supply. * Document with contact details of manufacturer, supplier and local service agent. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No | |  | |
| **10. Primary packaging label**   * Name and/or trademark of the manufacturer. * Model or product reference. * Information for particular storage conditions (temperature, pressure, light, humidity). * Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No | |  | |
| **11. Standards, for the manufacturer**   * Certified quality management system for medical devices (ISO 13485). General quality management * (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971). | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | | Bidder to specify | |
| **12. Regulatory approval/certification**   * Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. * Proof of regulatory approval and marketing authorisation issued by one of the GHTF Founding Members: European Union, United States, Canada, Australia or Japan. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | | Bidder to specify | |
| **13. Standards, for product performance**   * Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratory or third party) for:IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. * IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. * IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. * ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. * ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No | |  | |
| **14. Warranty**   * 2 years with regards efficiency and quality of the product. * Availability of accessories and spare parts for at least 2 years | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | | Bidder to specify | |
| **16. Estimated lifespan:**  Not less than 7 years. | | | | ☐ Yes ☐ No | | Bidder to specify | |
| 17. Name and address of the manufacturer and manufacturing site | | | |  | |  | |
| 18. Lead time | | | |  | |  | |
| 19. Weight and volume in kg and m3 per UOM (1 device) | | | |  | |  | |
| 20.Brand and model number | | | |  | |  | |
| 21. Unique Device Identification Number | | | |  | |  | |

*Any variation to be indicated in the offer.*

**Item 09:** Pulse oximeter: fingertip

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| **Item No** | **UNOPS minimum technical requirements** | **Qty** | **Is quotation compliant?** Bidder to complete | | **Details of goods offered.** Bidder to complete | |
| 09 | Medical device designed to monitor the haemoglobin oxygen saturation  (SpO2) through transcutaneous measurements using plethysmography. A portable, battery-powered device used on a patient’s finger, displays the SpO2  value | **Unlimited** | ☐ Yes ☐ No | |  | |
| **1. General technical requirements:**   * SpO2 and pulse rate monitor integrated into finger/toe clip. * Configurations required to apply to adults and children, and all skin pigmentations. * Suitable for spot check. * SpO2 detection to include the range: 70–99%. * SpO2 resolution: 1% or less. * SpO2 accuracy (in the range at least 70–99%): within ± 3%. If equipment is capable of a wider SpO2 detection range, the accuracy over that wider range shall be stated. * Pulse rate detection to include the range: 30–240 bpm. * Pulse rate resolution: 1 bpm or less. * Pulse rate accuracy within ± 3 bpm. * Suitable for detection in low perfusion conditions (as per ISO 80601-2-61, test method must be described). * Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests in ISO 80601-2-61. * Available probe sizes must accommodate finger/toe thicknesses at least including the range 8–25 mm. * Automatic correction for movement, ambient light artefacts (as per ISO 80601-2-61, test method must be described). * Display shows % SpO2, pulse rate, signal quality, sensor error or disconnect and low battery status. * Enclosure to have ingress protection level IPX2 or better. * Any aspects of usability as per IEC 62366-1 must be described. * Disinfectable with hospital grade detergents. * Automatic power-off. * Hours of continuous use, or number of tests, per battery set shall be stated. * Batteries must allow at least 2500 spot checks calculated at 30 s per spot check, or at least 12 hours of operation, or better. * Operated by internal battery. If rechargeable, batteries may be charged via USB connector or by external AC charger. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No  8.☐ Yes ☐ No  9.☐ Yes ☐ No  10.☐ Yes ☐ No  11.☐ Yes ☐ No  12.☐ Yes ☐ No  13.☐ Yes ☐ No  14.☐ Yes ☐ No  15.☐ Yes ☐ No  16.☐ Yes ☐ No  17.☐ Yes ☐ No  18.☐ Yes ☐ No  19.☐ Yes ☐ No  20.☐ Yes ☐ No  21.☐ Yes ☐ No | |  |
| **2. Displayed parameters**  pO2, pulse rate, battery and system status. Specify if signal quality is as well displayed. | | | | ☐ Yes ☐ No | |  |
| **3. Alarms**   * Audible and visual alarms for sensor error or disconnected, system errors, low battery. * Audible and visual alarms for low/high saturation and pulse rate. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | |  |
| **4. Consumables**  Rechargeable and/or non rechargeable batteries: 2 sets | | | | ☐ Yes ☐ No | |  |
| **5. Accessories**   * Battery charger (AC or USB if relevant): 1 per equipment. * Replacement flexible cover for patient finger contact (if removable): 2 per equipment. * Carry case and/or lanyard. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  |
| **6. Documentation requirements (English language mandatory)**   * User: manuals, hard and soft copies, in English (mandatory) and other languages. * Certificate of calibration and inspection (other means of assurance may be considered). * Troubleshooting separate manual or as part of the user manual. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  |
| **7. Primary packaging label**   * Name and/or trademark of the manufacturer. * Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). * Model or product reference. * Information for particular storage conditions (temperature, pressure, light, humidity). | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No | |  |
| **8. Standards, for the manufacturer**   * Certified quality management system for medical devices (ISO 13485). * General quality management (e.g. ISO 9001). * Application of risk management to medical devices (e.g. ISO 14971). | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No | |  |
| **9. Regulatory approval/certification**   * Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. * Proof of regulatory approval and marketing authorisation issued by one of the GHTF Founding Members: European Union, United States, Canada, Australia or Japan. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | | Bidder to specify |
| **10. Standards, for product performance**  Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for: IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.   * IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. * IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. * ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. * ISO/IEEE 11073-10404 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter (if capacity for data connection to a computer is included). * IEC 60068-2-31 Environmental testing – Part 2-31: Tests –Test Ec: Rough handling shocks, primarily for equipment-type specimens. * IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. * IEC 62133 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No  3.☐ Yes ☐ No  4.☐ Yes ☐ No  5.☐ Yes ☐ No  6.☐ Yes ☐ No  7.☐ Yes ☐ No | |  |
| **11. Warranty**   * 2 years with regards efficiency and quality of the product. * Availability of accessories and spare parts for at least 2 years. | | | | 1.☐ Yes ☐ No  2.☐ Yes ☐ No | |  |
| **12. Estimated lifespan:**  Not less than 7 years. | | | | ☐ Yes ☐ No | | Bidder to specify |
| 13. Name and address of the manufacturer and manufacturing site | | |  | |  | |
| 14. Lead time | | |  | |  | |
| 15. Weight and volume in kg and m3 per UOM (1 device) | | |  | |  | |
| 16.Brand and model number | | |  | |  | |
| 17. Unique Device Identification Number | | |  | |  | |

*Any variation to be indicated in the offer.*

**Delivery requirements and Comparative Data Table:**

|  |  |  |  |
| --- | --- | --- | --- |
| **UNOPS Requirements** | | **Is quotation compliant?** Bidder to complete | **Details**  Bidder to complete |
| **Delivery time** | Bidder to specify FCA Incoterms 2020 delivery time for the quantity ranges as per the Form B: Price Schedule Form. | ☐ Yes ☐ No | Insert details |
| **Delivery place and Incoterms rules** | Bidder to specify nearest FCA seaport and airport.  Incoterms 2020 apply. | ☐ Yes ☐ No | Insert details |
| **List of warehouse locations around the world, if any with nearest FCA port (Incoterms 2020).** | | | Insert details |