

Revised: 12/08/2020

PROVINCE OF KWAZULU-NATAL

DEPARTMENT OF HEALTH

**HEALTH TECHNOLOGY SERVICES
(H.T.S)**

**SPECIFICATION FOR:
High Flow Humidified Oxygen Delivery Device (Paediatrics)**

**UMDNS: 18076
SPECIFICATION: H.T.S A86A (Anaesthetics)**

Description:

The device must be capable of delivering high flow oxygen that is both heated and humidified and suitable for Paediatric patients

Intended Areas of Use:

District
Regional
Tertiary

Expert Advisory Group:

Paediatrics


Dr. MORAN
12/8/2020

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NB: GENERAL CLAUSES THAT DO NOT APPLY TO THE EQUIPMENT OFFERED MUST BE ANSWERED "COMPLIES", "DOES NOT COMPLY" OR ANSWER THE QUESTION UNDER BIDDERS COMMENTS.

NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY" OR ANSWER THE QUESTION.
Clause G1	<p>The space provided under "Bidder's Comments" for each clause must be used for this purpose. Bidders who neglect to provide answers to every Clause in this Bid Specification will be disqualified. Bidders must note that abbreviated answers e.g. N/A etc. will not be accepted.</p> <p>Bidders must also note that no part of any clause/s in this Bid Specification may be altered. Where there are traces of alterations found to any clauses in this Bid Specification during Adjudication, the Adjudication Committee will reserve the right to disqualify the bidder.</p> <p>The Bidder must clearly indicate if their offered product complies with the stated requirements, by indicating, "Complies" or "Does not comply" or answer the question next to the corresponding clause.</p>	
Clause G2	All responses must be clear and legible.	
Clause G3	GUARANTEE:	
Clause G3.1	<p>All Equipment, Materials and Workmanship provided under this Contract must be Guaranteed for a minimum period of twenty four (24) Months. The successful bidder must arrange with the respective Hospital / Institution and the Health Technology Services before Commissioning the Equipment at the respective Hospital / Institution.</p> <p>The bidder to note that the Guarantee period must only take effect upon successful Commissioning at the respective Hospital / Institution and successful test and acceptance by the Health Technology Services.</p>	
Clause G3.2	State percentage guaranteed up time of machine (Should be at least 99%).	
Clause G3.3	The recommended number of services, per annum, by the manufacturer, must be included during and up until the end of the guarantee period and all costs related to the provision of such service/s will be for the bidders account.	
Clause G3.4	The bidder must state the number of services that will be provided during and up to the end of the guarantee period.	
Clause G3.5	Any breakdown during the guarantee period must include all cost (spares, labour, travelling and sundries) for any prescribed maintenance services (major and minor) as well as any QA testing that is required by Department Health's Radiation Control Board during the guarantee period.	
Clause G3.6	Travelling and Travelling Time costs must be included during the Guarantee Period?	
Clause G3.7	Spares that may be required during the Guarantee Period will be supplied at the expense of the bidder.	
Clause G3.8	Downtime during the Guarantee Period must extend the Guarantee time on a Day-to-Day basis.	
Clause G3.9	Any repetition (twice or more) of the same type of fault that first occurred during the guarantee period must be considered as a repair under guarantee if it occurs within the first year after the expiry of the guarantee period.	
Clause G3.10	The same guarantee conditions must apply to replacement units.	
Clause G4	The successful bidder must Supply, Deliver, Commission and install the Equipment and will be required to demonstrate the product to the applicable Staff at the Institution and costs for the abovementioned must be included in	

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NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY" OR ANSWER THE QUESTION.
	the final bid price.	
Clause G5	Bidders must offer the Health Technology Service's In House Technicians a demonstration of the product, which will enable the Health Technology Service's In House Technicians to become acquainted with the equipment during the Test and Acceptance phase.	
Clause G6	Preference may be given to a make and model that has been technically and clinically evaluated by a Government Institution within the R.S.A. (Attach proof of evaluation where applicable).	
Clause G7	The successful bidder must provide the Health Technology Service's in house Technicians, full training in the calibration, maintenance, service and repair of the product down to PCB Level. N.B. The quality and level of the training must be equivalent to the manufacturer's original factory training and any costs incurred to provide this training will be for the bidders account. A Certificate of Competency must be issued on completion of the training. The Training must be provided by the successful bidder to the Health Technology Services within three months from date of initial supply and delivery of the equipment to the end user.	
Clause G8	SERVICING:	
Clause G8.1	The bidder must have a well established service and repair facility in KwaZulu-Natal, to service, repair and calibrate the equipment offered. (The Health Technology Services reserves the right to inspect the premises).	
Clause G8.2	If the service is subcontracted to a local service agent, a signed copy of the letter of appointment by the bidder and acceptance by the subcontractor must be submitted with this bid / quotation. (The Health Technology Services reserves the right to inspect the premises).	
Clause G8.3	State Number of other medical equipment "Repair & Service" Agencies (excluding your Agency) represented by the subcontractor.	
Clause G8.4	Supply the Name, Address and Telephone Number/s of the Local Service Department within KwaZulu-Natal. Please supply details as follows: Company name : _____ Physical Address : _____ _____ Telephone Number/s : _____ Fax number : _____ _____ <i>(The Health Technology Services reserves the right to inspect the premises).</i>	
Clause G8.5	State if the Technician(s) are in the direct employ of the bidder or a subcontractor.	
Clause G8.6	The bidder must supply information on the number of Technicians permanently working in KwaZulu-Natal and their names and contact	

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NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY" OR ANSWER THE QUESTION.
	Telephone Number/s must be listed (Directly employed or subcontracted) in an annexure to the bid document.	
Clause G8.7	The Technician(s) must be original equipment manufacturer trained to deal with the service, repair and calibration of the equipment quoted on. N.B. Proof of original equipment manufacturer training must be submitted with this bid / quotation offer.	
Clause G8.8	The Institution's requirement is that a technician is available within a reasonable time (24 hours) to attend to malfunctioning equipment. The Bidder to state the technician per install base e.g. equipment ratio to technician ratio, e.g. 1 technician per 10 pieces of equipment.	
Clause G9	The bidder must Guarantee that no additional equipment will be required for the successful operation of the equipment bided for on delivery and commissioning at the customers site. A starter pack of all essential accessories and disposables must be supplied so that the unit can be put into immediate operation. The cost of the starter pack must be included in the final bid price.	
Clause G10	Optional accessories must be offered for separately on the Schedule of optional accessories found at the end of this Technical specification, indicating catalogue numbers, correct descriptions and Prices inclusive of V.A.T.	
Clause G11	Bidder must state the period of time for delivery of Spare parts following the receipt of an official order as follows: 0 to 10 days; 0 to 20 days; 0 to 30 days; 0 to 60 days; 0 to 90 days; more than 90 days.	
Clause G11.1	The Bidder must supply with this offer a list together with the quantities of spares held locally in stock in the KwaZulu-Natal Province on the offered product. The Health Technology Services reserves the right to inspect the premises to verify the spares stock held.	
Clause G12	The bidder must include a firm commitment in writing, which must be attached with this bid that they would supply spares, components, upgrades, complete original service / repair manual, technical support and ongoing training support for technical staff of the Health Technology Services and the end users Department of Health, KwaZulu-Natal throughout the life cycle of the equipment offered.	
Clause G13	Spares must be available for 10 (Ten) years from the original equipment manufacturer for the product offered.	
Clause G14	The successful bidder must include in their offer at no extra cost to the final bid price:	
Clause G14.1	Complete user Operation / Maintenance Manual x 2 (two) Book / File; CD; DVD copies in English Language.	
Clause G14.2	Complete ORIGINAL Service / Repair Manual x 2 (two) Book / File; CD; DVD copies in English Language which MUST include the following information: Fault Finding Guide, Circuit Diagrams / Schematics, Circuit Descriptions, and PCB Layouts, Calibration Guide, Part Numbers and exploded diagram of Mechanical Parts / Panels.	
Clause G14.3	All the above Manuals must be properly bound in either a Book, File or CD form.	
Clause G14.4	The Bidder must supply all software (including software-keys and / or passwords) to allow for trouble shooting (faultfinding), maintenance, calibrations, repairs and services at no additional cost.	
Clause G15	Does your Company have an after hour service back up facility.	
Clause G16	If the equipment is taken away for repairs, a loan set must be made available	

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NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY" OR ANSWER THE QUESTION.
	on request to the end user by the Institution until the Institution's unit is returned. All costs incurred for providing the loan unit must be for the bidders account.	
Clause G17	Bidder must bid on the latest model and Technology that fully complies with this Technical Specification.	
Clause G17.1	The Bidder must state how long this technology has been commercially available (state when the model offered was launched).	
Clause G17.2	The bidder must state if there are any near future updates expected.	
Clause G18	The successful bidder must maintain a system for notifying and providing users with Updates, Modifications, new Software Releases and Recalls.	
Clause G19	The successful bidders must arrange for an acceptance test of the equipment with the Manager of the Health Technology Services and the Hospital Manager. A copy of the original answered Specification, copy of the invoice order and relevant paperwork (PH form) from the receiving Hospital must be submitted with the equipment when the ACCEPTANCE TEST is to be undertaken.	
Clause G20	Where equipment bided for, operates off 220 Volt, 50Hz a.c. supply, bidder must ensure that the product being quoted for is fitted with a 15 Amp approved mains plug top, which is held together by two screws.	
Clause G21	The unit must comply with an acceptable International Electrical Safety Standard such as IEC 60601-1 and 60601-1-2 for Medical Equipment where the quoted equipment operates off an electrical supply.	
Clause G22	All equipment, the installation and any alteration / additions must comply with:	
Clause G22.1	The Occupational Health and Safety Act (1993);	
Clause G22.2	The wiring code S.A.N.S. 0142.	
Clause G23	Units being quoted for must be CE Certified. (Attach a copy of certification). The make and the model offered must be reflected on the certificate.	
Clause G24	The Mains Cable of the unit being quoted for must be the Hospital Grade Type and it must be a minimum length of (3) three metres. N.B. The mains cable of the unit being quoted for must be S.A.N.S. colour coded.	
Clause G25	The equipment being quoted for must be protected against Electro magnetic interference.	
Clause G26	Only new equipment must be quoted for. Refurbished and reconditioned equipment being quoted on will not be accepted.	
Clause G27	Bidders must note that dedicated test equipment, spare parts and any special tooling required for the upkeep and maintenance of the equipment quoted on must be available to the Health Technology Services to procure if requested.	
Clause G28	All the necessary calibration and maintenance software, where applicable, required to maintain and calibrate the equipment, must be supplied with the equipment to the Health Technology Services at no extra cost to the final bid price.	
Clause G29	NB. HAZARDOUS SUBSTANCE ACT:	
Clause G29.1	If this type of equipment / apparatus appears on the schedule of Hazardous Substances issued by the Directorate: Health Technology of the Department of Health, a license in terms of the Act on Hazardous Substances (Act. 15/1973) must be submitted with this bid document. The license must be registered under the bidders name or a letter of joint venture must be	

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	submitted by the license holder where the license is not in the name of the bidder. Bidders that neglect to submit a license will not be considered.	
Clause G29.2	Bidder must state the Radiation Control licence number of the make and model of equipment offered.	License No:
Clause G29.3	Where it has been established by the bidder that the equipment offered does not require Radiation Control licence, proof from the Radiation Control authority must be submitted with this bid document.	
Clause G30	The system offered must comply fully with or exceed all of the minimum specification requirements per the Technical Clauses.	
Clause G31	The offer submitted must be supported by descriptive literature, colour pamphlets, colour brochures and technical data sheets applicable to the offer (i.e. supporting information for all components of the system) must accompany the bid, failing which the bid will not be considered.	
Clause G32	The equipment and any accessories ordered from the successful bidder will be delivered, installed, tested, calibrated, demonstrated (including specified training) and commissioned in the specific Hospital at the expense of the successful Bidder, prior to full payment being made.	
Clause G33	All prices are to include V.A.T. and must be quoted in the South African currency. The price must be valid for a period of 180 days from closing date of bid.	
Clause G34	If the product offered is unknown to the Department, the Department reserves the right to have the unit evaluated by a team of Technical and Clinical <u>experts</u> with regards to its functionality, performance and quality. The decision of this committee will be used as a motivation for the evaluation and recommendation of the bid. For this reason a demonstration unit must be readily available within 14 days, or the bidder must take arrangement for demonstration with representatives of the Department for the equipment offered at a site within South Africa where a same make and model of unit is installed and is in full clinical operation. The cost of this site visit is for the account of the bidder and it must therefore not place any obligation on the Department to procure from the bidder.	
Clause G35	The Institution requesting the unit reserves the right to clinically trial and evaluate the unit in order to ensure that the unit meets the clinical requirements of the Department before adjudication of the bid.	
Clause G36	UPGRADEABILITY WHERE APPLICABLE:	
Clause G36.1	Bidders are to state the policy with regard to future software updates and the costs that will be involved.	
Clause G36.2	The Bidder to state what hardware and software will be available, with costs and projected dates.	
Clause G37	UPGRADE POLICY:	
Clause G37.1	All future upgrades (hardware and software) involving <u>patient safety</u> must be offered at no additional cost.	
Clause G37.2	All future upgrades removing software viruses from existing software must be supplied at no cost.	
Clause G37.3	Any upgrade before or after installation of the equipment involving additional cost must be brought to the attention of the Manager, Health Technology Services.	
Clause G38	The Bidder must indicate the expected life of their offered unit and software in years.	

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TECHNICAL SPECIFICATION.

NO	SPECIFICATION	STATE YES OR NO Give information or values where appropriate. Supply information on a separate sheet if space provided is inadequate
Clause T1	A bid is called for the supply, delivery and commissioning of a High Flow Humidified Oxygen Delivery Device , which comprises the latest Technology with proven performance and reliability	
Clause T2	State the name and model of the unit on offer	
Clause T3	Application	
	<ul style="list-style-type: none"> i) The device must be capable of delivering high flow oxygen that is both heated and humidified and suitable for Paediatric patients from 1kg to 30kg ii) For use in District, Regional and Tertiary Hospital Children's Wards and ICUs iii) The unit must incorporate patient safety features and the bidder must specify all the patient safety features built into the unit being quoted for. iv) The device must be able to deliver humidified gases to a patient via the nasal route. 	<ul style="list-style-type: none"> i) ii) iii) iv)
Clause T4	System components:	
	The device must incorporate the following components: <ul style="list-style-type: none"> i) A graphical display menu to allow for easy machine setup and use ii) Humidifier iii) Flow generator/ Blender iv) Oxygen sensor 	<ul style="list-style-type: none"> i) ii) iii) iv)
Clause T5	Construction:	
	<ul style="list-style-type: none"> i) The unit must have a sturdy and robust construction ii) There must be no sharp corners or sides that may cause injury to patients and staff iii) The unit must be portable and fitted with, or on a trolley fitted with, castors in order to enable easy mobility of the unit from one area to another iv) At least two of the castors / wheels must be equipped with brakes v) The dimensions of the humidifier and flow generator unit must be no more than: <ul style="list-style-type: none"> • 30cm Height • 25cm Width • 25cm Depth • Weight ≤ 4.0Kg 	<ul style="list-style-type: none"> i) ii) iii) iv) v) • • • •
Clause T6	Power supply:	
	<ul style="list-style-type: none"> i) The unit must be fitted with an ON / OFF switch, it must be able to operate off the 220 Volt + 10%, 50-60Hz, single phase a.c. supply ii) The unit must provide visible indication that the unit is switched ON 	<ul style="list-style-type: none"> i) ii)

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Clause T7	Oxygenation i) The device must work off medical oxygen only and not require piped medical air ii) The device must allow for an oxygen fraction range of 21-95% iii) The device must contain an oxygen sensor with alarms that inform the user of high and low oxygen delivery states iv) The device must be able to provide the following range of oxygen flow rates: <ul style="list-style-type: none"> • a minimum rate of 2 liters/ minute • a maximum rate of 60 liters/ minute v) The change in oxygen flow rate must be in increments not more than 1 liter / minute below flow rates of 25 liters/minute and not more than 5 liters/ minute over 25 liters/minute	i) ii) iii) iv) • • v)
Clause T8	Humidification: i) The device must comply with ISO 80601-2-74:2017 standards for active humidification devices. ii) The device must be able to achieve the following parameters <ul style="list-style-type: none"> • A temperature of 33+/- 2 degrees Celsius • A water vapor level of >33mg/l at 37 C and >10mg/l at 31-36 C iii) The device must have an alarm to indicate when water in the humidifier needs replenishing	i) ii) • • iii)
Clause T9	ACCESSORIES i) The unit must be supplied with the necessary accessories in order that it can be put into use immediately ii) Include details of cost as well as catalogue numbers of accessories included in the bids price iii) As part of the bid, the unit must be supplied with the necessary consumables in order that it can be used on a minimum of 10 patients. These must include: <ul style="list-style-type: none"> • Humidification chambers • Heated respiratory tubing • 10 (each) of infant and paediatric nasal cannulae iv) Optional accessories and consumables must be listed (cost and catalogue numbers) in the schedule at the end of this specification	i) ii) iii) • • • iv)
Clause T10	GUARANTEE / WARRANTY i) The bidder must provide a minimum of 24-month warranty / guarantee period for the unit offered ii) A longer period of warranty will be an advantage	i) ii)
Clause T11	MAINTENANCE AND SERVICE AGREEMENT i) A fully costed COMPREHENSIVE MAINTENANCE AND SERVICE AGREEMENT for a period of 5 years (that will commence upon termination of the guarantee / warranty period) must be supplied with the bid ii) The agreement must be renewable/renegotiable iii) The service agreement may or may not be entered into	i) ii) iii)

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DETAILED TECHNICAL SPECIFICATION

GENERAL INFORMATION REQUIRED

FAILURE TO COMPLETE THIS PART WILL DISQUALIFY THE BIDDER

Make: _____

Model Number / Part Number for: _____

Country of Origin _____

Delivery Period _____

R S A Import Permit Holder (License No) _____

Bidder _____

Signature _____ Date _____

Address _____

Telephone No _____ Fax No. _____

Contact Person _____
(Please Print)

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