

NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY" OR ANSWER THE QUESTION.
	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.	

TECHNICAL SPECIFICATION.

Clause T1

The offered unit must be autoclavable up to 170°C.

BIDDER'S COMMENTS:

Clause T2

The offered unit must meet **I.S.O, A.S.T.A.M, C.S.A.** and **J.I.S.** standards.

BIDDER'S COMMENTS:

Clause T3

The unit offered must have a 3 (**three**) year warranty.

BIDDER'S COMMENTS:

Clause T4

The unit offered must be constructed of polysulfone, silicone rubber and polyvinyl chloride material.

BIDDER'S COMMENTS:

Clause T5

Dimensions to be 15/22mm **I.S.O.** patient connector, 24mm **I.D.** silicone neck, 26mm **I.D. (to silicone bag inlet)**, 25mm **O.D. (to oxygen reservoir)**, 6mm oxygen inlet.

BIDDER'S COMMENTS:

Clause T6

The unit offered must have Inspiratory and expiratory resistance to be less than 2cm H₂O at 5 **L.P.M.** flow.

BIDDER'S COMMENTS:

Clause T7

The unit offered must have a maximum / stroke volume of 1600ml and 1350ml.

BIDDER'S COMMENTS:

Clause T8

The unit offered must have a breath cycle rate of 45 **B.P.M. (600ml)**.

BIDDER'S COMMENTS:

Clause T9

The unit offered must have a reservoir volume of 2500ml – 2600ml.

BIDDER'S COMMENTS:

Clause T10

The unit offered must be able to deliver oxygen concentration of 99% **(15 l.p.m. oxygen supply) when reservoir attached.**

BIDDER'S COMMENTS:

Clause T11

The unit offered must have pressure relief of 60 ± 10 cm H₂O **(60 l.p.m. flow)** lock type overridden mechanism.

BIDDER'S COMMENTS:

Clause T12

A mechanism must exist for the attachment of a Positive – End Expiratory – Pressure (PEEP) valve.
If an accessory is required to allow this, the bidder must provide details in the schedule of optional accessories

BIDDER'S COMMENTS:

Clause T13

GUARANTEE / WARRANTY

The bidder must provide a minimum of 24-month warranty / guarantee period for the unit offered.

BIDDER'S COMMENTS:

Clause T14

MAINTENANCE AND SERVICE AGREEMENT

Upon termination of the guarantee / warranty period the DOH Health Technology Services Component Technicians will be responsible for the maintenance, repair and service of the unit offered.

BIDDER'S COMMENTS:

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) _____

PROVINCE OF KWAZULU-NATAL

DEPARTMENT OF HEALTH

HEALTH TECHNOLOGY SERVICES (H.T.S)

SPECIFICATION FOR:

UMDNS: 13360

MANUAL RESUSCITATORS – CHILD

SPECIFICATION: H.T.S. NO. A13 (ANAESTHETICS)

NB: GENERAL CLAUSES THAT DO NOT APPLY TO THE EQUIPMENT OFFERED, MUST BE ANSWERED 'NOT APPLICABLE' UNDER BIDDERS COMMENTS.

NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY"
Clause G1.1	<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" next to the corresponding clause.</p>	

NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY"
Clause G1.2	All responses must be clear and legible.	
Clause G2	At the end of the guarantee period the successful bidder must be prepared to enter into a planned preventative maintenance agreement with the Department of Health.	
Clause G3	GUARANTEE:	
Clause G3.1	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 both the respective Hospital / Institution and the Health Technology Services before Commissioning the Equipment at the respective Hospital / Institution. 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.	
Clause G3.2	State percentage guaranteed up time of machine. (Should be at least 99%).	
Clause G3.3	State the Guarantee Period. (State the number of years).	
Clause G3.4	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 G3.5	The bidder must state the number of services that will be provided during and up to the end of the guarantee period.	
Clause G3.6	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 G3.7	Travelling and Travelling Time costs must be included during the Guarantee Period?	
Clause G3.8	Spares that may be required during the Guarantee Period will be supplied at the expense of the bidder.	
Clause G3.9	Downtime during the Guarantee Period must extend the Guarantee time on a Day-to-Day basis.	
Clause G3.10	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 G3.11	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 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	

NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY"
	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	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.	
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 Telephone Number/s must be listed (Directly employed or subcontracted).	
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 G11.1	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.	

NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY"
Clause G11.2	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 G12.1	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, Department of Health, KwaZulu-Natal.	
Clause G12.2	The bidder must include a firm commitment in writing, which must be attached to this bid that they would provide ongoing training for end users throughout the life cycle of the equipment offered.	
Clause G13	Spares will be available for _____ 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 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 G17.1	Bidder must bid on the latest model and Technology that fully complies with this Technical Specification.	
Clause G17.2	The Bidder must state how long this technology has been commercially available (state when the model offered was launched).	
Clause G17.3	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.	

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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 licence in terms of the Act on Hazardous Substances (Act. 15/1973) must be submitted with this bid document. The licence must be registered under the bidders name or a letter of joint venture must be submitted by the licence holder where the licence is not in the name of the bidder. Bidders that neglect to submit a licence will not be considered.	
Clause G29.2	Bidder must state the Radiation Control licence number of the make and model of equipment offered.	Licence 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	

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	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 <u>not</u> 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 firm for a period of 6 months 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 experts 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, or the bidder must take arrange 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:	
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.	
Clause G39	The Bidder must provide a detailed breakdown of the cost of ownership of their offered system for the life cycle including cost of services, disposables etc. The following formula must be used: Cost of Ownership = Unit Price + Installation / Commissioning costs + Training costs (End User & Technical) + Comprehensive Maintenance / QA checks per year (Nett Present Value) X Life expectance in years. The cost of Ownership may be used as part of the feasibility evaluation of	

NO	SPECIFICATION	BIDDERS COMMENTS: STATE "COMPLIES" OR "DOES NOT COMPLY"
	bid.	
Clause G40	The successful Bidder at no extra cost must provide additional future training for end users and technical staff on the equipment offered.	

TECHNICAL SPECIFICATION.

Clause T1

The unit offered must be autoclavable up to 170°C.

BIDDER'S COMMENTS:

Clause T2

The unit offered must meet **I.S.O, A.S.T.A.M, C.S.A.** and **J.I.S.** standards.

BIDDER'S COMMENTS:

Clause T3

The unit offered must have a 3 **(three)** year warranty.

BIDDER'S COMMENTS:

Clause T4

The unit offered must be of polysufone, silicone rubber and polyvinyl chloride material.

BIDDER'S COMMENTS:

Clause T5

Dimensions to be 15/22mm **I.S.O.** patient connector, 24mm **I.D.** silicone neck, 26mm **I.D. (to silicone bag inlet)**, 25mm **O.D. (to oxygen reservoir)**, 6mm oxygen inlet.

BIDDER'S COMMENTS:

Clause T6

The unit offered must have Inspiratory and expiratory resistance to be less than 2cm H₂O at 5 L.P.M. flow.

BIDDER'S COMMENTS:

Clause T7

The unit offered must have maximum / stroke volume of 550 / 350ml.

BIDDER'S COMMENTS:

Clause T8

The unit offered must have a breath cycle rate of 105 B.P.M. (170ml).

BIDDER'S COMMENTS:

Clause T9

The unit offered must have a reservoir volume of 2500ml – 2600ml

BIDDER'S COMMENTS:

Clause T10

The unit offered must have oxygen concentration of 99% (15 l.p.m. oxygen supply), when reservoir is attached.

BIDDER'S COMMENTS:

Clause T11

The unit offered must have pressure relief of 40 ± 5cm H₂O (15 l.p.m. flow) lock type overridden mechanism.

BIDDER'S COMMENTS:

Clause T12

A mechanism must exist for the attachment of a Positive – End Expiratory – Pressure (PEEP) valve.
If an accessory is required to allow this, the bidder must provide details in the schedule of optional accessories.

BIDDER'S COMMENTS:

Clause T13

UPGRADABILITY

All future upgrades (hardware and software), where applicable, involving patient safety must be supplied at no additional cost.

All future upgrades removing software viruses from existing software, where applicable, must be supplied at no additional cost.

Any software upgrade, where applicable, before or after installation of the equipment must be brought to the attention of the CEO of the Institution and the Manager, Health Technology Services.

BIDDER'S COMMENTS:

Clause T14

MANUALS

The bidder must include in their offer at no extra cost to the final bid price:

- (a) Complete user Operation/Maintenance Manual x 2 (two) Book/File; CD; DVD copies in English Language
- (b) Complete **ORIGINAL** Service/Repair Manual x 2 (two) Book/File; CD; DVD copies in English Language which **MUST** include the following information:
 - (i) Fault Finding Guide
 - (ii) Circuit Diagrams/Schematics
 - (iii) Circuit Descriptions
 - (iv) PCB Layouts
 - (v) Calibration Guide

- (vi) Part numbers and exploded diagram of mechanical parts/panels.

The offer submitted must be supported by descriptive literature, colour pamphlets, colour brochures and technical data sheets applicable to the offer.

FAILURE TO SUBMIT THE ABOVE WILL RESULT IN THE BID BEING DISQUALIFIED.

BIDDER'S COMMENTS:

Clause T15

RADIATION CONTROL LICENCE

Bidders must state the Radiation Control Licence number of the make and model of the equipment offered. If this type of equipment/apparatus appears on the schedule of Hazardous Substances, issued by the Directorate: Radiation Control of the Department of Health, a licence in terms of the Act on Hazardous Substances (Act 15/1973) must be submitted with the bid document. The licence must be registered under the bidders name or the letter of Joint Venture must be submitted by the Licence holder where the licence is not in the name of the bidder.

BIDDERS THAT NEGLECT TO SUBMIT A LICENCE WILL BE DISQUALIFIED

BIDDER'S COMMENTS:

Clause T16

GUARANTEE / WARRANTY

The bidder must provide a minimum of 24-month warranty / guarantee period for the unit offered.

NB: The bidder must state the duration of warranty/guarantee period for the Transducers supplied with the main monitor unit at no extra cost to the Department of Health Institution.

BIDDER'S COMMENTS:

Clause T17

MAINTENANCE AND SERVICE AGREEMENT

Upon termination of the guarantee / warranty period the DOH Health Technology Services Component Technicians will be responsible for the maintenance, repair and service of the unit offered.

BIDDER'S COMMENTS:

DETAILED TECHNICAL SPECIFICATION

GENERAL INFORMATION REQUIRED

FAILURE TO COMPLETE THIS PART WILL DISQUALIFY THE BIDDER

Make: _____

Model Number / Part Number for: _____

Country of Origin _____

Final Bid / Quotation Price inclusive of V.A.T. _____

Local Agent (KZN) _____

Delivery Period _____

R S A Import Permit Holder _____

BIDDER _____

SIGNATURE _____ DATE _____

ADDRESS _____

TELEPHONE NO. _____ FAX NO. _____

CONTACT PERSON
(PLEASE PRINT) _____