PART A
INVITATION TO BID

YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE *(NAME OF DEPARTMENT/ PUBLIC ENTITY)*					
BID NUMBER:	**DOH (FS) 15/2023/2024**	CLOSING DATE:	**20 OCTOBER 2023**	CLOSING TIME:	**11H00**
DESCRIPTION	**SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING OF ONE INTEGRATED DIAGNOSTIC QUALITY MRI SCANNER & LINEAR ACCELERATORS SYSTEM AND HYPERBARIC OXYGEN CHAMBER AT ONCOLOGY FOR THE FREE STATE DEPARTMENT OF HEALTH.** **PERIOD: OUTRIGHT PURCHASE & FIVE (05) YEARS SERVICE AND MAINTENANCE PLAN *OR* OPERATING LEASE OF THE PROPOSED SYSTEM FOR A PERIOD OF FIVE (05) YEARS**				
BID RESPONSE DOCUMENTS MAY BE DEPOSITED IN THE BID BOX SITUATED AT *(STREET ADDRESS)*					
DEPARTMENT OF HEALTH FREE STATE					
GROUND FLOOR, BOPHELO HOUSE, BLOCK C-WEST, OPPOSITE MAIN DOOR.					
C/O CHARLOTTE MAXEKE STREET AND HARVEY ROAD, BLOEMFONTEIN.					

BIDDING PROCEDURE ENQUIRIES MAY BE DIRECTED TO		**TECHNICAL ENQUIRIES MAY BE DIRECTED TO:**	
CONTACT PERSON	**Me. CJB Naicker** **Mr. TE Mahlasi**	CONTACT PERSON	**Dr. L Strauss**
TELEPHONE NUMBER	**051 408 1160 / 1707**	TELEPHONE NUMBER	**073 207 3078**
FACSIMILE NUMBER	**N/A**	FACSIMILE NUMBER	**N/A**
E-MAIL ADDRESS	**MahlasiTE@fshealth.gov.za** **NaickerCJB@fshealth.gov.za**	E-MAIL ADDRESS	**StraussLJ@ufs.ac.za**

SUPPLIER INFORMATION					
NAME OF BIDDER					
POSTAL ADDRESS					
STREET ADDRESS					
TELEPHONE NUMBER	CODE		NUMBER		
CELLPHONE NUMBER					
FACSIMILE NUMBER	CODE		NUMBER		
E-MAIL ADDRESS					
VAT REGISTRATION NUMBER					
SUPPLIER COMPLIANCE STATUS	TAX COMPLIANCE SYSTEM PIN:		**OR**	CENTRAL SUPPLIER DATABASE No:	MAAA
B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE	TICK APPLICABLE BOX] ☐ Yes ☐ No		B-BBEE STATUS LEVEL SWORN AFFIDAVIT		[TICK APPLICABLE BOX] ☐ Yes ☐ No

[A B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE/ SWORN AFFIDAVIT (FOR EMES & QSEs) MUST BE SUBMITTED IN ORDER TO QUALIFY FOR PREFERENCE POINTS FOR B-BBEE]

ARE YOU THE ACCREDITED REPRESENTATIVE IN SOUTH AFRICA FOR THE GOODS /SERVICES /WORKS OFFERED?	☐Yes ☐No [IF YES ENCLOSE PROOF]	ARE YOU A FOREIGN BASED SUPPLIER FOR **THE GOODS /SERVICES /WORKS OFFERED?**	☐Yes ☐No [IF YES, ANSWER THE QUESTIONNAIRE BELOW]

QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS

IS THE ENTITY A RESIDENT OF THE REPUBLIC OF SOUTH AFRICA (RSA)?	☐ YES ☐ NO
DOES THE ENTITY HAVE A BRANCH IN THE RSA?	☐ YES ☐ NO
DOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA?	☐ YES ☐ NO
DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA?	☐ YES ☐ NO
IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION?	☐ YES ☐ NO

IF THE ANSWER IS "NO" TO ALL OF THE ABOVE, THEN IT IS NOT A REQUIREMENT TO REGISTER FOR A TAX COMPLIANCE STATUS SYSTEM PIN CODE FROM THE SOUTH AFRICAN REVENUE SERVICE (SARS) AND IF NOT REGISTER AS PER 2.3 BELOW.

PART B
TERMS AND CONDITIONS FOR BIDDING

1.	**BID SUBMISSION:**
1.1.	BIDS MUST BE DELIVERED BY THE STIPULATED TIME TO THE CORRECT ADDRESS. LATE BIDS WILL NOT BE ACCEPTED FOR CONSIDERATION.
1.2.	**ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS PROVIDED– (NOT TO BE RE-TYPED) OR IN THE MANNER PRESCRIBED IN THE BID DOCUMENT.**
1.3.	THIS BID IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT, 2000 AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2022, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT.
1.4.	**THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM (SBD7.1).**
2.	**TAX COMPLIANCE REQUIREMENTS**
2.1	BIDDERS MUST ENSURE COMPLIANCE WITH THEIR TAX OBLIGATIONS.
2.2	BIDDERS ARE REQUIRED TO SUBMIT THEIR UNIQUE PERSONAL IDENTIFICATION NUMBER (PIN) ISSUED BY SARS TO ENABLE THE ORGAN OF STATE TO VERIFY THE TAXPAYER'S PROFILE AND TAX STATUS.
2.3	APPLICATION FOR TAX COMPLIANCE STATUS (TCS) PIN MAY BE MADE VIA E-FILING THROUGH THE SARS WEBSITE WWW.SARS.GOV.ZA.
2.4	BIDDERS MAY ALSO SUBMIT A PRINTED TCS CERTIFICATE TOGETHER WITH THE BID.
2.5	IN BIDS WHERE CONSORTIA / JOINT VENTURES / SUB-CONTRACTORS ARE INVOLVED; EACH PARTY MUST SUBMIT A SEPARATE TCS CERTIFICATE / PIN / CSD NUMBER.
2.6	WHERE NO TCS PIN IS AVAILABLE BUT THE BIDDER IS REGISTERED ON THE CENTRAL SUPPLIER DATABASE (CSD), A CSD NUMBER MUST BE PROVIDED.
2.7	NO BIDS WILL BE CONSIDERED FROM PERSONS IN THE SERVICE OF THE STATE, COMPANIES WITH DIRECTORS WHO ARE PERSONS IN THE SERVICE OF THE STATE, OR CLOSE CORPORATIONS WITH MEMBERS PERSONS IN THE SERVICE OF THE STATE."

NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID.

SIGNATURE OF BIDDER: .....

CAPACITY UNDER WHICH THIS BID IS SIGNED: .....
(Proof of authority must be submitted e.g. company resolution)

DATE: .....

EXPLANATORY MEETING CERTIFICATE

BID NUMBER: **DOH (FS)15/2023/2024** Attendance list number: _____

DOH(FS)15/2023/2024: SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING OF ONE INTEGRATED DIAGNOSTIC QUALITY MRI SCANNER & LINEAR ACCELERATORS SYSTEM AND HYPERBARIC OXYGEN CHAMBER AT ONCOLOGY FOR THE FREE STATE DEPARTMENT OF HEALTH.

PERIOD: OUTRIGHT PURCHASE & FIVE (05) YEARS SERVICE AND MAINTENANCE PLAN
OR
OPERATING LEASE OF THE PROPOSED SYSTEM FOR A PERIOD OF FIVE (05) YEARS.

Attendance of the explanatory meeting/site visit is COMPULSORY

An official of the Department must sign this certificate at the explanatory meeting. No certificate will be signed outside the meeting. The original certificate must be included in the bid document and will not be accepted after the closing time and date of the bid.

COMPULSORY EXPLANATORY MEETING DATE: 04 OCTOBER 2023

TIME: 10H00

VENUE: National Hospital (Oncology-Seminar Room)
Roth Ave
Willows
Bloemfontein
9301

CONTACT PERSON/S: Dr. L. Strauss
073 207 3078

This is to certify that _____ in his/her capacity as

_____ of the company _____ has attended the

Compulsory Explanatory meeting on the _____ day of _____ 2023 and is

therefore familiar with circumstances and the scope of the items to be supplied.

_____ _____
SIGNATURE /DEPARTMENTAL OFFICIAL **RANK**

_____ _____
SIGNATURE OF REPRESENTATIVE OF COMPANY **DATE**

OFFICIAL DATE STAMP

*** Note: Only one certificate per company**

health

Department of
Health
FREE STATE PROVINCE

SUPPLY, DELIVERY, INSTALLATION, COMMISSIONING OF ONE INTEGRATED DIAGNOSTIC QUALITY MRI SCANNER & LINEAR ACCELERATORS SYSTEM AND HYPERBARIC OXYGEN CHAMBER AT ONCOLOGY FOR FREE STATE DEPARTMENT OF HEALTH

PERIOD : OUTRIGHT PURCHASE AND FIVE YEARS SERVICE AND MAINTENANCE PLAN

OR

OPERATING LEASE OF THE PROPOSED SYSTEM FOR A PERIOD OF FIVE YEARS

Contact person for enquiries:

Dr L. Strauss

Tel: 073 207 3078

Email: strausslj@ufs.ac.za

(4)

FREE STATE DEPARTMENT OF HEALTH

ITEM1 : ONE INTEGRATED DIAGNOSIC QUALITY MRI SCANNER AND LINEAR ACCELERATOR SYSTEM

NOTES:

1) The Bidder must clearly indicate if their product complies with the stated requirements, by indicating, "Comply" or "Does not comply" next to the corresponding clause.

2) Should the equipment offered deviate from any specified technical requirements, full details of such deviations must be given. In the event of the available space being insufficient such details shall be given on a separate sheet, indicating the relevant paragraph number in the specification.

3) The Bidder must clearly state any parameter values or additional information as requested in relevant clauses.

4) The Bidder must clearly indicate if their offered product exceeds the stated requirement by noting, with proof, "Above specification" next to the corresponding clause.

5) All responses shall be clear and legible.

6) All prospective Bidders will be requested to attend a site presentation at National Hospital on 04 October 2023 at 10:00. Failure to attend these site meetings shall lead to the disqualification of the Bidder's offer.

ITEM1 : ONE INTEGRATED DIAGNOSIC QUALITY MRI SCANNER AND LINEAR ACCELERATOR SYSTEM

Nr.	Specification	Compliance		Reference (Clear reference to this specification and page number in the bid is compulsory if compliance is YES). No reference lead to disqualification of this bid	Comment: full technical and other details of offer
	This specification establishes the requirements for an INTERGATED DIAGNOSTIC QUALITY MRI SCANNER AND LINEAR ACCELERATOR SYSTEM and INDEXED STEPPER AND ULTRASOUND IMAGING SYSTEM FOR TRANSRECTAL IMAGING for use in the RADIATION ONCOLOGY DIVISION, at Universitas Academic Hospital Annex.	YES	NO		
	Take note that "Linear Accelerator", "Accelerator", Linac or MR-Linac refers to the complete and operational Integrated Magnetic Resonance Imaging Scanner and Linear Accelerator System as described in Item 1, while Ultrasound Stepper System refers to the complete and operational Indexed Stepper and Ultrasound Imaging System For Transrectal Imaging as described in Item 1. These systems can be refered to as the "units" in this document.				
1.1	**SCOPE:**				
1.1.1	The units on offer shall be licensed for sale in the South African market by a recognized supplier who can prove that service, spares and application support is available in South Africa to maintain the systems at peak operating performance.				
1.1.2	The units offered to render the service shall be currently in production and have been tried and tested in the clinical setting. Evidence that the equipment being offered can meet the specifications shall be provided.				
1.1.3	A list of all users in South Africa where the units that are offered in this bid is currently in clinical use shall be provided, indicating the current models and equipment configurations per site. The Department of Health, Free State Province reserves the right to independently verify the performance and support on the offered units. In the case where no South African clinical user sites are available, reference sites outside of South Africa may be given.				
1.1.4	Provide a summary of the total number of units per continent worldwide of the units offered in this bid.				
1.1.5	The units offered shall comply with or exceed all of the minimum performance specifications as indicated below for the various sub-components, supported by factory-supplied product specifications / brochures.				
1.1.6	Descriptive literature, pamphlets, brochures and technical data sheets applicable to the offer (i.e. all components of systems) shall accompany the bid, failing which the bid will not be considered.				
1.1.7	The units and any accessories ordered from the successful Bidder will be delivered, installed, tested, calibrated, demonstrated (including specified training) and commissioned in the specified hospital at the expense of the successful Bidder, prior to full payment being made.				

(5)

1.1.8	The linear accelerator and magnetic resonance imaging device will be used for on-line and off-line MR image guided external beam radiation therapy and in the Department of Radiation Oncology at Universitas Hospital Annex, while the ultrasound device can also be used for image guided real-time brachytherapy				
1.1.9	The units shall be installed in the Radiation Oncology Department at Universitas Hospital Annex. Insofar as installation is concerned, existing infrastructure should be utilized. Systems should fit within existing vaults and be able to be installed and later uninstalled through the vault doors without the need for removal of walls/ceiling etc.				
1.1.10	Imaging should be possible without the production of lonizing radiation dose				
1.1.11	Fast and effective Online treatment adaptation for treatment individualization must be allowed, thus a requirement for online replanning or plan optimization for the geometries at hand.				
1.1.12	It is required that external beam continuous real-time monitoring and automatic beam gating based at least on tumour geometry and position be available as an integrated system.				
1.1.13	The MR-Linac should be capable of treating multiple isocenters simultaneously in the same treatment plan				
1.1.14	The Bidder is to offer the following accessories, and any others considered desirable by the bidder, for selection and inclusion by the institution:				
1.1.14.1	Couch accessories available to assist with patient set-up e.g.				
1.1.14.2	Immobilization devices to treat all sites currently offered/accessible by the bidder (MR compatible)				
1.1.14.3	Supporting devices for patient comfort (including audio-visual) and immobilization				
1.1.14.4	Equipment must be indexing compatible				
1.1.14.5	Complete imaging and treatment system, including but not limited to imaging, treatment, treatment planning, record and verify, scheduling, oncology information, complete QA system, independant dose verification and treatment and dose verification system for most advanced treatment techniques, including image guidance, online adaptation and gated treatment				
1.1.14.6	Treatment options shall include for example: Cranial and extra-cranial stereotactic radiosurgery and stereotactic radiotherapy, head-and-neck, cranial, extra-cranial, para-spinal, lung, liver and intra-abdominal, all with applicable immobilization and comfort devices where applicable.				
1.1.14.7	Bidder to supply a full catalogue of immobilization devices included in the bid and the selection of equipment shall be made at the discretion of the user considering needs. The user shall also specify the quantity of devices and consumables (e.g. Thermoplastic masks) required, with assistance from the bidder. A suitably large reserve should be included by the bidder to allow the user to make suitable decisions on immobilization equipment. The sme applies to quality assurance tools.				
1.1.14.8	It is a requirement that, during the pre-bid submission site visit by the bidder, all applicable MR Linac system and equipment under this bid, licenses must be discussed with the user to ascertain which licenses should be included in the bid.				
1.1.15	**SITE INSPECTION:**				
1.1.15.1	Before submitting the offer for these MR-linac and Ultasound units:				
1.1.15.1.1	The Bidder shall inspect the premises and determine what building constructions or alterations will be necessary to house the new equipment.				
1.1.15.1.2	The Bidder must be capable of compiling the necessary plans and, after approval, construct the required buildings or alterations and ensure that all electrical supplies, network requirements, radiation and magnetic shielding and other services are available for equipment installation, and that these would be adequate after installation at the time of operation, to finally allow the user to obtain an operating license for the intended use of the MR-Linac and Ultrasound units				
1.1.15.1.3	The Bidder must ensure that sufficient access routes are available for the correct and safe installation of the equipment.				
1.1.16	**APPLICABLE DOCUMENTS:**				
1.1.16.1	General Conditions of Contract (Annexure A).				
1.1.16.2	Additional Conditions of Tender Section B.				
1.1.16.3	IEC 60976: 1989 incl. Amd 1:2000 Medical Electron Accelerators – Functional Performance Characteristics				
1.1.16.4	IEC 60601, IEC 61217				
1.1.16.5	CE or FDA certification.				

1.1.16.6	Hazardous Substances Act No 15 of 1973.				
1.1.16.7	ISO 13485 : Medical Devices – Quality Management Systems				
1.1.16.8	ISO 14971 : Medical Devices – Application of Risk Management to Medical Devices				
1.1.16.9	All requirements as listed by the South African Health Products Regulatory Authority (SAHPRA)				
	SCHEDULE OF REQUIREMENTS:				
1.2.	**GENERAL:**				
1.2.1	The offered systems shall be installed and handed over fully functional, which shall include all the aspects as identified in the clauses below:				
1.2.2	The Bidder shall provide a clear pricing schedule listing all the requirements and the associated pricing, including any requested options. **All options on offer in the bid are accepted as included under the bid.**				
1.2.3	The offered systems shall be of the latest technology. The Bidder shall state how long this technology (hardware and software) has been commercially available (state when the model offered was launched), as well as if any near future updates are expected.				
1.2.4	What is the life expectancy of the units being offered?				
1.2.5	All accessories required for the offered systems to be fully functional, shall be included as part of the bid. A motivation for items not included in this specification, must be provided.				
1.2.6	What is the manufacturing company's policy regarding availability of spare parts after production of the new units stops?				
1.2.7	All prices are to include VAT and to be firm prices in Rand. The Bidder is to state the period for which the firm price is valid. The rate of exchange must be the rate as published 7 (seven) days before the tender closes. Proof of exchange rate must be attached (e.g. bank letter with official stamp)				
1.3	**TECHNICAL SPECIFICATIONS:**				
1.3.1	The MR-Linac system shall be a state-of-the-art system that allows photon treatments and delivers image-guided Intensity Modulated Radiation Therapy (IMRT) and 3D conformal treatments. The following aspects should be offered by this system:				
1.3.1.1	high- definition, diagnostic quality MR imaging to drive precise dose delivery, integrated so that online adaptive radiotherapy can be performed seamlessly				
1.3.1.2	real-time on-table adaptive radiotherapy allowing personalized treatment for anatomical changes;				
1.3.1.3	real-time, soft tissue tracking during beam delivery with automated beam control (without the requirement for implanted fiducials)				
1.3.1.4	compact design to easily install and fit into existing linac bunkers considering existing infrastructure.				
1.3.1.5	a digital beam steering and control system with easily accessible component logs (all components, e.g. mechanical and electronic or monitoring systems) at a logging rate no slower than 4 Hz (state frequency) for dose re-computation.				
1.3.1.5.1	Bidder to specify the rate of logging, the accuracy in logging rate and provide a thorough description of how log entries are recorded and assigned to timestamps				
1.3.1.6	Integrated multi leaf collimator system,				
1.3.1.7	an isocentric treatment couch				
1.3.1.8	a treatment console and integrated record and verify system that allows scheduling and at least an HL7 interface to connect to existing 3rd party Oncology Information Systems.				
1.3.1.9	This system should be fully compatible and interfaceable with the linac in order to function as an integrated system.				
1.3.1.10	Bidder to state whether the system will be fully integrated with the current Mosaiq patient management system regardless of software upgrades.				
1.3.1.11	It should enable the delivery of gated radiation such as breath-hold, free-breathing and tumour alignment.				
1.3.1.12	Two inverse optimization based treatment planning systems shall also be provided under this bid that will operate as an integrated unit with the MR linac system and communicate over a network system, fully connected to the Oncology Information and scheduling system, including image dataset handling as an integrated unit.				
1.3.1.13	Image (data) transfer between other existing planning and imaging systems, as well as other patient data related systems should be possible without additional requirements of third party software.				
1.3.1.14	The bidder shall provide clinical evidence for treatment capability and outcomes in the following cases, to illustrate the treatment capabilities:				
1.3.1.14.1	Oligo metastatic cancers				

1.3.1.14.2	Palliative hypofractionation				
1.3.1.14.3	Single fraction lung treatments				
1.3.1.14.4	Liver treatments				
1.3.1.14.5	inoperable pancreatic cancer				
1.3.1.14.6	Hypo fractionated prostate treatments, including medium and high risk				
1.3.1.14.7	cervix, anal and vulva cancers				
1.3.1.15	The bidder shall provide suitable data to demonstrate acceptable patient throughput rates with the equipment supplied. It is recommended that a suitably large selection of clinical sites where this equipment has been utilized for at least one year, be provided to the user for evaluation. It is required that the bidder must provide patient numbers and treatment statistics and not only fractions.				
1.3.1.16	The bidder is required to provide an expected installation time period for the complete system to be installed and operational, ready to be evaluated for licensing (provide references)				
1.3.1.17	The bidder shall supply uninterruptable power supply units (UPSs) for all components requiring such supply during power outages, especially unforeseen outages. Current and future power supply in the South African context must be considered and discussed with local engineers to ensure protection of the MR Linac system during loadshedding and unforeseen power outages. Protection of computer systems, the MR magnet and vacuum requirements (and whichever other elements) must be considered.				
1.3.1.18	Wherever green energy solutions can be applied, these should be considered and will increase the weight of the bid.				
1.4.1	**The MR Linac System:**				
1.4.1.1	Shall include dedicated state of the art components capable of performing current treatment techniques with adaptability for future treatment techniques.				
1.4.1.2	Shall be capable of producing at least a 6 MV beam quality . Bidder to state which energies can be supplied, flattening filter free or with flattening filter.				
1.4.1.3	The energy reproducibility of the accelerators shall be better than 1.0%. Bidder to state.				
1.4.1.4	The focal spot size on the target shall be less than 2.0 mm measured as full width at half the maximum intensity.				
1.4.1.5	The accelerators shall utilize multi-element ionization chambers to allow for compensation of beam changes both with regard to steering of the beam and beam output. Beam changes shall be corrected for at all possible gantry angles.				
1.4.1.6	The bidder is required to specify the lifetime of the electron gun.				
1.4.1.7	Indicate the downtime when an electron gun replacement is performed				
1.4.1.8	Indicate whether the RF power source is mounted in the gantry or is stationary.				
1.4.1.9	The RF power source shall deliver maximum dose rate within 400 ms from start-up with a dose/MU accuracy of less than 1% for small MU segments.				
1.4.1.10	State whether a magnetron or klystron is used for generating radio frequency.				
1.4.1.11	State the replacement time for the magnetron or klystron.				
1.4.1.12	State the full warranty period for a magnetron or klystron.				
1.4.1.13	State the accelerating waveguide being used				
1.4.1.14	State the resulting energy spread of the electron beam from the nominal energy when the beam strikes the x-ray target.				
1.4.1.15	State the warranty period for the accelerating wave-guide.				
1.4.1.16	All the movements of the offered linear accelerators are to conform to the IEC 1217 naming standard.				
1.4.2	**Gantry system:**				
1.4.2.1	State the full continuous gantry rotation possible by the system in degrees. Indicate and stop angles in this regard.				
1.4.2.2	State the Minimum and maximum Gantry rotation speed (RPM) during preparation, and treatment.				
1.4.2.3	State the height of the isocenter above the floor in cm.				
1.4.2.4	State whether the gantry rotation can be continuously variable during preparation for treatment or QA, and during treatment.				
1.4.2.5	The digital read out of gantry rotation angle shall have an accuracy of ± 0.3 degrees and resolution ± 0.1 degrees.				
1.4.2.6	The mechanical indicators for gantry read out shall similarly have an accuracy of ± 0.5 degrees and resolution of ± 0.5 degrees.				
1.4.2.7	State the source to axis distance of the system. It shall have an accuracy of ± 0.1 cm.				

1.4.2.8	Considering the mechanical isocenter to be defined by the intersection of the collimator, gantry rotation axes, imaging axis and the table motion axis, all axes of rotation/motion shall be confined to a sphere (or positioning in case of the couch) with ± 1 mm radius (vector).				
1.4.2.9	Bidder to state the distance from the end of the lower collimator to the isocenter.				
1.4.2.10	The electron gun shall be demountable from the accelerator to minimize cost and down time in case of gun replacement.				
1.4.2.11	The gantry shall have the necessary mechanical strength and stability to allow for Magnetic Resonance based Image Guided Radiotherapy (IGRT).				
1.4.3	**Treatment head:**				
1.4.3.1	The variation of the mechanical and radiation isocenters during gantry rotation shall be less than ± 1.0 mm (vector).				
1.4.3.2	The variation of the radiation and imaging isocenters during gantry rotation shall be less than ± 1.0 mm (vector).				
1.4.3.3	Bidder to specify whether patient comfort lighting in the bore is provided				
1.4.3.4	The MR Linac system frame or bore opening shall consist of appropriately hardened materials to ensure stability and accuracy, as well as protection against possible work related collisional damage.				
1.4.3.5	The bidder to state the smallest operational distance between the inner surface of the bore opening and the patient surface				
1.4.3.6	The bidder to state the full field of view usable with undisturbed accuracy (in terms of image quality, geometrical accuracy, dose calculation, etc.) for treatment.				
1.4.3.7	A transmission photon ionization chamber shall be used. The chamber shall incorporate completely separate collection electrodes consisting of at least 2 plates for dose monitoring and a quadrant plate for field symmetry, or a comparable design for the same purposes.				
1.4.3.8	The dosimetry system shall utilize two completely independent channels for monitoring accumulated dose (i.e. a primary and a secondary channel). A dose rate channel and a channel for monitoring differential field symmetry shall be provided. The redundant channel will terminate an exposure of no more than 25 MU higher than the machine setting.				
1.4.3.9	The system shall also provide a back-up timer with a minimum significant time setting of 0.01 min. The back-up time shall be automatically calculated and set at a users-specified value above the expected duration of the treatment.				
1.4.3.10	The dosimeters shall be reproducible to within ± 1% or 1 MU, whichever is greater at any fixed gantry angle from 0 to 360°.				
1.4.3.11	The linearity of the dosimeters shall be ± 1% or 1 MU, whichever is greater, for accumulated doses between 5 and 999 MU.				
1.4.3.12	The integral dose shall be retained on a counter, which indicates the monitor units delivered to that time with the unexpected loss of power or malfunction of the accelerator or dose measuring systems. The dose shall be retained for at least 20 minutes after power interruption.				
1.4.3.13	Bidder to specify how to locate the isocenter of the machine to within ± 1 mm mechanically. The maximum error over the range 80 to 120 cm shall be within ± 1 mm.				
1.4.3.14	Bidder to specify whether the system is equipped with lasers. If not, bidder to specify how patient setup will be performed accurately and reproducibly for the purpose of achieving the required cumulative dose				
1.4.3.15	Bidder to specify whether a full set of external lasers are used and supplied, with supporting motivation				
1.4.3.16	User to supply a proposed setup procedure for safe and accurate treatment in line with the design of their equipment and for the purpose of accurate, minimal PTV margin treatment				
1.4.4	**Photon beam characteristics:**				
1.4.4.1	The minimum dose rate shall equal at least 450 cGy/Min for a 10x10 cm field for a the photon beam (s) supplied with the system calibrated 1 cGy = 1 MU at 90cm SAD at Dmax.				
1.4.4.2	The time averaged dose rate shall be constant to within ± 2% over 2 min for any beam quality.				
1.4.4.3	Bidder to specify maximum achievable field size at isocenter.				
1.4.4.4	Bidder to specify minimum achievable field size at isocenter.				
1.4.4.5	The collimators in totality shall be motorized.				
1.4.4.6	The average leaf leakage shall be less than 0.5%				
1.4.4.7	The photon leakage rate at any point 1 meter from the target outside the cone defined by the primary x-ray collimator shall be < 0.1% on average of the absorbed dose at the isocenter for all photon beam qualities, but not exceed 0.2 % at any point of measurement				

1.4.4.8	The photon leakage outside of the patient plane shall be < 0.5% on average of the maximum absorbed dose at the isocenter for all photon beam qualities.				
1.4.4.9	Radiation leakage through collimation devices such as jaws and MLC shall comply with : • IEC 60601-2-1 (1998) + A1:2002 Medical electrical equipment – Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV. • IEC 60601-2-1 (2009) Edition 3 - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV				
1.4.4.10	Bidder to specify if any neutron radiation is present during beam-on, as well as the subsequent neutron leakage in the patient plane.				
1.4.4.11	Neutron leakage (if present) levels shall comply with : • IEC 60601-2-1 (1998) + A1:2002 Medical electrical equipment – Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV. • IEC 60601-2-1 (2009) Edition 3 - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV				
1.4.4.12	The radiation beam characteristics shall comply fully with the requirements of the Department of Health / South African Health Products Regulatory Authority for all photon beam qualities.				
1.4.4.13	Beam symmetry specifications:				
1.4.4.13.1	Within 3 % in In-plane and Cross-plane directions. Bidder to state both symmetry levels achievable and adjustable				
1.4.4.14	System must be able to perform at least segmented step-and-shoot IMRT. Any additional capabilities would increase the bid weight.				
1.4.5	**Operating licenses:**				
1.4.5.1	All operating licenses available at the time of this publication should be included, for example all external motion execution and control mechanisms, MRI acquisitions, patient positioning, dose predictions and re optimizations, real time soft tissue targeting, gating and treatment.				
1.4.5.2	Licenses should be included for full dynamic leaf IMRT capabilities				
1.4.5.3	Licenses should be included for full gated treatment capabilities (all available, please state)				
1.4.5.4	Licenses should be included for full imaging operation and imaging utilities, including image processing and imaging protocols				
1.4.6	**Collimator system including integral multileaf collimator:**				
1.4.6.1	The accelerators shall enable symmetrical and asymmetrical collimation of the photon beams.				
1.4.6.2	It shall be possible to adjust symmetrical and asymmetrical beams using both local and remote control.				
1.4.6.3	The field sizes shall range at least from 0.5x0.5 cm^2 to 22x22 cm^2 at isocenter.				
1.4.6.4	For the purpose of asymmetric collimation, full overtravel shall be possible in QA and clinical modes. Bidder to specify the magnitude of overtravel achievable.				
1.4.6.5	The multileaf collimator system shall include the necessary number of leaves to cover at least a 22x22 cm^2 field with a 5 mm resolution or better at 90 cm SSD in the central 15 x 15 cm^2 field.				
1.4.6.6	The bidder to state the leaf widths at isocenter				
1.4.6.7	The movement of the leaves shall be under control of individual motors allowing independent leave movement.				
1.4.6.8	It shall be possible to verify the position of every leaf to a resolution of 0.1 mm. Bidder to state technology applied to achieve this positional verification.				
1.4.6.9	Bidder to state how MLC (and other collimator devices) are calibrated, as well as a reasonable estimate of the time required to perform this calibration.				
1.4.6.10	The leaf speed shall be at least 35 mm/s.				
1.4.6.11	Individual leaf positioning accuracy should be ≤ 1 mm and repeatability ≤ 0.5mm.				
1.4.6.12	The beam penumbra shall be ≤ 6.5 mm for field sizes up to 10 x 10 cm^2				
1.4.6.13	Bidder to specify beam penumbra at Dmax in a 1 x 1 cm^2 field				
1.4.6.14	The transmission through individual leaves shall be < 1%.				
1.4.6.15	The transmission outside the beam shall be < 0.5%.				
1.4.6.16	The control system for the multileaf collimators shall be fully integrated into the accelerator control software.				
1.4.6.17	The control system shall be enabled for all available forms of IMRT and 3D conformal/conventional treatment. The bidder shall provide all required licenses to enable usage thereof.				

1.4.6.18	An electronic fault detection system and collision detection system shall be provided.				
1.4.6.19	The system used for detection of leaf positions shall be described.				
1.4.6.20	Independent monitoring of leaf position is a prerequisite, including electronic monitoring and recording of individual components, e.g. log files (containing leaf positions, dose rate, gantry angles, etc.) produced at least at 4 Hz. Bidder to state the rate of recording, as well as format and availability of such log details				
1.4.6.21	The vendor shall allow full access to Log files (named in 1.4.6.20) and software to extract predefined data from these logs (ex. Gantry angle, MLC leaf positions at any given time, etc.) in a user usable and interpretable format. The user shall utilize these in QA, research and dose re-calculations. Bidder to state how this can be accomplished.				
1.4.6.21.1	Bidder to specify whether log files can be imported for dose recalculation in the TPS, or independent dose calculation QA system and whether dose comparisons can be made.				
1.4.6.22	The system shall allow minor alterations during patient set-up and record any alterations on the treatment record sheet.				
1.4.6.23	Any interrupt of the beam should be properly registered by the system.				
1.4.6.24	The complete prescription of the leaf positions for each field for a specific patient shall be stored on the system allowing easy transfer of the prescription between systems such as a CT simulator, the treatment planning system and the MR linac system.				
1.4.6.25	The vendor shall allow full access to MLC gain, offset and calibration files to the Medical Physics team.				
1.4.6.26	Bidder to specify the number of leafs				
1.4.6.27	If a diaphragm is present, bidder to specify the diaphragm speed				
1.4.6.28	Bidder to state whether full interdigitation of the MLCs is possible				
1.4.6.29	Bidder to specify the leaf direction/orientation				
1.4.6.30	Bidder to state the minimum distance achievable between opposing leaves or leaves on the same leaf guide in cm				
1.4.7	**MR Imaging**				
1.4.7.1	Bidder to state the imaging settings available for the following:				
1.4.7.1.1	imaging for planning or virtual simulation				
1.4.7.1.2	imaging for patient positioning				
1.4.7.1.3	imaging for target position monitoring				
1.4.7.2	The Bidder to state the largest bore inner diameter upon assembly of the machine.				
1.4.7.3	The MRI system shall be capable of imaging within at least a 50 cm diameter spherical volume (DSV).				
1.4.7.4	Bidder to provide list of imaging protocols including the protocol, field of view (FOV) and resolution				
1.4.7.5	Bidder to specify the largest FOV (cm) in treatment mode				
1.4.7.5.1	Bidder to state the associated distortion in the expanded FOV region in the maximum FOV versus the conventional FOV				
1.4.7.6	The Spatial integrity (geometric accuracy) of MRI shall be better than 0.2 cm over a 35 cm DSV and 0.1 cm over a 20 cm DSV				
1.4.7.7	The temporal integrity of MRI acquisition with respect to the radiation therapy system shall be better than 0.01 s.				
1.4.7.8	At least 16-bit grey scale imaging depth is required.				
1.4.7.9	The bidder to supply a selection of pulse sequences included in the bid, with all applicable licenses activated. For example: T1, T2, DWI, etc.				
1.4.7.10	Bidder to specify which sequences are not included in the offer.				
1.4.7.11	Bidder to specify other imaging options, such as T1 or T2 mapping, BOLD or physiologic imaging, etc.				
1.4.7.12	Bidder to specify if pulse sequences can be manually changed, and which sequences				
1.4.7.13	The MR linac system shall allow imaging to be performed during radiotherapy treatment delivery with continuous imaging capabilities.				
1.4.7.14	Bidder to specify acquisition modalities, e.g.: Single plane (specify planes) acquisitions and frames per second (FPS). A higher frame acquisition rate would increase the weight of the bid.				
1.4.7.15	Bidder to specify the in-plane resolution and slice thicknesses for single plane acquisitions and associated FPS. Specify how many planar acquisitions can be made and displayed simultaneously				
1.4.7.16	3D volumes shall be acquired and reconstructed with a field of view of at least 40 x 40 x 40 cm^3				
1.4.7.17	Nominal axial slice thickness of at least 1.5 mm and larger shall be offered with in-plane resolutions of at least 0.75 mm x 0.75 mm and larger.				
1.4.7.17.1	Bidder to specify the flexibility in slice thickness settings, image resolution in both planning and treatment setup				

1.4.7.18	Bidder to state the nominal acquisition times associated with the specifications provided in 1.4.7.14				
1.4.7.19	The 3D volumetric images referred to above should allow quick and effective localization, positioning and image guided planning for treatments of patients.				
1.4.7.20	Provide an overview of advanced MR sequences available through the MR imaging console for imaging and research purposes				
1.4.7.21	Bidder to state the highest resolution available for 3D Scans				
1.4.7.22	Bidder to state the minimum slice thickness for 2D cines				
1.4.7.23	Bidder to state the highest resolution available for 2D cines				
1.4.7.24	Bidder to state the frame rates available for 2D cines				
1.4.7.25	Bidder to state the number of parallel cine images the offered system can produce simultaneously for multiple target and/or OAR tracking, as well as orientations				
1.4.7.25.1	Bidder to state how many targets (tumour volumes) and OARs can be tracked simultaneously				
1.4.7.25.2	Bidder to provide supporting documentation and clinical cases to support the answers in 1.4.7.25				
1.4.7.26	State the accuracy and temporal relationship with which tissue tracking and automated beam controls react. State the associated deviations expected.				
1.4.7.27	State whether the treatment process is fully automatic once executed, considering beam-off due to target displacement (based on imaging), and re-start based on imaging.				
1.4.7.28	Bidder to state the time frames for actual patient treatment including all tracking features including one re-plan for an integrated prostate boost. Provide appropriate dose calculation and image details				
1.4.7.29	The system offered shall have the ability to automatically gate the beam based on multiple targets and/or OAR motion recognition automatically and independently				
1.4.7.29.1	Bidder to state whether this is fully automated, or requires user intervention?				
1.4.7.30	Bidder to state how many sectional views (and which combinations) can be utilized in this way simultaneously				
1.4.7.31	The system offered shall have the ability to automatically gate the beam based on multiple targets simultaneously				
1.4.7.32	State the maximum number of orthogonal planes that can simultaneously be utilized for gating				
1.4.7.33	State the maximum number of parallel planes that can simultaneously be utilized for gating				
1.4.7.34	State whether the system can be easily and seamlessly used for patient simulation				
1.4.7.35	State whether images can be immediately accessible in the treatment planning system without the additional need for data transfer				
1.4.7.36	The bidder is to give a full description of the integration of MRI into the workflow including simulation, pretreatment and during delivery				
1.4.7.37	The bidder is required to provide list of imaging parameters available for Abdomen, Pelvis, Extremities, Thorax and Head and Neck. In addition, provide the minimum and maximum resolution, FOV and time required for each acquisition				
1.4.7.38	Bidder to provide details and examples of automatic motion management imaging and treatment included in the bid:				
1.4.7.38. 1	Free Breathing techniques, breath hold and other gating techniques, such as exception gating.				
1.4.7.39	Bidder to state MR sequences offered in combination of the list above				
1.4.7.40	Bidder to state whether the linac component's emitted RF waves interfere with the MR image quality, and how this is prevented. Also state which features of the system interferes with the image quality, and how the impact is minimized				
1.4.8	**Magnet**				
1.4.8.1	Bidder to specify the main Magnetic Field Strength (B0) in Tesla				
1.4.8.2	Specify whether the system uses a superconducting magnet				
1.4.8.3	Specify the Field Stability in ppm/hr				
1.4.8.4	Specify the magnet cooling				
1.4.8.5	Specify the Boil off rate				
1.4.8.6	Specify the signal to noise ratio (SNR)				
1.4.8.7	Bidder to state the image acquisition time for a clinically relevant breath hold scan (25cm ±2cm Cranio-caudal), available in treatment workflow.				
1.4.8.8	Provide actual FOV and resolution for the image acquisition in 1.4.8.7				
1.4.8.9	Gradient System Performance:				
1.4.8.9.1	Peak amplitude (mT/m)				
1.4.8.9.2	Peak Slew rate (T/m/s)				

1.4.8.10	Give a description of the all the receiver coils supplied for each anatomical region, as well as the uniformity, SNR, and attenuation of each				
1.4.8.11	Specify whether the coils are flexible or rigid				
1.4.8.12	Describe the number of elements in each receiver coil supplied				
1.4.8.13	For each receiver coil offered, describe the maximum imaging field length and window for treatment field.				
1.4.8.14	The system shall offer Diffusion-Weighted Imaging (DWI) protocols. Bidder to state the maximum B Value in use clinically				
1.4.8.15	The Bidder to state magnetic field homogeneity measured over a 45 and 50 cm diameter of spherical volume (DSV)				
1.4.8.16	Bidder to specify the magnetic field stability per hour.				
1.4.8.17	The MRI system shall be capable of automatic calibration for first order active shim values				
1.4.8.18	The Bidder to provide details of the following Multi-channel RF system:				
1.4.8.18.1	Body coil signal-to-noise (SNR) and Uniformity; *X*-Channel Torso Coil SNR (Sagittal, Transversal, Coronal) and Uniformity; *X*-Channel Head/Neck Coil SNR (Sagittal, Transversal, Coronal) and Uniformity				
1.4.8.19	It shall also be possible to store/archive images on external media				
1.4.8.20	The offered system shall have all the necessary DICOM options and licenses in order to perform image queries, image transfers, image printing, using DICOM 3, with the rest of the equipment purchased for this Department. These should include import and export of images, treatment plans, dose distributions, etc.				
1.4.8.21	The system shall provide DICOM and DICOM RT import and export of all images, all beam treatment parameters and all field shaping parameters, including all necessary licenses.				
1.4.8.22	The system shall provide DICOM and DICOM RT protocol image query, image transfer, and image printing with other compatible devices				
1.4.8.23	All imaging coils available shall be offered and included in the bid				
1.4.8.24	It should be possible to obtain up to 256 images for a movie sequence during patient treatment.				
1.4.9	**MR imaging for and during patient setup and treatment**				
1.4.9.1	System bore width should be ≥ 70cm				
1.4.9.2	Specify system bore length				
1.4.9.3	Specify couch (table) width and length in cm				
1.4.9.4	Couch positioning accuracy when loaded shall be ≤1mm				
1.4.9.5	The couch shall be capable of supporting patients to a weight of not less than 200 kg.				
1.4.9.6	Specify maximum table top height in cm				
1.4.9.7	Specify minimum table top height (for loading) in cm				
1.4.9.8	State maximum lateral motion of couch in cm				
1.4.9.9	State maximum vertical motion of couch in cm				
1.4.9.10	State maximum longitudinal motion (stroke length) of couch in cm				
1.4.9.11	The system shall allow couch movement using in-room controls on both sides of the couch				
1.4.9.12	The system shall allow couch motion from the console area				
1.4.9.13	Bidder to specify the extent and range of the following movements:				
1.4.9.14	Longitudinal movement;				
1.4.9.15	Lateral movement;				
1.4.9.16	Vertical movement;				
1.4.9.17	Bidder to state the vertical, longitudinal (and lateral where possible) movement speed, whether variable or not.				
1.4.9.18	The vertical, longitudinal (and lateral where possible) movement shall offer digital read-out to an accuracy of ± 1mm.				
1.4.9.19	Bidder to state whether movements are both manual and motorized.				
1.4.9.20	Bidder to state whether manual couch control is possible				
1.4.9.21	The bidder is to state the following:				
1.4.9.21.1	Couch top width				
1.4.9.21.2	Couch top length				
1.4.9.22	Bidder to state whether patient support panels in the couch (specify material) shall be provided and the combined dimensions, as well as restrictions imposed by such panels.				
1.4.9.23	A mechanical override shall be available in the event of a power failure to allow lowering of the table from the treatment position. Alternatively emergency power supplied to the vertical drive as well as the brakes of the lateral and longitudinal motion to allow easy removal of the patient. State full details.				
1.4.9.24	A high quality carbon fiber or equivalent table top is required being durable and sturdy.				

1.4.9.25	If the bidder can supply a treatment couch that can allow for remote patient setup corrections e.g. shifts in all three main axis (lateral, longitudinal, vertical, or any rotations), the weight of the bid of such a system will be increased to allow ease of setup and reproducibility. The translation accuracy must be better than 1 mm and rotational accuracy within 0.5 degrees (if applicable).				
1.4.9.26	The bidder must state the translation and rotation range of setup corrections/adjustments can be made using this couch				
1.4.9.27	Bidder to state whether one or two couches are included in the bid				
1.4.9.28	Bidder to state how many degrees of freedom is allowed for the included couch tops (e.g. lateral, vertical, longitudinal, yaw, pitch and roll)				
1.4.10	**Patient communication system and monitoring to be supplied**				
1.4.10.1	Patient Headphones				
1.4.10.2	Treatment Room Speaker(s)				
1.4.10.3	Control Room Audio/Video (Visual) Control Unit				
1.4.10.4	Treatment Room Video Camera(s)				
1.4.10.5	Head set integrated with intercom for communication				
1.4.10.6	Specify whether acoustic noise control is available				
1.4.10.7	The system shall have an integrated patient monitor system for visual feedback in breath-hold, gating, and to inform patient of treatment progress.				
1.4.10.8	Facility to play images and/or sound for distraction of patient shall be provided				
1.4.10.9	The patient communication headset shall be integrated with intercom for communication				
1.4.10.10	The patient communication system shall include at least headphones, treatment room speakers, control room audio/video control unit, control room audio control panel and a panic button				
1.4.10.11	The patient shall be monitored by in-room video cameras				
1.4.10.12	Control room display to monitor patients shall be of acceptable high quality				
1.4.10.13	A suitable monitoring system for pediatric patients receiving treatment while sedated shall be considered and provided				
1.4.11	**Treatment and control room aesthetic design and layout**				
1.4.11.1	Bidder shall supply the user with options for treatment room aesthetic designs, fully included in the bid, and user recommendation of the room design shall be considered.				
1.4.11.2	Bidder shall supply the user with options for control room aesthetic designs, fully included in the bid				
1.4.11.3	The Bidder shall supply six (6) ergonomically height-adjustable, high backed, strong and durable swivel chairs with armrests, a high quality finish as part of their main offer for use by the operators.				
1.4.11.4	The Bidder shall supply two (2) fashionable, comfortable, strong and durable chairs with armrests, and a high quality finish as part of their main offer for use by the operators and patients inside the treatment room or at the entrance to the treatment room/maze				
1.4.12	**Treatment Console, control panel and workflow**				
1.4.12.1	Simulation images shall automatically be saved after being acquired on MR				
1.4.12.2	Simulation parameters shall be available automatically for planning and treatment				
1.4.12.3	The system shall allow remote real-time review of image registration at treatment				
1.4.12.4	The system shall allow remote real-time contouring of patient on the couch for adaptive treatments				
1.4.12.5	The system shall allow remote real-time interaction with treatment workflow for ≥2 users				
1.4.12.6	Image guided treatments shall be possible using a seamless integration of imaging, couch positioning and treatment execution (with or without gating) procedure				
1.4.12.7	The system shall comprise of an integrated workflow on a single dedicated treatment delivery system, with no need to transfer data between systems for treatment				
1.4.12.8	The bidder to supply a thorough description of the integration of MRI into the workflow including simulation, pretreatment and during delivery.				
1.4.12.9	A computerized control console shall be located outside the treatment room. This console shall provide controls that must be activated in order for the accelerator to become operational in any of its various modes of operation and also provide display of accelerator and imaging parameters. A number of controls are specified below. It is required of the supplier to fully list the accelerator controls that are controllable from the offered console				
1.4.12.9.1	The total dose control shall set the desired total dose per field.				

1.4.12.9.2	The time control shall set time for the patient's treatment.				
1.4.12.9.3	The radiation ON control shall turn on the radiation.				
1.4.12.9.4	Activation of the interrupt control shall immediately stop treatment.				
1.4.12.9.5	It shall be possible to adjust the dose rate of the beam. Specify dose rates that can be set.				
1.4.12.9.6	A separate mode of operation (system calibration and servicing) shall be provided which is used to monitor accelerator parameters and facilitate adjustments to those parameters. List the adjustments that the operator shall be able to accomplish from the control console while in the calibration and service mode of operation.				
1.4.12.9.7	During clinical operation, the accelerator shall record relevant equipment parameters for later review in the event of abnormal machine conditions, such as dosimetry interlocks, minor interlocks, etc.				
1.4.12.9.8	It shall be possible to monitor essential parameters from the control console. List the parameters that can be monitored from the control console.				
1.4.12.9.9	An automated means of operating the accelerator at all clinical photon energies to perform a series of daily quality assurance checks shall be provided. This series of checks shall be programable by the hospital Medical Physics team and shall be capable of being edited.				
1.4.12.9.10	The control console shall be capable of receiving full correct treatment prescriptions and MLC beam shaping information from the treatment planning system via a patient information flow system.				
1.4.12.9.11	An additional workstation shall be provided for remote entry of patient prescription, and for editing, while the LINAC is being used for treatment				
1.4.12.9.12	The ability to store and print an electronic patient treatment chart recording the progress of daily treatment. The Bidder to state full details.				
1.4.12.9.13	An industry standard color laser printer shall be provided for printing of patient treatment records. Printer cartridges shall be supplied as required during the contract and payment period without requiring additional payments for these				
1.4.12.10	The system shall use a central database and networking to allow transfer of patients between future treatment units in the event of a scheduled and unscheduled downtime.				
1.4.12.11	The control room equipment shall be minimized. Please state numbers of computers, monitors and keyboards required to operate the requested LINAC configuration.				
1.4.12.12	The following monitors and displays shall be available at the control console and it shall be possible continuously to visually observe the values being registered on these displays and monitors from the position of the operator:				
1.4.12.12.1	A dose rate indicator shall indicate the dose rate at maximum build-up for a 10x10 cm^2 field at 90 cm SAD.				
1.4.12.12.2	Two dose counters shall count integral dose detected by each of the two dosimeters.				
1.4.12.12.3	In case of a power failure, a total dose counter shall reserve the total dose delivered to the patient under treatment.				
1.4.12.12.4	A total time counter shall count total treatment time in 0.01 min increments up to 20 minutes.				
1.4.12.12.5	An angle indicator shall indicate position of the gantry in degrees with precision of ± 0.5 degrees.				
1.4.12.12.6	A symmetry indicator shall indicate beam symmetry in both major axes.				
1.4.12.13	The treatment control unit or system must be able to control the patient setup and handling system.				
1.4.12.14	The treatment control unit or system must provide beam ON/OFF controls, as well as emergency interventions such as stop or interrupt controls.				
1.4.12.15	The treatment control unit or system must deliver complete treatment plans without requiring user intervention for individual treatment fields and multiple isocenters, and include control monitors and access to MRI acquisition, patient positioning, dose prediction, dose- and re-optimization, real time soft tissue targeting, treatment and review				
1.4.12.16	Interrupted treatments must be automatically saved and be completable upon user resume				
1.4.12.17	Bidder to state whether the system allows for real-time display of accumulated dose. Describe how dose accumulation is achieved.				
1.4.13	**Interlocks and indicators:**				
1.4.13.1	Metal detector to prevent entry to the treatment and imaging room in case of a person wearing or carrying an object with magnetic properties (alarm system). In other words a safety system				

1.4.13.2	Interlock mechanisms shall be provided in order to ensure proper operation of the accelerators.				
1.4.13.3	The status of each interlock shall be indicated on or near the control console.				
1.4.13.4	Only when all interlocks are in proper mode shall the accelerator be operable.				
1.4.13.4.1	The treatment control unit shall have warning lights for beam ON/OFF, associated with total treatment and real time beam status				
1.4.13.4.2	Warning lights are required in the control room, as well as in front of the entrance to the treatment room.				
1.4.13.5	The following interlocks are required. Other interlocks not listed below shall be listed by the bidder:				
1.4.13.5.1	Dose rate interlock.				
1.4.13.5.2	The accelerator shall be disabled when the dose rate is not within plus-minus 25% of the expected value within 10 seconds into the treatment.				
1.4.13.6	Emergency OFF switches:				
1.4.13.6.1	Provision for connecting Emergency OFF switches into the interlock chain shall be provided to allow immediate disabling of the accelerator in case of an emergency. There should be at least one Emergency OFF switch on the console and four on the treatment unit. Describe the location of all Emergency OFF switches.				
1.4.13.7	Dosimeter interlock:				
1.4.13.7.1	The normal treatment delivery will be designed to terminate upon a prescribed given dose at 90 cm SAD for a 10 x 10 cm^2 field at the depth of maximum dose. In addition, a timer shall be used as a safety device to terminate treatment in the case of failure of the integrated dosemeters. The timer should indicate the treatment time in units of tenths and hundredths of minutes and be accurate to within ± 0.1 min. The back-up treatment time shall be automatically calculated.				
1.4.13.8	Door interlock:				
1.4.13.8.1	The treatment room door and appropriate accelerator cabinet doors shall be closed before the accelerator can produce radiation.				
1.4.13.8	Collision protection:				
1.4.13.8.1	The bidder to describe the hardware and software mechanisms that are provided in the accelerator and MR design to avoid injury to the patient due to any possible collisions, as well as any other such safety features				
1.4.14	**Record and Verify System (Including Oncology Information System):**				
1.4.14.1	The R&V system should be supplied with the MR-Linac system				
1.4.14.2	The system should be interfaceable with industry standard OIS using for example, HL7				
1.4.14.3	The control software of the linear accelerator shall incorporate the record-and-verify functionality that is fully compatible with the MR linac system. The bidder to specify whether it is interfaceable with existing Mosaiq systems in the hospital.				
1.4.14.4	The record-and-verify functions shall include patient data set-up parameters, control of MLCs, control of monitoring units, dose recording and full recording of the treatment process as well as a summary of the fields given at conclusion of the treatment course.				
1.4.14.5	The Record and Verify System shall allow automatic set-up of patient parameters for a specific patient, drawn from the database as well as automatic set-up of subsequent beam parameters following application of each beam.				
1.4.14.6	The R&V system shall have the ability to record and verify the image registration, adapted plan dose and DVH and cine as captured during delivery along with "as delivered" treatment plan recalculated from the linac logfile.				
1.4.14.7	The system shall have the ability to automatically generate treatment reports				
1.4.14.8	The system shall have the ability to record delivered fractions to an OIS				
1.4.15	**Dosimetry and QA**				
1.4.15.1	The bidder to describe the full list of QA and Dosimetry tools that are supplied with the system and are MR compatible and safe to use in the treatment room				
1.4.15.2	The bidder to provide a list of optional QA, dosimetry and verification equipment offered to the user at no additional cost and included fully in the bid.				
1.4.15.3	The bidder shall make provision for a budgeted reserve of which the amount will be utilized, considering the requirements and input of the customer's Medical Physics team, to purchase the desired QA equipment for use on the delivered MR Linac system.				

1.4.15.3.1	The desire of the Medical Physics team is to perform automated QA and multiple dosimetric analyses in single measurements. This desire should be respected and considered when discussing the purchase of such equipment.				
1.4.15.3.2	The QA equipment should include, but is not limited to, for example: MRI compatible motion phantom for imaging and dosimetry, image quality phantoms allowing testing over the field of views stated in the bid that can be used clinically (for distortions, contrast, resolution, geometries, SRS and SBRT end-to-end testing, etc.)				
1.4.15.3.3	The items included in 1.4.15 relate to absolute dose measurement systems (electrometer/ionization chamber x2), 2D array, IMRT verification for patient treatment (2D or 3D array including software for dose calculation and comparisons, x2), image quality phantoms, 2D and 3D array software for instantaneous dose output, flatness, symmetry, field size analyses, SRS multi-target dosimetry, etc.				
1.4.15.3.4	A range of phantoms shall be provided considering the customer input for prostate, cervix, etc. ultrasound and CT imaging for external beam and brachytherapy training and exercises				
1.4.15.3.5	All software license and software upgrades should be included in the bid for the maintenance period of the MR Linac system				
1.4.15.3.6	SRS and SBRT QA devices, including holding devices, software packages and licenses, automated processes, etc.				
1.4.15.3.7	MR compatible and waterproof small volume ionization chamber and high resolution diode detector for absolute and relative dosimetry				
1.4.15.4	The bidder to provide recommended daily, weekly and monthly QA procedures				
1.4.15.5	Bidder to provide a holder to accurately and reproducibly position phantoms in three orientations (axial, coronal, sagittal). Provide the details of the holder, including technical drawings and compatible phantoms				
1.4.15.6	Bidder to describe the equipment and method for measuring and analyzing geometric distortions				
1.4.15.7	Bidder shall provide automated QA Analysis of geometric distortion in specified volumes				
1.4.15.8	The system shall include an integrated secondary dose calculation/verification for online adapted plan QA solutions				
1.4.15.9	QA Tools shall include:				
1.4.15.9.1	MR-MV alignment phantoms and software, as well as MR-MV QA phantoms and software				
1.4.15.9.2	Any positioning platforms for seamless and accurate phantom/detector positioning				
1.4.15.9.3	Complete MR Compatible high quality 3D water tank for continuous motorized scanning inside the MR-Linac system, as well as positioning platforms and software, as well as a manual/programmable MR 1D water tank. Customer input is a prerequisite for the decision on such equipment				
1.4.15.9.4	Phantoms and detectors for daily quick field profile, beam quality, output and beam alignment QA and software to log all results, keep results in a database and allow trend analysis from results				
1.4.15.9.5	MRI geometric distortion phantoms and software to be used to perform the MRI 3D geometric accuracy tests				
1.4.15.9.6	The QA tools shall include a 2D/3D detector array of the user's choice, appropriate to perform IMRT measurements at any gantry angle and full 3D dose reconstruction, allowing comparisons of at least DVHs, gamma analysis and other plan statistics at minimum effort level				
1.4.15.9.7	The QA tools shall include a standard class electrometer and long-cable farmer type ionization chamber of the user's choice with TNC connections, appropriate for use in the MR-Linac system				
1.4.15.9.8	The above mentioned dosimetry system shall be calibrated as a unit by an SSDL or similar and the bidder shall be responsible for bi-annual calibration of this dosimetry unit over the period of the maintenance contract				
1.4.15.9.9	3D Geometric Distortion phantom and test analysis system				
1.4.15.9.10	ACR MRI phantom				
1.4.15.9.11	A suitable micro-ionization chamber, required to measure and verify beam profile and dose distributions produced by the multi-leaf collimator (MLC) for stereotactic purposes. Sensitive volume should be smaller than 0.05 cc.				
1.4.15.9.12	Supporting documentation and peer reviewed publications for the equipment in 1.4.15 shall be provided, indicating their accuracy, resolution, maximum detection field size, range of measurements and full functionality.				
1.4.15.9.13	Two suitable high quality laptops in accordance with the user's approval shall be supplied for operation of the equipment, including the required software for full operation.				

1.4.15.9.14	Cables required by the quality assurance tools shall be permanently laid in ducts between the console area and the treatment room.				
1.4.16	**Treatment Planning System**				
1.4.16.1	Specify the TPS dose calculation algorithm and supply supporting literature relating to dose calculation accuracy in inhomogeneous media and magnetic fields, especially very low density media (e.g. Lung tissue and vicinity of air cavities)				
1.4.16.1.1	Although dose accuracy might be specified by the AAPM TGs 118 and 142, the bidder must specify conditions and accuracy achievable by its system and supply supporting scientific documentation				
1.4.16.1.2	The dose to a moving target should constantly be within </= 2% to that of a stationary target when employing motion adaptation or management mechanisms through real time tracking.				
1.4.16.2	The TPS should offer treatment options for 3D conformal treatment planning, intensity modulated radiotherapy, stereotactic radiosurgery, stereotactic body radiotherapy, image guided radiotherapy and image guided adaptive radiotherapy.				
1.4.16.3	Bidder to state whether on-table/couch adaptive planning can be performed				
1.4.16.4	Bidder to state whether adaptive planning considers dose already delivered in previous or current treatment fraction				
1.4.16.5	Bidder to state how future beam models will be considered for implementation on the existing TPS				
1.4.16.6	The TPS should include all available functionality (including all licenses), for example for treatment planning, import/export of CT/MR/PET/US images, plan data (including RTDose, RTPlan, etc.), Deformable registration or warping, rigid image registration, etc.				
1.4.16.7	The TPS should allow optimization of all listed techniques above				
1.4.16.8	It should be possible to create combinations of plans listed above				
1.4.16.9	The bidder shall provide means of an independent calculation of the MU or dose distribution of the treatment plans. The bidder must provide details of such calculations, when and where is it performed, and which tools are used to make comparisons (e.g. dose difference, gamma analysis, DVH comparison, etc.) between treatment planned dose and QA dose. Are the independent calculations performed automatically or not?				
1.4.16.10	Specify and fully describe any automatic contouring tools offered, including deformable registration or warping				
1.4.16.10.1	During treatment execution and subsequent interruption, can auto contouring be performed, and can it be performed remotely?				
1.4.16.11	Specify and describe any deformable registration options offered and how they are used to calculate the cumulative dose				
1.4.16.12	The TPS must have all licenses and ability to import DICOM images, dose and structures from 3rd party TPS				
1.4.16.13	In the case of a server solution being offered, specify the number of named users supported by supplied licenses. At least two licenses should be provided per TPS.				
1.4.16.14	The TPS shall have the ability to plan and deliver multi isocenter techniques in one plan (multiple-isocenter, not multiple-target)				
1.4.16.15	The TPS shall have the ability to calculate dose using deformed electron densities or synthetic CT data				
1.4.16.15.1	The bidder to state whether synthetic MR images can be produced from CT images, and if so, whether this option is included in the bid				
1.4.16.16	Bidder to state the time to complete optimization and calculation using a 2mm grid and 1% uncertainty for a 15 field integrated boost IMRT prostate plan. State dose calculation algorithm				
1.4.16.17	Bidder to fully describe the optimization algorithms available for planning, as well as all physical and biological objectives and constraints that can be used for treatment plan optimization, whether automatically or manually.				
1.4.16.18	Bidder to supply supporting literature or data to show the TPS ability to plan intercranial SRS treatment for targets 1-3 cc				
1.4.16.19	**Computers**				
1.4.16.19.1	Patient (including planning and simulation) and machine delivery data should be stored in a database server. Bidder to state the size and type offered, with adequate storage capacity (specify)				
1.4.16.19.2	Each computer to be supplied with an uninterruptable power supply unit (UPS). Bidder to specify what is offered.				
1.4.16.19.3	Bidder to specify the offered control console computer systems, including those for treatment delivery and imaging.				
1.4.16.19.4	Bidder to specify the offered treatment planning system computer systems.				
1.4.16.19.5	Installation, considering and including customer satisfaction, of the computers, screens and other utilities must be included in the bid.				

1.4.16.19.6	Specify the quantity (at least 5) remote/parallel workstations or nodes included in the offer to allow for remote functions (specify functions included) for imaging, treatment planning, OIS, QA and treatment. Please expand if more services are offered.				
1.4.16.19.7	Bidder to describe parallel and collaborative workflow on the system				
1.4.16.19.8	The bidder shall provide all necessary means to allow ease of patient, machine, treatment and record backup (automated systems are preferred) on at least 2 separate devices.				
1.4.16.19.9	The database server with patient data and machine data shall be an easily navigationable and connected system				
1.4.16.19.10	The local Medical Physics team should have full access to machine data, the image storage unit, etc.				
1.4.16.19.11	Local Medical Physicists shall be fully trained on beam modelling and TPS commissioning, al forms of treatment planning and QA of the TPS.				
1.4.16.20	**Control room operations**				
1.4.16.20.1	The control console outside the treatment room shall be computerized and digital.				
1.4.16.20.2	Bidder to specify all modules included in the control console.				
1.4.16.20.3	Control console must include a high quality audio and visual communication system for monitoring and communication with patients in the room.				
1.4.16.20.4	The control system screen displaying relevant patient, setup and treatment related information should also be visible inside the treatment room via high quality displays.				
1.4.16.20.5	Bidder to list and name which automated workflows from patient imaging to completion of treatment is offered, and how user intervention is alleviated and treatment time is reduced.				
1.4.16.21	Online adaptive planning				
1.4.16.21.1	Specify the dose calculation algorithm used for online adaptive planning and algorithm for plan optimization				
1.4.16.21.2	Such adaptive planning should form part of an integrated system and consider applicable geometries of the treatment case at hand				
1.4.16.21.3	Describe how intrafraction stoppages, imaging, and adaptations are performed				
1.4.16.21.4	Describe how previously delivered doses are considered when plans are adapted				
1.4.16.21.5	State whether the user/planner can make changes in the optimization criteria during the optimization process.				
1.4.16.21.6	State whether automatic contouring tools are available during this online process				
1.4.16.21.7	State whether this process ultimately allows on-line plan adaptation with automatic dose recalculation and verification				
1.4.16.21.8	Does the system allow for plan adaptation before the start of treatment, during treatment, all with consideration of the delivered dose to date?				
1.4.16.21.9	Does the system have a capability of automated plan adaptation with minimal user intervention?				
1.4.16.21.10	Does the system have the ability to adapt and deliver multi isocenter techniques as stated above?				
1.4.16.21.11	Does the system have the ability to calculate dose using deformed electron densities or synthetic CT				
1.4.16.21.12	Bidder to state the time required to complete online optimization and calculation for a 2mm grid and 1% uncertainty for a 15 field integrated boost IMRT prostate plan. State dose calculation algorithm used				
1.4.16.21.13	State whether the TPS has the ability to calculate dose from the reference plan onto newly acquired daily images with contours to aid in the decision of necessity for adaption. This requires quick statistical and dosimetric analysis and a record of such proceedings should be stored				
1.4.16.21.14	State whether remote access for physicians and physicists is possible during on table adaptive workflow. State whether remote access imposes any restrictions in the workflow.				
1.4.16.21.15	The system shall provide simultaneous user access (multiple users reviewing, contouring, planning, etc.) on the same patient via multiple portals.				
1.4.16.21.16	State whether online QA of adapted plan can be performed utilizing and independent calculation (state algorithm used) of the MU or dose distribution of the radiation plan, whether automatic comparison of both calculations can be performed and which tools can be utilized for quick, seamless and effective analysis. Can a report of this QA be produced and stored?				
1.4.16.21.17	The inclusion of future upgrades on the TPS software and hardware is required during the period for which a maintenance contract is enforced				

1.5	**INSTALLATION REQUIREMENTS:**				
1.5.1	The Bidder shall inspect and monitor the quality of the existing power supply and add any additional equipment / appliances necessary to prevent damage to the offered system as a result of electrical supply shortcomings / inconsistencies. The additional equipment / appliances shall form part of the main offer.				
1.5.2	All proposals must have complete plans (mechanical, electrical, building and gas installations). The financial implication and the duration of the project must be clearly stated.				
1.5.3	The successful Bidder shall first discuss all proposals with the relevant hospital department(s) and the Department of Works. The successful Bidder may only commence with the work when approval from the Department of Works is issued				
1.5.4	The successful Bidder shall make good any damages that may occur to the walls, floors, ceilings etc. during the equipment installation and commissioning period.				
1.5.5	Air conditioner:				
1.5.5.1	If needed, the successful Bidder shall install a suitable air conditioning system to regulate the bunker temperature for safe operation of the accelerator, as well as the control room				
1.5.5.2	The Bidder shall maintain the air conditioning system (new or existing) under a service contract.				
1.5.6	Electrical (not all inclusive):				
1.5.6.1	A suitable power conditioner device to the MR Linear Accelerator manufacturer's specification shall be supplied and installed by the successful Bidder. The device shall eliminate any harmful power disturbances that may affect the normal operation of the equipment. In addition to power conditioning, the earthing and bonding of the equipment shall receive very careful consideration (equipotential earthing)				
1.5.6.2	Connection and proper operation to the existing Emergency Generator shall be ensured				
1.5.6.3	The bidder shall supply:				
1.5.6.4	All Cabling and Wiring				
1.5.6.5	One Wall-mounted Cabinet with Tools				
1.5.6.6	All Drawings and Notices				
1.5.7	Servicing:				
1.5.7.1	Maintenance schedule and pricing for a minimum period of five years after a two year warranty period				
1.5.8	Acceptance:				
1.5.8.1	The bidder shall demonstrate full functionality of the total MR-Linac system under fully loaded conditions				
1.5.9	Chiller Unit and gas supply unit to the MR linac:				
1.5.9.1	The Bidder to include all costs (supply, delivery, storage, installation, interconnection and commissioning) of a chiller and magnet electrical and gas/conductivity supply requirements for full operation of the offered system. It will form part of the main bid price. Supply of gas shall be ensured during the full maintenance contract period. (Reference to gas includes amongst others, Helium, Nitrogen and SF6, and should include any gas requirements not listed here for full functionality of the system)				
1.5.10	Networking:				
1.5.10.1	The Bidder to supply an IT Network. A diagram of the proposed network, with a bill of material must be supplied inclusive to the bid document.				
1.5.10.2	A complete network setup according to departmental demands for remote workflow shall be performed by the successful bidder, including Medical Physics and Oncology staff				
1.5.11	Control Room:				
1.5.11.1	The Bidder shall supply and install the required plugs, worktops and shelving, including accessory mounts, in the control room area. The customer's input shall be considered and every attempt should be made to satisfy the customer's requests.				
1.5.12	Cupboards and Chest of Drawers:				
1.5.12.1	The Bidder to supply cupboards and various chests of drawers on wheels as required by the user for storage of linen, manuals, stationary, accessories and/or treatment moulds in the control room and linear accelerator bunker.				
1.5.12.2	Dressing room cubicles and lockers shall be installed as required by the user for changing of clothes and storing of metallic valuables or accessories during working ours for personnel working at the MR Linac				
1.5.13	Complience				

1.5.13.1	All equipment, installation and any alteration/additions shall comply (during or after installation) with the radiation safety regulations directive from the South African Health Products Regulatory Authority (SAHPRA).				
1.5.13.2	The onus will be on the successful Bidder to ensure that a license can be issued in terms of the Hazardous Substance Act (1973) by SAHPRA on the installed system and site.				
1.5.13.3	The Bidder shall be responsible to remove all building rubble generated, from the worksite on a daily/weekly basis, as well as removal and scrapping of removed equipment (e.g. Scrapping and removal of redundant equipment in an existing bunker)				
1.5.13.4	The Oncology and Medical Physics Departments at Universitas Academic Hospital Annex may require minor corrections or upgrades to existing offices and walkways (passages). The successful bidder shall assist in upgrading of these facilities to be in line with the aesthetics of the newly installed systems				
1.5.13.5	The safety of all equipment, tools and material remain the responsibility of the Bidder until the project is officially handed over to Universitas Academic Hospital				
1.5.13.6	The inclusion of future upgrades on all of the integrated MR-Linac system software and hardware is required for the duration of the maintenance contract when enforced				
1.5.13.7	Bidder to specify how beam modeling for the TPS and independent dose verification systems will be handled. The user will perform the measurements for this purpose through its Medical Physics team, with consulting assistance from the bidder where required.				
1.5.13.8	Bidder shall provide training to the Medical Physics team on the beam modeling required by the TPS and independent dose verification systems				
1.5.14	Site specific requirements:				
1.5.14.1	Installation of all hardware and software is included				
1.5.14.2	Application training for Therapy Radiographers, Medical Physicists and Oncologists – give details of training that is included in the bid				
1.5.14.2.1	**In so far as reasonably achievable, training should be provided at the installation site to increase the size of the group of trainees and preservation of local knowledge**				
1.5.14.2.2	Dedicated onsite & overseas training (provide details)				
1.5.14.2.3	Dedicated classroom training courses for Medical Physicists, Physicians and Radiation Therapists (at least 6 total attendees, provide details)				
1.5.14.2.4	Peer to peer Radiation Oncologist training (provide details)				
1.5.14.2.5	Minimum five days on site support for first patient treatment (provide details)				
1.5.14.2.6	Provision of a simulation/emulator environment for full workflow training and practice (provide details)				
1.5.14.2.7	The Bidder shall undertake to provide a comprehensive training schedule, for both User Departments and Clinical Engineering staff of the Hospitals to ensure:				
1.5.14.2.7.1	Correct use of the equipment, and				
1.5.14.2.7.2	Initial training of at least 6 users (e.g. Medical Physicists, Physicians and Radiation Therapists) shall be provided by the successful Bidder at no extra cost. The Bidder shall certify that the 6 initial trained users are competent to train other staff in the unit on the equipment. State period of initial training offered.				
1.5.14.2.7.3	Beyond the above, the successful Bidder shall, at no extra cost during the guarantee period, provide additional user support in the use of all features of the equipment for a total period of six (6) weeks.				
1.5.14.2.7.4	After mandatory upgrades (software and/or hardware) have been performed, training shall be free of charge.				
1.5.14.2.8	All power requirements should be installed and verified by the successful bidder for complete operation of the total MR Linac package, including all functionality and components offered in this bid.				
1.6	**GUARANTEE CONDITIONS:**				
1.6.1	The Bidder shall support a two-year guarantee period on all supplied items/goods.				
1.6.2	The time taken to attend to a malfunctioning unit within the guarantee period shall extend the guarantee period by that time.				
1.6.3	The supplier shall notify the user of any future software updates and shall supply these updates free of charge in the guarantee period.				

1.6.4	Loan units shall be supplied for immediately movable items e.g. all display units, workstations, keyboards and computer mice units during the guarantee period for no longer than five working days. The five working day period will provide the Bidder with ample time to repair/replace the malfunctioning devices. Failing this condition will result in the user renting/procuring a similar unit and the Bidder shall carry the cost. This is not applicable if user negligence can be proven.				
1.6.5	Any repetition (more than twice) of the same fault that first occurred during the guarantee period shall be considered as a repair under guarantee, if the same fault occurs within the first year after the expiry of the guarantee period. This is not applicable if user negligence can be proven.				
1.6.6	The same guarantee conditions shall apply to replacement units.				
1.6.7	The guarantee period shall include all costs (all spare parts, labor, travelling and sundries cost), prescribed maintenance services and any QA testing that are required by SAHPRA, that may be required under the guarantee period.				
1.7	**MAINTAINABILITY:**				
1.7.1	The Bidder to ensure all consumable and non-consumable items required for the normal operation and standard maintenance of the offered equipment is included in the bid.				
1.7.2	The Bidder to indicate which of these items are proprietary items that only the supplier of the equipment can supply.				
1.7.3	The Bidder must have an adequate quantity of factory-trained technicians in their direct employment. The Bidder shall have an established technical support base in the Free State Province or Gauteng Province. The Bidder to provide the physical address of the technical facility/workshop				
1.7.4	The institution's requirement is that a technician is available within a reasonable time (4 hours) to attend to malfunctioning equipment.				
1.7.5	The Bidder must keep stock in South Africa of the equipment's major spare parts as well as mandatory service spare parts. Scheduled services will be free of charge if it has to be postponed due to the unavailability of the prescribed replacement parts.				
1.7.6	The Bidder shall supply one set of all the original fully detailed technical maintenance manuals (not photocopies) at no additional cost.				
1.7.7	The Bidder shall supply all software (including software-keys and/or pass words) to allow for trouble shooting (faultfinding), maintenance, calibration, repairs and services up to 1st level, at no additional costs.				
1.7.8	The Bidder shall include a firm commitment (in writing) from the Principal Manufacturer that the latter would supply spares, components, upgrades and support for technical and clinical staff of Universitas Academic Hospital Annex , over the expected life expectancy of their offered system and software, should their local agent / supplier default.				
1.8.	**SAFETY:**				
1.8.1	The unit shall comply with the necessary safety standards.				
1.8.2	The offered system shall be CE or FDA certified/approved (not exclusive).				
1.9	**TRAINING:**				
1.9.1	Dedicated onsite & overseas training (provide details)				
1.9.2	Dedicated classroom training courses for Physicists, Physicians and Radiation Therapists (at least 6 total attendees, provide details)				
1.9.3	Peer to peer Radiation Oncologist training (provide details)				
1.9.4	Minimum five days on site support for first patient treatment (provide details)				
1.9.5	Provision of a simulation/emulator environment for full workflow training and practice (provide details)				
1.10	**DOCUMENTATION:**				
1.10.1	All tender and relevant documentation shall be in English and original (not copies), submitted in duplicate.				
1.10.2	Two (2) complete sets of user manuals, in English, shall be supplied.				
1.10.3	One (1) complete set of English workshop/service manuals, shall be supplied and be onsite.				
1.10.4	A license issued in terms of the Hazardous Substance Act, (Act no. 15 of 1973) shall be submitted with the tender. Failure to submit such a license may result in a tender not being considered.				
1.11	**UPGRADE POLICY:**				
1.11.1	The Bidder shall describe their upgrade policy for future equipment improvement (hardware and software).				
1.11.2	All future upgrades (hardware and software) involving patient safety shall be offered at no additional cost.				

1.11.3	All future upgrades removing software bugs from existing hardware and software shall be supplied at no cost.				
1.11.4	Any upgrade after the guarantee period of the equipment involving additional cost shall be brought to the attention of the Provincial Government of the Free State Province.				
1.11.5	The Bidder to state current CE and FDA approved upgrade paths with availability, delivery dates, and costs				
1.12	**MAINTENANCE CONTRACT:**				
1.12.1	Percentage guaranteed up time of machine must be at least 98%				
1.12.2	The Bidder to suggest a planned maintenance program, estimated on a year-by-year basis for at least 5 years **after** expiry of the guarantee/warrantee period				
1.12.3	The maintenance contract may be purchased and **paid for up front** with the purchase of the equipment.				
1.12.4	This contract is for the complete system including all possible options and associated equipment.				
1.12.5	The Bidder to state the cost of the upfront fully comprehensive maintenance contract, per annum, for 5 years, which shall be inclusive of VAT.				
1.12.6	This option shall be seen as an extended guarantee and shall include all the conditions as stipulated under the guarantee conditions and shall include all labor, travelling, sundries, all spares (including magnetron, thyratron, etc.) preventative maintenance, corrective maintenance (call outs), installations and QA checks (as prescribed by the Department of Health or the South African Health Products Regulatory Authority) over a 5 years period after the two year guarantee/warrantee period expired. All equipment provide a under this bid shall be included in this contract, including third party equipment (e.g. QA equipment).				
1.12.7	A **fully inclusive** preventative maintenance contract for a five (5) year period after the guarantee/warrantee expiry date **(not paid up front),** must be provided (to include all labor, travelling, sundries, all spares (including magnetron, thyratron, etc.) preventative maintenance, corrective maintenance (call outs), installations and QA checks, as prescribed by the Department of Health or the South African Health Products Regulatory Authority. The Bidder to provide a pricing schedule per year i.e. Year 1 to Year 5. (NB. Year 1 is the year following the guarantee period). All prices must include VAT				
1.12.8	Quality assurance test results according to the stipulated time frames shall be handed to the Section Head: Medical Physics, during this 5-year period.				
1.12.9	The successful Bidder shall be requested to sign the agreement based on the pricing supplied in the Bid Document.				
	The successful bidder shall assist the local Medical Physics team with applications and regulatory requirements required by the South African Health Products Regulatory Authority that is not familiar with MR Linac systems				
1.13	**COST OF OWNERSHIP: (quotation to be attached to the bid offer)**				
1.13.1	A minimum guarantee period of two months is applicable. All parts, labor, travelling, routine maintenance (including corrective maintenance) are to be included during the warranty period.				
1.13.2	The Bidder shall indicate the expected life expectancy of their offered system and software - minimum of 10 years support is required.				
1.13.3	The Bidder shall provide a detailed breakdown of the cost of ownership of their offered system for the life cycle (over the number of years indicated in 13.2). This quotation will form part of the final evaluation.				
1.13.4	The Bidder shall provide a firm commitment from the principle manufacturer on how long the offered unit's spare parts and software will be available. The spare parts will be available at market related prices (consideration will be given to normal price escalations and rate of exchanges).				
1.14.	**UNSPECIFIED OPTIONS:**				
1.14.1	The bidder is requested to offer (with costs) any additional available software or hardware options not specifically specified in this bid, and to motivate the benefits of each option.				
1.15	**Indexed Stepper and Ultrasound Imaging System**				
1.15.1	The bidder shall provide a remote controlled TRUS imaging system suitable for prostate and cervix cancer imaging and treatments and wholly compatible with existing brachytherapy treatment planning and delivery systems and other treatment equipment, or supply alternative treatment planning and remote controlled systems				

1.15.2	The system shall comprise of a high quality stepper for indexed automated and manual transducer positioning, a mounting device for the stepper that is sturdy and of high quality, as well as the Ultra Sound imaging system and at least a bi-planar transducer combination for TRUS, as well as a trans-abdominal ultrasound transducer. The system shall be used for prostate and cervix imaging and brachytherapy treatment, allowing MR image fusion as well				
1.15.3	Images should be displayed in real-time on both the US unit and the existing or offered TPS, where contouring and treatment planning can be performed in real time				
1.15.4	Consideration should be given for existing applicators for both prostate and cervix treatment, as well as afterloading system				
1.15.5	A large high quality screen for visual aid should be installed in the treatment/imaging room, connected to the TPS and/or US unit, considering user input in the layout and screen offered				
1.15.6	QA phantoms for total system QA should be included and full details shall be provided by the bidder, considering the requirements of the user. These should include prostate and cervix phantoms for ultrasound and be MR compatible.				
1.15.7	A set of high quality stirrups for patient positioning and immobilization shall be provided for prostate and cervix cancer lithotomy imaging and treatment procedures, also considering existing equipment				
1.15.8	Consideration shall be given to the existing CT Simulator couch design, which could be altered by the supplier to accommodate the stirrups and allow for convenient applicator implantation and subsequent imaging in a seamless manner				
1.15.9	A well-type ionization chamber and electrometer of high quality (including a standards laboratory calibration certificate) shall be supplied with the system for calibration of Ir-192 HDR sources				
1.15.10	Bidder to supply a high quality ECG monitor for patient monitoring in the treatment room, while under anesthesia				
1.15.11	Training				
1.15.11.1	The supplier will become obliged to provide a comprehensive training schedule to selected staff members. This training schedule should provide staff with the necessary knowledge and skills to ensure :				
1.15.11.2	The correct and optimal use of the stepper, ultrasound and treatment planning system				
1.15.11.3	Comprehensive technical support capability of the complete ultrasound system by eligible Medical Physicists				
1.15.11.4	Training should enable staff to perform all functionalities seamlessly during QA and clinical implementation				
1.15.11.5	The bidder shall provide one carton of gaphchromic film (EBT3 or equivalent, considering Medical Physics team input) once a year for the duration of the guarantee and maintenance contract.				
1.16	**Air conditioner**				
1.16.1	An appropriate air conditioning system shall be installed with the MR Linac and existing procedure room. Air conditioning requirements for an MR Linac room of existing bunker area and volume shall be met, as well as for the procedure room.				
1.16.2	State the required BTU/hr rating of the air conditioning unit and the recommended location of the unit in relation to the MR Linac, as well as procedure room. The supplier shall include the air conditioning unit in the bid and perform maintenance over the contracted period				
1.16.3	The successful bidder shall install a suitable air conditioning system to regulate the bunker temperature for safe operation of the MR Linac, or take responsibility of the existing air conditioner maintenance. The same applies to air conditioning in the control room, equipment room (including computers), waiting area and procedure room				

FREE STATE DEPARTMENT OF HEALTH

Specifications for

ITEM2 : ONE STANDALONE MONOPLACE HYPERBARIC CHAMBER

NOTES:

1) The Bidder must clearly indicate if their product complies with the stated requirements, by indicating, "Comply" or "Does not comply" next to the corresponding clause.

2) Should the equipment offered deviate from any specified technical requirements, full details of such deviations must be given. In the event of the available space being insufficient such details shall be given on a separate sheet, indicating the relevant paragraph number in the specification.

3) The Bidder must clearly state any parameter values or additional information as requested in relevant clauses.

4) The Bidder must clearly indicate if their offered product exceeds the stated requirement by noting, with proof, "Above specification" next to the corresponding clause.

5) All responses shall be clear and legible.

6) All prospective Bidders will be requested to attend a site presentation at National Hospital on 04/10/2023, from 10:00 to 12:00. Failure to attend these site meetings shall lead to the disqualification of the Bidder's offer.

ITEM2 : HYPERBARIC OXYGEN CHAMBER

Nr.	Specification	Compliance		Reference (Clear reference to this specification and page number in the bid is compulsory if compliance is YES). No reference lead to disqualification of this bid	Comment: FULL TECHNICAL AND OTHER DETAILS OF OFFER
	This specification establishes the requirements for a HYPERBARIC OXYGEN CHAMBER for use in the RADIATION ONCOLOGY DIVISION, at Universitas Academic Hospital Annex.	YES	NO		
1.1	**SCOPE:**				
1.1.1	The units on offer shall be licensed for sale in the South African market by a recognized supplier who can prove that service, spares and application support is available in South Africa to maintain the systems at peak operating performance.				
1.1.2	The units offered to render the service shall be currently in production and have been tried and tested in the clinical setting. Evidence that the equipment being offered can meet the specifications shall be provided.				
1.1.3	A list of all users in South Africa where the units that are offered in this bid is currently in clinical use shall be provided, indicating the current models and equipment configurations per site. The Department of Health, Free State Province reserves the right to independently verify the performance and support on the offered units. In the case where no South African clinical user sites are available, reference sites outside of South Africa may be given.				
1.1.4	Provide a summary of the total number of units per continent worldwide of the units offered in this bid.				
1.1.5	The units offered shall comply with or exceed all of the minimum performance specifications as indicated below for the various sub-components, supported by factory-supplied product specifications / brochures.				
1.1.6	Descriptive literature, pamphlets, brochures and technical data sheets applicable to the offer (i.e. all components of systems) shall accompany the bid, failing which the bid will not be considered.				

1.1.7	The units and any accessories ordered from the successful Bidder will be delivered, installed, tested, calibrated, demonstrated (including specified training) and commissioned in the specified hospital at the expense of the successful Bidder, prior to full payment being made.				
1.1.8	The hyperbaric oxygen therapy (HBOT) tank will allow high pressure oxygen treatment in the Department of Radiation Oncology at Universitas Hospital Annex				
1.1.9	The unit shall be installed in the Radiation Oncology Department at Universitas Hospital Annex. Insofar as installation is concerned, existing infrastructure should be utilized, but structural changes to the existing treatment room is allowed. If structural changes are required, they should be minor, and the systems should fit within the vault/room and be able to allow comfortable loading and extraction of the patients inside the room. Aesthetic changes to the environment should be included in the bid with input from the end user.				
1.1.11	Fast and effective individualized HBOT treatment must be allowed, thus a requirement for a series of settings or optimization for patient comfort and throughput should be possible.				
1.1.12	It is required that external continuous real-time monitoring and automated treatment be possible in an integrated system.				
1.1.13	The system shall provide comfortable and easy patient positionining options, with clear see-through chamber for patient comfort.				
1.1.14	The chamber shall have a sleek modern look that would fit into any hospital, also considering the aesthetic desires of the end user				
1.1.15	The HBO therapy equipment shall provide maximum comfort to patients and operators				
1.1.16	The Bidder is to offer the following features, and any others considered desirable by the bidder, for selection and inclusion by the institution:				
1.1.16.1	Spacious large diameter cylinder				
1.1.16.2	Mounted entertainment/media system				
1.1.16.3	Single handed door lock				
1.1.16.4	Precision controls and display for easy viewing by a technician or nurse				
1.1.16.5	Digital control systems				
1.1.16.6	Convenient private two-way communication system				
1.1.16.7	Wide stretcher with adjustable headrest				
1.1.16.8	Ability to treat the patient in a reclined position				
1.1.16.9	Ability to connect to an integrated entertainment system				
1.1.17	Chambers shall accommodate:				
1.1.17.1	Multiple intravenous transfusion lines				
1.1.17.2	Electrical monitoring including EEG, EKG, temperature and blood pressure				
1.1.17.3	Transcutaneous oxygen monitoring				
1.1.17.4	Patient air-break breathing system				
1.1.17.5	Interior diameter of at least 36"				
1.1.17.6	Emergency vent mode				
1.1.17.7	State Emergency Vent decompression time				
1.1.17.8	Headrest with incline of at least 30° to allow for increased patient comfort				
1.1.17.9	Bariatric patients up to 300 kg shall be comfortably supported with a mattress				
1.1.17.10	Integrated O2 tank holder and IV Pole				
1.1.17.11	Control panel can be located on either side of the chamber, considering room design and ease of access				

1.1.17.12	Indicators to instantaneously show gas supply				
1.1.17.13	Equipped with precision controls that do not require adjustment during pressure changes				
1.1.17.14	Oxygen conservation must be available through adjustable ventilation rates. Bidder to state the rates				
1.1.17.15	INTERNAL DIAMETER at least 90cm				
1.1.17.16	INTERNAL LENGTH at least 231 cm				
1.1.17.17	EXTERNAL LENGTH at least 269 cm				
1.1.17.18	EXTERNAL HEIGHT at least 168 cm				
1.1.17.19	EXTERNAL WIDTH at least 113 cm				
1.1.17.20	CHAMBER WEIGHT at least 1009 kg				
1.1.17.21	SUPPORTED PATIENT WEIGHT at least 300 kg				
1.1.18	Bidder to state:				
1.1.18.1	MAXIMUM OPERATING PRESSURE				
1.1.18.2	OPERATING TEMPERATURE RANGE				
1.1.18.3	OPERATING HUMIDITY RANGE				
1.1.18.4	SUPPLY PRESSURE REQUIRED				
1.1.18.5	PURGE RATE				
1.1.18.6	EMERGENCY VENT RATE				
1.1.18.7	RELIEF VALVES				
1.1.19	The system shall have a state of the art control panel for monitoring and maintaining a stable environment within the chamber				
1.1.20	Bidder to specify the absolute pressures at which the hyperbaric chamber can operate for therapeutic purposes				
1.1.21	State the material composition of the chamber				
1.1.22	State the diameters of the access hatch				
1.1.23	State whether the chamber has a small access hatch suitable for passing medications, instruments or food				
1.1.24	State whether a built-in breathing system (BIBS) to supply and exhaust treatment gas is provided				
1.1.25	Storage and Gurney Features				
1.1.25.1	Space-saving gurney storage				
1.1.25.2	Hydraulic gurney, simple to steer and stop while allowing ease incornering and control				
1.1.26	State whether the HBOT tank has a fire safety system				
1.1.27	The system shall include a CCTV to monitor the patient in the chamber				
1.1.28	An intercom system allowing two-way communications between the patient and the staff				
1.1.29	A control panel outside the chamber to control air flow by opening and closing valves to and from the chamber and regulate oxygen to hoods or masks if necessary				
1.1.30	An over-pressure relief valve				
1.1.31	A fire suppression system				
1.1.32	The design of the HBOT Treatment Area/ Room must follow the recommendations of local safety committees and guidelines, e.g. National Fire protection Associations and standards for health care facilities				
1,2	SITE INSPECTION:				
1.2.1	Before submitting the offer for these HBOT unit:				
1.2.2	The Bidder shall inspect the premises and determine what building constructions or alterations will be necessary to house the new equipment.				
1.2.3	The Bidder must be capable of compiling the necessary plans and, after approval, construct the required buildings or alterations and ensure that all electrical supplies, network requirements, gas supply and extractions and other services are available for equipment installation, and that these would be adequate after installation at the time of operation, to finally allow the user to obtain an operating license for the intended use of the HBOT unit				

1.2.4	The Bidder must ensure that sufficient access routes are available for the correct and safe installation of the equipment.				
1,3	**APPLICABLE DOCUMENTS:**				
1.3.1	General Conditions of Contract (Annexure A).				
1.3.2	Additional Conditions of Tender Section B.				
1.3.3	BS EN 14931				
1.3.4	CE or FDA certification.				
1.3.5	ISO 9001				
1.3.6	ISO 13485 : Medical Devices – Quality Management Systems				
1.3.7	ISO 14971 : Medical Devices – Application of Risk Management to Medical Devices				
1.3.8	All requirements as listed by the South African Health Products Regulatory Authority (SAHPRA)				
1.3.9	List all other comliance certificates or registers				
1,4	**GENERAL:**				
1.4.1	The offered systems shall be installed and handed over fully functional, which shall include all the aspects as identified in the clauses below:				
1.4.2	The Bidder shall provide a clear pricing schedule listing all the requirements and the associated pricing, including any requested options. **All options on offer in the bid are accepted as included under the bid.**				
1.4.3	The offered systems shall be of the latest technology. The Bidder shall state how long this technology (hardware and software) has been commercially available (state when the model offered was launched), as well as if any near future updates are expected.				
1.4.4	What is the life expectancy of the units being offered?				
1.4.5	All accessories required for the offered systems to be fully functional, shall be included as part of the bid. A motivation for items not included in this specification, must be provided.				
1.4.6	What is the manufacturing company's policy regarding availability of spare parts after production of the new units stops?				
1.4.7	All prices are to include VAT and to be firm prices in Rand. The Bidder is to state the period for which the firm price is valid. The rate of exchange must be the rate as published 7 (seven) days before the tender closes. Proof of exchange rate must be attached (e.g. bank letter with official stamp)				
1.4.8	**Patient communication system and monitoring to be supplied**				
1,5	**Treatment and control room aesthetic design and layout**				
1.5.1	Bidder shall supply the user with options for treatment room aesthetic designs, fully included in the bid, and user recommendation of the room design shall be considered.				
1.5.2	Bidder shall supply the user with options for control room aesthetic designs, fully included in the bid				
1,6	**Computers**				
1.6.1	Bidder to offer a means for computerized patient and treat machine delivery data capture, which should be stored in a database server. Bidder to state the size and type offered, with adequate storage capacity (specify)				
1.6.2	Bidder to state which processes are automated with respect to operation of the system, as well as data capture and backup				

1.6.3	Bidder to specify the offered control console computer systems, including those for treatment delivery and data capture (treatment records)				
1.6.4	Bidder to specify the offered computer systems.				
1.6.5	Installation, considering and including customer satisfaction, of the computers, screens and other utilities must be included in the bid.				
1.6.6	The bidder shall provide all necessary means to allow ease of patient, machine, treatment and record backup (automated systems are preferred) on a separate device.				
1.6.7	The database server with patient data and machine data shall be an easily navigationable and connected system				
1.6.8	The local Medical Physics team should have full access to machine data, the patient and treatment data storage unit, etc.				
1.6.9	Local Medical Physicists shall be fully trained on al forms of treatment execution and QA of the HBOT unit.				
1,7	**INSTALLATION REQUIREMENTS:**				
1.7.1	The Bidder shall inspect and monitor the quality of the existing power supply and add any additional equipment / appliances necessary to prevent damage to the offered system as a result of electrical supply shortcomings / inconsistencies. The additional equipment / appliances shall form part of the main offer.				
1.7.2	All proposals must have complete plans (mechanical, electrical, building and gas installations). The financial implication and the duration of the project must be clearly stated.				
1.7.3	The successful Bidder shall first discuss all proposals with the relevant hospital department(s) and the Department of Works. The successful Bidder may only commence with the work when approval from the Department of Works is issued				
1.7.4	The successful Bidder shall make good any damages that may occur to the walls, floors, ceilings etc. during the equipment installation and commissioning period.				
1.7.6	Electrical (not all inclusive):				
1.7.6.1	A suitable power conditioner device to the HBOT unit manufacturer's specification shall be supplied and installed by the successful Bidder. The device shall eliminate any harmful power disturbances that may affect the normal operation of the equipment. In addition to power conditioning, the earthing and bonding of the equipment shall receive very careful consideration (equipotential earthing).				
1.7.6.2	Connection and proper operation to the existing Emergency Generator shall be ensured				
1.7.6.3	The bidder shall supply:				
1.7.6.4	All Cabling and Wiring				
1.7.6.5	One Wall-mounted Cabinet with Tools				
1.7.6.6	All Drawings and Notices				
1.7.7	Servicing:				
1.7.7.1	Maintenance schedule and pricing for a minimum period of five years after a one year warranty period				
1.7.8	Acceptance:				
1.7.8.1	The bidder shall demonstrate full functionality of the total HBOT system under fully loaded conditions				
1.7.9	Treatment Room:				

1.7.9.1	The Bidder shall supply and install the required plugs, worktops and shelving, including accessory mounts, in the treatment room area. The customer's input shall be considered and every attempt should be made to satisfy the customer's requests.				
1.7.11	Complience				
1.7.11.1	All equipment, installation and any alteration/additions shall comply (during or after installation) with the radiation safety regulations directive from the South African Health Products Regulatory Authority (SAHPRA).				
1.7.11.2	The onus will be on the successful Bidder to ensure that a license can be issued in terms of the National pressure equipment directives				
1.7.11.3	The Bidder shall be responsible to remove all building rubble generated, from the worksite on a daily/weekly basis, as well as removal and scrapping of removed equipment (e.g. Scrapping and removal of redundant equipment in an existing bunker)				
1.7.11.4	The Oncology and Medical Physics Departments at Universitas Academic Hospital Annex may require minor corrections or upgrades to existing offices and walkways (passages). The successful bidder shall assist in upgrading of these facilities to be in line with the aesthetics of the newly installed systems				
1.7.11.5	The safety of all equipment, tools and material remain the responsibility of the Bidder until the project is officially handed over to Universitas Academic Hospital				
1.7.11.6	The inclusion of future upgrades on all of the integrated HBOT system software and hardware is required for the duration of the maintenance contract when enforced				
1.7.12	Site specific requirements:				
1.7.12.1	Installation of all hardware and software is included				
1.7.12.2	Application training for Nurses, Oncologists and Medical Physicists – give details of training that is included in the bid				
1.7.12.3	**In so far as reasonably achievable, training should be provided at the installation site to increase the size of the group of trainees and preservation of local knowledge**				
1.7.12.4	The Bidder shall undertake to provide a comprehensive training schedule, for both User Departments and Clinical Engineering staff of the Hospitals to ensure:				
1.7.12.5	Correct use of the equipment, and				
1.7.12.6	Initial training shall be provided by the successful Bidder at no extra cost. State period of initial training offered.				
1.7.12.7	Beyond the above, the successful Bidder shall, at no extra cost during the guarantee period, provide additional user support in the use of all features of the equipment for a total period of six (6) weeks.				
1.7.12.8	After mandatory upgrades (software and/or hardware) have been performed, training shall be free of charge.				
1.7.12.9	All power requirements should be installed and verified by the successful bidder for complete operation of the total HBOT system, including all functionality and components offered in this bid.				
1,8	**GUARANTEE CONDITIONS:**				
1.8.1	The Bidder shall support a one-year or longer guarantee period on all supplied items/goods.				
1.8.2	The time taken to attend to a malfunctioning unit within the guarantee period shall extend the guarantee period by that time.				
1.8.3	The supplier shall notify the user of any future software updates and shall supply these updates free of charge in the guarantee period.				

1.8.4	Loan units shall be supplied for immediately movable items e.g. all display units, workstations, keyboards and computer mice units during the guarantee period for no longer than five working days. The five working day period will provide the Bidder with ample time to repair/replace the malfunctioning devices. Failing this condition will result in the user renting/procuring a similar unit and the Bidder shall carry the cost. This is not applicable if user negligence can be proven				
1.8.5	Any repetition (more than twice) of the same fault that first occurred during the guarantee period shall be considered as a repair under guarantee, if the same fault occurs within the first year after the expiry of the guarantee period. This is not applicable if user negligence can be proven.				
1.8.6	The same guarantee conditions shall apply to replacement units.				
1.8.7	The guarantee period shall include all costs (all spare parts, labor, travelling and sundries cost), prescribed maintenance services and any QA testing that are required by SAHPRA, that may be required under the guarantee period.				
1,9	**MAINTAINABILITY:**				
1.9.1	The Bidder to ensure all consumable and non-consumable items required for the normal operation and standard maintenance of the offered equipment is included in the bid.				
1.9.2	The Bidder to indicate which of these items are proprietary items that only the supplier of the equipment can supply.				
1.9.3	The Bidder must have an adequate quantity of factory-trained technicians in their direct employment. The Bidder shall have an established technical support base in the Free State Province or Gauteng Province. The Bidder to provide the physical address of the technical facility/workshop				
1.9.4	The institution's requirement is that a technician is available within a reasonable time (4 hours) to attend to malfunctioning equipment.				
1.9.5	The Bidder must keep stock in South Africa of the equipment's major spare parts as well as mandatory service spare parts. Scheduled services will be free of charge if it has to be postponed due to the unavailability of the prescribed replacement parts.				
1.9.6	The Bidder shall supply one set of all the original fully detailed technical maintenance manuals (not photocopies) at no additional cost.				
1.9.7	The Bidder shall supply all software (including software-keys and/or pass words) to allow for trouble shooting (faultfinding), maintenance, calibration, repairs and services up to 1st level, at no additional costs.				
1.9.8	The Bidder shall include a firm commitment (in writing) from the Principal Manufacturer that the latter would supply spares, components, upgrades and support for technical and clinical staff of Universitas Academic Hospital Annex , over the expected life expectancy of their offered system and software, should their local agent / supplier default.				
1,1	**SAFETY:**				
1.10.1	The unit shall comply with the necessary safety standards.				
1.10.2	The offered system shall be CE or FDA certified/approved (not exclusive).				
1,11	**DOCUMENTATION:**				
1.11.1	All tender and relevant documentation shall be in English and original (not copies), submitted in duplicate.				

1.11.2	Two (2) complete sets of user manuals, in English, shall be supplied.				
1.11.3	One (1) complete set of English workshop/service manuals, shall be supplied and be onsite.				
1,12	**UPGRADE POLICY:**				
1.12.1	The Bidder shall describe their upgrade policy for future equipment improvement (hardware and software).				
1.12.2	All future upgrades (hardware and software) involving patient safety shall be offered at no additional cost.				
1.12.3	All future upgrades removing software bugs from existing hardware and software shall be supplied at no cost.				
1.12.4	Any upgrade after the guarantee period of the equipment involving additional cost shall be brought to the attention of the Provincial Government of the Free State Province.				
1.12.5	The Bidder to state current CE and FDA approved upgrade paths with availability, delivery dates, and costs				
1,13	**MAINTENANCE CONTRACT:**				
1.13.1	Percentage guaranteed up time of machine must be at least 98%				
1.13.2	The Bidder to suggest a planned maintenance program, estimated on a year-by-year basis for at least 5 years **after** expiry of the guarantee/warrantee period				
1.13.3	The maintenance contract may be purchased and **may be paid up front** with the purchase of the equipment.				
1.13.4	This contract is for the complete system including all possible options and associated equipment.				
1.13.5	The Bidder to state the cost of the upfront fully comprehensive maintenance contract, per annum, for 5 years, which shall be inclusive of VAT.				
1.13.6	This option shall be seen as an extended guarantee and shall include all the conditions as stipulated under the guarantee conditions and shall include all labor, travelling, sundries, all spares (including magnetron, thyratron, etc.) preventative maintenance, corrective maintenance (call outs), installations and QA checks (as prescribed by the Department of Health or the South African Health Products Regulatory Authority) over a 5 years period after the one year guarantee/warrantee period expired. All equipment provide a under this bid shall be included in this contract, including third party equipment (e.g. QA equipment).				
1.13.7	A **fully inclusive** preventative maintenance contract for a five (5) year period after the guarantee/warrantee expiry date **(not paid up front),** must be provided (to include all labor, travelling, sundries, all spares (including magnetron, thyratron, etc.) preventative maintenance, corrective maintenance (call outs), installations and QA checks, as prescribed by the Department of Health or the South African Health Products Regulatory Authority. The Bidder to provide a pricing schedule per year i.e. Year 1 to Year 5. (NB. Year 1 is the year following the guarantee period). All prices must include VAT.				
1.13.8	Quality assurance test results according to the stipulated time frames shall be handed to the Section Head: Medical Physics, during this 5-year period.				
1.13.9	The successful Bidder shall be requested to sign the agreement based on the pricing supplied in the Bid Document.				
1,14	**COST OF OWNERSHIP: (quotation to be attached to the bid offer)**				

1.14.1	A minimum guarantee period of 12 months is applicable. All parts, labor, travelling, routine maintenance (including corrective maintenance) are to be included during the warranty period.				
1.14.2	The Bidder shall indicate the expected life expectancy of their offered system and software - minimum of 10 years support is required.				
1.14.3	The Bidder shall provide a detailed breakdown of the cost of ownership of their offered system for the life cycle (over the number of years indicated in 13.2). This quotation will form part of the final evaluation.				
1.14.4	The Bidder shall provide a firm commitment from the principle manufacturer on how long the offered unit's spare parts and software will be available. The spare parts will be available at market related prices (consideration will be given to normal price escalations and rate of exchanges).				
1,15	**UNSPECIFIED OPTIONS:**				
1.15.1	The bidder is requested to offer (with costs) any additional available software or hardware options not specifically specified in this bid, and to motivate the benefits of each option.				

PRICING SCHEDULE - NON-FIRM PRICES (PURCHASES)

NOTE: PRICE ADJUSTMENTS WILL BE ALLOWED FOR RATE OF EXCHANGE AND STATUTORY INCREASES AS SPECIFIED IN THE BIDDING DOCUMENTS. PRICES FOR 1ST YEAR OF CONTRACT PERIOD MUST BE FIRM

Name of Bidder: _____ Bid Number: **DOH (FS) 15 /2023 / 2024**

Closing Time: **11H00** Date: **20 October 2023**

OFFER TO BE VALID FOR 120 DAYS FROM THE CLOSING DATE OF BID

ITEM NUMBER	QUANTITY	DESCRIPTION	BID PRICE IN RSA CUURENCY **(ALL APPLICABLE TAXES INCLUDED)
1	1	**Integrated diagnostic quality MIR Scanner and linear acceleratory system**	**OPTION 1** R _____ **outright purchase** R _____ **monthly service & maintenance post warranty** R _____ **Total amount for service & maintenance for five years** **OPTION 2** R _____ **monthly lease amount** R _____ **total lease amount for 5 years**

REQUIRED BY THE FREE STATE DEPARTMENT OF HEALTH

Required by:	Annex (Universitas) Academic Hospital
At:	
Brand and model:	_____
Country of origin:	_____
Does offer comply with specifications?	* YES / NO
If not to specifications, indicate deviation(s)	_____
Period required for delivery	_____
Delivery	* FIRM / NOT FIRM
Delivery basis	_____

** "All applicable taxes" included value-added tax, pay as you earn, income tax, unemployment insurance fund contributions and skills development levies

* Delete if not applicable

PRICING SCHEDULE - NON-FIRM PRICES (PURCHASES)

NOTE: PRICE ADJUSTMENTS WILL BE ALLOWED FOR RATE OF EXCHANGE AND STATUTORY INCREASES AS SPECIFIED IN THE BIDDING DOCUMENTS. PRICES FOR 1ST YEAR OF CONTRACT PERIOD MUST BE FIRM

Name of Bidder: _____ Bid Number: **DOH (FS) 15 /2023 /2024**

Closing Time: **11H00** Date: **20 October 2023**

OFFER TO BE VALID FOR 120 DAYS FROM THE CLOSING DATE OF BID

ITEM NUMBER	QUANTITY	DESCRIPTION	BID PRICE IN RSA CUURENCY **(ALL APPLICABLE TAXES INCLUDED)
2	2	**Standalone monoplace hyperbaric Chamber** • See attached detailed specifications	**OPTION 1** R _____ **outright purchase** R _____ **monthly service & maintenance post warranty** R _____ **Total amount for service & maintenance for five years** **OPTION 2** R _____ **monthly lease amount** R _____ **total lease amount for 5 years**

REQUIRED BY THE FREE STATE DEPARTMENT OF HEALTH

Required by: Universitas Academic Hospital

At:

Brand and model: _____

Country of origin: _____

Does offer comply with specifications? * YES / NO

If not to specifications, indicate deviation(s) _____

Period required for delivery _____

Delivery * FIRM / NOT FIRM

Delivery basis _____

** **"All applicable taxes" included value-added tax, pay as you earn, income tax, unemployment insurance fund contributions and skills development levies**

- **Delete if not applicable**

PRICE ADJUSTMENTS

A FIRM PRICES FOR PERIOD CONTRACTS SUBJECT TO ESCALATION - STATUTORY

1. IN CASES OF PERIOD CONTRACTS, PRICES MUST BE FIRM FOR THE FIRST 12 MONTHS OF THE CONTRACT PERIOD WHERE AFTER IT COULD BE ADJUSTED ON QUALIFICATION AND APPLICATION WITHIN THE REQUIRED PERIOD

2. IN THE FOLLOWING CATEGORY STATUTORY INCREASES WILL BE CONSIDERED IN TERMS OF THE FOLLOWING FORMULA:

$$Pa = (1-V)Pt\left(D1\frac{R1t}{R1o} + D2\frac{R2t}{R2o} + D3\frac{R3t}{R3o} + D4\frac{D4t}{D4o}\right) + VPt$$

Where:

Pa	=	The new escalated price to be calculated.
(1-V)Pt	=	85% of the original bid price. **Note that Pt must always be the original bid price and not an escalated price.**
D1, D2..	=	Each factor of the bid price eg. labour, transport, TAX, etc. The total of the various factors D1,D2…etc. must add up to 100%.
R1t, R2t.....	=	Index figure obtained from new index (depends on the number of factors used).
R1o, R2o	=	Index figure at time of bidding.
VPt	=	15% of the original bid price. This portion of the bid price remains firm i.e. it is not subject to any price escalations.

3. The following index/indices must be used to calculate your bid price:

Index: CPI Dated: September 2023

4. FURNISH A BREAKDOWN OF YOUR PRICE IN TERMS OF ABOVE-MENTIONED FORMULA. THE TOTAL OF THE VARIOUS FACTORS MUST ADD UP TO 100%.

FACTOR (D1, D2 etc. eg. Labour, transport etc.)	PERCENTAGE OF BID PRICE

B FIRM PRICES FOR PERIOD CONTRACTS - SUBJECT TO RATE OF EXCHANGE VARIATIONS

IN CASES OF PERIOD CONTRACTS, PRICES MUST BE FIRM FOR THE FIRST 12 MONTHS OF THE CONTRACT PERIOD WHERE AFTER IT COULD BE ADJUSTED ON QUALIFICATION AND APPLICATION WITHIN THE REQUIRED PERIOD

1. Please furnish full particulars of your financial institution, state the currencies used in the conversion of the prices of the items to South African currency, which portion of the price is subject to rate of exchange variations and the amounts remitted abroad.

PARTICULARS OF FINANCIAL INSTITUTION	ITEM NO	PRICE	CURRENCY	RATE	PORTION OF PRICE SUBJECT TO ROE	AMOUNT IN FOREIGN CURRENCY REMITTED ABROAD
				ZAR=		
				ZAR=		
				ZAR=		
				ZAR=		
				ZAR=		
				ZAR=		

2. Adjustments for rate of exchange variations during the second period of contract will be calculated per consignment by using the actual exchange rates as issued by your commercial bank at time of bidding and the actual direct change as a result of the rate of exchange for payment of the specific consignment to the contractors supplier. (Proof from bank for rate of exchange applicable to the bid at time of bidding MUST be attached to the bid)

   Claims must be provided within 90 days from date of change in price however payments to overseas suppliers must be made within 30 days from receipt of the Departments payment.

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest1 in the enterprise, employed by the state? **YES/NO**

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	Identity Number	Name of State institution

2.2 Do you, or any person connected with the bidder, have a relationship

1 the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.