SPECIFICATIONS FOR SUPPLY, DELIVERY, INSTALLATION, DEMONSTRATION AND COMMISSIONING OF A CEILING SUSPENSED DUAL DETECTOR X-RAY MACHNE FR THE ORTHOPAEDIC UNIT AT ROBERT MANGALISO SOBUKWE HOSPITAL, NORTHERN CAPE DEPARTMENT OF HEALTH

COMPULSORY SITE VISIT

Item	Specifications	Complies Yes/No	Provide your answers in this column. You are advised to be straight to the point
	Intended use – The unit must be able to perform routine diagnostic imaging x-ray procedures. Medical applications must include general radiography, orthopaedics on both adults and paediatrics.		
1.	**MANUFACTURER**		
2.	**MODEL**		
3.	**DELIVERY PERIOD**		
4.	**LIFESPAN OF THE EQUIPMENT** The Bidder must indicate the expected life of their offered unit and software in years		
5.	**YEAR FIRST SOLD**		
6.	**NUMBER OF UNITS INSTALLED IN SOUTH AFRICA** Please attach a list of reference sites plus contact details. 2 reference letters from end users compulsory		
8.	**FDA CLEARANCE & CE MARK (ATTACH CERTIFICATE)**		
9.	**REGISTRATION WITH NATIONAL DEPARTMENT OF HEALTH DIRCTORATE RADIATION CONTROL**		
9.1	Bidders must state the Radiation Control number of the make and model of the equipment offered. If this type of equipment/apparatus appears on the schedule of Hazardous Substances, issued by the Directorate: Radiation Control of the Department of Health, a license in terms of the Act on Hazardous Substance (Act		

	15/1973) must be registered under the bidders name of the letter of Joint Venture must be submitted by the License holder where the license is not in the name of the bidder		
10.	**SAHPRA APPROVED** Please attach certificate		
11.	**TYPE OF POWER SOURCE**		
12.	**X-RAY GENERATOR**		
12.1	state maximum power at 100 kV according - to IEC601 (kW) +-50kw		
12.2	State generator performance data: kW Ma at kV		
12.3	Minimum rated output power should be at least 65 kW		
12.4	Shortest switching time with automatic exposure control (1 ms)		
12.5	Shortest mAs product		
12.6	Must use 1 mAs per step		
12.7	Maximum switching frequency (f/s) bidder to state		
12.8	Maximum Tube voltage of more or equal to 150kV		
12.9	Dimensions of the generator cabinet - L x W x H in cm bidder to indicate		
12.10	Weight in kg bidder to indicate		
12.11	Automatic exposure techniques/programs must be available with the option of manual programming included.		
12.12	Bidders to supply details of programming facility and the number of programs.		
12.13	A monitoring and display of tube heat status should be provided		
12.14	Tube overload protection mechanism is required		
12.15	Automatic mains compensation must be provided		
12.16	Must have a two step hand switch retractable which can initiate the exposure from a safe distance		
13.	**DIGITAL SYSTEM PLUS STITCHING UNIT**		
13.1	A fully automatic, digital, radiographic examination and evaluation workstation based on detector technology for high image dynamics with excellent signal/noise ratio is required		
13.2	Must have Two flat panel detectors with one fixed detector and one wireless detector to be provided		
13.3	Examination table with mattress plus liquid resistant cover		
13.4	Erect wall stand		
13.5	A specialized patient positioning stand paired with software with software that combines multiple overlapping x-ray exposures into a single seamless long length image of the spine and lower limbs.		
13.6	The stitching stand must be equipped with steady hand grips, height adjustments and motorized tracking to		

	keep the patient stable across sequence exposures		
14.	**EXPOSURE SYSTEM**		
14.1	Detector- state type offered		
14.2	Exposure formats: 35cm x 35cm or 35cm x 43cm		
14.3	Full vertical		
14.4	Full horizontal		
14.5	Detector exposure matrix: State		
14.6	Detector element pitch: State microns		
14.7	Acquisition depth : State bit		
14.8	Description of the scattered radiation grid: TYPE		
14.9	State Minimum grid ratio		
14.10	Reading speed at maximum format from the exposure to preview on the monitor: State time in sec		
15	**CEILING SUSPENSION FOR TUBE**		
15.1	Ceiling suspended column for ceiling mounted tube must be provided.		
15.2	Longitudinal operation range to be at least+/- 3.5meter to cover the room.		
15.3	Transverse travel to be at least: +/- 3 meters to cover the room.		
15.4	Vertical travel to be: minimum 1.5 meters		
15.5	Holder for tube assembly to allow rotation of 4 x 90' about the vertical axis and 2 x 90° about the horizontal axis. Free movement in 360 degrees for quick positioning is required.		
15.6	Handlebar with electro-magnetic lock controls for all possible tube movements including rotation about the vertical axis.		
15.7	Control switches at the back of the column should be available to be able to work from any side of the patient. It must be possible to lock all movements with electromagnetic brakes.		
15.8	Centering device in longitudinal and transverse direction.		
15.9	The unit must have APR (anatomical program radiograph) control with LCD display.		
16	**X-RAY EXAMINATION TABLE/BUCKY TABLE**		
16.1	A floating, radiolucent with a scratch resistant finish and flat tabletop, table for general radiography must be offered. State loading capacity in kg		
16.2	Tabletop to be approximately 750mm (width) x 2200mm length in size. The table must have electromagnetic brakes so that the table remains braked in the event of a power supply failure.		

16.3	State the range of the table's capability to be electronically height adjustable with automatic **F.F.D** sensing and also the table height from ground. State offer		
16.4	The table movement must have a safely mechanism for protection of patient and unit in the downward movement.		
16.5	Emergency button must be accessible and not protruding outside the table frame range.		
16.6	State the tabletop travel dimensions in both transverse and longitudinal planes		
16.7	A foot operated electromagnetic braking system must be integrated into the table.		
16.8	Three field automatic exposures device/control		
16.9	Covered radiolucent mattress. Mattress must be fluid and stain resistant		
16.10	The table assembly must include the following accessories:		
16.11	Lateral cassette/detector holder		
16.12	State whether the x-ray tube has auto centering over the Bucky (in transverse direction after every exposure		
17	**ERECT DETECTOR BUCKY STAND**		
17.1	Fully digital wall mounted tilting Bucky stand.		
17.2	Built-in minimum size 35cm x 43cm fixed flat panel detector capable to take digital images in horizontal, vertical and oblique positions with suitable movements to allow for a complete range of exams from skull, skeletal body including spine, chest, weight-bearing knees and ankle joints.		
17.3	Must include Automatic Exposure Control with at least three fields.		
17.4	State the grid ratio and focus range, taking into consideration that horizontal examinations will be made		
17.5	It should have a vertical Bucky with oscillating/moving grid for chest radiography (State grid ratio)		
17.6	State the min vertical movement range min in cm with the lowest point (from cassette center to ground) stated in cm and the highest point also in cm.		
17.7	The Bucky should have electromagnetic lock that allow for easy positioning.		
17.8	Bucky tilting will be an advantage		

17.9	Patient support for lateral chest examinations. Interchangeable for both left and right lateral projections		
18	**DIGITAL FLAT PANEL DETECTORS**		
18.1	Two detectors to be provided, fixed detector in the vertical Bucky and detector in the table Bucky.		
18.2	These to provide excellent ergonomics, ease of use and high-performance technical specifications.		
18.3	The detector must allow fast and efficient exposures as well as special angulations across the table.		
18.4	The active image size of the detectors must be minimum size 35 x 43cm to ensure high projection flexibility even with large patients.		
18.5	Digital detector of amorphous silicon and caesium iodide flat panel for excellent image quality even with low dose, is required.		
18.6	Image matrix size must be minimum 2800 pixels x 2400 pixels.		
18.7	The acquisition depth conversion must provide minimum 14 bits/pixel.		
18.8	Please state pixel size.		
18.9	State the min image resolution in lp/mm.		
18.10	State the sensitivity range speed in rpm.		
19	**IMAGE PROCESSING**		
19.1	High resolution LCD monitors minimum 19" with good resolution.		
19.2	**The unit must have a RAM 8GB OR BETTER. OPERATING SYSTEM**		
19.3	The time required to display image on operators monitor must be 3 seconds or less		
20	**Image Workstation/Radiographer's console**		
20.1	The DR system must provide the ability to acquire appropriate patient and exam identification information from the RIS/HIS, via a DICOM (Digital Imaging Communication) "patient work list".		
20.2	The Workstation must provide a mechanism to support quality review of DR images and permit a radiographer to take remedial actions. Remedial actions include image flip (top to bottom, left to right), image rotation, window width and level, image rejection (deletion from the exam) and image reprocessing.		
20.3	The workstation must also cater for magnification of viewing and printing, multiple print formats (printing of one or more images through standard supplied templates on one piece of film), image labeling, image QC control and post processing [parameters.		

20.4	The DR system must be capable of routing images to PACS or any DICOM destination. Inclusion of DICOM store modules is mandatory. The bidder must make sure that the fully processed image together with annotations can be sent to the PACS system and not only the raw image.		
20.5	Printing to an existing DICOM dry printer must be possible from the radiographer's console.		
20.6	An automated as well as a manual shuttering system must be available.		
20.7	It must be possible to enter patient data manually for emergencies or when the network is down and must be done via a touch screen system that is integrated into the console.		
20.8	The workstation must automatically be able to send a selected study to a DICOM compatible CD/DVD writer		
20.9	The system must also provide the means of swapping patient images from one folder to the next, for example: patient name amendment if obvious errors are detected, free text annotation for entering the kilo Volts (kV) and milli Ampere (mA) and time of studies etc.		
20.10	Predefined anatomically specific processing sets; also manually customized to be possible		
20.11	DICOM grayscale display		
20.12	Fast Ethernet interface		
20.13	Fully customized patient worklist required		
20.14	Examination related pre-configured views to be possible		
20.15	The entire Local Area Network required for the system must be supplied and installed *bv* the successful bidder where necessary		
20.16	Quality Control software to be included as a standard		
21	**UNINTERRUPTABLE POWER SUPPLY FOR COMPUTERS** -		
21.1	UPS must be provided and included in the bid price to run the control panel computer for more than 30 min.		
22	**AIR CONDITIONING**		
22.1	Air conditioning must be supplied if needed to the room where image acquisition takes place and where the equipment will be installed.		
23	**POWER REQUIREMENTS**		
23.1	Bidders must state the power requirements for the system on offer.		
24	**END USER TRAINING**		
24.1	User training must be provided by the successful bidder in the operation of the unit at no extra cost to the final bid price,		
24.2	Application specialist should train all users on an on-going basis		

25	**ROOM/BUILDING ALTERATIONS REQUIREMENTS**		
25.1	The tenderer is to inspect the proposed installation site for complete site evaluation		
25.2	The tenderer will be required to provide room layout drawings and siting requirements		
25.3	All building alterations must be specified and included in the bid		
25.4	The successful shall make good any damages that occur to walls, floors, ceiling, electrical wiring and computer network during installation		
25.5	The successful bidder will be responsible for the supply and installation of the air conditioners needed in the area to support the unit in terms of air quality and temperature control		
25.6	Bidders to test the current power supply to ensure conformity with the equipment offered		
25.7	Provide an in-line UPS that allow for safe shutdown of the system during power outage/mains power failure		
25.8.	Adequate UPS systems must be supplied to prevent loss of data. The additional equipment/appliances must form part of the bid offer.		
25.9	All equipment supplied will be fitted with adequate surge protection devices that are not one-off surge, but multi-surge protection devices		
25.10	Bidders to ensure that the entire system is connected to the backup generator on the premises. This will be done at the bidders expense.		
25.11	A detailed summary of costs of all proposed siting related issues is to be included.		
25.12	The proposed equipment layout plan/drawing must be accepted and signed by the Head of Department as a mandatory requirement for tender acceptance.		
25.13	Tenderers are to attend a compulsory site inspection meeting as requested by the Hospital		
25.14	Bidder shall include and specify all additional costs not covered by the above to achieve this goal.		
25.15	Bidder to Supply 10 office chairs that will allow for 8 hour seating plus 2 comfortable chairs for patients with side hand bars		
30	**GENERAL TECHNICAL AND SAFETY SPECIFICATIONS**		
30.1	The unit must comply with an acceptable international electric safety such as IEC601-1 and 601-1-2 for the medical equipment, attached certification.		
30.2	System must comply to ISO 900 and ISO 13458 standards, attach proof of compliance.		
30.3	All electrical/electronic medical equipment must be licensed by **Radiation Control**, where applicable a copy of the license must be submitted.		

30.4	The bidder must be prepared to provide a unit for technical evaluation and clinical assessment on request.		
30.5	Spare parts must be guaranteed available for the specified life of the equipment, with a minimum of 10 years.		
30.6	The bidder must guarantee that no additional equipment, parts or software, excluding consumables, will be required for the successful operation of the equipment quoted, A starter pack of all essential accessories must be supplied so that the unit can be put into immediate operation. The cost of the starter pack must be included in the bid price.		
30.7	Optional accessories must be quoted for separately.		
30.8	No part shall be second hand or refurbished.		
30.9	Tender price to included delivery, installation, commissioning, two-year warranty and training. Acceptance of the equipment will only take place after commissioning of the equipment.		
30.10	The successful bidder must arrange for and acceptance test of the equipment. A copy of the acceptance test must be forwarded to the Clinical Director of the institution.		
30.11	Software changes to the equipment which are corrective in nature and initiated due to software errors, regulatory requirements or safety reasons, shall be delivered and installed at no charge for the life of the equipment.		
30.12	Bidders must have an established service and repair facility. State facilities		
30.13	Supply the name, address and telephone number/s of the service department		
30.14	Technicians must be qualified and factory equivalent trained to deal with service, repair and calibration of the equipment quoted on, **NB Certified copies of qualifications** (or equivalent) training must be submitted with this bid.		
30.15	The bidder must state how many technicians they have permanently employed and the Curriculum Vitae attached		
30.16	State if the technicians are in direct employ of the bidder.		
30.17	If the equipment is taken away for repairs during the warranty period, a loan set must be supplied for use by the institution.		

30.18	The up-time of the unit must be better than 98%, excluding scheduled preventative maintenance and software upgrades, measure on a quarterly basis. The percentage lower than 98% will be added to the warranty period. A sliding scale penalty clause will form part if the service contract. This will result in the maintenance payment being reduced by a pro rata amount that the up-time is less than 98%.		
30.19	Up-time is defined as follows: 24.7, i.e. 564 days times 24 hours = 8760 hours. A down time of 25 relates to 175 hours per annum.		
31	**WARRANTY AND MAINTENANCE**		
31.1	Bidders must supply a minimum of twenty-four-month warranty against poor workmanship and latent defects and parts. This must be all inclusive and include, BUT NOT LIMITED TO, amongst others, ALL PARTS (including, where appropriate, consumables, x-ray tubes and other glassware), labor, traveling and accommodation, the two-year warranty must also include all servicing, quality assurance requirements. Including all required calibrations, software updates. This two year warranty will commence after formal acceptance and handover of the equipment. The maintenance of air conditioners must be included during the 2 year warranty period		
31.2	Bidders must supply a separate 5year, all inclusive, fully comprehensive preventative maintenance, service repair plan covering all equipment, hardware and software, the bidder must provide a fully costed COMPREHENSIVE MAINTENANCE AND SERVICE AGREEMENT with an option to enter into a renewable agreement for the specified lifespan if the equipment. This contract would cover, but not be limited to the following: ALL PARTS (including, where appropriate, consumables, x-ray tubes and other glassware), labor, traveling and accommodation, service and maintenance. The five-year all-inclusive maintenance plan must also include all quality checks and quality assurance requirements. Including all required calibrations, software updates and upgrades to be includes. The maintenance and repair of air conditioners must be included during the 5-year maintenance contract period. Bidders must indicate exclusions on the maintenance plan. (**NB: Provide separate quote from the bid price)**		

32	**Scope of Work**		
	The scope of work will be discussed and finalized on the day of the compulsory site visit. Bidders who are not present at the site inspection will be excluded The x-ray room where the new machine will be installed is currently a general x-ray room with a xray machine The Bidders will be required to DE install the current condemned general machine and place it in storage on the hospital premises at RMSH The scope of work will therefore include changes that will make the room compliant with all radiation, infection control and optimal patient safety/privacy requirements.		

SPECIFICATIONS COMPILED AND CHECKED BY:

1.1 Ms J.A Du Plooy: Deputy Director-Diagnostic Radiography

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1.2 Dr. A. Swartbooi: HOU-Radiology

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1.3 Ms. D. Pienaar: Acting Assistant Director

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