Response To Pre-Bid Queries (Pre-Bid date: 09.10.2018)

NIB Ref:HITES/PCD/NCI-AIIMS/36/18-19

S.No:- 2 IORT Machine (Electron Based) (Rfx 3000003420)

Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	RESPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Point 1.9 page 62	**The Dose per pulse** shall be a value such that quality assurance (QA) procedures are simple to implement and are similar to those used in conventional radiotherapy treatment.	SIT	Quality Assurance (QA) procedures are simple to implement and are similar to those used in conventional radiotherapy treatment. **REASONS OF AMENDMENTS** This item has been modified since LIAC HWL has a higher dose per pulse. Such dose per pulse allows a higher dose rate. The language "The Dose per pulse shall be a value such that" might be referring to a low dose per pulse value.	**to be deleted**
Point 1.11 Page 62	Dual (primary and backup) dosimetry system for measuring radiation output, based on vented ion chambers with **automatic pressure** and temperature compensation	SIT	Dual (primary and backup) dosimetry system for measuring radiation output, based on vented ion chambers with temperature compensation. **REASONS OF AMENDMENTS** This item has been modified since LIAC HWL 12 MeV does not have pressure compensation. This feature since pressure variation inside any Operation Room are negligible due the Operating Room pressurization (in OR it must be kept a costant over pressure compared to surrounding rooms).	**To be Amended as:-** Dual (primary and backup) dosimetry system for measuring radiation output, based on vented ion chambers with temperature compensation.
Point 1.12 Page 62	It is preferable to use AAPM TG51 protocol or IAEA TRS-398 protocol to determine energy and absolute calibration. If these protocols cannot be used, the vendor shall state in detail what alternative protocol is used to determine energy and absolute calibration. Any alternative protocol must achieve the accuracy required by the AAPM TG-51 or IAEA TRS-398 protocols for electron beams.	SIT	This item has been modified since since LIAC HWL has a higher dose per pulse. Such dose per pulse allows a higher dose rate.The language including to "AAPM TG51 protocol or IAEA TRS-398" might be referring to low dose per pulse devices. **REASONS OF AMENDMENTS** This item has been modified since since LIAC HWL has a higher dose per pulse. Such dose per pulse allows a higher dose rate. The language including to "AAPM TG51 protocol or IAEA TRS-398" might be referring to low dose per pulse devices.	No change considered
Point 13. Page 62	Equipment should have appropriate beam-stopper.	Intra OP	**1.Integrated and interlocked, gantry mounted beam stopper** Mobile linear accelerator for electron IORT should be equipped with an integrated, gantrymounted beam-stopper, which automatically follows the movements of the head with an accuracy of 1 cm.The beam stopper should automatically track the head movement to ensure precise alignment with gantry position, including when underneath the surgical table or obscured by surgical drapes. What is more, it should include interlocks to inhibit the radiation beam if the beam shield is out of position. Manual positioning of beam-stopper and its precise alignment with gantry position is not only time consuming but also of questionable precision (especially for large gantry angles), which seriously undermines treatment accuracy and safety.	No change considered
Point 1.14 Page 62	Internal shielding limits stray x-ray radiation at 3m distance from the patient plane	SIT	Internal shielding limits stray x-ray radiation below 0.6 uSv/Gy at 3m distance from the patient plane. **REASONS OF AMENDMENTS** A limit value hs been added in order to allow a quantitative analysis; both competitor fully comply with the limit of 0.6 uSv/Gy at 3m.	No change consicered

Point 1.15 Page 62	The treatment head of the equipment should have at least 5 degrees of freedom	SIT	The equipment should have at least 5 degrees of freedom **REASONS OF AMENDMENTS** The language "treatment head of the equipment" has been deleted because describes a feature of Mobetron and, therefore, excludes LIAC HWL	**To be Amended as:-** **The equipment should** have at least 5 degrees of freedom
Point 2.1 Page 63	This software should be able to execute stability QA;report, print, and store machine calibration results, perform quality checks and **calculate the number of monitor units (MU)** required to administer a prescribed dose at a specified depth with all energies and all types of applicators.	SIT	The software offered should be able to execute stability QA; report, print, and store machine calibration results, perform quality checks and calculate the number of monitor units (MU) required to administer a prescribed dose at a specified depth and/or isodose with all energies and all types of applicators. **REASONS OF AMENDMENTS** **Amendment 1:** The language "This software" is excluding LIAC HWL 12 MeV since in case of LIAC HWL it is not a unique software providing the requested features; such features are in fact implemented in a software suite including the following software: - "MU Calculation"; - "Equipment monitor". **Amendment 2:** The language "and/or isodose" has been added since MU Calculation (see above Amendment 1) calculates Dose at a prescibred isodose and on a given depth. Note that dose can be prescribed either at a specified depth or at a certain isodose level.	**To be deleted**
Point 2.3 Page 63	Dose planning with the capability to mix different electron energies	SIT	Delete **REASONS OF AMENDMENTS** This feature has been deleted since it excludes LIAC HWL 12 MeV being referring to a specific function of Mobetron Software.	**To be Amended as:-** **DELETED**
Point 2.5 Page 63	The software shall be DICOM 3.0 Compliant and HL 7 compliant.	SIT	The software shall be DICOM 3.0 Compliant. **REASONS OF AMENDMENTS** The language "and HL 7 compliant" has been deleted since is excluding LIAC HWL 12 MeV. Please note that DICOM 3.0 is the standard commonly adopted communication protocol.	**To be Amended as:-** **DELETED**
Point 2.6 Page 63	The software shall track and record daily QA sessions including: - Beam energy and output statistics - Functionality Tests - Interlocks	SIT	The software shall track and record daily QA sessions. **REASONS OF AMENDMENTS** The language "including: - Beam energy and output statistics - Functionality Tests - Interlocks" has been deleted since it is excluding LIAC HWL and is based on Mobetron QA software specifications. Each manufacturer must specify what QA program is required.	**To be Amended as:-** The software shall track and record daily QA sessions.

Point 3.1 Page 63	3D Treatment Planning System for Electron based IORT for 1 workstation. Must include ability to calculate Dose Volume Histogram (DVH)	SIT	Vendor must illustrate its own strategy for treatment planification. System offered should be at least capable of calculating dose distribution on water equivalent target. REASONS OF AMENDMENTS Section 3 has been deleted since it refers to TPS provied by Intraop and lists its specific features and performances. IntraOp and SIT have developed different strategies about IORT planning system. IntraOp is distributing a software that uses preoperative images; SIT has developed a software capable of producing the correct dose distribution in water for all clinical configurations and is developing a innovative TPS that allows real time imaging of the target to be irradiated. The two approaches are too different to be compared in details in a Tender. The suggestion is therefore to ask the vendor to illustrate its own strategies and the software offered, being the software capable at least of calculating dose distribution on water equivalent target.	No change considered
Point 3.2 Page 63	The 3D TPS shall have FDA or CE Certification with certification from an internationally, independently recognized certification institution	SIT	Vendor must illustrate its own strategy for treatment planification. System offered should be at least capable of calculating dose distribution on water equivalent target.	**No change considered**
Point 3.3 Page 63	Simulation of the IORT procedure based on the pre-operative CT scans			
Point 3.4 Page 63	Selection of applicator (size and bevel angle) from pre-defined list of applicators. Position and orientation of the applicator should be defined in 3D space and with respect to the patient			
Point 3.5 Page 63	Calculate dose distribution using Pencil Beam algorithm taking into account electron density of patient's tissue and geometry of selected applicator (including bolus and shielding); and			
Point 3.6 Page 63	Calculate dose distribution using electron Monte Carlo algorithm taking into account electron density of patient's tissue and geometry of selected applicator (including bolus and shielding)			

Point 3.7 Page 63	Generate Treatment Reports with a full set of treatment parameters including: Position and orientation of applicator Applicator's diameter and bevel angle DVH Prescribed dose Normalisation level (normalisation method) Calculated Number of Monitor Units			
Point 3.9 Page 63	It should have at least two 19" or more TFT flat screen LCD colour monitor for display of 1024 x 1024 matrix or more			**To be amended as :** the system should have 19" or more TFT flat screen LCD colour monitor for display of 1024 x 1024 matrix or more.
Point 3.10 Page 63	Computer CPU systems should be running on a high-end workstation platform with UNIX/LINUX/ Window of latest configuration. RAM size must be at least 8 GB or better	SIT		Computer CPU systems should be running on a high-end workstation platform with latest configuration. RAM size must be at least 8 GB or better **No change considered**
Point 3.11 Page 63	Laser colour printer A4 size, latest model should be provided.: 1 no.	SIT		
Point 4 Page 64	Therapeutic Applicators with diameters of 6cm and less shall have thin walls in order to maximize the therapeutic ratio and reduce incision size.	Intra OP	**2. Half centimeter sized applicators** Applicators producing circular field sizes of 5 mm increment should be required. Half centimeter sized applicators are necessary to provide more flexibility in treating and a more optimal CTV coverage. What is more, broader selection of field sizes enables physicians to minimize required incision size and facilitate placement in tight body cavities, such as the pelvis. **3. Large field, non-circular applicators** Large field applicators in 3 sizes: 7cm x 12 cm, 8cm x 15 cm, and 8cm x 20 cm shall also be required. Large field applicators along with an adequate beam spreader enables the Radiation Oncologist to deliver uniform doses over areas as large as 8cm x 20cm (e.g. soft-tissue sarcoma). This solution avoids the need for multiple abutting or overlapping fields, thereby enhancing treatment precision and sparing healthy tissue.	No change considered

		SIT	Therapeutic Applicators with diameters of 6cm and less shall have thin walls (thickness less than 0,6 cm) in order to maximize the therapeutic ratio and reduce incisition size. **REASONS OF AMENDMENTS** The language "thickness less than 0,6 cm" has been added in order to allow a quantitative analysis and verification.	
Point 4.5 Page	Therapeutic Applicators shall be constructed of a material with density ≥1.3 g/cc to minimize radiation leakage through the applicator walls	SIT	Therapeutic Applicators shall be constructed of metal or PMMA. **REASONS OF AMENDMENTS** The language "a material with density ≥1.3 g/cc to minimize radiation leakage through the applicator walls" is excluding LIAC HWL 12 MeV since its aplpicators are in PMMA (density 1,19). Therefore such language has been deleted and the wording "metal or PMMA" has been added. It is well worth to stress that metallic applicators have walls little bit thinner respect to PMMA ones but are not transparent and produce more stray radiation.	No change considered
Point 20. Page 63	20. The offered equipment should have either Hard Docking CE soft Docking	Intra OP	**4. Soft-docking system** It should be required that the applicator shall be aligned through a "soft-docking" (non-contact) method for increased patient safety and positioning flexibility in treating a variety of anatomical sites. The alignment process shall use cameras or lasers and shall be interlocked to assure proper alignment. Soft docking method enables precise pre-alignment of the applicator to treatment site, first by the physician (with direct visualization of the field after applicator placement and prior to treatment), and then to the electron beam, without compromising the sterile field or electrical isolation to the patient. Soft docking system ensures that the applicator position is maintained during docking procedure and offers additional safety by halting the beam in case of patient movement. Soft docking system maximizes treatment accuracy and patient safety by quickly and accurately aligning the linear accelerator with better than 1 mm precision and eliminating all undesirable movement of the applicator during treatment.	No change considered
		SIT	The vendor should illustrate docking procedure. It is required to discuss risk mitigation strategy respect to docking process. **REASONS OF AMENDMENTS** The language "Hard docking system is offered, it must include force feedback sensor or mechanism to ensure the total force applied to the patient is safe" is excluding LIAC HWL since it is not equipped with such "sensor or mechanism". Note that such system is not included since hard docking proceure is safe (it has been certified after medical and clinical analysis). Any docking system, either Hard docking and soft docking, has intrinsic risks. Vendors must discuss in details their docking process	

Point 21. page 63	Range of motion and treatment flexibility:- The treatment head shall have the ability to move **in 5 axes** with following minimum ranges:- Gantry: +/- 45 degrees Tilt: +20/-10 degrees Vertical: 30 cm total range	Intra OP	**5. Sufficient patient reach — at least 70 cm in all treatment head orientations** Patient Reach (measured as the distance from the center of the bottom of the treatment applicator, i.e. beam central axis, to the inner surface of the LINAC body) shall be at least 70 cm in all treatment head orientations. The Linac shall have sufficient mechanical range to treat patients in a broad array of tumor locations and patient setups.	**To be Amended as:-** The treatment equipment should have 5 degree of motion for facilitating treatment
		SIT	Range of motion and treatment flexibility:The treatment head shall have the ability to move with following minimum ranges:- Gantry: +/- 45 degrees Tilt: +20/-10 degrees Vertical: 30cm total range **REASONS OF AMENDMENTS** The language "in 5 axes" has been deleted because describes a feature of Mobetron and, therefore, excludes LIAC HWL	
Point 12.4 Page 51	Multilayer ionization chamber (MLIC) vendor should provide one large diameter Multilayer ionization chamber (MLIC) for depth-dose profile measurements in the range 2–335 mm in water equivalent thickness (WET). MLIC should have 180 air-vented ionization chambers of 12 cm diameter with a water equivalent intrinsic resolution of about 2 mm.	Intra OP	**6. Specify the maximum treatment depth** To effectively treat the intended cancer indications targeted for IORT, the linac must have the ability to treat to a depth of at least 3.6 cm at the 90% depth dose point (D90) when measured by an ionization chamber in a water phantom for a 10 cm diameter applicator. While the tender does specify the treatment energies, there may be a wide range of treatment depths from manufacturer-to-manufacturer for the same energy. Therefore, the tender should specify the depth associated with the maximum energy.	to be deleted (As not relevant in IOERT)
Point 9.1 Page 65	The system should be integrated and connected to CT-Simulator, MR/PET.	SIT	Delete **REASONS OF AMENDMENTS** This item has been deleted since it is excluding LIAC HWL 12 MeV. For further details please refer to comments to above item 3. Note that the use of pre-operative images is not considered useful by the largest part of scientific community.	**To be Amended as:-** DELETED

Point 5 , Page 64	**Dosimetry Equipment** 1. Vendor must provide relevant QA device, Phantom and dosimetry equipment required for QA and dosimetric calibration. a) PDA :- Photo Diode Array: 5 diodes positioned orthogonally to each other to measure the radiation of the miniaturized accelerator. The objective of this test is to assure the isotropy of the emitted beam. b) PAICH :- Probe Adjuster Ion Chamber Holder: the output can be checked. An ion chamber is mounted onto the probe adjuster in such a way that the ion chamber window sits right above the tip of the miniaturized accelerator to enable for treatment planning until a coefficient has been computed			**To be Amended as :-** Vendor must provide relevant QA device, Phantom and dosimetry equipment required as follows; (i) Absolute Dosimetry Systems: Vendor should provide 3D mini water phantom. One water-proof cylinderical chamber and parallel plate chamber with suitable eletrometer for output measurements as per IAEA TRS-398 protocol (ii) Relative dosimetry Systems: Vendor should provide radiochromic films (two pockets of two different sizes) suitable for IORT depth dose measurements with suitable latest model flatbed film scanner system in addition to the system-specific dosimetric equipments and QA tools. (iii) One solid water phantom for daily QA checks. (iv) one specially designed water equivalant cylidercical phantom which is insertable with electron applicator for output factor measurements.

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Response To Pre-Bid Queries (Pre-Bid date: 09.10.2018)

NIB Ref:HITES/PCD/NCI-AIIMS/36/18-19

S.No:- 3 IORT Machine (X-Ray Based) (Rfx 3000003421)

Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	RESPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Point 1.1 Page 66	The machine should be dedicated Mobile Photon beam LINAC. It should have a point-source type x-ray emission, Spherical dose distribution around the isocentre of the miniaturized accelerator. Steep dose gradient (approx. 1/r3) in water (soft tissue equivalent).Positional accuracy of delivered dose +/- 1 mm.	Rosalina Instruments	The machine should be a dedicated Mobile Photon beam System with IORT capabilities. As well, it should be able to implement brachytherapy application procedures. It should have a point source type x-ray emission. A Spherical dose distribution around the spherical applicator must be achieved with one or more dwell positions, with a steep dose gradient (approx. 1/r3) in water (soft tissue equivalent). Dwell positions should have an accuracy of < +/- 1 mm.	The machine should be dedicated Mobile X-ray based IORT system. It should have a point-source type x-ray emission, Spherical dose distribution around the isocentre of the miniaturized accelerator, Steep dose gradient (approx. 1/r3) in water (soft tissue equivalent).Positional accuracy of delivered dose +/- 1 mm.
Point 1.2 Page 66	The LINAC should have mounted on mobile stand/mounting for LINAC having multiple axis movement.	Rosalina Instruments	The System should be highly mobile and ergonomic to be easily moved from one room to another or in within the different locations of the site guaranteeing a minimal impact in volume with the different rooms. Presence of stationary components when the emitting system component is not needed will constitute a penalty. The system should guarantee high degree of freedom in selecting the patient approach for the delivery phase in order to facilitate the IORT procedure as well as patient comfort.	The system should have mounted on mobile stand and easyly movable from room to room facilitating all treatments.
Point 1.3 Page 66	The equipment should be able to deliver photon energy of at least 50kV and not exceeding 100 kV for intra-operative Radiotherapy.	Rosalina Instruments	The equipment should be able to deliver photon energy of 50kVp.	No change considered
Point 1.4 Page 66	The equipment should have high dose rate to reduce the treatment time.	Rosalina Instruments	The equipment should have high dose rate to reduce treatment time. Shorter treatment time will be valued highest.	No change considered

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Pont 1.5 Page 66	The equipment should have positional accuracy of delivered dose +/- 1 mm	Rosalina Instruments	Emitting source point should have an accuracy < 1mm.	Either equipment positioing or emitting source point accuracy should be of ± 1mm
Point 1.7 Page 66	It should have inbuilt internal radiation monitor to enable real time measurement of dose delivered.	Rosalina Instruments	The Vendor has to describe the system effectiveness and stability to deliver the desired dose distribution and precisely describe what each individual component does.	It should have either inbuilt internal radiation monitor or any alternative mechanism to ensure the precise dose delivery.
Point 1.9 Page 66	High precision water phantom with < 100 µm accuracy for independent dose verificatcn should be included in the offer.	Rosalina Instruments	The System should come with the proper QA phantom to allow the site tech personnel to execute the proper dosimetric verification tests.	The System should come with the proper QA phantom to allow the site tech personnel to execute the proper dosimetric verification tests.
Point 1.10 Page 66	Integrated high voltage supply to ensure patient protection and to avoid high voltage cables in the body.	Rosalina Instruments	The high voltage, typical of a KV system, must not constitute any danger or hazard to the patient nor to the System operators.	No change considered
Point 1.11 page 66	The equipment should be in use globally for wide range of indications (Breast Cancer, Endometrial Cancer, Lung Cancer, Soft tissue Sarcoma, Skin cancer etc.).	Rosalina Instruments	The equipment should be in use globally for wide range of indications for IORT as well as for brachytherapy.	The equipment should be in use globally for wide range of indications for IORT.
		Rosalina Instruments	ADDED PARA :- The system should have spare parts of the radiation emitting components available to help guarantee a continuous use of the system. The system should have a high record of daily patient throughput, showing the evidence of high patient volume capabilities.	No change considered
Point 2.1 Page 66	It should have an integrated treatment planning system which enables treatment planning in pre, post and during beam delivery. TPS should be compatible to DICOM, so that the CT/ MRI/PET-CT/PET-MRI images can be imported for planning and verification.	Rosalina Instruments	The system should be preferably able to be compatible with the existing site's TPS system to enable planning in pre, post and during beam delivery for both IORT (if needed) and most importantly for the brachytherapy applications.	No change considered

Point 2.2 Page 66	TPS should have 3D treatment planning simulation software for IORT. For pre-, intra- and post-treatment operations. TPS should offer the possibility of case selection and dose computation near critical organs with the Monte Carlo algorithm to correct tissue heterogeneity and enables easy documentation.	Rosalina Instruments	If the System is not compatible with the existing site's TPS, then an AAPM TG43 dose calculation based TPS should be provided. The TPS should be compatible to DICOM, so that the CT/MRI/PET-CT/PET-MRI images can be imported for planning and verification.	No change considered
Point 2.3 Page 66	The software shall be DICOM 3.0 Compliant and HL 7 compliant.	Rosalina Instruments	Delete	No change considered
Point 3. 1 page 67	Spherical Applicator set including spherical applicators from 1 to 5cms with variable diameters for different incision length. The applicators are reusable and sterilizable.	Rosalina Instruments	A spherical dose distribution must be achieved and such dose distribution will have to be delivered to different volume cavities. The System will have to provide the maximum possible adjustment versatility to the existing cavity. Any spherical applicator should provide a full degree of operational versatility and flexibility. Entrances to reach the cavity by the surgeon, controller position, surgical technique. Multiple solutions as the chosen entrance approach should be available.	No change considered
Point 3.3 Page 67	Flat Applicators. The applicators are reusable and sterilizable	Rosalina Instruments	A flat and sharp penumbra dose profile must be achieved by the flat/surface applicators. These applicators should be reusable and re-sterilizable.	No change considered
Clause. 8. 1 Page No 68	1. The system should be integrated and connected to CT-Simulator, MRI/PET-CT, PET-MRI and Treatment planning station of Radiotherapy department, etc.	Rosalina Instruments	This can be done via Brachyvision, in general there is no communication between the controller and the other RT devices with IORT machine. So this need to be deleted.	1. The system should be integrated and connected toimaging system and Treatment planning system.

		Rosalina Instruments	Added Para :- The system should guarantee the maximum patient throughput by minimizing the time gap between two consecutive breast IORT patients. Internal radiation shields to protect potential OARs and/or healthy tissue should be provided. They should be reusable and re-sterilizable. Where applicable, the system applicators should facilitate unobstructed patient breathing movement.	No change considered
Point 4.1 Page 67	Vendor must provide relevant QA device, Phantom and dosimetry equipment required for QA and dosimetric calibration.	Rosalina Instruments	Vendor must provide relevant QA device, Phantom and dosimetry equipment required for QA and dosimetric calibration. At the same time, high value will be given to the system that will allow site's dosimetric equipment to make the proper dosimetric verifications.	To be deleted
		Rosalina Instruments	Added para :- The System should minimize the QA procedures to the hardware components of the emitting system part. The System should minimize the re-commissioning procedure after completion of QA checks.	No change considered
Point 5.3 Page 67	There should be provision of interlock/door interlock to avoid chances of radiation exposure.	Rosalina Instruments	There should be provision of an electrical signal output to warn personnel during the system ON phase	No change considered
Clause. 8. 2 Page No 68	System should be capable of integrating with standard record-and-verify and networking and PACS systems commercially available.	Rosalina Instruments	This can be done via Brachyvision, in general there is no communication between the controller and the other RT devices with IORT machine. So this need to be deleted.	No change considered

Clause. 8 Page No 68	Number of x-ray tube required for treatment of 1000 Patients (for Bid ranking only) =	Rosalina Instruments	Since IORT used for Breast cancer, skin cancer, Gynaecology cancer., so it requested to define the no of patient for praticular modality treatment.	Number of x-ray tube required for treatment of 1000 Patients (for Bid ranking only) . If the system uses, disposable x-ray tube along with required consubales for treatment, the following number of X-ray tubes with cooling tube and other consumable as below. Breast-500, Gynecological-300 and skin-200.
Point 6.2 Page 67	Vendor must quote unit rate for Offsite training per person for a period of 2 weeks (including air fare, local logistics and accommodation etc.) cost of 8 persons will be loaded for bid ranking purpose. However, NCI-AIIMS reserve the right to increase or decrease the number of persons being sent for training and accordingly payment will be made on per person basis.	Rosalina Instruments	Vendor must quote unit rate for Offsite training per person for the required period (including air fare, local logistics and accommodation etc.) cost of 8 persons will be loaded for bid ranking purpose. However, NCI-AIIMS reserve the right to increase or decrease the number of persons being sent for training and accordingly payment will be made on per person basis.	No change considered
Point 6.3 Page 67	The vendor should provide onsite training for user department/s for at least 4 weeks after successful commissioning of the machine.	Rosalina Instruments	The vendor should provide onsite training for user department/s for at least 4 weeks a week after successful commissioning of the machine.	No change considered

		Rosalina Instruments	Regarding the x rays tube. The tube is a disposable. It has an average life time of 500 minutes. Xoft is not selling the physical X-rays tubes whereas it sells operational/clinical minutes of tube usage to be exhausted in a year time. It is not user responsibility how many x-rays tubes are used by the system as long as the user is in within the source agreement minutes. Clinical minutes per year are decided based on the facility patient volume per purchased application. Kindly define approximately the number of Patient that will be treated for each Site. Xoft provides 500 minutes per year solution, 1000 minutes per year, 2000 minutes and so on up to the unlimited minutes per year, for which the user pays a certain amount and then the site has the right to use as many minutes as it can possibly be able to per one dedicated controller. As per the tube is a disposable, this can be easily changed (it is a plug and play method) and upon previous calibration it can be easily implemented in the clinical routine. So even in the scenario of a system failure due to a tube failure, the user is able to unplug the failed tube and replace with a newer one. Each user has a consignment of 5 tubes. Once one tube fails, it is returned to Xoft/Rosalina and a newer one is sent to keep the 5 working sources (to be used one or max two at the same time). In this way, the uptime definition/concept is something that is not really applicable to our system because even in case of	No change considered
Clause. 8. Page No 68	Number of x-ray tube required for treatment of 1000 Patients (for Bid ranking only)	Carl Zeiss India	Number of x-ray tube required for treatment of 2000 Patients **Justification:-** NCI-AIIMS being the apex body of cancer research institute in India the consumables required to be included should be minimum to treat 1-2 patients/day which is approximately 2000 patients for five years. This will benefit NCI and trouble free patient treatment during the warranty period. Kindly note that the consumables can be stored for long periods over five years. There are some vendors who minimize the equipment price to become L1 and escalate the price of X ray Source and related consumables	**To be Amended as:- Number of machine related consumables required to treat 1000 patients (including Xray tube, Cooling tube and any other if applicable)** **Any consumable required for treatment, if not quoted should be provided free of cost by the bidder during the validity of the contract.** Already covered in clause 8, Page 68.

Clause. 5.1 Page No 67	1. Equipment standard and safety should comply with the national regulatory AERB guidelines and offered model should have AERB type approval and NOC.	Carl Zeiss India	1. Equipment standard and safety should comply with the national regulatory AERB guidelines and offered model should have AERB type approval or NOC or NOC pending approvals. **Justification:-** We wish to offer the recently launched state of the art INTRABEAM 600 and this could be the first unit in India. Kindly accept the NOC applied status. We request you to issue the letter for getting NOC as per AERB norms	**To be Amended as:-** The model offered by the vendor may be of either AERB type approval/NOC approved or AERB type approval/NOCpending.
Clause. 5.2 Page No 67	Should be USA-FDA and/or European CE with 4 digit notified body no certified product.	Carl Zeiss India	Should be USA-FDA and European CE approved product. **Justification:-** FDA certificate brings lot of clinical authenticity and CE consider to be a third party certification	No change considered
Clause. 5.5 Page No 68	5. Factory trained service engineer/Application specialists should be available in Delhi-NCR tc look after the installation and maintenance of the system without patient treatment interruption	Carl Zeiss India	Factory trained service engineer/Application specialists should be available in Delhi-NCR. Appropriate certificate should be enclosed as a tender pre requisite. **Justification:-** This will ensure the service & application support of the installation from day one	**To be Amended as:-** Factory trained service engineer/Application specialists should be available in Delhi-NCR to look after the installation and maintenance of the system without patient treatment interruption. **Supporting certificate should be furnished.**
Clause. 1.11 Page No 66	The equipment should be in use globally for wide range of indications (Breast Cancer, Endometrial Cancer, Lung Cancer, Soft tissue Sarcoma, Skin cancer etc..)	Carl Zeiss India	The equipment should be in use globally for wide range of indications (Breast Cancer, Neuro/ GBM- Brain Metastasis, Endometrial Cancer, Lung Cancer, Soft tissue Sarcoma, Skin cancer etc..) **Justification:-** IORT Applications are increasing in neuro surgical applications and Intra Operative CT also adds value to the patient treatment & Planning during surgery	~~No change considered~~

		Carl Zeiss India	We request you to include the following for the betterment of patient care and they are as follows a. Dose at 1Cm depth should not be more than 5Gy. The dose fall off of the radiation beam should match this specifications. It should not require any chest wall shielding to pectoralis fascia in order to protect vital structures and organs due to high radiation doses at 10mm. b. Radiotherapy should be delivered using the same incision as the lumpectomy procedure. No additional / incision should be allowed to deliver the radiation to the lumpectomy cavity c. Air cooled x ray source should be supplied as source. Water/ Oil cooled systems should be avoided due to high degree of maintenance, less durability d. True isotropic output is preferred, without and collimators to support wide variety of applicators e. Offers submitted by local agents, other than the direct subsidiaries of the Principals, shall NOT be entertained f. The system shall have more than 250 international installations – submit list of international installations. More installations are preferred g. System operator should not be present during patient treatment as per radiation protection guidelines. Any system which mandates this criteria will not be considered h. The offered equipment should have a successful clinical case of 1. Over 10 years of clinical treatment experience in IORT Breast	No change considered

Point 4 , Page 67	4. Vendor must provide relevant QA device, Phantom and dosimetry equipment required for QA and dosimetric calibration.			**To be Amended as:** Dosimetry, QA and Safety Measurement Equipments: Vendor must provide relevant dosimetry equipments and QA devices, Phantom required for QA and dosimetric calibration as follows; 1.**The system which uses non-disposable x-ray tube should provide the following dosimetry and QA equipments.** (i) Absolute Dosimetry Systems: Vendor should provide specially designed water phantom with soft x-ray small volume parallel plate chamber with suitable holder and eletrometer for output measurements as per AAPMTG-61 Protocol. (ii) Relative dosimetry Systems: Vendor should provide radiochromic films (two pockets of two different sizes) suitable for IORT depth dose, profiles measurements along with suitable latest model flatbed film scanner system in addition to the system-specific dosimetric equipments/QA tools. 2.**The system which uses disposable x-ray tube should provide the following dosimetry and QA equipments:** (i) Absolute Dosimetry Systems: vendor should provide in-built or standalone calibrated Well-Type chamber with suitable electrometer for source strength or output calibration as per AAPM TG-43 protocol (ii) Relative dosimetry Systems: Vendor should provide radiochromic films (two pockets of two different sizes) suitable for IORT depth dose measurements

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Response To Pre-Bid Queries (Pre-Bid date: 09.10.2018)

NIB Ref:HITES/PCD/NCI-AIIMS/36/18-19

S.No:- 4 Mobile CT Scanner for IORT (Rfx 3000003422)

Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	RESPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Para 1.1, Page 70	The system should be a 32 Slice mobile CT Scanner. The imaging should be thin section and of high quality image	India Medtronic Pvt. Ltd.	The system should be a 32 slice or equivalent high resolution mobile CT scanner. The imaging should be thin section and of high quality image. **Remarks:** O-Arm is a CONE BEAM CT and subjectively/quantitatively equivalent to a 32 slice CT. Slice based CT is only observed in fan beam CT.	No change considered
Para 1.4, Page 70	b) X-ray Tube Current: up-to 250 mA or more	India Medtronic Pvt. Ltd.	X-Ray Tube Current- 100mA or more	No change considered
Para 1.6 Page 70	The system should have a bore size of 85 cm or more suitable for Intraoperative radiotherapy	Brainlab India Pvt Ltd	The system should have a bore size of minimum 100 cm or more suitable for CT simulation and Brachy Therapy applications. **Justification:-** Larger bore size allows Patient positioning for scanning & treatment of Cervix &Vaginal cases. It also minimizes the patient shifting from Minor OT table to CT scan and treatment room. It minimizes the risk of needle or applicator movement during the treatment. It provides precise and image guided brachytherapy treatment on the same couch	No change considered
Para 1.7 Page 70	The X-Ray detector system should have solid state detector with at least 1.25 mm to 10mm detector width to generate multi slice CT images of soft tissue and bone.	Brainlab India Pvt Ltd	The X-Ray detector system should have solid state detector with at least 2mm detector width to generate CT images of soft tissue and bone with 1mm Slice thickness. **Justification:-** 1mm Slice thickness is useful for small lesions identification and planning.	No change considered

		India Medtronic Pvt. Ltd.	The X-Ray detector system should have solid state detector with at least 1.25 mm or more detector width to generate multi slice CT images of soft tissue and bone. **Remarks:** Our detector is bigger than 10mm	
Para 1.8 Page 70	The system should have an Image reconstruction speed of at least 16 images per sec or more	Brainlab India Pvt Ltd	The system should have an Image reconstruction speed of at least 24 images per sec or more. **Justification:-** Faster reconstruction means the images are available immediately .This is useful for managing high patient throughput in the department.	**To be Amended as:-** The system should have an Image reconstruction speed of at **least 24 images** per sec or more.
Para 1.9 Page 70	The system should have capability for both axial and helical scan.	India Medtronic Pvt. Ltd.	System should have different scan modes. **Remarks:** O-Arm is a cone beam CT and can deliver the required high-quality scans with volumetric acquisition. Hence, other scan types which are available in fan beam CT are not possible.	No change considered
Para 1.10 Page 70	The system should allow motorized transportation with a front view camera for easy movement of the system between different Operating Rooms thus adding to its higher utilization	India Medtronic Pvt. Ltd.	The system should allow motorized transportation for easy movement of the system between different Operating Rooms thus adding to its higher. **Remarks:** O-Arm has telescopic door opening and hence, does not need a front view camera while transportation.	No change considered

Para 1.11 Page 70	The system shoulc be compatible with OT table for precise imaging in OR	Brainlab India Pvt Ltd	The Integrated radiolucent patient scanning table to be supplied as per following specification: a. The system should come with a fully compatible radiolucent patient scan/treatment table b. The patient table should allow patient weight of 180 KG or more. c. Table should have minimum Lateral tilt of +/- 30 degree or more d. The table should be provided with a shuttle system for the movement of the patient e. All positions can be adjusted through a wireless remote **Justification:-** An OT table integrated with the CT scanner will ensure that the relationship between the table and the CT gantry is fixed and rigid which will provide reliable, consistent and high quality imaging. In the absence of integrated table, there could be artefacts due to movement of gantry thereby severely affecting the image quality which is paramount is such advanced applications for which the CT scanners is being purchased	No change considered
Para 1.13 Page 70	The system should have small footprint that allows transport through standard doorways and elevators.	Brainlab India Pvt Ltd	The system should have small footprint and a maximum weight of less than 1000 kgs in transport mode that allows transport through standard doorways and elevators. **Justification:-** Smaller footprint and less than 1000kg weight enable the movement of CT through Patient lifts and standards doorways inside hospital between different treatments rooms, OTs and other location without any special design provisioning.	No change considered
Para 1.14 Page 70	The system should have a minimum scan range of one meter	India Medtronic Pvt. Ltd.	The system should have a scan facility to display image of as large as one meter scan area. **Remarks:** O-Arm allows two size scan areas i.e., 15cmX20cm and 15X40cm. It can take scan of desired area. These images of desired area of spine can be stitched to show as a single image.	No change considered

Para 1.15 Page 70	The system should be supplied with respective calibration devices to check the CT parameters and Quality control parameters.	India Medtronic Pvt. Ltd.	The system should be supplied with respective calibration devices to check the CT parameters and Quality control parameters. (optional). **Remarks:** O-Arm need not be calibrated on a daily basis and is done only during installation and during preventive maintenance done in accordance to the company policy by a trained company representative.	No change considered
Para 2.1 Page 71	System should be able to export image, volume and plan data in DICOM 3.0 standard along with all Radiotherapy specific data and private objects, DICOM RT plans and data sets	India Medtronic Pvt. Ltd.	System should be able to export image, volume and plan data in DICOM 3.0 standard.	No change considered
Para 2.2 Page 71	System should be able to import DICOM RT data to IORT Treatment planning system (TPS) available in OR.	India Medtronic Pvt. Ltd.	System should be able to export DICOM data to IORT Treatment planning system (TPS) available in OR.	No change considered

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