PHILIPPINE HEART CENTER
East Avenue, Quezon City

SUPPLEMENTAL BID BULLETIN No. 004-2021

SUBJECT : Revised Technical Specification

PROJECT : 1 pc. Mobile C-Arm Fluoroscopic Unit - ITB No. 010.21

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To ensure that the transactions are comparatively advantageous to the interests of the PHC, the originally pre-issued bidding documents as mentioned above was revised .

Item No. / Page No.	PHC – Technical Specifications FROM	Clarifications/Modifications (Should be read as) TO
	Schedule of Opening of Bids on February 16, 2021	**Re-set on February 23, 2021, 9:00 Am, 5F, Amphitheater**
		Attached herewith is the revised Technical Specification of the above-mentioned Project (marked as Annex "A")

This Supplemental Bid Bulletin is hereby issued to modify the original parameters as stated therein. All other requirements previously stated on the bid documents must be complied.

Please be guided accordingly.

Approved. Done this 8th day of February 2021, BAC Office, PHC.

MARIETTA A. VELASCO, RN, MAN
Chairman, BAC for Pharma Supplies and Med Equipment

"Annex A"

Technical Specifications

[Bidders must state here either "Comply" or "Not Comply" against each of the individual parameters of each Specification stating the corresponding performance parameter of the equipment offered. Statements of "Comply" or "Not Comply" must be supported by evidence in a Bidders Bid and cross-referenced to that evidence. Evidence shall be in the form of manufacturer's un-amended sales literature, unconditional statements of specification and compliance issued by the manufacturer, samples, independent test data etc., as appropriate. A statement that is not supported by evidence or is subsequently found to be contradicted by the evidence presented will render the Bid under evaluation liable for rejection. A statement either in the Bidder's statement of compliance or the supporting evidence that is found to be false either during Bid evaluation, post-qualification or the execution of the Contract may be regarded as fraudulent and render the Bidder or supplier liable for prosecution subject to the applicable laws and issuances.]

Directions in filling-up Schedule VII (Technical Specifications):
In filling-up the matrix on Statement of Compliance, the bidder shall provide relevant characteristics on each of the specific parameter such as its location in terms of the particular page, heading, and other provisions stated in the brochure, technical listing, operation manual, respectively.

To provide administrative ease in our evaluation, the bidder is required to provide a tab on each of the specific parameter (each correspondingly marked as Annex "A", Annex "B", etc.) for easy reference and validation purposes.

Item	Specifications Project: 1 pc. Mobile C-Arm Fluoroscopic Unit		Statement of Compliance
1	**Description of Function**		
	C-Arm Fluoroscopy is a type of x-ray image. X-rays create an image by pointing a low-intensity x-ray beam towards an x-ray detector/image amplifier. While x-rays in an imaging center are commonly used for looking at issues with bones, they can also be used to ensure that certain procedures are done properly. C-arm fluoroscopic x-ray is used in orthopedic, cardiac, emergency care, and interventional pain management procedures. The C-arm fluoroscopy is a mobile x-ray that moves around two axes to allow the doctor to take an image at almost any angle. This allows the doctor to optimize the picture taken depending on what is trying to see.		
2	**Operational Requirements**		
	2.1 System complete with all accessories as specified in the Technical Specifications below.		
3	**Technical Specifications**		
	A. Basic System Requirement		
	1. Compact mobile C-arm	Design for the use in the cardiovascular surgery, orthopedics trauma surgery and general surgery.	
	2. Digital system	Should be built based on digital flat detector technology	

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	3. C-arm and monitor	Should be equipped /touch-based user interfaces for optimal workflow.	
	B. C-arm Base Unit:		
	1. Vertical travel	Should at least 42 cm.	
	2. Horizontal travel	Should at least 20 cm.	
	3. Angulation	Should at least ± 190°	
	4. Swivel range	Should be at least 12°	
	5. Rotating range of orbital movement	Should be at least ± 130°	
	6. The orbital and angulation angle	Should be displayed on the monitor and touch panels.	
	7. Depth of the C-arm	Should at least 66 cm.	
	8. The tube to flat detector distance(free space)	Should at least 77 cm.	
	9. Source to FD distance	Should at least 99 cm.	
	10. Both the front and the rear wheel	Should have cable deflectors	
	11. The main C-arm chassis and the user interface and controls	Should be a touch-based control panel and should the same as the one on the monitor trolley.	
	12. A double footswitch for radiation release	Should be available	
	13. Footswitch	For easier disinfection. It should conform IPX8 standard so that it can be immersed and cleaned properly in disinfectant solution.	
	14. Hand switch	Should also be available for radiation release and image storage function.	
	15. Hand switch	Should conform to at least IPX standard and should be protected against dust and splashing of water.	
	16. Height of the C-arm base unit:	Not higher than 160 cm.	
	17. C-arm base unit:	Length and width is not more than 185 cm and 80cm.	
	18. C-arm base unit:	Maximum weight should not be more than 280 kg.	
	C. Monitor Trolley		
	1. Vertical travel	Must be easy to clean touch based control panel.	
	All castors of the monitor trolley	Should have cable deflectors.	
	X-ray warning lights	Should be available either on the C-arm or on the monitor trolley.	
	Length and width of the monitor trolley	Not more than 185 cm and 80cm	
	Maximum weight of the monitor trolley	Should not be more than 150kg	

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	D. X-ray Tube		
	1. Nominal peak output power	Should be at least 2.3 kW	
	2. KV range	Should encompass 40 KV to 110 kV	
	3. Continuous fluoroscopy	Should encompass the range of 0.2 mA to 13 mA	
	4. Pulsed fluoroscopy	Frame rate should include the range of 0.5 mA to 15 pulse/sec.	
	5. Variable frame rate	Should be 0.5 to 15 frames/sec. w/at least 30 f/s in continuous fluoroscopy mode.	
	6. Single Image or Digital Radiography	mA should encompass the range of 3 to 24 mA	
	7. Suitable power and dose levels	For each clinical application should easily selectable from the control panel.	
	E. X-ray Tube		
	1. Single focus anode tube	Single tank	
	2. Focal spot	Nominal value of at least 0.6 to 1	
	3. Optimal anode angle	Should at least 9°	
	4. Inherent filtration	Should at least 3mm AI w/ 75 kVp per 0.1 mm Cu in conformance with IEC 60601	
	5. Anode heat dissipation	Should at least 55,000 HU/min	
	6. Anode heat storage capacity of the tank	Should at least 100,000 in conformance to IEC 60613	
	7. Heat storage capacity of the tank	Should at least 1,100,000 HU with a continuous heat dissipation of at least 80W	
	8. Continuous fluoroscopy output	During fluoroscopy times of 50 min at 300W	
	9. Collimator	Should have a rectangular diagram for concentric, radiation free collimation and another slot diaphragm for symmetric and asymmetric, radiation free collimation w/ unlimited rotation.	
	F. Flat Detector		
	1. Size	Should be least 21cm x 21cm, w/an acquisition bit depth of 16 bits	
	2. Flat detector	Should support 3 image input formats (overview and 2zoom levels)	
	3. Removable grid	Should have anti scatter radiation (important for pediatric patients)	

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	G. Image/Patient Data management		
	1. Patient data base	Should have a configurable patient data base query	
	2. Patient registration	Should have a patient pre-registration as well as emergency registration Should be possible	
	3. Subsequent changes/addition to patient data as well as deletion of several images, series study	Should be possible	
	H. Display Monitor		
	Monitor	There should be at least two (2) 19" TFT color display w/ backlight LED technology and image display of at least 1280x1024 pixels	
	I. Image Display and Processing		
	1. The following should be available	1.1. It should be possible to save a scene from temporary memory.	
		1.2. It should be possible to save the image least recorded.	
		1.3. It should be possible to display a series images in split screen mode.	
		1.4. Aside from the usual single image, the number of images that can be displayed simultaneous in overview mode should be at least 16	
		1.5. There should be a movie function for playing back scenes.	
		1.6. Auto replay for playing back the scenes.	
		1.7. Magnification.	
		1.8. Digital image rotation.	
		1.9. Digital shutters	
		1.10. Horizontal and vertical image reversal	
		1.11. Spatial frequency filtration for edge-enhanced image display	
		1.12. Edge enhancement	
		1.13. Noise reduction	
		1.14. Motion detection with active noise reduction	
		1.15. Metal correction	

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	2. Software	That automatically and optimally balances image quality, dose, contrast and brightness	
	3. Image acquisition and operating mode a. Fluoroscopy both pulsed and continuous	Should be available	
	b. Single Image or Digital Radiography vessels as a Subtraction series of roadmap.	Should be available Should be available Acquisition rates of 0.5 to 15 frames/ se, and up to at least 30 f/s in continuous fluoroscopy. It should be possible to add anatomical background from 0 to 100 percent. There should be peak opacification for both iodine and CO2 contrast filled images and to reduce the amount of contrast medium administered: - Pixel shift - Landmark - Dual channel function - Roadmap technique for easy catheter guidance and dilation.	
	4. Touch-based control system	That would allow the end-user to operate the C-arm system.	
	5. Hand switch Footswitch	1 pc. Hand switch 1 pc. Foot switch	
	J. Measurement Function:		
	1. Integrated calibration	For measuring the distance and angles of an x-ray image	
	K. Interface and Image storage		
	1. Printer	1.1. For gray-scale printing on thermal paper	
		1.2. Should have excellent printing quality and contrast with high resolution of at least 325 dpi	
		1.3. Should have a fast printing time of approximately 8sec per print and be able to print multiple images per sheet.	
		1.4. Picture area should be at least 600c200mm w/a paper size of 210mm	

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	2. CD/DVD recorder	DVD for digital image storage on CD-R, DVD+R or DVD-R for offline data Exchange in DICOM 3, TIFF ad AVI formats.	
	3. Transfer image	Should be able to transfer image into USB in DICOM, TIFF and AVI of DICOM image data	
	4. WLAN/LAN	Should have WLAN in addition to LAN for wireless transmission of DICOM image data.	
	5. Internal storage	Should be able to internally store at least 300,000 images on the hard disc irrespective of the matrix size	
	L. DICOM 3 Functionalities:		
	1. DICOM Send	For sending and receiving patient data.	
	2. DICOM Storage Commitment	With feedback/storage confirmation from the archive.	
	3. DICOM Print	With film sheet preview, film sheet layout and image processing function	
	4. DICOM Dose Structured Report	Enabling the sending of dose values for each study to an archiving system.	
	5. DICOM Query/Retrieve		
	6. DICOM Worklist/MPPS		
	M. Operating Data		
	1. Mobile C-arm power requirements	Should have a universal power requirement of 220V- 240V, Single Phase 60HZ	
	2. Internal Unit Fuse	Must be available. a. 100V to 127V 20A slow-blow fuse b. 200V to 240V 15A slow-blow fuse	
	3. Integrated Uninterruptible power supply	To allow saving images in study, and proper shutdown of the system in the case of power fluctuation and outage. Should have visible display to enable user to monitor the charge state and status of the batteries.	
	N. PC Hardware minimum requirements:		
	1. Windows	Windows 10, 64bits, 8GB RAM, S-ATA drive, USB 3.0, high performance professional level graphics card and interface cards for detector/X-ray system.	

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	2. Intel-compatible dual-core microprocessor w/PCI bus architecture		
	3. Hard disc	Capacity of at least 2 TB	
	O. Radiation Safety:		
	1. Integrated dose area product (DAP) meter	Should be equipped w(DAP)meter to allow user to measure the accumulated dose and air KERMS values for proper reporting & monitoring	
	2. Easily selectable low, medium and high dose levels.	Depending on the preference of the end user, there should be also automatic control (AEC) of kV and mA values to ensure optimal image quality at the lowest dose possible.	
	3. Software	Should be provided to ensure that when in use, each individual detector pixel, contrast, and brightness are constantly and automatically adjusted to produce the best image quality at the lowest dose possible.	
	P. Others:		
	1. Starter pack for a. Flat detector b. X-ray tube c. C-arm w/a clamp or fixation device that would make it easier to attach sterile plastic Cover to the C-arm	The bidder should provide a starter pack of at least 15 pcs. of disposable plastic covers	
	2. Protective apparel. a. Thyroid shield b. Lightweight lead gown c. Lead goggles	a. The bidder should provide three (3) sets for each protection apparel b. The bidder should provide three (3) sets for each protection apparel c. The bidder should provide three (3) sets for each protection apparel	
	3. Three (3) years warranty and Preventive Maintenance	Inclusive of service, repair and replacement of parts and accessories as needed including x-ray tube and detector Semi-annual preventive maintenance Software and Hardware updates during the warranty period should be provided to make sure that the system is optimal condition Availability of a remote service system via the hospital's network.	

	R. Work Station:		
	1. Computer and printer	1 complete set of desk top computer and 1 inkjet printer (BROTHER)	

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	4. Training	Onsite training for five (5) end users and (5) Biomed Availability of access to a web based training system specially for the mobile C-arm Application refresher training course for the end user on the 2nd & 3rd yr.	
4	**System Configuration Accessories, spares and consumables**		
	4.1 System as specified		
5	**Environmental factors**		
	5.1 The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90%		
	5.2 The unit shall be capable of operating in ambient temperature of 20-30 deg C and relative humidity of less than 70%		
	5.3 Shall meet IEC-60601-1-2: 2001 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility. Or should comply with 89/366/EEC; EMC-directive		
6	**Other Requirements**		
	6.1 Auto volt 110-220/60 Hz electrical settings		
	6.2 Must include Three (3) years warranty service and consumables		
	6.3 Must include Three (3) years warranty service		
	6.4 Must include Quarterly PMS for Three (3) years		
	6.5 Accessories and consumables should be available for Ten (10) years		
7	**Standards, Safety and Training**		
	7.1 Manufactures/Supplier should have ISO 13485 certificate to Quality Standard.		
	7.2 Should be FDA, CE, UL or BIS approved product		
	7.3 Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements (OR EQUIVALENT international/national standard)		
8	**Documentation**		
	8.1 User/Technical/Maintenance manuals to be supplied in English.		
	8.2 Certificate of calibration and inspection.		
	8.3 List of important spare parts and accessories with their part number and costing.		
	8.4 Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.		
	8.5 Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page number of original catalogue/data		

	sheet. Any point, if not substantiated with authenticated catalogue/ manual, will not be considered.	
	8.6 List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.	
	8.7 To include delivery period of 90 calendar days.	