Sr. No.	Description of Work / Item(s)	Suggested Changes	Amendment needs to be done	Remark
		C-ARM Machine		
1	A Mobile C Arm image intensifier required for use in orthopedic, Urology, Neurology, Gastrointestinal, vascular, pain management and General Surgery. The Fluoroscopy, Pulsed fluoroscopy, snap shot and digital radiography operating modes are to be supported.	• Please amend it as, X-Ray generator with power output 6kW or more as asked vascular application required higher power output of the generator.	A Mobile C Arm image intensifier required for use in orthopedic, Urology, and General Surgery, Neurology,	Not Accepted as it is required for only Orthopedic surgeries, Urology, General Surgery & Neurology, So Vascular DSA is removed.
2	No's High Resolution TFT displays of size 18" or more.	<ul> <li>NO- We have one 24" Medical Grade Touch screen monitor with Split Screen New technology.</li> <li>Please amend it as it should be possible to have dual screen display. Facility for last image hold, simultaneous display of old &amp; new reference images (at least 2 or more images including last image hold) with individual freeze/de-freeze facility should be provided.</li> </ul>	No change	Not Accepted
3	Motorized Vertical movement 450 mm or more.	• Please generalize it as motorized vertical moment 430mm or more for open & healthy participation.	Motorized Vertical movement 430 mm or more	Accepted
4	Depth of C-Arm 670 mm or more	• Please generalize it as, Depth of C-Arm 650 mm or more for sufficient for all type of application.	Depth of C-Arm 650 mm or more	Accepted
5		<ul> <li>40KHz.</li> <li>50KHz (for better noise free performance)</li> </ul>	High frequency greater than or equal to 40KHz max up to 250KHz.	Accepted
6	Pulsed Fluoroscopy 40 to 110 KV in 1 KV Steps up-to 8 mm of Better	• Pulsed Fluoroscopy: change the KV range 40-120KV.	Pulsed Fluoroscopy 40 to 120 KV.	Accepted
7	Digital Radiography: up-to 110 KV and up to 70 mA or more.	• Digital Radiography change the KV range 40-120KV. And up to 120mA or more for better image quality.	Digital Radiography change the KV range 40-120KV and up to 120mA	Accepted
8	X ray generator with power output 3.5kW or more but less than 4 kW		X ray generator with power output 2.5kW or more. (We don't have need for Vascular application as mentioned in point no 1)	Accepted

9	Vascular Fluoroscopic Mode with Digital Subtraction & Roadmap.	• No- DSA required High Power C arm 2.5 Kw or more.	Point to be removed as we don't need for Vascular application as per users' suggestion.	Accepted
10	Enhanced Features: Mask, Peak and Road Map for Reduced dose and contrast media with reusable mask, Peak Opacification / subtracted image of vasculature, Road Map imaging techniques, pixel shift and land marking.	No- DSA required High Power C arm 2.5 Kw or more	Point to be removed as we don't need for Vascular application.	Accepted
11	Camera Rotation –By Image rotation through software means with control keys provided on the console.	Asked specification are company specific, we request delete this feature for open & wider participation	Image Rotation – through software. Control keys on consol or Image display cabinet.	Accepted
12	X-Ray Tube: The unit should have Stationary anode X Ray tube with dual focal spots. The minimal dual focal spot should be 0.6 mm and 1.8 mm or less. The tube should have overload protection.	As asked vascular application kindly to amend as rotating anode x-ray tube with focal spot 0.3mm small & large 0.6mm.	X-Ray Tube: The unit should have Stationary anode X Ray tube with dual focal spots. The minimal dual focal spot should be 0.6 mm and 1.8 mm or less. The tube should have overload protection.	Not Accepted as Vascular Fluoroscopic Mode with Digital Subtraction & Roadmap are removed
13	CAN controlled IRIS collimator with rotatable parallel shutter, should have Perfect Circular, at least 18 adjustable apertures steps or more. Continuous adjustable aperture area should be less than 5cm x 5cm – Digitally Controlled, radiation free collimation with digital control for rotation.	Please amend it as, IRIS collimator with rotatable parallel shutter, should have Perfect Circular. Digitally Controlled, radiation free collimation with digital control for rotation. Please remove numbers.	IRIS collimator with rotatable parallel shutter, should have Perfect Circular. Digitally Controlled or CAN controlled, radiation free collimation with digital control for rotation, can be make it more radiation free by maximum adjustable aperture steps.	Accepted

14	resolution TFT Medical grade monitors of size 18" or more. b. Image Capture Resolution & Frame-rate – at least	<ul> <li>NO- We have one 24" Medical Grade Touch screen monitor with Split Screen New Technology We have SSD With 50,000 images store.</li> <li>Please generalize it as, cine loop saves of 150 frames or more and have feature of review of cine loop by each frame.</li> </ul>	Workstation: a. 2 nos' high resolution TFT screen medical grade monitors of min. size 18" b. Image Capture Resolution & Frame- rate – at least 1024x1024 at Maximum Frame-rate 30 per second approx. (option of different frame rates). cine loop saves of 150 frames or more and have feature of review of cine loop by each frame. c. Should have image storage of at least 1 TB /SSD (50,000 images).	Not Accepted for No. of screen & storage.
15	Image Displays: It should be possible to have split screen display. Facility for Last image hold, simultaneous display of old and new reference images (at least 4 images including last image hold) with individual freeze / de-freeze facility should be provided	<ul> <li>Please amend it as, it should be possible to have dual screen display. Facility for Last image hold, simultaneous display of old and new reference images (at least 2 images including last image hold) with individual freeze / de-freeze facility should be provided.</li> <li>NO- We have one 24" Medical Grade Touch screen monitor with Split Screen New technology</li> </ul>	Image Displays: It should be possible to have dual screen (Corrected) display. Facility for Last image hold, simultaneous display of old and new reference images with individual freeze / de- freeze facility should be provided	Not Accepted.

16	Console Display: Independent Integrated Console Display - Should 10.4-inch TFT-LCD, Ana-glare Color Display with resistive Touch screen, Manual contrast and brightness adjustment, Edge enhancement, zooming, magnifying glass, image rotation, annotations, last image hold, image invert – negative & positive, horizontal & vertical flip should be possible, multi window image display.	Asked specification are company specific, we request delete this feature for open & wider participation. Or A very compact, soft touch control panel (APR) with L.C.D display on which KV, fluoro mA, radiography mAs, fluoro time, I.I Zoom, error interlocks for KV, filament and thermal overload are displayed.	Console Display: Independent integrated consol display TFT/LCD with better screen size which control KV, fluoro mA, radiography mAs, fluoro time, I.I Zoom, error interlocks for KV, filament and thermal overload are displayed, multiple additional functions like edge enhancement, zooming, image rotation, annotations & various	Accepted by adding additional features as per users' opinion.
		not have any diagnostic value	image settings.	Not Accepted
17	The unit shall be capable of being stored continuously in ambient temperature of 0 -50 deg C and relative humidity of 15-90%.	Please generalize it as, the unit shall be capable of being stored continuously in ambient temperature of 0 -40 deg C and relative humidity of 0-90%.	The unit shall be capable of being stored continuously in ambient temperature of 0 -50 deg C and relative humidity of 15-90%.	Not Accepted
18	The unit shall be capable of operating in ambient temperature of 20-30 deg C and relative humidity of less than 70%.	Please generalize it as, the unit shall be capable of operating in ambient temperature of 5-40 deg C and relative humidity of 30- 85%	The unit shall be capable of operating in ambient temperature of 5-40 deg C and relative humidity of less than 70%.	Partially accepted

10				
19	The system should have US FDA and European CE with four digit notified body number certificate and certificate to be submitted.	Please amend it as, the system should have US FDA / European CE with four digit notified body number certificate and certificate to be submitted.	The system should have US FDA /European CE with four digit notified body number certificate and certificate to be submitted	Accepted
20	If Machine repair time is more than 2 days vender should provide standby equipment for the same. A same make & model capacity	Our humble submission to amend the penalty in the form of increase in days of warranty /CMC/AMC period as being by various state governments.	If Machine repair time is more than 3 days, then penalty of Rs.3000/- per day will be applicable.	Not accepted but modified
21	All Technology should be mandatorily with safety approval- USFDA / European CE for Device. Approval certificate must be submitted for the total unit.	US FDA or CE	All Technology should be mandatorily with safety approval- USFDA / European CE for Device. Approval certificate must be submitted for the total unit.	Nullified
22	Add on request by Alleger	We request kindly add the following certification for better product quality and standard: • ICMED 13485 (Indian Certification for Medical Devices) – Based on the International Harmonized Standard of "Quality Management Systems for Medical	Alleger	Not accepted
		Devices" plus additional requirements specified under the scheme. • Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted. • If the generator is imported from other Country, complete specifications of data		

ensure that all technically qualified bidders are meeting the asked tender specifications.
--

User Sign

Lt.Col.Dr. Shailesh Oke. (Rtd). Medical Director Shri Saibaba Sansthan Hospital, Shirdi

Sr. No.	Description of Work / Item(s)	Suggested Changes	Amendment needs to be done	Remark
110.	item(5)	Cautery	be done	
1	The frequency of the machine should not be more than 350 KHz.	The frequency of the machine should be 350 KHz or more	The frequency of the machine should be 350 KHz or more	Accepted
2	TFT Display with Focused view of current active mode with easy touch buttons and should also have Colour display for better visuals.	better view and easy operation	TFT Display /LCD touch screen Colour display with focused view of current active mode with easy for better view and easy operation	Accepted
3	Facility to store 99 different programs according to user needs.	programs according to user needs.	Facility to store at least 10 different programs according to user needs.	Accepted
4	Facility to create sub programs within the main program making it easy to switch between modes from the sterile area.	Point should be omitted	Point is omitted	Accepted
5	Machine display should have pictorial representation of effect on the tissue for the selected modes during activation and setting the power or voltages	Machine should display mode activation during operating	Machine should display mode activation / pictorial representation during operating and setting the	Accepted
6	Machine should have the facility to show detailed information about the selected mode.	Point should be omitted	power or voltages. Machine should have the facility to show detailed information about the selected mode.	No change
7	Selection of patient plate type (Dual & Single) should be possible for safety during surgery	Selection of the patient plate type should be automatic	Selection of the patient plate type should be automatic/Manual	Accepted
8	Machine should have Facility to display Power output Graph for each activation	Should be omitted	Point will be omitted	Accepted
9	Footswitch provided should be washable and should have IP X8 ratings.	Point should be omitted	Footswitch provided should be washable and Splash proof.	Accepted
10	Monopolar cut modes: High Cut (for dense tissue), Dry/ Blend cut and Auto/ Pure cut, Endocut (for Endoscopy	Monopolar cut modes: High Cut (for dense tissue), Dry/ Blend cut and Auto/ Pure cut, Endocut (for Endoscopy) or equivalent modes	Monopolar cut modes: High Cut (for dense tissue), Dry/ Blend cut and Auto/ Pure cut, Endocut (for Endoscopy) or equivalent modes	Accepted
11	Endo Cut mode should have the facility to set Cutting duration & Cutting	facility to set Cutting duration &	Endo Cut or equivalent mode should have the facility to set Cutting	Accepted

	Interval		duration & Cutting Interval	
12	Monopolar Coag Modes: Classic Coag, Swift Coag, Spray Coag, Soft Coag and Forced Coag.	Monopolar Coag Modes: Classic Coag, Swift Coag, Spray Coag, Soft Coag and Forced Coag or Equivalent modes	Monopolar Coag	Accepted
13	Bipolar Cut and Bipolar Soft Coag, Bipolar Forced coag should be available for laparoscopic cases for tissue cutting and coagulation.	Point should be omitted	Bipolar Cut and Bipolar Soft Coag, Bipolar Forced coag should be available for laparoscopic cases fortissue cutting and coagulation. Or Equivalent modes	Accepted
14	Forced APC, Pulsed APC and Precise APC modes should be available once the machine is upgraded to Argon Plasma.	, , , , , , , , , , , , , , , , , , ,	Forced APC, Pulsed APC and Precise APC modes should be available once the machine is upgraded to Argon Plasma or Equivalent Mode	
15	The machine should weigh less than 10 kgs	Not more than 15 Kg	The machine weight should not be more than 15 KG	Accepted
16	All Technology should be mandatorily with safety approval- USFDA / European CE for Device. Approval certificate must be submitted for the total unit.	All Technology should be mandatorily with safety approval- USFDA and European CE for Device. Approval certificate must be submitted for the total unit.	All Technology should be mandatorily with safety approval- USFDA / European CE for Device. Approval certificate must be submitted for the total unit.	No change
17	All the accessories & Consumables should be from same OEM/Manufacturer	To maintain the product quality & clinical output all the accessories and consumables should be from same OEM / manufacturer	To maintain the product quality & clinical output all the accessories and consumables should be from same OEM / manufacturer	No change
	Machine should be provided with following accessories:1.1 Unit Laparoscopy -5mm diameter vessel sealer hand instrument.2.1 unit Open Vessel sealer hand instrument3.1 unit of BayonetForceps4.1 unit of Reusable/Steam SterilizableBipolar Cord5.1 unit of Reusable6.Patient plates Adult-	Mentioned accessories would ensure machine can start operating/usage of machine after installation	<ul> <li>Machine should be provided with following accessories:</li> <li>1. 1 Unit Laparoscopy - 5mm diameter vessel sealer hand instrument.</li> <li>2. 1-unit Open Vessel sealer hand instrument</li> <li>3. 1 unit of Bayonet Forceps</li> <li>4. 1 unit of Reusable/Steam</li> </ul>	Accepted

50 units, Pediatric-25 units and	Sterilizable Bipolar
Neonatal-12 units	Cord
	5. 1 unit of Reusable
	Bipolar resectoscope
	cable
	6. Patient plates Adult-
	50 units, Pediatric-
	25 units and
	Neonatal-12 units

Lt.col.(Rtd).Dr.Shailesh Oke Medical Director Shri Saibaba sansthan Hospital,Shirdi

Sr.	Description of Work /	Suggested Changes	Amendment needs to	Remark
No.	Item(s)		be done	
	BLO	<b>OD BANK REFRIDGERETOR 150</b>	Bag & 300 Bag	
1	Min. Triple pane door glass fitted in door frame made of 18swg CR sheet, powder coated with structure finish and filled with formed in position min.125 mm thick PUF	belongs to specific company, while standard PUF insulation in blood bank refrigerator 2-to-6-degree C. is	glass fitted in door frame made of 18swg	Accepted
2.	Input voltage of BBR – 160- 270 V, 50Hz, single phase AC	It seems this voltage range is for voltage stabilizer not for refrigerator. For all equipment's with refrigeration voltage stabilizer is recommended so that voltage is regulated & adequate voltage is supplied to equipment that is 200 to 240 volt.	200-250 V, 50Hz-60Hz,	Accepted

## Lt.col.(Rtd).Dr.Shailesh Oke Medical Director Shri Saibaba sansthan Hospital,Shirdi

Sr.	Description of Work /	Suggested Changes	Amendment needs to	Remark
No.	Item(s)		be done	
		BLOOD BANK CENTRIFUD	GE	
1	Rotor Capacity: 12 or more	Please specify the exact tube size.	Rotor Capacity: 12 or	Accepted
	positions (5 to 20 ml tubes),	For all applications in BB swing out	more positions (5ml	
	Rotor Type: Fixed angle	rotor for 5/7 ml tubes/ vacutainers are	tubes), Rotor Type:	
	rotor.	used for applications in pathology lab	Fixed angle rotor.	
		like urine application swing out rotor.		
		For 15 ml tubes.		

Lt.col.(Rtd).Dr.Shailesh Oke Medical Director Shri Saibaba sansthan Hospital,Shirdi

Sr. No.	Description of Work / Item(s)	Suggested Changes	Amendment needs to be done	Remark
110.	item(s)	Under Water Cautery		
1	The frequency of the machine should not be more than 350 KHz.	The frequency of the machine should be 350 KHz or more		Accepted
2	TFT Display with Focused view of current active mode with easy touch buttons and should also have Colour display for better visuals.	LCD touch screen Colour display for better view and easy operation.	TFT Display /LCD touch screen or non- touch screen Colour display.	Partially Accepted
3	Facility to store 99 different programs according touser needs.	Facility to store at least 10 different programs according to user needs.	Facility to store maximum numbers of different programs according to user needs.	Partially Accepted
4	Machine display should have pictorial representation of effect on the tissue for the selected modes during activation and setting the power or voltages.	Point should be omitted	Point is Omitted	Accepted
5	Machine should have the facility to show detailed information about the selected mode.	Machine should display mode activation during operating.	Machine should have the facility to show detailed information about the selected mode.	Not Accepted
6	Selection of patient plate type (Dual & Single)should be possible for safety during surgery	Selection of the patient plate type should be automatic	Selection of patient plate type (Dual & Single) should be possible for safety during surgery manual as well as Automatic	Point is actually same (Accepted)
7	Machine should have Facility to display Power output Graph for each activation	Should be omitted	Machine should have Facility to display Power output Graph for each activation	Not Accepted

			will be preferred	
8	Footswitch provided should be washable and should have IP X8 ratings.	Point should be omitted	Footswitch provided should be washable andwaterproof.	Not Accepted (Should provide with washable & waterproof no need of IP X8 rating)
9	Monopolar cut modes: High Cut (for dense tissue), Dry/ Blend cut and Auto/ Pure cut, Endocut (for Endoscopy)	Monopolar cut modes: High Cut (for dense tissue), Dry/ Blend cut and Auto/ Pure cut, Endocut (for Endoscopy) or equivalent modes	Monopolar cut modes: High Cut (for dense tissue), Dry/ Blend cut and Auto/ Pure cut, Endocut Endoscopy) or equivalent with different names	Partially Accepted
10	Endo Cut mode should have the facility to set Cutting duration & Cutting Interval	Endo cut mode should have the facility to set cutting duration & cutting interval (Optional)	Should be provide with Endo Cut or pulse mode or any equivalent name for interval cutting	Not Accepted
11	Monopolar Coag Modes: Classic Coag, Swift Coag, Spray Coag, Soft Coag and Forced Coag.	Monopolar Coag Modes: Classic Coag, Swift Coag, Spray Coag , Soft Coag and Forced Coag or Equivalent modes	Different Monopolar Coag Modes should be available for slow heating of tissue in close contact, then fluid loss with bubbling then steams release with cooling then restart slow heating of tissue in close contact.	Partially Accepted
12	Bipolar Cut and Bipolar Soft Coag, Bipolar Forced coag should be available for laparoscopic cases for tissue cutting and coagulation	Point should be omitted	The Equivalent mode should be available or selectable for bipolar cutting with proper cutting device for laparoscopic case for tissue cutting & coag.	Not Accepted
13	Forced APC, Pulsed APC and Precise APC modes should be available once the machine is upgraded to Argon Plasma.	Or equivalent modes	Different modes should be available for Arogen Plasma coagulation after upgradation.	Accepted.
14	The machine should weigh less than 10 kgs.	Not more than 15 Kg	The machine should weight less than 20 Kg. Minimum can be consider.	Accepted.

Lt.Col.Dr. Shailesh Oke. (Rtd). Medical Director Shri Saibaba Sansthan Hospital, Shirdi