Notice Inviting e-Tender

West Bengal Medical Services Corporation Limited
Swasthya Sathi
GN-29, Salt Lake, Sector-V
Kolkata-700091
Phone No (033) 40340307/20
E mail: procurement@wbmsc.gov.in

Supply and Commissioning of Robotics Surgical System with Instrumentation Accessories at IPGME&R and SSKM Hospital

(Submission of Bid through *online*)

2nd call of Bid Reference No.: WBMSCL/NIT-475/2023; dated-14.08.2023

Bid Reference No.: WBMSCL /NIT-591/2023	Dated–03.10.2023

Amendment-I

REVISED TECHNICAL SPECIFICATIONS

Robotics Surgical System with Instrumentation Accessories

A. Description

The following specification is for a system capable of working in the Master slave mode with the surgcon us the Master and his hand movement are transplanted into minimally invasive instrument n capable of navigating inside the human body and performing manoeuvres as desired by the surgeon as per the capabilities of the instruments for performing dissection and suturing in what is come to be called as a robot assisted surgery .

B. Capabilities Specification

1. The equipment must be capable of performing minimally invasive robot

assisted operative procedures in General Surgery, G1, Urology, Gynecology, Thoracic, Colorectal for benign, Head & Neck, Breast and cancer surgeries. The provided system must be the latest generation/procurement.

2. The main Equipment should comprise of the following fully integrated subsystems.

i. Surgeon's console open faced / stereo type - with Master controls and an integrated true High-Definition 3D display, head tracking safety feature and a secondary 2D display for DICOM images and other patient information or equivalent technology.

ii. Patient Side Cart or modular patient side arm carts with 4 universal 6mm to 9mm instrument/camera arms enabling 6 mm to 9mm post placements. Targeting laser will be added advantage (preferably)

iii. Vision cart containing camera, image processing units and 3D HD monitor displaying exactly the same 3D video as the principal surgeon for the patient side team, trainees and observers. Also, a 3D HD recording / playback / streaming system with secondary 2D monitor for controlling the video recording, live broadcasting and, pre-operative application interfacing (in-built or external facility will be provided).

iv. System should be capable for integration of skill simulator/endo trainer with the surgeon console with supplied model of robotic system to practice & enhance surgical skills of new & existing robotic surgeons.

3. High-quality Three-Dimensional view of the field of operation is to be provided by the vision system through its endoscope and the Surgeon should be able to magnify the images with his own controls.

4. The endoscopes should be capable to view at 0 degree and 30 degrees.

5. Camera should provide high resolution images of the operative filed along with perception of depth of filed.

6. The vendor should provide a list of Instruments, consumables and accessories available for the use of the system suitable for the capabilities of the system. The vendor must provide the quote of consumables complying with their system and the type of surgery. The complete range minimum to maximum must be put in Form 8(a) and its must be complying for next 2 years from the time of installation.

7. Instrument to be used with the systems should able to provides surgeons with natural dexterity and a range of motion equal to the human hand. Such instruments should be able to offer a wide range of tips suitable for performing procedures

for benign and oncology surgeries across multiple disciplines. These instruments shall offer Seven degrees of motion mimicking the dexterity of human hand.

8. The masters at the surgeon's console should be capable of translating the natural hand and wrist movements in to corresponding precise and scaled movements to the instruments and camera attached to the surgical cart arms minimizing fatigue. Such movements of the instrument tips shall replicate the experience of open surgery.

9. There should be facility for scaling of surgeon hand movements to corresponding smaller instrument tip movements. The surgeons hand movements shall be replicated at the instrument tip after filtering tremors if any in real time.

10. There should be facility for learning hand - eye coordination movements by simulators sub system.

11. The system should perform self-checks to provide safety during usage.

The system should have built in energy source functionality for monopolar and bipolar cautery also have ability to use external energy source of at least one compatible model for emergency use. Vessel sealing (Radio frequency and Ultrasonic mode) up to 7mm diameter, stapling with the help of fully wristed robotic instruments will be taken as additional optional advantage.

1. Ability to change instruments during surgery safely with proper guidance should be in built.

2. Should provide the flexibility to place scope in any one of the surgical arms / robotics arms during the procedure.

3. Features to provide ability for the assistants in the OR to see and communicate with the surgeon through monitor and telestration.

4. Ability to adjust the surgeons via ports and console to suit individual comfort and ergonomics should be available.

5. Ability to enable the surgeon to view two additional video sources from other medical systems with compatible video sources.

6. While the robotic arms shall be operated by sterile persons the vision system and

surgeon console shall be non-sterile are in the operating room.

7. Adequate safety features to prevent inadvertent movements of the surgeon affecting the instruments shall be available.

8. The sub systems shall be easily movable within the OR. If wheels are used there should be features to lock the wheel to prevent movements.

9. The system shall provide video output suitable for connecting to external devices such as recorders and additional video monitors.

10. The system shall have all software required to support all disciplines of surgery which is possible by the system under the control of the system.

11. System shall have features for emergency release of the robotic instruments from the surgery.

C. **Other requirements**

1. Surgeon Training

Ten surgeons nominated in a phased manner by the 'institution head .shall be trained and certified by the vendor for using the system to perform robot assisted surgeries. The duration of the training and the training method shall be as per International norms at an authorized training center.

The Vendor shall arrange for training at an appropriate facility for 6 surgeons from the centre where machine is installed for at least 7 days (off site) for the equipment by trained personnel for the seamless functioning of the entire system in a phased manner.

All necessary training should be provided by the vendor or company by its own cost (including fooding, lodging and transportation.)

Bidder has to arrange for onsite training in a phased manner for at least 15 working operating days to be confirmed by the Head of the Robotics Committee

2. OT staff training

A set of OT staff such as nurses and OT technicians and biomedical staff shall be trained by the vendor for handling the system covering powering on, moving and positioning the system and observing the system for right function and errors it any etch. The training method and duration shall be outlined by the vendor. There may be multiple batches of OT staff required to be trained over a period of time.

The Vendor shall arrange for training at an appropriate facility for 6 surgeons from the centre where machine is installed for at least 7 days (off site) for the equipment by trained personnel for the seamless functioning of the entire system in a phased manner.

All necessary training should be provided by the vendor or company by its own cost (including fooding, lodging and transportation.)

Bidder has to arrange for onsite training in a phased manner for at least 15 working operating days to be confirmed by the Head of the Robotics Committee.

Mentorship program for robotics surgery must be provided by the company for atleast 1(One) year.

3. Environment and Power

All equipment shall be capable of working on 230 V AC, +/-5%, 50 Hz Power supply. The system shall be capable of working between 22 to 30 Deg C air-conditioned environment.

4. Mandatory Terms and Conditions.

i. The vendor will perform a detailed Pre-site survey of the operation theatre/institute and will submit a detailed report of the same within 30 days of the tender submission to inform/update the institution about all the auxiliary equipment/s % other requirements if any, necessary for full functioning of the device and its unhindered us for surgery.

ii. System should be quoted with performance report/certificate of last 2 years by various user/users from government institutions or any teaching institution recognized by Govt.

iii. The vendor should have a training center in India.

iv. The vendor should be capable of providing the India proctor support if required during the initial cases / procedures at the institution.

v. The robotic system should have at least one of US FDA / European CE (4 digit notified body) / BIS/ CDSCO-Class C / CDSCO approved.