



Notice Inviting e-Tender

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

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL /NIT-374/2024	Dated-24.06.2024
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AMENDMENT-II

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 surgeon as the Master and his hand movement are transplanted into minimally invasive instrument and capable of navigating inside the human body and performing manoeuvres as required 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 should be capable of performing minimally invasive robot assisted operative procedures preferably in most of General Surgical, GI, Urological, Gynecological, Thoracic, surgical procedures. The provided system must be the latest generation/procurement.
2. The main Equipment should comprise of the following subsystems.
 - i. Surgeon's console should have 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. **Safety feature must be ensured depending on the system put for tender.**
 - ii. Patient Side Cart or modular patient carts/**equivalent** with 04 (four) side arms, along with 04 (four) universal compatible sizes instrument/camera arms enabling appropriate port placements.
 - iii. Vision cart/**similar device** containing camera, image processing units and **2D/3D** HD monitor **(20 inch or more)** displaying exactly the same 3D video as for the principal surgeon for the patient side team and trainees/observers. The system should have a 3D HD recording **(internal or external)/** 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.
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 (02) should be capable to view at 0 degree and 30 degrees.
5. Camera should provide high resolution images of the operative field along with perception of depth of field.
6. The vendor should provide a list of Instruments, consumables and accessories available for the use of the system.
 - 6.1 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 02 (two) years from the time of installation.
 - 6.2. The vendor must provide sketch and documentary evidence of successful running of the robotics program in terms of consumables cost for standard General Surgical, GI, Urological, Gynecological, Thoracic in any Govt./Teaching Facility. The sketch must be submitted with the tender document.
7. Instrument to be used with the systems should be able to provide surgeons with natural dexterity and a range of movement equal to 4 degrees or more of freedom/motion.

8. There should be facility for learning hand - eye coordination movements by simulators sub system.
9. The system should perform self-checks to provide safety during usage.
10. The system should have in-built / external energy source functionality for monopolar, bipolar cautery and vessel sealing. The vendor must take full responsibility of maintenance, repair, calibration and upgradation of the energy sources and vessel sealing devices at their own cost during the warranty and CMC period. In case of 3rd party involvement the details of the MoU between vendor and the 3rd party must be provided.
11. Ability to change instruments during surgery safely with proper guidance should be in built.
12. Adequate safety features to prevent inadvertent movements of the surgeon affecting the instruments shall be available.
13. 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.
14. The system shall provide video output suitable for connecting to external devices such as recorders and additional video monitors.
15. 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.
16. System shall have features for emergency release of the robotic instruments from the surgery.
17. Consumables are to be supplied with the system for the first 100 (hundred) surgical procedures.

C. Other requirements:

1. Surgeon Training:

06 (six) 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 centre.

The Vendor shall arrange for training at an appropriate facility for 06 (six) surgeons from the centre where machine is installed for at least 07 (seven) 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 (fifteen) 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 if any etc. 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 06 (six) surgeons from the centre where machine is installed for at least 07 (seven) 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 (fifteen) 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 at least 01 (one) year.

3. Environment and Power:

All equipment shall be capable of working on 230 V AC, +/-5%, 50Hz 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 (thirty) 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 use for surgery.
- ii. System should be quoted with performance report/certificate from at least for 02 (two) institutions, by various user/users from government institutions or any teaching institution recognized by Govt.
- iii. The vendor should have a training center/system in India.
- iv. The vendor should be capable of providing the India proctor (Trained Robotic Surgeon for that instrument) support, if required during the initial cases/ procedures at the institution.
- v. The bidder should submit valid CDSCO Certificate/Registration/License for both the manufacturer(s) and importer(s) as applicable.