Admn/Prop/112/2021-AIIMS.JDH Dated: 24th March 2022

**Subject:** Purchase of Co2 Surgical Laser System for the department of Otorhinolaryngology at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Co2 Surgical Laser System for the department of Otorhinolaryngology at AIIMS, Jodhpur from M/s Lumenis Ltd., Yokneam Industrial Park, 6 Hakidma St. POB 240, Yokeam, Israel 2069204 on proprietary basis. The proposal submitted by M/ Lumenis Ltd., Israel 2069204 and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/112/2021-AIIMS.JDH. The comments should be received by office of Deputy Director (Admin), Medical College at AIIMS, Jodhpur on or before 14th April 2022 upto 03:00 PM failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

**Yours faithfully,**

**Deputy Director (Admin)**

**Enclosed: Related documents enclosed.**

Lumenis®
Energy to Healthcare

**Proprietary Article Certificate (PAC) for Goods/Services Provided by Lumenis, Ltd.**

The goods/services relevant to this PAC are associated directly with the AcuPulse DUO medical laser system (the "System") as defined within accompanying product labeling for the purpose of medical therapeutic treatment of patients by or on the order of a duly licensed physician.

It is certified as of August 19, 2020 that:

(i) AcuPulse DUO goods (including accessories which include an Otology Kit and Robotic Drop-In Guide) are manufactured by Lumenis Ltd. and technically serviced by duly trained & qualified Lumenis Field Service Engineers (FSEs) in accordance with original product manufacturing specifications.

a. Lumenis Otology Kit is a specially designed CO2 laser fiber used only for the Ear together with disposable tips uniquely designed for Lumenis product offerings.

b. Lumenis Fiberlase Robotic Drop-In Guide is uniquely designed to assist fiberlase with robotically assisted surgeries.

(ii) No other alternative make or model/supplies/service provider to the AcuPulse DUO system is acceptable or available to either supply or service the AcuPulse DUO medical laser for the following reasons:

a. Lumenis AcuPulse DUO products are offered direct within India by Lumenis India, as sanctioned as a responsible license holder;

b. The Lumenis AcuPulse DUO contains a specifically designed "dual" delivery system capability unique to Lumenis product offerings;

c. Lumenis is the responsible legal manufacturer of the AcuPulse DUO system, directly responsible for product design, manufacturing, testing, and product release obligations;

d. As product designer and manufacturer of the AcuPulse DUO system, Lumenis is the responsible specification owner for product performance attributes, utilized materials, and spare/replacement parts for the systems; and

e. As design, manufacturing, test and product release owner for the AcuPulse DUO system with unique dual delivery capability, Lumenis is the qualified responsible party to provide product service and maintenance support in full compliance with original product specifications and release criteria for proper system operation.

(iii) Mr. Rohit Raina of Lumenis India is the authorized representative of Lumenis within the territory of India with respect to this matter.

Sincerely,

Michael M. Milo, Adv.
Associate General Counsel
Lumenis Ltd.

Lumenis Ltd.
Yokneam Industrial Park
6 Hakidma St. POB 240
Yokneam, Israel 2069204

T. +972-4-9599000
F. +972-4-9599050
www.lumenis.com

Vidhu Sharma

| Sr. No. | CO2 Laser |
|---|---|
| A) | **Laser System:** |
| 1 | LASER SYSTEM SHOULD BE EXCLUSIVELY CARBON DIOXIDE LASER WITH A WAVELENGTH 10.60 MICRO METERS, INFRARED |
| 2 | THE SYSTEM SHOULD BE STAND ALONE CO2 LASER WITH SIMPLE TOUCH SCREEN TRANSITION BETWEEN FIBER AND FREE BEAM MODALITIES WITHOUT SWITHCHING OFF THE SYSTEM OR REMOVING ANY ARM TO REPLACE WITH FIBER , OFFERING BROADEST RANGE OF CLINICAL APPLICATIONS IN OTOLARYNGOLOGY,HEAD AND NECK ONCOLOGY SURGERY,OTOLOGY (INCLUDING ONE SHOT STAPEDOTOMY),BOTH WITH FREE BEAM AND CO2 FIBERS. |
| 3 | LASER MACHINE SHOULD HAVE POWER OUTPUT 1-40 WATTS. |
| 4 | IT SHOULD HAVE 5Mw RED DIODE AIMING BEAM,635NM, ADJUSTABLE INTENSITY |
| 5 | THE BEAM DELIVERY SHOULD BE THROUGH (BOTH 1 & 2)<br>1) A 7-JOINT, FIXED MIRROR, SPRING BALANCED ARM, THE REACH OF THE ARM SHOULD BE AT LEAST 120 CM WITH 360 DEG ROTATION.<br>2) A LIGHT WEIGHT CARBON DIOXIDE GLASS HOLLOW FIBER. CO2 FIBER SHOULD BE 2 METER LONG, 1.04MM OUTSIDE DIAMETER, STERILE, SINGLE / MULTIPLE USE, 2.0 METER LONG. |
| 6 | IT SHOULD BE EQUIPPED WITH ONE TOUCH TAB/SWITCH TO CHOOSE EITHER WAVE GUIDE OR ARTICULATED ARM MODALITY WITHOUT SWITCHING OFF/STOPPING THE MACHINE AND WITHOUT CHANGING ANY PART. |
| 7 | SPOT SIZE: 295MM AT FIBER OUTPUT. UP TO 40 WATT |
| 8 | IT SHOULD BE MICROPROCESSOR BASED. |
| 9 | IT SHOULD HAVE A SEALED CO2 LASER TUBE. |
| 10 | IT SHOULD HAVE CONTINUOUS, SINGLE PULSE AND REPEAT PULSE TISSUE EXPOSURE MODES. |
| 11 | IT SHOULD HAVE CONTINUOUS POWER (CW) OF 01 – 40 WATTS |
| 12 | IT SHOULD HAVE A SUPER PULSE POWER OF 0.5 – 15 WATTS. |
| 13 | • IT SHOULD HAVE A TIMED EXPOSURE OF FOLLOWING DURATIONS:<br>1) ON TIME (SINGLE PULSE) – 0.05 – 1.0 SEC. AT 1.0 TO 4.5 WATTS<br>- 0.01- 1.0 SEC AT 5-40 WATTS<br>2) ON TIME (REPEAT PULSE) – 0.05 – 1.0 SEC AT 1- 4.5 WATTS<br>- 0.01 – 1.0 SEC AT 5-40 WATTS |
| 14 | IT SHOULD HAVE A REPEAT DELAY, OFF TIME, 0.01 TO 1.0 SEC. |
| 15 | IT SHOULD HAVE AT LEAST 100 USER DEFINED MEMORY SETTINGS. |
| 16 | IT SHOULD HAVE A 0.2MM FOCUSED HAND PIECE. |

डो सौरभ वार्ष्णेय/Dr. Saurabh Varshney
कार्यकारी निदेशक/Executive Director
अखिल भारतीय आयुर्विज्ञान संस्थान,देवघर
All India Institute of Medical Sciences,Deoghar

| | |
|---|---|
| 17 | IT SHOULD HAVE AT LEAST TWO BACTERIAL FILTERS. |
| 18 | IT SHOULD HAVE TEN LASER SAFETY GLASSES. |
| 19 | IT SHOULD HAVE A SELF CONTAINED CLOSED LOOP COOLING SYSTEM. |
| 20 | IT SHOULD HAVE A MULTI –COLOUR TOUCH SCREEN PANEL |
| 21 | IT SHOULD BE EQUIPPED WITH INTEGRATED ANIMATED ACCESSORIES VIDEOS DEMONSTRATING HOW TO SET UP IT BEFORE STARTING APPLICATION/SURGERY.<br>THESE VIDEOS/GRAPHICS SHOULD BE SPECIALITY AND PROCEDURE SPECIFIC. |
| 22 | IT SHOULD HAVE A USER FRIENDLY GRAPHIC DISPLAY TO PROVIDE STEP BY STEP OPERATING INSTRUCTIONS. |
| 23 | IT SHOULD BE COMPATIBLE WITH 230V, 3A, 50HZ POWER SUPPLY |
| B) | **MICROMANUPLATOR WITH FOLLOWING REQUIREMENTS FOR MICROLARYNGEAL LASER SURGERY:** |
| 1 | IT SHOULD HAVE AN OPTICAL DESIGN TO ASSURE PERFECT CO-INCIDENCE OF THE DIODE AND CO2 BEAMS EVEN AT HIGHEST MICROSURGICAL MAGNIFICATIONS. |
| 2 | IT SHOULD BE EASILY ADJUSTABLE AND SHOULD HAVE VARIABLE WORKING DISTANCE FROM 200MM TO 400MM AND THE SAME SHOULD BE ADJUSTABLE DEPENDING UPON PROCEDURAL NEEDS. |
| 3 | IT SHOULD HAVE CONTINUOUSLY VARIABLE DEFOCUS WITH A USER ADJUSTABLE DEFOCUS LIMITER. |
| 4 | ITS JOYSTICK HANDLE SHOULD BE TENSION ADJUSTABLE AND AUTOCLAVABLE. |
| 5 | IT SHOULD BE USER SELECTABLE FOR LEFT OR RIGHT HAND CONTROLS. |
| 6 | IT SHOULD BE LIGHTWEIGHT, TO MAINTAIN BALANCE OF THE SURGICAL MICROSCOPE |
| 7 | IT SHOULD HAVE A MINIMUM SPOT SIZE OF 160 MICRONS. |
| 8 | IT SHOULD HAVE A FOCUS RANGE OF 0.16 MM – 0.27 MM. |
| 9 | IT SHOULD HAVE MAXIMUM DEFOCUS RANGE OF 2.8 MM– 4.6.MM. |
| 10 | IT SHOULD HAVE A POWER TRANSMISSION OF GREATER THAN 70%, WITH UNLIMITED POWER INPUT. |
| 11 | IT SHOULD HAVE A ROBOTIC LASER MICROSURGERY SYSTEM WITH FOLLOWING REQUIREMENTS:<br>• IT SHOULD HAVE BEAM SCAN SHAPE:LINEAR & CURVED INCISIONS : 0.3MM TO 0.5MM IN LENGTH (USER DEFINED), 0.7MM TO 3MM FOR PAPILLOMATOSIS.<br>• IT SHOULD HAVE PENETRATION DEAPTH OF 0.2MM TO 2MM (USER DEFINED) |
| C) | IT SHOULD HAVE DEDICATED ORAL, PHARYNGEAL,OTOLOGY AND NASAL HANDPIECE SET FOR ORAL, PHARYNGEAL AND NASAL APPLICATIONS WHICH SHOULD INCLUDE |

डॉ० सौरभ वार्ष्णेय/Dr. Saurabh Varshney
कार्यकारी निदेशक/Executive Director
अखिल भारतीय आयुर्विज्ञान संस्थान,देवघर
All India Institute of Medical Sciences,Deoghar

| | |
|---|---|
| | • 230MM HANDPIECE UNIT (CVD OPTICAL UNIT, PORTS HOLDER,M CONICAL MAIN EXTENDER, EXTRA CONICAL MAUN EXTENDER,CONTAMINATION COLLECTOR)<br>• BACKSTOP EXTENDER – 3 NOS,<br>• TIP EXTENDER – 3 NOS,<br>• STRAIGHT TIP,<br>• KAMAMI NASAL TIP – 3 NOS,<br>• KAMAMI TONSIL TIP – 3 NOS,<br>• 90 DEGREE ANGLED MIRROR TIP EXTENDER,<br>• CLEANING BRUSH,<br>• TYGON TUBE(8MM ID,1.5M LONF) W/ REDUCER FITTING. |
| D) | **OTOLOGY KIT**<br>• IT SHOULD HAVE OTOLOGY STAINLESS STEEL HANDPIECES FOR EXTENDING LASER PRECISION TO THE DELIVERY SITE. SHOULD HAVE SMALL SHAFT BOTH ANGLED AND STRAIGHT HANDPIECES (PREFERABLY AUTOCLAVABLE).<br>• SHOULD INCLUDE DETACHABLE ULTRA THIN TIPS(DISPOSABLE) FOR HAND PIECES ,STRAIGHT & CURVED- OUTER DIAMETER OF WHICH SHOULD BE BETWEEN 0.67MM TO 0.8MM<br>• SHOULD INCLUDE STERILE DRAPES,LENGTH 165CM<br>• THE KIT SHOULD BE FROM THE SAME PRINCIPLE MANUFACTURER. |
| E) | **FIBER & FIBER ACCESSORIES - SHOULD INCLUDE SEPERATE CO2 FIBERS FOR LARYNX & OTOLOGY** |
| | REUSABLE FLEXIBLE HOLLOW CO2 FIBER- 01 NOS (DEDICATED SPECIALLY FOR STAPEDOTOMY,ONE SHOT STAPEDOTOMY,GLOMUS TUMOR,TYMPONOSTOMY) |
| | REUSABLE CO2 FIBER- 01 NOS<br>• CAN BE USED WITH FLEXIBLE ENDOSCOPY<br>• FOR USE IN TUMOR SURGERY IN THE LARYNX,PHARYNX,NASAL AND ORAL STRUCTURES<br>• SPECIALLY FOR USE IN STENOSIS & JUVENILE PAPILLOMATOSIS<br>• COMPATIBLE WITH WIDE VARIETY OF RIGID AND MALLEABLE HAND PIECES |
| | **RIGID HAND PIECE** KIT ATLEAST 8 RIGID HAND PIECES<br>✧ 60MM STRAIGHT,STRAIGHT TIP,<br>✧ 60MM STRAIGHT,CURVED TIP<br>✧ 140MM BENT, STRAIGHT TIP,<br>✧ 140MM STRAIGHT,CURVED TIP<br>✧ 180MM STRAIGHT, STRAIGHT TIP,<br>✧ 180MM STRAIGHT,CURVED TIP,<br>✧ 240MM BENT, STRAIGHT TIP,<br>✧ 240MM BENT, CURVED TIP.<br><br>**MALLEABLE HAND PIECE** KIT ATLEAST 4 MALLEABLE HAND PIECES<br>✧ 90MM<br>✧ 140MM<br>✧ 240MM<br>✧ 300MM |

Dr. Saurabh Varshney
कार्यकारी निदेशक/Executive Director
अखिल भारतीय आयुर्विज्ञान संस्थान,देवघर
All India Institute of Medical Sciences,Deoghar

| | |
|---|---|
| | |
| | ENDOSCOPE PROTECTION SHEATH – 2 NOS LENGTH: 640 MM, OD: 1.7 MM |
| | HAND PIECE BENDING TOOL |
| | **Robotic Drop in Guide:** SHOULD INCLUDE COMPANY MANUFACTURED,FLEXIBLE INSERT TO BE USED ALONG WITH FIBERS THROUGH 5MM TROCAR SLEEV CHANNEL TO COLLABRATE THE ADVANTAGES OF LASER TO ROBOTIC SURGERY FOR :-<br>**QUICK ACCESS OF TARGETED ANATOMY AND TISSUES.**<br>**CONTROL ENERGY DELIVERY TO ACHIEVE DESIRED CLINICAL OUTCOME.**<br>**THE FIBER SHOULD BE ABLE TO WITHSTAND THE MULTIPLE ANGLES OF ARTICULATION IMPOSED BY THE ROBOT.** |
| | HAND PIECE CLEANING KIT: INCLUDES 3 CLEANING BRUSHES AND 20 EXTRA SILICONE TUBE FOR HANDPIECES |
| | BENDING AND CUTTING TOOLS TO REUSE FIBER |
| | STERILIZATION TRAY FOR FIBERS. |
| F) | **SMOKE EVACUATOR**<br>• COMPATIBLE WITH THE LASER MACHINE,<br>• IMPORTED QUALITY-INCLUDE SMOKE EVACUATION UNIT WITH PNEUMATIC FOOTSWITCH,<br>• VI 6 FILTER-6 HOUR DOUBLE PORT 7/8" AND 1-1/4",7/8" TUBING WITH WAND AND TIP-2 NOS,<br>• 5ML OF 50-LASER MASK 0.1MM FILTRATION MEDIA(FLAT MASK)<br>• LASER MASK 0.1MM FILTRATION MEDIA(FLAT MASK) |
| G) | **UPS:** MINIMUM OF 3KVA OR MORE FOR THE WHOLE SYSTEM |
| H) | **POWER SUPPLY:** 220V,50HZ |
| | |
| I) | **TERMS & CONDITIONS** |
| 1 | INTERNATIONAL STANDARDS: THE UNIT SHOULD COMPLY WITH INTERNATIONAL STANDARDS AND SHOULD HAVE US FDA CERTIFICATIONS. |
| 2 | COMPANY SHOULD HAVE DIRECT SERVICE CENTRE IN INDIA (NO THIRD PARTY/DEALER ARRANGEMENT) |
| 3 | DURING NON-FUNCTIONAL/REPAIR OF THE EQUIPMENT,THE FIRM SHALL PROVIDE STANDBY EQUIPMENT WITH 99% UPTIME GAURANTEE FAILING WHICH A PENALTY OF RS.10,000/- PER WEEK WILL BE IMPOSED. OEM TO PROVIDE UNDERTAKING ON COMPANY LETTERHEAD TO THIS EFFECT. |
| 4 | THE COMPANY SHOULD HAVE SUPPLIED SIMILAR EQUIPMENT/SYSTEM TO REPUTED GOVERNMENT INSTITUTES IN INDIA IN LAST 3 YEARS WITH SATISFACTORY AND FAULTLESS FUNCTIONING. |

डॉ० सौरभ वार्ष्णेय/Dr. Saurabh Varshney
कार्यकारी निदेशक/Executive Director
अखिल भारतीय आयुर्विज्ञान संस्थान,देवघर
All India Institute of Medical Sciences,Deoghar

| | |
|---|---|
| 5 | LIST OF ALL OPTIONAL ACCESSORIES & CONSUMABLES REQUIRED FOR ONCO SURGERIES NEED TO BE PROVIDED AND QUOTE RATE FOR THE SAME. |
| 6 | BACK TO BACK ASSURANCE TO BE TAKEN BY THE SUPPLIER FROM THE OEM TO SUPPLY SPARES FOR MINIMUM 10 YEARS & TO BE SUBMITTED. |
| 7 | COMPREHENSIVE WARRANTY SHOULD BE 5 YEARS FROM THE DATE OF INSTALLATION |
| 8 | CAMC SHOULD BE 5 YEARS AFTER THE EXPIRY OF WARRANTY. |
| 9 | DEMO OF THE QUOTED MODEL WILL BE MANDATORY AT THE COST OF BIDDER IF SO DESIRED BY THE USER, AFTER THE OPENING OF THE TECHNICAL BID AND PRIOR TO OPENING OF FINANCIAL BID. THIS IS FOR TECHNICAL EVALUATION. |
| 10 | SHOULD PERFORM CALIBRATION YEARLY & PREVENTIVE MAINTENANCE HALF YEARLY DURING WARRANTY & CMC (IF CMC IS ENTERED INTO) WHICH WILL INCLUDE SPARES REPLACEMENT,PREVENTIVE MAINTENANCE & BREAKDOWN CALLS. |

कार्यकारी निदेशक/
अखिल भारतीय आयुर्विज्ञान संस्थान,देवघर
All India Institute of Medical Sciences,Deoghar