



अखिल भारतीय आयुर्विज्ञान संस्थान राजकोट, गुजरात 360001
All India Institute of Medical Sciences, Rajkot, Gujarat 360001

Dated: 07 Feb 2024

Subject: Proposal for Purchase of the Combined High-End RF, Argon Plasma and Water Jet Surgical Work Station with Automatic Surgical Smoke Evacuation System - 01 for the Department of Surgery on Proprietary basis at AIIMS Rajkot – Inviting Comments/Objection thereon.

The Institute is in the process for the purchase of above cited item from ERBE on a proprietary basis (PAC). The proprietary certificate submitted is attached & uploaded on website.

The above documents are being uploaded for open information to all principle manufacturers or their authorized distributors with the intention to invite objection/comments, if any with regard to proprietary nature of the above said system and accessories/consumables.

The comments/objections if any, should be received in the office of Stores, AIIMS Rajkot Khanderi, Para Pipaliya, Rajkot, Gujarat, INDIA, 360006, within 15 days from the date of notification, failing which it will be presumed that no other bidder/ manufacturer/ vendor is having any comments/objection against the proposition and the case shall be decided purely on merit.

Deputy Director (Admin.)

उप निदेशक (प्रशासन)
DEPUTY DIRECTOR (ADMINISTRATION)
अखिल भारतीय आयुर्विज्ञान संस्थान, राजकोट - ३६०११०
All India Institute of Medical Sciences, Rajkot - 360110

Enclosure: Related documents enclosed.

Technical Specification for Combined High-End RF, Argon Plasma and Water Jet Surgical Work Station with Automatic Surgical Smoke Evacuation system

RF Energy Platform -Electro surgery unit with Thermo fusion (Vessel Sealing)

An integrated RF, with Argon and Kinetic energy surgical platform, which can dissect, coagulate and seal the tissues during open and laparoscopic surgeries. System should comprise of below Type of Module Energies.

- The Electro surgical generator should be a 400watt touch screen display with 15 digital signal processors.
- Unit should facilitate functions of Monopolar, bipolar & vessel sealer with in-built regulated power supply adapter for bipolar resection.
- Unit should have a Stepguide suggesting appropriate setting configurations for every instrument and application.
- The system should make 25 million measurements / sec for better tissue effect and should measure tissue impedance through power peak system.
- System should have wifi compatibility for future OR integration.
- Unit should be plug & play with 5 or more universal multi-functional sockets to accommodate any instrument.
- System should have remode function to allow user to access 6 sub programmes directly from the sterile field.
- Unit should have high cut mode for mono polar modalities
- Each socket should support the Auto start function for bipolar instruments.
- Unit should have the facility for socket exchange.
- Unit should have Soft Coagulation mode with quick start function for any open or laparoscopic application
- Unit should have Precise Sect mode for optimized dissection in open or laparoscopic cases
- The generator should work on a supply voltage of 100 – 120 VAC & 220 – 240 VAC
- Power consumption at Max HF power should be 550 watts with max pulse power consumption of 1600 watts.
- Should have a special Coagulation mode called "Thermoseal" with auto start function for highly vascularized tissue bundles and vessels upto 7mm diameter and min. burst 360mmHg burst pressure.
- Unit should have an AutoCut bipolar mode to facilitate bipolar cutting instruments.
- Supply frequency should be in the range of 50 -60 Hz.
- Unit should have the facility to store 1800 programmes or applications.
- Unit should have the facility to show the active instruments on the screen display.
- The generator should have an inbuilt feature of accessory assignment.
- The unit should have high cut bipolar to facilitate bipolar resectoscopes.



- The generator should be supplied with Argon plasma coagulation unit having forced APC, pulsed APC and precise APC modes.
- The generator should be supplied with Hydrojet to facilitate use of unique hybrid technology instruments for All Surgical Modalities.
- Unit must be compatible & Supplied with Intelligent smoke evacuation module and suction module from Same OEM
- Unit should support Nussy as a neutral electrode.

Argon Plasma Coagulation

For management of bleeding and devitalisation of tissue abnormalities achieved by optimal coordination with RF generator

- The Argon Plasma Coagulation system should have automatic parameters setting for various types of instruments and automatic depth controlled plasma regulation.
- Should have three different APC modes suitable for different indications
 - Precise APC – adjustment made using the effect settings
 - Pulsed APC – adjustment made using the parameter power settings
 - Forced APC – adjustment made using the parameter power settings
- Should have Adjustable argon flow rate from 0.1L/min to 8L/ min in steps of 0.1 L /min with automatic regulation of selected flow rate.
- Should have the facility to use Argon plasma coagulation and monopolar coagulation simultaneously
- Should have automatic monitoring of flow rate and Argon supply and auto purge facility. It should have the facility to connect with central gas supply.
- Should give visual display of argon gas bottle content and should give Acoustic alarm when bottle content reaches a minimum.
- Should have facility for activation of unit by foot pedal of the Electro Surgical unit.
- Should have facility to use in double balloon endoscopy procedures.
- Should have facility for Argon supported cutting and coagulation.

Water Jet Tissue Dissection System

For management of separating the different tissue types with their varying elasticity and firmness with the help of adjusted water pressure based on the kinetic energy principle.

- Should have pressure range: 1–80 bars & Volume flow: 1–65ml/min. It should indicate delivered fluid vol.
- Should adapt any sterile saline solution bag (disposable) as separation medium.
- Should be integrated with Electro surgical workstation with other accessories and facility to connect Monopolar coagulation with the applicator

- Should have facility to individually configure programs for different surgeries.
- Water jet activation should be via footswitch and Remote facility for switching between two different user settings.
- Should have facility for various applicators to be used in Laparoscopy, flexible endoscopy and open surgeries.

Automatic Smoke Evacuation Unit

- The smoke plume evacuation system should be microprocessor controlled, US-FDA and / or European Certificate marked in accordance with the medical devices directive (93/42/EEC) & Electro Surgical Unit should comply with the requirement of the medical device directive of class I equipment and electromagnetic compatibility.
- The smoke plume evacuation system should be compatible with already installed VIO Surgical Workstation & Electrosurgical Units and should be fitted into same station trolley for smooth functioning and ergonomics.
- The smoke plume evacuation system should be able to extract and filter smoke and aerosol- laden air during surgical procedures & should be also able to filter COVID -19 like viruses and other microorganism present in surgical smoke generated during the procedure.
- The system should have a functional 5.7 inches touch screen display for better visibility & ease of control & display should be able to show settings, operating modes, filter run-time and information messages for the user.
- The System should have Bi-Turbo technology for effective filtration, should have ULPA-15 filter (5 stage filter protection) and active carbon filters & should also have ability to remove 99.9995% of all 0.1µm particles.
- The system filter should have maximum output of 730 l/min & have the ability to give a notification when volume flow of more than 300l/min is reached.
- The system should have ability to be used along with any electrosurgical unit, Laser and ultrasound devices & system should have automatic activation feature, no need of any additional footswitch for activation during monopolar electrosurgical applications.
- The system should display error if filter is not inserted to prevent damage & system should be able to used in vertical as well as horizontal way as per user needs.
- The system should have the ability to be fixed on the ceiling units (OT pendants) & should have the ability to be used with 2 instruments at the same time during any Surgical Procedures.
- The system should be able to used in open as well as lap surgical procedures with All required Accessories from same OEM only & system noise development at 100% evacuation should be \leq 59 dB as must have sound insulation cladding, integrated ducts and airborne sound absorbers for noise insulations.
- The user should be able to set critical features like - suction efficiency, standby suction efficiency as well as standby suction time in both lap and open surgery modes & should have footswitch activation facility for laser and ultrasonic uses during procedure.
- The system should be provided with self-sealing water trap to protect the main filter cartridge from liquids & weight of system should be < 10kgs.
- Service life of the unit filter should be for:

OPEN SURGERIES

- 40 hrs at 30% evacuation
- 32 hrs at 60% evacuation
- 25 hrs at 100% evacuation

LAPAROSCOPY SURGERIES

- 80 hrs at 30% evacuation
- 60 hrs at 60% evacuation
- 25 hrs at 100% evacuations

- The smoke evacuator unit should have an interface to connect it to the Electrosurgery system and should also be used as a "stand alone" unit.
- The unit should have provision to be activated via the interface to the Electrosurgery unit, and the time and type of activation can be selected and stored for every output socket and for every cutting or coagulation mode of each program of the Electrosurgery unit.
- The unit should additionally be activated manually using the START / STOP button or the footswitch. Deactivation should be controlled via the interface or by programming an after-run time.
- For safety reasons, an automatic function check of the unit and of the activation components connected to the unit should be performed after the mains switch has been switched on.
- A System display should indicate the filter level.

- The smoke evacuator unit should be supplied with essential accessory Filter Cartridge.
- The smoke evacuator unit should be supplied with essential accessories of same O.E.M
- One pedal foot switch AP & IP 100% waterproof endorsed by IPX8 certification of same O.E.M.

Following accessories to be supplied with the Surgical Workstation.

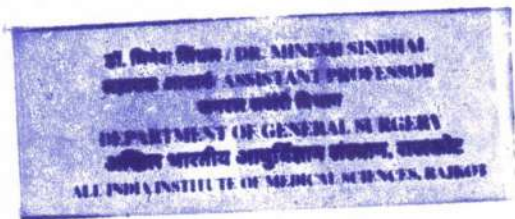
- Disposable Monopolar hand pencil with Coated Monopolar Electrodes – 20Nos.
- Reusable Thermo fusion hand instrument for open surgeries (for vasculatures up to 7mm) – 05Nos.
- Reusable thermo fusion hand instrument for Laparoscopic surgeries (for vasculatures up to (7mm) – 05Nos.
- Footswitch with facility for swapping between programs – 2Nos.
- 5mm bowel shaped sealing and cutting hand instrument with maximum of 1.1 mm thermal spread – 5Nos.Each (Open & Lap Surgeries)
- Reusable Premium Bipolar forceps with Non Sticky Effect with reusable & Autoclavable Bipolar cable – 05 Nos Each.(Straight & Bayonet)
- Patient plate with equipotential ring -100Nos.
- Argon assisted cutting instrument for open surgery and laparoscopic surgery -02 Each
- Water Jet accessories for Laparoscopy and open surgery -02 Each
- Pump Cartridges for Waterjet Surgeries Single Use – 10 Each
- Automatic Suction unit from same OEM – 1Nos.
- Automatic Smoke Evacuation unit from same OEM- 1 Nos



- Reusable Bipolar Scissor for open & Lap surgery with cable -- 05Nos.(Each)
- Laparoscopic Cable & Attachments for Minimal Invasive Instruments- 02 Nos.
- Surgical Workstation trolley with all attachments & Fastening Sets for All Units from Same OEM- 01 Nos.
- German Argon Gas Cylinders 5 Liters Capacity with Pressure Reducers from the Same OEM - 02 Qty.

Following Accessories from the same OEM only should be supplied as Standard Accessories Along with Automatic Smoke Evacuator unit.

- Main filter cartridge IES 3- 01 Qty
- Automatic Activation Device IES 3- 01 Qty
- Prefilter for smoke evacuation- 10 Qty
- Smoke evacuation pencil, single-use, short with coated spatula electrode, connecting cable 3 m- 10- Qty
- Smoke Evacuation Pencil ,single use with spatula electrode and integrated smoke evacuationshaft extension 100 mm.-10 Qty
- Evacuation tubing, \varnothing 22 mm, length 2.1 m (reusable)- 01 Qty
- Evacuation tube with optimized streaming- 05 Qty
- Evacuation funnel connection, \varnothing 22 mm- 05 Qty
- LAP tubing set IES 3 with trumpet valve 3m- 20 Qty
- One-pedal foot switch for IES 2, AP & IP X8 equipment; with connecting cable 5 m, with connecting plug 7 poles



Proprietary Certificate

To whom it may concern

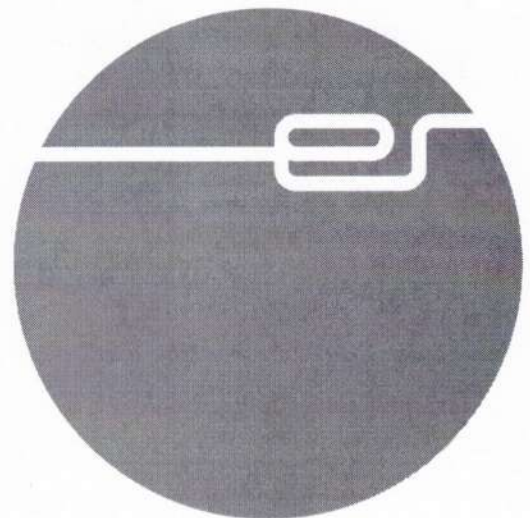
This is to certify that the modules and sub-modules can be combined on a workstation as listed below. The products are manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these products are not manufactured elsewhere.

1. VIO 3, APC 3 and ERBEJET 2
2. VIO 3, APC 3, ERBEJET 2 and IES 3
3. VIO 3, APC 3 and CRYO 2
4. VIO 300D, APC 2 and ERBEJET 2
5. VIO 300D, APC 2 and CRYO 2
6. VIO 200S and APC 2

M. Luz

Date 2023-03-21

Maik Luz, Product Specialist Global Sales Support



Proprietary Certificate

MANUFACTURER'S AUTHORIZATION

LOA 23-24/191

16.01.2024

AIIMS Rajkot,
Department of Surgery
Khanderi, Para Pipaliya, Rajkot, Gujarat, India, 360006

Sir,

Erbe Medical India Pvt. Ltd, is a 100% subsidiary of Erbe Elektromedizin GmbH Germany who are established and reputable manufacturers of Electrosurgical Diathermy Units, Advanced Vessel Sealing, and other energy solutions viz. Argon Plasma, Waterjet, Smoke evacuation and Cryo products. We have our manufacturing at Erbe Elektromedizin GmbH, Waldhorenlestrasse 17, D-72072, Tubingen, Germany.

This LOA intends to authorise **M/s Athena Medical Systems, B-1310, Ratnaakar 9 Square, Opp. Keshav Baug Party Plot, Mansi Circle Road, Vastrapur, Ahmedabad, Gujarat-380015** to submit technical specifications for Surgical workstation and related accessories, initiate all documentation formalities on our behalf. Once the tender is officially floated we would re-authorise **M/s Athena Medical Systems** to participate and do the needful formalities on or behalf."

No other vendor or supplier is authorized to represent us in the Department of Surgery.

The validity of this letter stands till 30th June 2024 or unless notified by us in writing.

Yours truly

For Erbe Medical India Pvt Ltd


Yash Sharma
Tender and Distribution Coordinator



Erbe Medical India Private Ltd., Plot No : 447, Pocket B, Sector-19, Dwarka, New Delhi – 110075, India Phone +91 11 41009808 www.erbe-india.com erbe@erbe-india.com

Deutsche Bank AG	Elektromedizin GmbH	Kreissparkasse Tuebingen	GSTIN
Chennai Branch	Walhoerndelstrasse 17	Konto 141	Delhi : 07AABCE7430L1ZK
Current Acc.No: 5006846-00-0	72072 Tuebingen,	SWIFT-BIC: SOLADES1TUB	Chennai : 33AABCE7430L1ZP
Swift Code: DEUT0916CNN	Germany	IBAN : DE546415 0020 0000 0001 41	Mumbai : 27AABCE7430L1ZJ
CIN: U33119TN2007PTC062336	erbe-med.com	BLZ: 641 500 20	Kolkata : 19AABCE7430L1ZF



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All India Institute of Medical Sciences, Rajkot, Gujarat 360110
A Central Autonomous Body under PMSSY, MoH&FW

Government of India www.aiimsrajkot.edu.in



Date: 02-12-2023

PROPRIETARY ARTICLE CERTIFICATE

GFR Rules 2017 – Rule 166(i) and 166(iii)

This is certified that

- (i) The indented goods are manufactured by ERBE
- (ii) No other make or model is acceptable for the following reasons:

Since the specification Mentioned/Attached is not Available with any other manufacturer.

- (iii) Concurrence of finance wing to the proposal vide:
.....

- (iv) Approval of the competent authority vide: *AIIMS RAJKOT / Surgery / 31/2/2024*

(Signature with date and designation
of the indenting officer)



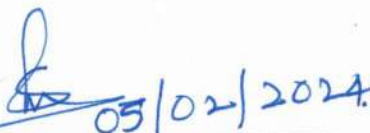


अखिल भारतीय आयुर्विज्ञान संस्थान राजकोट, गुजरात 360001
All India Institute of Medical Sciences, Rajkot, Gujarat 360001


Dated

Proprietary/Specification Brand Good Certificate

- Description of Goods : The Combined High-End RF, Argon Plasma and Water Jet Surgical Work Station with Automatic Surgical Smoke Evacuation System.
(Item/Type/Model No. required along with specifications)
- The indented goods are : **M/s Erbe Elektromedizin GmbH, Germany**
manufactured by M/s:
- Is the item a spare parts attachment : No
or accessory for an existing equipment
- Are they sole manufactures/sole : Yes
distributors of the item.
- What were the efforts made to : Open comments/objection circular may be
locate alternative source of supply or uploaded on institute website for open information
use other substitutes. and to ensure availability of any alternative item as applicable.
- Why open/limited tender can't be : PAC nature of item. The required specifications
resorted to, for locating alternative are not available with other manufacturers
source.
- No other make or model is : The required specifications are not available with
acceptable for the following reasons: other manufacturers
- Concurrence of finance wing to the :
proposal vide:
- Approval of the competent :- **AIIMSRAJKOT /surgery /31/2/2024**
authority vide:


Signature of Indenter

डॉ. मिनेश सिंधल / DR. MINESH SINDHAL
सहायक आचार्य / ASSISTANT PROFESSOR
जनरल सर्जरी विभाग
DEPARTMENT OF GENERAL SURGERY
अखिल भारतीय आयुर्विज्ञान संस्थान, राजकोट
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RAJKOT


उप निदेशक (प्रशासन)
DEPUTY DIRECTOR (ADMINISTRATION)
अखिल भारतीय आयुर्विज्ञान संस्थान, राजकोट - ३६०११०
All India Institute of Medical Sciences, Rajkot - 360110

All India Institute of Medical Sciences Rajkot

Ref No.- AIIMSRAJKOT/Surgery/31/2/2024

Dated: -05/02/24

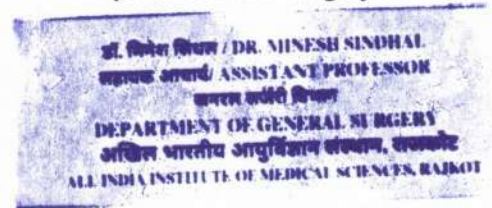
Subject: Procurement of Advanced Combined High-End RF, Argon Plasma and Water Jet Surgical Work Station with Automatic Surgical Smoke Evacuation System on PAC basis

Description	Encls No
1. It is proposed to procure Combined High-End RF, Argon Plasma and Water Jet Surgical Work Station with Automatic Surgical Smoke Evacuation System for Department of Surgery, AIIMS Rajkot.	Annexure 1
2. The technical specifications of the equipment are enclosed.	Annexure 2
3. The item is to be procured on PAC basis as it is manufactured by only one firm ERBE. The proprietary certificate submitted by OEM is enclosed.	Annexure 3
4. The equipment is also purchased by other AIIMS on PAC basis	Annexure 4
5. Draft notice required to be published on the institute website inviting comments/objections thereon from any manufacturer regarding proprietary nature of the item is enclosed.	Annexure 5
6. Approval may please be accorded to publish the notice and thereafter proceed.	

05/02/2024
Dr. Minesh Sindhal
Assistant Professor

Dept. of General Surgery

Administrative Officer



Alo i) AS Per Ref N.S-01

ii) Indent received from General Surgeon

iii) Procurement of Advanced Combined High-end RF, Argon Plasma and Water Jet Surgical Work Station with Automatic Surgical Smoke Evacuation System on PAC basis.

(P.T.O)

iv): Procurement as per GFR Rules 166.

v): P.O for approval.

J Bhatia
7/2/24

AO (Acc): (i) As per Ref. N.S. - 1

(ii) Indent received from General Surgery; Item proposed is 'proprietary' in nature. PAC certificates attached herewith; put up for approval

(iii) Expenditure will be met from GIA - Capital.

(iv) Item may be procured under GFR - 166.

S. Prasad
07/02/2024

DO (AS):

1. Ref NSI are

2. IO for consideration for procurement through PAC mode (PM) as proposed by the Dept of Surgery in line with provision of GFR 166.

[Signature]
07/02/24

THE SECRETARY TO GOVERNMENT OF PUNJAB
DEPARTMENT OF GENERAL ADMINISTRATION
CHANDIGARH

(E)

[Signature]
07/2/24