अखिलभारतीयआयुर्विज्ञानसंस्थान,गोरखपुर
All India Institute of Medical Sciences, Gorakhpur
(स्वास्थ्य एवंपरिवारकल्याणमंत्रालयभारतसरकारद्वारास्थापितएकस्वायत्तसंस्थान)
(An autonomous organization under the Ministry of Health & Family Welfare, Govt. of India)

Ref. no: - AIIMS/GKP/Admin/2022-23/5353 dated: 07.03.2023

Subject: Procurement of Cryo work station for Deptt of Pulmonary at AIIMS Gorakhpur on proprietary basis.

The Department of Pulmonary AIIMS Gorakhpur is going to procure Cryo work station for Deptt. of Pulmonary at AIIMS Gorakhpur on proprietary basis from Authorized agency M/S PCL Healthcare Ground floor, 2, Maqbara Rd, Hazratganj, Lucknow, Uttar Pradesh 226001 for Cryo work station.

Above mention documents are being uploaded for open information to submit their objections comments, if any from any manufacturer regarding proprietary nature of the above said keys within 07 days from the date of issue /uploading of the notification above given reference no.

The comments should be received by office of administrative officer, Medical College at AIIMS, Gorakhpur on or before 15th March. 2023 up to 17:00 Hrs. failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

S/D
Bhupesh Chandra
Administrative officer
AIIMS Gorakhpur

Enclosure

1. PAC certificate from ERBE Elektromedizin GmbH.

TECHNICAL SPECIFICATION OF MOBILE PULMONARY THEURAPAUTIC CRYO WORK STATION	
1	Unit should comprise of Cryo system with flexible Cryo Probes from the same OEM to perform Biopsies, Recanalization & devitalization.
2	Should be supplied with an integrated High End RF Electro Surgical Unit from the same OEM for electrosurgical Cut & Coag modes for optimum effect of HF surgery & dedicated high end Argon plasma coagulation unit also from the same OEM for homeostasis of bleeding tissues & devitalization of pathological tissues with non-contact technology for coagulation.
3	The offered equipments should have brand name / Model Number embossed / etched on the equipment, must be supported by Original Literature of the Original Equipment Manufacturer with mandatory regional & head office of the Original Equipment Manufacturer Principal company for providing after sales service with a dedicated trained service engineers / service representatives team of O.E.M Principal company.
4	The offered equipments Installation process & training should be perform by O.E.M trained service engineers / service representatives within 30 days of supply , Installation report to be submitted on O.E.M letterhead , with the mandatory provision of providing preventive services visit of O.E.M trained service engineer,' service representative quarterly per year till completion of warranty period(ie 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till completion of CMC period.
5	The offered equipments should strictly comply uptime guarantee of 95%.In case of technical snag / failure / breakdown the response time for the inspection of trained O.E.M service engineer should be within 24 hours and repair within 05 days, for major breakdown & repair time of the unit is more than a week, the mandatory provision of keeping a service machine till the period of recovery of breakdown of the unit, failing which attracts penal action.
6	The complete offered equipments accessories & consumables should be of same offered Original Equipment Manufacturer & demonstration mandatory of offered model at hospital premises at OEM cost.
7	The offered Cryc System should be, US-FDA - 510 K & European Certificate marked in accordance with the medical devices directive (93/42/EEC), EN 60601 - 1 type CF & Class I Equipment and Electromagnetic Compatibility Certificate & ISO Certificate.
8	The offered Cryo System should be programmable based, monochrome display , activation via footswitch and the minimum freezing temperature should reach within 5 seconds mounted on imported original mobile cart with wire basket & CO_2 Cylinder (01Units) compatible with cooling gas - CO_2 gas as coolant.& provided with connection pipe for gas exhaust.
9	The offered Cryc System should be flow controlled for operating gas pressure between 45 – 65 bar & should have feature to count the reprocessing cycle of the instrument.
10	The Offered System should have Effect Settings up to 5 depending on the type of instruments used, with an Programmable memory of up to 10 settings with activation from Foot Switch.
11	The offered System should work on Frequency of 50/60Hz with an line current of 0.4-0.8 Amp.
12	**The offered Cryo System should be supplied along with varrious Reusable flexible Probes,transbronchial single use probes . Reusble probes should have declared shelf life & should be recommended for Low Temperature sterilzation system ie Plasma Sterilizer or ETO or Autoclavable & compatible & existing endoscopy system**
13	The offered Mobile Cryo Workstation should be able to get synconrised with other compatible Energy Units of same make & OEM so that can be used an Advanced Workstation.
14	**Argon Plasma Coagulation** (For hameostasis of bleeding tissues & devitalisation of pathological tissues and stops bleeding, non contact technology for coagulation)
15	Should be able for the management of bleeding and devitalisation of tissue abnormalities achieved by optimal coordination with RF / ESU generator of the same make .

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16	The Argon Plasma Coagulation system should have automatic parameters setting for various types of instruments and automatic depth controlled plasma regulation.
17	Should have three different APC modes suitable for different indications
18	Precise APC – adjustment made using the effect settings
19	Pulsed APC – adjustment made using the parameter power settings
20	Forced APC – adjustment made using the parameter power settings
21	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.
22	Should have the facility to use Argon Plasma Coagulation & Monopolar Coagulation simultaneously
23	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.
24	Should give visual display of argon gas bottle content and should give Acoustic alarm when bottle content reaches a minimum.
25	Should have facility for activation of unit by foot pedal of the Electro Surgical unit.
26	Should have facility for Argon supported cutting & coagulation facility to use in double balloon endoscopy procedures
27	The Argon Plasma Coagulation system should be supplied along with following accessories/ Consumables : APC 3 button electrosurgical pencil, connecting cable probes and applicators for both Laproscopy & open Surgery (02 Units) & Argon assisted cutting instruments (applicators) for open Surgery & Laproscopic Surgery
28	The supplied Electro Surgical Unit shoulc be microprocessor controlled USFDA & European Certificate marketed in accordance with the medical devices directive (93/42/EEC), Class I Equipment & Electromagnetic Compatebility certificate & ISO Certificate
29	The supplied Electro Surgical Unit should be micro controller basec & should adjust the power to get the desired surgical effect on the tissue. All settings should be controlled by the machine and according to the tissue celiever. Power should be display on the screen with graph facility to show the deliever power.
30	The electro surgical unit should have 8 Cutting & more than 8 Coagulation Modes, namely Auto Cut, High Cut, Dry Cut, Bipolar Cut, Bipolar resection Cut (Saline). Coagulation modes should have - Soft Coagulation. Swift Coagulation , Forced Coagulation, Spray Coagulation, Bipolar soft coagulation, Bipolar forced coagulation, Bipolar resection Coagulation (Saline) Twin Coagulation, Biclamp- Bipolar Thermofusion & precise coagulation & Monopolar Cut & Coagulation Mode, two bipolar modes with Auto Bipolar start & stop & Vessel fussion technology all integratec in one system
31	The electro surgical unit should have Power and Voltage automatic regulation feature to prevent tissue damage and charring. The output voltage should be regulated in various levels with LCD Backlight adjustment for good visibility in operating room, patient plate monitoring facility, audiovisual alarm and deactivate output if contact between patient and patient plate is not proper to eliminate the risk of patient burns.
32	Should have three different APC modes suitable for different indications
33	Precise APC – adjustment made using the effect settings
34	Pulsed APC – adjustment made using the parameter power settings

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35	Forced APC – adjustment made using the parameter power settings
36	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.
37	Should have the facility to use Argon Plasma Coagulation & Monopolar Coagulation simultaneously
38	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.
39	Should give visual display of argon gas bottle content and should give Acoustic alarm when bottle content reaches a minimum.
40	Should have facility for activation of unit by foot pedal of the Electro Surgical unit.
41	Should have facility for Argon supported cutting & coagulation facility to use in double balloon endoscopy procedures
42	Should have facility for Argon supported cutting & coagulation

43 **The offered Cryo system should be also supplied along with:**

a **Flexible probes dia 1.1 mm , Length 1150 mm, with over sheath length 817 mm with over sheath dia 2.6 mm for trans bronchial procedures - 02 Box.**

b **Flexible probes dia 1.7 mm , Length 1150 mm, for trans bronchial procedures - 02 Box.**

c **Neutral electrodes / patient plate for Argon Plasma procedures - 02 Box.**

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Proprietary Certificate

To whom it may concern

ERBECRYO® 2

This is to certify that the electrosurgical device ERBECRYO® 2 is a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and this product is not manufactured elsewhere.

Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, Germany

Date 2021-01-26

Natalie Zierhut, Business Manager Asia Pacific

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Proprietary Certificate

To whom it may concern

endoCUT® I and Q

This is to certify that the modes endoCUT® I and endoCUT Q for fractionated cutting on erbe VIO electrosurgical units are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these products are not manufactured elsewhere.

Date 2019-01-21

Michael Reick, Director Business Management

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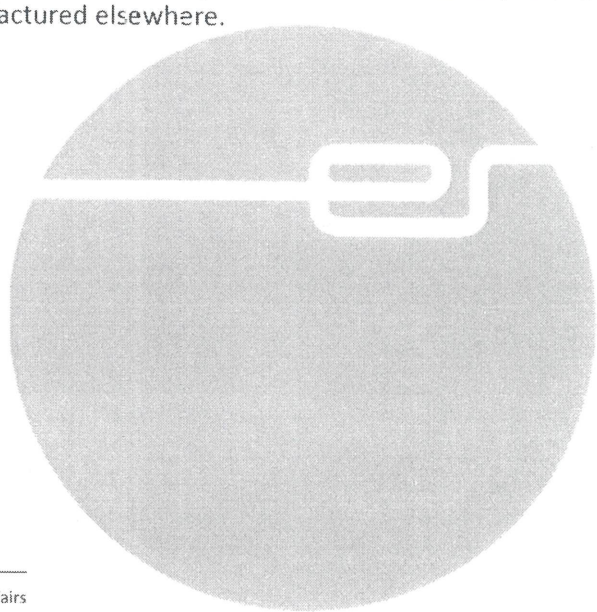
Proprietary Certificate

To whom it may concern

Erbe VIO® 3 and APC 3

This is to certify that the Erbe VIO® 3 with attached Argon Plasma Coagulation system (APC 3), that provides facility to change between programs by a ReMode button, specially designed Cut and Coag modes for different medical and surgical disciplines, like softCOAG®, preciseSECT and dryCUT® and also three different variations in Argon Plasma outputs namely FORCED APC, PULSED APC® and PRECISE APC® are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these products are not manufactured elsewhere.



Date 2019-06-12

Axel Retzlaff, Manager Regulatory Affairs