

To,

The Director RIMS,Imphal

05.01.2016

Thorugh,

Professor and HOD G.S.Moirangthem Department of Surgery GI & MAS, RIMS, Imphal

Subject: Proposal - GI Workstation

We ERBE Medical India Pvt Ltd, wholly owned subsidiary of ERBE Elektromedizin GmbH, Germany are established and reputable manufacturers of Electro surgery units having factory at Waldhoernlestrase 17, 72072 Tubingen, Germany. As a technology leader, we strive to develop the best systems – for all medical specialties and individual requirements.

The whole medical world today is moving towards the minimal invasive approach and early treatment for various diseases and disorders of mankind, for this purpose there are new treatments methods are adopted. To meet the needs of these new treatment techniques in Gastroentrology (endoscopy), ERBE Workstation supports the doctors with its state of technologies.

Please find different modules and their special roles in the field of Gastroentrology for your kind reference.

ERBE GI Workstation:

The ERBE Gastroentrology workstation is constructed at the state of art technology which contains an advanced electrosurgery generator, argon Plasma coagulator, Water jet surgery system and an irrigation pump with suitable cart for advanced gastro intestinal therapeutic applications.

Components of GI Workstation with its function:

VIO 300 D:

VIO 300 D is the advanced electrosurgery generator for endoscopy and master unit for argon plasma coagulation unit (APC 2) which provides Bipolar, Monopolar currents for all kinds of endoscopic therapeutic applications. The two special endoscopic electrosurgery modes called "ENDOCUT I "&" ENDOCUT Q" provided by VIO 300 D is proven to be the best of technologies for all endoscopic applications.



APC 2:

APC 2 is a sub system of ERBE VIO 300 D, which provides three modes of APC, such as:

- Forced APC
- Precise APC
- Pulsed APC (Effect 1, 2)

This three modes provide different characteristic out puts which is unique for treating different gastrointestinal applications such as Gastro intestinal bleed, stunt ingrowths, ablation of tumor and cancer cells, etc.,

ERBEJET 2:

ERBEJET 2 is a new dimension in waterjet surgery which have many applications in GI endoscopy and surgeries such as tissue management, needle less tissue selective elevation in GI tract for advanced endoscopic procedures.

EIP 2 and VIO Cart:

EIP 2 is the new modern irrigation system which is used for the cleaning of scope tip, flushing the procedure site for better visualization and bleed management.

VIO Cart is the one which combine all the above said technologies in one cart and provides mobile function for the workstation.



Major Applications of GI Workstation:

- 1. ERCP,
- 2. Polypectomy,
- 3. GAVE,
- 4. GI Bleed Management,
- 5. POEM (Per Oral Endoscopic Myotomy),
- 6. ESD (Endoscopic Mucosal Dissection),
- 7. EMR (Endoscopic Mucosal Resection),
- 8. STER (Submucosal Tunneling Endoscopic Resection),
- 9. Open & Lap (Liver Surgery)
- 10. Treating Barrett's Esophagus,
- 11. Treating Tumors,
- 12. Treating Cancerous tissues
- 13. Treating Stunt ingrowths, etc.

Yours Faithfully

For ERBE Medical India Pvt Ltd

Authorized Signatory



PROPRIETARY CERTIFICATE

Date: 05.01.2016

To,

The Director RIMS,Imphal

Thorugh.

Professor and HOD G.S.Moirangthem Department of Surgery GI & MAS, RIMS, Imphal

Dear Sir,

This is to certify that GI Workstation comprising of modules VIO 300D Electro Surgery Unit, APC2 Argon Plasma Coagulation Unit, ERBE JET 2 Water Surgery Unit and ERBE Endocut IQ is a proprietary item of ERBE Elektromedizin GmbH, Waldhoernlestrase 17, D-72072 Tubingen, Germany, is a proprietary product and to the best of our knowledge this product is not manufactured anywhere else.

- 1) Precise mode of APC
- 2) Filter Integrated FiAPC probe
- 3) Plug and Play function
- 4) Waterjet Surgery output for needless elevation.
- 5) Hybrid Technology for Advanced GI Applications.

Yours Truly

For ERBE Medical India P Ltd

Authorized Signatory



05th January 2016

TO WHOM SO EVER IT MAY CONCERN

This is to certify that

Shyamraj Group, A.M.S.A. Complex Opposite Pologround. Imphal-795004. INDIA.

is our authorised Channel Partner for the State of Manipur for the below mentioned products manufactured by us.

Electrosurgery Vessel Sealing Argon-Plasma Waterjet surgery Cryosurgery

They are also responsible for

- 1. All sales, marketing and promotional activities for ERBE Products.
- 2. To provide all after sales and service support.
- 3. To provide all installation, testing and commissioning of ERBE products.
- 4. To quote, negotiate, sell and handle all commercial terms directly.

They are supported by ERBE Medical India Pvt. Ltd., Chennai – 600096, India for all pre & post sales activities.

Yours Sincerely.

For ERBE Medical India Pvt. Ltd.

Authorized Signatory





Date: 5-01-16

PERFORMA INVOICE

Price for GI Work station							
. No	Cat. No	Description	Qty	Price in INR			
		Electrosurgical Unit		₹ 70,11,497.00			
1	10140-100	ERBE VIO 300 D incl. 4 socket modules, 1 system software, 1 power cord, 2 instruction manuals	1				
2	20188-300	One-pedal foot switch for VIO D/S, AP & IP X8 equipment with connecting cable 5 m	1				
3	20189-303	ReMode two-pedal foot switch for VIO D, AP & IP X8 equipment with connecting cable 5 m, ReMode function only available with VIO D	1				
		Argon Plasma Coagulation Unit					
4	10134-000	ERBE APC 2 (for VIO) Argon-Plasma-Coagulation Unit incl. 1 APC-socket module, 1 HF-socket module incl. assembly kit 20134-600, ECB-cable	1				
5	20134-004	Pressure reducer with sensor for APC 2, with manual connection gas cylinder connector to DIN 477 No. 6 m, W 21,8 outside, with hose 0,5 m with manual connection	1				
6	20132-171	Argon gas cylinder, 5 liters, empty gas cylinder connector to DIN 477 No. 6 m dimensions: height 60 cm, ø 14 cm weight 8,8 kg	2				



 		Price for GI Work station	tion		
SI.No	Cat. No	Description	Qty	Price in INR	
	***	Water Jet Surgery Unit		2000 (Million 2000)	
7	10150-000	ERBEJET 2®	1		
8	20150-101	ERBEJET 2 one pedal foot switch with ReMode; AP & IP X8 Equipment	1		
		Cart for ESU, APC and WATERJET			
9	20180-000	VIO-CART System carrier for VIO, inclusive: handle grip(high-grade steel), cable holder, footswitch holder, fastening strap and cylinder pad	1		
10	20180-131	Fastening set for VIO Cart to attach VIO/APC2/VEM2/ERBEJET2	2		
		Accessories for Vessel Sealing System			
11	20195-203	Biclamp 271T Curved 18°, L 270 mm	1		
127 10773	* ***	Accessories for Bipolar Mode		65,1010 4875	
12	20195-000	Bipolar forceps Classic, straight, tip 1 mm, blunt, length 190 mm	1		
13	20196-053	Bipolar cable BI 8/4, for Bipolar forceps, L 4m Autoclavable	1		
		Accessories for Monopolar Mode		b 0000	
•	20190-106	Electrosurgical pencil with 2 buttons, single use, sterile, pack. of 10	10	<u> </u>	
* * ***		Accessories for Neutral Electrode			
15	20193-074	Disposable Patient plate- ERBE NESSY Plate 70, split, with connecting cable 3 m	50		
	:	Accessories for Argon Plasma Coagulation System			
16	20132-043	APC handle with 2 buttons, APC 2 / VIO, APC 300 / ICC, with connecting cable 3 m with instrument recognition	1		

ShyamRaj Group



l.No	Cat. No	Description	Qty	Price in INR
17	20132-056	APC applicator, ø 5 mm, rigid, length 100 mm with adjustable spatula	1	
18	20132-133	APC-Applicator; rigid; Ø 5 mm; L 320 mm	1	
		Accessories for Water Jet System		
10	20150-300	Pump cartidge (pack of 5 nos)	5	
20	20150-038	Applicator, straight, L306 mm; ø 6 mm, with suction (pack of 5 Pics)	5	10 10 10 10 10 10 10 10 10 10 10 10 10 1
21	20340-013	Suction bag, 2.5 liters for use with suction container 20340-103	10	
22	20340-103	Suction container, 2.5 liters for use with suction bag 20340-013	1	
23	10340-000	ERBE ESM 2, suction module	1	
24	20150-050	Fastening set for ERBEJET 2 to connect to VIO/APC 2/VEM 2	1	
25	51709-008	ECB connection cable, 40cm (ERBE Communication Bus)	1	
26	20325-002	Hook for irrigation-liquid bag on bracket / VIO Cart	1	·
27	20340-002	Mounting bracket to connect to side rail	1	
28	20340-003	Switching valve w/suction hoses & mounting bracket	1	
29	20340-004	Suction hose, 60 cm length	1	2
30	20340-100	ESM membrane filter for use with silicone hose 20340-004	1	
	20183-067	Monopolar Adapter Bovie jack MO 8 - Socket - 4mm for LAP and Under water Cutting Surgery	1	
32	20132-221	FiAPC probe 2200 A, ø 2.3 mm, flexible, length 2.2 m with instrument recognition and integrated filter	1	
	le .	Su	b Total	₹ 70,11,497.00
	₹ 9,46,552.00			
100 Maria		Tot	al Price	₹ 79,58,049.00
	Ir	word, Rupees Seventy Nine lacs fifty eight thousand forty nir	ne only	
	Street attack and a street and a street attack at the street at the stre	Warranty 5 years from the date of insta		

ShyamRaj Group



Ref. No. SRG/RIMS/PROP/16/001

Date: 5th Jan 2016

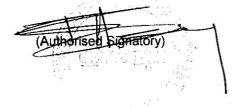
Terms and Condition:

- 1. Order: Should be place in the name of Shyamraj Group, Imphal, Manipur, India
- 2. Price: Quoted price are inclusive of Transportation and handling charge
- 3. Warranty: 5 (Five) years from the date of the installation
- 4. Installation : will be provide free of course
- 5. Training: Is Inclusive, Free at the site and as per requirement.
- 6. Delivery: will be within 45 days from the date of Order.
- 7. Annual Maintenance Contract /CMC

As Per offer of the company, CMC Charge will be as under:

- 6th Year CMC Rate Rs 3,50,574.00
- 7th Year CMC Rate Rs 3,85,632.00
- ❖ 8th Year CMC Rate Rs 4,20,689.00
- 9th Year CMC Rate Rs 4,55,747.00
- ❖ 10th Year CMC Rate Rs 4,90,804.00
- 8. All breakdown call will be attend on receipt of telephonic/Written fax message from the Institute within 24 hrs and repair will be done within 48 hours.

For, ShyamRaj Group of Companies



Usefulness of GI Workstation in

ERCP:

To open up the narrowed papilla of this ducts, a procedure called sphincterotomy is carried out with the ERBE ENDOCUT I mode, to have a bleed less precise cut of the papilla.

Polypectomy:

In GI, polypectomy is the removal of a polyp present in Upper GI and lower GI tracts.

This procedure is carried out with ERBE ENDOCUT Q (a mode resembles the instrument Snare "Q") for better haemostasis and homogenous resection.

Gastric Antral Vascular Ectasia (GAVE):

The common therapy for this disorder is applying ERBE Argon Plasma Coagulation (APC) on the bleeding spots.

POEM(Per oral Endoscopic Myotomy):

Achalasia is a motility disorder of the esophagus, characterized by aperistalsis of the esophageal body and incomplete relaxation of the lower esophageal sphincter (LES). Treatment of achalasia is currently aimed at decreasing the resting pressure in the LES. Peroral endoscopic myotomy (POEM) is an emerging novel endoscopic procedure for the treatment of achalasia with initial data suggesting an acceptable safety profile, excellent short-term symptom resolution, low incidence of postprocedural gastroesophageal reflux (GER), and improvement in manometric outcomes.

ERBE GI workstation with a multifunctional indtrument HybridKnife is used for this application.

All the steps of the POEM is carried out using ERBE Workstation and ERBE HybridKnife

:SD (Endoscopic SubMucosal dissection):

ERBE GI workstation with a multifunctional indtrument HybridKnife is used for this application.

All four steps of ESD in One station and one instrument.

- Marking
- Elevation
- Incision and Dissection
- Coagulation

STER (Submucosal tunnelling endoscopic Resection):

ERBE GI workstation with a multifunctional indtrument HybridKnife is used for this application.

All the steps of the STER is carried out using ERBE Workstation and ERBE HybridKnife



APC

Treatment of vascular malformations

Indications

- Angiodysplasia, a small vascular malformation of the gut. It is a common cause of otherwise unexplained gastrointestinal
- GAVE syndrome (watermelon stomach) Gastric antral vascular ectasia uncommon cause of chronic gastrointestinal bleeding or iron deficiency anemia.

Advantages of ERBE equipment

- Non-contact procedure, therefore no adhesion of the probe to the tissue
- Treatment that is gentle on tissue thanks to precise application
- Optimum ignition properties even at low power settings
- Axial, radial or lateral application possible Non-contact procedure, no sticking of the instrument tip to the tissue
- · Effective, even surface coagulation, for uniform hemostasis and devitalization
- Better dosage of penetration depth leads to safer application
- Minimal carbonization and smoke plume formation, minimal pollution through unpleasant odors
- Safe procedure with few complications

Tumor ablation with APC 2

Indications

- Endoluminal tumors
- · Stent ingrowth/overgrowth

- Non-contact procedure
- Effective, uniform and targeted staunching of bleeding and devitalization
- High surface energy density together with limited penetration depth
- Minimal risk of damage to metal stents

Hemostasis with APC 2

Indications

- Chronic and acute capillary bleeding
- · Bleeding following removal of biopsy samples
- Diffuse bleeding across a large area
- Acute ulcer bleeding (Forest I b to II b)

Advantages of ERBE equipment

- Non-contact procedure, no adhesion of the instrument tips
- · Effective, uniform and targeted staunching of bleeding and devitalization
- Better dosage of penetration depth leads to safer application
- Low risk of perforations thanks to limited penetration depth
- · Minimal carbonization and smoke plume formation, minimal pollution through unpleasant odors
- Axial, radial or lateral application possible
- Broad range of applications through different APC modes

Ablation of Barrett's esophagus with HybridAPC

Indications

- Low-grade dysplasia (LGD)
- · Remaining Barrett's epithelium with high-grade dysplasia following ESD, EMR

- The protective cushion increases the separation from the muscularis
- Limited APC penetration depth, minimal risk of stricture
- Effective, inexpensive procedure
- APC can be applied across surfaces or at individual spots
- · Neighboring healthy epithelium is preserved
- Targeted APC application is possible, including around corners



APC treatment of Zenker's diverticulum

Indications

• Zenker's diverticulum (pouch-like protrusion of the esophageal wall)

Advantages of ERBE equipment

- Non-contact procedure, no adhesion of the instrument tips
- Effective, uniform and targeted staunching of bleeding and devitalization
- Better dosage of penetration depth leads to safer application

ERBEJECT 2

EMR with ERBEJET® 2

Indications

- Sessile polyps
- Lesions > 2 cm using the piecemeal technique

- Needle-free, selective elevation of specific tissue layers
- Rapid tissue elevation with a high-pressure waterjet
- · Large fluid cushion
- Flat angle of application
- · Minimal risk of bleeding or perforation



POEM *(Peroral Endoscopic Myotomy) using HybridKnife®

Indications

- Esophageal motility disorders
- Achalasia
- Dysphagia

Advantages of ERBE equipment

- Waterjet and electrosurgery in a single instrument
- Shorter operation times
- Minimally-invasive surgical procedure
- Expansion of the submucosa as a result of the separation medium
- Tunnel dissection of the muscularis beneath the mucosa
- Fast convalescence as the mucosa covers the cut following surgery

Endoscopic resection of submucosal tumors (STER)

Indications

Submucosal tumors originating in the muscularis

Advantages of ERBE equipment

- Gentle exposure in the submucosal tunnel through to the target area
- Minimal risk of muscularis perforation
- Intact mucosa is used for coverage of the resection bed

ESD with HybridKnife®

Indications

- Early carcinomas
- Adenomas
- Other lesions in the gastrointestinal tract



Perhabitation of

Advantages of ERBE equipment

- High-pressure waterjet and electrosurgery in a single instrument
- · No change of instrument
- Shorter operation times
- Water cushion for mechanical and thermal protection
- Minimized risk of bleeding (blood vessels compressed by water cushion)
- En-bloc resection and RO resection possible

Recanalization of stenoses

Indications

- Stenoses (recanalization)
- Stent ingrowth/overgrowth

Advantages of ERBE equipment

- · Non-contact procedure, therefore no adhesion of the probe to the tissue
- Safe, effective and rapid coagulation, even of larger areas
- Low risk of perforations thanks to limited penetration depth
- · Minimal carbonization, better wound healing
- · Minimal risk of damage to metal stents

Partial liver resection with ERBEJET 2

Indications

- Hepatocellular carcinoma
- · metastases; arising from colorectal cancer
- Split-Liver
- Living donor / liver transplantation

Advantages of ERBE equipment

- Maximum protection of vessels
- Good visibility at the operative site due to integrated irrigation and suction
- · Minimized bleeding, controlled management of bleeding
- Reduction in the need for blood transfusions
- Shorter operation times
- Precise and intact margins along the line of dissection, no necrosis of the margins
- For open and laparoscopic surgery

VIO 300D

Polypectomy with ENDO CUT® Q

Indications

Polyps < 2 cm (flat, raised lesions, sessile, waisted or stalked polyps)

Advantages of ERBE equipment

- Precise and fast initial cut with Power Peak System
- Alternating cut and coagulation cycles
- Safe hemostasis together with a low risk of perforation
- Individual adjustment of the cutting duration and of cutting intervals
- Configurable and reproducible staunching of bleeding (4 effect settings)

Papillotomy with ENDO CUT® I

Indications

- Cholelitiasis with biliary obstruction (gallstones with bile duct blockage)
- Benign papillary stenoses
- Narrowing of the minor duodenal papilla with pancreas divisum.



- ENDO CUT I enables controlled cutting with sufficient hemostasis
- No "zipper effect"
- Fractionated cutting in CUT-COAG intervals
- Individual adjustment of the CUT-COAG intervals
- Configurable and reproducible staunching of bleeding (4 effect settings)

Technical Specifications for GI WORKSTATION:

- The unit should be GI Workstation with all necessary modalities for GI Surgery, comprising Electrosurgery unit, Argon Plasma Coagulation unit and Water Jet Resection unit with optional Suction unit, on single cart
- Electrosurgery unit should be Microprocessor controlled
- TFT Display with Focused view of current active mode
- Visual and audible alarms during activation
- Should have facility of ENDO Cut I & Q
- Facility to store programs
- Two Vessel Sealing outputs
- Should have Bipolar CUT/COAG facility
- Should have AutoStart and AutoStop facility for Bipolar modes
- Automatic control of output power according to tissue resistance
- Visual indicator for the actual power being delivered
- Vessel Sealing for Laparoscopic and open surgeries
- Monopolar CUT 200 to 300w and Monopolar COAG 60 to 200w
- Bipolar CUT 1 to 100w and Bipolar COAG 1 to 12
- Special mode for Vessel Sealing with AutoStop function
- FDA approved instruments for 7mm Vessel Sealing
- Reusable Vessel Sealing instruments for Open Surgery
- Automatic instrument recognition for vessel sealing instruments
- 5mm Laparoscopic instruments for Vessel Sealing with cutting facility
- Should have Universal Socket for Monopolar, Bipolar and Neutral electrode
- Should have continuous patient monitoring for neutral electrode

Continued.....

- Should be supplied with Argon Plasma Coagulation system
- Should have minimum three modes of Argon Plasma Coagulation including basic Argon Beam Coagulation, Pulsed Argon Beam Coagulation and Argon Beam Coagulation for Micro-surgical applications
- > Adjustable argon flow rates and automatic monitoring of argon supply
- > Visual and audible indicator for Argon Cylinder content
- Should be supplied with argon beam applicators for open and laparoscopic surgeries
- Should have facility to connect with central gas supply
- > Should have facility for activation of unit by foot pedal of the Electro surgical unit.
- > Should be supplied with Water Jet System for Liver Resection
- Pressure Range: 1 80 bar
- ➤ Volume Flow: 1 65 ml/min
- > Should have monochrome LCD display for clear view of various parameters on screen.
- > Should adapt any sterile saline solution bag (disposable) as separation medium.
- Should be compatible with Electro surgical Workstation.
- > Should have facility to individually configure programs for different specialties.
- > Water Jet activation should be via footswitch and ReMode facility for switching between two different User Settings.
- Should have facility for various Applicators suitable for Liver resection.
- > Should have facility to integrate optional suction unit and should be configurable to continuous suction or single foot pedal operation.
- Should have facility to integrate centralized suction on necessity.
- All units of workstation should be FDA/CE certified

Technical Specifications for Water Jet System:

- Pressure Range: 1 80 bar.
- Volume Flow: 1 65 ml/min.
- Should have monochrome LCD display for clear view of various parameters on screen.
- Should adapt any sterile saline solution bag (disposable) as separation medium.
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- Should have facility to integrate optional suction unit and should be configurable to continuous or single foot pedal operation.
- Should have facility to integrate centralized suction on necessity.