King George's Medical University U.P., Lucknow – 226003

Phone: 91-0522-2257540 Fax: 91-0522-2257539 Website: www.kgmu.org

No. 6503 /Finance & Account/Purchase/2023 Date: 27/09/2023

NOTICE

SUBJECT: Procurement of following item on proprietary/single source basis for Department of Surgical Oncology.

The KGMU, Lucknow intends to procure following item(s) manufactured as per mentioned against item names for Department of Surgical Oncology (CSR Fund-PFC) on Proprietary/single source basis from their authorized dealer/seller as per enclosed Technical Specifications.

S.No	Equipment/Item Name	Deptt.	Name of OEM/Make
1	HIPEC Machine with CO2 Agitation (Hyper Thermic Intra Peritoneal Chemo Therapy (HIPeC)	Surgical Oncology	M/s Combat Medical
2	COMBAT BRS HIPEC with CO2 Agitation Sets		
3	Electro-Chemotherapy Machine		M/s Sennex
4	Electro-Chemotherapy Sets		

The **Proprietary Certificate** for above item(s) submitted by principal company or their Authorized Seller/Company/Dealer is attached. The above documents are being uploaded for open information to all manufacturers/suppliers to submit objection/representation, comments on the above proposal/ proprietary/single source nature of the equipment/item within 10 days to the Finance Office, KGMU, Lucknow & Head, Department of Surgical Oncology, KGMU, Lucknow from the date mentioned above, failing which it will be presumed that any other supplier is having no comment to offer and the case will be decided on merits. The comments/objections/representations to be submitted on the following:-

1. Whether the above equipment/item is manufactured by any other manufacturer other than as per mentioned principal company or their Authorized Seller/Company/Dealer.
2. Fulfill all the parameters as per technical specifications.

Note: In case the objection is not received within 10 days, the process of procurement of the said items will be done through PAC bidding/single procurment on Gem portal.

Finance Officer
KGMU UP,Lucknow

HIPEC Machine with CO2 Agitation

1. Device should deliver the Hyperthermic intraperitoneal Chemotherapy through Peritoneal Recirculation System + Agitation with CO2.
2. It should allow aclosedtechnique togivefulldistributionof the drugwithoutthe heat loss.
3. It should have aluminium heatexchangerwhich ensures theheattransfer up to 8 locations.
4. It should have accuratetemperature delivery at settemperature between 15°C to43°C± 1°C,withautomaticagitation to ensurehomogenous drugand thermal distribution throughout the abdominal cavity and peritoneal surfaces.
5. It should have CO2 Inflow / Outflow Closed circuit CO2 supply, with 0.2µ filters.
6. It should be compatible to do open and closed HIPEC delivery techniques.
7. It should have a peristaltic pump which maintains accurate and continuous recirculation and flow rates of 1200ml/min.
8. It should have touch screen simple user interface Step by step guidance through all of the procedure. Continuous monitoring of pressure and graphical temperature readings. Easy in procedure management of pressure, flow and agitation.
9. Class I, Type B Electrical Risk Classifications.
10. Safety Alarms:
    a. Audible and visible alarms
    b. High- & Low-pressure alarm
    c. High Temperature alarms
    d. Safety lock
    e. Auto safety cut off
11. It should have pressure sensor and tube detection which ensures correct setup and use of disposable set. Pressure sensor detection of over pressure situations with automated cut off to ensure patient safety and comfort.
12. Its continuous delivery at set temperature between 15 to 43°C ± 0.5° C
13. It should have Fluid ingress protection: IPX2
14. It should have automated clamps, controlled from the touch screen, ensure a safe and easy procedure.
15. Certification : IEC/UL 60601 - 1; IEC 60601 - 1 - 2; EN 55011; CAN/ CSA - C22.2; CE120.
16. At the end of a treatment the system should enable the removal of Drug from the patient for safe disposal.
17. It should have a USB port to store data.
18. Equipment should have an integrated stand.

Essential Criteria:

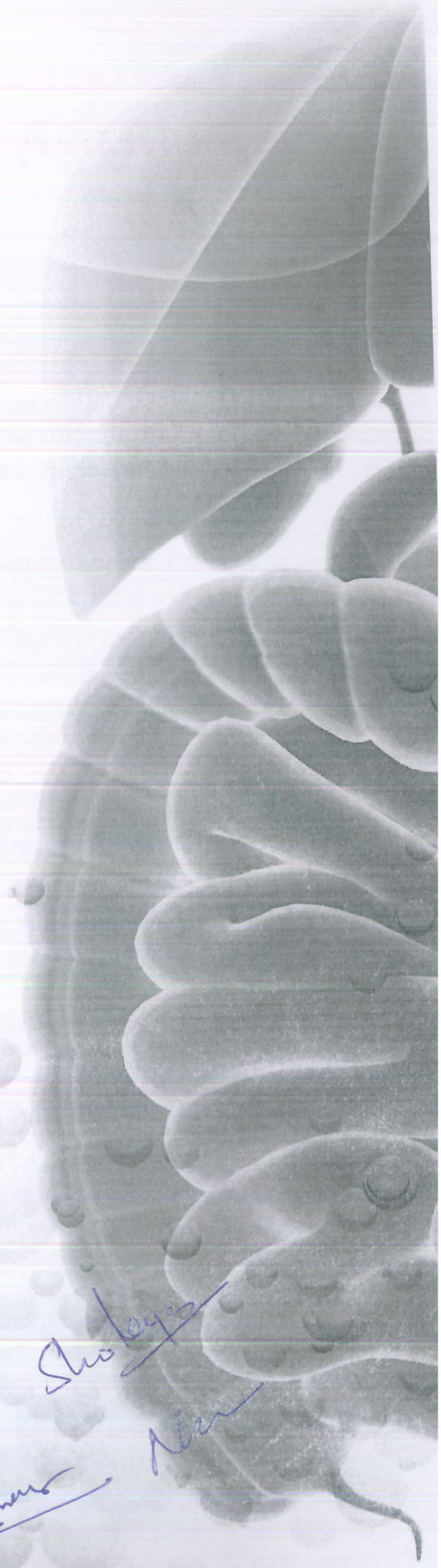
1. First 5 years equipment will be under warranty which will be covered with the cost of the equipment
2. Demonstration mandatory at hospital premises at OEM cost.
3. Training of 5 Doctors to be arranged at a centre of international repute.
4. CMC offered for quoted equipment should not be more than 5% of the quoted model with not more than 5% escalation per year after completion of warranty period – 6th to 10th year
5. CMC offered for the quoted equipment must be on OEM letterhead. (CMC offered on distributors/Vendor letterhead will not be considered).
6. Installation process should be performed by OEM trained service engineer/ service representative on OEM's letter head/ service report, with a mandatory provision of providing preventive service visit of OEM trained service engineer/service representative quarterly per year till completion of warranty period (i.e. 20 visit for first five years) and further quarterly visit (04 visits/ year) till the completion of CMC period.
7. The installation process must be completed by the OEM/Service provider within 30 days of supply.
8. In case of technical snag/ failure/breakdown, the response time for inspection should be within 24 hours and repair with 5 days, otherwise provide a service machine until the period of recovery of breakdown of the unit. Failing which will attract penal action as per the decision of the university (Uptime guarantee of 95%).
9. All the technical specifications accepted in the compliance statement must be supported by Original Literature from the firm/O.E.M with Highlighting, Numbering and flagging it's per below mentioned format for the compliance statement.

S. N o.	Technical Specification	Compliance Yes/No	Page No. in the proposal submitted where documentary evidence is enclosed as per tender Specs with highlighting Numbering & flagging

COMBAT MEDICAL

HIPEC + Agitation

Optimising **HIPEC** Delivery



HIPEC - **H**yperthermic Intra**PE**ritoneal **C**hemotherapy delivered by **COMBAT PRS+** **P**eritoneal **R**ecirculation **S**ystem + Agitation

COMBAT PRS+
Peritoneal Recirculation System + Agitation
Optimising HIPEC Delivery

HIPEC + Agitation

The COMBAT PRS System utilises an innovative, patented agitation system to optimise HIPEC treatment. Compatible with all HIPEC techniques, giving the surgeon and healthcare professionals the flexibility to choose the most suitable HIPEC technique for the patient and the disease.

Developed in collaboration with surgeons to optimise the Efficacy, Safety and Delivery of the HIPEC technique.

EFFICACY - **PRS+** is the only **HIPEC** System with automatic agitation to ensure homogenous drug and thermal distribution throughout the abdominal cavity and peritoneal surfaces to maximise safety and patient outcomes.[1,2,3]

SAFETY - Automatic agitation allows the chemotherapy to reach all peritoneal surfaces.[3] This allows a closed **HIPEC** technique to give full distribution of the drug without the heat loss and chemotherapeutic exposure of the theatre staff associated with open procedures.[1] Complete, visually confirmed filling of the abdominal cavity is also achieved via passage of the fluid into the CO_2 chamber.

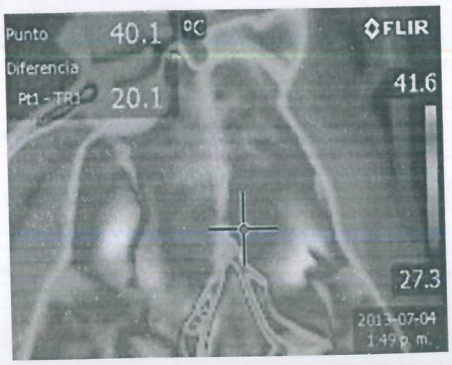
DELIVERY - Continuously monitors and controls both pressure and temperature. Temperature probes in up to 8 locations ensure heat is accurately controlled and measured to optimise both safe delivery and hyperthermic cytotoxic benefit.

Closed and laparoscopic **HIPEC** techniques using controlled intra-abdominal pressure, as performed with the **PRS+**, have also been shown to improve drug penetration into the tumour and peritoneum.[1,2]

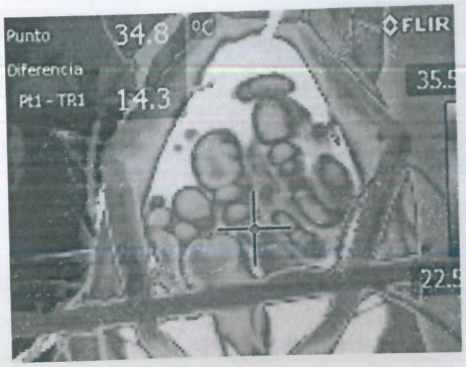
The **PRS+** patented heat exchanger and its flexible operating systems are compatible with all other open and closed **HIPEC** delivery techniques.

Successful efficacy and tolerability outcomes have been reported using the **PRS+** Agitation technique. Further results will be presented in 2018.

Closed Technique + Agitation



Open Technique

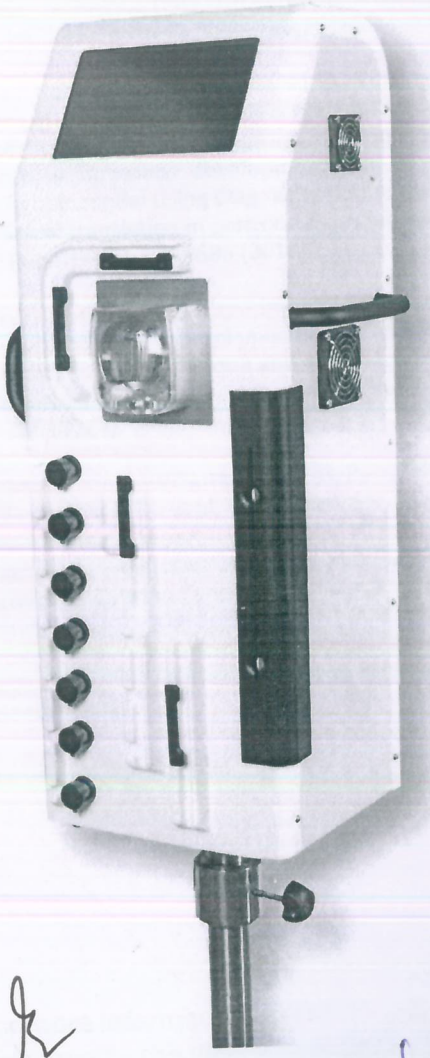


Thermographic images from the closed CO_2 technique using the COMBAT **HIPEC** + Agitation technique in a porcine model. Image shows a more homogenous delivery of heated chemotherapy in comparison to the open technique.[3]

Oncological effectiveness of the technique is demonstrated by an increase in overall survival or progression free survival in the patients studied.[1]

COMBAT Medical

The Combat group invests heavily in research & development and clinical trials to prove the **Safety, Efficacy** and **Delivery** of our technologies. We continue to work closely with clinicians on trials, evaluations and future developments to extend clinical use and optimise patient outcomes in an increasing number of disease areas.



Clinical trials

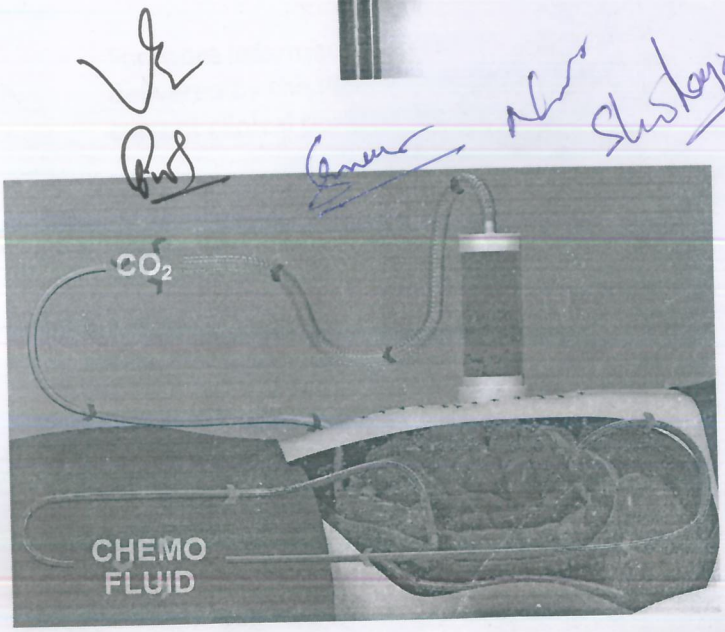
We work collaboratively with clinicians to extend the use of PRS+ to maximise the effectiveness of HIPEC. The PRS is currently being evaluated and trialled in the following areas:

Ovarian Cancer - NCT 02681432
A randomised, 72 patient, phase III clinical trial in women with epithelial primary ovarian cancer (Stage FIGO II, III and IV) or tumour recurrence. Estimated completion 2018. **Interim results from 72 patients presented in November 2017 show a 46% increase in mean survival and a 64% increase in disease free survival in the HIPEC group compared to the non HIPEC group.[4]**

Colo-Rectal - HIPECT4 - NCT02614534
Multi centre, randomised, 200 patient phase II trial across 15 centres, evaluating the safety and efficacy of HIPEC with Mitomycin C (MMC) for treating locally advanced colorectal carcinoma. Expected completion 2020.

Pancreatic - Eurdract - 2016 - 004298-41
A 42 patient, single centre, controlled, randomised, phase II trial using HIPEC with Gemcitabine in peritoneal carcinomatosis of pancreatic origin.
Trial commenced 2017, expected completion 2020.

PRS Registry
A collaboration with clinicians from the PRS working group to develop an independent and secure platform to record and analyse real world data. Helping to optimise HIPEC treatments across a range of disease areas.



Please contact us for more information on our current clinical programme.

Technical Specifications:

Physical characteristics COMBAT PRS+ System

Equipment external dimensions:
Height 870mm Width 370mm Depth 310mm

Equipment weight:
PRS system 29Kg plus stand

Safety alarms:
High temperature alarm
High pressure alarm
Auto safety cut off
Safety lock

Electrical risk classification:
Class I, Type B

Fluid ingress protection:
IPX2

Certification:
IEC/UL 60601 - 1; IEC 60601 - 1 - 2; EN 55011;
CAN/ CSA - C22.2;
CE120

Function mode:
Continuous delivery at set temprature between 15°C to 43°C ± 1°C

References:

1. Sánchez-García, S., Villarejo-Campos, P., Padilla-Valverde, D., Amo-Salas, M. & Martín-Fernández, J. Intraperitoneal chemotherapy hyperthermia (HIPEC) for peritoneal carcinomatosis of ovarian cancer origin by fluid and CO_2 recirculation using the closed abdomen technique (PRS -1.0 Combat): A clinical pilot study. Int. J. Hyperth. 32, 488–495(2016).

2. Sánchez-García, S., Padilla-Valverde, D., Villarejo-Campos, P., García-Santos, E. P. & Martín-Fernández, J. Hyperthermic chemotherapy intra-abdominal laparoscopic approach: development of a laparoscopic model using CO_2 recirculation system and clinical translation in peritoneal carcinomatosis. Int. J. Hyperth. 33, 684–689 (2017).

3. Sánchez-García, S. et al. Experimental development of an intra-abdominal chemohyperthermia model using a closed abdomen technique and a PRS -1.0 Combat CO_2 recirculation system. Surg. (United States) 155, 719–725 (2014).

4. Sánchez-García, S., Villarejo-Campos, P., Padilla-Valverde, D., et al. Hyperthermic Intraperitoneal Chemotherapy with a closed technique and recirculation of CO_2 with Paclitaxel in Advanced Ovarian Cancer. Preliminary results of clinical trial 10-008, EudraCT 2011-006319-69, NCT02681432. Oral Communication. Congreso SEOQ y Reunión GECOP, Palma de Mallorca, España, 8-10 noviembre 2017.

COMBAT Group continues to demonstrate:

- **Innovative product development**
- **Investment and commitment to clinical trials and support**
- **Excellence in training, education and customer service**
- **Expansion of its clinical working advisory group throughout Europe**

For more information on **HIPEC** + Agitation delivered by the **PRS+** including details of the current clinical programme please contact us on:

Tel/Fax: +44 1582 834 466
Email: prs@combat-medical.com
Visit: www.combat-medical.com

COMBAT MEDICAL

Manufactured by BIOsurgical
part of the COMBAT group

HIP001-01EN0118

PRS CO2 with agitation machine (HIPEC) sets (consumables) Technical Specifications

	Content	Characteristics
1	Heat exchanger	Component where the fluid is heated, in contact with the heating plates of the PRS+ HIPEC System. Purged volume: 200ml Maximum pressure: 450mmHg (600mBar)
2	Bag 2A: Aspiration tubing (Blue)	Tubes where the fluid circulates form the patient to the PRS+ HIPEC System. Includes a temperature probe and a pressure probe.
	Bag 2B: Irrigation tubing (white)	Tubes where the fluid is circulating form the PRS+ HIPEC System to the patient.
3	Bag 3A: Surgical field connection tubing	Includes the aspiration tubing (blue) and the irrigation tubing (white), both including a temperature probe. These tubes, situated in the surgical field, connect the aspiration and irrigation tubing from Bag 2 to Bag 3 catheters.
	Bag 3B1: Aspiration catheter (blue)	Includes the intraperitoneal catheters: - Fluid aspiration catheter - Fluid irrigation catheter - CO_2 injection catheter
	Bag 3B2: Irrigation catheter (white)	
	Bag 3B3: CO_2 injection catheter	
4	Sample collection tube	Allows collection of the fluid recirculated (Not in use).
5	Mushroom (reservoir connector)	Allows aspiration of CO_2 and fluid without damage to the viscera and secures the CO_2 chamber. Secures the tightness and the stability of the reservoir.
6	Wide ridged CO_2 tubes	Tubes connected to the PRS+ System for the injection and aspiration of CO_2 in the intraperitoneal space.
7	CO_2 HEPA filters and balloon	Includes: - 2 CO_2 filters connecting to the CO_2 entry and exit of the equipment. - A balloon which shows the quantity of gas inside the circuit.
8	Authority Letter	- The bidder should have authorization letter for this machine sets in original from the manufacturer.
9	Preheating and drainage bags	Includes: - 1 bag for the fluid pre-heating 2 bags for the collection of fluid at the end of the HIPEC treatment.

Electro-Chemotherapy machine- Technical Specifications

1. Electro-Chemotherapy system will be used for solid tumours of any histology and malignancy
3. Electro-Chemotherapy should be EU-CE Certified.
4. Electrochemotherapy (ECT) machine should produce high voltage (1000 V) 8 electric pulses for very short period of time with Pulses length 100 µs & pause between pulses is 100 MS.
5. ECT Machine should have Pre-programmed operating software & Linux based operating system.
6. ECT Machine should have Screen visualization with Pre & Post treatment pulse confirmation with beep sound.
7. ECT Machine should have storage to maintain the Patient treatment data.
8. Device compatible with Linear & pentagon Probe for the use of electrodes.
9. It should have VGA port for secondary display output.
10. ECT Machine must have Resistive Touch Screen & Panel PC with Alu-stand.
11. ECT Machine should be assisted with handle probe and foot pedal.
13. It should have USB compatible foot switch to give high voltage electric pulses.
14. It should have touch-screen facility. Feedback on cell response can be viewed on-screen.
15. Compatible with Power supply 100V - 240 VAC / 50-60 Hz Power input: 90 W
16. It should be installed in other AIIMS Institute or other Govt. Hospital with the mentioned technical specifications.
17. It should have Class I Protection for electrical risks & Type BF Protection for against electric shock according RL 93/42 EEC rule 9 of annex 9: active medical device of class IIb.

Essential Criteria:

1. First 5 years equipment will be under warranty which will be included in the cost.
2. Demonstration mandatory at hospital premises at OEM cost.
3. CMC offered for quoted equipment should not be more than 5% of the quoted model with not more than 5% escalation per year after completion of warranty period – 6th to 10th year

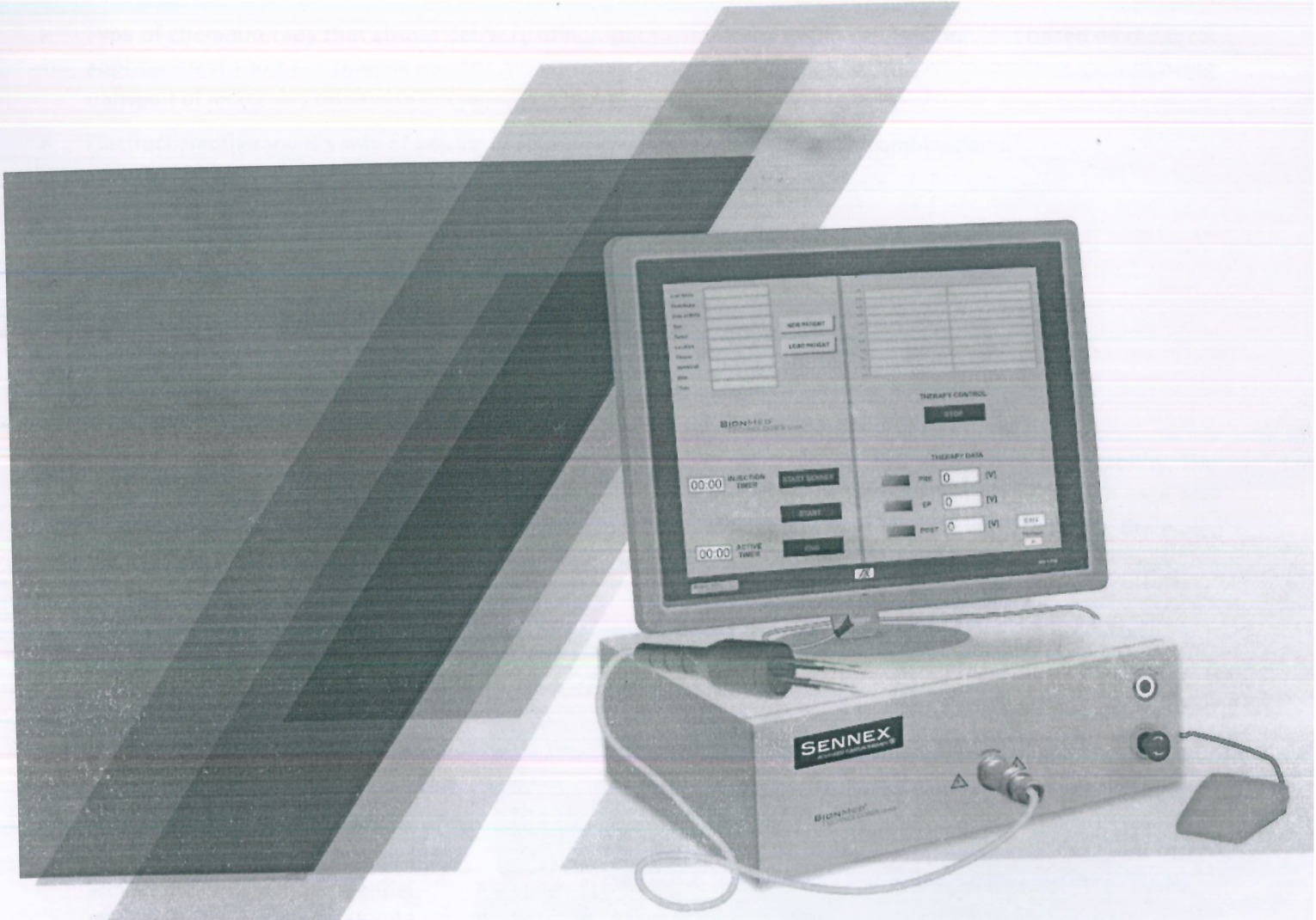
4. CMC offered for the quoted equipment must be on OEM letterhead. (CMC offered on distributors/Vendor letterhead will not be considered).
5. Installation process should be performed by OEM trained service engineer/ service representative on OEM's letter head/ service report, with a mandatory provision of providing preventive service visit of OEM trained service engineer/service representative quarterly per year till completion of warranty period (i.e., 20 visit for first five years) and further quarterly visit (o4 visits/ year) till the completion of CMC period.
6. The installation process must be completed by the OEM/Service provider within 30 days of supply.
7. The necessaries/consumables utilized during the period of installation process should be taken care FOC by OEM/Service provider.
8. In case of technical snag/ failure/breakdown, the response time for inspection should be within 24 hours and repair with 5 days, otherwise provide a service machine until the period of recovery of breakdown of the unit. Failing which will attract penal action as per the decision of the university (Uptime guarantee of 95%).
9. All the technical specifications accepted in the compliance statement must be supported by Original Literature from the firm/O.E.M with Highlighting, Numbering and flagging it's per below mentioned format for the compliance statement.

S. N o.	Technical Specification	Compliance Yes/No	Page No. in the proposal submitted where documentary evidence is enclosed as per tender Specs with highlighting Numbering & flagging

Brainrootz Labs

SENNEX®

ADVANCED TUMOUR THERAPY



ElectroChemo Therapy for Local Tumour Control

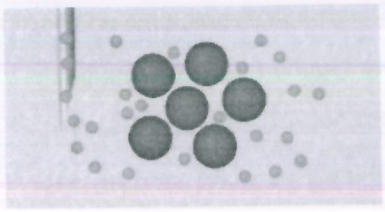
ONMED®
India

ElectroChemoTherapy

- Effective way of treating cutaneous and subcutaneous tumours, irrespective of their origin or of their current or prior treatment regime
- Type of chemotherapy that allows delivery of non-permeant drugs to the cell interior. It is based on the local application of short and intense electric pulses that transiently permeabilize the cell membrane, thus allowing transport of molecules otherwise not permitted by the membrane
- Electrochemotherapy is a way of getting chemotherapy into cancer cells. It is a combination of
  - + Chemotherapy injected into the tumour or bloodstream
  - + Using an electric pulse to send the chemotherapy into the cancer cells - electroporation

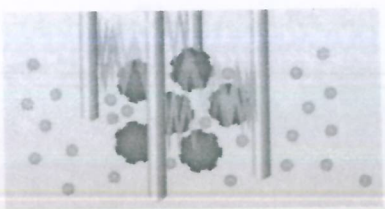
The Process - Injecting the drug

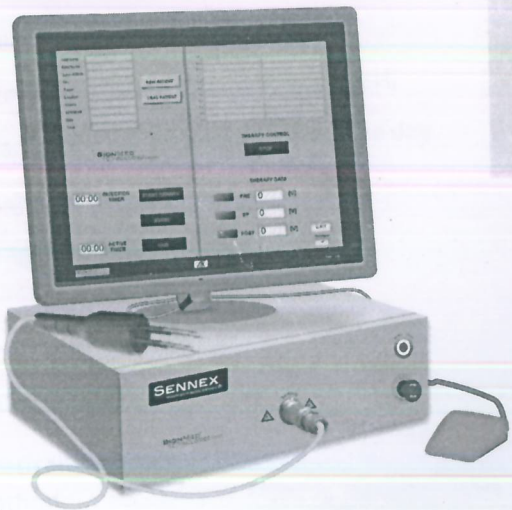
1. Chemotherapeutic drug Bleomycin is injected intra-tumorally or through I.V. after administering local anaesthesia at tumour location. In case of Cisplatin, the injection has to be intra-tumoral.



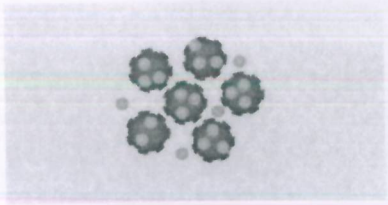
2. With the help SENNEX® device, electrodes are inserted into and around the tumour. It is essential that the electric field should cover the entire tumour.

   SENNEX® System is pre-programmed to deliver eight extremely short high voltage electric impulses. This results in creation of nano pores in the membrane of cancer cells.

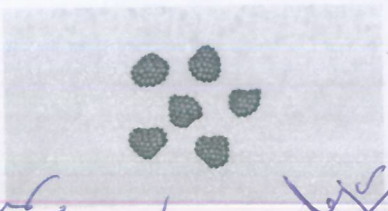




3. Pores increase cell membrane permeability. The drug diffuses into the tumour cells with ease and efficiency. When electric impulses stop, the pores close. Drug gets trapped inside the cancer cells.



4. Trapped drug targets the cell and unfolds its effect. Cell DNA is destroyed, resulting in cell necrosis. SENNEX® inhibits blood supply to tumour cells, which adds to the effect. Only cancer cells are affected. Normal cells remain intact.



Application

ECT is given locally at tumour site. Tumours which are within 15mm to 20mm depth from the skin's surface can be treated with SENNEX® Electrochemotherapy.

Tumours treated by electrochemotherapy :

- Head and neck squamous cell carcinoma
- Malignant melanoma
- Basal cell carcinoma
- Adenocarcinoma of the breast
  - Ductal carcinoma in SITU
  - Invasive ductal carcinoma
  - Inavasive lobular carcinoma
- Adenocarcinoma of salivary gland
- Hypernephroma
- Kaposi sarcoma
- Transitional cell carcinoma
- Breast Cancer

Advantages

- Achieves tumour control locally. Tumour either disappears completely or reduces in size.
- Achieves pain control at tumour site.
- It is a 20 to 30 minutes procedure.
- Affects only cancer cells. Healthy cells are unaffected.
- Stops oozing and bleeding from tumour.
- Improves quality of life and social interaction due to improved cosmesis.
- Usually done under local anaesthesia. Patient can go home on the same day.
- No major adverse side-effects, as drug dose is very small.
- Can activate body's immune system against cancer.
- Response rate to treatment is high.

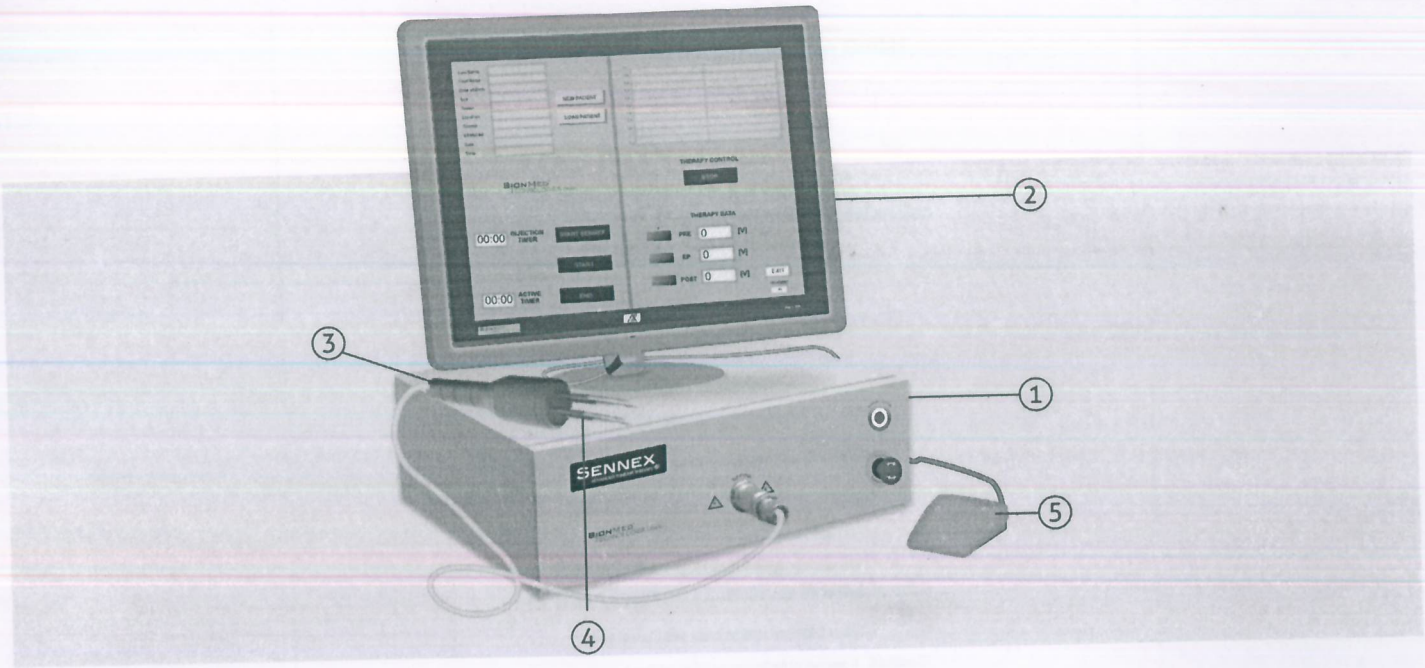
Success of Electrochemotherapy

Electrochemotherapy has been systematically examined in Europe. In a study conducted, a total of 1009 nodules in 247 patients were treated via ECT method. In accordance with objective criteria, the therapy was successful in an average of 85% of the treated cases responding to treatment. The response rate was 73.7%.

ElectroChemoTherapy - The Indian Journey.

- Long Journey
- from hesitant begining....
- Today
  - + around 50 Surgeons in multiple hospitals
  - + in over 10 cities using the methodology

SENNEX® ElectroChemoTherapy



① **Controller**
Controller is connected to the electric source. It controls the delivery of impulses.

② **Screen**
Details are entered with touch-screen facility. Feedback on cell response can be viewed on-screen.

③ **Probe**
Used for depositing electrodes and passing electric impulses.

④ **Electrodes**
The consumable material. New set of electrodes to be used for every procedure.

⑤ **Foot Pedal**
Device is operated with the foot pedal.

Features

- User friendly, comfortable touch screen operations.
- Very simple menu logic.
- Patient data and therapy parameters stored.
- Quick visual feedback on 'therapy progress'.

ONMED
ElectroChemoTherapy

SENNEX®
ADVANCED TUMOUR THERAPY

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

BIONMED® TECHNOLOGIES GmbH
Science Park 2, Universität des Saarlandes
66123 Saarbrücken
Germany

for the scope

system for tumour treatment SENNEX®

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2015-11-04
Valid until	2018-07-08
Registration no.	D1235100014
Report no.	P15-01275-53621
Stuttgart	2015-11-04

Head of Certification Body

medical device certification mdc

ZLG-BS-246.10.05

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

For electronic publication only

Medical Certification of the SENNEX®(Model Code PIE-Sys®)
Tumour System according to Directive 93/42/EEC
on Medical Devices Certificate

BRAINROOTZ LABS HAVING TECHNICAL COLLABORATION WITH BRYOGEN ONCOLOGY

BRYOGEN

CORPORATE OFFICE

BRYOGEN PHARMACEUTICALS PVT. LTD.
Building No - 5 Tower C, Level 20 DLF Epitome,
Phase III, DLF Cyber City Gurgaon - 122002

Brainrootz

BRANCH OFFICE

6A(6B),3rd Floor ,Bryogen Tower, Shivaji Marg,
Najafgarh Road, Industrial Area, Moti Nagar
New Delhi -110015 PH .: + 91-011-40204382
Email : support@brainrootzlabs.com
Web - www.brainrootzlabs.com

Specifications for Electrochemotherapy Tumor System needle electrodes (PAC)

Needle electrodes the material should be SUS303.

Should resist scaling at temperatures up to 1600 F (871 C).

During the treatment with the heat generation in the tissue around the needle electrodes should have a maximum of 37, 2 deg C.

Medically approved and sterilized needle electrodes (material: stainless steel; single use).

BIONMED®
TECHNOLOGIES GmbH

BionMed® Technologies GmbH · Science Park 2 · 66123 Saarbrücken · Germany

Science Park 2, Universität des Saarlandes,
66123 Saarbrücken, Germany
Fon: + 49 (0)681 6851903 / Fax: +49 (0)681 6851879
Mail: info@bionmed.de / Net: www.bionmed.de

Declaration for SENNEX® Tumor System about the material of the needle electrodes

In accordance to the manufacturer of the needle electrodes the material is SUS303.

SUS303 is one of the most popular of all the free machining stainless steels. SUS303 offers good strength, corrosion resistance and great machinability. It will resist scaling at temperatures up to 1600 F(871 C).

SUS303 Chemical composition :

	C	Cr	P	S	Mo	Fe	Mn	Ni	Si
Min		17		0.15		Balance		8	
Max	0.15	19	0.2		0.6	Balance	2	10	1

SUS303 Physical properties :

Density (lb / cu. in.)	0.282
Specific Gravity	7.84
Specific Heat (Btu/lb/Deg F - [32-212 Deg F])	0.12
Electrical Resistivity (microhm-cm (at 68 Deg F)	432
Melting Point (Deg F)	2650
Modulus of Elasticity Tension	28

Saarbrücken, Germany, 2016-09-08

Thomas Warnke

BIONMED TECHNOLOGIES GmbH
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Zertifiziertes QM-System
mdc
ISO 13485
ISO 9001

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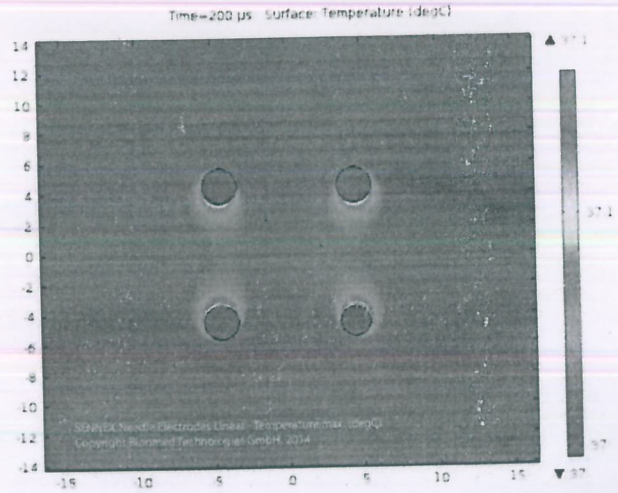
Declaration for SENNEX® Tumor System about the temperature development around the electrodes

We hereby declare that we are using for our medical product SENNEX® only medical approved and sterilized needle electrodes (material: stainless steel; single use).

During the treatment with SENNEX® the heat generation in the tissue around the needle electrodes has a maximum of 37,2 degC.



Pic.: Heat generation around the electrodes after a SENNEX® treatment session. Measurement done by Fraunhofer Institut, Germany.

Saarbrücken, Germany, 2016-09-08

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