

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

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

No. 6802/Finance & Account/Purchase/23

Dated: 17/10/2023

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

Ref.: Notice No. 6583/Finance & Account/Purchase/2023 dated 27.09.2023.

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	Electro-Chemotherapy Machine	Surgical Oncology	M/s Sennex
2	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 07 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 07 days, the process of procurement of the said items will be done through PAC bidding/single procurement on Gem portal.


Finance Officer
KGMU UP, Lucknow

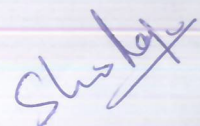
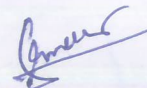
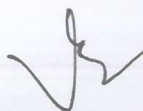
Finance Officer
King George's Medical University
Uttar Pradesh Lucknow

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 μ s & 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 (04 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 necessities/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

[Handwritten signature]

[Handwritten signature]

[Handwritten signature]

[Handwritten signature]

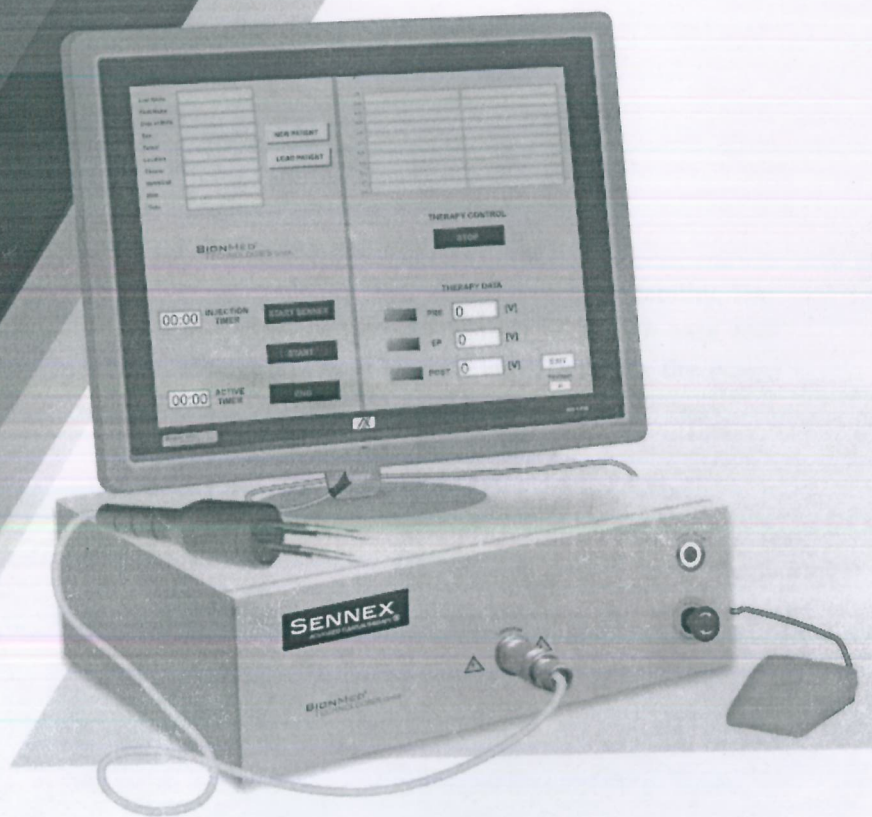
[Handwritten signature]



Brainrootz Labs

SENNEX[®]

ADVANCED TUMOUR THERAPY



ElectroChemo Therapy for Local Tumour Control

[Handwritten signatures]

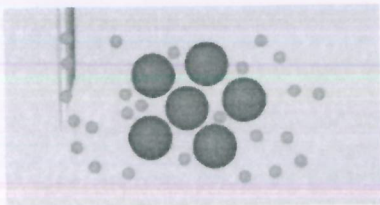
ONMED[®]
India

ElectroChemoTherapy

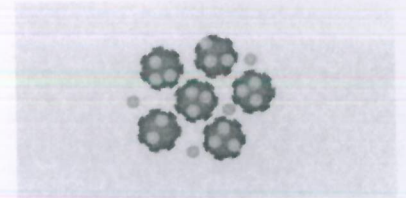
- Effective way of treating cutaneous and subcutaneous tumours, irrespective of their origin or of their current or prior treatment regime
- Type of chemotherapy that allows delivery of non-permeant drugs to the cell interior. It is based on the local application of short and intense electric pulses 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.



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.

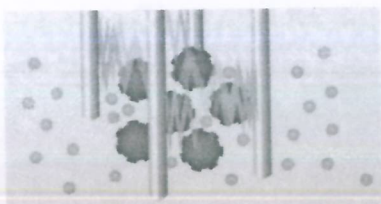


2 With the help SENNEX[®] device, electrodes are inserted into and around the tumour. It is essential that the electric field should cover the entire tumour.

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.



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.



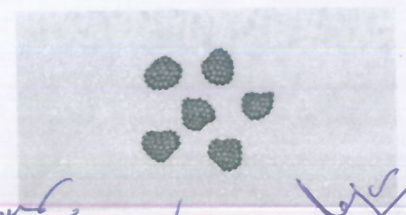
Handwritten signature

Handwritten signature

Handwritten signature

Handwritten signature

Handwritten signature



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
 - Invasive lobular carcinoma
- Adenocarcinoma of salivary gland
- Hypernephroma
- Kaposi sarcoma
- Transitional cell carcinoma
- Breast Cancer

Advantages

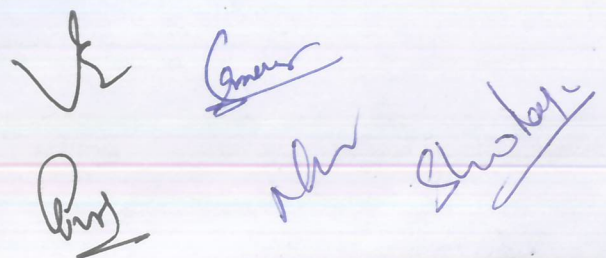
- Achieves tumour control locally. Tumour either disappears completely or reduces in size.
- Achieves pain control at tumour site.
- It is a 20 to 30 minutes procedure.
- Affects only cancer cells. Healthy cells are unaffected.
- Stops oozing and bleeding from tumour.
- Improves quality of life and social 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.

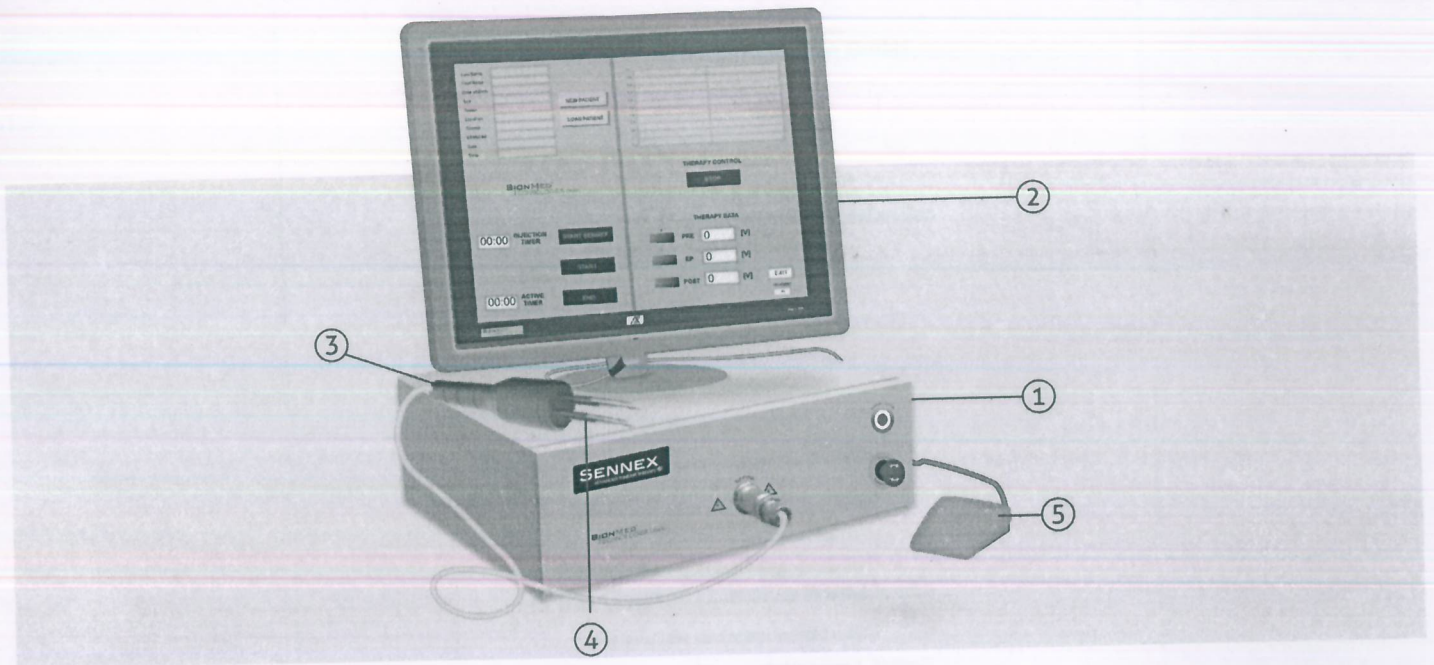
Success of Electrochemotherapy

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 beginning....
- 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'.

Vr

Prof

Sennex

Man

Sushep

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

Handwritten signature

Head of Certification Body



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



CORPORATE OFFICE

BRYOGEN PHARMACEUTICALS PVT. LTD.

Building No - 5 Tower C, Level 20 DLF Epitome,
Phase III, DLF Cyber City Gurgaon - 122002



Brainrootz^{lab}

BRANCH OFFICE

Handwritten signatures: V, P, S, C, M

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).

✓

PAC

Genova PLM

Sustops

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
Science Park 2 · 66123 Saarbrücken
Germany
Warnke

Bionmed Technologies GmbH
CEO

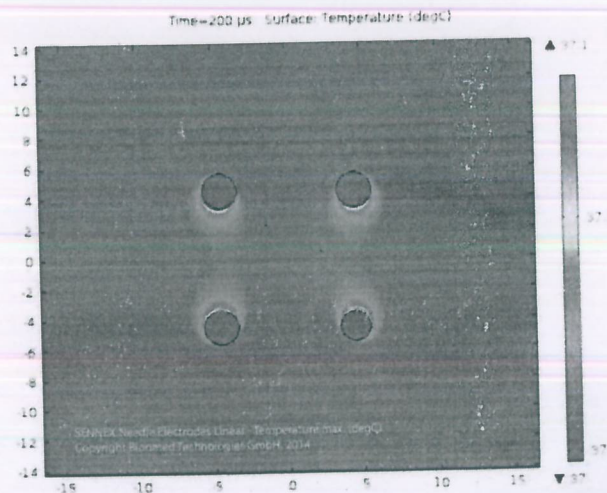
Warnke *Warnke* *Warnke* *Warnke*



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

Thomas Warnke

BIONMED TECHNOLOGIES
Science Park 2 · 66123 Saarbrücken
Germany *Warnke*

Bionmed Technologies GmbH
CEO

Warnke *Gruber* *Strohriegel*
Reich *Neu*

