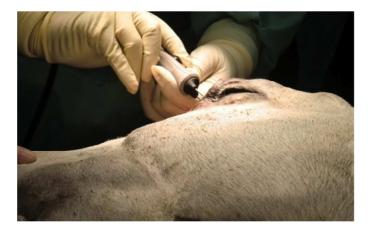
Btech



ELECTRO vet S13

Veterinary device for electrochemotherapy treatment of solid tumors



ELECTROCHEMOTHERAPY is a new method in the treatment of cancer. It combines the administration of an anticancer drug and electrical field pulses at the site of the tumor. By increasing the permeability of the cell membrane, a targeted injection of the cytotoxic molecule ensures a precise, efficient eradication of tumors.



BUREAU D'ETUDES TECHNIQUES EN AUTOMATISME, ELECTRONIQUE ET INFORMATIQUE INDUSTRIELLE 35 BOULEVARD DU LIBRE ECHANGE – 31650 SAINT-ORENS-DE-GAMEVILLE - TÉL : 33 (0)5 34 30 40 00 RCS Toulouse B 392 315 206 - N°TVA: FR10392315206 - A PE 7112B **ELECTRO vet S13** is an electropulsator <u>for use exclusively on animals</u>. The manufacturer is not responsable for any other use. This device has not yet received certification for medical use on humans.

This device must be used solely by trained professionals. Please refer to the User Manual for instructions, maintenance, and safety guidelines.

1. Description

ELECTRO vet S13 is composed of:

- > A square wave generator
- > Integrated software with a touch-screen interface to control electrical pulses
- > A hand-held electrode holder equipped with a pulse activating button, attached to the generator by a cord.
- Removable and re-usable electrodes in L-form; Please refer to the ELECTRO vet instruction manual for cleaning and disinfection procedures.
- > A foot-switch that controls electrical pulse delivery.

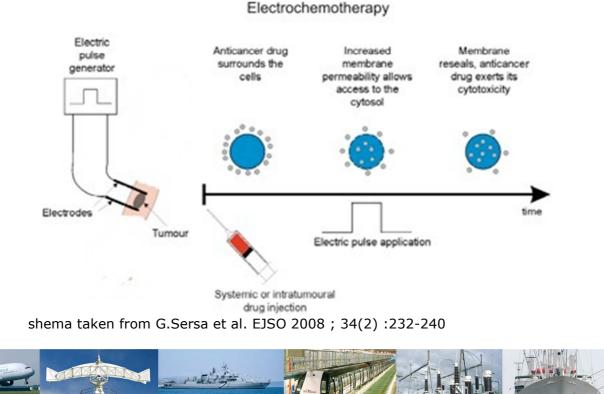
<u>2. Uses</u>

ELECTRO vet S13 was engineered for veterinary Electrochemotherapy (ECT) and Electrogenetherapy(EGT) treatments applied on cutaneous and subcutaneous tumor nodules, specifically in horses, cats and dogs.

3. Method

When electrical pulses are applied to the skin tissue, a temporary and reversible permeability of the cell membranes appears between the electrodes. This increases penetration of hydrophilic anticancer drugs and results in a significant therapeutic benefit.

Optimal parameters of electrical pulses (eg. number, duration, voltage and repetition frequency) are set according to the chosen protocol, ECT or EGT. For user and patient safety, these parameters cannot be adjusted.



4. Instructions for use¹

4.1. Important

Due to their intrinsic toxicity, anticancer drugs are to be used and handled according to Standards of Veterinary Practices followed by the resident country.

4.2. Treatment procedure

• 4.2.1. Drug administration

ECT treatment is conducted under short duration general anaesthesia. (Electrical treatment is not tolerated by conscious horses, even with heavy sedation.)

The tumor site is prepared aseptically. Anticancer drug is infiltrated into the lesion and surrounding 2cm using a syringe needle. Proceed carefully in order to obtain uniform drug distribution. For cisplatin, the recommended dose is 0,3mg/cm3 of targeted tumoral tissue.

• <u>4.2.2. Electrochemotherapy (ECT)</u>

ELECTROvet S13 switched on, screen proposes:

- 1. Select animal: Horse / Dog / Cat,
- 2. Select treatment: ECT,
- 3. Insert animal data: owner's name, animal's name, race, age,
- <u>4.</u> Prepare electrical pulse transmission by touching the screen or applying pressure to foot-switch,
- 5. Start electrical pulse delivery by pushing on the button of the hand-held electrode holder (series of 8 electrical pulses for ECT protocol, lasting 5 ms).

Within 5 to 15 minutes post drug injection, the electrical treatment is performed. The stainless steel electrodes are applied to skin prepared with ultrasonic gel for better contact.

The first delivery of 8 electrical pulses is obtained in one shot. A second series of 8 pulses is performed, placing the electrodes perpendicular to the first electrode placement. Parameters for each electrical pulse are 100µs at 1300V/cm, with a frequency of 500Hz.

Treatment should include a series of multiple ECT sessions given at 2 weeks interval depending on the tumor size and responsivity.

4.3. Side effects

Muscular contractions, mainly restricted to the skin muscle in the treated area, are observed in response to the electrical pulses.

In the hours and days post treatment, local tissue responses such as pain, oedema, and inflammation may occur. These reactions are classified as *grade I* and self-limiting.

¹ Data taken from study, Successful treatment of equine sarcoïds with cisplatinelectrochemotherapy : a retrospective study of 48 cases. -Y.Tamzali et al., Equine Vet J 2012 ;44(2) :214-220



5. Data retrieval

User interface is obtained through the LCD touch-screen. The device can also be set with a computer via an Ethernet connection.

A detailed description of each treatment session can be saved in a .CSV file, in text format.

6. Technical specifications

Power Supply		
Maximum output voltage	1350(ECT), 500(EGT)	V
Operating current	0 - 6	А
Capacitance value	94 +/-20%	μF
Pulse current circuit break	> 6	А
Load time at 90% full scale	< 20	S
Voltage precision	8	V
Command		
Pulses duration	100 (ECT), 5000 (EGT)	μs
Resolution	5	μs
Pulse length precision	<1	%
Pulse repetition frequency (1/P)	500 (ECT), NA(EGT)	Hz
Pulse number	8 (ECT), 1 (EGT)	
Commutation		
Rise up time 10 to 90% full scale	400	ns

7. Conformity and CE mark

ELECTRO vet S13 meets the requirements of the following European Directives:

- Low voltage directive 2006/95/EC (12/12/2006) applicable to electrical equipment and electrical appliances designed for use within certain voltage limits.
- **EMC directive 2004/108/EC (15/12/2004)** concerning ElectroMagnetic Compatibility.

8. References

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