DATA SHEET

Accustim-P

REF ACST-1P

CE 0476

Product code:	ACST-1P
National repertory number:	1432454
CND classification:	Z12101106
CE class:	IIa

ELECTRIC STIMULATOR FOR PERIPHERAL NERVOUS TISSUES

INDICATION

Occipital and Supraorbital Neuralgia, Neuropathic Abdominal Pain, Myofascial Pain, Post-Herpetic Pain, Post-Mastectomy Pain, Cicatricial and Post-operative Pain, Allodynia Pain, CRPS, "Phantom Limb" Syndromes, Peripheral SCS Trial.

DESCRIPTION

ACCUSTIM-P device is an external neurostimulator used in acute and chronic pain treatments. It is used combined to electrodes (Bioampere P-LEAD and E-CATH) specifically designed for subcutaneous neurostimulation, of several lengths, having different characteristics depending on the specific type of application. The whole system is designed for using of maximum 30 days.

Use of ACCUSTIM-P systems, combined to P-LEAD electrodes or E-CATH electrocatheter, is recommended in all cases where it is necessary a treatment peripheral neurostimulation in clinical pictures where the pharmacological treatment did not bring appreciable results.

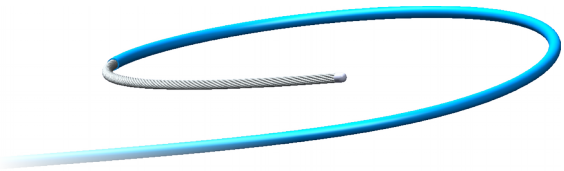
The ACCUSTIM-P neurostimulator is a DISPOSABLE electrical device powered by batteries. These one are contained inside the stimulator and are NOT interchangeable, because not required for the proper use of the stimulating system. The stimulator's autonomy is sufficient to carry out treatments up to 30 days. At the end of this period, the stimulator will not be necessary and may be thrown according to the present rules that governing the proper disposal of electronic equipment containing electric batteries.

The ACCUSTIM-P neurostimulator generates a series of bright electrical impulses of which it is possible to adjust all electrical parameters (amplitude, frequency, pulse width etc.). The electrical signal generated by the stimulator, is applied in target subcutaneous area of patient, through electrodes supplied with the stimulator. Parametric settings of the electrical stimulus must be set on the basis of the patient's relief sensations.

USING

The clinical picture of the patient, the kind of subcutaneous structure to be treated and the access area of the stimulation terminal, can induce the physician to use one of the following two types of stimulation terminal:

- P-LEAD electrode: It is a thin and flexible electrode (0.4mm section) that is inserted under the skin through the Tuohy needle included in the system. The electrode will be inserted subcutaneously for the exact portion to be used for stimulation: the stimulation current will go only in the inserted electrode portion under the skin, NOT in the rest of electrode outside the access hole. There are three standard sizes of electrodes from 50mm to 150mm. The 200mm electrode is available on request. It is possible to use one electrode in a monopolar configuration with the use of a dispersion ground-plate, or in a bipolar configuration with the simultaneous use of two P-LEAD electrodes.



- E-CATH electrocatheter: It is a thin electrocatheter (0.9mm section) with an infusional lumen, stylet and two electrodes on the lead tip to perform bipolar neurostimulation. These electrodes will be inserted subcutaneously, with its own introducer included in the system, until reaching the nerve structure to be treated. Once positioned, the stylet is pull out and the system is ready to perform the stimulation. The stimulation current will go from one electrode to another one, so the use of dispersion plates is not necessary. With this electrocatheter it is possible to combine the neurostimulation treatment with possible pharmacological treatment through the infusional lumen.

KIND OF TREATMENTS

Technical features of this neurostimulator allow programming several treatment cycles according to the clinical picture and the particular conditions of the patient. Most common treatments are already stored inside the device and will be sufficient simply to select them.

The stimulator has different ways of performing the stimulation signal and each treatment can be obtained from a particular combination of these different working modes.

With this neurostimulator it is possible to:

- To emit stimulation pulses in ***continuous mode*** during the whole treatment period: this working mode is useful and often selected in the trial neuromodulation treatments, to evaluate the of a definitive implant at the end of treatment;
- Stimulate the area in ***cyclic mode***. In this working mode the stimulator alternates periods of signal emission with periods of standby in which the stimulator does not generate any electrical stimulation; this feature allows to adjust periods and breaks from 5 minutes up to 12 hours..
- Stimulate the pain area simultaneously at low frequencies (typically 2Hz), where motor fibers are involved and at higher frequencies (typically 100Hz), where are involved sensory nerve structures. This kind of stimulation (***PENS Therapy***) can be regulated by varying the periods of "sensory" and "motor" stimulation starting from a few seconds, up to several minutes.
- Performing both ***monopolar stimulation*** and ***bipolar stimulation.*** The latter one is obtained by connecting to the stimulator two electrodes (instead of an electrode and a ground-plate), or by connecting the E-CATH electrocatheter that has two electrodes in the tip for the bipolar stimulation.

The combination of all these working modes, let the creation of customized treatments in which it is possible to take in account not only of the clinical picture but also the particular conditions of the patient.

Moreover, the small size of the stimulator and its total portability, let to perform several treatments simultaneously in different areas with different stimulators, that in other words, let to perform ***multi-channel stimulations***. The stimulators are designed to not to interfere each other during the working.

TECHNICAL FEATURES

Power supply	3V
Amplitude of electrical stimulation	0V ÷ 10V
Frequency of electrical stimulation	2Hz ÷ 200Hz
Pulse width	50 µsec ÷ 500µsec ± 20%
Operating time	30 days max.
Load impedance	500 Ω ÷ 1 KΩ
Packaging	non sterile
Class of protection	IP20
Classification applied Part	BF
Environmental conditions of use	temp 10°C ÷ 40°C / Relative Humidity: 20% ÷ 80%
Shelf life	5 years

The ACCUSTIM-P stimulator is an electro-medical device which needs special precautions regarding EMC. It has to be installed and put in service according to information in this manual.

BOX CONTENTS

The Accustim-P package includes:

- n° 1 Accustim-P stimulator;
- n° 1 connection cable for using combined with P-LEAD electrodes;
- n° 1 Instruction manual of stimulator;
- n° 1 Quick Reference;

Use of the ACCUSTIM-P stimulator is allowed ONLY combined with electrodes Bioampere P-LEAD or E-CATH electrocatheters.

NOTE FOR THE STORAGE AND TRANSPORT

Environmental conditions for storage and transport:

- Temperature: 10°C ÷ 40°C
- Relative Humidity: 20% ÷ 80%
- Pressure: 0,5bar ÷ 2bar

Store in a dry area and away from direct heat. Do not use after the expiration date. Keep out of children's reach.

NOTE FOR DISPOSAL

The crossed bin symbol on its packaging indicates that once used, the device must NOT be disposed of as household waste but must be made for it a different collection from other waste. Therefor the user must bestow the product to the appropriate differentiated collection centers for electronic and electro-technical waste, or return to Bioampere Research Srl, which will carry out the collection and proper disposal procedure. Appropriate separate collection or follow the above mentioned factors, helps to avoid possible negative effects on the environment and on health and promotes the reuse and/or recycling of the making up materials the equipment.

Illegal disposal of the product by the user entails the application of administrative sanctions provided by law.

MANUFACTURER

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