LLC RC ART, Ekaterinburg, Russia



Transcutaneous Electrostimulator Analgesic "Lados"

Operations Manual

Россия/ Russia	
EC, все страны/ EU, all	•
США/ USA	
Канада/ Canada	

LADOS

RC RT 10.0-03.71-01 RE



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This Operations Manual is intended for the Lados transcutaneous analgesic electrostimulator.



The Operations Manual includes the Technical Passport (part 1) and User's Instructions (part 2).



PART 1

Technical passport



1. SAFETY





All information in this operations manual contains important information about your safety and recommendations on proper use and maintenance of the device.



The device does not constitute any danger because of internal low voltage power source isolated from the body of the apparatus (article of type B and body of type F).



The apparatus must not be used for treatment of patients with implanted electronic devices (for example, pacemaker) and for treatment of patients who have individual electric current intolerance.



Use of the device in direct front projection of the heart is prohibited.





Don't switch the patient to any high-frequency electric device during stimulation. Simultaneous use of the device and other electric equipment can result in burns and possible damage of the device.



Work near short-wave and microwave equipment can result in instability of output parameters of the device.



The device has fragile elements. Keep it safe from blows.





The device is not waterproof. Keep it safe from water penetration.



All repair works on the device must be provided by qualified specialists at the manufacturer.



Transportation conditions: temperature -50° C to $+50^{\circ}$ C, relative air humidity 30 to 93%, atmospheric pressure 70 to 106 kPa.



Storage conditions: temperature -50°C to +40°C, relative air humidity 30 to 93%, atmospheric pressure 70 to 106 kPa.



Operation conditions: temperature $+10^{\circ}$ C to $+35^{\circ}$ C, relative air humidity 30 to 93%, atmospheric pressure 70 to 106 kPa.



Attention! In case of storing the device at temperature below 10°C, keep it under normal conditions minimum two hours before use.



Recycling: All packaging materials are environmental-friendly and can be recycled.



Individual assembly of electrical and electronic equipment.

The device contains valuable materials that may be used again after recycling considering the requirements for environment preservation. Deliver it to special service centers (consult with appropriate services of your region) for collection and recycling.



2. INTENDED USE

The Lados transcutaneous analgesic electrostimulator is intended for treatment of the zone of pain and damages (bruises, fractures, diseases of the musculoskeletal system, syndrome of chronic pain) in patient-care institutions and in life conditions.

3. SPECIFICATIONS



3.1. The electrostimulator provides for generation of electric impulses with the following parameters (at the nominal power voltage 3.0 \pm 0.1 V):

- **3.1.1.** Under minimum signal power with load of 20 \pm 1 kOhm:
- duration of the positive impulse is 25 ± 10 uS;
- amplitude of the positive impulse is maximum 30 V;
- amplitude of the negative impulse is maximum 60 V.

3.1.2. Under maximum signal power:

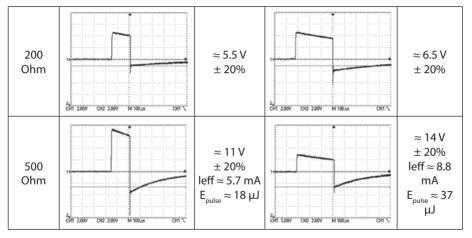
- duration of the positive impulse is 250 \pm 90 uS;
- amplitude of the positive impulse is $30 \pm 10 \text{ V}$;
- amplitude of the negative impulse with load 20 \pm 1 kOhm 150 \pm 90 V.



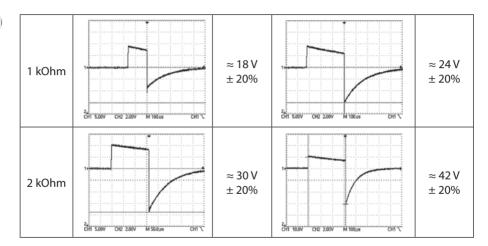
- **3.1.3.** Amplitude of treatment at the minimum power level is \approx 40 % of the amplitude at the maximum power level (R = 20 kOhm).
- **3.1.4.** Dependence of the impulse shape on the load resistance at the medium and maximum power levels

Landunaia	Power level: 5 units		Power level: 10 uni	ts
Load resis- tance	Shape of the output signal	V	Shape of the output	V
tance	Shape of the output signal	р-р	signal	v _{p-p}
No load	241-3000 CH2-2000 M190006 CH1	≈ 100 V ± 20%	25H 2000 OH 2000 M100.05 OH	≈ 100 V ± 20%

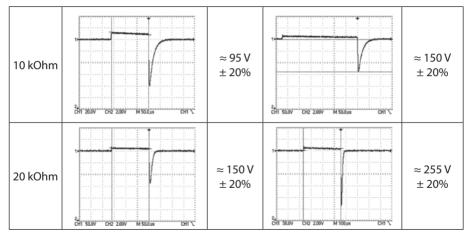














3.2. The apparatus provides for setting of three electrostimulation modes:

3.2.1. Mode 1 has the following characteristics:

- treatment with impulses with quasirandom frequency of impulse spacing in the range 75-132 Hz;
- duration of the 1st phase of the electrosrimulating impulse is constant, depending on the treatment power set by the user.

3.2.2. Mode 2 has the following characteristics:

- treatment with impulse groups with groups frequency 77 \pm 20 Hz and groups duration 1-2.5 mS:
- duration of the 1st phase of the electrosrimulating impulse is constant, depending on the treatment power set by the user.

3.2.3. Mode 3 has the following characteristics:

— treatment with impulse groups with groups frequency 1 \pm 0.1 Hz and groups duration 380-38 mS;





- duration of the 1st phase of the electrosrimulating impulse is variable, ramp is from zero to the duration corresponding to the power set by the user.
- 3.3. Maximum consumable current (with 3 V voltage) is maximum 200 mA.
- 3.4. Power source: 2 batteries type LR6/AA, voltage of each is 1.5 \pm 0.3 V. It is allowed to use accumulators of the similar type with nominal voltage 1.2 V*.
- 3.5. Weight of the apparatus is maximum 0.2 kg
- 3.6. Overall dimensions of the apparatus are maximum 130x50x55 mm.

^{*} order of operation (types of chargers, charging methods) is provided in the manual for accumulators. Period of apparatus operation with accumulators depends on the accumulators' specifications.



3.7. Automatic switching off of the apparatus

The apparatus will automatically switch off not later than in 3 minutes after the last pressing of on of the buttons (except for **b** button) or last application of the electrodes to the patient's skin surface.

3.8. Electromagnetic Radiation

Test	Compliance	Application Conditions
HF radiation CISPR 11	Class B	Lados is suitable for use in all establishments including home application.

3.9. HF Resistance

Test	IEC 60601-1-2 test conditions	Permissible level
IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms
IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m





Test	Test Level	Level of Com- pliance	Application Conditions
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV infl.	±4kV contact ±8kV infl.	Floors to be wooden, concrete or ceramic tile. If floors are covered with synthetic material, relative air humidity to be minimum 40%.
Magnetic fields IEC 61000-4-8	3A/m	3A/m	Magnetic fields parameters to be typical, for business buildings and medical and prophylactic institutions.



3.11. Recommendations on determining the required distance between the Lados electrostimulator and radio equipment

Stated maximum out-		Distance $d = 1.2\sqrt{P}$ (m)	
put power of the trans- mitter R (W)	At frequency 150 kHz to 80 MHz	At frequency 150 kHz to 800 MHz	At frequency 800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

3.12. Application Conditions



3.12.1. The Lados apparatus uses electromagnetic energy only for internal functions. Due to this, radiation from the device is very low and does not produce any influence on nearby electronic equipment. Lados can be applied by any doctor and as means of medical self- and mutual aid at home.

The Lados apparatus shall not be used together with other equipment. If simultaneous operation of Lados and other equipment is necessary, the device and equipment shall be checked for compatibility under conditions in which they will be operated.

3.12.2. The Lados apparatus is intended for operation under specific conditions of electromagnetic environment, the client (user) to be sure that electromagnetic environment condition correspond to required parameters.

Electrostatic discharge (ESD): floors to be wood, concrete, or covered with ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at minimum 40 %.



High-frequency radiation: portable and mobile devices to be used at the distance no closer to any part of Lados, than $d=2.3\sqrt{P}$ (800 MHz \div 2.5 GHz), where P is the maximum output power rating as per Manufacturer's Specifications.

3.14.4. Recommended Actions of the User

Electrostatic discharge (ESD): The user shall not wear synthetic clothing.

High-Frequency Radiation: Personnel (user) shall observe the following measures: minimum distance to portable communication devices (such as cellular/cordless telephones) to be approximately 3 meters in case output power of devices exceeds 2 W.





The complete set of delivery of the Lados device should correspond to the table.

Name of the device, part, document	Quantity
Analgesic electrostimulator Lados	1
Power source (AA type)	2*
Operations Manual	1
Case	1

* a complete set with 4 power sources is possible.



5. DESIGN OF THE DEVICE

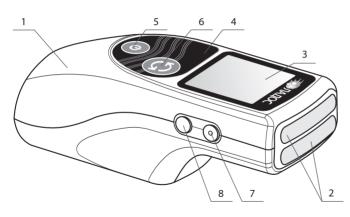
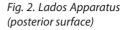


Fig. 1. Lados Apparatus (anterior surface)

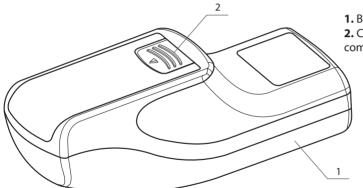
- 1. Body
- 2. Built-in Electrode
- **3.** Display liquid-crystal indicator
- 4. Keyboard
- 5. On/Off button
- 6. "Mode" button
- **7.** "Power increase" button
- **8.** "Power reduction" button







2. Cover of the battery compartment





Functions of Buttons on the Body of the Lados Apparatus are shown in the Table:

Buttons			
Button 7 on the apparatus front edge	Button 8 on the apparatus front edge	•	3
Increase of electro- stimulation power up to the maximum level by 1 – short pressing	Reduction of electro- stimulation power up to the minimum level by 1 – short pressing	Switching the apparatus on – at initial switched off state – by short and long pressing of the button	Cycling switch- ing of the op- eration mode
Automatic power level increase by constant pressing (the button is pressed more than 1.5 sec)	Automatic power level reduction by constant pressing (the button is pressed more than 1.5 sec)	Switching the apparatus off – at initial switched on state – by long pressing of the button Switching the lighting on – by short pressing of the button	"Mode 1" → "Mode 2" → "Mode 3" → "Mode 1" → and so on

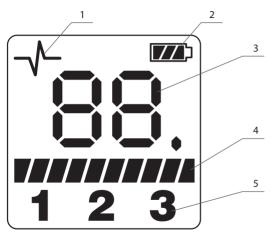


Fig. 3 Information on the Indicator



- **1.** Symbol of electrodes contact with skin surface
- 2. Symbol of the power source state
- **3.** Time in minutes passed since beginning of the procedure
- 4. Indicator of treatment power
- **5.** Indicator of the number of electrostimulation mode



6. OPERATION MODE

6.1. Switching the apparatus on

Press the **o** button. After the sound signal the apparatus will switch to "Mode 1".

6.2. Mode selection

To change the operation mode, press the button until you see the required mode "1", "2" or "3" on the display.

6.3. Changing treatment power

During operation in any of the electrostimulation modes you can change treatment power: with the button (power reduction) and the button (power increase)

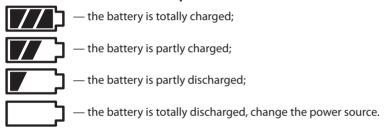
6.4. Switching the apparatus off

Press and hold (1-3 seconds) the **O** button. The apparatus will switch on the lighting,





6.5. Possible states of the power source





7. TECHNICAL MAINTENANCE

7.1. Daily technical maintenance

Daily technical maintenance should include the following:

- external examination of the apparatus;
- disinfection of electrodes.

Use standard disinfection means (e.g. 70% alcoholic solution) and soft napless napkins to clean the electrodes.

7.2. Checking the apparatus performance

The apparatus performance to be checked as per instructions in section 6.

7.3. Long-term storage of the apparatus

If the apparatus is supposed not to be used for a long period, remove the power sources from the compartment (Fig. 2).





When the battery symbol is blinking and the apparatus produces a sound signal, change the power sources (see section "Order of powers sources replacement").



8. ORDER OF POWER SOURCES REPLACEMENT

Power sources replacement:

- open the battery compartment (Fig. 2);
- take the power source out;
- set new power sources*, follow the polarity.

^{*} set only those power sources that are provided for this device – type LR6/AA, voltage rating 1.5 V, or appropriate accumulators with nominal voltage 1.2 V.





Trouble	Possible reason	Method of eradication	
	Power sources are missing	Set a new set of power sources (see section "Oder of Power Sources Replacement")	
The apparatus does not switch on after pressing the On/Off button	The polarity is mixed when power sources setting into the compartment	Check and, if necessary, set power sources per marking on the apparatus body	
	Voltage of power sources is less than 2.2 V	Replace power sources (see section "Oder of Power Sources Replacement")	



The device produces sound signals during switching on and automatically switches off	Voltage of power sources is less than 2.2 V	Replace power sources (see section "Oder of Power Sources Replacement")
The apparatus does not switch to the Therapy mode	The contact of electrodes with the skin surface is not good	Fix the apparatus electrodes on the skin surface. If necessary, wet the skin surface in the area of contact with electrodes
The apparatus does not switch off automatically when there is no contact of electrodes with the skin surface and not touching the controls more than 5 minutes	Current leakage on the therapeutic electrodes of the apparatus	Clean and wipe the apparatus therapeutic electrodes with an alcohol or alcohol-containing liquid



The apparatus switches off or during the procedure the battery symbol is blinking and intermittent sound signal is produced	Voltage of power sources is less than 2.2 V	Replace power sources (see section "Oder of Power Sources Replacement")
Power sources discharge very quickly	Bad quality of power sources	Use power sources of good quality (we recommend alkaline power sources) or accumulator of proper type and size of voltage maximum 1.5 V



10. WARRANTY CONDITIONS

10.1. Operation Lifetime

The operation lifetime is 5 years. Observation of operation conditions can considerably increase the lifetime set by the manufacturer officially.

10.2. Warranty Period of Operation

Warranty period of operation is 24 months from the date of sale.

10.3. Satisfying Customer's Demands

The seller (manufacturer) or organization carrying out functions of the seller (manufacturer) on a contractual basis is not responsible for defects should they occur after the disposal of the device as a result of:

- 1) a failure on the part of the consumer to comply with rules of transportation, storage, maintenance and operation provided in the present manual;
- 2) mechanical damages;

- 3) actions of the third party;
- 4) force-majeure.



10.4. Restriction of Warranty Obligations

Warranty obligations do not apply to products with broken manufacturer's seals.

10.5. Customer's actions in case of breakdown or malfunction of the device In case of unit breakdown or malfunction within the warranty period, as well as in case of incomplete shipping is found, the owner must send the following documents to the manufacturer's address or manufacturers' representative: claim for repair (exchange) with name, address, telephone number; defects list with brief description of the malfunction, date and conditions of its appearance.



Manufacturer's address:

LLC "RC ART", 620146 Russia Ekaterinburg, Akademika Postovskogo Str., 15 Phone: +7 (343) 267-23-30, http://www.denascorp.ru, e-mail: corp@denascorp.ru

Official Representative in the European Union:

DENAS-Deutschland GmbH Deutschland, 64347 Griesheim, Im Leuschnerpark 3 phone: +49 (6155) 66–57–73, fax: +49 (6155) 66-58-27 http://www.denasms.de, e-mail: denasms@t-online.de

Trade representative in the European Union:

DENAS-CZ s.r.o., Chech Republik, 360 01, Karlovy Vary, SHOPPING CENTER "atrium", Karla IV. 505/1, office 209, phone: (+420) 353 549 285; fax: (+420) 359 019 209

PART 2

User's instruction





1. MAIN PERFORMANCE DATA

The pain accompanies many human diseases. Being the sign of ill-being, pain, on the one hand, performs protective functions, promotes activation of the defense mechanisms and reduction of consequences of a harmful factor. On the other hand, pain is a constant reason of sufferings. Pain sensations have emotional overtone and can be the reason for serious disorders in the body mechanisms.

Nowadays, fundamental discoveries of pathophysiological pain mechanisms have conditioned appearance of new analgesic means, among which non-drug methods, dynamic electroneurostimulation (DENS) in particular, have a great importance. DENS apparatuses are successfully applied in the therapy of acute pain in case of different situations. They are efficient for first aid – bruises, ligamentous injuries, bone fractures, spastic colic and so on. The apparatuses are efficient for treatment of pain accompanying chronic diseases such as gastric and duodenal ulcer, chronic pancreatitis, chole-



cystitis, arthroses and arthrites, pain syndrome in case of osteochondrosis, traumas and other spine diseases.

The apparatuses help to eliminate acute disease symptoms, and easy operation algorithms and mechanism of feedback have fundamental importance and enable the person to provide help for himself and his family.



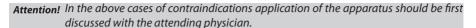
2. INDICATIONS AND CONTRAINDICATIONS FOR APPLICATION

2.1. Indications for Application

Acute and chronic pain syndromes, functional disorders and organic diseases of internals and musculoskeletal system.

2.2. Contraindication for Application:

- individual intolerance;
- presence of an implanted pacemaker;
- epilepsy;
- neoplasms of any etiology and localization;
- acute fevers of unknown etiology;
- venous thrombosis;
- condition of acute mental excitement, alcohol or drug intoxication.





Attention! In case of individual intolerance when during the treatment procedure the state of health is worsened and pain increases, stop the procedure and urgently consult a doctor.

Attention! Sharp pain of any localization can be the first and often the only sign of a serious disease. If the pain symptoms are unfamiliar and repeated, intensity of pain increases, one should immediately consult a doctor.



3. CONDITIONS OF TREATMENT

You do not need any special conditions for the procedure. You can conduct the treatment procedures yourself. The therapy is taken in a comfortable sitting or lying position. After the treatment procedure the patient should relax for 10–15 minutes.

Attention! After each procedure all electrodes to be treated with a standard disinfecting solution (e.g. 70% alcoholic solution). The device should be kept with dry electrodes.



4. OPERATION OF THE APPARATUS BY GENERAL-PURPOSE METHODS

Attention! Electrodes should be applied only on the skin surface.

Electrostimulation with the Lados apparatus is applied for local-segmental and general treatment of the body. Reflex zones are selected in accordance with the segmental innervation (see. Supplement 1) and a definite algorithm of treatment (see Supplement 2). One of the easiest and efficient methods of selection of zones for treatment is treatment of the pain focus directly. For instance, in case of lumbodynia – on the loins, in case of pains in the knee joints – on the skin in the zones of affected joints. It is allowed to treat additionally corresponding segmental reflex zones which make treatment more efficient.



4.1. Mode 1

This mode provides for efficient and long-term analgesia in case of most diseases. It is the most general-purpose mode and is recommended for application for beginning of the procedure of analgesia.

It is allowed to combine this mode with modes 2 and 3 for optimal analgesia degree.

4.2. Mode 2

This mode, in comparison with mode 1, provides for faster and better analgesia. But the duration of analgesia of this mode is less than of mode 1. It can be applied for treatment of pain of any genesis, but it is most efficient for treatment of traumatic pains and pains related to affection of the musculoskeletal system. It is recommended to apply this mode in case when fast analgesia is required and if pain is very intense. To increase efficiency and duration of the analgesia, it is possible for combine it with mode 1 or 3 during the procedure.

4.3. Mode 3



This mode is most efficient for treatment in case of pain syndromes related to muscles affection. It is recommended to combine this mode with mode 1 or 2.

4.4. Selection of the optimal analgesia mode. Combination of modes during the analgesia procedure.

At the initial selection of stimulation modes it is necessary to apply recommendations above. But one should remember that intensity and time when analgesia starts considerably depend on individual sensitivity of a person and features of the disease. If during the procedure you have enough analgesia under the selected by you mode, then there is no need to combine or change modes. But in cases when applying the selected mode during the first 10-15 minutes not total analgesia is registered, it is recommended to combine modes during the procedure. The time of application of this or that mode necessary for achieving the best result is selected individually depending on the intensity and time when analgesia starts. Mostly enough analgesic



effect is achieved within first 10-15 minutes of stimulation, and maximum analgesia is achieved within 25-40 minutes.

4.5. Intensity of the electrostimulating treatment

The intensity (power) of electrostimulation is determined by subjective patient's sensations. Electrostimulation intensity is conditionally divided into three energy levels (electric ranges).

The first minimum level – the patient does not have any subjective sensations or feels subtle vibrations in the subelectrode zone. It is applied in cases when treatment should not be intensive, in case of mild pain. For patients with diseases of the cardio-vascular system (arterial hypertension, arterial hypotension, and syndrome of vegetative-vascular dystonia) the procedure should be started at the minimum power level.

The second comfortable level – the patient feels light pricking, vibration or light burning without pain. It is applied for mild pains and medium intensity pains. This is the most frequently used power level.



The third maximum level – the patient feels painful pricking or burning. Such intensity can be accompanied by involuntary contraction of muscles close to the electrodes. It is used in case of intense pain syndrome.

Attention! Power of electrostimulation can be increased or reduced during treatment stages depending on the extent of the patient's sensitivity and as the pain syndrome reduces.

Attention! The power level is controlled subjectively following the patient's sensations. Do not surpass the pain threshold.

4.6. Methods of Application

Treatment with the Lados apparatus is applied using three methods: *stable, labile and labile-stable.*



Stable method of application (fixed electrodes) is used for treating small zones and on areas with defected skin (postoperative and post-burn scars, edemas and so on).

With *labile method of application*, built-in electrodes are moved smoothly within the application zone without taking them off the skin at 0.5 to 3 cm/sec. Movements are rectilinear, spiroid, circular and other depending on the size and relief of the zone treated and on the undamaged skin only.

Labile-stable method of application combines both variants of treatment when the apparatus electrodes are moved on skin and stop on definite places (for instance, in the zone of maximum painfulness).

The intensity of pressing of the skin with the apparatus is determined by subjective patient's sensations. Average duration of one procedure for adults is up to 40 minutes. It is recommended to treat not more than 3 zones during one procedure.



EN

Segmental Dermatomeres (segmental zones)



Fig. 1. Segmental innervation of the human body (anterior surface)

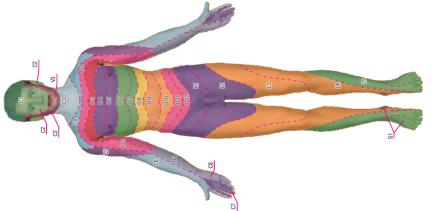
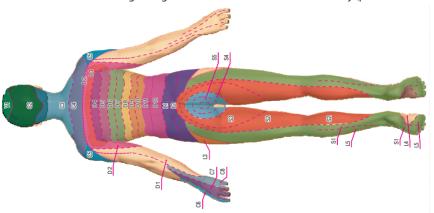




Fig. 2. Segmental innervation of the human body (posterior surface)





Some Indications for Treatment of Segmental Dermatomeres

Dermatom- eres	Symptoms, states and diseases
C1-C2	headache, pain in the throat and nose, pain in the occiput, pain in the shoulder area, hemiplegia;
C3-D1	headache, pain in the ears, pain in the throat, pain and tension of the occiput muscles, pains in the shoulder, back and loins
D1-D2	hemicrania and other headaches, tension and pain in the spine, pain in the shoulder blade, pain in the knee, pain in joints
D2-D3	pain and tension of muscles in the back, loins, shoulder, occiput area, intercostal neuralgia
D3-D4	pain and tension in the occiput area, pain in the exterior surface of the shoulder, shoulder blade, thorax area, in the loins, abdomen area, lumbodynia, pain in the sacrum and back



D4-D5	headache, pain in the neck area, pain the shoulder blade, in the area of shoulder and back, pain in area of the heart, pains in the stomach area
D5-D6	headache, pain in the back and thorax, intercostal neuralgia, pain in the spine
D6-D7	pain in the back and neck, restraint of the spine movement, intercostal neuralgia, pain in the back and heart, pain in the stomach
D7-D8	pain in the loins, pain in the abdomen
D9-D10	pain in the loins, pain in the thorax and hypochondrium, pain in the heart area, pain in the stomach
D10-D11	pain in the abdomen, loins and back, intercostal neuralgia, cough with pain, pain and heaviness in the abdomen
D11-D12	pain in the back, pain in the stomach, pain in the intestines
D12-L1	pain in the abdomen, back and spine, pain in the pit of the stomach
L1-L2	pain and contractions in the lumbar area, tension of the spine and loins muscles, pains and spasms in the stomach



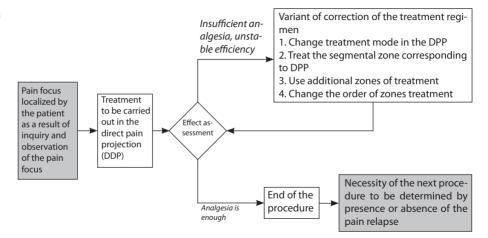
L2-L3	headache, pain and tension in the back and loins, sensation of tension in the spine muscles, pain in the hip, lumbodynia, intestinal colic (pain in the intestines), pain in the external genitalia, pain in the area of external genitalia
L3-L4	pain in the loins
L4-L5	pain in the loins and lateral part of the pelvis; pain in the external area of the knee joint, lumbodynia, intestine colic
L5-S1	lumbodynia, lumbago, ischias
S1-S2	pain in the abdomen, sacrum and hip joint, lumbago, intestine colic
S2-S3	pain in the sacrum, loins, spine, weakness in the knee joint, pain in the joints, labor pains
S3-S4	pain in the loins, ischias, pain in the spine, intestine colic
S4-S5	pain in the loins and back, sacral-coccygeal pains, pain in the area of lateral surface of the buttock, lumbodynia, ischias, cystodynia, pain in the urethra





General Algorithm of Application of the Lados Apparatus in case of Treatment of Pain Syndromes









COUPON FOR WARRANTY REPAIR



Name: LADOS	
Serial №	
Date of manufacture	
Date of selling	
Customer	
Address:	
Telephone	
home	
office	
Date of sending for repair	



Reason for repair
Note about repair
Signature of the company representative
responsible for acceptance after repair
The apparatus was checked, I have no claims to the complete set, appearance of the apparatus.
Signature of the customer
Date of acceptance

Warranty for a repaired product is valid for 6 months beginning as of the moment when product is accepted following repairs. If a warranty period beginning on the date of purchasing is more than 6 months, warranty is recalculated for a longer period. Warranty period is increased accordingly by the time a product has spent at a repair station.





CERTIFICATE OF ACCEPTANCE

Transcutaneous electrostimulator fnalgesic "Lados" Note on acceptance:

Date of selling:
Signature of the seller:
received information about warranty conditions, the apparatus was checked, and I have no
claims to the complete set, external appearance of the apparatus
Signature of the customer

Carefully examine the apparatus when buying! Body and display defects (scratches, cracks, fractures) are not warranty events. Apparatuses with such defects are not exchangeable, beyond repair and not returnable.