

Россия/ Russia	
ЕС, все страны/ EU, all	●
США/ USA	
Канада/ Canada	

**LLC RC ART,
Ekaterinburg, Russia**

Set of Therapeutic External Massage Electrodes

Operations Manual



Compliance with standards:

This medical device is CE marked according to the Directive 93/42 /EEC on medical equipment.

RC ART 06.7-03.71-01 RE

CONTENTS**Part 1. Technical Passport**

1. Safety.....	3
2. Function.....	5
3. Specifications.....	6
4. Complete Set.....	7
5. Technical Maintenance.....	9
6. Troubleshooting.....	10
7. Warranty Conditions.....	11

Part 2. User's Instructions

1. General Information.....	13
2. Conditions of Treatment.....	15
3. Methods of Application.....	15
4. Duration of the Procedure.....	16
5. Treatment with Apparatus.....	16
6. Recommended Treatment Zones.....	17
6.1. Application of Massage Electrode 1 for treatment of headache.....	17
6.2. Application of Massage Electrode 1 for treatment of mini-acupuncture systems of the scalp.....	18
6.3. Application of Massage Electrode 2 for cosmetic treatment of the face.....	19
6.4. Application of Massage Electrode 2 for treatment of cellulites.....	20

Supplement 1	21
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Coupon for Warranty Repair	25
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Certificate of Acceptance	28
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PART 1

TECHNICAL PASSPORT

1. SAFETY



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



The therapeutic external massage electrode 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.



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



Attention! Do not switch the electrode to any devices except for DENAS and DiaDENS series.



Attention! Do not switch two or more electrodes to one device at the same time.



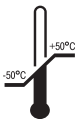
Use of the external zonal electrode in direct front projection of heart is prohibited.



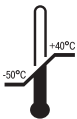
The device is not waterproof. Keep it safe from water penetration.



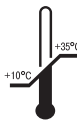
All repair works on the electrode must be provided by qualified specialists at the manufacturer.



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



Storage conditions: temperature -50°C to $+40^{\circ}\text{C}$, relative air humidity 30 to 93%, atmospheric pressure 70 to 106 kPa.



Operation conditions: temperature 0°C to $+35^{\circ}\text{C}$, relative air humidity 30 to 93%, atmospheric pressure 70 to 106 kPa.

In case of storing the device at temperature below 0°C , keep it under normal conditions minimum two hours before use.

Recycling



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



All materials of which the device is made are suitable for recycling.

Individual assembly of electrical and electronic equipment.

Used device is not absolutely useless garbage! It 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. FUNCTION

Therapeutic external massage electrodes (hereinafter – massage electrodes, electrodes or the device) are intended for treatment of pain and injury areas, reflexogenic zones of the body.

Massage electrodes are intended for multiple applications, for individual treatment in patients care institutions and in life conditions in compliance with the recommendations of the attending doctor.

Massage electrodes allow treatment of reflexogenic zones using two treatment factors – dynamic electroneurostimulation (DENS) and mechanotherapy (massage).

Massage electrodes are applied only together with the electrostimulators of DENAS and DiaDENS series.

3. SPECIFICATIONS

Specifications of an external therapeutic massage electrode # 1:

- weight, kg, maximum.....0.1
- overall dimensions, mm, maximum.....125x40x96

Specifications of an external therapeutic massage electrode # 2:

- weight, kg, maximum.....0.1
- overall dimensions, mm, maximum.....125x40x76

Cable length of the electrode (#1 and #2),
mm, minimum.....1000

Total weight of the set, kg, maximum.....0.4

4. COMPLETE SET

Name	Quantity
External massage electrode #1 (Fig. 1)	1
External massage electrode #2 (Fig. 2)	1
Operations Manual (includes Technical Passport and User's Instructions)	1
Case	1

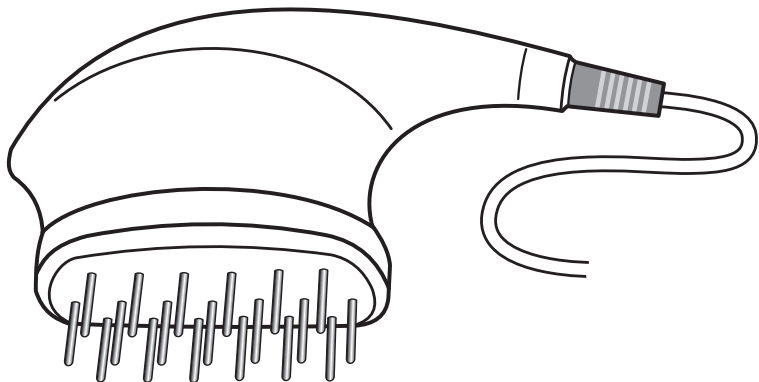


Fig. 1. Appearance of the External Therapeutic Massage Electrode #1

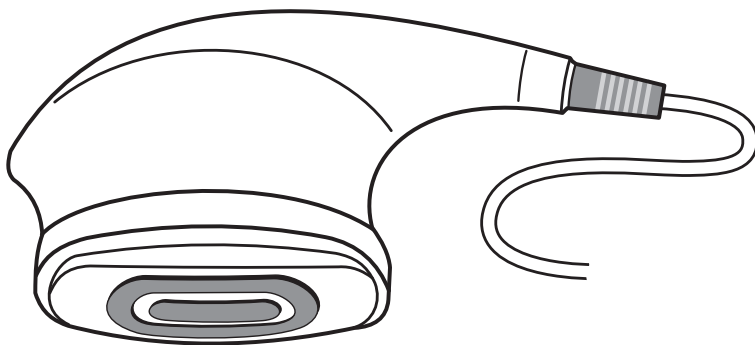


Fig. 2. Appearance of the External Therapeutic Massage Electrode #2

5. TECHNICAL MAINTENANCE

Technical maintenance shall be performed before using the device and include the following:

- external examination;
- disinfection (use standard disinfection means and soft napless napkins to clean the electrode);
- Check of serviceability of the electrode when switching it to apparatuses of DENAS and DiaDENS series.

6. TROUBLESHOOTING LIST

Possible problems and troubleshooting are provided in Table 1

Table 1

Trouble	Possible reason	Method of Eradication
No electro-stimulation	No contact between the device, the external electrode, adaptor (if any)	Check contacts of the connector, adaptor
	The adaptor is not working (if any)	Replace the adaptor
	Dry skin and/or small area of contact	Treat skin with a tampon wetted with water or physiological solution
	Power of the apparatus is set at zero	Set higher level of power

Attention! Other troubles must be eradicated by the manufacturer or at manufacturer's service centers.

7. WARRANTY CONDITIONS

7.1. Manufacturer guarantees the compliance of the device to technical conditions TU 9444.002.35266303-2005 if operation, transportation and storage conditions are observed.

7.2. The operation lifetime is 5 years.

Observation of operation conditions can considerably increase the lifetime set by the manufacturer officially.

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

7.4. The complete set and appearance of the device is to be checked by the buyer when receiving the goods at the seller's presence. Claims to complete set and appearance of the device after it was sold will not be admitted.

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

7.6. 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: claim for repair (exchange) with name, address, telephone number; defects list with brief description of the malfunction, date and conditions of its appearance.

Other malfunctions must be eradicated by the manufacturer or at manufacturer's service centers.

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 665773, +49 6155 665827
<http://www.denasms.de>,
e-mail: denasms@t-online.de

Trade representative in the European Union:

DENAS-CZ s.r.o., Czech 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 INSTRUCTIONS

1. GENERAL RECOMMENDATIONS

External zonal massage electrodes are applied for increasing efficiency of dynamic electroneurostimulation (DENS) procedures and more comfortable treatment of skin zones inaccessible or inconvenient for treatment with built-in electrodes of the DENS apparatuses.

Application of external massage electrodes allows treatment of reflexogenic zones using two therapeutic factors – dynamic electroneurostimulation (DENS) and mechanotherapy (massage).

Dynamic electroneurostimulation with application of external massage electrodes is used for treatment of a wide range of pain syndromes, and in face and body cosmetology.

Massage electrode # 1 allows treating any reflexogenic zone, and the skin with hair coat. This provides an opportunity of highly effective application for treatment of diseases in the scalp area (mini-acupuncture system of the scalp). In addition, there are points of several acupuncture channels in the scalp area stimulation of which allows for a considerable treatment effect for many diseases.

Being a main zone of treatment, the scalp area is treated during headaches, dizziness, sleep disturbance, undue fatigability, anxiety, alopecia, meningitis, encephalitis, craniocerebral injuries, cerebral atherosclerosis and apoplectic attacks.

In addition, inclusion of the scalp area treatment into the treatment regimen for enhancement of the therapeutic effect of DENS is indicated with some other diseases (refer table 2).

Massage electrode # 2 provides an opportunity for effective combination of dynamic electroneurostimulation and mechanical massage. The electrode can be successfully applied for solving cosmetic problems, convenient for treatment of hard-

to-reach zones, provides an opportunity for discovering latent trigger zones in the SCREENING mode during self-aid and easy to use when treating the discovered trigger zones.

Cosmetic effect of DENS is ensured by the set of complex physiological reactions. Systematic treatment provides for improvement of blood circulation in skin, enhancement of metabolic processes, and normalization of the muscle tone. All these result in rhytide effacement and reduction of their amount, reduction of edemas, improvement of complexion and skin elasticity.

External massage electrode # 2 can be successfully applied in skin and body cosmetology.

2. TREATMENT CONDITIONS

You do not need any special conditions for DENS treatment. The procedures can be carried out both personally and with a help of an operator. Electrotherapy is taken in a comfortable sitting or lying position. After the treatment procedure a patient should relax for 10–15 minutes.

3. METHODS OF APPLICATION

Dynamic electroneurostimulation with massage electrodes is applied using three methods: *stable*, *labile* and *labile-stable*.

Stable method of application is used with fixed electrodes on the selected zone during the whole procedure. It is applied for treating small zones for example, for treatment toothache or when treating the zones of the mini-acupuncture system of the scalp.

With **labile method of application**, the electrode is moved within the application zone. Moving should be smooth without taking the electrodes off the skin at 0.5 to 2-3 cm/s. Movements are rectilinear, spiral, circular and other depending on the size and shape (relief) of the zone treated with light pressing (reflexogenic zones, skin areas of internal organs projections) and with stringer pressing (back, hips, buttocks).

With **labile-stable method of application** electrodes are moved on skin with short fixation, for example on the zone of maximal painfulness, in the trigger zones.

Attention! When applying massage electrode #2 in the SCREENING mode, only stable method of application shall be used.

4. DURATION OF THE PROCEDURE

The duration of the procedure of dynamic electroneurostimulation on average is 30-40 minutes. During one procedure it is recommended to treat maximum 2-3 zones. For emergency aid the duration of the procedure can be determined by the following subjective criteria:

- the complaint is fully removed;
- the patient feels considerable improvement of the state of health;

5. TREATMENT WITH APPARATUS

Attention! *Following the hygienic requirements, treat the electrode working surface with a soft napkin wetted with a disinfection solution (e.g. 70% ethanol solution) before the procedure.*

Attention! *Selection of treatment intensity, method of application, zones and duration of the procedure shall be carried out as per the current operations manual for the electrode and operations manual for the respective apparatus and general recommendations set forth in the “Manual for Dynamic Electroneurostimulation”**.

1. Switch the electrode to the apparatus of dynamic electroneurostimulation. In case the electrode plug does not fit into the apparatus slot, use the adaptor supplied together with the apparatus.

Attention! *Do not switch the electrode to any devices except for DENAS and DiaDENS series.*

2. Turn the apparatus on.

*Manual for Dynamic Electroneurostimulation with DiaDENS-T and DiaDENS-DT apparatuses / edit. V.V. Chernyshev. – Ekaterinburg, 2005

3. Select the required mode and set individual power of treatment.
4. Carry out the procedure.
5. Turn the apparatus off and disconnect the electrode from the apparatus.

Attention! *It is recommended to apply massage electrode # 1 in the THERAPY mode only,*

Attention! *It is recommended to apply massage electrode # 2 in the THERAPY and SCREENING modes only.*

6. Treat the electrode with a disinfection solution (e.g. 70% ethanol solution).

Attention! *Keep the electrode dry.*

6. RECOMMENDED ZONES OF APPLICATION

Treatment with the external massage electrode is performed in the local zone of the lesion focus (the zone of direct projection of the complaint), in metameric and segmental zones and in the zones of respective systems.

During the course treatment it is recommended to include treatment of universal segmental zones and zones of the complaint direct projection into the treatment scheme*.

6.1. Application of the External Massage Electrode # 1 for Treatment of Headaches

When treating the headache one should take into account its localization. The procedure should be performed in the area of forehead, temple, occiput or crown of head in accordance with the headache localization. For diffuse nonlocalized headache DENS should be applied along the central line of the head and along pair lines parallel to the CL (refer Supplement 1, Fig. 1).

**Selection of zones to be treated should be made in accordance with general regulation of DENS set forth in the "Manual for Dynamic Electroneurostimulation".*

Treatment is in the THERAPY mode at frequencies 60, 20 or 10 Hz under comfortable energy level. Treatment is in the labile and labile-stable method, treatment duration is to be selected individually depending of the dynamics of the pain syndrome and can be 5 to 15 minutes.

6.2. Application of the External Massage Electrode # 1 for Treatment of Mini-Acupuncture Systems of the Scalp

Treatment is in the THERAPY mode, in the labile and labile-stable method at frequencies 60, 20 or 10 Hz and in the range 1 to 9.9 Hz taking into account indications for application. Treatment is to be carried out under minimum or comfortable energy level during 5 to 15 minutes.

Table 2

Indications for Application of Zones of Mini-Acupuncture System of the Scalp

Name of the Zone	Indications for Application
MS1	diseases of pharynx, oral cavity, nose, bronchopulmonary system
MS2	bronchial asthma, bronchitis, paroxysmal tachycardia, respiratory impairment of central genesis, pain in the thorax
MS3	stomach diseases, pain in the upper part of the abdomen, gallbladder and biliary ductules (dyskinesia) diseases
MS4	diseases of urogenital system and bowels
MS5	neuroses, psychosis, hemicrania and other headaches, dizziness
MS6	central paralysis and pareses
MS7	paresthesia, pains and sensitivity disturbance
MS8	sensitive and moving disturbance of lower limbs, lumbodynia, polyuria of central genesis, enuresis
MS9	speech disturbance, sensor-motor malfunction

MS10	hearing impairment and speech disturbance, pain in the temple, hemicrania, ear noise, pain in the external angle of the eye, rhinitis, trifacial neuralgia, peripheral neuropathy of the facial nerve, toothache, face edema
MS11	hearing impairment, ear noise, dizziness, Meniere's (syndrome) disease, speech disturbance
MS12	visual impairment of the central genesis, headache, pain and tension of occipital muscles; pain in the eyes, visual acuity reduction; neurasthenia, epileptiform fits, twilight state, anxiety; dizziness, vomiting, neck stiffness
MS13	visual impairment of the central genesis
MS14	dizziness, incoordination

6.3. Application of the External Massage Electrode # 2 for DENS Treatment Using Special Methods

External massage electrode # 2 allows carrying out DENS together with massage in the local zone of the lesion focus (the zone of direct projection of the complaint), in metameric and segmental zones. Massage application allows for more intensive therapeutic influence and considerably enhance such effects of dynamic electroneurostimulation as trophic (improvement of lymphotrophy), vascular and lymph drainage.

During the treatment procedure using electrode # 2 the massage treatment should be carried out along lymphatic vessels, movement direction – from periphery to the center. Limbs – from the hand (foot) to the elbow (knee) joint and further to the shoulder (hip) joint. Thorax – from the breast bone towards the muscles, back – from the spine. Treatment can be made using two main methods having different depths on influence on tissues:

— effleurage, this method is usually applied in the beginning and in the end of the procedure. During effleurage the elec-

trode is going along the surface without shifting and without making skinfolds or skin beads;

— attrition – this method is used mostly for treating skin area with low blood supply (back, buttocks, external surface of hips). This method is applied with circular, linear, spiral and other movements and pressure on the electrode should ensure shifting of tissues.

6.4. Application of External Massage Electrode # 2 for Treatment of Cellulites (refer Supplement 1, Fig. 3)

Cellulites is a chronic disease based on metabolic imbalance and wrong formation of the structure of subcutaneous fat. Deformed fat masses develop under skin – “humps” and such area looks like orange skin. Mostly cellulites can be found on hips, buttocks, abdomen and shoulders. Hormonal alteration of the body supported by stresses, physical inactivity and bad habits are a predisposing cause for cellulites.

Treatment of the abdomen skin, zone of buttocks and hips with external massage electrode is carried out by labile or labile-stable method with a considerable compression (pressure) on the electrode, with circular or spiral movements (Supplement 1, Fig. 3). Before the treatment procedure you can apply anti-cellulites cream of the zone to be treated. Treatment is in the THERAPY mode, at frequency 77 Hz with maximum energy level. One zone is to be treated during 10-15 minutes. The course duration is 15-17 procedures.

SUPPLEMENT 1



Fig. 1. Direction of Moving External Massage Electrode # 1 when Treating Diffuse Headache

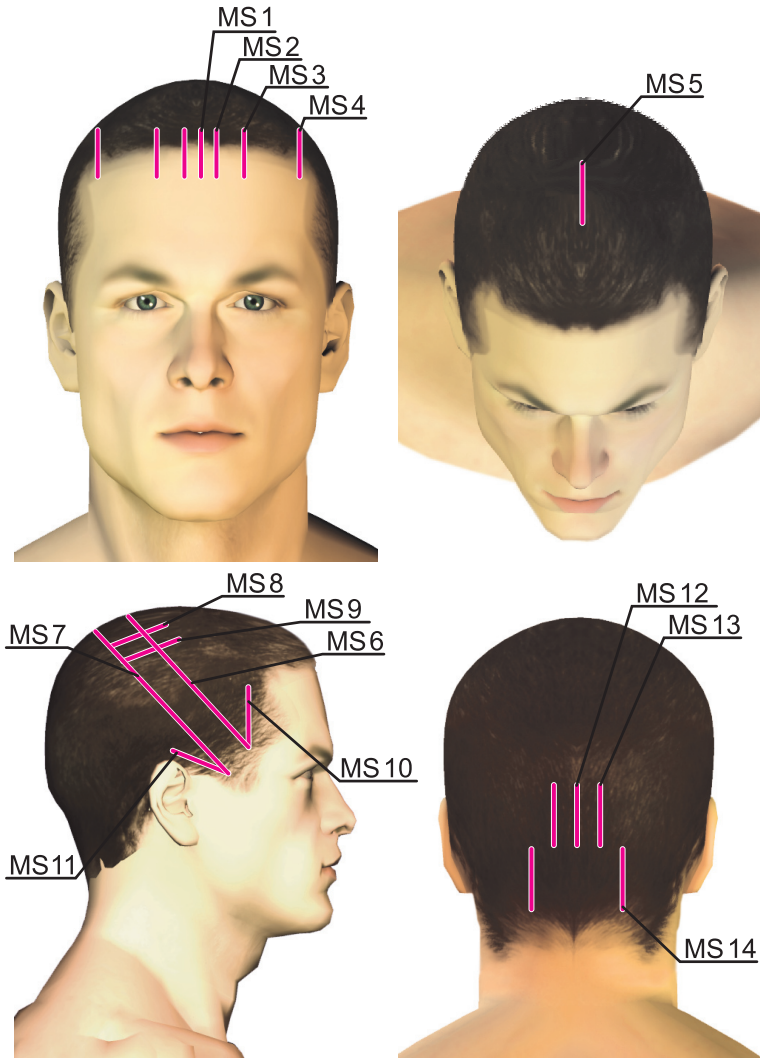


Fig. 2. Scheme of Mini-Acupuncture System of the Scalp

Notes to Fig. 2:

MS1 – nose, pharynx, bronchopulmonary system;

MS2 (pair) – thorax (bronchial asthma, bronchitis, paroxysmal tachycardia);

MS3 (pair) – stomach and gallbladder

MS4 (pair) – bowels and urogenital system;

MS5 – sensor-motor zone of legs (neuroses, psychoses, hemicrania, dizziness);

MS6 – motor zone under disordered motor functions, upper 1/5 part – lower limbs and body, next 2/5 part – upper limbs and upper part of the body, lower 2/5 parts – head, neck, face muscles;

MS7 – sensitivity disturbance – upper 1/5 part – lower limbs and body, next 2/5 parts – upper limbs and upper part of the body, lower 2/5 parts – head, neck, face muscles;

MS8 – sensitive and moving disturbance of lower limbs, lumbodinia, enuresis;

MS9 – sensor-motor area of the wrist – incoordination;

MS10 – hearing analyzer and Wernicke's center – pain in the temple, hemicrania, dizziness, ear noise, rhinitis, trifacial neuralgia, neuropathy of the facial nerve, toothache;

MS11 – vestibulo-cochlear and language zone – hearing impairment, ear noise, Meniere's disease, sensory aphasia;

MS12 – projection of the visual cortex – visual impairment of the central genesis, headache, pain and tension of occipital muscles; pain in the eyes, visual acuity reduction; neurasthenia, epileptiform fits, dizziness, vomiting;

MS13 (pair) – projection of the visual cortex – visual impairment of the central genesis;

MS14 (pair) – projection of the tentorium – cerebellar disturbances.

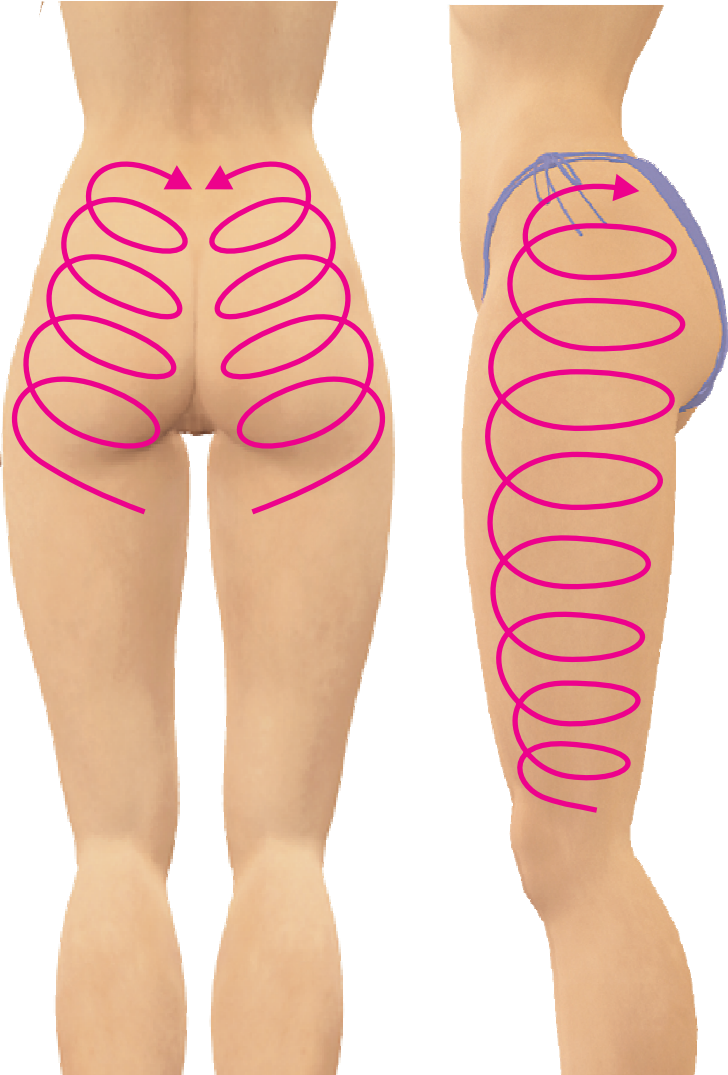


Fig. 3. Treatment of the Hip and Buttocks Areas Applying External Massage Electrode # 2 for Treatment of Cellulites

COUPON FOR WARRANTY REPAIR

Name:
Therapeutic External Massage Electrode # _____

Production date _____

Date of sale _____

Customer _____

Address: _____

Telephone: home _____

office _____

Date of sending for repair _____

Reason for repair _____

Note about repair _____

*signature of the official of the company
responsible for acceptance after repair*

The device was checked, I have no claims to the complete set, appearance of the device.

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 repair station.

CERTIFICATE OF ACCEPTANCE

The device is produced in accordance with TU 9444-002-35266303-2005 and acknowledged to be ready for operation.

Production date _____

signature of the official responsible for acceptance

Date of sale _____

signature of the seller

When there is no seal, signature of the seller, date of sale, the warranty period shall be calculated from the production date.

I know the warranty conditions, the device was checked, and I have no claims to the complete set, appearance of the device.

signature of the customer