ACTIVE MEDICAL DEVICE
FOR STIMULATION BY ELECTROMAGNETIC FIELD

USER MANUAL

TRIOMED COMPACT 1, 5 (31-38)

CE 2274

Version 3

Introduced on 24.07.2013

Saint Petersburg

2013

Declaration of Conformity

MANUFACTURER

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TRIOMED LLC declares that the following device meet the requirements of Directive 93/42/EEC + 2007/47/EC.

Product:
Active medical device for stimulation by electromagnetic field «TRIOMED COMPACT 1, 5 (31-38)»
emitters integrated with device.
Options: 40-43 GHz.

CE
2274

Reg. No in Russia: ФСР 2009/06554.

MEDICAL CLASSIFICATION
Classification: II a
Classification rule according to 93/42/EWG: Annex IX Rule: 9
GMDN 35169
UMDNS 18812.

CONFORMITY ASSESSMENT
Evaluation of this medical device was carried out with the participation of the Notified Body No 2274 TÜV NORD Polska Sp. z o.o ul. Mickiewicza 29 40-085 Katowice. Country: Poland.

General Director
Alexey Seledtsov

Dear Consumer!

This manual on how to use the TRIOMED COMPACT 1, 5 (31-38) device is meant for users and medical staff.

The device is supplied ready for use and can be utilised only for its intended purpose in strict compliance with the operation instructions, safety measures and rules of therapeutic application.

Please read this Manual carefully before using the device and follow all the instructions! Please take notice of the contraindications for use and prohibitions. You will be able to achieve high therapeutic efficiency, avoid possible risks and increase the longevity of the device.

In the event of improper use of the device the right to make claims shall be forfeited and the risk of possible dangers shall be exclusively with the owner.

This Manual is an integral part of the device. To have the information at hand, always keep the Manual together with the device.

If you have any questions concerning the use of the device, please refer to the information provided on the manufacturer's website at ***www.triomed-eu.eu*** *or contact your seller.*

After its manufacture, the device is carefully examined to ensure its normal operation as well as cleaned and disinfected using Aerodesin® 2000 disinfection agent.

The use of the device does not eliminate the need for the patient to remain under medical supervision.

Last updated on 24.07.2013

The following signs have been used in the Manual and for labelling the device.

Manufacturer

Authorised representative in the European Union

CE marking and notified body number

Non-ionising radiation

Device serial number

Not for general (household) waste

Important information about the device or its operation

Keep dry!

Consult instructions for use

Fragile, handle with care!

Caution, consult accompanying documents

On/off (press/ press)

Point of contact with the body of the patient

Class II equipment

TABLE OF CONTENTS

1. PURPOSE

The TRIOMED COMPACT 1, 5 (31-38) device has been designed for maintaining and strengthening the health of the elderly as well as for treating and preventing various pathological conditions by stimulating the skin with low intensity (up to 10 μW/cm^2) impulse electromagnetic radiation (EMR) in the millimeter (MM) and (up to 2 μW/cm^2) infrared (IR) band. Built-in radiators provide the EMR stimulation in the frequency band between 40 and 43 GHz (wave length between 7,5 and 6,9 mm) and between 250 and 375 GHz (wave length between 1,2 and 0,8 μm).

The device is recommended for use primarily for restorative treatment (rehabilitation) of patients with various socially significant and age-associated dieases.

Restorative treatment (rehabilitation) is carried out irrespective of the duration of the disease and aims to eliminate its consequences, prevent exacerbations and relapses, normalise (maintain) disturbed physiological functions, restore (optimise) physical capacity, increase the functional reserves of the body and improve the quality of life in medical terms. MM therapy can be used in comprehensive programmes at early and later states of restorative treatment of diseases and injuries, during rehabilitation and in the case of chronic diseases during a non-acute period.

The device is easy to operate, safe, secure and lightweight and can be used in-patient and out-patient settings (rehabilitation centres, rehabilitation departments), by outreach teams and independently at home in consultation with the treating physician.

In terms of its utilisation the device is classified as a product of multiple cyclic use.

The invention has been patented based on the research materials (registration number EE 05541).

2. MECHANISMS OF THERAPEUTIC EFFECTS

2.1. General mechanisms of action

Electromagnetic waves in the millimetre range have a low capacity to penetrate biological tissues (0,2-0,6 mm), are almost fully absorbed by the upper layers of the skin and by the water, hydrated proteins and collagen fibres contained in them and do not have a thermal effect. At the cellular level, electromagnetic waves in the MM range activate the metabolism through calcium-dependent processes. The response of the body is manifested in the skin and visceral reflexes as well in the general reaction aimed at strengthening the adaptation, adjustment and defence capacity. The healing effects are achieved through the central and peripheral nervous system as well as through the protective and regulatory systems of the body. Electromagnetic waves in the MM range thus regulate the cellular biochemical activity and physiological functions of the body in general.

The effects mentioned above are clinically manifested in anti-inflammatory, analgesic and anti-oedematous action, improved tissue regeneration, increased non-specific resistance of the body through stimulation of the immune system, in enhanced systemic and regional hemodynamics, normalised regulation of the autonomic nervous system and in anti-stress action.

IR radiation of the band used penetrates 1 cm beneath the skin and is absorbed by acceptor molecules and cellular membranes.

The mechanisms of impact of IR radiation on biological tissues comprise the totality of molecular and cellular effects including the local activation of energy-binding processes in pathological foci as well as the launching of a set of adaptation and compensatory reactions arising in response to the local stimulation at the cellular and molecular level.

The therapeutic effects include anti-inflammatory, lymph-draining and vasodilative action. The device accelerates regression of inflammatory processes and improves tissue regeneration, local resistive capacity and anti-infection defence.

2.2. Mechanisms of specialised action of MM radiation

Responses of biological objects (tissues, organs, organ systems) to EMR exposure in the MM band are specific. The direction of the MM therapy depends on the method of use (the location and duration of stimulation), the patient's initial condition and the characteristics of the MM stimulation.

An important role is played by the modulation of the carrying MM radiation with the low-frequency signal corresponding to the physiological rhythms of the organs, systems and the body as a whole. Complex modulated signals

demonstrate a great harmonising potential and biological effect and at the same time have a lower mean power.

Each therapeutic programme uses several low-frequency modulations which have a positive directed impact on the cells of various organs as well as on blood and lymphatic vessels thus raising the efficiency of treatment.

Clinical tests carried out over many years using the methods of molecular medicine at the Saint-Petersburg Institute of Bioregulation and Gerontology in cooperation with the centre of International Association of Gerontology and Geriatrics have shown that the use of the MM therapy through Triomed devices in elderly and old patients with various socially significant diseases helps normalise the oxidant, lipid, opioid and glucocorticoid balance, reduce the number of exacerbations, hospitalisations and admissions for emergency medical care as well as improve the emotional status and certain parameters of the quality of life.

3. INDICATIONS AND CONTRAINDICATIONS FOR USE

MM therapy can be used in prevention programmes, in comprehensive treatment of acute diseases and exacerbations of chronic illnesses as well as in restorative treatment (rehabilitation) programmes, including follow-up treatment.

3.1. Indications

MM therapy can be indicated in the following cases:

- **colds, influenza, acute respiratory infections, decrease in general immunity during recovery and rehabilitation after diseases:** for non-specific stimulation of the immune system, including to achieve a general invigorating effect;
- **chronic heart failure (ischemic heart disease, stable FC I-IV stenocardia; I-II degree arterial hypertension; rhythm disturbance:** rare ventricular arrhythmia, rare supraventricular ectopy): to increase the antioxidant capacity of the muscles, enhance the rheological properties of the blood, stabilise the processes of cholesterol metabolism, reduce the intensity of immune inflammation, improve the endothelial function, normalise lung ventilation during physical exertion, develop light peripheral vasodilatation, normalise the arterial blood pressure and the heart rate variability;

- **I-II degree arterial hypertension:** to lower high arterial blood pressure by adjusting sympathetic-adrenal and parasympathetic influences on the regulation of the heart function, improve the overall health;
- **organic diseases of the central nervous system (ischemic stroke, multiple sclerosis, internal brain injury, traumatic encephalopathy):** to improve the rheological properties of the blood, normalise cognitive and motor functions (increase the precision of simple and complex sensory-motor actions, improve intellectual and mnestic functions, enhance focusing), raise the endurance of nervous processes and restoration of nervous conductivity;
- **cerebral circulatory deficiency and mild and medium discirculatory encephalopathy:** to reduce headache, dizziness and buzzing in the ears, lower high arterial blood pressure, alleviate focal neurological symptoms (pyramidal, cerebellar, Parkinson's syndrome) and mental disturbances. It has a particularly positive impact on the sleep, emotions and the condition of higher cortical functions;
- **problems with vessels in the lower extremities (chronic venous insufficiency, varicose vein disease, post-thrombotic syndrome):** to improve local microcirculation by increasing the permeability of blood capillaries, enhance the rheological properties of the blood and intensify the regional lymph and blood flow;

- **chronic inflammatory diseases of the respiratory tract (chronic bronchitis, chronic obstructive pulmonary disease, asthma):** to improve bronchial permeability, normalise metabolic activity, stabilise the membranes of phagocyteised neutrophils, lower the intensity of peroxidation of lipids, lower the non-specific hyperactivity of the bronchi, improve the functions of external respiration, activate the discharge of bronchial mucus, reduce the frequency of coughing fits;
- **chronic diseases of the spine and joints (degenerative spine diseases, osteoarthrosis, spondylarthrosis):** to improve the mobility of the spine and joints, increase the amplitude of active movements in the joints (locomotor functions), reduce oedemas and relieve the pain syndrome;
- **gastroduodenal ulcers:** to relieve the pain syndrome and dyspeptic complaints, accelerate the healing of the ulcerous defect, alleviate psychoemotional problems;
- **diabetic polyneuropathy:** to reduce the severity of the pain syndrome and the sensation of numbness and burning, alleviate sensory disorders, improve microcirculation, help with psychoemotional problems;
- **climacteric syndrome:** to reduce the frequency and intensity of hot flashes, sweating, headaches and sleep disorders, increase physical capacity, normalise the oxidative status, arterial blood pressure and emotional condition;

- **chronic prostatitis:** to relieve pain, reduce inflammation, normalise urination, restore erection and copulative function, alleviate psychoemotional problems;
- **light depression:** for mild sedative and anti-stress effect, to lower irritability and psycho-emotional distress, to correct sleep disorders and raise spirits;
- **psoriasis (progressive and stationary state):** to achieve hyposensitisation (reduce circulating immune complexes in peripheral blood), improve the rheological properties of blood and microcirculation, normalise the lipid metabolism, help with psychoemotional problems, increase the length of remission, reduce the length of the progressive stage of the disease and lower the number of early relapses;
- **atopic dermatitis in adult and children:** to achieve clinical remission of the disease within a shorter time frame, positively affect the immune systems, increase the anti-inflammatory effect, accelerate resolution of infiltrates and stimulate the processes of skin regeneration;
- **viral hepatitis**: to normalise pigment metabolism and hepatic enzymes, stimulate the immune system and alleviate asthenoautonomic and dyspeptic syndromes;
- **bronchial asthma:** to reduce the activity of immune mechanisms capable of developing tissue damage reactions, alleviate oxidative stress, reduce coughing and short breath, activate the discharge of bronchial mucus

and normalise breathing and the psychoemotional state;

- **chronic forms of mild and medium generalised granulating, granulomatous and fibrous periodontitis, chronic apical periodontitis:** to stabilise the processes of free-radical oxidation and the antioxidant system of defence of the oral fluid, improve rheological properties of the blood and microcirculation and increase the local immunity of oral cavity tissues.

IR therapy can be indicated in the following cases:

- **sluggish wounds and ulcers,**
- **chronic and subacute non-purulent inflammatory diseases of internal organs,**
- **burns and frostbites,**
- **diseases of the peripheral nervous system with the pain syndrome (myositis, neuralgia),**
- **consequences of musculoskeletal injuries,**
- **preparation of the skin zones for MM stimulation.**

3.2. Contraindications

for using MM radiation:

- general contraindications to physical therapy;
- unknown diagnosis;
- idiosyncrasy to electromagnetic millimeter stimulation;
- febrile states of unclear aetiology;
- patients having an implanted device with autonomous power supply (in the area of the device installation).

Contraindications for using IR radiation:

- benign or malignant neoplasms,
- active forms of tuberculosis,
- III-degree hypertension, bleeding and II-III degree circulatory deficiency.

Stimulation of the eyes should be avoided.

In the case of diseases which pose a serious threat to life and health the device can be used only under the supervision of a doctor!

4. TECHNICAL AND OPERATIONAL CHARACTERISTICS

4.1. General technical characteristics

The device is produced without using any harmful chemical substances in compliance with the TRIOMED LLC technical documents and meets the requirements of Directives 93/42/EEC and 2007/47/EC.

As far as potential risks of use are concerned, the device is classified as Class IIa equipment according to Directive 93/42/EEC and has been designed as a product with internal safe power supply.

The TRIOMED COMPACT 1, 5 (31-38) device has in-built BioTrEM generator no.1 of millimeter electromagnetic radiation (carrier frequency between 40 and 43 GHz, wave length between 7,5 and 6,98 mm) and generator no.5 of IR radiation (wave length between 1,2 and 0,8 μm).

The software allows to generate MM and IR radiation with various modulation and distribution of stimulation during the treatment session. The device features 8 programmes (31-38) described in Section 11.

The number "1, 5" following the name refers to the type of generator installed and the number in brackets "(31-38)" refers to one of the eight treatment programmes (according to the unified register of the manufacturer).

For ease of use of the device and better memorisation of the programme numbers, the treatment programmes in this user manual are marked with numbers 1-8 corresponding to the programmes numbered 31-38 in accordance with the unified register of the manufacturer.

The main technical characteristics of the TRIOMED COMPACT 1, 5 (31 -38) device are given in Table 1 below.

Table 1

No	Characteristics	Description
1	Start–up time	no more than 5 sec
2	Type of work with specified characteristics	continuous, uninterrupted
3	Automatic shutdown function	after the end of the programme
4	Overall dimensions	no more than 75×45×13 mm
5	Weight	no more than 0.1 kg
6	Mean time between failures	no less than 1500 hours
7	Life cycle	no less than 8 years

8	Body material	polycarbonate plastic
9	Ambient temperature during use	between + 10 and + 35ºC
10	Rated air humidity (combination of relative humidity and temperature)	80 % at 25 °C
11	Rated direct voltage	3,0 V
12	Consumption current	no more than 30 mA
13	Power consumption	no more than 100 mVA

The device comes with a CR2032 battery.

Millimeter electromagnetic radiation is modulated by a simple low-frequency or complexly modulated signal. The frequency, duration and form of modulating signals are changed during the treatment session according to original programmes labelled by identification numbers. The modulation of millimeter radiation in accordance with various programmes ensures multimodality of exposure enhancing the therapeutic effect.

The external surfaces of the device are disinfected using a 3% solution of hydrogen peroxide or a 1% water solution of chlorhexidine.

No special safety measures are required.

4.2. Structure and functioning

The device is a monoblock unit.

The top panel of the body of the device (fig 1) houses the control button.

The following can be found under the top panel: a battery holder, 4 LEDs indicating the switched-on state and the stimulation programmes and a speaker.

The bottom panel of the body (fig 2) houses the IR radiator (IR diode) and two screws.

The generator of the MM EMR is located under the bottom panel.

The side panels (fig 1) house a hanging loop and a bridge for fastening a strap.

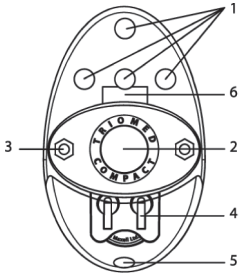


Figure 1. General view

1 – light indicators
2 – control button
3 – hanging loop
4 – battery holder
5 – strap fastening
6 – speaker

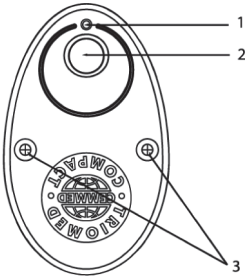


Figure 2. Bottom panel

1 – IR radiator
2 – location of the MM EMR generator
3 – screws of the bottom panel

When the control button is pressed, the device switches on and programme no.1 is selected. When the button is held in the pressed position, the device keeps changing the programmes as indicated by the LEDs switching on briefly (for approx. 2 seconds) in various combinations (fig 3-10). If the control button is not released, the programme switching cycle is repeated. When the button is released during the indication of a particular programme, the device activates it turning the radiation on.

To confirm that the device is working in accordance with the programme selected, the corresponding LEDs (fig 3-10) are switched on and a sound signal is produced briefly at certain intervals (3-4 sec).

To use the device without sound, enter again the programme selection mode by pressing and holding the control button. Wait for the LED combination selected earlier and release the control button. The device is programmed

to switch on the sound in every other programme selection cycle.

The device memorises and activates at the next start-up the programme used in the previous session. A brief press on the control button switches the device on and activates the programme that has been memorised skipping the selection mode. The programme currently in use is indicated.

Having finished its operation according to the programme selected the device switches off automatically. The device can be switched off at any time by pressing the control button.

4.3. Use of the device

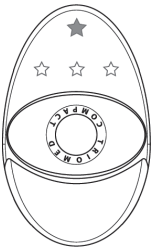
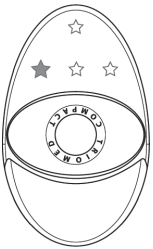
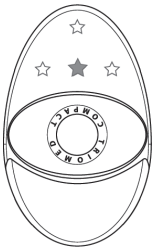
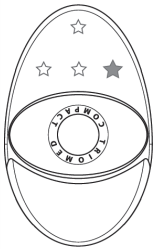
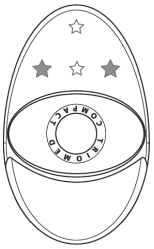
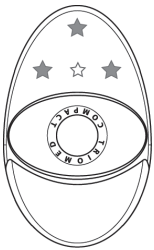
Decide on the suitable treatment programme (Section 11.1). Find out the LED combination which indicates it (Fig. 3-10).

Switch on the device and select the programme.

The device will activate the programme and start generating radiation after you release the control button.

If you want to use the programme that was running during the previous session, switch on the device by briefly pressing the control button.

The LED indication of the programmes in the selection and operation modes is shown in Fig. 3-10.

Fig. 3	Fig. 4	Fig. 5	Fig. 6
			
Programme 1	Programme 2	Programme 3	Programme 4
Fig. 7	**Fig. 8**	**Fig. 9**	**Fig. 10**
			
Programme 5	Programme 6	Programme 7	Programme 8

5. PACKAGE CONTENTS

Package contents:

- TRIOMED COMPACT 1, 5 (31-38) device;
- CR2032 battery installed;
- user manual;
- consumer packaging;
- warranty.

6. LABELLING

The marking is shown on the label placed at the bottom of the device.

Figure 11. Label

The label (Fig. 11) specifies:

- name and model of the device,
- factory number (serial number/two last digits of the year of manufacture),
- CE marking,
- certification body number.

Manufacturer, handling symbols, power consumption, the type and amount of nutrients and other necessary information is given in this manual.

7. PACKAGING

The packaging protects the device from weather and mechanical damage. The packaging (box) provides all the required information in English and the language of the seller's country about the product, package contents, manufacturer and authorised representative in the EU. It also contains handling symbols and data concerning the certification in the European Union.

8. DISPOSAL

The device is produced in accordance with the EU requirements for the content of harmful chemical substances. The device should be disposed of into a special container for radioelectronic equipment.

9. WARRANTY

The warranty is provided on a separate sheet which can be found in the box.

10. PREPARING THE DEVICE FOR USE

10.1. Operating restrictions

The device can be used only after reading the User Manual.

IT IS FORBIDDEN:

- to use the device without reading the User Manual;
- to use the faulty or damaged device;

- to use the device in rooms with high humidity;
- to put the device into water;
- to let water and chemical substances get inside the device;

- to handle the device roughly, expose it to excessive mechanical vibrations or shocks, crush or drop the device;

- to use self-made power supply devices;

- to keep the device in places accessible to children and animals;
- to use the device after it has been stored at a temperature below 0° C without leaving it first for at least 4 (four) hours to lie unpacked at the room temperature.

10.2. Safety precautions

- no special safety precautions are required for the patient in the case of device failure, emergency or urgent evacuation of the medical staff;
- the patient can assume any comfortable position during the treatment with the device.

10.3. Preparing the device for use

Before switching on the device, inspect the outside of the device and make sure that the body is not damaged. **IT IS FORBIDDEN** to use the device with the damaged body!

Fig 12 shows how to replace the battery.

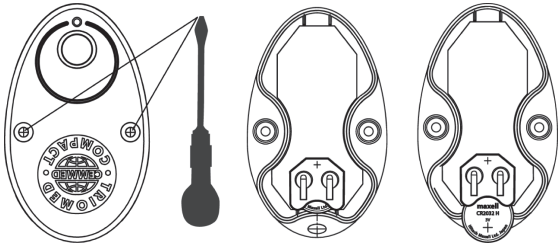


Figure 12. Battery replacement

- use a cross-point screwdriver to unfasten the screws;
- take off the top panel;
- remove the battery from the battery holder;
- insert a new CR2032 battery into the battery holder observing the polarity;
- reinstall the top panel and fasten it to the bottom panel with the screws.

The level of the battery charge is indicated by the brightness of the LEDs.

The serviceability of the device should be checked before every use. The normal functioning of the device is described in Section 4.2 “Structure and functioning”.

10.4. List of possible faults and suggested remedies

Possible faults and suggested remedies are listed in Table 2.

Table 2

No	Signs of a fault	Likely reason	Remedy
1	The LEDs do not switch on when the control button is pressed	The battery is defective or has discharged	Replace the battery. If following the insertion of a non-defective battery the device cannot be switched on, send it to be repaired
2	Lack of sound in the speakers following the activation of the programme	The silent mode has been selected	Select the programme with sound and activate the programme selected (Section 4.2) If there is no sound, send the device to be repaired

3	The device does not exit the selection mode and does not switch off	Electric circuit failure	Send the device to be repaired
4	The battery in the device discharges quickly (within less than a month) even if the device is used rarely.	Electric circuit failure	Send the device to be repaired
5	No radiation is generated when checked with the EMR EHF SKIT indicator	Electric circuit failure	Send the device to be repaired

In the case of other faults please contact the Seller. The addresses and contact numbers can be found in this Manual and on the package.

10.5. Technical maintenance

No technical maintenance is provided during the life cycle of the product.

The serviceability of the device and the characteristics of the radiation it generates are checked once a year at the technical maintenance centres of the Seller.

11. PROCEDURE FOR USING THE DEVICE

This User Manual regulates the therapeutic use of the device.

By exposing areas of the skin to a MM electromagnetic field using the TRIOMED COMPACT 1, 5 (31-38) device, you can exert a positive effect on the internal organs and vital functions of the organism.

Programmes no.1-7 generate EMR in the MM band with a uniform carrier frequency and varied distribution of the low-frequency modulation and integral capacity during the procedure.

Programmes no. 6 and 7 generate millimeter EMR and infra-red radiation.

Programme no. 8 provides only infra-red stimulation.

The combination of programme no. 1 used distantly and other programmes used locally ensures multimodal exposure and enhances the therapeutic effect.

In accordance with the rules and principles of physical therapy and restorative medicine (rehabilitation), the device can be used to stimulate the following areas:

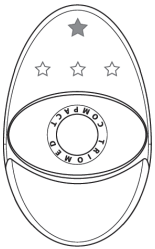
- the pathological focus or the area of its projection,
- the projection of the organs in the Head's zones,
- areas of biologically active points and zones,
- the area of the spinal column, joints and great vessels.

The selection of the programme and the areas of stimulation during MM and IR therapy of various conditions should be based on the main syndrome depending on the reason, location of the pathological focus, the stage of the disease and the state of the body.

The systemic effects of the therapy are of a prolonged character. Stimulation only produces an initial positive effect which builds up in the next 2-3 weeks after a course of stimulation. That is why a pause of 3 to 8 weeks (depending on the patient's state of health) is necessary between the courses.

The individual selection of the treatment programmes and the treatment plan takes into account the location and duration of stimulation as well as the number treatment sessions.

11.1. Programme description



Programme no. 1 Harmony (30 minutes). Distant stimulation.

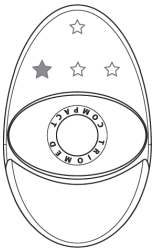
It is used as the main mode:

- to prevent acute conditions and exacerbations of chronic diseases;
- to reduce the risk of complications in the case of acute and chronic diseases by activating the general adaptation and optimising the response of the human body to the stress factors;

- to provide constant support in the case of chronic diseases;
- to produce a general invigorating effect in the case of intense physical, psychological and emotional exertion.

Distant stimulation

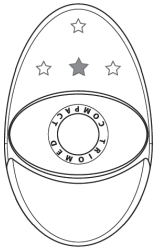
- helps restore the balance of activity of the sympathetic and parasympathetic parts of the autonomic nervous system;
- increases the total activity of neurohumoral influences in the human body;
- prevents the exhaustion of the sympathoadrenal system and the development of chronic stress;
- optimises the adaptive response of the body;
- helps restore the functional reserves of the body.



Programme no. 2 Universal (10 minutes) is designed to prevent the occurrence of acute conditions and exacerbations of chronic illnesses by improving the function of the autonomic nervous and immune systems and optimising the response of the body. It is used for I-II degree pathological conditions accompanied by the disadaptation syndrome.

The programme ensures a 10-minute exposure.

The device is used in the contact mode.



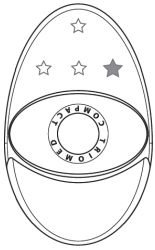
Programme no. 3 Healer (15 minutes) is meant for extended supportive therapy in the periods between courses of main treatment carried out, among other things, using the device in accordance with programmes no. 2-7.

It is also recommended to prepare weak or old patients for the main treatment course. Stimulation helps relieve the functional deficiency of the organs by activating the adaptation and compensatory mechanisms. It is used in pathological conditions characterised by considerable (II-III degree) malfunctions of the organs.

To use the Healer programme, first bring the device to the area selected and only then switch it on.

This programme is recommended for local stimulation in the pathological focus or in painful areas of the projection of the organs in the Head's zones.

The duration of stimulation of one zone is 15 minutes 1-2 times per day. The course of treatment last for 1-1,5 months.

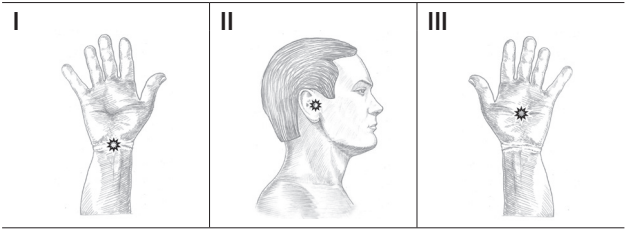


Programme no. 4 Stressbuster (12 minutes) is used to reduce the severity of the lingering stress syndrome in order to prevent stress damage to the cardiovascular, digestive as well as central and peripheral nervous systems, to relieve the pain syndrome as an auxiliary treatment during

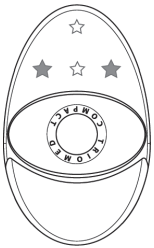
pharmacotherapy and to reduce the dose of the medication taken. The programme is indicated in the case of increased fatigability, overfatigue, increased irritability, psycho-emotional distress, sleep disorders and low spirits.

It improves local microcirculation due to the increase in capillary permeability, enhances the rheological properties of the blood, intensifies the regional lymph and blood flow, normalises the regulation of the activity of the central and autonomic nervous system and has a mild sedative and antidepressant effect.

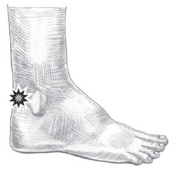
To activate the anti-stress effects it is recommended to use the programme to stimulate the projection of the radial artery in the area of the wrist (I), the tragus area (II) and (III) the centre of the left palm (in slow circular motions).

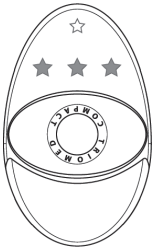


The duration of stimulation of one zone is 12 minutes once a day. The course of treatment consists of 10 sessions.



Programme no. 5 Fenix (10 minutes) has a anti-inflammatory effect. It is used for treating wounds, scratches and burns (as it reduces the likelihood of infection and considerably accelerates regeneration of damaged tissues) as well as various acute and exacerbated chronic (incl. articular) inflammations (as it reduces oedema and pain). To activate the anti-inflammatory effects it is recommended to use programme no.5 to carry out stimulation locally in the zone of the inflammation focus, in the projection of the radial artery in the area of the wrist (I) and in the area (II) between the lateral malleolus (in the middle) and the Achilles tendon.

I	II	
		The duration of stimulation of one zone is 10 minutes once a day. The course of treatment consists of 15 sessions.



Programme no. 6 Edelweiss (12 minutes) has an antihypoxic and antioxidant effect. This mode enhances the resistance to hemic, circulatory and tissue hypoxia.

The programme improves microcirculation and tissue respiration and normalises the functioning of the respiratory chain (gas

exchange in the lungs, haemoglobin in the blood, respiratory ferments, oxygen transport and utilisation, ATP synthesis). The activation of oxidation-reduction processes increases the supply of energy to the body.

The programme also activates the system of defence from free radicals which are formed when the supply of oxygen to the tissues of the body is insufficient.

Programme no.6 should be selected for conditions which create the risk of poor oxygen supply to the cells and acidosis of the blood (mountaineering, staying in poorly ventilated environments, living in air-polluted cities, suffering from overfatigue). It is recommended for acute and chronic diseases accompanied by intoxication and disturbed microcirculation or exacerbated by respiratory failure or circulatory deficiency.

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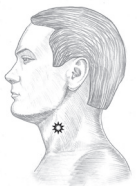
III



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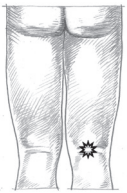
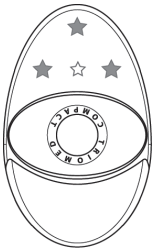


To activate antihypoxic and antioxidant effects it is recommended to use programme no.6 in the zone at the edge of the popliteal fold when the knee joint is bent on the inside (I), in the projection of the radial artery in the area of the wrist (I), in the projection

of the carotid areas (III) and in the area of the inner edge of the popliteal skin fold (IV).

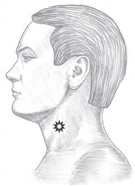
The duration of stimulation of one zone is 12 minutes once a day. The course of treatment consists of 15 sessions.



Programme no. 7 Youth (12 minutes) is used in the case of disturbed metabolism and to slow down aging. This mode restores the nourishment of the tissues and normalises the metabolism. The programme helps restore cells and tissues, increase the sensitivity of the receptor system to biologically active substances and hormones and improve the functioning of the organs.

I

II



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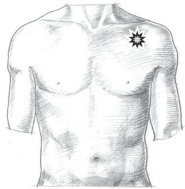

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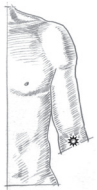
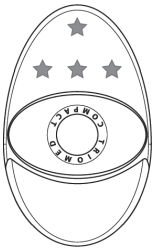


To activate the trophic effects it is recommended to use programme no.7 to carry out stimulation in the pathological focus (trophic ulcer, wound), in the projection of the radial artery in the area of the wrist, in the projection of the carotid areas,

in the zone of the outer third of the subclavian area and in the zone in the middle of the ulnar fold.

The duration of stimulation of one zone is 12 minutes twice a day. The course of treatment consists of 20 sessions.



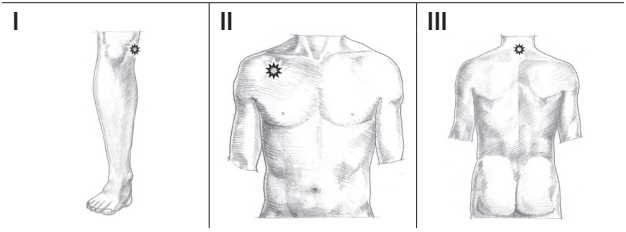
Programme no. 8 Photon (5 minutes) – low-intensity IR stimulation allows to optimise the energy supply to the cells, normalise the system of intracellular regulation and intensify biosynthetic processes. It facilitates resonant absorption of energy by the cell helping improve metabolic processes and increase the energy efficiency of the cell in situations of oxygen deficiency.

The main indications for using infra-red radiation are: preparation of zones for MM stimulation, cicatricial changes in tissues, subacute and chronic non-purulent inflammatory diseases of internal organs, sluggish wounds and trophic ulcers, diseases of the peripheral nervous system with the pain syndrome, residual effects of burns and frostbites, autonomic dysfunctions, complications of diabetes.

The contraindications for using infra-red radiation are: benign and malignant neoplasms, active forms of tuberculosis, III degree hypertension, bleeding and II-III degree circulatory deficiency. Stimulation of the eyes is not recommended.

Stimulation using programme no. 8 should be carried out locally in the pathological focus (wounded surfaces,

trophic ulcers, non-purulent inflammatory diseases, cicatricial changes), at the edge of the popliteal fold when the knee joint is bent on the inside (II), in the zone of the outer third of the subclavian area (II) and in area between the 7th cervical vertebra and the 1st thoracic vertabra (III).



The duration of stimulation of one zone is 5 minutes twice a day. The course of treatment consists of 10 sessions.

11.2. Treatment description

- The patient assumes a comfortable position.
- To begin the treatment, the suitable programme of stimulation is selected and the device is switched on by pressing again the control button.
- For programmes no. 2-8, the device is placed on the patient's body with the top panel facing up and is held by hand.
- To switch on the radiation and begin the treatment session, the control button needs to be pressed. When the device is working normally, the LEDs are periodically switched on in the combination that corresponds to the programme selected; the speaker produces sound.

- The duration of the stimulation is determined by the programme. It is recommended not to break off the session. At the end of the treatment session the device will switch off automatically.
- You can switch the device off earlier, by pressing the control button at any time.
  - When stimulating broad biologically active zones it is recommended to slowly move the device in circles.
  - When stimulating the area of the spinal column as well as large and great vessels the device should be moved longitudinally.

The methods described include a list of the basic zones for stimulation in accordance with programme 2.

In the case of disease manifestations (syndromes and symptoms) listed in the description of programmes no. 3-8, the relevant programme is additionally selected for the patient.

ATTENTION: in the case of deterioration or discomfort that persists after 3 treatment sessions, it is recommended to stop using the device and contact the treating physician.

11.3. Local stimulation in the pathological focus

If the pathological focus is located on the surface (injury, inflammation) and manifested through pain, reddening or swelling, the stimulation should be local.

At the initial stage of the disease, it is recommended to carry out stimulation for 5-7 minutes 4-5 times a day gradu-

ally reducing the number of treatment sessions when the patient starts feeling better.

11.4. Use of the device in the Head's zones

The is a close regulatory link between segments of the spinal cord and internal organs. That is why visceral diseases are accompanied by reflex changes in segmentally related functional formations mostly innervated by the same segments of the spinal cord. Reflex changes can occur in the skin, muscles and connective and other tissues and, in their turn, exert influence on the primary focus supporting the pathological process.

In physical therapy, the majority of therapeutic effects on the damaged internal organs are achieved through the Head's zones. In most cases such treatment gives positive results.

The figure shows the zones of increased skin sensitivity (hyperesthesia) which are called the Head's projection zones. In these areas of the skin, any normally painless irritation in the form of pressure, touch, heat or cold causes pain or discomfort.

The centres of projection zones are the so-called active spots of anxiety or points of concentrated pain where the affected organs send their signals of distress. Such points are easy to locate. When stimulated, they become sensitive, and even cause pain. Hypersensitivity disappears after the functioning of the organ or system of organs has been normalised.

It is recommended to stimulate the area corresponding to the sick organ.

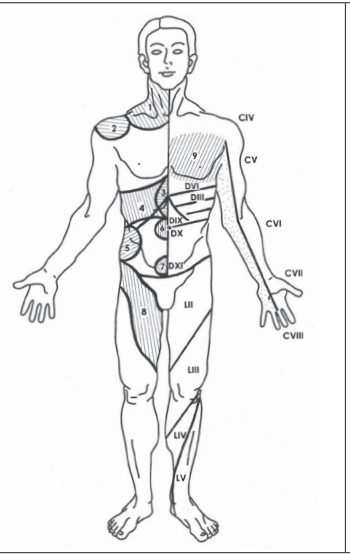


Figure 13.
Head's projection zones
1 - lungs,
2 - liver,
3 - stomach and pancreas,
4 - liver,
5 - kidneys,
6 - small intestine,
7 - large intestine,
8 - ureter,
9 - heart.

A specific zone or biologically active point should be stimulated for 10 to 15 minutes. The total duration of the stimulation should not exceed 60 minutes per day. In the initial period of treatment (1-2 days) it is practical use the device to activate the regulatory systems (1 treatment session per day). After the body has adapted to the stimulation, the intensity of the treatment is increased to 2-3 treatment sessions per day. If necessary, the course of treatment can be repeated in 2-3 months.

11.5 Stimulation of biologically active zones

The back of the neck, the back of the head, the shoulder girdle and the upper part of the back and the chest make up the so-called collar area which is extremely important because it houses the nerve plexuses of the neck affecting the vascular system, the trophism of the brain and the functional state of the anterior lobe of the pituitary gland and of the thyroid gland.

Stimulation of this area is indicated in the case of hypertension, sleep disorders and trophic disorders in the upper extremities.

Stimulation should be carried out at the level of the 4th cervical vertebra and the 3rd thoracic vertebra (C4-D3) paravertebrally covering the zone of the shoulder girdle top-down in slow longitudinal or zig-zag motions for 1 minute on each side in turn holding the device for 5-7 seconds on the most painful spots.

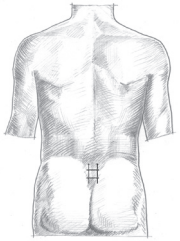
The total duration of the treatment sessions should be gradually increased: first sessions should last for 4 minutes, subsequent ones for 6-8 minutes daily. The treatment course consists of 10-12 sessions.

The lower thoracic and the upper lumbar areas are important reflexogenic zones by stimulating which you affect the functional state of the organs located within this metamere, in particular the kidneys and the adrenal glands.

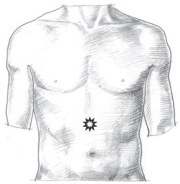
Stimulation should be carried out paravertebrally at the level of the 10th thoracic and the 2nd lumbar verte-

bra (D10-L2) bottom-upwards several times on each side staying longer on the most painful spots.

The first 2-3 treatment sessions should last for 8-10 minutes, each subsequent session should be increased by 1 minute until the duration reaches 12-15 minutes daily. The course consists of 12-15 sessions.



Stimulation of the lumbosacral area improves the blood circulation and the trophism of the tissues in the zone of stimulation, in the lower extremities as well as in the pelvic organs. It is indicated in the case of vascular diseases and injuries of the lower extremities and to stimulate the hormonal function of the sex glands. The treatment has a general tonic effect on the patient's body. Stimulation is carried out in slow longitudinal and circular motions vertebrally at the level of the 4th lumbar and the 3rd sacral vertebra (L4-S3) on each side in turn for 20-30 seconds. The duration of one session if 12-15 minutes, 2-3 times a day. The course consists of 12-15 treatment sessions.



The anticardium houses the solar plexus which is a collector of autonomic links of the abdominal, pelvic and thoracic organs and the centres of the spinal bulb. Stimulation of this area has a positive effect on the function of the above-mentioned organs and the central nervous

system. The treatment session in the pit of the stomach should be carried out for 1 minute 1-1,5 hours after a meal in circular, slow, sliding motions clockwise gradually covering the central spots. Then the device should be held still for 1 minute under the xiphoid process. During the session (that lasts 8-10 minutes) the sequence mentioned should be repeated 4-5 times. The treatment should be carried out daily or every other day. The course consists of 10-12 sessions.

Clinical research has shown a connection between the skin in the lower part of the anterior abdominal wall and the internal genitourinary organs. Stimulation of the anterior abdominal wall allows to actively influence the state of these organs. The radiator should be slowly moved in the lower part of the abdominal wall in alternating rectilinear, circular and zigzag motions. The duration of one session is 12-15 minutes. The course consists of 10-15 treatment sessions. In a number of cases it is practical to carry out the said procedure in combination with the massage of the lumbosacral area.

11.6. Stimulation of reflexogenic zones

In addition to segmental reflexogenic zones there are also other reflexogenic zones on the human body which correspond to the projection of various organs and body parts to the brain cortex and are topographically localised in particular areas. Such zones include the palmar surface of the hand, the plantar surface of the foot, the nasal region, the auricle and the cranial integuments.

11.7. Specific methods

The methods described include a list of the basic zones for stimulation in accordance with programme 2.

In the case of disease manifestations (syndromes and symptoms) listed in the description of programmes no. 3-8, the relevant programme is additionally selected for the patient.

To achieve the optimal therapeutic effect during one treatment session it is recommended to stimulate 2-3 zones. Treatment sessions are carried out 3-4 times a day.

The next day you should alternate the side of stimulation if the location is symmetrical or repeat the stimulation if the location is not symmetrical (for instance, the zone of the breastbone) Two days later next zones are stimulated.

Within one programme course the programmes and stimulation spots should alternate:

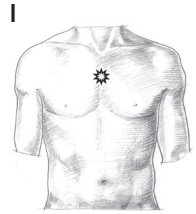
- in the morning and in the evening – basic zones (using programme no.2),
- in the middle of the day - zones specified in the description of the programme selected (using programme no. 3-8).

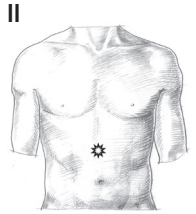
In the case of such alternation the general duration of the course of stimulation using programme no. 2 should be determined based on the lengthiest one of them.

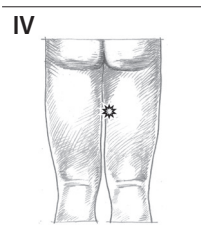
In these specific methods, contract stimulation is combined with distant exposure using the device in accordance with programme no. 1 Harmony two times a day. If necessary, the course of treatment can be repeated in 1-1,5 months.

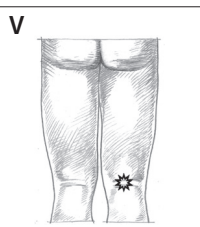
11.7.1. In the case of colds, influenza, acute respiratory infections, decrease in general immunity during recovery and rehabilitation after diseases

I. The area of the thymus gland (the spot between the internal ends of the collar bones in the hollow above the presternum).
II. The region of the solar plexus.
III. The vertex of the angle formed by the 1st and the 2nd metacarpal bones on the back of the hand.
IV. The middle of the inner thigh.
V. The popliteal space on the left and on the right.









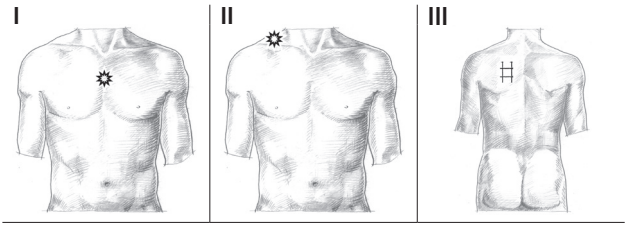
The duration of stimulation of one zone is 5-7 minutes. The course of treatment consists of 10-15 sessions.

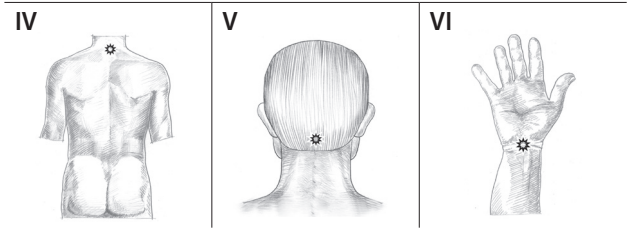
It is recommended to carry out stimulation 1-2 times a day.

11.7.2. In the case of chronic heart failure (ischemic heart disease, stable FC I-IV stenocardia; I-II degree arterial hypertension; rhythm disturbance: rare ventricular arrhythmia, rare supraventricular ectopy)

I. The zone of the breastbone and the zone to its left (the lower half).
II. The zone of the shoulder girdle and the area above the collar bone on the left
III. Behind and on the left above the shoulder blade, between the shoulder blades on the left, the scapular spine
IV. The projection of the 1st and the 2nd cervical vertebrae.
V. The occipital region.
VI. The projection of the radial artery in the area of the wrist on the right.

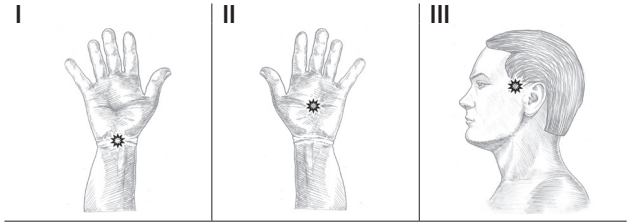
The therapeutic stimulation is carried out on the front surface and then on the rear surface of the body. You can use small circular clockwise motions 2-3 cm in diameter. The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 10 sessions.





11.7.3. In the case of organic diseases of the central nervous system (ischemic stroke, multiple sclerosis, internal brain injury, traumatic encephalopathy)

I. The projection of the radial artery in the area of the wrist on the right.
II. The middle of the left palm.
III. The temporal fossa on the left and on the right.
IV. The projection of the 1st cervical vertebra.
V. The neck and collar region.
VI. The projection of the carotid arteries in the neck region on the left and on the right.
VII. The zone of the popliteal fold



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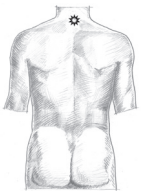

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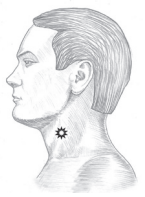

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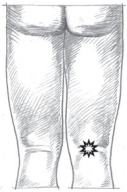
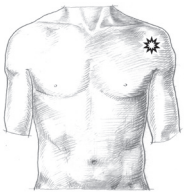


The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 15-20 sessions.

11.7.4. In the case of cerebral circulatory deficiency and mild and medium discirculatory encephalopathy



The device is placed on the outer surface of the shoulder joint at the level of the head of the humerus (on the side opposite to the location of the lesion of the brain and in the case of diffuse disorders preferably on the right shoulder joint).

The therapeutic stimulation should be carried out for 10 minutes in the morning and in the evening. In total, 10-15 daily sessions are needed.

11.7.5. In the case of problems with vessels in the lower extremities (chronic venous insufficiency, varicose vein disease, post-thrombotic syndrome)

I. The left shoulder joint at the level of the head of the humerus.
II. The area under the nuchal bone.
III. The projection of the 3rd lumbar vertebra.
IV. The popliteal space on the left and on the right.
V. The region extending from the small of the neck to the Achilles tendon except for the front of the thighs and the front of the lower legs. Slide the device slowly from the periphery to the centre (up) making small spiral movements.

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 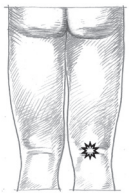 </td>
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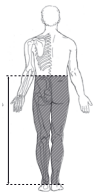
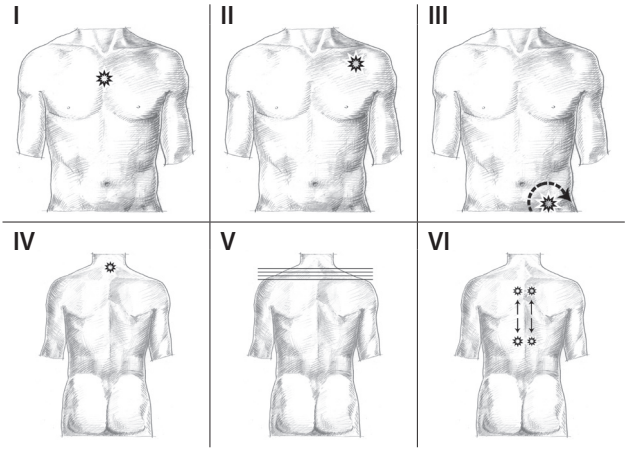
  </td>
<td>The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 10 sessions.</td>
</tr>
</table>

11.7.6. In the case of chronic inflammatory diseases of the respiratory tract (chronic bronchitis, chronic obstructive pulmonary disease, asthma)

I. The upper third of the sternum.
II. The projection of the left subclavian vascular bundle.
III. The left iliac region.
IV. The projection of the 1st cervical vertebra.
V The neck and collar region.
VI. Paravertebrally at the level of the 3rd and the 10th thoracic vertebrae.

The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 10-12 sessions.

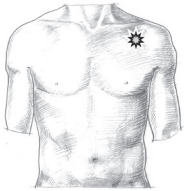


11.7.7. In the case of chronic diseases of the spine and the joints (degenerative spine diseases, osteoarthrosis, spondylarthrosis)

I. The zone of pain localisation.
II. The projection of the damaged joint and the adjoining areas.
III. The projection of the 1st and the 2nd cervical vertebrae.
IV. The projection of the left subclavian vascular bundle.
V. The lumbosacral region.
VI. Paravertebrally along the spinal column top-down.
VII. The area of the projection of the liver.

III

IV



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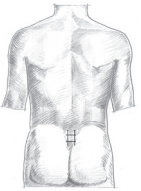

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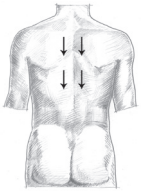

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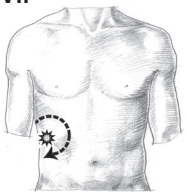

The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 15-20 sessions.

11.7.8. In the case of gastroduodenal ulcers

I. The vertex of the angle formed by the 1st and the 2nd metacarpal bones on the back of the hand.
II. The lateral outer surface of the knee joint (lateral condyle of the shin bone)
III. The recess under the 7th cervical vertebra.
IV. The zone of the solar plexus (midway between the xiphoid and the navel).
V. The projection of pain to the anterior abdominal wall. If there is no pain when the patient is at rest the zone of stimulation should be the spot of maximum painfulness or discomfort during surface or deep palpation.

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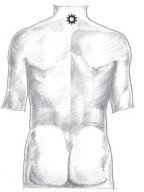

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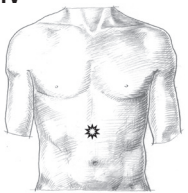
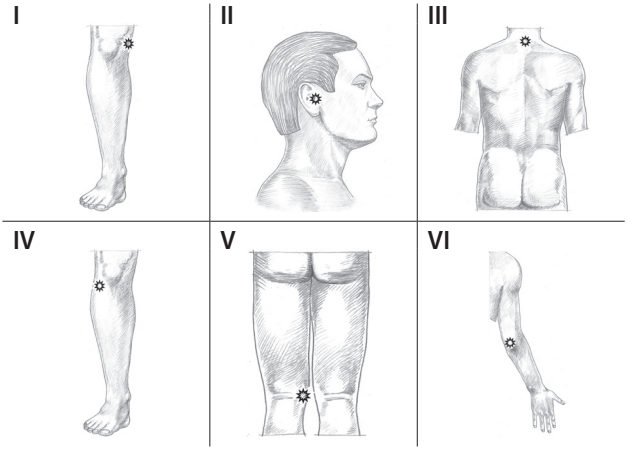


The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 10-25 sessions. It is recommended to carry out stimulation 1-2 times a day.

11.7.9. In the case of diabetic polyneuropathy

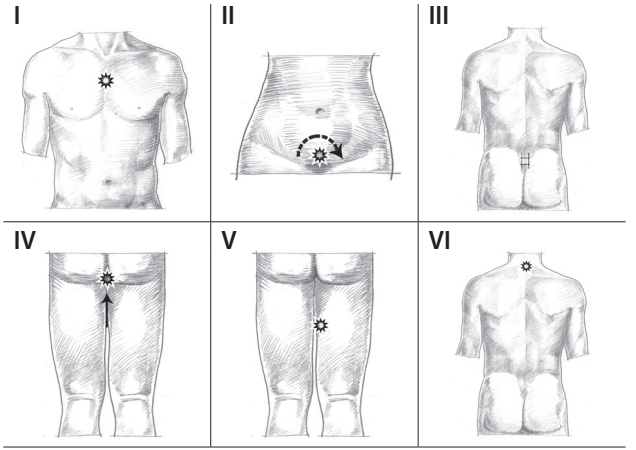
I. The zone at the edge of the popliteal fold when the knee joint is bent on the inside- on the right
II. The tragus area on the right.
III. The area between the 7th cervical vertebra and the 1st thoracic vertabra
IV. The zone near the inner edge of the knee joint 3 cm below the edge of the kneecap - on the right.
V. The area of the inner end of the popliteal skin fold - on the left.
VI. The zone of the shoulder above the olecranon of the ulnar bone (2 cm above the elbow) - on the right.
VII. The most painful spots on the inner surface of the lower leg.
VIII. The most painful spots on the back of the foot.



The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 20-25 sessions.

11.7.10. In the case of climax and prostatitis

I The area of the thymus gland (the spot between the internal ends of the collar bones in the hollow above the presternum).
II. The suprapubic region.
III. The lumbosacral region.
IV. The crotch
V. The middle of the inner thigh.
VI. The projection of the 1st cervical vertebra.
VII. The projection of the adrenal glands.
VIII. The projection of the radial artery in the area of the wrist on the right.



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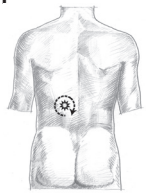		The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 20 sessions.

11.7.11. In the case of light depression

I. The zone of the posterolateral surface of the lower leg - on the left and on the right.
II. The zone at the end of the cross fold of the wrist joint on the side of the thumb - on the right.
III. The zone on the medial border of the foot backwards and downwards from the condyle of the first instep bone - on the left and on the right.
IV. The popliteal space - on the left and on the right.
V. The zone of the back surface of the middle third of the foot between the 1st and the 2nd toes - on the left and on the right.
VI. The zone near the cross fold of the wrist joint on the inside - on the left and on the right.

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		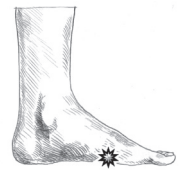

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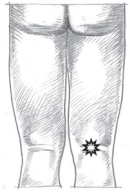

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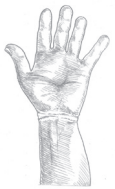
VI

The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 15 sessions.

11.7.12. In the case of disturbed coordination of movements

The disturbed coordination of movements may have various causes, including degenerative and dystrophic conditions of the central nervous system.

I.
The palm of the hand.



II.
The plantar surface of the foot.

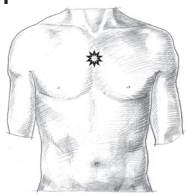
Each zone should be stimulated for 1 minute three times a day at the beginning of each treatment course and up to 10-12 minutes at the end of the course. During the course of treatment the duration of stimulation of each zone should be increased by 1 minute. The device is moved in slow spiral motions from the centre of the palm/foot toward the periphery gradually covering the entire surface.

The procedure includes the stimulation of 2 symmetric zones (both hands or both feet) and should be repeated 3 times a day by alternating the paired zones (1st session: the palms of the left and right hands; 2nd session: the plantar surfaces of the left and the right feet: 3rd session: the palms of the left and right hands, etc.) The duration of the course is 12-14 days. It is recommended to repeat the course in 2-3 weeks. The interval between the subsequent courses should be 3 to 6 weeks.

11.7.13. In the case of psoriasis (progressive and stationary state)

I. The junction of the presternum and the body.
II. The popliteal space - on the left and on the right.
III. The zone of the back surface of the middle third of the foot between the 1st and the 2nd toes - on the left and on the right.
IV. The zone of the posterolateral surface of the lower leg - on the left and on the right.
V. The area of the projection of the liver.

I



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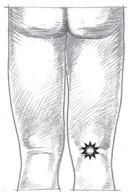

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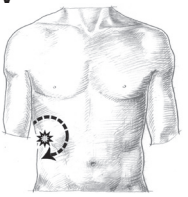

The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 20 sessions..

11.7.14. In the case of atopic dermatitis in adult and children

I. The vertex of the angle formed by the 1st and the 2nd metacarpal bones on the back of the hand.
II. The popliteal space - on the left and on the right.
III The zone of the back surface of the middle third of the foot between the 1st and the 2nd toes - on the left and on the right.
IV. The projection of the adrenal glands.
V. The zone of the posterolateral surface of the lower leg - on the left and on the right.
VI. The area of the projection of the liver.

The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 15 sessions.

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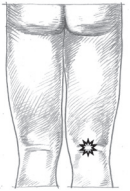

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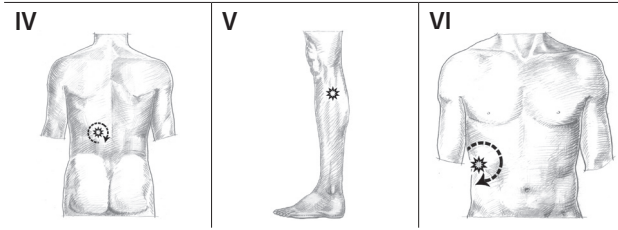
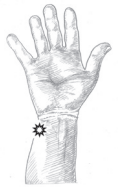
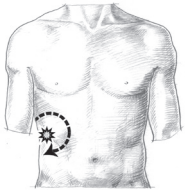
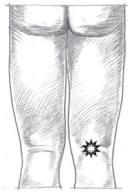


11.7.15. In the case of viral hepatitis

I. The zone at the edge of the popliteal fold when the knee joint is bent on the inside- on left and on the right
II. The area of the internal arch of the foot - on the left and on the right.
III. The zone near the wrist joint 1,5 cm above the radiocarpal fold on the side of the little finger -on the left and on the right
IV. The zone under the acantha of the 2nd lumbar vertebra - on the left and on the right
V. The area of the liver.
VI. The area in the middle of the popliteal space - on the left and on the right.
VII. The zone of the back surface of the middle third of the foot between the 1st and the 2nd toes - on the left and on the right.
VIII. The zone near the inner edge of the knee joint 3 cm below the edge of the kneecap - on the left and on the right.

I 	II 	III 
IV 	V 	VI 
VII 	VIII 	The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 15 sessions

11.7.16. In the case of asthma

I. The zone of palpation of the radial artery (the zone of the pulse) - on the left and on the right.
II. The zone of the rear surface of the right shoulder joint.
III. The zone of the back surface of the middle third of the

foot between the instep bones of the 1st and the 2nd toes - on the left and on the right.

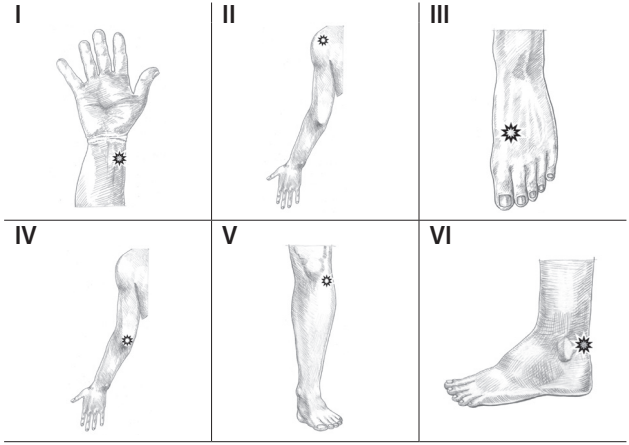
IV. The rear surface of the shoulder above the olecranon of the ulnar bone - on the left and on the right.

V. The upper third of the outer anterior surface of the lower leg - on the left and on the right.

VI. The area in the middle of the the Achilles tendon - on the left and on the right.

VII. The zone in the middle of the palm - on the left and on the right.

The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 15 sessions.

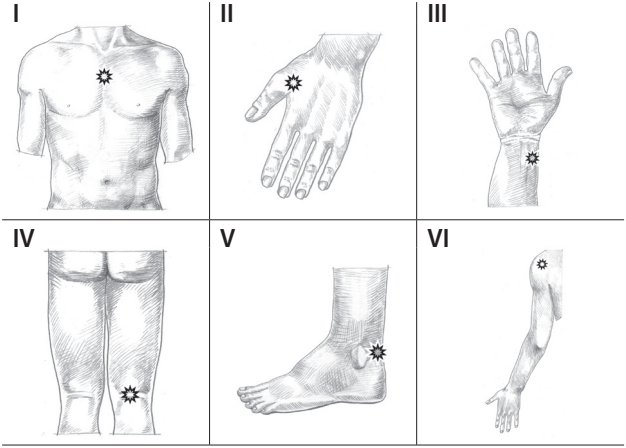


VII

11.7.17. In the case of chronic forms of mild and medium generalised granulating, granulomatous and fibrous periodontitis, chronic apical periodontitis

I. The junction of the presternum and the body.
II. The vertex of the angle formed by the 1st and the 2nd metacarpal bones on the back of the hand.
III. The zone of palpation of the radial artery (the zone of the pulse) - on the left and on the right.
IV. The area in the middle of the popliteal space - on the left and on the right.
V. The area in the middle of the the Achilles tendon - on the left and on the right.
VI. The area of the left shoulder joint at the level of the head of the humerus.

The duration of stimulation of one zone is 10 minutes. The course of treatment consists of 20 sessions.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