

**RITM OKB ZAO**

## **SCENAR-DEVICE**

CHANS-SCENAR, CHANS-01-SCENAR, CHANS-02-SCENAR,  
CHANS-SCENAR-M, CHANS-01-SCENAR-M, CHANS-02-SCENAR-M,  
SCENAR-1-NT (version 01), SCENAR-1-NT (version 02.1), SCENAR-1-NT (version 02.2),  
SCENAR-1-NT (version 02.3), SCENAR-1-NT (version 03),  
SCENAR-1-NT (version 01C), SCENAR-1-NT (version 02.1C), SCENAR-1-NT (version 02.2C),  
SCENAR-1-NT (version 02.3C), SCENAR-1-NT (version 03C),  
RITMSCENAR Expert, RITMSCENAR Expert C

## **Instruction for Use**



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### **Notified Body No.2265**

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Hraničná 18, Bratislava, 82105, Slovakia

**IMPORTANT INFORMATION!**

*PLEASE READ THIS PAGE CAREFULLY*

**WARNING!** Before using the medical device and in all cases of symptoms of disease or any health problems it is necessary consult with a healthcare professional.

**WARNING!** The information provided in this instruction is not a substitute for the recommendations of a healthcare professional and should not be used by the user to make a diagnosis, establish the cause of a health problem or to prescribe the medical device presented in the instruction.

**WARNING!** Any serious incident that occurs during the use of the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is registered.

**WARNING!** This device should NOT be used on an individual who has a heart pacemaker or other electrically powered implant fitted.

**WARNING!** Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

**WARNING!** Simultaneous connection of a patient to a HF surgical equipment may result in burns at the site of the stimulator electrode and possible damage to the stimulator.

**WARNING!** Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy equipment and mobile communicators may produce instability in the stimulator output.

**WARNING!** Aged people, children, and people with disabilities may not use the stimulator.


**WARNING!** The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Annex in Operating Manual.

**WARNING!** As the current densities for electrode exceeds  $2 \text{ mA r.m.s./cm}^2$ , the device requires the special attention of the user.

**WARNING!** The device should not be used adjacent to or stacked with other equipment.

This appliance is marked according to the European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product.



The symbol  on the documents accompanying the product, indicates that this appliance may not be treated as household waste. Instead it shall be handed over to the applicable collection point for the recycling of electrical and electronic equipment.

Disposal must be carried out in accordance with local environmental regulations for waste disposal.

For more detailed information about treatment, recovery and recycling of this product, please contact your local city office, your household waste disposal service or the shop where you purchased the product.

**Origin:** RITM OKB ZAO, 99, Petrovskaya, Taganrog, 347900, Russia.

**CHANS-SCENAR Models:**

- **CHANS-SCENAR** (Trade names RITMSCENAR Home, SCENAR Home),
- **CHANS-01-SCENAR** (Trade names RITMSCENAR Sport, SCENAR Sport, SCENAR Pain Genie, RITMSCENAR Home Device),
- **CHANS-02-SCENAR** (Trade names RITMSCENAR Basic, SCENAR Basic),
- **CHANS-SCENAR-M** (Trade names RITMSCENAR Home D, SCENAR Home D),
- **CHANS-01-SCENAR-M** (Trade names RITMSCENAR Sport D, SCENAR Sport D),
- **CHANS-02-SCENAR-M** (Trade names RITMSCENAR Basic D, SCENAR Basic D)

**SCENAR-NT Models:**

- **SCENAR-1-NT (version 01)** (Trade names RITMSCENAR Pro Prime, SCENAR Pro Prime),
- **SCENAR-1-NT (version 02.1)** (Trade names RITMSCENAR Pro Plus, RITMSCENAR Pro +, SCENAR Pro Plus, SCENAR Pro +),
- **SCENAR-1-NT (version 02.2)** (Trade names RITMSCENAR Pro Optima, SCENAR Pro Optima),
- **SCENAR-1-NT (version 02.3)** (Trade names RITMSCENAR Pro, SCENAR Pro),
- **SCENAR-1-NT (version 03)** (Trade names RITMSCENAR Pro Essential, SCENAR Pro Essential),
- **SCENAR-1-NT (version 01C)** (Trade names RITMSCENAR Pro Prime C, SCENAR Pro Prime C, RITMSCENAR Super Pro v.2, bioSCENAR Professional v.2, SCENAR Physio, SCENAR Urogyne),
- **SCENAR-1-NT (version 02.1C)** (Trade names RITMSCENAR Pro Plus C, RITMSCENAR Pro +, SCENAR Pro Plus C, SCENAR Pro + C),
- **SCENAR-1-NT (version 02.2 C)** (Trade names RITMSCENAR Pro Optima C, SCENAR Pro Optima C),
- **SCENAR-1-NT (version 02.3 C)** (Trade names RITMSCENAR Pro C, SCENAR Pro C),
- **SCENAR-1-NT (version 03C)** (Trade names RITMSCENAR Pro Essential C, SCENAR Pro Essential) ,
- **RITMSCENAR Expert,**
- **RITMSCENAR Expert C**

**Add-on electrodes:**

- Face electrode
- Comb electrode
- Point electrode
- Special Snail electrode
- Bent point electrode
- Double facial Pawns electrode
- Double cosmetic electrode
- Double ophthalmic Goggles electrode
- Double facial Stamps electrode
- Single ophthalmic Monocle electrode
- Special double Pencils electrode
- Multi-purpose zonal electrode
- Local electrode

**Classification:** *Type of protection against electric shock* – Internally powered equipment. Applied parts – Type BF.

**Waterproofing:** No special protection against liquid ingress provided (IPX0).

**Cleaning & Disinfecting:** Wipe electrode area with a cotton swab dampened with 3% hydrogen peroxide solution with the addition of 0.5% solution of an approved cleaning liquid. Allow to dry up thoroughly before use. Clean casing with a damp (not soaking) cloth and mild soap solution. Allow to dry before use.

**Clinical environment:** NOT suitable for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxides.

**Batteries:** Remove battery from device if not in use for an extended period. Connect correctly. DO NOT TRY TO RECHARGE disposable batteries! Dispose of used batteries responsibly. Use good quality, within-date long-life batteries.

**NOTE:** Total battery removal should be used during storage and transportation to avoid battery drain. The device should NOT be operated with the battery cover removed, as this exposes the operator to live battery circuits in contravention of the Safety Regulations.

## CONTENTS

1. GENERAL GUIDELINES .....	9
1.1 INTENDED PURPOSE.....	9
1.2 INTENDED USERS.....	9
1.3 INDICATIONS AND CONTRAINDICATIONS FOR USE.....	10
1.3.1 INDICATIONS WITH REGARD TO PAIN RELATED TO: .....	10
1.3.2 CONTRAINDICATIONS .....	10
1.3.3 PRECAUTIONS .....	11
1.3.4 KNOWN SIDE EFFECTS and RESIDUAL RISKS .....	11
1.4 SAFETY MEASURES .....	12
1.5 INFORMATION FOR LAY PERSON .....	12
1.6 REUSING THE DEVICE .....	12
1.7 USEFUL LIFE .....	12
1.8 APPEARANCE OF DEVICES .....	13
1.9 TRANSPORTATION AND STORAGE.....	15
2. GUIDELINES FOR TREATMENT .....	16
2.1 BASIC DEFINITIONS AND GENERAL TREATMENT METHODS.....	16
2.2 GUIDELINES FOR TREATMENT MODES AND METHODS OF AREA TREATMENT.....	17
2.3 GUIDELINES FOR TREATMENT SETTINGS .....	19
2.4 TREATMENT OF A COMPLAINT AREA IN SDM AND IDM.....	22
2.5 POTENTIAL PATIENT'S REACTIONS TO A SESSION .....	24
3. TREATMENT OF DISEASES AND PATHOLOGICAL STATES .....	24

3.1 ANALGESIC THERAPIES IN PAINS IN BONES, MUSCLES, JOINTS AND LIGAMENTS .....	24
3.2 TREATMENT OF ACUTE AND CHRONIC LOW-BACK PAINS (INCLUDING PAINS APPEARED IN THE PREHOSPITAL SETTING) .....	25
ANNEX 1.....	26
ADD-ON ELECTRODES.....	26
ANNEX 2 GENERAL TREATMENT METHODS.....	32
1. INTRODUCTION.....	32
2. “THREE PATH SIX POINTS” METHOD.....	33
2.1 TREATMENT AREAS.....	33
2.2 HOW TO CARRY OUT ‘THREE PATHS, SIX POINTS’ METHOD IN SDM .....	34
2.3 “TREE PATH, SIX POINTS” IN IDM.....	35
3. ‘CERVICAL-COLLAR AREA’ METHOD .....	38
3.1. TREATMENT AREAS.....	38
3.2 HOW TO CARRY OUT ‘CERVICAL-COLLAR AREA’ METHOD IN SDM.....	39
3.3 HOW TO CARRY OUT ‘CERVICAL-COLLAR AREA’ METHOD IN IDM.....	41
4. METHOD OF ‘PALMS’. TREATMENT AREAS AND PROCEDURE.....	42
5. ‘ABDOMEN’ METHOD .....	44
5.1 TREATMENT AREAS.....	44
5.2 HOW TO CARRY OUT ‘ABDOMEN’ METHOD.....	44
6. INDICATIONS AND PROCEDURE FOR TREATMENT OF THE LIVER PROJECTION AREA .....	45



Approved by Director General  
RITM OKB ZAO



Yury Starovoytov  
20.06.2022

## 1. GENERAL GUIDELINES

### 1.1 INTENDED PURPOSE

All the CHANS-SCENAR models (hereinafter referred to as **Home devices**) and, all the SCENAR-1-NT models (hereinafter referred to as **Professional devices**) are intended both for Professional healthcare facility environment and Home healthcare environment. The difference between "Professional" and "Home" devices is a simplified interface and limited functionality, for more convenient use for non-professional users.

Both CHANS-SCENAR models & SCENAR-1-NT models together with Add-on electrodes (see Annex 1) are used for non-invasive pain relief.

### 1.2 INTENDED USERS

**CHANS-SCENAR models & SCENAR-1-NT models** are designed to be operated by non-medical home users as well as by therapists, doctors and medical staff and for self-treatment.

## 1.3 INDICATIONS AND CONTRAINDICATIONS FOR USE

### 1.3.1 INDICATIONS WITH REGARD TO PAIN RELATED TO:

**SCENAR devices are indicated to be used in professional medicine and at home for pain reduction in adults over 18 years of age to 76 years and supplemental therapy in the following conditions:**

- acute post-traumatic pain;
- acute and chronic neck or low back pain;
- myofascial pain;
- fibromyalgia;
- osteoarthritis of the knee

### 1.3.2 CONTRAINDICATIONS

Do NOT use SCENAR devices in

- Overly sensitive individuals, including pregnant women.
- Patients with cardiac pacemakers or other electrically powered implants.
- Alcoholic intoxicated individuals.
- Patients with acute infection diseases.
- In cases of undiagnosed pain;
- In patients with heart disease;
- In patients with epilepsy;
- With active deep vein thrombosis or thrombophlebitis;
- Cancer unless used in palliative care with caution;
- Patients with untreated hemorrhagic disorders

### 1.3.3 PRECAUTIONS

Electrodes should NOT be placed:

- over the carotid sinus area;
- on broken skin including open wounds;
- on regions of known or suspected malignancy;
- on mucous membranes (unless specially designed and clinically approved electrode and treatment modes are used);
- transcranially;
- to areas near reproductive organs or genitalia (unless used by experienced clinicians with caution);
- to areas near or over eyes (unless specially designed and clinically approved electrode and treatment modes are used by experienced clinicians with caution);
- to recently radiated tissues;
- to the chest in persons with cardiac disease, arrhythmias, or heart failure;
- to areas with impaired circulation (unless used under control of experienced clinicians);
- to the anterior chest wall or lower abdomen (unless used under control of experienced clinicians).

### 1.3.4 KNOWN SIDE EFFECTS and RESIDUAL RISKS

Minor known side effects (skin irritation, discomfort, individual intolerance) were observed when using transcutaneous electrostimulation devices. These reactions will usually return to normal after a short time. If symptoms persists, discontinue use of the SCENAR device and consult your healthcare professional.

Residual risks are determined by the manufacturer, minimized and found acceptable. The likelihood of a hazard is assessed as rare. Most of residual risks can be eliminated if the user observe the following rules:

- Read the Instruction for Use before using the device.
- Using the Device according to the Instruction for Use.

## 1.4 SAFETY MEASURES

**The device type of protection against electrical shock.** The device complies with the standards EN 60601-1 and EN 60601-2-10 for internally powered equipment, type BF, which classifies it as a safe device for personal use.

A user should study the guidelines given in the present Instruction for Use and the Operating Manual before treating.

## 1.5 INFORMATION FOR LAY PERSON

➤ Before using the medical device and in all cases of symptoms of disease or any health problems it is necessary to have a consultation of a healthcare professional.

➤ The information provided in this manual is not a substitute for the recommendations of a healthcare professional and should not be used by the user to make a diagnosis, establish the cause of a health problem, to prescribe or use the medical device presented in the manual.

## 1.6 REUSING THE DEVICE

The devices are not critical and semi-critical items because they are not designed to contact mucous membranes or non-intact skin and only require (depending on the conditions of use) cleaning and/or disinfection prior to reuse.

### **WARNING!**

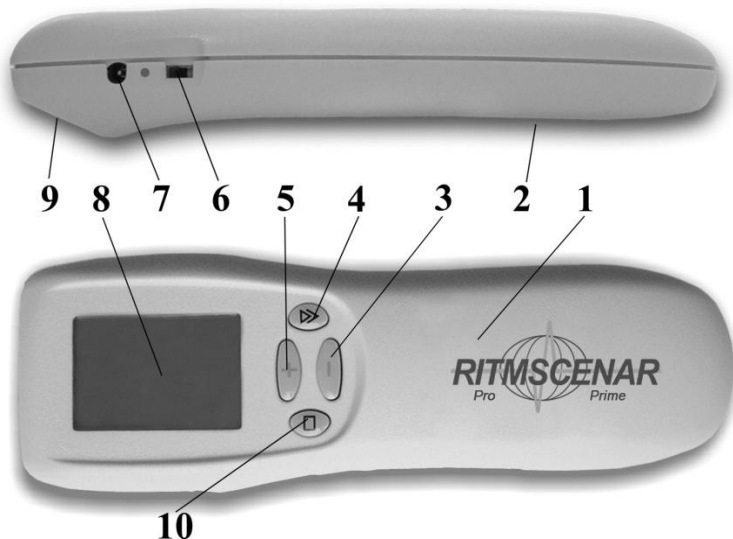
*The device should no longer be used/reused if the product's marketable (aesthetic) appearance is lost, there are signs of material degradation, for example, mechanical damage, and restoring its functionality is economically impractical.*

## 1.7 USEFUL LIFE

The average service life of the device is no less than five years. Useful life of the Device (duration of actual use) depends on the user's compliance with the instructions for use.

## 1.8 APPEARANCE OF DEVICES

### SCENAR 1NT device



The device has an upper cover 1 with a screen 8, case with a built-in electrode 9 and a battery cover 2

The LCD screen 8 displays the results of measuring, settings and device's state.

The device has the following controls on the upper side 1 of its case:



- ♦ button 3 (–) – is used to decrease the energy strength or value of a selected parameter;
- ♦ button 4 (▼) – is used to select parameters and exit the standby mode;
- ♦ button 5 (+) – is used to increase the energy strength or value of a selected parameter;
- ♦ button 10 (□) – is used to rotate the picture on the screen.

The lateral surface of the case has a switch button 6 to switch on/off the device and plug 7 for connecting add-on electrodes.

**CHANSE-SCENAR device**

On the back side of the casing (1) there is a built-in electrode (2) and a battery cover (8).

On the front side of the casing there is a liquid crystal display (LCD) (3) for the visual indication and a keyboard (four buttons):

- 4 – ‘’ button switches the SCENAR device ON and OFF;
- 5 – ‘’ button preselects the desired stimulation mode;
- 6 – ‘+’ button activates the preselected mode or increases the energy level (stimulus strength);
- 7 – ‘-’ button deactivates the preselected mode or decreases the energy level (stimulus strength).

## 1.9 TRANSPORTATION AND STORAGE

The transportation of the devices to a customer is carried out by all kinds of covered vehicles, except the plane compartments that have no heating, at the air temperature from  $-50$  to  $+50^{\circ}\text{C}$  and relative humidity not to exceed 100 % at a temperature of  $25^{\circ}\text{C}$  with a protection from a direct atmospheric precipitation.

After transportation at negative temperatures, the device should be kept in the transport container under normal climatic conditions for not less than 24 hours.

The device shall be stored in the manufacturer's package in a heated room, under the air temperature of  $5^{\circ}\text{C}$  to  $40^{\circ}\text{C}$  and relative humidity not to exceed 80 % at a temperature of  $25^{\circ}\text{C}$ .

## 2. GUIDELINES FOR TREATMENT

### 2.1 BASIC DEFINITIONS AND GENERAL TREATMENT METHODS

The treatment is carried out by stimulating skin areas (hereinafter referred to as the ‘**treatment areas**’) with electrical pulses.

The treatment areas should be determined before a session according to primary signs and complaints, and in the course of treatment according to secondary signs and complaints.

**The primary signs and complaints** of a patient include pain, itching, sensitivity loss and other unpleasant sensations, and also small wounds, cicatrices, skin discoloration, trophic disturbances which have been *detected before a session and cause discomfort in a patient*.

**The areas of primary signs and complaint projections** should be treated. If it is not possible to treat such areas (due to a wound, plaster bandages and etc.), treat symmetrical areas located at equal distance from the backbone horizontally to increase the treatment effectiveness (see Fig. 1).

If a complaint does not enable to determine its projection area or its area is very large, and if a patient can not specify a main complaint among his/her complaints, treat the **general treatment zones** (see Annex 2).

**The secondary signs** including **small asymmetry areas** are manifested while stimulating areas selected to be stimulated before treatment. The secondary signs include:

➤ change of a specific sound under the electrode. The treatment area on which a sound change has been the most perceptible should be stimulated additionally;

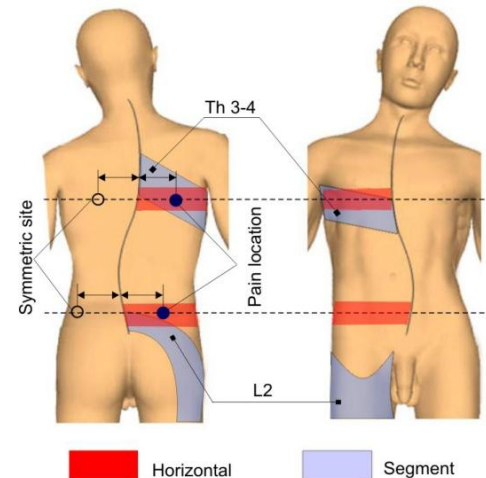


Fig. 1



- ‘stickiness’ of the device. The device electrode is as ‘gluing’ to the skin that prevents from moving it. This effect depends on direction in which a device is moving. For example: ‘stickiness’ can not appear if moving the electrode from the left to the right but ‘stickiness’ can appear if moving it from the right to the left. The ‘stickiness’ area should be additionally treated by moving the electrode in the direction in which such effect and ‘sliding’ of the electrode have been detected (to avoid effect of prevention for moving);
- skin discoloration in a treatment area (flushing or blanching of some areas). If treating an area the skin surface can be discoloured to red and pale spots can appear against such background or, vice versa, any highly colored spots can appear against the paler background of all the area. The skin area that changed most of all should be treated additionally;
- change of sensations. If a power level is constant on some areas being treated, a patient can feel such stimulation as strong or, vice versa – as weaker. The area on which such change has been the most perceptible should be treated additionally;
- change of pain localization (pain migration). If treating a pain projection area the sensation can migrate outside the treatment area. In this case you should follow the pain and treat a new area.

## 2.2 GUIDELINES FOR TREATMENT MODES AND METHODS OF AREA TREATMENT

The devices of **SCENAR** series can be operated in two modes of dosed stimulation: subjectively-dosed mode (**SDM**) which is to be defined by a doctor according to patient’s response reactions, and individually-dosed mode (**IDM**) which regulates time of treatment automatically.

**SDM is more preferred** to be used *if symptoms are clearly localized, in acute and clearly localized complaints, and also if stimulating treatment areas with relatively large surface.*

As a rule the treatment areas are to be stimulated in **SDM** by moving the device on the skin surface (the labile method) (Fig. 2).

In some cases an area can be treated in **SDM** by a constant method i.e. not moving and taking off the electrode from the skin surface until a session ends.

**If applying the labile method in SDM**, the electrode **should be** set on the skin surface with a slight compression and, without delay, smoothly and not changing its compression, move it on the treatment area. As a rule the electrode should be moved on the area from top to bottom, from the left to the right on the part of a person who treats.

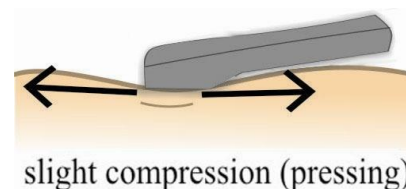


Fig. 2

The pressing force and movement rate should prevent a 'skin roll' to be formed before the device electrode, if possible.

The device electrode can be moved along any other lines from the right to the left, from bottom to top; from the left to the right, from top to bottom; from bottom to top, from the right to the left; diagonally and etc.

The areas can be treated in **IDM** only by setting the device within the treatment area (the constant mode).

**IDM is more preferred to be used** in treatment of system, chronic diseases especially if their symptoms are mild or slight, and also in treatment of 'weak' patients.

**If IDM is used** in the treatment, the electrode **should** be set on the skin surface with slight compression and not taken off until a signal indicating the end of a session beeps (see Operating Manual of the devices for details). After a signal indicating the end of treatment beeps, set the device on the other skin area (Fig. 3).

As a rule, the device should be moved from top to bottom, from the left to the right, without any overlaps and gasps.

The electrode can be moved in any other manner.

The electrode should be moved in such a way as to cover all the treatment area.

It is expedient to combine and alternate **SDM** and **IDM** during a session to increase efficacy of the treatment.

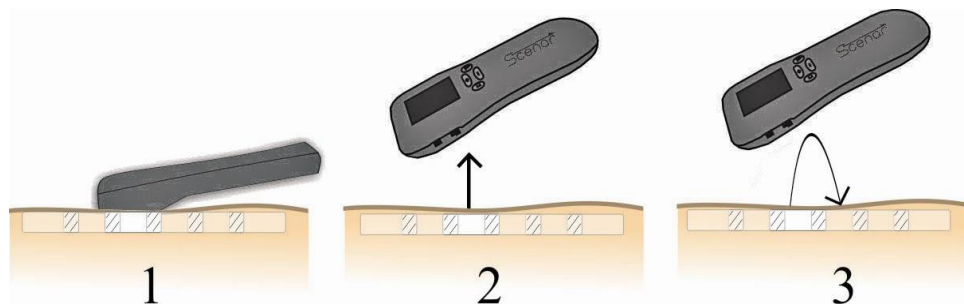


Fig. 3

## 2.3 GUIDELINES FOR TREATMENT SETTINGS

### Power

Power perception is very subjective.

The following power levels can be classified according to patient's sensations:

- a comfortable level (a patient feels a light tingling and vibration);
- a pain threshold level (patient's sensations are almost intolerable);
- an intensive level (patient's sensations are between comfortable and pain threshold);
- a weak level (a patient does not feel or does not almost feel any tingling).

A power level should be set outside treatment areas.

The **comfortable level** is recommended to be used in most cases.

If complaints are clearly localized, especially if a pain syndrome prevails, it is recommended to use an **intensive level** going into a **pain threshold level**.

The **pain threshold level** should be used in a severe pain syndrome. The pain threshold level can be combined with moving of the electrode on the treatment area to decrease sensations strength. If there are no pronounced specific complaints and general symptoms prevail (atony, vertigo, shiver and etc.), the **weak level** should be used.

When treating children, especially the very young, start treatment with a minimum power level and increase it to a comfortable level if there are no response reactions.

Use the frequency modulation mode (the oscillating frequency, see below) in treatment of pronounced pain syndrome or chronic pain.

Reduce a power level if subjective sensations become very painful while treating.

The power level should be set after all other settings are determined.

**Frequency**

In degenerative processes (especially with painful manifestations) – use low frequencies (15-60 or 90 Hz) at the beginning of a session and higher frequencies (higher than 90 Hz) or the **oscillating frequency** mode at the end of a session.

In acute inflammatory processes – use high frequencies (more than 120 Hz) to be set individually according to patient's response reaction. Use the 'oscillating frequency' mode in pronounced pain syndrome or in chronic pathological process.

When treating an area above small muscles - the frequency should be 40-90 Hz; when treating an area above large muscles – the general stimulation should be given at frequencies of higher than 350 Hz combined with frequencies of 15-90 Hz.

In pronounced pathological processes – it is expedient to use and combine frequencies during a session.

**Modulation** (discontinuous stimulation).

In acute pathological processes accompanied by a pronounced response reaction of the body – change the modulation from '3:1' for '1:1' during a session, the mode '1:1' should be final and more continuous.

In chronic processes and during the second part of acute processes treatment course – change the modulation from '3:1' for '5:1' with return to '3:1' or with change to the 'oscillating' frequency.

If stimulating motor functions, the stimulation frequency and modulation mode depend on a process stage, an area to be treated and individual response reaction of the body. The modulations '3:1' and '4:1' are preferred.

**Frequency Modulation (FM** – Frequency Modulation, oscillating frequency).

The frequency modulation is a periodic variation of stimuli frequency through time (the 'oscillating' frequency – from minimum to maximum and vice-versa).

Generally, this mode should be used in treatment of secondary sign areas, in pronounced pain syndrome or in chronic pathological process.

**Intensity, Damping, Gap – Delay between pulses in a batch.**

Only **Professional devices** provide an option to regulate these settings (see Operating Manual).

**Intensity** means setting of pulses in a burst under a particular algorithm which enable a power level to be increased not changing a power level of particular stimuli.

**Gap** means a delay between pulses in a batch. In some sense, such setting decreasing is equivalent to pulse frequency increasing.

**Damping** means a forcible variation of the influencing pulses shape.

As a whole these settings enable to provide comfortable subjective perception of a signal at its high power level. Specific values are to be determined according to patient's subjective sensations individually.

**2.4 TREATMENT OF A COMPLAINT AREA IN SDM AND IDM**

If using **SDM**, treat an area by moving the device in the above-mentioned way.

While moving the device, treat areas of secondary signs which appear in the treatment area (the asymmetry areas). Such areas with various (in a qualitative sense) secondary signs can be detected. In such a case an area that should be treated additionally should be determined according to signs manifestation intensity. For example – select the smallest and brightest point to be treated from some areas with flushing (hyperemia) or pale spots; if a sound changes in some points, select an area on which such change was the most pronounced; if pain appears in some points, treat the most painful area.

If some signs of various type are detected while treating and it is not impossible to reveal the most pronounced one, treat all the areas with the most pronounced signs.

If using **Home devices**, treat secondary signs areas in **IDM** or in the frequency modulation mode (the oscillating frequency).

If using **Professional devices** in **SDM**, treat secondary signs areas of smaller surface (smaller than this of a device electrode) in the **'FMVaR'** mode (see **Operating Manual**), at the comfortable power level within up to 5 minutes or till the sign intensity disappears/decreases. The secondary signs areas of larger surface should be treated in the same mode by moving the electrode from top to bottom and from the right to the left.

If using **Home devices** in **IDM**, the area of the electrode setting (position) on which a dose has been completed within the shortest period shall be considered as an analogous area of the small asymmetry. If using **Home devices**, the asymmetry detected should be treated additionally with three settings of a dose.

If using **Professional devices** in **IDM** to treat an area, a position when an **initial reaction value (IR) is higher as compared with the previous one** (see Operating Manual) should be considered as an analogue of the small asymmetry. This position should be immediately treated till a completed dose. If more than two positions have been set and additionally treated in the treatment area till a completed dose, a position when a current reaction value has been maximum should be considered as an analogue of the small asymmetry. This position should be immediately treated up to zero.

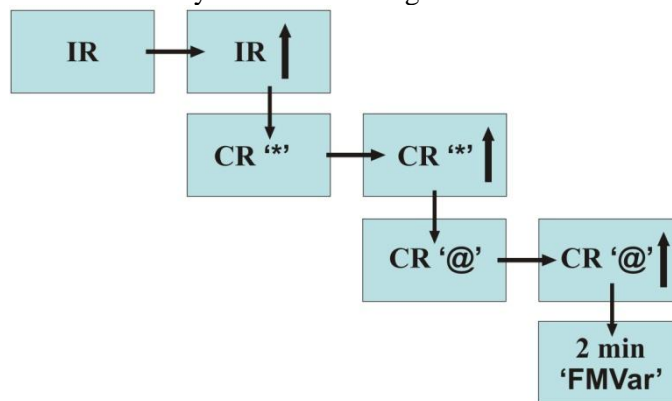


Fig.4

If more than one position have been detected and additionally treated to zero in the treatment area, a position when a current reaction value has been maximum should be considered as an analogue of the small asymmetry. This position should be additionally treated in the **'FMVaR'** mode during two minutes (Fig.4).

## 2.5 POTENTIAL PATIENT'S REACTIONS TO A SESSION

Sleepiness or, vice versa, a fit of energy may be observed within and after a session. Fever sensation, sweating may appear. Such vegetative reactions are typical for the treatment given by the devices of **SCENAR** series.

If such reactions are excessive and appear before the end of a session, such session can be ended.

## 3. TREATMENT OF DISEASES AND PATHOLOGICAL STATES

### 3.1 ANALGESIC THERAPIES IN PAINS IN BONES, MUSCLES, JOINTS AND LIGAMENTS

- *The guidelines given in section 2.4 should be observed in treatment of pains in bones, muscles and ligaments.*
- *The arthrotropic diseases can be accompanied both by inflammatory processes in the affected joint area (flushing, edema, local temperature rise, pain, dysfunctions) and without such inflammatory processes.*

If any inflammatory signs appear in the affected joint area, treat this joint in **SDM** using a high frequency of from 90 to 350 Hz (it depends on a device model) at a sub-comfortable power level.

After the acute pain is relieved, use **IDM** and standard frequencies of 90 (60) Hz and a comfortable power level to continue treatment. Use the amplitude modulation mode to obtain effect within shorter period (to accelerate effect).

In metabolic-dystrophic diseases of joints when pains are not accompanied by signs of inflammation, use low frequencies of from 15 to 60 or 90 Hz (it depends on a device model) at a comfortable or sub-comfortable power level.

If pains in a joint are moderate, start treatment from an affected joint and then treat a symmetrical joint on the other side of the body.

If pains in a joint are intensive, start treatment from the joint which is symmetrical to an affected joint and then treat the affected joint.



No more than two pairs of large joints can be treated within a session.

If pain remains in a joint after the end of the general treatment, define the most painful point on this joint and treat it additionally.

In arthrotropic diseases of metabolic-dystrophic type, the liver area should be treated additionally (see Annex 2). Treatment should be performed in **SDM** and/or **IDM**.

### **3.2 TREATMENT OF ACUTE AND CHRONIC LOW-BACK PAINS (including pains appeared in the prehospital setting)**

In low back pains not irradiating to the extremities and regardless of localization, treat the chest area in **SDM** until hyperemia develops.

The power level is comfortable, the frequencies are standard.

Do not treat small asymmetry areas additionally.

If pain disappears, stop a session.

If pain remains, treat the following areas in the similar manner:

- if pains remain in the cervical area – the lumbosacral area of the backbone;
- if pains remain in the chest area – the cervical and lumbosacral areas;
- if pains remain in the lumbosacral area – the cervical area.

If low back pain is irradiating to an extremity:

- treat a symmetrical area on the other extremity which the pains are irradiating to;
- treat an area on the extremity the pains are irradiating to.

While treating an extremity the pain can migrate from one area to another and its intensity can increase in different areas. In that case you should ‘follow’ the migrating pain should and treat points where it appears.

## ANNEX 1

### Add-on electrodes

Add-on electrodes are designed to support treatment in situations where the use of the built-in electrode of the SCENAR device is inconvenient or difficult due to electrode placement location.

Add-on electrodes split into two groups by construction principle:

- combined – with two poles located on the common arm;
- split or spaced – with poles located on different arms;

Add-on electrodes are an integral part of the SCENAR device and the procedure for using remote electrodes does not require special instructions, except for the Operating Manual for the SCENAR device and this IFU.

It is *not recommended* to use *individual dosing modes* when using any of spaced add-on electrodes for treatment. **SDM** treatment mode is preferred.

When using constant frequency treatment modes it is recommended to move electrodes on the skin not faster than 2 cm per second. When using Amplitude or Frequency modulation modes it is recommended to use constant **SDM** mode. If using Labile mode it is recommended to move electrodes not faster than 1 cm per 10 seconds.

#### Attention!

**Only special OKB RITM manufactured add-on electrodes can be used with SCENAR devices!**

**Not allowed other electrodes!**

#### Warning:

- connect add-on electrode to the SCENAR device only when Device is switched off;
- add-on electrodes should be tightly fit on the skin;
- increase power level when electrodes are placed to the skin;
- weak contact to the skin may lead to unpleasant sensations especially when moving the electrode.

**Attention!**

*Be especially careful when moving a device (or an add-on electrode) over the skin. It's easy to provide uniform contact between a skin and a motionless electrode, but while moving the electrode you can weak the contact. If a patient feels discomfort or pain the electrode must be removed immediately!*





**Attention!**





Add-on electrodes do not contain any serviceable parts. Unauthorized repair or self-modification of the electrode is prohibited. All repair activities are carried out by the Manufacturer only. Any unauthorized interference will result in voiding of the warranty for the electrode, and for the SCENAR device too.




DO NOT USE broken or damaged parts since it can cause harm to your health.



**Used Materials.**

Company policy is dealing with approved suppliers only and using certified components and materials. Products passed toxicity tests and are GOST R certified.

Combined electrodes		
Face electrode		used on the body regions with complex relief such as wrists, hands, feet and face
Comb electrode		used to treat hairy parts of the body
Point electrode		used to treat reflex points on the body, limbs and ears
Bent point electrode		used to treat reflex points on the body, limbs and ears

Special Snail electrode		used on parts of the body with complex relief such as fingers and toes, feet
Double ophthalmic Goggles electrode		used on the pre-orbital region and trigeminal nerve points
Single ophthalmic Monocle electrode		used on the pre-orbital region and trigeminal nerve points
Multipurpose zonal electrode		designed to treat areas on the body and limbs and in the back area.

Split electrodes		
Double facial Pawns electrode		used to treat the back, joints and limbs
Double cosmetic electrode		used to treat the back, face, joints and limbs
Double facial Stamps electrode		used to treat the back, joints and limbs

Special double Pencils electrode		used on parts of the body with complex relief such as fingers and toes, feet
Local electrode		designed to treat points on skin areas with complex relief, fingers and toes, ears

## *ANNEX 2*

### *GENERAL TREATMENT METHODS*

#### **1. INTRODUCTION**

The general treatment methods should be used in the following cases:

- if it is expressly specified in indications for a specific disease;
- if a complaint can not be related to a specific skin area (insomnia, anxiety, psychoemotional tension and etc.);
- if it is impossible to define limits of a painful area or such area is very large and, for example, covers one part of the body in full (the back, a leg, the abdomen and etc.);
- if there are many complaints and a patient can not specify a main one among his/her complaints;
- if any concomitant diseases are aggravated against the background of a main chronic disease which is not aggravated at this moment, to improve life quality.

All the general treatment methods can be carried out both in **SDM** and in **IDM**.

Treatment should be carried out at the comfortable power level and the standard frequency (60-90 Hz).

The general treatment methods include:

1. '3 tracks and 6 points';
2. Cervical-collar area;
3. 'Palms' method;
4. 'Abdomen' method.



## 2. “THREE PATH SIX POINTS” METHOD

### 2.1 TREATMENT AREAS

The method includes two treatment areas. The first area – **three path** i.e. three lines one of which is going along the backbone and other two lines goes in parallel of it on the right and on the left. **The first path** passes along the backbone spines, from the 7<sup>th</sup> cervical vertebra to the coccyx, then it continues from the hairy part of the head to the 7<sup>th</sup> cervical vertebra. A patient should be sitting while being treated. If this position is not comfortable for a patient a session can be given when he/she is lying on the bed.

The electrode should be set along the backbone spines during a session.

**The second and the third path** are located in parallel to the first one, on the left and on the right from it at the distance of 2-2.5 cm from the line passing along the spines (see Fig. 1).

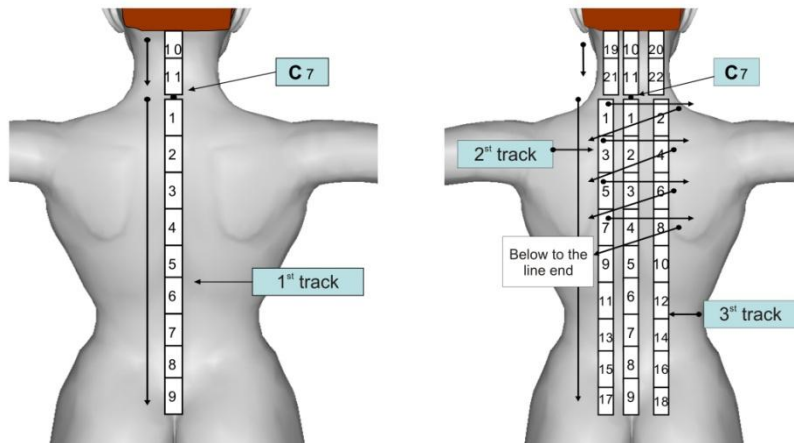


Fig. 1

The second area – ‘**six points**’. These points are trigeminal nerve exit points on the face.

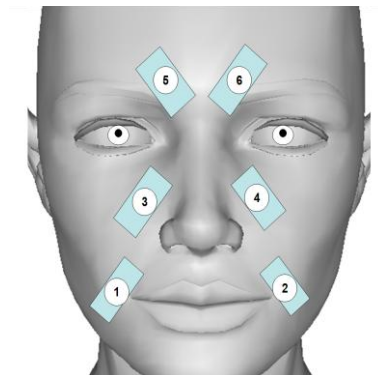


Fig. 2

## 2.2 HOW TO CARRY OUT ‘THREE PATHS, SIX POINTS’ METHOD IN SDM

The manner to be observed while carrying out the method in **SDM** is almost the same for **Professional devices** and **Home devices**.

The paths should be treated by slowly moving the electrode firmly pressed to the skin.

Prior to a session you should define where the seventh cervical vertebra is located: this is the most expressed vertebra in the lower part of the neck while inclining the head forward.

Set the electrode below the seventh cervical vertebra and move it slowly down along the backbone spines. After the coccyx is reached, set the electrode below the hairy part of the head and continue moving down. Finish moving just above the seventh cervical vertebra.

Repeat treatment till secondary signs appear but not more than 5 times.

If secondary signs are detected, treat them as specified in section 2.4 of the Instruction.

Treat the second and the third path in the similar manner.

Then, select the most pronounced sign among all secondary signs detected on the second and third paths and treat this area additionally as specified in section 2.4 of the Instruction.

**Warning!** *Reduce power to minimum before treating the face. Then, set the electrode on the side surface of the neck and increase the power level smoothly to reach its comfortable level. Then, you can start treating six points.*

‘**Six points**’ should be treated in the stable manner in the order specified in Fig. 2, by 1 min for a point. If secondary signs areas are detected, treat them additionally as specified in section 2.4 hereof.

### 2.3 “TREE PATH, SIX POINTS” IN IDM

The paths should be treated in **IDM** by setting the electrode from top to bottom, from the seventh cervical vertebra to the coccyx, and then from the hairy part of the head to the seventh cervical vertebra in the order specified in Fig. 1.

If using a device of **Home devices** series, set **IDM** (LED ‘D’ is switched on, see Operating Manual).

Each position should be treated till a completed dose i.e. when all four LEDs are switched on and a sound signal beeps (see Operating Manual).

The secondary signs areas should be detected according the shortest period required to obtain a completed dose. An area with the shortest treatment period should be considered as the most active (asymmetry).

If the minimum periods required to obtain a completed dose is almost equal in some areas, select an area which is located above all other areas.

The active area detected on the first path should be treated three times in sequence till a completed dose.

Then, treat the second and third paths in the order specified in Fig. 1.

Detect the most active areas on the second and the third paths and treat them three times in sequence till a completed dose.

Select the most active area among three active areas on three paths (according to the minimum period required till a completed dose) and treat it additionally three times till a completed dose but the frequency modulation mode should be switched on (the oscillating frequency).

**Warning!** *Reduce power to minimum before treating areas on the face and increase the power level smoothly to reach its comfortable level (see Operating Manual). A power level should be selected while stimulating the side surface of the neck.*

Treat each area on the face till a completed dose in the order specified in Fig. 2.

Treat the area with the minimum period required till a completed dose in the first passing additionally in sequence three times till a completed dose.

If using devices of **Professional devices** series in **IDM** under the method ‘3 paths, 6 points’, take the following actions.

Set the device in **IDM** (see Operating Manual). Search for secondary signs areas using an initial reaction (**IR**) value.

Set the electrode on the first area and treat till **IR** is obtained. Then set the electrode on the next area and also treat it till **IR** is obtained. Compare **IR** values with each other.

Treat the area on which the **IR** value was 4 units or more till a completed dose (‘\*’ signal is shown on the device display and a sound signal beeps. See Operating Manual).

Fix the **current reaction** value while completing a dose.

Then treat the next area till **IR** is obtained and compare it with the previous value of **IR**. Treat the area on which the **IR** value was 4 units or more again till a completed dose.

Fix the **current reaction** value while finishing a completed dose. Select the biggest value from two values of the **current reaction** while completing a dose and treat an area with the biggest value till zero (‘@’ sign is shown on the device display and a sound signal beeps). Fix the **current reaction** value while finishing a completed zero.

Select the next area which requires to be treated till zero in the similar manner by moving the device from one position to another and fix the **current reaction** value while finishing a completed zero.

Select an area with the maximum value of the current reaction among the areas which have been treated till a completed zero and treat it in '**FMVaR**' mode during two minutes (Fig. 3).

If **IRs** in all adjoining areas differ from each other for not more than 3 units and a **IR** value in the last area is equal to or less than four units, the treatment should be carried out in the previous position till a completed dose and the current reaction dose value should be fixed. Then continue setting the electrode in various positions and evaluate **IR**.

After all four areas are treated till a completed zero, two areas can be detected and each of them should be treated in '**FMVaR**' mode. **In that case**, the area with the biggest value of the **current reaction while being treated till a completed zero** should be treated in '**FMVaR**' mode during 3 minutes.

If no difference between the **IR** values is detected by more than four units along all the line '3 paths', the treatment should be carried out in the last position till a completed dose.

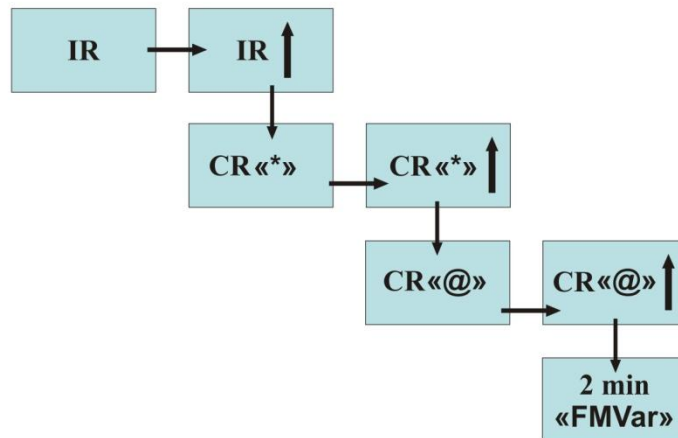


Fig. 3

**Warning!** *Reduce power to minimum before treating the face. Then, set the electrode on the side surface of the neck and increase the power level smoothly to reach its comfortable level. Then, you can start treating six points.*

Treat '6 points' on the face in the similar manner as '3 paths, compare **IR** values on the adjoining positions in the order specified in Fig. 2. Select an area with the biggest value of the initial reaction and treat it additionally.

If no difference between the **IR** values is detected by more than four units along all the line '6 points', the treatment should be carried out in the last position till a completed dose.

### 3. 'CERVICAL-COLLAR AREA' METHOD

#### 3.1. TREATMENT AREAS

The method includes three treatment areas:

- a) direct cervical-collar area (the first treatment area);
- b) forehead (the second treatment area);
- c) projection of the adrenal glands (the third treatment area).

The first area is located on the back surface of the neck and its part is located on the back that's why such area resembles a collar.

The second area is located on the forehead.

The adrenal glands projections constitute the third area. The area is located in the point of crossing of a line passing down from the sharp scapula angle with the last rib (Fig. 4).

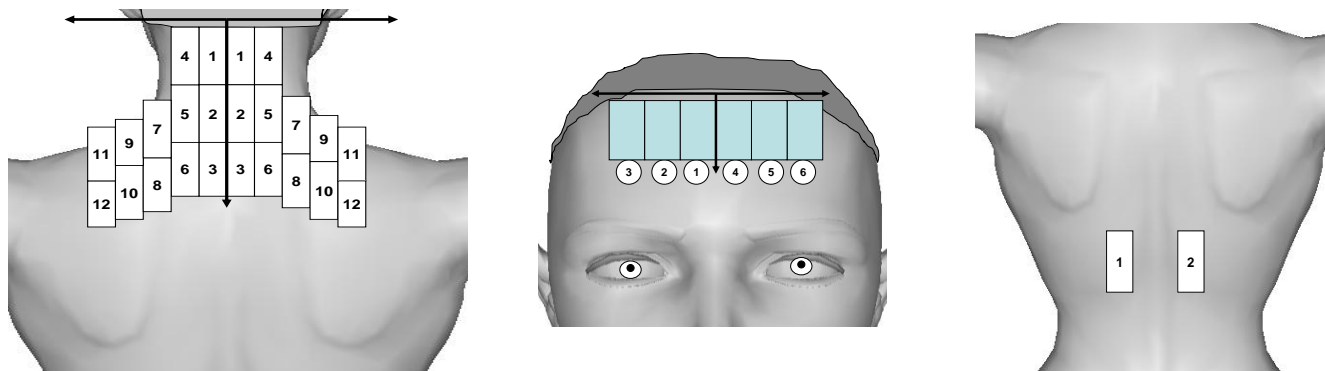


Fig. 4

First, treat the cervical-collar area and, then, the forehead and adrenal glands projection. The device electrode should be set vertically.

### 3.2 HOW TO CARRY OUT ‘CERVICAL-COLLAR AREA’ METHOD IN SDM

The manner to be observed while carrying out the method in **SDM** is almost the same for **Professional devices** and **Home devices**.

The left and right sides of the first area should be treated separately; a line passing along the backbone spines is considered as a separating line.

Start treating on the left from an area locating in conjunction with the hairy part of the head. The long edge of the electrode should be set at distance of one centimeter from the backbone spines.

The treatment should be carried out by slowly moving the electrode firmly pressed to the skin. Prevent a ‘skin roll’ to be formed before the device.

The scheme to be observed while moving the electrode is given in Fig. 5.

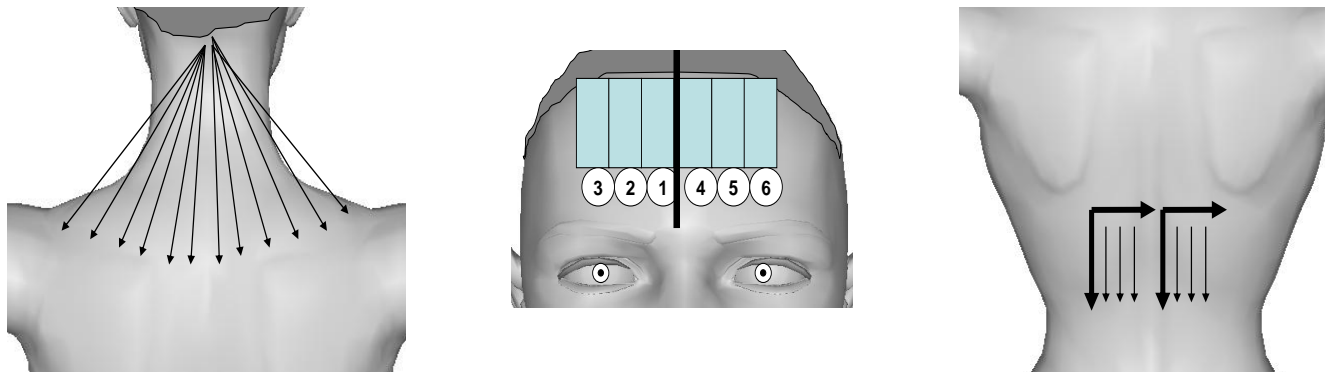


Fig. 5

Repeat treatment till secondary signs appear but not more than five times. If secondary signs are detected, treat their manifestation areas as specified in section 2.4 hereof.

Treat the right part of the area in the similar manner.

Then, select the most pronounced sign among all secondary signs detected on the left and right parts and treat this area additionally as specified in section 2.4 hereof.

The forehead is the next area to be treated.

**Warning!** Reduce power to minimum before treating the forehead areas and increase the power level smoothly to reach its comfortable level. The power level should be selected on the side surface of the neck.

Do not take off the electrode while treating the forehead but set it in sequence on skin areas in the order specified in Fig. 5. Each setting lasts 1 minute.

Treat secondary signs areas on each side of the forehead additionally as specified in section 2.4 hereof.



Treat the area of the adrenal glands projection by moving the electrode for short distance. First – in the left, then – on the right.

Select a power level before treatment.

Treat secondary signs areas additionally as specified in section 2.4 hereof.

### 3.3 HOW TO CARRY OUT ‘CERVICAL-COLLAR AREA’ METHOD IN IDM

The areas should be treated in **IDM** in sequence by moving the electrode in the order specified in Fig. 4.

If using devices of **Home devices** series, set **IDM**. (LED ‘D’ is switched on, see Operating Manual).

Each position should be treated till a completed dose i.e. when all four LEDs are switched on and a sound signal beeps (see Operating Manual).

The secondary signs areas should be detected according the shortest period required to obtain a completed dose. An area with the shortest treatment period should be considered as the most active (a small asymmetry area). If some areas are detected with almost equal minimum periods required to obtain a completed dose, an area which is located above all other areas should be selected.

The most active areas (small asymmetry areas) on the left and on the right should be treated three times in sequence till a completed dose.

The area on which the treatment till a completed dose requires more time should be treated additionally three times in sequence till a completed dose and the frequency modulation mode (the oscillating frequency) should be switched on.

Then, continue a session on the forehead.

At distance being equal to the electrode width from the center line of the forehead – make tree settings to the temple on the left and three settings to the temple on the right. Determine the most active areas on the left and on the right and treat them additionally three times in sequence till a completed dose.

The area on which the treatment till a completed dose requires more time should be treated three times in sequence till a completed dose and the frequency modulation mode (the oscillating frequency) should be switched on.

The area of the adrenal glands projection is located in the point of crossing of a line passing down from the sharp scapula edge with the last rib.

Treat the left and the right areas till a completed dose.

If using devices of **Professional devices** series in **IDM**, treat the areas in sequence as specified in Fig. 4. The actions should be taken in the same order as has been observed to carry out '3 paths' method, the most active areas should be treated in sequence till a completed dose, zero and finish the treatment with the most active area in '**FMVar**' mode.

The left and the right part should be treated independently i.e. the most active areas of the left and the right part should not be compared.

The last electrode setting in all three areas should be always treated till a completed dose.

#### 4. METHOD OF 'PALMS'. TREATMENT AREAS AND PROCEDURE

Treatment areas should be marked.

The areas should be marked when a patient is standing but a session should be given when a patient is lying.

Put the right palm of a patient above the pubic bone. The skin area which is covered with the palm is the **first treatment area**. The right palm of a patient should be placed behind the back and put on the coccyx area. The skin surface which is covered with the right palm is the **second treatment area**.

The seventh cervical vertebra and the suprasternal notch are **the third area** (Fig. 6).

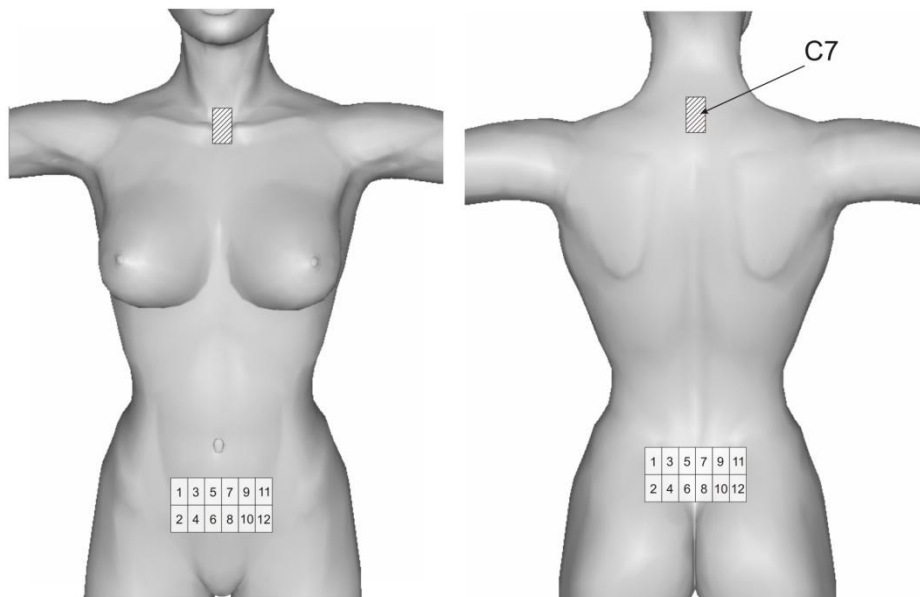


Fig. 6

The power level is comfortable and the frequency is standard.

After treatment areas are determined, treat them in **SDM** or **IDM** as areas of complaint projection (see section 2.4 hereof).

## 5. 'ABDOMEN' METHOD

### 5.1 TREATMENT AREAS

Determine treatment areas.

To do this, divide the abdomen surface area imaginatively into equal quadrants with an omphalus located in the center (Fig. 7).

Treat the center of each quadrant in **IDM** one time till a completed dose (for **Home devices**) from the left top or till an **IR** value appears on the display (for **Professional devices**).

Select the quadrant in the center of which the shortest period has been required till a completed dose (for **Home devices**) or maximum **IR** was bigger (for **Professional devices**) as the first treatment area. The opposite quadrant (diagonally) is the second treatment area.

If painful sensations appear in the stomach area, treat two upper quadrants; in gynecological diseases and pain syndrome localized in the bottom part of the abdomen, treat two bottom quadrants irrespective of the period required till a completed dose or **IR** value.

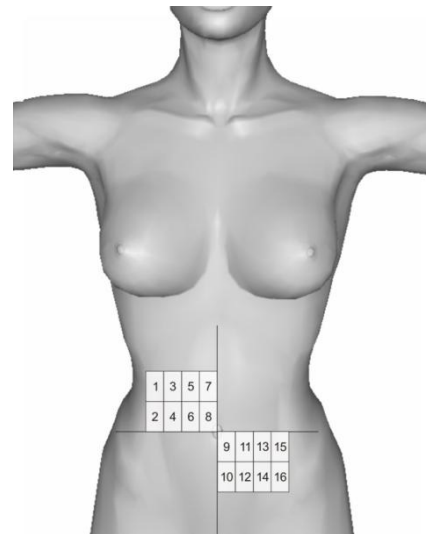


Fig. 7

### 5.2 HOW TO CARRY OUT 'ABDOMEN' METHOD

The distinctive feature of the Abdomen Method is that it should not be completely carried out in **SDM** i.e. **IDM** is used when selecting treatment areas (see item 5.1).

After treatment areas are selected, treat them in **SDM** or **IDM** as areas of complaint projection (see section 2.4 hereof).

## 6. INDICATIONS AND PROCEDURE FOR TREATMENT OF THE LIVER PROJECTION AREA

The dynamics of a patient recovery in treating many diseases mainly depend on the functional status of the liver.

So, the liver projection is recommended to be used additionally to the basic areas scheme.

The treatment should be performed in **IDM** or **SDM** from **top to bottom** (from the horizontal line passing for 2-3 cm below a teat (in men) or below the bottom edge of the mammary gland (in women) to the line passing on the lower edge of the ribs), **from the left to the right** (from the medium – axillary line to the front medium line) (Fig. 8).

The treatment should be carried out in **SDM** or **IDM** as when treating the complaint projection area (see section 2.4 hereof).

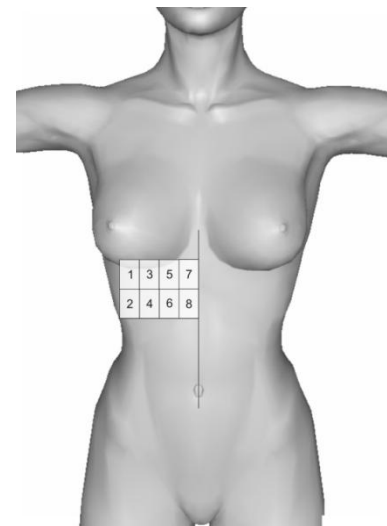


Fig. 8