

IR EHF Therapy apparatus

“TRIOMED”

Model “TRIOMED-KOMPACT 1-8”

Use Instructions

TGKB 941.526.002 IP

Saint-Petersburg

2011

CONTENT

1.APPLICATION

2. MAIN CHARACTERISTICS

3. USE INDICATIONS

4 COUNTRAINdicATIONS .

5.MECHANISM AND FUNCTIONING

6.SET

7. FUNCTIONS

8. TECHNICAL MAINTENANCE

9. OPERATION OF THE DEVICE

10. STORAGE AND USE

PRODUCER'S WARRANTY

DISPOSAL

1.APPLICATION

IR EHF Therapy apparatus model “TRIOMED-KOMPACT 1-8” (further referred to as apparatus) is a portable medical physiotherapy and reflexology apparatus for treatment and (prophylaxis) prevention of different pathologic states by (acting) influence of low-intensity electromagnetic radiation of extremely high-frequency (EHF) and infrared (IR) range on certain areas of human skin.

Inclusion of EHF - therapy into the complex treatment of many diseases allows to accelerate the treatment, to reduce drugs dosage and to potentiate their action, even to abolish them in some cases, to improve drug tolerability, reduce the severity of side effects, achieve positive clinical results in drug-resistant patients.

Apparatus can be used by medical and broad-based medical and care institutions as well as individually under supervision of physician in inpatient, outpatient and home conditions.

EHF- IR therapy effects manifest clinically in anti-inflammatory, analgesic and anti-edematous actions, in improvement of tissue regeneration, raising of nonspecific resistance, improvement of the systemic and regional hemodynamics, in anti-stress action, in normalizing of vegetative nervous system regulation and in a number of other clinical and physiological manifestations. No special safety measures are required.

2. MAIN CHARACTERISTICS

2.1. Technical characteristics

2.1.1. Apparatus complies with requirements of GOST R 50444, TU 9444-018-61005106-2010 and with the set of designers documentation TGKB 941.526.002.

2.1.2. According to application mode the apparatus belongs to the cyclic reusable type.

2.1.3. According to the potential risk the apparatus belongs to class 2a due to GOST R 51609 and Directive 93/42/EEC.

2.1.4. Apparatus is executed as a single unit. The apparatus is equipped with standard Generator EMI EHF “BioTrEM”, manufactured by OOO “Triomed” according to TU 6349-010-61005106-2010 and a set of designers documentation TGKB 435.729.004.

2.1.5. Apparatus is stocked with one battery CR 2032 with nominal DC voltage 3,0 v.

2.1.6. Depending upon EMI EHF “BioTrEM” and IR Generators used Apparatus ensures the following output characteristics shown in Table 1 :

Table 1

Generator	carrier frequency	Wavelength	Frequency of modulation	Time of exposure	Average EHF radiation power or IR radiation
-----------	-------------------	------------	-------------------------	------------------	---

type	GHz	mm	and carrier frequency, Hz	s	flow mW
No1	40 ÷ 43	7,5 ÷ 6,98	1÷100 ± of 0,5	1÷1800	0,001÷0,01

2.1.7. Apparatus body is made of plastic, permitted for application in terms of non-toxicity.

2.2. Labeling.

2.2.1. Labeling of the apparatus corresponds to GOST R 50444 and to set of designers documentation, it is inserted on the table glued to the inner surface of the lid.

2.3. Packaging.

2.3.1. Apparatus packing ensures protection against climatic and mechanical factors and is made according to GOST R 50444.

2.3.2. Apparatus is packed in a thermoplastic blister or in polyethylene according to GOST 10354.

3. USE INDICATIONS

- diseases of peripheral nervous system,
- disease of vegetative nervous system,
- narcological diseases,
- diseases of ENT organs,
- diseases of cardiovascular system,
- diseases of lungs and pleura,
- diseases of gastrointestinal tract,
- dermal and hypodermal diseases,
- diseases of locomotor apparatus,
- gynecological diseases,
- pain syndrome of any localization,
- joint pathology,
- diseases of the spine,
- wounds, burns,
- allergic diseases accompanied by dermal manifestations.

4. CONTRAINDICATIONS

- general contraindications for physiotherapy;
- unspecified diagnosis;
- individual intolerance of such treatment;

- fevers of unknown cause;
- implanted devices with autonomous power source (in the location of the device).

5. DESIGN AND OPERATION

5.1. The face panel of the apparatus (Fig. 2) bears:

- control button,
- 4 light-emitting diodes for indication of switching on of the apparatus and mode of action.

5.2. The back cover bears an IR oscillator (IR- diode) (Fig.3). An EHF generator and battery section are placed under the back cover fixed by two screws.

5.3. The side surfaces of the apparatus (Fig. 1) bear a hanger loop and straps in the body for fixing the belt.



Figure 1. General view
1. place for fastening the belt
2. loop

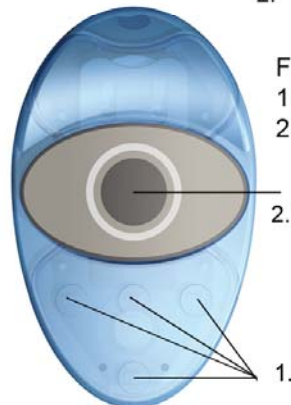


Figure 2. Front view
1. lights-indicators
2. control button

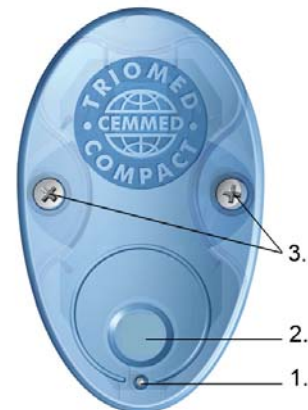


Figure 3. Rear view
1. IR oscillator
2. place of EHF generator
3. cover screws

5.4. At pressing control button and its holding the apparatus is switched on and in turn passes to the different programs that is indicated by switching on for approximately 2 sec. of light-emitting diodes in respective combinations (Fig. 4- 11). If control button remains pressed switching cycles continue. At releasing the button at the time of the chosen program the apparatus starts its execution, radiation is switched on.

5.5. In confirmation of the chosen program respective light-emitting diodes begin to blink with the period of 3÷4 sec. (Fig. 4- 11). Time of procedure in the mode is indicated under figures.

5.6. At the same time with light-emitting diodes buzzer is switched on. After completion of the program the apparatus is switched off automatically. It is possible to switch off the apparatus half-way by double pressing the control button.

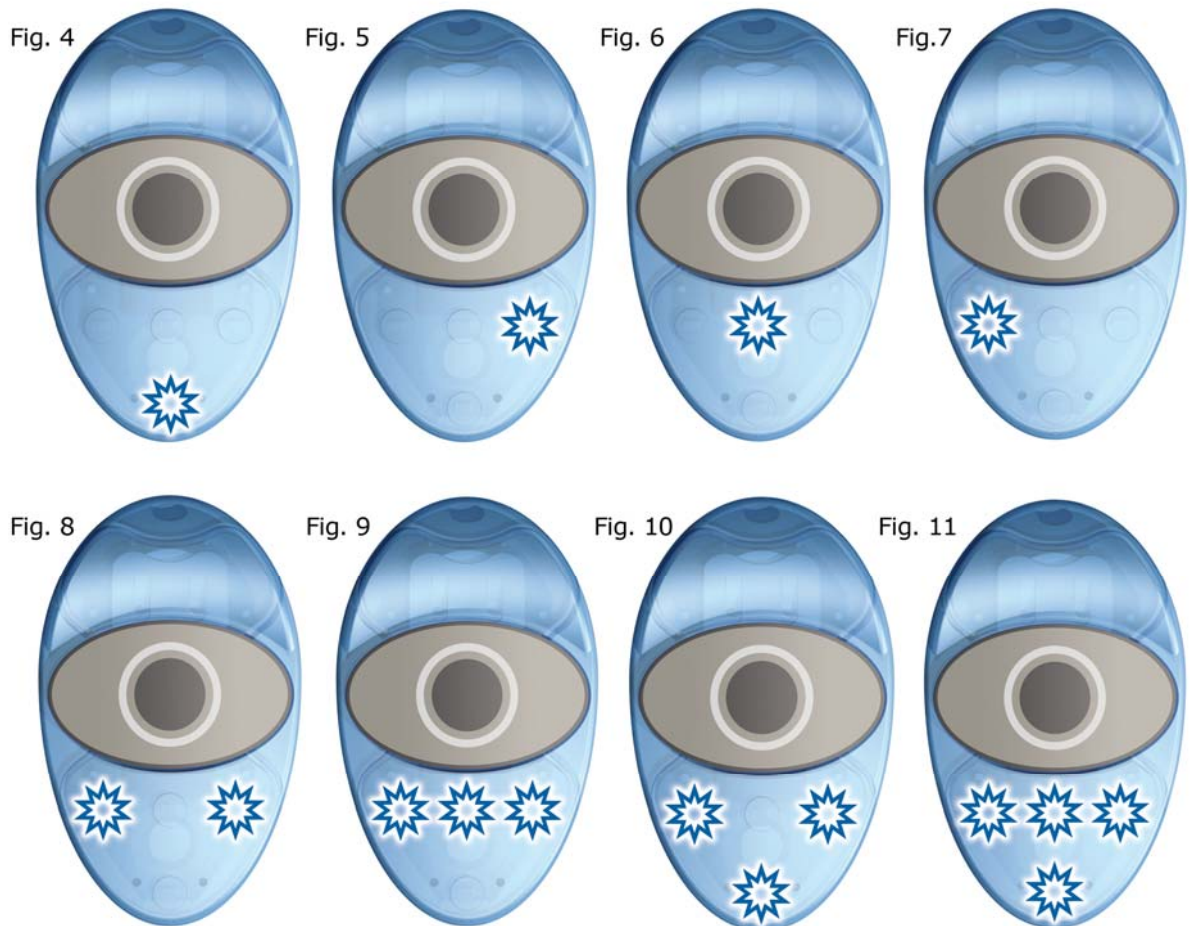


Fig. 4. Mode of distant action

30 min.

Fig.5 Set-up of Program 1

10 min.

Fig.6 Set-up of Program 2

15 min.

Fig.7 Set-up of Program 3

Fig.8 Set-up of Program 4

10 min.

Fig.9 Set-up of Program 5

Fig.10 Set-up of Program 6

12 min.

Fig.11 Set-up of Program 7

5 min.

6.SET

The delivery set of apparatus should comply with data in Table 2.

№ nn	Item	Mark	Quantity
1	IR EHF Therapy apparatus model "TRIOMED-KOMPACT 1-8"	TGKB 941.526.002	1
2	Operational documentation		
2.1	Manual	TGKB 941.526.002 RE	1
2.2	Application instruction Set-up of Program 1	TGKB 943.139.002 IP	1
3	Packaging	TGKB 941.526.002	1

7. FUNCTIONS

7.1. Operational restrictions

7.1.1. Work with the apparatus is permitted after studying Manual and the present Application instruction

7.1.2. It is prohibited:

- to use other power supplies;
- to expose apparatus to excessive mechanical stresses, bumps, falls;
- to hold the radiator at a distance less than 50 cm from medical personnel, carrying out procedures repeatedly or a technician during apparatus maintenance.

7.1.3. Penetration of water and chemical substances inside the apparatus and on its body is prohibited.

7.1.4. External surfaces of the parts of the apparatus should be cleaned and disinfected by 3% solution of oxygenated water according to GOST 177 with addition of 0,5% of detergent (washing powder) according to GOST 25644 by soaked and pressed napkin

7.1.5. After storage at temperature lower than 0° starting of operation is recommended not earlier than after a 4 (four) hour keeping at room temperature unpacked.

7.1.6. For apparatus transportation it is convenient to use consumer packaging. For maximum protection pack again the apparatus like it was originally packed by manufacturer.

7.1.7. Do not place apparatus on the working household appliances.

7.2. Preparation for operation

7.2.1. Before switching on examine the apparatus and make sure that the body is not damaged. The operation of device with damaged body IS FORBIDDEN!

7.2.2. Performance test of the apparatus:

- press control button and hold it. Apparatus will be switched on that is indicated by successive switching on for approximately 2 sec. of light-emitting diodes in different combinations. With release of the button the apparatus begins to execute one of the programs, light-emitting diodes begin to blink with the period of 3÷4 sec. radiation is switched on, the sound of the buzzer can be heard.
- Press control button again without waiting till the end of procedure, apparatus will be switched off.

7.2.3. Breakdowns and troubleshooting.

Absence of light and sound signals means malfunction of apparatus or discharge of battery. Check the battery and if necessary replaced it. If replacement by the proper battery did not lead to switch-on of the apparatus it should be sent to repair shop.

Disturbed order of light and sound signals is a sign of malfunction of the apparatus.

In case of malfunction of the apparatus it is necessary to contact the address indicated in the passport for inspection and repair of the apparatus.

7.2.4. Battery replacement

In order to replace the battery open the cover, turning off both screws (see Fig. 3), take out the old battery and put a new one observing polarity in accordance with the marking on the body of the apparatus and the battery.

7.2.5. User can check himself EHF radiation using Indicator of EHF electromagnetic radiation "Skit" produced by OOO "Triomed" according to TU 6349-012-61005106-2010 and to the set of design documentation (KD) TGKB 435.729.002.

7.2.6. In case of other malfunctions call manufacturer or his official representative.

Addresses and contact telephones are indicated in the passport.

7.3. Security measures

In case of failure of apparatus, emergency situations, urgent evacuation of medical staff special safety measures are not required.

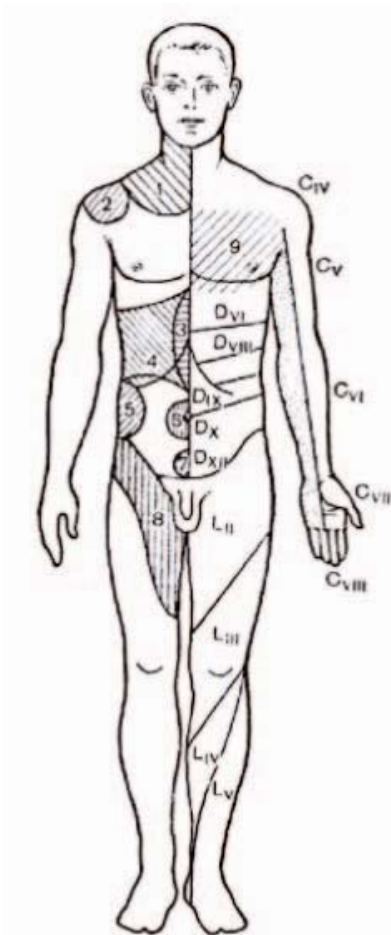
8. TECHNICAL MAINTENANCE

Maintenance is described in the Manual TGKB 941.526.002. RE.

9. OPERATION OF THE DEVICE

9.1. Clinical application of the apparatus is regulated by this Instruction.

9.2. According to the rules and principles of physiotherapy, reflexology and rehabilitation medicine there can be following places of application of apparatus "TRIOMED-KOMPACT": projection area of biologically active points, biologically active zones, pathological focus or its projection area, direct projection of organs, spine area, joints and great vessels, organs' projection in tender (Zakharina- Guesde) zones. During one treatment both point and zonal approaches can be carried out. Apparatus can also be operated due to guidelines, new and updated medical technologies, doctor's manuals approved by Russian Health Control Agency.



Projections of tender zones (Zakharina – Guesde) (1- lungs, 2- liver; 3- stomach and pancreas; 4- liver; 5- kidney; 6- small intestine; 7-colon; 8- ureter; 9- heart).

9.3. Depending on localization of a pathological focus, severity of clinical syndromes, stage of disease and initial state of the organism, treatment plan should be worked out individually taking into account place and duration of the influence, type of changeable radiator and number of treatments.

9.4. Recommendations regarding program use

- Program “0” – lowering of general resistance of the organism, periods of convalescence, after ailments, for preventive maintenance of decompensation and exacerbation of chronic diseases, infectious diseases in the pre-epidemic period.
- Program “1” - aggravation of acute and chronic diseases, before course of physiotherapy with the apparatus.
- Program “2” - chronic diseases and acute states, for prophylaxis of exacerbation of chronic diseases as supporting therapy at chronic diseases to stop pain.
- Program “3” – post traumatic stress disorders, overtiredness, irritability, psycho-emotional fatigue, overstrain, extreme irritability, psycho-emotional excitation, sleep disorders.
- Program “4” - treatment of wounds, abrasions, burns, different inflammations (including articulate).
- Program “5” - acute and chronic diseases accompanied by tissue hypoxia.
- Program “6” - disturbance of tissue metabolism.
- Program “7” - disturbance of tissue metabolism, preparation for subsequent EHF therapy.

9.4. Time of application on one zone or biologically active point is from 3 to 15 minutes. Total time of application should not exceed 30 minutes per day.

9.5. At the beginning of treatment (1- 2 days) it is advisable to use apparatus for step-by-step activation of the regulatory systems (1 manipulation in 1- 2 days). After organism’s adaptation period treatment intensity increases up to 2-3 procedures within 24 hours. If necessary the treatment can be repeated after 2 or 3 months.

9.6. Recommended number of manipulations is from 7 to 15, periodicity 1 or 3 times in 24 hours depending on the state of a patient.

9.8. To guarantee the continuity of outpatient treatment it is recommended to use apparatus at home under supervision of a physician. In order to enhance efficiency of the treatment at home it is recommended to apply treatment not only to the area of

biologically active points' projection , but also organs' projection in tender zones (Zakharina- Guesde zones) (Fig. 12).

9.9. Attention: if possible discomfort does not disappear after 3 procedures and recrudescence is noted it is recommended to consult your doctor.

9.9. Procedure description

- Patient takes comfortable position.
- Before beginning the therapeutic procedure it is necessary to select the program of treatment. Switch on the apparatus and tune it on the selected program.
- The apparatus is fixed on the body of the patient face panel up and it is held by the hand.
- Corresponding light-emitting diodes start blinking with periodicity of 3÷4 sec. and the sound of buzzer is heard.
- It is necessary to wait till the end of procedure. The apparatus will be turned off automatically at the end of procedure.
- For the early end of procedure control button should be pressed.

10. RULES OF STORAGE AND USE,

PRODUCER WARRANTY

Those are described the Manual TGKB 941.526.002. RE.

DISPOSAL

Apparatus is to be disposed into a special container designed for the radio-electronic equipment

Authors:

Medvedev D.S.

Director of Department of biomedical wellness technologies FGOU DPO

“National Institute of Health”, candidate of medical sciences, Associated

Professor, Senior research Fellow St. Petersburg Academy of medical sciences

Institute of Bioregulation and Gerontology.

Ishutin V.N.

Assistant Professor Department of biomedical wellness technologies FGOU DPO

“National institute of health”, Candidate of Medical Sciences, Assisting Professor