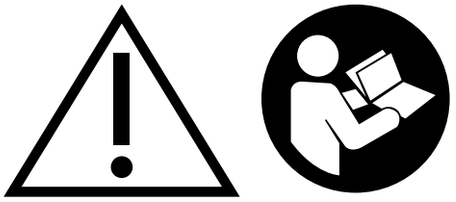
Electrotherapy device for blood pressure correction.

NEURODENS CARDIO

CONTENT

1. SECURITY REGULATIONS

Pay attention to all the information marked with this sign. It is important to ensure safe and efficient use of the machine.



The information contained in this Operating Manual is important for your safety and correct use and maintenance of the device.

In case of undesirable events, associated with the use of the device, it is necessary to send a message to the manufacturer or authorized representative.

The device does not pose a danger to users due to the use of an internal power supply isolated from the working part of the device (working part type BF).

The device should not be used for the treatment of patients with implanted electronic devices (e.g., a pacemaker), and for the treatment of patients with individual intolerance to electric current.

It is forbidden to use the device over the heart's direct projection.

During the session, the patient should not be connected to any high-frequency electrical device. Simultaneous use of the machine and other electrical equipment may cause burns and possible damage of the device.

Attention! Do not use the device on damaged or inmlamad areas of the skin.

Attention! In case of allergy reactions over treatment area, stop treatment and consult a doctor.

Attention! Do not use the device with damaged electrodes.

Attention! Before the session, remove all conductive elements in the field of treatment (watches, jewelry, etc.). The use of the device in the presence of conductive elements on the treatment area is prohibited and can cause electric shock.

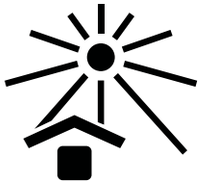
Operation near short-wave or microwave equipment may cause instability in the output parameters of the device.

The use of external power sources is prohibited.

The device contains fragile elements. Protect it from blows.

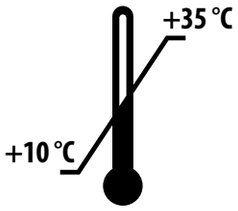
Attention!
Avoid dropping the device!

The device is not waterproof. Protect it from moisture.



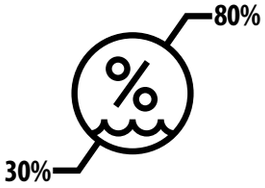
Avoid long-term direct sunlight expose at high (25 °C) air temperature. Keep the device away from heating devices.

All repair work should be carried out by qualified specialists at the manufacturer. Do not attempt to disassemble the unit, in whole or in part, or make unit's modifications!

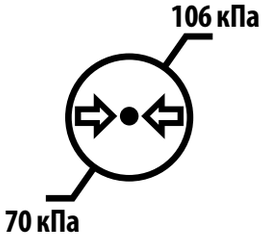


Operating conditions: temperature from +10 up to +35 °C.

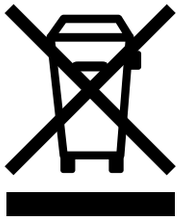
Attention! If the device has been stored at an ambient temperature below + 1°C, you should keep it at an operating temperature of at least two hours before use.



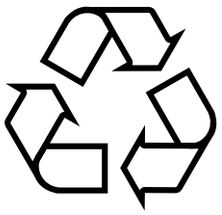
Relative humidity from 30 to 80 % at plus 25 °C.



Atmospheric pressure from 70 to 106 kPa (from 525 to 795 mm Hg. V.).



Separate collection of electrical and electronic equipment.



Recicle: the packaging materials of the device do not have a harmful effect on

environment, they can be used repeatedly. At the end of the service life (operation), the device is disposed of in accordance with SanPiN 2.1.7.2790 as medical waste of class A (epidemiologically safe waste, close in composition to solid domestic waste).

Attention! The device contains valuable materials, which can be reused after disposal, taking into account the requirements of environmental protection. They should be handed over to specially designated places (consult the relevant services of your area) for collection and processing.

The device does not contain medicines, materials of animal or human origin, carcinogenic, mutagenic and toxic materials.

When used for its intended purpose, the device does not create dangerous levels of radiation.

Setup and calibration by the user is not required to put the machine into operation.

Sources of noise in the apparatus do not exist.

There are no controlled studies of the use of the device in pregnant women.

Subject to the conditions and rules of operation, no side effects have been detected as described in this manual.

2 THE PURPOSE OF THE PRODUCT, INDICATIONS, CONTRAINDICATIONS, DIRECTIONS FOR USE

2.1 Appointment

NEURODES-CARDIO is electrotherapeutic device for blood pressure correction is designed for therapeutic non-invasive impact on biologically active zones (BAZ) of the person they are with pulses of electric current of low frequency for correction of blood pressure (BP) and normaliza-tion of the General condition of the body.

The device is intended for use in clinics, medical institutions, for home users and in domestic conditions in accordance with the instructions of the doctor.

Medical staff in medical institutions or individual users at the home should use the device after reading the operating manual.

The device is designed for long-term operation. No special conditions are required for the session. Sessions can be conducted both independently and with the help of the operator. The operator's help is needed if the self-treatment is difficult or impossible.

2.2 General information

NEURODANCE-CARDIO uses following frequencies 2.5; 3.3; 4.0; 6.2; 8.1; 9.2; 9.4; 10; 20; 77 Hz, which are traditionally recommended in the treatment of hypertension, correction of blood pressure and obtaining a meneral sedative, soothing effect.

For the convenience of the procedures, the frequencies for treatment are grouped into four programs (see section 5).

The application of the DiaDENS-CARDIO contribute

the normalization of tone of the vascular wall, expansion of capillaries, improve blood flow in the microcirculation system.

Owing to this:

- blood pressure stabilizes at an acceptable level for the patient;
- improves overall health;
- improves psycho-emotional state;
- increased efficiency;
- reduces the risk of complications of hypertension;
- improves the quality of life of the patient.

2.3 Indications for use

The NEURODENS-CARDIO device is indicated for the course of treatment for persons over 14 years:

- with episodic increase in blood PRESSURE in stressful situations, changes in weather conditions, etc. in persons with labile form of hypertension;

- with stable high blood pressure in patients with hypertension — as a supplement to complex medical treatment.

Attention! Even in the case of situational ((single, sharp) increase in blood pressure requires course treatment: at least 10 procedures, 1-2 procedures per day. At the same time, at the beginning of treatment, there may be a temporary destabilization of blood pressure with its next steady decrease.

2.4 Contraindications to use

Absolute:

- individual intolerance to electric current;
- the presence of an implanted pacemaker. Relative — in these cases, the use of the device is recommended to coordinate with the attending physician:
- epileptic status;

- neoplasms (tumors) of any etiology and localization;
- acute fevers of unknown etiology;
- vein thrombosis;
- a state of acute mental, alcoholic or narcotic excitement.

Attention! On the background of the device application NEURODENS-CARDIO compulsory acceptance of prescribed medicines! Changing the regimens of drug treatment and reducing the doses of drugs taken is possible only after a persistent decrease in blood PRESSURE, in agreement with the attending physician.

2.5 Recommendations for use

2.5.1 According to international recommendations, patients with hypertension are recommended to keep a "Diary of blood PRESSURE" with blood pressure measurement three times a day at the same time: in the morning,

in the middle of the day and in the evening — even in good health. At occurrence of complaints (headache, dizziness, pain in the heart, interruptions in heart, weakness, fainting, etc.) require extraordinary measurement of blood pressure.

Attention! During treatment using NEURO DENS-CARDIO it is unacceptable self-cancellation of drugs by the patient in persons with a significant increase in blood PRESSURE and a high risk of vascular complications (myocardial infarction, cerebral stroke, thromboembolism, etc.). After receiving a persistent hypotensive effect recorded in the "Diary of blood PRESSURE", the scheme and doses of drug treatment can be changed by the attending physician.

2.5.2 The procedure is performed 1-2 times a day, at about the same time, regardless of the level of blood pressure before the procedure.

2.5.3 One-time use apparatus NEURODENS - CARDIO in individuals with a tendency to increase blood pressure if you feel unwell: take antihypertensive recommended by the attending physician, and additional treatments should be performed exposure apparatus of NEURODENS - CARDIO, combining programs with PE-Riyami in 1-1,5 hours until disappearance of complaints. If high blood pressure persists for a long time, consult a doctor.

2.5.4 For course effects: spend 1-2 sessions a day for 10-15 days, regardless of blood PRESSURE before the procedure. With a stable form of hypertension, repeat the course monthly.

2.5.5 Patients with hypertension require repeated regular courses of exposure at least once a month (for example, from the 1st to the 15th day of each month).

Attention! Blood pressure (BP) control is not required after the procedure.

2.5.6 It is recommended slower rate of blood pressure decrease for 70+ patients - using NEURODENS-CARDIO once a day. The course of treatment should consist of 7-8 sessions. After a 10-15-day break, it is recommended to repeat the course of treatment.

During the first course of treatment, blood PRESSURE may fluctuate slightly, so the patient is obliged to continue taking hypotensive drugs prescribed by the doctor.

2.5.7 Patients with malignant hypertension – persistent consistently high blood pressure, above 180 mm Hg. art., which is not amenable to medical correction with competent and systematic administration of drugs: the duration of the course, the number of procedures per day and the combination of programs are determined after consultation with the treating physician.

Hardware impact has the effect of accumulation, that is, blood PRESSURE becomes stable by the end of the course of treatment.

3 THE UNIT

3.1 Appearance of the device

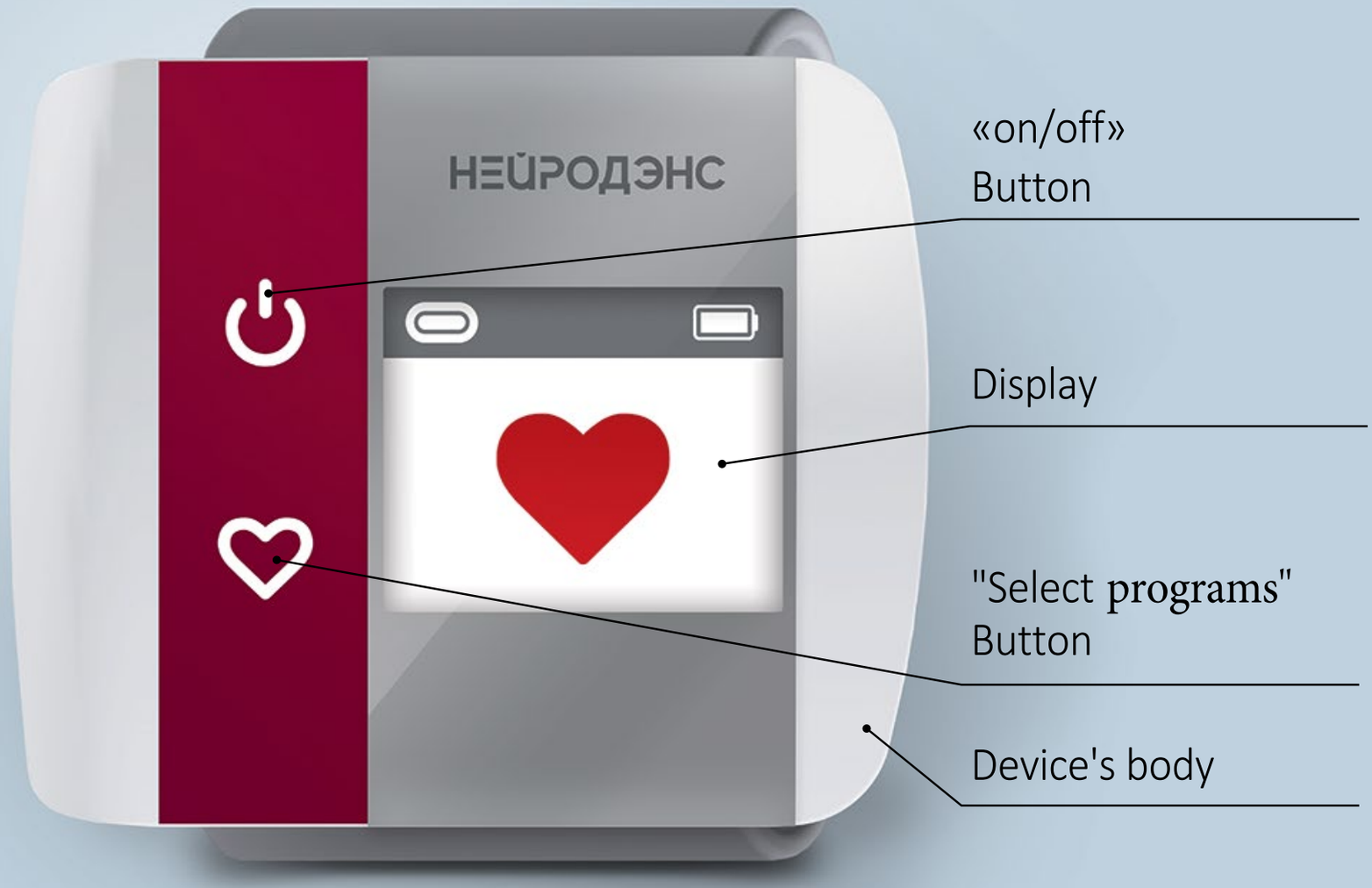


Figure 1 – Appearance of the device. Front side

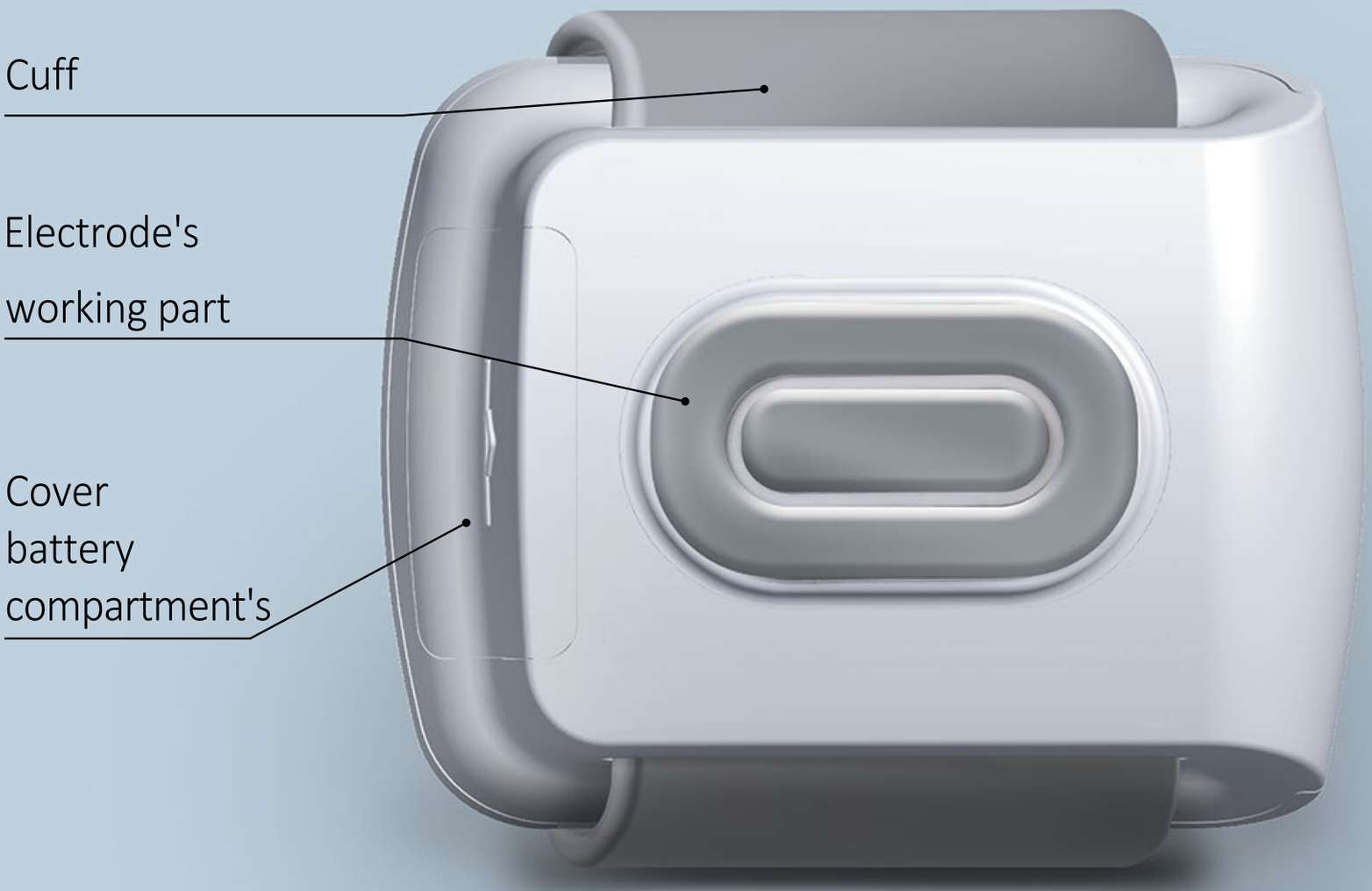
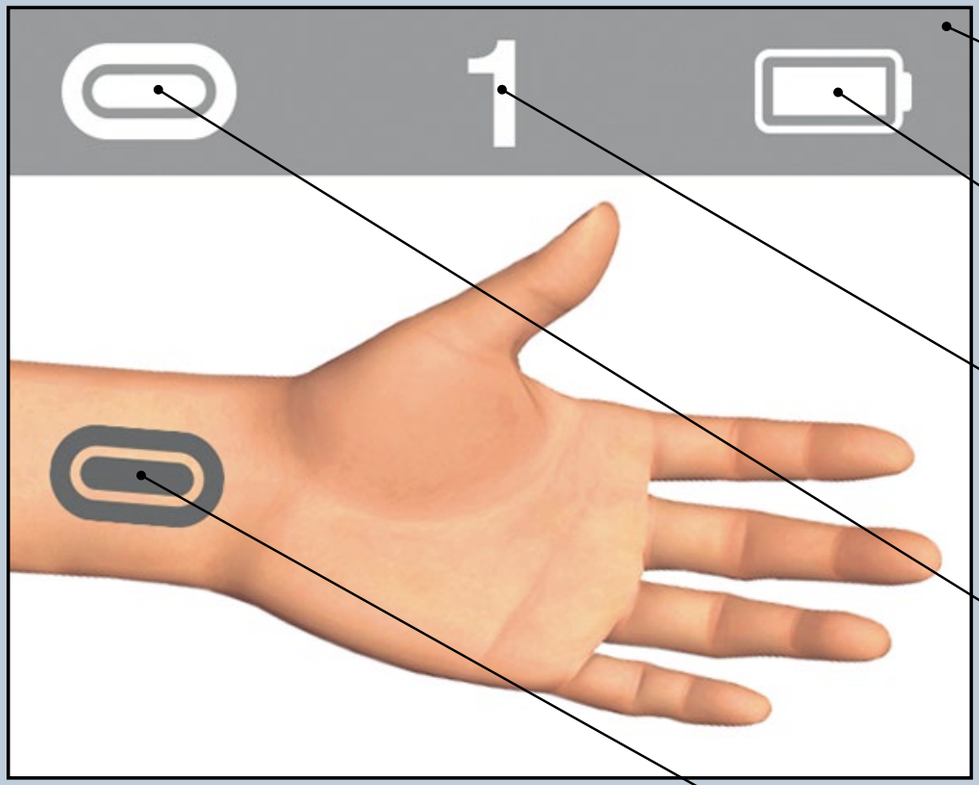


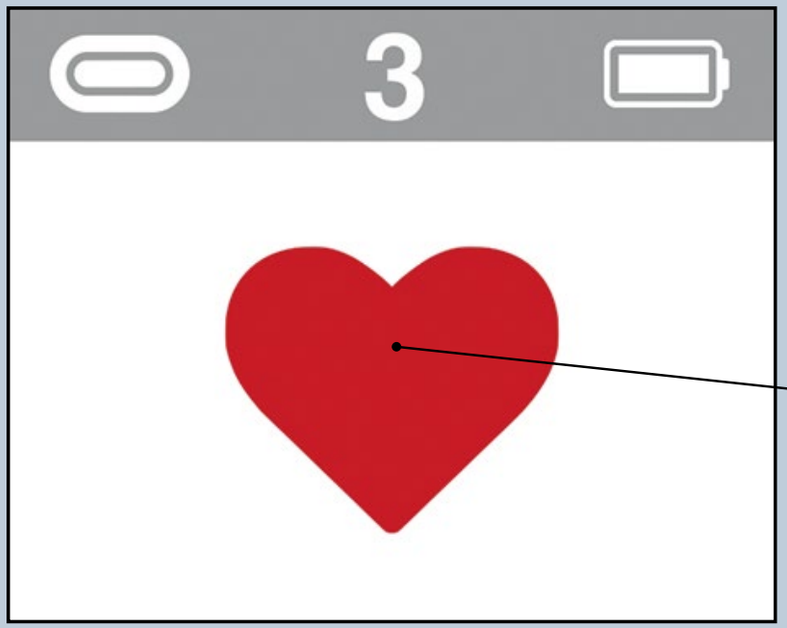
Figure 2 – Appearance of the device. Back

3.2 The appearance of the display in various modes

3.2.1 the selection screen of the program

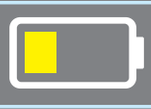


3.2.2 The window of the 1st phase of the program

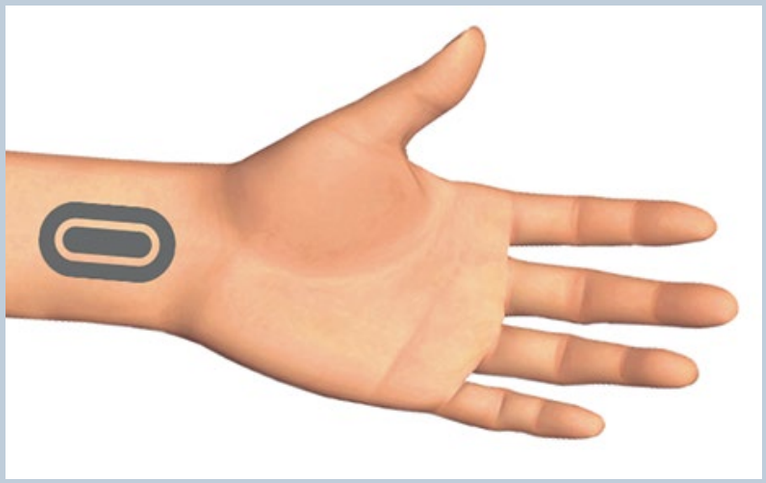


3.2.3 Timer window (2nd and 3rd phases of the program)

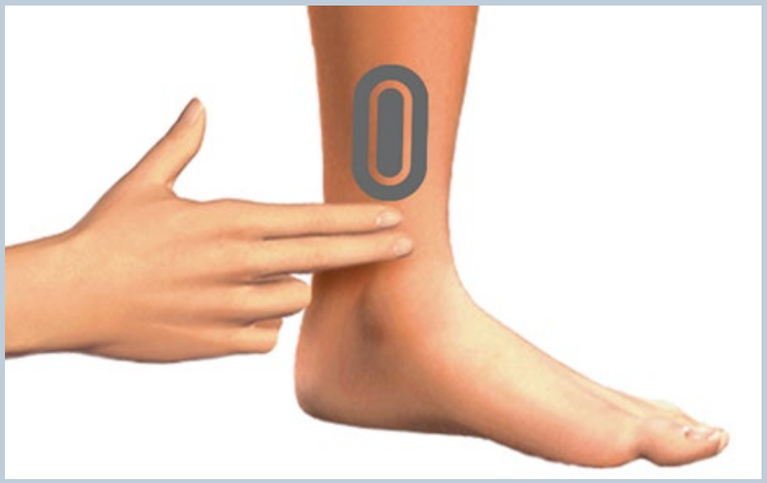
3.2.4 Symbols of status

	the presence of contact of the electrode with the skin
	the absence of contact of electrode with skin
1	programme 1
2	programme 2
3	programme 3
4	programme 4
	voltage indication on batteries 100 %
	75-99 %
	60-74 %
	45-59 %
	30-44 %
	15-29 %
	0-14 %

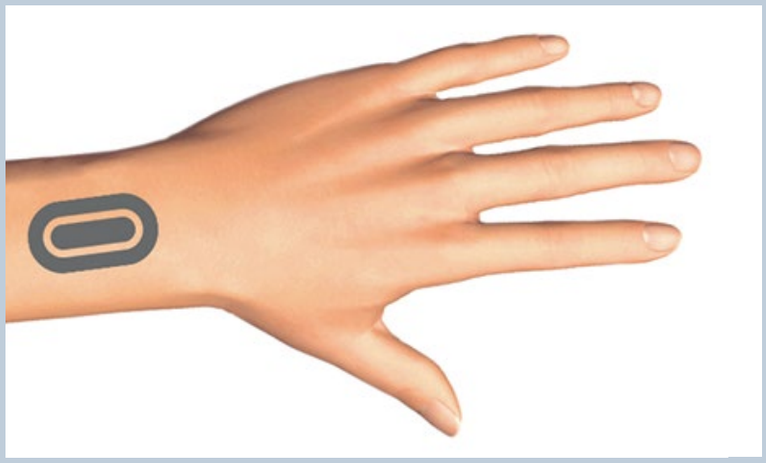
3.2.5 Recommended exposure area displayed on the display



the zone of impact
for the program 1



the zone of impact
for the program 2



the zone of impact
for the program 3

the zone of impact
for the program 4

3.3 An audible alarm is provided for the following events:

- on and off;
- the establishment or loss of contact of the electrode with the load (skin);
- the start and end of the program;
- at the end of the first phase of programs;
- when the voltage on the batteries is reduced to 2.2±0.1 V;
- when switching off, when the voltage on the batteries 2,1±0,1 V;
- when you press any button.

4 COMPLETE SET

Name	Quantity, PCs.
Composition:	
The electrotherapeutic apparatus for correction of blood pressure NEURODENS-CARDIO	1
The battery LR6/AA 1.5 V	2*
User manual	1
Accessories:	
The extension cuff	1

** Warranty does not apply.*

5.MODES (PROGRAMS)

The programs are designed to affect the biologically active zones, which are paired. The device can be used on any extremity, according to the selected program, at the user's request.

Exposure is carried out in a stable way (without moving the device over the skin). All modes (frequencies) are grouped into four programs as it makes device's usage more comfort.

- Program 1 is basic and is used in any variant of increasing blood PRESSURE (systolic, diastolic, labile).
- Programs 2, 3, 4 are optional and can be applied depending on the specific situation of the patient:
- Program 2: with a tendency to increase diastolic pressure (90 mm Hg. art. and above) and with a tendency to swelling (on the face and/or lower extremities);

- Program 3: for the patients with unstable (labile) blood pressure, as well as with increased blood pressure on the background of endocrine diseases (diabetes, thyrotoxicosis, etc.);

- Program 4: for the patients with blood pressure related to psycho-emotional stress (stress); increased blood pressure is accompanied by a pronounced emotional reaction (anxiety, fear, panic).

Each program consists of three phases, with different frequencies, time and amplitude.

5.1 Program 1 (combines the frequency of 9.2; 9.4; 10; 77 Hz) is designed to correct vascular tone, dysfunction of the central nervous system.

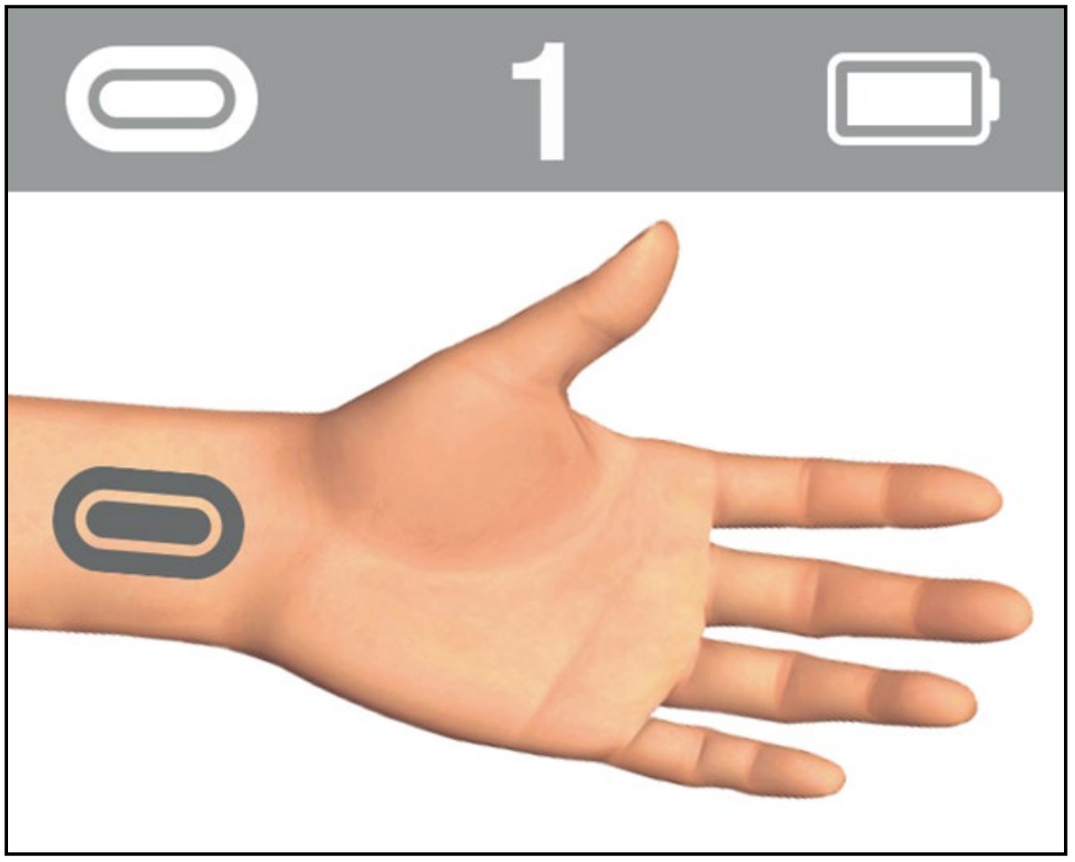
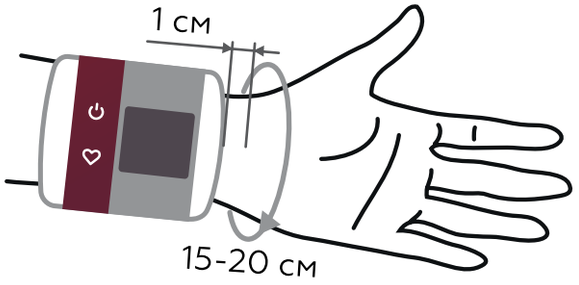


Fig 3 - Program 1

The recommended exposure area is located on the inner surface of the forearm, about 3 cm above the radiocarpal fold (biologically active point (hereinafter-AP) AP MC 6 (Nei-Guan)).



5.1.1 Holding the hand palm up, place the device indicator up at a distance of 1 cm from the wrist folds so that the electrodes touch the skin on the inner surface of the forearm. Tighten and fix the cuff of the device the way electrodes are tightly pressed to the skin.

5.1.2 Perform treatment session. Session usually takes 6-7 mins (depends on energy level of AP).

Chart 1 – Parameters of program №1

Program's phase	pulse's frequencies, Hz	Time, min
Phase 1	9,2±1,0	no longer than 2*
Phase 2	9,4±1,0	2
Phase 3	Alternation 10±2 и 77±3 during 0,25±0,05 seconds	3

* - after stabilization of skin resistance in the subelectrode zone.

5.2 Program 2 (combines the frequencies 3.3; 8.1; 20; 77 Гц) is designed to improve renal hemodynamics.

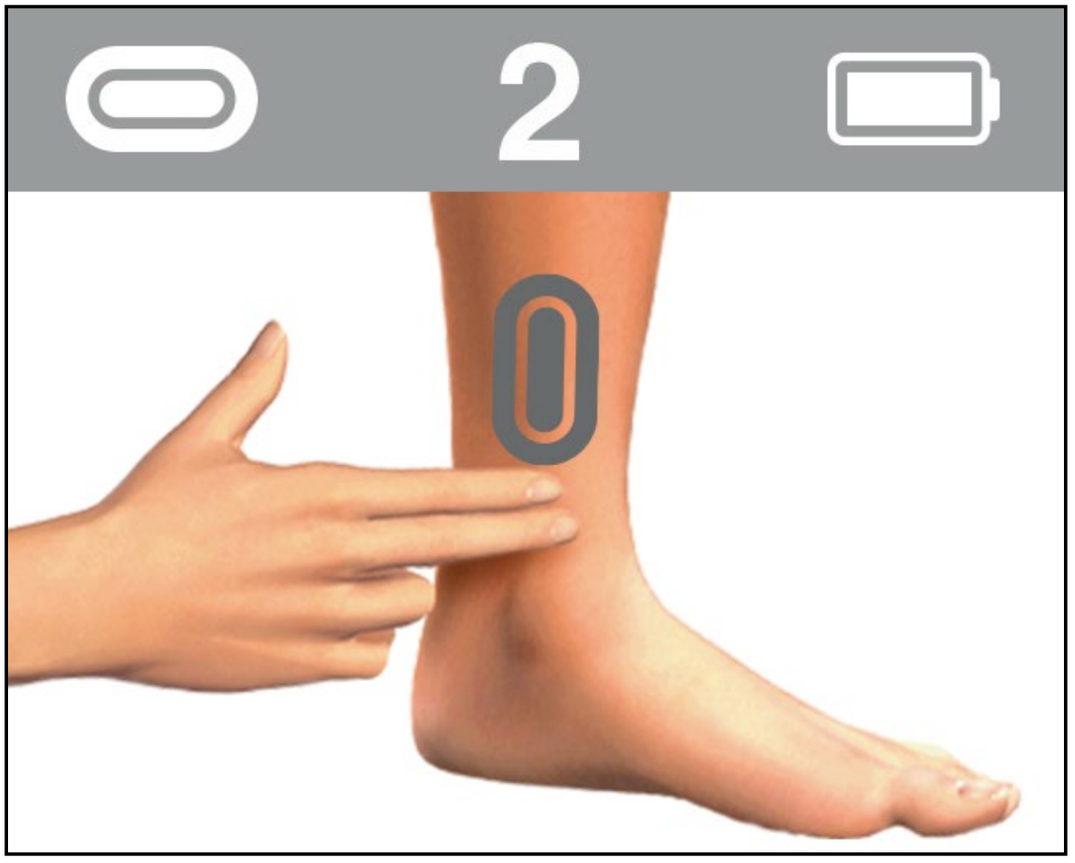
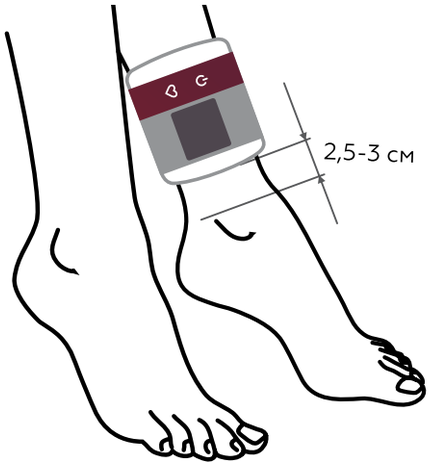


Fig 4 – Program 2

The recommended treatment area is located above inner ankle (AP RP 6 (San Yin-Jiao)).



5.2.1 Take the clothes off to get to ankle and lower leg. Place device's electrodes 2.5-3 cm above the most protruding part of the inner ankle. Tighten and fix the cuff of the device the way electrodes are tightly pressed to the skin.

5.2.2 Perform treatment session. Session usually takes 7-8 mins (depends on energy level of AP).

Chart 2 - Parameters of program №2

Program's phase	pulse's frequencies, Hz	Time, min
Phase 1	8,1±1,0	no longer 2*
Phase 2	3,3±1,0	3
Phase 3	Alternation of 20±2, duration 3±1 second and 77±3 duration 2±1 c	3

* - after stabilization of skin resistance in the subelectrode zone.

5.3 Program 3 (combines the frequencies 2.5; 4.0; 20; 77 Hz) is designed to correct vascular dysfunction, vegetative and metabolic disorders

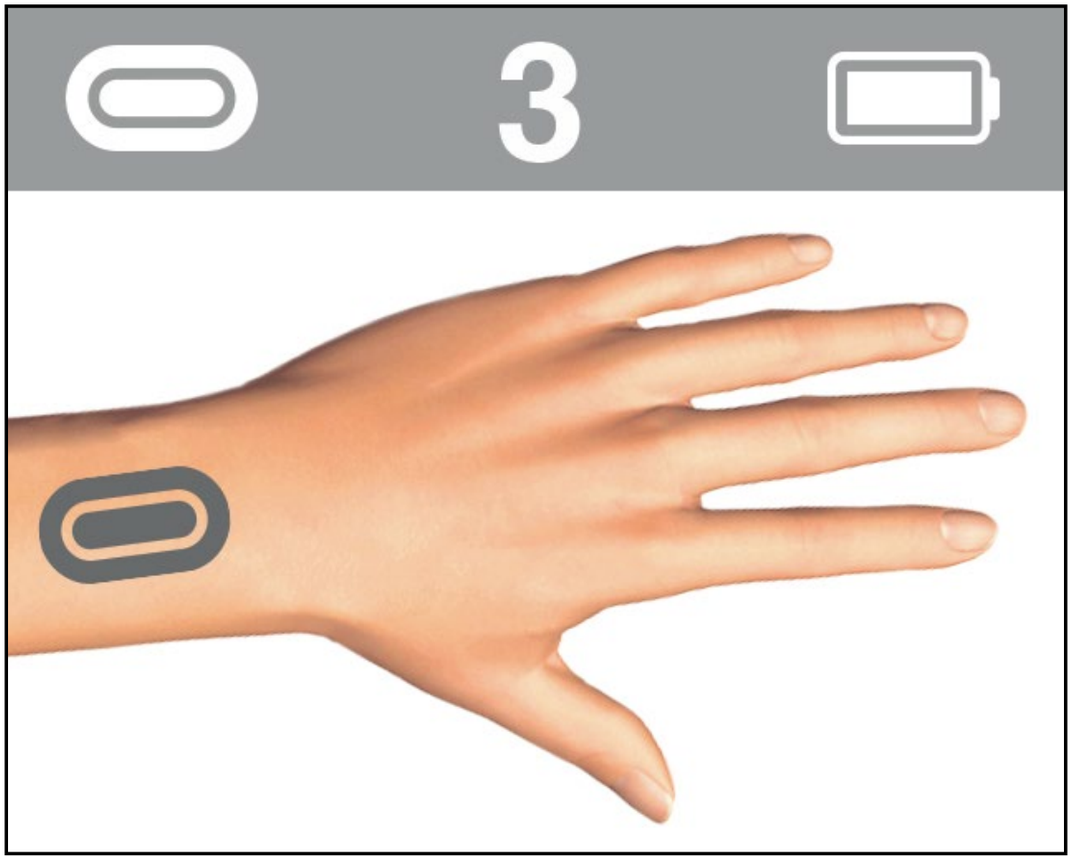
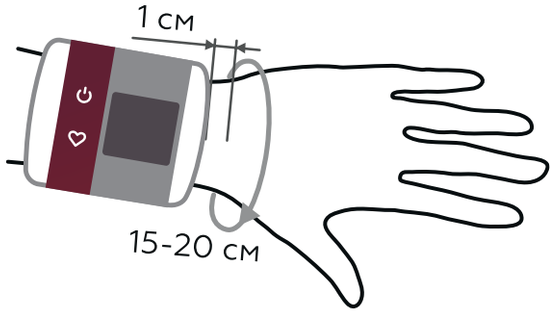


Fig 5 – Program 3

The recommended treatment area is located on the outside of the forearm, about 3 cm above the radiocarpal fold (AP TR 5 (Wai-Guan)).



5.3.1 Holding the palm down, place the device indicator up at a distance of 1 cm from the wrist folds so that the electrodes touch the skin on the outer surface of the forearm. Tighten and fix the cuff of the device the way electrodes are tightly pressed to the skin.

5.3.2 Perform treatment session. Session usually takes 6-7 mins (depends on energy level of AP).

Chart 3 - Parameters of program №3

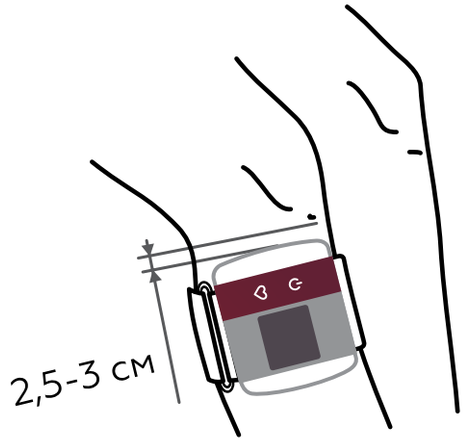
Program's phase	pulse's frequencies, Hz	Time, min
Phase 1	4,0±1,0	no longer than 2*
Phase 2	2,5±1,0	3
Phase 3	Alternation of 20±2 duration 3±1 seconds и 77±3 duration 2±1 seconds	3

* - after stabilization of skin resistance in the subelectrode zone.

5.4 Program 4 (combines the frequencies 6.2; 10; 20; 77 Hz) designed for correction emotional state and General well-being.

Fig 6 – Program 4

The recommended treatment area is located under the lower edge of the patella, on the line running along the outer edge of the patella (AP E 36 (Ju-San-Li)).



5.4.1. Take the clothes off to get open area of patella. Place the electrodes of the device on the outer surface at a distance of 2.5–3 cm below the patella. Tighten and fix the cuff of the device the way electrodes are tightly pressed to the skin.

5.4.2 Perform treatment session. Session usually takes 7-8 mins (depends on energy level of AP).

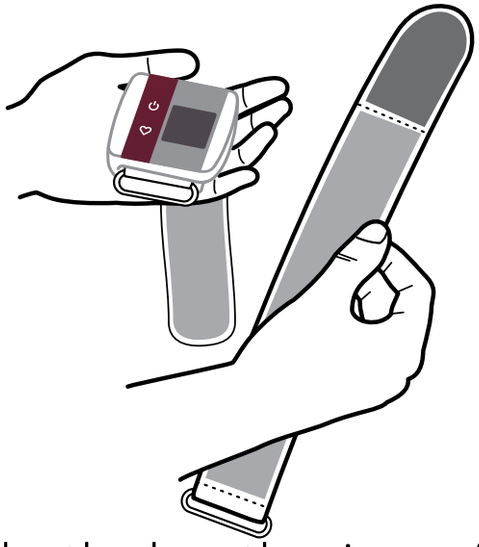
Chart 4 - Parameters of program №4

Program's phase	pulse's frequencies, Hz	Time, min
Phase 1	10±2	no longer than 2*
Phase 2	6,2±1,0	3
Phase 3	Alternation of 20±3 duration 1,0±0,2 seconds 77±3 длит. 1,0±0,2 с	3

* - after stabilization of skin resistance in the subelectrode zone.

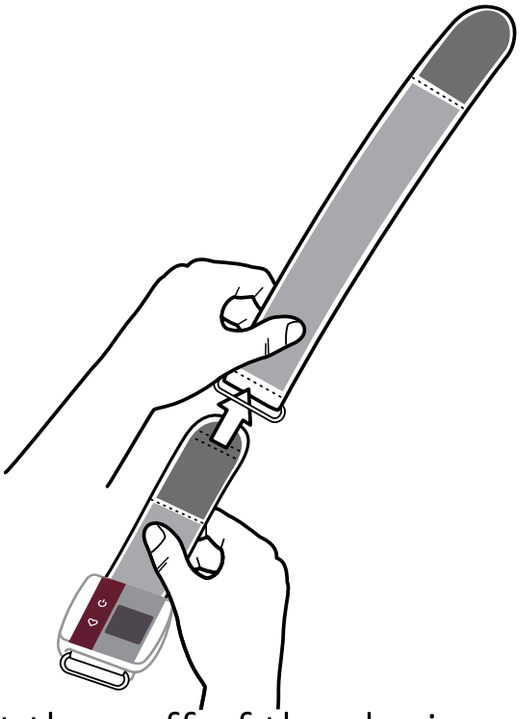
6 USING THE EXTENSION CUFF

1



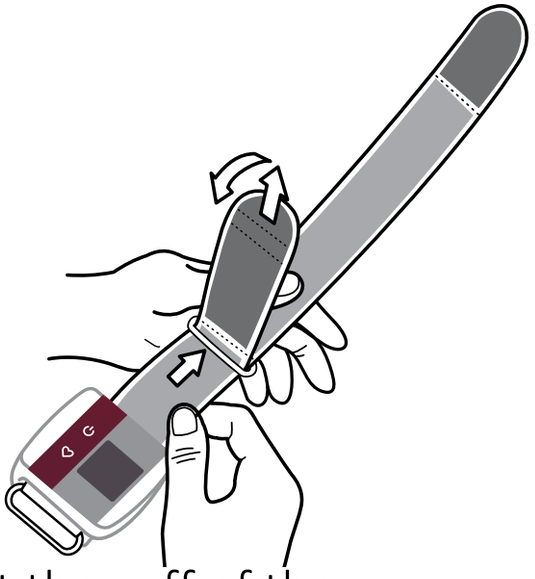
Take the lengthening cuff

2



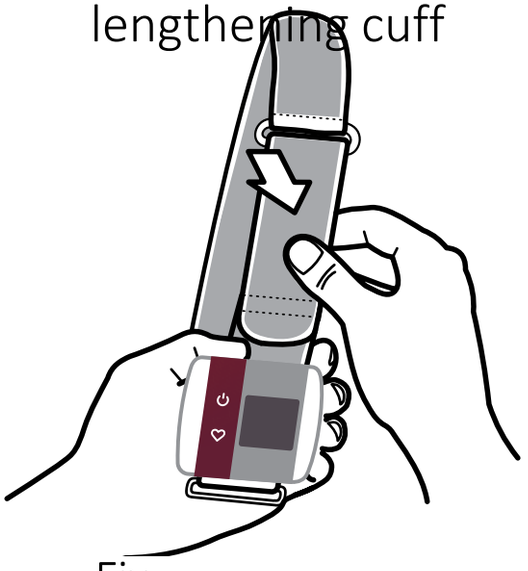
Insert the cuff of the device into the bracket of the lengthening cuff

3



Pull out the cuff of the

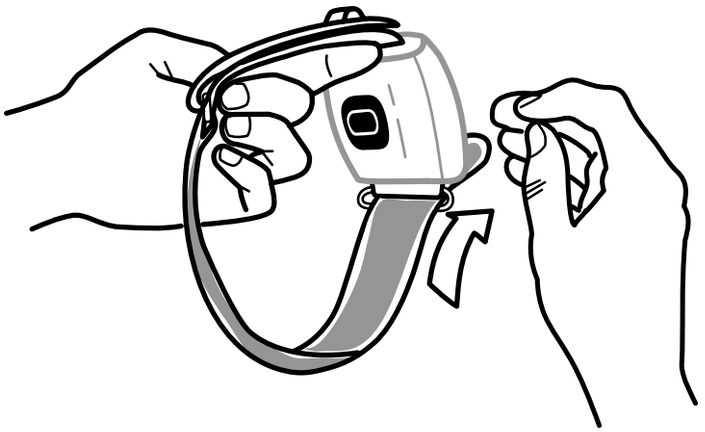
●



Fix

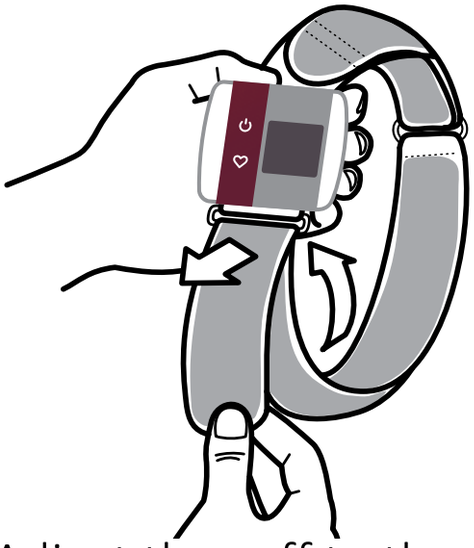
Note. Further actions are recommended to be carried out directly on the selected area of influence

5



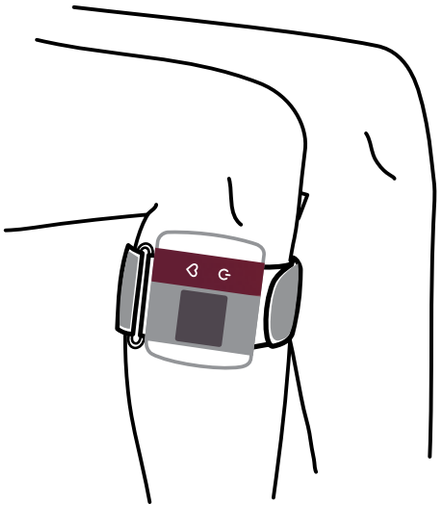
Thread extending through the cuff clip apparatus

6



Adjust the cuff to the desired size

7



Secure the machine to the selected exposure area

7 INSTALLATION PROCEDURE/ REPLACEMENT OF BATTERIES

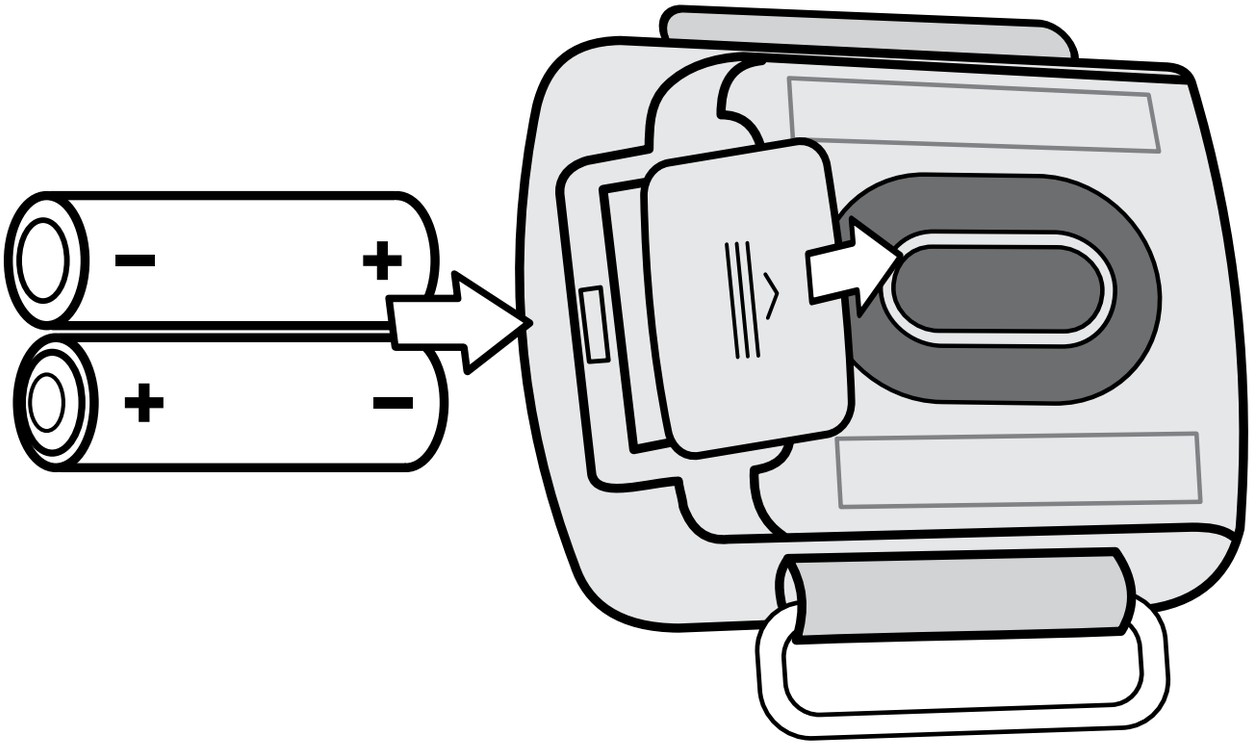
Replacement of batteries is necessary when a symbol appears on the indicator or when fully discharged.

Attention! install only items powered provided for this product type AAA rated voltage 1.5 V. do not use batteries other than those specified by the manufacturer.

Connection of unsuitable batteries can cause malfunction (not covered by the warranty of the manufacturer), as well as the defeat of the electric current.

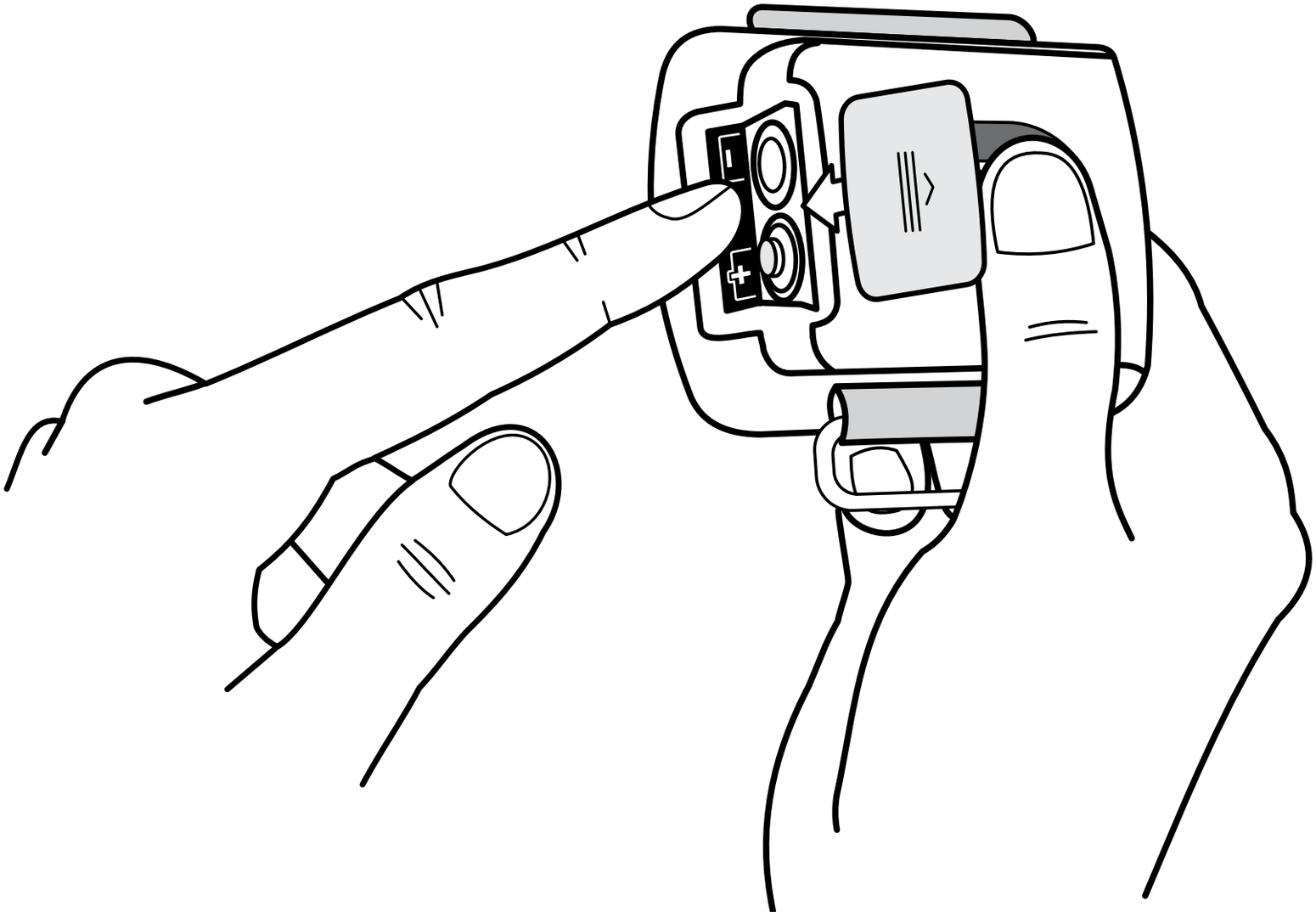
Attention! When storing the machine for a long time, remove the batteries to avoid electrolyte leakage. Use high quality batteries.

The procedure for installing/replacing the batteries:



7.1 Open the battery compartment and remove the used batteries.

7.2 Install new batteries, observing the polarity.



Attention! When replacing, it is recommended to use the same type of batteries and replace both batteries at the same time.

7.3 Close the battery compartment.

8 MAINTENANCE

8.1 Before using the machine, maintenance must include the following operations:

- external examination of the product;
- hygienic processing.

For processing and cleaning of the electrode, use standard disinfectants (3% hydrogen peroxide solution according to GOST 177 with the addition of 0.5% detergent solution according to GOST 25644) and soft napkins without lint.

8.2 If you do not intend to use the machine for a long time, you must remove the power sources from the battery compartment.

8.3 When a symbol  appears on the display, replace the batteries according to section 7.

9 USING THE APPARATUS

9.1 Preparation

Attention! Before using the machine read the safety instructions in section 1!

Attention! Before and after each procedure, the electrode of the device is treated with a standard disinfectant solution (for example, 3% of the hydrogen peroxide solution according to GOST 177 with the addition of 0.5% detergent solution according to GOST 25644) and soft napkins without lint. It is necessary to store the device with a dry electrode.

9.2 Install the batteries according to section 7.

9.3 Take a comfortable position for you (sitting or lying).

Attention! It is forbidden to carry out procedures with the NEURO DENS-CARDIO apparatus in a standing position!

Attention! Before the session, remove all conductive elements in the area of treatment (watches, jewelry, etc.). The use of the device in the presence of conductive elements on the treatment area is prohibited and can cause electric shock.

9.4 Turn the machine on by briefly pressing (less than 1 second) the button . After the beep and screen saver, the last selected program will be displayed. ⏻

9.5 Select the program according to section 5 (PROGRAMS) by clicking ♡

When pressed, the program number and recommended exposure area will be displayed.

9.6 Fix the device on the body.

Fixation should be carried out in such a way that the electrode of the device tightly touches the skin in the BAT area, without crushing the limb.

Attention! When fixing the device, do not over-tighten the wrist, Shin or knee with a cuff.

Attention! The cuff of the device is designed for use on the arm or leg with a girth of not more than 22 cm at the attachment point.

If necessary, use an additional cuff according to section 6.

9.7 Make sure you have skin contact.

If there is a contact, the device signals this with a short beep and displays a symbol.

If contact is lost, the unit signals this with a series of short beeps and displays a symbol.

9.8 Start the program by briefly pressing (less than 1 second) the button

Attention! The launch of the program occurs only in the presence of contact of the electrode with the skin!

After the beep, the device enters the first phase of the programs. The symbol "Pulsating heart" appears on the display . The end of the first phase of the program is accompanied by a sound signal.

During the transition into the second phase of the programme the display shows a countdown timer (see section 3.2.3). The timer shows the time left until the selected program is finished. The program time consists of the execution time of the second and third phases.

The duration of the session is determined by the program (see section 5).

Attention! After the program is started, the button ♡ is not active. If you need to change the program before it ends, you need to ensure that there is no contact and switch the program or turn off the device, turn it on again and carry out the selection of programs.

The end of the 3rd phase of the programs is accompanied by a sound signal.

9.9 Have a treatment session.

9.10 The end of the program accompanied by an audible signal and display on the display the selected program (see section 3.2.1).

At the end of the session, remove and turn off the machine by pressing and holding the button ⏻ for 3 seconds. The message "Good health" appears on the display»

after the beep, the machine will turn off.

The machine switches off automatically 3.0±0.5 minutes after the last press of the program selection button or after the end of the program.

After the session, the patient is recommended to rest for 20-30 minutes.

10 POTENTIAL FAILURES AND HOW TO SOLVE THEM

This section describes the machine States, which can be interpreted as a fault and resolved independently. In case of other faults, contact the manufacturer (see section 14), do not attempt to repair them yourself.

Fault	Possible cause	Method of elimination
The device does not turn on when you press the button ⏻	No batteries	Replace batteries according to section 7
	When installing batteries in the battery compartment of the device, their polarity is mixed	

When you turn on the machine beeps and turns off automatically	Battery voltage less than 2.1 V	Replace batteries according to with section 7
When working flickering symbol 		
The machine turns off		

"Fast consumption" of batteries	Poor quality batteries	Use quality batteries recommended by the manufacturer
The symbol  does not appear on the indicator if there is skin contact	Insufficient conductivity of the electrode with the skin surface	Tightly apply the electrode apparatus to the skin on top of-news. If necessary – pre-moisten the electrode contact area with the skin surface

The symbol  does not disappear on the indicator if there is no skin contact	Electrode is clogged or dirty	Clean the electrode in accordance with section 8

Attention! all faults are eliminated at the manufacturer

11 SPECIFICATIONS

11.1 Overall dimensions

Of the device (without cuff) mm	(87±2)x(69±2)x(32±2)
Apparatus (with cuff), mm	(87±2)x(360+36)x(32±2)
The extension cuff, mm	(500+20)x(50±2)x(3±1)

11.2 Mass

Of the device without battery, g	95±10
The extension cuff, g	35±5

11.3 Current consumed by the device:

with active backlight, mA	75±25
without backlight, mA	25±15
in the off state, MCA	0,2±0,1

11.4 The machine should turn off automatically

- ✔ when the supply voltage is reduced to 2.1±0.1 V;
- ✔ 3.0±0.5 minutes after the last press of the "program selection" button or after the end of the

programs.

11.5 The power of the machine should be from 2 cells of type LR6 size AA. The device must perform all functions at a supply voltage of 2.2 V to 3.2 V.

11.6 Degree of protection against penetration of water and solid particles IP20.

11.7 The dependence of the shape and parameters of the pulse from the load resistance

11.7.1 Amplitude and time parameters of the pulse before the start of the program (no load)

Pulse parameters	Amplitude-time characteristics
Duration of the 1st phase of the pulse t1, μs	12 ± 3
Amplitude of the 1st phase of the pulse u11, V	16 ± 5
Amplitude of the negative part of the pulse of the 2nd phase u22, V	160 ± 10

The pulse frequency before the start of the program, regardless of whether there is or is no contact with the load (skin) should be 1.0±0.1 Hz.

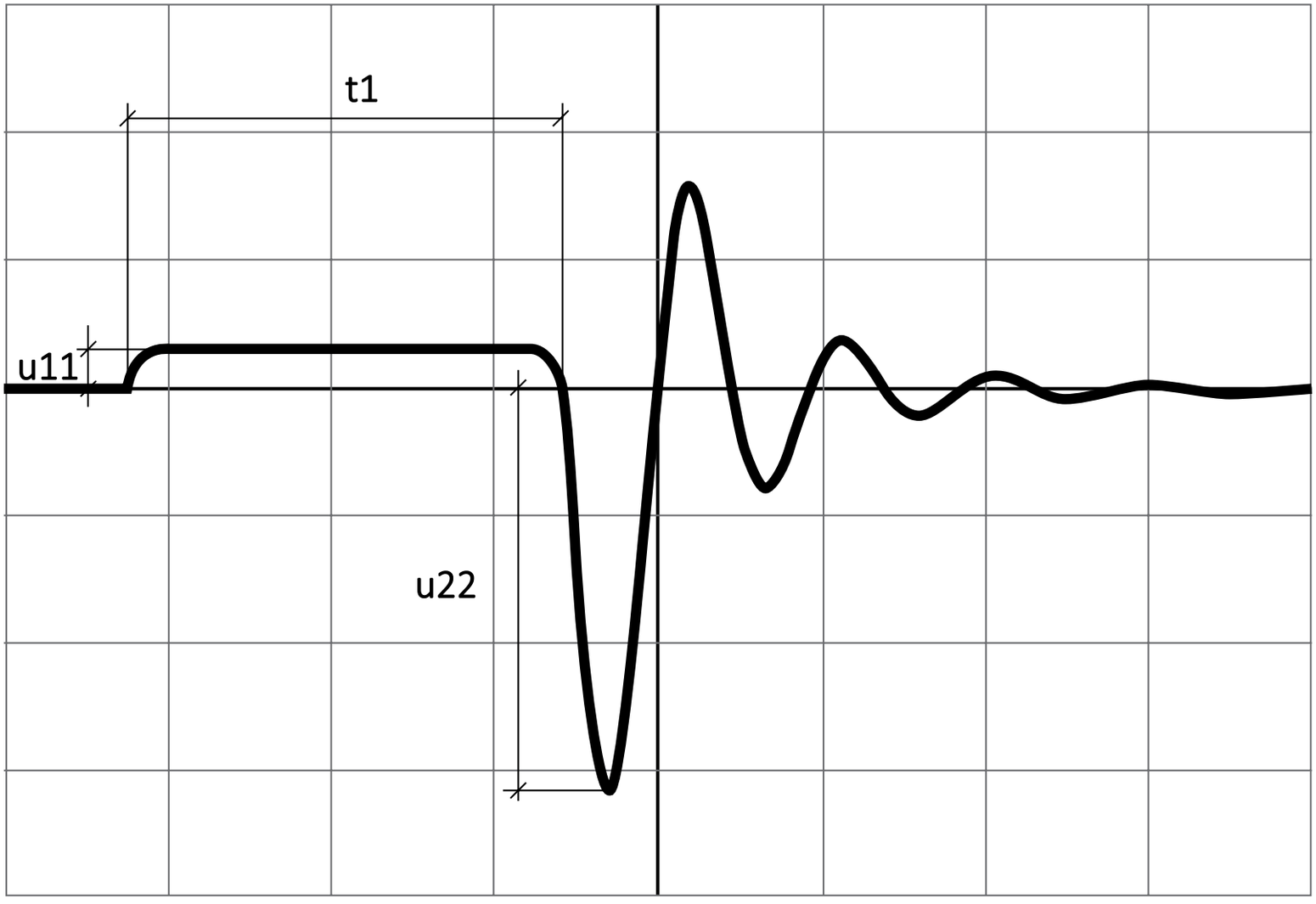


Figure 7 – pulse Shape before programs start (no load)

11.7.2 pulse Amplitude and time parameters at connected load rn=20 kω in programs 1, 2, 3, 4

The pulse repetition rate is described in section 5.

The duration of the 1st phase of the pulse in programs 1, 2, 3, 4
(except for phase 3 of program 4) should be 24±3 μs.

The duration of the 1st phase of the pulse in the 3rd phase of the program 4 should vary from 8±3 μs to 24±3 μs and back in increments of 1.0±0.2 μs.

Pulse parameters	Amplitude-time characteristics		
Duration of the 1st phase of the pulse t1, μs	8 ± 3	12 ± 3	24 ± 3
Amplitude of the 1st phase of the pulse u11, V	16 ± 5	16 ± 5	16 ± 5
Amplitude of the negative part of the pulse of the 2nd phase u22, V	80 ± 10	115 ± 10	220 ± 10

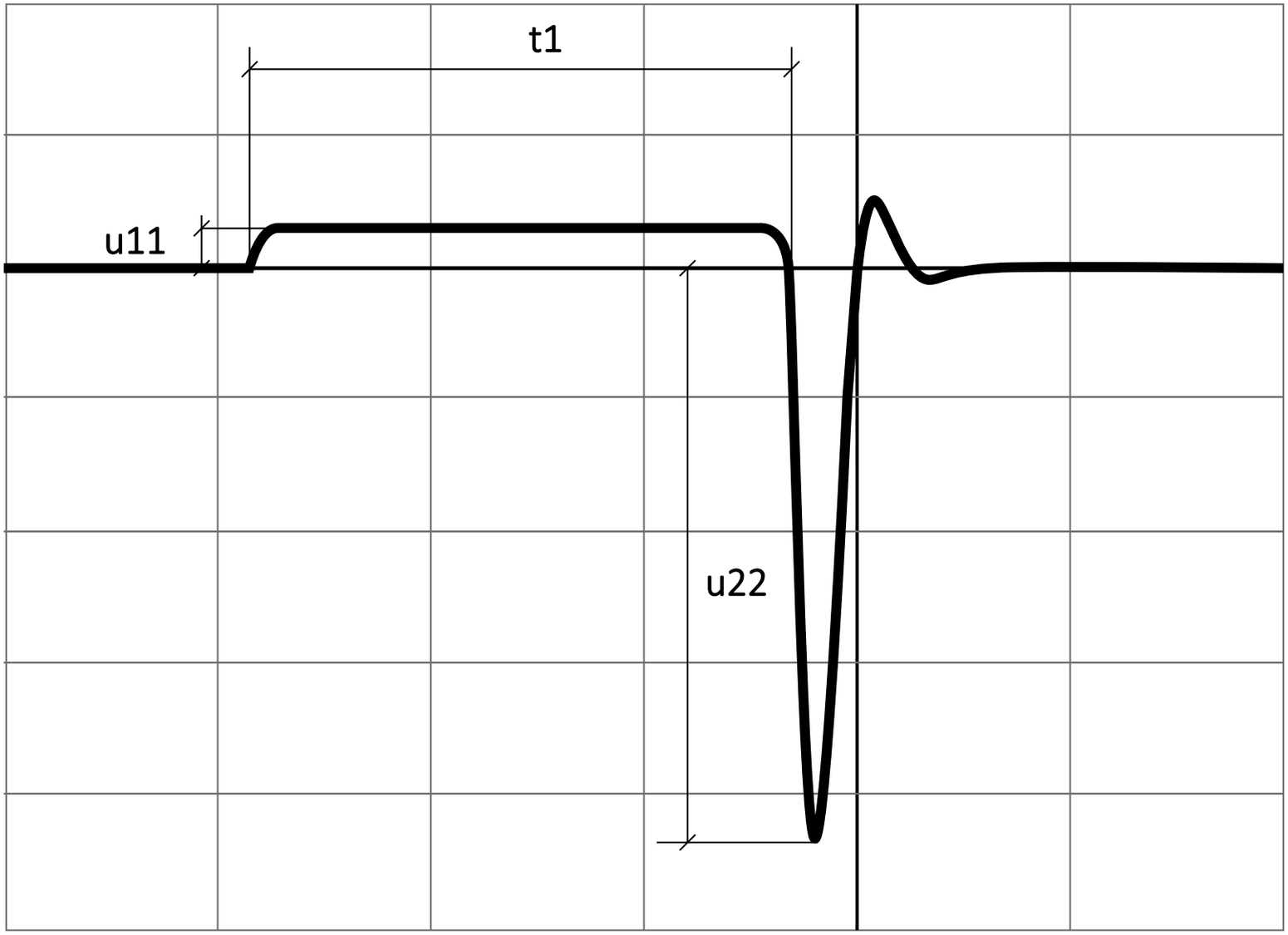


Figure 8 – pulse Shape on the load RL

11.8 Electromagnetic compatibility

The electromagnetic radiation of the working device does not exceed the levels set by GOST R IEC 60601-1-2 and GOST R 51318.11 (CISPR 11:2004). There is no need for additional protection against electromagnetic radiation.

No special measures, including commissioning, are required to ensure electromagnetic compatibility.

The use of mobile radio frequency means of communication can have an impact on the operation of the device. The minimum distance to the transmitters is shown in table 8.

The NEURO DENS-CARDIO apparatus is designed for use in the electromagnetic environment defined in table 5. The buyer or user of the NEURO DENS-CARDIO AP-parate should ensure its use in the specified electromagnetic environment.

Table 5 – electromagnetic emission

Electromagnetic emission test	Accordance	Electromagnetic environment – guidance
Interference by CISPR 11:2004 (GOST R 51318.11-2006)	Group 1	The NEURO DENS-CARDIO machine uses radio frequency energy only to perform internal functions. The level of radio frequency noise emission is low and is not likely to lead to malfunction of the nearby electronic equipment

Interference by CISPR 11:2004	Class B	The NEURO DENS-CARDIO machine is designed for use in any location, including homes and buildings that are directly connected to the electrical distribution network that supplies the homes.
Harmonic components of current IEC 61000-3-2	Not apply	
Voltage fluctuations and Flickr according to IEC 61000-3-3	Not apply	

Attention! The device should not be used in close proximity or in connection with other equipment, but if such use is necessary, verification of the normal functioning of the device in this configuration should be carried out.

11.9 The NEURO DENS-CARDIO apparatus is designed for use in the electromagnetic environment defined in table 6. The buyer or the user of the NEURO DENS-CARDIO apparatus should ensure their use in this electromagnetic environment.

Table 6 – Noise Immunity

noise immunity test	IEC 60601 test level	level of compliance	Electromagnetic environment – guidance
electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV– contact discharge ±8 kV– air discharge	±6 kV– contact discharge ±8 kV– air discharge	The floors of the room should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be at least 30%

Magnetic field of industrial frequency (50/60 Hz) according to IEC 61000-1-8	3 A/m	3 A/m	Industrial frequency magnetic field levels should be provided in accordance with typical commercial or hospital conditions

Table 7 – Noise Immunity

Noise immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment - guidance
Conductive noise induced by radio frequency electromagnetic fields according to IEC 61000-4-6	3 V (RMS) in the band from 150 kHz to 80 MHz		

Radio frequency electromagnetic field according to IEC 61000-4-3	3 V/m band from 80 MHz to 2.5 GHz	3 V/m	Field strength at the propagation of radio waves from stationary radio transmissions. according to the results of observations of the electromag-netic situation,[a] should be lower than the level of correlation in each frequency band [b]. Interference may occur in the vicinity of signed equipment 

a) The field strength at propagation of radio waves from stationary radio transmitters, such as base stations of radio telephone networks (cellular/ wireless), and ground mobile radio stations, Amateur radio stations, AM and FM broadcasting transmitters, television transmitters cannot be determined by calculation with sufficient accuracy. To do this, practical measurements of the field strength should be carried out. If the measured values at the location of the NEURO-DANCE-CARDIO apparatus exceed the applicable compliance levels, observations of the neuro-DANCE-CARDIO apparatus should be made to verify their normal functioning. If a deviation from normal operation is detected during observation, additional measures such as reorientation or movement of the apparatus may be necessary.

b) Outside the band from 150 kHz to 80 MHz, the field strength should be less than V1 V/m.

Notes

1 At frequencies of 80 and 800 MHz apply a higher value of stress-field news.

2 Expressions are not applicable in all cases. Electromagnetic propagation is affected by absorption or reflection from structures, objects and people.

11.10 The NEURO NEURO DENS-CARDIO apparatus is designed for use in electromagnetic environment, in which the levels of radiated noise are monitored. The buyer or user of the device can avoid the effects of electromagnetic interference by ensuring a minimum spatial separation between portable and mobile radio frequency communications (transmitters) and the device, as recommended below, taking into account the maximum output power of the communication means.

Table 8 – Recommended values of spatial spacing between portable and mobile radio-frequency means of communication and NEURODANCE-CARDIO apparatus

Nominal maximum output power of the transmitter, W	Spatial spacing, m, depending on the frequency of the transmitter		
	d = 1,2√P in the band from 150 kHz to 80 MHz	d = 1,2√P in the band from 80 MHz to 800 MHz	d = 2,3√P in the band from 800 MHz to 2.5 GHz
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

12 TRANSPORTATION AND STORAGE

The transport apparatus is carried out in the consumer packaging businesses-sacks manufacturer in Turkey. a dye of any kind of transport in covered vehicles in accordance with the requirements of TU 26.60.13-022-44148620-2018 and the rules of cargo transportation applicable to transportation of this species.

Conditions of transportation of the device regarding influence of climatic factors shall correspond to storage conditions 5 according to GOST 15150:

- temperature from minus 50 to plus 50 °C,
- relative humidity up to 100% at a temperature of plus 25 °C.

Storage of the device is carried out in consumer containers of the manufacturer: closed or other premises with natural ventilation without artificially controlled climatic conditions,

where fluctuations in temperature and humidity are significantly less than in the open air (for example, stone, concrete, metal with heat and other storage), located in macroclimatic areas with a temperate and cold climate.

Storage conditions of the apparatus in terms of the impact of climatic factors should correspond to the conditions of storage 2 according to GOST 15150:

- temperature from minus 50 to plus 40 °C,
- relative humidity up to 98% at a temperature of plus 25 °C.

After transportation and storage at a temperature of the ambient air is below plus 1 °C the device in the package of the manufacturer shall be matured at a temperature operating conditions did not exceed the planned two hours before use.

13 MANUFACTURER'S GUARANTEE

13.1 The manufacturer guarantees that the device meets the requirements of TU 26.60.13-022-44148620-2018 subject to the consumer conditions and rules of operation, storage and transportation. Guaranteed shelf life from the date of manufacture 3 years under the conditions specified in section 12.

13.2 The service life of the product — 3 years. The period of use of the product for its intended purpose can significantly exceed the service life established by the manufacturer if the consumer complies with all the established rules of operation, storage and transportation of the product.

13.3 The warranty period of the device — 12 months from the date of transfer of the product to the consumer. The date of delivery of the product to the consumer is indicated in the certificate of acceptance (the last page of the operating manual). In the absence of the date of transfer of the product to the consumer warranty

period is calculated from the date of manufacture specified in the certificate of acceptance.

13.4 In case of detection of defects during the warranty period, the seller (manufacturer) undertakes to meet the requirements of the consumer, provided by the Law of the Russian Federation "On protection of consumer rights". The seller (manufacturer) or the organization performing functions of the seller (manufacturer) on the basis of the contract with it is not responsible for shortcomings if they arose after transfer of the product to the consumer owing to:

1) 1) violations by the consumer of the rules of transportation, storage, maintenance and operation provided by this manual;
2) mechanical damage;
3) actions of third parties;
4) force majeure.

13.5 Warranty obligations do not apply

to products transferred to the consumer at the end of the warranty period of storage, and products with a broken factory warranty label.

13.6 On batteries warranty does not apply is.

13.7 In case of failure of the product or its malfunction during the warranty period, as well as the detection of incompleteness, the owner of the product must send to the manufacturer or its representative the device, the manual for ex-plication and a repair application indicating the name, patronymic, address, phone number, a brief description of the fault, the terms and date of its manifestation.

14 MANUFACTURE

«Tronitek» LLC

620146, Russia, Ekaterinburg,

Postovsky st. 15

15 RECYCLING

Disposal of the device is technically possible. The device does not pose a danger to life, health of people and the environment after the end of the period of service (operation) and does not require special measures for the preparation and dispatch of the components of the device for disposal. At the end of the service life (operation) the device is disposed of in accordance with SanPiN 2.1.7.2790 as medical waste class A.

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

The device contains valuable materials that can be reused after disposal, taking into account the requirements of environmental protection. They should be handed over to specially designated places (consult the relevant services of your area) for collection and processing.