

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



IMPORTANT INFORMATION!

PLEASE READ THIS PAGE CAREFULLY

Origin: OKB RITM, Joint-Stock Company, 99, Petrovskaya, Taganrog, 347900, Russia

Model: SCENAR-1-NT

Classification: *Type of protection against electric shock* – Internally powered equipment (3 batteries each of 1.5V) *Degree of protection against electric shock* – Type BF.

NOTE: Type BF denotes electrodes that are protected to a standard limit of leakage current. The symbol appearing on the device, denoting this rating is:



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

Cleaning & Disinfecting: Wipe electrode area with cotton swab dampened with surgical spirit before treating each new client. Clean casing with 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.

Physiological effects: Do not use on clients who have a heart pacemaker or other electrically powered implant (see Contraindications for details).

Add-on probes: Only insert extension probes supplied by the manufacturer that are suitably suppressed from electromagnetic radiation. Only insert extension probes in the socket provided.

DO NOT REMOVE the upper casing – this access is for the use of service personnel only.

Transport & Storage: *Packaging* – Always ship in special carrying wallet within appropriate cardboard boxes with built-in foam package protection. *Temperature* – minus 50°C to plus 50°C (but not in unheated aircraft holds). *Humidity* – less than 80% at 20° C, less than 60% at 40°C. After transportation and/or storage in extreme conditions allow device to reacclimatize to operating conditions for 24 hours before use.

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, 1.5V ALKALINE Type LR6 (AA) 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.

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1 PURPOSE

SCENAR-1-NT (version 03) – portable transdermal electroneurostimulator with graphic display, digital, light and audible indications with a built-in electrode for determining optimum zones, time and therapeutic effect of stimulation (hereinafter – the device) – is intended for delivering general therapeutic non-invasive treatment to the physiological systems of the organism via human skin areas in order to treat various pathologies.

The device is intended to treat and rehabilitate people and can be used by medical professionals in medical-prophylactic institutions, hospitals, emergency care units as well as at home according to the doctor's prescription.

The device should be stored and used in temperatures between 10°C and 35°C with relative humidity not to exceed 80% at a temperature of 25°C.

Potential risk from the device usage refers to Class 2a of GOST R 51609-2000.

Perceived mechanical effects of the device refer to group 2 of GOST R 50444-92, consequences of failures – to class V of GOST R 50444-92.

The device complies with the standards set by the Russian Government GOST R 50267.0–92, GOST R 50267.10–93 for internally powered equipment, type BF, which classifies it as a safe device for personal use.

2 SPECIFICATIONS

2.1 Supply voltage – from 3.3 up to 4.8V (three 1.5V alkaline batteries).

2.2 Maximum supply current – not greater than 300mA.

2.3 Basic modes of operation:

2.3.1 subjectively-dosed mode (also called 'constant mode') (the duration of stimulation for each skin area and the duration of the whole procedure is determined by the therapist in accordance with the User Manual provided with the device);

2.3.2 individually-dosed mode (the duration of stimulation for each treatment area is automatically determined by the device);

2.4. Basic modes of stimulation:

2.4.1 Continuous mode with a fixed frequency that can be selected among 15, 60, 120, and 350Hz \pm 5%;

2.4.2. Modulated modes:

2.4.2.1 frequency modulation (variable frequency) with the following settings:

- ◆ variation range – (30..120)Hz±5%
- ◆ variation period – (7.5±1) sec

2.4.2.2 Amplitude modulation (pulse energy variation):

- ◆ duration of pulse advancing at a set energy, sec: (1, 2, 3, 4, 5)±0.5
- ◆ duration of pulse advancing at the minimum energy, sec: 1±0.5

2.5 The duration of the pulse's 1st phase is controlled within the range, msec: 2..500±1.

2.6 Amplitude of the stimulating pulse at a standard load:

- ◆ minimum amplitude (at the energy of 1 unit) – not greater than 2.5V
- ◆ maximum amplitude (at the energy of 250 unit) – not greater than 150V

2.7 Device automatic turn-off time when not active – 0.5-20 min.

2.8 Device's weight – not greater than 0.4kg.

2.9 Overall dimensions – not greater than 182×62×32mm.

2.10 Average nonfailure operating time – not less than 1000 hours.

2.11 Average service life – not less than 4 years.

3 DELIVERY SET

Each complete delivery set of the devices includes (Table 1):

Table 1

Article	Documents	Quantity (units)
Portable transdermal electroneurostimulator with graphic display, digital, light and audible indications with a built-in electrode for determining optimum zones, time and therapeutic effect of stimulation 'SCENAR-1-NT version 03'	LTBG.941514.003-03	1
Add-on probes:		
face probe	LTBG.943132.001	1
skull probe	LTBG.943132.002	1

point probe	LTBG.943132.003	1
Alkaline battery	Included	3
Case	LTBG.466946.003	1
Operating Manual	LTBG.941514.003-03 PS	1
User Manual	LTBG.941514.003 IP	1
Note – Add-on probes are delivered on request of the Customer The attached probes are shown in Appendix A.		

4 DEVICE COMPONENTS AND CONTROLS

4.1 The device is illustrated in Fig. 1. The device has an upper cover 1 with a screen 8, case with a built-in electrode 9 and a battery cover 2. All components except for the batteries are located on the printed circuit board inside the device's case.

4.2 The LCD screen 8 (on the upper cover of the device) displays the results of measuring, settings and device's state.

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

- ◆ button 6 ("∇") – is used to switch the modes and exit the standby mode;
- ◆ button 11 ("▲") – is used to rotate the picture displayed on the screen;
- ◆ button 7 ("+") – is used to increase the energy strength or value of a selected setting;
- ◆ button 5 ("–") – is used to decrease the energy strength or value of a selected setting;
- ◆ switch button 10 – is used to switch on/off the device;

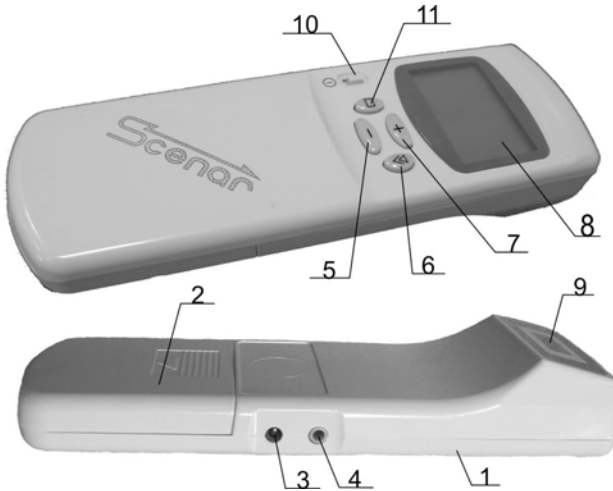


Fig. 1

4.4 On the lateral surface of the case there are: jack 3 – to connect attached (add-on) probes, and a technological jack 4.

ATTENTION! Jack 4 shall not be used during the device's operation.

4.5 The device is powered from 3 alkaline batteries.

5 PREPARING DEVICE FOR OPERATION

5.1 Before every procedure disinfect the electrode with a cotton wad wetted in a 3% hydrogen peroxide solution with the addition of 0.5 % solution of an approved cleaning liquid. Allow to dry up thoroughly before treating.

5.2 Open the battery compartment cover and install the batteries. Switch the device on using the switch button on the front panel. A message containing the information about the device's name and version and its software's release date (e.g. "*SCENAR-1-NT v3 01.12.05*") will be displayed for 2 seconds and a beep will sound.

5.3 Then the device will switch to the basic mode (hereinafter called "**B** mode"), and the major parameters of stimulation will be displayed (Fig.2).

The first line contains the timer, indicator of the device's contact with the patient's skin ("●" – contact, "○" – no contact), and a battery discharge indicator. **Upon pressing any button the timer is reset.**

5.4 Press the button "▽" to switch to the **Menu mode** (Fig.3). Press the button "▽" at an interval of no longer than 2 seconds to make sure that the highlighting switches cyclically between the lines.

Then wait until the device switches to the **"B" mode** (this will happen in 2 seconds after the latest pressing of the button "▽"), then press the "-" button once. A long (1 sec) beep will sound. Press and hold the button "+". The number in the right part of the top line will be changing from 1 to 250, and then a long beep will sound.

If you performed all the operations mentioned above in this item and the device works as described, the device is ready to be used for therapy. Otherwise, refer to the Chapter 8 (Troubleshooting).

5.5 Switch off the device using the switch button.

6 USING SCENAR-1-NT

6.1 Manipulate the device with one hand. Observe the indications on the screen and beeping.

6.2 A chart of the device's basic states is illustrated in the Fig. 4 (dotted lines mean that the Diagnostics mode is ON).

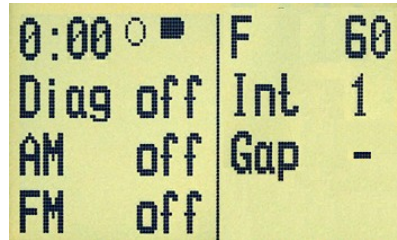


Fig.2

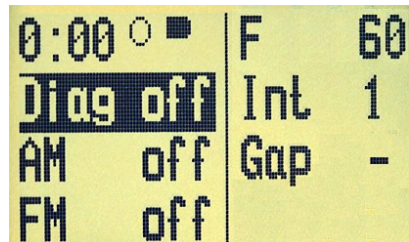


Fig. 3

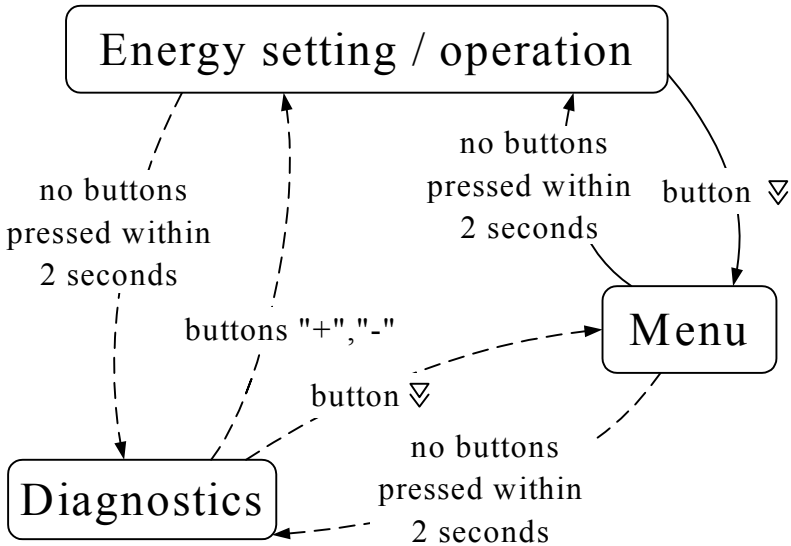


Fig.4

In the **“B” mode** the device will stimulate at the settings displayed on the screen. After being switched on, the device is always in the **“B” mode**. Use the **“+”** and **“-”** buttons to control the energy strength of stimulation. Use the ∇ button to switch the device to the **Menu** mode.

In the **Menu** mode you can set any parameter except for the energy strength. (For detailed description of the parameters see the items 6.10–6.13). A current parameter is highlighted inversely. Use the **“+”** and **“-”** buttons to change the current parameter’s value. Use the ∇ button to move down the menu, use the **“▲”** button to move up the menu. If no buttons are pressed within 2 seconds, the device will switch to the **“B” mode**, or, if the diagnostic mode is on, the device will switch to the Diagnostics mode.

To activate the Diagnostics mode, set the **“Diag”** parameter to 1 in the menu.

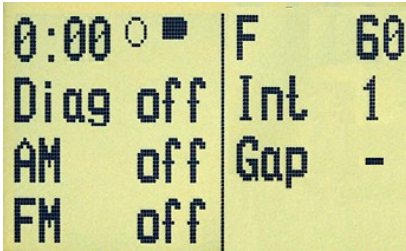


Fig. 5a

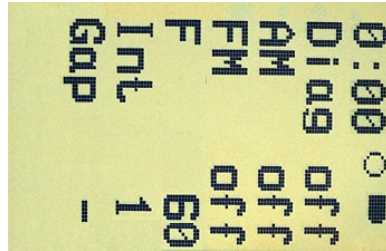


Fig. 5b

6.3 The device can display information on the screen in 3 possible directions: horizontal (Fig.5a), vertical for the right hand and vertical for the left hand (Fig.5b). This may be convenient, for example, when operating with the left and the right hands alternately. To rotate the image on the screen, press the "▲" button in the "B" mode or in the Diagnostics mode.

6.4 There is a battery discharge indicator in the right upper corner of the screen (for the horizontal location – in the right upper corner of the left half). The degree of its infill shows the battery's charge. If the indicator is blank, remove **all 3 batteries and install 3 new ones**.

6.5 When switching on the device, the following values of the parameters are set:

- ◆ the energy strength of the stimulating pulse is set to the minimum setting ("1");
- ◆ diagnostics is switched off ("off")
- ◆ amplitude modulation is switched off ("off")
- ◆ frequency modulation is switched off ("off")
- ◆ intensity is set to the minimum setting ("1")
- ◆ pulse frequency is set to "60"Hz

⚠ Attention! To avoid painful sensations when treating the most sensitive areas on the patient's body, it is recommended that the energy strength is decreased to minimum before the treatment by pressing and holding the "-" button until a long beep sounds).

6.6 Set the energy strength to minimum and apply the electrode on the skin on the zone to be treated. A short beep will sound indicating that the electrode is contacting the skin. And the "●" symbol will be displayed on the screen. Make sure that patient isn't experiencing unpleasant sensations. Press and hold down the "+" button till the first signs like prick-

ing, light burning or vibrations appear. The intensity should be comfortable and not painful, but must be felt on the skin.

6.7 To start therapy, set the required mode. Then put the electrode on the skin area to be treated (see the User Manual provided with your device).

6.8 To treat auricular zones and acupuncture points, connect the point add-on probe to the jack 3. Touch any area of the body by the probe to make sure of the contact. Hold the device in one hand, the add-on probe – in another one. Wet the attached probe in water every time before you treat the acupunctural points.

6.9 In the **“B” mode** the **“+”** and **“-”** buttons are used to control the energy strength within the range 1 to 250 units. To control the energy strength you can either press the buttons ‘step by step’ or press and hold the appropriate button (which is faster, 16 steps per second). When the energy strength reaches the value that cannot be further increased/decreased, the device will indicate it with a long beep.

6.10 **Setting the Diagnostics mode.** When **“Diag off”** is set (which is indicated by a long beep), the Diagnostics mode is turned off, and the device is operating in the continuous mode.

“Diag 1” (indicated by a short beep) activates the individually-dosed mode (hereinafter – IDM) with the adaptive integral criterion of the stimulation termination (**“Dose”**) and integral criterion of achieving the null relative dynamics (**“Zero”**).

After **“Diag 1”** has been selected (it is highlighted), if no buttons are pressed within 2 seconds, the device will switch to the **Diagnostics mode** (Fig.6).

Once the device detects that the electrode is contacting the patient’s skin, the device will give a short low pitch signal (**“o”** will change to **“●”** in the top line), and in a second it will give a short high pitch signal and the screen will display (both digitally and graphically) the results measured over the first second (the diagram will show reaction change with time).

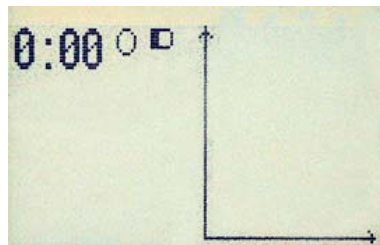


Fig.6

In the Diagnostics mode, pressing any button resets the timer and measurements.

Data displayed on the screen for the “**Diag 1**” mode are illustrated in Fig.7.

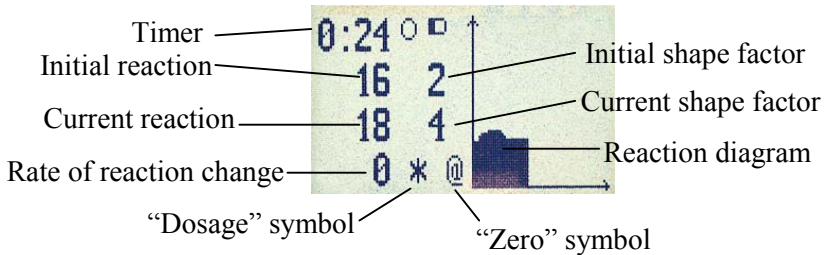


Fig.7

In IDM the values of initial shape factor and initial reaction won't change and will stay in the same positions on the screen until the electrode is taken up.

After 1 second more, in IDM measurement results for the 2nd second will be displayed on the screen. Then, current results of measuring (time, rate of reaction change, shape factor, reaction) illustrated in the Fig.7 will be updated every second, and the diagram will be completed. It will continue this way until either “Dose” or “Zero” is achieved.

The device will notify that the “Dose” is achieved by two simultaneous indications:

- ★ 2-second two-tone audible signal will be played
- ★ symbol “ * ” will be displayed on the screen.

The device will notify that the “Zero” is achieved by two other simultaneous indications:

- ★ series of low pitch sounds will be played for 2 seconds
- ★ symbol “@” will be displayed on the screen

Once you take the device up from the patient's skin, “●” will change to “○” in the top line, and all other information will stay the same on the screen.

If the automatic turn-off of the device is enabled (see p.6.17.1), in the “**Diag 1**” mode, when there is no contact with the patient's skin within 30 seconds, the device will automatically switch to the lowest power consumption mode (i.e. standby mode). And this will be accompanied by a long beep, message, and screen darkening.

To resume the device operation, press the √ button.

For more detail on diagnostic modes see recommendations for the individually-dosed mode in the User's Manual provided with your device.

6.11 Setting the Amplitude Modulation ("AM"). The amplitude modulation modes are the following:

- ♦ continuous mode ("**AM off**") is indicated by a long beep
- ♦ mode "**AM=1:1**": pause – 1 sec, pulses – 1 sec, the mode is indicated by a short beep
- ♦ mode "**AM=2:1**": pause – 1 sec, pulses – 2 sec, the mode is indicated by two short beeps
- ♦ mode "**AM=3:1**": pause – 1 sec, pulses – 3 sec, the mode is indicated by three short beeps
- ♦ mode "**AM=4:1**": pause – 1 sec, pulses – 4 sec, the mode is indicated by four short beeps
- ♦ mode "**AM=5:1**": pause – 1 sec, pulses – 5 sec, the mode is indicated by five short beeps.

6.12 Setting the Frequency Modulation ("FM"). The frequency modulation modes are the following:

- ♦ fixed frequency mode ("**FM off**"). Activating the mode is indicated by a short beep.
- ♦ variable frequency mode ("**FM on**"). Activating the mode is indicated by a two-tone beep. In this mode **the device ignores the "F" mode's settings.**

Also **keep in mind that** for SCENAR-1-NT, **version 03**, the number of pulses in a burst ("**Int**") and gap between them ("**Gap**") **can never be changed.**

The values that cannot be changed are indicated on the screen by asterisks (as, for example, in the Fig. 8).

6.14 Setting the Frequency ("F").

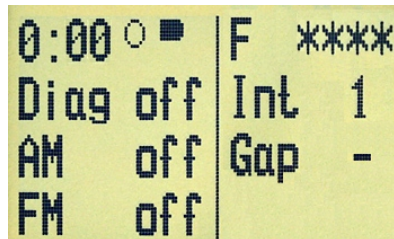


Fig.8

Frequency can be selected among 15, 60, 120, and 350Hz. When the maximum or minimum frequency is reached, the device emits a long beep.

6.14 **To switch off the device**, use the switch button on the front panel. The settings are NOT SAVED after switching off.

6.15 **To switch the device to the standby mode**, press simultaneously the buttons "▽" and "▲". To resume operation, press the button "▽".

6.16 If the automatic turn-off is enabled (see p. 6.17.1), and when Diagnostics is OFF, and no buttons have been pressed within several minutes (the time is set in the parameter "AOff" in the Service menu), the device automatically switches to the standby mode. When Diagnostics is ON, the device will automatically switch to the standby mode if there is no contact with the patient's skin for 30 seconds. In both cases the device saves all settings when its operation is resumed by the "▽" button.

6.17 The device has a Service menu. To enter the Service menu, press the buttons "▽" and "+" simultaneously (Fig.9). The parameters of the Service menu are selected and set in the same way as in the device's main Menu (to select a parameter, use the buttons "▽" and "▲", and to set the required value, use the buttons "+" and "-"). When no buttons are pressed within 2 seconds, the device switches to the previous mode, and the value of the highlighted parameter is saved in the permanent memory of the device. If the value has been changed, then a multitone beep will sound.

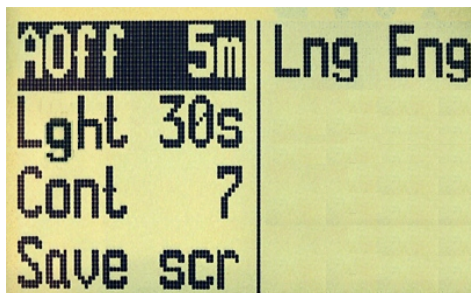


Fig. 9

6.17.1 The "AOff" parameter is the time to expire before the device turns off automatically, when no buttons are pressed and no contact with the patient's skin has been detected within the time set in "AOff" (minutes). When the "AOff" is set to **off**, the automatic turn-off is disabled. **(Attention! This may cause faster battery exhaustion when you leave the device switched on for a long time).**

6.17.2 The “**Lght**” parameter is the time of screen backlighting for the following events – pressing any button, achieving the “Dose” or “Zero”, expiration of the first second of measuring in the Diagnostics mode or expiration of every 30 seconds in the continuous mode.

6.17.3 The “**Cont**” parameter allows to control the picture contrast.

6.17.4 The “**Save scr**” parameter allows to change the direction of the picture displayed on the screen and save it in the permanent memory of the device.

6.17.5 The “**Lng**” parameter allows to select a language (two languages are available – Russian and English).

7 MAINTENANCE SERVICE

7.1 The device shall be serviced and repaired only by the manufacturer.

8 TROUBLESHOOTING

8.1 If the device is not operating properly, identify the problem and refer to the following trouble shooting chart for suggested solutions as indicated in the following Table 2.

Table 2.

Problem	Possible cause	Suggested solution
Some adjustments don't work or after the battery is replaced, the requirements of 5.4 are not fulfilled.	Processor mal-function.	Switch off the device, and in 5..10 sec switch it on. Check if the requirements of p.5.4 are fulfilled.
After the device is switched on, the picture on the LCD periodically disappears or is distorted.	The battery is discharged.	Replace the batteries.

8.2 Other malfunctions shall be repaired only by the manufacturer.

9 WARRANTY

9.1 The manufacturer guarantees that the device complies with this document when operated properly.

9.2 Warranty period is 18 months from the date of purchase.

9.3 In case of malfunction during the warranty period the device with this Operating Manual shall be returned to the manufacturer.

9.4 The warranty repair is not performed in case of device's Operating Manual absence or seal violation.

9.5 The device is repaired at the expense of the owner in the following cases:

- ◆ the device was operated improperly
- ◆ the manufacturer's seals are broken
- ◆ mechanical failure of the device
- ◆ the warranty period expired

10 TRANSPORTATION

10.1. 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 $+50^{\circ}$ C and relative humidity not to exceed 80% at a temperature of 20° C, 60% at 40° C with a protection from a direct atmospheric precipitation.

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

APPENDIX A

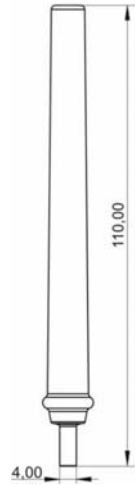
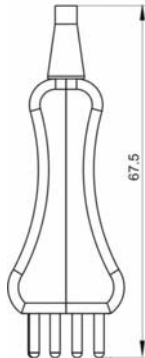
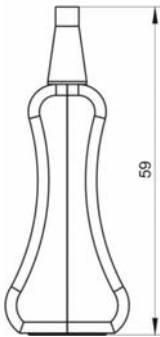
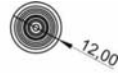
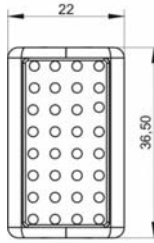
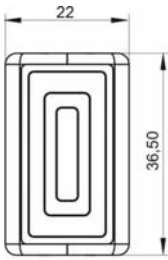


Fig A.1
Face probe

Fig A.2
Skull probe

Fig A.3
Point probe