

# BIOSONYC



## USER MANUAL

*Instructions for use*

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**WARNING: READ CAREFULLY THE  
INSTRUCTIONS BEFORE USE**

## **Chap. 1 – PRESENTATION**

BIOSONYC belongs to the new line of electromedical equipment for physiotherapy and beauty care. It is small, easy to use and versatile – these are the main features of this innovative line of products.

### **1.1 – What is BIOSONYC ?**

Unceasing research in the field of medical devices has led to the creation of this new system for ultra-sound therapy, consisting of the Biosonyc generator. Biosonyc can ensure the user the utmost **reliability and safety** in compliance with the current Safety Rules of Medical Devices. The technological innovation and the ease of use make it an **extremely versatile and innovative** product in the electromedical appliance business.

### **1.2 – Why use the BIOSONYC ?**

BIOSONYC houses inside itself all the technology needed to generate ultrasounds, through the use of pre-set programs contained in its memory. The generator carries out control tasks, while the memory – small electronic inside microchips - make it possible to generate Ultra-sounds for therapy and beauty treatment and for treating pathologies (wounds, accidents, illness) and aesthetic problems (cellulitis, skin affections).

### **1.3 – Whom is BIOSONYC addressed to ?**

The most suitable fields for BIOSONYC to express its full potential are medicine (especially physiotherapy) and beauty treatment. However, thanks to its ease of use, it can be used by physicians, by rehabilitation therapists and professional beauticians, but also by anybody who wants to take care of his or her own physical well being at home, thanks to the ease of use and the versatility of the product.

## Chap. 2 – INDICATIONS / CONTRAINDICATIONS

This Chapter lists the main situations where the use of ultrasounds is advisable, and the restrictions on the use of this therapy.

### 2.1 – Indications

The most common pathologies treated by ultrasounds are those involving the bone, muscle and tendon system, fats. They are especially indicated for:

#### Therapy:

- periostitis;
- tendinitis;
- arthrosis;
- muscular contractures;
- scarring;
- organized oedemas.

#### Aesthetics:

- Celulitis;
- Lymphatic draining;
- Local thinning;
- Skin pathologies.

Ultrasounds today also have proven validity in the treatment of such extra-articular rheumatological alterations as **scapulohumeral periarthritis**, elbow epicondylitis and other pathologies, thanks to their anti-pain, fibrolytic and decontracting effect.

The structures involved suffer their main traumas especially during physical activity; however, in many cases, they may also be due to aging (rheumatisms, muscular hypotrophy, lack of balance due to little movement); these cases are increasing steeply due to the progressive rising of the average age, not accompanied by a suitable improvement of the quality of life.

In sports, the most frequent traumas affect the articulations of the knee and the ankle and can be cured by ultrasounds through daily applications, repeated in several sessions. The treatments are especially performed for anti-pain purposes and are preparatory for kinesitherapy sessions.

### 2.2 – Contraindications

Ultrasounds have the same contraindications as any physical media which act through endogenous production of heat:

- degenerative osteoporosis;
- presence of metal fragments;
- varicose veins
- acute thrombosis and thrombophlebitis;
- obliterative arteriopathies haemorrhages;
- menstruations;
- neoplasms;
- tuberculosis;
- acute inflammatory processes;
- skin injuries;
- altered sensitivity.

During applications with ultrasound techniques, use on the following is not advisable:

- specialized tissues (fertile metaphysis, testicles, ovaries), since they could suffer damage;
- avoid use in the neighbourhood of the heart, especially if there are any electro-mechanical appliances (pace-maker), since this could damage them permanently.

Special precautions should be taken when carrying out applications on the rachis of patients with a diagnosis of laminectomy, for possible damage to the spinal medulla.

No applications must be made in the immediate neighbourhood of the eyes or the uterus (abdomen/lumbar area) in case of pregnancy, due to the risk of provoking cavitation, even with a proper dosage.

The presence of articular prostheses and metal synthesis media may cause problems, since they can absorb a higher amount of ultrasounds and thus deteriorate or damage the adjacent tissues.

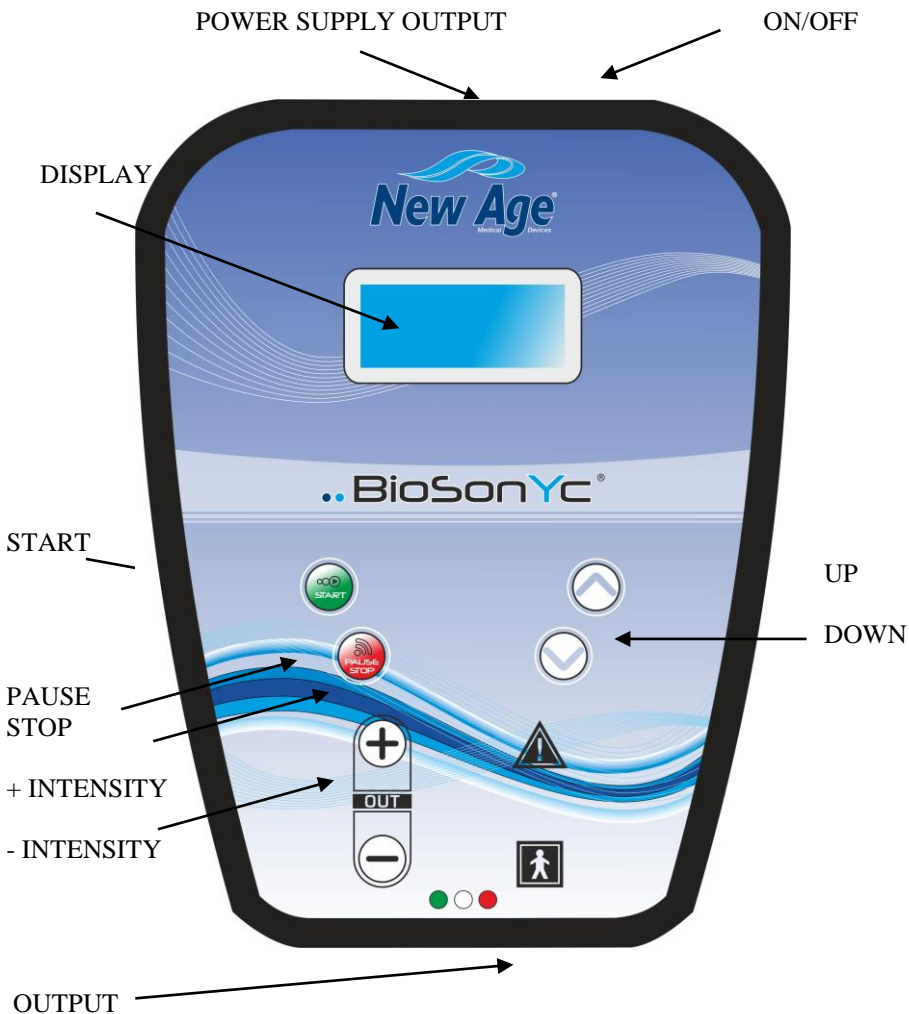
Use of such physical therapy is not advisable when treating pathologies of young people, especially children (e.g. fertile conjugation cartilage).

The staff performing the operations must not be exposed for too long a time to the action of ultrasounds, since this could cause lesions (the so-called “ultrasound illness”).

## Chap. 3 – OPERATION

BIOSONYC is very easy to use; at the same time, however, all the operations must be carried out properly and in the right sequence.

### 3.1 – The BIOSONYC keys



### 3.2 – Connecting the head

Before turning the device on, connect the head to the output socket of the device via the connector. To introduce the connector, turn it so that the connections coincide with the output socket; once you have introduced it, screw it all the way down in order to fasten the cable firmly to the device.

### **3.3 – Turn on the device**

In order to turn BIOSONYC on, press the button 1/0 – ON/OFF. The display will show a welcome message, with the name and the software version, and the Selection Menu screen will appear.

### **3.4 – Choose the program**

On the Menu, choose the program with UP/DOWN keys.

### **3.5 – Start of therapy**

To start the therapy press **start**; the power of the stimulation is already preset but can be set by pressing (+)(-) keys. The minimum increase of power is 0.1 W/cm<sup>2</sup> and the maximum is 3.0 W/cm<sup>2</sup>.

**NOTE:** if no head has been fitted into the device at the **start**, you can hear an acoustic warning and the display will show an error message until it is inserted, then it will start up again automatically.

### **3.6 – Setting the power of emission**

Use the (+) and (-) keys to set the intensity of emission. Generally speaking, it stays constant throughout the duration of the program; however, in case of pain or overheating of the area being treated, you must decrease the power using the (-) key or else break off the therapy by pressing **pause stop**.

**NOTE:** during the program it is possible to increase or decrease the Timer by pressing UP/DOWN keys (one minute each touch).

#### **3.6.1 – Contact control**

To detect the contact between head and skin, fasten the bracelet in the patient's wrist and in the back output of the device. If the head does not adhere perfectly to the treating area or to the mean of transmission (gel, water in immersion) the device will let out an acoustic signal and interrupt the program; adjust the contact to continue.

### **3.7 – Program interruption**

The stimulation will stop automatically as soon as the Timer reaches 0 and you hear the end program acoustic signal; if you want to interrupt the program before the end, press the **pause stop** key: once to make a pause (to continue press **start**), twice to stop the program.

### **3.8 – Free program setup**

Biosonyc allows to create and save up to 5 free programs listed from prog. no 41 to no. 45.

To save a free program go to the program list and select one of the mentioned programs. Press STOP. You enter the parameter configuration menu PARIMP. From here with the keys + and – adjust the value of the parameter shown, while with the up/down arrow key select another parameter.



Parameters are:

**Freq:** frequency from 1MHz to 3MHz

**Modul:** modulation CONTINUOUS, 50%, 20%, or 10%

**Power:** power from 1 to 30 that is from 0,1W/cm<sup>2</sup> to 3W/cm<sup>2</sup>

**Time:** duration of the program from 1 to 60 minutes.

Once you have set the parameters press START to enter the window of program name configuration.

Thanks to the arrows you can change the position of the flashing pointer while with + and – key it's possible to change the selected letter. Once the name is set up press START.

### **3.9 – Turn off the device**

To turn the device off, press the 1/0 - ON/OFF button on the back of the device.

## **Chap. 4 – APPLICATION TECHNIQUES**

There are different techniques of application for ultrasound therapy; they are usually performed in one of two ways: direct or indirect contact.

### **4.1 – Direct contact method**

With this technique, the head comes directly into contact with the skin through a medium allowing both surfaces to adhere perfectly to each other (e.g. gel for ultrasounds, provided together with the device); during direct contact the head may be:

- **fixed** – in order to treat a very limited surface, holding the handpiece firmly down on the area affected by hand or by the mechanical arm (not provided together with the device) which allows the operator to devote himself to other patients until the end of the program;
- **mobile** – in order to treat a large surface, making small movements, backward and forward or else circular, throughout the area to be treated. This technique is used to treat large flat and regular surfaces.

**Note:** if the surface to be treated is very small and/or hard to reach, we suggest you use a smaller head (see Accessories).

### **4.2 – Indirect contact method**

The indirect method consists of applying a medium between the head and the skin for transmitting the ultrasound waves (usually water). This way the number of vibrations which reaches the skin becomes uniform. This is used to treat body areas with an irregular surface (hands, feet), which are hard to reach and do not permit perfect adhesion between the two surfaces (head of the handpiece and skin). To perform the application, use a rather deep basin, full of water, and immerse the body part you want to treat entirely in the water together with the head; direct the flat surface of the head towards the area you want to work on, from a distance of about 10 to 15 cm, and then start the therapy.

**NOTE:** full colour pictures with examples of the applications (therapy / beauty) appear in the attachment to the centre of the manual; in any case, before applying ultrasound therapy, check the contraindications and refer to a physician or a professional beautician.

## **Chap. 5 – PRESET PROGRAMS**

Ultrasound therapy has long been used to treat certain pathologies which can benefit from the effects of mechanical vibrations: chronic pathologies, phlogosis, oedemas, etc. Actually it is used also for aesthetic treatments (cellulitis, fats, etc.). This chapter lists the techniques of application and certain examples on how to carry out ultrasound therapy sessions in order to cure these pathologies through use of the preset programs.

### **5.1 – Therapy programs**

BIOSONYC has a large number of **preset therapy programs**, i.e. with all the parameters memorized and ready to use. The various available programs are subdivided according to the kind of tissue being treated:

- 1) **Bone tissue**: programs which deliver ultrasounds with the most common parameters for the treatment of pathologies affecting the bone structure and related structures.
- 2) **Articulations**: preset programs for the therapy of the main problems affecting articulations and cartilages.
- 3) **Muscles**: specific programs for the therapy of pathological or traumatic situations affecting the muscles, due to physical activity or to daily life;
- 4) **Tendons**: programs of various kinds for carrying out therapy sessions applied to the tendon structures, to muscle-tendon insertions and to bursae containing synovial fluid.

The following sections list the preset THERAPY programs and then explain how to use them.

#### **5.1.1 – List of therapy programs**

BIOSONYC has 18 different preset therapy programs subdivided according to the areas to be treated as developed in the previous section, plus 7 new therapy programs for superficial pathologies with 3 MHz frequency. The Programs are listed on the following table.

##### **1 MHz Therapy Programs**

<b>Kind of Program</b>	<b>No.</b>	<b>Name of the program</b>
<b>Bone tissue pathologies</b>	1	Bone atrophy
	2	Callus
	3	Osteitis and Periostitis
	4	Ossification lag

Kind of Program	No.	Name of the program
<b>Articulation pathologies</b>	5	Arthritis-Arthrosis
	6	Articulation stiffness
	7	Sprains
	8	Lumbago
<b>Muscle pathologies</b>	9	Myalgia
	10	Pangs
	11	Strains
	12	Contractures
	13	Bruises
<b>Tendon pathologies</b>	14	Tenosynovitis
	15	Tenovaginitis
	16	Epicondylitis
	17	Periarthritis
	18	Bursitis

### 3 MHz Therapy Programs (new\*)

Programme Type	Name on display	Timer	Power	Freq. Mod.
<b>Superficial pathologies</b>	Sprains	10	1,5 W	Continue
	Strains	10	1,5 W	Continue
	Contractures	8	1 W	Continue
	Oedemas	10	1 W	Continue
	Tenonitis	10	1 W	1/2
	Epicondylitis	10	1 W	1/2
	Cicatrization	10	1 W	Continue

**NOTE (\*):** some 1 MHz therapy programs are available also with 3 MHz frequency for superficial pathologies (see table) except **Cicatrization** program, which is completely new and specific for skin scars, cuts, wounds, etc. For the use see 1 MHz Programs.

#### 5.1.2 – Description of therapy programs

The following tables describe the various preset programs, subdividing them according to the anatomic parts involved in the pathologies they were designed for. On each of the following tables, the first column shows the program on the display – so it can be identified immediately – together with its duration, while the second column contains explanations regarding the program and its applications.

**NOTE:** during the program it is possible to increase or decrease the Timer by pressing UP/DOWN keys.

## Program Description Tables

<b>PROGRAMS FOR BONE TISSUE</b>	
These programs feature specific parameters for treating pathologies involving the bone structure and related structure. They must be used every day until the problem disappears.	
NAME ON THE DISPLAY	USE OF THE PROGRAM
<b>Bone atrophy</b> 10 minutes	This helps regenerate the bone through stimulation of the metabolism of calcium and local circulation.
<b>Callus</b> 8 minutes	This prevents the development of callus after fractures; it helps the physiological regeneration of the bone.
<b>Osteitis and Periostitis</b> 8 minutes	Treatment of phlogosis affecting the bone structures and the periostium covering it.
<b>Ossification lag</b> 10 minutes	This stimulates local metabolism and helps the regeneration of the bone, delayed by problems of circulation or other situations.

<b>PROGRAMS FOR THE ARTICULATIONS</b>	
Programs for treating pathologies affecting the articulations and cartilages. They must be used every day until the problem disappears.	
NAME ON THE DISPLAY	USE OF THE PROGRAM
<b>Arthritis-Arthrosis</b> 10 minutes	Treatment of phlogosis affecting the articular cartilages; it stabilizes the local metabolism and favours the afflux of the blood.
<b>Articular stiffness</b> 15 minutes	Treatment of stiffness affecting the articular cartilages; it restores the trophism of the cartilage facilitating its articular mobility.
<b>Sprains</b> 10 Minutes	Treatment of sprains; it diminishes pain and functional limitation.
<b>Lumbago</b> 10 minutes	Treatment of pain affecting the lumbar spinal chord; it diminishes pain and functional limitation.

<b>PROGRAMS FOR MUSCLES</b>	
Programs for treating muscle problems of various kinds. They must be used every day until the problem disappears.	
NAME ON THE DISPLAY	USE OF THE PROGRAM
<b>Myalgia</b> 10 minutes	Treatment of muscle pain; it warms the area being treated and favours the afflux of blood.
<b>Pangs</b> 6 minutes	Treatment of phlogosis affecting the articular muscles; it stabilizes the local metabolism and favours the afflux of the blood.
<b>Strains</b> 10 minutes	Treatment of phlogosis affecting the articular muscles; it stabilizes the local metabolism and favours the afflux of the blood.
<b>Contractures</b> 8 minutes	Treatment of muscle contractures; it warms up the affected area and favours the afflux of the blood which eliminates the metabolites.
<b>Bruises</b> 10 minutes	Treatment of muscular oedemas after bruises; it warms the affected area and helps to reabsorb the oedema.

## PROGRAMS FOR TENDONS

Programs for the treatment of phlogosis to tendon structures, including bursae. They must be used every day until the problem disappears.

NAME ON THE DISPLAY	USE OF THE PROGRAM
<b>Tenosynovitis</b> 10 minutes	Treatment of phlogosis of the synovial sheath of the long tendons (e.g. fingers).
<b>Tenovaginitis</b> 10 minutes	Treatment of phlogosis of the wide and flat tendons (e.g. Achilles tendon).
<b>Epicondylitis</b> 10 minutes	Treatment of phlogosis of the insertion of the outside forearm muscles on the elbow (tennis elbow)
<b>Periarthritis</b> 10 minutes	Treatment of phlogosis of the tendons of the articulation of the shoulder (rotator cuff); this removes pain and allows you to get back the mobility of the arm.
<b>Bursitis</b> 10 minutes	Treatment of the phlogosis affecting the synovial bursae located between the tendons and the bones.

### 5.1.3 – Areas of application of the head

The following table shows some examples of application of the head on the main areas of the body affected by the most common kinds of pathology, to be carried out using the direct technique (mobile and fixed) and the indirect technique (by immersion).

DIRECT METHOD: MOBILE TECHNIQUE	
Area to be stimulated	Notes about the position of the head
Muscle	Move the head all over the surface of the muscle
Knee, ankle	Move the head over the hurting side of the articulation (if the pain is widespread, on the other side as well)
Back	Move the head over the hurting side of the back
Neck	Move the head over the back of the neck
Tendon (large)	Move the head backward and forward along the tendon
Shoulder	Move the head over the back of the shoulder

DIRECT METHOD: FIXED TECHNIQUE	
Area to be stimulated	Notes about the position of the head
Spinal chord	Place the head on the affected part of the back
Tendon (small)	Place the head on the inflamed tendon


INDIRECT METHOD: UNDERWATER	
Area to be stimulated	Notes about the position of the head
Hand	Immerse the head directed towards the hurting area
Foot	Immerse the head directed towards the hurting area

### 5.1.4 – Adjusting the power of emission

Adjusting the intensity of the vibrations is fundamental for the success of the ultrasound therapy program. The adjustment must differ depending on the kind of program being used, the technique of application and the features of the patient. The following table shows the initial adjustment of intensity, i.e. right after the START of the program, which

can be increased during the program, in order to increase the effects, or else diminished in case of skin overheating or pain.

<b>Initial intensity</b>	<b>Modulation</b>
The power of emission must be set by the user and will change depending on the kind of application (see following table).	The power of emission may be modified: increasing by a few tenths (+ 0,1) to increase the effects of the therapy; diminishing the value in case of overheating of the treated area. (*)

 Should the power of emission which has been set, or its adjustment, lead to excessive heating or pain in the area being treated, you must immediately reduce the intensity of stimulation or else turn the application off.

This table shows the intensities suggested for the most common applications:

<b>Application</b>	<b>Suggested intensity</b>
Ossification lag, articular stiffness, myalgia, epicondylitis, peri-arthritis	0.5 – 1 W/cm <sup>2</sup>
Bruises, tenosinovitis, bursitis	1 – 1.5 W/cm <sup>2</sup>
Arthritis - arthrosis, callus, lumbago, pangs, tenovaginitis	1.5 – 2 W/cm <sup>2</sup>
Bone atrophy, osteitis – periostitis, sprains	2 – 2.5 W/cm <sup>2</sup>

### 5.1.5 – Position to be kept during the sessions

During the therapy programs, the ideal position is a relaxed one, with the body either supine or prone, depending on the area of application. This position must be kept throughout the duration of the session, in order to facilitate the effects produced by the vibrations, especially the flow of blood increased due to vascular expansion, as a consequence of the heating induced in the affected area.

## 5.2 – Aesthetic treatments

Ultrasounds can also be used on the surface or below the skin to heal and treat certain pathologies of the skin and the derma. Also, steady application of such treatments can help local thinning and lead to a regression of cellulitis tissue.

### 5.2.1 – Preset aesthetic programs

BIOSONYC has **preset aesthetic programs**, i.e. programs with all the parameters memorized and ready for use. The various available programs are subdivided according to the kind of treatment to be performed:

1. **Cellulitis**: programs which deliver high frequency ultrasounds to treat cellulitis in the area where it tends to collect most (thighs, glutei, hips, abdomen...).
2. **Lymphatic draining**: preset programs for warming and stimulation of the circulation in areas with marked water retention and swelling.
3. **Local thinning**: specific programs to reduce fat accumulation in men (or in women without cellulitis) due to a sedentary lifestyle or to disorderly diets.
4. **Skin pathologies**: programs to be applied to the skin in order to cure various surface pathologies.

The following paragraphs list the preset BIOSONYC aesthetic programs and then explain how to use them.

### 5.2.2 – List of aesthetic programs

BIOSONYC has 15 different preset aesthetic programs, subdivided according to the differentiations described in the previous section. The programs are listed in the following table and can be selected as described in the Chapter on Operation.

**Aesthetic Programs**

Kind of Program	No.	Name of the program
<b>Cellulitis</b>	1	Localized oedematous cellulitis
	2	Localized flaccid cellulitis
	3	Localized compact cellulitis
	4	Diffuse oedematous cellulitis
	5	Diffuse flaccid cellulitis
	6	Diffuse compact cellulitis
<b>Lymphatic draining</b>	7	Localized lymphatic draining
	8	Diffuse lymphatic draining
<b>Thinning</b>	9	Local thinning
	10	Diffuse thinning
<b>Skin pathologies</b>	11	Boils
	12	Granulomas
	13	Local dermatosclerosis
	14	Paravertebral dermatosclerosis
	15	Warts

### 5.3 – Description of the preset programs

The following tables describe the various preset programs, subdivided according to the kind of treatment they were designed for. Each of the following tables is set up as follows: the first column shows the program on the display, in order to facilitate identification, together with its length in minutes, whereas the second column contains the explanations about the program and the relevant kind of application.

**NOTE:** during the program it is possible to increase or decrease the Timer by pressing UP/DOWN keys.

## CELLULITIS

Programs for treating every kind of cellulitis. They can be used every day until the problem disappears.

NAME ON DISPLAY	USE OF THE PROGRAM
<b>Localised oedematous cellulitis</b>	Treatment of localized and clearly limited cellulitis: it breaks down the fat, frees the fluids which are being withheld and facilitates local circulation and lymphatic draining.
10 minutes	
<b>Localised flaccid cellulitis</b>	Treatment of localized and clearly limited cellulitis: it breaks down the fat, frees the fluids which are being withheld and facilitates local circulation and lymphatic draining.
12 minutes	
<b>Localised compact cellulitis</b>	Treatment of localized and clearly limited cellulitis: it breaks down the fat, frees the fluids which are being withheld and facilitates local circulation and lymphatic draining.
15 minutes	
<b>Diffuse oedematous cellulitis</b>	Treatment of diffuse cellulitis; it breaks down the fat, frees the fluids which are being withheld and facilitates local circulation and lymphatic draining.
20 minutes	
<b>Diffuse flaccid cellulitis</b>	Treatment of diffuse cellulitis; it breaks down the fat, frees the fluids which are being withheld and facilitates local circulation and lymphatic draining.
25 minutes	
<b>Diffuse compact cellulitis</b>	Treatment of diffuse cellulitis; it breaks down the fat, frees the fluids which are being withheld and facilitates local circulation and lymphatic draining.
30 minutes	

## LYMPHATIC DRAINING

Programs for treating water retention and widespread swelling. They can be used every day until all the excess fluids have been drained away.

NAME ON DISPLAY	USE OF THE PROGRAM
<b>Localized lymphatic draining</b>	Treatment of water retention localized in certain clearly limited surface areas; it helps reabsorption of the lymphatic vessels and local circulation.
15 minutes	
<b>Diffuse lymphatic draining</b>	Treatment of diffuse water retention in certain body areas; it helps reabsorption of the lymphatic vessels and local circulation.
20 minutes	

## THINNING

Programs for treating the accumulation of fat in men and in women without cellulitis. They can be used every day until the desired goals have been achieved.

NAME ON DISPLAY	USE OF THE PROGRAM
<b>Local thinning</b>	Treatment of deposits of fat localized in certain well defined body areas; it helps to dissolve the adipose cells and reabsorb the fats through local circulation.
20 minutes	
<b>Diffuse thinning</b>	Treatment of deposits of fat spread through various body parts (e.g. men's waists); it helps to dissolve the adipose cells and reabsorb the fats through local circulation.
30 minutes	



## SKIN PATHOLOGIES

Programs for superficial beauty treatments and skin pathologies. They can be used every day until the problem disappears.

NAME ON THE DISPLAY	USE OF THE PROGRAM
<b>Boils</b> - 8 minutes	Programs for the treatment of boils.
<b>Granulomas</b> - 4 minutes	Programs for the treatment of granulomas.
<b>Local dermatosclerosis</b> 6 minutes	Programs for the treatment of local dermatosclerosis.
<b>Paravertebral dermatosclerosis</b> 6 minutes	
<b>Warts</b> - 8 minutes	Programs for the treatment of warts.

### 5.4 – Head application areas

The following table shows some examples of application of the head on the main areas of the body affected by the most common aesthetic problems, to be carried out using the direct technique (mobile and fixed).


DIRECT METHOD: MOBILE TECHNIQUE	
Area to be stimulated	Notes about the position of the head
<b>Arms</b>	Move the head over the back of the arm and repeat the program on the other arm
<b>Abdomen</b>	Move the head over the whole surface of the abdomen
<b>Hips</b>	Move the head over one hip and then repeat the program on the other
<b>Glutei</b>	Move the head over the whole area affected by cellulitis
<b>Thighs (inside/outside)</b>	Move the head over the side affected by cellulitis

DIRECT METHOD: FIXED TECHNIQUE	
Area to be stimulated	Notes about the position of the head
<b>Skin</b>	Rest the head against the affected skin part

### 5.5 – Adjusting the power of emission

Adjustment of the intensity of vibration is a basic component for the success of the ultrasound therapy program and differs according to the type of program being used, the technique of application and the features of the patient. The following table shows the initial adjustment of intensity, i.e. right after the START of the program, which can be increased during the program, in order to increase the effects, or else diminished in case of skin overheating or pain.

Initial intensity	Modulation
The power of emission must be set by the user and will change depending on the kind of application (see following table).	The power of emission may be modified: increasing by a few tenths (+ 0,1) to increase the effects of the therapy; diminishing the value in case of overheating of the treated area. (*)

 Should the power of emission which has been set, or its adjustment, lead to excessive heating or pain in the treated area, immediately reduce the intensity of stimulation or else turn the application off.

This table shows the intensities suggested for the most common applications:

<b>Application</b>	<b>Suggested intensity</b>
Boils, granulomas, dermatosclerosis (loc./paravert.)	1 – 1.5 W/cm <sup>2</sup>
Loc. oedem./flacc. cell., Loc. lymph. draining	1.5 – 2 W/cm <sup>2</sup>
Comp. loc. cell., Comp. oedem./flacc. cell., Diff. lymph. draining, Loc. thinning	2 – 2.5 W/cm <sup>2</sup>
Comp. diff. cell., Diff. thinning, Warts	2.5 – 3 W/cm <sup>2</sup>

## **5.6 – Position to be kept during the sessions**

During the aesthetic programs, the ideal position is a relaxed one, with the body either supine or prone, depending on the area of application. This position must be kept throughout the duration of the session, in order to facilitate the effects produced by the vibrations, especially the flow of blood increased due to the vascular expansions, as a consequence of the heating induced in the affected area, thus facilitating the draining of the freed substances (fats, excess fluids).

## **5.7 – Integrated thinning program**

To achieve the best results from the body thinning and modelling program, we suggest you integrate different methods: along with ultrasounds, which produce localized effects, it is good practice to carry out aerobic exercise (fast walking, cyclette/cycle, slow running or Aerobics or spinning in a gym) plus a controlled and regular **diet**, restricting hydrocarbons and drastically cutting down fat (sweets, fried foods, soft cheese). A very effective thing to do during local thinning sessions is to combine ultrasounds with **electrostimulation**, using specific beauty programs, CAPILLARIZATION and programs for firming and toning the more relaxed muscles.

## Chap. 6 – POWER SUPPLY

BIOSONYX is supplied by mains voltage at 230V~ 50Hz by the supply cable.



To identify the power supply cable provided with the appliance, refer to the chapter on “Technical specifications”.

## Chap. 7 – MAINTENANCE

The following **routine maintenance** must be performed so the appliance can work regularly and in a safe condition, even long after the date of purchase.

### 7.1 – Head and cables

The head and the connecting cable must be checked regularly in order to make sure there are no cracks which the conductor fluid (water, gel) can leak into; also, the head must be cleaned **after each application** using a damp cloth and dried before storing.

### 7.2 – Device

In order to clean the appliance, we suggest you use a damp cloth. **Never use any liquid, since it's not protected against their penetration (IP20).**

### 7.3 – Replacing the power supply cable

It is good practice to constantly check the state of wear of the insulation cable before connecting it to the power mains. If it has been damaged, even in part, replace the cable at once.

**Immediate maintenance:** New Age Italia or staff authorized by New Age Italia must perform immediate maintenance if:

- the device has been submitted to outside mechanical stress, such as serious falls;
- the device has been subject to strong overheating, for example if it is left near intense heat sources;
- one suspects that fluids may have leaked into the device;
- the power supply cable, the cover or any other part of the device is damaged, broken or missing;
- the operation of the device appears to be altered.



For safety purposes, do not work with any other accessories (for example head or power supply cable) different from those provided together with the device.



Maintenance, functional control and monitoring the compliance with the safety regulations EN60601-1 on medical devices – carried out using a secur-tester – must be performed once a year. The working life of the instrument is guaranteed by the company only if such maintenance is performed regularly.

**IMPORTANT NOTICE:** Service should be performed only by New Age Italia or by the specialized personnel appointed by New Age Italia. For maintenance purposes, the device may be sent directly to the company service laboratories or else delivered to the dealer it was purchased from.

**Service Centre:**

**New Age Italia srl**

Via Keplero, 7 - 48022 Lugo (RA)

Tel:+39-0545.32019 – Telefax: +39-0545.369028

Website: [www.newageitalia.it](http://www.newageitalia.it) e-mail: [info@newageitalia.it](mailto:info@newageitalia.it)

**Chap. 8 – SYMBOLS**



CLASS II APPLIANCE



BF TYPE APPLIANCE



WARNING, REFER TO ENCLOSED DOCUMENTATION



THIS DEVICE HAS CE MARKING ACCORDING TO THE EEC DIRECTIVE 93/42.

**O476**

## Chap. 9 – WARNINGS



Always use the head which has the same serial number as the appliance.



Pay special attention when using the head, in order not to compromise the effectiveness of the treatment.



Use the device only with power mains which comply with current Safety Regulations.



The device enjoys safety class IP20 (see the chapter on “Technical specifications”). It should not be used in the immediate neighbourhood of fluids, since it is not protected against their entry.



You should not use cellular phones in the immediate neighbourhood (keep them at least a few metres away).



Do not operate near (for example at a distance of 1 metre) a short wave or microwave therapy device, as this could make the stimulator output unsteady.



Never connect the patient simultaneously to the BIOSONYC and to an HF surgical device, in order to prevent danger both to the patient and to the device.



The instrument will work according to specification if the environment is kept at a temperature between 5° and 40° C and humidity less than 80%. The same conditions must be respected during transport and storage.



In case of faults or problems, the instrument should be sent only to the manufacturer.



Never work near any flammable substances.



Never use any kind of gel or accessories different from those provided with the device.



It is of the utmost importance to advise the patient about what he or she will feel during the therapy, so as to be able to act immediately, turning the session off via the instrument controls or else taking away the handpiece if there is the wrong kind of perception.



If the power of emission which has been set or its adjustment cause excessive heating or pain in the treated area, you must immediately reduce the intensity of stimulation or else turn the application off.



Keep it out of reach of children.

## Chap. 10 – TECHNICAL SPECIFICATIONS

The following sections list all the specifications of the BIOSONYC and of the material provided with it. This information should be kept in mind, especially when replacing certain components, such as spare parts or accessories.

### 10.1 – Power supply

Power supply: 230V~ 50Hz

### 10.2 – Output specifications

Max power intensity (P): 3 W/cm<sup>2</sup>

Frequency (f): 1/3 MHz

Modulation waveform: continuous or ON/OFF (1/2, 1/5, 1/10)

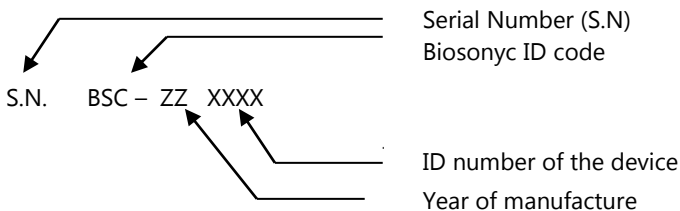
Modulation frequency: 2 Hz

### 10.3 – Other specifications

- > Size: 175x165x100h [mm]
- > Weight: 1 [Kg]
- > Class: II Type: BF
- > Classification in terms of fluid entrance: IP20
- > Safe when there are flammable anaesthetic gases present: it does not belong to categories AP or APG
- > Appliance designed to run: continuously

Manufactured according to the following standards:

- > EN 60601-1 (1998) – Electromedical appliances: General safety regulations
- > EN 60601-1-2 (1998) – Collateral regulation: electromagnetic compatibility – Prescriptions and tests
- > EN 60601-1-4 (1994) – Collateral regulation: Programmable electromedical systems
- > EN 60601-2-5 (2001) – Electromedical appliances: special regulations on safety of the ultrasound therapy appliances
- > CEI 62-84 (IEC487) – Symbols for electromedical appliances



## **Chap. 11 – BASIC EQUIPMENT AND ACCESSORIES**

BIOSONYC is provided with basic equipment for the main applications. In order to carry out other kinds of applications, or to replace consumed or finished material, you can purchase accessories separately.

### **11.1 – Basic BIOSONYC equipment**

BIOSONYC comes complete with:

Device

1/3 MHz Ø 45 mm head

Gel for ultrasounds

User manual

Instrument case

### **11.2 – Accessories and expendable materials**

Gel for ultrasounds

1/3 MHz Ø 20 mm head

Clutch arm for fixed applications

## **Chap. 12 – BIBLIOGRAPHY**

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