# **POCKET SONOVIT**

# Portable Ultrasound



# **MANUAL**

# **Instructions for use**

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# **INDEX:**

Cap.1 – INTRODUCTION	4
1.1 – What is POCKET SONOVIT?	4
1.2 – Why use POCKET SONOVIT	4
1.3 – Who can use POCKET SONOVIT	4
Cap.2 – INDICATIONS AND CONTRAINDICATIONS	4
<b>2.1</b> – Indications	4
2.2 – Contraindications	5
Cap.3 – FUNCTIONING	6
3.1 – Connection to the electrical supply	6
3.2 - Connection of the ultrasound probe	
3.3 – Application of ultrasound gel	6
3.4 – Turning on the device	7
3.5 - Programme choice	7
3.5.1 – Free Programmes	7
3.6 – Stimulation start	7
3.7 – Setting of intensity	7
3.8 – Interruption / termination of therapy	8
3.9 – Turning off the device	8
Cap.4 – PROGRAMMES	8
4.1 - Programme Description	9
Cap.5 APPLICATIONS	11
5.1 – Direct contact method	11
5.1.1 – Application examples	11
5.2 - Indirect contact method	
5.2.1 – Application examples	15
5.3 – Emission intensity regulation	15

5.4 – Position to be maintained during the session	15
Cap.6 – POWER SUPPLY	15
6.1 – Battery and power supply	15
6.1.1 Battery level indication	16
6.1.2 Battery recharge	16
6.1.3 Recommendations for battery protection	16
6.2 – Replacement of the battery	17
6.3 – Battery user precautions	17
Cap.7 – MAINTENANCE	17
7.1 – Emission probe	17
7.2 – Device and power supply unit	17
7.3 – Immediate maintenance	17
Cap.8 – WARNINGS	18
Cap.9 – TECHNICAL CHARACTERISTICS	19
9.1 – Power supply	19
9.2 – Output characteristics	19
9.3 – Other characteristics	19
Cap.10 – SYMBOLS	19
Cap.11 – STANDARD EQUIPMENT AND ACCESSORIES	20
11.1 – Standard equipment	20
11.2 – Accessories and consumer materials	20
Can 12 - RIRLIOGRAPHY	20

# WARNING: PLEASE READ THE USER'S MANUAL BEFORE USING THIS DEVICE

# Cap.1 - INTRODUCTION

POCKET SONOVIT belongs to a new generation of electromedical instruments for physiotherapy. Its main characteristics are its reduced dimensions, its ease of use and its versatility.

#### 1.1 - What is POCKET SONOVIT?

Thanks to the constant investigation and research we created this new system for ultrasound therapy, consisting of the POCKET SONOVIT. In order to offer to the user the maximum **reliability and safety**, in respect of the safety regulations for medical devices, this generator carries out controls, whereas the software allows therapeutic ultrasound generation for the treatment of the more common health related issues (contusions, accidents, on-going pathologies).

# 1.2 - Why use POCKET SONOVIT

POCKET SONOVIT generates ultrasounds and its parameters can be modified using the preset programs. Thanks to POCKET SONOVIT it is possible to apply ultrasound with standard programmes and run execute therapeutic sessions following the patient's needs.

#### 1.3 - Who can use POCKET SONOVIT

POCKET SONOVIT expresses its own potential in the medical field (physiotherapy particularly). Nevertheless, thanks to its ease of use and versatility, it can be used not only by physicians and therapists, but also from whoever desires to use it at home.

### Cap.2 - INDICATIONS AND CONTRAINDICATIONS

#### 2.1 - Indications

The more commune medical pathologies treated with ultrasound are those affecting osteomuscular and tendon tissues and, more in particular, periostitis, tendonitis, arthritis, muscle contractions, occlusions and organised oedemas. These days ultrasound has been recognised as a valid support in the treatment of non-joint related rheumatism such as **shoulder-joint and humerus periarthritis, epicondylitis** of the elbow and other pathologies, thanks to the analgesic, fibrolytic and muscle-relaxant effects of the therapy. The body parts being treated are subjected to an increased incidence of trauma during physical activity but, in many cases, these pathologies may be attributed to the ageing process (rheumatism, muscular hypotrophy, lack of balance due to low-level movement); these cases are increasing significantly with the progressive rise in the median age of the population that has not been followed by the necessary improvements in the quality of life.

As far as sports are concerned, the more frequent traumas are to the knee and ankle joints and these can be treated with ultrasound therapy via the daily and repeat application of a predetermined number of sessions. Treatments are carried out mainly for the analgesic effect and as a pre-medical treatment prior to kinesitherapy sessions.

4/20

#### 2.2 - Contraindications

- presence of metallic fragments;
- varicose veins
- thrombosis and acute thrombophlebitis;
- obliterative arteriopathy haemorrhage;
- menstruation;
- neoplasms;
- tuberculosis;
- acute inflammation in course;
- skin lesions:
- alteration to sensitivity.

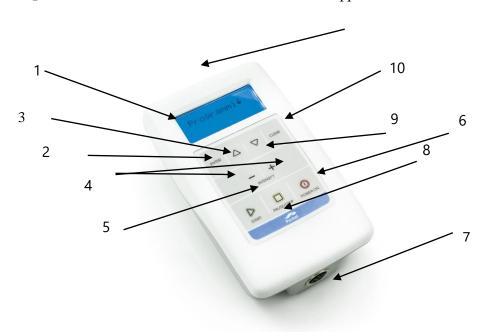
We do not recommend the use of ultrasound therapy on:

- special tissues (growing metaphyses, testicles, ovaries), as damage could occur;
- avoid the use in the zone of the heart and, in particular, where electro-mechanical apparatus (pacemakers) are present, as permanent damage could occur.

#### NOTE:

- Particular attention must be taken when therapy is applied to patients with diagnosed laminectomy, for reasons of possible spinal cord/marrow damage.
- Therapy should not be applied in close proximity to the eyeballs or uterus (abdomen/lumbar zone) where there is suspected pregnancy, to prevent the risk of cavitations, even with correct dosage.
- The presence of limb prosthesis or metallic syntheses causes problems as they could absorb superior quantities of the ultrasound and thus deteriorate or cause damage to surrounding tissue.
- This means of physiotherapy is not recommended in the treatment of pathologies in a young age and, especially, in infants (e.g.: growing joint cartilage).
- Personnel in charge of therapy must not be exposed for long periods to ultrasounds to avoid the onset of certain lesions (so called "ultrasound sickness").
- For disposal of the device, please refer to the manufacturer New Age Italia s.r.l., who will dispose of same in accordance to the laws in force.

5/20



- 1 LCD Display
- 2 ENTER: confirm selection
- 3 UP: forward
- 4 (+)/(-) intensity regulation
- 5 START:
- 6 (I) ON/OFF

- 7 Cable Outlet
- 8 PAUSE STOP: interruption / stop
- 9 DOWN: back
- 10 CLEAR: cancel / return
- 11 Power supply unit exit

<u>NOTE</u>: before applying ultrasound therapy, read through the contraindications carefully together with the indications from the doctor prescribing the magnetotherapy.

# 3.1 - Connection to the electrical supply

The device can be used with battery or connected to power supply (230V) and AC mains

# 3.2 - Connection of the ultrasound probe

Before starting the device, connect the probe through the cable outlet. Insert, rotate and tighten the connector into the output.

# 3.3 - Application of ultrasound gel

For direct body contact therapy, spread plenty of ultrasound gel (included) on the area to be treated and on the probe itself. For application techniques see Chapter APPLICATIONS.

## 3.4 - Turning on the device

To start POCKET SONOVIT, press the ON/OFF button (1) on the device's keypad. The welcome message will appear on the display along with the name and version of the software; subsequently the Programme Selection menu will appear, positioned by default on the first pre-set programme.

#### 3.5 - Programme choice

Choose the desired programme via the UP/DOWN key:

- Pre-set programmes;
- Free programmes (you can set new programmes with personalized settings).

Confirm by pressing ENTER to enter the following Menu.

#### 3.5.1 - Free Programmes

From **Free Prog.** you enter the Free Programmes Menu; by pressing ENTER on "------" it is possible to carry out a sequence of diversified therapies, which can be personalized with preferred parameters. Then the Phases Menu appears on the display and it is possible to set the Phases (1 to 4); select each Phase with the keys UP/DOWN (always start from Phase 1). By pressing ENTER it is possible to enter the parameter setting of each phase; each choice can be selected with the keys UP/DOWN and the value is settable by pressing (+)(-). Please find in the following table the available values.

NAME ON THE	TYPE OF PARAMETER	SETTABLE VALUE
DISPLAY		
Freq.	Frequency of Emission	1/3 MHz
Mod.	Frequency of Modulation	CONT, 1/2, 1/5, 1/10
Inten	Emission Intensity	1-30 (0,1-3 W/cm <sup>2</sup> )
Timer	Phase Duration	1-60 minutes
Stop	Phase Interruption	YES/NO

In the Menu **Prog.Lib.** it is possible to find also the Free Programmes which have been already saved by the user (if any have been already saved). By selecting one of the programmes saved on the Menu and pressing ENTER the display will show the following key words:

- **Start** + **ENTER** (to start the programme);
- **Edit** + **ENTER** (to change parameters and/or phases);
- **Delete** + **ENTER** (to cancel the programme and free memory capacity);

# 3.6 - Stimulation start

To begin therapy when >START< is visible on the display, press **START**.

<u>NOTE:</u> if the lead of the probe is not connected, the word "INS.HEAD" will appear on the display; when the lead is inserted the device will automatically restart. To return to the Menu press **PAUSE STOP**.

# 3.7 - Setting of intensity

Intensity is pre-set by a predefined value for each programme. These can be modified with the (+)/(-) keys of Channel 1. The minimum increase step is 0.1 W/cmq and the maximum intensity possible is 3 W/cmq. Usually the intensity is kept at a constant level, nevertheless, should pain occur or too much heat be perceived in the treated zone, intensity may be decreased with the (-) or the therapy interrupted.

# 3.8 - Interruption / termination of therapy

If you wish to interrupt therapy prior to the termination of the programme, press the PAUSE STOP button: once to pause (to restart press START); twice to terminate the programme and return to the selection phase.

# 3.9 - Turning off the device

To turn the device off, hold the (I) ON/OFF key down for a few seconds. If the device is not used following programme termination the device will automatically switch off following a few minutes. Disconnect all cables and ensure that the probe is cleaned thoroughly: remove all gel with a tissue, clean the probe with a damp cloth and dry thoroughly. Keep all accessories in the carry case and store in a cool, dry place.

# Cap.4 - PROGRAMMES

POCKET SONOVIT has 30 ready-to-use pre-set programmes and 10 free programmes. The programmes are listed in the following table.

Programme table		
Programme No.	Name appearing on display	Pathology treatable with this programme
P.1	Os.Atroph	Bone atrophy
P.2	Oss.Callu	Bone Callus
P.3	Ossificat.	Ossification lag
P.4	Osteitis	Osteitis and Periositis
P.5	Arthritis	Arthritis / Arthrosis
P.6	Stiffness	Articulation stiffness
P.7	Sprains	Sprains (knee/ankle)
P.8	Lumbago	Lumbar pain / Sciatica
P.9	Myalgia	Myalgia
P.10	Pangs	Pangs
P.11	Musc.tear	Muscular tears / Muscle pain
P.12	Contract.	Contractures
P.13	Contusio.	Contusions / Bruises / Oedemas
P.14	Tenosynov.	Tenosynovitis
P.15	Tenovagin.	Tenovaginitis
P.16	Tendoniti	Tendonitis / Bursitis / Epicondylitis
P.17	Periarth.	Periarthritis of the shoulder
P.18	Bursitis	Bursitis
P.19	Acute pai	All acute pains
P.20	Chron.pai	All chronic pains

POCKET SONOVIT also has 10 preset programs for aesthetic applications (cavitation) at 3MHz

21	Localized oedematous cellulitis
22	Localized flaccid cellulitis
23	Localized compact cellulitis
24	Diffuse oedematous cellulitis
25	Diffuse flaccid cellulitis
26	Diffuse compact cellulitis
27	Localized lymphatic draining
28	Diffuse lymphatic draining
29	Local thinning
30	Diffuse thinning

# 4.1 - Programme Description

In the following tables the pre-set programmes are described in detail: in the first column the name of the programme appearing on the display is listed for immediate identification, together with the duration of the programme in minutes and the pre-set emission intensity (adjustable); the second column contains an explanation of the programme and relevant applications.

**NOTE:** during a programme the Timer can be modified via the UP/DOWN keys.

# Program Description Tables

	PRUGRAMS FUR BUNE 1188UE	
These programs feature	specific parameters for treating pathologies involving the bone structure and	
related structure. They is	must be used every day until the problem disappears.	
NAME ON THE DISPLA	Y USE OF THE PROGRAM	
Bone atrophy	This helps regenerate the bone through stimulation of the metabolism of	
10 minutes – 3 W	calcium and local al circulation.	
Callus	This prevents the development of callus after fractures; it helps the	
8 minutes – 2 W	physiological regeneration of the bone.	
Osteitis and Periostit	is Treatment of phlogosis affecting the bone structures and the periostium	
8 minutes - 1 W	covering it.	
Ossification lag	This stimulates local metabolism and helps the regeneration of the bone,	
10 minutes – 2,5 W	delayed by problems of circulation or other situations.	
PROGRAMS FOR THE ARTICULATIONS		
Programs for treating pa	athologies affecting the articulations and cartilages. They must be used every day	
until the problem disapp	until the problem disappears.	
NAME ON DISPLAY	USE OF THE PROGRAM	
Arthritis-Arthrosis	Treatment of phlogosis affecting the articular cartilages; it stabilizes the local	
10 minutes – 2 W	metabolism and favours the afflux of the blood.	
Articular stiffness	Treatment of stiffness affecting the articular cartilages; it restores the trophism	
15 minutes – 1 W	of the cartilage facilitating its articular mobility.	

	PROGRAMS FOR THE ARTICULATIONS	
Sprains	Treatment of sprains; it diminishes pain and functional limitation.	
10 Minutes – 2,5 W		
Lumbago	Treatment of pain affecting the lumbar spinal chord; it diminishes pain and	
10 minutes – 2 W	functional limitation.	
	PROGRAMS FOR MUSCLES	
Programs for treating m	uscle problems of various kinds. They must be used every day until the problem	
disappears.		
NAME ON DISPLAY	USE OF THE PROGRAM	
Myalgia	Treatment of muscle pain; it warms the area being treated and favours the	
10 minutes – 1 W	afflux of blood.	
Pangs	Treatment of phlogosis affecting the articular muscles; it stabilizes the local	
6 minutes – 2 W	metabolism and favours the afflux of the blood.	
Strains	Treatment of phlogosis affecting the articular muscles; it stabilizes the local	
10 minutes – 2,3 W	metabolism and favours the afflux of the blood.	
Contractures	Treatment of muscle contractures; it warms up the affected area and favours	
8 minutes - 1,5 W	the afflux of the blood which eliminates the metabolites.	
Bruises	Treatment of muscular oedemas after bruises; it warms the affected area and	
10 minutes – 1,5 W	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 dis		
NAME ON DISPLAY	USE OF THE PROGRAM	
Tenosynovitis	Treatment of phlogosis of the synovial sheath of the long tendons (e.g. fingers).	
10 minutes – 1,5 W		
Tenovaginitis	Treatment of phlogosis of the wide and flat tendons (e.g. Achilles tendon).	
10 minutes – 2 W		
Epicondylitis	Treatment of phlogosis of the insertion of the outside forearm muscles on the	
10 minutes – 1 W	elbow (tennis elbow)	
Periarthritis	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	
10 minutes – 0,9 W	arm.	
Bursitis	Treatment of the phlogosis affecting the synovial bursae located between the	
10 minutes – 1,5 W	tendons and the bones.	
GENERAL PROGRAMMES		
	or the treatment of acute or chronic pain or pathologies for which there is no pre-	
	The programme must be executed daily until the problem is resolved.	
NAME ON DISPLAY	Programme Use	

NAME ON DISPLAY	PROGRAMME USE
Acute pain	Treatment of acute pain, sharp pains, traumas, acute inflammations etc.
10 minutes - 1,5 W	
Chronic pain	Treatment of chronic pain, aches, chronic inflammations etc.
15 minutes - 2,5 W	

CELLULITIS		
Programs for treating every kind of cellulitis. They can be used every day until the problem		
disappears.		
Program	USE OF THE PROGRAM	
Cellulitis	Treatment of diffuse cellulitis; it breaks down the fat, frees the fluids	
	which are being withheld and facilitates local circulation and	
May 30 minutes	lymphatic draining	

	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.	
PROGRAM	USE OF THE PROGRAM
Lymphatic draining	Treatment of diffuse water retention in certain body areas; it helps
Max 20 minutes	reabsorption of the lymphatic vessels and local circulation.

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.	
Program	USE OF THE PROGRAM
Thinning	Treatment of deposits of fat spread through various body parts (e.g.
Max 30 minutes	men's waists); it helps to dissolve the adipose cells and reabsorb the fats
	through local circulation.

# Cap.5 APPLICATIONS

#### 5.1 - Direct contact method

This technique foresees direct contact of the probe with the skin via a mean/substance, allowing perfect contact between the two surfaces (e.g.: ultrasound gel, included), to be spread on the area to be treated; in the direct contact method, the probe may be:

- **fixed** for treatment of a small surface area, maintaining the probe steady on the zone to be treated by hand or with the aid of a mechanical arm support (not included) that allows the operator to treat other patients at the same time.
- **mobile** for treatment of a larger surface area, via a series of small forward/backwards or circular movements across the entire zone to be treated. This technique is used for the treatment of large, flat and even surfaces.

### 5.1.1 - Application examples

(IMPORTANT: Please note that the following photos are merely demonstrative, the probe in endowment may not correspond in the aspect to the one represented below)

Rev. 01 of 29/03/22 11/20



Fig.1 – Arthritis of the hand

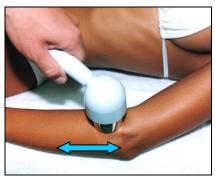


Fig.3 - Epicondylitis



Fig.5 – Periarthritis of the shoulder



Fig.2 – Arthritis of the wrist (keep probe steady in the exact point of treatment)



Fig.4 – Delay in humerus bone formation (keep probe still in the exact point of treatment)



Fig.6 - Rib contusions



Fig.7 – Lumbar pain



Fig.8 – Arthrosis of the hip



Fig.9 - Tear/contraction of quad



 $Fig. 10-Tear/contraction\ of\ hamstrings$ 



Fig.11 – Arthrosis of the knee (internal and/or external)



Fig.12 – Prepatellar bursitis (keep probe still in the exact point of treatment)



Fig.13 - Periostitis



Fig.14 – Bone callus on the tibia (keep probe still in the exact point of treatment)

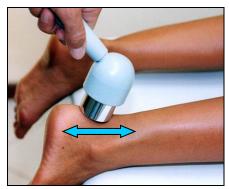


Fig.15 – Achilles' tendon



Fig.16 – Ankle sprains

#### 5.2 - Indirect contact method

With the indirect method of contact between the probe and the skin, the intervention of an ultrasonic wave transmission is used (usually water). This method evens the number of vibrations that reach the skin and it is used for body parts such as hands and feet (areas where the direct body contact would be more difficult to perform). For these applications a deep basin filled with water is required. The part of the body to be treated should be immerged in the water together with the probe; orientate the flat part of the probe towards the zone to be treated at a distance of approximately 10-15 cm and begin therapy.

#### 5.2.1 - Application examples





Fig.17 – Arthritis of the hand in immersion

Fig. 18 – Arthrosis of the foot in immersion

# 5.3 - Emission intensity regulation

The regulation of vibration intensity is fundamental for optimum results from ultrasound therapy programmes and depends on the type of programme and application technique used, and the characteristics of the patient. The intensity is pre-set, as indicated in the previuos tables; nevertheless, it may be increased during the course of the programme for greater effect or decreased in cases of elevated heating of the skin or if pain is perceived.

If the set emission intensity, or the regulation of same, causes elevated heating or pain in the treated area, reduce immediately the intensity or interrupt the programme.

# 5.4 - Position to be maintained during the session

Maintain a relaxed position during each session. Depending on the area of application, the body is lying supine or prone. The position must be maintained during the whole session to facilitate the effects produced by vibrations, especially the increased blood flow.

# Cap.6 - POWER SUPPLY

### 6.1 - Battery and power supply

The device can be powered from AC mains  $230V\sim50Hz$  through the endowed power supply or from the internal rechargeable battery Pocket Ni-Mh with 6V-1,8 Ah., with an autonomy of some hours under normal use conditions. The guaranteed autonomy may change depending on the program, intensity and time of application.

For the correct identification of battery and power supply, consult the Chap. "Technical features". Neither the power supply nor the battery must be replaced from not experienced staff. Do not use spare parts which are not provided or approved by the manufacturer.

Rev. 01 of 29/03/22 15/20

#### 6.1.1 Battery level indication

When the Pocket is used with the battery the BATTERY symbol will appear on the display.

**Key**: - Charged battery - Low battery

When the low battery symbol is displayed, a **complete recharge** should be carried out. To protect the battery, Pocket is equipped with an **automatic switch-off** system that, when the battery is completely low (after a couple of minutes that the low battery symbol flashes), will turn the device off.

The BATTERY symbol will only appear if the device is disconnected from the mains electrical supply, otherwise the ELECTRICITY symbol will appear.

#### 6.1.2 Battery recharge

To recharge the Pocket battery:

- 1- **switch off** the device;
- 2- take out the probe;
- 3- **connect the recharger** to the mains electrical supply and to the device;
- 4- **leave the device charging** (the battery symbol will appear with the charged/low status flashing). When full charge is completed (approx. 3 hours), the battery charged icon will appear (Once in a while we recommend leaving the device charging for 8-10 hours);
- 5- **Disconnect the recharger** from the mains electrical supply and from the device.

<u>WARNING</u>: when charging a device whose battery is completely low (e.g.: when the device has not been used for long periods of time), the display may not turn on immediately. Leave it charging for at least 2-3 hours and then disconnect and reconnect the recharger.

# 6.1.3 Recommendations for battery protection

The life of a rechargeable battery depends on the number and type of cycles of charge / discharge. Here below we provide some useful advice to increase the life of your battery:

- 1. Should the Pocket not be utilised on a frequent basis, recharge the battery at least once a month (for 8-10 hours) regardless of usage.
- 2. To lengthen the life of your battery, we recommend recharging the battery only when the low battery symbol flashes.
- 3. We recommend, when possible, to use the device connected to the mains electrical supply to avoid unnecessary charge/low charge cycles.

# 6.2 - Replacement of the battery

The indicating factor showing the end of battery life if the autonomy of the device after a complete recharge cycle. When the battery lasts for **less than one hour and does not permit a programme to be terminated** it must be replaced. For battery replacement please refer to a **New Age Italia Assistance Centre** who is able to replace the battery and ensure the safety of the device and the correct disposal of the old battery.

Never reverse the polarity of the connections of the battery, not to cause the destruction of the electronic circuits.

#### 6.3 - Battery user precautions

- (1) Do not dispose of used batteries in the normal garbage collection, hand in to an authorised collection and disposal centre.
- (2) Never open or throw used batteries onto fires.
- (3) Do not short-circuit the terminals.
- (4) Avoid provoking sparks or flames over or in proximity to the battery.
- (5) Should the internal electrolytes come into contact with the skin, or clothing, rinse immediately with water.
- (6) Should the internal electrolytes come into contact with eyes, rinse abundantly in water and consult a doctor.

# Cap.7 - MAINTENANCE

### 7.1 - Emission probe

The emission probe and the connection cable must be periodically controlled to verify that there are no cracks through which liquid could infiltrate (water, gel); further, the probe must be cleaned **after every use** with a damp cloth (remove all gel) and dried thoroughly.

# 7.2 - Device and power supply unit

To clean the device and power supply unit utilise a damp cloth. Do not, under any circumstances, use liquids as there is no protection against possible infiltration (IP20)

#### 7.3 - Immediate maintenance

Immediate maintenance must be performed by New Age Italia or authorized staff if one of the followings occurs:

- external mechanical stress (eg. serious falls);
- strong overheating (eg. if the device has been left close to sources of intense heat);
- some liquids may have been penetrating the device;
- the power supply, or other parts of the device are damaged, broken or missing;
- the functionality of the instrument seems altered.

Let Use the device with the endowed accessories only

Run every year a secur-tester to check the device following the legislation EN60601-1. The useful life of the device is guaranteed only if such maintenance is regularly performed.

**PLEASE NOTE:** We recommend that controls be carried out exclusively by New Age Italia s.r.l. or other authorised personnel. The device may be sent for maintenance directly to the company's assistance centres or delivered to the reseller from which it was purchased.

#### **Assistance centres:**

#### New Age Italia s.r.l.

Via De Brozzi, 3 - 48022 Lugo (RA) Tel.:+39-0545.32019 - Telefax: +39-0545.369028 Web: www.newageitalia.it - E-mail: info@newageitalia.it

# Cap.8 - WARNINGS

Always use the probe displaying the same serial number as the device (SN number).

Take special care when utilising the probe to avoid compromising the effectiveness of treatment.

Only use the device with electrical installations that conform to the Safety Regulations in force.

The instrument has degree of protection IP20 (see Chap. "Technical features"). Do not use it close to liquids, because it's not liquid proof.

Do not use close to cellular telephones (maintain at least one meter of distance).

Utilisation of the device in proximity (for example 1 metre) to devices for short wave or microwave therapy could cause instability in the stimulator emissions.

Never simultaneously connect a patient to the POCKET SONOVIT and a HF surgical device, to avoid danger to the patient and the device itself.

This device will function in accordance to its specifications if the environment is maintained at a temperature range of 5° and 40° C and a humidity level inferior to 80%. These same conditions must be maintained during transport and storage.

In cases of malfunction or breakdowns, only send the device to the manufacturer.

Me recommend that this device not be utilised near to flammable substances.

Do not use gel or other accessories different to those included.

It is very important that the patient be informed of the expected sensation to be perceived during therapy in order to be able to interrupt the session via the commands of the device or by removing the probe should the patient perceives a different sensation.

Should the set emission intensity or the regulation of same cause elevated heating or pain in the zone to be treated the intensity must be immediately decreased or the session interrupted altogether.

A Keep away from children's reach.

# Cap.9 - TECHNICAL CHARACTERISTICS

# 9.1 - Power supply

PRI: 230V ~ 50Hz SEC: 12V-1A

Internal power supply: Rechargeable battery Ni-MH 6V-1,8 Ah

# 9.2 - Output characteristics

Max Power intensity (P): 3 W/cmq

Frequency (f): 1/3 MHz Grade of modulation: 100%

Modulation waveform: continuous or pulsating ON/OFF (1/2)

Frequency of Modulation: continuous, 1 /2, 1/5, 1/10

#### 9.3 - Other characteristics

Dimensions: 175x105x40h [mm]

Weight: 400 [g]Class: Type II: BF

Classification for liquid infiltration: IP20

> Safety in the presence of inflammable anaesthetic gas: neither AP or APG category

> Type of device functioning: continuous

Built in accordance to the following regulations:

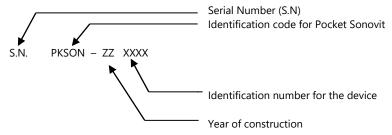
➤ EN 60601-1 (1998) – Electro-medical devices: General safety regulations

➤ EN 60601-1-2 (1998) – Collateral regulation: Electro-magnetic Compatibility – Regulations and testing

➤ EN 60601-1-4 (1997) – Collateral regulation: Programmable Electro-medical systems

➤ EN 60601-2-5 (2001) – Electro-medical devices: Special regulation for the safety of ultrasound therapy devices

➤ EN 980-2003 and EN 1041 – Symbols for electro-medical devices



# Cap.10 - SYMBOLS



II CLASS DEVICE



BF TYPE DEVICE



#### WARNING, REFER TO ATTACHED DOCUMENTATION



#### THIS DEVICE IS CE APPROVED PURSUANT TO EEC DIRECTIVE 93/42.

#### Cap.11 - STANDARD EQUIPMENT AND ACCESSORIES

### 11.1 - Standard equipment

Device Power supply unit Probe 1/3 MHz Ø 45 mm Ultrasound gel User Manual Carrying case

#### 11.2 - Accessories and consumer materials

Ultrasound gel Probe 1/3 MHz Ø 45 mm

# Cap.12 - BIBLIOGRAPHY

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