X LIFE PRO

1-3 Mhz modulated 40/60KHz



USER MANUAL

Instructions for use

New Age Italia srl

Via De Brozzi, 3 - 48022 Lugo (RA) Tel:+39-0545.32019 - Telefax: +39-0545.369028

Website: www.newageitalia.it e-mail: info@newageitalia.it

This document is the property of New Age Italia srl. All rights reserved. It is forbidden to copy or reproduce it in any way, including photocopying its contents in whole or in part, without written permission by New Age Italia srl.

TABLE OF CONTENTS:

Chap. 1 – PRESENTATION	4
1.1 – What is X LIFE PRO ?	4
1.2 – Why use the X LIFE PRO ?	4
1.3 – Whom is X LIFE PRO addressed to ?	4
Chap. 2 – INDICATIONS / CONTRAINDICATIONS	5
2.1 – Indications	5
2.2 – Contraindications	5
Chap. 3 – OPERATION	6
3.1 – The X LIFE PRO keys	6
3.2 – Connecting the head	7
3.3 – Turn on the device	
3.4 – Choose the program	7
3.4.1 - Manual mode	
3.4.2 - Preset program mode	
3.4.3 - Personal program mode	
3.5 – Start of therapy	
3.6 – Setting the power of emission	8
3.7 – Program interruption	8
3.8 – Turn off the device	8
Chap. 4 – TREATMENTS	9
4.1 – Therapy programs	10
4.2 Free program setting	11
4.3 – Adjusting the power of emission	12
4.4 – Position to be kept during the sessions	12
4.5 – Integrated thinning program	12

Chap. 5 – MAINTENANCE	12
5.1 – Head and cables	12
5.2 – Device	13
5.3 – Replacing the power supply cable	13
Chap. 6 – SYMBOLS	13
Chap. 7 – WARNINGS	14
Chap. 8 – TECHNICAL SPECIFICATIONS	15
8.1 – Power supply	15
8.2 – Output specifications	15
8.3 – Other specifications	15
Chap. 9 – BASIC EQUIPMENT AND ACCESSORIES	16
9.1 – Basic X LIFE PRO equipment	16
9.2 – Accessories and expendable materials	16
Chan 10 DIDLIOCDADIIV	17

WARNING: READ CAREFULLY THE INSTRUCTIONS BEFORE USE

Chap. 1 - PRESENTATION

X LIFE PRO 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 X LIFE PRO?

Unceasing research in the field of medical devices has led to the creation of this new system for ultra-sound therapy, consisting of the X Life Pro generator. X Life Pro 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 X LIFE PRO?

X LIFE PRO 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 aesthetic problems (cellulitis, skin affections).

1.3 - Whom is X LIFE PRO addressed to?

The most suitable fields for X LIFE PRO to express its full potential are medicine 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 local fat, cellulitis, skin pathologies, body slimming and firming. They are especially indicated for:

Aesthetics:

- Celulitis;
- Lifting;

• Local thinning;

• Skin pathologies.

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.

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

X LIFE PRO 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 X LIFE PRO keys

POWER SUPPLY OUTPUT



- 1 Display TOUCH SCREEN
- 2-STOP BUTTON
- 3- KNOB + PUSH BUTTON
- 4-OUTPUT 1
- 5-OUTPUT 2

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 X LIFE PRO 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

With X LIFE PRO it's possible to work with 3 different modes: Manual mode Preset program mode Personal

3.4.1 - Manual mode

Press **START** on the initial screen to access the manual mode area. In this area, by **TURNING THE KNOB** you can vary the value of the parameter selected, whereas by **PRESSING THE KNOB** you pass from one parameter to the next. The concerned parameters are: power output of the ultrasound, duration, modulation, frequency.

3.4.2 - Preset program mode

Press **START** on the initial screen (touch screen) to access the work area. Then press **PROGRAMS** (on touch screen) to enter the Menu for choosing specific protocols where first of all the therapy to be used is selected, by turning the encoder and then pressing **ENTER** (touch screen) or else **PRESSING THE KNOB** to confirm the program selected.

3.4.3 - Personal program mode

The custom-made programs are at the bottom of the list of pre-set programs. Press **START** on the initial screen (touch screen) to access the work area. Then press **PROGRAMS** (on touch screen) to enter the Menu for choosing specific protocols. At the bottom of the list first of all the therapy to be used is selected, by turning the encoder and then pressing **ENTER** (touch screen) or else **PRESSING THE KNOB** to confirm the program selected.

<u>NOTE:</u> if the ultrasound head cable is not inserted in the device, the display will show "elettr. Dist". When the cable is put in, press START and the program restarts. . To go back to the previous Menu press PAUSE STOP.

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/cm2 and the maximum is 3.0 W/cm2.

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**.

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

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 - Turn off the device

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

Chap. 4 - TREATMENTS

Programs 40KHz and 60KHz

N° Prog.	Name of program	Name on the display
1	Visage lifting	Visage lifting
2	Neck lifting	Neck lifting
3	Decolté lifting	Decolté lifting
4	Visage peeling	Visage peeling
5	Rosacea	Rosacea
6	Arm firming L1	Arm firming L1
7	Arm firming L2	Arm firming L2
8	Bust firming L1	Bust firming L1
9	Bust firming L2	Bust firming L2
10	Hips firming L1	Hips firming L1
11	Hips firming L2	Hips firming L2
12	Belly firming L1	Belly firming L1
13	Belly firming L2	Belly firming L2
14	Buttock firming L1	Buttock firm. L1
15	Buttock firming L2	Buttock firm. L2
16	Thigh firming L1	Thigh firming L1
17	Thigh firming L2	Thigh firming L2
18	Localized oedematous cellulitis L1	Loc. Oed. Cell. L1
19	Localized oedematous cellulitis L2	Loc. Oed. Cel. L2
20	Localized flaccid cellulitis L1	Loc. Flac. Cell. L1
21	Localized flaccid cellulitis L2	Loc. Flac. Cell. L2
22	Localized compact cellulitis L1	Loc. Comp. Cell. L1
23	Localized compact cellulitis L2	Loc. comp. Cell. L2
24	Diffuse oedematous cellulitis L1	Dif. Oed. Cell. L1
25	Diffuse oedematous cellulitis L2	Dif. Oed. Cell. L2
26	Diffuse flaccid cellulitis L1	Dif. Flac. Cell. L1
27	Diffuse flaccid cellulitis L2	Dif. Flac. Cell.L2
28	Diffuse compact cellulitis L1	Diff. comp. cell. L1
29	Diffuse compact cellulitis L2	Diff. comp. cell. L2
30	Localized thinning L1	Thinning Loc. L1
31	Localized thinning L2	Thinning Loc. L2
32	Diffuse thinning L1	Thinning diff. L1
33	Diffuse thinning L2	Thinning diff. L2

Rev. 02 of 10/12/04 9/17

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.

4.1 - Therapy programs

X LIFE PRO 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 treatment they offer. The first column, next to the name of the programs, shows its duration; the second column shows some explanations about it and the relative applications:

CELLULITIS		
Programs for treating ev	very kind of cellulitis. They can be used every day until the problem	
disappears.		
NAME ON DISPLAY	USE OF THE PROGRAM	
Localized oedematous	Treatment of localized and clearly limited cellulitis: it breaks down	
cellulitis	the fat, frees the fluids which are being withheld and facilitates local	
30 minutes	circulation and lymphatic draining.	
Localized flaccid	Treatment of localized and clearly limited cellulitis: it breaks down	
cellulitis	the fat, frees the fluids which are being withheld and facilitates local	
20 minutes	circulation and lymphatic draining.	
Localized compact	Treatment of localized and clearly limited cellulitis: it breaks down	
cellulitis	the fat, frees the fluids which are being withheld and facilitates local	
20 minutes	circulation and lymphatic draining.	
Diffuse oedematous	Treatment of diffuse cellulitis; it breaks down the fat, frees the fluids	
cellulitis	which are being withheld and facilitates local circulation and	
30 minutes	lymphatic draining.	
Diffuse flaccid	Treatment of diffuse cellulitis; it breaks down the fat, frees the fluids	
cellulitis	which are being withheld and facilitates local circulation and	
30 minutes	lymphatic draining.	
Diffuse compact	Treatment of diffuse cellulitis; it breaks down the fat, frees the fluids	
cellulitis	which are being withheld and facilitates local circulation and	
30 minutes	lymphatic draining.	

LIFTING		
Programs for treating wrinkles They can be used every day until all the skin tone gets visibly		
better.		
NAME ON DISPLAY	USE OF THE PROGRAM	
Face lifting	Treatment of wrinkles and face firming.	
15 minutes		
Neck lifting	Treatment of wrinkles and neck firming.	
15 minutes		
Low neckline lifting	Treatment of wrinkles and low neckline firming.	
15 minutes		

FIRMING		
Programs for the treatment of muscular sagging for man and woman. They can be used every day until the achievement of desired results.		
NAME ON DISPLAY	USE OF PROGRAMS	
Arm firming	Treatment of structural sagging of arms.	
30 minutes		
Bust firming	Treatment of structural sagging of bust.	
30 minutes		
Hips firming	Treatment of structural sagging of hips.	
30 minutes		
Belly firming	Treatment of structural sagging of belly.	
30 minutes		
Buttocks firming	Treatment of structural sagging of buttocks.	
30 minutes		
Thigh firming	Treatment of structural sagging of thighs.	
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	
Face peeling - 15 minutes	Programs for the natural skin exfoliation.	
Rosacea - 20 minutes	Programs for the stimulation of blood circulation in the treated area.	

LOSS OF WEIGHT	
Programs for the treatment of fat overstock for men and women with no cellulitis. They can	
be used every day until the problem disappears.	
NAME ON THE DISPLAY	USE OF THE PROGRAM
Localized loss of weight - 30 minutes	Programs for the treatment of fast stock in particular areas of the body. It enables fat cells melting and fat absorption through local blood circulation.
Diffused loss of weight - 20 minutes	Programs for the treatment of fast stock in several areas of the body. It enables fat cells melting and fat absorption through local blood circulation.

4.2 Free program setting

X Life Pro contains a memory including 20 free programs that can be set from prog. no. 34 to 53. To save a free program go to the program list and select one of these programs. Press STOP. Now you are in the configuration area called PARIMP. From here using + and – you can adjust the highlighted parameter, while with UP and DOWN you can change the selected parameter.

The parameters are:

FREQ: frequency, 60 Khz or 40KHz

MODUL: modulation, CONTINUOUS, 50%, 20%, 10%

POWER: power, from 1 to 30 (this means 0,1W/cmq to 3W/cmq).

DURATION: program duration from 1 to 60 minutes.

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

Should the power of emission which has been se, 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.

4.4 - 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).

4.5 - 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. 5 - 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.

5.1 - 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 (gel or cream) can leak into; also, the head must be cleaned **after each application** using a damp cloth and dried before storing.

5.2 - 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).

5.3 - 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.

<u>Immediate maintenance:</u> 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 De Brozzi, 3 - 48022 Lugo (RA) Tel:+39-0545.32019 - Telefax: +39-0545.369028

Website: www.newageitalia.it e-mail: info@newageitalia.it

Chap. 6 -	SYMBOLS
-----------	----------------

CLASS II APPLIANCE



BE TYPE APPLIANCE



WARNING. REFER TO ENCLOSED DOCUMENTATION

0476

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

Chap. 7 - WARNINGS



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

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

① 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.

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

① 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 X LIFE PRO 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.

1 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. 8 - TECHNICAL SPECIFICATIONS

The following sections list all the specifications of the X LIFE PRO 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.

8.1 - Power supply

Power supply: 230V~ 50Hz

8.2 - Output specifications

Max power intensity (P): 3 W/cm2

Frequency (f): 40/60 KHz

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

8.3 - 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

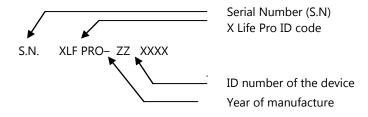
> Appliance designed to run: continuously

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. 9 - BASIC EQUIPMENT AND ACCESSORIES

X LIFE PRO 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.

9.1 - Basic X LIFE PRO equipment

X LIFE PRO comes complete with:

Device 40/60 KHz Ø 45 mm head Gel for ultrasounds User manual Instrument case

9.2 - Accessories and expendable materials

Gel for ultrasounds 40/60 KHz Ø 25 mm head

Chap. 10 - BIBLIOGRAPHY

- C. Menarini, M. Menarini: Manuale di terapia fisica, Aulo Gaggi Editore, Bologna 1985
- M. Burini, M. Rossi: Confronto tra i risultati di terapie fisiche associate o meno a trattamenti chiropratici in due serie di 100 casi ciascuna, Atti XVIII Congresso Nazionale S.I.M.F.E.R., Firenze, 30/9-3/10/1990
- M. Moselli, M. Manca: Fisioterapia pratica, Ed. Minerva Medica, Torino 1993
- D.A. Fletzer, F. Provenzano, V. Saraceni: **Gli ultrasuoni in Medicina Fisica**, Phoenix Editrice, Roma 1994
- B. Gialanella, G. D'alessandro, R. Santoro: **Terapia fisica pratica**, ED. Marrapese, Roma 1997
- G. van der Heijden, D. van der Windt, A. de Winter: **Physiotherapy for patients with soft tissue shoulder disorders: a systematic review of randomised clinical trials**, BMJ 1997, 315:25-30 (5 July)
- A. Vasta: Manuale pratico illustrato di terapia fisica, ED. Marrapese, Roma 1998
- C. Cisari, G. Severini: **Fisioterapia clinica pratica**, Edi-ermes, Milano 1999
- AAVV: Ultrasound therapy for Calcific Tendinitis of the Shoulder, NEJM, 1999, 340:1533-1538 (May 20)
- G. Nanni, G. S. Roi, D. Vasapollo: Le lesioni muscolari dell'arto inferiore nello sportivo, ED. Marrapese, Roma 2000
- D. van der Windt, G. van der Heijden, S. van der Berg, G. Ter Riet, A. de Winter, L. Bouter: **Ultrasound therapy for acute ankle sprains**, The Cochrane Library, 2000, Issue 2, pag. 1-15
- G. Pirazzini: **La ultrasuonoterapia in alcune patologie di interesse sportivo,** Tesi di Laurea in Scienze Motorie, Bologna Marzo 2001

17/17