

LEADERGUN®
Made in Italy



User Manual

mesoskinline® | mesotech®

User Manual

rev. 0.3 of 12-05-2017

ATTENTION:

Please, read carefully this manual before using Leadergun



Congratulations!

Thank you for purchasing



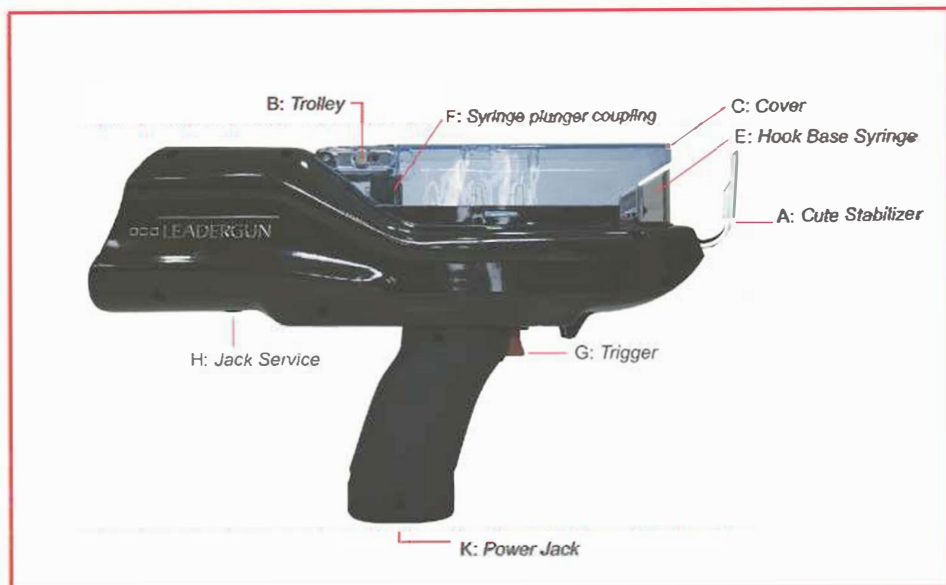
the most innovative injector for Mesotherapy

Completely designed and manufactured in Italy

Mesotech s. r. l.



Description



Main features

LEADERGUN® is one of the most advanced fully automated injection system.

LEADERGUN® has been developed thanks to Mesotech long experience in mesotherapy and has been designed to fix all the problems connected to portable devices.

LEADERGUN® is completely microprocessor-controlled and thanks to its color display (D) lets you to constantly view the programming values set.

LEADERGUN® is the only portable device which, thank to the use of a microprocessor controlled by stepper motor, can make accurate and precise injections without medicine leakage.

LEADERGUN® is able to work with 1.0ml, 2.0 ml, 2.5ml, 5.0ml and 10.0ml standard mesotherapy syringes and 4.0mm, 6.0mm and 13.0mm needles without any external adapter kit. The needle penetration depth is completely automatic and can be set, via a microprocessor controlled by stepper motor, between 1.0mm and 13.0mm.

LEADERGUN® has a Cover (C) used to protect the syringe from accidental operation during treatment.

LEADERGUN® is powered by an universal AC / DC adapter that provide power to the battery for recharging.

LEADERGUN® is equipped with a rechargeable high capacity Li-Ion battery that allows to operate without AC / DC adapter for several hours.

Package contents: N° 1 Charger Brand Globe Tek, Inc. mod. GTM91099-6015-3.0-T2, N° 1 Power Cord 100cm long, N° 5 Skin Stabilizer, N° 1 Instructions Manual, Warranty conditions.

Technical specifications

AC / DC adapter Power Box Medline EXM805118:

Input voltage: 100v – 240vac

Frequency: 50 / 60 Hz

Output voltage: 12V dc

Max output current: 5A dc

Power Plug Europe, UK, USA, New Zeland, Australia.

Li – Ion Battery:

Nominal Voltage: 7.4V

Capacity: 2200mA / h

Storage conditions:

Minimum temperature: -10°C

Maximum temperature: 75°C

Minimum Relative Humidity: 30% no-condensing

Maximum relative humidity: 95% no-condensing

Low atmospheric pressure: 700hPa
Maximum atmospheric pressure: 1060hPa

Operation:

Minimum temperature: 10° C
Maximum temperature: 40° C
Minimum relative Humidity: 30% non-condensing
Maximum relative humidity: 75% non-condensing
Low atmospheric pressure: 700hPa
Maximum atmospheric pressure: 1060hPa

Classification and Symbols:

Equipment not suitable for use in the presence of flammable anesthetics with air, oxygen or nitrous oxide

Device suitable for continuous operation

Device not protected against the penetration of liquids

Attention, check the documentation attached

Equipment subject to the provisions of the UE Directive (WEEE)

Device with Type B Applied Part

Device of Classe II b

Continue current

AC

Power Jack

Button (trigger) to initiate the dispense the product (G)

Manufactured by

IPX0



Maintenance and Technical Documentation:

In case of failure and / or request for technical specifications, please contact:

Mesotech s.r.l.
Via Mazzini n° 52 – 80022 – Arzano (Na) - Italy
Phone: +39 081 5736072
www.mesotech.it

Verifica CDD Involucro		Tester Bio-Tek 601PRO ver. SW 2.20 S.N. 131780
Prodotto: LeaderGun		

PRODOTTO	LEADERGUN	
NUM. SERIALE		
ULTIMO TEST		
CLASSE DISPOSITIVO	II B	
TENSIONE DI RETE: L1-TERRA L2- TERRA L1-L2		
CONSUMO DI CORRENTE		
CDD INVOLUCRO [μ A]		LIMITE [μ A]
NORM POL		100
NO L2		500
INV POL		100
NO L2		500



Analysis test

THE DEVICE MUST BE USED IN ACCORDANCE WITH THE FOLLOWS EMC INFORMATIONS

Prova di emissione	Conformità	Ambiente elettromagnetico
Emissioni RF	Gruppo 1	LeaderGun utilizza l'energia RF solo per il proprio funzionamento interno. Di conseguenza le sue emissioni RF sono molto basse e verosimilmente non provoca alcuna interferenza negli apparecchi elettronici posti nelle vicinanze
Emissioni RF	Classe B	LeaderGun è adatto per l'uso in tutti gli ambienti, compresi quelli domestici e quelli collegati direttamente ad un'alimentazione di rete pubblica a basso tensione che alimenta edifici utilizzati per scopi domestici
Emissione armonica	Classe A	
Emissioni di fluttuazioni di tensione/flicker	Conforme	

Prova d'umidità	Livello di prova IEC 60601	Livello di conformità	Ambiente elettromagnetico
Scarica elettrostatica	± 6 KV a contatto ± 8 KV in aria	± 6 KV a contatto ± 8 KV in aria	I pavimenti devono essere in legno, calcestruzzo o ceramica. Se i pavimenti sono in materiale sintetico, l'umidità relativa deve essere almeno del 30%
Transitori / Treni elettrici veloci	± 2 KV fase(I)-terra ± 1 KV fase(I)-fase(I)	± 2 KV modo comune ± 1 KV modo differenziale	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero
Sovratensioni	± 2 KV fase(I)-terra ± 1 KV fase(I)-fase(I)	± 2 KV modo comune ± 1 KV modo differenziale	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente residenziale o commerciale
Buchi di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso	< 5% UT (95% di buco) per 0,5 cicli 40% Ut (60% di buco) per 5 cicli 70% Ut (30% di buco) per 25 cicli < 5% UT (95% di buco) per 5 secondi	< 5% UT (95% di buco) per 0,5 cicli 40% Ut (60% di buco) per 5 cicli 70% Ut (30% di buco) per 25 cicli < 5% UT (95% di buco) per 5 secondi	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente residenziale o commerciale. Se l'utilizzatore di LeaderGun richiede un funzionamento continuato anche durante l'interruzione della tensione di rete si raccomanda di alimentare LeaderGun con un gruppo di continuità
Campo magnetico da frequenza di rete (50HZ)	3 A/m	3 A/m	I campi magnetici a frequenza di rete devono avere livelli caratteristici tipici degli ambienti residenziali o commerciali
Prove d'immunità	Livello di prove IEC 60601	Livello di conformità	Ambiente elettromagnetico

Prove d'immunità	Livello di prove IEC 60601	Livello di conformità	Ambiente elettromagnetico (distanza di un trasmettitore dall'apparecchiatura)
Radiofrequenza condotta	3 Veff	3 Veff	$d = 1,17 \cdot \sqrt{P}$ ove P è la potenza massima nominale d'uscita del trasmettitore in W secondo il costruttore del trasmettitore e d è la distanza di separazione in metri

			distanza di separazione in metri
Radiofrequenza irradiata	10 V/m (28 MHz+)	3 Veff	$d = 0,35 \cdot \sqrt{P}$ da 80 MHz a 800 MHz $d = 0,7 \cdot \sqrt{P}$ da 800 MHz a 1 GHz $d = 2,33 \cdot \sqrt{P}$ da 1 GHz a 2.5 GHz ove P è la potenza massima nominale d'uscita del trasmettitore in W secondo il costruttore del trasmettitore e d è la distanza di separazione in metri

Il Dispositivo è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati a radiofrequenza. L'operatore può contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) ed il dispositivo stesso come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.

Potenza di uscita massima del trasmettitore specificata (W)	Distanza di separazione alla frequenza del trasmettitore (m)			
	Da 15 KHz a 80MHz	Da 80MHz a 800MHz	Da 800MHz a 1GHz	Da 1GHz a 2,5GHz
0,01	0,12	0,04	0,07	0,23
0,1	0,37	0,11	0,22	0,74
1	0,17	0,35	0,70	2,33
10	3,69	1,11	2,21	7,38
100	11,67	3,50	7,00	23,33

Intended use

LEADERGUN "mesotherapy injector" is an electronic portable device for fully automatic injecting systems, it allows accurate and accurate injections without waste of medicine.

Environment: The Device is mainly used in the medical field in outpatient environments.

Operator type: The device can be used only by doctors possessing the necessary know how, about the use of DM in the field of treatments.

Clinical Purpose of the Device: Portable Electronic Device for Fully Automatic Injection Systems.

Restrictions on the use of the device: Transport and Storage: Minimum Temperature: -10° C, Maximum Temperature: 75° C, Minimum Relative Humidity: 30% Non Condensing, Maximum Relative Humidity: 95% No Condensation, Atmospheric Pressure Minimum: 700hPa, Maximum Atmospheric Pressure: 1060hPa

Operating: Minimum Temperature: 10° C, Maximum Temperature: 40° C, Minimum Relative Humidity: 30% Non Condensing, Maximum Relative Humidity: 75% No Condensation, Atmospheric Pressure Minimum: 700hPa, Maximum Atmospheric Pressure: 1060hPa.

Warnings - Possible side effects

No undesirable effects on the use of the device are observed when used in accordance with the manufacturer's instructions for use and maintenance.

Contraindications

Limits of use: The Device must be used in accordance with the EMC information referred to in Section 02. Radio equipment and mobile phones, if used near the Device, may affect the operation of the device. Use of accessories and cables other than those specified, with the exception of those sold by the device manufacturer as spare parts for internal components, may cause an increase in emissions or a decrease in the immunity of the device.

The Device should not be used near other Devices if it is not, you must be careful that the Device will continue to operate in its normal configuration.

Potential Hazard Situations:

environmental: if used outside the parameters indicated in this user manual.

Clinical Patient: according to the judgment of the physician using the device

Regarding device conditions: the device must be clean; syringes, needles must be sterile and disposable; the skin stabilizer (accessory supplied with DM) should be single use.

Of interaction between different devices or other devices: the Device interacts with the human body through the contact established by the "stabilizer for the skin" (accessory supplied with DM) with the area to be treated. In addition, the device operates with other devices such as sterile and disposable sterile syringes and needles that inoculate the suitable drug for treatment.

Handling of the product

Precautions and Warnings: LEADERGUN must be used in accordance with the EMC information contained in Annex 1 referred to in the last pages of this manual.

Radio equipment and cellular phones, if used near the LEADERGUN, may affect the operation of the device.

Use of accessories and cables other than those specified, with the exception of those sold by the LEADERGUN manufacturer as spare parts for internal components, may cause an increase in emissions or a decrease in the immunity of the appliance.

LEADERGUN should not be used near other Appliances otherwise you should be careful that LEADERGUN will continue to function in its normal configuration.

Cleaning the LEADERGUN:

WARNING: Maintenance is recommended before and after each use. Carefully clean the parts to be used at each treatment. Before and after each use, clean the body of the LEADERGUN and especially the end of the appliance and the sliding part with a cloth dampened with a septic product or cotton soaked with 90 ° alcohol.

Cleaning, Disinfection and Sterilization of Patient Contact Parties:

For more hygiene, sterile and single use syringes and needles should be used. Skin stabilizers (DM accessory) are disposable.

LEADERGUN Li-Ion Battery Management:

WARNING: Always charge the battery after a long period of inoperability.

For short periods of inoperability, it is advisable to leave the Charger Connected to the LEADERGUN Power Jack.

LEADERGUN penetration capacity:

In order to guarantee sufficient penetration capacity of the needle, it is advisable not to use LEADERGUN with the tip upwards. During use, the appliance must be held horizontally or with the tip down.

Device storage Mode:

In the original packaging (Carrying case).

Predictable improper use:

It is not foreseeable for improper use by the user if he or she strictly adheres to the manufacturer's instructions for use and maintenance of the DM.

Connecting and Disconnecting Leading Parts of LEADERGUN

Syringe Placement:

- Prepare the syringe with the product to be injected.
- Raise Cover (C).
- Turn on LEADERGUN.
- From the Home Home, by Joystick (J), select the desired work program (Glow, Lipo, Stretch, PRP or Botulinum) and press Enter.
- LEADERGUN will upload the selected work program.
- The Cute Stabilizer (A) will automatically move in such a way that it respects the programmed depth of penetration.
- Next, the Carrellino (B) will also move automatically and position it in such a way as to easily accommodate the syringe to be used.
- The Display (D) will display the PLEASE WAIT and then the Syringe Housing Improvement screen where the Joystick (J) up and down keys can refine the syringe housing.
- Place the needle in the Syringe Base Attachment (E).
- Next, place the syringe plunger in the Punching Punch Socket (F) compartment in the seat corresponding to the ml capacity of the syringe used.
- Get down the Cover (C).
- WARNING: Do not force the Push Tiller Cartridge (B) manually, but always use the Syringe Housing Enhancement Function.
- To enable this function, press the center button of the Joystick (J) for about 3s with the cursor positioned on SETUP.

Positioning of the Pocket Cute Stabilizer Port:

The LEADERGUN is equipped with a Metal Stabilizer Door Pad located at the front. It is used to accommodate the Cute Stabilizer (A) and define, by means of a stepper motor, the depth of the needle.

At power-up, once the work program is loaded, it will be positioned according to the preset depth data, while turning off will go back to its zero position.

Positioning of the Skin Stabilizer:

Once the Skin Stabilizer Push Point is positioned according to the preset depth data, you can accommodate the Skin Stabilizer (A) that serves to display the inoculation point of the product.

Connecting to the Power Supply

- Insert the power cord or plug of the Charger into an electrical outlet.
- Connect the Charger Output Cable to the Power Jack (K) located at the bottom of the device handle.
- The battery charging symbol will appear on the display.
- Wait about 3:00 hours for full charge or the Display shows battery charge.
- Battery charge is automatically handled by the microprocessor so an overload will not cause damage to the battery.
- The battery can not be switched on while charging the battery.

Removable parts and accessories used:

All accessories supplied with the LEADERGUN are referred to in the "Package Contents" section.

The use of other unqualified accessories by the manufacturer diminishes the safety of the appliance.

Their use demands responsibility to the user.

Functional features

How to recharge LEADERGUN battery:

Plug the AC/DC adapter's power cord into an electrical socket compliant with the specifications mentioned above.

Connect the AC / DC adapter's output cable in the Plug (J) located at the base of the device.

The display will show the battery charge icon.

Wait for about 3:00 hours to fully charge or the Display to give an indication of battery charged.

The battery charge process is automatically handled by the microprocessor so an overcharging will not cause damage to it.

While charging the battery you can turn the device on and possibly operate.

How to turn on the LEADERGUN:

Press for few seconds the middle Joystick (J) button.

The display lights on will shows LEADERGUN logo as shown in fig.1



Fig. 1. Turning on

Immediately after the Display (D) shows the main Home page as shown in fig.2



Fig. 2. Home

How to turn off the LEADERGUN:

Press for 3sec. the middle joystick (J) button with the cursor positioned on PW OFF. The LEADERGUN will turn off and if still plugged to the AC/DC adapter, a battery charge icon will be shown on the Display (D)

How to use the LEADERGUN:

You can select the following modes with the joystick (J), from the main Home page:

- **GLOW:** The LEADERGUN will load the MESOGLOW program in which working mode is preset by default as follows:
 - Syringe: 5.0ml
 - Needle: 4.0mm
 - Penetration depth: 2.0mm
 - Drop: micro
 - Penetration time: 0.2s
 - Injection: single (spot)
- or with the SETUP function you can set the following parameter
 - **Syringe:** 1.0 ml, 2.0 ml, 2.5ml, 5.0ml, 10.0ml

- Needle: 4.0mm, 6.0mm, 13mm
- Penetration depth: from 1.0mm to 13.0mm
- Drop:

Syringe	Pico	Micro	Macro
1.0ml	0.007ml	0.013ml	0.025ml
2.0ml	0.013ml	0.025ml	0.05ml
2.5ml	0.013ml	0.025ml	0.05ml
5.0ml	0.025ml	0.05ml	0.10ml
10.0ml	0.05ml	0.10ml	0.15ml

+/-20%

- Needle's time into the skin injection after:
 2.0ms, 3.0ms, 4.0ms, 5.0ms, 6.0ms, 7.0ms, 8.0ms, 9.0ms, 10.0ms
- Injection: single or repetitive
 In case of repetitive injection you can set the number of injections per minute. In details:

Syringe	Pico	Micro	Macro
1.0ml	150-120-80	116-82-55	82-51-34
2.0ml	141-109-73	107-73-49	72-44-29
2.5ml	141-109-73	107-73-49	72-44-29
5.0ml	120-86-57	82-52-34	51-29-19
10.0ml	91-59-39	55-32-21	40-22-14

+/-20%

- LIPO: The LEADERGUN will load the MESOLIPO program in which working mode is preset by default as follows:
- Syringe: 10.0ml
- Needle: 13.0mm
- Penetration depth: 9.0mm
- Drop: macro
- Needle's time into the skin injection after: 0.2s
- Injection: single (spot)
 or with the SETUP function you can set the following parameters:
- Syringe : 1.0 ml, 2.0 ml, 2.5ml, 5.0ml, 10.0ml
- Needle: 4.0mm, 13.0mm
- Penetration depth from: 1.0mm to 13.0mm

- Drop:

Syringe	Pico	Micro	Macro
1.0ml	0.007ml	0.013ml	0.025ml
2.0ml	0.013ml	0.025ml	0.05ml
2.5ml	0.013ml	0.025ml	0.05ml
5.0ml	0.025ml	0.05ml	0.10ml
10.0ml	0.05ml	0.10ml	0.15ml

+/-20%

- Needle's time into the skin injection after:
 2.0ms, 3.0ms, 4.0ms, 5.0ms, 6.0ms, 7.0ms, 8.0ms, 9.0ms, 10.0ms
- Injection: single or repetitive
 In case of repetitive injection you can set the number of injections per minute. In details:

Syringe	Pico	Micro	Macro
1.0ml	150-120-80	116-82-55	82-51-34
2.0ml	141-109-73	107-73-49	72-44-29
2.5ml	141-109-73	107-73-49	72-44-29
5.0ml	120-86-57	82-52-34	51-29-19
10.0ml	91-59-39	55-32-21	40-22-14

+/-20%

- STRETCH: The LEADERGUN will load the STRETCHMARKS program in which working mode is preset by default as follows:
 - Syringe: 10.0ml
 - Needle: 13.0mm
 - Penetration depth: 12.0mm
 - Flux: 1.0ml / min
 - Needle's time into the skin injection after: 0.4s
 - Injection: continuous
 or with the SETUP function you can set the following parameters:
 - Syringe : 1.0 ml, 2.0 ml, 2.5ml, 5.0ml, 10.0ml
 - Needle: 4.0mm, 13.0mm
 - Penetration depth from: 1.0mm to 13.0mm

- Injection: single or repetitive

In case of repetitive injection you can set the number of injections per minute. In details:

Syringe	Pico	Micro	Macro
1.0ml	150-120-80	116-82-55	82-51-34
2.0ml	141-109-73	107-73-49	72-44-29
2.5ml	141-109-73	107-73-49	72-44-29
5.0ml	120-86-57	82-52-34	51-29-19
10.0ml	91-59-39	55-32-21	40-22-14

+/-20%

- TOXIN The LEADERGUN will load the TOXIN program in which working mode is preset by default as follows:

- Syringe: 1.0ml
- Needle: 13.0mm
- Penetration depth: 2.0mm
- Drop: micro
- Needle's time into the skin injection after: 0.4s
- Injection: single (spot)

or with the SETUP function you can set the following parameter:

- Syringe : 1.0 ml, 2.0 ml, 2.5ml, 5.0ml, 10.0ml
- Needle: 4.0mm, 6.0mm; 13.0mm
- Penetration depth from: 1.0mm to 13.0mm
- Drop:

Syringe	Pico	Micro	Macro
1.0ml	0.007ml	0.013ml	0.025ml
2.0ml	0.013ml	0.025ml	0.05ml
2.5ml	0.013ml	0.025ml	0.05ml
5.0ml	0.025ml	0.05ml	0.10ml
10.0ml	0.05ml	0.10ml	0.15ml

+/-20%

- Needle's time into the skin injection after:
 2.0ms, 3.0ms, 4.0ms, 5.0ms, 6.0ms, 7.0ms, 8.0ms, 9.0ms, 10.0ms

Syringe	1.0ml / min	5.0ml / min	10ml / min
1.0ml	OK	OK	N. A.
2.0ml	OK	OK	OK
2.5ml	OK	OK	OK
5.0ml	OK	OK	OK
10.0ml	OK	OK	N. A.

- Needle's time into the skin injection after:
 2.0ms, 3.0ms, 4.0ms, 5.0ms, 6.0ms, 7.0ms, 8.0ms, 9.0ms, 10.0ms
 - Injection: continuous
 - LATEST: The LEADERGUN will return to the mode before the shutdown.
 - MR: The LEADERGUN will load from the internal memory a mode previously stored by the operator.
 - PRP: The LEADERGUN will load the PRP program in which working mode is preset by default as follows:
 - Syringe: 5.0ml
 - Needle: 13.0mm
 - Penetration depth: 2.0mm
 - Drop: micro
 - Needle's time into the skin injection after: 0.4s
 - Injection: single (spot)
- or with the SETUP function you can set the following parameter:
- **Syringe : 1.0 ml, 2.0 ml, 2.5ml, 5.0ml, 10.0ml**
 - Needle: 4.0mm, 6.0mm; 13.0mm
 - Penetration depth from: 1.0mm to 13.0mm
 - Drop:

Syringe	Pico	Micro	Macro
1.0ml	0.007ml	0.013ml	0.025ml
2.0ml	0.013ml	0.025ml	0.05ml
2.5ml	0.013ml	0.025ml	0.05ml
5.0ml	0.025ml	0.05ml	0.10ml
10.0ml	0.05ml	0.10ml	0.15ml

+/-20%

- Needle's time into the skin injection after:
 2.0ms, 3.0ms, 4.0ms, 5.0ms, 6.0ms, 7.0ms, 8.0ms, 9.0ms, 10.0ms

- Injection: single or repetitive

In case of repetitive injection you can set the number of injections per minute. In details:

Syringe	Pico	Micro	Macro
1.0ml	150-120-80	116-82-55	82-51-34
2.0ml	141-109-73	107-73-49	72-44-29
2.5ml	141-109-73	107-73-49	72-44-29
5.0ml	120-86-57	82-52-34	51-29-19
10.0ml	91-59-39	55-32-21	40-22-14

+/-20%

How to access the MESOGLOW program

From the main Home, select, with the joystick (J), the GLOW icon and press Enter.

The LEADERGUN will load the MESOGLOW program in which the icons are marked by a small green triangle.

The Display (D) will show the screen in fig.3



Fig. 3. GLOW-SETUP-SPOT

Once the program has been loaded, the Trolley (B) will move automatically and will position in such a way to easily accommodate the syringe loaded with 5.0ml.

The Display (D) will show first a "PLEASE WAIT" message and then the fig.4 screen in which it's possible to refine the syringe accommodation using UP and DOWN joystick button.



Fig. 4. Refining syringe accommodation

After about 5 sec., or pressing the middle Joystick (J) button, the Display (D) will show fig.3 screen once again.

In SETUP mode the Trigger (G) will be inactive while the Joystick (J) will be active in order to ensure maximum safety against accidental injections.

To activate the Trigger (G) and then operate according to preset parameters, you must switch from SETUP mode to OPERATE mode.

To do that, position the cursor on SETUP and press Enter. The Display (D) will show the following screen:



Fig. 5. GLOW-OPERATE-SPOT

Except for its middle button, the Joystick (J) will be inactive, while the Trigger (G) will be active. At each press of the Trigger (G) the LEADERGUN will make a single injection (SPOT) according to preset parameters.

How to access the MESOLIPO program

From the main Home, select, with the joystick (J), the LIPO icon and press Enter.

The LEADERGUN will load the MESOLIPO program, in which the icons are marked by a small red triangle.

The Display (D) will show the screen in fig.6



Fig. 6. LIPO-SETUP-SPOT

Once the program has been loaded, the Trolley (B) will move automatically and will position in such a way to easily accommodate the syringe loaded with 10ml.

The Display (D) will show a "PLEASE WAIT" message and then the fig.7 screen in which it's possible to refine the syringe accommodation using UP and DOWN joystick button.



Fig. 7. Refining syringe accommodation

After about 5 sec., or pressing the middle Joystick (J) button, the Display (D) will show fig.6 screen once again.

In SETUP mode the Trigger (G) will be inactive while the Joystick (J) will be active in order to ensure maximum safety against accidental injections.

To activate the Trigger (G) and then operate according to preset parameters, you must switch from SETUP mode to OPERATE mode.

To do that, position the cursor on SETUP and press Enter.

The Display (D) will show the following screen:



Fig. 8. LIPO-OPERATE-SPOT

Needle's time into the skin injection after



Except for its middle button, the Joystick (J) will be inactive, while the Trigger (G) will be active. At each press of the Trigger (G) the LEADERGUN will make a single injection (SPOT) according to preset parameters.

How to access the STRETCHMARKS program

From the main Home, select, with the joystick (J), the STRETCH icon and press Enter.

The LEADERGUN will load the STRETCHMARKS program, in which the icons are marked by a small blue triangle.

The Display (D) will show the screen in fig.9



Fig. 9. STRETCH - SETUP

Once the program has been loaded, the Trolley (B) will move automatically and will position in such a way to easily accommodate the syringe loaded with 10ml.

The Display (D) will show a "PLEASE WAIT" message and then the fig.10 screen in which it's possible to refine the syringe accommodation using UP and DOWN joystick button.



Fig. 10. Refining syringe accommodation

After about 5 sec., or pressing the middle Joystick (J) button, the Display (D) will show fig.9 screen once again.

In SETUP mode the Trigger (G) will be inactive while the Joystick (J) will be active in order to ensure maximum safety against accidental injections.

To activate the Trigger (G) and then operate according to preset parameters, you must switch from SETUP mode to OPERATE mode.

To do that, position the cursor on SETUP and press Enter.

The Display (D) will show the following screen:



Fig. 11. STRETCH - OPERATE

Except for its middle button, the Joystick (J) will be inactive, while the Trigger (G) will be active. At each press of the Trigger (G) the LEADERGUN will make a single injection (SPOT) according to preset parameters.

Except for its middle button, the Joystick (J) will be inactive, while the Trigger (G) will be active. At each press of the Trigger (G) the LEADERGUN will make a single injection (SPOT) according to preset parameters.

How to access the TOXIN program

From the main Home, select, with the joystick (J), the TOXIN icon and press Enter.

The LEADERGUN will load the TOXIN program, in which the icons are marked by a small blue triangle.

The Display (D) will show the screen in fig.9



Fig. 9. TOXIN - SETUP

Once the program has been loaded, the Trolley (B) will move automatically and will position in such a way to easily accommodate the syringe loaded with 10ml.

The Display (D) will show a "PLEASE WAIT" message and then the fig.10 screen in which it's possible to refine the syringe accommodation using UP and DOWN joystick button.



Fig. 10. Refining syringe accommodation

After about 5 sec., or pressing the middle Joystick (J) button, the Display (D) will show fig.9 screen once again.

In SETUP mode the Trigger (G) will be inactive while the Joystick (J) will be active in order to ensure maximum safety against accidental injections.

To activate the Trigger (G) and then operate according to preset parameters, you must switch from SETUP mode to OPERATE mode.

To do that, position the cursor on SETUP and press Enter.

The Display (D) will show the following screen:



Fig. 11. TOXIN - OPERATE

Except for its middle button, the Joystick (J) will be inactive, while the Trigger (G) will be active. At each press of the Trigger (G) the LEADERGUN will make a single injection (SPOT) according to preset parameters.

Except for its middle button, the Joystick (J) will be inactive, while the Trigger (G) will be active. At each press of the Trigger (G) the LEADERGUN will make a single injection (SPOT) according to preset parameters.

How to access the PRP program

From the main Home, select, with the joystick (J), the PRP icon and press Enter.

The LEADERGUN will load the STRETCHMARKS program, in which the icons are marked by a small blue triangle.

The Display (D) will show the screen in fig.9



Fig. 9. PRP- SETUP

Once the program has been loaded, the Trolley (B) will move automatically and will position in such a way to easily accommodate the syringe loaded with 10ml.

The Display (D) will show a "PLEASE WAIT" message and then the fig.10 screen in which it's possible to refine the syringe accommodation using UP and DOWN joystick button.



Fig. 10. Refining syringe accommodation

After about 5 sec., or pressing the middle Joystick (J) button, the Display (D) will show fig.9 screen once again.

In SETUP mode the Trigger (G) will be inactive while the Joystick (J) will be active in order to ensure maximum safety against accidental injections.

To activate the Trigger (G) and then operate according to preset parameters, you must switch from SETUP mode to OPERATE mode.

To do that, position the cursor on SETUP and press Enter.

The Display (D) will show the following screen:



Fig. 11. PRP- OPERATE

Except for its middle button, the Joystick (J) will be inactive, while the Trigger (G) will be active. At each press of the Trigger (G) the LEADERGUN will make a single injection (SPOT) according to preset parameters.

How to change preset parameters

In any programs is possible to change preset parameters.

In SETUP mode select with the Joystick (J) the icon with parameter to be changed and press Enter.

The Display (D) will show new parameters by mean of the Left and Right Joystick (J) buttons.

Select the new parameter and press Enter to confirm.

Select another icon, if necessary, to repeat the operation or switch to OPERATE mode to operate with the new parameters.

How to set Display contrast

While changing parameters is possible to change Display (D) contrast with Up and Down Joystick (J) buttons.

How to work in Repetitive Injection mode

It's possible to work in repetitive (burst) injection mode only in MESOGLOW and MESOLIPO programs.

To do that, select SPOT icon in SETUP mode and press Enter.

The LEADERGUN will switch from SPOT to BURST mode and the display will show fig 12 screen if you are in MESOGLOW program or fig. 13 if you are in MESOLIPO program:



Fig. 12. GLOW-SETUP-BURST



Fig. 13. LIPO-SETUP-BURST

In both cases is possible to change the number of injections per minute.

To change this setting select the middle icon with the Joystick (J) and press Enter.

The Display (D) will show new parameters by mean of the Left and Right Joystick (J) buttons.

Select the new parameter and press ENTER to confirm.

The screen with the new parameter will be shown on the Display(D).

Select another icon, if necessary, to repeat the operation or switch to OPERATE mode to work with the new parameters.

To do that, position the cursor on SETUP and press Enter

The Display (D) will show fig 14 screen if you are in MESOGLOW program or fig.15 if you are in MESOLIPO program:



Fig. 14. GLOW - OPERATE - BURST



Fig. 15. LIPO - OPERATE - BURST

Except for its middle button, the Joystick (J) will be inactive, while the Trigger (G) will be active. At each press of the Trigger (G) the LEADERGUN will make a cycle of repetitive injections (BURST) according to parameters set.

To return to single injection mode (SPOT), press Enter to switch to SETUP mode.

Select BURST function with the Joystick (J) and press Enter.

The LEADERGUN will return to single injection mode (SPOT).

How to store changed parameters in memory

In MESOGLOW, MESOLIPO and STRETCHMARKS is possible to store in memory the new configuration once you have changed the parameters.

Position the cursor on SETUP with the Joystick (J), select SAVE function and press Enter.

Select with Left and Right Joystick (J) buttons the memory location where you want to store the new configuration.

The Display (D) will show fig.16 screen if the selected memory location is still occupied otherwise will show fig.17 screen if memory location is empty.



Fig. 16. Save occupied



Fig. 17. Save empty

Press Enter to store in memory and return to the new working configuration.
To exit from SAVE function without storing the new configuration in memory, select EXIT (fig.18) with Left Joystick (J) button, then press Enter



Fig. 18. Memoria Exit

How to return to main HOME

In SETUP mode, position the cursor on BACK and press Enter.
The Display (D) will show the main Home screen (fig.2).

How to return to working program before shutdown

In the main Home select LATEST function with the Joystick (J) and press Enter.
The LEADERGUN will load the last program before shutdown and the Display (D) will show the parameters set.

How to recall from memory a saved work program

From main Home select MR function with the Joystick (J) and press Enter.
The Display (D) will show fig.19 screen concerning the first program stored in memory.



Fig. 19. MR 1

Select the desired work program stored using Left and Right Joystick (J) buttons and press Enter.
The LEADERGUN will load the program from the memory and the Display (D) will show the parameters set.
To exit from MR function without recalling a stored work program select EXIT (fig.20) using Left Joystick (J) button and press Enter



Fig. 20 MR Exit



1. Premessa / *Premise*

In questo documento il **Fabbricante** garantisce e dichiara, sotto la propria responsabilità, che il dispositivo immesso in commercio soddisfa i requisiti essenziali previsti dalla Direttiva 93/42/CEE e del Decreto legislativo n. 46 del 24/02/1997.

In this document, the Manufacturer guarantees and declares, under his own responsibility, that the device placed on the market satisfies the essential requirements of the Directive 93/42 / EEC and of the Legislative Decree n. 46 of 24/02/1997.

2. Modello / *Model*

DICHIARAZIONE DI CONFORMITÀ CE / *DECLARATION OF CE CONFORMITY*
per marcatura CE in base a Direttiva Dispositivi Medici 93/42/CEE – Allegato II
for CE marking according to Medical Devices Directive 93/42 / EEC -Annex II

Emessa da / *Issued by:* Mesotech S.r.l

Sede Legale / *Registered office:* Via Riviera di Chiaia, 242 – 80121 Napoli

Sede operativa / *Operational headquarters:* Via Mazzini, 52 – 80022 Arzano (NA)

Prodotto / *Product:* Iniettore per mesoterapia / *injector for mesotherapy*

Modello / *Model:*  LEADERGUN

GMDN: 45726 **CND:** V0502

Classe di rischio secondo 93/42/CEE / *Risk class according to 93/42 / EEC* **Classe / *Class:*** IIb

Norme applicabili / *Applicable standards:*

- Direttiva Dispositivi Medici 93/42/CEE, pubblicata sulla GUCE L. 169 del 1993 e successive modifiche ed integrazioni.
- D.Lgs n. 46 del 24 febbraio 1997 "attuazione della direttiva 93/42/CEE del 14 giugno 93" e successive modifiche ed integrazioni
- CEI IEC 62304:2019 "Medical devices software—Software life cycle processes"
- CEI EN 60601-1-4:2000 "Apparecchi elettromedicali. Parte 1: Norme generali per la sicurezza. 4. Norma collaterale: sistemi elettromedicali programmabili"
- CEI EN 60601-1:2012 "Apparecchi elettromedicali. Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali"
- CEI EN 60601-1:2006+A12:2014 "Apparecchi elettromedicali. Parte 1: Norme generali per la sicurezza"
- CEI EN 60601-1-6:2016 "Apparecchiature elettromedicali. Parte 1: Prescrizioni generali relative alla sicurezza fondamentale e alle prestazioni essenziali – Norma collaterale: Usabilità"
- CEI EN 60601-1-2:2014 "Apparecchi elettromedicali -Parte 1: Prescrizioni generali per la sicurezza fondamentale e prestazioni essenziali - Norma collaterale: Compatibilità elettromagnetica - Prescrizioni e prove"
- UNI CEI EN 15223-1:2017 "Simboli utilizzati per l'etichettatura dei dispositivi medici"
- UNI CEI EN 1041:2013 "Informazioni fornite dal fabbricante dei dispositivi medici"
- Direttiva Comunitaria 85/374/CEE in materia di responsabilità per danno da prodotti difettosi.

Intervento notificato / *Notified body:* Kiwa Cermet Italia S.r.l. cod. 0476

Certificazione / *Certification:* n° MED 29109 (CEE 93/42 Allegato II) / n° MED 29109 (CEE 93/42 Annex II)

Le relative documentazioni tecniche sono a disposizione delle autorità competenti nella sede della Mesotech S.r.l.
The related technical documentation is available to the competent authorities at the headquarters of Mesotech S.r.l.

Napoli / Naples, 23/01/2020

Roberto Ferrarì

(Rappresentante Legale della Mesotech S.r.l.)

(Legal representative of Mesotech S.r.l.)

Sistema di segnalazione per i dispositivi medici *Reporting system for medical devices*



A) Dati relativi al dispositivo medico / <i>Details about the Medical Device</i>	
Fabbricante (nome, ragione sociale e indirizzo, codice fiscale o VAT Number) <i>Manufacturer (name, reason name and address, tax identification number or VAT Number)</i>	
Distributore (nome, ragione sociale e indirizzo, codice fiscale o VAT Number) <i>Distributor (name, name and address, tax or VAT Number)</i>	
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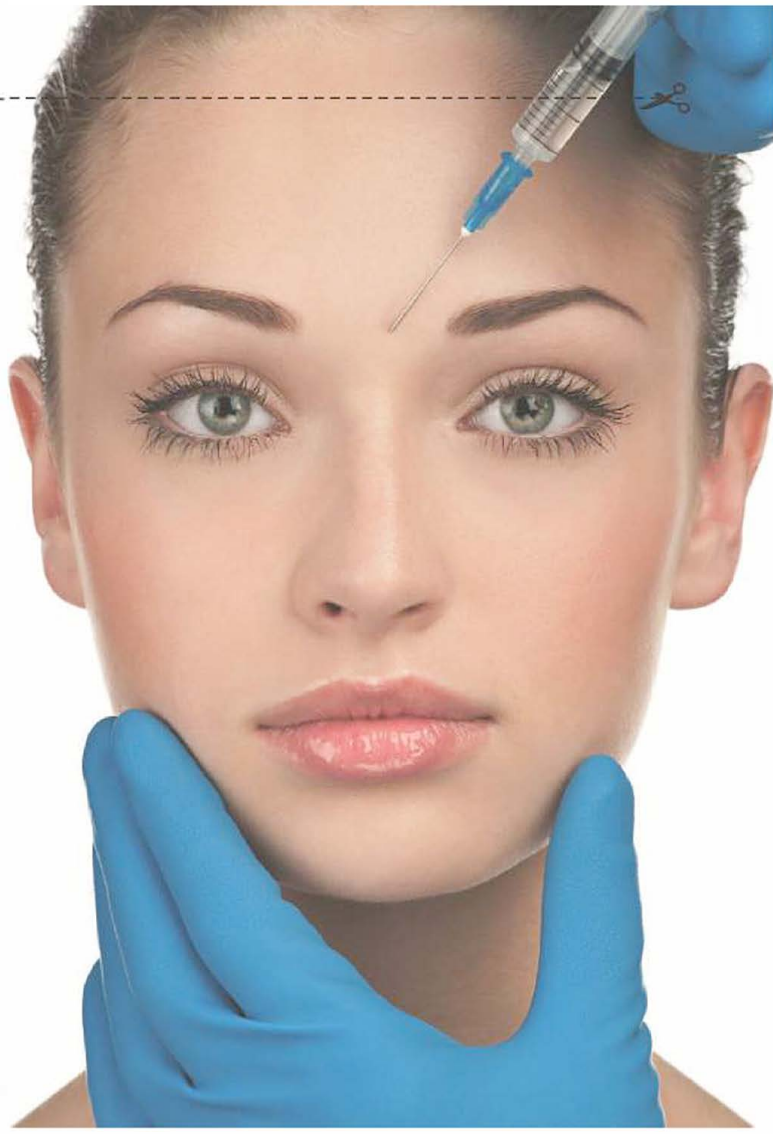
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- Perfect exibility and strength of the steel tube and the plastic "hub"
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- Needleflex reduces the risk of bruising and inflammatory reactions.
- A box contains 100 pieces

- Needletech hypodermic needles are made with a careful selection of raw materials, maintaining a particular attention during the packaging phase, in order to avoid any defect of the tips of the needles.
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- Accurate sharpening of needles minimizes the pain associated with the injection.
- Ultrathin diameters (0.3 and 0.20 mm) make this product excellent for mesotherapy, filler, botulinum and sclerosing treatments.
- 100 piece box.
- In sterile single-use EO blister packs.

Cone	Size	Lenght
Luer	30G	25mm
Luer	27G	38mm
Luer	27G	50mm
Luer	25G	38mm
Luer	25G	50mm
Luer	22G	50mm
Luer	22G	100mm
Luer	18G	50mm
Luer	18G	100mm



Cone	Size	Lenght
Luer	33G	4mm
Luer	32G	8mm
Luer	32G	4mm
Luer	31G	13mm
Luer	31G	6mm
Luer	31G	4mm
Luer	30G	13mm
Luer	27G	13mm
Luer	26G	13mm



Mesotech is specializing in providing aesthetic and skin care technologies for the beauty and medical institutes. Customer satisfaction and quality are the first priorities for our staff. We develop our Range in a continuous dialogue with our customers. Development of new products from original ideas to deep research. Original formulations where unique ingredients are selected to normalise and correct skin disorders and imbalances

Mesotech è un'azienda innovativa impegnata nella progettazione, produzione e vendita di apparecchiature per il settore medico, estetico e del fitness. Con la nostra offerta desideriamo prenderci cura della bellezza dei vostri Clienti, e per questa ragione utilizziamo le più innovative tecnologie, selezioniamo con cura i materiali, in perfetta sintonia con le direttive per la marcatura CE.



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