

CARBOXYTHERAPY MEDIKA

INSTRUCTION MANUAL



Wrocław, April 2017

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I. DEVICE FEATURES

The Carboxytherapy Medika device is a modern exclusive appliance developed with implementation of innovative solutions. Its production process involves domestic high quality components, and its operation comfort and durability are obtained due to Corian enclosure application, resistant to abrasion and chemicals used in parlours. This makes the device resistant to discoloration and accidental impact as well as facilitates keeping it clean.

Selecting the proper function in the control panel, we enter the list of possible procedures. Our appliance has 22 ready procedure programmes for various body parts. Using the touch panel, parameters can be modified and saved in the particular programmes, whereas the big colour display and intuitive menu facilitate the procedure significantly.

After selection of the proper program, the control panel is opened, allowing for precise selection of parameters, suggesting proper setting of dosage, gas temperature, etc. to the user. Using the arrows, we can customise the procedure, adjusting the parameters to the needs of the given client. Pre-set software will not allow to exceed safe values.

Destination of medical device and indication for surgery

II. DESTINATION OF MEDICAL DEVICE AND INDICATION FOR SURGERY

Medical device Carboxytherapy is a machine containing software and working in connection with this software and it is destined to use for people in therapeutic purposes, where intradermal and subcutaneous methods of carbon dioxide injections are used for the following disease units:

- Local obesity – E65.1
- Stretch marks – L90.6
- Psoriasis – L40, L40.8, L40.9
- Scars – L90.5

Two software panels are used in this unit:

1. First panel: “Automatic panel” – designed for doctors and beauty salons.

This panel has 22 ready treatment programs divided into individual parts of the body. Gas flow is in the range 40 ccm/min – 200 ccm/min. Dose of gas in single treatment 5 ccm – 500 ccm. Gas temperature at the outlet is adjustable from 20 to 50 Celsius degrees.

2. Second panel: “Manual Panel” – designed only for doctors and doctor's office.

Additionally in this program, the option of increased gas flow rate is set – regulation in range 40 ccm/min – 300 ccm/min. Dose regulated in range 5 ccm to 20000ccm.

Manual panel is available with enabled medical work option.

III. CONTRAINDICATIONS

- Acute cardiac failure
- Kidney failure, dialyses
- Recent stroke
- Chronic pulmonary diseases, COPD
- Uncontrolled blood pressure
- Epilepsy
- Recent phlebitis or pulmonary embolism
- Uncontrolled diabetes
- Cancer, chemotherapy
- Wound healing disturbances, connective tissue diseases
- Von Willebrand disease
- Haemophilia
- Bacterial, viral and fungal infection
- Foreign body in the region under therapy
- Pregnancy
- Severe lung failure
- Herpes
- Inflammation of the skin, fungal infections
- Bacterial and viral infections
- Intake of anticoagulants, such as: (Acenocumarol WZF, Sintrom, Cilostop, Cilozek, Decilosal, Noclaud, Pradaxa, Fragmin, Clexane, Clexane forte, Arixtra, Coaparin, Agregex, Carder, Clopidix, Clopidogrel, Clopidogrelum 123ratio, Clopigamma, Grepid 75 mg, Pegorel, Plavix, Plavocorin, Trombex, Vixam, Zyllt, Fraxiparine, Fraxiparine Multi, Fraxodi, Efiend, Xarelto, Biostrepta, Distreptaza, Vessel Due F, Brilique, Aclotin, Apo-Clodin, Iclopilid, Ifapidin, Ticlo, Warfin.
- Intake of anti-glaucoma drugs, such as: (Diuramid, Azopt, Brinzolamide Sandoz, Optilamid, Azarga, Simbrinza, Dolopt, Dorzolamid STADA, Dorzolamid Teva, Dorzolamide Genoptim, Dorzostill, Dropzol, Nodom, Oftidor, Rozalin, Trusopt, Cosopt, Dolopt Plus, Dorzolamide + Timolol Genoptim, Dotiteva, Dropzol Tim, Nodom Combi, Oftidorix, Rozacom, Tymolamid

IV. TECHNICAL DATA

1. Operating conditions

- Operating gas - certified, medical, laparoscopic, CO₂ "LAPAROS"
- Adjustable temperature of the supplied gas, from 20°C to 50°C;
- Adjustable gas flow, from 40cc/m to 200cc/m;
- Adjustable gas dosage, from 5cc to 5000cc;
- Use of bacterial hydrophobic filters;
- CO₂ pressure control for the supply device;
- Full automation;
- Large 8" screen with intuitive menu;
- 22 ready procedure programs divided according to body parts;
- Possibility of modification and saving of set parameters in the particular procedure programs;
- Touch panel control;
- Stylish, black and white casing, made of Corian® material;
- Manufacturer's warranty - 30 months;

2. Technical conditions

- Dimensions: 97cm x 40cm x 40 cm;

- Weight: 20 kg;
- Maximum device power - 120 VA;
- Power supply – 230V; 50Hz;
- Designed and manufactured in Poland;
- Degree of IP protection

V. SAFETY DURING USE



”WARNING! READ THE INSTRUCTION MANUAL”

Marking has been placed on the casing of the device since its handling, in violation of the instructions for use, could jeopardize the safety of the person undergoing the treatment or operating the device.

- Before first use please read the instructions carefully.
- Do not bend the power cable to the central control unit.
- Keep the device away from electric heaters and other heat sources.
- Protect from humidity, water and dust.
- Keep the device away from water. Direct contact with water is unacceptable and risk of electric shock.
- After the treatment ends or before cleaning, turn off the device and disconnect from the power outlet.
- Do not pull the mains plug out of the appliance.
- Keep the device in place not available for children.
- Do not put the device into a sealed container, do not block the vents.

SAFETY OF USING CO₂ MEDICAL CYLINDERS

- Independent connection of the gas cylinder should be preceded by training.
- Always ensure that the cylinder is properly connected.
- After each operation, fully tighten the cylinder valve.
- When unscrewing and turning the bottle, hold the bottle with the other hand.
- The bottle must always be clamped on the clamping bracket.
- The CO₂ cylinder should be transported and stored vertically, secured against accidental displacement.
- The cylinder should not be subjected to direct sunlight or severe temperature changes.
- Do not hit, do not drop the bottle.
- Self repair and filling of CO₂ cylinders are not permitted.

HYGIENE AND SAFETY

- Before the procedure clean the skin (treatment area) very carefully.
- The person performing the treatment must use disposable gloves.
- During the procedure do not touch any objects, which are not sterile or were not disinfected.
- Use always sterile needles, tubing and filters (disposable equipment) for every client and every procedure cycle; disposable procedures should be taken out of the package directly through the procedure.
- Ensure that disposable packaging and accessories are not damaged (if the packaging is damaged, the material may not be fully sterile).
- Do not use disposable accessories after the expiry date.
- When inserting the needle into the tubing, do not touch the top of the needle.
- When mounting the filter on the device, do not touch its tabs.

- During the procedure be careful that the needle does not come in contact with contaminated materials accidentally.
- Just after the procedure dispose of disposable accessories to a medical waste container (proper medical waste must comply with local regulations).
- Improper handling can cause injury.
- In case of contaminated needle, consult your physician immediately.

PRECAUTIONS

To prevent skin damage:

- adjust the dose and flow rate to the type of treatment and individual characteristics of the client,
- very carefully inject the needle, maintaining the right angle and depth of introduction,
- avoid sun exposure, use the sauna and swimming pool area for 24 hours after the treatment.
- maintain hygienic areas of puncture (avoid touching, dirty clothing, prevent dirt) for at least 24 hours after treatment.

CONDITIONS OF USE OF THE DEVICE

The device is designed for indoor use where condensation of water steam has not occurred.

Required climatic conditions:

- temperature: from 10°C to 40°C
- relative humidity of air: from 30% to 80%
- atmospheric pressure: from 700 hPa to 1060 hPa

The device is designed only for professional use and **can only be handled by a trained person**. The manufacturer is not liable for any damage caused by improper use of the equipment.

The device is powered by mains voltage, any damage to the wires or the casing may cause electric shock, fire or serious damage to equipment

VI. LIST OF ALL PARTS OF THE DEVICE

Make sure all parts are in the package

Fixed parts:	
Device	1
Power cord	1
Foot switch	1
“Lapros” CO ₂ cylinder	1

CO ₂ reducer	1
Grip	1
Starter pack:	
Gas infusion tubes	10
Antibacterial filters	3
CO ₂ administration needles	10

VII. DEVICE SPECIFICATIONS

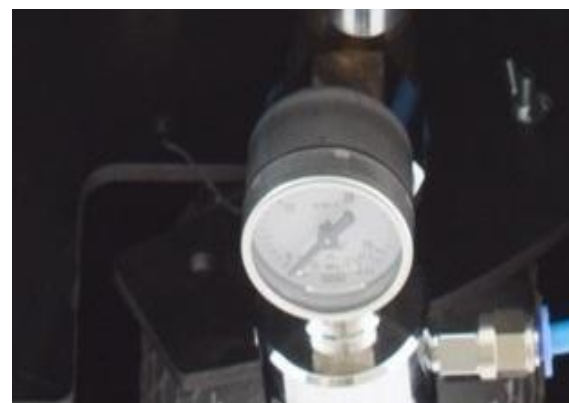
Device's back panel



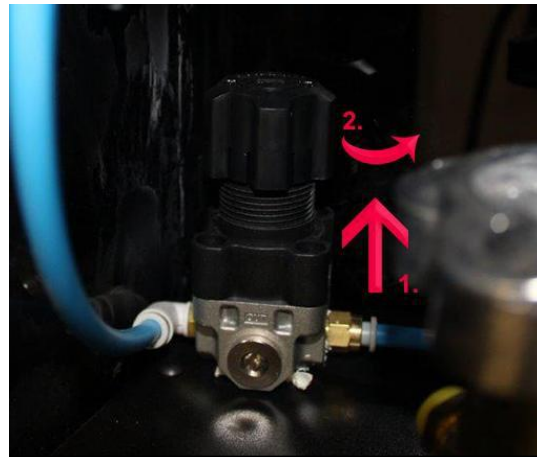
CO₂ cylinder



CO₂ cylinder opening direction



CO₂ reducer



Pressure reducer

Device's side panel



Needle grip



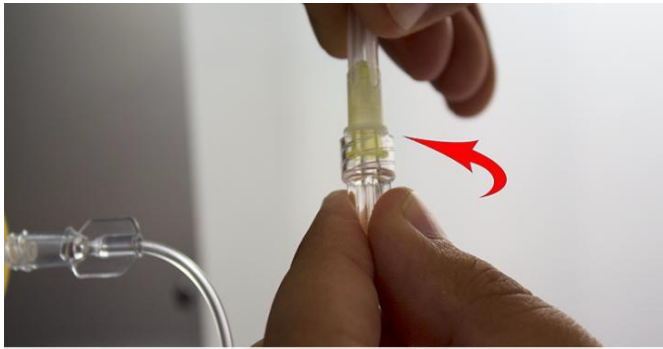
Filter attachment



Removal of the infusion hose cap



CO₂ infusion hose connection



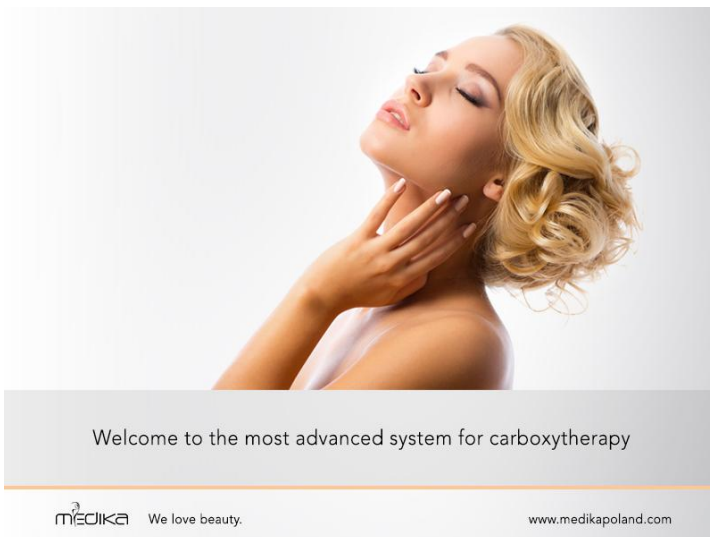
Mounting the filter to the needle



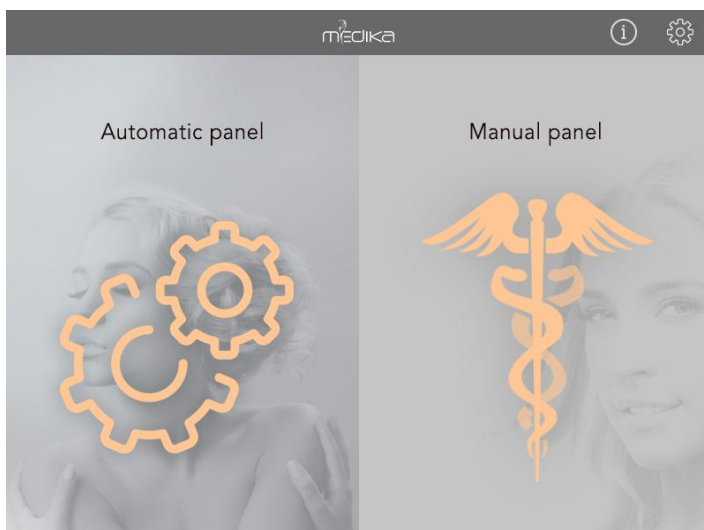
Properly attached needle on the grip

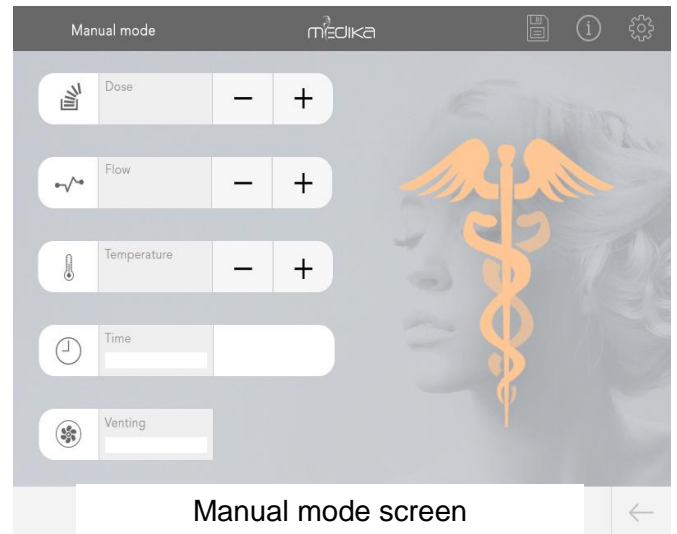
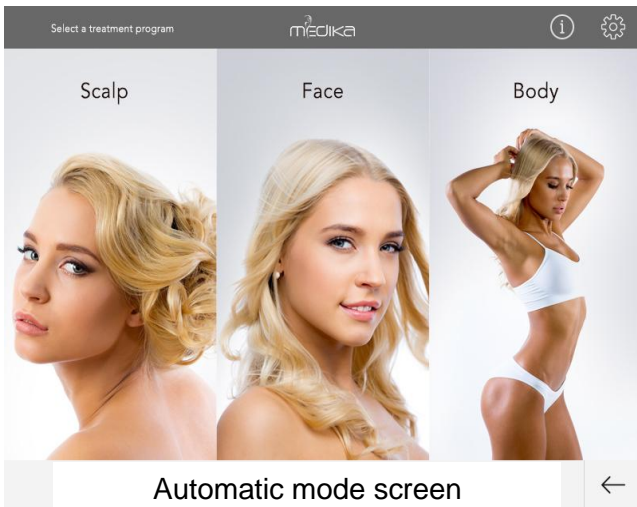
Device front panel (screen)

Home screen



Panel selection

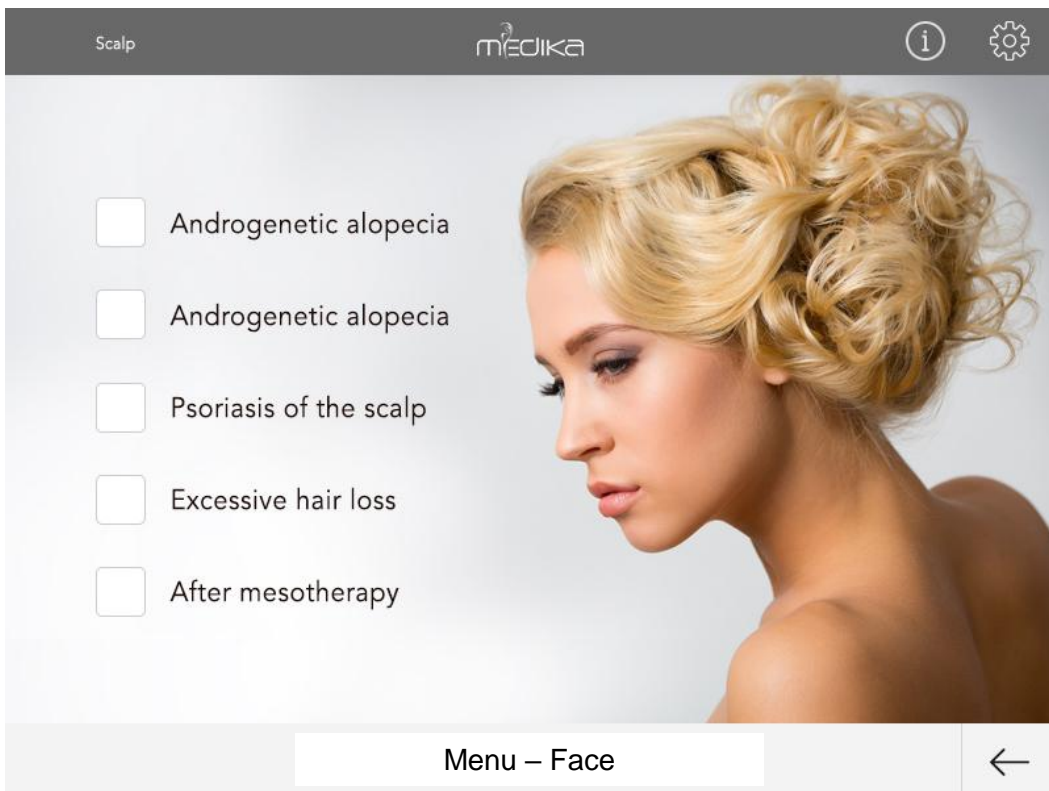
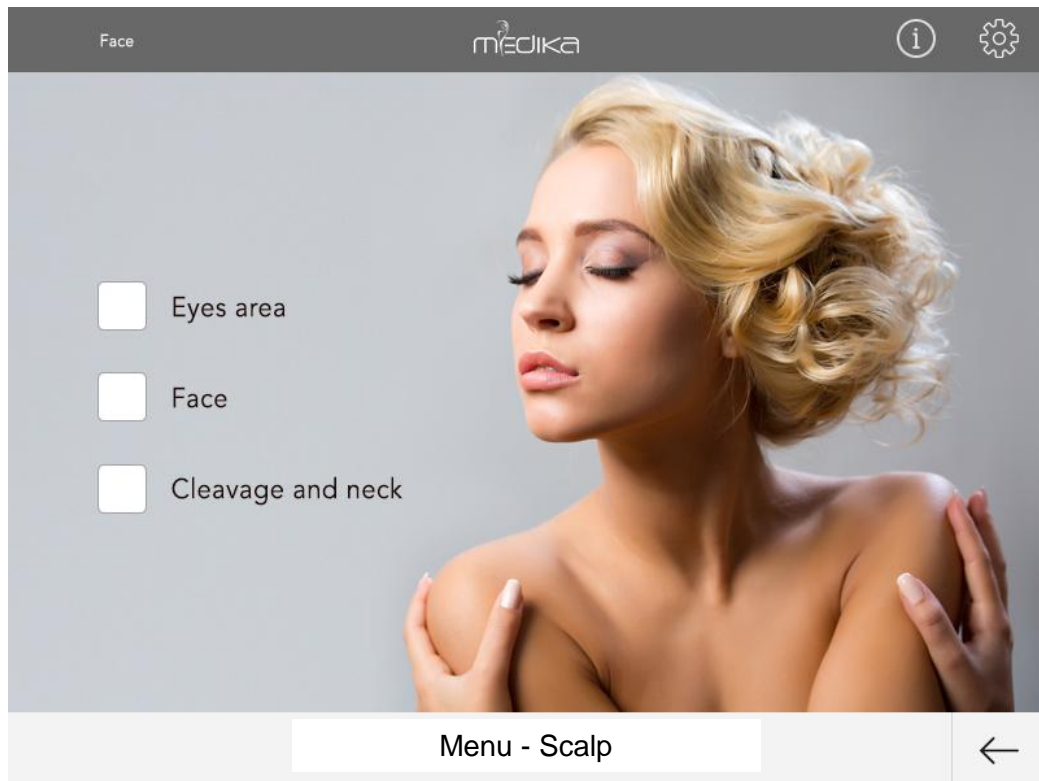


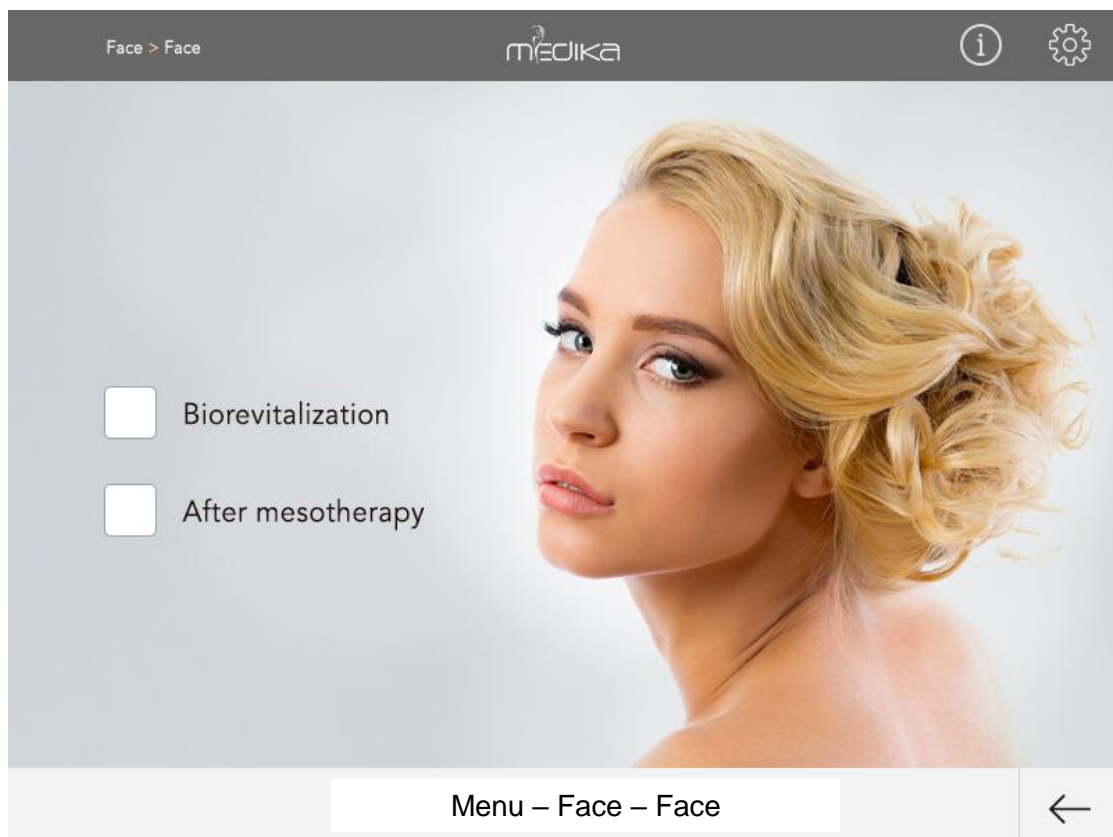
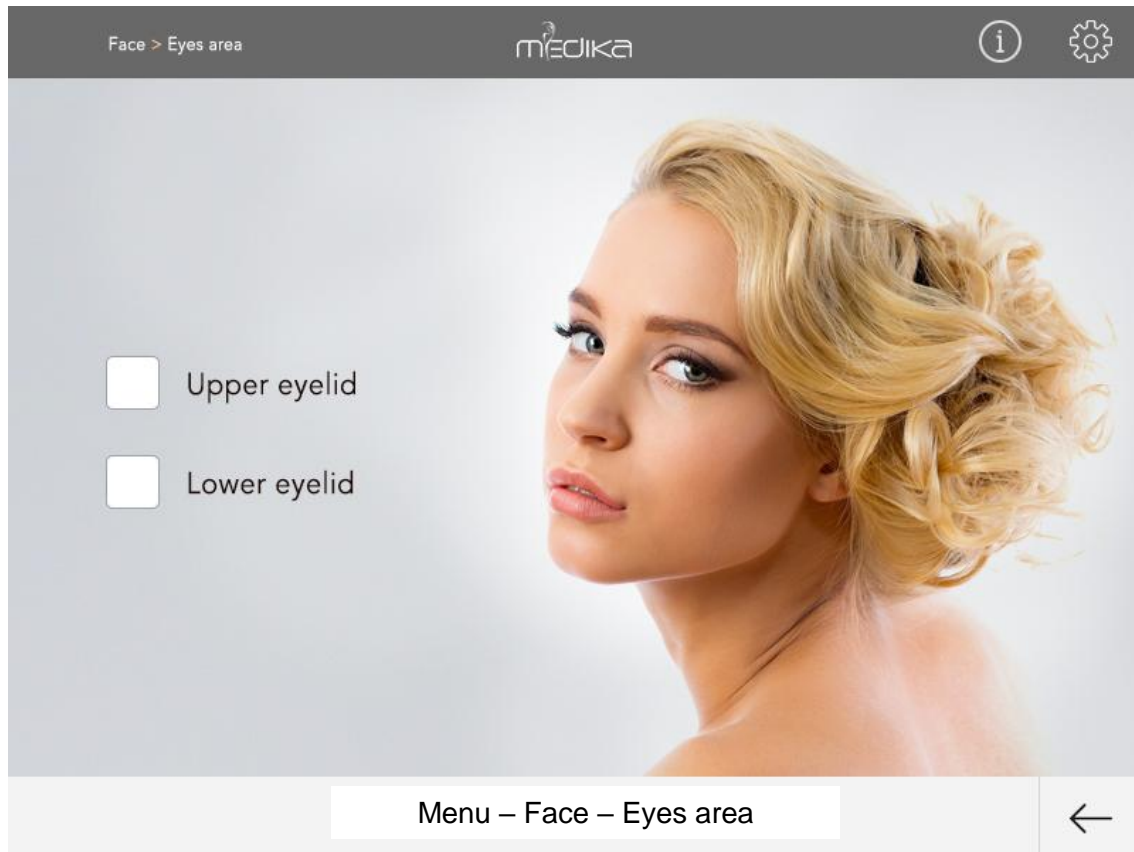


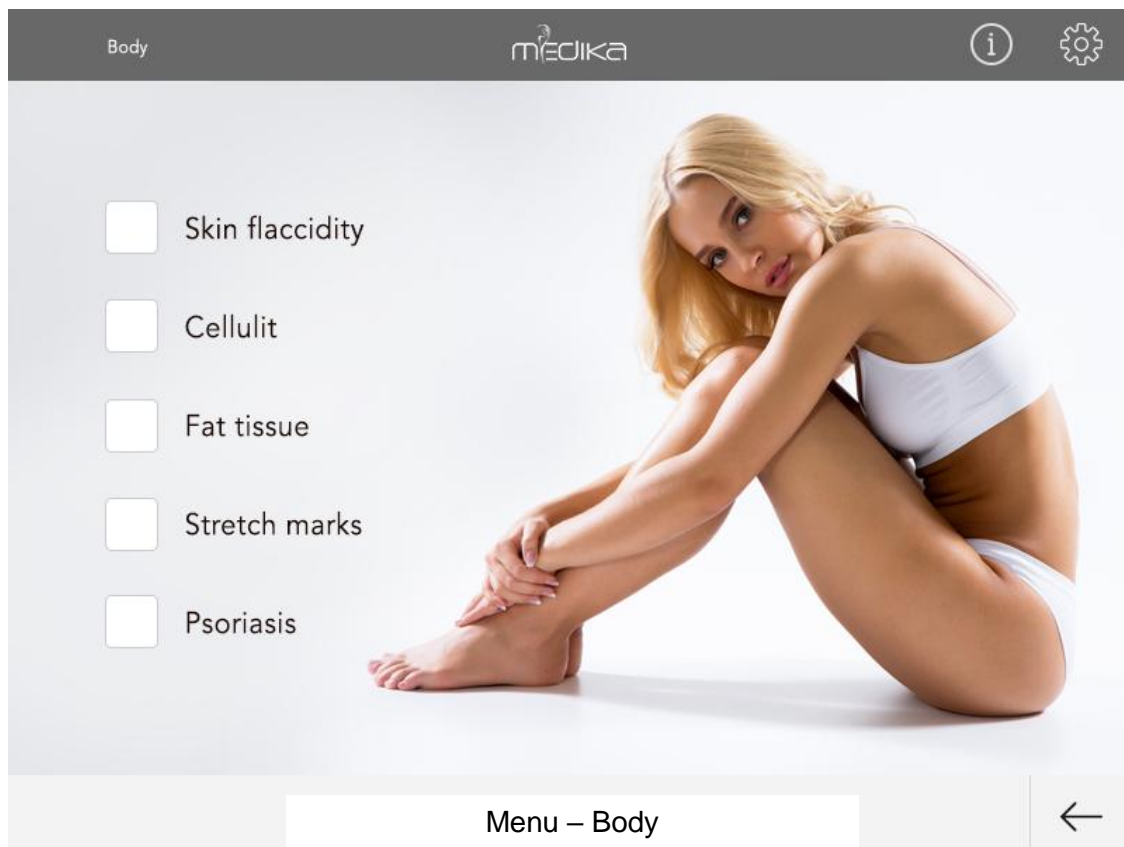
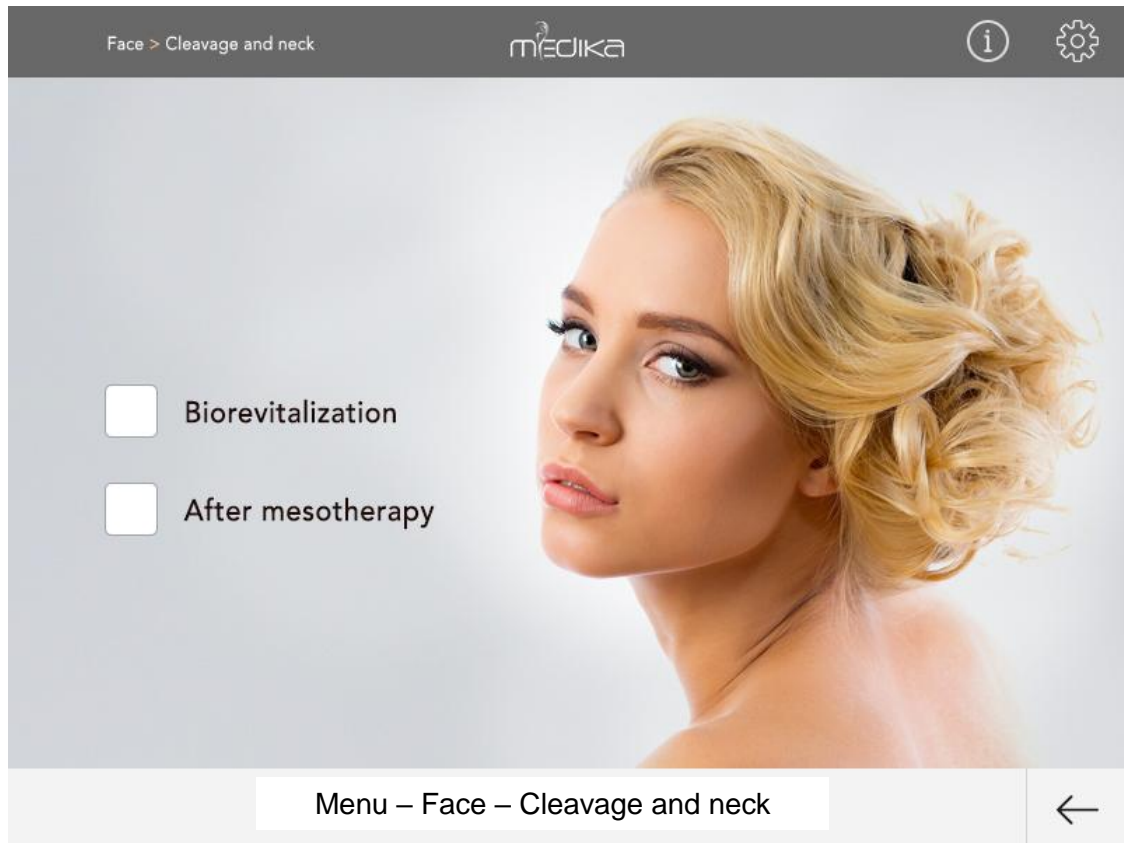
VIII. PROGRAMS TO CHOOSE FROM

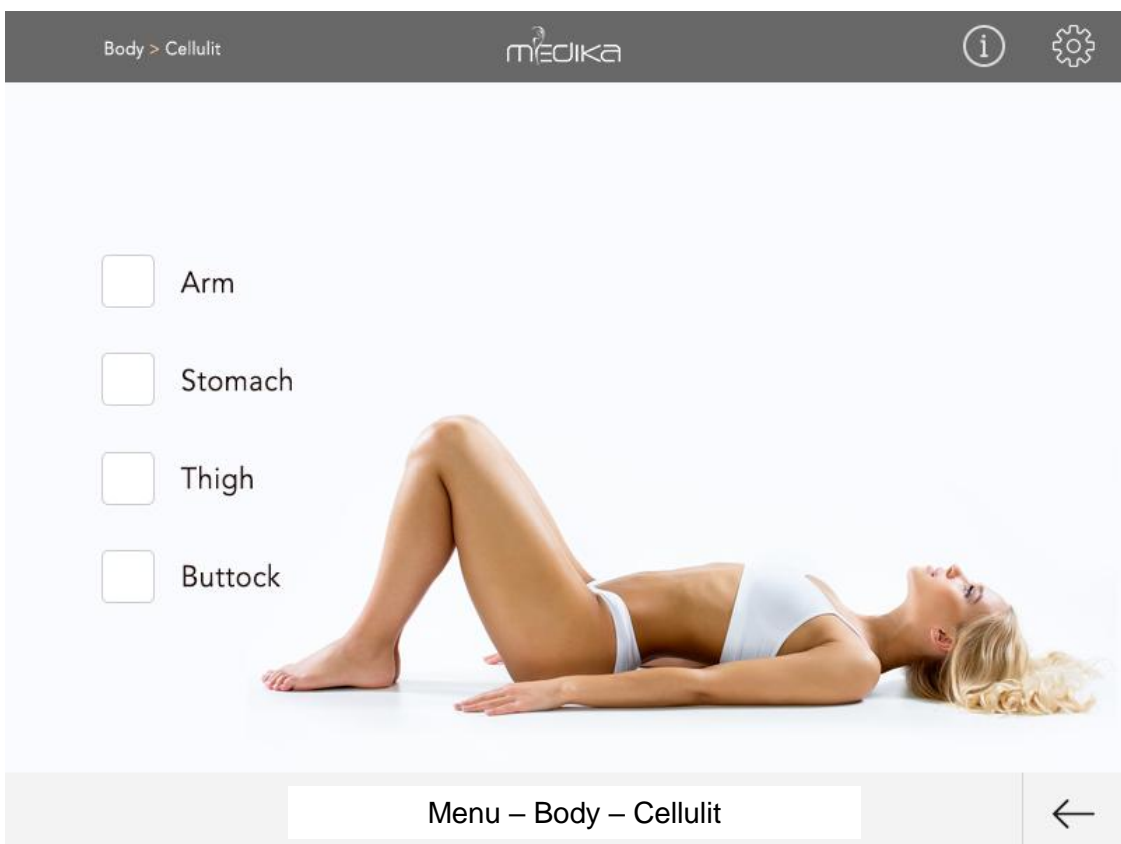
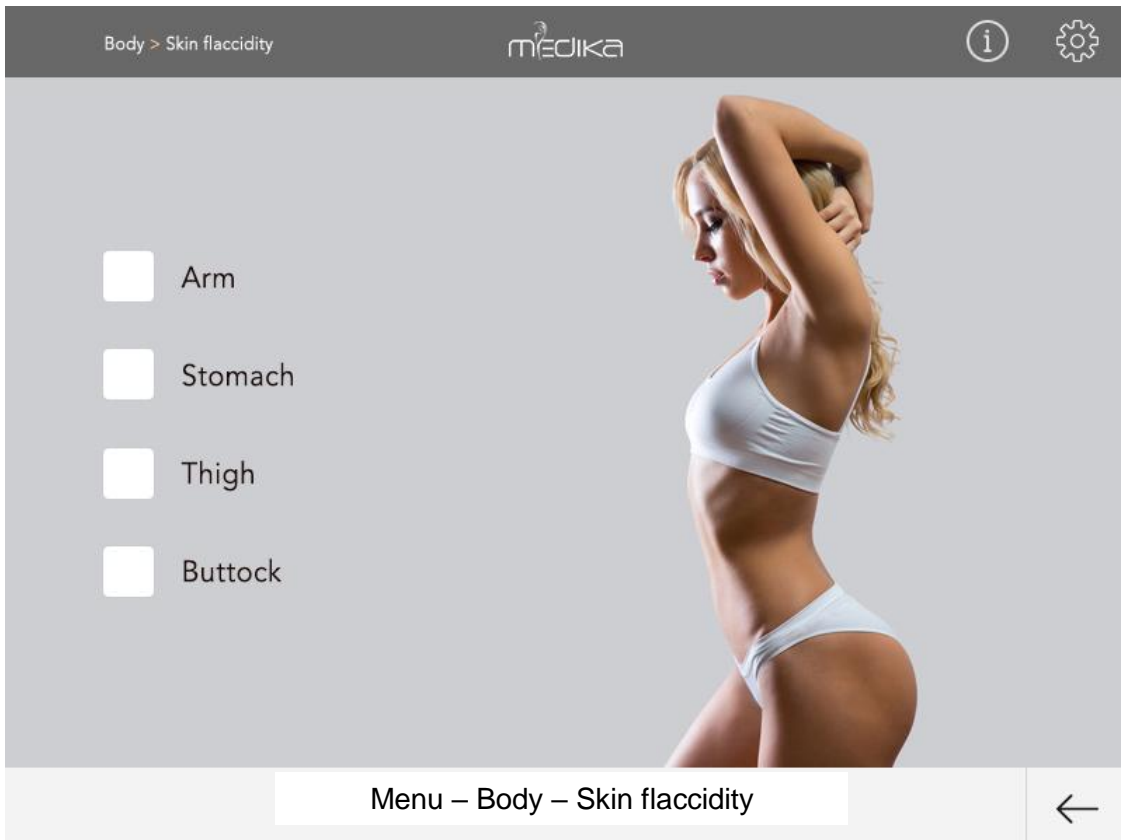
Procedure program map

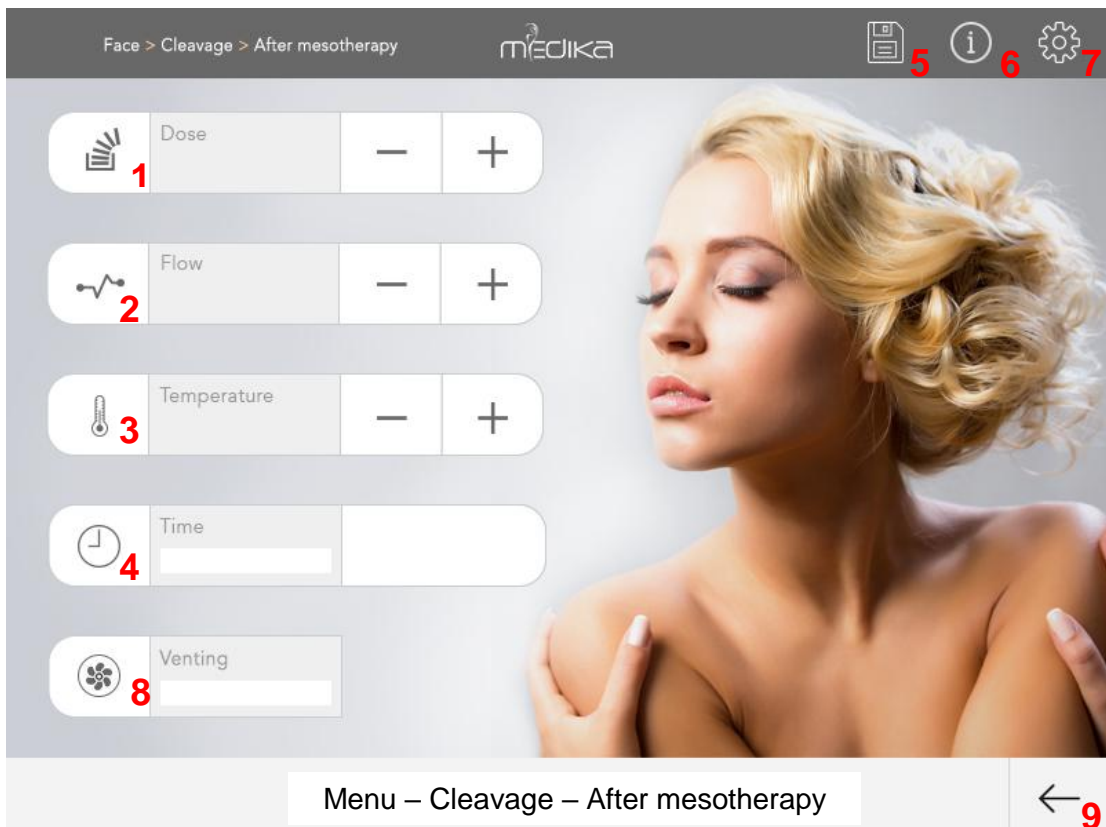
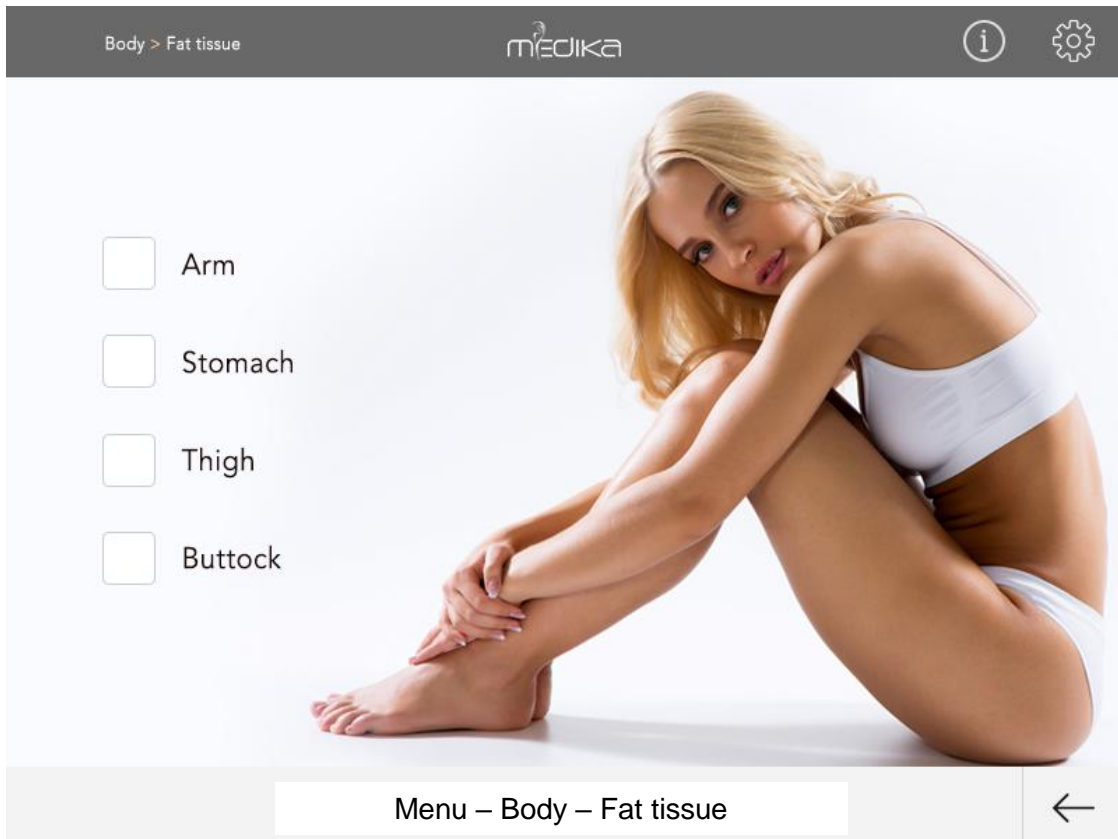
SELECTABLE PROGRAMS	SCALP	Androgenic alopecia		
		Alopecia areata		
		Head skin psoriasis		
		Excessive hair loss		
		After mesotherapy		
	FACE	Eye region		Upper eyelid
				Lower eyelid
		Face		Bio-revitalisation
				After mesotherapy
				Bio-revitalisation
	Cleavage and neck		After mesotherapy	
	BODY	Skin sponginess		Arm, abdomen, thigh, buttock
				Arm, abdomen, thigh, buttock
				Arm, abdomen, thigh, buttock
		Stretch marks		
Psoriasis				















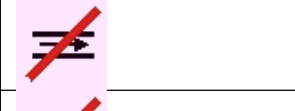








1. gas dose adjustment
2. gas flow setting
3. supplied gas temperature reaching signal
4. remaining procedure time signal
5. procedure on-going parameters saving icon
6. help panel entry
7. additional function menu entry icon
8. infusion system venting button
9. return to main menu

IX. POSSIBLE ALARMS

	
	Device venting status icons and buttons
	
	
	Status signal: Gas supply stopped
	Status signal: Gas supply on
	Set gas temperature reaching signal
	Temperature not reached signal
	Warning on too low gas pressure at the device inlet
	Warning on excessive gas pressure at the device inlet
	Gas flow control system error signal
	Blocked gas flow signal
	Gas supply control system error signal

X. STARTUP DEVICE

WARNING!

Connect the equipment to a grounded power outlet 230 V AC.

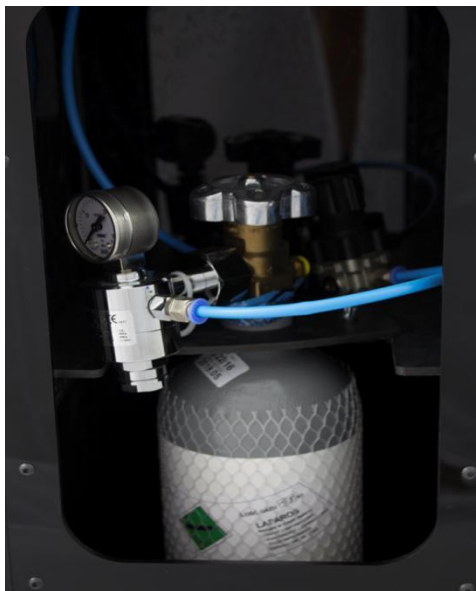
Connect the power cord to the device



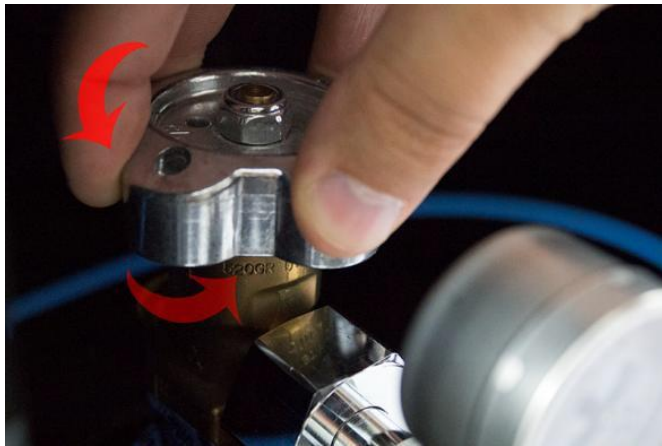
Connect the foot switch to the proper socket:



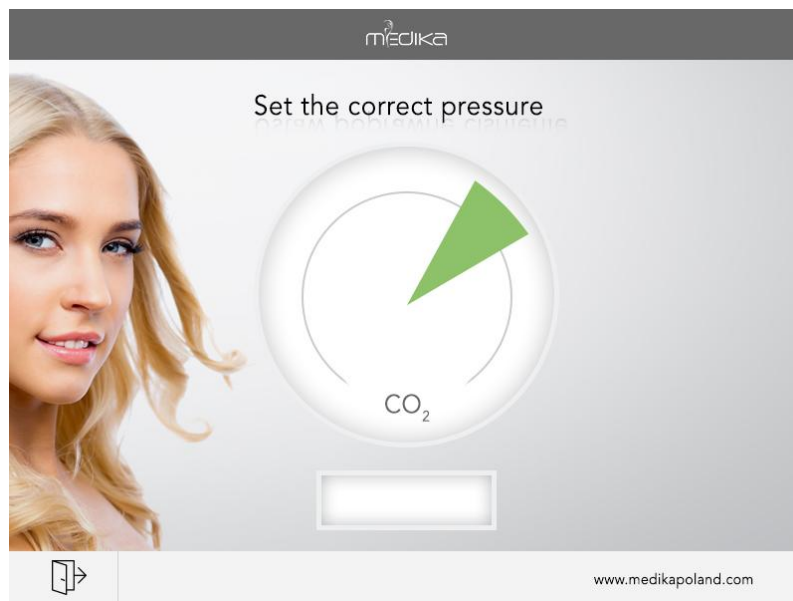
The device has a pre-installed CO₂ cylinder with connected pressure reducer



After all elements are connected, start from turning the power on and then open the gas cylinder in the direction showed in the figure below.



Gas operating pressure adjustment field will appear on the touch screen.



The operating pressure must be set within the range of the green field on the screen. Remember!!! The operating pressure must range from 320 kPa to 330 kPa.

The device has an excessive pressure setting lock. The manufacturer bears no liability for any third party interventions or improper adjustment.

Having completed the adjustment properly, you can prepare the device for the procedure.

REMEMBER!!!

Vent the device prior to all procedures.

1. **Preparation of the procedure site:**
 - a.) clean the skin thoroughly in the procedure region,
 - b.) secure the procedure region with a tissue or other protective materials, pulling the client's clothing away in such a way to leave only the procedure region uncovered
 - c.) using the skin disinfection preparation, disinfect thoroughly the procedure region and cover it with a gauze pad

2. **Preparing CARBOXYTHERAPY device for operation:**
 - a) Turn the carboxytherapy device on and after you hear the characteristic click, open the CO₂ cylinder with half a turn to the left (counter clockwise)
 - b) Check the gas pressure, clicking the "cogwheel" icon on the device screen in its right upper corner. Then, press digit 1 on the displayed numerical panel and click "enter". A clock with pressure will appear, the clock hand should be in the green field. If otherwise, please contact the company: Tel. +48 510-226-916
 - c) Exit the tool panel, clicking (X) on the left side.
 - d) The device is ready for operation.

3. **Procedure program selection:**
 - a) Select proper procedure program
 - b) The procedure panel will appear with proposed settings. You can change the following parameters at any time: gas flow speed, gas dosage and temperature.
REMEMBER! It is the device operator who sets the final gas dosage parameters.

4. **Connection of disposable accessories:**
 - a) On the right side of the device, there is a gas outlet onto which the sterile fine-particle 22 micron filter must be placed - the filter is effective for 24 hours. Replace it with a new one after this period of time.
 - b) Connect the disposable hose to the filter. The hose is disposable, for a single patient and single procedure only. After use, dispose of it according to medical waste procedure!
 - c) Connect the disposable injection needle to the hose tip. We recommend using the following needles: 30G/ 13mm, 31G, 32g/4mm. Remember to dispose of the needle using a special container for medical waste. Be careful not to puncture yourself!
 - d) Take off the needle tip and put it in the device grip. Do not take the needle sheath off!

5. **Preparation of the procedure site:**
 - a) clean the skin thoroughly in the procedure region,
 - b) secure the procedure region with a tissue or other protective materials, pulling the client's clothing away in such a way to leave only the procedure region uncovered
 - c) using the skin disinfection preparation, disinfect thoroughly the procedure region and cover it with a gauze pad.

XII. STANDARD PROCEDURE SCHEMES

REMEMBER! You cannot give more than 3500 units of gas per day!!!

Bio-revitalisation:

Head skin, neck, cleavage

The procedure is performed in a problematic region, usually on the head skin crown. Perform single 2 mm deep punctures, at the angle of 45 degrees. Apply ca. 5 gas units at the distance of ca. 1.5 cm.

Eye area:

Perform 4 ca. 1-2 mm deep punctures in the eyelid region and apply ca. 20 gas units per eyelid.

Fatty tissue, cellulite:

Abdominal walls, front

Depending on the size of the fatty tissue, perform 6-14 punctures using the 30G/13mm needle. Puncture angle from 45 - 80 degrees. Amount of gas for one puncture: 150-250 gas units

Abdominal walls, sides

Depending on the size of the fatty tissue, perform 3-6 punctures using the 30G/13mm needle. Puncture angle from 45 - 80 degrees. Amount of gas for one puncture: 150-250 gas units

Buttocks:

Depending on the size of the fatty tissue, perform 3-6 punctures per one buttock using the 30G/13mm needle. Puncture angle from 45 - 90 degrees. Amount of gas for one puncture: 100-250 gas units.

Thighs:

Depending on the size of the fatty tissue, perform 3-5 punctures per each thigh side using the 30G/13mm needle. Puncture angle from 45 - 90 degrees. Amount of gas for one puncture: 150-250 gas units.

Skin sponginess:

Apply the gas on the problematic skin region by means of the 30G/13mm needle, with a ca. 2 mm deep puncture, at the angle of 15-30 degrees, with application of ca. 50 gas units per puncture.

Stretch marks, scars:

Apply the gas directly in the stretch mark, up to the depth of ca. 1 mm, at the angle of 45 degrees, and wait for the stretch mark/scar to go white. Work on each consecutive stretch mark this way.

CAUTION!!!

Hoses, filters and needles are disposable;

XIII. CYLINDER REPLACEMENT

Step 1



Grip fitting screw loosening

Step 2



Cylinder fitting grip unlocking



Cylinder fitting grip unlocking

Step 3

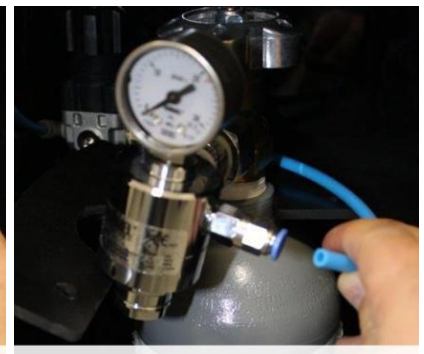


Cylinder closing

Step 4



Pressure hose removal



Pressure hose removal

Step 5



Pressure reducer removed

Step 6



Loosening the reducer to the left
(wrench no. 32)

Step 7



Unscrewing the pressure reducer

Step 8



Disassembled pressure reducer

Step 9

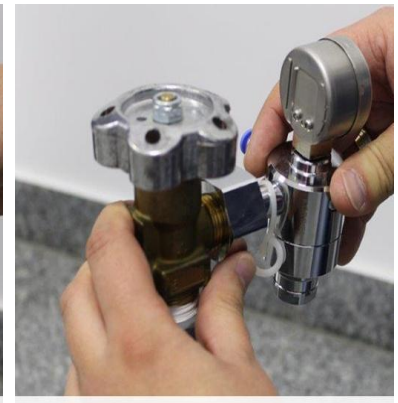


New cylinder - observe cylinder protection

Step 10



Attachment of the reducer to the cylinder



Tightening of the pressure reducer

Step 11



Reducer tightening (wrench upwards)

Step 12



Inserting the cylinder in the device

Step 13



Attachment of the cylinder fitting grip

Step 13.1



Attachment of the cylinder fitting grip

Step 14



Tightening the grip fitting screw

Step 15



Pressure hose fitting

XIV. CLEANING AND MAINTENANCE OF THE DEVICE

Clean device Carboxytherapy Medika with detergent alcohol-free.

The liquid should be applied to a cloth. With soaked cloth clean the device.

Never apply detergent directly on the device!!!

Recommended by the manufacturer of alcohol-free disinfectants:

1. Microzid sensitive
2. Desprej sensitive
3. Anios DDSH (active foam)

CAUTION!!!





All consumables like: CO₂ cylinders, hoses, filters and needles are in continuous sale.

XV. NAMEPLATE AND EXPLANATION OF PICTOGRAMS ON IT

MODEL: CARBOXYTHERAPY



BRAND: MEDIKA

POWER SUPPLY:
230V 50Hz 120VA












SN

REF

MaxMedik Łukasz Chabros
ul. Jerzmanowska 107
54-530 Wrocław
e-mail: kontakt@maxmedik.pl
tel. 794 151 415

 <p>MAXMEDIK Łukasz Chabros Jerzmanowska 107 54-530 Wrocław tel: 794-151-415 e-mail: kontakt@maxmedik.pl</p>	MANUFACTURER
	PRODUCTION YEAR
	WARNING (power supplied device)
	INFORMATION ON THE NOTIFIED BODY
	SEE INSTRUCTION MANUAL

	Do not throw it in the trash
REF	Technical documentation no.
SN	DEVICE SERIAL NO.

XVI. SERVICE AND MAINTENANCE CONDITIONS

The user is obliged to check the technical condition of the device every 2 years from the date of production of the medical device.

These inspections are performed at the manufacturer and the declaration must be made by contacting by phone which is on the label on the device.

These reviews are performed by the manufacturer at the expense of the user.

XVII. TIME OF USE AND STERILIZATION OF THE DEVICE

Carboxytherapy life time is set at 5 years. Further operation is possible, provided positive results of device inspection by the manufacturer.

After disposing of the appliance, dispose of it in accordance with applicable electronic waste disposal regulations.

XVIII. TERMS OF COMPLAINT

1. The purchaser is obliged to submit the complaint on www.maxmedik.pl (COMPLAINTS tab). The basis for acceptance of the complaint is the proof of purchase (VAT invoice, receipt) and warranty card.

2. 30-months seller's liability is awarded for all products complained about under warranty as a result of non-conformity of the product with the contract.

3. The shipment of the product subject to complaint is incurred by the purchaser.

4. The warranty complaint must include:

- exact address of the claimant
- proof of purchase, warranty card
- telephone contact
- precise failure description
- description of the situation in which the failure was found
- all provided information must be LEGIBLE.

5. The complaint will be reviewed and responded to within 21 days from delivery of the damaged goods to the service centre address or from delivery of the required documents by the claimant.

The service centre does not accept any COD shipments.

6. Warranty shipments without data required in points 1 and 4 **will not be reviewed** until

the data or documents are supplemented by the claimant. Soiled equipment will be cleaned at the cost of net PLN 50.

7. Anonymous shipments where the sender cannot be determined will be disposed of upon lapse of 3 months.

8. The date of complaint receipt is the date of delivery of the shipment to MaxMedik or delivery of the required documents by the claimant. The date of repair is the date of dispatch of the product under complaint to the Client.

9. Differences arising from individual Computer settings (colour, proportions, etc.) cannot be the basis for complaint.

10. The warranty covers only concealed effects attributable to the manufacturer. The following are not covered by the warranty:

- Fuses • Power cords • Grips, procedure probes, lamps, filters • Flooded products
- Mechanical damage • Damage resulting from dusting
- Failures resulting from improper maintenance and operation • Products purchased with a discount, from outlets or exposition
- Device overheating due to excessively long operation

11. In case of an unjustified complaint, the purchaser will be charged with the service centre costs (net PLN 100/man-hour) and product return costs.

12. If the product is non-compliant with the contract, the purchaser can demand repair free of charge.

13. Damage or product deficiencies in the orders performed via Poczta Polska postal service or courier companies will be reviewed only on the basis of the protocol drafted by the courier at the time of parcel delivery. Remember that the damage protocols must be drafted accurately and truthfully.

All shipments are insured.

XIX. TERMS OF WARRANTY

The device is provided with a warranty for a period of 30 months with the date of purchase of the equipment.

The warranty does not apply to:

- mechanical damage and resulting from misuse and instruction
- damage caused by self-dismantling or repair of the device. The warranty card should be stamped by the seller (manufacturer).

Keep the warranty card.

WARRANTY CARD

Device type and name	
Serial no.	Seller's stamp and signature
Date of sale	