swiss color ®
International

Swiss Liner TOP sensi drive

Operating Manual

Table of Content

Version 1.2, 01/2015

Distributor

SC-International AG
Neugasse 26
CH 9000 St. Gallen

SC Cosmetics Handels GmbH
Baumgarten 26
A - 6320 Angerberg

Tel: +43 (0)5332 / 56671
Fax: +43 (0)5332 / 5667120
Email: info@swiss-color.ch

Congratulations...
...on having chosen this micropigmentation device, a high quality system optimally controlled by means of special electronics for today's cosmetic studio.
The use of the pigmentation device provides every experienced make-up artist with the opportunity and facility to enhance and, if necessary, correct the natural appearance of clients.
This device introduces a technology to the make-up studio which permits a gentle, silky-soft and convincing handling when applying permanent or at least long-lasting make-up elements.
The individually adjustable needle stroke ensures a mildly invasive pigmentation with a minimum penetration depth, creating an aesthetically convincing make-up with maximum durability.

1. General Notes

1.1. Operating Manual

This operating manual explains the proper use of the device and serves to meet health and safety requirements. All persons who use, maintain or control this device must read and observe this operating manual. This operating manual is part of the device and must be at the operator's disposal at all times. If the device is passed onto a third party, the operating manual should also be passed on.

1.2. Basic Principles

This device must only be operated by an authorized and qualified person and used only for the purpose specified in the operating manual. These operating instructions do not replace the essential requirement for training in micropigmentation and Lift MESO concept. Essential - please note the contraindications listed in the corresponding chapter.
The operator is obliged to follow the principles of cleanliness and hygiene and only to work with sterile or disinfected material. For further information, please turn to chapter „Important Hygiene And Safety Instructions".
Inform your patients about any potential risk prior to the treatment. A training course will provide information regarding any possible risks that are occasionally associated with the treatment; such as scarring or allergic reactions.
The manufacturer does not accept liability for any adverse result, resulting from the improper use of the device, which has not been outlined in this operating manual!
It is essential to read the operating manual thoroughly prior to using the device.
Please take note, that the color pigments can not be removed. Intensive insolation or use of a solarium can cause fading or changing of the color of a recent micropigmentation.

1.3. Technical Progress

The manufacturer reserves the right to alterations providing they are in the interest of technical progress.

2. Effectiveness

2.1. Micropigmentation

During micropigmentation a fine needle penetrates the skin inserting a colour pigment into the upper layer of the skin.
A micropigmentation lasts several years depending on type of skin and colour but a minimum durability or a total fading cannot be guaranteed. It is possible, that the color cannot be removed, residues of the color could stay in the skin or scarring could occur.
During the initial 4 to 6 weeks, the intensity of the applied colour that has been applied fades to its „permanent level". This is normal, because the epidermis (upper level of the skin) renews itself and the pigments within this layer of the skin grows out. The remaining visible colour is beneath the epidermis. The thickness of the epidermis varies from person to person and also depends on the treated area of the body.

2.2. Lift MESO concept

The Lift MESO concept is a gentle non-invasive cosmetic method used for short-term opening of the epidermal barrier for the optimized entry of cosmetic products into the skin. In contrast to the conventional needle cartridges used in micropigmentation, Lift MESO concept uses special needle plate cartridges. Each needle plate is equipped with 0.5 mm short needles for optimal substance entry into the skin. Through the uniform partial perforation of the epidermis the absorption and thus the effect of the cosmetic products used is improved. Besides, the high frequency partial perforation of the upper dermis comes to a non invasive induction of the cell activity and the blood circulation of the skin is visibly improved.

3. Areas of Application

The most common applications for the micropigmentation device are listed below:

Micropigmentaion (PMU):
- hair drawing of the eyebrows
- attachment of eyelid lines
- full liüp drawing of improvement of liüp contours
- application of body tattoos

Lift MESO concept (cosmetic):
- short-term opening of the epidermal barrier for the introduction of cosmetic preparations into the skin
- Non-invasive stimulation of dermal cell activity by the high frequency partial perforation of the epidermis

4. Contraindications and side effects

4.1. Contraindications

The following contraindications emerge from a thorough analysis of the clinical literature for micropigmentation. Even if the Lift MESO concept, in contrast to micropigmentation, is a non-invasive method , the manufacturer recommends consideration of the following contraindications for greatest patient safety. If responsible therapist has minimal doubt that the safety of the subject being treated is not guaranteed, e.g. because of accompanying diseases, the treatment has to be omitted or stopped immediately and medical advice is to be caught up.

In the subsequent cases micropigmentation is strictly contraindicated:
- Haemophilia / bleeding disorder
- Uncontrolled diabetes mellitus
- Treatment of skin areal with dermatosis, e.g. skin tumor, eczema, rashes, open wounds, keloid (or extreme keloidal tendency), scars, acute acne, solar keratosis, warts, pigmentation disorders such as vitiligo or birth marks
- Acute systematic infections (e.g. HIV)

In the subsequent cases micropigmentation is temporarily contraindicated until the normalö health status is recovered;
- On anticoagulant therapy, e.g. warfarin, heparin, salicylic acid
- Systemic infection (e.g. hepatitis), febrile infections or acute skin infection (e.g. herpes)
- On chemotherapy, radiotherapy or high doses of corticosteroids over 4 weeks befor to 4 weeks after end of thetherapy
- Acute conjunctivitis in Vytal Cell Boost-treatment for the eye area
- Pregnancy and lactation
- Alcohol or drugs

Temporarily defined local contraindications for micropigmentation are given in the following cases:
- Acute conjunctivitis in microigmentation of the eyelid
- Skin areal with plastic surgery in the past 12 months
- Skin areal with filler injection in the past 6 months

4.2. Side effects

Side effects of the Lift MESO concept are unknown.

Micropigmentation caused side effects are rare and normally mild in their appearance. The subsequent side effects were reported in the clinical literature:

- Pain on the first day after treatment
- Occurrence of inflammation, hematoma, erythema and edema on the first 3 to 5 days after the treatment
- Skin irritation (e.g. warming, itching) which normally resolves in 12 to 48 hours after treatment
- Temporary occurrence of hyperpigmentation with body's own pigments, especially after treatment of darker skin types. However, hyperpigmentation will disappear after a few weeks
- If skin has not been thoroughly cleaned fine scabs may cause tiny pustules or milia
- Retinoid reaction (from mild redness to peeling of skin)
- Possibly heating of the treated skin areal at PET and MRI irradiation
- Contact allergy to color pigments
- Allergic reactions to components of aseptic color

Furthermore, the following problems with the introduced micropigmentation may occur:

- Color differences
- Loss of pigment
- Generally, just treated skin areal should be protected of UV light and sunbeam.

The treatment must be interrupted immediately at:

- Excessive sensitivity to pain
- Excessive leakage of wound fluids
- Fainting/dizziness

5. Important hygiene and safety instructions

In principle micropigmentation can transmit infection diseases, if the required hygiene standards are not followed properly! Basically, situations are conceivable in which the Lift MESO concept might result in the transmission of infectious diseases if the required hygiene standards are not followed properly! Therefore subsequent warnings and safety instructions have to be strictly followed:

- Micropigmentation devices are allowed to be used only by skilled qualified personal only.
- Operator has to wear sterile gloves to protect cross-contamination.
- The complete device and the handpiece must be cleaned before use by wiping it with a soft cloth soaked in cleaning disinfectant.
- During treatment the device, the handpiece the cable of the handpiece and the handpiece holder must be provided with a protective film. Note: The handpiece is coated with protective film before docking of the needle cartridge.
- The procedure has to be conducted in a qualified room for cosmetic treatment.
- Before procedure subject's skin has to be cleaned with a mild skin disinfectant. The choice of disinfectant has to comply with the relevant national guidelines of each country.
- If a skin anaesthetic was used, this must be wiped off before treatment.
- Only a dedicated sterile skin marking pen is allowed to be used for skin marking before treatment.
- Needle cartridges are sterile consumables for single use only!
- Needle cartridges have to be used in sterile condition only! Sterility of needle cartridges is only guaranteed in undamaged packaging.

- During assembly of the needle cartridge into the handpiece operator has to pay attention that the needle cartridge is not touched at the tip. Also during treatment operator has to pay attention that the needle cartridge is not contaminated, e.g. by clothing. If the needle cartridge was contaminated by unsterile treatment it has to be exchanged immediately.
- Touching of just needled skin should be avoided in general.
- NEVER touch the needle tip of the cartridge during the operating mode - injury hazard!
- In non-operating state all needles must be inserted into the needle cartridge. Inaccurate cartridges have to be exchanged carefully. Injury hazard!
- ATTENTION: A needle-stick injury with a used or contaminated cartridge might cause a transmission of hazardous diseases. In case of such needle-stick injuries you should seek the advice of a medical doctor.
- Entire consumables including the needle cartridges must be used before end of expiry date. Adequate storage conditions have to be maintained.
- After expiry date or after single use all needle cartridges have to be disposed in special containments (safety boxes) and must be treated as hospital waste. Compliance with the relevant national disposal directive of each country has to be assured.
- NEVER dump needle cartridges into the garbage – injury hazard with risk of infection!
- A contamination of the handpiece with body fluids has to be controlled in a regular manor. In case of such contamination the operation has to be stopped immediately and an adequate cleaning and disinfection procedure must be conducted.
- Only the enclosed foot switch ensures a safe operation! (provided that the device will be run with foot pedal)
- The advices for device disinfection in subsequent chapters have to be followed in addition.

Specific warnings for micropigmentation:

- The use of the needle cartridges is permitted only with sterile and antiseptic color solutions. Color solutions for cosmetic purposes ensure maximum sterility and biocompatibility.
- Also, make sure that the expiration date of the dye solution was not exceeded and proper storage took place.

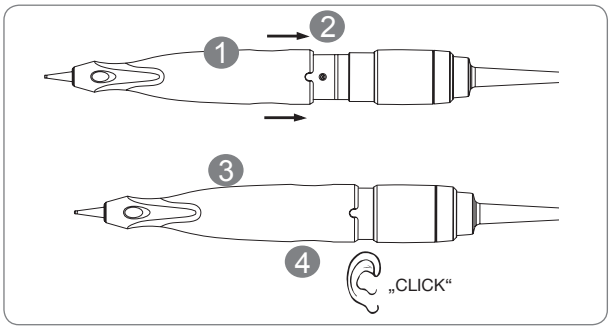
6. Needle cartridge

Before the use of the safety cartridge, please take heed of Chapter „Important hygiene and safety instructions“.
All cartridges are labeled with the lot number, date of manufacture, and use-by date. The lot number helps with the clear identification of the batch and has been issued by manufacturer in case of any problems. The lot number has to be noted in the customer‘s file.
Provided the packaging is closed and not damaged, the cartridge manufacturer guarantees their sterility for 5 years under conditions as set out in chapter “Transport and storage conditions”. The cartridges have to be stored in their original packs. After expiry date or after single use all needle cartridges have to be disposed in special containments (safety boxes) and must be treated as hospital waste. Never dump needle cartridges into the garbage – injury hazard with risk of infection!

6.1. Attaching/Removing the needle cartridge to the handpiece

To illustrate the technique of attaching and removing of the needle cartride onto the handpiece (see Fig. 1).

Fig.1



Attaching/Removing of the cartridge

1. Replace cartridge
2. Allign the cartridge with the notch in the srew direction
3. Slide the cartrdige with lateral pressure on the handle scales onto the handpiece until you feel the stop
4. Push the handle scales of the cartrige and pull to remove it from the handpiece

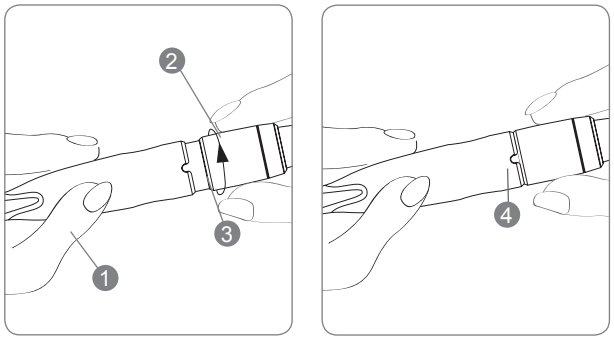
7. Handpiece

Note: The handpiece and especially the drive inside is a mechanical precision instrument and must not be soiled. Therefore colour must not get into the drive. Easily flowing colours support the running back effect.
There is a risk of contaminated substances running back down into the machanism. Therefore investigate the handpiece carefully prior to use. Do not use it if contamination is suspected. It is important not to break the cable of the handpiece.

7.1. Adjusting of the penetration depth

Only adjust the depth of penetration while the device is running (Fig. 2). A complete rotation of the handpiece causes, depending on the direction, a difference in length of the needle of +/- 1.0 mm. Turn the safety cartridge to achieve the optimum needle projection for each respective purpose.
The correct needle projection depends on the application, on the skin type, the desired effect, and other factors.

Fig. 2



Needle adjustement

1. Hold cartrige
2. Penetration depth is adjustable by turniing the backpart of the handpiece
3. In this setting the needle out level is zero
4. By further screwing the needle length is individually adjustable

8. Disinfection / Sterilization

Before operating the device, the chapter: Important hygiene and safety instructions must be followed properly.
A new cartridge must be used for each customer and every subsequent treatment.
The cartridges are designed for single use and must only be used once.
The cartridges are sterilized and packed in a sterile way by the manufacturer of the device.
Use only sterile needles that are taken out of the sterile packaging immediately before use.
The controller unit, the holders for the handpiece, the handpiece itself and the foot pedal must also be cleaned and disinfected immediately prior to the treatment of each customer. Each piece must be treated with the appropriate disinfectant, normally by wiping it with a soft damp cloth and disinfectant.
It is important to use admitted disinfectants which complies with the relevant national hygiene guidelines of each country. In addition disinfectant has to go with the materials and surfaces of the device pieces: With regard to DGHM the manufacturing firm recommends the disinfectant Lysetol® Med of the company Schülke & Mayr.
The handle of the handpiece should be cleaned periodically in an ultrasound bath (Lysetol® Med is suitable for ultrasound). The handpiece must never be immersed in disinfectant as the internal parts might corrode.
Note: The handpiece and especially the drive inside is a mechanical precision instrument and must not be soiled. Such damage does not come within the warranty.
During operation the handpiece, cable of handpiece, the controller device and the holder for the handpiece must be protected with a protective film (snake skin). The handpiece is protected with the film before assembly of the needle cartridge.

9. Start-Up

The device is designed as a table top unit, i.e. it should be set up on a solid and even surface. The handpiece should be placed on the tray covered with a protective film when not in use.
The connection sockets for the power supply and the various handpieces are on the rear of the device and clearly labelled. The device is connected to the electrical mains by the power supply and immediately operative, which is indicated by the "⏻" button lit.
The device may only be used with the power supply identified on the type label.
Ensure that the mains voltage matches that of the power supply as indicated on the label on the power supply!
The device is intended for indoor use only and at an ambient temperature between 10° C and 35° C. Before starting the device make sure that the device as adapted to the ambient temperature in the room, as otherwise condensate forming inside the unit may damage the electronics system inside (wait at least three hours if the temperature difference is 10° C).

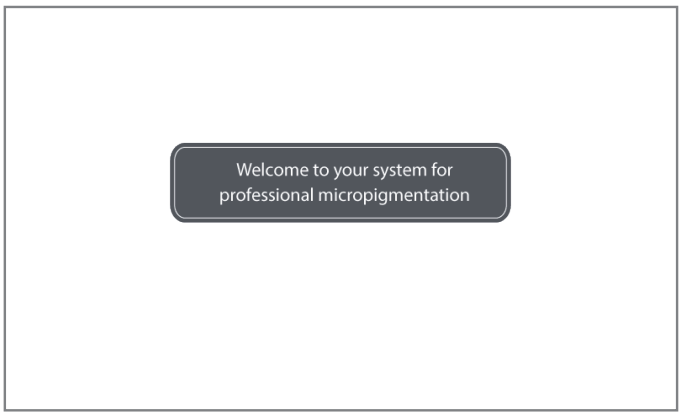
Safe operation is not guaranteed if:
- the device or the accessories have visible evidence of damage
- the device is not working properly
- the device is operated outside the prescribed temperature range after extended storage.

In these cases the device should handed over to an authorized specialist dealer for inspection.

10. Operation

After connecting the power supply the device is operative and the push button "⏻" is lit. The device is switched on by pushing the "⏻" button, and the light changes. A welcome screen is displayed (see Fig. 3).

Fig. 3



General Operation Information:

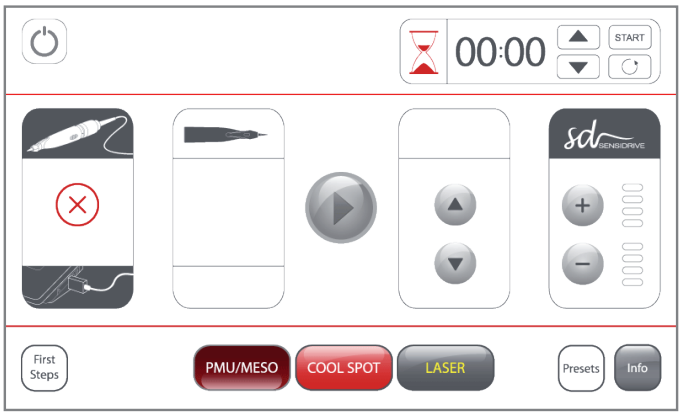
The device provides three selectable main functions. The main function selected by the user is indicated by a pushed button in the menu. Functions that are not available cannot be selected, they are highlighted. Selectable functions are identified by pushbuttons coloured.

After the welcome screen the system automatically switches to the PMU/MESO function.

11. PMU/MESO Treatment

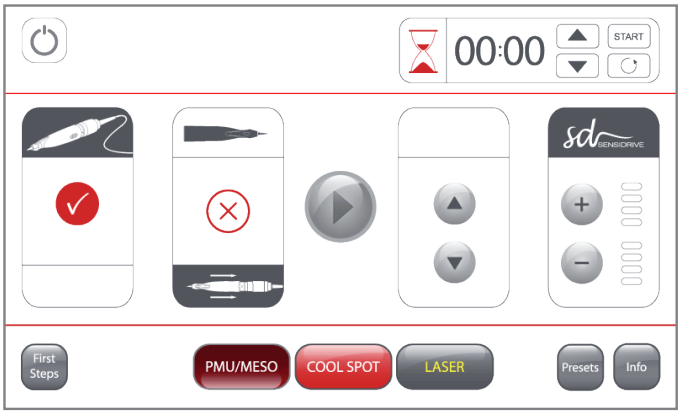
If no handpiece is connected to the device this is indicated by a sequence of images in the lower part of the handpiece screen display (see Fig. 4).
Any further treatment must only be carried out with a connected handpiece.

Fig. 4



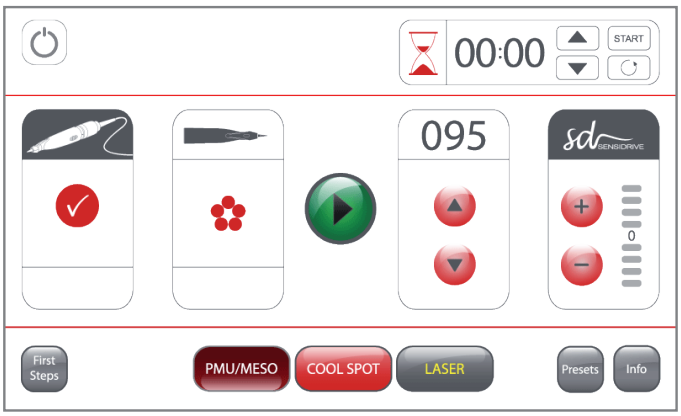
When a handset is connected to the device this is recognized by the device and is ticked on the display.
The device is fitted with an automatic cartridge detection facility. If no cartridge is connected or the connected cartrdige is not recognized by the device, a sequence of images is displayed on the lower part of the cartridge detection screen, indicating that the cartridge is relocked on the handpiece (see Fig. 5).
Any further treatment is only possible if the cartridge is properly locked in the handpiece.

Fig. 5



After the connected needle cartridge has been detected by the device this is indicated by the display in the cartridge detection field.
Finally the buttons for setting the frequency, the SensiDrive® and starting the handpiece are made available indicated by a colouring of the buttons (see Fig. 6).

Fig. 6



11.1. Setting The Needle Frequency

The needle frequency can be set to the required value with the respective arrow push buttons in the operating panel.

11.2. Setting the SensiDrive®

The SensiDrive® function adjusts the needle frequency of the cartridge used depending in the skin resistance and the preset SensiDrive® mode.

Soft mode (SensiDrive® set to -2 or -1):

The needle frequency is automatically reduced if the higher resistance of harder skin is measured. This setting is best for soft shading of the areola or the lips.

Neutral mode (SensiDrive® set to auf 0):

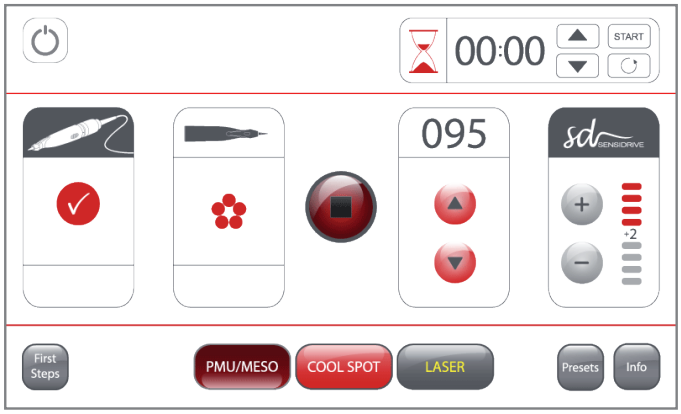
In this mode the device will work with a constant frequency, regardless of the skin resistance; this neutral mode is recommended for all regular pigmentation techniques.

Power mode (SensiDrive® set to +1 or+2):

If the SensiDrive® function detects a higher resistance on harder or thicker skin the system automatically increases the needle frequency. This is recommended particularly for line techniques such as drawing hairs or lip contours. The Power mode permits the drawing of precise and accentuated lines.

After the system has successfully detected and identified the handpiece and the connected cartridge and the needle frequency and the SensiDrive® have been set, the handpiece can be started by pushing the PLAY-button or by actuating a foot switch.
Fig. 7 shows the display on the device during operation with a needle frequency of 95 and a SensiDrive® setting of +2. The handpiece is switched off by pushing the STOP-button or actuating a foot switch.

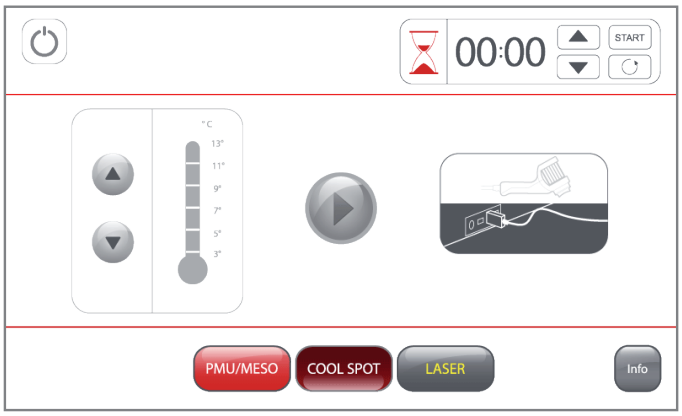
Fig. 7



12. COOL SPOT Treatment

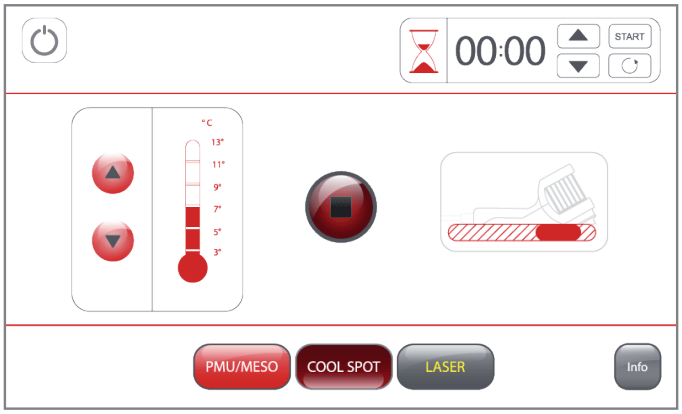
To change to the COOL SPOT treatment, push the COOL SPOT-button on the screen of the device. If no COOL SPOT handpiece is connected to the device, this is indicating by the image sequence at the bottom of the COOL SPOT handpiece display screen (Fig. 8).
Further treatment is only possible with a connected COOL SPOT handpiece.

Fig. 8



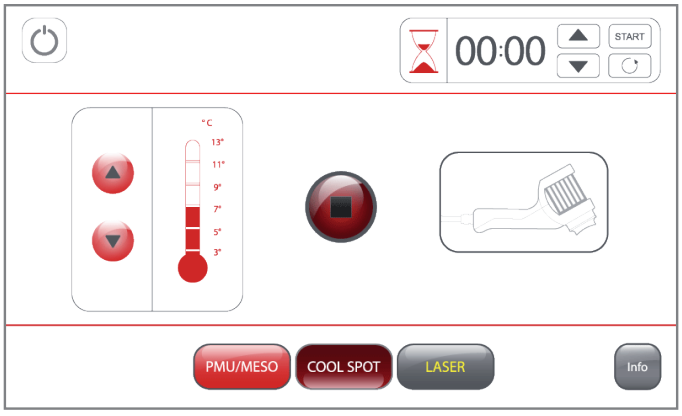
After a COOL SPOT handpiece is connected to the device the image sequence disappears from the screen and the buttons in the display change the highlighted colour.
Next a temperature range has to been set for the COOL SPOT handpiece between +3°C and +13°C. By pushing the PLAY-button the COOL SPOT handpiece is cooled down. The cooling progress is shown in the screen section for the COOL SPOT handpiece on a coldness scale (Fig. 9).

Fig. 9



When the pre-set temperature of the COOL SPOT handpiece has been reached the progress bar disappears and the COOL SPOT symbol lights up (Fig. 10).
A COOL SPOT treatment can then be carried out.
The COOL SPOT handpiece is switched off by pushing the STOP-button.

Fig. 10



13. Timer

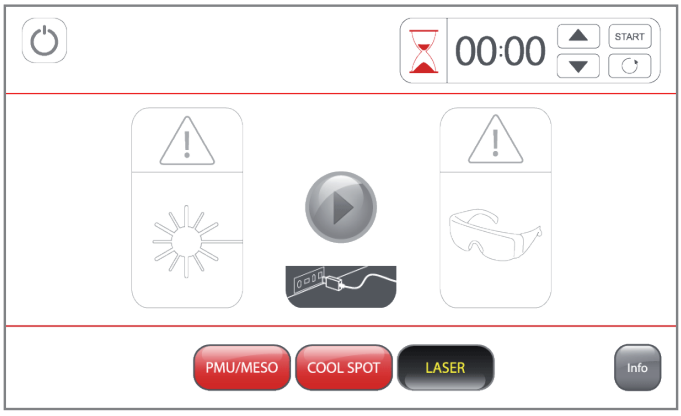
The timer for the device is located in the top right corner of the display. It is used to set certain treatment times (Fig. 11).
The timer is set by the push buttons ▲ and ▼.
Start and, if required, stop the timer with the START-button.
When the timer countdown is complete there is a signal tone.
The RETURN-button will set the timer to the previously setting.

Fig.11

14. LASER Treatment

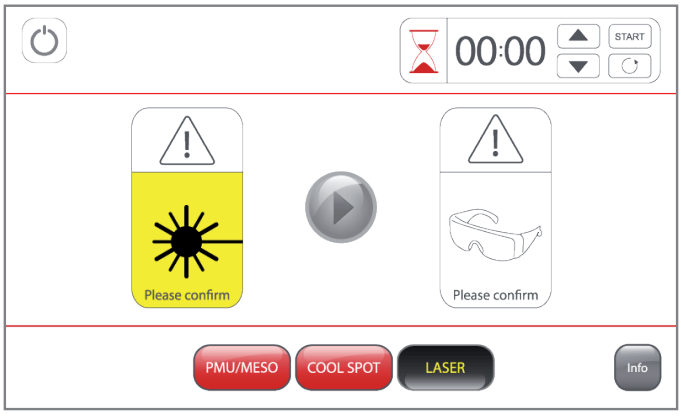
To carry out a LASER treatment, push the LASER-button. If no LASER handpiece is connected to the device, this is indicated by the image sequence (Fig. 12).
A LASER treatment is only possible with a connected LASER handpiece.

Fig. 12



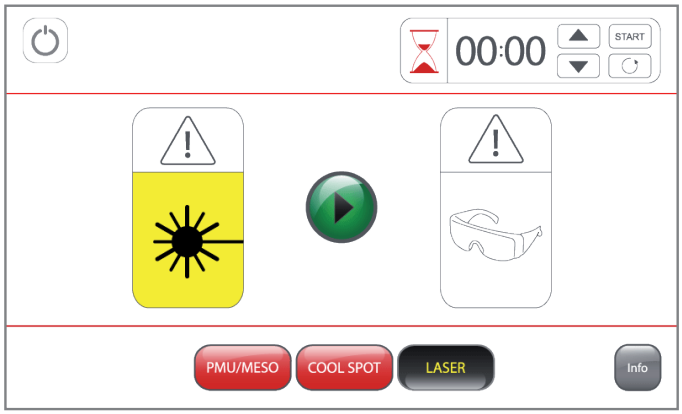
After a LASER handpiece has been connected to the device, the image sequence will disappear.
Next the warnings on the screen must be confirmed by touching on the screen (Fig. 13).
The warning symbol on the left of the display indicates that a LASER product is being used and that extreme care should be taken and maximum safety must be provided.
The warning on the right reminds the user to always wear safety goggles during the treatment.

Fig. 13



A LASER treatment is only possible after both warnings have been acknowledged.
Then the LASER hand is activated and can be used (Fig. 14).
The LASER handpiece is switched on and off by means of the push button on the handpiece itself.

Fig. 14



15. First Steps

If the selection of the cartridge or the correct setting of needle frequency of the SensiDrive® function is unclear, the First Steps-function (bottom left on the display) can be selected.
The First Steps-function asks for which treatment help is needed: PMU or MESO.
The RETURN-button will take the system back to the PMU/VYTAL treatment.

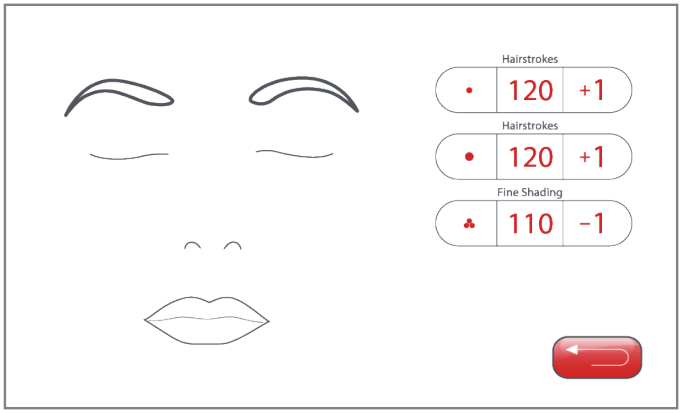
15.1. PMU Help

The PMU help is accessed by pushing the PMU-button; the different areas for which a treatment is possible are displayed (see Fig. 15).

Fig.15

Tip on the individual areas to call up help information on the treatment of the selected area on the display, including the correct cartridge to be used, the needle frequency and the recommended SensiDrive® setting (Fig. 16).

Fig. 16



By pushing the help information the system will return to the PMU/MESO-function of the device, and the selected settings from the First Steps-function are transferred to the PMU/MESO section of the device (Fig. 19).

15.2. MESO Help

The MESO help is accessed by pushing the MESO-button; the different areas for which a treatment is possible are displayed (see Fig. 17).

Fig. 17

Tip on the individual areas to call up help information on the treatment of the selected area on the display, including the correct cartridge to be used, the needle frequency and the recommended SensiDrive® setting (Fig. 18).

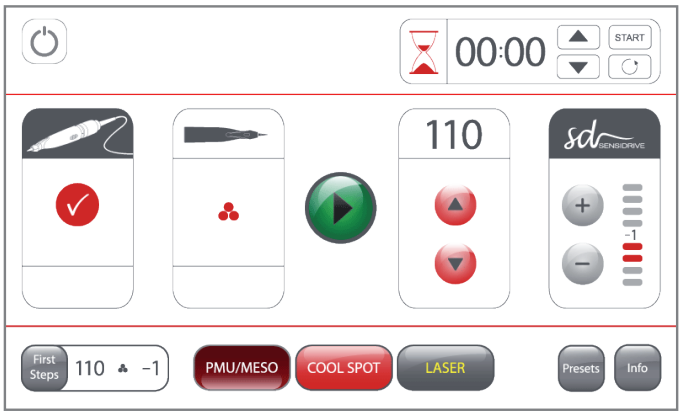
Fig. 18

By pushing the help information the system will return to the PMU/MESO-function of the device, and the selected settings from the First Steps-function are transferred to the PMU/MESO section of the device (Fig. 19).

If an incorrect cartridge is attached onto the handpiece for the selected treatment, this is indicated by a sequence of images in the bottom part of the cartridge recognition screen (Fig. 19).

Any further treatment is only possible with the correct cartridge being attached on the handpiece. The help information is displayed as a reminder and for checking the preset values in the bottom part of the PMU/MESO section of the screen.

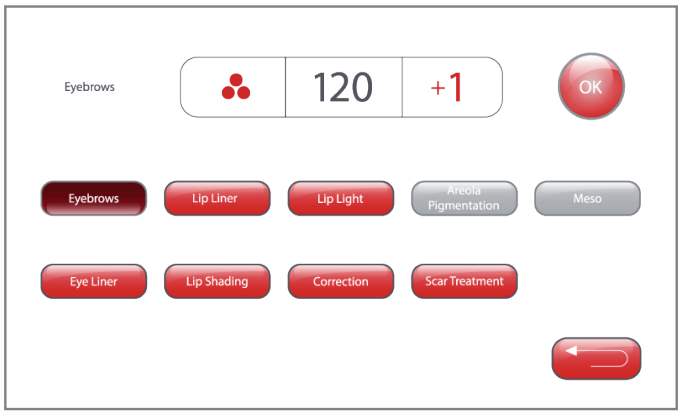
Fig. 19



16. Presets

When the PRESETS-button is pushed, the display will change to the Preset screen (Fig. 20). In the Preset screen the cartridge previously locked in the handpiece is recognized and shown in the respective section of the display. Various presets which are compatible with the installed cartridge can be selected. Presets which are not compatible with the installed cartridge are highlighted. When a Preset has been selected the setting is confirmed by pushing the Hook-button and the settings are transferred to the display of the PMU/MESO treatment.
If an abort is necessary the Preset screen can always be left by pushing the RETURN-button.

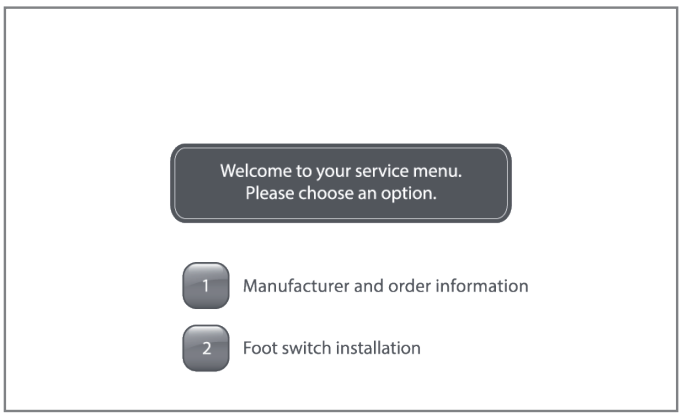
Fig. 20



17. Info

If the Info-button is pushed the information screen is shown on the display (Fig. 21). The info screen shows manufacturer information (1) and can also be used to install and connect the foot pedal to the device (2).

Fig. 21



17.1. Installation of the wireless foot pedal

If you want to install the wireless foot pedal to the device, you have to choose „2“ on the Info screen. The Info screen changes then into the Installation screen of the wireless foot pedal (Fig. 22). The instructions on the display are to be followed. The succesfull installation is confirmed in the display with a hook (Fig. 23).

Fig. 22

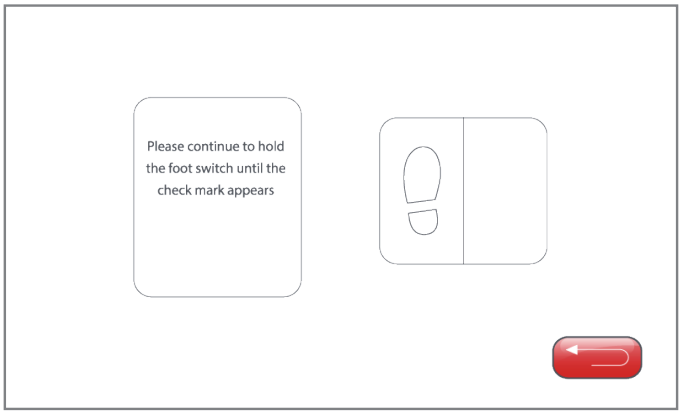
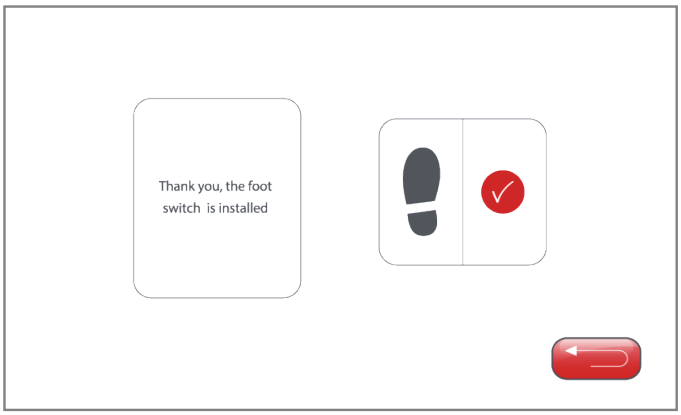


Fig.23



17.2. Selection of the foot pedal (wireless or wired)

For safety reasons, the device can be operated only with one of the two possible versions of foot pedals (wireless or wired) at the same time.
For this reason, the foot pedal which is pressed after switching the device on is registered as main foot pedal, while the other foot pedal has no influence on the device.
If a change of the foot pedal is needed, this can be realized by powering the device off and on and operating the desired foot pedal.

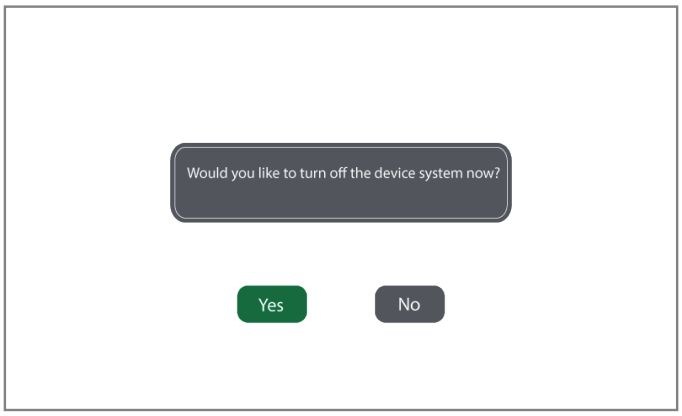
17.2.1. Operation with the foot pedal

Both foot pedals (wireless and wired) are only operable for the PMU/MESO treatment. That means that it is possible to operate in the PMU/MESO treatment of the device while cooling down the COOL SPOT handpiece in the COOL SPOT treatment section.

18. Switching Off

When the ⏻-button is pushed on the upper part of the display the screen will change and display the query as shown in Fig. 24. Confirm that the device is to be switched off.

Fig. 24



19. Purification and care

Always unplug the device from the mains before any maintenance or care!
Clean the device regularly. Before and after each treatment, the handpiece has to be cleaned with a soft cloth and a mild disinfectant, e.g. 50-% aqueous 1-propanol solution. Protect handpieces from damage and always put them down securely after use.

19.1. Material compatibility

Resistant against weak acids (e.g. boric acid, acetic acid ≤ 10%, citric acid ≤ 10%), aliphatic hydrocarbons (e.g. pentane, hexane), ethanol as well as the most common inorganic salts and their aqueous solutions (e.g. sodium chloride, calcium chloride, magnesium sulfate).
Not resistant against strong acids (e.g. hydrochloric acid ≥ 20%, sulphuric acid ≥ 50%, nitric acid ≥ 15%), oxidising acids (e.g. peracetic acid), bases (e.g. sodium hydroxide solution, ammonia; all substances with a pH-value >7), aromatic/halogenated hydrocarbons (e.g. phenol, chloroform) as well as acetone und benzine.

19.2. Recommended disinfectants

Supplier	Product	Residence time
Antiseptica	Big Spray „new“	1 - 5 min
Bode Chemie	Bacillol	30s - 1 min
Ecolab	Incidin Foam	1 - 2 min
Schülke & Mayr	Mikrozid Liquid	1 - 2 min

19.3. Product liability

The lifetime of the product purchased is 10 years. Due to the progressive device technology a replacement of damaged parts on the device can not be guaranteed after this time.

20. Failure of function, repairs, complaints, disposal

If the device does not work properly, start by unplugging the main power supply and all the component parts i.e. handpiece etc., from the device. After checking and reconnecting all the parts and the power supply, the device should work again.
If you are not able to rectify the malfunction, take the device to your authorized dealer/supplier. Claims are to be handled by your dealer/supplier.
To safely dispose of the device, please send it back to the manufacturer or distributor. After expiry date or after single use all needle cartridges have to be disposed in special containments (safety boxes) and must be treated as hospital waste. Compliance with the relevant national disposal directive of each country has to be assured.
NEVER dump needle cartridges into the garbage - injury hazard!

21. Warranty

With this device, you have purchased a high quality brand product. The most modern testing technology guarantees the reliability of this device.
The device is covered by the statutory 2-year warranty for malfunctions as a result of material defects or production faults. No liability is accepted for consequential damage. The manufacturer is categorically not liable for any damage as a result of improper use or failure to comply with our operating instructions.

22. Transport and storage conditions

Ambient temperature:	-40 °C to +40 °C
Relative humidity:	30% to 75%
Barometric pressure:	500 to 1060 hPa

If you assume that the device can not longer be operated in a safe manner, you have to take it out of service and safeguard it against unsupervised or unauthorized use.
Visually check the device on arrival, prior to the initial start-up in order to note any transport damage immediately.

Note: The device must be transported in the original package or a similar package!

23. Technical Parameters

Type:	DT-5.1
Rated voltage:	15V – (DC)
Power input:	45 VA max
Power supply unit:	as listed on the type indication plate
Safety class:	2
Drive:	Precision DC motor
Operating mode:	Continuous operation
Operating conditions:	
Ambient temperature:	+10 °C to +35 °C
Relative humidity:	30% to 75%
width x height x depth:	250 x 215 x 87 mm
weight of the handpiece:	ca. 100 g
weight of the device:	ca. 930 g

24. Accessories, spare parts, consumables

Artikel	Lieferumfang	Stück/VPE
Swiss Liner TOP sensi drive incl. handpiece	1	1
Power Supply	1	1
Foot switch	1	1
1-liner cartridge	1	5
1-micro cartridge	1	5
3-outline cartridge		5
3-micro cartridge		5
5-shader cartridge	1	5
7-round cartridge		5
9-magnum cartridge		5
Lift MESO hygiene cartridge		8
Operating Manual	1	1

25. EC-Declaration of Conformity

The Manufacturer: MT.DERM GmbH
Gustav-Krone-Str. 3
D-14167 Berlin

declares under sole responsibility that the following product:

Name of the Product: Swiss Liner TOP sensi drive
Article No.: DT-5.1

comply with the provisions of the following directives:

EMC-Directive:	2004/108/EC
Machinery Directive:	2006/42/EC
RoHS-Directive:	2011/65/EC

The following harmonized European standards have been applied:

DIN EN 60950-1:2014-08	Information technology equipment - Safety - Part 1: General requirements
DIN EN 55022:2011-12	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement
DIN EN 61000-6-1:2007-10	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity for residential, commercial and light-industrial environments
DIN EN 61000-6-3:2011-09	Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments
DIN EN 1037:2008-11	Safety of machinery – Prevention of unexpected start-up
DIN EN ISO 12100:2011-03	Safety of machinery - General principles for design - Risk assessment and risk reduction
DIN EN 82079-1:2013-06	Preparation of instructions for use - Structuring, content and presentation - Part 1: General principles and detailed requirements

This Statement is made for the manufacturer by:

Berlin, December 15, 2014, Jörn Kluge

_____
(Signature of the CEO or his representative)

Manufactured by:

MT.DERM GmbH

MT.DERM GmbH • Gustav-Krone-Str. 3 • 14167 Berlin • Germany