

KYRO-LINER

Operating Instructions



1. General Notes

1.1 Operating Instructions

These operating instructions explain the proper use of the micropigmentation device and serve to prevent danger. They must be read and observed by all persons who use, maintain, and control this device. These operating instructions are part of the device and must be at the operator's disposal at all times. If the device is passed on to third parties, the instructions should also be passed on.

1.2 Basic Principles

This device must only be operated by authorized or respectively medically trained qualified personnel and only for the purpose specified in these operating instructions! These operating instructions do not replace the essential requirement for training in the use of micropigmentation.

Essential – please note the contraindications listed in Chapter 4.

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 5 “Important hygiene and safety instructions”.

Inform your customers about potential risks prior to any treatment. A training course will have provided information about the – albeit very rarely occurring – risk's associated with micropigmentation. Amongst them are risks of scarring or of allergic reactions.

The manufacturer does not accept liability for any result of any use of the device other than the proper one as outlined in these operating instructions!

Prior to using the device, you must read through the entire operating instructions!

1.3 Technical Progress

The manufacturer reserves the right to alterations as long as these are in the interest of technical progress.

2. Cosmetic effectiveness

During the pigmentation process, needle pricks are used to insert colored pigments visible inserted into the skin and thus to draw lines. In this way, outlines are created so that a daily application of eyebrow pencil, kraal liner, or lipstick becomes unnecessary.

The pigments remain permanently inside the skin. The color generally begins to fade after 3 to 5 years, but not in all cases. The process depends on the color pigments used, the skin type, the exposure to the sun, the depth of pigmentation, and other factors.

During the initial 4 to 6 weeks, the intensity of the applied color fades to its “permanent level”. This is normal, because the epidermis (upper level of the skin) renews itself and the pigments within this part of the skin grow out. The remaining visible color is thus underneath the epidermis. The thickness of the epidermis varies from person to person and also depends on the body region.

3. Areas of application

The most common cosmetic applications for the micropigmentation device are:

- Eyebrows

- Eyeliner

- Full lip color or lip liner (improving the lip contours)

- Body tattoos

Micropigmentation has also proven successful in the after-treatment of surgical procedures, e.g. the camouflaging of scars or to the reconstruction of areolas.

4. Contraindications

Pigmentations must not be applied to anyone to whom the following conditions apply:

- Hemophilia

- Diabetes

- Infectious diseases

- Allergies

- Taking certain prescription drugs (consult the prescribing physician)

- Skin Anomalies in the area to be pigmented

- Under the influence of alcohol or drugs

- Congenital heart defect

- Pregnancy

5. Important hygiene and safety instructions

Prior to treatment, the customer’s skin has to be cleaned with a mild cleanser or disinfectant. The choice of disinfectant has to comply with the relevant national guidelines of each country.

The operator must wear single-use gloves as protection against possible infections. Do not touch with these gloves any items that are non-sterile or not disinfected. Avoid touching the freshly pigmented and still open skin. This applies both to the single-use gloves and to all other non-sterile utensils.

Always use a new sterile cartridge for each customer and each treatment cycle. They are designed for single use only and must only be removed from the sterile package immediately prior to treatment. Make sure that the packaging is undamaged. If the package is damaged, the sterility of the cartridges cannot be guaranteed. Only use cartridges within their use-by dates. When inserting the cartridge, take care not to touch during the treatment that the cartridge does not accidentally come into contact with contaminated items such as clothing. If that happens, replace the cartridge with a new sterile one.

After the treatment, dispose of the cartridges in a safety box as clinical waste. The proper disposal has to comply with local regulations.

Caution: Injury hazard!

The cartridge contains needles that can cause injuries when improperly handled. For that reason, you must never push the needle out of the cartridge from the back by pressing on the needle shaft, and touch the tips of the needle or cartridge while the hand piece is switched on.

An injury with a contaminated needle can result in the transmission of dangerous diseases. In case of such injury, consult a doctor immediately.

Immediately prior to treatment, the hand piece and the hand piece holder have to be cleaned by wiping with a soft cloth soaked in disinfectant or a cleaning agent. Never soak the hand piece or the device in disinfectant, because this can result in the corrosion of internal parts.

If a protective cap is used, the cap has to be sterilized. It is possible to buy sterilized caps from your distributor or the used cap has to be cleaned and sterilized after every treatment. During treatment, the hand piece cable, and the hand piece holder have to be covered with a protective cover or tube.

Pigmentation treatment must be carried out in a clean room with a strict ban on smoking. Please observe the relevant local regulations regarding workplace design.

Only use color pigments that are dermatologically harmless and designed for this kind of application.

6. Cryo-element Dermacool

6.1 Control unit

The cryo-hand piece is connected with the control unit by putting the plug of the hand piece into the appropriate socket connector “Cryo” on the back of the device. By pressing the key “Cryo” the cryo-element is switched on/off. The user can choose between 5 fixed-programmed operating modes.

With the help of the keys “Brow”, “Eye” and “Lip” are re-called fixed-programmed values for temperature and duration of treatment.

Program Temperature Duration of Treatment

Programmed	Temperature	Duration of Treatment
Brow	+ 9C	7 Minutes
Eye	+10C	5 Minutes
Lip	+8C	10 Minutes

The programmed “Hand” is designated for the use of individually adjusted parameters. It starts with the following values:

Program	Temperature	Duration of Treatment
Hand	+15C	6 Minutes

The pre-set values for temperatures and duration of treatment can be changed without choice with the help of the keys and within the following intervals:

Duration of treatment (time)	1 minute to 99 minutes
Temperature (temp.)	+3C to + 18C

The changes remain available as long as the device is on (socket connector is switched on). After the main current is interrupted (socket connector is switched off) the changes made get lost and the fixed-programmed initial parameters can be re-called. The cooling process starts when the key on the cryo-hand piece is pressed. It lasts until the pre-set-duration of treatment is finished.

The program "Fixed Temp." switches the time control on. Cooling down to the set temperature starts immediately and lasts until the key "Fixed Temp." is pressed again.

6.2 Cryo-hand piece

The cryo-hand piece produces the cold necessary for the treatment. It has a metal surface on its front side with the help of which cold can be applied to the appropriate skin areas. In order to match the shape of the different application regions there can be attached applicators to this metal surface. This ensures a better contact to the skin areas that have to be cooled. On the back of the cryo-hand piece is a fan that dissipates the excess heat from the cooling process.

There must be guaranteed that the air-exit hold is not obstructed or closed.

6.3 Use

Note: There must be cleaned the application areas of the hand piece for each client. The application areas must not be put directly on the skin of the client to avoid the transfer of infectious germs. For this reason sterile separating foil is to put on the skin and the application areas on the separating foil.

To start cryo-application the control unit is switched on (socket connector ON) and the cryo-element is put into operation (Key Kryo).

Now the basic state is adjusted.

Hand, 15C, 6 minutes

Now can be chosen one of the fixed-programmed operation modes

Brow, Eye, Lip

By pressing of the appropriate key or the desired treatment parameters

Temperature (Temp) or Time (Time)

by hand mode.

After this application area of the cryo-hand piece is put onto the skin area that should be treated and the key beneath the handle of the cryo-hand piece is pressed shortly. Now the device begins to cool down the applicator area to the pre-set temperature and the timer starts working.

After the end of the chosen treatment time the cooling process ends and the time is reset to the pre-adjusted value. This is indicated by an acoustic signal (beep). Now the treatment can be continued on another area in the same way. Otherwise the applicator warms up again slowly to room temperature.

Note: Due to the cooling down there is developing condensation water on the applicator areas. This process is physically conditioned and can't be avoided. Therefore, it is recommended to dry the applicator areas with a soft cloth from time to time after work with the device is finished.

7. Control unit (Micropigmentation device)

There is a holder for the hand piece on the control unit.

Note: Before the device is put into operation, it should be checked visibly in order to detect transport damage immediately.

After the power supply unit is connected with the device and the network it is ready for operation. The Power-LED (red) indicates the connection with the network. The hand piece is fitted in by connecting it with the socket "A" or "B" on the backside of the device.

By pressing the key "POWER" on the backside the device can be switched on. Pressing the key "On" switches the hand piece on or off. The needle frequency can be adjusted in steps of 10 between 50 and 150 Hz in an on state with the help of the keys "up" or "down". The chosen step is indicated as a luminous figure. This alteration will be stored up to device is switched off.

It is also possible to operate the device with the help of the enclosed foot pedal. For this the connecting plug of the foot pedal is put into the socket "Foot" on the back of the device. The pedal can be used instead of the "On" key and switches the hand piece on and on another pedal pressing off.

8. Safety cartridge

Attention – risk of injury! The cartridge contains needles that can come out at improper handling and may lead to injuries. Avoid pressure on the needle shaft (back of the cartridge) since it forces the needle to exit the needle tube.

The cartridges are sterilized by the manufacturer and delivered in a sterile packaging. They are designed for single use and to be taken out of the sterile packaging immediately before use. When inserting the cartridges one must not touch them on the tip (area that comes in contact with the patient).

During work one has also to take care that areas of the cartridge that get into touch with the patient do not come in contact with contaminated items, for instance clothes. In this case one has to use a new sterile cartridge.

After the treatment cartridges must be disposed of into a safety box for clinical waste.

On each package containing 5 safety cartridges is a label indicating lot number, production and expiry date. The lot number serves the explicit identification of the batch and has to be submitted to the manufacturer in case of problems. There must be

guaranteed classification and back tracing for all cartridges in the packaging; this means that the safety cartridge with the label has to be used last. The delivered cartridges are sterile. Don't use cartridges from a damaged packaging. The manufacturer guarantees sterility for a period of 5 years if the packaging is closed and not damaged.

9. Hand piece with safety cartridge

Note: The hand piece and especially the drive inside are a mechanical precision instrument and must not be soiled. Therefore color must not get into the drive. This can be guaranteed if the hand piece is always in an almost vertical down position. It is important to put the client in a position that allows keeping the hand piece in an almost vertical down position. It is important to put the client in a position that allows keeping the hand piece in an almost vertical position when using it. For other purposes, i.e. when putting the device down during a break or for adjusting or checking the projection of the needle one has to keep the needle vertically down in order to avoid the color running back into the hand piece. Easily flowing colors support the running back effect. There is a risk of a contaminated color running back down. Therefore investigate the hand piece carefully prior to use and do not use it in case of a contamination. It is to respect not to break the cable at the hand piece.

Damage due to color penetrated into the drive shall not be recognized as a reason for complaint and repair must be paid by the client.

9.1. Inserting of the cartridge

Essential for the use of the safety cartridge, please take heed of Chapter 5. "Important hygiene and safety instructions". All cartridges bear a label with the lot number, date of manufacture, and use-by date. The lot number helps with the clear identification of the batch and has to be given to the manufacturer in case of any problems. 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 kept stored in the stores in the original packs of ten. The cartridge is screw-fitted to the hand piece. Test the cartridge for secure fit to the hand piece immediately after fitting it.

Turn the adjusting ring to the right (inserting slot facing upwards) until it stops to prevent the needle from coming out of the tube while inserting the cartridge. Insert the cartridge and turn it left until it is securely locked.

Fill the cartridge with 2 or 3 drops of color. Alternatively, the cartridge tip can be dipped into the color for 2 to 3 seconds. If the device is switched on, the color is sucked into the cartridge. Avoid any contact of the needle tip with the color container during this procedure.

9.2. Adjusting of the puncture depth

Only adjust the puncture depth when the device is running. 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. This expertise needs to be acquired in a training course.

9.3. Removing the cartridge

Turn the adjusting ring to the right (cartridge tip facing upwards) until it stops to avoid handling with the contaminated needle. Unlock cartridge by turning it left and remove it with a straight movement.

10. Disinfection/Sterilization

There must be used cartridges for each client and each treatment. The cartridges are designed for single use and shall be used only once. The cartridges are sterilized and packed in a sterile way by the producer of the device. They shall use only sterile needles and needle nozzles that are taken out of the sterile packaging immediately before use.

The holders and the protecting caps for the hand piece and the handle of the hand piece must also be cleaned and disinfected immediately before the use/before the treatment of each client. For this they have to be treated with an appropriate disinfectant (the holder normally by wiping it off with a soft cloth wet with the disinfectant, protecting caps and handles by putting them into the solution). Please ask your distributor about sterilized disposable protecting caps. There must be used exclusively DGHM admitted disinfectants which go with the materials and surface of the device pieces. The manufacturing firm recommends the disinfectant Lysetol Med of the company Schulike & Mayr. The handle of the hand piece should be cleaned periodically in an ultrasound bath (Lysetol Med is suitable for ultrasound). The hand piece never in disinfectants soak, since otherwise the parts inside can corrode. Such damage does not fail under the warranty.

11. Maintenance and care

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

Material compatibility:

Resistant against weak acids (e.g. boric acid, acetic acid $\leq 10\%$, citric acid $\leq 10\%$), aliphatic hydrocarbons (z.B. 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 $\leq 20\%$, sulphuric acid $\geq 50\%$, nitric acid $\geq 15\%$), oxidizing 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 benzene.

12. Failure of function, repairs, complaints, disposal

If the device does not work properly, start by unplugging from the device all components such as the mains power supply and the hand piece. After checking and re-plugging all connections, the device should work again. If you are not able to rectify the malfunction, take the device to your authorized specialist dealer/supplier. Claims are to be handled by your dealer/supplier

To dispose of this device, please send it back to the manufacturer or distributor.

13. Accessories spare parts, consumables

Art. No.	Item	Scope of Supply	Units/PU
C 9.7	Hand Piece NII incl. Cable	1	1
E 1000	Food pedal incl. Cable	1	1
E 0021	1 point cartridge	1 pc.	15
E 0023	3 point cartridge	1 pc.	15
E 0024	4 point cartridge	0	15
E 0025	5 point cartridge	1 pc.	15
E 0025M	5M point cartridge	0	15
E 0027	7 point cartridge	0	15
E 0029	9 point cartridge	0	15
E 0030	3 point outline cartridge	0	15
E 0030MIC	3 point micro cartridge	0	15
E 0507	Protective cap for hand piece	1	1
7E D 7.1	Operating Instructions	1	1
GB 2,3	Cyro Hand piece	1	1
FG B2.3-16	Adapter, big	1	15
FG B2.3-17	Adapter, small	1	15

14. 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.

15. Technical parameters

Type:	B 2.3
Nominal voltage:	90-..240 V
Frequency:	50..60 Hz
Power input:	250 VA max
Safety class:	Operations with SELV
Working frequency:	50 to 150 motions/s+/-10%

Drive:	Precision DC Motor
Operating mode:	Continuous operation
Operating conditions	
Ambient temperature:	+10 C to 35 C
Relative humidity:	30% t 5%
Dimensions:	
(width x height x depth)	430 x 380 x 90 mm
Weight of hand piece:	about 120 g
Weight of Cryo hand piece	about 550 g
Total weight:	about 7 kg
CE Marking:	The device meets the requirements of the 89/336/EWG/EWV guideline
Area	Operating temperature/ Duration of treatment Area
Hand	3 C bis 8 C / 1 bis 99 min
Brow	15 C adjustable / 6 min adjustable
Eye	10 C / 5 min
Lips	8 C / 10 min

16. Transport and storage conditions

Ambient temperature:	+5 C to +40 C
Relative humidity:	30% to 75%
Barometric pressure	900 to 1060 hPa

If you assume that the device can no 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 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.

The end