

NOUVEAU CONTOUR®
MASTERS IN MICROPIGMENTATION

iQ



MANUAL



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CE

EN



NC iQ

EN | 35

BUTTONS AND CONNECTIONS

- | | |
|---|---|
| 1 | Display |
| 2 | Button for RUN (RUN) |
| 3 | Button for Frequency up (▲) / Button Frequency down (▼) |
| 4 | Buttons for Preset options |
| 5 | Standby-LED |
| 6 | Socket for power supply plug |
| 7 | Socket for handpiece |
| 8 | Socket for foot-operated switch |
| 9 | On/-Off Button (⏻) |

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13 NOTES

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

12 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: Nouveau Contour IQ
Article No.: DD11101

comply with the provisions of the following directives:

EMC-Directive: 2014/30/EU
Machinery Directive: 2006/42/EC
RoHS-Directive: 2011/65/EU

The following harmonized European standards have been applied:

DIN EN 60335-1:2012-10	Household and similar electrical appliances – Safety – Part 1: General Requirements
DIN EN 55014-1:2012-05	EMC –Electromagnetic compatibility, Requirements for household appliance, electric tools and similar apparatus Part 1: Emission (CISPR 14-1:2005+A1:2008+Cor.:2009+A2:2011)
DIN EN 55014-2:1997 +A1:2001+A2:2008	EMC –Electromagnetic compatibility, Requirements for household appliance, electric tools and similar apparatus Part 2: Immunity (CISPR 14-2:1997+A1:2001+A2:2008)
DIN EN 62233:2008-11	Assessment of electronic and electronical equipment related to human exposure restrictions for electromagnetic fields
DIN EN 1037:2008-11	Safety of machinery – Prevention of unexpected start-up
DIN EN ISO 14971:2013	Medical devices – Application of risk management to medical devices

This Statement is made for the manufacturer by:

Berlin, 01th June, 2017, Jörn Kluge

(Signature CEO or his authorized representative)

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1 ABOUT THESE OPERATING INSTRUCTIONS



This User Manual is for the NC-iQ (DD11101) and its accessories. It contains important information to put the device into operation, to use and maintain it safely and pursuant to its intended use.

This Instruction for Use is limited to all information required for safe operation of the device. Please read the following documents for further information required for safe operation of the device and its accessories:

- Safety data sheets for disinfectants and cleaning agents
- Provisions on workplace safety and legal requirements for micropigmentation.

1.1 Representation of Warning Notices

Warning notices draw attention to the risk of personal injury or property damage and are laid out as follows:

	SIGNAL WORD
Nature of the danger	
Consequences	
► Defence	
ELEMENT	MEANING
	identifies risk of injury
Signal word	indicates the severity of the danger (see following table)
Nature of the danger	designates type and source of danger
Consequences	describes possible consequences in the event of non-compliance
Defence	specifies how to avoid the danger
SIGNAL WORD	MEANING
Warning	indicates a risk of death or that serious injury can result if the danger cannot be avoided
Caution	indicates a risk of slight to semi-severe injury that can result if the risk cannot be avoided
Attention	identifies potential risks that can lead to environmental, property or equipment damage if the hazard cannot be avoided

To remove further function disturbances:

- First disconnect all components, such as the handpiece and the power supply unit from the control unit.
- Check all connections and reassemble all the components.
- Recheck all device functions.

In the event of continued function disturbances and for questions or complaints, please contact the authorised dealer.

11 WARRANTY DECLARATION

This device is a high-quality product.

The statutory warranty of 2 years applies to this product for malfunctions attributable to material defects or processing faults.

We guarantee sterility of the needle modules for 5 years, as long as all packaging stays sealed and undamaged in accordance with transport and storage conditions. In the event of a warranty claim for a needle module, please indicate the lot number printed on the label.

We cannot assume any liability for the following damages:

- Damage and consequential damage caused by the improper use or non-compliance with the operating instructions.
- Any damage caused by ingress of liquids or debris into the inside of the handpiece, the control unit or the power supply plug

10 IN THE EVENT OF QUESTIONS AND PROBLEMS

The following malfunctions or error messages may occur:

FAULT/ MESSAGE	FAULT	CAUSE	ACTION TAKEN
"Handpiece detached!"	The handpiece is not detected.	The connection cable is not properly connected	<ul style="list-style-type: none"> ▶ Carry out all the work steps in this chapter 5.4 "Connecting the handpiece" on page 20.
"System Overloaded Press any Key!"	There is a fault signal at the handpiece.	The connection cable is not properly connected. The needle module is not properly installed.	<ul style="list-style-type: none"> ▶ Check the connections between the handpiece and the control unit. ▶ Press any button on the control unit to return to the default screen. ▶ Check the fit of the needle module in the handpiece. ▶ Press any button on the control unit to return to the default screen.
"System Error - Restart Device"	An error has occurred at the handpiece or the control unit.		<ul style="list-style-type: none"> ▶ Switch the control unit to the standby mode and wait 30 seconds (see chapter 6.1 on page 20). ▶ Switch the control unit back into operating mode.
The control unit does not switch into standby mode.	The power supply has been disconnected.	The power supply plug is not properly connected.	<ul style="list-style-type: none"> ▶ Check the connection of the power supply plug to the control unit (see chapter 5.2 "Connecting the handpiece" on page 18). ▶ Check the mains power supply to the workstation.
The control unit automatically shuts off during operation.	The power supply has been disconnected or a fault has occurred at the control unit.	The power supply plug is not properly connected.	<ul style="list-style-type: none"> ▶ Check the connection of the power supply plug to the control unit (see chapter 5.2 "Connecting the handpiece" on page 18). ▶ Check the mains power supply to the workstation. <p>When the power supply has been connected:</p> <ul style="list-style-type: none"> ▶ Switch the control unit into standby mode and wait about 30 seconds (see chapter 6.1 "Switching the control unit into operating or stand-by mode" on page 24). ▶ Switch the control unit back into operating mode.

Symbols used in this manual

SYMBOL	MEANING
▶	Action request
•	List item
-	List sub-item

2 IMPORTANT SAFETY NOTES



2.1 General safety notes

- ▶ Read these operating instructions carefully and completely.
- ▶ Store these instructions and keep them available at all times for all personnel using, cleaning, disinfecting, storing or transporting the device.
- ▶ If passing on the device to other personnel, make sure these instructions always accompany the device.
- ▶ Follow the safety regulations for micro pigmentation in your country. Make sure to keep your workstation clean and hygienic and ensure adequate lighting.
- ▶ Utilise the device, its accessories and all connection cables only in technically perfect condition.
- ▶ Only use original NOUVEAU CONTOUR needle modules, accessories and spare parts.

2.2 Product-specific safety instructions

- ▶ Never modify the device, the needle modules or other accessories.
- ▶ Children must be supervised not to play with the appliance.
- ▶ Prevent liquids from entering into the device interior, the handpiece, the foot-operated switch or the power supply.
- ▶ Place the appliance in such a way that the recommended safety distance from possible sources of interference is always observed. Information about recommended safety distances may be found in chapter 11.2.3 "Recommended safety distances for portable and mobile RF communications equipment" on page 32. Avoid possible sources of interference by not operating any portable or mobile radio devices in the vicinity of the device.
- ▶ Protect the handpiece and the connection cable with a hygiene sheath to prevent impurities from bodily fluids or substances contaminated by bodily fluids (see chapter 5.6 "Inserting or replacing the needle module" on page 21).
- ▶ When you are not using the device, disconnect it from the power supply and store the handpiece on the handpiece rest so that it cannot roll away and fall down.
- ▶ Observe the technical data as stated in these operating instructions and follow the operating, transport and storage specifications (see chapter 8 "Transport and Storage Requirements" on page 29).
- ▶ Should the product display visible damage, not operate as usual or if liquids may have entered the device or handpiece, take it to an authorised dealer for inspection.

- ▶ We recommend dropping the device off for an inspection at an authorised service dealer at regular 24 month intervals. For details, please refer to chapter "7.1 Inspection" on page 27.

2.3 Important hygiene and safety regulations

To prevent the transfer of contaminants or infectious diseases to the patient or the user during the procedure:

- ▶ Follow all work steps for disinfecting the equipment before each procedure (see chapter 5.5 "Cleaning and disinfecting the equipment" on page 20).
- ▶ Use disposable gloves made of nitrile or latex for the procedures and disinfect them before use. Make sure you observe the applicable guidelines for your country when selecting suitable disinfectants.
- ▶ Before treatment, clean the respective patient skin areas with a mild cleaning and disinfecting agent. Make sure you observe the applicable guidelines for your country when selecting suitable disinfectants.
- ▶ Use exclusively micro pigmentation colours for the treatment that have been tested and approved for puncturing human skin. Make sure to also observe the applicable guidelines of your country during your selections. Infections or possible side effects may occur if you inject into the skin micro pigmentation colours that have not been designed for a PMU procedure or that may not be guaranteed to be sterile.
- ▶ Use only new needle modules in sterile packaging for each customer. Before each use, ensure that the packaging is intact and that the expiry date has not been exceeded. Note the lot number of the needle module used in the corresponding customer file, so that it may be available for the manufacturer in the event of a later claim.
- ▶ Needle modules are sterile disposable products (consumables) and must never be reused!
- ▶ Discard used or defective needle modules, as well as needle modules in damaged packaging in a puncture-proof container (Sharps container) according to the regulations of your country.
- ▶ Make sure to check before each treatment, even with the device in the OFF position, that the needle is fully retracted inside the needle module. Should this not be the case, dispose of the needle module immediately.
- ▶ Prevent needles coming into contact with contaminated objects, like clothing etc. Contaminated needle modules must be disposed of immediately.
- ▶ All equipment, i.e. the handpiece, the cable to the handpiece, the device, including the integrated handpiece rest have to be covered with protective foil during the procedure. The handpiece is covered with protective foil before the needle module is inserted (see chapter 5.7 Fitting the hygiene sheath) on page 22.
- ▶ Avoid skin contact right after the procedure. Protect freshly treated skin areas from contamination, UV radiation and direct sunlight.
- ▶ Check regularly if the handpiece has been contaminated by backsplashing bodily fluids or if the pigment colours are visibly contaminated. In that event, also note chapter "7.4 Cleaning surfaces" on page 28 for regular disinfection and 7.2 "Material compatibilities" on page 28, and the "Product-specific safety instructions" on page 7.
- ▶ Should you be using a local anaesthetic, this product must be thoroughly removed before the treatment.

8 TRANSPORT AND STORAGE REQUIREMENTS

8.1 Device, handpiece with connection cable, power supply plug and foot-operated switch

ATTENTION

Product damage caused by dropping

The control unit or the handpiece may suffer damage if dropped.

- ▶ Always rest the control unit on its rubber feet on a level and stable surface so that it cannot fall easily.
- ▶ Place the handpiece after each use onto the handpiece rest to keep it safe.
- ▶ Should the control unit or the handpiece accidentally drop, perform a visual inspection of its components.
- ▶ Send the control unit or the handpiece to an authorised dealer for inspection, if any of the components are visibly damaged or are not functioning normally.

- ▶ Transport the device and its accessories only in the original packaging.
- ▶ Always store the device and its accessories under the following conditions:

Ambient temperature	-10°C to +40°C
Relative humidity	10% to 90%
Air pressure	540hPa to 1070hPa

8.2 Needle module

Ambient temperature	+15°C to +25°C
Relative humidity	30% to 65%

9 DISPOSAL



- ▶ Dispose of the product, displaying an icon as shown to the side, according to the applicable regulations for electronic waste. Check with your authorised dealer or with the responsible authorities about the applicable regulations.
- ▶ Provide a container at the workstation for the proper disposal of contaminated parts.
- ▶ Discard used or defective needle modules, as well as needle modules in damaged packaging in a puncture-proof container (Sharps container) according to the current regulations of your country.

7.2 Material compatibilities

- ▶ To clean the device we recommend a mild soap solution as permitted in your country or a 50% solution of water and 1-propanol solution.
- ▶ Use one of the following disinfectant agents to clean the device:

MANUFACTURER	PRODUCT	REACTION TIME
Antiseptics	Big Spray "new"	1 to 5 min
Bode Chemie	Bacillol	30 s to 1 min
Ecolab	Incidin Foam	1 to 2 min
Schülke & Mayr	Mikrozid Liquid	1 to 2 min

You can also assess what other cleaning agents and disinfectants are suitable on the basis of the following material compatibilities.

The device surface finishes are **resistant** to:

- Weak acids (e.g. Boric acid $\leq 10\%$, acetic acid $\leq 10\%$, citric acid $\leq 10\%$)
- Aliphatic hydrocarbons (e.g. Pentane, Hexane)
- Ethanol
- Most inorganic salts and their water based solutions (e.g. sodium chloride, calcium chloride, magnesium sulphate)

The device surface finishes are **not resistant** to:

- Strong acids (e.g. hydrochloric acid $\geq 20\%$, sulphuric acid $\geq 50\%$, nitric acid $\geq 15\%$)
- Oxidising acids (e.g. peracetic acid)
- Alkalis (e.g. caustic soda, ammonia and all substances with a pH value > 7)
- Aromatic/halogenated hydrocarbons (e.g. Phenol, Chloroform)
- Acetone and Benzene

7.3 Disinfecting surfaces

Before and after each use:

- ▶ Disinfect the connection cables, the handpiece and the handpiece rest as described in 5.5 "Cleaning and disinfecting the equipment" on page 20 chapter.

7.4 Cleaning surfaces

For contaminants on the outside:

- ▶ Wipe the device and its accessories with a soft cloth, moistened with cleaning solution or disinfectant.

- ▶ Always firmly hold the handpiece before turning it on, or put it down on the handpiece rest. An unsecured handpiece could possibly injure a person or prick someone during its vibrations while being turned on (see chapter 6.5 "Switching the handpiece on and off" on page 26).

Injuries caused by contaminated needles or needle modules can result in the transmission of diseases (see chapter 5.6 "Inserting or replacing the needle module " on page 21):

- ▶ Should you incur an injury from a contaminated needle, make sure to seek the help of a physician!

To prevent the treatment from exceeding the desired intensity:

- ▶ To avoid the risk of injury by excessive needle protrusion (see chapter 6.3 "Selecting the projection position of the needle" on page 25).
- ▶ Avoid risk of injury as a result of puncture frequency that is set too high (see chapter 6.4 "Selecting the puncture frequency" on page 26).

2.4 Contraindications

In the event of the following contraindications, micro-pigmentation must **not** be performed.

- Haemophilia (blood disease) or other blood clotting disorders.
- Uncontrolled diabetes mellitus
- Treatment of mucous membranes, gums or eyeballs
- Treatment of skin areas with dermatosis, (e.g. skin tumours, keloids) or in case of severe keloid tendencies, solar keratosis, warts or birthmarks.
- Systemic infections (such as hepatitis types A, B, C, D, E or F or HIV infection).
- Allergic reactions to one or more ingredients of the pigment colour(s).
- Allergy to topical anaesthetics (local anaesthetics)
- Client is under the influence of alcohol and/or drugs

In the following cases, a micro pigmentation (tattoo) must **not be done for some time until the normal state of health** has been restored:

- If the client is currently taking blood-thinning and/or pain-relieving substances (e.g. Warfarin, heparin, acetyl/salicylic acid, Aspirin)
- In case of infections accompanied by fever
- During chemotherapy or radiotherapy treatment and/or while currently taking high doses of corticosteroids.
- During pregnancy or while breast feeding

Temporary, limited and local contraindications:

- Eczema, exanthema or open wounds
- Acute inflammation of the conjunctiva (contraindicated when pigmenting eye-liner)
- All types of scars
- Skin areas after plastic surgery performed less than twelve months ago
- Skin areas after filler or laser IPL treatments performed less than six months ago

- Four weeks before and after chemotherapy
- Make sure that patients with a herpes simplex virus infection have received prophylactic antiviral therapy before treatment

If there is the slightest doubt concerning the customer's safety, then treatment may not be begun or, if applicable, treatment must be immediately discontinued.

Treatment must be immediately discontinued in the case of:

- Excessive pain
- Fainting spells/dizziness

2.5 Side effects

Complications during micro-pigmenting procedures are rare and usually minor. Industry literature has mentioned the following side effects:

Frequent:

- Local bleeding on the surface of the freshly treated skin
- Pain may be noticeable on the first day after the procedure
- Occurrence of inflammatory reactions, haematoma, erythema and oedema in the first three to five days after the procedure
- Occurrence of skin irritations (e.g. itching or warming) that normally subside within the first 12 to 48 hours after the procedure

Rare:

- Occurrence of hyper pigmentation with endogenous pigments, in particular on darker skin types, which generally disappear completely after a few weeks
- In cases of careless or inadequate skin cleaning, there have been reports of scab formation, small pustules or milia
- Retinoid reaction (slight reddening to skin peeling)
- Possible warming of the pigmented area under PET and MRT radiation
- Allergic reactions to parts of the aseptic colour
- Formation of herpes simplex virus type I (HSV-I) blisters in cases of previously untreated infections.

Furthermore, the following problems may arise after micro-pigmentation:


- Colour differences
- Pigment loss

Freshly treated skin areas should generally be protected against UV radiation and from direct sunlight.

To turn the handpiece off:

- ▶ Press the **RUN** button again (RUN).

7 CLEANING AND MAINTENANCE

	CAUTION
<p>Short circuiting hazard and risk of slight electric shock does exist.</p> <p>If components of the device are dismantled and cleaned while the unit is turned on, you run the risk of incurring a slight electrical shock or damaging the electronics in the drive motor.</p> <p>▶ Disconnect the control unit from the power supply before beginning any cleaning and maintenance work.</p>	

ATTENTION	
<p>Damage resulting from moisture/liquids</p> <p>If cleaning or disinfecting agents should enter the inside of the handpiece, the control unit or the power supply plug, it can cause short circuiting. In addition, the mechanical and electrical components may corrode.</p> <p>▶ Never soak the handpiece, control unit or the power supply plug in cleaning or disinfectant agents.</p> <p>▶ Never clean the handpiece, the control unit or the power supply plug in an autoclave or an ultrasonic bath.</p> <p>▶ When selecting cleaning and disinfecting agents, note material compatibilities (see chapter 7.2 "Material compatibilities" on page 28).</p>	

7.1 Inspection

An inspection may only be carried out by an authorised dealer.

We recommend to drop off the device at an authorised service dealer at regular 24 month intervals for an inspection according to the manufacturer's specifications.

6.4 Selecting the puncture frequency



CAUTION

Risk of injury due to high puncture frequency

The skin may be cut if the puncture frequency is set too high.

- ▶ Always begin with a low puncture frequency, e.g. 100 Hz
- ▶ Always select the puncture frequency suitable for your customer's skin texture and the speed you will be working.

The preset puncture frequency is 100 punctures per second. The control unit resets itself to this presetting automatically each time it is turned on. The puncture frequency has 10 adjustment options between 70 and 150 punctures per second.

The per second puncture number displayed on the handpiece may deviate by $\pm 10\%$ from the actual number when running stationary.

To set the appropriate puncture frequency:

- ▶ Press the **Frequency up** button (\blacktriangle), to increase the puncturing frequency.
- ▶ Press the **Frequency down** button (\blacktriangledown), to decrease the puncturing frequency.

6.5 Switching the handpiece on and off




CAUTION

Risk of injury when operating the handpiece

An unsecured handpiece could possibly injure a person or prick someone during uncontrolled vibrations while being turned on.

- ▶ Firmly hold the handpiece before turning it on, or put it down on the handpiece rest.

To turn on the handpiece:

- ▶ Make sure that the power supply has been established (see chapter 5.2 "Connecting the power supply plug" on page 18).
- ▶ Make sure that the control unit has been switched on (see chapter 6.1 "Switching the control unit into operating or stand-by mode" on page 24).
- ▶ Make sure that the handpiece has been connected properly (see chapter 5.4 "Connecting the handpiece" on page 20).
- ▶ Press the **RUN** button (RUN) on the control unit.
The current operational mode of the handpiece is displayed on the control unit with a symbol  next to the frequency.

If the connected handpiece does not start:

- ▶ Please refer to chapter 10 "In the event of questions and problems" on page 30.

2.6 Required Qualifications (User Requirements)

The device including its accessories is not to be used by persons (including children) with reduced physical, sensory or mental capabilities. The device including its accessories is not to be used by persons with lack of experience and knowledge, unless they have been given supervision or instruction (training).

The device may only be used by persons that have completed the following training:

- Qualification for micro-pigmentation/PMU
- Basic knowledge of micro-pigmentation treatments (see chapter 6.4 and 6.5) on page 26
- Knowledge of the hygiene and safety regulations (see 2.3 "Important hygiene and safety regulations" on page 8ff)
- Knowledge of the risks and side effects (see chapter 2.4 "Contraindications" on page 9 and 2.5 "Side effects" on page 10)

2.7 Purpose, scope and intended use

2.7.1 Purpose

The purpose of the device is to facilitate the minimally invasive micro-pigmentation of sterile or aseptic pigments of mineral or organic origin into the dermis (permanent make-up).

No open wounds are left in the skin due to minimally invasive puncturing of the epidermis or dermis. This allows the epithelial function to be restored very quickly and the treatment requires only a very short recovery period.

2.7.2 Area of application

Application examples for micro-pigmentation (PMU) are:

- Pigmenting eyebrows
- Pigmenting eye-liners
- Pigmenting lip-liners and/or filling in lip colour
- Cosmetic pigmentation of the areola
- Cosmetic pigmentation of the body

2.7.3 Intended use

The procedure must be done in a dry, clean and smoke-free environment, and always under hygienic conditions. The device must be prepared, used and maintained as described in this operating manual. In particular, the applicable provision of workplace design must be taken into account and the materials used must be sterile.

Proper use also includes these operating instructions and especially the chapter "Important Safety Notes" being fully read and understood.

Intended use includes only the following groups of consumers: Adult men and women at least 18 years of age who are in a good state of health.

It is considered improper or unintended use if the device or its accessories are used in any way other than described in this user manual, or if the operating conditions are not observed. Particularly forbidden are treatments with contraindications (see chapter 2.4 "Contraindications" on page 9).

2.8 Symbols displayed on the Product

2.8.1 Miscellaneous symbols

The following symbols may be found in this user manual, on the product, its accessories or the packaging:


SYMBOL	MEANING
	Device complies with the requirements of the 2006/42/EG & 2004/108/EC Directive
IP21	Housing provides protection against coarse dust and water droplets.
IPX6	Housing provides protection against pressurised water jets.
IP40	Housing provides protection against foreign objects thicker than 1 mm.
	Applied part Type B: Applied part offers safety against electric shock and leakage.
	Handpiece
	Foot-operated switch
	DC power connector/inner pin positive
	DC current
	AC current
	Observe manual!
	Manufacturer
	Date of manufacture

- ▶ The (RUN) button starts the treatment process and stays illuminated during the entire procedure.
- ▶ In addition, the Play icon will display on the screen.
- ▶ Frequencies can be changed at any time during the procedure.
- ▶ Selecting a preset mode during the procedure is not possible.
- ▶ The procedure is ended by pressing the (RUN) button again.

6.2.2 Working in the Preset mode

- ▶ Should you select a preset, it will be displayed as a graphic. A default working frequency is displayed for this mode.
- ▶ The (RUN) button will start the selected application. You are able to change the frequency during this procedure too, while remaining in the preset mode.
- ▶ If you press the same Preset button 2x consecutively, you will exit the preset mode and the Preset symbol will disappear. The last frequency setting will remain displayed and can be changed at any time.
- ▶ If the device is inactive for 30 minutes, it prepares to go into sleep mode.
- ▶ You will see the message "automatic shut down" for approx. 1 minute.

6.3 Selecting the projection position of the needle

**CAUTION**

Risk of injury if needle protrudes too far
A far-protruding needle position makes a deeper puncture possible. If needle protrusion and puncture depth are too large, the risk of side effects such as haematoma, erythema, or oedema will increase, (see chapter 2.5 "Side effects" on page 10).

- ▶ Select the needle protrusion depending on your customer's skin texture in the area of the procedure.

- ▶ Switch the control unit into operating mode.
- ▶ Adjust the needle position by twisting the flexible part of the handpiece (1).

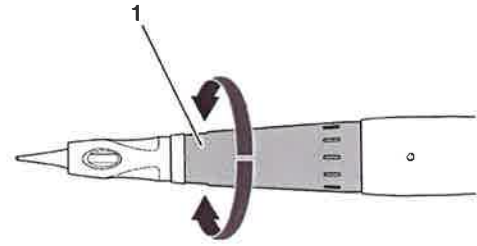


Fig.8: Adjusting the needle projection



5.9 Checking the equipment

- ▶ Perform a visual inspection of the equipment:
 - Should there be visible external damage (e.g. kinks in the cable connection, a loose cap at the cable connection point)?
 - Are cables exposed?
 - Are the needle module and the needle aligned correctly? Have all needles been retracted all the way into the needle module?
 - Does the control unit display a fault signal?
- ▶ Switch on the handpiece and perform a sound check: Do operating noises or volume appear abnormal?
- ▶ Refer to the following chapters in case of any abnormalities 10 "In the event of questions and problems" on page 30 and 11.1 "Warranty declaration" on page 31.
- ▶ Do not continue using the device if it can no longer be operated safely; take it out of service and contact your authorised dealer.

6 OPERATION

6.1 Switching the control unit into operating or stand-by mode

To switch the control unit into operating mode:



- ▶ Make sure that the power supply has been established (see chapter 5.2 "Connecting the power supply plug" on page 18).
- ▶ The control unit is switched ON/OFF  at the button on the right side of the device. You will hear a brief signal tone when turning the unit on (sequence of a short and a long beep). All buttons are slightly dimmed. To turn off the device, press and hold the button for a moment (approx. 1-2 seconds). The unit will turn off. If the device is inactive for 30 minutes, it prepares to go into sleep mode. You will see the message "automatic shut down" for approx. 1 minute. A blue LED below the display is lit in sleep mode. Press the ON / OFF button  to turn the unit back to operating mode.






When a fault signal appears:




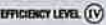






- ▶ Please refer to chapter 10 "In the event of questions and problems" on page 30.

6.2 Configuring the control unit

6.2.1 Working without a preset

- ▶ If no selection of a suitable preset is made within approx. 5 seconds, the standard setting of (100 Hz) will appear.
- ▶ A preset can be selected at any time.
- ▶ A change in frequency can be made via the button **Frequency up** () and the button **Frequency down** () in increments of 10.
- ▶ The frequency buttons light up briefly when pressed.

SYMBOL	MEANING
	Catalogue number, order number
	Serial number
	Lot code
	Sterilised with ethylene oxide
	Use by
	Caution!
	Temperature limit
	Humidity limit
	Keep dry
	For indoor use only
	Fragile
	Do not use if packaging is damaged!
	Not available for re-use
	Do not resterilise

SYMBOL	MEANING
	Properly dispose of as electronic equipment
	Warning - risk of injury due to cuts or punctures.
	JAPAN TUV R-PSE
	Energy Efficiency Level VI
	Device complies with Japanese VCCI Standards
	CHINA SJ/T 11364-2014
	Distinctive component for Canada and US
	Double insulation/Protection category II device
	GHOST-R mark for Russia
RoHS2	Device meets the requirements of RoHS 2
	SIQ Mark License EN60601-1

- ▶ Tape the end of the hygiene sheath to the flexible part of the handpiece.

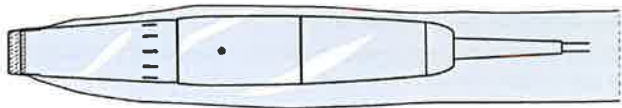



Fig. 6: Hygiene sheath fitted into place

- ▶ Make sure to discard used hygiene sheaths after each completed procedure into the containers for proper disposal of contaminated parts.

5.8 Fill the needle module

	WARNING
Risk of infection and side effects due to prohibited or contaminated micro pigmentation colours.	
Should you inject into the skin micro pigmentation colours that are not intended for PMU procedures or with sterile or antiseptic properties that cannot be guaranteed, infections or other side effects may be result.	
<ul style="list-style-type: none"> ▶ Use exclusively antiseptic and sterile micro pigmentation colours for the procedure that have been tested and approved for penetration into human skin. ▶ Make sure you observe the applicable guidelines of your country when selecting suitable micro pigmentation colours. ▶ Take note of the information supplied with the micro pigmentation colours to be used. ▶ Use suitable applicators when inserting the micro pigmentation colours into the needle module to maintain the sterile integrity of the substances. 	

- ▶ Check for a secure seat of the needle module.
- ▶ Inject the desired companion product with a suitable applicator that guarantees sterility, through the fill opening (1) into the needle module. Please note the fill capacity of the needle modules of approximately 1 ml.

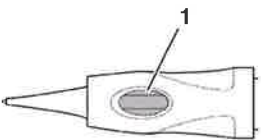


Fig. 7: Filling the needle module

- Insert the bayonet connector of the needle module into the opening of the handpiece as shown below. You can insert the needle module aligned in any direction.

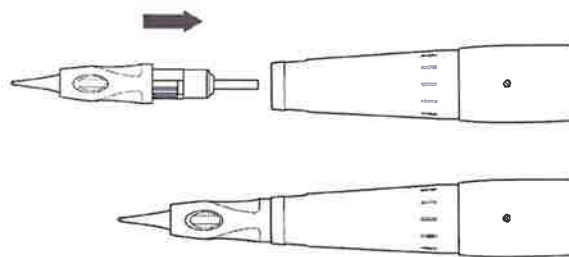


Fig. 4: Inserting the needle module

- Twist the needle module clockwise until you can feel resistance. The needle module is now firmly placed in the handpiece.

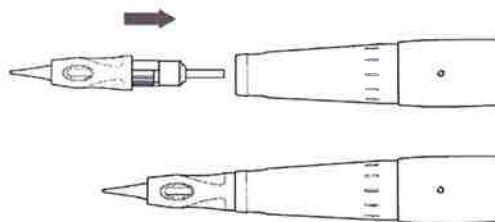


Fig. 5: Inserting the needle module

- Check for a secure seat of the needle module.
- To remove the needle module, twist it counter-clockwise and remove it from the handpiece.

5.7 Fitting the hygiene sheath

To protect the handpiece and connection cable during the treatment from contamination with bodily fluids, or from companion products that have been contaminated with bodily fluids, the handpiece should be covered with a hygiene sheath with a diameter of 20 to 27 mm. That corresponds to a sheath width of approx. 30 to 45 mm.

Proper application of the hygiene sheath:

- Slide the hygiene sheath completely over the connection cable and the handpiece.

SYMBOL	MEANING
	Ukraine UKRSepro



For further information, see Instruction for Use

3 SCOPE OF DELIVERY

- 1 Control unit
- 1 Handpiece with connection cable
- 1 Power supply plug with travel charger (EU, UK and USA)
- 1 Manual
- 1 Needle module point Safety Needle
- 1 Needle module 3 point Safety Needle
- 1 Needle module 5 point Shader Safety Needle
- 1 Foot-operated switch
- 1 Warranty declaration

The hygiene sheaths (25500) needed for practising the procedures are not included in the supply. The accessories to match your handpiece are available at your respective authorised dealer, see "Accessories and spare parts" on page 16.

4 PRODUCT INFORMATION

4.1 Technical Data

Device type:	10100
Rated voltage	100-240 V AC, 50-60 Hz
Power consumption	max. 10 VA
Power supply plug model	WR9QG1200CSPCR6B2958 (GlobTek)
Protection class	IP21
Puncture rate	70-150 Hz
Drive	Precision motor – DC
Operating mode	Continuous operation
Dimensions (W x H x D)	253 mm x 133 mm x 168 mm
Handpiece weight	approx. 100g
Total weight	approx. 1500g

4.2 Operating conditions

Ambient temperature	+15°C to +25°C
Relative humidity	30 to 75%
Air pressure	700 to 1070 hPa

4.3 Accessories and spare parts

The following accessories and spare parts are available for purchase at your authorised dealer.

ACCESSORIES	ARTICLE NUMBER	SCOPE OF DELIVERY	QTY./PACK-ING UNIT
Needle modules:	11201 (1 point Safety Needle)	1	15 pcs
	11203 (3 point Safety Needle)	1	15 pcs
	11215 (5 pont Shader Safety Needle)	1	15 pcs
Hygiene sheath for hand-piece	25500		
Foot-operated switch	10860	1	1 pcs

SPARE PART	ARTICLE NUMBER	SCOPE OF DELIVERY	QTY./PACK-ING UNIT
Control unit	10100	1	1 pcs
Handpiece	10700	1	1 pcs



ATTENTION

Product damage resulting from using unauthorised cleaning or disinfectant agents.

Cleaning and disinfectant agents that are not compatible with the product's materials can cause damage to its surface finish.

- ▶ Exclusively use cleaning and disinfectants that have been approved according to the regulations of your country.
- ▶ When selecting cleaning and disinfecting agents, note material compatibilities (see chapter 7.2 "Material compatibilities" on page 28).

- ▶ Disconnect the control unit from the power supply.
- ▶ Wipe down the control unit, the connection cable, the handpiece and the handpiece rest with a soft cloth moistened with a cleaning agent.
- ▶ Wipe down the handpiece, the control unit, the connection cable and the handpiece rest with a soft cloth moistened with a disinfectant agent.

5.6 Inserting or replacing the needle module



WARNING

Risk of injury from needles

Injuries from contaminated needles can transmit diseases.

- ▶ Exclusively use original needle modules for the device to fit the included handpiece. Due to the built-in safety diaphragm of this needle module, bodily fluids cannot enter the drive, nor can pathogens pass through the membrane.
- ▶ Never touch the tip of the needle module.
- ▶ Always turn off the handpiece before replacing the needle module.
- ▶ Never remove the needles from the needle module by pressing.
- ▶ When removing a needle module, make sure that any companion products and colours do not overflow from the needle module into the handpiece.
- ▶ Please check that the needle has been completely retracted into the module after a used needle module has been removed.
- ▶ Properly dispose of any used needles that are no longer needed for the current procedure as specified (see chapter 9 "Disposal" on page 29).
- ▶ The needle modules are always supplied sterile. Do not remove them from their sterile packaging until right before you are ready to use them.
- ▶ Always place the handpiece on the handpiece rest, so that the needle module does not touch the surface.
- ▶ Should you incur an injury from a contaminated needle, make sure to seek the help of a physician!

- ▶ Turn off the handpiece.

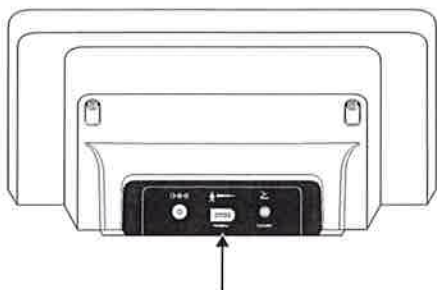
5.4 Connecting the handpiece

A message will be displayed on the control unit as long as there is no handpiece (—) connected to the control unit:



Fig.3: No handpiece connected

- Insert the FireWire plug of the connection cable completely into the output jack of the control unit.



The handpiece will be recognised by the control unit and the preset puncture frequency will appear on the display.

If the connected handpiece is not detected:

- Please refer to chapter 10 "In the event of questions and problems" on page 30.

5.5 Cleaning and disinfecting the equipment



ATTENTION

Damage resulting from moisture/liquids

If cleaning or disinfecting agents should enter the inside of the handpiece, the control unit or the power supply plug, it can cause short circuiting. In addition, the mechanical and electrical components may corrode.

- Never soak the handpiece, control unit or the power supply plug in cleaning or disinfectant agents.
- Never clean the handpiece, the control unit or the power supply plug in an autoclave or an ultrasonic bath.

SPARE PART	ARTICLE NUMBER	SCOPE OF DELIVERY	QTY./PACKING UNIT
Power supply plug (without travel charger)	10800	1	1 pcs
Country-specific travel adapter	10800 EU	1	1 pcs
	10810 UK	1	1 pcs
	D-ADP USA	1	1 pcs
Manual	50010100 EN	1	1 pcs
	50110100 DE	1	1 pcs
	50210100 NL	1	1 pcs

5 OPERATION



ATTENTION

Damages caused by condensation

If the device is subjected to great temperatures difference, i.e. during transport, condensation may develop on the inside, which will damage the electronics.

- Make sure the device has acclimated to the ambient temperature before commissioning. Should it have been subjected to great temperature differences, wait at least 3 hours for each 10°C temperature fluctuation before putting it into operation.
- Operate the device only in temperatures between +15 to +25°C.



CAUTION

Short circuiting hazard and risk of slight electric shock does exist.

Should there be noticeable damage to cables or cable connections, there is a risk of electric shock and damage to the electronics.

- Carry out a visual inspection of the device and cables for damage such as faulty cable connections.
- Never bend the product cables.




CAUTION

Risk of tripping due to cable

Inappropriately routed cables can present a tripping risk and cause injuries.

- Install all cables in such a way that no one will trip over or accidentally pull them.

5.1 Setting up the control unit

**CAUTION**

Restricted operation due to electromagnetic interference

Portable and mobile RF communication devices, such as mobile telephones or WLAN routers can affect device function by emitting electromagnetic radiation. The safe operation of the device can then no longer be guaranteed.

- ▶ Place the appliance in such a way that the recommended safety distance from possible sources of interference is always observed. Information about recommended safety distances may be found in chapter 11.2.3 "Recommended safety distances for portable and mobile RF communications equipment" on page 32.
- ▶ Avoid possible sources of interference by not operating any portable or mobile radio devices in the vicinity of the device.
- ▶ Make your customers aware of this risk of interference sources.

- ▶ Set up the control unit on a clean, firm and level support surface. This device should never be set up and operated beneath other devices.

5.2 Connecting the power supply plug

The device may only be operated with the plug-in power supply specified on the name plate of the device. The mains voltage must be the rated device voltage as it is indicated on the plug-in power supply name plate.

- ▶ If the scope of delivery did not contain a country-specific adapter, please contact your authorised dealer (also see chapter 10 "In the event of questions and problems" on page 30).

To remove the currently connected country-specific adapter, if necessary:

- ▶ Pull and hold back the holding bracket for the adapter and simultaneously lift out the country-specific adapter from the cavity in the power supply plug.

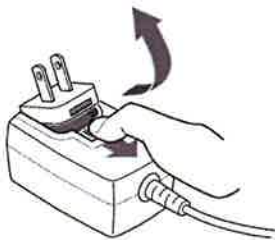


Fig. 1: Remove the country-specific adapter

How to insert the desired country-specific adapters:

- ▶ Insert the country-specific adapter into the power supply plug recess as shown below.

- ▶ Press the adapter into the bracket until it clicks into place.

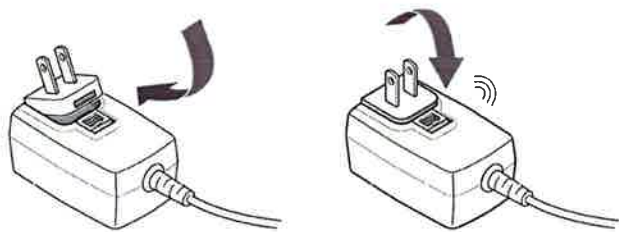

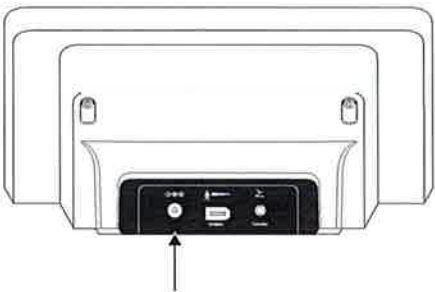


Fig. 2: Insert the country-specific adapter


To establish the voltage supply:

- ▶ Connect the DC plug of the power supply plug into the power supply plug socket on the back of the control unit. ()



- ▶ Insert the power supply plug into the mains socket. The stand-by LED at the control unit lights up in blue.

5.3 Connect the foot-operated switch (optional)

Insert the RCA plug of the foot-operated switch into the foot switch socket () on the back of the control unit.

Only the foot-operated switch authorised as an accessory in 4.3 can ensure safe operation!

