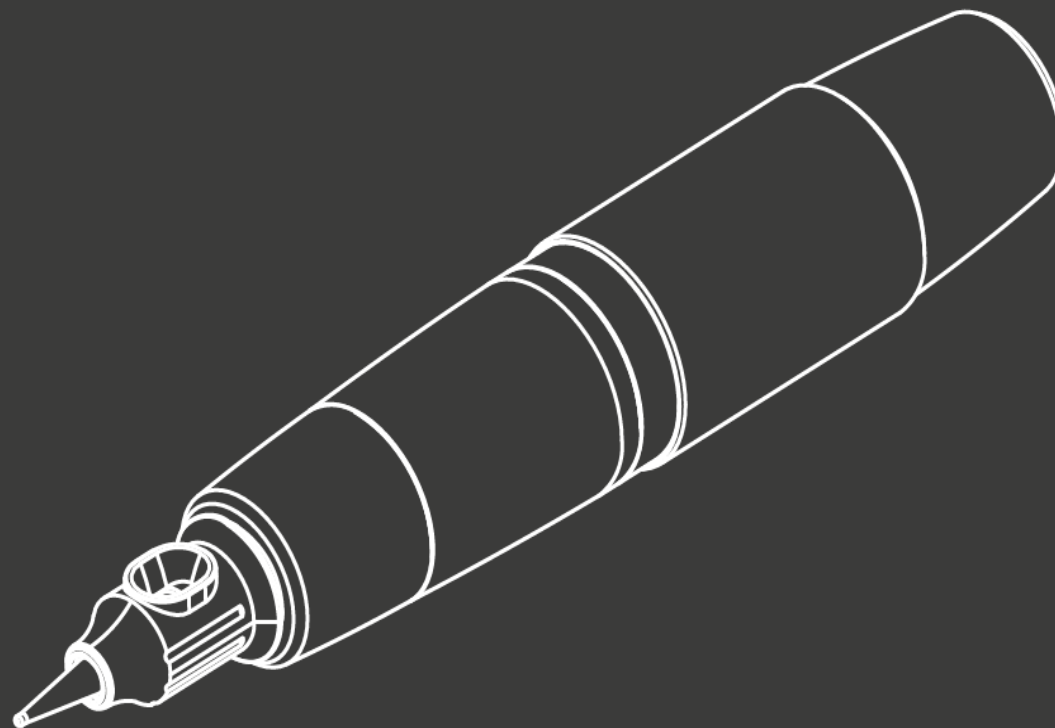


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GEM**



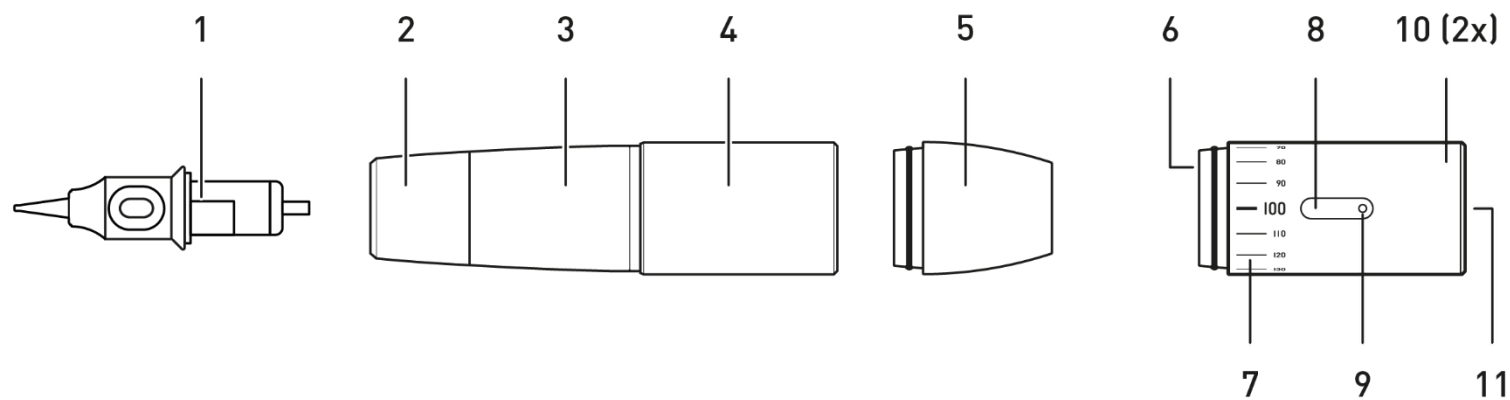
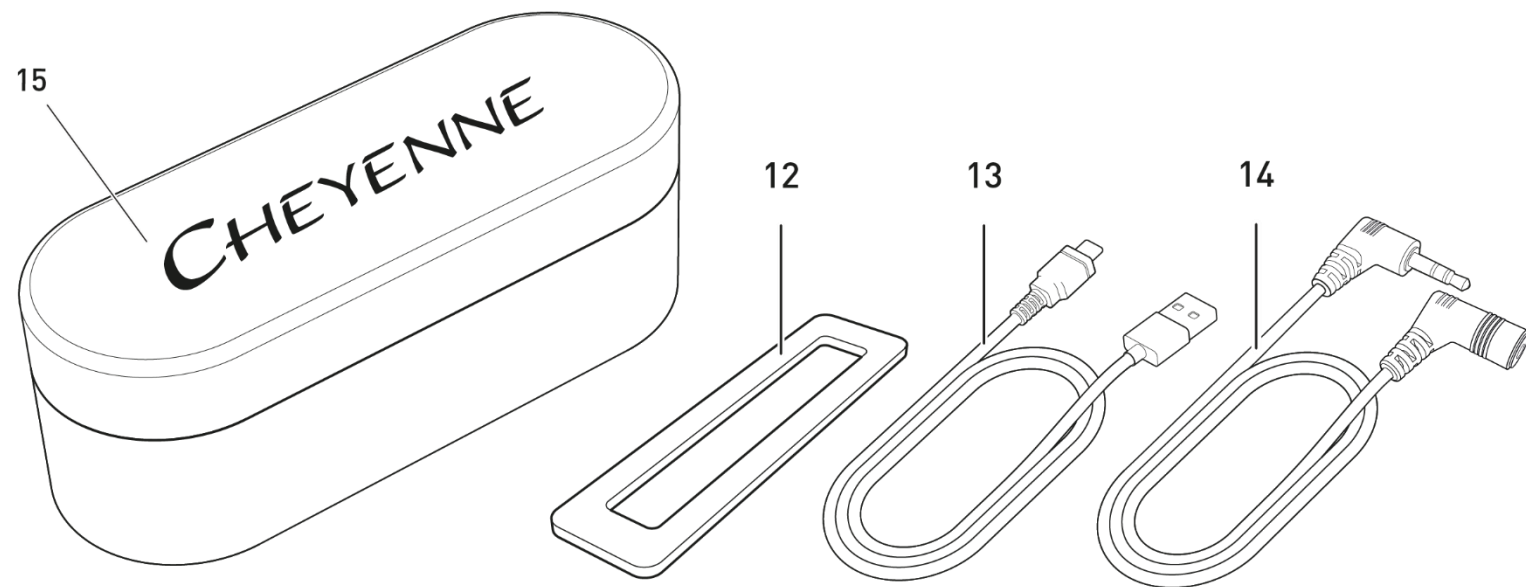
Gebrauchsanweisung
Operating instructions
Gebruiksaanwijzing
Instructions
Istruzioni per l'uso
Instrucciones de uso

Manual de instruções
Οδηγίες
Opskrift
Bruksanvisning
Ohjeet
Instrukcja obsługi

Instrukce
Navodila nt pl za uporabo
Utasítás
инструкции
说明

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	1*	2	3	4	5	6	7	8	9	10	11	12	13	14	15
DE	Nadel-modul	Modul-aufnahme	Antriebs-einheit	Verstell-hülse	Control Unit (CU)-Connector	Kontakt-fläche	Stichzahl Skala	Multi-switch	LED	Batterie Pack	USB-C Buchse	Ablage	Lade-kabel	Verbin-dungs-kabel	Etui
EN	Needle cartridge	Cartridge mount	Drive unit	Adjust-ment sleeve	Control Unit (CU)-Connector	Contact surface	Skala stitch rate	Multi-switch	LED	Batterie Pack	USB-C jack	Tray	Charging cable	Con-nection cable	Case
NL	Naald-module	Module-houder	Aan-drijfunit	Verstel-bus	Control Unit (CU)-Connector	Contac-topper-vlak	Slags-nelheid schaal-verde-ling	Multi-switch	LED	Batterie Pack	USB-C aanslui-ting	Afleg-plank	Oplaad-kabel	Verbin-dingska-bel	Etui
FR	Module d'aiguilles	Loge-ment du module	Unité d'entraî-nement	Man-chon de réglage	Control Unit (CU)-Connector	Surface de contact	Nombre de pénétra-tions - Échelle	Multi-switch	LED	Batterie Pack	Prise USB-C	Support	Câble de charge-ment	Câble de raccor-dement	Étui
IT	Modulo aghi	Sede del modulo	Unità di aziona-mento	Boccola di rego-lazione	Control Unit (CU)-Connector	Super-ficie di contatto	Scala numero punture	Multi-switch	LED	Batterie Pack	Presa USB-C	Portau-tensile	Cavo di ricarica	Cavo di collega-mento	Astuccio
ES	Módulo de agujas	Aloja-miento del módulo	Unidad de acciona-miento	Man-guito de ajuste	Control Unit (CU)-Connector	Super-ficie de contacto	Escala de número de pun-ciones	Multi-switch	LED	Batterie Pack	Toma de conexión USB-C	Bandeja	Cable de carga	Cable de cone- xión	Estuche
PT	Módulo de agulhas	Corpo do módulo	Unidade de aciona-mento	Mandril de ajuste	Control Unit (CU)-Connector	Super-fície de contato	Escala de nú- mero de perfura- ções	Multi-switch	LED	Batterie Pack	Porta USB-C	Bandeja	Cabo de carrega-mento	Cabo de conexão	Bolsa
EL	Μονάδα βελονών	Υποδοχή μονάδας	Μοτέρ	Χιτώνιο ρύθμισης	Control Unit (CU)-Connector	Επιφάνεια επαφής	Κλίμακα αριθμών στίξης	Multi-switch	LED	Batterie Pack	Υποδοχή USB-C	Βάση απόθε-σης	Καλώδιο φόρτισης	Καλώδιο σύνδεσης	Θήκη

	1*	2	3	4	5	6	7	8	9	10	11	12	13	14	15
DA	Nålemo- dul	Modul- holder	Driven- hed	Juste- rings- muffe	Control Unit (CU)- Con- nector	Kontakt- flade	Antal penetre- ringer skala	Multi- switch	LED	Batterie Pack	USB-C- stik	Holder	Ladeka- bel	Tilslut- ningska- bel	Etui
SV	Nålmo- dul	Modul- hållare	Driven- het	Juste- rings- hylsa	Control Unit (CU)- Con- nector	Kontak- tyta	Stick- antal skala	Multi- switch	LED	Batterie Pack	USB-C- hylsa	Hylla	Laddka- bel	Anslut- ningska- bel	Etui
FI	Neula- moduuli	Moduuli- kiinnitys	Käyt- töyk- sikkö	Säätö- holkki	Control Unit (CU)- Con- nector	Koske- tuspinta	Pisto- lukuas- teikko	Multi- switch	LED	Batterie Pack	USB-C-lii- tämä	Alusta	Lataus- johto	Liitos- johto	Laukku
PL	Moduł igłowy	Uchwyt modułu	Jed- nostka napędo- wa	Tuleja prze- stawna	Control Unit (CU)- Con- nector	Po- wierzch- nia stykowa	Liczba kresek skali	Multi- switch	Dioda LED	Batterie Pack	Gniazdo USB-C	Półka	Kabel ładowa- nia	Kabel połącze- niowy	Etui
CS	Jehlový modul	Uchycení modulu	Pohonná jednotka	Nasta- vovací pouzdro	Control Unit (CU)- Con- nector	Kon- taktní plocha	Stupnice počtu vpichů	Multi- switch	LED	Batterie Pack	Zásuvka USB-C	Uložení	Nabíjecí kabel	Připo- jovací kabel	Pouzdro
SL	Igelni modul	Držalo modula	Po- gonska enota	Nasta- vitveni tulec	Control Unit (CU)- Con- nector	Kon- taktna površina	Skala za nasta- vitev števíla vbodov	Multi- switch	Svetlob- na dioda LED	Batterie Pack	Vtičnica USB-C	Odlá- galna plošča	Polnilni kabel	Priključni kabel	Etui
HU	Tűmodul	Modul- befogó	Meghaj- tóegység	Állító- persely	Control Unit (CU)- Con- nector	Érintke- zőfelület	Arány- szám skála	Multi- switch	LED	Batterie Pack	USB-C persely	Lerakó	Töltőká- bel	Ösz- szekötő kábel	Tok

- * Nicht im Lieferumfang enthalten
- * Not included in the scope of delivery
- * Niet in de leveringsomvang opgenomen
- * Non fourni
- * Non incluso nell'oggetto della fornitura

- * No incluido en el volumen de suministro
- * Não contido no escopo de fornecimento
- * Δεν περιλαμβάνεται στην έκταση παράδοσης
- * Medfølger ikke
- * Ingår inte i leveransen

- * Ei sisälly toimitukseen
- * Nieobjęty zakresu dostawy
- * Není součástí dodávky
- * Ni vključeno v obseg dobave
- * Nem része a szállítási terjedelembek

Die für die Verwendung nötigen Nadelmodule, Hygieneschläuche und ein Steckernetzteil sind nicht im Lieferumfang enthalten. Sie können diese Zubehörteile passend zum Produkt über den zuständigen Fachhändler erwerben (siehe Kapitel 4.2 auf Seite 16).

The needle cartridges, handpiece covers, and power supply needed for use are not included in the scope of delivery. You can purchase these accessories to match your product from your local specialist retailer (see chapter 4.2 on page 47).

De voor het gebruik benodigde naaldmodule, hygiëneslang en voedingsadapter zijn niet in de leveringsomvang opgenomen. U kunt deze bij het product passende accessoires kopen bij uw dealer (zie hoofdstuk 4.2 op pagina 78).

Les modules d'aiguilles, tuyaux hygiéniques et le bloc d'alimentation nécessaires à l'utilisation ne sont pas fournis. Vous pouvez obtenir ces accessoires adaptés au produit auprès d'un revendeur agréé (voir chapitre 4.2, page 108).

I moduli aghi, i tubi flessibili igienici e un alimentatore a spina, necessari per l'uso, non sono inclusi nell'oggetto della fornitura. Questi accessori possono essere acquistati presso il rivenditore specializzato (vedere capitolo 4.2 a pagina 140).

Los módulos de agujas, las fundas higiénicas y el adaptador de red necesarios para la utilización no se incluyen en el volumen de suministro. Los accesorios adecuados para el producto se pueden adquirir por medio del distribuidor correspondiente (véase el capítulo 4.2 de la página 172).

Os módulos de agulhas, as mangas de higiene e o transformador necessários para a utilização do equipamento não estão incluídos no escopo de fornecimento. Esses acessórios, compatíveis com o produto, podem ser adquiridos através do revendedor autorizado (veja o capítulo 4.2 na página 204).

α τὰ τα κατάλληλα για το προϊόν σας αξεῖρ από το αρμόδιο εξεικεμένο κατ'οχήμα (βλέπε κεφάλαιο 4.2 στη σελίδα 237).

De nålemoduler, hygiejneslanger og strømforsyningsstik, der er nødvendige for brugen, medfølger ikke. Disse tilbehørsdele, der passer til produktet, kan købes hos den relevante specialforhandler (se afsnit 4.2 på side 268).

De nålmoduler, hygienslangar och den kontaktnättdel som behövs till användningen ingår inte i leveransen. De tillbehörsdelar som passar till produkten säljs i fackhandeln (se kapitel 4.2 på sidan 297).

Käyttöön tarvittavat neulamoduulit, hygienialetkut ja pistokeverkko-osa eivät sisälly toimitukseen. Nämä tarvikkeosat voit hankkia tuotteeseen sopivasti vastaavalta jälleenmyyjältä (katso luku 4.2 sivulla 325).

Wymagane do użycia moduły igłowe, rękawy higieniczne i zasilacz wtykowy nie są objęte zakresem dostawy. Akcesoria te odpowiednie do produktu można zakupić u właściwego wyspecjalizowanego dystrybutora (patrz rozdział 4.2 na stronie 356).

Jehlové moduly, hygienické hadice a síťový adaptér potřebné k použití nejsou součástí dodávky. Toto příslušenství, které se hodí k výrobku, můžete zakoupit u svého odborného prodejce (viz kapitola 4.2 na straně 387).

Igelni moduli, higienske cevi in vti...ni napajalnik, ki so potrebni za uporabo, niso vklju...eni v obseg dobave. To dodatno opremo, ki ustreza izdelku, lahko kupite pri svojem specializiranem prodajalcu (glejte poglavje 4.2 na strani 416).

A használathoz szükséges tfmodulok, higiéniai tömlők és egy csatlakozódugós hálózati egység nem része a szállítási terjedelemnek. Ezeket a tartozék alkatrészeket a terméknek megfelel/en az illetékes szakkeresked/nél szerezheti be (lásd a 4.2 fejezetet a 448. oldalon).

Translation of the
original instructions
for use. The original
instructions for use
were written in
German.

Instruction for use

Table of Contents

1	About this Operating Manual	39	6	Using the product	54
1.1	Depiction of warnings	39	6.1	Using the machine with Batterie Pack	54
2	Important safety information	40	6.2	Use at the control unit	57
2.1	General Safety Information	40	6.3	Setting the needle depth.....	58
2.2	Batterie Pack safety instructions.....	40	6.4	Filling needle cartridges.....	58
2.3	Product-dependent safety information	41	7	Cleaning and maintaining the product	59
2.4	Important hygiene and safety regulations.....	41	7.1	Material compatibilities.....	59
2.5	Contraindications and side effects	43	7.2	Disinfecting surfaces	60
2.6	Purpose, application area and intended use	45	7.3	Cleaning surfaces	60
2.7	Symbols on the product	45	7.4	Cleaning or replacing o-rings.....	61
3	Scope of delivery	46	8	Operating, loading, transport, and storage conditions	61
4	Product information	46	9	Disposal of equipment	63
4.1	Technical Data.....	46	10	For questions or problems	63
4.2	Accessories	47	10.1	General.....	63
5	Preparing the machine for use	48	10.2	Operation at the Batterie Pack.....	63
5.1	Checking the equipment	48	10.3	Operation at the control unit	64
5.2	Disinfecting equipment	49	11	Manufacturer Declarations.....	64
5.3	Charging the Batterie Pack.....	50	11.1	Disclaimer of warranties.....	64
5.4	Connecting and disconnecting the drive unit with the Batterie Pack	52	11.2	Declaration of Conformity	66
5.5	Pull on the handpiece cover	52	11.2	UK-Declaration of Conformity.....	68
5.6	Changing the needle cartridge	53			

1 About this Operating Manual

This operating manual applies to the listed components within the scope of supply (see chapter 3 on page 46). It contains important information about how to operate and maintain these products safely and in the intended manner.



This operating manual does not include all information needed to safely and properly commission, operate, and maintain the system composition consisting of handpiece, control unit and its accessories.

As such, it is essential that you also observe the following additional documents:

- The operating manual of the selected control unit
- Information about the needle cartridges and PMU inks
- The safety datasheets of the suitable cleaning agents and disinfectants
- The applicable occupational safety regulations and statutory provisions for micropigmentation/permanent make-up

1.1 Depiction of warnings

Warning notices draw attention to the risk of personal injury and damage to materials and are structured as follows:

 SIGNAL WORD	
Type of hazard	
Consequences	
► Remedy	
Element	Meaning
	Indicates a risk of injury
Signal word	Specifies the severity of the hazard (see table below)
Type of hazard	Gives the type and source of the hazard
Consequences	Describes potential consequences of non-compliance
Remedy	gibt an, wie man die Gefahr umgehen kann

Signal word	Meaning
Hazard	Indicates a hazard that will definitely lead to death or to serious injury if the hazard is not avoided
Warning	Indicates a hazard that may lead to death or to serious injury if the hazard is not avoided
Caution	Indicates a hazard that can lead to minor to relatively serious injury if the hazard is not avoided
Attention	Indicates potential risks to the environment, property or equipment if this hazard is not avoided

Symbols used in this operating manual

Symbols	Meaning
►	Call for action
•	List point
-	List sub-point

2 Important safety information

2.1 General Safety Information

- ▶ Read the entire operating manual carefully.
- ▶ Keep this operating manual in a readily accessible location for everyone who uses, cleans, disinfects, stores or transports the device.
- ▶ Follow the safety regulations for permanent make-up applications in your country. Keep your studio in a hygienic, clean condition and ensure sufficient lighting.
- ▶ Use the device, its accessories and all handpiece cables only if in perfect technical condition.
- ▶ Always use original needle cartridges, accessories and spare parts.

2.2 Batterie Pack safety instructions

- ▶ Only use the Batterie Pack as described in this operating manual and with drive units approved by the manufacturer.

- ▶ Disconnect the Batterie Pack from the drive unit and switch it off (=Stand-By mode) whenever you transport or store the product.
- ▶ Protect the Batterie Pack from heat (> 60 °C, for example, also from prolonged sun exposure to sunlight) and fire, and from immersion in liquids. Do not charge, store, or operate the Batterie Pack near hot or flammable objects. There is a risk of explosion.
- ▶ When not in use, keep the Batterie Pack away from paper clips, coins, keys, nails, screws, or any other small metal objects that can cause the contacts to be bridged.
- ▶ A short circuit between the Batterie Pack's contacts may cause burns or result in a fire.
- ▶ The Batterie Pack must not be exposed to mechanical impacts. There is a risk of damaging the battery.
- ▶ If damaged, or if the Batterie Pack is improperly used, vapors may escape from the battery. Introduce fresh air and seek out a physician if you have any physical symptoms.

- ▶ Never attempt to open the Batterie Pack. The user cannot replace the supplied battery (Li-Po).
- ▶ Keep the Batterie Pack out of the reach of children.
- ▶ Check the Batterie Pack for damage before use or charging. Do not use or charge the Batterie Pack if it is unusually hot or shows other signs of damage. Contact your specialist dealer.
- ▶ Only charge, operate, transport, or store the Batterie Pack under the specified conditions (see chapter 8 on page 61).
- ▶ The Batterie Pack must never be charged unsupervised.
- ▶ Charge the Batterie Pack fully before first-time use. It is delivered partially charged.
- ▶ Do not charge the Batterie Pack near hot or flammable materials. The Batterie Pack must be dry while charging. Theoretically, there is a risk of fire due to the heat that builds up while charging. Choose a fire-safe location for charging. It is normal for the Batterie Pack to heat up slightly during charging and this is not a danger.

Charging will be interrupted if temperatures exceed the permissible limits.

- ▶ Fully charge the Batterie Pack once every 6 months to avoid leakage or performance loss.
- ▶ Only use the charging cable included with the product connected to a suitable power source that meets the properties listed in chapter 4.1 on page 46 under the conditions described in chapter 8 on page 61 to charge the Batterie Pack.

2.3 Product-dependent safety information

- ▶ Never modify the device, the needle cartridges or other accessories.
- ▶ Children must be supervised and steps must be taken to keep them from playing with the device.
- ▶ Make sure that no liquids can seep into the interior of the device, the handpiece, the foot switch or the power supply.

▶ While working, use the handpiece cover to protect with the handpiece and the handpiece cable against contamination by body fluids or substances contaminated with body fluids.

▶ If you are not using the device, disconnect it from the power supply and place the handpiece in the handpiece tray to ensure that it cannot roll away and fall down.

▶ Observe the technical data specified in this operating manual and comply with operating, transport and storage conditions (see chapter Operating, loading, transport, and storage conditions).

▶ Hand over the device to a specialist retailer for inspection if it exhibits any external signs of damage, does not function as usual or liquids have seeped into the device or handpiece.

2.4 Important hygiene and safety regulations

Please observe the following instructions to prevent contamination or infectious diseases from being transmitted to the client or user during treatment:

▶ Before treatment, follow all the steps required to disinfect the equipment (chapter 7 on page 59).

▶ During treatment, wear disposable nitrile or latex gloves and disinfect them before use. When selecting an appropriate disinfectant, observe the regulations that apply in your country.

▶ Before treatment, clean the affected areas of the client's skin with a mild cleanser and disinfectant. When selecting an appropriate disinfectant, observe the regulations that apply in your country.

▶ For each treatment, only use inks, which have been tested and approved for penetrating human skin. Observe the regulations that apply in your country when making the selection. If micro-pigmenting inks are introduced into the skin that are not intended for permanent make-up treatment or whose sterility is not guaranteed, infections or possible side effects may occur.

▶ For each client always use new, sterile-packaged needle cartridges. Before each usage, ensure that the packaging is undamaged and that the expiration date

has not passed. Note the batch number (lot number) of the needle cartridges used in the corresponding client file in order to be able to inform the manufacturer if any problems occur.

- ▶ Needle cartridges are sterile, disposable products (consumables) and must always only be used once!
- ▶ Dispose of used or defective needle cartridges as well as such needle cartridges with packaging that has been damaged, in a puncture-proof container (sharps container) in accordance with the regulations that apply in your country.
- ▶ Check that the needles are completely retracted into the needle cartridge before treatment and while the handpiece switched off. If this is not the case, dispose of the needle cartridge immediately.
- ▶ Prevent needle cartridges from coming into contact with contaminated objects, e.g. clothing. Contaminated needle cartridges must not be used, but must instead be disposed of immediately.

▶ During use, the handpiece, handpiece cable and device, including the integrated handpiece tray, must be covered with a protective sheet. The handpiece is covered with the plastic sheet before the needle cartridge is attached (see the operating manual for the device).

- ▶ Regularly check whether the handpiece has become visibly contaminated by the return flow of bodily fluids or accompanying preparations used. In this case, in addition to disinfecting regularly, observe chapter 7.3 on page 60 and 7.1 on page 59 as well as chapter 2.3 on page 41.
- ▶ If a local anesthetic is used, it must be carefully removed before treatment.
- ▶ Comply with the regulations that apply in your country.
- ▶ Always hold the handpiece securely before switching it on, or place it on the handpiece tray. If an unsecured handpiece is switched on, it can move due to vibrations and injure or prick people.

Injuries caused by contaminated needles or needle module may transmit diseases:

- ▶ Seek medical attention immediately if you experience a puncture wound from a contaminated needle!

To prevent the intensity of treatment from exceeding the desired extent:

- ▶ Avoid risk of injury due to excessive needle protrusion depth (see chapter 6.3 on page 58).
- ▶ Avoid risk of injury due to too high of a piercing frequency (see chapter 6.1.4 on page 56).

Please advise your clients to avoid contact with recently treated skin to the extent possible. Recently treated areas of skin should also be protected from:

- Contamination and
- UV radiation and sunlight

And also stimuli, such as

- swimming pool or sauna visits,
- abrasive or chemical peels,
- hair removal at the treated areas or
- self-tanning lotions

The client should avoid these in the first two to three days after the treatment.

2.5 Contraindications and side effects

The following contraindications and side effects are the result of careful analysis of clinical literature on micropigmentation. If the person responsible for treatment should have even the slightest doubt that the safety of the client to be treated cannot be guaranteed, for example due to accompanying illnesses, the treatment must be refrained from or stopped immediately.

2.5.1 Contraindications

Micropigmentation treatment is **not** permitted under the following circumstances:

- Hemophilia or other blood coagulation disorders
- Current consumption of blood thinners (e.g. acetylsalicylic acid, heparin, aspirin, warfarin)
- Uncontrolled diabetes mellitus
- Any form of active acne in the treatment area
- Dermatoses (e.g. skin tumors, keloids or extreme inclination for keloid formation, solar keratosis, warts and/or moles) in the treatment area
- Open wounds and/or eczema and/or skin rashes in the treatment area
- Scars in the treatment area
- Systemic infections and infective diseases (e.g. hepatitis A, B, C, D E or F; HIV infection) or acute local skin infections (e.g. herpes, rosacea)
- For eyelid pigmentation: Conjunctivitis
- During chemotherapy, radiotherapy or high-dosage corticosteroid therapy (recommendation: less than 4 weeks before the beginning until 4 weeks after the end of the therapy)
- Up to 12 months after plastic surgery in the treatment area
- Up to 6 months after filler injections in the treatment area
- Allergy to topical anesthetics (local anesthesia)
- Under the influence of alcohol and/or drugs
- Pregnancy and lactation

Treatment of mucous membranes and eyeballs is strictly prohibited.

The treatment must be terminated immediately in the event of:

- Excessive sensations of pain
- Fainting / dizziness
- Excessive release of wound fluid

In rare cases, the following problems can be caused by the introduction of micropigmentation ink:

- Color differences
- Pigment loss
- Allergic reactions to components of the aseptic pigment color

2.5.2 Side effects

In some cases, minor side effects can arise during and after the micropigmentation treatment. These side effects are listed below.

Frequent:

- Local bleeding on the surface of the freshly treated skin
- Pain and discomfort on the first day after treatment
- Temporary inflammatory reactions, erythema and/or edema up to 6 days after treatment
- Skin irritations (e.g. itching or heating), which normally wear off during the first 12 to 72 hours after treatment
- Scabbing, which normally recedes within the first 5 days
- Temporary flaking of the skin, which normally wears off within 8 days

Rare:

- Formation of blisters of the herpes simplex virus type I (HSV-I)

- Formation of small pimples or skin eruptions if skin is not cleaned carefully before the treatment
- Hyper-pigmentation with body's own pigments, in particular on dark skin types, but which disappear completely within a few weeks
- Inflammatory reactions, haematomas, erythema and edema
- Retinoid reaction (slight irritation up to peeling of skin)
- Possible warming of the pigmented area when exposed to PET and MRT radiation

As a general rule, recently treated areas of skin should be protected from UV radiation and sunlight.

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

- Color differences
- Pigment loss
- Allergic reactions to components of the aseptic PMU ink

2.5.3 Required qualifications (user requirements)

The device, including its accessories, may not be used by persons with reduced physical, sensory or mental capabilities, or by children. The device, including its accessories, may not be used by persons who lack experience and knowledge, unless they are being supervised or instructed (training).

The device may only be used by people who have acquired the following knowledge:

- Qualification training for micropigmentation (permanent makeup)
- Basic knowledge of micropigmentation treatment (see chapter 6.1.4 on page 56 Setting the stitch frequency and chapter 6 on page 54)
- Knowledge of the hygiene and safety regulations (see chapter 2.4 on page 41)
- Knowledge of the risks and side effects (see chapter 2.5.1 on page 43 and 2.5.2 on page 44)

2.6 Purpose, application area and intended use

2.6.1 Purpose - Indications for use

The purpose of the device is the minimally invasive penetration of sterile or aseptic PMU inks of mineral or organic origin into the dermis by means of micropigmentation (permanent make-up).

Due to the minimally invasive puncturing of the epidermis (top layer of skin) and dermis (middle layer of skin), the skin does not bear any open wounds. Therefore, the skin needs only a very short regeneration phase, in which the epithelial function is quickly restored.

Application examples for micropigmentation (permanent makeup) are:

- Pigmenting eyebrows
- Pigmenting eye-liners
- Pigmenting lip-liners or filling in the lip color
- Cosmetic pigmentation of the body

2.6.2 Application area

Body tattoos

2.6.3 Intended use - requirements for safe use

The treatment must take place in a dry, clean and smoke-free environment, and under hygienic conditions. The device must be prepared, used and maintained in the manner described in this operating manual. In particular, the applicable provisions for workplace layout must be observed, and the materials to be used must be sterile.

Intended use also includes thoroughly reading and understanding this operating manual, in particular the chapter 2 on page 40.








The intended use exclusively includes the following consumer groups: Adult men and women who are in good health.

Unintended use is defined as using the device or its accessories in a way other than as described in this operating manual, or failing to comply with its operating conditions. In particular, treatment of

contraindications is prohibited (see chapter 2.5.1 on page 43).

2.7 Symbols on the product

The symbols described below can be found in this operating manual, on the needle cartridge, or packaging:

Symbol	Meaning
	The product satisfies the applicable requirements stipulated in the European Community harmonization regulations.
	It also satisfies the applicable requirements stipulated in legal regulations of the United Kingdom.
	Refer to operating manual!
	Date of manufacture
	Catalog number, order number
	Serial number
	Temperature limit

	Humidity limit
	Cannot be used if packaging is damaged
	Protection class 3
	Warning of cutting or puncture wounds
	Direct current
	Attention!
	Dispose of properly as used electronic equipment
IP20	Housing provides protection against coarse dust
	Protect from wetness
	Fragile

3 Scope of delivery

- 1 Drive unit
- 1 Control unit (CU) - Connector

- 2 Batterie Packs
- 1 Handpiece tray
- 1 Charging cable
- 1 Connection cable
- 1 Case

4 Product information

This product is a professional high-performance machine for permanent makeup applications. It is low-vibration and quiet, featuring high piercing forces and stitch frequencies.

You have the option of **wired operation** on the control unit as well as **wireless operation** using the Batterie Pack.

4.1 Technical Data

Complete system

Model | CC0412X004XV,
CC0415X004XV,

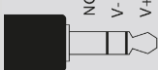

Drive units

Model | GCC04150410,
GCC06120410

Power intake | 1,4 W


Puncture frequency	60 to 150 Hz
Stroke	CC04xxX004XV = 3,0
Needle depth	0,5 – 3,5 mm (6 rotations)
Drive	DC motor
Operating mode	Continuous operation
Diameter	Ø 25,6 mm
Length	90 mm (with CU-Connector 120 mm, with Batterie Pack 140 mm)
Weight	86 g (with CU-Connector 103 g, with Batterie Pack 127 g)
Emission sound pressure level	max. 70 dB(A)
Vibration total value	max. 2,5 m/s ²
Degree of protection	IP20
Protection class	3
Connection assignment	

CU-Connector

Model	GCC04150007 GCC06120007
Diameter	Ø 24 mm
Length	31 mm
Weight	17 g
Cable length	2 m
Connection assignment 3.5 mm connector	
Input	
Output	

Batterie Pack

Model	GCC06150013, GCC06120013
Input voltage	5 V
Input current, max.	500 mA
Diameter	Ø 25,6 mm
Length	50 mm
Weight	42 g
Stich frequency	60 to 150 Hz
Charge cut-off voltage	4,2 V

Charge cut-off current	< 100 mA
Charging cable length	1 m
Connection assignment	
Input	USB-C (VBUS/GND)
Output	

Integrated battery

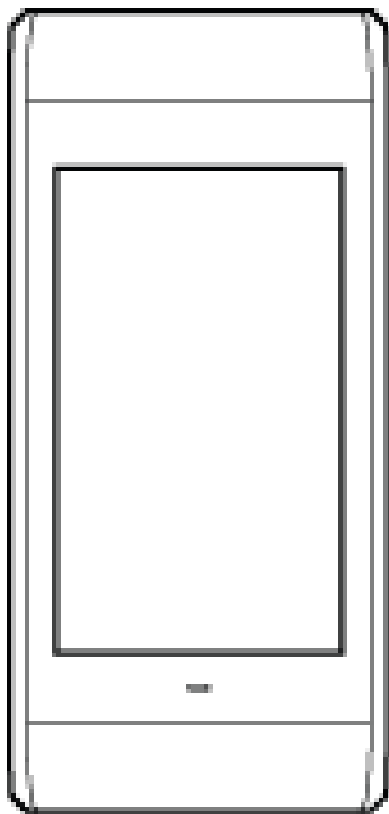
Battery designation	HEP102335
Battery manufacturer	Axcom GmbH
Battery type	Li-Po
Rated battery voltage	3,7 V
Dimensions	L 35 mm x B 23 mm x H 10 mm
Capacity	800 mAh
Charging voltage	4,2 V
Charging current, max.	500 mA
Charing method	CC-CV
Weight	16 g
Energy density	185 Wh/kg
Power	2,96 Wh

4.2 Accessories

The following accessories can be purchased from your local specialist retailer:

- Handpiece tray
- Connection cable to the control unit
- Charging cable
- Charger
- Needle cartridges
- Handpiece cover

The manufacturer has designed this permanent make-up machine for use with the following control unit (PU 2). Use the enclosed connection cable and the CU-Connector for this purpose.



5 Preparing the machine for use

NOTICE

Damage from condensate

If the machine is exposed to significant temperature fluctuations, during transport, for example, condensate may form inside, which may cause damage to the electronics.

- ▶ Ensure that the device has reached ambient temperature before using it. If the device has been exposed to high temperature variations, wait for at least 3 hours per 10°C/50°F of temperature difference before using it.
- ▶ Only use the machine at the defined ambient temperatures (see chapter 8 on page 61).

5.1 Checking the equipment

! WARNING

Danger of Explosion

Damaged battery cells can explode or burn.

- ▶ Never used a damaged Batterie Pack.
 - ▶ Dispose of a damaged Batterie Pack immediately (see chapter 9 on page 63).
-
- ▶ Conduct a visual inspection of the equipment:
 - Are there any visible signs of external damage (e.g. loose or bent components)?
 - Are there any exposed cables?
 - Are the needle cartridge and the needles correctly aligned?
 - Are both O-rings in place and intact?
 - ▶ Make sure that no vapors are escaping from the Batterie Pack or that it becomes unusually hot. If so, do not continue using it.

- Make sure that contact surfaces on the Batterie Pack and on the CU-Connector are not contaminated or have metallic particles adhering to them.
- Switch on the machine and conduct a noise test: Can you hear any unusual operating noises, or is the unit running loudly?
- If you detect anything unusual, refer to chapters 10 on page 63 and 11.1 on page 64.
- If the product is no longer operating safely, take it out of service and consult your local specialist retailer.
- Never attempt to repair it on your own or make changes to the handpiece.

5.2 Disinfecting equipment

CAUTION

Risk of short circuits and risk of minor electric shocks

If components of the device have been removed and cleaned while still powered, there is a risk of minor electric shock and damage to the electronics in the drive unit.

- Before starting any cleaning and maintenance work, pull the power adapter out of the socket to disconnect the control unit from the power supply.

NOTICE

Damage to drive caused by fluid

If any liquids penetrate into the drive unit, the Batterie Pack or the CU-Connector, this can corrode electrical and mechanical components.

- Never dip the product into liquids.

NOTICE

Product damage caused by non-approved disinfectants

Disinfectants that are not compatible with the materials of the product may damage its surface.

- Always use disinfectants that are approved, i.e. that comply with stipulations in your country.
- Observe the list of recommended disinfectants in chapter 7.1 on page 59.

- Disconnect the machine from the power supply.

When using the Batterie Pack, switch it to Stand-By mode (see chapter 6.1.5 on page 57) and disconnect it from the drive unit.

When using a control unit, release the connection between the CU-Connector and the control unit (see chapter 6.2 on page 57).

- Check whether the drive unit, the CU-Connector, or the Batterie Pack are contaminated. If this is the case, perform the steps described in chapter 7.3 on page 60.
- Wipe down the machine, the CU-Connector, and the Batterie Pack with a soft cloth moistened with disinfectant.

5.3 Charging the Batterie Pack

WARNING

Danger of explosion and fire

Charging, operating, transporting and storing under unfavorable conditions may damage the product and in particular the lithium polymer battery contained in the Batterie Pack.

- Charge, operate, transport and store the product and only under the specified conditions.
- **Never** charge the Batterie Pack in its cover.
- Never transport the Batterie Pack loose in a bag, because metal parts (such as keys) can result in a short circuit.

- **Never** transport the drive unit with the Batterie Pack plugged in. Before transporting, disconnect the drive unit and the Batterie Pack and switch the Batterie Pack into Stand-By mode.
- Never store the Batterie Pack at temperatures exceeding 60° C (e.g. in a car at high exterior temperatures). This might result in significant damage.
- **Never** open the Batterie Pack. Only qualified personnel must be allowed to remove the included lithium polymer battery.

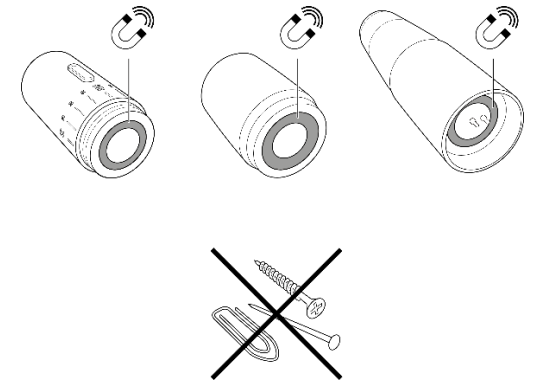
WARNING

Danger of explosion

If the Batterie Pack is charged outside of the charging temperature range, there is a risk of explosion.

- Charge the Batterie Pack at a permissible ambient temperature (see chapter 8 on page 61).
- Charge the Batterie Pack on a non-flammable surface under supervision.

- Charge the Batterie Pack no later than when the LED turns red to avoid damaging the battery.
- Only charge the Batterie Pack using a voltage source that supplies max. 5V/DC via the enclosed charging cable. Excessive voltages can destroy the unit.



- Disconnect the drive unit and Batterie Pack before charging.
- Connect the Batterie Pack to a USB-A jack using the supplied charging cable.

Observe the output data of the USB-A port used. The output voltage should be 5 V and the output current should be at least 0.5 A. Lower charging currents may prolong charging! Suitable, for example, are:

- The USB power adapter of a smart phone or tablet

- A power bank
- The power adapter from among the recommended accessories

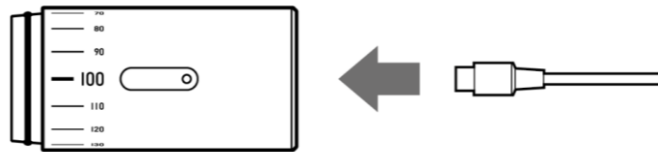
The information on the output power can generally be found on the nameplate of the power adapter or the power bank. If a USB-A port is available, charging should work without problems.

Powerdelivery is not supported and the Batterie Pack is not charged.

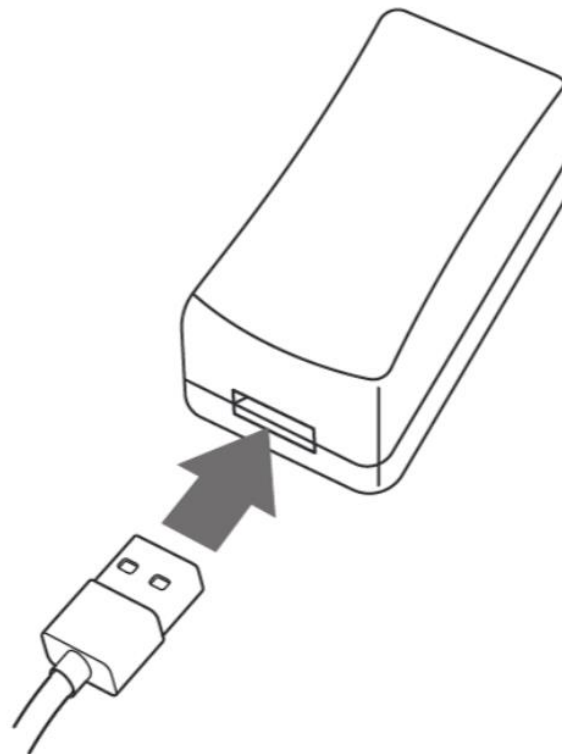
The Batterie Pack is delivered partially charged. To ensure full output of the Batterie Pack, charge it completely prior to first-time use. The Batterie Pack can be charged individually at any time. An interruption in the charging process will not damage the battery.

Each Batterie Pack is charged with a charging current of a maximum of 0.5 A. Charging time is approx. 1.5 hours.

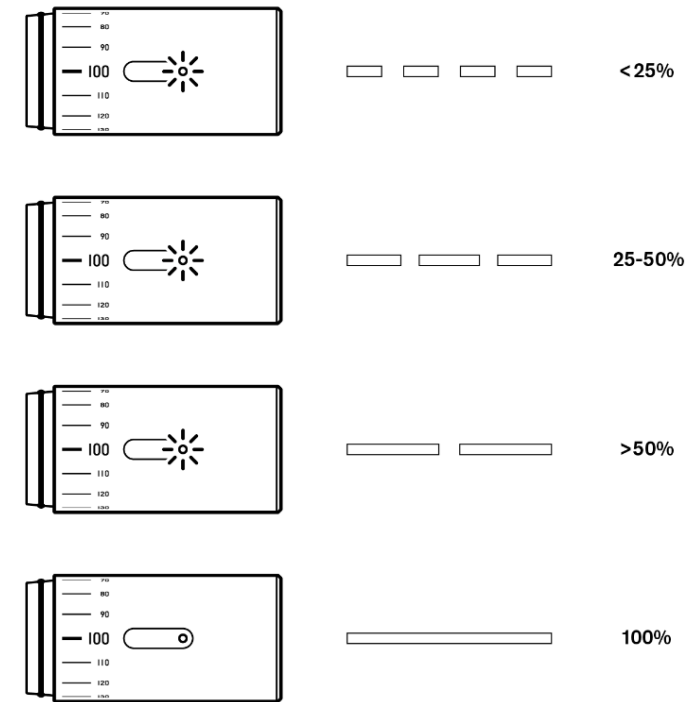
- Insert the USB-C plug of the included charging cable into the Batterie Pack.



- Plug the USB-A connector of the enclosed charging cable into a suitable source.



The Batterie Pack will immediately switch to charging mode. The LED in the Multiswitch indicates the current charge status.



- Only remove the charging cable from the voltage source and then from the Batterie Pack when the LED in the Multiswitch is continuously lit.

The Batterie Pack cannot be set to operating or work mode while it is charging.

5.4 Connecting and disconnecting the drive unit with the Batterie Pack

NOTICE

Risk of short-circuit

If small parts adhere to the magnets of the interfaces, this can result in short circuits. This may destroy the product.

- ▶ Make sure that the contact surfaces are free of impurities.
- ▶ Remove any impurities before connecting the drive unit to the Batterie Pack.
- ▶ Do not touch the contact surfaces of the Batterie Pack.
- ▶ Do not use the device if any gases are escaping or if it becomes abnormally hot.

The drive unit and the Batterie Pack are equipped with a magnetic interface. This enables a safe connection of the drive unit and Batterie Pack components.

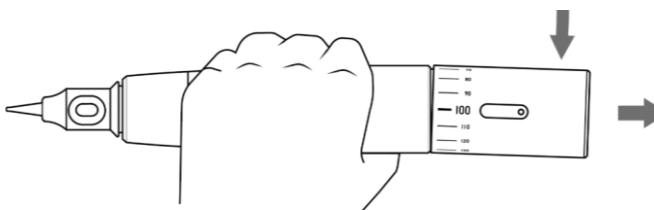
- ▶ Use a charged Batterie Pack for maximum treatment time.

- ▶ Disconnect the charging cable from the Batterie Pack and the power source.
- ▶ If the O-ring of the Batterie Pack is lost or worn, replace it as described in chapter 7.4 on page 61.
- ▶ Make sure that the Batterie Pack is in Stand-By or operating mode.
- ▶ Connect the Batterie Pack with the drive unit.



The machine is now ready for use.

- ▶ Please use a handpiece cover for maximum protection.
- ▶ To detach the Batterie Pack from the drive unit, tilt it slightly and remove it to the rear. Be careful not to drop it on the floor.



5.5 Pull on the handpiece cover

! CAUTION

Infection from contaminated handpiece cover

Failure to replace the handpiece cover may lead to a transmission of diseases.

- ▶ Use a new handpiece cover for each customer.

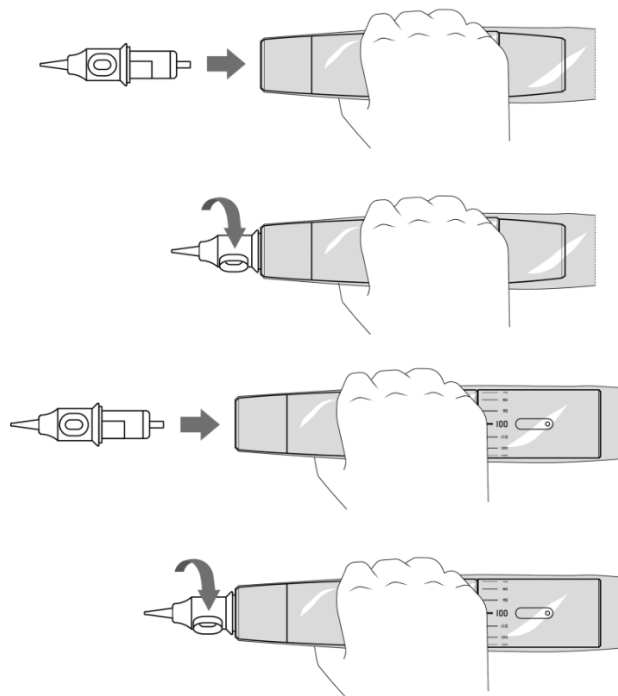
NOTICE

Damage to machine from liquids

If any liquid gets inside the product, this may corrode the electrical and mechanical components.

- ▶ Always use a handpiece cover that is suitably sized.

Use a translucent, color-less handpiece cover. Otherwise, there may be problems with the needle protrusion setting, the visibility of the LED, or finding the Multiswitch.



We recommend using the handpiece cover from the accessories. Alternatively, you can use an equivalent handpiece cover with a diameter of 20 to 27 mm. This corresponds to a hose width of approx. 30 to 45 mm.

To pull the handpiece cover on correctly:

- ▶ Switch off the handpiece and remove the needle cartridge.
- ▶ If you are using the handpiece cable, pull the handpiece cover completely over the handpiece cable and fasten it at the ends with adhesive tape.
- ▶ Cut another handpiece hose to a length of approx. 15 cm.
- ▶ Place the handpiece hose up to the cartridge mount.
- ▶ Fold the end of the handpiece cover tightly around the cartridge mount.
- ▶ Then position the needle cartridge as described in chapter 5.6 on page 53.

The needle cartridge clamps the handpiece cover in place.

- ▶ Each time after a treatment is completed, dispose of used handpiece covers in containers for them to be disposed of professionally as contaminated parts (see chapter 9 on page 63).

5.6 Changing the needle cartridge

! WARNING

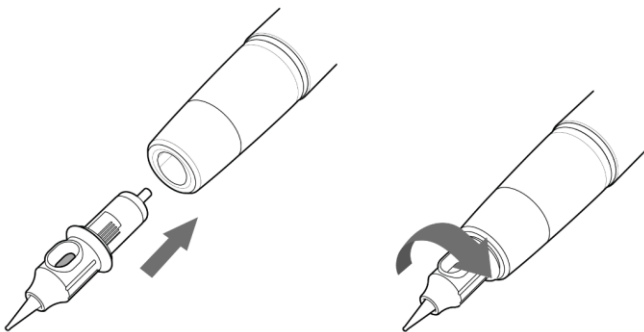
Risk of injury from needles

Injuries caused by contaminated needles may transmit diseases.

- ▶ Always use the manufacturer's original needle cartridges. The installed safety membrane prevents the ingress of ink into the drive, and also prevents pathogens from entering the appliance.
- ▶ Never hold the needle cartridge by its tip.
- ▶ When removing a used needle cartridge, ensure that no ink remnants can run into the cartridge mount.
- ▶ Never press the needles out of the needle cartridge.
- ▶ Check while removing a used needle cartridge that the needles are completely retracted into the needle cartridge.
- ▶ Properly dispose of used needle cartridges that are no longer required for the current application (see chapter 9 on page 63).

- ▶ The needle cartridges are delivered in sterile packaging. Do not remove them from their packaging until immediately before you intend to use them.
- ▶ Always set the machine down so that the needle cartridge is not on it. Use the enclosed tray.
- ▶ Seek medical attention immediately if injured by a contaminated needle.

- ▶ Switch off the machine at the control unit or Batterie Pack, or disconnect its magnetic connection.
- ▶ Insert the needle cartridge in the opening of the cartridge mount as illustrated below.



- ▶ Due to its locating points on the top and bottom, the cartridge can only fit in the oval opening in two ways.

- ▶ Rotate the needle cartridge clockwise by approx. 45°. As you rotate it, the multiple locating points will engage audibly until the needle cartridge is firmly locked into position.
- ▶ To remove the needle cartridge, turn it counterclockwise and remove it from the cartridge mount.

6 Using the product

6.1 Using the machine with Batterie Pack

6.1.1 Explanation of the Batterie Pack operating modes

- **Charging mode** – The Batterie Pack is being charged. The Batterie Pack automatically reverts to charging mode when connected to a charging source. The LED in the Multiswitch indicates the charge status (see chapter 5.3 on page 50).
- **Stand-By mode** – Batterie Pack is switched off, the LED in the Multiswitch is not lit. Use this mode at times when the Batterie Pack is not in use or while traveling (see chapter 6.1.5 on page 57).

- **Operating mode** – Batterie Pack has woken up and is waiting for input; the LED in the Multiswitch is lit or flashing, depending the charge status (see chapter 6.1.2 on page 54).
- **Working mode** – Battery must be connected to the drive unit! Motor has started. LED in the Multiswitch goes off 10 seconds after the motor starts (see chapter 6.1.3 on page 55).

6.1.2 Set the Batterie Pack to operating mode

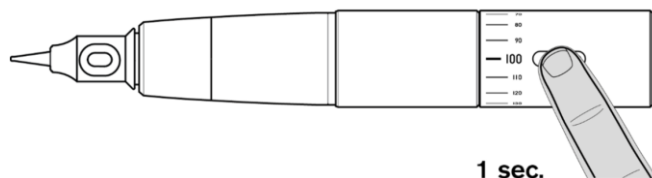
After disconnecting the charging cable, the Batterie Pack is in Stand-By mode.

- ▶ Connect with the drive unit as described in chapter 5.4 on page 52.

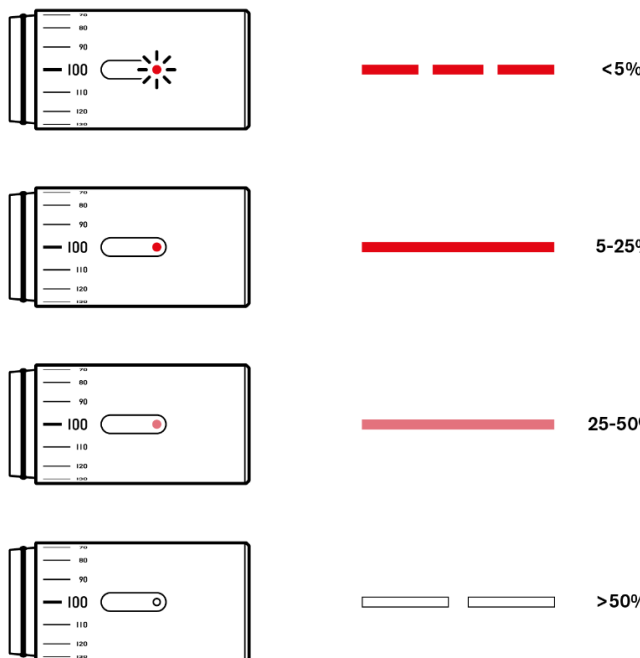
The Batterie Pack must first be set to operating mode so that the motor can be started.

- To do this, keep the Multiswitch pressed for at least 1 second.

The LED in the Multiswitch will then start to light up.



In operating mode, the LED in the Multiswitch indicates the current charge status.



A low charge status is indicated by a fast flashing red LED in the Multiswitch. The Batterie Pack automatically reverts to Stand-By mode when the battery is empty.

- In that case, exchange the Batterie Pack with a charged one (see chapter 5.4 on page 52).
- Charge the empty Batterie Pack (see chapter 5.3 on page 50).

6.1.3 Starting and stopping working mode

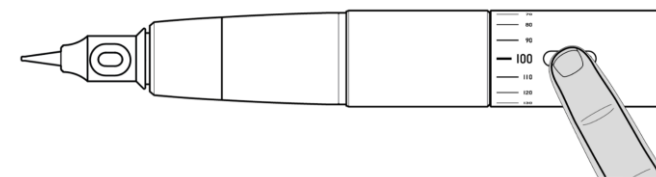
Keep in mind that you cannot start the motor unless you have set the Batterie Pack in operating mode as described in chapter 6.1.2 on page 54. In addition, the Batterie Pack must be properly connected to the drive unit.

If the Batterie Pack is not connected correctly, a warning will be displayed when you attempt to turn on the motor. The LED will flash quickly in white for 5 seconds. This will also occur if the Batterie Pack is disconnected from the drive unit while the motor is running. The Batterie Pack will automatically switch to operating mode.

- Press the multi-switch briefly once to start the motor.

The handpiece is now in working mode.

- To stop the motor, also press the Multiswitch once briefly.



After it is switched on, the motor rotates with a frequency of 100 Hz. If you have only briefly stopped the motor and resume the treatment within 5 minutes, the Batterie Pack remembers the last selected frequency.

If the Batterie Pack has switched itself off automatically in the meantime (Stand-By mode), then it will start up again at 100 Hz.

To ensure you can work with your machine uninterrupted, while the motor is running, the LED in the Multiswitch will turn off after 10 seconds.

The LED will light up for 10 seconds at a time if the charge status exceeds certain limits (see chapter 6.1.2 on page 54).

If the Batterie Pack flashes red quickly, only around 5% battery capacity remains.

- ▶ Disconnect the Batterie Pack and exchange it with a charged one.
- ▶ Connect the empty Batterie Pack for charging as described in chapter 5.3 on page 50.

An error can be assumed if the Batterie

Pack does not work as expected. You can find more information on this in chapter 10 on page 63.

6.1.4 Setting the stitch frequency

CAUTION

Risk of injury due to high stitch frequency

If the stitch frequency is too high, the skin can be cut.

- ▶ Always start at a low piercing frequency.
- ▶ Select the piercing frequency depending on the skin condition of the client and suitable for the working speed.

The Batterie Pack must be in “Motor on” working mode in order to set the piercing frequency. To do so, follow the steps as described in chapter 6.1.3 on page 55.

Each Batterie Pack has a motion sensor in order to adjust the number of penetrations. The number of penetrations can be set in increments of 10 between 60 to 150 Hz.

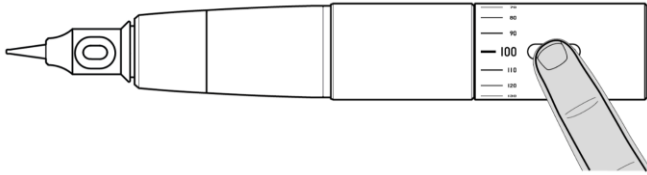
Keep in mind that the Batterie Pack can provide an additional lower frequency level (60 Hz) as compared to the control unit from the accessories. The piercing frequency can be set on the recommended control unit in increments of 10 from 70 to 150 Hz. For more details on setting the frequency on the control unit, refer to the documentation that come with the control unit.

If the Batterie Pack has switched to Stand-By mode, the motor is operated at 100 Hz when it is first switched on. If the motor is only stopped or the Batterie Pack is disconnected from the drive unit, the Batterie Pack remembers the last set frequency until it is set in Stand-By mode or is automatically switched off because of a low charge status.

Take the following steps to change the piercing frequency:

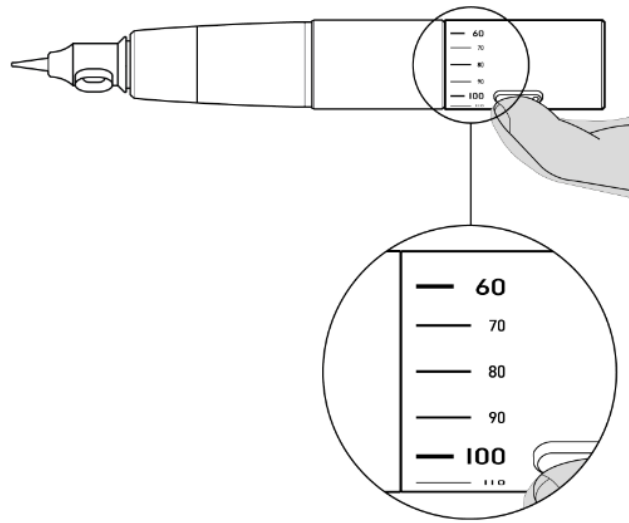
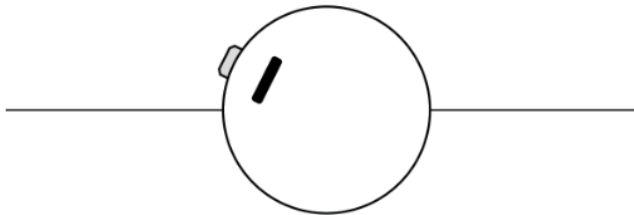
- ▶ Make sure that the motor is running (see chapter 6.1.3 on page 55).

- Only hold the machine by the Batterie Pack so that you can look at the mark on the machine from above.



- Turn the machine in the desired direction until the mark of the set frequency points up.
- Press and hold the Multiswitch in this position.

80 Hz



- Release the Multiswitch again once the desired frequency is set.

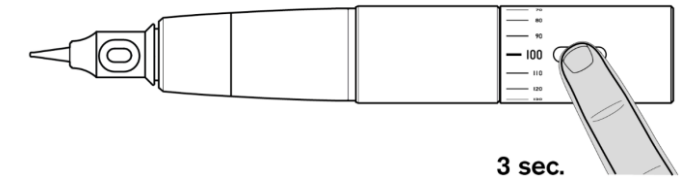
6.1.5 Placing the Batterie Pack in Stand-By mode

If you are not using the Batterie Pack or if you want to transport it, put it into Stand-By mode.

- Set the Batterie Pack in operating mode. Exist working mode “Motor off” as described in chapter 6.1.3 on page 55.

- Keep the Multiswitch pressed for at least 3 second.

The Batterie Pack is set to Stand-By mode and the LED in the Multiswitch turns off.



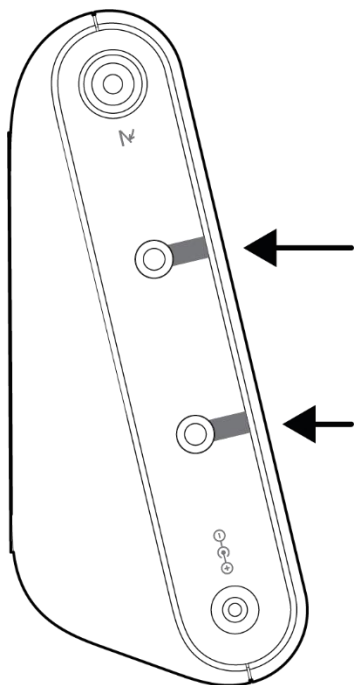
The Batterie Pack automatically switches to Stand-By mode if it is not used in operating mode for 5 minutes or if the charge status has reached 0%.

An error can be assumed if the Batterie Pack does not work as expected. You can find more information on this in chapter 10 on page 63.

6.2 Use at the control unit

- You may need to remove the Batterie Pack from the drive unit.
- Check the contact surfaces of the CU-Connector for contamination or adhering particles.
- Connect the CU-Connector to the drive unit.

- ▶ Connect the socket of the included connection cable to the CU-Connector.
- ▶ Connect the plug of the included connection cable to the corresponding output on the control unit.



- ▶ Following the instructions in the documents that came with the control unit to switch it on and to select the frequency.
- ▶ If the O-ring of the CU-Connector is lost or worn, replace it as described in chapter 7.4 on page 61.

6.3 Setting the needle depth

⚠ CAUTION

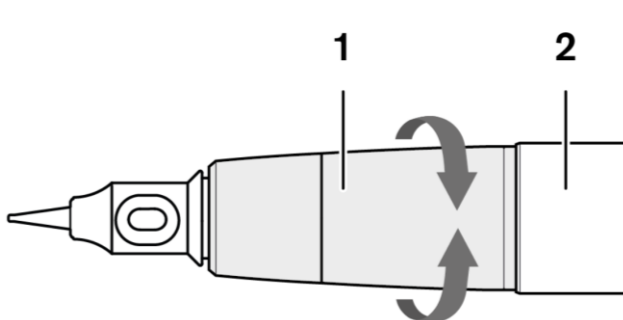
Risk of injury from excessive needle Depth

A large needle depth permits a deep puncture depth. If needle depth and puncture depth are excessive, this can damage the subcutaneous layer.

- ▶ Always start at a low needle protrusion depth.

- ▶ Start the machine.
- ▶ Hold the machine by the front part (1) and turn the adjustment sleeve (2) to set the desired needle protrusion depth.

One rotation of the adjustment sleeve effects a change in the needle protrusion depth of ± 0.5 mm, depending on the direction of rotation.



Turning counterclockwise (viewing direction on the needle cartridge) increases the needle protrusion depth.

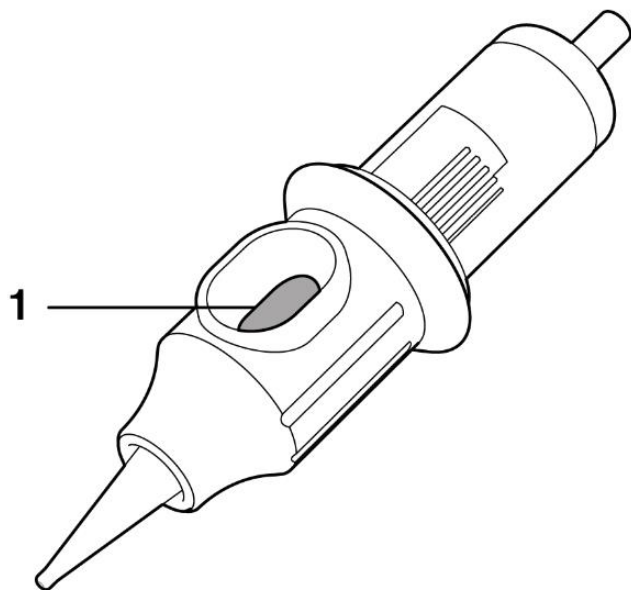
Turning clockwise (viewing direction on the needle cartridge) reduces the needle protrusion depth.

- ▶ Check the needle protrusion depth before starting treatment.

6.4 Filling needle cartridges

- ▶ Check that the needle cartridge is firmly seated.

Insert the desired pigment color into the needle cartridge through the filling opening (1) using a suitable applicator that guarantees sterility. In doing so, note the ca. 1 ml capacity of the needle cartridge.



7 Cleaning and maintaining the product

! CAUTION

Risk of short-circuit

If components of the machine are dismantled and cleaned while still powered, there is a risk of damage to the electronics in the drive unit.

- ▶ For any cleaning and maintenance work, always disconnect the product completely from its power source.
- ▶ Never clean the Batterie Pack while it is charging or is in operating mode. Switch it to Stand-By mode.

! CAUTION

Needle puncture injuries

If the needle remains in the product during cleaning, injuries may occur due to unwanted needle punctures.

- ▶ Remove the needle cartridge before cleaning or disinfecting the product.

NOTICE

Damage to product from liquid

If cleaning fluid or disinfectant gets inside the product components, this can corrode the electrical and mechanical components.

- ▶ **Never** dip the product components into disinfectants.
- ▶ **Never** clean the product components (such as the cable, Batterie Pack) in an autoclave or an ultrasonic bath.
- ▶ Pay attention to compatibility of materials when selecting cleansers and disinfectants (see chapter 7.1 on page 59).

7.1 Material compatibilities

- ▶ Wherever possible, use one of the following disinfectants:

Manufacturer	Product	Exposure time
Antiseptica	Big Spray „new“	1 to 5 mins
Bode Chemie	Bacillol	30 s to 1 min
Ecolab	Incidin Foam	1 to 2 mins

Manufacturer	Product	Exposure time
Schülke & Mayr	Mikrozid Liquid	1 to 2 mins

Based on the material compatibility, you can also assess which other cleansers and disinfectants are suitable.

The anodized aluminum components and seals of the tattoo machine 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 aqueous solutions (e.g. sodium chloride, calcium chloride, magnesium sulphate)

The anodized aluminum components and seals of the machine are **not resistant** to:

- Strong acids (e.g. hydrochloric acid $\geq 20\%$, sulphuric acid $\geq 50\%$, nitric acid $\geq 15\%$)
- Oxidizing acids (e.g. peracetic acid)
- Lyes (e.g. caustic soda, ammonia and all substances with a pH value > 7)

- Aromatic/halogenized hydrocarbons (e.g. phenol, chloroform)
- Acetone and benzene

7.2 Disinfecting surfaces

Before and after each usage:

- ▶ Disinfect all surfaces of the machine and its accessories as described in chapter 5.2 on page 49.

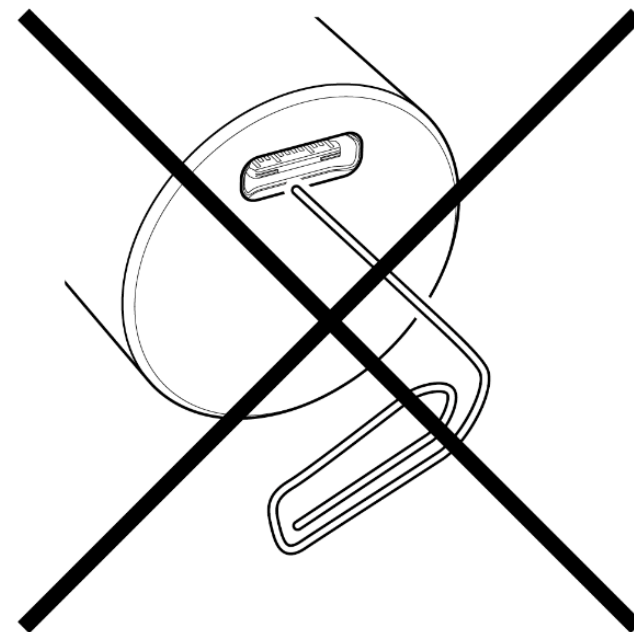
7.3 Cleaning surfaces

In the event of external contamination:

- ▶ Disconnect the drive unit, the CU-Connector, and the Batterie Pack.
- ▶ Wipe the drive unit, the CU-Connector, and the Batterie Pack with a soft cloth moistened in a cleaning agent or a disinfectant.
- ▶ Clean inaccessible surfaces (e.g. the thread) of the product with a softbristled nylon brush or a swab. In the process, stay away from the contact surfaces of the Batterie Pack and the CU-Connector.
- ▶ Proceed with particular care at the contact pins of the drive unit so that

they do not break off or become damaged.

- ▶ Keep in mind that due to the surface finish of the case components, there may be color streaks on the product.
- ▶ Do not insert any objects into the USB-C jack of the Batterie Pack.



7.4 Cleaning or replacing o-rings

The O-rings on the Batterie Pack and CU-Connector provide a smooth "snap" connection and seal the electrical connection between the supply and drive unit.

The O-rings may become brittle or crack with use.

- ▶ Remove worn O-rings with blunt tweezers.
- ▶ Replace the O-rings with matching NBR-70 Ø 17x1 (NBR = Nitrile Butadiene Rubber) as required.

8 Operating, loading, transport, and storage conditions

WARNING

Danger of explosion and fire

Charging, operating, transporting and storing under unfavorable conditions may damage the product and in particular the lithium polymer battery contained in the Batterie Pack.

- ▶ Charge, operate, transport and store the product and only under the specified conditions.
- ▶ **Never** charge the Batterie Pack in its cover.
- ▶ Never transport the Batterie Pack loose in a bag, because metal parts (such as keys) can result in a short circuit.
- ▶ **Never** transport the drive unit with the Batterie Pack plugged in. Before transporting, disconnect the drive unit and the Batterie Pack and switch the Batterie Pack into Stand-By mode.

- ▶ Never store the Batterie Pack at temperatures exceeding 60° C (e.g. in a car at high exterior temperatures). This might result in significant damage.
- ▶ Never open the Batterie Pack. Only qualified personnel must be allowed to remove the included lithium polymer battery.

WARNING

Danger of explosion

If the Batterie Pack is charged outside of the charging temperature range, there is a risk of explosion.

- ▶ Charge the Batterie Pack at a permissible ambient temperature (see chapter 8 on page 61).
- ▶ Charge the Batterie Pack on a non-flammable surface under supervision.
- ▶ Charge the Batterie Pack no later than when the LED turns red to avoid damaging the battery.
- ▶ Only charge the Batterie Pack using a voltage source that supplies max. 5V/DC via the enclosed charging cable. Excessive voltages can destroy the unit.

NOTICE

Damage to product caused by dropping it

If the product or one of its components falls, they could be damaged.

- Always set down the components carefully so that it cannot roll away or fall. Use the handpiece tray included.
- If one of the components does fall, perform an inspection of it as described in chapter 5.1 on page 48.

Batterie Pack

Activity	Temperature range	Relative humidity (non-condensing)
Charging and operation	+10 °C to +35 °C	30% to 75%
Transport	-20 °C to +50 °C	

Activity	Temperature range	Relative humidity (non-condensing)
Storage	-20 °C to +50 °C < 1 month	
	-20 °C to +45 °C < 3 months	
	-20 °C to +35 °C < 1 year	
	(Charge every six months)	

Drive unit/ CU-Connector

Activity	Temperature range	Relative humidity (non-condensing)
Charging and operation	+10 °C to +35 °C	30% to 75%
Transport	-20 °C to +50 °C	
Storage	-20 °C to +50 °C	

- We recommend using the cover included for transport and storage so that your product is kept safe.

- Avoid exposure to direct sunlight during storage.

The Batterie Pack contains a rechargeable lithium polymer battery.


When traveling by air, most airlines will only allow you to transport the product in your carry-on luggage:


- Obtain the information from your airline before your departure.
- Set the Batterie Pack to Stand-By mode before transporting it or before traveling.


Usually, the following information is important to the airlines:

- The power of each Batterie Pack is 2.96 Wh (2 Batterie Packs = 5.92 Wh).
- The weight of the battery only is approx. 16 g (2 Batterie Packs = 32 g).

9 Disposal of equipment

- ▶  Dispose of the product components (drive unit and CU-Connector) in accordance with the applicable regulations for used electronic equipment (WEEE Directive 2012/19/EU). If necessary, consult the specialist retailer or the responsible authorities to learn about applicable national regulations.

- ▶  Never dispose of the Batterie Pack in household waste, but instead in accordance with the applicable regulations for batteries and accumulators (EU Directive 2006/66/EU). If necessary, consult the specialist retailer or the responsible authorities to learn about applicable regulations.

- ▶  Dispose of used or defective needle cartridges and those with damaged packaging, in a puncture-proof container

(sharps container) in accordance with the regulations that apply in your country. Have a relevant container available at your workstation.

10 For questions or problems

10.1 General

If the needle motion suddenly stops during treatment (at low frequencies):

- ▶ Make sure that you are using an original needle cartridge.
- ▶ Increase the frequency on the Batterie Pack or the control unit.
- ▶ Reduce the needle protrusion depth on the drive unit.
- ▶ During operation, check the Batterie Pack
 - For its charge status and replace the Batterie Pack if necessary.
 - The connection between the drive unit and the Batterie Pack.
- ▶ If a malfunction occurs on the Batterie Pack while the motor is running

(working mode), the motor shuts down. For safety reasons, you must then restart the motor as described in chapter 6.1.3 on page 55.

- ▶ If the Batterie Pack heats up excessively, it shuts itself off automatically for safety reasons. Allow it to cool down for a few minutes.
- ▶ Contact your specialist retailer if the problem continues.

10.2 Operation at the Batterie Pack

The Batterie Pack does not wake up:

Check the charge status by plugging in the charging cable and the connection with a 5 V/DC | 0.5 A charging source. The LED in the Multiswitch shows the current charge status. If not, disconnect the connection and contact your specialist retailer.

The Batterie Pack cannot be set in Stand-By mode:

- ▶ Wait for at least 5 minutes and check whether the Batterie Pack sets itself automatically in Stand-By mode.
- ▶ Make sure that the Multiswitch can move freely and is not stuck.

- Contact your specialist retailer if the problem continues.

The motor does not start:

- Make sure that the Batterie Pack is properly connected to the drive unit.
- Remove the needle cartridge and attempt to start the product again. If this works, reinsert the needle cartridge, increase the number of penetrations and/or reduce the needle protrusion depth. Continue the treatment.
- Contact your specialist retailer if the problem continues.

The motor does not shut off:

- Disconnect the connection between the drive unit and the Batterie Pack. The motor will stop immediately. The LED in the Multiswitch shows the error signal and the Batterie Pack is set to operating mode.
- Contact your specialist retailer if the problem continues.

10.3 Operation at the control unit

The machine does not switch on:

- Check the indicator on the control unit.

„CONNECT HANDPIECE“ indicates an error in the connection between the drive unit and the control unit. Take the following steps:

- Check the connection between the drive unit and the CU-Connector.
- Make sure that you use the connection cable that matches the control unit and that the plug connections are properly plugged in.
- Contact your specialist retailer if the problem continues.

„SYSTEM OVERLOAD“ indicates an overload of the control unit. Take the following steps:

- Make sure that you use the connection cable that matches the control unit and that the plug connections are properly plugged in.
- Remove the needle cartridge and press the start button again. If the machine is now working, reduce the needle protrusion depth and increase the frequency. Resume the treatment with a new needle cartridge.

- If the problem continues, this indicates a problem with the motor. In this case, contact your specialist retailer.

For any malfunctions other than those listed, refer to the operating manual of the control unit. If you have any questions or complaints, please contact your responsible specialist retailer. Try to give as accurate a description as possible of the malfunction and the circumstances under which it occurred.

11 Manufacturer Declarations

11.1 Disclaimer of warranties

With this handpiece, you have purchased a high-quality product.

For this product, the statutory warranty period of 2 years applies to radio interference problems resulting from defects in material and workmanship.

We do not provide warranty cover in respect of the following types of damage:

- Damage and secondary damage arising from unintended use or failure to comply with the operating manual.
- Damage arising from the ingress of fluids or dirt into the drive
- Damage and secondary damage arising from dropping it or it falling

11.2 Declaration of Conformity

Declaration of Incorporation (in accordance with 2006/42/EC, Annex II A)

Manufacturer	MT.DERM GmbH Blohmstr. 37–61 12307 Berlin, Germany
Authorized representative for compiling the relevant technical documentation:	MT.DERM GmbH Blohmstr. 37–61 12307 Berlin, Germany

Description of the machine

Product designation:	Permanent Make-Up Machine with Batteriepack
Product name:	ERA Gem
Article description:	CC04*
The manufacturer declares that the products indicated above comply with the EC Machinery Directive 2006/42/EG.	
The manufacturer hereby declares furthermore that the products indicated above comply with the provisions:	
RoHS Directive:	2011/65/EU
EMC directive:	2014/30/EU

The following harmonized standards were applied:

EN 60335-1:2012 + AC:2014 + A11:2014 + A13:2017 + A15:2021	Household and similar electrical appliances – Safety – Part 1: General requirements
EN 55014-1:2017 + A11:2020	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission
EN 55014-2:1997 + AC:1997 + A1:2001 + A2:2008	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 2: Immunity – Product family standard
EN 62233:2008 + AC:2008	Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

The following other technical specifications/standards were applied:

IEC 60335-1:2020	Household and similar electrical appliances – Safety – Part 1: General requirements
CISPR 14-1:2020-09	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission
CISPR 14-2:2020-08	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 2: Immunity – Product family standard
IEC 62233:2005	Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure
EN ISO 14971:2019 + A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 13485:2016 + AC:2018 + A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes

Berlin, 3/1/2023, Jörn Kluge



Signature of the CEO or his representative

11.2 UK-Declaration of Conformity

(acc. 2008 No. 1597 Annex II A)

Manufacturer	MT.DERM GmbH Blohmstr. 37–61 12307 Berlin, Germany
Authorized representative for compiling the relevant technical documentation:	Dr. Andreas Pachten MT.DERM GmbH Blohmstr. 37–61 12307 Berlin, Germany

Description of the machine

Product designation:	Permanent Make-Up Machine with Batteriepack
Product name:	ERA Gem
Article description:	CC04*

The manufacturer declares that the above products are in conformity with the provisions of The Supply of Machinery (Safety) Regulations 2008.

The manufacturer declares that, in addition, the above products are compliant with the provisions of the:

2016 No. 1091	Electromagnetic Compatibility Regulations 2016
2012 No. 3032	The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

The following designated standards have been applied:

EN 60335-1:2012 + AC:2014 + A11:2014 + A13:2017 + A15:2021	Household and similar electrical appliances – Safety – Part 1: General requirements
EN 55014-1:2017 + A11:2020	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission
EN 55014-2:1997 + AC:1997 + A1:2001 + A2:2008	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 2: Immunity – Product family standard
EN 62233:2008 + AC:2008	Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

The following other technical specifications/standards were applied:

IEC 60335-1:2020	Household and similar electrical appliances – Safety – Part 1: General requirements
CISPR 14-1:2020-09	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission
CISPR 14-2:2020-08	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 2: Immunity – Product family standard
IEC 62233:2005	Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure
EN ISO 14971:2019 + A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 13485:2016 + AC:2018 + A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes

Berlin, 3/1/2023, Jörn Kluge



Signature of the managing director or his authorized representative