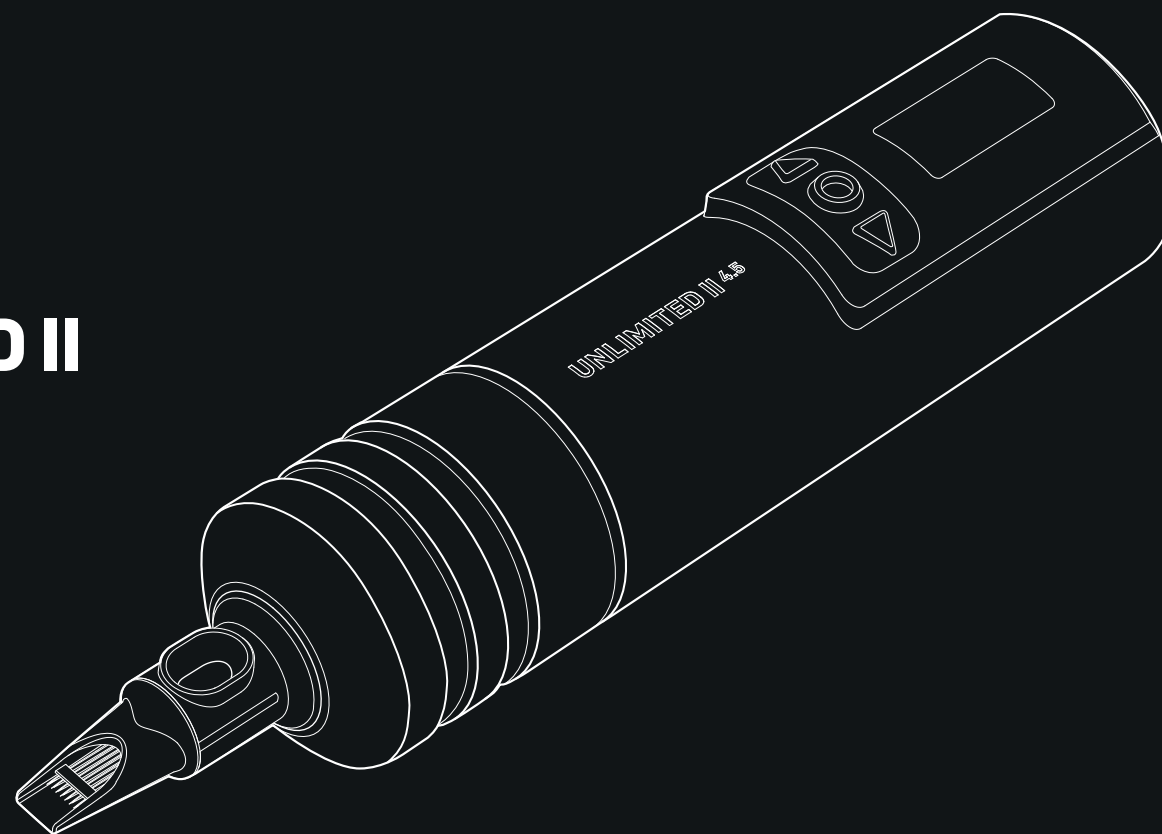


*CHEYENNE*<sup>®</sup>

**SOL**  
**NOVA UNLIMITED II**

**2.5 | 3.5 | 4.5**

---



**Gebrauchsanweisung**  
**Operating instructions**  
**Instrucciones de uso**

**Manual de instruções**  
**инструкции**  
**Kullanım kılavuzu**

**Instructions**  
**说明**

## Operating instructions

### Illustration types used

---

### Illustration types used

#### Instructions for action

Perform an action as follows:

1. Do this.
2. Do that.
  - ◆ This is the interim result.
3. Do that.
  - ✓ You have performed the action.

#### Danger classes and advice


 <b>WARNING</b>	Life-threatening injury
 <b>CAUTION</b>	Minor to moderate injury
<b>ATTENTION</b>	Property damage possible
 <b>NOTE</b>	Advice / useful information

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English  
Version 1.1  
25/10/2024

Original  
Operating  
instructions

 **NOTE:**  
Follow these  
instructions for use  
for proper and safe  
use.  
Keep them in a safe  
place for later use.

## Operating instructions

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## 1 Safety

### 1.1 Intended use

The SOL Nova Unlimited II is to be used in the commercial sector.

The SOL Nova Unlimited II is a professional tattoo machine for tattooing human skin.

These instructions for use do not contain all the information required for the safe operation of SOL Nova Unlimited II and its accessories. Please also note the following documents:

- Information on tattoo modules and tattooing inks,
- Safety data sheets for disinfectants and cleaning agents,
- Workplace safety regulations and legal requirements for tattooing.

### 1.2 Misuse

Any other or additional use of the SOL Nova Unlimited II other than that described in the chapter “1.1 Intended use” is considered improper and thus inappropriate.

This is particularly true if you

- do not comply with the ambient and operating conditions intended for the use of SOL Nova Unlimited II, see chapter “2.5.1 Operating conditions”,
- use any other inks other than those permitted by MT.DERM,
- or want to tattoo any animals.

### 1.3 Warning signs

	General warning
	Substances harmful to the skin
	Danger from batteries
	Biological hazard
	Electrical voltage
	Toxic substances
	Pointed object

## 1 Safety

### 1.4 Requirement signs

---

#### 1.4 Requirement signs



Observe instructions



Use hand protection (protective gloves)

#### 1.5 Qualification

##### 1.5.1 Required qualification

The tattooing machine must only be used by persons who have acquired the following knowledge:

- basic knowledge of the tattooing process, in particular the correct puncture depth and frequency
- Knowledge of hygiene and safety regulations (see chapter “1.9 Risks and dangers” on page 9)
- Knowledge of what the tattooing ink does under the skin
- Knowledge of risks and side effects (see chapter “1.9 Risks and dangers” on page 9 and “1.10 Adverse effects” on page 10).

##### 1.5.2 Personal protective equipment

Always use disposable nitrile or latex gloves when working with or on the SOL Nova Unlimited II.



#### 1.6 Limited abilities

Persons with reduced physical, sensory, or mental abilities or persons with a lack of experience or knowledge must not use the SOL Nova Unlimited II.

There is a risk of suffocation from plastic bags and if swallowed.

Keep children away from packaging material (e.g., film, polystyrene).

Children will underestimate the danger of using electrical appliances.

**NEVER** leave any children unattended with the SOL Nova Unlimited II.

Rechargeable batteries can be life-threatening. Keep batteries out of reach of small children accordingly. Medical assistance must be sought immediately if a battery has been swallowed.



#### 1.7 Basic security

Special safety provisions may apply to particular activities. Safety notices and warnings can be found in the respective chapters of these instructions for use.

Ensure that the safety notices in these instructions for use are observed. Read these instructions for use carefully, especially the safety-related information,

## 1 Safety

### 1.8 Contraindications

---

and adhere to these instructions for use before using the SOL Nova Unlimited II.

Only work with the SOL Nova Unlimited II if you can perform the work reliably. **Do NOT** use the SOL Nova Unlimited II if your ability to react is affected, e.g., by drugs, alcohol, or medication.

#### 1.7.1 Modifications

Modifications of the SOL Nova Unlimited II are strictly prohibited.

Please discuss any necessary modifications with MT.DERM GmbH in advance and obtain written authorisation.

Otherwise, your warranty and guarantee rights will be voided and a new conformity assessment may be necessary.

### 1.8 Contraindications

The SOL Nova Unlimited II must not be used:

- in cases of haemophilia or other blood clotting disorders,
- while taking blood thinners (e.g., acetylsalicylic acid, heparin, aspirin, warfarin),
- in cases of uncontrolled diabetes mellitus,
- in cases of any form of active acne in the skin area to be tattooed,

- in cases of dermatoses (e.g., skin tumours, keloids, or extreme tendency to develop keloids, solar keratosis, warts, and/or moles) in the skin area to be tattooed,
- if there are any open wounds and / or eczema and / or skin rashes in the skin area to be tattooed,
- if there are any scars in the skin area to be tattooed,
- in cases of systemic infections and infectious diseases (e.g., hepatitis type A, B, C, D, E or F, HIV infection) or acute localised skin infections (e.g., herpes, rosacea),
- during chemotherapy, radiotherapy, or high-dose corticosteroid therapy (recommendation: from four weeks before the start to 4 weeks after the end of therapy),
- for up to 12 months after cosmetic surgery in the skin area to be tattooed,
- for up to 6 months after filler injections in the skin area to be tattooed,
- under the influence of alcohol and / or drugs,
- during pregnancy and breastfeeding.

Treatment must be interrupted without undue delay if the person to be tattooed experiences excessive pain, fainting, or dizziness.



## 1 Safety

### 1.9 Risks and dangers

---

#### 1.9 Risks and dangers

##### 1.9.1 Explosion hazard

**Damaged batteries cells may cause explosion and fire.**

- ▶ Never use a damaged battery.
- ▶ Charge the battery in an ambient temperature of +10 °C ... +40 °C.
- ▶ Never charge any obviously damaged batteries.
- ▶ Never recharge a deep-discharged battery.
- ▶ Only charge rechargeable batteries.
- ▶ Never use any damaged chargers.
- ▶ Dispose of damaged batteries or chargers immediately.



##### 1.9.2 Toxic substances

**Danger to life possible due to unsuitable tattooing inks.**

- ▶ Only work with the SOL Nova Unlimited II if you are sufficiently trained.
- ▶ Only use dermatologically safe inks intended for tattooing.



##### 1.9.3 Poor hygiene

**Possible danger to life due to infection.**

- ▶ Only work with the SOL Nova Unlimited II if you have received sufficient training.
- ▶ Only handle the SOL Nova Unlimited II and its accessories with clean, disinfected gloves.
- ▶ Use a new protective tube, new gloves, and a new tattoo module for every person to be tattooed.
- ▶ Dispose of used protective tubes, gloves, and tattoo modules properly after use.
- ▶ Do not touch any freshly tattooed skin. Protect freshly tattooed areas of skin from dirt, UV, and sunlight.



## 1 Safety

### 1.10 Adverse effects

---

#### 1.9.4 Risk of stabbing and cutting

Careless operation may cause cuts and punctures.



- ▶ Only work with the SOL Nova Unlimited II if you have received sufficient training.
- ▶ Only use original tattoo modules from Cheyenne.
- ▶ Never touch the tattoo module at the tip or the cap.
- ▶ Switch off the SOL Nova Unlimited II to change a tattoo module.
- ▶ Never push the needles out of the tattoo module.
- ▶ When removing the tattoo module, check that
  - the needles are completely in the tattoo module,
  - no ink residue runs into the handle.
- ▶ Dispose of tattoo modules professionally.
- ▶ Only remove tattoo modules from their sterile packaging immediately before use
- ▶ Place the SOL Nova Unlimited II so that the tattoo module is **NOT** resting on top.
- ▶ Have any wounds examined by a doctor immediately.

#### 1.10 Adverse effects

In some cases, slight adverse effects may occur during and after tattooing. These are listed below.

##### Frequent:

- Localised bleeding in the tattooed skin area,
- Pain and discomfort on the first day after tattooing,
- Short-term inflammatory reactions, erythema, and/or oedema up to 6 days after tattooing,
- Skin irritation (e.g., itching or warming); this usually subsides in the first 12 to 72 hours after tattooing,
- Formation of scabs that will usually disappear within the first 5 days,
- Temporary flaking of the skin that usually subsides within 8 days.
- Increased UV sensitivity.

##### Rare:

- Formation of blisters from herpes simplex virus type I (HSV-I),
- Formation of small pustules, or milia as a result of careless skin cleansing before tattooing,
- Hyperpigmentation with the body's own pigments, in particular in darker skin types; this will disappear entirely again within a few weeks,
- Retinoid reaction (slight reddening or even peeling of the skin),

## 1 Safety

### 1.11 Behaviour in an emergency

---

- possible heating of the pigmented area.

The following problems can also occur with the tattoo:

- Differences in the shade of colour,
- Pigment loss,
- Allergic reactions to components of the aseptic pigment ink.

### 1.11 Behaviour in an emergency

Switch off the SOL Nova Unlimited II if there is a risk of:

- injuries,
- damage to the SOL Nova Unlimited II.

Take immediate action and call the local emergency number in cases of accidents.

## 2 Product description

### 2.1 Functional description

Table 2-1: Identification features

Product name / designation	SOL Nova Unlimited II 2.5   3.5   4.5
Model	GCB527* * Ink variant 10 - 49

The SOL Nova Unlimited II injects ink into the skin of a person to be tattooed using a high-frequency piercing needle.

The SOL Nova Unlimited II is generally operated via the following options:

- C button,
- Circle button,
- ◀▶ button
- Gesture recognition.

### 2.2 Scope of delivery

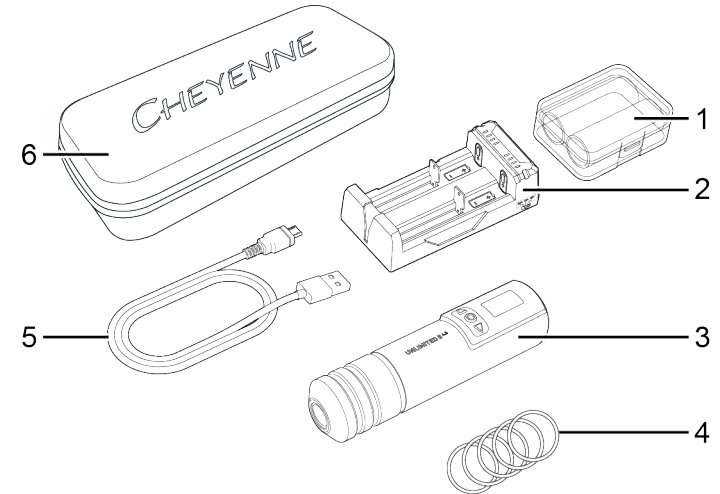


Figure 2-1: Scope of delivery

Item	Designation
1	1 battery box with 2 lithium-ion batteries
2	1 charger
3	1 Cheyenne SOL Nova Unlimited II
4	5 O-rings
5	1 USB cable
6	1 case
	1 quick guide
	1 declaration of conformity

## 2 Product description

### 2.3 Symbols on the product

#### 2.3 Symbols on the product

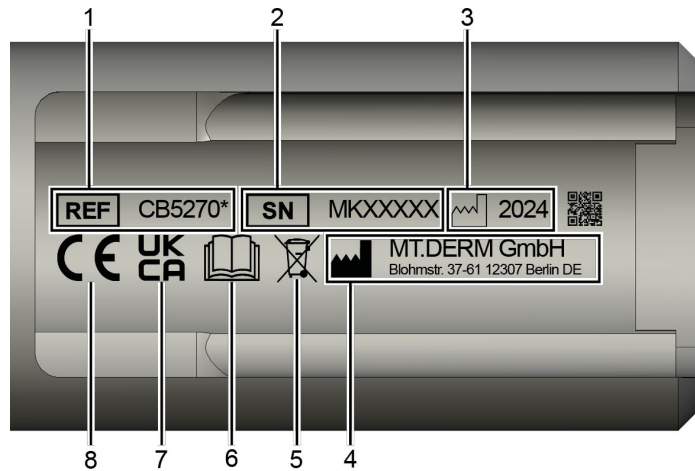


Figure 2-2: Symbols on the product

Item	Designation
1	Model number
2	Serial number
3	Year of manufacture
4	Manufacturer
5	Dispose of old electronics properly
6	Follow the instructions for use!
7	Satisfies UK legislation
8	Complies with the CE directives

#### 2.4 Available accessories and consumables

You can purchase the following accessories from specialist dealers or in the [Cheyenne webshop](http://www.cheyennetattoo.com) at [www.cheyennetattoo.com](http://www.cheyennetattoo.com):

- Cheyenne tattoo modules,
- Cheyenne handles:
  - Cheyenne aluminium grips,
  - Cheyenne steel handles,
  - Cheyenne disposable handles.
- Cheyenne battery,
- Cheyenne charger,
- Cheyenne SOL Nova II case,
- Cheyenne O-rings.

The following parts must be replaced for each new person to be tattooed:

- Protective tubes with diameters of 36 ... 40 mm,
- Cheyenne tattoo module.

#### NOTE

- ▶ *Protective tubes must be replaced for each new person to be tattooed.*
- ▶ *Dispose of the protective tube after each tattoo.*

## 2 Product description

### 2.5 Technical data

## 2.5 Technical data

### 2.5.1 Operating conditions

Table 2-2: Ambient conditions

Operation		
Ambient temperature	[°C]	+10 ... +35
	[°F]	+50 ... +95
Charging temperature	[°C]	+10 ... +40
	[°F]	+50 ... +104
Relative humidity	[%]	30 ... 75 (non-condensing)
Air pressure	[hPa]	200 ... 1060
Emitted noise level	[dB]	≤ 70
Storage		
Storage temperature	[°C]	-20 ... +50
	[°F]	-4 ... +122
Relative humidity	[%]	30 ... 75 (non-condensing)
Air pressure	[hPa]	200 ... 1060

The conditions at the place of use of SOL Nova Unlimited II must at least comply with these conditions. Any use under other conditions is at your own risk. We recommend contacting [our customer service](#) beforehand.

### 2.5.2 Dimensions

Table 2-3: Dimensions

Length	[mm]	135.5
Diameter (thickest point)	[mm]	33 (36)
Weight	[g]	211
Weight (without battery)	[g]	177
Weight (entire case)	[g]	584

### 2.5.3 Operating values

Table 2-4: Dimensions

Penetration frequency	[Hz]	25 ... 150
Stroke	[mm]	
SOL Nova Unlimited II 2.5		2.5
SOL Nova Unlimited II 3.5		3.5
SOL Nova Unlimited II 4.5		4.5
Needle protrusion	[mm]	-1 ... 4
Total vibration value	[m/s <sup>2</sup> ]	< 2.5

## 2 Product description

### 2.5 Technical data

---

#### 2.5.4 Charger data

Table 2-5: *Charger data*

Designation		Cheyenne® FC2 Charger
Input		QC3.0
Input voltage	[V DC]	5
Input current	[A]	2.0
Charging current	[A]	0.5 ... 1.8 (x 2)
End-of-charge voltage	[V]	4.16 ... 4.24
End-of-charge current	[mA]	< 100
Operating temperature	[°C] [°F]	0 ... 40 32 ... 104

#### 2.5.5 Battery data

Table 2-6: *Battery data*

Battery designation		NCR18500A
Battery type		Li-ion
Charging method		CC-CV
Nominal battery voltage	[V]	3.7
Length	[mm]	53
Diameter	[mm]	18.5
Battery weight	[g]	≤ 33.5
Nominal capacity	[mAh]	2000
Capacity min.	[mAh]	1940
Typical capacity	[mAh]	2040
Charging voltage	[V]	4.2
Insulation class		III
IP code		IP20

## 2 Product description

### 2.6 Material compatibilities

---

## 2.6 Material compatibilities

### 2.6.1 Standard disinfectant

Preferably use one of the following disinfectants:

Table 2-7: *Disinfectant*

Manufacturer	Product	Application time
Antiseptica	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

### 2.6.2 Other disinfectants

You can also use the following material compatibilities to determine which other cleaning agents and disinfectants are suitable.

The anodised aluminium components, plastic parts, silicone parts of the control unit, and seals of SOL Nova Unlimited II 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 anodised aluminium components, plastic parts, silicone parts of the control unit, and seals of SOL Nova Unlimited II 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),
- caustic solutions (e.g., caustic soda, ammonia, and all substances with a pH value  $>$  7),
- aromatic / halogenated hydrocarbons (e.g., phenol, chloroform),
- acetone and petrol.



## 2.7 Operating concept

### 2.7.1 Operating elements

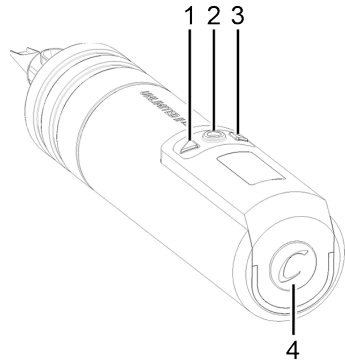


Figure 2-3: Operating elements

Item	Designation
1	◀ button - decreasing value
2	Circle button
3	▶ button - increasing value
4	C button

#### NOTE

- ▶ The arrow key designations depend on the orientation of the upright font on the display:
  - The arrow button above the text is the ▶ button - increasing value,
  - The arrow button below the text is the ◀ button - decreasing value.

### 2.7.2 Error displays and device warning signals

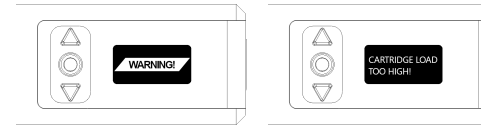


Figure 2-4: Error displays

#### NOTE

- ▶ Warning displays alternately show the warning message, e.g., “Warning!” and the corresponding error text.

Refer to the troubleshooting table, see chapter “6.2.2 Troubleshooting” to remedy errors.

## 2 Product description

### 2.7 Operating concept

#### 2.7.3 Navigation

Pressing the buttons is displayed as follows for clarity:

Press the [x] button briefly.	[x] ↓○
Press the [x] button for a longer time.	[x] ↓⊙
Hold down the [x] button.	[x] ↓●
Press the [x] button for more than [y] seconds.	[x] ↓ > [y] s
Press the [x] button for less than [y] seconds.	[x] ↓ < [y] s
Press the [x] or [z] buttons.	[x]↓/ [z]↓

#### NOTE

- ▶ *The SOL Nova Unlimited II switches to the main screen after 5 s of inactivity.*
- ▶ *The SOL Nova Unlimited II switches off after 5 min of inactivity.*
- ▶ *The SOL Nova Unlimited II dims its display after 5 s of inactivity.*
- ▶ *Pressing one of the four buttons ends the dimmed state.*

Table 2-8: Navigation

Action	Keyboard shortcuts / approach
Switch the SOL Nova Unlimited II on / off.	C ↓○ / ↓⊙ or 1/3 s
In the main screen, switch between: <ul style="list-style-type: none"> <li>• Penetration frequency</li> <li>• Motor mode</li> <li>• Timer</li> </ul>	Circle button ↓○
Call up the main menu. The display shows the first menu item.	Circle button ↓⊙
Jump one menu item forwards or backwards.	◀ / ▶ ↓○
Select a menu item.	Circle button ↓○
Return to the main screen	Wait for 5 s Select “Back” in the main menu.

## 2 Product description

### 2.7 Operating concept

Table 2-9: Operating concept

Action	Keyboard shortcuts / approach
<i>Changing the penetration frequency</i>	
Change the penetration frequency step by step (1 Hz).	◀ / ▶ ↓ ○
Change the penetration frequency (jumps up/down by 5 Hz).	◀ / ▶ ↓ ⊙
<i>Change motor mode on the main screen</i>	
Switching mode.	◀ / ▶ ↓ ○
<i>Showing the timer on the main screen</i>	
Display the session timer.	Circle button ↓ ○
<i>Switching the motor on / off</i>	
Switch the motor on or off, regardless of which menu you are in.	C ↓ ○
<i>Gesture control when motor is on</i>	
Use the gesture control to change the penetration frequency.	Circle button ↓ ●, perform gesture
	C ↓ ●, perform gesture

#### NOTE

- ▶ You can set the gesture for setting the penetration frequency in the “Gesture” submenu.

## 2 Product description

### 2.8 Menus

## 2.8 Menus

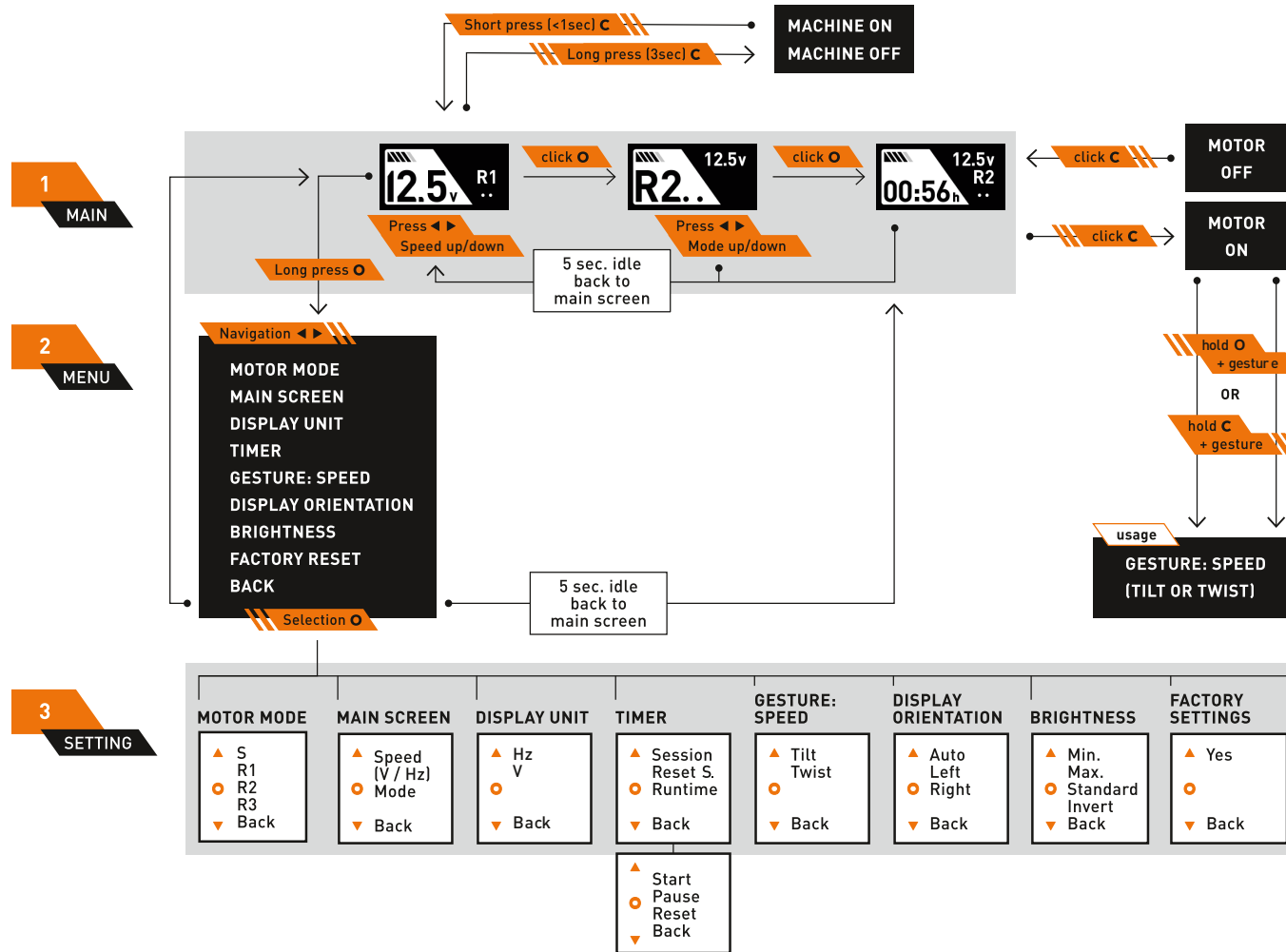


Figure 2-5: Menu structure

## 2 Product description

### 2.8 Menus

---

#### 2.8.1 Main menu

The main menu comprises the following items:

- MOTOR MODE
- MAIN SCREEN
- DISPLAY UNIT
- TIMER
- GESTURE (SPEED)
- DISPLAY ORIENTATION
- BRIGHTNESS
- FACTORY RESET
- BACK

#### 2.8.2 MOTOR MODE

You can choose between the motor modes here:

- S (Steady Mode)
- R1 (Responsive Mode 1)
- R2 (Responsive Mode 2)
- R3 (Responsive Mode 3)

For more information on the motor modes, see chapter “5.5 Steady Mode and Responsive Mode”.

#### 2.8.3 MAIN SCREEN

The MAIN SCREEN allows you to switch the MAIN SCREEN display between SPEED and MOTOR MODE:

- SPEED (HZ/V)
- MOTOR MODE
- SESSION TIME (display only)

#### 2.8.4 DISPLAY UNIT

Select the unit for SPEED:

- HZ
- V

#### 2.8.5 TIMER

The TIMER displays:

- SESSION: Running time since last activation.
- START/PAUSE/CONTINUE: Start / stop / continue the session counter.
- RESET SESSION: Sets the SESSION TIME to 00:00 H
- RUNTIME: Total period of use of your SOL Nova Unlimited II (cannot be reset).

## 2 Product description

### 2.9 Gesture control

---

#### 2.8.6 GESTURE

- TILT
- TWIST

For more information on gesture control, see chapter “2.9 Gesture control”.

#### 2.8.7 DISPLAY ORIENTATION

Specify how the display should be aligned:

- AUTO
- LEFT
- RIGHT

#### 2.8.8 BRIGHTNESS

Set the display brightness:

- MIN
- MAX
- STANDARD
- INVERT

#### 2.8.9 FACTORY RESET

Reset the SOL Nova Unlimited II to factory settings:

- YES

### 2.9 Gesture control

#### NOTE

- ▶ *You can only use gesture control when the motor is switched on and the circle button or C button is pressed.*
- 

#### 2.9.1 Tilt

Use “Tilt” for the following settings:

- The further upwards you hold the tip of the SOL Nova Unlimited II, the faster the penetration frequency will become.
- The further down you hold the tip of the SOL Nova Unlimited II, the slower the penetration frequency will become.
- If you hold the SOL Nova Unlimited II horizontally, a frequency of 90 Hz is set.

#### 2.9.2 Twist

Use “Twist” for the following settings:

- Turn the SOL Nova Unlimited II clockwise to increase the penetration frequency.
- Turn the SOL Nova Unlimited II counter-clockwise to reduce the penetration frequency.

### 3 Transporting, storage, unpacking

#### WARNING

**Risk of explosion and fire due to improper transport of lithium-ion batteries.**

- ▶ Only transport and store your batteries subject to the specified storage and transport conditions.
- ▶ Always use the plastic battery box to transport the batteries.
- ▶ **NEVER** transport the batteries loose in the bag since metal parts (e.g., keys) may cause a short circuit.
- ▶ Remove the battery before transporting the SOL Nova Unlimited II and store it in the battery box.



#### ATTENTION

**Damage to the motor may occur if the SOL Nova Unlimited II falls.**

- ▶ Always put the SOL Nova Unlimited II down carefully so that it cannot roll away and fall down.
- ▶ Perform a visual inspection and a listening test for unusual noise by gently shaking the device if the SOL Nova Unlimited II has fallen.

#### CAUTION

**Injuries may occur due to malfunction of the SOL Nova Unlimited II.**

- ▶ Do not switch the SOL Nova Unlimited II on if it looks or sounds unusual.
- ▶ Do not continue to use the SOL Nova Unlimited II.
- ▶ Send the SOL Nova Unlimited II to MT.DERM GmbH for testing and repair.



## 3 Transporting, storage, unpacking

### 3.1 Transport

---

#### 3.1 Transport

Table 3-1: Transport dimensions case

Length	[mm]	280
Width	[mm]	110
Height	[mm]	75

The SOL Nova Unlimited II is shipped in a cardboard and plastic parcel.

 **NOTE**

- ▶ *Either send the SOL Nova Unlimited II in the original box or label the box as hazardous goods because of the batteries.*

---

Transport the SOL Nova Unlimited II as follows:

1. Transport the SOL Nova Unlimited II and its accessories with sufficient padding.
  2. Leave the handle mounted during transport to protect the drive.
  3. Use the supplied case to transport the SOL Nova Unlimited II and its accessories.
  4. Observe the ambient conditions, see chapter “2.5.1 Operating conditions”.
  5. Always carry the case with the SOL Nova Unlimited II to its destination with care.
- ✓ You have transported the SOL Nova Unlimited II.

#### 3.2 Storing

Always store the SOL Nova Unlimited II and all supplied accessories in the case.

Store the case in its original packaging in a covered, dry room that has been swept clean if storing it for longer periods of time.

Observe the information on storage temperature and humidity, see chapter “2.5.1 Operating conditions”.

 **NOTE**

- ▶ *Most airlines will only permit transport of the SOL Nova Unlimited II, including the batteries, in an aircraft in hand luggage.*
  - ▶ *Check with the airline before travelling.*
  - ▶ *Always store the SOL Nova Unlimited II and its accessories under the specified storage conditions.*
-



### 3.3 Unpacking

The packaging material comprises cardboard and plastic.

Remove the case from the box.

 **NOTE**

- ▶ *Keep the packaging in case you need to repack the SOL Nova Unlimited II or want to store it for longer.*
- 

Recycle the packaging material in an environmentally friendly manner.

## 4 Prepare for use

### 4.1 Assembling

## 4 Prepare for use

### ATTENTION

Condensation may cause damage to the electronics.

- ▶ Do not use the SOL Nova Unlimited II for at least 30 minutes to allow the SOL Nova Unlimited II to acclimatise if the SOL Nova Unlimited II has been exposed to large temperature fluctuations, for example during transport.
- ▶ Check that the SOL Nova Unlimited II has reached the ambient temperature before commissioning.  
Wait for at least 3 hours per 10 °C temperature difference before operating the SOL Nova Unlimited II after any large temperature fluctuations.
- ▶ Observe the specified ambient conditions, see chapter “2.5.1 Operating conditions”.

## 4.1 Assembling

Assemble the SOL Nova Unlimited II as follows:

1. Charge the battery, see chapter “4.3.1 Charging the battery”.

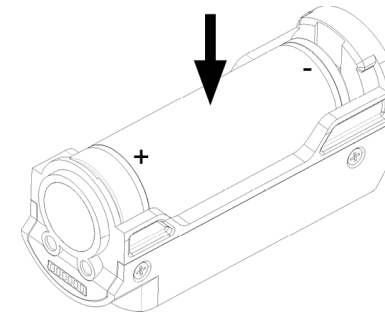


Figure 4-1: Inserting the battery

2. Insert the charged battery into the control unit.

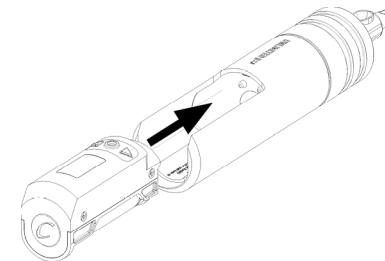


Figure 4-2: Inserting the operating unit

3. Ensure that the positive pole of the battery is pointing towards the tattoo module.
  4. Push the operating unit into the drive unit until you hear it click into place.
- ✓ You have assembled the SOL Nova Unlimited II.

## 4.2 Disinfecting the equipment

### ATTENTION

**Penetrating liquids may damage the drive.**

- ▶ **NEVER** soak your SOL Nova Unlimited II (drive unit + control unit) in any disinfectant.
- ▶ **NEVER** spray any liquids directly onto the SOL Nova Unlimited II.

### ATTENTION

**Unauthorised disinfectants may cause damage.**

- ▶ Disinfectants that are not compatible with the materials of the product may cause damage to its surface.
- ▶ Only use disinfectants that are approved in accordance with the regulations of your country.
- ▶ Observe the list of recommended disinfectants, see chapter “2.6.1 Standard disinfectant”.

Disinfect the SOL Nova Unlimited II as follows:

1. Switch off the SOL Nova Unlimited II.
2. Check whether the SOL Nova Unlimited II is grossly contaminated by ink or body fluids that have run back.



Figure 4-3: Unscrewing the handle

3. Unscrew the handle from the drive unit.
4. Remove the control unit.
5. **ATTENTION! Property damage caused by penetrating liquids. Do NOT** spray any liquids onto the SOL Nova Unlimited II and do not soak it in disinfectant.  
Wipe the SOL Nova Unlimited II and its components with a soft cloth moistened with cleaning agent or disinfectant.
6. Use a soft nylon brush or a cotton bud to clean surfaces that are difficult to access, such as the thread of the drive unit.
7. Ensure that the contact pins are not bent when cleaning the housing sleeve.
  - ▶ Ink streaks may occur due to the nature of the surface.
8. Screw the handle onto the drive unit and insert the operating unit.



Figure 4-4: Screwing on the handle

- ✓ You have disinfected the SOL Nova Unlimited II.

### 4.3 Working on the battery

**⚠ WARNING**

Contaminated accessories may lead to infection.

- ▶ Touch the SOL Nova Unlimited II and its accessories **ONLY** with clean, disinfected gloves.



**⚠ WARNING**

Risk of explosion and fire due to incorrect handling of batteries.

- ▶ **ONLY** charge the battery in an ambient temperature of +10 °C ... +40 °C.
- ▶ **NEVER** recharge any deeply discharged batteries. Battery cells that have been discharged below 2.5 V are irreversibly damaged.
- ▶ **ONLY** charge rechargeable batteries.
- ▶ **NEVER** charge any damaged batteries.
- ▶ **NEVER** use any damaged chargers.
- ▶ Dispose of damaged batteries or chargers immediately.



### 4.3.1 Charging the battery

**ATTENTION**

Incorrect power supply may cause property damage.

- ▶ Only use the charger included in the scope of delivery or a charger recommended by MT.DERM GmbH.
- ▶ Observe the output data of the USB socket used.
- ▶ Only use USB sockets whose output data matches that of the charger, see chapter “2.5.4 Charger data”.
- ▶ If the output current is too low, the charging time will be accordingly longer.
- ▶ Suitable voltage sources include:
  - the USB power adapter from your smartphone or tablet,
  - your power bank.

You can use the charger included in the scope of delivery for the following Li-ion batteries:

- with the voltage: 3.6 / 3.7 V,
- of the types IMR / INR / ICR,
- sizes 16340 / 10440 / 14500 / 18500 / 18650 / 20700 / 26650.

## 4 Prepare for use

### 4.3 Working on the battery

---

#### NOTE

- ▶ *The battery is supplied partly charged.*
- ▶ *Fully charge the battery with the charger before using the device for the first time to ensure full battery performance.*
- ▶ *You can charge an additional battery at any time.*
- ▶ *Interrupting the charging process will not harm the battery.*
- ▶ *You can manually set the charging current to 1.8 A / 1.0 A / 0.5 A.*
- ▶ *The charger works optimally with a power supply unit that uses QC3.0.*
- ▶ *If a power adapter without QC3.0 technology is used, the charging time will be longer.*

Perform a charging process as follows:

1. Connect the charger to a USB socket using the USB cable.

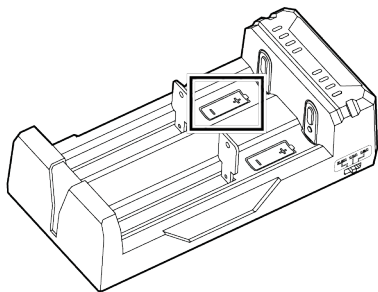


Figure 4-5: Inserting the battery correctly

2. Place one or two rechargeable batteries in the slots of the charger in the orientation / polarity shown.
  - ▶ The charger charges each battery with a maximum charging current of 1.8 A. The charging time for a 2000 mA battery is approx. 2 hours.
  - ▶ The LEDs on the charger flash while the battery is charging.
  - ▶ Depending on the charge level, the LEDs start to light up continuously:
    - LED1 ... LED4 flash: State of charge 0 ... 25%,
    - LED1 lights up, LED2 ... LED4 flash: State of charge 25 ... 50%,
    - LED1 ... LED2 light up, LED3 ... LED4 flash: State of charge 50 ... 75%,
    - LED1 ... LED3 light up, LED4 flashes: State of charge 75 ... 99%,
    - LED1 ... LED4 light up: Charge level 100%.
  - ▶ All LEDs flash simultaneously if an error has occurred. This happens, for example, in case of a short circuit or if the battery is inserted the wrong way around.
  - ✓ You have completed the charging process.

## 4 Prepare for use

### 4.3 Working on the battery

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#### 4.3.2 Replacing the battery

Replace the battery as follows:

1. Switch off the SOL Nova Unlimited II.

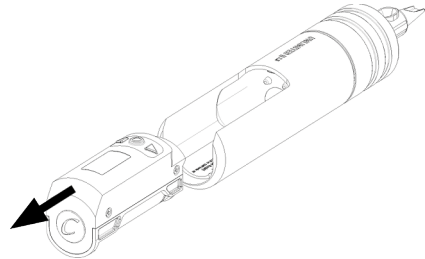


Figure 4-6: *Pulling out the control unit*

2. Pull the operating unit out of the drive unit.

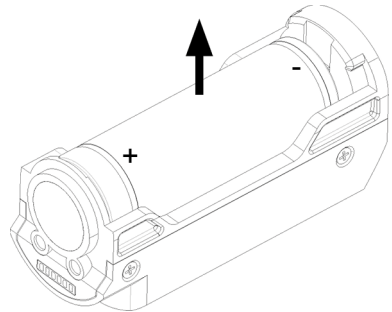


Figure 4-7: *Removing the battery*

3. Remove the battery from the control unit.

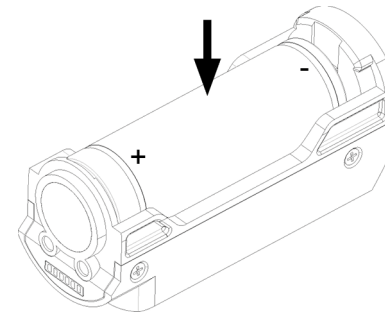


Figure 4-8: *Inserting the battery*

4. Insert a charged battery into the control unit.
5. Ensure that the positive pole of the battery is pointing towards the tattoo module.

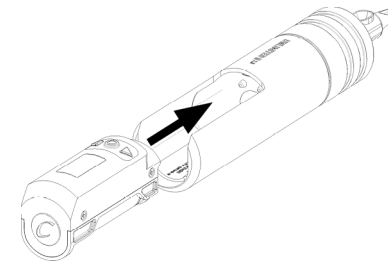


Figure 4-9: *Inserting the operating unit*

6. Push the operating unit into the drive unit until you hear it click into place.
- ✓ You have changed the battery.

## 4 Prepare for use

### 4.4 Attaching the protective tube

#### 4.4 Attaching the protective tube

##### **⚠ WARNING**

Contaminated protective tubes may cause infection.

- ▶ Use a new protective tube for each person to be tattooed.



##### **ATTENTION**

Penetrating liquids may damage the drive.

- ▶ Only use protective tubes with suitable dimensions.

Pull on the protective tube as follows:

1. Prepare a protective tube of sufficient length.



Figure 4-10: Unscrewing the handle

2. Unscrew the handle from the drive unit entirely.

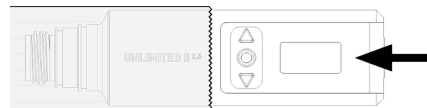


Figure 4-11: Pulling on the protective tube

3. Pull the end of the protective tube completely over the SOL Nova Unlimited II.

4. Prepare the handle hygienically:
  - Aluminium handle: Clean the handle by wiping, in an ultrasonic bath or in an autoclave, see chapter “7.2 Clean”.
  - Disposable handle: use a new, sterile handle.

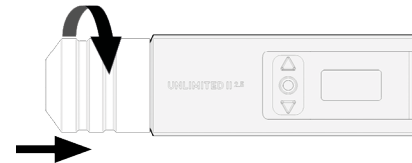


Figure 4-12: Tightening the handle

5. Screw the handle onto the thread of the drive unit.
  - ✓ You have put on the protective tube.

## 4.5 Installing the tattoo module

 **WARNING**

**Contaminated needles may cause infection.**

- ▶ **NEVER** work without disposable gloves
- ▶ **NEVER** touch the used tattoo module by the tip or the needle shaft.
- ▶ Check that the needles are fully retracted into the tattoo module after removing a used tattoo module.
- ▶ Consult a doctor after any injuries with a contaminated needle.
- ▶ The tattoo modules are delivered in sterile packaging. Only remove them from their sterile packaging immediately before use.
- ▶ Only use original Cheyenne tattoo modules. The built-in safety diaphragm prevents ink and bodily fluids from penetrating your SOL Nova Unlimited II.
- ▶ Dispose of used tattoo modules properly, see chapter “8.2 Storage and disposal”.



 **CAUTION**

**Punctures from the needle may occur.**

- ▶ Switch off SOL Nova Unlimited II before changing the tattoo module.
- ▶ **NEVER** touch the needle module by its tip or the bayonet catch.
- ▶ Always place the SOL Nova Unlimited II so that the tattoo module is not resting on top.
- ▶ **NEVER** push the needles out of the tattoo module.
- ▶ Prevent ink residue from running into the handle when removing a used tattoo module.
- ▶ Initiate suitable first aid measures immediately after any injury with a contaminated needle.
- ▶ Consult a doctor after any injuries with contaminated needles.
- ▶ Dispose of used tattoo modules properly, see chapter “8.2 Storage and disposal”.





## 4 Prepare for use

### 4.5 Installing the tattoo module

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Change the tattoo module as follows:

1. Switch off the SOL Nova Unlimited II.

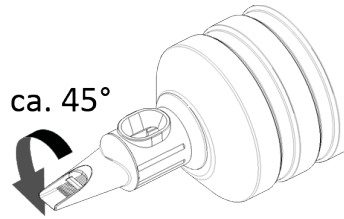


Figure 4-13: *Unscrewing the tattoo module*

2. Turn the old tattoo module counter-clockwise by approx. 45°.

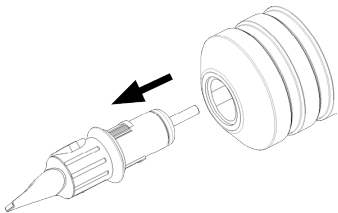


Figure 4-14: *Pulling out tattoo module*

3. Pull the old tattoo module out of the opening of the handle.

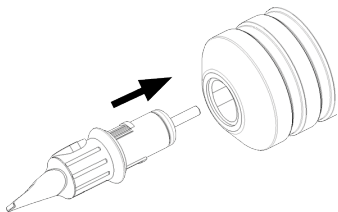


Figure 4-15: *Inserting the tattoo module*

4. Insert the new tattoo module into the opening of the handle.

You can only insert the tattoo module into the oval opening in two ways due to its locking points.

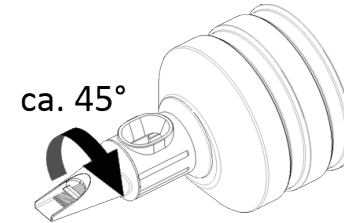


Figure 4-16: *Latching the tattoo module*

5. Rotate the tattoo module clockwise by approx. 45°.

You will feel several locking points until the tattoo module engages completely when turning.

6. Check that the tattoo module is firmly in place.  
✓ You have changed the tattoo module.

## 4.6 Checking the equipment

Check the equipment of SOL Nova Unlimited II as follows:

1. Check the SOL Nova Unlimited II equipment for external damage.
2. **WARNING! Damage to the SOL Nova Unlimited II may cause injuries and property damage.**
  - If you notice any external damage, do not use the SOL Nova Unlimited II.
  - Contact MT.DERM GmbH for the repair.
3. Check that the tattoo module is correctly aligned.
4. **WARNING! A damaged tattoo module may cause injuries and property damage.**
  - Always use a tattoo module with correct alignment.
5. Check the battery for visible damage.
6. **WARNING! Damaged battery cells may pose a risk of explosion and fire.**
  - **NEVER** use any damaged batteries.
  - Dispose of any damaged batteries in accordance with the provisions in your country.



7. Switch on the SOL Nova Unlimited II and perform a listening test.

8. **WARNING! Damage to the SOL Nova Unlimited II may cause injuries and property damage.**



- Switch off the SOL Nova Unlimited II immediately if you hear any noticeably loud or unusual noises. This suggests damage to the SOL Nova Unlimited II.

- Contact MT.DERM GmbH for the rep (support@cheyennetattoo.com)

- ✓ You have checked the equipment of SOL Nova Unlimited II.

## 5 Use


### 5.1 Preparation on the person to be tattooed

---

## 5 Use

### 5.1 Preparation on the person to be tattooed

Clean the skin of the person to be tattooed as follows before tattooing:

1. Use disposable gloves made of nitrile or latex.
  2. Disinfect the disposable nitrile or latex gloves.
  3. **CAUTION! Aggressive disinfectants may cause skin damage.** 
    - Observe the applicable guidelines in your country when selecting suitable cleaning agents and disinfectants.
  4. Clean the affected areas of the skin of the person to be tattooed with a mild cleanser and disinfectant person to be tattooed.
- ✓ You have cleaned the skin of the person to be tattooed before tattooing.

### 5.2 Starting and stopping

#### NOTE

- ▶ *Operation is as described in the chapter "2.7 Operating concept".*
- 

Start and stop the SOL Nova Unlimited II as follows:

1. Switch on the SOL Nova Unlimited II, C ↓○.
  2. Start the motor, C ↓○.
    - ♦ The motor starts.
  3. Stop the motor, C ↓○.
    - ♦ The motor stops.
- ✓ You have started and stopped the SOL Nova Unlimited II.

### 5.3 Needle protrusion

#### CAUTION

Punctures may reach the subcutaneous fatty tissue at excessive needle protrusion.

- ▶ A large needle protrusion enables a large penetration depth.
- ▶ If the needle protrusion and penetration depth are too great, the subcutaneous fatty tissue can be damaged.
- ▶ Always start with a low needle protrusion when using the SOL Nova Unlimited II.



#### ATTENTION

The safety diaphragm may be damaged if the needle protrudes too far.

- ▶ The safety diaphragm of the tattoo modules can be overstretched and damaged if the needle protrudes too far.

Set the needle protrusion as follows:

1. Switch on the SOL Nova Unlimited II, C ↓○.
2. Turn the handle to adjust the needle protrusion.

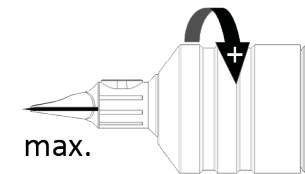


Figure 5-1: Increasing the needle protrusion

3. Increase the needle protrusion by turning clockwise.

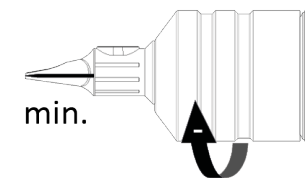


Figure 5-2: Reducing the needle protrusion

4. Reduce the needle protrusion by turning counter-clockwise.
  5. Check the needle protrusion of SOL Nova Unlimited II before tattooing.
- ✓ You have adjusted the needle protrusion.

## 5.4 Penetration frequency

### ⚠ CAUTION

An excessive penetration frequency may cause cuts.

- ▶ Always start with a low penetration frequency.



### ✎ NOTE

- ▶ The adjustable frequency is between 25 Hz and 150 Hz.
- ▶ The SOL Nova Unlimited will start with the last settings made after restarting or battery replacement. The SOL Nova Unlimited II must have been started with the settings previously for this.
- ▶ The frequency can only be set using the gesture control when the motor is running.
- ▶ Operation is as described in the chapter "2.7 Operating concept".

Set the penetration frequency as follows:

1. Switch on the SOL Nova Unlimited II, C ↓○.
  - ▶ The main screen will appear on the display and show the last set or used penetration frequency as a frequency (in Hz) or as a voltage (in V), depending on the setting.

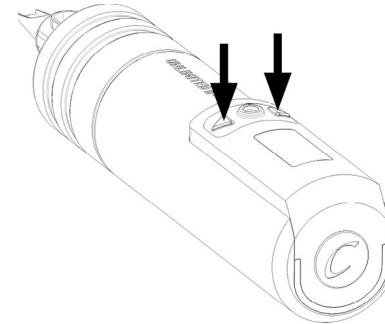


Figure 5-3: Pressing one of the ◀/▶ buttons

2. Set the appropriate penetration frequency with ◀/▶. The penetration frequency must match:
    - Skin condition of the person to be tattooed,
    - Needle protrusion and individual penetration depth when working and
    - Working speed.
- ✓ You have set the penetration frequency.

## 5.5 Steady Mode and Responsive Mode

On the SOL Nova Unlimited II, you can choose between the two operating modes “Steady Mode” and “Responsive Mode”. The operating modes differ due to a different motor control.

You can only change the mode of SOL Nova Unlimited II when the motor is stopped.

Access these via:

- fast Access via display screen or
- Main menu.

 **NOTE**

- ▶ *Operation is as described in the chapter “2.7 Operating concept”.*
- 

### 5.5.1 Access via fast Access

Switch between the operating modes as follows:

1. Stop the SOL Nova Unlimited II.
  2. Call up the motor mode via fast Access by pressing the circle button  $\downarrow \bigcirc$ .
  3. Select the desired motor mode with  $\blacktriangleleft / \blacktriangleright \downarrow \bigcirc$ .
  4. The display jumps back to your main screen after 5 s or switch to the main screen by pressing the circle button twice  $\downarrow \bigcirc$ .
  5. Start the SOL Nova Unlimited II.
- ✓ You have changed the mode.

### 5.5.2 Access via main menu

Switch between the operating modes as follows:

1. Stop the SOL Nova Unlimited II.
  2. Call up the main menu, circle button  $\downarrow \odot$ .
  3. In the main menu, jump to the “Motor Mode” menu item,  $\blacktriangleleft / \blacktriangleright \downarrow \bigcirc$ .
  4. Select the desired motor mode using the circle button  $\downarrow \bigcirc$ .
  5. Jump to the “Back” menu item in the main menu,  $\blacktriangleleft / \blacktriangleright \downarrow \bigcirc$  or wait for 5 s until the display returns to the main screen.
- ✓ You have changed the mode.

## 5 Use

### 5.6 Picking up ink

---

#### 5.5.3 Steady Mode

The SOL Nova Unlimited II always operates at the same penetration frequency in Steady Mode.

The SOL Nova Unlimited II adapts to the load and energises the motor appropriately.

#### 5.5.4 Responsive Mode

In “Responsive Mode”, the motor reacts more sensitively to the resistance of the skin. This means that the penetration frequency is reduced slightly with a time delay.

The SOL Nova Unlimited II has three levels of Responsive Mode. Set this via the “Motor Mode” menu, see chapter “2.8.2 MOTOR MODE”.

### 5.6 Picking up ink

Pick up ink with the needles as follows:

1. Dip the tip of the tattoo module into the desired ink for 2 to 3 seconds while the machine is running immediately before use.
2. Avoid contact with the ink tank.
  - ✦ The needles absorb the ink.

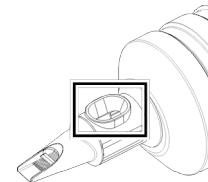


Figure 5-4: *Alternative: Ink opening*

3. Alternatively, you can fill the ink into the opening on the tattoo module using a sterile pipette.
- ✓ You have picked up ink with the needles.

## 6 Faults, messages, and errors

### 6.1 Procedure in case of faults

Always remedy any faults as follows:

1. Make sure that there is no danger to any persons or objects. Switch off the SOL Nova Unlimited II immediately if any danger threatens.
  2. Record the circumstances that led to the fault.
  3. Record the error messages displayed, see chapter "6.2.2 Troubleshooting".
  4. Check whether you can remedy the fault directly or whether you need to instruct authorised specialists to do so.
  5. Contact MT.DERM GmbH if necessary.
- ✓ You have remedied the fault.

### 6.2 Eliminate errors

#### 6.2.1 Uneven needle protrusion

Eliminate an uncontrolled change in needle protrusion as follows:

1. If the handle no longer remains fixed, thoroughly clean the inside of the handle, the thread of the drive unit, the grooves and the small O-ring (see chapter "7.2 Clean").
  2. Also replace the small O-ring if the problem persists.
    - ✦ The needle protrusion should be fixed during operation.
  3. If the problem persists, please contact a specialist dealer or MT.DERM GmbH.
- ✓ You have eliminated the uncontrolled change in needle protrusion.



## 6 Faults, messages, and errors

### 6.2 Eliminate errors

#### 6.2.2 Troubleshooting

 **NOTE**

- *If you are unable to rectify the fault, contact a specialist dealer or contact [support](#).*

Table 6-1: Troubleshooting

Error displays	Remedy
ERROR DRIVE UNIT	C ↓ 3 s The SOL Nova Unlimited II switches off. C ↓ ○ The SOL Nova Unlimited II restarts.
ERROR POWER UNIT	Contact our support team. Determine whether you need to send in the SOL Nova Unlimited II as a whole or just the control unit.
CARTRIDGE LOAD TOO HIGH!	Change the tattoo module. If the error persists: send in SOL Nova Unlimited II.

Error displays	Remedy
MOTOR MISSING	Insert the drive unit correctly. Check that there is nothing in the sleeve to prevent the control unit from being positioned correctly. If the error persists: send in SOL Nova Unlimited II.
EXCESS TEMPERATURE MOTOR	Take a break from tattooing. Wait until the SOL Nova Unlimited II has cooled down. If the error persists: send in SOL Nova Unlimited II.
BATTERY ALMOST EMPTY	Charge the battery.
BATTERY EMPTY	Charge the battery.
BATTERY OVERVOLTAGE	The battery may be faulty. Replace the battery. An incorrect battery was inserted. Use an original battery.
EXCESS TEMPERATURE BATTERY	The battery may be faulty. Replace the battery.

## 7 Care

### 7.1 Periodic inspection

## 7 Care

### 7.1 Periodic inspection

Table 7-1: Inspection schedule

Interval	Component	Inspection / work
Before each use	SOL Nova Unlimited II overall	Visual inspection for wear or damage
	Handle, surfaces	Clean / disinfect
AT visible soiling	Handle	Clean in an ultrasonic bath
		Sterilise in an autoclave
Daily	Labelling and / or engraving on the components	Visual inspection, clean illegible labelling and / or engravings as necessary
In case of wear	O-rings	Visual inspection, replace O-rings as necessary

#### NOTE

- ▶ Contact MT.DERM GmbH if you encounter any difficulties during the activities / tests that you cannot resolve.

### 7.2 Cleaning

#### ATTENTION

**Damage to the drive due to short circuit possible.**

- ▶ **NEVER** disassemble or clean any components of the SOL Nova Unlimited II while they are energised.
- ▶ Always disconnect the SOL Nova Unlimited II from its power source entirely for any cleaning and maintenance work (remove control unit, remove battery).

## 7 Care

### 7.2 Cleaning

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#### ATTENTION

##### Penetrating liquids may damage the drive.

- ▶ Never soak the SOL Nova Unlimited II in disinfectant.
- ▶ **NEVER** clean the drive unit, the control unit, and other electrical parts (e.g., battery) in an autoclave or in an ultrasonic bath.
- ▶ When selecting cleaning agents and disinfectants, observe the material compatibility, see chapter “2.6 Material compatibilities”.

#### 7.2.1 Surface

Clean the surfaces of SOL Nova Unlimited II before and after each use as follows:

1. Disinfect all surfaces of the SOL Nova Unlimited II, see chapter “4.2 Disinfecting the equipment”.
2. Check for external soiling.
3. Remove the handle from the drive unit if there is any external soiling.
4. **ATTENTION! Damage to the drive unit possible.** Ensure that the contact pins are not damaged during cleaning.  
Wipe the handle, drive unit, control unit, and the protective tube with a soft cloth moistened with cleaning agent or disinfectant.
5. Dispose of the protective tube properly.

6. Use a soft nylon brush or a cotton bud to clean surfaces that are difficult to access, such as the thread of the drive unit.

Due to the nature of the surface, ink fogging may occur on SOL Nova Unlimited II.

7. Screw the handle and drive unit together.
- ✓ You have cleaned the surfaces of SOL Nova Unlimited II.

#### 7.2.2 Clean the handle in an ultrasonic bath

Clean the handle in an ultrasonic bath as follows if it is very dirty:

1. Use the cleaners Tickomed 1 or Tickopur R33 from the manufacturer Dr H. Stamm GmbH according to the manufacturer’s instructions.
  2. The pH value must not exceed 7.
  3. Perform the cleaning for 10 minutes at a frequency of 35 kHz.
  4. Dry the handle completely after cleaning before using it again.
- ✓ You have cleaned the handle in an ultrasonic bath.

## 7 Care

### 7.3 Repair

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#### 7.2.3 Sterilising a contaminated handle in an autoclave

Sterilise the contaminated handle in the autoclave as follows:

1. Disinfect all surfaces of the SOL Nova Unlimited II, see chapter “4.2 Disinfecting the equipment”.
  2. Sterilise the handle in the autoclave for 20 minutes at a temperature of 121 °C and a pressure of 2 bar.
  3. Dry the handle completely after cleaning before using it again.
- ✓ You have sterilised the contaminated handle in the autoclave.

#### 7.2.4 O-rings

Clean or replace the O-rings if the handle is too easy to turn and the needle protrusion changes uncontrollably as follows:

1. Degrease the O-rings with a soft cloth moistened with cleaning agent or disinfectant.
  2. If the problem persists, replace the O-rings with new ones and grease them with silicone grease if necessary.
- ✓ You have cleaned or changed the O-rings.

### 7.3 Repair

Send your SOL Nova Unlimited II in if it is damaged.

Contact our [support](mailto:support@cheyennetattoo.com) (support@cheyennetattoo.com).

For further contact details, see the end of these instructions.

## 8 Storage and disposal

### 8.1 Repacking and storage

#### ATTENTION

**Incorrect storage may cause damage.**

- ▶ Observe the information on storage temperature and humidity, see chapter “2.5.1 Operating conditions”.
- ▶ Only store the SOL Nova Unlimited II in its case and original packaging.

### 8.2 Disposal and recycling

Ensure safe and proper disposal, in particular of parts or substances that are harmful to the environment.



Disposal of the SOL Nova Unlimited II, including operating materials and cleaning fluids, is subject to local disposal regulations and environmental laws.

The local municipal authority can provide you with information on this.

Properly dispose of any materials that can be recycled with consideration for our environment.

Rechargeable batteries (including damaged ones) should not be disposed of in the household waste.



Li-ion

Dispose of any old or used batteries properly, e.g., in the collection boxes in shops or at municipal collection centres.

The packaging material comprises cardboard and plastic. Separate the packaging materials and recycle each fraction in an environmentally friendly manner.

## 9 Annex

### 9.1 Warranty statement

You have purchased a high-quality branded product with the SOL Nova Unlimited II 2.5 / 3.5 / 4.5 from Cheyenne.

The SOL Nova Unlimited II is guaranteed to be reliable based on the latest testing techniques and certification. MT.DERM GmbH is certified to DIN EN ISO 13485:2016 (quality management system for medical devices).

The product is guaranteed for one year against malfunctions caused by defects in material or workmanship.

We guarantee sterility of the tattoo modules in sealed and undamaged packaging in compliance with the transport and storage conditions until the specified expiry date.

The expiration date can be found on the label of the tattoo modules. If you have a complaint about tattoo modules, please inform us of the batch number printed on the label.

MT.DERM GmbH accepts no liability for the following damage:

- Damage and consequential damage caused by improper use or non-compliance with the instructions for use.
- Damage caused by the ingress of liquids or dirt into the drive unit.
- Damage and consequential damage caused by falling or dropping.

## 9 Annex

### 9.2 EU/EC Declaration of Conformity

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## 9.2 EU/EC Declaration of Conformity

Der Hersteller MT.DERM GmbH (Blohmstraße 37-61, 12307 Berlin, Germany) erklärt, dass die folgenden Produkte

**Produktbezeichnung:** Tattoo machine with battery-operated control unit

**Artikelnummer** CB527\*

den Bestimmungen folgender Richtlinien entsprechen:

Maschinenrichtlinie 2006/42/EG

EMV-Richtlinie 2014/30/EU

RoHS-Richtlinie 2011/65/EU

**Folgende Normen wurden angewandt:**

IEC 60335-1:2020 und EN 60335-1:2012 + AC:2014 + A11:2014 + A13:2017 + A15:2021 Sicherheit

elektrischer Geräte für den Hausgebrauch und ähnliche Zwecke - Teil 1: Allgemeine Anforderungen

CISPR 14-1:2020-09 und EN 55014-1:2017 + A11:2020 Elektromagnetische Verträglichkeit - Anforderungen

an Haushaltgeräte, Elektrowerkzeuge und ähnliche Elektrogeräte - Teil 1: Störaussendung

CISPR 14-2:2020-08 und EN 55014-2:1997 + AC:1997 + A1:2001 + A2:2008 Elektromagnetische Verträglichkeit - Anforderungen

an Haushaltgeräte, Elektrowerkzeuge und ähnliche Elektrogeräte - Teil 2: Störfestigkeit - Produktfamiliennorm

EN IEC 63000:2018 Technische Dokumentation zur Beurteilung von Elektro- und Elektronikgeräten hinsichtlich der Beschränkung gefährlicher Stoffe

**Folgende sonstige technische Spezifikationen / Normen wurden angewandt:**

EN ISO 14971:2019 + A11:2021 Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte

EN ISO 13485:2016 + AC:2018 + A11:2021 Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke

**Bevollmächtigter für die Zusammenstellung der relevanten technischen Unterlagen:** Dr. Andreas Pachten, MT.DERM GmbH, Dokumentationsbeauftragter

Diese Erklärung wird verantwortlich für den Hersteller abgegeben durch:



Berlin, den 01.03.2024, Jörg Kluge

(Unterschrift des Geschäftsführers oder seines Bevollmächtigten) Original

**Figure 9-1:** Declaration of Conformity p. 1

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