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Instructions for use

TCM 3000 BL

NOUVAG

Vorwort

Herzlichen Glückwunsch zum Kauf eines Produktes der Firma NOUVAG AG. Wir freuen uns, dass Sie sich für ein NOUVAG Erzeugnis entschieden haben und danken Ihnen für Ihr entgegengebrachtes Vertrauen.
Diese Bedienungsanleitung wird Sie mit dem Gerät und seinen Eigenschaften vertraut machen, damit eine möglichst lange und problemlose Funktion gewährleistet werden kann.
Im Anhang finden Sie die Konformitätserklärung und unsere autorisierten Servicestellen.

- **Bitte lesen Sie diese Anleitung vor Inbetriebnahme aufmerksam durch!**

Foreword

Congratulations on your purchase of a NOUVAG AG product. Thank you for the confidence shown in our products.
Please consult the instruction manual for the use and maintenance of the device to ensure that it will function properly and efficiently for many years.
You will find the conformity statement and list of authorized service representatives attached.

- **Please read instructions carefully before operating!**

Préface

Félicitations vous venez d'acheter un produit NOUVAG AG. Merci de la confiance que vous montrez en nos produits.
Merci de consulter le mode d'emploi pour l'utilisation et l'entretien de cet appareil de manière à vous assurer qu'il fonctionnera correctement et efficacement pendant de nombreuses années.
Vous trouverez ci-joint les déclarations de conformité et la liste des agents agréés pour l'entretien.

- **Lire soigneusement les instructions avant utilisation !**

Prefazione

Ci congratuliamo con Lei per l'acquisto di un prodotto NOUVAG AG e le auguriamo un susseguirsi di successi professionali.
Questo manuale l'aiuterà a conoscere meglio l'apparecchiatura e le sue caratteristiche. Contiene indicazioni utili che le assicureranno un funzionamento efficiente ed una lunga durata.
Qui allegato troverete la dichiarazione di conformità e la lista dei rivenditori autorizzati.

- **Prego leggere attentamente le istruzioni per l'uso prima di mettere in funzionamento!**

Preposición

Muchas gracias por la compra de un producto NOUVAG AG.
Felicidades por la elección y la confianza depositada en nuestros productos.
Para garantizar una función duradera y eficiente del aparato, por favor consultar el manual de instrucciones.
El Certificado de Conformidad y la lista de Centros de Servicio se encuentran en el apéndice.

- **Por favor leer las instrucciones detenidamente antes de poner en marcha el aparato!**

Table of contents

1 General information

1.1 Intended use and operation

The TCM 3000 BL is a device for controlling an electronic motor combined with an appropriate handpiece according to the intended use. It's applied in an operation theater for Dermabrasion and Reconstructive Surgery as well as for sawing, drilling, milling, and grinding at bones. Handpieces like the 1: 1 handpiece, dermatomes, the tattooing handpiece, and different kind of micro saws can be applied.

1.2 Contraindication

Relative or absolute contraindications can arise from the general medical diagnose, or in special cases by a significantly increased risk to the patient by motor-driven systems.
Relevant cases in the literature must be taken into consideration.

1.3 Users / Target Group

Patient population:

a) Age: all age groups
b) Weight: all weight categories
c) Health condition: stable health condition, partial or local anesthesia required
d) Nationality: not relevant
e) Patient condition: patient is NOT OPERATING; patient is locally anesthetized or under partial anesthesia and must be monitored.
f) Gender: not relevant

1.4 Technical data, TCM 3000 BL

Voltage ---------- variable: 100 V~/ 115 V~/ 230 V~, 50/60 Hz
Fuse, power supply ---------- 2 fuses T 1 AL 250 V AC
Power consumption ---------- 60 VA
Motor speed range ---------- 500 – 40.000 rpm
Maximum motor torque ---------- 6 Ncm
Motor coupling ---------- INTRA coupling ISO 3964
Cable length, motor ---------- 3 m
Cable length, pedal ---------- 3 m
Protection class ---------- Class I
Applied part ---------- Type BF *
IP code, pedal ---------- IPX8
Dimensions (W x D x H) ---------- 120 x 180 x 115 mm
Net weight, control unit ---------- 1.8 kg

** Applied part of type BF is the instrument (handpiece) attached to the electronic motor*

1.5 Ambient conditions

	Transport and storage:	**At operation:**
Relative humidity:	max. 90 %	max. 80 %
Temperature:	0 – 50°C	10 – 30°C
Atmospheric pressure:	700 – 1060 hPa	800 – 1060 hPa

1.6 Warranty conditions

With the purchase of the TCM 3000 BL you are entitled to 1 year warranty. If the warranty card is returned for registration within 4 weeks from the date of purchase, the warranty coverage is extended by 6 months. Wear parts are excluded from the warranty. Improper use and repair, as well as non-compliance with our instructions, will release us from any warranty service and other claims.

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2 Symbols

	Important information		Autoclave at 134 °C
	Warning		Suitable for thermal disinfection
	Manufacturer	IPX8	Protection against continual submerging.
	Type BF applied part. Applied part is the instrument	SN	Symbol indicating the serial number with the date of manufacturing
	Certified by the TÜV Rheinland North America Group		Electrical and electronic devices that have reached the end of their service life comprise hazardous waste and may not be disposed of together with household waste. Valid local disposal regulations apply.
CE 0197	Conform to European standards, with notified body	REF	Symbol indicating the order number.
	Observe instructions for use		Motor
	Pedal		Biohazard
	Potential Equalization		Date of manufacturing
EC REP	European representative		

3 Safety information

Your safety, the safety of your team, and of course that of your patients is very important to us. It is therefore essential to bear the following information in mind:

Every use of the TCM 3000 BL different to the product description defined in chapter 1.1, “Intended use and operation”, causes risks for patients and trained personnel. If physical examinations and therapies are carried out without use of the devices, then the devices must be removed from the place of treatment. Avoid any connection or close adjacency to other devices.

3.1 EMC Manufacturer’s Declaration of Conformity

The use of (RF) Radio Frequency emitting devices and equipment as well as the occurrence of negative environmental factors in the close area of the TCM 3000 BL may cause unexpected or adverse operation. The connection or the placing of other devices in close vicinity is not allowed.

The product is suitable for use in establishments of the industrial sector and hospitals. When used in the domestic establishments, this unit may not provide adequate protection for radio services. The user must take remedial measures such as implementation or reorientation of the product.

Use only accessories and cables as specified in the product description. Further observe the EMC manufacturers declaration of conformity.

3.2 Post market surveillance

In the event of problems with the product or in the event of a serious incident, please immediately download the following form: https://nouvag.com/media/attachments/2022/05/19/for_8-308.pdf, fill it out and send it to the following address: mailto:omplaint@nouvag.com

3.3 Modification and misuse

- Modification or manipulation of the TCM 3000 BL and its accessories is prohibited.
  The manufacturer is not liable for any damages resulting from unauthorized modifications or manipulations. The warranty will be cancelled.
- Use of the TCM 3000 BL outside the indications described in Section 1.1 is prohibited.
  The user or operator is solely responsible for any such use.

3.4 Essential requirements

⚠	Before use read this manual and the manuals for all other equipment used in the procedure thoroughly. Familiarize yourself with the functions and handling of the appliance.	⚠	The products described in this manual must be used by trained and qualified medical personnel only in accordance with the requirements and with reference to the manual.
⚠	For the protection of the patient, the user and third parties the products used must be prepared as specified in the manual.	⚠	Improper use or repair of the device, or failure to observe these instructions, will relieve us from any obligation arising from warranty provisions or other claims.
⚠	The use of third-party products is the responsibility of the operator. Functionality and patient safety cannot be guaranteed with third-party accessories.	⚠	Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile, and operational.
⚠	Repairs may only be performed by service technicians, authorized by the manufacturer of the device, Nouvag AG.	⚠	Use Lubrifluid spray for maintenance and care of the motor and handpieces. Using other care products can result in malfunctions and/or cause the warranty to be revoked.

3.5 During use

⚠	The device is not sterile on delivery. All sterilizable parts must be sterilized before use (see Chapter 8, cleaning, and disinfection).	⚠	Do not remove handpieces while the motor is running. It could result in instrument damage
⚠	Operate the device only outside the danger zone of explosive, flammable mixtures, or gases.	⚠	The TCM 3000 BL must be operated under the continuous supervision of medically qualified persons only.
⚠	The motor ventilation slots must be kept clear to prevent the motor from overheating.	⚠	Ensure that the operating voltage setting corresponds to the local mains voltage.
⚠	"The rotation of the instrument, supply of heat energy by friction due to too high motor speed is leading to damage of the tissue and pain of the patient"		

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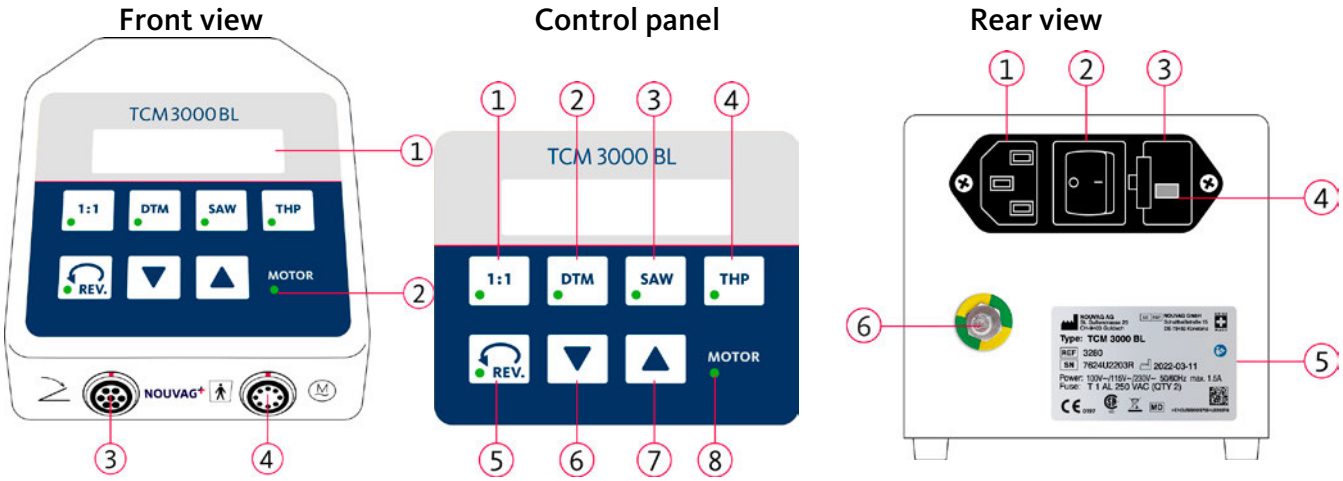
4 Scope of delivery

REF	Description	Quantity
3285	**TCM 3000 BL set comprises the following products**	1
3280	TCM 3000 BL control unit, device connecting cable 3 m, (country specific)	1
1507nou	VARIO-Pedal, IPX8, connecting cable 3 m	1
1170	Handpiece cradle, white	1
2112nou	Electronic motor 21 with ISO 3964 coupling, 3-meter motor cable, operations manual included	1
2128	Lubrifluid care spray	1

In line with regulations pertaining to hazardous materials, the item"Lubrifluid" care spray (REF 2128) is not delivered with the control unit but can be ordered separately from any official Nouvag service center. www.nouvag.com

5 Device overview



1. Display
2. LED Motor indication light
3. Pedal connection
4. Motor connection (M)

1. «1: 1» key (Program for 1:1 handpiece)
2. «DTM» key (Program for Dermatome)
3. «SAW» key (Program for all micro saws)
4. «THP» key (Program for Tattoo handpiece)
5. «Changing rotational direction» (Device emits a signal tone)
6. «▼» (decrease value)
7. «▲» (increase value)
8. Motor-LED

1. Mains connection
2. ON/OFF main switch
3. Fuse module
4. Country voltage indication
5. Type plate with type designation, reference number, serial number, information on power supply and device fuse
6. Potential equalization

6 Before use

6.1 Device Setup

- Installation layout

- Place the TCM 3000 BL and all required accessories and instruments on an even, non-slip surface and make sure you have good access to all controls.
- The installation of the device near other devices is prohibited due to EMC – please see section 3.1 and the manufacturer's EMC declaration in the appendix of this manual.
- Do not allow the operating range of the device (including the cable and handpiece) to be compromised by limiting factors.
- The system display must be always fully visible.
- The pedal must be placed within stepping distance between the patient and the surgeon.
- It must be explicitly ensured that no objects can fall on the pedal.
- The power plug at the rear of the device must be always accessible.
- The motor ventilation slots must be kept clear to prevent the motor temperature from becoming excessive.

6.2 Potential equalization connection according to DIN 42801

At the back of the device a potential equalization plug is installed, according to DIN 42801.

The additional potential equalization has the task of equalizing potentials between different parts of conductive materials that can be touched at the same time or reducing potential differences.

This connection must be used, to protect the patient, the user and third parties from touch voltages.

The equipotential plug is marked with the following symbol: 

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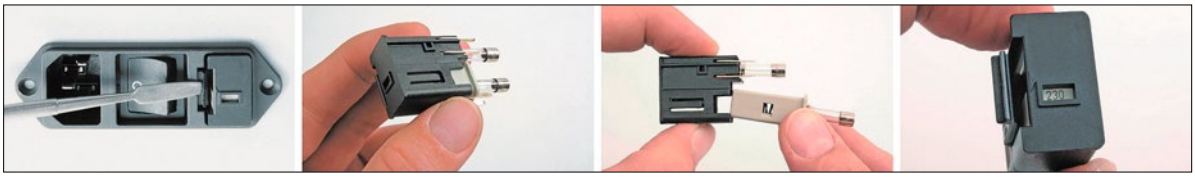
6.3 Connection to the power supply

- Before plugging the power cable into the power socket for the first time, you must check the supply voltage setting next to the power switch.
- To prevent the risk of electric shock, the device may only be connected to a power network with a PE protective earth conductor.

If the voltage shown does not correspond to the local mains voltage, the grey fuse holder must be set to the correct voltage:



1. Switch the device off.
2. Unplug the power cable.
3. Use a screwdriver to open the fuse slot.
4. Remove the fuse holder.
5. Remove the grey fuse holder and reinsert it so that the local mains voltage setting is shown in the small window.
6. Slide the grey fuse holder back in and close the fuse slot.
7. Check the mains voltage shown on the fuse slot.
8. Plug the power cable back into the device.

6.4 Device preparation

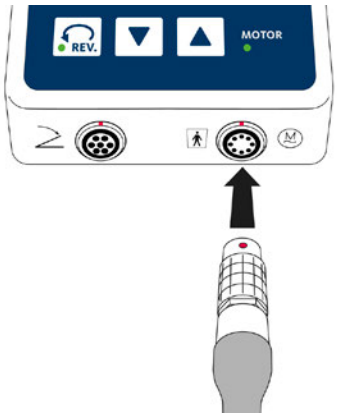
The device is not sterile on delivery. All sterilizable parts must be sterilized before use (see Chapter 8 Cleaning and disinfection).

If the accessories have already been sterilized: when removing them from the sterile packaging, ensure that the sterile packaging is not damaged, and that the sterility indicator confirms sterility and shelf life of the sterile item has not expired.

The assembly of accessories is carried out under sterile conditions (wear gloves and a mask, place accessories on a sterile surface).

6.4.1 Connecting the motor cable

Align the red dot on the device connection plug of the motor with the red dot on the motor connection of the control unit.
Plug the motor device connection plug into the motor connection of the control unit. The plug must lock in position.

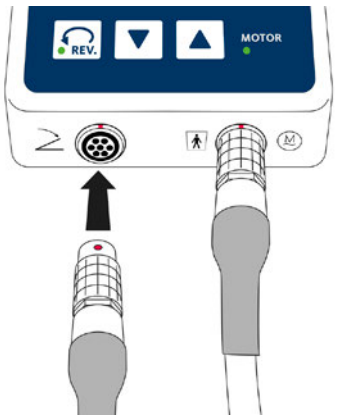


With the TCM 3000 BL control unit only the electronic motor 21 (REF 2112nou) may be used.

Sterilize the motor (motor is not sterile on delivery). If the motor has already been sterilized when removing from the sterile packaging, ensure that the sterile packaging is not damaged, and the sterility indicator confirms sterility. The sterile packaging must show the date on which the shelf life of the sterile item is due to expire. (Refer to chapter 8, cleaning, and disinfection)

6.4.2 Connecting the pedal cable

Align the red dot on the device connection plug of the pedal with the red dot on the pedal connection of the control unit. Plug the pedal device connection plug into the pedal connection of the control unit. The plug must lock in position.



With the TCM 3000 BL control unit only the VARIO pedal (REF 1507nou) may be used.

6.4.3 Attaching the handpiece onto the motor

Attach desired handpiece onto the motor. The following handpieces are available:

Handpiece 1: 1
REF 1710nou

Dermatome 75/100 mm
REF 1990nou/1983nou

Micro Sagittal Saw, REF 5110nou
Micro Oscillating Saw, REF 5090nou
Micro jig Saw, REF 5040nou

Tattoo handpiece
REF 5020nou

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7 Operation

7.1 Switching the TCM 3000 BL on or off

The device is switched on (**I**) or off (**O**) with the main switch „**I/O** “, at the power supply module, at the rear of the device. The display on the TCM 3000 BL is then illuminated.

After switching the device on the last used setting will be activated and displayed.

7.2 Program overview

Select the program on the operation panel according to the applied handpiece.
The activated Program is confirmed with an indication light on the key as well as on the display.

The setting values described can deviate from the actual value by a maximum of ± 10 %.

7.2.1 Program for 1: 1 handpiece

Press **1: 1** key according to the applied 1: 1 handpiece on the motor.

Press ▼-key for decreasing or ▲-key for increasing the value of the desired speed.

Press **REV.**-key to change the direction of rotation of the applied instrument (a tone signal is emitted, and the display shows an arrow).

7.2.2 Program for the Dermatome

Press **DTM**-key according to the applied Dermatome handpiece on the motor.
The ideal rotational speed for the dermatomes is 14.000 rpm and can not be changed.

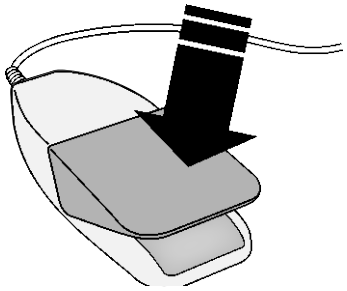
7.2.3 Program for surgical micro saws

Press **SAW**-key according to the applied micro saw handpiece on the motor.
The ideal rotational speed for the micro saws is 15.000 rpm and cannot be changed.

7.2.4 Program for the Tattoo handpiece

Press **THP**-key according to the applied Tattoo handpiece on the motor.
The ideal rotational speed for the Tattoo handpiece is 12.000 rpm and can not be changed.

7.3 Setting the handpiece in motion



The motor with the attached handpiece is only set in motion when the pedal is pressed. The speed for the 1: 1 handpiece is regulated by variation of the pressure on the pedal.
The Dermatomes, the Tattoo handpiece and the micro saws are all running with a fixed speed. The variation of the pedal therefore has no influence on the speed. The rotational speed stays constantly the same.

7.4 Functional check

Prior to each use of the device a functional check must be performed for the device and the whole periphery.

- Check motor and attached handpiece for lose parts and eventually loose connection.
- Are all labels and inscription well readable?
- Switch on device.
- Press the pedal all the way it will go for about 20 seconds. Motor and handpiece must reach and hold the preset rotational speed.
- Release the pedal and switch off the device.

The motor with the attached handpiece can only be operated via the connected pedal.

8 Cleaning and disinfection

Risk of infection!
The product should be prepared in accordance with the instructions given in this manual before using it for the first time and for each subsequent use. The inadequate and/or incomplete preparation of the product can cause an infection of the patient. Observe the following specific instructions.

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8.1 Reprocessing of the control unit and the pedal

The control unit and the pedal do not come into direct contact with the patient.
Wipe the outside using microbiologically tested surface disinfectant or a 70 % isopropyl alcohol solution.

8.2 Reprocessing of the Electronic motor 21

The reprocessing instructions of the electronic motor are described in the operating instructions of the electronic motor, which are supplied together with the electronic motor. The front panel of the control unit is suitably sealed and washable.

8.3 Reprocessing of the handpieces used

The reprocessing instructions for the applied handpiece is included in the packaging of the handpiece used.

9 Maintenance and repair

9.1 Replacing the motor cable

- Replace defective motor cable by a new one (REF 76052)

9.2 Replacing the control unit fuse

Users can replace faulty control unit fuses themselves. These are located at the rear of the device in the fuse slot besides the power switch:

1. Switch the device off.
2. Unplug the power plug.
3. Open the fuse slot using a screwdriver.
4. Replace the faulty fuse **T 1 AL, 250 V AC**.
5. Slide the fuse holder back in and close the fuse slot.
6. Check the mains voltage shown in the fuse slot window.
7. Plug in the power plug.

1. Fuse slot locking mechanism
2. Window showing the voltage setting
3. Fuse slot
4. Fuse 1
5. Fuse 2

9.3 Safety inspections

The essential requirements have been defined and within the risk analysis assessed. The approved results have been filed in the risk management deposited with the manufacturer.

The performance of safety inspections on medical devices is required by law in several countries. The safety inspection is a regular safety check that is compulsory for those operating medical devices. The objective of this measure is to ensure that device defects and risks to patients, users or third parties are identified in time.

The STI (Safety technical inspection) for the TCM 3000 BL shall be executed every 2 years by authorized experts. Results shall be documented.

The service instructions, diagrams and descriptions are available on request from the manufacturer.

NOUVAG AG offers a safety inspection service for its customers. Addresses can be found in the appendix of this operation manual under “Service centers”. For further information please contact our technical service department.

Further international service centers are listed on the Nouvag website:

Service - Nouvag AG | Swiss Dental and Medical Precision Tools

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9.4 Malfunction and troubleshooting

Malfunction	Cause	Solution	Refer to the operation instruction
Device is not operational (Display is not active)	Control unit is not switched on.	Set the power switch I/O to **„ I “**	7.1 Switching the TCM 3000 BL on or off
	Control unit is not connected to the power supply.	Connect the control unit with the power supply.	6.2 Connection to the power supply
	Incorrect operating voltage	Check for correct operating voltage	6.2 Connection to the power supply
	Faulty fuse	Replace the fuse	9.2 Replacing the control unit fuse
Motor is not running	Motor is not activated	Press pedal to activate the motor	7.3 Setting the handpiece in motion
	Motor is not connected	Connect motor cable with the control unit	6.3.1 Connecting the motor cable
	Handpiece is not correctly attached	Firmly press handpiece against the motor until it engages.	7.4 Functional check
Pedal is not functioning (Display is active)	Pedal is not or not correctly connected	Connect pedal cable with the pedal plug of the control unit.	6.3.2 Connecting the pedal cable

If a fault cannot be rectified, please contact your supplier or an authorized service center.
The addresses are provided on the last page of the operating instructions.

9.5 Fault messages on the display

Error message	Cause	Solution
	Motor fault	Switch device off and on again.
	The device has detected undervoltage while the motor is running.	The pedal must be released for a short period.
	Pedal was pressed while switching on the device.	The pedal must be released for a short period.

If an error cannot be rectified, please contact the supplier or an authorized service center.
The addresses can be found on the last page of the operating instructions.

10 Spare parts and Accessories

Spare parts	**REF**
Electronic motor 21, up to 40.000 rpm, motor cable 3 m, including operation manual	2112nou
VARIO pedal, IPX8, connection cable 3 m	1507nou

Accessories	**REF**
Dermatome 75 with ISO 3964 coupling, 75 mm cutting width, 1.00 mm max. cutting depth, 14.000 rpm	1990nou
Dermatome 100 with ISO 3964 coupling, 100 mm cutting width, 1.00 mm max. cutting depth, 14.000 rpm	1983nou
Blades for Dermatome 75 mm cutting width	1995
Blades for Dermatome 100 mm cutting width	1919
Reduction base plate for Dermatome 100 to 75 mm	19872
Reduction base plate for Dermatome 100 to 50 mm	19871
Reduction base plate for Dermatome 100 to 25 mm	19869
Reduction base plate for Dermatome 75 to 50 mm	19887
Reduction base plate for Dermatome 75 to 25 mm	19886
Surgery handpiece 1:1 with ISO 3964 coupling, attachable cooling nozzle, quick release clamping, for instruments with 44 mm length and Ø 2.35 mm, up to 50.000 rpm	1710nou
Micro Jigsaw, MSS 5000 with ISO 3964 coupling, attachable cooling nozzle, clamping mechanism with knurled screw for blade clamping, 15.000 rpm	5040nou
Micro Jigsaw, OMS 5000 with ISO 3964 coupling, attachable cooling nozzle, clamping mechanism with knurled screw for blade clamping, 15.000 rpm	5090nou
MOS 5000 Osseoscalpel -Microsaw with ISO 3964 coupling, attachable cooling nozzle, clamping mechanism with screw nut for blade clamping, 15.000 rpm	5110nou
Tattoo handpiece with ISO 3964 coupling, stitching depth up to max. 2.0 mm, 12.000 rpm	5020nou

To order additional parts, please contact our customer service department.

The instructions for use are enclosed with this product in printed form. If instructions for use in electronic form (PDF) are preferred, we will be happy to send them to you by e-mail.

To reorder the instructions for use as a PDF, please specify the article number and the version number, which can be found on the title page and in the footer of the instructions for use respectively.

10.1 Information on disposal

Electrical and electronic devices that have reached the end of their service life comprise hazardous waste and may not be disposed of together with household waste. Prevailing national and local disposal regulations apply.

When disposing of the device, device parts and accessories, the requirements specified in the legislation must be followed. To ensure environmental protection, old devices can be returned to the dealer or manufacturer.

Motors that have reached the end of their service life must not be disposed of with household waste. Motors must be sterilized before disposal. The national and local regulations for disposal of electronic waste must be observed. If these are disposed of non-sterile, please observe the customary/local regulations for infectious waste.

Contaminated disposable tubing sets must be disposed of in a special way. Please observe the local regulations of the country for the disposal of infectious waste.

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Anhang DE
Appendix EN
Appendice FR
Appendice IT
Apéndice ES

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Electromagnetic compatibility (EMC)

Remark:
The **Product** subsequently referred to herein always denotes the TCM 3000 BL.

Changes or modifications to this product not expressly approved by the manufacturer may result in increased emissions or decreased immunity performance of the product and could cause EMC issues with this or other equipment. This product is designed and tested to comply with applicable regulations regarding EMC and shall be installed and put into service according to the EMC information stated as follows.

WARNING
Use of portable phones or other radio frequency (RF) emitting equipment, including accessories (antennas e.g.) in distances below 30 cm (12 inches) to the product, may cause unexpected or adverse operation.

WARNING
The product is suitable for use in hospitals other than in the vicinity of active devices of the HF surgical devices or except in HF screening rooms used for magnetic resonance imaging.

WARNING
The product shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the product shall be tested to verify normal operation in the configuration in which it is being used.

Essential Performance
The essential performance is that the drilling, milling and grinding of the bone and tissue, taking into account the speed is maintained. The maximum speed deviation is -20%, +5% at a range between 500 – 40'000 RPM.

Compliant Cables and Accessories

WARNING
The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the product.
The table below lists cables, transducers, and other applicable accessories for which the manufacturer claims EMC compliance.
NOTE: Any supplied accessories that do not affect EMC compliance are not listed.

Description	Length max.
Power supply cord REF 22261 / 22262 / 22264 / 22266	3.0m
Electronic motor REF 2112nou	2.9m
Foot pedal IPX8 REF 1507nou	2.9m

Guidance and manufacturer's declaration – electromagnetic emissions		
The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Product is suitable for use in buildings other than residential buildings and buildings that are immediately connected to the public power supply network that also supplies buildings used for residential purposes provided the following warning is observed: **Warning:** The Product is only intended for use by specialized medical staff. This product can cause radio interference which may make it necessary to take suitable remedial measures such as new alignment, new positioning or screening of the product or a filter in the connection to the installation site.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines	+/- 2 kV with 100kHz for power supply lines +/- 1 kV with 100kHz for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode	+/- 0.5 kV, +/- 1 kV differential mode +/- 0.5 kV, +/- 1 kV, +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage	0 % U_T; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree	0 % U_T; for 0,5 cycle with 0, 45, 90, 135, 180, 225, 270, 315 degree	Mains power quality should bet hat of a typical commercial or hospital environment.

variations on power supply input lines IEC 61000-4-11	0 % U_T; for 1 cycle 70 % U_T; for 25/30 cycles 0 % U_T; for 5 sec	0 % U_T; for 1 cycle 70 % U_T; for 25/30 cycles 0 % U_T; for 5 sec	If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity for not life support equipment

The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that it is used in such an environment.

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V rms 0.15 MHz to 80 MHz 6 V rms inside ISM bands between 150 kHz to 80 MHz 80% AM bei 1 kHz	3 V rms 0.15 MHz to 80 MHz 6 V rms inside ISM bands between 150 kHz to 80 MHz 80% AM bei 1 kHz	$d = 0{,}35\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM bei 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM bei 1 kHz	$d = 0{,}35\sqrt{P}$ 80 MHz to 800 MHz $d = 0{,}7\sqrt{P}$ 800 MHz to 2,7 GHz
			Where *P* is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Product is used exceeds the applicable RF compliance level above, the Product should b observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Product.

b over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic immunity against high-frequency wireless communication devices						
Test frequency MHz	**Frequency band** MHz	**Communication service**	**Modulation**	**Maximum Performance** W	**distance** m	**Test level** V/m
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0.3	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 8785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Recommended separation distances between
portable and mobile RF communications equipment and the not life support equipment

The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 0{,}35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0{,}7\sqrt{P}$
0,01	0,04	0,04	0,07
0,1	0,11	0,11	0,22
1	0,35	0,35	0,7
10	1,1	1,1	2,2
100	3,5	3,5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the higher frequency range applies.

Note 1: At 80 MHz and 800 MHz, the separation distance fort the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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EC REP

A complete list of Nouvag certified service centers are found on the Nouvag website at:
www.nouvag.com/service

Post market surveillance

In the event of problems with the product or in the event of a serious incident, please immediately download, compile and send the following form

https://nouvag.com/media/attachments/2022/05/19/for_8-308.pdf

as a PDF to this address: **complaint@nouvag.com**

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