

## Instructions for use

**iM3<sup>®</sup>**



**ultra LED**  
iM3 Code U8000

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# iM3 Symbols

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Symbols in the instructions for use



**WARNING!**  
(Risk of injury)



**ATTENTION!**  
(to prevent damage occurring)



General explanations,  
without risk to  
persons or objects



Thermo washer disinfectable



Sterilizable  
up to the stated temperature







Suitable for the ultrasonic bath





iM3 Service

# iM3 Symbols

## Symbols on the Ultra LED

	Follow instructions for use
	Consult instructions for use
	Date of manufacture
	Not suitable for intracardiac application – Type B applied part

	Do not dispose of with domestic waste
	Foot switch

<b>REF</b>	Catalogue number
<b>SN</b>	Serial number
<b>V</b>	Supply voltage of the unit
<b>AC</b>	Alternating current
<b>W</b>	Electric power consumption of the unit
<b>A</b>	Supply current
<b>Hz</b>	Frequency of the alternating current

# iM3 Symbols

## Symbols on the packaging



This way up



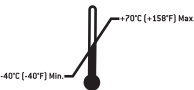
Fragile, handle with care



Keep away from rain



General symbol for recovery/recyclable



Temperature limit



Humidity limitation



CE from manufacturer



Caution: Federal law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the device

# 1. Introduction

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## **For your safety and the safety of your patients**

These instructions explain how to use your product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team and, of course, the safety of your patients, are of paramount importance to us.



It is therefore essential that you observe the safety notes on pages 12 – 16.

## **Intended use**

Drive unit with a piezo-ceramic oscillation system, which sets the scaler tip in linear vibration. The drive unit is used to remove supragingival plaque and subgingival concretions, as well as for endodontic applications and for preparing dental enamel.

Misuse can damage the Ultra LED and hence cause risks and hazards for patients, users and third parties.

## **Qualified use**

Ultra LED is only intended for qualified use in veterinary dental medicine according to the applicable health and safety regulations, accident prevention measures and in observance of these instructions for use. Ultra LED must only be prepared and maintained by persons who have been instructed in infection protection, personal protection and patient safety. Improper use (e.g. due to lack of hygiene or maintenance), non-compliance with our instructions or the use of accessories and spare parts not approved by iM3 invalidates all claims under warranty and any other claims.


# Introduction

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## Qualifications of the user

Ultra LED has been developed and designed for the target group veterinary use.

## Production according to EU Directive

 EU Directive 93/42/EEC has been used as a basis in the design and manufacture of this medical product and this applies to

- > Ultra LED (control unit with supply hose, foot control, handpiece)

in the condition as supplied by us. This declaration does not apply to non-specified fittings, mountings etc.



## Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of Ultra LED when there is compliance with the following directions:

- > Ultra LED must be used in accordance with these instructions for use.
- > Ultra LED has no components which can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized iM3 service partner (see page 39).
- > The electrical installation at the premises must comply with the regulations of IEC 60364-7-710 («Installation of electrical equipment in rooms used for medical purposes») or with the regulations applicable in your country.
- > Unauthorized opening of the equipment invalidates all claims under warranty and any other claims.



## 2. Electromagnetic compatibility (EMC)

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### **Notes on electromagnetic compatibility (EMC)**

Medical electrical equipment is subject to particular precautions with regards to EMC and must be installed and put into operation in accordance with the EMC notes included.

iM3 guarantees the compliance of the device with the EMC requirements only when used with original iM3 accessories and spare parts. The use of other accessories/other spare parts can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.



You can obtain the EMC declaration directly from the manufacturer.

### **HF communication equipment**

Do not use any portable and mobile HF communication equipment (e.g. mobile telephones) during operation. These may affect medical electrical equipment.



### 3. Equipment supplied

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#### Ultra LED / U8000

U8000	Control unit (100 - 230 V), including 1,8 m supply hose with coupling
U8005	Handpiece LED
U801U	Tip changer with insert universal tip
U801P	Tip changer with insert perio tip
U8007	Foot control
U8008	Switch-mode power supply

#### Accessories

U802U	Tip changer with insert universal tip
U803U	Tip changer with insert universal tip

## 4. Safety notes

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**Please observe the following instructions under all circumstances**

- > Before using Ultra LED for the first time, store it at room temperature for 24 hours.
- > Ultra LED is not suitable for surgical treatment.
- > Ultra LED is not designed to administer drugs or similar substances.
- > Ultra LED approved for use only with supply units with category 5 backflow prevention devices as defined in EN 1717.
- > Always ensure correct operating conditions and that sufficient and adequate cooling is delivered.
- > Always provide sufficient coolant and ensure the appropriate suction.
- > Turn off the handpiece immediately in the event of failure in the coolant supply (max. operating time without coolant is 30 seconds).
- > Provide sufficient space for unrestricted operation of the foot control.
- > Sterilize the handpiece, the tips and the accessories before using for the first time.
- > Perform a test run prior to each treatment.
- > Check Ultra LED, the handpiece and the supply hose for damage and loose parts (e.g. tip, LED, O-ring) every time before using. Correct any faults or contact an authorized iM3 service partner (see page 39). Do not operate Ultra LED if it is damaged.
- > Check the parameter settings every time the device is restarted.
- > Never touch the patient and the connections for the foot control or coolant hose simultaneously.
- > Rinse the supply hose through once a day (see page 20).
- > Do not connect the control unit to the hot water supply. (>30 °C).

## Safety notes

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- > Disconnect the control unit from the water supply connection after each use (the control unit does not have an automatic aquastop).
- > Switch Ultra LED off after every application.
- > Replace faulty or leaky O-rings in the hose coupling immediately.
- > Only replace the LED socket when the handpiece is at rest.
- > Avoid eye contact with the optic outlet.

### **Applied parts (parts that come into contact with the patient)**

- > Handpiece, tips, supply hose

### **Tips**

- > Only use tips approved by iM3 and the associated tip changer or spanner.
- > An overview for the correct power setting is included with each tip.
- > Ensure that the original shape of the tip is not changed (e.g. by dropping).
- > Tips must not be bent back to shape or reground.
- > Only insert the tip when the handpiece is at rest.
- > Never touch the tip when vibrating.
- > Place the tip changer onto the inserted tip of the handpiece at rest after each treatment (protection against injuries and infections, tip protection).
- > Use the tip card supplied to check the wear to the tips.

# Safety notes

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## **Inappropriate use**

Improper use, in addition to incorrect assembly, installation, modification or repairs of Ultra LED or failure to comply with our instructions invalidates all claims under warranty and any other claims!



The control unit is designed for use with the iM3 handpiece which means that only these devices must be used with the control unit. The use of other handpieces may cause incorrect functioning or destruction of the electronics.



Only use the switch-mode power supply and mains cable supplied.  
Only connect to a grounded socket outlet.



In dangerous situations, the device can be disconnected from the power supply using the power cable.

## **Control unit**

The control unit is classed as »conventional equipment« (closed equipment without protection against the ingress of water).

## **System failure**

A total system failure of the Ultra LED does not constitute a critical fault.

Simply switch the unit off and then on again.

# Safety notes

## Intermittent operating mode S6 (5 min operating time / 2 min pause time)

The permissible relative load time is 5 minutes to 2 minutes pause time.

If the operating mode specified is observed no overheating of the system and therefore no injury to the patient, user or third persons arises. The responsibility for the use and timely shutdown of the system lies with the user.



### Danger zones M and G

In accordance with IEC 60601-1/ANSI/AAMI ES 60601-1, Ultra LED is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.



Ultra LED is not suitable for use in oxygen-enriched atmospheres.



**Zone M** is defined as a »medical environment« and constitutes the part of a room in which potentially explosive atmospheres may form due to the use of anaesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary. Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.



**Zone G**, also known as an »enclosed medical gas system«, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.

## Safety notes

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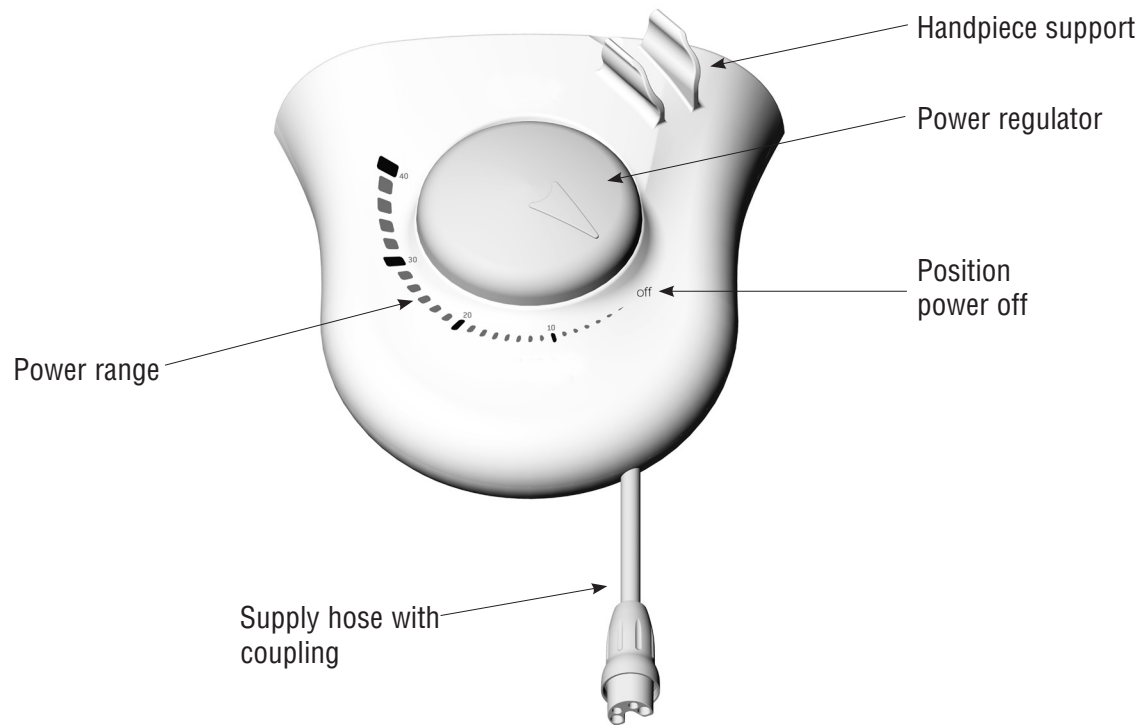


### **Risks due to electromagnetic fields**

The functionality of implantable systems, such as cardiac pacemakers and ICDs (implantable cardioverter defibrillators) can be affected by electric, magnetic and electromagnetic fields.

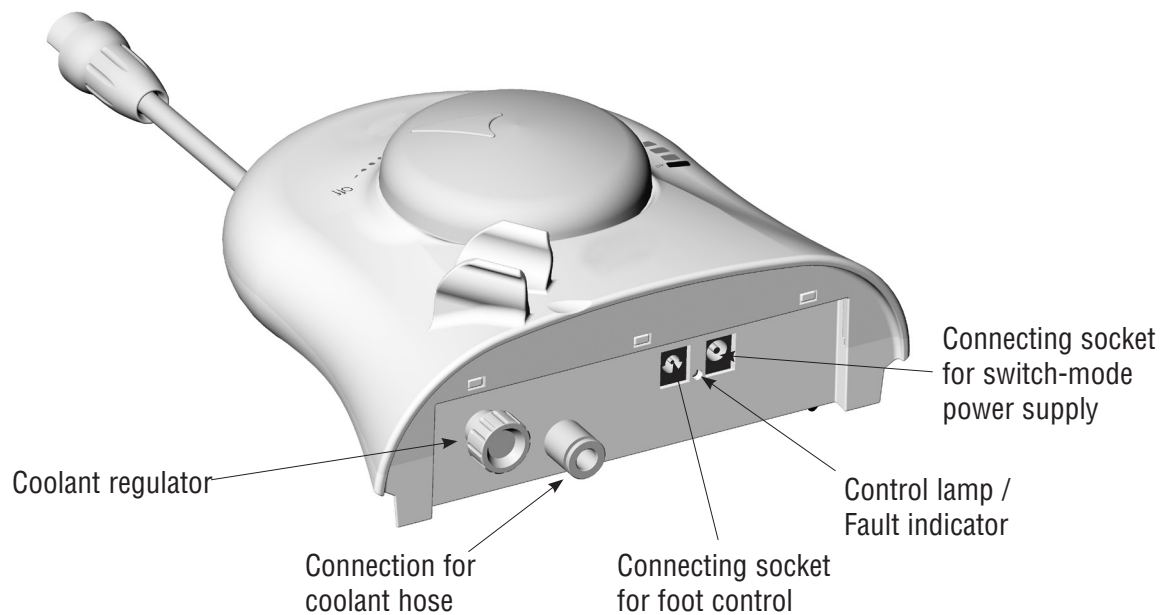
- > Ultra LED must not be used on patients with cardiac pacemakers or ICDs (implantable cardioverter defibrillators).
- > Ultra LED must not be used by persons who are themselves patients with cardiac pacemakers or ICDs (implantable cardioverter defibrillators).
- > Before using the product, check that it can be used by asking patients if they have have an implanted device.
- > Keep the product away from implanted devices.

## 5. Description of front panel control unit



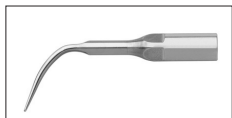


## 6. Description of rear panel control unit



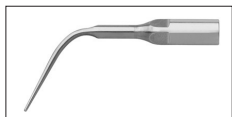
## 7. Description tips

Area of application for the approved iM3 tips.

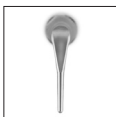
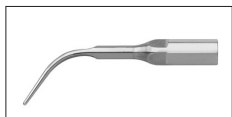


### Universal tips

**U801U:** For coarse depuration of supragingival calculus.



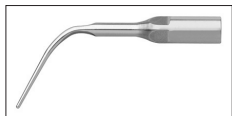
**U802U:** For fine depuration of supragingival calculus.



**U803U:** For polishing to remove supragingival calculus, particularly suitable for interdental cleaning.



With the U801P, the handpiece is suitable for the removal of concretions in the subgingival region, but not for applications which demand sterile conditions.



### Perio tip

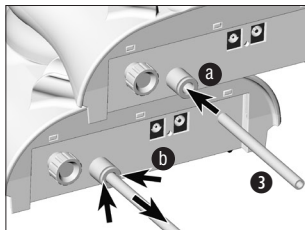
**U801P:** Removal of subgingival deposits, particularly suitable for deep periodontal pockets.

## 8. Starting operation – General



Always place Ultra LED on a flat level surface.

Make sure that it is easy to disconnect Ultra LED from the power supply.

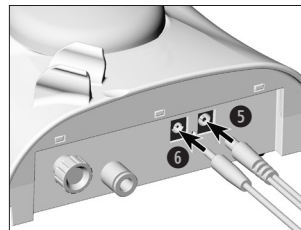


### 4 insert:

a Insert coolant hose until back stop.

### remove:

b Push connection ring to the rear and remove coolant hose.

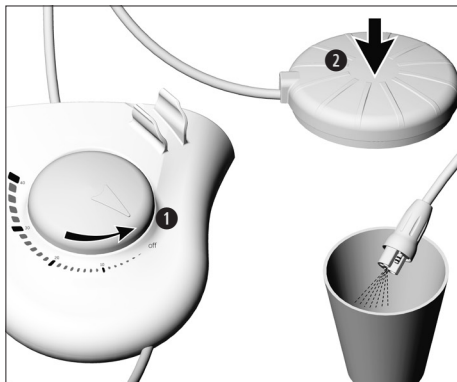


5 Connect switch-mode power supply.

Control lamp illuminates!

6 Connect foot control.

## 9. Rinsing the supply hose thoroughly / Starting operation handpiece

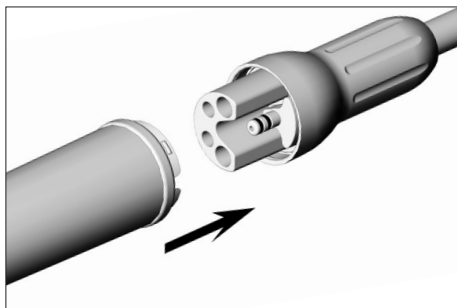


Ensure that the handpiece is not inserted!

- ❶ Turn the power regulator to the »off« position.
- ❷ Press the foot control 3 times within 3 seconds.

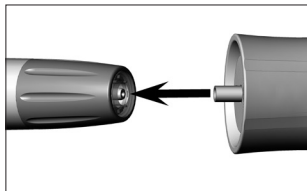


The rinse function is audible by means of a click and visible for 30 seconds through the coolant!

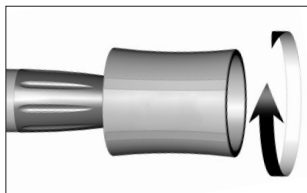


- ❶ Push the handpiece onto the supply hose.
- Hand pointing icon: Note the positioning of the connections!

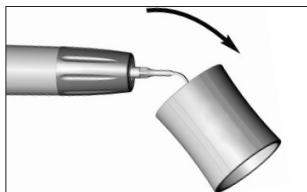
## 10. Insert/remove tip



- ❶ Position the tip on the thread of the handpiece.



- ❷ Turn the tip changer until it audibly engages.



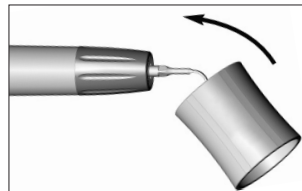
- ❸ Carefully withdraw the tip changer.



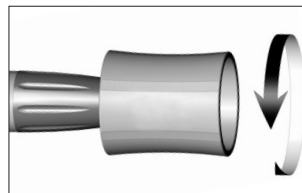
Check secure location of the tip by applying slight axial tension.



Press the tip with about 1 N (= 100 g) pressure onto a firm sterile object to test the loading capacity of the tip.



- ❶ Place the tip changer onto the tip.

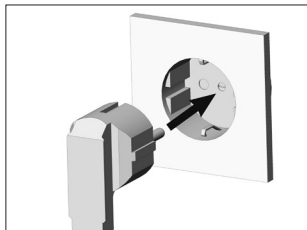


- ❷ Unscrew the tip with the tip changer.



Leave the tip in the tip changer until the hygiene and maintenance process!

## 11. Switching Ultra LED on / off



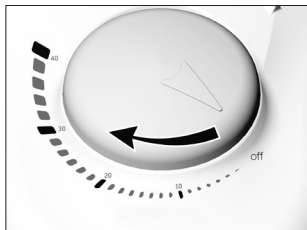
### Switching Ultra LED on

- 1 Connect Ultra LED to the mains socket.

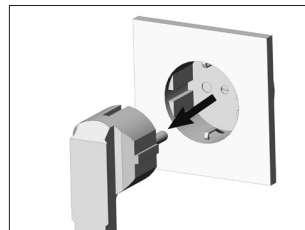


### Switching Ultra LED off

- 1 Turn Ultra LED off at the power regulator.



- 2 Turn Ultra LED on at the power regulator.



- 2 Unplug Ultra LED from the mains socket.

## 12. Test run

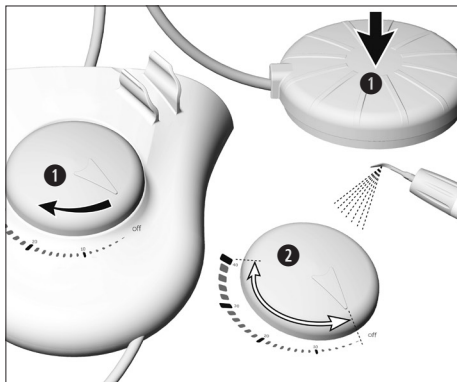
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Do not hold the handpiece at eye level.

- > Attach the handpiece to the supply hose.
- > Insert the tip.
- > Start the Ultra LED (flush the handpiece for approx. 30 sec. if it has not been run for a longer period of time).
- > In the event of malfunctions (e.g. vibrations, unusual noises, overheating, coolant failure or leakage), or change of LED colour, **stop the Ultra LED immediately** and contact an authorized iM3 service partner (see page 39).

## 13. Starting operation Ultra LED



❶ Turn the power regulator to the necessary operating range and then press the foot control.

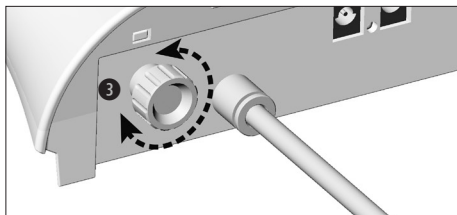
☞ Operation is audible by means of a click, visible by means of coolant and LED! When the foot control is no longer active, the LED will remain lit for a further 30 seconds!

☞ If the LED fails, change the LED socket (see page 28).

❷ Turn the power regulator in order to adjust the power.



After every use, turn the power regulator to the »off« position!  
(Risk of injury)



❸ Turn the coolant regulator in order to adjust the coolant supply volume.



## 14. Fault repair

Flashing cycle	Error messages	Solution
1-1	No clear point of response found	Test tips (breakage/wear/tightening torque)
1-1-1	Handpiece not recognised when starting Ultra LED	Test handpiece connection to supply hose
1-1-1-1	Rinse supply hose thoroughly – handpiece recognised when starting Ultra LED	Remove handpiece
1-1-1-1-1	> Foot control continuously active for longer than 15 mins > Switch-mode power supply plugged-in during foot control operation (supply voltage restored) > Foot control operation before adjustment of power supply	Deactivate foot control / restart
1-1-1-1-1-1	Electronics temperature error	Allow to cool / restart
1-1-1-1-1-1-1	Overload at handpiece outlet	Service technician
Intermittent	Various system errors	Service technician



If the error messages described cannot be resolved by switching off and restarting Ultra LED, it is necessary for an authorized iM3 service partner to check (see page 39). A possible total failure of the device caused by external influences requires switching off and restarting.

## 15. Hygiene and maintenance

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Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilization.



- > Wear protective clothing.
- > Remove the tip from the handpiece.
- > Remove the handpiece from the supply hose.
- > Clean and disinfect the handpiece immediately after each treatment, to rinse out any liquid (e.g. blood, saliva etc.) that may have entered and to prevent the inside parts from seizing.
- > Sterilize the handpiece, the tips and accessories following manual or mechanical cleaning and disinfection.



- > The control unit is not approved for mechanical cleaning (thermodisinfectant) and sterilization.
- > Do not immerse the control unit or clean it under running water.

# Hygiene and maintenance

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## Control unit with supply hose, foot control

### Pre-disinfection

> If heavily soiled, clean first with disinfectant cloths.



Only use disinfectants that have no protein-fixing effects.

### Manual cleaning and disinfection



The front of the control unit and the foot control are sealed and may be wiped clean.  
iM3 recommends wiping disinfection.

- > Use only disinfectants which do not contain chlorine and which are certified by officially recognised institutes.
- > Note the manufacturer's specifications for the use of the disinfectants.



### Before resuming operation

Wait until the supply hose is completely dry.

Moisture in the supply hose can lead to a malfunction! (Risk of short circuit)

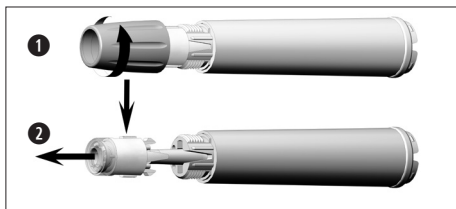
# Hygiene and maintenance

## Handpiece, tips and accessories

### Pre-disinfection

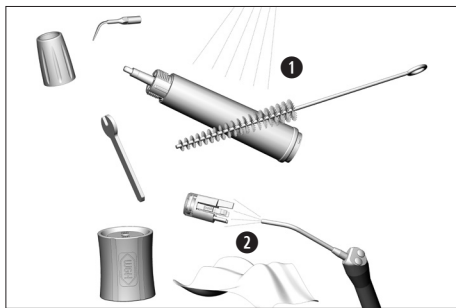
> If heavily soiled, clean first with disinfectant cloths.

 Only use disinfectants that have no protein-fixing effects.



### Disassemble handpiece with LED

- ① Unscrew the handpiece cap.
- ② Simultaneously push the marking (push) located opposite and unplug the LED socket.



### Manual cleaning inside and outside

- ① Rinse and brush off under demineralized water (< 38 °C)
- ② Remove any liquid residues (absorbent cloth, blow dry with compressed air).

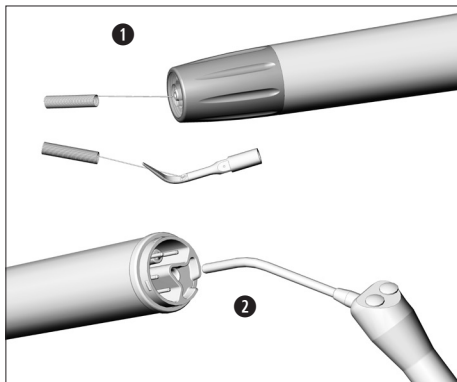


Do not place the handpiece and the tip changer in disinfectant solution or in an ultrasonic bath.



You can clean and disinfect the tips in a bur bath or ultrasonic bath.

# Hygiene and maintenance



## Cleaning the spray nozzles

❶ Use the nozzle cleaner to remove dirt and deposits from the outlets.



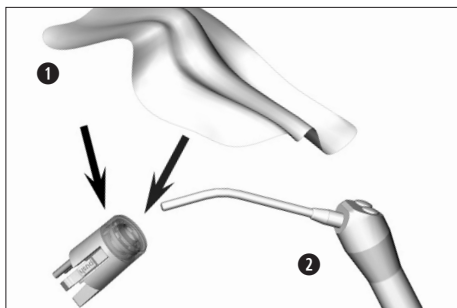
Clean and disinfect the nozzle cleaner in the ultrasonic bath / drill bath.

## Cleaning the coolant channel

❷ Blow through the coolant channel with the air gun.



If the exit openings or coolant channels are blocked, contact an authorized iM3 service partner (see page 39).



## Cleaning of the optic outlet



**Avoid scratching of the optic outlet!**

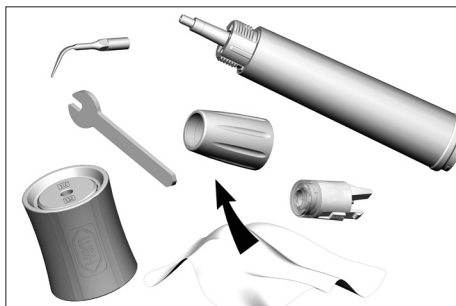
❶ Wash the optic outlet with cleaning fluid and a soft cloth.

❷ Dry the optic outlet with the air syringe or carefully with a soft cloth.



Carry out a visual inspection after cleaning each time. Do not put the handpiece into operation if the optic outlet is damaged and contact an authorized iM3 service partner (see page 39).

# Hygiene and maintenance



## Manual disinfection

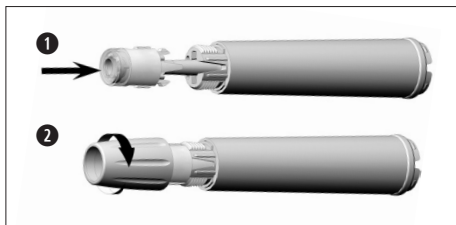


iM3 recommends wiping disinfection.

- > Use only disinfectants which do not contain chlorine and which are certified by officially recognised institutes.
- > Note the manufacturer's specifications for the use of the disinfectants.



After manual cleaning and disinfection, you must carry out a final sterilization (wrapped) in a class B or S steam sterilizer (as per EN 13060).



## Reassemble handpiece



**Always operate the handpiece with the handpiece cap fitted!**

### with LED

- ❶ Fit LED socket onto handpiece.



Note the positioning of the connections!

- ❷ Screw on the handpiece cap.

# Hygiene and maintenance

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## Handpiece, Tips and Accessories Sterilization and storage



iM3 recommends sterilization according to EN 13060, class B

- > Note the instructions of the unit manufacturer.
- > Clean and disinfect before sterilizing.
- > Only sterilize the tip in the tip changer.
- > Wrap the handpiece and the accessory in sterile goods packing according to EN 868-5.
- > Make sure that you only remove dry sterile goods.
- > Store sterile goods dust-free and dry.

# Hygiene and maintenance

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## Approved sterilization procedures



Follow your country-specific directives, standards and guidelines.

- > Steam sterilization class B with sterilizers in accordance with EN 13060.  
Sterilization holding time a minimum of 3 minutes at 134 °C.

or

- > Steam sterilization class S with sterilizers including drying program in accordance with EN 13060.  
The sterilizer manufacturer must give their express approval for the sterilization of handpieces.  
Sterilization holding time a minimum of 3 minutes at 134 °C.



### **Before resuming operation**

Wait until the handpiece is completely dry.

Moisture in the handpiece can lead to a malfunction! (Risk of short circuit)

Wait until the tip, the tip changer and the spanner have completely cooled down. (Risk of burns)



## 19. Servicing

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### **Regular checking of Ultra LED**

Regular servicing of function and safety including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The inspection must be undertaken by a qualified organisation and needs to include the following procedures:

- > visual inspection for outside damage
- > measurement of device leakage current
- > measurement of earth leakage current
- > measurement of enclosure leakage current
- > internal visual inspection on suspicion of safety interference,  
e. g. mechanical damage of the enclosure or indicators of overheating

We recommend that these tests only be undertaken by an authorized iM3 service partner (see page 39).

# Servicing

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## Handpiece

The standard ISO 22374 stipulates a durability of at least 250 sterilization cycles. In the case of the handpiece from iM3, we recommend you to have a regular service carried out after 500 sterilization cycles or one year.

## Repair

If a defect occurs, always return all the equipment, due to the fact that with handpiece malfunctions, an inspection of the electronic controls is also necessary!

## Returns

- > Refer all questions to an authorized iM3 service partner (see page 39).
- > Always return equipment in the original packaging!

## Technical data

### Ultra LED

#### Control unit

Voltage:	24-27 V <sub>===</sub>
Rated current:	max 1,200mA
Permitted voltage fluctuation:	±10%
Max. power output to the handpiece with load (ultrasonic):	10W
Frequency (ultrasonic):	27-32KHz
Fuse:	LF T 1.5A SMD in the unit
Operating mode:	S6 (5min/2min)
Max. oscillating amplitude (Tip 1U):	0.2 mm
Max. water pressure:	6 bar
Max. coolant supply volume:	*ca. 50ml/min
Dimensions in mm (WxDxH):	164 x 170 x 77
Weight:	460 g

\*adjustable

#### Switch-mode power supply

Input:	100-240 V 47-63Hz 0.9-0.34 A
Output:	24-27 V <sub>===</sub> 1.25-1.11 A

# Technical data

## Physical characteristics

Temperature during storage and transport:	-40 °C to +70 °C (-40 °F to +158 °F)
Air humidity during storage and transport:	8 % to 80 % (relative), non-condensing
Temperature in operation:	+10 °C to +35 °C (+50 °F to +95 °F)
Air humidity in operation:	15 % to 80 % (relative), non-condensing

Pollution level:	2
Overvoltage category:	II
Altitude:	up to 3,000 m above sea level

## Temperature information

Temperature of the handpiece at the operator side:	max. 55 °C (131 °F)
Temperature of the handpiece at the patient side (front area of the handpiece):	max. 48 °C (118.4 °F)
Temperature of the handpiece at the patient side (LED ring):	max. 48 °C (118.4 °F)
Temperature of the working part (tip):	max. 41 °C (105.8 °F)

**Classification according to Paragraph 5 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1/UL 60601-1**



Type B applied part (not suitable for intracardiac application)



U8007 foot control is protected against drops of water falling vertically (IPX1 as per IEC 60529)

# 21. Recycling and Disposal

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## Recycling

iM3 considers that it has a special duty towards the environment. Ultra LED along with its packaging has been designed to be as environmentally friendly as possible.



### **Disposal of Ultra LED (control unit, foot control, handpiece and accessories)**

Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.



Ensure that the parts are not contaminated on disposal.

## **Disposal of the packaging material**

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. This way, you will contribute to the recycling of raw materials and the avoidance of waste.

# Explanation of warranty terms

This iM3 product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the instructions for use have been followed.

**As the manufacturer, iM3 is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase.**

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by iM3.

Claims under warranty – accompanied by proof of purchase – must be sent to the supplier or to an authorized iM3 service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

# 24 months warranty

## Authorized Service Partners

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### iM3 Inc

12414 NE 95th St, Vancouver, WA 98682 USA

Ph: +1 800 664 6348 Fax: +1 360 254 2940 Email: [info@im3usa.com](mailto:info@im3usa.com)

### iM3 Pty Ltd

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Ph: +61 (0)2 9420 5766 Fax: +61 (0)2 9420 5766 Email: [sales@im3vet.com](mailto:sales@im3vet.com)

### iM3 Dental Limited

Unit 9, Block 4, City North Business Park, Stamullen, Co. Meath, Ireland

Ph: +353 (0)16911277 UK Direct: +44 (0)1423 224297 Email: [support@im3dental.com](mailto:support@im3dental.com)

iM3 Authorised Distributors - see [www.im3vet.com](http://www.im3vet.com)

Manufactured for:

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