

Maxima™ by  HENRY SCHEIN®

ELITE 2

Ⓝ Electric Attachment

Ⓞ Accesorio Eléctrico

Ⓡ Accessoire Électrique





INSTRUCTIONS FOR USE




Read before use. Keep in a safe place for future reference.






WARNING: Federal (US) law restricts this device to sale by or on the order of a licensed professional.

Safety instructions are intended to avoid potential hazards that could result in personal injury or damage to the device. Safety instructions are classified as follows in accordance with the seriousness of the risk.

Class	Degree of Risk
	Hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed
	Hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.

Symbols	
	Serial Number
	Date Of Manufacture
	Reference Number

	Thermo Washer Disinfectable
	Sterilizable up to the stated temperature
	Instructions for Use

INDICATION FOR USE

This dental contra-angle handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing and polishing of tooth and restoration surfaces.

Skilled application

The medical device is intended only for skilled application according to the intended use as well as in compliance with the valid health and safety at work regulations, the valid accident prevention regulations and in compliance with these instructions for use.

The medical device should be prepared for use and maintained by staff who have been trained in procedures for infection control, personal safety and patient safety.

Improper use, (e.g., Through poor hygiene and maintenance), non-compliance with our instructions or the use of accessories and spare parts which are not approved by Henry Schein, invalidates all claims under warranty and any other claims.



- Before each use, check for vibration, noise, and overheating. If any abnormalities are observed, stop using immediately and contact Henry Schein ProRepair.
- Do not drop, hit or subject to excessive shock.
- Sterilization is required before first use.

- Do not wipe or immerse in acidic solutions. The user is responsible for correct operation, maintenance, and inspection.
- Do not disassemble or alter the motor, attachments or heads.
- Never operate handpiece without a rotary instrument.
- Observe the safety notes.
- Misuse may damage the medical device and hence cause risks and hazards for patient, user and third parties.
- Store sterile goods dust-free and dry.
- The shelf life of the sterile goods depends on the storage conditions and type of packaging.
- Run the rinse function for the dental unit once per day.

- The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- Before using the medical device for the first time, store it at room temperature for 24 hours.
- Always ensure the correct operating conditions and cooling function.
- Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction.
- In case of coolant supply failure, the medical device must be stopped immediately.
- Use only filtered, oil-free and cooled air supplied by dental compressors to operate the medical device.
- Check the medical device for damage and loose parts each time before using (e.g., push-button).
- Do not operate the medical device if it is damaged.
- Perform a test run each time before using.

- Avoid overheating at the treatment site.
- Do not touch the soft tissue with the head of the medical device. Risk of burning if the medical device overheats!

SPECIFICATIONS

Maxima ELITE 2	570-2660	570-2661	570-2662	570-2663
Transmission ratio	1:5	1:5	1:1	1:1
Contra Angle Type	Regular	Short	Regular	Short
Color coding	orange	orange	blue	blue
Motor coupling acc. to	ISO 3964	ISO 3964	ISO 3964	ISO 3964
Instrument shaft diameter ISO 1797 (mm)	1.6	1.6	2.35	2.35
Length in mm approved by Henry Schein (mm)	25	25	34	34

Min. chucking length		until back stop	until back stop	engaging	engaging
Max. operating part diameter	(mm)	2.5	2.5	–	–
Max. motor speed	(min-1)	40,000	40,000	40,000	40,000
Spray flow rate	ISO 14457 (ml/min)	> 50	> 50	> 50	> 50
Water setting range (rec. water pressure) **	(bar)	0.5 – 2 (1.5)	0.5 – 2 (1.5)	0.5 – 2 (1.5)	0.5 – 2 (1.5)
Chip air setting range (rec. chip air pressure) **	(bar)	1.5 – 3 (2)	1.5 – 3 (2)	1.5 – 3 (2)	1.5 – 3 (2)
Chip air consumption at 2 bar	[NI/min]	> 1.5	> 1.5	> 1.5	> 1.5

** The chip air / water pressure must be set at the same time

The chip air must be higher than the water pressure-min-1 (Revolutions per minute)

 **Warning**

- When using longer rotary instruments, the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties. See table - “Length in mm approved by Henry Schein” on Page 7



Warning

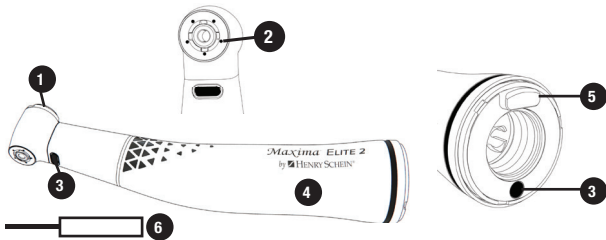
Ambient conditions:

- Temperature during storage and transport: -40°C to $+70^{\circ}\text{C}$ (-40°F to $+158^{\circ}\text{F}$)
- Humidity during storage and transport: 8% to 80% (relative), non-condensing
- Temperature during operation: $+10^{\circ}\text{C}$ to $+35^{\circ}\text{C}$ ($+50^{\circ}\text{F}$ to $+95^{\circ}\text{F}$)
- Humidity during operation: 15% to 80% (relative), non-condensing

Temperature information:

- Temperature of the medical device on the operator side: maximum 55°C (131°F)
- Temperature of the medical device on the patient side: maximum 50°C (122°F)
- Temperature of the working part (rotary instrument): maximum 41°C (105.8°F)

1. Push-button
2. Spray nozzle
3. Compact glass rod
4. Grip profile
5. Retractable lug
6. Nozzle cleaner



Connecting / Disconnecting Attachments (Fig. 1)

Warning

- This attachment can only be operated on dental motors with an ISO coupling measuring no longer than 23 mm.
- Make sure the attachment sits flush on motor. If not, repeat connecting process.
- Do not operate the attachment at eye level.
- Use only rotary instruments which are in perfect condition. Follow the operating instructions of the manufacturer.
- Insert the rotary instrument only when the medical device is stationary.
- Never touch the rotary instrument while it is still rotating.
- Do not lift the cheek or tongue with the contra-angle head. The push-button may heat up during operation.

Attention

- Do not assemble or remove the medical device during operation!



Fig. 1

Connecting



- Verify full engagement

1. Slide the attachment over the nose portion of the motor and rotate until it clicks.
2. Verify attachment is secure.

Disconnecting

1. Pull attachment away from motor to separate.

Inserting and Removing Rotary instrument (Fig. 2)



- Insert the rotary instrument only when the medical device is stationary.
- Do not activate the chucking system of the medical device during operation. This leads to detachment of the rotary instrument, damage to the chucking system and/or heating up of the medical device. Risk of burning!

Inserting rotary instrument



Warning

- Verify full engagement.

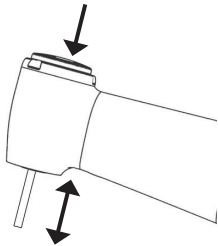
1. Press push-button and insert rotary instrument into head until it stops.
2. Release pressure on button; rotary instrument should now be secure.
3. Firmly tug on rotary instrument to ensure that it is properly secured.

Removing rotary instrument

1. Press push-button on end cap with thumb.
2. Pull to remove rotary instrument.

CLEANING AND LUBRICATION

Cleaning agents and disinfectants



 **Warning**

- Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
- Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
- It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
- Use disinfectants which have been tested and found effective by the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).

Initial treatment at the point of use

 **Warning**

- Clean the medical device immediately after every treatment, to flush out any liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.
1. Operate the medical device for at least 10 seconds at idle speed.
 2. Ensure that all coolant outlets are rinsed out.
 3. Wipe the entire surface of the medical device with disinfectant.
 4. Remove the rotary instrument.
 5. Remove the medical device.

Handpiece Maintenance (Fig. 3)

Note: Cleaning and lubrication is required before each sterilization cycle.



 **Warning**

- Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.

 **Attention**

- Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
- Remove any liquid residues using compressed air.
- Sterilize the medical device following cleaning, disinfection and lubrication.

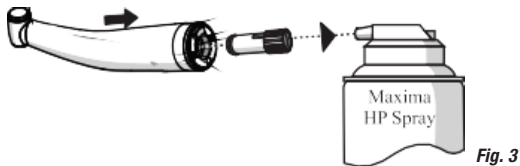


Fig. 3

! Attention

- Lubricate the dry medical device immediately after cleaning and disinfection
1. Remove rotary instrument.
 2. Detach handpiece from motor.
 3. Fit E-type spray adapter onto universal cap nozzle of Henry Schein® Maxima HP Spray (112-6928)
 4. Insert spray adapter completely into back of handpiece and hold it in place (Fig. 3).

5. Dispense spray for 1-2 seconds, then re-attach hp to motor while holding upside down, run handpiece to purge cleaner/lubricant.
6. Repeat steps 4 and 5 until cleaner/lubricant expelled from head is clear.
7. Wipe excess cleaner/lubricant from handpiece with dry, lint-free cloth.

Chuck Maintenance (Fig. 4)

Note: It is recommended that the push-button chuck be cleaned once every week.

1. Remove rotary instrument.
2. Detach handpiece from motor .
3. Fit chuck adapter onto universal cap nozzle of Henry Schein® Maxima HP Spray.
4. Insert spray adapter into chuck and dispense spray for 1 - 2 seconds (Fig. 4).
5. Work chuck mechanism to distribute cleaner/lubricant by repeatedly pressing button.
6. With push button depressed, insert and remove rotary instrument several times to break-up remaining debris.

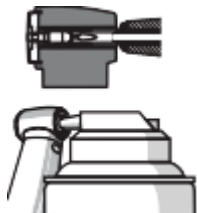


Fig. 4

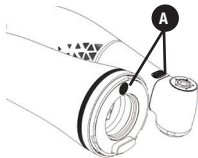
Cleaning Light Guide (Fig. 5)



- Carry out a visual inspection after each cleaning process.
- Do not use the medical device if the optic outlet is damaged and contact Henry Schein ProRepair.

⚠ Attention Avoid scratching the optic outlet!

1. Clear light guide surfaces (A) of particulates by spraying with air syringe.
2. Wash the optic outlet with cleaning fluid and a soft cloth.
3. Blow the optic outlet dry using compressed air or dry it carefully with a soft cloth.



Cleaning and Lubrication with Maxima XTEND Handpiece Maintenance Machine Handpiece maintenance

Note: Cleaning and lubrication is required before each sterilization cycle.

1. Remove rotary instrument.
2. Detach handpiece from motor.
3. Attach handpiece to appropriate connector in Henry Schein® Maxima XTEND® Maintenance Machine (570-0072).
4. Run maintenance cycle. See Maxima XTEND instructions for further information.
5. Remove handpiece from Maxima XTEND Maintenance Machine after cycle completes.
6. Wipe excess cleaner/lubricant from handpiece with dry, lint-free cloth.

Chuck maintenance

Note: It is recommended that the push-button chuck be cleaned once every week.

1. Remove rotary instrument.
2. Place chuck opening against tapered end of chuck cleaning nozzle.
3. Press start. Keep handpiece in place until beep sounds indicating that cleaning cycle is completed. See Maxima XTEND instructions for additional information.

Test after lubrication

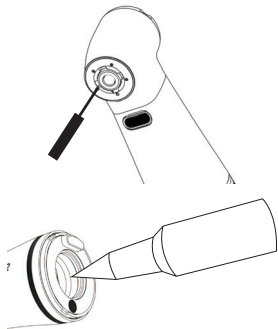
1. Direct the medical device downwards.
2. Take the medical device into operation so that excess oil can escape.
3. Excess oil may result in the medical device overheating.

Clean spray nozzles

1. Clean coolant outlets carefully with the nozzle cleaner to remove dirt and deposits.
2. The nozzle cleaner can be cleaned in an ultrasonic bath and/or in the washer-disinfector.

Cleaning the coolant tube

1. Blow through the coolant tube using compressed air.
2. In the case of blocked coolant outlets or coolant tubes contact Henry Schein ProRepair.



STERILIZATION



- Sterilization is required before first use.
- Sterilize by steam autoclave after each patient use.
- Do not place the medical device in liquid disinfectant or in an ultrasonic bath.
- Do not autoclave at temperatures that exceed 275° F (135° C).
- Do not autoclave together with other instruments.
- Do not use dry heat sterilization.
- Wear appropriate personal protective equipment during sterilization and maintenance process. Wear protective clothing, safety glasses, face mask and gloves.

- Keep in sterilization pouch until ready to use.
- Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
- Reprocess any medical devices that are still soiled.
- Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
- The program selected must be suitable for the medical device.



- Pack the medical device and the accessories in sterilization packages that meet the following requirements:

- The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization method.
- The sterilization package must be large enough for the sterilization goods.
- The filled sterilization package must not be under tension.

Recommended sterilization procedures

- Fractionated pre-vacuum process (type B)
- Gravity displacement process (type N)
- Sterilization time at least 30 minutes at 121°C (250°F) or at least 3 minutes at 134°C (273°F)
- Maximum sterilization temperature 135°C (275°F)

* according to EN 13060, EN 285, ISO 17665 / ** according to ANSI/AAMI ST55 , ANSI/AAMI ST79

1. Wipe handpiece with damp cloth.

2. Place handpiece in sterilization pouch and seal. Bag handpieces individually.
3. Steam autoclave for a minimum of 3 minutes at 273° F (134° C). Let autoclave cycle completely. Do not remove before handpiece is completely cool and pouch is dry.

REPLACEMENT PARTS & ACCESSORIES



- Ensure that the parts are not contaminated on disposal.



Use only original Henry Schein accessories and spare parts or accessories approved by Henry Schein.

570-0072 Maxima XTend Handpiece Maintenance Machine

570-1174 Maxima XTend AX Handpiece Maintenance Machine

570-0086 Maxima XTend E-Type Adapter
112-6928 Henry Schein® Maxima HP Spray
112-6934 E-Type Nozzle Adapter

SERVICE



Ensure that the medical device has been completely processed before returning it.



- We recommend a regular service for the medical device after 1,000 processing cycles or one year.
- The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

- Send worn or damaged medical devices and/or medical devices with material changes to Henry Schein ProRepair.

For items that require service, including warranty service, please send to Henry Schein ProRepair.

Henry Schein ProRepair

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WARRANTY

These products are designed for use in a dental office and this warranty is not applicable to other uses.

The products are warranted against manufacturing defects in materials and workmanship for 3 year

from date of purchase.

Henry Schein® will repair or replace products at its sole discretion. This warranty shall be limited to replacement or repair of the products or their parts and shall not extend to any other claims, including but not limited to loss of profit, cost of removal or replacement, incidental or consequential damages or other similar claims arising from use of this product.

Damage to products resulting from acts of God, faulty installation, misuse, tampering, accident, abuse, negligence, alterations, unauthorized repairs or problems unrelated to materials and workmanship are not covered by this warranty.

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