A-dec 501

Electric Motor



INSTRUCTIONS FOR USE

Please read these Instructions For Use carefully before use, and file for future reference.

Rx Only MADE IN JAPAN

OM-DE1001EN 000

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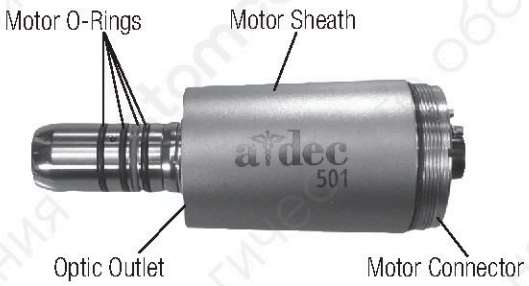
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Content Map







A-dec 500 Deluxe Plus Touchpad



A-dec 300 Deluxe Touchpad

(For touchpad functions, see the Instructions for Use that came with your delivery system.)

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3 Abbreviations Used in This Document

ANSI/AAMI	American National Standards Institute / Association for the Advancement of Medical Instrumentation
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
USFDA	United States Food and Drug Administration

4 Responsibility of the Manufacturer and End User

CAUTION

The manufacturer can only accept responsibility for the safety, reliability, and performance of the motor and the motor tubing when it is used in compliance with the following directions:

- The motor and the motor tubing must be used in accordance with these Instructions for Use.
- The motor and the motor tubing cannot be repaired by the end user. Assembly, modifications, or repairs must only be undertaken by A-dec or an authorized A-dec dealer.
- The motor is intended for use only with A-dec 501 motor tubing and the A-dec delivery system with deluxe style touchpad, and must therefore be only used with A-dec products. Using other manufacturer's systems or components could lead to unexpected performance or damage to the system.

5 Regulatory Information

The Regulatory Information, Specifications, and Warranty document (p/n 86.0221.00) is delivered with A-dec dental equipment as mandated by agency requirements.
If you need this information, please go to the Resource Center at www.a-dec.com.

6 Product Service

Product service is available through your local authorized A-dec dealer. For service information, or to locate an authorized dealer, contact A-dec at +1.503.538.7478, or visit www.a-dec.com.

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7 Intended Users

We have based our development and design of the electric motor system (includes tubing, electric motor, and control unit) on the "dentists, dental hygienists, dental employees (prophylaxis), and dental assistants" target group.

The motor and motor tubing are intended for use only by trained dental or medical practitioners for the purposes listed under the "Indications for Use" and in accordance with this document and the applicable health and safety regulations. The motor and motor tubing should be prepared for use and maintained by staff who are 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 that are not approved by A-dec invalidates all claims under warranty and any other claims.

8 Indications for Use

The A-dec 501 electric motor system is comprised of a control unit that drives a direct current (DC) electric micromotor that is activated by means of a foot control. It is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis, and endodontic treatment, with use of a straight, right-angle, or contra-angle, ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed.

9 Warnings, Cautions, and Notes

This section provides general warning and caution statements. Other specific warnings and cautions are provided as needed throughout this document.

- Please read this section carefully and use only as intended or instructed.
- Safety instructions are intended to avoid potential hazards that could result in personal injury or damage to the device.
- Safety instructions are classified in accordance with the seriousness of the risk.



WARNING

- Implantable systems, such as cardiac pacemakers and ICDs (implantable cardioverter defibrillators) can be affected by electric, magnetic, and electromagnetic fields. This motor system emits electromagnetic fields, which means there are some potential risks. For instance, interference may occur and a malfunction of these devices is possible. A-dec recommends the following:
  - Ask patients and users if they have an implanted device before using this product.
  - Explain the circumstances to them.
  - Weigh the risks and benefits.
  - Keep this product away from implanted devices.
  - Make appropriate emergency provisions and take immediate action if patients become ill. Symptoms including a raised heartbeat, irregular pulse, and dizziness may signal problems with a cardiac pacemaker or ICD.
- Do not use any high frequency (HF) communication equipment (e.g. mobile telephones) during operation. These devices may affect electrical medical equipment.
- Do not attempt to disassemble or tamper with the product except as recommended in these Instructions for Use.
- Do not drop the motor. This may cause damage resulting in electrocution or product malfunction.
- In accordance with IEC 60601-1/ANSI/AAMI ES60601-1, the motor is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anesthetic substances containing oxygen or nitrous oxide where such gases may accumulate in concentration in a closed space. The motor and handpiece tubing are not suitable for use in oxygen-enriched atmospheres.

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CAUTION

- Always follow the manufacturer's recommendations for the electric motor and attachment. Misuse may damage the motor, create risks, and poses hazards for patients, users, and others.
- This product should only be used for dental treatment by qualified personnel. Do not use the product for applications other than for the purposes listed under the Indications for Use.
- Check the motor, motor tubing, and O-rings for damage, loose fit, and leaks prior to each use. Ensure that the motor tubing is not kinked. Do not use the motor if damage is detected. Service or replace as necessary.
- Do not look directly into the optic outlet, which could lead to vision impairment.
- Sterilize the motor prior to initial use. See "13-2. Sterilizing the Motor" on page 8.
- Make sure to supply coolant air to the motor. Otherwise, the motor surface temperature may rise to 150°F (60°C) or more.

NOTE

- For information on cautions for use, handling, and maintenance/inspection, etc. of the attachment, see the instruction manual of the attachment.
- If a repair is required, contact an authorized A-dec dealer. An A-dec service technician will inspect the product and perform a repair according to the service manual.

10 Conditions and Environment for Operations

- Use only potable water and air from dental units for the supply.
- Use only non-contaminated, filtered, oil-free and dry compressed air to operate the motor and motor tubing.
- Perform regular function and maintenance checks.
- The dental motor is designed for intermittent operation with an operating time of 3 minutes and an idle time of 10 minutes.

If the surface temperature of the motor rises abnormally high during treatment, the output torque is gradually reduced. The output torque is restored if you stop the motor and wait until the surface temperature has cooled sufficiently.

11 Attach and Detach the Motor

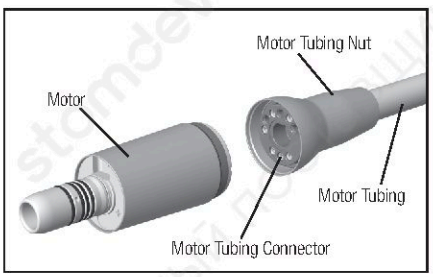
Final Equipment Checks

- Before using the motor and motor tubing for the first time, ensure that the operating conditions are met.
- Always ensure that adequate cooling is delivered to the handpiece (except in endodontic applications). In case of a coolant supply failure, the motor must be stopped immediately.
- Check the motor, motor tubing, and o-rings for damage, loose fit, leaks, and biofilm formation prior to each use. Ensure the motor tubing is not kinked. Do not use the motor or motor tubing if damage is detected. Service or replace as necessary.
- Perform a test run prior to each treatment.

11-1 Connect / Disconnect the Motor and Motor Tubing

Align Motor Pin with Motor Tubing Connector and firmly insert the motor pins into the pin holes of the motor tubing connector. Fasten the motor tubing nut securely.

To remove the motor tubing from the motor, unscrew and detach the motor tubing nut, and gently pull out the motor tubing connector.



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11-2 Connect / Disconnect the Motor and Attachment

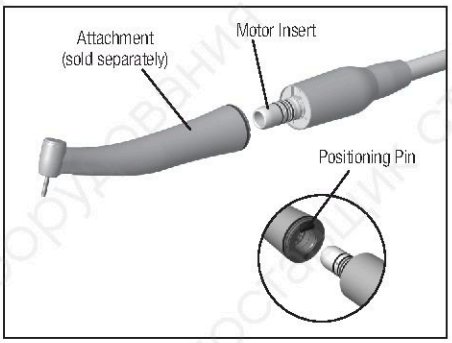
WARNING

- Never step on the foot control while installing or removing the motor. Damage may occur.

CAUTION

- Confirm that the attachment is properly connected. It is extremely dangerous if the attachment becomes detached during operation.
- Do not leave a lubricated attachment attached to the motor when not in use. Oil may enter the motor and cause malfunction.
- Only use ISO E–type attachments (20 mm diameter, gear driven) that conform with ISO standard 3964.

To install the ISO E-type attachment on the motor, properly align the attachment with the motor insert, connect, then turn until you hear a click, which indicates positioning pins are aligned.
To remove the attachment, simply pull out the attachment from the motor.



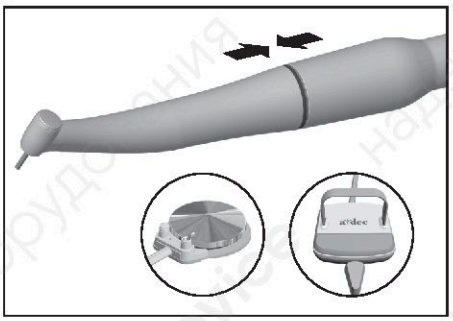
12 Inspection Before Use

WARNING

- Ensure that the motor and attachment are completely dry before operating. Moisture in the motor can lead to a malfunction.

To test the complete electric motor system:

1. Verify the attachment is properly connected and has a secure hold on the motor. The attachment should not come off with a gentle pull.
2. Activate the motor using the foot control lever or disc. For foot control operating information, see the Instructions for Use that came with your delivery system or foot control.
3. If you observe problems, such as vibrations, unusual noise, overheating, smell, leakage, or lights not working, stop the motor immediately and contact your authorized A-dec dealer or A-dec customer service.



13 Cleaning, Disinfection, and Sterilization

Clean and disinfect the motor and motor tubing immediately after each patient. Sterilize the motor following cleaning and disinfection.
Please note the following before cleaning and disinfecting the A-dec 501 electric motor system:

CAUTION

- Follow your local directives, standards, and guidelines for cleaning, disinfection, and sterilization.
- Wear protective clothing and personal protective equipment (PPE).
- Do not use disinfectants that contain chlorine or protein fixatives.
- Ensure that no liquid enters the motor during cleaning and disinfecting.
- Do not use a thermal washer disinfector to clean the motor or motor tubing.
- Do not lubricate the motor, which is permanently lubricated.

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13-1 Clean and Disinfect the Motor and Motor Tubing

CAUTION

- Do not place the motor or motor tubing in liquid disinfectant or an ultrasonic bath.

NOTE

- Wipe the exterior of the motor and the motor tubing with a clean cloth moistened with disinfectant or ethanol with a concentration of 60-90%.
- Use only disinfectants that are certified by officially recognized institutes and do not contain chlorine or protein fixatives. Follow the disinfectant manufacturer's specifications for proper use.

WARNING

- Routinely monitor dental unit water quality to ensure microbial counts are below the levels for drinking water recommended by your local agency. The U.S. Centers for Disease Control and Prevention (CDC) recommends a level of <500 CFU/ml of heterotrophic water bacteria.

13-2 Sterilize the motor

NOTE

- Sterilize the motor after each patient

WARNING

- Do not use an autoclave sterilizer that uses rapid heating or cooling. Sudden changes in temperature may cause the components to deteriorate.
- Do not use a sterilizer that exceeds 277°F (136°C), including the drying process. Doing so may cause product malfunction.
- Do not touch the product immediately after sterilization as it will be at a high temperature which could result in a burn injury.

CAUTION

- Follow your local directives, standards, and guidelines.
- Clean and disinfect before you sterilize the motor to ensure the sterilization process is effective and to prevent damage to the motor.
- Do not sterilize the motor tubing.
- Ensure that you only remove dry sterile goods from the sterilizer.
- Store sterile goods dust-free and dry.
- Sterilize the motor in a USFDA-cleared paper/foil laminate sterilization wrap, compliant to ISO 11607-1.
- If this motor or any instruments sterilized with this motor include residue of disinfectant or other chemicals, the surface of the motor may be discolored and internal components may be damaged. Ensure there are no chemicals inside the autoclave sterilizer.
- Autoclave sterilization is recommended for the motor. The validity of other sterilization methods is not confirmed.
- Handle the motor with care and avoid scratching the optic outlet.

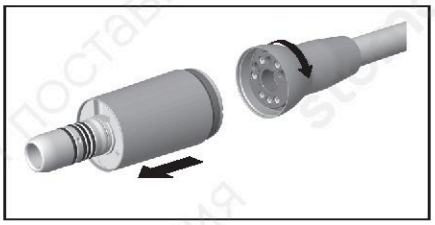
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NOTE
- A-dec recommends sterilization according to ANSI/AAMI ST79 and EN 13060 (class B). Other sterilization methods may reduce the life span of your motor.

IMPORTANT
- Follow the manufacturer's Instructions for Use that came with your sterilizer.

Prior to sterilization:
1. Purge the waterlines with air.
2. Unscrew the motor from the motor tubing coupling and pull the motor straight out from the tubing terminal.



CAUTION
- Do not twist, kink, or squeeze the motor tubing. Doing so may cause malfunction.

3. Clean and disinfect the motor before sterilization.
4. Seal the motor in a USFDA-cleared paper/foil laminate sterilization wrap, compliant to ISO 11607-1.
5. Sterilize the motor at 270°F (132°C) for the following times*:
   - Dynamic-air-removal sterilizers: 4 minutes
   - Gravity displacement sterilizers: 15 minutes

WARNING
- Do not use a sterilizer that exceeds 277°F (136°C), including the drying process. Doing so may cause product malfunction.

6. Allow the load to dry for approximately 30 minutes or more before removing from the sterilizer. Ensure the load is completely dry and no water droplets are visible on the sterilization pouch prior to removal from the sterilizer. Store the motor in the sterilization pouch to keep it clean and dry.

* For more information about sterilization standards, refer to the medical device regulations specific to your location.

14 Maintenance

CAUTION
- The electric motor should be maintained according to these instructions and in line with infection control procedures for patient safety and well-being.
  Improper maintenance, non-compliance with the instructions, or the use of accessories and service parts that are not approved by A-dec invalidates all claims under warranty and any other claims.
- Regular servicing of the motor including the attachments, is necessary for proper function and safety and should be carried out at least once every three years, unless shorter intervals are prescribed by law. This service should be performed by an authorized A-dec dealer or A-dec customer service.

DANGER
- Failure to turn off the power before you perform maintenance can lead to electrical shock.

WARNING
- Failure to turn off the power before you perform maintenance can lead to product damage and result in serious injury or death.

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14-1 Replace the O-Rings

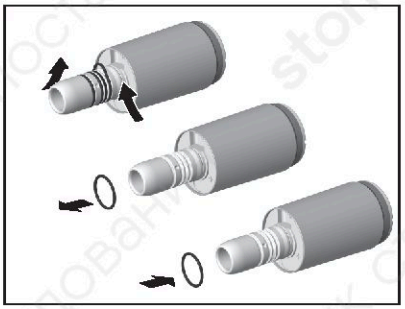
CAUTION

- The following may occur if an O-ring becomes damaged:
  - Air/water leak.
  - Air/water does not function properly with the attachment.
  - Vibration.
  - The attachment is difficult to connect/disconnect.

14-1-1 Motor Insert

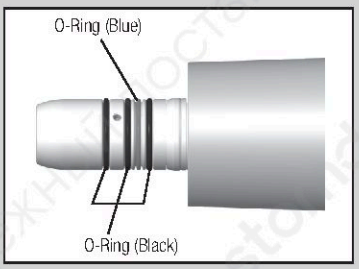
If the attachment is difficult to connect to the motor, or if you detect an air/water leak, the motor insert O-rings may be damaged and should be replaced.
Use an appropriate tool to remove the damaged O-rings from the motor insert. Be sure to install the new O-rings in their proper location (see below).

- For information on replacement O-rings, see "16. Service Parts."



NOTE

- There are four O-rings on the motor insert. The blue O-ring is thinner than the other three O-rings. Make sure all O-rings are placed in the proper position.
- If an O-ring becomes damaged, replace it immediately.
- Care should be taken when using any attachment that requires lubrication (ISO E-type attachment). Following lubrication, stand the attachment vertically until excess lubricant has drained. Wipe the attachment and connect it to the motor.



14-1-2 Motor Tubing Connection

If you detect an air/water leak coming from the motor tubing connection, replace the O-rings.
Remove the damaged O-rings in the rear of motor with a dental explorer or similar instrument and insert new O-rings into the O-ring groove.
(O-rings to replace for air circuit: 2, water circuit: 2, coolant air circuit: 1)

- For information on replacement O-rings, see "16. Service Parts."



15 Symbols

This product can be sterilized in a steam sterilizer at 135°C.

GS1 DataMatrix for Unique Device Identifier.

Type B applied part

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16 Service Parts

Service Parts List

Item	A-dec Part Number	AX Description
O-ring	54.0803.00	O-ring, Blue, 501 motor insert
O-ring	54.0804.00	O-ring, Black, 501 motor insert
O-ring	54.0805.00	O-ring, 501 motor tubing connection

17 Specifications

Specifications

Item	Value
Model (motor)	A-dec 501
Model (tubing 63inch)	501 CDAS
Model (tubing 68inch)	501 CDAM
Model (tubing 82inch)	501 CDAL
Rotation speed (standard mode)	1,000 - 40,000 rpm (min^{-1})
Rotation speed (endo mode)	100 - 5,000 rpm (min^{-1})
Torque (standard mode)	0.029 ft-lb (4.0 N·cm)
Torque (endo mode)	0.022 ft-lb (3.0 N·cm)
Weight	2.01 oz (57 g)
Spray water supply	>0.0023 CFM (65 mL/min) (29 psi/0.2 MPa)
Spray air supply	>0.05 CFM (1.5 NL/min) (29 psi/0.2 MPa)
Coolant air supply	>0.25 CFM (6.5 NL/min) (36 psi/0.25 MPa)
Max air pressure	60 psi/0.4 MPa
Mode of operation	ON: 3 min, OFF: 10 min

Environmental Specifications

	Temperature	Humidity	Atmospheric Pressure
Usage Environment	50 - 104°F (10 - 40°C)	30 - 75% RH*	–
Transportation and Storage Environment	14 - 122°F (-10 - 50°C)	10 - 85% RH*	500 - 1060 hPa

*No condensation.

NOTE

- Specifications are subject to change without notice. Requirements may vary depending on your location. For more information, contact your authorized A-dec dealer.

18 Product Disposal

Ensure the motor is sterile prior to disposal to avoid risks to health and environment.

19 Warranty

Warranty information is provided in the *Regulatory Information, Specifications, and Warranty* document (p/n 86.0221.00), which is available in the Resource Center at www.a-dec.com.

CAUTION

- U.S. 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 this device.

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Issued Date: 2021

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