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a-dec

Air Motor

A-dec 301

INSTRUCTIONS FOR USE

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

Rx Only MADE IN JAPAN

OM-DM0906EN 000

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1 User and Indications for Use

User: Qualified Professionals (Dentist/Dental hygienist)
Indications for Use:
Air Motor is intended for the following application(s):
A connection equipment to transfer energy (rotation, air, water, light) required for handpieces.
The device is used in combination in tooth restoration, periodontics and endodontics.

For identification of symbols, refer to the "12. Symbol" section on page 16 and *Regulatory Information, Specifications, and Warranty* document (p/n 86.0221.00), which is available in the Resource Center at www.a-dec.com.

2 Precautions for Handling and Operation

- Please read these precautions 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 as follows in accordance with the seriousness of the risk.

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

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NOTICE	General product specification information highlighted to avoid product malfunction and performance reduction.

⚠ WARNING

- Clean and lubricate the motor immediately (within 1 hour) after each treatment to remove residue. Failure to properly maintain the motor may cause infection, product failure or overheating, leading to burn injuries. (Refer to "7. Post-use Maintenance".)

⚠ CAUTION

- Read this Instructions For Use before use to fully understand the product functions and file for future reference.
- When operating the product, always consider the safety of the patient.
- Users are responsible for the operational control, maintenance and continual inspection of this product.
- Prior to clinical use, inspect the motor. Check for vibration, noise and overheating. If any abnormalities are found, stop using the motor immediately and contact your Authorized A-dec Dealer. (Refer to "6. Check Before Treatment".)
- Do not disassemble or alter the motor except as described in this Instructions For Use.
- Do not allow any impact to the product. Do not drop the product. Deformation may cause the motor to fail during use.
- Operators and all others in the area must wear eye protection and a mask when operating this motor.

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⚠ CAUTION

- Should the motor function abnormally during use, stop using the motor immediately and contact your Authorized A-dec Dealer.
- Do not use the following fluids to wipe, immerse or clean the product; strong/super acid water, strong acid/alkaline chemicals, chlorine containing solutions, solvents such as benzine or thinner.
- The motor is delivered in a non-sterile condition and must be autoclaved prior to use.
- Perform regular function and maintenance checks. (Refer to "9. Periodical Maintenance Checks".)
- If the motor has not been used for a long period, rotate the motor and check for noise, vibration and overheating before use.
- To avoid clinical downtime, A-dec recommends that you keep a spare to replace one that breaks during treatment.

⚠ CAUTION

- U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

NOTICE

- Repairs of this product are only to be performed by authorized service technicians according to A-dec requirements. Contact your Authorized A-dec Dealer if repairs are necessary.

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3 Preparation for Use

3-1 Setting of Air & Water Supply Pressure

Measure the supply pressure at the motor/hose connection point and set the pressure to the value specified on the specification table (Fig. 1).

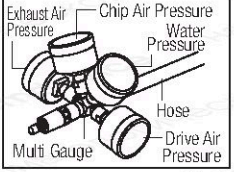


Fig. 1

Please contact your local dealer for Multi Gauge **REF** Z109400.

⚠ WARNING

- Do not exceed the optimum pressure specified on the specification table.

⚠ CAUTION

- Do not use air contaminated by dust, moisture or oil.

3-2 Connecting and Disconnecting the Motor

3-2-1 Connecting

1) Insert the motor correctly into the hose connector and tighten the hose nut (Fig. 2).
2) Make sure the motor is connected firmly to the hose (Fig. 3).

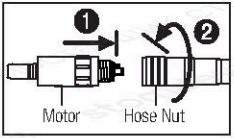


Fig. 2

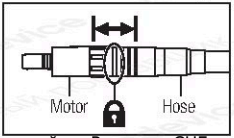


Fig. 3

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3-2-2 Disconnecting
Loosen the hose nut and remove the motor from the hose (Fig. 4).

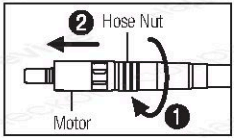


Fig. 4

⚠ CAUTION

- If the connection to the hose is loose, the motor may pop out during treatment, causing injury to the patient's mouth, face, etc., and injury to the operator.

4 Connecting and Disconnecting the Handpiece from the Motor

4-1 Connecting

1) Insert the handpiece directly into the motor (Fig. 5).
2) Confirm that the handpiece is firmly connected to the motor.

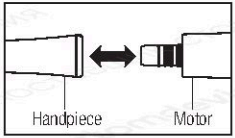


Fig. 5

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4-2 Disconnecting

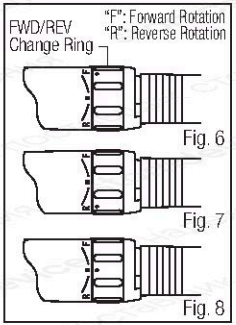
Hold the motor and the handpiece, then pull apart. (Fig. 5)

⚠ CAUTION

- Do not connect or disconnect the handpiece until the motor has completely stopped.
- Make sure that the motor and handpiece are securely connected. The motor and coolant air pressure may cause the handpiece to jump out of the motor, which could result in injury.
- Connect ONLY to E type handpieces (ISO 3964 (EN ISO 3964)).

5 Forward / Reverse Rotation

1) Forward Rotation: Turn the FWD/REV Change Ring to "F". (Fig. 6)
2) Reverse Rotation: Turn the FWD/REV Change Ring to "R". (Fig. 7)
3) When the FWD/REV Change Ring is positioned at the middle of "F" and "R" , the drive air is interrupted and the motor does not rotate. (Fig. 8)



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6 Check Before Treatment

Follow the check below before use. If any abnormalities are found, stop using the handpiece immediately and contact your Authorized A-dec Dealer.

1) Connect the handpiece and make sure that it is securely connected.
2) Rotate the motor for about one minute at the maximum rotation speed. During rotation, check for abnormalities such as abnormal rotation, vibration, noise.
3) After the motor rotation has completely stopped, touch the motor to confirm there is not heating abnormally.

7 Post-use Maintenance

After each patient, maintain the product as follows.

⚠ WARNING

- To ensure cleaning and sterilization efficacy, use only the following procedures for reprocessing.
- Follow any additional local directives, standards, and guidelines for cleaning and sterilization.
- Clean and lubricate the motor immediately (within 1 hour) after each treatment to remove residue. Failure to properly maintain the motor may cause infection, product failure, overheating leading to burn injuries.

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7-1. Cleaning at point-of use

⚠ CAUTION

- Do not use the following liquids to wipe, immerse, or clean the product: strong/super acid water, strong acid/alkaline chemicals, chlorine-containing solutions, solvents such as benzine or thinner.
- Do not immerse A-dec instruments in disinfectant solution or clean in ultrasonic devices.

1) Always wear protective gloves, a mask, and protective goggles for safety purposes and to minimize the risk of infection. (Fig. 9)

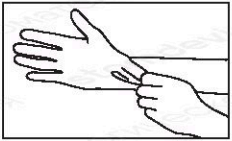


Fig. 9

2) Remove the bur. (Fig. 10)

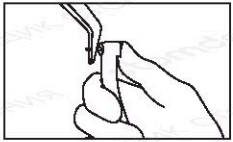


Fig. 10

3) Wipe the exterior of the handpiece and motor clean using a cloth moistened with disinfectant or ethanol with a concentration of 60-90%. (Fig. 11)
When using disinfectant, follow the instructions given by the manufacturer of the disinfectant.

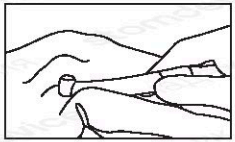


Fig. 11

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Use a state-sanctioned disinfectant with proven bactericidal, fungicidal, and virucidal properties.
The following disinfectants can be used in the United States and Canada.
CaviCide®, CaviWipes® (manufactured by Metrex)

4) Remove the handpiece from the motor and remove the motor from the hose (Fig. 12).
For reprocessing of the handpiece, refer to the Instructions For Use of the handpiece's manufacturer.

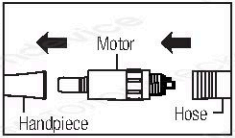


Fig. 12

5) Carry the motor to the decontamination area.

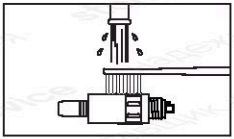
7-2 Cleaning and Drying

Perform cleaning and drying using the manual or automatic method.

Manual Method (Cleaning and Drying the Exterior)

Wash the motor under running water following the procedures below.
(Water condition: ≤100°F (38°C), ≥1 gal/min (3.5L/min); water should be of the same quality as drinking water)

1) Brush the exterior of motors under running tap water using a soft bristled brush for one minute (Fig. 13).


Fig. 13

2) Rinse the motors under running tap water for 20 seconds.

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3) Remove any moisture from the motor with compressed air and wipe off any external moisture using a dry lint free cloth.
Under appropriate lighting (natural office lighting, 500 lx or higher), inspect the motor for blood or other debris. If any visible debris remains, repeat the process until the motor is visually clean.

4) Wipe the exterior of the motor clean using a cloth moistened with disinfectant or ethanol with a concentration of 60-90% (Fig. 14).

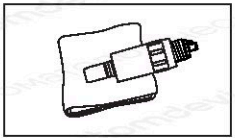


Fig. 14

When using disinfectant, follow the instructions given by the manufacturer of the disinfectant.
Use a state-sanctioned disinfectant with proven bactericidal, fungicidal, and virucidal properties.
The following disinfectants can be used in the United States and Canada.
CaviCide®, CaviWipes® (manufactured by Metrex)

After cleaning, if residual moisture is present, wipe it off with a dry cloth or blow it off with compressed air (≤50psi (0.35MPa)) until there is no moisture in the interior and exterior.
When blowing off with compressed air, cover the motor with a cloth to prevent scattering of water. Proceed to "7-3 Lubrication".

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■PANA SPRAY Plus (Lubricating the Interior)

1) Attach a tip nozzle* to the nozzle of the PANA SPRAY Plus.
   * Tip nozzle is the accessory of the PANA SPRAY Plus.
2) Shake the can 3 or 4 times, and insert the tip nozzle into the drive air port of the motor while holding the motor with a cloth.
3) Hold the motor and spray for approximately 2-3 seconds. Apply lubricant until it expels from the exhaust air port for at least 2 seconds. (Fig. 15)

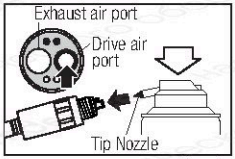


Fig. 15

⚠ CAUTION

- Hold the spray can upright.
- Firmly hold the motor to prevent it slipping when spray pressure is applied.

Please contact your local dealer for PANA SPRAY Plus **REF** Z182600.

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7-4 Packaging, Sterilizing, and Drying

1) Insert the motor into an FDA-approved sterilization pouch that conforms to ISO 11607-1 (EN ISO 11607-1), and seal the pouch.
2) Perform steam sterilization with the following conditions.

Type	Gravity Displacement	Dynamic Air Removal
Temperature	270°F (132°C)	270°F (132°C)
Full Cycle Time	15 min	4 min
Drying Time	30 min	30 min

⚠ CAUTION

- Use an FDA-approved steam sterilizer to perform sterilization.
- Follow local rules, regulations, and guidelines regarding the reprocessing of devices.
- Do not touch the product immediately after steam sterilization as it will be very hot and must remain in a sterile condition.
- Do not perform steam sterilization on the product with other instruments even when it is in a pouch. This is to prevent possible discoloration and damage to the product from chemical residue on other instruments.
- Clean and lubricate the motor prior to sterilization. If blood remains on the internal surface it can become clotted and cause product failure.
- Do not heat or cool the product too quickly. Rapid change in temperature could cause damage to the product.

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⚠ CAUTION

- Be sure to use sterilizers that can perform sterilization no higher than 275°F (135°C). In some sterilizers, the chamber temperature may exceed 275°F (135°C). Do not use these sterilizers as failure of the motor could occur. Contact the sterilizer manufacturer for detailed information about cycle temperatures.
- Steam sterilization is recommended for the product. The validity of other sterilization methods (such as plasma sterilization or EOG sterilization) is not confirmed.

7-5 Storage

Store the product in a dry, clean location.

⚠ CAUTION

- After the sterilization and drying cycles are complete, remove the motor immediately from the sterilizer to store it.
- Store the product in a well ventilated place out of direct sunlight and within the range of temperature, humidity and pressure specified in "10. Specifications".
- Sterilization is not guaranteed after the sterilization retention period specified by the manufacturer and seller of the sterilization pouch has elapse.
  If the sterilization retention period has elapsed, perform sterilization again with a new sterilization pouch.

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8 Maintenance

If a deteriorated O-ring makes it difficult to attach the handpiece, replace the O-ring. Using a needle or other pointed tool, remove defective O-ring from the motor insert section, and fit new O-ring into the O-ring groove. (Fig. 16)

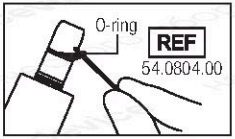


Fig. 16

9 Periodical Maintenance Checks

Perform periodical maintenance checks every three months, referring to the checklist below. If any abnormalities are found, contact your Authorized A-dec Dealer.

Points to check	Details
Rotation	Rotate the motor and check for abnormalities such as abnormal rotation, vibration, noise, and overheating.
Connection	Check the connection between the motor and the handpiece for any problems.

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10 Specifications

Model	301
Hose Connection Type	ISO 9168 (EN ISO 9168) Type 2 (Midwest 4 hole)
Handpiece Connection Type	E Type ISO 3964 (EN ISO 3964)
Rotation Speed	19,800 - 24,200rpm (36psi (0.25MPa))
Breakdown Torque	≥1.5N·cm (36psi (0.25MPa))
Drive Air Pressure	29 - 36psi (0.20 - 0.25MPa)
Air Consumption	<66NL/min (36psi (0.25MPa))

Use Environment	Temperature: 50 - 95°F (10 - 35°C), Humidity: 30 - 75% (No Condensation)
Transportation and Store Environment	Temperature: 14 - 122°F (-10 - 50°C), Humidity: 10 - 85%, Pressure: 500 - 1,060hPa

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

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11 Warranty

IMPORTANT For warranty, electrical specifications, identification of symbols, and other regulatory requirements, see the *Regulatory Information, Specifications, and Warranty* document (p/n 86.0221.00), which is available in the Resource Center at www.a-dec.com.

12 Symbol

State of being fixed.

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13 Disposing product

To avoid the health risks of operators handling the disposal of medical equipment, as well as the risks of environmental contamination caused thereof, a surgeon or a dentist is required to confirm the equipment is sterile. Ask specialist firms who are licensed to dispose of specially controlled industrial wastes, to dispose the product for you.

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