



Premium AirSonic Endo

Pneumatic handpiece

Operating Instruction



Only for USA
 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.

Introduction

Dear User
 Congratulations on purchasing this Jindell Quality product as your professional tool. This device is designed for dental treatment purpose. By following the instructions below, you will be able to work smoothly, economically and safely.
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Symbols:

- Refer to the chapter on Safety/ Warning symbol
- Important information for users and service technicians
- Thermo washer Disinfectable
- Can be steam-sterilized at 134°C -1°C/ +4°C (273°F -1.6°F/ +7.4°F)

This Medical Device production meets the requirements of the applicable EU directive 93/42/EEC & 2007/47/EC.

Disclaimer

- The Jindell Company will not be responsible for accidents, equipment damage, or bodily injury resulting from:
- repairs made by personal not authorized by the Jindell Company
 - any changes, modifications, or alterations of its products
 - the use of products or equipment made by the other manufacturers, except for those procured by the Jindell Company
 - maintenance or repairs using parts or components other than those specified by the Jindell company and other than in the original condition
 - operating the equipment in ways other than the operating procedures described in the manual or resulting from the safety precautions and warnings in this manual not being observed
 - workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply
 - fires, earthquakes, flood, lightning, natural disasters, or acts of God
- The Jindell Company will supply replacement parts and be able to repair the product for a period of 10 years after the manufacture of the product has been discontinued.
 - Warranty is honored only when a claim is accompanied by the warranty agreement with purchase date, product name and model, serial number (inscribed on the body of the product) and name of the distributor.
 - Products are subjected to change without notice.

Product Description



- RISPI SONIC® / SHAPER SONIC® Instruments
- Spring Loaded head (sliding sleeve).
- Water Spout (Spray Nozzle)
- Depth Locking Gauge
- Power Adjustment Ring (handpiece control ring)
- Connect to handpiece tubing
- Lubricate oil inlet hole.
- *M4 / B2 type Fixed Connections:
 - Drive inlet air channel/ lubricate oil inlet hole
 - Internal Inlet Water channel
 - Spray air
 - Return (Exhaust) air

Technical data

Drive Condition	■ Drive Air Pressure: 2.2 – 3.5 bar (32 – 51 psi) ■ Water Spray: 0.8 – 2.5 bar (12– 36 psi) ■ Frequency (Hz): 1,500 - 3,000 Hz
Recommend Condition	■ Drive Air Pressure: 2.5 bar (2.5 kg/ cm ² , 36 psi) ■ Water Spray flow volume> 50ml/min (@2.0 bar)
Air Consumption	18 – 51 NL/min

*The device should be operated with the described operating pressure. After starting, the intensity can be regulated using the foot switch at maximum drive pressure.

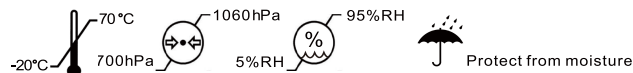
Transportation and storage condition

Prior to start-up, very cold products must be heated to a temperature of 20 °C to 25 °C (68 °F to 77 °F). Otherwise it can cause the medical device to malfunction.

DO NOT STORE THIS DEVICE IN EXCESSIVELY COLD LOCATION

Storage conditions:

Surrounding Temperature from -20°C (-4°F) to +70°C (+158°F); Atmospheric pressure from 700hPa to 1060hPa (10 to 15 psi); Relative humidity from 5%RH to 95%RH absence of condensation



Caution

- The device is not supplied sterile condition before shipping. It must be autoclaved or sterilized before first use and after each use.
- Use the handpiece only for operations of endodontics and exclusively with MICRO-MEGA® instruments. Any other use or alteration of the device is banned and may be dangerous.
- A supply of dry, clean, cooling and contamination-free compressed air according to EN ISO 7494-2 must be provided.
- The instruments must be pre-disinfected, cleaned and sterilized at 135°C for 18 min before first use.
- Proper cleaning & lubrication before sterilizations is essential to prevent the build-up of debris.
- The handpiece of fastening to the handpiece tubing (hose) or connector must meet the standard of ISO 9168.
- The handpiece is well turned when the tip of the rotary instrument discontinues moving when your finger touches its flute.
- This same principle applies when the instrument touches the wall of the canal.
- Do not attempt to disassemble the handpiece nor tamper with the mechanism.
- Do not use Dry-Heat sterilization; it will result in malfunctions and lead to premature bearing wear.
- Do not use wire brush to clean the handpiece sheath. Wipe clean with alcohol-immersed cloth or cotton swab.
- Do not immerse handpiece in disinfectant solution or boiling water, acidic water or acidic solutions, nor chemicals, and not to be cleaned by ultrasonic cleaning bath device process.
- Avoid crashing the handpiece. Take care not to drop the handpiece as it may cause serious damage and void the warranty. Be carefully!
- It is recommended to wear appropriate protection gloves and eye-protection while handling the handpiece and the rotary instruments.
- Use a dental dam during intervention on a patient.
- During long treatments, repeat lubrication every ten minutes.
- Do not pull back the sliding sleeve while the handpiece is running.
- Irrigate while using the handpiece.
- The handpiece must only be used with a rotary instrument inserted into the head.
- Daily maintenance procedure will be recommended: step 1 is remove the handpiece from the handpiece tubing (hose), step 2 is remove the Insert/ Tips, step 3 is scrub handpiece under running water with soft sponge or cloth to remove external debris, step 4 is lubrication, final is Sterilization.
- Check for vibration, noise and overheating outside the patient's oral cavity before use. If any abnormalities are found, stop using the handpiece immediately. Contact your authorized Jindell Dealer for service. Never dismantle the handpiece. Any dismantling of the handpiece may only be carried out by an approved dealer or the manufacturer.

Installation

- The handpiece must only be used with the following instruments:
 - RISPI SONIC® to debride the coronal two thirds. These instruments are used leaning on the canal walls and while irrigating through the spray tube. Turn the contra-angle only once the instrument is inside the canal (passive insertion). It is important to select an instrument with a size adapted to the canal lumen. Working amplitude from 0 to 1.5 mm.
 - SHAPER SONIC® for simultaneous debriding of the apical and coronal thirds. These instruments are used leaning on the canal walls and while irrigating through the spray tube. Turn the contra-angle only once the instrument is inside the canal (passive insertion). It is important to select an instrument with a size adapted to the canal lumen. Working amplitude from 0 to 1.5 mm.

Connect to the Units:

- Connect the AirSonic handpiece to the Handpiece tube (hose). In case the supply air pressure at the connection (where the device is connected to the handpiece hose) is set at the recommended 0.3 - 0.4 MPa (3.0 - 4.0 kgf/cm²), the device is ready usable.
- Place a RispiSonic instrument into the AirSonic Endo handpiece. While fully depressing the rheostat pedal, slowly turn the Power Adjustment ring (at the bottom of the handpiece) from the "-" position towards the "+" direction. You should hear a distinct humming sound coming from the handpiece.
- Pull the spring-loaded cone down toward the base of the handpiece. Place the plastic hub (head) of a RispiSonic or ShaperSonic instrument through the cradle of the wire stop into the open hole in the handpiece. Inserting the instrument into the handpiece may require the spring-loaded cap to be pressed down with the free hand.
- Tighten the instrument in place at the desired length by simply releasing the spring loaded cone.
- Do not use a rubber stop on the sonic instruments. Measure instrument length from the wire stop on the AirSonic Endo handpiece.
- Introduce the stationary file into the canal until the required working length less 1 mm.
- Press the foot control in order to make the rotary instrument oscillate.
- Irrigation must be performed during use of the handpiece.
- Prepare the apical portion of the canal with a vertical movement of 2 to 3 mm, then increase the movement to 3 to 5 mm to widen the coronal portion.

- While in use, the air restrictor valve in the AirSonic Endo handpiece will cause the line pressure in the dental unit to show a higher psi
- To operate the AirSonic Endo handpiece at maximum efficiency, always fully depress the foot pedal.

Checking the pressure:

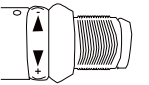
- Recommended pressure is 2.5 bar (36 psi).
- Moisture and debris in drive air may cause the device to malfunction. It is important to drain the air compressor on a regular basis, even though an air filter or air drying device is provided in the air line.

Checking the amount of water:

- Adjust the water volume for the coolant to 50 ml/ min (cm³/min) or 3.1 inch³/ min above.
- At the beginning of each workday, the water-conducting systems should be rinsed for at least 2 min. without the instrument being attached; if there is a risk of contamination from reflux or back suction, the system must be rinsed for 20-30 seconds.

Adjustment of Instrument amplitude

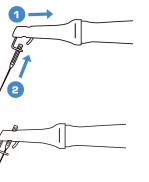
- The AirSonic Endo handpiece offers the unique advantage of tuning for the correct frequency and amplitude regardless of size and length of instrument.
- Once the RispiSonic or ShaperSonic instrument is locked into the handpiece, tuning is accomplished by slowly turning the Power Adjustment ring from the "-" arrow (stationary) position towards the "+" arrow until the rotary instrument reaches an amplitude of about 0.5mm.
- This increases the air pressure and also the amplification of the instrument.
- The AirSonic Endo handpiece is properly tuned when the visible vibration of the instruments are agitating approximately 0.5 mm on both sides of the instrument from the rest position.



To Change the rotary instruments

Insertion of the instrument:

- Make sure that the air supply has been turned off.
- Pull the Spring loaded cone (sliding sleeve) down towards the back to clear the head's opening.
- Insert the plastic hub (head) of instruments file through the cradle of the wire stop into the open hole in the handpiece.
- Inserting the instrument into the handpiece may require the spring-loaded cap to be pressed down with the free hand.
- Place the instrument's stop on a gauge and adjust the instrument to the desired length.
- Tighten the instrument in place at the desired length by simply releasing the spring loaded cone.
- Remove the instrument by pulling it forward via the depth-stop, to avoid leaving debris on the head.



Removal of the instrument:

- Make sure that the air supply has been turned off.
- Pull the Spring loaded cone (sliding sleeve) down towards the back to clear the head's opening.
- Remove the instrument by pulling it forward via the depth-stop, to avoid leaving debris on the head.
- Release the sliding sleeve.

Cleansing & Shaping with Rispi-Sonic and Shaper-Sonic Instruments:

Cleansing and shaping of the root canal system with the AirSonic Endo handpiece follows the basic principles of enlargement as suggested for hand instrumentation:

- Confine the instrument within the canal.
- Maintain the basic anatomy of the canal.
- Use sequential instrumentation.
- Use copious irrigation.
- Maintain patency.

- Do not use the AirSonic Endo handpiece to gain initial access into canals.

Coronal Two-Thirds Flaring:

- After gaining access, finding canals, achieving patency and establishing working length with a #10 hand reamer or file, flaring of the coronal two-thirds of the canal can now be accomplished.
- Depending on canal curvature and length, the RispiSonic or ShaperSonic instrument (usually a size 0 or 1 Rispi; or a size 10 or 15 Shaper) is placed two-thirds of working length down the canal and then activated (remember to fully depress the rheostat pedal).
- The instrument is applied in a circumferential movement and kept in constant contact with the canal walls while a vertical movement of 3-5mm is maintained.
- Within a few seconds, the instrument will move freely, and if additional shaping is desired, progression to the next size is applicable.
- The action of the sonic instruments, combined with an outstroke shaping motion and a consistent water flow from the AirSonic Endo handpiece, will safely and rapidly remove dentin.
- Coronal flaring with a RispiSonic or ShaperSonic instrument in the AirSonic Endo handpiece will normally eliminate the need for orifice openers associated with rotary niti instrumentation systems.

Apical Shaping

- Also depending on canal curvature, length, or difficulty in gaining apical patency, apical shaping may be performed using sonic instrumentation.
- Once working length has been established, each canal should be instrumented to at least a size 10 file before a sonic instrument is inserted.
- Once a canal has been enlarged to this extent, it will easily accommodate a 10 Shaper-Sonic to sonic length (SL). Sonic length refers to a point 1mm short of the apex (or 1mm short of the working length).
- The Sonic instrument is inserted into the canal to sonic length and then activated.
- The instrument is kept in constant contact around the canal walls while a vertical movement of 2-3mm is maintained.
- Within a few seconds, the instrument will move freely, and if additional apical shaping is desired, progression to the next size is applicable.
- Apical shaping is usually accomplished with sizes 10, 15 and 20 Shaper-Sonics.
- To minimize any chance of impacting dentinal debris, recapitulate with a #10 hand instrument to full working length before introducing the next size Sonic instrument into the canal.
- In difficult cases, many clinicians prefer to complete apical shaping using either hand instrumentation or engine-driven niti instrumentation systems.

Canal Disinfection Using The AirSonic Endo Handpiece

- After completing the cleaning and shaping aspects of the root canal procedure, complete canal system disinfection can now be accomplished by using the AirSonic Endo handpiece to cavitate irrigating solutions within the canals.
- The cavitating action of the irrigant allows the solution to discover, open and debride lateral canals and/or an isthmus, which otherwise would not be achieved without the acoustic streaming of the Sonic.
- The high-speed bubbling action safely removes tissue and bacteria and significantly reduces sterilization time.
- Using a syringe, place an irrigating solution (sodium hypochlorite, aqueous EDTA, chlorhexidine 2%) into the canal before introducing a sonic irrigating file.
- Insert a Sonic irrigating file into the AirSonic Endo handpiece (the #15 Shaper-Sonic is recommended and is used passively in the canal to cavitate the irrigating solution).
- The irrigating file is then placed into the canal and can be taken to sonic length (SL) if desired. Fully depress the rheostat pedal and maintain a 3-5mm vertical motion for 1-2 minutes per irrigating solution.
- Before the AirSonic Endo handpiece is used to cavitate irrigating solutions, be sure to turn off the water to the handpiece from the dental unit.

Lubrication:

For the M4 (4 hole) / B2 (2 hole) type backend fixed connection handpiece; supply 2-3 drops of oil into the drive air tube or hole of the handpiece once or twice a day. Operate the handpiece for 5 - 10 seconds to remove residual debris and oil. Lubricate at least twice a day.

- The AirSonic Endo handpiece needs only one drop of oil at every 5 times of autoclave.
- Excessive lubrication can clog the motor which will stop it from oscillating.
- Also, never apply disinfectants or handpiece cleaners on or into the sonic handpiece before sterilization.
- Detach the handpiece from the supply hose and lubricate using the special can. Immediately after, screw the handpiece back to the hose and operate the instrument for a few seconds, until the characteristic hissing sound can be heard.
- Only high quality lubricants recommended for use with dental instruments must be used.
- Always cleaning & lubricate before sterilization!
- Do not immerse handpiece or cartridges/ rotor in disinfectant solution or boiling water, nor chemicals, and not to be cleaned by ultrasonic cleaning bath device process.
- Only use lubrication maintenance products and/or components approved by spray oil or the automatic cleaning & lubrication device.
- Manually clean debris off with a brush off the handpiece outside under running water 30°C ± 5°C or clean with 70%- 80% alcohol solution for Disinfection.
- Wire cleaner may be inserted into exterior spray holes to dislodge any foreign matter and debris. If the blockage is located in the interior portion of the spray tubes, the instrument must be sent to Jindell or an authorized repair facility for repair.

Sterilization

- Sterilization in a steam sterilizer (autoclave) in accordance with EN 13060 / ISO 17665-1 (135°C) The Jindell medical device has a maximum temperature resistance up to 138°C (280.4°F). (Depending on the available autoclave,) select a suitable procedure from the following sterilization processes: Recommended sterilization methods/parameters for wrapped loads are as follows:
 - Autoclave with three times with an pre- vacuum Pressure pulse "S" cycle (According with EN 13060, class S) at least 3 minutes at 134°C -1°C / +4°C (273.2°F -1.6°F / +7.4 °F) and cool at room temperature.
 - Autoclave using the gravitation method: at least 10 minutes at 134°C -1°C / +4°C (273.2°F -1.6°F / +7.4 °F) or alternatively at least 60 minutes at 121°C -1°C / +4°C (250°F -1.6°F / +7.4 °F) and cool at room temperature.
- Insert into an autoclave pouch and seal the pouch before Sterilization is recommended according to EN 868-5.
- Follow the steam sterilizer (autoclave) manufacturer's Instructions for Use.

- Do not use Dry-Heat sterilization; it will result in malfunctions and lead to premature bearing wear.
- Sterilization is recommended by DIN EN 13060 or EN554. Jindell recommended sterilization according to EN 13060, class B (pre & post vacuum).
- Proper cleaning & lubrication before sterilizations is essential to prevent the build-up of debris & remove the bur (rotary instrument).
- Wrap the turbine handpiece and the accessory in sterile goods packing (autoclave pouch) and seal according to EN 868-5.
- Make sure, that you only remove dry sterile goods. & Store sterile goods dust-free and dry.
- Immediately remove the product from the steam sterilizer after the sterilization cycle will damaged to product!
- Sterilization is required before the first use and between each patient use to prevent cross-infection.
- If the sterilizer chamber temperature must exceed during 135°C (or 275°F) during the drying cycle, then delete the drying cycle.
- Always place the handpiece in the center or upper shelf of the chamber, as the local temperature at the bottom of the chamber could rise beyond the level indicated on the autoclave.
- Never heat or cool the handpiece quickly; Rapid change in temperature could damage the glass rod or subject other metals to abnormal stress.
- Do not wash, soak, or wipe off the handpiece with a Potentially Corrosive Solution (strong acid, super acid solution) or cold sterilization solution.

Guarantee:

The following warranty conditions apply to this Jindell medical device:
 Jindell provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 6 to 12 months from the date of the invoice, subject to the following conditions:
 In case of justified complaints, Jindell will honor its warranty with a free replacement or repair. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
 Jindell shall not be liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with Jindell's instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to lamps, light conductors made of glass and glass fiber optic, glassware, rubber parts, and the colorfastness of plastic parts.
 All liability is excluded if defects or their consequences originate from manipulations or changes to the product made by the customer or a third party that is not authorized by Jindell.
 Warranty claims will only be accepted if the product is submitted along with proof of purchase in the form of a copy of the invoice or note of delivery. The dealer, purchase date, type, and serial number must be clearly evident from this document.

DECLARATION OF CE CONFORMITY

Manufactured/ Distributed by: **Jindell Medical Instruments Co., Ltd.**
 No. 367, Zhuliao Rd., Dashu Dist., 84043, Kaohsiung City, Taiwan (R.O.C.)
<http://www.taiwantrade.com.tw/jindell>

Y.Sung Handelsvertretung
 Dusselthaler Str.24, 40211, Dusseldorf, Germany

Declares under its own responsibility that following products:
 Product Name: **Dental AirSonic Handpiece**; Model in the Version: **Premium AirSonic Endo Series**
 It fully conforms to the following ISO 13485, EU directive 93/42/EEC & 2007/47/EC Annex II (Medical Device Directive)

Class which the equipment belongs to: **Ila**
 It conforms to the following standards:
ISO 15606; -ISO 9168; -ISO 1797; -ISO 7494-2; -ISO 14971; -EN 15223-1; -EN 15883-1

※ Specifications may be changed without notice. 20181101-A02

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