

Instructions for use



BA Ultimate

Air motors BA604L (IEEBA640560) BA602S (IEEBA641080) BA604S (IEEBA641060)

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1. Introduction

Customer satisfaction is the main priority under the B.A. International Ltd. quality policy. This B.A. International Ltd. product has been developed, manufactured and subjected to final inspection according to legal regulations, quality norms and industry standards.

For your safety and the safety of your patients

Prior to initial use please read the Instructions for use. These explain how to use your B.A. International Ltd. product and guarantee a smooth and efficient operation.

Intended use

The air motor is intended for the following applications: Drive for dental transmission instruments for dental restoration and prophylaxis. Supply of dental transmission instruments with cooling air, chip air, spray water and light.

Misuse may damage the air motor and hence cause risks and hazards for patient, user and third parties.

Qualifications of the user

We have based our development and design of the air motor on the dentist, dental hygienist, dental employee (prophylaxis) and dental assistant target group.

C \in Production according to EU Directive

The air motor is a medical product according to the EU Directive 93/42/EEC.

Responsibility of the manufacturer

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

- > The air motor must be used in accordance with these Instructions for use.
- > The air motor has no components that can be repaired by the user. Modifications or repairs must only be undertaken by an authorized B.A. International Ltd. service partner.

Skilled application

The air motor is intended only for skilled application in the dental or medical field according to its purpose of use in compliance with the valid health and safety at work regulations and the valid accident prevention regulations as well as in compliance with these Instructions for use. The air motor 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 B.A. International Ltd., invalidates all claims under warranty and any other claims.

Service

In the event of malfunctions immediately contact an authorized B.A. International Ltd. service partner. Service and maintenance work must only be carried out by an authorized B.A. International Ltd. service partner.

2. Safety notes

> The operation of the air motor is permitted only on dental units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).

The power supply unit for the dental unit must satisfy the following requirements to be guaranteed by the system assembler:

- > Double insulation for the highest expected supply voltage must be provided between the primary and secondary power circuits.
- > Double insulation for the highest expected secondary voltage must be provided between the secondary voltage and protective earth (PE).
- > The secondary circuits must be galvanically isolated from each other.
- > The secondary circuits must be protected against short-circuiting and overloading (maximum 700 mA).
- > The leakage currents of the applied part must be kept.
- > The secondary voltage must be limited to a maximum of 3.3 V AC / DC.



> 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 air motor must be stopped immediately.

> Use only non-contaminated, filtered, oil-free and dry compressed drive air to operate the air motor.

> Check the air motor for damage and loose parts before each use (e.g. 0-ring).

> Do not operate the air motor if it is damaged.

> Do not touch the electrical contacts.

> Replace faulty or leaky 0-rings immediately.

> Perform a test run before each use.

- > Run the rinse function for the dental unit once per day.
- > Do not look directly into the LED.

> Always follow recommendations made by the manufacturer of the transmission instrument and the rotary instrument.



Danger zones M and G

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



The air motor 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.

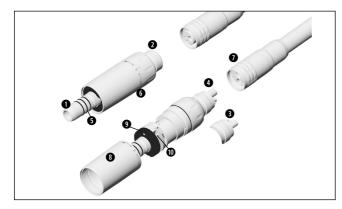
Hygiene and maintenance prior to initial use



The air motor is in a clean condition and sealed in PE-film when delivered.

- > Lubricate the air motor.
- > Sterilize the air motor.
- > Oil service page 20 21
 > Sterilization page 22 23

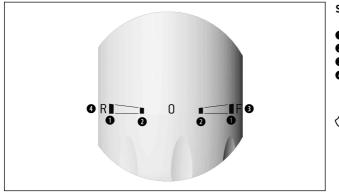
3. Product description



BA604L / BA602S / BA604S

ISO 3964 connection Borden 2/3-hole Standard 4-hole Standard 6-hole • 0-ring **6** Speed control ring Union nut Motor sheath LED-ring
 Electrical contacts

3. Product description



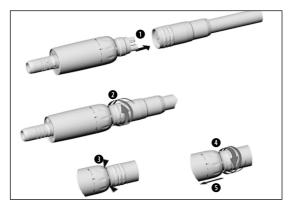


Maximum speed
50 % of the maximum speed
Forward drive (F)
Reverse drive (R)



The air motor is set to »F« (forward) when delivered.

4. Operation – Assembly/Removal



Do not assemble or remove during the operation!



- Push the air motor with BC/RM connection into the supply hose apertures.
- O Screw the union nut on.
- Check the air motor with RM connection for leakages (not possible with BC connection, because the return air is expelled through the outer sheath).
- Unscrew the union nut.
- S Remove the air motor from the supply hose.

Test run

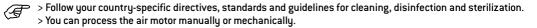


Do not hold the air motor at eye level.

- > Start the air motor.
- > Turn the speed control ring to »F« forward or »R« reverse.
- > Vary the speed from minimum to maximum across a period of 10 seconds.
- > Wipe off the air motor with a soft cloth.

> If you observe problems (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) stop the air motor immediately and contact an authorized B.A. International Ltd. service partner.

5. Hygiene and maintenance



> Wear protective clothing.

> Remove the transmission instrument from the air motor.

> Set the speed control ring to F or R.

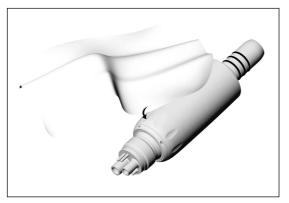
> Remove the air motor from the supply hose.

> Clean and disinfect the air motor immediately after every treatment.

> Sterilize the air motor following manual or mechanical cleaning, disinfection and lubrication.



After manual cleaning, disinfection and lubrication you must carry out a final thermal disinfection (unwrapped) or sterilization (wrapped) in a class B or S steam sterilizer (according to EN 13060).

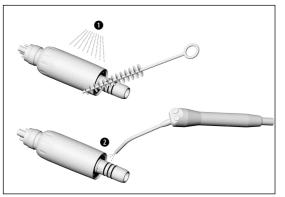


Pre-disinfection

> If heavily soiled: Clean first with disinfectant cloths.



 Only use disinfectants that have no proteinfixing effects.

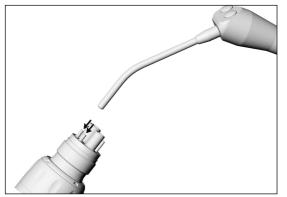


Manual cleaning internal and external

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



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

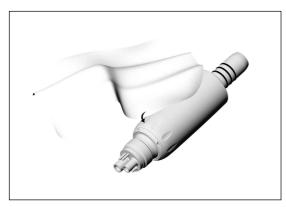


Cleaning the coolant tubes

Blow through the coolant tube with the air syringe.



In the case of clogged up coolant tubes contact an authorized B.A. International Ltd. service partner.



Manual disinfection



- B.A. International Ltd. recommends wiping down with disinfectant.
- > Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.
 For USA and Canada:

Use EPA registered surface disinfectants.

> Note the manufacturer's specifications for the use of the disinfectants.

Mechanical cleaning and disinfection internal and external

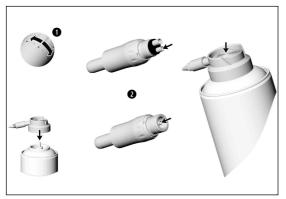


The air motor can be cleaned and disinfected in a thermo washer disinfector .

> Note the manufacturer's specifications on equipment, cleaning agents and detergents.

> Make sure, that the air motor is completely dry internally and externally after thermo washer disinfection. Remove any liquid residues with compressed air.

> Lubricate the dry air motor immediately after thermo washer disinfection.



Oil service

Recommended lubrication cycles

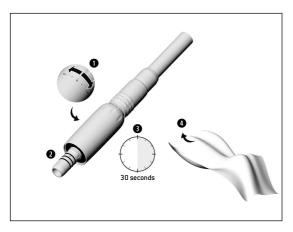
- > Essential after every internal cleaning
- > Before each sterilization

or

- > After 30 minutes of use or
- > at least twice daily
- Set the speed control ring to F or R.

With BA Ultimate Spray

 Follow the instructions on the oil spray can and on the packaging.



Test run following oil service

- Set the speed control ring to F or R.
- Position the air motor with the ISO connection downwards.
- Run the air motor for 30 seconds to remove excess oil.
- > Repeat the lubrication if dirt emerges.
- Wipe with gauze or soft cloth.

Sterilization and storage



B.A. International Ltd. recommends sterilization according to EN 13060, class B Other sterilization methods may reduce the life span of your motor.

- > Note the instructions of the unit manufacturer.
- > Clean, disinfect and lubricate prior to sterilization.
- > Wrap the air motor and the accessory in sterile goods packing according to EN 868-5.
- > Make sure that you only remove dry sterile goods from the sterilizer.
- > Store sterile goods dust-free and dry.



The standard ISO 14457 stipulates a durability of at least 250 sterilization cycles. In the case of the air motor from B.A. International Ltd., we recommend you to have a regular service carried out after 500 sterilization cycles or one year.

Approved sterilization procedures



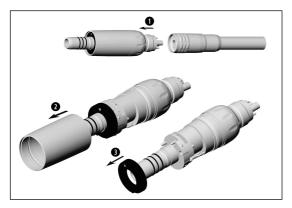
Follow your country-specific directives, standards and guidelines.

> Steam sterilization class B (pre and post vacuum) with sterilizers in accordance with EN 13060. Sterilization holding time a minimum of 3 minutes at 134 °C

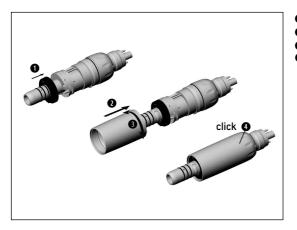
or

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

6. Exchanging the LED-ring (BA604L)

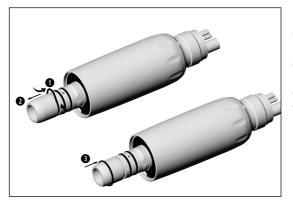


- Remove the air motor from the supply hose.
- Remove motor sheath.
- 8 Remove LED-ring.



- Slide on LED-ring.
- Push on the motor sheath.
- **3** Turn the motor sheath until it engages.
- Push the motor sheath firmly into place.

7. Exchanging O-rings (BA604L, BA602S, BA604S)



> Exchange damaged or leaking 0-rings immediately.

> Do not use sharp instruments!

- Squeeze the O-ring together between thumb and forefinger to form a loop.
- Pull off 0-rings.
- Slide on new 0-rings.

8. Accessories and spare parts

Use only original B.A.International Ltd. accessories and spare parts or accessories approved by B.A.International Ltd. **Suppliers:** B.A.International Ltd. partners

BAOIL	BA Ultimate Spray
2036100	Oil spray cap with nozzle for air motors
2083500	Intermediate adaptor for BA602S
1862300	0-ring (BA604L, BA602S, BA604S)
7389100	LED-ring (BA604L)

		BA604L	BA604S	BA602S	
Coupling hose-side acc	ording to standard	ISO 9168			
Motor/transmission instrument connection according to standard		ISO 3964			
Outer diameter of the m	notor sheath (mm)	ı) 20			
Speed range (rpm) at an operating pressure of: 2.5 bar		5,000 - 20,000**			
[at resultant exhaust air pressure of maximum 0,25 bar] 3		5,000 – 25,000**			
Maximum torque		4			
Maximum power	(W)	20			
Air consumption (NI/min) at an operating pressure of:	2.5 bar	42			
	3 bar	50 60		60	
Spray water flow acc. to ISO 14457 (ml/min)		> 100			
Operating pressure	(bar)	2.2 – 3			
Water pressure	(bar)	1,5 – 2,5*			
Chip air pressure	(bar)	2 – 3*			
Supply voltage	(V)	3.2 ± 0.1 AC/DC	-	-	

* only at air motors with internal and external cooling Chip air pressure / water pressure must be set at the same time

** Power and speed are dependent on the quality of the supply hoses used and may differ from the specified values.

rpm = min⁻¹ (Revolutions per minute)

Temperature information

Temperature of the air motor at the operator side: maximum 55 °C

Physical characteristics

Temperature for storage and transport: Air humidity for storage and transport:

Ambient temperature during operation: Air humidity during operation: -40 °C to +70 °C 8 % to 80 % (relative), non condensing

+10 °C to +35 °C 15 % to 80 % (relative), non condensing

Recycling

B.A. International Ltd. considers that it has a special duty towards the environment. The air motor along with its packaging has been designed to be as environmentally friendly as possible.

Disposal of the air motor



- 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 B.A. International Ltd. 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 manufacturer, B.A. International Ltd. is liable for material or manufacturing defects within a warranty period of 12 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 B.A. International Ltd.!

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



Authorized B.A. International Ltd. service partners

You can find your nearest B.A. International Ltd. service partner at www.bainternational.com under the service section.

Alternatively please contact us at service@bainternational.com

Symbols Instructions for use



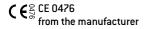




General explanations, without risk to persons or objects



Symbols Air motor / Packaging





Data Matrix Code for product identification, e.g. in hygiene/ maintenance process REF Catalogue number



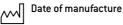
Thermo washer disinfectable

R 10 F Forward-/Reverse drive

SN Serial number



Sterilizable up to the stated temperature



B.A. International Ltd.

[Manufacturer] Unit 9, Kingthorpe Business Centre,



CER Studland Road, Kingsthorpe, Northampton, NN2 6NE U.K.

Rev2021/03



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MD

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Made in Austria