Vigor Air Motor

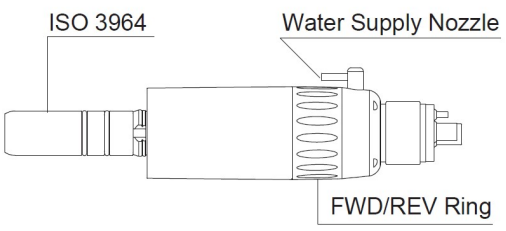
Operation Manual

CE 2797

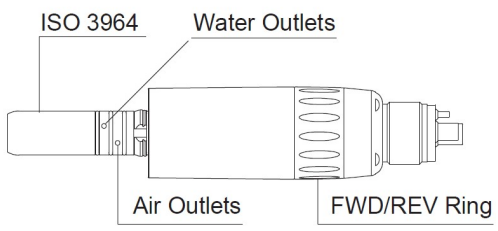
www.ttbio.com

1. Product Description

Vigor A65 Air Motor



Vigor A68 Air Motor



Indications for Use: The air motor powered by air supplied by a dental unit, designed to transform energy to drive the low speed handpiece.

Use environment/Intended user: This device is to be connected to dental low speed handpiece and operated by qualified professional (dentist) in the clinic.

Patient population: Any patient (except babies). The user's discretion is required prior use.

Indications: Removing carious material, reducing hard tooth structure, cavity preparation, and finishing tooth preparations/restorations. (*Air motor to be used with handpiece)

Contraindications: N/A

The clinical benefits of our air motor enable to transform the air supplied by a dental unit to drive the low speed handpiece.

2. Specifications

Air motor	Vigor A65 / Vigor A68
Hose connection	ISO 9168
Instrument connection	ISO 3964
Max. speed (rpm)	20,000
Water flow rate (ml/min)	> 50
Water pressure (bar)	1.5 – 2.5*
Air pressure (bar)	2.0 – 3.0*

* Spray Air Pressure must be greater than Water Pressure and both values need to be set at the same time

3. Safety Notes

1. The Vigor Air Motor are intended only for use within dentistry as part of dental treatment; any form of misuse or modifications to the product are prohibited and may cause danger.
2. Once air motor is damaged (i.e. deformed cause by hit) or improperly used (i.e. sterilized above suggested temperature), be sure not to continue using them.
3. Before operation, always make sure the product and its accessories meet the specified requirements (i.e. air pressure, water pressure).
4. It is the duty of the user to use only faultless tools, for the correct purpose, and protect patients and third parties from all dangers.
5. Higher temperature might cause the sense of oral surface tissue unadaptable. Stop using the handpiece if overheated.
6. Read this Operation Manual before use to fully understand the product functions.

4. Forward / Reverse Rotation of Air Motor

- Forward: Turn the FWD/REV Switch Ring to "F" Mode.
- Reverse: Turn the FWD/REV Switch Ring to "R" Mode.
- When FWD/REV Switch Ring is positioned in the middle between "F" and "R", the air motor stops operating.

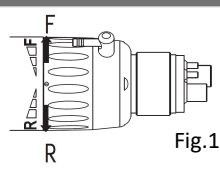


Fig.1

5. Water and Chip Air Supply

1. Vigor A65:
   - When water is required at the bur, connect the spray tube attachment to the water supply nozzle of the motor and connect the other end to the water supply nozzle of the Straight or Contra-angle Handpiece.
   - Trim the tube to the required length.
   - The spray tube attachment for Straight handpiece is an option (※0PL0227)

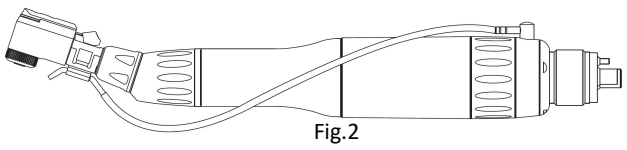


Fig.2

2. Vigor A68:
   - When water is required, connect relevant Straight or Contra-angle Handpiece.
   - When water leak after long use, replace the O-ring (※0PL0300)

6. Cleaning

Evidence of the medical device's basic suitability for effective manual cleaning and automated cleaning were provided by an independent test laboratory.

⚠ **Manual cleaning <u>OR</u> Automated cleaning**

Air motor with thermal disinfection mark may be cleaned by a washer-disinfector which comply with EN ISO 15883-1.

6.1 Manual cleaning

1. Using a soft-bristled brush, brush the external surfaces of the entire device under running utility (tap) water.
2. Prepare a detergent bath using a mild enzymatic detergent (such as "METREX" EmPower Instrument Cleaner) with the ratio of 1 oz "METREX" EmPower Instrument Cleaner per gallon of warmed distilled water.
3. Using a lint-free cloth soaked in the detergent solution, wipe the devices thoroughly to remove any visible soil.
4. Use a soft bristled brush moistened with the detergent solution to clean any remaining debris from the Vigor series handpiece. Brush device for at least 1 minute and 30 seconds.
5. Rinse the air motor under running tap water for 30 seconds.
6. Wiped dry the air motor with lint-free clothes.

6.2 Automated cleaning

1. TTBIO recommends to place the air motor in a cassette or container prior to wash in "Miele G7883" washer-disinfector, by switching the preprogrammed mode to "Vario TD". The recommended cleaning agent is alkaline detergent, such as "neodisher® mediclean" and the neutralizing agent is acid neutralizer, such as "neodisher® Z".

※Operate washer-disinfector according to user manual provided by the original manufacturer. The automated cleaning will be processed by pressing one "Vario TD" button and the preprogrammed procedures and parameters set by "Miele G7883" are shown as below:

Pre-wash	Main wash	Rinse	Rinse	Final rinse	Drying
Cold water	Cold water; 55°C for 5 minutes (Default); Alkaline detergent (neodisher® mediclean is recommended)	Hot water; Acid neutralizer (neodisher® Z is recommended)	Hot water	Deionized Water; 93°C for 5 minutes (Default)	10 minutes (Default)

2. Dry the handpiece with a lint-free cloth. If any visible soil is still found, please repeat step 1.

7. Lubrication

1. Use dental handpiece lubrication oil for maintenance, any unspecified oil not intended for lubricating handpieces could shorten the lifetime and harm human body.
2. Be sure to lubricate the handpieces prior to sterilization and run the handpieces for 20~30 seconds to emit residual oil and dirt.
3. After unpacking and prior to first use, be sure to lubricate with oil and run the handpiece in low rotation speed for 30 seconds and in full speed for 10~20 seconds to emit residual oil.

Fig. 3

- Air motor:

1. Put Shaft Spray Nozzle(※0PL0044) into nozzle of the lubrication oil can.
2. Inject the oil into the drive air pipe for 2~3 seconds, at the back end of the motor.

8. Sterilization

1. Before sterilization, the air motor must be placed into a legally marketed disposable sterilization pouch made by a combination of plastic film and material which can allow penetration of steam (e.g. paper).
2. Sterilization must be in compliance with ISO 17665-1 (choose **<u>ONE</u>** from the following methods):
   i. Gravity-displacement steam sterilization: place in autoclave in accordance with: ANSI/AAMI ST55 at 132°C for 15 minutes and drying duration is 30 minutes.
   ii. Dynamic-air-removal steam sterilization: place in autoclave in accordance with EN13060 at 134°C for 4 minutes and drying duration is 15 minutes.
3. Always perform complete drying process and remove the air motor from steam sterilizer once the sterilization cycle is completed as the user manual of sterilizer manufacturer.
4. Chemical sterilization is **<u>NOT</u>** applicable. **<u>DO NOT</u>** immerse the entire air motor or cartridge/rotor into chemical sterilant, otherwise could damage the air motor or harm the users or patients (e.g. allergic contact dermatitis, asthma, mucosal damage and so forth).

⚠ We recommend a regular service for the TTBIO handpiece after 250 reprocessing cycles.

9. Disposal

Follow your local and national laws, directives, standards and guidelines for disposal.
-Medical device
-Packaging

⚠ Remove the dental bur from the handpiece, and dispose it according to the user manual provided by the original manufacturer to eliminate the biohazard and physical hazards.

10. Disclaimer

1. Information in this operation manual has been carefully reviewed. We will not take any liability for any damage arising from improper use of the handpiece or misuse of this manual.
2. Products are subject to change without notice.
3. Please refer to the bar code on the packing box for manufacturing.
4. The product can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.

11. Quality and Service

1. All of our products have passed strict QC procedures before delivery.
2. Please note that improper use or not using the recommended parts and accessories or modifying our products without our approval may shorten the lifetime of the product or cause damage.
3. Please contact us or dealers with proof of purchase for consultation whenever you have any questions.
4. Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority.
5. eIFU use the ref on https://www.ttbio.com/download.php.

12. Symbol

	Manufacturer		Caution
CE 2797	CE mark (European Conformity)	SN	Serial number
EC REP	Authorized representative in the European Community	135°C	Sterilizable up to the temperature specified
	Data Matrix Code for product information including UDI (Unique Device Identification)		Washer-disinfector for thermal disinfection

Dealer

Manufactured by
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