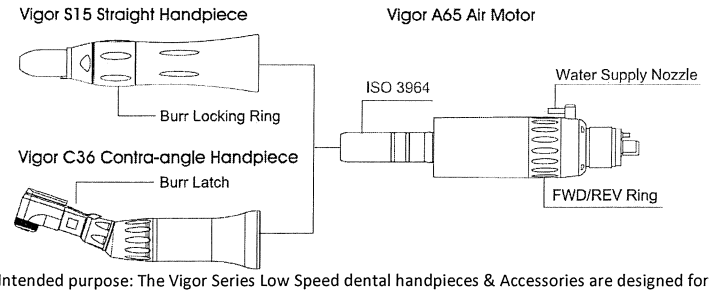
TT BIO Vigor Series Operation Manual

Vigor S15 Straight Handpiece
Vigor C36 Contra-angle Handpiece
Vigor A65 Air Motor

CE 2797

www.ttbio.com

1. Product Description



Intended purpose: The Vigor Series Low Speed dental handpieces & Accessories are designed for teeth cutting, cavity and crown preparation, restorations and polishing teeth.
Use environment/Intended user: This device is to be connected to dental unit 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.
Contraindications: N/A
The clinical benefits of our handpieces enable dentists to operate effectively in teeth cutting, cavity and crown preparation, restorations and polishing teeth.

2. Specifications

Model	Vigor S15	Vigor C36	Vigor A65
Category	Straight Handpiece	Contra angle Handpiece	Air motor
Gear ratio	1 : 1		
Connection types	Instrument connection: ISO 3964		Hose connection: ISO 9168 Type 2 Instrument connection: ISO 3964
Bur / Max. length (mm)	Ø 2.35 / 44.5 ISO 1797 Type 2	Ø 2.35 / 22.5 ISO 1797 Type 1	N/A
Max. speed (rpm)	20,000	20,000	20,000
Drive air pressure (bar)	N/A		2.5 – 3.0
Recommend drive air pressure (bar)	N/A		3.0
Water flow rate (ml/min)	N/A		> 50
Drive air flow rate (L/min)	N/A		< 80
Water pressure (bar)	N/A		1.5 – 2.5*
Chip air pressure (bar)	N/A		2.0 – 3.0*
Transportation and Store Environment	Temperature: -10-50°C Humidity: 30-85% Atmospheric Pressure: 700-1,060 hPa		

The allowable Max. speed of Straight / Contra-angle handpiece means connect to Vigor A65 air motor. The bur speed might be slightly lower than the theoretical speed as given above, due to a loss at the gear train.
* Spray air pressure must be greater than water pressure and both values need to be set at the same time.
* The water flow rate was measured at a pressure of 2.5 bar, and the drive air flow rate was measured at a pressure of 3.0 bar.

3. Safety Notes

1. The Vigor series handpieces and 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 handpiece or 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. Check for handpiece overheating outside the patient's oral cavity. Higher temperature might cause the sense of oral surface tissue unadaptable. Stop using the handpiece if overheated.
6. Be sure it is functioning correctly before using on a patient.
7. Read this Operation Manual before use to fully understand the product functions.
8. This device complies with relevant safety and performance standards and incorporates state-of-the-art risk controls. Nonetheless, not all risks can be completely eliminated. There is still a very low chance that residual risks will arise, including:
   - Device functional failures, loose parts, or misuse, potentially causing foreign body issues in patients or treatment delays.
   - Biocompatibility hazards, such as infections, allergic reactions, irritation, or inhalation hazards.
   - High temperature hazards, which could result in burn injuries.
   - Acoustic hazards, which could lead to hearing impairments.
9. Vigor series handpieces and air motors are supplied as non-sterile to the user and require the user to clean and sterilize the device prior to its use.

4. Assembly and Removal

■ Assembly
Push the Straight / Contra-angle handpiece onto the motor and turn it until it engages audibly. Pull on the handpiece before each treatment to check that it is engaged and locked in place.

■ Removal
Remove the Straight / Contra-angle handpiece from the motor by pulling in an axial direction.

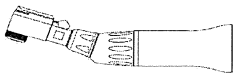


Fig.1

Fig.2

⚠ DO NOT assemble / remove during the operation

5. 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.

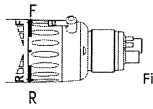


Fig.3

6. Water and Chip Air Supply

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 Contra-angle or Straight Handpiece. Trim the tube to the required length.
* Spray tube attachment for Straight handpiece is an option (※OPL0227)

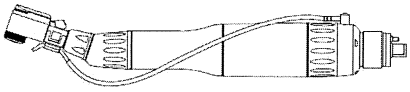


Fig.4

7. Changing Bur

■ Straight Handpiece
1. Turn the Bur Lock Ring anti-clockwise (black arrow) to open the chuck. Insert the bur up to the limit stop.
2. Turn the Bur Lock Ring clockwise (white arrow) until it clicks. Check that the handpiece rotary chuck is closed and the bur has engaged.
3. Check that the bur is held securely by pulling on it in axial direction.
4. Turn the Bur Lock Ring anti-clockwise (black arrow) to open the chuck. Remove bur from the chuck.

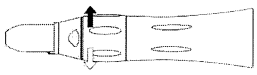


Fig.5

■ Contra-angle Handpiece
1. Swing the latch rightward and insert the bur to the center of spindle and turn it until it snaps to place.
2. Swing the latch leftward to lock the bur.
3. Swing the latch rightward and take out the bur.

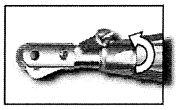


Fig.6

⚠
■ Use only rotary instruments which are in perfect condition. Follow the operating instructions of the manufacturer.
■ Insert rotary instruments only when the Contra-angle / Straight handpiece is stationary.
■ Do not interfere with the running or slowing down of rotary instruments.
■ Do not activate the rotary chuck of the handpiece or press latch of the Contra-angle during operation or slowing down.

8. Cleaning for Dental Unit Tubing

1. Internal cleaning waterlines must be conducted through the main dental unit by connecting to air motor and follow the instruction for handpiece and hose waterlines disinfection of the main dental unit. (It is recommended to use Waterline Maintenance Tablets for main dental unit, it is the simple way to maintaining clean dental unit waterlines.)
2. Do not remove attached handpiece from the connecting cable during internal waterlines cleaning and disinfection procedure.
3. Hold the handpiece over the cuspidor or over a waterproof container on main dental unit with sufficient capacity and press the purging key on the main dental unit. Setting time to clean and disinfect the waterlines base on manual instruction of main dental unit.

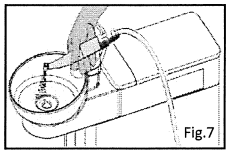


Fig.7

9. 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 OR Automated cleaning**

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

9.1 Manual cleaning

1. If included, remove the cutter or grinder.
2. Using a soft-bristled brush, brush the external surfaces of the entire device under running utility (tap) water.
3. 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.
4. Using a lint-free cloth soaked in the detergent solution, wipe the devices thoroughly to remove any visible soil.
5. 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.

6. Rinse the Vigor series handpiece under running tap water for 30 seconds.
7. Wiped dry the Vigor series handpiece with lint-free clothes.

9.2 Automated cleaning

1. If included, remove the cutter or grinder.
2. TTBIO recommends to place the handpiece 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 forte" 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 forte is recommended)	Hot water; Acid neutralizer (neodisher® Z is recommended)	Hot water	Deionized Water; 93°C for 5 minutes (Default)	10 minutes (Default)

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

10. 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.

■ Straight / Contra-angle Handpiece:

1. Put E-type spray nozzle(※0PL0114) into nozzle of the lubrication oil can.
2. Connect handpiece with the nozzle and inject lubrication oil for 2~3 seconds.
3. Clean and lubricate at least once a day after each treatment or before high pressure and high temperature sterilization.

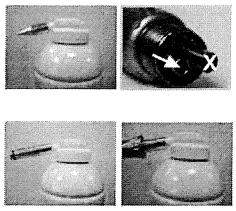


Fig. 8

■ 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.

11. Sterilization

1. Before sterilization, the handpiece 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 **ONE** 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 handpiece from steam sterilizer once the sterilization cycle is completed as the user manual of sterilizer manufacturer.
4. Chemical sterilization is **NOT** applicable. **DO NOT** immerse the entire handpiece or cartridge/rotor into chemical sterilant, otherwise could damage the handpiece 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.

12. 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.

13. 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 date.
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.

14. Reporting

Any serious incident and adverse event (e.g. bur detached accidentally and poor clamping) caused by device deficiency must be reported to the manufacturer, the authorized representative and the local competent authorities.

15. 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. eIFU use the ref on https://www.ttbio.com/download.php.

16. 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
	Instructions for use		Date of manufacture
	Transportation and storage conditions (Temperature limit)		Transportation and storage conditions (Humidity limitation)
	Transportation and storage conditions (Atmospheric pressure limitation)		

Dealer

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