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Congratulations on your purchase of DP-10 Dental Air Polishing Handpiece from Guilin Veirun Medical Technology Co.,Ltd. . It will bring you a new experience and convenience.

The manual is compiled in accordance with the relevant laws and regulations and the specific conditions of the DP-10 manufactured by Guilin Veirun Medical Technology Co.,Ltd.

The manual includes the latest information as of the time of printing. Guilin Veirun Medical Technology Co.,Ltd. is solely responsible for the revision and explanation of the simplified the manual, and reserves the right to change the relevant content after the manual is printed without prior notice. The pictures involved in this manual are schematic diagrams and are for reference only. If the pictures do not match the actual product, the actual product shall prevail.

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The operator must strictly follow this manual to operate. Otherwise, Guilin Veirun Medical Technology Co.,Ltd. shall not be responsible for any errors and equipment failures caused by illegal operations.



Guilin Veirun Medical Technology Co.,Ltd. does not promise that the device will be used for a certain special purpose and make any implied guarantee for its marketability and applicability. If you need after-sales service support, please contact Guilin Veirun Medical Technology Co., Ltd. or an authorized agent.

If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the

Member State in which the user and/or patient is established.

1. Introduction

1.1 Product name: Dental Air Polishing Handpiece

1.2 Product model: DP-10

1.3 Product description: It consists of body, nozzle, air polishing handpiece and powder chamber.

1.4 Intended use: The product removes dental plaque, soft deposits and surface stains from pits, grooves, interproximal spaces or smooth surfaces of the teeth.

Intended patient population: Adults and pediatrics patients.

Indications: This product is suitable for patients with too much plaque and stains.

Pediatrics: Age levels ranged from 12 to 18 years.

Intended user: Trained dentist.

Place of use: Professional dental clinics and hospitals.

1.5 The product life time or shelf time is 5 years.

2. Technical parameters

2.1 The A-weighting sound pressure level produced by the Dental Air Polishing Handpiece does not exceed 80 dB.

2.2 When the input water pressure is the required minimum value of 0.07 MPa, the water output is not less than 20 mL/min.

2.3 The handpiece can withstand 250 cycles of sterilization without corrosion and damage.

2.4 The polisher nozzle is rotatable.

2.5 Within the normal water supply pressure of 0.07 MPa to 0.22 MPa and the air supply pressure of 0.25 MPa to 0.4 MPa, there is no leakage of water or air.

3. Operation environment

3.1 The recommended air supply pressure is 2.5 bar to 4.0 bar (0.25 MPa to 0.4 MPa), and use only dry and clean air.

3.2 The recommended water supply pressure is 0.7 bar to 2.2 bar (0.07 MPa to 0.22 MPa).

3.3 The water and air supply at the rear of the

Dental Air Polishing Handpiece adopts the Type 1 connector according to ISO 9168:2009, without optical fiber holes, which is connected by the connector in the accessory.

3.4 Operation environment

- a) Ambient temperature: 5 °C to 40
- b) Relative humidity: $\leq 80\%$
- c) Atmospheric pressure: 70 kPa to 106 kPa

4. Installation

4.1 Components

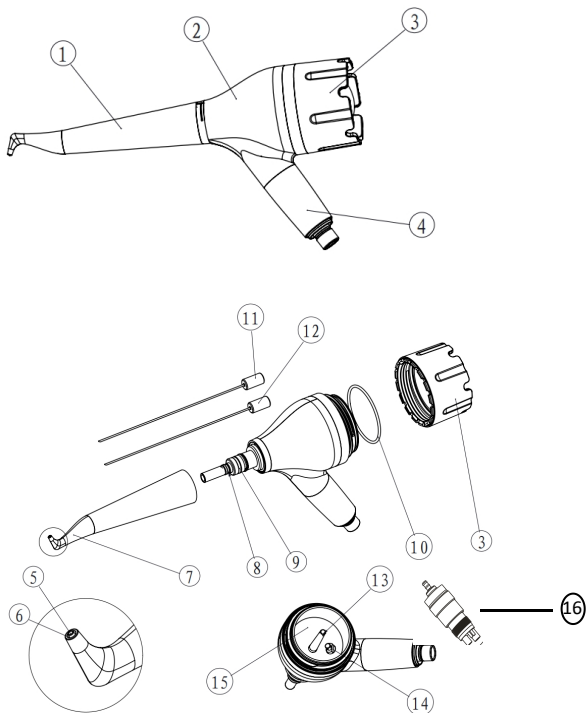


Figure 1

1. Air-polising handpiece
2. Main unit
3. Powder chamber cap
4. Connector
5. Powder outlet tube
6. Water outlet port
7. Nozzle
8. Small O-ring for handpiece connection
9. Large O-ring for handpiece connection
10. Powder chamber seal
11. Fine cleaning needle
12. Long cleaning needle
13. Air outlet tube
14. Air inlet tube
15. Powder chamber
16. Quick connector

4.2 Handpiece installation

Connect handpiece by arrow direction (See Fig.2)

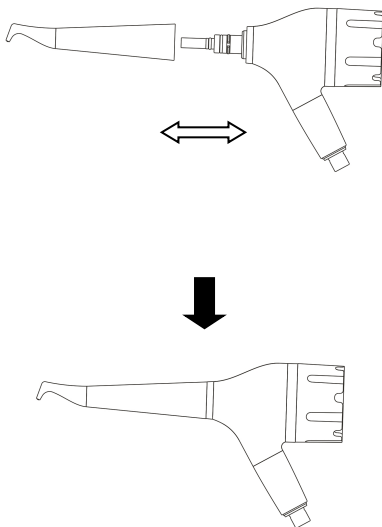


Figure 2

4.3 Filling the powder

Firstly unscrew the powder chamber cap counterclockwise, fill the powder in the container, and then install the cap clockwise (See Fig.3).

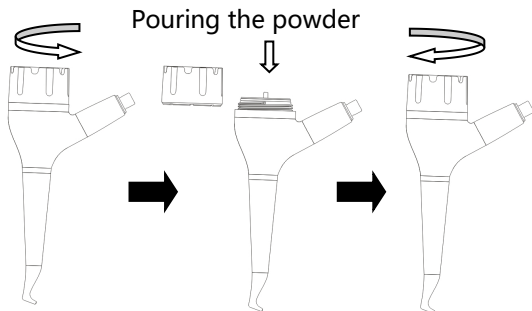
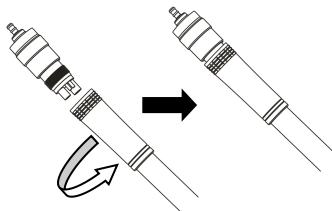
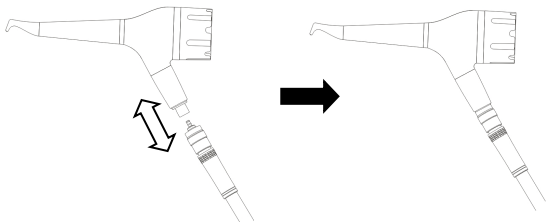


Figure 3

4.4 Connection of air-polisher handpiece and dental unit.



Firstly, screw the connector to the tail line of the dental unit.



Then, insert the other part of connector to the dental air polishing handpiece.

5. Contraindication

Patients suffering from chronic bronchitis or asthma must not, under any circumstances, be treated with Dental Air Polishing Handpiece. The jet of air and powder could cause respiratory difficulties.

6. Precautions

6.1 Please read carefully and understand the instructions before operating.

6.2 Follow all the warnings and instructions on the device when operating.

6.3 The product is specially used for oral therapy and is not available for other use.

6.4 The product is limited to professional dentist.

6.5 Before each use, please operate the device outside the patient's mouth for inspection. If you find any abnormalities such as loosening, noise, air or liquid leakage, please stop using it immediately and contact the original dealer.

6.6 In order to prevent serious damage to Dental Air Polishing Handpiece, please avoid it from being hit or accidentally dropped.

6.7 The pressure of the water and air input must meet the requirements of this manual. If the

pressure is too high, it will cause the risk of air or water leakage and bursting of Dental Air Polishing Handpiece.

6.8 It must use the dry and clean compressed air, and the air compressor, water and air filtration systems must be maintained regularly to ensure the quality of the compressed air and water. Using undried compressed air will cause powder blocking in the container or handpiece.

6.9 The air/powder jet is powerful. It can cause injury to the gums or an emphysema caused by the introduction of air into the soft tissue spaces. It is strongly recommended that the operator never direct the nozzle directly at the gum tissue or into the gingival sulcus.

6.10 After each use, please pour out the remaining powder in the container, and use compressed air to clean the outer surface of the handpiece and the powder in the container. Finally, use Dental Air Polishing Handpiece normally without powder for 5 to 8 seconds to clean the internal tube.

6.11 After each use and clean, the cap of

container should be installed for storage to prevent moisture from entering the container, causing powder blocking when the next use.

6.12 The maintenance of the product should be done by professionals.

6.13 It is necessary to comply with the relevant regulations about waste disposal of the local medical and health administration when cleaning, disposing and discharging waste.

7. Reprocessing

Preparation

This part provides instructions for cleaning, sterilization and packaging of Dental Air Polishing Handpiece intended to be reprocessed in medical facilities. Reprocessing components include handpiece and nozzle.

The goal of reprocessing reusable products is to reduce bioburden and to achieve sterility of those products in order to eliminate the risk of product reuse related infection. Decisions regarding cleaning or sterilizing dental instruments are based on the potential risk of infection associated with their use.

It is recommended to use steam sterilization.

Remember that sterilization cannot be achieved unless the elements of the assembly are cleaned first.

Basic principles

It is only possible to carry out effective sterilization after the completion of effective cleaning. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning and sterilization, and that the validated parameters are adhered to during every cycle. Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic.

7.1 Initial treatment at the point of use



The treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. Additional information, where necessary, is provided in the respective product-specific usage instructions.

Steps

- 1) Completely disassemble the handpiece and

nozzle from Dental Air Polishing Handpiece, if applicable. Rinse away any surface soiling of them with distilled deionized water or cleaning agent.

- 2) Rinse through all lumina (e.g. irrigation and aspiration connection) at least 3 times in the normal direction of flow (no back rinsing) using a disposable syringe (min. volume 50 ml) filled with distilled/deionized water applied to the back nozzle.

An aldehyde-free cleaning and disinfection solution that is compatible with the products may also be used as an alternative rinsing solution. In such cases, it is necessary to rinse thoroughly afterwards at least 3 times with distilled, or deionized water.

7.2 Cleaning

Preparation

When selecting the cleaning agent to be used, ensure that:

- These are fundamentally suitable for the cleaning of the products and compatible with one another,

- The chemicals used are compatible with the products.



It is absolutely essential that the concentrations and contact times specified by the manufacturer of the cleaning agent are adhered to. Only freshly prepared solutions may be used. The solution is not permitted to foam. Only sterilized or low microbe count distilled/deionized water (< 10 cfu/ml) can be used for all rinsing steps.

Steps for manual cleaning

- 1) Place the handpiece and nozzle in the cleaning solution for at least the minimum the time and the concentration specified by the manufacturer of the cleaning agent.
- 2) Remove any externally-attached soiling by brushing carefully with a soft brush or a soft cloth.
- 3) Rinse the products vigorously at least five times, each time with fresh distilled or deionized water (each product lumen with at least 50 ml of water). Repeat the cleaning process if the last rinsing does not run clear, or if stains are still visible on the product.



The product adopts manual cleaning and it has been verified. Please do not modify the cleaning method without authorization, such as using disinfectant for automated cleaning.

7.3 Drying

After cleaning, use compressed air to remove the cleaning fluid remaining in the product.

7.4 Inspection and maintenance

If stains are still visible on the product after cleaning, the entire cleaning procedure must be repeated. Products with visible damage, chip/flake loss, corrosion or bent out of shape must be disposed of (no further use is permissible).

7.5 Packaging

Only cleaned products are permitted to be sterilized. Prior to sterilization, the products need to be placed in a suitable sterilization container:

- Resistant to 138 °C , with adequate steam permeability,
- Maintained on a regular basis.

If single-use sterilization packaging is to be used, this must be suitable for steam sterilization

(temperature resistant to 138°C with adequate steam permeability). The material of sterilization packaging is made of medical paper and PET/PP.

Steps for packaging

- 1) Select a suitable sterilization packaging according to the size of the sterilized item and put the items in.
- 2) Place the sharp and specially shaped devices in the correct position for safe removal when opened.
- 3) Affix the strip of sterilization packaging and mark the sterilization time.
- 4) Put the sealed sterilization packaging rightly into steam sterilizer.
- 5) Pay attention to the color-changing: if sterilization is really implemented, it will turn black/grey from initial blue under steam sterilization.
- 6) Open the strip along the direction printed on the packaging and then takes the items out.

7.6 Sterilization



The product can withstand 250 reprocessing cycles. Do not exceed the maximum number of reprocessing cycles.

Use only the following listed steam sterilization procedures for sterilization; other sterilization procedures are not permissible:

- Steam sterilizer in accordance with EN 13060 or EN 285 validated in compliance with EN ISO 17665,
- Maximum sterilization temperature 134 °C.

Steps for sterilization

- 1) Sterilization at 134°C for 4 minutes.
- 2) Sterilization at 134°C for a maximum of 20 minutes is permissible.



The body and connector of device can not be sterilized by high temperature and pressure. It is strictly forbidden to sterilize the handpiece and nozzle in the following ways:

- Put them in the solution and cook.
- Soak them with disinfectant water such as

iodine, alcohol, glutaraldehyde, etc.

- Put them into the oven or microwave oven to bake at high temperature.

The hot-air sterilization and radio-sterilization procedure may not be used (as it causes the destruction of products). The manufacturer assumes no responsibility for the use of other sterilization procedures (e.g. ethylene oxide, formaldehyde and low temperature plasma sterilization).

7.7 Service life

The products have been designed for 250 reprocessing cycles and have 5 years service life from start with production, if the nozzle and handpiece exceed 250 reprocessing cycles or 5 years, it should be not used any more. The materials used in their manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The use of ultrasound baths and strong cleaning and disinfection fluids (alkaling

pH > 9 or acid pH < 5) can reduce the life span of products. The manufacturer accepts no liability in such cases. The products may not be exposed to temperatures above 134°C.

7.8 Storage

After sterilization, keep sterilization packaging and stored it in the following environment to avoid infection and sterilization failure:

- Temperature: -20 °C~55 °C,
- Relative humidity: 0%~90%,
- Atmospheric pressure: 70kPa~106 kPa.

The product can keep sterile for 6 months in sterilization packaging, when exceed the 6 months, it shall be reprocessed again before use.



After reprocessing, it is necessary to confirm that the products can work normally before use. If products with visible damage, chip/flake loss, corrosion, rust or bent out of shape must be disposed of (no further use is permissible).

8. Maintenance

8.1 There are two waterproof O-rings at the connecting end of the device body and the handpiece. As they need to be plugged and unplugged repeatedly, once they are damaged or excessively worn, the waterproof O-rings should be replaced in time.

8.2 There is a sealing O-ring at the connecting end of the device body and container. As the container cap needs to be removed repeatedly, once it is damaged or excessively worn, the sealing O-ring should be replaced in time.

8.3 After each use, please pour out the remaining powder in the container, and use compressed air or a clean, dry cloth to clean the outer surface of the handpiece, container or threads of container cap, O-ring and the residual powder in the container, and finally use Dental Air Polishing Handpiece for 5 to 8 seconds without powder to clean the internal tube.

9. Storage and transportation

9.1 Store temperature: -20°C to 55°C , relative humidity: 0%~90%, atmospheric pressure from 70 kPa to 106 kPa.

9.2 The device should be handled with care, and should be installed or stored in a cool, dry and ventilated place.

9.3 Do not mix with toxic, corrosive, flammable and explosive materials during storage.

9.4 The device should be far away from the earthquake source.

9.5 Transport should not be mixed with dangerous goods.

9.6 Avoid excessive shock and vibration during transportation.

9.7 Keep away from rain, sunlight or snow during transportation.

10. Accessories list

No.	Name	PCS
1	Dental Air Polishing Handpiece	1
2	AH-3 handpiece	1
3	Connector	1
4	O-ring 6*1.5 mm	2
5	O-ring 11*1.5 mm	2

6	O-ring 33*1.5 mm	2
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The manual does not exhaustively list the accessories and specifications of the DP-10. Please refer to the delivery materials and packing list for details.

11. Troubleshooting

Error	Possible causes	Solutions
Air leakage of container	O-ring is aging	Replace the O-ring
Liquid leakage of handpiece	O-ring is aging	Replace the O-ring
Air or liquid leakage of	O-ring or seals are aging	Replace the O-ring or seals
When operating, powder, air or water do not escape	There are no air or water	Check if there is air or water in dental quick connector.
	Handpiece is	Pull out the

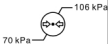
from the polisher nozzle	blocked by powder	handpiece and check if air or powder is sprayed out from the device, if powder, air and water can be sprayed out, please use a steel wire to dredge the handpiece, and then clean the handpiece with compressed air
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No powder, with air supply	There is too little powder in container	Check if there is too little powder in the container
	The supply of air is wet and the powder is caking in container	Empty and dry the container, refill the powder, and ensure a dry and clean air source.

12. After-sales service

This device is guaranteed by the warranty card from the date of sale, and is responsible for lifetime maintenance. Irreparable device damage caused by non-designated dedicated maintenance personnel is not covered by the free warranty.

13. Symbols

Symbol	Description	Symbol	Description
	Manufacturer's logo		Caution
	Consult instructions for use		Serial number
	Manufacturer		Date of manufacture
	Sterilizable at up to 134°C in the steam sterilizer (autoclave) at temperature specified.		Use-by date
	Atmospheric pressure limitation		Humidity limitation
	Temperature Limit		This way up

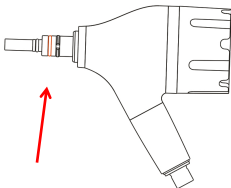
Symbol	Description	Symbol	Description
	Fragile, handle with care		Keep dry
	Medical device		Catalogue number
	Unique device identifier		CE marking
	Authorized representative in the European Union		

14. Manufacturer's rights

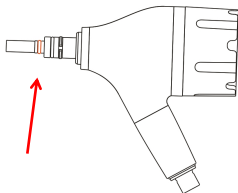
The company reserves the right to modify the design, technology, accessories, user manual content and packing list content of the product at any time without notice. In case of discrepancies, the actual product shall prevail.

15. Specification sheet of the seals

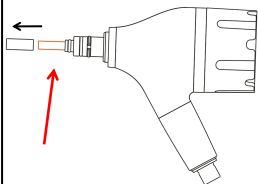
Specification: $\Phi 11 \times \Phi 1.5$
Place: handpiece connector



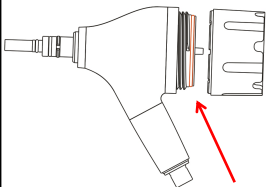
Specification: $\Phi 6 \times \Phi 1.5$
Place: handpiece connector



Specification: rubber seals
Place: handpiece connector



Specification: $\Phi 33 \times \Phi 1.5$
Place: container



16. Information about powders

1. Product Name: Prophylaxis Powder

2. Product Model: Classic

3. Manufacturer Name: Guilin Veirun Medical Technology Co., Ltd.

Address: No. D-07 Information Industry District,
High-Tech Zone, 541004 Guilin, Guangxi,
PEOPLE'S REPUBLIC OF CHINA

4. Contraindications:

- Under any circumstances, patients or users with chronic bronchitis or asthma should not use pneumatic polishing equipment for treatment, otherwise the exhaled gas and tooth powder may cause breathing difficulties for the patients or users.
- People with allergies may be allergic to dental sandblasting powder. If an allergic reaction is observed, please stop using this product and completely remove the dental powder from the mouth immediately.
- Periodontal pocket treatment may lead to

bacterial infection. For patients at the following risk conditions (endocarditis, pregnant women, breast feeding, contact infectious diseases), immune deficiency (neutropenia, granulocytopenia, diabetes, hemophilia), and patients undergoing treatment (radiotherapy, chemotherapy, antibiotic treatment), please take appropriate protective measures.

- Do not aim the nozzle of the sand blasters at dental fillings, crowns or dentures, as this may cause damage to these restorations.
- Patients with severe periodontal disease are advised to eliminate the inflammation before sandblasting treatment.

5. Scope of application: Used in the oral cavity to grind and polish tooth tissue or prostheses to make their surfaces smooth and uniform. This product is not sterile.

6. Safety data sheet: please refer to File No.: VRN-SDS-001 for detail.

7. Storage conditions: temperature: – 10 °C to 40 °C , relative humidity: 10% to 95%, sealed

storage.

8. Shelf life: Expiry date for bottle opening: After bottle opening, the bottle cap needs to be tightly closed, and the expiration date for bottle opening under specified storage conditions is 3 months.

Note:

- Patients on a low salt diet must not be treated with the powder containing sodium bicarbonate. For patients on a low salt diet use the powder without sodium bicarbonate provided by VRN.
- The powder containing sodium bicarbonate provided by VRN can be used only for supra-gingival application. For sub-gingival application, please use the specific powder provided by VRN and refer to its operation instructions.
- Never use an abrasive powder i.e. alumina based. This would damage the unit.

17. Product disposal

1. For metals and metal compounds, please put them to the waste sorting recycling bin of metals.
 2. For nonmetal, please put them to the waste sorting recycling bin of organic substances which are not used as solvents, which can be used for composting and other biological transformation processes.
 3. Powder shall be disposed and destroyed according to relevant local regulations after expiration, and shall not be discarded in drainage ditches or rivers or mixed with household garbage.
-  Please recycle where facilities exist. Check with your local authority or retailer for recycling advice if you are unclear.