

Instructions for use




PATTERSON[®]
DENTAL

PD-95 RM
PD-20 RM, PD-43, PD-58
PD-68

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WARNING!
[risk of injury]



CAUTION!
[to prevent damage
occurring]



General
explanations,
without risk to
persons or objects



Disposable
article



Do not dispose of
with
domestic waste

Symbols

on the medical device / packaging



Sterilizable up to the stated temperature



Catalog number



Serial number



DataMatrix Code for product information including UDI (Unique Device Identification)



Caution! Federal law restricts this device to sale by or on the order of a dentist, physician, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

1. Introduction

This medical device has been developed, manufactured and subjected to final inspection according to legal regulations, quality and industry standards.

For your safety and the safety of your patients

Prior to initial use please read the instructions for use completely; they explain how to use your medical device and ensure proper, efficient and safe operation.



Observe the safety notes.

Intended use

The dental turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration of surfaces.

The air motor is particularly suitable for the following applications: Drive for dental transmission instruments for dental restoration and prophylaxis. Supply of dental transmission instruments of drive air, cooling air and coolant.

The straight and contra angle handpiece is intended for the following applications: Removal of decayed materials, cavities and crown cement, removal of fillings, finishing of tooth and restoration of surfaces.

The prophy contra angle handpiece is particularly suitable for the following applications: Cleaning and polishing of the tooth surface and fillings.



Misuse may damage the medical device, 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 medical device on the dentists, dental hygienists, dental employees (prophylaxis) and dental assistants target group.

Responsibility of the manufacturer

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

- > The medical device must be used in accordance with these Instructions for use.
- > Only the components approved by the manufacturer may be replaced (see maintenance chapter).
- > The medical device has no components that can be repaired by the user.
- > Repairs must only be undertaken by an authorized Patterson repair location.



Skilled application

The medical device is intended for use only by trained dental or medical practitioners for the purposes listed under the Indications for Use, in accordance with this document, the applicable health and safety regulations, and the valid accident prevention regulations.

The medical device should be prepared for use and maintained by staff who are trained in procedures for infection control, personal safety, and patient safety.

Improper use, (e.g., through poor hygiene and maintenance), noncompliance with our instructions, or the use of accessories, and spare parts that are not approved invalidates all claims under warranty and any other claims.



Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

Service

In the event of operating malfunctions immediately contact your local Patterson Representative or call your local Patterson Branch at 800-873-7683.

Repairs and maintenance work must only be undertaken by authorized Patterson repair locations.

2. Safety notes



- > The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- > Before using the medical device for the first time, store it at room temperature for 24 hours.
- > Use only the supply hoses as specified by EN ISO 9168.
- > 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 medical device must be stopped immediately.
- > Use only the filtered, oil-free and cooled air supplied by dental compressors for drive air.
- > Check the medical device for damage and loose parts before each use (e.g. push-button).
- > Do not operate the medical device if it is damaged.
- > Perform a test run before each use.



- > Avoid overheating at the treatment site.
- > Do not use the medical device if there are soft tissue wounds in the mouth. The air pressure can cause septic substances to enter the tissue or trigger embolisms.
- > Do not lift the cheek or tongue with the medical device. Risk of burning due to the push-button heating up!
- > Do not touch the soft tissue with the head of the medical device. Risk of burning if the medical device overheats!
- > It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the treatment water decontamination system, as well as its handling.

Hygiene and maintenance prior to initial use



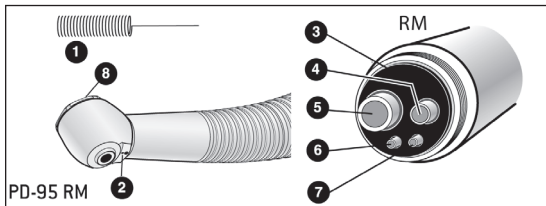
- > The medical device is sealed in PE film and not sterilized when delivered.
- > The PE film and the packaging are non-sterilizable.



- > Clean, disinfect and lubricate the medical device.
- > Sterilize the medical device and the cleaning wire.

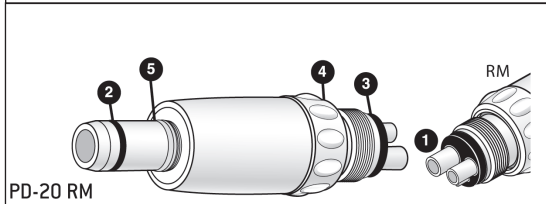
3. Product description

PD-95 RM, PD-20 RM



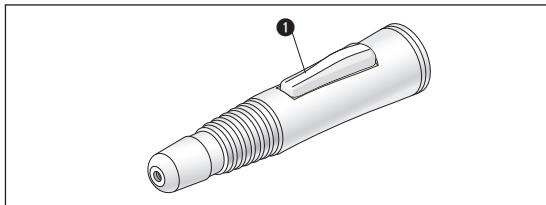
PD-95 RM

- ① Cleaning wire
- ② Spray ports
- ③ Seal
- ④ Drive air
- ⑤ Exhaust air
- ⑥ Spray air
- ⑦ Coolant
- ⑧ Push button PD-95



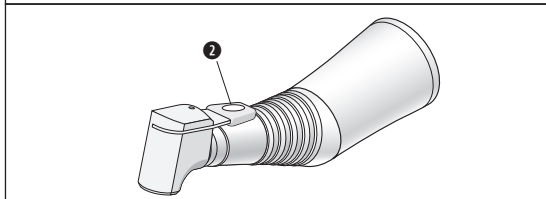
PD-20 RM

- ① Standard 4-hole
- ② O-ring
- ③ Seal
- ④ Union nut
- ⑤ ISO 3964 connection



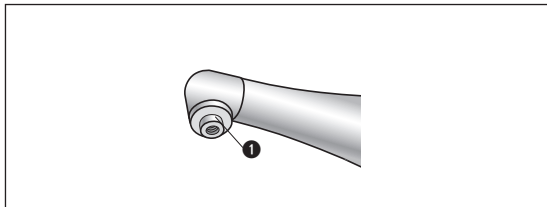
PD-43

① Chuck lever



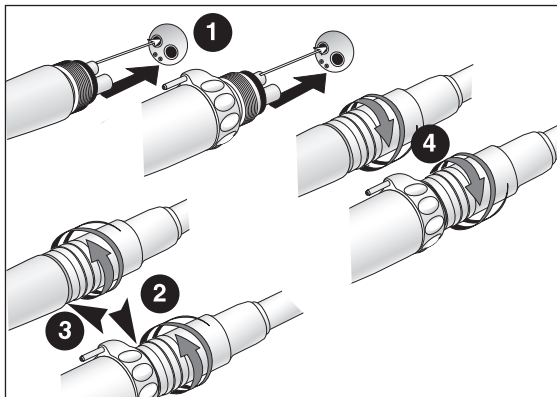
PD-58

② Latch




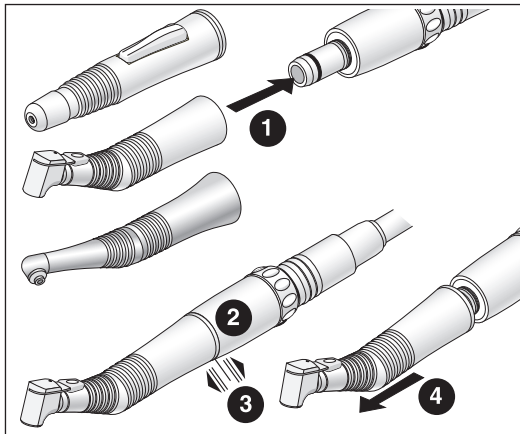
PD-68

① Thread



Do not assemble or remove the medical device during operation!

- 1** Insert the high-speed handpiece with RM connection into the openings in the handpiece tubing.
 - 1** Insert the air motor with RM connection into the apertures of the supply hose.
-  **2** Verify full engagement.
- 3** Firmly screw the union nut on in a clockwise direction.
 - 4** Check for leakages.
 - 5** Unscrew the union nut counterclockwise from the supply hose.



❶ Push the straight/contra angle handpiece onto the motor until it engages audibly ❷.



❸ Verify full engagement.

❹ Remove the straight/contra angle handpiece by pulling in an axial direction.

Rotary instruments (dental burs, cups, brushes)



- > Use only dental rotary instruments which are in perfect condition. Follow the operating instructions of the manufacturer. Insert the rotary instrument only when the medical device is stationary.
- > Insert the rotary instrument only when medical device is stationary.
- > Do not activate the medical device without a rotary instrument in place.
- > Do not activate the chucking system of the medical device during operation.
This leads to detachment of the rotary instrument, damage to the chucking system and/or heating up of the medical device. Risk of burning!
- > Only use rotary instruments up to the maximum operating speed stipulated by the manufacturer.

Changing cups and brushes

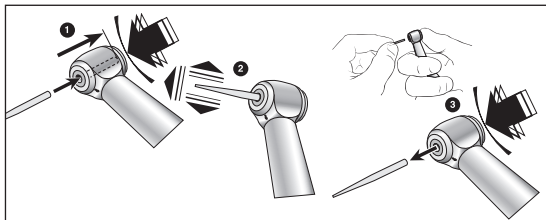


The prophy handpieces may only be run in a clockwise direction! In a counterclockwise direction the cups or brushes can become detached – leading to a danger of swallowing.



PD contra angle handpiece (Universal system)

> You can use any popular screw-in cups/brushes (screw thread 1-72 UNF 2A)



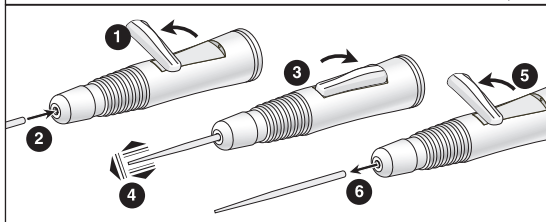
PD-95 RM

① Push the push button while simultaneously pushing in the dental bur as far as it will go.



② Verify full engagement.

③ Remove the dental bur by pushing the push button.



PD-43

① Open the chuck lever.

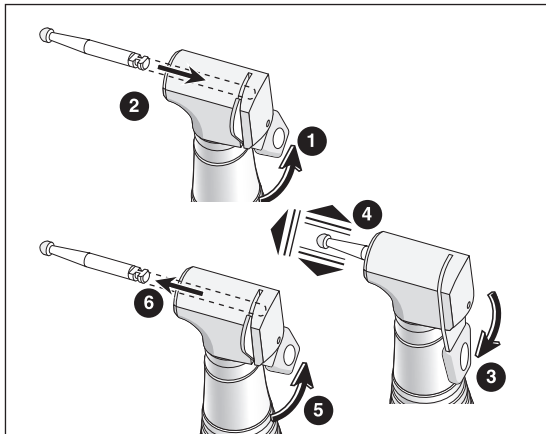
② Insert the dental bur up to the limit stop.

③ Close the chuck lever.




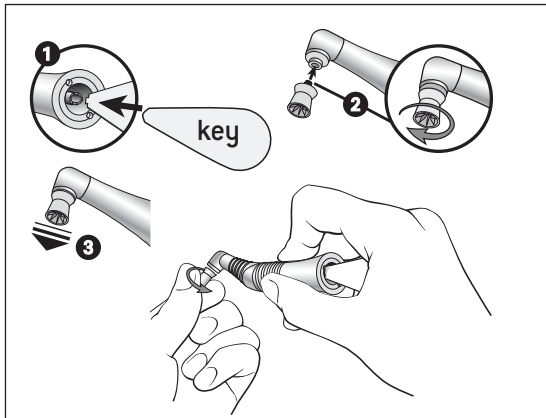
④ Verify full engagement.

⑤ Open the chuck lever and remove the dental bur ⑥.




PD-58

- 1 Open the latch.
- 2 Insert the dental bur up to the limit stop and turn until it engages.
- 3 Close the latch.
-  4 Verify full engagement.
- 5 Open the latch and remove the dental bur 6.




PD-86

Attaching screw-type disposable cups and brushes

 Only use once!

- 1** Block the handpiece drive by inserting the key in the driver.
- 2** Screw the cup or brush clockwise as far as possible into the thread of the handpiece head until it is firmly seated.

 **3** Verify full engagement.

Test run



Do not hold the medical device at eye level!

- > Insert the rotary instrument.
- > Operate the medical device.



In the event of operating malfunctions, such as vibrations, unusual noise, overheating, smell, coolant supply failure or leakage, **stop the medical device immediately** and contact an authorized Patterson repair location.



Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.



The information on the validated reprocessing methods serves as an example for an ISO 17664 compliant reprocessing of the medical device.



> Wear protective clothing, safety glasses, face mask and gloves.



> Use only oil-free, filtered compressed air with a maximum operating pressure of 43.5 psi (3 bar) for manual drying.



> The products PD-95 RM, PD-20 RM, PD-43, PD-58, PD-68 are not suitable for thermo disinfection.


Cleaning agents and disinfectants



- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
- > Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
- > It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
- > Use disinfectants which have been tested and found effective by the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA).




The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.


 The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.


- > Send worn or damaged medical devices and/or medical devices with material changes to an authorized service partner.

 **Processing cycles**

- > We recommend a regular service for the Patterson medical devices after 1,000 processing cycles or one year.

- 
- Clean and disinfect the medical device immediately after every treatment, to flush out liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.
- > Operate the medical device for at least 10 seconds at idle speed.
 - > Ensure that all outlets are rinsed out.

- 
- > Wipe the entire surface of the instrument with disinfectant.
 - > Remove the dental bur.
 - > Remove the high-speed handpiece from the hose.
 - > Remove the transmission instrument from the air motor.
 - > Remove the air motor from the supply hose.
 - > Remove the straight/contra angle handpiece from the air motor.

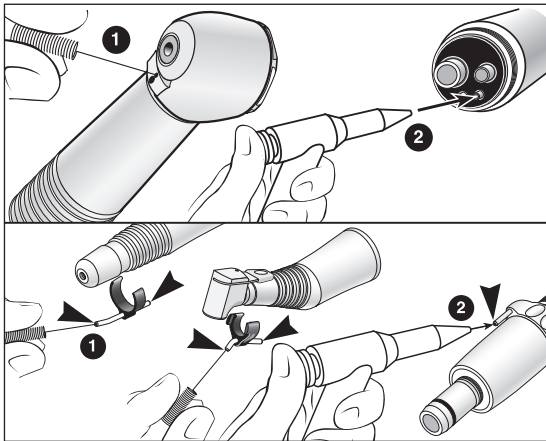


Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfectant step after cleaning.



Do not place medical device in liquid disinfectant or in an ultrasonic bath!

- > Clean the medical device under running tap water (<35°C / 95°F).
- > Rinse and brush off all internal and external surfaces.
- > Move moving parts back and forth several times.
- > Remove any liquid residues using compressed air.
- > When using the external coolant supply, remove the spray clip and the coolant hose.



Spray ports cleaning

- 1 Clean spray ports with the cleaning wire.
- 2 Blow through the coolant channel with the air syringe.

Clean PD-E kit

- 1 Clean the spray tubes with the cleaning wire and blow through using air syringe 2.



Clean and disinfect the cleaning wire in an ultrasonic bath/disinfection bath.



Patterson recommends wiping down with disinfectant.



Evidence of the medical device's basic suitability for effective manual disinfection (intermediate level) was provided by an independent test laboratory using the disinfectant "CaviWipes™" (Metrex).

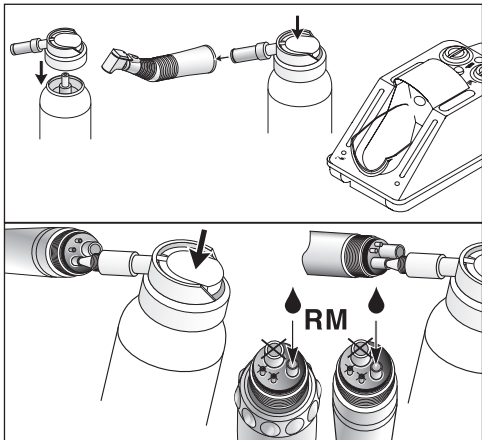


- > Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
- > Remove any liquid residues using compressed air.

Inspection



- > Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
- > Reprocess any medical devices that are still soiled.
- > Sterilize the medical device following cleaning, disinfection and lubrication.



Lubrication



- > Lubricate the dry medical device immediately after cleaning and/or disinfection.
- > Direct the medical device downwards.

Recommended lubrication cycles

- > Essential after every internal cleaning.
 - > Before each sterilization.
- or
- > After 30 minutes of use or at least twice daily.
 - > Chucking system once a week.

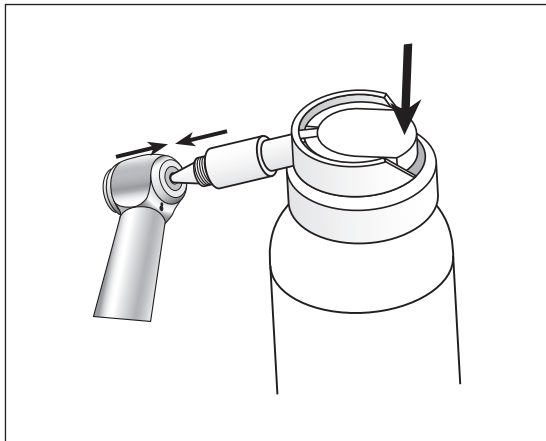
With a high quality handpiece lubricant 085-2715

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

or

With a general handpiece maintenance unit 035-4035

- > Follow the instructions in the Instructions for use of the maintenance unit.



Lubrication of the chucking system with a high quality handpiece lubricant

- > Fit the spray nozzle 089-3123 on the spray can.
- > Grip the high-speed handpiece firmly.
- > Press the tip of the spray nozzle firmly into the chuck system.
- > Spray for approx. 1 second.

Testing after lubrication




- > Direct the medical device downwards.
- > Operate the medical device so that excess oil can escape.
- > Remove any oil that has escaped.



Pack the medical device and the accessories in FDA cleared sterilization packages that meet the following requirements:

- > The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization method.
- > The sterilization package must be large enough for the sterilization goods.
- > The filled sterilization package must not be under tension.

 The manufacturer recommends sterilization according to ANSI/AAMI ST55, ANSI/AAMI ST79.

- 
- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
 - > The program selected must be suitable for the medical device.

Recommended sterilization procedures

- > “Dynamic-air-removal prevacuum cycle”
132°C (270°F) for at least 4 minutes
- > “Steam-flush pressure-pulse cycle”
132°C (270°F) for at least 4 minutes
- > Maximum sterilization temperature 135°C (275°F)



Evidence of the basic suitability of the medical device for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L steam sterilizer (W&H Sterilization S.r.l., Brusaporto [BG]) and the Systec VE-150 steam sterilizer (Systec).

“Dynamic-air-removal prevacuum cycle”: temperature 132°C (270°F) – 4 minutes

“Steam-flush pressure-pulse cycle”: temperature 132°C (270°F) – 4 minutes


Minimum drying times:

“Dynamic-air-removal prevacuum cycle”: temperature 132°C (270°F) – 30 minutes

“Steam-flush pressure-pulse cycle”: temperature 132°C (270°F) – 30 minutes

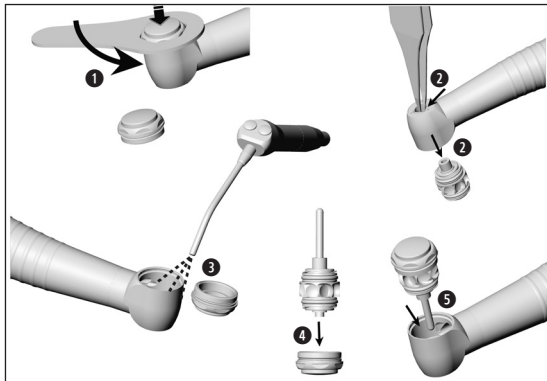
ISO 17665

ANSI/AAMI ST55, ANSI/AAMI ST79

- 
- > Store sterile goods dust-free and dry.
 - > The shelf life of the sterile goods depends on the storage conditions and type of packaging.

6. Maintenance

Changing the turbine PD-95 RM

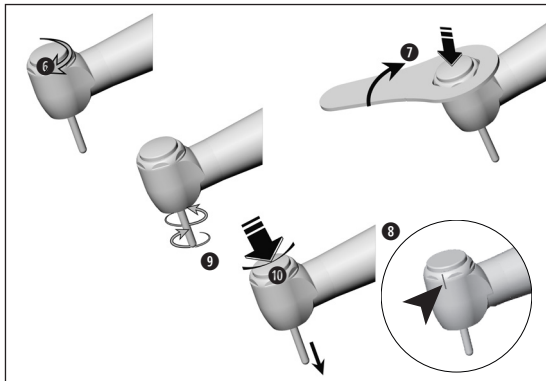


- 1 Unscrew the push-button using the hexagon wrench.
- 2 Push the turbine out of the turbine head using the tip of a pair of tweezers.



Clean the inside of the turbine head and the push-button with a cloth soaked in isopropyl alcohol.

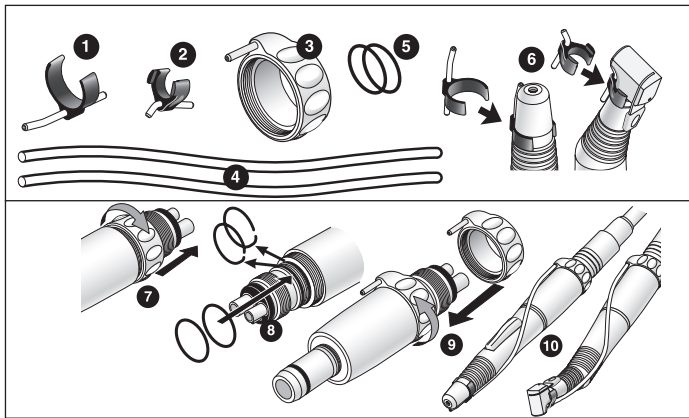
- 3 Blow dry the push-button and the turbine head with compressed air.
- 4 Place the new turbine into the push-button.
- 5 Place the turbine with the push-button into the turbine head.



- 6 Screw the push-button onto the turbine head.
- 7 Tighten the push-button using the hexagon wrench, turning it clockwise up to the mark. 8
- 9 Check free running of the chucking system.
- 10 Activate the push-button chuck and remove the mandrel.



- > Perform a test run.
- > Repeat the complete cleaning and maintenance process.



- ❶ Spray clip PD-43
- ❷ Spray clip PD-58
- ❸ Spray connection ring
- ❹ 2 x coolant hose
- ❺ 2 x O-ring
- ❻ Assemble spray clip onto PD-43/PD-58
- ❼ Screw off union nut
- ❽ Replace O-rings
- ❾ Screw on spray connection ring
- ❿ Assemble coolant hose



- > Perform a test run.
- > Repeat the complete hygiene and maintenance process.

7. Servicing

Repairs and returns

In the event of operating malfunctions immediately contact your local Patterson representative or call your local Patterson branch at 800-873-7683.

Repairs must only be undertaken by an authorized Patterson service partner.



> Ensure that the medical device has been completely processed before returning it.

8. Accessories and spare parts



Use only original Patterson accessories and spare parts or accessories approved by Patterson.

089-3123	Spray nozzle	040-4046	PD-95 RM spare high-speed handpiece
089-3131	Spray cap ISO	089-3180	PD-E spray kit
040-4004	PD-20 RM airmotor	089-3172	PD-95 RM Spare turbine kit
040-4020	PD-43 straight handpiece	089-3149	Seal RM
040-4012	PD-58 contra angle	089-3164	Cleaning wire
040-4061	PD-68 prophy angle	085-2715	Handpiece lubricant
089-3156	Plastic key for prophy angle	035-4035	Handpiece maintenance unit

9. Technical data

Turbine handpiece	PD-95 RM
Connection according to standard	EN ISO 9168 hose-side Ritter Midwest
Dental burs	EN ISO 1797 (∅ mm) 1.6 -0.01
Maximum length approved	[mm] 25*
Minimum chuck length	[mm] until back stop
Maximum operating part diameter	[mm] 2
Idle mode speed ($\pm 30,000$ rpm)	[rpm] 330,000
Coolant supply volume	ISO 14457 [gal/min] > 0.013
Water setting range (recommended water pressure)	[psi] 7.25 – 29***
Chip air setting range (must be higher than water pressure) (recommended chip air pressure)	[psi] 7.25 – 29***
Exhaust air pressure	[psi] < 7.25
Recommended operating pressure	[psi] 31.9-36.25
Air consumption	[l/min] 42

* see page 48

rpm = min^{-1} (Revolutions per minute)

Technical data

		PD-20 RM	PD-58	PD-43	PD-68
Coupling	Hose-side acc. to standard	ISO 9168			
Motor coupling		ISO 3964			
Speed range at 32 psi – 43.5 psi	(rpm)	20,000			
Maximum rated speed	(rpm)		20,000		
Stationary torque	(Ncm)	4			
Max. power	(W)	20			
Air consumption at 32 psi – 43.5 psi	(NI/min)	42 – 50			
Operating pressure	(psi)	31.9-43.5			
Transmission ratio			1:1		8:1
Dental bur EN ISO 1797	(ø mm)		2.35		
Approved length	(mm)		34 *	50 **	
Min. chuck length	(mm)		engaging	12 **	
Coolant supply volume E	(gal/min)	> 0.026 (ISO 14457)	> 0.013 (ISO 7785-2)		
Recommended setting range E	(psi)	7.25-29			

* see page 48

rpm= min⁻¹ (Revolutions per minute)



- * When using longer dental burs (or if the dental is not inserted up to the limit stop), the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.
- ** If the dental bur is not inserted up to the limit stop, the minimum chucking length must be maintained. In this case, or when using dental burs longer than 50 mm, the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

*** The chip air / water pressure must be set at the same time.
The chip air pressure must be higher than the water pressure.

Power and speed data of the medical devices are largely dependent on the quality of the turbine hoses used and may therefore differ from the specified values.

Temperature information



Temperature of the medical device on the operator side:

maximum 131°F (55°C)

Temperature of the medical device on the patient side:

maximum 122°F (50°C)

Temperature of the working part (dental bur):

maximum 105.8°F (41°C)

Ambient conditions

Temperature during storage and transport:

-40°F to +158°F (-40°C to +70°C)

Humidity during storage and transport:

8% to 80% (relative), non-condensing

Temperature during operation:

+50°F to +95°F (+10°C to +35°C)

Humidity during operation:

5% to 80% (relative), non-condensing

10. Disposal



Ensure that the parts are not contaminated on disposal.

Instrument disposal



Follow your local and national laws, directives, standards and guidelines for disposal.

- > Medical device
- > Packaging

Warranty

Patterson warrants all products in this document against defects in material or workmanship for one year from time of delivery. Patterson's sole obligation under the warranty is to provide parts for the repair, or at its option, to provide the replacement product (excluding labor). The buyer shall have no other remedy. All special, incidental and coincidental damages are excluded.

Written notice of breach of warranty must be given to Patterson within the warranty period. The warranty does not cover damage resulting from improper installation or maintenance, accident or misuse. The warranty does not cover damage resulting from the use of cleaning, disinfecting or sterilization chemicals and processes. Failure to follow instructions provided in the Patterson owner's guide (operation and maintenance instructions) may void the warranty.

No other warranties as to merchantability or otherwise are made.

Manufactured for:

**Patterson Dental Supply, Inc.
1031 Mendota Heights Road
St. Paul, MN 55120
pattersondental.com
800-873-7683**

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Rev. 003 / 05.08.2024
Subject to alterations**