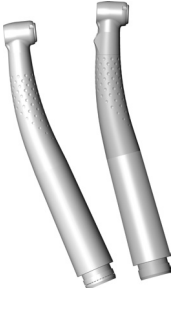
PEOPLE HAVE PRIORITY

W&H

Instructions for Use

Edition USA



CE
0297

primea

RK-97 L, RG-97 L

Contents

Symbols

in the Instructions for use

WARNING!
(risk of injury)

ATTENTION!
(to prevent
damage occurring)

General explanations,
without risk to
persons or objects

Do not dispose of with
domestic waste

Symbols

on the medical device / packaging

CE XXXX — CE marking with identification number of the Notified Body

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

HIBC — Data structure in accordance with Health Industry Bar Code

REF — Catalogue number

Thermo washer disinfectable

135°C — Sterilizable up to the stated temperature

SN — Serial number

c UL us — UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements

Date of manufacture

℞ only — Caution! According to Federal law, this medical device may only be sold by or on the order of a dentist, physician or any other medical practitioner licensed by the law of the State in which he or she practices and who intends to use or order the use of this medical device.

1. Introduction

Customer satisfaction has absolute priority in the W&H quality policy. 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. These explain how to use your medical device and guarantee a smooth and efficient operation.


Observe the safety notes.

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


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.

CE 0297

Production according to EU Directive
The medical device meets the requirements of Directive 93/42/EEC.

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.
> The handpiece has no components that can be repaired by the user.
> Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 46).

Skilled application
The medical device is intended only for skilled application according to the intended use as well as in compliance with the valid health and safety at work regulations, the valid accident prevention regulations and in compliance with these Instructions for use.

The medical device 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 these instructions or the use of accessories and spare parts that are not approved by W&H, invalidates all claims under warranty and any other claims.

2. Safety notes

> Before using the medical device for the first time, store it at room temperature for 24 hours.
> 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).

> 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.
> The leakage currents of the applied part must be kept.
> The secondary voltage in operation must be limited to a maximum of 4,2 V AC or 6 V DC.

- 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!

> Observe national and local guidelines on dental unit water line maintenance.
> Do not use the medical device as a light probe.
> Do not look directly into the LED.

RK-97 L, RG-97 L are not approved for operation in potentially explosive atmospheres.

Risks due to electromagnetic fields

RK-97 L, RG-97 L

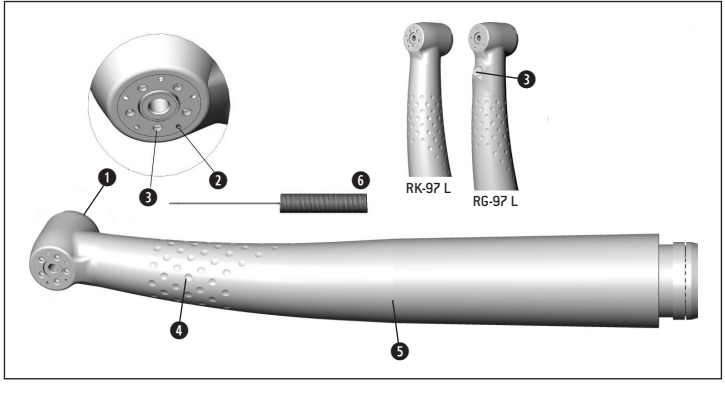
The functionality of implantable systems, such as cardiac pacemakers and cardioverter defibrillators (ICD) can be affected by electric, magnetic and electromagnetic fields.

> Find out if patient and user have implanted systems before using the medical device and consider the application and explain the circumstances to them.
> Weigh the risks and benefits.
> Keep the medical device away from implanted systems.
> Make appropriate emergency provisions and take immediate action on any signs of ill-health.
> Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD (implantable cardioverter defibrillator).

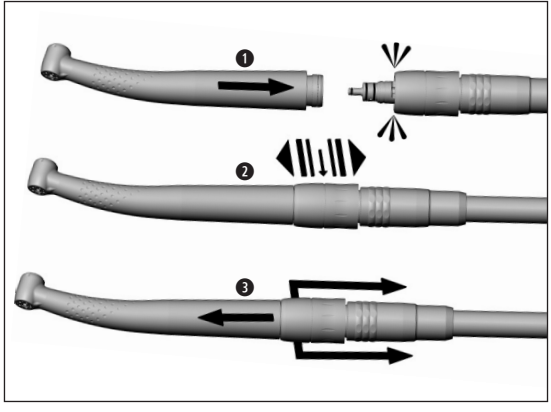
Hygiene and maintenance prior to initial use

> 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.



1. Push-button
2. Spray ports
3. LEDs
4. Grip profile
5. Sheath
6. Cleaning wire



Do not assemble or remove the medical device during operation!

❶ Push the medical device onto the Roto Quick coupling.

❷ Verify full engagement.

❸ Pull the retention sleeve of the Roto Quick coupling back and remove the medical device by pulling in an axial direction.

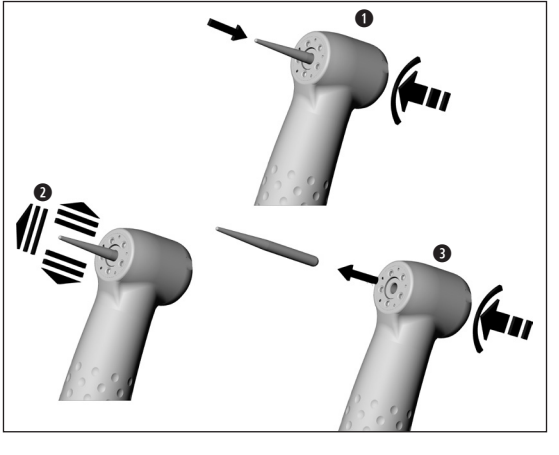
Rotary instruments

- > Use only rotary instruments which are in perfect condition. Follow the operating instructions of the manufacturer.
- > Insert the rotary instrument only when medical device is stationary.
- > Do not interfere with the running or slowing down of the rotary instrument.
- > Do not activate the push-button of the medical device during operation or slowing down. This leads to detachment of the rotary instrument resp. heating of the push-button (risk of injury).
- > Only use rotary instruments up to the maximum operating speed stipulated by the manufacturer.

Operation without W&H control unit

The functions of the medical device are limited, if it is not operated with a W&H control unit!

- > no speed control
- > RK-97 L: no light



To change rotary instrument

❶ Insert the rotary instrument.
Activate push-button, at the same time insert the rotary instrument until back stop.

❷ Verify a secure connection.

❸ Remove the rotary instrument by pushing the push-button.

Test run

Do not hold the medical device at eye level!

> Insert the rotary instrument.
> Start the medical device.

In the event of operating malfunctions (e.g. vibrations, unusual noise, overheating, coolant failure or leakage) stop the medical device immediately and contact an authorized W&H service partner.

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

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

> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar (43,5psi) for manual drying.

- > 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, for example by: the Verbund für Angewandte Hygiene e.V (VAH = Association for Applied Hygiene), the Österreichischen Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) or the U.S. Environmental Protection Agency (EPA).

It is the user's responsibility to validate the efficacy of cleaning agents and disinfectants if the above listed conditions are not met.

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 W&H service partner.

Processing cycles

> We recommend a regular service for the W&H medical device after 1,000 processing cycles or one year whatever is earlier.

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 only if heavy soiling occurs.

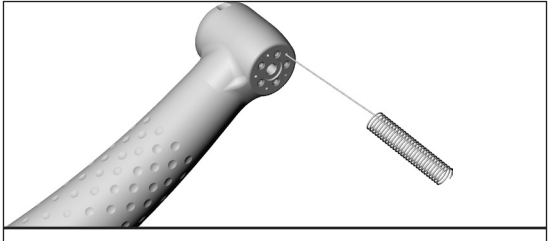
> Operate the medical device for at least 10 seconds at idle speed .
> Ensure that all outlets are rinsed out.

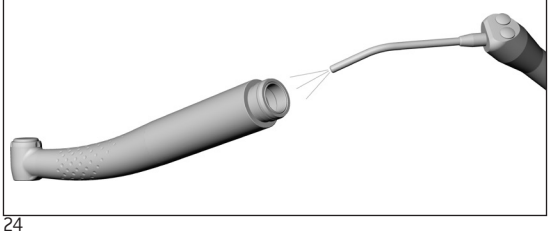
> Wipe the entire surface of the medical device with disinfectant.
> Remove the rotary instrument.
> Remove the medical device.

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

Do not place the 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.





Cleaning of the spray ports

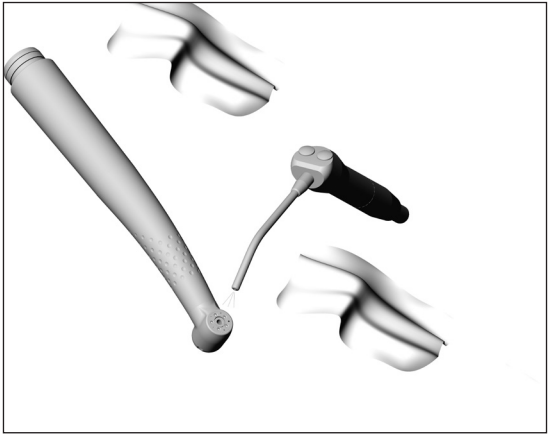
> Clean coolant outlets carefully with the cleaning wire to remove dirt and deposits if necessary.

The cleaning wire can be cleaned in an ultrasonic bath and/or in the washer-disinfector.

Cleaning of the coolant tubes

> Blow through the coolant tube using compressed air if necessary.

In case of blocked coolant outlets or coolant tubes contact an authorized W&H service partner.



Cleaning of the optic outlet

Avoid scratching of the optic outlet!

1. Wash the optic outlet with cleaning fluid and a soft cloth if necessary.
2. Blow the optic outlet dry using compressed air or dry it with a soft cloth if necessary.

> Carry out a visual inspection after each cleaning process.
> Do not use the medical device if the optic outlet is damaged and contact an authorized W&H service partner.

W&H recommends automated cleaning and lubrication with W&H Assistina TWIN.

> Follow the instructions in the Assistina Instructions for use.

> W&H recommends wiping down with disinfectant.

Evidence of the medical device's basic suitability for effective manual disinfection was provided by an independent test laboratory using the »mikrozid® AF wipes« disinfectant (Schülke & Mayr GmbH, Norderstedt).

W&H recommends automated cleaning and disinfection using a washer-disinfector (WD).

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of washer-disinfectors, cleaning agents and/or disinfectants.

Evidence of the medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Miele PG 8582 CD« washer disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) according to ISO 15883.

> Cleaning at 55°C (131°F) – 5 minutes
> Disinfection at 93°C (200°F) – 5 minutes

> 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 once daily.
> Chucking system once a week.

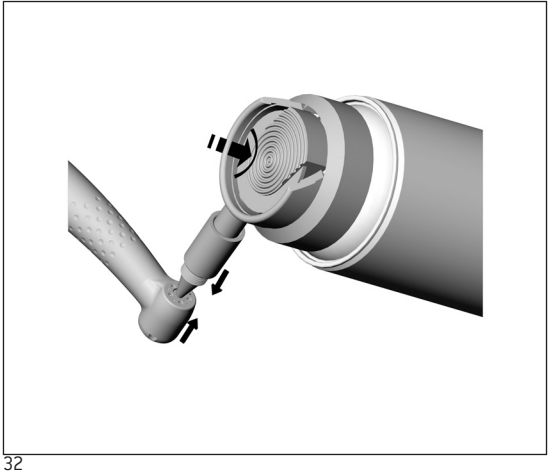
With W&H Service Oil F1, MD-400

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

or

With W&H Assistina

> Follow the instructions in the Assistina Instructions for use.



Lubrication of the chucking system

With W&H Service Oil F1, MD-400

> Fit the spray adaptor REF 02036100 onto the spray can.
> Hold the medical device firmly.
> Press the tip of the spray adaptor firmly into the chucking system.
> Spray for approx. 1 second.

or

With W&H Assistina TWIN / Assistina 301 plus

> Follow the instructions in the Assistina Instructions for use.

Testing after lubrication

> Direct the medical device downwards.
> Operate the medical device so that excess oil can escape.
> Remove excess oil.

Pack the medical device and the accessories in 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.

W&H recommends sterilization according to EN 13060, EN 285 or 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 (type B)
> Steam-flush pressure-pulse cycle (type S)
> Gravity displacement cycle (type N)
> Sterilization time at least 3 minutes at 134°C (273°F) or 4 minutes at 132°C (270°F) or 30 minutes at 121°C (250°F)
> Maximum sterilization temperature 135°C (275°F)

Evidence of the medical device's basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 522* steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)), Systec VE-150 steam sterilizer (Systec) and the Siroclav S3** gravitation sterilizer (Sirona).

> Dynamic air removal prevacuum cycle (type B)/
Steam-flush pressure-pulse cycle (type S): temperature 134°C (273°F) – 3 minutes* or
temperature 132°C (270°F) – 4 minutes*/**

> Gravity displacement process (type N): temperature 121°C (250°F) – 30 minutes** or
temperature 132°C (270°F) – 15 minutes**

* EN 13060, EN 285, 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. Servicing

Repairs and returns
In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

> Ensure that the medical device has been completely processed before sending it in for service.

7. W&H Accessories and spare parts

Use only original W&H accessories and spare parts or accessories approved by W&H.
Suppliers: W&H partners

000301xx	W&H Assistina 301 plus
19922000	W&H Assistina 3x2 (MB-200)
19923000	W&H Assistina 3x3 (MB-300)
30310000	W&H Assistina TWIN (MB-302)
02690400	Assistina adaptor for all W&H products with Roto Quick system
02693000	Assistina adaptor for chucking system
10940021	W&H Service Oil F1, MD-400 (6 pcs)
02038200	Spray cap for straight and contra-angle handpieces
02036100	Spray cap for chucking system
02015101	Cleaning wire

Operate the medical device with W&H control unit and RQ-24/RQ-34 coupling.

RK-97 L, RG-97 L			RK-97 L		RG-97 L	
Light			yes		yes	
Coupling according to standard	EN ISO 9168:2009 hose-side		W&H Roto Quick		W&H Roto Quick	
Instrument shaft diameter	ISO 1797 (Ø mm)		1.6 – 0.01		1.6 – 0.01	
Maximum length approved by W&H *	(mm)		21		21	
Maximum operating part diameter	(mm)		2		2	
Minimum chuck length			until limit stop		until limit stop	
Speed range	(rpm)		60,000 – 320,000		60,000 – 320,000	
Operating pressure	(bar)	(psi)	variable		variable	
Exhaust air pressure	(bar)	(psi)	< 0.8	< 11.5	< 0.8	< 11.5
Air consumption at an operating pressure of 5.5 bar / 79,8 psi:	(Nl/min)		75		75	
Water setting range (recommended water pressure) **	(bar)	(psi)	0.7 – 2 (1.5)	10 - 29 (22)	0.7 – 2 (1.5)	10 - 29 (22)
Chip air setting range (recommended chip air pressure) **	(bar)	(psi)	1.5 – 3 (2)	22 - 43.5 (29)	1.5 – 3 (2)	22 - 43.5 (29)
Coolant supply volume	ISO 14457 (ml/min)		> 50		> 50	
Chip air consumption at 2 bar / 29 psi	(Nl/min)		> 1.5		> 1.5	
Supply voltage	(V DC or V AC)		variable		variable	
Current consumption	(A)		variable		variable	

* see page 42

RK-97 L, RG-97 L			RK-97 L		RG-97 L	
Light			no		yes	
Coupling according to standard	EN ISO 9168:2009 hose-side		W&H Roto Quick		W&H Roto Quick	
Instrument shaft diamenter	ISO 1797(0 mm)		1.6 – 0.01		1.6 – 0.01	
Maximum length approved by W&H *	(mm)		21		21	
Maximum operating part diameter	(mm)		2		2	
Minimum chuck length			until limit stop		until limit stop	
Idle mode speed (± 30.000)	(rpm)		400,000		400,000	
Operating pressure	(bar)	(psi)	3 ± 0.3	43.5 ± 4.5	3 ± 0.3	
Exhaust air pressure	(bar)	(psi)	< 0.5	< 7	< 0.5	
Air consumption	(Nl/min)		45		45	
Water setting range (recommended water pressure) **	(bar)	(psi)	0.7 – 2 (1.5)	10 - 29 (22)	0.7 – 2 (1.5)	10 - 29 (22)
Chip air setting range (recommended chip air pressure) **	(bar)	(psi)	1.5 – 3 (2)	22 - 43.5 (29)	1.5 – 3 (2)	22 - 43.5 (29)
Coolant supply volume	ISO 14457 (ml/min)		> 50		> 50	
Chip air consumption at 2 bar / 29 psi	(Nl/min)		> 1.5		> 1.5	
Supply voltage Roto Quick connection nominal	(V AC or V DC)		no light without W&H control unit		3.2/ -	
Supply voltage range	(V AC)				2.2 – 4.2/ -	
Supply voltage range	(V DC)				2.2 – 6/ -	
Current consumption Roto Quick connection	(A)				0.4/ -	

* see page 42

* When using longer rotary instruments, the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

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

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

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

Temperature information

Temperature of the medical device on the operator side:	maximum 55°C (131°F)
Temperature of the medical device on the patient side:	maximum 50°C (122°F)
Temperature of the working part (rotary instrument):	maximum 41°C (105.8°F)

Ambient conditions

Temperature during storage and transport:	-40°C to +70°C (-40°F to +158°F)
Humidity during storage and transport:	8 % to 80 % (relative), non-condensing
Temperature during operation:	+10 °C to +35°C (+50°F to +95°F)
Humidity during operation:	15 % to 80 % (relative), non-condensing

9. 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
> Waste electrical equipment
> Packaging

Explanation of warranty terms

This W&H 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 theinstructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 24 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 W&H!

Claims under warranty accompanied by proof of purchase, must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

24 months warranty

Authorized W&H service partner

Find you nearest W&H service partner at http://wh.com
Simply go to the menu option »Service« for full details. Alternatively please contact:

A-dec Inc., 2601 Crestview Drive, Newberg, OR 97132 USA
t +1.800.547.1883, **f** + 1.503.538.0276, www.a-dec.com

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