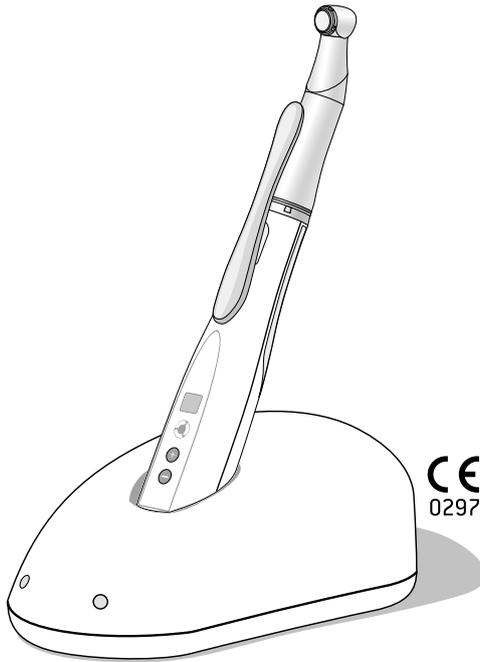


Instructions for use



Prosthetic screwdriver
IA-400

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W&H Symbols

Symbols in the Instructions for use



WARNING!
(risk of injury)



ATTENTION!
(to prevent damage occurring)



General explanations,
without risk to persons or objects



Thermo washer disinfectable



Sterilizable
up to the stated temperature



W&H Service

W&H Symbols

Symbols on rechargeable battery / charging station / contra-angle handpiece / handpiece drive

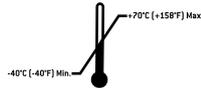
	Consult instructions for use		Not suitable for intracardiac application – Type BF applied part	REF	Catalogue number
	Class II equipment		Do not dispose of with domestic waste	SN	Serial number
	Date of manufacture		Data Matrix Code for product identification, e.g. in hygiene / maintenance process	V	Supply voltage of the unit
	CE 0297 from the manufacturer		MEDICAL – GENERAL MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1:2006, CAN/CSA-C22.2 No. 601.1-M90, CAN/CSA-C22.2-No. 60601-1:08, ANSI/AAMI ES 60601-1:2005. 25UX (Control No.)	AC	Alternating current
	Thermo washer disinfectable			A	Supply current
	Sterilizable up to the stated temperature			Hz	Frequency of the alternating current
	Not sterilizable				

W&H Symbols

Symbols on the packaging



This way up



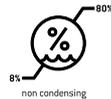
Temperature limits

R_xonly

Caution: Federal law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the device



Fragile, handle with care



Humidity limitation



Keep away from rain



CE 0297 from the manufacturer



»Der Grüne Punkt«
Identification mark of Duales System Deutschland AG



Data Matrix Code for product identification, e.g. in hygiene / maintenance process



General symbol for recovery/
recyclable

1. Introduction



For your safety and the safety of your patients

These Instructions for Use explain how to use your product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team, and of course, the safety of your patients are of paramount importance to us.



It is therefore essential to read the safety notes on Pages 11 to 16.

Intended use

The prosthodontic screwdriver is an electronically controlled screw system with adjustable torque for fixing and removing prosthesis retaining screws.

It consists of:

- a battery-operated handpiece drive
- a 80:1 mechanical transmission instrument (contra-angle handpiece)

Misuse may damage the prosthodontic screwdriver and hence cause risks and hazards for patients, users and third parties.

Introduction

Qualifications of the user

We have based our development and design of the prosthodontic screwdriver on the »dentists« target group.

Skilled application

The prosthodontic screwdriver is intended only for informed use in the medical dental field according to its purpose of use in compliance with the valid health and safety at work regulations and the valid accident prevention regulations as well as in compliance with these Instructions for use. The prosthodontic screwdriver 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 hygienic maintenance), non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

Introduction

CE **Production according to EU Directive**
0297 EU Directive 93/42/EEC has been used as a basis in the design and manufacture of this medical product and it applies to the

- > Prosthodontic screwdriver IA-400 consisting of handpiece drive, charging station, contra-angle handpiece and rechargeable battery Li-Ion 3.7 V

in the condition as supplied by us. This declaration does not apply to non-specified fittings, mountings etc.

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

- > The prosthodontic screwdriver must be used in accordance with these Instructions for use.
- > The prosthodontic screwdriver has no components that can be repaired by the user. Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see Page 47).
- > The electrical installation at the premises must comply with the regulations of IEC 60364-7-710 (»Installation of electrical equipment in rooms used for medical purposes«) or with the regulations applicable in your country.
- > Unauthorized opening of the equipment invalidates all claims under warranty and any other claims.

2. Electromagnetic compatibility (EMC)



Notes on electromagnetic compatibility (EMC)

Medical electrical equipment is subject to particular precautions with regards to EMC and must be installed and put into operation in accordance with the EMC notes included.

W&H guarantees the compliance of the device with the EMC requirements only when used with original W&H accessories and spare parts. The use of other accessories / other spare parts can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.



You can find the current EMC manufacturer's declaration on our website at

http://wh.com/en_global/emc

Alternatively, you can obtain it directly from the manufacturer.



HF communication equipment

Do not use any portable and mobile HF communication equipment (e.g. mobile telephones) during operation. These may affect medical electrical equipment.

3. Scope of delivery

After unpacking the following parts must be present:

Prosthetic screwdriver set IA-400, consisting of

- Handpiece drive IA-40 H with key pad
- Contra-angle handpiece IA-80 with hexagon chuck system
- Charging station IA-400
- Rechargeable battery Li-Ion 3,7 V REF 05451300
- Mains cable REF 05464400 (Europe)

Alternative specification

- Mains cable REF 05456100 (USA, CAN, J) / REF 05457700 (UK, IRL) / REF 05467600 (AUS, NZ)

4. Safety notes



It is essential to comply with the following instructions when using the prosthodontic screwdriver:

- > Before using the handpiece drive and the charging station for the first time, store it at room temperature for 24 hours.
- > Check the handpiece drive, the contra-angle handpiece, the charging station and the mains cable for damage and loose parts prior to every use. Correct any faults or refer to an authorized W&H service partner (see page 47). Do not operate the Prosthodontic screwdriver if it is damaged.
- > Always ensure the correct operating conditions.
- > Only use the W&H IA-80 contra-angle handpiece.
- > Only attach the contra-angle handpiece when the handpiece drive is stationary.
- > Perform a test run prior to each treatment.
- > Do not activate the press-button of the contra-angle handpiece during operation or slowing down.
This leads to detachment of the rotary instrument and overheating of the press button.
- > Do not place the Prosthodontic screwdriver on the patient!



Hygienic maintenance prior to initial use

- The prosthodontic screwdriver is in a clean condition when delivered.
- Disinfect the handpiece drive and the charging station (see Page 32).
- Sterilize the contra-angle handpiece and the key pad (see Page 36).

Safety notes



It is essential to comply with the following Instructions when using the rechargeable battery:

- > The Li-Ion 3.7 V rechargeable battery is not sterilizable.
- > Only use W&H rechargeable batteries with REF 05451300. Other types of rechargeable battery may lead to a risk of fire or explosion.
- > Only use the W&H rechargeable battery REF 05451300 in connection with the W&H handpiece drive IA-40 H and the W&H charging station IA-400.
- > The rechargeable battery used in the unit may cause a risk of fire or acid burns if not used properly (e.g. charging in a charging station other than the one provided).
- > The rechargeable battery must not be taken apart, heated to above 100 °C (212 °F) or burnt.
- > Do not short-circuit a rechargeable battery.
- > Do not subject rechargeable batteries to mechanical shock.
- > Defective or disused rechargeable batteries must be disposed of immediately.
- > In the event of a rechargeable battery leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- > Keep the rechargeable battery out of the reach of children.



Use only suitable and serviceable tools

Ensure that you comply with the manufacturer's instructions for prosthodontic screws with respect to maximum torque, proper use and forward/reverse operation.



Inappropriate use

Improper use, in addition to incorrect assembly, installation, modification or repairs of the prosthodontic screwdriver or non-compliance with our instructions invalidates all claims under warranty and any other claims.

Safety notes



Risks due to electromagnetic fields

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

- > Find out if patient and user have implanted device before using the product and consider the application.
- > Weigh the risks and benefits
- > Keep the product 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).

Safety notes



Danger zones M and G

In accordance with IEC 60601-1/ANSI/AAMI ES 60601-1, the prosthodontic screwdriver are not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.



Prosthodontic screwdriver is not suitable for use in oxygen enriched atmospheres.



Zone M is defined as a »medical environment« and constitutes the part of a room in which potentially explosive atmospheres may form due to the use of anaesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary. Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.



Zone G, also known as an »enclosed medical gas system«, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.

Safety notes

Prosthetic screwdriver (handpiece drive)

The unit is classed as »conventional equipment« (closed equipment without protection against the ingress of water).



The W&H handpiece drive IA-40 H is intended for use with the charging station IA-400. Use of other handpiece drives / charging stations could damage or destroy the electronics / the rechargeable battery.

Mains cable

Only use the mains cable supplied.



Set up the charging station so that the power switch is easily accessible.

In dangerous situations, the charging station can be disconnected from the power supply using the power switch or mains cable.

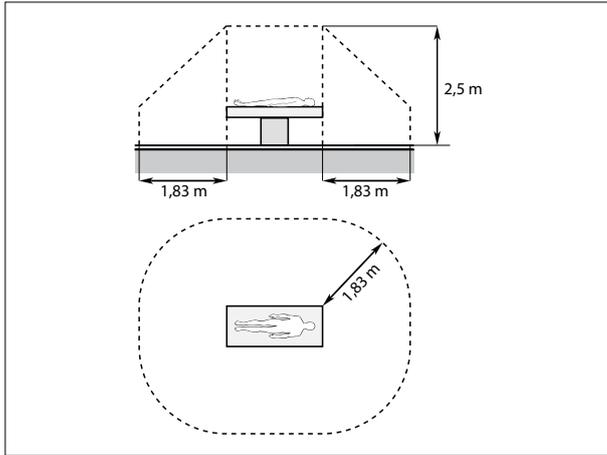
The power switch can also be used to safely stop the charging station.

System failure

A total system failure of the prosthetic screwdriver does not constitute a critical fault.

Simply switch the device off and then on again.

Safety notes

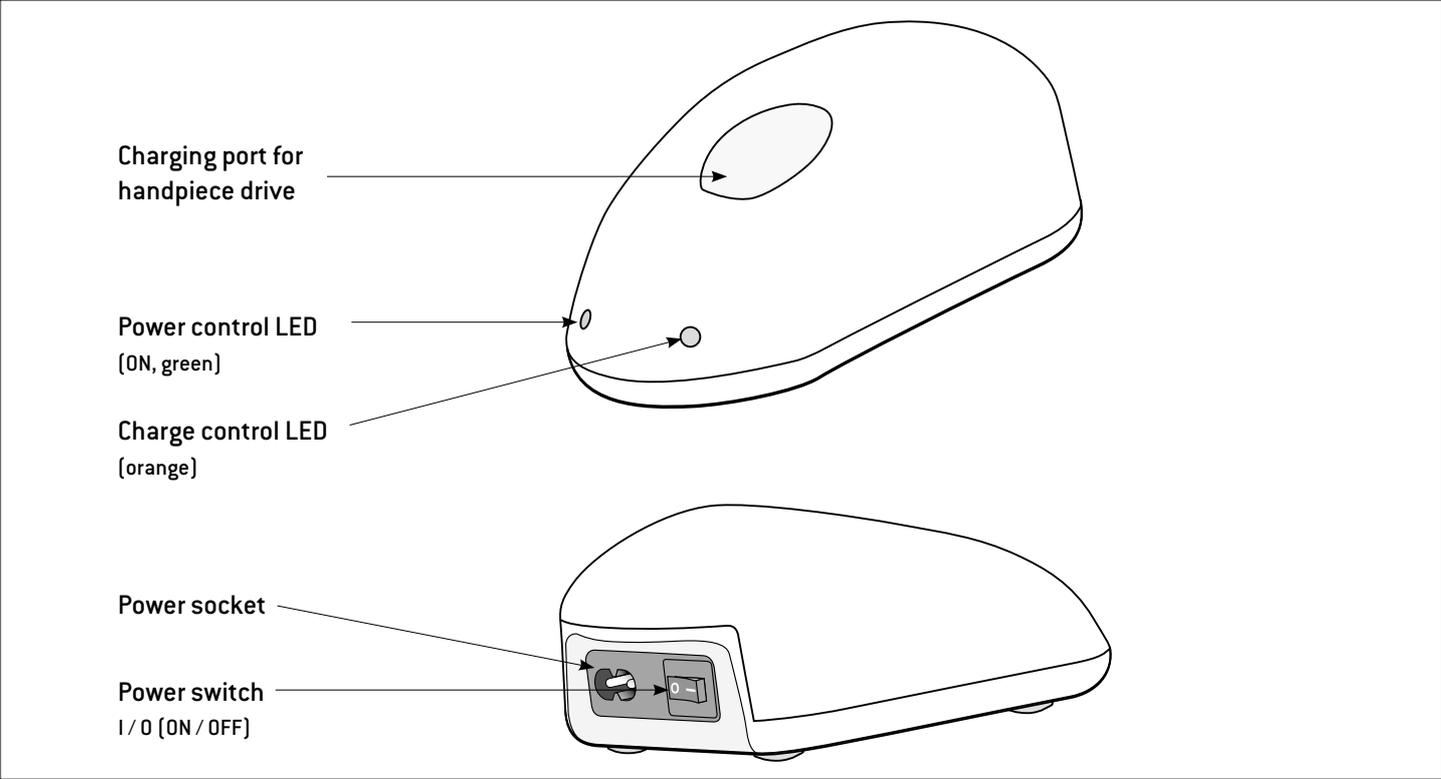


The patient's surroundings (see illustration) are deemed to be an area of 2.50 m above and 1.83 m around the patient.

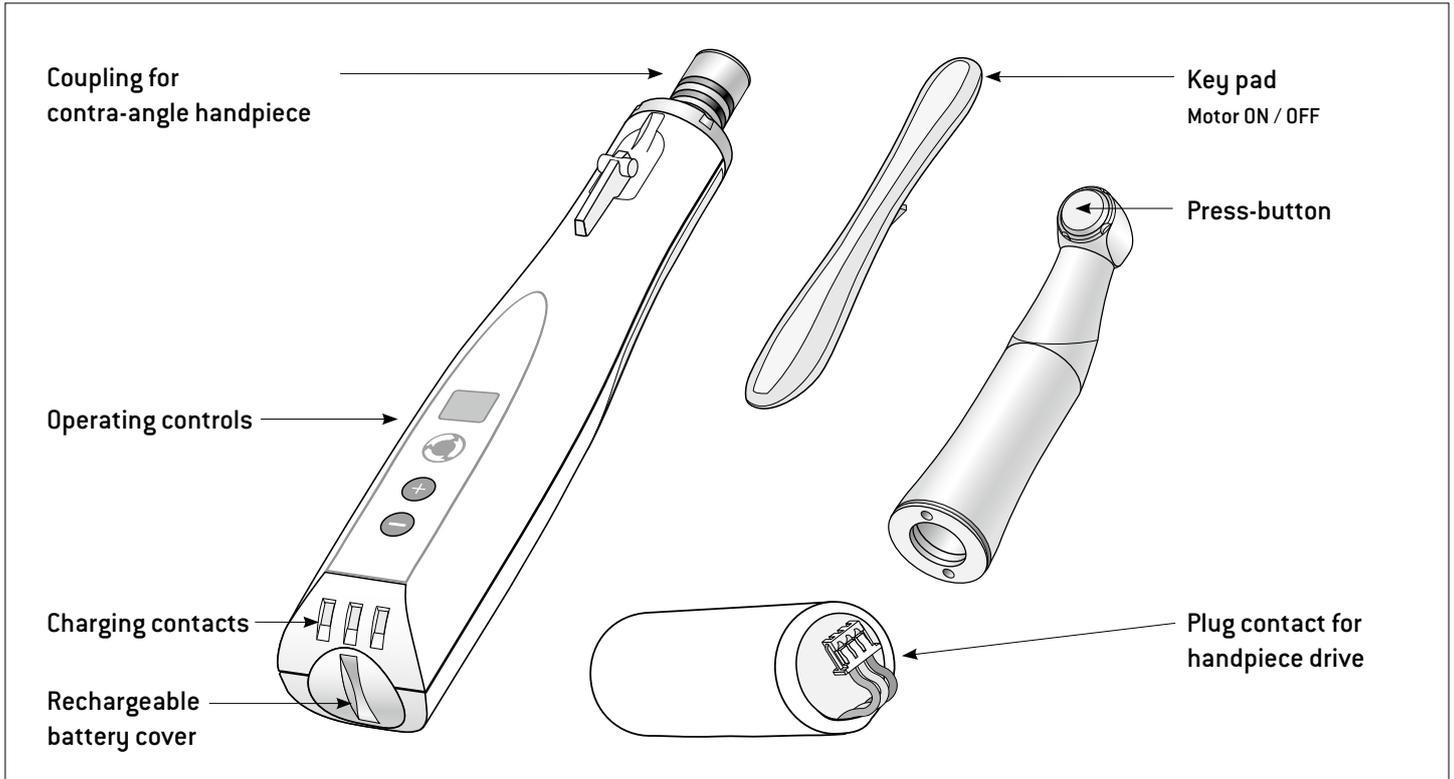


Do not use the charging station in the patient's surroundings.

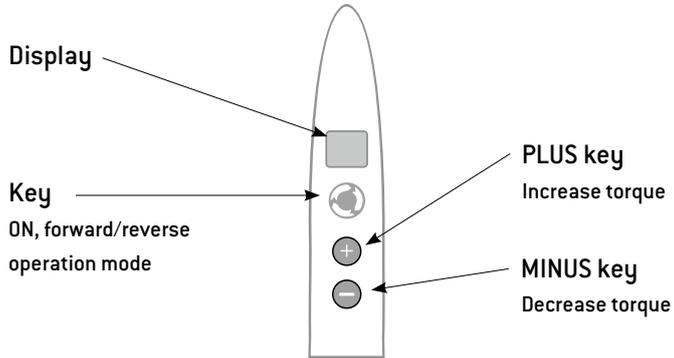
5. Description – Charging station



6. Description – Handpiece drive / Contra-angle handpiece / Rechargeable battery



7. Description – Operating controls



When the handpiece drive is switched on, the following displays can be seen:



❶ Display test »88«



❷ Rechargeable battery capacity display

❸ Last setting used

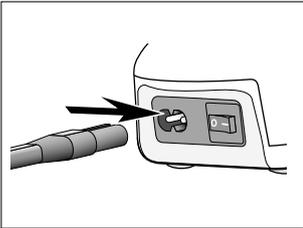
8. Starting operation – Charging battery



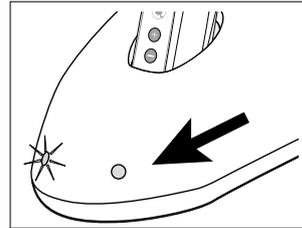
Always place the charging station on a flat level surface.

Ensure that the charging station can be disconnected easily from the power supply.

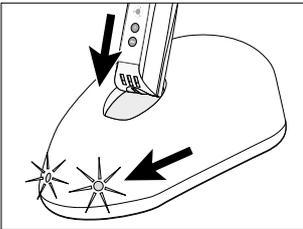
- > Charge the rechargeable battery completely before the first use. This will take about 100 minutes.
- > The handpiece drive can remain on the switched-on charging station until the next use.
- > If the rechargeable battery has enough capacity, the charge control LED (orange) will light up briefly (for about 1 sec.). Rechargeable battery is not charging.
- > If the rechargeable battery does not have enough capacity, the charge control LED (orange) lights up. Rechargeable battery is charging.



- 1 Plug the mains cable into the charging station.

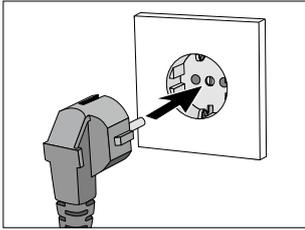


- 3 Rechargeable battery is charged.
Charge control LED (orange) goes out.



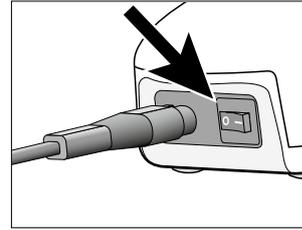
- 2 Place the handpiece drive in the charging station. Rechargeable battery is charging.
Charge control LED (orange) lights up.

9. Starting operation – switch on / switch off prosthodontic screwdriver



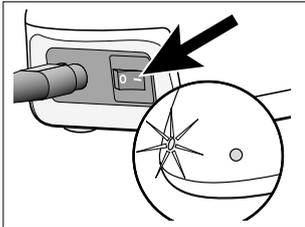
Switch on prosthodontic screwdriver

- 1 Connect the prosthodontic screwdriver to the power supply.

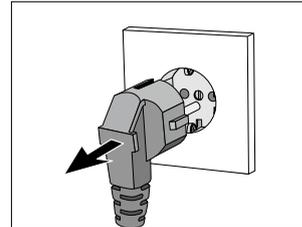


Switch off prosthodontic screwdriver

- 1 Turn the prosthodontic screwdriver off at the power switch.



- 2 Turn the prosthodontic screwdriver on at the power switch.
Power control LED (green) lights up.



- 2 Disconnect the prosthodontic screwdriver from the power supply.

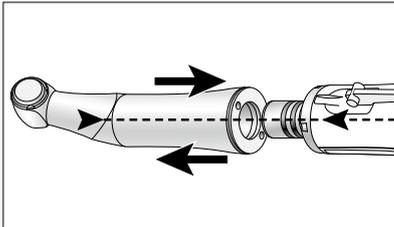
10. Starting operation – Assembly / removal of the contra-angle handpiece



The contra-angle handpiece must not be disassembled.
The contra-angle handpiece must not be oiled [lubricated for life].



Only change the contra-angle handpiece when the handpiece drive is stationary.



- 1 Attach the contra-angle handpiece by applying axial pressure [any position can be chosen].
- 2 Check the secure hold on the handpiece drive.
- 3 Remove the contra-angle handpiece by pulling in an axial direction.

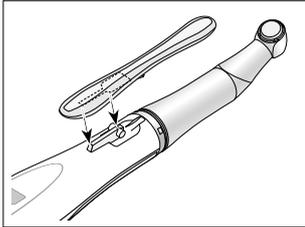


The contra-angle handpiece is defined as a type BF applied part.

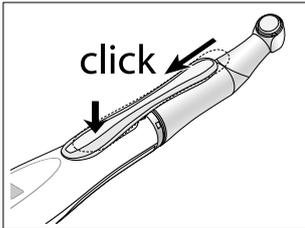
11. Starting operation – Assembly / removal of the key pad

 > When the key pad is activated, all keys are locked. The display lighting goes out.

Connect the key pad

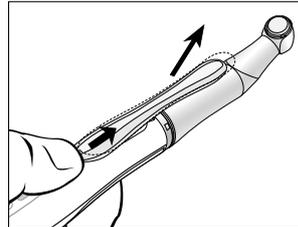


- 1 Insert the key pad into the guide rail.



- 2 Slide the key pad back as far as the stop.

Remove the key pad



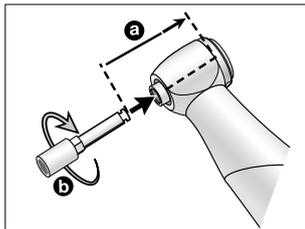
- 1 Slide the key pad off the guide rail.

12. To change rotary instrument (e.g. insertion tools)

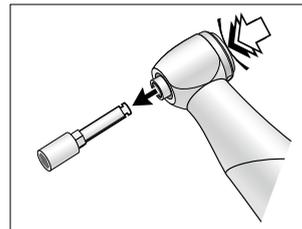


Rotary instruments

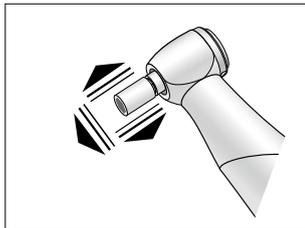
- > Use only rotary instruments which are in perfect condition and be careful when the rotary instrument is rotating. Follow the operating instructions of the manufacturer.
- > Insert rotary instruments only when the contra-angle handpiece is stationary.
- > Do not interfere with the running or slowing down of rotary instruments.



- 1 Insert the rotary instrument until back stop [a] and turn the rotary instrument until it engages [b].



- 3 Remove the rotary instrument by pushing the press-button.



- 2 Check secure location by applying slight axial tension.

13. Test run

- > Plug the contra-angle handpiece into the handpiece drive.
- > Insert rotary instrument.
- > Start the handpiece drive.
- > If you observe problems (e.g. vibrations, unusual noises, overheating), **stop the handpiece drive immediately** and contact an authorized W&H service partner (see Page 47).

14. Operation – Setting the torque

-  > The torque can only be set when the handpiece drive is stationary.
- > The handpiece drive switches off automatically 5 minutes after it has last been used.
- > The last torque setting is saved.

- > Adjustable range from 8 up to 40 Ncm. Keeping PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.



1 Increase torque in 1-Ncm-steps



1 Decrease torque in 1-Ncm-steps

14. Operation – Switching between forward / reverse operation mode



> By pressing the  key, it is possible to switch between forward and reverse operation mode.

Reverse operation

- 1 Press the  key.
- 2 »LL« will appear on the display.



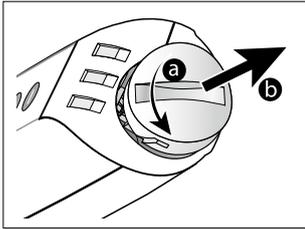
The max. torque (40 Ncm) is set and cannot be changed.

Switching to forward operation

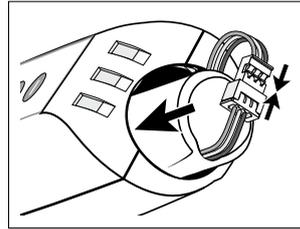
- 1 Press the  key.
- 2 The last torque set will appear on the display.

16. Replacing the rechargeable battery

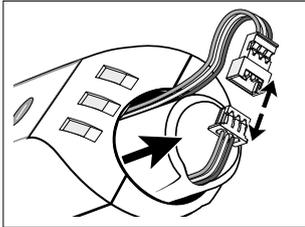
 Replace the rechargeable battery when the capacity decreases relatively quickly following full charging.



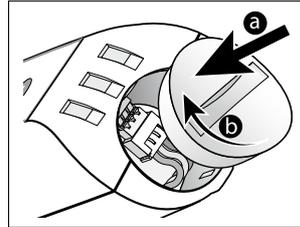
1 Remove rechargeable battery cover.



3 Insert the new rechargeable battery. Connect the plug contacts.
 Note the positioning!



2 Disconnect the plug contacts. Remove rechargeable battery.



4 Close rechargeable battery cover.
 Note the positioning!

17. Troubleshooting

Handpiece drive

Display	Description	Remedy
--	Rechargeable battery empty, torque cannot be reached	Charge rechargeable battery
00	Torque has not been reached, key pad is blocked	Press  key
Er	System fault, key pad is blocked	Press  key
FF	System failure	Send to an authorized W&H service partner
°C	Temperature too high	Leave handpiece drive to cool for at least 5 minutes at least 5 minutes
	Handpiece drive cannot be switched on	Charge or replace rechargeable battery
	Rechargeable battery overheats	Replace rechargeable battery

Troubleshooting

Charging station

Description	Remedy
Charge control LED (orange) flashes	Remove handpiece drive and insert again
Charge control LED (power / charge) does not light up.	Plug in mains cable, switch on power switch



If one of the error messages described cannot be remedied using the solutions above, then an inspection must be carried out by an authorized W&H service partner (see page 47).

18. Hygiene and maintenance



- > Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilization.
- > The contra-angle handpiece and the key pad can be prepared manually or mechanically.



- > Wear protective clothing.
- > Remove the mains cable from the charging station.
- > Remove the contra-angle handpiece from the handpiece drive.
- > Remove the rotary instrument.
- > The handpiece drive and charging station have not been approved for mechanical cleaning (thermo washer disinfectant) and sterilization.

- > Clean and disinfect the contra-angle handpiece **immediately after every treatment** to rinse out any liquids (e.g. saliva etc.) that may have entered and to prevent the internal parts seizing up.
- > Clean and disinfect the handpiece drive and the key pad **immediately after every treatment**.

- > Sterilize the contra-angle handpiece and the key pad following manual or mechanical cleaning and disinfection.

Hygiene and maintenance

Handpiece drive and charging station



> Do not immerse the handpiece drive and the charging station unit or clean it under running water.

Pre-disinfection

> If heavily soiled, clean first with disinfectant cloths.



Only use disinfectants that have no protein-fixing effects.

Manual cleaning and disinfection



The surface of the handpiece drive and the charging station may be wiped clean.

- > Disinfection using disinfectants or application of disinfectant by wiping is recommended.
- > Only use disinfectants which are certified by officially approved institutions and which do not contain chlorine.
- > Observe the manufacturer's recommendations regarding the use of disinfectants.



Ensure that no liquids penetrate the handpiece drive or charging station.

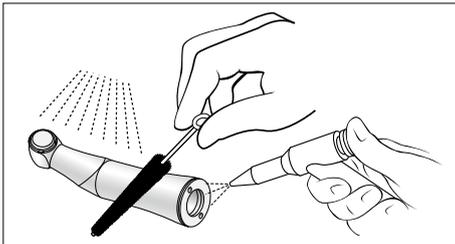
Hygiene and maintenance

Contra-angle handpiece and key pad

Pre-disinfection

> If heavily soiled, clean first with disinfectant cloths.

 Only use disinfectants that have no protein-fixing effects.



Manual cleaning (internal and external)

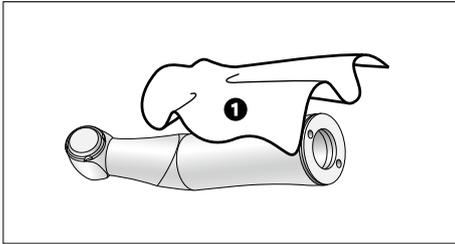
- ① Rinse under demineralized water (< 38 °C) with the aid of a brush.
- ② Remove any liquid residues (absorbent cloth, blow dry with compressed air).



Do not place the contra-angle handpiece or the key pad in liquid disinfectant or in an ultrasonic bath.

Hygiene and maintenance

Contra-angle handpiece and key pad



Manual disinfection



W&H recommends wiping disinfection.

- > Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.
- > Note the manufacturer's specifications for the use of the disinfectants.



After manual cleaning and disinfection, you must carry out a final thermal disinfection (unwrapped) or sterilization (wrapped) in the class B or S steam sterilizer (according to EN 13060).

Hygiene and maintenance

Contra-angle handpiece and key pad

Mechanical cleaning and disinfection internal and external



The contra-angle handpiece and the key pad can be cleaned and disinfected in a thermo washer disinfectant.



W&H recommends processing with thermo washer disinfectant.

Note the manufacturer's specifications on equipment, cleaning agents and detergents.



> Make sure, that the contra-angle handpiece is completely dry internally and externally after thermo washer disinfection. Remove any liquid residues with compressed air.

Hygiene and maintenance

Sterilization and storage



W&H recommends sterilization according to EN 13060, class B

- > Note the instructions of the unit manufacturer.
- > Clean and disinfect before sterilizing.
- > Wrap the contra-angle handpiece and key pad in sterile goods packaging according to EN 868-5.
- > Make sure, that you only remove dry sterile goods.
- > Store sterile goods dust-free and dry.

Hygiene and maintenance

Approved sterilization procedures



Follow your country-specific directives, standards and guidelines.

- > Steam sterilization class B with sterilizers in accordance with EN 13060.
Sterilization holding time a minimum of 3 minutes at 134 °C (273.2 °F)

or

- > Steam sterilization class S with sterilizers in accordance with EN 13060.
The sterilizer manufacturer must give its express approval for the sterilization of contra-angles.
Sterilization holding time a minimum of 3 minutes at 134 °C (273.2 °F)

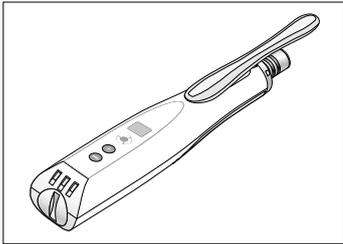


Before restart operation

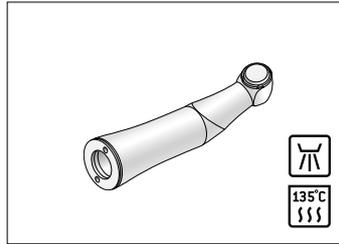
Wait until the contra-angle handpiece and the key pad have cooled down and are completely dry.

19. W&H Accessories

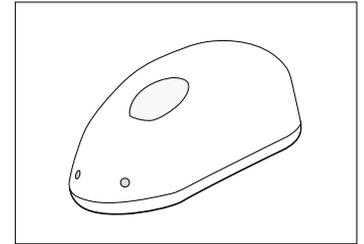
Use only original W&H accessories / spare parts
or accessories approved by W&H



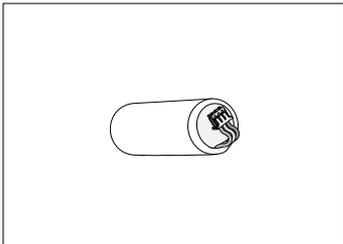
handpiece drive IA-40 H
with key pad



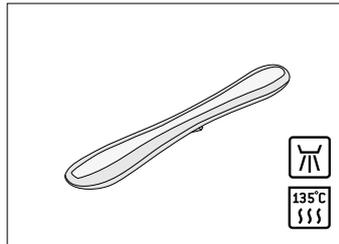
contra-angle handpiece IA-80



charging station IA-400



05451300
rechargeable battery Li-Ion 3,7 V



05937000
key pad

20. Servicing



Regular checking of the prosthodontic screwdriver

Regular servicing of function and safety of the prosthodontic screwdriver including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The inspection must be undertaken by a qualified organization and must include the following procedures:

Handpiece drive

- > Visual inspection for outside damage
- > Visual inspection of internal components and electronic boards on suspicion of safety interference, e. g. mechanical damage of the enclosure or indicators for overheated or burned (electronic) components
- > Functional test

Charging station

- > Visual inspection for outside damage
- > Measurement of enclosure leakage current
- > Visual inspection of internal components and electronic boards on suspicion of safety interference, e. g. mechanical damage of the enclosure or indicators for overheated or burned (electronic) components
- > Functional test

We recommend that only an authorized W&H service partner (see Page 47) should undertake this servicing and checking.

Servicing

Repairs

If any faults occur, always return the complete prosthodontic screwdriver, because an inspection of all components will be necessary!

Returns

- > Refer all questions to an authorized W&H service partner (see Page 47).
- > Always return equipment in the original packaging!

21. Technical data

Handpiece drive IA-40 H

Rechargeable battery type:	Li-Ion
Rated voltage:	3,7 V
Rated capacity:	680 mAh
Speed on the rotating instrument:	approx. 25 min ⁻¹
Torque levels on the rotating instrument:	8 – 40 Ncm in 1-Ncm-steps
Dimensions (WxDxH):	143 x 28 x 26 mm
Weight:	90 g

Charging station IA-400

Supply voltage:	100 – 240 V
Permitted voltage fluctuation:	± 10 %
Frequency:	50 – 60 Hz
Rated current:	0,08 – 0,12 A
Power:	5 W
Dimensions (WxDxH):	95 x 159 x 65 mm
Weight:	345 g

Technical data

Contra-angle handpiece IA-80

Transmission ratio:	80:1
Coupling type:	W&H coupling
Recommended rotary instruments*:	Use only the rotary instruments recommended by the manufacturer (e.g. insertion tools)
Instrument shaft diameter (type 1) in accordance with EN ISO 1797-1	∅ 2,35 mm*
Min. chuck length:	engaging
Weight:	55 g

* In choosing the correct operating conditions, the user must ensure that there is no risk to the user, the patient or third parties.

Physical characteristics

Temperature for storage and transport:	-40 °C [-40 °F] to +70 °C [+158 °F]
Air humidity for storage and transport:	8 % to 80 % (relative), non condensing
Ambient temperature during operation:	+10 °C [+50 °F] to +40 °C [+104 °F]
Air humidity during operation:	15 % to 80 % (relative), non condensing
Pollution level:	2
Overvoltage category:	II
Altitude:	up to 3,000 m above sea level

22. Recycling and disposal

Recycling

W&H considers that it has a special duty towards the environment. The prosthodontic screwdriver along with its packaging has been designed to be as environmentally friendly as possible.



Disposal of the prosthodontic screwdriver

(handpiece drive / rechargeable battery / charging station / contra-angle handpiece)

Follow your country-specific laws, directives, standards and guidelines for the disposal of used electrical devices.

Ensure that the parts are not contaminated on disposal.

Disposal of the packaging material

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. This way, you will contribute to the recycling of raw materials and the avoidance of waste.

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 the Instructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects from the date of purchase within a warranty period of

**24 months for the handpiece drive, the contra-angle handpiece and the charging station and
12 months for the rechargeable battery Li-Ion 3,7 V.**

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 / 12 months warranty

Authorized W&H service partner

Visit W&H in the Internet on <http://wh.com>

Under the menu option »Service« you can find your nearest authorized W&H service partner.

If you do not have internet access, please contact

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