

User's Manual

Tabletop

- ☐ US30m
- ☐ US30em
- ☐ US30 Unicorn
- ☐ US30 Double

Handpiece

- ☐ Ergo Basic
- ☐ Ergo Ultra
- ☐ Ergo UltraLight

Add-on equipment

- ☐ MD Unicorn
- ☐ MD Double



Important!

Read this manual carefully before using the product.

How to read this manual

This manual contains instructions for several models of scalers. Each chapter starts with a section with general instructions for all models, which is followed by sections with additional information concerning each model. First read the general section and then proceed to the section that applies to your model of scaler.

If there are any questions regarding the contents of this manual, please contact Amdent AB.

Trademarks

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Printed in Sweden, December 2005

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Safety

Intended use

This scaler is designed for dental purposes. It is designed for removal of tartar or calculus on teeth and other dental work where the ultrasonic vibration is beneficial. Do not use it for applications where it is not intended. If you are unsure about your application, please contact your local dealer or place of purchase.

General requirements

Installation and service of the product is only to be performed by authorized service personnel.

The product must be connected to electricity supply and water supply meeting the requirements specified in the **Technical data** section on page 33.

The product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the **Declaration of conformity** section on page 36.

Portable and mobile RF communications equipment can affect the product.

Contraindications

Do not use the scaler on patients with cardiac pacemakers. The scaler may disturb the function of the pacemaker.

General precautions

- The product is not suitable for use in the presence of flammable gases.
- Systemic antibiotics must be used appropriately and with the advice of a medical doctor.
- Only use the product in combination with Amdent scaler tips.
- If the handpiece tubing is damaged or worn-out, it must immediately be replaced to avoid exposing the user or the patient to electric hazard.
- Use the original packaging when returning equipment for service.

Warnings

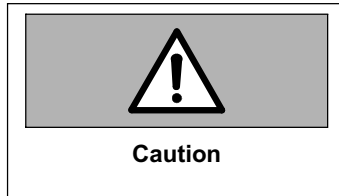
The product should not be used adjacent to or stacked with other equipment.

If adjacent or stacked use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.

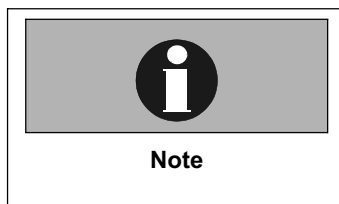
Safety notices in this manual



Warning indicates a potentially dangerous situation. Non-observance may lead to death or injury.



Caution indicates a potentially harmful situation. Non-observance may damage the equipment.



Note indicates a situation where special notice should be observed.

Consignes de securite (Canada)

Utilisation destinée

Cet écailleur ultrasonique de piezo est conçu pour des buts dentaires. Il est conçu pour le déplacement de tartar/calculus sur les dents et tout autre travail dentaire où la vibration ultrasonique est salutaire. N'utilisez pas l'écailleur pour des applications où on ne le destine pas. Si vous êtes incertain au sujet de votre application, contactez s'il vous plaît votre distributeur local et/ou où vous l'avez achetée.

Conditions générales

L'installation et le service du produit doit être exécutée seulement par le personnel de service autorisé avec les outils et le matériel appropriés.

Le produit doit être relié à l'approvisionnement de l'électricité et à l'approvisionnement en eau répondant aux exigences définies dans la section **Technical data** à la page 33.

Le produit exige des précautions spéciales concernant la CEM et doit être installé et mis en service selon la section **Déclaration de conformité** à la page 36.

L'équipement de communication RF portable et mobile peut affecter le produit.

Précautions générales

- Des antibiotiques systémiques doivent être utilisés convenablement et avec le conseil d'un docteur médical.
- Le produit n'est pas approprié pour l'usage en présence d'un mélange anesthésique inflammable.
- Utilisez seulement le produit en combinaison avec des extrémités d'écailleur d'Amdent.
- Si la tuyauterie de pièce à main est endommagée ou usée, elle doit immédiatement être substituée pour éviter d'exposer l'utilisateur ou le patient au risque électrique.
- Utilisez l'original empaquetant en renvoyant le matériel pour le service.

Avertissement

Le produit ne doit pas être utilisé à proximité ou stocké avec d'autres équipements.

Si l'usage ou le stockage à proximité est nécessaire, le produit doit être surveillé pour une utilisation normale suivant la configuration dans laquelle il sera utilisé.

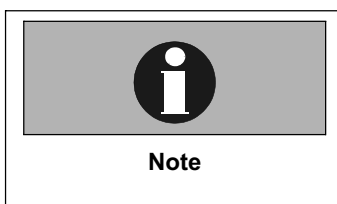
Notifications de sûreté en ce manuel



“*Warning*” indique une situation probablement dangereuse. La inobservance peut mener à la mort ou des dommages.



“*Caution*” indique une situation probablement nocive. La inobservance peut endommager le matériel.



“*Note*” décrit si on observe la notification spéciale.

1 Unpacking



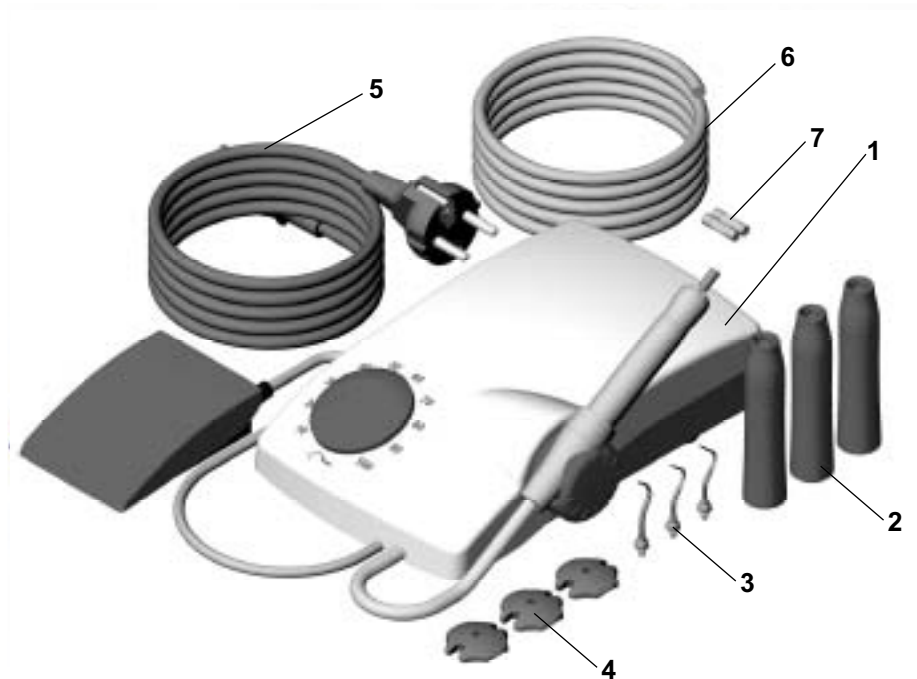
Note

This chapter describes the components of the delivery and can be used as a checklist when unpacking. Contact your place of purchase if anything is missing.

For a description of the features of the equipment, read the **Equipment description** section on page 13.

Carefully unpack your Amdent ultrasonic scaler and verify that all accessories and components are included according to the content lists below:

1.1 General content of delivery



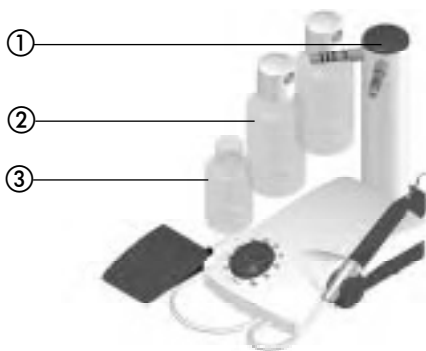
1. Scaler with handpiece and foot control
2. ErgoGrips (type and quantity depending on what was ordered)
3. Tips (type and quantity depending on what was ordered)
4. Tip wrenches (type and quantity depending on what was ordered)
5. Power cord
6. Water hose 1/4" (not included in US30 Unicorn and US30 Double)
7. Spare fuses

1.2 US30 Unicorn additional content



1. Medicament dispenser MD Unicorn
2. Medicament dispenser bottle (250 ml) with connector
3. Medicament dispenser bottle (125 ml)

1.3 US30 Double additional content



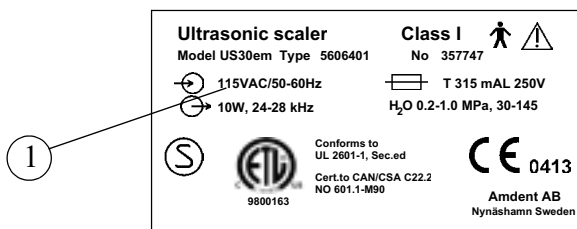
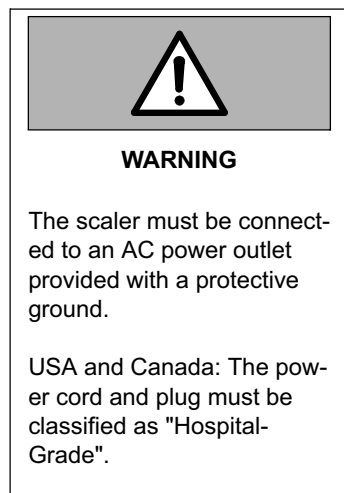
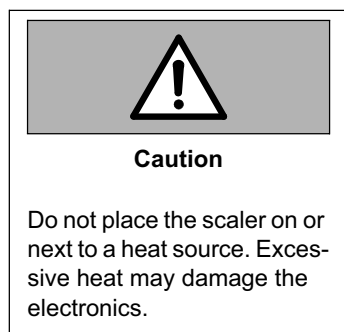
1. Medicament dispenser MD Double
2. Medicament dispenser bottle (250 ml) with connector (2 pieces)
3. Medicament dispenser bottle (125 ml)

2 Installation

2.1 General installation instructions

Checklist

- ☐ Position the scaler horizontally with the handpiece in the holder and the hose hanging free.
- ☐ Position the scaler where air is free to circulate on all sides and beneath it. Do not position the scaler on a wall or next to a heat source.
- ☐ Avoid placing the scaler in the immediate vicinity of sources of electromagnetic radiation, for example an electrosurgery equipment.
- ☐ Verify that the voltage rating on the type plate on the bottom side match the voltage of the AC power outlet.



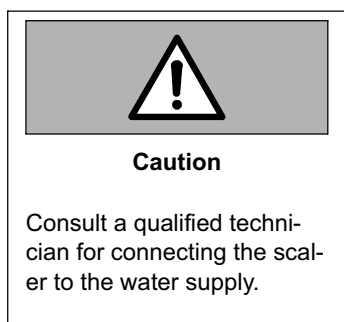
1. Example of voltage rating on the type plate.

- ☐ Verify that the AC power outlet is provided with a protective ground.
- ☐ Connect the power cord to the scaler and connect the power cord to the AC power outlet.

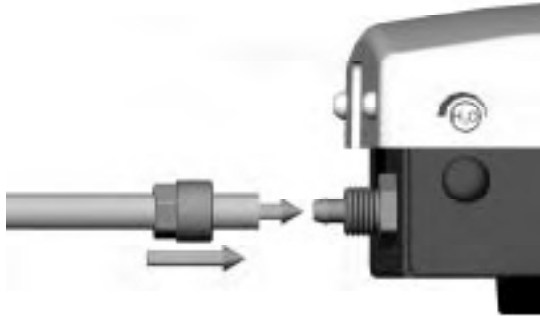
2.2 US30m and US30em additional instructions

Connecting to the water supply

1. Verify that the water supply can be turned off.
2. Verify that the water pressure conforms to the data in the **Water supply pressure** section on page 33.
3. Verify that the water supply fulfills the medical demands of hygiene.



4. Remove the red protection cap from the hose coupling nipple on the scaler.
5. Unscrew the nut from the nipple and thread it on the hose.
6. Push the hose onto the coupling nipple.



7. Tighten the nut firmly and insure that the hose is securely attached to the scaler.
8. Connect the other end of the hose to the water supply.

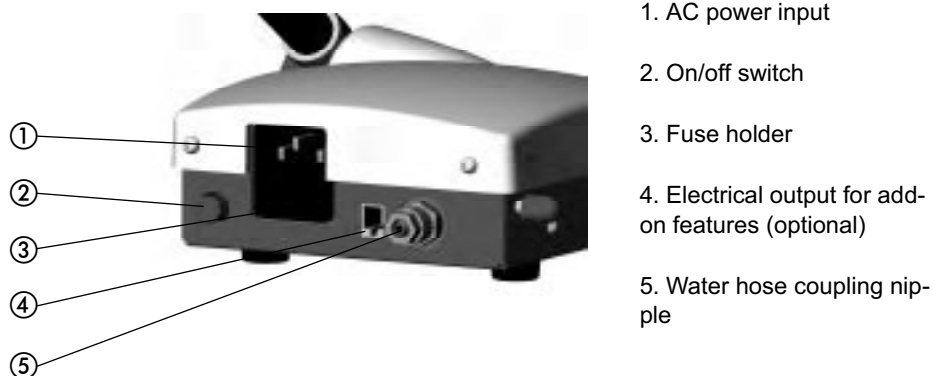
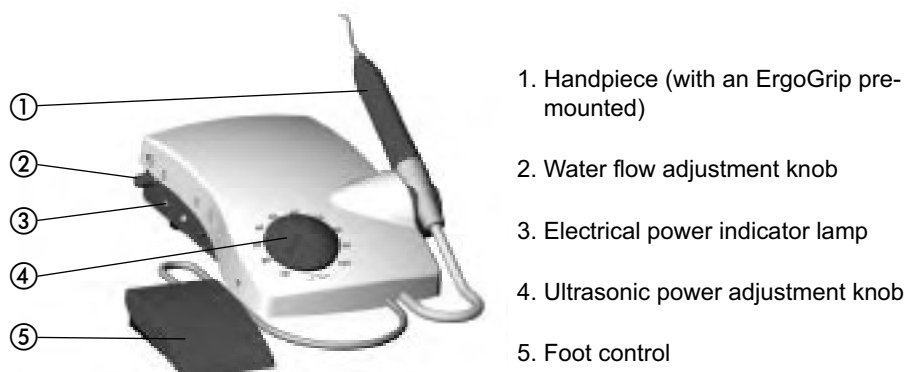
3 Equipment description

3.1 General description

The Amdent US30 series is a range of piezo ultrasonic scalers. The ultrasonic power can be regulated to provide a wide range of settings.

The US30 is equipped with one of the handpieces; Ergo Basic, Ergo Ultra or Ergo UltraLight. The tips can easily be changed during the treatment and can also be cleaned and autoclaved together with the individual ErgoGrips in the same procedure.

Some US30 models can be modified to add enhanced function. For more information, see the **Add-on features** section on page 25.



3.2 US30em additional description

US30em is equipped with an endo switch and have a special, low power range available when performing endodontic treatments.



1. Switch for endodontic/scaling mode
2. Endodontic mode indicator lamp (yellow)
3. Scaling mode position (right)
4. Endodontic mode position (left)

3.3 US30 Unicorn additional description

The Amdent US30 Unicorn is a freestanding piezo ultrasonic scaler including a medicament dispenser system, making the device independent of a fixed water supply connection. The bottle of the medicament dispenser can be used for either medicament solutions or ordinary clean water.

The dispenser unit contains an electrically driven air compressor. When operating the scaler, the compressed air forces the fluid from the bottle through the hose to the handpiece and the tip.



1. Medicament dispenser unit
2. Medicament dispenser bottle with connector
3. Depressurization button



WARNING

Systemic antibiotics must be used appropriately and only in consultation with a medical doctor.

3.4 US30 Double additional description



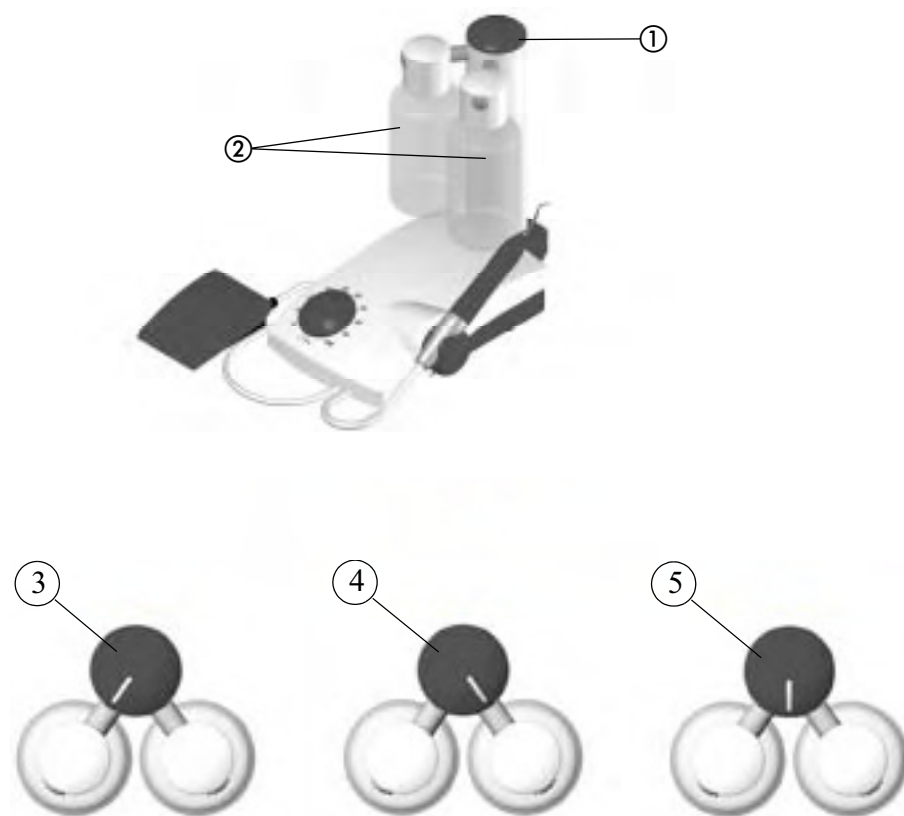
WARNING

Systemic antibiotics must be used appropriately and only in consultation with a medical doctor.

The US30 Double is a freestanding piezo ultrasonic scaler including a medicament dispenser system, making the device independent of a fixed water supply connection. The bottles of the medicament dispenser can be used for either medicament solutions or ordinary clean water.

The dispenser unit contains an electrically driven air compressor. When operating the scaler, the compressed air forces the fluid from the bottle through the hose to the handpiece and the tip.

The US30 Double is also equipped with an endo switch and have a special, low power range available when performing endodontic treatments.



1. Medicament dispenser unit with bottle selector knob
2. Medicament dispenser bottles with connectors
3. Left bottle selected (bottle selector viewed from above)
4. Right bottle selected (bottle selector viewed from above)
5. Position for dry mode and removal of bottles, no fluid. (bottle selector viewed from above)

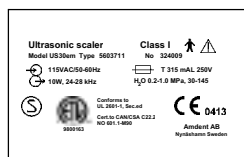


1. Switch for endodontic mode
2. Endodontic mode indicator lamp (yellow)
3. Scaling mode position (right)
4. Endodontic mode position (left)

3.5 Handpiece Ergo UltraLight additional description

The light will illuminate when the foot control is depressed and will continue to illuminate for approximately 10 seconds after the foot control has been released.

3.6 Symbols on the equipment



Example of type plate. The type plate is placed on the bottom side of the scaler unit.



Attention! Consult accompanying documents!



Medical electrical equipment classified by ETL with respect to electric shock, fire, mechanical, and other specified hazards in accordance with UL 2601-1, second edition and the Canadian Standard CAN/CSA-C22.2 No 601.1-M90



Compliance label indicating compliance with the Medical Device Directive 93/42/EEC

0413 is the ID-number of the Notified Body: SEMKO



Withstands autoclave temperature 135°C (275°F).



Withstands autoclave temperature 121°C (248°F)



Type B equipment according to the degree of protection against electrical shock



Fuse



Input



Output



Water flow adjustment



On/off



Ultrasonic power adjustment



Endodontic mode



Scaling mode



Protective ground



Please do not throw the equipment into the domestic refuse. Please use the return and collection systems available in your country for the disposal of this product.

4 Operating instructions

4.1 General

Mode of operation

With cooling fluid (medicament or water), the unit can be operated continuously. Recommended flow: 20 ml/min.

Without cooling fluid, the unit may only be operated for shorter periods and the maximum operating time is 2 minutes followed by a cooling down period of 8 minutes. Operating without cooling fluid is recommended only for special clinical treatments, for example, crown removal and thixotropic cementing when cooling of the treated surface is not necessary. When performing root canal treatments, the canal must be filled with fluid.

Before treatment

1. To rinse the water line, hold the handpiece over the bowl. Depress the foot switch and allow the water to flow for 30 seconds.
2. Gently slide the ErgoGrip on to the handpiece.



3. Carefully align the tip and screw it clockwise into the handpiece.



Note

These instructions are valid for the Ergo Basic, Ergo Ultra and Ergo UltraLight handpiece.



Caution

Without cooling fluid, the maximum operating time is 2 minutes followed by a cooling down period of 8 minutes. Operating the scaler for more than 2 minutes may cause overheating and damage to the handpiece.



WARNING

A tip that is bent, altered, scratched or worn more than 2 mm will loose performance and must be exchanged. Prolonged use may cause tip breakage and injury to the patient.



WARNING

The operator should be aware of that ultrasonic instruments with small diameters are subject to breakage at any time. If not used correctly or with too much power or force the instrument WILL break.



WARNING

A tip that is bent, altered, scratched or worn more than 2 mm will loose performance and must be exchanged. Prolonged use may cause tip breakage and injury to the patient.

The operator should be aware of that ultrasonic instruments with small diameters are subject to breakage at any time. If not used correctly or with too much power or force the instrument WILL break.

4. Use the tip wrench to firmly tighten the tip to the handpiece.



WARNING

New tips are not sterile upon delivery. Sterilize before use according to the clinic's routines.

Keep the patient's lips, cheeks, and tongue out of the way of the activated tip, since contact may cause burns.

Scaling

1. Turn on the scaler by pressing the on/off switch at the rear side of the scaler. The green indicator lamp lights.
2. Set the ultrasonic power control knob to maximum position.
3. Keep the handpiece over the bowl and depress the foot control to activate the scaler.
4. Adjust the ultrasonic power according to the specific tip requirement.
5. Keep the patient's lips, cheeks, and tongue out of the way of the tip and perform treatment according to the instructions on page 20.



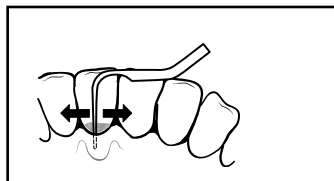
Note

At low power settings there will be no spray.

How to use the scaler

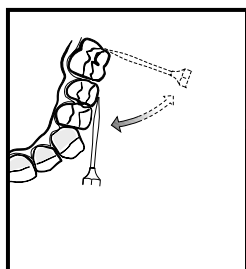
The **side** of the tip-end shall be applied to the tooth so that the movement of the tip is parallel to the surface of the tooth. The first 2 mm of the tip are the most efficient! Place the tip on the tooth surface before activating the foot switch.

Normal scaling rarely requires more than 50% power level. however, hard to remove calculus might require a higher power setting.



Ensure that contact between the tip and the tooth surface is maintained during scaling. Keep moving the tip slowly back and forth and let the instrument do the work. Use short and long strokes so that the whole surface of each tooth is scaled.

The tip is normally aimed towards the toothpocket.



To keep the tip working parallel to the surface of each tooth, it is important to follow the anatomy of the tooth.

With the correct power setting, appropriate pressure against the tooth (approximately 20 grams but not exceeding 50) and the tip operating parallel to the surface, treatment will be gentle, quiet and efficient.

If, during the treatment, a squeaking sound is heard (loud and dominating), the pressure against the tooth might be too low or the tip not parallel to the surface of the tooth.

After treatment

1. Screw off the tip, counter-clockwise, with the tip wrench.



2. Squeeze the ErgoGrip gently at the top and at the same time slide it off the handpiece. Do not squeeze too hard at the ErgoGrip as this can make the removal difficult.
3. Clean and sterilize the equipment according to the **General cleaning procedure** section on page 27.

4.2 US30em additional instructions

Endodontic treatment

Set the endo switch to endodontic mode position. The yellow endodontic indicator lamp indicates that the scaler is operating in endodontic mode. The power is reduced over the entire setting range to approximately half the power used in the scaling mode.



WARNING

Do not use nickel-titanium files, since they easily break at high frequencies.

The operator should be aware of that ultrasonic instruments with small diameters are subject to breakage at any time. If not used correctly or with too much power or force the instrument WILL break.

4.3 US30 Unicorn additional instructions

Preparations before scaling

1. Fill the dispenser bottle with water or medicament solution according to the **Medicaments that can be used in dispensers** section on page 33.
2. Screw the bottle connector onto the bottle and press it onto the dispenser unit.



Removing the dispenser bottle

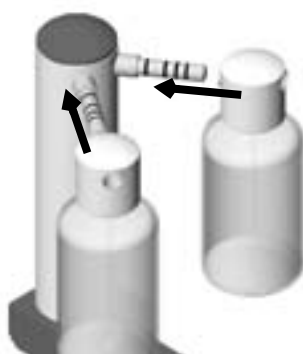
1. Press the depressurization button.
2. Pull the bottle from the dispenser unit.



4.4 US30 Double additional instructions

Preparations before scaling

1. Check that the endo switch is turned to scaling mode position. The yellow indicator lamp is off.
2. Fill the dispenser bottle with water and/or medicament solution according to the **Medicaments that can be used in dispensers** section on page 33.
3. Screw the bottle connectors onto the bottles and press them onto the dispenser unit.



Note

After switching from one fluid to another, flush the system for 30 seconds at a normal rate (15-30 ml/min), to insure that no previously used fluid remains.

4. Select a bottle or dry mode position by turning the bottle selector knob on the top of the dispenser as shown in the **US30 Double additional description** section on page 15.

Endodontic treatment

Set the endo switch to endodontic mode position. The yellow endodontic indicator lamp indicates that the scaler is operating in endodontic mode. The power is reduced over the entire setting range to approximately half the power used in the scaling mode.



WARNING

Do not use nickel-titanium files, since they easily break at high frequencies.

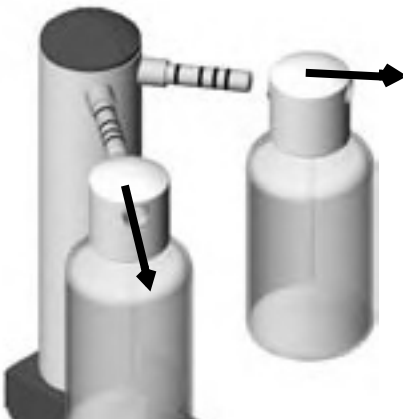
The operator should be aware of that ultrasonic instruments with small diameters are subject to breakage at any time. If not used correctly or with too much power or force the instrument WILL break.

Removing the dispenser bottles

1. Turn the bottle selector knob to the bottle removal position. The bottles are depressurized.



2. Pull the bottles off the dispenser unit.



5 Add-on features



Note

Also read the previous chapters for essential operating instructions.



Caution

Amdent add-on accessories are only intended for use in combination with Amdent scalers.

Some US30 models can be modified to add enhanced functions. This chapter describes installation and features of medicament dispenser accessories.

For further information regarding scaling tips for different treatments and other accessories, contact your local Amdent dealer.

5.1 MD Unicorn and MD Double

Installation

1. Disconnect the power cord from the AC power outlet and from the scaler.
2. Turn off the water supply and disconnect the water hose from the scaler.

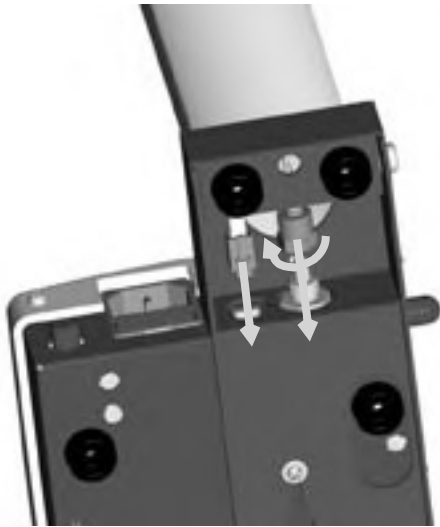


3. Turn the scaler upside down and screw in the two enclosed screws slightly.
4. Match the screws to the holes of the dispenser unit and push the dispenser forward.



5. Tighten the screws with a screwdriver and insure that the dispenser unit is securely attached to the scaler.

6. Connect the power cord and the water hose from the dispenser to the scaler.



7. The dispenser unit is now installed.

For further operating instructions, read the previous chapters.

6 Cleaning and maintenance

6.1 General cleaning procedure



Caution

Do not sterilize any scaler accessories using dry heat or chemical autoclaves. This may damage the material.

Do not immerse the handpiece in any fluid. Moisture may permeate into it and damage the ultrasonic generator.

After each treatment

1. Remove the silicone knob covers and clean and autoclave according to the clinic's routines. Replace with sterilized covers.
2. Wipe off the cover with a soft cloth. Use a 45% isopropanol and detergent solution.
3. Wipe off the handpiece and the hose with a soft cloth. Use a 45% isopropanol and detergent solution.
4. Wash the ErgoGrip, the tip and the tip wrench and autoclave according to the clinic's routines.

6.2 US30 Unicorn and US30 Double additional procedure

Beginning of the day

Flush each line of the system with clean water for 1 minute.

After each treatment

Flush the hose and the hand piece with clean water for about 30 seconds.

End of the day

1. Flush each line of the system with clean water for 30 seconds.
2. Air purge each line of the system for 30 seconds (with an empty bottle).
3. Remove and autoclave medicament bottles and bottle connectors at a maximum temperature of 121°C (248°F).

Weekly

1. Flush each line of the system with clean water for 30 seconds.
2. Air purge each line of the system for 30 seconds (with an empty bottle).

(Continues on the next page)

3. Flush each line of the system with a 1% Chlorhexidine solution for 30 seconds.
4. Flush each line of the system with clean water for 30 seconds.
5. Air purge each line of the system for 30 seconds (with an empty bottle).

6.3 Autoclave temperatures



135°C (275°F)

- ☐ Tips
- ☐ Endo file
- ☐ Silicone covers
- ☐ Tip wrench



121°C (248°F)

- ☐ Medicament bottles
- ☐ Bottle connectors
- ☐ ErgoGrip Basic
- ☐ ErgoGrip Ultra
- ☐ ErgoGrip UltraLight

6.4 Maintenance

Power cord

Inspect the power cord and the handpiece hose daily to insure that the equipment is in good condition without mechanical damage.

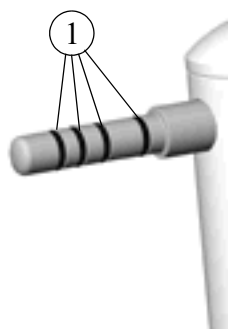
O-rings

Lubricate the O-rings regularly with KY-jelly or other glycerine based, water soluble lubricant. Vaseline may also be used, but it may shorten the durability time of the O-rings. Replace O-rings if necessary.



Caution

A petroleum based lubricant on the o-rings may shorten their durability time.



1. Medical dispenser O-ring, 7,1 x 1,6 mm



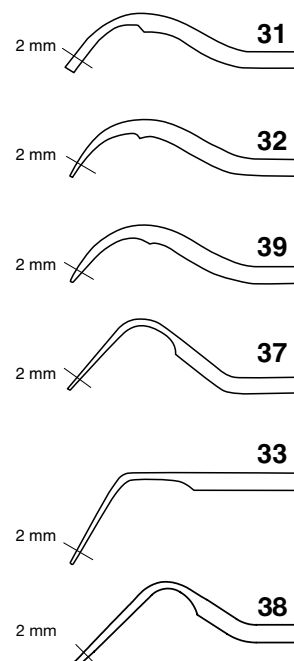
WARNING

A tip that is bent, altered, scratched or worn more than 2 mm will loose performance and must be exchanged. Prolonged use may cause tip breakage and injury to the patient.

The operator should be aware of that ultrasonic instruments with small diameters are subject to breakage at any time. If not used correctly or with too much power or force the instrument WILL break.

Tips

When a tip is bent, altered, scratched or worn more than 2 mm it will loose performance and must be exchanged. Check the tip length weekly by comparing the tip to the template below.



Exchanging fuses

1. Disconnect the power cord from the AC power outlet and the scaler.
2. Open the fuse holder on the rear side of the scaler.



3. Inspect the fuses for damages. Replace damaged fuses with new ones from the spare parts kit. Verify the fuse specifications according to the **Primary fuse** section on page 33.
4. Close the fuse holder.

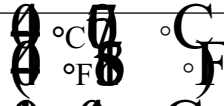




7 Troubleshooting

Problem	Action
The tip does not vibrate and the green power indicator lamp is off.	<p>Check that the power cord is connected properly.</p> <p>Check that the on/off switch is in on position.</p> <p>Check the fuses and replace if necessary. Additional fuses are found in the spare parts kit. For further instruction, read the Exchanging fuses section on page 30.</p>
The green power indicator lamp is on, but the tip does not vibrate properly.	<p>Check that the tip is firmly tightened.</p> <p>Check that the tip is not worn more than acceptable according to the tip template in the Maintenance section on page 29.</p> <p>If the problem is not resolved, try another tip, preferably unused.</p> <p>US30em additional information: Check that the endo/scaling switch is in scaling mode position (the yellow lamp is off).</p>
The tip threads don't fit smoothly onto the handpiece.	<p>If the tip threads are damaged, blow off the handpiece threads with compressed air and try another tip, preferably unused. Throw away the damaged tip.</p> <p>If the problem still remains, contact your dealer for service instructions, because the handpiece threads might be damaged.</p>
<i>The troubleshooting guide continues on the next page</i>	

Insufficient fluid flow	Open the water adjustment knob completely by turning it counterclockwise as much as possible.	
	If the fluid flow is still insufficient, remove the tip and inspect if fluid comes out of the handpiece. If yes, replace the tip.	
	US30 Unicorn/ US30 Double: Listen if the pump is running. If not, check the electrical connection to the pump on the rear side of the scaler. Check the fluid level in the bottle and that appropriate bottle is selected. Check that the bottle connector is tightened and connected correctly to the dispenser. Check that the O-rings on the dispenser connector are lubricated and are in good condition. Replace them if leakage occur, see the O-rings section on page 29.	US30m/US30em: Check that the water supply conforms to the pressure data in the Technical data section on page 33.
The handpiece is overheated	Check that the fluid flow is sufficient (recommended: 20 ml/min).	
If problems cannot be resolved according to this troubleshooting guide, please contact your dealer for further service support.		

8 Technical data

Voltage (three different models)	100 VAC, 50 Hz - 60 Hz 115 VAC, 50 Hz - 60 Hz 230 VAC, 50 Hz - 60 Hz	
Primary fuse	100 VAC: T400 mA, 250 V (2 pieces) 115 VAC: T315 mA, 250 V (2 pieces) 230 VAC: T160 mA, 250 V (2 pieces)	
Power cord	Separate, with protective ground plug (USA and Canada: Hospital grade)	
Output	Maximum 10 W, 24 kHz - 28 kHz, automatic tuning	
Ambient temperature	Transport & storage	
	Operation	
Relative humidity	Transport & storage	10% to 100%
	Operation	
Water consumption	10 ml/min - 50 ml/min	
Water supply pressure	1 bar - 10 bar (0.1 MPa - 1.0 MPa; 14.5 PSI - 145 PSI)	
Medicaments that can be used in dispensers	<ul style="list-style-type: none"> • Cetylpyridinium chloride • Chlorhexidine • Essential oils • Hydrogen peroxide, 3% USP • Povidine iodine, 10% solution • Saline solution • Sangurinara extract • Clean water 	

Dimensions in millimeters (L x W x H)	US30m	205 x 155 x 55
	US30em	205 x 155 x 55
	US30 Unicorn	250 x 155 x 230
	US30 Double	250 x 180 x 230
Weight in grams	US30m	1400
	US30em	1400
	US30 Unicorn	2600
	US30 Double	2800

Further technical descriptions on request. The manufacturer provides the qualified technical staff of the dealer or distributor with necessary information for service of the equipment.

9 Warranty and Declaration of conformity

9.1 Warranty

The manufacturer hereby warrants that the Amdent Scaler will be free from defects arising from faulty materials or workmanship for a period of twenty-four (24) months from the date of purchase by a customer from an authorized dealer (“Limited Warranty”). This Limited Warranty does not cover the ultrasonic scaling tips, which are only warranted for a period of three (3) months from the date of purchase by a customer from an authorized dealer. This Limited Warranty is limited to, free of charge, repair or replacement of any defective parts by the authorized dealer or distributor from whom the Amdent scaler was purchased by the customer. This Limited Warranty applies only if the Amdent scaler and/or the Amdent ultrasonic scaling tips are installed and used by the customer according to the instruction furnished herein, is connected to a proper power supply, is not misused or abused, and there is no evidence of tempering, mishandling, neglect, accidental or wilful damage or modifications. The customer must contact the authorized dealer from whom the Amdent Scaler and/or ultrasonic scaling tips were purchased to request repair or replacement under this Limited Warranty. This Limited Warranty is void if service or repair is performed by persons not authorized by the manufacturer. Normal wear and tear is specifically excluded from this Limited Warranty. Manufacturer disclaims any express warranty not provided herein and any implied warranty, guarantee or representation as to suitability for any particular purpose, performance, quality, and absence of hidden defects, and any remedy for breach of contract, which but for this provision, might arise by implication, operation of law, custom of trade, or course of dealing, including implied warranties of merchantability and fitness for a particular purpose, except as provided in this limited warranty. The manufacturer further disclaims any responsibility for losses, expenses, inconveniences, special, indirect, secondary, or consequential damages arising from ownership or use of the product.

9.2 Declaration of conformity

The manufacturer hereby declares that the

Piezo Ultrasonic Scalers US30m, US30em, US30 Unicorn,
US30 Double

Class I, type B according to EN60601-1

conform to the essential requirements of the Medical Device Directive 93/42/EEC with reference to the following harmonized standards:

EN 60601-1: 1990 with A1 and A12:1993, A2: 1995 and A13:1996.


Classification: Medical products, Class IIa:



EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The US30 is intended for use in the electromagnetic environment specified below. The customer or the user of the US30 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The US30 uses RF energy only for its internal function. Therefore, it's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The US30 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The US30 is intended for use in the electromagnetic environment specified below. The customer or the user of the US30 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the US30 requires continued operation during power mains interruption, it is recommended that the US30 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The US30 is intended for use in the electromagnetic environment specified below. The customer or the user of the US30 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the US30, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,2\sqrt{P}$</p> <p>Radiated RF IEC 61000-4-3</p> <p>3 V/m 80 MHz to 2,5 GHz</p> <p>$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>were P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the US30 is used exceeds the applicable RF compliance level above, the US30 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the US30.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended separation distances between
portable and mobile RF communications equipment and the US30**

The US30 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the US30 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	150 kHz to 80 MHz
	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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