

AIRFLOW

ONE

INSTRUCTIONS FOR USE

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1. BEFORE USE






CONGRATULATIONS!

You are now the owner of this new EMS device!

Please read the instructions carefully before use →

-  TO AVOID the risk of electric shock, this equipment must only be connected to a mains supply with protective earth/grounding. This device uses a Class-I insulating system that requires protective earth.

FOR USA AND CANADA: GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED "HOSPITAL ONLY" OR "HOSPITAL GRADE".

-  DO NOT modify this equipment and/or any of its accessories.
No modification of any part of this medical device is allowed.
-  DO NOT open the device. There are no serviceable parts inside.
-  If any serious incident occurs that is directly or indirectly related to the device, report it immediately to the manufacturer and to the competent authority of your country and of where the patient is established (if different).
-  Disconnect the mains plug from electrical outlet for the purposes of maintenance, in the case of malfunction or when the device is left unattended.
-  Turn off the water inlet when not in use. The device is not equipped with Aquastop and the EG-110 water hose may disconnect or leak: risk of flooding.



- The instructions for use of the device are provided in electronic format. However, if you want a hard copy, you can request one free of charge on our website, by telephone or in writing, and receive it within 7 days.
- The instructions for use are available for download in PDF format at <http://www.myems.dental> using the Product/Key Code FT-230.
A PDF reader is required and, in case of need, it can be downloaded from the same web site.
- It is essential to first read and understand all the instructions for use before operating the device and using the related accessories.
- We recommend that you visit our website regularly to consult and/or download the latest version of the instructions for use of your device at <http://www.myems.dental>
- Please contact EMS technical support or your local EMS representative for further information and support.
- Always keep this documentation close at hand.

1.1. Intended Use

The device is a fixed table top unit having:

- AIRFLOW®: air polishing technology

Intended for use in

PREVENTION, MAINTENANCE AND TREATMENT

during dental prophylaxis to remove biofilm and early calculus
from natural teeth, restorations and implants

1.2. Application Fields

Natural teeth include smooth surfaces, pits, fissures, interproximal areas and around restorations.

AIRFLOW® applications include:


- Plaque removal for the placement of sealants
- Surface preparation prior to the bonding/cementation of inlays, onlays, crowns and veneers
- Surface preparation prior to placing composite restorations
- Effective plaque and stain removal for orthodontic patients
- Cleaning prior to the bonding of orthodontic brackets
- Cleaning the implant fixture prior to loading
- Stain removal for shade determination
- Plaque removal prior to a fluoride treatment
- Plaque and stain removal prior to a whitening procedure

PERIOFLOW® applications include:

- Maintenance of periodontal deep pockets up to 10mm following initial treatment
- Removal of periodontal biofilm
- Cleaning of implants

1.3. Intended User

Only **qualified dentists** and **dental hygienists** must use this device by fully complying with their respective country's regulations, accident prevention measures, and strictly follow these instructions for use.

-  The device must be prepared and maintained only by persons who have been instructed in infection control, personal protection and patient safety.
- Improper use (e.g. due to lack of hygiene or routine maintenance), non-compliance with our instructions, or the use of accessories and spare parts that are not approved by EMS invalidates all claims under warranty and any other claims.*

No specific training other than initial professional training is required to use this medical device. The practitioner is responsible for performing the clinical treatments and for any dangers that may arise due to a lack of skill and/or training.

For optimal patient comfort, safety and efficiency, we suggest that you regularly follow our:

SWISS DENTAL ACADEMY Training Program



Do you know the Guided Biofilm therapy? If not:

GET TRAINED NOW

Please contact your local EMS representative for further information.




Professional product installation and product introduction by EMS certified person is highly recommended for optimal setup and reliability.


1.4. Patient Population

AIRFLOW® devices are intended for use on patients requiring dental treatment, including cleaning and polishing of teeth (natural or implant) by the projection of water, air and dental powders onto the tooth surface, regardless of age or gender.

-  This medical device is not intended for use on newborn (neonate) and infant patient populations.

1.5. Contraindications

 Treatments contraindications:			Suggestion for alternatives:
AIRFLOW [®] and PERIOFLOW [®]	are contraindicated with	Patients with upper respiratory tract infections, chronic bronchitis/asthma ¹ .	PIEZON [®]
AIRFLOW [®] subgingival + PERIOFLOW [®]	are contraindicated with	Pregnant and breastfeeding patients ²	AIRFLOW [®] Supragingival
PERIOFLOW [®]	is contraindicated with	Patients taking bisphosphonate therapy, with severe inflammation and/or osteonecrosis.	AIRFLOW [®] PLUS

 The decision to use **AIRFLOW**[®] and/or **PERIOFLOW**[®] on contagious patients or on patients with risk of infection, has to be taken by the dentist/medical doctor on an individual basis following practitioner protection level, patient risk assessment and specific country regulations.

 AIRFLOW [®] powders contraindications:			Suggestion for alternatives:
CLASSIC powder	is contraindicated with	Low-salt diet patients.	AIRFLOW [®] PLUS
Flavored CLASSIC powder	is contraindicated with	Patients allergic to flavor aroma.	AIRFLOW [®] PLUS Or CLASSIS NEUTRAL
PLUS powder	is contraindicated with	Patients allergic to Chlorhexidine.	AIRFLOW [®] PERIO
PERIO & SOFT powder	is contraindicated with	Patients allergic to Glycine (Glycocol).	AIRFLOW [®] PLUS

1.6. Compatibility

This device is compatible with the following accessories:

AIRFLOW [®] Powders	PLUS powders: DV-082, DV-086 series CLASSIC powders: DV-048 series PERIO and SOFT powders: DV-070, DV-071 series
AIRFLOW [®] Handpiece	EL-308
PERIOFLOW [®] Handpiece	EL-354

Applied Parts

The following items are Medical Device Applied Parts:

- **AIRFLOW**[®] (EL-308) handpiece
- **PERIOFLOW**[®] (EL-354) handpiece

 Applied Parts, under certain operating conditions, may exceed 41°C of temperature and reach a maximum temperature of 51°C.


¹ Related to possible powder inhalation during **AIRFLOW**[®] treatment.


² Related to the use of antibiotics in case of emphysema.

1.7. General Precautions




USE EMS ACCESSORIES ONLY!

 The use of any other accessories could lead to patient injury, malfunction or damage to the device

 DO NOT use this device in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N₂O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.

 DO NOT store the powder near acids or heat sources.

 TAKE the following precautions to prevent any adverse events to the patient and/or to the user in case of electromagnetic disturbances:

- Always refer to the information listed in the chapter “Electromagnetic Compatibility”.
- In case of a wireless pedal malfunction, presumably caused by electromagnetic disturbances, use the wired pedal instead.
- In case of a device malfunction, presumably caused by electromagnetic disturbances, first verify the cabling, and then move any portable RF communications equipment and mobile devices placed nearby as far away as possible to rule out interference.
- Stop using the device if the electromagnetic disturbances persist and contact EMS technical support for assistance.

2. INSTALLATION

2.1. Equipment included in the box

! Check contents for any damage that may have occurred during transportation.



AIRFLOW ONE Unit

with Master Screw,
water & air filters
installed
FT-230/A



Quick Guide

providing links to
eIFU download and
product registration



Power cord

Plug type depends on
country



AIRFLOW® PLUS Prophylaxis Powder

DV-082
or DV-086



Powder Chambers

PLUS : EL-607
CLASSIC: EL-606



Water hose

EG-110

Air hose

EH-142



AIRFLOW® CLASSIC Prophylaxis Powder

DV-048



NIGHT CLEANER®

DV-146
(800 ml)



CLIP+CLEAN

2x AB-613
(Package EL-655)



WATER bottle

EG-121



AIRFLOW® handpiece cord

EM-145

One of the following pedals:



Boost wireless pedal

EK-404A
with 2x AA 1.5V type
lithium batteries



NIGHT CLEANER® bottle

EG-120



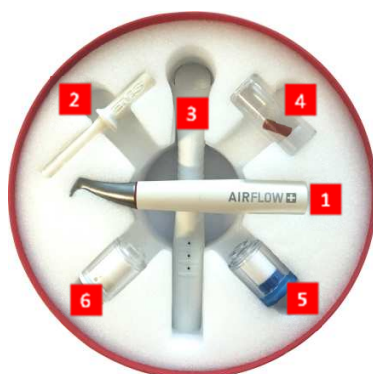
Foot switch (Wired pedal)

EK-410

AIRFLOW[®]

SUB & SUPRAGINGIVAL

FS-442 / FS-447 (See below)³

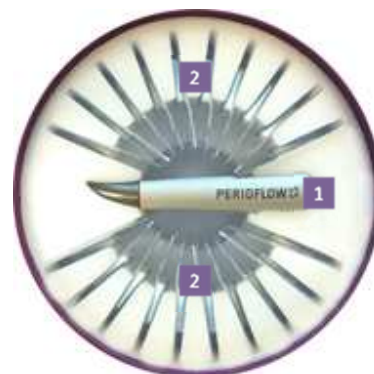


- 1 EL-308: AIRFLOW[®] handpiece
- 2 AB-470A/A: Easy Clean
- 3 Ultra FS ClasenUNO Cannula¹
- 4 EL-651: Cord gaskets
- 5 EL-600: Water filter
- 6 EL-599: Air filter

PERIOFLOW[®]

PERIO & IMPLANT

Optional: FS-444



- 1 EL-354: PERIOFLOW[®] handpiece
- AB-358/A Nozzle extractor (under)
- 2 20x AB-327A/A: PERIOFLOW[®] nozzle

³ AIRFLOW[®] application box FS-442 integrates ClasenUNO Cannula in the European Union. In the rest of the world, the reference is FS-447.

2.2. Step-by-step installation

Find an appropriate area to place the device.

❗ Place the medical device (control unit) within the dental cabinet in a suitable position for your activity and leave enough free space to allow easy handling and proper aeration.

⚠ Keep 10cm of clearance around at all times and do not stack over other devices.

The medical device must be placed on a secure and flat surface (with a maximum slope of 5 degrees).

Check for proper water and air supply lines.

Verify that your dental cabinet has a filtered tap water source and a compressed air source using air and water hoses EG-110 and EH-142, respectively.

❗ In case your cabinet water and air lines are not provided with the required hoses EG-110 and EH-142, a proper installation by qualified personnel is required. Call EMS Service for support.

⚠ In order to prevent retro contamination, connect the cable to EN-1717 or DVGW⁴ compliant fluid sources.

Check for a proper and safe power grid.

⚠ This device uses a Class-I insulating system that requires protective earth.

⚠ Plug the unit only into an FI protected mains supply (FI = Residual current protection).
For USA and Canada: connect only to a hospital-grade outlet.

⚠ Check that the rated voltage of the device is suited for the local line voltage to prevent damaging the unit, risk of fire and electric shock.

⚠ The mains plug of the unit must be accessible at all times.

⛔ DO NOT INSTALL the device in case your dental cabinet does NOT have protective earth. If you have any concerns about this, call EMS Service for on-site support by qualified personnel.

Be aware

⚠ The use of cables and accessories other than those supplied by EMS may negatively affect EMC performance. Use only parts supplied by EMS.

⚠ The device uses a low power radio, 1 dBm EIRP max, Bluetooth® 2.4 GHz, to communicate with the wireless pedal. Interference may occur in the vicinity of this equipment.

The Bluetooth® radio is automatically disabled (powered off) when a wired pedal is connected.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables. Otherwise, degradation of the performance of this equipment could result.

⁴ German Technical and Scientific Association for Gas and Water



Connect air and water hoses

Turn the device over and place it upside down.

- 1 Connect the air hose EH-142 to the cabinet/dental unit.
Push the hose connector into the air jack firmly (it may be hard).

Pressure: 4.5 to 7 bar
Dry air. Max. humidity: 1.032 g/m³
Filtration: max. 1 µm

Connect the water hose EG-110 to the cabinet/dental unit.

- 2  To prevent retro contamination, connect the cable to an EN-1717 or DVGW compliant fluids source.
 DO NOT install the WATER or NIGHT CLEANER® bottles before connecting the air and water lines.

Drinking water
Pressure: 2 to 5 bar
Salinity: max. 0.2%
Temperature: 10°C to 30°C

Install accessories

Continue to keep the device upside down and disconnected from the power grid!



- 1 **EH-142**
Air hose – filter pre-installed
PUSH VERY HARD

- 2 **EG-110**
Water hose – filter pre-installed

- 3 Power cord into socket
(Fuse holder in the socket)

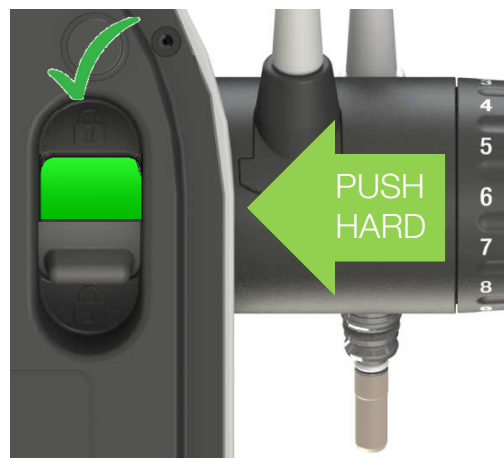
- 4 **EK-410**
Wired pedal
ONLY IF APLICABLE

- 5 **EM-145**
AIRFLOW® handpiece cord +
lock actuator
PUSH HARD

Check the cord connections



The handpiece cord is not fully connected.



PUSH HARD to lock in.

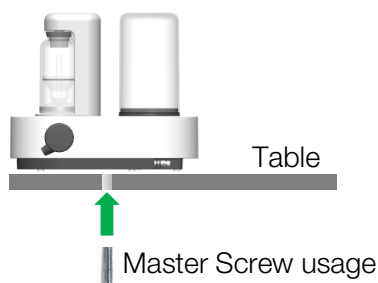
The system is well connected & locked.

To disconnect the handpiece cord system, unlock the connection and pull at the same time.

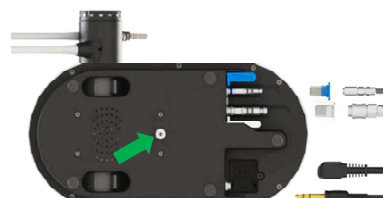
Fix the device

You will find a “Master Screw” provided on the bottom center of the device.

Unscrew the Master Screw first and use it to secure the device firmly to a table or onto the AL-125 device support in your cabinet (the AL-125 part is available through our after-sales support and dealers).



Master Screw usage




Master Screw placement

- ❗ Fix your device with the provided “Master Screw” in order to ensure that the unit cannot be removed without the use of a tool.
- ❗ Check the position of the medical device so that it corresponds to your line of sight and the characteristics of your personal workstation (the lighting and the distance between the user and the device). The device must remain quickly and easily accessible at all times.
- ❗ Check that the water and air lines and the power cord do not hinder physical movement.

Power your device

You can now connect the power cord to the mains grid.


 Protective earth is required!
Be sure your power grid has an efficient protective earth.

Voltage: 100-240 Vac
Frequency: 50 to 60 Hz.
Operating current: 4 A max.

Installation of the wireless pedal



Insert two (2) AA 1.5V lithium batteries into the wireless pedal. Close the cover and operate your device.

 **Risk of fire:** use only batteries that have current limiter/short-circuit and over-temperature protection (compliant to IEC 60086-4:2014 Safety of lithium batteries).

The optional wireless pedal supplied with your device is already paired and ready to use (Note: A pedal can only command one single device at a time. Pairing is maintained even if the batteries are removed).

When you receive your new machine, all you need to do is insert the two (2) AA lithium batteries into the wireless pedal and your device is ready to work.

In case you replace your pedal, you will need to pair it with your device. For instructions, please read the specific Maintenance & Troubleshooting chapter.

The Bluetooth® radio is automatically disabled (powered off) when a wired pedal connected.



The wireless pedal uses a low power, 1 dBm EIRP max, Bluetooth® 2.4 GHz radio, to communicate with the control unit. Interference may occur in the vicinity of this equipment.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables. Otherwise, degradation of the performance of this equipment could result.

2.3. Powder Chambers

- ⚠ Clinical risk: Only use PLUS or PERIO powder with the PLUS powder chamber.
- ⚠ Clinical risk: Only use PLUS powder chamber (red) for subgingival treatments.

PLUS



The PLUS powder chamber is designed for the PLUS powder. It can be used for supra and subgingival treatments.

Pressure is automatically reduced for compatibility with subgingival treatments, including Perioflow treatments (Supra applications also possible).

Compatible EMS powders: PLUS and PERIO (refer to paragraph "Compatibility" for details).

CLASSIC



The CLASSIC powder chamber is designed for the CLASSIC powder and can only be used for supragingival treatments.

Sodium Bicarbonate: Use only this powder and chamber for supragingival applications.

Compatible EMS powders: CLASSIC and SOFT (refer to paragraph "Compatibility" for details).

- ⚠ Check bottle and powder chamber integrity: There should be no crack on the body.
 - ⚠ The powder chamber is pressurized during use. Replace faulty parts immediately.
- ⚠ Make sure that the powder chambers are dry.
- ⚠ Use only PLUS or PERIO powders for restorations, crowns, bridgework, implants and orthodontics.
- ⊘ Do not sterilize the powder chambers and their caps/parts by steaming or dry thermal reprocessing. Use only ambient temperature active disinfectant and cleaning agents.



- ⚠ By hand only: remove the powder chamber cap to refill powder up to the indicated MAX level, then insert the cap back fully onto the bottle. Pour the powder in freely. The central tube can be fully filled without problem.
- ⊘ Do not fill the chamber higher than the indicated MAX level. The powder level will go down slightly a few minutes after the filling (powder compaction).

Before pressurizing, position the powder chamber into the device. Magnetic attraction will position it correctly.

- ⊘ Do not insert upside-down.

2.4. Water supply and WATER bottle

Without Bottle:

AIRFLOW® uses external water supply.



⚠ The CLIP+CLEAN shall be previously cleaned and disinfected before use. Non-disinfected CLIP+CLEAN may contaminate the device.



! Place the CLIP+CLEAN into the device's bottle receptacle for dust protection.

With WATER bottle connected:

AIRFLOW® uses bottle liquid supply.



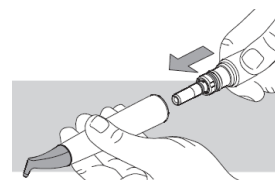
Connect the WATER bottle

⚠ Only use the WATER bottle EG-121 (transparent) for water.

⊘ Do not sterilize the WATER bottle and its nozzle cap by thermal reprocessing. Use only ambient temperature active disinfectant and cleaning agents.

2.5. AIRFLOW® and PERIOFLOW® handpieces

⚠ AIRFLOW® and PERIOFLOW® handpieces are reusable, but they shall have been previously reprocessed: cleaned, disinfected and sterilized. Non-sterile handpieces and accessories may cause bacterial or viral infections.



Connect the
AIRFLOW® or PERIOFLOW® handpiece.


⚠ Follow the “Reprocessing of EMS parts” instructions and the present-day regulations on reprocessing enforced in your country.

In case the AIRFLOW® handpiece gets clogged, refer to the “Maintenance & Troubleshooting” section for instruction.

3. DEVICE USE

3.1. Interfaces



1	ON/OFF-mode Standby	<p>ON: the device goes into operating mode. OFF: the device reverts back to standby. (After 1 hour of inactivity, the unit switches to off-mode standby)</p>
2	Powder chamber pressurization / depressurization	<p>Powder chamber is pressurized or depressurized. A white light illuminating the powder chamber will turn on when pressurized. During chamber depressurization, the AIRFLOW® cord will automatically purge and the white light will turn off at the end of the process. Entering Standby mode: The powder chamber depressurizes automatically.</p> <p>❗ Powder chamber depressurization may take up to 10 seconds to complete. During this time, it is recommended that you leave the AIRFLOW® handpiece in its holder with the nozzle facing down to avoid spraying the purged air and residual powder upward.</p>
3	Power setting	 <p>Place your finger in the groove below the numbers to adjust AIRFLOW® air pressure:</p> <ul style="list-style-type: none"> 0 (water only, blue indicator) 10 (Maximum) <p>Memorization of the preselected settings.</p>
5	AIRFLOW® water	Sets the AIRFLOW® water flow rate.
6	Pedal (normal)	Press the edge of the pedal for normal operation. The pedal is deactivated when both handpiece cords are placed in their holders.
7	Pedal BOOST (Only on the wireless pedal)	Pressing hard on the center of the wireless pedal activates power boost. For easy boost activation: leave the foot on the pedal and put the heel up.

AIRFLOW[®] pressure setting



Both the PLUS and CLASSIC powder chambers have an integrated dynamic pressure regulator that automatically set the optimal pressure range for the selected powder chamber and related powder type as detailed in chapter “Powder Chambers”.

The following table shows the static and approximate dynamic pressures⁵ as per selected powder chamber and user power setting:

AIRFLOW[®] Pressure	Pressure Setting	0	1	2	3	4	5	6	7	8	9	10
	Static [Bar]	/	2.5	2.7	3.0	3.2	3.5	3.7	4.0	4.2	4.5	4.7
	CLASSIC dynamic [Bar]	/	1.9	2.1	2.3	2.6	2.8	3.0	3.2	3.5	3.7	3.9
	PLUS dynamic [Bar]	/	1.5	1.7	1.9	2.0	2.2	2.4	2.6	2.7	2.9	3.1

AIRFLOW[®] BOOST



Pressing hard on the center of the wireless pedal activates the BOOST mode and results in an increase of power, as the following table shows:

AIRFLOW[®] Boost	Power Setting	0	1	2	3	4	5	6	7	8	9	10
	Corresponding Boost Level	0	6	7	8	8	8	9	10	10	10	10

⁵ Dynamic pressures depend on handpiece and powder type too. The listed pressures are for information purpose and referring to the commonly used EL-308 AIRFLOW[®] handpiece with DV-082 and DV-048 powders.

Wireless pedal battery saving

Each time the wireless pedal is released, it enters into a low power mode. Even if unused for long, it is not required to remove the batteries.

To avoid an involuntary depletion of the wireless pedal batteries, in the case the pedal stays uninterruptedly pressed for 10 minutes, it will automatically enter into switch-off mode.

To resume from the switch-off mode, it is required to first release the wireless pedal and then power cycle the device (switch off for 30s and then power on again).

Water temperature and acoustic feedback settings

AIRFLOW® water temperature is 40°C by default.

To adjust the water temperature or the acoustic feedback, follow the procedure below:

1. Turn the device ON.
2. Securely place the AIRFLOW® handpiece back into its holder.
3. Press ⑩ + ⑩ simultaneously to access the menu. (See image below – place fingers in the groove below the numbers)



4. Colors will appear on the numbers:
 - 0 to 4 for setting water temperature (5 is not used)
 - 6 to 10 for setting acoustic feedback (5 is not used)

Water temperature					Acoustic feedback				
0	1	2	3	4	6	7	8	9	10
No Heating	25°	30°	35°	40°	No sound	Low volume	Medium volume	High volume	Maximum volume

5. Change the settings according to your wish.
6. Press the ON/OFF button to save the setting and exit.

Note:

- After a few seconds of keyboard inactivity, the device automatically exits the mode.

3.2. Treatment sequence

AIRFLOW®

- 1 Position the powder chamber.
- 2 Pressurize the chamber.
- 3 Set the AIRFLOW® power.
- 4 Set the water flow.
- 5 Take the AIRFLOW® handpiece.
- 6 Press the pedal to start treatment.
- 7 [Step hard on the center of the BT pedal for BOOST.]
- 8 Release the pedal to stop treatment.
- 9 Put the handpiece back into its holder.



⚠ Treatment does not stop immediately. Beware there is a small delay between the release of the pedal and the effective stop of the treatment (approximately 0.2 second).

⚠ Risk of patient injury. If you are not trained on a specific treatment, do not execute it. Always get trained before executing new treatments.

4. OPTIONAL EQUIPMENT

4.1. PERIOFLOW® Nozzles



Single-use nozzle.



Cannot be reprocessed.

Do not use the nozzle if the package is damaged or open.

Connect the nozzle.

Make sure the nozzle is correctly attached = fully inserted.

4.2. Mirror Suction Cannula



Ultra FS ClasenUNO Mirror Suction Cannula is only available in the European Union.



Cannula is reusable, but shall be previously reprocessed before use: cleaned, disinfected and sterilized. A non-sterile cannula may cause bacterial or viral infections.



Follow the ClasenUNO Reprocessing instructions and the present-day regulations on reprocessing enforced in your country.




Connect it to the high-speed suction hose of your dental unit and check for compatibility before use (It may not be compatible with your dental unit suction hoses).

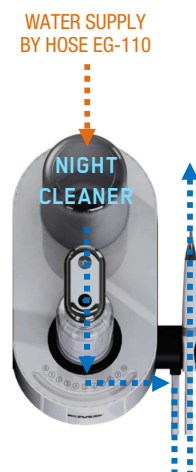
5. CLEANING & REPROCESSING

5.1. Water Line Cleaning & Disinfection

Keeping the device's water lines clean and disinfected is mandatory to prevent patient infection.

A regular daily cleaning using the EMS NIGHT CLEANER[®] agent cleans and disinfects the device's water lines, and helps to prevent the growth of biofilm and calcification in the long term.


 The water supply hose and related device connection will not be cleaned by this procedure.



Each morning before the first patient: Rinsing




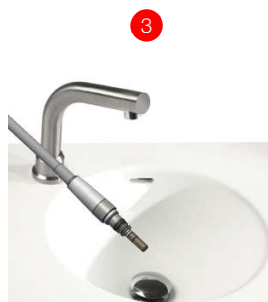
1
Place a fully filled water bottle onto the device

 To reduce the risk of ingestion of the cleaning agent by the patient, always use a fully filled 800ml water bottle.




2
Set water to 10
Turn the device ON

 Set water regulator to 10 to ensure optimal rinsing.




3
Hold cord over a sink

Contamination prevention:
 Do not make any contact between the sink and the cord.




4
Press the pedal during 30 seconds minimum

To rinse all the device's water line of the cleaning agent.

 Risk of ingestion of the cleaning agent. Check that no more blue residue is flushing out of the cord. Otherwise, repeat the rinsing procedure.

 Always empty out and wash the water bottle used for rinsing before any new use.

 Risk of ingestion of residue of cleaning agent. During rinsing, a small quantity of cleaning agent flows back into the water bottle.

Between each patient

Overall cleaning and disinfection



Clean the external surface of the device with a cloth and alcohol

- ! Clean the unit only with an alcohol-based (ethanol, isopropanol), colorless disinfectant.
- ⊘ Never use scouring powder or an abrasive sponge. It will damage its surface.



⚠ Reprocess handpieces

See the specific following chapters.

- ⚠ Risk of contamination. Always disinfect the bottom and top areas of device air connections.

End of day: Overnight cleaning

⚠ Use only EMS NIGHT CLEANER^{®6} as a cleaning agent.

Other products may damage or not clean the unit, and cause patient intoxication.



1 Place the NIGHT CLEANER[®] bottle onto the device

- ! Before placing, remove CLIP+CLEAN from the device.
- ! Before cleaning, check that the liquid level is above the external black line of the bottle's neck.



2 Set water to 10 Turn the device ON

- ! Set water regulator to 10 to ensure the flow of the cleaning agent.



3 Hold cord over a sink

- Contamination prevention:
- ⚠ Do not make any contact between the sink and the cords.
 - ⚠ CLIP+CLEAN shall be reprocessed after each use. (Do not exceed 135°C).



4 Press the pedal during 30 seconds minimum

- Cleaning can be paused and resumed by releasing and pressing the pedal again.
- Once completed, leave the NIGHT CLEANER[®] bottle on the device overnight.

The NIGHT CLEANER[®] agent can remain active in the device's water lines for up to 1 week.

⁶ Alternative long-term disinfection liquid, Alpro Bilpron, can be used.



Refill the blue NIGHT CLEANER[®] bottle with NIGHT CLEANER[®] agent only

NIGHT CLEANER[®] has the following properties:

- Long-term disinfection
- Remains stable in the NIGHT CLEANER[®] bottle
- Blue color increases user awareness of the cleaning procedure

⊘ Do not sterilize the NIGHT CLEANER[®] bottle and its nozzle cap by steaming or dry thermal reprocessing. Use only ambient temperature active disinfectant and cleaning agents.

⊘ Do not use Hydrogen Peroxide as EMS Ultra Clean. It deactivates after some time in the device's bottle.

5.2. Safety Information on NIGHT CLEANER[®]

⊘ DO NOT mix NIGHT CLEANER[®] with other cleaning solutions.



NIGHT CLEANER[®] should not be swallowed. Take this product protected from child.
In case of ingestion, rinse the mouth with water. Do not induce vomiting.
In case of discomfort, ask advice to a medical doctor.



Avoid contact with eyes. In case of contact, rinse the eyes intensively during few minutes with water. In case of contact lenses, remove these lenses as soon as possible and continue to rinse.



Manipulate the product with gloves. In case of skin contact, wash it with water and soap.

In case of soiled clothes, take off these immediately. If you have any contamination concern, promptly ask advice to a medical doctor.



For further information refer to the specific NIGHT CLEANER[®] instructions for use provided with the product

Manufacturer information and point of contact

For any information and/or complaints, you can also contact the legal manufacturer:

Dr. Wittmann GmbH & Co KG

Rieslingstraße 8

D-64673 Zwingenberg, Germany

Phone: +49 6251 770 76 90

Email: service@dr-wittmann.com

5.3. Reprocessing of EMS parts

EMS recommends the use of cleaning, disinfection, packaging for sterilization and sterilization procedures accordingly with ISO 17664.

! Report adverse events related to device reprocessing directly to EMS.

! Reusable products must be cleaned and sterilized prior to first use. Do not reprocess the products over the allowed number of sterilization cycles, but replace: refer to the “Service life” section of the “Technical Description” chapter.

! Concentrations and contact times specified by the manufacturer of the cleaning and disinfection agent must be followed. Only freshly prepared solutions shall be used.


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



If there is anything in the following instructions that is not clear or seem to be inadequate, do not hesitate to contact/inform EMS.

Preparation

Immediately after use, rinse the lumen(s) line of the part (device / instrument) and remove gross soiling by wiping the instrument.

 For AIRFLOW[®] and PERIOFLOW[®]: always carry out handpiece powder unclogging and check for both lumens (water and powder) clearance before proceeding.



Cleaning shall need to be performed within 1 hour from the use.

Cleaning

Any part can be cleaned manually or automatically by washer or disinfectant. EMS recommends the use of automatic washer-disinfectant (WD) for an optimal effectiveness and part service life.

 DO NOT use any Ultra Sound Bath cleaning procedure with the AIRFLOW[®] and PERIOFLOW[®] handpieces: it may destroy the products.

Manual Cleaning

The following validated process can be used:

- Remove away any surface soiling (gross contamination) on the product with a wetted cloth and drinking water.
- For part having a lumen, flush the lumen 3 times for 5 seconds each using a water jet pistol.
- Immerse in cold tap water for 5 min.
- Brush all accessible parts with a soft bristled nylon brush.
- Immerse in 0.5% cleaning solution of Neodisher MediClean (Dr. Weigert, Hamburg) at 40°C for 5 min. All surfaces must be moistened.
- Rinse for 60 seconds with a water jet pistol and rinse thoroughly afterwards under running tap water.
- Fully dry with an air pistol for at least 20 seconds.

Automated Cleaning

Washer-disinfectant must have suitable baskets to hold small fragile products and has rinsing connections for the attachment to product lumen.


Manual pre-cleaning is required and the following validated process can be used:

- Immerse in cold tap water for 5 minutes.
- With a syringe, flush 3 times the lumen of the part with 50 ml deionized water.

Place the instrument to a suitable rack and start the automated cleaning.


The following validated (on Miele G 7735 CD) automated cleaning process can be used:

- 2 min pre-washing with cold water.
- Drain.
- 5 min cleaning with deionized water with 0.5% detergent of Neodisher MediClean (Dr. Weigert, Hamburg) at 55°C.
- Drain.
- 3 min rinsing and neutralization with deionized water.
- Drain.
- 2 min final rinse with deionized water.

 Also instructions of the manufacturer of the washer disinfectant shall be followed.

Disinfection

Any part can be disinfected manually or automatically by a disinfectant. EMS recommends the use of automatic washer-disinfectant (WD) for an optimal effectiveness and part service life.

 DO NOT use any Ultra Sound Bath disinfecting procedure with the AIRFLOW[®] and PERIOFLOW[®] handpieces: it may destroy the products.

Manual Disinfection

- ASP CIDEX OPA[®] 0.55% disinfectant solution shall be used not diluted and within its Use-Life and Shelf-Life, respecting the manufacturer's Warnings and precisely following its Instruction for Use.
- Disinfectant shall be poured into a proper tray having secure lid. Tray size shall have to allow the complete submersion of the device and to facilitate the evacuation of air from the inside.
- Warm up the disinfectant to at least 20°C.
- Immerse the product completely, and if applicable, fill all lumens and eliminate air pockets by means of a syringe fulfilled of disinfectant (to guaranty full internal lumen contact with the disinfectant).
- Close the tray with the secure lid.
- Wait for at least 5 minutes and be sure that the temperature of the disinfectant solution doesn't drop below 20°C.
- The ASP CIDEX OPA disinfectant requires a total of three (3) rinses, with large volumes of fresh water to properly remove its residues. Sterile water shall be poured into proper rinsing trays. Tray size shall have to allow the complete submersion of the device and to facilitate the evacuation of air from the inside.
 - For each of the 3 rinses do:
 - Flush all lumens with large volumes (not less than 100 ml) of rinse water. Use a syringe or a water jet pistol to correctly accomplish this task.
 - Keep the device totally immersed for a minimum of 1 minute in duration.
 - Remove the device from the rinsing tray and discard the rinse water.
- Finally, fully dry it internally and externally.

Automated Disinfection

Automated Thermal Disinfection in a disinfectant under consideration of national requirements in regards to A0-Value accordingly to ISO 15883.


The following validated (on Miele G 7735 CD using program "DESIN 93° C-3'") process can be used to achieve an A₀ Level of 3000:

- Holding time: 3 minutes
- Min temperature: 93°C
- Final automated drying cycle executed in full

Special instructions and warnings of the manufacturer of the washer disinfectant have to be followed.



Follow carefully the instructions provided by the disinfection solution manufacturer.

 Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose. Residues of disinfectant may cause serious side effects.

Drying

Any part can be dried manually or automatically by washer-disinfector. EMS recommends the use of automatic dryer for an optimal effectiveness and part service life.

Manual Drying

Dry the outside of the parts with a lint free towel.


Dry the lumen of the products with filtered compressed air (max. 3 bars) for 20 seconds.

Automated Drying


Dry the part through the automated drying cycle of washer/disinfector within the disinfection program or just immediately after.

Never heat up over 138°C.

If needed, additional manual drying can be performed using air pistol and sterile air.

 Sterilization shall be performed immediately after cleaning-disinfection.

Inspection before sterilization

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

Packaging for sterilization




 Only previously cleaned and disinfected products can be sterilized.

Prior to sterilization, the products need to be placed in a suitable sterilization packaging:

- Use Single or Double Pouches ISO 11607 compliant
- Resistant to 138°C, with adequate steam permeability

Sterilization

 Sterilization must be performed immediately after cleaning-disinfection.

-  DO NOT exceed the maximum number of sterilization cycles allowed.
-  DO NOT exceed a sterilization temperature of 138°C and a holding time of 20 minutes.
-  DO NOT use hot-air sterilization and radio-sterilization procedures: they destroy the products.

Moist heat sterilization of parts shall be performed according to ISO 17665 and under consideration of the respective country requirements.

The following validated Pre-vacuum Moist Heat (steam) process can be used:

Parameters for the Pre-vacuum Moist Heat cycle:

- 3 pre-vacuum phases
- Sterilization temperature of 132°C
- Pressure of 3 bar
- Humidity of 100%
- Holding time of 4 minutes minimum (full cycle)
- Drying time of 20 minutes



It is the duty of the user to ensure that the reprocessing processes, including resources, materials and personnel, are capable to reach the required results and maintained over the time: keeping actual the validation of the reprocessing processes is under the responsibility of the user.

Storage



Store the sterilized instruments in a dry, clean and dust free environment at a temperature of 5°C to 40°C.

Service life



Refer to the section “Service life” of the “Technical Description” chapter for details.

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However, with every renewed preparation for use, thermal and chemical stresses will result in the ageing of the products.



If the number of permissible re-sterilization cycles is restricted, this will be stated in the product's specific instructions (if any) and/or in the “Service life” section of the “Technical Description” chapter.



Always replace products that present sign of worn-out or of early degradation, regardless of the number of sterilization cycles left unused.



DO NOT expose the products to temperature exceeding the 138°C.

5.4. Reprocessing of ClasenUNO Cannula



The Ultra FS ClasenUNO Mirror Suction Cannula requires an EN ISO 17664 compliant reprocessing. Check the cannula regularly before use and replace it as signs of wear are detected.

Cleaning and disinfection

Only disinfectants that are suitable for polypropylene (PP) and used according to the guidelines may be employed for cleaning and disinfection. To avoid the risk of scratching the mirror and cannula, do not use hard brushes (wire brushes) for cleaning. The requirements stated in EN ISO 17664 must be observed. Firstly, remove the coarse dirt, and then rinse the ClasenUNO under running water. For the ClasenUNO with Ultra mirror, use distilled water for rinsing. Place the contaminated ClasenUNO in a suitable disinfectant solution. Follow the recommendations of the solution manufacturer regarding the concentration levels of the disinfectant and the duration of disinfection. Rinse it well with water after disinfection and dry carefully. Next, disinfect/sterilize using one of the methods below.

Ultrasonic disinfection

Make sure that the surface of the mirror is completely dry, particularly with the Ultra version, as lime residue could be burnt in otherwise. Place the ClasenUNO in an ultrasonic bath (e.g. Bandelin Sonorex Super RK 514). Add a cleaning and disinfection agent suitable for polypropylene (PP) (e.g. 0.55% Cidex OPA) and set the washing cycle as per the manufacturer's instructions. Keep it in the ultrasonic bath for 12 minutes and ensure that the temperature does not drop below 18°C. Then, rinse with sterile water until all cleaning agent residue has been removed. Check to ensure that the ClasenUNO is thoroughly clean and, if necessary, repeat the cleaning cycle. Finally, dry the ClasenUNO carefully.

Disinfection with a thermal disinfectant

To clean and disinfect with a thermal disinfectant, use a device that corresponds to EN ISO 15883 (e.g. Belimed WD 100) and observe the manufacturer's instructions when choosing the cleaning and disinfection cycle and cleaning agent. Position the ClasenUNO in the thermal disinfectant in such a way that the inside surfaces are rinsed and the water can flow off. 0.5% (V/V) deconex 24 LIQ has proven suitable as the cleaning solution and 0.2% (V/V) deconex 26 Plus as the neutralizing solution. Disinfection is performed at 90°C for a hold time of 5 minutes. At the end of the cleaning and disinfection cycle, ensure that the ClasenUNO is thoroughly clean and, if necessary, repeat the cleaning cycle.

Sterilization

Steam sterilization must be performed using a device that complies with EN 13060 or EN 285 (e.g. autoclave with fractionated pre-vacuum, W&H, type LISA 517), observing the sterilization procedure as per EN ISO 17665-1. The cycle must be conducted at a sterilization temperature of 134°C with a hold time of 5 minutes, or at a sterilization temperature of 121°C with a hold time of 12 minutes.

Manufacturer information and point of contact

For any information and/or complaints, you can also contact the legal manufacturer:

Cleverdent Ltd.,

Theresiengrund 31, DE - 48149 Münster, Germany.

Tel: +49 (0) 251 98292828

Website: www.clasen.uno

Email: info@clasen.uno

6. MAINTENANCE & TROUBLESHOOTING

6.1. AIRFLOW[®] handpiece powder unclogging

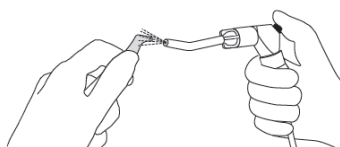
! In case of a clogged handpiece and before the reprocessing of AIRFLOW[®] and PERIOFLOW[®] handpieces.



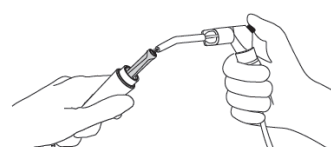
Easy Clean FV-083
Provided in your **AIRFLOW[®]** Application box



! Rinse through central lumina in the normal direction of flow (no back rinsing) using Easy Clean with a disposable syringe filled with more than 2 ml of drinking water



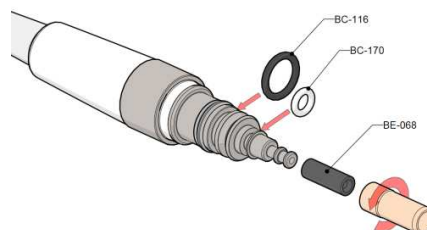
Blow air to dry.



The Easy Clean tool can be thermally disinfected and also sterilized at up to 135°C in the autoclave.

6.2. AIRFLOW[®] handpiece leakage

In case of leakage at the AIRFLOW[®] handpiece connection with the AIRFLOW[®] cord, replace the o-rings of the cord with the spare provided in the EL-651 Kit located in the **AIRFLOW[®]** application box.



6.3. Handpiece cord replacement

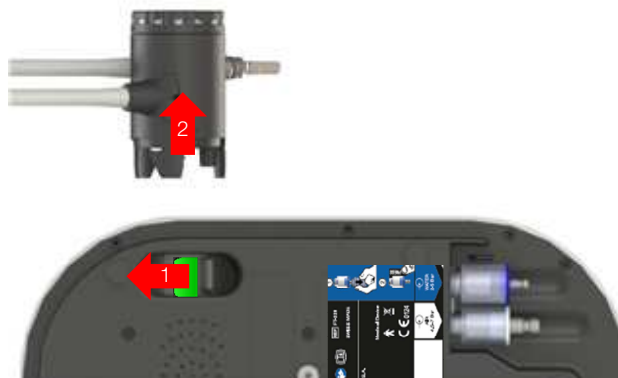


Disconnect the mains plug for purposes of maintenance and in case of malfunction.



Depressurize the powder chamber before disconnecting the AIRFLOW® cord.

In case of persistent malfunction or damage to AIRFLOW® handpiece cord system, the part can be easily replaced by the user. Follow the directions for replacement provided with the spare part supply.



Handpiece cord disconnecting procedure:

1. Unlock the cord system by pushing the lock switch to the front (Switch located under the device).
2. The cord system is now unlocked and can be removed by pulling it.

6.4. Monthly check

Each month check both air and water filters for cleanliness.



Disconnect the mains plug for purposes of maintenance and in case of malfunction.



No maintenance is allowed while in use with a patient.



! Check water and air filter cleanliness.

Filter color has to be white without significant visible impurities. If not, replace the filter.

If the water filter needs to be changed more than 3 times a year, please check the quality of your water line.

Air filters usually remain cleaner for longer periods of time. Replace once a year. (The yearly maintenance service includes the replacement of both filters.)



Good

Worn-out

1. **!** **Disconnect the power cord from the grid first.**
2. Disconnect the water hose by pulling it off the connector.
3. Pull the filter off by hand or by using a small flat screwdriver.
4. Replace with a new filter and reconnect the hose.

6.5. Yearly maintenance & repair



⚠ This device must only be maintained and/or repaired by EMS and by authorized EMS repair centers.

⚠ A yearly preventive maintenance or 2000 hours usage maintenance, whichever comes first, is required as means of safety and performance guarantee for both the patient and the user.

Qualified service repair may also be required anytime persistent malfunctioning is detected by the user and/or reported by the device diagnostic.



When returning the device for service, it is recommended that you ship the device with its pedal, powder chamber, bottle and cords in its original packaging for optimal protection against damage during transportation.

Provide the contact details of your EMS dealer for a quicker service process.

6.6. Pairing a new pedal



1. Remove one battery from the pedal (no need to remove both).
2. Place the handpiece in its holder.
3. Turn the machine OFF, wait 10 seconds, then turn it ON again.
4. Press ⑩ + ⑤ first, then also press ⑩ simultaneously.

A sonar sound will start playing (if not, repeat step 4).

Respect the order and the three-finger sequence (see figure below – place fingers in the groove below the numbers).

5. While the sonar sound plays, replace the lithium batteries into the wireless pedal.
6. Within a short time (less than 15 seconds), the pairing will be complete, the white LEDs will blink for a while and the device is then ready for use.



If the process takes longer than 1 minute, it means the pairing has failed and the device will automatically exit the mode. (No more sonar sound and no blinking at exit).

In case of this process failure, redo it from the beginning.

6.7. Troubleshooting



The device is whistling or making strange noises



Risk of bottle explosion.



First disconnect the mains plug.

This symptom is generally caused by a problem to the pressure regulator (fault or low temperature) or by a crack in the water bottle.

1° Stop using your device immediately and disconnect it from the grid.

2° Check the bottle in use for crack or any damage and, if the case, replace it with a new one.

3° If the device temperature is below 10°C (device too cold), wait for it to warm-up at ambient temperature and then reconnect to the power grid and switch it on again.

4° If the device temperature is over 10°C, or the problem reoccurs, definitively stop to use it and contact EMS aftersales service.



The device is making smoke (and fire)



Risk of fire and electric shock.



First disconnect the mains plug.

Stop using your device immediately, disconnect it and contact EMS aftersales service.



Cord or device leakage



Risk of fire and electric shock.



First disconnect the mains plug.

1° If the leak is from the AIRFLOW® handpiece, replace the o-rings.

2° If the leak is from the device (handpiece support and water regulator), replace the complete handpiece cord.

3° If still not solved, contact EMS aftersales service.



LED 1 is SOLID orange



Safety Warning: You can still operate the device to terminate the ongoing treatments. The device requires the yearly maintenance. Promptly contact EMS aftersales service.

LED 1 BLINKING orange



Safety Warning: Permanent or transitory hardware fault condition detected.

1° Unplug the device power cord, wait for 30 seconds, then plug it back again and restart the device (to check for effective permanent fault condition).

2° If the error is still present, contact EMS aftersales service for repair.



LED 2 SOLID orange

The wireless pedal's 2x AA lithium batteries are depleted. Replace both with new AA high-quality lithium batteries having current limiter protection.



LED 3 SOLID orange

The problem may have multiple causes. A step-by-step multiple checks are required.

1° No pedal detected (at least one pedal must be connected to operate the device):

- Wired pedal may be disconnected. Check if the jack is fully inserted. Restart the device.
- Wireless pedal is not paired. Execute the procedure "Pairing of new pedal"

2° If the error is still present, contact EMS aftersales service for repair.

LED 3 BLINKING orange

The AIRFLOW® cord systems are not detected or missing. At least one cord system is required to operate the device.

1° First, switch OFF the device, then disconnect the AIRFLOW® handpiece cord and clean the electric contacts (jacks) present on the cord system connections. Also blow air to clean the device connection receptacles.

2° Reinstall the handpiece cord, check the lock actuator and start the device again.

3° If error is still present, contact EMS aftersales service.

4


LED 4 BLINKING orange



Risk of fire and electric shock.



First disconnect the mains plug.

1° Your device is too hot. Unplug it, wait for 1 hour and start the device again.

2° If error is still present, contact EMS aftersales service.

Note: This error also shows up when the device is operating below the minimum temperature. In this case, just wait for the device to warm up to ambient temperature.



Water filter leakage



First disconnect the mains plug.

1° Replace the water filter (blue cartridge).

2° If still not solved, contact EMS aftersales service.



Bottle or bottle connection leakage

1° Ensure the bottle cap has been correctly closed.

2° Clean the connection: cap and device sides.

3° Replace the bottle.

4° If still not solved, contact EMS aftersales service.



AIRFLOW® connection leakage

1° Ensure the handpiece has been correctly connected to the cord.

2° Clean the interior of the handpiece and the cord terminating end.

3° Replace the AIRFLOW® cord gasket as described in paragraph "AIRFLOW® handpiece leakage".

4° If still not solved, contact EMS aftersales service.



Insufficient or no water from handpiece

1° Make sure you have set your water regulator to 10 (maximum flow on the cord) and verify that the handpiece is not clogged by removing it and checking the water flow without handpiece.

2° Check your water filter cleanliness and replace it if necessary.



Disconnect the mains plug before servicing any filter.

2° Make sure you have well-connected and sufficient pressure from your water supply.

3° If still not solved, contact EMS aftersales service.

Night Cleaner



Still some blue liquid remaining after rinsing

1° Make sure you have set your water regulators to 10: maximum flow on the cords.

2° Make sure you have well-connected and sufficient pressure from your water supply.

3° Perform a second rinsing phase before treatment.

4° If still not solved, contact EMS aftersales service.



The unit does not start

1° Check the electrical connection and power socket.

2° Check the fuses at the back of the unit:



First disconnect the mains plug.

Fuses are housed within the power cord socket.

1° Remove the power cord from the device.

2° With the help of a small flat screwdriver, open the fuse-holder cover.

3° Replace fuses only with the exact type required (refer to the "Technical Description" section).

4° If still not solved, contact EMS aftersales service.



Wireless pedal does not work

In the case is evident that the pedal remained pressed for longer than 10min, simply release the pedal and power cycle the device. If not this case, the problem may have multiple causes. A step-by-step multiple checks are required:

1° Switch-off the device and disconnect and reconnect the AIRFLOW® cord systems. Try again.

2° Perform a new pairing. This procedure is explained in the paragraph "Pairing a new pedal". Try again.

3° Change the 2x AA lithium batteries and try again.

4° If still not solved, contact EMS aftersales service.



Wired pedal does not work

- 1° Disconnect and reconnect the pedal. Check the cable for damage. Restart the device.
- 2° If still not solved, contact EMS aftersales service.



No pressurization of the powder chamber

- 1° Check that your device is ON: at least 1 LED light should be ON.
- 2° Check that the AIRFLOW® cord system is well connected (full green mark on the lock actuator).
- 2° If still not solved, contact EMS aftersales service.

Powder chamber white light is BLINKING at pressurization attempt

Either the air line is not connected or there is not enough air pressure.

- 1° Check the air line for no kinking and check the air compressor unit.
- 2° Check air filter for cleanliness and replace if dirty.
- 3° If still not solved, contact EMS aftersales service.

Powder chamber white light is BLINKING at depressurization

- 1° The handpiece could be clogged. Unclog with Easy Clean (see paragraph below).
- 2° AIRFLOW® cord could be clogged. Dismount and clean the airflow cord extremity.
- 3° If still not solved, contact EMS aftersales service.



Powder sprays out of chamber at depressurization

- 1° Powder chamber is filled beyond the maximum level marked.
- 2° Remove the powder exceeding the MAX sign on the bottle.



Powder leaks under the AIRFLOW® handpiece cord system

The AIRFLOW® pinching element might be worn out or the air interface is dirty and is leaking powder.

- 1° Disconnect the cord, clean the air jack and connect again. If problem persists, go to Step 2.
- 2° Replace your AIRFLOW® handpiece cord with a new one.
- 3° If still not solved, contact EMS aftersales service.



Powder chamber is leaking

- 1° Clean the chamber with a wet cloth, in particular the cap and the bottom o-rings. Also clean the connecting elements on the device.
- 2° If still not solved, replace the powder chamber with a new one.

6.8. To contact EMS Service support

E.M.S. Electro Medical Systems S.A.

Ch. de la Vuarpillière 31
1260 Nyon – Switzerland

Phone: +41 (0) 22 99 44 700

Email: TSAV@ems-ch.com

7. SUSTAINABILITY

7.1. Disposal of waste parts



The device must not be discarded in domestic household waste. Should you wish to definitively dispose of the device, please comply with the regulations that apply in your country.

Other parts of this device, including tips/inserts, and chemicals must be disposed of according to your country's regulations.

Waste Electrical and Electronic Equipment belonging to customers located in the European Union may be shipped to EMS for recycling in accordance to the WEEE regulations. The costs of recycling, exclusive of shipping fees, are covered by EMS.



Keep the original packaging until the device is to be disposed of permanently. It can be used for shipping or storing.

7.2. Sustainable design



The device, on a voluntary basis, respects the latest Eco design low energy standby and off mode consumption regulation⁷. Packaging cardboards are recycled and recyclable.



Printed instructions respect the highest standards in sustainable development as My Climate neutral Imprimerie and FSC certification.

8. WARRANTY

Warranty is void if the device has been used with non-original EMS powder, instruments and handpieces. Warranty is void if the device has been opened.

EMS and the distributor of this device accept no liability for direct or consequential injury or damage resulting from improper use, arising in particular through non-observance of the instructions for use, or improper preparation and maintenance.

























EMS declines the responsibility for the safety of the device and declares the warranty null and void if service or repair is carried out by an unauthorized third party or if non-genuine spare parts are used.

⁷ European Commission Regulation N°1275/2008 of 17 December 2008 regarding the Eco design requirements for standby and off mode electric power consumption of electronic household and office equipment.

9. TECHNICAL DESCRIPTION

Manufacturer	EMS ELECTRO MEDICAL SYSTEMS SA, CH-1260 Nyon, Switzerland
Models	AIRFLOW One, product code FT-230
Classification EM 60601-1	Electrical Insulation Class-I Applied part Type B IP20 Control unit IP21 Foot pedal
Classification EU MDD 93/42/EEC	Medical Device Class IIa
Essential Performance	This medical device, in the meaning of the EU MDD 93/42 has no Essential Performance
Operating mode	Continuous operation
Power supply	100-240VAC, 50-60Hz, 4A max.
Power consumption	OFF-mode / Stand-by: 0.5W max. Max: 700VA
Fuse	5A, T (slow), 250VAC, H type (=T5H250V)
Wireless communication module	Max 1dBm EIRP, 2.4 GHz band, Bluetooth® radio module
Weight	Control Unit 5kg max. (full operating condition) Foot pedal: 0.35kg max. (wireless pedal)
Dimensions	Control Unit: Height: 245 mm, Width: 205 mm, Length: 290 mm Wireless pedal: Diameter 135 mm, Height 35 mm
Operating conditions	Temperature: 10°C to 35°C Humidity: 30% to 75% Altitude: Max 2000m
Storage conditions	Temperature: -10°C to 30°C, no water inside Humidity: 95% not condensed
Transport conditions	Temperature: -29°C to 38°C, no water inside Humidity: 95% not condensed
Input fluids	Water: pressure 2-5 Bar, temperature 10-30 °C, salinity 0.2% max., RECTUS 20KA connector type. EN-1717 compliant water network/inlet is required. Air: pressure 4.5-7 Bar, dry-only (humidity 1.032g/mq max.), oil filtered 0.1 mg/mq max., RECTUS 21KA connector type
Output fluids	Water: max. 90ml/min. for Airflow, with pressure 1.3 bar max. Air: max pressure 5 bar for Airflow
Service life	Device: 7 years, having regular yearly preventive maintenance WATER and NIGHT CLEANER® bottles: 3 years Handpieces: 1000 sterilization cycles

9.1. Symbols

	General Warning
	Warning Electricity
	Non-ionizing radiation (radio communication)
	Read the operation instructions
	Device requiring protective earth
	Disconnect the mains plug for purposes of maintenance and in case of malfunction
	Electronic instructions for use
	Mandatory action
	Expiration date
	Single use. Do not re-use.
	Do not do.
	Protection against water permeability
	Applied part, type B
	Disposal of old electronic equipment (European Union & other countries with separate collection systems)
	Manufacturer
	Manufacturing date
	Serial number
	Catalog number / Product reference
	Sterilizable at up to 135°C in the autoclave
	Thermal disinfection
	Input
	Output
	Fuse
	Wired foot pedal connection



9.2. Electromagnetic Compatibility

The use of parts other than those supplied or listed as accessory may negatively affect EMC performance. The device has embedded a low power, 1 dBm EIRP max, Bluetooth 2.4 GHz module, for communication with the wireless pedal. This radio module is disabled when a wired pedal is connected (device reboot required). The product is intended for use and Basic Safety is maintained in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Electromagnetic emissions compliance

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The product 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity compliance

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be > 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines 100 kHz repetition frequency		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles 0 % UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle single phase		Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 5 s 0% UT for 250 cycles		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m (50 Hz or 60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6V in ISM bands 150kHz and 80 MHz 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 \sqrt{P}$, $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz, $d = 2.4 \sqrt{P}$ 800 MHz to 2.7 GHz where 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ⁸ , should be less than the compliance level in each frequency range ⁹ . Interference may occur in the vicinity of equipment marked with the following symbol:  or 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table below		

⁸ 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 product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.

⁹Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Notes:

- UT is the a. c. mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Proximity fields from RF wireless communications equipment
IEC 61000-4-3

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0,2	0,3	9
810 870 930 1720 1845 1970	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0,3	28
	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse Modulation 217 Hz	2	0,3	28
2450	2400 -2570	Bluetooth, WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0,3	28
5240 5500 5785	5100 – 5800	WLAN 802.11a/n	Pulse Modulation 217 Hz	0,2	0,3	9

Recommended separation distances

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product 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 $d = \frac{3.5}{V} \sqrt{P}$ with $V=3V$	80 MHz to 800 MHz $d = \frac{3.5}{E} \sqrt{P}$ with $E=3V/m$	800 MHz to 2,5 GHz $d = \frac{7}{E} \sqrt{P}$ with $E=3V/m$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.4
100	11.67	11.67	23.4

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: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception which can be determined by turning the equipment off and on, the user is encouraged to try to correct interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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