AIRFLOW® ONE

INSTRUCTIONS FOR USE

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This IFU is not valid for the United States, Canada and Australia. Please refer to FB-621/US, FB-621/CA, and FB-621/AU.

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.

⚠ 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, as well as the Treatment Recommendations, are provided in electronic format and are part of the product documentation. However, if you want these in hard copy, you can request one set free of charge on our website, by telephone or in writing, and receive it within 7 days.

- The Instructions for Use of the device (FB-621), as well as the Treatment Recommendations (FB-648), are available for download in PDF format at www.ems-instruction.com 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 of the device before operating it and using the related accessories. The Treatment Recommendations are an integral part of the device's Instruction for Use and each one document is complementary to the other. Always keep this documentation close at hand.
- We recommend that you visit our website regularly to consult and/or download the latest version of the documentation for your device at www.ems-instruction.com
- Please contact EMS technical support or your local EMS representative for further information and support.

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

Application on natural teeth including all smooth surfaces, pits, fissures and interproximal areas, dental restorations and dental implants.

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 9 mm following initial treatment
- Removal of periodontal biofilm
- Cleaning of implants

1.3. Intended Users

Only **qualified dentists**, **dental hygienists** and **dental professionals** 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

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 (< 2 years old) patient populations.

1.5. Contraindications

⚠ Treatments contraindications:			Suggestion for alternatives:
AIRFLOW® and PERIOFLOW®	are contraindicated with	Patients with severe or unstable upper respiratory tract infections, chronic bronchitis/asthma[1].	PIEZON®
PERIOFLOW®	is contraindicated with	Pregnant and breastfeeding patients	AIRFLOW® and PIEZON® PS
PERIOFLOW®	is contraindicated with	Patients 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 assessement and specific country regulations.

⚠ On patients under Bisphosphonate therapy, the decision to use AIRFLOW® and/or PERIOFLOW® has to be taken by the dentist/medical doctor depending on the oral health of the patient.

⚠ 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/PERIO and CLASSIC NEUTRAL
PLUS Powder	is contraindicated with	Patients allergic to Chlorhexidine.	AIRFLOW® PERIO
PERIO & SOFT Powder	is contraindicated with	Patients allergic to Glycine (Glycocoll).	AIRFLOW® PLUS

1.6. Compatibility

This device is compatible with the following accessories:

AIRFLOW® Powders	PLUS Powders: DV-082, DV-167 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.

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
12x DV-082
Or 3x DV-167/Z[3]

Powder Chambers
PLUS : EL-607
CLASSIC: EL-606

Air hose
EH-142

Water hose
EG-110

AIRFLOW® CLASSIC Prophylaxis Powder
2x DV-048

NIGHT CLEANER[23]
DV-154
(800 ml)

CLIP+CLEAN
2x AB-613
(Package EL-655)

One of the following pedals:

WATER bottle
EG-121

AIRFLOW® Handpiece cord
EM-145

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

NIGHT CLEANER bottle
EG-120

Foot switch (Wired pedal)
EK-410

BIOFILM DISCLOSER[3]
DV-158

[2] Not for end point sterilisation
[3] If available in your country.

AIRFLOW

FS-472 / FS-447 / FS-473 (See below)[4]

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

PERIOFLOW

FS-444 / FS-474

1 **EL-354: PERIOFLOW® handpiece**
AB-358/B Nozzle extractor (under)
2 **20x AB-1010: PERIOFLOW® nozzle**

[4] AIRFLOW® application box FS-472 integrates ClasenUNO Cannula in the European Union. In the rest of the world, the reference is FS-447 / FS-473.

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 a minimum of 10 cm clearance around the unit. Do not stack it with other equipment.

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 DVGW[5] 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, 8 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.

[5] 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/m^3
Filtration: max. 1 µm

2 Connect the water hose EG-110 to the cabinet/dental unit.
⚠ 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 <u>disconnected from the power grid!</u>

1 EH-142
Air hose – filter pre-installed
PUSH <u>VERY</u> HARD

2 EG-110
Water hose – filter pre-installed

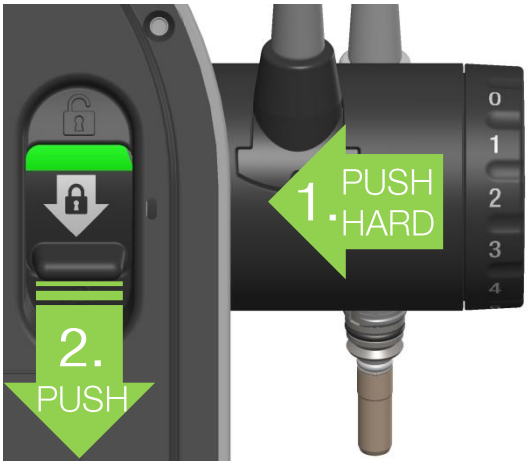
3 Power cord into socket
(Fuse holder in the socket)

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.

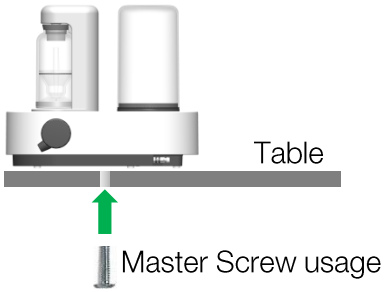


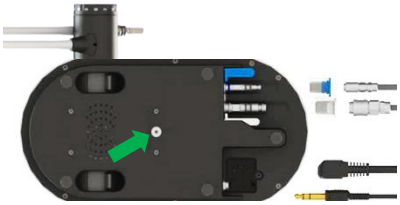
PUSH HARD *to lock in.*
The system is well connected & locked.

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 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, 8 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: Only use 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.

With WATER bottle connected:
AIRFLOW® uses bottle liquid supply.

1

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

2

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

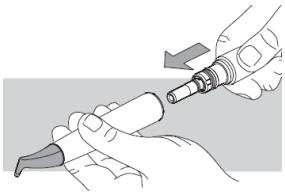
Connect the WATER bottle

⚠ 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. Not reprocessed 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	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)
2	Powder chamber pressurization / depressurization	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. 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 upwards.
3	Power setting	 Place your finger in the groove below the numbers to adjust AIRFLOW® air pressure: • 0 (water only, blue indicator) • 10 (Maximum) Memorization of the preselected settings.
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 pressures[4] 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

[4] 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 case the pedal remains pressed without interruption 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.

<u>To adjust the water temperature or the acoustic feedback, follow the procedure below:</u>

1. Turn the device ON.
2. Securely place the AIRFLOW® Handpiece back into its holder.
3. Press ⓪ + 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[5]					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.

[5] The target temperature is determined into the device's body.
On AIRFLOW® side, water temperature decreases along the cord. Air spray also decreases the temperature.
Final temperature of AIRFLOW® spray is lukewarm, lower than 40°C.

3.2. *Treatment sequence*

Consult the Treatment Recommendations (document series FB-648) before starting any treatment to the patient.

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).

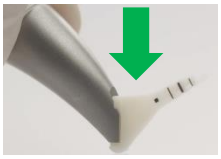
Risk of patient injury. If you are not trained on a specific treatment, do not execute it. Always get trained before executing new treatments.

4. OPTIONAL EQUIPMENT

4.1. *PERIOFLOW® Nozzles*

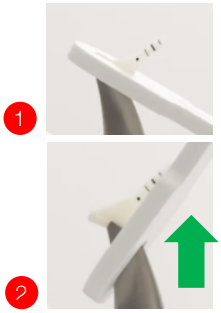
Single-use nozzle.

⚠ Cannot be reprocessed.
DO NOT use the nozzle if the package is damaged or open.



Fully connect the nozzle by pushing on a hard surface.

Make sure the nozzle is correctly attached = fully inserted.



Remove the nozzle by using the nozzle extractor.

⚠ Risk of injury: Always USE the nozzle extractor AB-358/A. DO NOT remove by hands.

4.2. *Mirror Suction Cannula*

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

Ultra FS ClasenUNO Mirror Suction Cannula is a combination of a dental mouth mirror and a medical suction cannula. The device is designed to improve the view of the area under treatment and/or for the suction of fluids and particles from the patient's mouth cavity.

⚠ The ClasenUNO Cannula must be reprocessed before use: cleaned, disinfected and sterilized.

⚠ 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).

❗ The mirror surface shall be dried thoroughly. Chalky coating on the mirror may be difficult, if not impossible, to remove.
The Ultra FS ClasenUNO Mirror Suction Cannula has been designed for a large number of sterilization cycles. Its service live is predominantly determined by wear and tear through use.

❗ Always replace the medical device as it presents any sign of worn-out or damage.

5. CLEANING & REPROCESSING

5.1. Water Line Cleaning & Disinfection

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

NIGHT CLEANER[6] ensures the decontamination and prevents biofilm formation in water lines of AIRFLOW® Prophylaxis Master.
NIGHT CLEANER[6] removes and protects from algae and limescale, after longer idle times or heating of the process.

⚠ 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

<u>Contamination prevention</u>:
⚠ 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 of NIGHT CLEANER[6] 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. EMS recommends a weekly use of a bottle cleaning agent (e.g. BC-San 100 from Alpro Medical GMBH).

[6] If available in your country. Not for end point sterilization.

⚠ 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[7] 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 black flange 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

<u>Contamination prevention</u>:

⚠ Do not make any contact between the sink and the cords.

⚠ CLIP+CLEAN shall be reprocessed after each use.

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 at least 12h minimum.

[7] If available in your country. Not for end point sterilization.

The NIGHT CLEANER[8] agent can remain active in the device's water lines (weekend, holidays or over night) and requires at least 12 hours (3 months maximum) of contact time for an optimal efficacy.

Refill the blue NIGHT CLEANER bottle with NIGHT CLEANER[8] agent only

NIGHT CLEANER[8] has the following properties:

- Bactericidal/ fungicidal
- Removes and prevents lime and algae formation 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 like EMS Ultra Clean. It deactivates after some time in the device's bottle.

5.2. Safety Information on NIGHT CLEANER[8]

🚫 DO NOT mix NIGHT CLEANER[8] with other cleaning solutions.

⚠ NIGHT CLEANER[8] should not be swallowed. Keep this product away from children.
In case of ingestion, rinse the mouth with water. Do not induce vomiting. In case of discomfort, consult a medical doctor.
⚠ NIGHT CLEANER[8] should not be inhaled.
In case of inhalation, supply fresh air and if necessary, consult a physician.

⚠ Avoid contact with eyes. In case of contact, flush eyes with flowing water for several minutes holding eyelids apart. Remove contact lenses, if present and easy to do.

❗ 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 consult a medical doctor.

❗ For further information refer to the specific NIGHT CLEANER[8] 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:
ALPRO MEDICAL GMBH
Mooswiesenstrasse 9
78112 St. Georgen, GERMANY
Phone: +49 7725 9392-0
www.alpro-medical.com

[8] If available in your country. Not for end point sterilization.

5.3. *Reprocessing of EMS parts*

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

Always report adverse events related to device reprocessing directly to EMS.

Reusable products must be cleaned disinfected and, if applicable, 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.

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.

The following instructions have been validated as being capable of preparing for re-use the EMS medical devices and parts listed in the "Intended Use and Compatibility" chapter. It remains the responsibility of the user to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

The user shall also observe any applicable legal requirements in their country as well as the hygiene regulations of the hospital or clinic. This applies especially with regard to the additional requirements for the inactivation of prions.

Preparation

Manual pre-cleaning is required:

20 s - Immediately after use, rinse the lumen(s) line of the handpiece/instrument with water.
Coarse soiling must be removed immediately after application.
Safely transport to the reprocessing area to avoid any damage to the products, contamination of the environment or of the persons involved in the reprocessing process.

Cleaning is to be performed within 1 hour from use.

Wear personal protective equipment according to the type of preparation.

AIRFLOW® and PERIOFLOW®: always carry out handpiece powder unclogging and check for both lumens (water and powder) clearage before proceeding. Use Easy Clean.

Any part can be cleaned manually or automatically by washer or disinfector. EMS recommends the use of an ISO 15883 compliant automatic washer-disinfector (WD) for an optimal effectiveness and part service life.

AUTOMATIC

Clean, disinfect and dry

The washer-disinfector must comply with ISO 15883, must have suitable baskets to hold small fragile products and must have rinsing connections with diameter of approximately 16mm for the attachment to product lumen.

Correctly place the product into a suitable rack, connect all lumens to the rinsing connectors and start the automated cleaning.

Instructions of the manufacturer of the washer disinfector must also be observed.

In case of use of a chemical disinfectant, follow carefully the instructions provided by the disinfection solution manufacturer.

The following automated process[9] can be used to achieve an A0 Level of 3000:

2 min	Pre-clean with cold tap water[10].
	Drain
5 min	Clean at 55°C with tap water[10] and 0.5% cleaning solution.
	Drain

MANUAL

Clean

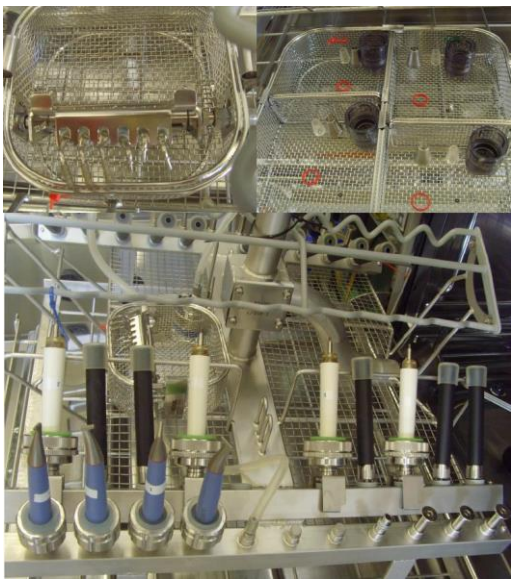
The following process can be used with any EMS product:
Brush the devices in a cleaning solution of 0.5% neodisher[12] in deionized water at 40°C with a suitable soft bristled brush[13] until all visible residue has been removed.

15 s	For products with lumens, flush all lumens with a spray gun (water jet gun, with a static water pressure of 2 bar) with cold tap water.
15 min	Place the product in 0.5% solution of neodisher[12] with deionized water at 40°C. Make certain that all lumens are filled with cleaning solution (use a syringe if needed).
15 s	Rinse all lumens by flushing with a spray gun (water jet gun, with a static water pressure of 2 bar) with cold deionized water.
10 s	Rinse the whole product under cold running deionized water.

DO NOT use any ultrasound bath cleaning procedure with the handpieces: it may destroy the products.

[9] For example: Miele Professional G 7836 CD with Miele Rack E429
[10] Cold tap water = 16°C +/- 2°C

3 min	Rinse and neutralize with cold demineralized water[11].
	Drain
2 min	Rinse with cold demineralized water[11].
	Drain
3 min	Perform thermal disinfection (final rinse) with deionized water at 93°C minimum.
	Drain
20 min (at least)	Dry at 100°C.



Example of correct placement of the parts in the WD Miele Professional G 7836 CD using the Mobile Injector Unit (Rack) Miele E429

Disinfection

ASP CIDEX® OPA solution must be used undiluted, within its useful and shelf life, and in compliance with the manufacturer's warnings and instructions for use.

5 min	Immerse the product completely into CIDEX® OPA solution at minimum 20°C. Make certain that all lumens are filled with disinfectant solution (use a syringe if needed).
1 min (each rinse)	The ASP CIDEX® OPA disinfectant requires a total of three rinses : keep the product totally immersed, and use a large volume[14] of fresh water.

Do not reuse the water for rinsing or any other purpose. Residues of disinfectant may cause serious side effects

Dry

Use an air pistol (compressed air) to fully dry the lumen and the whole product until no more residues of water are present (visible or detectable

[12] For example: MediClean Dental, Dr. Weigert Hamburg
[13] Medisafe MED100.33
[11] Cold demineralized water = 20°C +/- 2°C
[14] e.g. 2 gallons

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 deformation must be disposed of (no further use is permissible). Check also the integrity of O-rings and gaskets and replace if damaged or deformed.

❗ Verify the part to be fully dry. In case of detection of residues of water, remove these using an air pistol (clean compressed air). Fully dry the lumen and the whole part until no more residues of water are present (visible or detectable).

Reassembly and packaging for sterilization

⚠ Only previously cleaned and disinfected products can be sterilized.
⚠ Effective sterilization can take place only on fully dry products. Ensure each part (internal lumens and any surface) to be perfectly dry before reassembling and packing.

Prior to sterilization, the products need to be reassembled for ready use and placed in suitable sterilization packaging.

❗ AIRFLOW® and PERIOFLOW®: No need to reassembly

Package your products with a single or double pouch:
- suitable for prevacuum moist heat sterilization,
- compliant with ISO 11607-1 or EN 868,
- resistant to 138°C
- and with adequate steam permeability (e.g. Wipak STERIKING flat rolls Type R43 and R44).

Sterilization

⚠ Sterilization must be performed immediately after cleaning-disinfection.
The loading pattern defined by the autoclave manufacturer must be follow.

🚫 DO NOT exceed
- the maximum number of sterilization cycles allowed.
- a sterilization temperature of 138°C and a holding time of 20 min.

🚫 DO NOT use hot-air sterilization and radio-sterilization procedures: they destroy the products.

Moist heat sterilization of products shall be performed according to ISO 17665 and in compliance with respective country requirements.

The prevacuum moist heat (steam) process can be used with any EMS product packaged in appropriate single or double pouches:

Parameters for the prevacuum moist heat cycle:

- 3 prevacuum phases
- Pressure of 3 bar15
- Humidity of 100%
- Temperature of 132°C
- 3 min (minimun) Hold time (full cycle)
- 20 min (mininum) Dry

⚠ Users must ensure that the reprocessing processes, including resources, materials and personnel, are capable to reach the required results and maintained over time: it is the user's responsibility to ensure that validation of the reprocessing procedures is kept up to date at all times.

Storage

❗ Store the sterilized products at a temperature of 5°C to 40°C in a:

- dry,
- clean
- and dust-free environment.

Service life

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

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.

❗ 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.

[15] Absoluter Druck

5.4. Reprocessing of ClasenUNO Cannula

The following instructions are from the Cleverdent documentation “ClasenUNO Instructions” edition 03/2016 and are current at the date of issue. We recommend that you regularly consult Cleverdent website or contact them for the latest version of their instructions for use and reprocessing.

⚠ 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 disinfector

To clean and disinfect with a thermal disinfector, 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 disinfector 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

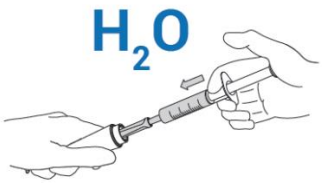
For any information and/or complaints, you can also contact the legal manufacturer:
Cleverdent Ltd.,
Theresiengrund 31, DE - 48149 Münster, Germany.
Tel: +49 (0) 251 98292828
Website: www.clasen.uno - Email: info@clasen.uno

6. MAINTENANCE & TROUBLESHOOTING

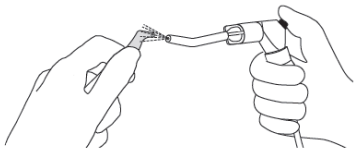
6.1. AIRFLOW® Handpiece powder unclogging

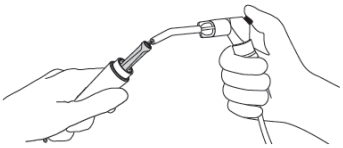
In case of a clogged handpiece and before the reprocessing of AIRFLOW® and PERIOFLOW® Handpieces.

Easy Clean
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



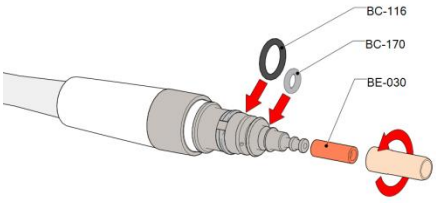


Blow air to dry.

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.

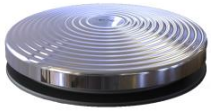
⚠ A yearly preventive maintenance or 2000 hours usage maintenance (LED ① solid orange), whichever comes first, is required as means of safety and performance guarantee for both the patient and the user.

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 (see § 6.9).

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 ⓪ + 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° Check the supplied air pressure: it shall be 4.5 bar minimum.
4° 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.
5° If the device temperature is over 10°C, or the problem recurs, definitively stop to using 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

Automatic maintenance reminder. It is time to send your device to yearly maintenance service. 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.

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.

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).
3° 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
Fax: +41 (0) 22 99 44 701
Email: TSAV@ems-ch.com

6.9. To report an Adverse Event

If any serious incident occurs that is directly or indirectly related to the treatment, report it immediately to EMS and to the competent authority of your country and of where the patient is established (if different).

Adverse Event notification to EMS
By email: vigilancemailbox@ems-ch.com
By fax: +41 (0) 22 99 44 701
By post: E.M.S. Electro Medical Systems S.A., Ch. de la Vuarpillière 31, 1260 Nyon – Switzerland

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 regulation[16]. Packaging cardboards are recycled and recyclable.

Printed instructions are aligned with a sustainable development policy and are certified « Myclimate neutral imprimerie » and « FSC ».

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.

[16] 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 DATA COLLECTION AND PRIVACY POLICY

During maintenance and/or repair of the device, EMS or any authorized EMS repair center will have access to certain technical information such as usage statistics (hereinafter “Technical Data”), collected during the device service.

Such technical data shall be analyzed and used by EMS in its legitimate interest, e.g. to carry out statistical analysis and to improve its customer service and/or its Research and Development processes.

EMS may also use such technical data along with your personal details in order to be able to understand your personal usage of the device and offer you a better customer experience and tailored service. However, you can unsubscribe from this process at any time, by simply sending us an email at privacy@ems-ch.com.

Rest assured that these activities will be carried out in compliance with applicable data protection laws. For any questions regarding your personal data, please consult our privacy policy at www.ems-company.com or send an email to privacy@ems-ch.com.

10. TECHNICAL DESCRIPTION

Manufacturer	EMS ELECTRO MEDICAL SYSTEMS SA, CH-1260 Nyon, Switzerland
Models	AIRFLOW One, product code FT-230
Classification IEC 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 8dBm EIRP, 2.4GHz 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 (device)	Temperature: -10°C to 30°C, no water inside Humidity: 10% to 95% not condensed Pressure: 500hPa to 1060hPa
Storage conditions (application box)	Temperature: up to 40°C
Transport conditions	Temperature: -29°C to 38°C, no water inside Humidity: 10% to 95% not condensed Pressure: 500hPa to 1060hPa
Input fluids	Water: pressure 2-5bar, temperature 10-30°C, salinity 0.2% max., hardness from 8 to 12°dH, minimum flow-rate 100ml/min, RECTUS 20KA connector type. EN-1717 compliant water network/inlet is required. Air: pressure 4.5-7bar, dry-only (humidity 1.032g/m3 max.), oil filtered 0.1mg/m3 max., minimum flow-rate 20 Nl/min at 4.5bar, RECTUS 21KA connector type
Output fluids	Water: min. 40 ml/min. for AIRFLOW® Air: max pressure 5bar for AIRFLOW® A few drops may escape when the water setting is at "0"
Shelf life / lifetime	WATER and NIGHT CLEANER bottles: 5 years Handpieces : 1000 sterilization cycles
Expected service life	Device: 7 years, having regular yearly preventive maintenance

10.1. 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
	Australian RCM compliance marking for wireless equipment
R-NZ	New Zealand R-NZ compliance marking for wireless equipment
CE 0124	Medical Device compliant with EU Directive 93/42/EEC Number of the Notified Body
	Ukraine Technical Regulation conformity mark UA – Symbol of Ukraine; TR – Provisional symbol of the Conformity Assessment Body that is assigned to perform conformity assessment to the requirements of technical regulations; 028 – Identification number of the designated Conformity Assessment Body.
	South African ICASA compliance marking for wireless equipment TA-2017/2826: BLE113 Bluetooth module approval number TA-2018/3027: BLE121LR Bluetooth module approval number

	Korean KC compliance marking for wireless equipment R-RMM-E23-FT-229: System approval number KCC-CRM-BGT-BLE113: Bluetooth module approval number
AGREE PAR L'ANRT MAROC Numéro d'agrément: MR 17713 ANRT 2018 / MR 14883 ANRT 2017 Date d'agrément: 16-10-2018 / 09-10-2017	Moroccan ANRT compliance marking for wireless equipment MR 17713 ANRT 2018: Wireless pedal approval number MR 14883 ANRT 2017: Device approval number
	United Arab Emirates TRA compliance marking for wireless equipment ER64514/18: BLE113 Bluetooth module approval number ER67538/18: BLE121LR Bluetooth module approval number
Complies with IMDA Standards (DB106919)	Singaporean IMDA compliance marking for wireless equipment DB106919: Dealer's Licence No.
CMIIT ID: 2018DJ3399	Chinese SRRC compliance marking for wireless equipment 2018DJ3399: System approval number
	Serbian RaTT certification label "Triple A" for the the R&TT equipment И005: Identification number of the designated Conformity Assessment Body Kvalitet 20: Two digits of the year when the certificate was issued
	GOST R for products in conformance with Russian standards

10.2. 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, 8 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 Bluetooth module complies with all the restrictions foreseen by the ERC recommendations 70-03 for the CEPT countries concerning the Annex 3 (Wideband Data Transmission System band A 2400-2483.5 MHz) without requiring any modifications of the products by the user.
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 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 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 Airflow Prophylaxis Master, including its cables. Otherwise, degradation of the performance of this equipment could result. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[17], should be less than the compliance level in each frequency range[18]. 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		

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.

[17] 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.
[18] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0,3	28
1720 1845 1970	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

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.

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.
RF emissions CISPR 11	Class B	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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

10.3. Radio Equipment Compliancy

This Medical Device and all of its accessories having radio equipment are compliant with the European Directive 2014/53/EU (RED – Radio Equipment Directive).

EMS

TFD-245
ed. 2017.06.14

RED 2014/53/EU DECLARATION OF CONFORMITY

We,

Manufacturer's Name: E.M.S. Electro Medical Systems S.A.

Business Address: Ch. de la Vuarpillière 31, CH-1260 Nyon, Switzerland

Declare under our sole responsibility that the products:

Product name	Product Reference	Embedded radio module type	Starting from Serial Number
AIRFLOW Prophylaxis Master®	FT-229	Bluetooth V4.0, 2.4 GHz band	KU00001
AIRFLOW® One	FT-230	Bluetooth V4.0, 2.4 GHz band	LD00010
Boost Wireless Pedal	EK-404	Bluetooth V4.0, 2.4 GHz band	KZ00051

To which this declaration relates, are conforming with the essential and other relevant requirements of the RED Directive 2014/53/EU, especially, but not limited to the following standards and/or normative documents:

SAFETY
- IEC 60601-1:2005 + A1:2012
- EN 62311: 2008

EMC
- ETSI EN 301 489-1 v2.1.1 (2016-11)
- ETSI EN 301 489-17 v3.1.1 (2016-11)

SPECTRUM
- ETSI EN 300 328 v2.1.1 (2016)

Supplementary information
The Notified Body LCIE (Laboratoire Central des Industries Electriques), with the identification number 0081, performed a conformity assessment of the above-mentioned products using an EU-type examination followed by the conformity to type based on internal production control.
Then, he issued the EU-type examination certificate: N°147779-701316-A.

The complete Technical Construction File is kept available by E.M.S. Electro Medical Systems S.A.

Place and date of issue: Nyon, 2017-06-14

Authorised Signatory:

Timothée Deblock, Head of Quality

P. 1/1

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