User Manual

AIR-N-GO® easy

ACTEON

This document is an English translation of the original French version.
Reference J10120 version V8 and drawing number ND27FR050H

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1 Documentation

This document contains the following information:

- Patient, practitioner and environment safety
- Installing your medical device in optimum conditions
- Identifying the manufacturer or the latter's representatives if necessary
- Indications for use
- Medical device description
- Installation of the medical device
- Medical device use
- Preparation for cleaning and disinfection of the medical device
- Medical device sterilisation
- Monitoring and general maintenance of the medical device
- Maintenance to be performed by the user

1.1 Associated documentation

This document must be used in association with the following documents:

Document title	References
Consulting electronic user instructions	J00007
AIR-N-GO® easy Quick Start	J10100
AIR-N-GO® easy Quick Clean	J10101
AIR-N-GO® easy seal maintenance	J10104
AIR-N-GO® easy user manual	J10121

> The Quick Start and Quick Clean documents are summaries created for your approval. The only binding instructions are the user manuals and regulatory documentation associated with the medical device.

1.2 Electronic documentation

The user instructions for your device are available in electronic format on the specified website and not in printed format. If the website is unavailable, try again later. You can also request a free printed copy of the user instructions within seven days via our website, by telephone or in writing.

The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file reader installed to read the electronic user instructions. It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories.

> Never use your device without first reading the user instructions.

The device user instructions can be consulted at the following addresses:www.ultradent.com and www.satelec.com.

When you receive your device, you are asked to print and/or to download all documents or sections of documents that you may need to refer to in the event of an emergency, if you are unable to connect to the internet or if your electronic display tool is not working (computer, tablet, etc.). We recommend that you visit the website regularly to consult and to download the latest version of your device's user instructions. Users are asked to keep documentation close at hand for reference when necessary.

All paper or electronic documentation relating to your medical device must be kept for the device’s entire service life. Keep the original documentation for your medical device and its accessories for future reference. When loaning out or selling the medical device, the documentation must be provided with it.

2 Warnings

2.1 Federal Law

> The indication below applies to the United States of America only.

The United States Federal Law restricts the use of this medical device in its territory to qualified, fit and certified dental health professionals (either directly or under their supervision).

2.2 Warning applicable to all countries in which the device is sold

> The information below is based on the requirements of standards to which the manufacturers of medical devices must adhere (as stated in standard IEC62366).

2.3 User population

This medical device must only be used by qualified dental health practitioners, fit and certified to perform their professional duties.

Users must know and comply with the rules of dental practice in compliance with knowledge acquired in the field and the key medical hygiene principles including cleaning, disinfection and sterilisation of medical devices.

The medical device can be used by any adult dental practitioner of any weight, age, height, gender and nationality.

The user must wear gloves.

The user is not the patient.

The user must not be prone to any of the following:

- visual impairments: any vision problems must be corrected by glasses or lenses.
- arm disability that may prevent the user from holding a handpiece;
- leg disability that may prevent use of a footswitch;
- hearing difficulties that could prevent the user hearing audible alarms depending on medical devices;
- difficulty memorizing or concentrating that could affect the setting of sequences or the performance of treatment protocols.

2.4 Specific user training

No specific training other than initial professional training is required to use this medical device.

The practitioner is responsible for performing clinical treatments and for dangers that may arise due to a lack of skill and/or training.

2.5 Patient population

This medical device is designed to be used with the following patient populations:

- Children,
- Teenagers,
- Adults,
- Old Age Pensioners.

This medical device can be used on any patient of any weight (except children), age, height, gender and nationality.

Patients wearing prescription glasses or contact lenses must remove them before the treatment and wear the safety goggles provided during the treatment.

2.6 Patient population restriction

This medical device must not be used on the following patient populations:

- Infants,
- pregnant or breastfeeding women due to restrictions associated with the possible use of medical solutions such as anaesthetics;
- patients with medical issues,
- Patients allergic to some of the medical device components,
- patients with a clinical site not suitable for treatment,

The patient must be calm, relaxed, still, ideally lying flat on a dental chair.

The user is the only person who can decide whether or not to treat his/her patients.

2.7 Parts of the body or types of tissues treated

Treatments must only be performed on the patient's oral environment.

2.8 Applied parts

Elements in direct contact with the patient	Polishing nozzle
Part in indirect contact with the patient	Front body of the medical device

2.9 Essential performance

As stated in the applicable safety standard pertaining to electrical medical devices, The manufacturer has determined that the medical device did not manage essential performances.

2.10 Basic safety in normal use

The active part, the handpiece is held by the practitioner throughout the treatment. Being medically qualified, the practitioner is qualified to immediately detect any problem at the treatment site and to react accordingly.

It is advisable to have a spare medical device or an alternative means with which to perform the medical treatment in the event of device failure.

The practitioner must wear a mask to limit the risk of powder inhalation and to mitigate the risk of bacterial or viral airborne contamination.

2.11 Normal usage conditions

The normal usage conditions are as follows:

- storage;
- installation;
- use;
- maintenance;
- disposal.

2.12 Service life

The shape of the nozzles is decisive in achieving the maximum performance of the air polisher. The medical device will perform best if the user pays attention to this characteristic. Therefore, we strongly advise against the modification of the structure of the nozzles by filing, twisting or by performing other types of modification.

As it is not possible to establish a maximum number of uses, that may be determined by many parameters such as frequency of use, duration of use, quality of routine maintenance or the care taken with the parts of the device, we recommend that the most used nozzles are replaced once a year.

3 Required information

3.1 Indication for use

This medical device is designed for supra- and subgingival prophylactic treatments of dental and prosthetic surfaces.
It is used with dental polishing powders Acteon.
This medical device is used with a dental ultrasonic handpiece to which an ultrasonic instrument is attached. It is designed for prophylaxis, periodontics, endodontics and restorative and conservative dentistry treatments.
With the Perio option, it is used for prevention and maintenance purposes in treated patients and for the treatment of periodontal diseases: periodontitis and peri-implantitis.

3.2 Operating principle

Air, water and air polishing powder are supplied to the medical device. The air fed into the closed tank suspends the powder, which is projected onto the treatment site via a nozzle. Air, water and powder are mixed when they come out of the medical device.

3.3 Connecting and disconnecting accessories during use

No accessories must be disconnected during use, the nozzle must not be unscrewed and the AIR-N-GO® easy body protection must not be removed.
To prevent powder from spraying all over the surgery, the powder tank must not be opened when the AIR-N-GO® easy is in use.

3.4 Repairing or modifying the medical device

Contact the supplier of your device. Using the services of an unapproved repairer could render your device dangerous for you and your patients.
Do not repair or modify the device without seeking the prior permission of SATELEC, a company of Acteon group.
If the device is modified or repaired, specific checks and tests must be carried out to ensure that the medical device is still safe to use.
In the event of doubt, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team:
`www.acteongroup.com`
`satelec@acteongroup.com`

> SATELEC, a company of Acteon group, at the request of technical personnel working for the network of approved dealers, will provide any information required to repair defective parts on which they may perform repairs.

3.5 Warranty

Only clearly indicated parts of the medical device can be unscrewed by the user. Unscrewing any other parts may void the warranty. The container and the adapter cannot be and must never be detached from the body of the medical device.

3.6 Latest document update

03/2018

3.7 Date of first CE marking

2011

4 Interactions, contraindications, prohibitions

This includes information relating to the interactions, contraindications and prohibited operations known by the manufacturer on the date on which this document was written.

4.1 Contraindications

It is important to determine a patient's state of health prior to treatment. If one or more of the following applies to your patient, please do not treat them:

- known allergy to one of the ingredients in the polishing powder used
- endocarditis
- immune deficiency
- taking a course of antibiotics, undergoing chemotherapy/radiotherapy treatment
- diabetes
- haemophilia
- asthma, chronic bronchitis or another breathing disorder

Pregnant or breastfeeding women cannot be treated with this medical device.

A sensitivity or allergy to any of the powder ingredients may become apparent during treatment. Rinse the patient's mouth thoroughly to remove all traces of the powder.

> Never point the medical device directly at the eyes even when it is not in use.

4.2 Using accessories not supplied by the manufacturer

The medical device was designed and developed with its accessories to guarantee maximum safety and performance. The use of accessories from another source could put you and your patients at risk and could damage your medical device.

Do not try to connect accessories not provided by SATELEC, a company of Acteon group to your medical device connector(s) or to the handpiece.

The medical device is designed to be used with Acteon Classic, Pearl or Perio polishing powders.

The use of other powders may cause the device to function incorrectly or compromise its effectiveness and the safety of your patients.

Even if the manufacturer or dealer of your accessory claims full compatibility with SATELEC, a company of Acteon group equipment, it is advisable to exercise caution with regards to the origin and safety of the product offered. Look out in particular for lack of information, information in a foreign language, very attractive prices, suspect appearance, mediocre quality or premature wear. If necessary, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team.

The medical device is designed to work with SATELEC, a company of Acteon group nozzles and powders. Using nozzles or powders from other manufacturers will cause damage to the medical device.

4.3 Prohibited uses

- Do not immerse or use outdoors.
- Do not place the medical device next to a source of heat or in direct sunlight.
- Do not expose the medical device to water spray or mist.
- Do not use the medical device in an AP or APG gas-filled atmosphere.

The medical device is not designed to operate near a source of ionising radiation.

A hot/cold temperature contrast can cause condensation to form in the medical device, which may be dangerous. If the medical device needs to be moved from a cold place to a warm place, do not use the device immediately. Wait until it reaches room temperature.

The medical device may not be stored or used outside the temperature, atmospheric pressure and humidity ranges recommended in the User Manual supplied with your medical device.

Only use the medical device for the purpose for which it has been designed.

Do not put water in the powder container and use a completely dry powder.

5 Unpacking the medical device

When you receive your medical device, check for any damage that may have occurred during transportation.

If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.

If you have any questions or requirements, contact your supplier.

The AIR-N-GO® easy includes the following items:

- a handpiece with a non-detachable turbine adapter
- a SUPRA 120° nozzle
- servicing and maintenance equipment including:
    - silicone grease tube
    - silicone grease applicator brushes
    - spare O-rings
    - a syringe and a cannula
    - a metal shaft cleaning probe
    - a maintenance instructions leaflet [J10104]
- A [J10100] Quick Start guide;
- A [J10101] Quick Clean guide;
- a starter kit comprising 10 Classic powder sachets and 2 Pearl powder sachets.

> Check that the AIR-N-GO® easy adapter is compatible with your quick coupling.

6 Installing the medical device

The AIR-N-GO® easy connects directly to the quick coupling on your dental chair.

1. Remove the turbine
2. Dry the quick coupling using the multi-purpose syringe air function
3. Do not activate the turbine function when connecting the AIR-N-GO® easy
4. Remove the container plug.
5. Connect the turbine coupling to the AIR-N-GO® easy adapter
6. Adjust the water flow to drop-by-drop
7. Wipe the inside walls of the container with a dry, lint-free cloth
8. Press the footswitch to eliminate any moisture still in the circuit. Repeat the procedure until there are no more droplets on the inside walls of the container
9. Wipe the inside walls of the container with a dry, lint-free cloth
10. Fill the tank with the correct amount of powder for the intended treatment. Fill the container to the indicated limit
11. Wipe with a dry, lint-free cloth to remove all traces of powder from the container threads and plug
12. Check that the O-ring is correctly seated in the container plug
13. Close the container
14. Remove the nozzle and the body from their sterile bags
15. Install them and start the treatment

> If droplets continue to appear on the inside walls of the container in step 8, read the chapter *Water in the powder tank page 27*

Adjust the position of your medical device to correspond to your angle of vision and the characteristics of your workstation, e.g. lighting or distance between the user and the medical device.
Ensure that your medical device is readily accessible. Do not install your medical device near or on another device.

> Inspect the condition of the O-rings on your quick coupling prior to each use. A damaged O-ring can cause irreparable damage to your medical device.

> Before connecting the AIR-N-GO® easy, dry the chair's quick coupling using the air syringe.

6.1 Fitting a nozzle

6.1.1 Supra 120° nozzle

The Supra 120° nozzle is used for supragingival polishing treatments.
It is only compatible with Classic and Pearl supragingival powders.

6.1.2 Perio easy nozzle

The Perio easy nozzle is used for periodontal polishing treatments for three to eight millimetre-deep periodontal pockets.
It is only compatible with Perio powder.

6.1.3 Perio nozzle

The Perio nozzle is used for subgingival polishing treatments for eight to ten millimetre-deep periodontal pockets.
It is only compatible with Perio powder.

6.1.4 Perio Maintenance nozzle

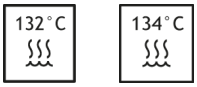
The Perio Maintenance nozzle is used for periodontal maintenance treatments for four millimetre-deep periodontal pockets or below.

It is only compatible with Perio powder.

7 Dispensing a treatment

7.1 Accessory usage conditions

The AIR-N-GO® easy's nozzle and plastic tube must be cleaned, disinfected and sterilised before use.



Refer to the cleaning, disinfection and sterilisation instructions for accessories listed in the chapter *Clean and disinfect the medical device page 17*.

7.2 Pre-use test

You must perform tests prior to using the medical device on your patients. Perform your tests on a piece of oxidized metal, such as a coin.

7.3 First use

7.3.1 Turbine adapter

The turbine adapter is equipped with water and air check valves. These prevent any air or water rising back up in the direction of the dental chair.

The following nozzles can be fitted to the AIR-N-GO® easy. Each nozzle has specific characteristics to enable all clinical treatments to be performed, in direct association with the various types of powder available.

7.3.2 Powder tank

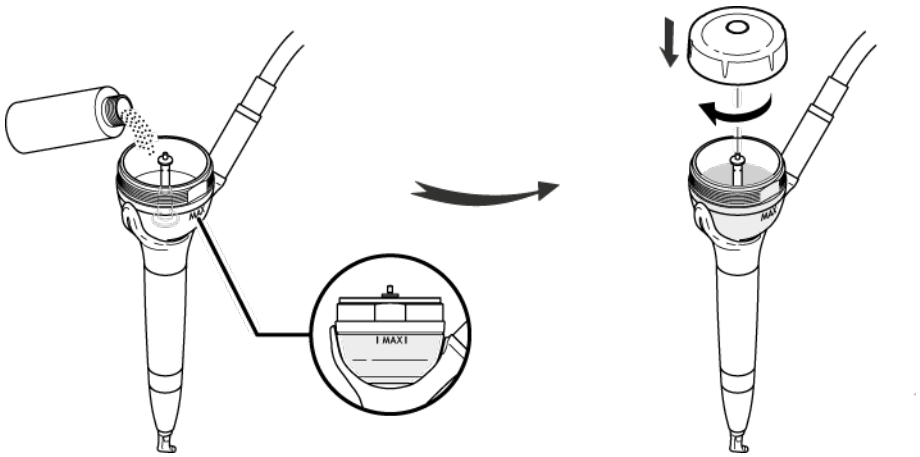
The medical device's tank is fitted with a plug. The maximum capacity is shown by the MAX mark on the tank.

The tank is part of the handpiece and neither the tank nor its plug can be sterilised.

7.3.3 Filling the tank

- Check the expiry date of the powder.
- Blow around the seal of the plug and the tank threads with an air syringe to remove any powder residue.

Fill the tank with the required amount of powder for the treatment to be performed. Do not fill past the maximum line indicated to ensure correct operation of theAIR-N-GO® easy.



7.3.4 Setting the irrigation flow

The irrigation flow can be configured at the dental chair. Drop-by-drop irrigation is required to ensure correct operation of AIR-N-GO® easy. Please check the irrigation flow prior to all treatments.

7.3.5 Using the medical device

- The patient and the practitioner must wear safety goggles. The practitioner must also wear a mask.
- Install a large surgical-type suction cannula and keep it near the area being treated.

> Apply medical Vaseline to the patient's lips and commissures before polishing.

1. Press your chair's footswitch to adjust irrigation to drop-by-drop
2. Point the nozzle at the dental enamel, holding it 3 to 5 mm away
3. Ensure a spray angle of 30 ° to 60 ° between the nozzle and the surface of the tooth
4. Make gentle circular movements over the area being treated
5. Continue treatment until the desired result is obtained
6. Apply a fluoride gel to the patient's teeth.

Air-water will continue to spray for a few seconds after releasing pressure on the footswitch. To protect the mucosa, wait for the spray to stop completely before removing the device from the patient's mouth.

> For an optimum result, ask your patient to refrain from smoking or from eating any foods that could stain their teeth for 2 to 3 hours following treatment.

7.4 Switching off the medical device

Release the footswitch of the chair to switch off the medical device.

8 Disinfection and sterilising

The cleaning, disinfection and sterilisation instructions for the medical device and accessories provided by Acteon have been approved for each part. Follow the instructions step by step, making absolutely sure that you comply with the products and times indicated.

> Any step that is performed without complying with the instructions creates a risk of contamination.

In all cases, the local regulations in force relating to the cleaning, disinfection and sterilisation protocols for accessories take precedence over the information provided by SATELEC, a company of Acteon group.

8.1 Cleaning cycle limits

Repeated packaging cycles involving manual washing have little effect on air polishing nozzles. End of service life is normally determined by wear and damage due to use.

8.2 Clean and disinfect the medical device

After installation and prior to first use, at the end of the day and following an extended period of non-use of the medical device, it is necessary to clean the medical device.

8.3 Containment and transportation

Soiled devices must be transported separately from non-contaminated devices to avoid any contamination.

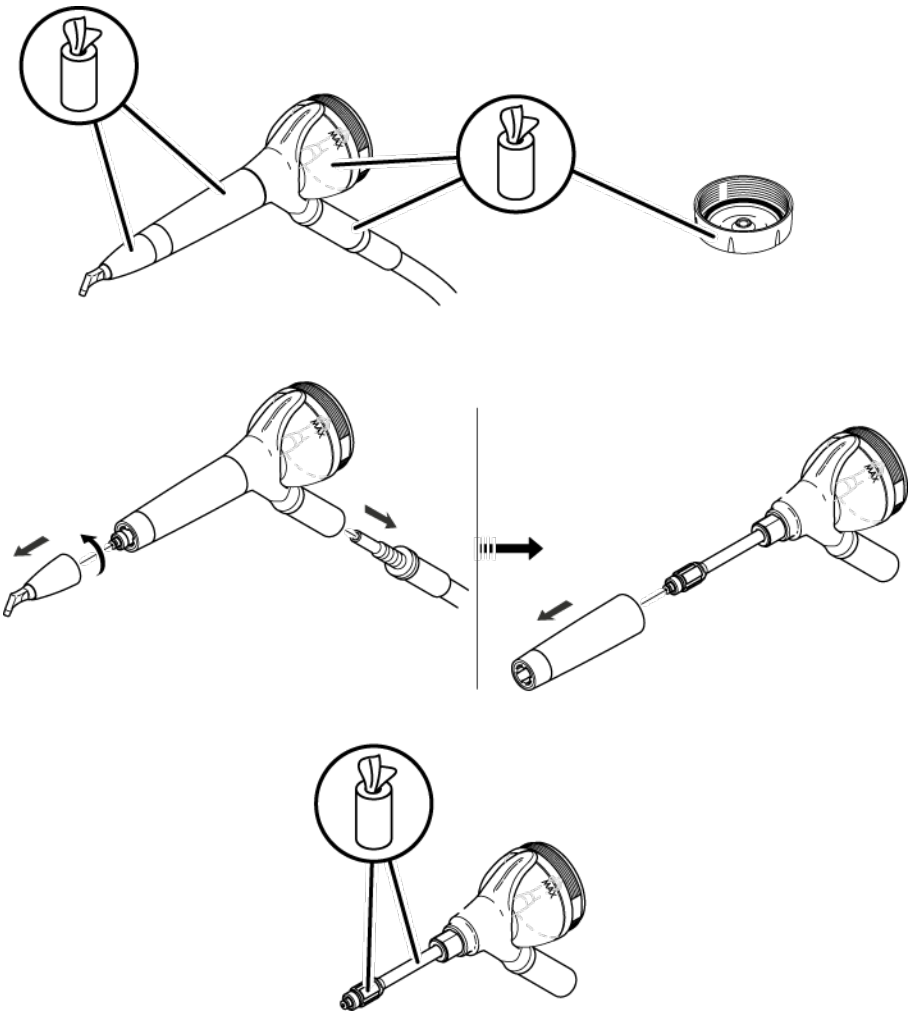
8.4 Preparation for pre-disinfection

It is advisable to recondition devices as soon as possible after use. SATELEC, a company of Acteon group devices must be reconditioned within two hours of use.

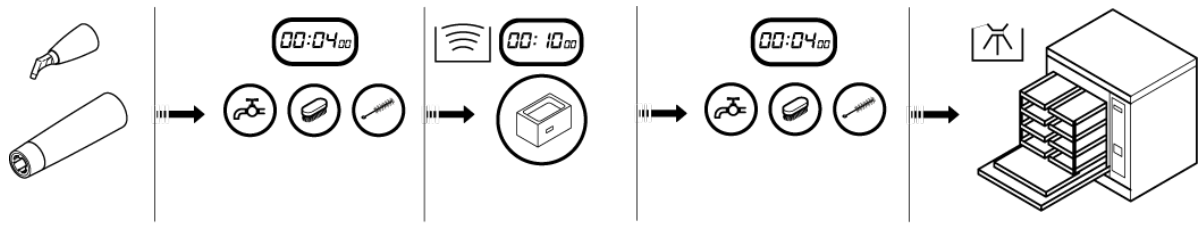
8.5 Pre-disinfection

1. Clean the outside of the AIR-N-GO® easy with an alcohol disinfection wipe
2. Unscrew the nozzle
3. Remove the plastic body
4. Clean the metal part of the body with an alcohol disinfectant wipe.

> Do not clean the inside of the tank with an alcohol disinfectant wipe.



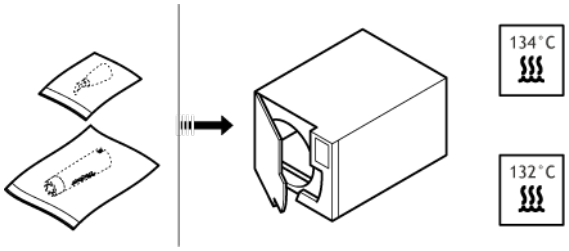
1. Wash the nozzle under water;
2. Wash the body under water
3. Use a soft-bristled brush or a swab to remove most of the contamination
4. Immerse the nozzle and the body in an ultrasonic tank filled with an alkaline or enzymatic solution ensuring compliance with the concentration and times recommended by the solution manufacturer
5. Remove the nozzle and the body
6. Tap the nozzle on a hard surface to remove any remaining particles;
7. Rinse the nozzle under water;
8. Rinse the body under water
9. Use a syringe to rinse difficult-to-reach parts
10. Dry the nozzle and the body with a single-use soft, lint-free cloth
11. Transfer the nozzle and the body to the washer-disinfector.



8.6 Sterilisation

> Single-use sterilisation bags must comply with ISO standard 11 607 or any equivalent standard required by a national regulation.

1. Remove the nozzle and the body from the washer-disinfector:
2. Dry them
3. Pack each individual part in its own sterilisation bag
4. Sterilise them in a vacuum steam autoclave steriliser according to the usual cycle in your activity area:



In Europe, depending on the country:

- 18 minutes at 134°C and 20 minutes drying time;
- 4 minutes at 134°C and 20 minutes drying time;
- 3 minutes at 134°C and 20 minutes drying time.

Pressure of at least 2 bar.

In the USA - 4 minutes at 132 °C and 20 minutes drying time.

Pressure of at least 1.85 bar.

8.7 Storage

Store the sterilised parts in a dry place, away from dust and at ambient temperature. Prior to each use, check the integrity of the packaging and if necessary, re-sterilise.

> If there is any visible contamination inside the bag, place the part in an infectious clinical waste container to ensure it is disposed of without risk.

9 Monitoring and routine maintenance

The only preventive maintenance the medical device requires is:

- Monitoring of accessories
- Routine cleaning, disinfection and sterilisation
- Cleaning

Before and after use, check the medical device and its accessories entirely for any problems. This is necessary to detect any electrical isolation fault or damage. If necessary, replace damaged parts.

The AIR-N-GO® easy is an air polisher that operates with polishing powders. Powders for use with the AIR-N-GO® easy contain sodium bicarbonate, calcium carbonate or glycine. However, in powder form, these three ingredients are hygroscopic. Leaving the powder exposed to ambient air for one night is enough to cause a blockage of the AIR-N-GO® easy.

9.1 Performing preventive cleaning

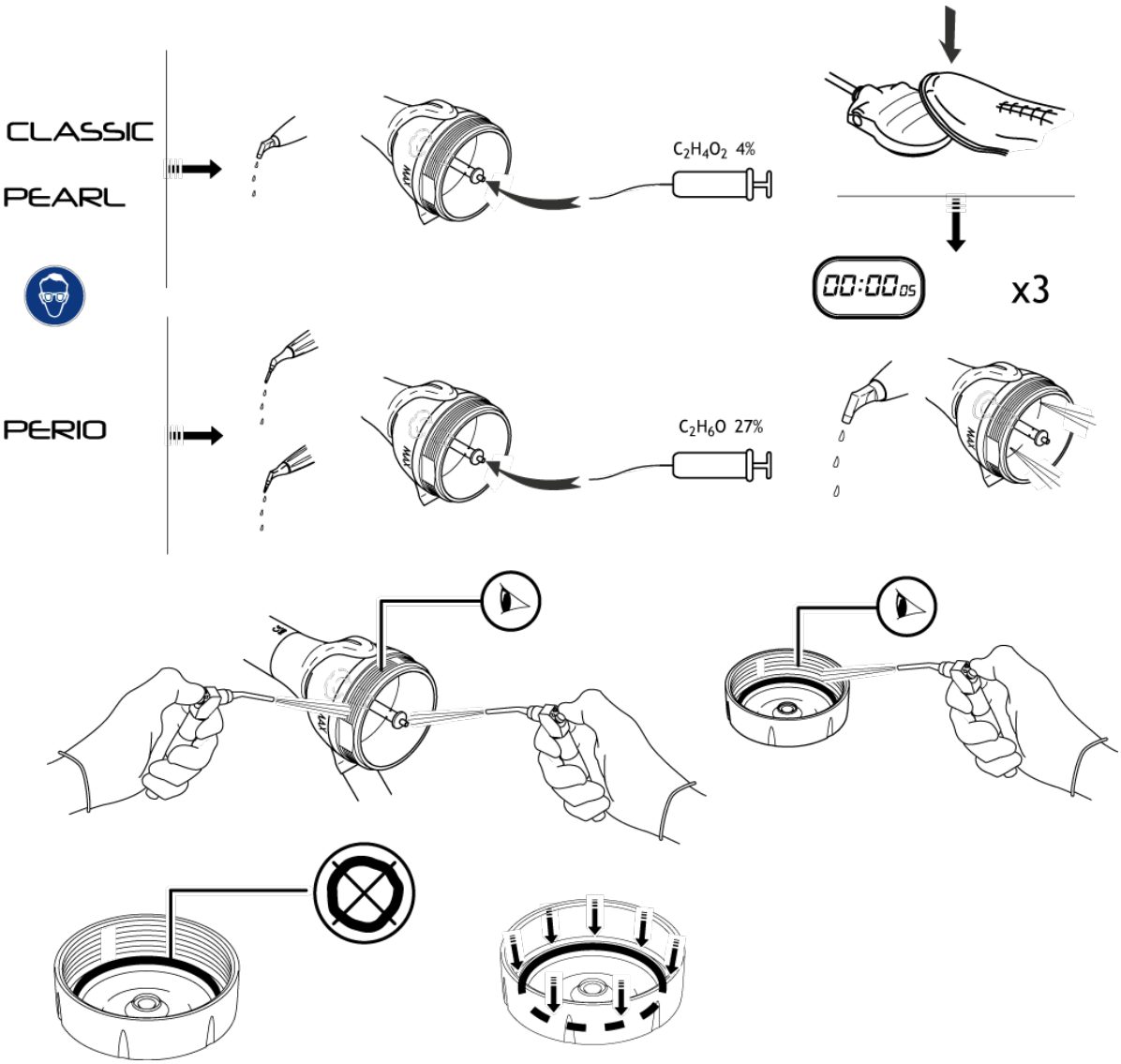
Preventive cleaning must be carried out each time the AIR-N-GO® easy is used.

> Wear safety goggles.

> Devices that use sodium bicarbonate and calcium carbonate powders are cleaned with a 4% acetic acid aqueous solution such as $C_2H_4O_2$ molecular formula spirit vinegar or diluted lemon juice.

> Devices that use glycine powders are cleaned with a C_2H_6O formula 27 % ethanol aqueous solution such as green Listérine®.

1. Fill the syringe with liquid compatible with the cleaning powder.
2. Inject the liquid into the metal shaft of AIR-N-GO® easy through the opening on the tank.
3. Inject as much as necessary until the liquid comes out of the nozzle.
4. Wait until the liquid has come out entirely.
5. Clean the AIR-N-GO® easy's air circuit until the inside walls of the tank show no signs of moisture.
6. Dry the metal shaft using the multi-purpose syringe air function
7. Using the multi-purpose syringe air function, clean the tank threads, tank plug threads and underneath the tank plug O-ring.
8. Check the tank plug O-ring and make sure that it is correctly reinstalled.

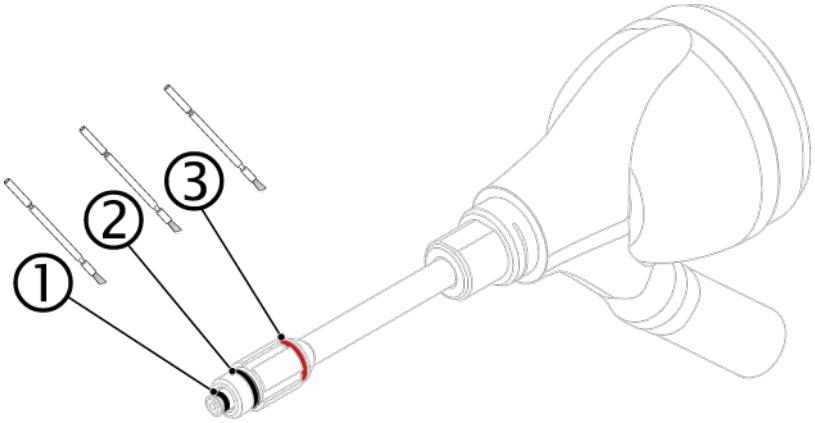


The Classic and Pearl powders are cleaned using a 4 % acetic acid aqueous solution.
The Perio powder is cleaned using a 27 % ethanol aqueous solution.

9.2 Lubricating O-rings

After a certain time, the O-rings on the AIR-N-GO® easy body may dry out and become defective. They should be lubricated with the silicone grease supplied by Acteon as follows:

- Remove the AIR-N-GO® easy body and the nozzle
- Pour a drop of silicone grease into a small cup
- Using the brush provided, take a small amount of this grease and spread it over the O-rings indicated



- Wipe off any excess grease with a dry, lint-free cloth
- Condition the body of the AIR-N-GO® easy pending its next use

> Never use turbine spray lubricant to lubricate the O-rings. This will damage them instantly and render them irreparable.

> Never apply grease to the O-ring inside the container plug as this will instantly block the AIR-N-GO® easy.

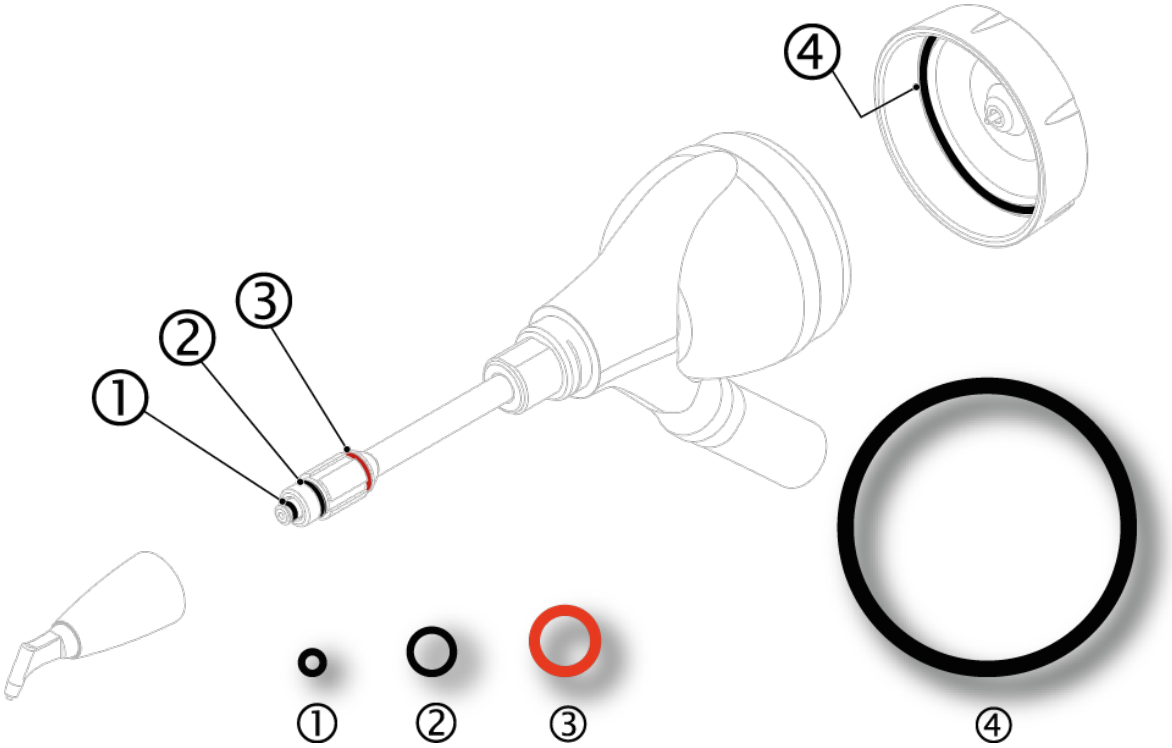
9.3 Corrective Maintenance

In the event of faulty operation, the following corrective maintenance actions may be performed by the user.

9.3.1 Replacing O-rings

Regularly check the condition of the AIR-N-GO® easy handpiece O-rings. Any damaged O-ring must be immediately replaced using the kit [F10121].

If the AIR-N-GO® easy sputters, indicating the presence of air in the water, or if the water drips between the handpiece body and the nozzle, the AIR-N-GO® easy O-rings must be replaced as shown.



10 Identifying incorrect operation

In the event of incorrect operation, refer to the tables below to quickly identify and repair the non-complex parts of the medical device.

If the incorrect operation is not described in the tables below, please contact your supplier or the customer service team at SATELEC, a company of Acteon group.

Do not use the medical device if it appears to be damaged or faulty. Isolate the medical device and make sure that it cannot be used.

> The medical device will need to be sent away for repair.

10.1 Not working

Symptoms: the medical device is not working

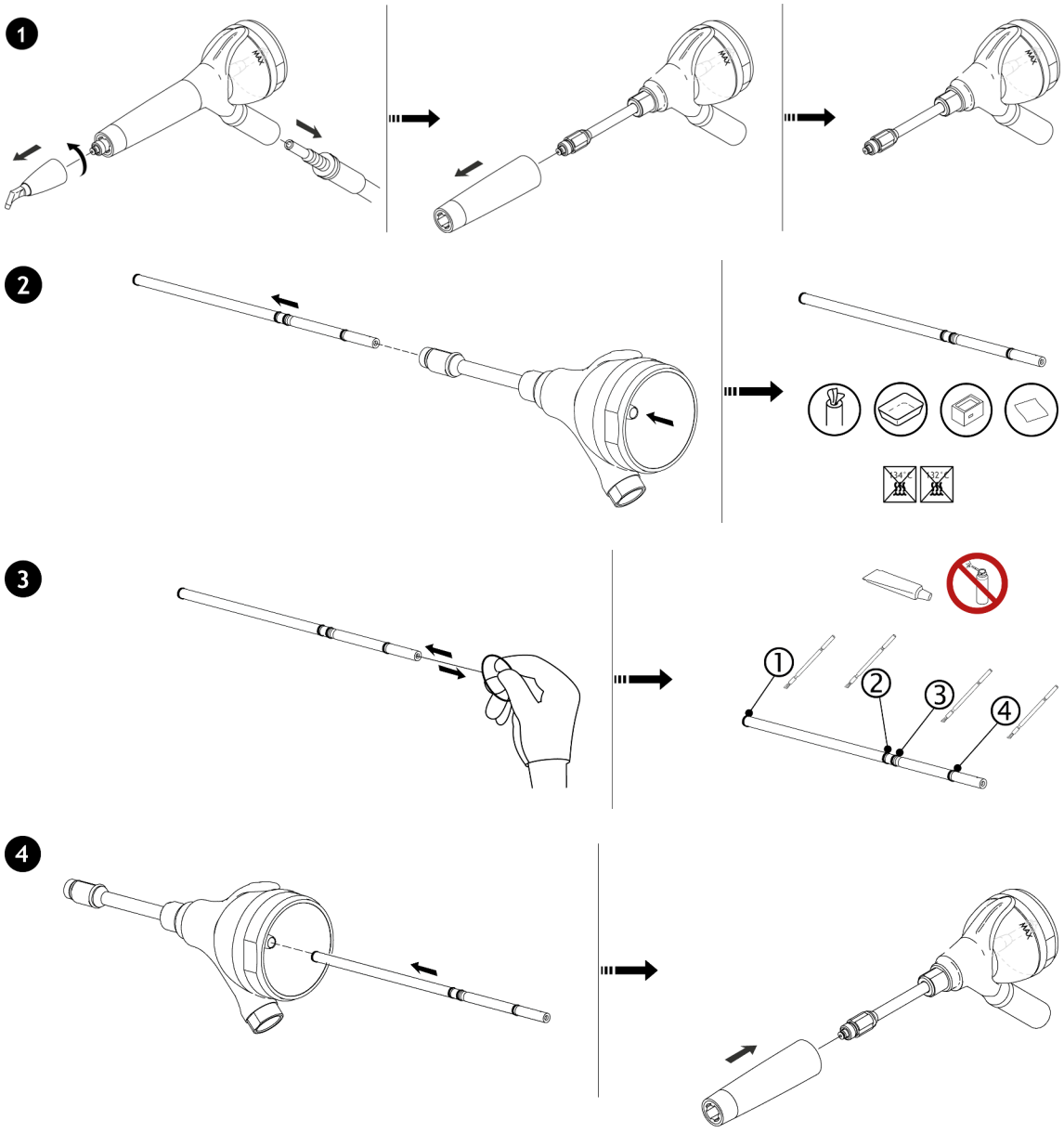
Possible causes	Solutions
The chair is not supplying any air or water	• Disconnect the AIR-N-GO® easy from the quick coupling • Press the chair's footswitch • Check that air is coming out of the quick coupling • Check that water is coming out of the quick coupling. If neither air nor water or if only air or only water is coming out of the chair, the malfunction is with the dental chair. If air and water are coming out of the chair, refer to the procedure chapter *page 25*.

10.2 No spray

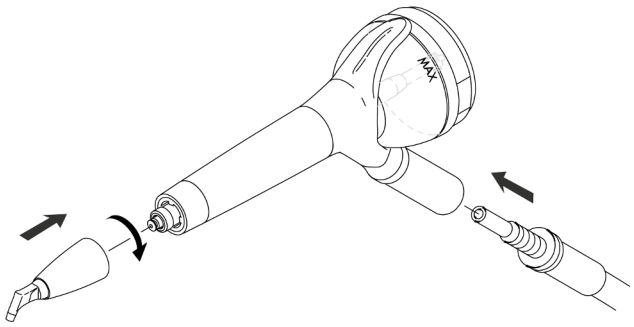
Symptoms: The air polisher is not producing any spray.

Possible causes	Solutions
The chair is not supplying any air or water	Refer to the procedure in the chapter *page 25*.
The nozzle is blocked	• Immerse the nozzle in a solution that is compatible with the powder used • Place the nozzle in its solution in the ultrasonic tank for at least 10 minutes • Remove the nozzle and tap it on a cloth to remove any remaining particles • Without rinsing it, screw the nozzle back onto the handpiece • Connect the handpiece to the quick coupling with the tank empty and clean • Actuate the handpiece and test it If there is still a blockage, contact Acteon's Customer Services team If the AIR-N-GO® easy works, unscrew the nozzle and rinse it under water, then screw the nozzle back onto the handpiece.

Possible causes	Solutions
The irrigation flow is not adjusted	• Remove the tank plug. • Dispose of the powder in an infections clinical waste container. • Adjust the irrigation flow to drop-by-drop • Purge the air circuit • Wipe the inside walls of the tank with a dry, lint-free cloth. • Pour the powder into the tank • Screw the plug back onto the tank.
The AIR-N-GO® easy air duct is blocked	Follow the procedure below.



5



10.3 Powder coming out of the tank

Symptoms: powder is coming out of the tank

Possible causes	Solutions
The tank plug is not screwed on properly.	Screw the plug tightly onto the tank.
The plug O-ring is incorrectly positioned. There are traces of powder under the plug O-ring.	• Remove the tank plug. • Dispose of the powder in an infections clinical waste container • Remove the plug's O-ring and inspect it. • Use the multi-purpose syringe's air function to blow air and clean the lid threads. • Place the O-ring back onto the plug. • Fill the tank to the maximum level with suitable powder • Screw the plug back onto the tank.
The plug O-ring is defective.	Contact Acteon Customer Service team to replace the plug seal.
The tank is cracked	Contact Acteon Customer Service team to replace the tank.

10.4 Water in the powder tank

Symptoms: drops of water appear in the powder tank.

Possible causes	Solutions
The tank wasn't dry when the powder was added	• Remove the tank plug. • Dispose of the powder in an infectious clinical waste container • Run at least three five-second purge cycles in the air circuit • Dry the air circuit using the multi-purpose syringe air function • Dry the inside walls of the tank • Fill the tank to the maximum level with suitable powder • Screw the plug back onto the tank.
The quick coupling O-ring is defective	The malfunction is with the dental chair. Contact a technician.
There is water in your compressor	Contact a technician to check your compressor.

11 Technical specifications of the medical device

11.1 Identification

Manufacturer	SATELEC, a company of Acteon group
Name of the medical device	AIR-N-GO® easy

11.2 Air polisher

Length	180 mm - 205 mm depending on adapter
Height	70 mm - 95 mm depending on adapter
Diameter	46 mm max
Weight	110 g - 155 g depending on adapter

11.3 Irrigation

Intake air pressure	3 to 4 bar (44 to 58 p.s.i.)
Water pressure at inlet	1 to 5 bar (15 to 72.5 p.s.i.)
Recommended water output flow at the end of the nozzle	15 ml/min to +/-5 ml/min
Maximum water output flow at the end of the nozzle	>30 ml/min

11.4 Environmental characteristics

Ambient operating temperature	+10°C to +30°C
Operating RH	30% to 75 %
Atmospheric operating pressure	Between 800 hPa and 1060 hPa
Maximum operating altitude	Less than 2000 metres
Storage temperature	0°C to +50°C
Storage temperature for air polishing powders	+5°C to +25°C
Storage humidity	5% to 75%, including condensation
Atmospheric storage pressure	Between 500 hPa and 1060 hPa

11.5 Environmental restrictions

Usage premises	Usable in all medical premises. The medical device must not be used in an operating theatre or outdoors.
Use in gas-filled atmosphere	The medical device is not designed for use in a type AP or APG gas-filled atmosphere or in the presence of anaesthetic gases.
Immersion	The handpiece must not be immersed.

11.6 Main performance characteristics

- pressure/air flow
- pressure/water flow
- Acteon dental powder with a controlled grain size.

12 Regulations and standards

12.1 Applicable standards and regulations

This medical device complies with the essential requirements of European Directive 93/42/EEC. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.

12.2 Medical class of the device

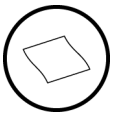
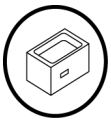
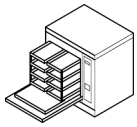
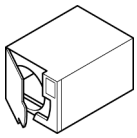
Class of medical device: IIa according to 93/42/EEC directive

12.3 Symbols

Symbol	Meaning
	Always wear safety goggles
	Always wear protective gloves
	Refer to the supporting documentation
	Consult the User Manual
	The accompanying documentation is available in electronic format
	Pressure limit
	Temperature limit
	Humidity limit
	Packaging unit

Symbol	Meaning
	Fragile, handle with care
	Store in a dry place
	Biohazard
	Sterilisation at 134°C in an autoclave
	Sterilisation at 132°C in an autoclave
	Washer-disinfector for thermal disinfection
	Ultrasonic bath
	CE marking
	CE marking
YYYY 	Year of manufacture
	Manufacturer
	Do not dispose of as household waste
	Recycle your lamps and professional electrical equipment with Récylum
Rx Only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.
IPX1	**IP**: ingress protection ratings procured by a range **X**: no ingress of protection rating claim against the penetration of solids **1**: protects against the vertical falls of drops of water

12.4 Quick Start and Quick Clean symbols

	Use a soft brush for cleaning
	Use a lint-free cloth for cleaning
	Use an ultrasonic tank for cleaning.
	Use a swab for cleaning
	Use an alcohol disinfectant wipe for pre-disinfection and cleaning.
	Clean under running water
	Use a washer-disinfector for cleaning and disinfection
	Use a pre-vacuum air autoclave for sterilisation

12.5 Manufacturer identification

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www.acteongroup.com

CE 0459
CE Marking

12.6 Manufacturer responsibility

The manufacturer shall under no circumstances be liable in the following cases:

- Non-compliance with manufacturer recommendations during installation, whether this is the network voltage or the electromagnetic environment
- Maintenance or repair procedures performed by people who are unauthorised by the manufacturer.

- Use on an electrical fixture that is not compliant with regulations in force.
- Use of the device for purposes other than those specified in this manual.
- Use of accessories or handpiece not supplied by SATELEC, a company of Acteon group .
- Non-compliance with the instructions contained in this document.

> Note: the manufacturer reserves the right to modify the medical device and any documentation without notice.

12.7 Branch addresses

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12.8 Disposal and recycling

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or the Acteon head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapter *Branch addresses page 35*.

The indication below applies to France only.

In compliance with the provisions of the French Environment Code relating to the disposal of electronic and electrical equipment waste or WEEE (Decree no. 2012-617 dated 2 May 2012), our Company fulfils its obligations to reclaim and dispose of its electrical and electronic equipment through the means established by the approved organisation Récylum, NOR approval: DEVP1427651A.

As a manufacturer, our Company is listed in the National Register of Producers kept by the ADEME (French Environment and Energy Management Agency). Professionals buying our products directly from the distribution chain are responsible for passing on this information about our established recycling methods to the end user.

In addition, the buyer agrees to take back our brand's devices at the end of their service life and to transfer them to one of the collection centres set up by Récylum for recycling (see list of collection centres on the site `http://www.recylum.com/`).

If necessary, Récylum can come and collect these devices from you free of charge once the quantity of devices has reached a certain level in the pallets-containers with which you are provided to store this waste.

An accessory that has reached the end of its service life must be disposed of in infectious clinical waste containers.

A medical device that has reached the end of its service life must be disposed of in infectious clinical waste containers.

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14 Glossary

A

Adapter
part used to connect the AIR-N-Go easy directly to the quick coupling on the dental chair.

C

C2H4O2
an acetic acid molecular formula used to service devices used with sodium bicarbonate or calcium carbonate powders.

C2H6O
an ethanol molecular formula used to service devices used with glycine powders.

Classic Powder
air polishing powder containing sodium bicarbonate and available in different flavours

H

Hygroscopic
describes a body which has affinities with water, which causes condensation and which has the ability to absorb moisture from the air.

I

Infectious clinical waste container
container designed for the disposal of waste created during the treatment of patients and that presents a risk of infection or contamination for humans and the environment. The contents of this container are disposed of by specialists and must never be disposed of with normal household waste.

L

Listérine®
Listérine® is a patented trademark of the Pfizer company.

P

Pearl Powder
air polishing powder containing calcium carbonate

Perio Powder
air polishing powder containing glycine

Powder
air polishing powder manufactured by Satelec. The ingredients vary depending on the target treatment.

Q

Quick coupling
coupling to which the turbine is connected. Depending on the dental chair and the manufacturer. Connects to the AIR-N-GO easy adapter.

T

Tank
clear tank that is part of the AIR-N-GO easy body. Has a maximum fill line to ensure correct operation (MAX). Also called a container.

CE Marking 0459

User Manual | AIR-N-GO® easy | J10121 | V8 | (11) | 03/2018 | ND27EN050H

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