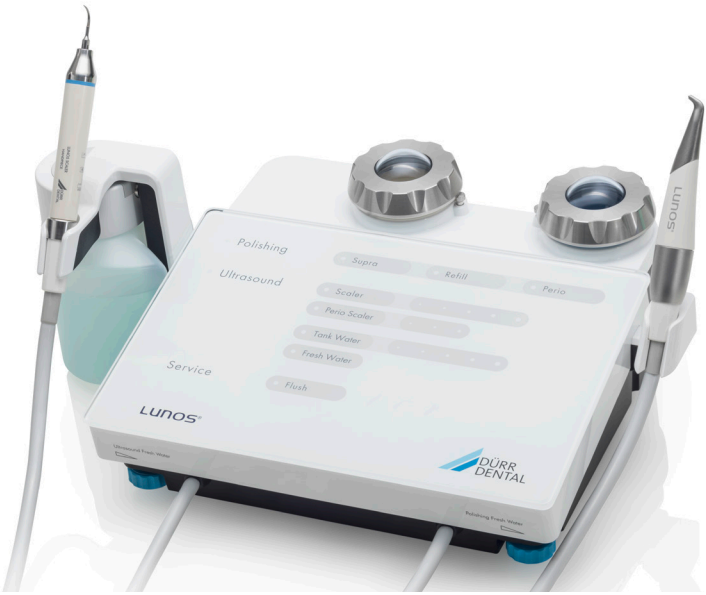
MyLunos Duo

EN



Use and maintenance manual

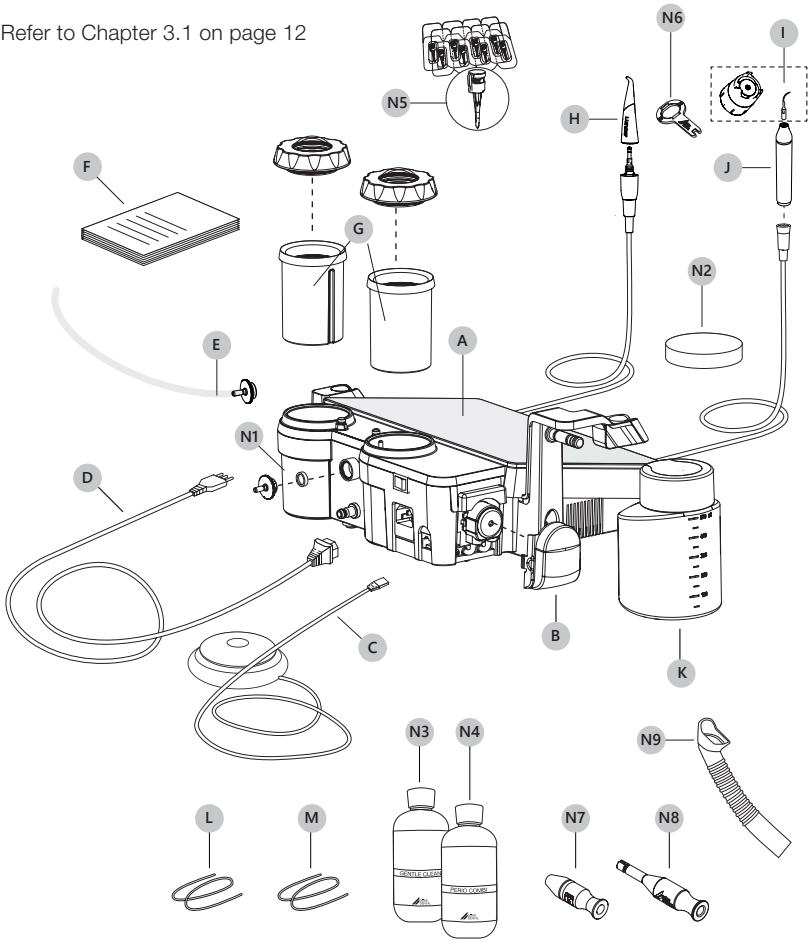
CE 0051

2044100016L02

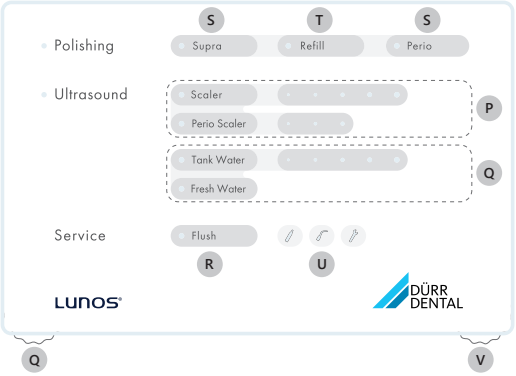
DÜRR DENTAL

EN

Refer to Chapter 3.1 on page 12



Refer to Chapter 5.2 on page 22



EN

Contents

EN

EN

1 Introduction

Carefully read this manual before proceeding with the installation, use, maintenance, or other operations on the device. Always keep this manual within reach.

The purpose of this manual is for the operator knowledge regarding the safety precautions, the installation procedures, and the instructions for correct use and maintenance of the device and its accessories.

Use of this manual for purposes other than those strictly tied to the installation, use and maintenance of the device is forbidden.

The information and illustrations in this manual are up-to-date as of the revision indicated in the footer.

The manufacturer is committed to continually updating its products with possible modifications to device components. In the event you uncover discrepancies between what is described in this manual and the device in your possession, contact your Retailer or the After-Sales Service of Dürr Dental SE for clarifications and support.

1.1 Intended Use

The device combines a multifunctional piezoelectric scaler and a water jet, air and prophylaxis powder polisher in a unique device, intended for a supragingival and subgingival prophylaxis treatment.

The device can be used on patients of any age or sex who need dental treatment aimed at cleaning their teeth. There are no contraindications for specific population groups.

WARNING
The device must be used in a dental practice or ambulatory facility. The device cannot be operated in environments where anesthetic or flammable mixtures are present.

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:

General warning symbol

The warnings are structured as follows:

SIGNAL WORD
Description of the type and source of danger
Here you will find the possible consequences of ignoring the warning. Follow these measures to avoid the danger.

The signal word differentiates between two levels of danger:

– **WARNING**
Always refers to personal injury.
– **CAUTION**
Refers to possible damage to property.

WARNING
Qualified and specialized personnel.
The device must exclusively be used by specialized personnel with proper medical education; no particular training activities are intended for the use of the device. The use of the device does not cause side effects if applied correctly. An improper use might cause tissues heating.

WARNING
Use the device for intended use only. Failure to observe this precaution may cause serious injury to the patient, the operator, and damage/breakdown to the device.

EN

Ultrasonic piezo scaler

Using the appropriate instruments, the following dental applications can be performed:

- scaling: all procedures for the removal of bacterial plaque deposits and supragingival, subgingival, and interdental calculus, and for the removal of stains;
- periodontology: periodontal treatment for scaling and root-planing/debridement, including cleaning and irrigation of periodontal pockets;
- cleaning of implant surfaces.

Polisher for prevention and dental hygiene.

The device is equipped with a water jet, air and prophylaxis powder polisher for dental use, intended for a complete, supra and subgingival dental prophylaxis treatment, with specific intended use depending on the type of powder.

EN

Air polisher for supra-gingival indications:

- Removal of supra-gingival bacterial plaque;
- Removal of stains on the tooth surface;
- Preparation of cavities for better adhesion between enamel and filling material;
- Prophylaxis on patients undergoing orthodontic treatment.

Air-polisher for subgingival indications:

- Removal of subgingival bacterial plaque;
- Removal of biofilm in the implant patient for the purpose of preventing periimplantitis.

WARNING
In the presence of composite resin surfaces, the jet must be directed towards the part to be treated, on average 2-3 seconds per tooth.

1.2 Clinical Benefits

Hereafter is a summary of the clinical benefits based on a review of the state of the art and on the clinical evaluation:

Polisher for Prevention and Dental Hygiene

- Air-polishing treatment is useful in the removal of supra and subgingival bacterial plaque, thus it is useful in gingivitis and periodontitis prevention. Air powder abrasion is a cleaning method demonstrated to be gentle and efficient on enamel, dentin, and cementum and gums.
- Air-polishing treatment supports the removal of subgingival bacterial plaque that can colonize implants. The use of air-polishing system may control the infection and detoxify the implant surface. Thereby air-polishing is useful in peri-implant mucositis and peri- implantitis prevention.
- Air powder abrasion is the most efficient surface decontamination and less surface damaging treatment modality for implant.
- Beneficial for the short-term improvement of subclinical inflammation.

Scaling Application

- Ultrasonic scalers are useful in the removal of supra and subgingival bacterial plaque and calculus. Thereby, it is useful in gingivitis and periodontitis prevention. It is also effective and safe in scaling technique for the management of severe chronic periodontitis.
- Ultrasonic scalers are useful in the removal of supra and subgingival bacterial plaque and calculus. Thereby, it is useful in peri-implant mucositis and peri- implantitis prevention. While peri-implantitis occurs, the use of ultrasonic scalers system may useful in the control the infection and detoxify the implant surface.
- Safe on soft tissue.
- Reduce pain during the postoperative period.

1.3 Description of the Device

The device combines a multifunctional piezoelectric scaler and a water jet, air and prophylaxis powder polisher in a unique device, intended for a supragingival and subgingival prophylaxis treatment.

Concerning the various treatments possible using ultrasound, the device allows work to be performed using the water supply of the dental practice and with independent irrigation through a dedicated water tank, which can house different types of solutions.

The device is equipped with an automatic tuning circuit, which compensates for the wear of the instruments, thus always allowing operation in conditions of maximum efficiency.

The polishing side makes the use of different types of powder possible, depending on the type of treatment to be performed: Prophylaxis powder dedicated to supragingival prophylaxis and dedicated to subgingival treatment based on trehalose with an average grain size of 65 and 30 µm, respectively.

The operating principle of the polisher is based on the mechanical action obtained from a jet of various types of particles accelerated by a flow of compressed air. The kinetic energy applied to the particles, dissipates almost completely due to impact against the surface of the enamel, producing a gentle yet effective cleaning action. The action is completed by a jet of water which, using the vacuum created around the nozzle, forms a cone around the main flow, thus producing a dual effect: to prevent much of the rebound and the leakage of the cloud of powder and perform continuous washing of the treated area, dissolving the powder.

Patient Group Directions

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

- Children;
- Adolescents;
- Adults;
- Elderly.

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

Patient Selection Criteria

The use of the device is not recommended in the following cases.

Air-polisher for supra- and subgingival indications:

- Upper respiratory tract infections, chronic bronchitis / asthma;
- Pregnant and breastfeeding women;
- Patients under treatment (radiotherapy, chemotherapy, antibiotics);
- Acute infectious oral lesions.

Piezoelectric ultrasonic scaler:

- Patients with active implantable medical devices (for example: pacemakers, hearing aids and / or other electromagnetic prostheses) without the prior authorization of their doctor;
- Patients with clinical conditions unsuitable for site treatment (for example: local anesthesia).

The use of powders is not recommended in the following cases:

- Allergy to the aroma of the powder;
- Patients who suffer from severe respiratory problems, such as chronic bronchitis, asthma, pulmonary emphysema, etc., unless otherwise specified by the doctor.

WARNING
For specific contra-indications and safety warnings refer to the IFU accompayning the powder.

All models of air-polishing devices and piezoelectric ultrasonic scalers are intended for professional use only. Therefore, the user is the only person able to decide if and how to treat their patients.

Indications for Use

The use of the device is suitable for all the appropriate patients (see Chapter Patient Selection Criteria on page 5) for whom the treating physician has prescribed a treatment among those present in the intended use of the device (see Chapter 1.1 Intended Use on page 3).

Users

The device must be used only by specialized and properly trained personnel such as a physician / dentist or dental hygienist, able-bodied adults of any weight, age, height, gender and nationality.

1.4 Disclaimer

The manufacturer disclaims any liability, expressed or implied, and shall have no responsibility for any direct, indirect or other damages and personal injury arising out of or in connection with any errors in the use of the device and its accessories.

The manufacturer shall be under no liability, expressed or implied, with respect to any damages (personal injury and/or damage to property) which might arise or be caused, whether by the customer or by any of the users of the product, and its accessories, as result of:

- Use or procedures not expressly indicated and foreseen in the intended use of the product;
- Environmental conditions for the preservation and storage of the device not compliant with the precautions indicated in Chapter 12 on page 92;
- Device not being used in compliance with all instructions and precautions described in this manual;
- Electrical system located in the premises in which the device is used not compliant with the electrical code compliance standard and to relative precautions;
- Assembly operations, extensions, adjustments, updates, and repairs on the device performed by personnel not authorized by the manufacturer;
- Improper use, mistreatments, and/or incorrect interventions;
- Any and all attempts to tamper with or modify the device, under any circumstance;
- Use of non-original instruments that cause a finite damage to the threading of the handpiece, thus compromising correct operation and causing risk of harm to the patient;
- Use of instruments other than authentic instruments, used in accordance to the designed and tested settings of authentic instruments. The correct use of the settings is guaranteed only with original instruments;
- Backup components and accessories (handpiece, instruments, wrenches, scaler handpiece, Lunos® nozzles, subgingival Lunos® Perio Tips) have to be used in the event of deviations from device proper use due to defects or other occurrences.

1.5 Safety Precautions

WARNING
Contraindications.
Do not use the device on patients who carry heart stimulators (Pacemakers) or other implantable electronic devices. This precaution also applies to the operator.

CAUTION
Contraindications. Ultrasonic Scaler.
Do not perform treatments on restorations made of metal or ceramics. As a result, the ultrasonic vibrations could lead to de-cementing of restorations.

WARNING
Contraindications.
Do not perform scaling treatments without irrigation to avoid instrument over-heating, which may cause damage to the tooth. Depending on the selected water source, assure either that the tank level or the tap water connection provides proper irrigation.

WARNING
Contraindications. Interference from other equipment.
An electrical scalpel or other electro-surgical units near the device may interfere with its correct operation.

WARNING
Contraindications. Interference from other equipment.
Though compliant to the IEC 60601-1-2 standard, the device may nonetheless interfere with other devices nearby. The device must not be used near to or stacked on other devices. However, if this is necessary, you must check and monitor correct operation of the device in that configuration.

WARNING
Checking device status before the treatment.
Always ensure there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are in efficient working order. In the event you uncover operating abnormalities, do not perform the treatment. Contact the Dürr Dental Service Center if you observe abnomalities in the device.

CAUTION
The electrical system located on the premises in which the device is installed and used must be compliant with the electrical code compliance standards in force and to the relative electrical safety precautions.

WARNING
To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING
Risk of explosion.
The device cannot operate in environments where the atmosphere is saturated with flammable gases (anaesthetic mixtures, oxygen, etc.).

WARNING
All of the non single-use accessories provided with new or repaired devices are not sterile.
All new and repaired accessories are supplied in non-sterile conditions. Before use, and after each treatment, they must be cleaned and sterilized in strict compliance with the instructions given in the Chapter 9 on page 60.

WARNING
Infection control.
To ensure maximum safety of patient and operator, before using all the reusable parts and accessories, they should first be cleaned and sterilized, following the instructions in Chapter 9 on page 60.

CAUTION
Contraindications.
Prior to re-usage, allow reusable, autoclavable items (handpiece, instruments, torque wrench, and any other accessory that can be sterilized) to gradually return to room temperature after steam sterilization. The cooling process must not be accelerated.

CAUTION
In case the final user, operating in their own medical room or surgery, in order to comply with mandatory requirements, must periodically inspect the equipment present in the surgery, the test procedures to apply to medical electrical equipment and medical electrical systems for the safety assessment must be carried out following the standard EN 62353 'Medical electrical equipment - Periodic inspections and tests to be carried out after repair of medical electrical equipment'. The frequency of periodic inspections in the intended conditions of use described in this Use and Maintenance manual is once per year or every 2000 hours of use, whichever condition is satisfied first.

To check and guarantee the perfect operation of the device and prolong its service life, maintenance should be carried out by an Authorised Service Centre on an annual basis.

EN

EN

WARNING
Instrument breakage and wear.
High frequency oscillations and wear and tear may, in rare circumstances, lead to instrument breakage.
Deformed or otherwise damaged instruments are susceptible to breakage during their use. These instruments must never be used.
If an instrument breaks, check that none of its fragments remain in the treated area and, at the same time, apply effective suction to remove them.
The patient must be instructed to breathe through their nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken instruments.
Re-sharpening the instrument damages it and is therefore forbidden. Always check that the instrument is not worn out.
During the treatment, frequently check that the instrument is intact, especially in its apical part.
During the treatment, avoid prolonged contact with dental metallic equipment in use. Do not exert excessive pressure on the instruments during use.

WARNING
Only use authentic instruments, accessories, and replacement parts.

CAUTION
No modification of this equipment is allowed.

CAUTION
Contraindications. Jet Polisher.
Prior to re-usage, allow reusable, autoclavable items (handpiece, instruments, torque wrench, and any other accessory that can be sterilized) to gradually return to room temperature after steam sterilization. The cooling process must not be accelerated.

WARNING
Contraindications. Jet Polisher.
Patients that suffer from serious respiratory problems, such as chronic bronchitis, asthma, emphysema, etc. must not undergo the prophylaxis treatment, until they have consulted with their doctor.

WARNING
Contraindications. Jet Polisher.
Patients wearing contact lenses or glasses should remove them prior to receiving treatment with the jet polisher.

WARNING
Contraindications. Prophylaxis powder jet polisher.
Do not use "Lunos® Nozzle Supra" in conjunction with "Lunos® Prophylaxis Powder Gentle Clean" for treatments on soft tissues or inside the gingival sulcus. Failure to comply with this direction can cause gingival tissue emphysema (emphysema of the mucosa and/or subcutaneous).

WARNING
Always use SUPRA powder container (left) with "Lunos® Prophylaxis Powder Gentle Clean". Always use PERIO powder container (right) with "Lunos® Prophylaxis Powder Perio Combi".
Do not use other powders than "Lunos® Prophylaxis Powder Gentle Clean" or "Lunos® Prophylaxis Powder Perio Combi".

WARNING
Temperature of the water spray - Jet polisher.
This device is equipped with a double safety mechanism that controls the temperature of the water spray. Before treatment, it is however recommended to instruct the patient to inform the operator if they perceive an excessive increase in the temperature of the water.

WARNING
Adverse Event
If an adverse event and/or serious accident attributable to the device occurs during correct and intended use, it is recommended to report it to the Competent Authority and to the manufacturer indicated on the product label.

1.6 Symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.

Caution!

Consult instructions for use or consult electronic instructions for use

MD Medical Device

CE 0051 Device compliant with Regulation (EU) 2017/745. Notified body: IMQ S.p.A.

CE Class I device (Torque Wrench) compliant with Regulation (EU) 2017/745

Manufacturer

Date of Manufacture

Distributor

Dispose of correctly in accordance with EU Directive 2012/19/EU (WEEE).

NON STERILE Not sterile

Do not reuse

Do no use if the packaging is damaged and consult instructions for use

Expiry date

Thermal disinfection and cleaning

134 °C Steam sterilise at 134 °C

135°C Can be sterilized in autoclave up to a maximum temperature of 135 °C

IPXX International Protection Code of the mechanical casing

Applied part of type B as per EN 60601-1 recommendation

Alternating current

Connection of the foot pedal

I Activation switch “on”

0 Activation switch “off”

Lower and upper temperature limits

Lower and upper humidity limits

Lower and upper atmospheric pressure

Keep away from sunlight

Fragile, handle with care

Keep dry

Correct vertical position of the package

LOT Batch code

STERILE EO Sterilised with ethylene oxide (STERILE EO)

HIBC Health Industry Bar Code (HIBC)

REF Catalogue number

SN Serial number

UDI Unique Device Identifier

Model number

Wear protective gloves.

Wear protective goggles.

Use a mask.

Use protective clothing.

EN

2 Identification Data

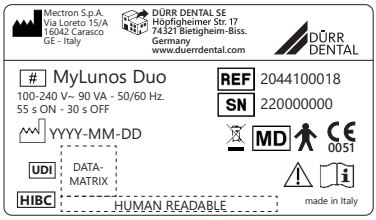
An exact description of the model and serial number of the device will enable our After-Sales Service to provide fast and efficient support.

Always provide this information whenever you contact an Authorized Dürr Dental Service Center.

2.1 Device Identification Label

EN

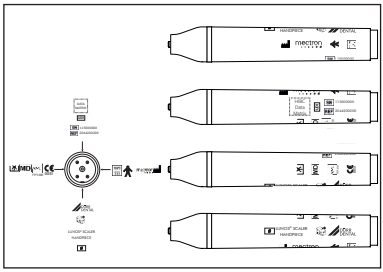
Every device has an identification plate that bears the technical characteristics and the serial number. The identification plate is located on the inferior panel of the device. Additional specifications are reported in this manual (See Chapter 12 on page 92).



2.2 Handpiece Identification Data

The handpiece is laser-marked with:

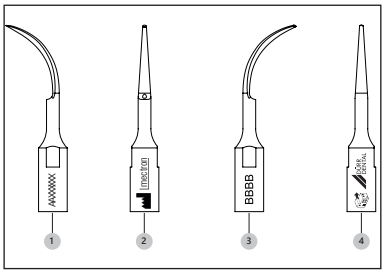
- its serial number (SN);
- its product number (REF);
- its date of manufacturing;
- the model number (LUNOS® SCALER HANDPIECE);
- the Dürr Dental logo;
- the HIBC 128 Data Matrix;
- the CE, MD, Applied Part and Sterilizable symbols.



The complete list of symbols and their description are reported in Chapter 1.6 on page 9.

2.3 Instruments Identification Data

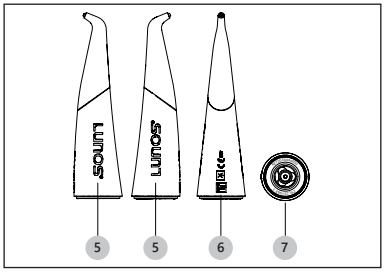
The following data are laser-marked on each instrument: the lot number to which the instrument belongs (ref. 1), the Mectron logo (ref. 2), the name of the instrument (ref. 3), the Dürr Dental logo and the distributor symbol (ref. 4).



The complete list of symbols and their description are reported in Chapter 1.6 on page 9.

2.4 Lunos® Nozzles Identification Data

The following data are laser-marked on each nozzle: the LUNOS® logo (ref. 5), symbols and CE mark (ref. 6), the reference number of the Lunos® nozzle (ref. 7) and the serial number (ref. 7).



The complete list of symbols and their description are reported in Chapter 1.6 on page 9.

3 Delivery

3.1 List of Components

(see inside cover)

The device consists of:

A Device body (REF 2044100018)

B Peristaltic pump cover (REF 2044100047)

C Foot pedal with cord and connector (REF 2044100019)

D Electrical power supply cable with country specific plug:

- Power cable CH (REF 2044100039);
- Power cable D (REF 2044100038);
- Power cable UK (REF 2044100041).

E Irrigation Circuit Cleaning Kit (REF 2044100045)

F Leaflet for downloading the Use and Maintenance Manual or for requesting a paper copy

G Two Polisher containers:

- Supra Container MyLunos Duo (REF 2044100033);
- Perio Container MyLunos Duo (REF 204100034).

H Two Lunos® nozzles [a]:

- Supra Nozzle (REF 2034440000);
- Perio Nozzle (REF 2034430000).

I Lunos® Scaler Instruments:

- S2 with torque wrench (REF 2044100020);
- P10 with torque wrench (REF 2044100046);
- P11 with torque wrench (REF 2044100023);
- P12 with torque wrench (REF 2044100024).

J Lunos® Scaler handpiece with LED (REF 2044200200)

K Water tank with cap: (REF 2044100032)

L Water supply tubing with quick coupling (REF 2044100030)*

M Air supply tubing with quick coupling (REF 2044100029)*

*Components requiring installation (See Chapter 4 on page 15) and are integral parts of the device)

N Accessories:

1 Water filter MyLunos Duo (REF 2044100031)

2 Screw-on lid for the Water tank (REF 2044100044)

The screw-on lid for the Water tank (REF 2044100044) is an optional accessory (see Chapter 3.2 on page 13).

3 Lunos® prophylaxis powder Gentle Clean [b] (available in "Lunos Prophylaxis powder Gentle Clean Neutral 4 bottles/180g", REF CPZ610A2250)

4 Lunos® prophylaxis powder Perio Combi [b] (availabe in "Lunos Prophylaxis powder Perio Combi 4 bottles/100g", REF CPZ640A1950)

5 Lunos® Perio Tips [a] (REF 2034100020)

6 Combination wrench [a] (included in the Adapter Set, REF 2044100010)

7 Rinsing adapter for the nozzle (yellow) for use during reprocessing [a] (included in the Adapter Set, REF 2044100010)

8 Rinsing adapter for the nozzle (blue) to remove powder residues after every treatment and in case of blockage [a] (included in the Adapter Set, REF 2044100010)

9 Prophylaxis cannula available in set of 4 [a] (REF - 0700-058-50)

Only one sample is provided with the device.

- Lunos Scaler ToolCard (REF 2044100052)

The device has accessories available that can be ordered separately.

The package of the device is sensitive to strong collisions, because it contains electronic components.

Therefore, special precautions must be taken for transport and storage.

Do not stack multiple boxes, in order not to damage the packages underneath.

The device is delivered duly protected and packed.

When receiving the device, check for the possible presence of damages incurred during the transport and, should that be the case, file a complaint with the transporter.

Preserve the package in the event that you need to send the device to an Authorized Dürr Dental Service Center and for storing the device during prolonged periods of non-use.

WARNING
Before commencing operation of the device, make sure that you have additional accessories, such as, scaler handpiece, instruments, wrenches, Lunos® nozzles, Lunos® Perio Tips, available to use in case of deviations from device proper use due to defects or other occurrences.

3.2 Optional Accessories

The following optional items can be used with the device:

– Lunos Perio Nozzle [a] (REF 2034430000)
– Lunos Supra Nozzle [a] (REF 2034440000)
– Lunos® Scaler Handpiece (REF 2044200200)
– Footpedal MyLunos Duo (REF 2044100019)
– Adapter set [c] (REF 2044100010)
– Lunos® Scaler Instruments:
  - S2 with torque wrench (REF 2044100020);
  - S1-S with torque wrench (REF 2044100021);
  - P10 with torque wrench (REF 2044100046);
  - P11 with torque wrench (REF 2044100023);
  - P12 with torque wrench (REF 2044100024);
  - P16R with torque wrench (REF 2044100025);
  - P16L with torque wrench (REF 2044100026);
  - ICS with torque wrench (REF 2044100027);
  - IC1 (REF 2044100028).
– K10 torque wrench (REF 2044100048)
– Use and maintenance manual (see leaflet included in the delivery)
– Electrical power supply cable with country specific plug:
  - Power cable JP (REF 2044100037);
  - Power cable D (REF 2044100038);
  - Power cable CH (REF 2044100039);
  - Power cable KOR (REF 2044100040);
  - Power cable UK (REF 2044100041);
  - Power cable CN (REF 2044100042);
  - Power cable AU (REF 2044100036).
– Screw-on lid for the water tank (REF 2044100044)

3.3 Consumables

The following materials are consumed during operation of the device and must be ordered separately:

– Lunos® Perio Tips [a] (REF 2034100020)
– Lunos® Prophylaxis powder Perio Combi 4 bottles /100g [b] (REF CPZ640A1950)
– Lunos® Prophylaxis powder Gentle Clean Neutral 4 bottles/180g [b] (REF CPZ610A2250)
– Lunos® Prophylaxis powder Gentle Clean (each one 4 bottles/180g):
  - Orange (REF CPZ620A2250);
  - Spearmint (REF CPZ630A2250);
  - Wild Berry (REF CPZ650A2250).

a) Manufactured by Dürr Dental SE.
b) Manufactured by Orochemie Gmbh + Co. KG.
c) Manufactured by a third party supplier.

3.4 Wear Parts and Replacement Parts

The following working parts need to be changed at regular intervals (refer to the Chapter 10 on page 80):

- O-rings at powerjet handpiece [c] (REF 2044100014)
- Air supply tubing MyLunos Duo (REF 2044100029)
- Water supply tubing MyLunos Duo (REF 2044100030)
- Water filter MyLunos Duo (REF 2044100031)
- Water tank MyLunos Duo (REF 2044100032)
- Peristaltic pump (REF 2044100054)
- Supra Container MyLunos Duo (REF 2044100033)
- Perio Container MyLunos Duo (REF 2044100034)
- O-RING KIT MyLunos Duo [c] (REF 2044100051)
- Scaler light conductor (REF 2044100119)
- Blue silicone ring (REF 2044100120)

Information about replacement parts is available from the portal for authorised specialist dealers at: www.duerrdental.net.

Usage

4 Installation

4.1 First Installation

The device must be installed in a comfortable and suitable place for its use.

4.2 Safety Precautions During Installation

WARNING
Contraindications. Interference with other equipment.
Though compliant with the standard IEC 60601-1-2, the device may nonetheless interfere with other devices nearby.
The device must not be used near to or stacked on other devices. However, if this were to prove necessary, you must check and monitor correct operation of the device in that configuration.

WARNING
Contraindications. Interference from other equipment.
An electrical scalpel or other electro-surgical units near the device may interfere with its correct operation.

CAUTION
The electrical system located on the premises in which the device is installed and used must be compliant to the electrical code compliance standards in force and to the relative electrical safety precautions.

CAUTION
To avoid any risk of electric shock this device must be grounded.

WARNING
Risk of explosion.
The device cannot be operated in environments where the atmosphere is saturated with flammable gases (anesthetic mixtures, oxygen, etc.).

WARNING
Install and use the device in a place protected against collisions or against accidental sprays of water or liquids.

WARNING
Do not install the device above or near heat sources. Adequate air circulation around the device when installing it is necessary.

CAUTION
Do not expose the device to direct sunlight or to of UV light sources.

CAUTION
The device can be transported, but it must be handled with care. Position the foot pedal on the ground, so that it can only be activated intentionally by the operator.

CAUTION
Before connecting the handpiece to its hose, make sure that the electrical contacts are entirely dry, on both sides. If necessary, dry them with compressed air.

CAUTION
Position the device in a way that the power plug is easily accessible at all times; to take it off the electrical power easily.

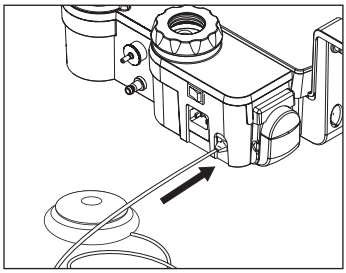
CAUTION
The water tank has a maximum capacity of 500 ml.

EN

4.3 Connection of the Accessories

1

> Connect the foot pedal to the back of the device in the socket marked with the symbol ⇗ with the plug of the foot pedal cable, until you hear a “click” sound.

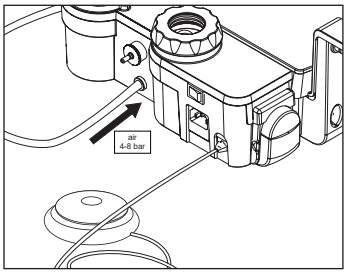


CAUTION
Pay attention to the positioning of the foot pedal, so that the foot pedal is only activated intentionally by the operator.

EN

2

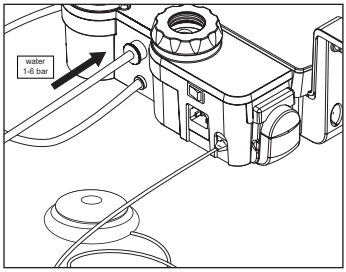
> Discharge any condensation from the compressed air supply - connect the air supply hose to the practice’s air supply using a proper reduction and cut-off valve (not included in the scope of delivery). Connect the hose quick coupling to the air inlet connection located on the rear of the device and labelled with "air 4-8 bar";



3

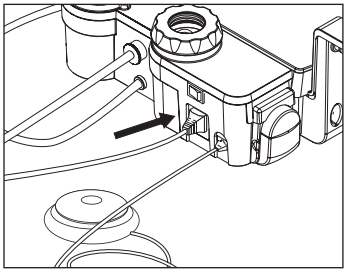
> Connect the water supply hose to the practice’s water circuit using a proper reduction and cut-off valve (not included in the scope of delivery). Connect the hose quick coupling to the water inlet connection located on the rear of the device and labelled with "water 1-6 bar";

The water circuit connector can be identified by the blue O-ring.



4

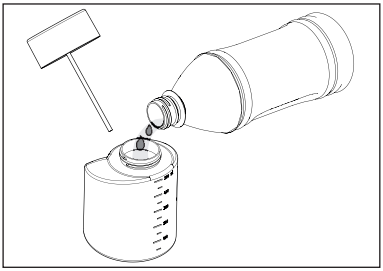
> Insert the power supply cable in its connection located at the back of the device. Connect it to the power outlet;



CAUTION
Position the device in such a way that the power plug is easily accessible at all times; this is considered a disconnecting means.

5

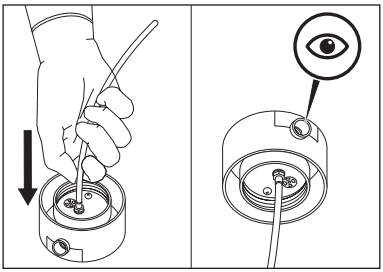
> >Unscrew the cap from the water tank and fill the water tank with the needed solution;



CAUTION
The water tank can contain liquids up to a maximum of 500 ml.

6

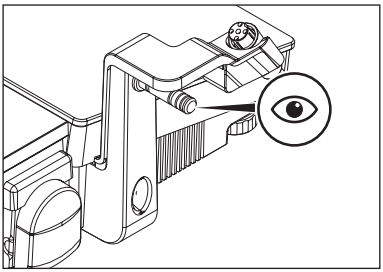
> Check that the hose connected to the water tank's cap is correctly installed, then screw the cap back on the water tank;



CAUTION
Check that the female tank coupling on the cap is clean and free from impediments.

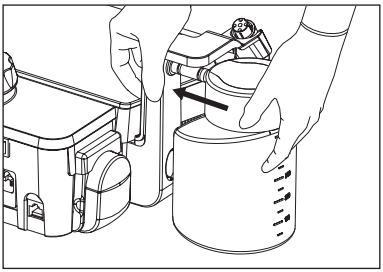
7

CAUTION
Check that the male tank coupling on the system is clean and that the O-rings are not worn.



8

> Keep the water tank in a vertical position and push it towards the unit's body until it is firmly connected;



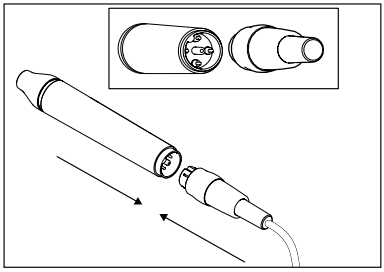
CAUTION
Do not capsize the water tank as its cap is not watertight. The leaking of potentially aggressive liquids can damage the surfaces.

EN

EN

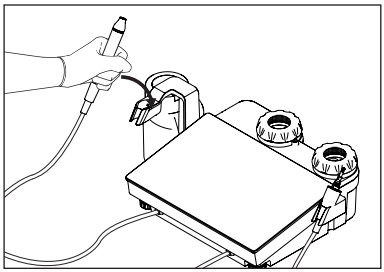
> Correctly connect the handpiece to its hose making sure to match the dot on the handpiece connector with the groove on the hose connector.
Make sure that the electrical contacts of both handpiece and hose are entirely dry; if necessary, dry them by blowing compressed air;

9



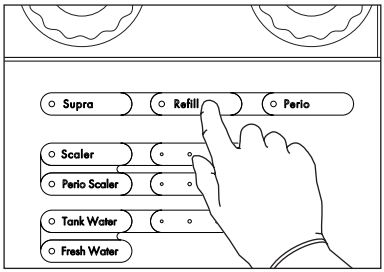
> Position the handpiece on its support.

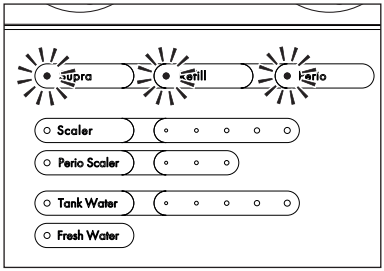
10



CAUTION
Before extracting the powder containers or unscrewing the caps, make sure that the “Refill” function has been selected and the corresponding LED is ON with a fixed light (see Chapter 5.7 on page 36).

11

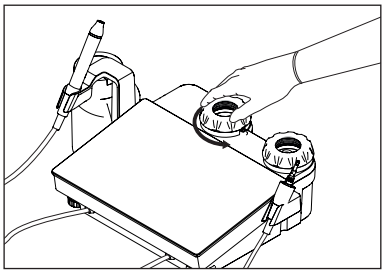




> Loosen the cap of the white Supra powder container on the left.

CAUTION
The Supra powder container can be identified by means of its **white** color and it is located on the left.

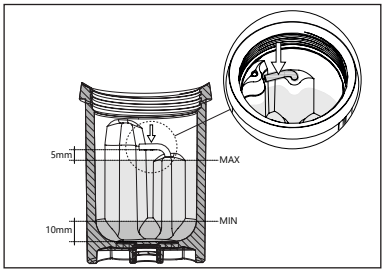
12



> Pour the Lunos® Prophylaxis Powder Gentle Clean into the container, assuring that the powder level is beneath the angled pressurization duct located inside (the diffuser).

WARNING
Introduce **only** appropriate powder for this device and for supragingival application ("Lunos® Gentle Clean") into the Supra container.

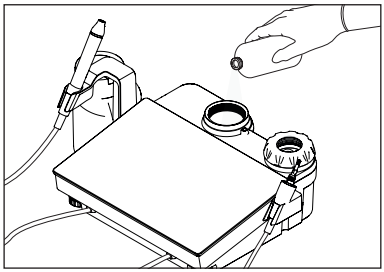
13



CAUTION
Correct level of powder in the container.

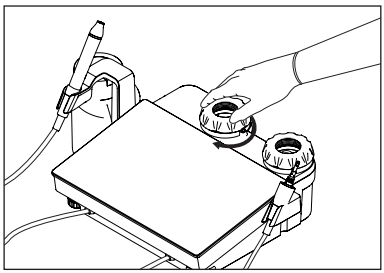
Minimum level: The level of powder in the container must not be lower than one centimetre to prevent cleaning performance from dropping.

Maximum level: The level of the powder in the container must remain below the diffuser (at least 5 mm).



> Close the cap on the container without tightening it excessively.

14

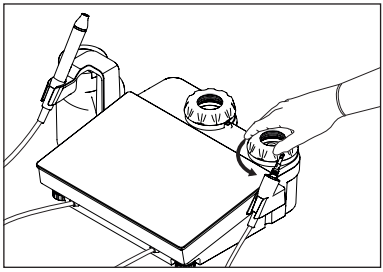


EN

> Loosen the cap of the blue PERIO powder container on the right.

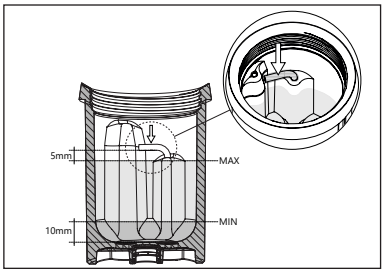
CAUTION
The PERIO powder container can be identified by means of its **blue** color and is located on the right.

15



> Pour the Lunos® Prophylaxis Powder Perio Combi into the container, assuring that the powder level is beneath the angled pressurization duct located inside (the diffuser).

16

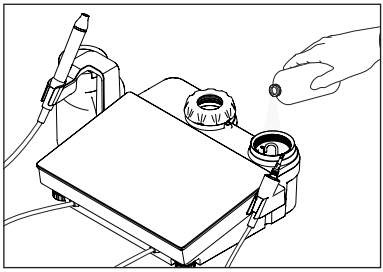


WARNING
Introduce **only** appropriate powder for this device and for subgingival application ("Lunos® Perio Combi") into the PERIO container.

CAUTION
Correct level of powder in the container.

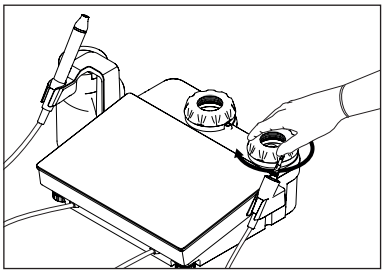
Minimum level: The level of powder in the container must not be lower than one centimeter to prevent cleaning performance from dropping.

Maximum level: The level of the powder in the container must remain below the diffuser (at least 5 mm).



> Close the cap on the container without tightening it excessively.

17



5 Use

5.1 Switching the Device ON and OFF

Turning the Device ON

With the device in view from its front side, position the switch on the left of the device body on position “I”, being careful not to press the foot pedal.

On the device, all of the signals switch on and switch off successively. The touch surface remains off for a few seconds until an acoustic signal, which indicates the end of the diagnostics cycle. At this point, the device positions itself on the default setting and is ready for use.

Default setting:

- ULTRASOUND side
  - Scaler function - power level ”1”
  - Water supply: "Tank Water" - flow level ”3”
- POLISHING side
  - “Perio” function

The device should be switched on only after having performed the steps reported in Chapter 4 Installation on page 15.

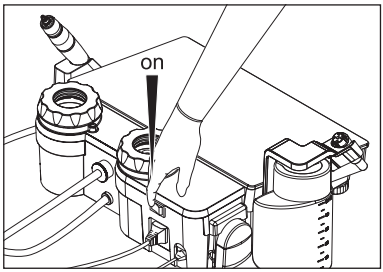
– If the powder containers have NOT being installed, the default condition for the POLISHING side will be the "Refill" (refer to Chapter 5.7 Instructions For Use - Refill Function on page 36),
– if only the Supra powder container has been installed, the default condition for the POLISHING side will be Supra,
– if only the Perio powder container has been installed, the default condition for the POLISHING side will be Perio,
– if both the powder containers have been installed, the default condition for the POLISHING side will be Perio.

The setting operations for both the scaler and the polisher side can be performed, even simultaneously, only with both the handpieces in their respecting housing. If one of the two handpieces is extracted, only the settings of the active function can be changed.

Turning the Device OFF

With the device in view from its front side, position the switch on the left of the device body on position “O”, being careful not to press the foot pedal.

The device turns off.



CAUTION

Position the device in a way that the power plug is easily accessible at all times; this is considered a disconnecting means.

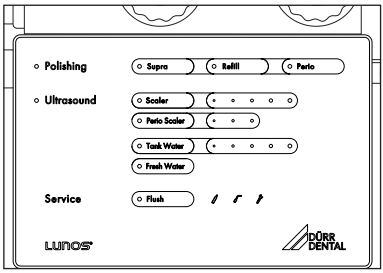
EN

5.2 Description of the Keyboard

Touch Keyboard

The user can configure the device by simply touching on the touch surface.

A brief acoustic signal is emitted to indicate the selection of a key.
A prolonged acoustic signal is emitted to indicate that the key cannot be selected for the setting.



EN

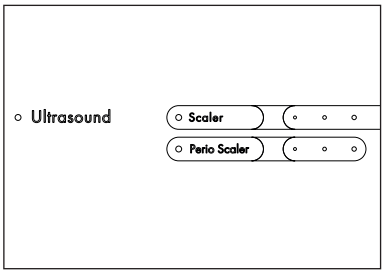
Ultrasound - Scaler Side

Functions

(Ref. P inside front cover)

Depending upon the type of treatment, it is possible to choose one of the two options available:

- **Scaler**: dedicated to supragingival prophylaxis procedures.
- **Perio Scaler**: dedicated to supra- and subgingival prophylaxis procedures, to root planing and to implant cleaning.



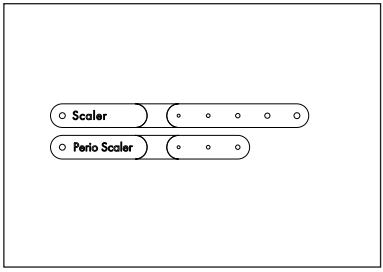
Power

(Ref. P inside front cover)

For all functions previously described, the power for use can be adjusted by selecting the scale besides the chosen function.

For the "Scaler" function, five power levels are available. The operating power can be adjusted in an incremental manner (from 1 LED on to 5 LEDs on > maximum power).

For the "Perio Scaler" function, three power levels are available. The operating power can be adjusted in an incremental manner (from 1 LED on to 3 LEDs on > maximum power).



Irrigation

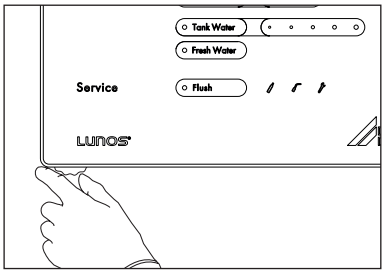
(Ref. Q inside front cover)

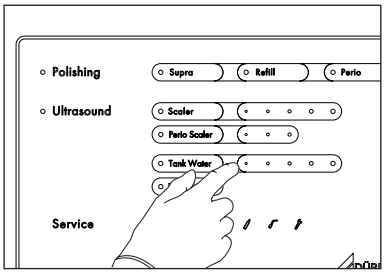
For the scaler side, the device allows the use of two types of irrigation: the fresh water circuit or the tank circuit. The choice of the water supply is made by the function buttons "Tank Water" (tank circuit) and "Fresh Water" (fresh water circuit).

The flow rate of the two circuits can be regulated as follows:

- for the fresh water circuit, it can be regulated continuously through the left hand knob at the front of the device;
- for the tank circuit it can be adjusted in an incremental manner in 5 steps using the button scale besides "Tank Water" on the touch display (1 LED on >minimum irrigation, 5 LEDs on >maximum irrigation).

The "Tank Water" irrigation flow rate cannot be changed while pressing the foot pedal.





"Flush" Function

(Ref. R inside front cover)

The device has a “Flush” key, which allows the irrigation circuit to be filled and rinsed.

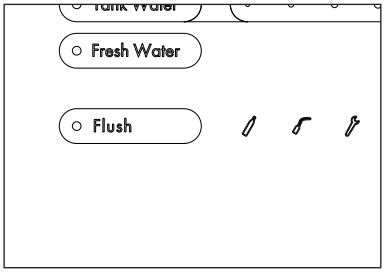
> Filling the irrigation circuit:

- Before starting the treatment, the “Flush” function can be used, which allows the liquid to reach the instrument in order to start the treatment with the necessary irrigation.

> Cleaning the irrigation circuit:

- The “Flush” function allows the irrigation circuit rinse cycle to be performed. This function must be used at the end of the treatment and before cleaning and sterilizing all parts.

If both handpieces are in their respecting housing, the “Flush” function cannot be activated.



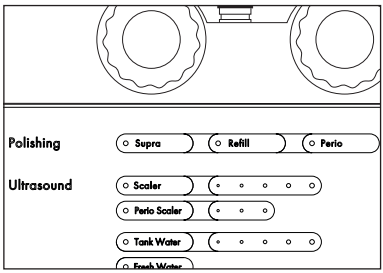
Polishing - Polishing side

Functions

(Ref. S inside front cover)

Depending on the type of application, one of the 2 types of powder can be selected as follows:

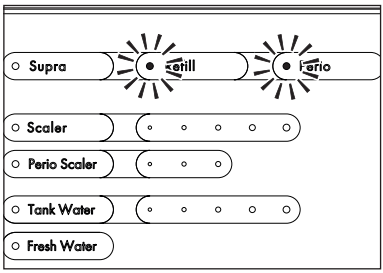
- **Supra**: dedicated to the clinical indications of Lunos® Prophylaxis Powder Gentle Clean;
- **Perio**: dedicated to the clinical indications of Lunos® Prophylaxis Powder Perio Combi;



Refill Function

(Ref. T inside front cover)

The “Refill” function must be used to depressurize the powder containers in order to be able to open and remove them from the device.

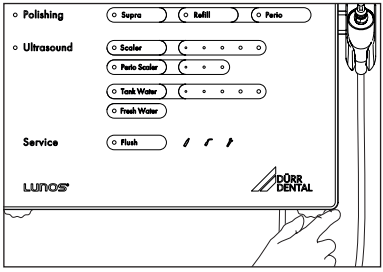


Irrigation

(Ref. V inside front cover)

For the polishing function, the device uses only the fresh water circuit.

The water circuit flow rate for the powder jet handpiece can be regulated continuously through the right hand blue knob at the front of the device.



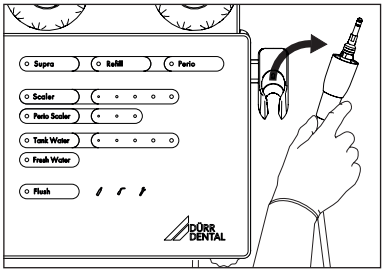
"Flush" Function

(Ref. U inside front cover)

The “Flush” function can be used when you want to pass from the Lunos® Gentle Clean to Lunos® Perio Combi Powder, and vice versa, in order to be sure that the powder circuit is clean from that previously used.

If both handpieces are in their respecting housing, the “Flush” function cannot be activated.

As an effect of the "Flush" function, both the powder containers will be depressurized.

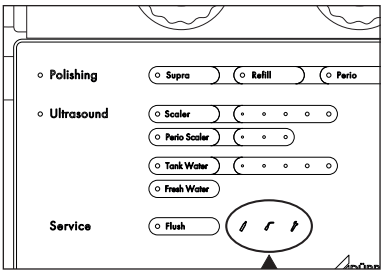


Symbols

(Ref. U inside front cover)

The device is equipped with a diagnostic circuit that allows for detection of operating abnormalities and to view their type on the touch surface via their relative symbol.

To help the user identify the malfunctioning part, three symbols are visible which are described in Chapter 13.1 on page 101.



5.3 Safety Precautions Before and During Use

WARNING
Only use authentic instruments, accessories, and replacement parts.

WARNING
Before starting to operate with the device, make sure that you have additional material (scaler handpiece, instruments, wrenches, Lunos® nozzles, subgingival Lunos® Perio Tips) available to use in case of deviations from device proper use due to defects or other occurrences.

WARNING
Checking device status before the treatment.
Always check that there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are in working order. In the event you uncover operating abnormalities, do not perform the treatment. Contact an Authorized Service Center concerning device abnormalities.

WARNING
Infection control.
First use:
All new and repaired accessories which can be reused are supplied in NON STERILE conditions. Before use, and after each treatment, they must be cleaned and sterilized in strict compliance with the instructions provided in Chapter 9 on page 60.
Subsequent uses:
After every treatment, clean and sterilize all the reusable parts and accessories, following the instructions provided in Chapter 9 on page 60.

WARNING
The patient must not come into contact with the device body or the foot pedal.

CAUTION
"Flush" function.
The “Flush” function must be used after every treatment, before starting the cleaning and sterilization procedures.

WARNING
When the system is powered on and when performing a treatment, do NOT execute any maintenance task on the device.

EN

Ultrasonic Scaler

WARNING
Use of non-authentic instruments:
This use will cause finite damage to the handpiece threading, thus compromising correct operation and risking harm to the patient.

CAUTION
Contraindication.
Do not perform treatments on prosthetics made of metal or ceramics. The ultrasonic vibrations could lead to the de-cementing of the prosthetic dental work.

WARNING
Contraindication.
Do not use the device on patients who carry heart stimulators (Pace-makers) or other implantable electronic devices. This precaution also applies to the operator.

WARNING
Contraindication.
Do not perform scaling treatments without water spray in order to avoid the instrument over-heating which may cause damage to the tooth.

WARNING
Treatments that require irrigation.
Always check the operation of the irrigation before and during use. Make sure the fluid outflows from the instrument.
Do not use the device if the irrigation does not work or if the pump is defective.

WARNING
Always activate the handpiece with the irrigation circuit correctly installed and filled. To fill the irrigation circuit, always use the "Flush" function.

CAUTION
To correctly use the device, you must press the foot pedal and start it with the instrument not making contact with the part to be treated, so that the electronic circuit can recognize the best point of resonance of the instrument without interferences, allowing its optimal performance.

WARNING
Before every treatment, make sure that the instrument appropriate for the treatment is inserted on the handpiece. Exclusively use the original delivered torque wrench to fasten the instrument to the handpiece.

WARNING
Do not change the instrument while the handpiece is operating, to prevent causing injury to the operator.

CAUTION
"Flush" function.
After the device is used with aggressive and non-aggressive solutions, it is necessary to perform a cleaning cycle on the tubes and the handpiece with the "Flush" function (see Chapter 6 on page 37). If the tubes are not maintained clean, the crystallization of the salts may seriously damage the device.

CAUTION
Contraindications.
After sterilization of reusable, autoclavable items (the handpiece, the instruments, the torque wrench, and any other accessory that can be sterilized) allow them to gradually return to room temperature. The cooling process must not be accelerated.

CAUTION
The electrical contacts of both handpiece and hose connectors must be dry.
Before connecting the handpiece to its hose make sure that the electrical contacts of both connectors are entirely dry, especially after the sterilization cycle in the autoclave.
If necessary, dry the contacts by blowing compressed air onto them.

CAUTION
Due to its configuration, the handpiece can roll away. When not in use, the handpiece must always be placed on its support.

WARNING
Breakage and worn instruments.
High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the instrument.
Do not bend, change the shape of, or re-sharpen an instrument in any way. Bending an instrument or applying leverage on it can lead to its breakage.
Deformed or otherwise damaged instruments are susceptible to breakage during their use. If this occurs, these instruments must never be used again.
Excessive pressure on the instruments during their use can lead to their breakage.
If an instrument breaks, check that none of its fragments remain in the treated area and, at the same time, apply effective suction to remove them.
The patient must be instructed to breathe through their nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken instruments.
Re-sharpening the instrument damages it and is therefore forbidden. Check that the instrument is not worn out.
During the treatment, frequently check that the instrument is intact, especially its top.
During the treatment, avoid prolonged contact with metallic instrumentation in use.

Jet Polisher

WARNING
Contraindications. Jet Polisher.
Patients that suffer from serious respiratory problems, such as chronic bronchitis, asthma, emphysema, etc. must not undergo the prophylaxis treatment, until they have consulted with their doctor.

WARNING
Contraindications.
Patients wearing contact lenses or glasses should remove them prior to receiving treatment with the jet polisher.

WARNING
Contraindications - Supragingival treatment
Do not aim the jet of air/Lunos® Gentle Clean/water onto the soft tissues or inside the gingival sulcus. Failure to comply with this instruction can cause a gingival tissue emphysema (emphysema of the mucous and/or subcutaneous).

WARNING
Temperature of the water spray.
The device is equipped with a double safety device that controls the temperature of the water spray. Before the treatment, it is however recommended to instruct the patient to inform the operator if they perceives an excessive increase in the temperature of the water.

WARNING
Infection control and cleaning the water and air circuits.
For maximum safety of the patient and operator, after every treatment, follow the instructions provided in Chapter 9 on page 60.

WARNING
Do not use the device without water.
Make sure that the device is connected to the water circuit and the water cap is open.

WARNING
Do not attempt to unscrew the cap of the powder container before having performed the “Refill” cycle.

EN

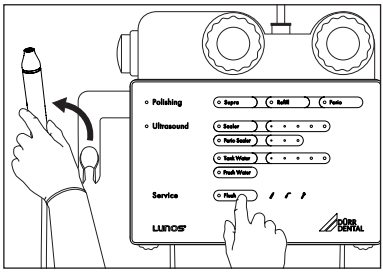
5.4 Instructions For Use - Scaler Side

After having connected all the accessories as described in Chapter 4.3 on page 16 proceed as follows:

1

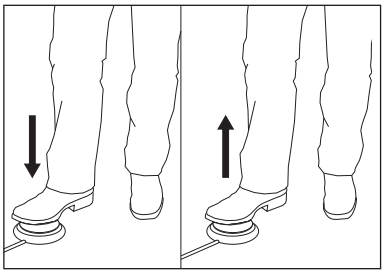
> Raise the scaler handpiece, with or without instrument, load the irrigation circuit by selecting “Flush” on the touch surface.
The “Flush” function LED flashes.
The device allows the use of two types of irrigation: the fresh water circuit or the tank circuit.

Make sure that the polisher handpiece is in its housing, otherwise the device remains inactive.



2

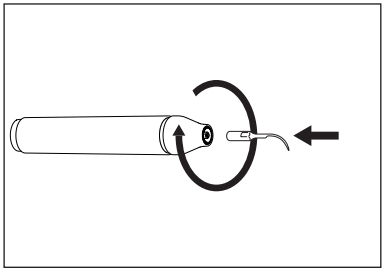
> Press the foot pedal for a moment to start the cycle. The LEDs of the “Flush” function and type of irrigation selected flash.
The performance of the cycle is indicated with brief sequence of acoustic signals.
The cycle lasts 23 seconds, but can be interrupted by pressing the foot pedal as soon as liquid is observed escaping from the handpiece.
Upon completion of the “Flush” cycle, the device goes back to being active and repositions itself at the last setting used.



3

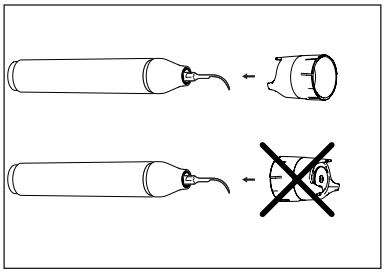
> Screw the chosen instrument onto the scaler handpiece, until it reaches its limit and can go no further.

CAUTION
For Implant Cleaning instrument, refer to „Implant Cleaning“ chapter.



4

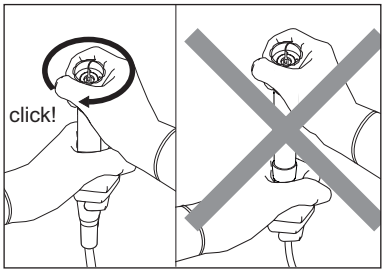
> Tighten the instrument by using the provided torque wrench. Place the instrument inside the wrench as shown.



5

> Firmly hold the central body of the handpiece.
> Rotate the wrench clockwise until the friction snaps (the external body of the wrench rotates compared to the handpiece, emitting mechanical “CLICK” sounds).
> The instrument is now perfectly tightened.

CAUTION
The handpiece must not be grabbed by its terminal part and/or hose, but only by its central body.
The handpiece must not be rotated, but must be grasped firmly, and you must only rotate the wrench.



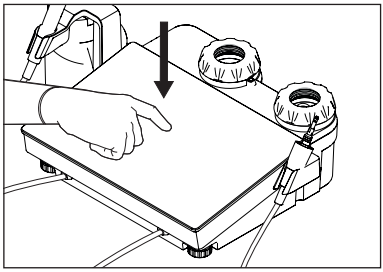
EN

EN

> On the touch surface, select the type of function (refer to Scaler Instruments Power Settings chapter) and irrigation necessary;
Lift the handpiece and press the foot pedal in order to start the treatment;

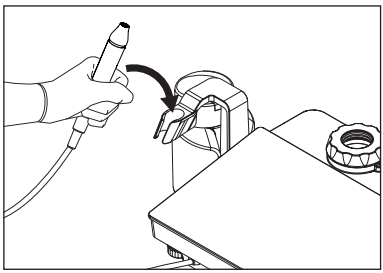
The "Tank Water" irrigation flow rate cannot be changed while pressing the foot pedal.

6



> At the end of the treatment, position the scaler handpiece on its support.

7



Implant Cleaning

The Implant Cleaning instrument consists of two parts: an instrument holder and a tip. It has been designed for removing plaque or biofilm from the surfaces of implants, metal and ceramic dentures and natural teeth.

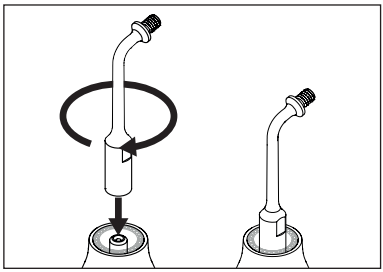
CAUTION
The IC1 tip is prone to deterioration in the form of wear and deformation.
Wear will lead to a reduction in the length of the tip.
Deformation, normally localised on the end of the tip, will make the shape unsuitable for use. In both case, the damage will lead to a progressive drop in functional performance. When it becomes visible, it will be necessary to replace the IC1 tip.

> Assure of having performed step 1 and 2 of the procedure described in Chapter 12.1 on page 94.

WARNING
If the liquid is not loaded beforehand into the hose/handpiece/tip holder system, there will be a risk of breakage of the IC1 tip.

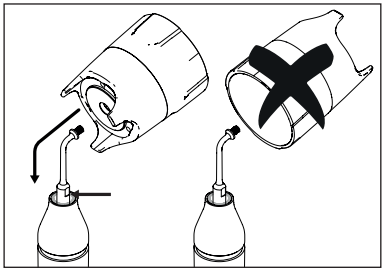
> Screw the instrument holder onto the scaler handpiece until it reaches its limit and can go no further.

1



2

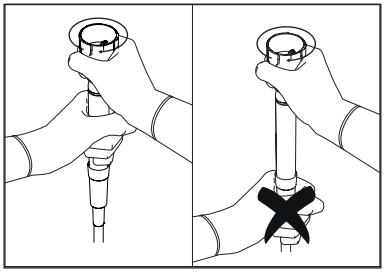
> Insert the torque wrench into the instrument holder as shown.



3

> Firmly hold the central body of the handpiece.
> Rotate the wrench clockwise until the friction snaps (the external body of the wrench rotates compared to the handpiece, emitting mechanical “CLICK” sounds).
> The instrument is now perfectly tightened.

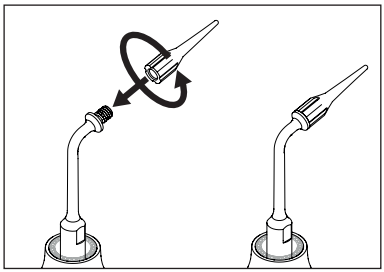
CAUTION
The handpiece must not be grabbed by its terminal part and/or hose, but only by its central body.
The handpiece must not be rotated, but must be grasped firmly, and you must only rotate the wrench.



4

> Screw the IC1 tip onto the tip holder, position it against the surface and tighten it hard with the strength of your fingers

WARNING
Care is required in the initial stage of screwing, when the threads must match precisely. If this is not done correctly, the thread of the IC1 tip could get damaged, causing it to come unscrewed during treatment.



EN

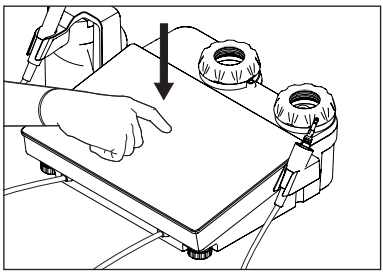
> On the touch surface, select:
- Function: Perio Scaler - Power: 1 to 3;
- Irrigation Level: 3.

The "Tank Water" irrigation flow rate cannot be changed while pressing the foot pedal.

WARNING
The device MUST be used with the Power Level and Irrigation Level listed above.

> Lift the handpiece and press the foot pedal in order to start the treatment;

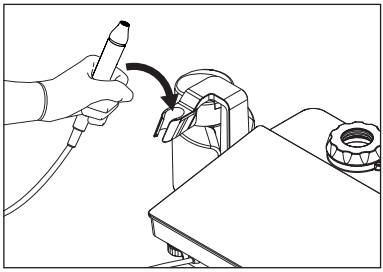
5



WARNING
During the operation, check that the IC1 tip is always tightened against the tip holder; if the IC1 tip is no longer correctly screwed into place, tighten it again hard onto the tip holder.

> At the end of the treatment, position the scaler handpiece on its support.

6



Scaler Instruments Power Settings

The following table reports the proper scaler instruments power settings.

	ULTRASOUND functions	
	Scaler	**Perio Scaler**
SCALING INSTRUMENTS		
S1-S	1 - 3	
S2	1 - 5	
PERIO INSTRUMENTS		
P10 - P11 - P12	1 - 4	1 - 3
P16R - P16L		1 - 3
IMPLANT CLEANING INSTRUMENT		
ICS + IC1		1 - 3

5.5 Important Information on the Instruments

WARNING

- The instrument is a consumable. Thoroughly inspect the instrument before and during every treatment, looking for damage and/or excessive wear. Do not use an instrument if it is scratched or rusted. The instrument may break during use. If damage or deterioration in performance is noted, replace the instrument with a new one. Use of a worn instrument shall lower performance in terms of cutting power.
- Before the treatment, check that the instrument is firmly secured to the handpiece. Properly secure the instrument onto the handpiece using the torque wrench.
- Do not modify the shape of the instrument in any way. Any bending or prying of the instrument may cause it to fracture. Never use deformed instruments.
- Do not attempt to sharpen used instruments insofar as they may break during use.
- Replace the instrument/s only with original spare parts. Use of instruments other than original instruments shall void the warranty of the device. Never use instruments other than original instruments insofar as they will damage the device and may cause injury to operators or the patient. The use of instruments other than original instruments shall damage the threaded pin of the handpiece, thus compromising the secure attachment of instruments, even if original, to the handpiece.
- It is advisable to avoid the application of excessive force or prolonged contact of the instrument on the soft tissues to avoid thermal damage and / or injury.

WARNING

- Let the ultrasonic vibrations work, do not exert excessive pressure on the instruments during use. Apply a light force on the instrument to obtain the best efficiency.
- The instrument must always be kept moving. If the instrument is blocked, it can cause overheating of the treated part. It is recommended to use continuous movement to minimize contact between the tip and the part. Do not block it against the tissue so as not to cause it to overheat. It is advisable to use high levels of irrigation as the power level increases.
- The instruments vibrate with a longitudinal oscillation, with forward and backward movement. During treatment, always keep the instrument tangential to the tooth surface. Move the handpiece back and forth while applying light lateral pressure.
- Do not aim the instrument directly on the surface of the enamel or implant. Position the tip/operative part only tangentially to the surface of the tooth or implant.
- When the instrument is used in the interproximal spaces, do not block the instrument or leverage the operative part. The instruments must be left free to vibrate.
- Check the threaded parts of the instrument and those on the handpiece. These parts must be thoroughly cleaned – see Chapter 9 on page 60.

EN

5.6 Instructions For Use - Polisher Side

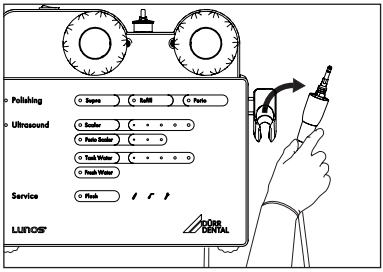
After having connected all of the accessories as described in Chapter 4.3 on page 16, proceed as follows:

EN

1

> Lift the polisher handpiece.
The POLISHING function is activated.

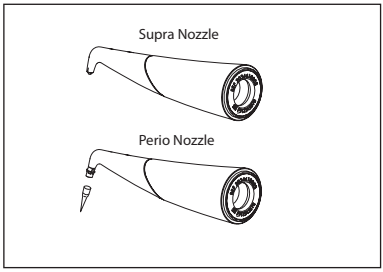
CAUTION
Make sure that the scaler handpiece is in its housing; otherwise the device remains inactive.



2

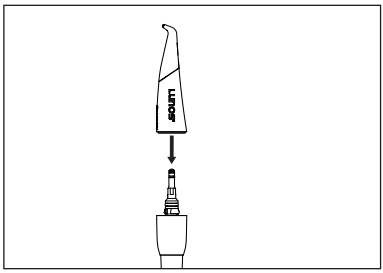
> Select the type of Lunos® nozzle on the basis of the operation to be performed.

CAUTION
The subgingival Lunos® Perio Tip can only be used with the perio nozzle.



3

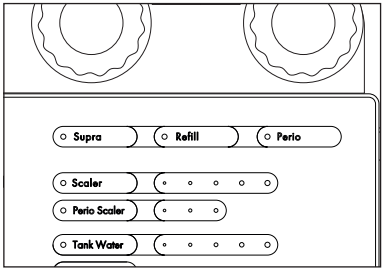
> Connect the Lunos® nozzle to the polisher quick coupling.



4

> Select the desired “Supra” or “Perio” function.
- **Supra** function: use Lunos® Prophylaxis Powder Gentle Clean;
- **Perio** function: use Lunos® Prophylaxis Powder Perio Combi.

WARNING
Before proceeding with successive operations, make sure that the Lunos® nozzle is inserted correctly, fully to the home position on the polisher quick coupling connector.



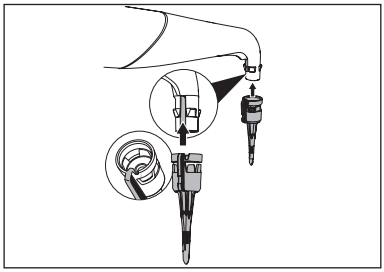
5

CAUTION
If the PERIO nozzle has been selected, the subgingival Lunos® Perio Tip must be inserted onto the front.

CAUTION
Handle the subgingival Lunos® Perio Tip with care.

CAUTION
Use only device-compatible powders ("Lunos® Perio Combi") for subgingival application with the PERIO nozzle and tip.

> Insert the subgingival Lunos® Perio Tip onto the perio nozzle, pushing it fully home.

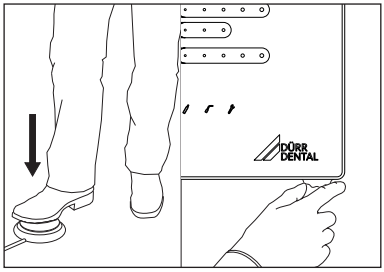


WARNING
Make sure that the subgingival Lunos® Perio Tip is correctly inserted fully home on the perio nozzle; the two pieces must be in contact.

CAUTION
Use authentic accessories only.

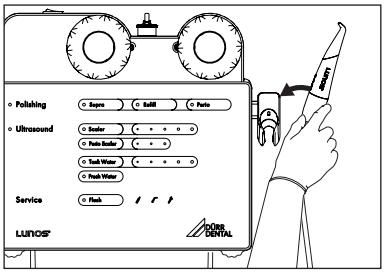
6

> Press the foot pedal to start treatment. The flow of water can be regulated by the right hand knob until the desired amount is reached.



7

> At the end of the treatment, put the polisher handpiece back in its housing.



5.7 Instructions For Use - Refill Function

The “Refill” function allows removal of pressure from the powder containers, enabling opening or removal, and preventing powder from escaping. This function must be used whenever a container is to be reloaded or cleaned.

The powder containers are under pressure only when, after being selected, the foot pedal is pressed.

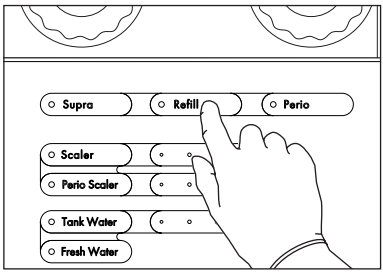
During the “Refill” cycle, air and powder flow out from the polisher handpiece.

Operation

To run the “Refill” cycle, proceed as follows:

1

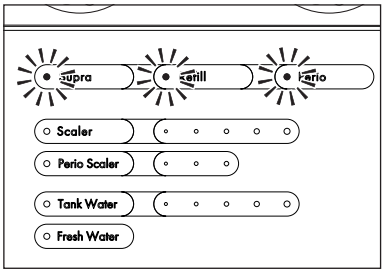
> Press the “Refill” button.



2

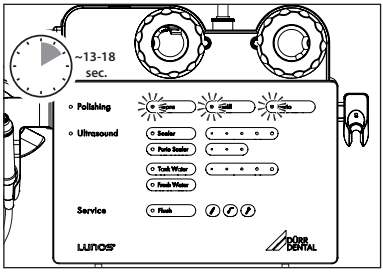
> Wait for completion of the cycle, during which the LED of the “Refill” button will flash together with that of the pressurised powder containers emitting a beep (the “Refill” LED will flash alternatively to the Supra and Perio ones).

If both of the powder containers are pressurised the “Refill” cycle will depressurise both.



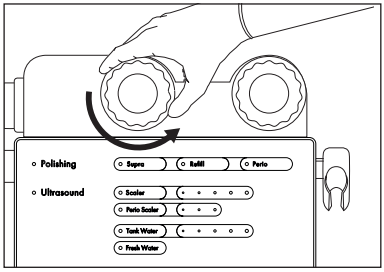
3

The duration of the “Refill” cycle varies according to the presence of only one or both of the depressurised powder containers (about 13 seconds for a single powder container under pressure, about 18 seconds if both powder containers are under pressure).



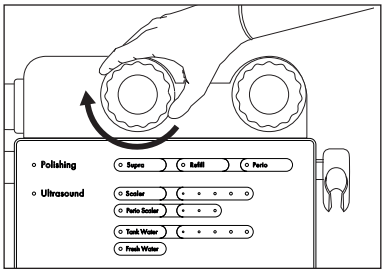
> At the end of the cycle the LED of the “Refill” button will remain on and steady, and it will then be possible to open or remove the containers.

4



> At this point simply close or re-insert the containers to continue using the device.

5



If the powder containers are not opened or removed, simply press the “Refill” button to exit the function. The “Refill” button will remain on and steady. Select the desired “Supra” or “Perio” function to operate with the polishing side.

EN

6 "Flush" Function

The “Flush” function allows the inner irrigation circuits to be filled and rinsed. This function can be performed separately for the following circuits:

a) Ultrasound side by using both the type of irrigations:
   - "Tank Water"
   - "Fresh Water"

b) Polishing side

CAUTION
Scaler side.
If the tubes are not maintained clean, the crystallization of the salts may seriously damage the device.

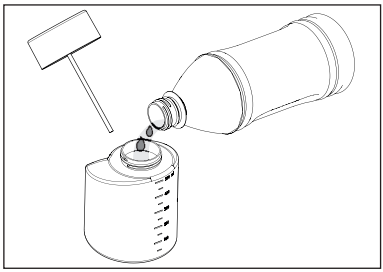
CAUTION
"Flush" function.
The "Flush" function must be used for each circuit and for all the used type of irrigations: (i) before the first treatment of the day and (ii) after every treatment, before starting the cleaning and sterilization procedures (iii) at the end of the day, before starting the cleaning and reprocessing. In the latter case the "Flush" on the powder jet side has to be performed with empty powder containers in order to remove residual powder from the internal circuits (refer to Chapter 10.2).

6.1 Water Tank Preparation

This part has to be performed if “Tank Water” is the selected type of irrigation for flushing the ultrasound side

1

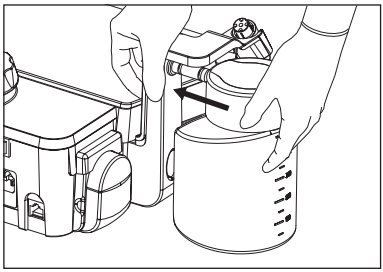
> Fill the water tank with water.



2

> Connect the Water Tank to the device.

CAUTION
Do not capsize the Water Tank as its cap is not watertight.

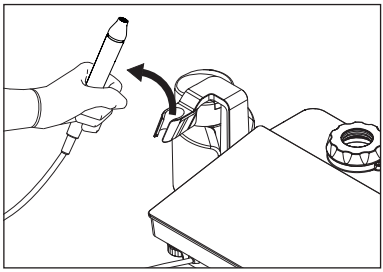


6.2 "Flush" - Scaler Side

1

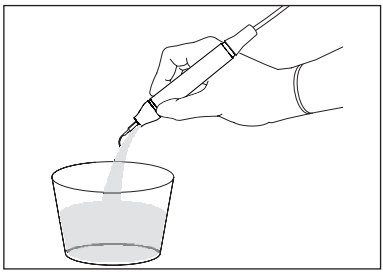
> Lift the scaler hose with or without the handpiece.

CAUTION
Make sure that the polisher hose is in its housing otherwise the device remains inactive.



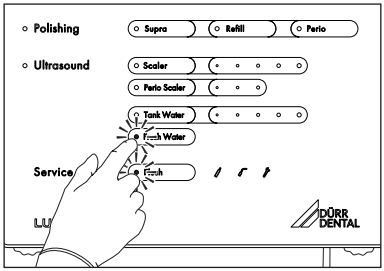
2

> Position the scaler handpiece, with or without instrument, above a container to contain the liquid that will flow out during the cycle.



> It is possible to change the type of irrigation with which to perform the “Flush” cycle, by pressing the key "Tank Water" or "Fresh Water";

3

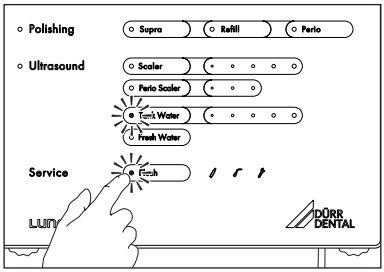


Before performing the “Flush” cycle after selection of “Tank Water” fill in the tank with water (Chapter Chapter 6.1 on page 38).

Before performing the “Flush” cycle after selection of “Fresh Water”, check that the lefthand knob for water amount regulation (Ref. Q inside front cover) is open.

> To enter the "Flush" mode, select "Flush" on the touch surface: all the other selection options present on the display are disabled.
The type of irrigation previously selected remains active and the corresponding LED fades in and out. The other selections present are deactivated.

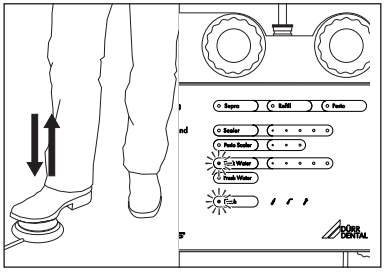
4



You can exit the "Flush" mode at any time by pressing the foot pedal. The touch surface is enabled again and displays the last setting used.

> To start the "Flush" function, press the foot pedal once and release it.
The LEDs of the function and the type of irrigation selected will alternately flash.
The progress of the cycle is indicated with brief sequence of acoustic signals;

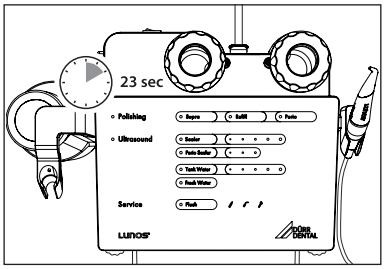
5



When selecting the "Flush" mode, if the cycle is not started in 25 sec., the system will automatically exit the "Flush" mode and it will be re-set to the last used settings.

> The cycle lasts 23 seconds. Once it has ended, the touch surface is enabled again, and displays the last setting used.

6



> Step 3 to 6 have to be performed for each irrigation source used during treatment, "Tank Water" and/or "Fresh Water" by selecting the respective water source before starting "Flush" mode.

7

6.3 "Flush" - Polisher Side

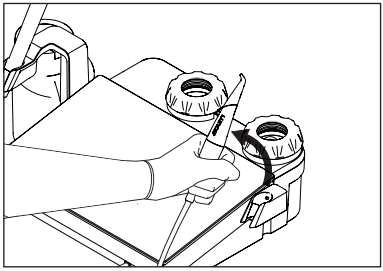
EN

1

> Lift the polisher hose with or without the handpiece

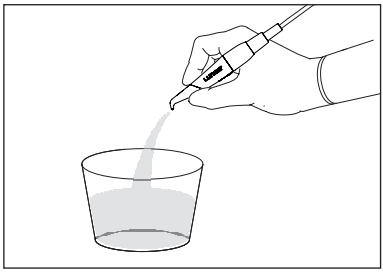
CAUTION
Make sure that the scaler hose is in its housing otherwise the device remains inactive.

CAUTION
Before starting the “Flush” function make sure that both containers with their lids are firmly inserted in the device.



2

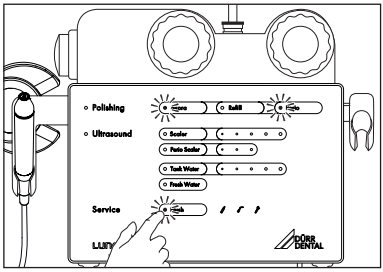
> Position the polisher handpiece, with or without the polisher nozzle, on a receptacle that can contain the liquid and powder that will escape during the “Flush” cycle;



3

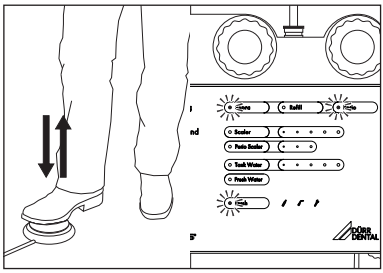
> Select “Flush” on the touch surface to start the “Flush” function: the powder containers are activated and the corresponding LED flashes, the other selections present are deactivated.

The execution of the “Flush” cycle cannot be interrupted; before performing the “Flush” cycle, check that the right-hand knob (Ref. V inside front cover) is open;



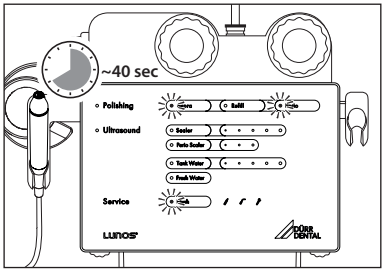
4

> Press the foot pedal once and release it to start the cycle. The LEDs of the function and the powder containers will flash. The execution of the cycle is indicated with a brief sequence of acoustic signals;



> The “Flush” cycle is performed contemporary on both powder containers. The cycle lasts about 40 seconds. Once it has ended, the touch surface is enabled again, and displays the last setting used.

5



CAUTION
Please remember not to remove the powder containers during the execution of the Flush cycle.

CAUTION
If the handpiece is positioned on its support, with the “Flush” function selected (flashing LED), but not running, the function is exited.

CAUTION
During execution of the “Flush” cycle; i.e., when the function has been selected and activated by pressing the foot pedal, if the handpiece is put back on the support, the cycle is not interrupted.

EN

7 Inner Circuits Disinfection

Disinfection of the irrigation circuits has to be done before firts use, every 4 weeks or before and after periods of non-usage of more than 72 h.

After running the "Flush" function (see Chapter 6 on page 37) and before proceeding with the subsequent cleaning procedures, perform disinfection of the inner irrigation circuits.

The procedure must be performed on both the polisher and scaler side ("Tank Water" and "Fresh Water" type of irrigation).

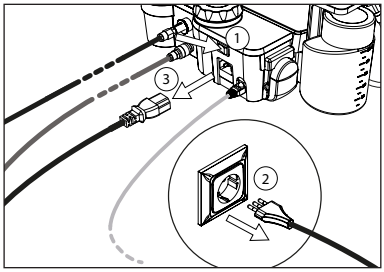
To disinfect the irrigation circuit, proceed as follows:

7.1 Required Materials

– Disinfectant solution Vector/RinsEndo;
– 20 ml syringe with eccentric Luer Slip cone, without needle;
– Irrigation circuit cleaning kit (REF 2044100045) for disinfection of the external irrigation circuit.

7.2 Device Preparation

1



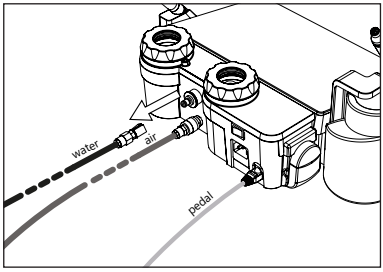
WARNING
Before to start disinfection procedure, make sure that the polisher and scaler handpieces are disassembled from the device (see Chapter 8 on page 55)

WARNING
Turn off the device using the switch (Ref. 1), disconnect the power cord from the wall socket (Ref. 2) and from the machine body (Ref. 3) before cleaning and sterilizing.

EN

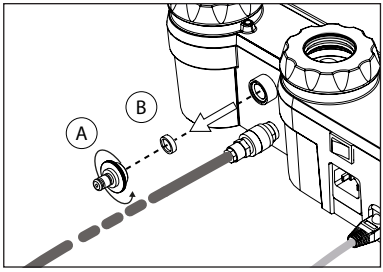
2

> Disconnect the quick-coupling connector of the external water supply from the device;



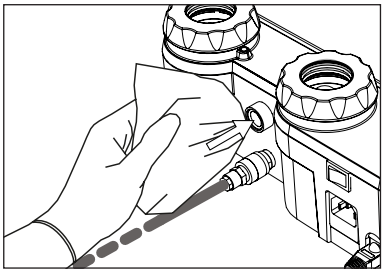
3

> Unscrew the knurled bush of the male coupling for the connection to the water supply (Ref. A);
> Remove the water filter (Ref. B); use tweezers, if necessary;
> Store the filter and the male coupling for connection to the external water circuit in a clean and safe place for subsequent re-use.



4

> Disinfect the internal surfaces of the seat, where the male coupling for connection to the external water circuit will be inserted, with a clean, soft and low-fiber-releasing cloth, moistened with the disinfectant solution (Vector/RinsEndo Disinfection, Dürr Dental)

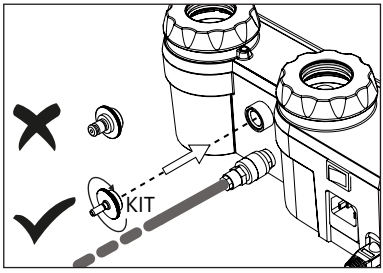


5

> Screw the male coupling supplied with the Irrigation circuit cleaning kit into the housing until it reaches the stop;

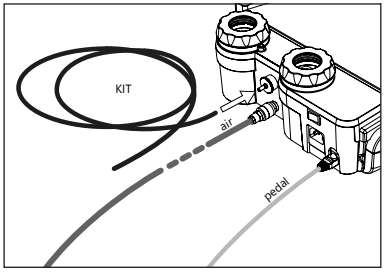
CAUTION
Check the integrity of the Irrigation circuit cleaning kit. Replace the Irrigation circuit cleaning kit in case of wear or damage.

CAUTION
Before first use and subsequent uses.
The kit is supplied non-sterile, therefore, before use, it must be reconditioned in accordance with the procedures described in Chapter 9 on page 60.



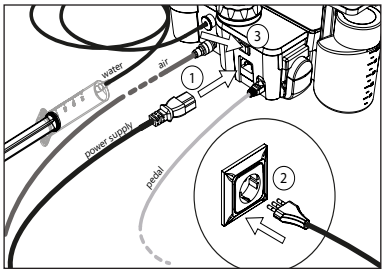
> If it has been previously disconnected (for example for cleaning), connect the hose supplied with the kit to the male water connection;

6



> Connect the power cord to the device (Ref. 1) and to a wall outlet (Ref. 2). Turn on the device using the switch located on the back (Ref. 3);

7

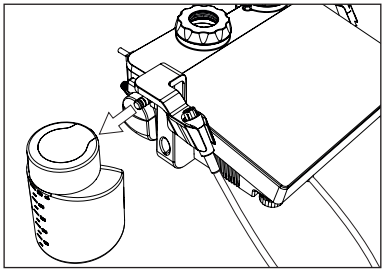


7.3 Scaler Side Inner Circuit Disinfection

7.3.1 Scaler Side Disinfection – Tank Water Circuit

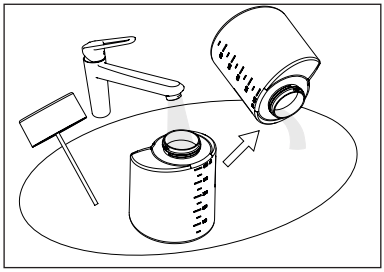
> Disconnect the water tank from the device by pulling it outwards;

1



> Unscrew the cap from the water tank and empty it;

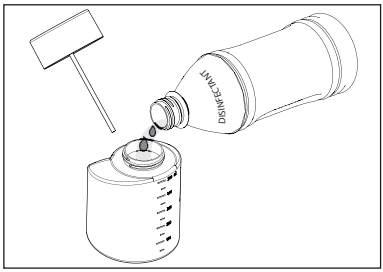
2



EN

3

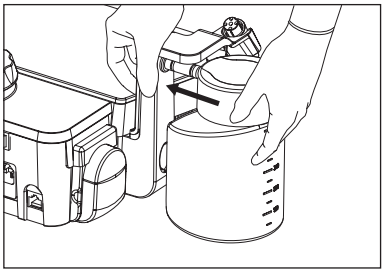
> Fill the water tank with 60 ml of disinfectant (Vector/RinsEndo Disinfection, Dürr Dental). Close the cap of the water tank.



4

> Keep the Water Tank in a vertical position and push it towards the unit's body until it is firmly connected;

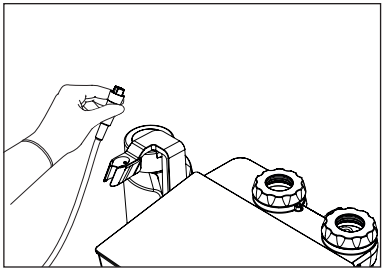
CAUTION
Do not capsize the Water Tank as its cap is not watertight. The leaking of potentially aggressive liquids can damage the surfaces.



5

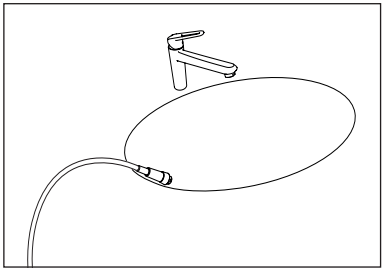
> Lift the scaler hose.

CAUTION
Make sure that the polisher hose is in its housing, otherwise the device remains inactive.



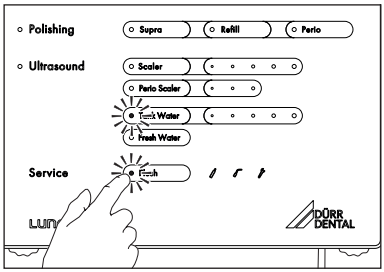
6

> Place the hose over a container or sink to contain the liquid that will flow out;



7

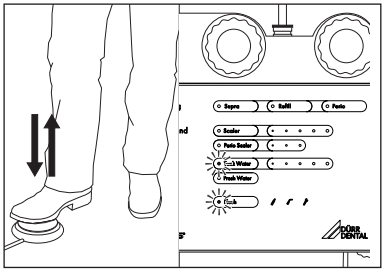
> Select the "Tank Water" irrigation type, by pressing the key "Tank Water";
> Select "Flush" on the touch surface (see Chapter 6 on page 37).
> All other selectable options on the touch surface will be disabled.



You can exit the "Flush" mode at any time by pressing "Flush", the touch surface is enabled again, and displays the last setting used.

8

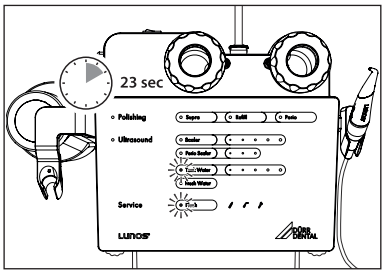
> To start the "Flush" function, press the foot pedal once and release it.
The LEDs of the function and the type of irrigation selected will alternately flash.
The progress of the cycle is indicated with brief sequence of acoustic signals;



When selecting the "Flush" mode, if the cycle is not started in 25 sec., the system will automatically exit the "Flush" mode and it will be re-set to the last used settings.

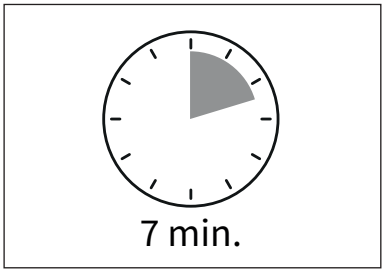
9

> The cycle lasts 23 seconds. Once it has ended, the touch surface is enabled again, and displays the last setting used.



10

> Directly continue with disinfection of the scaler side –fresh water circuit from step 2 (see *Chapter 7.3.2 on page 46*).
Before starting to work again, the disinfectant has to be removed from the system according to the rinsing procedure (see Chapter 7.5.2 on page 52)



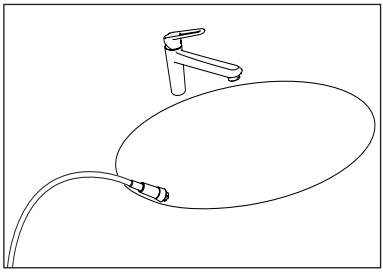
Make sure that the disinfectant acts for at least 7 min.

7.3.2 Scaler Side Disinfection – Fresh Water Circuit

1

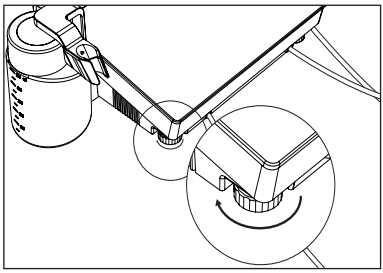
> Perform steps 1 to 7 described in the Chapter 7.2 on page 41 device preparation, if not yet done;
> Lift the scaler hose without the handpiece and place it over the sink

CAUTION
Make sure that the polisher hose is in its housing otherwise the device remains inactive.



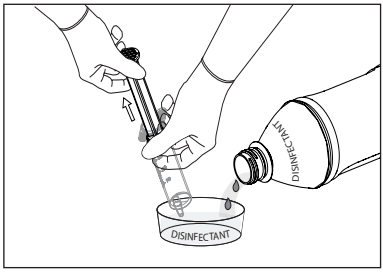
2

> Fully open the left knob on the front of the device (Ref. Q inside front cover);



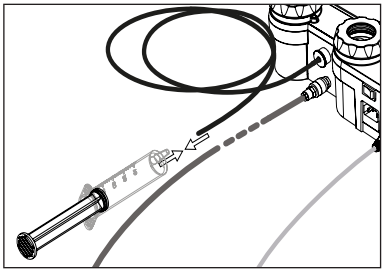
3

> Aspirate with the syringe at least 12 ml of disinfectant (Vector/RinsEndo Disinfection, Dürr Dental) making sure that there is no air inside;



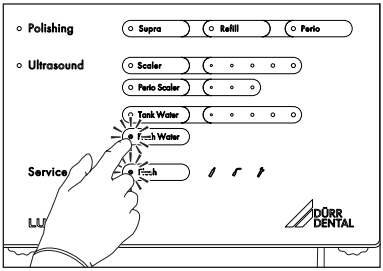
4

> Connect the syringe to the end of the tube previously connected to the male water connection;



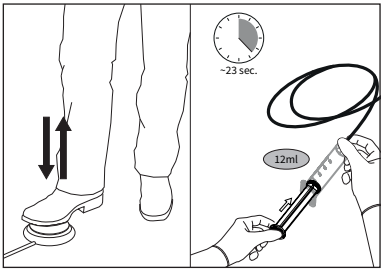
5

> Select the "Fresh Water" irrigation circuit;
> Press the "Flush" button on the touch surface (see Chapter 6 on page 37);



6

> Press and release the foot pedal. At the start of the "Flush" cycle, start injecting the disinfectant with the syringe.
> During the "Flush" cycle, inject 12 ml of disinfectant.
> The "Flush" cycle on the Ultrasound side lasts about 23 seconds;



The execution of the "Flush" cycle on the Ultrasound side can be interrupted at any time by pressing and releasing the foot pedal. Before running the "Flush" cycle on the Ultrasound side, check that the left knob on the front of the device (Ref. Q inside front cover) is open. At the end of the “Flush” cycle, stop the injection of liquid with the syringe.

If you finish injecting the 12 ml of disinfectant before the completion of the "Flush" cycle, wait for it to complete. If the cycle ends before having injected all 12 ml, repeat the "Flush" cycle until the injection of 12 ml is complete.

If disinfectant inside the syringe was more than 12 ml, leave it inside the syringe.

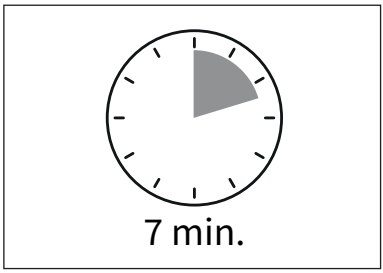
Fix the hose/syringe connection with one hand while inserting the solution, to avoid unintentional removal of the hose and spilling of the disinfectant.

CAUTION
Do not exert excessive pressure on the syringe plunger. The size of the irrigation circuit pipes is small and it is normal for that the injection proceeds slowly.

> Directly continue with disinfection of the polisher side circuit from step 1 (see Chapter 7.4 on page 48).
Before starting to work again, the disinfectant has to be removed from the system according to the rinsing procedure (see Chapter 7.5.3 on page 53).

Make sure that the disinfectant acts for at least 7 min.

17

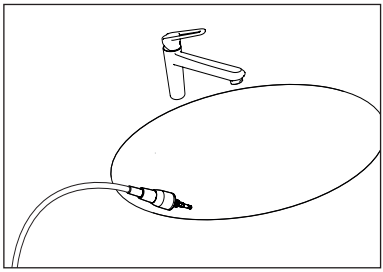


7.4 Polishing Side Inner Circuit Disinfection

1

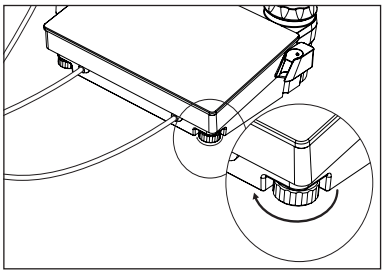
> Lift the polisher hose and place it over a sink. The Polishing function is activated.
> Perform steps 1 to 7 described in the Chapter 7.2 on page 41, if not yet done.

CAUTION
Make sure that the scaler hose is in its housing otherwise the device remains inactive.



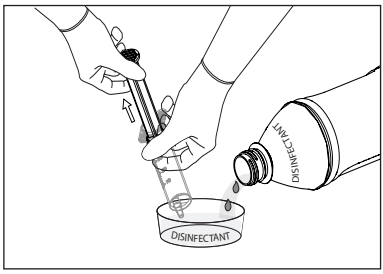
2

> Fully open the right knob on the front of the device (Ref. V inside front cover);



3

> Aspirate with the syringe at least 12 ml of disinfectant (Vector/RinsEndo Disinfection, Dürr Dental) making sure that there is no air inside;



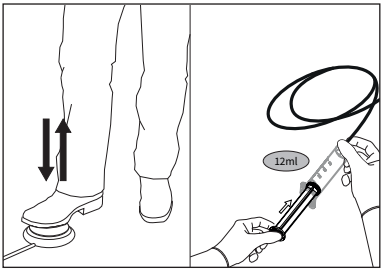
4

> Press and hold the foot pedal and contemporary start injecting the disinfectant with the syringe until 12 ml of disinfectant are injected

Make sure that the polishing channel is active and that both the powder containers are inserted correctly in their seats.

If disinfectant inside the syringe was more than 12 ml, leave it inside the syringe.

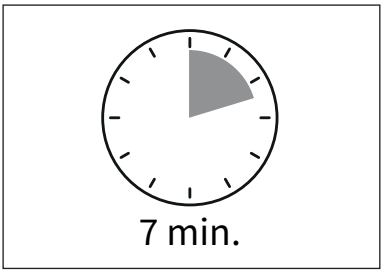
Fix the hose/syringe connection with one hand while inserting the solution, to avoid unintentional removal of the hose and spilling of the disinfectant.



CAUTION
Do not exert excessive pressure on the syringe plunger. The size of the irrigation circuit pipes is small and it is normal for that the injection proceeds slowly.

5

> Let the disinfectant act for at least 7 min.
> Before starting to work again, the disinfectant has to be removed from the system according to the rinsing procedure (see Chapter 7.5.4 on page 54).



7.5 Rinsing

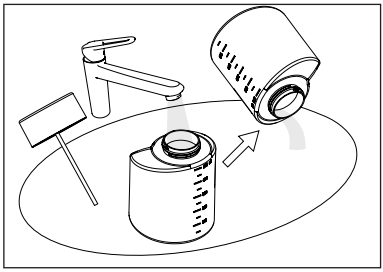
7.5.1 Rinsing preparation

Do not leave the disinfectant solution inside the inner circuit more than a weekend (or 62 h).

EN

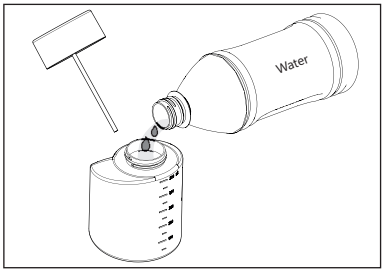
1

> Disconnect the Water Tank from the device;
> Unscrew the cap from the Water Tank and empty the remaining liquid;
> Rinse the Water Tank with running water;



2

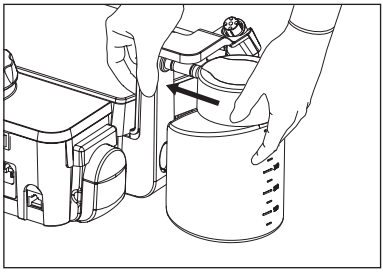
> Fill the Water Tank with 100 ml of water. Close the cap of the Water Tank.



3

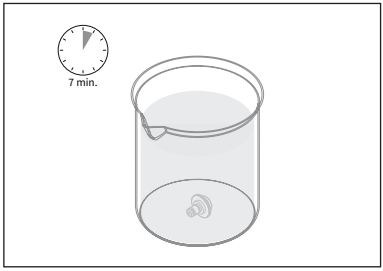
> Keep the Water Tank in a vertical position and push it towards the unit's body until it is firmly connected;

CAUTION
Do not capsize the Water Tank as its cap is not watertight.



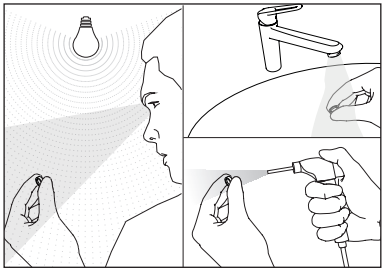
4

> Completely immerse the male coupling previously removed from the fresh water connection (see Chapter 7.2 on page 41) in the disinfectant solution (Vector/ RinsEndo Disinfection, Dürr Dental). Leave to soak for 7 minutes.



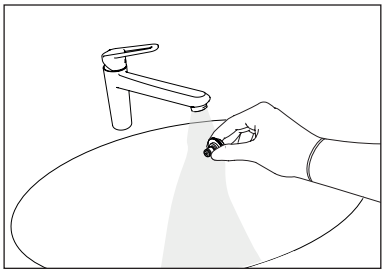
5

> Check the integrity of the water filter previously removed from the fresh water connection (see Chapter 7.2 on page 41). Rinse it, dry it with compressed air, making sure to remove any residual impurities;



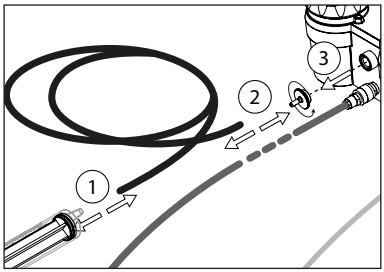
6

> Remove the male coupling for connection to the external water circuit from the disinfectant solution and rinse it under running water;
> Store the male coupling for connection to the external water circuit in a clean and safe place for subsequent re-use.



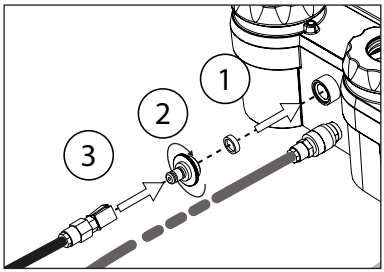
7

> After filling all internal circuits with disinfectant (see Chapter 7.3 on page 43 and Chapter 7.4 on page 48), remove the syringe (Ref. 1), the tube (Ref. 2) and unscrew the male coupling of the irrigation circuit cleaning kit (Ref. 3).



8

> Re-insert the previously cleaned water filter (see point 5) in its seat - Ref. 1 -, screw the original and previously disinfected male coupling (see point 6) - Ref. 2 - and reconnect the quick connector of the external water circuit - Ref. 3.

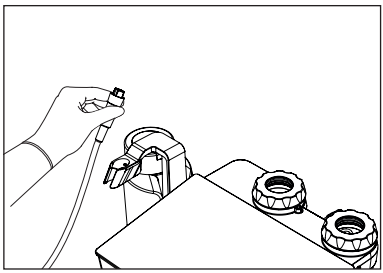


7.5.2 Scaler Side Rinsing – Tank Water Circuit

1

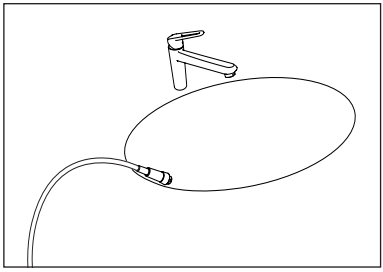
> Lift the scaler hose.

CAUTION
Make sure that the polisher hose is in its housing otherwise the device remains inactive.



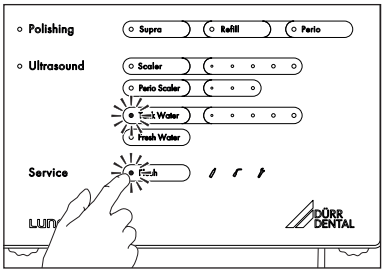
2

> Place the hose over a container or sink to contain the liquid that will flow out;



3

> Press the key "Tank Water“ and select "Flush" on the touch surface (see Chapter 6 on page 37).
> Perform 3 "Flush" cycles;

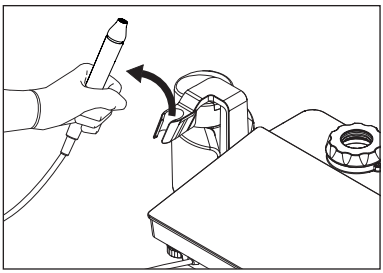


7.5.3 Scaler Side Rinsing – Fresh Water Circuit

1

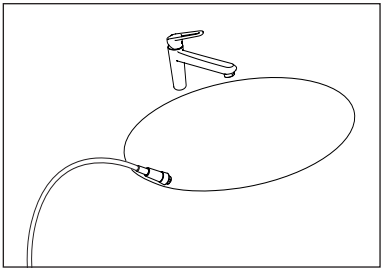
> Lift the scaler hose.

CAUTION
Make sure that the polisher hose is in its housing otherwise the device remains inactive.



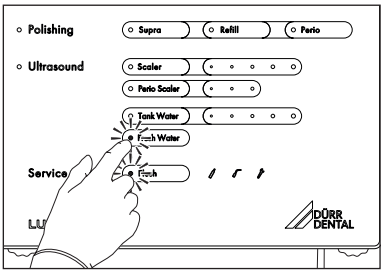
2

> Place the hose over a container or sink to contain the liquid that will flow out;



3

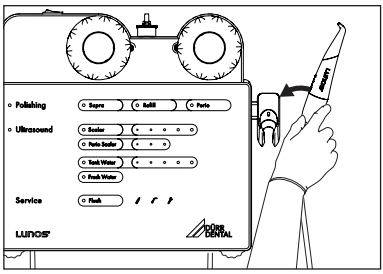
> Press the key “Fresh Water“ and select "Flush" on the touch surface (see Chapter 6 on page 37).
> Perform 3 "Flush" cycles;



7.5.4 Polishing Side Rinsing

1

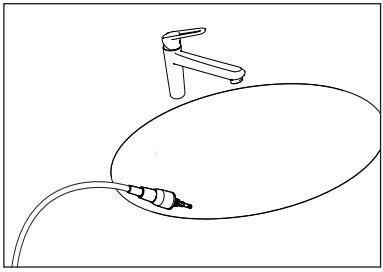
> Lift the polisher handpiece.
The Polishing function is activated.



WARNING
Make sure that the scaler hose is in its housing otherwise the device remains inactive.

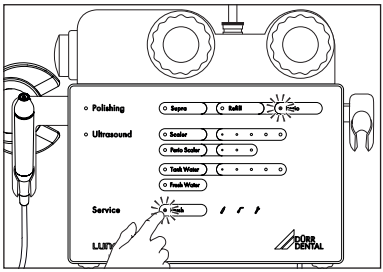
2

> Place the hose over a container or sink to contain the liquid that will flow out;



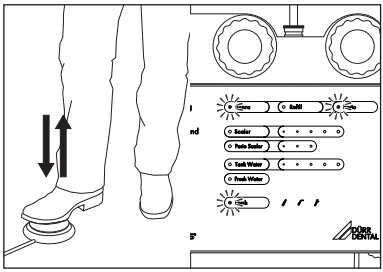
3

> Press the “Flush” button on the touch surface (see Chapter 6 on page 37)



4

> Press and release the foot pedal. The “Flush” cycle on the polishing side lasts about 40 seconds



5

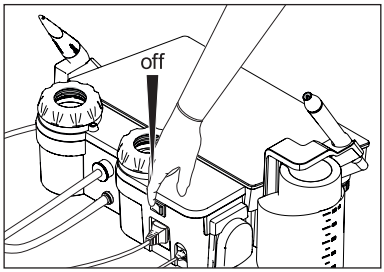
> Repeat step 3 and 4 for three times.

8 Disassembly of Parts for Cleaning and Sterilization

Before proceeding to the cleaning procedures described in Chapter 9 on page 60, disconnect all the accessories and components of the device.

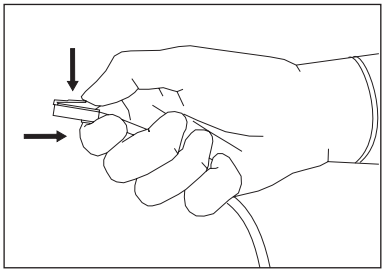
1

WARNING
Switch the device off.
Always turn the device off by its switch, and disconnect the power supply cable from the power outlet and from the device body, before performing the cleaning and sterilization procedures.



2

> Disconnect the foot pedal from the device:
- grab the connector of the foot pedal,
- press the release flap, and
- pull the connector back;

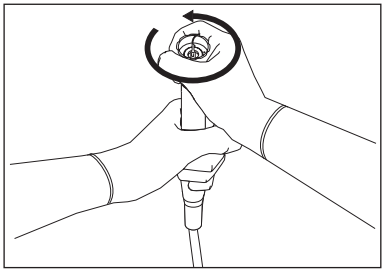


CAUTION
Do not attempt to unscrew or twist the connector during the disconnection: the connector could become damaged.

CAUTION
When disconnecting the foot pedal, always and only hold the connector of the cord. Never actually pull on the cord itself.

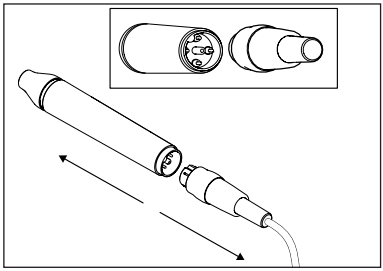
3

> If an instrument is connected to the handpiece, unscrew the instrument from the handpiece by using the torque wrench;



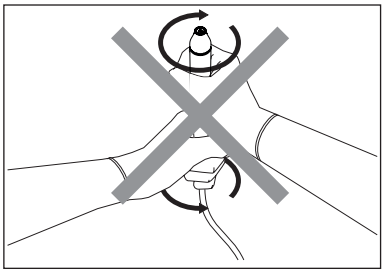
> Disconnect the handpiece from its hose;

4



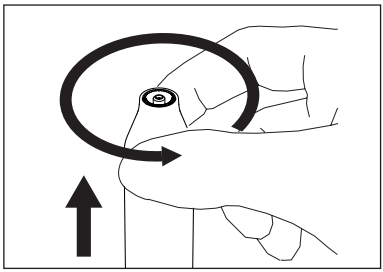
5

CAUTION
Do not attempt to unscrew or turn the connector when disconnecting the scaler handpiece.
The connector could be damaged.



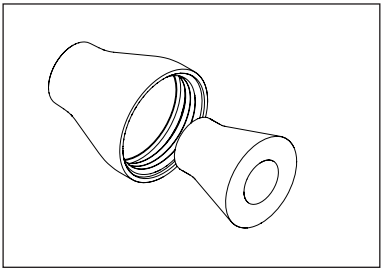
6

> Unscrew the front terminal of the handpiece;



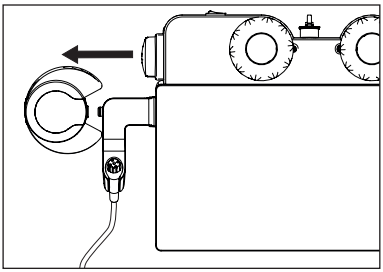
> Remove the light conductor from the front terminal.

7



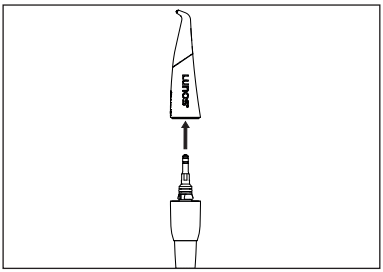
> Disconnect the Water Tank from the device body by pulling it outwards;

8



> Remove the Lunos® nozzle with a slight twist movement;

9

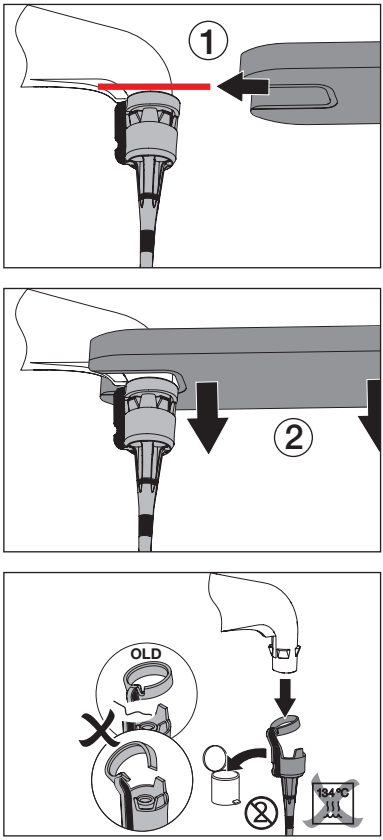


CAUTION
The polisher handpiece and its lead cannot be separated.

> If the Lunos® Perio Tip has been used, remove the subgingival perio tip using the combination wrench supplied and then proceed with the disposal (Chapter 11 on page 91);

Introduce the combination wrench exactly into the position indicated in the figure.

10

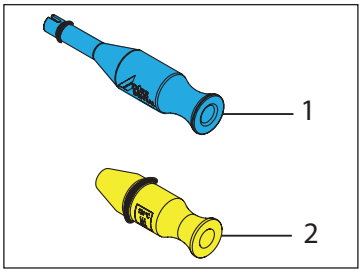


8.1 Check the Rinsing Adapters

> Check that the O-rings are properly seated on the rinsing adapters. The rinsing adapters must be replaced if the O-rings are lost.

1 Rinsing adapter for the nozzle (blue) for cleaning after every treatment and following blockage;

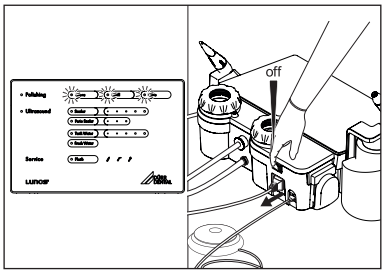
2 Rinsing adapter for nozzle (yellow) for use during reprocessing.



8.2 Extract the Powder Containers

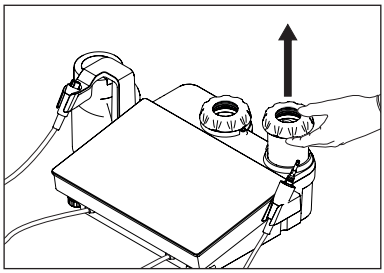
CAUTION
Before extracting the powder containers or unscrewing the caps, make sure that the “Refill” function has been selected and the corresponding LED is ON with a fixed light (see Chapter 5.7 on page 36). Once the “Refill” cycle is complete, switch off the device.

1



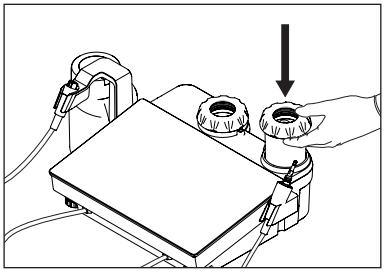
2

> Extract the powder container from the device, remove the cap and empty it. Proceed with the Cleaning. (See Chapter 10.13 on page 90)
> Repeat the operation on the second powder container of the device if both have been used.

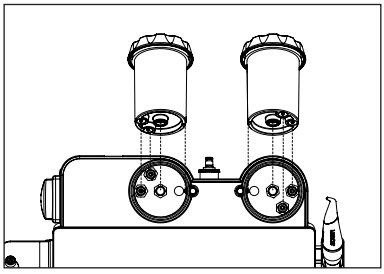


3

> When the cleaning operation has been completed, re-position the containers in the device.



WARNING
Insert the powder containers in such a way that the side alignment groove and the connectors on the base match the counterparts on the housing.



9 Reprocessing

9.1 Risk Analysis and Categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator.

Comply with all national directives, standards and specifications such as e. g. the Recommendations from the Commission for Hospital Hygiene and Infection Prevention.

Accessories of the medical device are also subject to reprocessing.

Classification recommendation given intended use of the product: semi-critical B to critical B
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

9.2 Reprocessing Procedure in Accordance with EN ISO 17664

The reprocessing procedure after each patient treatment is carried out according to the reprocessing procedure established by EN ISO 17664.

Important Information
The reprocessing notes in accordance with EN ISO 17664 have been independently tested by the manufacturer for the preparation of the device and its components for their reuse.

The person conducting the reprocessing is responsible for ensuring that the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.

Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially influenced by the amount of wear and tear or damage resulting from its use.

The impermissible use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing procedure was validated as follows:

– Pre-cleaning
  - Wipe disinfection with FD 322 premium wipes (Dürr Dental)
- Manual cleaning and disinfection
  - Pre-cleaning with FD 322 premium wipes (Dürr Dental)
  - ID 213 Instrument disinfection (Dürr Dental)
- Automatic cleaning and disinfection
  Was performed in accordance with EN ISO 15883 with tested efficacy.
  - Pre-cleaning with FD 322 premium wipes (Dürr Dental)
  - Cleaning agent: Neodisher MediClean, washer-disinfector RDG: G 7836 CD (Miele), programme:
    D-V-MEDICLEAN at 90 °C (5 min)
- Steam sterilisation was performed in accordance with EN ISO 17665 with the fractionated vacuum procedure.
  Sterilise the parts for sterilisation, e.g.
  - 4 minutes at 132 °C
    (also valid for 5 minutes at 134 °C)

9.3 General Information

NOTICE
Equipment damage due to unsuitable products
Oils and care products containing oil will damage the device.
> The device and its O-rings must not be maintained with oil or with a care system that contains oil.

> Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.
> Clean and disinfect all parts a maximum of two hours after use.
> Comply with the specifications (see Chapter 9.5 on page 62, Chapter 9.6 on page 63, and Chapter 9.7 on page 71) when selecting the cleaning and disinfectant agents to be used.
> Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
> Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.
> Only use disinfectants that are aldehyde-free and display material compatibility with the product.
> Do not use any rinse aid (danger of toxic residue on the components).
> Only use freshly-produced solutions.
> Only use distilled or deionised water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. legionella bacteria).
> Use clean, dry, oil and particle-free compressed air.
> Do not exceed temperatures of 138 °C.
> Subject all devices used (cleaning and disinfection device (CD), sealing device, steam steriliser) to regular maintenance and inspections.

9.4 Preparation at the Operating Location


Wear protective gloves.


Wear protective goggles.


Use a mask.


Use protective clothing.

WARNING
Risk of infection from contaminated products
Danger of cross contamination
> Reprocess the product correctly and promptly before its first use and after every subsequent use.

> **Run the “Flush” function** (see Chapter 6 on page 37);
> Check that all of the following accessories have been removed/disconnected from the device body (see Chapter 8 on page 55):
- Electric power supply cable;
- Foot pedal;
- Scaler handpiece;
- Instruments;
- Lunos® Nozzles;
- Water and air pipe.

WARNING
Always turn the device off by its switch and disconnect it from the electrical network before performing the cleaning and disinfection procedures.

CAUTION
The polisher handpiece and the cable cannot be separated.

CAUTION
Always disconnect the instrument from the scaler handpiece before cleaning and sterilizing it.

CAUTION
Do not immerge the scaler handpiece in an ultrasonic tank.

> Transport the device from the treatment location to the reprocessing location in such a way as to protect against contamination.

> Remove course organic and inorganic soiling with a disinfectant cloth.

EN

9.5 Pre-cleaning

Do not leave the pre-cleaning more than 15 minutes after the unit has been used.

> Clean the exterior surfaces completely with cleaning cloths such as Dürr Dental FD 322 premium wipes for at least 1 min. Make sure that all surfaces are sufficiently moistened.

> Note the action time of the cleaning agent (at least 1 min for FD 322 premium wipes).

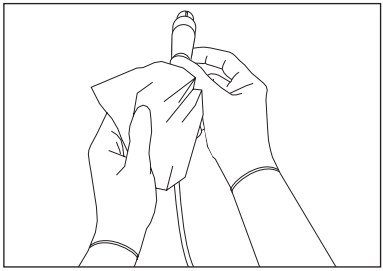
WARNING
Always dry scaler coupling electrical contacts
After the cleaning and before connecting the scaler handpiece make sure that the scaler hose and the scaler coupling electrical contacts are perfectly dry. Dry the scaler coupling electrical contacts by using filtered compressed air. DO NOT blow the compressed air directly into the hose; keep the coupling upside down and direct the compressed air from its side (refer to figure on the right).

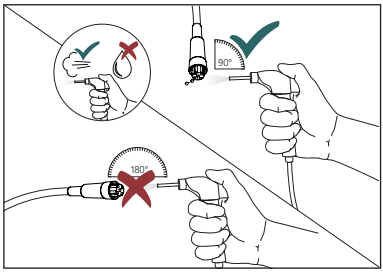
WARNING
Material failure due to steam sterilisation
The single-use tip "LUNOS Perio Tip" cannot be steam-sterilised and must be removed after every treatment.
Single-use tips must only be used once.

> Check that the O-rings are properly seated on the rinsing adapters.
The rinsing adapters must be replaced if the O-rings are lost or damaged.

This procedure applies to all the device parts and, in particular, to those parts that are not protected against the penetration of liquid and/or that cannot be sterilized, such as:

- Device body;
- Powder container caps;
- Foot pedal and relative connection cable to the device;
- Polisher coupling and hose;
- Scaler coupling and hose;
- Water tank and cap.





Pre-cleaning of Parts that can be sterilized

The following parts of the device can be sterilized:

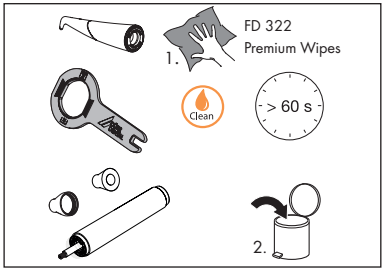
- Scaler handpiece;
- Scaler front terminal;
- Scaler light conductor;
- Lunos® scaler instruments;
- Instruments torque wrench;
- Lunos® nozzles;
- Combination wrench;
- Irrigation Circuit Cleaning Kit.

Assure that the male coupling and the hose of the Irrigation Circuit Cleaning Kit have been previously disassembled.

After having observed the indication provided in the Chapter 9.4 on page 61, proceed as follows:

1

> Completely wipe down the external surfaces with FD 322 Premium Wipes (Dürr Dental) for at least one minute until they are visually clean. Make sure that the surfaces are sufficiently moistened.
> Note the action time of the cleaning agent.



9.6 Manual Cleaning and Disinfection

Manual cleaning and disinfection applies to the following parts:

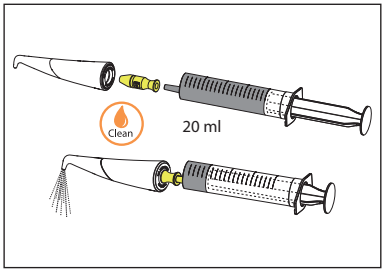
- Scaler handpiece;
- Scaler front terminal;
- Scaler light conductor;
- Lunos® scaler instruments;
- Instruments torque wrench;
- Lunos® nozzles;
- Combination wrench;
- Irrigation Circuit Cleaning Kit.

Assure that the male coupling and the hose of the Irrigation Circuit Cleaning Kit have been previously disassembled.

After having observed the indication provided in the Chapter 9.4 on page 61 and having performed the procedure described in the Chapter 9.5 on page 62, proceed as follows:

1

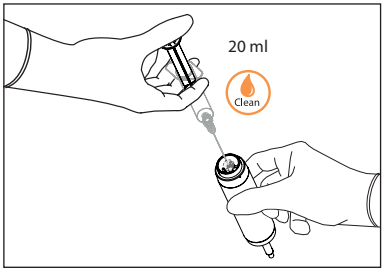
> Attach the yellow rinsing adapter to the nozzle and rinse through 1x with a cleaning solution (2% (v/v) ID 213 solution, Dürr Dental) using a 20 ml disposable syringe.



EN

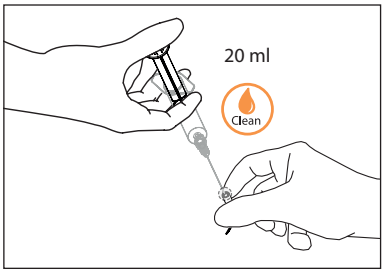
> Rinse the internal channel of the scaler handpiece with a 20 ml syringe previously filled with a cleaning solution (2% (v/v) ID 213 solution, Dürr Dental);

2



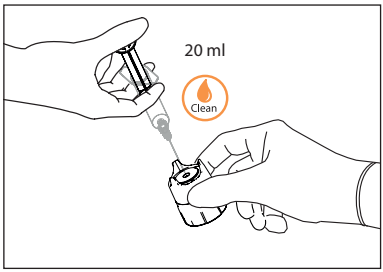
> Use a disposable syringe to aspirate and inject a cleaning solution (2% (v/v) ID 213 solution, Dürr Dental) into Lunos® scaler instrument's lumen (internal channel).

3



> Use a disposable syringe to aspirate and inject a cleaning solution (2% (v/v) ID 213 solution, Dürr Dental) into instruments torque wrench hard-to-reach areas (through holes, internal cavities, grooves and crevices).

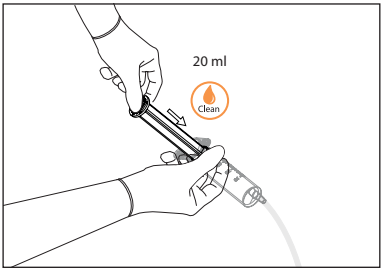
4

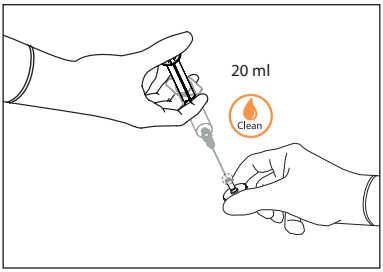


5

> Use a disposable syringe to aspirate and inject a cleaning solution (2% (v/v) ID 213 solution, Dürr Dental) into the hose and the male coupling of the Irrigation Circuit Cleaning Kit.

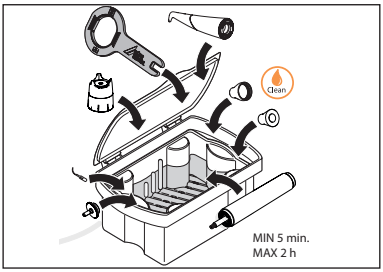
Assure that the male coupling and the hose of the Irrigation Circuit Cleaning Kit have been previously disassembled.





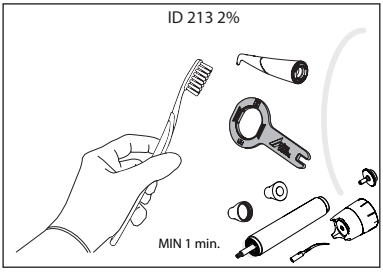
6

> Remove all rinse adapters.
> Afterwards place the individual parts in a cleaning and disinfecting bath (non-fixing, aldehyde-free) for the stated reaction time (for 2% ID 213, Dürr Dental, min. 5 minutes, max. 2 hours). Make sure that all parts are covered. See Chapter 9.3 on page 61 - General Information.



7

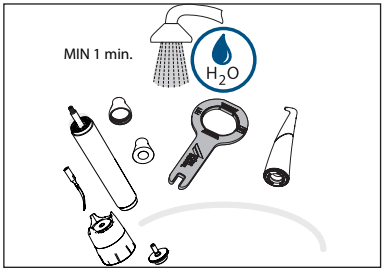
> In the disinfectant bath, brush all exterior and interior surfaces completely with a soft hygienic brush.
> Comply with the action times of the cleaning agent and disinfectant (minimum 1 minute).



EN

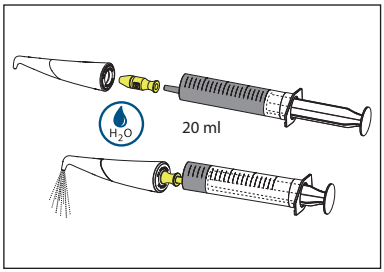
8

> After the action time prescribed by the manufacturer of the cleaning and disinfectant solution, rinse all components under water for minimum 1 minute (temperature < 35 °C).



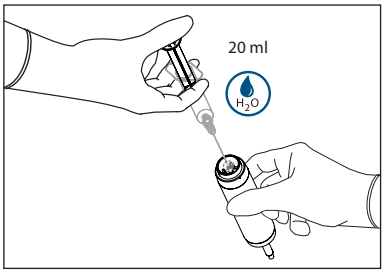
9

> Attach the yellow rinsing adapter to the nozzle and rinse with tap water for minimum 1 minute (temperature < 35 °C) using a 20 ml disposable syringe.



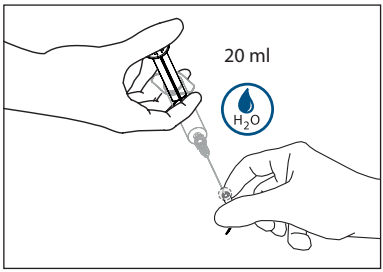
10

> Rinse the internal channel of the scaler handpiece with tap water for minimum 1 minute (temperature < 35 °C) using a 20 ml disposable syringe.



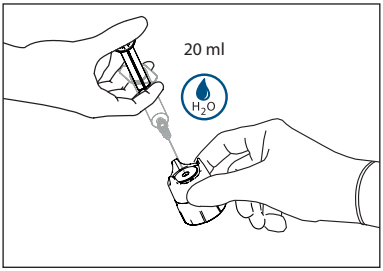
11

> Use a disposable 20 ml syringe to aspirate and inject tap water for minimum 1 minute (temperature < 35 °C) into Lunos® scaler instrument's lumen (internal channel).



12

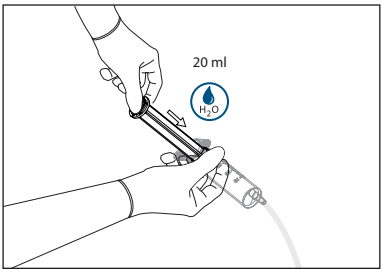
> Use a disposable 20 ml syringe to aspirate and inject tap water for minimum 1 minute (temperature < 35 °C) into instruments torque wrench hard-to-reach areas (through holes, internal cavities, grooves and crevices).

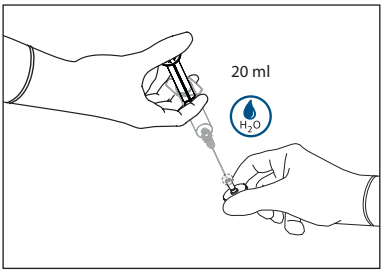


13

> Use a disposable 20 ml syringe to aspirate and inject tap water for minimum 1 minute (temperature < 35 °C) into the hose and the male coupling of the Irrigation Circuit Cleaning Kit.

Assure that the male coupling and the hose of thelrrigation Circuit Cleaning Kit have been previously disassembled.

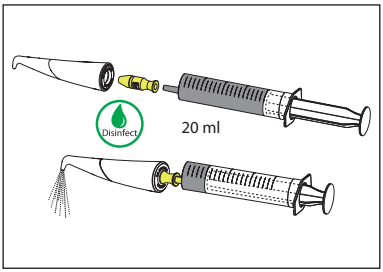




After cleaning and rinsing all parts, proceed with disinfection and rinsing of all parts.

14

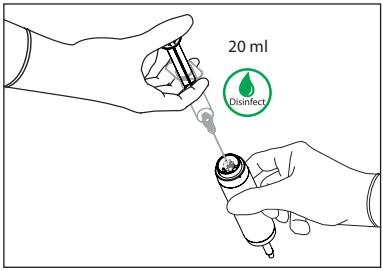
> Attach the yellow rinsing adapter to the nozzle and rinse through 1x with a disinfectant solution (2% (v/v) ID 213 solution, Dürr Dental) using a 20 ml disposable syringe.



EN

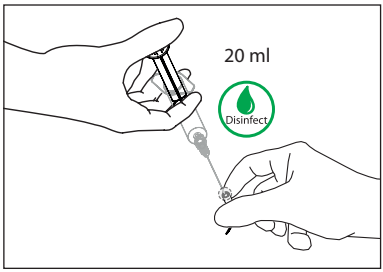
> Rinse the internal channel of the scaler handpiece with a 20 ml syringe previously filled with a disinfectant solution (2% (v/v) ID 213 solution, Dürr Dental);

15



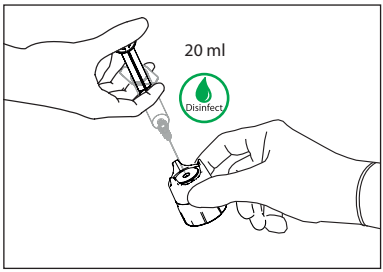
> Use a disposable syringe to aspirate and inject a disinfectant solution (2% (v/v) ID 213 solution, Dürr Dental) into Lunos® scaler instrument's lumen (internal channel).

16



> Use a disposable syringe to aspirate and inject a disinfectant solution (2% (v/v) ID 213 solution, Dürr Dental) into instruments torque wrench hard-to-reach areas (through holes, internal cavities, grooves and crevices).

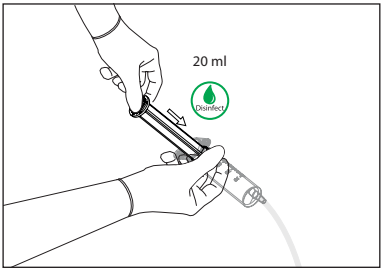
17

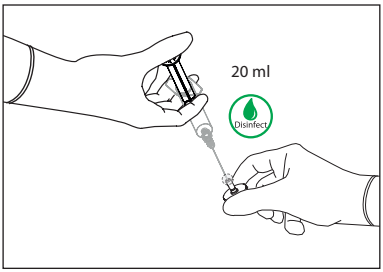


18

> Use a disposable syringe to aspirate and inject a disinfectant solution (2% (v/v) ID 213 solution, Dürr Dental) into the hose and the male coupling of the Irrigation Circuit Cleaning Kit.

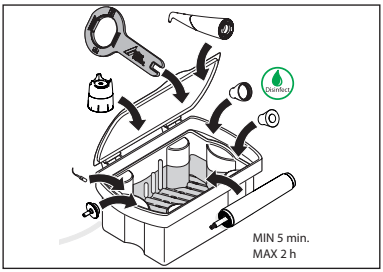
Assure that the male coupling and the hose of the Irrigation Circuit Cleaning Kit have been previously disassembled.





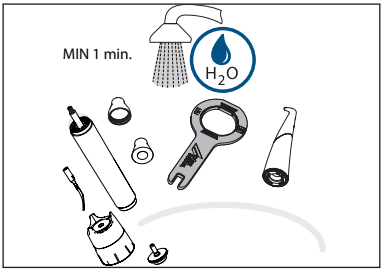
19

> Remove all rinse adapters.
> Afterwards place the individual parts in a cleaning and disinfecting bath (non-fixing, aldehyde-free) for the stated reaction time (for 2% ID 213, Dürr Dental, min. 5 minutes, max. 2 hours).
Make sure that all parts are covered.
See Chapter 9.3 on page 61 - General Information.



20

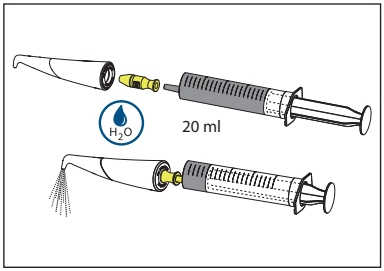
> After the action time prescribed by the manufacturer of the cleaning and disinfectant solution, rinse all components under deionised water for minimum 1 minute (temperature < 35 °C).



EN

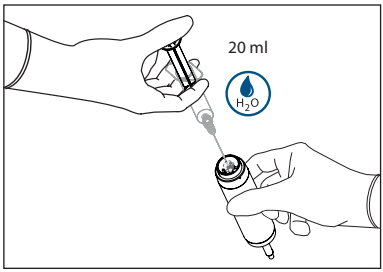
> Attach the yellow rinsing adapter to the nozzle and rinse with deionised water for minimum 1 minute using a 20 ml disposable syringe.

21



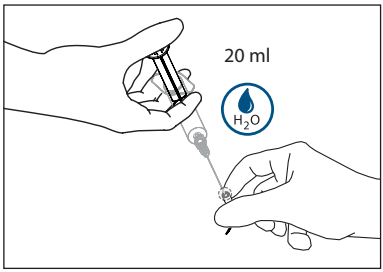
> Rinse the internal channel of the scaler handpiece with deionised water for minimum 1 minute using a 20 ml disposable syringe.

22



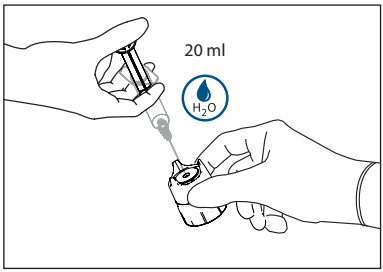
> Use a disposable 20 ml syringe to aspirate and inject deionised water for minimum 1 minute into Lunos® scaler instrument's lumen (internal channel).

23



> Use a disposable 20 ml syringe to aspirate and inject deionised water for minimum 1 minute into instruments torque wrench hard-to-reach areas (through holes, internal cavities, grooves and crevices).

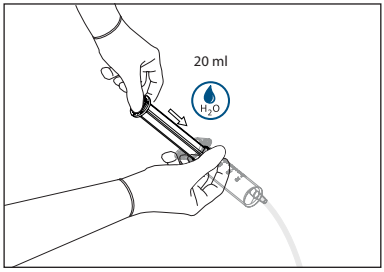
24

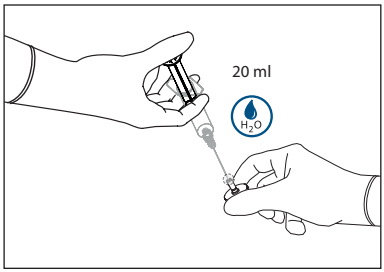


> Use a disposable 20 ml syringe to aspirate and inject deionised water for minimum 1 minute into the hose and the male coupling of the Irrigation Circuit Cleaning Kit.

Assure that the male coupling and the hose of the Irrigation Circuit Cleaning Kit have been previously disassembled.

25





9.7 Automatic Cleaning and Disinfection

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:

– Corresponds to and tested in accordance with EN ISO 15883
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 90°C)

Programme is suitable for the components and provides sufficient rinsing cycles.

For more information, refer to Chapter 9.3 on page 61.

Selection of the cleaning agent automatic

The following properties are required:

– Material compatibility with the product
– Corresponds with the manufacturer's specifications of the CD

For further information, see Chapter 9.3 on page 61.

Cleaning and Disinfection

Make sure that the accessories are appropriately blocked in the basket and cannot move during washing. Any contact could damage them. Position the instruments in a way that the water can flow through all the surfaces, even internally.

WARNING
Avoid overloading the thermal disinfector, as this could compromise cleaning effectiveness.

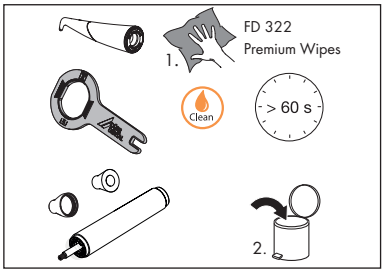
WARNING
Upon completion of the cleaning cycle in the thermal disinfector, the scaler handpiece remains at the heated washing temperature. Use appropriate precautions when extracting the scaler handpiece from the thermal disinfector to prevent injury to the operator.

CAUTION
Due to its shape, the scaler handpiece can rotate. When not in use, the scaler handpiece must always be placed on its support.

EN

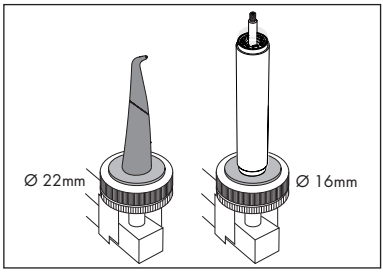
1

> Completely wipe down the external surfaces with FD 322 Premium Wipes for at least one minute until they are visually clean. Make sure that the surfaces are sufficiently moistened.
> Note the action time of the cleaning agent.



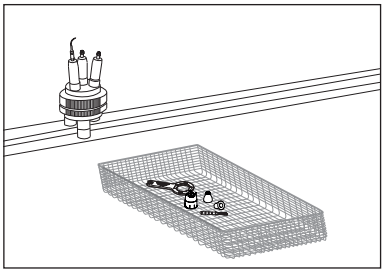
2

> Attach the Lunos® nozzle and the Lunos® scaler handpiece to the special mountings for transmission instruments (e.g. Miele: ADS 3 or MELAG universal adapter for MELAtherm 10) in the washer-disinfector.



3

> Repeat the same operation for the scaler intruments, connecting them to the relevant adapters supplied as an optional.
> Secure all the other components with a suitable fixture of the cleaning and disinfection unit.



4

> Sequence and parameters applicable to the cycle:
  - 1 min, rinse with cold water;
  - 5 min, wash with alkaline detergent at 55 °C ±2 °C;
  - 1 min, neutralisation with suitable solution (1/3 cold water, 2/3 hot water);
  - 1 min, rinse with water (1/3 cold water, 2/3 hot water);
  - 5 min, thermal disinfection at 93 °C with demineralised water.

In compliance with ISO 15883-1, Table B.1 [4] thermal disinfection at a temperature of 90 °C for 5 min determines a value A0 3000.

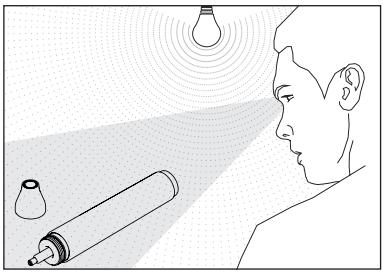
9.8 Cleaning Verification

Materials Necessary

- Light source; - Magnifying glass 2.5X.

> Once the cleaning operations have been completed, visually inspect the scaler handpiece and scaler front tip under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to the details that could conceal dirt residue (threading, cavities, grooves) and, if necessary, repeat the cleaning cycle if dirt is still visible;

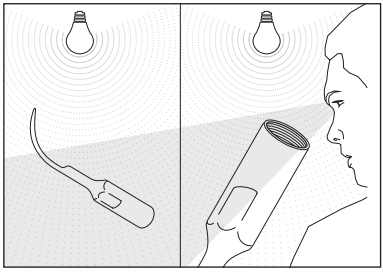
1

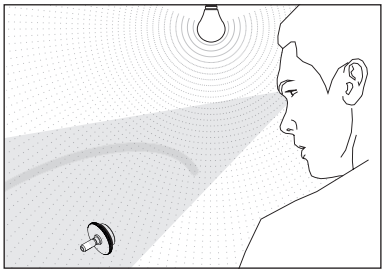


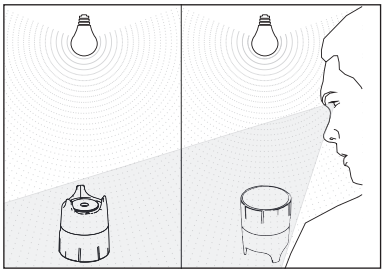
> Finally, check the integrity of those parts and those elements that could have deteriorated during use;

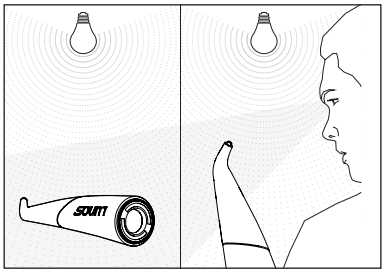
> Repeat the checks on the other accessories (scaler instruments, torque wrenches, Lunos® nozzle, combination wrench, cleaning adapters, irrigation circuit cleaning kit), repeating the cleaning cycle if necessary. If necessary, replace any damaged parts.

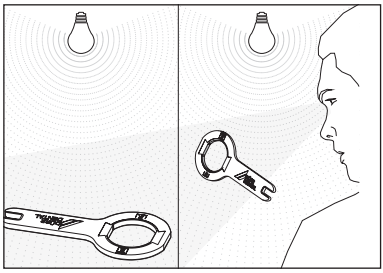
2











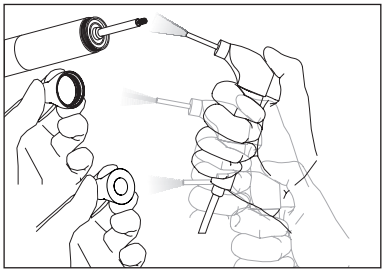
9.9 Drying and Lubrication

Materials Necessary

- Compressed air;
- Soft cloth with low fibre release;
- Medical grade lubricant.

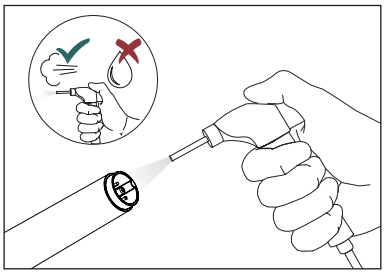
1

> Dry all parts of the scaler handpiece of the scaler front terminal and of the light conductor by blowing compressed air;



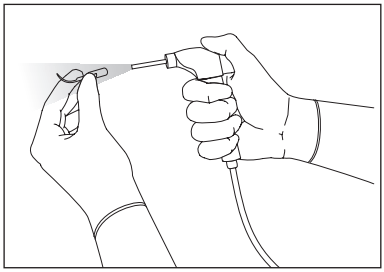
2

CAUTION
The scaler handpiece electric contacts must be dry before the end of the sterilization cycle, before connection of the device lead. Always make sure that the connector electric contacts are entirely dry; dry them by blowing compressed air if necessary.



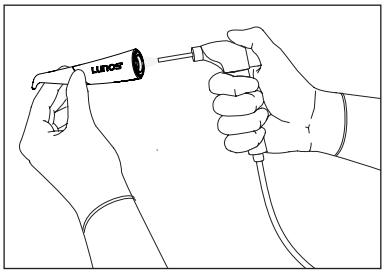
3

CAUTION
Before starting the sterilization cycle, make sure that the instrument is thoroughly dry both internally and externally. To do this, blow compressed air both externally and through the internal passage hole. This will prevent the appearance of stains, streaks on the surface or oxidation inside the instrument.



4

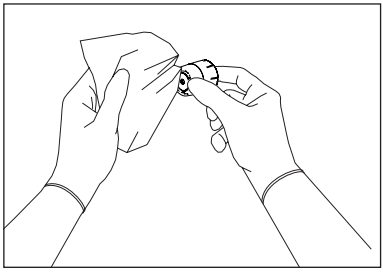
CAUTION
Before starting the sterilization cycle, make sure that the Lunos® Nozzles Supra and Perio are thoroughly dry both internally and externally.
To do this, blow compressed air both externally and through the internal passage holes. This will prevent the appearance of stains, streaks on the surface or oxidation inside the nozzle.



EN

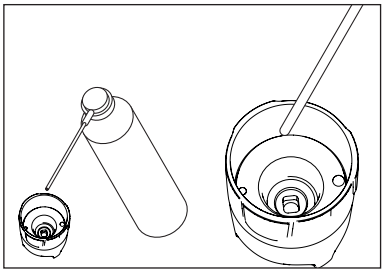
> Make sure that the torque wrench is completely dry, both externally and internally, before starting the sterilisation cycle. Use filtered compressed air to eliminate any moisture from cavities, grooves, fissures and other hard-to-reach areas. Dry the torque wrench with a clean, dry and low fiber release cloth. This will prevent the appearance of marks or stains on the surface and oxidation;

5



> Before sterilisation, the torque wrench must be lubricated with a commercial medical-grade lubricant. The lubricant must be applied by spraying it directly onto the peripheral contact surface inside the torque wrench, as indicated in the figure. After having applied the lubricant, remove any excess oil using a clean lint-free cloth.

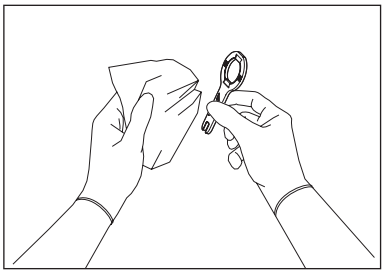
6



CAUTION
Do not use oil or silicone-based lubricants.

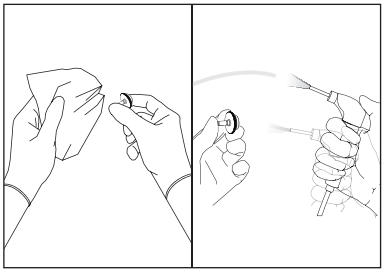
> Dry the combination wrench using a soft cloth with low fiber release.

7



> Dry the hose and the coupling surfaces with a clean, non-abrasive, low fiber release cloth.
> Dry the internal surfaces with a jet of compressed air until the water is completely eliminated.

8



9.10Sterilization

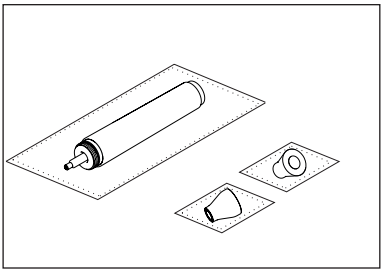
Sterilization applies to the following parts:

- Scaler handpiece;
- Scaler front terminal;
- Scaler light conductor;
- Lunos® scaler instruments;
- Lunos® nozzles;
- Torque wrench;
- Combination wrench;
- Irrigation Circuit Cleaning Kit.

Preparation

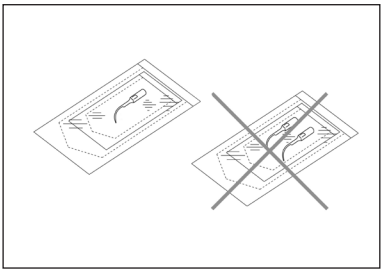
1

> Seal the scaler handpiece (without instruments), the scaler front terminal and the light conductor individually, separately in disposable sterilization pouches.



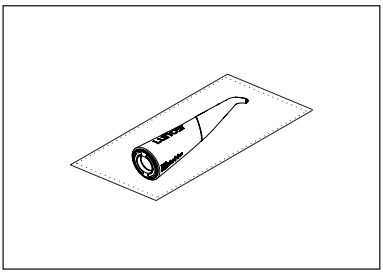
2

> Seal the instruments individually inside a disposable pouch for sterilization.



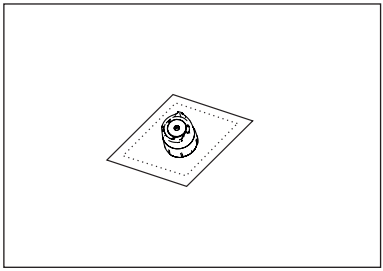
3

> Seal the Lunos® nozzles individually inside a disposable pouch for sterilization.



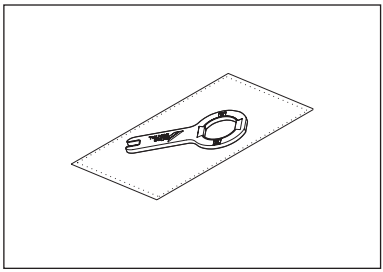
4

> Seal the wrench individually inside a disposable pouch for sterilization.



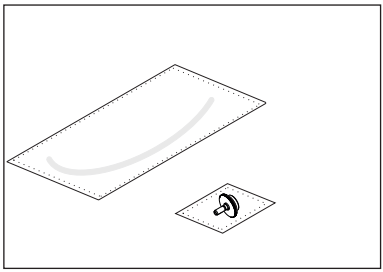
5

> Seal the combination wrench individually inside a disposable pouch for sterilization.



6

> Individually seal the hose and the coupling, separately, in disposable steam sterilisation pouches.



Sterilization Method

The scaler handpiece and the other accessories that can be sterilized are manufactured with materials that resist a maximum temperature of 135 °C for a maximum time of 20 minutes.

Lunos® nozzles resist a maximum temperature of 138 °C.

Once the scaler handpiece and the other accessories that are able to be sterilized have been put into bags individually, perform the sterilization process in the steam autoclave.

The sterilization process validated by the manufacturer, in a steam autoclave, guarantees SAL 10^{-6} by setting the parameters indicated in the following:

- **Type of cycle**: 3 times Pre-vacuum (min. pressure 60 mBar).
- **Minimum sterilization temperature**: 132 °C (interval 0 °C÷ +3 °C).
- **Minimum sterilization time**: 4 minutes.
- **Minimum drying time**: 20 minutes.

CAUTION
Always make sure that the scaler handpiece electric contacts are thoroughly dry at the end of the sterilization cycle and before the connection of the device lead. If necessary, dry them by blowing filtered compressed air.

All of the stages of sterilization must be performed by the operator in compliance with ISO 17665-1:2007, ISO 556-1:2002 and ANSI/AAMI ST 46:2002.

Particular information:

- Sterilization parameters, in steam autoclave, used in Great Britain:
  - temperature: 134 °C ,
  - time: 3 minutes.

CAUTION
Do not sterilize the handpiece with the instrument screwed onto it.

WARNING
Infection control - Parts that can be sterilized.
Diligently remove all residues of organic dirt before the sterilization.

CAUTION
Perform the sterilization using a water steam autoclave only. Do not use any other sterilization procedure (dry heat, irradiation, ethylene oxide, gas, low temperature plasma, etc.).

CAUTION
Do not exceed the allowed load of the steam sterilizer.

WARNING
On completion of the sterilization cycle in autoclave, the scaler handpiece remains at the sterilization temperature for a long time.
Use appropriate precautions when extracting the scaler handpiece from the autoclave to prevent injury to the operator.

CAUTION
Wait for the scaler handpiece to cool down completely before use.

Marking

> Mark the packaged, treated medical product in such a way as to ensure safe application.

Issue Clearance for the Parts for Sterilisation

> The reprocessing of the medical products ends with the documented clearance for storage and renewed use.
> Document the clearance of the medical product after reprocessing.

EN

10 Maintenance

10.1 Maintenance after every treatment

At the end of each treatment, proceed with the activities described in the following.

> Perform a complete cleaning cycle of the irrigation circuits using the “Flush” function (see Chapter 6 on page 37) both on the Ultrasound side and the Polishing side for all types of irrigation;

> Immediately disassemble the different parts (see Chapter 8 on page 55) and proceed to their cleaning and sterilization (see Chapter 9 on page 60).

> Perform pre-cleaning of the device (see Chapter 9.5 on page 62)

10.2 Daily Maintenance

Regardless of the time elapsed since the last treatment and use of the device, at the end of the day, proceed with the activities described in the following.

Ultrasound Side

1 Perform “Flush” by using both the type of irrigations:
- "Tank Water"
- "Fresh Water"

2 Remove and empty the water tank (refer to Chapter 8 on page 65, step 8).

WARNING
Infection control. Do not leave liquids in the tank for long periods of time. The tank must be filled just immediately before a treatment. If the tank has been filled without having used the device, it must be emptied at the end of the day.

3 Lift scaler hose, select "Flush", select “Tank Water” type of irrigation and press the foot pedal to empty the circuit (refer to Chapter 6 on page 37).

Polishing Side

4 Start the Refill function if the powder containers are still pressurized (refer to Chapter 5.7 on page 36).

5 Remove and empty both the powder containers (refer to Chapter 8.2 on page 69).

6 Blow compressed air in the powder container housings, each time the containers are removed in order to eliminate any powder residual. Do not use water or lubricants.

7 Clean the powder containers with compressed air (refer to Chapter 10.11 on page 99). Put the empty powder containers back into their correct position in the device.

8 Start "Flush" on Polishing side (refer to Chapter 6 on page 37).

9 In case the device is not used for a weekend (or more than 14h) follow the steps outlined in Chapter 7.2 on page 41 in order to prepare the device. After that repeat the procedures described in Section 7.3.2 and 7.3.3 but this time the syring should be filled with air instead of disinfectant. Repeat all the steps, there will be no need to wait for 7 minutes after the air injection.

10 Perform pre-cleaning of the device (see Chapter 9.5 on page 62).

11 Reconnect the empty water tank.

10.3 Transport or long inactivity periods

If the device will not be used for a prolonged time (more than 72 hours), observe the following recommendations:

- Empty the powder containers;
- Perform a complete cleaning cycle of the irrigation circuit using the “Flush” function (see Chapter 6 on page 37) both on the Ultrasound side and the Polishing side;
- Perform a complete disinfection of all the irrigation circuits (see Chapter 7 on page 41)
- Empty the Water Tank and irrigation circuits, removing the Water Tank and performing the “Flush” cycle of the Ultrasound side (see Chapter 6 on page 37);
- Empty all the circuits with a syringe: follow the steps outlined in Chapter 7.2 on page 41 in order to prepare the device. After that repeat the procedures described in Section 7.3.2 and 7.3.3 but this time the syring should be filled with air instead of disinfectant. Repeat all the steps, there will be no need to wait for 7 minutes after the air injection;
- Eliminate any condensation from the air filter (see Chapter 10.10 on page 86);
- Disconnect the device from the mains electricity and the water and air circuits;
- Clean and dry the water filter (see Chapter 10.7 on page 83);
- Before using the device after a long inacitivity period :
  - Perform a complete cleaning cycle of the irrigation circuit using the “Flush” function (see Chapter 6 on page 37) both on the Ultrasound side and the Polishing side;
  - perform again a complete disinfection of all the irrigation circuits (see Chapter 7 on page 41)
  - clean and sterilize the scaler handpiece, Lunos® nozzles and the accessories, following the instructions given in Chapter 9 on page 60;

WARNING
Before blowing compressed air into the powder containers, make sure that they have been emptied.

- Check that the scaler instruments are not worn out, deformed, or broken, paying special attention to the integrity of their tip.

EN

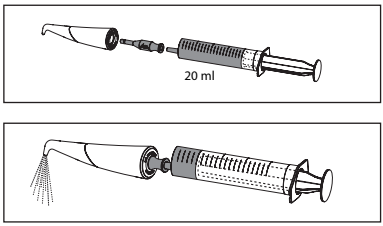
10.4 Maintenance Intervals

Ref.	Description	Q.ty each unit	Replace every:
	Full device maintenance at approved Dürr Dental service center		1 year
2044100014	Spare parts MyLunos Duo (O-Rings at powderjet handpiece)	1	3 months
2044100051	6,5x2 O-ring (on Water tank connector)	3	1 year
2044100051	49,2x3,53 O-ring (Powder cap)	2	1 year
2044100031	Water filter	1	1 year
2044100033	Supra Powder container	1	18 months
2044100034	Perio Powder container	1	18 months
2044100054	Peristaltic pump	1	2 years
2044100119	Scaler light conductor	1	2 years
2044100120	Blue silicone ring	1	2 years

10.5 Remove Residual Powder from the Nozzles

1

> Place the rinse adapter (blue) on the nozzle and rinse with a 20 ml disposable pipette using water.



2

> Remove all the residual moisture by blowing the powder-air line dry for 10 seconds before using the nozzle.

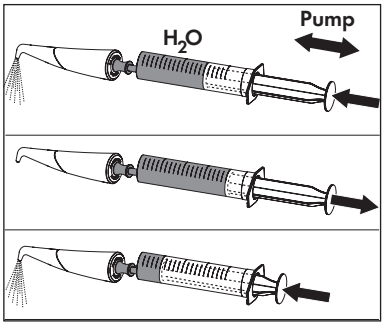
10.6 Free Nozzles from Blockages

1

> In the event of nozzle blockage, vent the entire system before pulling off the nozzle.

2

> Place the rinsing adapter (blue) on the nozzle and pump in water with a 20 ml disposable pipette until the blockage has been rectified.



3

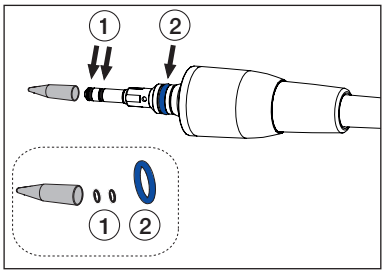
> Remove all the residual moisture by blowing the powder-air line dry for 10 seconds before using the polisher.

10.7 Change and Replacement of the O-rings of the Lunos® Powder Hose

Replace every 3 months.

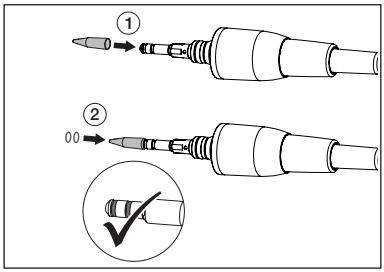
1

> Check the O-rings for damage before every treatment. Replace if necessary.



2

> Use the two small O-rings as assistance in tightening.



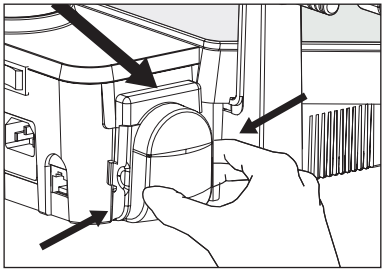
10.8 Replacement of the Peristaltic Pump

The peristaltic pump is consumed during operation of the device and should be replaced every 2 years (if not previously needed).

CAUTION
Before performing any kind of service on the peristaltic pump, make sure that the device is disconnected from the power outlet and that the liquid container is not connected.

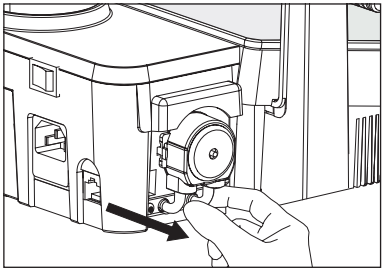
1

> There is a plastic protection on the left side of the device, which covers the peristaltic pump housing. Remove this protection by pressing on the sides and pulling towards yourself;



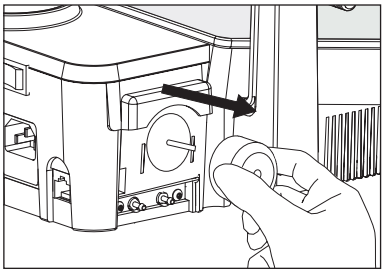
> Disconnect the two silicon tubes of the peristaltic pump from their respective couplings, which are positioned beneath the pump;

2



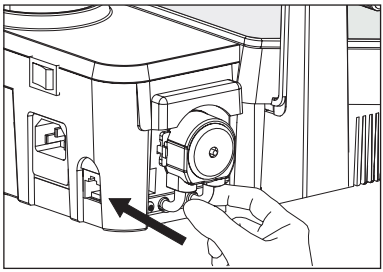
> Extract the peristaltic pump from its base, pulling it towards yourself. Pay close attention, as pieces may detach;

3



> Connect the new peristaltic pump (REF 2044100054) to its seat until a “click” sound is heard and then connect the two pump tubings to their respective couplings positioned beneath the pump;

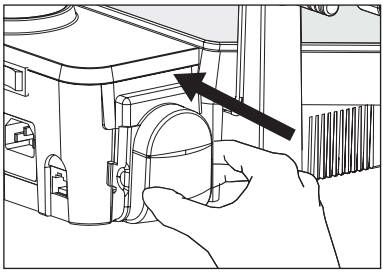
4



WARNING
Only use authentic spare parts.

> Re-position the plastic cover on the peristaltic pump.

5

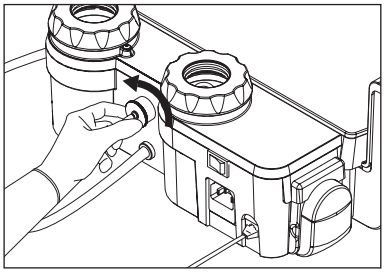


10.9 Cleaning and/or Replacing the Water Filter

Check and clean the water filter monthly, performing the following operations:

1

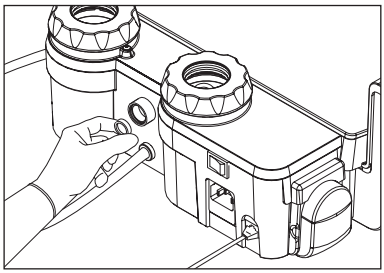
> Disconnect the water supply pipe from the male coupling.
> Unscrew the knurled bush of the male coupling;



CAUTION
Before cleaning and/or replacing the water filter, make sure that the device is disconnected from the main electricity and that the liquid container is not connected.

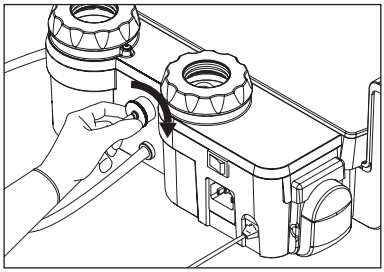
2

> Extract the filter and wash it under running water to eliminate the impurities that obstruct it.



3

> Re-introduce the filter into its seat and screw the knurled bush back into its housing tightly until it is fully in position.



Replace the filter with a new one (REF 2044100031) if it is damaged, washing is not effective and, in any case, at least once a year.

10.10 Replacing the Tank O-rings

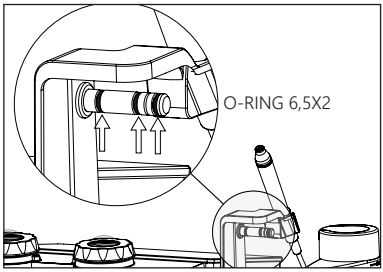
Spare tank O-rings are available in the O-ring kit MyLUNOS Duo (REF 2044100051).

CAUTION
Periodically check the O-ring state of wear and when necessary proceed to the replacement. It is suggested to replace the tank O-rings once a year.

CAUTION
In case of no or difficult delivery of water from the tank and if the other procedures described in the Chapter 10 on page 80 have not been successful, replace the O-rings even if they are not visually worn or damaged.

If all 3 O-rings need to be replaced, remove and insert one O-ring at a time starting with the innermost one.

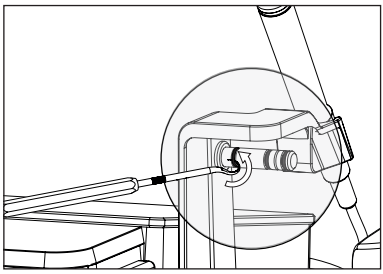
1

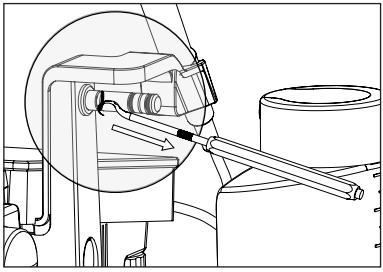


2

> Remove the worn O-ring being careful not to damage and/or scratch the surface where it is located.

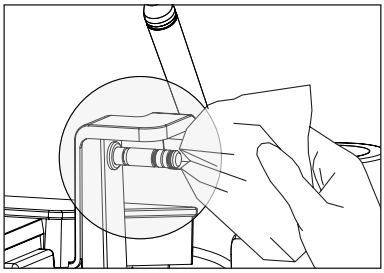
The procedure requires the use of a tool to extract and insert the O-rings. This tool is not included in the standard supply.

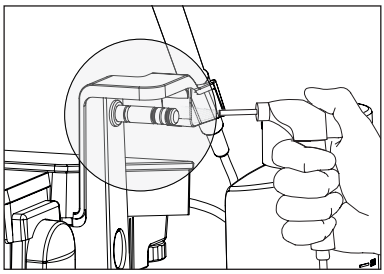




> Clean and eventually dry accurately the o-ring seat, by blowing compressed air;

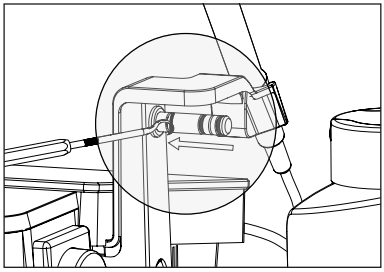
3





> Place the new o-ring in its seat being careful not to damage it by drilling it with the removal tool and dilating it as little as possible during insertion.

4



CAUTION
Do not use sharp tools/utensils to position the new o-ring in its location.

10.11 Powder Containers Cap O-Ring Maintenance

Spare powder containers cap O-rings are available in the O-ring kit MyLUNOS Duo (REF 2044100051).

CAUTION
Periodically check the o-ring state of wear and when necessary proceed to the replacement. A worn or damaged o-ring could cause powder leakage and a loss of pressure. Independently from its status, replace the powder containers cap O-rings at least once a year.

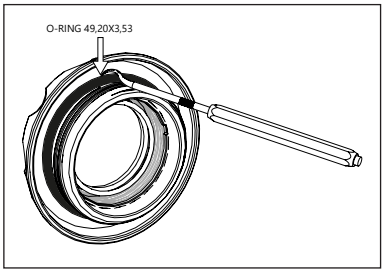
CAUTION
Periodically clean the powder containers cap O-rings under running water. Dry then carefully before re-inserting them in their seats (refer to Replacing the Powder Cap O-Ring procedure for extraction and insertion).

Replacing the Powder Cap O-Ring

1

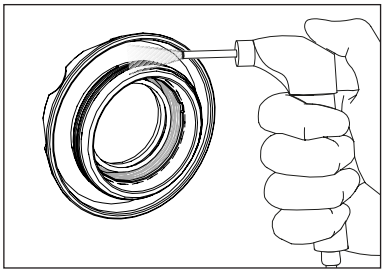
> Remove the worn o-ring being careful not to damage and/or scratch the surface where it is located.

The procedure requires the use of a tool to extract and insert the O-rings. This tool is not included in the standard supply.



2

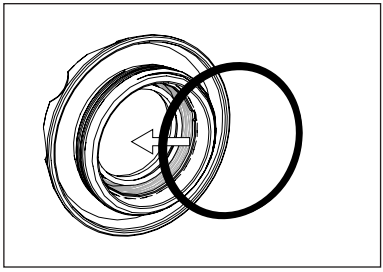
> Clean accurately the o-ring seat from powder residues, by blowing compressed air;



3

> Place the new o-ring in its seat dilating it as little as possible during insertion.

CAUTION
Do not use sharp tools/utensils to position the new o-ring in its location.



10.12 Eliminating Condensation

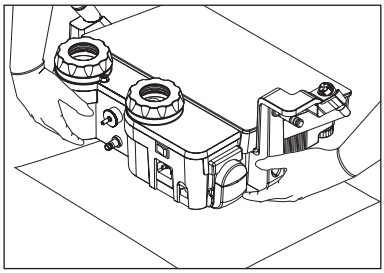
The device has an air filter, which intercepts any impurities and the condensate present in the pneumatic circuit.

To prevent the condensation from entering into circulation in the device, check and empty the air filter monthly by performing the following operations:

1

> Position an absorbent cloth underneath the device to collect the condensate;

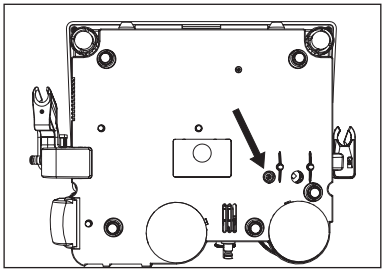
CAUTION
This maintenance operation must be performed with the appliance on in order for the air circuit to be pressurised.



2

> With the device on and in an exact horizontal position, press the air filter vent valve positioned on the bottom of the device, just until air escapes.

However, it is recommended to use dry compressors and introduce a dehumidifier into the practice's pneumatic circuit.



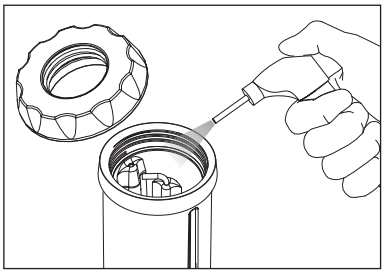
10.13 Cleaning Powder Containers and Caps

Check cleanliness of the powder container and, in particular, the cap as powder residues in the presence of moisture could solidify and make opening and closing operations difficult.

CAUTION
Always switch the device off using the I/O switch and disconnect it from the mains electricity before cleaning the powder containers and the caps.

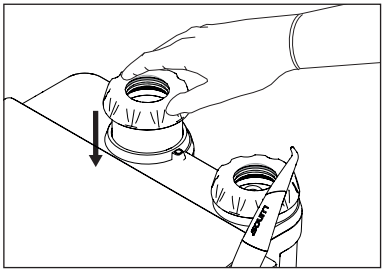
WARNING
Before blowing compressed air into the powder containers, make sure that they have been emptied.

1



> Blow compressed air inside the container and on the threading of both the powder containers and the caps.

2



> When the cleaning operation has been completed, re-position the containers on the device.

CAUTION
Insert the powder containers in a way that the grooves on the bottom of the device are in line with the convexity of the powder containers.

11 Disposal Modes and Precautions

WARNING
Hospital wastes.
Treat the following items as hospital waste:

- Instruments: when they are worn out or broken;
- Torque wrench for instruments: when worn out or broken.
- Lunos® Nozzles, when worn or broken;
- Lunos® Perio Tips, at the end of each treatment.

The use and disposal of materials, and materials that entail a biological risk, must be disposed of in accordance to the local regulations in force concerning hospital wastes. The device must be disposed of and treated as a waste for separate collection.

Disregarding the previous points may entail a fine, pursuant to the Waste of Electric and Electronic Equipment (WAEE) Directive.

It is up to the purchaser to hand over the device for its disposal to the retailer who supplies them with new equipment; the instructions for proper disposal are available from Dürr Dental SE.

12 Technical Data

Device compliant to Regulation (EU) 2017/745:	Class IIa
Classification as per EN 60601-1:	I Applied part type B (instrument) IP 20 (device) IP 22 (footpedal MyLunos Duo model)
Essential performance:	According to the standard IEC 80601-2-60 the device has no essential performance.
Device for intermittent operation:	55sec. ON - 30sec. OFF with irrigation (ULTRASOUND function and POLISHING function).
Power supply voltage:	100-240 V ~ 50/60 Hz
Max. power absorbed:	90 VA
Fuses:	Type 5 x 20 mm T 2AL, 250V
Water supply:	Working pressure from 1 to 6 bar. Cleaning function of the polishing part and scaler water circuit - See Chapter 6 on page 37. Connection via the pipe supplied with quick coupling through a built-in and removable filter.
Air supply:	Inlet pressure between 4 and 8 bar. Air circuit cleaning function - See Chapter 10.11 on page 87 Connection via pipe supplied with quick coupling through a filter and built-in pressure reducer.
Operating conditions:	from +10 °C to +35 °C Relative humidity from 30 % to 75 % Pressure of air P: 800 hPa/1060 hPa
Transport and storage conditions: (Powders not included)	from -10 °C to +60 °C Relative humidity from 10 % to 90 % Pressure of air P: 500 hPa/1060 hPa
Altitude:	less than or equal to 2000 meters
Weights and sizes:	4.8 kg L - W - H 410 x 260 x 145 mm

ULTRASOUND Part	
Operating frequency:	Automatic scan From 24 KHz to 36 KHz
Amplitude of Scaler handpiece	10-250 µm
Power types (mode):	“scaler" "perio scaler”
Power Levels:	from 1 to 3 for perio scaler; from 1 to 5 for scaler.
Irrigation:	Fresh water circuit: - Adjustable continuously Tank Water circuit: - Adjustable on the touch screen 5 flow levels: - from 1 (approx. 5 ml/min) to 5 (approx. 30 ml/min).
LED system of the handpiece:	Automatic ON/OFF function: LED system of the handpiece switches ON as soon as the device starts to operate and switches OFF 3 seconds after the foot pedal is released. White LED light power risk free according to IEC/EN 62471.
Protections of the APC circuit:	No handpiece detected. Hose interruption. Instrument not tightened correctly or broken.
POLISHING Part	
Allowed powder types:	Trehalose
Polisher Function:	Can be selected via touch screen: “Supra” function - “Perio” function
Irrigation:	Continuous regulation via knob. Water heated via heating element (outflow water temperature from 18 °C to 37 °C depending on the water flow rate and temperature).

12.1 Electromagnetic Compatibility EN 60601-1-2

WARNING
Interference with other equipment.
Though compliant with the standard IEC 60601-1-2, the device may nonetheless interfere with other devices nearby.
The device must not be used near or stacked on other devices. However, if this is necessary, you must check and monitor the correct operation of the device in that configuration.

WARNING
Portable and mobile radio communication devices may affect the correct functioning of the device.

WARNING
Interference from other equipment.
An electrical scalpel or other electro-surgical units near the device may interfere with its correct operation.

WARNING
The device requires specific EMC precautions and must be installed and activated in accordance with the EMC information given in this paragraph.

WARNING
The use of cables and accessories not supplied by the manufacturer might negatively affect the EMC performance.

EN

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The device is designed to operate in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and probably do not cause any interference with nearby electronic devices.
RF Emissions CISPR 11	Class B	The device is suitable for use in professional healthcare environment (professional healthcare) including hospitals, medical dispensaries, surgical centres and structures for specific care, where the equipment and the systems are operated by qualified and specialized personnel.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions of fluctuations voltage/flicker IEC 61000-3-3	Compliant	

Accessible Parts of the Casing

The device is designed to operate in the electromagnetic environment specified below.
The customer or the user of the device should ensure that it is used in such environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30 %.
Radiated RF EM fields [a]	IEC 61000-4-3	3 V/m [e] 80 MHz - 2,7 GHz [b] 80 % AM a 1 kHz [c]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Chapter Specifications of the tests for the Immunity of the Accessible Parts of the Casing to the Wireless RF Communications Device on page 99	
RATED power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz o 60 Hz	The magnetic fields at the mains frequency should have levels characteristic of a typical location in a commercial or hospital environment.
Proximity magnetic fields	IEC 61000-4-39	See Chapter Immunity to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz on page 100	Portable and mobile RF communication devices shall be used with a separation distance of at least 0,15 m from the field sources.

a) The interface between the PATIENT physiological signal simulation, if used, and the device shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the device.

b) The device that intentionally receives RF electromagnetic energy for the purpose of its operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Applies only to devices with magnetically sensitive components or circuitry.

e) Before modulation is applied.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Power Connection A.C. Input

The device is designed to operate in the electromagnetic environment specified below.
The customer or the user of the device should ensure that it is used in such environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrical fast transients / bursts [l) o)]	IEC 61000-4-4	±2 kV on contact 100 KHz repetition frequency	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges [b) j) o)] Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges [b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0.15 MHz - 80 MHz 6 V [m)] in the ISM bands between 0.15 MHz and 80 MHz [n)] 80 % AM at 1 KHz [e)]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.
Voltage dips [f) p) r)]	IEC 61000-4-11	0% UT; 0,5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)]	The quality of the network voltage should be that of a typical commercial or hospital environment.
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles [h)] Single phase: at 0°	
Voltage inter-ruptions [f) i) o)]	IEC 61000-4-11	0% UT; 250/300 cycle [h)]	The quality of the network voltage should be that of a typical commercial or hospital environment.

a) Void.

b) All device cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEMS. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

g) Applicable only to the device connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). The device with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that does not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).

k) Not applicable to CLASS II device.

l) Direct coupling shall be used.

m) r.m.s. , before modulation is applied.

n) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.

q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT shall provide BASIC SAFETY during and after the test.

r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the power input voltage specified in Table 1 - "Power input voltages and frequencies during the tests" of the IEC 60601-1-2:2014/AMD1:2020.

EN

Points of Contact with the Patient

The device is designed to operate in the electromagnetic environment specified below.

The customer or the user of the device should ensure that it is used in such environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) [c]	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30 %.
Conducted disturbances induced by RF fields [a]	IEC 61000-4-6	3 V [b] 0.15 MHz - 80 MHz 6 V [b] in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 KHz	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

a) The following apply:

- All PATIENT-COUPLED cables shall be tested, either individually or bundled
- PATIENT-COUPLED cables shall be tested using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b) R.M.S., before modulation is applied.

c) Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

Parts Accessible to the Input / Output Signals

The device is designed to operate in the electromagnetic environment specified below.

The customer or the user of the device should ensure that it is used in such environment.

Phenomenon	Basic EMC standard or test method	Immunity test levels	Electromagnetic Environment Guidance
Electrostatic discharges (ESD) [e]	IEC 61000-4-2	±8 kV on contact ±2 kV, ±4 kV, ±8 kV, ±15 kV in air	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least equal to 30 %.
Electrical fast transients / bursts [b] [f]	IEC 61000-4-4	±1 kV on contact 100 KHz repetition frequency	The quality of the network voltage should be that of a typical commercial or hospital environment.
Surges Line-to-ground [a]	IEC 61000-4-5	± 2kV	The quality of the network voltage should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields [d] [g] [j] [k]	IEC 61000-4-6	3 V [h] 0.15 MHz - 80 MHz 6 V [h] in the ISM bands between 0.15 MHz and 80 MHz [i] 80 % AM a 1 KHz [c]	Portable and mobile RF communication devices should not be used near any part of the product, including cables, except when they respect the recommended distances, calculated from the equation applicable at the frequency of the transmitter.

a) This test applies only to output lines intended to connect directly to outdoor cables.

b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.

c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

d) Calibration for current injection clamps shall be performed in a 150 Ω system.

e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.

f) Capacitive coupling shall be used.

g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

h) R.M.S., before modulation is applied.

i) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

j) See IEC 61000-4-6:2013, Annex B, for modified start frequency versus cable length and equipment size.

k) SIP/SOPS whose maximum cable length is less than 1 m are excluded.

Specifications of the tests for the Immunity of the Accessible Parts of the Casing to the Wireless RF Communications Device

The device is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The customer or the user of the device can help prevent electromagnetic interference by ensuring a minimum distance between the mobile and portable RF (transmitters) communication devices and the device, as recommended, in relation to the maximum output power of radiocommunications equipment.

Test Freq. (MHz)	Band [a] (MHz)	Service [a]	Modulation	Max power (W)	Distance (m)	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460 FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 to 787	LTE band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 Band LTE 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulateci using a 50 % duty cycle square wave signal at 18 Hz. While it does noi represent actual modulation, it would be worst case.

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the device may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

EN

WARNING
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 specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Immunity to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

The following table reports the test specifications tor ENCLOSURE PORT IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz.

Test Frequency	Modulation	Immunity test level (A/m)
30kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

a) This test is applicable only to devices intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

13 Troubleshooting

13.1 Diagnostic System and Symbols on Keyboard

The device is equipped with a diagnostic circuit that allows for the detection of operating abnormalities and to view their type on the touch surface via their relative symbol.

By using the following chart, the user is guided toward the identification and possible solution of the malfunction detected.

Problem	Possible Cause	Solution
	Handpiece electric contacts/lead wet.	Thoroughly dry the contacts with compressed air (See Chapter 9.9 on page 75).
	Scaler handpiece not connected to device.	Connect the scaler handpiece (See Chapter 4.3 on page 16).
	Scaler handpiece failure.	Replace the scaler handpiece.
	Sync circuit malfunction.	Contact an Authorized Dürr Dental Service Center.
	Instrument not tightened correctly on handpiece.	Unscrew the instrument and correctly screw it on again with the torque wrench (See Chapter 5.4 on page 28).
	Instrument broken, worn-out or deformed.	Replace the instrument.
	Handpiece/hose contacts wet.	Thoroughly dry the contacts with compressed air (Chapter 9.9 on page 75).
	Turn-on procedure incorrect: the device has been turned on with the foot pedal depressed.	Check that the foot pedal is not depressed. If the problem persists, disconnect the foot pedal and, if need be, contact an Authorized Dürr Dental Service Center.
	Peristaltic pump malfunction.	Check that there are no impediments to pump rotation. Check that the peristaltic pump and the pipes are installed correctly. (See Chapter 10.7 on page 83).
	The device has been turned off and on again without waiting 5 seconds.	Turn device off and wait 5 seconds before turning it on again.
	Abnormalities on electrical network or excessive electrostatic discharges or internal abnormalities.	Turn device off and wait 5 seconds before turning it on again If the signal persists, contact an Authorized Dürr Dental Service Center.
	A powder container has been opened without performing the “refill” cycle.	Before opening one of the powder containers, the “refill” cycle must be performed (See Chapter 5.7 on page 36).
	One of the powder containers has been removed from its seat without performing the “refill” cycle.	Before removing one of the powder containers, the “refill” cycle must be performed (See Chapter 5.7 on page 36).
	The selected powder container is not correctly inserted in place.	Correctly insert the powder containers to the furthest point possible.

13.2 Quick Solution to Problems

Problem	Possible Cause	Solution
The device does not turn on after having brought the switch into position “I”	The electrical power cable terminal is poorly inserted in the rear plug of the device.	Check that the power supply cable is firmly connected.
	The electrical power cable is defective.	Check that the power supply socket works properly. Replace the electrical power cable.
	The fuses are out of order.	Replace the fuses (See Chapter 13.4 on page 106).
The device is on but not working. There are no anomalies signalled on the touch surface.	The foot pedal plug is incorrectly inserted in the device socket.	Correctly insert the foot pedal plug in the socket on the back of the device (See Chapter 4.3 on page 16).
	The foot pedal does not work.	Contact an Authorized Dürr Dental Service Center.
The device is on but not working. One of the following symbols appears on the screen: 	See Chapter 13.1 on page 101 for the possible cause, according to the symbol that has been displayed.	See Chapter 13.1 on page 101 for the action to be undertaken, according to the symbol that has been displayed.
A slight whistling sound coming from the scaler handpiece is heard during operation	The instrument is not correctly tightened on the handpiece.	Unscrew and correctly screw the instrument on again with the torque wrench (See Chapter 5.4 on page 28).
	The irrigation circuit has not been completely filled.	Fill the irrigation circuit via the function “Flush” (See Chapter 5.4 on page 28).
The pump turns correctly but when it stops, liquid escapes from the handpiece	The peristaltic pump is worn.	Replace the peristaltic pump (See Chapter 10.7 on page 83).
By pressing the foot pedal, a prolonged signal is emitted and the ULTRASOUND and POLISHING function LEDs flash	The foot pedal has been depressed with both handpieces in their respective housings.	Lift the handpiece to be used before depressing the foot pedal.
Insufficient performance	The instrument is not correctly tightened on the handpiece.	Unscrew and correctly screw the instrument on again with the torque wrench (See Chapter 5.4 on page 28).
	Instrument broken, worn-out or deformed.	Replace the instrument with a new one.
	Insufficient or excessive powder level in the container.	Correct level of powder in the container (See Chapter 5.4 on page 28).

Problem	Possible Cause	Solution
No liquid outflows from the instrument during operation	Device not connected to the water circuit.	Check the connection to the water circuit (See Chapter 4.3 on page 16).
	The instrument is obstructed.	Unscrew the instrument from the handpiece and free the instrument water passage by blowing compressed through it. If the problem persists, replace the instrument with a new one.
	The handpiece is obstructed.	Contact an Authorized Dürr Dental Service Center.
	The water blue knob on the device is closed.	Regulate the flow of water using the knob dedicated to the function used.
	Water filter clogged.	See Chapter 10.8 on page 83.
	The Water Tank is empty.	Fill the Water Tank.
	The Water Tank is not installed correctly.	Connect the Water Tank to the device body correctly.
	The silicon tubings of the pump are incorrectly installed.	Check the connection of the silicon tubing of the pump (See Chapter 10.7 on page 83).
	The peristaltic pump is over-used.	Replace the peristaltic pump with a new one (See Chapter 10.7 on page 83).
Water issued from between the Lunos® Nozzle and the Lunos® powder hose	O-ring between the Lunos® Nozzle and the Lunos® powder hose is defective.	Check the O-ring 2 and change if necessary (see Chapter 10.6 on page 82).
During operation powder does not escape from the polisher nozzle	Device not connected to the air circuit.	Check the connection to the air circuit (See Chapter 4.3 on page 16).
	Lunos® Nozzle clogged due an excessive amount of moisture in the powder or insufficient cleaning/maintenance.	See Chapter 10 on page 80.
	Polisher handpiece channel clogged due to an excessive amount of moisture in the powder or insufficient cleaning.	See Chapter 9 on page 60.
	The level of powder in the container exceeds the maximum allowed.	Remove the powder from the container and clean it using a dry cloth. Check the correct level of powder in the container. (See Chapter 4 on page 15).
	Unsuitable powder.	Use the correct powder for correct device operation.

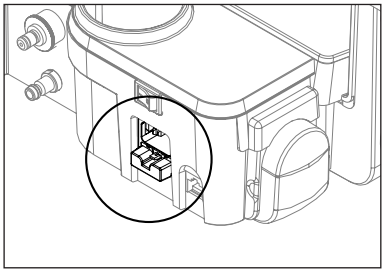
Problem	Possible Cause	Solution
Loss of powder through the powder container cap	Cap not correctly tightened.	Screw the cap correctly.
	Powder residues in the threading.	Clean the threading of the powder container (See Chapter 10.12 on page 89).
Insufficient cleanliness	Insufficient pressure in the air supply circuit.	Check air supply circuit pressure (4-8 bar max).
	Insufficient or excessive powder level in the container.	Correct level of powder in the container.
	Unsuitable powder.	Check the correct powder for correct device operation.
	Lunos® Nozzle clogged due an excessive amount of moisture in the powder or insufficient cleaning/maintenance.	Remove the powder from the container and clean it using a dry cloth. Remove the blockage from the nozzle (see Chapter 10 on page 80)
One of the powder container caps does not unscrew	The device is on and the powder container is pressurised.	Perform the “refill” cycle before opening one of the powder containers (See Chapter 5.7 on page 36).
	The “refill” cycle has been performed but the powder containers have remained pressurised because the Lunos® Nozzle is clogged.	Proceed as described in Chapter 10.5 on page 82.
		Contact an Authorized Dürr Dental Service Center.

13.3 Replacement of the Fuses

WARNING
Switch the device off.
Always turn the device off with the main switch and disconnect it from the electrical power socket before performing the following procedure.

1

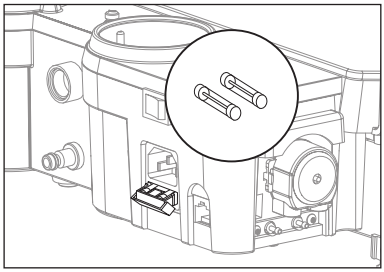
> Use a flat tool, if necessary, to open the fuse-holder drawer located under the power supply socket;



2

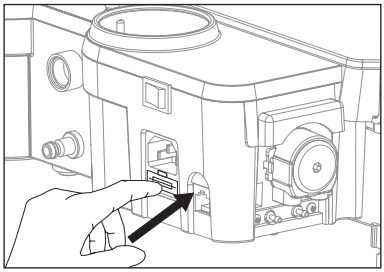
> Pull out the fuse-holder drawer;

WARNING
Replace the fuses, complying with the characteristics indicated in Chapter 12 on page 92.



3

> Reinsert the drawer in its housing.



EN

13.4 Sending the Device to an Authorised Dürr Dental Service Center

In the event that technical assistance is needed on the device, contact one of the Authorized Dürr Dental Service Centers or your Retailer. Do not attempt to repair or modify the device and its accessories.

Clean and sterilize all the parts that need to be sent to an Authorized Dürr Dental Service Center, following the instructions provided in the Chapter 9 on page 60.

Return all parts in sterilization pouches to provide evidence that the sterilization process has been performed.

The cleaning and sterilization requirements are in line with those in force concerning the safeguarding of health and safety in the workplace.

In the event that customer does not fulfill the requirements, Dürr Dental reserves the right to charge him or her for the cleaning and sterilization expenses, or to reject the goods received in unsuitable conditions, returning them to the customer, at the customer's expense, for them to be correctly cleaned and sterilized.

The device must be returned properly packaged, accompanied by all the accessories, and by a document bearing the:

- Owner information including complete address and telephone number
- Product name
- Serial number and/or lot number
- Reason for goods returned / description of the malfunction
- Photocopy of packing list or purchase invoice of the device

CAUTION
Package.
Pack the device in its original packaging to prevent damages during transport.

Before shipping the device remember to perform all the steps outlined in Chapter 10.3.

Pack the device in its original packaging to prevent damages during transport.

Once the material has been received by the Authorized Dürr Dental Service Center, qualified technical personnel will provide an evaluation based on the given circumstances. The repair work will be performed only upon the prior acceptance by the customer. For further details, contact the closest Authorized Dürr Dental Service Center or your retailer.

Unauthorized repair works may damage the system and make the warranty void, and will absolve Dürr Dental of any responsibility for direct or indirect harm to persons or damages to anything else.

14 Warranty

Before being marketed, MyLunos Duo is subjected to a thorough final check that verifies the full functionality.

The manufacturer warrants its products, purchased new from a MECTRON dealer or importer, against defects in material and workmanship for

– 2 YEARS (TWO) for the device, starting from the purchasing date;
– 1 YEAR (ONE) for the handpiece, starting from the purchasing date.

The other accessories are not included in the warranty.

During the period of validity of the warranty, the manufacturer undertakes to repair (or, at his free choice, replace) free of charge those parts of products that in their opinion prove being defective.

The manufacturer disclaims any responsibility for direct or indirect damage to people or things, and the manufacturer's warranty and device approval is not valid in the following cases:

– The device is not used according to the intended use for which it is provided.
– The device is not used in accordance with all the instructions and requirements described in this manual.
– The electrical system of the places where the equipment is used do not comply with the laws in force and the related regulations.
– Assembly operations, extensions, re-adjustments, modifications, replacements and repairs are carried out by personnel not authorized by the manufacturer or in breach of what is provided in this manual also in regard to the origin of the authorised material.
– The environmental conditions for preservation and storage of the device are not complying with the requirements indicated in Chapter Technical Data.
– Non-original instruments, accessories or spare parts have been used that may affect the correct working of the device, and cause injury to the patient.
– Accidental breakage is caused during transport.
– Damage caused by incorrect use or negligence, or to connection to a power voltage other than the one foreseen.
– The cleaning and sterilisation procedures have not been properly performed.
– The warranty has expired.

The expected service life of the device is 5 years, minimum.

The service life/duration does not define a limit of use; the service life of the device defines the period of time, subsequent to installation and/or commissioning, during which the original performances or, in any case, adequate for the intended use are guaranteed, without any degradation occurring such as to compromise its functionality and reliability.

The service life is a minimum qualitative target of the design, therefore, it is not excluded that single parts or components guarantee performances and reliability higher than those declared by the manufacturer.

The service life is intended in compliance with the maintenance plans provided for in this manual, it does not include components normally subjected to "wear" and it is independent of the warranty period: the service life period does not establish any implicit or explicit extension of the warranty period.

14.1 Warranty Conditions

The warranty starts from the date of purchase of the device, which evidence is given by the delivery note/purchase invoice issued by the Dealer / Importer or, in case of device with activation code, from the date of activation of the same.

In order to avail of the warranty service, the customer must return, at its own expense, the device to be repaired to the Dealer / Importer from which they purchased the product.

The device must be returned together with the original packaging, accompanied by all the accessories and by a form containing:

– The data of the owner and telephone number;
– The data of the Dealer / Importer;
– Photocopy of the delivery note/purchase invoice of the device by the owner where are reported the date, the name of the device and the serial number;
– Description of the failure.

The transport and the damage caused by transport are not covered by the warranty.

The indications that appear in this publication are not binding and can be modified without forenotice.

The English version of this manual is the original document from which its translations have been obtained. In case of any discrepancy, the English version will have pertinence.

Mectron S.p.A.
Via Loreto 15/A
16042 Carasco (Ge)
Italy

DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerrdental.com