Endo Easy Efficient®

# Erratum Corrige

## Chapter 8. Maintenance, cleaning, disinfection and sterilization

## VDW.GOLD® RECIPROC®


Erratum for Manual Vol. 1,2,3 Rev.2 17.02.2014

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Dear customer,

Despite the extreme care and commitment we always put in the realization of the documentation that we provide to you, we identified the necessity to review and update Chapter 8 of the operating manual.

The present document contains updated information regarding the maintenance, cleaning, disinfection and sterilization of the VDW.GOLD® RECIPROC® device and is intended to replace the original operating manual's Chapter 8.

This document is not to be considered as a standalone document, but as an integration and an overwrite of VDW.GOLD® RECIPROC® 's operating manual, which is also part of this packaging (Rev.2 17.02.14).

We thank you for your comprehension and apologize for the inconvenient.

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# 8. Maintenance, cleaning, disinfection and sterilization

Maintaining proper hygiene when working with the VDW.GOLD® RECIPROC® is only possible with regular device care. Follow the maintenance, cleaning, disinfection and sterilisation instructions in the following chapters to ensure this.

## 8.1. Maintenance

**NOTE**

*Service and repair work should on/y be done by factory-trained service personnel.*

| Components | Routine Maintenance |
|---|---|
| Cable | Inspect the various cables of charger, micromotor, lip clip, file clip and foot pedal at least once every six months.<br>Contact your service centre if any of the cable coatings show signs of wear and tear. |
| VDW 6:1 contra-angle | • The contra-angle needs to be lubricated after cleaning and disinfection, but before sterilisation. Follow the instructions given in the separate operating instructions of the VDW 6.1 contra- angle, as well as the following notes:<br>• When lubricating the contra-angle, make sure no lubricant penetrates the micromotor.<br>• If the contra-angle is being lubricated manually, use pressurised air to remove excess lubricant (blow for about 5 sec.) before re- applying the contra-angle back onto the micromotor. Calibrate the contra-angle after lubrication.<br>• If the contra-angle is being lubricated automatically using a maintenance or lubrication device, follow the device manufacturer‘s instructions carefully, and make sure no excess lubricant remains in the contra-angle.<br>• Do not lubricate the micromotor under any circumstances. Lubricant can contaminate the micromotor and create a safety hazard. Doing this invalidates the warranty. |
| Central unit | Check whether the central unit is leaking fluids or emitting smoke. If so, unplug the device immediately from the power source and contact your service centre. |
| Battery | For optimal performance, the battery should be replaced at your service centre once every 3 years.<br>Never open the device yourself in order to change the battery, as this can cause a short- circuit. Opening the device voids the warranty. The battery should thus only be replaced by personnel at your service centre. |

Clean the cables and the outer surfaces of the device using a paper towel or soft cotton cloth lightly moistened with an aldehyde-free cleaning and disinfectant (bactericidal and fungicidal) solution, e.g. Mikrozid AF Liquid or Minuten Spray Classic.

- DENTIRO® wipes, Oro Clean Chemie AG, Switzerland
- TopActiv wipes, ad-Arztbedarf GmbH, Germany
- SprayActiv, ad-Arztbedarf GmbH, Germany
- DY wipes, DENTSPLY, France

**⚠ WARNINGS**

- *To disinfect the equipment and the measuring cable, wipe the surface with a clean cloth or wipe that has been wetted only slightly with a non-aggressive disinfectant;*
- *Do not use any liquids or sprays directly on the equipment, particularly the display;*
- *Do not use strong alcohol to disinfect surfaces.*

Remove the lip clip and the file clip from the cables before cleaning. The lip clip and file clip need to be cleaned, disinfected and sterilised before each use. This includes first use. Thorough cleaning and disinfection are crucial for effective sterilisation. Follow the special instructions given in chapter "8.2. Cleaning, Disinfection and Sterilisation (in accordance with DIN EN ISO 17664)". Consult the user manuals of the devices used in your practice as well.

Ensure that only validated cleaning/disinfection and sterilisation methods are used, that the devices (disinfector, steriliser) are maintained and inspected at regular intervals, and that the validated parameters are preserved throughout every cycle.

In addition, ensure that you always comply with the applicable statutory rules and regulations with regard to hygiene in your practice or clinic. In particular, this applies to the guidelines regarding effective prion inactivation.

For your own safety, when handling contaminated accessory parts, always wear gloves, protective eyewear and a surgical mask.

**⚠ WARNINGS**

- *The measuring cables cannot be autoclaved;*
- *Using substances other than those described above can cause damage to the device and the accessory parts;*
- *Do not use hot-air or radiation sterilisation, and do not sterilise using formaldehyde, ethylene oxide or plasma;*
- *The plastic casing is not sealed. Do not use any liquids or sprays directly on the console, especially on the display or near the electrical sockets.*

## 8.2. Cleaning, Disinfection and Sterilisation (in accordance with DIN EN ISO 17664)

The cleaning, disinfection and sterilization process applies only to the lip clip and file clip. As long as they are treated with due care and are not damaged or contaminated, these accessories can be reused multiple times.

We accept no liability in the event that these instructions are disregarded or processes that have not been validated are used to prepare the accessories for reuse.

Make sure undamaged sterile packaging is used.

## 8.2.1. Pre-Treatment

• Pulp and dentine residues must be removed from the accessory parts immediately; if necessary, use a brush to carefully clean the products (no later than 2 hours after use). Do not allow remnants to dry on. After using the accessories on the patient, place them directly into a dish filled with a suitable cleaning and disinfection solution (e.g. CIDEZYME®, ENZOL® Enzymatic Detergent Solutions, Johnson & Johnson Medical, 0.8% for between 1 minute and 2 hours) for cleaning, pre-disinfection and interim storage. Make sure that the products are fully immersed.

Then wash the accessories under running sterile, deionized water or in a disinfection solution at least three times for one minute each time, in order to remove all visible traces of contamination and remnants. The disinfectant should be aldehyde-free (aldehyde causes blood to stain permanently), tested for efficacy (e.g. VAH/DGHM or FDA certification or CE mark), suitable for disinfecting the accessories, and compatible with the accessories (see section "8.2.7. Material Durability");

• Only use clean, soft brushes to manually remove contamination and remnants, or a clean, soft cloth or wipe that is only used for this purpose. Do not use metal brushes or wire wool. Check that no visible contamination or remnants remain, and repeat the pre-cleaning process if necessary;

• The file clip must be squeezed together and then released five times during cleaning to allow the inner parts to be cleaned more effectively. Please note that disinfectant used for pre-treatment is only for personal protection and dœs not obviate the need for disinfection once cleaning has been completed. Pre-treatment should never be omitted.

> ⚠ **WARNING**
>
> *Do not use any automatic processes or ultrasonic baths to clean or disinfect the accessories.*

## 8.2.2. Manual Cleaning and Disinfection

When selecting cleaning and disinfectant solutions, make sure that:

• They are intended for use in cleaning or disinfecting instruments;

• The disinfectant's effectiveness has been tested (e.g. VAH/DGHM- or FDA-approved or CE-certified) and that it is compatible with the cleaning solution;

• The chemicals used are compatible with the accessory parts (see chapter "8.2.7. Material Durability").

Combined cleaning/disinfectant solutions should only be used if the instruments are only slightly contaminated (no visible contamination/ remnants). Follow the instructions provided by the manufacturers of the cleaning and disinfectant solutions regarding concentration, application time and rinsing.

Only use freshly-prepared solutions made with water which is either sterile or contains only low levels of bacteria (< 10 cfu/ml) and endotoxins (< 0.25 EU/ml, e.g. purified water (PW/HPW)), as well as filtered, oil-free air for drying.

Make sure that the accessories are not in direct contact with one another.

### Step-by-Step Procedure

### Cleaning

• Place the pre-cleaned accessory parts in the cleaning bath for the stipulated application time (e.g. CIDEZYME®, ENZOL® Enzymatic Detergent Solutions, Johnson & Johnson Medical, 0.8% for 1 minute); ensure that they are covered sufficiently (if necessary, use a soft brush to carefully brush them off). When cleaning the file clip, press it closed and release it five times in order to clean the inner parts more effectively;

• Then take the instruments out of the cleaning bath and rinse them thoroughly with water at least three times for one minute each time with sterile, deionized water; press and release the file clip five times when rinsing. Next, place the accessories in an ultrasonic bath with a cleaning agent (e.g. CIDEZYME®, ENZOL® Enzymatic Detergent Solutions, Johnson & Johnson Medical, 0.8% for 20 minutes); make sure that the products are fully immersed (if necessary, use a soft brush to carefully brush them down). The file clip must be squeezed together and then released five times during cleaning to allow the inner parts to be cleaned more effectively;

• Then, remove the accessories from the ultrasonic bath and rinse them off thoroughly at least three times for one minute each time with sterile, deionized water; when you rinse it, squeeze the file clip together and then release it five times.

Disinfection

• Once the accessories have been cleaned and inspected, place them into the disinfection bath for the prescribed contact time (e.g. Cidex OPA, Johnson & Johnson Medical, 100% for 20 minutes); the accessories must be sufficiently immersed in the solution. The file clip must be squeezed together and then released five times during disinfection to allow the inner parts to be disinfected more effectively;

• Then take the instruments out of the disinfection bath and rinse them thoroughly with water at least five times for one minute each; open and close the file clip five times when rinsing;

• Dry the accessories by blowing them down fully with oil-free, filtered compressed air and then leaving them to dry further in a clean place for at least 20 minutes. Once the accessories are dry, inspect and pack them as soon as possible (see the section entitled "Inspection/maintenance" and "Packaging").

## 8.2.3. Inspection/Maintenance

Check all accessory parts after cleaning or cleaning/ disinfection. Dispose of defective accessory parts immediately. Defects may include:

• Deformation of the plastic;

• Corrosion;

• Discoloration of the plastic.

Accessory parts which are still contaminated must be cleaned and disinfected again. Maintenance is not required. Do not use instrument lubricant.

## 8.2.4. Packing

Pack the accessory parts in disposable sterilisation packaging (individual single-use packaging) which meets the following requirements:

• In compliance with DIN EN ISO/ANSI AAMI ISO 11607;

• Suitable for steam sterilisation (temperature-safe to 142 °C (288 °F), sufficiently steam-permeable).

## 8.2.5. Sterilisation

The sterilisation procedure only applies to the lip clip and the file clip.

**⚠ WARNING**

*Never put the micromotor or other accessory parts in an autoclave or an ultrasonic bath. Do not sterilise any VDW.GOLD® RECIPROC® components (with the exception of the lip clip, the file clip (not including cables) and the VDW 6:1 contra-angle. See also the separate operating instructions on sterilising the VDW 6:1 contra-angle.*

Only use the sterilisation methods given below; other sterilisation procedures are not permissible.

• Steam sterilisation;

• Fractional vacuum/pre-vacuum procedures (at least three vacuum cycles) or gravity method with sufficient product drying (product must be sufficiently dry). The drying time that is actually required depends directly on parameters that are the sole responsibility of the user (loading configuration, how many items are loaded and how closely together they are loaded, condition of the sterilizer, etc.) and must therefore be established by the user. However, the drying time must never be less than 20 minutes;

• The gravity method is less effective and must only be used if it is not possible to use the fractionated vacuum method;

• Steam sterilisers in compliance with DIN EN 13060 or DIN EN 285, ANSI/AAMI ST 79;

• Sterilisation validation must be done in accordance with DIN EN ISO 17665 (valid installation and operation qualifications (IQ and OQ) as well as product specific performance qualifications (PQ));

• Maximum sterilisation temperature 135 °C ( 275 °F); plus tolerance as specified in ISO DIN EN ISO 17665;

• Sterilisation time (application time at sterilisation temperature) at least 3 minutes at 134 °C (273 °F).

**WARNINGS**

*• Rapid-sterilisation processes and sterilisation processes with unpackaged accessory parts are not permitted;*

*• Do not use hot-air sterilisation, radiation sterilisation or sterilisation involving formaldehyde, ethylene oxide or plasma;*

*• Regional requirements have to be followed additionally.*

## 8.2.6. Storage

After sterilisation, the instruments must be stored dry and dust-free in the sterilisation packaging.

## 8.2.7. Material Durability

When selecting cleaning and disinfection products, make sure that they do not contain any of the following substances:

• Phenol;

• Strong acids (pH < 6) or strong alkalis (pH > 8);

• Aldehydes;

• Anti-corrosive substances (especially di- or triethanolamine);

• Oxidants (hydrogen peroxide, sodium hypochlorite over 5% strength);

• Solvents;

• The material is temperature-resistant up to 137 °C / 279 °F (maximum application temperature).

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