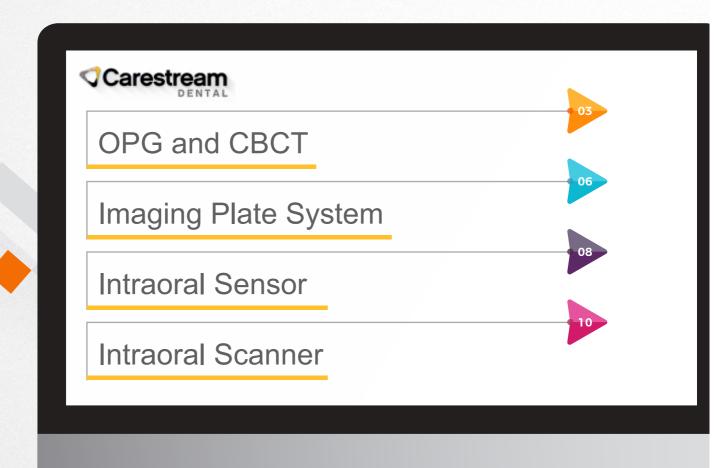


JUNE 2020



Hygiene and Disinfection

INDEX





OPG and **CBCT**

Hygiene & Disinfection

Follow These Steps for Cleaning the Equipment

- Switch off the unit.
- Remove all visible soil, if any, with disposable cloth or paper wipe.

 Note: No disassembly shall be performed on the unit
- Dampen (not soak) a lint-free cloth with soap and running water.
- Thoroughly clean all accessible parts of the unit, including the temporal head clamps, with the dampened lint-free cloth.
- Dry the unit with hygienic disposable cloth.
- Dampen (not soak) a lint-free cloth with a low-level disinfectant that is recognized by your Local Authority (for example, quaternary ammonium compounds and some phenolics).
- Wipe thoroughly all accessible parts of the unit with the dampened lintfree cloth. You must follow the disinfectant manufacturer's instructions for use, especially with respect to contact time.
- Allow to dry in the open air for a minimum of five minutes.
- Visually inspect the unit for signs of deterioration. If any damage is noted, do not use the unit and contact a service technician.

CAUTION

Avoid applying any cleaning liquid to the inside parts of the unit





Accessories

Hygiene & Disinfection

Cleaning and disinfecting accessories that have contact with mucous membranes

CAUTION

You MUST cover all bite blocks with FDA-cleared or CE-mark protective sheaths for each patient

The following accessories must first be cleaned and then steam-sterilized between each patient:

OPG: TMJ nose rest, standard and Frankfort guide bite blocks, bite blocks for edentulous patient, all chin rests

CBCT: 3D bite blocks, Face Scan and Radiology Kit (CS 9600), all chinrests

Cephalometric Unit: Nasion support, Frankfort tool, carpus support (available only with carpus exam option in CS 8100 Family)

CI FANING

To clean accessories that have contact with mucous membranes, follow these steps:

- Remove and discard the protective sheath from the accessory.
- Remove all visible soil with a disposable cloth or paper wipe.
- Rinse at least one minute under running water to thoroughly clean the accessory from any excess soil.
- Using a soft brush, apply medical enzyme detergent solutions (basically, with a multi-enzymatic formula) to all surfaces of the accessory. Detergent manufacturer's directions must be strictly adhered to.
- Rinse thoroughly under running water for at least one minute to remove detergent residue.
- Dry the accessory with compressed air or a hygienic disposable cloth.
- Visually inspect the accessory for residual soil. If soil is visible, either repeat steps two to five, or safely dispose the accessory.

Note: Thoroughly clean the ear cones manually with the dampened lint-free cloth.

CAUTION

If an accessory is visible contamination with blood, you must clean the accessory with intermediate level disinfectant that is recognized by your Local Authority to fight against hepatitis B after cleaning. The disinfectant's manufacturer's instructions for use must always be followed, especially with respect to contact.





Steam Autoclave

Hygiene & Disinfection

To steam autoclave the accessory, once cleaning is complete, follow these steps:

CAUTION

You must use a medical autoclaving equipment cleared by the FDA or that is recognized by your Local Authority. You must always follow the operating parameters recommended by the manufacturer of the autoclaving equipment.

Use FDA-cleared or CE-mark standard packaging material.

- Wrap the cleaned accessory using a standard packaging material for autoclaving.
- Steam autoclave at 132°C (270°F) for four minutes or depending on your local regulation you can steam autoclave at 134°C (273°F) for 18 minutes.
- Visually inspect the accessory for signs of deterioration. If any damage is noted, do not use the accessory and contact your representative.
- Once disinfected, the accessory can be used immediately or stored in a dry and dust-free location.





Imaging Plate System Hygiene & Disinfection

Cleaning and Disinfecting the Imaging Plate

WARNINGS:

To prevent damage to the imaging plates and the possibility of image artifacts, avoid contact between the imaging plates and the following materials/solutions/solvents: Isopropyl alcohol, hydrogen peroxide and other peroxides, citrus-based cleaners, hand lotions and waterless hand sanitizers, as well as surfactants and lubricants.

Do not soak the hygienic sheath in any cleaning or disinfecting solutions. Hygienic sheaths must be discarded after use (single use component).

Cleaning the Imaging Plate

If the imaging plate is visibly contaminated with dirt, dust particles or finger prints, you must clean the imaging plate before disinfecting it with clean, dry, non-abrasive, lint-free wipes or cloths. DO NOT leave the imaging plate TO air-dry. Apply pressure to remove persistent dirt, if necessary.

Disinfecting the Imaging Plates

The imaging plate must be disinfected after each scan. To disinfect, use a commercially prepared product that adheres to the following specifications and restrictions:

A commercially prepared equivalent solution of diluted bleach that does not contain any ingredients (Isopropyl alcohol, hydrogen peroxide and other peroxides, citrus-based cleaners, hand lotions and waterless hand sanitizers, as well as surfactants and lubricants) that can cause damage to the hygienic sheaths and imaging plates.







Imaging Plate System Hygiene & Disinfection

Follow the disinfectant manufacturer's instructions for disinfecting the sheaths and imaging plates:

- The sheaths and plate should be kept visibly wet for the full Contact time specified on the disinfectant label.
- Wipe with a non-abrasive, lint-free cloth after keeping the plate wet for the specified amount of time.

Note: Do not soak the sheath or imaging plate in disinfectant solution.

Disposing of the Image Plate

WARNING: The imaging plate contains Barium and should be considered hazardous or special waste in specific conditions during its useful service life. For disposal or recycling information, contact local authorities

Scanner Care

Cleaning the Scanner Body

Use disinfectant wipes for medical equipment to clean the scanner body thoroughly from all sides.

Cleaning the Detachable Insertion Panel

To clean and disinfect the insertion panel, follow these steps:

- Remove the installed insertion panel.
- Use disinfectant wipes for medical equipment to clean the detachable insertion panel thoroughly from all sides including the slot.
- Install the cleaned and disinfected insertion panel.

WARNING: Do not autoclave the insertion panel. Do not use chemical autoclave for disinfecting the detachable insertion slot panel.







Intraoral Sensor Hygiene & Disinfection

Cleaning the Sensor Head

Warning

Disinfect the sensor head after each patient. Never place a sensor in an autoclave as this could result in serious damage to the sensor. Do not move the sensor using its cable when you remove the protective hygienic sleeves. You must first clean the RVG sensor before disinfecting it. You must use the disinfectant according to the manufacturer's instructions.

You must first clean the RVG sensor before disinfecting it. To do so, follow these steps:

- Remove the protective hygienic sleeves
- Remove the debris or organic matter from the sensor surface with a disposable wipe or surface brush.
- Inspect the sensor for debris. Repeat cleaning if there is any debris left
- Disinfect the sensor head with disinfecting wipes or soak it in a disinfecting solution with intermediate-level hospital disinfectant with label claims of tuberculocidal activity (for example: A chlorine-containing product, a quaternary ammonium compound with alcohol, a phenolics, an iodophors, an Environmental Protection Agency (EPA)—registered chlorine—base product). You must follow the manufacturer instructions for use





Intraoral Sensor Hygiene & Disinfection

Cleaning the Sensor Cable

The cable must be cleaned with disposable disinfecting wipes with intermediate-level hospital disinfectant with label claims of tuberculocidal activity.

- · Cleaning and disinfecting positioning accessories
- · Positioning Accessories daily maintenance tasks

Accessory RVG Holder

- Maintenance Tasks
- · Cleaning the RVG holder
- You must clean the RVG sensor holder before you disinfect it.
- · Top clean the sensor holder, follow these steps
- Remove all debris and organic matter with a disposable wipe.
- Rinse under running water
- Using a soft brush, scrub with warm tap water and soap or detergent
- Rinse under running water
- Dry with compressed air or hygienic disposable cloth
- Visually inspect the RVG sensor holder for residual debris, repeate steps from one to five if you see residual debris

Disinfecting The RVG Holder

Warnings

- You must use medical autoclaving equipment cleared by the FDA in the USA or one that is recognized by your local Authority
- DO NOT USE a chemical autoclave to disinfect the RVG sensor holder.
- You must always follow the operating parameters recommended by the manufacturer of the autoclaving equipment.
- Use FDA-cleared or CE-marked standard packaging material

To Disinfect the RVG Sensor Holder after Cleaning it, Follow these Steps:

Steam autoclave at 134°C (273°F) for 3minutes using distilled water





Intraoral Scanner

Hygiene & Disinfection

Perform the following maintenance activities on your scanner and accessories regularly. To ensure maximum hygienic safety for the patient, carefully follow the instructions to prepare the scanner for use. After each patient, clean and sterilize the tip.

To minimize the risk for cross-contamination, after each patient: Clean and disinfect the scanner. Clean and sterilize the scanner tip.

Cleaning and Disinfecting the Scanner

General Warnings

WARNINGS

Scanner tips received from the manufacturer are NOT sterilized. You must sterilize the tips before the first use.

You must wear gloves while cleaning and disinfecting the scanner.

The scanner must be disinfected with a U.S. Environmental Protection Agency (EPA) registered or CE-marked intermediate-level disinfectant solution with tuberculocidal activity between patients.

DO NOT use a disinfectant containing phenolics or iodophors; doing so will damage the surface coating of the scanner.

Never put the scanner in an autoclave device or immerse it in water or a disinfectant solution. Excessive fluids can damage the scanner.

Do not use cotton, cloth, or tissues soaked with disinfectant to disinfect the scanner.

Cleaning The Scanner

If the scanner is visibly contaminated with blood and/or body fluids, you must clean it before disinfecting it.

To clean the scanner, follow these steps:

Dampen (do not soak) a lint-free cloth with lukewarm water.

Remove the blood and/or body fluids with the dampened lintfree cloth.





Intraoral Scanner

Hygiene & Disinfection

Disinfecting the Scanner

After each patient, the scanner must be thoroughly disinfected. To adequately disinfect the scanner, follow the disinfectant manufacturer's instructions for the appropriate contact time.

To disinfect the scanner, follow these steps:

- · Remove the reusable tip.
- · Remove all visible soil

Use a commercially prepared intermediate level disinfectant wipe. Follow the manufacturer's instructions for contact time.

- Approved disinfectant wipes: Mikrozid AF Jumbo Wipes, CaviWipes, Oxivir Tb Wipes, Clorox Healthcare Bleach Germicidal Wipes, PDI Sani-Cloth Bleach Germicidal Wipes.
- Important: If the scanner is visibly soiled, it must be thoroughly cleaned prior to disinfecting. A disinfectant that has not been approved may cause damage to the scanner.
- Thoroughly wipe all surfaces of the scanner.
- Allow to air dry.
- After the scanner has dried, use a clean, lint-free cloth dampened with water to remove residual disinfectant from the surface of the scanner.

Cleaning and Sterilizing the Scanner Tips

Scanner tips received from the manufacturer are NOT sterilized. You must sterilize the tips before the first use. The removable scanner tips are autoclavable up to 20 cycles. After 20 cycles, discard the tip. If you limit the exposure time at 134°C to no more than four minutes, you can autoclave the tip up to 60 cycles.







Intraoral Scanner

Hygiene & Disinfection

Cleaning the Scanner Tips

- To manually clean the scanner tips, follow these steps:
- Rinse excess soil from the tip.
- Using a soft brush, apply an enzymatic detergent solution to all surfaces.
- Rinse under clean, running water. Load the tip into the washer/disinfector equipment if you are using an automatic washer of disinfector.
- Inspect the tip. If the tip is not clean, repeat the steps.
- Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.
- Using a cotton swab, carefully insert the folded gauze into the tip window.
- Place the tip in an FDA-cleared or CE-mark sealed sterilization pouch. The pouch should be sealed airtight. Use either a self-adhesive pouch or a heat-sealed pouch.

Sterilizing the Scanner Tips

To sterilize the scanner tips, follow these steps:

- Place the cleaned tips, each prepared with a piece of folded gauze in the tip window, in an FDA-cleared or CE-mark sealed sterilization pouch.
- Place the tips in a steam autoclave for the following times:

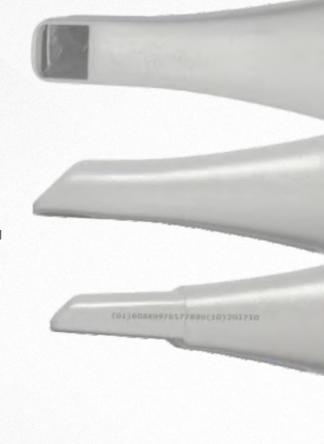
Pre-Vacuum Autoclave

Exposure Time at 132°C	Exposure Time at 134°C	Minimum Drying Time
Minimum 4 Minutes	Minimum 3 Minutes	20 - 30 Minutes

Gravity Autoclave

Exposure Time at 132°C	Exposure Time at 134°C	Minimum Drying Time
Minimum 15 Minutes	Minimum 10 Minutes	15 - 30 Minutes

Important: Never autoclave a tip that does not have gauze covering the mirror and is not wrapped, as this will leave stains on the mirror that cannot be removed.







We Care For You!

We are committed to support you- Today, Tomorrow and Always

Please Contact Remote Service Team to take additional measures for monitoring of Dental **Equipment and Adapting** to the New Normal

Contact for Further assistance



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