

CS 3700
Safety Information Sheet

Notice

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All trademarks and registered trademarks are the property of their respective holders.

The CS 3700 is intended for professional use only.

U.S. Federal law restricts this device to sale by or on the order of a dentist.

If any serious incident occurs in relation to the device, the user must report it to Carestream Dental and to the competent authority of its Member State in the European Union.

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The CS 3700 complies with Medical Device Regulation (EU) 2017/745 and Medical Devices Regulations 2002 (SI618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).



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CS 3700 Safety Information Sheet

Warnings and Safety Instructions



DANGER OF ELECTRIC SHOCK

This is an electrical unit. Do **NOT** expose it to water spray. Such action can cause an electric shock or a malfunction of the unit.



IMPORTANT: All known residual risks, contraindications, or undesirable side effects are listed in this guide. If any serious incident occurs in relation to the device, you must report it to Carestream Dental and to the competent authority of your Member State in the European Union.



Warnings

CS 3700:

- You **MUST** read and understand this safety information before using the scanner.
- This scanner shall only be used inside hospitals and other professional healthcare facilities and **MUST NOT** be used near high frequency surgical equipment and the RF shielded room of an ME System for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.
- Before using the scanner, check the outer surfaces of the unit and any accessories to ensure there are no rough surfaces, sharp edges, or protrusions which may cause a safety hazard.
- You are responsible for the operation and maintenance of the scanner. You **MUST** have training to use the scanner.
- **DO NOT** place objects within the field of operation of the unit.

- When the unit is not in use, ensure that the scanner is turned OFF.
- DO NOT use the scanner in conjunction with oxygen-rich environments. This unit is not intended for use with flammable anesthetics or flammable agents.
- DO NOT pull or twist the cable.
- DO NOT drop the scanner or the accessories.
- DO NOT expose the scanner to water spray or submerge it in water or disinfectant.
- DO NOT heat sterilize the scanner.
- DO NOT expose the scanner to high vibrations.
- DO NOT expose the scanner to ultraviolet radiation directly. The scanner is not designed for ultraviolet disinfection.
- Do not stare at the LED emission window.
- When the tip is removed, DO NOT touch the heater.
- When the tip is removed, install the rubber sleeve to protect the scanner lens window.
- DO NOT remove the cover of any scanner components. The scanner contains no user-serviceable parts. For any repairs, contact a qualified Carestream Dental service technician.
- DO NOT replace the cables provided with the scanner with other cables. Doing so may damage the scanner and adversely affect the safety protection and EMC performance of the scanner.
- DO NOT replace the power adapter provided with the scanner with any other power adapter. Substitutes may not provide the required protection against electric shocks and other safety hazards.
- Any other equipment not complying with IEC 60601 shall be kept at least 1.83 meters away from the patient.
- If the equipment is faulty, turn it OFF, display an “Out of Service” notice, and contact a qualified Carestream Dental service technician.
- Using components, accessories, cables and spare parts other than those specified or provided by the manufacturer of this equipment may impair the safety protection of the scanner and may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- No modification of this equipment is allowed.
- Additional multiple outlet strips or extension cords should not be connected to the system.
- The maximum temperature of the applied part may reach to 43 °C; to avoid overheating, do not use it for extended periods.

- To power off the device, push the power button for 3 seconds. To isolate the device from the mains supply on all poles, unplug the adapter from the mains power outlet.
- Always position the unit in such a way that it is easy to disconnect the adapter from the mains power outlet.

Computer:

- **DO NOT** place the computer and the peripheral equipment connected to it in the immediate vicinity of the patient. Leave at least 1.83 meters distance between the patient and the equipment.
- The scanner is only intended to be connected to a computer that has agency approval according to the latest edition of applicable safety and EMC standards. Connecting the scanner to other equipment may be hazardous.
- See the installation guide for your computer for information about the data processing system, computer, and screen. Leave a sufficient amount of clear space around the computer to ensure that it is properly ventilated.
- Position the screen to avoid light reflections from internal or external lighting for maximum image quality and visual comfort.

Disposal:



This equipment contains certain materials and chemical compounds incidental to the manufacture of electrical and electronic equipment, and improper “end-of-life” disposal of such equipment can result in environmental contamination. Therefore, this equipment should not be disposed of as ordinary household waste but should instead be delivered to a designated electrical and electronic waste disposal or recycling center. For further information on disposing of electrical and electronic waste, contact the cognizant authority within the local jurisdiction.

Dispose of the scanner tips according to standard operating procedures or local regulations for the disposal of contaminated medical waste. For additional scanner tips, contact your dealer.

Cleaning, Disinfecting, Sterilizing

Cleaning and Disinfecting the Scanner



WARNINGS

- Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) for the disinfectant used to process the scanner for reuse.
- You must wear gloves while cleaning and disinfecting the scanner.
- The scanner must be disinfected with an 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 the 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:

- 1 Dampen (**do not soak**) a lint-free cloth with lukewarm water.
- 2 Remove the blood and/or body fluids with the dampened lint-free cloth.

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.



Important: If the scanner is visibly soiled, it must be thoroughly cleaned prior to disinfecting. See ["Cleaning the Scanner."](#)

To disinfect the scanner, follow these steps:

- 1 Remove the reusable tip.
- 2 Remove all visible soil (see ["Cleaning the Scanner"](#)).
- 3 Use a commercially prepared intermediate level disinfectant wipe. Follow the manufacturer's instructions for contact time.
Approved disinfectant wipes: Mikrozyd AF Jumbo Wipes, CaviWipes, Oxivir Tb Wipes, Clorox Healthcare Bleach Germicidal Wipes, PDI Sani-Cloth Bleach Germicidal Wipes.



WARNING: Using a disinfectant that has not been approved may damage the scanner.

- 4 Thoroughly wipe all surfaces of the scanner.



WARNING: Do not rinse.

- 5 Allow to air dry.
- 6 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 not more than 4 minutes, you can autoclave the tip up to 60 cycles.**



WARNINGS

- **Wear gloves when handling a contaminated scanner tip.**
- **Read and follow the warnings and personal protection instructions provided in the manufacturer's SDS for the detergent used to clean the scanner tip prior to sterilization.**
- **Do not soak the scanner tips in disinfectant overnight.**
- **Dry the scanner tips thoroughly before mounting onto the scanner.**
- **Do not use an ultrasonic cleaning machine to clean the scanner tips.**

Manually Cleaning the Scanner Tips

To manually clean the scanner tips, follow these steps:

- 1 Rinse excess soil from the tip.
- 2 Using a soft brush, apply an enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces.
- 3 Rinse under clean, running water.
- 4 Inspect the tip. If the tip is not clean, repeat the steps.
- 5 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

Cleaning the Scanner Tips in an Automatic Washer or Disinfecter

To clean the scanner tips in an automatic washer or disinfecter, follow these steps:

- 1 Rinse excess soil from the tip.
- 2 Using a soft brush, apply an enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces.
- 3 Load the tip into the washer/disinfecter equipment.
- 4 Run the cycle per the equipment manufacturer's instructions.
- 5 If the machine does not have an automatic rinse cycle, rinse thoroughly to remove detergent residues by immersing in clean water.
- 6 Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

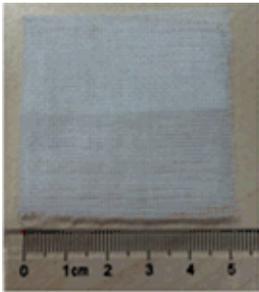
Sterilizing the Scanner Tips



Note: The removable scanner tips can be autoclaved for up to 20 cycles. After 20 cycles, discard the tip. **If you limit the exposure time at 134°C to not more than 4 minutes, you can autoclave the tip up to 60 cycles.**

To sterilize the cleaned tips, follow these steps:

- 1 Fold a 2x2-inch (5x5cm) 4-ply sterile non-woven gauze sponge in half.



- 2 Using a cotton swab, carefully insert the folded gauze into the tip window. Ensure that the mirror is fully covered by the gauze. To facilitate removal, leave an edge of gauze outside the tip window.



- 3 Place the tip in an FDA-cleared or CE-marked sealed sterilization pouch. The pouch should be sealed air-tight. Use either a self-adhesive pouch or a heat-sealed pouch.

- 4 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: Do NOT exceed 134°C.



Important: Do not exceed 18 minutes of exposure time.



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.

Precautions Before Use

Perform the following maintenance activities on your scanner and accessories regularly.

Cleaning, Disinfecting, and Sterilizing

To ensure maximum hygienic safety for the patient and minimize the risk of cross-contamination, carefully perform the following maintenance activities on your scanner and accessories.

After each patient:

- Clean and disinfect the scanner. See [“Cleaning and Disinfecting the Scanner” on page 4](#).
- Clean and sterilize the scanner tip. See [“Cleaning and Sterilizing the Scanner Tips” on page 6](#).

In the event that you see poor scan quality or an unclear video preview in the software, clean the tip mirror and the scanner's lens window using a microfiber cleaning swab, applying ethanol that is free of impurities.

Visually Inspecting the Scanner for Damage

Visually inspect the scanner for damage or signs of deterioration by doing the following:

- Inspect the scanner's lens window.
- Inspect around the scanner buttons and the cable.

If damage is noted, do not use the scanner and contact your representative.

Visually Inspecting the Scanner Tips for Damage

Visually inspect the scanner tips for signs of deterioration by doing the following:

- Verify that the tip is not damaged and its components are not detached.
- Verify that the tip mirror does not have any smudges or scratches on it. This can affect image quality.

If deterioration is noted, replace the tip.



WARNINGS

- **The lens window on the scanner is a delicate optical component. Mount the rubber sleeve to protect the lens window from damage and dirt when the scanner is not in use.**
- **The mirror in the tip is a delicate optical component. Its clean and undamaged surface is critical to scan quality.**

Electronic Labeling



This symbol on the packaging indicates that the Instructions for Use (User and Installation Guide, and Safety and Regulatory Guide) for the product are available electronically on the Help menu of the software and on our webpage at www.carestreamdental.com/documentation.



Note: You need a computer with a screen and mouse. Make sure that you have Adobe Acrobat Reader installed on your computer. If you do not have it or if you are unsure if you have it, you can download the current free version from <https://get.adobe.com/reader/>.

To access the Instructions for Use webpage, you need an internet connection.

Accessing Instructions for Use on the Carestream Dental Webpage

To access the Instructions for Use on the Carestream Dental webpage, follow these steps:

- 1 Go to the www.carestreamdental.com/documentation website.
- 2 Select the product for which you need the Instructions for Use.
- 3 Open the Instructions for Use pdf file in the language you require.

You can view, save, and print the Instructions for Use.

If requested, we will send you a free printed copy of the Instructions for Use in the language you require within 7 days. You can use the order form provided on our webpage for this purpose.

Contact Information

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