iTero

Cleaning and Disinfection Protocol
iTero Element Scanners

> **Hygiene, safety, and care**

Improving safety for patients and colleagues is at the heart of everything we do. We are consolidating our hygiene protocols in a simple format, helping you to reassure patients and to save time.

The iTero Element intraoral scanner uses disposable single-use sleeves. They're easy to install and disposal is simple and efficient.

Disposable sleeves can be opened in front of the patient. A clear, visual demonstration that they are in a safe, sterile environment. Use it as a gesture to reassure patients or as a conversation starter to explain how you're improving safety procedures.

An efficient, streamlined hygiene protocol lowers the risk of cross-contamination. Reducing unnecessary touchpoints and enhancing safety for your patients and colleagues.

1 Purpose of this document

This document replaces the following chapters in your current user documentation:

Documentation	Chapter
iTero Element Operation Manual	Chapter 5, Scanner Handling, Cleaning, and Disinfection Instructions
iTero Element 2 and iTero Element Flex User Manual	Chapter 10, Care and maintenance
iTero Element 5D User Manual N/A for iTero Element 5D customers in the USA	Chapter 10, Care and maintenance

Please note that the images of the wand and cradle are for illustration purposes only.

2 Care and maintenance

If you will be performing any sanitation procedures in the office that involve fogging or spraying, make sure that the iTero scanner is not in the room.

To avoid cross-contamination, it is mandatory to:

Clean and disinfect the wand, cradle, touch screen, and wheel-stand handle, as described in the following sections.

Replace the wand sleeve, before each patient session.

CAUTION: OPTICAL SURFACE! Avoid touching the optical surface of the wand, as contact may cause damage. If additional cleaning besides that listed in section 2.2.2 is necessary, use the anti-static cloth found inside the wand sleeve box. For more details, refer to the instructions in the box.
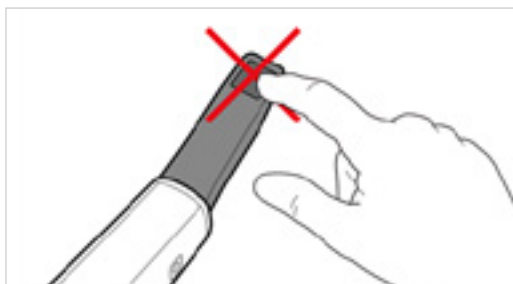
Figure 1: Optical surface of the wand

Dispose of wand sleeves according to standard operating procedures or local regulations for the disposal of contaminated medical waste.

Remove and replace gloves after each patient procedure.

Discard torn, contaminated, or removed gloves.

Wand sleeves

There are two types of sleeves intended for use with the wand:

Disposable sleeve

The white sleeve is a single-use sleeve for patient scanning. Always replace the white sleeve on the wand between patients to avoid cross-contamination. Please dispose of the white sleeve after every patient.

Protective sleeve

The blue protective sleeve is used to protect the optical surface when the wand is not in use. Please keep the blue sleeve in a safe place so that it does not get lost or damaged.

2.1 Handling the wand and cable

The wand contains delicate components and should be handled with care.

When not in use, the wand should be kept in its cradle, with the blue protective sleeve attached. If you have a laptop-configuration scanner, the wand should be stored in the supplied carry case when the system is not in use.

Between patients, undo any twists and knots in the wand cable in order to relieve all tension. If the cable cap detaches from the wand, gently reattach it.

2.2 Cleaning and disinfecting the wand

The iTero wand requires the procedures in the following sections for cleaning and disinfection.

These procedures must be carried out:

After the scanner assembly, before first-time use

Between patients

WARNING Avoid deviating from the recommended cleaning and disinfection process, and modifying or substituting recommended materials to prevent biological hazard.

You must follow all the cleaning and disinfecting steps below to ensure that the wand is properly reprocessed and ready for use.

2.2.1 Preparation before cleaning and disinfection

1. To avoid false activation during the cleaning and disinfection procedures, make sure to exit a scan completely either by sending the case or by going back to the home screen.

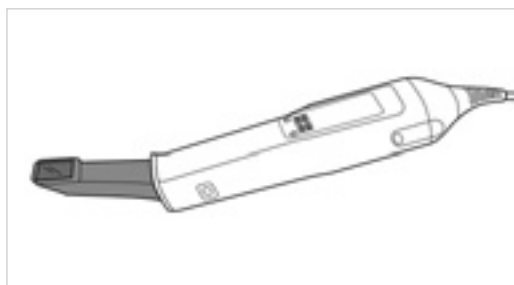2. Remove the wand sleeve, making sure not to touch the optical surface of the wand.
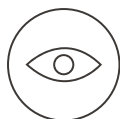

Figure 2: Wand without a sleeve

3. Visually inspect the wand for any noticeable damage, for example, deterioration such as corrosion, discoloration, cracks.

WARNING Do not clean, disinfect, or use the wand if any damage is found. Please contact iTero Customer Support for further instructions.

4. Prepare the following:

Required cleaning and disinfecting materials:

- CaviWipes1 (or, for a list of alternative materials and the required contact time, see section 3)
- 70% isopropyl alcohol (IPA)
- Dry lint-free wipes
- Soft bristle brush (e.g. the smaller end of a Healthmark Trumpet Valve Brush 1mm diameter, Cat # 3770 or equivalent)

Personal Protective Equipment (PPE) and work environment

- Please follow the cleaning and disinfection material manufacturers' instructions

Note: Replace cleaning and disinfection materials (brushes/wipes) if visibly damaged or soiled.

Before starting the cleaning and disinfection procedure, put on your PPE.

2.2.2 Wand cleaning and disinfection

Before cleaning and disinfecting the wand, ensure that the sleeve has been removed.
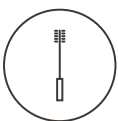
> CLEANING

1. Using CaviWipes1, remove any gross contaminants on the wand body and wand tip for a minimum of one (1) minute.

   Note: If you are using an alternative disinfectant, please refer to section 3 for the required contact time.

Figure 3: Remove gross contaminants using CaviWipes1

2. Using the soft bristle brush, remove any remaining marks and stains on the wand body and wand tip, paying special attention to the grooves, indents, joints, vents, etc. Brush until visibly clean.

   CAUTION: Do not use the brush on the optical surface to prevent damage to the wand.

Figure 4: Remove marks and stains using a soft bristle brush

3. Using CaviWipes1, remove any remaining contaminants on the wand body and wand tip.

4. Visually inspect the device in a well-lit area to ensure all surfaces are visibly clean.

> DISINFECTION

1. Using CaviWipes1, thoroughly dampen all external surfaces of the wand body and wand tip, including the optical surface and ensure they remain wet for a minimum of one (1) minute.
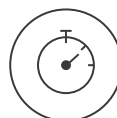
   Note: Use multiple fresh wipes, as necessary, to keep the wand surfaces wet for the full one (1) minute contact time.
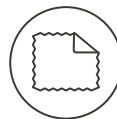
2. Using lint-free wipe(s) wetted (but not dripping) with 70% Isopropyl Alcohol (IPA), thoroughly wipe the optical surface of the wand one (1) time until visibly clean.

Figure 5: Wipe the optical surface of the wand with IPA

3. Wait until the optical surface dries (approximately 5–10 seconds).

4. Remove any residue from the optical surface using a dry lint-free wipe.

2.2.3 Drying – wand body

Air-dry the disinfected wand at room temperature.

2.2.4 Storage and maintenance

1. Visually inspect the wand for any noticeable damage, for example, deterioration such as corrosion, discoloration, pitting, and cracks. Pay special attention to the optical surface, making sure it remains clean.

WARNING Do not use the wand if any damage is found. Please contact iTero Support for further instructions.

2. Place the blue protective sleeve on the wand tip.

3. Place the wand in the cleaned and disinfected cradle, as described in section 2.3, below.

4. If you have a laptop-configuration scanner, store the wand in the carrying case when not in use.

2.3 Cleaning and disinfecting the cradle

The wand cradle requires the procedures in the following sections for cleaning and disinfection.

These procedures must be carried out:

After the scanner assembly, before first-time use

Between patients

WARNING Avoid deviating from the recommended cleaning and disinfection process, and modifying or substituting recommended materials, to prevent biological hazard.

You must follow all the cleaning and disinfecting steps below to ensure that the cradle is properly reprocessed and ready for use.

2.3.1 Preparation before cleaning and disinfection

1. Visually inspect the cradle for any noticeable damage, for example, deterioration such as discoloration, pitting, and cracks.

   CAUTION: Do not clean, disinfect, or use the cradle if any damage is found. Please contact iTero Customer Support for further instructions.

2. Prepare the following:

   Required cleaning and disinfecting materials:

   • CaviWipes1 (or, for a list of alternative materials and the required contact time, see section 3)

   • Soft bristle brush (e.g. the smaller end of a Healthmark Trumpet Valve Brush 1mm diameter, Cat # 3770 or equivalent)

   PPE and work environment

   • Please follow the cleaning and disinfecting material manufacturers' instructions.

   Note: Replace cleaning and disinfection materials (brushes/wipes) if visibly damaged or soiled.

   Before starting the cleaning and disinfection procedure, put on your PPE.

2.3.2 Cradle cleaning and disinfection

〉 CLEANING

1. Using CaviWipes1, remove any gross contaminants on the cradle for a minimum of one (1) minute.

Figure 6: Remove gross contaminants on the cradle using CaviWipes1

   Note: If you are using an alternative disinfectant, please refer to section 3 for the required contact time.

2. Using the soft bristle brush, remove any remaining marks and stains on the cradle, paying special attention to the grooves, indents, joints, etc.
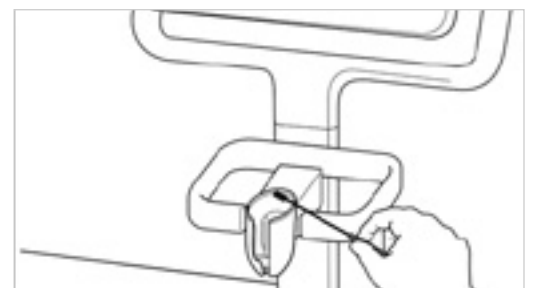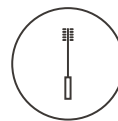
Figure 7: Remove remaining marks and stains on the cradle using the soft bristle brush

3. Using CaviWipes1, remove any remaining contaminants on the cradle.

4. Visually inspect the cradle in a well-lit area to ensure all surfaces are visibly clean.

> DISINFECTION

Using CaviWipes 1, thoroughly dampen all external surfaces of the cradle and ensure they remain wet for a minimum of one (1) minute.

Note: Use multiple fresh wipes, as necessary, to keep the cradle surfaces wet for the full one (1) minute contact time.

2.3.3   Drying – cradle

Air-dry the disinfected cradle at room temperature.

2.3.4   Storage and maintenance

Visually inspect the cradle for any noticeable damage, for example, deterioration such as discoloration, pitting, and cracks.

WARNING Do not use the cradle if any damage is found. Please contact iTero Customer Support for further instructions.

The laptop-configuration cradle should be stored in the carrying case when not in use.

2.4 Cleaning and disinfecting the scanner touch screen and the wheel-stand handle

The scanner screen and wheel-stand handle must be cleaned between patients, as follows:

1. Clean all outer surfaces using approved disinfectant wipes, or spray approved disinfectant on a clean lint free wipe and follow the manufacturer's instructions. For a list of approved materials, see section 3.

2. Remove any residual liquid disinfectant with a clean lint-free wipe.

Note: Do not use abrasive cleaners and/or corrosive cleaning agents or disinfectants with acids, bases, oxidizing agents, or solvents.

2.5 General cleaning

All scanner parts and accessories not outlined above should be cleaned according to standard operating procedures or local regulations.

3 Approved cleaning and disinfecting materials

The following table lists the approved cleaning and disinfecting materials, as well as the minimum contact time required.

If you are using liquid disinfectant, soak a clean, sterile, lint-free wipe in the liquid and squeeze until moist, and then follow the cleaning and disinfection instructions described in this document.

Material	Active Ingredient	Contact time (minutes)
CaviWipes1/CaviCide1	Quats-alcohol	1
CaviWipes/CaviCide	Quats-alcohol	3
OPTIM 1	0.5% Accelerated Hydrogen Peroxide	1
OPTIM 33TB	0.5% Accelerated Hydrogen Peroxide	5
BirexSE	Phenolics	10
ProSpray	Phenolics	3
Opti-Cide 3 Wipes	Quats-alcohol	2
Opti-Cide 3	Quats-alcohol	2
Sani-Cloth AF3	Quats	3
Sani-Cloth Super	Quats-alcohol	1
DisCide ULTRA	Quats-alcohol	1
Lysol IC III	Quats-alcohol	6
Clorox HP Wipes	1.4% Hydrogen Peroxide	5
Medibase	Quats-alcohol	15
FD 312 Wet Wipes	Quaternary Ammonium	15
Oxivir® 1 Wipes	AHP Hydrogen Peroxide	1
Oxivir® Tb Wipes	AHP Hydrogen Peroxide	5
PREempt™ Wipes	0.5% Hydrogen Peroxide	5

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iTero

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CE compliance

This device complies with Council Directive 93/42/EEC for Medical Devices.

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