

EzAim™

Intraoral Digital X-ray Sensor Positioning System Instructions For Use



Manufactured for: Pac-Dent, Inc.
670 Endeavor Circle, Brea, CA 92821
info@pac-dent.com • (909) 839-0888

Cleaning: Manual / Mechanical (Ultrasonic)

1. Rinse the disassembled device under potable running water while brushing away debris with a soft-bristled brush.
2. Prepare an enzymatic instrument cleaning solution and immerse the device according to manufacturer's instructions.
3. Rinse the device under potable running water for at least 30 seconds and dry the device using a disposable lint-free cloth.
4. Visually inspect the device for visible debris. Repeating the cleaning procedure as needed to remove all visible debris.

Cleaning and Disinfection: Automated Instrument Washer/Disinfector

Use only properly maintained, calibrated, and approved washer/disinfectors according to ISO 15883.

1. Rinse the disassembled device under potable running water while brushing away debris with a soft-bristled brush.
2. Follow the manufacturer's instructions for instrument washer solution, closely observe concentration rates and contact times as well as the instrument washer's recommended cleaning and/or thermal disinfection cycle (1 minute at 90°C).
3. Visually inspect the device for visible debris. Repeating the cleaning procedure as needed to remove all visible debris.

Device Description

EzAim Intraoral Digital Sensor Holders are disposable, self-adhesive sensor holders with peel-and-stick adhesive technology that firmly secures digital sensors to holders. Easy and accurate placement of sensors makes even the most difficult shots easy to obtain. The holders are color coded for easy identification and fits all types of sensors on the market. EzAim holders can be used with your existing aiming rings and positioning arms. Tabs can be managed with hemostats.

Indications for Use

EzAim holders are indicated for holding digital sensors for intraoral dental radiographs. EzAim arms and rings are indicated for positioning and alignment of dental intraoral radiographs.

Warnings: Properly sterilize device before use. DO NOT use phenol-based glutaraldehyde or ultrasonic cleaners. DO NOT chemiclave, dry-heat sterilize or cold sterilize. ONLY sterilize with steam sterilization according to the provided EzAim sterilization instructions. DO NOT exceed 273°F (134°C).

It is the user's responsibility to qualify any alternative methods of disinfection and sterilization. Failure to follow properly EzAim's validated sterilization processes and approved aseptic techniques may result in cross contamination. All methods of sterilization will shorten the life of plastic parts.

Sterilization

1. Ensure that the device is thoroughly dry prior to sterilization.
2. Enclose the device into an appropriately sized sterilization pouch intended for steam sterilization.
3. Place the pouched device into the sterilizer per the manufacturer's instructions. Sterilize the device according to one of the recommended methods listed below. Sterilize metal and plastic components in separate pouches to avoid damage to the components. DO NOT exceed 273°F (134°C).

Steam Sterilization Cycle	Minimum Temperature	Minimum Full Cycle Exposure Time	Minimum Dry Time
Pre-vacuum	270° F (132° C)	3 minutes	16 minutes
Steam-flush Pressure-pulse	270° F (132° C)	3 minutes	16 minutes
Gravity Steam Sterilization	270° F (132° C)	10 minutes	15 minutes

Precautions: Follow the provided sterilization instructions carefully to prevent plastic damage. When using EzAim with corded digital sensors, use a sensor barrier sleeve. Do not pull on sensor cord during use.

Residual Risks: Failure to follow the validated EzAim reprocessing instructions provided may result in exposing the patient to cytotoxic residuals and/or cross-contamination.

Step-by-Step Instructions

1. Insert positioning arm into the matching color-coded channel of the aiming ring.
2. Attach the appropriate biteblock for desired area to be imaged. When correctly assembled, the imaging area should be centered when viewed through the aiming ring.
3. Position the holder in patient's mouth and slide ring close to patient's face.
4. Align the x-ray tube to the ring.
5. Take the exposure.
6. Adjust as needed for the next desired imaging position.

Reprocessing

Arm and Ring: Disassemble the device(s) and separate all parts prior to reprocessing.

Alternate Method

Place the non-pouched device into the sterilizer and sterilize according to one of methods listed above. A non-pouched device must be used immediately following sterilization to avoid contamination.

Storage

To maintain device sterility, the device should remain in the sterilization pouch until it is to be used in a procedure. Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the relevant Authority.



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