

EXABLATE PROSTATE (WS 8.1) CLEANING AND HIGH-LEVEL DISINFECTION PROCEDURE

Introduction:

1. The Exablate Prostate **probe** is considered a semi-critical device, as per Spaulding classification, and should undergo this cleaning and high-level disinfection (HLD) procedure, **immediately** at the point of use after every treatment.
2. Immediately after treatment, **all single-use** items: (1) probe shell, safety pin and white O-ring, (2) all drapes and covers, and (3) water bag must be discarded in marked hazardous material containers and handled using applicable **personal protective equipment (e.g., gloves, protective glasses, etc.)**, according to the policies of the medical facility.
3. Used cleaning and disinfection materials should be **disposed** of according to their **manufacturer instructions** and the medical facility policy.
4. Individuals handling cleaning and disinfecting agents must follow the instructions of the agent manufacturer, including instructions for **personal protective equipment**.
5. Follow the steps in this procedure consecutively and without delays in between.
6. Please refer to Exablate Prostate Operator's Manual for full system instructions.
7. Users should also refer to professional organizations' clinical practice guidelines or clinical guidelines of the Center for Disease Control (CDC).

List of materials required for cleaning and HLD procedure:

1. Cleaning and disinfection cart, with **four (4) containers**:
 - a. Container #1 for cleaning Solution
 - b. Container #2 for water
 - c. Container #3 for disinfectant
 - d. Container #4 for water
2. Sodium hypochlorite (5.25-6.15%, also known as household bleach)
3. Purified water
4. Enzol® Enzymatic Detergent
5. Revital-Ox™ RESERT® HLD
6. Disposable disinfection wipes containing 0.2-0.4% benzalkonium chloride active ingredient (e.g., Clorox® disinfection wipes or equivalent product)
7. Lint free cloths
8. Probe storage cover + probe cover label

Please do not use other materials for this procedure.

EXABLATE PROSTATE (WS 8.1) CLEANING AND HIGH-LEVEL DISINFECTION PROCEDURE

HLD procedure:



HLD procedure must be performed using clean applicable **personal protective equipment**, according to the cleaning and disinfection materials' manufacturer instructions and the medical facility policy.

1. Cleaning and disinfection cart preparation:

It is recommended to perform this step prior to treatment ending, in order to allow for the immediate probe cleaning and disinfection, when treatment ends.

- a. Verify that the cleaning and disinfection cart is stable and that the four (4) containers situated and **leveled** inside the cart openings, now and after each removal of the containers from cart.
- b. **Remove (open)** both the **wide** and the **narrow** container caps.
- c. **Completely** fill the four (4) cart containers with Sodium hypochlorite (5.25-6.15% household bleach), diluted approximately 1:100 with **potable water** (e.g., **25 cc** of Sodium hypochlorite for **2.5 liters** of water or **40 cc** of Sodium hypochlorite for **4 liters** of water).
- d. Wait **five (5) minutes** and then completely drain the containers.
- e. Rinse the containers, **twice**, by filling them with potable water and then drain completely.
- f. **Fill** the containers **up to their lower marker**, according to the following instructions:
 - i. Fill container #1 ("cleaning solution") with **20 ml of Enzol®** enzymatic detergent and **then** add approximately **2.5 liters** (85 oz) of **purified water**. Gently shake the container to mix the solution.
 - ii. Fill container #3 ("disinfectant") with approximately **2.5 liters** (85 oz) of **Revital-Ox™**.
 - iii. Fill containers #2 and #4 with **purified water**, approximately **4 liters** (135 oz) in each.

2. Post-treatment procedure:

- a. Remove **disposable shell** from the probe - pull its balloon "dress" over the inflated part to expose the locking pin. **Release** the **pin** by firmly pulling its nylon cord, and then pull the disposable shell assembly from the probe. Remove **white O-ring** from the probe as well.
- b. Dispose all **single-use** items according to the policies of the medical facility.
- c. Place the cleaning and disinfection cart adjacent to the Exablate table and **attach (screw)** the **water fitting connector** (previously connected to the water bag) to the **connector** in the back of the cleaning and disinfection cart.

3. Probe cleaning:



The transducer surface is **very delicate**. Clean and handle it very gently during the procedure (e.g., when wiping the probe) and avoid any contact with sharp objects.

- a. Press "**Clean**" on the Exablate table **water system display** ("display") and choose "**HLD**".

EXABLATE PROSTATE (WS 8.1) CLEANING AND HIGH-LEVEL DISINFECTION PROCEDURE

- b. Press **“Next”** on the display (if the cleaning cart preparation, described above, was completed).
- c. Verify that the table **water fitting connector** is properly attached to the connector at the back of the **cleaning and disinfection cart** and press **“Next”** on the display.
- d. Use **two (2) disinfection** wipes (consecutively) to carefully wipe the probe for **two (2) minutes**, then press **“Next”**.
 - i. If necessary, press **“Back”** on the display to go to previous screen.
- e. **Lock** probe’s shell and soak the probe in the cleaning solution by inserting it into **container #1** (“cleaning solution”) for **six (6) minutes**, then press **“Next”**.
- f. Remove the probe from container #1, **wait** until it stops dripping, and soak it in **water** by inserting it into **container #2** (“water”) for **three (3) minutes**, and then press **“Next”**.
- g. Remove probe from container #2 and dry it entirely with a **lint free** cloth for **two (2) minutes**, and then press **“Next”**.
- h. Visually **inspect** the probe for visible soil/residues and press **“Next”**.
 - i. If soil/residues are found - repeat probe cleaning by pressing **“Repeat”** on the display.
 - ii. If other visible signs of deterioration such as corrosion, discoloration, pitting, or cracks are noticed, contact Technical Support.

4. Probe disinfection:

- a. Use **two (2) disinfection** wipes (consecutively) to carefully wipe the probe for **two (2) minutes**, and then press **“Next”**.
- b. Dry the entire probe with a **lint-free** cloth for **two (2) minutes** (if necessary, continue until visually dry), and then press **“Next”**.
- c. Verify that the **white tray** of the cart is placed over **container #4**.
- d. Connect the **water hose** (on the cleaning and disinfection cart) to **container #3** (“disinfectant”), as shown on display, and then press **“Next”**.
- e. Soak the probe in **Revital-Ox™** by inserting it into **container #3** (“disinfectant”).
 - i. **Verify that the probe and the water hose are properly connected to container #3.**
- f. Press **“Start”** to begin **circulation** and wait for system to finish.
 - i. The system will circulate automatically for **one (1) minute**.
 - ii. If necessary, press **“Stop”** to stop circulation (to resume press **“Start”** again).
- g. When requested, confirm that the liquid level in container #3 is **up to its upper marker**. Add **disinfectant** if needed.
 - i. To **quit** HLD, press **“Home”** and confirm pop-up message to return to **“Home”** screen.
- h. Press **“Start”** to begin **circulation** and wait for system to finish.
 - i. The system will circulate automatically for **approximately thirteen (13) minutes**.
 - ii. If necessary, press **“Pause”** to pause circulation.

EXABLATE PROSTATE (WS 8.1) CLEANING AND HIGH-LEVEL DISINFECTION PROCEDURE

- iii. When circulation is **paused**, it is possible to do one of the following:
 1. Resume circulation by pressing "**Start**".
 2. Return to previous screen by pressing "**Back**".
 3. Go back to "**Home**" screen by pressing "**Home**" and confirming the pop-up message.

Note: If the temperature of the water in the system is below threshold, the system will first go through a warming stage ("Warming" will appear on top of the display), and only when completed, will the system **automatically** move to circulation.

5. Probe rinsing:

- a. After probe disinfection is successfully completed, **carefully** disconnect **both** the **water hose** and the **probe** from container #3 and **wait** until the **probe** stops dripping.
- b. Move the **white tray** of the cart over **container #3** and then connect **both** the **water hose** and the **probe** to **container #4** ("water").
 - i. To **quit** HLD, press "**Home**" and confirm pop-up message to return to "Home" screen.
 - ii. **Verify that the probe and the water hose are properly connected to container #4.**
- c. Press "**Start**" to begin **circulation** and wait for system to finish.
 - i. The system will circulate automatically for **two and a half (2.5) minutes**.
 - ii. If necessary, press "**Pause**" to pause circulation.
 - iii. When circulation is **paused**, it is possible to do one of the following:
 1. Resume circulation by pressing "**Start**".
 2. Go back to "Home" screen by pressing "**Home**" and confirming the pop-up message.

6. Post-HLD:

- a. After probe rinsing is completed, disconnect **both** the **water hose** and the **probe** from container #4, then press "**Next**".
- b. Dry the entire probe with **three (3) lint-free** cloths for **three (3) minutes**, and then press "**Next**".
- c. Cover the probe with **probe storage cover** and **secure** with the **cover label**.
- d. Then, put the **mechanical protective cover** (P/N MEC501043) over the transducer (probe tip) and press "**Next**".
- e. **Disconnect** the Exablate table **water fitting connector** from the **connector** in the back of the cleaning and disinfection cart.
- f. **Dispose** of the cleaning and disinfection materials (contents of the 4 containers) according to the respective manufacturer instructions and the medical facility policy.

EXABLATE PROSTATE (WS 8.1) CLEANING AND HIGH-LEVEL DISINFECTION PROCEDURE

- g. **Completely** fill the four (4) containers with Sodium hypochlorite (5.25-6.15%) diluted approximately 1:100 with **potable water** (e.g., **25 cc** of Sodium hypochlorite for **2.5 liters** of water or **40 cc** of Sodium hypochlorite for **4 liters** of water).
- h. Wait for five (**5 minutes**) and then completely drain the containers.
- i. Rinse the containers, **twice**, by filling them with potable water and then drain completely.
- j. Dry all the containers and caps with a **lint-free** cloth.
- k. Allow the containers and caps to **air-dry** before storing them.
- l. Press "**Finish**" on the display and confirm pop-up message to finish and exit HLD procedure.
- m. If HLD procedure is completed **successfully**, an approval message will appear on display.
 - i. Press "**OK**" to return to "Home" screen.
- n. If the HLD procedure was **not completed successfully**, a warning message will appear on the display.
 - i. Press "**OK**" to return to "Home" screen.
- o. Continue to system shutdown, as described in Operator's Manual, or to probe and table preparation for treatment (**only if HLD completed successfully**).



If HLD procedure failed to be completed successfully – do not treat patients and contact technical support at TechSupp@insightec.com, or by calling your local service/applications team!



After the issue is resolved by Technical Support, perform full HLD procedure successfully, before treating any patient.



After six (6) months, contact Technical Support for maintenance.