

Maintenance and Cleaning of Benchtop Processing Station (BPS)

Background

This document outlines the necessary maintenance and cleaning process steps for the Benchtop Processing Station (BPS). Basic daily cleaning is a critical part of any clinical environment and should be performed on the BPS after each point-of-care use. It is the responsibility of the user to ensure appropriate cleaning. Under normal circumstances, the BPS is exposed to transient-contact only with the biologics associated with PRP (Platelet-Rich Plasma) preparation. Application of the cleaning protocol, described below, will ensure the device is properly prepared for the next use.

Disinfection or Deep Cleaning from Significant Contamination

Disinfecting procedures for the BPS device are not provided as part of this documentation. Should the BPS become exposed to blood or blood components requiring disinfecting, please perform the daily cleaning procedure outlined below, place the unit in a biohazard bag, and notify Apex using the return information below. Additional shipping instructions will be provided. A replacement BPS device may be obtained from Apex.

Please send all returns to the following BPS Return Address:

Apex Biologix
Attn: BPS Return
2561 S 1560 W, Suite B
Woods Cross, UT 84087
844-897-4910
orders@apexbiologix.com

Maintenance

The BPS is a maintenance-free device, but damage may occur overtime due to improper handling / use. In the event the device does not perform as intended, or is visibly damaged, please return to Apex Biologix for evaluation. Include the appropriate contact information with a description of the identified issue(s); this information may also be sent to orders@apexbiologix.com.



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Cleaning Procedure

Prior to performing the step-by-step instructions outlined below, please review the images of the BPS device and associated components.

Supplies and Equipment

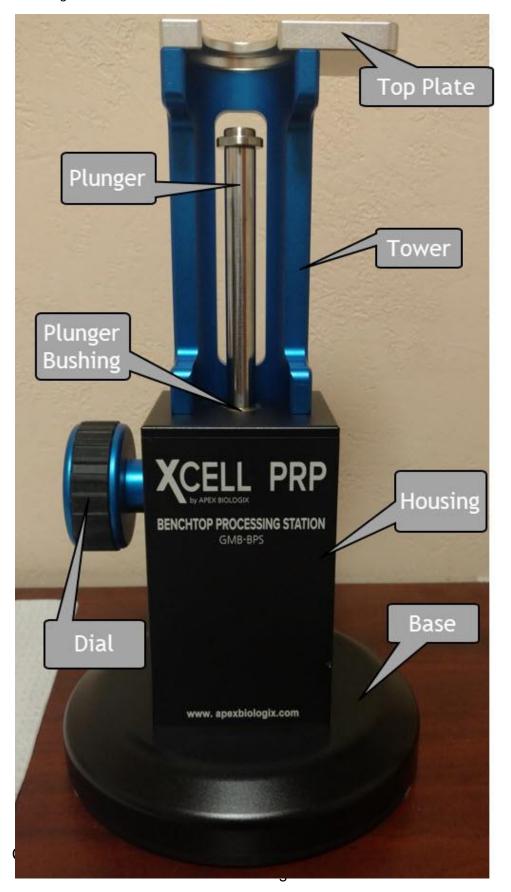
- 1. Gloves, lab coat, goggles
- 2. Warm water
- 3. Lint-free cloth / gauze or cleaning pads
- 4. Neutral detergent or 70% IPA. Approved detergents:
 - a. 10% bleach (or 5500 PPM) solution
 - b. Oxycide, by ECOLAP, mixed per manufacture instructions
 - c. Oxivir, by Diversey, mixed manufacturer instructions
- 5. 70% Isopropyl Alcohol (or equivalent cleaning pads)
- 6. Biohazard bag

Caution: Do not use acetone, caustic detergents, or detergents that contain chlorite ions, hydroxide, silica, or phosphates, which can corrode the anodize coating of the BPS and/or cause oxidation. Do not use steel wool, metal tools, wire brushes or other abrasives as they could likewise damage the anodize coating.

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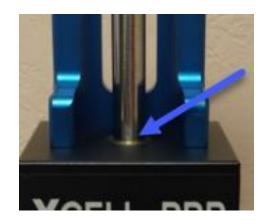
Figure 1: BPS Device





- 1. Dress in Personal Protective Equipment (gloves, lab coat, goggles), as applicable.
- Begin the cleaning process by inspecting the entire device for exposure to biologic contaminants. If heavily contaminated, or contamination inside the BPS Housing is suspected, please refer to the disinfection instruction above.
- 3. Visually inspect the BPS device for any cracks or other surface damage caused by improper handling.
 - a. If any damage is noted, please contact Apex Biologix for further assistance, at orders@apexbiologix.com; include a description and a picture of the damaged BPS.
- 4. Place the Plunger in the full-up position, as seen in the images below.
- Dampen lint-free cloth with neutral detergent. Wipe down the entire device with the cloth, removing any biologic contamination. Note: the cloth and BPS should not be dripping. If so, excessive detergent has been applied and should be removed.
- 6. Using a lint-free cloth, dry the BPS with special attention to the Plunger and the Plunger Bushing (blue arrow). These areas should be fully dry before proceeding.

Tip: Its helpful to cycle the Plunger up/down to expose excess detergent, allowing more complete drying.



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- 7. Using 70% IPA cleaning pads, wipe down all surfaces of the BPS, paying specific attention to following areas:
 - a. Top Plate: top and underside where the Concentrating Device meets the Top Plate.



Figure 2: Top Plate

b. Plunger: Wipe down the top of the plunger



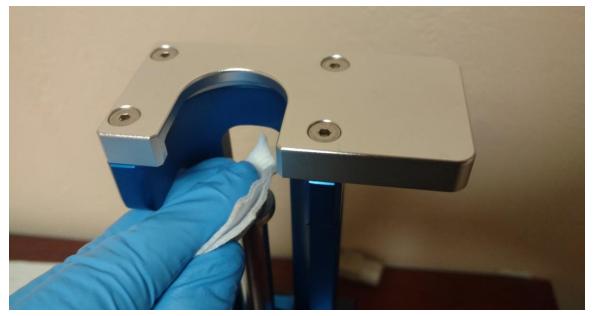


Figure 3: Plunger

c. Dial: Wipe down the Dial on all sides.

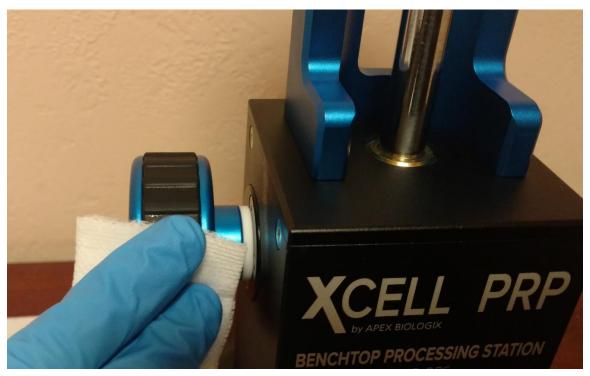
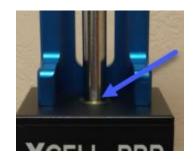


Figure 4: Knob



- 8. When cleaning is complete, move the Plunger to full up position and verify it is dry. Perform additional drying asneeded and/or wipe with 70% IPA pad. When fully dry, move the Plunger to it down position.
- BPS cleaning is complete. The BSP should be stored in an appropriate location consistent with other medical reuse hardware.



10. Dispose of the used cleaning material in a biohazard bag and in accordance with local regulations.

BPS Warranty & Cautions

The manufacturer, Apex Biologix, warrants that the BPS (Benchtop Processing Station, PN 80-003) is free from defects in materials and workmanship under normal and proper use for two (2) years from the date of purchase. Apex will exchange or repair (at Apex discretion) any BPS found to be defective during the two (2) year period specified.

This warranty will be considered void if, in Apex's opinion, defects or damage has been caused by neglect, misuse, improper storage or improper cleaning. If voided, the user is responsible for repair or replacement costs.

This equipment is intended to be operated by properly trained personnel who have read all applicable training materials related to the equipment and are familiar with its functions. Operation of the equipment by untrained or unfamiliar personal may create a safety hazard and/or warranty violation.

For questions or concerns regarding the BPS cleaning, maintenance, or warranty please contact Apex Biologix.

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