

BAX® System

RETURN AUTHORIZATION AND DECONTAMINATION FORM

Hygiena International 8 Woodshots Meadow Watford, Hertfordshire WD18 YU Hertfordshire United Kingdom Telephone: +44 1923 818 821

Email: customerserviceuk@hygiena.com

Attach this form to the outer shipping container before returning equipment to Hygiena International

| This document must be completed in full and signed before product is returned to Hygiena International. | | | |
|--|--|---------------|----------------------------|
| All equipment must be thoroughly decontaminated to comply with shipping regulations | | | |
| Customer Questionnaire | | | |
| Instrument / model / type: | | | |
| Instrument / module serial number: | | | |
| Reason for return: | | | |
| Case number: | | | |
| Has this product been exposed to any infectious agents assigned to biosafety levels 2, 3 or 4? | | | \square Yes \square No |
| If yes, please indicate agent and biosafety hazard class: | | | |
| Has this product been exposed to toxic or carcinogenic substances? | | | ☐ Yes ☐ No |
| If yes, please indicate types and quantities used: | | | |
| By accepting authorization to return this product, I assume all responsibility and liability for biological and chemical decontamination and cleaning. I understand that Hygiena International has no obligation to process this equipment unless adequate information is provided to ensure the safety of all personnel handling the exposed product. | | | |
| Customer Name (print): | | Title: | |
| Company / Institution: | | Phone number: | |
| Signature and date: | | Fax number: | |
| | | | |
| Decontaminator Questionnaire | | | |
| Has this product been thoroughly decontaminated according to the protocol described in this return authorization form? Hygiena International will not accept product that has not been decontaminated according to the provided procedures. | | | □ Yes □ No |
| Were any additional decontamination procedures used to clean or disinfect this product? If yes, please describe. Attach additional documentation if necessary. | | | |
| Decontaminator Name: | | Title: | |
| Company / Institution: | | Phone number: | |
| Signature and date: | | Fax number: | |

Effective date: 07/07/2021

BAX® System Instrument Decontamination Protocol

This document establishes the procedure for the cleaning and decontamination of the BAX System instrument and standard equipment.

This procedure applies to all BAX® System equipment being returned to the Hygiena International Distribution Center for repair and/or replacement and to modules currently received at Hygiena International.

It is the responsibility of the customer to perform this procedure before returning equipment to Hygiena International.

Required Equipment

- Gloves Neoprene or equivalent
- Eye Protection Safety glasses, goggles, or face shield
- Lab Coat
- 70% Isopropyl alcohol
- 1:10 solution of 5.25% bleach Clorox or equivalent
- Deionized water

Safety Precautions

Always power off and unplug all equipment before beginning the decontamination procedure. Ensure that all equipment has cooled to room temperature.

Avoid direct contact of the exposed electronic circuit boards or electrical connections with wet disinfecting wipes, water or isopropyl alcohol. Permanent damage may occur.

Never submerge a module into water, alcohol or other disinfecting solutions. Permanent damage to the module may occur.

Decontamination Procedure

BAX® System cycler, computer, heating blocks, any other returning lab equipment.

- 1. Use a towel with applied bleach solution to thoroughly wipe the following sections of the equipment
- 2. Let the equipment sit with the solution visibly wet on the surfaces for at least 5 minutes.
- 3. Wipe all surfaces with 70% isopropyl alcohol to remove any bleach residue.
- 4. Discard all used materials according to your labs SOP.



Hygiena BAX® System Q7

Hygiena International

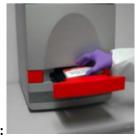
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Service Instrument Shipment

This Service BAX® Q7 instrument has been shipped to you in either a custom designed wooden crate or Kubox Shipping container. These are designed to contain and protect the instrument during shipment. Please follow directions below based on which container has been sent.

Before shipping your BAX® System Q7 for repair, please make sure that these steps have been completed. If not, the optics in the BAX® system Q7 cycler might be damaged during transportation. These instructions are also mentioned in the BAX® System Q7 User Guide Section: "Shutting Down the System":



- 1. Load the shipping plate that came with the system back into the tray:
- 2. Select DIAGNOSTICS > CYCLER from the menu bar. The Instrument Diagnostics window opens.
- 3. Select Control Block and Raise from the list of options.
- 4. Click the RUN button. The bottom pane of the window displays the status.



5. Power down the instrument.

This procedure allows the instrument optics block to rest upon the plate, protecting it during storage or shipment.

Note: Do not turn on power to the instrument after performing this long-term shutdown procedure until the instrument is in place for use. Powering on the instrument lowers the plate, exposing the optics block to potential damage during storage or shipment. If you power on the instrument by mistake, make sure to repeat steps 2-5 for long-term shutdown.

Wooden Crate Unpacking:

- 1. Release the 2 latches by turning the handles counterclockwise.
- 2. Open the hinged front and top panels.
- 3. Remove the top foam padding
- 4. The instrument can now be lifted out of the crate.

Wooden Crate Outbound Shipment:

- 1. Place the defective instrument inside the shipping crate along with a completed equipment return form.
- 2. Place the foam pad on top of the instrument, then close and latch the shipping crate doors.
- 3. Affix the enclosed pre-addressed FedEx Airbill to the top of the crate.

Kubox Unpacking:

- 1. Slide black pins out of each top corner using any flat tool. Keep pins! These are needed for reassembly.
- 2. Take off top cover and sides as necessary, then remove the BAX® Q7 instrument. Keep sides and internal foam, these are needed for reassembly!

Kubox Repacking:

- 1. Place broken instrument in bottom Kubox, with the mini pallet underneath. Make sure the bottom foam is present and the Q7 slides into it in the correct direction.
- 2. Re-assemble the sides, and top lid just as it was shipped to your location. Make sure the top foam is also in place to hold the Q7 in place.
- 3. Slide the black pins back into the top corner holes to lock the lid and sides in place.

A sheet with Kubox directions is also sent in the shipment. The Kubox website can provide assistance as well.

Please – Included are 3 strapping bands and buckles. Please affix these to the outside of the crate. FedEx could refuse pickup if these are not installed.

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