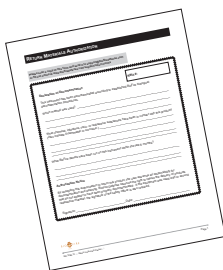


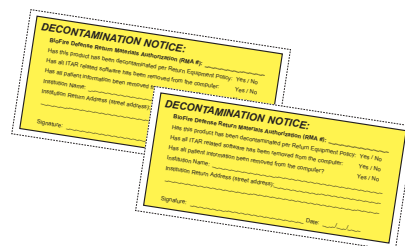
INSTRUMENT RETURN PROCEDURES

An instrument problem may be reported by calling, e-mailing, faxing or mailing BioFire Defense. The contact numbers are located below. You will also need the following documents:

Declaration of Decontamination



Decontamination Labels (2 labels)



Phone	E-mail
1-801-262-3592 - United States and Canada IDD+1-801-262-3592 - International	support@BioFireDefense.com - Technical Support
Address	Website
BioFire Defense Service Center 79 West 4500 South, Suite 15 Salt Lake City, UT 84107 USA	www.biofiredefense.com/support/return-forms

REPORTING AN INSTRUMENT PROBLEM AND RETURNING AN INSTRUMENT

If you need assistance with your BioFire Defense instrument or a problem with the instrument occurs, contact BioFire Defense Technical Support. If the problem cannot be worked out onsite, then Technical Support will issue an **Return Material Authorization (RMA)** number and instructions for returning the instrument. The steps for returning an instrument are listed below.

1 Obtain an RMA Number

 **NOTE:** An RMA number is absolutely necessary for returning an instrument.

You should receive an RMA number when you initially contact Technical Support. If you did not receive an RMA number at that time, contact Technical Support for a number. You will need to supply the serial number and purchase date of the instrument, if your instrument is still under warranty. If your instrument is out of warranty, please supply a blank PO# for the repair charges.

The RMA number must be recorded on the Decontamination Form and the Decontamination Labels.

2 Decontaminate All Returned Equipment

You must decontaminate all equipment being returned to BioFire to remove amplicon contamination and to ensure that personnel handling the equipment are not harmed by pathogenic organisms.

1. Put on a lab coat and gloves.
2. Wipe the area to be decontaminated with water.
3. Wet a paper towel with 10% bleach (1-part bleach to 9-parts water) and wipe the exterior of the instrument, the surface of the inner sample chamber and under the lid.
4. Change gloves.
5. Repeat steps 3 to 5 twice with fresh paper towels for a total of three bleach wipes.
6. Wet a paper towel with distilled water and wipe the exterior of the instrument, the surface of the inner sample chamber and under the lid.
7. Change gloves.
8. Repeat step 6 with a fresh paper towel



Biological Lab Decontamination

The person responsible for the return must thoroughly survey the instrument for contamination and ensure its compliance to regulations. If the instrument has been used with live agents, a licensed person must complete the necessary forms and follow standard procedures by law.


3 Use the Decontamination Labels and Form

After the above steps have been completed, you must complete and sign two decontamination labels. Attach one label to the instrument and the other to the exterior of the shipping container.

You should also complete and sign the Declaration of Decontamination form. Make a photocopy for your records, and place the original with the instrument. Two copies of removable forms and labels have been provided for your convenience.

4

Packaging and Shipping

 **NOTE:** To ensure there is no loss of data, any computers being returned must be backed up before shipping. BioFire Defense is not responsible for any lost data. Additionally, be sure that all ITAR related software has been removed from the computer before shipping. Contact BioFire Defense Technical Support for any software or ITAR questions.

1. Pack instruments as follows: (see instrument operator manual for box dimensions). **Please include the completed Decontamination Form.**
 - **RAZOR® Instruments:** Place instrument in the Pelican™ case with its accompanying accessories. Place Pelican case in a large heavy-weight box. (See an appropriate *RAZOR Operator's Manual* for an accessories list and box dimensions.)
 - **BioFire FilmArray® / FilmArray Torch Instruments:** Place all accessories, instrument, and the laptop computer back in the original packaging, if available. If the original packaging material is not available, contact BioFire Defense Technical Support. If you are returning the instrument to BioFire Defense, follow the procedures outlined in Instrument Return Procedures in the *appropriate FilmArray Operators Manual*. Repair returns may not require all accessories to be returned. BioFire Defense Technical Support will advise.
4. Fill all sides and top of the shipping box around the instrument and accessories with at least 2 in. of packing material for protection against shipping damage.
5. Seal the box with packing tape.

 **NOTE:** The RMA number and decontamination label must be visible on the exterior of the shipping container.

 **WARNING:** BioFire Defense reserves the right to return or refuse receipt of any materials at the customer's expense that do not meet the above requirements.

All returns should be sent to the following address:

BioFire Defense Service Center
79 West 4500 South, Suite 15
Salt Lake City, UT 84107
USA

Contact BioFire Defense Technical Support with any packaging or shipping questions (see page 1 for contact information).

RETURN MATERIALS AUTHORIZATION

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This form can be filled out online at www.biofiredefense.com/support/return-forms or can be emailed or faxed to our return center. It must also be included with the returned instrument.

If your equipment is still under warranty, please supply the purchase date and instrument serial number. If your instrument is out of warranty, please supply a blank PO# for the repair and shipping charges. Visit www.biofiredefense.com/support/return-forms to obtain price information for nonwarranty service and repairs. Please note that your item must be returned with a BioFire assigned RMA# and decontamination documentation.

Personal Info

Name: _____
Company: _____ Department _____
Phone: _____ Fax _____
Email: _____

Instrument Info

Is the instrument under warranty? Yes No
Model No: _____ Serial No: _____
Computer Serial/Service No: _____
Computer Login Username _____ Computer Password _____

Billing Info

RMA or PO No: _____
If your instrument is out of warranty, please supply a PO number for repair and shipping charges

Notes

Ship Instrument to

BioFire Defense Service Center
79 West 4500 South, Suite 15
Salt Lake City, UT 84107
USA

The decontamination form and labels must be completed before the instrument is returned to BioFire Defense. If the unit is returned without decontamination documentation, it will be shipped back to you at your expense. If the unit cannot be repaired, it will either be returned to you or disposed of upon your request. Thank you for your business and for supporting the health and well being of our employees.

Signature: _____ Date: _____



Please scan a copy of this form and send it to support@biofiredefense.com or fill out online at www.biofiredefense.com/support/return-forms

RMA #:

Declaration of Decontamination

This instrument has been decontaminated according to established BioFire biological decontamination procedures.

Which method was used? _____

What chemical, infectious, toxic, or radioactive substances have been in contact with this product? (Also indicate if flammable or corrosive.) _____

What BioFire panels have been run on this instrument within the last 6 months?

Authorization Notice

By accepting this authorization to return this product, the user assumes all responsibility for decontamination and cleaning. BioFire Defense reserves the right to refuse the delivery of products that do not appear to have been properly decontaminated. If the equipment was used with or around radioactive material, the signature of the safety officer is also required.

Signature: _____ Date: _____



DECONTAMINATION LABELS

Please complete these decontamination labels and affix one to the instrument and the other to the exterior of the shipping carton next to the shipping label. Failure to decontaminate before shipping to BioFire Defense will result in the immediate return of the instrument at your expense.

Cut out label and attach it to the product being returned.

DECONTAMINATION NOTICE:

BioFire Defense Return Materials Authorization (RMA #): _____

Has this product has been decontaminated per Return Equipment Policy: Yes / No


Has all ITAR related software has been removed from the computer: Yes / No

Has all patient information been removed from the computer? Yes / No

Institution Name: _____

Institution Return Address (street address): _____

Signature: _____ Date: ____/____/____



Cut out label and attach it to shipping container.

DECONTAMINATION NOTICE:

BioFire Defense Return Materials Authorization (RMA #): _____

Has this product has been decontaminated per Return Equipment Policy: Yes / No

Has all ITAR related software has been removed from the computer: Yes / No

Has all patient information been removed from the computer? Yes / No

Institution Name: _____

Institution Return Address (street address): _____

Signature: _____ Date: ____/____/____

