RAZOR® Mk II
Operator's Manual

For Environmental and Basic Research Use
Not for Diagnostic Use

CE

BIOFIRE DEFENSE
A bioMérieux Company

This document is used solely for the purpose of RAZOR® Mk II Instrument Operation. This document shall not be duplicated, used, or disclosed in whole or in part for any purpose.

Always maintain the instrument in good working order. If the instrument is used in a manner not specified by BioFire Defense, then protection provided by the equipment may be impaired.

CUSTOMER AND TECHNICAL SUPPORT

Reach Us On the Web

BioFire Defense Web site
http://www.BioFireDefense.com

We strongly encourage users to visit our Web site for answers to frequently asked questions, updated information, and additional insights into operating the RAZOR Mk II System.

Reach Us By E-mail

Contact BioFire Defense by e-mail
support@BioFireDefense.com - Technical Customer Support

Reach Us By Phone

Technical Support is available during the following times:
8 a.m. to 5 p.m. - Mountain Standard Time

For Technical Customer Support call
+1 (801) 262-3592

International Returns

Call Technical Customer Support for instructions on returning instruments from outside of the United States.

CONTENTS

ABBREVIATION OF TERMS

-.....negative
+.....positive
A.....amp (ampere)
BFDF .....BioFire Defense
CD-ROM .....compact disk read-only memory
cm .....centimeters
Cp .....crossing point
DC.....direct current
DNA .....deoxyribonucleic acid
dNTP.....deoxyribonucleotide triphosphate
FRET.....fluorescence resonance energy transfer
F.....fluorescence
LED .....light emitting diode
min. .....minute
mL .....milliliters
nm.....nanometers
OS.....operating system
PBS.....phosphate-buffered saline
PCR .....polymerase chain reaction
POST .....power on self-test
PPE.....personal protective equipment
PTFE.....polytetrafluoroethylene (Teflon)
RNA .....ribonucleic acid
sec. .....second
SNP.....single nucleotide polymorphism
Taq .....enzyme from *Thermus aquaticus*
Tm.....melting temperature
USB .....universal serial bus
UV.....ultraviolet
V .....volt
W .....watt

SYMBOLS GLOSSARY

The following symbols can be found on the instrument, on pouches, or throughout this manual. Use the definitions below as a guideline for interpreting the symbols.

ISO 7000 Graphical Symbols for Use on Equipment – Registered Symbols					
3082 	Manufacturer	2492 	Batch Code (Lot Number)	2607 	Use-By Date (YYYY-MM-DD)
1641 	Operator's Manual	0632 	Temperature Limit	0659 	Biological Risks
W017 	Caution, Hot Surface		0434A 	Caution	
European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)					
	WEEE - Do not throw in trash			European Conformity	
Manufacture Symbols (BioFire Defense, LLC)		**USB Implementers Forum**		**Underwriter's Laboratory Listing Mark for Canada and the United States**	
	NOTE - explains how to operate the instrument more efficiently.		USB cable		Underwriter's Laboratory Listing Mark

CHAPTER 1: TECHNICAL COMPONENTS

INTRODUCTION

BioFire Defense's (BFDF) RAZOR Mk II instrument is a user-friendly real-time polymerase chain reaction (PCR) system that requires no special lab equipment or skills. Some of its unique features that make it ideal for field use include the following:

- The instrument can run repeatedly on a rechargeable battery pack or a DC power supply.
- The instrument doesn't require a computer for operation. Although data can be downloaded, stored, and printed on a computer using a universal serial bus (USB) (Contact Technical Support for desktop computer software).
- You can easily use a needle-free syringe to insert samples into a pouch with self-contained freeze-dried chemical reagents.
- Test pouches are provided with a preparation kit that includes all the necessary components to collect and prepare test samples.
- You can scan the barcode on the pouch to program the instrument. The instrument displays positive calls in real time.

The technology behind the RAZOR Mk II instrument is based on advanced laboratory principles and techniques; however, the system is designed for users who have minimal laboratory experience. This manual provides comprehensive step-by-step instructions on how to prepare and load samples; perform, view, and analyze runs; perform maintenance; and troubleshoot common errors.

The RAZOR Mk II Instrument's major components

How the RAZOR® Mk II Instrument Works

The RAZOR Mk II Instrument operation is based on fluorimetric measurements and PCR. PCR uses heating and cooling cycles to make copies of target deoxyribonucleic acid (DNA) which are the genetic material of an organism. For more details, see *Appendix A*.

This instrument is designed to run 12 samples at one time in a flexible sample pouch. Each sample pouch contains freeze-dried reagents designed to detect specific biologic agents. These freeze-dried reagents contain everything needed to identify one or more specified target agents in an unknown sample.

After the user prepares the reagent pouch, it is inserted into the instrument through the top slot. The instrument moves samples between heat zones to achieve temperature cycling. During temperature cycling, reagents in the pouches copy or amplify target DNA that is present. The sample pouch sits next to fluorimeter optics, where the instrument can take real-time fluorescence readings during the run. As more copies are made, the sample fluorescence increases. Over many cycles, the fluorescence increase has the shape of an exponential curve showing amplification of the target.

If the organism being tested has RNA as its genetic material, reverse transcription must be performed. This requires that the pouch be held at a steady temperature for an extended period of time, after which PCR is performed.

The RAZOR Mk II software makes pathogen identification simple due to its ability to make positive calls as they occur during the run.

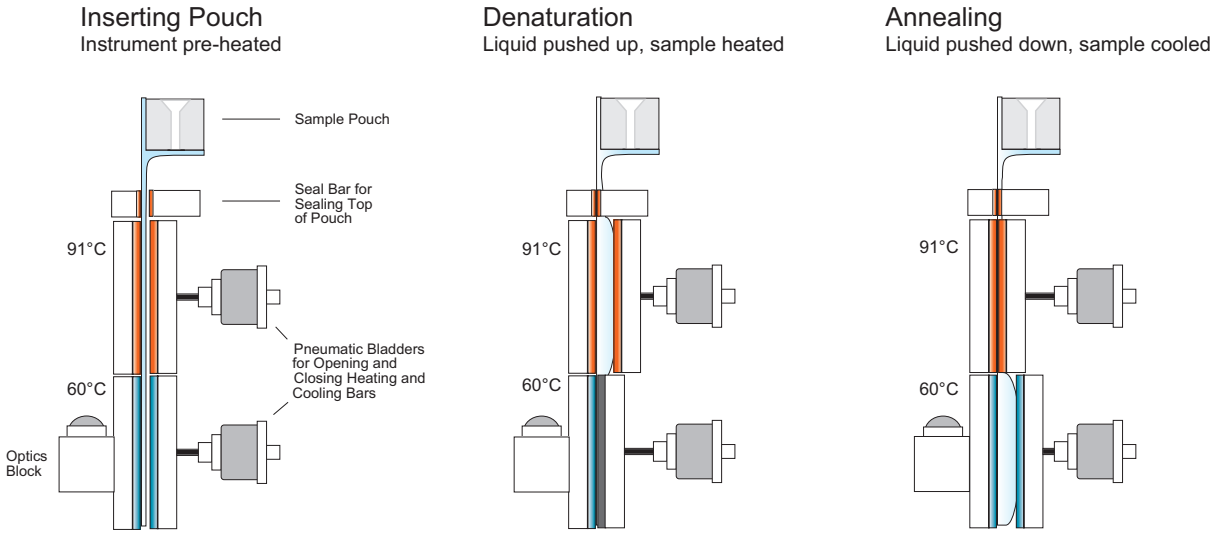
The RAZOR Mk II can do multiple runs and analyses as a hand portable instrument in the field. The instrument can run and store 100 runs per assay before management of the run data is necessary. After using the instrument, you can download the run data to a computer for storage, review, and printing.

Display Keypad

Note: To turn off instrument, press the Power Button on the key pad.

Button Name	Function
Power	Turns power on and off (press for 5 sec.)
Arrow Back	Takes user back to the previous screen
Arrow Up	Allows user to scroll up in a screen
Arrow Down	Allows user to scroll down in a screen
Orange Select	Selects highlighted option on the screen

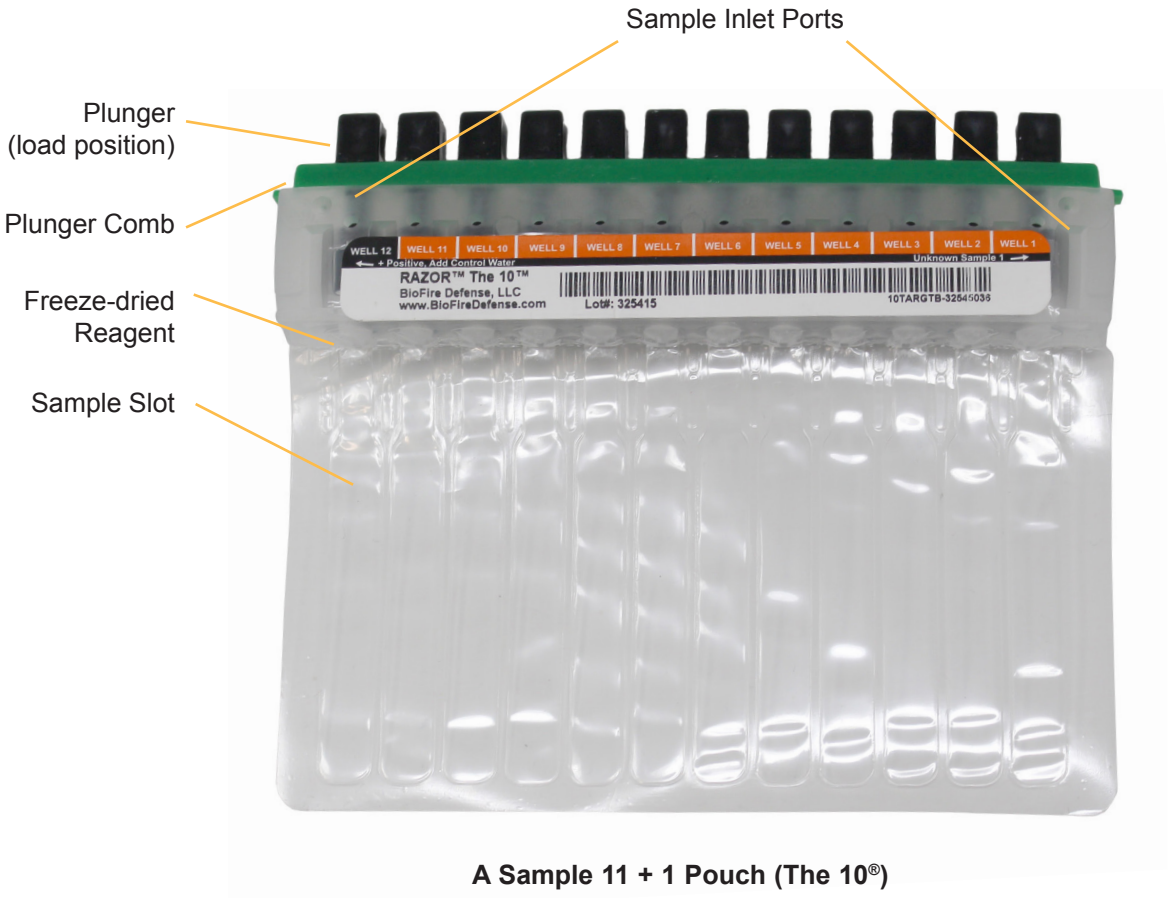
Running a Pouch in a RAZOR



Schematic of a sample pouch inserted into a RAZOR instrument

The above cross-section of the RAZOR shows how the instrument moves samples between heat zones. The reagent pouch is described in more detail below.

RAZOR Reagent Pouches



A Sample 11 + 1 Pouch (The 10®)

Pouch Bottom

The RAZOR reagent pouches are made of thin, clear, flexible plastic attached to a semi-flexible loading body. The clear plastic provides a large surface area to allow for rapid heat exchange and efficient fluorescence monitoring. Preparation of the sample pouch does not require a centrifuge or a pipette, making it ideal for field use. Liquid or powder samples are collected, prepared in liquid, and inserted into the pouches with syringes. When the syringe is inserted into the inlet port, the correct amount of the liquid sample is drawn by vacuum into the sample pouch. The reagent pellet, freeze-dried inside each well, dissolves upon contact with the liquid sample. Each vacuum-sealed sample pouch contains freeze-dried reagents and are labeled with a **rectangular** barcode that contains the pouch lot and serial number. The pouch comes with a sampling kit for liquids, powder, or surfaces, as well as a loading kit containing syringes, sample buffers, and reagent grade water.

Equipment Specification

Sample Description	• 12-reaction capacity • Plastic reaction pouch • Pouch dependent (see directions for each reagent pouch)
Fluorescence Acquisition	• Single-color optic module • Blue LED excitation with peak excitation of 470 nm • Emission wavelengths of 690 nm
Power Supply	• 24Vdc 6.25A external power supply (included) • Rechargeable battery pack (included); 5 runs per charge when instrument is run at temperatures between 0°C and 40°C
Power Input	• 100 - 240V, 47-63 Hz, 2.5 A, 150W
Dimensions and Weight	• Approximate size (W x D x H): 26 x 11 x 19 cm (10.25 x 4.5 x 7.50 in.) • Weight: 4.9 kg (11 lbs)
Performance Parameters	• Instrument setup time ≤ 5 min. • PCR in less than 30 min.
User Interface	• Bar code reader to load run-specific information • Color screen, large membrane push-button interface
Data Output	• Real-time display of fluorescent readings • USB support for data download and archiving • Automatic analysis with end-of-run interpretive calls • Real-time positive calls

Environmental Parameters

Description	Specifications
Ambient temperature required to maintain specifications during operation	0°C - 40°C (32°F - 104°F)
Humidity	20% to 90%, noncondensing*
Altitude	Sea level to 3048 m (10,000 ft)
Shipping/storage conditions	-20°C - 60°C (-4°F - 140°F)

Note: *Condensation can be damaging to the instrument. If removing the instrument from long-term cold storage, warm the instrument gradually to prevent condensation.

CHAPTER 2: INSTALLATION AND SET UP

INTRODUCTION

This chapter describes the following:

- Setting up the instrument
- Power connection
- Pouch preparation
- Battery charging
- Loading protocols

INSTALLATION OF THE RAZOR MK II INSTRUMENT

Installation Requirements

The requirements for space and power are:

- 13 x 9 in. (approx. 33 x 23 cm) of space
- 24Vdc 6.25A power supply or the rechargeable battery pack (included with the instrument)

Setup Conditions

For operation, select a clean, well-ventilated area that is large enough for the instrument and power supply to operate correctly. Additionally, be sure that the work space is large enough for the instrument to quickly be disconnected from the power source if a problem should occur.

Note: Even when using the power supply, run the RAZOR Mk II with the battery installed to guard against unexpected power failures and intermittent or poorly regulated power.

Note: Cold temperatures may decrease the battery life.

CAUTION: When you use the instrument, the instrument and the pouch will be hot. Handle both the instrument and pouch with caution.

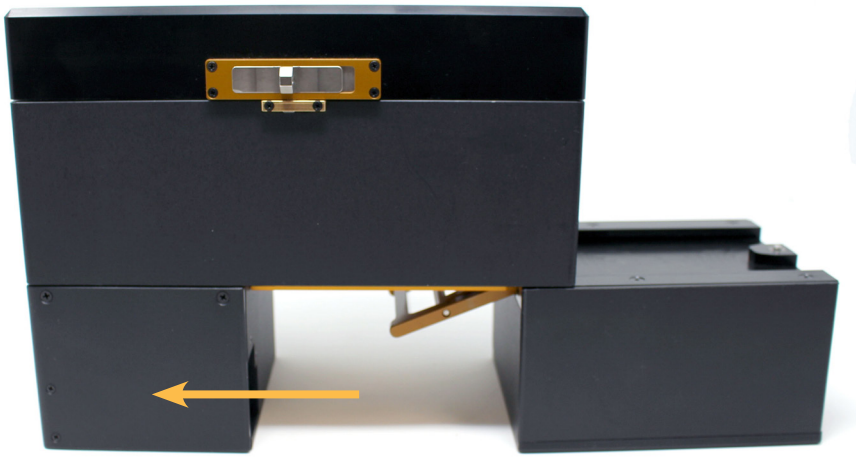
Setting Up the Instrument

1. Unpack the RAZOR Mk II instrument from the carrying case and set it on a solid, flat surface. The battery is separated from the instrument to prevent the battery from depleting during storage.

Note: Save the boxes and shipping material that accompany the instrument so that it can be packaged correctly if the instrument is shipped to a different location.

2. Slide the battery into position on the bottom-right side of the instrument and confirm that the locking pin slides into place. Use the label on top of the battery as a guide to help insert the battery correctly.

Note: The instrument stand may need to be collapsed to slide on the battery.



Slide Battery onto the Bottom of the Instrument

Note: If the internal components have been serviced by the user, confirm that the internal movable heater is closed and locked into place before you turn on the instrument. Refer to *Chapter 4, Maintenance and Troubleshooting, "Accessing Heater Bars and Optic Lenses*," for more information.

3. Unlock the lid by sliding the lid latch to the right.

4. Open the protective lid.

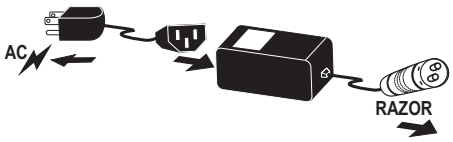
5. Press and hold the **Power** button for 5 sec. to turn the instrument on. The screen will activate and display its current status. The instrument performs a self-diagnostics test when turned on. If the machine generates an error message, refer to *Chapter 4, Maintenance and Troubleshooting*.

POWER INPUT

The RAZOR Mk II instrument can be powered by the supplied RAZOR Mk II battery or by external power using the 24V power supply provided with the instrument (**Note**: This is the same supply that is used to recharge the battery). If you connect both power sources, you can hot swap between the RAZOR Mk II battery and external power. If external power is plugged in, the instrument will use the external power as its default.

External Power Supply

1. Plug the 24V power supply into a grounded power source.
2. Connect the other end to the RAZOR Mk II power port by lining up the red dots and pushing the locking connector into the power port receptacle. To remove the cable, retract the knurled collar on the plug.



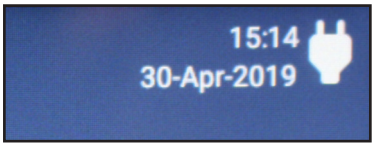
Battery Maintenance

The RAZOR Mk II battery allows approximately 5 runs at 25°C ambient when fully charged. Be sure to charge the battery before taking the instrument into the field. If the battery power is low, a prompt from the instrument will advise you to charge the battery or switch to the power supply.

Note: The battery will allow 5 runs per charge when runs are performed in temperatures between 0°C and 40°C.

Battery Level Indicator

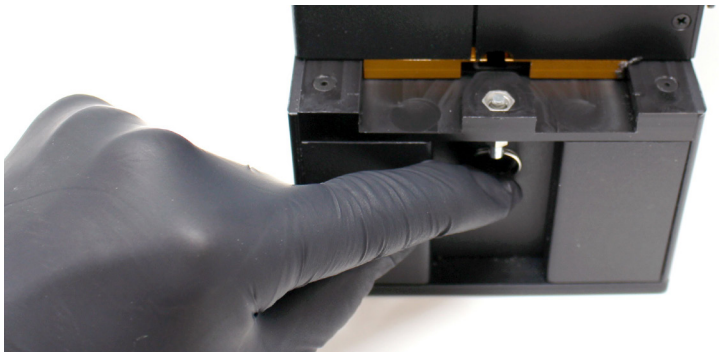
The RAZOR Mk II contains a battery level indicator. This can be viewed at the top of most screens. Additionally, when external power is connected to the instrument, the battery indicator will change to a plug icon.



Battery Removal

WARNING: Unless the instrument is plugged in, do not change a battery while the machine is running. If you have to change a battery mid-run, plug in the 24V power supply to the external port first or you will lose the run data. **IF YOU LOSE THE RUN DATA, YOU CANNOT RECOVER IT.**

1. Locate the locking pin on the lower left side of the RAZOR Mk II and pull the pin down to unlock the battery.

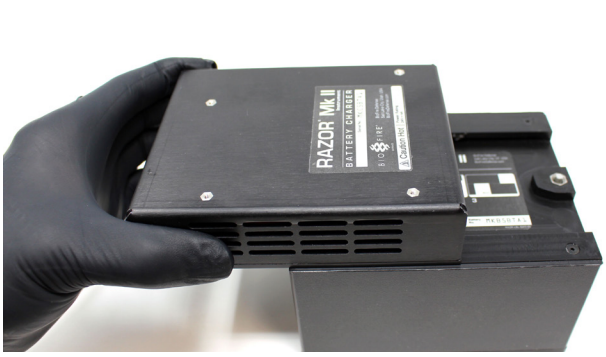


2. Slide the unlocked battery out from the instrument. An instrument stand will release from the bottom to support the instrument.

Recharging Batteries

Note: Keep the vent on the charger free of obstruction.

1. Turn the instrument off by pressing the **Power** button, then selecting **Power off**.
2. After the RAZOR Mk II turns off, remove the battery by pulling the pin down and sliding the battery off the bottom of the instrument.
3. Line up the battery and the recharger. Slide the battery onto the recharger.
4. Plug the 24V power supply into a grounded AC power source and connect the other end to the recharger. When the recharger is plugged in, the red light will come on.



5. Allow the battery to charge. The green light blinks while the battery is charging. When the battery charge is full, the green light will be solid.

Note: A fully depleted battery takes approximately 4 hours to fully charge. The battery does not charge when it is plugged into the RAZOR instrument.

SAMPLE HANDLING

HAZARDOUS MATERIAL: Use standard laboratory procedures when you handle biohazardous material. Sample pouches are made of plastic and, if damaged, could cause contamination. Consider all samples biohazardous and carefully dispose of pouches and syringes in a biohazard waste container.

Note: When you handle and load samples, avoid contamination problems by using standard laboratory techniques and following appropriate protocols for loading samples. Change gloves frequently to avoid cross-contamination of samples.

The format of the RAZOR Mk II freeze-dried reagent pouches are target specific and fixed. The reagent pouch is disposable and contains all of the ingredients for real-time fluorescent detection of target nucleic acid using the RAZOR Mk II system. Each pouch has a unique serial number and corresponding **rectangular** barcode. The unknown samples for the RAZOR Mk II are loaded in liquid form into the freeze-dried reagent pouch.

LOADING PROTOCOLS

Run protocols for each RAZOR test kit have been pre-programmed into the instrument allowing for quick and simple pouch loading. However, if a protocol is removed and needs to be loaded back onto the instrument, follow the steps below.

Note: The lens of the barcode reader needs to be free of dust and scratches to scan the protocol and pouch barcodes. See "*Barcode Reader Window Cleaning*" in *Chapter 4, Maintenance and Troubleshooting*, for cleaning instructions.

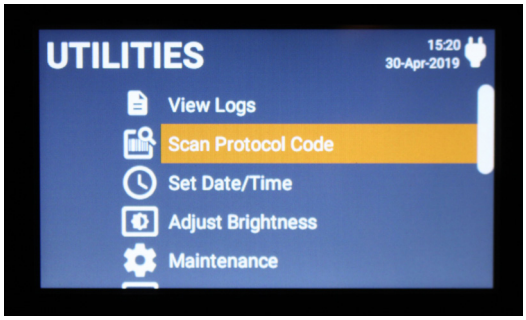
Protocols are preprogrammed in the **square** barcode printed on the Assay Card that is included with each kit. Use the barcode reader to scan them into the instrument. If you prefer, you may scan the protocols into the instrument before you take the RAZOR Mk II to the field.

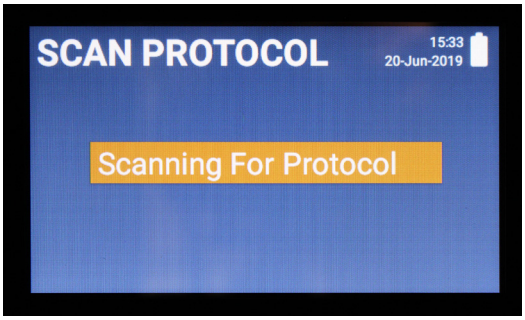
Kit Part Number: PATH-ASY-0092
Protocol Code: GENERICB

You will also need to verify that the run protocol for this test is loaded onto the instrument before you load the sample into the pouch by scanning the **rectangular** barcode printed on the sample pouch label. If the protocol has not been loaded before the **rectangular** barcode is scanned, a message appears that prompts you to load it.

GENERICB-GENB0002

1. To load the protocol, select **Main Menu > Utilities** by using the Up and Down arrows and the Select buttons, select **Scan Protocol Code**. Confirm the steps by following the screen prompts.





2. Scan the **square** protocol barcode found on the Assay Card using the barcode reader on the back of the instrument.
3. After you scan the protocol barcode, return to the Main Menu by selecting **Back**. See *Chapter 3* for instructions on loading the pouch barcode information.

Note: Be sure that all barcodes are smooth and flat for an easy scanning experience.

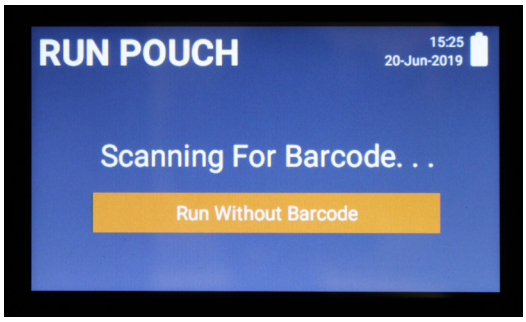
Note: During the scan, the barcode reader emits a bright green aiming beam surrounded by red light. Hold the barcode approximately 6 - 8 inches from the back of instrument and move the bright green aiming beam close to the barcode to scan. If you hold the barcode more than 8 inches away from the reader, you will need to center the green aiming beam on the barcode to scan.

When the scan is complete, the aiming beam turns off and the instrument will display the **Starting Run** screen. If the scan does not complete within 15 sec., flatten the image and/or move the barcode gradually closer to the instrument to scan it.

LOADING PROTOCOLS WITHOUT A BARCODE

If the square (protocol) barcode is not available or not functioning, users have the option of selecting a preloaded protocol on the RAZOR Mk II.

1. From the **Main Menu**, select **Run Without Barcode**. This will bring up the **Select Protocol** screen.



2. Scroll through the available protocols and select the one that applies.

3. Once a protocol has been selected, the user will be taken to the **Starting Run** screen. Follow the screen instructions from this point on to prepare and load the sample onto the RAZOR Mk II.

WARNING: The barcode on each pouch includes the pouch protocol and serial number which are critical information needed for the run. It is recommended to always run a pouch using the barcode when it is available.

POUCH PREPARATION

The following instructions are for a typical pouch loading example (4 x 3 format). For specific instructions for each pouch, see the *RAZOR Pouch Instruction Booklet* and assay card supplied with each test kit.

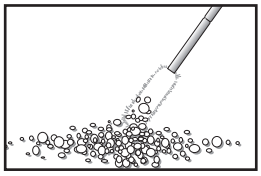
Note: Always ensure that you use the supplied control and sample buffers. Using buffers that do not come with this kit may result in the controls and/or samples failing.

You need the following materials to prepare a pouch.	
RAZOR pouch containing freeze-dried reagents in a foil bag	Syringes with tips
Unknown sample bottles	Reagent grade water or control buffer bottles
Sample swabs	Transfer pipettes

Sample Handling

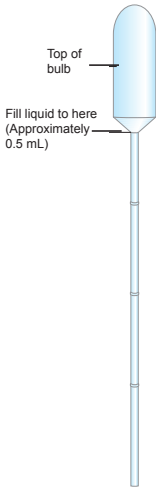
Sampling should be done before reagent preparation. Each sample must be in liquid form before running PCR. Sample preparation is essential because samples must be free of any contaminating salts or other compounds that would disrupt or inhibit the enzymatic reactions and fluorescent dyes required to run the reaction.

Dry Sample (Powders, etc.)



1. Touch the dry swab to the unknown powder or swab a 2 x 2 in. area of solid surface.
2. Place the swab into the appropriately labeled vial and break off at break point.
3. Secure the cap on the vial and shake vigorously for 30 sec.
4. If dilution is **NOT** necessary, proceed to the “Reagent Pouch Loading” section.
5. Repeat for the remaining samples using a fresh swab and correctly labeled vial.

Liquid Sample (Automatic Air Samplers, etc.)



1. Transfer approximately 0.5 mL of liquid to the appropriately labeled vial.

   Note: To draw a sample with the transfer pipette, first squeeze and hold the top of the bulb. Insert the tip of the pipette into the liquid and release the bulb to draw sample up to the fill line (see illustration). Transfer the pipette to the vial and squeeze the bulb to empty the sample into the vial.
2. Secure the cap on the water vial and shake vigorously for 30 sec.
3. Repeat for the remaining samples using a fresh pipette and appropriately labeled vial.
4. If further dilution is **NOT** necessary, proceed to “Reagent Pouch Loading” section.

Dilution

For a sample that might contain a high level of inhibitors, a dilution step may be necessary.

To perform a dilution on a 4 x 3 pouch with dry or liquid samples, follow these steps:

1. Add sample to a vial as described in the previous two sections.
2. Transfer approximately 0.5 mL from the vial to another labeled vial (i.e., Diluted Sample 1) using a transfer pipette.
3. Secure the cap and shake vigorously for ~30 sec.
4. Load both the undiluted and diluted samples into a pouch using the “Reagent Pouch Loading” section.

To rerun an 11 x 1 pouch that gives a result of “Inhibition Control Failure”, follow these steps:

1. Transfer approximately 0.5 mL from the previous sample vile to another labeled vial (i.e., Diluted Sample 1) using a transfer pipette.
2. Secure the cap and shake vigorously for ~30 sec.
3. Load the diluted sample into a new pouch using the “Reagent Pouch Loading” section.

Reagent Pouch Loading

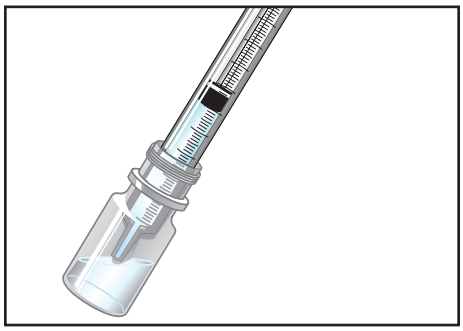
⚠ **WARNING: Do not open the pouch until you are ready to scan the rectangular barcode and load the sample. Once opened, you must use the pouch within 30 min., or the pouch will lose vacuum and will not pull in the correct volume of sample.**

1. Confirm that the foil bag is air tight. If the bag is not air tight, contact Technical Support, the reagents in the pouch may have been compromised.
2. Open the foil bag and remove the freeze-dried reagent pouch from the aluminum can.
3. Place the pouch on a flat, clean surface with the inlet ports and label face up. Make sure the plunger comb is in place.

Loading a Syringe

⚠ **WARNING: Do not prepare syringes until indicated by the instrument pouch prompts.**

1. Uncap the end of a syringe. The end of the syringe is preloaded with a tip necessary for RAZOR Mk II freeze-dried pouch loading.
2. Insert the tip end of the syringe into reagent grade water or the prepared sample.



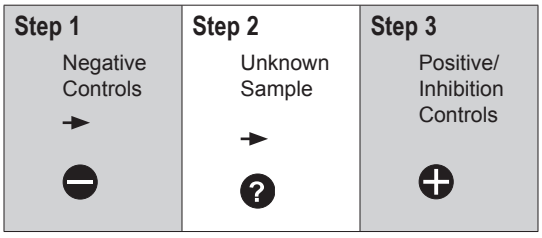
3. Draw reagent grade water or the sample into the syringe by pulling up on the syringe plunger until it reaches the appropriate mark (see the assay card for specific instructions):
   - 0.5 mL for a 4 x 3 format
   - 0.2 mL for a 12 x 1 format
   - 2.0 mL for an 11 + 1 format (The 10® pouch)
   - 0.35 mL for a 6 x 2 format

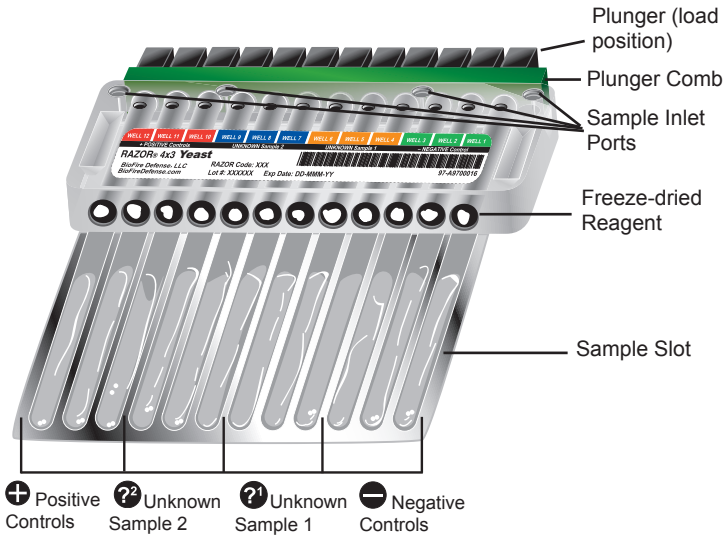
   Avoid introducing any air into the syringe, which can cause bubbles.

⚠ **WARNING**: If there are air bubbles in the syringe, DO NOT remove them by tapping and then pushing bubbles out of the tip into the air (this could contaminate both you and your area). Instead, reinsert the syringe into the sample vial and slowly express the liquid. Slowly redraw the sample into the syringe. Repeat until the liquid in the syringe is free of air bubbles.

Sample Insertion

Follow the prescribed order below to minimize cross-contamination and errors. You may also use the loading instructions located on the assay card.





A Sample 4 x 3 Pouch with Key Parts Labeled

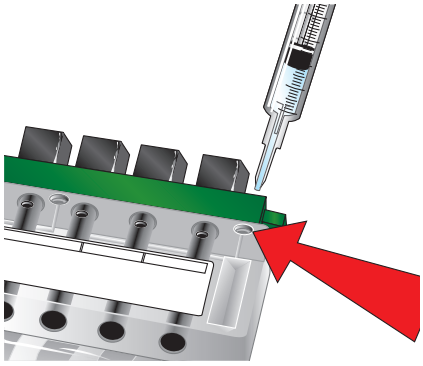
The procedure is essentially the same for loading the negative controls, the unknown samples, and the positive controls.

1. Load a syringe with the correct volume. Refer to the section named “Loading a Syringe” for instructions on how to correctly load a syringe. Fill the syringe with the correct fluid for the inlet port you want to fill.

    - For the **Negative** control inlet port, you will insert **reagent grade water** or **control buffer**. The appropriate bottle will be provided with your pouch.
    - For the **Unknown Sample** inlet ports, you will insert the correct **unknown sample**. Repeat for remaining unknown samples.
    - For the **Positive** control inlet port, you will insert the **reagent grade water** or **control buffer**.

2. After you prepare the syringe, hold it by the syringe body and gently insert the tip into the correct inlet port. Push the syringe down until you feel a faint pop and an ease in resistance. This indicates that the seal on the inlet port has been broken. A broken inlet port allows the liquid to be pulled into the pouch by vacuum. Allow the syringe to sit in the inlet port for at least 30 sec. to allow the liquid to dispense evenly.

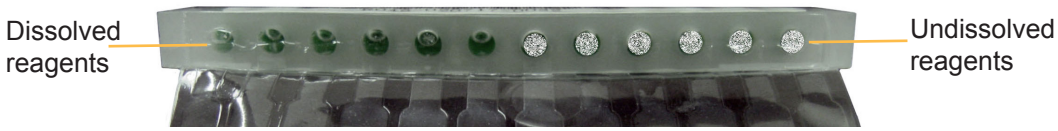
    The illustration below shows the syringe being inserted into a **Negative** inlet port.



CAUTION: DO NOT push the syringe plunger to force liquid into the pouch. This can fill the pouch with air and may damage the pouch or cause contamination.

3. Once the syringe plunger has stopped moving, remove the syringe and discard it into a biowaste container. If the liquid does not flow into the pouch automatically, the pouch might be damaged. Consult the "*Pouch Troubleshooting*" section in *Chapter 4, Maintenance and Troubleshooting*, for more information about what to do.

4. After you have emptied all of the syringes into the reagent pouch, confirm that all of the dried reagents have dissolved in the liquid.



If the reagents are dissolving slowly, shake the pouch gently by hand. If they fail to dissolve, contact BFDF Technical Support.

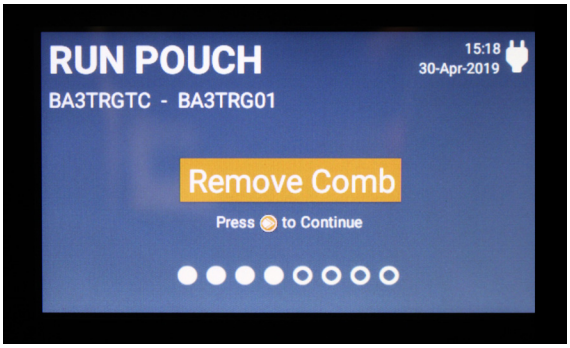
Removing the Comb and Plunging

WARNING: Depressing the pouch plungers when the pouch is not in the pouch bracket may damage the pouch, prevent the sample from entering the sample slot, or cause backflow leading to contamination. If at any time during the preparation process you suspect that the exterior of the pouch became contaminated with any suspected biohazardous materials, be sure to wipe off the pouch with 10% bleach (one part chlorine bleach and nine parts water) before inserting it into the RAZOR Mk II. This will help prevent contamination of the instrument's internal components which may result in erroneous test results.

Note: Be sure that the outside of the pouch looks clean before you insert it into the instrument. If the pouch looks unclean, gently wipe it with a dry, lint-free cloth.

Note: When you handle and load samples, avoid contamination problems by using standard laboratory techniques and following the appropriate protocols for loading samples. Change gloves frequently to avoid cross-contamination of samples.

1. Remove the plunger comb(s) by pulling it away from the pouch.



2. Twist plunger by using the Plunger Twist Tool (Part No. TOOL-DRV-0016) or the end of the plunger comb and rotate each of the plungers 90º towards the center of pouch; this prevents leaking and cross-contamination of neighboring wells. You can also rotate the plungers by hand or with a small flat-head screwdriver.

3. With the pouch plungers up, lightly tap the pouch on a flat surface.

4. To plunge the pouch, place the pouch onto the plunge bracket located near the pouch slot on the instrument. Holding the reagent pouch in the bracket, ***slowly*** push the pouch plungers down to force the liquid into the individual sample slots.

5. When all of the plungers have pushed liquid into the sample pouch, the samples are ready to be run.

6. A confirmation screen will appear before the RAZOR starts the run.

CHAPTER 3: RUNNING A POUCH AND THE SYSTEM SOFTWARE

INTRODUCTION

The RAZOR Mk II interface is designed for the basic user. The instrument screens will guide the user through each step of preparing, loading, and running samples in the pouch.

This chapter describes the following applications:

- Loading the run information
- Preparing the reagent pouch
- Inserting the pouch into the RAZOR Mk II
- Performing the run
- Analyzing the results

This chapter contains the following main sections:

- **Scanning the pouch and initiating a run:** Includes instructions for loading the pouch information by scanning the reagent pouch, inserting the pouch into the RAZOR Mk II, and performing the run.
- **Reviewing results:** Explains how to interpret the format of the test results you will see on the screen of the RAZOR Mk II after you finish a run.
- **Instrument utility menus:** Allows you to delete files, scan protocol codes, view logs, set the date and time, adjust screen brightness and view the software version.

SCANNING THE POUCH AND INITIATING A RUN

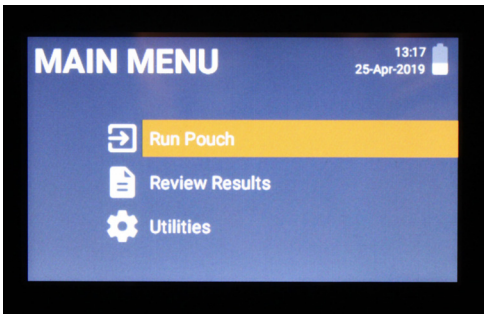
Scanning a reagent pouch and performing a run consists of the following parts:

1. Scanning the pouch barcode.
2. Following the preparation instructions for the pouch and the instructions on the screen after the RAZOR Mk II initiates the run.

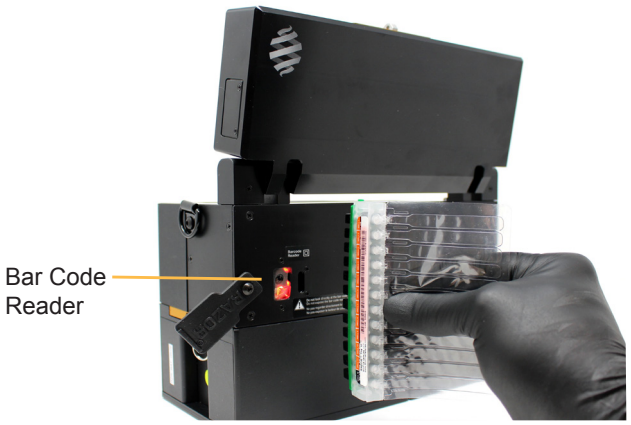
Scanning the Pouch Barcode

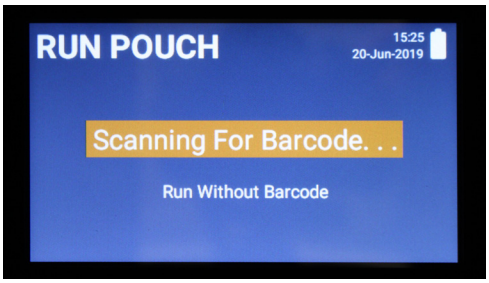
The RAZOR Mk II instrument displays instructions on the screen to walk you through the steps of scanning a reagent pouch and performing a run. Each reagent pouch has a unique serial number that is also encoded in a rectangular barcode.

1. From the Main Menu select **Run Pouch** to start the loading instructions.



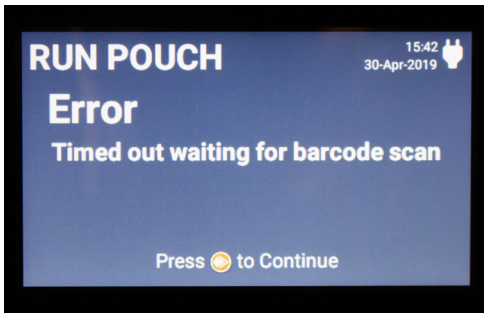
2. When **Scanning for Barcode...** displays, scan the **rectangular** pouch barcode from the reagent pouch label by holding it vertically and as flat as possible in front of the barcode scanner (located on the back of the instrument). The pouch should be approximately 6 to 8 inches from the scanner. Press **Back** to abort the barcode scan.





Note: If the barcode is not scanned immediately, flatten the barcode or move it closer to the scanner.

If the barcode is not read in time, the reader will abort the scan. Press **Select** to return to the **Main Menu**, then select **Run Pouch** again.



If the wrong barcode is scanned, an Error message will appear **Error, Invalid Barcode Data**. Rescan the rectangular barcode on the pouch's label. If any barcode becomes smeared or unscannable, barcodes are available on the assay card or in *Appendix G* of this manual.

3. If the barcode is scanned correctly, the screen will display the protocol and pouch serial number. It will ask you to **Remove Old Pouch**.

Note: Do not damage the pouch when you remove it; the contents could contaminate the instrument and surrounding area.

HAZARDOUS MATERIAL: Use standard laboratory procedures when handling biohazardous material. Consider all samples biohazardous and carefully dispose of pouches and syringes in a biohazard waste container.

Note: If the correct protocol is not present on the instrument, the machine will prompt you to scan the **square** protocol barcode from the assay card included with the kit.

4. The instrument displays an **Inject All Ports** screen. Load the syringes and inject the ports as described in *Chapter 2, Installation and Setup*.

5. When you have injected the ports, press the **Select** button to continue. A Preheating screen displays. The preheating time depicted on the screen depends on the current temperature of the instrument. An instrument at room temperature (18 - 30ºC) requires approximately 2 - 4 min. to preheat.

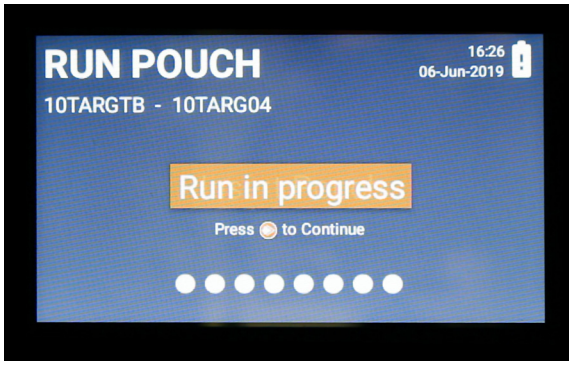
   Once preheating is complete, the instrument displays a **Preheat Complete** prompt. Press the **Select** button to continue.

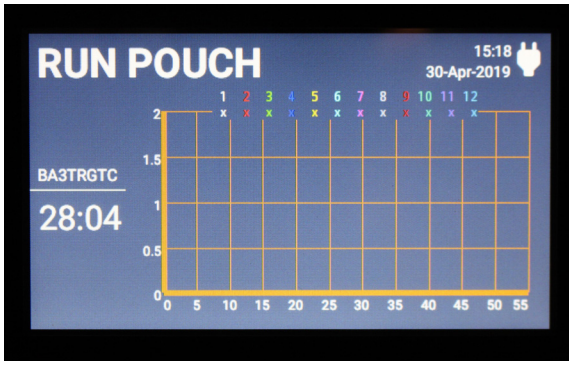
6. Follow the remaining pouch prompts to help you prepare your pouch for testing. For more details, see *Pouch Preparation in Chapter 2, Installation and Setup*.

7. Once the pouch is ready, insert the prepared pouch into the instrument with the label facing up and the plungers toward the front of the instrument. The pouch fitment should sit perfectly in the groove over the insert slot. After you insert the pouch, press the **Select** button.

Note: A confirmation screen will appear before the run begins.

8. A Run in Progress screen is quickly displayed and then the Run graph and time to finish is displayed.





9. The run can be canceled anytime by pushing the back button and selecting **Yes**.

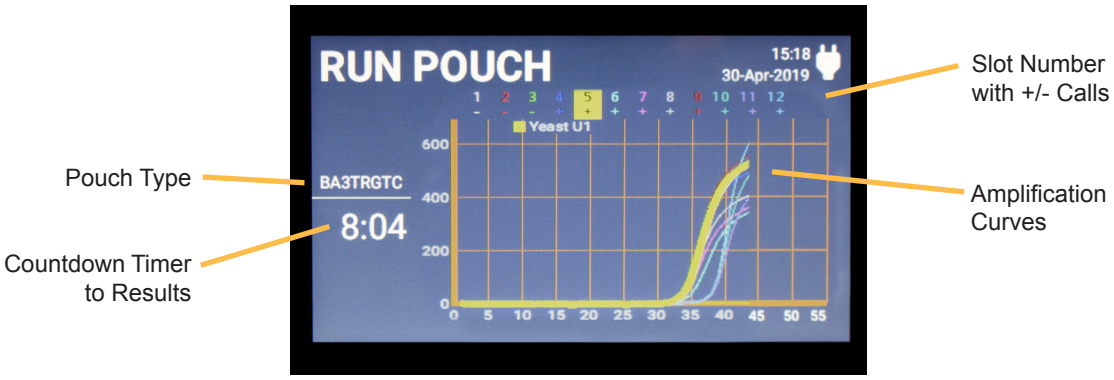
MONITORING PCR PROGRESS DURING A RUN

Real-Time Graph

The Real-Time Graph provides a graph that displays the amplification curves of each sample in real time during the run. Slot numbers are displayed at the top of the graph and the pouch type and a countdown timer are to the left of the graph.

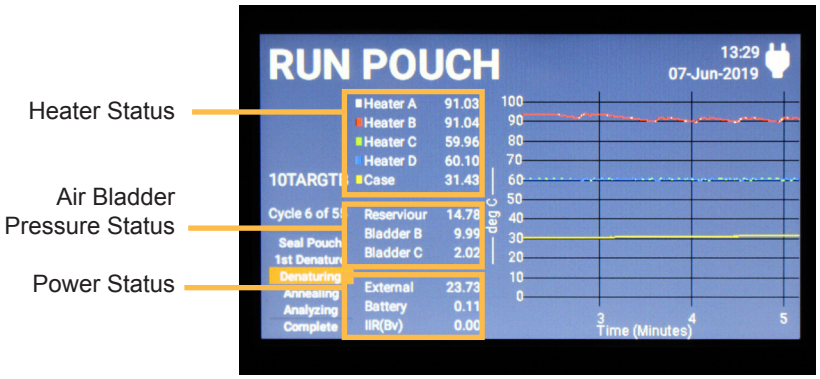
This screen also displays positive (+) and negative (–) detector calls. A positive (+) call indicates presence of the specific reagent target. A question mark (?) will be indicated until such time as a positive or negative (+/-) call is determined or the run is completed.

Use the up / down arrows to highlight specific samples and amplification curve in the graph.



Instrument Status

Instrument Status displays a screen that shows the current heating and cooling temperatures, instrument air pressure bladder status and battery / power status during the run. This screen is used for troubleshooting issues if the instrument is not working properly.



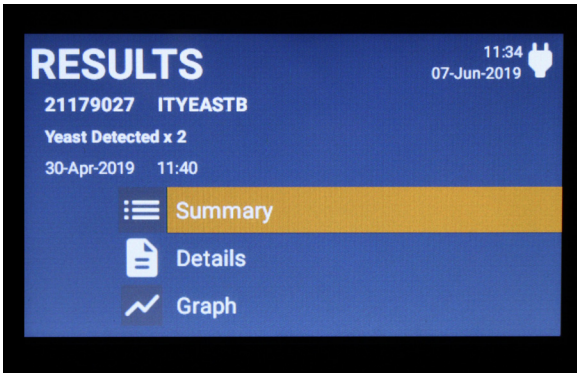
Note: Return to the Run Pouch menu by pressing the **Back** arrow.

Quit Run

The run can be canceled anytime by pushing the back button and selecting **Yes**.

RESULTS

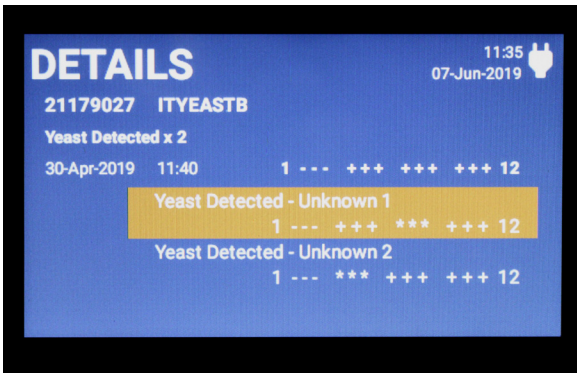
When a run is finished, the screen automatically displays a Results screen with the results for the run. These results rely on the Detector software algorithm to determine the presence or absence of the target being tested.



Detector

Detector is an advanced algorithm that determines if each slot in the pouch has detectable amplification (that is, whether copies were made of the target DNA).

Slots are called independently of each other. Detector runs in real-time on the instrument: positive (+) slots are called while the machine runs; negatives (-) are not called until the run is finished.



Calls	Meaning of each call
+	The software has detected an amplification curve for a slot position.
–	The software has not detected an amplification curve for a slot position
?	The software has not determined the correct call yet.

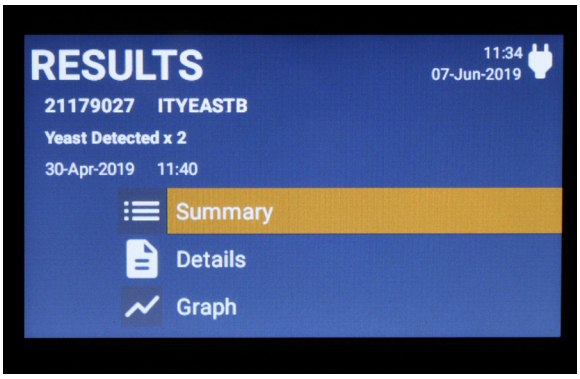
Metacalls

The Metacalls program takes the Detector calls for individual slots and gives you combined information about unknowns and assay controls (see Qualitative Detection Analysis in this chapter for an explanation of controls). Protocols contain all the necessary information for results, summaries, and details. This information is specific to the reagents present in the pouch and their configuration.

REVIEW RESULTS SCREENS

The Results screen displays the pouch serial number, the name of the protocol, and the date and time of the run. It also displays the following:

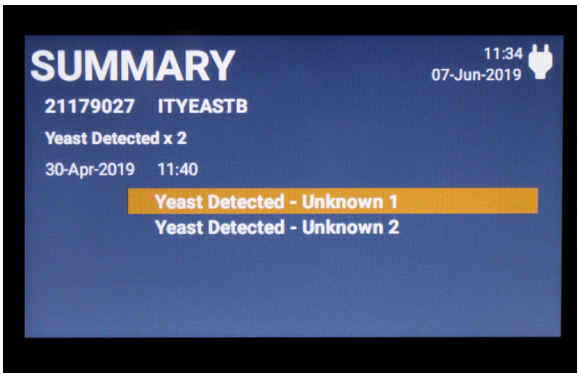
- **Summary**: Displays an overall summary of the run and indicates what targets were detected.
- **Details**: Displays the summary of the run along with the Metacalls for each slot of what was detected.
- **Graph**: Displays the summary of the run next to a graph of the amplification curves for each slot.



Summary

The following screen is an example of what you will see when you look at a Summary of results screen.

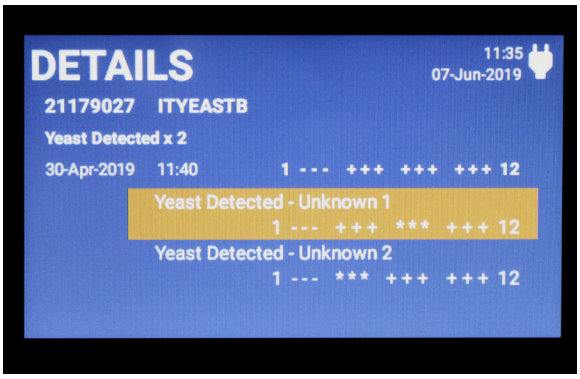
This screen shows the results for the RAZOR Yeast Pouch. It displays the two Yeast Detected results that are found in this training pouch. It also displays the date and time the pouch was tested on as well as the pouch serial number.



Details

The Details screen shows the same information as the Summary screen, along with the calls for each slot. However, if there are no metacalls, the Results (Details) screen will display “No Metacalls Found.” Also, if a control fails, the test has failed, and the software will not display the metacalls.

The Detector calls for each slot are shown as negatives (-), positives (+) and asterisk (*). The first slot number (1) is listed on the left, the last slot number (12) is listed on the right, and twelve symbols representing the detector calls for the 12 slot numbers are sandwiched in between. The screen contains the metacalls for each pouch slot.

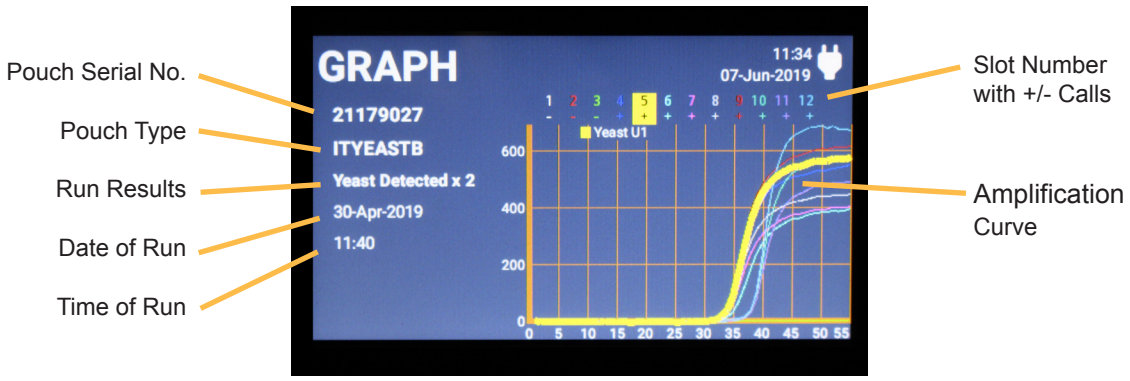


The possible results are shown in the following table.

Calls	Meaning of each call
–	Call is negative
+	Call is positive
*	Call is not relevant

View Graph

This screen displays the full amplification graph with Detector calls at the top of the screen. You can use the directional arrows to highlight specific samples. When you highlight a sample, the number and detector call are highlighted, and the curve appears with a thicker colored line.



FINISHING THE RUN

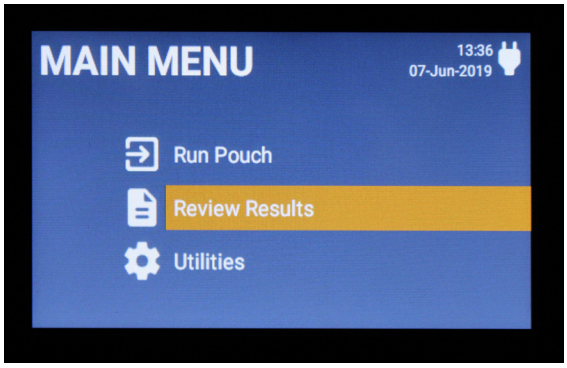
HAZARDOUS MATERIAL: Use standard laboratory procedures when handling biohazardous material. Consider all samples biohazardous and carefully dispose of pouches and syringes in a biohazard waste container. When the run is finished, carefully remove the pouch and dispose of it as biohazardous waste. Do not allow the bag to tear; the contents of a finished run can contaminate the instrument and the testing area.

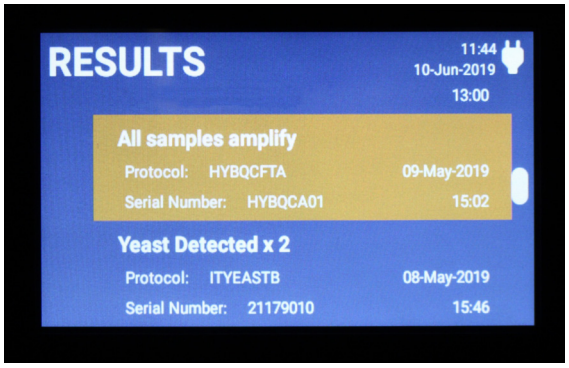
CAUTION: When the RAZOR Mk II is finished, the instrument and pouch will be hot. Use caution when you handle the instrument and pouch after a run.

Opening Previous Runs

To look at the results of a previous run, select **Main Menu > Review Results**.

The results are sorted with the most recent test at the top. Use the directional arrows to scroll down to view additional tests.



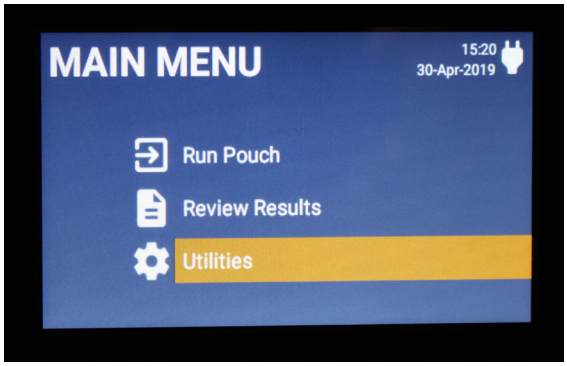


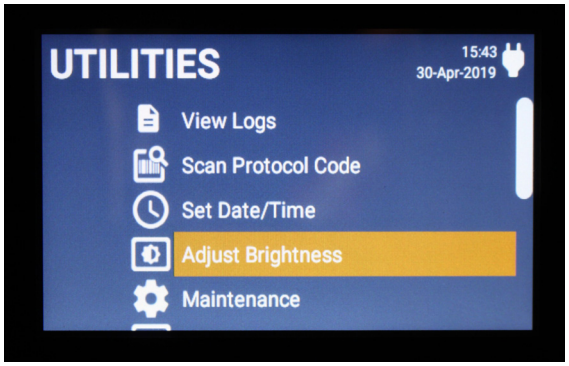
You will then have the same Results viewing options that appear at the end of a run.

INSTRUMENT UTILITIES MENUS

The instrument's Utilities menu allows you to View Logs, Set Date/Time, Delete Files, Scan Protocol Codes, and many other instrument utilities.

To access the Utility menu, select **Main Menu > Utilities**.



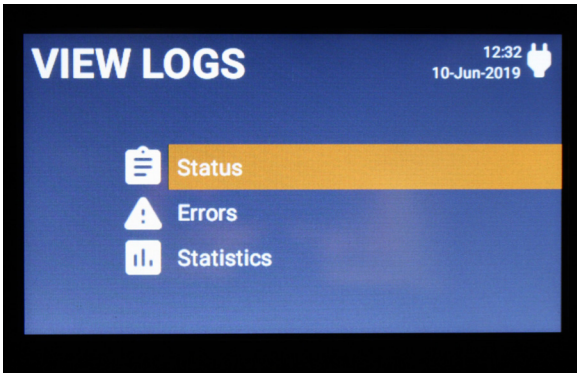


Below is a list of the Utilities that are available.

View Logs	Delete File
Scan Protocol Code	View Software Versions
Set Date / Time	Set File Order
Adjust Brightness	Language
Maintenance	Instrument Info
Connect PC	

View Logs

The View Logs utility is divided into 3 sections:



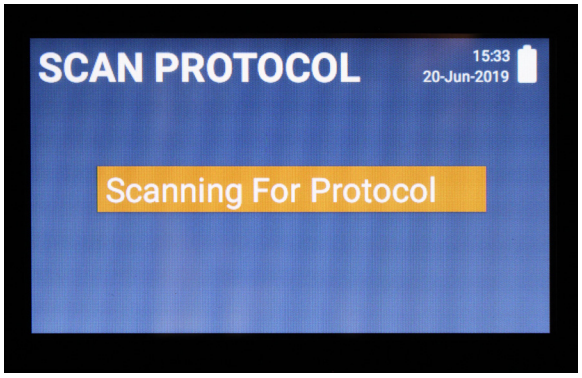
Status: Displays the status of the instrument and the major tasks that take place while the instrument is powered on.

Errors: Displays the errors that may occur while the instrument is running and powered on. This information is used to troubleshoot any failure issues that may occur.

Statistics: Displays useful information about the instrument. Such as Runs Completed, Positives Detected, Run Time, Battery Time, Etc.

Scan Protocol Code

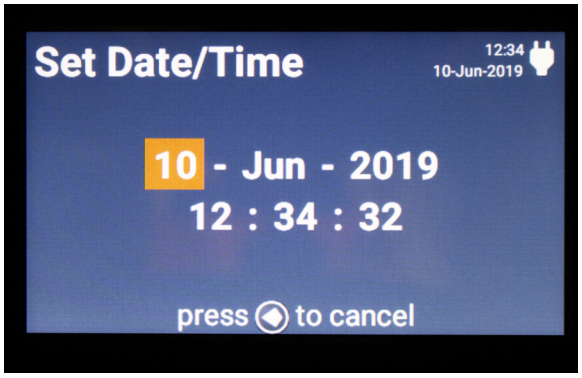
This utility allows a user to load a run protocol into the instrument, see *Chapter 2 on Loading Protocols*. Protocols provide the instructions to the instrument on how to run the pouch and display the results.



When this utility is initiated, the barcode scanner on the back of the instrument is turned on. If a barcode is not scanned in 30 seconds, an error screen will display.

Set Date / Time

The date and time is displayed in the top right corner of every screen and is used as a time stamp on each run. It is important that the date and time is correct before a run is performed. Use the directional arrows to adjust the date and time.

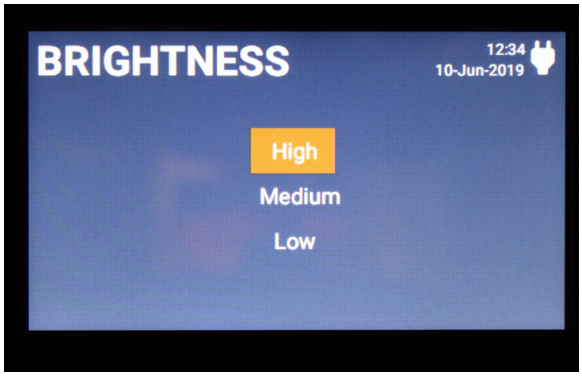


Note: The date and time do not change automatically when the instrument is moved between time zones. The date and time must be changed manually.

Adjust Brightness

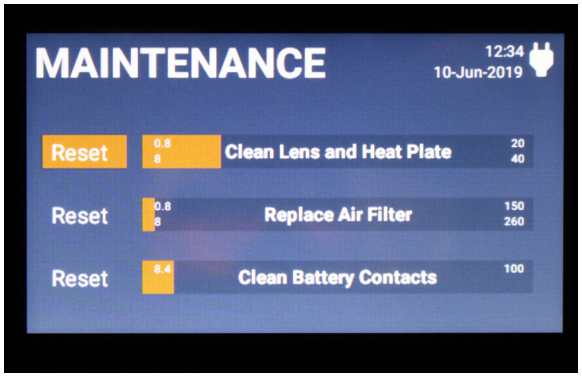
Use this utility to adjust the brightness of the screen.

It has 3 settings: High, Medium and Low.



Maintenance

The RAZOR Mk II needs regular maintenance to make sure that it continues to run properly. This Maintenance utility keeps track of 3 tasks that need to be performed regularly, see *Chapter 4: Maintenance and Troubleshooting* on how to perform these tasks.

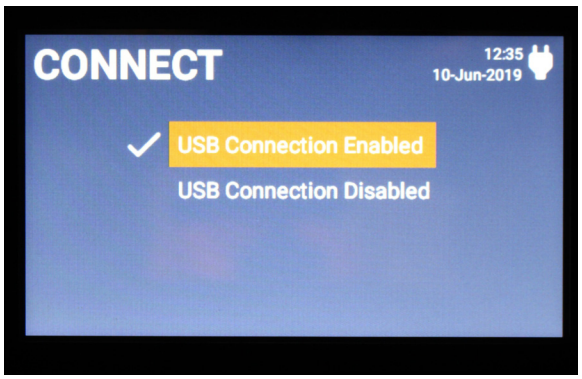


- Clean Lens and Heat Plate
- Replace Air Filter
- Clean Battery Contacts

After these tasks have been performed, their status will need to be **Reset** in this utility. Use the directional arrows to Reset the individual tasks.

Connect to PC

The RAZOR Mk II can connect to a PC using the USB port. This enables runs to be downloaded and analyzed for additional information. Contact BioFire Defense Technical Support for the computer software and information on downloading and analyzing run data.

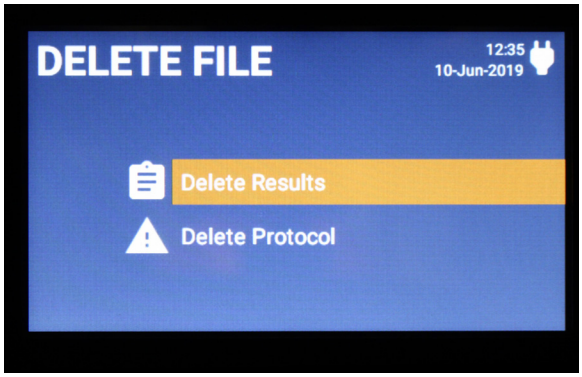


Note: Only UL 60950 and UL 61010 compliant USB devices should be connected to the instrument.

Delete File

This utility allows you to delete 2 types of files on the RAZOR Mk II.

- Delete Results
- Delete Protocol

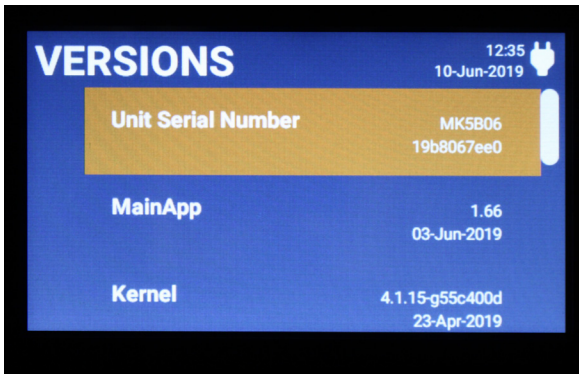


Note: If results are deleted, they cannot be restored. Be sure to only delete results that are not needed. The RAZOR Mk II can hold the results for 100 runs of each assay. An alert message will appear to alert you when you have reached your limit.

If a Protocol is deleted, it can be restored using the square barcode, see *Chapter 2 on Loading Protocols.*

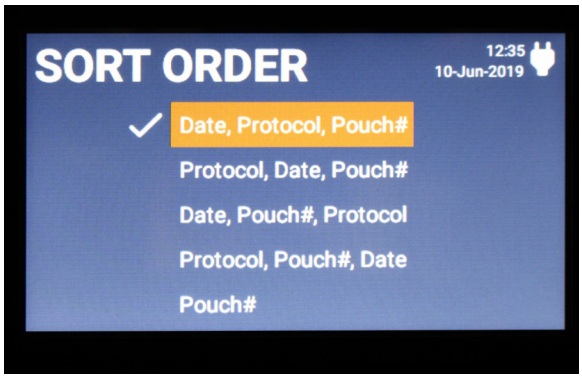
View Software Versions

This utility displays the most current version of the software modules that are running on the RAZOR Mk II. This information is useful for troubleshooting any issues that may occur with the instrument.



Set File Order

When viewing run results on the RAZOR Mk II, it is displayed by date with the most recent run on top and then sequentially to the bottom. The file order can be changed using the direction arrows with this utility.

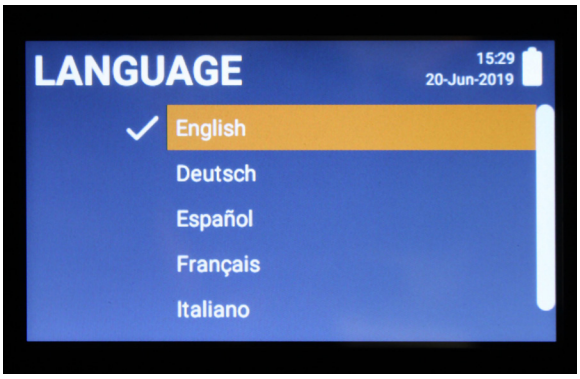


- Date, Protocol, Pouch# (default)
- Protocol, Date, Pouch#
- Date, Pouch#, Protocol
- Protocol, Pouch#, Date
- Pouch#

Language

The RAZOR Mk II offers on-the-fly translation of the language that is used for the user interface of the instrument. Six of the most common languages are available. Use the directional arrows to change the language.

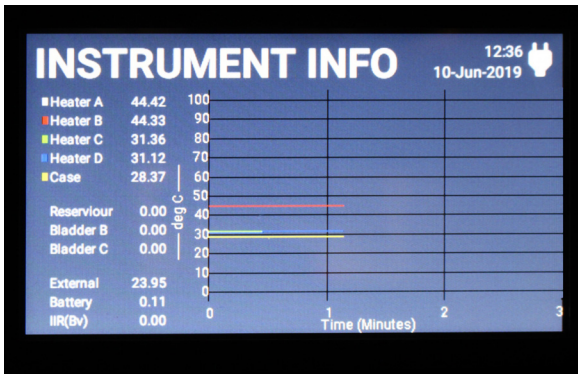
When switching languages, a notification screen will alert you about switching languages and that Google Translate was used to obtain the translation. For the most accurate information, use English.



Instrument Info

This utility provides useful information for troubleshooting any issues that may occur with the instrument. It provides information on the following areas:

- Heaters
- Bladders
- Battery and External Power



Note: Return to the Run Pouch menu by pressing the **Back** arrow.

CHAPTER 4: MAINTENANCE AND TROUBLESHOOTING

INTRODUCTION

Note: Contact BioFire Defense Technical Support before you access any internal components on the RAZOR Mk II. It is always a good idea to run the RAZOR Mk II with the battery installed, especially if poor power conditions are suspected.

WARNING: To maintain a safe working environment, turn off the power, remove the battery, disconnect both the power and the USB cables and allow the instrument to cool before accessing internal components of the RAZOR Mk II. Wear safety glasses and protective gloves.

CAUTION: Use caution when you remove sample pouches from the instrument; a tear in the bag could contaminate the instrument and the surrounding area. Carefully dispose of sample pouches in a biohazard waste container.

The RAZOR Mk II is a field-hardened instrument designed for field use, but it is neither waterproof nor indestructible. With proper care and maintenance, the RAZOR Mk II will perform accurate and sensitive PCR-based pathogen identification.

GENERAL MAINTENANCE

- As needed, wipe down the surface of the RAZOR Mk II and heater plates by using a cloth or paper towel and a 10% bleach solution (one part household chlorine bleach and nine parts water). Repeat process twice followed by two wipes with a cloth or paper towel dampened with water. Use this method to decontaminate the RAZOR Mk II instrument before returning it for service. See Appendix B for additional instrument return requirements.

  CAUTION: Do not get bleach on the lenses or the battery contacts. Use lens cleaner and a lens cloth to clean the lenses.

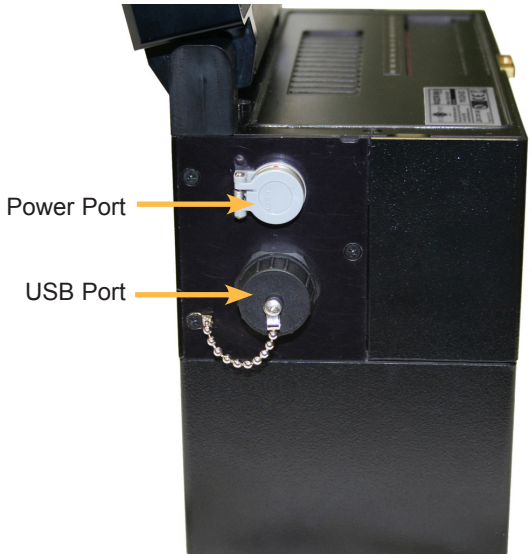
- Periodically, use canned air to clean the sample chamber area between the internal heater plates by blowing it out. Be sure to wear eye protection and decontaminate the area first, if necessary (see "*Lens and Heat Plate Cleaning*").

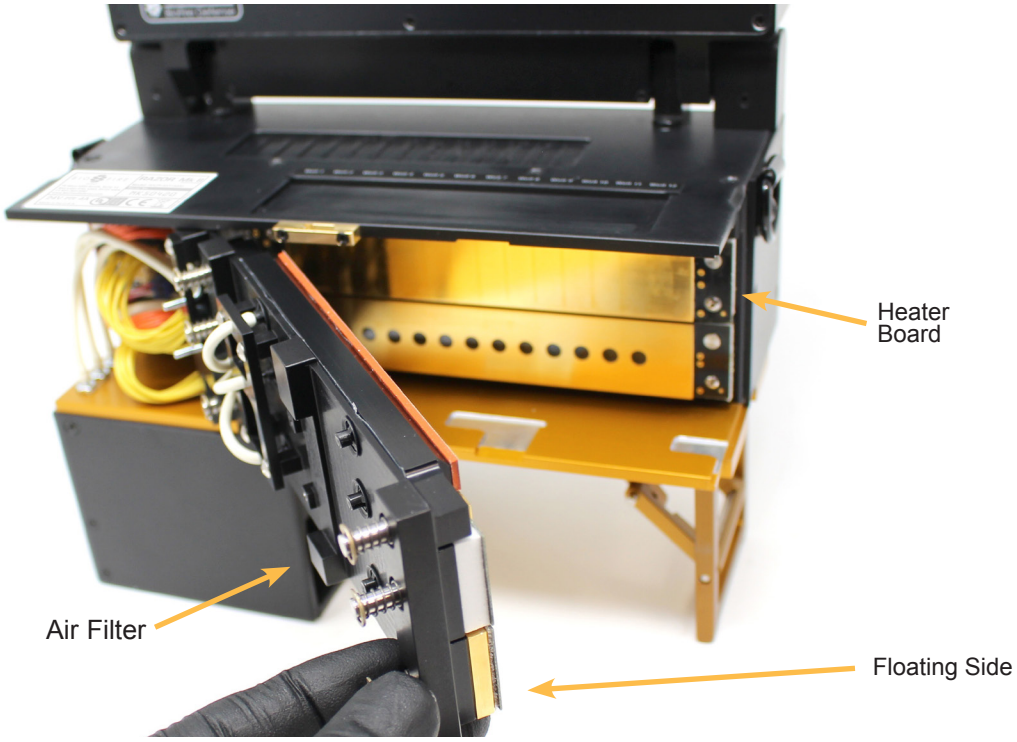
- Periodically, use an optical lens cleaner and a lens cloth to clean the lenses and heater plates (see "*Lens and Heat Plate Cleaning*").

- Always wear gloves when you access and maintain internal parts.

INSTRUMENT OVERVIEW

Use the following images to familiarize yourself with the RAZOR Mk II Instrument.

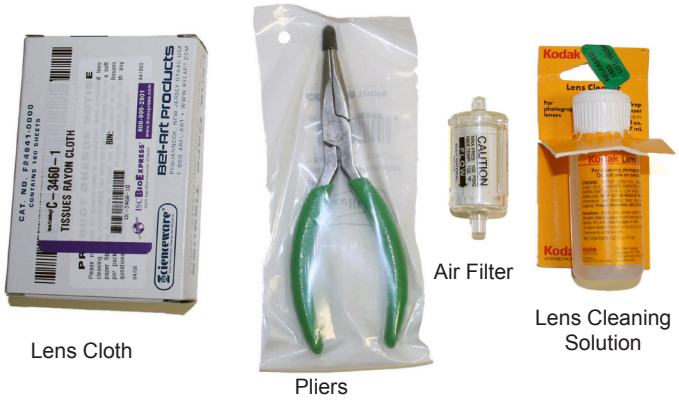



Heater
Board
Air Filter
Floating Side


Air Filter Removed

PREVENTIVE MAINTENANCE

Each RAZOR Mk II Instrument comes complete with a tool kit that enables you to perform the tasks outlined in this manual. Use the image below to help you identify the necessary tools. If any tool becomes damaged or lost, contact Technical Support for a replacement.



Lens Cloth

Pliers

Air Filter

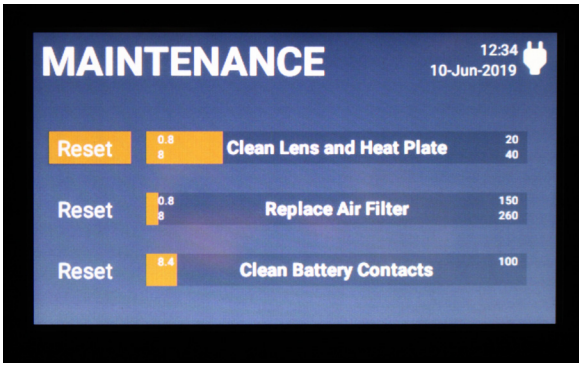
Lens Cleaning Solution

Maintenance Tracking

The RAZOR Mk II tracks required maintenance tasks by the number of runs or hours of operations. The instrument tracks the following maintenance task:

- Clean Lens and Heat Plate
- Replace Air Filter
- Clean Battery Contacts

To check the status of these task, selecting Utilities > Maintenance. After these tasks have been performed, they will need to be reset using the directional arrows on this screen.



Accessing Internal Components, Heaters, and Lenses

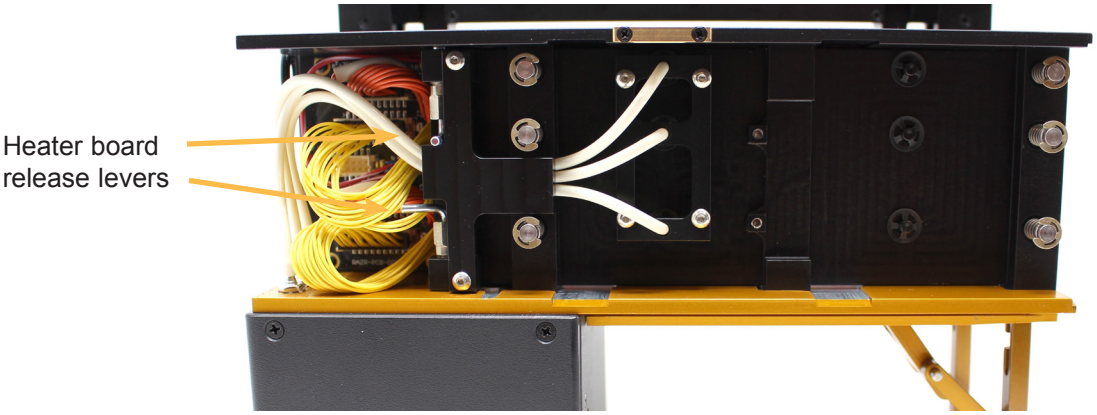
⚠ **WARNING**: To maintain a safe working environment, turn off the power, remove the battery, disconnect both the power and the USB cables and allow the instrument to cool before accessing internal components of the RAZOR Mk II. Wear safety glasses and protective gloves when performing maintenance on the RAZOR Mk II.

⚠ **WARNING**: When accessing internal components, keep the instrument in its upright position as shown. Also, be sure to use care to avoid damaging delicate components.

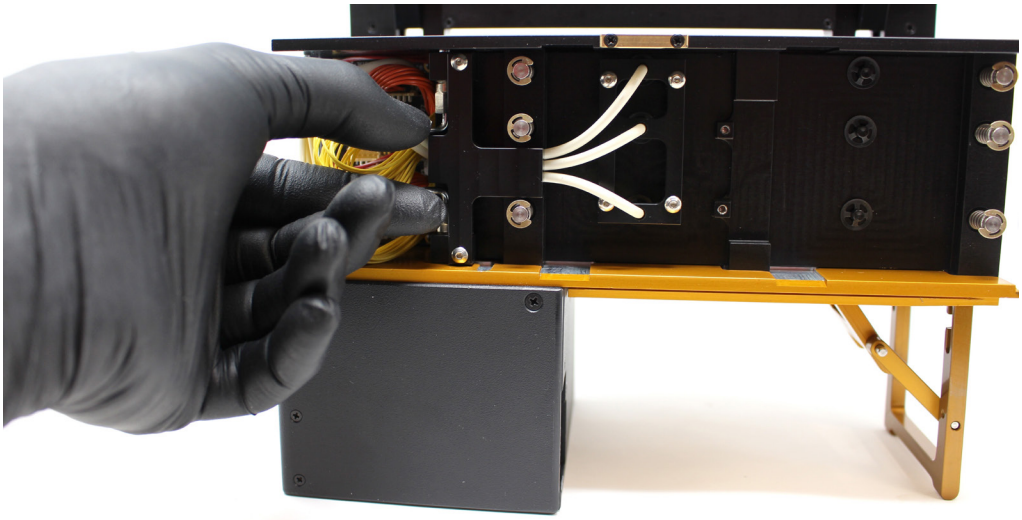
1. Locate the access panel side handles on the top sides of the RAZOR Mk II and carefully pull outward on one side to remove the access panel.

2. Carefully remove the other side of the access panel and place it to the side on a clean surface.

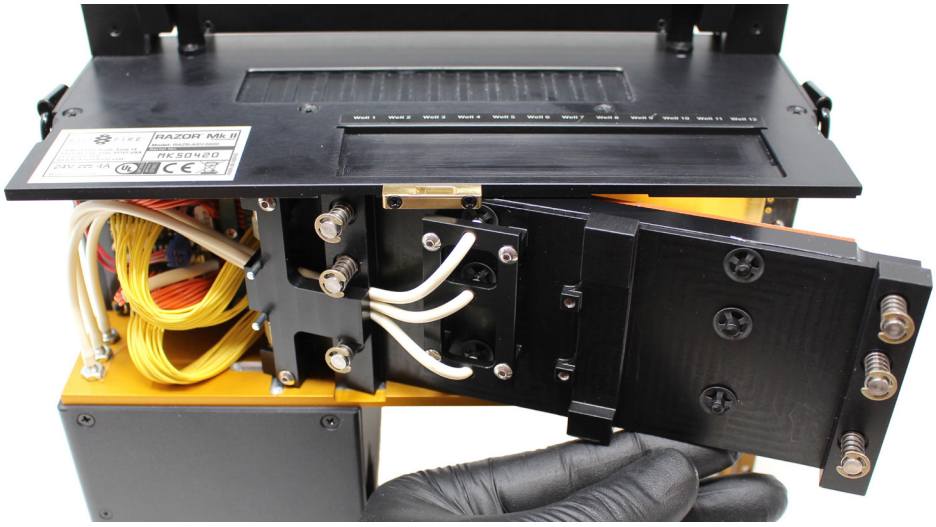
3. Locate the heater board release levers located on the top and bottom on the back of the floating side heater board.



4. Gently squeeze the levers together to unlock the heater board, then slide the board to the right about 1/2 in.



5. As the heater board slides, it will hit a stop. At this point, slide the whole board toward you until the levers hit the final stop.



6. After you slide the board to the outside edge of the machine, pivot the right end of the board out, exposing the internal heater plates and lenses.

7. To close the instrument when you are done working on it, follow steps 1 through 5 in reverse order.

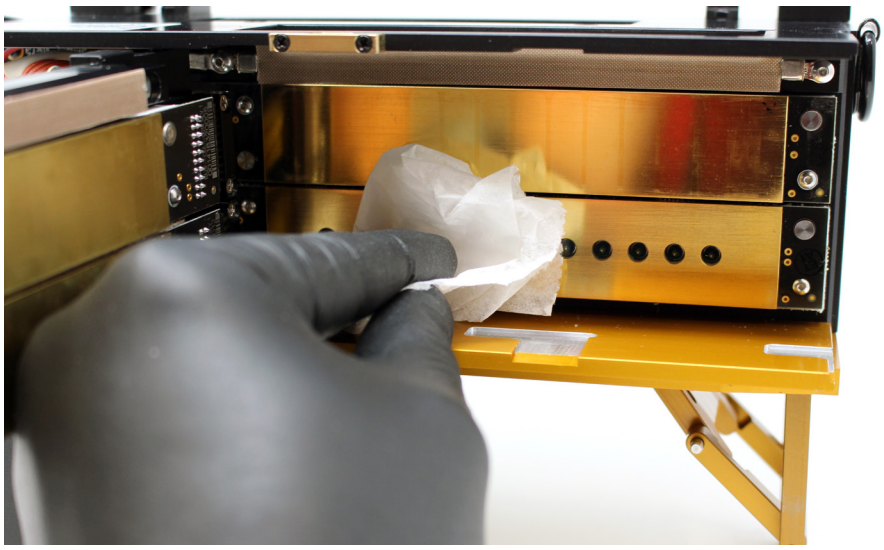
⚠ **WARNING:** Be sure that the internal heater board is closed and locked into place before you turn on the instrument.

Lens and Heat Plate Cleaning

Type of Service:	Preventive Maintenance/Corrective Maintenance
Recommended Frequency:	Every 40 runs (about 20 hours of use), or after operation in an extreme environment such as a dust storm.
Possible Symptoms:	Low fluorescence, spikes in real-time graph
Required Parts:	None
Required Materials/Tools:	Lens cloth (from the startup kit) or microfiber cloth, lens cleaning solution, canned air
⚠ **Caution:**	Make sure gloves and cleaning cloth are clean before using on the lens. DO NOT POLISH IN A CIRCULAR MOTION. Dust particles can be ground into the lenses, decreasing the RAZOR Mk II's ability to identify DNA targets.

You should clean the lenses and heat plates periodically to ensure that the fluorescence acquisition is not impeded by dust that might accumulate on the surfaces.

1. Follow the instructions on "*Accessing Internal Components, Heater Bars, and Lenses*" from the previous section.
2. After you have exposed the optic lenses and heaters, use canned air to clean the sample chamber area between the internal heater plates by blowing it out. Be sure to wear eye protection and decontaminate the area first, if necessary.
3. Wet a lens cloth (supplied with the instrument), and/or a microfiber cloth that will not scratch the optic lenses, with the lens cleaning solution that has been supplied.
4. Drag the cloth across the lenses in a single direction.



5. Use a clean, wet area of the cloth by changing the position of your finger on the cloth and repeating the steps in this procedure as necessary.
6. After you have cleaned the lenses, clean the gold heater plates in the same way.

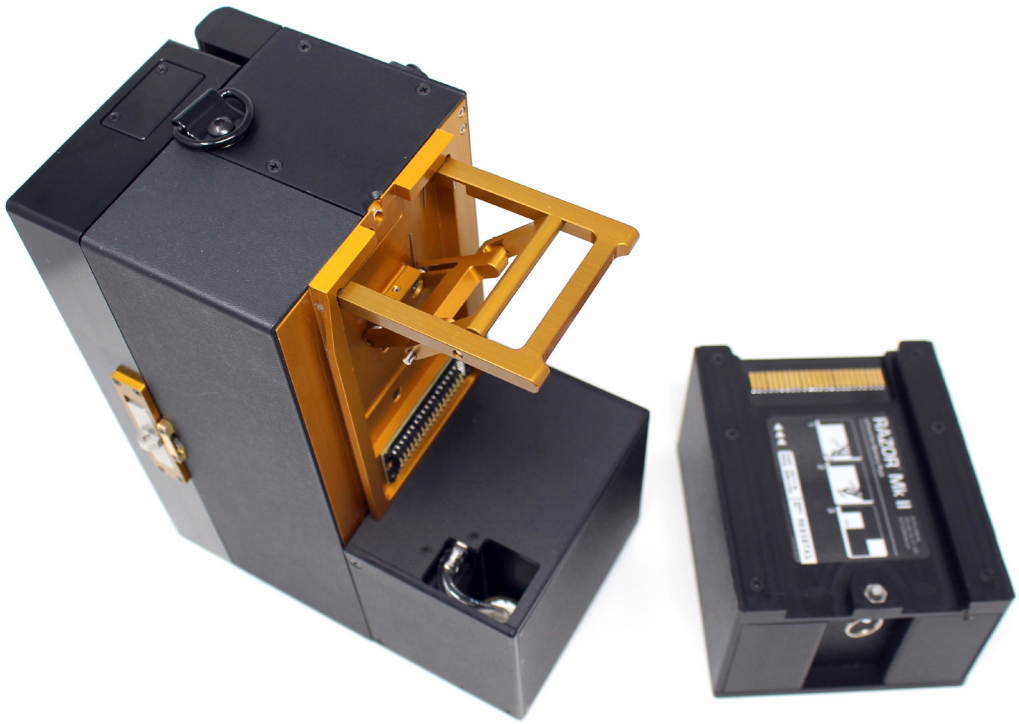
Replacing the Air Filter

Type of Service:	Preventive Maintenance/Corrective Maintenance
Recommended Frequency:	Every 260 runs or 150 hours of use in normal environment. Every 125 runs or 75 hours in harsher environments (such as sand and blowing dust).
Possible Symptoms:	Error codes: V131 “Elevation, filter, leak, or sensor failed, POST.” OR M130 “Pressure Timeout. Unable to Reach X PSI in bladder Y”
Required Parts:	Air filter (RAZR-ASY-5300)
Required Materials/Tools:	None
⚠ **Caution:**	None

You should replace the air filter periodically to ensure that the instrument’s air system flows correctly. Make sure your hands are clean and that the environment is dust free. Allowing dust to get into the air system may damage the RAZOR Mk II. In turn, the damage can diminish the instrument’s ability to identify DNA targets.

1. Remove the battery.

   The air filter is a small clear cylinder that sits to the side of the battery in the compressor housing.

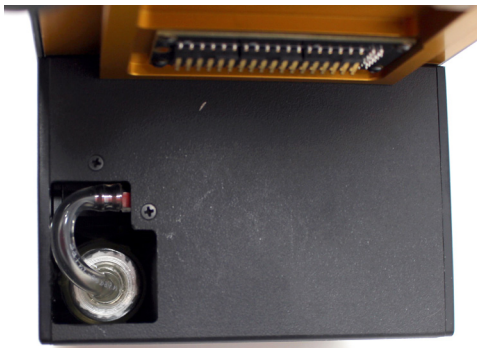


2. Pull the filter out with the connector hose. Notice the position of the tubing so that when you put the filter back, you will be able to put the tubing in the correct position.

3. Gently pull the tubing off the installed filter fitment.

4. Replace the filter with a new air filter (part no. RAZR-ASY-5300) that you have obtained from BioFire Defense.

⚠ WARNING: Make sure the arrow on the filter is pointing towards the intake tube. Insert the filter with the tubing into the instrument in its original position being careful not to kink or bend tubing. Replace only the filter unless the tubing is damaged.

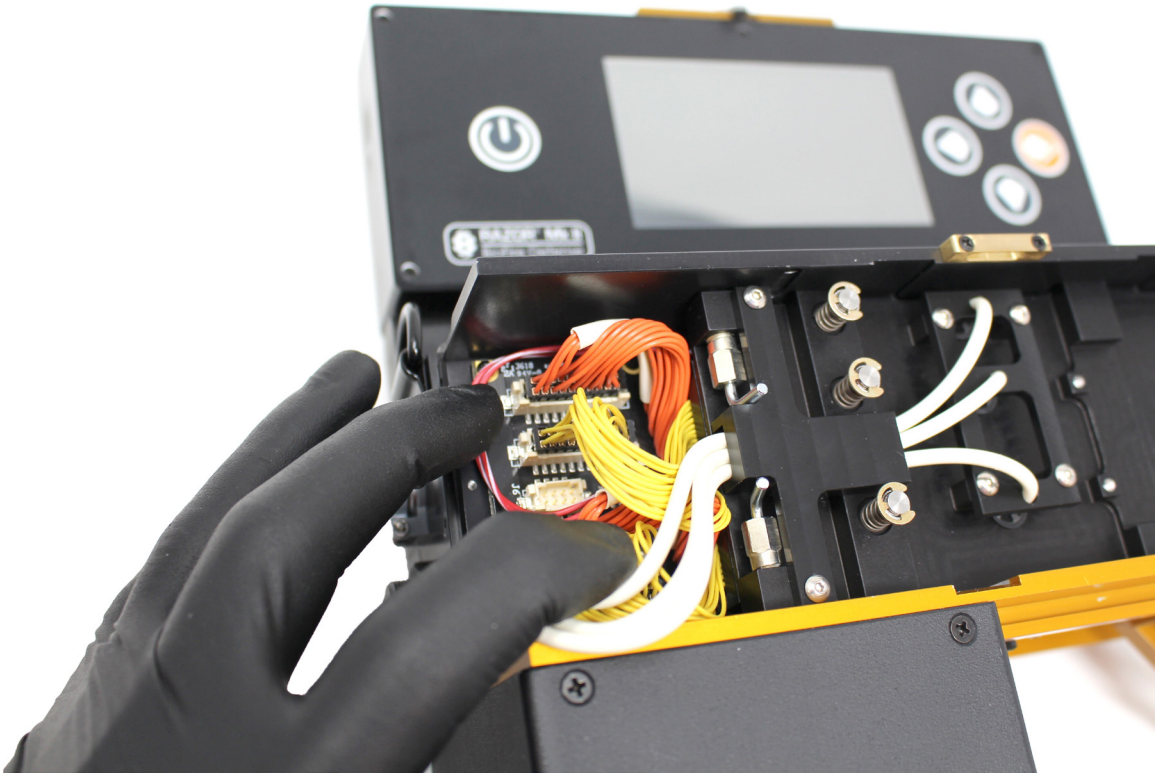


Checking the Heaters

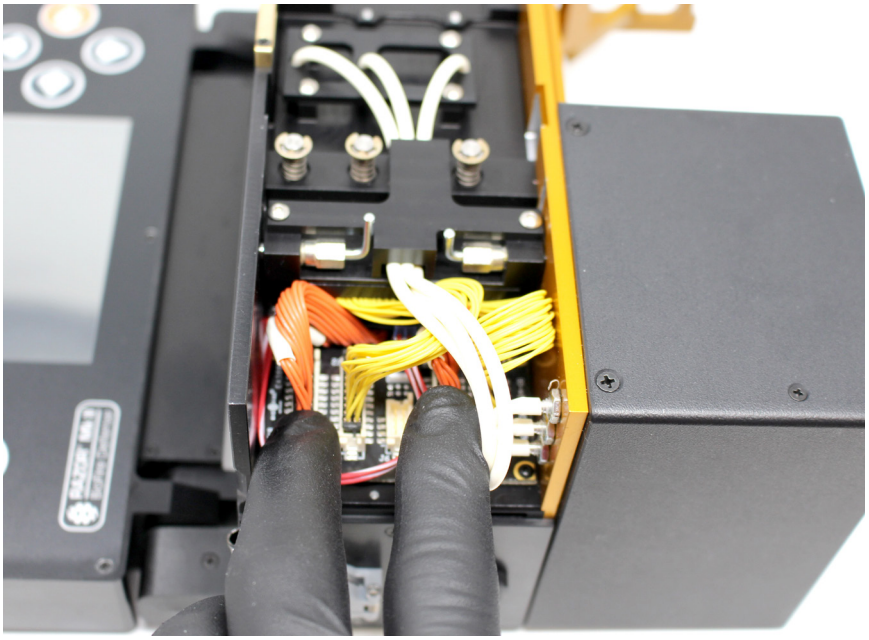
Type of Service:	Corrective Maintenance
Recommended Frequency:	As needed or if prompted by error codes.
Possible Symptoms:	Error codes: H128 “Too cold or open sensor on Heater A.” OR H129 “Too cold or open sensor on Heater B.” OR H130 “Too cold or open sensor on Heater C.” OR H131 “Too cold or open sensor on Heater D.”
Required Parts:	None
Required Materials/Tools:	None
⚠ **Caution:**	Be sure that you disconnect the RAZOR Mk II from an external power supply and battery before you attempt this procedure.

1. Follow the instructions on “*Accessing Internal Components, Heaters, and Lenses*” found in this chapter.
2. Check the heater plugs leading into the RAZOR Mk II internal electronics.

   There are two sets of red-wired plugs and two sets of yellow-wired plugs. Gently press the wire harnesses into the base plugs to ensure that they are seated correctly.



3. Check the heater plugs that lead into the back of the two heater boards.

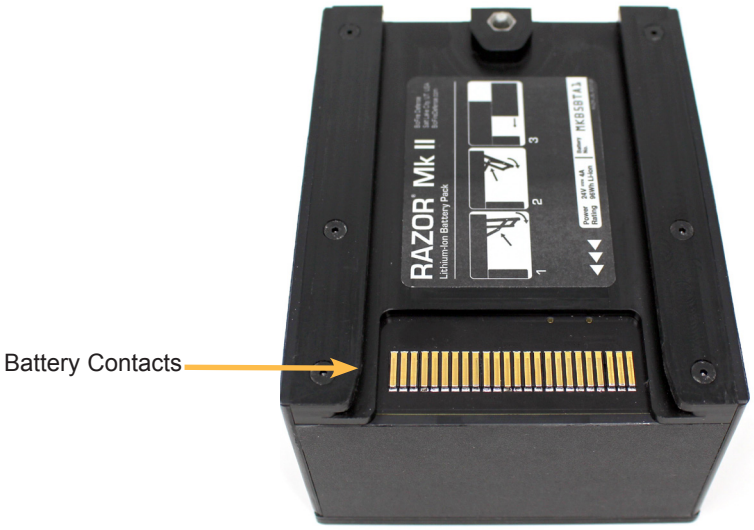


4. Check the heater plugs leading into the front two heater boards.
5. Reassemble and close instrument.
6. Reconnect power and power on the instrument allowing it to run its power-on self-test. If errors persist, contact Technical Support.

Battery Contact Cleaning

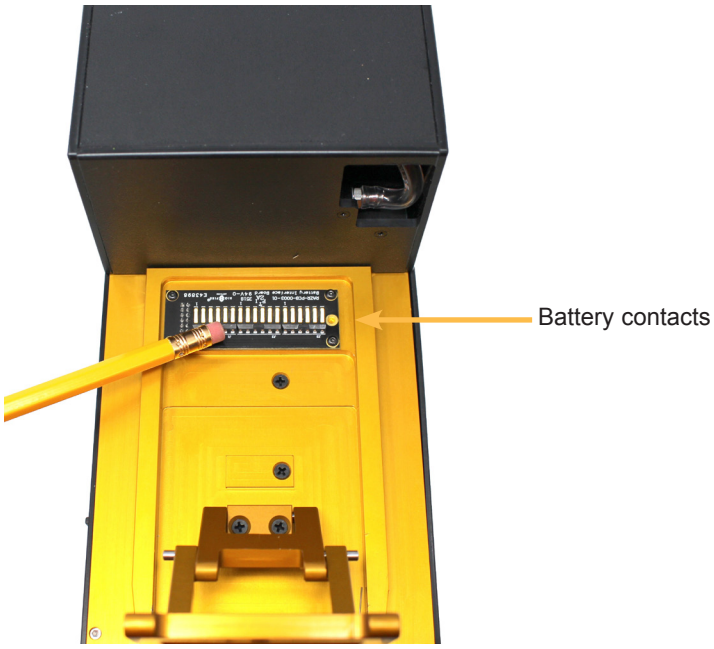
Type of Service:	Corrective Maintenance
Recommended Frequency:	Every 100 hours of battery use
Possible Symptoms:	Intermittent power supplied from battery pack. Battery not reaching full charge. Error codes: M002 “Low Battery” (Warning) OR M138 “Battery Too Low”
Required Parts:	RAZOR Mk II Battery Pack
Required Materials/Tools:	Pencil Eraser
⚠ **Caution:**	Do not change a battery while the machine is running unless the instrument is plugged in. If you have to change a battery mid-run, first plug in the external power supply to the external port. If you don’t, you will lose the run data and you will not be able to recover it. **Do not incinerate battery pack. Do not expose to high temperatures (140 ºF / 60 ºC). Do not disassemble.**

1. Place the RAZOR Mk II battery pack on a flat surface such as a table or workbench. The gold colored battery contacts should be facing up as shown. Look for discoloration, such as black streaks on the battery contacts.



2. Using a standard pencil eraser, lightly rub each contact until you remove the streaks. DO NOT rub the contact with a ‘back and forth’ motion. Rub in only one direction. On the underside of the RAZOR Mk II instrument and on the RAZOR Mk II battery charger, the contacts are spring loaded, and you must take care to rub from the spring attachment point outward. When you are done, the contacts should be free from dark discoloration.

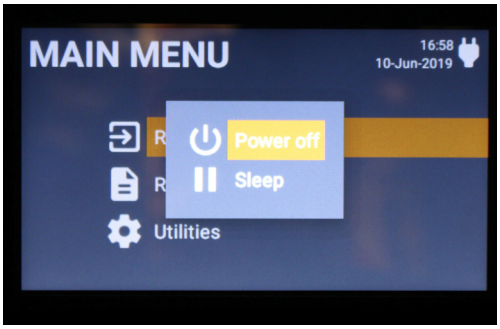
You can follow the same procedure on the contacts that are located on the underside of the RAZOR Mk II Instrument and on the contacts that are located on the RAZOR Mk II battery charger.

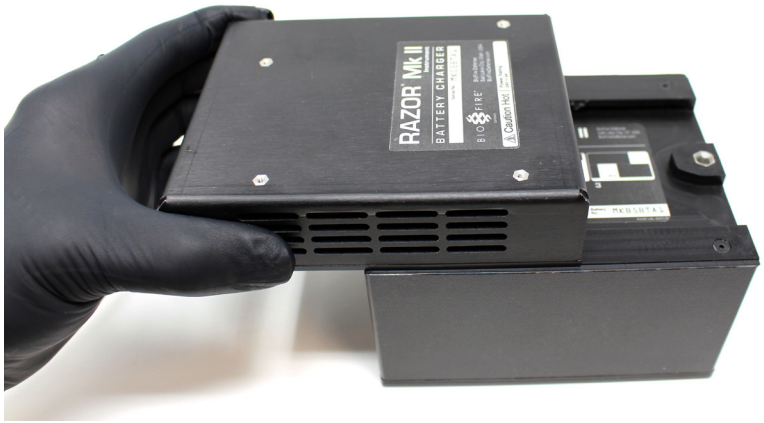


Battery Charging

Type of Service:	Corrective Maintenance
Recommended Frequency:	Every 3 - 4 hours of instrument use on battery power
Possible Symptoms:	The RAZOR Mk II instrument will not power up on battery power, but it does power up on external power. Error codes: M002 “Low Battery” OR M138 “Battery Too Low”
Required Parts:	RAZOR Mk II Battery Charger and External Power Supply RAZOR Mk II Battery Pack
Required Materials/Tools:	N/A
⚠ **Caution:**	Do not change a battery while the machine is running unless the instrument is plugged in. If you have to change a battery mid-run, first plug in the external power supply to the external port. If you don’t, you will lose the run data and you will not be able to recover it. **Do not incinerate battery pack. Do not expose to high temperatures (140 ºF / 60 ºC). Do not disassemble.**

1. To turn off the instrument, press the **Power button** and select **Power Off**.
2. When the RAZOR Mk II has turned off, remove the battery by pulling down the pin and sliding the battery off the bottom of the instrument.
3. Slide the battery onto the charger.





4. Plug the power supply into a grounded AC power source and connect the other end to the recharger. When you have plugged in the recharger, the red light will come on.

5. In addition to the red light, the green light also comes on when the battery begins to charge.

   The green light will blink while the battery is charging. When the battery is fully charged, the green light will stop blinking.

Note: A fully depleted battery takes approximately 4 hours to fully charge.

Barcode Reader Window Cleaning

Type of Service:	Preventive Maintenance/Corrective Maintenance
Recommended Frequency:	After operation in an extreme environment such as a dust storm or as needed.
Possible Symptoms:	Difficulty reading barcode data into the instrument. It might take longer than usual, or it might not read at all.
Required Parts:	None
Required Materials/Tools:	Lens cloth (from the startup kit) or microfiber cloth
⚠ **Caution:**	DO NOT POLISH IN A CIRCULAR MOTION (you will grind any particles picked up by cloth into the window).

You should clean the rear protective window for the barcode reader periodically to ensure that the data acquisition is not impeded by dust that might accumulate on the surfaces. You should be very careful, because if you scratch the window by cleaning it incorrectly, you will diminish the ability of the RAZOR Mk II to read protocol barcodes. Wear gloves when you clean the lens.

1. Remove the rubber protective cover to access the bar-code reader window on the lower-left corner of the instrument window's rear panel. Use a lens cloth (supplied with the instrument) and/or a microfiber cloth that will not scratch the optic lenses. Wet the cloth with the cleaning solution that has been supplied.

2. Drag the cloth across the lens in a single direction.

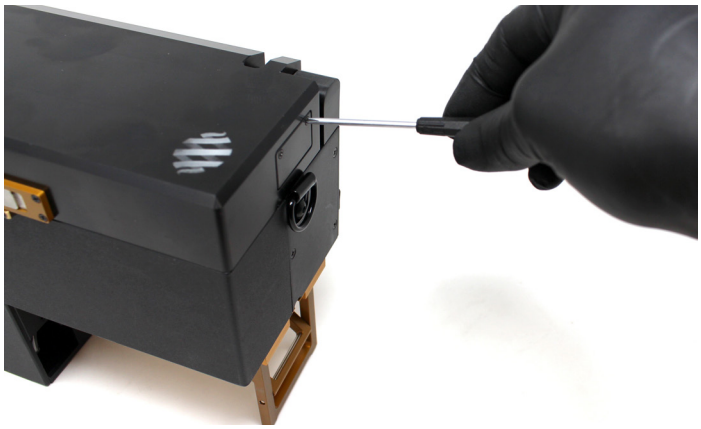
3. Use a clean area of the cloth by changing the position of your finger on the cloth and repeat steps.

4. Once you have cleaned the lens, replace the rubber protective cover. This cover should be in place at all times (when the reader is not in use) to ensure that the window stays as clean as possible.

Coin Battery Replacement

Type of Service:	Corrective Maintenance
Recommended Frequency:	Needs to be replaced about every 2 years or sooner if the instrument is used frequently
Possible Symptoms:	The date and time on the instrument will not stay current.
Required Parts:	Replacement Coin Battery CR 2032 3V
Required Materials/Tools:	#1 Phillips Screwdriver
⚠ **Caution:**	Make sure to wear gloves, remove the battery and external power and to discharge any static electricity. If the battery is inserted incorrectly, it could damage the instrument.

1. Using a #1 phillips screwdriver, remove the 2 screws that secure the battery access door to the lid of the instrument.



2. Using the pull tab that is on the battery, gently pull the battery out of the battery slot in the instrument.

3. Obtain a new battery (CR 2032 3V) and replace the pull tab on the positive side of the battery.
4. Ensuring the correct polarity of the battery, gently insert the new battery into the instrument.
5. Return the battery access door to the lid of the instrument and secure it using the 2 screws.

ERROR CODE TROUBLESHOOTING

The RAZOR Mk II is enabled with self-diagnostics that run continuously while you operate the instrument. The self-diagnostics can generate two types of errors: Fatal Errors and Warnings.

- **Fatal Errors;** are problems diagnosed within the instrument that are beyond the operating tolerances of the system. These errors will not allow the instrument to run correctly and require that you turn off the instrument. Error resolution requires that you set the system in its normal configuration and either restart it or return it for repair.
- **Warnings;** are problems diagnosed within the instrument that fall within operating tolerances. The RAZOR Mk II can compensate for these errors in most cases and run within its operating tolerances. Resolution of some of these errors can be done onsite, while others require that you return the instrument for repair. Contact Technical Support to help resolve these issues.

Be sure to note all error messages before you call Technical Support. A complete list of error messages will help Technical Support resolve the instrument error.

An error can occur in a number of the instrument's subsystems: the fluorimeter, the heater, and the master or valve controllers. The error format is a code indicating the source of the error (F, H, M, P or V) followed by three numbers corresponding to the type of error and a message to the user.

Note: for any errors not listed below, contact BioFire Defense Technical Support.

Error Codes

Xnnn error message
time stamp

Code	Description of Code
F	The fluorimeter controller detected the error
H	The heater controller detected the error
M	The master controller detected the error
P	The power controller detected the error
V	The valve controller detected the error
nnn	A three-digit error number specifying the type of error
The "error message" is specific to the type of error.	

The instrument logs all errors and warnings under Utilities\View Logs\Error Log so that they are always available for display through the utilities function.

The POST is an internal diagnostic routine the instrument runs every time you turn on the instrument power. When fatal errors occur during POST, normal operation cannot continue. When a warning situation occurs during POST, the software displays a message but continues normal operation.

Note: The POST may fail if a pouch is present or if the instrument is open when you turn on the machine. If an error occurs during POST, confirm that the pouch from the previous run has been removed and that the heater bars and access panel are in place. Shut down the instrument and then restart it.

If a warning occurs during normal operation, the instrument will display the warning message for 30 seconds. When there is a fatal error during operation, the instrument will shut down.

If there is a battery charger error, both LED's will blink. Confirm that the external power source is the cable and converter provided with the RAZOR Mk II instrument. If it is, and blinking continues, then contact BFDF Technical Support.

Below is a list of Error Codes and the solutions to fix the issues.

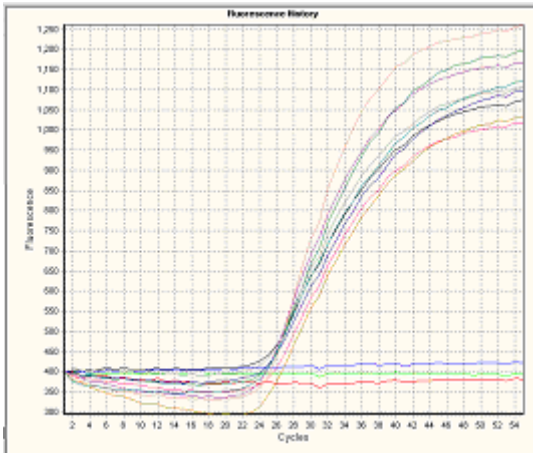
Error Code	Solution
H128 "Too cold or open sensor on Heater A." OR **H129 "Too cold or open sensor on Heater B." OR** **H130 "Too cold or open sensor on Heater C." OR** **H131 "Too cold or open sensor on Heater D."**	1. Warm the instrument until it is above 0°C. 2. Confirm that the heaters are connected. (See "Checking the Heaters" in this chapter.) 3. Restart the instrument. 4. If the error recurs, contact BFDF Technical Support.
H136 "RAZOR too cold to run."	1. Warm the instrument until it is above 0°C. 2. Restart the instrument. 3. If the error recurs, contact BFDF Technical Support.
H137 "RAZOR too hot to run."	1. Cool the instrument until it is below 40°C. 2. Restart the instrument. 3. If the error recurs, contact BFDF Technical Support.
M128 "Unable to Shutdown"	1. Disconnect the external power supply and battery. 2. Reconnect the external power supply or battery. 3. Restart the instrument. 4. If the error recurs, contact BFDF Technical Support.
M130 "Pressure Timeout. Unable to Reach X PSI in bladder Y"	1. Check the air filter and replace it if necessary. (See "Replacing the Air Filter" in this chapter.) 2. If the error recurs, contact BFDF Technical Support.

M138 "Battery Too Low"	1. Connect the external power supply (if it is running) or a new, charged battery. 2. Charge the battery before replacing it onto the instrument. (See "Battery Charging" in this chapter.) 3. If the battery was fully charged, see "Battery Contact Cleaning" in this chapter. 4. If the error recurs, contact BFDF Technical Support.
M003 "Low External Power" (Warning) OR **M139 "External Power Too Low" OR** **M141 "External Power Too High"**	1. Use only an BFDF-provided power supply. 2. If the error recurs, contact BFDF Technical Support.
V131 "Elevation, filter, leak, or sensor failed, POST."	1. Remove air filter from housing. 2. Check the air filter and replace it if necessary. (See "Replacing the Air Filter" in this chapter.) 3. Check tubing and replace if kinked or damaged. 4. If the error recurs, remove battery, straighten filter tubing, and reboot instrument. Run instrument with filter out. 5. If the error continues to recur, contact BFDF Technical Support.
V148 "Valve(s) too slow, POST." OR **V154 "Unable to heat manifold, POST."**	1. Warm the instrument until it is above 0°C. 2. Restart the instrument. 3. If the error recurs, contact BFDF Technical Support.

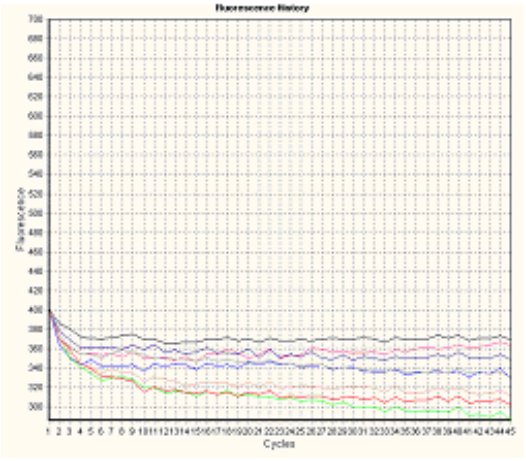
Note: Removing the battery during a run will cause the machine to shut down unless you have also connected an external power supply. Similarly, removing the external power supply during a run will cause the machine to shut down unless you have also connected a charged battery.

PCR TROUBLESHOOTING

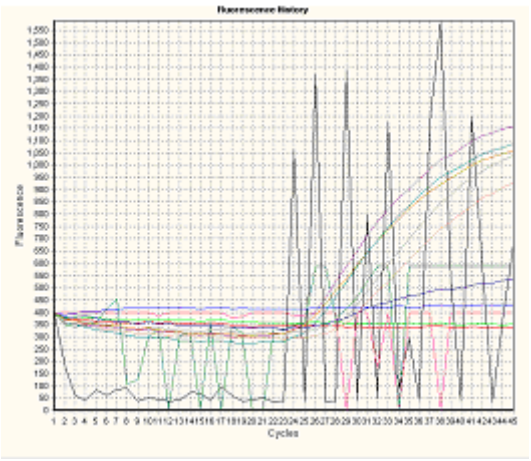
This section contains examples of normal and abnormal PCR data. For the abnormal PCR data, this section also contains possible causes and resolutions. For more details, see the RAZOR Pouch Instruction Booklet.



Normal PCR Data



Abnormal PCR Data
(no amplification of positive controls)



Abnormal Spikes or Noise in Fluorescence Curves (caused by air bubbles introduced into the pouch during loading)

Error Cause	Solution
No pouch in the RAZOR Mk II.	Check to make sure that the pouch was in the RAZOR Mk II during the run.
The liquid was not plunged into the sample slot of the pouch.	Check the plungers to make sure that they are pressed down all the way.
The pouch was placed incorrectly in the machine so that sample slots were not directly over the fluorimeters.	Make sure that the fitment in the pouch sits perfectly in the groove over the insert slot in the machine.
Expired reagents.	Check the pouch expiration date. If the date has expired, repeat the run with a new pouch.
Bad reagents.	Did the pellets look white and fill the wells? If a pouch issue is suspected, contact BFDF Customer Support.
Amplification Inhibition/ Inhibition Control fails.	Make sure that the water and the sample used to resuspend reagents are clean and free of amplification inhibitors. Repeat the run with 1:10 dilution of sample.
Plungers not twisted.	Check that the plungers were twisted so that the arrows point to the middle (parallel with the fitment) before plunging.
Sample not added.	Confirm that liquid was pulled out of the syringe into the pouch fitment.
USB connection lost with intermittent or poorly regulated power.	Reset USB port by either resetting port on the PC or unplugging then replugging the USB cable.
Bar code reader quits after electrostatic discharge to RAZOR case.	Reboot RAZOR Mk II. If intermittent or poorly regulated power conditions are suspected, run the instrument with the battery pack installed.
Positive control fails.	Use only sample and control buffers included in the RAZOR Mk II pouch kit.

Causes for Abnormal Fluorescence Curves	Solution
A loss of vacuum allowed air into the channel.	If the pouch did not pull liquid from the syringe into the channel while it was loading, or if it pulled very little liquid, contact BFDF Customer Support.
Air in the syringe allowed air into the channel.	Make sure the syringe is full of liquid with no air bubbles before you load it.
The syringe does not have enough liquid.	Before you load the pouch, ensure that the syringe has at least: • 0.5 mL of liquid per port in a 4 x 3 100 µL pouch • 0.2 mL per port in a 12 x 1 100 µL pouch • 0.35 mL per port in a 6 x 2 100 µL pouch • 2.0 mL per sample port for 1 x 12, 11 + 1, and 10 + 2 100 µL pouches; .4 mL for control port

DECONTAMINATION AND CLEANING PROCEDURES

Note: The procedures in this section describe 3 bleach wipes and 3 distilled water wipes for general maintenance decontamination. If you have a spill or pouch breakage, BioFire Defense recommends 10 bleach wipes and 10 distilled water wipes to ensure complete amplicon eradication. If the instrument has been used with pathogenic agents, gas decontamination may be required.

Contact BioFire Defense Technical Support for any concerns about these decontaminating procedures and properly maintaining the RAZOR instrument.

If a spill occurs, the decontamination and cleaning procedures in this section are intended to limit the spread of DNA or RNA, PCR amplicon, or biohazards. For instance, if a spill occurs in the RAZOR reaction chamber, decontaminate the RAZOR instrument and the bench top (or other areas) surrounding the RAZOR.

Warning: It is the users responsibility to decontaminate the instrument and all work areas that might have been contaminated to prevent false-positive readings in subsequent runs.

Warning: Do not wipe bleach on the optics or battery contacts.

After a spill, change gloves and other potentially contaminated personal protective equipment (PPE). Change gloves often during the decontamination process, especially during the first steps of decontamination and before touching any clean surface. Dispose of all PPE after the decontamination.

This list provides items that are necessary in a laboratory to keep contamination to a minimum.

- 10% bleach solution in a squeeze or spray bottle (1 part bleach to 9 parts water)
- Distilled water in a squeeze or spray bottle
- 95% ethanol in a squeeze bottle
- DNA*Zap*™, or an equivalent DNA degrading system

- Paper towels
- Bleach wipes
- Lens cleaner
- Lens cloth

Warning: Do not use or mix any decontamination or cleaning agents that could cause damage or react with the instrument.

RAZOR Internal Instrument Decontamination

Note: Decontaminate the interior of the instrument before decontaminating the outside.

1. Put on gloves. Open the heater boards. (See "*Accessing Internal Components, Heaters and Lenses*" in this chapter for detailed instructions.)
2. Wet the lens cloth with the 10% bleach solution.
3. Gently wipe the following items. When you are cleaning the heater plate, wipe around, but not across, the optic lenses; be very careful not to scratch the lenses.
   - The heater plate
   - The bottom of the heater chamber
   - The inside of the access panel
4. Repeat step 3 twice changing gloves each time.
5. Change gloves. Wet a fresh lens cloth with distilled water and repeat step 3 three times changing gloves each time.

RAZOR External Instrument Decontamination

1. Put on gloves. Wet a paper towel with the 10% bleach solution and wipe the entire exterior of the instrument, including the bottom and the bench top where the instrument had contact and the battery. Avoid the battery contacts, just as you avoided the optic lenses.
2. Repeat step 1 twice, with fresh paper towels and clean gloves, for a total of three bleach wipes.
3. Change gloves, then wet a new paper towel with distilled water and repeat step 1 using the water wipe.
4. Repeat step 3 twice with distilled water for a total of three wipes.

Decontamination of Bench Tops and Other Areas

1. Spray the 10% bleach solution on the area that may have been contaminated. Let it stand for 5 min.
2. Wipe the area with a clean paper towel, and then change gloves.
3. Repeat steps 1 and 2 twice, for a total of three wipes.
4. Change gloves and spray the area with distilled water.
5. Wipe the area dry with a new paper towel. Change gloves.
6. Spray the area with DNA*Zap*, or an equivalent product. Follow the product's instructions for correct use. Change gloves.
7. Rinse the area by spraying it with distilled water and wiping it dry.

General Statements

This section provides important statements that apply to this product.

WARNING: Laboratory Safety

- Equipment is intended for professional use only.
- Laboratory personnel should be trained and adhere to the principles of good laboratory practice.
- All the user documents supplied must be read prior to use of the equipment.
- Under no circumstance should the user dismantle equipment owing to the risk of touching dangerous parts, including parts that are infectious or connected to a source of electric power.
- Do not obstruct the equipment and hardware ventilation apertures, and leave sufficient clearance around the equipment for the circulation of air.
- All biological fluids should be considered as potentially infectious.
- Suitable individual protective equipment is required when handling chemical or biological substances.
- BioFire Defense is in no case liable for the harmful consequences of incorrect use or improper handling of these substances.

WARNING: Electromagnetic Compatibility (EMC)

- Do not use this device near strong sources of electromagnetic radiation (for example, intentionally unprotected radio-electric sources), which could interfere with the running of the equipment.
- It is recommended to evaluate the electromagnetic environment before starting up the device.

WARNING: Decontamination of equipment at the end of its life cycle

- The instructions below must be followed by all users in countries where local legislation imposes the treatment and recycling of equipment at the end of its life cycle.
- As a general rule, and as a precautionary measure, any part of the equipment (including sub-assemblies, components, material, and so on) considered to be potentially infectious, must be decontaminated, whenever possible, or removed if decontamination is impossible or presents a risk.
- Any part considered to be potentially infectious, which is not decontaminated, must be removed from the instrument before following the normal channels for elimination of infectious products,in accordance with local regulations.
- The decontamination instructions in the user documentation correspond to the parts of the equipment that are potentially infectious according to their intended use. These operations must be performed before the equipment is transferred to a third party.
- However, BioFire Defense cannot exclude that other parts of the equipment have not been contaminated in other circumstances, in particular as the result of spillage of infectious substances. In this case, the user is solely responsible for decontaminating these parts or removing them before they follow the normal channels for elimination of infectious products.

WARNING: Waste Electrical and Electronic Equipment European Directive

- This statement only applies to European countries with regard to the waste electrical and electronic equipment European Directive 2012/19/EU.
- You can play an important role in contributing to reuse, recycling, and other forms of recovery of waste electrical and electronic equipment. Sorting this type of waste significantly reduces potential negative effects on the environment and human health as a result of the presence of hazardous substances in electrical and electronic equipment.
- At the end of the life cycle of this product, these items must be disposed of via designated collection facilities appointed by the government or local authorities. For more information about the disposal of your old product, please contact your city office or waste disposal service; or contact BioFire Defense (contact information available on www.biofiredefense.com).

IMPORTANT: Electrical or other connections should only be done using the accessories supplied with the equipment.

IMPORTANT: It is important to follow all the restrictions on use, particularly concerning temperature, storage, installation, voltage, and so on, which are indicated on the product label or in the user documentation.

IMPORTANT: The accuracy of results obtained with this equipment depends on the maintenance operations described in the user documentation (user maintenance and/or periodic preventive maintenance performed by BioFire Defense).

IMPORTANT: The user should be aware that if the maintenance operations are not performed, are only partially performed, or are not performed as described in the user documentation, BioFire Defense is in no case liable for any false test results obtained.

IMPORTANT: It is recommended to keep the original packaging materials in case the equipment needs to be moved. Any damage directly or indirectly resulting from the transport of the equipment without adequate containers will not be covered by the warranty.

Maintenance Log

A decontamination and cleaning record should be kept on a log similar to the one shown.

RAZOR Instrument Maintenance Log

Date	User Name	User Trained on RAZOR	RAZOR Serial #	Assay	Lot # of Assay	Date of Issue/ Maintenance	Description of Issue/Maintenance	Corrective Action
11/19/2017	User 1	Yes	RAZOR-1001	Anthrax Target 1	700704		Error V131	Replaced air filter

APPENDIX A: FLUORIMETRIC REAL-TIME DETECTION PRINCIPLES

COMPONENTS OF POLYMERASE CHAIN REACTION

Polymerase chain reaction (PCR) is the process of making billions of copies of nucleic acid. This process involves separating the double-stranded deoxyribose nucleic acid (DNA) into separate strands and making multiple copies of each strand. A large quantity of DNA is needed for detectable and recordable fluorescence.

To copy DNA, four components are needed:

1. DNA polymerase
2. A supply of the four nucleotide bases—deoxyribonucleotide triphosphate or dNTPs
3. Primers
4. Target DNA

The DNA polymerases, whether from humans, bacteria, or viruses, cannot copy a chain of DNA without a short sequence of nucleotides to “prime” the process, commonly called a primer. Once the primer anneals, DNA polymerase can take over making the rest of the new chain.

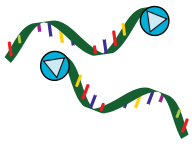
Real-time PCR is a complex mixture of sample DNA, primers, probes, dNTP molecules, DNA polymerase enzyme, and buffer. The PCR reaction is incorporated with either nonspecific DNA binding dyes or a fluorescent-based probe system to monitor the amplification of DNA during the temperature cycling.

Sample DNA

- Provides the target template

Primers

- Approximately 25 bases long (nucleotides adenine (A), thymine (T), cytosine (C), and guanine (G), which act as the building blocks and backbone of DNA).
- Define each end of the sequence of DNA to be amplified.
- Complementary to a specific region of interest.
- Anneal to denatured (separated) DNA template.
- Docking station for polymerase.
- Excess amounts in master mix ensures the primer will bind to the complementary sequence of interest.



Probes

- Approximately 25 bases long (nucleotides adenine (A), thymine (T), cytosine (C), and guanine (G), which act as the building blocks and backbone of DNA).
- Specific to target DNA and have fluorescent dyes attached to their sequences.
- Types of probes
- Hybridization probes have one red probe and one green probe that are designed to hybridize together and then fluoresce.
- Hydrolysis probes have one green probe that is cut and then fluoresces.
- Fluorescence is proximity dependent.
- When bound, instrument LED excites the green dye, which then excites the red dye leading to measurable fluorescence.
- Fluorescence proportional to PCR (number of copies of the target sequence).

dNTPs—Deoxynucleotide Triphosphates

- Needed for DNA synthesis.
- dNTPs have a nucleotide and an energy donor.
- Nucleotide bases are the actual building blocks used to create the copied DNA strand.
- Bind in pairs: A and T, C and G.
- Equal amounts of nucleotides are used to prevent mismatches of bases.

- Defines amplicon (targeted area of DNA).

Enzyme

- Polymerase enzyme builds the DNA copy by placing each nucleotide base in its proper position.
- Stable at very high temperatures >100 °C.
- Must have a template strand of DNA to copy.

Buffer

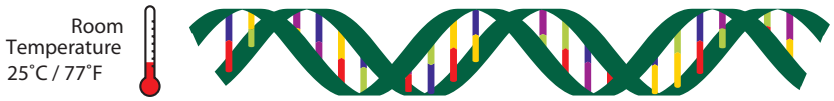
- Maintains the optimal reaction pH (a measure of the strength of acids and bases) for PCR.
- Contains stabilizing ions.
- Polymerase requires free ions for activity.

Water

- The universal solvent and standard diluent.

POLYMERASE CHAIN REACTION BASICS

The three parts of PCR are carried out in the same slot, but at different temperatures. Each PCR cycle is comprised of three processes: denaturation, primer annealing, and primer extension. First, the DNA is heated to achieve denaturation. The primers cannot bind at a high temperature, so the DNA is then cooled, which allows the primers to anneal and extend. The PCR reaction therefore involves temperature cycling, and the DNA polymerase used in the reaction must be tolerant of high temperatures and rapid heating and cooling.



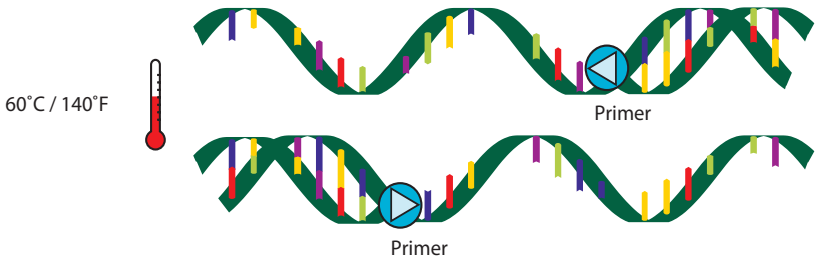
DNA at room temperature in a normal environment is double stranded

Step 1. Denaturation

A sample containing double-stranded DNA target strands is heated to about 91ºC (about 196ºF). This process separates the DNA strands.

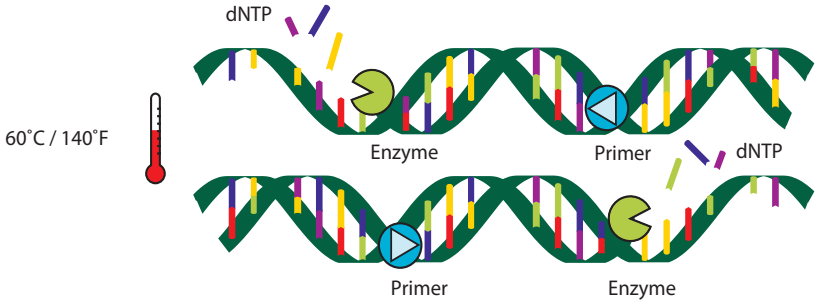
Step 2. Annealing

The sample is cooled to about 60ºC (about 140ºF), which allows the primers to bind or “anneal” to the DNA strands at a specific sequence. Sequence, composition of nucleotides, and length of primers determine optimal annealing temperatures.



Step 3. Extension

The final step of the reaction is to make a complete copy of the templates. The sample is held at the anneal temperature to allow the nucleotides to fill in and read the fluorescence of the probes. At temperatures close to the annealing temperatures, the enzyme is effective and efficient.



The DNA polymerase begins adding nucleotides to the primer and eventually makes a complementary copy of the template. If the template contains an A nucleotide, the enzyme adds on a T nucleotide complementary to the target strand. If the template contains a G, it adds a C to the new chain, and so on until it reads to the end of the DNA strand. This completes one PCR cycle.

The three steps in PCR—denaturation, annealing, and extension—take less than 30 seconds. Each is carried out in the same sample slot. At the end of a single cycle, each piece of DNA has been duplicated. A typical PCR program will run a total of 45–55 cycles.

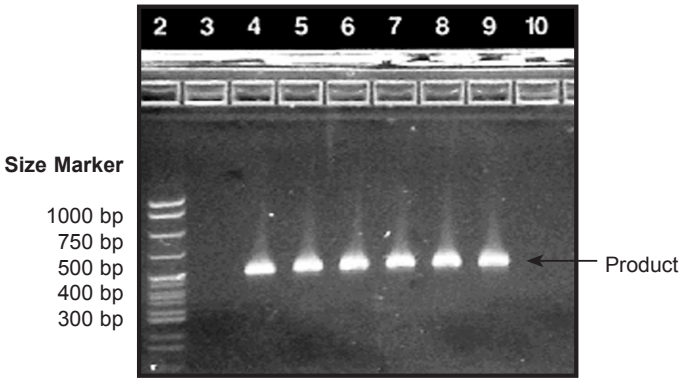
Each newly synthesized double-stranded DNA copy acts as a new template, so after 30 cycles, 1 billion copies of a single piece of DNA can be produced! Taking into account the time it takes to change the temperature of the sample pouch, 1 billion copies can be created in about 30 minutes.

ANALYSIS METHODS

Agarose Gel Electrophoresis

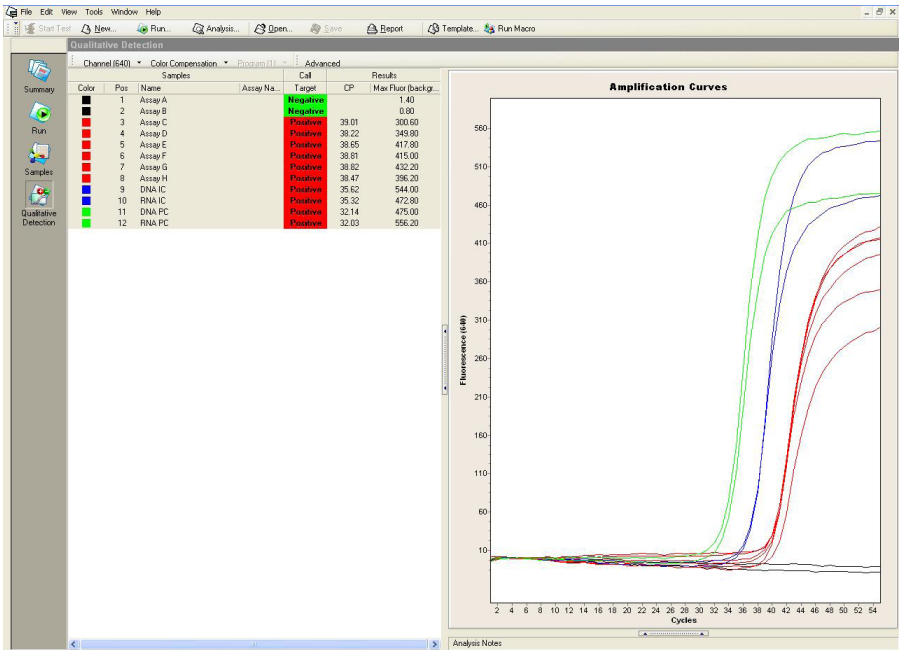
Electrophoresis is a technique used in the laboratory that results in the separation of charged molecules. The DNA molecule is negatively charged and moves by electric current through a matrix of agarose.

Once the PCR cycle is complete, the user needs a tool to view the duplicated product. One conventional method is an agarose gel viewed under an ultraviolet (UV) lamp.



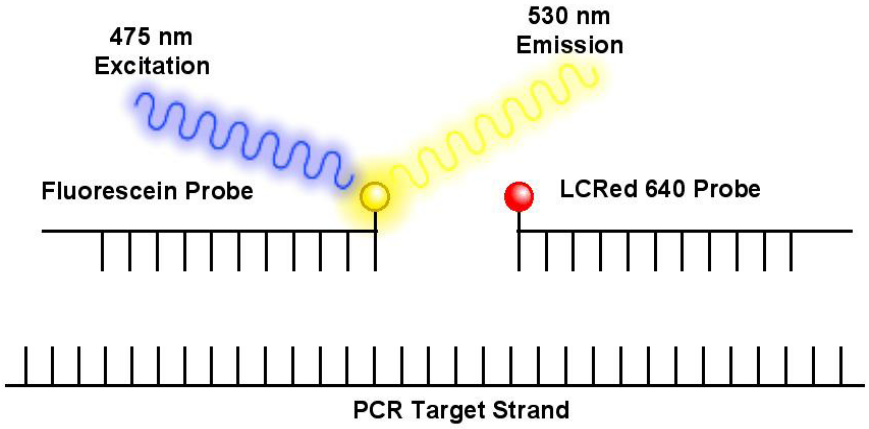
Fluorimetric Detection Real-time Polymerase Chain Reaction

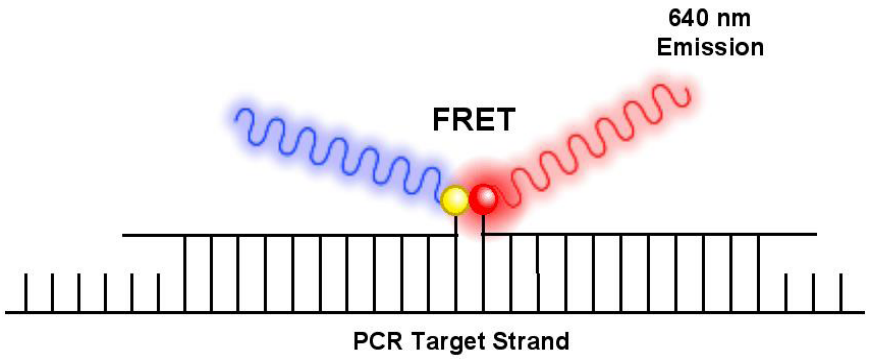
In real-time PCR, a short specific DNA sequence called a probe is used to measure DNA amplification. Probes have fluorescent dyes attached to their sequences, which enables a user to measure DNA quantity.



Hybridization Probes

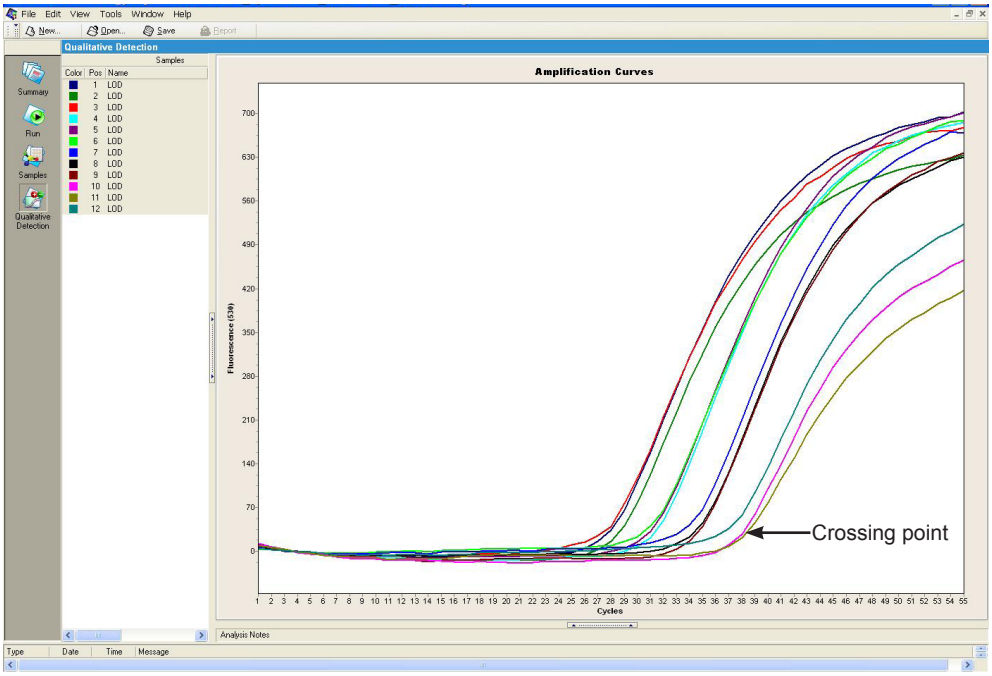
Hybridization probes are composed of a pair of DNA strands designed to hybridize adjacent to each other. Each carries a dye (fluorophore) at its facing end, which interact. The shorter green wave dye, fluorescein, is excited by blue light from the instrument's LED and transfers its energy to the longer red wave dye, LCRed 640. This fluorophore emits red light, which is detected by the instrument. Therefore, the signal will only activate when both probes bind adjacent to each other. This transfer of energy is called fluorescence resonance energy transfer, or FRET. The fluorescent signal will be proportional to the number of copies of the target sequence.





Understanding Sample Crossing Points

In an amplification reaction, the cycle at which the fluorescence of a sample rises above the threshold level of background fluorescence is called the crossing point (Cp) of the sample. The presence of a Cp indicates that target DNA is present. A Cp is the point at which amplified product is first visible in the data. The Cp is given to determine the amount of fluorescent PCR product present. The software uses the second derivative maximum of each data curve (where the slope of the curve changes) to extrapolate the point where the threshold is crossed. A sample's Cp is expressed as a cycle number. An earlier Cp indicates the presence of more starting target DNA than a later Cp. The PCR process is exponential; it approximately doubles every cycle. Consequently, a 10-fold dilution should be approximately 3.5 PCR cycles later than an undiluted sample. A sample with a lower initial concentration of target DNA has a higher Cp because it requires more amplification cycles to reach the threshold. A sample with a higher concentration of DNA generally has an earlier, lower Cp because it requires fewer cycles to reach that threshold.



Understanding Max Fluorescence

Fluorescence increases as more PCR product is made. Max fluorescence measures the highest level of fluorescence reached by a sample during the PCR run. The fluorescence has the initial background fluorescence subtracted, thus providing a baseline to compare different samples.

If a large amount of template is initially present, the fluorescence may plateau near the end of the run. This is most likely due to the necessary components for PCR being consumed by the reaction.

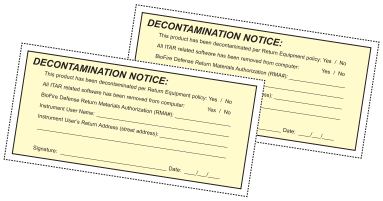
APPENDIX B: DECONTAMINATION AND RETURN FORMS

Note: For international returns, please call BioFire Defense Technical Customer Support for detailed instructions.

An instrument problem may be reported by calling, e-mailing, or mailing BioFire Defense using the information below. If you are returning an instrument for repair, follow the guidelines outlined in this appendix. You will also need the following documents:

Declaration of Decontamination

Decontamination Labels (2 labels)



Phone

+1-801-262-3592 - United States and Canada
IDD+1-801-262-3592 - International

E-mail

support@BioFireDefense.com - Technical Customer Support

Web Site

www.biofiredefense.com/support/return-forms

Address

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

Step 1: Obtain a Return Materials Authorization Number

The first step in returning an instrument to BFDF is to obtain a Return Materials Authorization (RMA) number from our Service Department by filling out the RMA form at **http://biofiredefense.com/support/return-forms/.**

A Technical Service specialist will contact you with an RMA number and further instructions. If your instrument is still under warranty, please supply the purchase date and serial number, if your instrument is out of warranty, please supply a blank PO# for the repair charges.

Step 2: Decontaminate All Returned Equipment

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

The person responsible for the return must thoroughly decontaminate the unit by following the instructions in “Decontamination and Cleaning Procedures,” in *Chapter 4, Maintenance and Troubleshooting*.

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.

Step 3: Decontamination Labels

After the above steps have been completed, the person responsible for the return must complete and sign two decontamination labels and attach one to the instrument and the other to the exterior of the shipping container. Complete and sign the Declaration of Decontamination form; a photocopy should be made for your records and the original must be returned with the instrument.

Note: An RMA number must be obtained from BFDF before shipping. The RMA number and decontamination labels must be visible on the exterior of the shipping container.

BFDF reserves the right to return or refuse receipt of any materials at the customer’s expense that do not meet these requirements.

Step 4: Packaging and Shipping

1. Package the RAZOR Mk II instrument inside its Pelican case and put it into a large heavy-weight box (recommended box size 24" x 19" x 23" or larger). Pack all sides with 2 inches of instant packing foam or packaging material.
3. Pack all accessory components in packing materials and place in packing box.
4. Fill all sides and top of the shipping box with at least 2 inches of instant packing foam or packaging material to protect against shipping damage.
5. Seal the box with packaging tape.

Return Instrument Check-off List

To avoid complications with the return of an instrument, please check off each box before returning the instrument to BioFire Defense. All items on this list should be included when returning an instrument.

- ❒ Did you get an RMA number from BioFire Defense?
- ❒ Did you complete the decontamination procedures?
- ❒ Did you attach the decontamination labels to the outside of the box and on the instrument?
- ❒ Did you include all of the startup kit and accessory kit items with the instrument? (For loaner or replacement only.)

The following parts should be included with the returned instrument.

- ❒ RAZOR instrument
- ❒ Battery
- ❒ Battery charger
- ❒ Power cords
- ❒ USB cable

Please check appropriate box if parts below are included with the returned instrument:

- ❒ Operator manual
- ❒ Quick guides
- ❒ Needle nose pliers
- ❒ Air filter (spare)
- ❒ Lens cleaning solution
- ❒ Lens cleaning tissues

Declaration of Decontamination

Declaration of Decontamination

This instrument has been decontaminated according to established BioFire Defense biological decontamination procedures (found in Chapter 4).

Which method was used? _____

_____

_____

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

_____

_____

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 case and the other to the exterior of the shipping carton. Failure to decontaminate before shipping to BioFire Defense will result in the immediate return of the unit at your expense.

Copy this page and cut out the label and attach it to the case of the instrument being returned.

DECONTAMINATION NOTICE:

This product has been decontaminated per Return Equipment policy: Yes / No

BioFire Defense Return Materials Authorization (RMA#): _____

Instrument User Name: _____

Instrument User's Return Address (street address): _____

_____

Signature: _____ Date: ____/___/____

Copy this page and cut out the label and attach it to the case of the instrument being returned.

DECONTAMINATION NOTICE:

This product has been decontaminated per Return Equipment policy: Yes / No

BioFire Defense Return Materials Authorization (RMA#): _____

Instrument User Name: _____

Instrument User's Return Address (street address): _____

_____

Signature: _____ Date: ____/___/____

APPENDIX C: QUICK GUIDES FOR THE RAZOR MK II

INTRODUCTION

This appendix contains the quick guides for the RAZOR Mk II Instrument. These guides have been developed as an abbreviated version of certain tasks that are repeated often and is provided as a guide for a trained operator. For more detailed descriptions of the items contained in these quick guides, refer to the specific sections in this manual.

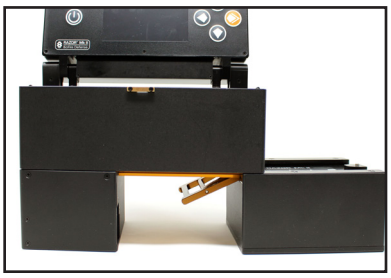
This Quick Guide describes the following procedures:

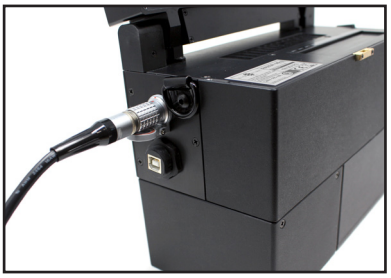
- Setting up the RAZOR Mk II Instrument
- Recharging the Battery
- Scanning the Protocol Bar Codes
- Loading the RAZOR Mk II Pouch

RAZOR® Mk II
SETTING UP

Setting Up the RAZOR Mk II Instrument

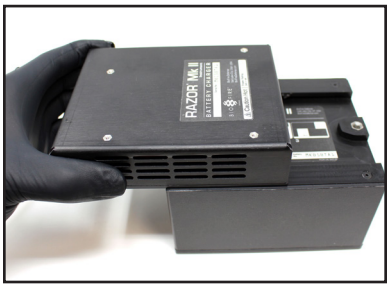
1. Unpack the RAZOR Mk II instrument and set it on a solid, flat surface.
2. Slide the battery into the bottom-right side of the instrument. Be sure the locking pin slides into place. Install the battery even if using the power supply to avoid power disruption during a run.
3. If using external power, plug the power supply into a grounded power source and connect the other end to the RAZOR Mk II power port by lining up the red dots.
4. Open the protective lid.
5. Press and hold the **Power** button for **5** sec.
6. The instrument will perform a 40-sec. self-diagnostics test. If you get an error message, refer to "*Error Code Troubleshooting*" in *Chapter 4* of the operator's manual.





Charging the Battery

1. Turn the instrument off.
2. Pull the ring on the battery down and slide the battery off of the instrument.
3. Slide the battery onto the recharger until it clicks.
4. Plug the power supply into a grounded AC power source and connect the other end to the recharger.
5. When the battery is charging, the green light will blink. When the battery charge is full, the green light will be solid.



Scanning the Protocol Barcode

Note: Protocol barcodes can be scanned before field deployment.

Note: Hold the barcode approximately 6–8 in. from the back of instrument and center the bright green aiming beam over the barcode in any direction (vertically, horizontally, diagonally). When the scan completes, the aiming beam will disappear and the instrument will display a success message. If the scan does not complete within 15 sec., flatten the image and/or move the barcode gradually closer to the instrument while you are scanning it.

1. Select **Main Menu > Utilities.**

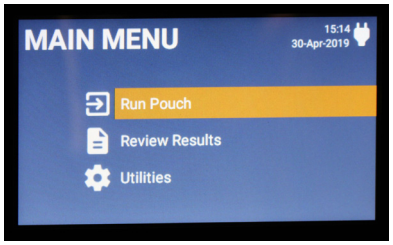
2. Select **Scan Protocol Code**.

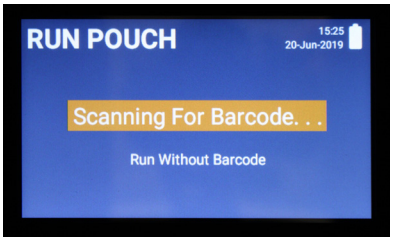
3. Scan the **square** protocol barcode on the kit box by holding it up to the scanner at the back of the RAZOR Mk II instrument.

Kit Part Number: PATH-ASY-0092
Protocol Code: GENERICB

Scanning the Pouch Bar Code

1. Select **Run Pouch** from the **Main Menu**. When **Scanning For Barcode...** displays, scan the **rectangular** barcode on the pouch (barcode must be held vertically). After the scan, the screen will display **Starting Run**.





Note: If the barcode does not scan properly, an error message will display. If the wrong barcode is scanned, the message "**Invalid Barcode Data**" will appear.

GENERICB-GENB0005

RAZOR® Mk II

LOADING A POUCH

Sample Collecting

Dry Sample (Powders, etc.)

1. Touch the dry swab to the unknown powder.
2. Place the swab into the appropriately labeled vial and break off at break point.
3. Secure the cap on the vial and shake vigorously for 30 sec.

Liquid Sample (Automatic Air Samplers, etc.)

1. Transfer approximately 0.5 mL of liquid to the appropriately labeled vial.

   To draw a sample with the transfer pipette, first squeeze and hold the top of the bulb. Insert the tip of the pipette into the liquid and release the bulb to draw sample up to fill line. Transfer the pipette to the vial and squeeze the bulb to empty the sample into the vial.
2. Secure the cap on the water vial and shake vigorously for 30 sec.

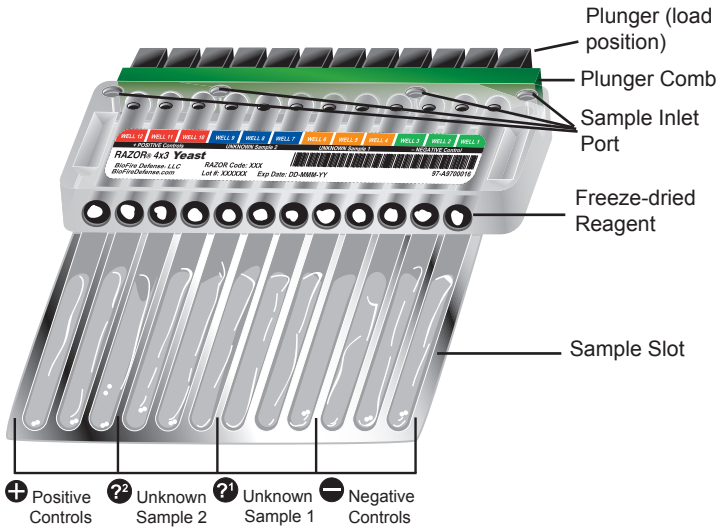
Once the raw sample has been prepared, load the sample into the pouch.

Loading the RAZOR Pouch

⚠ **CAUTION:** In the following procedure, DO NOT push the syringe plunger to force liquid into the pouch. This can fill the pouch with air and may damage the pouch or cause contamination.

1. Confirm that the foil bag is air tight.
2. Open the foil bag and remove the freeze-dried reagent pouch from the aluminum can.
3. Place the pouch on a flat, clean surface with the inlet ports and label face up. Make sure the plunger comb is in place.
4. Uncap the end of a syringe and insert the tip end into reagent grade water or the sample.
5. Draw reagent grade water or the sample into the syringe until it reaches the mark for the appropriate volumes. Avoid introducing any air into the syringe, which can cause bubbles.
6. Follow the prescribed order below to minimize cross-contamination and user error. Loading instructions are also found on the reagent pouch label.

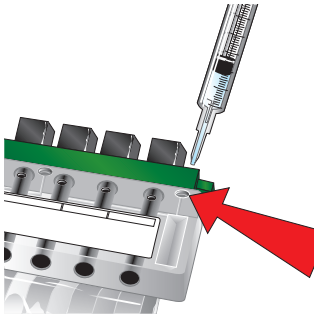
Step 1	Step 2	Step 3
⊖ Negative Controls →	? Unknown Samples →	⊕ Positive / Inhibition Controls



Example Pouch with Key Parts Labeled

Follow the same procedure for loading the negative controls, the unknown sample, and the positive control:

7. Load a syringe with the correct volume of sample.
   - For the **Negative** control inlet port and the **Positive** control inlet port, use the **Reagent Grade Water** supplied in the reagent kit.
   - For the **Unknown Sample** inlet port use the **Unknown Sample**.
8. Hold the syringe by the syringe body and gently insert the tip into the **correct** inlet port. Push the syringe down until you feel a faint pop and ease in resistance.



Negative Control Inlet Port

9. Allow the syringe to sit in the inlet port for at least 30 sec. to allow the liquid to dispense evenly.

   After all of the syringes have emptied into the reagent pouch, confirm that each of the dried reagents are dissolved in the liquid.

   If the reagents are dissolving slowly, shake the pouch gently by hand.

APPENDIX D: RAZOR MK II PARTS

PARTS

The following table includes items that are packaged with the RAZOR Mk II instrument as well as items that are required and recommended to perform pathogen identification. Descriptions and part numbers for these items have been included to make ordering easier. Please contact BioFire Defense to report defects in materials or manufacture, this will help us improve the quality of our products.

Item	Part Number
RAZOR Mk II Instrument	RAZR-ASY-5000
USB Cable	ELEC-CAB-0040
Battery Charger	RAZR-ASY-5200
24Vdc 6.25A Power Supply	POWR-SUP-0011
Instrument Battery Pack	RAZR-ASY-5100
Air Filter Assembly	RAZR-ASY-5300
Power Cord 110V	POWR-CRD-0001
Power Cord 220–230V	POWR-CRD-0002
Hard Carrying Case	RAZR-CAS-0002
Instrument Grab Strap	RAZR-SUB-5029
Plunger Twist Tool	TOOL-DRV-0016
RAZOR Mk II Operator's Manual	RAZR-PRT-0025
Quick Guide - Setting Up	RAZR-PRT-0026
Quick Guide - Loading a Pouch	RAZR-PRT-0027
Tool Kit	
5 1/2" Needle Nose Pliers	5234
Lens Cleaning Solution	1803
Lens Cleaning Tissue	1802

For a complete list of test kits, visit us at www.BiofireDefense.com.

GLOSSARY OF TERMS

Annealing: The second step in a PCR cycle where the primers bind the DNA sequence to initiate product extension. This step is optimized according to the melting temperature of the primers (i.e., 40–65ºC).

Conjugated (i.e., attached): Containing two or more double or triple bonds in alternation with single bonds. Used to describe a double chemical bond separated by a single bond.

DNA: Deoxyribonucleic acid. One of two types of molecules that encode genetic information. (The other is RNA. In humans DNA is the genetic material, and RNA is transcribed from it. In some other organisms, the reverse occurs: RNA is the genetic material, and DNA is transcribed from it.)

Denaturation: The first step in a PCR cycle where the double-stranded DNA is melted at high temperature (92ºC) into single strands.

Excitation: The light energy transfer between the dyes on two hybridization probes in close proximity when bound to a DNA strand.

FAM: 6-carboxyfluorescein. A fluorescence dye commonly used in hydrolysis probes.

Fluorescence Monitoring: Measurement of light emitted from a fluorescent probe.

Fluorescein (FITC): 5-carboxyfluorescein. Commonly used in hybridization probes.

F.R.E.T.: Fluorescence Resonance Energy Transfer. Light energy transfer between the dyes on two hybridization probes in close proximity when bound to a DNA strand.

Gel Electrophoresis: Separation of nucleic acid or protein through a matrix of either agarose or polyacrylamide by subjecting it to an electric field.

Hydrolysis Probes: These probes rely on the 5' exonuclease activity of Taq polymerase to cleave the DNA between two dyes. One dye is fluorescent, and the other dye acts as a fluorescence quencher. Cleavage of the DNA probe between these two dyes releases the fluorescent dye from quenching.

Hybridization Probes: These probes show an increase in FRET as product accumulates. One probe is labeled at the 5' end with a fluorescent dye, and, to avoid extension, modified at the 3' end by phosphorylation. The second probe is labeled at the 3' end with a different fluorescent dye. Only after hybridization to the template DNA do the two probes come in close proximity, resulting in FRET between the two fluorophores.

Inhibition: Interference with DNA amplification or detection of target sequences.

Inhibition control (IC): A positive control to which an unknown sample is added. Inhibition controls are considered a success if they amplify. The IC is used to determine the presence of inhibitors (agents such as bleach, EDTA, or ethanol), which might affect detection of target sequences.

mL: Milliliter (1/1,000 of a liter). A unit of measurement for liquids.

Negative control (NC): Contains all components needed for performing PCR, but does not contain the nucleic acid target for which the unknown samples are being analyzed. A negative control is located separately from the unknown samples. If amplification occurs in the negative control, then the control fails. In this case, the negative control is contaminated, and unknown samples may also be contaminated

LED: Light emitting diode. Light source for fluorescing the probes in the samples.

PCR: Polymerase chain reaction. A key technique in molecular genetics used to analyze and reproduce (amplify) selected short sequences of DNA (or RNA). Previously, amplifying was done in bacteria and took weeks. But now, with PCR done in capillaries, it takes less than 30 min. The method is highly efficient so that untold numbers of copies can be made of DNA.

Positive control (PC): The positive control contains all components needed for performing PCR, including a target that should amplify. A positive control is located separately from the unknown samples, and its results apply to the unknowns in the run. If amplification does not occur in the positive controls, then the control fails.

RNA: Ribonucleic acid. A nucleic acid molecule formed upon a DNA template and similar to DNA but containing ribose rather than deoxyribose. There are several classes of RNA molecules, all of which play crucial roles in protein synthesis and other cell activities.

Transcription: The first step in carrying out genetic instructions in living cells wherein the genetic code is transferred from DNA to molecules of messenger RNA, which subsequently directs protein manufacture.

Taq polymerase: Enzyme essential for PCR to occur. It “reads” the DNA sequence and facilitates the product extension by assembling each nucleotide.

µL: Microliter (1/1,000,000 of a liter). A unit of measurement for liquids.

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