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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.



RAZOR® EX Operator's Manual

RAZR-PRT-4018 Rev. 08 05/2019

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### Reach Us On the Web

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BioFire Defense' Web site is - <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 EX instrument.

### Reach Us By E-mail

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Contact BioFire Defense by e-mail in the following areas:

**support@BioFireDefense.com** - Technical Support

**it@BioFireDefense.com** - General Support

### Reach Us By Phone

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Technical support is available during the following times:

8 a.m. to 5 p.m. - Mountain Standard Time

For technical support call:

**(801) 262-3592** - United States and Canada

**+1-801-262-3592** - International

### International Returns

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



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## ABBREVIATION OF TERMS

-.....	negative
+.....	positive
A.....	amp (ampere)
BDFD .....	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 <i>Thermus aquaticus</i>
Tm.....	melting temperature
USB .....	universal serial bus
UV.....	ultraviolet
V .....	volt
W .....	watt

## INSTRUMENT MANUAL SYMBOLS

The following symbols can be found throughout this manual. Use the definitions below as a guideline to interpreting the symbols.



The heat symbol identifies a potentially hot surface. To avoid bodily injury, use caution when working near hot surfaces. You should also keep flammables and combustibles at a safe distance.



The warning symbol warns you to operate the instrument according to the instructions provided in this manual. If you do not, you might create a potentially hazardous situation or invalidate the results.



The tips symbol tells you how to operate the instrument more efficiently.



The biohazard symbol identifies a biohazard danger. Use standard laboratory techniques when you handle pathogenic material.



The ground symbol indicates a protected ground terminal. Connect this terminal to ground before making any electrical connections.



All instruments shipped to the European Union (EU) have the CE label on the instrument. This label signifies that this instrument complies with the Electromagnetic Compatibility and Low Voltage Directives and the safety requirements for laboratory equipment.

# CHAPTER 1:

# TECHNICAL COMPONENTS

## INTRODUCTION

BioFire Defense' (BFDF) RAZOR® EX 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) or Bluetooth®.
- You can easily use a needle-free syringe to insert samples into a pouch with self-contained freeze-dried chemical reagents.
- Pouches are provided with a prep kit that includes all the necessary components to collect and prepare unknown samples.
- You can scan the bar code on the pouch to program the machine. The instrument displays positive calls in real time.

The technology behind the RAZOR EX 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 EX Instrument's major components**

## How the RAZOR® EX Instrument Works

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The RAZOR EX Instrument operation is based on fluorimetric measurements and PCR. PCR uses heating and cooling cycles to make copies of target deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), 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 proprietary 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.

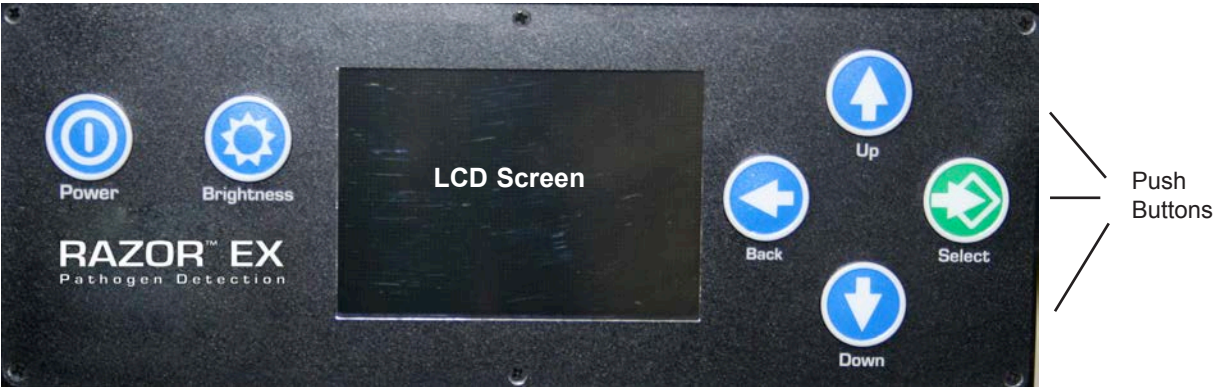
After the user prepares the reagent pouch, it is inserted into the instrument through the top slot. The instrument moves samples between heat zones to achieve temperature cycling. During temperature cycling, reagents in the pouches copy or amplify target DNA that is present. The sample pouch sits next 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 EX software makes pathogen identification simple due to its ability to make positive calls as they occur during the run.

The RAZOR EX can do multiple runs and analyses as a hand portable instrument in the field. The instrument can run and store 75 runs 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.

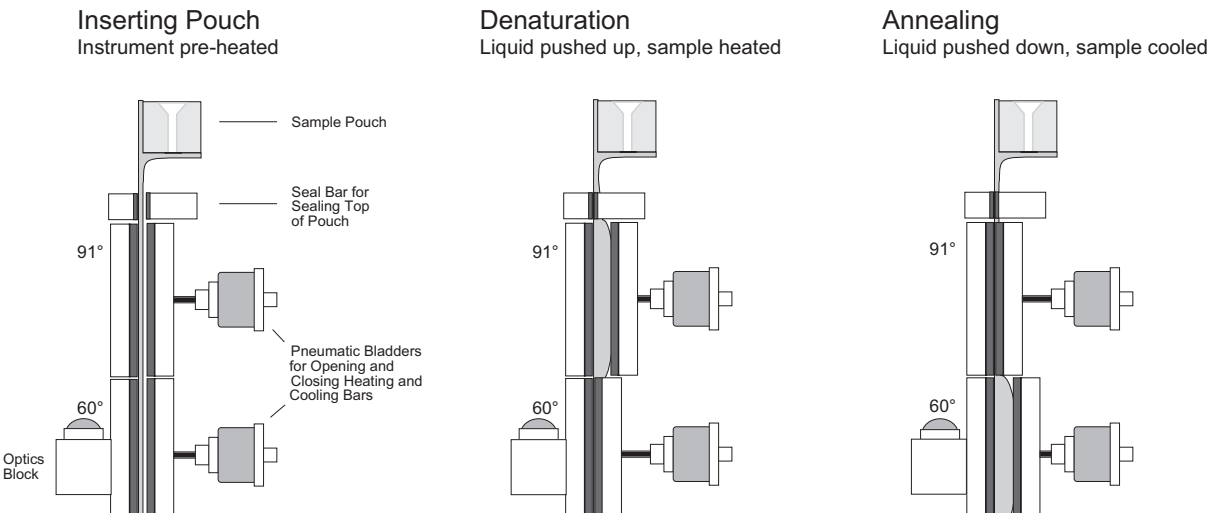
Display Keypad



 **Note:** To turn off instrument, select **Shut Down** from the main menu.

Button name	Function
Power	Turns power on (press for 5 sec.)
Brightness	Controls brightness of the LCD screen display
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
Select	Selects highlighted option on the screen

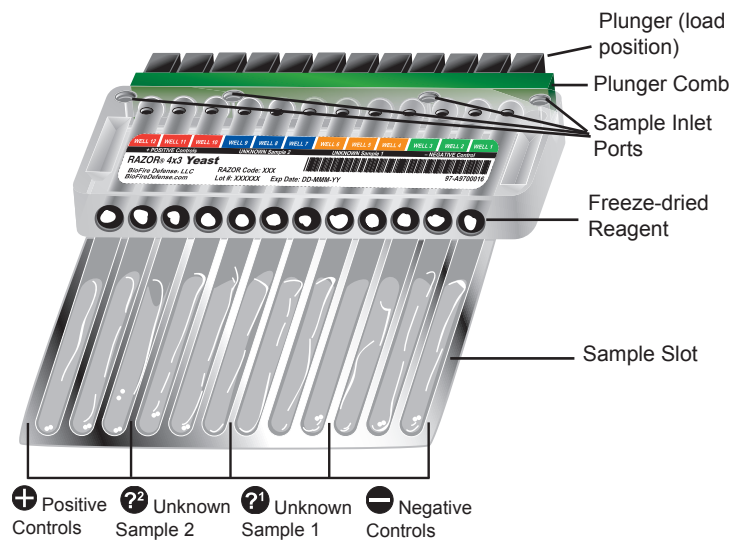
Running a Pouch in a RAZOR



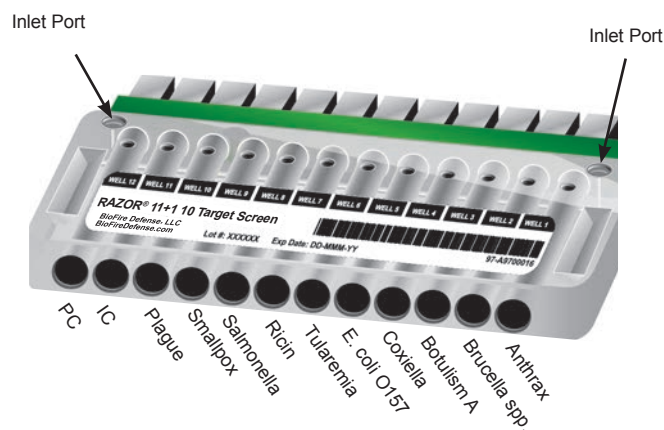
Schematic of a sample pouch inserted into a RAZOR instrument

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

## RAZOR EX Instrument Reagent Pouches



**A Sample 4 x 3 Pouch with Key Parts Labeled**



**A Sample 11 + 1 Pouch (The 10®)**



**Closeup of the Pouch Bottom**

The RAZOR EX reagent pouches are made of thin, clear, flexible plastic attached to a semiflexible 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. Pouches also include a **square** bar code for programming the instrument and a **rectangular** bar code that contains lot and serial numbers. 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

<b>Sample Description</b>	<ul style="list-style-type: none"> <li>• 12-reaction capacity</li> <li>• Plastic reaction pouch</li> <li>• Pouch dependent (see directions for each reagent pouch)</li> </ul>
<b>Fluorescence Acquisition</b>	<ul style="list-style-type: none"> <li>• Single-color optic module</li> <li>• Blue LED excitation with peak emission of 470 nm</li> </ul>
<b>Power Supply</b>	<ul style="list-style-type: none"> <li>• 24-V 4-A external power supply (included)</li> <li>• Rechargeable battery pack (included); 4 runs per charge when instrument is run at temperatures between 0°C and 40°C</li> </ul>
<b>Power Input</b>	<ul style="list-style-type: none"> <li>• 100 V to 240 V, 47–63 Hz, 1.5 A</li> </ul>
<b>Dimensions and Weight</b>	<ul style="list-style-type: none"> <li>• Approximate size (W x D x H): 26 x 11 x 19 cm (10.25 x 4.5 x 7.50 in.)</li> <li>• Weight: 4.9 kg (10 lb 12 oz)</li> </ul>
<b>Performance Parameters</b>	<ul style="list-style-type: none"> <li>• Instrument setup time ≤ 5 min.</li> <li>• Optional reverse transcription step</li> <li>• Reverse transcription + PCR in less than 45 min.</li> </ul>
<b>User Interface</b>	<ul style="list-style-type: none"> <li>• Bar code reader to load run-specific information</li> <li>• Color screen, large membrane push-button interface</li> </ul>
<b>Data Output</b>	<ul style="list-style-type: none"> <li>• Real-time display of fluorescent readings</li> <li>• USB 2.0 support and Bluetooth for data download and archiving</li> <li>• Automatic analysis with end-of-run interpretive calls</li> <li>• Real-time positive calls</li> </ul>

## Environmental Parameters

Description	Specifications
Ambient temperature required to maintain specifications during operation	0°C to 40°C (32°F to 104°F)
Humidity	20% to 60%, noncondensing*
Altitude	Sea level to 3048 m (10,000 ft)
Shipping/storage conditions	-10°C to +60°C (14°F to 140°F)

\*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 SETUP

## INTRODUCTION

This chapter describes the following:

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

## INSTALLATION OF THE RAZOR® EX INSTRUMENT

### Installation Requirements

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The requirements for space and power are:

- 13 x 9 in. (about 33 x 23 cm) of space
- 24-V 4-A power supply or a rechargeable battery pack (included with the instrument)

### Setup Conditions

---

For operation, select a clean, well-ventilated area that is large enough for both the instrument and the computer (if using a computer).



**Note:** Even when using the power supply, run the RAZOR EX 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 EX 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 you can package it correctly if you ship it for maintenance or repair.

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 directional arrows on the side of the battery and instrument as a guide for sliding the battery onto the tracks.



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



 **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.



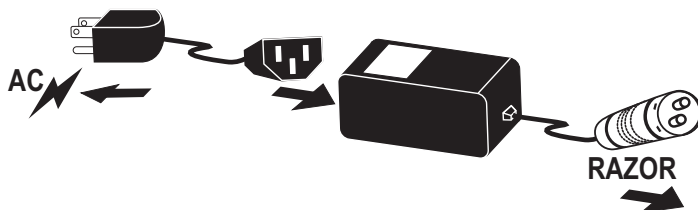
5. Press and hold the **Power** button for 5 sec. to turn the instrument on. The screen will activate and display its current status. The instrument performs a 40-sec. self-diagnostics test when turned on. If the machine generates an error message, refer to Chapter 4, Maintenance and Troubleshooting.
6. Adjust display lighting by pressing the **Brightness** button , which is located next to the Power  button.

## POWER INPUT

The RAZOR EX instrument can be powered by the supplied RAZOR EX battery or by external power using the 24-V 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 EX battery and external power. If external power is plugged in, the instrument will use this power as its default.


### External Power Supply

1. Plug the 24-V power supply into a grounded power source.
2. Connect the other end to the RAZOR EX 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 EX battery allows approximately 4 runs when fully charged at 25°C ambient. 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 4 runs per charge when runs are performed in temperatures between 0°C and 40°C. If the instrument is operated in environments above or below that range, the number of runs per charge may differ.

### Battery Level Indicator

The RAZOR EX contains a battery level indicator. This can be viewed at the bottom of the Utilities menu before a run, in the pouch prompt steps during analysis initialization, and in the status window during a run. The number of solid white boxes indicates the approximate number of runs remaining, e.g., three runs remain in the example below.



**Note:** If external power is attached to the instrument, the battery indicator will be grayed out.



## 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 24-V 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 RAZOR EX and pull the pin down to unlock the battery.



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

## Recharging Batteries



**Note:** Keep the vent on the recharger free of obstruction.

1. The instrument will alert you when the batteries need to be recharged.
2. Turn the instrument off by selecting **Main Menu > Shut Down**.
3. After the RAZOR EX turns off, remove the battery by pulling the pin down and sliding the battery off the bottom of the instrument.
4. Line up the battery and the recharger. Slide the battery onto the recharger using the directional arrows on the side of the battery and recharger as a guide.



5. Plug the 24-V 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.
6. 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 8 hours to fully charge.



**Note:** The battery does not charge when operating a plugged in RAZOR EX.

## 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.

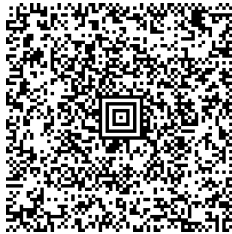
The format of the RAZOR EX freeze-dried reagent pouches are target specific and fixed. The reagent pouch is disposable and contains all of the ingredients for real-time fluorescent detection of target nucleic acid using the RAZOR EX system. Each pouch has a unique serial number and corresponding **rectangular**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

## LOADING PROTOCOLS



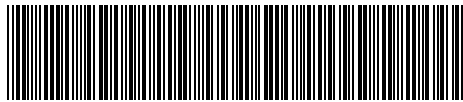
**Note:** The lens of the bar code reader needs to be free of dust and scratches to scan the protocol and pouch bar codes. See “Bar Code Reader Window Cleaning” in Chapter 4, Maintenance and Troubleshooting, for cleaning instructions.

Protocols are preprogrammed in the **square** bar code printed on the assay kit box. Use the bar code reader to scan them into the instrument. If you prefer, you may scan the protocols into the instrument before you take the RAZOR EX to the field.



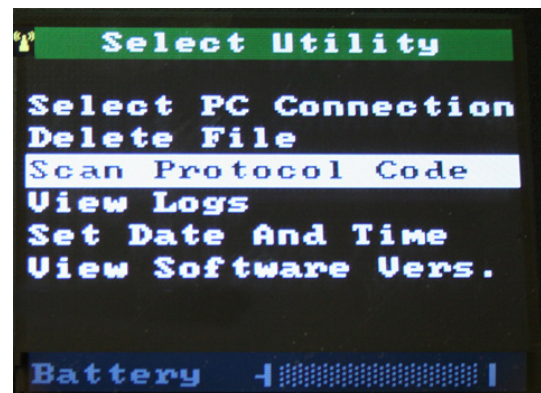
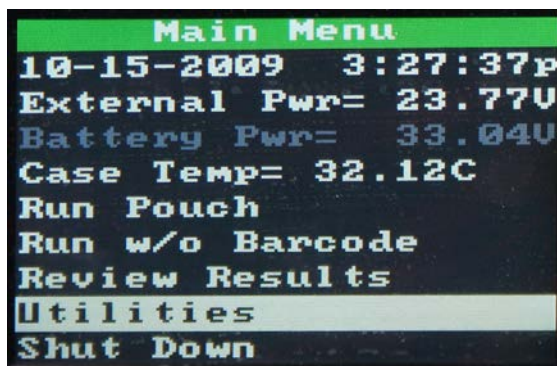
Kit Part Number: PATH-ASY-0092  
Protocol Code: GENERICB

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** bar code printed on the sample pouch label. If the protocol has not been loaded before the **rectangular** bar code 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. Confirm the steps in the next section by following the screen instructions.



2. Scan the **square** protocol bar code found on the box. You may scan more than one protocol. The bar code reader is the camera lens at the back of the instrument.



3. After you scan all of the correct protocol bar codes, return to the Main Menu by selecting **Back**. See Chapter 3 for instructions on loading the pouch bar code information.

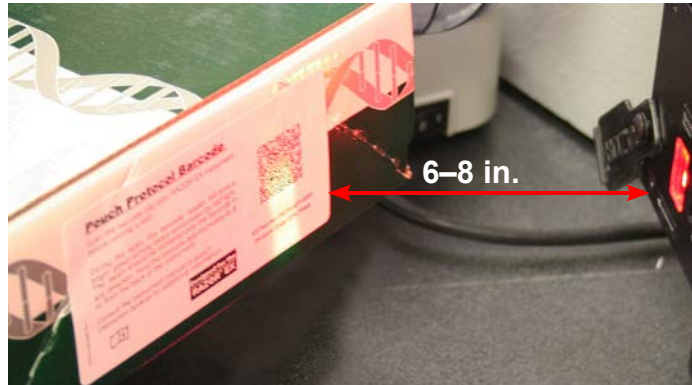


**Note:** Be sure that all bar codes are as smooth and flat as possible.





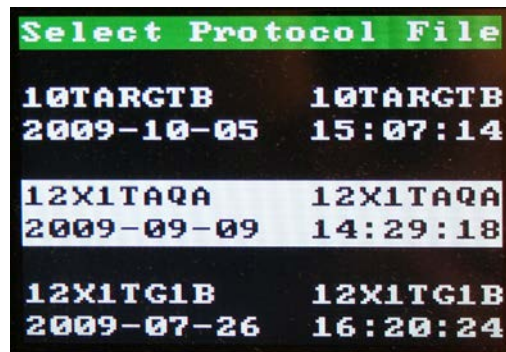
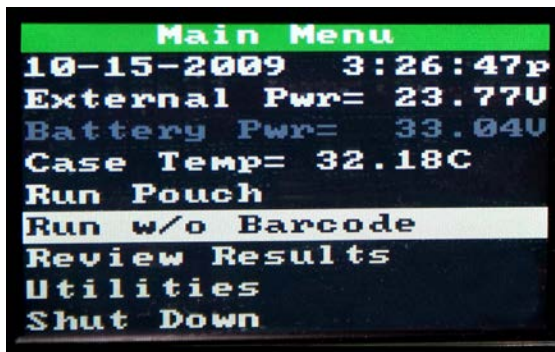
**Note:** During the scan, the bar code reader emits a bright green aiming beam surrounded by red light. Hold the bar code approximately 6–8 in. from the back of instrument and move the bright green aiming beam close to the bar code to scan. If you hold the bar code more than 8 in. away from the reader, you will need to center the green aiming beam on the bar code to scan. When the scan is complete, the aiming beam turns off and the instrument will display the message, “Loading Barcode Data.” If the scan does not complete within 15 sec., flatten the image and/or move the bar code gradually closer to the instrument to scan it.



## LOADING PROTOCOLS WITHOUT A BAR CODE

If the square (protocol) bar code is not available or not functioning, users have the option of selecting a generic protocol on the RAZOR EX.

1. From the **Main Menu**, select **Run w/o 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 **Remove Old Pouch** screen. Follow the screen instructions from this point on to prepare and load the sample onto the RAZOR EX.



**WARNING:** The bar code on each pouch includes critical information such as lot numbers. You should always run a pouch using its bar code when you are able.

## 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 nonsupplied buffers may result in the controls and/or samples failing.

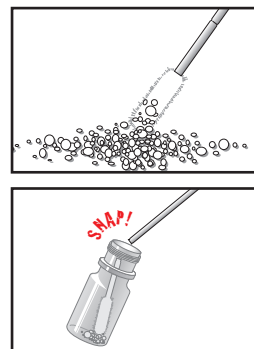
You need the following materials to prepare a pouch.	
RAZOR pouch containing freeze-dried reagents in a foil bag	Syringes with tips
Unknown sample bottles	Reagent grade water or control buffer bottles
Sample swabs	Transfer pipettes

### 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.



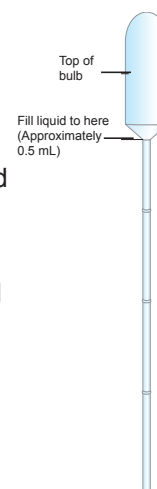
#### Liquid Sample (Automatic air samplers, etc.)

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 dry or liquid sample, 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.

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

## Reagent Pouch Loading

**⚠ WARNING:** Do not open the pouch until you are ready to scan the rectangular bar code 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 BFD Technical Support, because reagents 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.

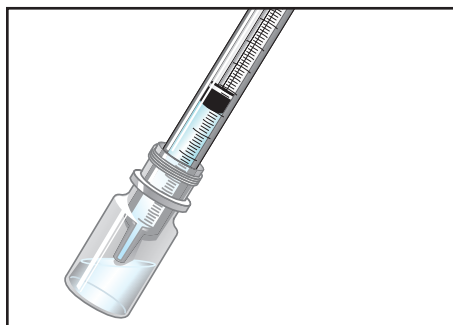


## Loading a Syringe

**⚠ 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 EX freeze-dried pouch loading. If you have syringes without the preloaded tip, load the tip onto the syringe using aseptic technique (avoid touching the tip to other surfaces).

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<sup>®</sup> pouch)
- 0.35 mL for a 6 x 2 format

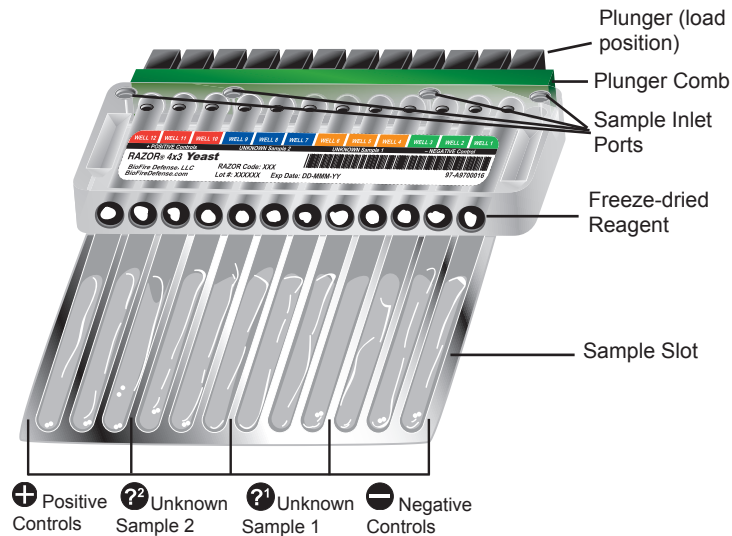
Avoid introducing any air into the syringe, which can cause bubbles.

**⚠ 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.

Step 1 Negative Controls ➔ —	Step 2 Unknown Sample ➔ ?	Step 3 Positive/ Inhibition Controls ➔ +
--	---------------------------------------	---

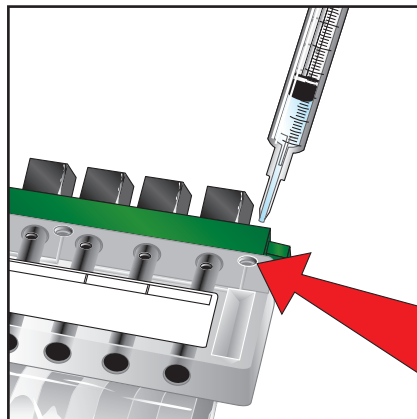


**A Sample 4 x 3 Pouch with Key Parts Labeled**

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**.
  - For the **Inhibition** control inlet port (if present), you will insert the correct **unknown sample**.

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



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. 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.

**⚠ 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. 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 BFD Technical Support.

### Removing the Comb and Plunging

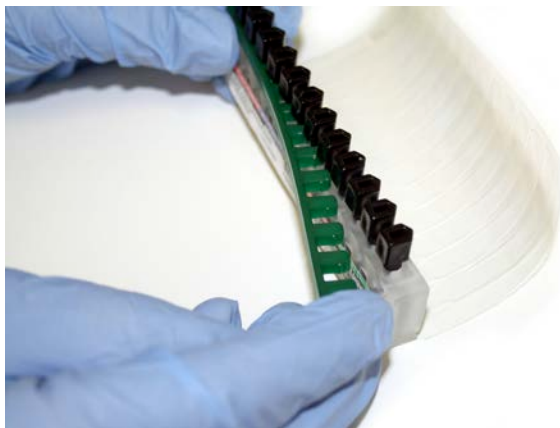
**⚠ WARNING:** Depressing the pouch plungers when the pouch is not in the pouch bracket may damage the pouch, prevent the sample from entering the sample slot, or cause backflow leading to contamination. If at any time during the preparation process you suspect that the exterior of the pouch became contaminated 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 EX. 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.

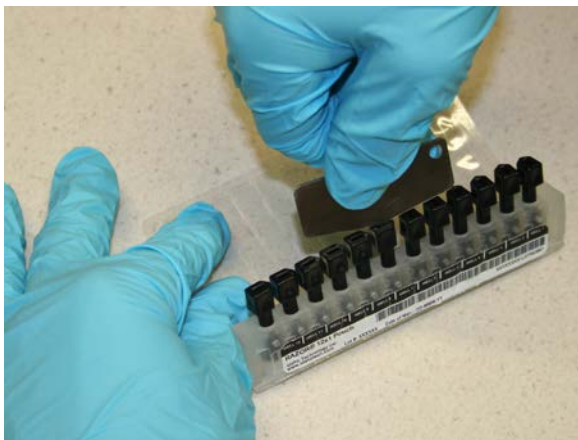
**🔑 Note:** When you handle and load samples, avoid contamination problems by using standard laboratory techniques and following the appropriate protocols for loading samples. Change gloves frequently to avoid cross-contamination of samples.

**🔑 Note:** DO NOT push pouch plungers down until step 4.

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



2. Twist plunger by using the plunger twist tool or the end of the plunger comb and rotate each of the plungers 90° 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 screw-driver.



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



# CHAPTER 3:

# RUNNING A POUCH AND

# THE SYSTEM SOFTWARE

## INTRODUCTION

The RAZOR® EX software 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 for the RAZOR EX:

- Loading the run information
- Preparing the reagent pouch
- Inserting the pouch into the RAZOR EX
- Performing the run
- Analyzing the results
- Downloading the results to a computer

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 EX, 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 EX after you finish a run.
- **Instrument utility menus:** Gives you an understanding of how to transfer information from the RAZOR EX to a computer. You can also delete files, scan protocol codes, view logs, set the date and time, and view the software version.
- **RAZOR EX desktop software:** Explains details of the desktop software and how to interact with the RAZOR EX.
- **Qualitative Detection analysis:** Explains crossing points and controls and how they are used in test results reporting.
- **Reports:** Explains how to create and print a test report.
- **Change history and audit trail information:** Explains data storage and how to create audit trails.



- **Managing database contents:** Explains how to copy items and how to rename, delete, and export files.
- **Charts:** Explains how to use charts.
- **User accounts and system access:** Explains account management and system access.

## SCANNING THE POUCH AND INITIATING A RUN

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

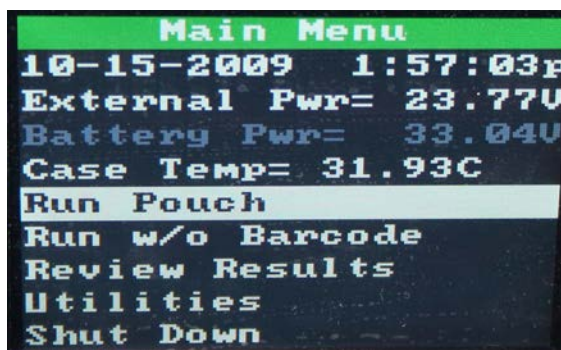
1. Scanning the pouch bar code.
2. Following the preparation instructions for the pouch and the instructions on the screen after the RAZOR EX initiates the run.

### Scanning the Pouch Bar Code

The RAZOR EX 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 bar code, as shown in the following picture.



1. Select **Main Menu > Run Pouch** to start the loading instructions.





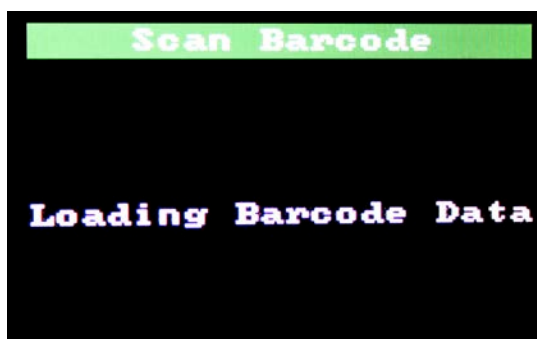
- When **Scan POUCH Barcode** displays, scan the **rectangular** pouch bar code from the reagent pouch labeling by holding it vertically and as flat as possible in front of the bar code scanner (located on the back of the instrument). The pouch should be approximately 6 to 8 in. from the scanner. Press **Back** to abort the bar code scan.

If the bar code is not scanned immediately, flatten the bar code or move it closer to the scanner. If the bar code is not read in time, the reader will abort the scan. Press **Select** to return to the **Main Menu**, then select **Run Pouch** again.



**Note:** If the bar code does not scan properly, the message **Aborting Barcode Scan**, will display. If you scan the wrong bar code, the message **Invalid Barcode Data (Barcode Should Be Rectangular)** will appear. You should then scan the rectangular bar code on the pouch's fitment label. If any bar code becomes smeared or unscannable, generic codes are available on the assay card and in Appendix G.

- If the bar code is scanned correctly, the screen displays **Loading Barcode Data**.



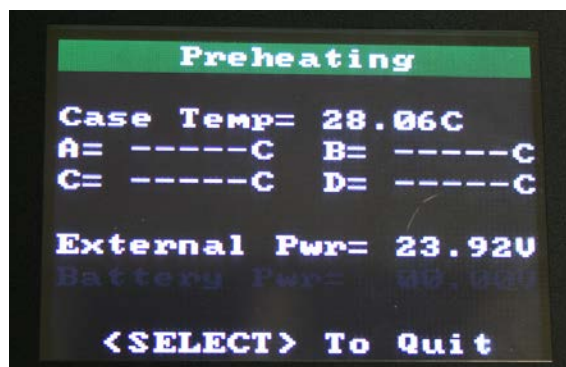
**Note:** If the correct protocol is not present on the instrument, the machine will prompt you to scan the **square** protocol bar code from the labeling on the outer box.

- After you scan the bar code, the instrument begins preheating. The preheating time depicted on the screen depends on the current temperature of the instrument. An instrument at room temperature (18–30°C) requires approximately 8 min. to preheat. When it is complete, a message will appear that says **Preheat Complete**. Press **Select** to continue.

**Note:** Do not tear the pouch when you remove it during the next step; the contents could contaminate the instrument and surrounding area.

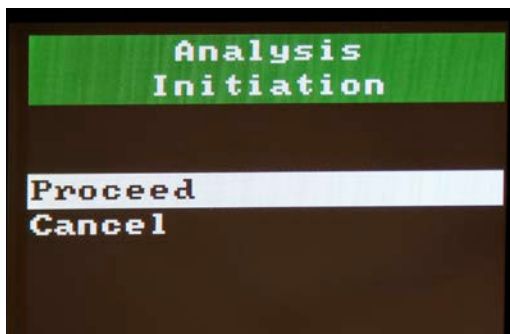
**HAZARDOUS MATERIAL:** Use standard laboratory procedures when handling biohazardous material. Consider all samples biohazardous and carefully dispose of pouches and syringes in a biohazard waste container.

5. The instrument displays the message **Remove Old Pouch**. Remove the pouch from the previous run and discard it as biohazardous waste.
6. Press the **Select** button to continue.
7. The instrument displays an **Inject All Ports** screen. Load the syringes and inject the ports as described in Chapter 2, Installation and Setup.
8. When you have injected the ports, press the **Select** button to continue. A Preheating screen displays with information about the case temperature. To stop the run, press the **Select** button.

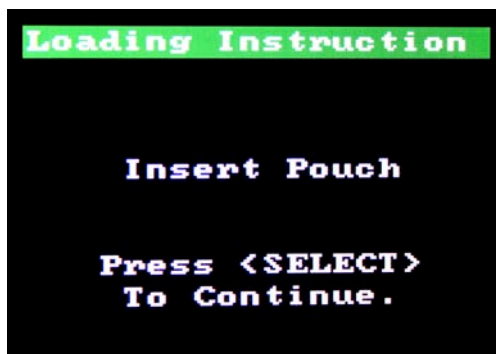


Once preheating is complete, the instrument displays a **Preheat Complete** window. Press the **Select** button to continue.

9. 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. After pressing **Select**, the **Analysis Initiation** screen displays.



10. Select **Proceed**.  
An **Insert Pouch** screen displays.



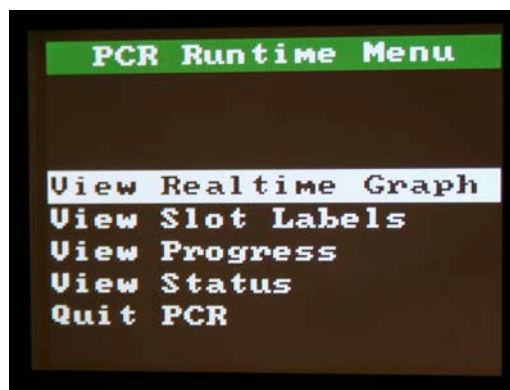
11. Insert the prepared pouch into the instrument with the label facing up and the plungers toward the front of the instrument. The pouch fitment should sit perfectly in the groove over the insert slot. After you insert the pouch, press the **Select** button.



The **PCR Runtime Menu** screen displays.

### The PCR Runtime Menu

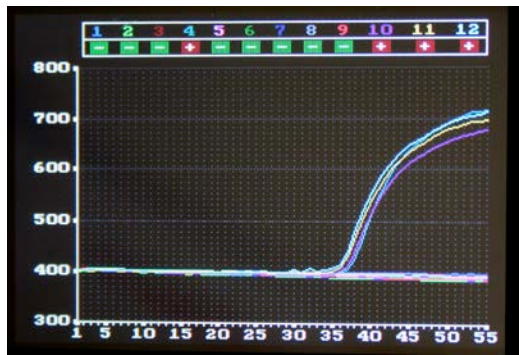
Unless you choose to quit by selecting **PCR Runtime Menu > Quit PCR**, the instrument will begin PCR. You can leave the screen at the current display during PCR, or you can select the progress screens listed on the PCR Runtime Menu to view the progress of the run or the status of the instrument. Select the **Back** button on any of the progress screens to return to the PCR Runtime Menu.



## MONITORING PCR PROGRESS

### View Realtime Graph

To view the progress of the run on a graph, select **View Realtime Graph**. **View Realtime Graph** provides a graph that displays the curves of each sample. Slot numbers are displayed at the top of the screen. You can use the up and down arrows to highlight specific samples. The 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 (+) call is determined or the run is completed. At this point the negative (-) call will be displayed if no amplification is detected.



### View Slot Labels

**View Slot Labels** displays the name and slot position of the pouch reagents. This information is uploaded in the **square** protocol bar code.

Reagent Labels		
Slot #1:	Ant	NEG
Slot #2:	Ricin	NEG
Slot #3:	F tul	NEG
Slot #4:	Ant	U1
Slot #5:	Ricin	U1
Slot #6:	F tul	U1
Slot #7:	Ant	U2
Slot #8:	Ricin	U2
Slot #9:	F tul	U2
Slot #10:	Ant	POS
Slot #11:	Ricin	POS
Slot #12:	F tul	POS

### View Progress

**View Progress** displays a screen that lists the pouch serial number, the protocol, the estimated time to completion, cycle status, and estimated power. The power source used (External or Battery) will be bright, and the one not used will be dimmed.

```

Serial #: 00000099
Protocol: ANTHRAX0

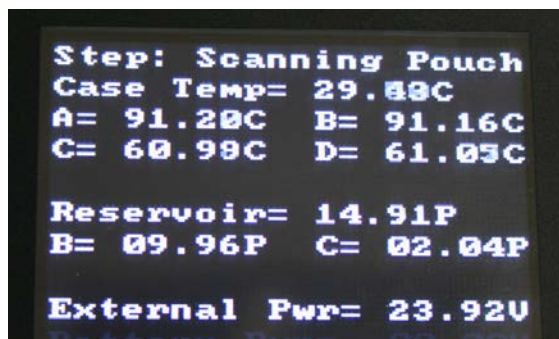
Estimated Time To
Completion: --:--

Current Cycle: 01/45

External Pwr= 23.88V
Battery Pwr= 00.00V
  
```

## View Status

**View Status** displays a screen that shows the current heating and cooling temperatures of the run and instrument air pressure. The A and B heaters are the denaturing heaters at the top; C and D are the annealing heaters on the bottom.



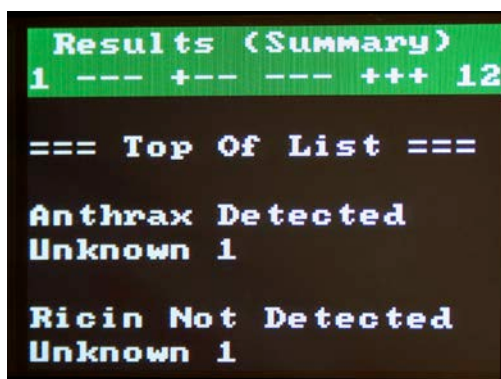
**Note:** Return to the run-time menu by pressing the **Back** arrow.

## Quit PCR

The **Quit PCR** menu item stops the PCR run.

# RESULTS

When a run is finished, the screen automatically displays a Results (Summary) screen with the metacalls 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 mathematical 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: strongly positive slots are called while the machine runs, and the Detector calls at the top of the screen are updated. Negatives are not called until the run is over.

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.

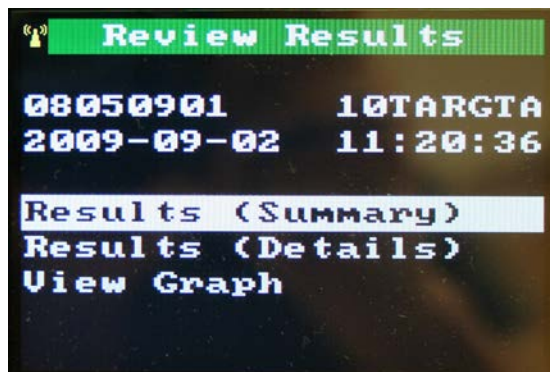


## Metacalls

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

To access specifics about the metacalls, select the **Back** button from the Results (Summary) screen.

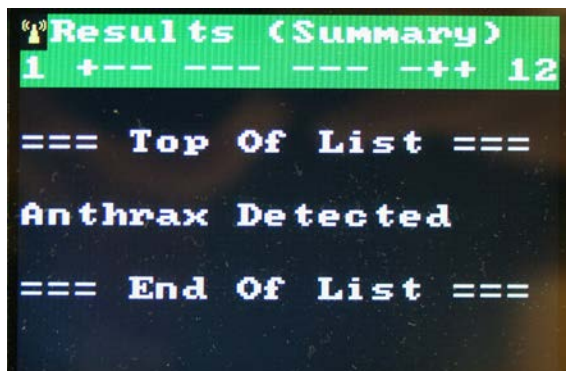


Three choices of viewing results are then displayed, as well as the pouch number, the name of the protocol, and the date and time of the run:

- Results (Summary): displays combined calls (Metacalls) for unknowns and controls. This screen comes up immediately after a run.
- Results (Details): specific results for any control failures.
- View Graph: A graph of the test results

## Results (Summary)

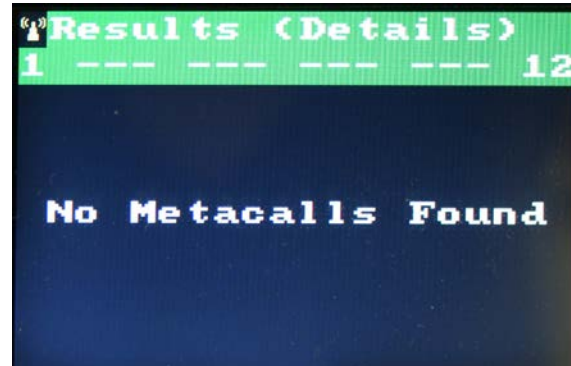
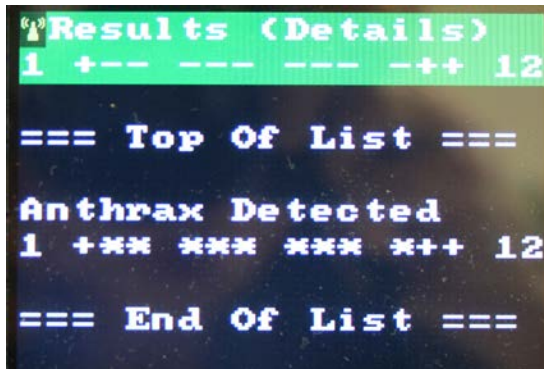
The following screen is an example of what you will see when you look at a summary of results. The top green section of the screen contains the screen title in the first line and a slot map in the second line. The slot map starts with '1' (slot 1) on the left side of the line and ends with '12' (slot 12) on the right side of the line. Between 1 and 12 there are four groups of three characters each. Each character represents one of the slots from 1 to 12. In this particular screen, you can see a plus symbol and a minus symbol, which are Detector call symbols. Plus symbols show that amplification was detected in the slot.



The 11+1 (The 10®) screen above shows a positive test result for the first unknown sample (Anthrax) and positive results for the PCR Inhibition and Positive Control slots. The first line identifies the assay.

### Results (Details)

Results (Details) shows the summary call along with the call 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 in green at the top of the screen. Again, 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 masks for each pouch slot. The Detector masks the test results using a mask that was designated in the protocol, then displays the appropriate message.

For the masks, the possible results are shown in the following table.

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

The Detector call for the same slot can generate multiple messages.

#### In the mask for Anthrax Detected for Unknown 1:

- The mask has the number 1 on the left and the number 12 on the right. In between are twelve characters, arranged in four three-character groups.
- The first group of symbols, + \* \*, represent slots 1 through 3. In this pouch, these slots contain the sample slots for anthrax, *Brucella*, and botulism A. To generate the result text for this particular example and to match the mask, slot 1 must be positive since it is the sample slot for the anthrax assay.
- The second group of three symbols, \* \* \*, masks the test results for *Coxiella*, *E. coli*, and tularemia. Since the detector call is not relevant to the detection of anthrax, the mask shows only asterisks in these slots.
- The third group of symbols, \* \* \*, masks the test results for ricin, *Salmonella*, and smallpox. This group also had no relevant calls and shows only asterisks.
- The fourth group of symbols, \*++ , represent slots 10 through 12. Slot 10 represents plague and displays an \* as there were no relevant calls. Slot 11 is for the inhibition control and slot 12 is for the positive control. These both display a positive call indicating that there are no

inhibitors and the positive control amplified properly. To generate the result text for this particular example and to match the mask, slot 11 must be positive to show that there is no inhibition and slot 12 must be positive, since it is the positive control for the anthrax assay.

The following examples shows the results of four test runs. The table identifies the wells, assays, and reagent types. The text following the table shows the test results for this table. The Detector calls are listed first, followed by the summary of results and the details.

## Examples of Test Run Results

### Example 1—Anthrax Pouch

In this specific example, one unknown straight and one unknown with a dilution was tested for three anthrax assays (target 1, target 2, and target 3). In this run, the Positive Controls failed. Wells 10, 11, and 12 were all negative but should have amplified and been called positive.

Identification	1st Set of Wells			2nd Set of Wells			3rd Set of Wells			4th Set of Wells		
Well	1	2	3	4	5	6	7	8	9	10	11	12
Assay	Ant T1	Ant T2	Ant T3	Ant T1	Ant T2	Ant T3	Ant T1	Ant T2	Ant T3	Ant T1	Ant T2	Ant T3
Reagent Type	Negative Control			Unknown 1			Unknown 1 Dilution			Positive Control		

Detector Calls are --- --- --- ---

Summary Metacalls

Pos Control Failure

Ant T1-Run New Pouch

Pos Control Failure

Ant T2-Run New Pouch

Pos Control Failure

Ant T3-Run New Pouch

Details Metacalls

Pos Control Failure

Ant T1-Run New Pouch

1 \*\*\* \*\* \_\* 12

Pos Control Failure

Ant T2-Run New Pouch

1 \*\*\* \*\* \*\_12

Pos Control Failure

Ant T3-Run New Pouch

1 \*\*\* \*\* \*\_12

Control Failure

Positive

1 \*\*\* \*\* \_\*\* 12

2 \*\*\* \*\* \_\* 12

1 \*\*\* \*\* \*\_ 12



**Example 2—11 + 1 Test Run Results (The 10®)**

The following example shows the results of a test run, where the reagents are in a 11 + 1 pouch. The table identifies the wells, assays, and reagent types. The text following the table shows the test results for this table. The detector calls are listed first, followed by the summary of results and the details, if applicable.

In this specific example, an 10-target screen kit was used to test one unknown. The results show the following: 1) the PCR Positive Control worked; 2) the PCR Inhibition Control worked, 3) *Coxiella* (well 4) was detected in Unknown 1, and 4) no other assays were detected.

Identification	1st Set of Wells											2nd Set of Wells
Well	1	2	3	4	5	6	7	8	9	10	11	12
Assay	Antx	Bru	Bot A	Cox	E coli	Tul	Ricin	Salm	Smpx	Plag	PCR	PCR
Reagent Type	Unknown 1										Inhibition Control	Positive Control

Detector Calls are --- +- - - - -++

Summary Metacalls

Coxiella Detected

Details Metacalls

Coxiella Detected

1 \*\*\* +\*\* \*\*\* \*++ 12

**Example 3—10 + 2 Test Run Results**

In this specific example, an 8-target screen kit was used to test one unknown. The results show the following:

- Positive controls for RT and PCR worked.
- Inhibition controls for RT and PCR both failed.
- No assays were detected potentially because the sample contained inhibitors possibly preventing amplification.

Identification	1st Set of Wells										2nd Set of Wells	
Well	1	2	3	4	5	6	7	8	9	10	11	12
Assay	A	B	C	D	E	F	G	H	RT	PCR	RT	PCR
Reagent Type	Unknown 1								Inhibition Controls		Positive Controls	

Detector Calls are --- --- --- -++

Summary Metacalls

Control Failed

Inhibition Control

Details Metacalls

Control Failed

Inhibition Control

1 \*\*\* \*\* \_\*\* 12

1 \*\*\* \*\* \_\*\* 12

Control Failure

PCR Inhib. Control

1 \*\*\* \*\* \_\*\* 12

Control Failure

RT Inhib. Control

1 \*\*\* \*\* \_\*\* 12

**Example 4—11 + 1 Test Run Results (The 10®)**

In this specific example, a 10-target screen kit was used to test one unknown. The results show the following:

- Positive control for PCR worked.
- Inhibition control for PCR failed.
- Coxiella amplified. The sample contains inhibitors possibly preventing amplification.
- 

Identification	1st Set of Wells											2nd Set of Wells
Well	1	2	3	4	5	6	7	8	9	10	11	12
Assay	Antx	Bru	Bot A	Cox	E coli	Tul	Ricin	Salm	Smpx	Plag	PCR	PCR
Reagent Type	Unknown 1										Inhibition Control	Positive Control

Detector Calls are --- +- - - - - +

Summary Metacalls

Coxiella Detected

Presume UNK+, IC Fail

Details Metacalls

Coxiella Detected

Presume UNK+, IC Fail

1 \*\*\* +- \*\* \*\*\* \*- + 12



Control Failed

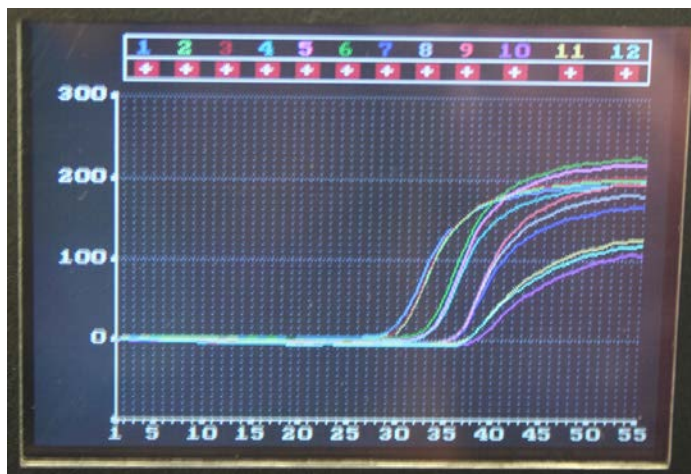
Inhibition Control

1 \*\*\* \*\*\* \*\*\* \*- \* 12

For this pouch, Assay 4 has a presumptive positive, so appropriate action can be taken while the same sample is run on a new pouch to confirm that no other agents are present. This process is similar if a positive control fails but the inhibition control is detected.

### View Graph

This screen displays the full amplification graph with Detector calls at the top of the screen. You can use the up arrow  and the down arrow  to highlight specific samples. When you highlight a sample, the number and detector call are outlined, and the curve appears with a thicker white line.



## FINISHING THE RUN



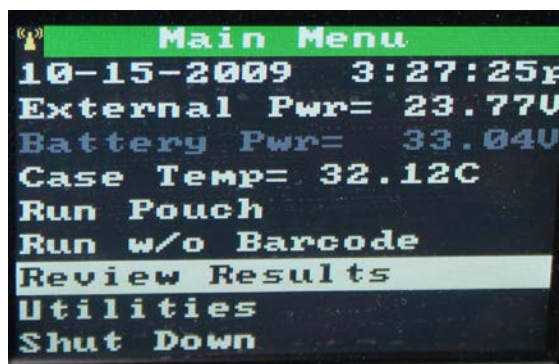
**HAZARDOUS MATERIAL:** Use standard laboratory procedures when handling biohazardous material. Consider all samples biohazardous and carefully dispose of pouches and syringes in a biohazard waste container. When the run is finished, carefully remove the pouch and dispose of it as biohazardous waste. Do not allow the bag to tear; the contents of a finished run can contaminate the instrument. Run another pouch or turn the RAZOR EX off by selecting **Main Menu > Shut Down**.



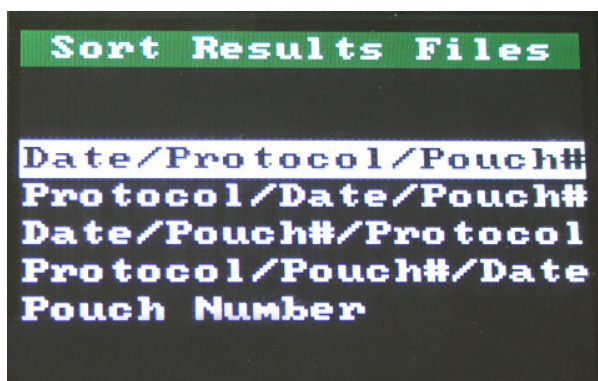
**CAUTION:** When the RAZOR EX is finished, the instrument and pouch will be hot. Use caution when you handle the instrument and pouch after a run.

### Opening Previous Runs

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



A **Sort Results Files** window displays.



This window allows you to organize the data according to the parameters you want. You can sort by the date of run, the protocol used, and the serial number of the pouch in the orders shown. Runs are sorted by the first parameter, then the second parameter, and so on. The following list shows the same possible ways of organizing your data that are also shown in the **Sort Results File** screen above.

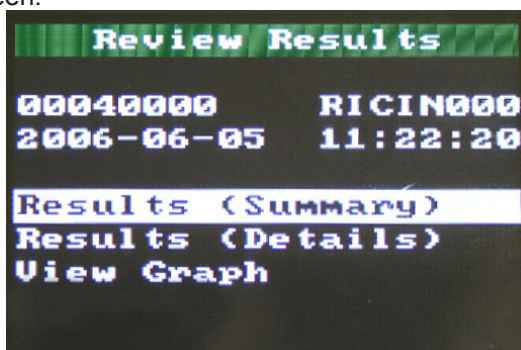
- Date/Protocol/Pouch#
- Protocol/Date/Pouch#
- Date/Pouch#/Protocol
- Protocol/ Pouch#/Date
- Pouch Number

These parameters sort in the following way:

- **Date** sorts list files starting with the most recent.
- **Protocol** sorts alphabetically by protocol name.
- **Pouch Number** sorts by serial number. For example: A0000001 to Z9999999.

After you sort the file, highlight the file you want by using the up or down arrows, then press the **Select** button.

The run will open in the screen:

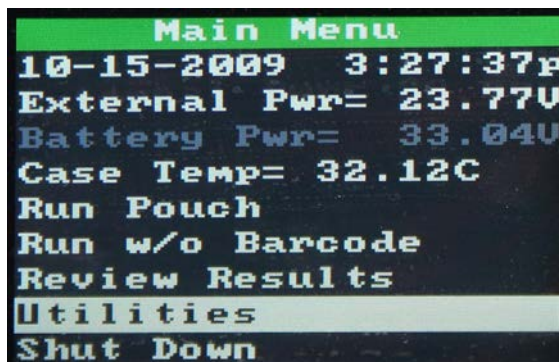


You will then have the same Results viewing options that appear at the end of a run. A computer can perform more analyses by downloading run data from the RAZOR EX and examining the fluorescence curves and the detector calls with the RAZOR EX Desktop Software.

## INSTRUMENT UTILITY MENUS

The instrument's Utility menu allows you to select a PC connection (USB or Bluetooth), delete files, scan protocol codes, view logs, set the date and time, view the battery life, and view the software version for the instrument.

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



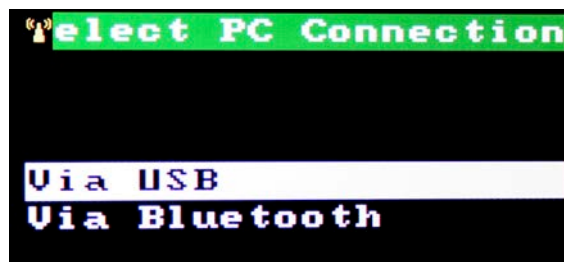
The following screen will display:



**Note:** At the bottom of this screen is a battery level indicator. If the display shows only two white bars or less, you will need to recharge the battery before performing the run.

### Select PC Connection

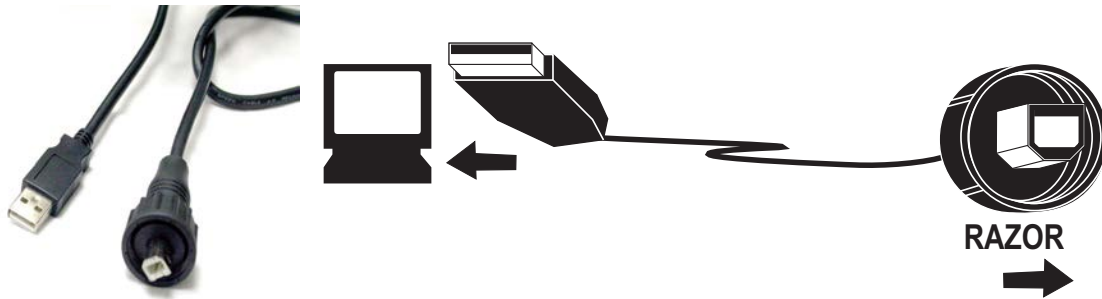
The PC Connection option gives you the option of connecting to a PC with the USB cable that comes with the equipment or by Bluetooth® with your own module and software. Choose **Select Utility > Select PC Connection**.



On the **Select PC Connection** menu, select either **Via USB** or **Via Bluetooth**.


**USB**

1. Plug the USB cable into the RAZOR EX and the computer you want to use.



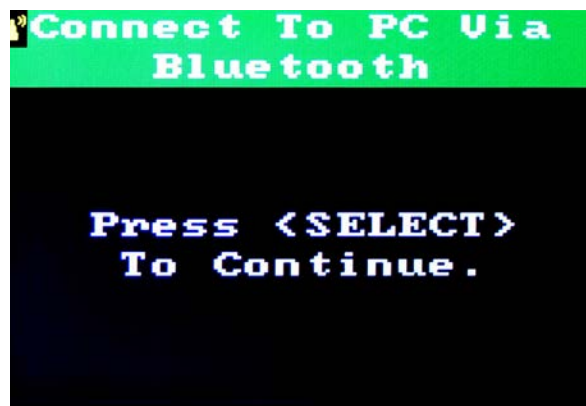
2. Select **Connect to PC Via USB**.



 **Note:** If the computer does not recognize the RAZOR hardware device when initially connected by USB, use the Windows “Add Hardware Wizard” to confirm the USB drivers. The Wizard can be found in the Control Panel under the Add Hardware icon.

**Bluetooth**

1. Select **Connect to PC Via Bluetooth**.



2. When Bluetooth is enabled, a yellow wireless icon will flash in the top left-hand corner of each screen.



Yellow icon



**Note:** Bluetooth models vary; check the device manual for specific instructions.

3. To connect from the PC, open the Bluetooth program.
4. Search for wireless devices. When the RAZOR EX is detected, connect to it as a serial device. The instrument name will appear after it is connected to the instrument. This can be repeated for multiple RAZOR EX instruments.



**Note:** Users can only connect to one instrument at a time. To view a different instrument, you must disconnect and connect to another RAZOR EX.

### Delete File

This selection allows users to delete “single results,” “all results,” a “single protocol,” or “all protocols.” It also has a sort feature that allows you to sort files to delete them. For more information about the sorting feature, see the “Finishing the Run” section in this chapter.

### Scan Protocol Code

Use this option to scan the protocol codes before you begin a run. A red warning will display if the wrong type of bar code is used (such as the **rectangular** pouch bar code instead of a **square** protocol bar code), the system is unable to read the bar code, the data is invalid, or the protocol memory is full. For more details, see Chapter 2, Installation and Setup.

### View Logs

This option allows you to view or delete the ERROR and STATUS Logs. The error log displays messages from the instrument, including date and time, error code, and error description. ERROR and STATUS Logs are critical to troubleshooting and may be requested by Technical Support.

### Set Date and Time

This allows you to set the time and date. To move the date or time forward, use the up and down arrows to highlight the **+** option (i.e., + Day), and then press the **Select** button repeatedly to reach the correct date or time. To move backward, use the up and down arrows to highlight the **–** option (that is, – Hour) and then press the **Select** button.

### View Software Vers.

This option provides the date and time of the versions for each of the major RAZOR EX instrument software components.

## RAZOR EX DESKTOP SOFTWARE

The RAZOR EX software allows you to perform and analyze test runs. The data (including run analysis and user accounts) is stored separately in a database called Exor.

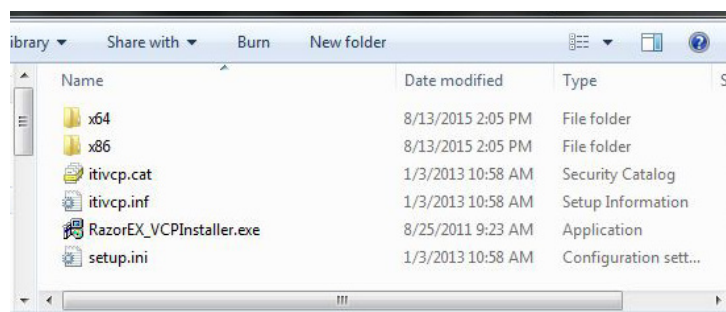
### Installing on a Windows 7 Computer or Windows 8 Computer

When using Windows 7 or 8 the driver must be installed before the RAZOR EX software. Contact [support@biofiredefense.com](mailto:support@biofiredefense.com) to obtain the Windows 7 or 8 driver.

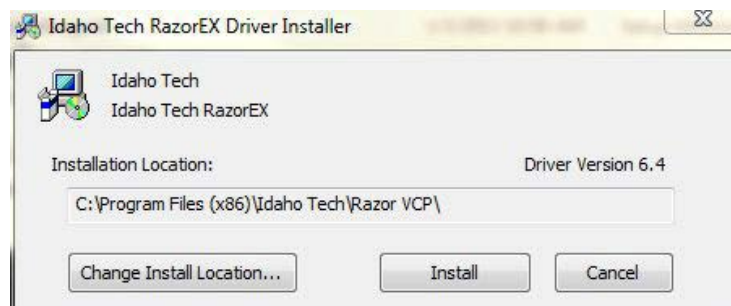
If the RAZOR EX software has already been installed on Windows 7 or 8 without the correct driver follow these steps:

To install the Windows 7 or 8 driver:

1. Uninstall Exor3 (making sure that it is not active in your system tray).
2. Uninstall the RAZOR Software.
3. Delete the following file: C:\Program Files (x86)\IdahoTech.
4. Delete the following file that contains the RAZOR drivers: C:\Program Files (x86)\Silabs.
5. Uninstall the Idaho Tech RazorEX (Driver Removal).
6. Restart your computer.
7. Download the Razor-VCP6.4.zip file from the filedrop site provided by BioFire Defense customer support. This file contains the VCP installer and all the associated files together.
8. Move the Razor-VCP6.4.zip file from your download list to your desktop.



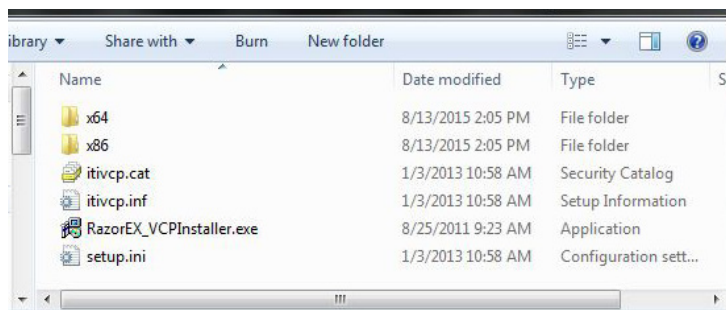
9. Launch the VCP installer.



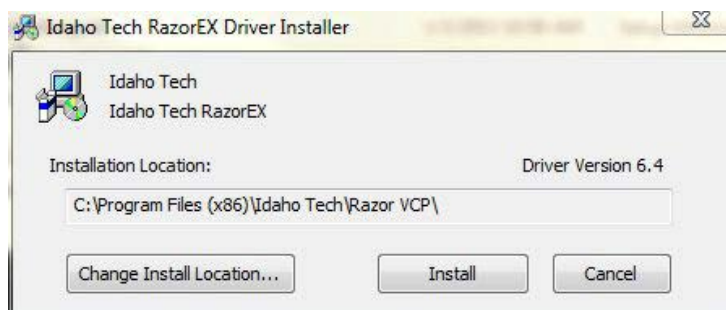
10. Reinstall RAZOR EX software and Exor3 as described in the next section.
11. Launch Exor 3 and RAZOR EX software.
12. Connect to RAZOR EX instrument.

If the RAZOR EX software has not been previously installed:


13. Download the Razor-VCP6.4.zip file from the filedrop site provided by BioFire Defense customer support. This file contains the VCP installer and all the associated files together.
14. Move the Razor-VCP6.4.zip file from your download list to your desktop.



15. Launch the VCP installer.

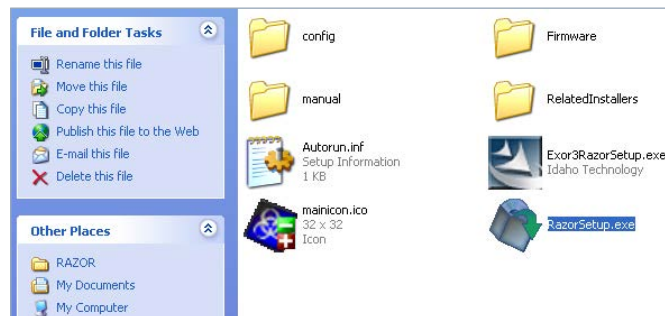


16. Install the RAZOR EX software and Exor3 as described in the next section.

 **Note:** When connecting a RAZOR EX using Windows 7 be consistent with the type of connection used. BioFire Defense recommends using USB only. It has been found that when switching between USB and Bluetooth in Windows 7 the software will stop responding to both. For questions contact [support@biofiredefense.com](mailto:support@biofiredefense.com).

## Installing the RAZOR EX Software

1. Load the RAZOR EX software using the CD provided with the instrument. A file menu will display.



2. Select **RazorSetup.exe** from the file menu. A Welcome screen will display. Select **Next**.
3. The **InstallShield Wizard** will display. Select **Next** to start the Wizard.



4. When the InstallShield Wizard has completed installing, click **Next**. The **End User License Agreement** will display. Read through the agreement. If you agree with the terms, select **Yes**.



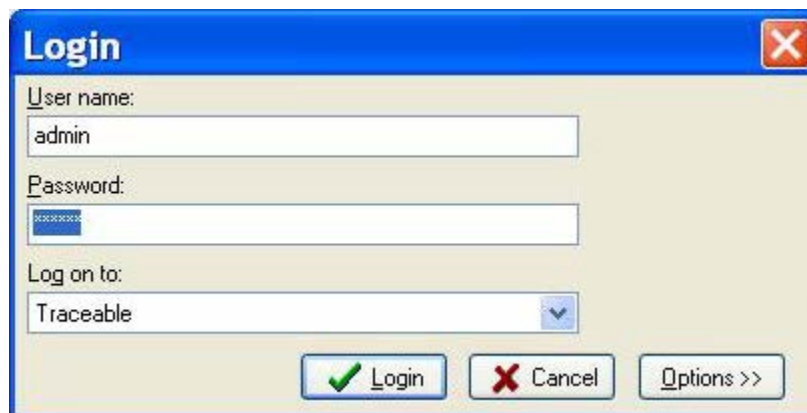
5. A message will display asking you where you want the RazorSW software to be located. Either use the browse window to select a location or use the displayed default location by selecting **Next**.



6. The wizard will then allow you to choose which icons are added for the software.
7. If the Exor database has not been installed on your computer, the Exor InstallShield Wizard will begin installing.
8. After Exor has been installed, the software install will then launch the install for the correct USB drivers.

## Starting the RAZOR EX Software

1. Start the RAZOR EX instrument, then start the computer connected to the instrument according to the setup instructions in Chapter 2, Installation and Setup.
2. Verify that the double-arrow database icon appears in the system tray, which is in the lower right corner of your desktop.  
The icon indicates that the database management software (called Exor) has started. You can also start the database by opening the Start menu, then selecting Programs\IdahoTech\Exor3.
3. A login dialogue box opens.



4. Enter your user name and password, leave **Traceable** in the **Log on to:** box, and then click **Login**.

The default user name is admin and the password is master.



**Note:** You will need to change your password the first time you log in.

The front screen for the RAZOR EX software opens.



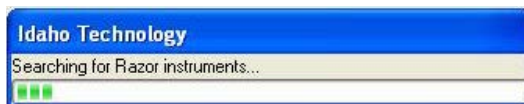
The front screen displays two buttons:

- **Connect to Razor:** This button allows users to move files from the RAZOR EX to a computer. This requires a connection between the instrument and computer (that is, USB or Bluetooth).
  - **Analysis:** This button allows users to view files that have already been stored in the software database.
5. Click one of the buttons, or to work with items already in the database, select **View > Navigator**. Navigator displays the contents of the database in a tree list to the left of the front screen.

## Connecting to the RAZOR EX Software

To view RAZOR EX files, you must first connect to the RAZOR EX instrument to download test runs, save them to the computer's hard drive, and then import them into the software.

1. Connect to the instrument by selecting **Main Menu > Utilities > Select PC Connection**. Choose **USB** or **Bluetooth**, and then either connect the USB cable or find the device with your Bluetooth software.
2. Click **Connect To Razor** on the front screen



3. The software opens a dialogue box, **Searching for Razor Instruments**, and a progress bar. If any RAZOR EX instruments are connected to the computer and powered on, the software will detect them. If the software does not find any RAZOR EX instruments, it displays a message.
4. If the software detects RAZOR EX instruments, the **Searching** dialogue box will disappear. Select the correct I/O port from the I/O port drop down menu.





5. The serial number of the instrument appears in the Instrument Name box after you select the correct I/O port.



**Note:** You **MUST** select the I/O port for the instrument name to appear.

Copy Razor Files

This button copies files from the instrument.

Copy/Delete Razor File

This button copies files and then deletes them from the RAZOR EX.

6. A browse window opens, allowing you to select the location where you want to save the files. The preferred location for RAZOR EX files is c:\Program Files\IdahoTech\RazorSW\Data.



7. A dialogue box appears with a progress bar as the software copies the files. After all the files are copied, the dialogue box disappears.
8. A new dialogue box will now appear asking if you wish to import the data. Selecting Yes will take you to the batch import function (see "Importing a Directory of Files" in the next section).
9. If you do not wish to import files, you may select No. You may then connect to another RAZOR EX and repeat the process to download runs or copy files.



## IMPORTING FILES

To view analytical run information in RAZOR EX Software, the test file must be stored in the RAZOR EX software database. Therefore, if run files from the RAZOR EX are currently stored on a hard drive or a diskette, you have to import the files into the database. Importing a file copies the file into the database; it does not remove the file from the original location. You have to import an .RZ4 file into the RAZOR EX software, which creates an .ixo file so you can view the file, print the file, or create a report. Creation of the .ixo file does not remove or delete the .RZ4 file.

### Run Names

The default run name is formatted as follows:

**serial number of the instrument\_protocol\_date\_pouch serial number.RZ4**

The RZ4 file extension designates RAZOR EX files from the instrument. For example, the run name RAZOR-EX1024\_Training\_2006-10-20\_A0000003.RZ4 is a run on instrument 1024 with the Training Protocol on 10/20/2006 using pouch A0000003.

### Importing Selected Files

You can import one or more selected files by using the **File > Import** command.

To use the Import command to import files do the following:

1. From the RAZOR EX software, select **File > Import**, then select the correct type of file as follows:
  - For RAZOR EX Software files, select RZ4 Files.
  - For RAZOR III Software files, select **Object .ixo Files**.
2. Select the files you want to import.

RAZOR EX files are stored on the local hard drive at c:\Program Files\IdahoTech\RazorSW\Data (or a different location if the person who downloaded the data selected something other than the preferred location). The run name includes the instrument serial number, protocol, and pouch serial number, which makes it easy to locate files.

To select multiple files, press **Ctrl** while selecting the file names or press **Shift** to select consecutive files.

3. Click **Open**.



**Note:** These files have been imported into the software, but have not been saved in the RAZOR EX database.

4. To save the currently displayed file in the RAZOR EX Software database, click **Save**, select the folder to store the file in, then click **Save**. You cannot save a file to a folder where it already exists unless you either rename it or replace the original file.
5. To save each of the remaining imported files (if any), click the file name in the task bar to make the file active in the work pane; click **Save**, select a folder, then click **Save**.

## Importing a Directory of Files

1. From the RAZOR EX software, select **File > Batch Import**.

The Batch Import dialogue box displays.



2. Click **Add**.
3. Find and select the directory you want to import, then click **OK**.
  - The directory path is added to the window.
  - The default location for RAZOR EX files is c:\Program Files\IdahoTech\RAZORSW\Data (or a different location if the person who downloaded the data selected something other than the preferred location).
4. Check **Include subdirectories** if you want to include the subdirectories of the directory.
5. Repeat Steps 2–4 to add additional directories as needed.
6. To remove any of the paths you have added:
  - Click in the Remove column for the file. The software displays a gray button.
  - Click the button to remove the file.
7. Repeat the process to add more directories.
8. When you are finished adding directories, click **Next**.
9. Select the folder in the database where you want to store the imported files, then click **Next**.
10. Scroll down to and select the type of file to import. RAZOR EX files are .RZ4 files, and RAZOR III files are .ixo object files.
11. Select the action for duplicate files.
12. The next tab displays the current status of the imported files. Any failed imports will have information reported in the Messages column. Maximizing the window and resizing the columns will allow you to read long messages. You cannot save a file to a folder where it already exists unless you either rename it or replace the original file.
 

When all the files have been imported, view the results on the **Import Done** tab.
13. To redo the import with different import parameters:
  - Click **Previous** twice to return to the **Start Import** tab.
  - Click **Reset**.
  - Change the parameters you want, then click **Next** to re-import the files.
14. When you are finished, close the dialogue box by clicking **Done** on the **Import done** tab.

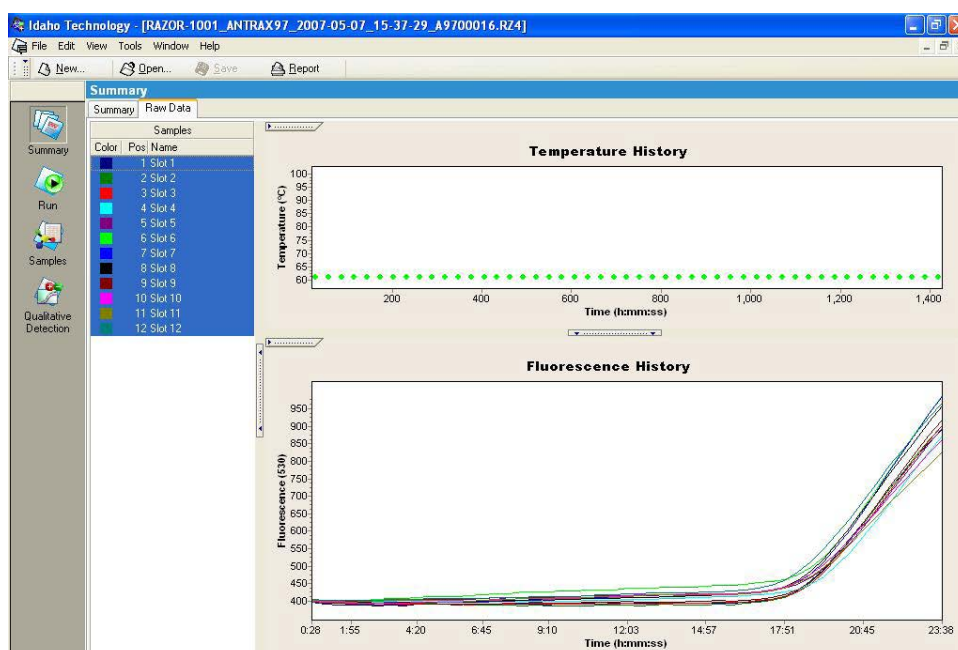
## UNDERSTANDING THE SOFTWARE WINDOW

Follow the procedure below to open any saved test. The example below illustrates the software features and components described in the rest of this section.

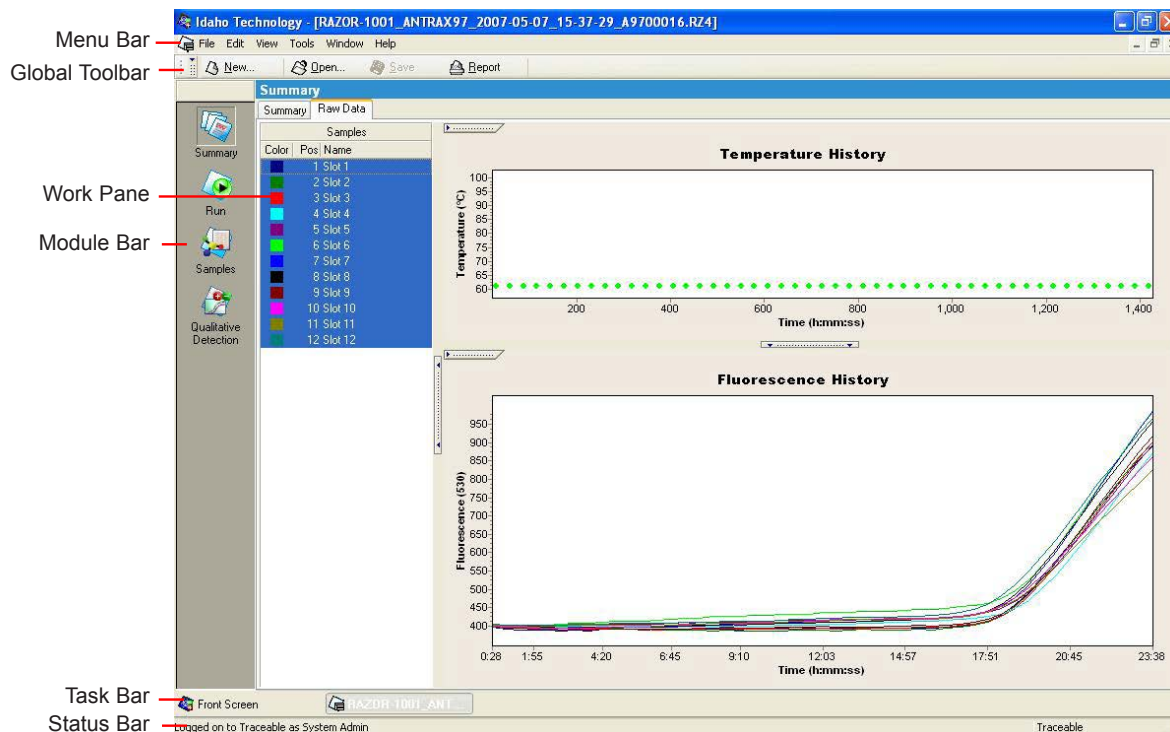
### Opening a Test

1. Log on to the RAZOR EX software. (The computer does not need to be connected to an instrument for you to view a finished and imported test.)
2. Select **View > Navigator**.
3. In **Navigator**, click the plus sign (+) next to the **Analytical Runs** folder.
4. Double-click the test name; for example, **RAZOR-1001\_ANTRAX97\_2007-05-07\_15-37-29\_A9700016.R24**.
5. A **Summary** tab displays general test information including run notes, which contain the meta-calls results (summary and details) from the run.
6. Select the **Raw Data** tab to view the test data. The tab displays a list of samples and charts of test data.

The figure below illustrates the **Raw Data** tab of the software window containing information from a demonstration test.



## The Software Window



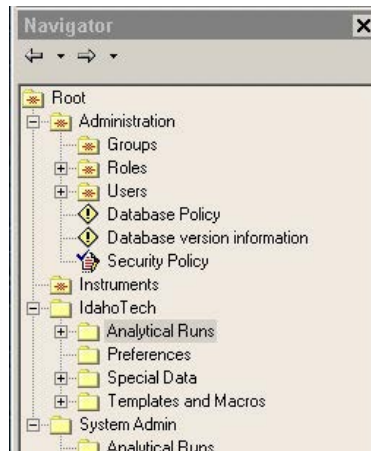
The software window contains the following areas:

- **Navigator:** The Navigator tree structure organizes and displays folders and files of users, instruments, and tests.
- **Menu bar:** The menu bar contains menus used to access data and perform software functions.
- **Global toolbar:** The global toolbar at the top of the window contains buttons for common tasks.
- **Work pane:** The work pane is used to perform the specialized operations of the software, such as viewing data or analyzing results.
- **Module bar:** The module bar provides access to the components of a test. It is visible only when a new or saved test is opened.
- **Task Bar:** The task bar displays icons for all open windows, including ones “hidden” behind the current window.
- **Status bar:** The status bar displays the name of the current user and computer.
- **Messages window:** The message window displays any messages generated as you use the software.

The following sections describe the main areas of the RAZOR EX software window in more detail. This includes the following areas of the software window: Navigator; the menu bar and global toolbar; the work pane; and the module bar. In addition, the following sections also contain information about showing or hiding items under a folder, managing items, and how to close or reopen the Navigator.

## Navigator

To open the Navigator, select **View > Navigator**.



The Navigator, on the left side of the RAZOR EX software window, provides access to items stored in the RAZOR EX software database. Items are organized into folders in a tree structure and always include the following default folders:

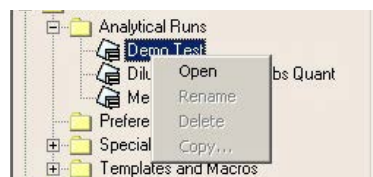
- **Administration folder:** Contains user groups, user roles, user accounts, and security policies. This folder is not editable.
- **User folders:** Contains folders and default subfolders for each user account. The default subfolders include Analytical Runs, Preferences, Special Data, and Templates and Macros. You can also create your own subfolders.
- **IdahoTech folder:** Contains objects anyone can view and use. This folder can be used by anyone with access to RAZOR EX software. (To modify an item, you must first copy it to your own user folder.)

### Showing or Hiding Items Under a Folder

Double-click the folder name or click the plus (+) or minus (–) sign next to the folder.

### Managing Items

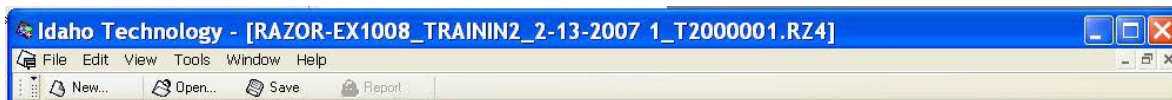
- Right-click an item name in the Navigator to display a context, and then select a command.
- The menu commands vary, depending on the type of item and your user account privileges.



### Closing and Reopening the Navigator



1. To close **Navigator**, choose one of the following:
  - From the **View** menu, deselect **Navigator**.
  - Click the **X** in the upper-right corner of the **Navigator** pane.
 Closing Navigator causes the work pane to extend the full width of the window.
2. To reopen the **Navigator**, select **View > Navigator**.



## The Menu Bar and Global Toolbar



The menu bar and the global toolbar are located at the top of the software window. Many of the buttons duplicate the commands found on the menus. If a button or menu item is inactive (dimmed) either it is not available, or the task does not apply to the item that is currently open.

Menu	Use
<b>File</b>	<ul style="list-style-type: none"> <li>Create new files, open files, and close files.</li> <li>Save items.</li> <li>Log out of the software (without closing the software).</li> <li>Import and export individual files or batches of files.</li> <li>Open a test report.</li> <li>Print the current window.</li> <li>Exit (close) the software.</li> </ul>
<b>Edit</b>	<ul style="list-style-type: none"> <li>Cut, copy, and paste data in the work pane or items in the Navigator.</li> <li>Select all items.</li> </ul>
<b>View</b>	<ul style="list-style-type: none"> <li>Display or hide these sections of the RAZOR EX software window: global toolbar, task bar, status bar, Navigator, and messages.</li> <li>Display the Front Screen (the window you see after you first start RAZOR EX software).</li> </ul>
<b>Tools</b>	<ul style="list-style-type: none"> <li>Change your password.</li> <li>Manage user accounts (create, disable, change names and passwords).</li> <li>View database status, including a list of logged-in users and information about the query engine (see "Updating the Database," later in this chapter).</li> </ul>
<b>Window</b>	<ul style="list-style-type: none"> <li>Close, minimize, and arrange windows when multiple windows are open in the work pane.</li> <li>Select an open window to make it the active window. (The bottom of the <b>Window</b> menu displays a list of all currently open windows, with the active window checked.)</li> </ul>
<b>Help</b>	<ul style="list-style-type: none"> <li>Display online versions of RAZOR EX software manuals.</li> <li>Open the <b>About</b> window to view version and copyright information about the software.</li> </ul>

Button	Use
 New...	Create a new item. A dialogue box displays icons for all available items; select the correct item.
 Open...	Open any item. A popup navigator opens so you can select the item you want. (You can also double-click an item in the main Navigator to open it.)

Button	Use
 Save	Save changes made to an item. The software enables the <b>Save</b> button only when the item in the active window has been modified.
 Report	Generate a test report and display it in a test report window.

## The Work Pane

The RAZOR EX software work pane contains information specific to the operation you are performing. For example, if you open the Run module of a saved test, the work pane displays three tabs: a Programs tab containing the program protocol, an Online Data Display tab containing the raw data returned from the instrument during a run, and a Run Notes tab where you can enter information about the test.





The application is designed to allow multiple open tests or other items. A label for each open item is visible in the task bar at the bottom of the window. Click the label in the task bar to display the item in the work pane.

To size individual sections of an item in the work pane:

1. Drag the horizontal borders between sections to size them.
2. Click the handle on the border of a section to hide or show the section.

## The Module Bar

The module bar displays the following icons for the components of a test. It is visible only when a new or existing test is open.

Button	Use
 Summary	Opens the Summary module of the test run, which contains information about the run—such as name, date, owner—and charts of raw data generated during the run.
 Run	Opens the Run module, which includes the details of the run protocol, charts of raw data returned during the run, and notes entered by the person running the test.
 Samples	Opens the Samples module, which contains general sample information, such as sample names and assays tested.
 Qualitative Detection	Opens the associated analysis module. This is the icon for a qualitative detection analysis.



To use the module bar:

1. Click an icon to open the module.

Or

Use the keyboard shortcut for the icon, **Ctrl+Shift+N**, where **N** is the number of the icon counting from the top. For example, the Samples icon is always third in the list of icons, so to open the **Samples** module, press **Ctrl+Shift+3**.

2. Hold the mouse pointer over an icon to see the name of the related module and the keyboard shortcut for opening the module.

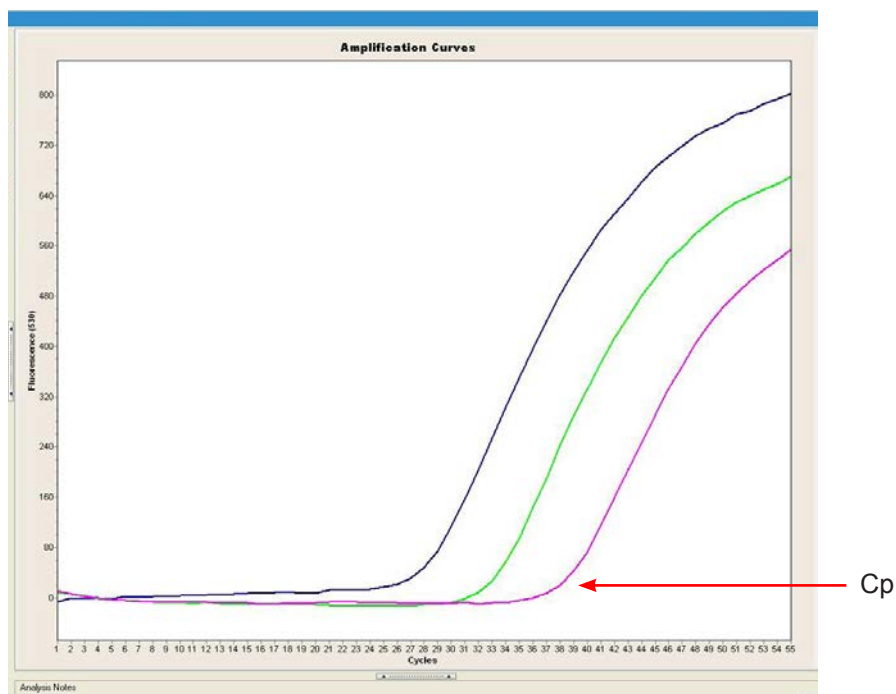
## QUALITATIVE DETECTION ANALYSIS

The Qualitative Detection analysis module analyzes unknown samples for the presence of a nucleic acid target based on the presence or absence of a *crossing point* (Cp) in each sample's data. The RAZOR EX Software uses the Qualitative Detection analysis to generate results.



**Note:** Temperature graphs are not imported for RAZOR EX files; only the temperature at the fluorescence acquisition is displayed.

### Crossing Points



In an amplification reaction, the point in the cycle at which the target DNA has amplified enough so that its fluorescence is visible above the background fluorescence is called the Cp of the sample. It appears as a sharp upward turn in the sample's curve on a fluorescence chart.

Assuming that there is no contamination, a Cp indicates the presence of the target DNA and is expressed in cycles. Crossing points are used by the Qualitative Detection modules to determine the presence or absence of the target DNA. Samples are listed by name showing their positions and color on the graph.

## Controls

Control samples provide information about the quality of the reagents, sample contamination, inhibitors, and reaction conditions. Controls are expected to behave in a certain way. If they fail to behave as expected, then the results for the unknown samples are considered invalid.

- **Positive control (PC).** A positive control contains a known concentration of a nucleic acid sequence and should have a Cp value that is characteristic of the sequence. The positive control is located in a separate slot from the unknown samples. Its result applies to all the slots for the specified assay in the run. If the positive control does not amplify, then the control fails. Failure may be caused by PCR inhibitors contaminating the sample, damaged pouch or reagents, or user error.
- **Negative control (NC).** A negative control does not contain any target DNA sequence and should not have a Cp. The negative control is located in a separate slot from the unknown samples. Its result applies to all the slots for the specified assay in the run. If the negative control amplifies, then the control fails. Failure indicates that the control is contaminated and, therefore, that unknown samples may also be contaminated.
- **Inhibition control (IC).** An inhibition control contains a known concentration of a DNA sequence and should have a Cp value characteristic of the sequence. The sample is added to the inhibition control to determine whether inhibitors are present that would stop a sample with template present from amplifying. The inhibition control is located in a separate slot from the unknown samples. Its result applies to all the slots for the specified assay in the run. If the inhibition control does not amplify, then the control fails. Failure may be caused by PCR inhibitors contaminating the sample, damaged pouch or reagents, or user error.

## Understanding the Results

Results for each slot include a section labeled Calls and a section labeled Results. The Target column displays the amplification result for the slot position based only on the slots amplification profile.

Value	Explanation of the Target Column
<b>Positive</b>	Amplification was detected in the slot.
<b>Negative</b>	Amplification was not detected in the slot.
<b>Target Call</b>	A positive or negative call for the slot based on amplification curve. Calls are made by Detector (which is part of the RAZOR EX instrument).

Results columns show the following:

Contents	Comments
<b>Cp</b>	The sample crossing point, in cycles.
<b>Max Fluor (Background)</b>	The level of fluorescence increase determined by subtracting baseline fluorescence level from highest level of fluorescence reached by the sample.

You can highlight individual samples by selecting them with the mouse. To view multiple samples, hold down the **Ctrl** key while selecting samples you want to examine or **Shift** for consecutive samples.

## VIEWING AND PRINTING A TEST REPORT

This section contains information about the following subjects:

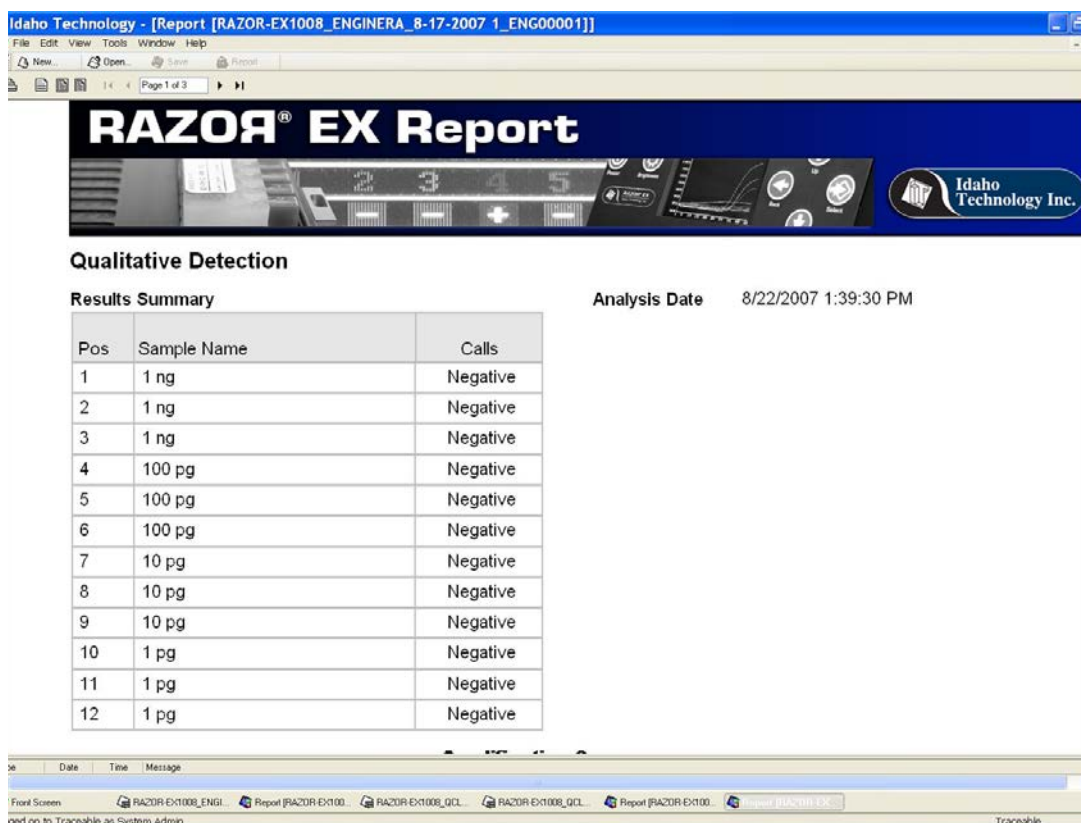
- Generating a test report
- Viewing and printing the report
- Regenerating a report

### Generating a Test Report

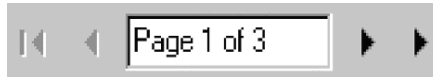
The test report contains the following information:

- Sample names and detector calls for each slot
- Test information (such as a run name, start and stop time, and date)
- A graph of the amplification curves
- Metacalls from the instrument including results (summary) and results (details)
- Assay information with results for each assay's controls
- Instrument information, including the serial number
- Pouch information with the pouch serial number and protocol name

1. Open the test or click **Save**.
2. Click **Report**, or select **File > Report**. The report window opens in the work pane.



3. To see additional pages of the report, use the page forward and backward controls:



To change the scale of the report within the window, click one of the three buttons on the top left of the report screen:



- **Left:** The report is displayed at its printed size.
- **Middle:** The entire report page fits in the window.
- **Right:** The width of the report page fits in the window.

To print the report, click **Print**:



To close the report, click the X above the report toolbar.

## Viewing and Printing the Report

Use the report controls in the report tool bar as described on the previous page.

## Regenerating a Report

You cannot save a report, but you can easily regenerate the report for any test:

1. Open the test and make any necessary edits.
2. Click **Save**. You must save the test before you can create a report.
3. Click **Report** on the global toolbar, or select **File > Report**. The report window opens in the work pane and can be modified as described above.

# CHANGE HISTORY AND AUDIT TRAIL INFORMATION

The RAZOR EX desktop software runs in Audit Trail mode. An audit trail allows revisions and changes to each test to be stored and accessed.

Audit-trail mode imposes the following limits:

- In audit-trail mode, it is impossible to overwrite or delete tests or analyses.
- You cannot copy a test or save a test with a new name. Names for test records must be unique within the database.
- The audit trail stores the following information about each saved version of a test: date, operator, change notes, and revision number.

## Revisions

Change notes are required for every change after the completion of the test and analysis. Previous revisions of the test are saved in the database as read-only information. You can change only the latest revision of a test, and you can only change a limited number of fields. These include the sample names and sample notes.

To view revisions:

1. Open the test and select **File > Revisions**  
A Revision list opens, displaying the revision number, date, the user name, and the reason for the change.
2. To open a previous revision, double-click on the correct selection. The previous revision of the test opens in the work pane with the number of the revision appended to the front of the run name.
3. To generate a report, click **Report** in the global toolbar.

## Change Notes



Whenever you attempt to save a test that you have modified (for example, by adding sample notes or run notes), the software prompts you to enter change notes. Informative and detailed change notes are *essential* to the audit trail process. For each change, enter the following:

1. The name of the person making the changes
2. Specific changes that were made
3. The reasons for making the changes

These change notes are the major record detailing the revisions of test. You cannot save a test without entering change notes.

# MANAGING DATABASE CONTENT

This section describes how to manage the data that is stored in the RAZOR EX database (Exor) and is visible in the Navigator.

## Copying Items

You can copy an item from another person's folder into your own folder or subfolder. However, your user role may limit which folders are visible to you and which items are available.

Once the item is in your own folder, it becomes your item, and you can modify it as necessary (subject to the limitations of your user role). For example, you might want to copy a sample preference file from another user's folder into your own preferences folder and then modify it.

To copy items from another person's folder:

1. Right-click the item you want to copy in the Navigator, then select **Copy**.  
A dialogue box opens.
2. Select your user folder (or a subfolder under your user folder), enter a new name for the item if you want to do so, then click **OK**.

## Exporting Files

To store test runs or other data outside the database or to transfer data between databases, you must *export* the data. Exporting data does not remove it from the database, but copies it into an .ixo file and stores it at the location you designate.

An exported test is stored as a file with an .ixo extension. You can also export a run's raw data (its temperature and fluorescence measurements) in text format (a file with a .txt extension) and export other items, such as chart preferences. Like tests, preferences have .ixo extensions.

## Exporting an Individual Item

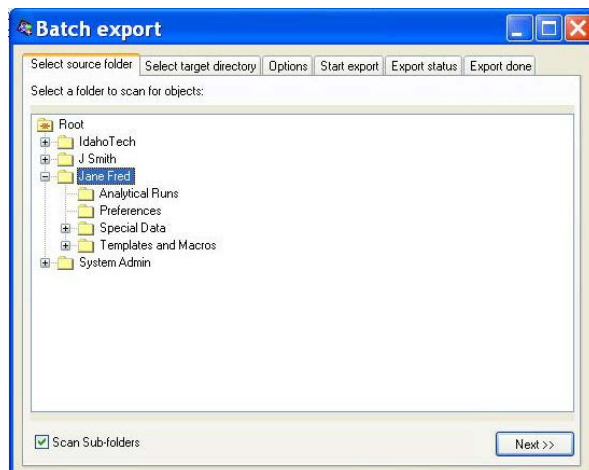
1. In RAZOR EX software, open the run to be exported. The item must be open in the work pane before it can be exported.
2. Select **File > Export**.
3. Navigate to a location to save the exported file, make sure that **XML Object Files (.ixo)** is selected as the file type, enter a new file name (or keep the existing name), and then click **Save**. The file is saved with an .ixo extension.

## Exporting a Test's Raw Data

1. In RAZOR EX software, open the test containing the data you want to export. The item must be open in the work pane before you can export it.
2. Select **File > Export**.
3. Navigate to a location to save the exported data, select **Raw data file (.txt)** as the file type, enter a new file name (or keep the existing name), and then click **Save**. The text file contains the raw fluorescence and temperature values for each data acquisition point in the test. You can use any text editor, such as Notepad, to open the file.

## Exporting a Folder of Items

1. Select **File > Batch export**. The Batch export dialogue box is displayed.



2. In the folder tree, highlight the folder containing the items to export.
3. Leave **Scan Sub-folders** selected if you want to include subfolders in the export.
4. Click **Next**.

5. Click **Browse** to display a file selection dialogue box.
6. Find and select the location in which to store the exported files, then click **OK**.
7. Click **Next**.

A tab with export options is displayed.



8. Select the object types to export.
9. Select the date range for the objects by creation date or modification date.
10. Select the operation to perform if a file should already exist with the same name as a file being exported.
11. Click **Next**.  
The tab displays a summary of the export paths (from and to).
12. If the paths are correct, click **Next** to begin the export. (Otherwise, click **Previous** to return to previous tabs and make corrections.)  
The export begins. The tab displays the current status of the export operation for each file. Maximizing the window and resizing the columns allows you to read long messages. When all the files have been exported, the **Export done** tab is automatically displayed.
13. View results on the **Export Done** tab, then click **Done** to close the dialogue box.

## Updating the Database

If you install an updated version of software, you may see a message instructing you to update the database. Follow the steps below (all other people must be logged out of the database before you can update it.):

1. Select **Tools > Database Status**.
2. Check that there are no user names displayed in the **Logged In Users** tab.
  - If other people are logged in, you must ask them to log out or wait until a time when no one is logged in.
  - If no one else is logged in, select the **Query Engine** tab, and then click **Update**.
  - The system displays a message to remind you that the update will take several minutes.
3. Click **Yes** to clear the message and continue.



After the database is updated, a message states that the update is complete.

4. Click **OK** to clear the message.

A message on the Query Engine tab states that the query engine is now up to date.

5. Close the **Database Status** dialogue box.

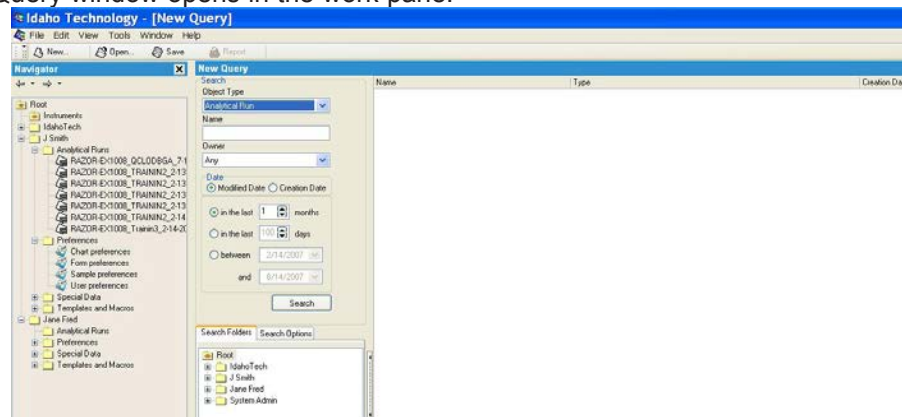
## USING QUERIES

RAZOR EX software includes a query tool you can use to search for and retrieve test runs and other items stored in the software database.

### Creating and Executing a Query

1. Click **New**, select the **Query** icon, and then click **OK**.

The Query window opens in the work pane.



2. In the **Object Type** box, select the type of item to look for, such as Analytical Run (a test).
3. (Optional) Enter the **Name** of the item to search for or the **Owner** of the item, if known.
4. Select **Modified Date** or **Creation Date** to specify which type of date you want to use in the query.
5. Select a date range.

You can specify the number of months or days before the current date to search, or you can select a beginning and ending date.

6. Click **Search**.

Results are displayed to the right of the search criteria. The results include the following:

- Item name
- Item type
- Date the item was created
- Date the item was last modified



**Note:** If an error message is displayed stating that the query engine needs to be updated, you must update the database. See previous section, “Updating the Database.”

7. To open an item, double-click the item name.

8. To save the query, click **Save**.
9. Enter a name and select a location (or leave the defaults), and then click **Save**.  
Saving a query lets you quickly reexecute the search without needing to respecify the search parameters.
10. To close the search window, click **Close**.

### Executing a Saved Query

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1. Find the query you want in the **Navigator**.  
The default location for saved queries is the Query folder under the Special Data folder for your user account.
2. Double-click the query name to open the query in the Query window.
3. In the **Query** window, click **Search** to execute the query.

### Specifying Default Paths and Folders

---

You can specify default paths and folders for the following:

- Default directories for importing and exporting files.
- Default database folders in which to save RAZOR EX software items such as test runs, preferences, and queries.

To specify default paths and folders:

1. In the **Navigator** window, select **Preferences** under your user folder and open the **User preferences** subfolder.  
The **User preferences** tabs are displayed in the work pane. The **Directories** tab is active.
2. In the **Import from** box, type a path to a location on your local computer or network.  
Or  
Click "...", then navigate to a location on your local computer or network and click **OK**. The path will become the default location from which to import files into the database.
3. In the **Export to** box, type a path to a location on your local computer or network.  
Or  
Click "...", then navigate to a location on your local computer or network and click **OK**. The path will become the default location that is displayed when you export files from the database.
4. Select the **Folders** tab.  
A row is displayed for each type of item you can store in the database, such as experiments (tests) or queries.
5. On each row, type a path to a subfolder under your database user folder.  
Or  
Click "..." then navigate to a folder under your user folder. Click **OK**.  
The folder will become the default location for storing items of this type.
6. Click **Save** to save all of your preferences.

# CHARTS

## Using Charts

The RAZOR EX software allows you to zoom in to view chart details and to print, export, and copy charts and their data.

## Zooming

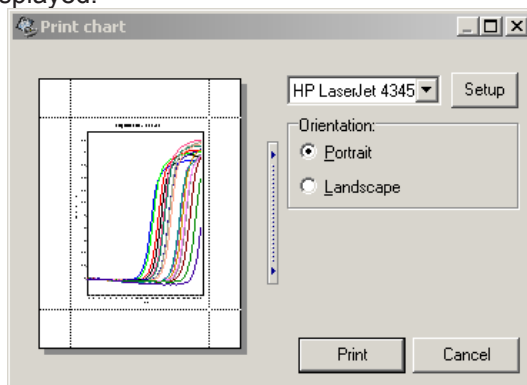
1. Display the chart you want to see.
2. Place the cursor above and to the left of the chart area you want to enlarge.
3. Click and drag the mouse pointer down and to the right (the pointer changes to a rectangle.) Release the mouse button when the rectangle covers the area you want to see. The area within the rectangle expands to fill the work pane.
4. Repeat Steps 2 and 3 as often as necessary until the chart details are as large as you want.
5. To restore the chart to its original size, click and drag the mouse pointer up and to the left. (Do this only once to restore the chart to its original size.)

To print the entire window, select **File > Print Window**.

## Printing Only a Chart Image

1. Display the chart you want to print.
2. Right-click within the chart boundaries and then select **Print**.

A set-up window is displayed.



3. To change the size of the chart, click and drag the gray margin lines that surround the image.

 **Tip:** You can resize the dialogue box to adjust the chart margins more easily.

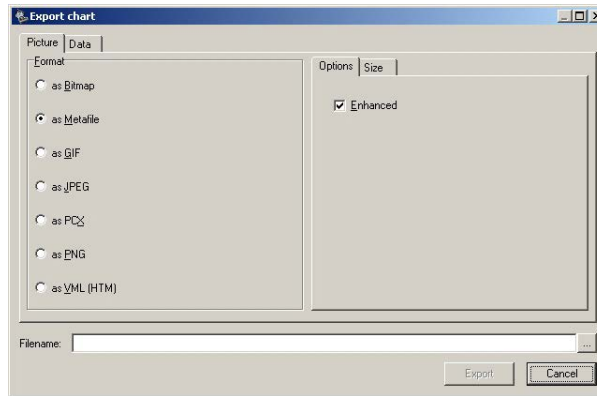
4. If necessary, select a printer. (Your default Windows printer is automatically selected.)
5. To change printer configuration options, click **Setup**.

A standard Windows printer setup dialogue box is displayed. Enter the necessary information, then click **OK**.

6. Select **Portrait** or **Landscape**.
7. Click **Print**.

## Exporting a Chart Image as a File

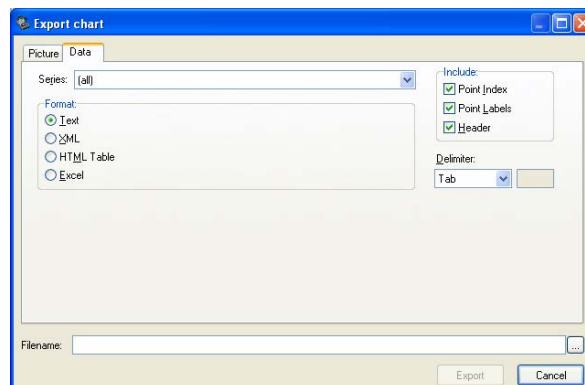
1. Display the chart you want to export.
2. Right-click within the chart boundaries, and then select **Export**.  
An Export Chart dialogue box opens.



3. On the **Picture** tab, under **Format**, select the graphic format for the exported chart.
4. If an Options tab is displayed (on the right), select conversion options as needed.  
The tab is not displayed for all graphic formats. If the tab is displayed, the options vary, depending on the format you selected.
5. To change the size of the exported image, select the **Size** tab, then enter the new width and height values. Select **Keep aspect ratio** if you want to maintain the proportions of the chart.
6. Click the button labeled "... " (to the right of the Filename box).
7. Browse to the location where you want to save the exported chart image, enter a name for the image, and then click **Select**.
8. Click **Export** to export the chart image.

## Exporting Chart Data as a File

1. Display the chart containing the data you want to export.
2. Right-click within the chart boundaries, then select **Export**.
3. Select the **Data** tab.



4. In the **Series** box, select the data item you want to export.  
The items vary, depending on the chart type.
5. In the **Include** box, select the text labels to export with the data.
  - Point Index: Adds a number to each row
  - Point Labels: Identifies the acquisition points in each sample
  - Header: Provides informational data for each row
6. In the **Format** box, select a format for the exported data.
  - Text: The data is exported as a .txt file
  - XML: The data is exported as an .xml file
  - HTML Table: The data is exported as an .html file
  - Excel: The data is exported as an .xls (Microsoft Excel) file
7. If you selected Text as the format, select a delimiter (that is, a data separator) in the Delimiter box. The default delimiter is Tab.
8. Select the button labeled "... " (to the right of the Filename box).
9. Browse to the location where you want to save the exported data, enter a name for the data file, and then choose **Select**.
10. Select **Export** to export the data.

### Copying a Chart Image or Chart Data

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1. Display the chart you want to copy.
2. Right-click within the chart boundaries, then select **Copy to clipboard**. The chart is saved as a bitmap, and the data is saved as text.
3. To paste the chart image, open a graphics application such as **Paint**, then copy the image using the application's **Paste** command.
4. To paste the chart data, open a text editor such as **Notepad**, then copy the data using the application's **Paste** command.

## USER ACCOUNTS AND SYSTEM ACCESS

The level of access you have to software features depends on the role assigned to your User Account in the RAZOR EX software. The system has two account types, *admin* and *operator*. The admin user account has an administrator role. There is only one admin account, and it is created automatically when the software is installed. The admin user creates the other user accounts. All other user accounts, except the admin account, have the operator role.

The table below describes software features available to operators and to the admin user.

Task	Operator	Admin
Create and modify your own subfolders and files	X	X
Connect to instruments	X	X
View tests and other objects belonging to other users	X	X
Modify files belonging to other users		X
Create, modify, and disable user accounts		X
Import and export files	X	X
View and print reports	X	X

## MANAGING USER ACCOUNTS

Only the admin user can manage user accounts.

### Creating a New User Account

1. Select **Tools > Manage Users**.
2. Click **New User**.
3. Enter a full name.
4. Enter a login name (the default is the full user name)
5. Enter a temporary password (the user will be prompted to change the password upon first login).
6. Reenter the password.
7. Select the **Operator** role from the drop-down list.
8. Click **Done**.

A folder is created for the new user, and the new user account is listed in the User Management window.

### Editing a User Account

1. Select **Tools > Manage Users**.
2. Select a name in the window and click the **Edit User** button, or right-click the name and select **Edit User** from the drop-down menu.
3. Modify the user information, as needed.
4. Select **Done**.

### Disabling a User Account

---

1. Select **Tools > Manage Users**.
2. Select the name in the window and select the **Edit User** button, or right-click the name and select **Edit User** from the drop-down menu.
3. Check **Access Disabled**.
4. Select **Done**.

The user account is no longer active, but it still exists in the database.

## MANAGING SYSTEM ACCESS

Only the admin user can view or change system access settings.

### Setting Auto-Logout

---

1. Select **Tools > Manage Users**.
2. Select **Edit Access**.
3. Under **Logout on Inactivity**, select **Enabled**.
4. Click the arrows in the **Minutes of Inactivity** box to specify the number of minutes of inactivity that should occur before someone is automatically logged out of the database.
5. Select **Done**.

### Disabling User Access after Invalid Login Attempts

---

1. Select **Tools > Manage Users**.
2. Select **Edit Access**.
3. Under **Disable Access on Invalid Password**, select **Enabled**.
4. Click the arrows in the **Maximum Login Attempts** field to specify the number of times someone can attempt to log in before account is deactivated.
5. Select **Done**.

### Setting Password Expiration

---

1. Select **Tools > Manage Users**.
2. Select **Edit Access**.
3. Click the arrows in the **Password Expiration Days** field to specify the number of days someone's password remains valid, counting from the day the password is created.
4. Select **Done**.



## VIEWING APPLICATION ERROR MESSAGES

Error messages generated by the software can be displayed in a message pane at the bottom of the RAZOR software window.

To display the messages pane:

1. Select **View > Messages**. The software displays the messages pane at the bottom of the window.



2. Double-click an error message in the message pane to display a pop-up containing the message.



3. Click **Details** to display additional information about the error.
4. If you plan to contact BFD Technical Support, copy and paste the detailed information into a text editor (such as Notepad) so that it is available to support personnel. You should also provide the .ixo file for troubleshooting and indicate what was being attempted when the error occurred.
5. Click **OK** to close the message pop-up.

Error messages are also logged in an application error log file located at C:/Program Files/IdahoTech/RazorSW/Data/RazorErrors.txt. This log contains a list of application errors that have been generated since the software was installed. Each error entry includes the date and time of the error, the error message, and the exception or call stack. Support personnel will also request this file.

# CHAPTER 4:

# MAINTENANCE AND

# TROUBLESHOOTING

## INTRODUCTION



**Note:** Contact BDFD Technical Support before you access any internal components on the RAZOR® EX.



**Note:** It is always a good idea to run the RAZOR EX with the battery installed, especially if poor power conditions are suspected.



**WARNING:** Before you perform maintenance on the RAZOR EX, turn off the power, unplug the USB and power cables, and allow the instrument to cool. 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 EX is a field-hardened instrument designed for field use, but it is neither waterproof nor indestructible. With proper care and maintenance, the RAZOR EX will perform accurate and sensitive PCR-based pathogen identification.

## GENERAL MAINTENANCE

- As needed, wipe down the surface of the RAZOR EX and heater boards 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 EX instrument before returning it for service. See Appendix B for additional instrument return requirements.

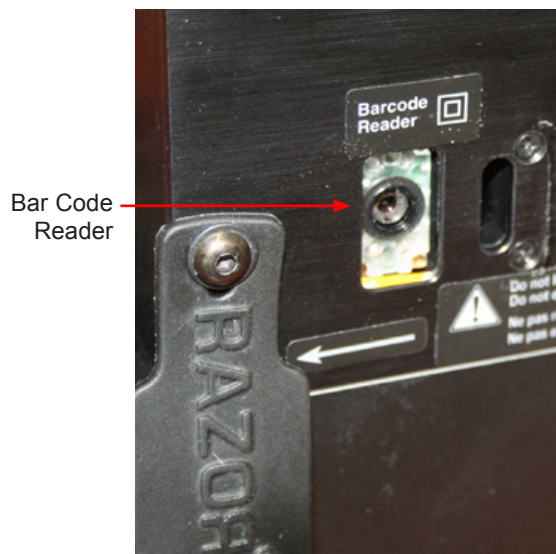
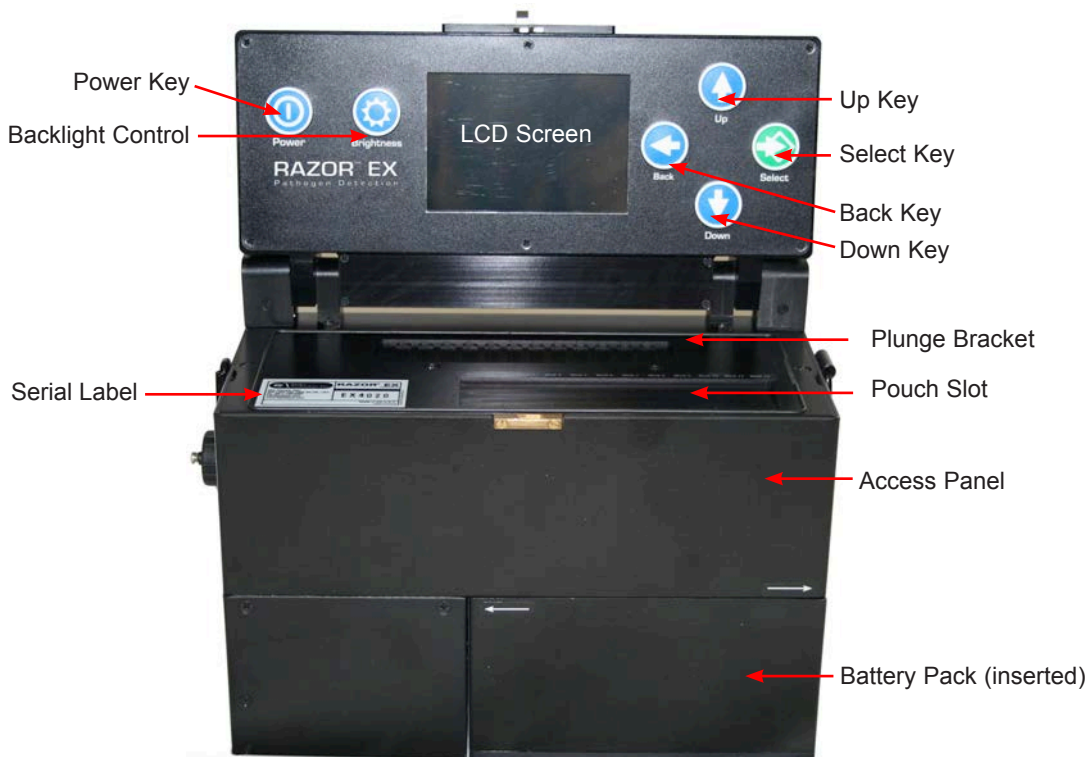


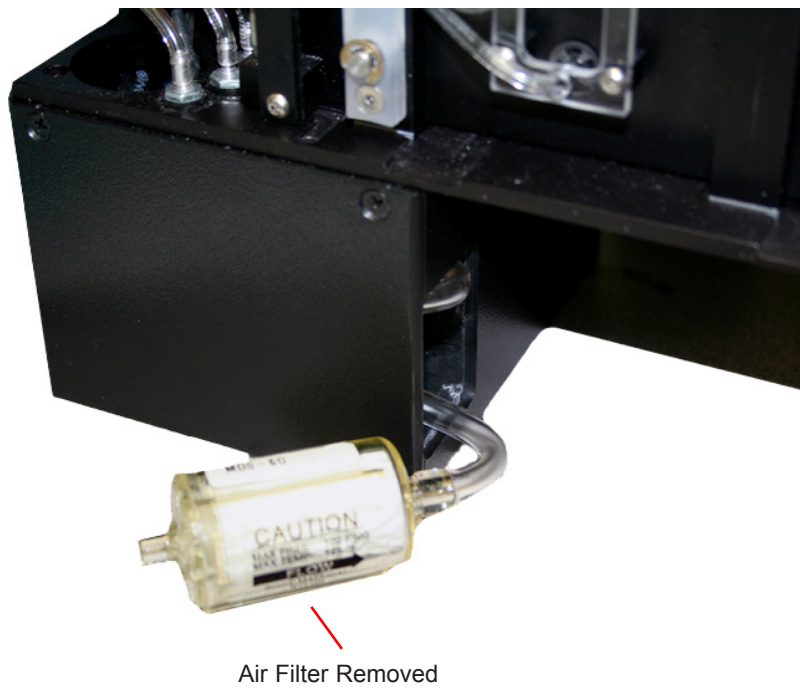
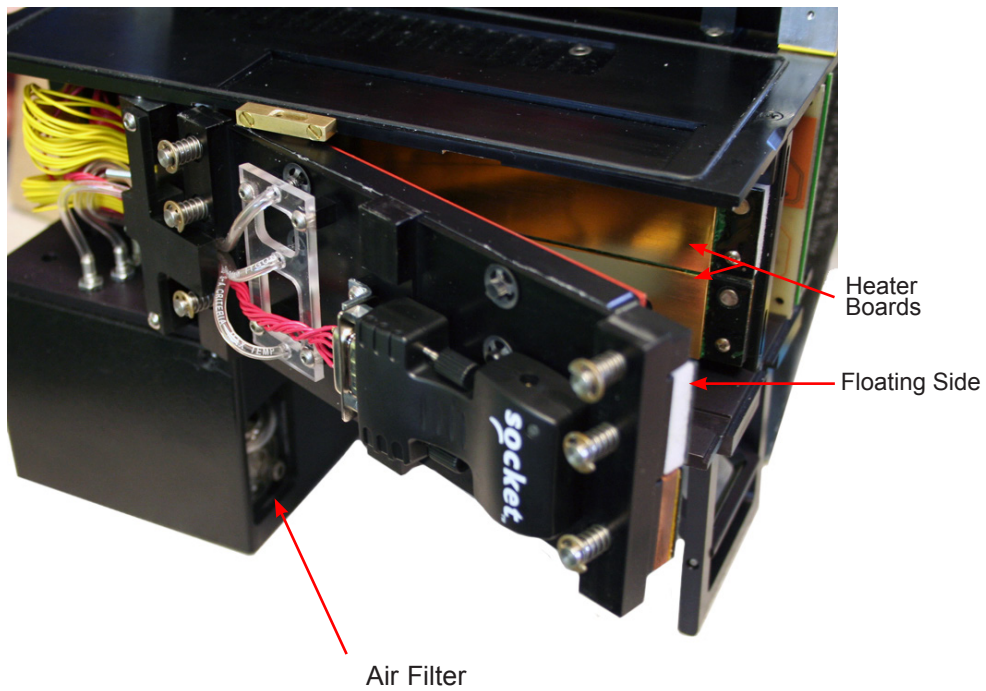
**CAUTION:** Do not get bleach on the lenses or the battery contacts. Use lens cleaner and a lens cloth to clean the lenses.

- 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 EX Instrument.





## PREVENTIVE MAINTENANCE

Each RAZOR EX 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 BFDF Technical Support for a replacement.



## ACCESSING INTERNAL COMPONENTS, HEATERS, AND LENSES

**!** WARNING: Before you access internal components of the RAZOR EX, turn off the power, remove the battery, and disconnect both the power cable and the USB cable.

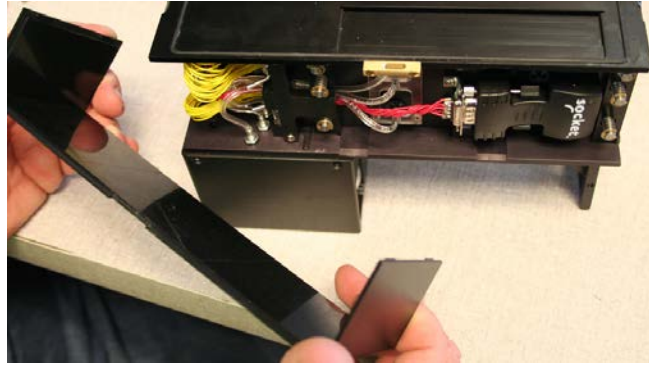
**!** WARNING: When you access internal components, keep the instrument in its upright position as shown in the images below. Also, be sure to use care to avoid damaging delicate components.

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

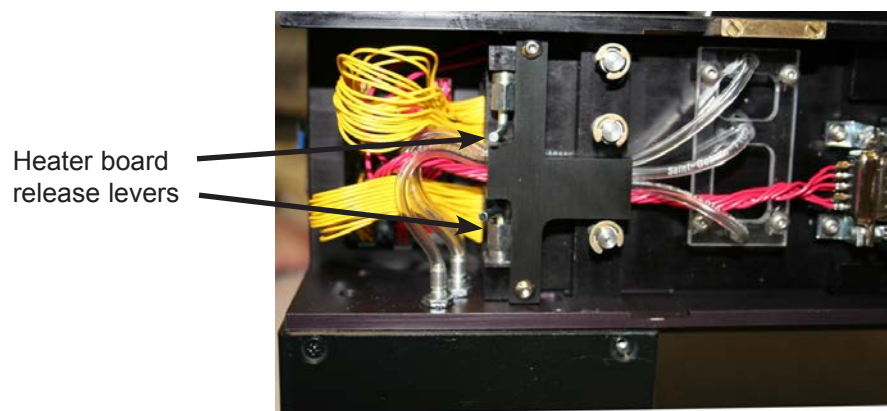


2. Carefully remove the other side of the access panel and place it to the side on a clean surface.





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.

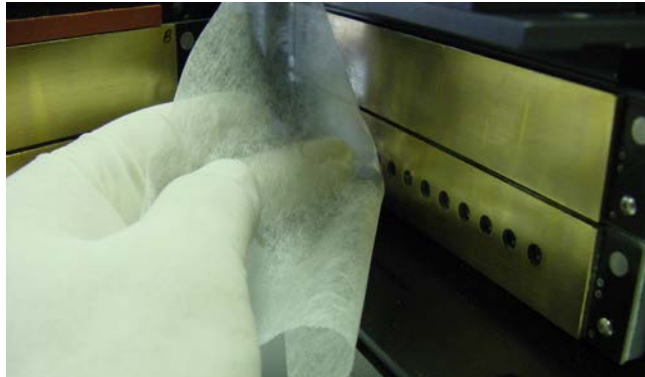


## Lens and Heat Plate Cleaning

<b>Type of Service:</b>	Preventive Maintenance/Corrective Maintenance
<b>Recommended Frequency:</b>	Every 40 runs (about 20 hours of use), or after operation in an extreme environment such as a dust storm.
<b>Possible Symptoms:</b>	Low fluorescence, spikes in real-time graph
<b>Required Parts:</b>	None
<b>Required Materials/Tools:</b>	Lens cloth (from the startup kit) or microfiber cloth, lens cleaning solution, canned air
 <b>Caution:</b>	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 EX's ability to identify.


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.

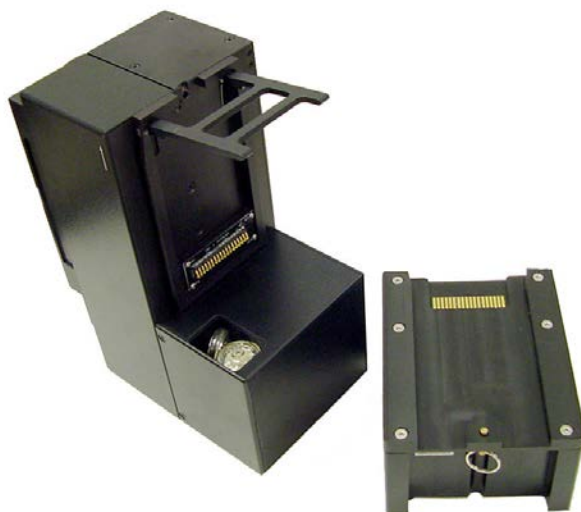
## Replacing the Air Filter

<b>Type of Service:</b>	Preventive Maintenance/Corrective Maintenance
<b>Recommended Frequency:</b>	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).
<b>Possible Symptoms:</b>	Error codes: V131 "Elevation, filter, leak, or sensor failed, POST." OR M130 "Pressure Timeout. Unable to Reach X PSI in bladder Y"
<b>Required Parts:</b>	Air filter (RAZR-SUB-0406)
<b>Required Materials/Tools:</b>	None
 <b>Caution:</b>	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 EX. 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-SUB-0406) that you have obtained from BFDf. There are two valid configurations for the filter and tubing:

**!** 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.

- a. If your RAZOR EX has approximately 4.5 in. of tubing between the filter and the housing, the filter is oriented with the inlet side facing the opening in the housing.




- b. If your RAZOR EX has approximately 2 in. of tubing between the filter and the housing, the filter is oriented with the outlet side of the filter with the tubing connected facing the opening in the housing. The filter for this configuration also has two small holes drilled thru the inlet barb of the filter.

**!** WARNING: DO NOT Use the 2-in. tubing configuration unless you have a filter with the two holes drilled in the inlet barb of the filter.

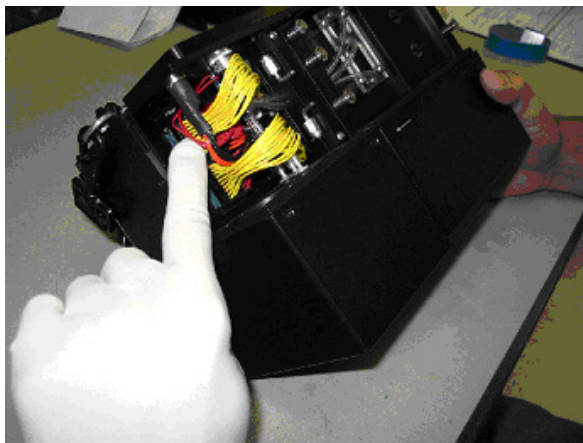


## Checking the Heaters

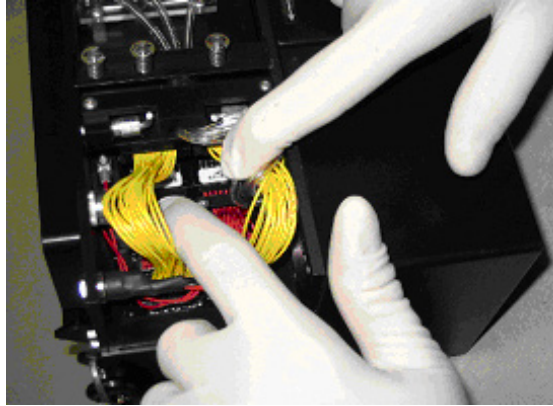
<b>Type of Service:</b>	Corrective Maintenance
<b>Recommended Frequency:</b>	After 40 runs (about 20 hours of use), or after any internal maintenance or shipping
<b>Possible Symptoms:</b>	Error codes: H128 "Too cold or open sensor on Heater A." OR H129 "Too cold or open sensor on Heater B." OR H130 "Too cold or open sensor on Heater C." OR H131 "Too cold or open sensor on Heater D."
<b>Required Parts:</b>	None
<b>Required Materials/Tools:</b>	None
 <b>Caution:</b>	Be sure that you disconnect the RAZOR EX 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 EX 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 (POST). If errors persist, contact BFD's Technical Support.

## Battery Contact Cleaning

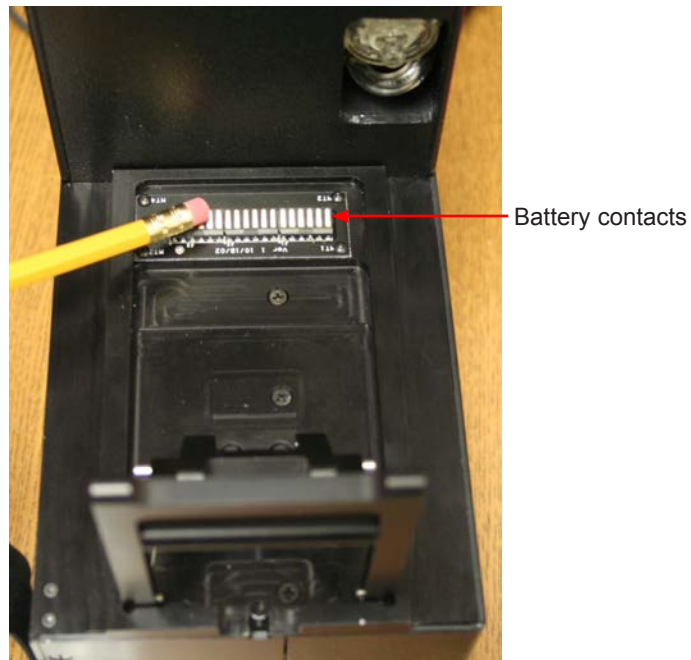
<b>Type of Service:</b>	Corrective Maintenance
<b>Recommended Frequency:</b>	Every 100 hours of battery use
<b>Possible Symptoms:</b>	Intermittent power supplied from battery pack. Battery not reaching full charge. Error codes: M002 "Low Battery" (Warning) OR M138 "Battery Too Low"
<b>Required Parts:</b>	RAZOR EX Battery Pack
<b>Required Materials/Tools:</b>	Pencil Eraser
 <b>Caution:</b>	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.  <b>Do not incinerate battery pack. Do not expose to high temperatures (140 °F / 60 °C). Do not disassemble.</b>

1. Place the RAZOR EX 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 EX instrument and on the RAZOR EX 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 EX Instrument and on the contacts that are located on the RAZOR EX battery charger.

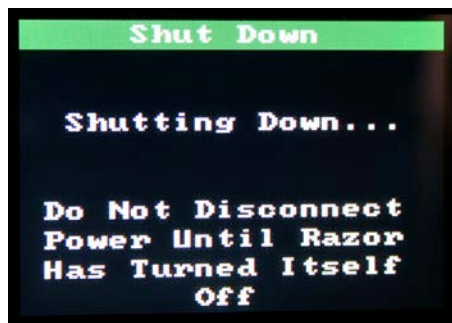




## Battery Charging

<b>Type of Service:</b>	Corrective Maintenance
<b>Recommended Frequency:</b>	Every 3–4 hours of instrument use on battery power
<b>Possible Symptoms:</b>	The RAZOR EX 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”
<b>Required Parts:</b>	RAZOR EX Battery Charger and External Power Supply RAZOR EX Battery Pack
<b>Required Materials/Tools:</b>	N/A
 <b>Caution:</b>	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.  <b>Do not incinerate battery pack. Do not expose to high temperatures (140 °F / 60 °C). Do not disassemble.</b>

1. To turn off the instrument, select **Main Menu > Shut Down**.



2. When the RAZOR EX has turned off, remove the battery by pulling down the pin and sliding the battery off the bottom of the instrument.



3. Using the directional arrows on the side of the battery and charger as a guide, line up the battery and the charger. Slide the battery onto the charger until the green light blinks.



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.



**Note:** Ensure that the vent on the charger is not obstructed while the charger is running.




5. In addition to the red light, the green light also comes on when the battery begins to charge. The green light will blink four times then pause, then repeat while the battery is charging. As the battery charges, the number of blinks decreases (4, 3, 2, 1) and then becomes solid once the battery charge is full.



**Note:** A fully depleted battery takes approximately 8 hours to fully charge.

## Bar Code Reader Window Cleaning

<b>Type of Service:</b>	Preventive Maintenance/Corrective Maintenance
<b>Recommended Frequency:</b>	Every 15 hours of use, or after operation in an extreme environment such as a dust storm.
<b>Possible Symptoms:</b>	Difficulty reading bar code data into the instrument. It might take longer than usual, or it might not read at all.
<b>Required Parts:</b>	None.
<b>Required Materials/Tools:</b>	Lens cloth (from the startup kit) or microfiber cloth
 <b>Caution:</b>	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 bar code 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 EX to read protocol bar codes. 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.

## ERROR CODE TROUBLESHOOTING

The RAZOR EX 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 EX 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 BFDf Technical Support to help resolve these problems.

You should note all error messages before you call BFDf for technical service. A complete list of error messages will help the people in technical service 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, 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 BFDf Technical Support.

See the chart below for error codes:

Xnnn error message  
time stamp

Code	Description of Code
<b>F</b>	The fluorimeter controller detected the error
<b>H</b>	The heater controller detected the error
<b>M</b>	The master controller detected the error
<b>V</b>	The valve controller detected the error
<b>P</b>	The power controller detected the error
<b>nnn</b>	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 continues until it is powered down. When it is powered back on, the software displays the contents of the log before proceeding to normal operation. When there is a fatal error during operation, the machine shuts 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 EX instrument. If it is, and blinking continues, then contact BFDf Technical Support.

**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.



**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.

**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.

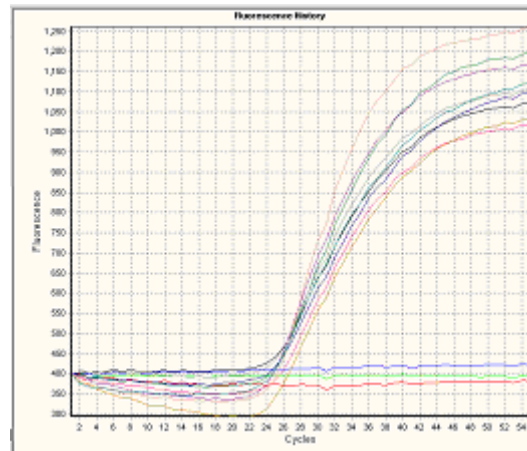
**V148 “Valve(s) too slow, POST.” OR****V154 “Unable to heat manifold, POST.”**

1. Warm the instrument until it is above 0°C.
  2. Restart the instrument.
- If the error recurs, contact BFDF Technical Support.

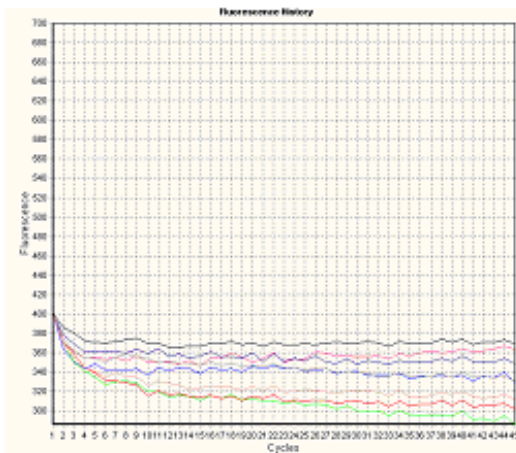


## PCR TROUBLESHOOTING

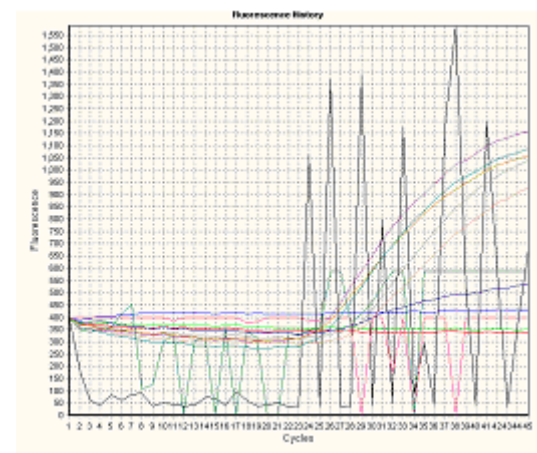
This section contains examples of normal and abnormal PCR data. For the abnormal PCR data, this section also contains possible causes and resolutions. For more details, see the RAZOR Pouch Instruction Booklet.



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 EX.	Check to make sure that the pouch was in the RAZOR EX 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 EX.  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 EX 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: <ul style="list-style-type: none"> <li>• 0.5 mL of liquid per port in a 4 x 3 100 µL pouch</li> <li>• 0.2 mL per port in a 12 x 1 100 µL pouch</li> <li>• 0.35 mL per port in a 6 x 2 100 µL pouch</li> <li>• 2.0 mL per sample port for 1 x 12, 11 + 1, and 10 + 2 100 µL pouches; .4 mL for control port</li> </ul>

## DECONTAMINATION AND CLEANING PROCEDURES

 **Note:** The procedures in this section describe 3 bleach wipes and 3 distilled water wipes for general maintenance decontamination and for returning an instrument. If you have a spill or pouch breakage, BFDF 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 BFDF Technical Support.

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. You have to decontaminate all areas that might have been contaminated to prevent false-positive readings in subsequent runs. For instance, if a spill occurs in the RAZOR EX reaction chamber, decontaminate the RAZOR EX instrument and the bench top (or other area) surrounding the RAZOR EX.

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

After a spill, change gloves and other potentially contaminated personal protective equipment. Change gloves often during the decontamination process, especially during the first steps of decontamination and before touching any clean surface. Dispose of all personal protective equipment 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
- DNAZap™, or an equivalent DNA degrading system
- Paper towels

- Bleach wipes
- Lens cleaner
- Lens cloth

### RAZOR EX Internal Instrument Decontamination



**Note:** Decontaminate the interior of the RAZOR EX instrument before decontaminating the outside.

1. Put on gloves. Open the heater boards. (See “Accessing Heater Bars and Optic 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 board, wipe around, but not across, the optic lenses; be very careful not to scratch the lenses.
  - The heater board
  - 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 EX 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 DNAZap, 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.

## RAZOR® EX &gt; Operator's Manual

[illegible]

# 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).

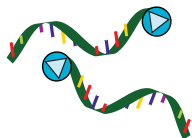
Define each end of the sequence of DNA to be amplified.

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**

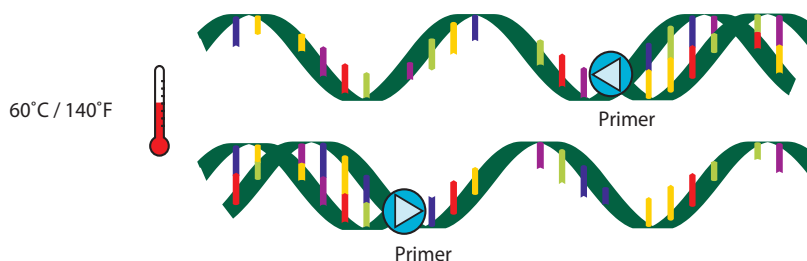
### Step 1. Denaturation

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



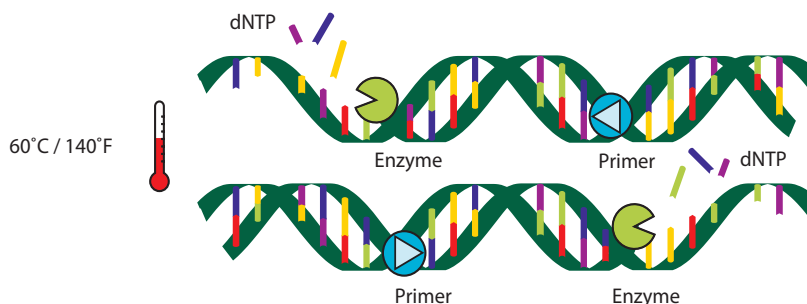
### Step 2. Annealing

The sample is cooled to about 60°C (about 140°F), 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 2 min. 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 less than 30 min.

## REVERSE TRANSCRIPTION

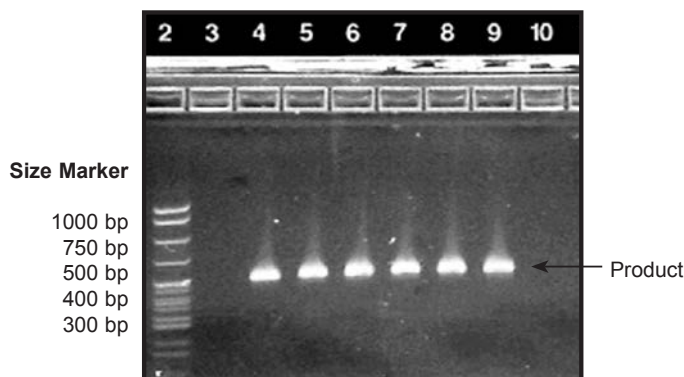
Some microbes have RNA as the genetic material. Some assays therefore target cellular RNA molecules. When RNA is the starting material, reverse transcription must be done before performing PCR. Reverse transcription converts RNA to amplifiable DNA. This process involves using an enzyme called reverse transcriptase, which builds a DNA strand from the RNA strand (a T for thymine is substituted for the U of uracil in RNA). Once the DNA strand is built, it is then amplified as described in the previous section.

## ANALYSIS METHODS

### Agarose Gel Electrophoresis

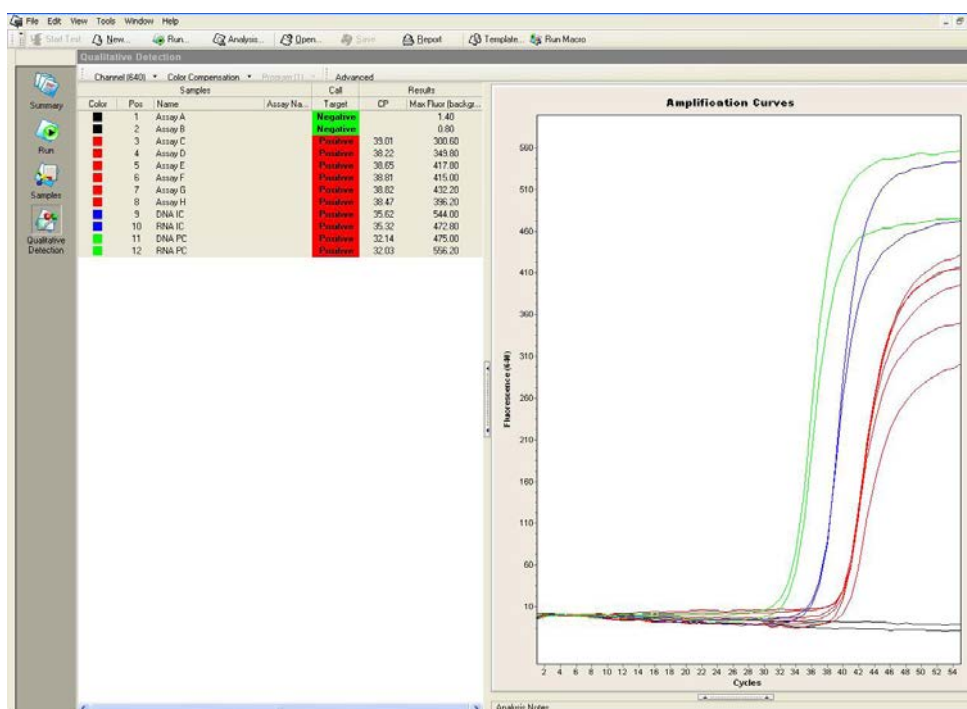
Electrophoresis is a technique used in the laboratory that results in the separation of charged molecules. The DNA molecule is negatively charged and moves by electric current through a matrix of agarose.

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.



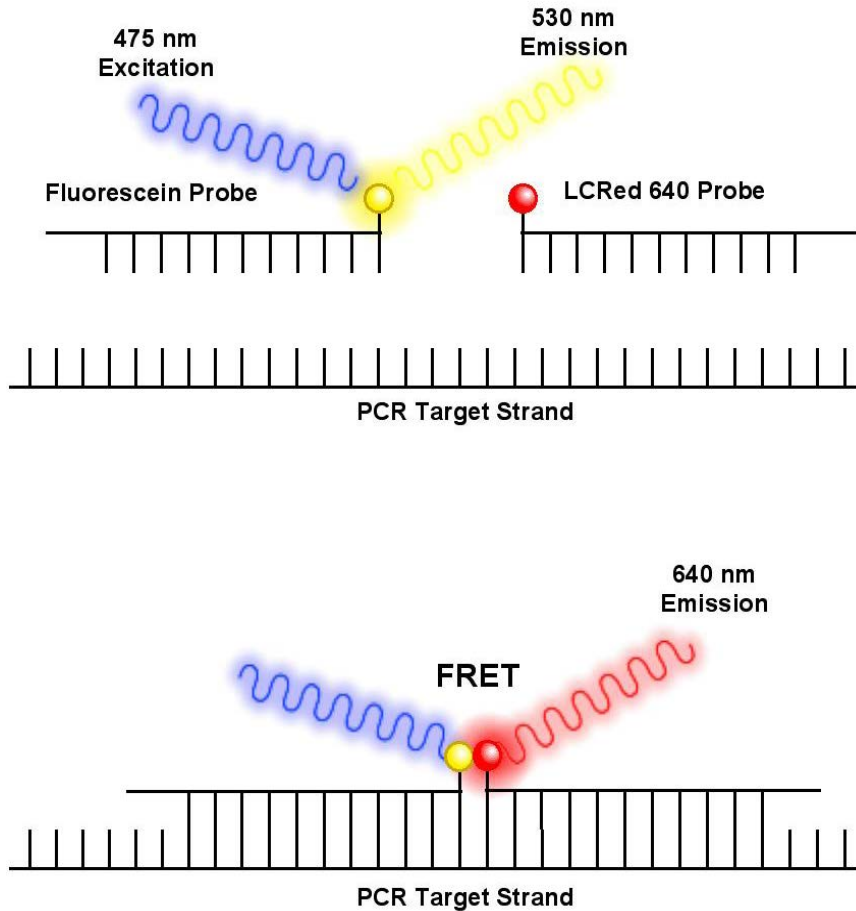
### Fluorimetric Detection Real-time Polymerase Chain Reaction

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. Two types of probe methods are described in the following sections.



## Hybridization Probes

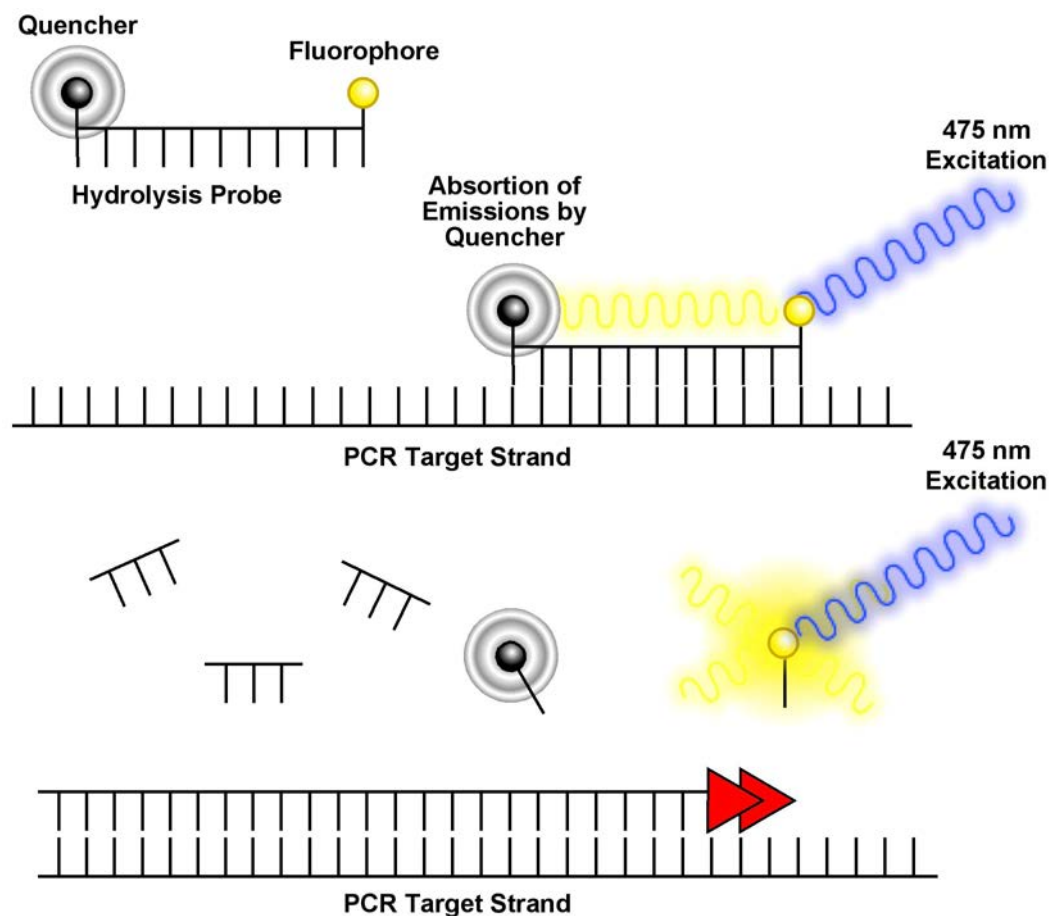
Hybridization probes are composed of a pair of DNA strands designed to hybridize adjacent to each other. Each carries a dye (fluorophore) at its facing end, which interact. The shorter green wave dye, fluorescein, is excited by blue light from the instrument's LED and transfers its energy to the longer 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.



## Hydrolysis Probes

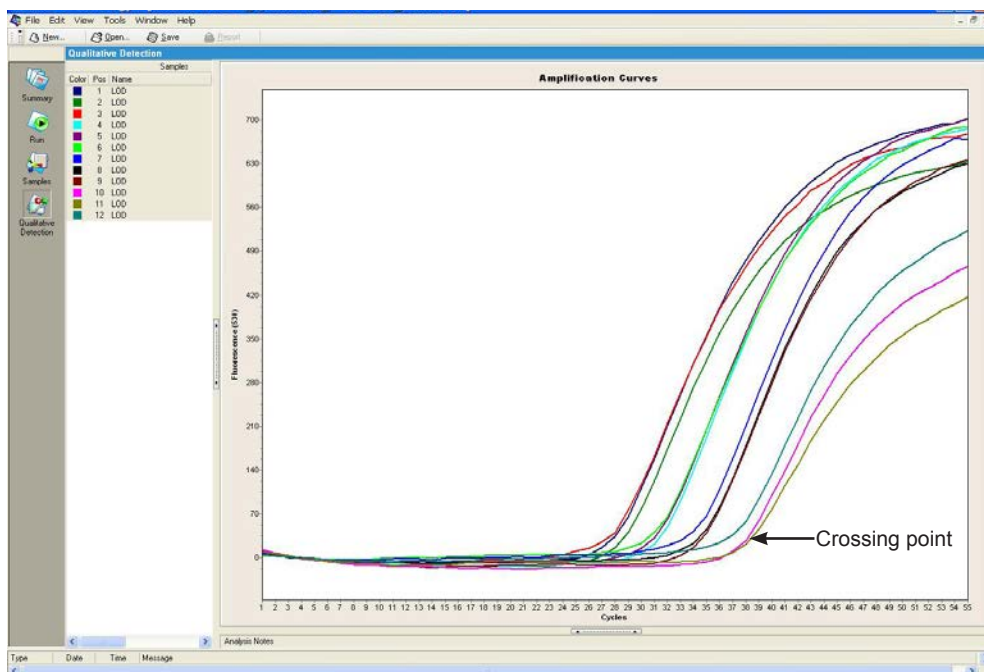
A hydrolysis probe (often sold under the tradename TaqMan®) provides a quantitative signal of amplified samples. The shortcoming of this technique is that it doesn't provide a melt profile for subsequent analysis, because the probe is destroyed during the PCR process.

The probe consists of a DNA strand of approximately 20–30 bases with a quencher dye at one end and a reporter (fluorescent) dye at the other end. Light from the instrument's LED stimulates the reporter dye to emit a signal, which is absorbed by the quencher. After the probe hybridizes with the target DNA strand and the Taq enzyme hydrolyzes (decomposes) the probe, the quencher is separated from the reporter (along with the synthetic DNA bases), and the excited reporter fluoresces. A detectable signal occurs only when the probe is hydrolyzed by the Taq enzyme. As DNA is amplified, this process repeats, increasing the fluorescent signal of the sample.



## 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:

# U.S. DECONTAMINATION

# AND RETURN FORMS



**Note:** For international returns, please call Technical Support for detailed instructions.

An instrument problem may be reported by calling, e-mailing, or mailing BioFire Defense. The contact numbers are located below.

If you are returning an instrument for repair, follow the basic guidelines prescribed in this appendix. You will also need the following documents:

**Declaration of Decontamination**  
**Decontamination Labels**

These forms and instructions can also be downloaded from:  
**<http://biofiredefense.com/product-support>**

**Phone**

**(801) 262-3595** - United States and Canada  
**+1-801-262-3595** - International

**E-mail**

**[support@BioFireDefense.com](mailto:support@BioFireDefense.com)** - Technical Support

**Web Site**

**<http://biofiredefense.com/product-support>**

**Address**

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

### Step 1: Obtain a Return Materials Authorization Number

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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 <https://www.biofiredefense.com/product-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

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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.

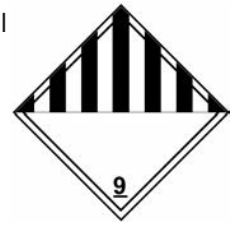
### Step 4: Packaging and Shipping

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1. Package the RAZOR EX 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.

**Battery Pack Shipping Instructions**

6. If you are returning the battery pack with the RAZOR EX instrument, you will need to label your return shipping package with the appropriate hazardous materials label. Also consult with your shipping carrier for the latest shipping regulations [https://www.ups.com/content/us/en/resources/ship/packaging/guidelines/batteries.html?WT.mc\\_id=VAN701573](https://www.ups.com/content/us/en/resources/ship/packaging/guidelines/batteries.html?WT.mc_id=VAN701573)

**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 EX 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
- ☐ Software CD
- ☐ 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 and cut out the label and attach it to the case of the instrument being returned.

<p><b>DECONTAMINATION NOTICE:</b></p> <p>This product has been decontaminated per Return Equipment policy: _____</p> <p>BioFire Defense Return Authorization (RMA#): _____</p> <p>Customer Name: _____</p> <p>Customer Address: _____</p> <p>_____</p> <p>Signature: _____ Date: ____/____/____</p>
---

Copy and cut out the label and attach it to shipping container of the instrument being returned.

<p><b>DECONTAMINATION NOTICE:</b></p> <p>This product has been decontaminated per Return Equipment policy: _____</p> <p>BioFire Defense Return Authorization (RMA#): _____</p> <p>Customer Name: _____</p> <p>Customer Address: _____</p> <p>_____</p> <p>Signature: _____ Date: ____/____/____</p>
---



# APPENDIX C:

# QUICK GUIDES FOR THE RAZOR EX INSTRUMENT

## INTRODUCTION

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

This Quick Guide describes the following procedures:

- Setting up the RAZOR EX Instrument
- Recharging the battery
- Scanning the protocol bar codes
- Loading the RAZOR EX pouch



# Setting Up the RAZOR® EX Instrument

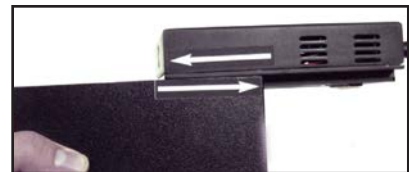
## Setting Up the RAZOR® EX Instrument

1. Unpack the RAZOR EX instrument and set it on a solid, flat surface.
2. Slide the battery into the bottom-right side of the instrument using the directional arrows on the side of the battery as a guide. You may need to collapse the instrument stand. Be sure the locking pin slides into place. Install the battery even if using the power supply.
3. If using external power, plug the power supply into a grounded power source and connect the other end to the RAZOR EX power port by lining up the red dots.
4. Open the protective lid.
5. Press and hold the **Power** button for **5 sec.** The screen will display the instrument's current status.
6. The instrument will next 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.
7. Press the **Brightness** button to adjust display lighting.



## Recharging the Battery

1. Turn the instrument off.
2. Pull the ring on the battery down and slide the battery out.
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.



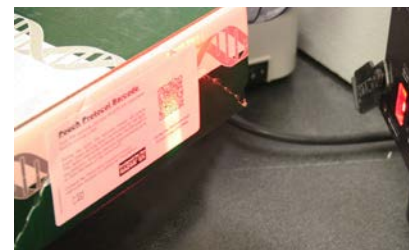
## Scanning the Protocol Bar Code



**Note:** Protocol bar codes can be scanned before field deployment. Be sure that all bar codes are as smooth and flat as possible.



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





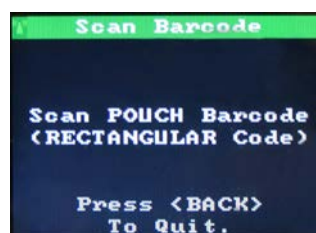
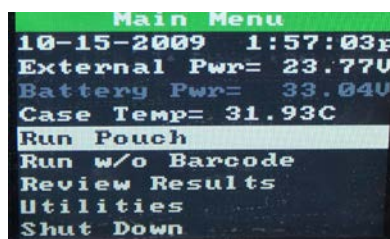
1. Select **Main Menu > Utilities**.
2. Select **Scan Protocol Code**.
3. Scan the **square** protocol bar code on the kit box by holding it up to the scanner at the back of the RAZOR EX.



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

## Scanning the Pouch Bar Code

1. Select **Run Pouch** from the **Main Menu**. When **Scan POUCH Barcode** displays, scan the **rectangular** bar code on the pouch (bar code must be held vertically). After the scan, the screen will display **Loading Barcode Data**.



**Note:** If the bar code does not scan properly, the message “Aborting Barcode Scan,” will display. If you scan the wrong bar code, the message “Invalid Barcode Data (Barcode Should Be Rectangular)” will appear.



GENERICB-GENB0005





# Loading the RAZOR® EX Pouch

## Sampling

### 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 (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.

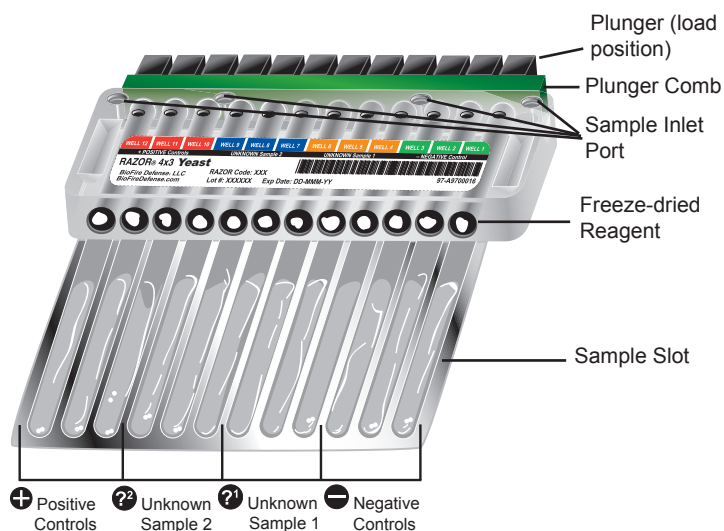
Once the raw sample has been prepared properly, load the sample into the pouch.

## Loading the RAZOR® EX 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

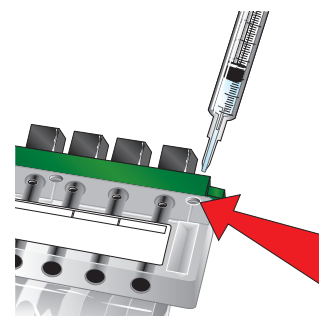


Sample Loading	
Pouch Type	Sample Volume
12 x 1	0.20 mL
6 x 2	0.35 mL
4 x 3	0.5 mL
10 + 2	2.0 mL
11 + 1	2.0 mL
1 x 12	2.0 mL

Example Pouch with Key Parts Labeled

The procedure is essentially the same for loading the negative controls, the unknown sample, and the positive control:

- Load a syringe with the correct volume of sample. (See Table 1 above or the pouch assay card.)
  - 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 ports and the **Inhibition** control inlet port (if present), use the **unknown sample**.
- 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.
- Allow the syringe to sit in the inlet port for at least 30 sec. to allow the liquid to dispense evenly.



Negative Control Inlet Port

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 EX INSTRUMENT PARTS AND TEST KITS

### PARTS

The following table includes items that are packaged with the RAZOR EX instrument as well as items that are required and recommended to perform pathogen analysis. 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 or model of product offered.

Item	Part Number
RAZOR EX Hybridization Probe System	RAZR-ASY-4000
USB 2.0 Cable, 3.28' ft long	RAZR-PRT-0080
RAZOR EX Operator's Manual	RAZR-PRT-4018
Quick Guides (in Manual)	RAZR-PRT-4019, -4020
Battery Recharger	RAZR-SUB-4200
24 V 4 A Power Supply	POWR-SUB-0022
Instrument Battery Pack	RAZR-SUB-0009
Air Filter Assembly	RAZR-SUB-0406
Power cord 110V	POWR-CRD-0001
Power cord 220–230V	POWR-CRD-0002
RAZOR EX Desktop Software	RAZR-SCD-4000
Hard Carrying Case	RAZR-CAS-0002
Instrument grab strap	RAZR-SUB-0029
RAZOR EX Training CD	RAZR-SCD-4001
RAZOR EX Training Manual	RAZR-PRT-4024
Tool Kit	
5 1/2" Needle Nose Pliers	5234
Lens Cleaning Solution	1803
Lens Cleaning Tissue	1802



## TEST KITS

The following RAZOR kits are available through BioFire Defense.

Item	Part Number
<b>RAZOR The 10® Target Screen Kit</b> Tests for ten pathogens (Anthrax, <i>Brucella</i> spp, Botulism A, <i>Coxiella</i> , <i>E. coli</i> O157, Tularemia, Ricin, <i>Salmonella</i> , Smallpox, and Plague) in one pouch.	PATH-ASY-0061
<b>RAZOR BA 3 Target Kit</b> Tests for <i>B. anthracis</i> , Targets 1, 2, and 3	PATH-ASY-0007
<b>RAZOR Food Screen 3 Target Kit</b> Tests for <i>Campylobacter</i> , <i>L. monocytogenes</i> , and <i>Salmonella</i>	PATH-ASY-0010
<b>RAZOR Water Screen 3 Target Kit</b> Tests for <i>Cryptosporidium</i> Target 1, <i>E. coli</i> O157, and <i>Salmonella</i>	PATH-ASY-0011

## TRAINING KITS

BioFire Defense offers several different training pouches for remaining proficient with your RAZOR EX or RAZOR instruments. Training kits contain all items that come in standard assay pouch kits. Training pouches are available in 11+1 or 4x3 formats allowing for training applicable to real-world scenarios.

Item	Part Number
<b>RAZOR Training Pouch (color dyes) and Sample Prep Kit</b> A 4x3 formatted pouch loaded with color dyes provides training on pouch loading procedures. With the color dyes, you receive instant feedback on loading techniques, for example, ensuring air bubbles are not loaded into the pouch. Note: the color dyes will not amplify on the RAZOR EX or RAZOR instrument.	PATH-ASY-0005
<b>RAZOR Simulant Training Pouch (The 10®) and Sample Prep Kit</b> A 11+1 formatted pouch that mimics the format of The Ten® Target Screen. A yeast and a BG assay allow you to train in a real-world scenario from sampling, pouch loading to running a RAZOR EX or RAZOR instrument complete with data analysis.	PATH-ASY-0091
<b>RAZOR Yeast Kit and Sample Prep Kit</b> A 4x3 formatted pouch that mimics the format of the BA3, Food Screen and Water Screen Pouches. A yeast assay allows you to train in a real-world scenario from sampling, pouch loading to running a RAZOR EX or RAZOR instrument complete with data analysis.	PATH-ASY-0006



# APPENDIX E:

## CHART PREFERENCES

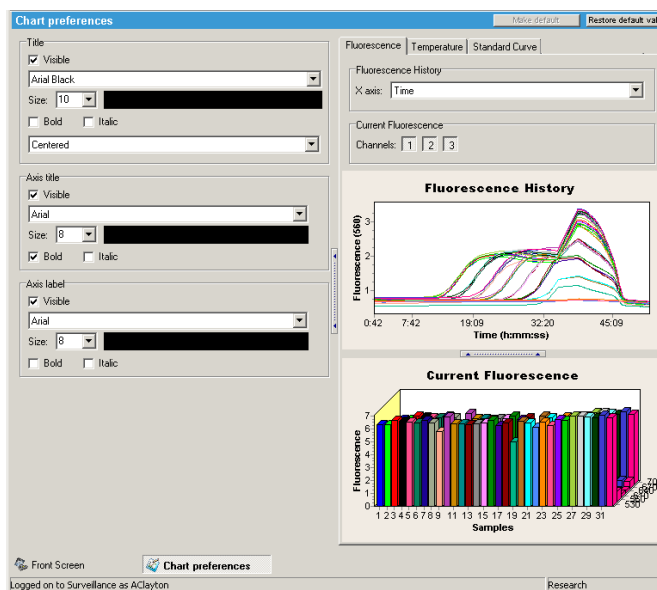
By default, your user account includes an item called **Chart preferences** that determines the default appearance and content of your charts. You can change these default chart settings as needed. You can also save a modified version of a chart preferences item with a new name, then apply the preferences in place of the defaults. You can have as many different chart preference items as you want, each one defining a different look and feel for your charts. For more information, see “Creating a Separate Preferences Item and Making it the Default,” in this section.

You can override the current chart preferences for individual charts, analyses, or tests.

### Opening the Chart Preferences Item

1. In the **Navigator**, open **Preferences**, located in your user folder.
2. Double-click **Chart preferences** to open the **Chart preferences** window.

The Chart preferences window is shown below.



Edit the settings you wish to change and select **Save** in the global toolbar to save your settings.

## Creating a Separate Preferences Item and Making It the Default

---

You can create multiple chart or sample preferences items, each with different settings, and then choose which one to use as the default.

To save additional chart or sample preference items:

1. Open the **Preferences** folder.
2. Select the preferences item and right-click it.
3. Select **Copy**.
4. Enter a unique name for the preferences item, choose a location to save the item, and then select **Save**.

To make a preference item the default:

1. Open the preferences item you want to use as the default item.
2. In the title bar, select **Make Default**. The new settings are applied to the charts.

## Overriding Default Chart Preferences

---

In some cases, you may want an individual chart, analysis, or test to use different chart settings from the defaults specified in the Chart preferences item. You can override the default settings at the following levels:

- On an individual chart
- On all charts within an analysis
- On all charts within a run

When you specify custom settings at any of these three levels, the new settings take precedence over the default values for the charts at that level.

To override chart preferences:

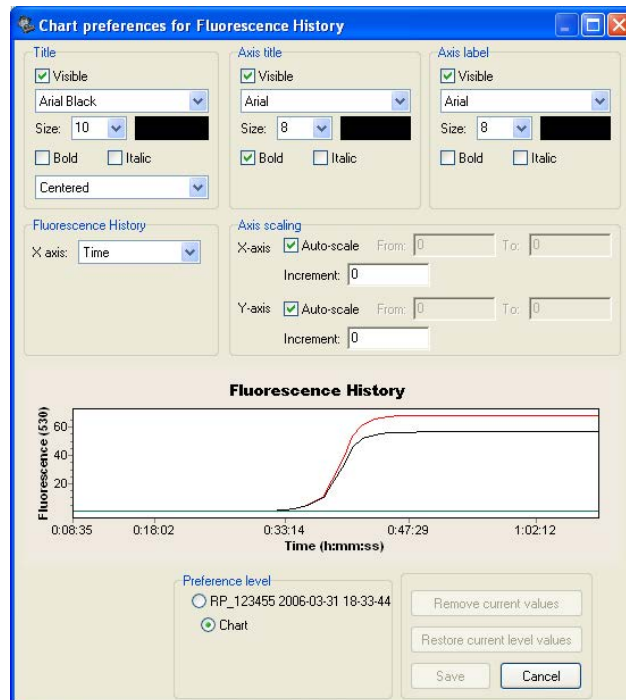
1. Right-click the chart you want to modify

Or

To override preferences for all charts within an analysis or within a run, right-click any chart in the test.

2. Select **Chart preferences**

A Chart preferences dialogue box opens that contains options for the chart type similar to those in the Chart preferences window described above. However, the dialogue box includes additional options for setting the chart x- and y-axis scales.



3. In the **Preferences level** area at the bottom of the window, choose the level at which to override the current chart preferences:
  - Select the test name to apply the settings to all charts in the current run.
  - Select the analysis name to apply the settings to all charts in the current analysis. (You must have opened the menu from an analysis chart for this option to be available.)
  - Select **Chart** to apply the settings only to the current chart.
4. Change text settings in the Title, Axis title, and Axis label boxes, as needed.
5. Change the chart-specific settings (if any) in the box below the Title section.  
 The options displayed depend on the type of chart that was active when you opened the dialogue box. For some chart types, there are no chart-specific settings.
6. In the Axis scaling area, set the range of units for the chart's x-axis and y-axis and the increment size.  
 If you select 0 as the increment size, the increment size is determined automatically. If you set an increment size so small that the unit labels overlap, the setting is ignored, and the increment size is determined automatically.
7. If you need to undo your changes and restore the previous values for the selected level, click **Remove current values**.
8. When you are finished making changes, click **Save**.

## Customizing Sample Names and Appearance

You can modify the appearance of sample lines and points on charts in two ways:

- You can modify the sample preferences that apply to all tests by modifying the default sample preferences item or creating multiple versions of the sample preferences and then applying the version you want.
- You can override the sample preferences for multiple samples in the current test or for an individual sample on a chart.



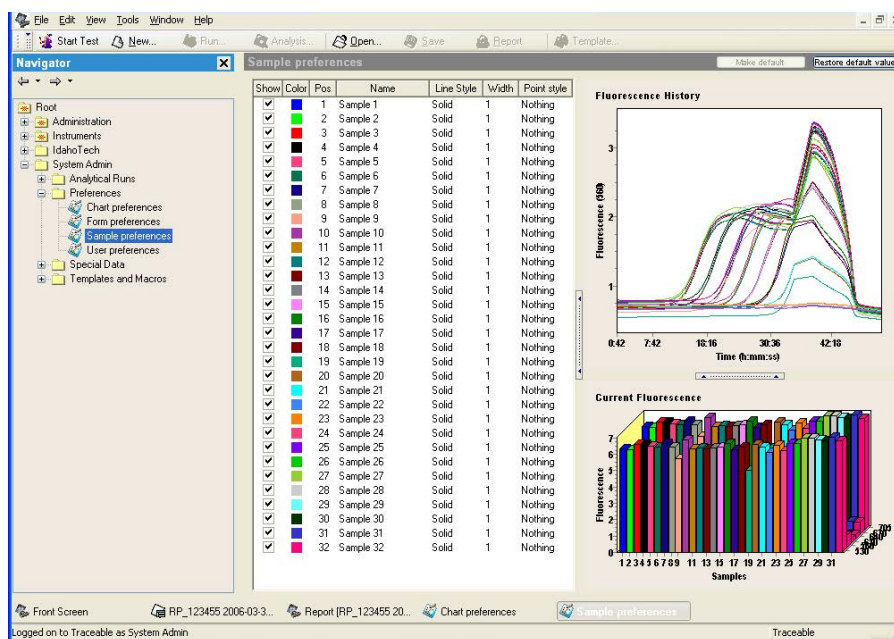
**Note:** Only samples 1–12 apply to RAZOR EX runs.

## Modifying Default Sample Preferences for All Tests

By default, your user account includes an item called Sample preferences that determines the default sample names and the appearance of sample lines and points on all software charts. You can change the settings in the sample preferences item as needed. You can also save multiple versions of the sample preferences item and then apply the preferences you want.

- In the **Navigator**, double-click **Sample preferences** located under **Preferences** in your user folder.

The Sample preferences window is shown below.



- To include or exclude a sample in the preview charts on the dialogue box, select or deselect the sample's check box.



**Note:** As you follow steps 3–8 below, remember that you can change settings for a contiguous group of samples at one time. To change settings for a group:

- Select the item you want to change for the first sample in the group.
- Hold down the **Shift** key, then select the same item for the last sample in the group.

c. Press **F2**.

d. Change the value for the first sample.

The changes are applied to all the selected samples.

3. To change a sample's default color, click the colored square next to the sample name in the sample list to open a color palette, select the color you want, and then click **OK**.

The sample color appears next to the sample name in test results and is used for sample lines and points in the charts.

4. To change the default sample name, click the sample name, and then type a new name.

The default sample name is applied to new test runs—existing runs are not affected.

5. To change the line style used for the sample, click in the **Line Style** column, and then select a new style from the pull-down list.

6. To change the line width, click in the **Width** column, and then enter a new width.

7. If you prefer to see a sample line as a string of measurement points, click in the **Point Style** column, then select a style from the pull-down list. (If you prefer solid lines, leave the **Point Style** set to **Nothing**.)

8. Click **Save** in the global toolbar to save your settings.

### Making a Sample Preferences Item the Default

1. Open the sample preferences item you want to use as the default item.
2. In the title bar, select **Make Default**. The new settings are applied to the charts.

### Overriding Default Sample Preferences

At times you may want to change the appearance of samples in just one test without changing the defaults applied to all tests. You may also want to save the modified settings as a sample preferences item that can be applied to other test runs.

At the test level, you can:

- Use a sample preference editor to change the appearance of samples in the test run
- Apply an existing sample preferences item to a single test
- Change the appearance of an individual sample line
- Save test settings as a sample preferences item
- Clear any changes and reapply the default sample preferences

### Using a Sample Preferences Editor to Override Sample Settings

1. Open the test that contains the sample settings you want to modify.
2. Right-click on the chart that contains the sample information.
3. Select **Sample preferences**.

A Sample preferences editor opens.

4. Modify the settings, and then click **Save**.

Modify the settings as you would if you were modifying the default sample preferences item. For more information, see “Modifying Sample Preferences for All Tests,” above.

5. Click **Save** in the global toolbar to save the test with the new settings.

Your settings are applied to all the samples in the current test, but they do not affect other test runs or the default sample preferences settings.

### Applying a Different Sample Preference Item to an Individual Test to Override Sample Settings

---

1. Open the test that contains the sample settings you want to modify.
2. Right-click on any of the charts that contains sample information.
3. Select **Load Sample Preferences**.
4. Select a sample preferences item from the **Navigator**, and then select **Open**.

The settings are applied to all the samples in the current test, but do not affect other test runs or the default sample preferences settings.

5. Select **Save** on the global toolbar to save the test with the new settings.

### Saving Test Settings as a Sample Preferences Item

---

1. Open the test that has the settings you want to save as a sample preferences item.
2. Right-click a chart that contains sample information.
3. Select **Save Sample Preferences**.
4. Navigate to a location to save the sample preferences item, type a name for the item, and then select **Save**.
5. You can apply the new sample preferences item to individual tests, or you can make it the default item.

### Reapplying the Default Sample Preferences to a Test with Overridden Settings

---

1. Open the test for which you want to reapply the default sample preferences.
2. Right-click on any of the charts that contains sample information.
3. Select **Clear Sample Preferences**.

The samples in the charts are reset to the current default sample preferences.

4. Select **Save** in the global toolbar to save the test with the settings.

# APPENDIX F: CERTIFICATIONS

## CE CERTIFICATION



### Declaration of Conformity

#### CE Declaration of Conformity

<b>Manufacturer/ Supplier Information:</b>	<b>BioFire Diagnostics, Inc.</b> 390 Wakara Way Salt Lake City, Utah 84108, USA Phone: 1-800-735-6544 <a href="mailto:it@BioFireDX.com">it@BioFireDX.com</a> <a href="http://www.BioFireDX.com">http://www.BioFireDX.com</a>
<b>Date of Issue:</b>	03 JUNE 09

#### BioFire Diagnostics declares that the products:

<b>Product Name:</b>	RAZOR EX
<b>Description:</b>	Biodetection instrument using real time PCR.

To which this declaration relates, meets the protection requirements laid down in Council Directive 73/23/EEC on low voltage equipment safety and 89/336/EEC on the alignment of the legal provisions of the Member States on electromagnetic compatibility (EMC).

To assess the product with regard to electromagnetic compatibility, the following relevant harmonized standards were applied:

<b>EN 55022: 2006</b> Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement
<b>EN 55024: 1998</b> Information technology equipment – Immunity characteristics – Limits and methods of measurement
<b>EN 61000-3-2: 2005</b> Electromagnetic compatibility (EMC) – Limits – Limits for harmonic current emissions (Equipment input current ≤ 16 A per phase)
<b>EN 61000-3-3: 2002</b> Electromagnetic compatibility (EMC) – Limits – Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤ 16 A
<b>EN 61010-1: 2001</b> Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements

We hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all essential requirements of the Directives.

**Gina Bergman**  
Director of Quality Assurance and Regulatory  
Affairs

**Brian Dorcheus**  
Manager of Instrument Production







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RAZR-PRT-4032-01





# APPENDIX G: BAR CODES

 ITYEASTB-YETB0001  Kit Part Number: PATH-ASY-0006 Protocol Code: ITYEASTB RAZOR Yeast Pouch	 ITFCTRNA-00000001  Kit Part Number: PATH-ASY-0005 Protocol Code: ITFCTRNA RAZOR Training Pouch (Color Dyes)	 SIMUL10A-SIMUL002  Kit Part Number: PATH-ASY-0091 Protocol Code: SIMUL10A Simulant Training Pouch
 10TARGTB-10TAR002  Kit Part Number: PATH-ASY-0061 Protocol Code: 10TARGTB RAZOR The 10® Target Screen Kit	 BIOTRT1B-BIO1B010  Kit Part Number: PATH-ASY-0008 Protocol Code: BIOTRT1B BioThreat 1 Kit	 BIOTRT2B-BIO2B018  Kit Part Number: PATH-ASY-0009 Protocol Code: BIOTRT2B BioThreat 2 Kit

 <p>BA3TRGTB-BA3TB007</p>  <p>Kit Part Number: PATH-ASY-0007 Protocol Code: BA3TRGTB</p> <p>RAZOR BA3 Target Kit</p>	 <p>WATRSCNB-WATRB016</p>  <p>Kit Part Number: PATH-ASY-0011 Protocol Code: WATRSCNB</p> <p>RAZOR Water Screen 3 Target Kit</p>	 <p>8GTSCNB-8GTB001</p>  <p>Kit Part Number: PATH-ASY-0056 Protocol Code: 8GTSCNB</p> <p>8 Target or CDN Screen Kit</p>
 <p>FOODSCNB-FOODB001</p>  <p>Kit Part Number: PATH-ASY-0010 Protocol Code: FOODSCNB</p> <p>RAZOR Food Screen 3 Target Kit</p>	 <p>GENERICB-GENB0001</p>  <p>Kit Part Number: PATH-ASY-0092 Protocol Code: GENERICB</p> <p>Generic Barcode</p> <p>The GENERICB protocol can be used with both RAZOR-ASY-4000 and RAZOR-ASY-4001. However, it requires REV 2 or higher of the RAZOR Master Controller Software. To check your instrument's version, select <b>Utilities</b> from the RAZOR instrument's main menu, then select <b>View software vers.</b> and scroll down to the master controller.</p>	

# 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., 40–65°C).

**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 (92°C) 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.

**TAMRA:** Tetramethyl, 6-carboxyrhodamine, a fluorescent dye commonly used as the quencher in 5' FAM/3' TAMRA hydrolysis probes. TAMRA quenches the fluorescence of FAM until the probe hybridizes to the target and is cleaved by the 5' exonuclease activity of the polymerase.

**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.

**Translation:** the process by which information in messenger RNA directs the sequence of amino acids assembled by a ribosome during protein synthesis.

**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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