

# Custom BioGenic Systems

## IntelliRate i67C

### Set-Up and Technical Manual



Designed and manufactured by:  
Custom BioGenic Systems, a BioLife Solutions Company



## IMPORTANT INFORMATION



**Read and understand this manual completely before proceeding to set-up.**

**Save these instructions for future use.**

- Ensure all parts are accounted for and that no damage has occurred during shipping.
- The safety of any system incorporating this equipment is the responsibility of the assembler of the system.
- If this equipment is used in a manner not specified by Custom BioGenic Systems, the protection provided by the equipment may be impaired.
- Modifications or part substitutions to this unit are strictly forbidden. The unit does not have any user serviceable parts inside, DO NOT remove the rear maintenance panel.
- For maintenance, service, replacement and/or repair needs or if unsure of the proper set-up and use of this product, please contact Custom BioGenic systems.

Customer / Technical Service:

Phone: (800) 523-0072 (US Only)

Phone: (586) 331-2600

Fax: (586) 331-2600

[www.custombiogenics.com](http://www.custombiogenics.com)

## WARRANTY INFORMATION

Custom BioGenic Systems warrants all manufactured cryogenic equipment to be free from defects in workmanship or materials for a period of one-year warranty. Custom BioGenic Systems' liabilities under the warranty shall be limited to correcting or replacing defective workmanship or materials. A claimant under the warranty must notify Custom BioGenic Systems within ten (10) days after the discovery of the defect. Custom BioGenic Systems reserves the right, at their discretion, to correct the defect(s) in the field without return shipment to the factory. This warranty does not cover defects on cryogenic equipment resulting from abusive handling and subsequent structural failure.

Serial Number: \_\_\_\_\_

Model Number: \_\_\_\_\_

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\*THE PRODUCT IMAGES ARE FOR ILLUSTRATION PURPOSES ONLY AND MAY NOT BE AN EXACT REPRESENTATION OF THE PRODUCT.

## SYMBOLS

### Safety Symbols



#### CAUTION

The safety statement that follows this safety alert symbol indicates a hazardous situation which, if not avoided, has the potential to cause damage to property or equipment.



#### WARNING

The safety statement that follows this safety alert symbol indicates a hazardous situation which, if not avoided, has the potential to cause bodily harm or death.

### Product Symbols



**PINCH HAZARD – Keep hands clear during operation**



**BIOLOGICAL HAZARD**



**HOT SURFACE WARNING – Avoid contact during operation**



**COLD WARNING – See LIQUID NITROGEN SAFETY**



**ELECTRICAL HAZARD – See PRODUCT SAFETY**



**PROTECTIVE TERMINAL CONNECTION**



**REFER TO MANUAL**



**ALTERNATE CURRENT**

## LIQUID NITROGEN SAFETY

**IMPORTANT:** The following section on LIQUID NITROGEN SAFETY should be read carefully and be followed completely but is by no means a complete volume on the safe use of cryogenic liquids. All personnel should have a complete knowledge of the correct procedures, as well as the hazards of working with liquid nitrogen. Failure to do so could result in serious injury or death. Always review the latest safety data sheet.

### Properties of Liquid Nitrogen (LN2)

Boiling Point @ 1 atm	-195.8°C, -320.3°F, 77.4 K
Thermal Conductivity (Gas)	25.83 mW/(m·K)
Heat of Vaporization (Liquid)	198.38 kJ/kg
Density @ 1 atm (Liquid)	1.782 lbs/L, 807.4 g/L , 808.6 kg/m <sup>3</sup>



Liquid nitrogen is extremely cold, -196°C at atmospheric pressure. This can cause **severe frost bite** or **eye damage** upon contact. The use of personal protective equipment is required.



On vaporization liquid nitrogen expands by a factor of 700; one liter of liquid nitrogen becomes 24.6 cubic feet of nitrogen gas. This can cause **explosion** of a sealed container, or it can displace oxygen in the room and cause **suffocation without warning**.



## Handling Liquid Nitrogen

- All personnel should have a complete knowledge of the correct procedures, as well as the hazards of working with liquid nitrogen. Have available the Safety Data Sheet (SDS) provided by the liquid nitrogen supplier for appropriate first aid measures.
- Always wear proper Personal Protective Equipment (PPE) when working with liquid nitrogen, including a face shield, safety goggles, cryo-gloves, and cryo-aprons. Gloves should be loose fitting, so they could be thrown off if liquid were to pour inside them.
- Wear closed toe shoes, long pants without cuffs and a buttoned lab coat. Do not tuck pants into shoes/boots.
- Use only unsealed containers approved for use with liquid nitrogen. Never pour it into a coffee thermos. Never seal it in any container (it will explode).
- Handle the liquid nitrogen slowly to minimize boiling and splashing. Introducing room temperature items into liquid nitrogen may cause boiling and splashing.
- Substances may become brittle upon contact with liquid nitrogen and shatter, sending pieces flying.
- Never dip a hollow tube into liquid nitrogen, it may spurt liquid.
- Never dispose of liquid nitrogen by pouring it on the floor. It could displace enough oxygen to cause unconsciousness and asphyxiation.
- Never use liquid nitrogen in a small poorly ventilated area. Liquid nitrogen is a heavy gas, it falls to the floor first and fills the room from floor to ceiling. In all areas where liquid nitrogen is used, install oxygen sensors with low-oxygen alarms placed at typical breathing height.
- When transferring liquid nitrogen, nitrogen in the air surrounding a cryogenic containment system can dissolve and create an oxygen-enriched environment. Since the boiling point of nitrogen is lower than oxygen, liquid oxygen evaporates slower than nitrogen and may build up to levels which can increase the flammability of materials such as clothing near the system. Equipment containing cryogenic fluids must be kept clear of combustible materials in order to minimize the fire hazard potential. Condensed oxygen in a cold trap may combine with organic material in the trap to create an explosive mixture.
- Never use in combination with other substances without knowing what the result will be.

## PRODUCT SAFETY



**ELECTRICAL SHOCK HAZARD.** To avoid risk of electrical shock, this equipment must be connected to a properly grounded power source outlet. If the power supply outlet is not grounded, it will be necessary to install a ground by qualified engineers. **DO NOT** remove enclosure.

- DO NOT use the unit outdoors or in a wet environment.
- DO NOT install the unit in a flammable, volatile, or corrosive location.
- DO NOT insert objects into any vent, gap, or outlet on the unit. This may cause electric shock or injury.
- Disconnect the power supply to the unit prior to any repair or maintenance to prevent electric shock or injury.
- DO NOT touch any electrical parts with a wet hand, this may cause electric shock.
- DO NOT splash liquid directly onto the unit as this may cause electric shock or short circuit.
- DO NOT put containers with liquid on the unit as this may cause electric shock or short circuit if the liquid is spilled.
- Ensure the power supply cord and plug remain free of damage.
- DO NOT replace the detachable MAINS supply cord with an inadequately RATED cord. Replacement cord sets must be fully approved and rated for the country of use.
- DO NOT disassemble, repair, or modify the unit yourself.
- When removing the plug from the power supply outlet, grip the power supply plug, NOT the cord.
- DO NOT position the device in such a way that it is difficult to operate the disconnecting device (power cord or MAIN power switch).

# INITIAL INSTALLATION

## Introduction

Welcome to the IntelliRate i67C controlled rate freezer. This system consists of a freezing chamber, computer, controlled rate freezing software, a sample rack, a sample probe, and a liquid nitrogen transfer hose.

The software that is provided and comes pre-loaded on your controlled rate freezer computer operates using the same navigation and conventions as windows based operating systems (menus, basic commands, etc.).

This manual will provide you with the information you will need to operate, maintain, troubleshoot, and safely operate this equipment. It is important to completely read and understand the material in this manual before attempting to install, operate or service this equipment.

## Transport, Handling, and Storage



- Vehicles used to transport the device should be properly designed and equipped to ensure protection from the different environmental and weather conditions in which it operates. The use of vehicles with defects that could affect the quality of the device should be avoided.
- The device must be handled and transported in an upright position.
- Do not stack or store material on the device or its surfaces.
- Do not lift the device using machinery unless properly packaged.
- The device is considered stationary equipment.
- Areas designated for the storage of these devices shall be designed or adapted as to meet the following conditions:
  - The area should be clean and dry.
  - All doors should preferably be outward opening and wide enough to provide easy access and exit routes for personnel.
  - The area should be suitably spaced to allow cleaning and inspection.
  - All surfaces should be made of or covered by an impermeable material to enable proper and safe cleaning.
  - Areas should be adequately lit and ventilated for tasks to be performed in a correct and safe manner.
  - In case of a recall by the manufacturer, the establishment shall be able to trace a product in the storage area by its lot / batch / serial number.

### Prolonged Storage

For prolonged storage before installation, re-pack the rate freezer in the shipping container and store in a cool, dry area. We do not recommend storage of the rate freezer for more than six months. If longer storage time is required, contact the factory for additional storage information.

## Unpacking

Always inspect the bill of lading for accuracy and external crate/packaging for damage before accepting the shipment. Each IntelliRate i67C controlled rate freezer will arrive on a pallet in a box that is 37" x 30" x 40" (L x W x H).

1. Cut the banding that is holding the box to the pallet and discard.
2. Open the box from the top and remove the foam surrounding the unit. Discard foam.
3. Using a box cutter, cut down the corners of the box and pull the box off the pallet. Discard packing material.
4. Lift the unit off the pallet and set it in the desired location. Due to the weight and size of the unit, it is recommended that two people lift the unit.

## Initial Inspection

Check to make sure that the unit is received in its entirety. At a minimum, this includes the freezing chamber, the controller, a freezer rack, a sample probe, and a liquid nitrogen transfer hose. If optional equipment was ordered, check that those items were also received. If an ordered item was not received, please contact Custom BioGenic Systems immediately.

## Detected Damage

Once all items are removed from their packaging, check them for damage. Check that all equipment is present and matches the order. If damage is detected after unpacking the rate freezer, immediately report it to the shipping agent and re-pack the rate freezer for return to the factory.

## Equipment Return

Before returning damaged or malfunctioning equipment to the factory for repair, contact the sales organization from which the equipment was purchased. A Return Merchandise Authorization (RMA) number MUST be obtained from the factory before returning equipment for any reason.

## Installation Specifications

The rate freezer is intended to operate in the following environment:

**Intended Use:** The unit is a general-purpose controlled rate freezing system consisting of a freezing chamber, computer, built in controlling software, and LN2 transfer hose. The unit allows users to program and manipulate freezing rates using LN2, heater, and fans. It is not intended for use in a medical theater setting or with flammable anesthetic mixtures. It is not provided sterile. It is primarily used by laboratory professionals for the purpose of freezing various biological samples.

**Indoor use only**

**Installation Category II**

**Pollution Degree Level II**

**Altitude (max): 2,000 m**

**Temperature: 13°C to 33°C**

**Humidity:** Maximum relative humidity 60% for temperatures up to 31°C decreasing linearly to 30% relative humidity at 33°C.

**Liquid Nitrogen Supply Pressure:** Must be between 18-22 psi, 22 psi max.

**Input Power:** 100-120VAC or 220-240VAC depending on destination country. Check indication on unit.

**Rated Frequency:** 50/60Hz (100 VAC)  
60Hz (110-120 VAC)  
50/60Hz (220-240 VAC)

**Max Amperage:** 14.8A (120VAC)  
7.4A (240VAC)

**Outputs:** 2 USB ports

**No. of Sensor Channels:** Single Probe - 2, Multi Probe - 8

**Thermocouples:** Type T, +50°C to -200°C

**Range of Programmable Rates:** 0.1 to 99 °C per minute

## Bench Top Installation

The rate freezer should be set on a bench top in a vertical position to ensure proper operation. Ensure that there are the proper clearances for the liquid nitrogen connection.

### Connections

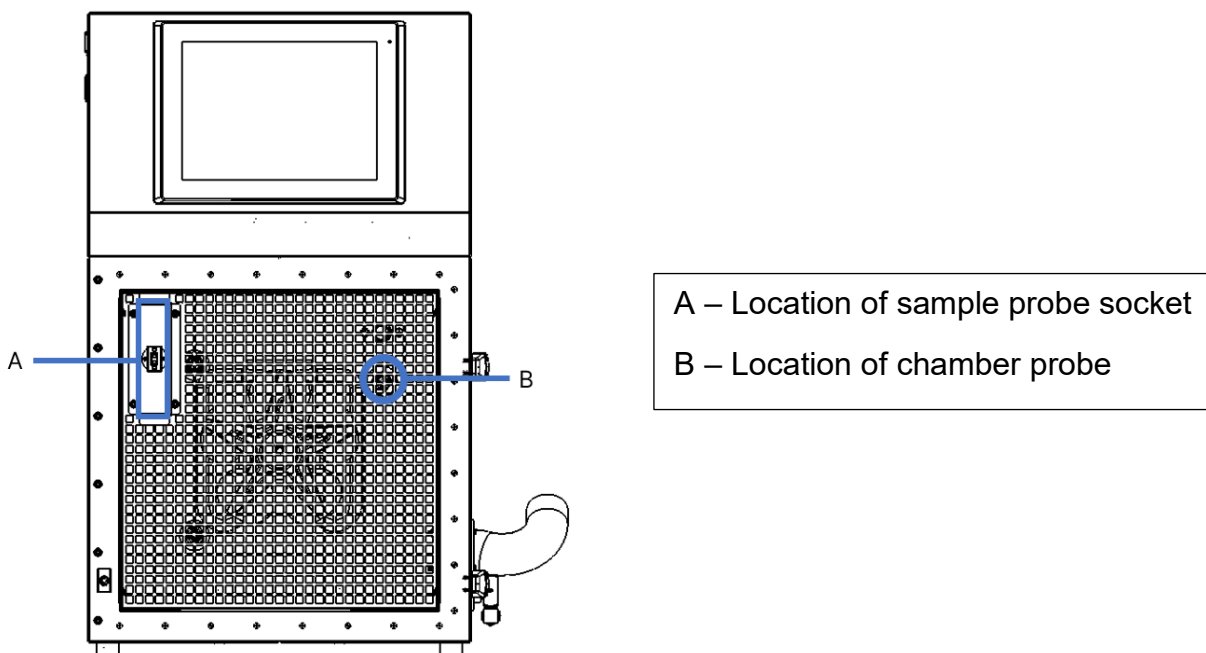
Make all the following connections BEFORE turning on the freezer.

#### Power Connections

The rate freezer is designed to operate on either 120VAC or 240VAC (must be specified when unit is ordered), depending on the user's needs. Check to make sure that the rate freezer voltage is the correct voltage for the local power system. The rate freezer is supplied with either a North American style plug or a European style plug, depending on the destination country. User supplied adapters may still need to be utilized to properly connect to main power.

#### Thermocouple Connections

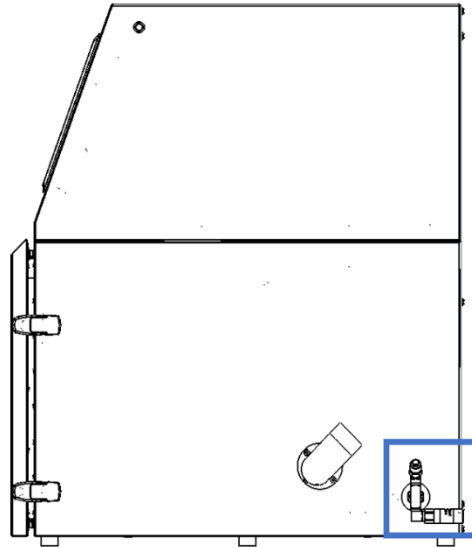
The rate freezer uses two different Type T thermocouples, labeled as CHAMBER and SAMPLE probes. The CHAMBER probe is factory installed and should not need to be adjusted. The SAMPLE probe connection is located on the inside of the chamber in the upper left-hand corner of the fan guard. Insert the plug on the SAMPLE probe into the socket in the fan guard. The thermocouple plugs are designed to only fit one way, so make sure that the plug and socket are lined up correctly.



*1. Freezer Front View, Door Open*

## Liquid Nitrogen Supply Connection

The liquid nitrogen supply connection is located on the right rear corner. This connector accepts a standard LN2 transfer hose.



Liquid Nitrogen Supply Tanks must be operated in accordance with the manufacturer / supplier instructions. Safety instructions will also be posted on the side of each tank. Liquid nitrogen tanks must be kept in a well-ventilated area protected from weather and away from heat sources. The supply tank must be replenished at regular intervals to ensure proper operation of the cryogenic system. When exchanging supply tanks, follow the procedure below:

1. Allow all plumbing components to warm to room temperature before changing supply tanks.
2. Close all valves associated with the supply tank.
3. Loosen the plumbing connection for the transfer hose at the supply tank.
4. Remove empty supply tank and replace with a full supply tank pressurized to 22 psi (1.52 bar).
5. Attach the provided transfer hose to the plumbing connection on the supply tank. Ensure the hose is connected to the connection labeled "LIQUID".
6. Tighten the transfer hose plumbing connection at the supply tank.
7. Open the liquid supply valve on the supply tank.
8. Inspect plumbing for leaks. Leaking valves or connections must be depressurized before rectification.



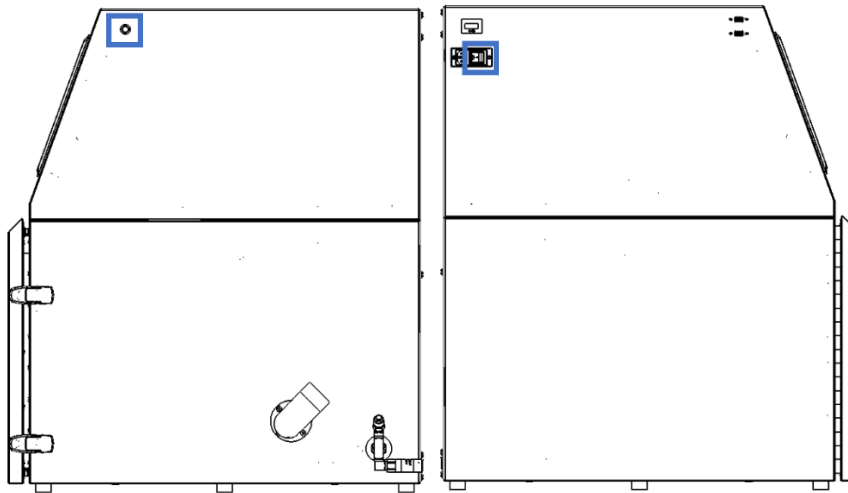
# OPERATING INSTRUCTIONS

## Power On

1. Power on the main unit by pressing on the POWER switch. The switch is in the rear upper corner on the left side of the freezer.

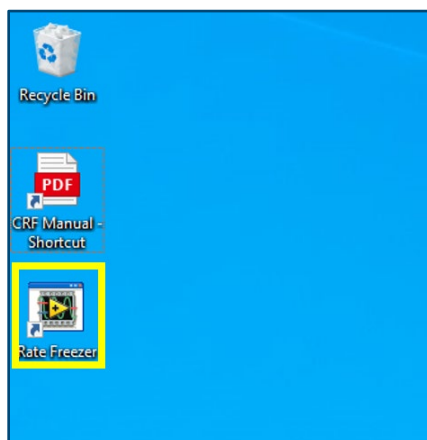
**NOTE:** If you are asked to log into the computer, the initial username is *RateFreezer* and the password is *custombio*.

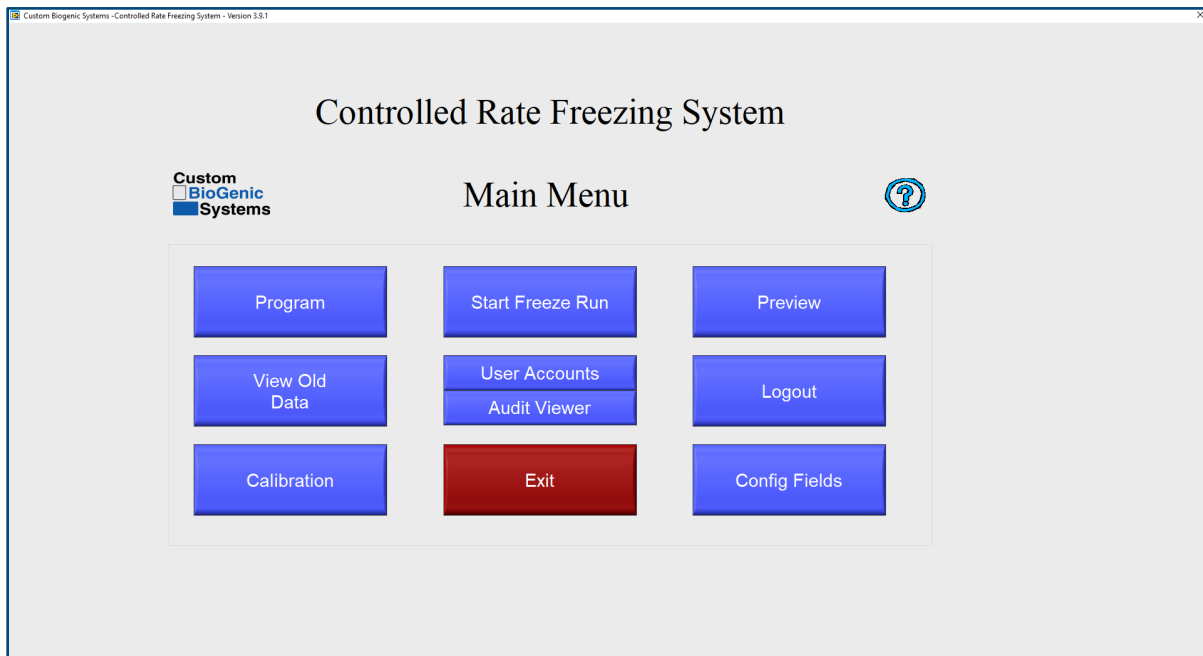
2. The touch screen controller is designed to power with main power. If main power is on but the touchscreen is off, turn on the touch screen by pressing the screen power button, which is located on the right side of the freezer.



*Figure 2 Screen Power Button (left) and Main Power Switch (right)*

3. Once you have logged in, click the icon labeled Rate Freezer to launch the application.





**PROGRAM** - This menu button allows the user to program, edit, and save freezing profiles.

**VIEW OLD DATA** - This menu button allows users to view and print previously saved freeze runs. The default print out consists of information header and the graph. See page 44 Advanced Setup for other printing options.

**NOTE:** In aiding with compliance to 21 CFR Part 11, the temperature profile and associated data is time-stamped and stored after each event. The data is stored on a Windows based computer hard-drive, or user directed to a specific file location to be stored. Security, permissions, and associated user rights to this stored data is the responsibility to the user and the Information Technology Management Department in which the storage of the data resides. Custom BioGenic Systems claims no responsibility or rights to the data, permissions, or security of the data once time-stamped and stored to the selected storage location. Custom BioGenic Systems suggests this location have restricted user rights, limited permissions, and proper file security based on standard Information Technology Management practices within the organization that comply with 21 CFR Part 11.

**CALIBRATION** - This menu button allows the user to access the thermocouple calibration screen.

**NOTE:** Calibration is done for the supplied probes at the factory. It is recommended that calibration be done at least once a year or if a probe is replaced.

Calibration should only be attempted by CONFIDENT users. Please contact Custom BioGenic Systems for more information on calibration.

**START FREEZE RUN** - This menu button brings up the profile and freeze name selection screen.

**AUDIT FUNCTIONS** - This menu button brings up the audit trail details after enabling User Accounts / Security

**USER ACCOUNTS** - This menu button allows the user to configure multiple users and passwords, and to enable or disable security. There are also different levels of access that can be assigned to each user. Click on the blue question mark in the upper right-hand corner to see a description of the access levels.

**EXIT** - Closes software.

**PREVIEW** - This menu button allows the user to preview a previously programmed profile, or to see a graph of the rates in their programming as they make changes.

**LOGOUT** - This menu button is only usable when security is enabled in the user accounts menu. It allows users to logout of the system.

**CONFIG FIELDS** - This menu button allows the user to define the labels only for the database fields that can be saved for each freeze run. This information is entirely optional and is used for database searching of freeze run information.



- Help with the current screen.

**NOTE:** The usernames and passwords set up within the Rate Freezer Software are not related to the Windows usernames and passwords. They are separate and independent.

## 21 CFR PART 11

21 CFR Part 11 is a component of the CGMP regulations in parts 210 and 211 (21 CFR Parts 210 and 211) governing electronic signatures and records in all program areas. Entities that choose to keep electronic records and signatures that may be submitted to the FDA must follow these guidelines.

It is important to note that as of time of writing there is no certifying body for this guideline therefore no vendor can claim to be 21 CFR Part 11 Certified.

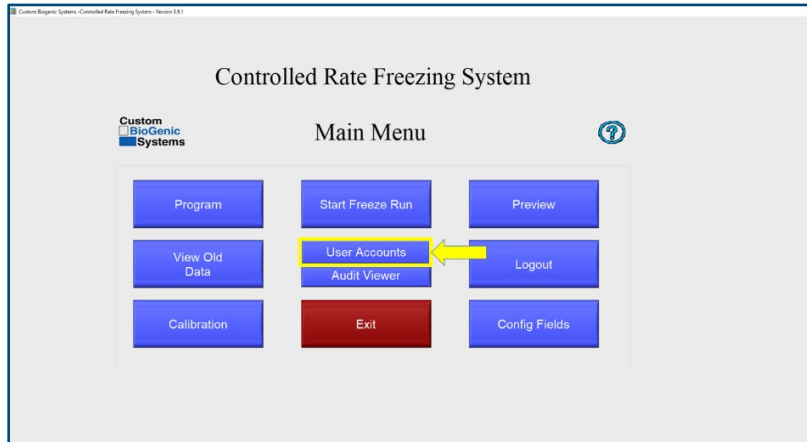
The Controller Software is designed to aid in compliance with 21 CFR Part 11. A list of the requirements and an explanation on how the controller addresses the requirements is listed in the Response to 21 CFR Part 11.

# Enabling Security / 21 CFR Part 11

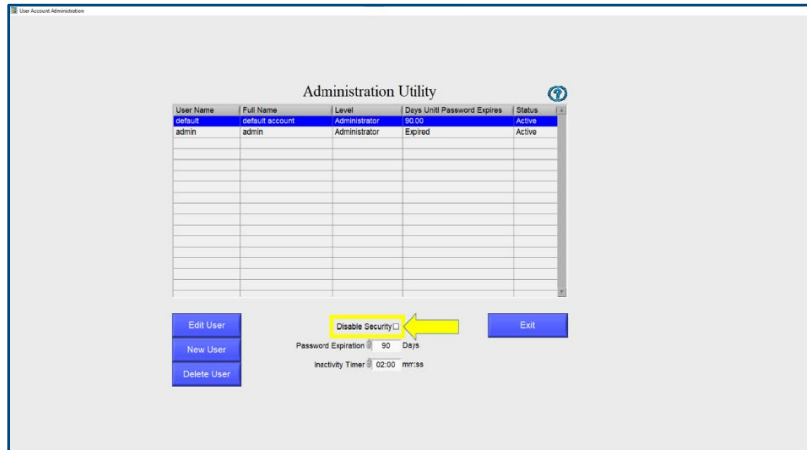
The Security / 21 CFR Part 11 module is disabled by default.

To enable the process, perform the following steps:

1. From the main menu select User Accounts:



2. Un-check the box "Disable Security":



3. Log in as the Administrator:

The first time you log in the username and password are as follows:

Username: default

Password: administrator

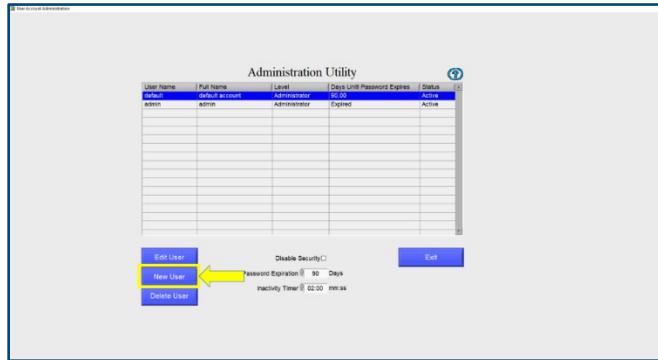
**NOTE:** Both the username and password are lower case.

At this time, you should create a new administrator account and delete the default administrator account.

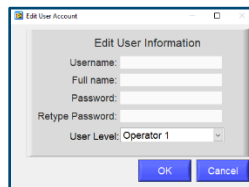
## Creating a New Account

To create a new User:

1. Ensure that you are logged in as the Administrator
2. From the Main menu select User Accounts
3. Click New User



4. Enter the Username and Full Name



5. Enter a Password, then Retype the password
6. Select the User Level

The first time that you use the system, ensure that you create a new Administrator Account.

There are 4 possible User Levels:

- Operator 1- Has access to Program, Start Freeze Run, Preview and View Old Data
- Operator 2 – Has access to Start Freeze Run, Preview, View Old Data
- Operator 3 – Has access to Preview Only
- Administrator – Has access to all system functions.

**NOTE:** Only Administrators can view the audit log and access security functions.

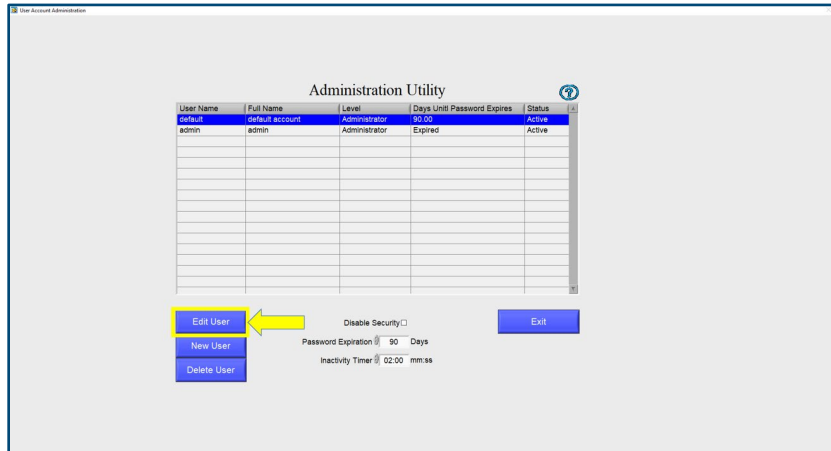
**NOTE:** When the new user logs in for the first time, they will be required to change their password.

Your SOP should prevent the sharing of passwords with other users or the Administrator.

# Edit a User

To Edit a User:

1. Ensure that you are logged in as the Administrator
2. From the Main menu select User Accounts
3. Click Edit User

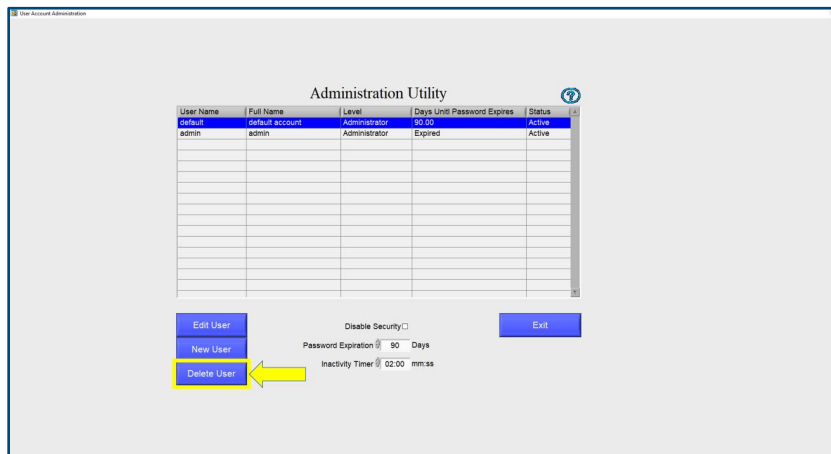


4. Change the information as necessary

# Deleting a User

To Delete a User:

1. Ensure that you are logged in as the Administrator
2. From the Main menu select User Accounts
3. Click Delete User

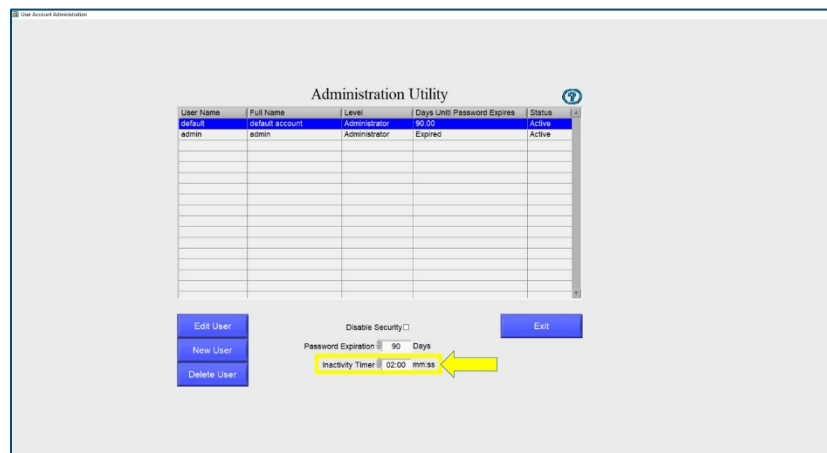


## Setting the Inactivity Timer

According to the 21 CFR Part 11 ruling the system must allow you to set an inactivity timer. Once this time limit is reached the user is logged out and must log in again.

To set the Inactivity Timer do the following:

1. Ensure that you are logged in as the Administrator.
2. Select User Accounts
3. Set the Inactivity Time to the desired number of minutes and seconds – The default is 30 seconds.



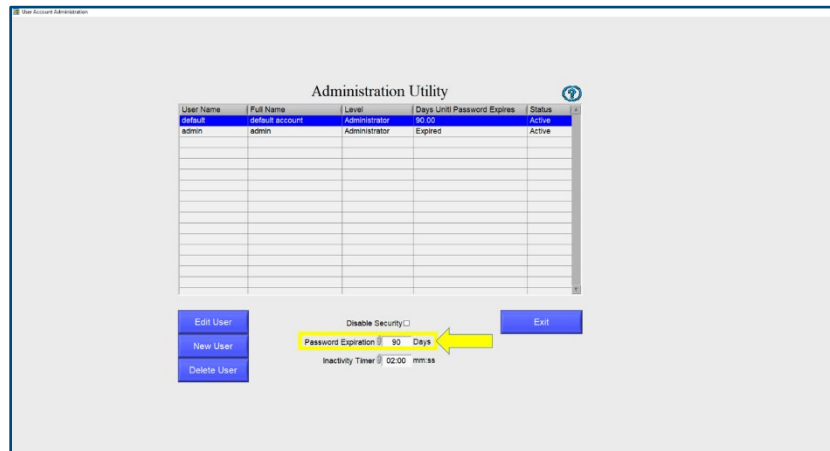
**NOTE:** The Inactivity Timer applies to ALL users.  
The Inactivity Timer will not engage during a run cycle.

## Setting the Password Expiration

According to the 21 CFR Part 11 ruling, Passwords must expire (and therefore be changed) a minimum of every 90 Days.

To set the expiration period do the following:

1. Ensure that you are logged in as the Administrator.
2. Select User Accounts
3. Set the Password Expiration to the desired number of days – The default is 30



**NOTE:** The Password Expiration applies to ALL users.  
The grid displays the number of days before a Password will expire.

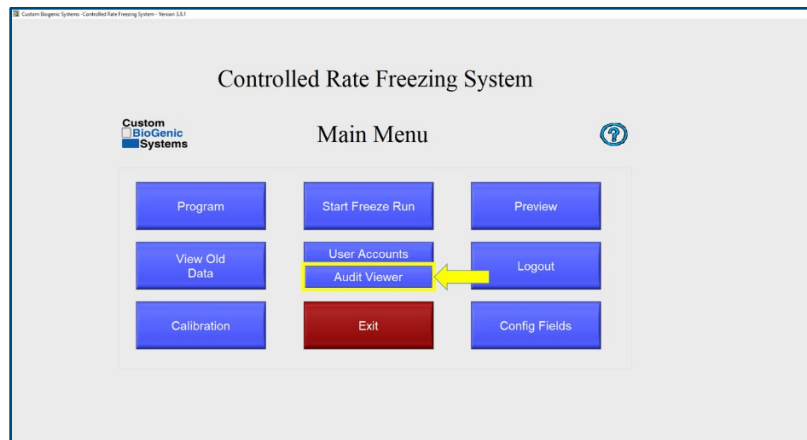


## Viewing the Audit Trail

According to the 21 CFR Part 11 ruling the system must keep a complete history of all security related interactions with the system. The Audit Trail provides a record of all changes made to the Controlled Rate Freezer by users.

To View the Audit Trail:

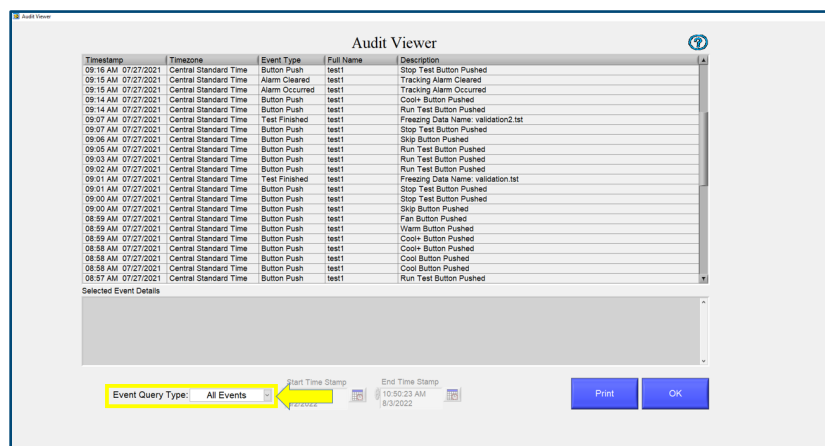
1. Ensure that you are logged in as the Administrator
2. From the Main Menu click Audit Viewer



The system will now display a list of the events in the system.

You can filter this list by date as follows:

1. Click on the Event Query Type drop down, change from All Events to “In Date Range”.
2. The Start Time Stamp and End Time Stamp will now be enabled.
3. Enter the Start Time and Date and End Time and Date. Alternatively, you can click the calendar icon to select the time and date.
4. The Audit Trail will automatically be filtered as you make your selection.



## Printing the Audit Trail

The Audit Trail can be printed from the same screen by clicking the Print Button. The system will print the records that are currently displayed in the grid.

**NOTE:** If a printer is connected to the freezer, the Audit Trail will physically print. If no printer is connected, the user will be prompted to select a location to save the file.

**NOTE:** The Audit Trail may contain information about users and passwords. Care must therefore be taken when printing this log to ensure that it is not accessible by unauthorized persons.

## Create a Program

The screenshot displays the 'Program Profile Screen' with the following data in the table:

Step	Cooling Rate (C/min)	Target Temp (C)	Hold Time (HH:MM:SS)
1	70.00	-4.00	00:00:00
2	1.00	-4.00	00:00:00
3	25.00	-40.00	00:00:00
4	15.00	-12.00	00:00:00
5	1.00	-40.00	00:00:00
6	10.00	-90.00	00:00:00

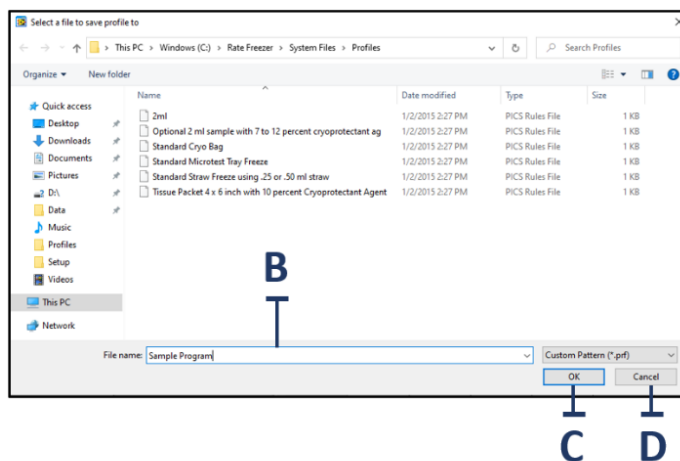
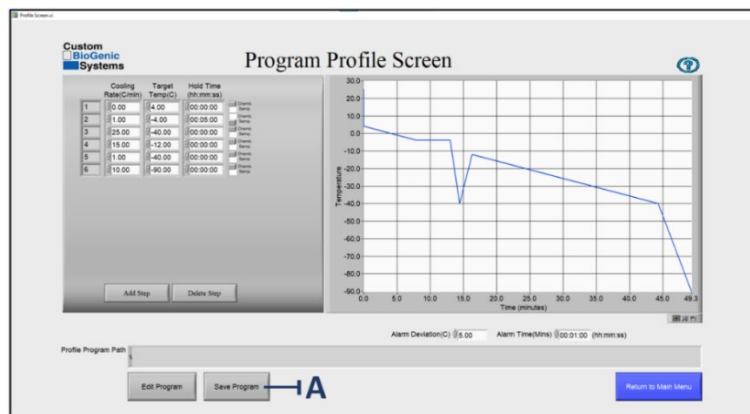
The graph shows a temperature profile starting at 0°C, cooling to -4°C, holding at -4°C, cooling to -12°C, holding at -12°C, cooling to -40°C, holding at -40°C, and finally cooling to -90°C.

1. At the main menu click on the program button [A].
2. Clicking the program button [A] will open a new window called PROGRAM PROFILE. The program profile screen is where you will enter the steps of the program. The step number [C] will automatically be created when entered.
3. Click the pointer on the cooling rate area [B] and enter a desired cooling rate.
4. Click the pointer on the target temperature area [D] and enter desired target temperature.
5. Click the pointer on the hold time area [G] and enter the desired time (HH:MM:SS)
6. Click on add a step area [E] to add a program step.
7. Click on delete a step [F] to remove entire last step.
8. Verify all information is correct.
9. Continue steps 3-6 until program is complete.

**NOTE:** The recommended method for starting a freezing cycle is to program a “wait” function. Enter a 0 (zero) as the cooling rate by clicking the cooling rate area [B] (see program profile p.29). Enter a target temperature in area [D] (see program profile p.29). This function will pre-cool the chamber and hold the chamber temperature at the programmed target temp [D] (see program profile above). A 0 (zero) degree rate will hold indefinitely at the programmed target temp [D] (see program profile p.29). **NOTE:** If you desire a negative number for the target temperature you must enter a minus sign for temperatures below zero. (Example: -50 °C.)

**NOTE:** This software does not require an “end of program” command.

## Save a Program

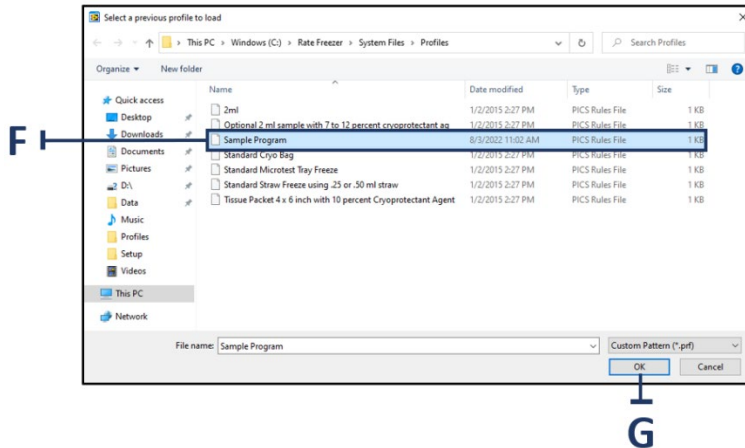
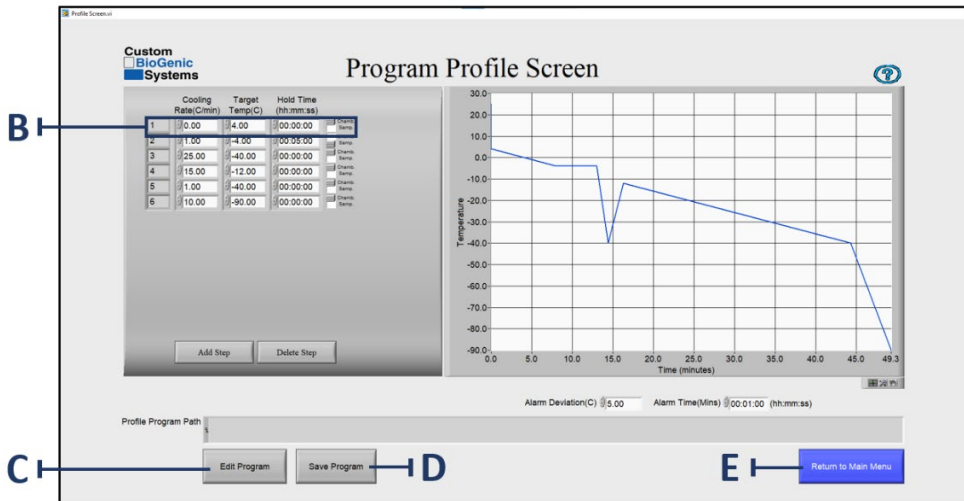
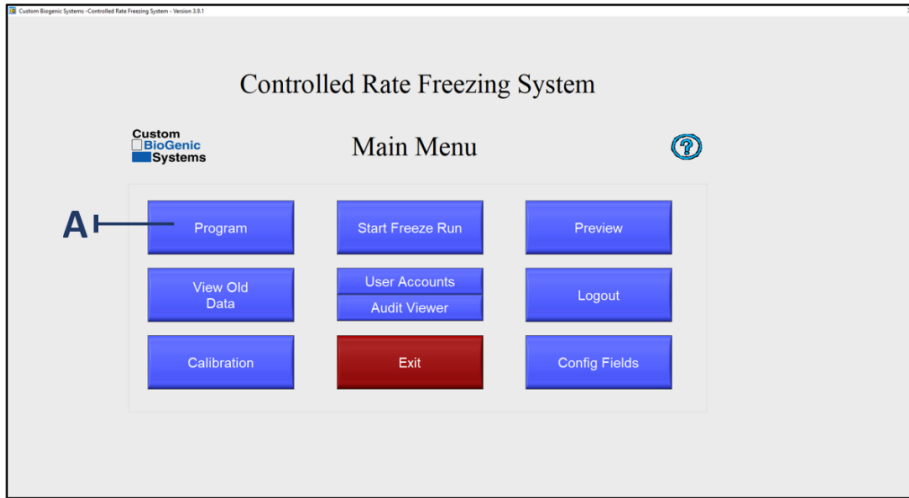


After you have created a program, you may save, edit, or delete it. To save a program:

1. Create a program. (See page 26; steps 1-8)
2. Click on the SAVE PROGRAM button [A].
3. Type the name you wish to give to this program in the save profile window [B].
4. Click on the OK button [C]. The program is now saved in the computer.

**NOTE:** If you do not wish to save the new program click the CANCEL button [D].

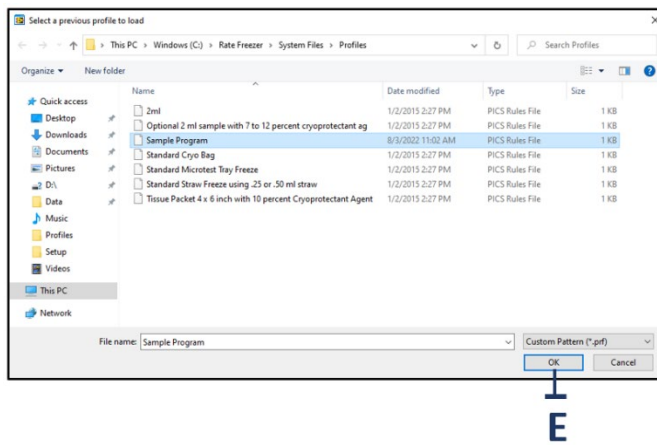
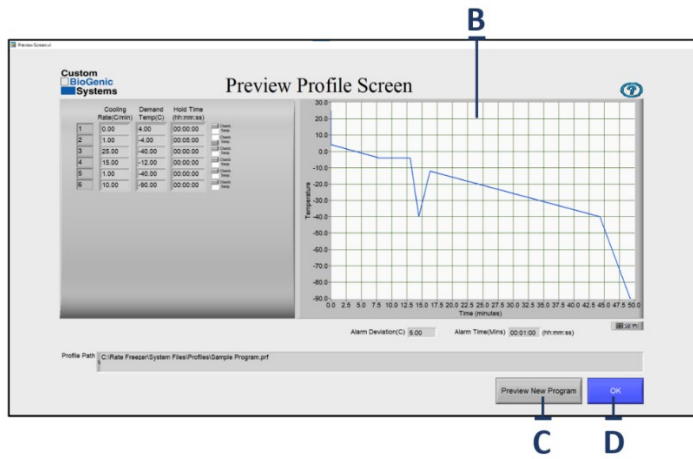
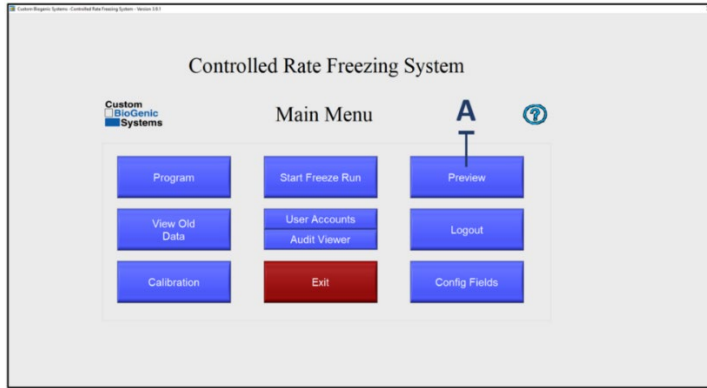
# Edit a Program



Custom BioGenic Systems has provided you with six preset programs that you can use as templates for many common freezing processes. (Both user-created and preset programs can be edited.)

1. At the main menu screen press the PROGRAM button [A].
2. At the program profile screen click the EDIT PROGRAM button [C]
3. Locate the program to be edited [F] and click OK [G] to open it.
4. Move the pointer to the step you wish to change and click on that area [B].
5. Use the backspace or delete keyboard keys to delete the value you wish to change.
6. Enter a new value.
7. Repeat steps 4-6 until you have made all the changes you desire.
8. If you wish to save your changes, click the save program button [D]. (See page 27 for saving instructions)
9. If you do not wish to save your changes, click the return to main menu button [E].

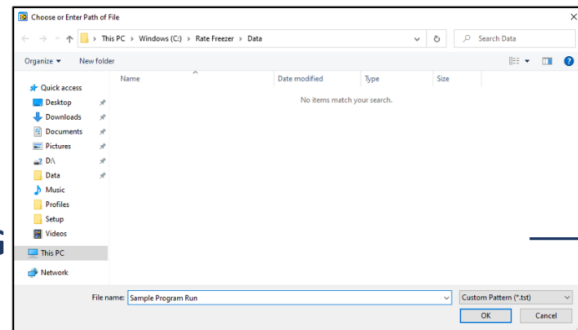
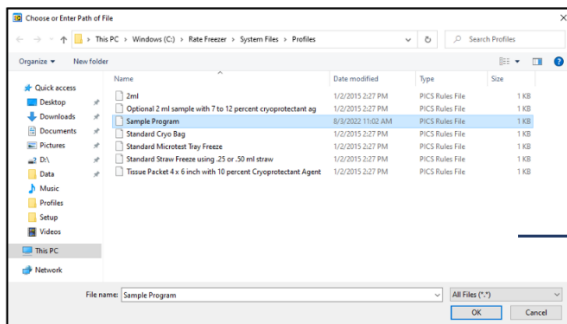
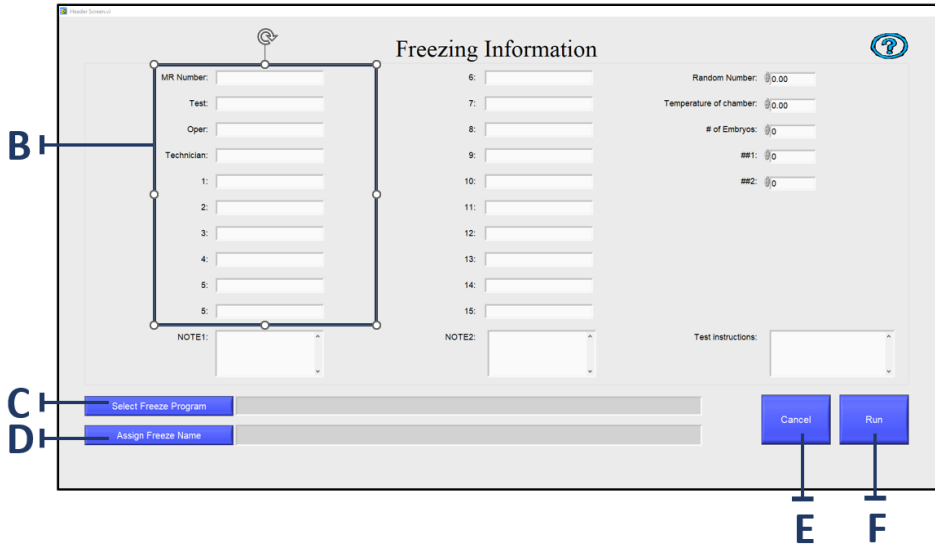
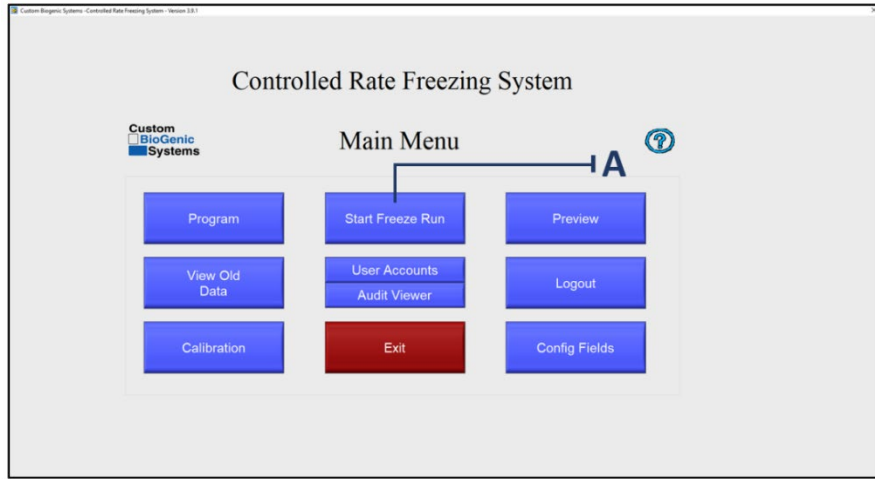
# Preview a Profile



**NOTE:** Custom BioGenic Systems recommends that you preview a program before running it. By doing this you can often identify incorrect information by previewing the program as a graph.

1. At the main screen press the PREVIEW button [A].
2. At the preview profile screen select a profile to load and click OK [B].
3. Watch the screen [C] display the freezing protocol.
4. When you have finished previewing the protocol hit the OK button [D] to return to the main menu.
5. To preview a different program click PREVIEW NEW PROGRAM [E].

# Run a Program





Every time you run a program you create a unique set of data. In many cases you will wish to save this data using a unique file name; if you don't your old program data will be overwritten by the latest data.

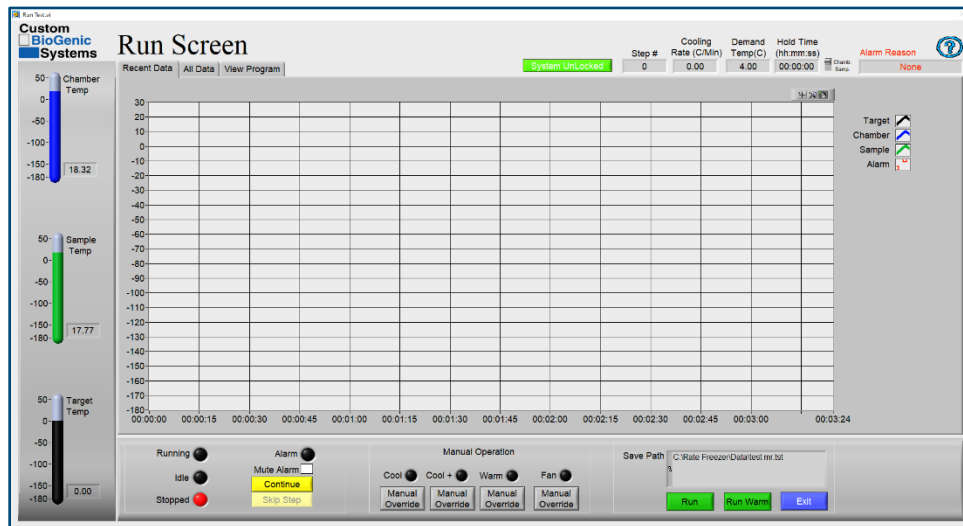
1. At the MAIN MENU screen click the START FREEZE RUN button [A].
2. At the FREEZING INFORMATION screen fill in the optional fields [B] with the information you desire.

**NOTE:** The freezing information [B] is a form that is customized to each customer's need.

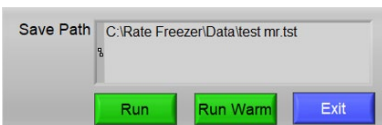
The information entered will differ according to use and customer.

3. Click the SELECT FREEZE PROGRAM button [C].
4. Select a program profile from the window and click OK [G].
5. Click ASSIGN FREEZE NAME [D].
6. Assign the freeze a name and click OK [H]
7. To continue click RUN [I].
8. To cancel a freeze click CANCEL [J]

## Run Screen



## Run Controls

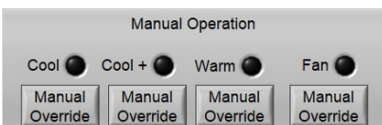


**Run** – Start the freeze run

**Run Warm** – Warms the chamber up to 25°C for shut down. Typically used at the end of a freeze run.

**Exit** – Ends the freeze run and returns to main menu.

## Manual Operation



**Cool** – Light is on when the cool valve is open.

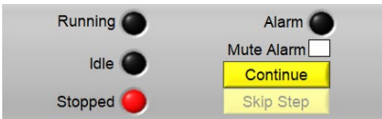
**Cool+** – Light is on when the cool+ valve is open.

**Warm** – Light is on when the heating element is on.

**Fan** – Fan is on when the fan is spinning.

**Manual Override** – When pressed, manually overrides the current state of the respective element (e.g., if the cool valve is closed, pressing manual override will open the cool valve).

## Freezer Status



**Running** – Light is on when the freeze run is in progress.

**Stopped** – Light is on when the freeze run is not running.

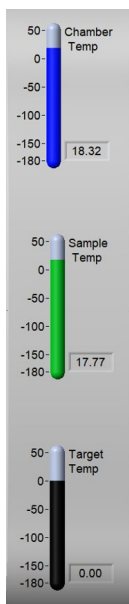
**Alarm** – Light is on when there is an active alarm.

**Mute Alarm** – Checking this box will mute any active alarm. The alarm state will remain active.

**Continue** – When pressed, the freeze run will start the next step of the freeze profile. Only functions during a hold time, including 0:00 time hold.

**Skip Step** – When pressed, the freeze run will skip to the next step of the freeze profile.

## Current Temperature

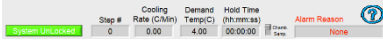


**Chamber Temp** – Displays the current reading of the chamber probe.

**Sample Temp** – Displays the current reading of the sample probe.

**Target Temp** – Displays the current target temperature from the freezing profile

## Header Information



The screenshot shows a header information panel with a green 'System Unlocked' status bar on the left. To the right, there are four columns: 'Cooling Rate (C/Min)', 'Demand Temp(C)', 'Hold Time (hh:mm:ss)', and 'Alarm Reason'. The values are: Step # 0, Rate 0.00, Demand 4.00, Hold Time 00:00:00, and Alarm Reason None. There are also small icons for 'Alarm' and 'Help'.

Cooling Rate (C/Min)	Demand Temp(C)	Hold Time (hh:mm:ss)	Alarm Reason
0.00	4.00	00:00:00	None

**System Unlocked/Locked** – When pressed, prevents user interaction with the screen. To unlock, press again.

**Step #**– Displays the current step of the freezing profile.

**Cooling Rate**– Displays the current cooling rate from the freezing profile.

**Demand Temp**– Displays the target temperature at the end of the current step.

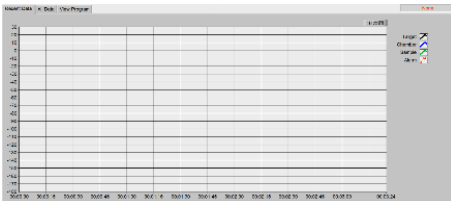
**Hold Time**– Displays the hold time at the end of the current step.

**Chamb/Samp** – Displays whether the demand temp is for the chamber or sample probe.

**Alarm Reason**– Displays the type of alarm of the current alarm state.

**?**– Press for help with the run screen.

## View Area

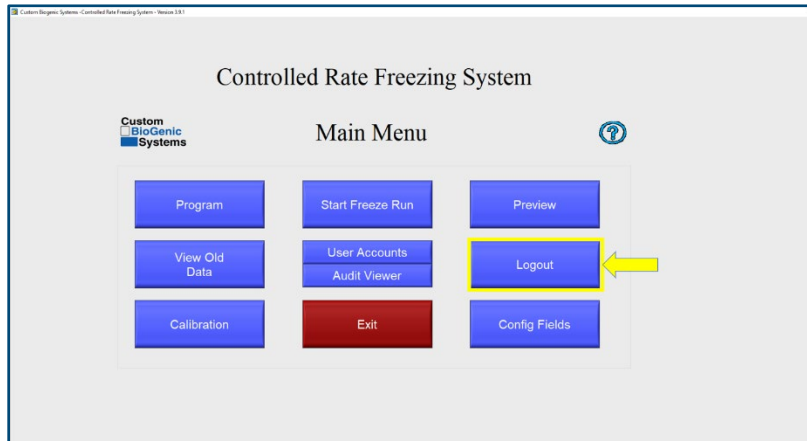


**Recent Data** – Displays a plot of the recently recorded data in real time.

**All Data**– Displays a plot of all the recorded data for the current freeze run, in real time.

**View Program**– Displays the freezing profile for the current freeze run.

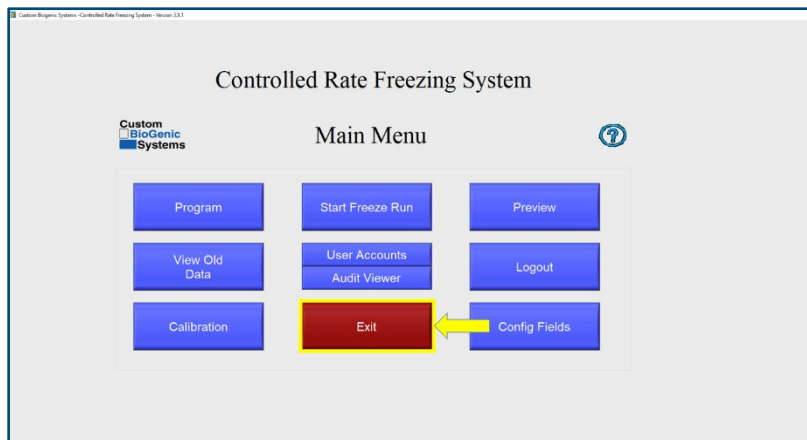
# Logout of the System



1. At the main menu screen click the LOGOUT button [A].

**NOTE:** Logging out of the system brings up the Log On screen so another user can enter their login and password if desired.

# Exiting the System

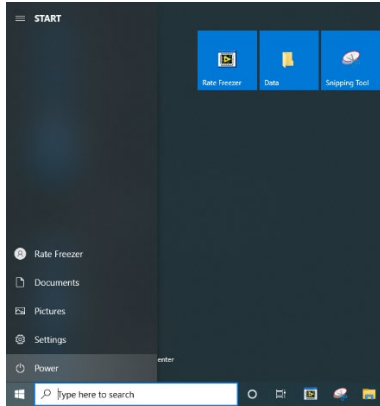


1. At the main menu screen click the EXIT button.

**NOTE:** Exiting the system shuts down the software.

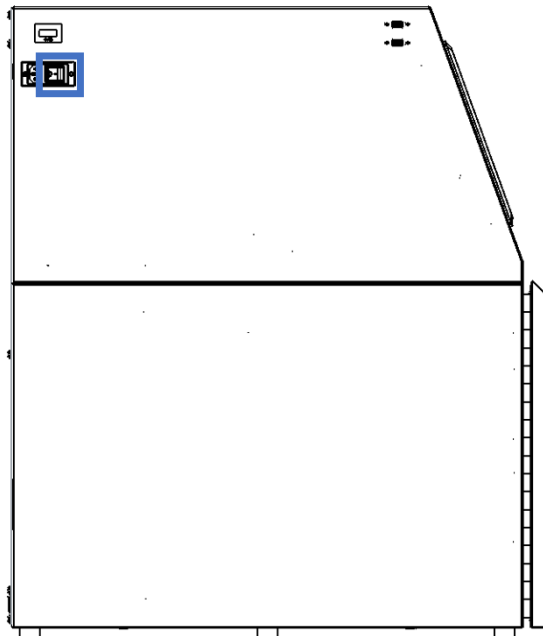
## Power Off the Freezer

1. Navigate to the START menu in the lower left corner of the screen.
2. Click POWER.
3. Click SHUT DOWN.



**NOTE:** It is recommended to keep the main power switch on, and the main power cord plugged in during regular use. This will keep the backup power system in the freezer charged. Follow the remaining instructions only in situations that require a full power off, e.g., to transport the unit.

4. Press the POWER switch to off position. The switch is in the rear upper corner on the left side of the freezer.
5. Remove the power cable from the unit. The power cable is located next to the POWER switch.



## BASIC OPERATION

### Theory Of Operation

This Cryogenic Rate Freezer freezes at pre-defined, user programmable rates. This means that the user has total freedom when it comes to programming their freezing profiles. A few good practices when programming and running profiles is:

- 1) The chamber temperature should be used for controlling the freezing of the sample.

This means that, due to the principles of Thermodynamics, any mass (such as a sample) that is within the chamber MUST follow that chamber's temperature profile.

- 2) The sample temperature should only be used to automatically control the advancement of steps within a profile, not to control the entire freezing process.
- 3) Placing the sample probe within the sample will always yield the most accurate and repeatable graph line.

If it is not possible to place a probe inside a sample due to the sensitivity of the material, an equivalent dummy sample can be used. This just involves using the same type of sample receptacle (i.e., vial, bag, straw) that has an equivalent mixture of whatever is being frozen, minus the actual sample material (See page 45 & 46 for probe placement). In this way the user can be confident they're getting the most accurate and repeatable results possible, without compromising an actual sample.

### The Touchscreen Display Controller

The Touchscreen Display Controller is a Windows Based Computer running specific drivers and software to actuate the Controlled Rate Freezer in a manner that is reproducible and consistent. The controller is configured in a specific way to prevent other software from interrupting or slowing processing cycles while executing directives to the National Instruments DAC's.

Installation of 3rd party Software or connection to the internet may cause the controller to deviate from its intended function and is therefore prohibited. Connecting to the internet or executing 3rd Party Software will void the Warranty.

Rationale:

1. The Controlled Rate Freezer has passed verification and validation tests that will be invalidated if 3rd Party Software is installed on the device.
2. The Controller has been validated and verified with a specific version of windows and specific drivers.

Updating the windows version or drivers will invalidate the verification and validation tests as there is no guarantee that future updates or driver changes will not change the function of the controller.

3. The controller has no access to the internet which reduces exposure to viruses.
4. An exception is made for printer drivers and USB memory Sticks used with the Touchscreen controller.
5. It is recommended that USB Memory Sticks used with the Touchscreen controller are periodically scanned for Viruses and only used for the purpose of moving run files from the rate freezer to the USB Memory Sticks.

## The Hold Function

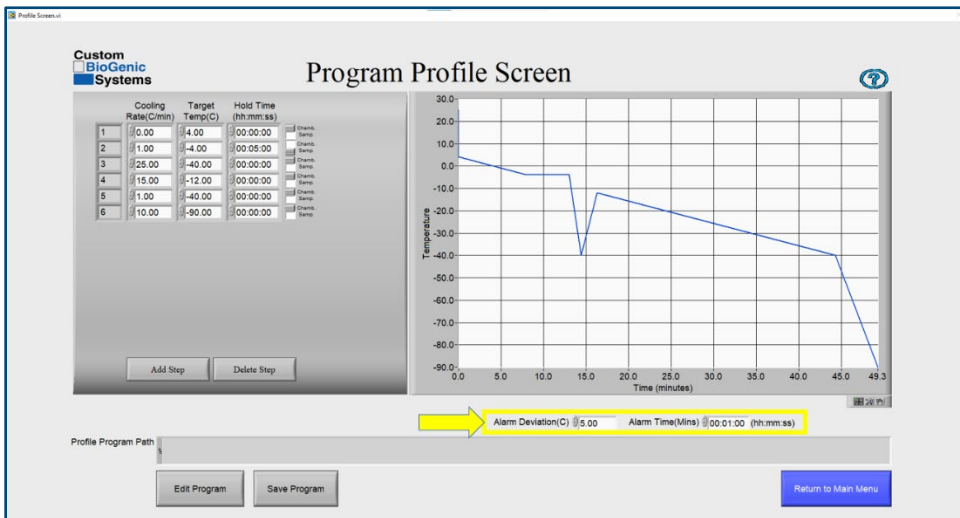
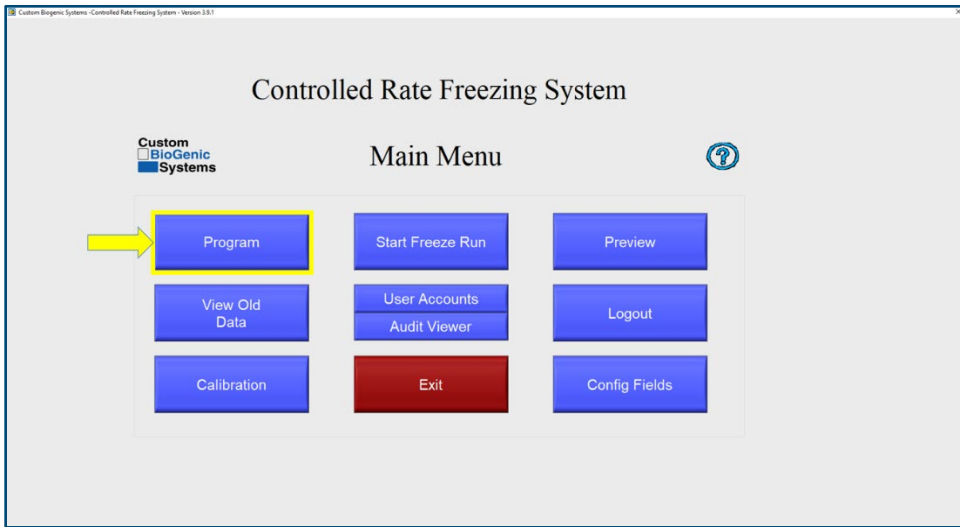
Another important aspect of the Controlled Rate Freezer is the fact that any step within a profile that is programmed with a zero-degree rate automatically gets interpreted by the software as a “Hold” function. This means that if the step is programmed to cool at 0° per minute, the machine will attempt to cool to the set point as fast as possible and then hold there until the “Continue” button is pressed, regardless of if any hold time is programmed in. This is typically done during the first step in a profile based on how the user prepares the samples for insertion into the chamber.

EXAMPLE: A user is freezing 2ml vials of fluid. They keep the samples in an ice bath until they are ready to insert them into the chamber. An ice bath is typically no warmer than +4°C, so the user programs the first step in the profile to cool at 0° per minute down to +4°C. The ZERO DEGREE RATE causes the chamber to cool to and hold at +4°C. The user then loads the samples into the chamber, presses the button, and the freezing profile advances to the next step. It will then continue to advance through the programmed steps as long as another ZERO DEGREE RATE is not encountered.



# Alarm Deviation

The alarm deviation consists of two things. 1) The temperature difference between the CHAMBER and TARGET values that must exist for a TRACKING ALARM to occur, and 2) The amount of time that these two values are not equal before a TRACKING ALARM occurs. The default settings are 5°C for 1 minute. This means that if the CHAMBER temperature is deviated 5°C or more from the TARGET temperature, for 1 minute, a TRACKING ALARM occurs. These values can be changed in the PROGRAM menu.



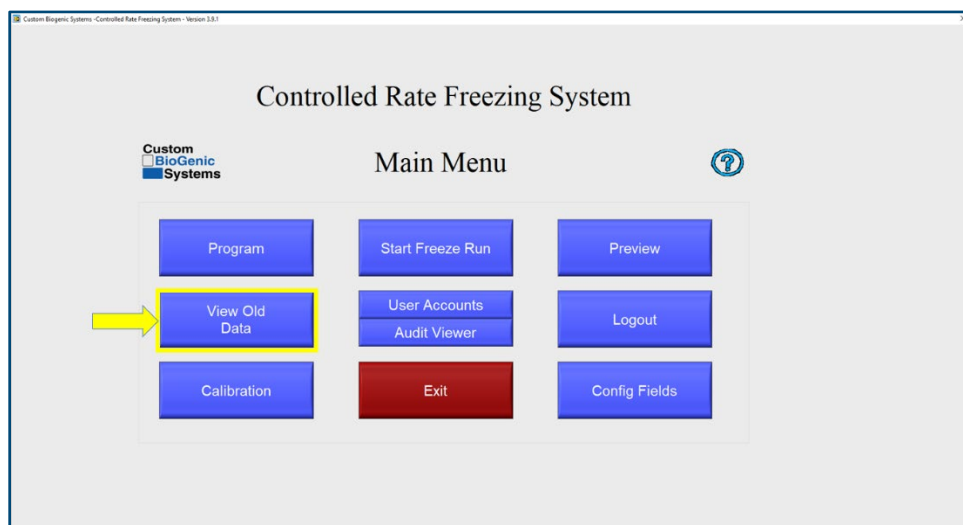
## Reviewing Data

Data can be viewed as it is being acquired, and after the freeze run has completed. When viewing data during a freeze run, there are two tabs at the top of the graph labeled RECENT DATA and ALL DATA. The RECENT DATA view is selected by default and shows only the most recent portion of the freeze run. The ALL DATA view is used to see the entire run up to the current time.

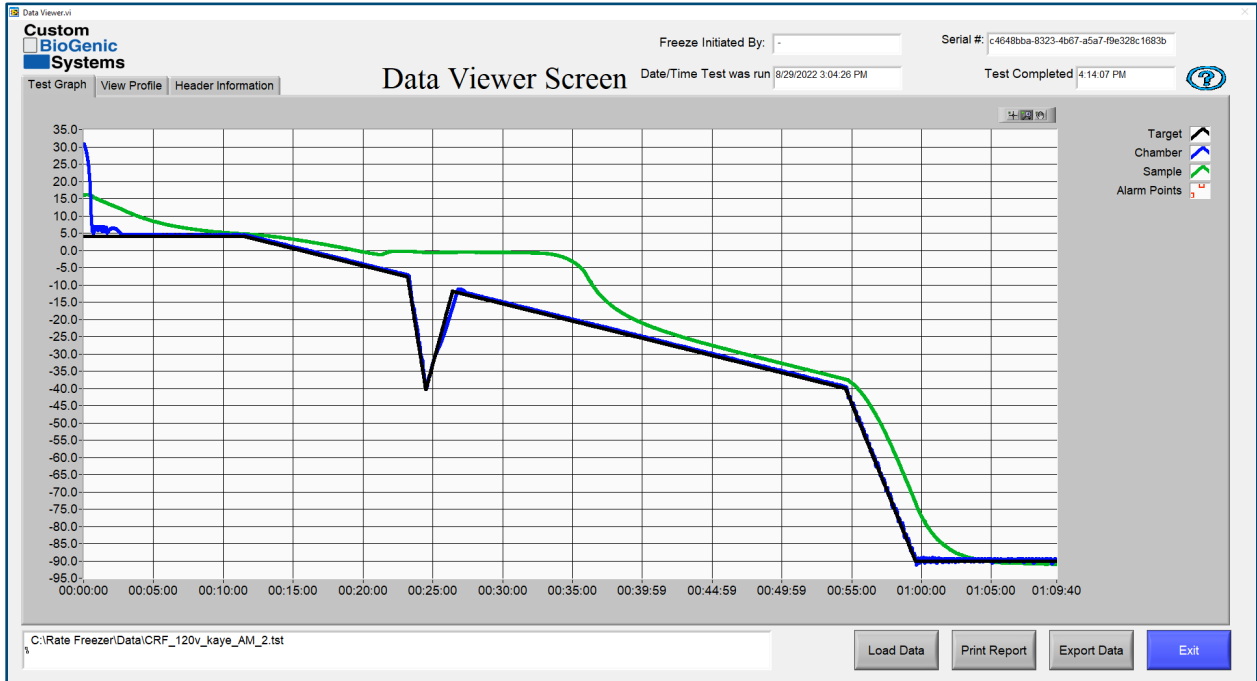
**IMPORTANT:** The RECENT DATA view should be selected for most of the run. The ALL DATA view is used to periodically check the entire run up to the current time. If the ALL DATA view is left selected during the entire run, the time that is logged will become offset from “real time”.

Because the software is continually updating and displaying a growing number of data points, the same loop of code takes longer and longer to execute as time goes on. This manifests itself as a time loss as compared to real time. It has been observed to be 10-15 seconds of loss per hour. While it does not adversely affect the operation of the Cryogenic Rate Freezer, this time loss does exist, but only builds up when the ALL DATA view is selected for an entire freeze run. Most users will not be concerned with this effect.

When viewing data after a freeze run, click on the button on the main menu to select a file to view. Use the DATA VIEWING FUNCTIONS, indicated by the small magnifying glass, cross hair, and hand icons located to the right of the graph to view the data. Clicking on these icons reveals zoom, selection, and manipulation modes. The DATA VIEWING FUNCTIONS are also available during a freeze run.



# Example Data View Screens



Custom BioGenic Systems

Freeze Initiated By:  Serial #: c4648bba-8323-4b67-a5a7-f9e328c1683b

Date/Time Test was run 8/29/2022 3:04:26 PM Test Completed 4:14:07 PM

Cooling Rate(C/min)	Demand Temp(C)	Hold Time (hh:mm:ss)	
0.00	4.00	00:00:00	Chamb. Samp.
1.00	-4.00	00:00:00	Chamb. Samp.
25.00	-40.00	00:00:00	Chamb. Samp.
15.00	-12.00	00:00:00	Chamb. Samp.
1.00	-40.00	00:00:00	Chamb. Samp.
10.00	-90.00	00:10:00	Chamb. Samp.

Alarm Time(hh:mm:ss)  
00:01:00

Alarm Deviation(C)  
5.00

Profile used  
CRF-67-F\_AM\_kaye.prf

C:\Rate Freezer\Data\CRF\_120v\_kaye\_AM\_2.tst

Load Data Print Report Export Data Exit

## Advanced Setup

The following options require the modification of an INI file located in the hard drive of the notebook PC:

C:\Program Files\Cryogenic Rate Freezer\release custom biogenic systems\data\crfs

**DO NOT ATTEMPT TO MODIFY THIS FILE UNTIL THIS ENTIRE MANUAL IS READ AND UNDERSTOOD.**

After the INI file is modified correctly, press CTRL's to save the INI file in its modified form. Only then will the changes take effect.

## Printing Options

There are several printing options that can be enabled through the modification of the INI file.

These are as follows:

SHORT = info header and graph, default setting.

LONG = info header, graph, and every data point taken from the thermocouples during the run.

GRAPH = graph only printouts.

**WARNING:** This option produces hundreds of pages of data and is usually only needed for validation purposes. If it needs to be used, make sure to switch the option back to SHORT or GRAPH to avoid printing hundreds of pages of data every time a freeze run graph is printed.

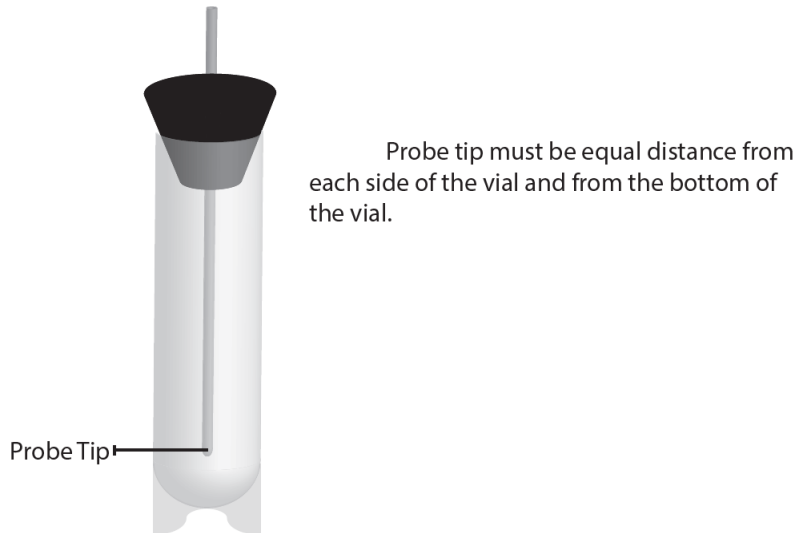
## Audit Trail Functions

The audit trail is an advanced feature that allows the tracking of freeze runs, new users added, users deleted, users edited, and profile changes. It also keeps track of invalid logins and locks the system out after repeated failed attempts. It only operates if security is "Enabled" in the user accounts menu. The audit trail is saved as an un-modifiable file and builds up indefinitely until the hard drive runs out of space. It is possible to disable the audit trail while still retaining user account functionality. Consult factory for details.

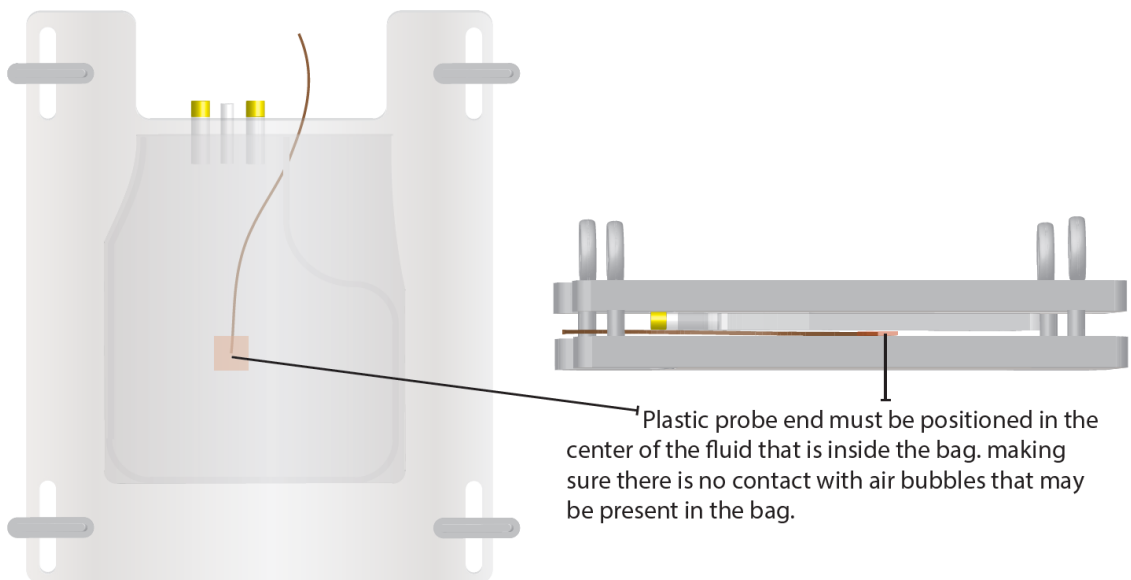
## SAMPLE PROBE PLACEMENT

Sample probe placement is very important. The position of this probe determines the accuracy and repeatability of the sample trace line on the viewer screen.

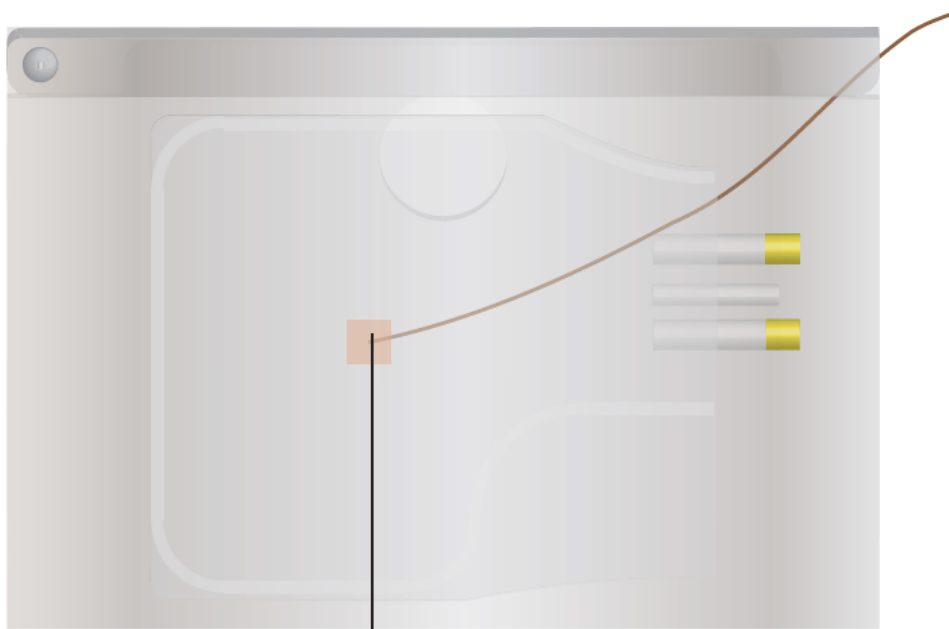
### Vial Probe Placement



### Bag Press Probe Placement



## Canister Probe Placement



Plastic probe end must be positioned in the center of the fluid that is inside the bag. making sure there is no contact with air bubbles that may be present in the bag.



## CLEANING AND DECONTAMINATION

**NOTE:** It is the responsibility of the organization to determine cleaning method and schedule that is appropriate for the intended use. The units are **NOT** provided sterile.

A solution that does not react with stainless steel can be used in the cleaning process of the interior of the unit. **DO NOT use any petroleum-based cleaning solutions.** A mixture of 30% chlorine bleach with 70% water solution is considered a suitable method for decontamination. A household detergent or mild soap solution is also suitable. Other cleaners that can be safely used include hydrogen peroxide, and denatured alcohol.

- Disconnect power before cleaning the unit.
- Do not expose the enclosure(s), electronics and/or display(s) to water or excessive moisture.
- Exterior may be cleaned with a damp, lint-free cloth using mild, non-abrasive household type cleaner.
- Do not saturate the cloth.
- Do not spray or pressure wash.

To perform the cleaning procedure, cover all inner surfaces with the cleaning solution, let stand for 30 minutes and remove. Spraying the solution into the inner vessel is preferred. Rinse the surface with clean water and ensure all cleaner residue has been removed. Allow the unit to dry completely before putting back into service.

Contact the manufacturer if there are any questions about the cleaning process.

**NOTE:** The user is responsible for appropriate decontamination if hazardous materials contact the unit.

## DISPOSAL



The WEEE (Waste Electrical and Electronic Equipment) symbol indicates compliance with the European Union Directive. The directive sets requirements for the labeling and disposal of certain products in affected countries. When disposing of this product in countries affected by this directive:

- Do not dispose of this product as unsorted municipal waste.
- Collect this product separately.
- Use the collection and return systems available locally. For more information on the return, recovery, or recycling of this product, please contact your local distributor or Custom BioGenic systems.



## TROUBLESHOOTING

Issue	Solution
No Power to Freezer	<ul style="list-style-type: none"><li>• Confirm the main power cord is plugged into a power source and into the freezer. Confirm the main power switch is set to ON.</li></ul>
Display Black / Does not Turn On	<ul style="list-style-type: none"><li>• See “No Power to Freezer”</li><li>• If the screen remains black after checking power to freezer, press the screen power button (on the right) to turn on the screen.</li></ul>
Sample Probe Alarm	<ul style="list-style-type: none"><li>• One (or both) of the thermocouple’s conductors are broken or disconnected. This can occur anywhere between the tip of the probe and the NIDAQ Modules.</li><li>• This alarm is NOT self-correcting, and only goes away once the cause has been fixed and the software re-started. Isolate the open (or broken) connection(s). The most common cause is within the thermocouple connection jacks, anywhere between the tip of the probe and the NIDAQ modules. Start by shorting the sample probe socket located in the upper left corner of the fan guard. If the alarm goes away, you know the problem is in the probe. If it doesn’t go away, continue your way back towards the NIDAQ modules, checking the connections.</li></ul>

## Chamber Probe Alarm

- One (or both) of the thermocouple's conductors are broken or disconnected. This can occur anywhere between the tip of the probe and the NIDAQ modules.
- This alarm is NOT self-correcting, and only goes away once the cause has been fixed and the software re-started. Isolate the open (or broken) connection(s). The most common cause is within the thermocouple connection jacks, anywhere between the tip of the probe and the NIDAQ modules. Start by shorting the Chamber probe plug located in the rear housing. If the alarm goes away, you know the problem is in the probe. If it doesn't go away, continue your way back towards the NIDAQ modules, checking the connections.

## Tracking Alarm

- The chamber temperature has been deviated from the target temperature for the programmed amount of time and temperature deviation.
- This alarm is self-correcting, which means that the alarm will reset once the values come back into range. Verify proper LN2 supply operation, i.e. correct pressure (18-22 psi, 22 psi max), and use of the shortest possible transfer hoses. Also, alarm time and deviation are saved along with the steps in a freezing profile. The default values are 5 degrees of deviation for 1 min. These may need to be adjusted depending on the installation of the user's LN2 supply and freezing program. Adjustments to the Default values can be made on the Program Screen.





**NOTE:** Custom BioGenic Systems Rate Freezers are Class A devices pursuant to FCC Part 15 Subpart B / ICES-003 IEC 61326-1:2012 / EN 61326-1:2013. A 'Class A' device may be marketed for use in a commercial, industrial, or business environment.


**CAUTION:** This is a Class A product. In a domestic environment this product may cause radio interference, in which case the user may be required to take adequate measures.

Custom BioGenic systems Rate Freezers have been tested to:

CAN/CSA C22.2 No. 61010-1:2012/R:2018-11, CSA C22.2 No. 61010-2-011:2019, UL 61010-1:2012/R:2019-07, EN 61010-1:2010/A1:2019, EN 61010-2-011:2019.

- The equipment has not been investigated for protection against ingress of water (IP code per IEC 60529)
- All wiring and installation shall be in accordance with electrical codes acceptable to the authorities in the countries where the equipment is installed and used.
- The equipment has been investigated for continuous operation in dry, pollution degree 2 environments at a maximum operating ambient temperature of 40°C.



 <b>Biolife Solutions</b> <sup>®</sup>	<b>Controlled Rate Freezer</b> <b>IntelliRate i67C Instructions for Use -</b> <b>English</b>	ES-RF-IFU-005-EN Page 55 of 55 Revision: ORG
Cryogenic Freezer Platform		

CHANGE HISTORY		
Revision	Reason/Description of Change	Effective Date
Original	Formal release of IFU – English version	10AUG2023