



Controlled Rate Freeze Thaw unit

CRFT

Operating Manual

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1. Introduction

1.1. Product Description

The Grant CRFT is a controlled rate freezer for biological material preservation. It is designed for use with pre-sealed vessels (e.g. CBS straws or cryovials) that act as effective containment of any possible biohazard.

The CRFT is not a Medical Device as defined by Regulation (EU) 2017/745, UK Medical Devices Regulations 2002, or any other international regulations on medical devices.

1.2. Product Accessories

The following optional extras may also be supplied with the CRFT freeze-thaw unit:

CRFT CRYOPEN Cryopen nucleating tool
CRFT CARTRIDGE Cryopen spare cartridges

Brief operating instructions for these product accessories are given in **Error! Reference source not found.**. Please refer to accessory manuals for full operating instructions.

2. How to use this Operating Manual

This operating manual will allow you to unpack, correctly set-up and operate the CRFT (henceforth referred to as "the equipment") both efficiently and safely. Important safety information is listed in the following section. The technical specification is included in section 4.

If there is a technical matter that this operating manual does not address or any other question concerning the equipment please do not hesitate to contact Grant Instruments (Cambridge) Ltd.

The general details of your warranty for the equipment are detailed in section 9.

3. Safety Information

3.1. Safety Compliance

The equipment meets the requirements of international safety standard IEC 61010: Safety requirements for electrical equipment for measurement, control, and laboratory use.

3.2. Meaning of safety symbols on equipment

The following symbols, on the equipment or documentation, mean:



Read these instructions before installation or use of the equipment



Warning, hazard: read these instructions before proceeding to ensure you understand the nature of the hazard.



Warning: cold surface - can be cold (-100 °C) during and after use.



Warning: hot surface - can be hot during and after use.

3.3. Safety Warnings

Always observe the following safety precautions:



Use only as specified by the operating instructions: if the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.



This equipment is only for indoor use by a professional user.



If the unit is used with accessories not provided or recommended by the manufacturer or in a manner not specified by the manufacturer, the protection provided by the unit may be impaired



Only connect the unit to the mains supply using the power supply unit and cables provided.



Ensure suitable protection is worn when accessing the freezing/thawing head, as temperatures down to -100°C can be reached during and after the freezing cycle



It is the user organisation's responsibility to carry out a risk assessment when operating this product within their own operating environment.



The equipment should only be used with sealed sample containers that are free from contamination on their exterior.



If a sample becomes stuck to the head do not attempt to lever it out as this may cause a breach of the containment of the sample leading to a biohazard as well as contamination/destruction of the sample.



It is the user organisation's responsibility to carry out appropriate decontamination if hazardous material is spilt on or inside the equipment.



Do not check the head temperature by touch as it may be very cold or very hot



Ensure that the mains switch and isolating device (mains plug) are easily accessible during use



Before moving, disconnect from the mains power supply.



If a warning message or warning light appears on the equipment, do not touch the freezing/thawing head - it may be very hot.



The equipment should be switched off immediately if the head temperature exceeds 40°C



The device contains a pressurised container and should not be incinerated.



Do not use the equipment in an area where there are aggressive or explosive chemical mixtures or atmospheres.

3.4. Cryopen Nucleating Tool

When using the cryopen nucleating tool (if supplied) read the instruction manual and safety instructions supplied with the product before use.



Ensure that suitable safety precautions are taken during use of the Cryopen and never point the device towards the face.

4. Technical Specification

4.1. Operating Conditions

The equipment is designed for operation in dry locations indoors in a standard laboratory environment with temperature and humidity control;

Ambient temperature: +20°C to +30°C Altitude: up to 2000m.

Humidity: maximum relative humidity 80 % for temperatures up to 31 °C

decreasing linearly to 50 % relative humidity at 40 °C

4.2. Electrical Details

Mains Supply: 100-240V, 50-60Hz 3.5A (max)

Permissible mains supply variation: ±10%
Unit Supply: 24V dc, 7A
Unit Power Consumption: 170W (max)

Pollution degree: 2

4.3. Physical details

Size WxDxH: 350 x 290 x 454 mm

Weight: 8.9kg

Operating (ambient) temperature limits: +20°C to +30°C Storage (ambient) temperature limits: -30°C to +40°C

4.4. Accessory interchangeable heads available

Model	Description	Compatible Vessels
H00	Head for 16 0.5ml CBS straws	Cryo Bio Systems straws (014650)
H01	Head for 18 0.3ml IMV straws	IMV Technologies straws (Paillette fine)
H02	Head for 55 1.8ml cryovials	NUNC cryovials (363401 - round)
	Max working volume per vial is 0.5 ml	NUNC cryovials (377267 – starfoot)
H03	Flat plate head	
H05	Head for 1 SBS microplate	NUNC cryobank, 96 2D tube system (374084)
		FluidX data matrix tube 96 (65-52319)
H06	Head for 55 1.8ml cryovials	NUNC cryovials (363401 - round)
	Max working volume per vial is 1.0 ml	NUNC cryovials (377267 – starfoot)

4.5. Performance

Max Head Temperature²: 30°C

Min Head Temperature²: Dependent on accessory head type

H00, H01, H03, -100°C H02, H05, H06 -80°C (typical)

Max Cooling Rate²: 10°C/min (dependent on model & head temperature)

Max Temperature Stabilisation Time¹ 5 minutes (all models)
Head Temperature Accuracy³ $\pm 0.5^{\circ}$ C (all models)
Head Temperature Stability² $\pm 0.1^{\circ}$ C (all models)
Head Temperature Uniformity² $< \pm 1.0^{\circ}$ C (all models)

^{1.} Time to achieve a stable 20°C start temperature from switch on

Unloaded head

^{3.} Calibrated accuracy taken as an average of 4 points at defined locations on an unloaded head

5. Installation

5.1. Unpacking

Standard equipment includes:

CRFT controlled rate freeze/thaw unit Power supply unit with mains lead adaptor USB communications lead Quick Start Guide Unpacking instructions

If the cryopen nucleating tool has been ordered in addition to the CRFT it will also be included.

Read and carefully follow the unpacking instructions included with the unit to ensure the unit is ready for installation and operation.

Remove packing materials carefully, and retain them for future shipment or storage of the equipment. Inspect the unit to ensure that no damage has occurred during transit. If the unit shows any sign of damage, or any items are missing, please contact Grant Instruments immediately.

When lifting the equipment place hands underneath the unit and do not move by pressing on the casework.

5.2. Equipment Position

Ensure the equipment is positioned on a flat, stable surface so that the side and rear vents are not blocked. Leave a clearance of at least 200mm all around the unit. Ensure that the unit is not placed directly in line with a heating or air conditioning vent, is protected from draughts from fans, doors or windows, is not near a radiant heater and is not in direct sunshine.

5.3. Electrical Connection

For normal connection to the mains, plug the external power supply into the 24 VDC socket at the rear of the equipment (Figure 1) and connect the mains plug into an appropriate single-phase mains supply which has an earth contact. If a UPS is being used, please read the instruction manual supplied with the UPS before use. If the mains power supply fails then the UPS should allow the equipment to complete any freezing cycle that is running.



Figure 1: Rear panel of CRFT unit

5.4. PC Setup

The equipment user software can be run on any laptop or desktop computer using Windows 7 or Windows 10. However, there are several elements that must be considered before starting any data run.

Ensure any laptop used has sufficient power to maintain its powered-on state during the whole run. For complete security, the laptop should be powered directly from the mains supply.

To ensure run data is not lost, check the power settings do not allow the laptop to go into standby or hibernation mode.

Do not close the laptop during a data run as this could cause a loss of run data.

5.5. Switching the Equipment On

Before switching on the unit, connect the USB communications lead between a USB port of the computer and the back of the equipment.

Switch on the equipment unit using the power switch on the rear panel of the unit (Figure 1: Rear panel of CRFT unitFigure 1). The On/Off indicator on the front panel illuminates red when the power is switched on (Figure 2).

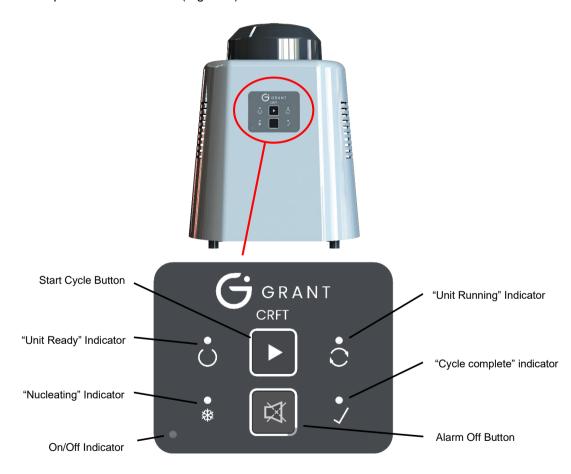


Figure 2: Front panel of CRFT unit

5.6. Fitting CRFT interchangeable heads



Align the notch on the head to the "unlock" symbol on the CRFT case. Carefully lower the head onto the unit, and twist clockwise until the notch aligns with the "Lock" symbol.

Figure 3: Fitting CRFT interchangeable head

6. Grant CRFT Software

The software described in this manual is Grant CRFT Software version 1.1

Grant CRFT Software is available free of charge from your main distributor or from Grant Instruments (Cambridge) Ltd.

6.1. Installation and Setup

6.1.1. Loading the software

The installation requires Windows 10 or Windows 11.

In addition to loading the Grant CRFT software you will also be installing the drivers for the USB to serial converter (FTDI). This will all be handled by the installer.

Administrator rights on the computer are needed to install the software requisites, software and USB to serial converter driver.

Visit the <u>CRFT product page – Grant Instruments</u>, at the bottom of the page will be a **Download** section where the CRFTInstaller.zip will be available for download.

Once downloaded open the file and run the setup installer (Setup.msi).

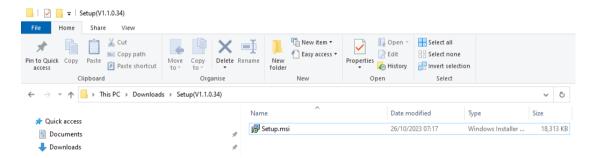


Figure 4: Installation

Ensure the CRFT is **powered on** and **connected via USB** to the PC. If the software is started before the unit is on and connected, the software will fail to find the unit and will need to be **restarted** to find it.

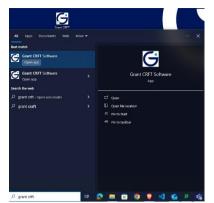


Figure 5: Desktop shortcut icon and windows start menu search

Start the software by either double-clicking on the shortcut icon on your desktop or by selecting 'Grant CRFT Software' from the program list in the start menu on your computer.



Figure 6: Loading splash screen

A loading splash screen will appear stating the software version number and the USB port the CRFT is connected into will be located.

6.1.2. Logging in

When the software is run for the first time the default User ID is **Admin** and the default Password is **Admin1** (see **Figure 7Error! Reference source not found.**). The **Admin** user is an administrator level user and has access to all software options. Other levels of access are available to Standard and Advanced users – these user levels can be set up via the Users page (see Section 6.8).

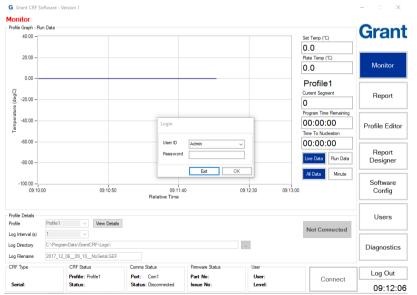


Figure 7: Log In

6.1.3. CRFT connection & synchronisation

If instructions were followed correctly up to this point the software should have located the CRFT com port automatically.

Wait at least 15 seconds after turning the CRFT on before trying to connect. To establish the connection, click the *Connect* button at the bottom of the software (see Figure 8**Error!**Reference source not found.). The CRFT and software will synchronise with each other. While this occurs, two bars show the progress.

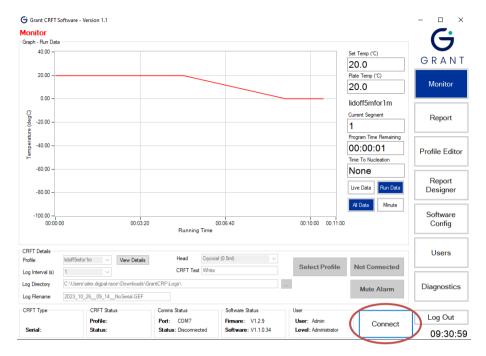


Figure 8: Connect

When the synchronisation is complete, the *Connect* button will change to *Disconnect* and the software will show *Status: Connected* (see Figure 9Error! Reference source not found.) in the Comms Status tile at the bottom of the panel. Other details such as the unit model and serial number will also be displayed. If the software fails to connect to the unit, see Appendix A1.3 for help.

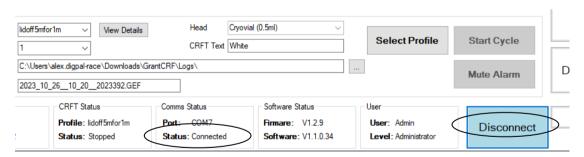


Figure 9: Connected

When the software and CRFT is connected the CRFT status and data will be viewable in the software and will be continually updated. The CRFT temperature will drift with the ambient temperature until a **profile** is **selected**.

The equipment will remain connected until the Disconnect button is pressed, always disconnect from the software first before powering off the unit or disconnecting the USB.

When a profile has been **created** and **selected** the system will be ready to use when the equipment head temperature has stabilised at the Start Temperature. This may take approximately 5 minutes and is viewable in the Monitor page when the **Plate Temp** reaches and settles on the **Set Temp**. Text will display whilst the temperature is being reached and the **Start Cycle** button will remain disabled (see Figure 10).

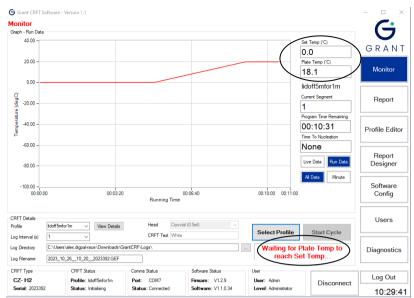


Figure 10: Profile selected

When the equipment has reached a stable temperature the **CRFT Status** tile will display 'Status: Ready'. See Figure 11 below. The 'Ready' orange light will illuminate on the equipment front panel and the **Start Cycle** button will be enabled.

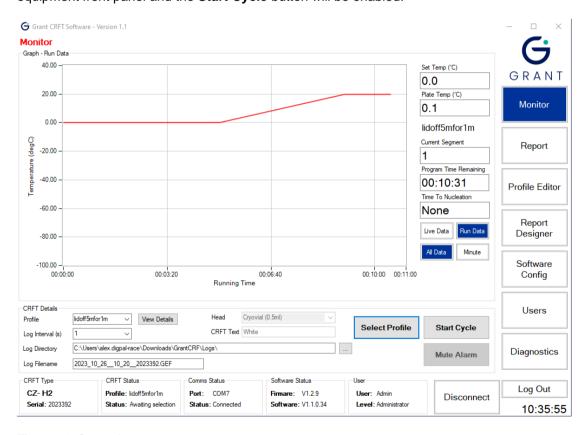


Figure 11: Status bar

The software suite can now be used to control the freezing cycle as well as configure the equipment, edit and create new freezing and thawing cycles, as well as generate reports with graphs and data of each freezing cycle run.

6.1.4. Software overview

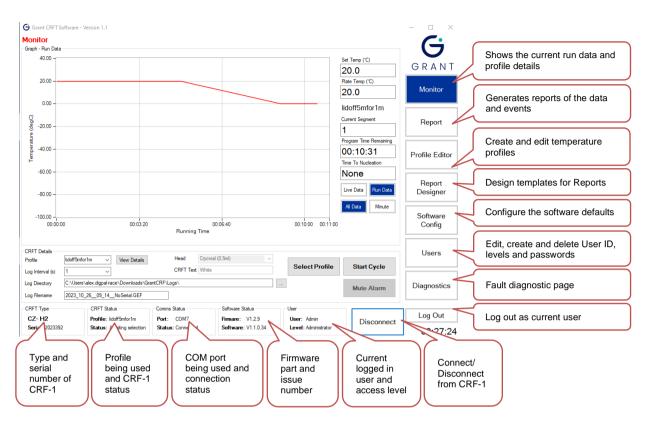


Figure 12: User Software Overview

6.2.

6.3. Creating a Profile

6.3.1. Profile Editor Page

To run a profile, it first needs to be setup and configured. Click on the **Profile Editor** button to view the Profile Editor page.

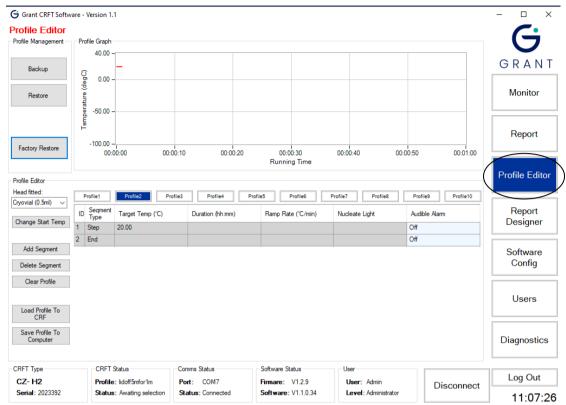


Figure 13: Profile Editor page

The CRFT has 10 internal slots for profiles to be saved to and are originally configured with blank profiles. When **connected**, editing the profiles will update the CRFT of any changes instantaneously.

Note: When making significant changes to a profile a backup of all or individual profiles should be made to avoid losing any data

Note: The CRFT is designed for use by a professional user, it is the user's responsibility to ensure the profile created or used meets their needs.

The **Profile Editor** page contains three windows:

Profile Management – provides backup and restore functions for profiles
 Profile Graph – provides a graph of the selected profile
 Profile Editor – shows all the parameter values of the selected profile and enables editing of a profile or the creation of a new one

The following sections provide information about how to change heating and cooling profiles.

6.3.2. Changing the start temperature

After selecting one of the profiles (1-10) to edit, click *Change Start Temp* to change the profile start temperature. Update the *Start Temp* box with the required value and click *Set Temp* in the *Set Start Temp* dialog box (see Figure 14). Click *OK* in the *Confirm* dialog box to apply the change to the selected profile.

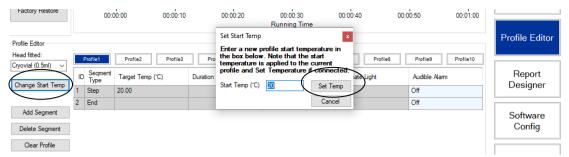


Figure 14: Change start temp of profile

6.3.3. Changing the Profile Head type

Before producing a cooling and heating curve consideration should be made into which head type will be fitted when this profile is run. There are 6 different heads to choose from, and the range of allowable temperature and rates differ for 2 sets of 3 heads.

1 set of heads (H00, H01, H03) have a temperature of -100C to 30C with a max heating/cooling rate of 10C/min.

The other set of heads (H02, H05, H06) have a temperature range of -80C to 30C with a max heating/cooling rate of 5C/min.

Note: The head type is changeable at any point of profile editing however values out of range will be changed to be within the acceptable range.

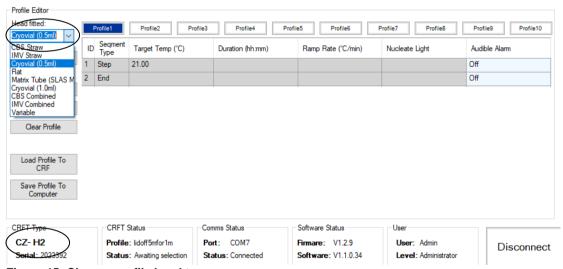


Figure 15: Change profile head type

Note: Changing the **Head fitted** will change the **CRFT Type** parameter with the correct head index, see Figure 15.

6.3.4. Adding a segment

A Profile is made up of a maximum of segments, there are three different types of segments to choose from.

- A Dwell will hold the temperature of the previous segment for a chosen length of time.
- A Rate will change the **Set Temperature** of the CRFT and will heat or cool the **Plate Temperature** in a **controlled** way where a Rate in C/min is configurable.
- A **Step** will change the **Set Temperature** of the CRFT and will heat or cool the **Plate Temperature** as fast as possible in an **uncontrolled** way.

To add a segment to the profile click **Add Segment** this will add a new segment at the end of the profile, to add in a different place click the segment ID above the intended place to add a segment.

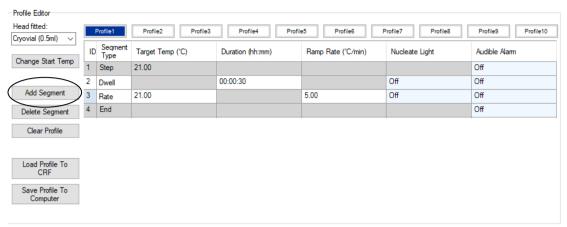


Figure 16: Adding a segment to a profile

The default segment added is a **Dwell** of 30 seconds. To change the **Segment Type** click the **Segment Type** column of the segment. A menu will display allowing selection of one of the three segment types available.

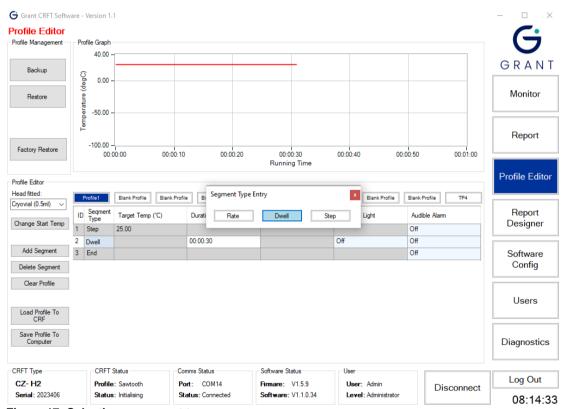


Figure 17: Selecting a segment type

A profile has a maximum of 25 segments that can be added. There are certain rules that need to be follow when adding segments. A **Rate** segment must always be proceeded with a 30 second **Dwell**. The software should add in a **Dwell** above any **Rate** segment added.

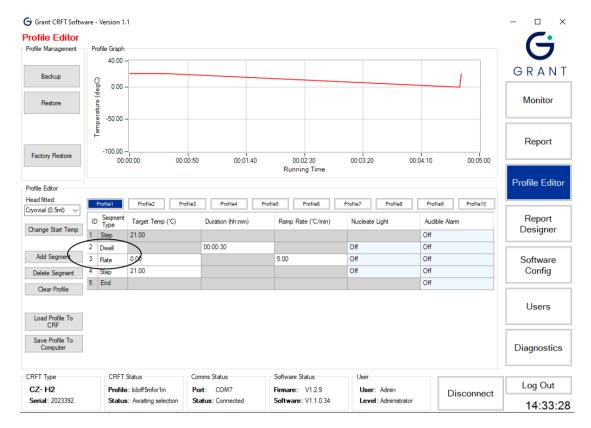


Figure 18: A Rate must be proceeded by a Dwell

6.3.5. Deleting a segment

Click the *ID* box of the segment to be deleted. The number is highlighted in light blue to show it has been selected. Click the *Delete Segment* button. The segment is removed and the ID numbers for the other segments are adjusted.

6.3.6. Clearing a profile

Clearing a profile will remove all segments. Click the **Clear Profile** button. Accept the **Profile Warning** to confirm the deletion of the selected profile (see Figure 19**Error! Reference source not found.** – the profile name highlighted in blue – in this example this is 'Profile1').

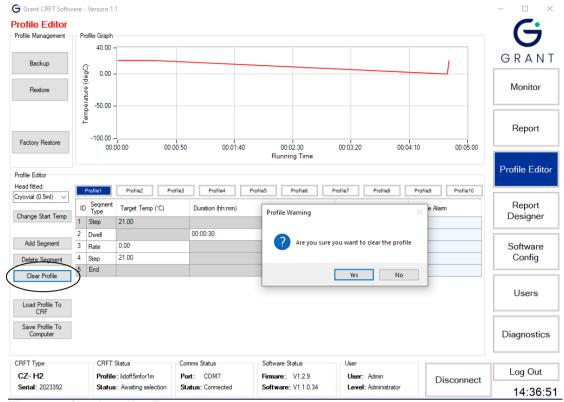


Figure 19: Clearing a Profile

6.3.7. Configuring a segment's parameters

A **Dwell** segment has a single **unique** configurable parameter, **Duration** must be a minimum of 30 seconds. Clicking the **Duration** column of the segment to edit will bring up a menu to change the hours, minutes, or seconds.

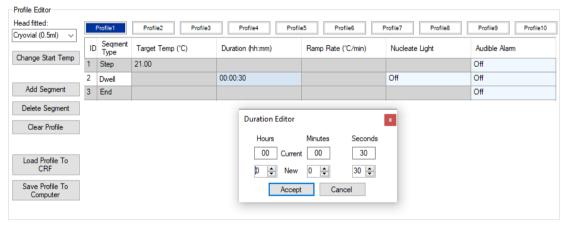


Figure 20: Configuring a Dwell

A Rate segment has two unique configurable parameters. Double click the segments **Target Temp** column to edit the value within range of the selected **Head fitted** type, when finished press **Enter** on the keyboard for the changes to be saved to the unit. **Ramp Rate** can be edited in the same way.

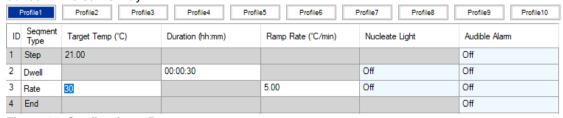


Figure 21: Configuring a Rate

A **Step** segment has a single unique configurable parameter. **Target Temp** is edited in the same way as in a **Rate**.

All three segments have two common configurable parameters. **Nucleate Light** is a parameter that controls the state of The orange 'Necleating' light on the CRFT control panel. It can be used to signal a certain event has happened on a segment e.g., Nucleation has occurred. The **Audible Alarm** parameter works in a similar way however outputs an alarm on the unit speaker where it can be used to signal a certain event has happened on specific segment/s.

6.3.8. Changing a profile name

To change a profile name, single click the profile name box if it is already selected, the name box will turn from dark blue to grey. If **unselected**, double click the profile name box. Type in the new profile name (up to 16 characters only) and press 'enter'. The profile name box will then turn back to dark blue to show its **selected**.

6.3.9. Segment ID

The ID is the numerical position of the segment in a profile. It is automatically adjusted by the software.

6.3.10. Saving & loading profiles

Profiles created can be saved onto the PC such that they can be restored in the future. This also allows many profiles to be created and stored without exceeding the limit of 10 profiles available in the CRFT. Saved profiles can be loaded back into the CRFT in place of any other profile.

6.3.11. Saving profiles to the computer

Click on the name box of the profile to be saved. The name box turns dark blue and the **Profile Graph** window will show the profile curve. Click **Save Profile To Computer**. The **Save As** dialog box opens with the default file name. Click **Save** to save with the default file name.

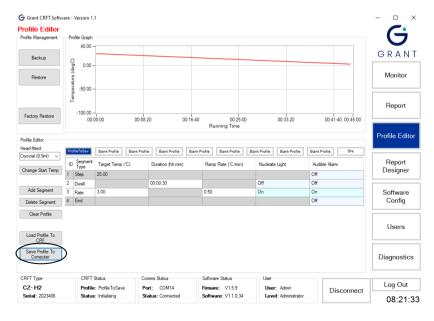


Figure 22: Saving a Profile to the computer

Note: It is advised to rename a default profile e.g., Profile2 before saving. Profiles can be loaded into any slot, and it may be confusing to load in Profile2 to slot 8 when it comes to selecting profiles.

6.3.12. Loading profiles to the CRFT

Note: The CRFT must be connected and synchronised before profiles can be loaded to it.

Click on the name box of the profile from the 10 displayed on the screen where the profile is to be loaded. The name box turns dark blue.

Note: When a profile is loaded into a specific slot it will overwrite (permanently) the previous profile stored. Care and consideration should be taken before loading profiles as information can be lost.

Click **Load Profile To CRFT**. The **Open** dialog box opens in the default profiles directory and shows all saved profiles. Select the profile then click **Open** to load the profile. The profile is loaded to the CRFT and the name box initially highlighted will now display the name of the new profile.



Figure 23: Loading a profile into the CRFT from the PC

6.3.13. Creating & restoring backups

A back up of all profiles can be saved onto the PC such that they can be restored in the future if necessary.

Note: To create a backup of profiles that are installed in the CRFT then the unit MUST be switched on and connected. Taking a backup when not the CRFT is not connected will only back up offline profiles.

6.3.14. Creating a backup

Click on **Backup** in the **Profile Management** window to create a backup of all of the profiles. A **Save As** dialog box opens (see **Error! Reference source not found.**). Edit the backup name if required and click **Save**.

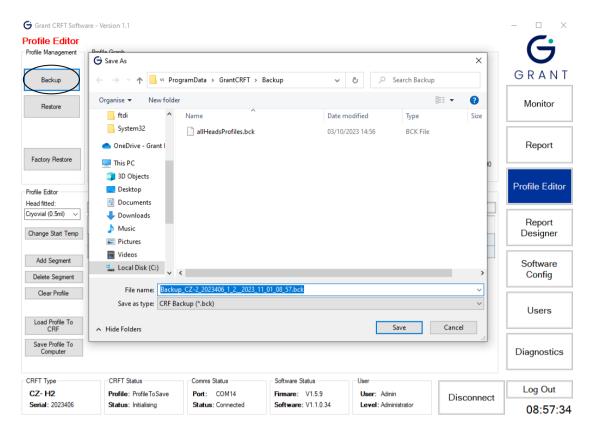


Figure 24: Creating a backup of all profiles

6.3.15. Restoring a backup

Click on **Restore** in the **Profile Management** window to restore a backup of all the profiles. Select the backup file to restore from the list (or navigate to where you saved the back-up files) in the **Open** dialog box and click **Open**. The **Restore Profile Selection** dialog box opens. Tick the checkboxes of the individual profiles that you wish to restore. Leave all checkboxes ticked to restore all profiles. Click **Accept** to confirm the restore.

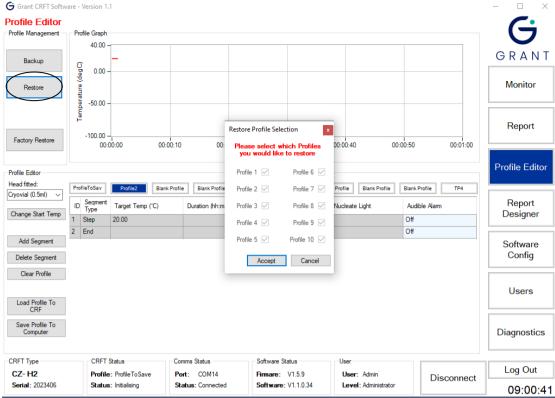


Figure 25: Restoring all profiles from a backup

6.3.16. Completing a factory restore

To completely wipe the CRFT of all profiles and reset to the default blank profiles originally set, press the **Factory Restore** button in the **Profile Management** section.

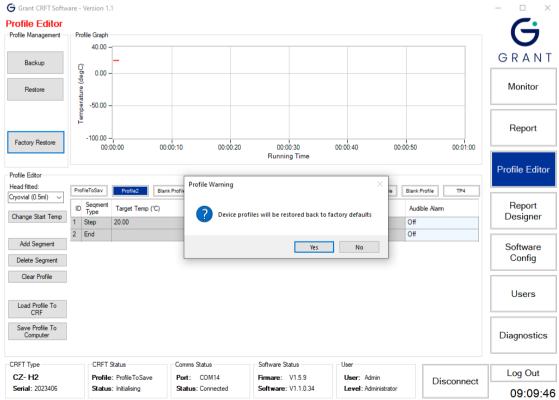


Figure 26: Factory restore the CRFT

A warning will pop-up to confirm the resetting of the CRFT.

6.4. Running a Profile

Once the profiles are setup and configured they are ready to be run on the CRFT. To select a profile to run go to the **Monitor** page.

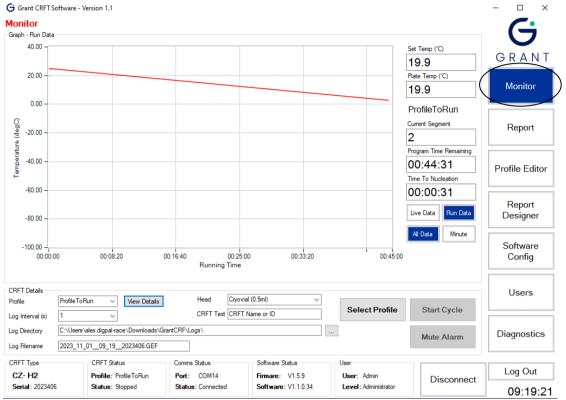


Figure 27: Monitor page

6.4.1. Selecting the profile & details

Before running a profile check the following are correct:

- The heating and cooling curve
- The logging interval
- The name and storage folder of the log file

6.4.2. Setting the log file parameters

Set the Log Interval, Log Directory and Log Filename in the Profile Details window.

Note: Shorter logging intervals and long cryopreservation profiles result in very large log files that may not provide any more information. For applications that need prolonged freezing stages, the interval can be increased to up to 60 minutes between logging points dependent on application.

The location and filename of the directory where the log files are stored should be confirmed before starting the run.

Note: The default settings for the profile details can be changed using the Software Config page (see Section 6.7 for further details)

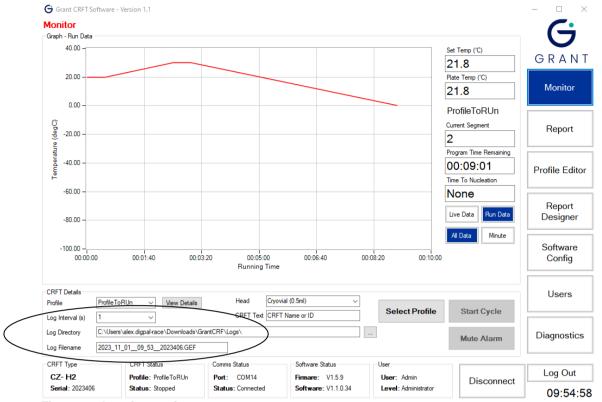


Figure 28: Logging settings

6.4.3. Choosing the profile to run

In the **CRFT Details** window choose a profile from those loaded on the CRFT from the **Profile** drop down field. The specific temperature details of the chosen profile can be viewed by clicking on the **View Details** box. This will help ensure you have chosen the correct profile before it is run.

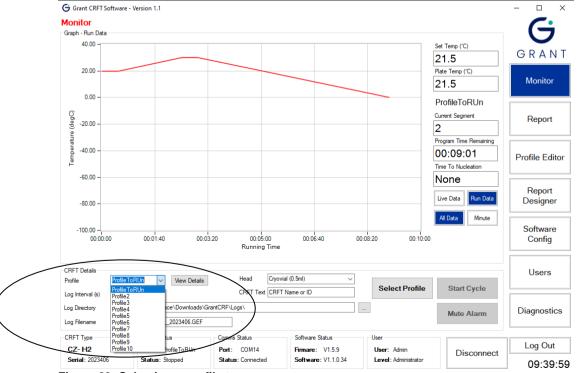


Figure 29: Selecting a profile to run

After selecting a profile from the **Profile** drop-down field click **Select Profile** to load the selection into the CRFT. Red text will display stating the CRFT is now trying to reach temperature and the CRFT Status will change to **initialising**.

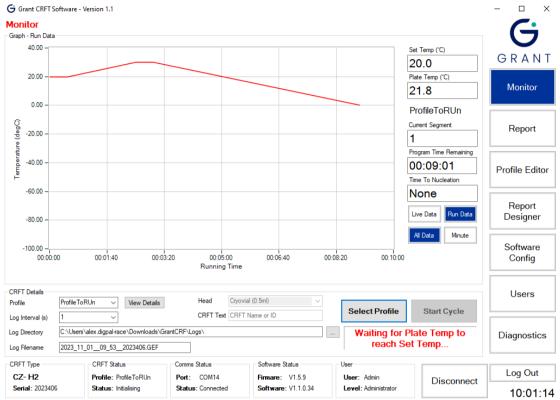


Figure 30: CRFT initialising

6.4.4. Running the profile

Once the CRFT has settled on the target temperature the green 'Unit Ready' light will display on the front panel of the CRFT, the **Start Cycle** button will be enabled allowing the profile to be run.

Load the samples onto the head according to the appropriate protocol, wait for the temperature to settle again then click **Start Cycle** button.

The CRFT Status will change to **Run** and the green 'Unit Running' light will be displayed on the CRFT, the **Start Cycle** button will change to display **Stop Cycle**.

The Graph will display the progress of the selected profile, the data is updated at 1 second intervals.



Figure 31: Profile ready to run

Note: Not waiting for the CRFT head and samples to settle before starting may cause control problems.

Note: Clicking the Stop Profile button will abort the run and the CRFT will return to the start temperature.

Once the run has completed the CRFT will hold the **Plate Temp** to the final **Set Temp** until the profile is stopped. Press **Stop Cycle** to stop the profile run, allowing the CRFT to drift back up to ambient.

6.5. Creating reports

6.5.1. Generating a run report

6.5.2. Report formats

The software stores log files and an event log in an encrypted GEF file format. This ensures that source files cannot be altered without detection and are suitable for validation and archiving purposes.

Four reports can be produced from the encrypted log file using the *Report* page:

- PDF Detailed Report: Includes a graph of the actual and set temperatures, a profile summary section, a notes box for handwritten information and a quality control box which gives a detailed analysis of each profile segment.
- PDF Standard Report: As the PDF Detailed Report except with no quality control analysis box.
- TSV Detailed Report: Includes a profile summary section and a quality control box which gives a detailed analysis of each profile segment. Suitable for a program capable of displaying TSV (Tab Separated Variable) data such as Excel.
- **TSV Standard Report:** As the TSV Detailed Report except with no quality control analysis box.

6.5.3. Generating PDF reports

Click **PDF Standard Report** or **PDF Detailed Report** to produce a PDF report. Browse to an GEF log file using the dialog box which appears then click **Open**. The relevant report will appear in the viewing area. The report can be saved or printed by clicking on the **Save** or **Print** buttons at the foot of the page.

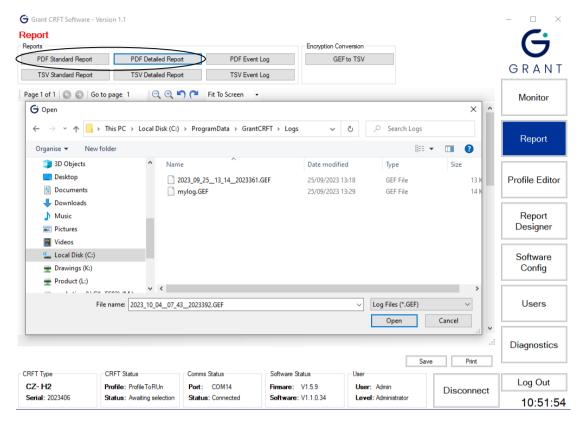


Figure 32: Generating PDF Reports

6.5.4. Generating TSV reports

Click **TSV Standard Report** or **TSV Detailed Report** to produce a TSV report. Browse to an GEF log file using the dialog box which appears then click **Open**. The relevant report should be saved in a suitable location using the dialog box which appears (see Figure 33).

Note: The TSV will not appear in the viewing area.

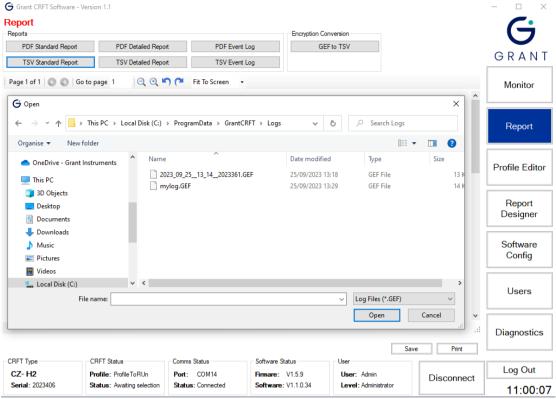


Figure 33: Generating TSV Report

6.5.5. Running a TSV log file conversion

Click **GEF to TSV** in the **Encryption Conversion** window on the **Report** page. Highlight the GEF file to convert and click **Open**. The TSV file should be saved in a suitable location using the dialog box which appears.

Note: The conversion provides a TSV file of the data log file (all data points recorded) rather than a summary of the profile run.

6.5.6. Generating an event log report

The software automatically creates a log of all key events as an encrypted GEF file. This information includes every user interaction, condition and profile status. Click *PDF Event Log* in the *Reports* window on the *Report* page. Highlight the event log GEF file and click *Open*. The PDF report will appear in the viewing area. The report can be saved or printed by clicking on the *Save* or *Print* buttons at the foot of the page.

A TSV format report can also be generated using the above method.

Note: The location of the event log can be changed according to your file system

6.6. Designing and configuring reports

The reports created are based on a standard template that can be customised via the **Report Designer** page.

6.6.1. User defined report header

The **Report Template** has two header fields at the top of the report which can be determined by the user. The header fields on the top left and top right can be set to either an image or text using the **Text** box or the **Logo** box. Figure 34 shows an example where '**Grant.jpg**' has been added to the left-hand **Logo** box and '**Program Series A1**' text added to the right-hand

Text box.

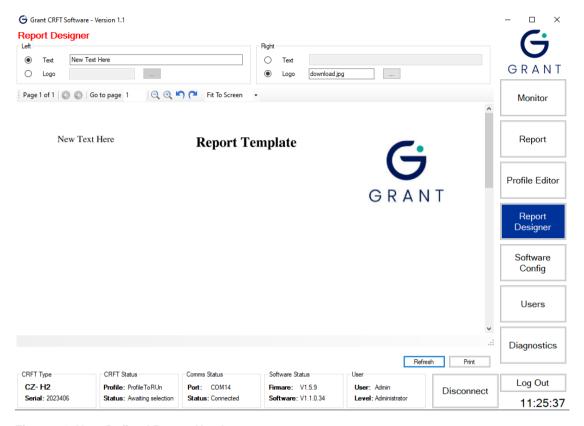


Figure 34: User Defined Report Header

These user defined conditions will appear at the top of a generated report.

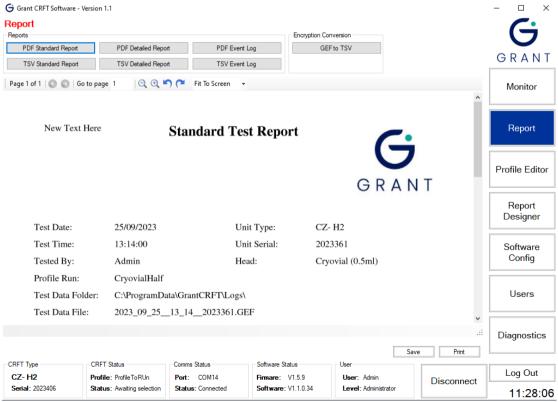


Figure 35: User Defined Report

6.6.2. Report template storage location

The default storage location of the report template is defined in the **Report** window on the **Software Config** page. This location can be changed if required.

6.7. Configuring the software

All parameters and defaults can be changed in the **Software Config** page.

6.7.1. Log file configuration options

The default directory where the log files are stored is not normally in the folder where the main software is located. The default log file location is: C:\ProgramData\GrantCRFT\Logs

The log file location can be varied to suit your file set up and can be a network share. Click on the "Browse for Folder" button next to the **Default Dir** option to choose a new location see Figure 36.

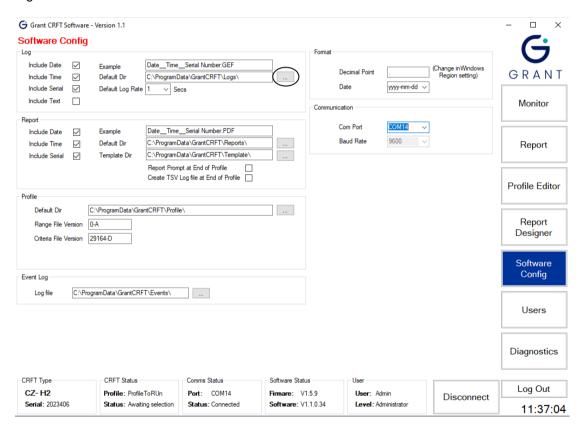


Figure 36: Log File Configuration Options

Note: Ensure that the Windows User has WRITE permissions to the folder where the log file is stored otherwise data may be lost.

By default, each log file will be named based on a combination of *date_time_serial-number.GEF*. The GEF file is an encrypted format that can be automatically converted to .PDF or .TSV (Tab Separated Variable) by the reporting function.

If date, time or CRFT serial number is not required in the log file name, then the default situation can be overwritten. In the example below **Include Date** and **Include Time** box have been unchecked so date or time is not in the log file name box.

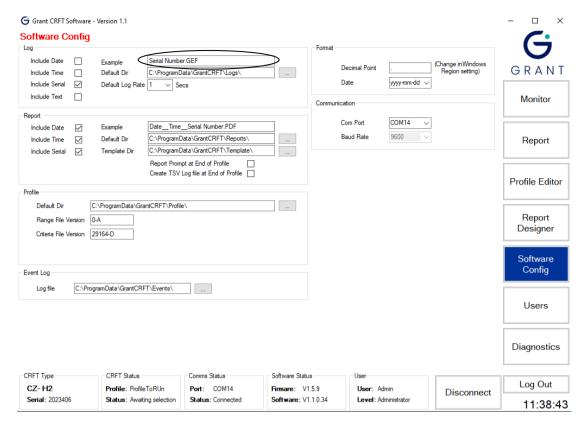


Figure 37: User Defined Conditions

To add user specific text to the file name, such as an assay name, ensure that the **Include Text** box in the **Log** window on the **Software Config** page is checked.

When Include Text box is checked – a User Text box next to the Log Filename box on the Monitor page becomes visible, see Figure 38 (with example user text of 'Test A235' in the User Text box which then appears in the name of the file in the Log Filename box)

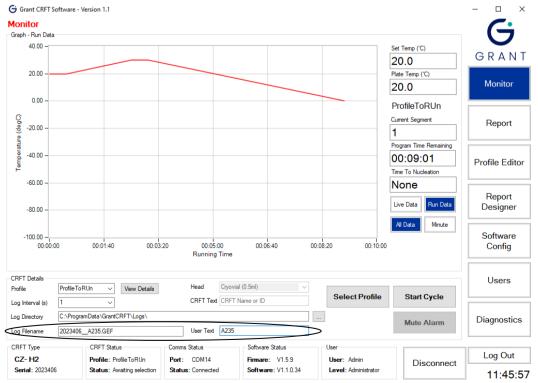


Figure 38: User Text

6.7.2. Report configuration options

The default storage location and naming format for reports is defined in the **Report** window on the **Software Config** page. The default report name is composed of three fields **Date_Time_Serial Number** in a similar manner to the log file naming. If any of these fields is not required then the relevant box (**Include Date, Include Time, Include Serial**) should be unchecked.

Note: The report name can be changed when it is being saved if required

6.7.3. Profile configuration options

The **Default Dir** box in the **Profile** window defines the default storage folder for saved profiles. This location can be varied to suit your file set up and can be a network share. Click on the "Browse For Folder" button next to the **Default Dir** box to choose a new location.

Note: Other software config options in the profile window should not be altered.

6.7.4. Event log configuration options

The **Log file** box in the **Event Log** window defines the default storage folder for the event logs. The event log location can be varied to suit your file set up and can be a network share. Click on the "Browse For Folder" button next to the **Log file** box to choose a new location.

6.7.5. Format configuration options

The **Decimal Point** indicator and **Date** boxes allow specific formats to be set. The defaults are a 'full stop' for decimal point and yyyy-mm-dd for the date. Three formats are available for the date format.

6.7.6. Communication configuration options

The appropriate **Com Port** that is connected to the CRFT can be set using this option.

6.8. Users

The software is programmed with one administrator level user: User ID: *Admin*; Password: *Admin1*. It is recommended that this user is employed as the main administrator and is not deleted. The password can be changed if required using the notes below.

6.8.1. Creating new users

New users can only be created when logged on as **Admin** or another administrator level user. Click **Users** to open the **Users** page. The first user in the list will be highlighted in blue and the **User Details** for that user will be shown (see Figure 39).

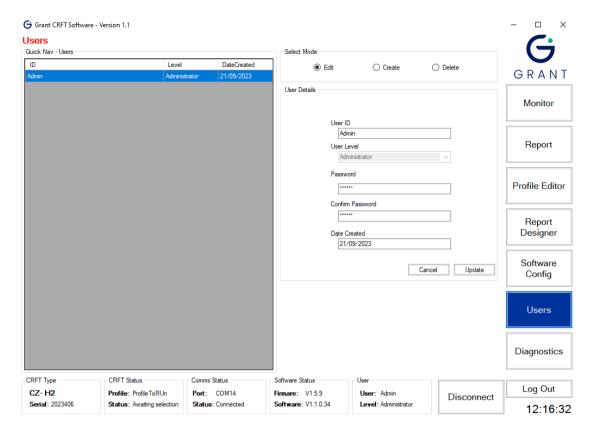


Figure 39: User Details

Select **Create** from the **Select Mode** window. The fields in the **User Details** become available to enter user data. Enter the required information and click **Update**. The new user appears in the **Quick Nav – Users** window.

The **User Levels** are defined as follows:

Administrator – has access to all areas of the software with the ability to make changes. **Advanced** – has access to Monitor, Reports, Profile Editor and Report Designer only. **Standard** – has access to Monitor and Reports only.

6.8.2. Editing existing users

Click the user that needs to be changed in the **Quick Nav – Users** window. Select **Edit** from the **Select Mode** window. The fields in the **User Details** are updated to show the selected users information. Update the required information and click **Update**.

Note: Be sure not to edit the Administrator's User Level. If there is no user with Administrator permissions, it will be necessary to reinstall the software to make significant changes.

6.8.3. Deleting existing users

Click the user that needs to be deleted in the **Quick Nav – Users** window. Select **Delete** from the **Select Mode** window. Click **Update** to remove the user.

Note: Deleting a user cannot be undone and the user that is currently logged on cannot be deleted.

7. Operating Procedure for the equipment

7.1. Pre-operation Checks

Before operating, ensure that:

The CRFT has been installed, selected head has been fitted and switched on (Section 5)

The software suite has been opened and communications established (Sections 6)

It is recommended that an initial test run is completed using the maximum volume of liquid allowed at the fastest cooling rate to ensure that everything has been set up correctly. This should be done before first use or if the unit has been transported to a different location and is especially important when using the H03 flat plate head where the mass of the user supplied vessel and the effectiveness of its thermal coupling to the head could adversely affect performance. It is also recommended that this test is repeated periodically to ensure consistency of results.

7.2. Nucleating Tool Preparation

The cryopen is a medical device that can be used to nucleate the samples in a sterile environment. If the cryopen has been ordered with the equipment, please refer to its operating instructions on how to prepare and use it.

Alternative tools for nucleating (e.g. forceps) may be used if sterility of the operating environment is not essential.

7.3. Sample Preparation

Before preparing samples, remove the lid and check that the interchangeable head is dry. If there is any condensation on the head, gently dry it with a tissue or soft cloth. The head should never be dried using a hot-air gun as this could result in damage to the equipment. Care should also be taken not to damage or scratch the surface of the head during drying or cleaning.

Samples should not be added to the head until the 'Ready' light on the front of the equipment has illuminated.

7.3.1. Head H00 - 0.5ml CBS Straws

Load up to 16 high security straws with samples for freezing and seal as recommended by the manufacturer. Thoroughly dry the outside of the straws after preparation to prevent them from freezing to the head.

Position the straws into the head and fully press them into the grooves (Figure 40). Place the lid over the head checking that it is located correctly. Straws should be positioned such that the samples are in the centre of the head; the label section of the straw can overhang the head if required.

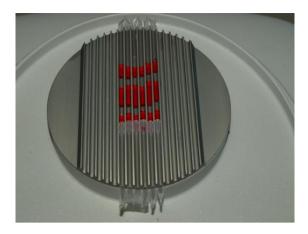


Figure 40: 0.5ml CBS straws positioned on H00 head

7.3.2. Head H01 - 0.25ml IMV Straws

The H01 is designed for 0.25ml capacity straws, for example the CBS Paillette Cristal. Load up to 18 straws as normal and seal with a straw plug, cristaseal etc. Thoroughly dry the outside of the straws after preparation to prevent them from freezing to the head.

Position the straws into the head and fully press them into the grooves (Figure 41). Place the lid over the head checking that it is located correctly. Straws should be positioned such that the samples are in the centre of the head; the straw plug should overhang the head if required.



Figure 41: 0.25ml IMV straws positioned on H01 head

7.3.3. Head H02 - 1.8ml Cryovials, 0.5ml max fill

The H02 is designed for 12.0mm diameter cryovials including Nunc 363401 and Nunc 340711. The maximum fill for each cryovial is 0.5ml. Load up to 55 cryovials on the head. Cryovials should always be loaded starting at the centre of the head. Thoroughly dry the outside of the cryovials after preparation to prevent them from freezing to the head.

Position the cryovials (Figure 42). Place the lid over the head checking that it is located correctly.



Figure 42: Cryovials positioned on H02 head

7.3.4. Head H03 - Flat Plate

The H03 is a flat plate to accommodate non-standard vessels.

Note that it is recommended that the user performs one or more test runs to ascertain that the required cooling rate can be achieved with the intended vessel and volume of liquid, see Appendix 1 for more help.

Place the vessel at the centre of the head such that contact with the head is maximised to achieve the best thermal transfer required for freezing. Once in position, place the lid over the head checking that it is located correctly.

7.3.5. Head H05 - 1 SBS microplate

The H05 is designed a single SBS type microplate including the NUNC cryobank (374084) and FluidX data matrix tube (65-52319). The head matches the footprint of the microplate exactly. Position the microplate such that the rack is securely located and the tube bottoms are in good thermal contact with the head (Figure 43: SBS microplate positioned on).

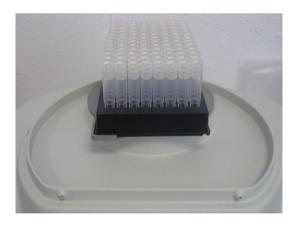


Figure 43: SBS microplate positioned on H05 head

Once in position, place the lid over the head checking that it is located correctly.

7.3.6. Head H06 - 1.8ml Cryovials. 1.0ml max fill

The H06 is designed for 12.0mm diameter cryovials including Nunc 363401 and Nunc 340711. The maximum fill for each cryovial is 1.0ml. Load up to 55 cryovials on the head. Cryovials should always be loaded starting at the centre of the head. Thoroughly dry the outside of the cryovials after preparation to prevent them from freezing to the head.

Position the cryovials. Place the lid over the head checking that it is located correctly.

7.4. Starting the Cycle

When the samples have been positioned correctly, put the lid back on. A few more minutes may be required for the head temperature to stabilise again. When it is ready to start, the **Start Cycle** button will enable.

Follow the instructions below to start the profile.



Figure 44: Monitor Panel. Ready to start

Once started, the **CRFT Status** will change to 'Run' and the head temperature data is plotted on the graph.

During the cycle, the temperature of the head is logged automatically in an encrypted format. The data is stored in the file location shown on the Monitor panel. At the end of the cycle the data can be used to create a report or analysed for quality control purposes.

Note that the 'Ready' light on the equipment may remain on for a short time at the same time as the 'Cycle' light. It will switch off automatically when the temperature starts to decrease.

7.5. Sample Nucleation

The Monitor Panel constantly shows the time remaining and also shows the **Time To Nucleation** if configured.



Figure 45: Monitor Panel. Time to Nucleation

When the samples reaches the nucleation point, the time displayed changes to **Nucleate**. The alarm may sound (if also configured) and the **Nucleate light** on the equipment illuminates. Nucleation should be done at this time.

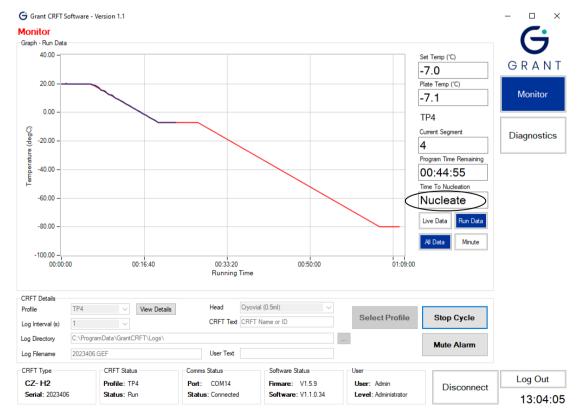


Figure 46: Monitor Panel. Nucleate

Remove the lid of the equipment completely. Turn off the buzzer by pressing either the **Mute** button on the CRFT keypad or on the software screen. Start the nucleating process using the chosen nucleating tool, as per their operating instructions.

7.6. End of Profile

When the profile is complete the **Program Time Remaining** will show **Complete** on the Monitor panel. On the equipment the **Complete light** will illuminate. The samples can now be removed from the equipment and placed in long term storage. The equipment will hold at the final temperature of the cycle until the **Stop Cycle button** is pressed or the equipment is switched off. Head temperature data will continue to be logged.

7.7. Stopping the Cycle and Generating a Report.

When all the vessels have been transferred, click on the **Stop Cycle button** on the software Monitor panel. Temperature logging will stop, and the unit will return to the start temperature.

A message box will appear asking if a report is required. Click **Yes** to generate a report in pdf or TSV (tab separated value) format. Click **No** if a report is not required immediately. It is recommended that a report is generated and checked after each run.

Reports can still be generated at any time after the cycle has been stopped using the Report Panel.

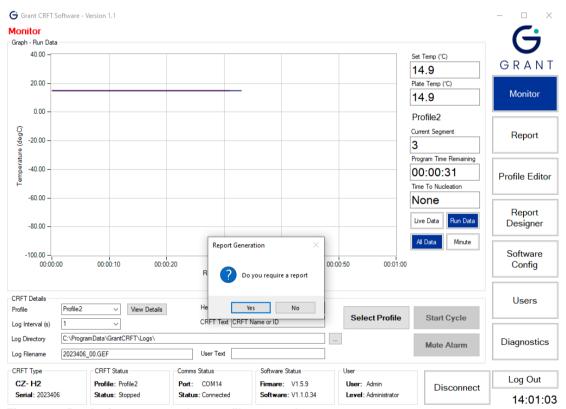


Figure 47: Producing a report when profile stopped

7.8. Starting a New Cycle

To start a new cycle click **Select Profile**, the **CRFT Status** will change to **Initialising** again and the CRFT will start to reach temperature the instructions can then be begun again.

Remember to dry the interchangeable head between cycles to prevent vessels sticking during the freezing cycle.

8. Maintenance and Service

No routine maintenance is required except for cleaning, there are no user serviceable parts inside the equipment.

Warning: Attempted disassembly could cause damage that could seriously affect the operation of the unit and its ability to follow the desired temperature profile.

8.1. Cleaning

The equipment and interchangeable heads are designed to be easily cleaned and sterilised. It is important to use a cleaner which does not leave a residue and will not attack the heads (chlorine based products must not be used).

We recommend the use of Klercide™ Sporicidal Low Residue Peroxide (formerly known as Premier Klercide™ -CR Sterile Filtered Biocide C) which meets these requirements. Before using any other cleaning or decontamination method, check with Grant Instruments to ensure that the proposed method will not damage the equipment.

Side and rear vents should be kept clean and free of dust to ensure good ventilation.

If a potentially hazardous liquid is spilt onto the equipment, disconnect it from the power supply and have it checked by a competent person. It is the user's responsibility to carry out appropriate decontamination if hazardous material is spilt on the equipment.

8.2. Replacement parts

The following is a list of purchasable spare parts:

8.3. Service & Calibration

If any unit servicing is required, switch off the unit and contact Grant Instruments.

Grant recommends the equipment is calibrated annually.

Servicing and calibration should only be completed by Grant Instruments Service Department or via a Grant Instruments worldwide distributor.

A service contract for the equipment is available. For full details of the service contract, calibration and verification please contact Grant Instruments.

Service Department Grant Instruments (Cambridge) Ltd Evolution House, Unit 2 Durham Way, Royston Gateway, Royston SG8 5GX England.

Tel: +44 (0) 1763 260 811

E-mail: service@grantinstruments.com

9. Warranty

The warranty period for the equipment is **two years**. Please visit www.grantinstruments.com/support to register your warranty.

Additional extended warranties are available from Grant Instruments and their distributors. These warranties are chargeable and will be added onto your standard free warranty period. A warranty certificate will be supplied. This should be retained and submitted should a repair be necessary during the extended warranty period.

For details of extended warranties please contact the sales department at Grant Instruments. salesdesk@grantinstruments.com

10. Product Compliance

10.1. Disposal & WEEE

In Europe, at the end of its life the equipment must be disposed of in accordance with the WEEE directive. For information regarding WEEE collections in the UK please contact our B2B Compliance Scheme directly on +44 1691 676 124.

Grant Instruments complies fully with the EU Waste Electrical & Electronic Equipment (WEEE) regulations 2006. We are a member of the B2B compliance scheme (Scheme Approval Number WEE/MP3338PT/SCH), which handle our WEEE obligations on our behalf. Grant Instruments have been issued with a unique registration number by the Environmental Agency; this reference number is WEE/GA0048TZ.

For other countries please contact your equipment supplier.

For General WEEE information please visit: www.b2bcompliance.org.uk



Please note that because it contains a pressure vessel the CRFT series freezer is treated as "Special Waste".

10.2. RoHS Directive

This product complies with the requirements of the UK Restriction of the Use of Certain Substances in Electrical and Electronic equipment Regulations 2012 and the EU RoHS Directive (2011/65/EC including 2015/863). This means the products are free of Lead and other hazardous substances covered by the directive.

10.3. Electrical safety and Electromagnetic compatibility

This product complies with the requirements of the UK Electrical Equipment (Safety) Regulations 2016 and the European Union Low Voltage Directive (2014/35/EC) for Electrical safety.

This product complies with the requirements of the UK Electromagnetic Compatibility Regulations 2016 and the European Union EMC directive (2014/30/EC).

10.4. REACH Regulation

This product does not contain any substances of very high concern (SVHCs) at greater than 0.1% that must be identified in accordance with Regulation (EC) No 1907/2006 and therefore does not have an entry in the SCIP database.

Appendix 1 Troubleshooting

A1.1 Loud Mechanical Clicking or Tapping Noise or Unit Fails to Follow Cooling Ramp

If there is a loud noise then switch the power off immediately as permanent damage can occur. The noise is caused by the pistons in the Free Piston Stirling Compressor hitting each other, usually because the system is overloaded.

Some causes and solutions are listed below:

Too large a mass on the head – reduce the total number of containers or reduce the volume in each container if using a standard head or reduce the mass of or volume of liquid in a non-standard vessel used with the H03 flat plate head.

Too high a cooling rate has been selected – either reduce the mass on the head as indicated above or reduce the cooling rate.

The unit is in a high ambient temperature—ensure that the unit is operating in an ambient of less than 30°C, is not placed directly in line with a heating or air conditioning vent or radiant heater and is not in direct sunshine.

A1.2 No Power To Unit

The power switch is switched to the OFF position Switch on. The power switch will illuminate red.

The power lead is not properly connected to the unit Check the power lead is properly connected into the rear of the unit.

There is no power to the power lead Check the power lead is plugged into a socket and that the socket is switched on.

The protective fuse in the equipment unit has blown Contact Grant Service Department.

A1.3 The Software Suite will not Communicate with the Equipment.

Communications lead between the equipment and the computer is not properly connected Check the connections at both ends.

The Software is using the wrong COM port.

On the Software Config Panel, check the correct COM port is set.

If connected directly (no USB to serial converter) this is likely to be COM1.

When using the USB to serial converter this should be set to the COM port allocated to the USB port. To find this out, use the computers Device Manager, open Ports (COM & LPT1) and see which COM port number has been allocated to the USB Serial Port. The Software suite should then be set to use this port.

CRFT unit not switched on

Check power switch is illuminated and switched to the ON position.

The CRFT USB drivers were not installed correctly.

Open **Device Manager** in Windows and check the **Ports (COM & LPT)** section. Locate the **Grant Instruments CRFT USB driver** and ensure the driver is installed correctly by right clicking on it and selecting **Properties.** If the **Device Status** does not show 'This device is working properly' seek support.

A1.4 Straws Stuck To head

Interchangeable head not dried properly before samples placed in grooves
The head may be damp and as the samples fit tightly into the head they may have frozen
onto the head. Ensure the head is dried before freezing (Section 7.3). Samples can be
removed with careful use of tweezers.

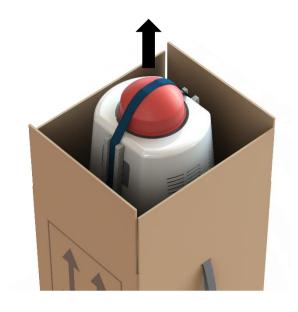
Samples not dried before placing in grooves

The samples may be damp and as they fit tightly into the head they may have frozen onto the head. Ensure the samples are dry before freezing (Section 7.3). Samples can be removable with careful use of tweezers.

Appendix 2 Unpacking instructions

THE CRFT IS A DELICATE SCIENTIFIC INSTRUMENT AND SHOULD BE HANDLED WITH CARE AT ALL TIMES. THESE INSTRUCTIONS **MUST** BE FOLLOWED TO UNPACK THE UNIT.

WARNING:DO NOT USE THE STRAP AS HANDLE. GRASP THE UNIT VIA THE SIDE AND BASE WHILE UNPACKING



- 1. After opening carton from top, remove accessories and foam trays.
- 2. Reach inside, grasp the by the base and side of the equipment and draw it from the carton

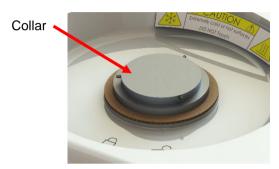


- 3. Carefully place the unit upright on a firm surface. Undo the strap and remove the foam strips and the collar support.
- 4. Remove the unit from the bag, and consult the separate instructions to install interchangeable head
- 5. RETAIN ALL PACKAGING AS IT **MUST** BE USED TO REPACK THE UNIT FOR FURTHER TRANSPORTATION. SEE OVER FOR PACKING INSTRUCTIONS.

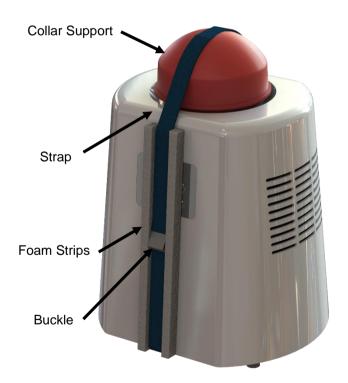
Appendix 3 Packing instructions

THE CRFT IS A DELICATE SCIENTIFIC INSTRUMENT. FAILURE TO CORRECTLY PACK THE UNIT MAY RESULT IN DAMAGE TO THE UNIT AND RENDER THE WARRANTY VOID.

WARNING: ENSURE INTERCHANGEABLE HEAD IS REMOVED BEFORE PACKING THE UNIT. DO NOT USE THE STRAP AS HANDLE. GRASP THE UNIT VIA THE SIDE AND BASE WHILE PACKING



1.Remove interchangeable head. Protect the collar surface with low tack tape to prevent scratching during transit.



- 2. Place CRFT Unit into a large polythene bag (Grant part no. 00402). Place Collar support (35507) over the top of the unit. ensure the notch on top is facing the front/rear of the unit.
- 3. Run the packing strap (Grant part no. 29159) under and over the unit as shown.
- 4. Place foam strips between the strap and the front/back of the unit casing as shown, then tighten the strap until it is taut and the collar support is held secure to the unit. Place the buckle in the middle of foam strip as shown. Avoid the buckle touching the unit.
- 5. Grasp unit by the base and side and lower the unit into the packing case.
- 6. Refit Packing foam tray, power supply, leads, lid and other accessories into their appropriate slots before closing.



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