

ThawSTAR[®] CB

User Manual



Table of Contents

1. General Information.....	4
1 General Information	4
1.2 Important Safety Information.....	4
1.3 On-Product Safety Symbols	6
1.4 System Components, Terminology, and Interface Conventions.....	6
2. Installation	10
2.1 Unboxing.....	10
2.2 Plug In / Power Up.....	10
3. Operator Functions	11
3.1 Running a Thaw.....	11
3.2 Thaw Results	16
3.3 Aborting a Thaw.....	17
4. Administrator Passwords and Functions	19
4.1 Archive	19
4.1.1 Viewing Archive Entries	20
4.1.2 Exporting Archive Entries.....	21
4.2 Settings	22
4.2.1 Users.....	23
4.2.1.1 Creating Users	23
4.2.1.2 Editing Users.....	25
4.2.1.3 Deleting Users.....	25
4.2.1.4 Exporting Users	27
4.2.1.5 Importing Users.....	28
4.2.2 Thaw Profiles.....	29
4.2.2.1 Viewing Thaw Profiles.....	30
4.2.2.2 Deleting Thaw Profiles	31
4.2.2.3 Exporting Thaw Profiles	33
4.2.2.4 Importing Thaw Profiles.....	34
4.2.3 Utilities.....	35
4.2.3.1 Exporting Data	35

4.2.3.2 Importing Data.....	38
4.2.3.3 Validation Sequence	39
4.2.3.4 Connection of ThawSTAR® CB via Ethernet	40
5. Troubleshooting	44
5.1 Power Failure — Emergency Cryobag Removal	44
5.2 Thaw Results — Errors and Failures	46
5.2.1 Emergency Release Error	46
5.2.2 Sensor Qualification Error	46
5.2.3 Sensor Qualification Error Prevention	47
5.2.4 Power Loss	47
5.3 User-correctable Errors	48
5.3.1 Emergency Release Error	48
5.3.2 Storage Full.....	48
5.3.3 Drawer Timeout.....	48
5.4 Technical Errors.....	49
5.4.1 Clamp Timeout	49
5.4.2 Rocker Timeout	49
5.4.3 Communication Error.....	49
5.5 Restore Defaults	50
5.6 Factory Reset.....	51
6. Cleaning	52
7. Product Specifications	52
7.1 System Dimensions	52
7.2 Electrical Inputs and Outputs.....	52
7.3 Cryobag Dimensions	53
7.4 Environmental Requirements	53
7.5 Supplies	53

1. General Information

1 General Information

The ThawSTAR® CB is intended to be used in research labs, manufacturing suites, or other laboratory settings. The ThawSTAR® CB provides a standardized thawing process for cryobags containing cryopreserved biologic materials. It is designed to only accept cryobags that have been frozen in a flat orientation such that both major surfaces of the bag are planar and parallel as possible. It thaws one cryobag at a time, covering a range of bag sizes with nominal capacity from 25ml to 1000ml and 10ml to 275ml actual fill volume, when following proper pre-thaw preparation procedures.

The ThawSTAR® CB is for research or further manufacturing use.

ThawSTAR® CB functions:

- Thaw cryogenically frozen biologic material
- Import and export thaw settings
- Access and manage the thaw archive, with export to a USB drive
- Manage operator account privileges

1.2 Important Safety Information

The following conventions are used throughout this manual and on the screens of the display. Warnings and cautions are presented in the manual where relevant to the use of the ThawSTAR® CB.



WARNING

Warnings in this document alert the reader to a situation which, if not avoided, could result in death or serious injury. Because of their serious nature, Warnings are clearly marked with standard red symbols and the word WARNING written in boldface, with all capitals. Warnings may also include situations that could lead to the destruction or decreased viability of the cell samples in the cryobag.



CAUTION

Cautions in this document inform the reader of potentially hazardous situations which, if not avoided, may result in minor or moderate injury to the user, damage to the ThawSTAR® CB or other property, or degraded system performance. Cautions are clearly marked with standard orange symbols and the word CAUTION written in boldface, with all capitals.

Before using the ThawSTAR® CB, users should read and understand:

- The ThawSTAR® CB system components, terminology, and interface conventions
see more starting on page 6
- The processes described in this manual, with their attendant warnings and cautions
see more starting on pages 4, 10, 15, 16, 45, 52
- Troubleshooting information
see more starting on page 45
- Contact information
see more on pages 9, 55

In addition, users should read and understand the following general warnings and cautions:



WARNING

Cryogenically frozen materials are extremely cold. To avoid injury by frostbite, use extreme care whenever handling liquid nitrogen, liquid nitrogen storage or transfer vessels, or any objects which have come in contact with liquid nitrogen. Particular care should be taken when handling metallic objects that are at cryogenic temperatures.

- Always wear proper safety attire over clothing: face shield, cryogenic gloves, and cryogenic apron
- Avoid all contact of exposed skin to objects that are at low or cryogenic temperatures
- Get immediate medical attention for any frostbite injuries



WARNING

Use extreme care to prevent dropping or subjecting frozen cryobags to shock.

- Do not damage the edges of frozen cryobags
- Do not scratch cryobags when handling
- Failure to heed this warning can cause premature cryobag failure.



CAUTION

Handle the ThawSTAR® CB with care. If the equipment is used in a manner not specified by BioLife Solutions, protections provided by the equipment may be impaired.

- Never store a ThawSTAR® CB on its side or upside down
- Never drop, or subject to shock, any ThawSTAR® CB
- Never leave the ThawSTAR® CB in an outdoor condition
- Never stack other objects on ThawSTAR® CB



CAUTION

The ThawSTAR® CB is not designed to handle tubing extensions or accessories. It is assumed that all tubing has been removed during processing and preparation of cryobags for freezing in cassettes.

All performance data published for these products is based on static laboratory environmental conditions only. Actual performance will vary upon the nature of use. Manual manipulation of the drawer or vibration due to external sources will decrease the working duration/reliability of these products.

1.3 On-Product Safety Symbols



SHOCK WARNING

Always disconnect power to the equipment and unplug before performing any service or maintenance. Contact with high voltage could result in injury or death.



SHOCK CAUTION

Do not operate without proper electrical ground.



REFER TO INSTRUCTION MANUAL

Read the instruction manual before using the ThawSTAR® CB system.

1.4 System Components, Terminology, and Interface Conventions

The ThawSTAR® CB is a table-top system featuring the following user interfaces:

Display

This touch-sensitive LCD displays the operating mode and provides controls for opening and closing the drawer, managing and selecting thaw profiles, starting a thaw, exporting data from a USB drive, and managing the archive of past thaws.

Drawer

A cryobag can be loaded when the drawer is open. An Isolation Barrier Bag inside the drawer properly orients the cryobag, based on the shape and volume of the cryobag. The drawer will close automatically before a thaw begins. Obstructing the drawer from opening and closing properly will trigger an error condition.



Figure A: Front of the ThawSTAR® CB



Figure B: Back of the ThawSTAR® CB

The plastic cover can be removed in the event of an emergency (e.g., power loss), to manually disengage the internal clamping mechanism and force open the drawer so that the user may remove the cryobag from the ThawSTAR® CB without completing the thaw.



SHOCK WARNING

Always disconnect power to the equipment and unplug before performing any service or maintenance. Contact with high voltage could result in injury or death.



Figure C: Back of the ThawSTAR® CB with Emergency Release Cover Removed

The following terms are used throughout this manual, and on the screens of the display:

Cryobag

A compatible plastic package indicated for use in protecting, storing and freezing cells and tissues. Cryobags are single use, and typically have a fill volume of 10-275 mL. The default thaw profiles in the ThawSTAR® CB refer to the actual volume capacity of the cryobag, not the fill volume (which is typically a fraction of the overall cryobag capacity). See Section 7 **Product Specifications** for a table of cryobag sizes that are compatible with ThawSTAR® CB. Cryobags must be thawed one at a time.

Barrier Bag

Also referred to as an Isolation Barrier Bag, a BioLife Solutions Barrier Bag (Figure D) is a consumable secondary containment bag required for proper positioning of the cryobag within the ThawSTAR® CB. The Barrier Bag is matched to the size of the cryobag for placement/alignment and contains a zip-lock style seal with registration holes along the bottom edge corresponding to the standing registration pins on the drawer. In addition to its role in proper cryobag positioning, the Barrier Bag also protects against condensation and cryobag leakage.



Figure D: Barrier Bag

Thaw Profile

Since many cell types are sensitive to the thawing procedure, cell viability is preserved through the control of temperature and the rate of temperature change. The algorithm that controls a unique set of thaw parameters (e.g., target temperatures and times at specific points in the thaw event) is referred to as a profile. The ThawSTAR® CB software comes pre-loaded with default thaw profiles that have been developed for a variety of specific cryobag sizes and fill volumes. BioLife can also create custom profiles optimized to preserve the viability of specific cell types.

Archive

A list or history of thaw events that have been previously performed on the system. Archive entries can only be deleted after they have been exported to a USB drive.

User Types

The ThawSTAR® CB software is configured with different permissions and functionality for two distinct types of system Users: Operators and Administrators.

Operators can:

- Select a thaw profile from the available library of profiles
- Perform a thaw event

Administrators can:

- Perform all of the tasks of an Operator
- Create, edit, import, export, and delete Usernames (i.e., login accounts) for Operators and other Administrators
- Access thaw event entries in the Archive, export them to a USB drive, and delete them after export
- View, import, or export thaw profiles to a USB drive
- Perform a Factory Reset or Restore Default settings

The following conventions are used on the screens of the display:

Menu Buttons:

The **Home** button returns you to the main screen. The Home screen is also displayed when the ThawSTAR® CB is powered on.

The **Archive** button gives you access to the record of previously completed thaw events.

The **About** button brings you to a screen listing contact information for BioLife Solutions Customer Support and system information.

Customer Support: 1-866-424-6543

Supplies: www.biolifesolutions.com/ThawSTAR

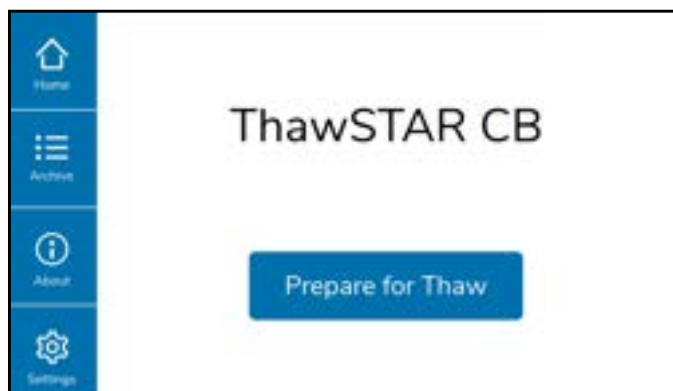
Technical Inquiries: ThawTechSupport@BioLifeSolutions.com

The **Settings** button provides Administrators with the restricted functions of the ThawSTAR® CB.

NOTE: Buttons that are selectable are indicated in blue. Not all menu buttons are selectable in all screens. Buttons that are not selectable are gray.

At any step during a process, a selectable **Back** button will bring you to the previous screen instead of continuing to the next step.

The **Continue** button can be selected to advance to the next screen.



2. Installation

2.1 Unboxing



WARNING

The ThawSTAR® CB system weighs 25 lbs (11.35 kg). Use safe lifting techniques to avoid the risk of injury or dropping the ThawSTAR® CB. Before lifting, assess whether you can lift it by yourself. Ask for help if it is too heavy. Use a cart to transport the ThawSTAR® CB longer distances.



CAUTION

Never remove any of the screws attaching the cover to the base as this may result in a dangerous separation of the cover and potential droppage while carrying the ThawSTAR® CB.



CAUTION

The ThawSTAR® CB Drawer will automatically open the first time the system is powered after being packed for Shipping. See Section 2.2 for Plug In/Power Up.

2.2 Plug In / Power Up

Ensure that the ThawSTAR® CB is powered by a 110 or 220 VAC socket.



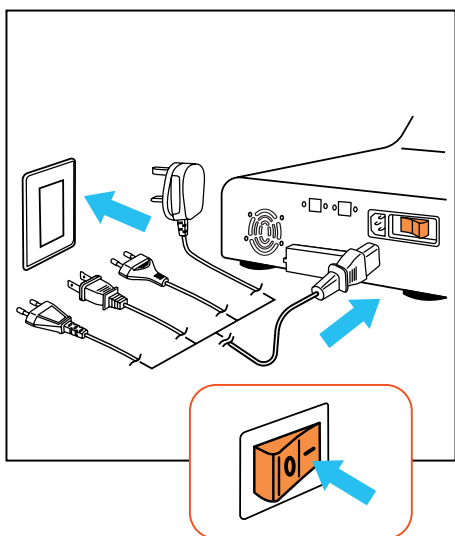
CAUTION

The Drawer will automatically retract if open when the ThawSTAR® CB is powered on. Keep hands and other objects out of the Drawer path as it is closing.



CAUTION

Do not block fan on the rear wall of the machine. Keep at least three inches of unobstructed space between the rear wall of the ThawSTAR® CB and any other equipment or walls to ensure proper airflow.



- 1 Use the Power Switch on the back of the system to turn on the ThawSTAR® CB. The BioLife Solutions logo behind the dead-front glass will illuminate and the Display will activate and run through a boot sequence.

The ThawSTAR® CB is now ready for use.

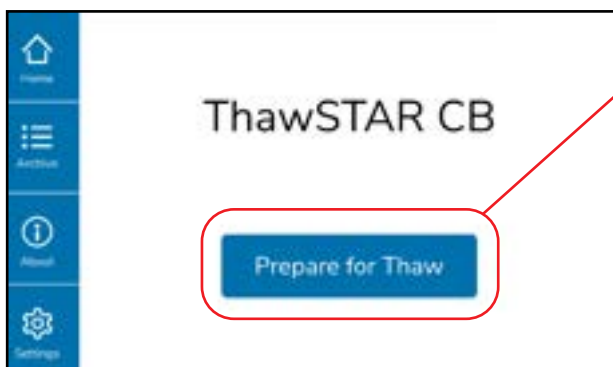
3. Operator Functions



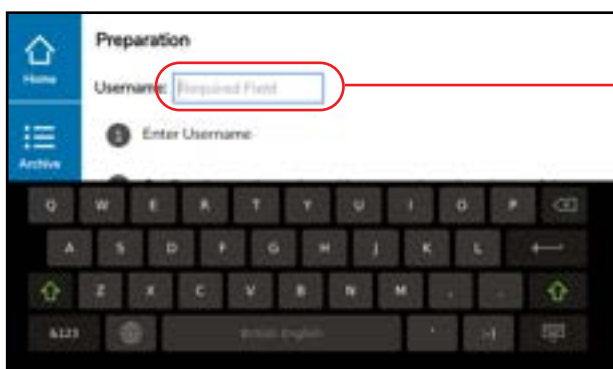
CAUTION

Cryobags must be frozen in cassettes (typically aluminum) in a flat orientation so that the liquid forms a uniform wafer upon solidification. Failure to freeze the cryobags flat inside a cassette will severely impact the performance of the ThawSTAR® CB.

3.1 Running a Thaw

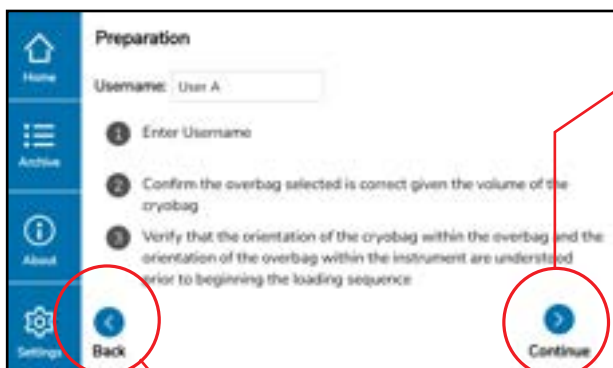


1 From the default Home Screen, select the **Prepare for Thaw** button.



2 Enter your **Username** using the pop-up keyboard. Your Username must match a profile stored in the machine (as set up by an Administrator).

NOTE: Usernames are case sensitive



3 Select **Continue** to proceed.

4 At any step during the process you may select the **Back** button to go to the previous screen instead of continuing to the next step.



5

Scroll through the list of available **Thaw Profiles** and select the appropriate **Biologic Name** and **Bag Size**. Select **Continue** to proceed.



6

Leaving the frozen **cryobag** in storage but ready for retrieval with protective gloves, select an appropriately sized **Barrier Bag**. Confirm the **Barrier Bag** is the correct size and configuration for the given cryobag. Review that the **Username** and selected **Thaw Profile (Biologic and Bag Size)** are correct, then select **Continue** to proceed.



CAUTION

Overwraps or other secondary containment bags on cryobags must be removed prior to thawing. If a cryobag comes in an overwrap it will need to be removed before the cryobag can be inserted into the BioLife Solutions Barrier Bag.



CAUTION

Cryobag label flaps (reference CS-50) need to be oriented facing upwards. Sensing components in the ThawSTAR® CB are located on the bottom of the drawer and the system will not function properly unless the sensors can make thermal contact with the cryobag through the Barrier Bag.



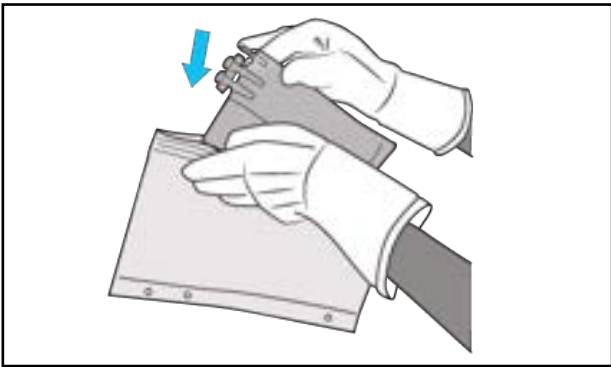
CAUTION

The heaters are de-energized when the drawer opens to reduce risk of thermal injury, so work as quickly as possible on the following steps.



CAUTION

Wear protective gloves when handling cryogenically frozen materials to avoid frostbite.



7 Using protective gloves, remove the cryobag from any transportation or storage containers and freezing cassette.

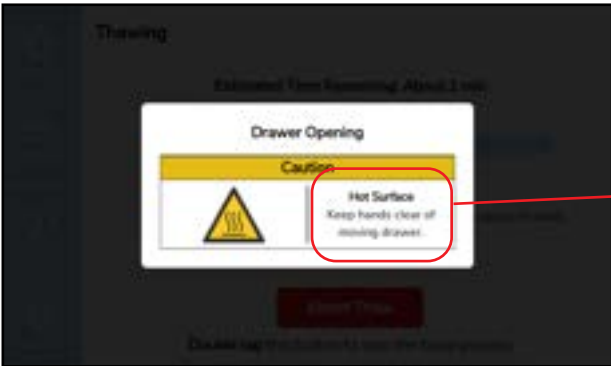
8 Insert the cryobag into the correctly sized **Barrier Bag**. It is preferable that the underside of the frozen cryobag remains the underside that contacts the **Drawer** of the ThawSTAR® CB.

9 Line up the cryobag with the heat-staked markings on the **Barrier Bag**, ensuring that the neck of the cryobag is on the left side when the **Barrier Bag** is facing letters-up with respect to the **Drawer**.



10 Carefully expel excess air from the **Barrier Bag** before sealing the Zip-loc. Confirm completion of the zip-seal closure.

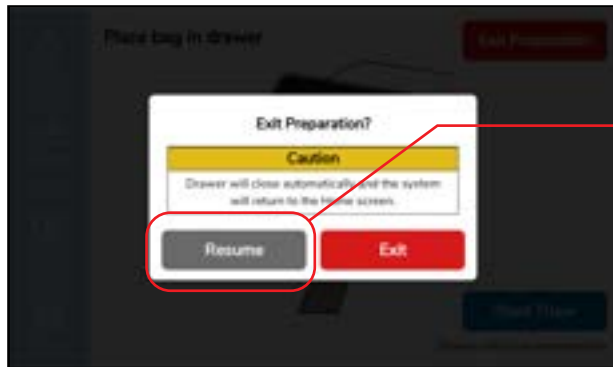
11 Select **Open Drawer** to proceed.



12 Keep hands and other objects clear of the moving **Drawer**.



13 If you wish to stop the thaw preparation process, select Exit Preparation. You will be returned to the Home Screen, otherwise proceed to step 16.



- 14 A confirmation screen will appear. Select Exit to end the thaw preparation process.
- 15 If you wish to continue with the thaw preparation process, select Resume.



CAUTION

Ensure the drawer is clear to close with the Barrier Bag's sealing side placed under the top cover and the registration pins properly aligned.



- 16 Place the **Barrier Bag** containing the cryobag into the **Drawer**, lining up the 3 registration holes located along the lower seam of the **Barrier Bag** with the corresponding registration pins in the **Drawer**. The labels on the **Barrier Bag** should be facing up so they are legible when standing in front of the machine.
- 17 Press firmly atop the **Barrier Bag** for 5 seconds to ensure any unevenness in the frozen contents is liquified by the warmed **Drawer**. Confirm that the domed thermal sensors midline to the cryobag in the **Drawer** bottom are in contact with the frozen materials.

- 18 Select **Start Thaw** to close the **Drawer** and start the automated thaw event.



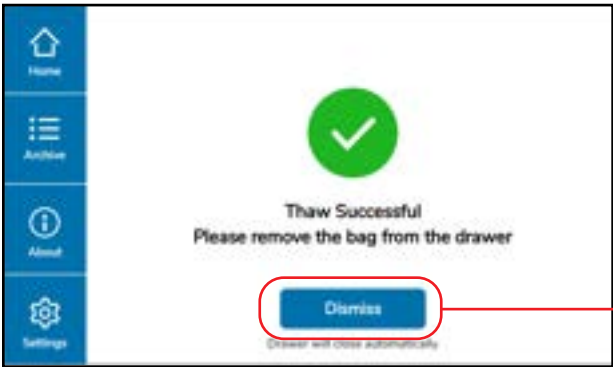
- 19 Wait for the thaw event to complete.

If you wish to abort the thaw event, see Section 3.3 for **Aborting a Thaw**.

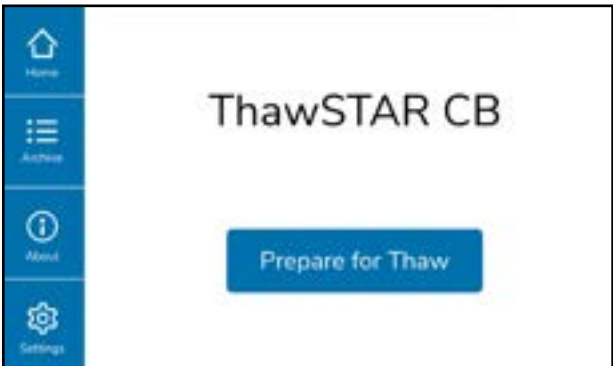


- 20 At the end of the thaw event, the **Drawer** will automatically open and the system will display either a Thaw Successful or Thaw Failure screen. See Section 3.2 for **Thaw Results**.
- 21 Keep hands and other objects clear of the moving Drawer.

NOTE: All thaw results are automatically saved to the system **Archive**.



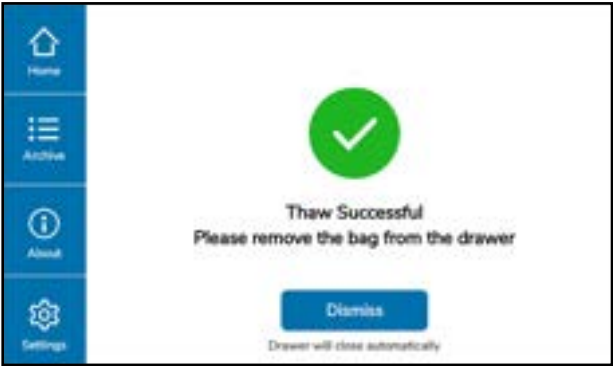
- 22 The **Dismiss** button will cause the door to close and take you back to the Home Screen.



You are ready to start another thaw event.

3.2 Thaw Results

At the end of a thaw event, the Drawer will automatically open and the ThawSTAR® CB will display either a Thaw Successful or Thaw Failure message.

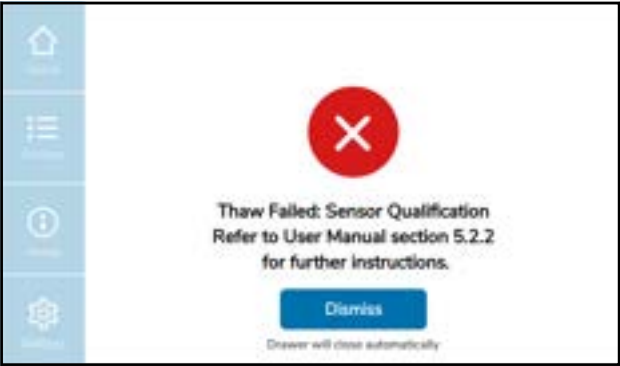


Successful thaw results are automatically saved to the system **Archive**.



WARNING

If a Thaw Failure message occurs, it is critical to consult any other issued SOPs for proper cryobag handling guidelines.



Thaw events may fail for a variety of reasons.

If the ThawSTAR® CB displays a Thaw Failure message, please note the corresponding error description and see Section 5 for additional details and support.

Failed thaw events are automatically saved to the system **Archive**.

3.3 Aborting a Thaw



1 Once a thaw has been started, it is possible to abort the process by **double-tapping** the **Abort Thaw** button.



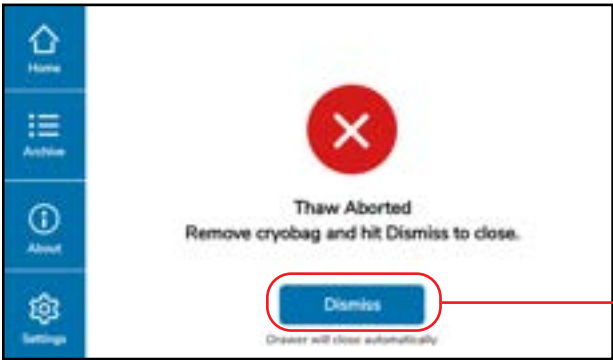
2 On the Abort Thaw screen, press and hold the two Stop Thaw buttons simultaneously.



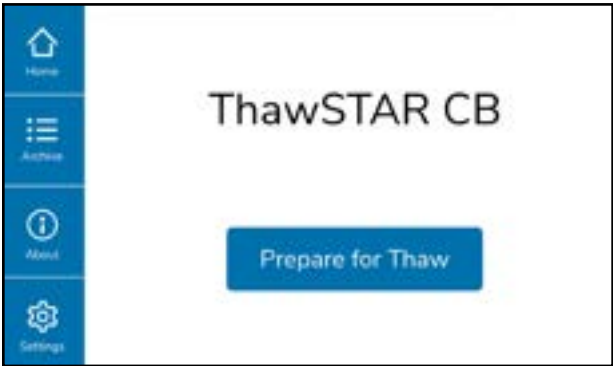
3 Once the thaw has been aborted, the Drawer will automatically open.



CAUTION
Keep hands and other objects clear of the moving Drawer.



4 Selecting the **Dismiss** button on the resulting Thaw Failure screen will take you back to the Home screen.



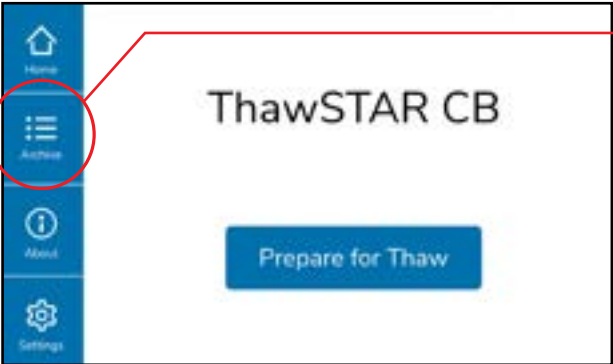
You are ready to start another thaw event.

4. Administrator Passwords and Functions

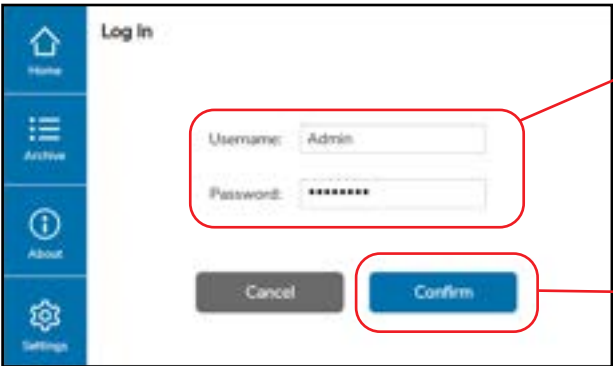
Administrators are able to access password-protected functions related to the system Archive, Users, and Thaw Profiles. Administrator functions may include the ability to edit and add new Users, Thaw Profiles, and Archives; and export/import data from a USB drive, and delete.

NOTE: The default password is “password” and should be changed. See Section 4.2.1.2.

4.1 Archive



1 From the Home screen, select **Archive**.



2 Enter Administrator’s **Username** and **Password** using the pop-up keyboard.

NOTE: The default Admin password is “password”.

3 Select **Confirm** to advance to the next screen.

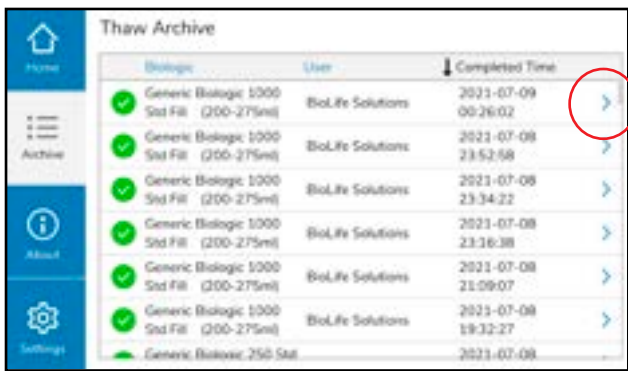
Thaw Archive			
	Biologic	User	Completed Time
✓	Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-09 09:26:02
✓	Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 23:52:58
✓	Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 23:34:22
✓	Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 23:36:38
✓	Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 21:09:07
✓	Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 19:32:27
✓	Generic Biologic 250 Std		2021-07-08

You will see a simple view of the system’s **Thaw Archive**, which lists all of the saved thaw events.

For each thaw event, you will see whether the thaw was successful or not, the name of the biologic, the Operator responsible for the thaw event, and the time of thaw event completion.

To exit this screen, select one of the Menu buttons on the left side of the screen.

4.1.1 Viewing Archive Entries



Biologic	User	Completed Time
Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-09 00:26:02
Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 23:52:58
Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 23:34:22
Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 23:16:38
Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 21:09:07
Generic Biologic 1000 Std Fill (200-275ml)	BioLife Solutions	2021-07-08 19:32:27
Generic Biologic 250 Std		2021-07-08

1 Starting from the **Thaw Archive** screen (see Section 4.1), select the caret to the right of the specific thaw event entry you would like to view.



General	Targets	Sensor Qualification	Parameters
Status: Success	Bag Size: 1000ml		
Name: BioLife Solutions	Completed Time:	2021-07-09	00:26:02
Username: Admin			

You will see additional information for that specific thaw event.

4.1.2 Exporting Archive Entries

When viewing a single archive entry, it is possible to export that entry to a USB drive (no option to delete upon export in single entry archive review/export mode). Batch archive exports allow deletion via the Utilities screen (see Section 4.2.3).



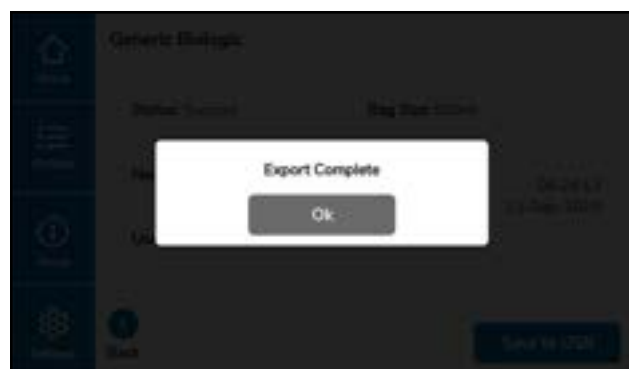
- 1 Starting from the specific thaw event entry that you wish to export (see Section 4.1.1), insert a USB drive into the **USB Port**.



- 2 Select **Save to USB**.

NOTE:

Filenames are auto-generated. Users are not prompted to enter a file name. Filenames are only customizable when “exporting data” and it is called-out during that step.



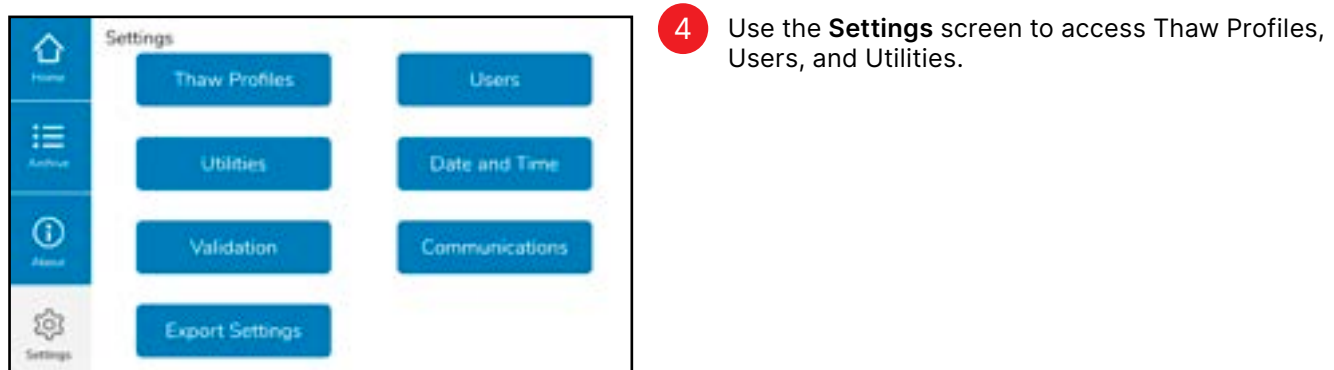
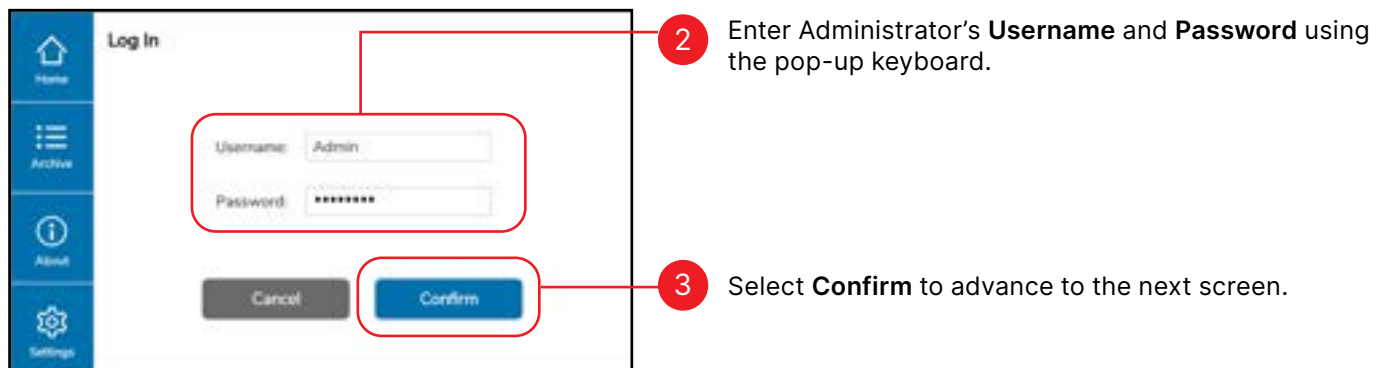
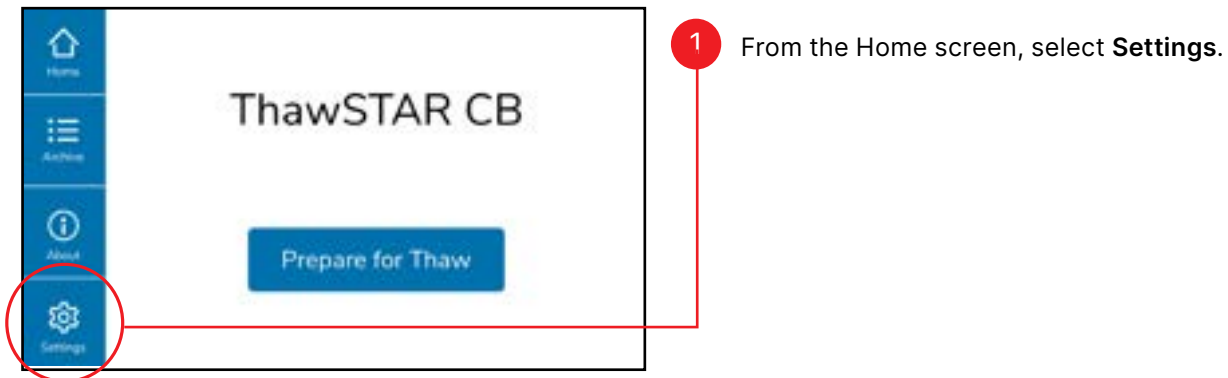
- 3 An “**Export Complete**” or “**Export Failed**” screen will appear. Selecting Ok on either screen will return you to the previous archive entry screen.

If you receive the “Export Failed” screen, check to see if your USB drive is corrupted. You may need to reformat the USB drive.

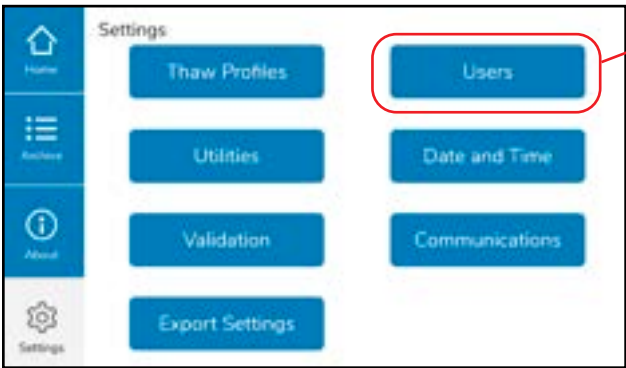
The file format of exported Archive Entries will be **.db**.

4.2 Settings

System User and Thaw Profile management functions are accessed via the **Settings** menu button.

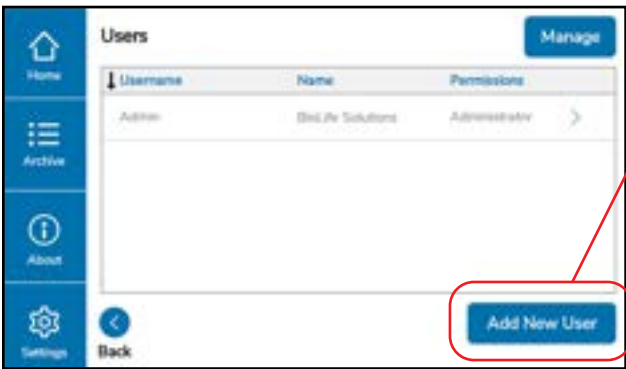


4.2.1 Users



1 On the Settings screen (see Section 4.2), select Users.

4.2.1.1 Creating Users



2 On the Users screen, select Add New User.



3 Use the pop-up keyboard to enter the new Username and User identity on the Create New User screen.

The screenshot shows the 'Create New User' form. The 'Permissions' section has two radio buttons: 'Operator' (selected) and 'Administrator'. A red circle highlights the 'Operator' button. The form includes fields for 'Username' (containing 'User 1') and a 'Save' button at the bottom right. A 'Back' button is at the bottom left.

4 Determine whether the new User should have Operator- or Administrator-level permissions. Select the corresponding radio button.

The screenshot shows the 'Create New User' form with the 'Administrator' permission selected. The 'New Password' and 'Confirm New Password' fields are visible and highlighted with a red circle. The 'Save' button is also highlighted with a red circle. The form includes fields for 'Username', 'Full Name' (split into 'First' and 'Last'), and a 'Back' button at the bottom left.

5 If "Administrator" is selected, you will be prompted to enter a password for the new User.

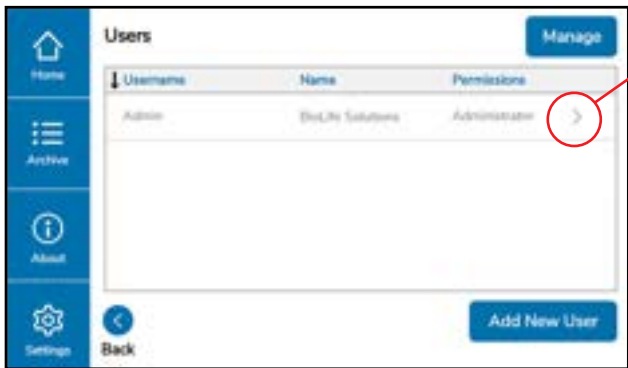
6 Select **Save** to add the New User to the system.

The screenshot shows the 'Users' screen. A table lists the users with columns for 'Username', 'Name', and 'Permissions'. The first row shows a user with 'Admin' as the username, 'BioLife Solutions' as the name, and 'Administrator' as the permissions. A 'Manage' button is at the top right, and an 'Add New User' button is at the bottom right. A 'Back' button is at the bottom left.

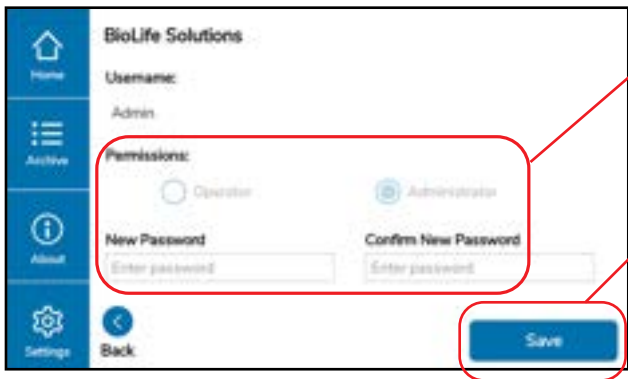
Username	Name	Permissions
Admin	BioLife Solutions	Administrator

7 You should see the newly created User listed on the Users screen.

4.2.1.2 Editing Users



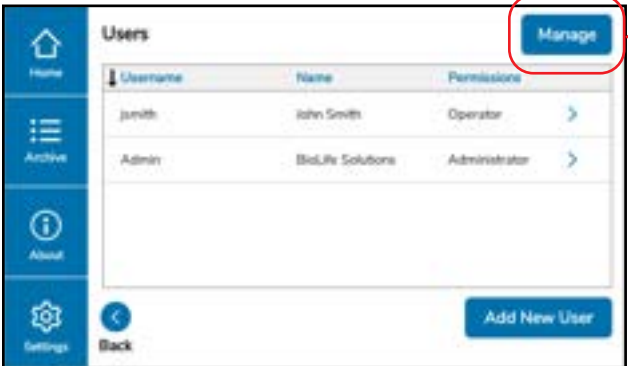
1 On the **Users** screen, select the caret to the right of the User you wish to edit.



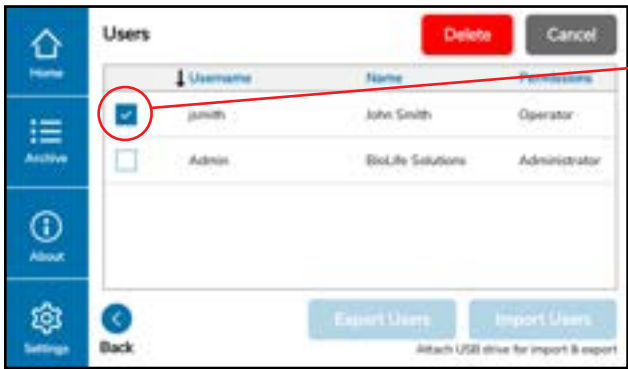
2 Edit the User's password using the pop-up keyboard. Permissions can be edited if desired.

3 Select **Save** to save your changes and return to the Users screen.

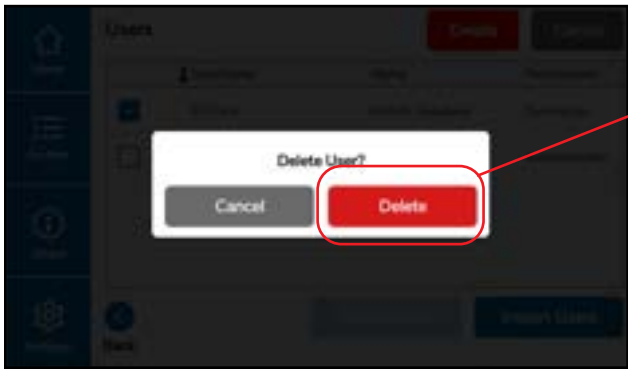
4.2.1.3 Deleting Users



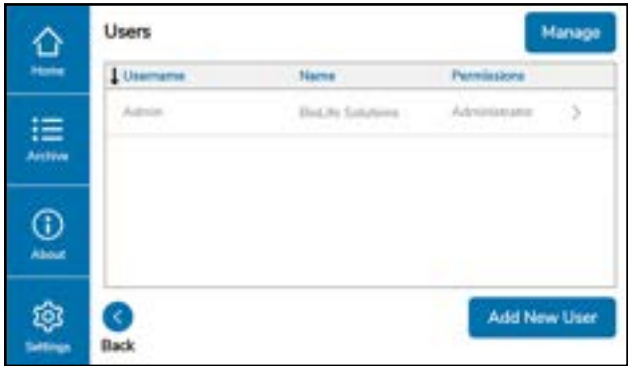
1 On the Users screen, select **Manage**.



2 Check the box next to the **User** you wish to delete.



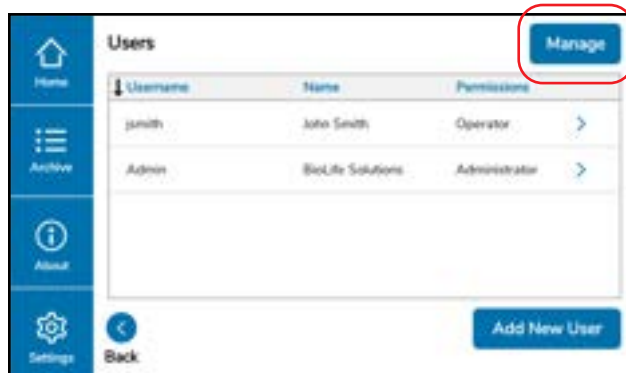
3 Select **Delete** to confirm.



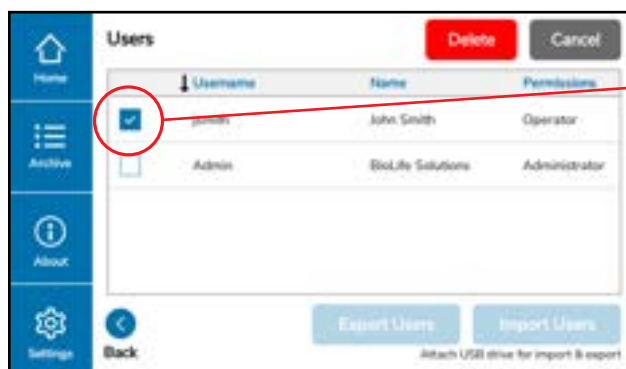
The list of Users on the **Users** screen should reflect the deletion.

4.2.1.4 Exporting Users

Users can either be Deleted or Exported (there is no option presented to delete after Export as with Thaw Archives). There is a secondary means by which Users and other data from the machine can be exported and deleted (reset to factory defaults) by using the Utilities Screen (see Section 4.2.3).

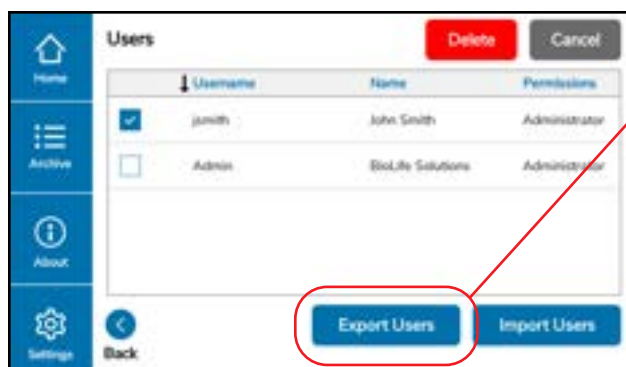


1 On the Users screen, select **Manage**.

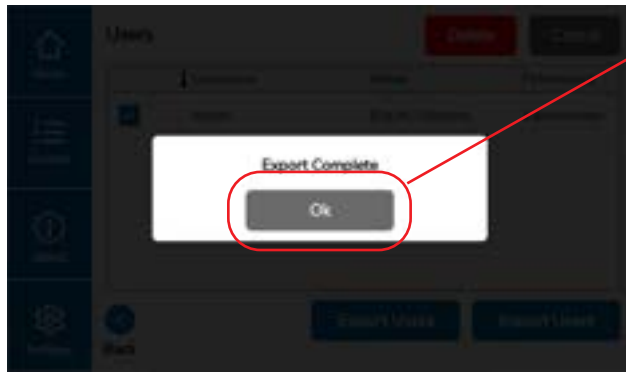


2 Check the box next to the **User(s)** you wish to export.

Insert a USB drive into the **USB Port**.



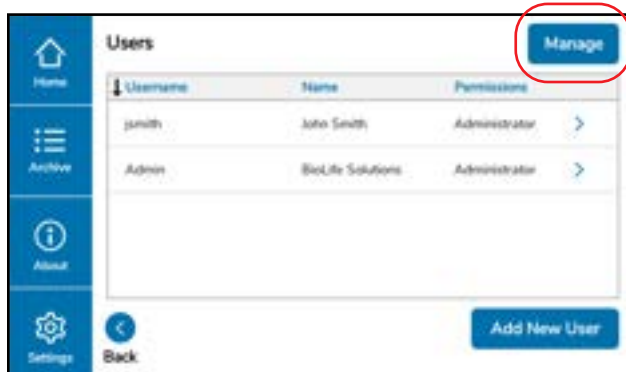
3 Select **Export Users**.



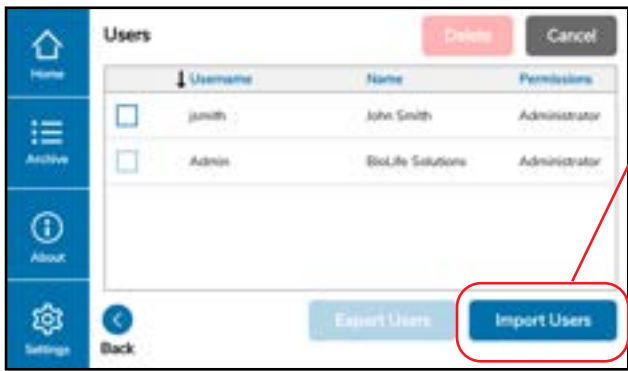
4 An “**Export Complete**” or “**Export Failed**” screen will appear. Selecting **Ok** on either screen will return you to the previous Users screen.

NOTE: If you receive the “**Export Failed**” screen, check to see if your USB drive is corrupted. You may need to reformat the USB drive.

4.2.1.5 Importing Users



1 On the Users screen, select **Manage**. Insert USB drive containing desired users to import.



2 Select **Import Users**.

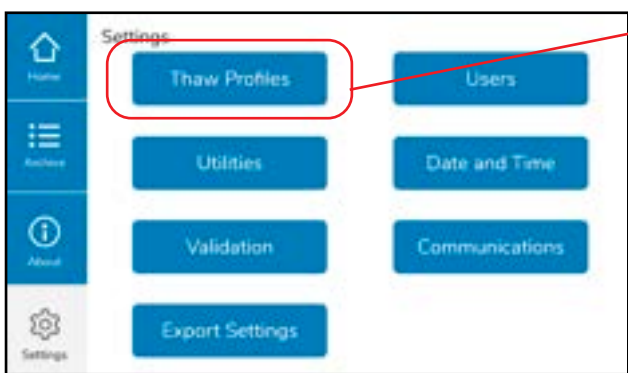


3 Check the box next to **Users**.

Select **Import** to import users.

4.2.2 Thaw Profiles

This section details the viewing, editing, and import/export of Thaw Profiles. Thaw Profiles determine parameters set to perform a Thaw. Each ThawSTAR® CB is shipped with a default set of Thaw Profiles. Additional Thaw Profiles can be optimized for your specific biomaterial by a BioLife Solutions technical expert, and added by a local Admin User to the Thaw Profile library.

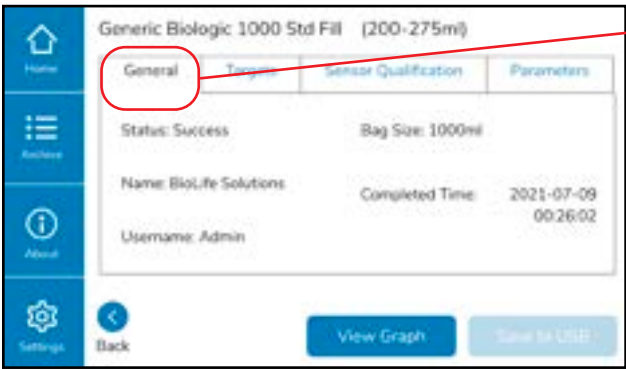


1 On the Settings screen (see Section 4.2), select **Thaw Profiles**.

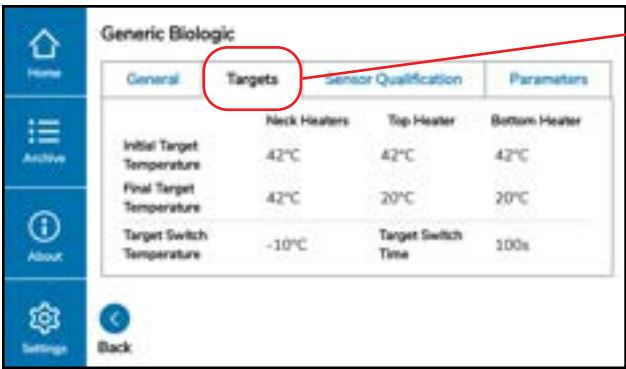
4.2.2.1 Viewing Thaw Profiles



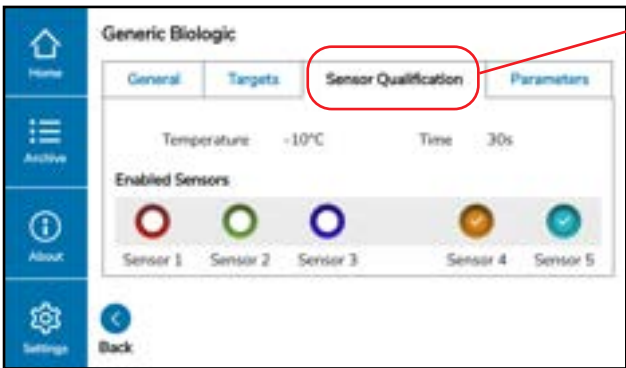
1 On the Thaw Profiles screen, select the caret to the right of the individual Thaw Profile that you would like to view.



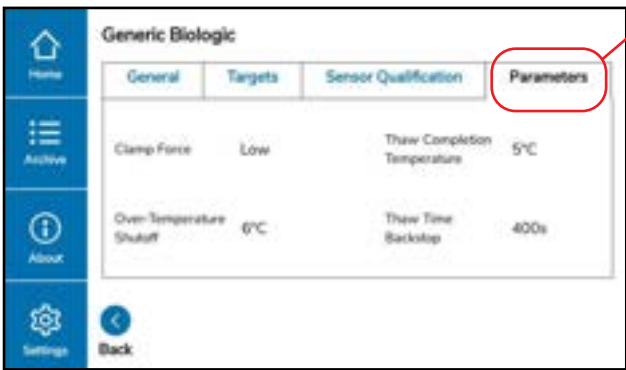
2 Information regarding individual Thaw Profiles is presented on four tabs. The **General** tab lists the biologic name and bag size.



3 The **Targets** tab provides information regarding target temperatures and switch time..



4 The **Sensor Qualification** tab displays information regarding the ThawSTAR® CB's enabled sensors.

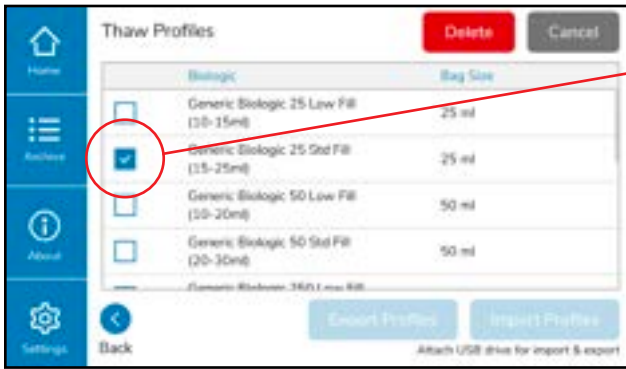


5 The **Parameters** tab displays other thaw settings.

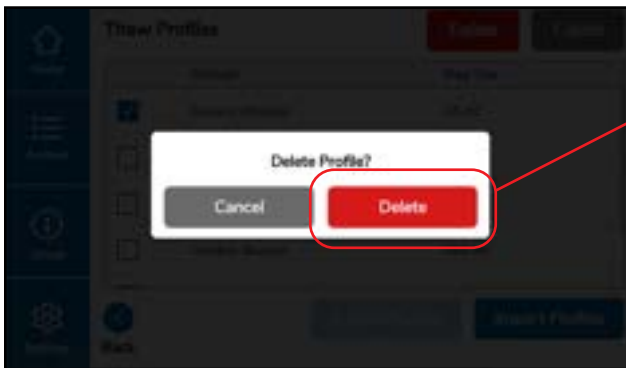
4.2.2.2 Deleting Thaw Profiles



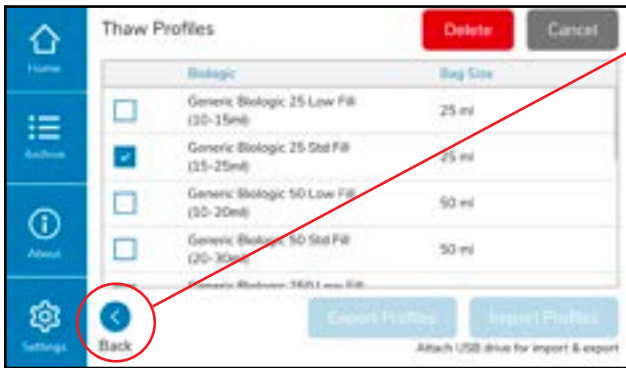
1 On the Settings screen (see Section 4.2), select **Thaw Profiles**. Press the **Manage** button.



2 Check the box next to the Thaw Profile(s) you wish to delete.




3 Select **Delete** to confirm.



4 The list of Thaw Profiles should reflect the deletion.
Select **Back** to return to the Settings screen.

4.2.2.3 Exporting Thaw Profiles


When exporting Thaw Profiles from the Thaw Profiles screen, there is no option to delete after exporting. The only way to delete Thaw Profiles after exporting is via the Utilities screen (see Section 4.2.3).



The screenshot shows the 'Thaw Profiles' screen. On the left is a sidebar with icons for Home, Archive, About, and Settings. The main area has a table with columns 'Biologic' and 'Bag Size'. It lists four profiles: 'Generic Biologic 25 Low Fill (10-15ml)', 'Generic Biologic 25 Std Fill (15-25ml)', 'Generic Biologic 50 Low Fill (10-20ml)', and 'Generic Biologic 50 Std Fill (20-30ml)'. At the bottom, there is a 'Back' button, an 'Idle Temperature' field set to '40°C', and a 'Create Profile' button. A red circle highlights the 'Manage' button in the top right corner.

Biologic	Bag Size
Generic Biologic 25 Low Fill (10-15ml)	25 ml
Generic Biologic 25 Std Fill (15-25ml)	25 ml
Generic Biologic 50 Low Fill (10-20ml)	50 ml
Generic Biologic 50 Std Fill (20-30ml)	50 ml

1 On the Thaw Profiles screen, select **Manage**.

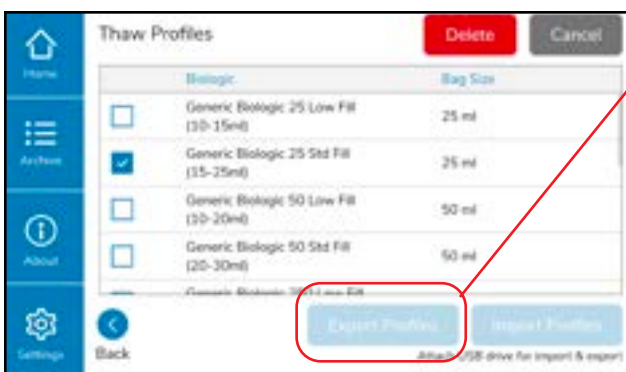


This screenshot shows the 'Thaw Profiles' screen with a 'Delete' button and a 'Cancel' button at the top right. The table from the previous screenshot is shown, but now each row has a checkbox on the left. The checkbox for 'Generic Biologic 25 Std Fill (15-25ml)' is checked. At the bottom, there are 'Export Profiles' and 'Import Profiles' buttons. A red circle highlights the checked checkbox.

	Biologic	Bag Size
<input type="checkbox"/>	Generic Biologic 25 Low Fill (10-15ml)	25 ml
<input checked="" type="checkbox"/>	Generic Biologic 25 Std Fill (15-25ml)	25 ml
<input type="checkbox"/>	Generic Biologic 50 Low Fill (10-20ml)	50 ml
<input type="checkbox"/>	Generic Biologic 50 Std Fill (20-30ml)	50 ml

2 Check the box next to the Thaw Profile(s) you wish to export.

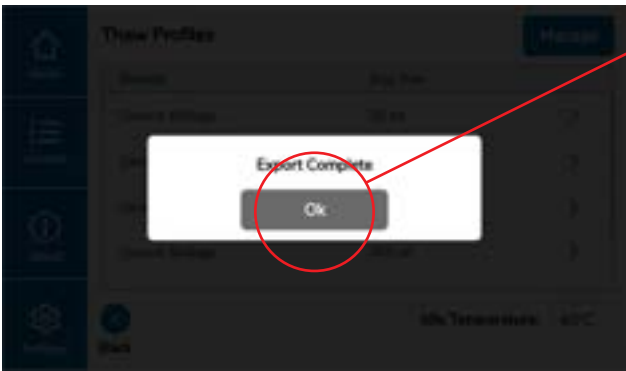
Insert a USB drive into the **USB Port**.



This screenshot is identical to the previous one, showing the 'Thaw Profiles' screen with the 'Generic Biologic 25 Std Fill' profile selected. A red circle highlights the 'Export Profiles' button at the bottom.

	Biologic	Bag Size
<input type="checkbox"/>	Generic Biologic 25 Low Fill (10-15ml)	25 ml
<input checked="" type="checkbox"/>	Generic Biologic 25 Std Fill (15-25ml)	25 ml
<input type="checkbox"/>	Generic Biologic 50 Low Fill (10-20ml)	50 ml
<input type="checkbox"/>	Generic Biologic 50 Std Fill (20-30ml)	50 ml

3 Select **Export Profiles**.



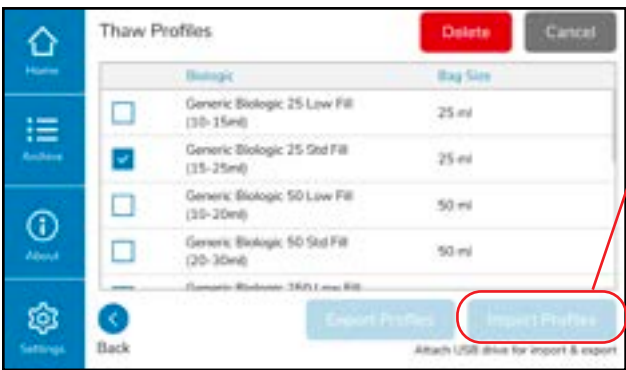
4 An “**Export Complete**” or “**Export Failed**” screen will appear. Selecting **Ok** on either screen will return you to the previous Thaw Profiles screen.

If you receive the “**Export Failed**” screen, check to see if your USB drive is corrupted. You may need to reformat the USB drive.

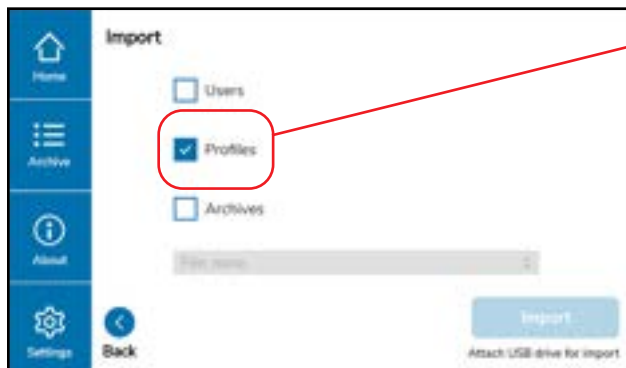
4.2.2.4 Importing Thaw Profiles



1 On the Thaw Profiles screen, select **Manage**.



2 Select **Import Profiles**.

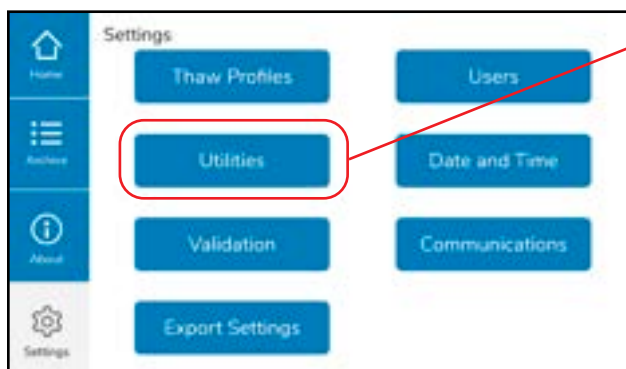


4 Check the box next to Profiles.

Insert the USB drive into the USB Port.
See Section 4.2.3.2 **Importing Data**.

4.2.3 Utilities

The Utilities Section of the ThawSTAR® CB enables Admins to Batch Export and Import Data, Reset the machine to factory defaults or Restore Default Thaw Profiles to their factory settings, and Pack the ThawSTAR® CB for transit.

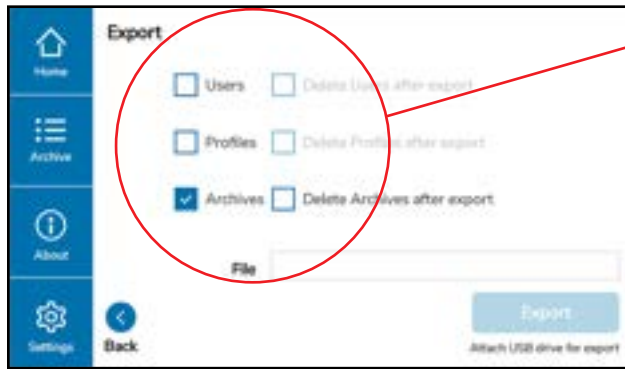


1 On the Settings screen (see Section 4.2), select **Utilities**.

4.2.3.1 Exporting Data



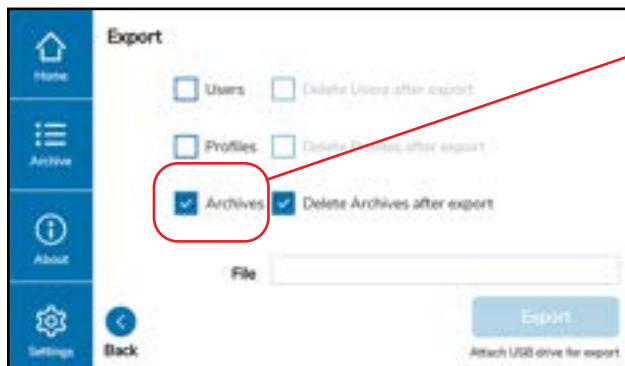
1 On the Utilities screen, select **Export Data**.



2 From the Export screen, it is possible to export Users, Thaw Profiles, or the system Archives.

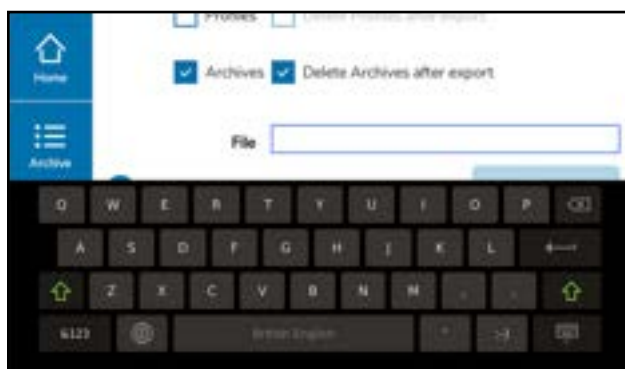
It is also possible to delete or keep the files on the system after export.

We will illustrate the process using **Archives**. The steps are the same when exporting Users and Thaw Profiles from this screen.



3 Check the box next to **Archives**.

If you wish to delete the system Archives after exporting, check the box next to **Delete Archives after export**.



4 Using the pop-up keyboard, enter a name for the exported Archives file.



5 Insert a USB drive into the **USB Port**.



6 Select **Export**.



7 If **Delete Archives** after export was selected, you will be asked to confirm deletion of the data from the system.

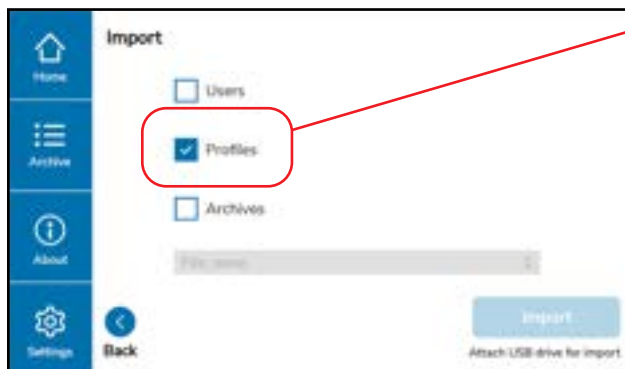
If you select **Cancel** you will return to previous Export screen, and the data will remain on the system.

If you select **Delete**, the Archives will be exported to the USB drive and deleted from the system. You will be returned to the Settings screen.

4.2.3.2 Importing Data



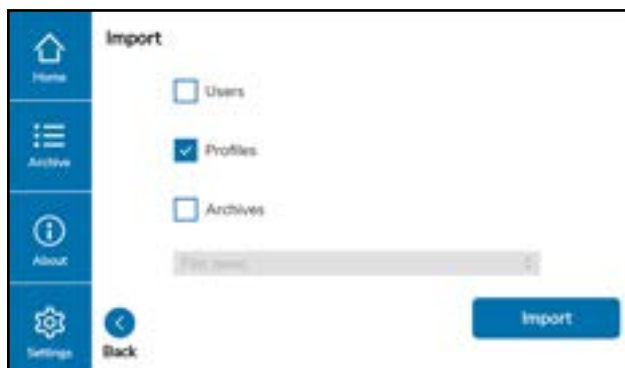
1 On the Utilities screen, select **Import Data**.



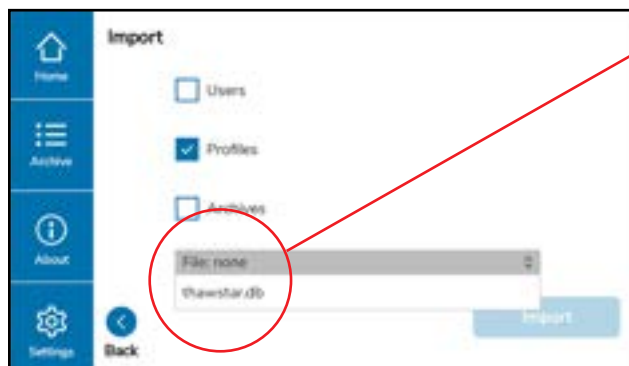
2 From the Import screen, it is possible to import Users, Thaw Profiles, or Archives.

We will illustrate the process using Thaw Profiles. The steps are the same when importing Users and Archives from this screen.

Check the box next to **Profiles**.



3 Insert a USB drive into the **USB Port** containing desired profiles for import.



4 Select the correct file from the drop-down menu of filenames.

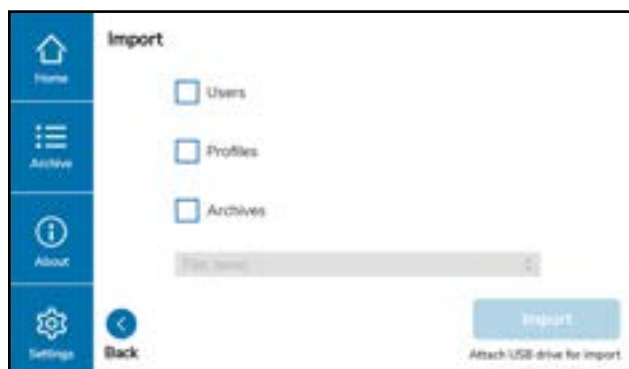


5 Select **Import** to download the file from the USB drive.

If **Delete Archives** after export was selected, you will be asked to confirm deletion of the data from the system.

If you select **Cancel** you will return to previous Export screen, and the data will remain on the system.

If you select **Delete**, the Archives will be exported to the USB drive and deleted from the system. You will be returned to the Settings screen.



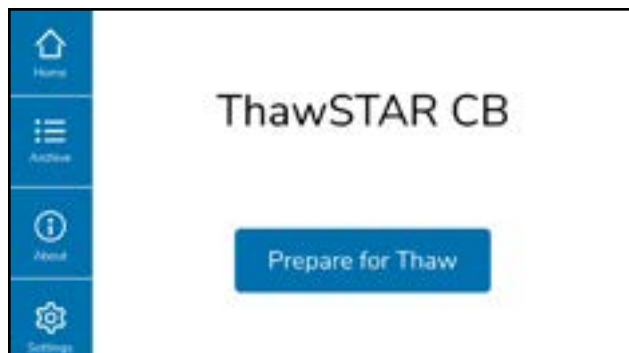
You are now ready to select other files for import.

4.2.3.3 Validation Sequence

The Validation section of the ThawSTAR® CB enables Admins to perform an automated sequence of internal checks for the instrument. This test is designed for initial qualification and diagnostics purposes only.

4.2.3.4 Connection of ThawSTAR® CB via Ethernet

- Requires software version 4.2.0 or above
- Ensure set up is performed with appropriate Laboratory and IT personnel



- 1 Turn on the ThawSTAR CB and allow the Home screen to load upon startup.



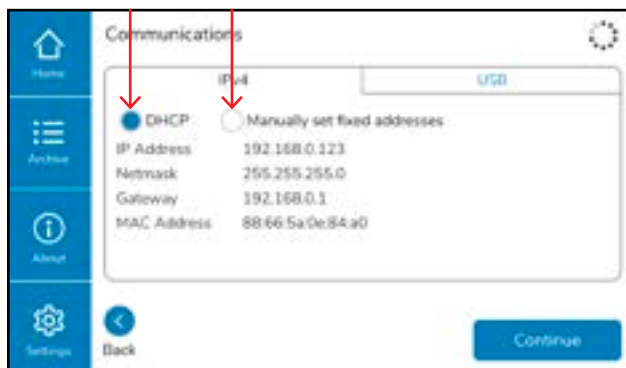
- 2 To begin setup, plug in ThawSTAR CB into a network switch using the Ethernet port at the rear of the unit.



- 3 A dialog box will appear on the ThawSTAR CB screen prompting the user to set up Ethernet Data Mode.
Press the "Ok" button when the dialog box appears on the ThawSTAR CB to set up Ethernet Data Mode at the Communications page (Step 5). Sign in when prompted with Admin credentials.



4 The Communications page can also be accessed from the Home page via signing into the **Settings** tab in the bottom left corner of the Home screen and signing in as an Admin user.



5 Under the IPv4 tab, by default, **DHCP** mode may be used if IP address, Netmask and Gateway can be automatically assigned by a DHCP server on the connected network.

If a specific IP address, Netmask, or Gateway is required, these settings can be changed by selecting the **Manually set fixed addresses** radio button.

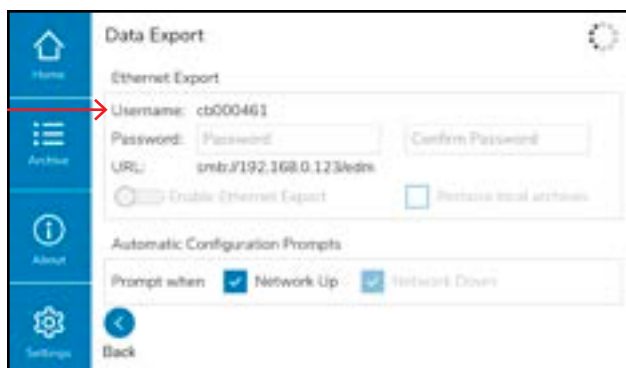
Select the USB tab for USB security settings.



6 If laboratory and IT personnel require **USB** ports to be disabled for security purposes, move the slider to the left to disable USB functionality.

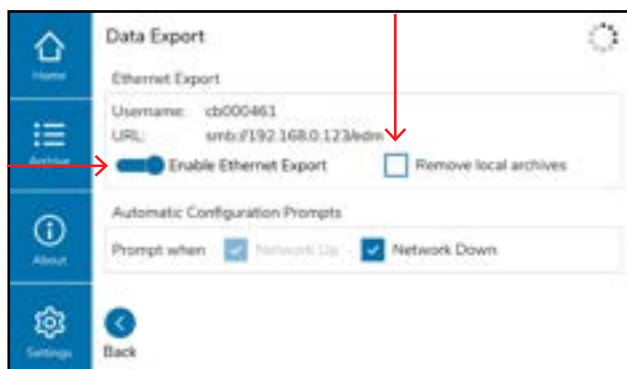
The default setting on this page is to leave the USB ports enabled.

Once the desired settings are inputted, press Save and **Continue**.



7 On the Data Export Page, the ThawSTAR CB serial number (found in the "About" Tab and on the rear of the unit) is the **Username**. Note the lower case "cb" prefix.

Enter a password between 6 and 8 characters in the boxes provided. Passwords must match to continue.

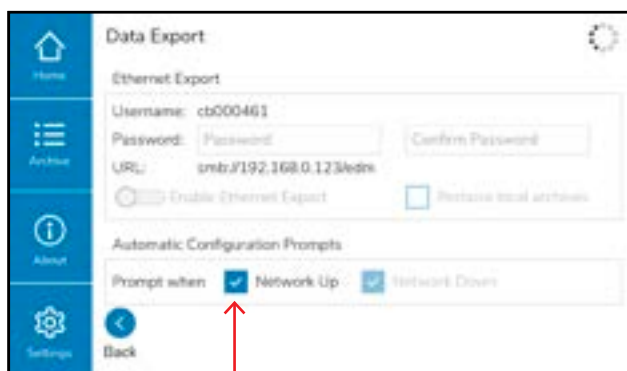


- 8 Move the slider to the right to **Enable Ethernet Export**.

If laboratory and IT personnel require all local archives of data to be removed from the instrument, click the **Remove Local Archives Checkbox**

Warning: no data will be stored for retrieval on this unit when “Remove Local Archives” Checkbox is selected.

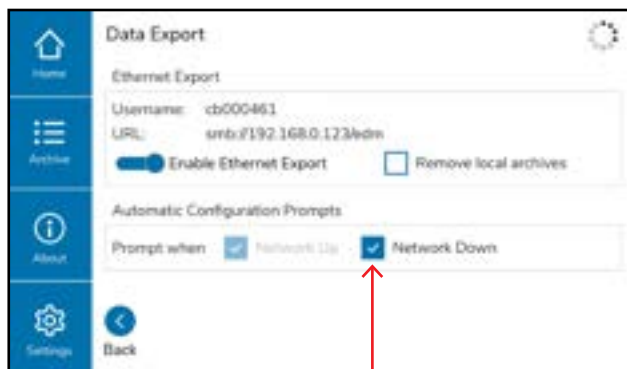
The default setting on this page is to leave the local archives in the system’s memory.



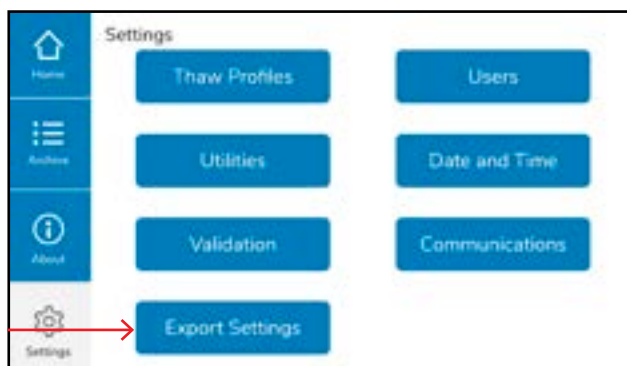
- 9 If laboratory and IT personnel would like to disable the prompts to connect or disconnect to Ethernet:

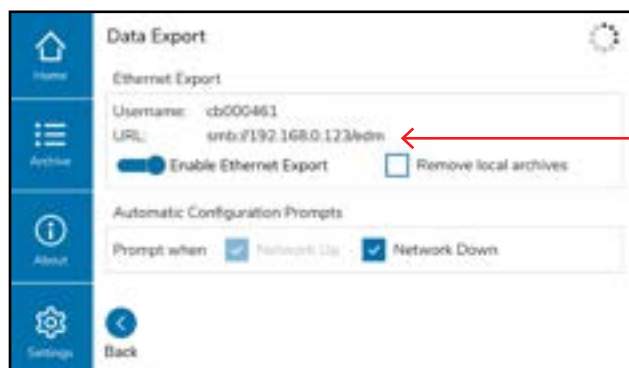
Deselect the **Network Up** checkbox to disable prompts to connect to Ethernet.

Deselect the **Network Down** checkbox to disable prompts to disconnect from Ethernet.

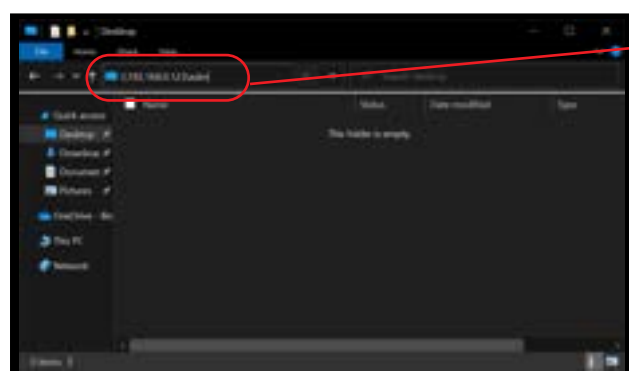


- 10 The Data Export page can also be accessed directly through the **Export Settings** button on the Settings page.

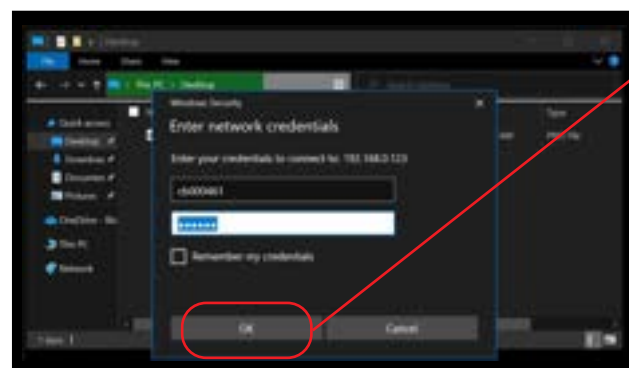




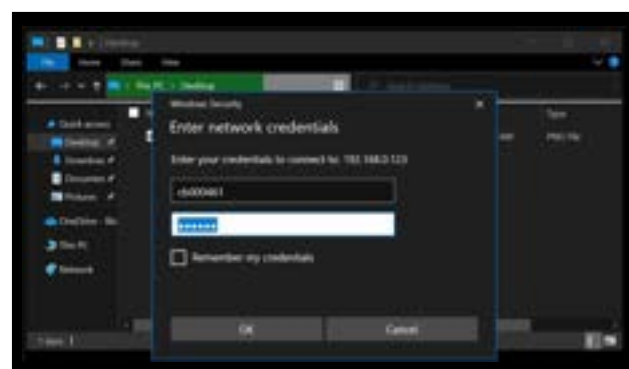
- 11 If setting up a file share on a Windows computer attached to the local network, the destination file path for the ThawSTAR CB can be found at `\\192.168.0.123\edm` in the example in the image to the left.



- 12 To connect to ThawSTAR CB from a networked Windows machine, open a File Explorer window and type into the address field: `\\192.168.0.123\edm` and press return. Replace the IP address in this example with the address chosen above.



- 13 Windows will ask for file share credentials. Use the serial number of ThawSTAR CB, with a lower case prefix. The password should be the same as chosen above. **Click OK.**

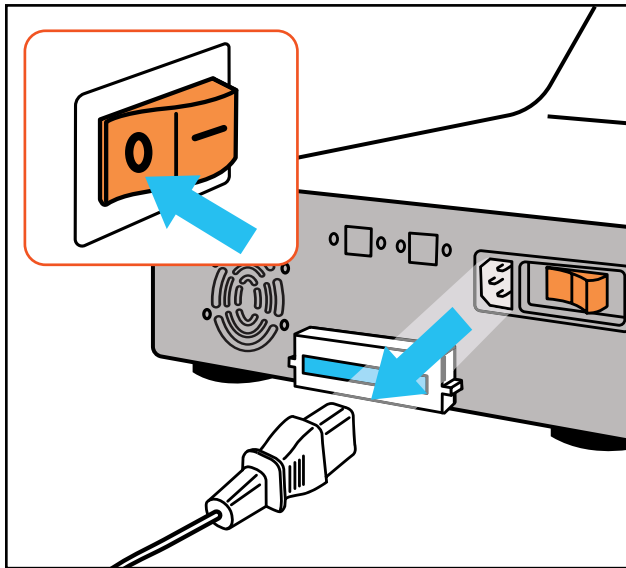


- 14 ThawSTAR CB network share will open. Any thaws performed since enabling Ethernet Data Mode will be present. Copy and remove the thaw archives as desired. The removal of the thaw archive data triggers deletion of the local copy, if "Remove Local Archives" was chosen above.

Contact IT personnel or ThawTechSupport@biolifesolutions.com for additional support.

5. Troubleshooting

5.1 Power Failure — Emergency Cryobag Removal



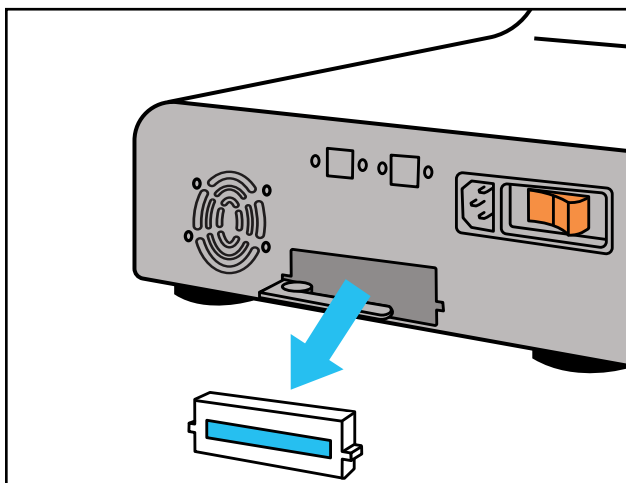
In case of unexpected power loss, the ThawSTAR® CB has been equipped with an Emergency Release Lever to release the internal clamping mechanism and allow the drawer to be manually opened. To retrieve the cryobag in the event of power loss, follow the procedure outlined below:

- 1 Turn off the power on the rear of the unit and remove the power cord.



SHOCK WARNING

Always disconnect power cable from the unit before pulling the **Emergency Release Lever**. Contact with high voltage could result in injury or death.



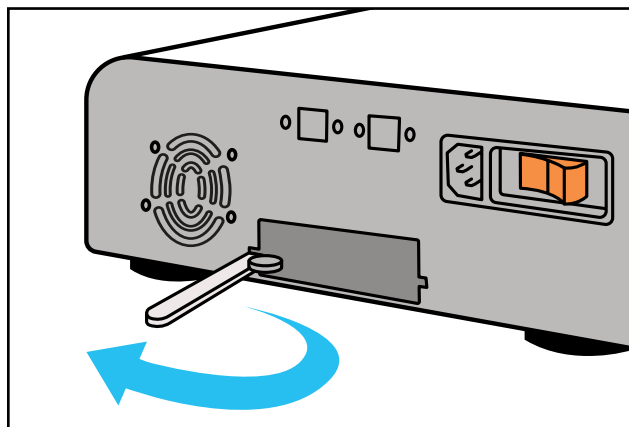
- 2 Pinch both sides **Emergency Release Cover** at the same time and pull the **Emergency Release Cover** away from the rear face of the ThawSTAR® CB.

With the **Emergency Release Cover** removed, the **Emergency Release Lever** will be exposed.

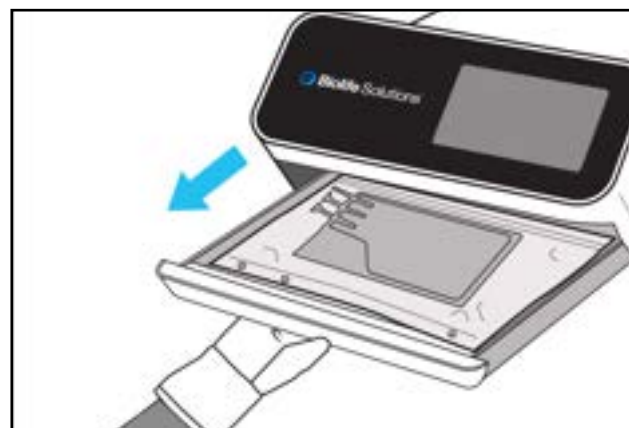


CAUTION

Do not force the **Emergency Release Lever**. It should not reach 90 degrees perpendicular to the rear plate—stop when you feel a noticeable increase in resistance.



- 3 Gently pull on the **Emergency Release Lever** away from the rear face of the ThawSTAR® CB.



- 4 Gently pull open the **Drawer** by grabbing it from the underside.

- 5 Remove the cryobag from the **Drawer**.



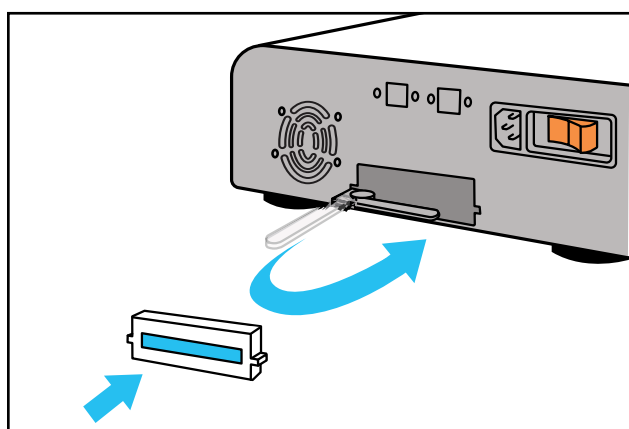
CAUTION

Do not turn on the ThawSTAR® CB with the Emergency Release Lever rotated away from the instrument. The Emergency Release Lever must be returned to its normal operating position.



CAUTION

The Drawer will automatically retract if open when the ThawSTAR® CB is powered on. Keep hands and other objects out of the Drawer's path as it is closing.



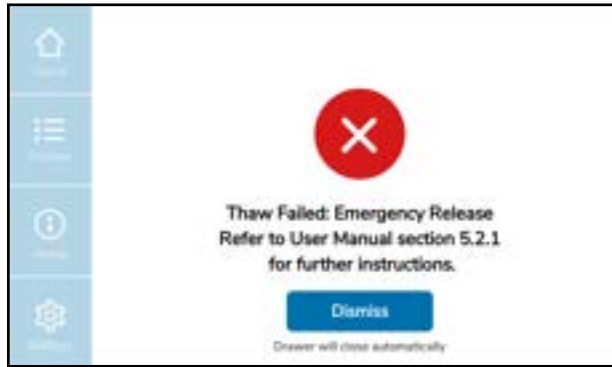
- 6 Return the **Emergency Release Lever** to its normal operating position and replace the Emergency Release Cover.

- 7 The **Drawer** will automatically close once the system is powered on.

5.2 Thaw Results — Errors and Failures

5.2.1 Emergency Release Error

Pulling the Emergency Release Lever during a thaw event causes this error.



Push the **Emergency Release Lever** in towards the rear wall and replace the cover before restarting a new Thaw.

For detailed corrective action see Section 5.3.1.

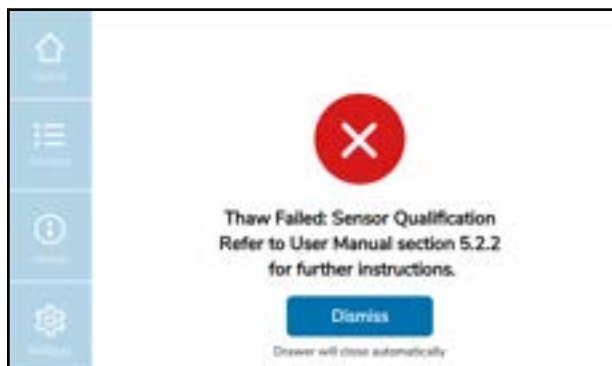
5.2.2 Sensor Qualification Error

This error could be caused by any of the following scenarios; bag misalignment, bag not present, bag too warm.



CAUTION

Cryobags with low-fill volume may require special attention during the freezing process to ensure they are flat along the bottom surface so that ThawSTAR® CB temperature sensors can attain good contact. Unevenly frozen low-fill cryobags that have been stored or brought to a $\sim -80^{\circ}\text{C}$ temperature may result in Sensor Qualification Errors as the ThawSTAR® CB will have difficulty determining an accurate temperature of the cryo-material. If a Sensor Qualification Error occurs, cryo-materials may already be partially or completely thawed.



Check to see if the frozen bag is in the correct position, if the bottom of the bag is flat and pressed against the five sensors that are midline to the drawer, and if the bag is frozen below the qualification temperature. If all of these conditions are met, contact Customer Support for further assistance.

An Admin can view the sensor qualification temperature or any Thaw Profile stored in the machine (see Section 4.2.2.1 **Viewing Thaw Profiles**).

5.2.3 Sensor Qualification Error Prevention

Sensor qualifications errors are typically caused by lack of contact between bags and sensors, and can be addressed by modifications to the freezing process. To improve contact between bags and sensors the following options are recommended to be applied to the freezing process: Press OK to return to the main menu.



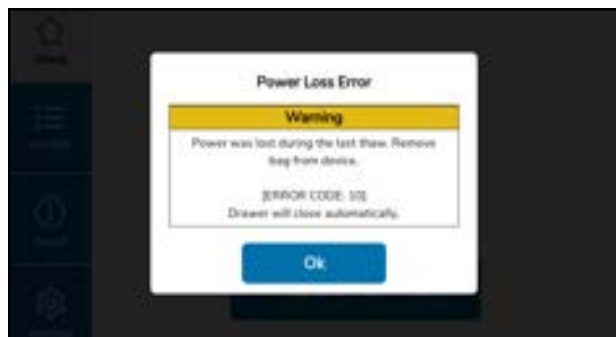
- 1 Eliminate gas pockets within the cryobag prior to sealing. A gas pocket over active sensors prevents accurate sensing of the media temperature.
- 2 Freeze the bag with the liquid contents evenly distributed within the bag. Unevenness within the bag media can result in incorrect temperature readings and extend thaw time durations.



- 2a Bags should be frozen in a flat orientation (see image left) to produce a wafer-like frozen product.
- 2b Cassette inserts may be applied to the freezing process to ensure evenness. Cassette inserts are recommended for cryobags that are not frozen in a flat (horizontal) orientation.
- 3 Cryobags with low-fill volume are more susceptible to natural bag stress interfering with even media distribution upon freezing. Application of cassette inserts can help mitigate bag stresses and ensure consistent thaws.

5.2.4 Power Loss

If power loss occurs during a thaw, the power-loss alert will appear and the drawer will open once power is regained. The archive entry for this thaw will have an entry of Failed: Power Loss.



Press **OK** to return to the main menu.

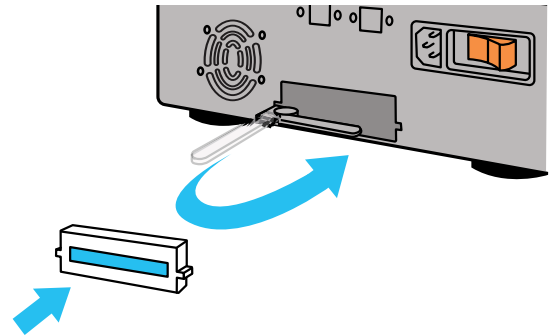
5.3 User-correctable Errors

5.3.1 Emergency Release Error

This error is caused by pulling the Emergency Release Lever while the machine is powered. The first step of the Emergency Procedure (see Section 5.1 or Quick Start Guide) is to unplug the machine. To correct this error the User should replace the lever to its original position.



After replacing the Emergency Release Lever, ensure the power switch is turned OFF ('0') before plugging in the power cable.



5.3.2 Storage Full

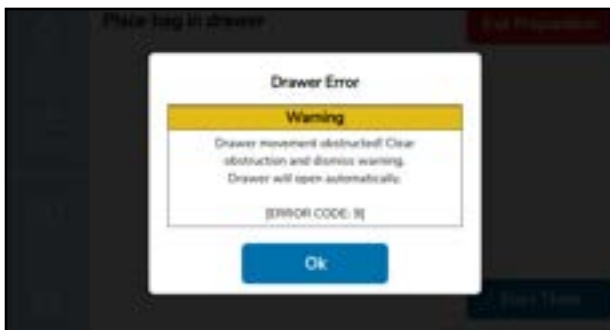
This error occurs when there is not enough space on the device to store the data for another thaw event.



Contact an administrator to archive data to USB and clear the memory before attempting a new Thaw.

5.3.3 Drawer Timeout

This error occurs when the drawer movement is obstructed.



Clear obstruction and press **Ok** to restart drawer movement.

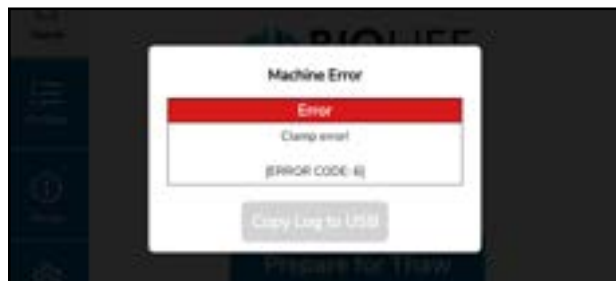
5.4 Technical Errors

These are errors that require technical support.

For service or repair support please call BioLife Solutions at **1-866-424-6543** or **ThawTechSupport@BioLifeSolutions.com**

5.4.1 Clamp Timeout

This error is serious and must be corrected by a BioLife-authorized technician.

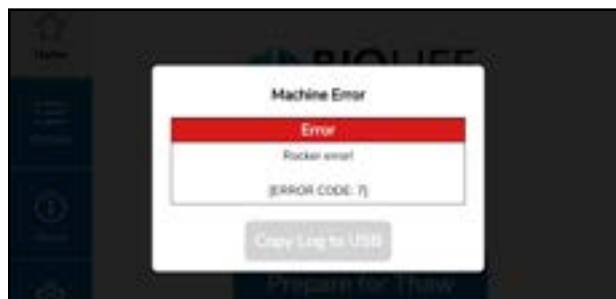


For service or repair support please call BioLife Solutions at **1-866-424-6543**.

Note the error code so you can report it to service technicians.

5.4.2 Rocker Timeout

This error is serious and must be corrected by a BioLife-authorized technician.

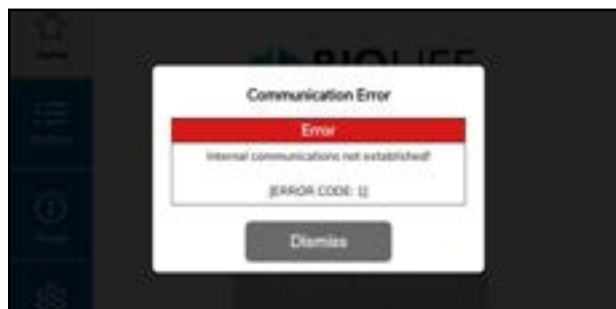


For service or repair support please call BioLife Solutions Corporation at **1-866-424-6543**.

Note the error code so you can report it to service technicians.

5.4.3 Communication Error

This error is serious and must be corrected by a BioLife-authorized technician.



For service or repair support please call BioLife Solutions Corporation at **1-866-424-6543**.

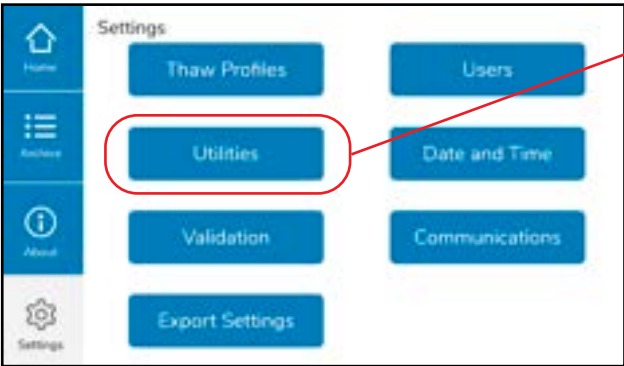
Note the error code so you can report it to service technicians.

The communication error can be dismissed.


The communication error does not impact the ability to export data from the machine, including users, profiles, and archives.

5.5 Restore Defaults

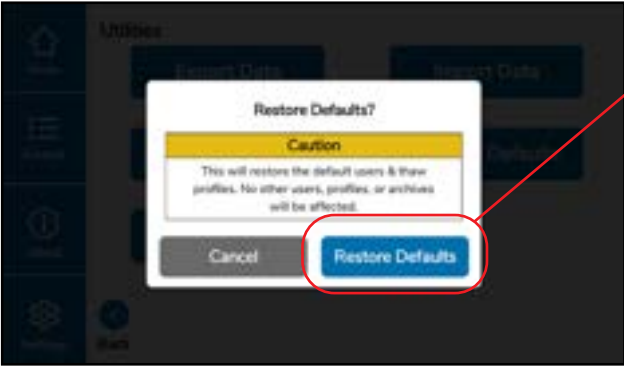
Restoring Defaults recreates the default Admin User and default Thaw Profiles.



1 On the Settings screen (see Section 4.2), select **Utilities**.



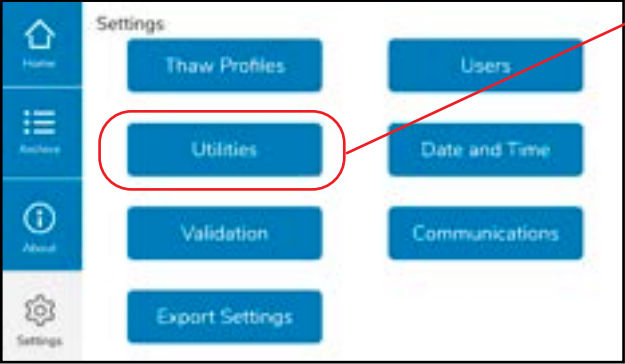
2 On the Utilities screen, select **Restore Defaults**.



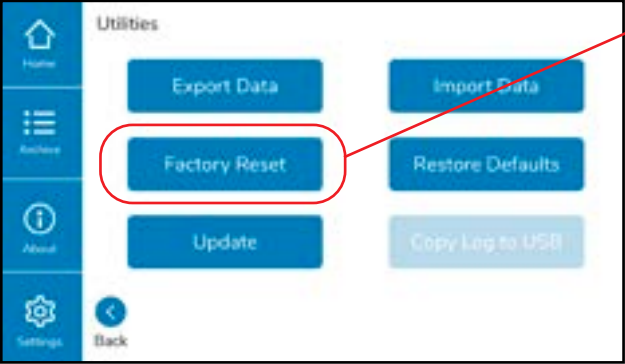
3 Confirm **Restore Defaults**.

5.6 Factory Reset

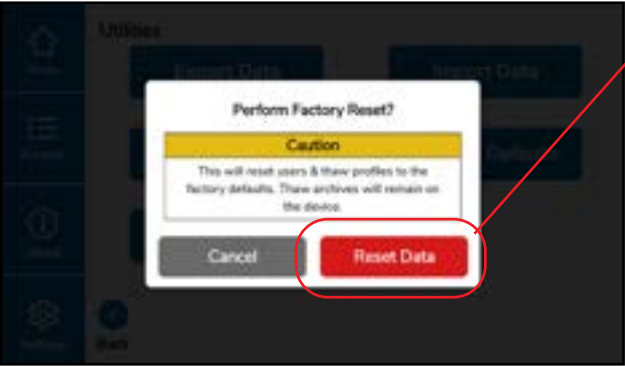
Factory reset will remove all Thaw Profiles and Users and recreate the default Admin User and default Thaw Profiles.



1 On the Settings screen (see Section 4.2), select **Utilities**.



2 On the Utilities screen, select **Factory Reset**.



3 Confirm **Reset Data**.

6. Cleaning



CAUTION

Do not attempt to clean or service internal components. Do not introduce any cleaning objects or solutions into the ThawSTAR® CB with the exception of the drawer surface. No regular mechanical maintenance is necessary or advised for the ThawSTAR® CB. No customer-serviceable parts are contained within the system. For service or repair support please call BioLife Solutions Corporation at **1-866-424-6543**.

Clean exterior or drawer surfaces only with a soft, non-abrasive laboratory wipe moistened with a **70 percent isopropyl alcohol solution** followed by a laboratory wipe moistened with pure water, then wipe dry. Any liquified condensate that might be present on the drawer surface following a thaw event should be dried with a non-abrasive laboratory wipe prior to conducting subsequent thaw events.

7. Product Specifications

7.1 System Dimensions

External dimensions	Measurement	Unit
Height	8	inches
Width	15	inches
Length	18	inches
Total system weight	25	lbs
Height	20	centimeters
Width	38	centimeters
Length	46	centimeters
Total system weight	12	kilograms

7.2 Electrical Inputs and Outputs

Electrical inputs and outputs	Measure and Unit
Input voltage (AC to Power Brick)	100–120V, 200–240V
Rated Input current	Maximum 8A
Frequency	50Hz / 60Hz
2 x USB inputs	5V, 1A each
Power input type	IEC 320-C14

7.3 Cryobag Dimensions

Bag external dimensions and features	Min	Max	Unit
Length	2.5	10.5	inches
Width	3.75	6	inches
Thickness	0.375	0.75	inches
Fill volume	10	275	mL
Starting temperature	-196	-60	°C
Bag Manufacturers	OriGen, Miltenyi, Charter		
Bag size ranges	Nominal sizes 25ml through 1000ml		
Length	6.35	26.67	centimeters
Width	9.52	15.24	centimeters
Thickness	0.925	1.90	centimeters

7.4 Environmental Requirements

The ThawSTAR® CB is designed to operate at room temperatures in a laboratory environment.

External environment	Min	Max	Unit
Operating air temperature	15	35	°C
Operating humidity	10	85	%Rh
Storage and shipping temperature	-10	70	°C
Operating altitude	0	4000	m
EMI/RFI	CE mark: WEEE, EN 60601, EN 61010 FCC or other CE certs due to Wireless		

7.5 Supplies

Order additional Barrier Bags at www.BioLifeSolutions.com/Thawstar

For technical inquiries email ThawTechSupport@BioLifeSolutions.com.

