

# ThawSTAR® CB

INSTRUCTIONS FOR USE



**Water-free  
Thawing**

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# 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 25 mL to 1000 mL and 10 mL to 275 mL 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.

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## 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, 5, 10, 11, 13, 15, 19, 47, 48, 49, 56**
- Troubleshooting information. **See more starting on page 47**
- Contact information. **See more on pages 9, 58, 60**

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.

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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:

### 1 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.

### 2 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

1.4 System Components, Terminology, and Interface Conventions (continued)



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 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.

## 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

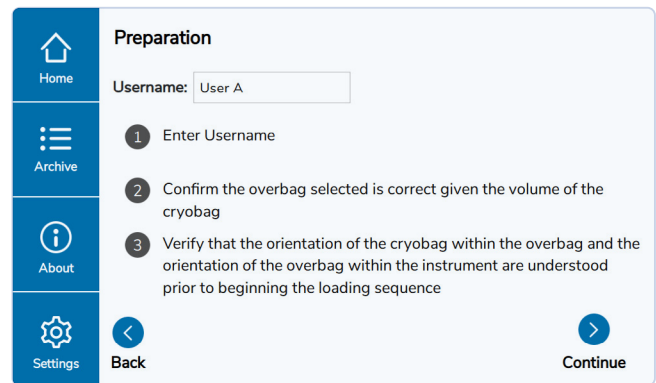
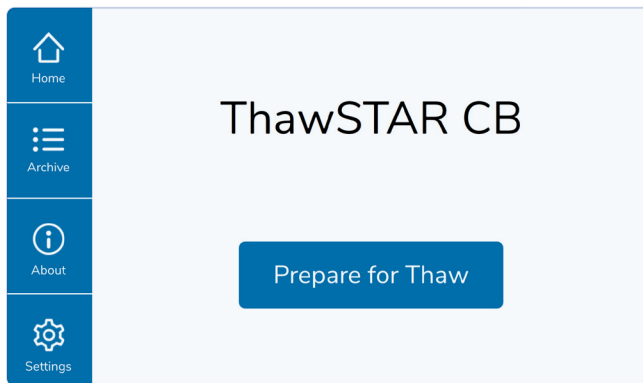
The ThawSTAR CB software is configured with different permissions and functionality for two distinct types of system users: Operators and Administrators.

### 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.

**Mailing Address:** 3303 Monte Villa Parkway, Suite 310 Bothell, WA 98021 USA

**Phone:** +1 (866) 424-6543

**General Inquiries:** [info@biolifesolutions.com](mailto:info@biolifesolutions.com)

**Support:** [support@biolifesolutions.com](mailto:support@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.



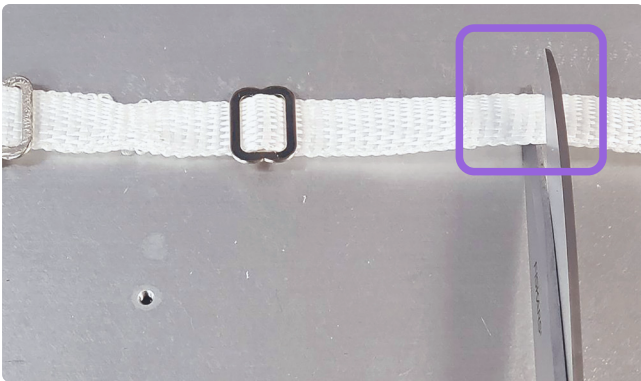
#### CAUTION

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

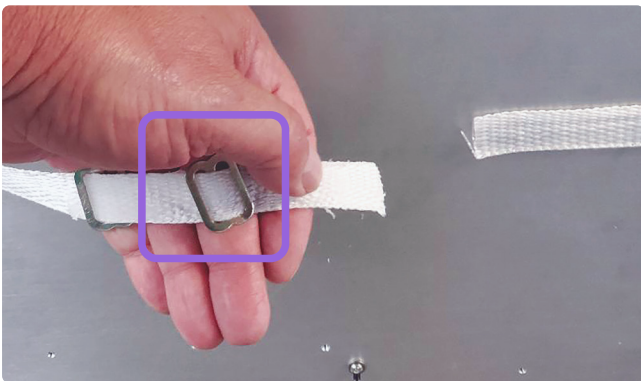
The ThawSTAR CB Drawer will automatically open the first time the system is powered after being packed for Shipping. See Section 2.2 for Plug In/PowerUp.



- 1 Remove ThawStar CB unit from shipping container and remove all foam protectants and plastic bag.

Place the ThawStar CB on a flat surface and lift the front, tilting the unit back until the bottom is exposed and the white shipping strap is visible.

**Cut white strapping** approximately 3-4 inches away from the buckle.



- 2 **Gripping the buckles**, pull the strapping from within the unit until completely removed and place unit back on the flat surface, resting on the rubber feet. Do not pull the buckles through the unit as it may cause interior damage.

## 2.2 Plug In/Power Up



### 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.

**Note:** If drawer is already open, remove the cardboard shipping insert inside of the drawer.

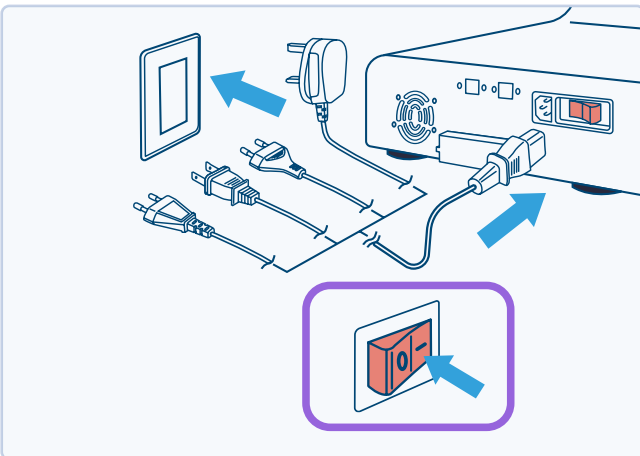


### 1 ThawSTAR CB Packaging Insert



### 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.

- 2 Log onto the system using User I.D. and Password. Work through the menu in the following order: **Settings > Diagnostics > Testing > Motors > Open Drawer**. Remove cardboard shipping drawer insert if not done previously, then press **Close Drawer**.

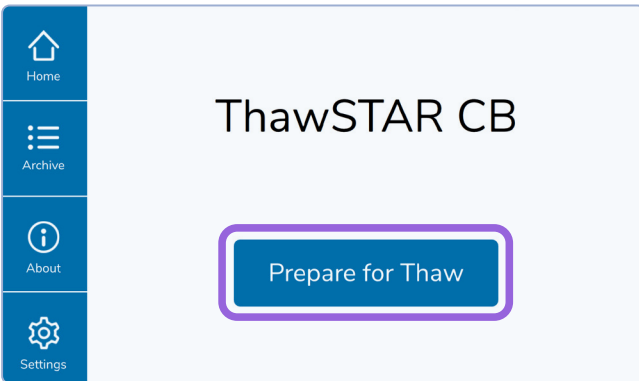
## 3 Operator Functions



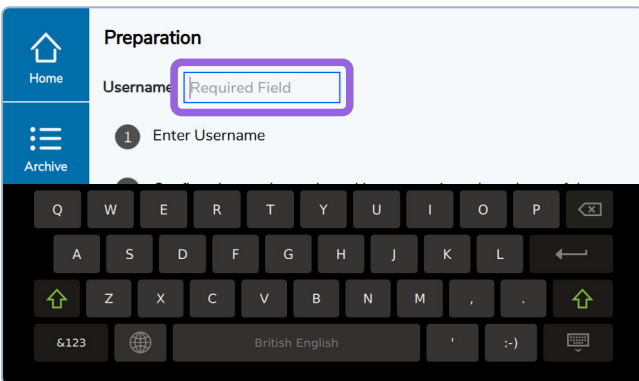
### CAUTION

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

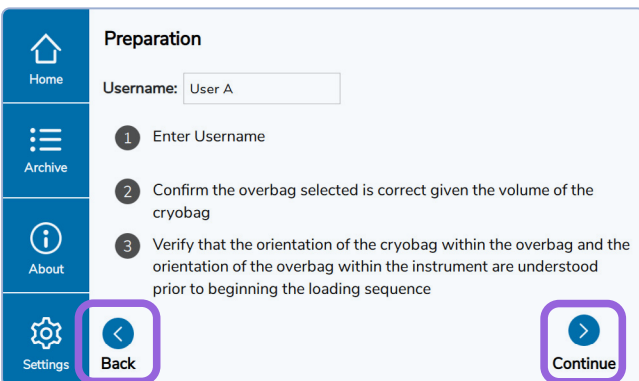


- 1 From the default Home Screen, select the **Prepare for Thaw** button.

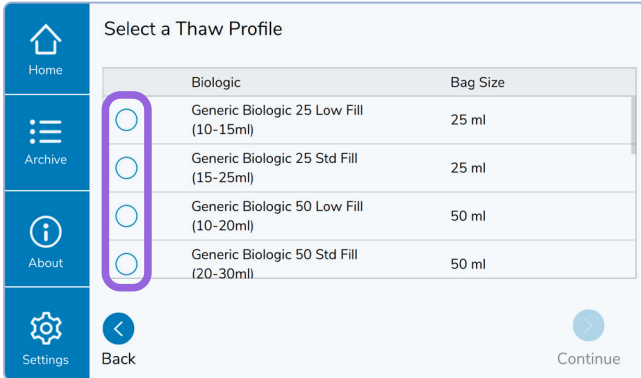


- 2 Enter your **Username** using the pop-up keyboard. Your Username must match a profile stored in the machine (as set up by an Administrator).

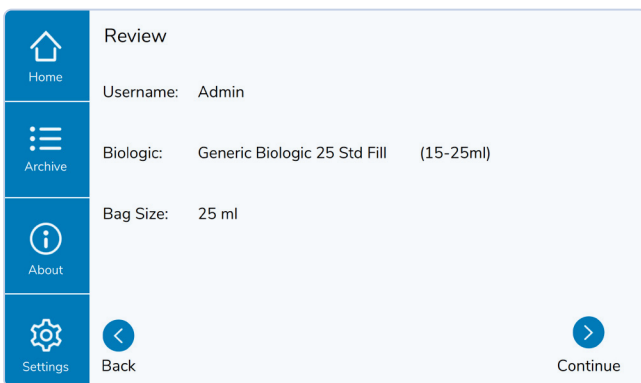
**NOTE:** Usernames are case sensitive.



- 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

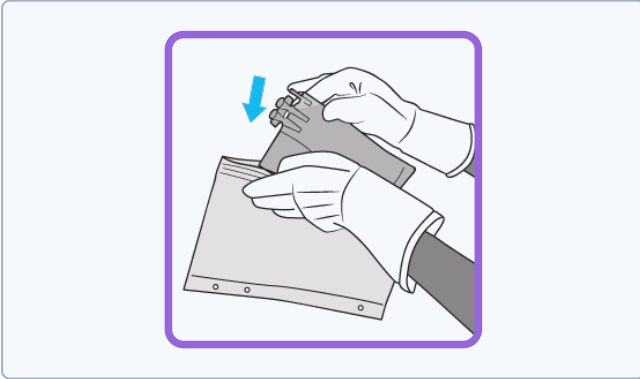
The heaters are de-energized when the drawer opens to reduce risk of thermal injury, so work as quickly as possible on the following steps.



### CAUTION

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

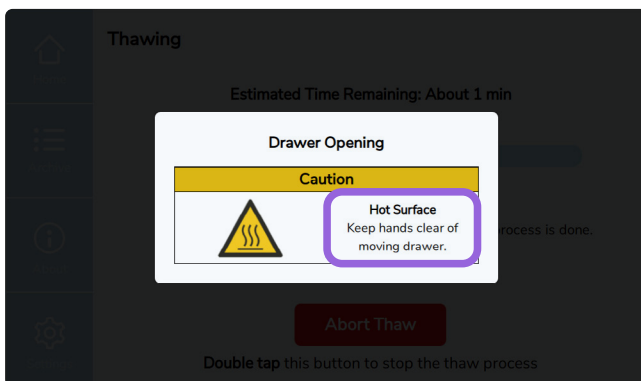
### 3.1 Running a Thaw (continued)



- 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 zipper seal. Confirm completion of the zip-seal closure.
- 11 Select **Open Drawer** to proceed.

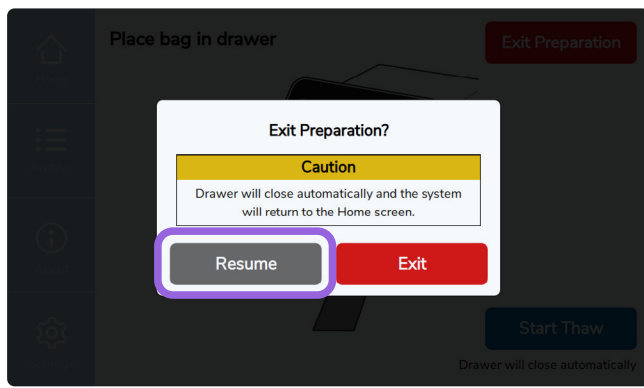


- 12 Keep hands and other objects clear of the moving **Drawer**.

### 3.1 Running a Thaw (continued)



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**.



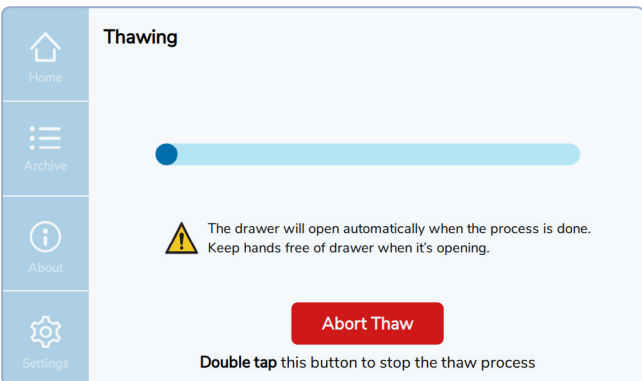
#### CAUTION

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.

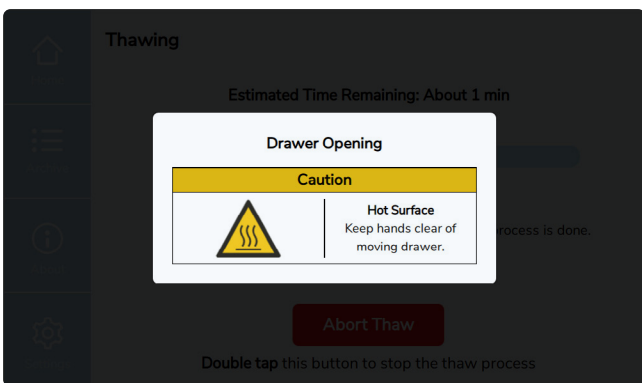
### 3.1 Running a Thaw (continued)



- 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.

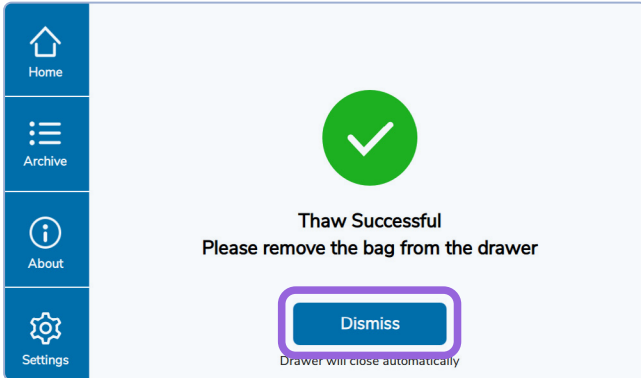


- 19 Wait for the thaw event to complete.  
If you wish to abort the thaw event, see Section 3.3 for **Aborting a Thaw**.

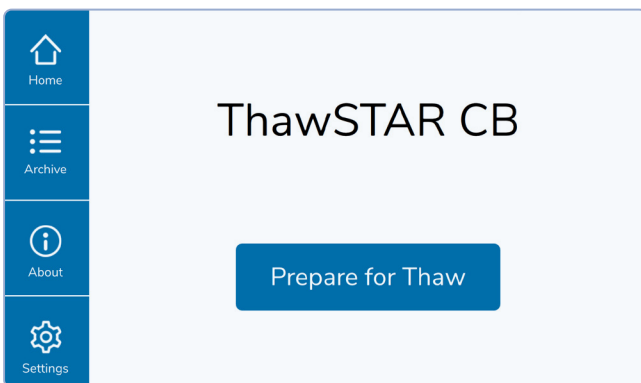


- 20 At the end of the thaw event, the **Drawer** will automatically open and the system will display either a Thaw Successful or Thaw Failure screen. See Section 3.2 for **Thaw Results**.
- 21 Keep hands and other objects clear of the moving Drawer.  
**NOTE:** All thaw results are automatically saved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

### 3.1 Running a Thaw (continued)



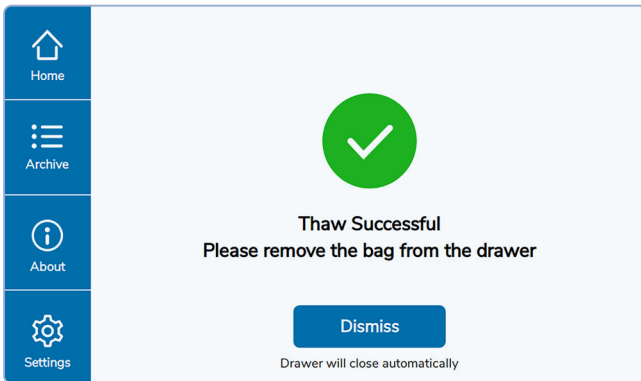
22 The **Dismiss** button will cause the door to close and take you back to the Home Screen.



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.

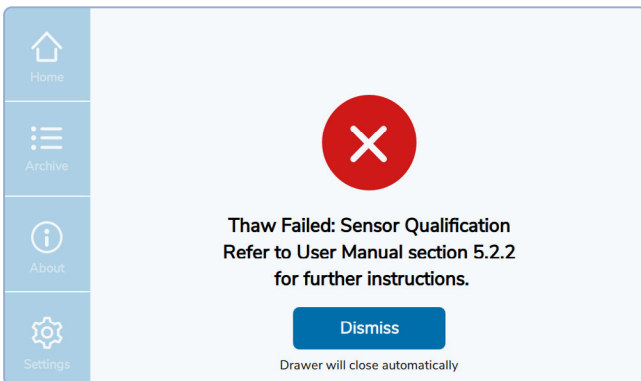


Successful thaw results are automatically saved to the system **Archive**.



### WARNING

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

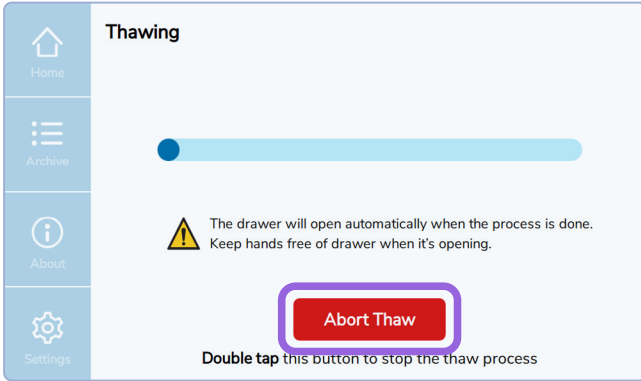


Thaw events may fail for a variety of reasons.

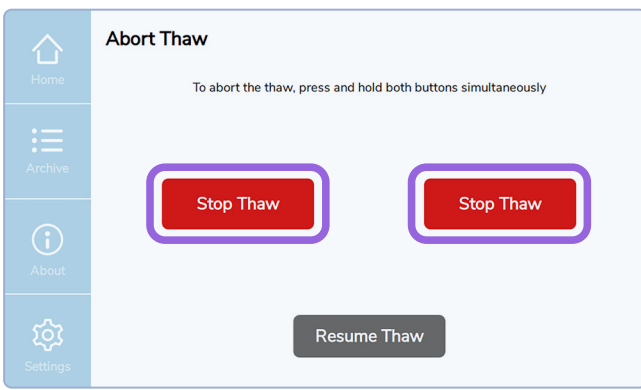
If the ThawSTAR CB displays a Thaw Failure message, please note the corresponding error description and see Section 5 for additional details and support.

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

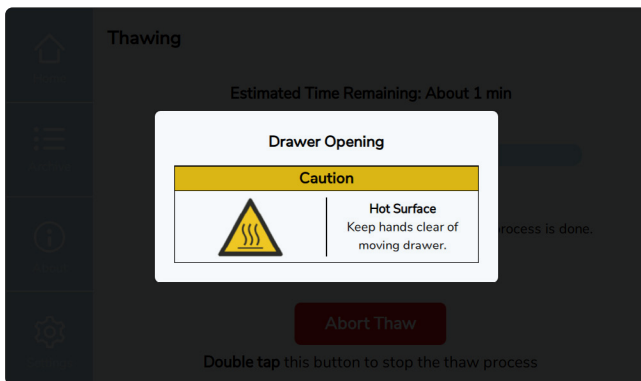
### 3.3 Aborting a Thaw



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.



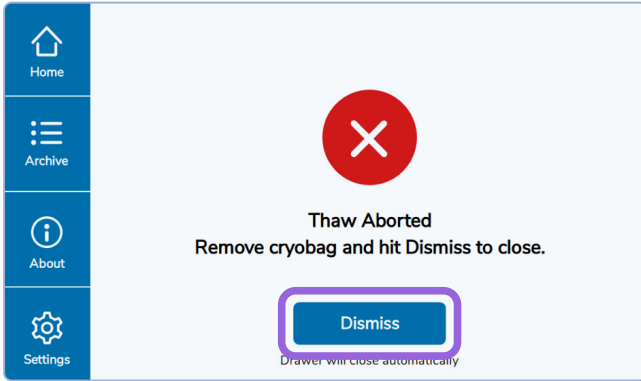
3 Once the thaw has been aborted, the Drawer will automatically open.



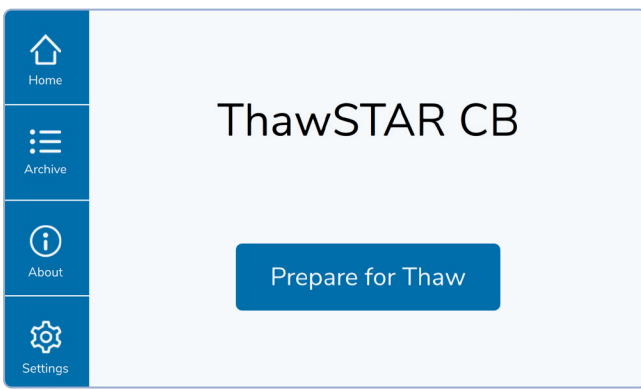
#### CAUTION

Keep hands and other objects clear of the moving Drawer.

### 3.3 Aborting a Thaw (continued)



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



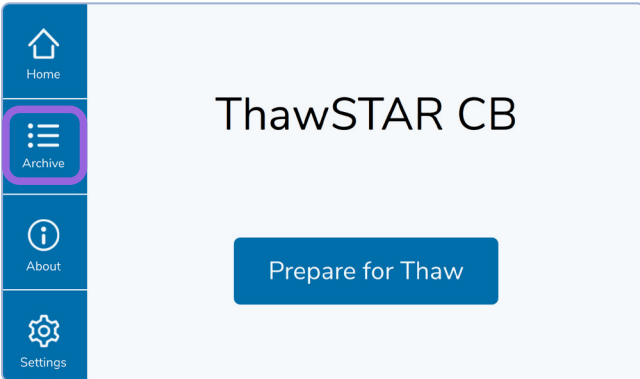
You are ready to start another thaw event.

## 4 Administrator Passwords and Functions

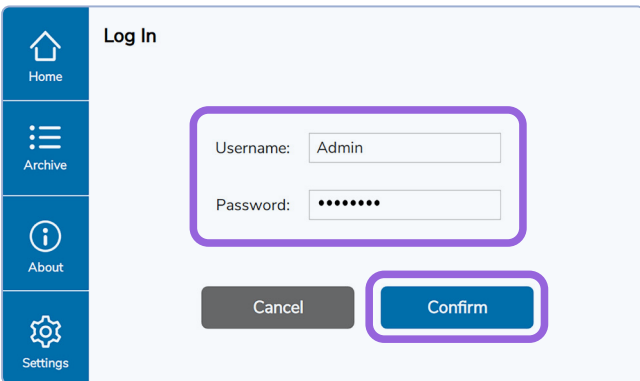
Administrators are able to access password-protected functions related to the system Archive, Users, and Thaw Profiles. Administrator functions may include the ability to edit and add new Users, Thaw Profiles, and Archives; and export/import data from a USB drive, and delete.

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

### 4.1 Archive



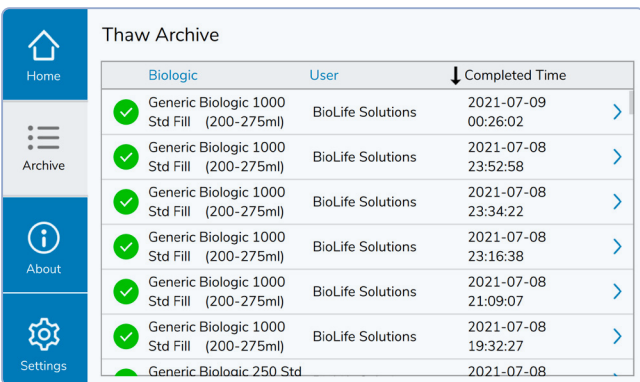
1 From the Home screen, select **Archive**.



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.



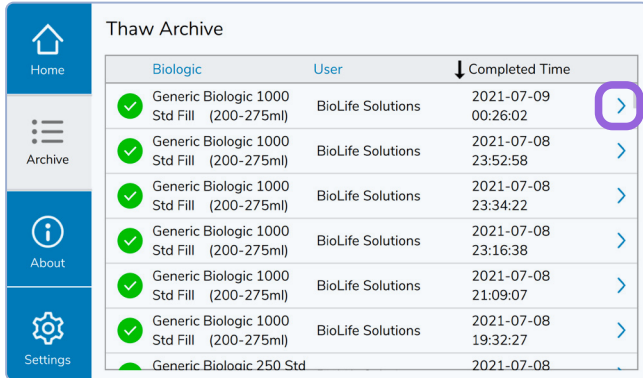
You will see a simple view of the system’s **Thaw Archive**, which lists all of the saved thaw events.

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

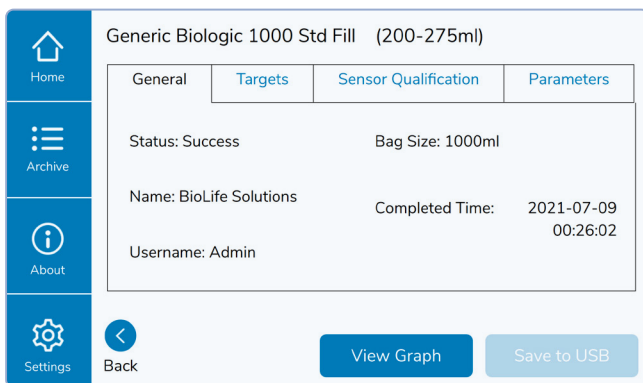
## Viewing Archive Entries



Thaw Archive

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.



Generic Biologic 1000 Std Fill (200-275ml)

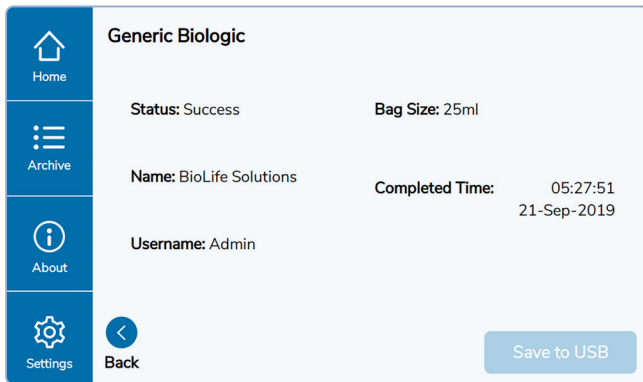
General	Targets	Sensor Qualification	Parameters
Status: Success		Bag Size: 1000ml	
Name: BioLife Solutions		Completed Time:	2021-07-09 00:26:02
Username: Admin			

Back View Graph Save to USB

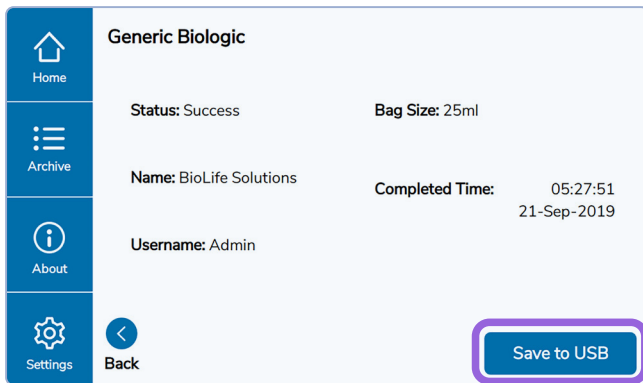
You will see additional information for that specific thaw event.

## 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).

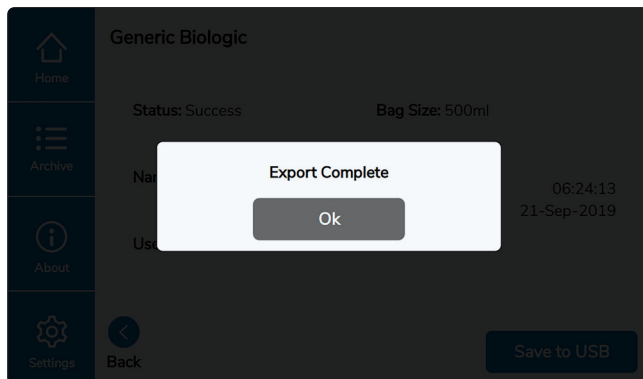


- 1 Starting from the specific thaw event entry that you wish to export (see Section 4.1.1), insert a USB drive into the **USB Port**.



- 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.



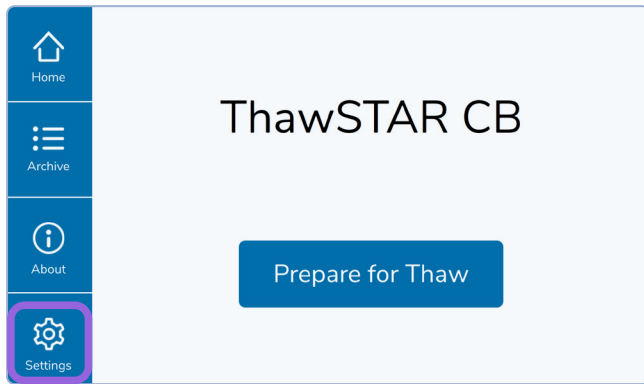
- 3 An “**Export Complete**” or “**Export Failed**” screen will appear. Selecting Ok on either screen will return you to the previous archive entry screen.

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

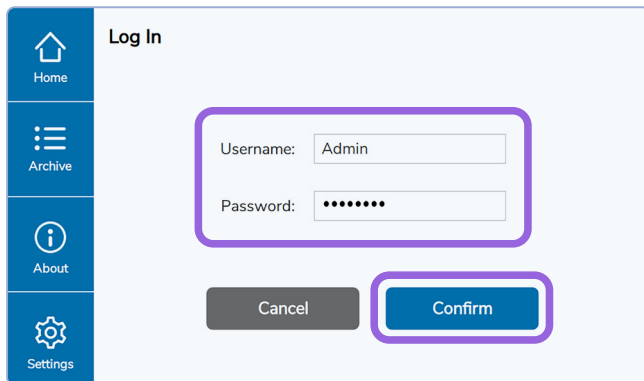
The file format of exported Archive Entries will be **.db**.

## 4.2 Settings

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

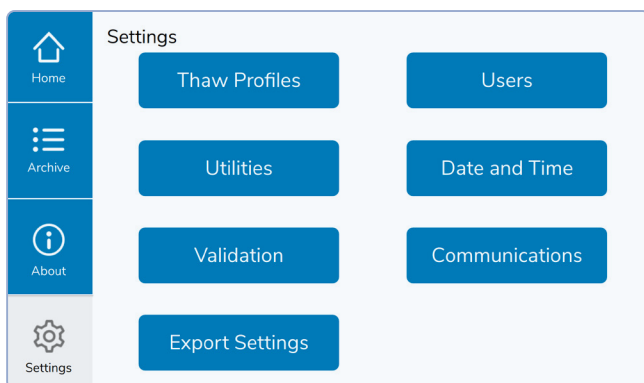


1 From the Home screen, select **Settings**.



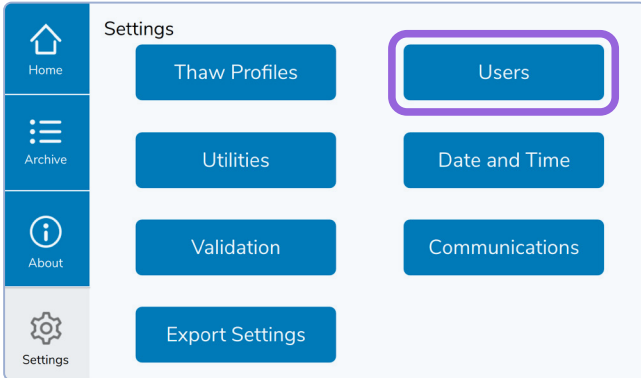
2 Enter Administrator's **Username** and **Password** using the pop-up keyboard.

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



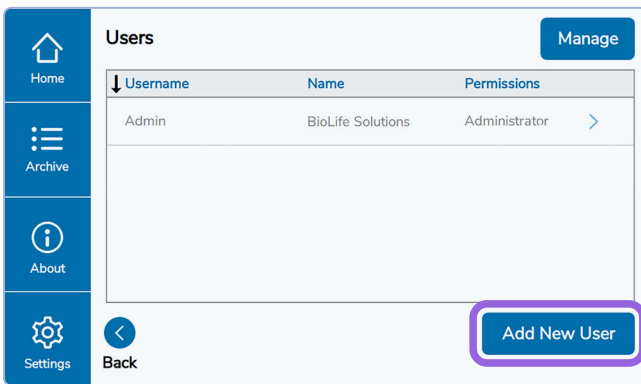
4 Use the **Settings** screen to access Thaw Profiles, Users, and Utilities.

## 4.2.1 Users

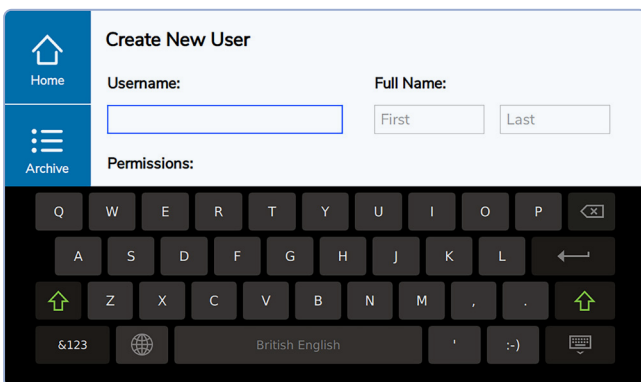


- 1 On the Settings screen (see Section 4.2), select **Users**.

### 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.

#### 4.2.1.1 Creating Users (continued)

**Create New User**

Home

Archive

About

Settings

Back

Save

Username:

User 1

Permissions:

Operator  Administrator

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

**Create New User**

Home

Archive

About

Settings

Back

Save

Username:

Full Name:

First Last

Permissions:

Operator  Administrator

New Password

Confirm New Password

Enter password Enter password

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.

**Users**

Home

Archive

About

Settings

Back

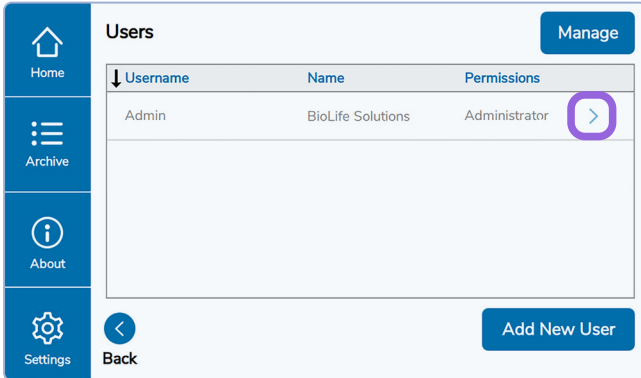
Manage

Username	Name	Permissions
Admin	BioLife Solutions	Administrator >

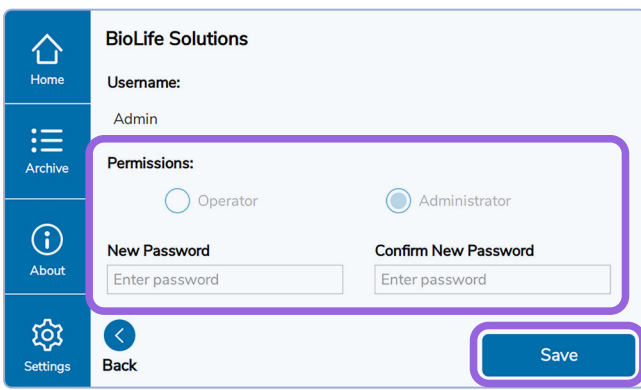
Add New User

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

### 4.2.1.2 Editing Users



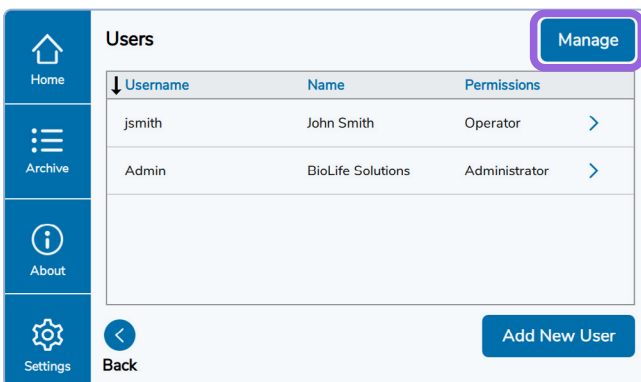
1 On the **Users** screen, select the caret to the right of the User you wish to edit.



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

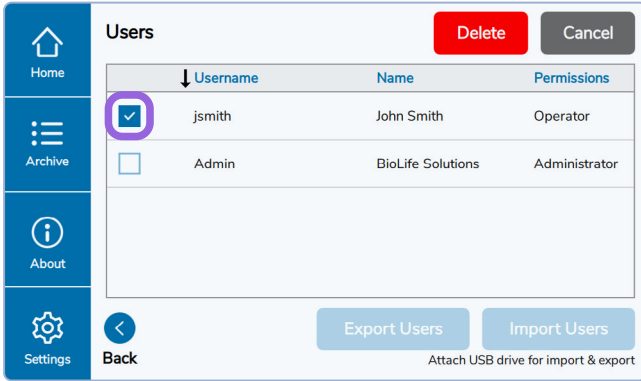
3 Select **Save** to save your changes and return to the Users screen.

### 4.2.1.3 Deleting Users

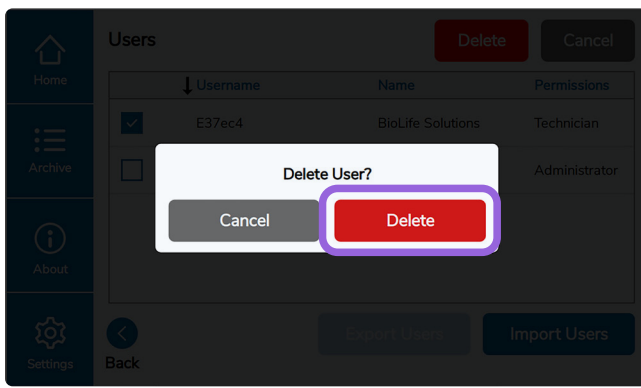


1 On the Users screen, select **Manage**.

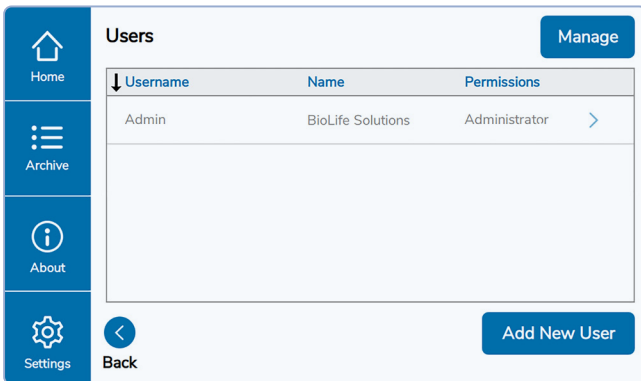
### 4.2.1.3 Deleting Users (continued)



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



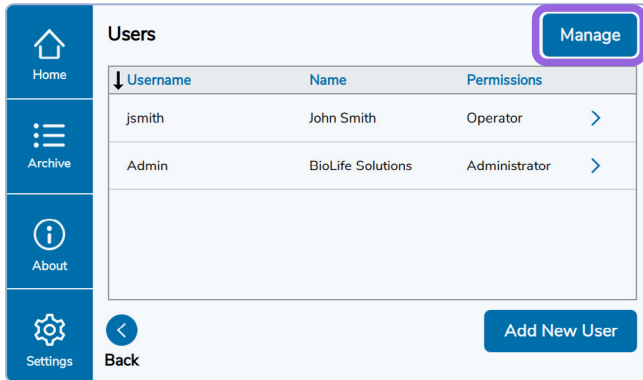
3 Select **Delete** to confirm.



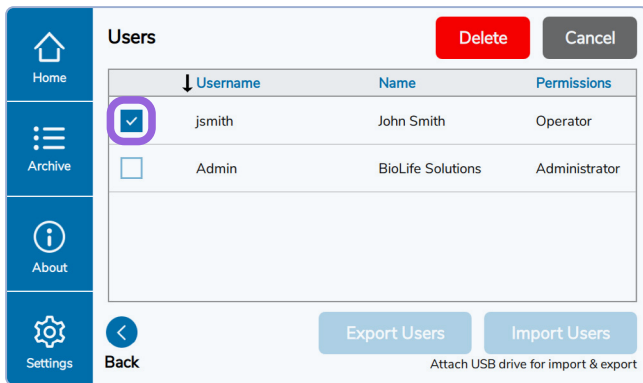
The list of **Users** on the Users screen should reflect the deletion.

#### 4.2.1.4 Exporting Users

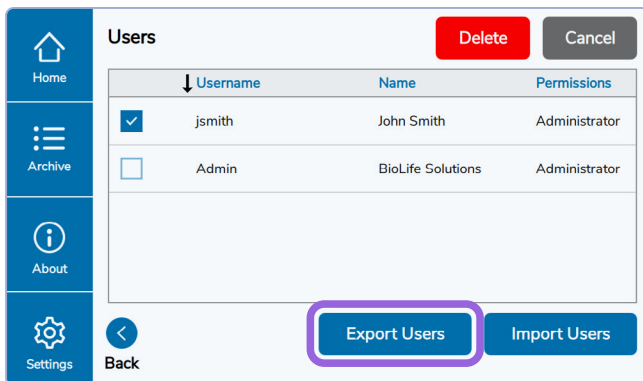
Users can either be Deleted or Exported (there is no option presented to delete after Export as with Thaw Archives). There is a secondary means by which Users and other data from the machine can be exported and deleted (reset to factory defaults) by using the Utilities screen (see Section 4.2.3).



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

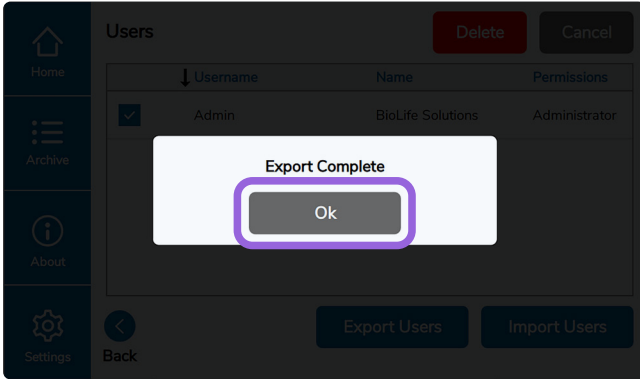


2 Check the box next to the **User(s)** you wish to export.  
Insert a USB drive into the **USB Port**.



3 Select **Export Users**.

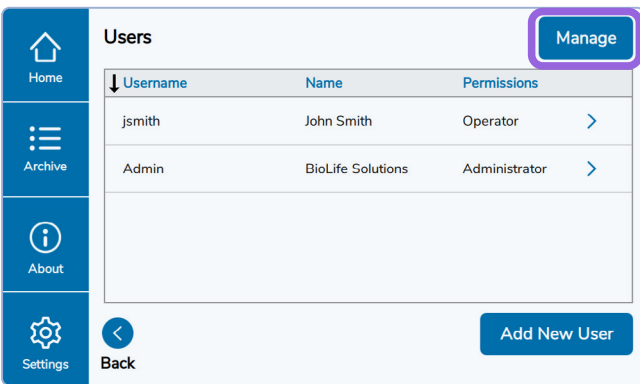
#### 4.2.1.4 Exporting Users (continued)



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

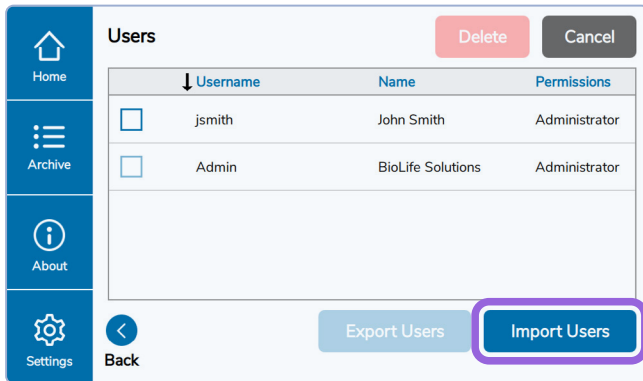
**NOTE:** If you receive the “Export Failed” screen, check to see if your USB drive is corrupted. You may need to reformat the USB drive.

#### 4.2.1.5 Importing Users

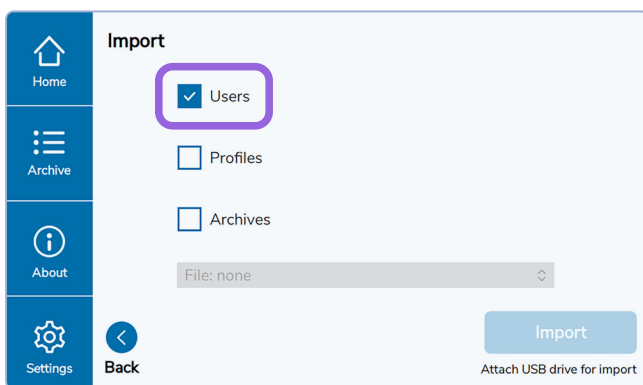


1 On the Users screen, select **Manage**. Insert USB drive containing desired users to import.

### 4.2.1.5 Importing Users (continued)



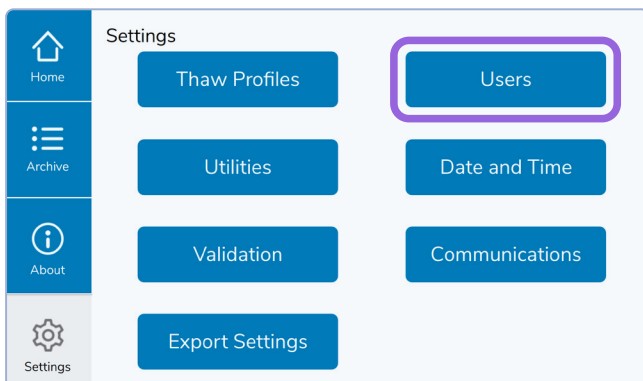
2 Select **Import Users**.



3 Check the box next to **Users**.  
Select **Import** to import users.

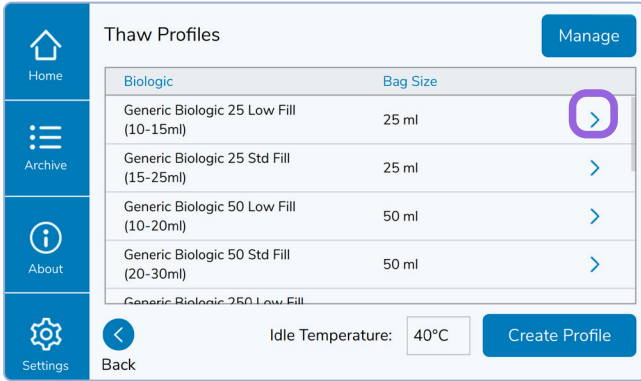
### 4.2.2 Thaw Profiles

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.

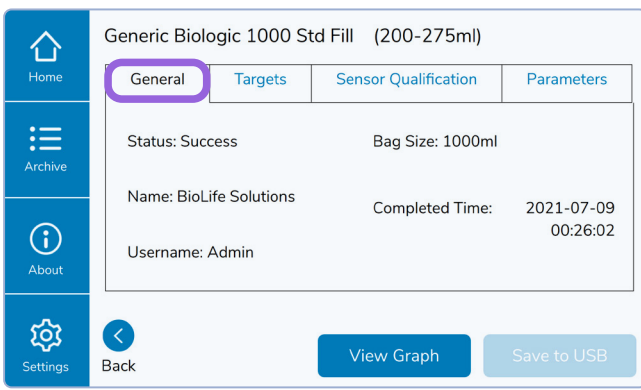


1 On the Settings screen (see Section 4.2), select **Thaw Profiles**.

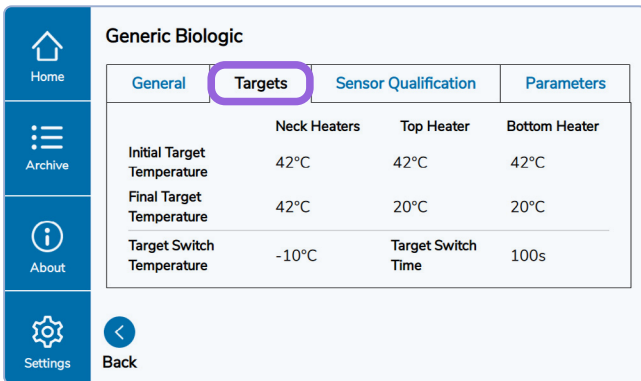
### 4.2.2.1 Viewing Thaw Profiles



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

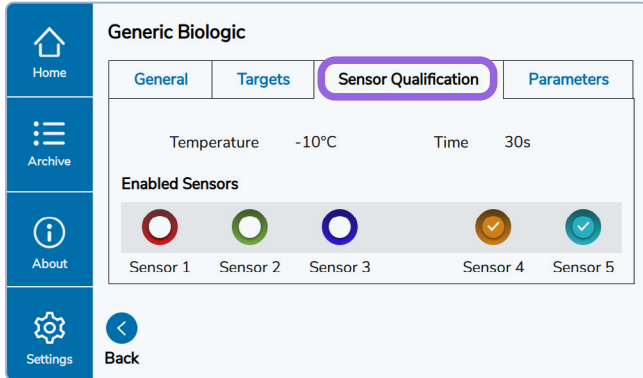


2 Information regarding individual Thaw Profiles is presented on four tabs. The **General** tab lists the biologic name and bag size.

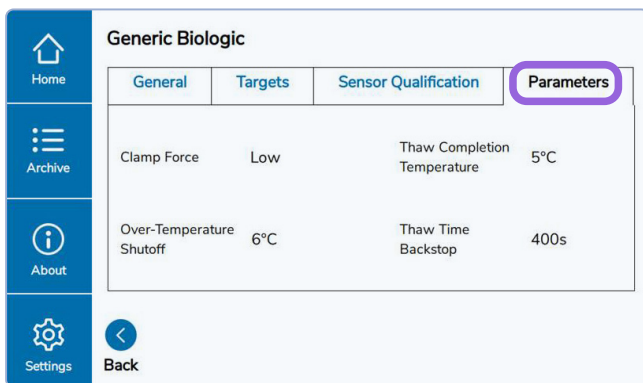


3 The **Targets** tab provides information regarding target temperatures and switch time.

#### 4.2.2.1 Viewing Thaw Profiles (continued)

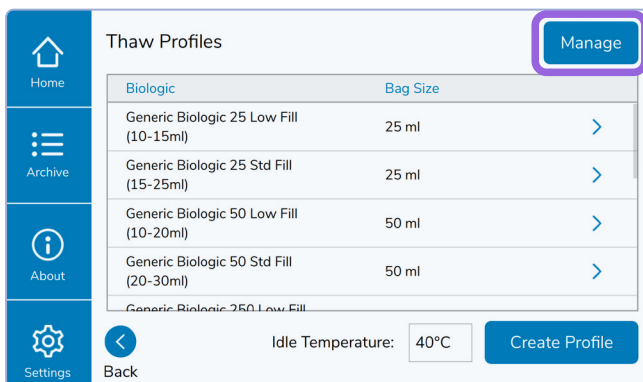


4 The **Sensor Qualification** tab displays information regarding the ThawSTAR CB's enabled sensors.



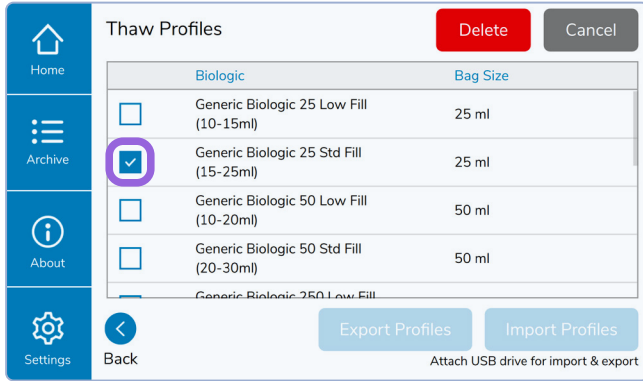
5 The **Parameters** tab displays other thaw settings.

#### 4.2.2.2 Deleting Thaw Profiles

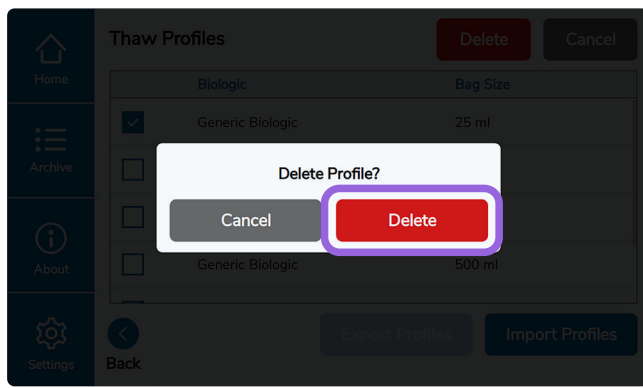


1 On the Settings screen (see Section 4.2), select **Thaw Profiles**. Press the **Manage** button.

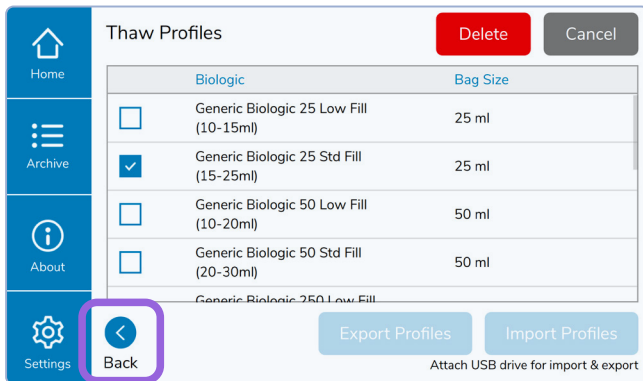
#### 4.2.2.2 Deleting Thaw Profiles (continued)



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



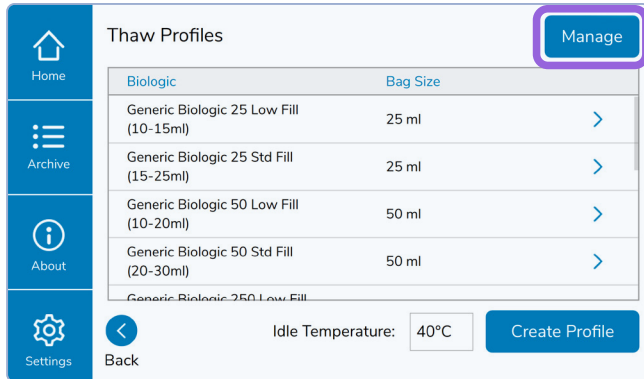
3 Select **Delete** to confirm.



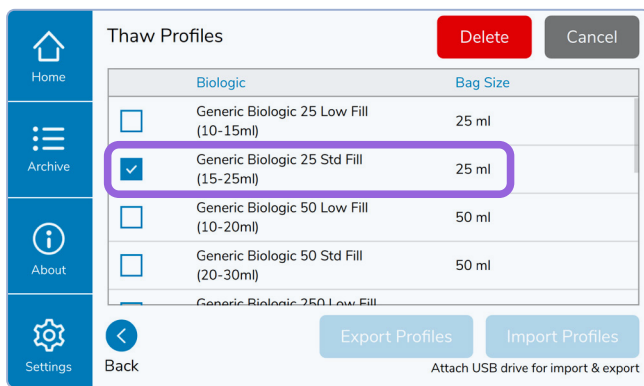
4 The list of Thaw Profiles should reflect the deletion.  
Select **Back** to return to the Settings screen.

### 4.2.2.3 Exporting Thaw Profiles

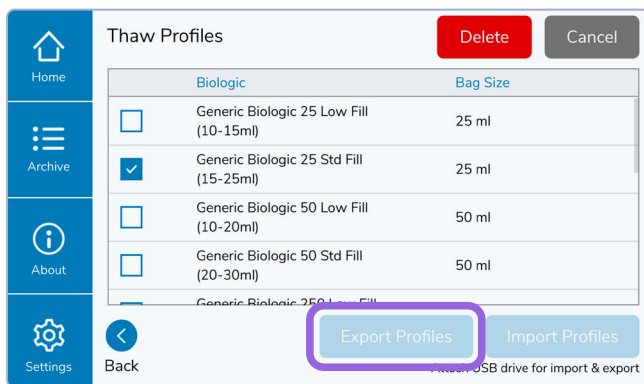
When exporting Thaw Profiles from the Thaw Profiles screen, there is no option to delete after exporting. The only way to delete Thaw Profiles after exporting is via the Utilities screen (see Section 4.2.3).



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

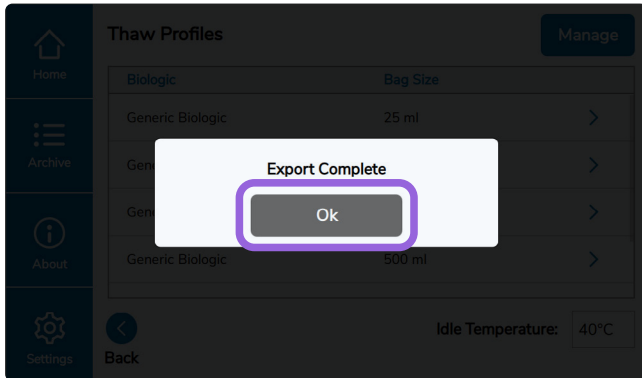


2 Check the box next to the Thaw Profile(s) you wish to export.  
Insert a USB drive into the **USB Port**.



3 Select **Export Profiles**.

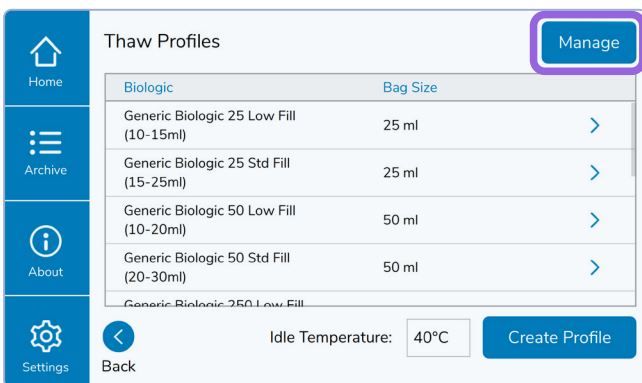
### 4.2.2.3 Exporting Thaw Profiles (continued)



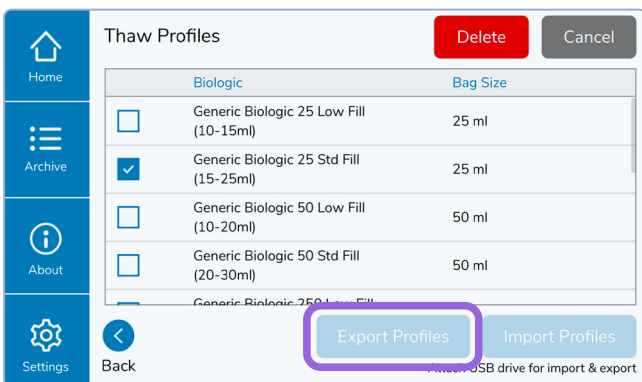
4 An “Export Complete” or “Export Failed” screen will appear. Selecting **Ok** on either screen will return you to the previous Thaw Profiles screen.

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

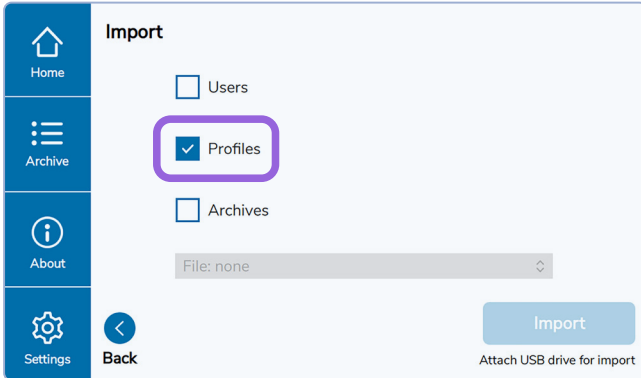


1 On the Thaw Profiles screen, select **Manage**.



2 Select **Import Profiles**.

#### 4.2.2.4 Importing Thaw Profiles (continued)

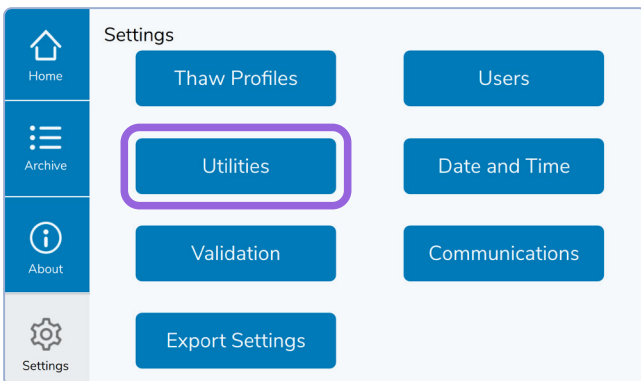


3 Check the box next to Profiles.

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

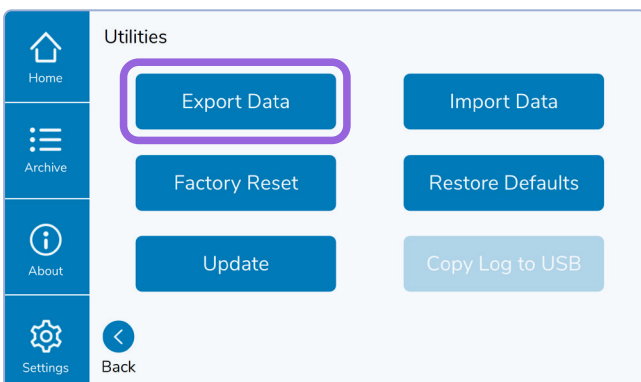
#### 4.2.3 Utilities

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.



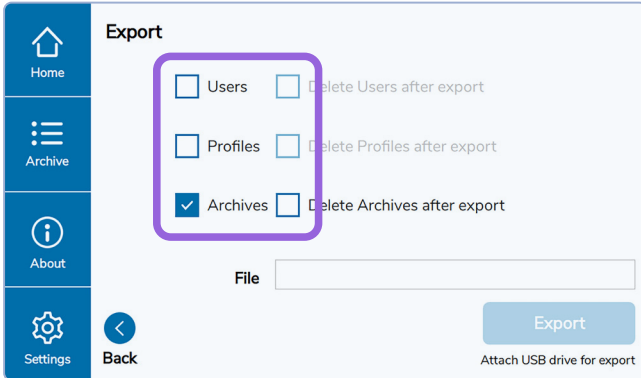
1 On the Settings screen (see Section 4.2),  
select **Utilities**.

#### 4.2.3.1 Exporting Data



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

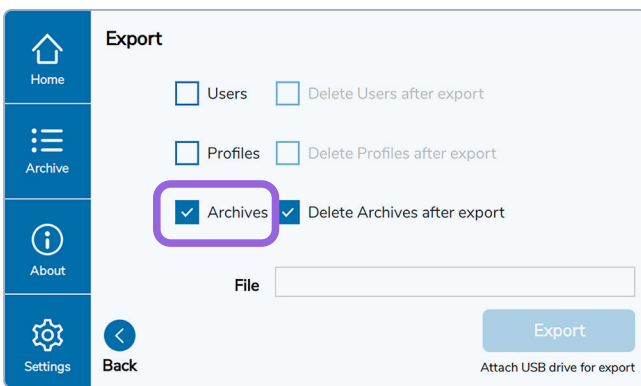
### 4.2.3.1 Exporting Data (continued)



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

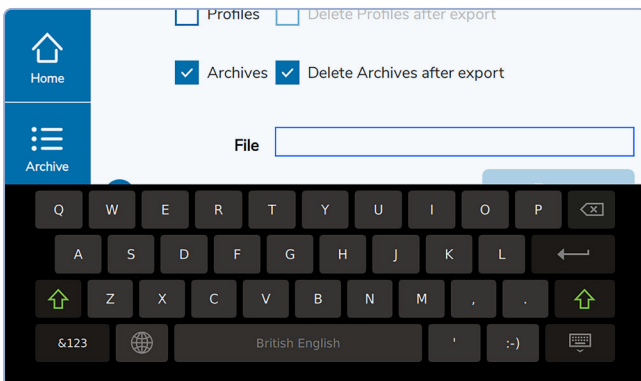
It is also possible to delete or keep the files on the system after export.

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



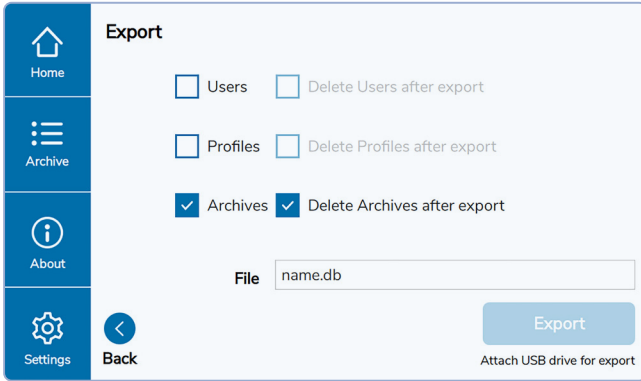
3 Check the box next to **Archives**.

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

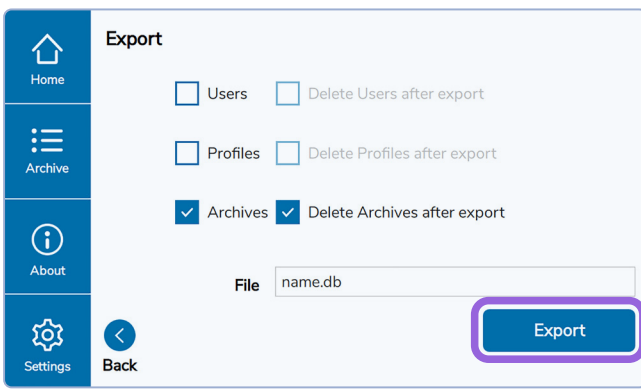


4 Using the pop-up keyboard, enter a name for the exported Archives file.

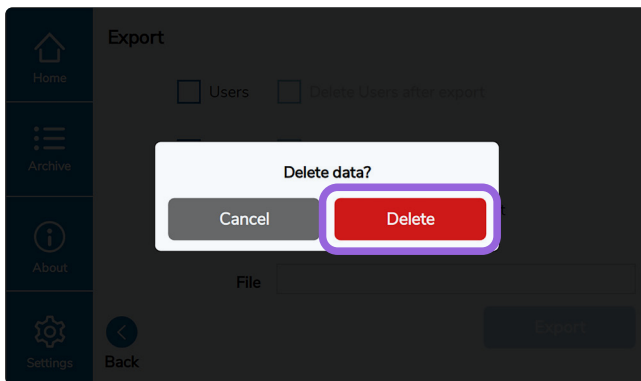
### 4.2.3.1 Exporting Data (continued)



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



6 Select **Export**.

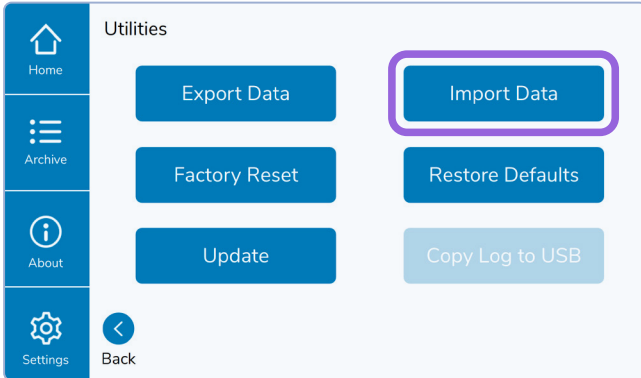


7 If **Delete Archives** after export was selected, you will be asked to confirm deletion of the data from the system.

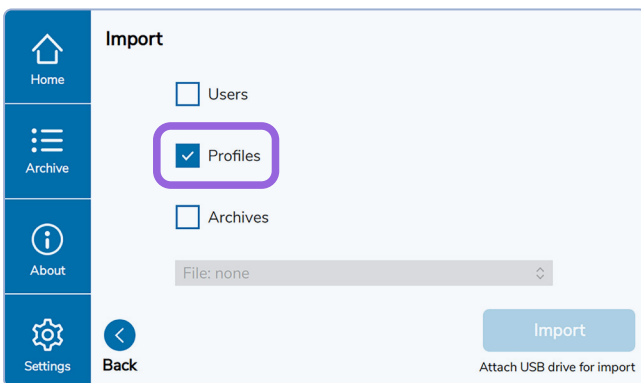
If you select **Cancel** you will return to the previous Export screen, and the data will remain on the system.

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



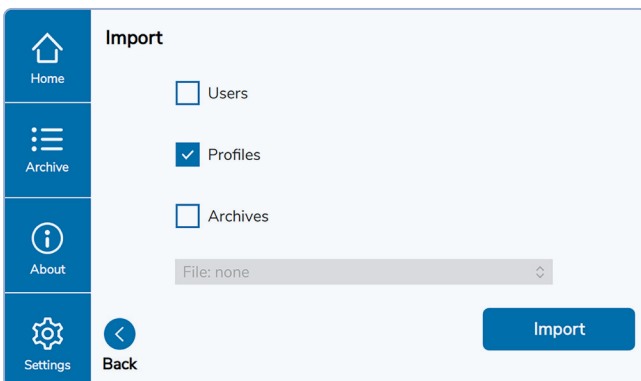
1 On the Utilities screen, select **Import Data**.



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

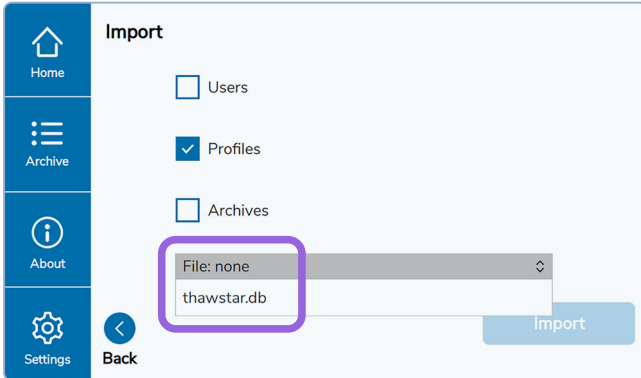
We will illustrate the process using Thaw Profiles. The steps are the same when importing Users and Archives from this screen.

Check the box next to **Profiles**.

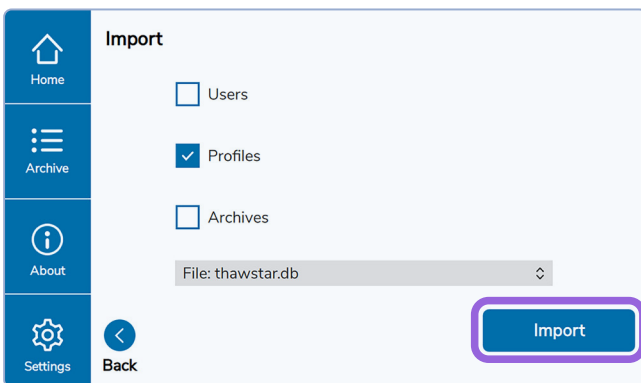


3 Insert a USB drive into the **USB Port** containing desired profiles for import.

### 4.2.3.2 Importing Data (continued)



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

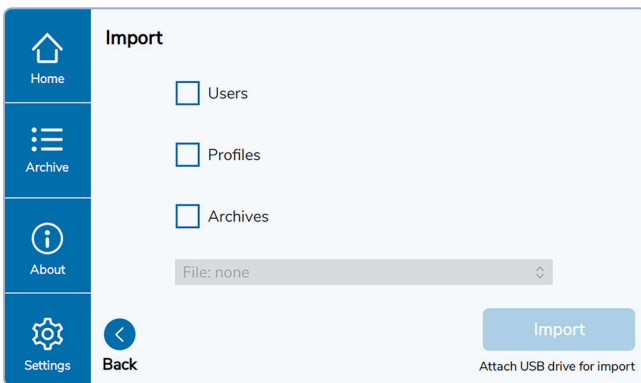


5 Select **Import** to download the file from the USB drive.

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



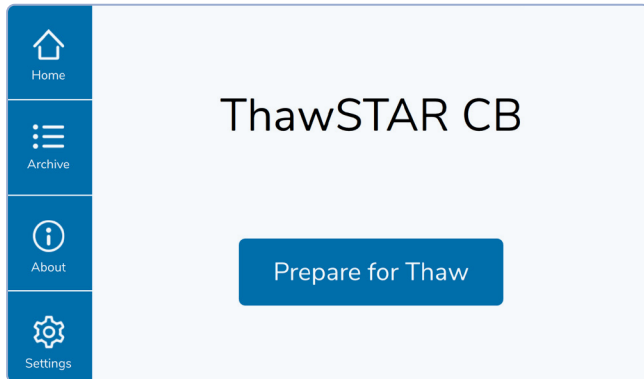
You are now ready to select other files for import.

### 4.2.3.3 Validation Sequence

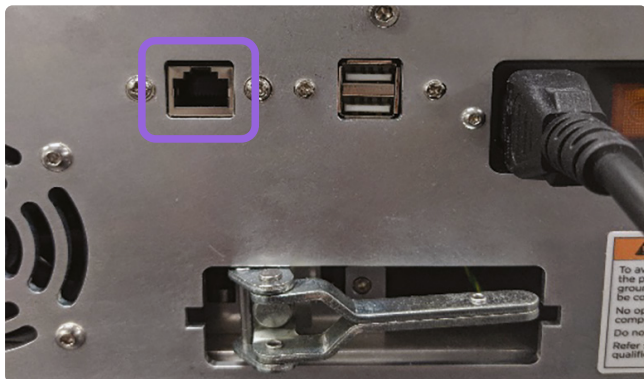
The Validation section of the ThawSTAR CB enables Admins to perform an automated sequence of internal checks for the instrument. This test is designed for initial qualification and diagnostics purposes only.

### 4.2.3.4 Connection of ThawSTAR CB via Ethernet

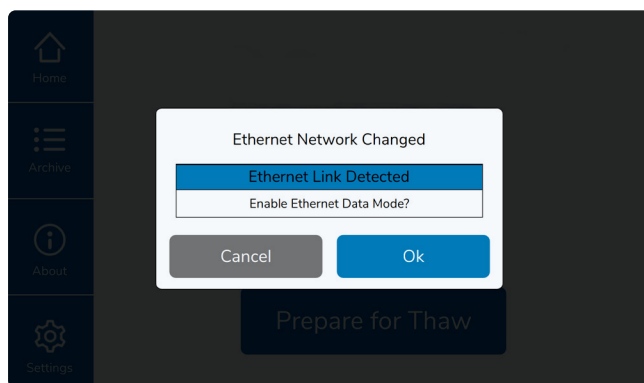
- Requires software version 4.3.0 or above
- Ensure set up is performed with appropriate Laboratory and IT personnel



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

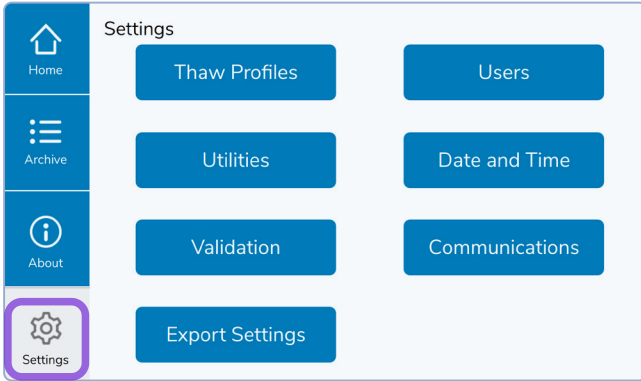


- 2 To begin setup, plug in ThawSTAR CB into a network switch using the **Ethernet port** at the rear of the unit.

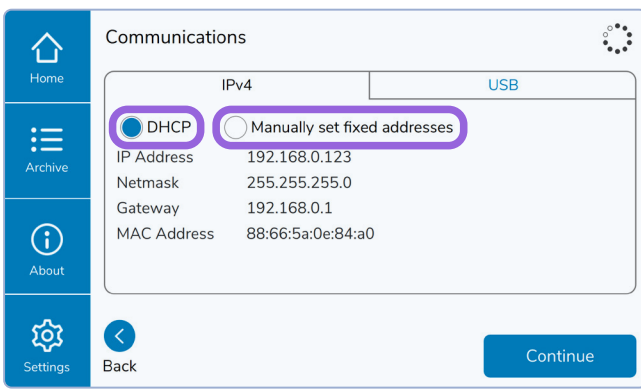


- 3 A dialog box will appear on the ThawSTAR CB screen prompting the user to set up **Ethernet Data Mode**.  
Press the “**Ok**” button when the dialog box appears on the ThawSTAR CB to set up Ethernet Data Mode at the Communications page (Step 5). Sign in when prompted with Admin credentials.

#### 4.2.3.4 Connection of ThawSTAR CB via Ethernet (continued)



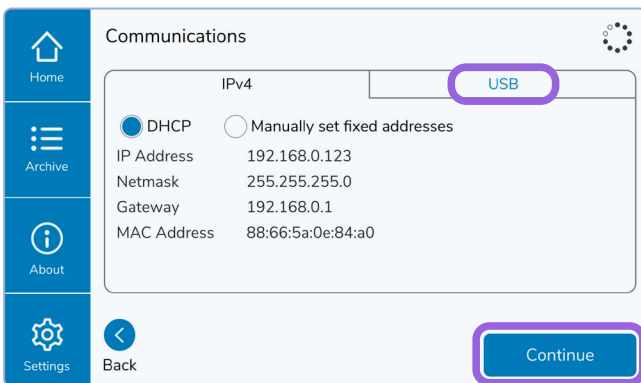
4 The Communications page can also be accessed from the Home page via signing into the **Settings** tab in the bottom left corner of the Home screen and signing in as an Admin user.



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.

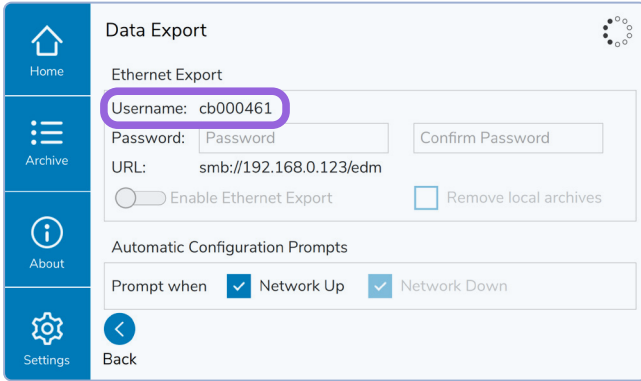


6 If laboratory and IT personnel require **USB** ports to be disabled for security purposes, move the slider to the left to disable USB functionality.

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

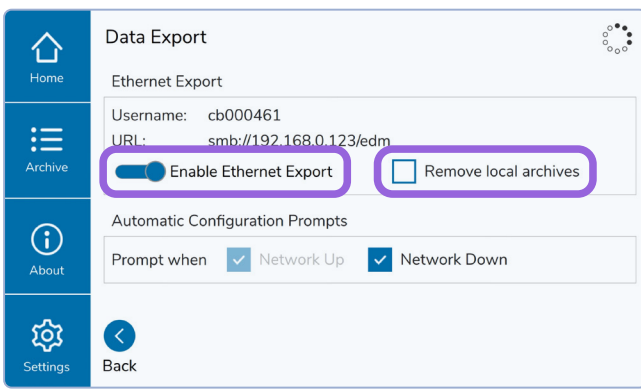
Once the desired settings are inputted, press Save and **Continue**.

#### 4.2.3.4 Connection of ThawSTAR CB via Ethernet (continued)



**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.

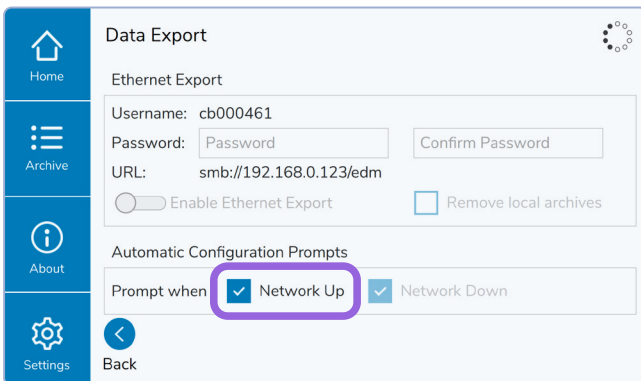


**8** Move the slider to the right to **Enable Ethernet Export**.

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.

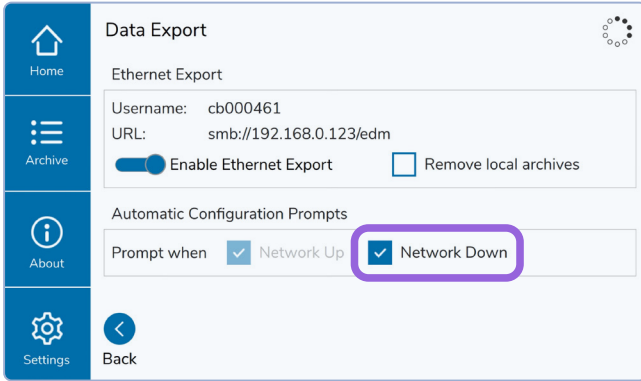
The default setting on this page is to leave the local archives in the system’s memory.



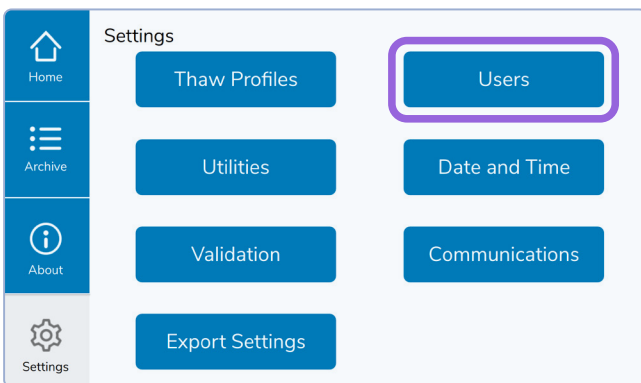
**9A** If laboratory and IT personnel would like to disable the prompts to connect or disconnect to Ethernet:

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

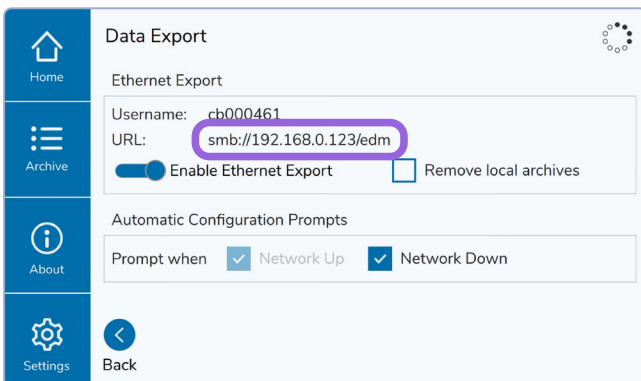
#### 4.2.3.4 Connection of ThawSTAR CB via Ethernet (continued)



**9B** Deselect the **Network Down** checkbox to disable prompts to disconnect from Ethernet.

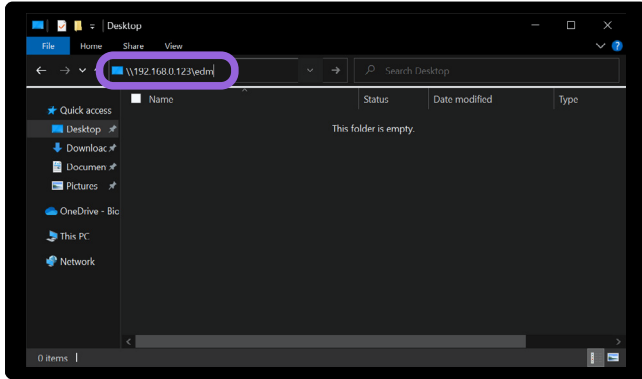


**10** The Data Export page can also be accessed directly through the **Export Settings** button on the Settings page.

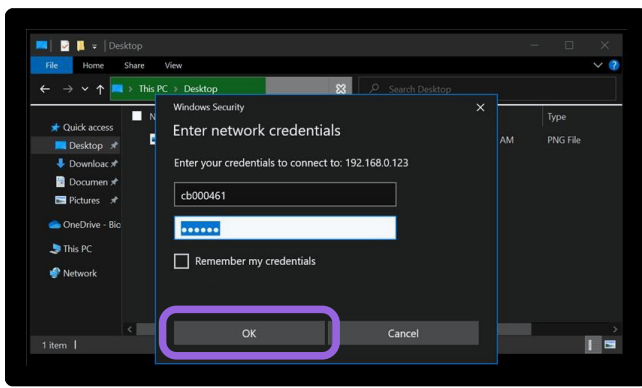


**11** If setting up a file share on a Windows computer attached to the local network, the destination file path for the ThawSTAR CB can be found at **\\192.168.0.123\edm** in the example in the image to the left.

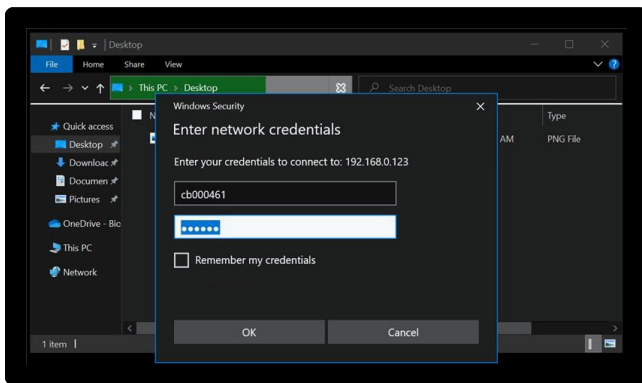
#### 4.2.3.4 Connection of ThawSTAR CB via Ethernet (continued)



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.**

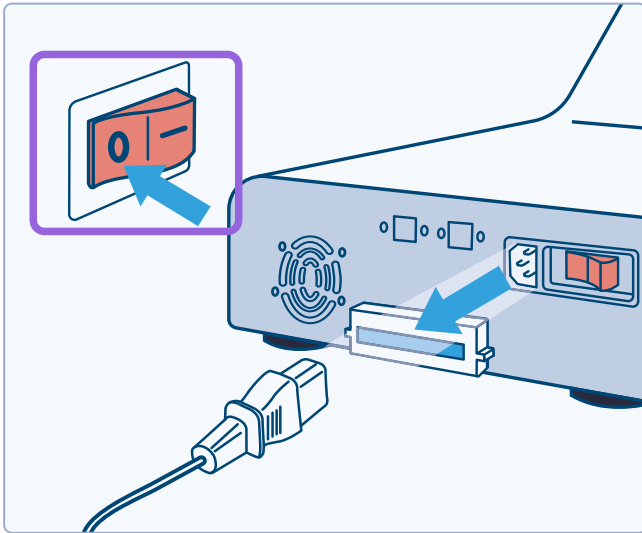


14 ThawSTAR CB network share will open. Any thaws performed since enabling Ethernet Data Mode will be present. Copy and remove the thaw archives as desired. The removal of the thaw archive data triggers deletion of the local copy, if "Remove Local Archives" was chosen above.

Contact BioLife customer support at +1-866-424-6543 or at [ThawTechSupport@biolifesolutions.com](mailto:ThawTechSupport@biolifesolutions.com) for assistance.

## 5 Troubleshooting

### 5.1 Power Failure – Emergency Cryobag Removal



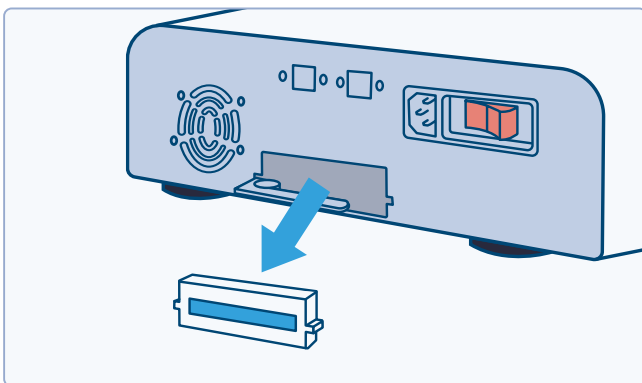
In case of unexpected power loss, the ThawSTAR CB has been equipped with an **Emergency Release Lever** to release the internal clamping mechanism and allow the drawer to be manually opened. To retrieve the cryobag in the event of power loss, follow the procedure outlined below:

- 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.



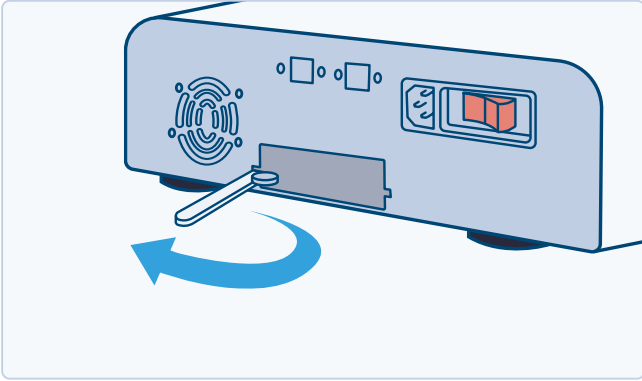
- 2 Pinch both sides of the **Emergency Release Cover** at the same time and pull the **Emergency Release Cover** away from the rear face of the ThawSTAR CB.

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

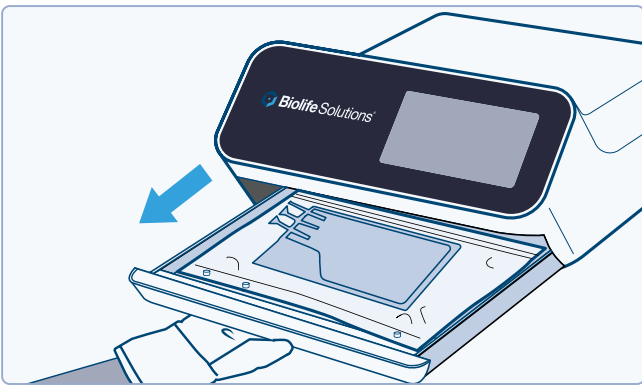


#### CAUTION

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.

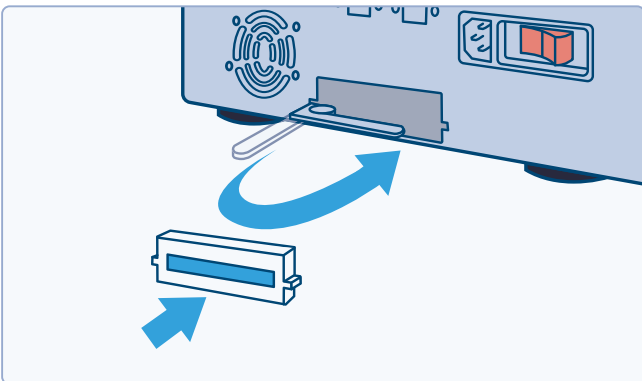
- 5 Remove the cryobag from the **Drawer**.



### 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

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.



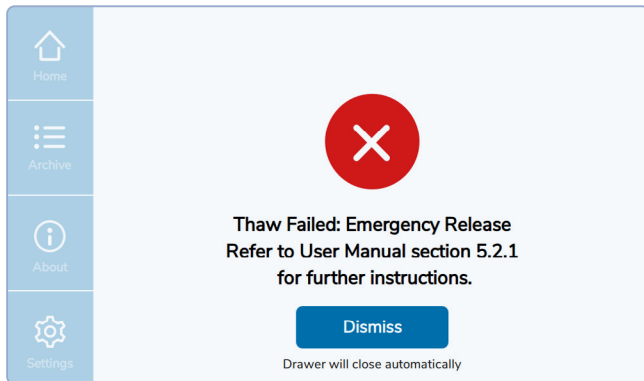
- 6 Return the **Emergency Release Lever** to its normal operating position and replace the **Emergency Release Cover**.

- 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.

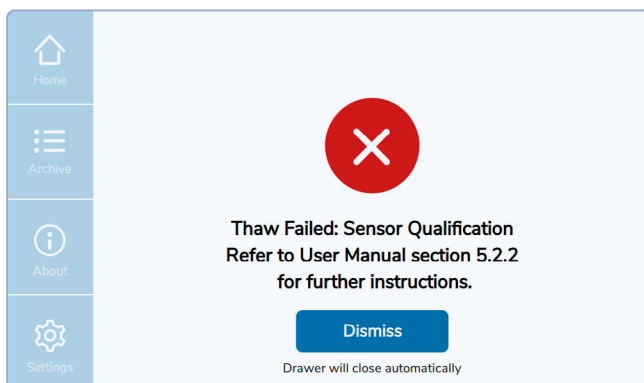
### 5.2.2 Sensor Qualification Error

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 approximately  $-80^{\circ}\text{C}$  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.

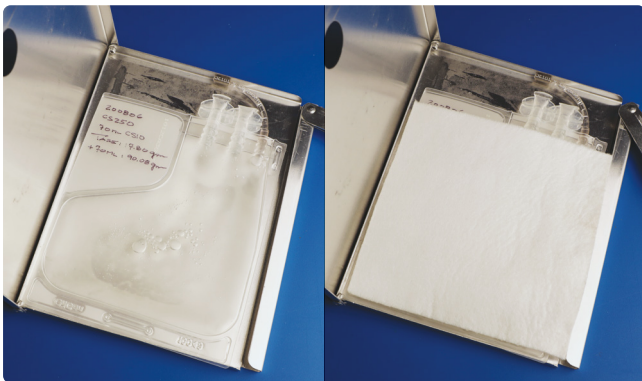
An Admin can view the sensor qualification temperature or any Thaw Profile stored in the machine (see Section 4.2.2.1 **Viewing Thaw Profiles**).

### 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.



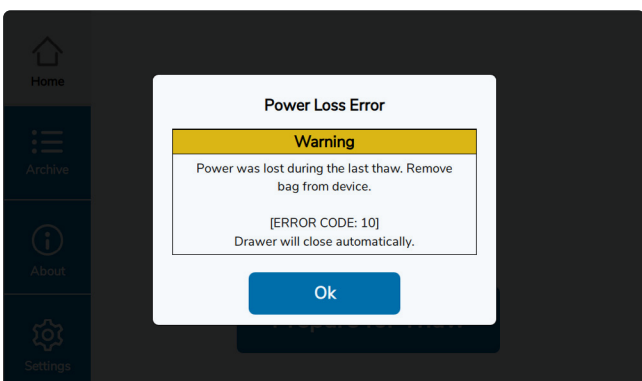
- 1 Eliminate gas pockets within the cryobag prior to sealing. A gas pocket over active sensors prevents accurate sensing of the media temperature.
- 2 Freeze the bag with the liquid contents evenly distributed within the bag. Unevenness within the bag media can result in incorrect temperature readings 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 (see image right).
- 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.

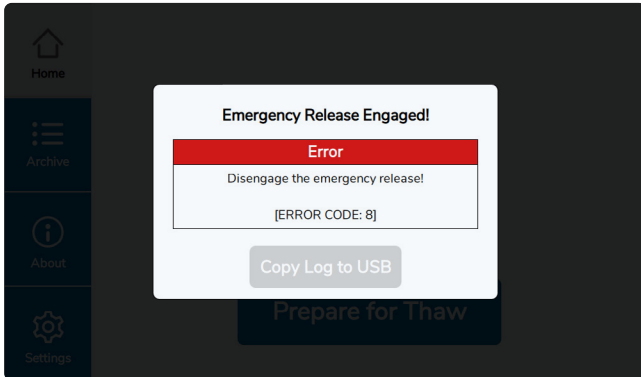


Press **OK** to return to the main menu.

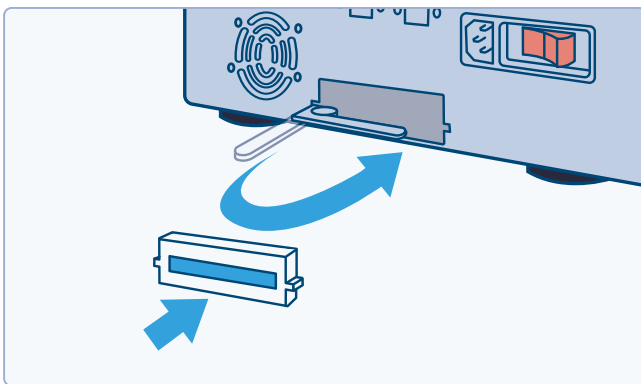
## 5.3 User-correctable Errors

### 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.

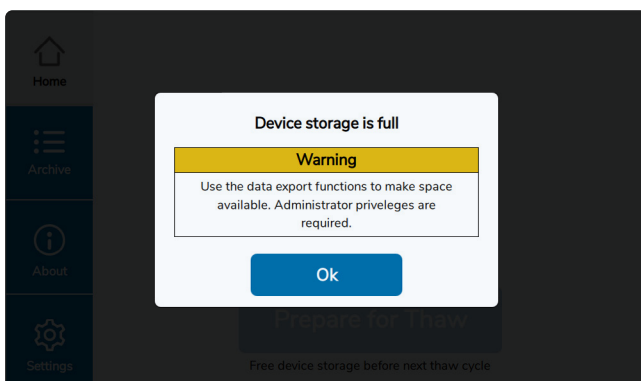


After replacing the Emergency Release Lever, ensure the power switch is turned OFF ('0') before plugging in the power cable.



### 5.3.2 Storage Full

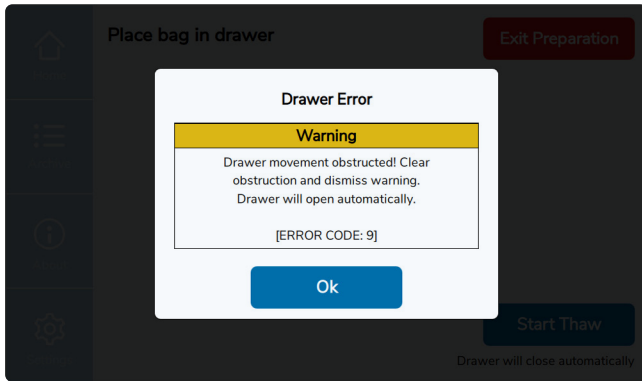
This error occurs when there is not enough space on the device to store the data for another thaw event.



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.

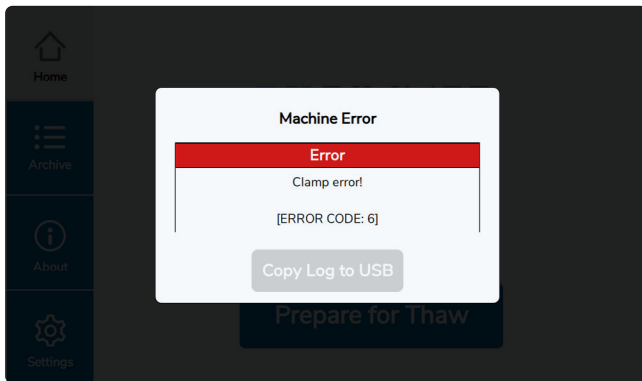
## 5.4 Technical Errors

These are errors that require technical support.

For service or repair support please call BioLife Solutions at **1-866-424-6543** or email [ThawTechSupport@BioLifeSolutions.com](mailto:ThawTechSupport@BioLifeSolutions.com).

### 5.4.1 Clamp Timeout

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

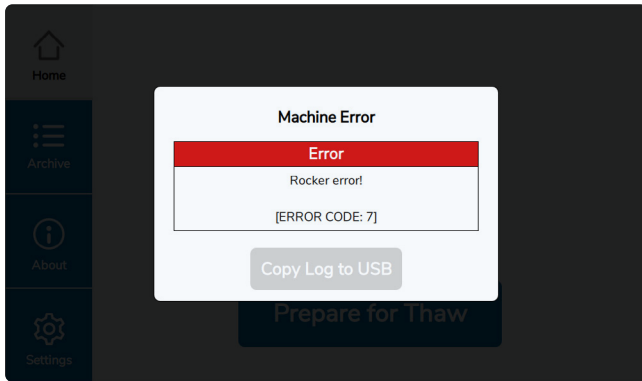


For service or repair support please call BioLife Solutions at **1-866-424-6543**.

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.

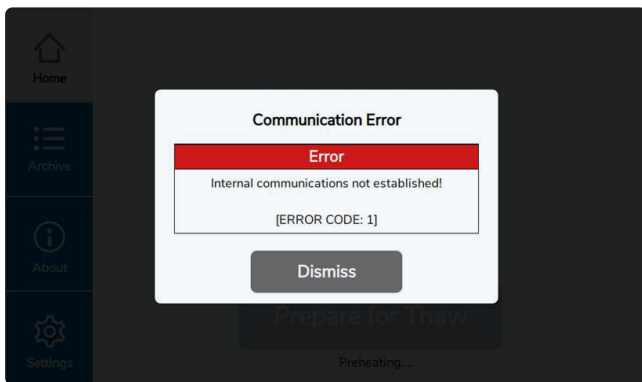


For service or repair support please call BioLife Solutions at **1-866-424-6543**.

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 at **1-866-424-6543**.

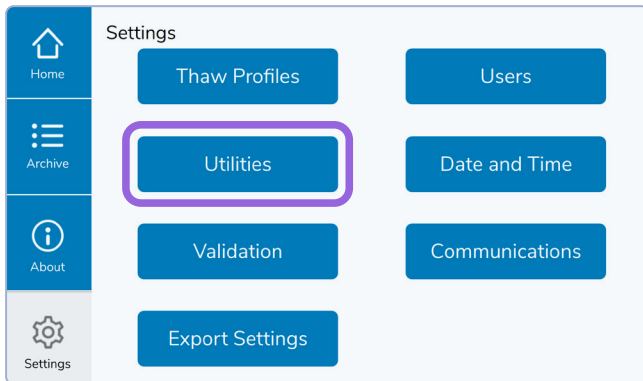
Note the error code so you can report it to service technicians.

The communication error can be dismissed.

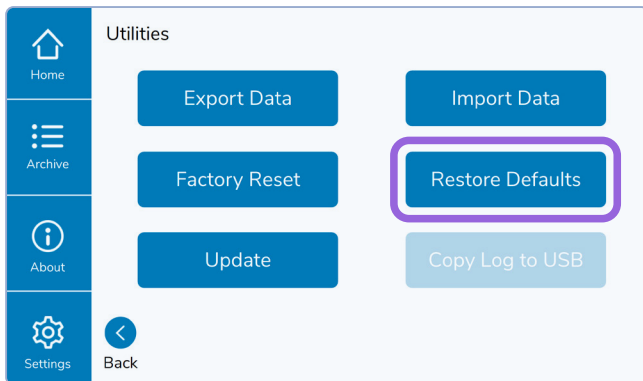
The communication error does not impact the ability to export data from the machine, including users, profiles, and archives.

## 5.5 Restore Defaults

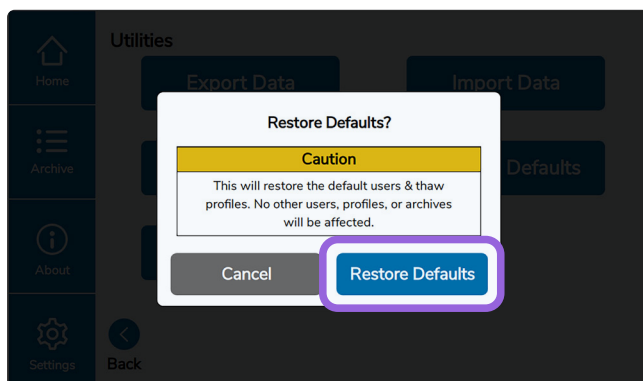
Restoring Defaults recreates the default Admin User and default Thaw Profiles.



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



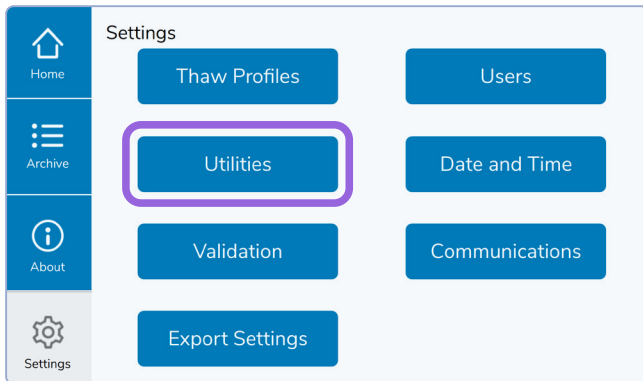
- 2 On the Utilities screen, select **Restore Defaults**.



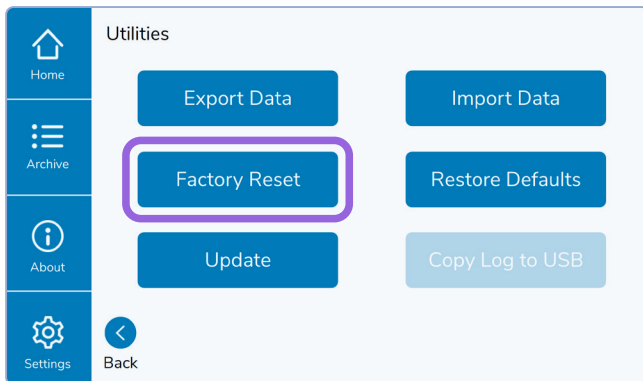
- 3 Confirm **Restore Defaults**.

## 5.6 Factory Reset

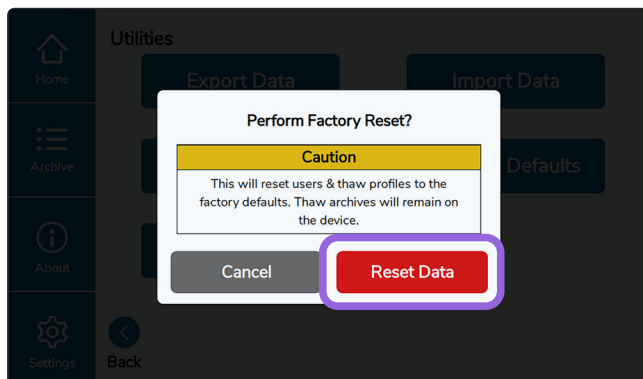
Factory reset will remove all Thaw Profiles and Users and recreate the default Admin User and default Thaw Profiles.



- 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 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	pounds
Height	20	centimeters
Width	38	centimeters
Length	46	centimeters
Total system weight	12	centimeters

### 7.2 Electrical Inputs and Outputs

Electrical Inputs & Outputs	Measure & Unit
Input voltage	100–120V, 200–240V
Frequency	50Hz / 60Hz
2 x USB inputs	5V, 1A each
Power input type	IEC 320-C14

## 7.3 Cryobag Dimensions

Bag External Dimensions & 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	milliliters
Starting temperature	-196	-60	celsius
Bag Manufacturers	OriGen, Miltenyi, Charter		
Bag size ranges	Nominal sizes 25 mL through 1000 mL		
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	celsius
Operating humidity	10	85	% relative humidity
Storage and shipping temperature	-10	70	celsius
Operating altitude	0	4000	meters
EMI/RFI	CE mark: WEEE, EN 60601, EN 61010 FCC or other CE certs due to Wireless		

## 8 Customer Service Information

Contact BioLife customer support at +1-866-424-6543 or at [support@biolifesolutions.com](mailto:support@biolifesolutions.com) for assistance.

### 8.1 Technical Service and Repair

Contact BioLife technical support at +1-866-424-6543 or at [ThawTechSupport@biolifesolutions.com](mailto:ThawTechSupport@biolifesolutions.com) for assistance.

**⚠ CAUTION:** If it is necessary to return your ThawSTAR CB Automated Thawing System for any reason, it is required that you decontaminate the unit prior to sending. Contact BioLife technical support or a BioLife authorized representative for decontamination instructions and a Return Material Authorization (RMA) Number.

## 9 Ordering Information

Part Number	Product
AST-90000	ThawSTAR CB (Cryo Bag) Automated Thawing System
AST-90011	ThawSTAR CB Extended Limited Warranty
AST-90013	ThawSTAR CB Power Cords
AST-90015	ThawSTAR IOPQ Packet for CB System
AST-90025	ThawSTAR CB Barrier Bags, 25mL, 25 per pack
AST-90050	ThawSTAR CB Barrier Bags, 50mL, 25 per pack
AST-90250	ThawSTAR CB Barrier Bags, 250mL, 25 per pack
AST-90500	ThawSTAR CB Barrier Bags, 500mL, 25 per pack
AST-90750	ThawSTAR CB Barrier Bags, 750mL, 25 per pack
AST-91000	ThawSTAR CB Barrier Bags, 1000mL, 25 per pack

Order additional ThawSTAR CB supplies at: [shop.biolifesolutions.com/range/thawing-solutions](https://shop.biolifesolutions.com/range/thawing-solutions)

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

## 10 Recycling Information



### 10.1 Decontamination

The product must be decontaminated before decommissioning. All local regulations must be followed with regard to scrapping of the equipment.

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### 10.2 Disposal of the Product

When taking the product out of service, the different materials must be separated and recycled according to national and local environmental regulations.

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### 10.3 Disposal of Electrical Components

Waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.

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**Water-free Thawing**

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CFD-0039\_1.0