

# Instructions for Use

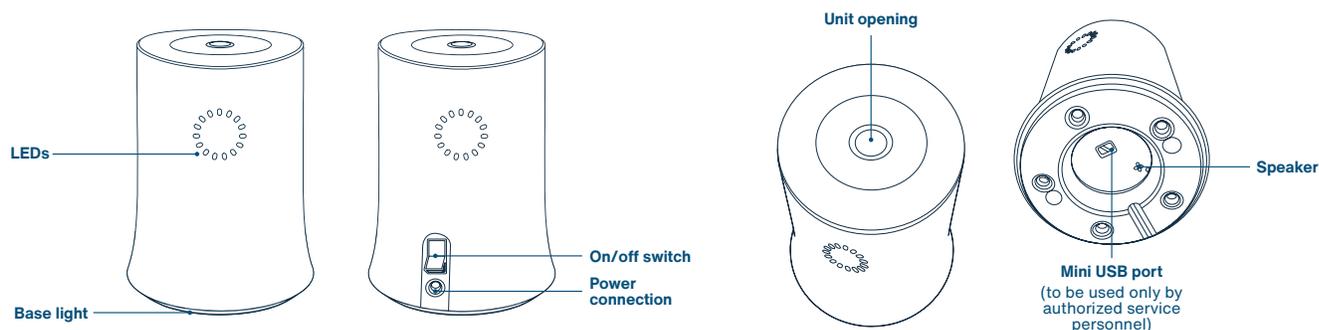


## 1 ThawSTAR<sup>®</sup> CFT2 Automated Cell Thawing System Function and Description

### Overview

ThawSTAR<sup>®</sup> Automated Cell Thawing System (Item No. AST-601) is designed to rapidly thaw live biological contents of 1.8 mL to 2.0 mL cryogenic vials taken directly from liquid nitrogen (LN2) storage, a -80°C freezer or vials equilibrated and held at dry ice temperature (-78.5°C) in a container such as the ThawSTAR<sup>®</sup> CFT2 Transporter (Item No. AST-602). Utilizing patent-pending STAR™ adaptive sensing technology, each vial receives a customized thaw cycle based upon multiple built-in detection parameters. The intended result is a thermal profile equivalent to a water bath thaw, but without the water, and comparable post-thaw cell recovery and viability.

### 1.1 General Safety



ThawSTAR<sup>®</sup> Automated Cell Thawing System is intended for exclusive use by trained and experienced laboratory personnel.

**1.1.1** Review instructions before installing, using or cleaning the unit.

**1.1.2** **⚠ DANGER:** To prevent risk of severe or fatal electrical shock, use only the supplied AC power supply with cables for the US, UK and EU packaged with the unit.

**1.1.3** **⚠ WARNING:** Do not place near flammable materials. This unit is not designed to be explosion-proof or spark-proof.

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## 1 ThawSTAR® CFT2 Function and Description (Continued)

- 1.1.4  **WARNING:** Avoid prolonged exposure to ultraviolet light such as sunlight or germicidal lamps unless covered by light resistant plastic bag or a large piece of unbroken aluminum foil placed over the unit when not in use.
- 1.1.5  **WARNING:** Do not clean unit with ketone solvents; use recommended cleaning protocol in section 5.
- 1.1.6  **CAUTION:** Do not place near or immerse in water or other liquids.
- 1.1.7  **WARNING:** Removal of shell without authorization will void your limited warranty. Do not remove the exterior shell of the unit unless instructed to do so by an authorized BioLife representative.
- 1.1.8  **WARNING:** Unit has a covered mini-USB port on the bottom; do not insert any USB plug into this port or attempt to connect unit with any other device, (eg. a computer), unless instructed to do so by an authorized BioLife representative.
- 1.1.9  **WARNING:** Do not use flag labels or labels that have a tab extending beyond the vial body or with folds or ridges with the unit as these features may interfere with heat transfer or cause vial to become lodged in the unit.
- 1.1.10  **CAUTION:** The unit is designed for stationary indoor laboratory bench top use; outdoor “field” use or use on a laboratory bench subject to strong vibrations such as near a centrifuge, shaker, or vortex mixer is not advised.
- 1.1.11 Ensure the unit is placed securely on a level surface during operation.
- 1.1.12 Recommended for use with 1.8 mL to 2.0 mL cryogenic vials containing cryopreserved cells; the ThawSTAR® system is optimized for 1.0 mL to 2.0 mL volume of aqueous solution at a starting temperature of -70°C.
- 1.1.12.1 Ensure vials were frozen in an upright and vertical position and that frozen contents are at the bottom of the vial.
- 1.1.12.2 Vials should be gently inserted into the top opening of the unit;
-  **CAUTION:** NO other objects (e.g. forceps) should be inserted into the unit at any time.
- 1.1.13  **CAUTION:** Keep liquids out of the unit; ensure cryogenic vials have clean exteriors and are tightly capped to prevent leaks.
- 1.1.14  **CAUTION:** Do not touch the vial with hands or any other object until the thawing process is finished (after cryogenic vial is inserted into the opening of the unit and the thawing process has been initiated).
- 1.1.15 Thawing time is typically 2-3 minutes from the time of vial insertion. Laboratory personnel are advised to be in close proximity to the unit while in use so that vials may be immediately retrieved upon thaw completion.
- 1.1.16 Before moving the unit, ensure that any cryogenic vial has been removed from unit opening.
- 1.1.17 Keep unit opening covered while not in use.
- 1.1.18  **HOT SURFACE WARNING:** The heating elements inside the vial opening are heated while the unit is turned on. Avoid inserting body parts such as fingers or any object except a 1.8 mL to 2.0 mL cryogenic vial into the vial opening at any time.
- 1.1.19 Ensure the power cord can be easily disconnected from the power supply when placing the unit on a laboratory bench.

# 1 ThawSTAR® CFT2 Function and Description (Continued)

## 1.2 Use As Intended

If the ThawSTAR® Automated Cell Thawing System is used in a manner not specified by BioLife in these Instructions for Use, operators are regarded as proceeding under their own risk and warranty terms and conditions may be voided.

## 1.3 Packing Components

The ThawSTAR® Automated Cell Thawing System contains the following components:

Item	Quantity	Photo
ThawSTAR® Automated Cell Thawing System	1	
AC power supply with cable for US, UK, EU	1 power supply 3 power cables	
ThawSTAR® Confirmation Vials	2 Vials	
Quick Start Guide	1	
Instructions for Use	1	
Limited Product Warranty	1	

## 1.4 Unpacking

Remove plastic tie inserted into opening and associated tape/padding completely before using. If you are missing any components, please contact BioLife. See customer service contact information in Section 7.

# 1 ThawSTAR® CFT2 Function and Description (Continued)

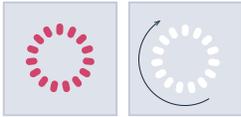
## 1.5 Specifications

Unit	
Thawing temperature	Equivalent to a 37°C water bath
Thawing time	Typically less than 3 minutes
Operating environment temperature	5°C to 35°C; 75% room humidity (maximum)
Storage temperature	-20°C to 60°C
Maximum altitude	2,000 m
Power rating	12V DC, 3.0 A
Power adaptor input/output	AC 100 - 240V, 50 - 60 Hz / 12V DC, 5.0 A
Phase	IØ
Electrical plug formats	US, UK, EU
Dimensions (Diameter x Height)	11.0 cm x 14.5 cm (4.3 in x 5.7 in)
Weight without power supply	0.7 kg (1.6 lbs)
Weight with power supply	1.2 kg (2.6 lbs)
Compliance	CE mark (IEC61326 and IEC61010), RoHS, WEEE
Cryogenic Vial Compatability	
Vial body external diameter	12.19 mm to 12.37 mm (0.480 in to 0.487 in)
Vial body external height below cap ring (minimum)	26.6 mm (1.05 in)
Overall height of vial with cap ring (minimum)	44 mm (1.73 in)
Vial cap diameter (maximum)	14.3 mm (0.56 in)
Vial capacity	One 1.8 mL to 2.0 mL cryogenic vial
Recommended fill volume	1.0 mL to 2.0 mL
Vial contents	Optimized for cells in cryopreservation medium such as 10% DMSO / 20% FBS / 70% DMEM
Vial label thickness (maximum)	0.1 mm

## 2 Unit Assembly

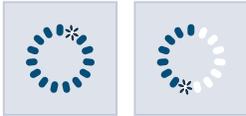
Plug the power supply into the port in the back of the ThawSTAR® Automated Cell Thawing System and attach the appropriate power cord (US, UK or EU) to the power supply.

## 3 Unit Start-Up

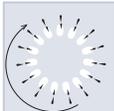
Step	Action	Light Sequence	Sound
3A.	Check to ensure that assembled unit is plugged into an electrical outlet.	N/A	N/A
3B.	Turn on unit using the rocker switch above the unit's power source connection port, ensuring that the side of the switch labeled "I" is depressed.	 <p><b>Front:</b> Red light flash (3x), then full circle light chase, one cycle.</p>	Two-tone, descending.
3C.	Allow up to 5 minutes for unit to warm up.	 <p><b>Front:</b> Rising symmetric semicircle in red background. <b>Base:</b> Slow pulsing pattern.</p>	N/A
3D.	The unit will shift into "ready" state.	 <p><b>Front:</b> Top light of light circle will be illuminated. <b>Base:</b> Not pulsing.</p>	Single tone at transition to ready.
<p><b>Note:</b> If unit does not reach a "ready" state within 10 minutes of powering up and the power supply was properly connected to the unit and plugged into an electrical outlet with a provided cable, please contact BioLife customer service.</p>			

## 4 Operating Instructions

**Note:** Use of the ThawSTAR® CFT2 Transporter (Item No. AST-602) is recommended to keep samples below -70°C during sample transport and holding time to ensure sample integrity and provide a standardized starting vial and thaw temperature. Use of a ThawSTAR® Confirmation Vial, frozen and handled under the same conditions as biospecimens to be thawed, to evaluate and log unit thaw performance at least once daily before thawing biospecimens, is recommended. Initial time to warm up, thawing time of ThawSTAR® Confirmation Vial, vial lot number, vial expiration date, ambient room temperature, ambient humidity level, unit serial number, evaluation start time and date are data which could be logged.

Step	Action	Light	Sound
4A.	Carefully insert a clean, sealed frozen 1.8 mL to 2.0 mL cryogenic vial (below -70°C) into the opening on the top of the unit and allow vial to drop into place.  <b>Tip:</b> Before freezing, cap cryogenic vial tightly after filling to avoid leaks and clean exterior of vial with 70% alcohol wipe or sprayed 70% alcohol.	 <b>Front:</b> Top light of light circle will be illuminated. <b>Base:</b> Not pulsing.	N/A
4B.	Push the top of the vial down gently until the unit emits a deep dual tone. The vial will now remain in a depressed position.  The unit will begin phase change detection using STAR™ sensing technology.	 <b>Front:</b> Three LED light triangle rotating clockwise. <b>Base:</b> Pulsing pattern.	Two-tone, rising.
4C.	Beginning of solid to liquid phase change is detected by unit.	 <b>Front:</b> LED circle shows progressive fill-in sequence clockwise to finish, leading light always blinking. <b>Base:</b> Pulsing pattern.	N/A
4D.	Countdown of the last 10 seconds of the thawing process begins.	 <b>Front:</b> Progressive fill-in sequence continues, leading light continues blinking. <b>Base:</b> Pulsing pattern.	Tone on each one second interval.

## 4 Operating Instructions (Continued)

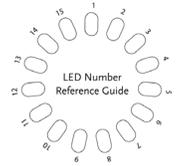
Step	Action	Light	Sound
4E	Upon thaw completion, the vial is raised approximately 1 cm (0.4 in).	 <p><b>Front:</b> Filled LED circle. <b>Base:</b> Not pulsing.</p>	Two tone climbing sequence.
4F.	Remove vial immediately and for a few seconds, manually agitate the vial gently from side to side to equilibrate the liquid temperature until no ice can be seen within the vial. Begin downstream protocol.	 <p><b>Front:</b> Return to single LED illuminated at top of the light circle (“ready” state). <b>Base:</b> Not pulsing.</p>	N/A
<b>Post-thaw Alerts</b>			
Step	Action	Light	Sound
4G.	If vial is not removed within 7 seconds of ejection, unit will signal an alert.	 <p><b>Front:</b> Progressive fill-in sequence clockwise, one LED per second up to 15 seconds with double flash.</p>	Two beeps every half-second for up to 10 seconds.
4H.	If vial is not removed within 12 seconds of ejection, unit will switch into “abandoned vial” (error code 7) mode. See Section 6, Troubleshooting, for “abandoned vial” (error code 7) recovery.	 <p><b>Front:</b> Display red light and error code 7.</p>	Four tone sequence for 5 seconds, then two tone sequence every 15 seconds. After 3 minutes error code 7 is unclearable.

## 5 Care and Cleaning

**⚠ WARNING:** Do not attempt to clean internal components. Do not insert any cleaning objects or solution past the green guide chute on the top opening of the unit. Clean exterior only with a soft, non-abrasive laboratory wipe moistened with 70% alcohol before and after each use period. Condensation from frozen vials should not present an issue, as it will vaporate during the thawing process or stand-by interval.

## 6 Troubleshooting

Refer to steps in Section 3 (Unit Start-Up) and Section 4 (Operating Instructions).



Situation	Error Code	Light	Sound	Instruction		
Unit Start-Up (Refer to <b>Section 3</b> )						
6A.	<b>Step 3C</b> Failure to warm up properly; or other mechanical fault in the heating system.	2		<b>Front:</b> A red light background with <b>error code 2</b> (two LEDs at the bottom of the circle: 8,9).	Single tone repeated twice.	Check power source connection at back of unit, cable connection to power adaptor and the plug connection to the electrical outlet. Turn the unit off and back on. If the unit displays the same error code 2, contact BioLife customer service.
6B.	<b>Step 3C</b> Failure to warm up properly due to vial present in the unit.	4		<b>Front:</b> A red light background with <b>error code 4</b> (four LEDs at the bottom of the circle: 7,8,9,10).	Single tone repeated twice.	Carefully remove any obstruction from the unit and restart the unit. If the problem persists, contact BioLife customer service.
Operating Instructions (Refer to <b>Section 4</b> )						
6C.	<b>Step 4A</b> Vial too warm and/or too thawed.	3		<b>Front:</b> Flash full circle with red light background once and then display red light background with <b>error code 3</b> (three LEDs at the top of the circle: 15,1,2)	Single tone repeated twice. After 3 minutes, error code 3 is unclearable until the unit is power cycled. To power cycle, turn the power switch to the off position and then back to the on position.	Gently remove vial that is too warm. Unit will display a single light at the top, indicating that the unit is ready for the next thaw.

## 6 Troubleshooting (Continued)

Situation	Error Code	Light	Sound	Instruction
Operating Instructions (Refer to <b>Section 4</b> )				
6D.	<b>Step 4B</b> Vial cannot be seated properly (e.g too wide, too short, etc).	5		<b>Front:</b> Flash full circle with red light background once and then display red light background with <b>error code 5</b> (three LEDs at the top of the circle: 14,15,1,2,3).
			Single tone repeated twice.	Gently remove the vial. Unit will display a single light at the top, indicating that the unit is ready for the next thaw. <b>(1)</b> Look into opening to see if there is anything lodged in the heater grasping mechanism. Invert unit to gently shake out obstructions, if any. <b>(2)</b> Ensure that the thermal pads lining the internal heating blocks are intact and undamaged. Note: If thermal pads are not intact and/or damaged, contact BioLife customer service. <b>(3)</b> Ensure vial is within specifications outlined in section 1.5. <b>(4)</b> Try to thaw frozen ThawSTAR® Confirmation Vial. If situation repeats itself with same error code 5, hardware issue (latching fault) may be the root cause; contact BioLife customer service.
6E.	<b>Step 4H</b> “Abandoned” vial left in unit more than 15 seconds after thawing process is completed.	7		<b>Front:</b> Flash full circle with red light background once and then display red light background with <b>error code 7</b> (seven LEDs at the top of the circle: 13,14,15,1,2,3,4)
			Four tone sequence for 5 seconds, then two tone sequence every 15 seconds. After 3 minutes, error code 3 is unclearable until the unit is power cycled. To power cycle, turn the power switch to the off position and then back to the on position.	Gently remove vial. Unit will emit a single tone. Unit will display a single light at the top, indicating that the unit is ready for the next thaw.

## 6 Troubleshooting (Continued)

Situation	Error Code	Light	Sound	Instruction
Operating Instructions (Refer to <b>Section 4</b> )				
6F.	<b>Step 4E-H</b> Vial fails to rise after thaw process is finished.	9		Single tone repeated twice.
		<p><b>Front:</b> Flash full circle with red light background once and then display red light background with <b>error code 9</b> (nine LEDs at the top of the circle: 12,13,14,15,1,2,3,4,5)</p>		<p>Grasp the vial top only with fingers or forceps and rock vial gently to dislodge and remove from opening, taking care not to open the vial. Ensure that the thermal pads lining the internal heating blocks are intact and undamaged.</p> <p>Error code 9 is unclearable until the unit is power cycled. To power cycle, turn the power switch to the off position and then back to the on position.</p> <p>After error code 9, run test vials to ensure unit is functioning properly.</p> <p><b>Note:</b> If thermal pads are not intact and/or damaged, contact BioLife customer service. Avoid sticking forceps or other foreign objects into the opening.</p>

## 7 Customer Service Information

Contact BioLife customer support at **+1-866-424-6543** or at **ThawTechSupport@biolifesolutions.com** for assistance.

### 7.1 Technical Service and Repair

Contact BioLife technical support at **+1-866-424-6543** or at **ThawTechSupport@biolifesolutions.com** for assistance.

**⚠ CAUTION:** If it is necessary to return your ThawSTAR® Automated Cell 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.

## 8 Ordering Information

Item No.	Quantity
AST-600	ThawSTAR® Automated Thawing System (AST-601) and Transporter (AST-602), complete
AST-601	ThawSTAR® CFT2 Automated Thawing System
AST-602	ThawSTAR® CFT2 Transporter
AST-603	ThawSTAR® Confirmation Vials, pack of 20 vials
AST-606	Power Supply and Adaptors
AST-614	IOP Qualification Packet for ThawSTAR® CFT2 System

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

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## 9 Recycling Information



### 9.1 Decontamination

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

### 9.2 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.

### 9.3 Disposal of Electrical Components

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