Plasma Thawing System Operation Manual

QuickThaw™

Document History

Revision	Date	CO	Supersession	Revision Description
L	08 MAY 2013*	8409	Supersedes A, B, C, D, E, F, G, H, I, J, K	Revised layout for ease of navigation and locating information.
M	16 MAY 2014*	9492	M supersedes L	Removed 0086 mark from manual.
N	9 OCT 2019	15059	N supersedes M	Reformatted for consistency with other Helmer manuals. Removed PM table as it is duplicated in the Service Manual. Added EMC content to Product Specifications and Compliance sections.
O	27 OCT 2020	15707	O supersedes N	Updated programmed settings for Thaw Cycle.
P	4 OCT 2021	16380	P supersedes O	Updated Safety Compliance section

* Date submitted for Change Order review. Actual release date may vary.

Document Updates

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This manual is intended as a guide to provide the operator with necessary instructions on the proper use and maintenance of certain Helmer Scientific products.

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The screenshots and component images appearing in this guide are provided for illustrative purposes only, and may vary slightly from the actual software screens and/or product components.

Contents

1   About this Manual

1.1   Intended Audience

This manual is intended for use by end users of the plasma thawing system and authorized service technicians.

1.2   Model References

Generic references are used throughout this manual to group models that contain similar features. For example, "DH models" refers to all models of that type (DH2, DH4, DH8). This manual covers all plasma thawing systems, which may be identified singly, by their size, or by their "series" (DH).

1.3   Intended Use

Helmer plasma thawing systems are intended for thawing frozen blood products and other medical, biological, and scientific products.

1.4   Safety Precautions and Symbols

Symbols found in this document

The following symbols are used in this manual to emphasize certain details for the user:

Task Indicates procedures which need to be followed.

Note Provides useful information regarding a procedure or operating technique when using Helmer Scientific products.

NOTICE Advises the user against initiating an action or creating a situation which could result in damage to equipment; personal injury is unlikely.

Symbols found on the units

Caution: Risk of damage to equipment or danger to operator

Refer to documentation

Caution: Pinch point

1.5   Avoiding Injury

Review safety instructions before installing, using, or maintaining the equipment.
   ♦ Before moving unit, ensure chamber water has been removed.
   ♦ Never physically restrict any moving component.
   ♦ Avoid removing electrical service panels and access panels unless so instructed.
   ♦ Use supplied power cords only.
REQUIRED: Decontaminate parts prior to sending for service or repair. Contact Helmer or your distributor for decontamination instructions and a Return Authorization Number.

1.6   General Recommendations

General Use

Allow plasma thawer to come to room temperature before switching power on.
During initial startup, low temperature alarm may sound while plasma thawer reaches operating temperature.

Initial Loading

Allow chamber temperature to stabilize at the setpoint before thawing frozen product.

2   Installation

2.1   Location Requirements

> **Note**
>
> Helmer recommends placing the drain or waste container on the same side as the drain port.

♦ Has a sturdy, level surface
♦ Has a grounded outlet meeting national electric code (NEC) and local electrical requirements
♦ Is clear of direct sunlight, high temperature sources, and heating and air conditioning vents
♦ Minimum 8" (203 mm) above
♦ Access to a water supply
♦ Adjacent to a sanitary drain or waste water container
♦ Meets limits specified for ambient temperature and relative humidity

2.2   Placement

> **NOTICE**
>
> Ensure chamber has been drained before moving.

> ⚠️
>
> Unplug unit from AC power before moving.

2.3   Install External Thermometer (Optional)

Install the external thermometer according to the manufacturer's documentation. Refer to the Digital Thermometer Manual for more information on the Helmer DT1 digital thermometer.

3   General Operation

3.1   Initial Start Up

1. Plug the power cord into a grounded outlet that meets the electrical requirements on the product specification label.
2. Press the AC ON/OFF button to power the plasma thawer **ON**.

ℹ Notes

- The AC ON/OFF switch also controls the fan on 100V DH8.
- High temperature alarm activates quickly when chamber is empty.

3.2   Fill the Chamber

Two fill lines are marked on the rear wall of the chamber. The lines indicate the maximum water level for the following applications:

- ♦ **Upper line:** maximum level for thawing random bags
- ♦ **Lower line:** maximum level for thawing apheresis bags
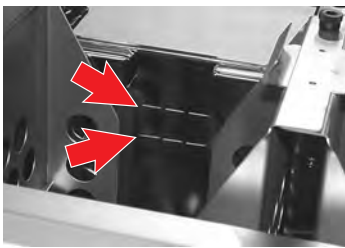
Chamber fill lines.

ℹ Notes

- Determine the type of water to be used (tap or distilled), according to your organization's requirements.
- Use of a bacterial growth inhibitor, such as Helmer CleanBath, is recommended.
- Do not use deionized water as it may be corrosive to the chamber and baskets.

☑ Add water to the chamber:

1. Ensure the chamber and drain are free of debris or contaminants.
2. Ensure the drain tube is not connected.
3. Fill the chamber to the appropriate level.
4. Add bacterial growth inhibitor (optional).

3.3   Drain the Chamber

⚠️

• Disconnect the plasma thawer from AC power before draining the chamber.
• Do not move the plasma thawer when the chamber is filled or if the plasma thawer is connected to AC power.

The plasma thawer has a drain port to drain water from the chamber. The drain valve is integrated into the drain fitting on the side of the plasma thawer. The drain valve remains closed until the drain tube is connected to the valve. When the drain tube is connected, the chamber begins to drain immediately.

The drain coupling must be installed on the drain tube before the drain tube can be connected to the drain valve. The 90º elbow may be installed in the drain tube to facilitate convenient routing of the drain tube.

Left: Drain port with coupling valve and drain tube connected (release button identified with arrow).
Middle: Drain tube with coupling valve installed. Right: 90° elbow fitting.

☑️ **Drain water from the chamber:**

1. Press the AC ON/OFF button to power the plasma thawer **OFF**.
2. Disconnect the power cord from AC power.
3. Place the open end of the drain tube into a waste container or sanitary drain.
4. On the opposite end of the drain tube, push the coupling valve into the drain port. The coupling valve will click when it is properly seated. Water immediately begins to drain from the chamber.
5. After the water has drained from the chamber, release the drain tube by pressing down on the release button on the coupling valve and pulling the coupling valve out of the drain port.

3.4   Determine the Correct Thaw Time

Thaw time varies by bag type and how the bags were manipulated when frozen (flat or folded). The table below indicates median thaw times for bags previously stored at -30 °C.

Plasma Bag (Size and Type)	Manner Frozen	Median Thaw Time (Minutes)
10 mL to 15 mL cryoprecipitate	Folded	5
250 mL standard	Flat	10
250 mL thick plastic	Flat	16
250 mL standard	Folded	17
300 mL standard	Flat	14
500 mL (jumbo) apheresis	Flat	18

3.5   Load Bags

⚠ ✈

- Do not manually lift the baskets out of the chamber. Manually lifting baskets will damage the system. Press the **LIFT OUT** button to raise the baskets.
- Press the **LIFT OUT** button only if the baskets are installed. The basket must be installed for the lift out system to operate correctly.

♦ DH2 basket holds 2 standard bags.
♦ DH4 uses 2 of the same basket used in the DH2, for a total capacity of 4 compartments.
♦ DH8 basket holds 8 standard bags.

ℹ Note
On the DH8, the divider between compartments on each side can be removed to hold jumbo or wide bags.

When thawing a plasma bag (of any type or size), a plasma overwrap bag must be used. The plasma bag is placed inside the overwrap bag, and the overwrap bag is attached to the basket.
Overwrap bags provide the following benefits:
♦ Secure the plasma bag to the basket
♦ Protect the plasma bag from water-borne contaminants
♦ If the plasma bag breaks, the contents will not contaminate the water bath

ℹ Note
Use only 1 overwrap bag, of the appropriate size, per plasma bag.

The following recommendations will aid in thawing plasma bags:
♦ Use security snaps on smaller bags that tend to float
♦ Load plasma bags together that require the same thaw time
♦ When loading 2 bags on same side of the basket in DH8 models, place thicker bag in the front-most compartment

☑ Load the bag(s):

1. Insert plasma bag into appropriate size overwrap bag.   *LIFT OUT button.*
2. On control panel, press the **LIFT OUT** button to raise and open basket.
3. **DH8 models:** Remove the basket divider if a jumbo or wide bag is loaded by squeezing sides of the divider together and pull divider away from basket.

Removing divider from DH8 basket.

4. Place overwrapped plasma bag in basket. Hook the slot at the top of the overwrap bag over the tab on the basket. For large overwraps, ensure both slots are hooked over the tabs.
5. Insert a security snap through top set of holes on the basket compartment. Push the snap toward the basket until it snaps against the overwrap bag.

Bag in standard-sized overwrap bag with security snap.

3.6   Thaw Cycle Functions

⚠️

Keep fingers and clothing away from basket(s) while in motion.

ℹ️ Note

- If a temperature alarm is active, a thaw cycle cannot be initiated until the alarm condition is cleared.
- A lift-out malfunction alarm for one basket will not prevent the other basket from performing a thaw cycle (DH4 and DH8 models).
- Allow the water temperature to stabilize at the setpoint between thaw cycles.

Button	Button Name	Function
	CYCLE TIME	► Set thaw cycle time (in minutes) ► Extend thaw cycle time ► Select the hold ("HO") setting
	CYCLE START	Start a thaw cycle
	LIFT OUT	► Pause a thaw cycle in process (press to raise the basket) ► Resume a paused thaw cycle (press to lower the basket) ► Stop a thaw cycle

Start a Thaw Cycle

When the thaw cycle is started, the lift out system closes the basket and lowers it into chamber. If agitation motion is enabled, the basket begins to agitate after the basket reaches the bottom of its travel. The remaining cycle time (in minutes) is displayed on the cycle time indicator (located on the control panel).

Programmed time settings of 0, 3, 5, 8, 10, 12, 14, 16, 18, 20, 25, 35, 45 and 55 minutes, as well as a hold ("HO") setting, are pre-programmed in to the timing system.

- ♦ Pressing the **TIME SET** button advances through each pre-programmed time setting.
- ♦ To indefinitely extend a thawing cycle that is already in progress, press the **TIME SET** button until the display reads "HO".
- ♦ Press the **TIME SET** button again and the cycle will finish its initial programmed time.

✅ Start a Cycle:

ℹ Note

The cycle time, cycle start, and lift out for each basket is controlled individually on DH4 and DH8 models.

1. Confirm the chamber has been filled to the appropriate level.
2. Confirm the water temperature stabilized at temperature setpoint.
3. Enable or disable agitation motion, depending on your organization's specific needs.
4. Load overwrapped bags into basket(s), with security snap(s) as needed.
5. For each basket, press the **CYCLE TIME** button to select the desired time.
6. Press the **CYCLE START** button to lower basket and start the thaw cycle.

✅ Stop, Pause, or Resume a Thaw Cycle

ℹ Notes

- When a thaw cycle is stopped or paused, the basket lifts out of the chamber before the thaw cycle is completed.
- The hold ("HO") setting may be selected while the thaw cycle is paused (**LIFT OUT** button pressed).

1. Press the **LIFT OUT** button to raise the basket and temporarily pause the thaw cycle. The remaining time is displayed on the cycle time indicator.
2. Press the **LIFT OUT** button again to resume the thaw cycle. The basket is lowered into the chamber and the agitation motion resumes.

Complete a Thaw Cycle

When a thaw cycle reaches the end of its programmed time setting, the basket stops agitating, lifts out, and opens. An audible alert sounds to indicate the thaw cycle has completed, and the cycle time indicator resets to the previously selected time setting.

3.7   Unload Bags

⚠ ⚠

- Do not manually lift the baskets out of the chamber. Manually lifting baskets will damage the system. Press the **LIFT OUT** button to raise the baskets.
- Press the **LIFT OUT** button only if the baskets are installed. The basket must be installed for the lift out system to operate correctly.

✅ Unload the bag(s):

1. On control panel, press the **LIFT OUT** button to raise and open basket.
2. Remove the security snap from the basket.
3. Unhook the slot at the top of the overwrap bag from the tab on the basket.
4. Remove the overwrap bag from the basket.
5. Remove the plasma bag from the overwrap bag. Discard the overwrap bag.

 LIFT OUT button.

3.8   Enable or Disable Agitation Motion

Default is enabled. Agitation reduces thaw time. It is controlled with the switch located at the rear of thawer. For DH4 and DH8, top and bottom switches control right and left basket agitation, respectively.

Agitation switches.

3.9   Mute an Audible Alarm

Audible alarms can be muted. The temperature controller will still continue to flash an alarm message if the alarm has been muted. To mute an audible alarm, press the **MUTE** button.

Mute button.

Pressing the **MUTE** button silences alarms for both baskets (DH8 models). If a second audible alarm activates while the first audible alarm is muted, the second alarm will be muted as well.

When an alarm is muted, the duration is indefinite. Muting is cleared under the following conditions:

♦ The condition that triggered the alarm is resolved
♦ AC power to the plasma thawer is switched off

Alarm Reference

If an alarm condition is met, an alarm activates. The following table indicates if an alarm is audible (A) or visual (V). Messages for visual alarms, if applicable, appear in the table as well.

Alarm	Alarm Type
High Temperature	A, V ("-AL-" on temperature controller, "E1" on all cycle time indicators)
Low Temperature*	A, V ("-AL-" on temperature controller)
Lift Out System Malfunction	A, V ("E2" on affected cycle time indicator)

* Low temperature alarm is available but not used.

4   Temperature Monitor Setpoints

4.1   Change the Chamber Temperature Setpoint

ⓘ Note

Do not change any other temperature controller parameter unless instructed in this manual or by
Helmer Technical Service.

The default chamber temperature setpoint is 36.5 °C. If the chamber temperature falls below the setpoint, the temperature controller activates the chamber heater until the setpoint is reached. The chamber heater and sensor are located underneath chamber.

☑ Change the setpoint:

1. Determine setpoint, if other than default.
2. The chamber temperature appears on the display.

ⓘ Note

The displayed temperature may differ from the setpoint, especially if chamber temperature has not stabilized at the setpoint.

Temperature controller display.

3. Press and hold the ✱ button. The setpoint value is displayed.
4. Press the **UP** or **DOWN** buttons to change the setpoint value. The setpoint value is adjusted up or down in increments of 0.1 °C.
5. Release all buttons to exit the setpoint value adjustment. New setting is saved.

4.2   View or Change Temperature Alarm Setpoints

ⓘ Notes

*   Changing parameter values affects plasma thawer operation. Do not change values unless instructed in product documentation or by Helmer Technical Service.
*   By default, the Low Temperature alarm is not enabled. If the Low Temperature alarm is enabled, follow regulations for your organization to determine the appropriate temperature setting.
*   Ensure the Low Temperature alarm setting is no higher than 30.0 ºC.

The monitoring and control system has alarms which activate if the temperature is too high or too low (if the Low Temperature alarm is enabled). The setpoints for these alarms may be viewed and/or changed using the temperature controller.

Temperature controller display.

The High Temperature alarm setpoint (AL.hi) specifies the temperature at which the High Temperature alarm should activate. If the temperature detected by the temperature control sensor is greater than or equal to this value, the alarm activates.

The Low Temperature alarm setpoint (AL.Lo) specifies the temperature at which the Low Temperature alarm should activate. If the temperature detected by the temperature control sensor is less than or equal to this value, the alarm activates.

☑ **View or change parameter values:**

ⓘ **Notes**
- Default High Temperature alarm setpoint is 37.6 °C.
- Low Temperature alarm setpoint is disabled by default (setpoint is 0.0 °C).
- When setting alarm setpoints, maintain at least a 1.0 °C difference above or below the plasma thawer setpoint.
- When there is no interaction for 60 seconds, the temperature controller exits program mode.

1. Enter Level 1 program mode by pressing and holding the **UP** and **DOWN** buttons simultaneously for approximately 3 seconds. The display will flash "tunE" and "oFF".
2. Press and release the **UP** or **DOWN** buttons until the desired parameter flashes on the display. For the High Temperature setting, select the "AL.hi" parameter. For the Low Temperature setting, select the "AL.Lo" parameter.
3. Change a parameter value by pressing and holding the * button, then press the **UP** or **DOWN** buttons to change the parameter value.
4. Release all buttons to exit the parameter. New settings are saved.
5. Press and hold the **UP** and **DOWN** arrow buttons simultaneously for approximately 3 seconds to exit program mode.
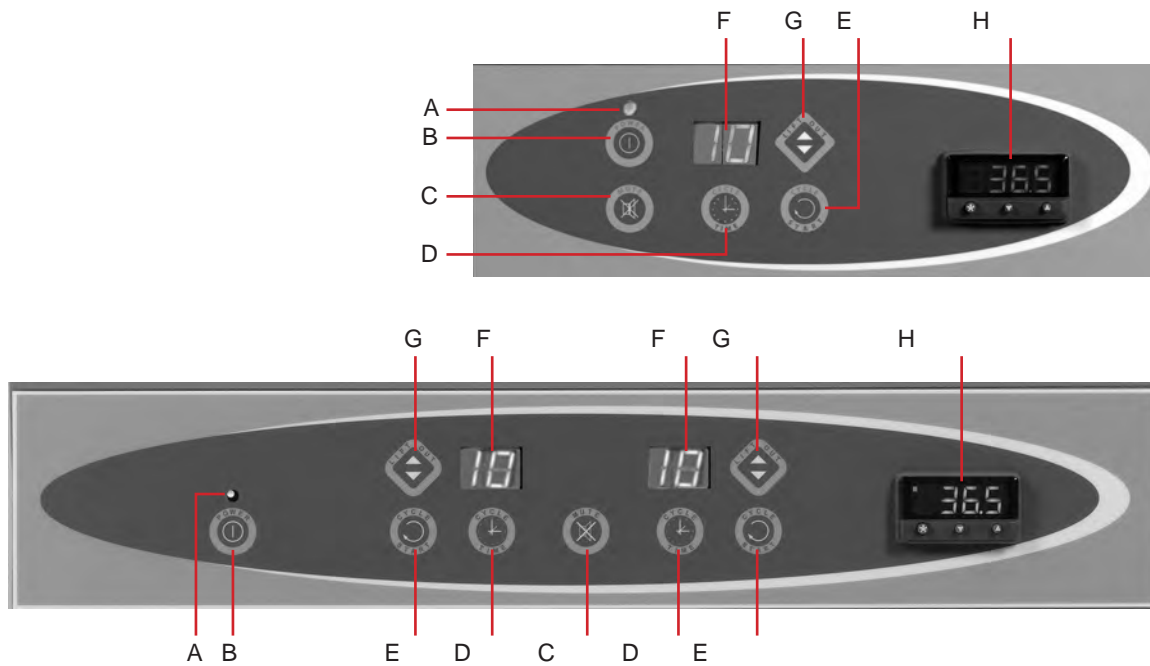
5   Components

5.1   Front and Sides
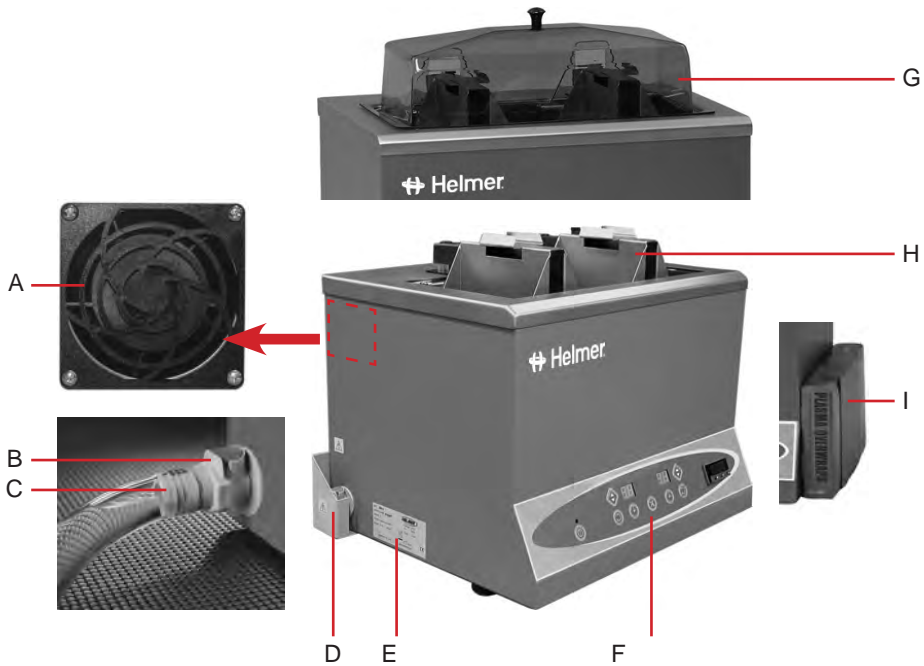
Front and left sides (115 V DH4 model shown).

Label	Description		Label	Description
A	Fan (DH8 100 V models)		F	Control panel
B	Drain port		G	Cover
C	Drain tube with coupling valve		H	Basket
D	Drain port cover		I	Plasma overwrap holder
E	Product specification label			

5.2   Control Panel

Control panel. Top: DH2 model. Bottom: DH4 and DH8 models.

Label	Description	Label	Description
A	Power indicator LED	E	CYCLE START button
B	POWER button	F	Cycle time indicator
C	MUTE button	G	LIFT OUT button
D	CYCLE TIME button	H	Temperature controller

5.3   Chamber
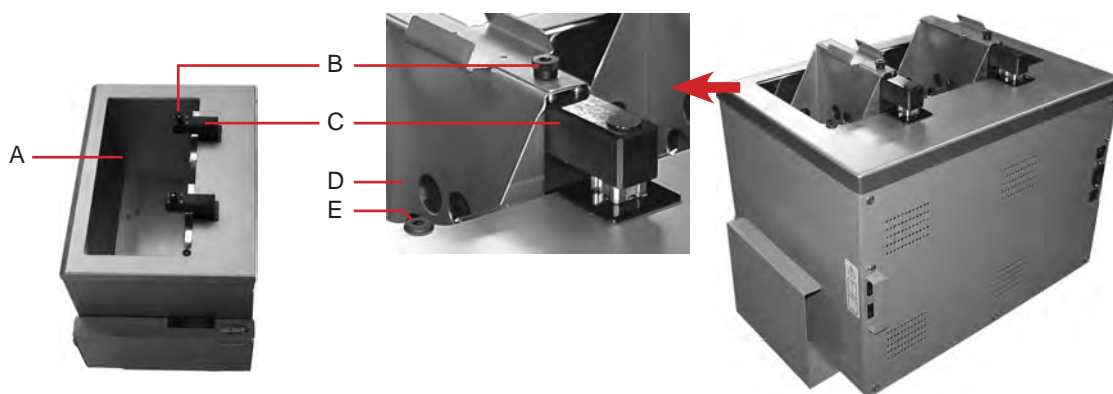
Rear of thawer (230 V DH4 model shown with parts from various models).

Label	Description	Label	Description
A	Chamber	D	Basket
B	Finger knob	E	External thermometer access port
C	Lift-out system		

5.4   Thawer Basket
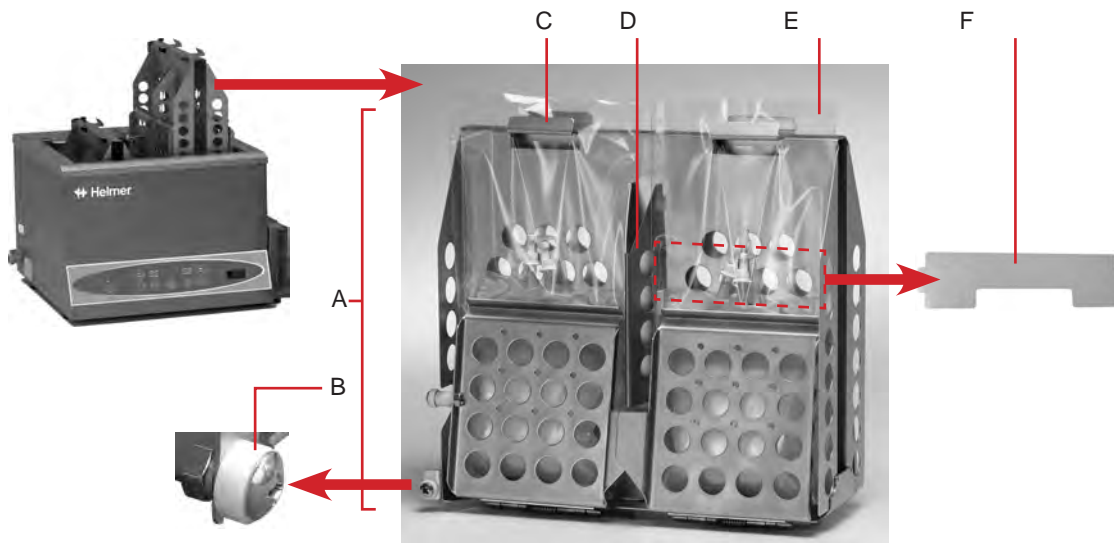
DH8 basket shown with 2 plasma bags in standard overwraps.

Label	Description		Label	Description
A	Basket		D	Basket divider (DH8)
B	Bearing		E	Overwrap bag
C	Tab		F	Security snap

5.5   Rear
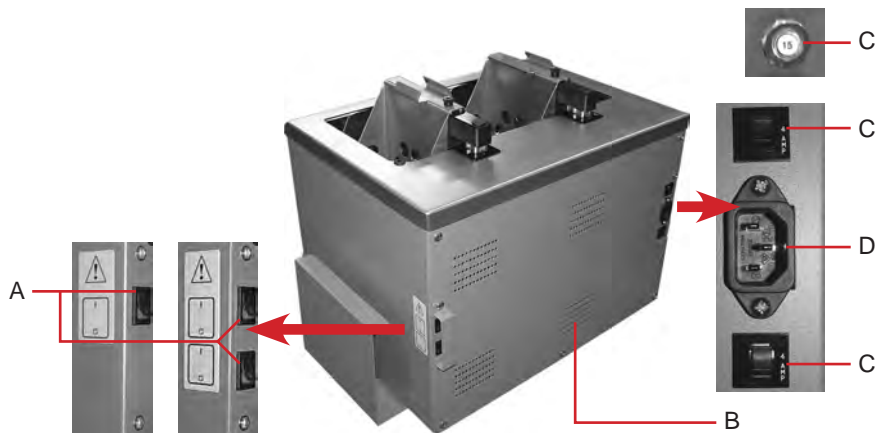
Rear of thawer (230 V DH4 model shown with parts from various models).

Label	Description		Label	Description
A	Agitation switch		C	Circuit breaker
B	Vent		D	Power connector

6 Product Specifications

6.1 Operating Standards

These units are designed to operate under the following environmental conditions:

♦ Indoor use only
♦ Altitude (maximum): 2000 m
♦ Ambient temperature range: 15 ºC to 32 ºC (59 ºF to 90 ºF)
♦ Relative humidity (maximum for ambient temperature): 80% for temperatures up to 31 ºC (88 ºF), decreasing linearly to 50% at 40 ºC (104 ºF)
♦ Pollution degree: 2 (for use in USA and Canada only)
♦ Sound level is less than 70 dB(A).
♦ EMC Environment: Basic

ⓘ Notes
- Power consumption is measured in full-load Amperes.
- Product specification label is located on the left side of the plasma thawer.

Electrical Specifications

	DH2	DH4	DH8
Input Voltage and Frequency	100 V, 50 Hz / 115 V, 50-60 Hz / 230 V, 50-60 Hz		
Voltage Tolerance	±10%		
Circuit Breakers	5 A (100 V) 4 A (115 V) 2 A (230 V, quantity 2)	10 A (100 V) 7 A (115 V) 4 A (230 V, quantity 2)	15 A (100 V) 15 A (115 V) 6 A (230 V, quantity 2)
Power Consumption	3.0 A (100 V) 2.5 A (115 V) 1.25 A (230 V)	8.0 A (100 V) 6.0 A (115 V) 3.0 A (230 V)	12.0 A (100 V) 10.0 A (115 V) 5.0 A (230 V)
Power Source	Varies (refer to product specification label)		

Plasma Thawer Specifications

	DH2	DH4	DH8
Height (Baskets Lowered)	16.25" (413 mm)	16.25" (413 mm)	16.25" (413 mm)
Height (Baskets Raised)	23.00" (584 mm)	23.00" (584 mm)	23.00" (584 mm)
Width	15.50" (368 mm)	21.75" (553 mm)	21.75" (553 mm)
Depth	15.50" (394 mm)	15.50" (394 mm)	22.50" (572 mm)
Weight	38 lbs (17 kg)	58 lbs (26 kg)	74 lbs (34 kg)
Chamber Volume	2.2 gal. (8.2 L)	4.75 gal. (18 L)	8.5 gal. (32 L)
Basket Capacity	2 units	4 units	8 units
External Port	Standard (for external thermometer)		

7   References and Compliance

7.1   Safety Compliance

This device complies with the requirements of directive (EU) 2017/745 concerning Medical Devices.

This product is certified to applicable UL and CSA standards by a NRTL.

7.2   Environmental Compliance

This device falls under the scope of Directive 2102/19/EU Waste Electrical and Electronic Equipment (WEEE) .

When disposing of this product in countries affected by this directive:
♦ Do not dispose of this product as unsorted municipal waste.
♦ Collect this product separately.
♦ Use the collection and return systems available locally.

For more information on the return, recovery, or recycling of this product, contact your local distributor.

7.3   Electromagnetic Compliance

The Helmer Scientific Plasma Thawing System meets the applicable requirements of IEC61326 and EN55011 and is intended for use in the electromagnetic environment specified in 6.1 Operating Standards. The customer or the user of these devices should assure they are used in such environment.

END OF MANUAL