Platelet Storage Instructions for Use and Operation Manual

Pro Line Incubator - Pro Line Agitator

Countertop Incubator

PC100-Pro
PC900-Pro
PC1200-Pro

Countertop Agitator

PF15-Pro
PF48-Pro
PF96-Pro

360415/B

Document History

Revision	Date	CO	Supersession	Revision Description
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B	19 MAY 2020	15365	B supersedes A	• Added detail regarding agitator speed to Enable or Disable Motion section. • Updated Notified Body information in the Compliance section.

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

Document Updates

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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.

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Part No. 360415/Rev B

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1 About this Manual

1.1 Intended Audience

This manual provides information on how to use the Pro Line platelet incubator and platelet agitator. It is intended for use by end users of the platelet incubator and platelet agitator and authorized service technicians.

1.2 Model Reference

This manual covers all Pro Line platelet incubators and platelet agitators which may be identified by size or model number.

1.3 Intended Use

Note

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Helmer platelet incubators are intended to provide the controlled temperature environment required for the storage of platelet products. Helmer platelet agitators are intended to provide controlled agitation required for the storage of platelet products.

The devices are intended to be operated by personnel who have procedures in place for meeting FDA, AABB, EU or any other applicable regulations for the processing and storage of platelet 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

The following symbols may be found on the incubator or agitator or incubator packaging or agitator packaging:

Caution: Risk of damage to equipment or danger to operator

EC REP Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands

EU Authorized Representative

Refer to documentation

1.5 Avoiding Injury

Review safety instructions before installing, using, or maintaining the equipment.

Platelet Incubator

- Before moving unit, remove the installed agitator (if applicable).
- Before moving unit, ensure door is closed.
- Before moving unit, disconnect the AC power cord and secure the cord.
- When moving unit, use assistance from a second person.
- Never physically restrict any moving component.
- Avoid removing electrical service panels and access panels unless so instructed.
- Do not store or place objects or liquid containers on top of the incubator.
- Keep hands away from pinch points when closing the door or when agitation motion is enabled (if applicable).
- Avoid sharp edges when working inside the electrical compartment.
- Ensure biological materials are stored at recommended temperatures determined by standards, literature, or good laboratory practices.
- Proceed with caution when adding and removing product from the platelet incubator.
- Use manufacturer supplied power cord only.
- Using the equipment in a manner not specified by Helmer Scientific may impair the protection provided by the equipment.
- The platelet incubator is not considered to be a storage cabinet for flammable or hazardous materials.

Platelet Agitator

- Before moving unit, remove contents from the drawers.
- Do not open multiple drawers at the same time.
- Before moving unit, disconnect the DC power cord and secure the cord.
- When moving unit, use assistance from a second person.
- Never physically restrict any moving component.
- Avoid removing electrical service panels and access panels unless so instructed.
- Keep hands away from pinch points when agitation motion is enabled.
- Ensure both left and right side drawer stop panels are fully installed prior to operating the agitator.
- Avoid sharp edges when working inside the electrical compartment.
- Ensure biological materials are stored at recommended temperatures determined by standards, literature, or good laboratory practices.
- Proceed with caution when adding and removing products from the platelet agitator.
- Use only manufacturer supplied power supply/cord when operating stand-alone or within incubator.
- Using the equipment in a manner not specified by Helmer Scientific may impair the protection provided by the equipment.
- The platelet agitator is not considered to be a storage cabinet for flammable or hazardous materials.

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

Platelet Incubator

Allow platelet incubator or platelet agitator to come to room temperature before switching power on.

During initial startup, motion alarm may sound if the motion is disabled. The low temperature alarm may sound while the platelet incubator reaches operating temperature.

Platelet Agitator

Allow platelet agitator to come to room temperature before switching power on.

During initial startup, motion alarm may sound if the motion is disabled.

During initial startup for stand alone operation, device selection of “X” is required for motion to occur.

Initial Loading

After the platelet incubator reaches room temperature, allow chamber temperature to stabilize at the setpoint before storing product.

After the platelet agitator reaches room temperature, begin storing product.

Platelet Incubator (stand-alone)

2 Installation

2.1 Location

Note

Hot ambient temperatures with high humidity may cause condensation on the outside of the incubator.

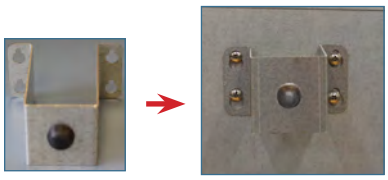
- Has a sturdy, level surface.
- Has a grounded outlet meeting national electric code (NEC) and local electrical requirements.
- Is clear of direct sunlight, high temperature sources, and heating and air conditioning vents.
- Meets limits specified for ambient temperature (15 °C to 35 °C) and relative humidity.
- Minimum 24” (610 mm) above for ambient temperatures of 28 °C to 35 °C.
- Minimum 4” (102 mm) above for ambient temperatures of 15 °C to 28 °C.
- Minimum 12” (305 mm) behind for ambient temperatures of 28 °C to 35 °C.
- Minimum 4” (102 mm) behind for ambient temperatures of 15 °C to 28 °C.

2.2 Placement and Leveling

- The product should not be used adjacent to other equipment. If adjacent use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other than those specified for the product by Helmer is not recommended. They may result in increased emissions or decreased immunity of the device.
- Refer to the Electromagnetic Compliance section for additional information.

Notes

- Ensure the AC power and backup battery power are turned off on the incubator prior to connecting an agitator.
- Rear stand-off brackets are provided with the platelet incubator and should be installed prior to placing the incubator in its location.



1. Align keyhole openings in stand-off bracket with screws on back of incubator and slide down to engage.
2. Tighten screws using a #2 Phillips screwdriver to secure.
3. Place platelet incubator on sturdy surface.
4. Ensure platelet incubator is level

2.3 Chart Recorder

Note

For complete information, refer to the Temperature Chart Recorder Operation and Service Manual.

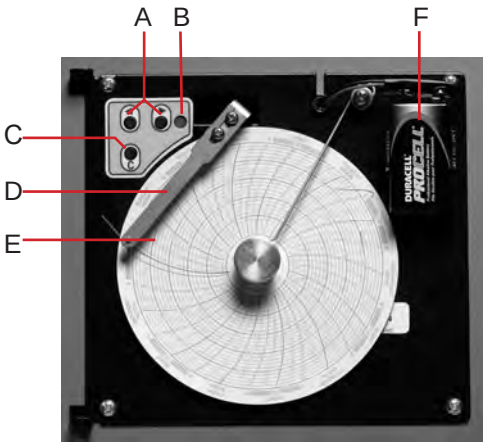


Chart recorder with paper and battery installed.

Table 1. Chart Recorder

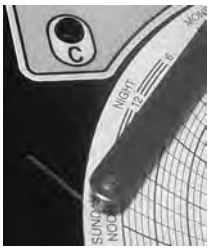
Label	Description	Function
A	Left and Right Arrow buttons	Adjust settings and stylus position.
B	LED	Indicates status of chart recorder in operating mode, or selected temperature range in paper change mode.
C	Chart change button	Adjust position of stylus when changing chart paper, or run a test pattern.
D	Stylus	Mark temperature line on paper.
E	Reset button	Restart chart recorder.
F	Backup battery	Provides power during AC power failure. Connect prior to use.

Install / Replace Chart Paper

Note

For accurate temperature reading, ensure the current time is aligned with the time line groove when the chart knob is fully tightened.

1. Press and hold C button. When stylus begins to move left, release button. The LED flashes.
2. When stylus stops moving, remove chart knob then move knob up and away.
3. Place chart paper on chart recorder.
4. Gently lift stylus and rotate paper so current time line corresponds to time line groove.
5. Hold chart paper in place while making sure the chart knob is fully tightened. *(Failure to fully tighten the knob can result in paper slipping and losing time.)*
6. Press and hold C button. When stylus begins to move right, release button.
7. Confirm stylus is marking on paper and stops at the correct temperature.
8. Calibrate chart recorder to match primary temperature if needed and close recorder door.



Stylus and time line groove

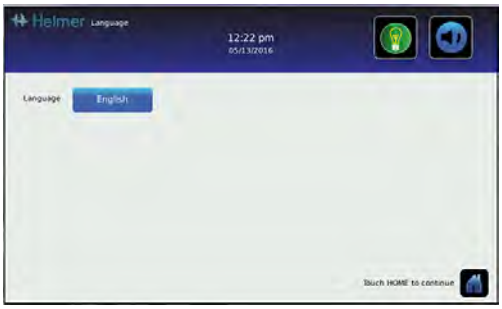
3 Pro Line Platelet Incubator Operation

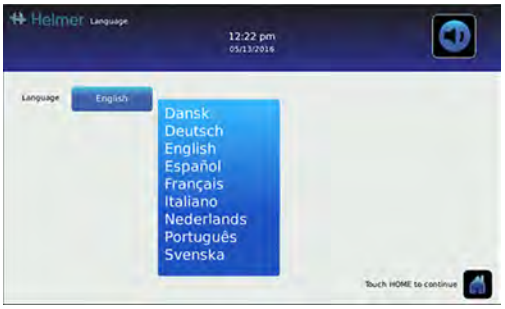
3.1 Initial Start-Up

1. Plug the power cord into a grounded outlet meeting the electrical requirements on the product specification label.
2. Turn the AC power switch ON.
3. Turn the backup battery switch ON.
4. The Start screen is displayed.

Start screen

The language screen is displayed when the i.C³ is powered on. Use the Language screen to select the i.C³ display language.





Language screens

Note
English is the default language.

If an alarm sounds, temporarily mute the alarm by touching the Mute button.

Home screen

Mute icon

Note
Active alarms are displayed on the Home screen. If an alarm condition other than High Temperature occurs, refer to the service manual for troubleshooting.

3.2 Operation

Notes

- Refer to the i.C³ User Guide for complete information regarding the i.C³ User Interface.
- The i.C³ Home screen displays temperature and alarm information, and provides icons to gain access to other functions of the i.C³.
- After two minutes of inactivity, the screensaver will be displayed. To return to the Home screen, touch the screensaver.

Home screen

Home screensaver (touch to return to Home screen)

3.3 Users and Passwords

The Users and Passwords screen provides a way for the administrator-level user to limit access to certain screens. The administrator-level password can be changed by selecting Change Password. The Access Control Setup screen can be opened by choosing the Access Setup button from the Users and Passwords screen as well as from the Access Log screen.

> Enter settings password. Select Users and Passwords.

Users and Passwords screen

Change Password keypad

Note

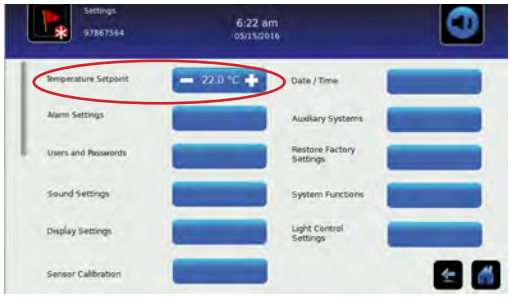
Default Settings password is 1234

Change Password

1. Select the Change Password button. A numeric keypad is displayed.
2. Enter a unique 4-digit code and select the √. A numeric keypad appears
3. Re-enter the 4-digit code to confirm and select the √.
4. Select the Back arrow icon to return to the previous screen or the Home icon to return to the Home screen.

3.4 Change Temperature Setpoint

> Enter Settings password. Select Temperature Setpoints. Touch minus (-) or plus (+) on spin box to change value.



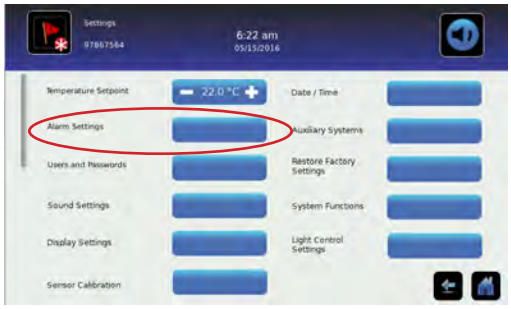
Settings screen

Notes

- Default Settings password is 1234.
- Default setpoint is 22.0 °C.

3.5 Set Alarm Parameters

> Enter Settings password. Select Alarm Settings. Touch minus (-) or plus (+) on spin box to set each alarm parameter.



Settings screen

Alarm Settings screens

Alarm settings control the circumstances and timing of alarm condition indicators displayed on the i.C³ Home screen.

3.6 Active Alarms

Active alarms are displayed on the Home screen. Refer to Appendix A for a list of potential active alarms.

Home screen with active alarm

Notes

- When the door switch is bypassed, the incubator and door open alarm continue to operate as if the door is closed.
- The door switch may be bypassed by opening the door and pulling the switch cylinder.
- The number of agitators, internal and external fans, and heat pumps will vary based on incubator model.
- Fan failure alarm may occur if facility power is lost.

3.7 Mute and Disable Active Alarms

Audible alarms may be temporarily muted by touching the Mute icon. The delay duration can be set and changed by selecting Sound Settings from the Settings screen. The duration may be set to any value from 1 - 60 minutes. The delay time remaining will be displayed in the bottom right corner of the icon. If the alarm is still active after the mute delay has ended, the audible alarm will sound.

Unmuted

Muted

> Enter the Settings password. Scroll down to select Sound Settings. Touch minus (-) or plus (+) on spin box to set the mute duration.

3.8 Min/Max Temperature Monitoring

The Min/Max temperature display provides the highest and lowest Primary Monitor probe temperature reading since the last system reset (power-on event) or manually-initiated reset. Touch the Reset icon to the right of the display to manually reset.

Notes

- The Min/Max temperature display can be turned on or off through Display Settings.
- Once the time reaches the maximum display of 999 hours and 60 minutes, the message will display “>999:60”, but minimum and maximum temperatures will continue to be tracked.

3.9 Electronic Access Control (Optional)

Allows user-specific secure access to the incubator. The Access Control Setup screen can be opened from the Access Log screen or by choosing the Access Setup button from the Users and Passwords screen.

Notes

- During a power failure, the optional Access Control lock will remain locked. It can be unlocked using backup battery power until battery power is depleted or until the backup battery switch is switched **OFF**.
- Switching the back-up battery key switch **OFF** will disable the monitoring system during a power failure.
- During a power failure, use the mechanical door key to provide secure storage for incubator contents.
- Refer to i.C³ User Guide for complete information regarding Access Control.

Setup

Configure and manage user-specific accounts to allow controlled access to the incubator.

Access Control Setup password screen

Access Control Setup screen

Enter the supervisor PIN to set up Access Control and follow the on-screen prompts to set up users.

Notes

- Initial factory supervisor PIN is 5625
- The supervisor PIN cannot be deleted, and should be changed to prevent unauthorized user ID setup. The supervisor PIN does not allow access to the unit. At least one user ID must be set up to gain access to the unit.

Open Incubator with Access Control

Access Control Home screen

Enter a valid PIN using the keypad.

Pro Line Platelet Agitator (stand-alone)

4 Installation

4.1 Location

- The product should not be used adjacent to other equipment. If adjacent use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other than those specified for the product by Helmer is not recommended. They may result in increased emissions or decreased immunity of the device.
- Refer to the Electromagnetic Compliance section for additional information.

Note

Add 1.5” (38 mm) to the agitator width to accommodate the trolley frame when agitation motion is enabled.

- To ensure continuous operation of linearly shifting loads, the location surface must be level and adequately accommodate the full weight of the agitator when loaded with product.
- Has a grounded outlet meeting the electrical requirements listed on the product specification label.
- Is clear of direct sunlight, high temperature sources, and heating and air conditioning vents.
- Minimum 0.5” (13 mm) behind.
- Minimum 0.75” (20 mm) on left and right sides.
- Meets limits specified for ambient temperature (15˚C to 35˚C) and relative humidity.

4.2 Power Connection

Note

Use only the optional Helmer AC/DC power supply for stand-alone configuration.

The platelet agitator may be used in a stand-alone configuration. A power supply with adaptable plugs is available for stand-alone use. Select and install the desired plug prior to attaching the power supply to the agitator. The power supply is not used when configured inside a Pro Line platelet incubator.

Configure and Attach Power Supply

1. Remove the cover plate by using the thumb to push and hold the spring loaded locking key downward while sliding the plate forward. Retain the cover plate in secure location for future use.
2. Select the desired plug and slide in place until it locks (a clicking sound will occur).Make sure the plug is firmly attached.
3. Attach the power supply to the platelet agitator, and ensure the rotating lock is finger tight prior to plugging power supply into facility AC.

4.3 Mounting Brackets

Mounting brackets are included and may be installed for use inside the incubator or in stand-alone configuration.

Install Mounting Brackets

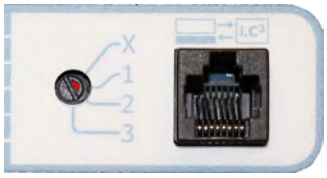
1. Carefully place the agitator on its back on a solid surface allowing access to the bottom of the unit.
2. Locate the two nutserts in the right or left side toward the front of the unit and align with the two holes in the mounting bracket.
3. Hand thread the screws through each hole, and secure using a #2 Phillips screwdriver.
4. Repeat steps 2 and 3 for the opposite side.
5. Return the agitator to the upright position.
6. Carefully place the agitator in the desired location aligning the hole in each bracket with the holes in the mounting surface.
7. Hand thread the screws through the bracket and into the mounting surface. Secure using a #2 Phillips screwdriver.

4.4 Placement, Leveling and Setup

NOTICE

- To prevent damage to the platelet agitator, lift using the ends of the base. Do not use the platelet agitator storage frame, trolley or trolley drawer to lift agitator. If the platelet agitator base is not accessible, lift using the ends of the storage frame.
- The platelet agitator communication switch is fragile, do not use excessive force when changing the setting.

1. Place platelet agitator on sturdy surface.
2. Ensure platelet agitator is level.
3. Using a small flathead screwdriver, turn the communication switch to the X position. Ensure the arrow *(shown in red for visibility in the adjacent picture)* is pointing to the X.



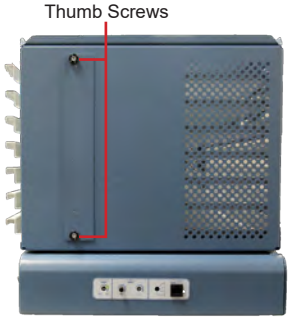
4.5 Storage Configuration

Drawers can be removed or moved to create additional storage space. Label holders are available and may be installed on drawers.

To avoid injury, ensure both left and right side drawer stop panels are fully installed prior to operating the agitator.

Remove and Replace Drawers

1. Remove the thumb screws securing the drawer stop panels to the left and right sides of the agitator. (Note the orientation of each panel)
2. Carefully pull each panel from the agitator and set panels and thumb screws aside.
3. Slide the drawer(s) out and remove.
4. Reinstall drawer in desired location by aligning the outer edges of the drawer with the slots in the drawer guides and push inward.
5. Reinstall the drawer stop panels in the same orientation as removed, and secure with thumb screws ensuring they are finger tight.



Install Label Holders (optional)

1. Insert the tabs on the label holder into the slots on the drawer.
2. Pivot the holder around the drawer handle and align the hole on the label holder with the corresponding hole on the drawer.
3. Push thumb screw through the hole in the label holder and through the hole in the drawer to secure.

4.6 Load the Platelet Agitator

PF15-Pro

Table 2. Agitator Capacity

Model	Capacity	
	WBD/Random Bags	**SDP/Apheresis Bags**
PF15-Pro	15 (2 per drawer; 3 per shelf)	7 (1 per drawer/shelf)
PF48-Pro	48 (6 per drawer/shelf)	16 (2 per drawer/shelf)
PF96-Pro	96 (12 per drawer/shelf)	32 (4 per drawer/shelf)

NOTICE

When opening drawer, grasp the center of the handle (not label holder). Open one drawer at a time.

Open the drawer to be loaded and lay the platelet bags flat. The top of the storage frame may also be used for bag storage. Avoid stacking bags. Maintain enough space around each bag for air circulation. For thicker bags, remove and/or adjust drawers. Place the bag tubing under or around the bag.

5 Pro Line Platelet Agitator Operation

5.1 Initial Start-Up

Use only rechargeable 9V NiMH batteries (1 included) for backup power to the motion alarm.

Notes

- Backup battery may need charging for 24 to 48 hours prior to use. Charging occurs when system is on facility power.
- Turning the alarm ON/OFF switch **ON** turns the motion alarm on and further allows the backup battery to recharge. When in the **OFF** position, the Alarm is not activated and the battery will not recharge.

1. Plug the power supply cord into a grounded outlet that meets the electrical requirements on the product specification label.
2. Switch the alarm ON/OFF switch **ON**.
3. Select alarm volume and alarm delay settings.
4. Set the communication switch to “X” when in stand-alone configuration using a small flathead screwdriver.
5. Switch power ON/OFF switch **ON**.

5.2 Motion Alarm

- Enable the motion alarm when using the platelet agitator. The red LED will illuminate.
- Disable the motion alarm when not using the platelet agitator. Lack of motion triggers the alarm.

5.3 Motion Alarm Controls

Motion alarm switch. *Alarm volume and delay controls*

When platelet agitator motion stops the motion alarm is activated. The alarm condition is communicated as follows:

- Red alarm LED on motion alarm switch flashes.
- Audible alarm buzzer sounds when in stand-alone mode, the motion alarm switch is turned on, adjustable alarm delay time has been exceeded, and volume has been turned up.
- Through a dry (no voltage) connection to an external monitoring device (if connected).
- Through a 9V connection to an external monitoring device (if connected).

Enable and Disable Motion Alarm

1. Switch the motion alarm ON/OFF switch **ON**.
2. Set volume to desired level.
3. Switch the motion alarm ON/OFF switch **OFF**.

NOTICE

If motion stops while the motion alarm is switched **OFF**, communication of the alarm (visual, audible, and signals to external devices) is suppressed.

Alarm Delay

The duration of time between when agitation stops and when the alarm sounds is the alarm delay. The alarm delay is set using the alarm delay control.

Notes

- The minimum alarm delay that can be set is approximately 10 seconds.
- Maximum alarm delay is approximately 10 minutes.
- The default motion alarm delay is set at the halfway point (approximately 4 to 5 minutes).

Set Alarm Delay

1. Using a small flat-head screwdriver, rotate the control to the left (counterclockwise) to shorten the motion alarm delay.
2. Using a small flat-head screwdriver, rotate the control to the right (clockwise) to extend the motion alarm delay.

Alarm Volume

The motion alarm volume has a variable setting.

Notes

- Rotating the volume control fully counter-clockwise will silence the audible alarm. If the motion alarm switch is turned **ON**, the LED will blink providing a visual alarm when the agitator is in an alarm condition.
- Alarm volume is applicable only when the agitator alarm switch is in the **ON** position and the platelet agitator is in stand-alone mode, or when communication is lost when configured in a platelet incubator.

Set Alarm Volume

Rotate the motion alarm dial to the appropriate position for the desired volume level.

5.4 Enable or Disable Motion

Agitation switch. *Agitator Speed Control*

Notes

- The agitator speed is factory set to 72 CPM (as displayed in green) and is applicable when used in stand-alone operation.
- For a setpoint of 72 CPM, rotate the arrow into the center of the green zone. The green zone represents an expanded 72 CPM area. Any point to the right of the green zone is a setpoint greater than 72 CPM.
- Contact Helmer Technical Service for instructions regarding Agitator Speed Verification (T3I468).
- For a platelet agitator in stand-alone configuration, switching the agitation ON/OFF switch **ON** will start the agitation motion.
- For a platelet agitator in stand-alone configuration or installed in a platelet incubator, switching the agitation ON/OFF switch **OFF** will stop the agitation motion.

Start/Stop Agitation

1. Select the desired speed from 40 to 80 CPM.
2. Load items into the platelet agitator.
3. Switch the agitation ON/OFF switch **ON** to begin movement.
4. Switch the motion alarm switch ON/OFF switch **ON**.
5. Switch the motion alarm switch ON/OFF switch **OFF**.
6. Switch the agitation ON/OFF switch **OFF** to stop movement.
7. Remove items from the platelet agitator.

Pro Line Platelet Agitator (installed in Platelet Incubator)

6 Installation

6.1 Location

Notes

- Only Helmer Pro Line platelet agitator may be used with Pro Line platelet incubator.
- Hot ambient temperatures with high humidity may cause condensation on the outside of the incubator.
- When placing a Pro Line agitator in the PC900-Pro or PC1200-Pro, ensure agitator placement allows the roll-top door to open.
- Add 1.5” (38 mm) to the agitator width to accommodate the trolley frame when agitation motion is enabled.

To ensure continuous operation of linearly shifting loads, the location surface must be level and adequately accommodate the full weight of the incubator with installed agitator when loaded with product.

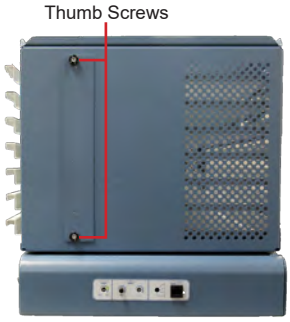
6.2 Storage Configuration

Drawers can be removed or moved to create additional storage space. Label holders are available and may be installed on drawers.

To avoid injury, ensure both left and right side drawer stop panels are fully installed prior to operating the agitator.

Remove and Replace Drawers

1. Remove the thumb screws securing the drawer stop panels to the left and right sides of the agitator. (Note the orientation of each panel)
2. Carefully pull each panel from the agitator and set panels and thumb screws aside.
3. Slide the drawer(s) out and remove.
4. Reinstall drawer in desired location by aligning the outer edges of the drawer with the slots in the drawer guides and push inward.
5. Reinstall the drawer stop panels in the same orientation as removed, and secure with thumb screws ensuring they are finger tight.



Install Label Holders (optional)

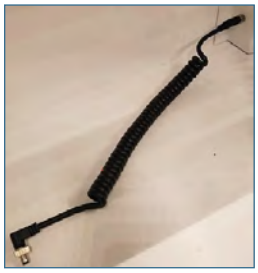
1. Insert the tabs on the label holder into the slots on the drawer.
2. Pivot the holder around the drawer handle and align the hole on the label holder with the corresponding hole on the drawer.
3. Push thumb screw through the hole in the label holder and through the hole in the drawer to secure.

6.3 Power and Communication Connection

Notes

- Use only the DC power cord supplied with the incubator when configuring the agitator within the incubator.
- Ensure the angled end of the DC power cord is attached to the agitator.
- Ensure AC power and backup battery power are turned **OFF** prior to connecting a Pro Line agitator to a Pro Line incubator.

The Pro Line platelet agitator may be installed in a Pro Line platelet incubator.
Connect the data cable and DC power cable supplied with the incubator prior to placing the agitator inside the incubator.



DC Power Cable

Communication Cable

Attach Power and Communication cables

1. Attach the DC power cable to the platelet agitator, ensuring the elbowed end is attached to the agitator and the rotating locks at each end are finger tight.
2. Insert the communication cable in the data cable port.

6.4 Agitator Mounting Brackets

Mounting brackets are included and may be installed for use inside the incubator or in stand-alone configuration.

Install Mounting Brackets

1. Carefully place the agitator on its back on a solid surface allowing access to the bottom of the unit.
2. Locate the two nutserts in the right or left side toward the front of the unit and align with the two holes in the mounting bracket.
3. Hand thread the screws through each hole, and secure using a #2 Phillips screwdriver.
4. Repeat steps 2 and 3 for the opposite side.
5. Return the agitator to the upright position.
6. Remove screws in the floor of the incubator prior to installing the agitator.
7. Carefully place the agitator inside an incubator,
8. Hand thread the screws through the bracket and into the holes in the floor of the incubator. Secure using a #2 Phillips screwdriver.

6.5 Placement and Leveling

- The product should not be used adjacent to other equipment. If adjacent use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other than those specified for the product by Helmer is not recommended. They may result in increased emissions or decreased immunity of the device.
- Refer to the Electromagnetic Compliance section for additional information.

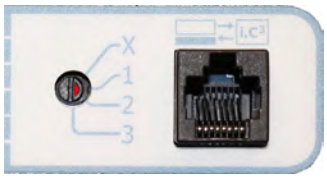
NOTICE

- To prevent damage to the platelet agitator, lift using the ends of the base. Do not use the platelet agitator storage frame, trolley or trolley drawer to lift agitator. If the platelet agitator base is not accessible, lift using the ends of the storage frame.
- The platelet agitator communication switch is fragile, do not use excessive force when changing the setting.

Notes

- Only Helmer Pro Line platelet agitators may be used with Pro Line platelet incubators.
- Ensure the AC power and backup battery power are turned off on the incubator prior to connecting an agitator.
- Ensure data cable is carefully positioned to the right of the agitator to prevent damage caused by agitation motion.
- The communication switch is fragile, do not use excessive force when changing the setting.
- To ensure continuous operation of linearly shifting loads, the location surface must adequately accommodate the full weight of the incubator and agitator when loaded with product.
- Incubator restraining brackets are recommended when configured with an agitator operating at a setpoint speed greater than 75 CPM, or when placed on a slick surface.

1. Using a small flathead screwdriver, turn the communication switch to the 1 position. Ensure the arrow *(shown in red for visibility in the adjacent picture)* is pointing to the 1.
2. Connect the data cable and DC power cable supplied with the incubator prior to placing the agitator inside the incubator.
3. Place platelet agitator inside platelet incubator.
4. Ensure platelet agitator is level.



6.6 Load the Platelet Agitator

PF48-Pro agitator with platelet bags (shown in a Helmer PC900-Pro incubator).

Table 3. Agitator Capacity

Model	Capacity	
	WBD/Random Bags	SDP/Apheresis Bags
PF15-Pro	15 (2 per drawer; 3 per shelf)	7 (1 per drawer/shelf)
PF48-Pro	48 (6 per drawer/shelf)	16 (2 per drawer/shelf)
PF96-Pro	96 (12 per drawer/shelf)	32 (4 per drawer/shelf)

NOTICE

When opening drawer, grasp the center of the handle (not label holder). Open one drawer at a time.

Open the drawer to be loaded and lay the platelet bags flat. The top of the storage frame may also be used for bag storage. Avoid stacking bags. Maintain enough space around each bag for air circulation. For thicker bags, remove and/or adjust drawers. Place the bag tubing under or around the bag.

7 Pro Line Platelet Agitator Operation

When a platelet agitator is installed in a platelet incubator, power is supplied to the agitator through a dedicated DC power cord. Motion data is transmitted between the platelet agitator and platelet incubator through the data cable. The platelet incubator interprets the motion data and provides information regarding the status and state of the agitator.

7.1 Initial Start-Up

Notes

- Only Helmer Pro Line platelet agitator models may be used with Pro Line platelet incubator models.
- Refer to platelet agitator service manual for more information regarding installation of a platelet agitator in a platelet incubator.
- Ensure data cable is carefully positioned to right of agitator to prevent damage caused by agitation motion.
- Use only manufacturer supplied DC power cord when configuring platelet agitator in platelet incubator.
- Ensure power switch and alarm switch are switched **OFF** prior to connecting agitator power cord to incubator.
- Ensure agitator communication switch is set to 1.

1. Switch alarm ON/OFF switch **ON**.
2. Select alarm volume and alarm delay settings.
3. Switch power ON/OFF switch **ON**.

7.2 Motion Alarm

When installing the Pro Line platelet agitator in a Pro Line platelet incubator, the motion alarm on the agitator will be suppressed when the agitator is in communication with the incubator. The incubator generates its own motion alarm, based on its own alarm delay period. If the agitation motion alarm switch is enabled, the motion alarm on the platelet agitator will sound only if motion has stopped and communication to the incubator has been lost.

Notes

- Helmer recommends the motion alarm ON/OFF switch remain in the **ON** position.
- Motion information is transmitted through the data cable to the platelet incubator, even when the agitator motion alarm is disabled.
- The platelet incubator interprets the motion information and generates its own motion alarm, based on its own alarm delay period.
- Once the agitator has been connected to the incubator, communication will be interrupted, and the incubator will alarm, if the agitator power switch is turned **OFF**.
- With the alarm enabled, the agitator alarm will time out and sound if power to the incubator is turned off for a duration greater than the motion delay.
- In the event of a communication failure with the incubator, the agitator alarm will only become active (audible and visual) if the agitator alarm switch is turned ON.

7.3 Motion Alarm Controls

Motion alarm switch. *Alarm volume and delay controls*

When platelet agitator motion stops the motion alarm is activated. The alarm condition is communicated as follows:

- Red alarm LED on motion alarm switch flashes.
- Through a dry (no voltage) connection to an external monitoring device (if connected).
- Through a 9V, 100mA connection to an external monitoring device (if connected).
- Through a data cable to the Pro Line Platelet incubator causing an alarm condition to appear on the display and an audible alarm to sound.

Enable and Disable Motion Alarm

1. Switch the motion alarm ON/OFF switch **ON**.
2. Set volume to desired level.
3. Switch the motion alarm ON/OFF switch **OFF**.

NOTICE

If motion stops while the motion alarm is switched **OFF**, communication of the alarm (visual, audible, and signals to other external devices) is suppressed.

Alarm Delay

The duration of time between when agitation stops and when the alarm sounds is the alarm delay. The alarm delay is set using the alarm delay control.

Notes

- The minimum alarm delay that can be set on the platelet agitator is approximately 10 seconds.
- Maximum alarm delay on the platelet agitator is approximately 10 minutes.
- The default motion alarm delay on the platelet agitator is set at the halfway point (approximately 4 to 5 minutes).

Set Alarm Delay

1. Using a small flat-head screwdriver, rotate the control to the left (counterclockwise) to shorten the motion alarm delay.
2. Using a small flat-head screwdriver, rotate the control to the right (clockwise) to extend the motion alarm delay.

Alarm Volume

The motion alarm volume has a variable setting.

Notes

- Rotating the volume control fully counter-clockwise will silence the audible alarm. If the motion alarm switch is turned **ON**, the LED will blink providing a visual alarm when the agitator is in an alarm condition.
- Alarm volume is applicable only when the agitator alarm switch is in the **ON** position and the platelet agitator is in stand-alone mode, or when communication is lost when configured in a platelet incubator.

Set Alarm Volume

Rotate the motion alarm dial to the appropriate position for the desired volume level.

7.4 Enable or Disable Motion

Agitation switch. *Communication switch*

Notes

- For a platelet agitator in stand-alone configuration or installed in a platelet incubator, switching the agitation ON/OFF switch **OFF** will stop the agitation motion.
- For a platelet agitator installed in a platelet incubator, the communication switch must be switched to 1. If the communication switch is set to X, the agitator will not start/stop based on the platelet incubator door position.

The door switch on Helmer platelet incubators controls whether the installed platelet agitator is turned on or off. When the incubator door is opened, agitation motion is paused. When the incubator door is closed, agitation motion is resumed.

Start / Stop Agitation

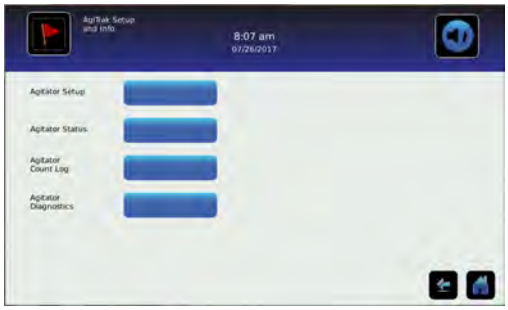
1. Open the platelet incubator door. Agitation motion stops.
2. Load items into the platelet agitator.
3. Close the platelet incubator door. Agitation motion resumes.
4. Open the platelet incubator door. The platelet agitator motion stops.
5. Remove items from the platelet agitator.
6. Close the platelet incubator door.

7.5 AgiTrak Setup and Information

Note

Agitation speed is set through the AgiTrak system when an agitator is configured inside an incubator. This setting overrides the setting on the agitator speed control.

Select the AgiTrak icon to open the AgiTrak Setup and Info screen. Enter the agitator information to allow monitoring and control of the device.



AgiTrak Setup and Info screen

Agitator Setup screen

Note

Default Setup password is 1234.

Setup Agitator(s)

1. From the Home screen, select the AgiTrak icon .
2. Select Agitator Setup button. A numeric keypad appears.
3. Enter the Agitator Setup password. The Agitator Setup screen appears.
4. Enter agitator information for each agitator installed.
5. Select the Back arrow to return to the previous screen or the Home icon to return to the Home screen.

8 Product Specifications

8.1 Operating Standards

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

Platelet Incubator

- Indoor use only
- Altitude (maximum): 2000 m
- Ambient temperature range: 15 °C to 35 °C
- Relative humidity (maximum for ambient temperature): 80% for temperatures up to 31 °C, decreasing linearly to 45% at 35 °C
- Internal temperature control range: 20 °C to 35 °C
- Overvoltage category: II
- Pollution degree: 2
- Sound level is less than 70 dB(A) under normal operation

Platelet Agitator

- Indoor use only
- Altitude (maximum): 2000 m
- Ambient temperature range: 15 °C to 35 °C
- Relative humidity (maximum for ambient temperature): 80% for temperatures up to 31 °C, decreasing linearly to 45% at 35 °C
- Overvoltage category: I
- Pollution degree: 2
- Sound level is less than 60 dB(A).
- Mains supply voltage: ±10% of nominal voltage

Notes

- Power Draw and Power Consumption specifications include internally operating Pro Line agitator supplied from the Pro Line incubator through a 24 VDC umbilical cable (DC power cord).
- Pro Line agitator Power draw is measured in full-load Amperes during stand-alone operation and includes power supply.
- Pro Line incubator Power Draw measured in Watts.
- 100 V Pro Line incubator models have only 1 circuit breaker.

Table 4. Pro Line Platelet Incubator Electrical Specifications

	PC100-Pro		PC900-Pro	PC1200-Pro
	monitor battery backup (12V)	w/ full system battery backup		
Input Voltage and Frequency	100-240VAC, 50 Hz/60 Hz			
Voltage Tolerance	±10%			
Circuit Breakers	7.0A quantity 2 *(100V units - quantity 1)*			
Agitator Power Draw *(if installed)*	16 W at 24V (DC)	16 W at 24V (DC)	16 W at 24V (DC)	16 W at 24V (DC)
Incubator Power Consumption *(with agitator installed)*	65 Watts* 352 Watts**	75 Watts* 415 Watts**	65 Watts* 352 Watts**	65 Watts* 352 Watts**
Power Source	Varies (refer to product specification label)			
Remote Alarm Capacity	1A at 33V (AC) RMS or 30V (DC)			
Internal Outlet Maximum Current Draw	1.5A AT 24V (DC)			

** 22°C in 24°C ambient static operation*
*** Pull down (full power)*

Table 5. Pro Line Platelet Agitator Electrical Specifications

	PF15-Pro	PF48-Pro	PF96-Pro
Input Voltage and Frequency	Stand-alone (power supply): 100-240VAC, 50/60 Hz Agitator Unit: 24VDC		
Voltage Tolerance	±10% (AC input to power supply)		
Power Draw	≤ 16 Watts nominal		
Power Source	24VDC AC/DC power supply (stand-alone) 24VDC umbilical cable (configured with incubator)		
Agitation Speed (cycles / minute)	40-80 CPM		
Remote Alarm Capacity	1A at 33V (AC) RMS or 70V (DC)		

Notes

- The interface on the remote alarm monitoring system is intended for connection to the end user's central alarm system(s) that uses normally-open or normally-closed dry contacts.
- *Platelet Incubator:* If an external power supply exceeding 33V (RMS) or 30V (DC) is connected to the remote alarm monitoring system's circuit, the remote alarm will not function properly; may be damaged; or may result in injury to the user.
- *Platelet Agitator:* If an external power supply exceeding 33V (RMS) or 70V (DC) is connected to the remote alarm monitoring system's circuit, the remote alarm will not function properly; may be damaged; or may result in injury to the user.

Table 6. Pro Line Platelet Storage Specifications

	PC100-Pro	PC900-Pro	PC1200-Pro	PF15-Pro	PF48-Pro	PF96-Pro
Height	27.2” (689 mm)	30.4” (772 mm)	30.4” (772 mm)	13.5” (343 mm)	14.9” (379 mm)	14.9” (379 mm)
Width	20.8” (528 mm)	26.0” (661 mm)	40.3 (1023 mm)	16.0” (407 mm)	17.8” (453 mm)	32.8” (834 mm)
Depth	22.3” (565 mm)	30.2” (766 mm)	30.2” (766 mm)	9.1” (232 mm)	14.9” (379 mm)	14.9” (379 mm)
Weight	116 lbs (53 kg)	136 lbs (62 kg)	173 lbs (79 kg)	33 lbs (15 kg)	50 lbs (23 kg)	80 lbs (37 kg)

Note

Add 1.25” (31.75 mm) to depth of the PC100-Pro for handle.

9 Compliance

9.1 Safety Compliance

This device complies with the requirements of directive 93/42/EEC concerning Medical Devices, as amended by 2007/47/EC.

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

This product is IECEE CB Scheme certified and complies with national differences for safety certification beyond IEC 61010-1-12 3rd edition.

9.2 Environmental Compliance

This device complies with the 2011/65/EU Directive for the Restriction of Hazardous Substances (RoHS).

This device falls under the scope of Directive 2012/19/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.

9.3 Electromagnetic Compliance

This device complies with FCC Radiated and Conducted Emissions Approval to CFR47, Part 15; Class A levels

This product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure the product is used in such an environment.

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The product is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

- The product should not be used adjacent to other equipment. If adjacent use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.
- The use of accessories other than those specified for the product by Helmer is not recommended. They may result in increased emissions or decreased immunity of the device.

Electromagnetic Immunity

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV ±1 kV for I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode for AC ±2 kV common mode for AC ±1 kV common mode async for I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions IEC 61000-4-11	100% drop, 0.5 cycle, 6 times each (@ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 100% drop, 250 cycles, 6 times (@ 0°) 30% dip, 25 cycles, 6 times (@ 0°)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power source.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 5.7 GHz where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level[b] in each frequency range. Interference may occur in the vicinity of equipment marked with this symbol.
Radiated RF IEC 61000-4-3	3 V/m to 28 V/m at frequencies up to 5.785 GHz	

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed. If abnormal operation is observed, additional measures may be necessary such as reorienting or relocating the product.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Notes
- At 80MHz and 800MHz, the higher frequency range applies
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

Recommended Separation Distances

This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product – according to the maximum output power and frequency of the communications equipment – as recommended in the following table.

Rated maximum output power of transmitter in watts (W)	Separation distance according to the frequency of transmitter in meters (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 kHz to 800 MHz $d = 1.2\sqrt{P}$	800 kHz to 5.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes
- At 80MHz and 800MHz, the higher frequency range applies
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

Appendix A: i.Series Active Alarms

Alarm	Description
Primary Monitor Probe High Temp	Primary monitor probe reading is above high temperature alarm setpoint
Primary Monitor Probe Low Temp	Primary monitor probe reading is below low temperature alarm setpoint
Primary Monitor Probe Failure	Primary monitor probe is not functioning properly
Control Probe Failure	Control probe is not functioning properly
Agitator 1 Communication Failure	Agitator 1 not installed; communication cable not installed; Agitator On/Off switch turned OFF
Agitator 1 High Speed	Agitator 1 speed (CPM) is above high speed alarm setpoint
Agitator 1 Low Speed	Agitator 1 speed (CPM) is below low speed alarm setpoint
Agitator 1 Maintenance Required	Check and replace trolley support wheels
Condensate Tray Full	Rear condensate tray is full *(recommendation is to empty soon to avoid overflow)*
External Fan 1 Failure	External Fan 1 is not functioning properly
External Fan 2 Failure	External Fan 2 is not functioning properly
Internal Fan 1 Failure	Internal Fan 1 is not functioning properly
Heat Pump 1 High Temp	Heat Pump 1 probe reading is above high temperature alarm setpoint
Heat Pump 1 Connection Error	Temperature is moving away from setpoint
Heat Pump 1 Failure	Heat Pump 1 is not functioning properly
Drive Space is Low	SD card is near capacity
Drive Space is Full	SD card is full, no history being recorded
Power Failure	Power to unit has been disrupted
Door Open (time)	Door is open beyond user-specified duration
Low Battery	Rechargeable battery voltage is low
No Battery	Battery is not connected
MPB Communication Failure	Communication is lost with heat pump controls
Communication Failure Messages 1, 2, 3	1 Communication lost between i.C³ display board and control board 2 Communication lost between i.C³ display board and internal system memory 3 Corrupt database

Appendix B: i.Series Application Icons

Icon	Description	Icon	Description	Icon	Description	Icon	Description
	Home		Temperature Graph		CSV Download		Save
	Event Log		Alarm Test		PDF Download		Cancel
	Mute		Information Logs		Upload		Back Arrow
	Reset		AgiTrak		Access Control		Scroll
	Zoom Information		Contact Information/ Contact Helmer		Access Log		Temperature Graph Forward/Back
	i.C³ Applications		Display Brightness		Alarm Conditions		Zoom Out
	Settings		Icon Transfer		Cancel Test		Battery Power

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