

iMX105 BD Pyxis™ ES Refrigerator

Operation Manual

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Document History

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Document Updates

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1 **About this Manual**

Intended Audience

This manual is for end users of the iMX105 BD Pyxis™ ES Refrigerator. For information on how to use the BD Pyxis MedStation™ ES which provides medication management capabilities to the iMX105 BD Pyxis™ ES Refrigerator, please refer to the Pyxis MedStation™ ES User Guide.

1.2 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.

The iMX105 is intended for the storage of pharmaceuticals, vaccines and other medical and scientific products. The iMX105 supports CDC performance and feature recommendations for vaccine storage without the need for third-party digital data logger (DDL) equipment.

Safety Symbols and Precautions

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 this product.

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

Symbols and Labels found on the units

The following symbols may be found on the refrigerator or refrigerator packaging:



Caution: Risk of damage to equipment or danger to operator



Earth / ground terminal



Caution: Hot surface



Protective earth / ground terminal



Caution: Shock / electrical hazard



Refer to documentation



Danger: Risk of Fire or Explosion Flammable refrigerant used



Caution: Unlock all casters



Warning: Crushing of hands / fingers



Caution: Dispose of properly



Caution: Follow handling instructions carefully.



Danger: Repair only by trained service personnel.



Caution: Consult instruction manual prior to installation or service.



Danger: Do not use mechanical devices to





Pantone 185 (Red) Warning: Refrigeration Line. Avoid puncturing or opening refrigeration circuit.



Caution: Follow handling instructions carefully in compliance with U.S. Government

regulations

Avoiding Injury



- Do not use mechanical devices or other means to accelerate the defrosting process, other than those recommended by the manufacturer.
- · Do not damage the refrigerant circuit.

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

- Before moving unit, ensure door is closed and casters (if installed) are unlocked and free of debris.
- ♦ Before moving unit, disconnect the AC power cord and secure the cord.
- Never physically restrict any moving component.
- Avoid removing electrical service panels and access panels unless so instructed.
- ♦ Keep hands away from pinch points when closing the door.
- Avoid sharp edges when working inside the electrical compartment and refrigeration compartment.
- Avoid staring into the bin illumination LEDs for extended periods of time as eye injury may occur.
- ♦ Ensure pharmaceutical products are stored at recommended temperatures determined by standards, literature, or good laboratory practices.
- Proceed with caution when adding and removing product from the refrigerator.
- Do not open multiple, loaded bins at the same time.
- ♦ Use manufacturer-supplied power cord only.
- Avoid risk of ignition by using only manufacturer-supplied components and authorized personnel when servicing the unit.
- ◆ Using the equipment in a manner not specified by the manufacturer may impair the protection provided by the equipment.
- ♦ Ensure product is stored safely, in accordance with all applicable organizational, regulatory, and legal requirements.
- ♦ The refrigerator is not considered to be a storage cabinet for flammable or hazardous materials.
- Required: Decontaminate parts prior to sending for service or repair. Contact the Pyxis Technical Support Center at BD-Pyxis-Support@bd.com or 800-727-6102.

1.5 General Recommendations

General Use

Allow refrigerator to come to room temperature before switching power on.

During initial startup, a high temperature alarm may appear while refrigerator reaches operating temperature.

Initial Loading

Allow chamber temperature to stabilize at the setpoint before storing product.

Product Loading Guidelines

When loading your refrigerator, take care to observe the following guidelines:

- ♦ Never load refrigerators beyond capacity.
- ♦ Always store items within shelves or bins.
- ♦ Temperature uniformity is maintained by air circulation, which could be impeded if unit is overfilled, particularly at the top or back. Ensure a minimum of 2" (50 mm) clearance is provided below the fan.



Products stacked against back wall may obstruct air flow and affect performance of unit.

2 Installation

2.1 Location Requirements



Keep all ventilation openings in the enclosure or, in the structure for building-in, clear of obstruction.

- ♦ Has a grounded outlet meeting the electrical requirements listed on the product specification label.
- ♦ Is clear of direct sunlight, high temperature sources, heating vents, and air conditioning vents.
- ♦ Has a minimum of 3" (76 mm) of space behind the refrigerator for clearance and feature access.
- Meets the limits specified for ambient temperature (15 °C to 32 °C) and relative humidity.

2.2 Placement and Leveling

NOTICE

- · To avoid damaging refrigerant tubing or risking refrigerant leak, use caution when moving or operating the unit.
- To prevent tipping, ensure the casters (if installed) are unlocked and the door is closed before moving the refrigerator.
- · Use of leveling feet or casters is required.
- Do not sit, lean, push or place heavy objects on the top surface.
- 1. Remove refrigerator from shipping carton.
- 2. Remove and discard interior packing material.
- 3. Remove accessory package from inside refrigerator.
- 4. Ensure door is secured.
- 5. Move refrigerator into place.
- 6. Adjust leveling legs as needed to ensure refrigerator is level, or lock casters (if installed).
- 7. Ensure bins are locked in place within the modules.

2.3 AC Power Cord

NOTICE

Use manufacturer supplied power cord only.

Install power cord

If packaged with modular cord, insert plug securely into the refrigerator power receptacle prior to connecting to grounded outlet.

2.4 Temperature Probes

A solid ballast is installed on the upper left interior side of the unit. A temperature probe for the temperature display is inserted into the solid ballast and secured with thumb screws.

1 Notes

- Temperature probes are fragile; handle with care.
- Remote probes may also be introduced through the existing port on the back of unit.

The solid ballast may be relocated within the unit as necessary. Recalibration of temperature probes is recommended when the ballast is moved from the original location. Refer to the Refrigerator Service and Maintenance manual for instructions regarding recalibration.

3 Operating the i.C³ Monitoring System

3.1 Initial Power-up

- 1. Plug power cord into grounded outlet that meets electrical requirements on the product specification label.
- 2. Switch AC ON/OFF switch ON.
- 3. Switch back-up battery key switch ON. The Power-up screen is displayed followed by the System Boot screen.



The i.C3 will take approximately 2-5 minutes to start.







System Boot screen

The Home screen is displayed when the i.C³ is powered on. This screen is the primary screen that will appear on the i.C³ display during normal operation and when a user is not interfacing directly with the i.C³. The i.C³ Home screen displays temperature, door lock status and alarm information, and provides buttons for accessing other functions of the i.C³.

Note

No password is required to view the Home screen.



Home screen

3.2 Temperature Setpoint

1 Notes

- The default settings password is 1234.
- The default setpoint is 40°F.

Change Temperature Setpoint

- 1. From the Home screen, select the Settings button. The password numeric keypad is displayed.
- 2. Enter the password. (If accessing for the first time, use the factory default password.) The Settings screen is displayed.
- 3. Touch + or on the Temperature Setpoint spin box to change the value.

3.3 Active Alarms

When an alarm condition occurs, an alarm message appears across the top of the screen.



Home screen with active alarm

Table 1. Alarm Conditions

Alarm	Description		
Communication Failure 1	Communication lost between i.C3 display board and control board		
Communication Failure 2	Configuration file is corrupt or i.C3 is unable to access the configuration file		
Communication Failure 3	Corrupt database		
Compressor Probe Failure	Probe not functioning properly		
Compressor High Temperature	Compressor temperature reading is above high temperature alarm setpoint		
Control Probe Failure	Probe not functioning properly		
Drive Space Low	SD card is approaching capacity		
Drive Space Full	SD card is full		
Door Open	Door is open beyond user-specified duration		
Inverter Communication Failure	Communication is lost between the i.C3 control board and the VCC inverter		

Alarm	Description		
Low Battery Voltage	Backup battery voltage is low		
Backup Battery Failure	Backup battery voltage is deficient		
Main Power Failure	Power to the unit has been disrupted		
Primary Temperature Probe Failure	Probe not functioning properly		
Over Maximum Temperature Limit	Chamber temperature reading is above high temperature alarm setpoint		
Below Minimum Temperature Limit	Chamber temperature reading is below low temperature alarm setpoint		

4 Module Assembly Operation



Module Assembly

4.1 Bin Operation

Bins remain locked at all times unless unlocked by the Pyxis MedStation $^{\mbox{\tiny TM}}$ ES system.

Bins will be illuminated and unlocked when specified via the Pyxis MedStation™

Under normal operation, bins will lock upon full insertion.

Close open bins by hand to ensure bins are fully inserted and locked within the compartment.

A metal stop within the compartment will impede the bin from full extension and removal.

Bins have been designed to contain leaks.

NOTICE

Take care when opening a fully loaded deep bin to ensure the metal stop prevents unintended removal from the compartment.



Refer to the Refrigerator Service & Maintenance Manual for instructions on bin removal for cleaning or replacement.

5 Operation During Power Failure

The iMX105 BD Pyxis™ ES refrigerator is equipped with a backup battery system. The backup battery system provides electrical power to the i.C³ temperature monitoring system, alarm system, and magnetic door lock. Individual bins cannot be unlocked while the refrigerator is running on backup battery system power.

NOTICE

- In the event of a power failure, the backup battery system does not provide refrigeration of the chamber or stored product.
- It is recommended that the iMX105 BD Pyxis™ ES refrigerator be connected to the emergency power system.
- In order to maintain product integrity, follow facility standard operating procedures for instructions on accessing products during a power failure, or for instructions on moving products to a refrigerator operating on an emergency power source.
- If an emergency power source is not available, the temperature of stored products must be checked (according to
 facility standard operating procedures) to ensure stored products have not warmed to an unacceptable temperature
 during a power failure.

If a main electrical power failure is anticipated to last no longer than two hours, the backup battery system will provide temperature monitoring and alarm functions, and will allow secure access to the refrigerator. However, it will not allow access to the individual bins or provide power to the refrigeration system.

If a power failure is anticipated to last beyond two hours, and the facility has an emergency power source, refer to Section 5.2 for instructions regarding operating the refrigerator after the emergency power source has come online.

NOTICE

During a power failure:

- The backup battery system does not provide continued refrigeration of the chamber. The chamber temperature may
 rise above the established limits necessary to maintain integrity of stored product.
- The backup battery system will provide power to the electromagnetic door lock, alarm system, and communication boards for approximately two hours (the Low Battery alarm message will appear when backup battery power for the refrigerator is nearly depleted).
- While the electromagnetic door lock is energized, the backup battery is rapidly depleted, and the magnetic lock holding force diminishes as the backup battery power depletes.
- The electromagnetic door lock will remain locked until battery power is depleted.
- The backup battery system provides power to the i.C³ monitoring system, refrigerator communication components, and electromagnetic door lock until battery power is depleted.

During an extended power failure:

Move the refrigerator main electrical power supply to the facility's emergency power system.

1 Notes

- The backup battery system will provide backup power for approximately two hours only if the backup battery has been allowed to charge for at least 48 hours since the last interruption.
- During a power failure, the backup battery provides power to the monitoring system and the power failure alarm. If the
 backup battery is not functioning, the power failure alarm will not be activated.
- If the backup battery does not provide power to the monitoring system during the power failure alarm test, replace
 the battery.

5.1 Operating the Refrigerator on an Emergency Power System

After the emergency power system is online, the BD Pyxis™ ES Refrigerator will resume normal operation.

NOTICE

- If AC power has failed and the emergency AC power system is started, the refrigerator will restart using emergency AC power.
- Do not switch off the i.C³ monitoring/Access Control backup battery if operating on the emergency AC power system.
- When AC power is restored and the emergency power system is shut down, the refrigerator will resume normal operation.

5.2 Accessing the Refrigerator and Bins During a Power Failure

The BD Pyxis™ ES Refrigerator may be accessed in two ways during an AC power failure. While the refrigerator is operating on backup battery power, the door may be unlocked using the BD Pyxis MedStation or by switching the door lock key switch **OFF**. Doing either of these will disengage the integrated magnetic lock and allow access to the refrigerator.

NOTICE

If medications are manually removed from the refrigerator during a power failure, it is the responsibility of the user to follow the facility's standard operating procedures for safe transfer practices.

Access Bins

- 1. Open the exterior door.
- 2. Using the module assembly keys (Figure 1), unlock the manual release access cover.
- 3. Lift the cover upward to disengage the tabs (Figure 2) and pull out to remove the cover and reveal the bin release lever(s).







Figure 1

Figure 2

Figure 3

- 4. Pull the red tabbed manual release lever outward until the notch on the bottom edge of the lever is aligned with the module frame, then push down to secure the lever in place (Figure 3). This releases the locking mechanism for each bin in the module. Repeat for each module installed.
- 5. Pull out only the bin(s) containing the medication(s) to be removed.
- 6. Remove the medication(s) from the bin.
- 7. Slide the bin(s) into the module location until it stops.
- 8. Lift up on the red tabbed manual release lever and slide it into the slot in the module frame.





Figure 4 Figure 5

- 9. Replace the manual release cover by aligning the tabs on the cover with the slots in the bracket and slide downward to engage (Figure 4).
- 10. Push the locks in to lock the cover (Figure 5) and close the refrigerator door.

6 Product Specifications

6.1 Operating Standards

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

- ♦ Non-residential, indoor use only
- ♦ Altitude (maximum): 6.56k ft (2000 m)
- ◆ Ambient temperature range: 59°F to 90°F (15°C to 32°C)
- ◆ Relative humidity (maximum for ambient temperature): 80% for temperatures up to 89°F (31°C); 76% at 90°F (32°C)
- ◆ Temperature control range: 36°F to 46°F (2°C to 8°C)
- ♦ Overvoltage Category II
- ♦ Pollution Degree 2
- ♦ RF Emissions: Group 1 Class A
- ◆ EMC Environment: Basic
- ♦ Sound level is less than 70 dB(A).

Table 2. Electrical Specifications

	105			
Input Voltage and Frequency	115V 60 Hz	230V 50/60Hz		
Voltage Tolerance	±10%			
Circuit Breakers	4.0A quantity 2			
Current Draw*	1.4A	0.85A		
Power Source	Grounded outlet, meeting National Electric Code (NEC) in the U.S. and local electrical requirements in all locations.			
Remote Alarm Capacity	1 A at 33 V (RMS) or 30 V (DC)			

^{*} Amperage values are subject to change. Refer to the product specification label on your unit for current values.

NOTICE

- 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.
- 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.

- Notes
- Notes
- The maximum height added with leveling feet installed is 1" (25.4 mm).
- The maximum weight added per shelf is 6 lbs (3 kg).
- The maximum weight added per standard module is 16 lbs (7 kg).
- The maximum weight added per deep module is 20 lbs (9 kg).
- Net weight may vary depending on storage configuration. Refer to the product specification label for an accurate weight
 of your unit.
- Maximum load per standard bin 4 lbs (1.8 kg).
- Maximum load per deep bin 11 lbs (5 kg).
- Maximum load per shelf 100 lbs (46 kg).

Table 3. Refrigerator Specifications

	Model	l Voltage Code		Cu. Ft (Liters)	Cabinet	Door	Dimensions W x H x D in. (mm) Exterior*	Net Wt. lbs (kg)**
	iMX105	115V 60 Hz	1.4	5.3 (150)	Undercounter	Single hinged solid	24.3 x 31.9 x 28.1	172
		220-240V 50/60 HZ	0.85				(617 x 809 x 714)	(78)

^{*} Exterior dimensions include components that protrude from the cabinet and door, such as handle and leveling feet (set at lowest level).

^{**} Net Wt represents the weight of the unit with no storage features added.

7 Compliance

7.1 Regulatory Compliance



This device complies with the requirements of the following directives: 2011/65/EU (Restriction of Hazardous Substances), 2014/30/EU (Electromagnetic Compatibility (EMC) Directive), and 2014/35/EU (Low Voltage Directive).

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

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



7.2 EMC Compliance

Helmer Scientific Refrigerators meet the applicable requirements of IEC61326 and EN55011 and are intended for use in the electromagnetic environment specified in 6.1 Operating Specifications. The customer or the user of these devices should assure they are used in such environment.

7.3 Manufacturer of Record

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