PharmAssist™ Pro

Peristaltic Pump

User Manual

DS1000

For use with Software
Release V3.0 Only

IFU0001265 (04, 2026-04)

icumedical
human connections

Change History

Part Number	Description of Change
IFU0001265 (01, 2025-10)	Initial Release
IFU0001265 (02, 2025-12)	Changed manufacturer address on back cover
IFU0001265 (03, 2026-01)	· Added note under section Scale (DS1030) · Added a trademark 'TM' on Introduction and title CADD™ Ambulatory Cassette Holder (CADDH01). · Added a warning under section System Operation and Bag Holder (BAGH01). · Modified the Interval Time on Table 9: Batch Quantity and Interval Time. · Deleted key words under section Entering Compound Details, and Search Drugs. · Modified a Warning and Caution to add the statement related to accessories under section Intended Use,Warnings, Cautions, and Recommendations.
IFU0001265 (04, 2026-04)	· Updated Labeling Symbols Glossary section. · Images of the back of the pump are updated under section PharmAssist Pro Description. · Added a step under the section Appendix B: Recommended Preventative Maintenance. · Updated image step 2 under sections Closed Loop Transfer Mode, Volumetric Mode, Gravimetric Mode with External Scale, Gravimetric Mode with Connected Scale. · Updated image step 1 under sections CADD Filling – Air Removal Mode and Fill and Air Removal. · Updated images of Warning under section Volumetric Mode.

Contents

Introduction 7
Intended Use 7
Important Safety Instructions 7
Warnings, Cautions, and Recommendations 7
General 7
Liquids Handling 8
Power Supply 8
Tubing and Compounding Tubing Sets 8
Drug Details 9
Calibration 9
System Operation 10
Service and Maintenance 10
Storage and Disposal 11
Cleaning 11
Symbols 12
Labeling Symbols Glossary 12
List of Symbols on the Back of the Pump Unit 13
Conventions 14
Illustrations, Screen Displays, and Software Messages 15
PharmAssist Pro System Overview 16
PharmAssist Pro Description 16
PharmAssist Pro Hardware Version 18
PharmAssist Pro Unit (DS1000-04-03) Installation 19
PharmAssist Pro Graphic User Interface (GUI) 19
Guidance Text 20
Touch Screen Usage 21
Data Entry 21
Tubing Set 21
Tubing Set Overview 21
Tubing Set Information and Compatibility 22
Scanner (DS1010) 23
Printer (DS1020) 24
Scale (DS1030) 24
Foot Pedal Kit (DS1040) 25
USB Adapter (DS1050) 26
CADD™ Ambulatory Cassette Holder (CADDH01) 26
Bag Holder (BAGH01) 27
Syringe Holder Adapter (SH01) 28
General Operation Details 30
Power On and Initial Setup 30
Tubing Set Installation / Removal 34
Tubing Set Installation 35
Tubing Set Removal 37
Tubing Preparation – Recommended for Heavy Duty Tubing 37
Entering Compound Details 39
Order Number 40
Drug Name and Drug ID 40
Lot Number 42
Lot Expiration Date 43
Specific Gravity 43

Source Container 45
Accept Drug Information 46
Tubing Connections 47
Priming 47
Circle Priming 48
Calibration 48
Warnings During Calibration 49
Recalibration 50
Batch Compounding 50
Power Off 51
PharmAssist Pro Compounding Workflow 53
Overview 53
Basic Transfer Mode 53
Basic Mode Features and Functions 54
Basic Transfer Workflow 58
ADJUST Calibration 60
Closed Loop Transfer Mode 61
Advanced Transfer Mode 67
Volumetric Mode 67
Gravimetric Mode with External Scale 73
Gravimetric Mode with Connected Scale 79
Scale Only Mode 87
Scale Check 88
CADD Filling – Air Removal Mode 91
CADD Mode – Set Up 92
CADD Filling Process 98
Bag Filling – Air Removal Mode 103
Fill and Air Removal 104
Air Removal Only 112
Settings 116
General 117
Language 117
Screen & Volume 118
Version Information 119
Perform Scale Check 119
Preparation Log 121
Password 125
Drugs 126
Add Drug 126
Search Drugs 128
Advanced Settings 130
Speed Settings 130
Deviation Borders 133
Priming Settings 134
Requirement Settings 135
Duration Settings 136
Administrator 139
Date and Time 139
User Management 140
Label Printing 143
Technical Services 146
Troubleshooting 147
Temperature Warning 147

General Troubleshooting 148
Database Error 153
Specifications and Maintenance 154
Accuracy Specifications 154
Environmental Specifications 155
Lithium-Ion Coin Battery Service 155
Fuse Replacement 156
Tubing Replacement 157
Duty Cycle 157
Pump Unit Software Update 158
Transport 162
Service and Contact Information 163
Warranty and Service Information 164
Limited Warranty 164
Disclaimer of Warranties 164
Limitation of Liability 164
Appendix A: Cleaning and Disinfection of the PharmAssist Pro 165
Cleaning and Disinfection of PharmAssist Pro Accessories 165
Foot Pedal Kit 165
Printer 165
Scale, Bag Holder, CADD Holder, & Syringe Holder 166
Appendix B: Recommended Preventative Maintenance 167
Labels Inspection 167
AC (Mains) Power Cord Inspection 168
Power Inlet Module Inspection 168
Roller Head Assembly Inspection 169
Rubber Feet Inspection 169
Touch Screen Display Inspection 170
Power Button Inspection and Test 170
Appendix C: Accuracy Verification Protocol 171
Appendix D: Training Practice Examples 172
Syringe Batching in Basic Mode 172
Syringe Batching in Advanced Volumetric Mode 172
Bag Filling in Advanced Mode with Connected Scale 174
Bag Filling in Advanced Mode with External Scale 175
CADD Cassette Batching with Barcode Scanner 176

Table of Figures

Figure 1: Back Panel 13
Figure 2: PharmAssist Pro Unit 16
Figure 3: Front and Side 17
Figure 4: Back of the Pump Unit 17
Figure 5: Hardware Version 18
Figure 6: PharmAssist Pro Hardware 19
Figure 7: UI Components 20
Figure 8: Guidance Text 21
Figure 9: Data Entry 21
Figure 10: Tubing Set 22
Figure 11: Scanner (DS1010) 23
Figure 12: Printer (DS1020) 24
Figure 13: Scale (DS1030) 25
Figure 14: Foot Pedal 26
Figure 15: USB Adapter (DS1050) 26
Figure 16: Ambulatory Cassette Holder (CADDH01) 27
Figure 17: Bag Holder (BAGH01) 28
Figure 18: Syringe Holder Adapter (SH01) 29
Figure 19: Changing the Specific Gravity 44
Figure 20: The Deviation Exceeds Acceptable Limits 50
Figure 21: Power Off 52
Figure 22: PharmAssist Pro Home Screen 53
Figure 23: Basic Mode 54
Figure 24: Settings Menu 116
Figure 25: General 117
Figure 26: Version Information 119
Figure 27: Scale Check 120
Figure 28: Advanced Settings 130
Figure 29: Deviation Borders 134
Figure 30:Date and Time 139
Figure 31: Temperature Warning - Pause Transfers 147
Figure 32: Temperature Warning - Power Off System 147
Figure 33: Database Error (05) 153
Figure 34: Lithium-Ion Coin Battery Replacement 156
Figure 35: Fuse Replacement 156
Figure 36: Tubing Replacement 157
Figure 37: Label Inspection 168
Figure 38: Power Inlet Module Inspection 169
Figure 39: Roller Head Assembly Inspection 169

Introduction

Intended Use

The PharmAssist Pro™ system is intended for use by healthcare professionals allowed by law to perform manual pharmaceutical reconstitution, admixture, or compounding.

The PharmAssist Pro system is not intended to screen, monitor, treat, diagnose, or prevent any specific condition or disease.

In this manual, the meaning of liquid refers to a substance that flows freely, but it is of constant volume, having a consistency like water or oil.

The PharmAssist Pro and its accessories are designed for use in laminar airflow boxes, biological safety cabinets, gloveboxes, laminar airflow hoods and/or safety work benches in clean rooms.

The PharmAssist Pro is intended for use by pharmacists, pharmacy technicians, doctors, and nurses who are properly trained to use this system. Please follow the information contained in this manual as a self-paced training guide before operating the system for the first time. Refer to this manual as a reference guide when needed. Frequent training is not required to use this system.

The PharmAssist Pro System (often referred to as “System” throughout the User Manual) consists of:

- PharmAssist Pro Unit (Required) (often referred to as just the “pump unit” throughout the User Manual)
- Tubing Set (Required)
- This User Manual (Required)
- Foot Pedal Kit (Optional)
- Scale Kit (Optional)
- Printer Kit (Optional)
- Scanner Kit (Optional)
- CADD™ Ambulatory Cassette Holder (CADDH01)
- Bag Holder (BAGH01)
- Syringe Holder Adapter (SH01)

Important Safety Instructions

The operator must be properly trained in the use of the System. Please follow the information contained in this manual regarding its operation.

The pharmacist or pharmacy technician must wear Personal Protective Equipment (PPE) when operating the System, and adhere to facility protocols and standards for operating compounding equipment.

Always follow published guidelines related to work protection and accident prevention and ensure professional diligence.

Warnings, Cautions, and Recommendations

Read this user manual carefully before using the PharmAssist Pro and its accessories. For safe operation of the PharmAssist Pro, refer to the Warnings, Cautions, and recommendations in the following sections.

General

WARNING: DO NOT USE FOR BIOLOGICAL TISSUE, CELLS, OR BODY FLUIDS.

WARNING: DO NOT USE THE COMPOUNDING SYSTEM IN THE PRESENCE OF FLAMMABLE SUBSTANCES, INCLUDING ANESTHETICS. A POSSIBLE EXPLOSION HAZARD EXISTS WHEN OPERATING IN THE PRESENCE OF FLAMMABLE SUBSTANCES.

WARNING: READ THIS USER MANUAL BEFORE OPERATING THE DEVICE.

WARNING: TO AVOID INJURY OR DAMAGE TO THE SYSTEM, DO NOT ATTEMPT TO DISASSEMBLE OR SERVICE THE SYSTEM. MALFUNCTIONING SYSTEMS MUST BE SENT BACK TO ICU MEDICAL FOR REPAIR.

WARNING: IF THE PUMP UNIT IS DAMAGED DURING OPERATION, SWITCH OFF IMMEDIATELY AND DISCONNECT FROM THE POWER SUPPLY.

CAUTION: DO NOT PLACE THE PHARMASSIST PRO COMPOUNDER ON AN UNSTABLE SURFACE.

CAUTION: ALWAYS CARRY THE SCALE ACCESSORY BY THE BOTTOM PLATE CONNECTED TO THE RUBBER LEGS. DO NOT CARRY THE SCALE BY THE TOP PLATE AS THIS MAY LEAD TO INACCURATE CALIBRATION.

Important: No modifications to the System are allowed. Do not modify in any way, otherwise there is a possibility of operator injury, impairments, or damage to the System.

Important: The PharmAssist Pro does not contain any user-serviceable parts.

Liquids Handling

WARNING: TO AVOID THE POTENTIAL FOR CROSS-CONTAMINATION BETWEEN DRUGS, REPLACE THE TUBING SET WHEN A NEW DRUG IS TO BE COMPOUNDED.

CAUTION: LIQUID INGRESS INTO THE SYSTEM COMPONENTS MAY CAUSE DAMAGE AND IMPACT PERFORMANCE. CLEAN SPILLS IMMEDIATELY.

Note: When using the pump unit to transfer liquid to rigid containers such as vials or bottles, care should be taken to ensure the containers always remain upright and ensure containers are not over-pressurized prior to connecting to the pump unit.

Note: Avoid direct contact with liquids. If a spill occurs, quickly remove liquids in accordance with the facility protocol.

Power Supply

WARNING: IF POWER CORD IS DAMAGED, STOP USING THE PUMP UNIT AND UNPLUG THE CORD FROM THE POWER SOURCE.

WARNING: THE PUMP UNIT SHOULD ONLY BE USED WITH THE MANUFACTURE-PROVIDED POWER CORD (ICU KIT NUMBER DS1902, ICU PART NUMBER: 826-11518-403).

WARNING: THE POWER CORD MUST BE CONNECTED TO A PROPERLY GROUNDED HOSPITAL GRADE 120V RECEPTACLE FOR PROPER PUMP UNIT PERFORMANCE AND SAFETY.

WARNING: AVOID ROUTING THE POWER CORD ACROSS THE FLOOR WHERE IT CAN CREATE A TRIPPING HAZARD.

Important: The pump unit should only be connected to a properly grounded electrical supply outlet.

Important: Refer to the requirements for medical electrical systems in the current edition of IEC 60601-1 for proper use.

Note: Position the pump unit to assure easy access to its power plug (so that it can be disconnected from electrical supply in the event of an emergency).

Tubing and Compounding Tubing Sets

WARNING: THE TUBING SET SHOULD BE CHANGED WITHIN 24-HOURS DUE TO TOUCH CONTAMINATION.

WARNING: DO NOT RE-STERILIZE OR REUSE THE TUBING SET. RE-STERILIZING OR REUSING MAY CAUSE DAMAGE TO THE TUBING.

WARNING: CHANGE THE TUBING SET PRIOR TO EACH CHANGE OF MEDICATION OR IV FLUID TO AVOID DRUG INCOMPATIBILITY AND/OR TRANSFERRING THE INCORRECT VOLUME.

WARNING: DO NOT REMOVE THE PROTECTIVE CAPS FROM EITHER END OF THE TUBING SET.

CAUTION: INCORRECT INSERTION OF THE TUBING SET MAY DAMAGE THE PUMP UNIT.

CAUTION: DO NOT USE THE SAME TUBING SET FOR MORE THAN 60 LITERS. OVERUSE MAY RESULT IN DAMAGE TO THE TUBING SET AND LIQUID SPILLAGE.

Important: The tubing set fluid path is sterile (sterilized using irradiation) and non-pyrogenic in unopened and undamaged packaging. Use aseptic techniques with tubing set when removing caps, spiking diluent containers, and making connections to luer adapter.

Important: DO NOT use tubing set if the sterile packaging has signs of damage. If the tubing set's sterile packaging is damaged, replace the set with a new one and discard the damaged set.

Note: Inspect/test tubing set sensor and ensure the adjustment screw is neither loose nor damaged.

Note: Refer to tubing set label for important use information.

Drug Details

WARNING: SPECIFIC GRAVITY IS SET BY DEFAULT TO 1.0 FOR ALL DRUGS IN THE PRE-LOADED DRUG LIST. THIS DEFAULT SPECIFIC GRAVITY VALUE DOES NOT REPRESENT ACTUAL DRUG SPECIFIC GRAVITY AND MUST BE UPDATED BY THE USER BEFORE THE SPECIFIC GRAVITY CAN BE USED TO ACCURATELY CORRELATE WEIGHT AND VOLUME FOR EACH DRUG. SEE SPECIFIC GRAVITY FOR DETAILS ABOUT HOW DEFAULT VERSUS USER ENTERED SPECIFIC GRAVITY VALUES ARE REPRESENTED WITHIN THE SYSTEM. SEE SPECIFIC GRAVITY FOR DETAILS ABOUT HOW TO UPDATE THE DEFAULT SPECIFIC GRAVITY VALUES FOR DRUGS.

Important: Accurate specific gravity configuration is essential for gravimetric accuracy. Accuracy reported by the System is directly related to the accuracy of the specific gravity entered by the user for the liquid to be transferred.

Calibration

WARNING: DO NOT RE-STERILIZE OR REUSE THE TUBING SET. RE-STERILIZING OR REUSING MAY CAUSE DAMAGE TO THE TUBING.

WARNING: WHEN USING ADVANCED MODE OR BASIC TRANSFER MODE, CALIBRATE THE PUMP UNIT EACH TIME THE TUBING SET IS CHANGED. ONLY THE INTENDED DIRECTION NEEDS TO BE CALIBRATED. CALIBRATE AGAIN IF DIRECTION IS CHANGED. EITHER DIRECTION CAN BE RECALIBRATED AS OFTEN AS DESIRED.

WARNING: WHEN USING ADVANCED MODE OR BASIC TRANSFER MODE, CALIBRATION MAY NEED TO BE PERFORMED WHEN THERE IS A CHANGE IN PUMP UNIT SPEED, USE OF NEEDLES, USE OF IN-LINE FILTERS, OR FILLING CONTAINERS THAT CREATE BACK PRESSURE.

WARNING: CALIBRATION SHOULD ALWAYS BE PERFORMED WITH THE DRUG OR IV FLUID INTENDED TO TRANSFER, BECAUSE THE TUBING SET SHOULD BE CHANGED PRIOR TO EACH CHANGE OF LIQUID.

CAUTION: DO NOT USE THE GRAVIMETRIC CALIBRATION PROCESS UNLESS YOU ARE CERTAIN THAT THE FLUID'S SPECIFIC GRAVITY HAS BEEN ENTERED ACCURATELY.

CAUTION: DURING A SCALE CHECK, IF THE VALUE REPORTED FOR THE CALIBRATION WEIGHT IS OUTSIDE THE TOLERANCE ESTABLISHED FOR THE FACILITY, PLEASE CONTACT ICU MEDICAL, INC. FOR ASSISTANCE.

Important: Accurate specific gravity configuration is essential for gravimetric accuracy. Accuracy reported by the System is directly related to the accuracy of the specific gravity used for the liquid to be transferred.

Important: For highest accuracy, calibration should be performed using a container similar to the one intended for transfer and at a volume similar to the intended transfer volume.

Important: The pump unit must be used in conjunction with ICU Medical Transfer Tubing Sets. These sets have been specifically designed to ensure accuracy and decrease user variability. The set contains a bar connector which fits into a slot on the pump unit. The slot keeps the tubing seated properly and decreases user variability in the tubing installation.

System Operation

WARNING: DO NOT OPERATE THE PUMP UNIT WITHOUT THE ROLLER COVER IN PLACE, AS INJURY MAY OCCUR. IF THE ROLLER COVER IS BENT OR DAMAGED, CONTACT THE ICU MEDICAL SERVICE CENTER FOR REPAIR.

WARNING: THE DEVICE SHOULD ONLY BE USED WITH PROPER PERSONAL PROTECTIVE EQUIPMENT AND ADHERE TO FACILITY'S PROTOCOLS.

WARNING: DO NOT OPERATE THE PUMP UNIT IF AT ANY POINT THE ROLLER ASSEMBLY IS ROTATING WHILE THE LID IS OPEN. IN SUCH AN EVENT, UNPLUG THE PUMP, DISCONTINUE OPERATION, AND CONTACT THE ICU MEDICAL SERVICE CENTER FOR REPAIRS.

WARNING: DO NOT USE THE FOOT PEDAL ON A WET FLOOR.

WARNING: DO NOT USE THE BAG HOLDER ON A WET SURFACE.

CAUTION: VERIFY PUMP UNIT ACCURACY PERFORMANCE BEFORE USE TO ENSURE IT MEETS FACILITY PROTOCOLS. SEE ACCURACY SPECIFICATIONS FOR DETAILS.

Important: Use Heavy Duty "BX01", "BX02", or "BX03" tubing when filling containers used with ambulatory pumps or other hard to fill containers.

Important: Pump unit operation must be monitored at the beginning of each batch and at intervals during the batch to ensure the pump unit is operating within acceptable limits (out of limits conditions displayed during use). Use the calibration function to achieve specified accuracy (see Calibration for more details).

Important: The system shall not be connected to hospital networks. Connection to an IT network could result in unidentified risks to patients.

Note: Consider the drug manufacturer's labeling and USP compounding guidelines when performing compounding.

Recommendation: Upon first power up, 'Require User Login' at startup defaults to Deactivated. It is recommended that an Administrator enables 'Require User Login' at startup using Advanced settings.

Recommendation: It is recommended that each user creates an individual account.

Service and Maintenance

WARNING: ENSURE THE SYSTEM AND ITS ACCESSORIES ARE PLACED ON A LEVEL, STABLE, AND CLEAN SURFACE.

WARNING: VERIFY PUMP UNIT ACCURACY PERFORMANCE BEFORE USE TO ENSURE IT MEETS FACILITY PROTOCOLS. SEE ACCURACY SPECIFICATIONS FOR DETAILS.

WARNING: DO NOT INSERT ANY FOREIGN OBJECTS INTO THE PUMP UNIT PORTS OR OPENINGS.

CAUTION: SOME METAL PARTS MAY BE WARM AFTER HEAVY USE OF THE PUMP UNIT. THE USER SHOULD NOT USE THE PUMP UNIT FOR 30 MINUTES BEFORE TRANSPORTATION TO ALLOW THE METAL PARTS TO COOL.

Save the original box and packaging. If the System needs to be sent in for servicing, return the PharmAssist Pro in its original packaging. If the original box cannot be located, contact ICU Medical, Inc. at 800-824-7890 and ask for a shipping box to be provided.

Note: Service performed by persons other than ICU Medical, or its authorized agents may cause the warranty to be voided, at the discretion of ICU Medical.

Note: The System is not suitable for use in mobile equipment.

Note: DO NOT use the pump unit continuously for more than 8 hours or 240 liters. Upon reaching this limit, allow the System to rest for 30 minutes before additional use.

Storage and Disposal

WARNING: THE SYSTEM IS DESIGNED TO BE USED IN BIOLOGICAL SAFETY CABINETS, LAMINAR AIRFLOW HOODS AND/OR SAFETY WORK BENCHES IN CLEAN ROOMS IN A HEALTHCARE SETTING.

Important: At the end of service life, please contact ICU Medical, Inc. for further directions on how to properly dispose the system components and consumables.

Note: When storing the System, ensure the location is in compliance with the Storage Temperature, Humidity, and Altitude listed in Table 15.

During storage and use, avoid impacts and vibration which could result in a malfunction of the System.

Cleaning

WARNING: NEVER IMMERSE THE PUMP UNIT IN LIQUIDS FOR CLEANING PURPOSES. DO NOT ATTEMPT TO STERILIZE USING MECHANICAL OR STEAM STERILIZATION EQUIPMENT.

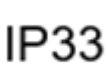
Note: ll cleaning of the System should be performed according to the detailed instructions in this manual.

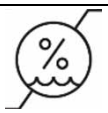
Symbols

Labeling Symbols Glossary

This section describes the symbols used in the labeling for the PharmAssist Pro System. The System complies with the symbols mentioned below.

Table 1: Symbols Glossary

Symbol	Reference	Description
	IEC 60417 – 5010	“ON”/ “OFF” (push-push)
	ISO 7010 - M002	Follow Instructions for Use
	ISO 15223-1: 2021 Symbol 5.4.3	Consult Electronic Instructions for Use at www.icumed.com/dianaPPM
	IEC 60417 – 5032	Alternating current
	IEC 60417-5019	Connect an earth terminal to the ground
	ISO 7010 - W001	General warning sign
	ISO 7010 - W012	Warning; electricity
	ISO 7000 – 3082 ISO 15223-1:2021 Symbol 5.1.1	Manufacturer
	ISO 7000 – 2498 ISO 15223-1:2021 Symbol 5.1.7	Serial number
	SGS	SGS Certification mark indicates that the product has been tested against applicable North American safety standards requirements.
	ISO 15223-1: 2021 Symbol 5.1.2	Authorized European Representative
	IEC 60529	Ingress protection (protected against solid foreign objects 2.5 mm diameter or greater and spraying water)
	IEC 60529	Protection against vertically falling water drops, flow rate of 1 mm/min for a duration of 10 minutes.

Symbol	Reference	Description
	IEC 60417 – 6414 Directive 2012/19/EU ANNEX IX Symbol	WEEE; waste electrical and electronic equipment; crossed- out wheeled bin
	ISO 7000 – 0632 ISO 15223-1:2021 Symbol 5.3.7	Temperature limit
	ISO 7000 – 2620 ISO 15223-1:2021 Symbol 5.3.8	Humidity limitation
	CE Mark	European Conformity [BM1]
	AS/NZS 4417.1 & 2 and the EESS	Regulatory Compliance Mark (RCM)

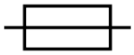
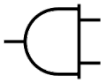
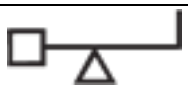
List of Symbols on the Back of the Pump Unit

Figure 1 shows the back panel of the instrument and the location of various connectors and switches for the pump unit.

Table 2 provides depiction, references, and description of the symbols on the back.

Figure 1: Back Panel

Table 2: Back Symbols

Symbol	Description	Reference
	Indicates the fuse is held inside the housing.	IEC 60417, Reference Number: 5016
	Indicates plug to be used to Power on the pump unit.	IEC 60417, Reference Number: 5534
	Indicates socket to be used for USB Update port.	ISO 7000-365ar0
	Indicates socket for connecting the Foot Pedal Kit.	IEC 60417, Reference Number: 6378
	Indicates socket for connecting the Printer Kit.	IEC 60417, Reference Number: 5851
	Indicates socket for connecting the Scanner Kit.	N/A
	Indicates socket for connecting the Scale Kit.	IEC 60417, Reference Number: 0143

Conventions

This section describes the conventions used throughout this manual, as follows:

Table 3: Conventions

Convention	Application	Example
Italic, bold, blue	Reference to a section, figure, or table	Table 1
Initial Caps lowercase	Screen displays, modes and device labels (as appropriate)	…will enable the Infinite Transfer mode
Bold	Button, Icons, or messages names. Emphasis	Pressing the Yes button confirms the user's entry.
Red	Warnings and Cautions	WARNING: INCORRECT INSERTION OF THE TUBING SET MAY DAMAGE THE PUMP UNIT.

Throughout this manual, warnings, cautions, and notes are used to emphasize important information as follows:

WARNING: A WARNING CONTAINS SPECIAL SAFETY EMPHASIS AND MUST BE OBSERVED AT ALL TIMES. FAILURE TO OBSERVE A WARNING MAY RESULT IN PATIENT INJURY AND BE LIFE-THREATENING.

CAUTION: A CAUTION USUALLY APPEARS IN FRONT OF A PROCEDURE OR STATEMENT. IT CONTAINS INFORMATION THAT COULD PREVENT HARDWARE FAILURE, IRREVERSIBLE DAMAGE TO EQUIPMENT, OR LOSS OF DATA.

Important: Highlights information on the proper use of the product, user expectations, error situations, and related actions.

Note: Highlights information that helps explain a concept or procedure.

Recommendation: Provides advice to help users when using the system.

Illustrations, Screen Displays, and Software Messages

Illustrations and screen examples in this manual are graphic depictions, not exact representations of the product.

PharmAssist Pro System Overview

The PharmAssist Pro System consists of the PharmAssist Pro Unit (Required), the Tubing Set (Required), the Connected Scale Kit (Optional), the Printer Kit (Optional), the Barcode Scanner Kit (Optional), and the Foot Pedal Kit (Optional), USB Adapter (DS1050), CADD Ambulatory Cassette Holder (CADDH01), Bag Holder (BAGH01), and Syringe Holder Adapter (SH01).

PharmAssist Pro Description

The PharmAssist Pro (Figure 2) is a software-controlled automated pharmacy-compounding system intended for use in a healthcare facility by Pharmacists and Pharmacy Technicians to dispense a specified volume of medication from a set of source containers into a destination container.

Figure 2: PharmAssist Pro Unit

Figure 3 and Figure 4 show the pump unit with the major components labeled and reference in Table 4.

Figure 3: Front and Side

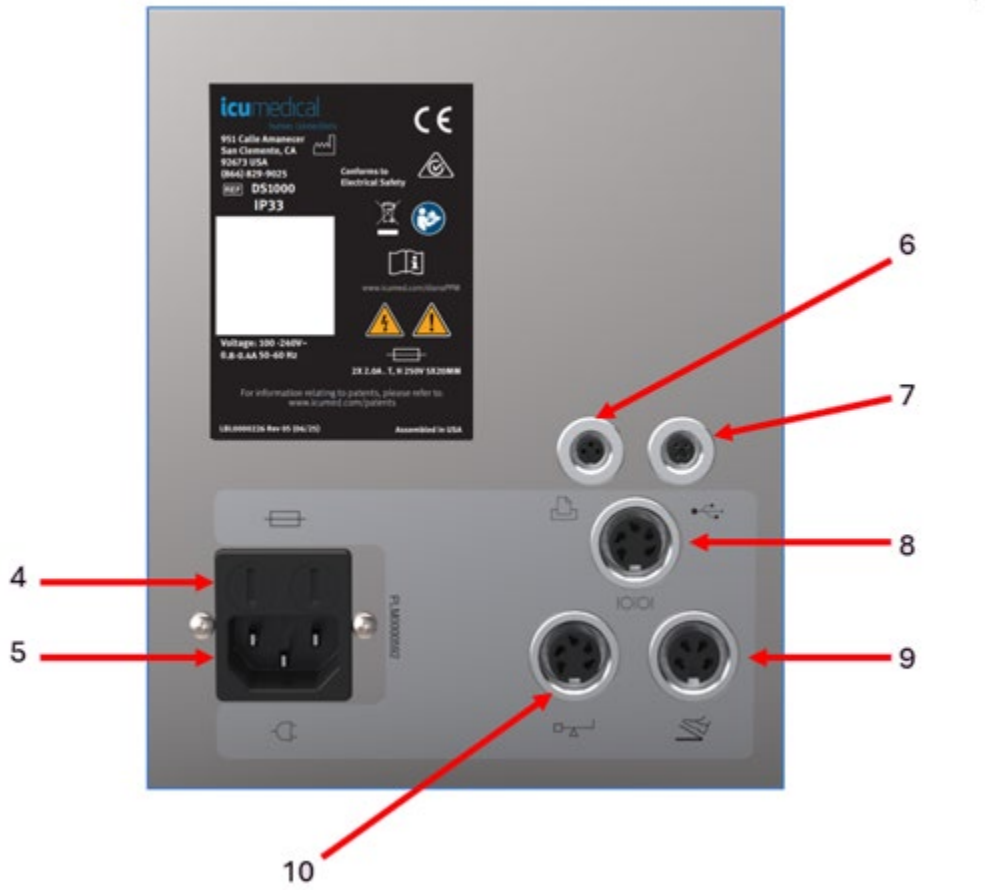


Figure 4: Back of the Pump Unit

Table 4: Pump Unit Components

Reference	Component	Description
1	Power Button	Power ON/OFF Button.
2	Tubing Detection Sensor	Detects the presence and proper placement of the tubing set.

Reference	Component	Description
3	Flap	The flap protective cover must be closed while the pump unit is actively pumping.
4	Fuses	Protect the electrical equipment.
5	Power Inlet	Connects the pump unit to the electrical outlet using the provided power cord.
6	Printer Port	Connects the optional printer accessory.
7	USB Port	For use by ICU Medical authorized personnel to service the System. The user can export or import files with a USB drive.
8	Scanner Port	Connects the optional scanner accessory.
9	Foot Pedal Port	Connects the optional Foot Pedal Kit accessory.
10	Scale Port	Connects the optional scale accessory.

PharmAssist Pro Hardware Version

There are two versions of the PharmAssist Pro hardware that are in the field. The version of hardware can easily be distinguished by looking at the label on the back panel of the pump unit, note the elements outlined in red in Figure 5.

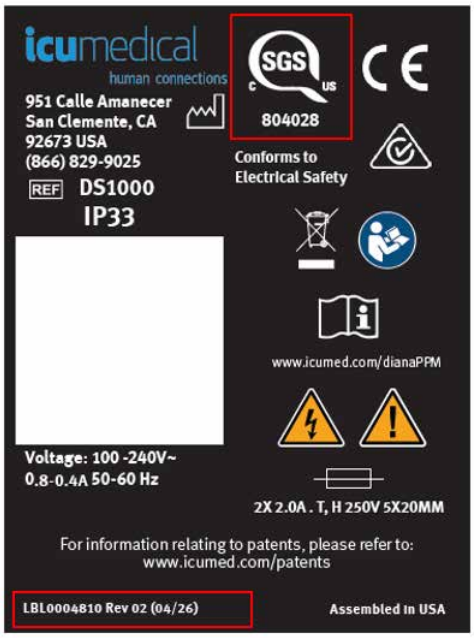
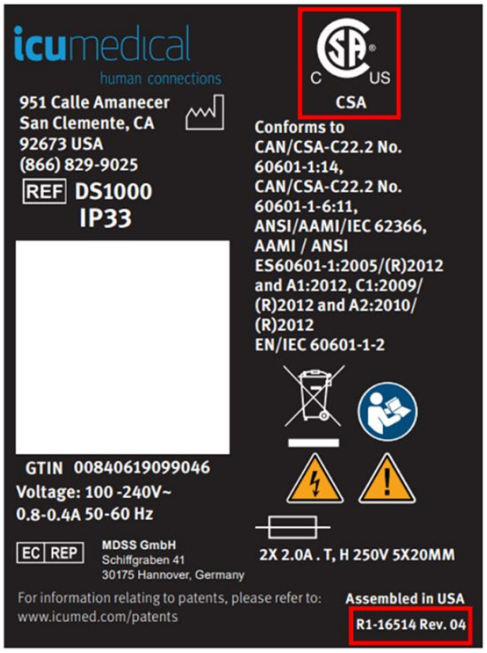


Figure 5: Hardware Version

The models Diana PPM 2.2 and PharmAssist Pro have the same version of hardware. See Figure 6.

Diana PPM 2.1 Hardware



Diana PPM 2.2 Hardware

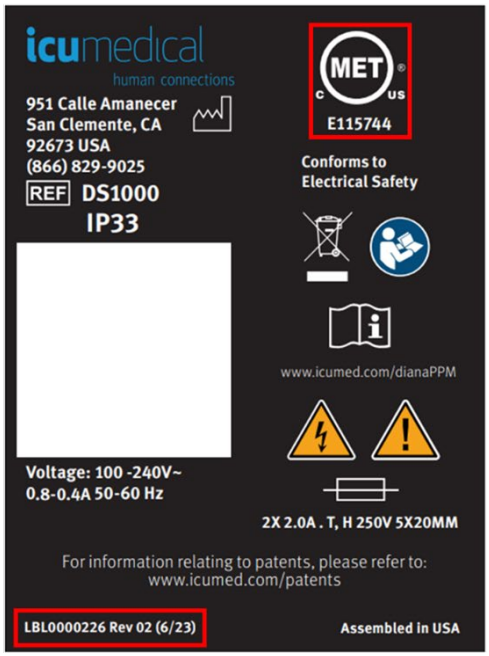


Figure 6: PharmAssist Pro Hardware

PharmAssist Pro Unit (DS1000-04-03) Installation

To install the pump unit:

1. Place the pump unit onto a stable surface.
2. Plug the power cord supplied by ICU Medical into the back of the pump.
3. Plug the power cord into an electrical outlet.

   Important: Only connect the pump unit to a properly grounded electrical supply outlet. Refer to the requirements for medical electrical systems in the current edition of IEC 60601-1 for proper use.

4. Once the System is plugged in, press the circular on/off switch located on the front of the pump unit.

Important: We recommend the System be sent to ICU Medical Service once a year for inspection and maintenance.

Important: An authorized ICU Medical representative must perform all maintenance.

Important: The manufacturer must complete all maintenance work except for routine cleaning.

PharmAssist Pro Graphic User Interface (GUI)

The user interface of the pump unit features a Home screen with six modes that allow navigation to specific workflows. Figure 7 shows the labeled user interface and lists the labeled components.

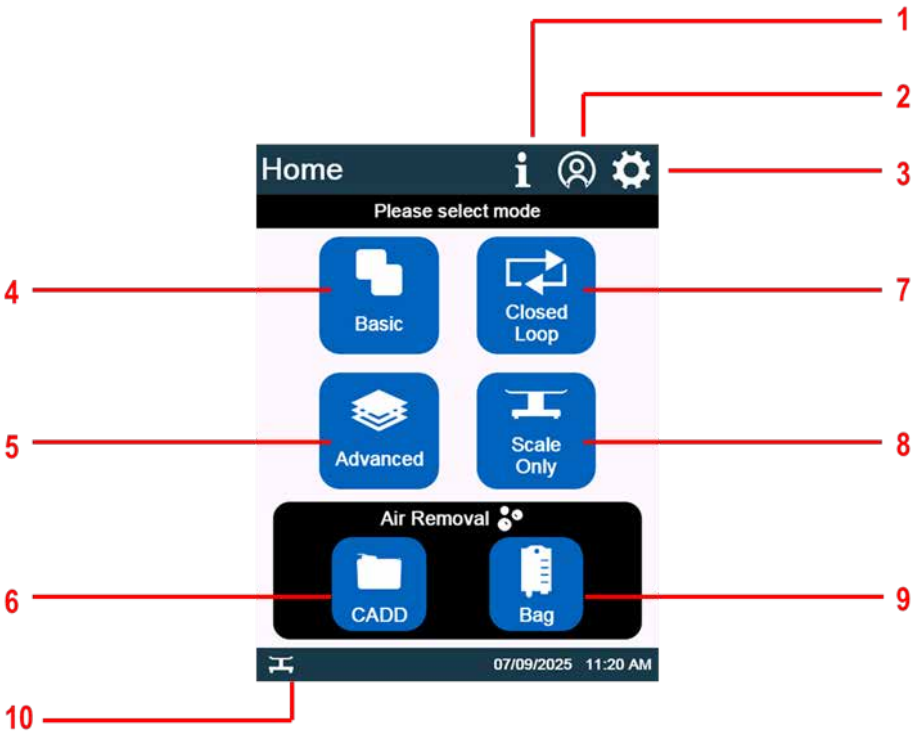


Figure 7: UI Components

Table 5: User Interface Components

Reference	Component	Description
1	Mode Information	Provides additional information on the modes.
2	Logout Icon	Displays the Logout Confirmation message and returns to the Login screen.
3	Settings Icon	Displays the Settings Menu.
4	Basic Mode	Basic Transfer Mode has a simplified workflow that displays a single transfer screen which mimics the functionality of previous generation peristaltic pumps.
5	Advanced Mode	Advanced Transfer Mode allows the user to choose the drug and volume, volumetrically or gravimetrically, to calibrate the System for transfer.
6	CADD Mode	CADD Filling Mode is designed to fill CADD cassettes and remove air from the cassette to minimize air pockets.
7	Closed Loop Mode	Closed Loop Mode uses the connected scale to continuously measure the weight of the output container during a transfer.
8	Scale Only Mode	Scale Only Mode uses the connected scale to measure the weight of a container for accuracy and verification. This mode can also be used to complete a Scale Check, which verifies if the connected scale provides an accurate measurement.
9	Bag Mode	Bag Filling Mode is designed to fill and remove air from bag containers. For bags that are already filled, the user can opt to remove air only.
10	Scale Icon	Indicates the Scale Kit is connected to the System.

Guidance Text

The System provides guidance for priming, calibration, set up, and compounding in a black bar near the top of the screen as shown in Figure 8.

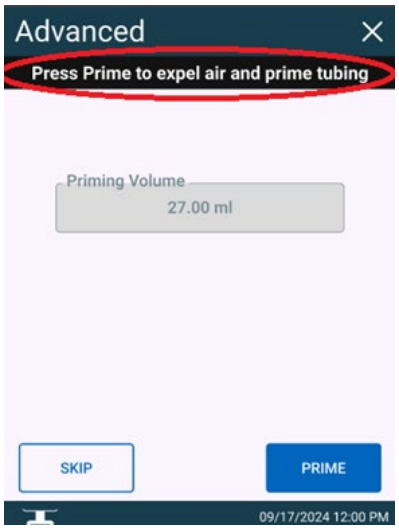


Figure 8: Guidance Text

Touch Screen Usage

The touch screen is not like those used for tablets and mobile phones; it is designed for use in a clean room environment with gloved hands. Firmly select and enter values.

Data Entry

Enter numeric or alphanumeric values and dates by using the keypad as shown in Figure 9.

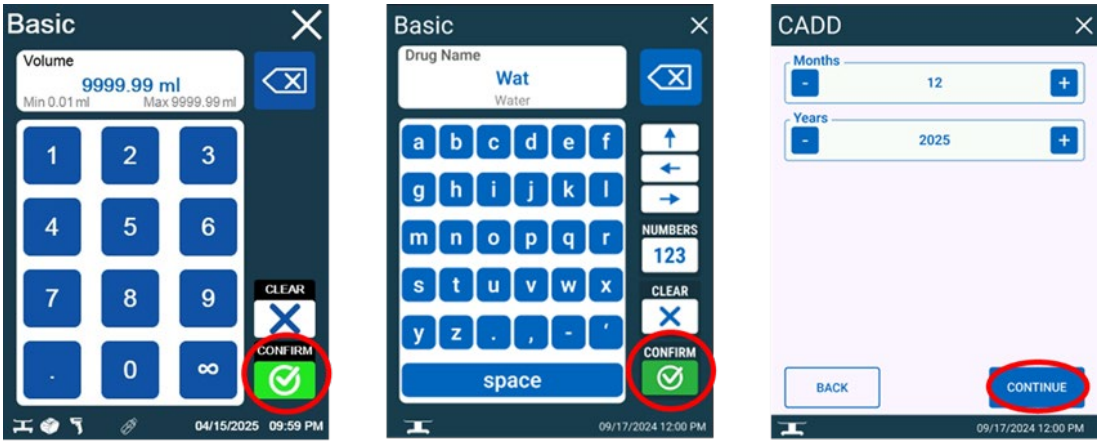


Figure 9: Data Entry

Tubing Set

Tubing Set Overview

Important: The following consumables are not included with the System. They must be ordered separately. Contact an ICU Medical representative for assistance.

The tubing set, which consists of an input port, output port, and tubing set handle, is for use in conjunction with the pump unit.

Figure 10 shows the tubing set and describes the labeled components.

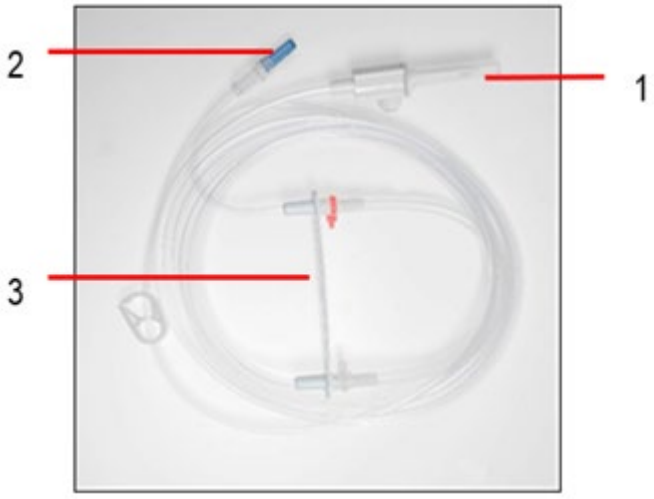


Figure 10: Tubing Set

Table 6: Tubing Set Components

Reference	Component	Description
1	Input Port	An IV spike used for bags or bottles (excepting PA01LL which has a luer lock connector on the input port)
2	Output Port	A luer lock connector
3	Tubing Set Handle	Allows the easy placement of the tubing set into the Tubing Detection Sensor Ensure the red clip is on the top of the Tubing Detection Sensor.

Tubing Set Information and Compatibility

ICU Medical recommends that only compatible tubing sets tested by the manufacturer should be used for compounding.

Table 7: Tubing Set Description and Compatibility

ICU Medical Item Part Number	Description
Heavy Duty Tubing Sets	
BX01	Single Lead Heavy Duty Tubing Set
BX01LL	Single Lead Heavy Duty Tubing Set – w/ Double Luer
BX02	Dual Lead Heavy Duty Tubing Set
BX03	Triple Lead Heavy Duty Tubing Set
Normal Tubing Sets	
LPA01	Single Lead Tubing for use w/Lipids
PA01	Single Lead Tubing Set
PA02	Dual Lead Tubing Set
PA03	Triple Lead Tubing Set
PA01LL	Single Lead Tubing Set- w/Double Luer
PA01-XS	Single Lead Short Tubing Set

Note: The pump unit must be used in conjunction with ICU Medical Transfer Tubing Sets which have been specifically designed to ensure accuracy and decrease user variability. The set contains a bar connector which fits into a slot on the pump unit. The slot keeps the tubing seated properly and decreases user variability in the tubing installation.

Important: Use a Heavy Duty “BX01”, “BX02”, or “BX03” tubing when filling containers that create back pressure and/or when transferring viscous fluids.

The following table lists the components that are compatible with ICU Medical Tubing Sets:

Table 8: Component Type Compatibility

Component Type
Spiros
Clave
16-gauge needle
18-gauge needle
0.2-micron filter
0.5-micron filter
Elastomeric pump
CADD cassette

Scanner (DS1010)

To use:

1. Insert the Connector into the Scanner Port on the back of the pump unit and screw it in.

   Note: All accessories must be connected while the pump is powered off for proper detection.

   Note: When the scanner is connected to the pump unit, the scanner symbol ( ) appears at the bottom of the pump screen.

2. Place the Scanner next to the PharmAssist Pro.

Figure 11: Scanner (DS1010)

Printer (DS1020)

The following modes are compatible with printing a preparation label: Basic, CADD, Bag, Closed Loop, and Advanced mode. See Label Printing for details on setting up a print label.

Note: The pump unit should only be used with an approved medical grade power supply for the printer.

To connect the printer:

1. Properly connect the Power Source to the Printer.
2. Properly attach the Rs232 end of the Printer cable to the Printer Rs232 Port.
3. Insert the Connector into the Printer Port on the back of the pump unit and screw it in.
4. Place the Printer next to the PharmAssist Pro Unit.

Figure 12: Printer (DS1020)

Note: When the printer is connected to the pump unit, the printer symbol ( ) appears at the bottom of the pump screen.

Note: Users need to ensure the label printer paper is full or contains an adequate number of labels remaining prior to starting a transfer or a batch.

Scale (DS1030)

WARNING: ALWAYS CARRY THE SCALE HOLDING THE BOTTOM PLATE CONNECTED TO THE METAL LEGS. DO NOT CARRY THE SCALE HOLDING THE TOP PLATE AS THIS MAY LEAD TO INACCURATE CALIBRATION.

Note: All accessories must be connected while the pump is powered off for proper detection.

To use:

1. Insert the Connector into the “Scale Port” on the back of the pump unit, and screw it in.

   Note: When the scale is connected to the pump unit, the scale symbol ( ) appear at the bottom of the pump screen.

2. Place the Scale next to the PharmAssist Pro on a flat stable surface.
3. To level the scale, locate the four adjustable plastic feet at each corner of the base. Rotate each leveling foot clockwise to lift or counterclockwise to lower the corner. Verify the scale is level by using the built-in bubble level located at the base of the scale and ensure the bubble is centered in the circle.

Figure 13: Scale (DS1030)

Foot Pedal Kit (DS1040)

To use:

1. Ensure the pump unit is powered on.
2. Insert the Connector into “Foot Pedal Port” on the back of the pump unit. Screw it in.
3. Place the Foot Pedal on the ground with the hinge away from the user.
4. Step on the front of the Foot Pedal to activate it.

The Foot Pedal (Figure 14) can be used instead of pressing the touch screen during Transfer, Batch Mode, and Infinite Transfer Mode operations. For example, pressing “Next”, “Start”, “Stop”, “Continue”, or “Pause” on the touch screen can also be done by activating the Foot Pedal. This provides a hand free alternative to manipulate input containers, output containers, and tubing during transfers.

WARNING: DO NOT USE THE FOOT PEDAL ON A WET FLOOR.

Figure 14: Foot Pedal

USB Adapter (DS1050)

The USB Adapter is used for completing Software Updates or exporting preparation log files.

To install:

1. Line up the groove on the 4 pin USB Adapter Connector with the guide pin on the USB Port on the back of the pump unit.
2. Insert the 4 pin USB Adapter Connector into the USB Port.
3. Turn housing until the USB Adapter Connector is securely tightened into the USB Port.
4. Once installed the USB Adapter provides a standard USB Socket for connection of approved accessories.

Note: Only install passive USB storage devices (such as USB Sticks) into the USB connector.

Note: When a USB is connected to the pump unit, the USB symbol ( ) appears at the bottom of the pump screen.

See Preparation Log for instructions on how to use an attached USB storage device to download system logs from the pump unit. See Pump Unit Software Update for instructions on how to use an attached USB storage device to update the software and drug database in the pump unit.

Figure 15: USB Adapter (DS1050)

CADD™ Ambulatory Cassette Holder (CADDH01)

The CADD Ambulatory Cassette Holder is to be used in CADD Air Removal mode to hold a CADD Cassette at the proper angle. The occlusion clip at the top of the cassette should be oriented upward as shown in Figure 16.

Figure 16: Ambulatory Cassette Holder (CADDH01)

Bag Holder (BAGH01)

WARNING: DO NOT USE THE BAG HOLDER ON A WET SURFACE.

To secure the Bag Holder to the connect scale:

1. Loosen the two screws at the bottom of the Bag Holder by rotating to the right.
2. Slide the Bag Holder onto the scale such that each hinge slides under the open slots on each side of the scale.
3. Secure the Bag Holder to the scale by rotating the corresponding screws to the left. Ensure that the holder is tightened to the scale before placing a fluid bag.

To place a fluid bag onto the Bag Holder:

- Orient the IV bag so that the medication ports are facing upward. There are two methods to secure a fluid bag to the Bag Holder:
- If the bag has holes near the tubing ports, hang the fluid bag onto the Bag Holder by sliding each post through the perforated holes in the bag.
- If the bag does not have holes near the tubing ports, place the bag onto the shelf with the medication ports facing upward. Let the bag rest on the shelf and ensure it is centered on the bag holder.

The orientation of the posts can be adjusted by sliding side-to-side to position the IV bag at the center of the holder. Secure the posts in position by rotating the corresponding screws to the right to tighten and left to loosen. The Bag Holder can hold up to 3 liters of fluid.

Figure 17: Bag Holder (BAGH01)

Syringe Holder Adapter (SH01)

The Syringe Holder Adapter is used to hold the dispensing pump tubing and syringe adapter while filling single Luer-Lock syringes.

To use:

1. To open the Syringe Holder Adapter, unscrew the clamp by twisting it to the left.
2. Thread the tubing through the designated opening with the Luer-Lock facing upward.
3. Close the clamp by twisting it to the right until securely locked in place.
4. Attach a syringe to the Luer-Lock port using a Syringe Adapter.

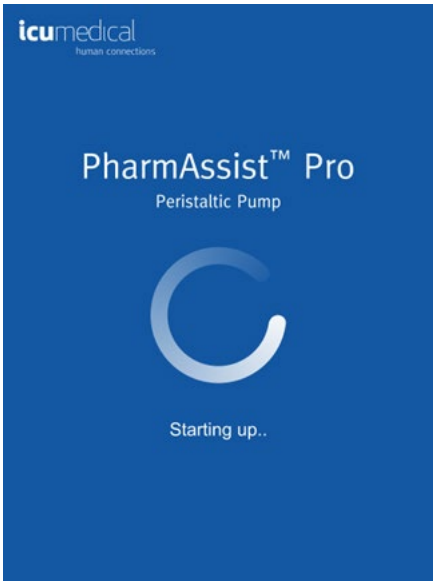
Figure 18: Syringe Holder Adapter (SH01)

General Operation Details

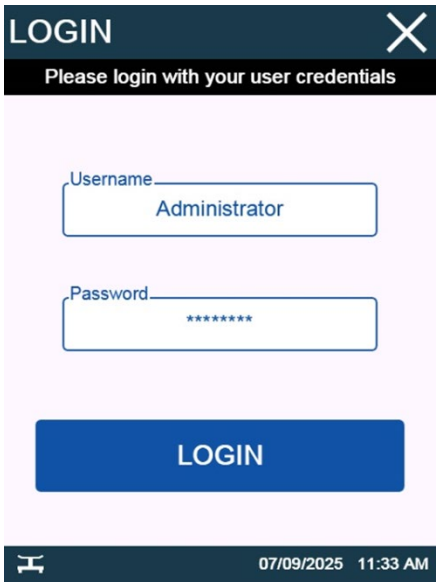
Power On and Initial Setup

1. Press the Power button on the front of the pump unit (lower right) to turn it on.

When the pump unit starts, a welcome screen is displayed.



Upon first power up, the System displays the Login screen where the user must enter a Username and Password.



2. The system has a predefined user account that an Administrator should use for the first login. Enter the credentials below:

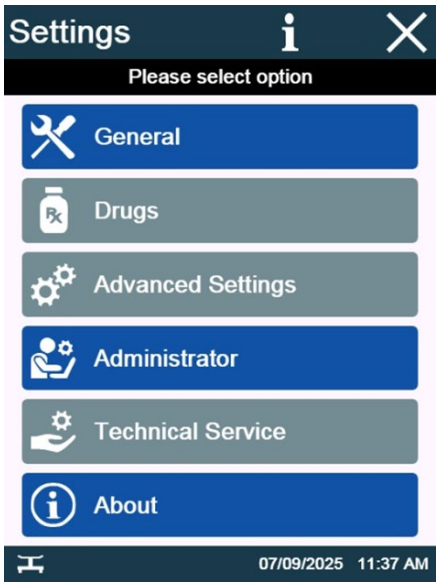
   Username: Administrator

   Password: ChangeMe

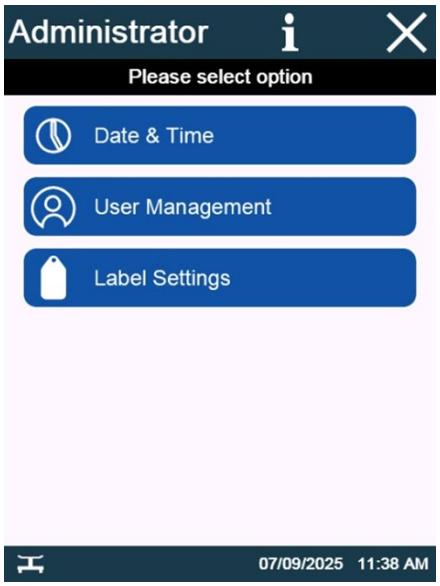
   After successfully logging in, the user is directed to the home screen.

   Note: The preset Administrator account does not appear in the User Management and should no longer be used at this point. It is strongly recommended to immediately make a personal Administrator account.

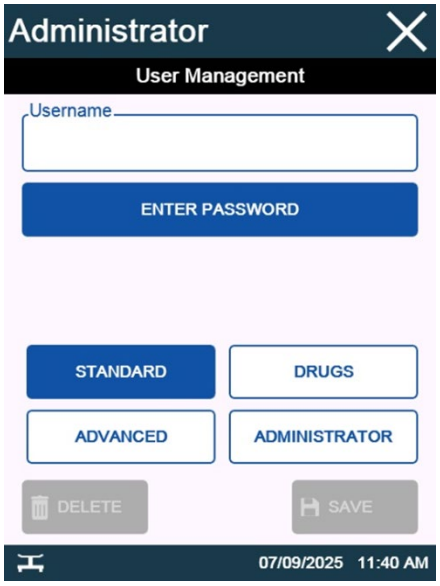
3. To create a personal Administrator account, navigate to the Settings menu.



4. Select Administrator to open the Administrator Settings.
5. Select User Management.



6. Select Add User and fill out the fields for Username and Password.

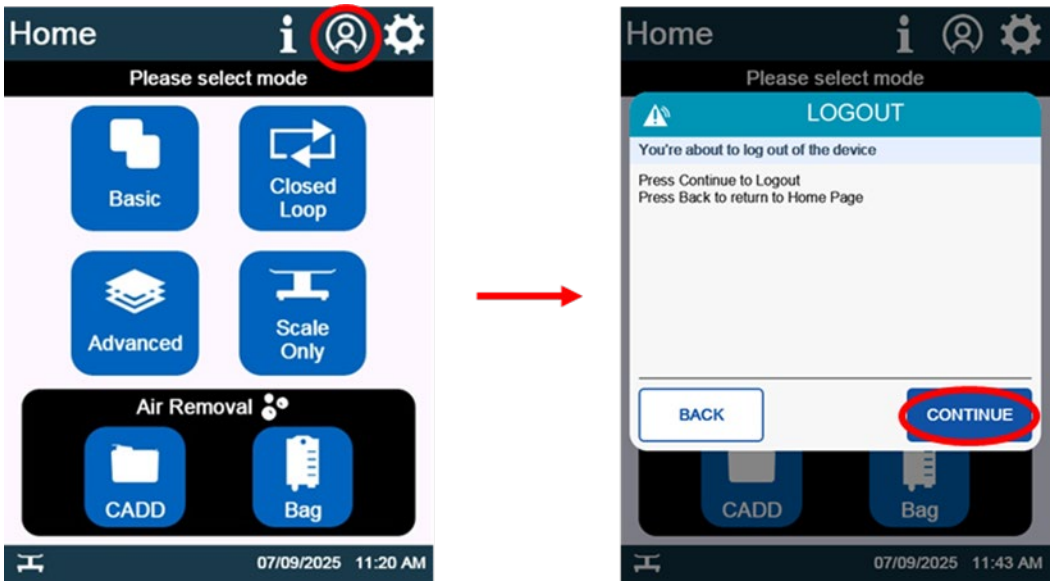


7. Select and enable each role (General, Drugs, Advanced, Administrator) to have access to all settings.
8. Select Save to add the new Administrator account.
9. Add all additional User Account using the User Management Settings. Select only the necessary roles required for each user. See User Management for details on each role.

   Recommendation: Each user should create an individual account, rather than a group account, to better track preparations.

10. Tap X and navigate back to the Home screen.

11. To Logout of a predefined account, select the User icon and press Continue on the Logout message.



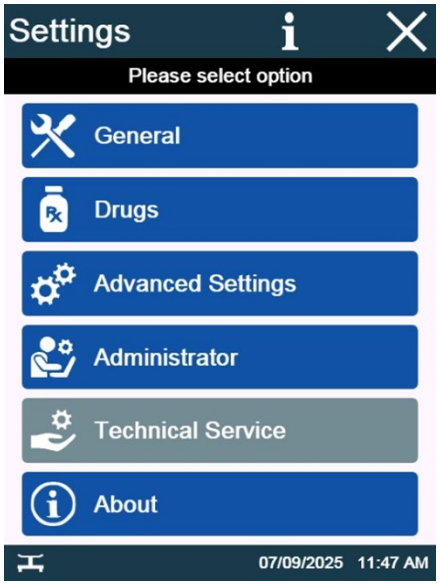
12. On the Login screen, enter the Username and Password for one of the newly created accounts using the on-screen keyboard. Tap LOGIN to sign into the device.

    Note: If the Username or Password field is missing information, it is highlighted in red.

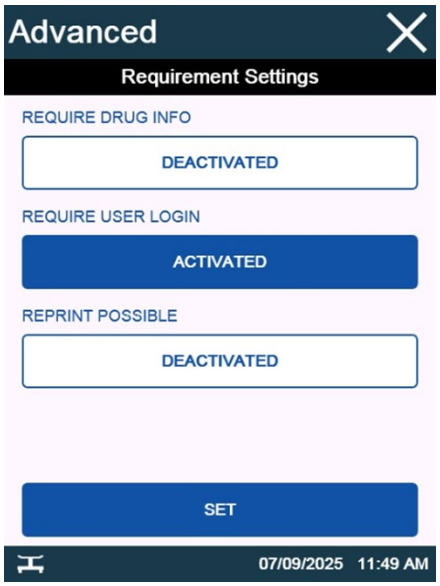
    Recommendation: Upon first power up, 'Require User Login' at startup defaults to Deactivated. It is recommended that an Administrator enables 'Require User Login' at startup using Advanced settings.

To require user login at startup:

1. Ensure the user currently logged in has Advanced role privileges.
2. Navigate to the main Settings menu.



3. Select Advanced Settings.
4. Select Requirement Settings.
5. Under Require User Login, select the Deactivated button so that it changes to Activated and is highlighted in blue.



6. Select SET to save the setting.

Tubing Set Installation / Removal

The following section describes how to properly install and remove the tubing set into the pump unit.

Important: DO NOT use tubing set if the sterile packaging has signs of damage. If the tubing set's sterile packaging is damaged, replace the set with a new one and discard the damaged set.

WARNING: THE TUBING SET SHOULD BE CHANGED WITHIN 24-HOURS DUE TO TOUCH CONTAMINATION.

WARNING: DO NOT RE-STERILIZE OR REUSE THE TUBING SET. RE-STERILIZING OR REUSING MAY CAUSE DAMAGE TO THE TUBING.

WARNING: CHANGE THE TUBING SET PRIOR TO EACH CHANGE OF MEDICATION OR IV FLUID TO AVOID DRUG INCOMPATIBILITY AND/OR TRANSFERRING THE INCORRECT VOLUME.

WARNING: DO NOT REMOVE THE PROTECTIVE CAPS FROM EITHER END OF THE TUBING SET.

CAUTION: DO NOT USE THE SAME TUBING SET FOR MORE THAN 60 LITERS. OVERUSE MAY RESULT IN DAMAGE TO THE TUBING SET AND SPILL OF THE LIQUID.

CAUTION: INCORRECT INSERTION OF THE TUBING SET MAY DAMAGE THE PUMP UNIT.

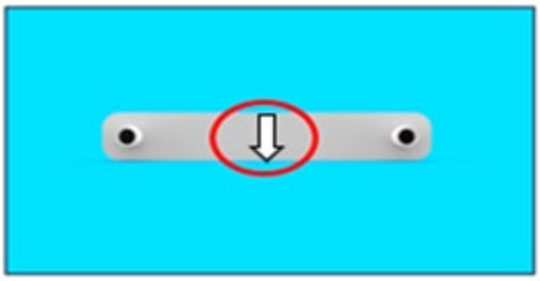
Important: Use an aseptic technique to open the package and remove the tubing set.

Important: For the system to properly register a new tubing set is installed, the pump must be powered on when inserting the new set.

Tubing Set Installation

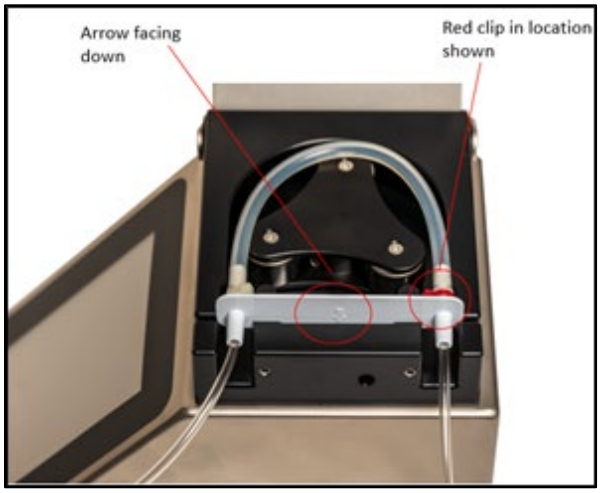
1. Place the pump unit with the display view facing the user.

2. Open the tubing's sterile package using sterile technique, and inspect the set for any damage prior to continuing.
3. Locate the embossed arrow pointing downwards on the handle of the tubing set.

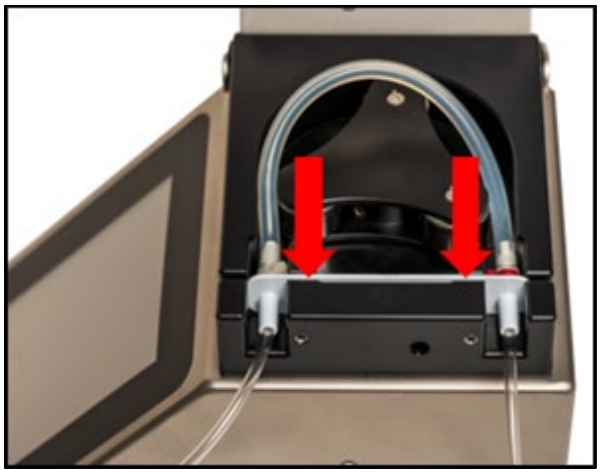


4. Insert the handle into the slot in the roller head as shown in picture below, ensuring that the embossed arrow is still pointing downward.

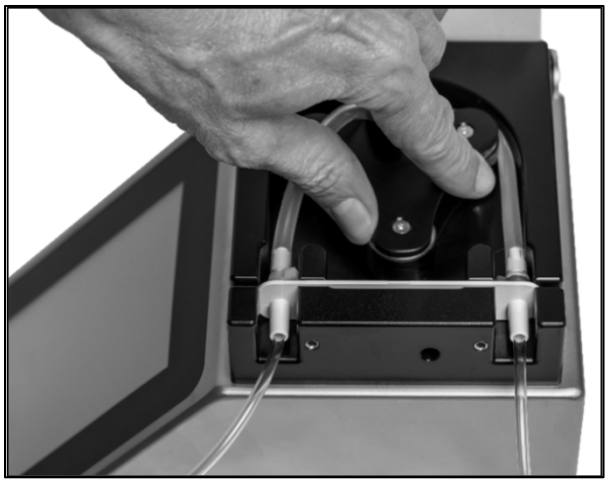
5. Align the white handle of the tubing set as shown below.



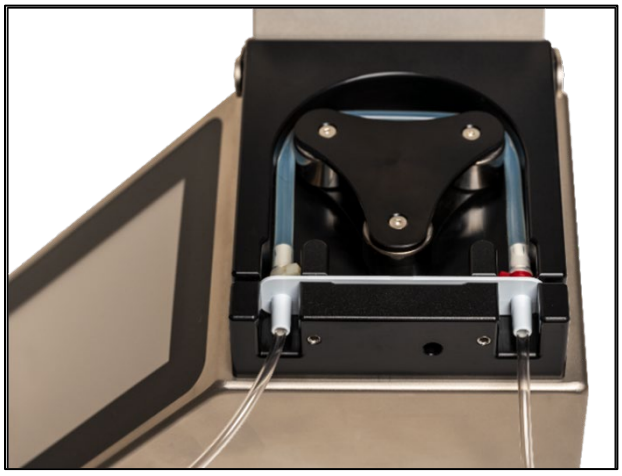
6. Press down the white handle until fully engaged into the pump unit.



7. Engage a roller onto the tubing and then continue turning the roller head until the tubing set is secure around the perimeter of all the roller heads.



8. Installation is complete when the tubing is positioned between the roller head and surrounding pump unit wall.



9. Ensure there is no kinking of the tubing set and that the roller clamp is not engaged.

Tubing Set Removal

Note: When removing the tubing set, it is recommended to engage the roller clamp to prevent spillage.

When ready to remove the tubing set:

1. Lift upward on the white handle of the tubing set to remove it from the pump unit.
2. While turning the rollers by hand, pull up on the white handle to disengage the tubing.
3. Remove the tubing set from the pump unit roller.

Tubing Preparation – Recommended for Heavy Duty Tubing

When using heavy duty tubing (BX01, BX01LL, BX02, or BX03) with the PharmAssist Pro, it is recommended to prepare the tubing set before fluid priming to assist in normalizing tubing set performance prior to pump calibration or fluid transfer.

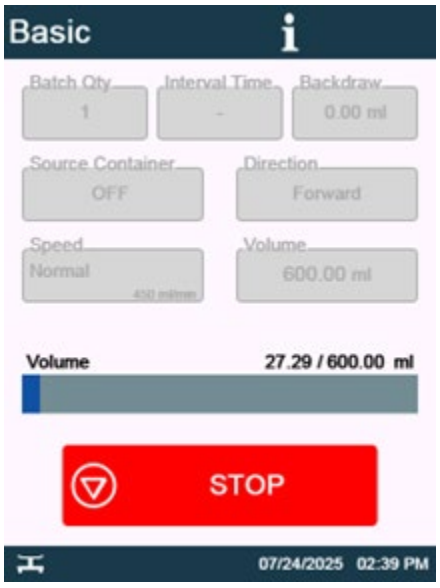
To Install the tubing set, see Tubing Set Installation for a description of how to install a new tubing set.

WARNING: DO NOT REMOVE THE PROTECTIVE CAPS FROM EITHER END OF THE TUBING SET.

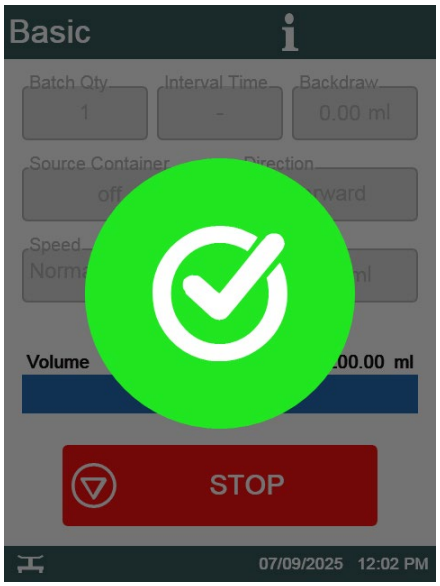
Note: Failure to perform these steps could cause the roller head to not turn and could contribute to inaccuracy during fluid transfers.

1. Close the lid.
2. On the Home screen, enter Basic mode.

3. Enter 600mL into the Volume field. Leave all other entry fields as their default values.
4. Without connecting the input container, start Tubing Preparation by pressing START.



5. The white checkmark in the green circle indicates the process is complete.



Entering Compound Details

The Compound Details screen provides the System with details about the drug. On this screen, the user enters Drug Information that the system uses to track. The following modes support entry of compound details: CADD, Bag Air Removal, Advanced, or Closed Loop.

Notes on Drug Database:

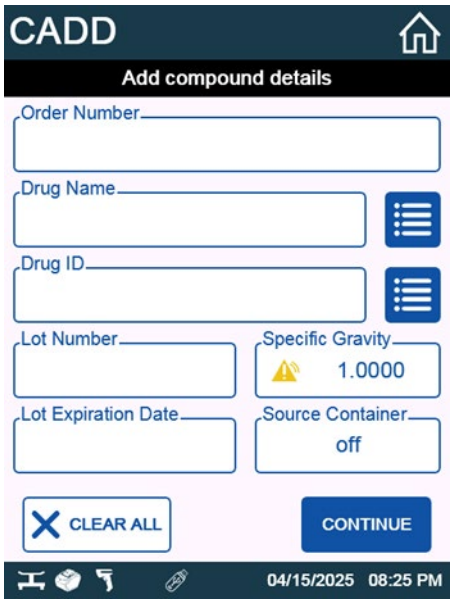
- The System includes a pre-loaded default drug list, the drugs listed are a sub-set of the full FDA drug database. The System drug list includes only drug name and NDC code from the FDA drug database.
- The System default drug list was chosen based on selecting drugs that match the intended use of the System. If a drug is not in the database provided, it can be added using the "Add Drug" functionality. See Add Drug for details on how to use the “Add Drug” feature.
- Follow manufacturer and facility protocols for any drug added to the database.
- Default drug list is not translated when System language is changed from English (drug names remain in English).

Compound Details Entry Fields:

- Order Number
- Drug Name
- Drug ID
- Lot Number
- Lot Expiration Date
- Specific Gravity
- Source Container

When the user enters the Drug Information, the system records the drug used for compounding in the system logs. The user also needs to decide if they want the system to track Source Container. This section describes how to set the system to track Drug Information and Source Container.

Note: If Require Drug Info is not enabled, the user has the option to transfer without entering drug information by tapping CONTINUE on the Compound Details screen to skip drug entry.

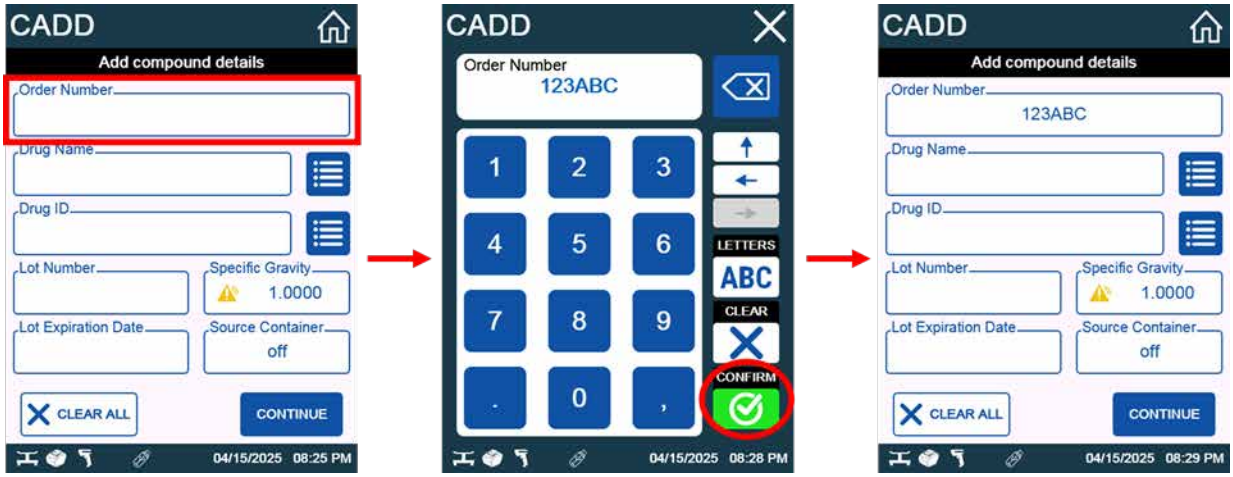


See Basic Transfer Mode to compound without the system keeping track of Drug Information.

Order Number

To enter the Order Number:

- Select the Order Number field.
- Start typing the Order Number using the on-screen keyboard.
- Press CONFIRM to proceed.



Drug Name and Drug ID

Each Drug Name has an associated Drug ID. There are three ways to enter the Drug Name and the Drug ID: enter the Drug Name field, enter the Drug ID field, or select the drug from the Quick Feature list.

Note: The drug must exist in the database.

Option 1 – Enter the Drug Name:

- Select the Drug Name field.

- Start typing the name of the drug. Press the **List** button to view the options for drugs in the database that match the entry.
- Select the drug and press CONFIRM. The Drug Name and corresponding Drug ID are filled in.

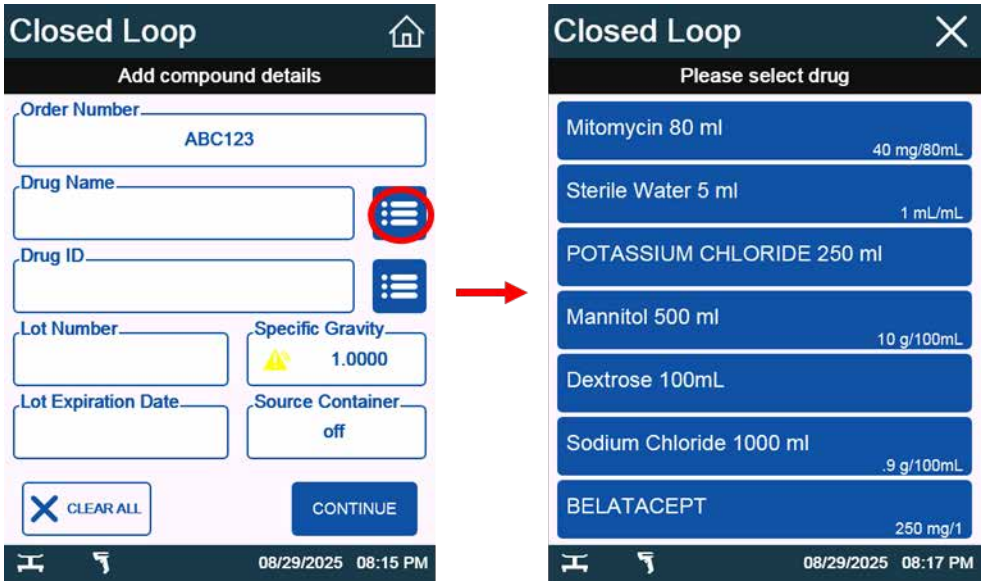
Option 2 – Enter the Drug ID:

- Select the Drug ID field.
- Start typing the ID for the drug. Press the **List** button to view the options for Drug IDs in the database that match the entry.
- Select the ID and press CONFIRM.

The Drug Name and corresponding Drug ID are filled in.

Option 3 – Select Preset:

- The circled icons represent a preset list of Drug Name and Drug ID's that capture the last seven drugs that were recently used. Tapping one of the blue entries will fill in its corresponding Drug Name and Drug ID.



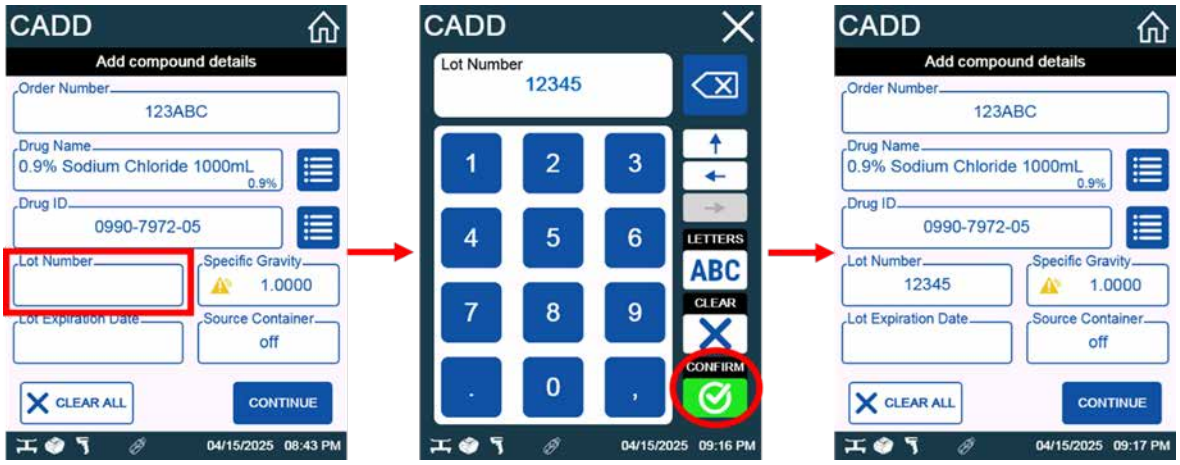
Note: If 'Require Drug Info' is Activated under Advanced settings, then it is required that a Drug Name and Drug ID must be entered to proceed. To change the drug information after completing a transfer, the user must replace the tubing with a new set. If the user changes the drug information on the Compound Details screen without changing the tubing set, the Drug Warning message appears. The tubing set must be replaced with a new set to proceed.

Lot Number

To enter the Lot Number:

1. Select the Lot Number field.

2. Enter the lot number from the input container in the Lot Number field and tab CONFIRM.



Lot Expiration Date

To enter the Lot Expiration Date:

1. Select the **Lot Expiration Date** field.
2. Select the **Lot Expiration Date** using the buttons to enter the Month and Year. Tab CONTINUE to proceed.

Specific Gravity

WARNING: SPECIFIC GRAVITY IS SET BY DEFAULT TO 1.0 FOR ALL DRUGS IN THE PRE-LOADED DRUG LIST. THIS DEFAULT SPECIFIC GRAVITY VALUE DOES NOT REPRESENT ACTUAL DRUG SPECIFIC GRAVITY AND MUST BE UPDATED BY THE USER BEFORE THE SPECIFIC GRAVITY CAN BE USED TO ACCURATELY CORRELATE WEIGHT AND VOLUME FOR EACH DRUG. REVIEW THIS SECTION FOR DETAILS ABOUT HOW DEFAULT VERSUS USER ENTERED SPECIFIC GRAVITY VALUES ARE REPRESENTED WITHIN THE SYSTEM. THIS SECTION REVIEWS DETAILS ABOUT HOW TO UPDATE THE DEFAULT SPECIFIC GRAVITY VALUES FOR DRUGS.

The specific gravity of a drug can be changed on the Compound Details screen if a user has been granted permission by an authorized user in Advanced Settings.

A blue square with a yellow triangle containing an exclamation mark (Figure 19) appears indicating the current value is the default and the user can change the specific gravity to a different value.

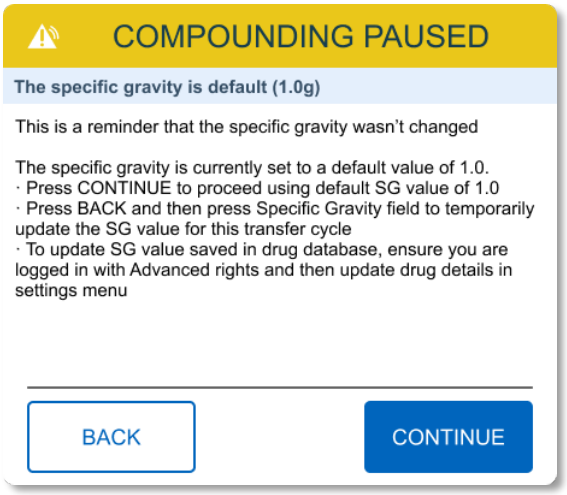
Figure 19: Changing the Specific Gravity

Important: A yellow warning triangle appears next to the Specific Gravity field for all drugs that have default values and must be updated to accurately represent the given fluid properties. The yellow warning triangle disappears after Specific Gravity has been updated by the user.

To change the Specific Gravity:

1. Press the Specific Gravity field.
2. Enter the desired Specific Gravity using the keypad, press the CONFIRM button to save the new value.
   The orange warning triangle becomes blue once the Specific Gravity has been updated.
3. Press the 'X' icon to cancel and the Specific Gravity is not saved.

Note: If the user does not update the Specific Gravity on the Compound Details screen, a warning message appears to verify that the default Specific Gravity is accurate.



4. Press CONTINUE to proceed with the default value (Specific gravity 1.0 g).
5. Press BACK to return to the Compound Details screen.

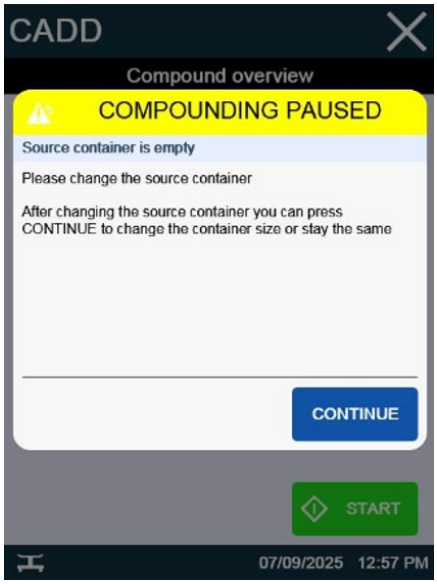
Source Container

The default value for Source Container is "off". This indicates that the user wants to monitor the Source Container volume independently. If the Source Container field is set to "off." the system does not track the Source Container volume and does not warn the user when the Source Container is empty. When the Source Container volume is entered on the Compound Details screen, the system tracks the volume removed from the Source Container (including priming, calibration, and transfer steps).

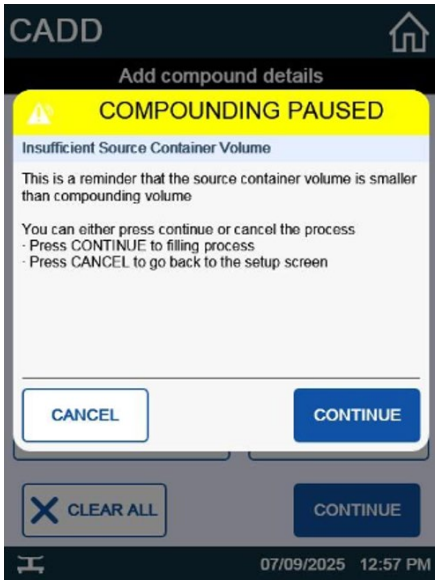
To enter a Source Container Volume:

1. Select the Source Container field.
2. Enter a value for Source Container Volume. The system tracks how much fluid has been removed from the Source Container and informs the user when it becomes empty. Then, the system asks for information about the replacement Source Container once it is empty. Enter the source volume in the Source Container field and press CONFIRM.

When the System predicts that the Source Container is empty, it displays the following warning message:



When the Source Container value is smaller than the transfer volume, the system displays the following message:



Accept Drug Information

1. Tap CONTINUE to proceed.

WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

Note: If Require Drug Info setting is enabled under Advanced Settings, then the user must enter a Drug Name, Drug proceed. The CONTINUE button is only available if the required fields are filled out.

Note: If Require Drug Info setting is NOT enabled, the user has the option to transfer without entering drug information. To do so, tab CONTINUE on the Compound Details screen to skip drug entry.

Tubing Connections

Prior to performing Priming, Calibration, and Fluid Transfer, the tubing must be connected to the appropriate input and output containers. Compatible tubing sets come in options with 1, 2, and 3 source leads (each equipped with roller clamps). When connecting source containers:

1. Install the tubing set (see Tubing Set Installation).
2. Spike and hang source containers.
3. Once all source leads are connected to source containers, open all source lead clamps.

   Note: If using a bifurcated or trifurcated set with fewer than the maximum number of source containers, unused leads must still be primed to avoid introducing air intermittently during use. Open only the clamp(s) on connected source lead(s). Prime unused source leads one at a time by raising the spike above the level of fluid in the source containers, opening the clamp, allowing fluid to fill the tubing up to the clamp (clamp can be moved down to reduce priming volume of unused source lead) then closing the clamp.

Priming

Priming means to fill the tubing set with fluid. Fluid is pumped from the input container into the tubing until it is filled with fluid and no air remains. Priming is typically performed into a disposable container that will be used for priming and calibration and then destroyed.

See the Circle Priming section of this document for a description of when it might be useful to do a technique called “Circle Priming” and how to do it.

Note: If it is necessary to calibrate the pump unit, ensure the tubing set is properly primed following these instructions. Failure to do so may result in an incorrect transfer of liquid volumes.

To prime in Basic Mode:

See Basic Transfer Mode for details on priming the tubing in Basic mode.

To prime in Advanced, CADD, or Closed Loop Mode:

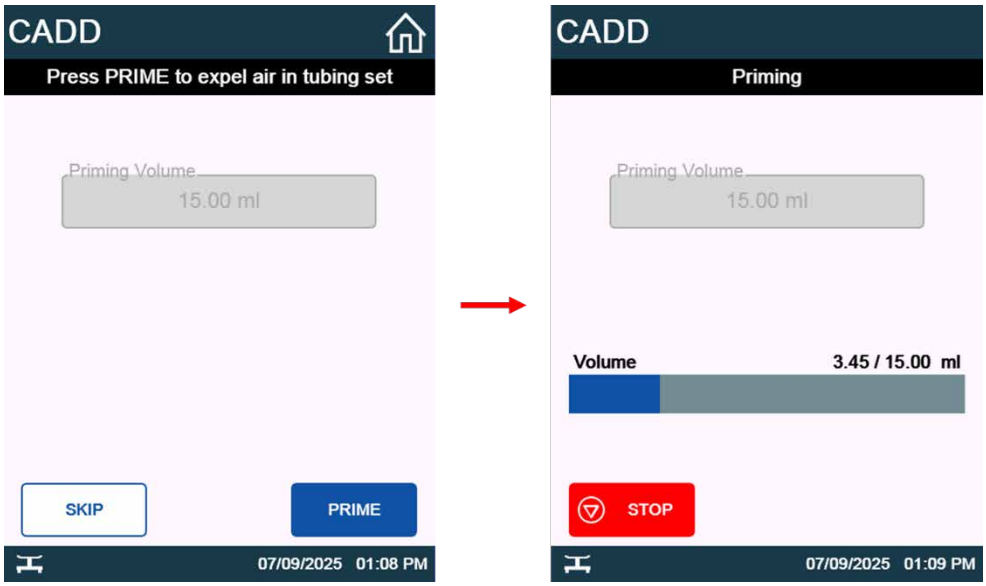
1. If not already connected, connect the input (proximal) end of the tubing set to a source container. If a multi-lead tubing set is used, connect each of the input (proximal) ends of the tubing set to a source container.

   Note: For Circle Priming, see the Circle Priming section of this document.
2. If not already connected, connect the output (receiving) end of the tubing set to a disposable container.
3. Navigate to Advanced, CADD, or Closed Loop mode and follow the instructions to access the Priming screen.
4. Press Prime and the pump unit automatically starts to prime the tubing set.

   Note: For Advanced and Closed Loop mode, the default priming volume is 27mL for standard length tubing sets. For CADD mode, the default priming volume is 15mL for short length tubing sets. Reference the tubing set packaging to find the specific priming volume that corresponds to the tubing set.

   Note: Reference section Priming Settings for details on changing the priming volume.
5. Visually confirm that priming was successful, then disconnect the disposable container from the tubing set.

   Note: Follow facility protocols for the disposal of fluids used for calibration and priming.



If SKIP is selected, the tubing set is not primed, and the System proceeds to the next screen.

If STOP is selected during priming, the fluid transfer pauses. The user then has the option to resume priming or press X to exit the priming screen.

Note: Priming is always required for new tubing sets prior to proceeding to calibration or transfer.

Circle Priming

When using the Circle Priming process, air primed out of the tubing and any excess liquid is transferred back to the source container. This provides the following advantages: conserves excess drug used during normal priming, prevents the drug used for priming from air contact, and eliminates the need for a disposable container.

Note: If it is necessary to calibrate the pump unit, ensure the tubing set is properly primed following these instructions. Failure to do so, may result in an incorrect transfer of liquid volumes.

To Circle Prime:

1. Connect the input end of the tubing set to a source container.

   Note: If a multi-lead tubing set is used, connect each of the input ends of the tubing set to each individual source container.

2. Connect the output end of the tubing set to a separate port on the source container.

   Note: If a multi-lead tubing set is used, make sure that the source container connected to the output end of the tubing has sufficient capacity to safely receive the full priming volume.

3. Press Prime and the pump unit automatically starts to prime the tubing set.

   Note: There may be a few seconds delay between pressing “Prime” and the pump unit starting.

4. Visually confirm that priming was successful, then disconnect the output (receiving) end of the tubing set from the source container.

Calibration

The System allows a user to choose the drug and volume with which to calibrate the System in Advanced Mode. The drug can be selected in the Compound Details screen. It is recommended to calibrate the pump unit after changing the drug, tubing set, transfer volume, or destination container. Because the tubing set should be replaced when a new drug is to be compounded, it should be calibrated with the drug the user intends to transfer.

WARNING: CALIBRATION SHOULD ALWAYS BE PERFORMED WITH THE DRUG OR IV FLUID INTENDED TO TRANSFER BECAUSE THE TUBING SET SHOULD BE CHANGED PRIOR TO EACH CHANGE OF LIQUID.

WARNING: WHEN USING ADVANCED MODE OR BASIC TRANSFER MODE, CALIBRATION MAY NEED TO BE PERFORMED WHEN THERE IS A CHANGE IN PUMP UNIT SPEED, USE OF NEEDLES, USE OF IN-LINE FILTERS, FILLING CONTAINERS THAT CREATE BACK PRESSURE.

WARNING: WHEN USING ADVANCED MODE OR BASIC TRANSFER MODE, CALIBRATE THE PUMP UNIT EACH TIME THE TUBING SET IS CHANGED. ONLY THE INTENDED DIRECTION NEEDS TO BE CALIBRATED. CALIBRATE AGAIN IF DIRECTION IS CHANGED. EITHER DIRECTION CAN BE RECALIBRATED AS OFTEN AS DESIRED.

CAUTION: DO NOT USE THE GRAVIMETRIC CALIBRATION PROCESS UNLESS YOU ARE CERTAIN THAT THE FLUID'S SPECIFIC GRAVITY HAS BEEN ENTERED ACCURATELY.

Note: Calibration is not necessary when using the system with the Connected Scale in Closed-Loop Mode or Air Removal Modes. The three calibration methods referenced below are only used in Advanced Transfer Mode.

Note: See ADJUST Calibration for details on calibrating in Basic Mode.

Note: For highest accuracy, calibration should be performed using a container similar to the one intended for transfer and at a volume similar to the intended transfer volume.

Calibration is typically performed into the same disposable container that was used for priming, then the container should be destroyed.

Note: If circle priming is performed, a separate disposable container should be used for calibration then destroyed. See Circle Priming for a description of how to perform Circle Priming.

Calibration is only available via the Advanced Transfer Mode. There are three ways that calibration can be performed in Advanced Transfer Mode:

- Volumetric Mode
- Gravimetric Mode with External Scale
- Gravimetric Mode with Connected Scale

See Advanced Transfer Mode for complete details on calibration and transferring using each method.

Note: It is important to determine which method the facility will use for calibration and carefully read and follow the directions and guidance below for the method that you choose.

Warnings During Calibration

The following warning is displayed during gravimetric and volumetric calibration if the difference between the expected and measured weight/volume is higher than expected.

The warning message of "The deviation exceeds acceptable limits" (Figure 20) is displayed when the discrepancy between the expected and the measured weight is large enough to suggest something went wrong with the calibration.

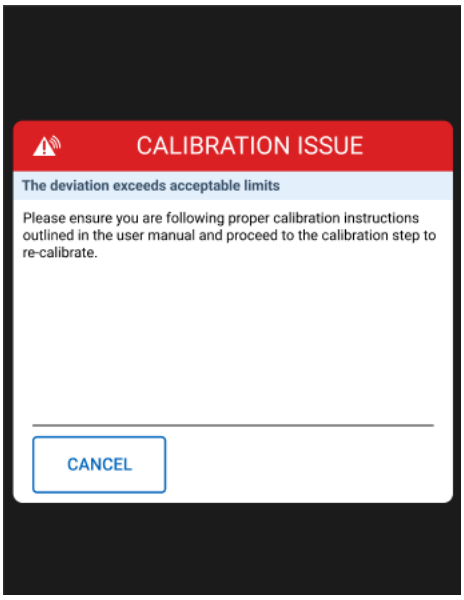


Figure 20: The Deviation Exceeds Acceptable Limits

Press CANCEL on the warning message to return to the previous screen. Then press BACK on the to return to the calibration screen. Repeat the calibration processes to ensure the accuracy of the pump unit.

Recalibration

If the Measured Weight or Volume entered is not compliant with facility's guidelines, a recalibration may be performed, and the calibration transfer process repeated. Press the BACK button to go through the calibration process again.

Note: By Pressing BACK, the pump unit calibration is not updated based on the previous transfer and the System allows the user to repeat the calibration steps again.

Batch Compounding

The Batch feature can be used for compounding multiple destination containers/doses. The user can confirm the transfer accuracy using their own equipment and methods. When specifying the Batch details, the user fills in the number of containers and the Interval Time between transfers.

Table 9: Batch Quantity and Interval Time

Option	Description
Batch Quantity	The number of destination containers that the user wants to fill. To enter a Batch Quantity: 1. Tap the Batch Quantity field and enter the number of containers using the on-screen keypad. 2. The maximum value that can be entered is 999.
Interval Time	This number specifies the time (in seconds) the System waits after completing the current transfer before initiating the next transfer. Interval time can have values from 1 to 99 seconds or 'm' for a manual interval time. When the interval is set to Manual, the pump stops after each transfer and the user must press START to proceed with the next transfer in the batch. See details below this table on how to select "Manual" for Interval Time.

Select Manual for Interval Time:

1. Select the Interval Time field, on the keypad screen select "m" and press CONFIRM.

Power Off

When the user is done with compounding processes, the pump unit can be turned off. Press the Power button on the front of the pump unit to turn it off (Figure 21).

Figure 21: Power Off

PharmAssist Pro Compounding Workflow

Overview

Before operating the system, the components must be installed, and the settings configured. For details regarding installation, see PharmAssist Pro System Overview. General Operation Details provides detailed descriptions of Powering On, Tubing Set Installation, Entering Compound Details, Priming, and Calibration. Settings describes how the System settings can be customized to the procedures and policies of the user's clean room and organization.

Figure 22 provides an overview of the System's different modes that can be selected:

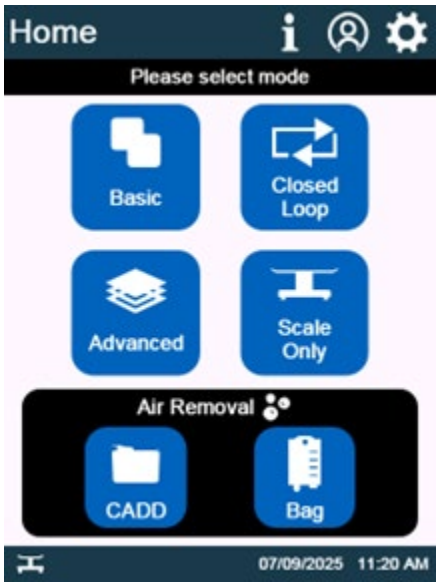


Figure 22: PharmAssist Pro Home Screen

Once a tubing set is installed or replaced, the user can complete multiple fluid transfers, until it is necessary to change the tubing set of the drug. Understanding these workflows reduce the chance of errors during usage of the system. The rest of this chapter provides more detail about the PharmAssist Pro System workflows, what options are available, and why you might choose certain options.

Basic Transfer Mode

Basic Transfer Mode is designed for users who prefer a simple interface with focused on time-efficiency and accuracy. This mode has a simplified workflow that displays a single transfer screen to most efficiently transfer fluid. Basic Transfer Mode allows you to enter data into the fields listed in Table 10. This workflow is designed to mimic the functionality of previous generation peristaltic pumps.

Basic Mode Features and Functions

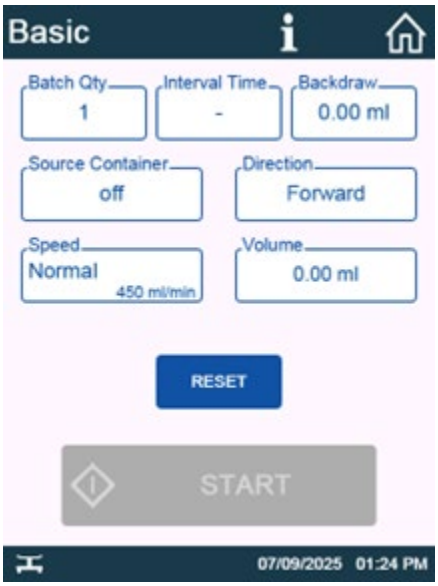
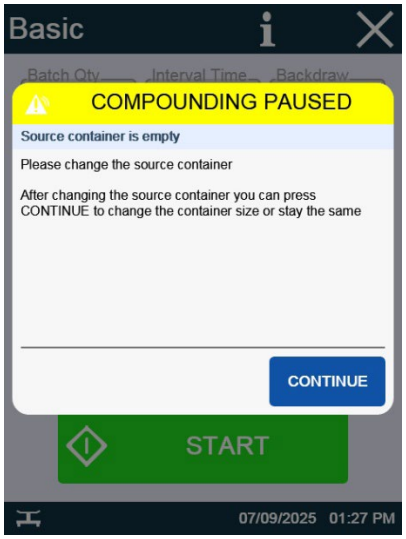
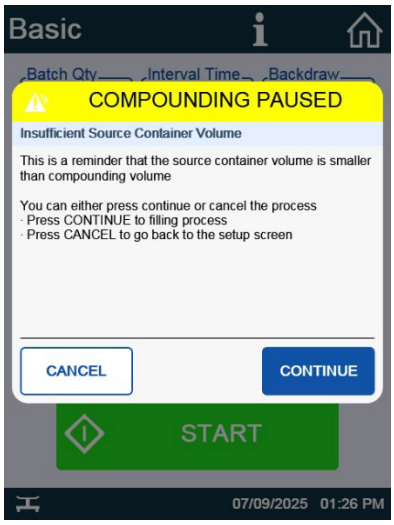


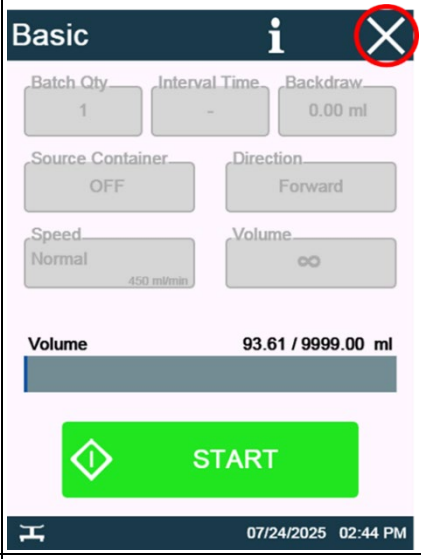
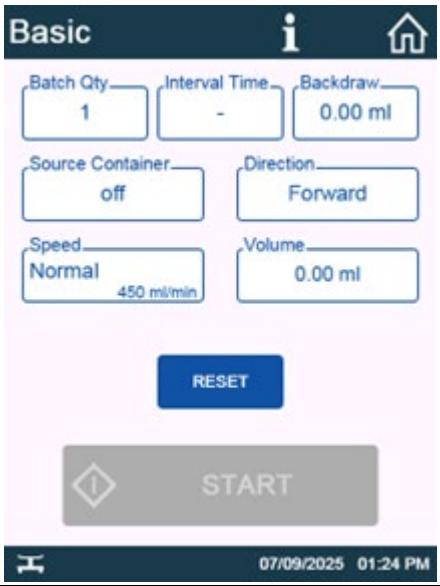
Figure 23: Basic Mode

Table 10: Basic Mode Features and Functions

Field	Description
Batch Quantity	The number of destination containers that the user wants to fill. The maximum value that can be entered is 999.
Interval Time	This number specifies the time (in seconds) the System waits after completing the current transfer before initiating the next transfer. Interval time can have values from 1 to 99 seconds or 'm' for a manual interval time. When the interval is set to Manual, the pump stops after each transfer, and the user must press Start to proceed with the next transfer in the batch. To select Manual for Interval Time: 1. Tap the Interval Time field, on the keypad screen select 'm' and press CONFIRM. 

Field	Description
Backdraw	Backdraw reduces line pressure and is designed to minimize excess dripping between transfers. The pump first delivers the specified transfer volume. Then, if a backdraw volume is entered, the rotor reverses to pull fluid from the inlet back through the tubing set. Backdraw can have values ranging from 0.01 to 5.00 mL.
Source Container	The **Source Container** default is “off”. If a Source Volume (mL) is entered into the **Source Container** field, the system tracks the volume removed from the Source Container (including priming, calibration, and transfer steps). When the System predicts that the Source Container is empty, it displays the following warning message:  When the Source Container value is smaller than the transfer volume, the system displays the following message: 
Direction	The default direction of transfer is forward. Forward directs fluid flow from the spike end to the luer end. Reverse direction pumps fluid from the luer end to the spike end.
Speed	The user can change the speed at which the pump transfers fluid. Tap the Speed field and select a speed from the menu. Use the Up and Down arrows to scroll through the list of speeds. Basic Mode defaults to Normal Speed (450 mL/min). The minimum transfer speed is 50 mL/min and the maximum transfer speed is 700 mL/min.

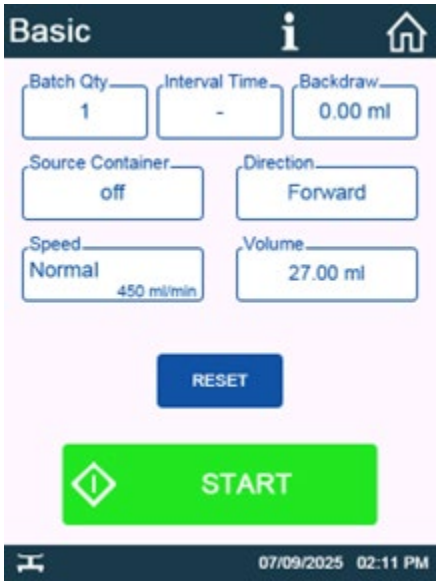
Field	Description
Volume	The Volume field is used to enter the desired volume to be transferred by the pump. Tap the Volume field and enter the desired volume using the keypad. The minimum transfer volume is 0.01 mL. The maximum transfer volume is 9999.99 mL. Infinite Transfer Volume: The user can select the Infinity symbol in the Volume field to trigger a continuous transfer that a user must manually stop. On the keypad, select the Infinity symbol and tap CONFIRM to use this feature.   Press START or tap the foot pedal again to continue compounding.  During the transfer, press STOP or tap the foot pedal to pause compounding. To exit compounding, press STOP to pause the transfer and then press the Exit (X) symbol.

Field	Description
	
RESET button	RESET sets all entry fields back to the default value. The RESET feature cannot be used while a transfer is in progress. 
START button	Pressing START initiates the transfer of fluid.
HOME Icon	Pressing the HOME icon returns the user to the home screen consisting of the following mode options: Basic, Closed Loop, Advanced, Scale Only, CADD, and Bag mode.
EXIT Icon	The white Exit icon ( ) returns the user to the previous screen.

Basic Transfer Workflow

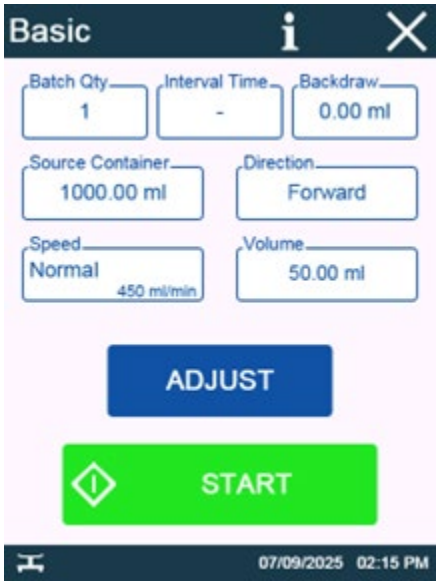
Set Up and Transfer:

1. Ensure a tubing set is installed and primed before starting the transfer. See Tubing Set Installation / Removal and Priming for detailed descriptions.
2. To prime the tubing set, the user needs to complete an initial transfer. Tap the Volume field and use the numeric keypad to enter the priming volume. Reference the tubing set packaging to use the specific priming volume that corresponds to the tubing set. Otherwise, 27mL is the standard priming volume for all ICU Medical tubing sets.



3. Press START to prime the tubing set. Once the transfer is complete, verify the tubing set is free of air and large bubbles.
4. Priming is now complete, and the system is ready for fluid transfer. Enter all transfer details into the Basic Mode entry fields (see Table 10).

Note: To clear the entry fields, tap the Exit (X) button and follow the prompt.



WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

5. After confirming that the entered information is accurate, tap the START button to initiate transfer. The pump unit begins liquid transfer, and the progress bar indicates the status of the transfer.

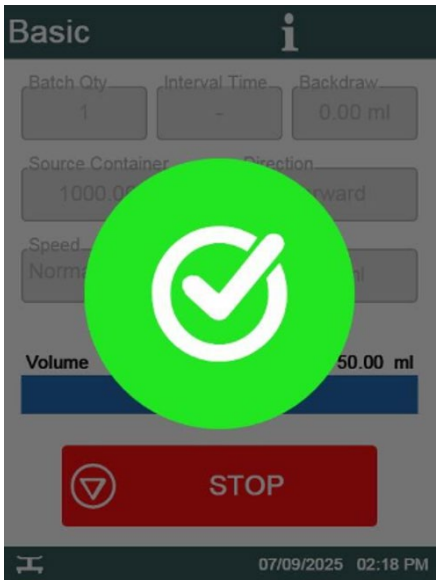
   Note: If the optional Foot Pedal Kit is installed, pressing the Foot Pedal can be used to “Start” a transfer, or “Stop” a transfer in progress.

6. To pause the transfer, tap the red STOP button.

   Note: To cancel the transfer, tap the EXIT (X) icon while the transfer is paused.

7. To resume the transfer again, tap the START button.

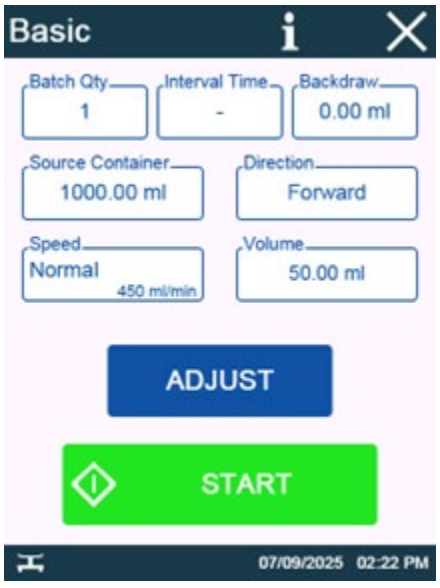
8. Once the transfer is complete, the System displays a green circle with a white checkmark. The System automatically returns to the transfer details screen.



Note: After the transfer is complete, the entry fields remain filled with the values from the completed transfer.

Note: If the transfer has multiple Batches, the Interval Time countdown begins once the system returns to the Set-up screen. Once the Interval Time has elapsed, the pump automatically starts the next transfer. The User can select STOP at any point during the Interval Time countdown to pause the countdown.

9. After each transfer, if the actual measured volume is different from the desired volume, the user can use the completed transfer to calibrate the pump by selecting ADJUST. See ADJUST Calibration below for more details.



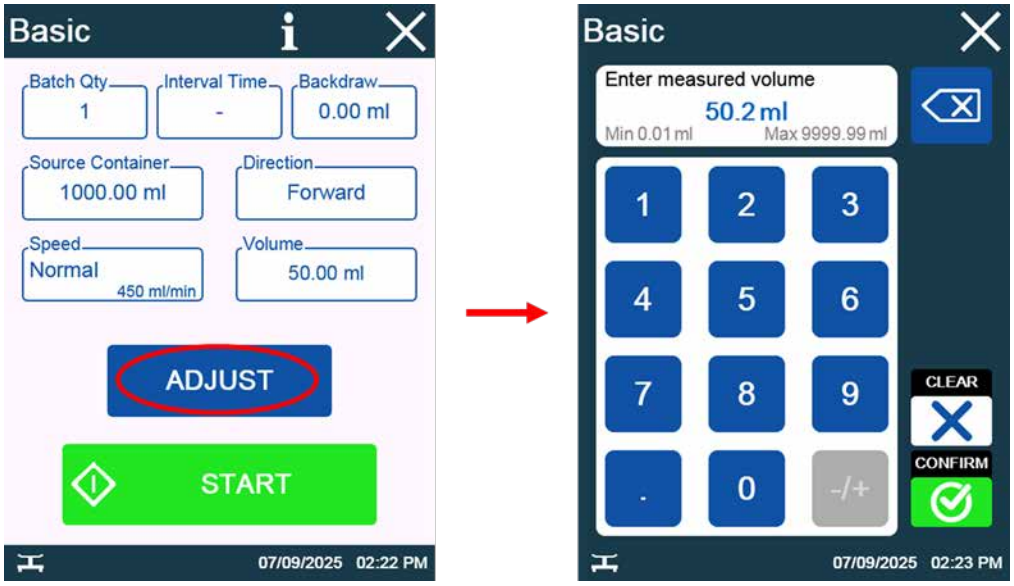
ADJUST Calibration

The ADJUST function is used after a transfer is complete to calibrate the pump when the actual measured volume is different from the desired volume.

To use the completed transfer to calibrate the pump unit:

Note: Do not change the values in the entry fields if intending to use the ADJUST feature. The values in the entry fields must correspond to the completed transfer to accurately calibrate the pump.

1. Tap ADJUST after the transfer is complete to open the keypad.
2. Enter the actual measured volume by using the numeric keys and tap Confirm to continue. Tap Clear to remove the entered value.



The actual measured volume should always be checked with the desired volume. If the actual measured volume differs from the desired volume, ADJUST should be used.

Any change in pumping parameters will necessitate additional use of the ADJUST feature. These parameter changes include, but are not limited to:

- Change in drug,
- Change in pump speed,
- Change of transfer connector (i.e. luer, needle),
- Use of compounding filters,
- Use of containers that create back pressure (i.e. elastomeric pump, vial),
- Substantial change in desired volume,
- Change in transfer direction.

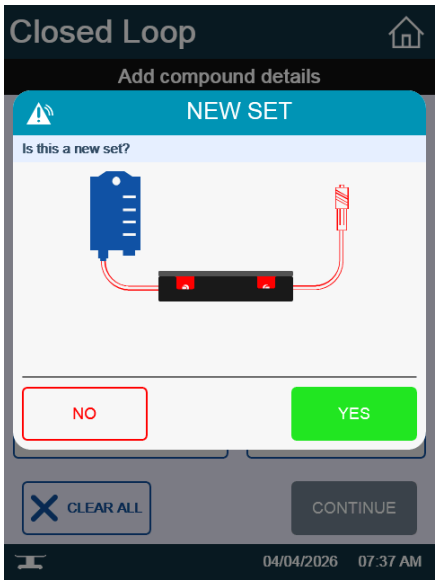
Closed Loop Transfer Mode

Closed Loop Mode utilizes the connected scale to continuously measure the weight of the output container during a transfer. The pump will monitor and adjust the speed of transfer to reach the desired output volume.

Set Up:

1. Select Closed Loop Mode from the Home screen.
2. If not already installed, insert a tubing set into the pump unit and select Yes or No to indicate if a new set has been inserted.

Note: See Tubing Set Installation / Removal for more details.



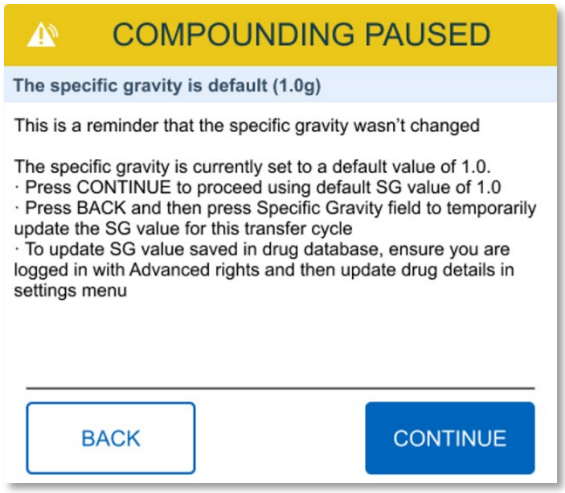
3. On the Compound Details screen, enter all drug details into the entry fields.

   Note: See Entering Compound Details for more information.

4. After confirming that the entered information is accurate, tap CONTINUE.

Note: If Specific Gravity is not changed, a Warning message will appear to verify that the value is correct. Press CONTINUE to proceed with the default Specific Gravity of 1.0. Press BACK to go back and change the specific gravity.

Note: Accuracy performance obtained by the System is directly related to the accuracy of the specific gravity used for the fluid to be transferred.



5. If not already connected, connect the input (proximal) end of the tubing set to a source container. Connect the output (receiving) end of the tubing set to a destination container that will be used for priming the tubing set.
6. Tap PRIME to begin priming the tubing set. Select SKIP if the tubing set has already been primed.

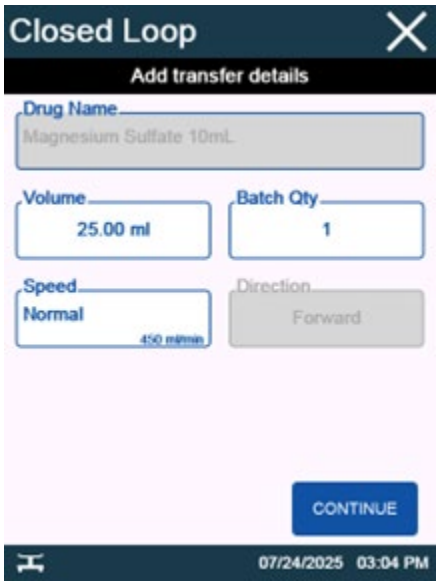
   Note: See Priming for more details. See Priming Settings to change the default priming volume.

7. Once priming is complete, the System displays a green circle with a white checkmark. Tap CONTINUE to proceed or tap RE-PRIME to prime the tubing again if not complete.

Transfer:

1. Connect the output (receiving) end of the tubing set to a destination container intended for compounding.

2. On the Transfer Details screen, enter the desired Volume to be transferred, the quantity of Batches to fill, the Speed for transferring, Tap CONTINUE to proceed.



3. Place the container connected to the tubing onto the scale. Tap CONTINUE to proceed.

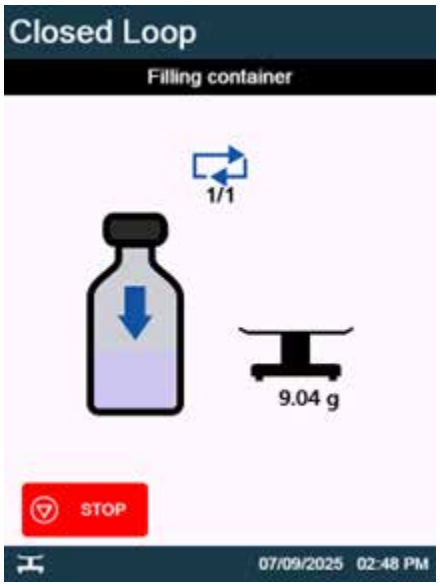
4. After confirming the container is placed on the scale, the system is ready for transfer and will automatically TARE the scale once pressing CONTINUE. The user also has the option to manually zero the scale weight by pressing the TARE button.

⚠ WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

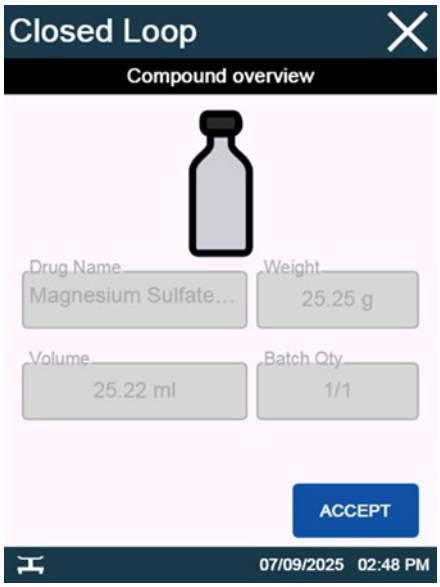
Note: If the entered compound details are not accurate, tap BACK to return to the previous screen.

5. Verify both source container and destination container are connected to the pump and the roller clamp is open.
6. After confirming that the Drug and transfer information is accurate, tap START to initiate transfer. The pump unit will begin transferring fluid and the scale icon will display the corresponding gravimetric weight to indicate the status of the transfer.

Note: The circular arrow indicates which batch the transfer is currently compounding.



7. Once the transfer is complete, the System displays a green circle with a white checkmark. The System will automatically return to the Compound Overview screen.



Note: Review the drug details, weight, volume, and batch quantity and press ACCEPT to finalize the transfer. The user will then be directed to remove the container from the scale.

Note: If there are multiple batches, the user will be directed to place a new container onto the scale after the previous one is removed.

Advanced Transfer Mode

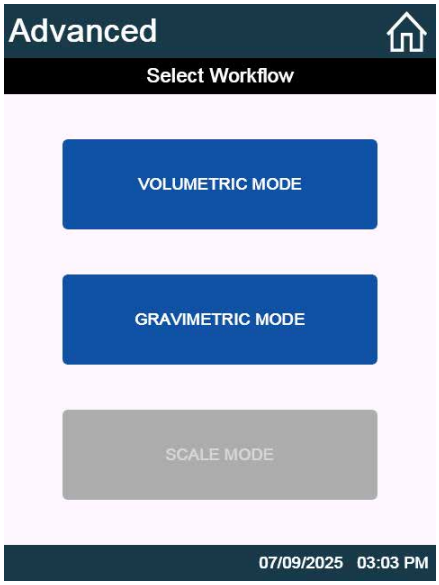
In Advanced Transfer Mode, the System allows a user to choose the drug and volume with which to calibrate the System. The drug can be selected in the Add Compound Details screen. It is recommended to calibrate the pump unit after changing the drug, tubing set, desired volume, or destination container. See Calibration for a detailed description on calibrating the pump unit.

There are three ways that calibration can be performed:

- Volumetric Mode: Volumetric Calibration
- Gravimetric Mode: Gravimetric Mode with External Scale
- Scale Mode: Gravimetric Mode with Connected Scale

Note: It is important to determine which method the facility will use for calibration and carefully read and follow the directions and guidance below for the method that is chosen.

If the Connected Scale Kit is not connected to the pump unit, then only Volumetric Mode and Gravimetric Mode will be available.



Volumetric Mode

When a scale is not available, the System supports volumetric calibration. Volumetric calibration is an option that is selected in Advanced Mode.

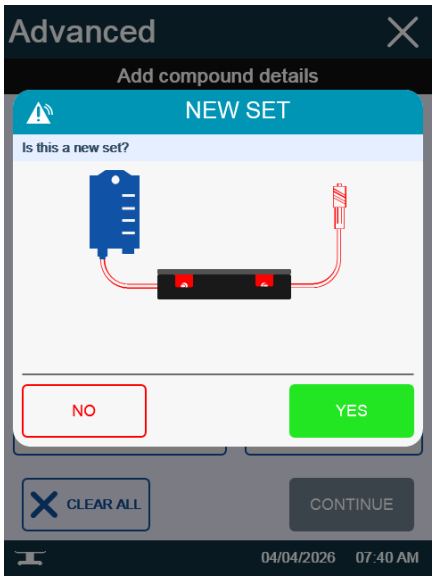
Note: When performing volumetric calibration, the user should use an output container with accurate graduated volume markings (example: syringe or graduated cylinder).

In Volumetric Mode, the System will ask for a volume at the end of the calibration steps.

Set Up:

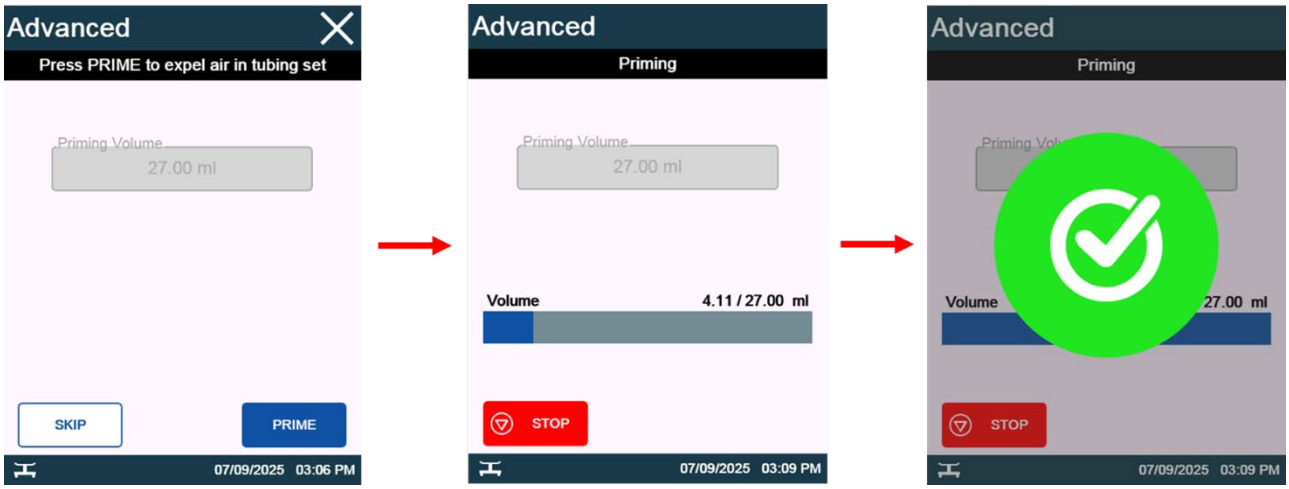
1. Select Advanced Mode from the Home screen.
2. If not already installed, insert a tubing set into the pump unit and select Yes or No to indicate if a new set has been inserted.

Note: See Tubing Set Installation / Removal for more details.



3. On the Select Workflow screen, select Volumetric Mode.
4. If not already connected, connect the input (proximal) end of the tubing set to a source container. Connect the output (receiving) end of the tubing set to a destination container that will be used for priming the tubing set.
5. Tap PRIME to begin priming the tubing set. Select SKIP if the tubing set has already been primed.

Note: See Priming for more details.



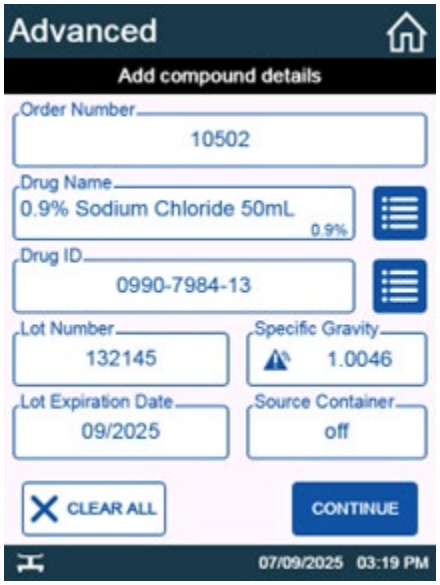
6. Once priming is complete, the System displays a green circle with a white checkmark.

7. Press CONTINUE to proceed or RE-PRIME to prime the tubing again if not complete.

8. On the Compound Details screen, enter all drug details into the entry fields.

   Note: See Entering Compound Details for more information.

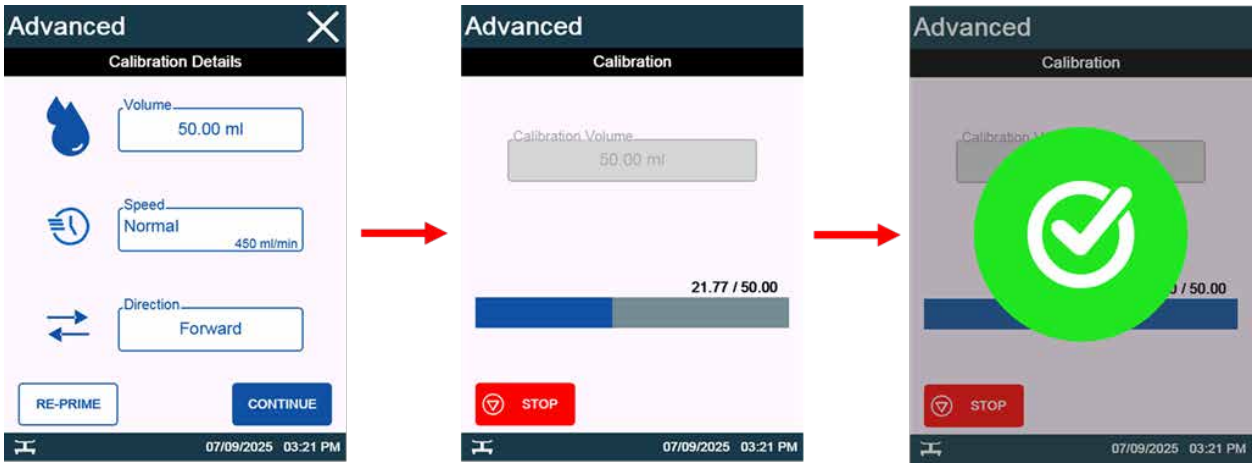
9. After confirming that the entered information is accurate, tap CONTINUE.



Calibration:

1. Connect the output (receiving) end of the tubing set to a destination container (graduated cylinder or syringe) that will be used for volumetric calibration.

2. Enter the Calibration Volume, Speed, and Direction for transfer. Press CONTINUE to initiate the calibration transfer.

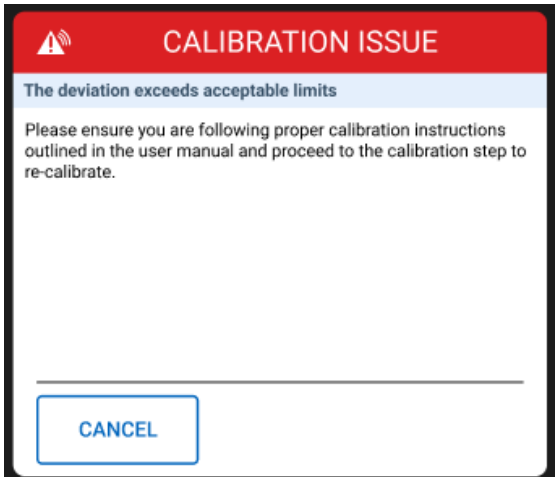


3. Enter volume transferred as indicated on the output container.

4. To use the measured volume to update the pump unit calibration, press ADJUST.

   Note: Pressing ADJUST will update the calibration of the pump unit to account for the over/underfill of the transfer as indicated on the screen (difference between specified volume vs measured volume).

Note: If the measured volume is significantly different than the expected volume, the System will display a warning before allowing the pump unit calibration to be updated. Press CANCEL on the warning message to return to the previous screen. Then press BACK to return to the calibration screen. See the Warning During Calibration for details.

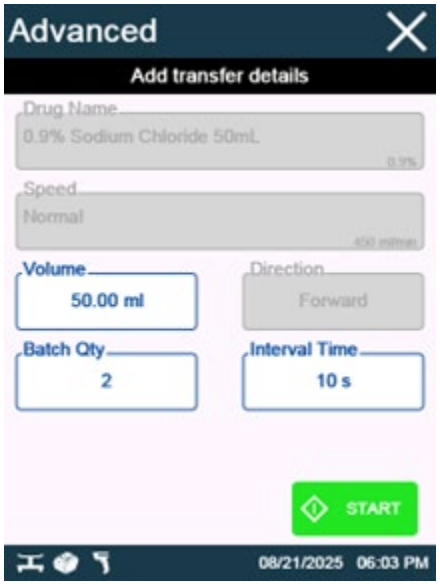


Note: See Recalibration section of this manual for steps to follow if the user does NOT want to use the entered volume to update the pump unit calibration.

Note: Follow facility protocols for the disposal of fluids used for calibration and priming.

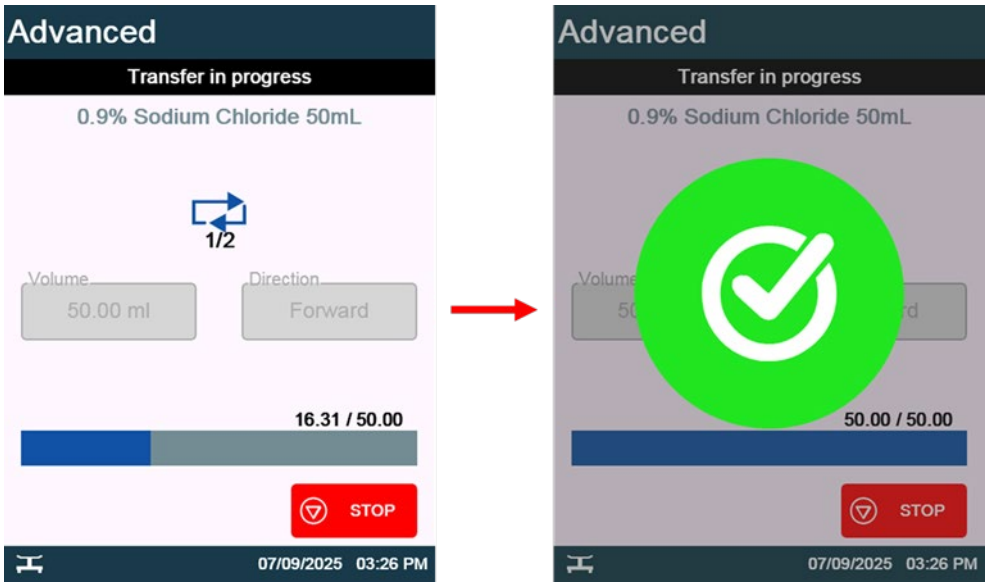
Transfer:

1. Calibration is now complete, and the user is ready to initiate the first transfer. Connect the output (receiving) end of the tubing set to a destination container intended for compounding.
2. On the Transfer Details screen, enter the desired Volume to be transferred, the Batch Quantity to fill, and the Interval Time between each fill.



WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

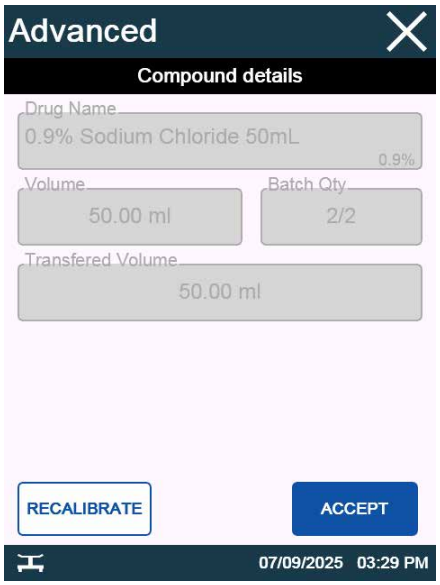
3. After confirming that the entered information is accurate, tap START to initiate transfer.



4. Once the transfer is complete, the System displays a green circle with a white checkmark. The System will automatically return to the Compound Details screen.

Note: If there are multiple Batches, the Interval timer will begin counting down on the Compound Details screen. The next batch transfer will automatically start once the countdown is depleted. To pause the countdown, press STOP.

5. Review the Compound Details screen and press ACCEPT to return to the Compound Details screen to repeat the same transfer. Press CANCEL to change the transfer details.



Note: After accepting a transfer, the user will return to the Compound Details screen to complete another transfer of the same volume. Press CANCEL on the Compound Details screen to change the Volume, Batch Quantity, or Interval Time.

Gravimetric Mode with External Scale

The calibration process of the pump unit can be performed using a separate third-party scale, referred here as an external scale. Accurate specific gravity configuration is essential for gravimetric accuracy.

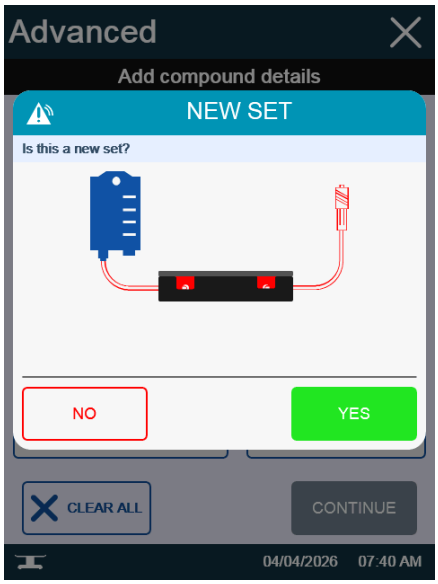
Note: Accuracy performance obtained by the System is directly related to the accuracy of the specific gravity used for the fluid to be transferred.

WARNING: DO NOT USE THE GRAVIMETRIC CALIBRATION PROCESS UNLESS CONFIDENT THAT THE SPECIFIC GRAVITY HAS BEEN ACCURATELY ENTERED FOR THE FLUID BEING TRANSFERRED.

Set up:

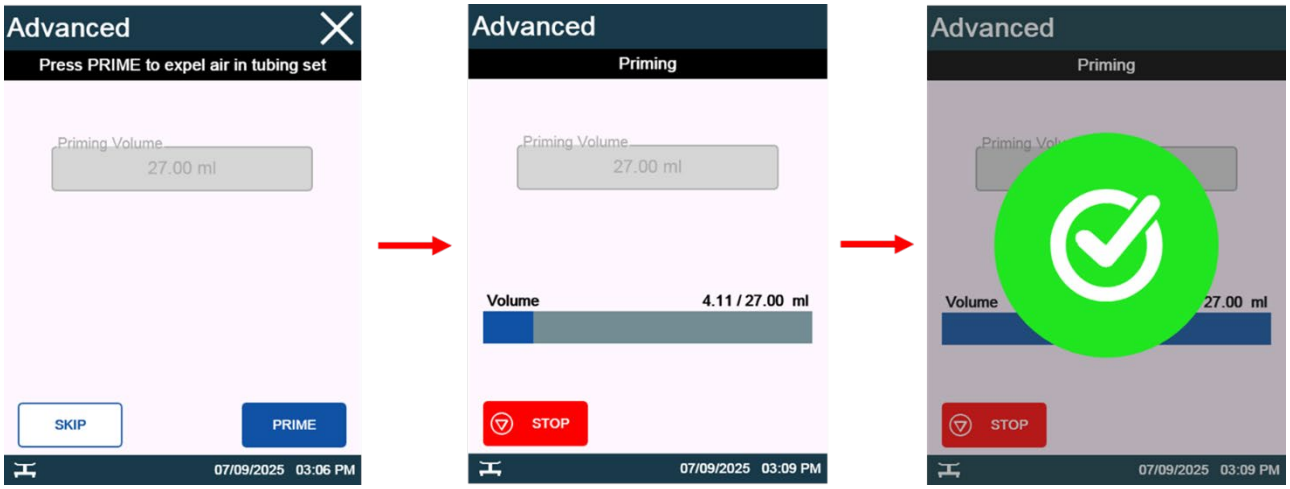
1. Select Advanced Mode from the Home screen.
2. If not already installed, insert a tubing set into the pump unit and select Yes or No to indicate if a new set has been inserted.

Note: See Tubing Set Installation / Removal for more details.



3. On the Select Workflow screen, select Gravimetric Mode.
4. If not already connected, connect the input (proximal) end of the tubing set to a source container. Connect the output (receiving) end of the tubing set to a destination container that will be used for priming the tubing set.
5. Tap PRIME to begin priming the tubing set. Select SKIP if the tubing set has already been primed.

Note: See Priming for more details.



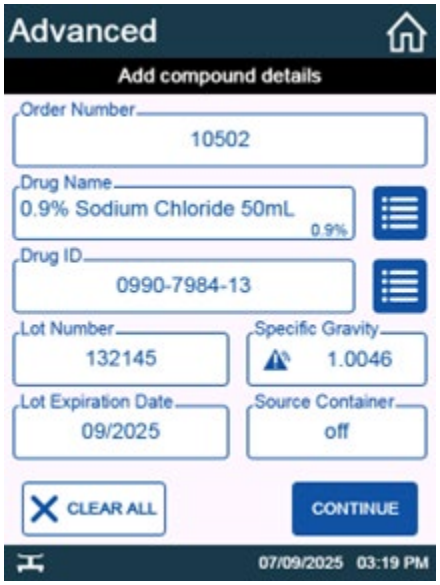
6. Once priming is complete, the System displays a green circle with a white checkmark.

7. Press CONTINUE to proceed or RE-PRIME to prime the tubing again.

8. On the Compound Details screen, enter all drug details into the entry fields.

   Note: See Entering Compound Details for more information.

9. After confirming that the entered information is accurate, tap CONTINUE.



   Note: If Specific Gravity is not changed, a Warning message will appear to verify that the value is correct.

Calibration:

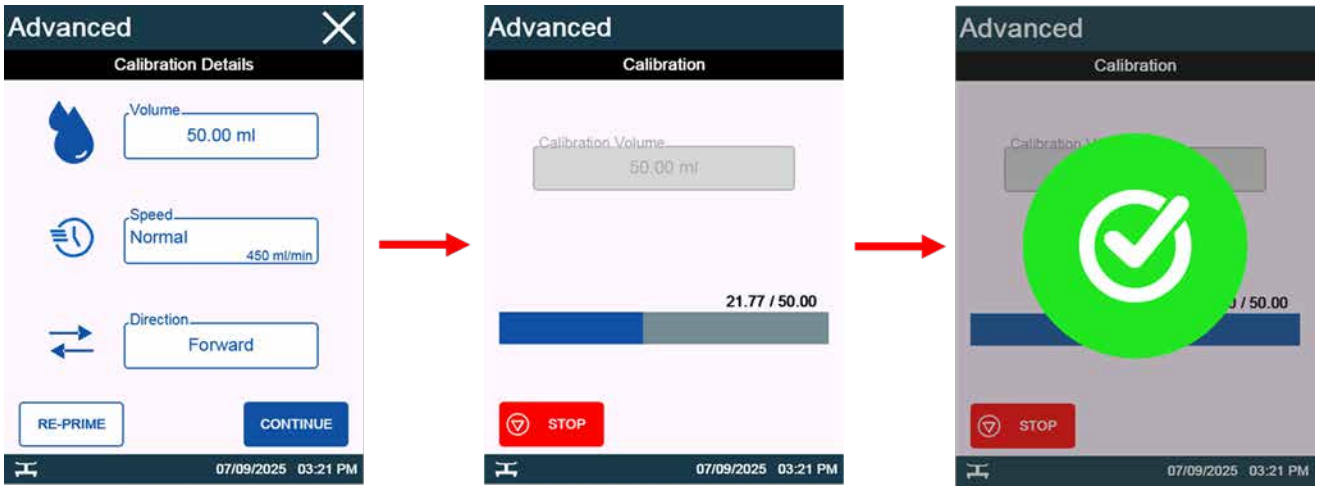
1. Enter the Calibration Volume, Speed, and Direction for transfer.

   Note: The transfer speed should be selected based on the volume, output container type, connector type, and viscosity of the fluid. To adjust the speed of the pump unit, tap on the Speed field and select the intended speed.

2. Place the empty destination container (calibration container) on the external scale.

   Note: To ensure proper calibration, it is recommended to detach the destination container from the tubing set during the Weighing Process. Failure to do so may result in inaccurate calibrations.

3. Tare the external scale.
4. Remove the container from the external scale and connect the output (receiving) end of the tubing set to the destination container that will be used for gravimetric calibration.
5. On the Calibration Details screen, Press CONTINUE to initiate the calibration transfer.

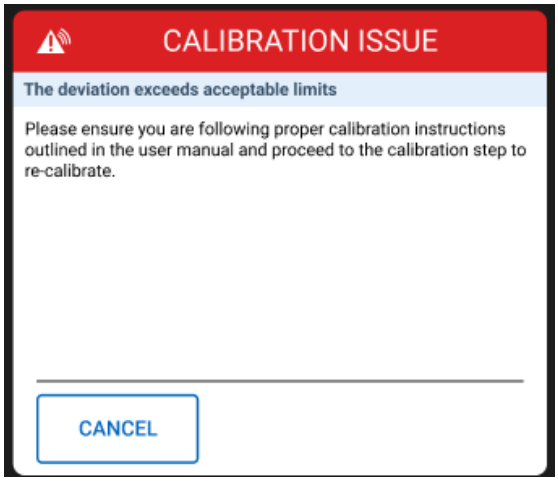


6. After the calibration transfer is complete, detach the calibration container from the tubing set and weigh the container using the external scale.

7. Enter the weight measured by the external scale into the screen as shown below. To use the entered weight to update the pump unit calibration, press ADJUST.

Note: Pressing ADJUST will update the calibration of the pump unit to account for the over/underfill of the transfer as indicated on the screen (difference between specified volume/weight vs measured weight).

Note: If the measured weight is significantly different than the expected weight, the System will display a warning before allowing the pump unit calibration to be updated. Press CANCEL on the warning message to return to the previous screen. Then press BACK to return to the calibration screen. See Warnings During Calibration for details.



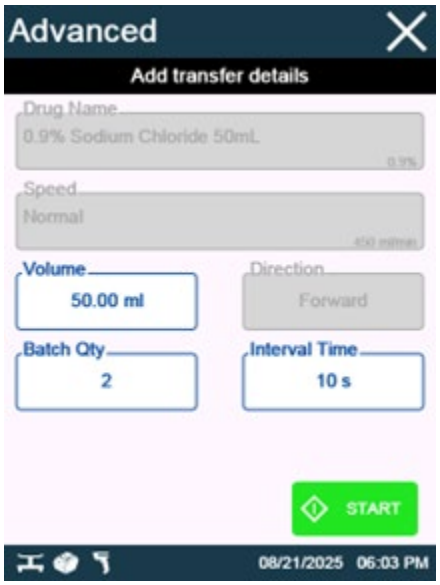
Note: See Recalibration section of this manual for steps to follow if the user does NOT want to use the entered weight to update the pump unit calibration.

Note: Follow facility protocols for the disposal of fluids used for calibration and priming.

Transfer:

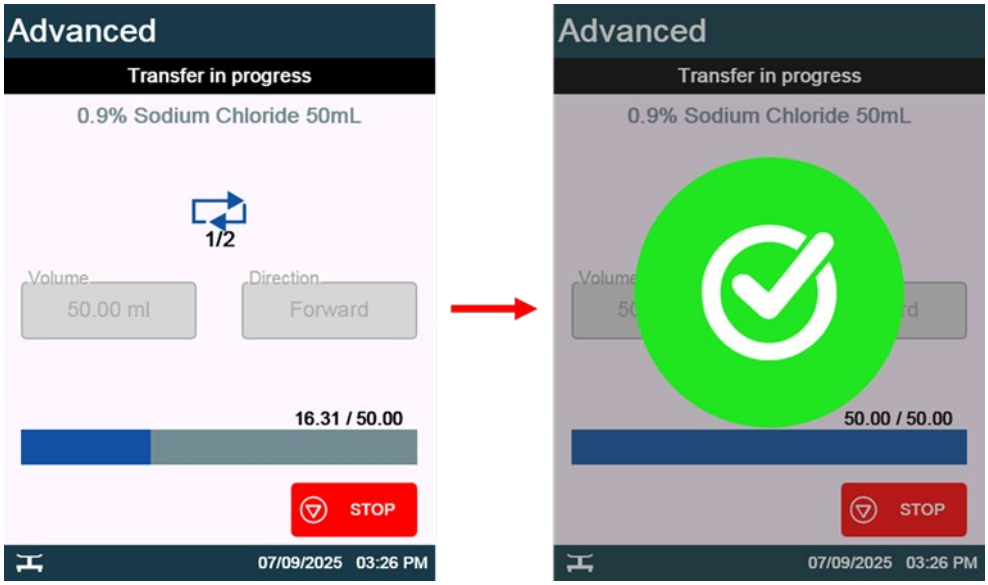
1. Calibration is now complete, and the user is ready to initiate the first transfer. Connect the output (receiving) end of the tubing set to a destination container intended for compounding.

2. On the Transfer Details screen, enter the desired Volume to be transferred, the Batch Quantity to fill, and the Interval Time between each fill.



WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

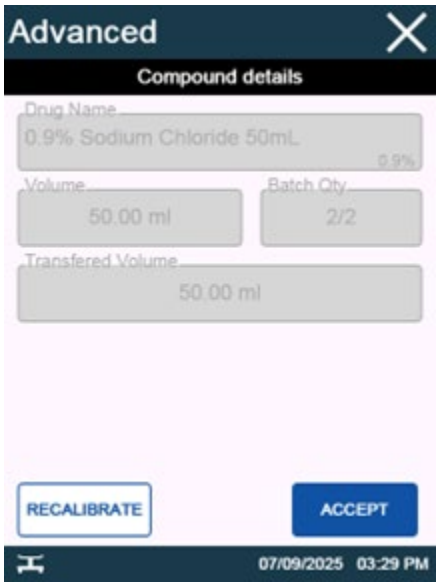
3. After confirming that the entered information is accurate, tap START to initiate transfer.



4. Once the transfer is complete, the System displays a green circle with a white checkmark. The System will automatically return to the Compound Details screen.

Note: If there are multiple Batches, the Interval timer will begin counting down on the Compound Details screen. The next batch transfer will automatically start once the countdown is depleted. To pause the countdown, press STOP.

5. Review the Compound Details screen and press ACCEPT to return to the Compound Details screen to repeat the same transfer. Press CANCEL to change the transfer details.



Note: After accepting a transfer, the user will return to the Compound Details screen to complete another transfer of the same volume. Press CANCEL on the Compound Details screen to change the transfer details.

Gravimetric Mode with Connected Scale

The calibration process of the pump unit can be performed using the connected scale kit. Accurate specific gravity configuration is essential for gravimetric accuracy.

Note: Accuracy performance obtained by the System is directly related to the accuracy of the specific gravity used for the liquid to be transferred.

WARNING: DO NOT USE THE GRAVIMETRIC CALIBRATION PROCESS UNLESS CONFIDENT THAT THE SPECIFIC GRAVITY HAS BEEN ACCURATELY ENTERED FOR THE FLUID BEING TRANSFERRED.

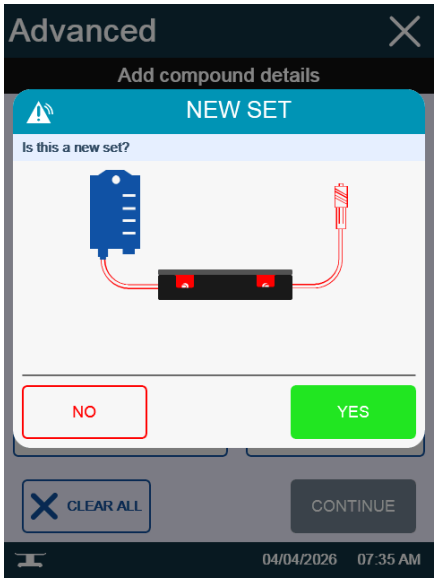
WARNING: ALWAYS CARRY THE SCALE HOLDING THE BOTTOM PLATE CONNECTED TO THE RUBBER LEGS. DO NOT CARRY THE SCALE HOLDING THE TOP PLATE AS THIS MAY LEAD TO INACCURATE CALIBRATION.

Set up:

Note: To use Gravimetric Mode with the Connected Scale, ensure the scale is connected to the pump unit and the scale icon appears at the bottom of the screen.

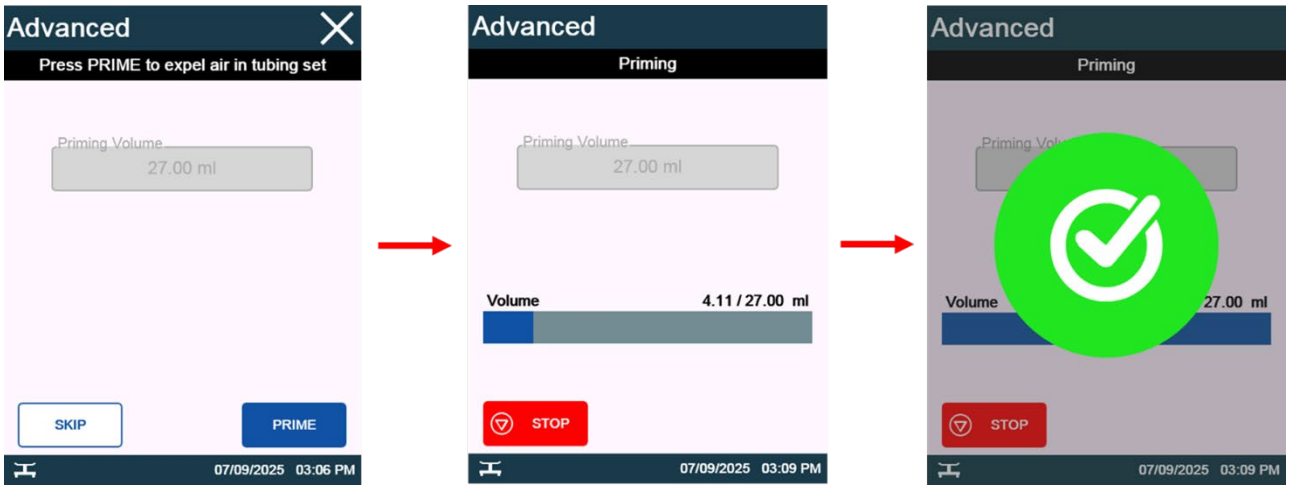
1. Select **Advanced Mode** from the Home screen.
2. If not already installed, insert a tubing set into the pump unit and select Yes or No to indicate if a new set has been inserted.

   Note: See Tubing Set Installation / Removal for more details.



3. On the Select Workflow screen, select **Scale Mode**.
4. If not already connected, connect the input (proximal) end of the tubing set to a source container. Connect the output (receiving) end of the tubing set to a destination container that will be used for priming the tubing set.
5. Tap **PRIME** to begin priming the tubing set. Select **SKIP** if the tubing set has already been primed.

   Note: See Priming for more details.



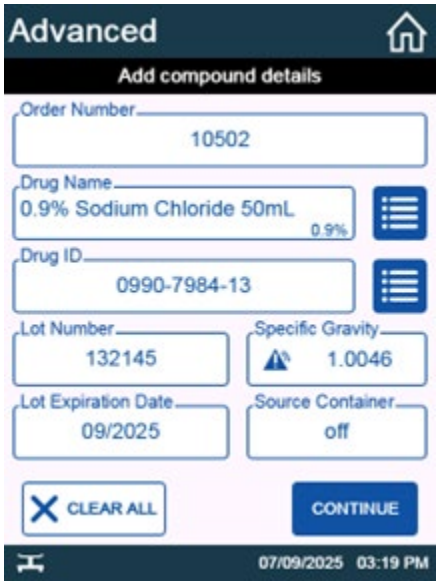
6. Once priming is complete, the System displays a green circle with a white checkmark.

7. Press CONTINUE to proceed or RE-PRIME to prime the tubing again.

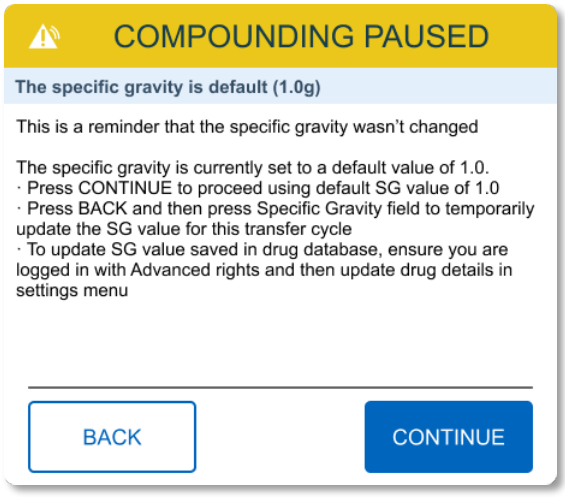
8. On the Compound Details screen, enter all drug details into the entry fields.

   Note: See Entering Compound Details for more information.

9. After confirming that the entered information is accurate, tap CONTINUE.



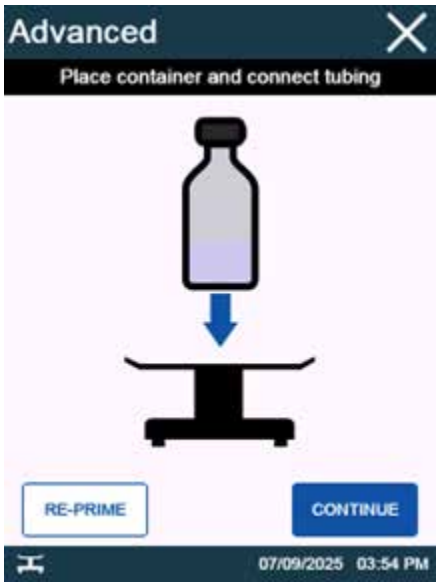
Note: If Specific Gravity is not changed, a Warning message will appear to verify that the value is correct.



Calibration:

1. Connect the output (receiving) end of the tubing set to a destination container that will be used for gravimetric calibration.
2. Place the destination container (calibration container) on the connected scale. Tap CONTINUE to proceed.

   Note: The system will automatically tare the scale once pressing CONTINUE. The user also has the option to manually zero the scale weight by pressing the TARE on the next screen.



3. Enter the Calibration Volume, Speed, and Direction for transfer.

Note: The transfer speed should be selected based on the volume, output container type, connector type, and viscosity of the fluid. To adjust the speed of the pump unit, tap on the Speed field and select the intended speed.

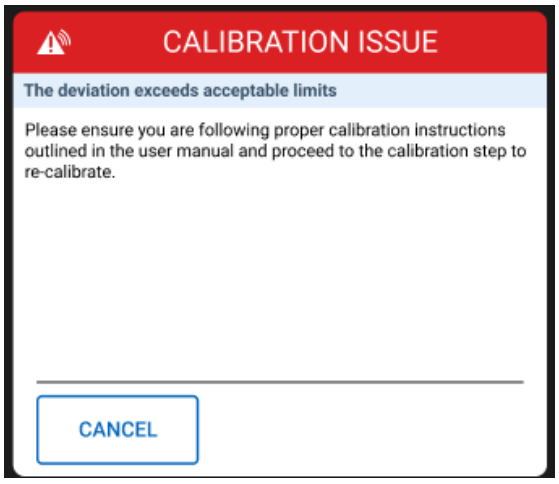
4. After confirming the entered information is accurate, press START to initiate the calibration transfer.

5. After the calibration transfer is complete, the System displays a green circle with a white checkmark. The System will automatically proceed to the Calibration Review screen.

6. The measured Volume and Weight will be displayed next to the Specified Volume and Weight. To use the measured weight to update the pump calibration, press ADJUST.

Note: Pressing ADJUST will update the calibration of the pump unit to account for the over/underfill of the transfer as indicated on the screen (difference between specified volume/weight vs measured weight).

Note: If the measured weight is significantly different than the expected weight, the System will display a warning before allowing the pump unit calibration to be updated. Press CANCEL on the warning message to return to the previous screen. Then press BACK to return to the calibration screen. See Warnings During Calibration for details.



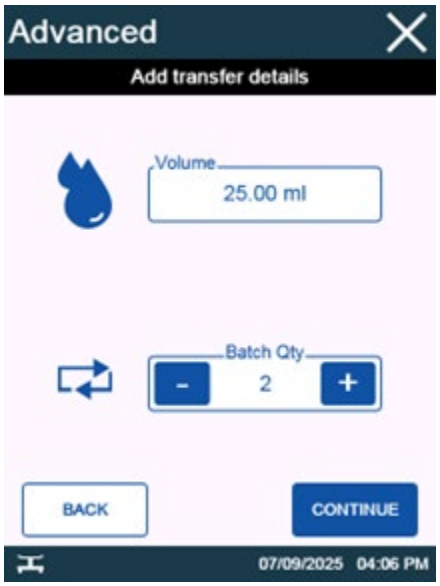
Note: See Recalibration section of this manual for steps to follow if the user does NOT want to use the measured weight to update the pump unit calibration.

Note: Follow facility protocols for the disposal of fluids used for calibration and priming.

Transfer:

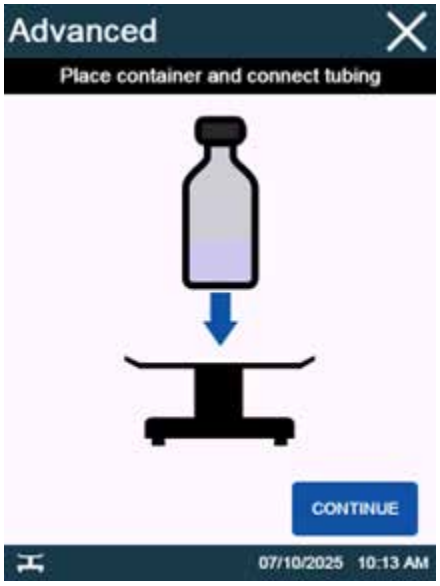
1. Calibration is now complete, and the user is ready to initiate the first transfer. Connect the output (receiving) end of the tubing set to a destination container intended for compounding.

2. On the Transfer Details screen, enter the desired Volume to be transferred and the Batch Quantity to fill.



3. Place the destination container onto the connected scale. Tap CONTINUE to proceed.

Note: The system will automatically tare the scale once pressing CONTINUE. The user also has the option to manually zero the scale weight by pressing the TARE on the next screen.

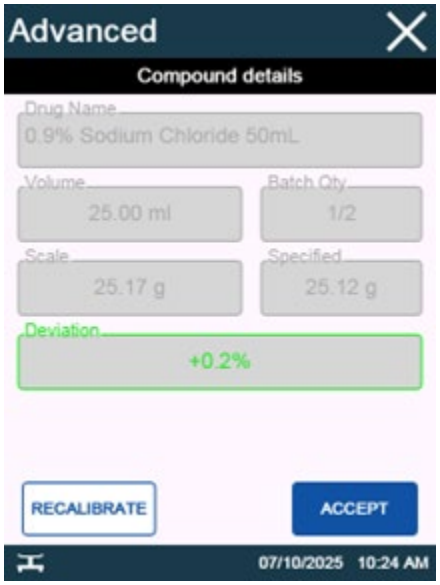


WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

4. After confirming that the entered information is accurate, tap START to initiate transfer.

5. Once the transfer is complete, the System displays a green circle with a white checkmark. The System will automatically proceed to the Compound Details screen. The Compound Details screen will display the Specified Volume, Scale Weight, Specified Weight, and the Weight Deviation Percentage.

   Note: See Deviation Borders for details on Deviation Percentage meaning and changing deviation borders.

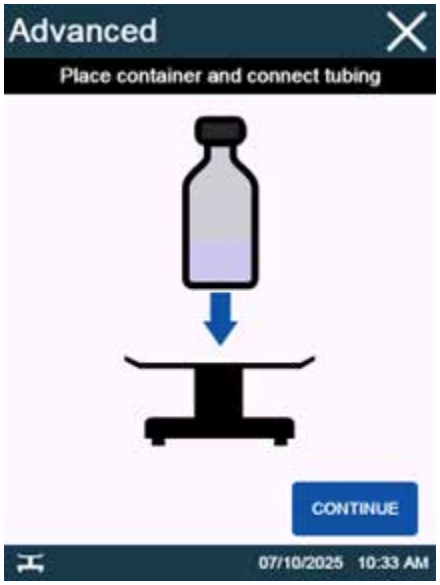


6. Review the Compound Details screen and press ACCEPT. Remove the container from the scale to return to the Compound Details screen.

Note: If the Deviation is Out of Range, the user can only select RECALIBRATE.

7. Remove the container from the scale.

Note: If there are multiple Batches, the System will notify the user to place the next destination container onto the connected scale and will return to the Compound Details screen after selecting CONTINUE.



Scale Only Mode

Scale Only mode is designed to use the connected scale to measure the weight of a container for accuracy and verification. This mode can also be used to complete a Scale Check, which verifies if the connected scale provides an accurate measurement.

The system does not store this information in the compounding logs as this is designed to be a standalone feature. This may be common when a user uses PharmAssist Pro to move diluent into a container, but then manually adds drug and wants to verify again the final weight.

WARNING: ALWAYS CARRY THE SCALE HOLDING THE BOTTOM PLATE CONNECTED TO THE METAL LEGS. DO NOT CARRY THE SCALE HOLDING THE TOP PLATE AS THIS MAY LEAD TO INACCURATE CALIBRATION.

Note: The maximum weight placed on the connected scale should be 2000 grams.

Scale Only:

To measure the weight of a container:

1. Place the container onto the center of the scale.
2. The screen will show a live reading of the container's measured weight in grams.

To measure the weight of the fluid inside a container:

1. Place the empty container onto the center of the scale.
2. Press TARE to zero out the weight on the scale.
3. Fill the container with fluid.
4. Place the filled container onto the scale.
5. The screen will show a live reading of the measured weight of fluid in the container.

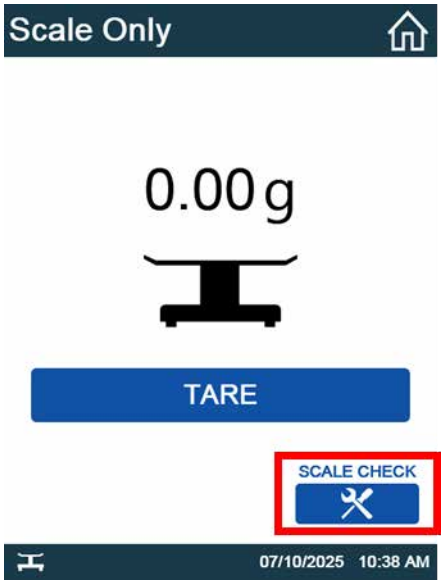
Scale Check

The Scale Check feature allows the user to check the function of the connected Scale Kit by weighing a test weight of known mass. The Scale Check feature can be used for weights between 51 and 2000 grams.

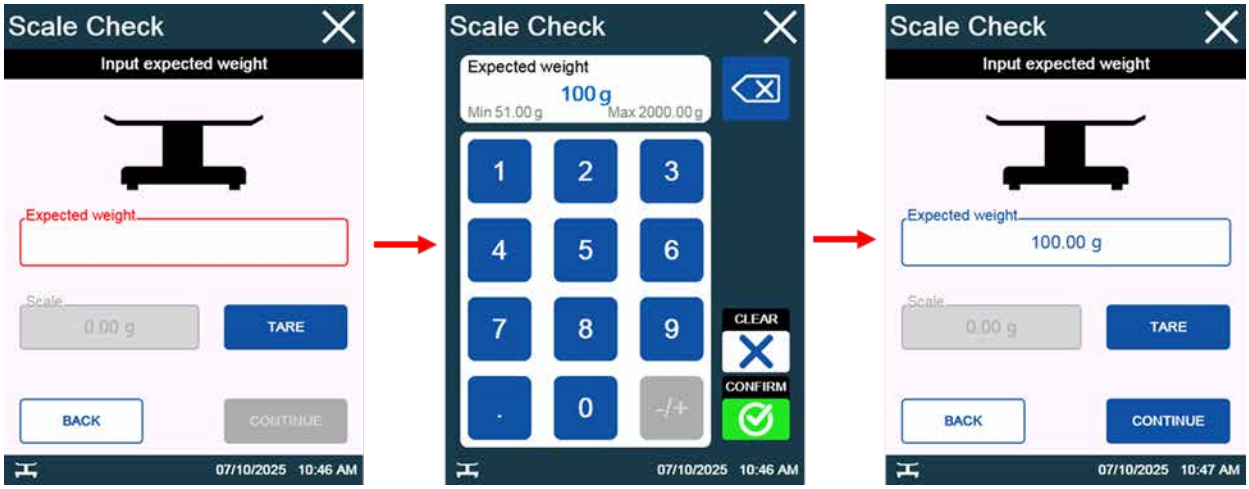
WARNING: IF THE VALUE REPORTED FOR THE CALIBRATION WEIGHT IS OUTSIDE THE TOLERANCE ESTABLISHED FOR THE FACILITY, PLEASE CONTACT ICU MEDICAL, INC. FOR ASSISTANCE.

To complete a Scale Check:

1. Press the SCALE CHECK icon at the bottom of the screen.



2. In the Expected Weight field, enter the weight of the known mass.

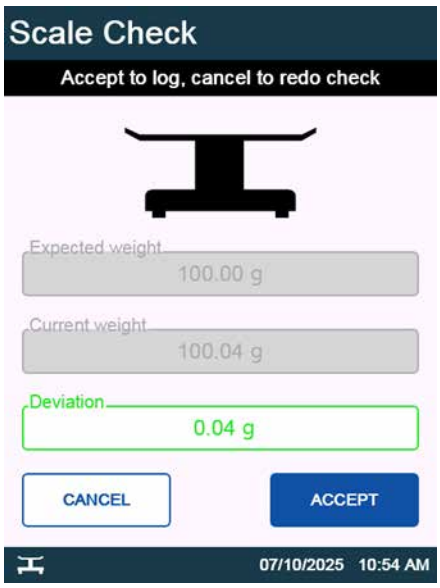


3. Press TARE to zero the scale weight. Then press CONTINUE to proceed.
4. Place the known mass onto the center of the scale. Then press CONTINUE to proceed.

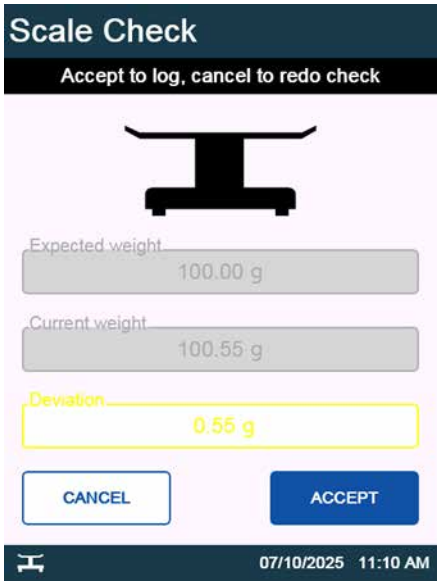
Note: The CONTINUE button will only become enabled once the expected weight is placed on the scale.

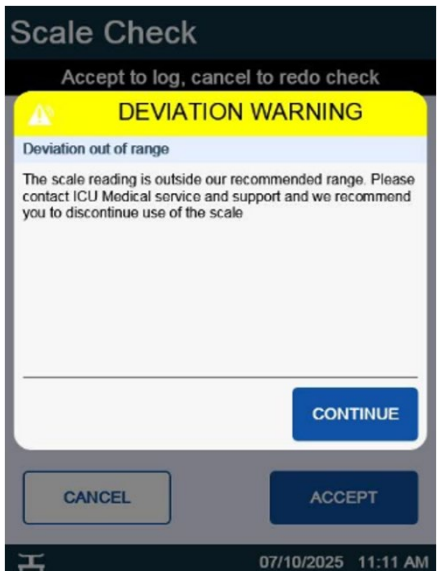
5. The screen will show the Current Measured Weight and the deviation from the Expected Weight. The Deviation field will be highlighted in Green, Yellow, or Red based on the amount of deviation.

   A Deviation highlighted in Green indicates that the difference between the Expected Weight and the Measured Weight is within the acceptable recommended range of accuracy.

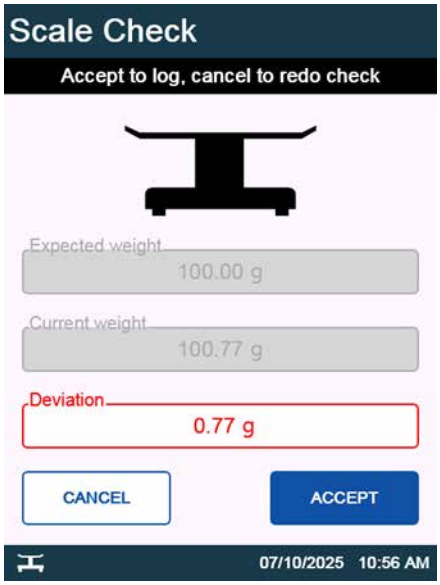


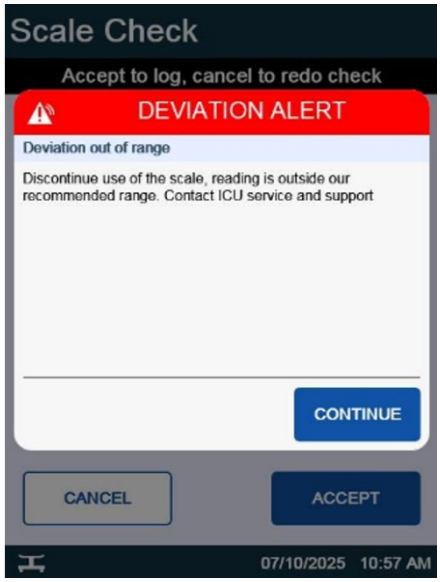
A Deviation highlighted in Yellow indicates that the scale reading is out of range. The "Deviation is out of range" warning message will appear. The user has the option to Accept the scale check or redo the check. It is recommended you discontinue use of the scale with deviations in this range. Contact ICU Medical Service.





A Deviation highlighted in Red indicates that the scale reading is significantly out of range. The red "Deviation is out of range" alert will appear. Discontinue use of the scale with deviations in this range. Contact ICU Medical Service.





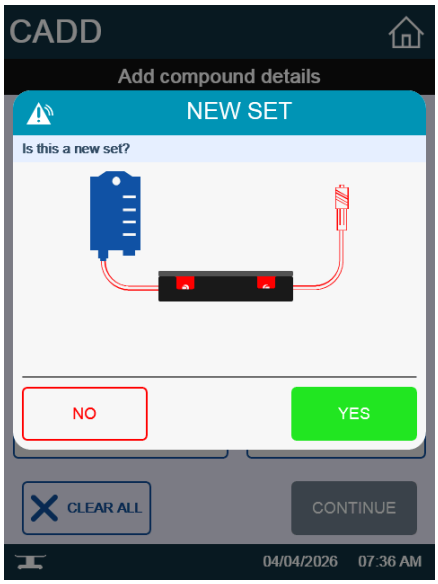
CADD Filling – Air Removal Mode

CADD Filling mode is designed to safely and efficiently fill CADD cassettes. This process includes removing air from the cassette to minimize air pockets and filling the reservoir with a specified drug and volume.

CADD Mode – Set Up

Set Up:

1. If not already installed, insert a short tubing set (PA01-XS) into the pump unit and select Yes or No to indicate if a new set has been inserted.



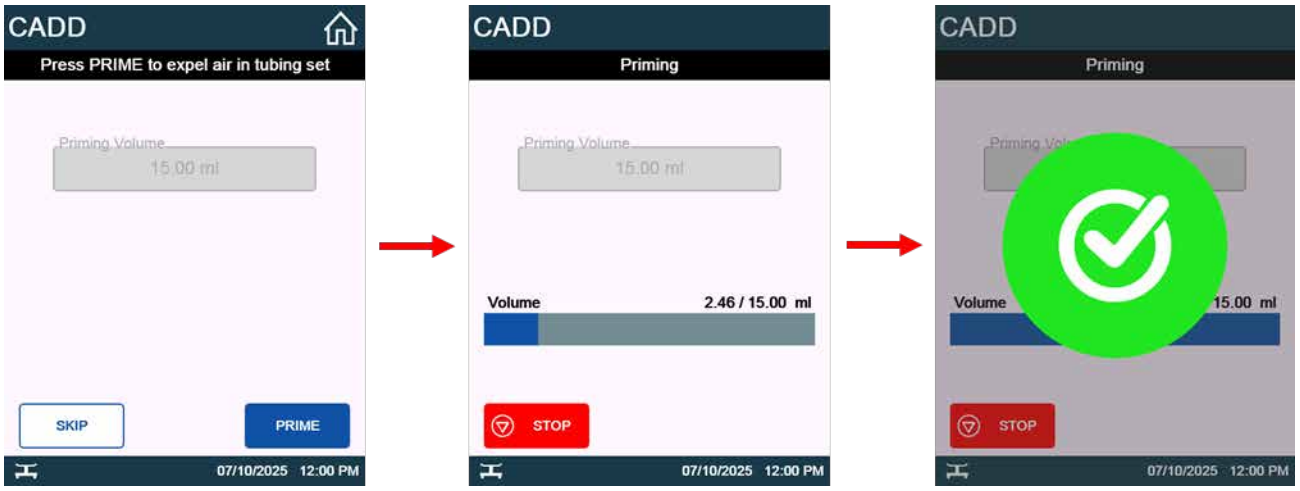
2. After confirming the short tubing set is installed, tap on CONTINUE to proceed.

   Note: See Tubing Set Installation / Removal for more details.

   Note: A Short Tubing Set (PA01-XS) must be used for this mode. If a short tubing set cannot be obtained, select the Home button and use a different mode.

3. If not already connected, connect the input (proximal) end of the tubing set to a source container. Connect the output (receiving) end of the tubing set to a destination container that will be used for priming the tubing set.
4. Tap PRIME to begin priming the tubing set. Select SKIP if the tubing set has already been primed.

Note: See Priming for more details.



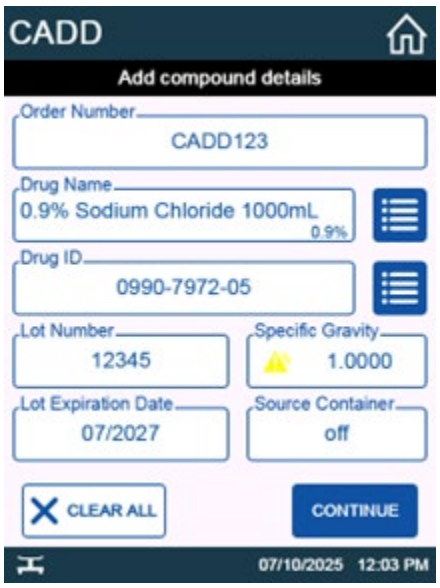
5. Once priming is complete, the System displays a green circle with a white checkmark. Tap CONTINUE to proceed or tap RE-PRIME to prime the tubing again.

6. Connect the output (receiving) end of the tubing set to an empty CADD Cassette.

7. Place an Ambulatory Cassette Holder (CADDH01) onto the connected scale and tap CONTINUE.

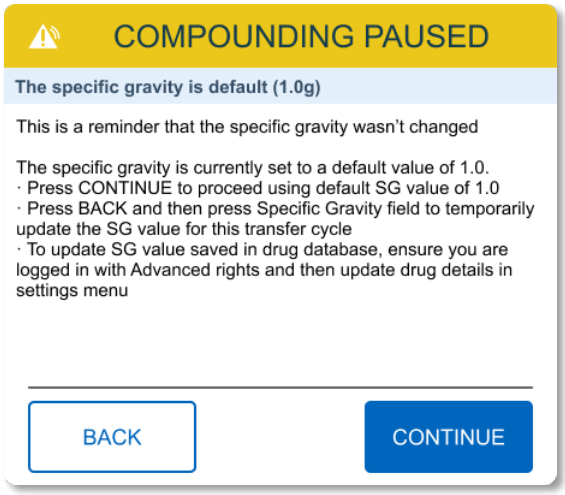
8. On the Compound Details screen, enter all drug details into the entry fields.

   Note: See Entering Compound Details for more information.



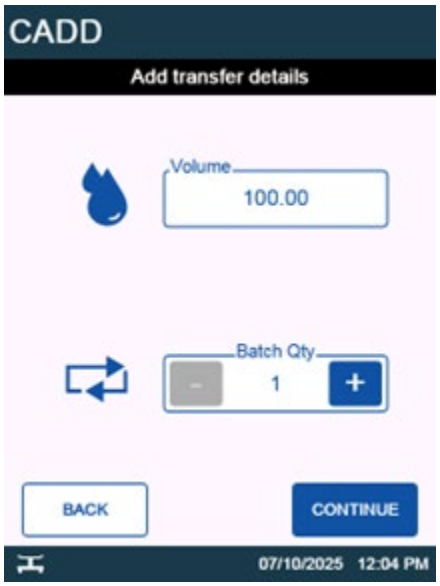
9. After confirming that the entered information is accurate, tap CONTINUE.

Note: If Specific Gravity is not changed, a Warning message will appear to verify that the value is correct.



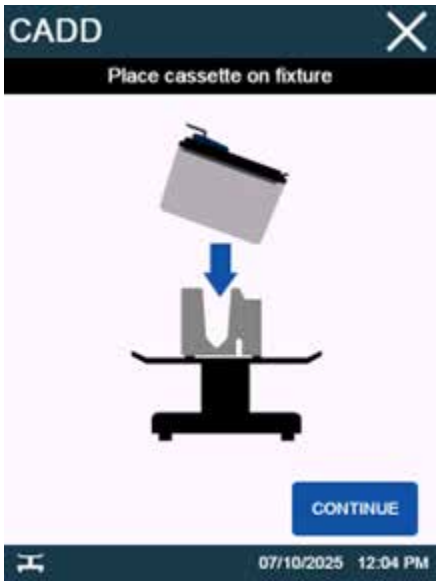
Note: Accuracy performance obtained by the System is directly related to the accuracy of the specific gravity used for the liquid to be transferred.

10. Enter the desired Volume to be transferred and the Number of Cassettes to fill.



11. After confirming that the entered information is accurate, tap CONTINUE.

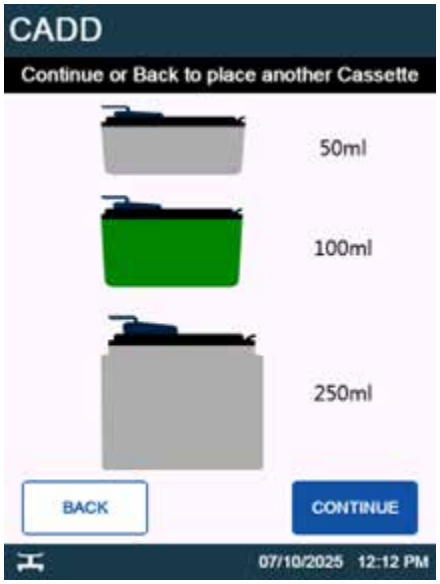
12. Place the empty CADD Cassette onto the CADD Ambulatory Cassette Holder (CADDH01) as pictured on the screen. Tap CONTINUE.



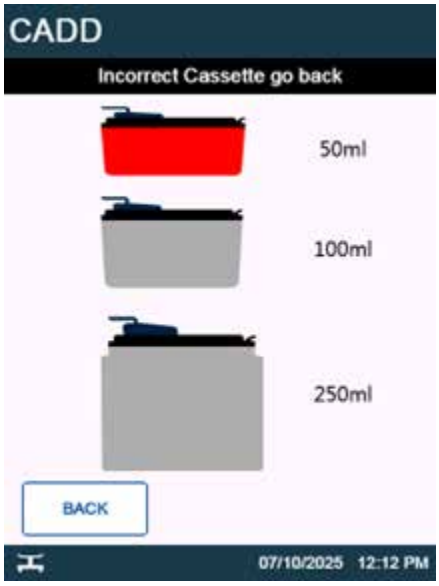
13. The measured cassette size will automatically be selected and highlighted in green if compatible. Tap CONTINUE to proceed.

Note: The acceptable volume for each CADD Cassette size is the following:

- 50 mL Cassette: 15.00 - 50.00 mL
- 100 mL Cassette: 51.00 - 100.00 mL
- 250 mL Cassette: 101.00 - 250.00 mL



Note: If the transfer Volume entered is incompatible with the selected cassette size, the system will highlight the cassette visual in red and the user will need to go back and enter a valid transfer volume or place a valid cassette size on the scale.



14. After confirming the cassette size, the system is ready for transfer and will automatically TARE the scale once pressing CONTINUE. The user also has the option to manually zero the scale weight by pressing the TARE button.

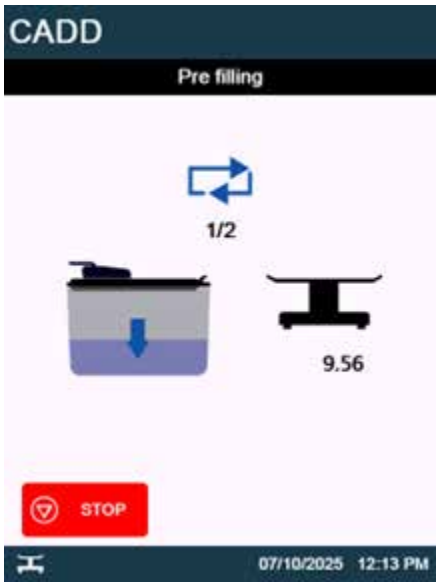
Note: If the entered Drug information if not accurate, tap BACK to return to the previous screen.

CADD Filling Process

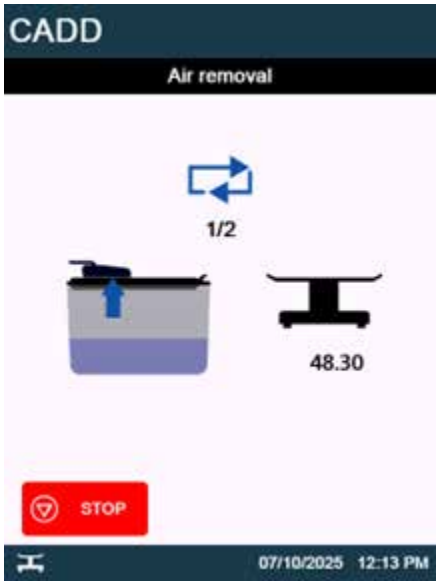
Filling and Air Removal:

WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

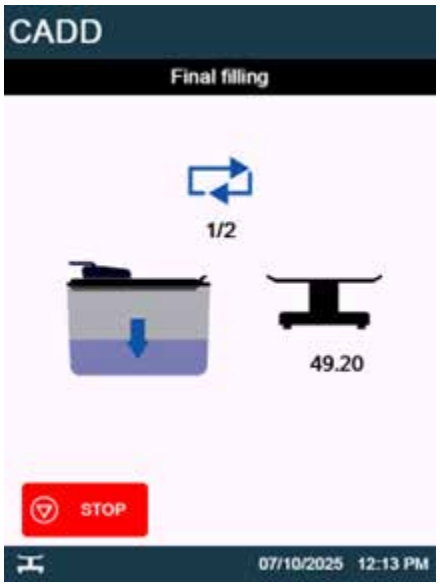
1. Press START to initiate transfer. Once the transfer is initiated, the pump unit will begin pre-filling the cassette and the scale icon will display the corresponding gravimetric weight to indicate the status of the transfer.



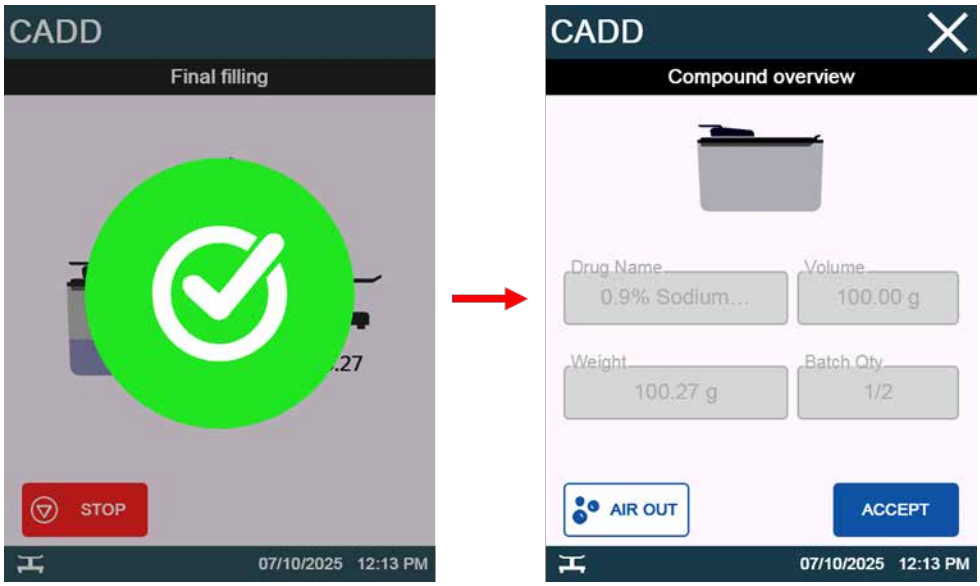
2. The pump unit will automatically remove air from the CADD cassette after pre-filling with fluid.



3. The pump will automatically begin filling the final amount of fluid to reach the desired volume after air removal.



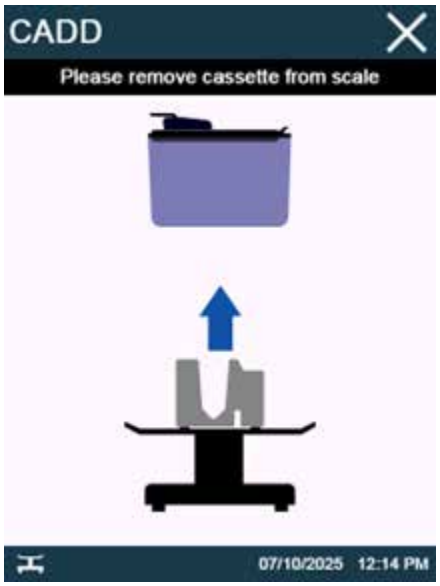
4. Once the transfer is complete, the System displays a green circle with a white checkmark. The System will automatically return to the Compound Overview screen.



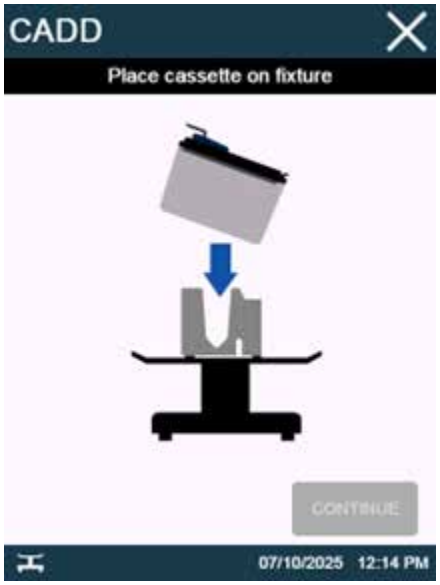
5. Review the Compound Overview screen and press ACCEPT to finalize the transfer.

   Note: If the CADD Cassette is removed from the scale while on the Compound Overview screen, the ACCEPT button will be disabled. Place the cassette back onto the CADD Holder to proceed.

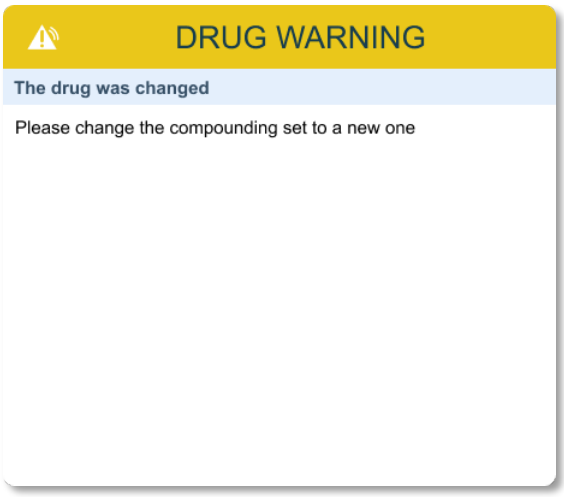
6. The user will then be directed to remove the cassette from the scale.



Note: If there are multiple Batches, the user will be directed to place a new cassette onto the scale after the previous one is removed.

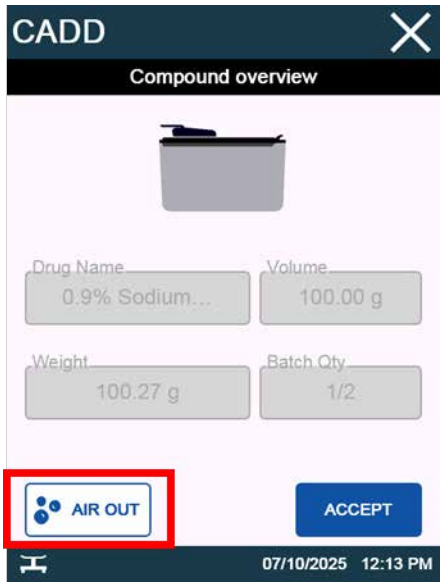


Note: Once the CADD fillings are complete, the System will navigate back to the Transfer Details screen to start another CADD filling using the same drug information. To change the drug information, the user must replace the tubing with a new set. If the user changes the drug information on the Compound Details screen without changing the tubing set, the Drug Warning message will appear only if 'Require Drug Info' is activated under Advanced Settings. The tubing set must be replaced with a new set to proceed.



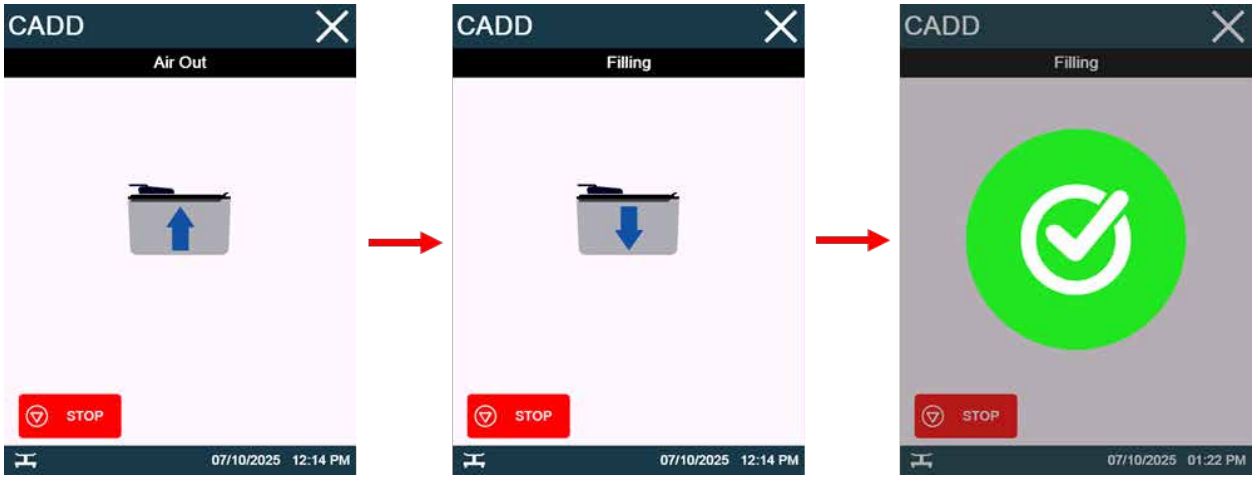
Air Out Feature:

1. If additional air removal is needed, press AIR OUT on the Compound Overview screen.

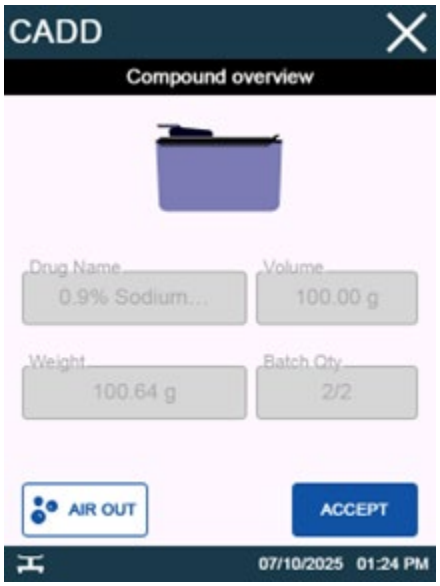


2. Manually manipulate the cassette to push any remaining air bubbles to the top. Then replace the cassette back on the scale and tap CONTINUE.

3. The pump will automatically begin the additional air removal and fill the final amount of fluid. Once the air removal is complete, the System displays a green circle with a white checkmark. The System will automatically return to the Compound Overview screen.



4. Review the Compound Overview screen and press CONTINUE to finalize the transfer.



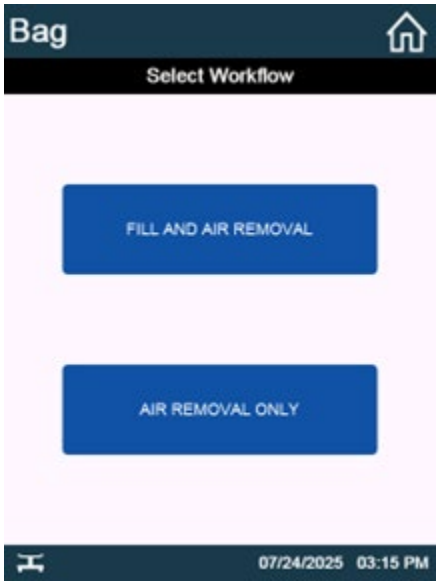
Bag Filling – Air Removal Mode

Bag Filling mode is designed to fill and remove air from bag containers. For bags that are already filled, the user can opt to remove air only.

Note: A Bag Holder (BAGH01) must be utilized in order to complete transfers in Bag Mode.

There are two workflows that can be performed:

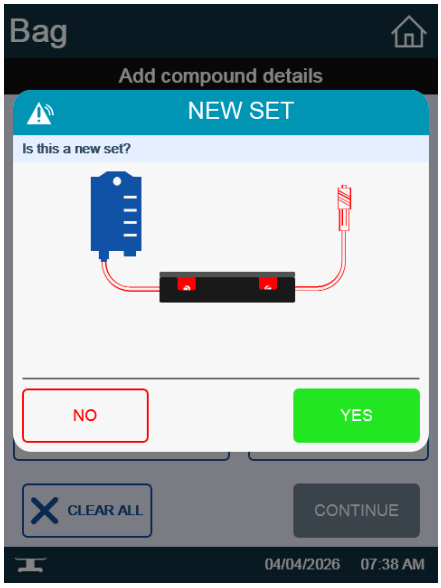
- Fill and Air Removal
- Air Removal Only



Fill and Air Removal

Set Up:

1. If not already installed, insert a short tubing set (PA01-XS) into the pump unit and select Yes or No to indicate if a new set has been inserted.



2. Select the workflow for Fill and Air Removal.
3. After confirming the short tubing set is installed, tap on CONTINUE to proceed.

Note: See Tubing Set Installation / Removal for more details.

Note: A Short Tubing Set (PA01-XS) must be used for this mode. If a short tubing set cannot be obtained, select the Home button and use a different mode.

4. Place the bag holder on the connected scale. Tap CONTINUE to proceed.

Note: See Bag Holder (BAGH01) for details on securing the Bag Holder to the connected scale.

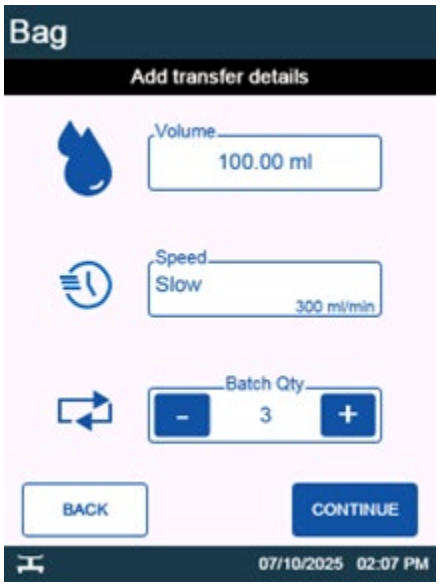
5. If not already connected, connect the input (proximal) end of the tubing set to a source container. Connect the output (receiving) end of the tubing set to the destination bag that will connect to the bag holder.
6. On the Compound Details screen, enter all drug details into the entry fields.

Note: See Entering Compound Details for more information.

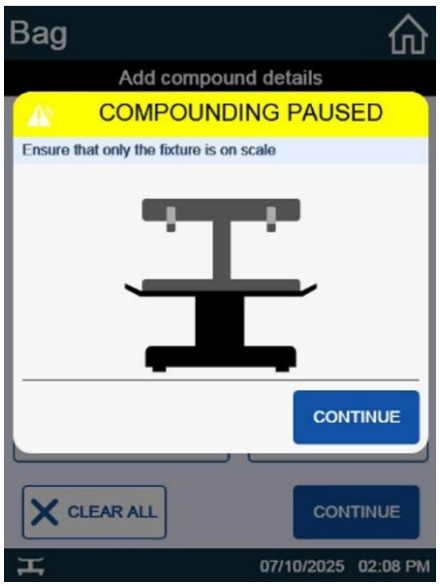
7. After confirming that the entered information is accurate, tap CONTINUE.

Note: If Specific Gravity is not changed, a Warning message will appear to verify that the value is correct. Accuracy performance obtained by the System is directly related to the accuracy of the specific gravity used for the liquid to be transferred.

8. Enter the desired Volume to be transferred, the transfer Speed, and the Batch Quantity to fill.



9. After confirming that the entered information is accurate, tap CONTINUE.
10. The Bag Holder Warning will appear to ensure that only the Bag Holder is placed on the scale. Tap CONTINUE.



11. Place the output bag onto the bag holder. Tap CONTINUE to proceed.

Note: See Bag Holder (BAGH01) for details on securing a bag to the Bag Holder.

12. After confirming the bag is placed on the scale, the system is ready for transfer and will automatically TARE the scale once pressing CONTINUE. The user also has the option to manually zero the scale weight by pressing the TARE button.

Note: If the entered Drug information if not accurate, tap BACK to return to the Transfer Details screen.

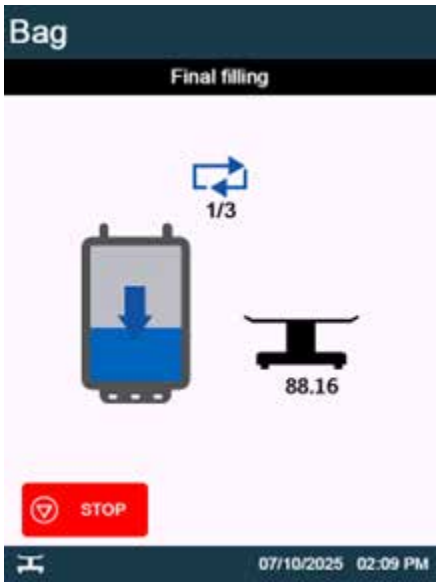
Fill and Air Removal:

WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

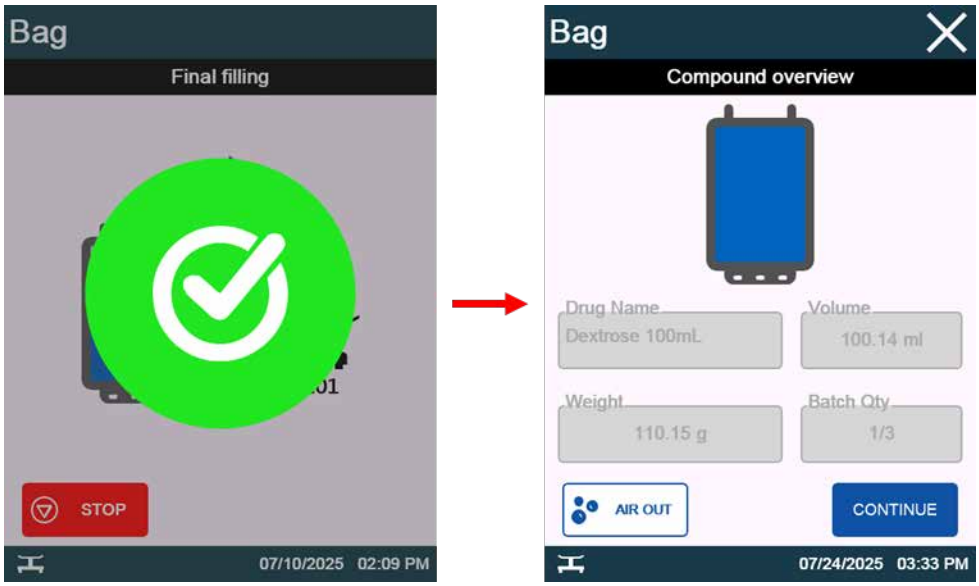
1. Press START to initiate transfer. Once the transfer is initiated, the pump unit will begin pre-filling the bag and the scale icon will display the corresponding gravimetric weight to indicate the status of the transfer.

2. The pump unit will automatically remove air from the bag after pre-filling with fluid.

3. The pump will automatically begin filling the final amount of fluid to reach the desired volume after air removal.



4. Once the transfer is complete, the System displays a green circle with a white checkmark. The System will automatically return to the Compound Overview screen.



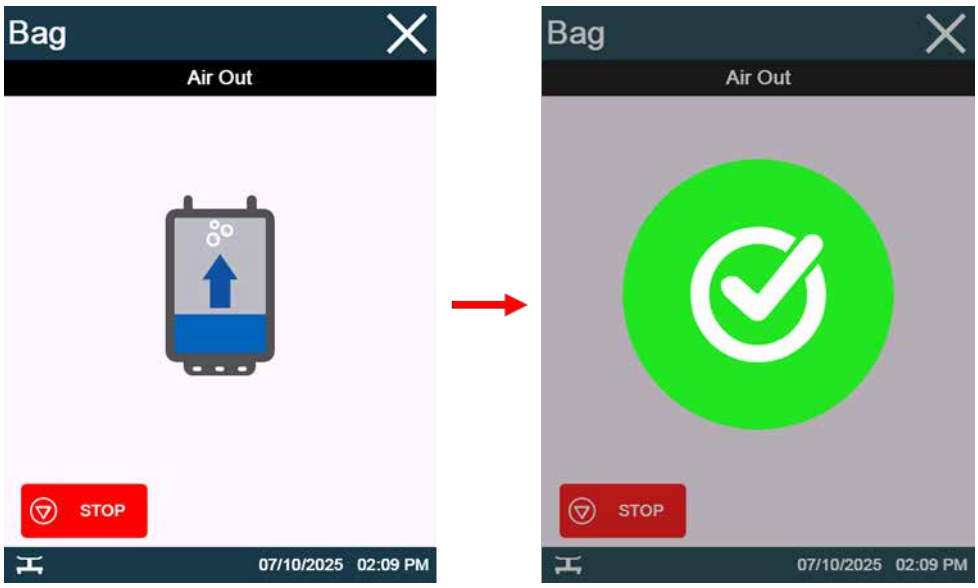
5. Review the Compound Overview screen and press CONTINUE to finalize the transfer. The user will then be directed to remove the bag from the scale.

Note: If there are multiple Batches, the user will be directed to place a new bag onto the scale after the previous one is removed.

Air Out Feature:

1. If additional air removal is needed, press AIR OUT on the Compound Overview screen.

2. The pump will automatically begin the additional air removal and filling the final amount of fluid. Once the air removal is complete, the System displays a green circle with a white checkmark. The System will automatically return to the Compound Overview screen.



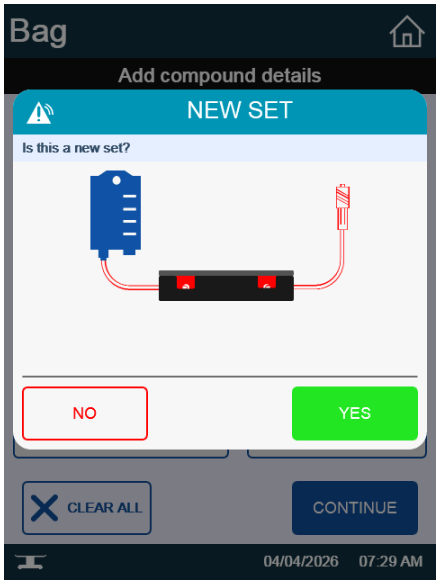
3. Review the Compound Overview screen and press CONTINUE to finalize the transfer.

Air Removal Only

Set Up and Air Removal:

1. If not already installed, insert a tubing set into the pump unit and select Yes or No to indicate if a new set has been inserted.

   Note: See Tubing Set Installation / Removal for more details.



2. Select the workflow for Air Removal Only.
3. Place the bag holder on the connected scale. Tap CONTINUE to proceed.

   Note: See Bag Holder (BAGH01) for details on securing the Bag Holder to the connected scale.

4. If not already connected, connect the input (proximal) end of the tubing set to an empty bag or waste container. Connect the output (receiving) end of the tubing set to the pre-filled bag of fluid that will connect to the bag holder.
5. On the Transfer Details screen, enter the number of grams of fluid to remove from the bag. The system will stop removing air once the scale detects the specified weight is removed. A small amount of fluid will be removed from the bag in order to remove all air.

Note: The minimum weight to remove is 2 grams and the maximum weight to remove is 20 grams.

6. Place the bag of fluid onto the bag holder with the tubing connections oriented upwards. Once the scale detects the bag on the Bag Holder, then the CONTINUE button will become enabled. Tap CONTINUE to proceed.

Note: See Bag Holder (BAGH01) for details on securing a bag to the Bag Holder.

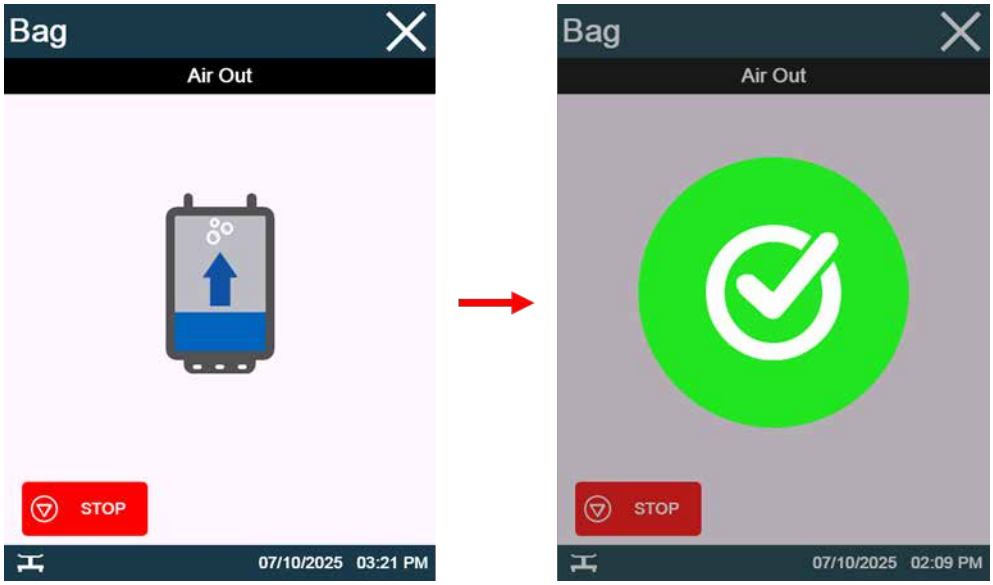
7. Press TARE to zero the scale weight.

WARNING: VERIFY ALL COMPOUND DETAILS ARE ACCURATE BEFORE INITIATING TRANSFER.

8. Press START to begin removing air from the fluid bag.

   Note: If the scale value is greater than 0.5 grams, the START button will become disabled. The user should press Tare again before proceeding.

9. Once air removal is complete, the System displays a green circle with a white checkmark



10. On the Overview screen, the System will display the weight removed from the bag and the final weight of the bag after air removal.
11. After reviewing, press ACCEPT to proceed with preparing the next bag for air removal.

12. Press the ‘X’ button to return to the beginning of the workflow.

Settings

To access the Settings Menu, press on the **Settings** Icon ( ) located in the top right of the toolbar. The Settings Menu will be displayed.

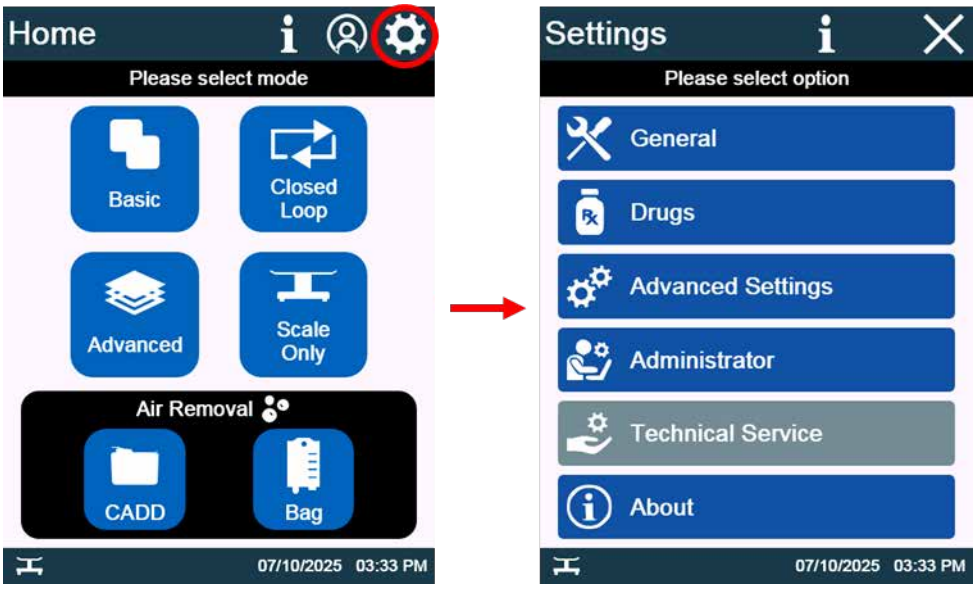


Figure 24: Settings Menu

Note: If a user is not logged in, only General and About Settings will be available. If a user is logged in, the available settings will be based on the user's role privileges.

Note: See Power On and Initial Setup for details on creating User Account upon first startup.

The following table describes the settings menu:

Table 11: Settings Menu

Option	Description
General	Allows updates to language, brightness & volume, allows user to view version information and preparation logs, perform Scale Checks, and manage passwords.
Drugs	Allows user to add and modify drug listings.
Advanced Settings	Allows updates to speed settings, scale deviation limits, priming volumes, required configurations, and duration settings. (User login required)
Administrator	Allows updates to date and time, user management, network connections, and label settings.
Technical Service	ICU Medical Personnel only.
About	Provides information on the system.

General

Press on the General tab to modify settings that are user controllable. A window will display the general options for the System as shown in Figure 25: General .The available General settings are: Language, Screen and Volume, Version Information, Perform Scale Check, and Preparation Logs.

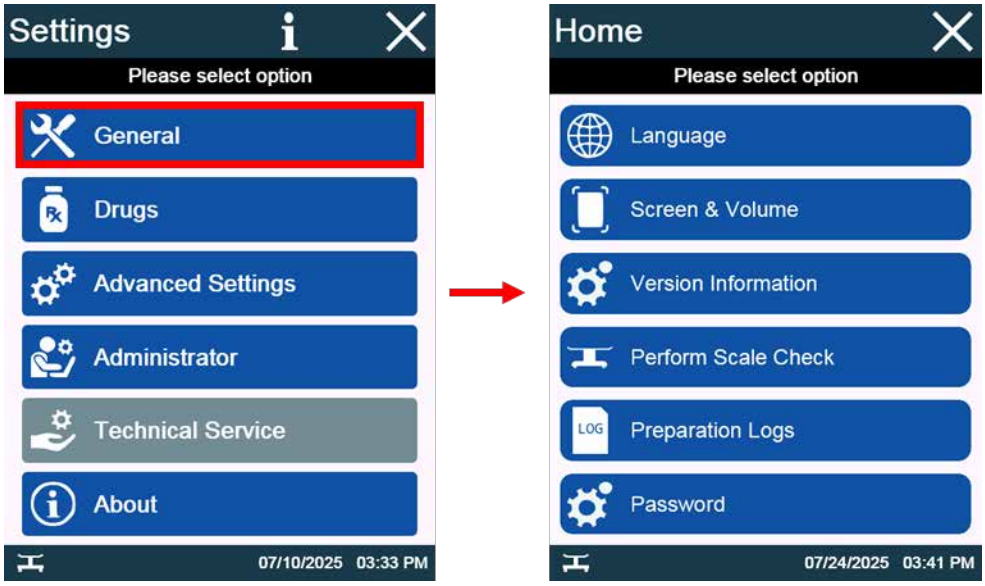


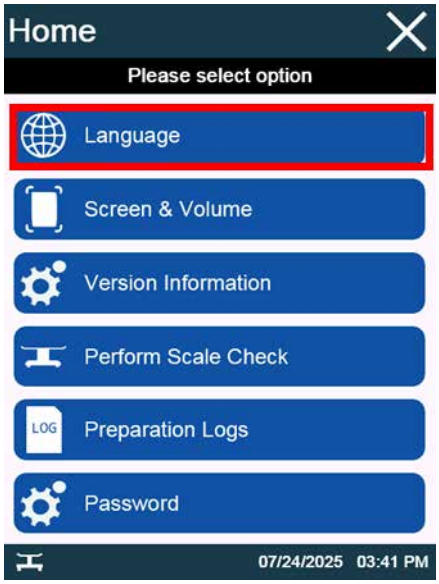
Figure 25: General

Language

The pump unit user interface can be displayed in multiple languages. The Language menu allows the user to switch the language.

To Select Language:

1. Go to General Settings menu and press on Language.



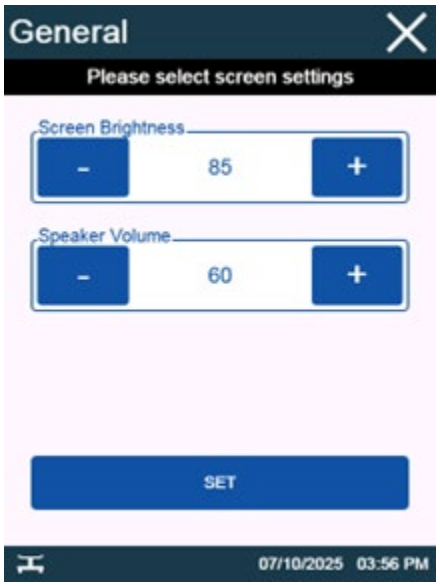
2. Press the desired choice to select the Language.

3. Press Set to save the new language.

Screen & Volume

1. Press on the Screen & Volume setting to adjust the screen brightness and speaker volume.
   - The user can select the desired screen brightness by selecting the '+' and '-' buttons to increase or decrease the brightness level.
   - The user can select the desired speaker volume by selecting the '+' and '-' buttons to increase or decrease the volume level.

2. Select the Set button to save the desired brightness and volume levels.



Version Information

Press on **Version Information** setting to see the pump unit software component versions, see Figure 26.

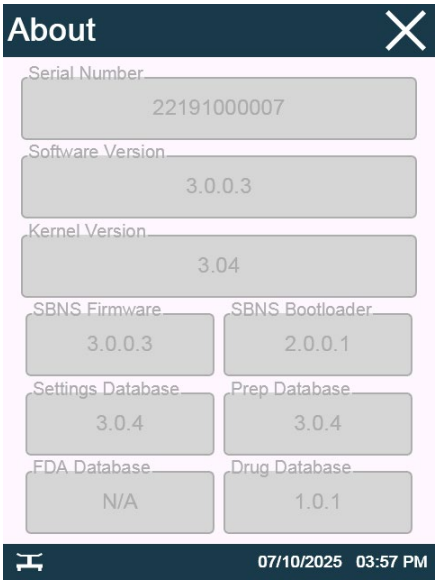


Figure 26: Version Information

Perform Scale Check

The Scale Check feature (Figure 27) allows the user to check the function of the connected Scale Kit by weighing a test weight of known mass.

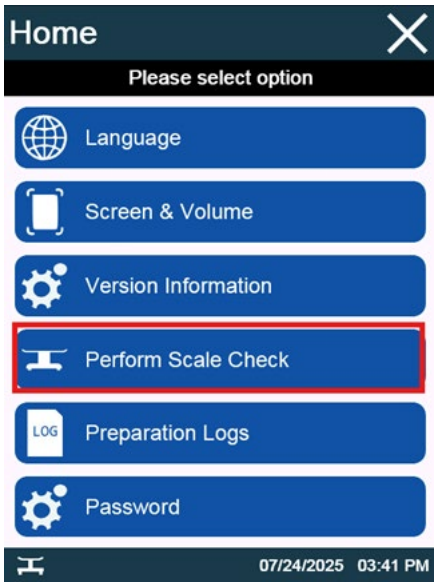


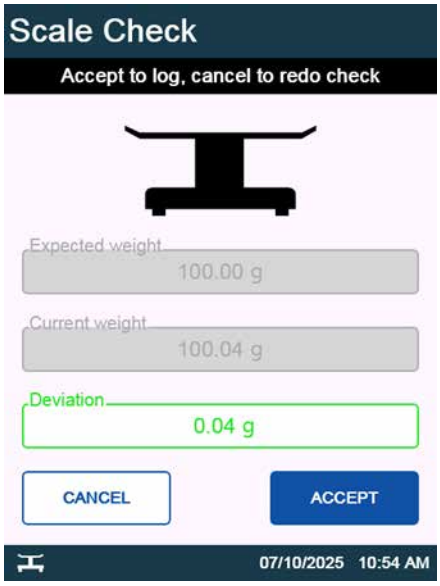
Figure 27: Scale Check

To perform a Scale Check:

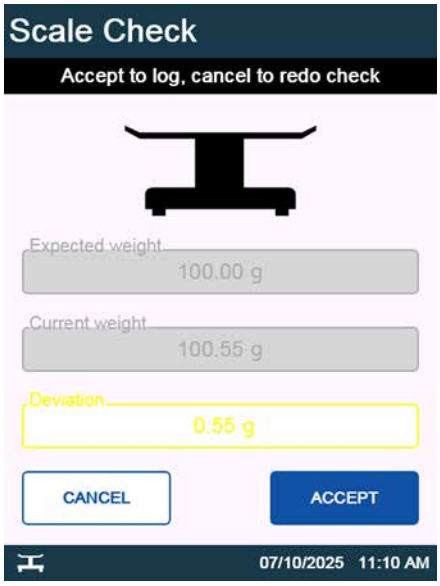
1. Ensure the Scale Kit is connected prior to turning on the pump.
2. Select Perform Scale Check from the General settings menu.
3. In the Expected Weight field, enter the weight of the known mass.
4. Press TARE to zero the scale weight. Then press CONTINUE to proceed.
5. Place the known mass onto the center of the scale. Then press CONTINUE to proceed.
6. The screen will show the Current Measured Weight and the deviation from the Expected Weight. The Deviation field will be highlighted in Green, Yellow, or Red based on the amount of deviation.

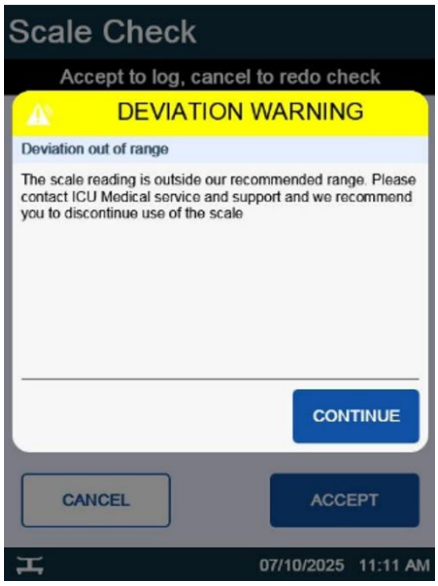
Note: See Scale Check for additional details on performing a Scale Check.

A Deviation highlighted in Green indicates that the difference between the Expected Weight and the Measured Weight is within the acceptable recommended range of accuracy.

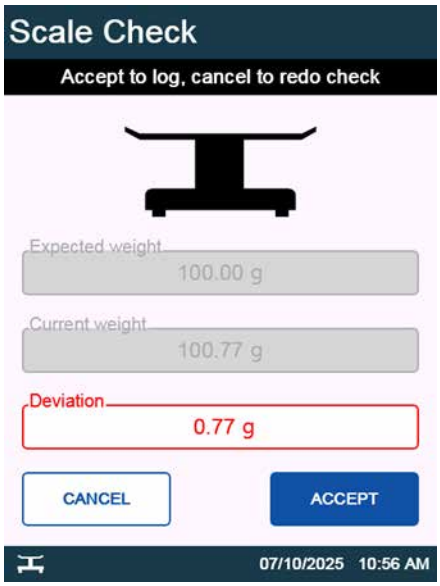


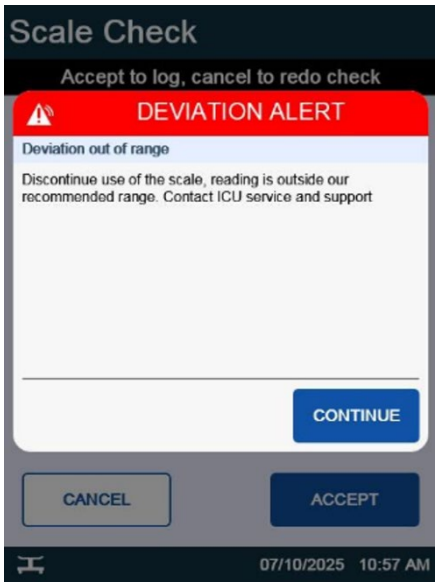
A Deviation highlighted in Yellow indicates that the scale reading is out of range. The "Deviation is out of range" warning message will appear. The user has the option to Accept the scale check or redo the check. It is recommended you discontinue use of the scale with deviations in this range. Please contact ICU Medical Service.





A Deviation highlighted in Red indicates that the scale reading is significantly out of range. The red "Deviation is out of range" alert will appear. Discontinue use of the scale with deviations in this range. Please contact ICU Medical Service.





Preparation Log

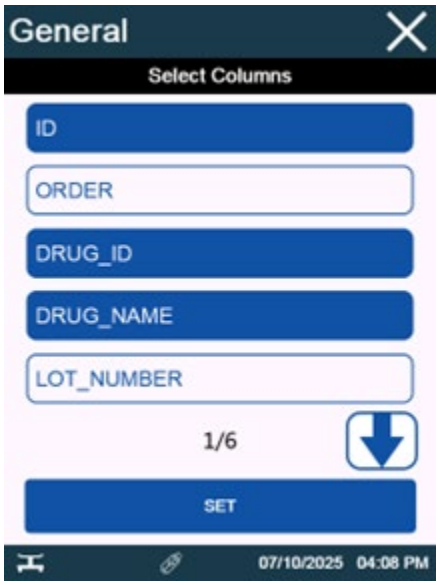
1. Insert a USB stick into the adapter.

   Note: See USB Adapter (DS1050) for detailed description of adapter.

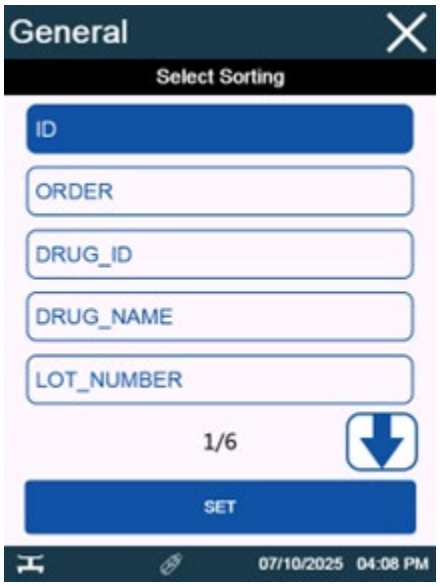
2. Insert the adapter into the pump unit USB adapter port.
3. Select Preparation Logs from the General settings menu.

4. Enter the timestamp (Day, Month, Year, Hour, and Minute) in the fields at the top to export preparation logs starting from and up to the specified dates. Select SET to save the timestamp.

5. Tap the Columns field and select the categories to export in the preparation logs. The user can select a minimum of 2 categories and maximum of 4 categories to display as columns. Select SET to save the selection.

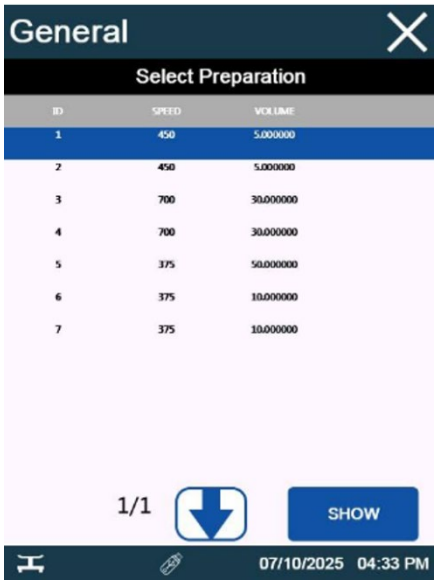


6. Tap the Sort field and select the category to sort the preparations logs by.

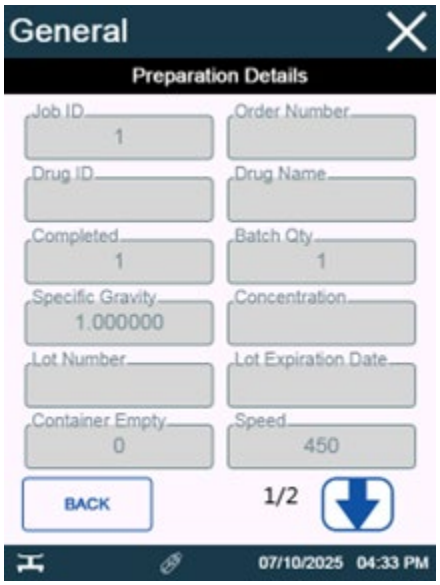


7. Select Ascending or Descending to set the order the preparations are sorted by.

8. Select Export Filtered Logs to export the preparations within the specified timeframe onto the USB. Select Export All Logs to export all preparations in the database onto the USB.
9. Select Show to display a list of the preparations from the specified timeframe.



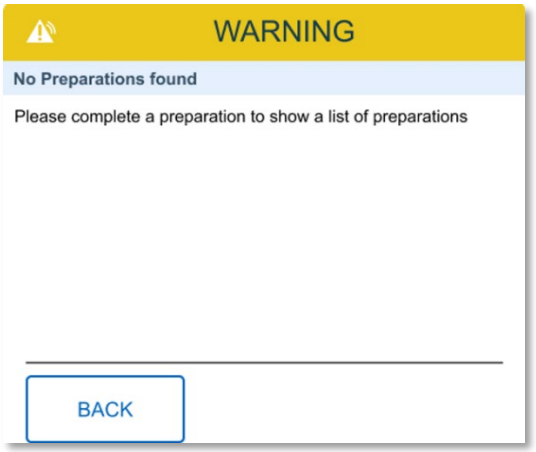
10. From the list of preparations, the user can tap a specific row and select Show to display the preparation details. Use the up and down arrows to scroll through the list of preparations.



11. Remove the USB and adapter from pump unit once completed with exporting preparation logs.

    Note: Log file saved in CSV (Commas Separated Value) format.

    Note: If no preparations exist in the entered timeframe, the following message will appear when requesting the logs:



Password

To change the current User's Password:

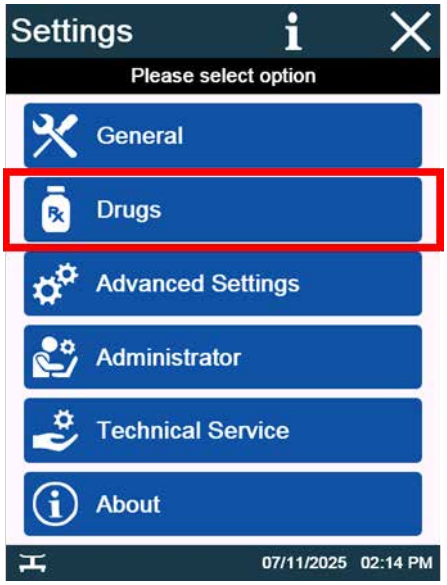
1. Enter the Current Password, New Password, and re-enter the new Password in the Confirm Password field.

Tap **Set** to save the new password.

Drugs

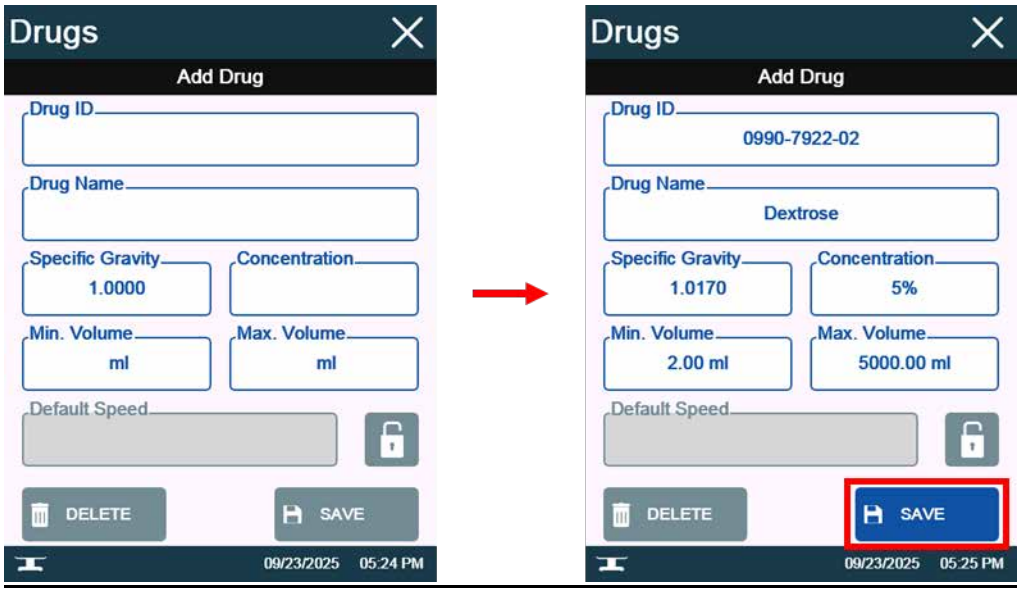
Add Drug

Note: Drug Name and Drug ID are required fields to save a new drug. Save button will not be enabled until a Drug Name and NDC are entered.



To add a new drug:

1. Select Add Drug from the Drugs Settings menu.
2. Enter the Drug information in the specified fields.

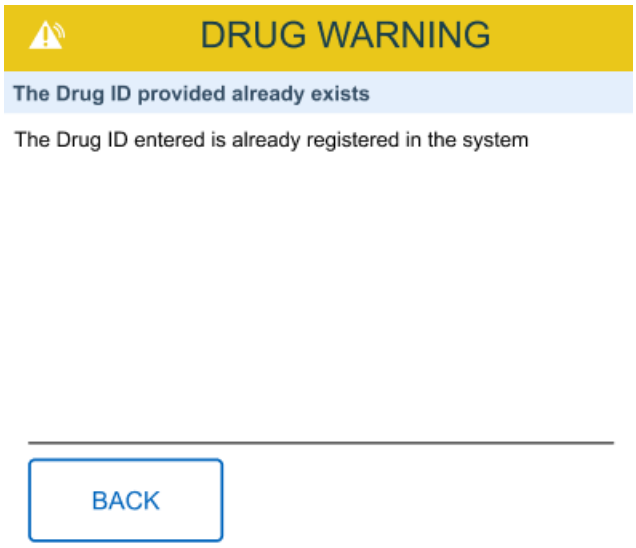


3. Drug Name Specifications
   - May be a combination of alphanumeric characters.
   - Up to 100 characters allowed, but using less than 20 characters is recommended for readability on the device.
   - The recommendation is to include name and concentration as part of Drug Name entered.
4. Drug ID Specifications
   - May be a combination of alphanumeric characters and special character "-".
   - The recommendation is to use numbers only.
   - May not enter NDC that is already saved in the database.
   - Up to 100 characters allowed, but using less than 20 characters is recommended for readability on the device.
   - The recommendation is to adhere to FDA standard formats for 10-digit numeric NDCs.
5. Once the user identifies the Drug Name and Drug ID information, add missing information for Specific Gravity, Concentration, Minimum Volume, and Maximum Volume if required.

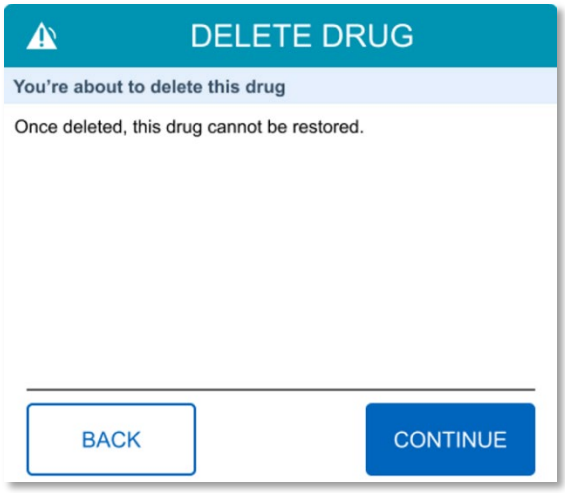
   Note: Default Speed is not available for the current Software Version.

6. Verify the correct information is entered in the designated fields and tap Save.

Note: When adding a new drug, you must use a Drug ID that does not already exist in the system. If the Drug ID already exists, the user can modify the drug information by using the Search Drug ID setting.



7. To delete the drug from the System, select the drug and press the **Delete** button. The user must confirm the deletion on the pop-up message by pressing Continue.



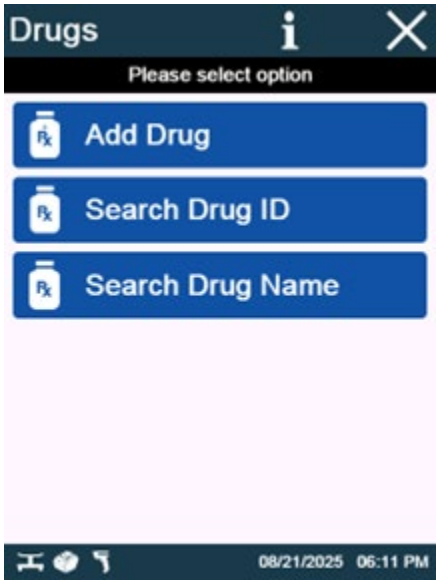
Search Drugs

Notes on Drug Database:

- The System includes a pre-loaded default drug list, the drugs listed are a sub-set of the full FDA drug database. The System drug list includes only drug name and NDC code from the FDA drug database.
- The System default drug list was chosen based on selecting drugs that match the intended use of the System. If a drug is not in the database provided, it can be added using the "Add Drug" functionality. See Add Drug for details on how to use the “Add Drug” feature.
- Follow manufacturer and facility protocols for any drug added to the database.
- Default drug list is not translated when System language is changed from English (drug names remain in English).

To Search or modify a drug:

1. Select Search Drug Name or Search Drug ID from the Drugs Settings menu.

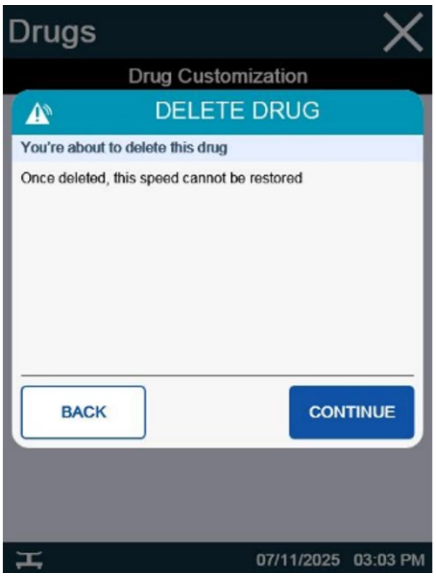


2. The user can search by Drug Name or Drug ID. Enter the Drug Name or Drug ID using the on-screen keyboard. Press the List button and select the drug from the list.

Note: If the required drug does not exist in pump unit's database, then the List button will not be enabled and the user must add the new drug to the database.

3. After selecting the specified drug, the drug information will be displayed.
4. To modify the drug Information, select the designated fields and update the drug information using the on-screen keyboard.
5. Verify the correct information is entered in the designated fields and tap Save.
6. To delete the drug from the System, select the drug and press the Delete button. The user must confirm the deletion on the pop-up message by pressing Continue.

Note: Drugs from the FDA database **cannot** be not deleted. Only custom added drugs can be deleted from the system.



Advanced Settings

The Advanced Settings will allow the user to adjust various settings of the System. The Advanced Settings menu is shown in Figure 28. This menu is available only to authorized users with Advanced role privileges.

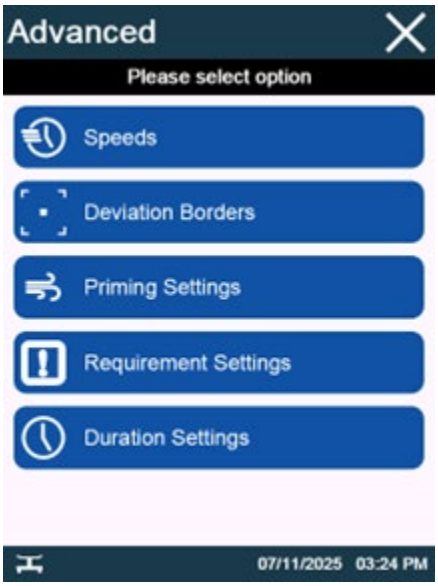


Figure 28: Advanced Settings

Speed Settings

The user of the System can modify the name or activation status of the speed settings of the pump unit in the Customization tab.

The System has 10 speed settings, and it allows the user to set each speed as Active or Inactive. The speed is measured in mL/min. Default speed settings are shown in the table below.

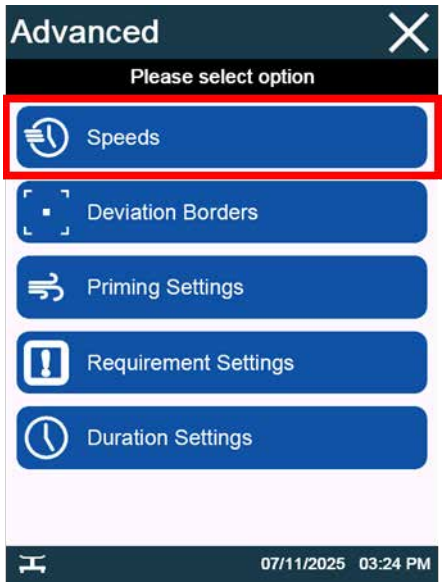
Table 12: Default Speed Settings

Number	Default Name	mL/min*	Backdraw (mL)
1	Minimum	70	
2	Slow	150	
3	Normal	450	
4	Luer Max	700	
5	16G Thick	375	0.5
6	16G Max	500	
7	18G Thick	100	0.5
8	18G Max	350	
9	Elastomeric	200	0.5
10	CADD	200	

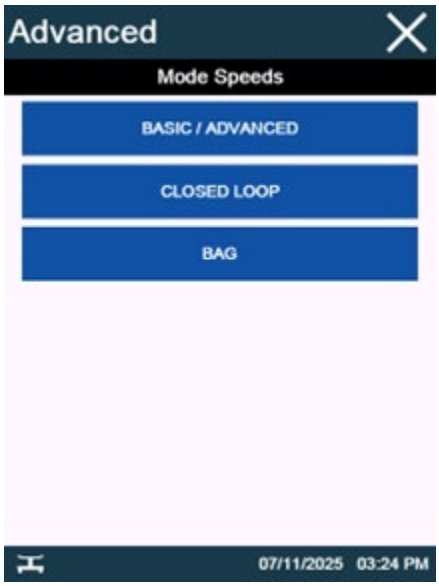
Note: The pump unit speed is not user-configurable; only named identified presets are available.

To Customize the speed settings:

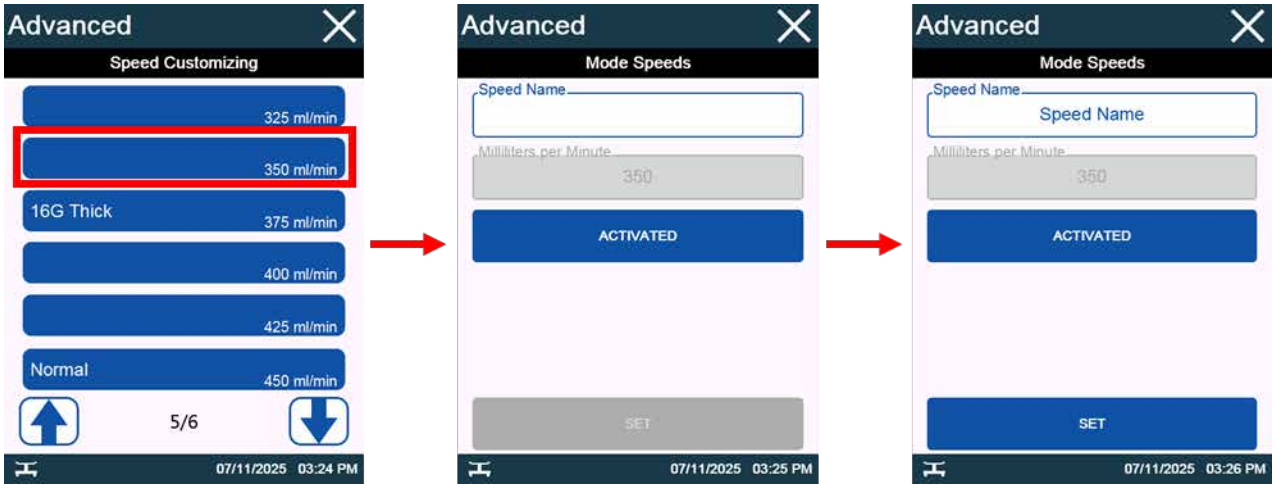
1. In the Advanced settings menu, press on the Speeds option.



2. From the list, select the mode(s) to view the Speed settings.



3. Change the name or activation status of a speed setting by selecting a speed from the list.



Note: Active speed settings are shown with Blue shaded number next to the speed name.

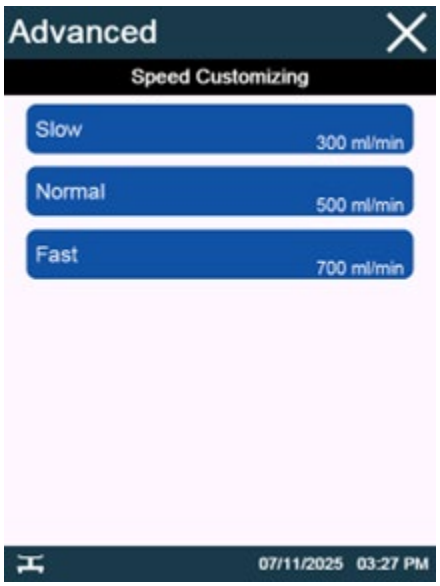
4. Select a Speed Name to change it. Press the blue button to Activate or Deactivate the speed setting. Press Set to confirm the changes.

Note: At installation, the pump unit defaults to setting “Normal” (450 mL/min) for all drugs.

Note: If the setting “Normal” (450 mL/min) is deactivated, the next active speed will be used as the default.

Note: The user will be able to select activated speed settings, using the names the user customized, for calibration and fluid transfers.

Note: Bag mode only has three customizable speeds available: Slow (300 mL/min), Normal (500 mL/min), and Fast (700 mL/min)



Deviation Borders

Deviation Borders apply only to Advanced mode when using the Connected Scale. After compounding is complete, the system will display the percentage of deviation based on the Expected Weight and Measured Weight of the final filling. Authorized Users can adjust the Deviation border percentages in order to define which accuracy range a final filling is categorized in, according to facility protocol.

The default Deviation Border percentages are as below:

- The deviation is shown in GREEN (Acceptable) if the deviation percentage is ±2.99%.
- The deviation is shown in YELLOW Value (Out of Range, but optional for user to continue use) if the deviation percentage is ±4.99%.
- The deviation is shown in RED Value (Out of Range, Stop Using Scale) if the deviation percentage is ±5.00% or greater.

To adjust the Deviation Border percentages:

1. Tap the '+' and '-' buttons to increase or decrease the border value for the Green, Yellow, and Red range.

Figure 29 displays the default Deviation Border values.

Figure 29: Deviation Borders

Priming Settings

The User can manually adjust the volume for priming the tubing set. Select Priming Settings from the Advanced Settings menu.

The Priming Volume (mL) field sets the priming volume for all standard-length tubing (PA01, PA01LL, BX01, BX01LL). This will be the default priming volume for Advanced mode and Closed Loop mode.

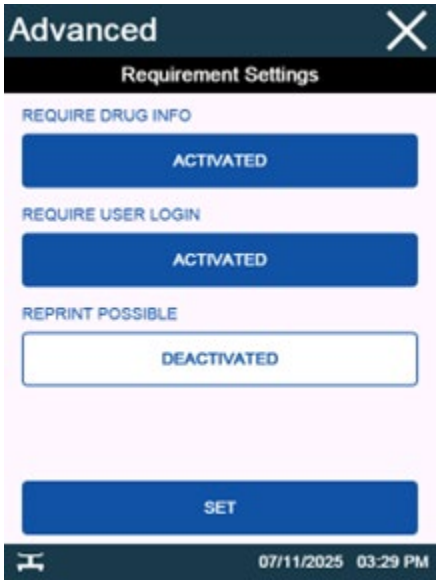
The Priming Volume Short Set (mL) field sets the priming volume for all short length tubing (PA01-XS). This will be the default priming volume for modes with air removal features, CADD mode and Bag mode.

There are two ways to set a custom Priming Volume:

1. Select the intended priming field and enter the desired volume using the on-screen keyboard. After entering the new value, press Set.
2. Tap the '+' or '-' buttons to increase or decrease the volume by 1 mL. Press Set to save the value.

Note: Reference the tubing set packaging to use the specific priming volume that corresponds to the tubing set. Otherwise, 27mL is the recommended priming volume for standard length ICU Medical tubing sets.

Requirement Settings



Require Drug Information

The System allows a user to require the presence of drug information before compounding begins. This aids in the proper documentation of the liquid being transferred.

Note: By default, Require Drug Information is set to Activated.

To enable the Require Drug Information option:

1. Press the box below Require Drug Info in the Requirement Settings section so that the box is highlighted in blue and states “Activated”.
2. Press Set to save the configuration.

Require User Login at Startup

The authorized user with Advanced role privileges can require a user login on the pump unit.

See Power On and Initial Setup for details on adding a user with Advanced privileges after first start-up of the pump.

Note: Upon first power up, **Require User Login** at startup will default to Deactivated.

To require Login at Startup:

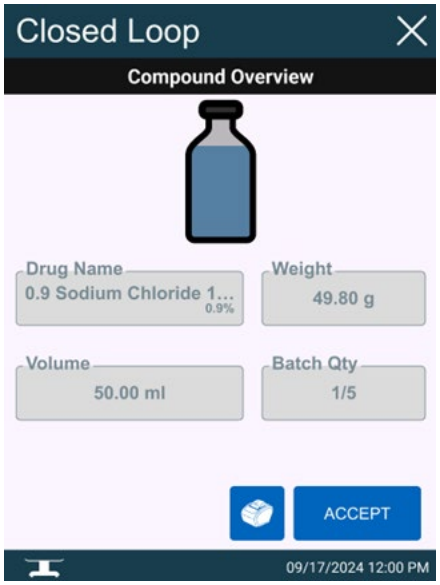
1. Press the box below Require User Login in the Requirement Settings section so that the box is highlighted in blue and states “Activated”. Tap the box again to disable the setting.
2. Press **Set** to save the configuration.
3. Once activated, the user login will be required each time the pump unit is powered on.

Reprint Label Screen Enable

The System allows the user to reprint preparation labels. The **Reprint Possible** feature defaults to Disabled.

To allow users to Reprint Labels:

1. Press the box below Reprint Possible in the Requirement Settings section so that the box is highlighted in blue and states “Activated”.
2. Press Set to save the configuration.
3. After completing a transfer in Closed Loop, Advanced, CADD, or Bag mode, a **Printer** button ( ) will be available on the Compound Overview screen to re-print the label. By selecting the **Printer** icon, the user will have the option to re-print the labels that are currently set to print.



Duration Settings

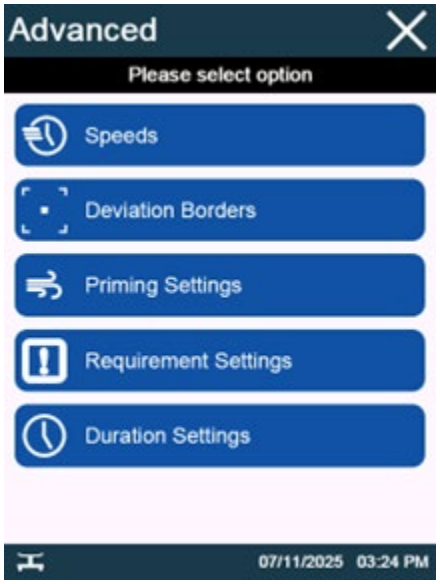
Transfer Complete Duration

A timer can be set for how long the display of the finished filling operation should be displayed.

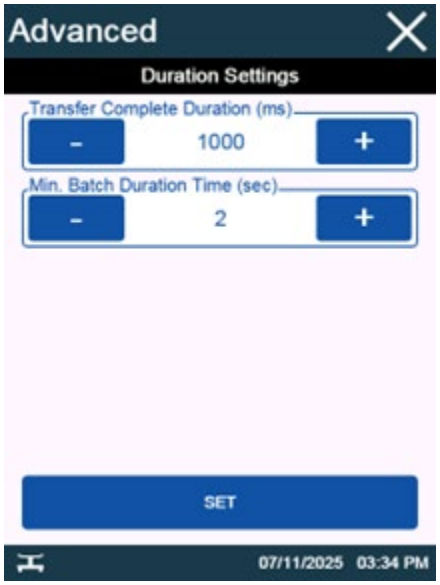
Note: This time adjustment can only be done after an authorized user enters the password to access the **Advanced Setting** menu.

To adjust the Transfer Complete Display Interval:

1. Select Duration Settings from the Advanced Settings menu.



2. On the Transfer Complete Duration (ms) field, use the "+" and "-" buttons to adjust the desired time-out interval. The interval can be set between 100 and 2000 milliseconds.

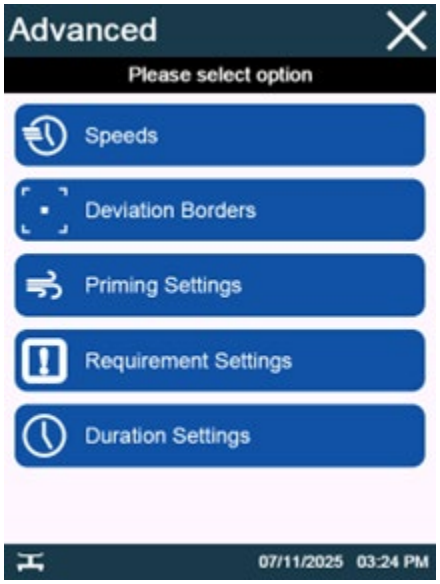


Batch Duration Time

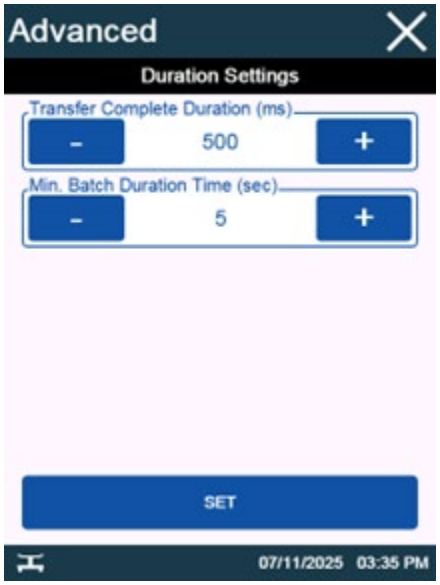
The user can set a minimum Batch Interval time in which a timer counts down between batch transfers. The minimum interval time can be set between 1 and 10 seconds.

To adjust the Minimum Batch Interval Time:

1. Select Duration Settings from the Advanced Settings menu.

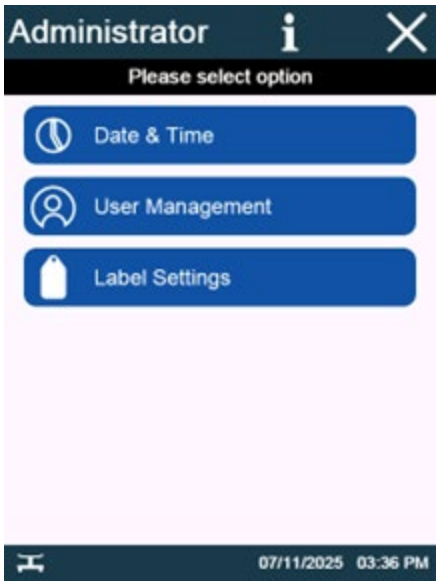


2. On the Min. Batch Duration Time (sec) field, use the "+" and "-" buttons to select the minimal time value in seconds. The interval can be set between 1 and 10 seconds.



Administrator

The Administrator Settings will allow the user to adjust various settings of the System. These are available only to authorized users by entering an administrative password.



Date and Time

The user can update the date and time of the pump unit under the Administrative Settings Menu. Enter the current date and/or time and press Set as in Figure 30.

Note: The time can be set in 12 hours interval or 24 hour interval.

Note: It may take several seconds for the pump time to update after saving.

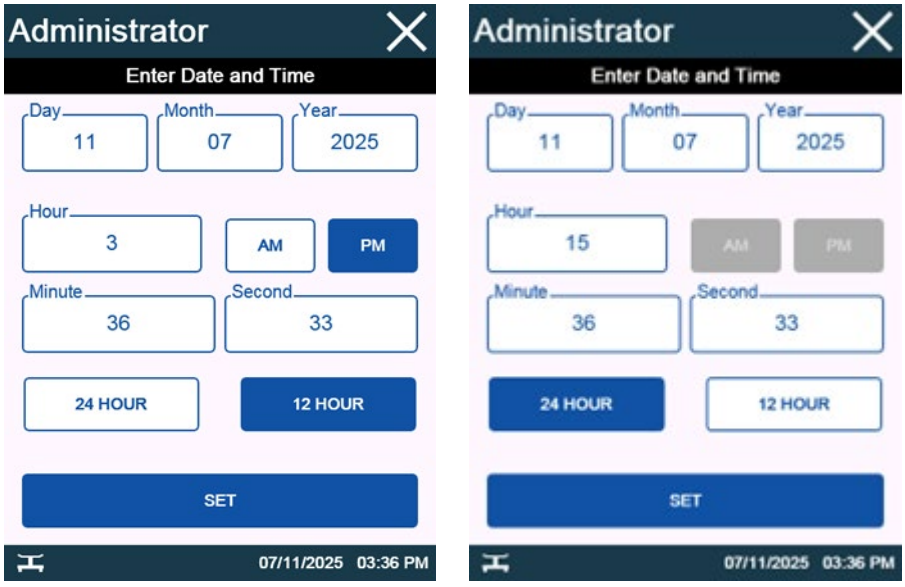


Figure 30:Date and Time

User Management

User Management involves the creation of individual or group accounts for the people on the team. When an account is created, it can have up to four levels of permission:

- General (Access to Language, Screen & Volume, Version Information, Scale Check, Preparation Logs, and Password Settings).
- Drugs (Access to Add Drug, Edit Drug Settings)
- Advanced (Access to Speeds, Deviation Borders, Priming, Requirement, and Duration Settings).
- Administrator (Access to Date & Time, User Management, and Label Settings).

Note: All users will have general role privileges.

Note: It is recommended that each user creates an individual account, rather than group account, to better track preparations.

To support the creation of accounts, the system comes with a default account named “Administrator.” It is recommended that accounts be managed through the “Administrator” account. The “Administrator” account has the General and Administrator level of permissions.

Note: See Power On and Initial Setup for details on creating new accounts upon first start up using the preset Administrator account.

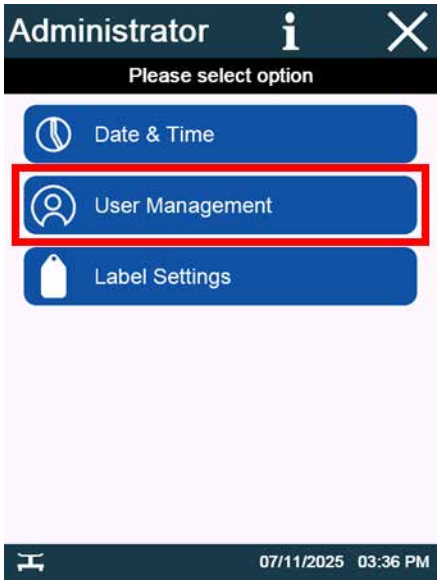
The default setting on the pump unit does not require user login upon power on. The user login settings can be updated by an authorized user. Once activated, the user is prompted to enter the username and password when the System is turned on. Requiring User login can be set within the Advanced Settings menu.

To Add a new User:

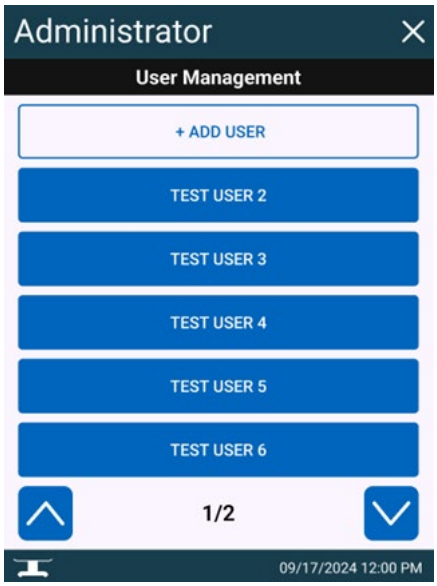
1. Ensure the current user is logged in under an account with Administrator Settings privileges.

   Note: See Power On and Initial Setup for details on logging in using the preset Administrator account.

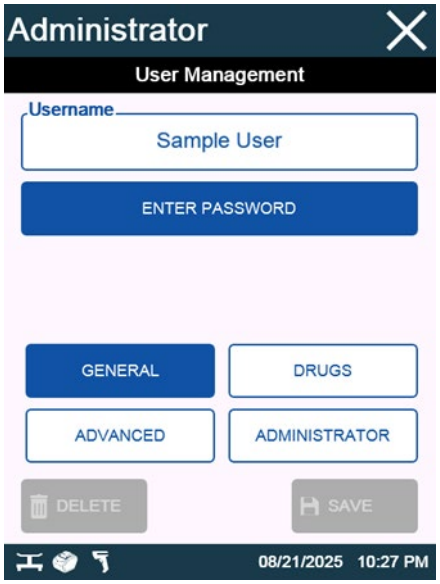
2. Select User Management from the Administrator Settings menu.



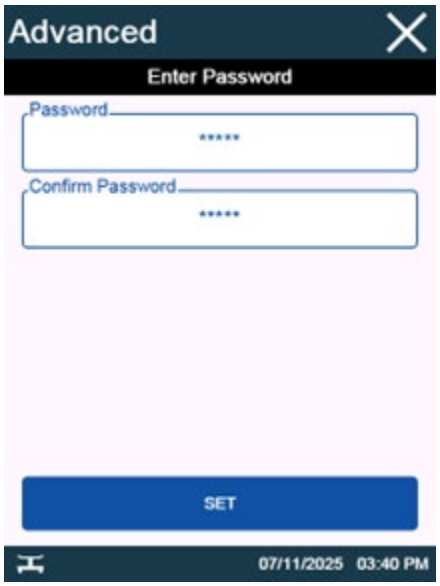
3. Select Add User.



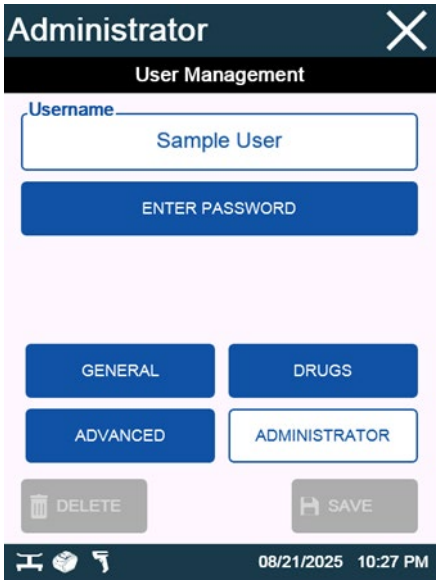
4. Enter a unique username in the Username field.



5. Fill out the Password and Confirm Password field. Press Set to save the password.



6. Select the role(s) that the user will have permission to access.



7. Press Save to confirm the user settings.

To activate User Login upon Startup:

1. Ensure the current user is logged in under an account with Advanced Settings privileges.

   Note: If the existing user accounts do not have these privileges, then an administrator must login using the preset Administrator account and create a new user with Advanced privileges. See Power On and Initial Setup for details on the preset Administrator account.

2. Select Requirement Settings under the Advanced Settings menu.
3. Select the box under Require User Login so that it is highlighted in blue and states Activated.
4. Select Set to save the configuration.

To Edit or Delete a User:

1. Select User Management from the Administrator Settings menu.
2. Select the intended user from the list.

3. To edit the user information, update the Username, Password, or role permissions and press Save to confirm the changes.
4. To Delete the user information, select Delete. On the Delete User message, press Continue to confirm deletion.

   Note: Once a user is deleted, the user information cannot be restored.

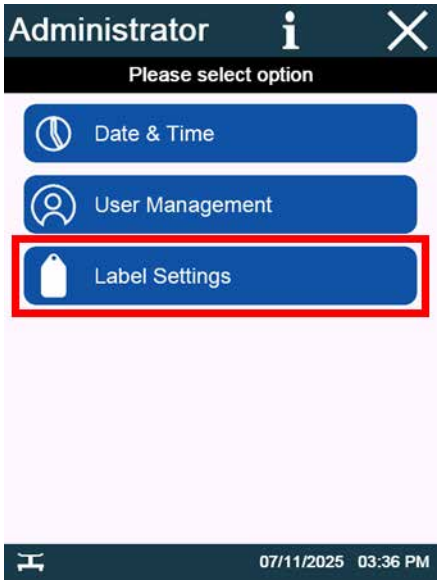
Label Printing

Label Settings are available to specify which modes will print labels and define the information to be printed.

Note: Labels are not printed for Basic Mode.

To access Label Settings:

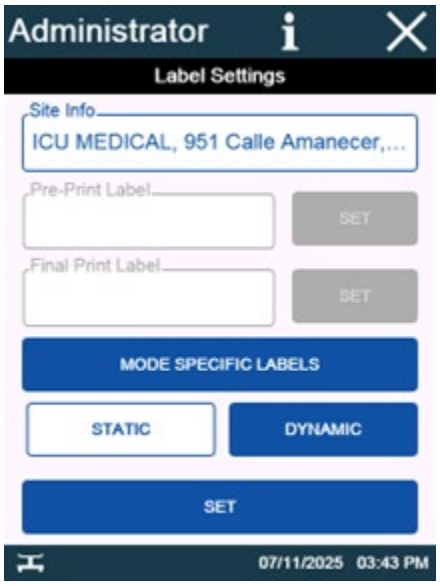
1. Select Label Settings from the Administrator Settings menu.



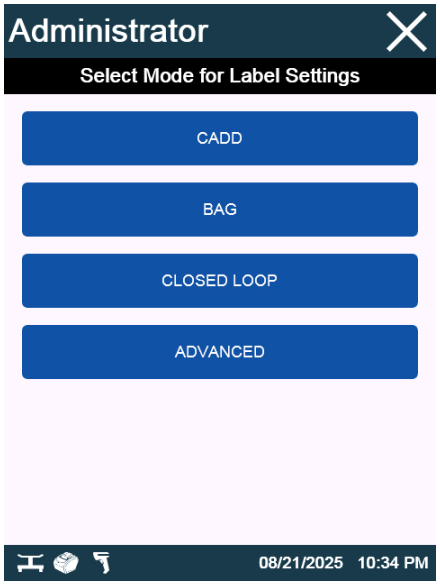
2. Select the Site Info field and enter the Site information using all four lines if including an address.

3. Static Labels:
   - The System will default to enable Static Labels. While Static is enabled, the same label settings will apply to all modes. Select Pre-Print, Final-Print, or both to indicate when a label should print.
   - Next to the Pre-Print Label and Final-Print Label fields, select Set to choose which label template to print for the corresponding field.

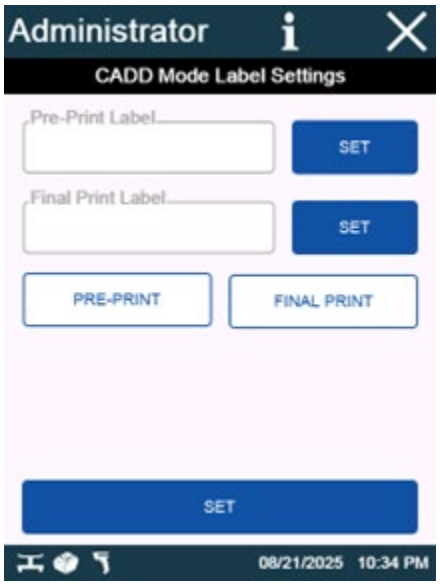
4. Dynamic Labels:
   - Select Dynamic to enable mode specific labels.



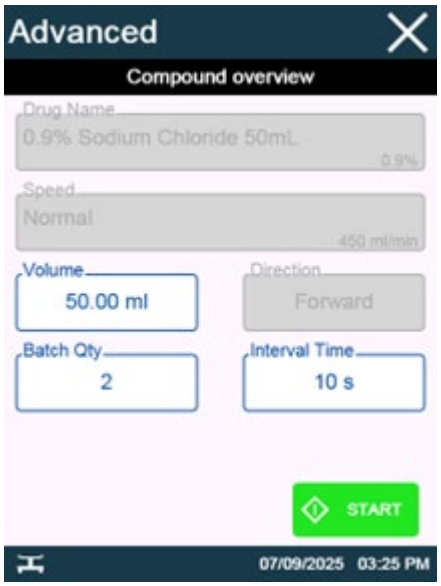
5. Select Mode Specific Labels.
6. Select the Mode from the list to specify the label settings.

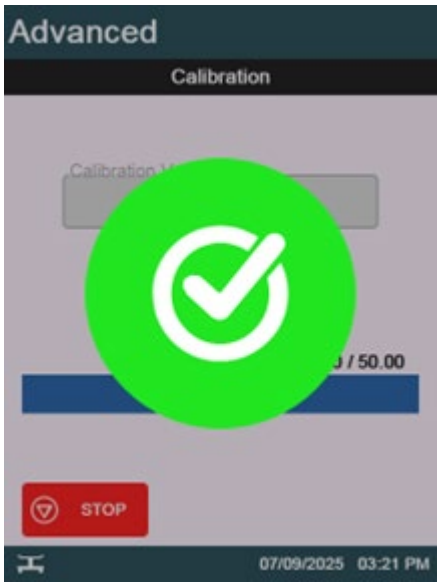


7. For each mode, enable or disable Pre-Print and Final Print labels. Then select the desired label from the list using the Set button next to the corresponding field.



8. Press Set at the bottom of the screen to save the inputs.

Print Selection	Description
Pre-Print Label	The Pre-print label will trigger when pressing START to initiate a transfer.  The Pre-Print Label will include the following information: · Site Information · Pump Serial Number · Date of Preparation · Timestamp when Label is printed · User · Drug Name · Drug ID · Drug Lot Number · Drug Specific Gravity · Lot Expiration

Print Selection	Description
	· Order Number · Transfer Speed · Transfer Direction · Scale Enabled or Not · Scale Calibrated or Not · Scale Calibrated Date · Order Volume · Batch Quantity · Scannable Barcode for Drug ID
Final-Print Label	The Final-Print label will trigger upon completion of the transfer when the white checkmark in a green circle displays.  The Final-Print Label will include the following information: · Site Information · Pump Serial Number · Date of Preparation · Timestamp when Label is printed · User · Drug Name · Drug ID · Drug Lot Number · Drug Specific Gravity · Lot Expiration · Order Number · Order Volume · Actual Volume · Use By Date/Time: _____ · Batch # (Current Batch/Total Batches)
Pre-Print and Final Print Label	A print label will trigger before and after completion of a transfer.

Technical Services

Technical Service menu item is for ICU Medical authorized personnel only.

Troubleshooting

Temperature Warning

The Pump Unit contains temperature sensors that are monitored to determine when the fans should be turned on to cool the unit. The system also has a maximum temperature limit. When the system approaches its limit, the warnings shown in Figure 31 will appear.

Note: When the left warning message appears, it is recommended to stop using the pump until the temperature cools down and the notification disappears. When the right warning message appears, it is recommended to stop using the unit for 30 minutes.

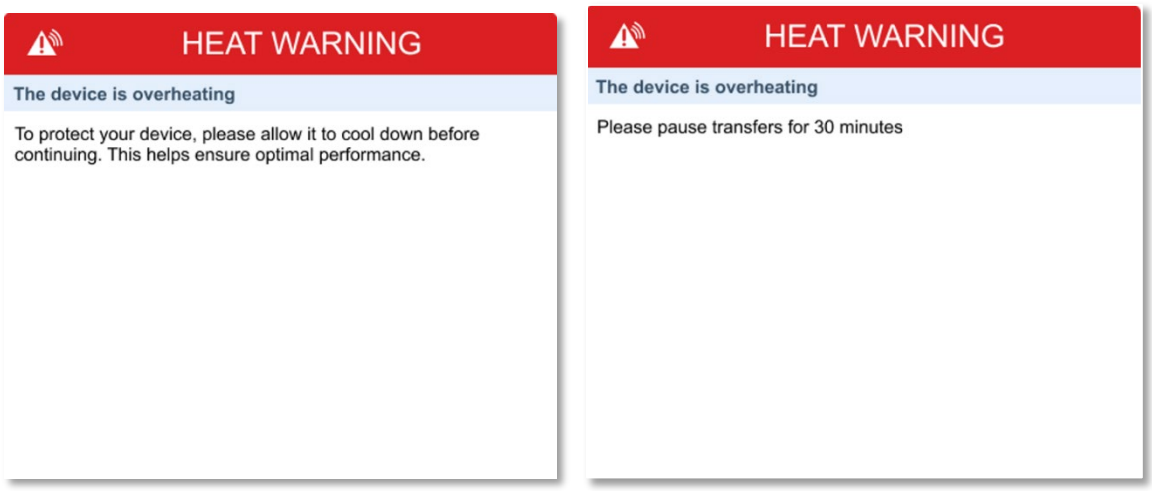


Figure 31: Temperature Warning - Pause Transfers

When the system temperature exceeds the maximum temperature limit, the warning shown in Figure 32 will be displayed. When the warning notification appears, it is recommended to shut off the pump unit for 30 minutes before using it again.

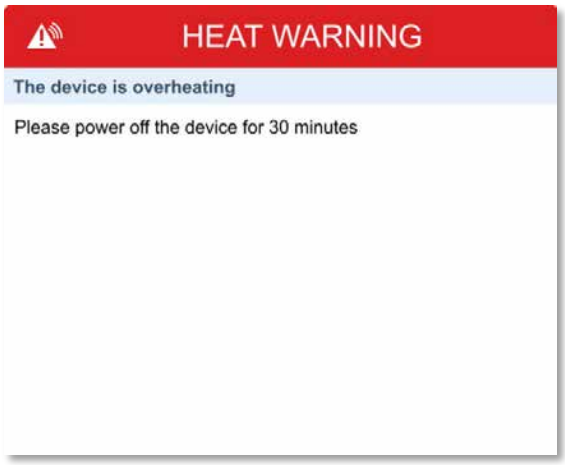


Figure 32: Temperature Warning - Power Off System

When these warnings occur, please check that the vents on the bottom of the pump unit are not blocked and that there is sufficient air flow around the unit. Also, ensure the system is operated in an environment that is within the Operating Temperature, Pressure, and Humidity limits listed in Environmental Specifications. If the warnings persist, contact ICU Medical Service for assistance.

Table 13: Temperature Limits

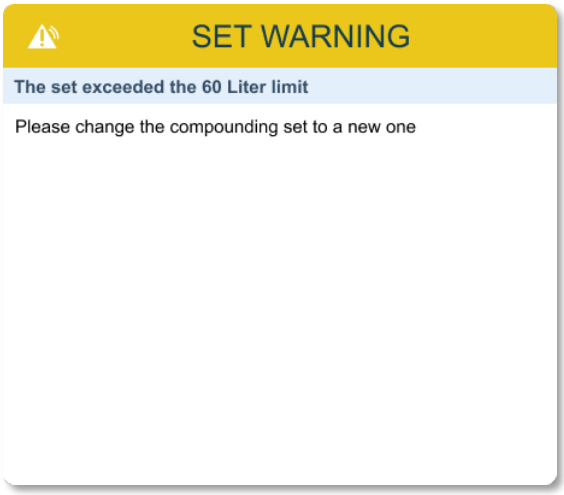
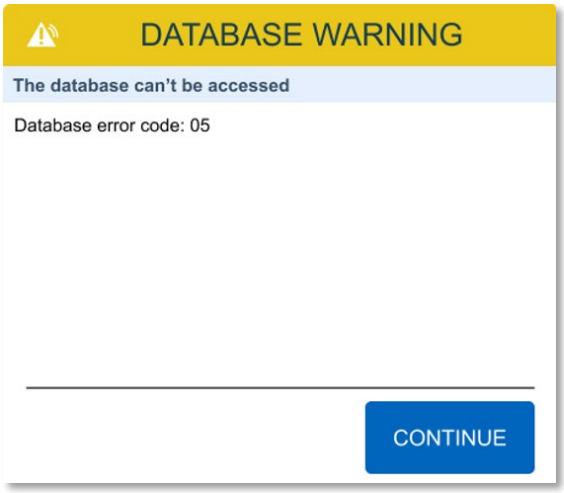
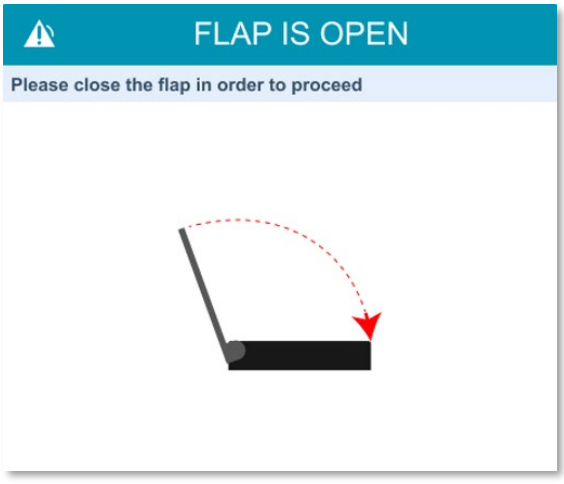
Run Time Variable	Setting
Max Temperature Limit	55° C
Recommended Cool Down Period	30 minutes

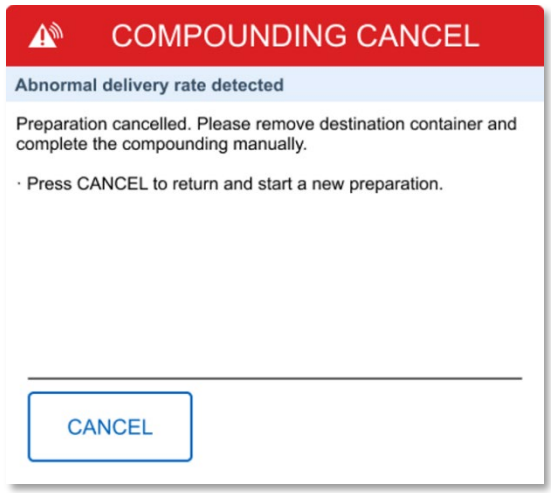
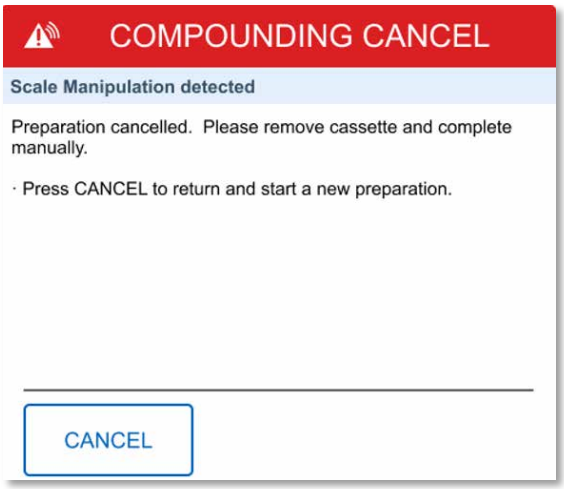
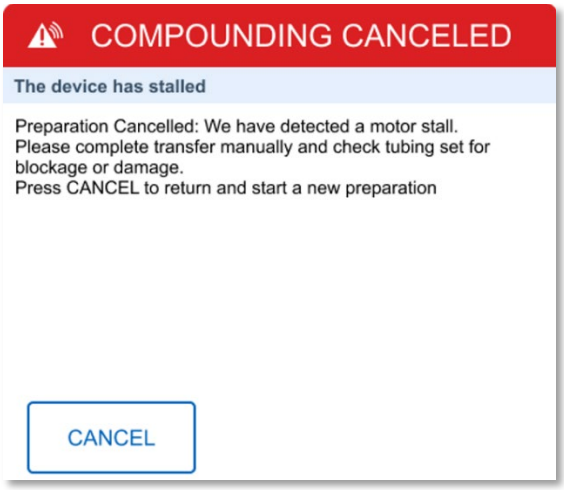
Note: Some metal parts may be warm after heavy use of the pump unit. The user should not use the pump unit for 30 minutes before transportation to allow the metal parts to cool.

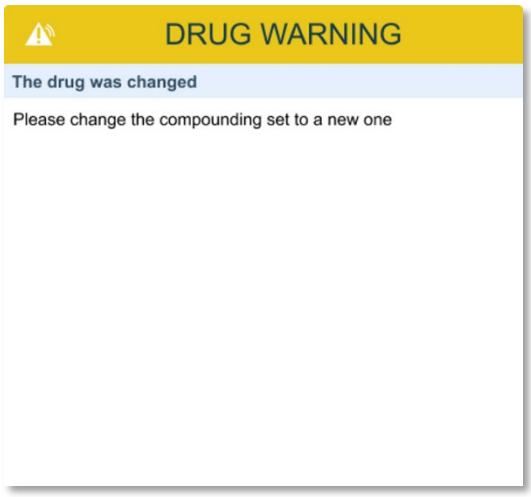
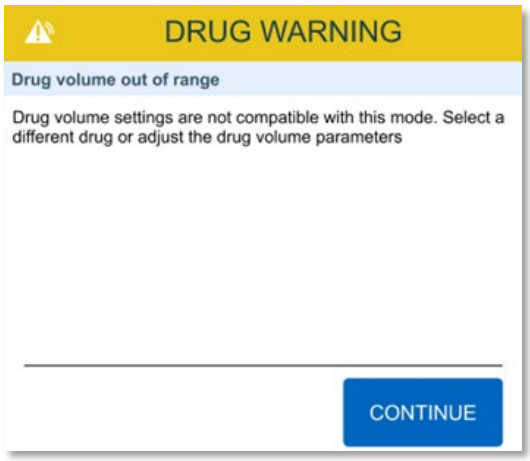
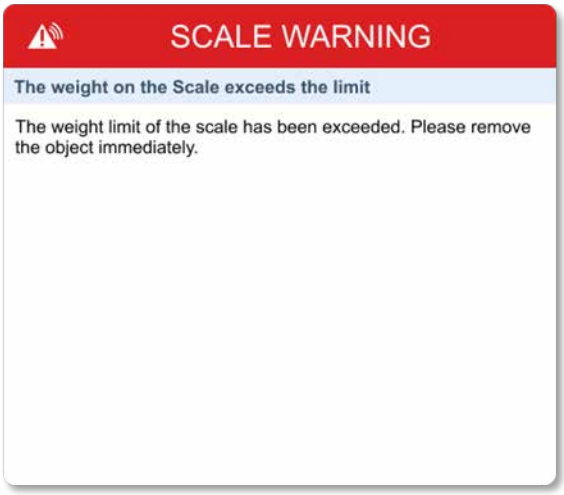
General Troubleshooting

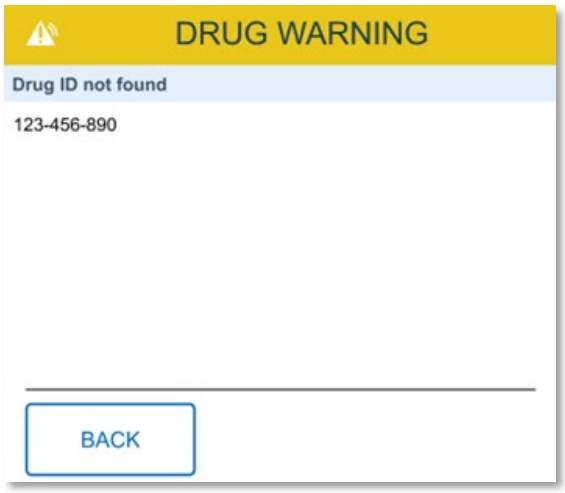
Table 14: General Troubleshooting

Description of Fault	Possible Causes	Solution
Silicone tubing herniates or balloons and prevents pumping of liquid	Using output containers with back-pressure (like containers used with ambulatory pumps or elastomeric pumps)	Use Heavy Duty tubing (BX series)
	Using smaller than 16 G needle	Switch to 16 G needle or reduce the speed of the pump unit to reduce the back pressure
	Using inline filter	Reduce speed to reduce back pressure
Tubing kicks out of the pump unit	Too much back pressure for the speed (use of needles, filters, or filling units)	Decrease back pressure or lower speed
	Tubing was not installed correctly	Remove tubing and re-install
Consistently inaccurate filling	Incorrect calibration	Use the calibration function
Inaccurate filling, not repeatable (varies)		Lower the speed
Does not pump and make loud grinding noise		Decrease back pressure (use larger needle or remove filter)
		Lower the speed of the pump unit
		Use “BX” series tubing
Pump unit display is dark		Check Power Cord and ensure connection
The pump unit providing alert to change compounding set	The tubing set has transferred that maximum recommended Liters of fluid	Insert a new tubing set Important: Ensure the pump is powered ON when changing the tubing set. The pump must be powered on to detect the new tubing and reset the fluid counter.

Description of Fault	Possible Causes	Solution
		
Database Error Messages 	System malfunction	Please contact ICU Medical Technical Support.
Flap is Open 	Flap is not fully closed.	Reinstall the tubing. Ensure tubing is securely installed and the flap makes contact with the top of the pump exterior.

Description of Fault	Possible Causes	Solution
Compounding Canceled: Abnormal Delivery Rate Detected 	The scale is detecting less weight than the expected weight	Ensure the container is positioned fully on the scale while transfer
	The output container is moved or removed from scale during compounding	Ensure the output container is centered and stable on the scale
Compounding Canceled: Scale Manipulation Detected 	The scale is detecting additional weight than the expected weight	Ensure there are not any additional items or tension pulling on the scale plate
Stall Detection: Compounding Canceled 	The motor has stalled potentially due to kinked tubing set, back pressure, or material build up blocking the rotation of the roller head.	Ensure there are no kinks in the tubing setting. Open the flap and examine the tubing set near the roller head. Replace the tubing set if there is any noticeable damage or material build up. Transfer at a slower speed and use a Heavy Duty tubing to minimize back pressure.

Description of Fault	Possible Causes	Solution
Drug Warning 	This indicates that the user has changed the Drug information on the Compound Details screen without inserting a new tubing set. This warning will only appear when 'Require Drug Info' is Enabled under Advanced settings.	Insert a new tubing set to transfer a new drug.
Drug Volume Out of Range 	The selected drug has restricted volume parameters that are out of range for the selected mode. The Drug's transfer volume parameters are set in the **Drugs Settings**.	To use the specified drug with the desired mode, a user with **Drugs Setting** privileges must change the Min. Volume and Max. Volume to be compatible with the mode's acceptable volume range. Navigate to **Settings** > **Drugs** > **Search Drug ID** or **Drug Name**. Select the specified Drug and modify the volume parameters.
Scale Warning 	The weight on the scale has exceeded 5,500 grams.	Please remove weight from the scale to avoid damage.

Description of Fault	Possible Causes	Solution
Drug Not Found 	The Drug Name or Drug ID does not exist in the Drug database.	Add the specified drug to the Drug Library by navigating to **Settings** > **Drugs** > **Add Drug**. Once added, the drug can be entered or scanned on the **Add Compound Details** screen.
System Error 	The system has detected an issue during startup that prevents further use.	Contact ICU Medical, Inc.

Database Error

This database error occurs when the pump unit software cannot read the database. The number in brackets indicates the error (Figure 33). If this error occurs, please contact a service technician immediately.

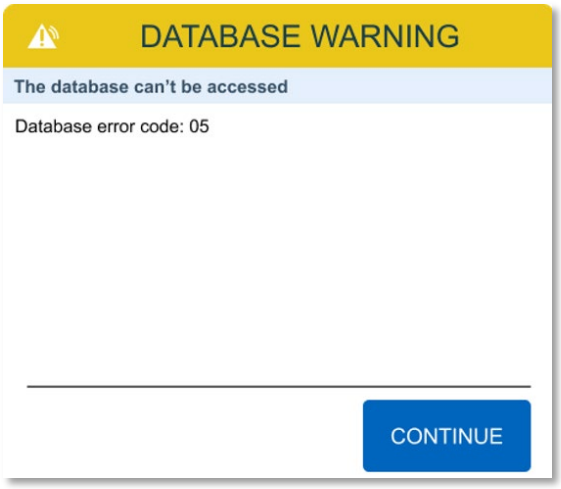


Figure 33: Database Error (05)

Specifications and Maintenance

All maintenance must be performed by an authorized ICU Medical representative except for routine cleaning and specifically excluded activities.

For more information on ICU Medical's service options, contact your ICU Medical sales or service representative, or call the Technical Service Center at: (800) 241-4002.

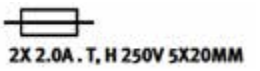
Accuracy Specifications

Important: Verify pump unit accuracy performance before use to ensure it meets facility protocols.

- Pump unit accuracy with Water/Isopropyl Alcohol at a Slow-speed setting using ICU Medical Luer-based components, 16G needle, or 18G needle:
- +/- 1% for volumes greater than or equal to 10 mL
- +/- 2% for volumes greater than or equal to 5 mL and less than 10 mL
- +/- 4% for volumes greater than or equal to 1 mL and less than 5 mL
- +/- 10% for volumes greater than or equal to 0.5 mL and less than 1 mL
- Pump unit accuracy with Lipids at a viscosity-specific speed using ICU Medical Lipids tubing set (Luer-based):
- +/- 10% for volumes greater than or equal to 5 mL
- The pump unit can provide a sustained transfer rate (measured with Water) using ICU Medical tubing set:
- 700 mL/min ("Fast" default speed) with Luer-based sets
- 560 mL/min with 16G needle
- 150 mL/min ("Slow" default speed) with 18G needle

Environmental Specifications

Table 15: Environmental Specifications

Reference	Specification
Operating Temperature	+10°C to +40°C
Operating Humidity	15% to 60% (non-condensing)
Operating Altitude	0 to 2000 meters above sea level
Storage Temperature	0°C to +60°C
Storage Humidity	15% to 85% (non-condensing)
Storage Altitude	0 to 2,000 meters above sea level
Transportation Temperature	0°C to +60°C
Transportation Humidity	15% to 85% (non-condensing)
Transportation Altitude	0 to 2,000 meters above sea level
Physical Dimensions	5.7 in x 9.8 in x 8.6 in (145 mm x 249 mm x 218 mm)
Weight	11.2 pounds (5.09 kg)
Electrical Operating Power Range	100 – 240 V AC 0.8 A – 0.4 A 50 – 60 Hz
Electrical Fuse	

Lithium-Ion Coin Battery Service

Important: The pump unit relies on a 3-volt Lithium battery (CR2032). Service on the battery is recommended to be done only by an authorized ICU Medical Representative. Incorrect insertion of the Lithium-ion battery may result in damage of the pump unit.

The battery indicator () will appear on the bottom panel when the lithium-Ion coin battery requires service as shown in Figure 34. If the battery indicator icon appears, please contact ICU Medical, Inc. for service. See Service and Contact Information.

Figure 34: Lithium-Ion Coin Battery Replacement

Fuse Replacement

The pump unit uses two fuses located in the rear of the pump unit (Figure 35); fuses are a part of the Power Inlet (See PharmAssist Pro Description for illustration of location).

Figure 35: Fuse Replacement

Service on the fuses can be performed by the end-user (end-user buys the fuses from local hardware/electrical store).

The Fuse type to be used is ceramic fuse model number T2AH250V.

Important: Incorrect insertion of the fuses may result in no power to the pump unit.

To replace the fuse:

1. Make sure the pump unit is powered-off and the power cord is unplugged.
2. Use a flat head screwdriver to remove the fuse holder from the Power Inlet by turning the fuse holder in a counterclockwise direction.
3. Remove the old fuse(s) from the holder and replace them with new fuse(s). It is recommended to replace both fuses at the same time.

4. Re-insert fuse holder back into Power Inlet and rotate the fuse holder in a clockwise direction gently until it stops. Be careful when threading the fuse holder back into the pump unit to avoid damaging the fuse holder or Power Inlet.

Tubing Replacement

The System will display the warning shown in Figure 36 if a tubing set has compounded more than 60L of fluid. When the user replaces the tubing set, the workflow may continue.

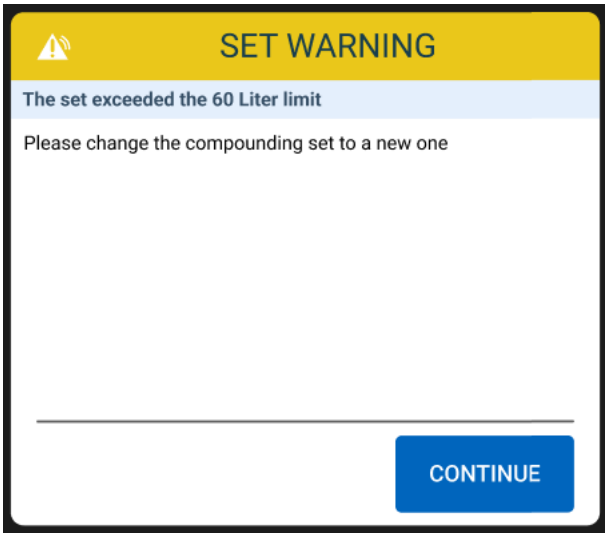


Figure 36: Tubing Replacement

Note: This warning will continue to be displayed even if the pump unit is turned off and then on again.

Duty Cycle

For best performance of your system, it is recommended to allow the Pump Unit a 30-minute cooldown period after:

- 8 hours of continuous fluid transfer
- Pumping 240 liters of fluid

The Pump Unit can remain on but should not be actively transferring fluid during the 30-minute cooldown period.

Pump Unit Software Update

Note: The USB sticks and adapters must be requested from ICU Service personnel.

Note: This Software Update Procedure is only for updating pumps from Version 2.2.1.5 to Version 3.0.

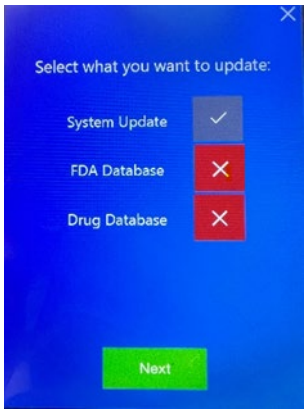
The folders drp / update can be found on each of the USB sticks to update the pump unit software.

Note: Carefully read the instructions before starting the Software Update Procedure.

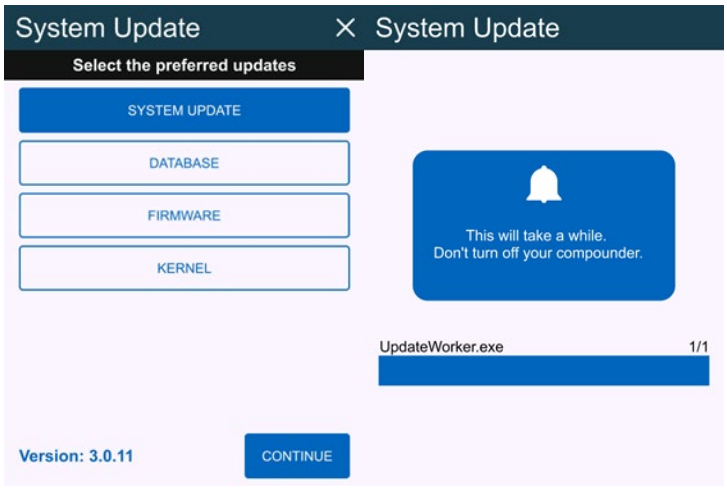
Steps to Complete the Pump Unit Software Update:

1. Obtain the USB stick and adapter.
2. Turn on the pump unit and wait for it to completely power on.

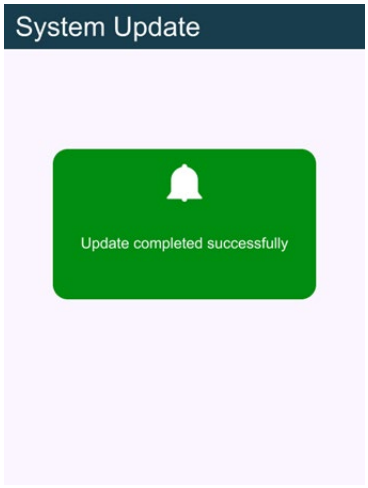
3. Insert the USB stick with the update on it into the designated port on the back of the pump unit (adapter cable required).
4. Wait for the Update screen to appear. Ensure only System Update is selected. Press Next.



5. The System Update screen below will appear. Press **Continue**.

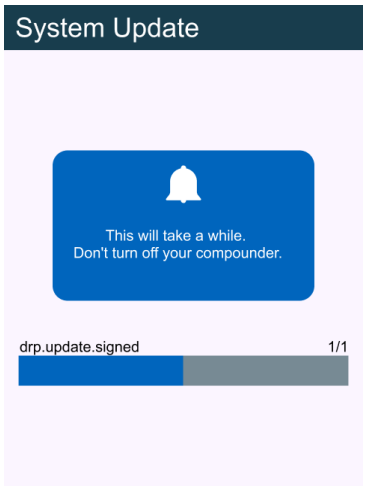


6. When the update is complete, the screen will briefly display a green message indicating "**Update Completed Successfully**".

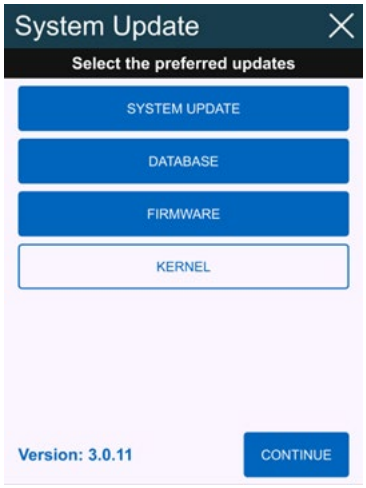


7. The 3.0 Upgrade is now ready to proceed by pressing **Start Update**.

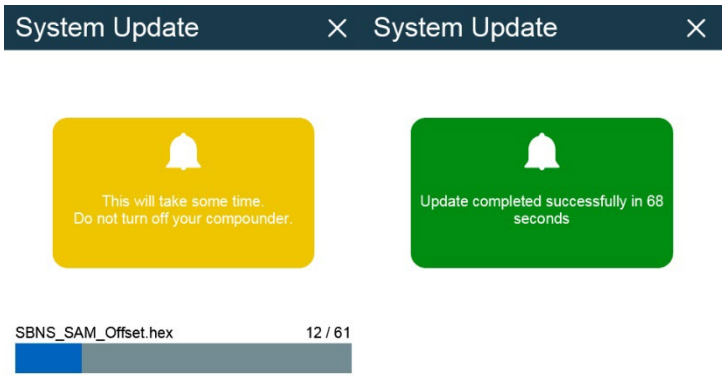
8. Wait for the process to complete. This may take some time.



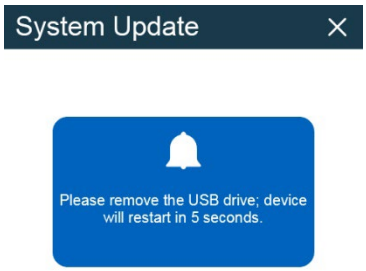
9. After the process has been completed successfully, the **System Update** screen will appear again. Ensure **System Update**, **Database**, **Firmware** are all selected. Press **Continue**.



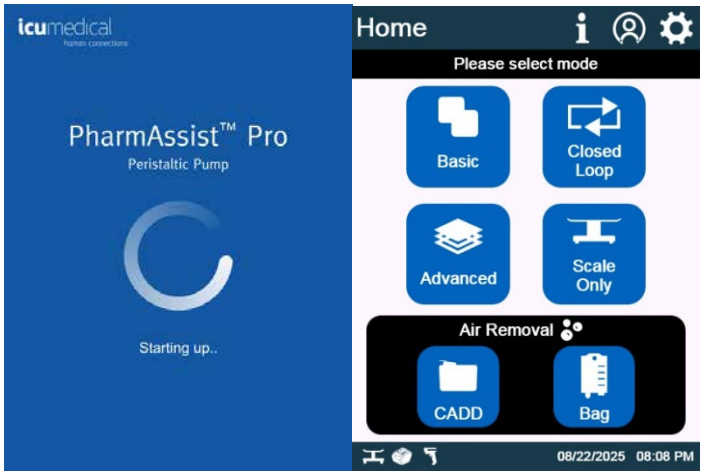
10. When the update is complete, the screen will briefly display a green message indicating "**Update Completed Successfully**".



11. The message below will automatically appear, indicating “Please remove the USB drive; device will restart in 5 seconds”. Remove the USB drive.



12. Wait for the device to fully start up and display the Home screen.



13. The pump unit has now successfully completed the System Update.
14. To verify the Software Version, select the Settings icon from the Home screen. Then navigate to General > Version Information.

If a red error screen displays, then the Software Update was not successful. Please contact ICU Medical, Inc. for assistance

Transport

Please note that some metal parts may be warm after heavy use of the pump unit. The user should not use the pump unit for 30 minutes before transportation to allow the metal parts to cool. However, the pump unit should remain switched on during the cooling phase.

Service and Contact Information

For customer service, technical assistance, product return authorization and to order parts, accessories, or manuals contact ICU Medical Technical Support Operations nearest the user:

ICU Medical, Inc.
951 Calle Amanecer
San Clemente, CA 92673
(866).829.9025
(949).366.2183

ICU Medical Germany GmbH
Altenaer Str. 136
58513 Lüdenscheid
Phone: +49 2351 9548 26
Fax: +49 2351 9548 20

Warranty and Service Information

Limited Warranty

ICU Medical warrants the System to be free from defects in material and workmanship for one (1) year from the date of delivery, when operated in accordance with the User Manual. Sensors and accessories are warranted to be received in good condition, and ICU Medical agrees to accept return if found defective upon installation, provided that ICU Medical is notified within five (5) days from initial installation and the items not deemed ineligible for warranty under the conditions and exclusions from warranty listed in this manual. ICU Medical cannot honor warranty claims due to damages resulting from transport.

This warranty extends to the designated original purchasers of the equipment from ICU Medical and will not extend to any subsequent purchaser. This warranty shall not apply where: service is required due to purchaser's failure to operate or maintain the equipment in a manner consistent with the specifications and guidelines set forth in the User Manual; service is required due to misuse or unauthorized service; unauthorized accessories or parts are used with the System; or where the equipment is found to be functioning within the published specifications. This warranty includes repair or replacement of components that do not function as intended during the term of this warranty. Warranty components or assemblies shall be of equal or better quality than the component or assembly replaced. Such components replaced by ICU Medical become the property of ICU Medical.

This warranty is extended to original purchasers of the equipment from ICU Medical in lieu of all other warranties expressed or implied and all other obligations or liabilities on the part of ICU Medical, and no person, agent, or dealer is authorized to give any warranties or to assume any other liability on behalf of ICU Medical. For ICU Medical to properly administer the warranty, the purchaser must notify ICU Medical promptly after the occurrence or discovery of any alleged failure.

Disclaimer of Warranties

THIS LIMITED WARRANTY IS PROVIDED IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, AND ICU MEDICAL HEREBY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE AND NON-INFRINGEMENT.

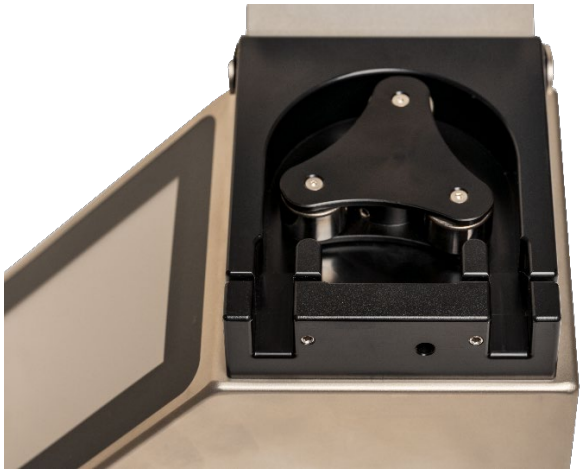
- Excluded from warranty coverage are damages resulting from:
- Incorrect connection of PharmAssist Pro unit or accessories.
- Unauthorized cleaning of the PharmAssist Pro unit or accessories.
- Transportation damages of any sort.
- Accident, fire, water, vandalism or causes other than ordinary usage.
- Misuse of the equipment or accessories.
- Disregard the user manual instructions.

Limitation of Liability

IN NO EVENT WILL ICU MEDICAL BE LIABLE FOR COSTS OF PROCUREMENT OF SUBSTITUTE PRODUCTS OR SERVICES, OR BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING OUT OF THIS WARRANTY, INCLUDING BUT NOT LIMITED TO LOSS OF ANTICIPATED PROFITS, EVEN IF ICU MEDICAL HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THESE LIMITATIONS WILL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

Appendix A: Cleaning and Disinfection of the PharmAssist Pro

Switch off the power supply of the pump unit. Spilled liquid and drops must be wiped promptly to avoid ingress into the pump unit. Use only lint-free cloths or swabs with cleaning and disinfection solutions. Do not use abrasives. Also clean the pump unit under the stainless-steel plate, including rollers when the System is turned off.



Following is a list of approved cleaning, decontamination, and disinfection agents approved for use with the System and scale.

Table 16: Approved cleaning, decontamination, and disinfection agents for the pump unit

Agent	Concentrations (water solutions)
Isopropyl Alcohol	Equal or less than 70.0% w/w
Peracetic Acid	Equal or less than 2.0% w/w
Hydrogen Peroxide	Equal or less than 7.5% w/w
SurfaceSafe	See Agent product labeling
HD Clean	See Agent product labeling
Peridox RTU	See Agent product labeling
Contec TB-1 3300	See Agent product labeling
PREempt	See Agent product labeling

Note: If the facility uses cleaning, decontamination, and disinfection agents not included on this list, please contact ICU Medical, Inc.

Cleaning and Disinfection of PharmAssist Pro Accessories

Foot Pedal Kit

The Foot pedal is made from Nylon plastic material; thus, it is suggested to clean it with an isopropanol wipe and sterile water only.

Printer

Reference the Zebra Manufacturer User Manual for guidance on cleaning and disinfecting Zebra Healthcare Printers.

Do Not Use: Abrasive cleaners or harsh chemicals like ammonia, bleach, acetone, or strong solvents, as these can damage the printer's surfaces.

Adhere to manufacturer guidelines and your facility's cleaning protocols for proper use of disinfectants and cleaning frequency to prevent the spread of infections.

Scale, Bag Holder, CADD Holder, & Syringe Holder

To clean the Connected Scale, Bag Holder, CADD Holder, or Syringe Holder, use only the approved cleaning, decontamination, and disinfection agents listed in Table 16. Spilled liquid and drops must be wiped promptly to avoid ingress into the scale. Use only lint-free cloths or swabs with cleaning and disinfection solutions. Do not use abrasives.

Note: If the facility uses cleaning, decontamination, and disinfection agents not included on this list, please contact ICU Medical, Inc.

Appendix B: Recommended Preventative Maintenance

1. ICU Medical recommends that the preventive maintenance (PM) listed below to be performed at least once every 12 months. Replace components as required by visual inspection and test results.
2. If using an ICU Medical connected scale, perfom the Scale Check (see section Scale Check). See Service and Contact Information for technical assistance.
3. Perform an accuracy test according to the user manual guidelines with the new tubing set. Use a scale or graduated cylinder to ensure the pump meets the stated accuracy. See Appendix C: Accuracy Verification Protocol for more instructions.
4. Inspect the rubber feet to ensure that the screws are tight and there is no visible damage or corrosion.
5. Inspect the touch screen cover for any holes or damage that may affect the touch functionality or screen visibility.
6. Inspect the lid screws are secure and free from corrosion or loosening.
7. Inspect/test tubing set sensor and ensure the adjustment screw is neither loose nor damaged.
8. Inspect the roller head orientation set screws to ensure they are secure and undamaged. See Service and Contact Information for assistance if any issues are found, as these should not be adjusted manually.
9. Inspect the roller head assembly for cleanliness, corrosion, or any build-up. Ensure there is no damage.
10. Inspect the ports at the back of the unit to ensure they are clean and undamaged.
11. Inspect/test power button to ensure it is securely attached, free from corrosion, and in good working condition.
12. Inspect the display screen to ensure it is working properly and that the screen is not damaged.
13. Inspect housing for any corrosion or damage that could affect the unit's performance.
14. If while performing the inspection or testing the customer finds that any of the tests or inspections find failure or issue, see Service and Contact Information for technical assistance.

Labels Inspection

Visually inspect the compounder labels at least once every 12 months.

To inspect the labels, see Figure 37, and proceed as follows:

1. Place the device on a flat, stable surface.
2. Confirm that the following labels are present (all labels are on the back of the unit):
   - Rating Label
   - Device Label
   - Port Label

Inspect the labels for legibility and peeling. To replace the label, see Service and Contact Information.

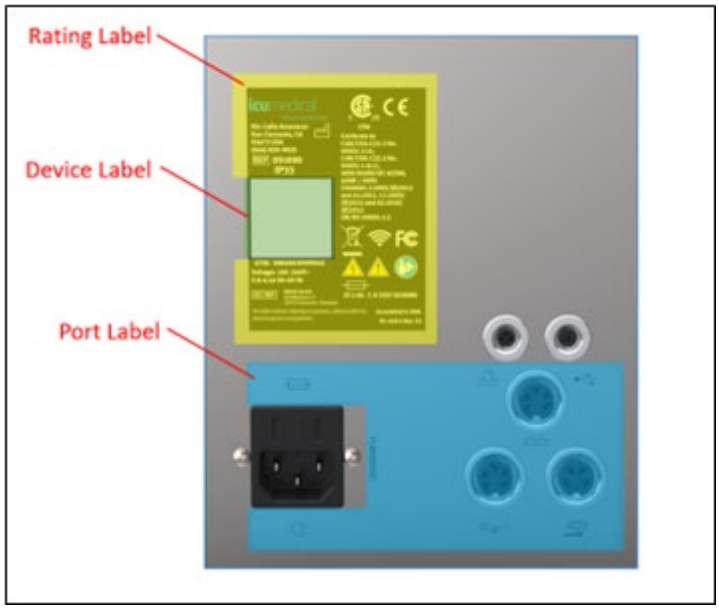


Figure 37: Label Inspection

AC (Mains) Power Cord Inspection

Inspect the power cord at least once every 12 months.

To inspect the power cord, proceed as follows:

1. Turn off the device and disconnect the device from AC (mains) power.
2. Remove the power cord from the device by pulling on the cord.
3. Confirm the power cord label is attached to the cord and legible. If the label is missing or not legible, replace the power cord.
4. Inspect both ends of the power cord for any signs of electrical arcing, burn marks, or heat scorching or melting. If any damage is observed, replace the power cord.
5. Inspect the plug end of the power cord for bent blades or a bent or missing ground pin. If any damage is observed, replace the power cord.
6. When inspections are completed, reassemble the power cord to the device by aligning the cord with the power inlet module and pressing firmly.
7. Connect the device to AC (mains) power and press the power button to turn the pump on and confirm proper device functionality.

Power Inlet Module Inspection

Inspect the power inlet module at least once every 12 months.

To inspect the power inlet module, see Figure 38, and proceed as follows:

1. Turn off the device and disconnect the device from AC (mains) power.
2. Remove the power cord from the device by pulling on the cord.
3. Inspect the module area for any signs of electrical arcing, burn marks, heat scorching or melting. If any damage is observed, replace the power inlet module.
4. Inspect the module for bent blades or a bent or missing ground pin. If any damage is observed, re-place the power inlet module.

5. When inspections are completed, reassemble the power cord to the device by aligning the cord with the power inlet module and pressing firmly.
6. Connect the device to AC (mains) power and press the power button to turn the pump on and confirm proper device functionality.

Figure 38: Power Inlet Module Inspection

Roller Head Assembly Inspection

Inspect the roller head assembly at least once every 12 months.

To inspect the roller head assembly, Figure 39, proceed as follows:

1. Turn off the device and disconnect the device from AC (mains) power.
2. Open the lid.
3. Inspect the underside of the lid and roller head for visual signs of wear or damage. Replace roller head if wear is excessive or damaged.
4. Manipulate the roller head (rotate in both directions) with your hand to ensure roller head orientation is locked onto the motor shaft. If there is any mis-aligned motion between the roller head and the shaft, see Service and Contact Information for assistance.

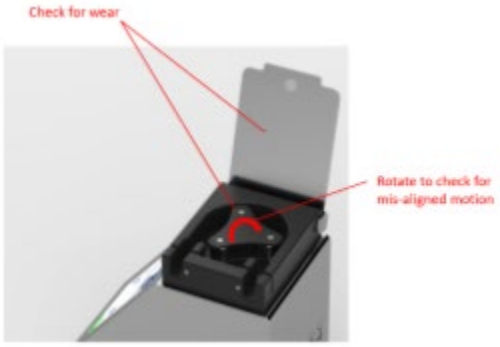


Figure 39: Roller Head Assembly Inspection

Rubber Feet Inspection

Perform a visual inspection of the rubber footpads at least once every 12 months.

To inspect the rubber footpads, proceed as follows:

1. Turn off the device and disconnect the device from AC (mains) power.
2. Place the device on its side or upside down.

3. Inspect for missing or loose rubber foot pads, and rubber foot pads that are damaged. Replace them if damaged or missing.

Touch Screen Display Inspection

Perform a visual inspection and functional test of the touch screen display at least once every 12 months.

To inspect the touch screen display, proceed as follows:

1. Inspect the screen cover for signs of damage (cracks, holes, etc.), wear, or lack of clarity (cloudy appearance, excessive debris, etc.). Replace it if damaged.
2. Turn on the device, inspect the display to ensure all sections of the display illuminate properly. Replace it if damaged.

To test the touch screen display, proceed as follows:

1. Connect the device to the AC (mains) power.
2. Press the power button to turn on the device.
3. Verify touch screen performance by performing all or part of the Training Practices described in Appendix D: Training Practice Examples.

Power Button Inspection and Test

Perform a visual inspection and functional test of the power button at least once every 12 months.

To inspect the power button, proceed as follows:

1. Turn off the device and disconnect the device from AC (mains) power.
2. Manipulate the power button outer flange with your fingers to ensure it is securely positioned. No movement or rattling of the power button should occur when manipulating. See Service and Contact Information for assistance if movement is detected.
3. Press the power button. Audible “click” should be heard when pressing the button. Button should alternate between the two positions listed below when pressed. See Service and Contact Information for assistance if proper button function is not observed.

   Flush with outer flange (off position)
   Recessed relative to outer flange (on position)

To test the power button, proceed as follows:

1. Connect the device to the AC (mains) power.
2. Press the power button to turn on the device (button should move to the recessed position)
3. Observe the device to ensure it powers on and normally enters operating mode. See Service and Contact Information for assistance if the device does not power on.
4. Press the power button to turn off the device (button should move to the flush position)
5. Observe the device to ensure it powers off. See Service and Contact Information for assistance if device does not power off.

Appendix C: Accuracy Verification Protocol

A standalone scale is recommended to perform this protocol. If a scale is not available, a graduated cylinder can be used.

With Standalone Scale:

After a new tubing set is installed, primed, and calibrated, the user may do an accuracy verification at any point.

To do an accuracy verification test with Standalone Scale:

1. Select Advanced mode from the home screen.
2. Select gravimetric mode.
3. Follow prompts to install and prime the tubing set.
4. Hit continue button on compound details screen and confirm no change to specific gravity.
5. Place the empty container on the standalone scale and tare the scale.
6. Connect the empty calibration container to the tubing output.
7. Enter the calibration volume and select appropriate speed and direction.
8. Hit Continue to perform calibration transfer.
9. Take output container and weigh on the standalone scale.
10. Enter measured weight on PharmAssist Pro screen and select Accept.

With Graduated Cylinder (If no scale available)

After a new tubing set is installed, primed, and calibrated, the user may do an accuracy verification at any point.

To do an accuracy verification test with Graduated Cylinder:

1. Select Advanced mode from the home screen.
2. Select volumetric mode.
3. Follow prompts to install and prime the tubing set.
4. Hit continue button on compound details screen and confirm no change to specific gravity.
5. Enter calibration volume and select appropriate speed and direction.
6. Hit Continue to perform calibration transfer.
7. Enter measured volume of the graduated cylinder on screen and hit Accept.

With a Connected Scale:

1. Select Advanced mode from the home screen.
2. Select gravimetric mode.
3. Follow prompts to install and prime the tubing set.
4. Hit continue button on compound details screen and confirm no change to specific gravity.
5. Place empty container on the connected scale with the tubing set connected and hit continue.
6. Enter speed, volume, and direction. Then hit tare button and start button to begin transfer.
7. The screen will display the results with the % deviation displayed. Select accept or back to try again.

Appendix D: Training Practice Examples

Syringe Batching in Basic Mode

Description: Prepare a batch of 10 sterile 50 mL syringes with 0.9% Sodium Chloride using the PharmAssist Pro compounder. You do not need to track drug information in the system.

You are provided the following accessories, consumables, and solutions to complete the order:

- Single Lead Heavy Duty Tubing (BX01)
- Syringe Holder (SH01)
- Syringe Adapter (SA250)
- 50 mL Sterile Syringes (15ct)
- 1000 mL 0.9% Sodium Chloride bag
- Graduated Cylinder

Instructions:

1. Power ON the pump unit.
2. Install the BX01 tubing set.
3. Enter Basic mode.
4. Prepare Heavy Duty tubing set: Enter 600 mL in the Volume field and press START to dry prime BX01 tubing set.
5. Connect the 1000 mL 0.9% Sodium Chloride bag to the input port of the tubing set.
6. Place and hold the output end of the tubing set in the graduated cylinder (waste container).
7. Prime tubing: Enter 27 mL in the volume field and press START to prime tubing set.
8. Connect a 50 mL syringe to a Syringe Adapter (SA250) and connect the adapter to the output port of the tubing set.
9. Insert the connected syringe into the Syringe Holder (SH01).
10. Calibration Transfer: Enter 50 mL in the volume field and press START to initiate the calibration transfer.
11. Calibrate the pump: Press ADJUST and enter the actual measured volume in the syringe. Press Confirm.
12. Enter Transfer Information:

    Batch Quantity: 10ct
    Interval Time: m (manual)
    Volume: 50 mL
    All other fields can be left as default.
13. Connect a new 50 mL sterile syringe to the Syringe Adapter connected to the Syringe Holder.
14. Press START to initiate the first syringe filling. The white checkmark in a green circle indicates the transfer is complete.

    Note: For highest accuracy, examine the actual measured volume after each fill and use the ADJUST feature as needed to re-calibrate the pump.
15. Connect the next sterile syringe to the output Syringe Adapter and press START to initiate the next fill.
16. Repeat Step 13-15 until the batch of 10 syringe fills are complete.

Syringe Batching in Advanced Volumetric Mode

Description: An order has been placed for a batch of 5 syringes, each syringe containing 10 mL of Magnesium Sulfate Heptahydrate 100 mL. Prepare the batch of 5 syringes using the PharmAssist Pro compounder. Please review the order summary and track the drug information in the system. The Connected Scale kit is not available for this order.

You are provided the following accessories, consumables, and solutions to complete the order:

- Single Lead Tubing (PA01)
- Syringe Holder (SH01)
- Syringe Adapter (SA250)
- 10 mL Sterile Syringes (10ct)
- Magnesium Sulfate Heptahydrate 100 mL injection bag
- Graduated Cylinder (waste container)

Order Summary
Order Number: 4035837
Drug Name: Magnesium Sulfate Heptahydrate 100 mL
Drug ID: 0264-4400-54
Lot Number: SLMN84
Lot Expiration: 10-2027
Specific Gravity: 1.308
Source Container: 100 mL

Instructions:

1. Power ON the pump unit.
2. Install the PA01 tubing set.
3. Enter Advanced mode. The scale should not be connected when intending to use Volumetric mode.
4. Select Volumetric mode.
5. Connect the 100 mL Magnesium Sulfate bag to the input port of the tubing set.
6. Place and hold the output end of the tubing set in the graduated cylinder (waste container).
7. Prime tubing: On the priming screen, select Prime to remove air from the tubing set.
8. Connect a 10 mL syringe to a Syringe Adapter (SA250) and connect the adapter to the output port of the tubing set.
9. Insert the connected syringe into the Syringe Holder (SH01).
10. On the Compound Details screen, enter all drug information based on the Order Summary.
11. Volumetric Calibration: Enter 10 mL in the volume field and press START to initiate the calibration transfer.
12. Review Calibration: Once the transfer is complete, enter the actual measured volume in the syringe. Press Accept.

    Note: If the measured volume is out of range, the user will need to repeat the calibration step.

13. Enter Transfer Information:

    Batch Quantity: 5
    Interval Time: m (manual)
    Volume: 10 mL
14. Connect a new 10 mL sterile syringe to the Syringe Adapter connected to the Syringe Holder.
15. Press START to initiate the first syringe filling. The white checkmark in a green circle indicates the transfer is complete.
16. Review the Compound Overview screen and press Continue to proceed.
17. Connect the next sterile syringe to the output Syringe Adapter and press START to initiate the next fill.
18. Repeat Step 15-17 until the batch of 5 syringe fills are complete.

Bag Filling in Advanced Mode with Connected Scale

Description: An order is placed for a Vancomycin 1g/250mL IV bag (Vancomycin 1g in 250 mL 0.9% Sodium Chloride). To prepare this order, fill a sterile IV bag with 0.9% Sodium Chloride using the PharmAssist Pro compounder and Connected Scale kit. Please review the order summary and track the drug information in the system.

You are provided the following accessories, consumables, and solutions to complete the order:

- Connected Scale kit
- Single Lead Tubing (PA01)
- CH-10 Bag Spike Clave®
- 250 mL empty IV bag (2ct)
- 1000 mL 0.9% Sodium Chloride bag
- Waste container bag

Order Summary
Order Number: 1845233
Drug Name: Sodium Chloride 1000mL
Drug ID: 0264-7800-09
Lot Number: J2L764
Lot Expiration: 05-2027
Specific Gravity: 1.0046
Source Container: 1000 mL

Instructions:

1. Connect the Scale to the back of the pump using the designated port.

   Note: The Scale must be connected prior to powering ON the pump.

2. Power ON the pump unit.
3. Install the PA01 tubing set.
4. Enter Advanced mode. Select Gravimetric mode.
5. Connect the 1000 mL 0.9% Sodium Chloride bag to the input port of the tubing set.
6. Connect a waste container to the output port of the tubing set using a CH-10 Bag Spike.
7. Prime tubing: On the priming screen, select Prime to remove air from the tubing set.
8. Connect a 250 mL sterile bag to the output end of the tubing set for a calibration transfer.
9. On the Compound Details screen, enter all drug information based on the Order Summary.
10. Place the empty calibration container onto the scale while connected to the tubing. Press Continue.
11. Gravimetric Calibration: Enter 250 mL in the volume field and press START to initiate the calibration transfer.

    Note: If the scale reading is > 0.5g, it's recommended to press TARE before starting the transfer.

    Note: For highest accuracy, it's recommended to use a calibration volume that is similar or the same to the transfer volume.

12. Review Calibration: Once the transfer is complete, examine the gravimetric weight reading.

    Press ACCEPT to approve the calibration.
    If the calibration is out of range, press BACK to recalibrate.

13. Enter Transfer Information:

    Volume: 250 mL
    Batch Quantity: 1

14. Connect a new 250 mL sterile bag to the output end of the tubing set.
15. Place the empty destination bag onto the scale while connected to the tubing. Press Continue.
16. Press START to initiate the transfer. The white checkmark in a green circle indicates the transfer is complete.

Note: If the scale reading is > 0.5g, it's recommended to press TARE before starting the transfer.

17. Review the Compound Overview screen after the transfer is complete.

    If the Deviation percentage is within an acceptable range, Press ACCEPT to approve the transfer.
    If the Deviation percentage is not within an acceptable range, Press RECALIBRATE.

18. Remove the bag from the scale.

Bag Filling in Advanced Mode with External Scale

Description: An order is placed for Acyclovir in D5W for renal-dosed IV therapy. To prepare this order, fill a sterile IV bag with 100 mL Dextrose 5% using the PharmAssist Pro compounder and an external scale. Please review the order summary and track the drug information in the system.

You are provided the following accessories, consumables, and solutions to complete the order:

- External Scale
- Single Lead Tubing (PA01)
- CH-10 Bag Spike Clave®
- 100 mL empty IV bag (2ct)
- 1000 mL Dextrose 5% IV bag
- Waste container bag

Order Summary
Order Number: 1948833
Drug Name: Dextrose Monohydrate 100mL
Drug ID: 0990-7923-23
Lot Number: H3L421
Lot Expiration: 12-2026
Specific Gravity: 1.0200
Source Container: 1000 mL

Note: There should not be a scale connected to the pump in order to use Gravimetric mode with an External Scale.

Instructions:

1. Power ON the pump unit.
2. Install the PA01 tubing set.
3. Enter Advanced mode. Select Gravimetric mode.
4. Connect the 1000 mL Dextrose 5% bag to the input port of the tubing set.
5. Connect a waste container to the output port of the tubing set using a CH-10 Bag Spike.
6. Prime tubing: On the priming screen, select Prime to remove air from the tubing set.
7. On the Compound Details screen, enter all drug information based on the Order Summary.
8. Place the empty 100 mL calibration container onto the External Scale and press TARE to zero the bag weight.
9. Connect the 100 mL calibration bag to the output end of the tubing set for a calibration transfer.
10. Gravimetric Calibration: Enter 100 mL in the volume field and press START to initiate the calibration transfer.

    Note: For highest accuracy, it's recommended to use a calibration volume that is similar or the same to the transfer volume.

11. Detach the calibration container from the tubing set and weigh the container using the external scale.
12. Enter the measured value into the Measured Weight field.
13. Review Calibration:

    Press ACCEPT to approve the calibration.

If the calibration is out of range, press BACK to recalibrate.

14. Enter Transfer Information:

    Volume: 100 mL
    Batch Quantity: 1

15. Place a new empty 100 mL bag (destination container) onto the External Scale and press TARE to zero the bag weight.
16. Connect the empty 100 mL bag (destination container) to the output end of the tubing set.
17. Press START to initiate the transfer. The white checkmark in a green circle indicates the transfer is complete.
18. Review the Compound Overview screen after the transfer is complete. Press ACCEPT to approve the transfer or RECALIBRATE to return to the calibration screen.

CADD Cassette Batching with Barcode Scanner

Description: An order is placed to fill a batch of three (3) CADD cassette reservoirs with Hydromorphone 50 mg in 100 mL Normal Saline. To prepare this order, fill three (3) batches of 100 mL CADD cassette with 0.9% Sodium Chloride using the PharmAssist Pro compounder and Connected Scale kit. Please review the order summary and utilize the Barcode Scanner to enter drug information into the system.

You are provided the following accessories, consumables, and solutions to complete the order:

- Connected Scale Kit
- Barcode Scanner
- 100 mL CADD Cassettes (3ct)
- CADD Holder (CADDH01)
- CH-10 Bag Spike Clave®
- Single Lead Short Tubing (PA01-XS)
- 1000 mL 0.9% Sodium Chloride IV bag
- Waste container bag

Oder Summary
Order Number: 775092
Drug Name: Sodium Chloride 1000mL
Drug ID: 0264-7800-09
Lot Number: J32NL76
Lot Expiration: 08-2026
Specific Gravity: 1.0046
Source Container: 1000 mL

Instructions:

1. Connect the Scale to the back of the pump using the designated port.

   The Scale must be connected prior to powering ON the pump.

2. Power ON the pump unit.
3. Install the PA01-XS short tubing set.
4. Enter CADD mode.
5. Connect the 1000 mL 0.9% Sodium Chloride bag to the input port of the tubing set.
6. Connect a waste container to the output port of the tubing set using a CH-10 Bag Spike.
7. Prime tubing: On the priming screen, select Prime to remove air from the tubing set.
8. Connect a 100 mL CADD cassette to the output end of the tubing set.
9. Place the CADD Holder on the scale and press Continue.
10. On the Compound Details screen, enter all drug information based on the Order Summary.
11. Place the empty calibration container onto the scale while connected to the tubing. Press Continue.

12. Enter Transfer Information:

    Volume: 100 mL
    Batch Quantity: 3

13. Place the CADD cassette on the CADD holder. Press Continue.
14. On the Cassette Detection screen, press Continue to confirm the cassette size.
15. Review the transfer details and press START to initiate the transfer.

    Note: If the scale reading is > 0.5g, it's recommended to press TARE before starting the transfer.

16. Allow the pump to partially fill the cassette, remove air, and complete the final filling. The white checkmark in a green circle indicates the transfer is complete.
17. Review the Compound Overview screen after the transfer is complete:

    Press ACCEPT to approve the transfer.
    To remove additional air from the cassette, press Air Out.

18. Remove the cassette from the scale.

Place the next CADD cassette onto the CADD Holder and repeat Step 13-18 until completing all three batches.

CE

ICU Medical, Inc.
951 Calle Amanecer
San Clemente, CA 92673, USA

EC REP **ICU Medical B.V.**
Hofspoor 3
3994 VZ Houten
The Netherlands

www.icumed.com

icumedical
human connections