Diana Peristaltic Pump™ User Manual

DS1000

For use with Software Release V2.2 Only

IFU0000587 (01, 2023-12)

icumedical
human connections

Change History

Part Number	Description of Change
IFU0000587 (01, 2023-12)	Initial Release

Contents

Chapter 1: Introduction

Intended Use

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

The Diana PPM systems 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 Diana Peristaltic Pump is designed for use in laminar airflow boxes, biological safety cabinets, gloveboxes, laminar airflow hoods and/or safety work benches in clean rooms.

The Diana Peristaltic Pump 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 Diana Peristaltic Pump System (often referred to as “System” throughout the User Manual) consists of:

- Diana Peristaltic Pump Unit (Required) (often referred to as just the “pump unit” throughout the User Manual)
- Tubing Set (Required)
- This User Manual (Required)

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 relating to work protection and accident prevention and ensure professional diligence.

Warnings and Cautions

Read this User Manual carefully before using the Diana Peristaltic Pump. For safe operation of the Diana Peristaltic Pump, refer to the Warnings, Cautions, and recommendations in the following sections.

General

- **DO NOT connect the System directly to humans.**
- **DO NOT USE for intravenous administration or other routes of direct patient delivery.**
- **DO NOT USE for biological tissue, cells, or body fluids.**
- **DO NOT operate the System in the presence of flammable substances, including anesthetics.**
- **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 Diana Peristaltic Pump does not contain any user-serviceable parts.

- **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.**
- **If the pump unit is damaged during operation, switch off immediately and disconnect from the power supply.**
- **If the pump unit has observable sharp edges, contact an ICU Medical representative immediately.**
- **DO NOT place the compounder on an unstable surface.**

Liquids Handling

- **To avoid the potential for cross-contamination between drugs, replace the tubing set when a new drug is to be compounded.**
- **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.**
- **Liquid ingress inside the System components may cause damage and impact performance. Clean spills immediately.**

Power Supply

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

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

- **If power cord is damaged, stop using the pump unit and unplug the cord from the power source.**
- **The pump unit should only be used with the manufacture-provided power cord (ICU Kit Number DS1902, ICU Part Number: 826-11518-403).**
- **The power cord must be connected to a properly grounded hospital grade 120V receptacle for proper pump unit performance and safety.**
- **Avoid routing the power cord across the floor where it can create a tripping hazard.**
- **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 Dispensing Sets

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.

- **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.**
- **The dispensing set should be changed within 24-hours due to touch contamination.**
- **DO NOT re-sterilize or reuse the tubing set. Re-sterilizing or reusing may cause damage to the tubing.**
- **Change the tubing set prior to each change of liquid to avoid drug incompatibility and/or transferring the incorrect volume.**

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

- **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.**

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 (includes the key words in the "route" field: "EPIDURAL", "HEMODIALYSIS", "INTRA", "PARENTERAL", "SUBCUTANEOUS", "SUBMUCOSAL"). If a drug is not in the database provided it can be added using the "Add Drug" functionality. See Section Edit Drug for details on how to use the "Add Drug" feature.**
- **Follow manufacturer and facility protocols for any drug added to the database.**
- **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 Section Changing the Specific Gravity for details about how default verses user entered specific gravity values are represented within the System. See Section Changing the Specific Gravity for details about how to update the default specific gravity values for drugs.**
- **Default drug list is not translated when System language is changed from English (drug names remain in English).**

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.

- **DO NOT use gravimetric calibration process unless confident that the specific gravity has been accurately entered for the fluid being transferred.**

Calibration

- **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 such as elastomeric or microbore tubing, or a significant change in desired volume.**
- **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. The System retains calibration for both directions to allow repeated switching of direction without recalibrating. Either direction can be recalibrated as often as desired.**
- **Calibration should always be performed with the liquid intended to transfer because the tubing set should be changed prior to each change of liquid.**

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

- **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 ICU Service for repair.**
- **The system shall not be connected to hospital networks.**

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 cycle and at intervals during the cycle 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 the **Calibration** section for more details).

- **Verify pump unit accuracy performance before use to ensure it meets facility protocols.**
- **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 ICU Medical service center for repairs.**

Service and Maintenance

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

- **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.**
- **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.**
- **Some metal parts might be warm when in use. The user should allow the pump unit to cool down prior to moving or transporting it.**
- **Consider the drug manufacturer's labeling and USP compounding guidelines when performing compounding.**
- **Ensure the System is placed on a stable surface. If applicable, allow Biomedical Engineering to confirm electrical requirements are met.**
- **The System is not suitable for use in mobile equipment.**
- **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.**
- **Verify pump unit accuracy performance before use to ensure it meets facility protocols – Accuracy Specifications for details.**
- **Do not insert any foreign objects into the pump unit ports and openings.**

Storage and Disposal

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

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

- **When storing the System, ensure the location is in compliance with the Storage Temperature, Humidity, and Altitude listed in Table 12.**

- **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.**

Cleaning

- **Avoid direct contact with liquids. If a spill occurs, quickly remove liquids in accordance with the facility protocol.**
- **Never immerse the pump unit in liquids for cleaning purposes. Do not attempt to sterilize using mechanical or steam sterilization equipment.**
- **All 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 Diana Peristaltic Pump 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
	IEC 60417 – 5032	Alternating current

Symbol	Reference	Description
	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
	CSA	Canadian Standards Association Certification mark indicates that the product has been tested against applicable North American standards requirements.

Symbol	Reference	Description
	ISO 15223-1: 2021 Symbol 5.1.2	Authorized European Representative
IP33	IEC 60529	Ingress protection (protected against solid foreign objects 2.5 mm diameter or greater and spraying water)
	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

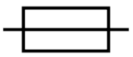
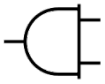
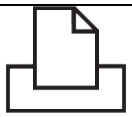
List of Symbols on the Back of the Pump Unit

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 (Accessory not included in the current version of the system).	EC 60417, Reference Number: 6378
	Indicates socket for connecting the Printer Kit (Accessory not included in the current version of the system).	IEC 60417, Reference Number: 5851
IOIOI	Indicates socket for connecting the Scanner Kit (Accessory not included in the current version of the system).	N/A
	Indicates socket for connecting the Scale Kit (Accessory not included in the current version of the system).	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	Tapping the **Yes** button confirms the user's entry.

Convention	Application	Example
Red	Warnings and Cautions	**WARNING: INCORRECT INSERTION OF THE TUBING SET MAY DAMAGE THE PUMP UNIT.**

Illustrations, Screen Displays, and Software Messages

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

Chapter 2: Diana Peristaltic Pump System Overview

Diana Peristaltic Pump Description

The Diana Peristaltic Pump is a software-controlled automated pharmacy-compounding system intended for use in a healthcare facility by Pharmacists and Pharmacy Technicians to dispense a specified quantity of liquid from a set of source containers into a destination container.

Figure 2. Diana Peristaltic Pump Unit

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

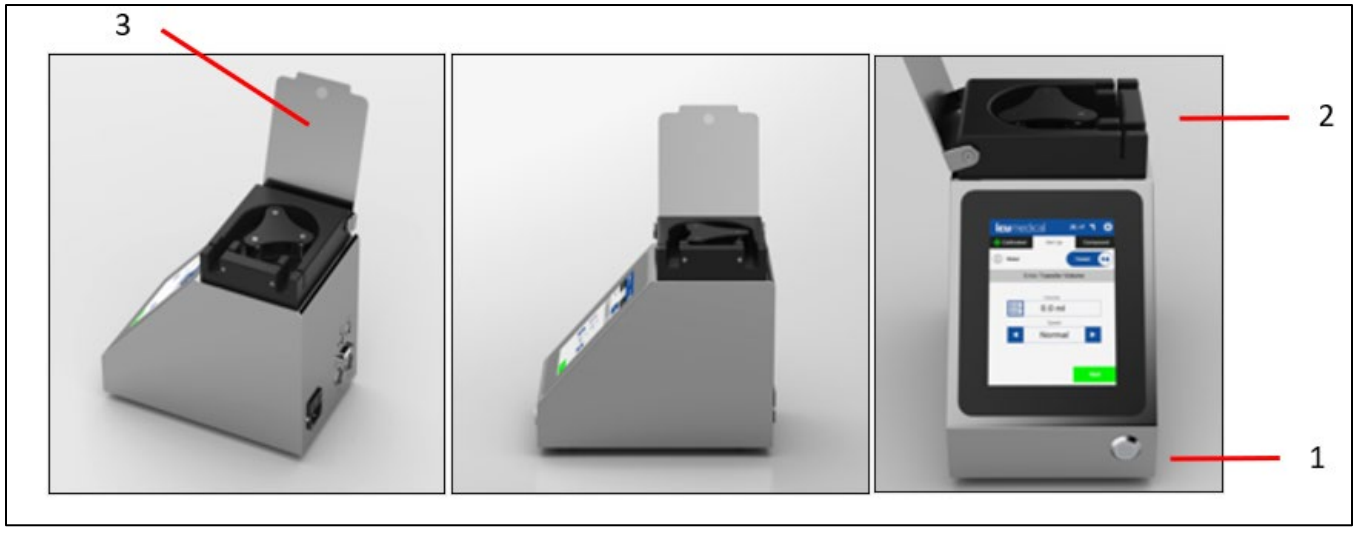


Figure 3. Front and Sides

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
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	This port is not used by the system, plugged by cap.
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	This port is not used by the system.
9	Foot Pedal Port	This port is not used by the system, plugged by cap.
10	Scale Port	This port is not used by the system, plugged by cap.

Diana Peristaltic Pump Unit (DS1000) 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.

Diana Peristaltic Pump Unit Graphic User Interface (GUI)

The user interface of the pump unit features three tabs at the top of the screen (Drug Set Up, Set Up, Compound) that allow navigation to specific workflows. **Figure 5** shows the labeled user interface and **Table 5** lists the labeled components.

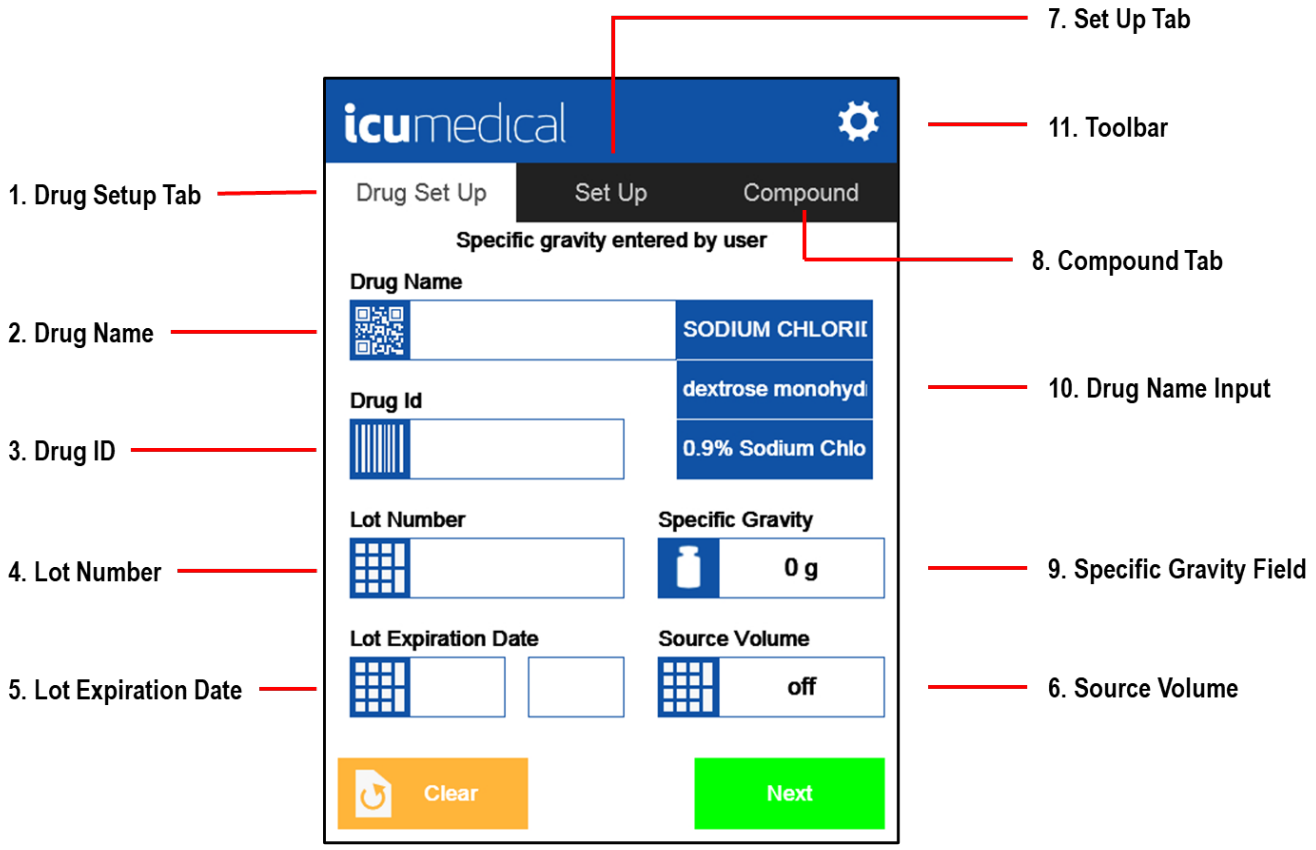


Figure 5. UI Components

Table 5: User Interface Components

Reference	Component	Description
1	Drug Set Up Tab	First screen to be displayed and allows users to assign drug information to a container, which generates a compounding log and labeling for future use.
2	Drug Name	Enter the drug to be used. Most common drugs will show up on the right side of the menu.
3	Drug ID	Identification number associated with the Drug Name that displays on screen
4	Lot Number	Enter the lot number of the drug. This information can then be retrieved in compounding reports.
5	Lot Expiration Date	The expiration date for the drug (MM/YYYY)
6	Source Volume	The amount of liquid (mL) in the source container, used to ensure that there is enough liquid to fill the destination container. Default value is “off”, which turns off the source container volume tracking.

Reference	Component	Description
7	Set Up Tab	Allows a user to provide the amount of volume (mL) to be transferred and change the transfer speed (mL/min). Once this information is entered, tap “Start” to initiate a transfer.
8	Compound Tab	Provides a visual confirmation that the pump unit is transferring liquid. **Note:** This tab is only functional during a transfer.
9	Specific Gravity Field	Displays entered Specific Gravity of chosen drug. **Note:** The default specific gravity is set to 1.0 g. The specific gravity of a drug can be changed on the Drug Set Up screen or Edit Drug settings page. Edit Drug settings require an operator to be an authorized user in Advanced Settings.
10	Drug Name Input	A list of the most recent 3 drugs that were added or changed in the database. Tapping will fill the Drug Set Up tabs with data from the drug database for that drug.
11	Settings	Provides the user access to the settings.

Guidance Text

The System provides guidance for priming, calibration, set up, and compounding in a grey bar near the top of the screen.

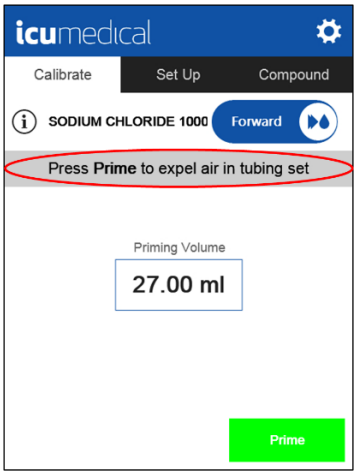


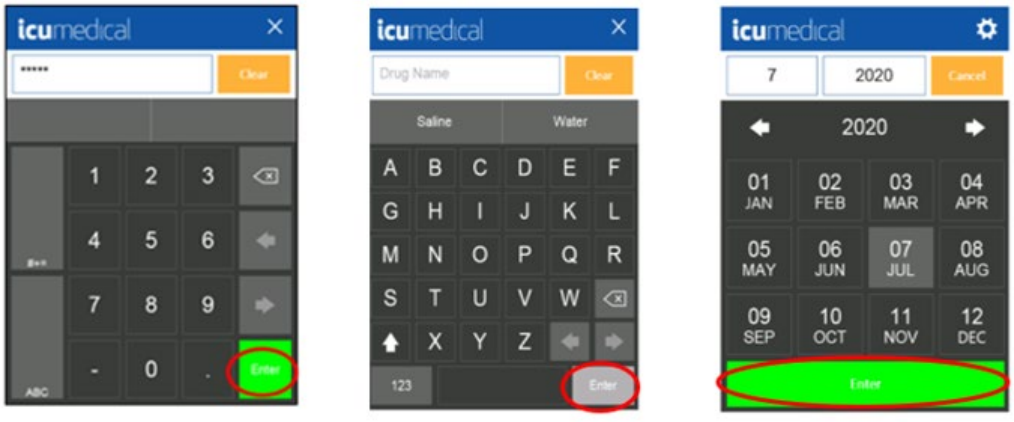
Figure 6. Guidance Text

Touch Screen Usage

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

Data Entry

Enter numeric or alphanumeric values and dates by using the keypad.



Enter the numeric value and press **Enter**

Enter the alphanumeric value and press **Enter**

Enter the date and press **Enter**

Figure 7. 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 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 8 shows the tubing set and **Table 6** describes the labeled components.

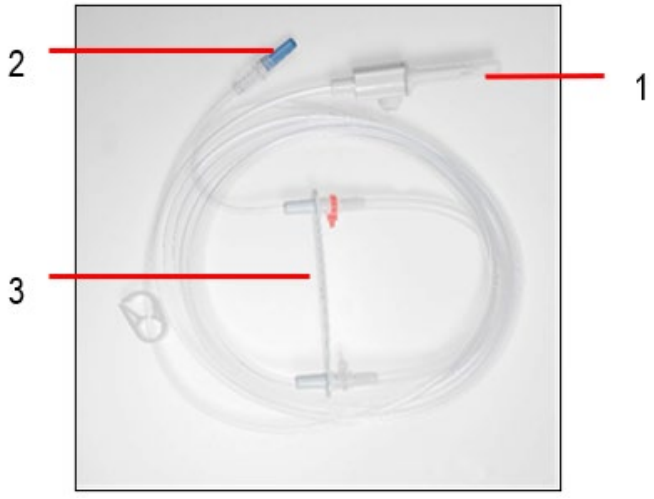


Figure 8. Tubing Set

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

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 used with ambulatory pumps or other hard to fill container.

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

Chapter 3: Operating the Diana Peristaltic Pump

Overview

Before operating the system, the components must be installed, and the settings configured. For details regarding installation, see **Chapter 2: Diana Peristaltic Pump System Overview**. **Chapter 4: Settings** describes how the System settings can be customized to the procedures and policies of the user's lab and organization.

The following figure provides an overview of the overall workflow of the system:

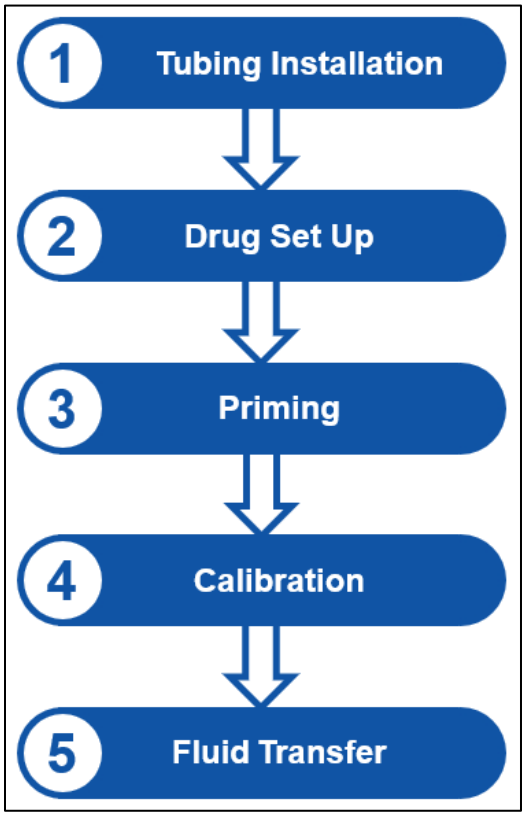


Figure 9 - General Workflow of the Diana PPM System

When replacing the tubing set or changing drugs, complete steps 1 through 4. Once those steps are completed, the user can complete multiple Fluid Transfers (step 5), until they need to change the tubing set of the drug. Understanding this workflow reduces the chance of errors during usage of the system. The rest of this chapter provides more detail about the Diana Peristaltic Pump System workflow, what options are available, and why you might choose certain options.

Tubing Set Installation / Removal

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

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

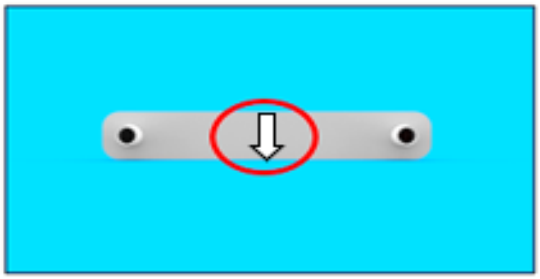
Important: Before opening, inspect the tubing set package. If packaging is not intact, discard it and use a new set.

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

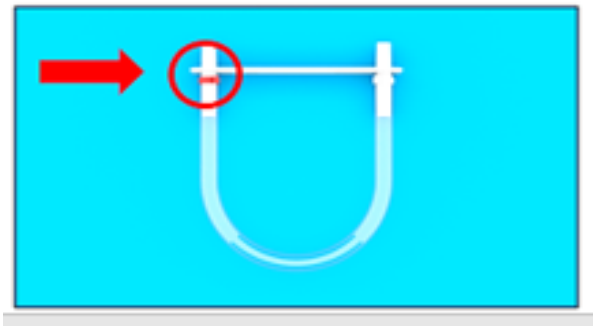
Tubing Set Installation

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

2. Locate the embossed arrow pointing downwards on the handle of the tubing set.

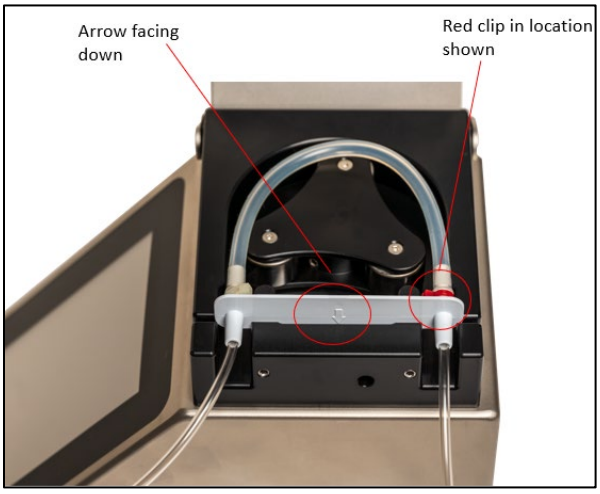


3. Locate the red clip behind the handle.

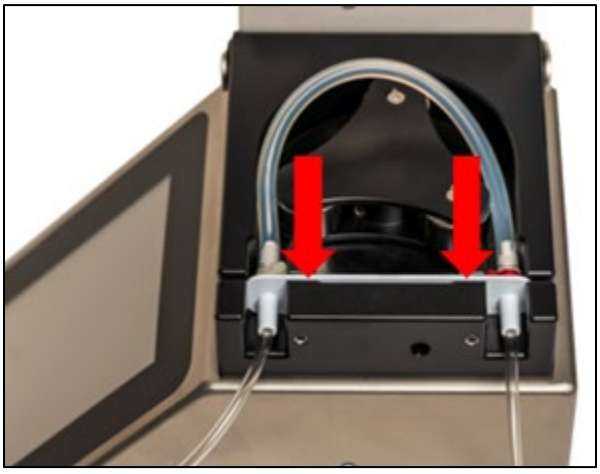


4. Insert the handle into the slot in the roller head, aligning the red clip with the red arrow.

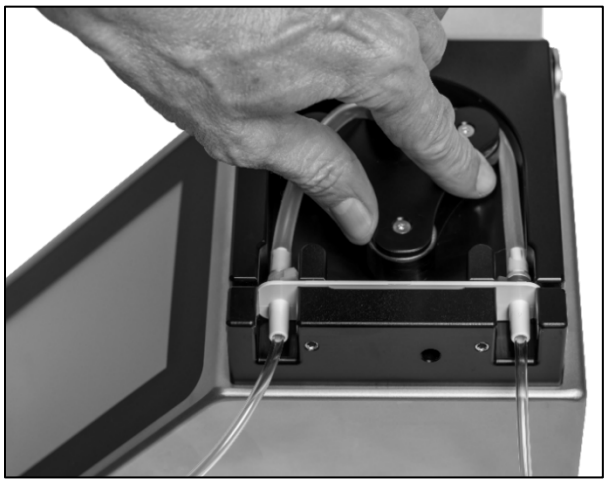
5. Align the white handle of the tubing set as shown below.



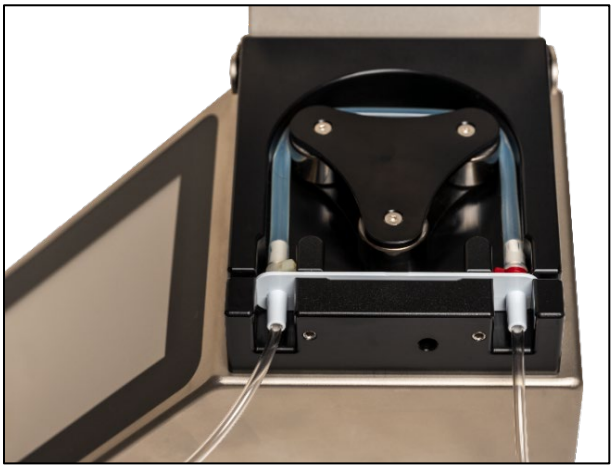
6. Press down the white handle until fully engaged into the pump unit.



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.

Tubing Set Removal

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

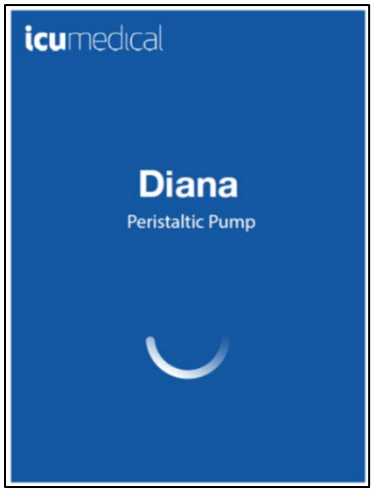
When ready to remove the tubing set:

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.

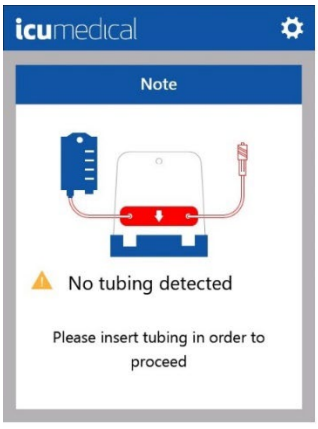
Power On

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

2. When the pump unit has been started, a welcome screen is displayed.

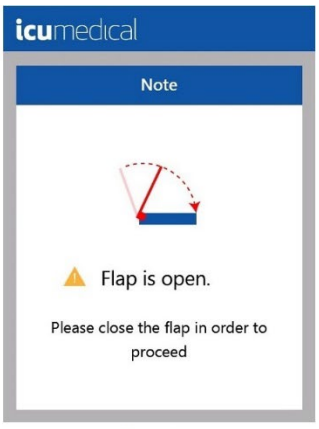


3. Next, a series of alerts will display, depending on the state of the pump unit.



No Tubing Set Detected

Tubing Set Detected



Flap is open

4. Follow the on-screen commands or answer the questions to access the home screen.

Tubing Preparation – Recommended for Heavy Duty Tubing

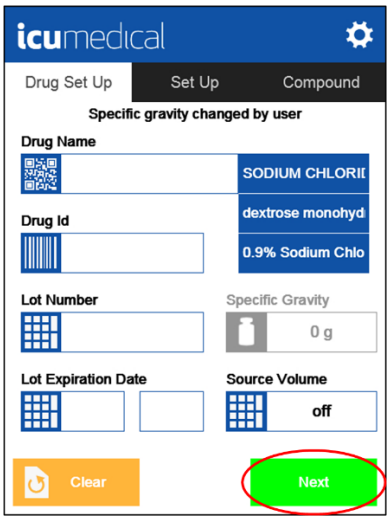
When using heavy duty tubing (BX01, BX01LL, BX02, or BX03) with the PPM, it is recommended to prepare the tubing set before fluid priming to assist in normalizing tubing set performance prior to pump calibration.

1. Install the tubing set - See **Tubing Set Installation** for a description of how to install a new tubing set.

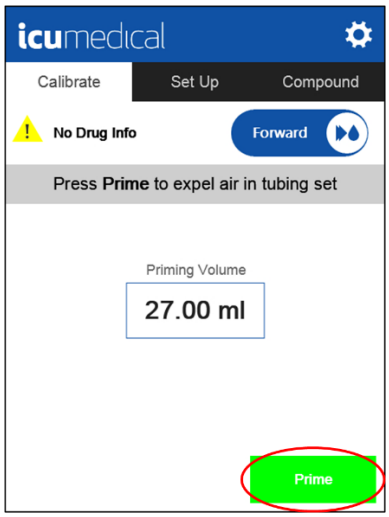
   Note: Do not remove the protective caps from either end of the tubing set.

   Note: In some situations, failure to perform these steps could cause the roller head to not turn and could contribute to inaccuracy during fluid transfers.

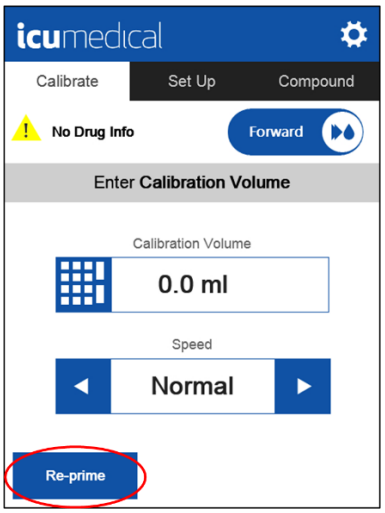
2. Close the lid.
3. Leave Drug Information empty, set Container Volume to off, and press **Next**.



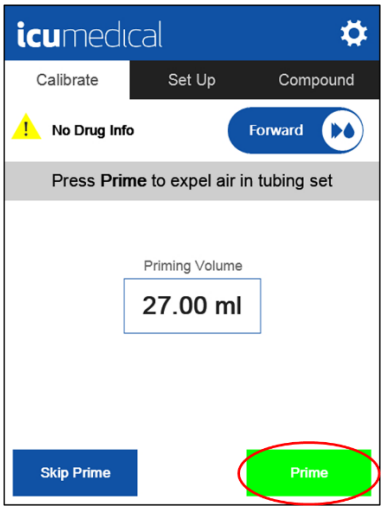
4. Without connecting the input container, start Tubing Preparation by pressing **Prime**.



5. Press **Re-prime** to return to Priming screen.



6. Press **Prime** to do additional Tubing Preparation.



7. Repeat steps 5 and 6 two additional times to complete Tubing Preparation.
8. Tap **"No Drug Info"** to return to **Drug Set Up** to enter Drug Information and connect your tubing to input and output containers to start your transfer.

Drug Set Up

The Drug Set Up screen provides the System with details about the drug. On this screen, the user enters Drug Information the system needs to track.

- Drug Name
- Drug ID
- Lot Number
- Lot Expiration Date
- Specific Gravity

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 Volume. This section describes how to set the system to track Drug Information and Source Volume.

Note: When entering Drug Information, all fields must be filled in before the **Next** button appears.

Note: For all required drug information, field labels are red and fields have a red border until the information is entered.

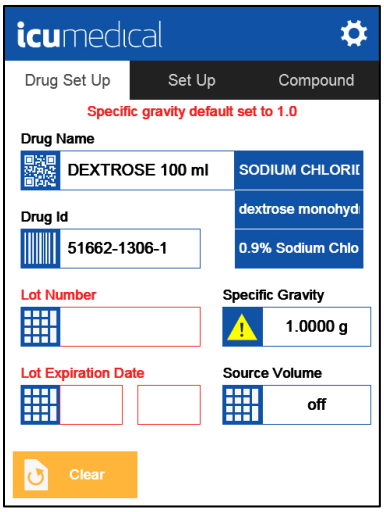


Figure 10. Required Fields

See **No Drug Information** to compound without the system keeping track of Drug Information. See **Source Container Volume Tracking** to compound without the system keeping track of Input Container Volume.

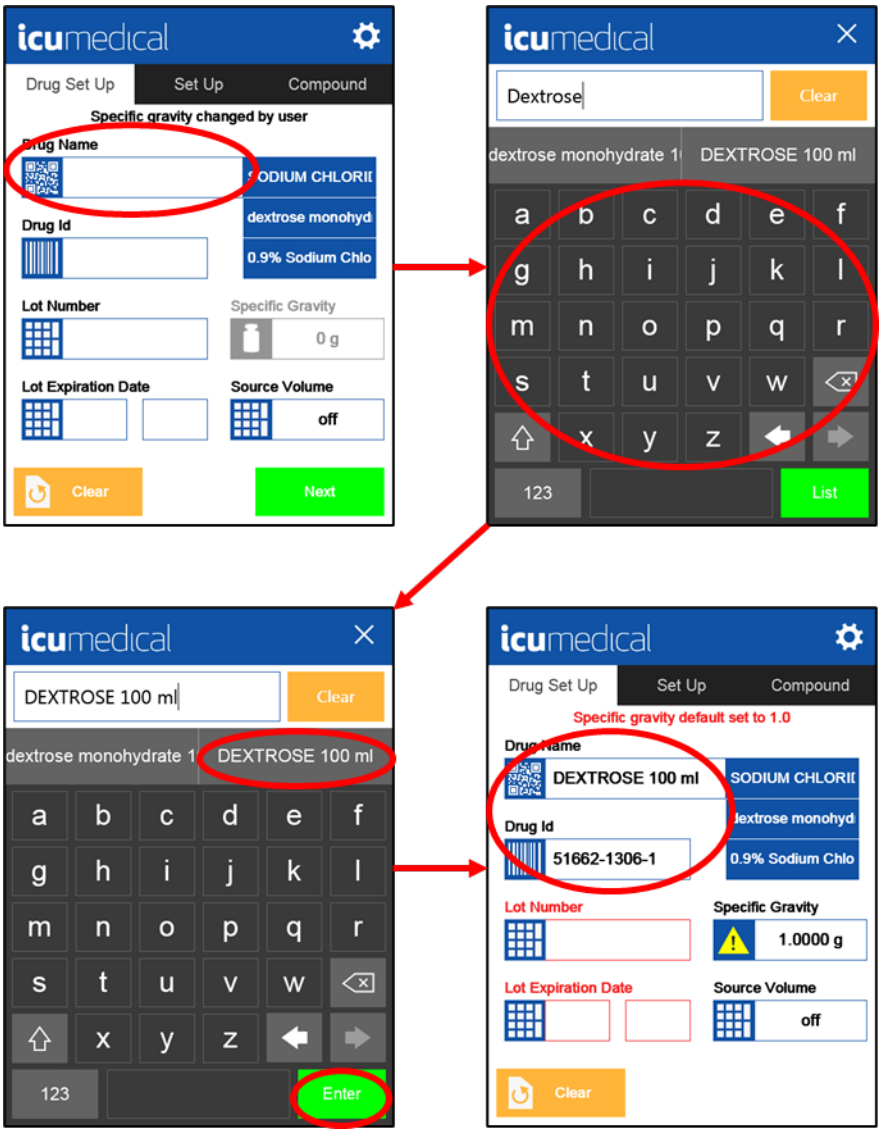
Entering Drug Name and Drug ID

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

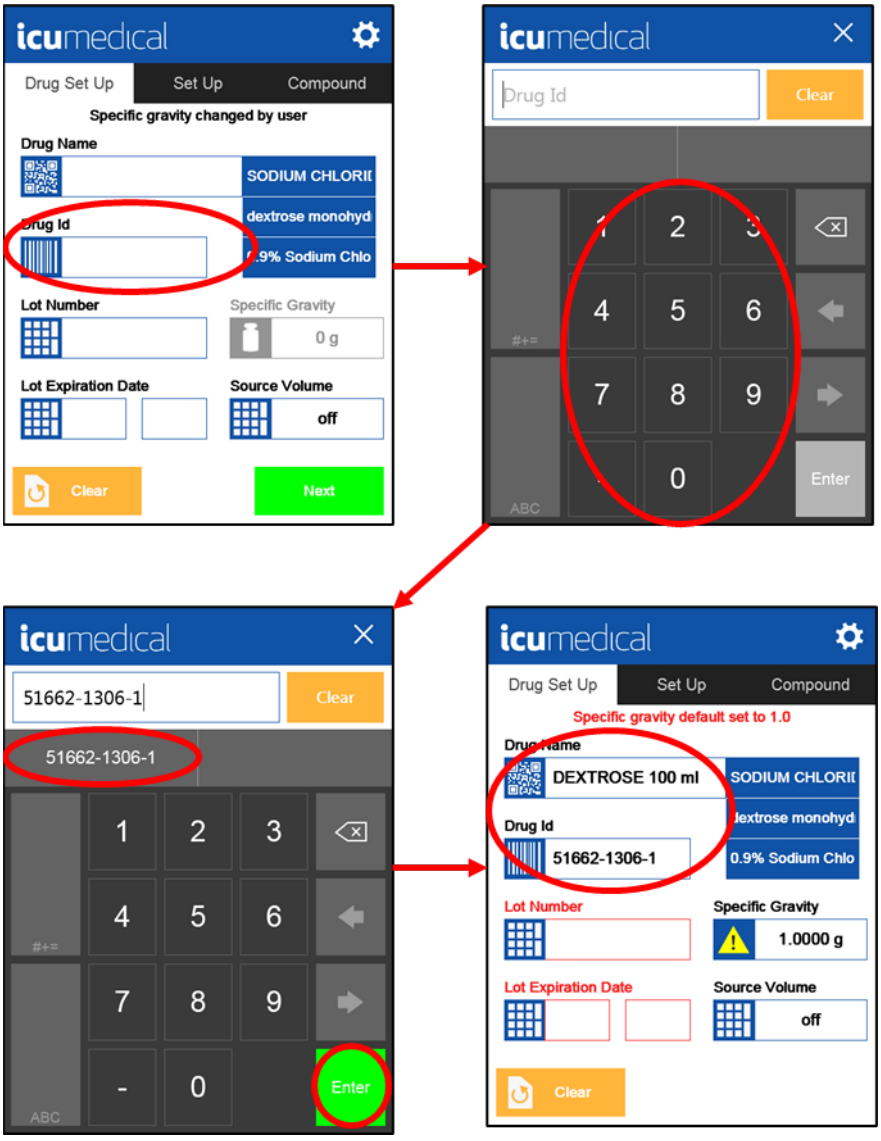
- Select the Drug Name field.
- Start typing the name of the drug. Autocomplete options for drugs in the database appear below your entry.
- Select the drug and press Enter. The Drug Name and corresponding Drug ID are filled in.



Option 2: Enter the Drug ID

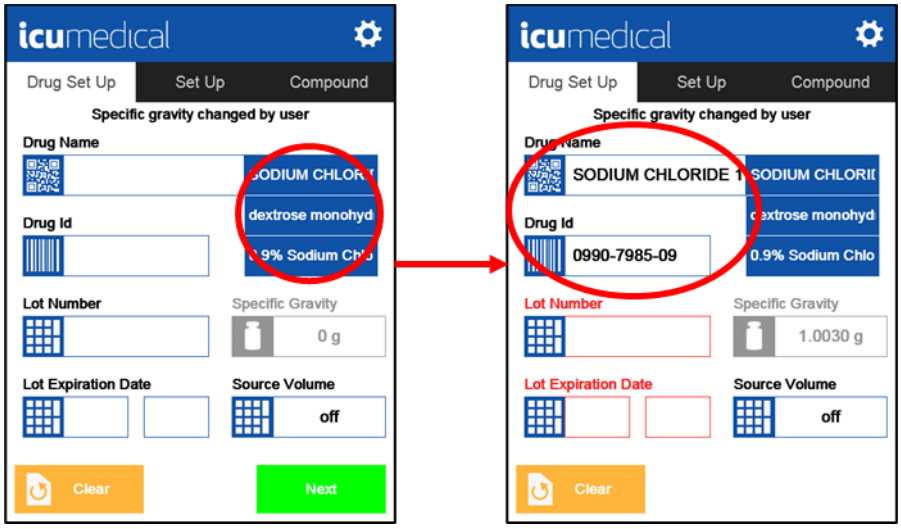
- Select the Drug ID field.
- Start typing the ID for the drug.
- Select the ID and press **Enter**.

The Drug Name and corresponding Drug ID are filled in.



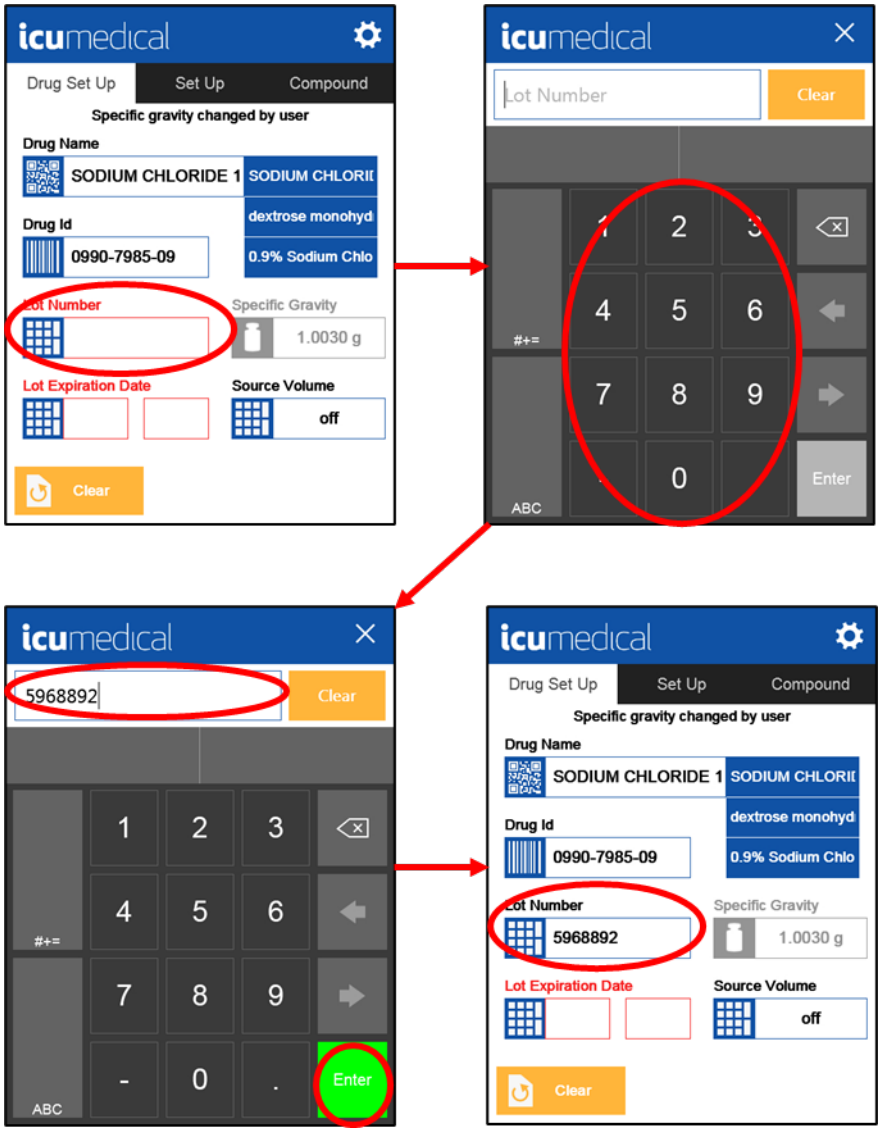
Option 3: Select Preset

The circled presets capture the last 3 drugs that were added or changed in the database. Tapping one of the blue entries will fill in its corresponding Drug Name and Drug ID.



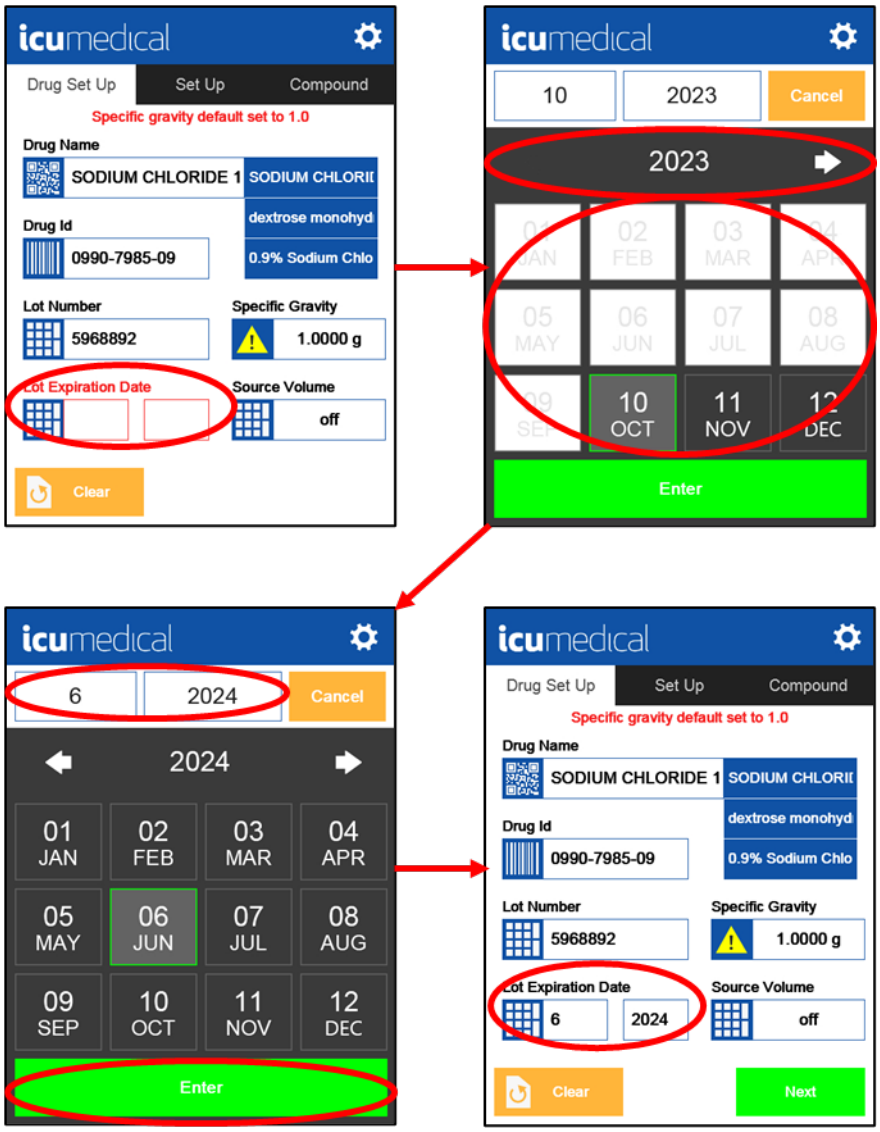
Enter Lot Number

1. Select the Lot Number field.
2. Enter the lot number from the input container in the Lot Number field and press **Enter**.



Enter Lot Expiration Date

1. Select the **Lot Expiration Date** field.
2. Select the **Lot Expiration Date** using the Month and Year picker. Select Year, then select Month and press **Enter**.

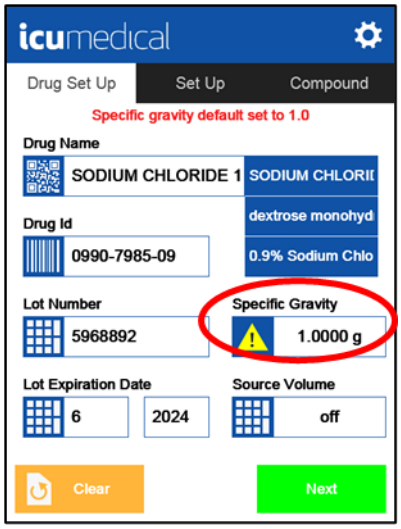


Enter Specific Gravity

1. Enter a specific gravity for the selected fluid in the Specific Gravity field. See **Changing the Specific Gravity** for more details on how to set Specific Gravity.

   Note: Specific Gravity is set by default to 1.0 for all drugs in the default drug list. The default specific gravity value does NOT represent actual drug specific gravity and must be updated before the specific gravity can be used to accurately correlate weight and volume for each drug.

   Important: A yellow warning triangle is displayed next to the Specific Gravity field for all drugs that have default value and need updating prior to accurately represent the given fluid properties. The yellow warning triangle disappears after specific gravity has been updated by the user.



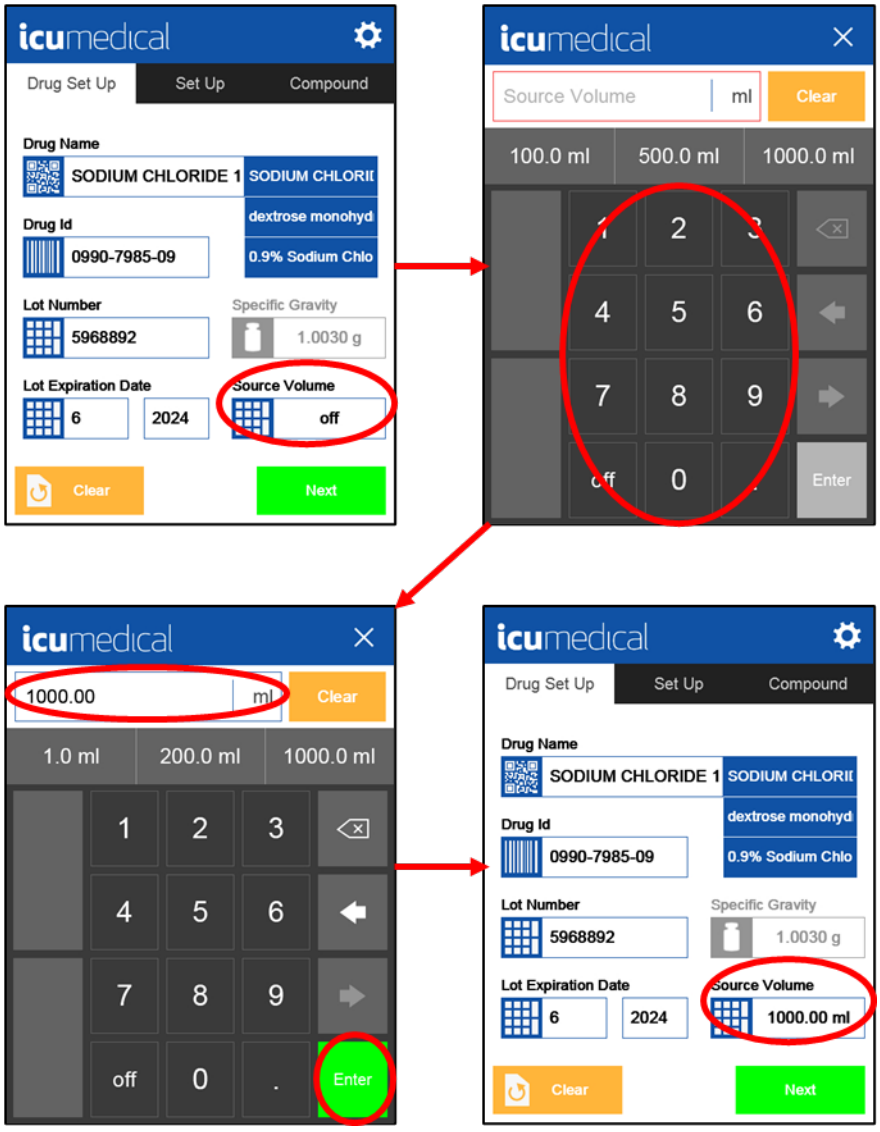
Enter Source Volume

The default value for Source Volume is “off”. This indicates that the user wants to monitor the source container volume independently.

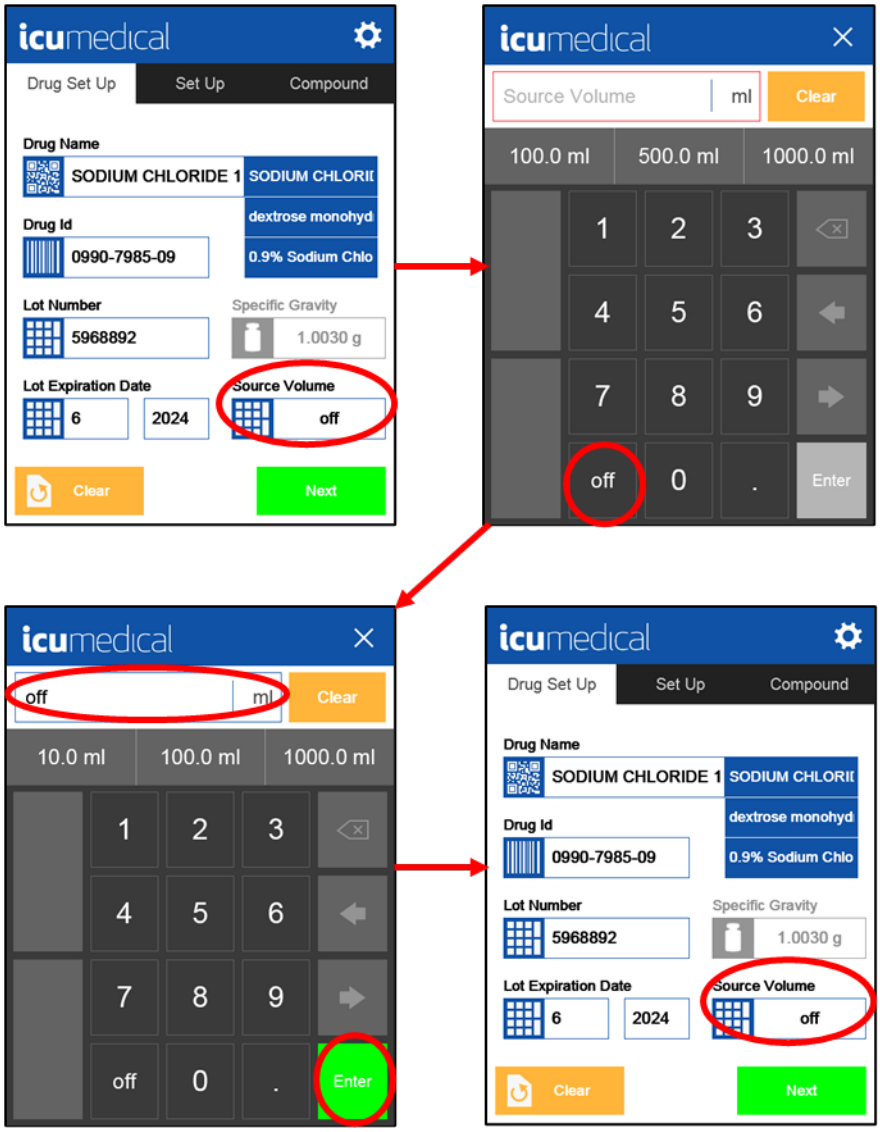
1. Select the **Source Volume** field.

   There are two options:

   - Enter a value for Source Volume. The system will track how much fluid has been removed from the Source Container and will inform the user when it becomes empty. Then, the system will ask for information about the replacement Source Container once it is empty. Enter the Source Container volume in the **Source Volume** field and press **Enter.**



- If the user wishes to keep track of the Source Container Volume on their own, enter "**off**" for Source Volume and press **Enter**.



Accept Drug Information

1. Tap the **Next** button.

   Note: The **Next** button is only available if all fields are filled out.

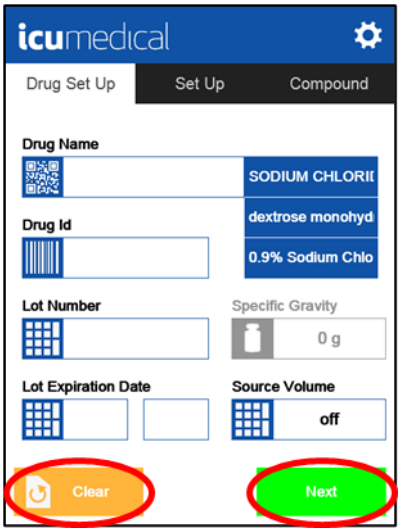
No Drug Information

The Drug Set Up screen defaults to No Drug Information and Source Volume “off”. If the user has entered Drug Information and/or Source Volume and wishes to clear that:

1. Press 

.
2. Press 

to continue with transfer.



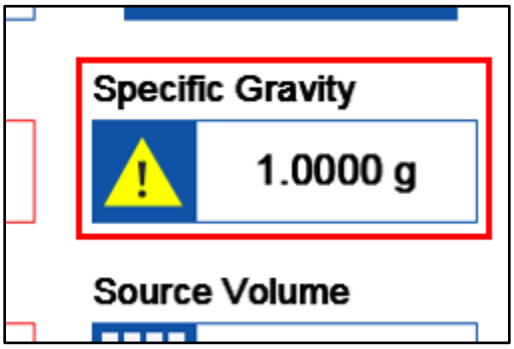
Note: Users can control whether entering Drug Information is required through the setting **Require Drug Information**.

Changing the Specific Gravity

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

Important: Specific Gravity is set by default to 1.0 for all drugs in the default drug list, which 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.

When access is granted, a blue square with a yellow triangle containing an exclamation mark appears indicating the current value is the default and the user can change the specific gravity to a different value.



Important: A yellow warning triangle appears next to the Specific Gravity field for all drugs that have default value 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.

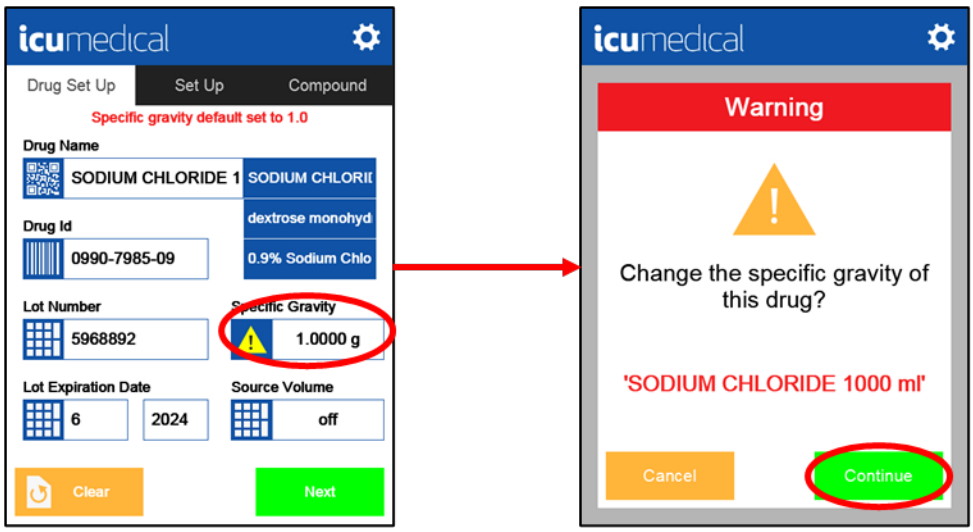
To change the specific gravity:

1. Tap on the **Specific Gravity** field.

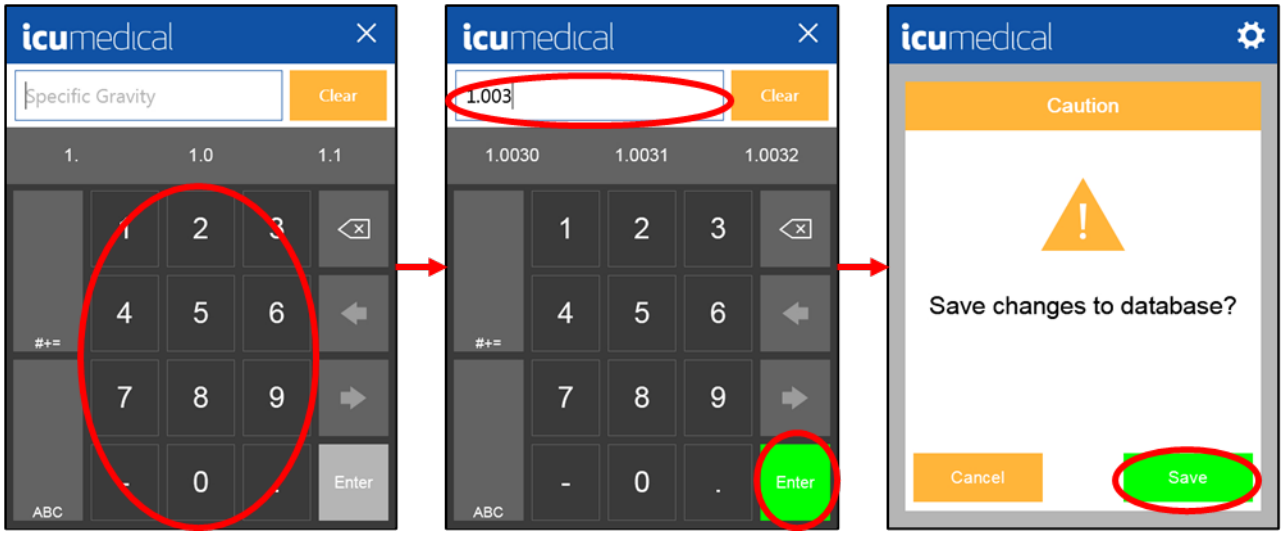
   A warning message about the change in the specific gravity appears.

   Tap **Continue** to change the specific gravity of the selected drug using the keyboard.

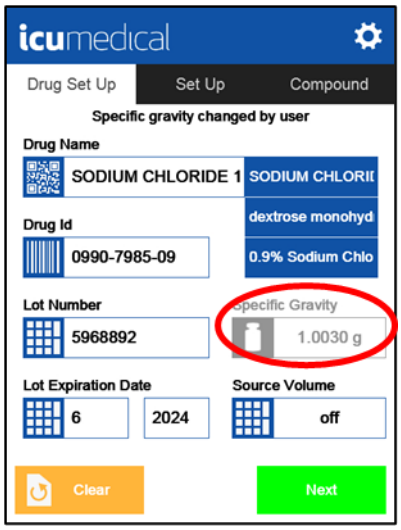
   Tap **Cancel** to return to the default Drug Set Up screen (Specific gravity 1.0 g).



2. Enter the desired specific gravity using the keypad, tap the **Enter** button to save the new value.
   A warning message about the change in the specific gravity appears.
   Tap **Save** to store the changed specific gravity value into the database.
   Tap **Cancel** and the specific gravity will not be saved.



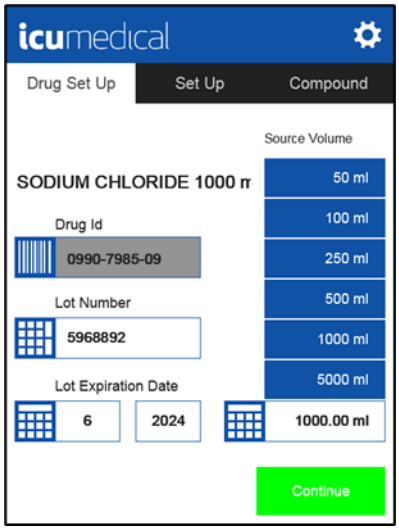
3. Once the specific gravity has been changed, the button is greyed out and cannot be changed on the **Drug Set Up** screen. The specific gravity can only be changed or adjusted by the authorized user in the Advanced Settings.



Source Container Volume Tracking

When the Source Volume is entered on the Drug Set Up screen, 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:

The System displays the details of the new Source Container to enter.



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 clamps). When connecting source containers:

1. Install the tubing set (see **Tubing Set Installation**).
2. Close all source lead clamps.
3. Spike and hang source containers.
4. 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: To properly 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:

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.

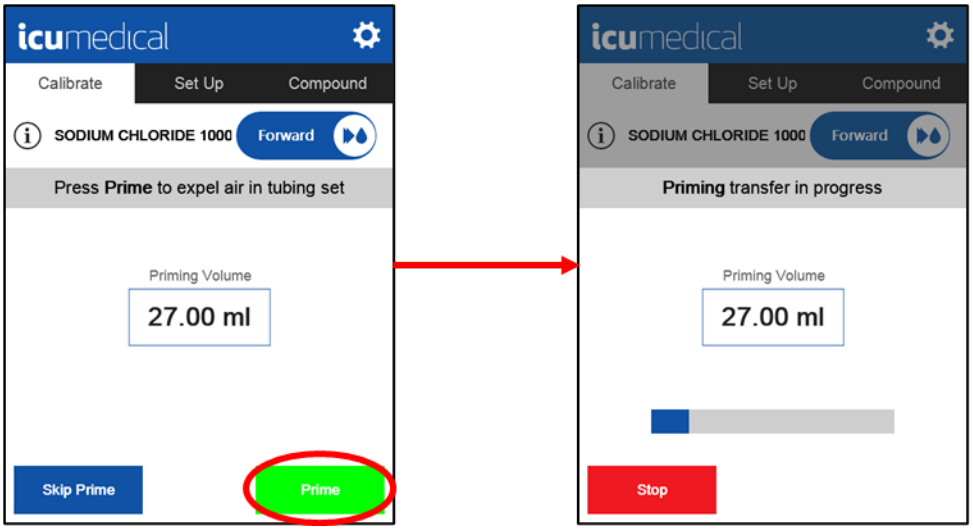
   Note: For Circle Priming, see the **Circle Priming** section of this document.

2. If not already connected, connect the receiving (distal) end of the tubing set to a destination container.

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

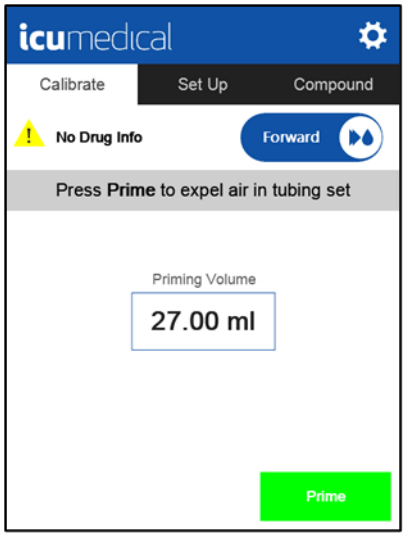
   Note: There may be a delay of a few seconds between tapping **Prime** and the pump unit starting.

4. Visually confirm priming was successful, then disconnect the destination container from the tubing set.



If **Skip Prime** is selected, the tubing set will not be primed, and the System will return to the Calibrate screen.

Note: The **Skip Prime** option will not be available (see screen shot shown below) if the user has indicated that they are using a new tubing set. 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 priming container.

Note: To properly 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 a source container.

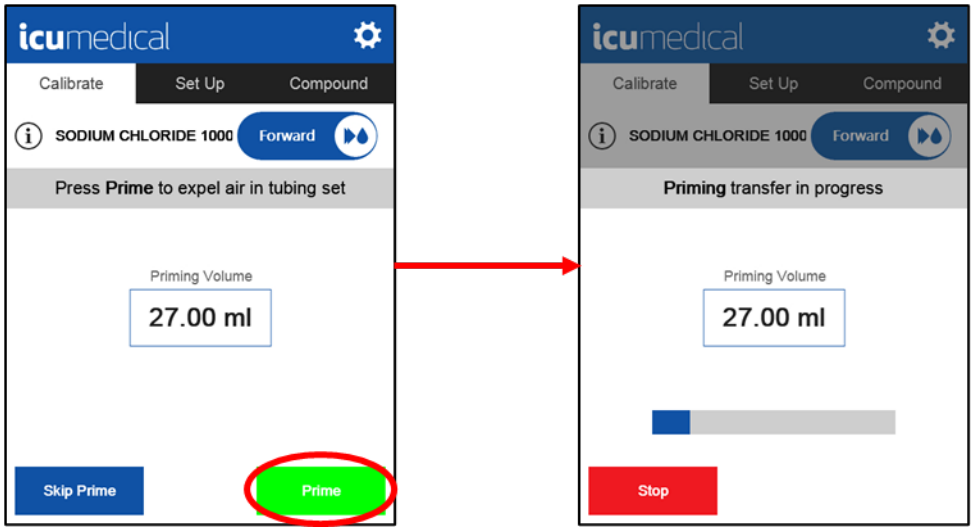
2. Connect the output end of the tubing set to a separate port on the source container.

   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. Tap **Prime** and the pump unit automatically starts to prime the tubing set.

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

4. Visually confirm priming was successful, then disconnect the receiving (distal) 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. The drug can be selected in the Drug Set-Up Tab. It is recommended to calibrate the pump unit after change of the drug, tubing set, desired 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.

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.

There are two ways that calibration can be performed:

- **Gravimetric Calibration with External Scale**
- **Volumetric Calibration**

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.

Gravimetric Calibration with External Scale

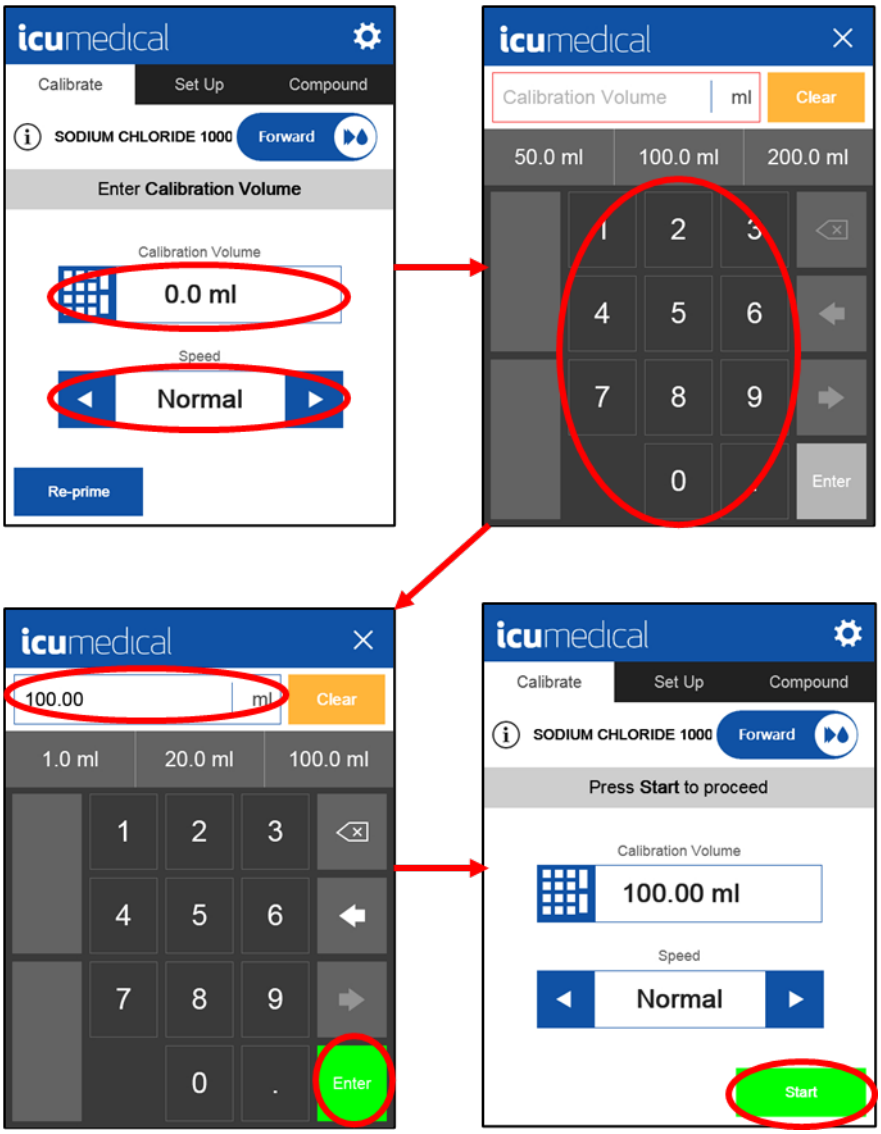
The calibration process of the pump unit can be performed using a separate third-party scale, referred here as an external scale. Accurate specific gravity configuration is essential for gravimetric accuracy.

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

DO NOT use the gravimetric calibration process unless confident that the specific gravity has been accurately entered for the fluid being transferred.

To calibrate the pump unit:

1. Enter the Calibration Volume and Speed.



Note: The transfer speed should be selected based on the volume, output container type, connector type, and viscosity of the liquid. To adjust the speed of the pump unit, tap the arrows on either side.

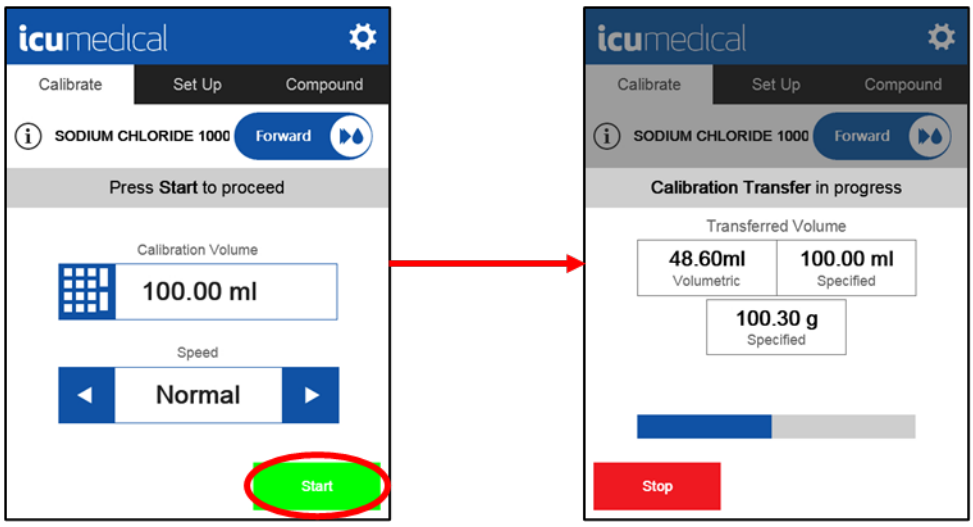
2. If not already placed, place the destination container (calibration container) on the external scale.

   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.

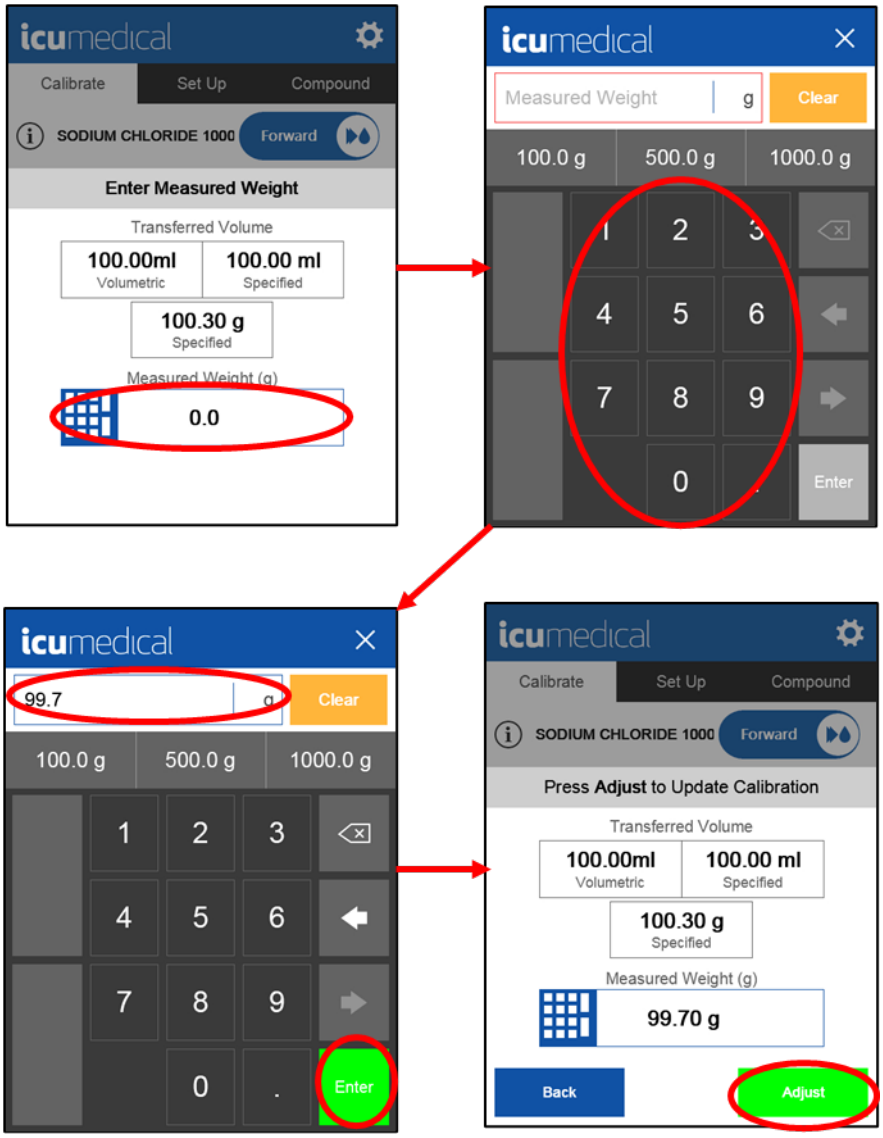
3. Take the external scale.
4. Remove the destination container from the external scale and reattach it to the tubing set.

5. Press **Start** to initiate the transfer.

   Note: There may be a few seconds delay between tapping **Start** and the pump unit starting.



6. After the calibration transfer is complete, enter the weight measured by an external scale into the screen as shown below. To use the entered weight to update the pump unit calibration, press **Adjust**.

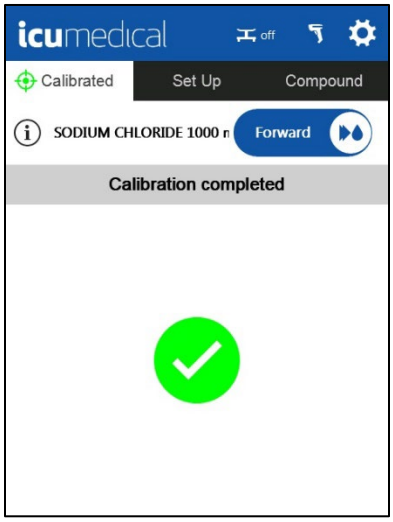


Note: Tapping **Adjust** will update the calibration of the pump unit to account for the over/underfill of the transfer as indicated on the screen (difference between specified volume/weight vs measured weight).

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. See the **Warnings During Calibration** section of this manual 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.

7. After a successful calibration, the pump unit will display a Calibration completed message. At this point, calibration is completed and the user will be directed to the Set Up menu.



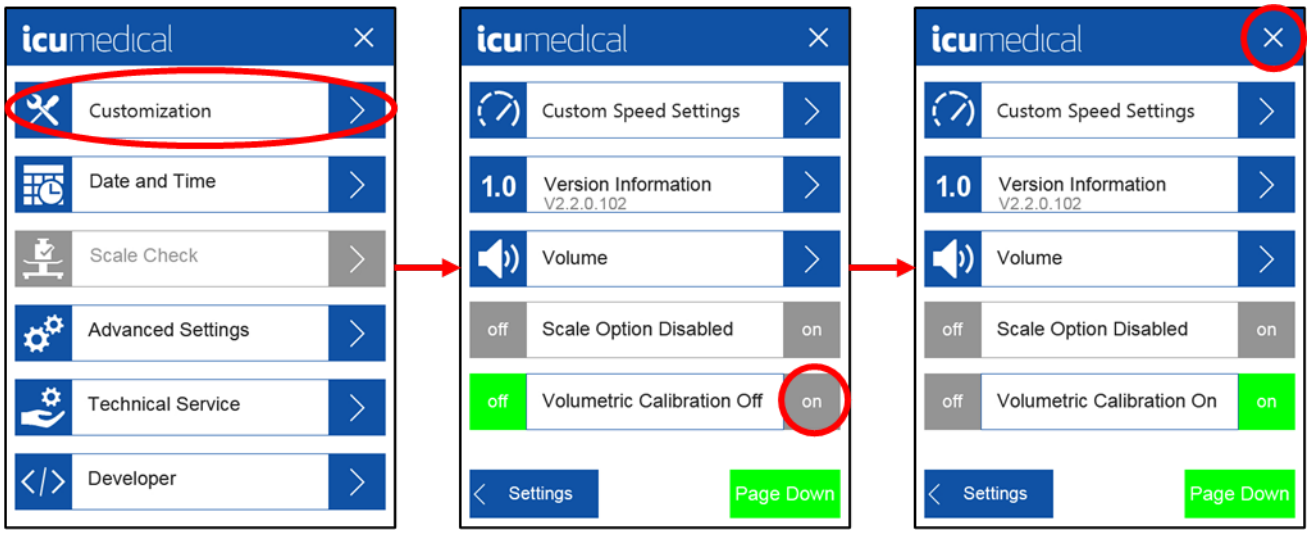
Volumetric Calibration

When a scale is not available, the System supports volumetric calibration. Volumetric calibration is an option that is selected in the Settings menu. It is a one-time setting that is done when the user decides which calibration protocol they want to use for the facility.

Note: Volumetric Calibration is set to **On** by default.

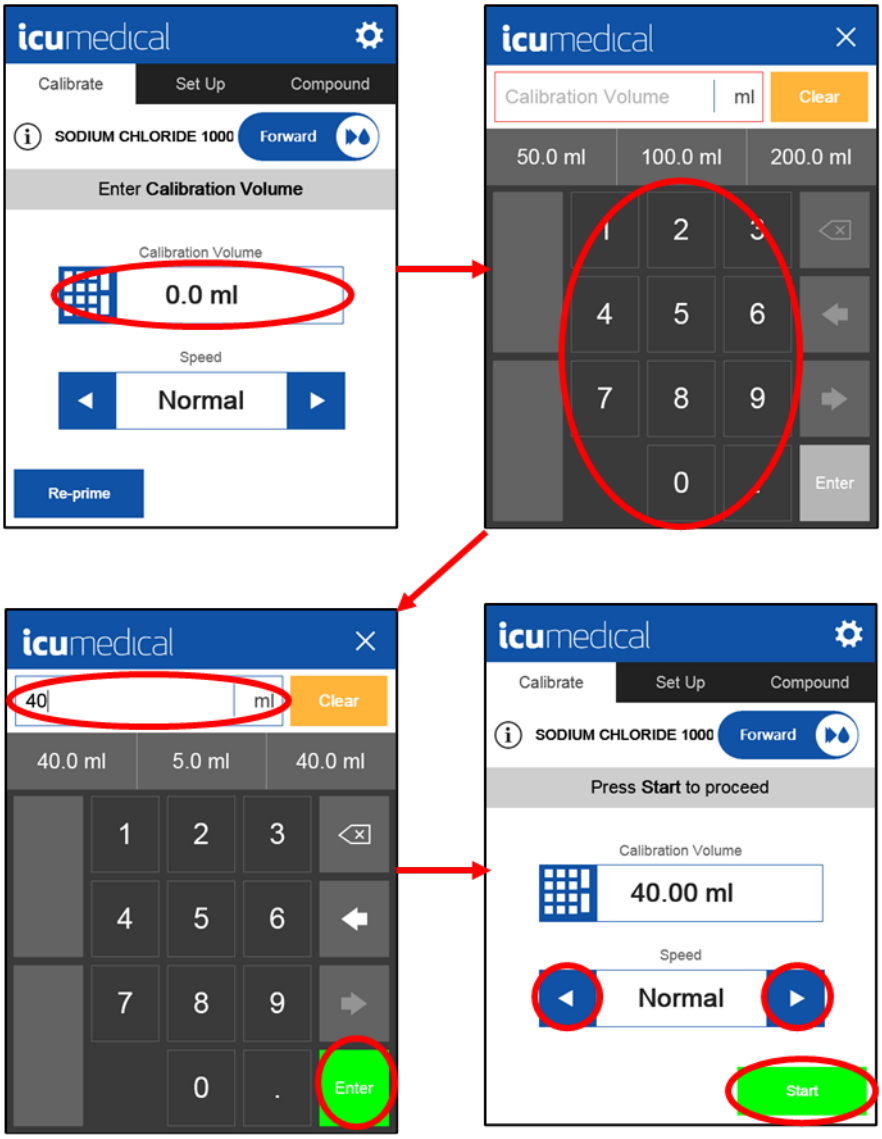
Note: When performing volumetric calibration, the user should use an output container with accurate graduated volume markings (example: syringe or graduated cylinder).

To turn On the Volumetric Calibration feature, select **Settings**, then **Customization**, then tap the **On** button next to the **Volumetric Calibration** text.

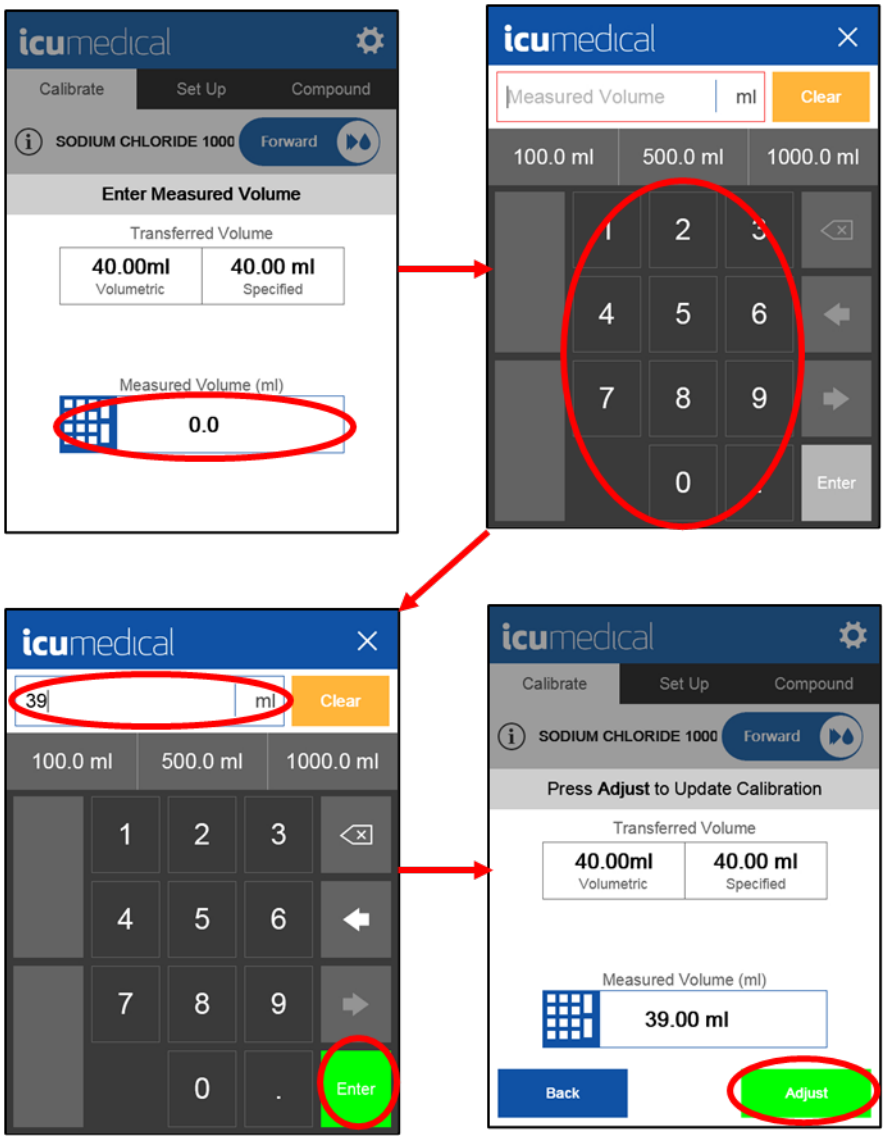


When Volumetric Calibration is **On,** the System will ask for a volume instead of a weight at the end of the calibration steps.

1. Enter Calibration Volume.
2. Select **Speed**.
3. Press **Start**.



4. Enter volume transferred as indicated on the output container.
5. To use the entered volume to update the pump unit calibration, press **Adjust**.

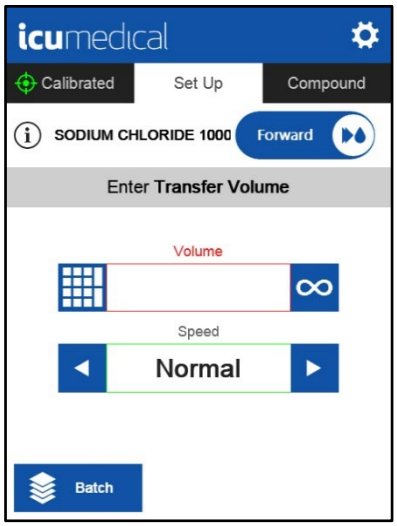


Note: Tapping **Adjust** will update the calibration of the pump unit to account for the over/underfill of the transfer as indicated on the screen (difference between specified volume vs measured volume).

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. See the **Warnings During Calibration** section of this manual 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.

After a successful calibration, the user will be directed to the Set Up menu.



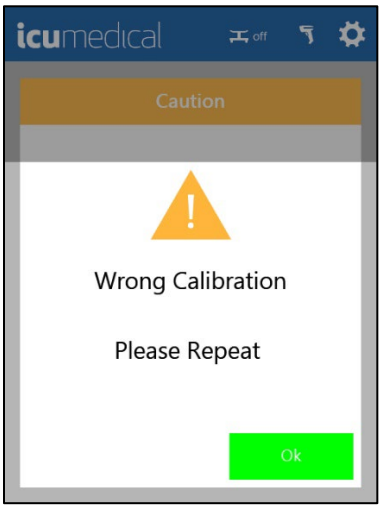
Warnings During Calibration

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

The first warning message of **Calibration out of regular range Accept?** is displayed when the discrepancy between expected and measured weight is greater than 20%. When the user receives this message, it is an opportunity to consider whether the calibration operation was performed correctly.

Tapping the **Yes** button confirms the user's entry and completes the calibration process. Tapping on the **No** button returns the user to Prime part of the workflow. Repeat the priming and calibration to ensure the accuracy of the pump unit.

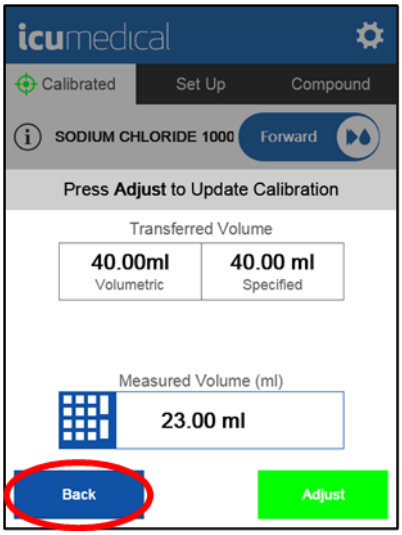
The second warning message of **Wrong Calibration Please Repeat** is displayed when the discrepancy between the expected and the measured weight is large enough to suggest something went wrong with the calibration.



Tap the **OK** button to return to the Prime part of the workflow. Repeat the priming and 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.



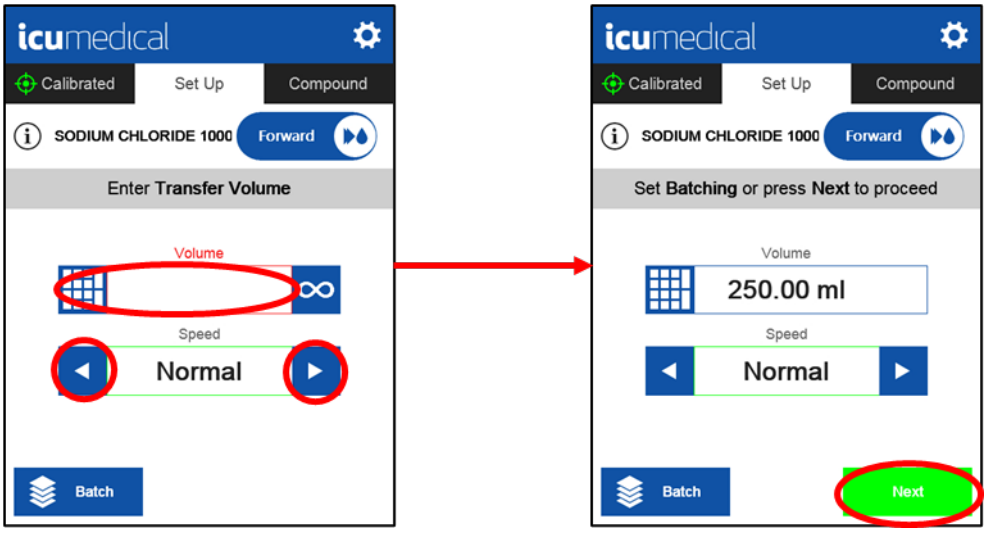
Note: By tapping **Back**, the pump unit calibration will NOT be updated based on the previous transfer and the System will allow the user to repeat the calibration steps again.

Set Up and Transfer

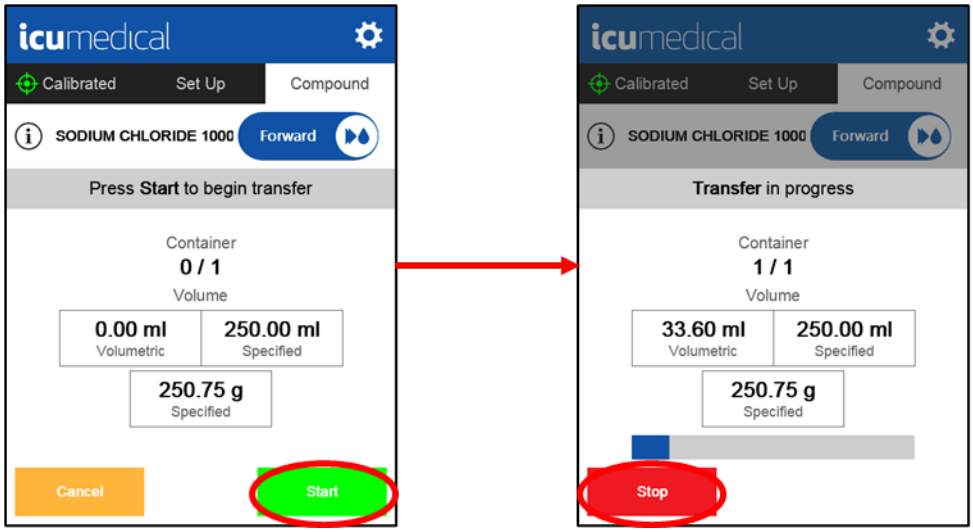
Upon proper calibration, the System allows a desired volume to be transferred and the desired speed to be set up before initiating a transfer.

1. If not already connected, connect the input (proximal) end of the tubing set to a source container.
2. If not already connected, connect the receiving (distal) end of the tubing set to a destination container.
3. Enter Volume to be transferred and select the speed.

4. Tap **Next** to confirm the transfer settings.

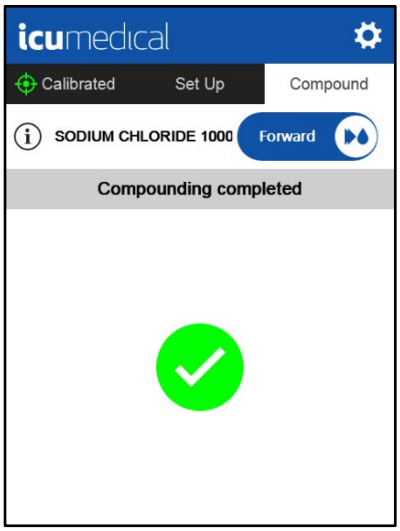


5. After confirming that the entered information is accurate, tap **Start** to initiate transfer. The pump unit will begin liquid transfer and the progress bar will indicate the status of the transfer. The volumetric measurement will provide an indication of what has been transferred into the bag. Tapping **Stop** will interrupt the transfer.



Note: There may be a few seconds delay between tapping **Start** and the pump unit starting.

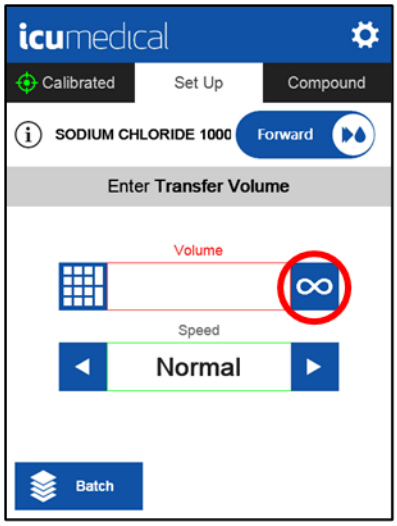
Once the transfer is complete, the System displays the **Compounding Completed** message. The System will automatically return to the **Set-Up** screen. The duration of **Compounding Completed** message display is configurable in the Advanced Settings.

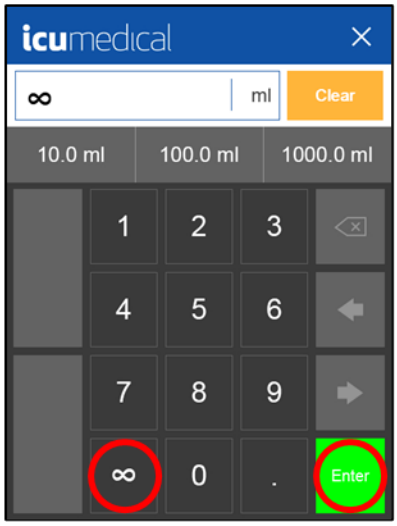


Infinite Transfer Mode

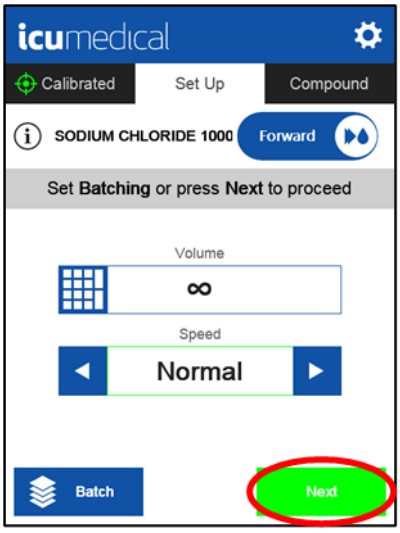
In Infinite Transfer Mode user has direct control of when fluid transfer is started and stopped. To enter this mode:

1. If not already connected, connect the input (proximal) end of the tubing set to a source container.
2. If not already connected, connect the receiving (distal) end of the tubing set to a destination container.
3. Select Infinity Mode by pressing the infinity symbol on the Set Up screen or selecting Infinity when entering Volume.



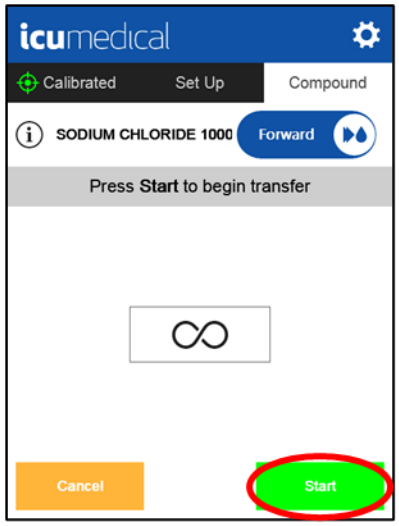


4. Tap **Next** to confirm the transfer settings.

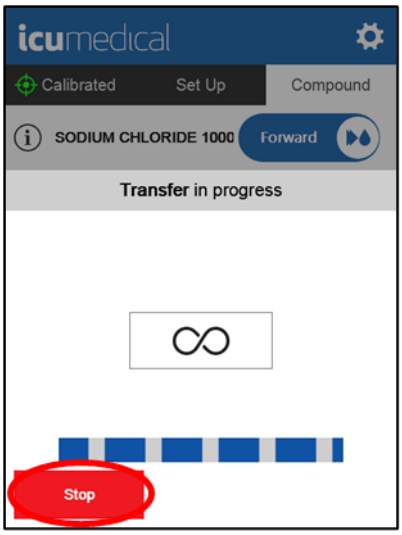


The user is now in Infinite Transfer Mode.

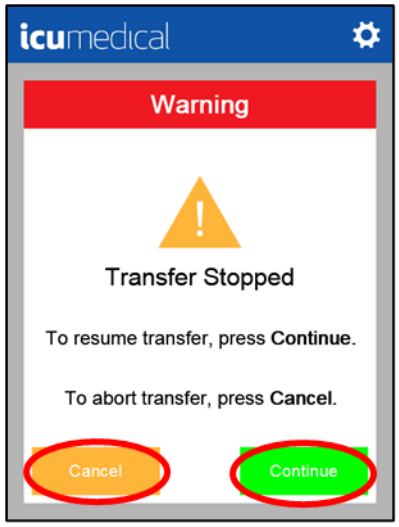
5. Press **Start** to start transfer.



6. Press **Stop** to stop the transfer.



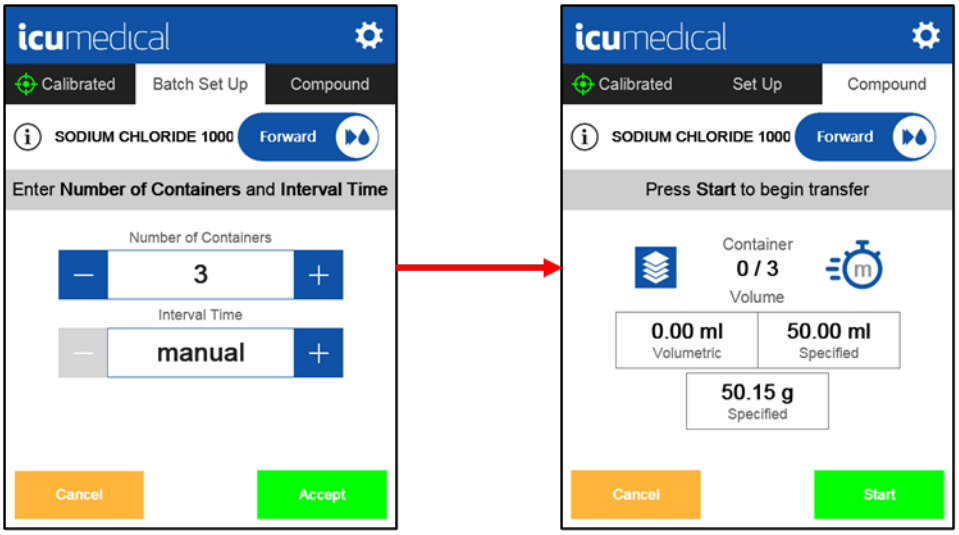
7. Press **Continue** to resume transfer or press **Cancel** to exit Infinite Transfer mode.



Batch Mode

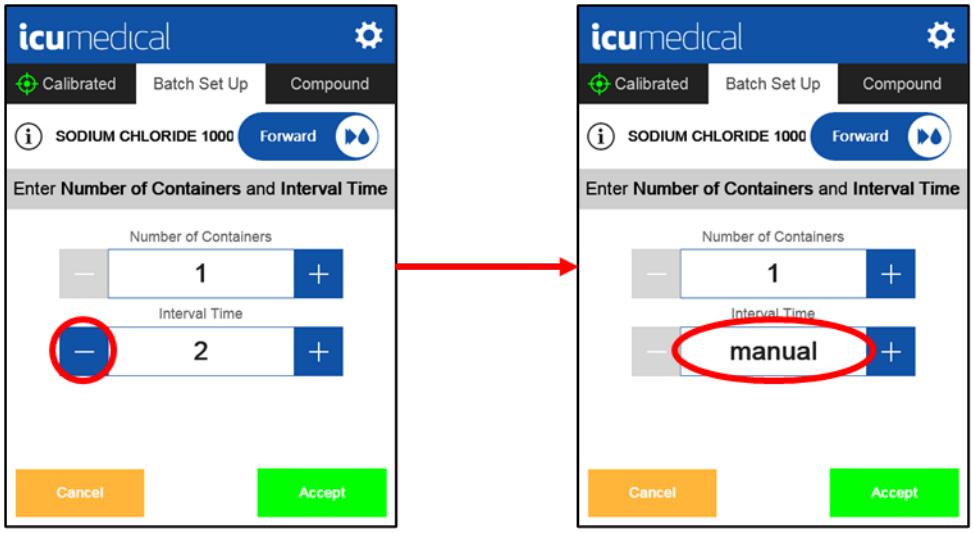
Batch mode can be used for compounding multiple destination containers/doses. The user can confirm the transfer accuracy using their own equipment and methods. When specifying the details of Batch Mode, the user will fill in the Number of Containers and the Interval Time.

Table 9: Batch Mode Settings

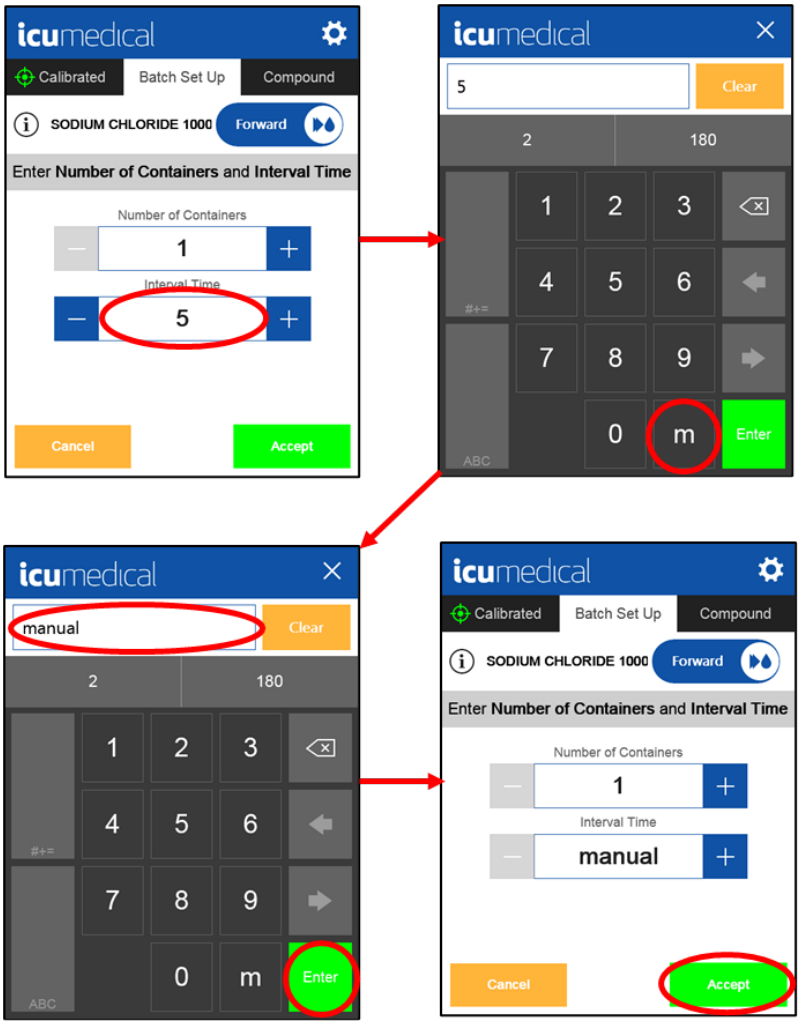
Option	Description
Number of Containers	The number of destination containers that the user wants to fill. The maximum value that can be entered is 999.
Interval Time	This number specifies the time (in seconds) the System will wait after completing the current transfer before initiating the next transfer. Interval time can have values from 2 to 180 seconds and Manual. When the interval is set to Manual, the pump will stop 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. 

Selecting Manual for Interval can be accomplished in two ways:

1. To select the option **manual** in the **Interval Time** field, press '-' until the number 2 is reached; then, press '-' one last time, and the option **manual** will be available for selection.

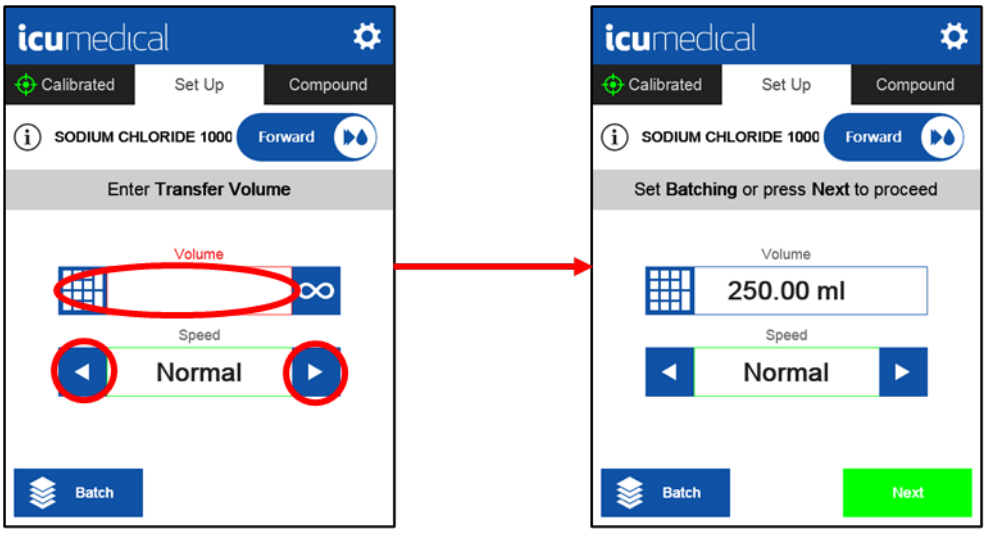


2. Select the **Interval Time** field, on the keypad screen select 'm' and press **Enter.**

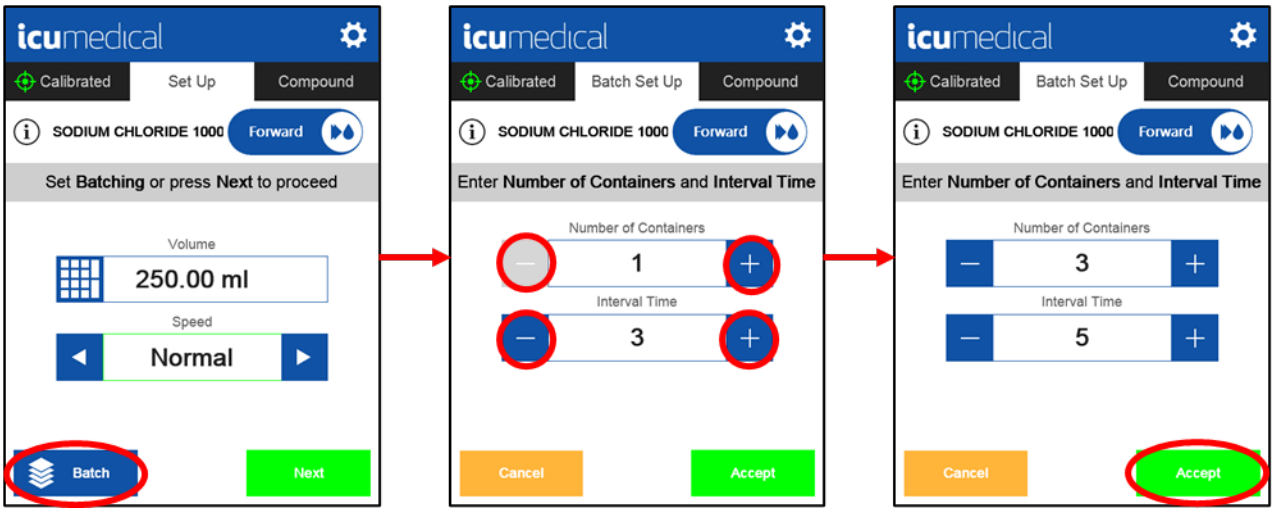


Using Batch Mode

1. Connect the input (proximal) end of the tubing set to a source container.
2. From the Set-Up screen, select **Volume** and **Speed** as you would normally do for a transfer.

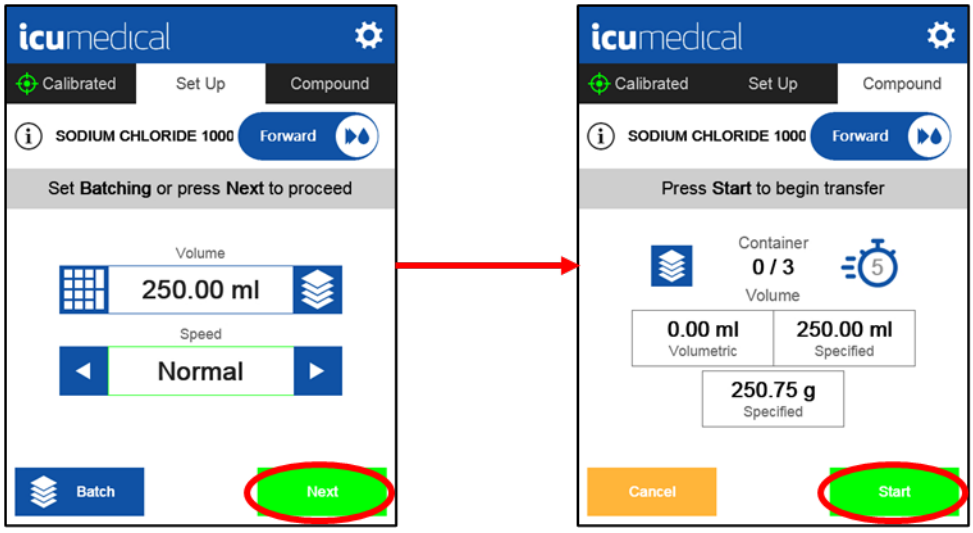


3. Tap **Batch** to set the number of (destination) Containers and Interval Time.



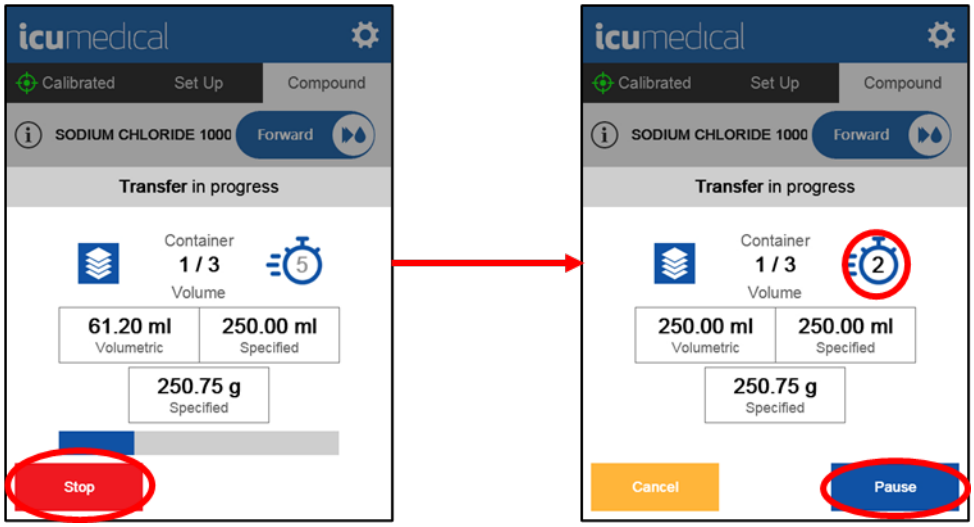
Note: The minimum interval time between the individual fillings is set to a default of 2 seconds.

4. Tap **Next** on the Set Up screen and then **Start** on the Compound screen to start the batch transfers.



When the transfer is complete, a countdown on the top right of the screen will alert the user about how many seconds are left until the next transfer is automatically initiated.

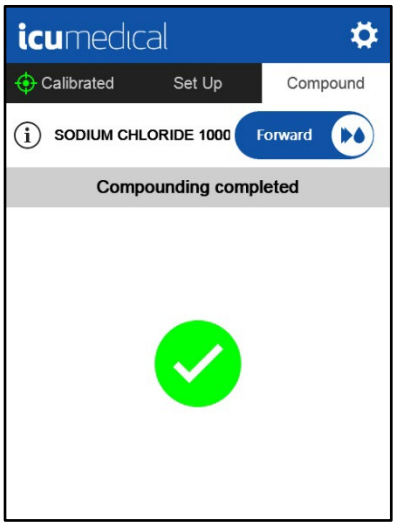
Note: If you are interrupted or need more time to switch output containers, press **Pause** or **Stop**.



5. When each transfer is complete and during the timer countdown, connect the receiving (distal) end of the tubing set to the next destination container.

Note: There may be a few seconds delay between tapping **Start** and the pump unit starting.

When all transfers in the batch are complete, the following screen appears:

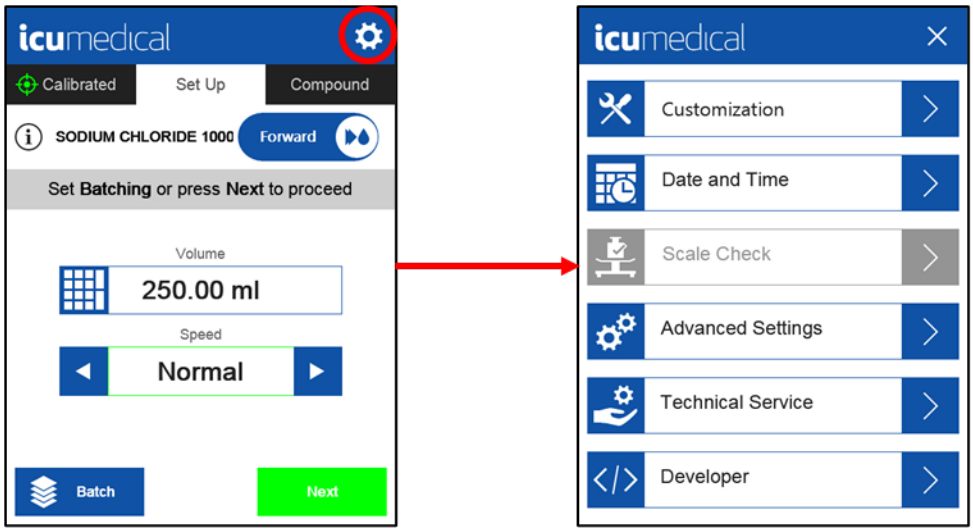


Power Off

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.

Chapter 4: Settings

To access the Settings Menu, tap on the **Settings** Icon ( )located in the top right of the toolbar. The Settings Menu will be displayed. Any menu items that are greyed out are not available.



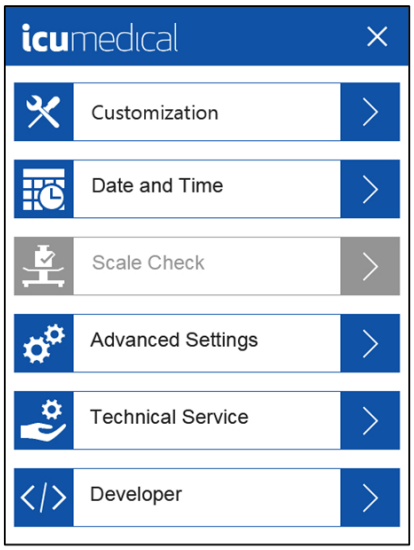
Important: The Settings Icon cannot be accessed until a tubing set is installed and the flap is closed.

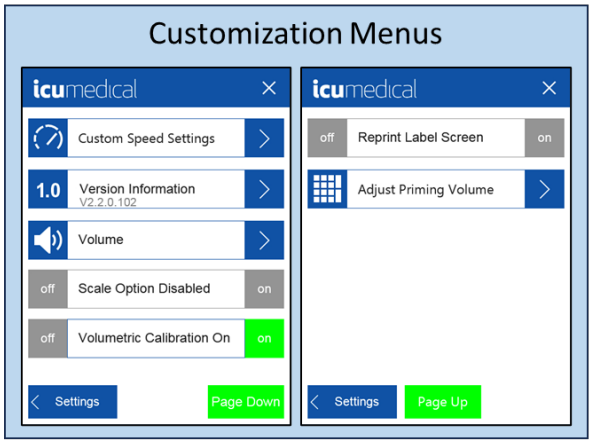
The following table describes the settings menu.

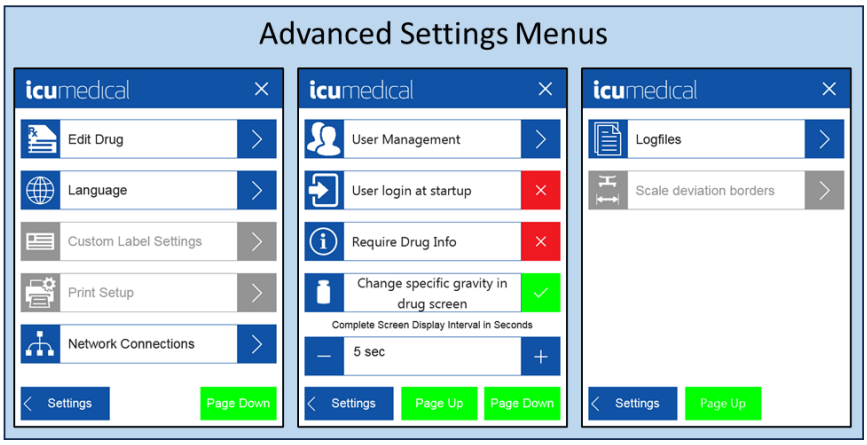
Table 10: Settings Menu

Option	Description
Customization	Allows updates to speed, volume options, and the user to view software version.
Date and Time	Allows updates to the date and time.
Scale Calibration Check	Allows user to perform Scale Kit calibration checks.
Advanced Settings	Allows updates to drug listings, language options, and network connections. (Password-protected).
Technical Service	ICU Medical Personnel only.
Developer	ICU Medical Personnel only.

The following is a map of the Settings Menu structure. Each Setting is described in detail in the following sections. Press Customization to enter the Customization Menus. Press Advanced Settings to enter the Advanced Settings Menus. Use Page Up and Page Down buttons to move between pages in the Customization and Advanced Settings Menus.



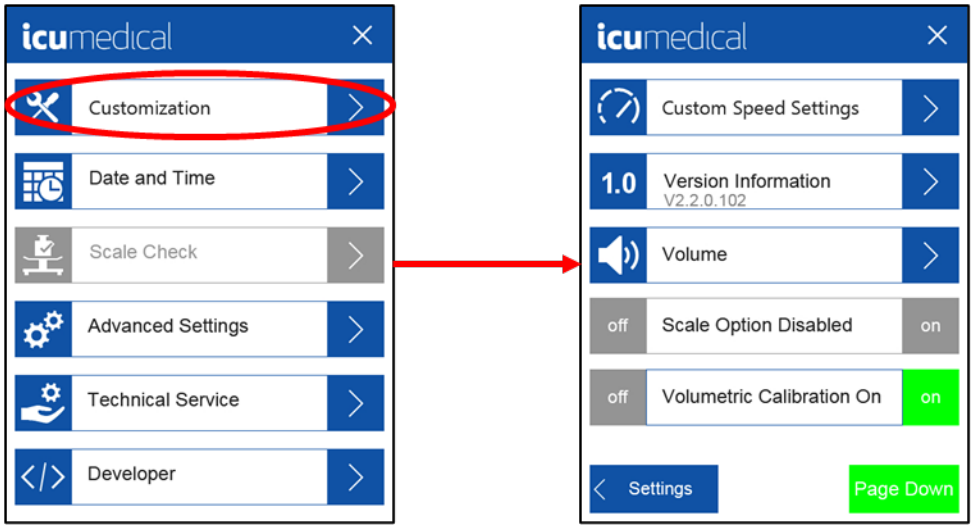




Customization

Tap on the **Customization** tab to modify settings that are user controllable. A window will display the customization options for the System.

The available Customization settings are: **Custom Speed Settings, Version Information, Volume, Volumetric Calibration Enable, and Adjust Priming Volume, and User Logout** (If the user management is activated).



Custom 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.

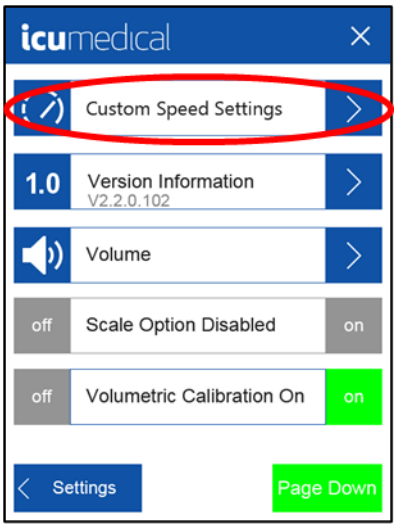
Table 11: Default Speed Settings

Number	Default Name	mL/min*	Backdraw (mL)
1	Minimum	75	
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	

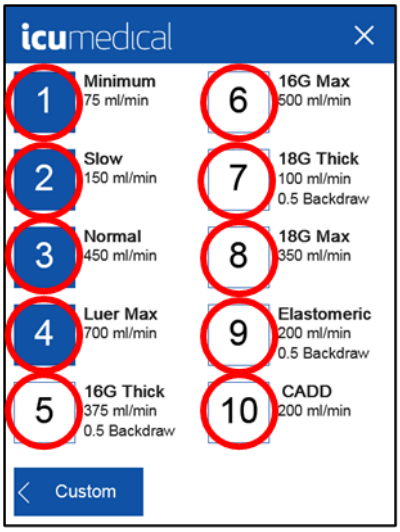
***Note:** The pump unit speed is not user-configurable; only named identified presets are available.

To Customize the speed settings:

1. In the **Customization** settings menu, tap on the **Custom Speed Settings** option.

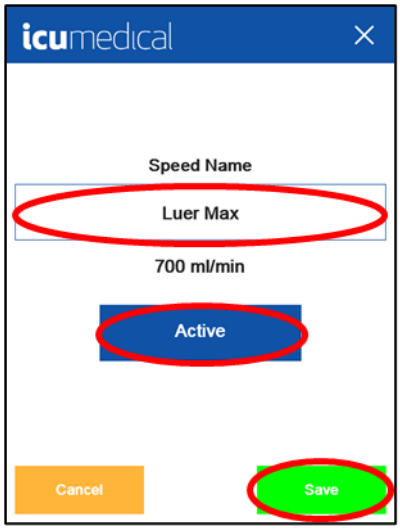


2. Change the name or activation status of a speed setting by tapping the number next to the name.



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

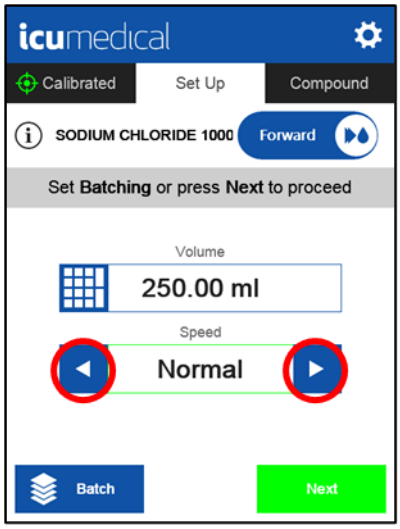
3. Select a **Speed Name** to change it. Tap the blue button to **Activate** or **Deactivate** the speed setting. Tap **Save** to confirm the changes.



Note: At installation, the pump unit defaults to setting 3 “Normal” (450 mL/min) for all drugs.

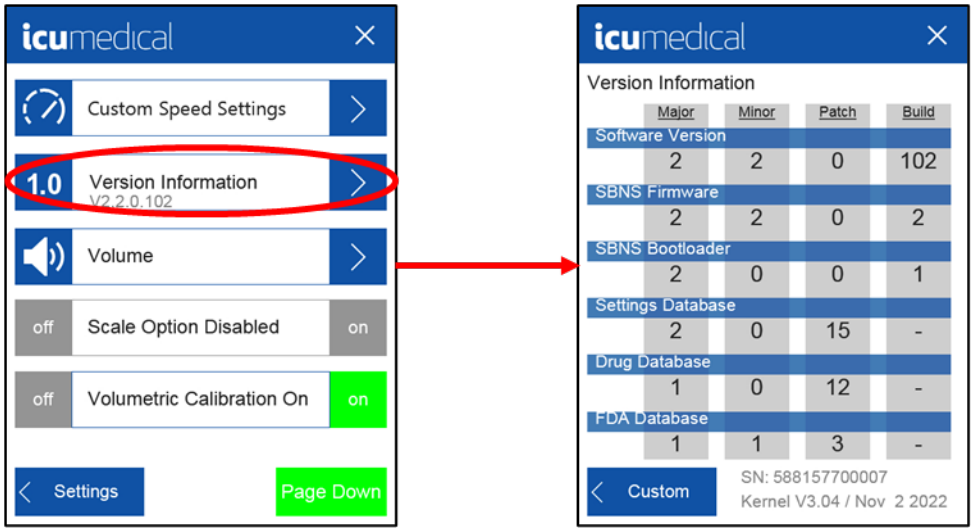
Note: If the setting 3 “Normal” (450 mL/min) is deactivated, the next active speed will be used as the default.

Note: The user will be able to select activated speed settings, using the names the user customized, for calibration and fluid transfers. The user can tap left/right arrows to change the speed.



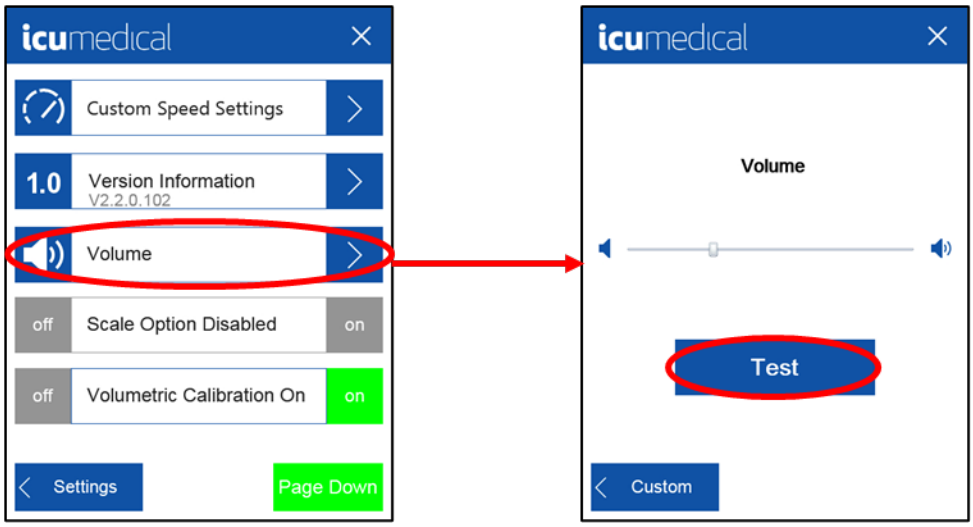
Version Information

Tap on **Version Information** setting to see the pump unit software component versions.



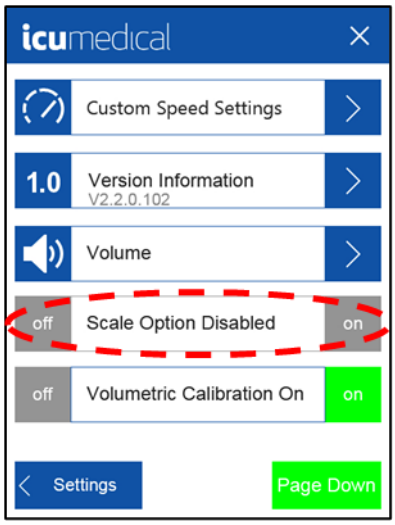
Volume

1. Tap on the **Volume** setting to adjust the sound volume. The user can select a desired volume by clicking the desired position on the bar, the slide will move accordingly.
2. To test the current volume, Tap the **Test** button.



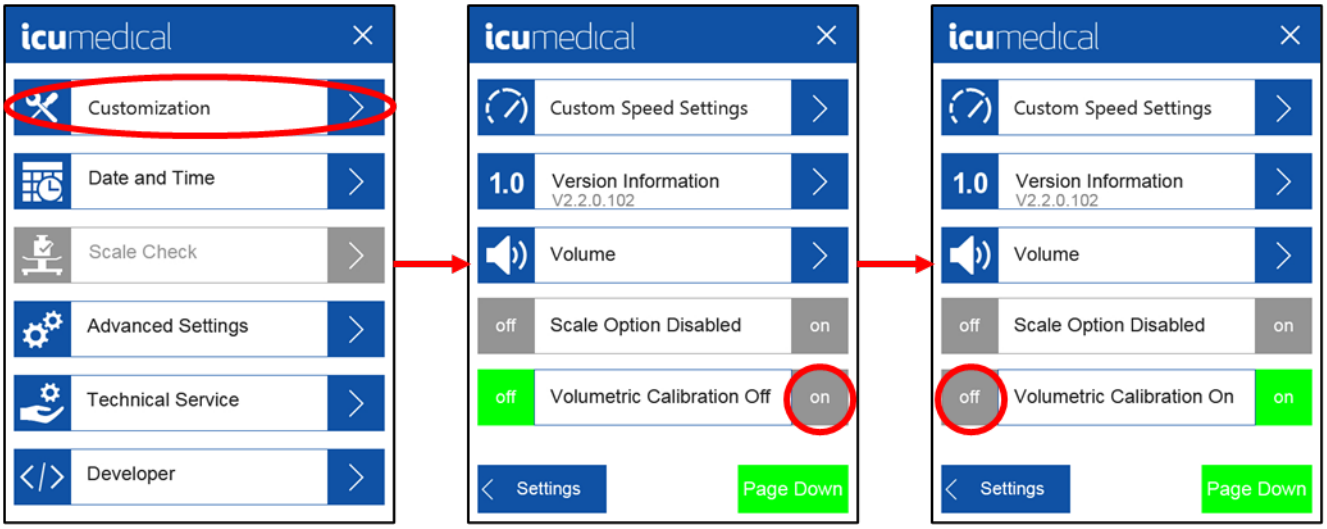
Scale Option

There is no option for a connected scale in this System version. This option is marked “Scale Option Disabled” and cannot be turned on or off.



Volumetric Calibration Enable

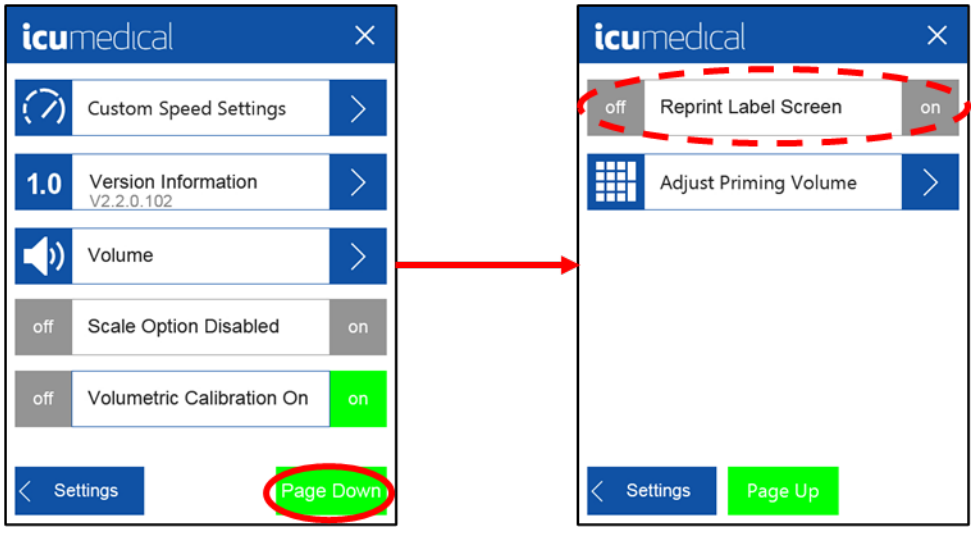
When using the System without a scale, the user has the option of Enabling Volumetric Calibration. This will allow the user to calibrate without a scale and the calibration interface will ask for a volume in ml when reading the calibration results. Find the Volumetric Calibration setting on the Customization Menu. To enable this option tap **On**. If later an External Scale is incorporated into the workflow, go to this screen and tap **Off**.



Note: Volumetric Calibration is set to **On** by default.

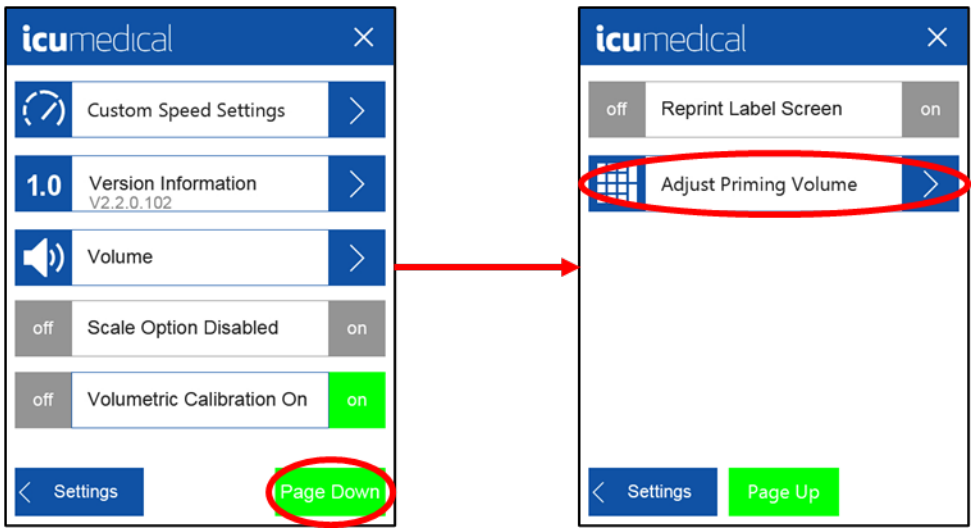
Reprint Label Screen Enable

Printer is not an available option in this System version. Reprint Label Screen is a disabled option and cannot be turned on or off.

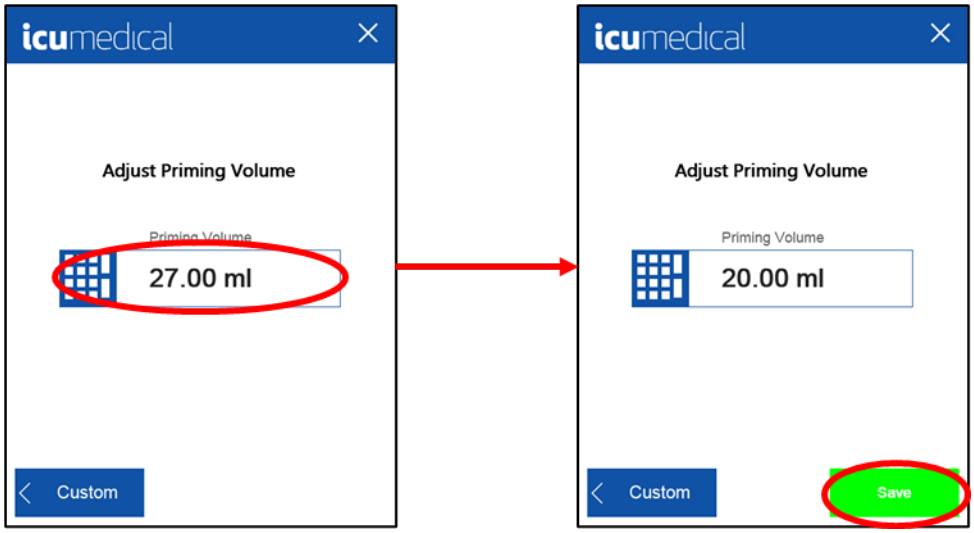


Adjust Priming Volume

The User can manually adjust the volume for priming the tubing set. This setting is on the second page of the **Customization** Menu. Tap the text to adjust the priming volume.

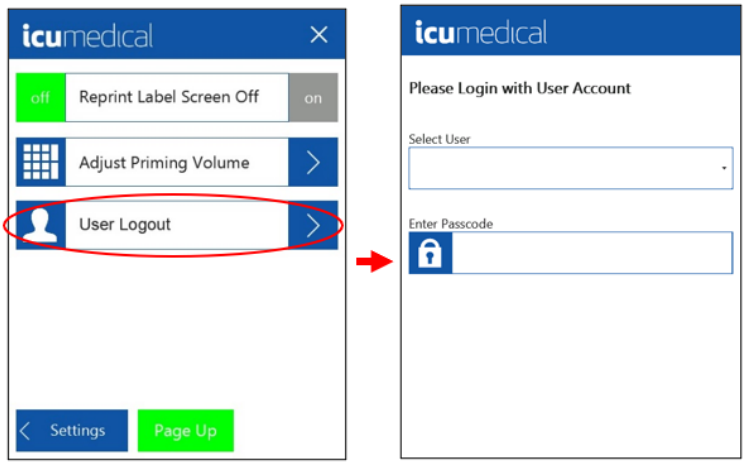


Select the current Priming Volume value. After entering the new value, press **Save**.



User Logout

If **User login at startup** is enabled in Advanced Settings, the user will be required to login when the System is powered on. That will add **User Logout** as a selection on the second page of the Customization Menu. Tap **User Logout** to logout of the System. The System will then show the **User Login** screen so the next user can Login.



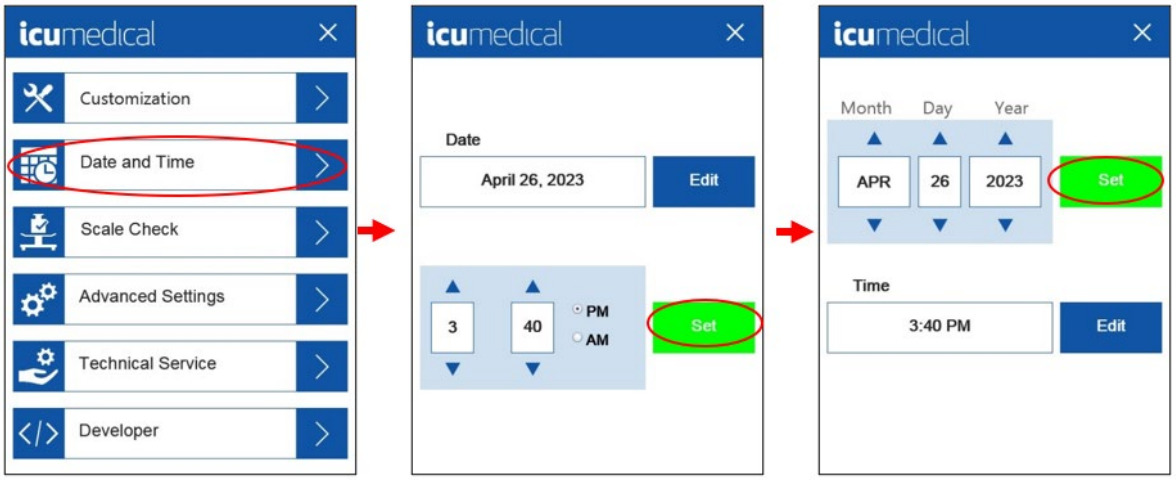
User Login

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. User login settings can be updated within the **Advanced Settings** menu (see **User Login at Startup**).

Date and Time

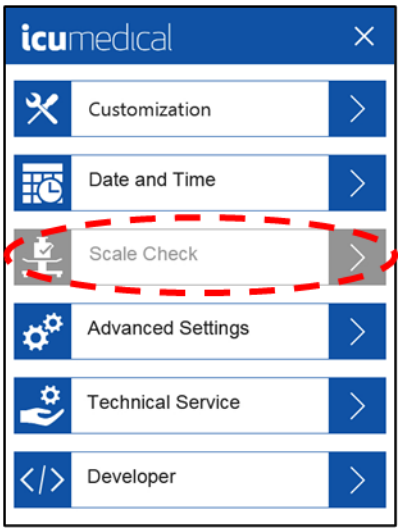
The user can update the date and time in the pump unit on the first page of the **Settings** Menu.

Enter the current date and/or time and tap **Set**:



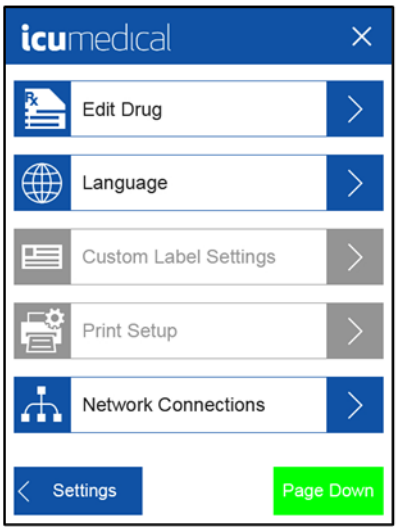
Scale Check

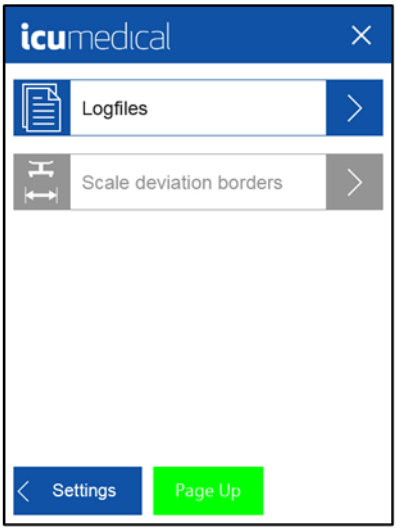
The Scale Check feature allows the user to check the function of the connected Scale Kit by weighing a test weight of known mass. Connected scale is not available in this version, so this option is greyed out and not selectable.



Advanced Settings

The Advanced Settings will allow the user to adjust various settings of the System. There are three pages of Advanced Settings as shown below. These menus are available only to authorized users by entering the **Rotating Passcode** (see below for details).

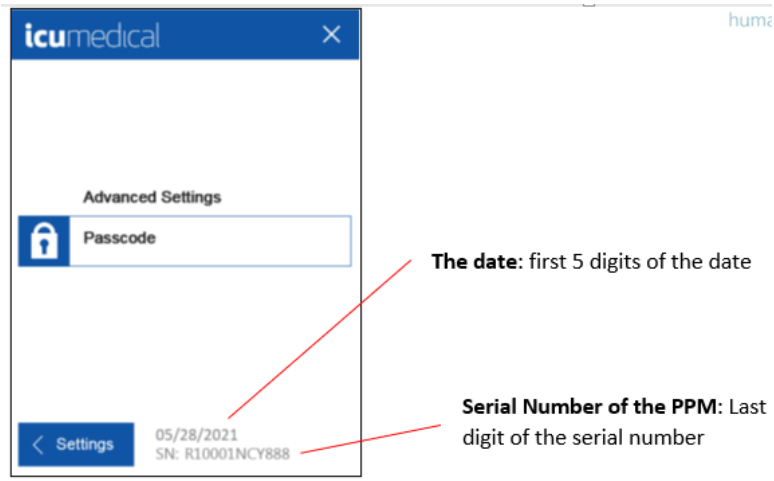




Rotating Passcode

The rotating passcode is composed of three different components and must be recalculated by the user every day.

- The first component is the current date, the first 5 digits of the date.
- The second component is the last digit of the serial number of the pump unit.
- The third component is the value for the setting area (3 -> for the Advanced settings).



Below is an example of how the rotating password is calculated. To get the correct password, the user must add the three components consisting of Serial Number, X and Y together.

Passcode: Base PIN + X + Y

Base PIN	First 5 digits of the date
X	Last digit of the serial number of the pump unit
Y	Value for setting area (3 -> Advanced)

Example for calculating the passcode:

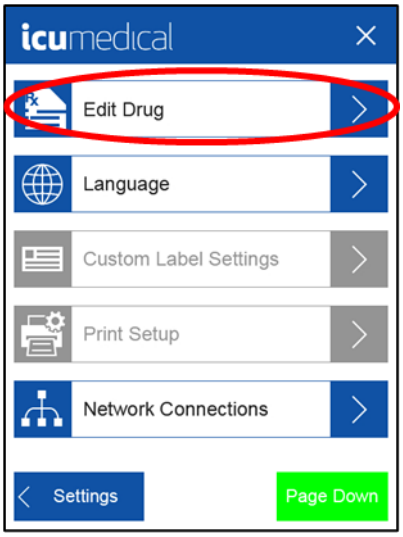
The digits which are marked in red are the digits that must be used in the rotating passcode.

Date	05/28/2021
Serial number of the used PPM	R10001NCY888
Value setting area	3 (Advanced settings)

The Passcode for the Advanced setting area is: 05282 + 8 + 3 = 05293 (this is the correct passcode).

Edit Drug

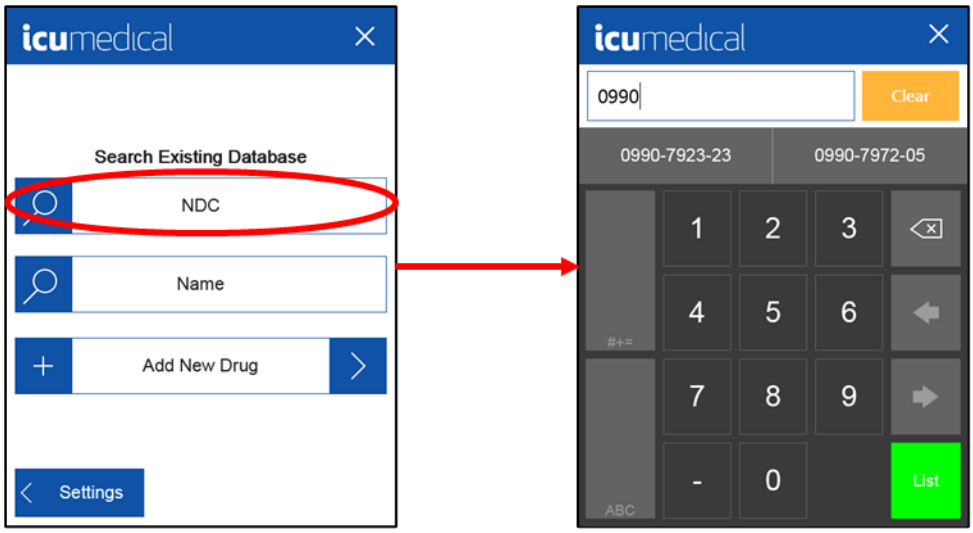
1. Select Edit Drug in the **Advanced Settings** menu.



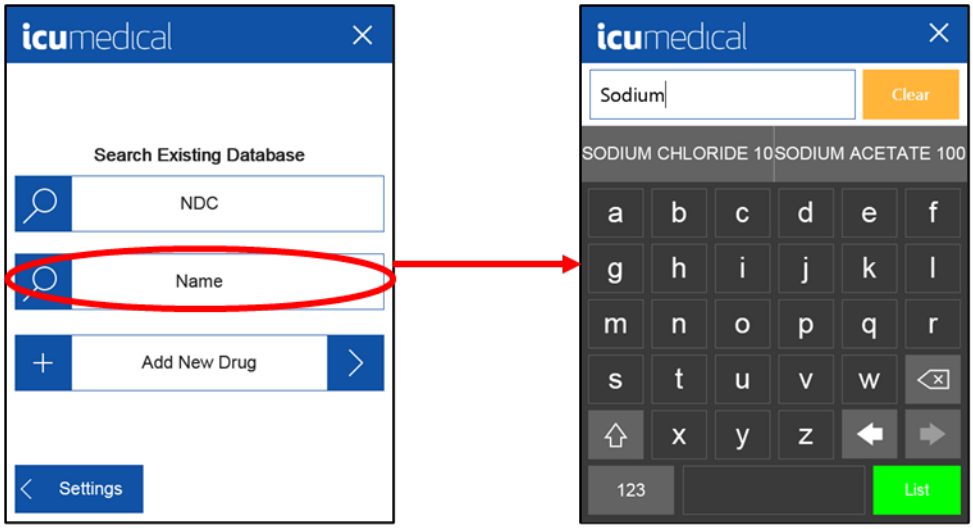
The user can search drugs by **NDC** or **Name** (drug name).

2. To search by NDC, select **NDC** option. Enter the NDC code and tap **Enter**.

Note: As user enters the NDC number, System will suggest the NDC number to autofill.



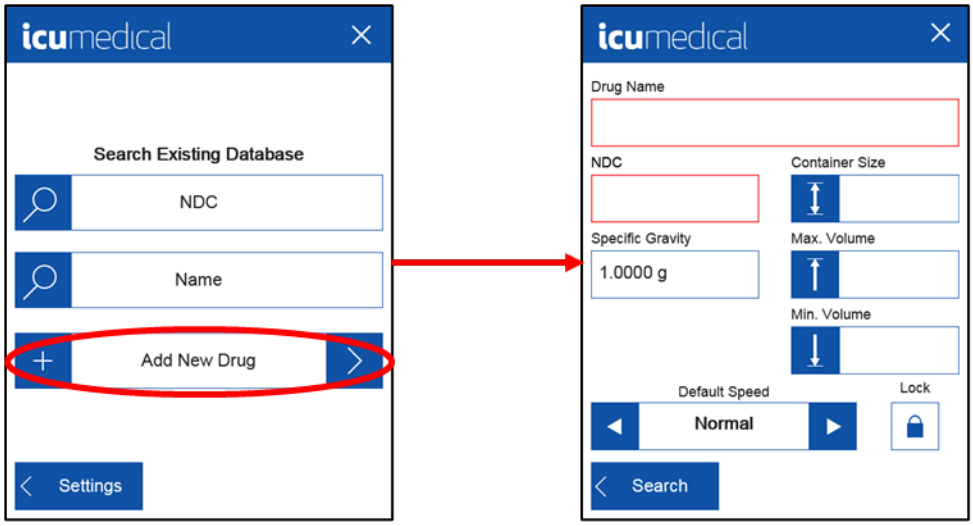
3. To search by name, select **Name**. Enter the name and tap **Enter**.



Note: As user enters the drug name characters, the System will suggest the name to autofill.

If the required drug does not exist in pump unit's database, then the user will need to add the new drug to the database.

4. To add new drug, tap on **Add New Drug**. Enter the new drug information and tap **Enter**.



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

a. Drug Name Specifications

i. May be a combination of alphanumeric characters.

ii. Up to 100 characters allowed, but using less than 20 characters is recommended for readability on the device.

iii. The recommendation is to include name and concentration as part of Drug Name entered.

b. NDC Specifications

i. May be a combination of alphanumeric characters.

ii. The recommendation is to use numbers only.

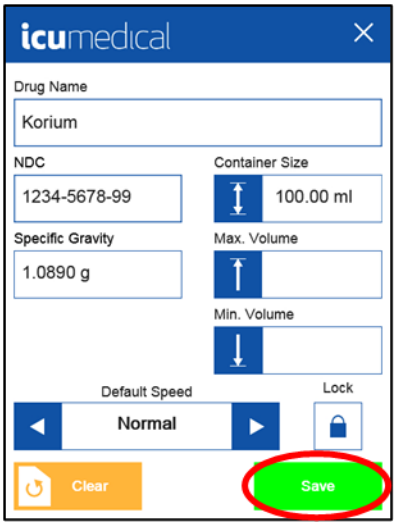
Note: System search functions may not properly identify NDCs that utilize letters or special characters.

iii. May not enter NDC that is already saved in the database.

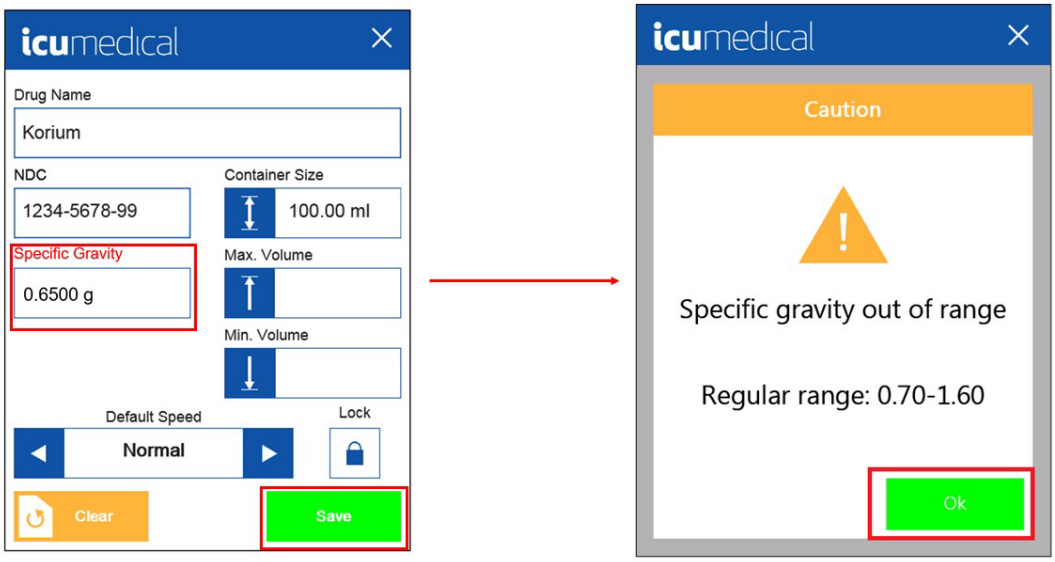
iv. Up to 100 characters allowed, but using less than 20 characters is recommended for readability on the device.

v. The recommendation is to adhere to FDA standard formats for 10-digit numeric NDCs.

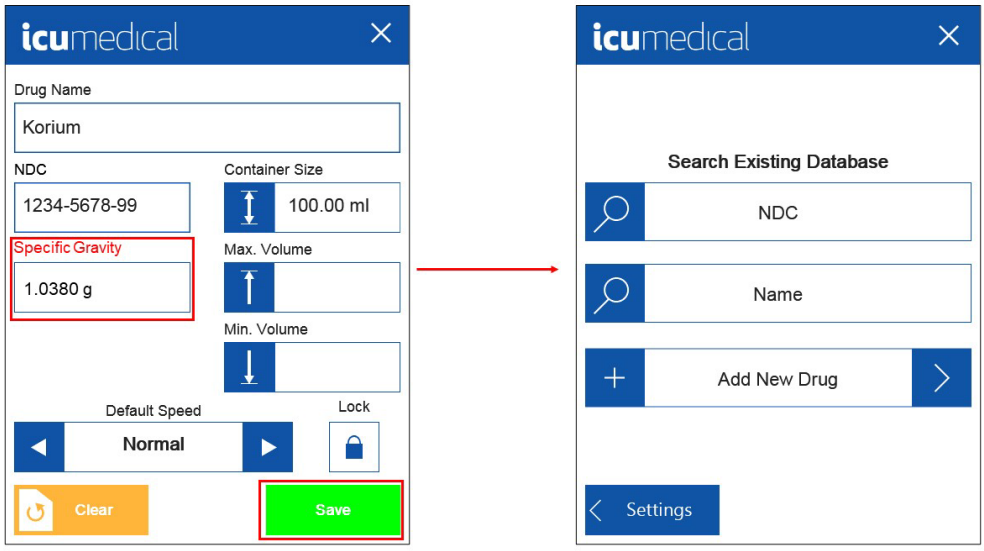
5. Once the user identifies the drug, add missing information if required.
6. Verify the correct information is entered in the designated fields and tap **Save**.



If a specific gravity is entered outside the value range defined in the System (0.70-1.60), the text “Specific Gravity” will be displayed in red. If the user continues and taps the **Save** button, a warning message appears. Pressing **Ok** acknowledges the warning and returns the user to the previous screen to correct the Specific Gravity entry.



7. Enter a specific weight in the range 0.70 – 1.60 g and then tap **Save**. The System will return to the initial Edit Drug screen.

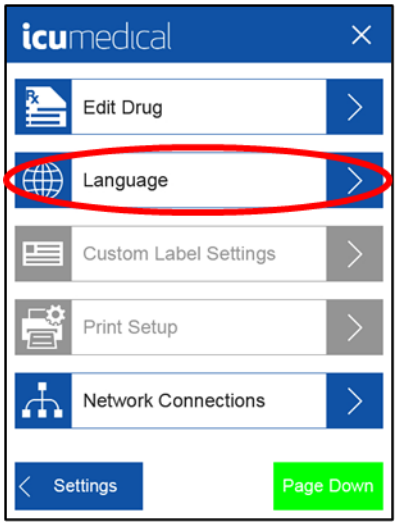


Language

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

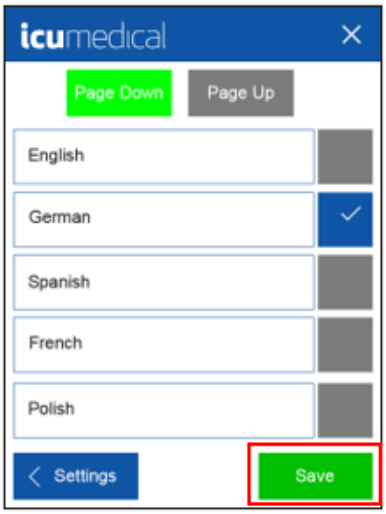
To Select Language:

1. Go to Advanced Settings menu and tap on **Language**.



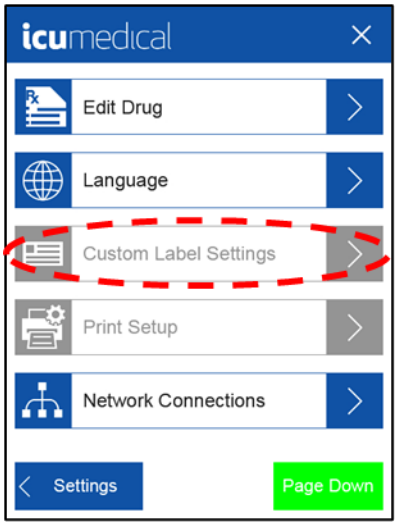
2. Tap on the gray square next to the desired choice to select the Language.

3. Tap **Save** to set the new language.



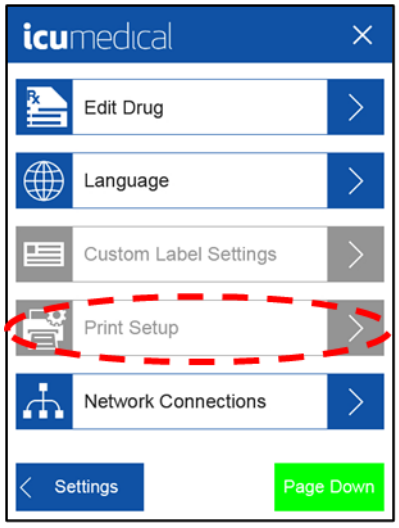
Custom Label Settings

Printer is not an available option in this version. Custom Label Settings is a disabled option.



Print Setup

Printer is not an available option in this version. Print Setup is a disabled option.



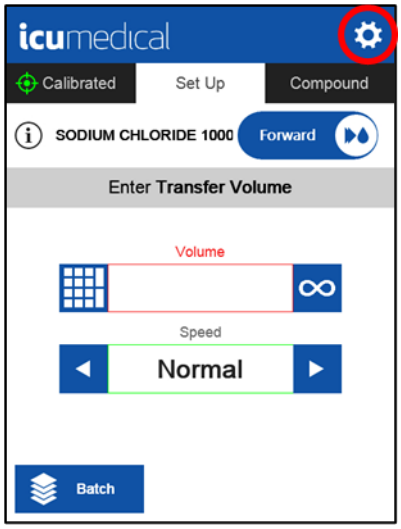
User Management

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

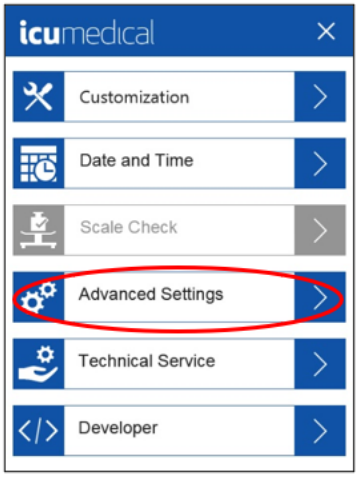
- Standard (Access to Customization, Date and Time, and Scale Check)
- Advanced (Access to Customization, Date and Time, Scale Check, and Advanced Settings)

To support the creation of accounts, the system comes with a default account named “User Manager.” It is recommended that accounts be managed through the “User Manager” account. The “User Manager” account has the Technical level of permissions. To access the “User Manager” account:

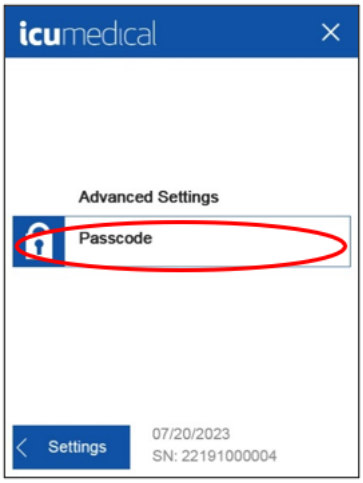
1. Select **Settings**.



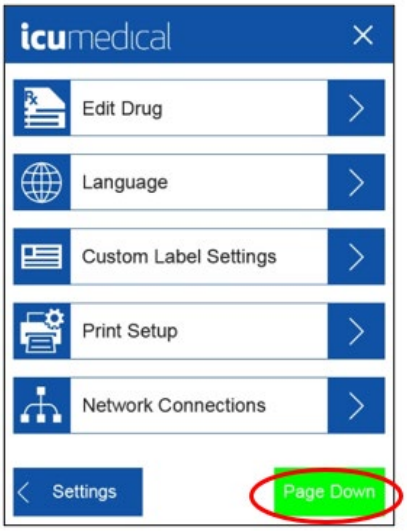
2. Select **Advanced Settings**.



3. Enter Advanced Setting Passcode.



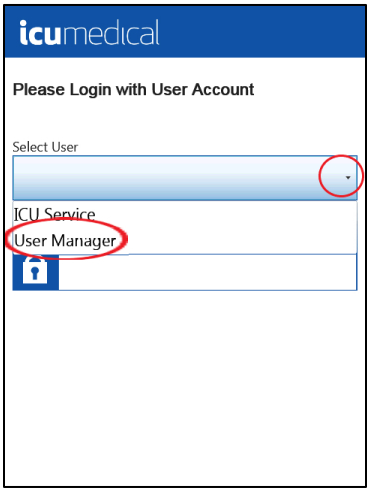
4. Select **Page Down**.



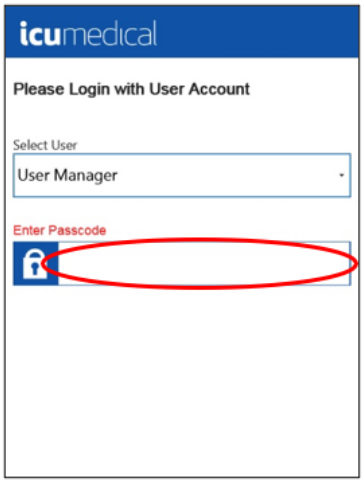
5. Select User Login at Startup.

6. Confirm “User Login at Startup” is set.

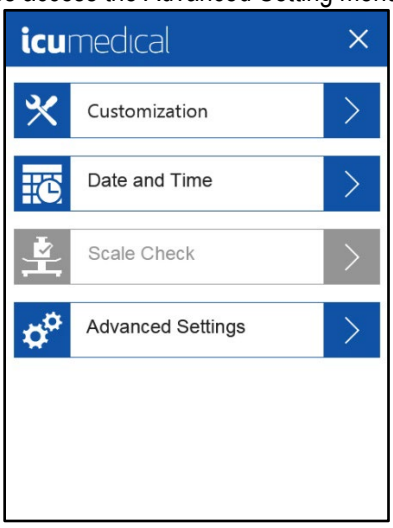
7. Power cycle the pump unit. Press down arrow on "Select User", choose User Manager.



8. Enter passcode for User Manager (“43210”).



The “User Manager” is now logged in. After logging in, the screen shown below will display. The “User Manager” has Advanced permissions which enables access the Advanced Setting menu items without entering a passcode.



The “User Manager” can now create additional accounts.

To create a user:

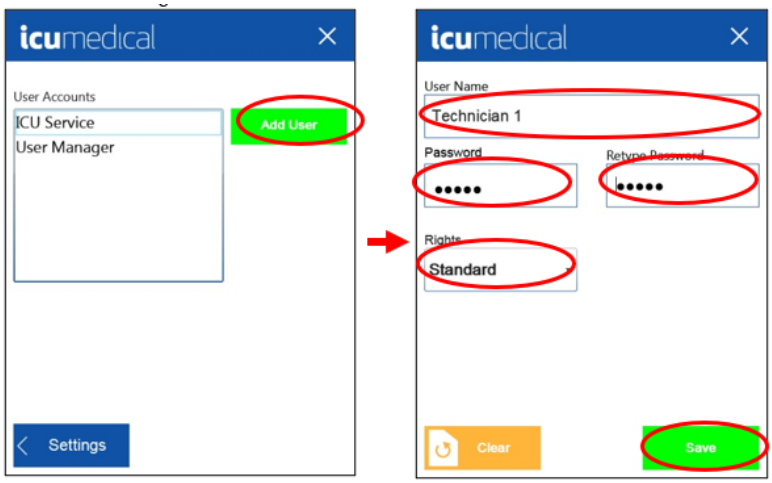
The following steps create a user named “Technician 1” with Standard rights and Password “11111” as an example.

Note: The User Manager can choose between Standard or Advanced Rights (Permission Levels).

1. Tap on **User Management** in the Advance Settings section.

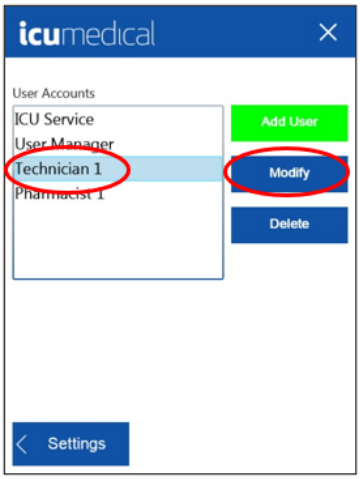
2. Tap on **Add User**.
3. Enter “Technician 1” as User Name and Password “11111”
4. Retype the password to confirm it.
5. Select **Standard** for Rights.

6. Press **Save**.



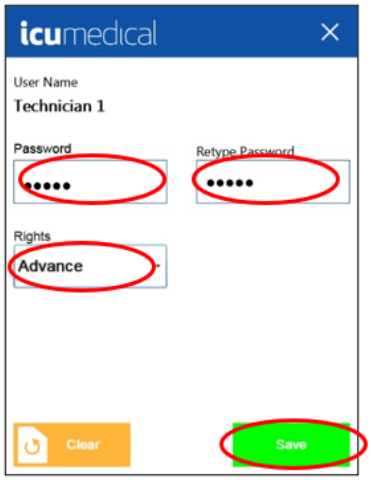
To modify a user:

1. Select an existing user and tap **Modify**.



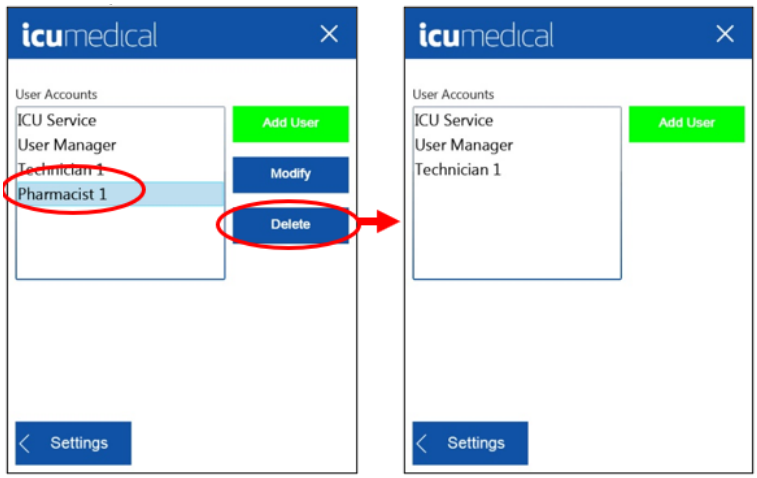
Modify allows the Password and/or Rights for a User to be changed.

2. Once changes are made tap **Save**.



To delete a user:

Select an existing user and Tap **Delete**. The user is removed from the User Accounts list.

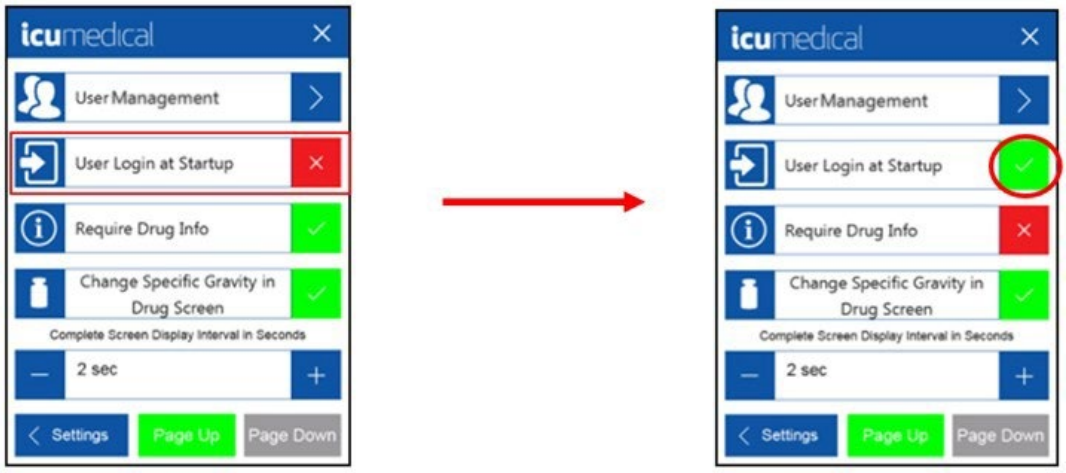


User Login at Startup

The authorized user can require a user login on the pump unit.

To Login at Startup:

1. Tap on **User Login at Startup** in the Advanced Settings section.



When the green check mark is set by the authorized user, the user login will be required each time the pump unit is powered on.

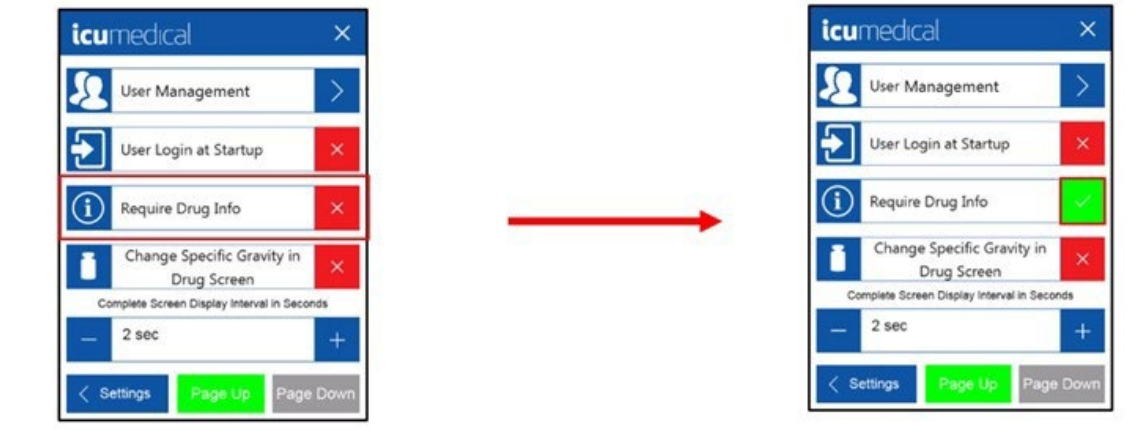
Require Drug Information

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

Note: By default, Drug Info is set to Not Require Drug Information.

To enable the Require Drug Information option:

1. Tap **Require Drug Info** in the Advanced Setting section.
2. Tap on red box to enable the option. A Green checkmark will be displayed.



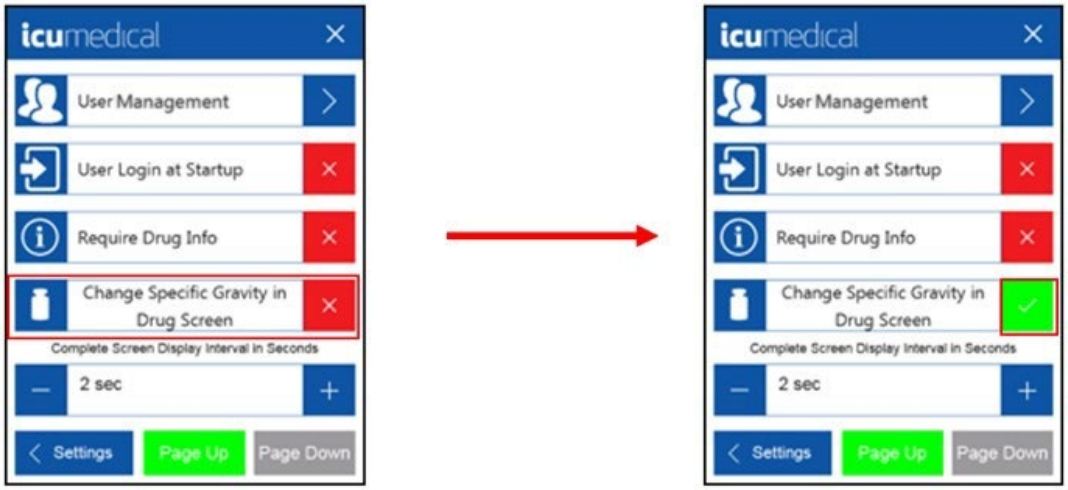
Drug Information is NOT required

Drug Information is required

Change Specific Gravity in the Drug Screen

The authorized user can decide whether the specific gravity of a drug can be changed in the Drug Set Up screen.

1. Tap on **Change Specific Gravity in Drug Screen** in the Advanced Settings section.



2. Toggle between (✓) and (x) to change the specific gravity or not.

Complete Screen Display Interval in Seconds

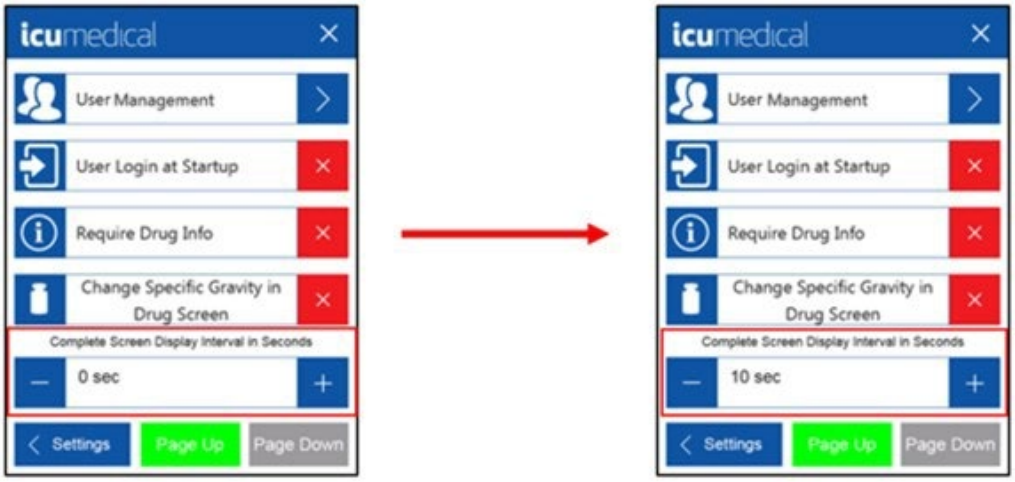
A timer can be set for how long the display of the finished filling operation should be displayed.

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

To adjust the Complete Screen Display Interval in Seconds:

1. Go to Complete Screen Display Interval in Seconds in the Advanced Settings section.

2. Using the "**+**" and "**-**" buttons, adjust the desired time-out interval. The interval can be set between 0 and 60 seconds.



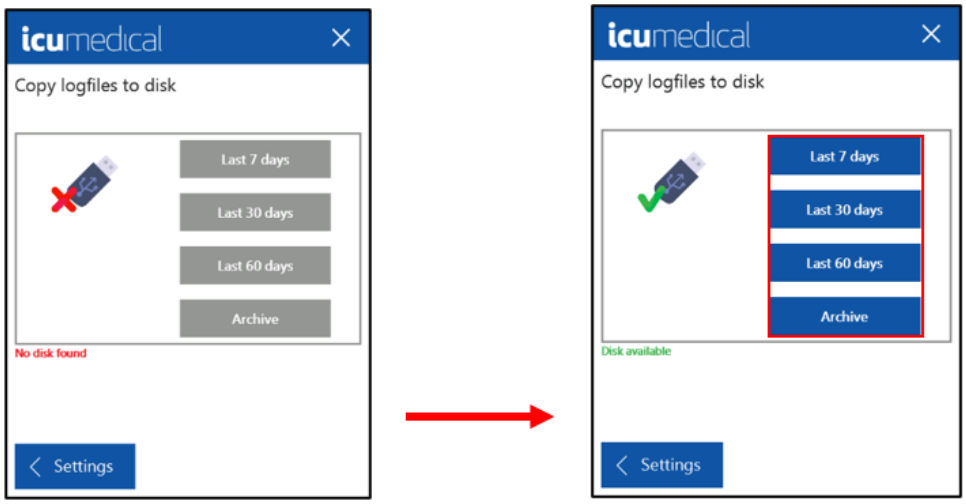
Logfiles

1. Insert an USB stick into the adapter.

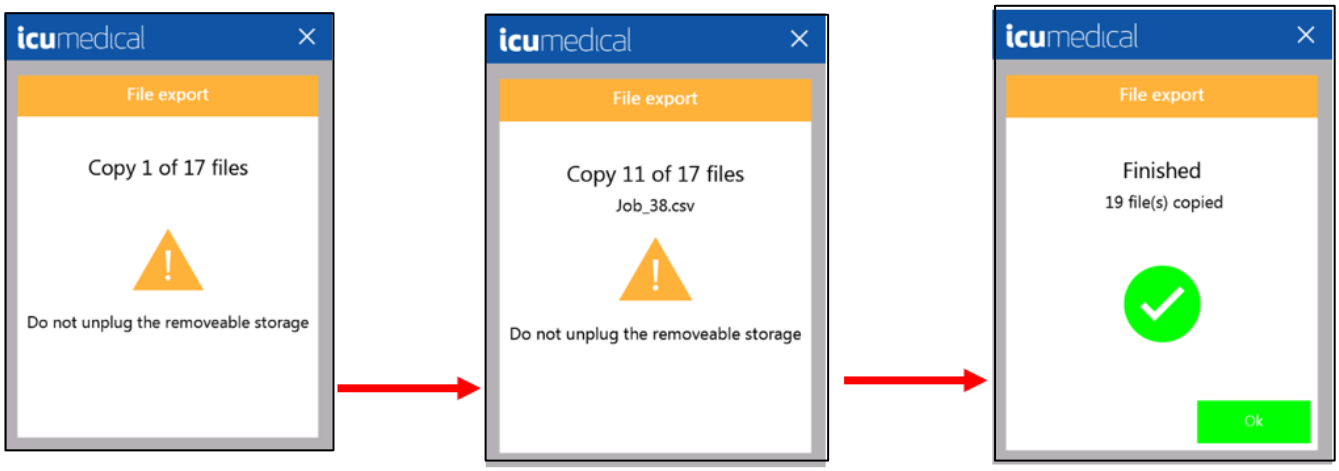
Note: The USB stick and adapter must be requested from ICU Service personnel.

2. Insert the adapter into the pump unit USB port.
3. Select desired option (Last 7 days, Last 30 days, Last 60 days, Archive).
4. Wait for the “Finished” message to be displayed on the pump unit.
5. Remove the USB and adapter from pump unit.

Note: Archive will save all available log files.

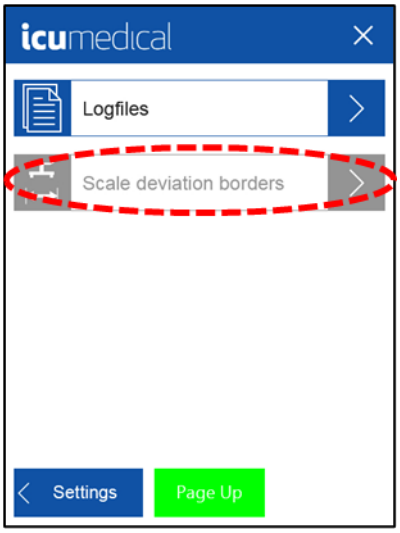


Note: System will display progress until log files are all transferred to the USB stick.



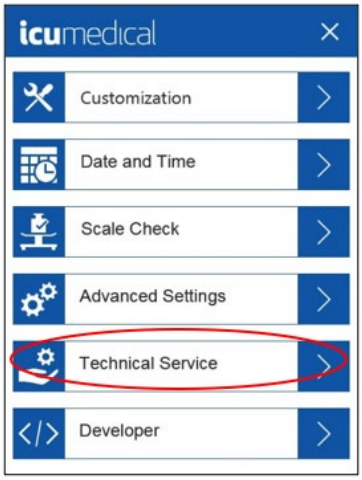
Scale Deviation Borders

Connected Scale is not available in this version. Scale Deviation Borders is a disabled option, it only applies when there is a Connected Scale.



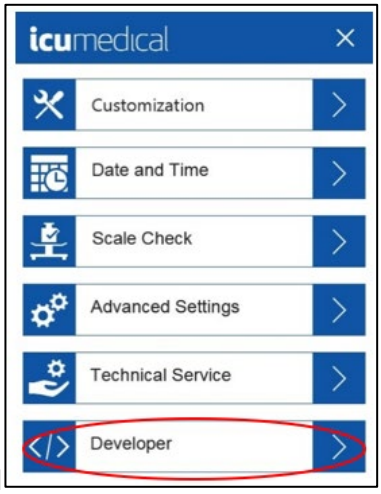
Technical Services

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



Developer

Developer Menu Item is for ICU Medical authorized personnel only.



Chapter 5: Specifications, Maintenance and Troubleshooting

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

ICU Medical recommends sending the pump unit to ICU Medical Service department once a year for inspection and maintenance. Please contact the local ICU Medical representative or ICU Medical Service department for instructions.

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 12: Environmental Specifications

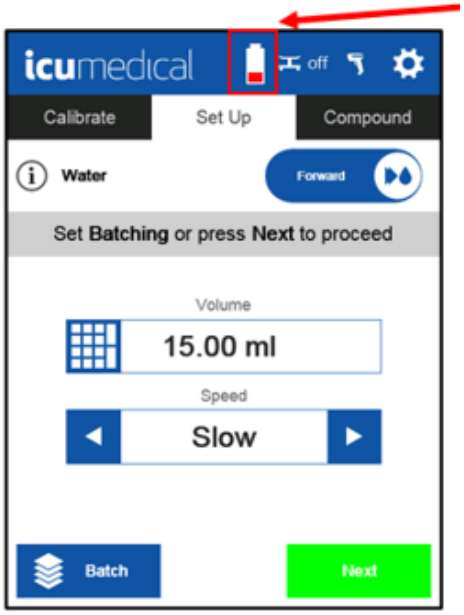
Reference	Specification
Operating Temperature	+10°C to +40°C
Operating Humidity	15% to 60% (non-condensing)
Operating Altitude	0 to 2000 meters above sea level
Storage Temperature	0°C to +60°C
Storage Humidity	15% to 85% (non-condensing)
Storage Altitude	0 to 2,000 meters above sea level
Transportation 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	 **2X 2.0A . T, H 250V 5X20MM**

Lithium-Ion Coin Battery Replacement

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 on the Lithium-ion battery may result in damage of the pump unit.

 Battery location can be identified by this symbol in this pump unit.

The battery indicator () will appear on the front panel when the lithium-Ion coin battery requires service.



Fuse Replacement

The pump unit uses two fuses located in the rear of the pump unit; fuses are a part of the Power Inlet (See **Diana Peristaltic Pump Description** for illustration of location).

Figure 11. 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.

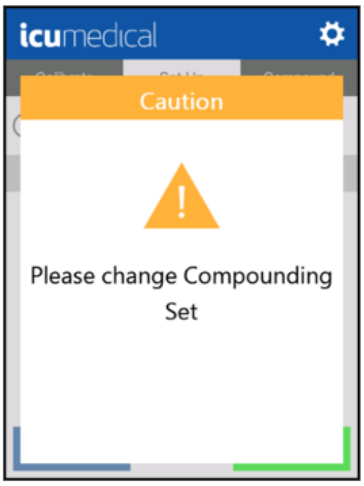
Important: Incorrect insertion of the fuses may result in no power to the pump unit.

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 below if a tubing set has compounded more than 60L of fluid. When the user replaces the tubing set, the workflow may continue.

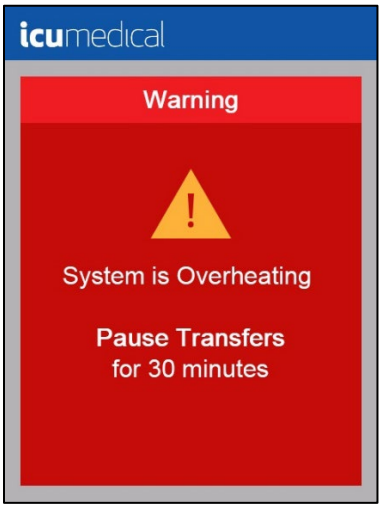


Note: This warning will continue to be displayed even if the pump unit is turned off and then on again.

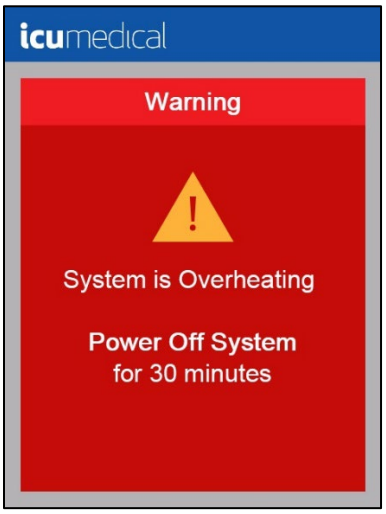
Temperature Warning

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 following warning will show.

Note: When the warning notification appears, it is recommended to stop using the unit for 30 minutes.



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



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.

Duty Cycle

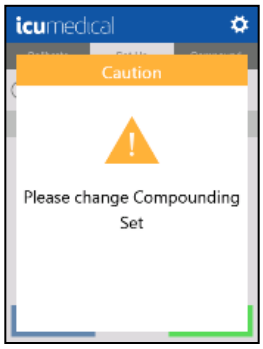
For best performance of your system, it is recommended to allow the Pump Unit a 30 minute cooldown period after:

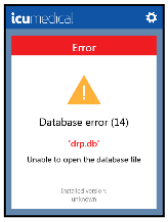
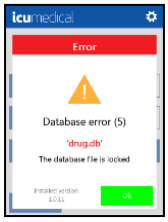
- 8 hours of continuous fluid transfer
- Pumping 240 liters of fluid

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

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 makes 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 	Compounding set (tubing set) has been used to transfer 60 liters.	Replace tubing set.

Description of Fault	Possible Causes	Solution
Database Error Messages  	System malfunction	Please contact ICU Medical Technical Support.

Chapter 6: Pump Unit Software Update

Note: The USB stick and adapter must be requested from ICU Service personnel.

The folder **drp / update** can be found on the USB stick to update the pump unit software.

After the pump unit has booted up, the prefabricated USB stick is plugged into the USB interface of the pump unit (the user will need the enclosed adapter cable). A selection window opens automatically. The window will allow the user to select which components should be updated. It is possible to perform a complete pump unit update, or the user selects the appropriate components to be updated.

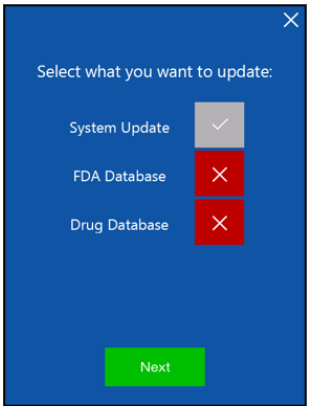
If the drug database and / or the FDA database is updated, the user will receive a short message (green message) on the display after a successful update and the pump unit automatically restarts. If the pump unit update is also checked, a new window opens with a progress bar and with an indication of which file is currently being updated.

After the update has been successfully transferred, the pump unit will restart and return to the setup screen.

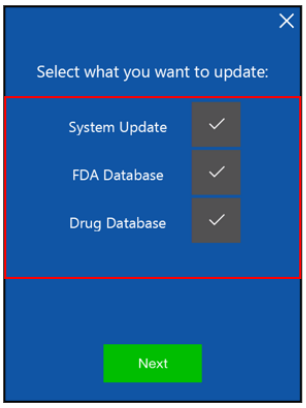
Note: Prerequisite for the pump unit restart is that no new firmware or Kernel is included in the pump unit update. ICU Personnel will provide further instructions if firmware or Kernel updates are required.

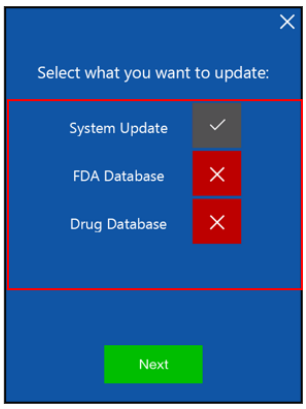
1. Turn on the pump unit and wait for it to completely power on.

2. Insert the USB stick with the update on it into the designated port on the back of the pump unit (adapter cable required). The selection window will open automatically.



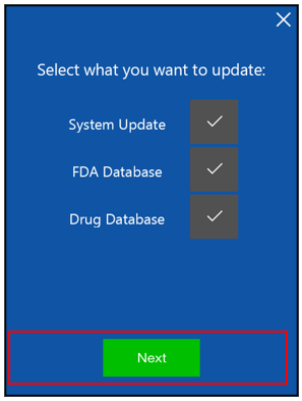
3. Follow instruction provided by ICU Medical service personnel and make the selection of which components need to be updated.



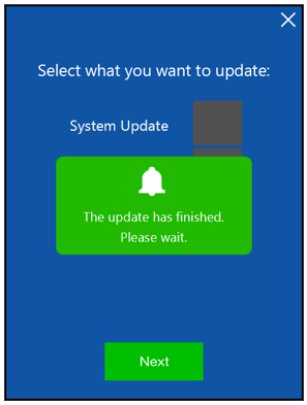


Note: Components marked with a red cross cannot be updated because they are not available on the USB stick.

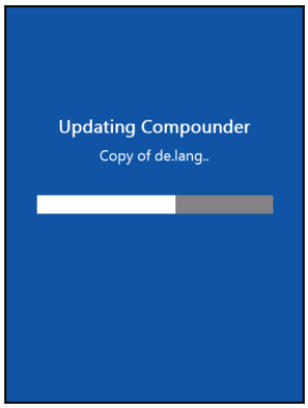
4. Then tap the **Next** button to start the update.



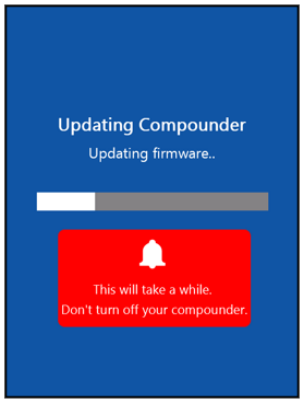
5. Once the pump unit is updated, the following message will be displayed:



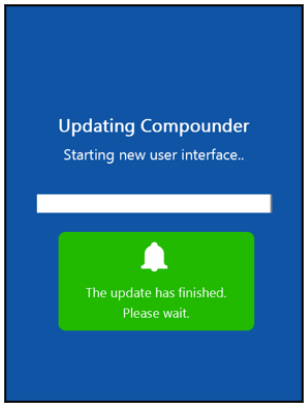
6. A progress bar indicates how far the update has progressed and which file is currently being updated.



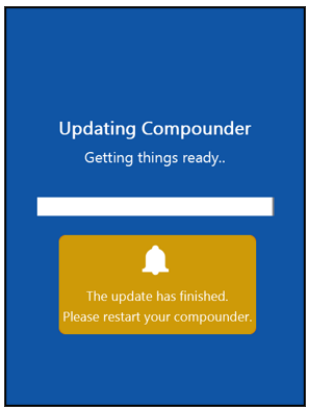
Note: This message is displayed to the user only if a firmware update is performed to prevent the pump unit from being turned off by the user while the update is in progress.



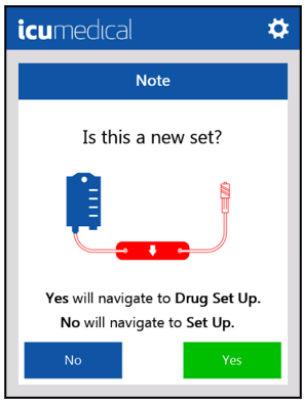
7. After completing the update (if no firmware update has been made), the user will receive a confirmation message that the update has been successfully completed. Then the pump unit automatically restarts.



8. If a firmware update is executed, the user receives a message, and the pump unit must be restarted manually by tapping **the On / Off** button. Switch the pump unit off. Wait some seconds before the user restarts.



9. After a successful update and restart of the pump unit, the user can start with the workflow as usual.

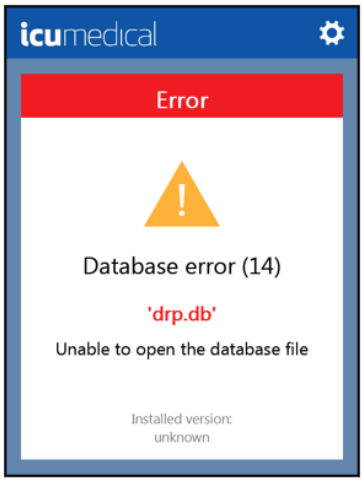


Chapter 7: Transport

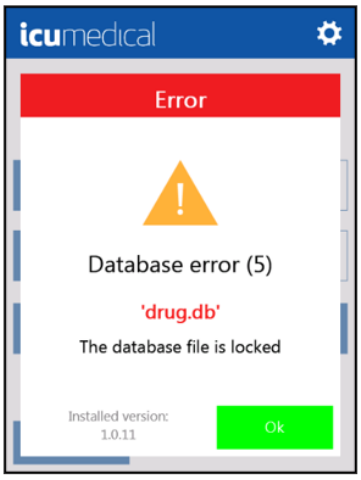
Please note that some metal parts may be warm after heavy use of the pump unit. The user should not use the pump unit for 30 minutes before transportation to allow the metal parts to cool. However, the pump unit should remain switched on during the cooling phase.

Chapter 8: Database Error

This database error occurs when the pump unit software cannot read the database. The number in brackets indicates the error. The user will find the error designation in the following list (see **List of Database Errors**). If this error occurs, please contact a service technician immediately.



The database error listed here can occur while the System is running, but writing to the database (e.g., creating a new medicine) cannot be performed. However, the user can confirm this error message by tapping the **OK** key and then follow up with the usual workflow. If the user receives this error message, please contact a service employee to be able to correct this database error as quickly as possible.



List of Database Errors

Table 15: Database Errors

Displayed error	Description of the error
#define SQLITE_ERROR	1 /* Generic error */
#define SQLITE_INTERNAL	2 /* Internal logic error in SQLite */
#define SQLITE_PERM	3 /* Access permission denied */
#define SQLITE_ABORT	4 /* Callback routine requested an abort */
#define SQLITE_BUSY	5 /* The database file is locked */
#define SQLITE_LOCKED	6 /* A table in the database is locked */
#define SQLITE_NOMEM	7 /* A malloc() failed */
#define SQLITE_READONLY	8 /* Attempt to write a read only database */
#define SQLITE_INTERRUPT	9 /* Operation terminated by sqlite3_interrupt()*/
#define SQLITE_IOERR	10 /* Some kind of disk I/O error occurred */
#define SQLITE_CORRUPT	11 /* The database disk image is malformed */
#define SQLITE_NOTFOUND	12 /* Unknown opcode in sqlite3_file_control() */
#define SQLITE_FULL	13 /* Insertion failed because database is full */
#define SQLITE_CANTOPEN	14 /* Unable to open the database file */
#define SQLITE_PROTOCOL	15 /* Database lock protocol error */
#define SQLITE_EMPTY	16 /* Internal use only */
#define SQLITE_SCHEMA	17 /* The database schema changed */
#define SQLITE_TOOBIG	18 /* String or BLOB exceeds size limit */
#define SQLITE_CONSTRAINT	19 /* Abort due to constraint violation */
#define SQLITE_MISMATCH	20 /* Data type mismatch */
#define SQLITE_MISUSE	21 /* Library used incorrectly */
#define SQLITE_NOLFS	22 /* Uses OS features not supported on host */
#define SQLITE_AUTH	23 /* Authorization denied */
#define SQLITE_FORMAT	24 /* Not used */

Displayed error	Description of the error
#define SQLITE_RANGE	25 /* 2nd parameter to sqlite3_bind out of range */
#define SQLITE_NOTADB	26 /* File opened that is not a database file */
#define SQLITE_NOTICE	27 /* Notifications from sqlite3_log() */
#define SQLITE_WARNING	28 /* Warnings from sqlite3_log() */

Chapter 9: 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

Chapter 10: 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 Diana Peristaltic Pump unit or accessories.

Unauthorized cleaning of the Diana Peristaltic Pump unit or accessories.

Transportation damages of any sort.

Accident, fire, water, vandalism or causes other than ordinary usage.

Misuse of the equipment or accessories.

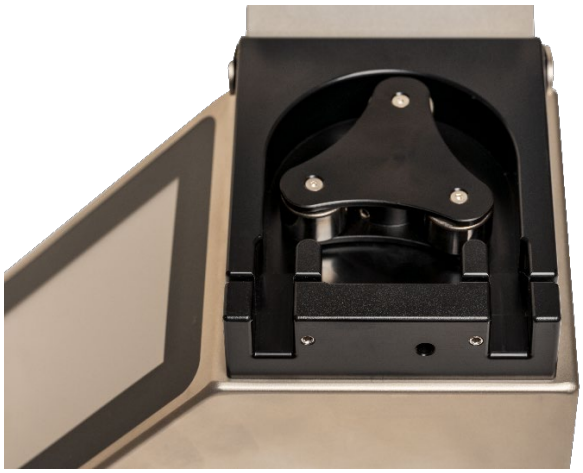
Disregard the user manual instructions.

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 Diana Peristaltic Pump

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.

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.

Appendix B: 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. Install empty calibration container.
2. Ensure the Volumetric Calibration setting is turned OFF.
3. Select the Calibrate Tab.
4. Follow the directions in **Gravimetric Calibration with External Scale** section.

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. Disconnect the output container and put distal end of tubing into a graduated cylinder of at least 150 mL size.
2. Ensure the Volumetric Calibration setting is turned ON.
3. Select the Calibrate Tab.
4. Follow the directions in the **Volumetric Calibration** section of the User Manual (use 100 mL as volume to transfer).
5. Remove the tubing set from the Graduated Cylinder.
6. Read the volume in the Graduated Cylinder and enter it as instructed.