Diana Peristaltic Pump™

DS1000

For use with Software Release V2.1 Only

User Manual DF-4369-EN (04-Feb-2022)

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1.0 Introduction

1.1 Intended Use

The Diana Peristaltic Pump is an automated pharmacy compounding system and it is intended to be used in a healthcare facility to dispense a specified quantity of liquid from a set of source containers into a destination container. For the purposes of this manual, a liquid is a substance that flows freely but is of constant volume, having a consistency like that of water or oil.

Intended users/operators of the System are Pharmacists and Pharmacy Technicians. The operator must be properly trained in the use of the System. Please follow the information contained in this manual as a self-paced training guide prior to operating the unit for the first time. Refer to this manual as a reference guide on as-needed basis, recurring training is not required to operate this unit.

1.2 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.

Always follow published guidelines relating to work protection and accident prevention, and ensure professional diligence at all times.

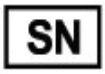
1.3 Warnings and Precautions

- Read this User Manual carefully before using the Diana Peristaltic Pump.
- **DO NOT** connect unit directly to humans.
- No modifications to the Diana Peristaltic Pump are allowed. Do not modify in any way, otherwise there is a possibility of operator injury, impairments or damage to the unit.
- The Diana Peristaltic Pump does not contain any user-serviceable parts. To avoid injury or damage to the instrument, do not attempt to disassemble or service the instrument. Malfunctioning systems must be sent back to ICU Medical for repair.
- If unit is damaged during operation, switch off immediately and disconnect from the power supply.
- If the Diana Peristaltic Pump has observable sharp edges, contact an ICU Medical representative immediately.
- DO NOT place the compounder on an unstable surface.
- To avoid the potential for cross-contamination between drugs, replace the tubing set when a new drug is to be compounded.
- When using the Diana Peristaltic Pump to transfer liquid to rigid containers such as vials or bottles, care should be taken to ensure the containers remain upright at all times and ensure containers are not over-pressurized prior to connecting to the Diana Peristaltic Pump.
- The System should only be used with the manufacture-provided power cord.
- If the power cord is damaged, stop using the system and unplug the cord from power source.
- The Diana Peristaltic Pump should only be connected to a properly grounded electrical supply outlet. User should refer to the requirements for medical electrical systems in the current edition of IEC 60601-1 for proper use.
- Avoid routing the power cord across the floor where it can create a tripping hazard.
- Position the Diana Peristaltic Pump to assure asy access to its power plug (so that it can be disconnected from electrical supply in the event of an emergency).
- 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 damage, 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.
- DO NOT USE Diana Peristaltic Pump to compound hazardous drugs and medications (for example acids, ethers and other chemicals known to be incompatible with silicone tubing). The system is designed only for non-hazardous liquids.
- Refer to tubing set label for important use information.
- DO NOT USE for intravenous administration or other routes of direct patient delivery.
- Calibrate the system 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.
- 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.
- 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 may need to be performed when there is a change in pump 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.
- Use of tubing set that are not compatible with the Diana Peristaltic Pump may adversely affect volume accuracy, pump reliability and performance. See Compatible Tubing Sets section for more details.
- DO NOT operate the system without the roller cover in place as injury may occur. If the roller cover is bent or damaged contact ICU Service for repair.
- The power cord must be connected to a properly grounded hospital grade 120V receptacle for proper pump performance and safety.
- Liquid ingress inside the pump may cause damage and impact performance. Clean spills immediately.
- RECOMMENDED: Use Heavy Duty "BX01", "BX02", or "BX03" tubing when filling ambulatory pumps or other hard to fill containers.

- Pump operation must be monitored at the beginning of each cycle and at intervals during the cycle to ensure the Diana Peristaltic Pump is operating within acceptable limits (out of limits conditions displayed during use). Use the calibration function to achieve specified accuracy (see Calibration Process section for more details).
- Verify pump accuracy performance before use to ensure It meets facility protocols.
- Do not operate the pump 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.
- Save the original box and packaging. In the event that the pump 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 Diana Peristaltic Pump continuously for more than 8 hours or 240 liters. Upon reaching this limit, allow the system to rest for 30 minutes before additional use.
- 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.
- Some metal parts might be warm when in use. The user should allow the unit to cool down prior to moving or transporting the unit.
- Consider the drug manufacturer's labeling and USP compounding guidelines when performing compounding.
- Ensure Diana Peristaltic Pump is placed on a stable surface. If applicable, allow Biomedical Engineering to confirm electrical requirements are met.
- At the end of service life, dispose of pump, accessories, and consumables by contacting ICU Medical for further information.
- During storage and use, avoid impacts and vibration which could result in a malfunction of the Diana Peristaltic Pump.
- The System is designed for use in Biological Safety Cabinets, Laminar Airflow Hoods and/or Safety Work benches in clean rooms in a healthcare setting.
- Do not insert any foreign objects into the unit ports and openings.
- Avoid direct contact with liquids. If a spill occurs, quickly remove liquids in accordance with the facility protocol.
- Never immerse the unit in liquids for cleaning purposes. Do not attempt to sterilize using mechanical or steam sterilization equipment.
- All cleaning of the Diana Peristaltic Pump should be performed according to the detailed instructions in this manual.
- The System is not suitable for use in mobile equipment.
- Some metal parts may be warm after heavy use of the unit. The user should not use the unit for 30 minutes before transportation to allow the metal parts to cool.
- Verify Diana Peristaltic Pump accuracy performance before use to ensure it meets facility protocols – see section 5.1 for details.

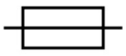
1.4 List of Symbols Used on the Instrument

This instrument is compliant with the symbols mentioned below.

Symbol	Reference	Description
	IEC 60417 – 5010	“ON”/ ”OFF” (push-push)
	ISO 7010 - M002	Refer to instruction manual/booklet Symbol
	IEC 60417 - 5032	Alternating current
	ISO 7010 - M005	Connect an earth terminal to the ground
	ISO 7010 - W001	General warning sign
	ISO 7010 - W012	Warning; electricity
	ISO 7000 - 3082	Manufacturer
	ISO 7000 - 2498	Serial number
	CSA	Certification mark
	ISO 15223-1: 2016 (Symbol 5.1.2)	Authorised European representative
IP33	IEC 60529	Ingress protection
	IEC 60417 - 6414	WEEE; waste electrical and electronic equipment; crossed- out wheeled bin
	ISO 7000 - 0632	Temperature limit
	ISO 7000 - 2620	Humidity limitation

1.4.1 List of Symbols on the Back of the Instrument

The graphics below show the back panel of the instrument. The callouts indicate the location of various connectors and switches for the Diana Peristaltic Pump.

Symbol	Reference	Description
	IEC 60417, Reference Number: 5016	Indicates the fuse is held inside the housing
	IEC 60417, Reference Number: 5534	Indicates plug to be used to Power on system.
	ISO 7000-3650	Indicates socket to be used for USB Update port

2.0 Diana Peristaltic Pump Overview

2.1 Installation

To install the unit, place the unit onto a stable surface. Plug the ICU supplied power cord into the back of the unit and then into an electrical outlet.

> **Note**: The Diana Peristaltic Pump should only be connected to a properly grounded electrical supply outlet. Users should refer to the requirements for medical electrical systems in the current edition of IEC 60601-1 for proper use.

Once the system is plugged in, press the circular on/off switch located on the front of the instrument.
We recommend the system be sent to ICU medical Service once a year for inspection and maintenance.

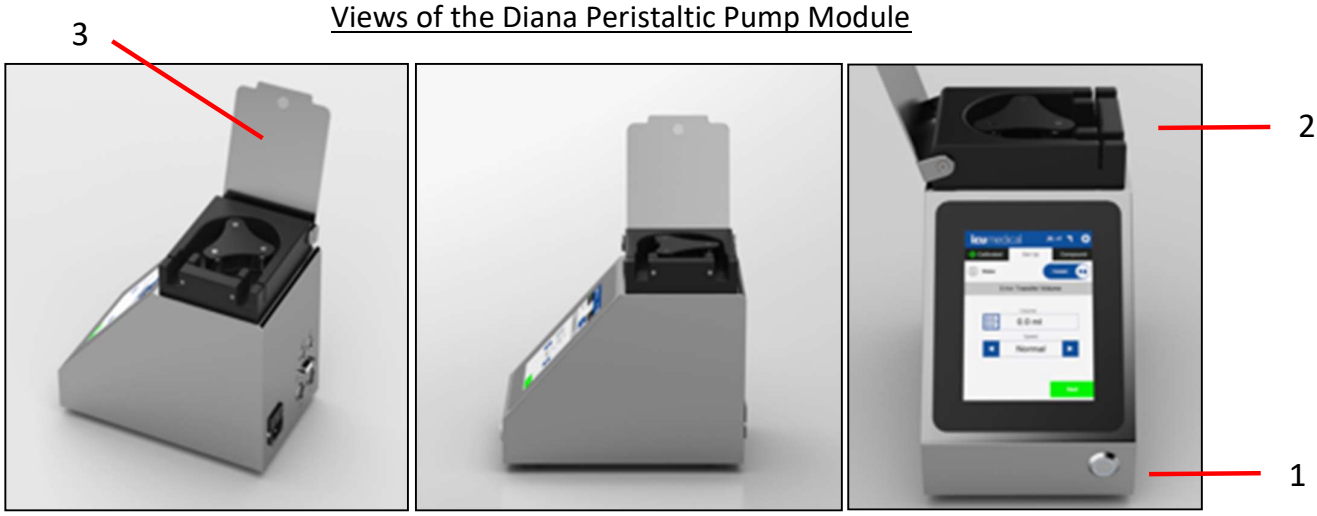
All maintenance and installation must be performed by an authorized ICU Medical representative. All maintenance work should be completed by the manufacturer with the exception of routine cleaning.

2.2 Equipment Description

The Diana Peristaltic Pump is an automated pharmacy compounding unit controlled by software and is intended to be used 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.

The pictures below show the Diana Peristaltic Pump with the major components labeled and reference the table that follows. Descriptions of the components can be found in Table 1 following the pictures.

Views of the Diana Peristaltic Pump Module



Back of the pump

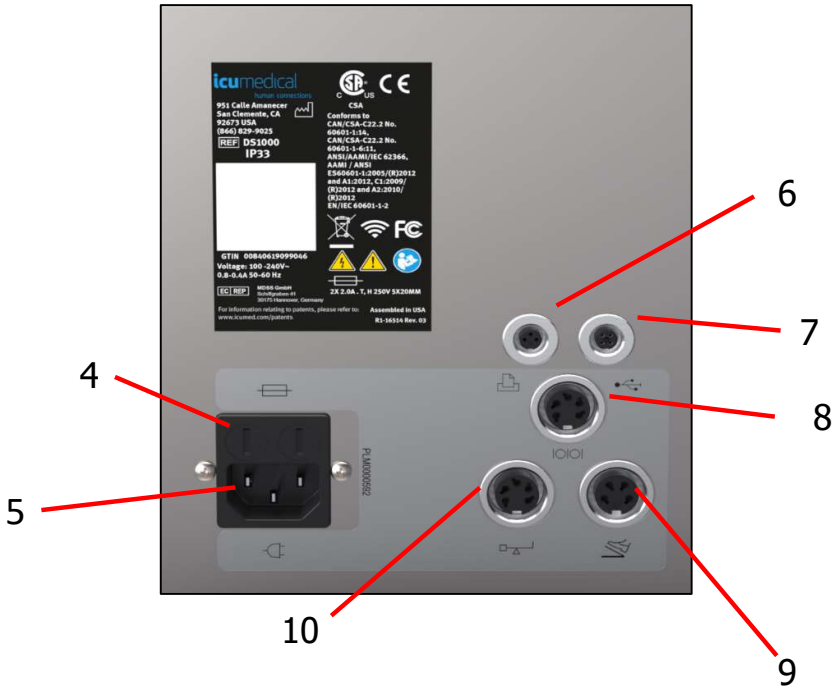


Table 1

Reference	Component	Description
1	Power Button	Power ON/OFF Button.
2	Tubing Detection Sensor	The Tubing Detection Sensor detects the presence and proper placement of the tubing set.
3	Flap	Protective cover, must be closed while unit is actively pumping
4	Fuses	Replaceable fuses, used to protect electrical equipment
5	Power Inlet	The Power Inlet is used to connect the Diana Peristaltic Pump to the electrical outlet using the provided power cord.
6	Printer Port	The ports not used by the system. They are plugged by a cap.
7	USB Port	The USB port is for use by ICU Medical authorized personnel to service Diana Peristaltic Pump. User can use it for to export or import files with a USB Stick.
8	Scanner Port	The ports not used by the system. They are plugged by a cap.
9	Foot Pedal Port	The ports not used by the system. They are plugged by a cap.
10	Scale Port	The ports not used by the system. They are plugged by a cap.

2.3 Graphic User Interface (GUI)

The user interface of the Peristaltic Pump has been designed so that there are three tabs at the top of the screen (Drug Set Up, Set Up, Compound) where a user can navigate to a specific workflow.

The figure below show the user interface screen on the Diana Peristaltic Pump with key items labeled. Descriptions of the these key items can be found in Table 2 following the figure.

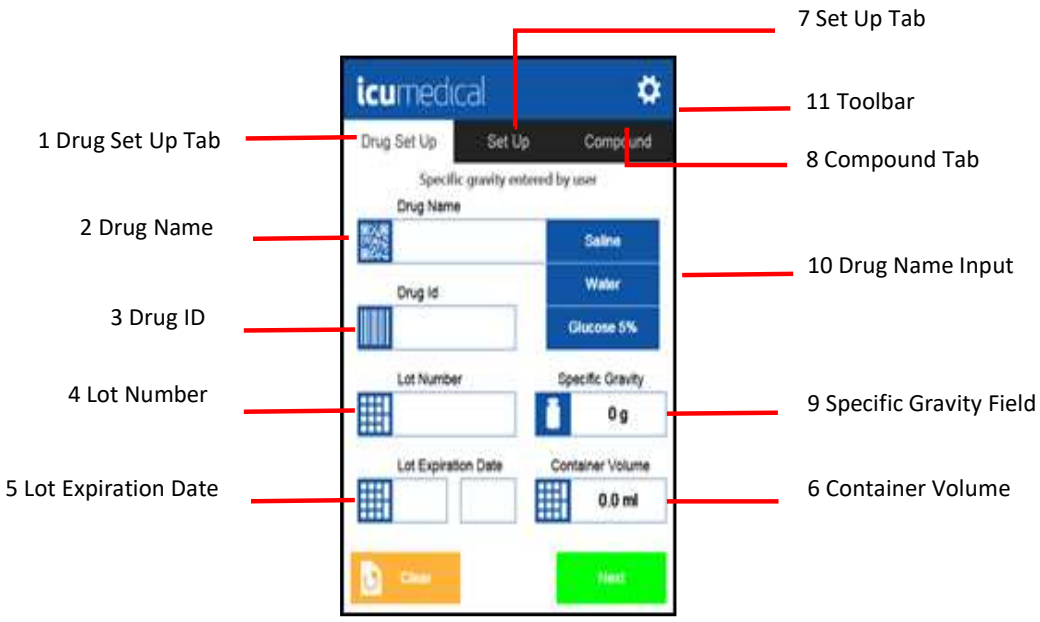


Table 2

Reference	Component	Description
1	Drug Set Up Tab	This tab is the first screen to be displayed and allows a user to assign drug information to a container. This information will then be used to generate a compounding log and labelling for future use.
2	Drug Name	Enter the drug which is used in preparation. Most common drugs will show up on the right side of the menu.
3	Drug ID	Identification Number associated with the Drug Name will display on screen.
4	Lot Number	Enter 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	Container Volume	The amount of liquid (in mL) in the source container. This is used to ensure that there is enough liquid to fill the destination containers.
7	Set Up Tab	Allows a user to provide the amount of volume (in mL) to be transferred. Within this tab, a user can also change the speed of transfer (mL/min). Once this information is entered, a user can tap “Start” to initiate a transfer.

Reference	Component	Description
8	Compound Tab	Provides user a visual confirmation that the system 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 by the user on the Drug Set Up screen or in Edit Drug settings page. Edit Drug settings require an operator to be an authorized user in the "Advanced Settings".
10	Drug Name Input	Provides the user a list of recently used drug names for quick input into the drug compounding log. A user can tap the drug name for quick data entry.
11	Toolbar	Provides the user access to the settings

2.4 Data Entry

Enter the numeric value and press “Enter”

Enter the alphanumeric value and press “Enter”

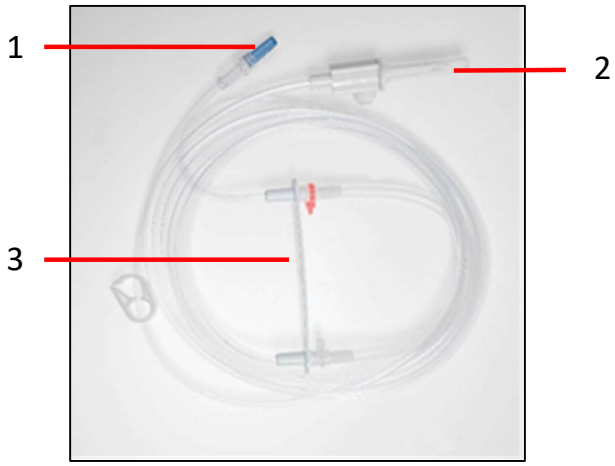
Enter the date and press “Enter”

2.5 Consumables

2.5.1 Tubing Set Overview

The following accessories/consumables are not included with the Diana Peristaltic Pump. They must be ordered separately. Contact an ICU representative for assistance in ordering.

The picture below shows the tubing set with key features labeled. Descriptions of the these key features can be found in Table 3 following the picture.



The tubing set is to be used in conjunction with the Diana Peristaltic Pump. The set consists of an input port, output port, and tubing set handle.

Table 3

Reference	Component	Description
1	Input Port	The Input Port is a proprietary ICU Medical Connector that mates with a proprietary ICU Medical connector to establish a closed system during liquid transfer.
2	Output Port	The Output Port is a proprietary ICU Medical Connector that mates with a proprietary ICU Medical connector to establish a closed system during liquid transfer.
3	Tubing Set Handle	The Tubing Set Handle allows a user to easily place the tubing set into the Tubing Detection Sensor. Ensure the red clip is on the top of the Tubing Detection Sensor.

2.5.2 Tubing Set Information and Compatibility

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

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

The following components are compatible with ICU Medical Tubing Sets:

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

3.0 Operating the Diana Peristaltic Pump

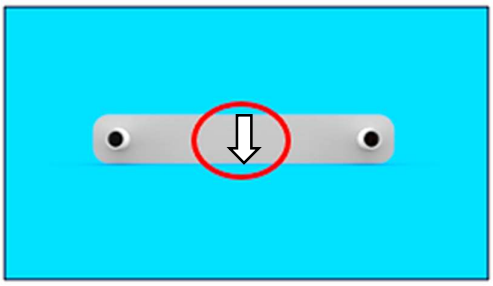
3.1 Tubing Set Installation / Removal

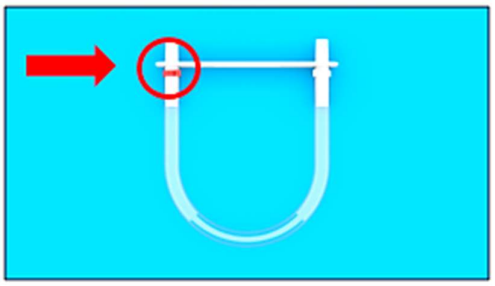
The following section describes how the user of the Diana Peristaltic Pump Module properly inserts and removes the tubing set unto the unit.

Note: Incorrect insertion of the tubing set may damage the unit.

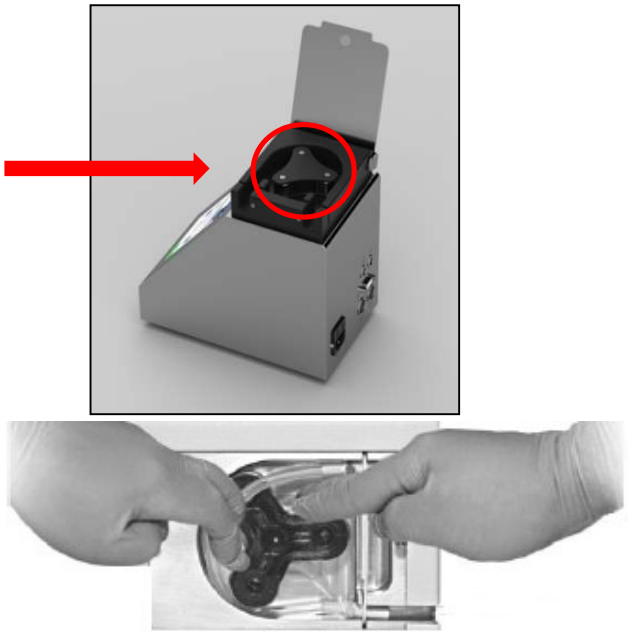
1. The Diana Peristaltic Pump should be placed with the display view facing the user.

2. Before opening, inspect the tubing set package. If packaging is not intact, discard it and use a new set.
3. Using aseptic technique, open the package and remove the tubing set.
4. Locate the embossed "arrow" pointing downwards on the handle of the tubing set. Locate a "red clip" behind the handle.





5. Turn the roller head by hand to insert the white clip into the roller pump. Hand turn the roller head until the tubing set is secure around the perimeter of the roller head.



Note: Ensure there is no kinking of the tube.

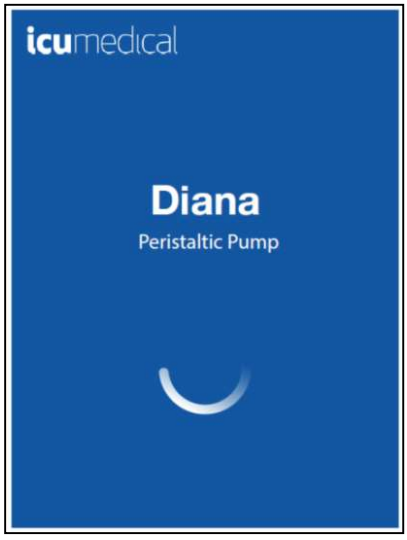
When removing the tubing set, it is recommended to clamp the lines to prevent spillage.

6. When ready to remove the tubing set, pull white clip upwards.
7. Turn the rollers by hand while removing the tubing.
8. Pull red clip upwards and remove the tubing set from the roller pump.

3.2 Power On

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

When the pump has been started, a welcome screen is displayed (see below).



Next, a series of alerts will display, depending on the state of the unit (see below):

No Tubing Set Detected

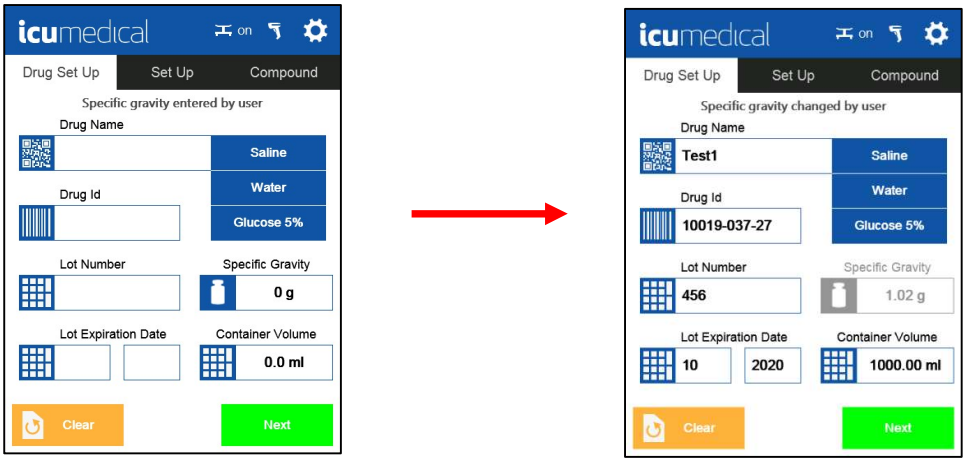
Tubing Set Detected

Flap is Open

Satisfying the unit command or answering the questions will bring the user to the home screen.

3.3 Drug Set Up

Enter the drug information by selecting the Drug Name text field and entering the data.
The drug must exist in the database. Additionally, the unit has a “quick feature” list on the right that defaults to the most commonly transferred drugs.



The “Next” button will only be activated if all fields are filled out.

Note: User must enter a specific gravity for the selected fluid in the Specific Gravity field before proceeding, see “Changing the Specific Gravity” section 3.3.1 for more details.

Note: User must enter the input container volume in the Container Volume field before proceeding, see “Entering the Container Volume” section 3.3.2 for more details.

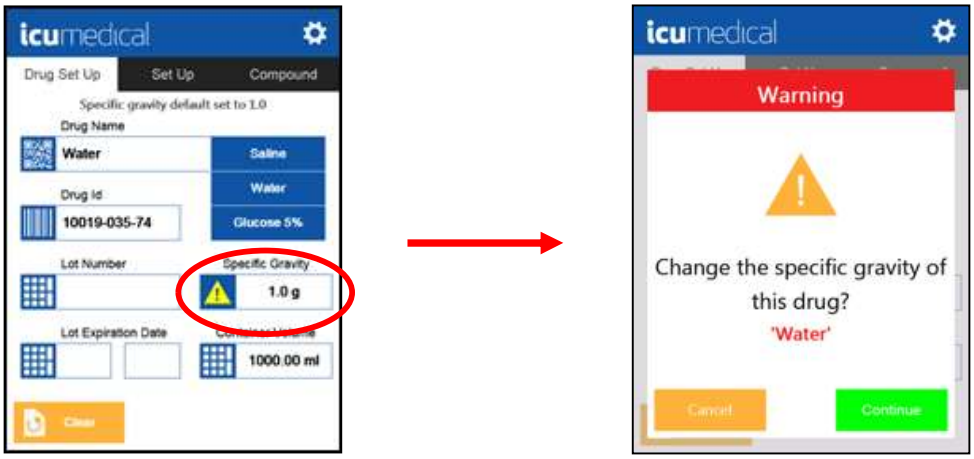
Press the “Next” button. The next step is to start the priming and calibration process.

3.3.1 Changing the Specific Gravity

The specific gravity of a drug can be changed by the user on the Drug Set Up tab. Changes to this option require a user permission to be enabled by the authorized user in the "Advanced Settings."

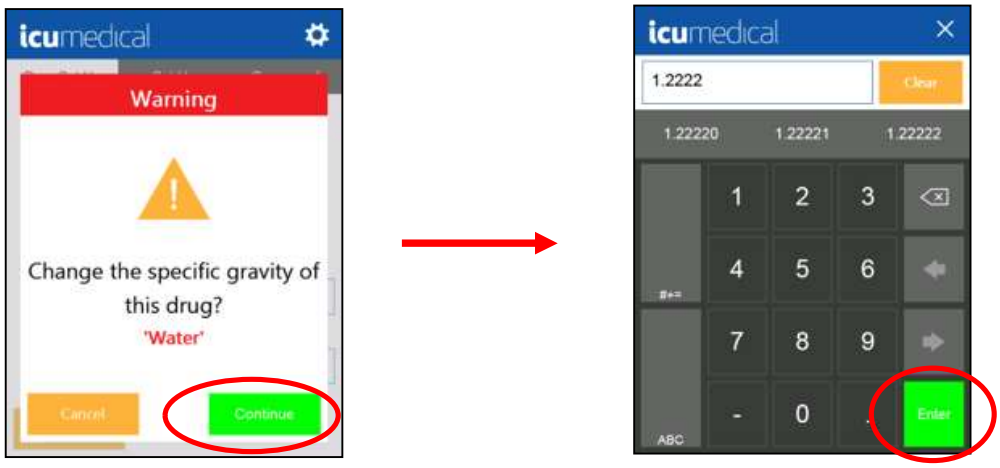
Note: The default specific gravity for most drugs is set to 1.0 g.

1. The default specific gravity is set to 1.0g for most fluids. User will see a blue square with a yellow triangle containing an exclamation mark (see below) - this means that the specific gravity can be changed by the user to a different value. When user clicks on the specific gravity field a warning message will appear advising that user is about to change the specific gravity for that particular drug (see below).

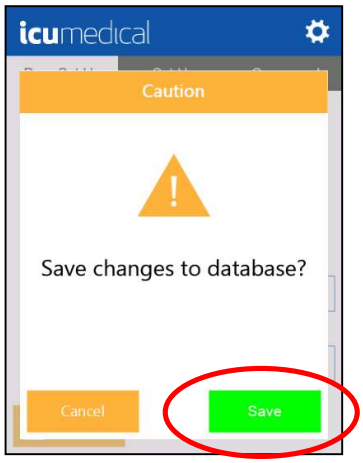


Note: If user presses “Cancel”, system will return to the Drug Set up screen with the specific gravity selected at the default of 1.0 g.

2. Press "Continue" to change the specific gravity of the selected drug by manually entering using the keyboard. Then press the "Enter" button.

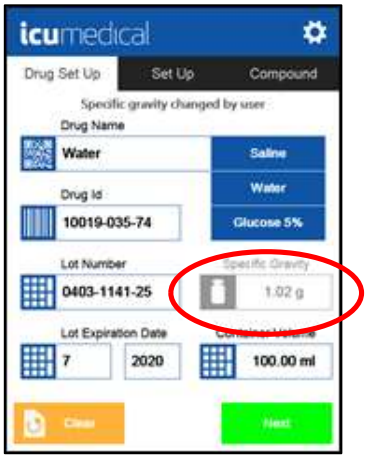


Note: User will receive a warning message after the modified specific gravity is entered. User must acknowledge the message by pressing the "Save" button. The changed specific gravity is then permanently saved into the database.

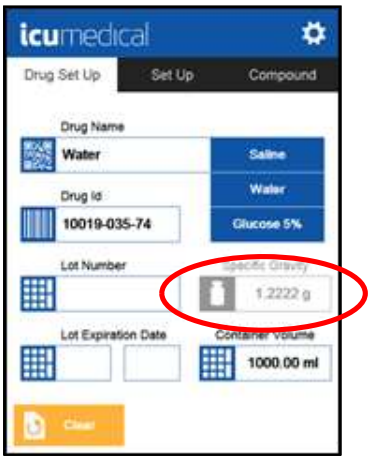


Note: When the Cancel button is pressed, the Peristaltic Pump returns to the drug Set Up screen. The specific gravity has not been changed.

3. Saved changes to the specific gravity in the database will appear in gray font and a notification stating that “specific gravity changed by user” will display above the drug name.



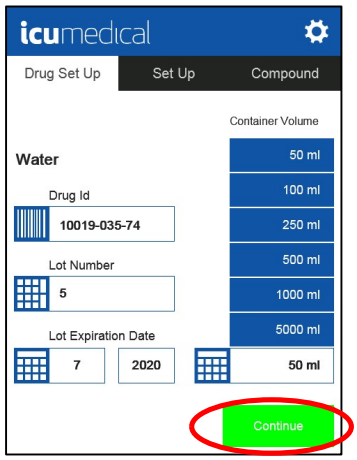
4. If the user selects a drug from the database where the specific gravity has already been changed, the button is grayed out and cannot be changed on the Drug Set Up screen. The specific gravity can only be changed or adjusted by the authorized user in the Advanced Settings.



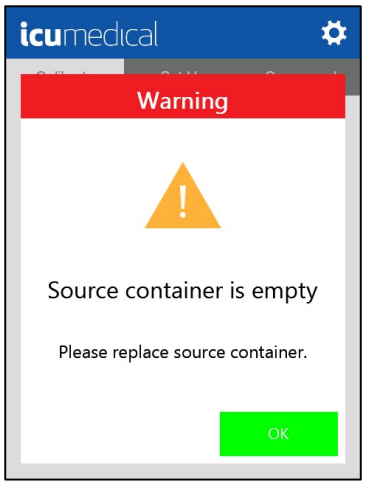
3.3.2 Entering the Container Volume

The user must enter, in the Container Volume field, the volume of liquid has been attached to the system in the source container. The system will track the volume that has been removed from the source container during use. The system will provide a warning message (see below) to the user when the unit predicts that the source container will be empty based on the previous subset of transfers.

On the Drug Set Up screen, select the volume of the source container. User can manually enter the volume or select a predetermined container size. Enter Lot number and Lot Expiration Date of the new source container. Press “Continue”.



The system will automatically stop once the source container is empty with no air within the set.



A new source container volume can be entered if additional transfers are necessary.

3.4 Priming

Priming is typically performed into a disposable container that will be used for priming and calibration and then destroyed. In this process, air primed out of the tubing and any excess liquid is transferred to the priming container. See the "**Priming to Container**" section of this manual.

In certain circumstances, it may be useful to prime the tubing using a modified method known as Circle Priming. See the "**Circle Priming**" section of this document.

3.4.1 Priming to Container

Note: In order to properly calibrate the unit, ensure the tubing set is properly primed following these instructions. Failure to do so may result in incorrect liquid volumes being transferred.

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. For Circle Priming, see the "Circle Priming" section of this document.

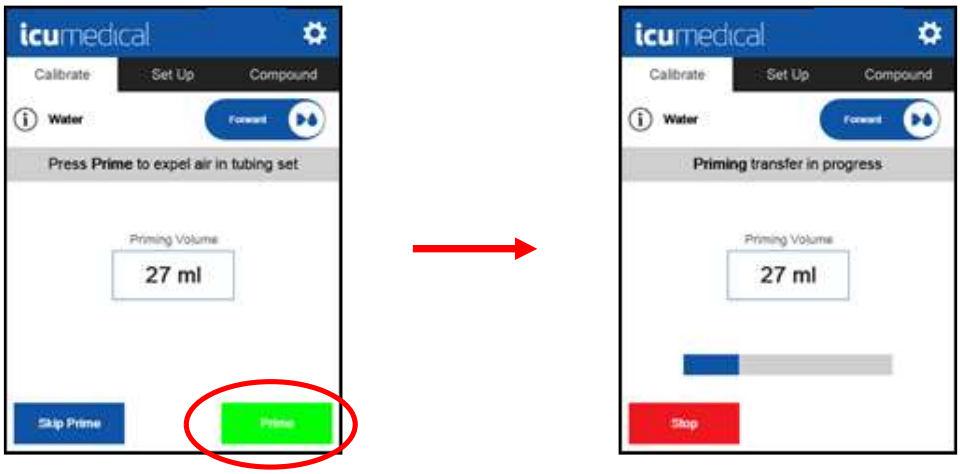
2. If not already connected, connect the receiving (distal) end of the tubing set to a destination container.

   Note: Make sure that the receiving (distal) end of the tubing set is connected to a destination container.

3. The unit prompts the user if the tubing set needs to be primed. Press "Prime" and the unit automatically starts to prime the tubing set.

   Note: There may be a few seconds delay between pressing "Prime" and the 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, system will return to the Calibrate screen.

3.4.2 Circle Priming

In certain circumstances, it may be useful to prime the tubing using a modified method known as “Circle Priming”. In this process, air primed out of the tubing and any excess liquid is transferred back to the source container.

Note: In order to properly calibrate the unit, ensure the tubing set is properly primed following these instructions. Failure to do so may result in incorrect liquid volumes being transferred

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.

2. For circle priming, if not already connected, connect the receiving (distal) end of the tubing set to a separate port on the source container.

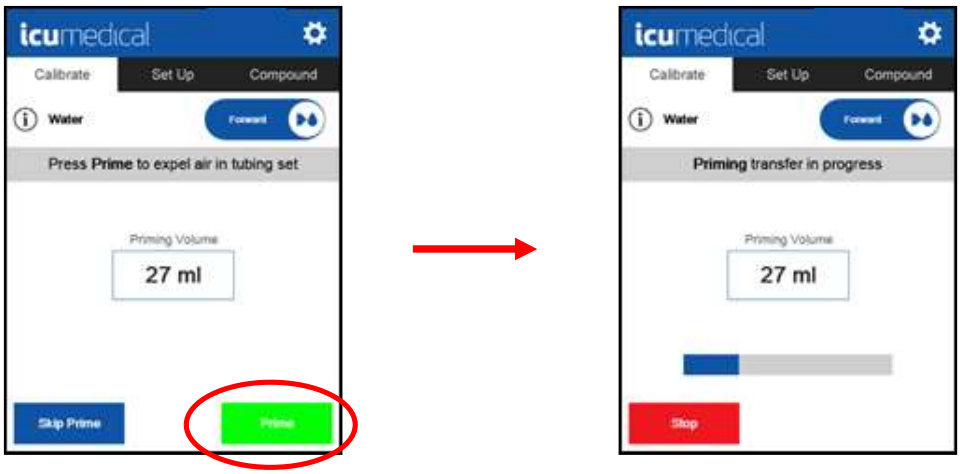
   Note: Make sure that the receiving (distal) end of the tubing set is connected to the source container.

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

3. The unit prompts the user if the tubing set needs to be primed.
   Press "Prime" and the unit automatically starts to prime the tubing set.

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

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



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

3.5 Calibration

The unit allows a user to choose the liquid type and volume with which to calibrate the system. The liquid type can be selected in the Set Up Tab. It is recommended to calibrate the machine after change of the tubing set, desired volume, destination container, or when the unit has transferred over 60,000 mL from all liquid transfers. Because the tubing set should be replaced when a new drug is to be compounded, it should be calibrated with the drug you intend to tranfer.

> **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.

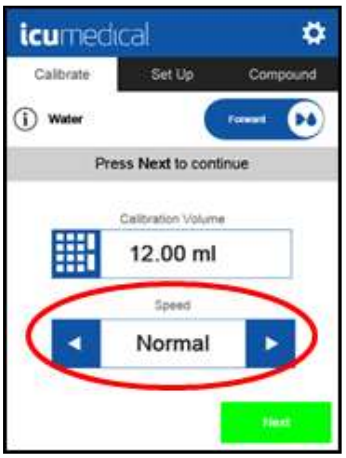
The calibration process of the Peristaltic Pump can be performed using a separate third-party scale, referred to here as an external scale. Accurate specific gravity configuration is essential for gravimetric accuracy.

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

Calibration is typically performed into the same disposable container that was used for priming, then the container should be destroyed. In certain circumstances, it may be useful to prime the tubing using a modified method known as Circle Priming.

If circle priming is performed, a separate disposable container should be be used for calibration then destroyed.

1. Enter Calibration Volume and identify the speed.



> **Note:** The transfer speed will be based on the volume and viscosity of the liquid. To adjust the speed of the pump, tap the arrows on either side.

2. If not already placed, place the destination container (calibration container) on the 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. Ensure destination container is reconnected to the tubing set before proceeding and pressing “Start”.

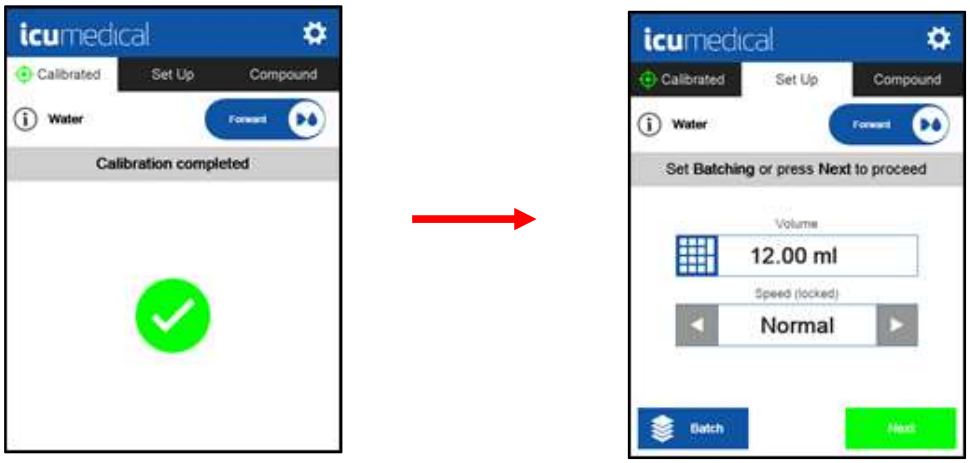
3. Tare the external scale.

4. Press “Start” to initiate the transfer.

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

5. After the calibration transfer is complete, enter the weight measured by an external scale into the screen as shown below. After entering the weight, press “Accept”.

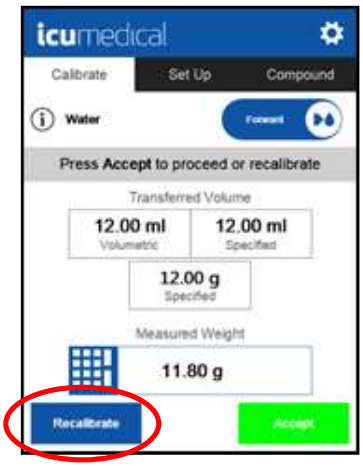
6. After a successful calibration, the unit will display a confirmation that calibration has been completed and the user will be directed to the Set Up menu.



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

7. Disconnect the calibration container from the tubing set.

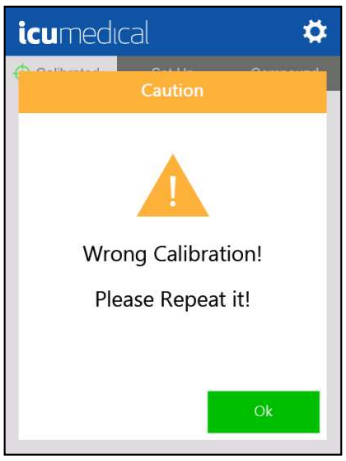
8. If the measured weight entered is not compliant with facility's guidelines, a recalibration may be performed and the calibration transfer repeated.

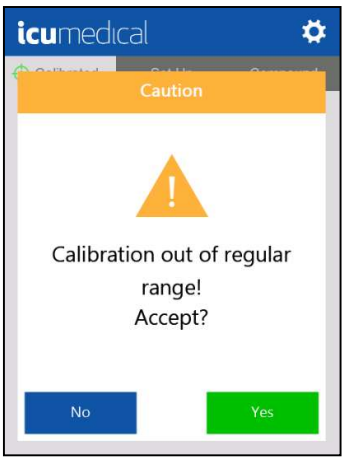


Note: By pressing Recalibrate, the unit will adjust its calibration setting based on the previous transfer and then a new calibration process begins to ensure accurancy

3.5.1 Warnings During Calibration Process

The following warnings can be encountered during an incorrect calibration process.





The first warning message of “Wrong Calibration!” is displayed when the discrepancy between the expected and the measured weight is more than 30%. Pressing the “OK” returns user to Prime part of the workflow.

Repeat the priming and calibration to ensure the accuracy of the unit.

The second warning message of “Calibration out of regulatr range!” is displayed when the discrepancy between expected and measured weight is within 10-30% range.
Pressing "Yes" button confirms the user's entry and completes the calibration process. Pressing "No" button returns user to Prime part of the workflow.

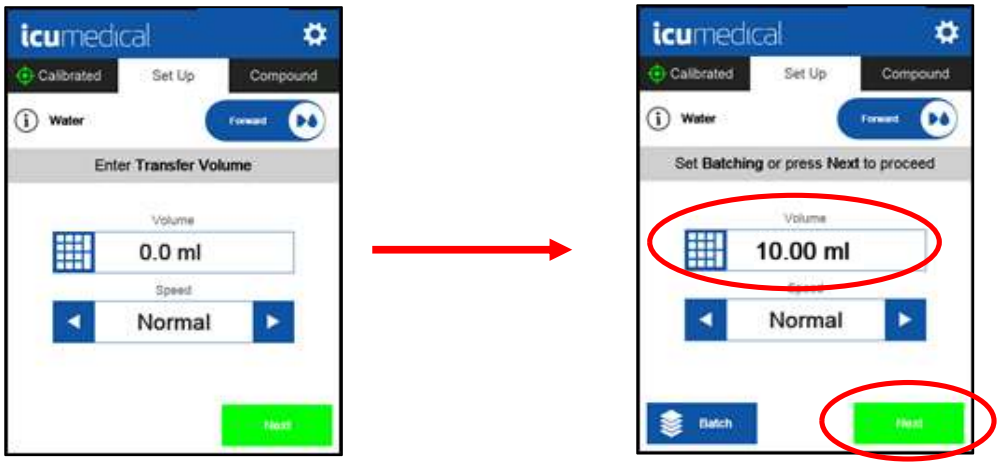
3.6 Basic Set Up and Transfer

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

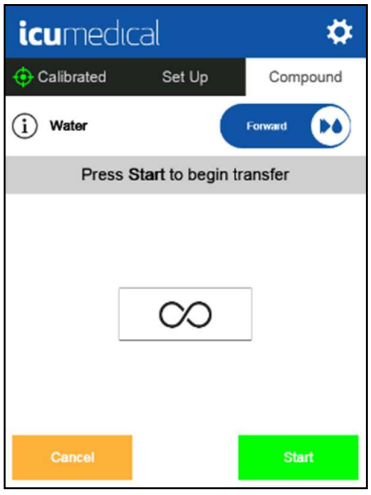
1. If not already connected, connect the input (proximal) end of the tubing set to a source container.

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

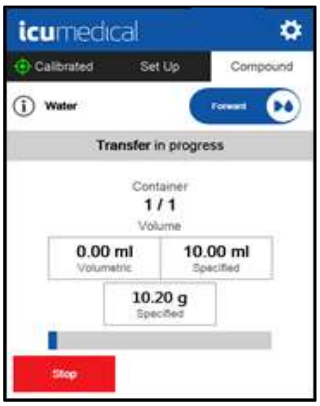
3. Enter Volume to be transferred and select the speed. Press “Next” to confirm the transfer process.



Note: Pressing “Next” without entering a volume will enable the “Infinite Transfer” mode. Pump will indicate that “Infinite Transfer” mode is about to be initiated, volume number will change to an infinity symbol (See below). Infinite mode will continue until the user manually stops the transfer.

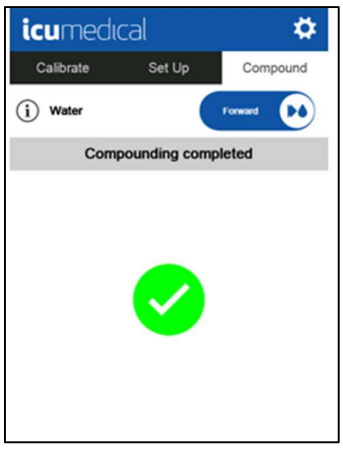


4. Unit will move to the Compound tab screen.
   After confirming that entered information is accurate, press “Start” to initiate transfer. The unit will begin liquid transfer and the progress bar will indicate the status of the transfer. The volumetric measurement will provide an indication of what has been transferred into the bag. Pressing “Stop” will interrupt the transfer.



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

5. 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).



6. Disconnect the Tubing Set and place the destination container on the External Scale for weighing. Check the weight and verify that the correct volume is transferred.

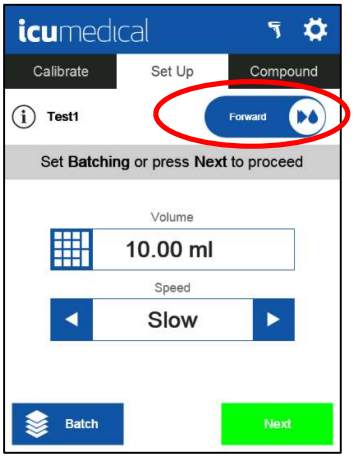
7. After compounding is complete, follow facility’s medication handling protocol and procedures.

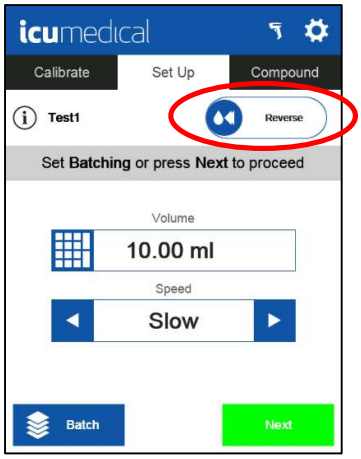
3.7 Forward / Reverse Transfer

When on the Set Up tab, the user can manually change the forward or reverse (right/left) rotation of the pump. This setting allows residual liquids to be returned to the source container.

Note: Forward rotation (counterclockwise rotation) is activated by default.

Note: The Calibration is only accurate for the direction you use at the Calibration Step. Both Forward and Reverse directions should be calibrated separately to achieve specified accuracy.

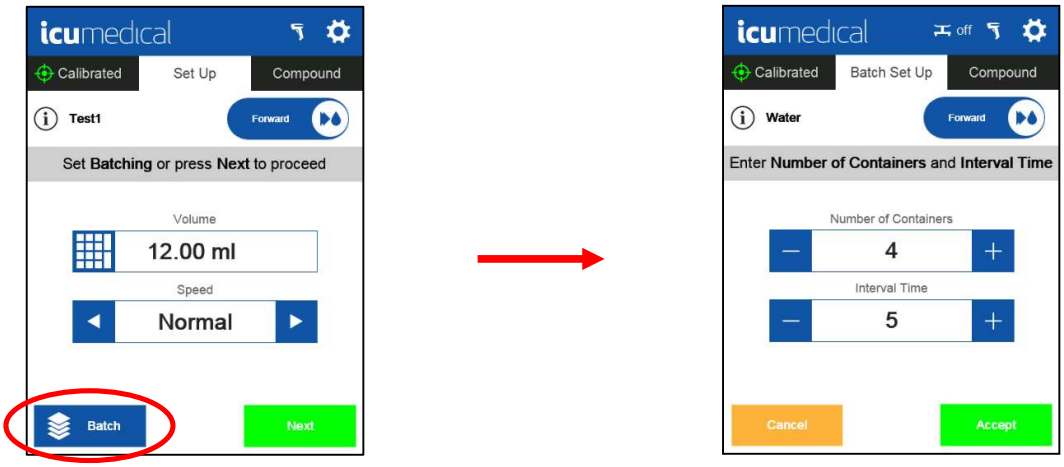




3.8 Batch Mode

For compounding multiple destination containers/doses, batch mode can be used. User can specify a set interval time to wait between the transfers, allowing a user to efficiently batch-fill multiple destination containers (e.g. vials).

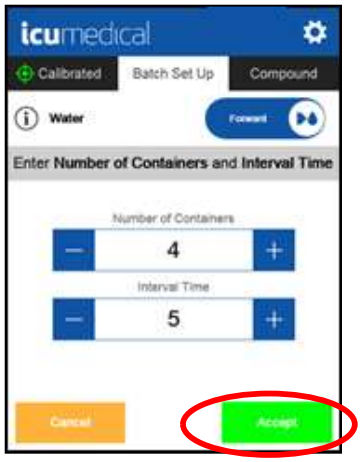
1. From the Set Up screen, press “Batch” to set the number of (destination) Containers and Interval Time.



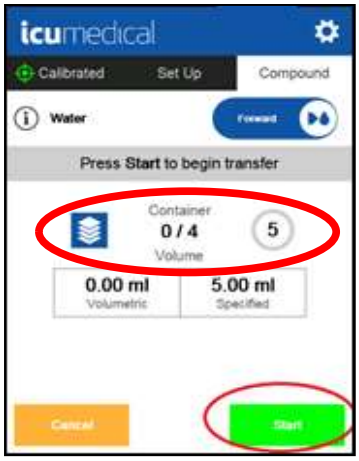
Note: The minimum interval time between the individual fillings is set to a default of 2 seconds.

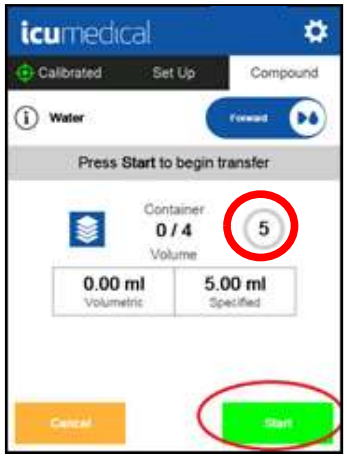
Option	Description
Number of Containers	This number specifies the quantity of destination containers planned to be filled. For example, if the machine is to fill 10 syringes, the Number of Containers would be 10. **Note:** Maximum number of destination containers is 999.
Interval Time	This number specifies the time (in seconds) the unit will wait to initiate next transfer. **Example:** If the interval time is set to 5 seconds, the unit will perform a transfer then wait 5 seconds before automatically initiating next transfer. **Note:** Minimum time delay between transfers is 2 seconds, maximum is 180 seconds.
Quality Control Check	This number specifies which transfer (in order) should be used for a weighing check to ensure that unit calibration is still valid.

2. Press “Accept” to continue.



Note: When batch settings are entered, the number of destination containers to be filled and the interval/pause times between the individual fillings appear on the display of the unit.





3. If not already connected, connect the input (proximal) end of the tubing set to a source container. For Circle Priming, see the “Circle Priming” section of this document.

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

5. Press “Start” to begin batching. As each destination container is filled, the Container number on the unit will update accordingly. The user will be alerted with a countdown on the top right of how many seconds are left until the next transfer is automatically initiated.

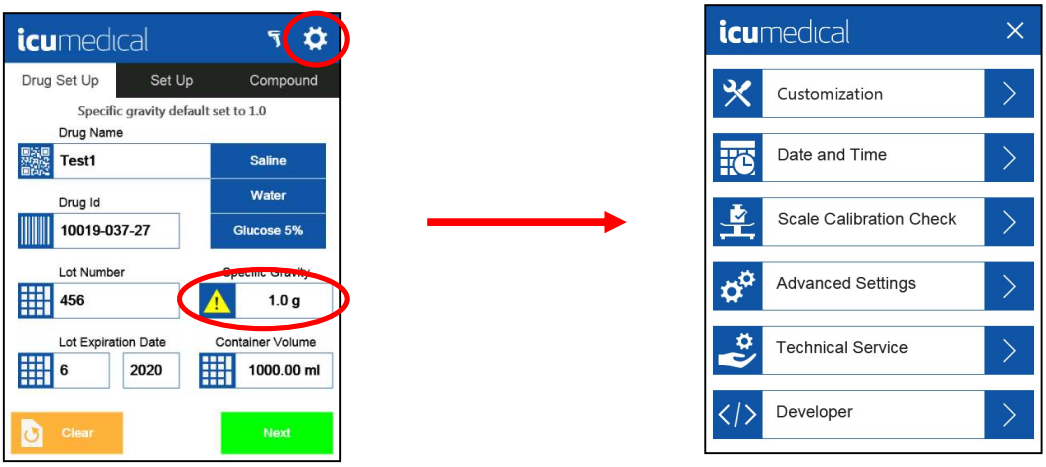
Note: There may be a few seconds delay between pressing “Start” and the unit starting.

3.9 Power Off

When user is done with compounding processes, the unit can be turned off. Press the Power Button on the front of the unit to turn it off.

4.0 Settings

1. Click on  for Settings located in the top right of toolbar. The Menu Screen will appear.



The settings menu as described below, provides the user access to the basic settings of the unit.

Option	Description
Customization	Allows updates to speed and volume and also allows user to view software version
Date and Time	Allows updates to the date and time
Scale Calibration Check	This feature is not used
Advanced settings	Allows updates to drug listings, language options, and network connections. (password-protected)
Technical Service	Allows access to technical settings (password-protected). This option is reserved for ICU Medical personnel.
Developer	This is a settings screen for Administrators only

4.1 Customization

The Customization tab allows the user to modify settings that are user-controllable.

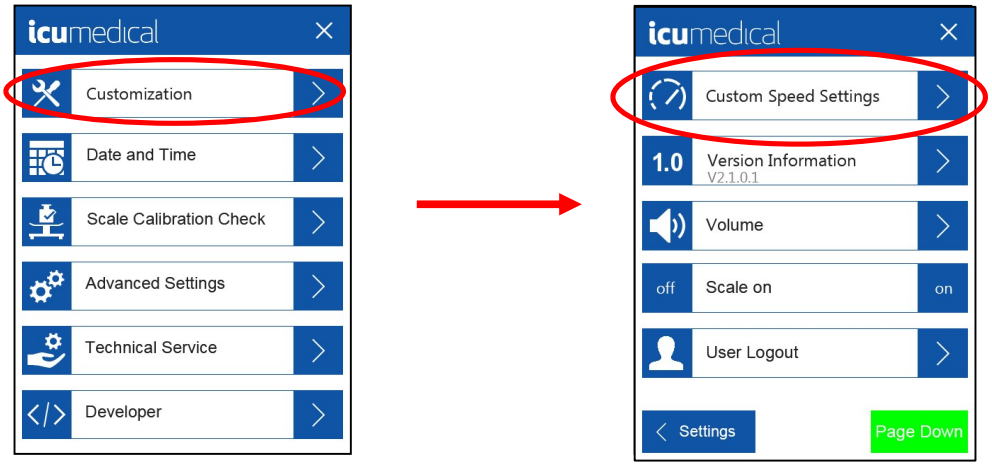
4.1.1 Custom Speed Settings

The user of Diana Peristaltic Pump can modify the speed settings of the pump in the Customization tab. The unit allows the user to select up to 20 different speed settings. Unique named identifiers can be created and matched to a specific speed setting (e.g., the highest flow rate is equal to pump speed 20, while the slowest flow rate is equal to pump speed 1). The speed is measured in mL/min. Default speed settings are show in the table below.

Speed	mL/min
Slow (3)	165
Normal (9)	440
Fast (14)	700

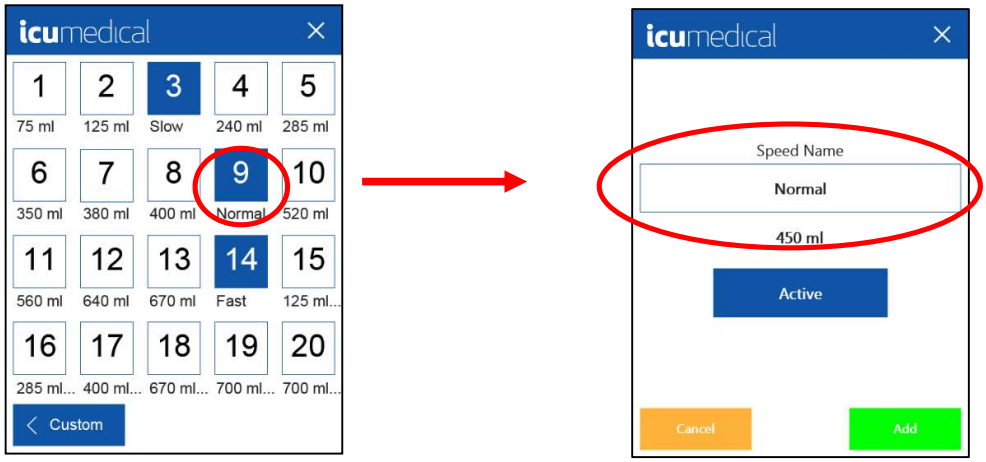
Note: Precise pump speed is not user-configurable during compounding; only named identified presets are available.

1. In the menu setting, select "Customization" and then the menu item "Cusom Speed Settings".

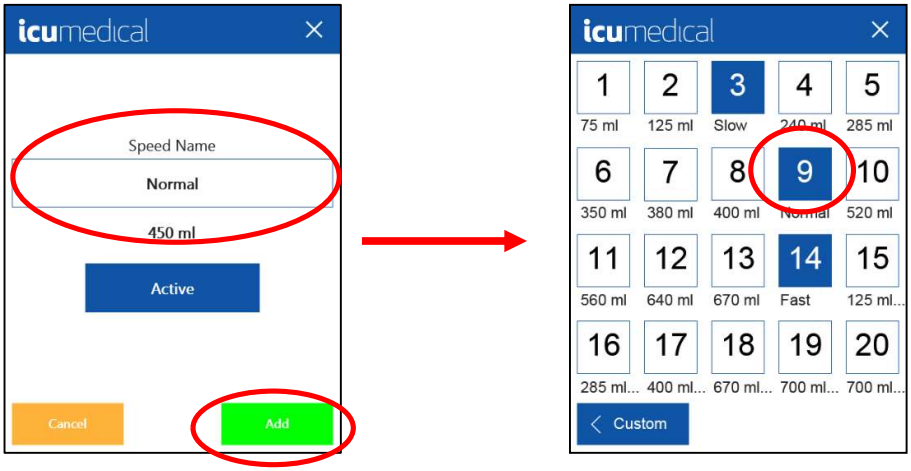


2. A window will appear with the customization options for the Diana Peristaltic pump stored in the system. In the next steps, the user can change the name of the speed settings. Speed settings can be activated or deactivated for the user to see during liquid transfer.

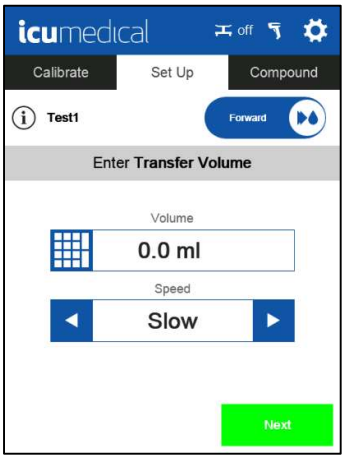
Note: After a start-up, the pump defaults to a normal speed of 9.



3. Press the “Add” button to select a specific name of a speed. The speed setting will be updated once the name is selected.

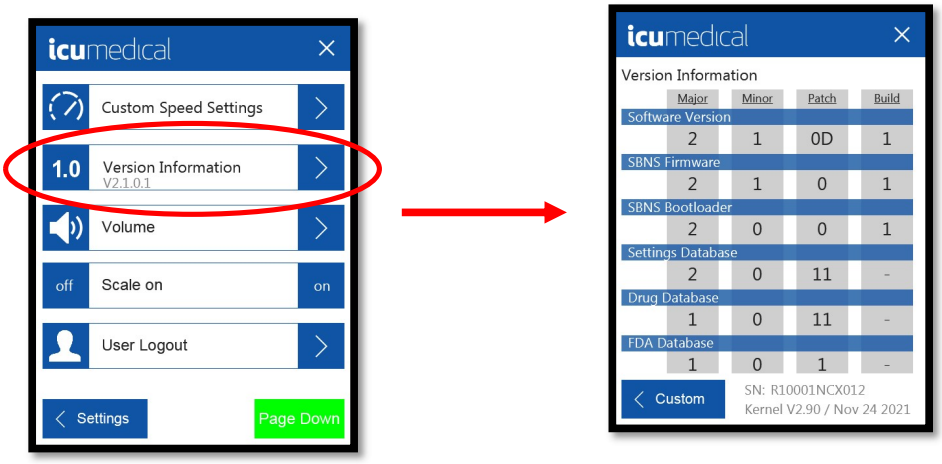


4. User will now be able to see the selected speed name when performing a liquid transfer from the Set Up screen. The user can press left/right arrows to change the speed.



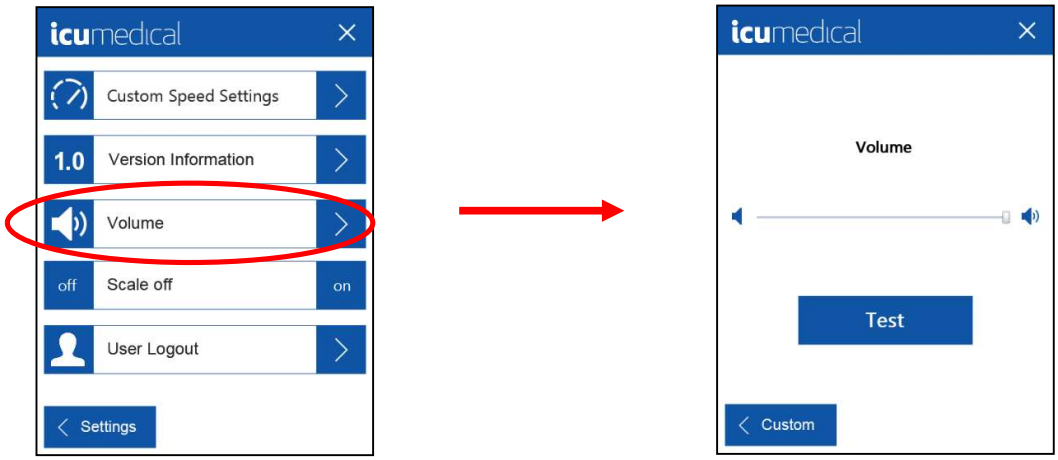
4.1.2 Version Information

The user and ICU Medical personnel can view the version of software components as well as unit.



4.1.3 Volume

With this setting, the user can adjust the sound volume. User can select a desired volume by clicking the desired position on the scale, the slide will move accordingly. To test the current volume, press the Test button.



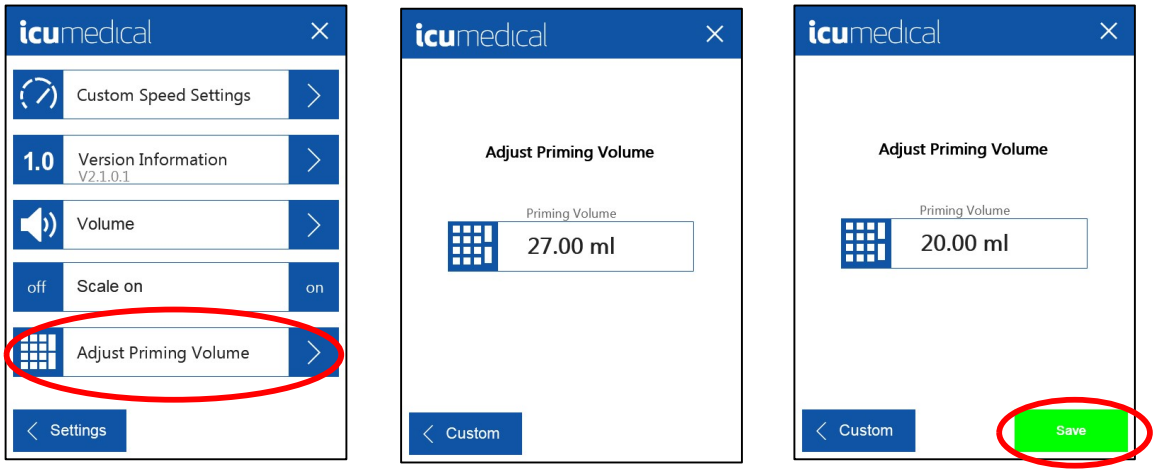
4.1.4 User Login

The default setting on the Diana Peristaltic Pump system 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 user name and password when the system is turned on. User login settings can be updated within the Advanced Settings menu (see section 4.3 of this manual).

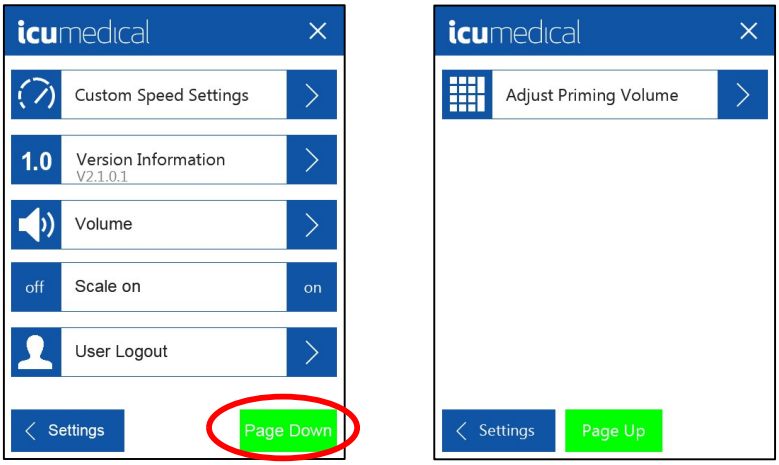
4.1.5 Adjust Priming Volume

The User can manually adjust the volume for priming the tubing set. If User Management (see section 4.3.4 of this manual for details on User Management) is not activated, the user could find the menu item “Adjust Priming volume” on the first page of the Customization. If the user management is activated, the user could find the menu item “Adjust priming volume” on the second page of the customization.

1. When User Management is not activated, choose the menu item “Adjust priming volume” from the first page of the customization menu. Press the displayed field and enter the volume by using the keyboard. Confirm the entered volume by pressing the “save” button.



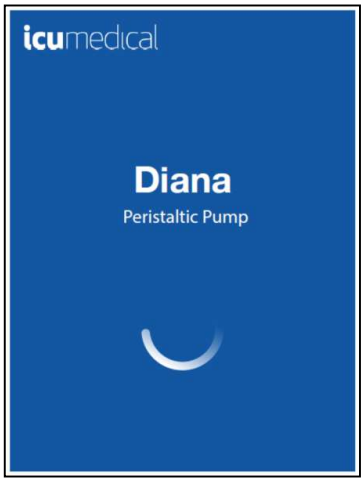
2. If the User Management is activated, the user could find the menu item “Adjust priming volume” on the second Page of the customization.



4.1.6 Activate / Deactivate User Login

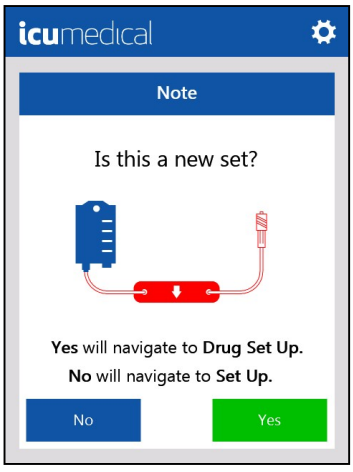
The User Login can be activated or deactivated in the advanced settings of the Diana Peristaltic Pump system by the authorized user.

1. Start the PPM module by pressing the on / off button and you will see the following screen after some seconds.



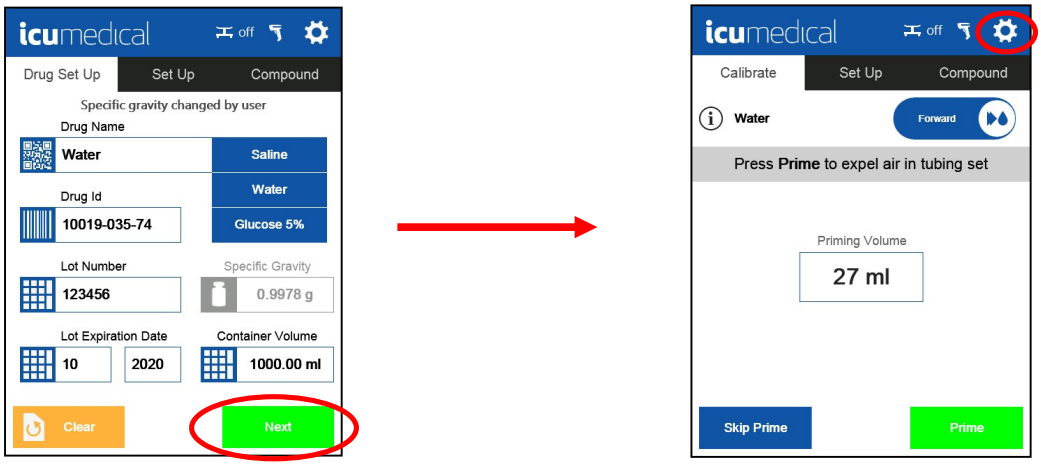
2. Open up the Flap and insert the tubing set clip into the slot. Rotate the roller head so that the tubing is wrapped around the motor. (See Section 3.1 for detailed instruction for installing the tubing set)

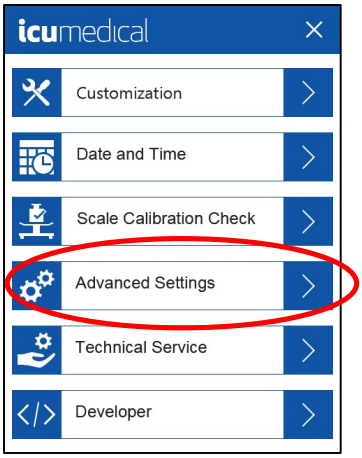
3. After the system has booted up, the query appears, asking if a new tubing set has been inserted. Choose between "yes" and "no".
   To remove the tubing set from the pump, lift the white clip out of the insert and unwrap the tubing set from the Rotor.



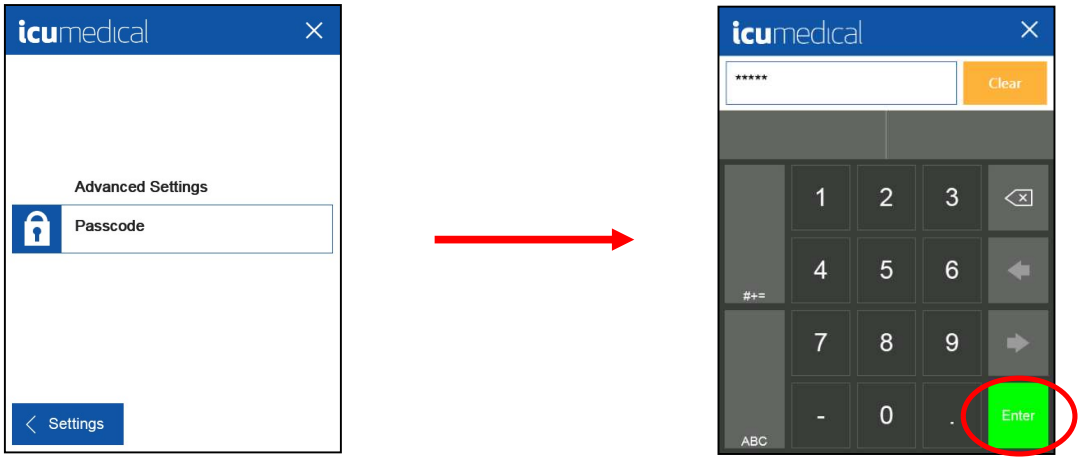
Note: if you choose between "yes" or "no" you will get different start screens. See chapter 5.2.

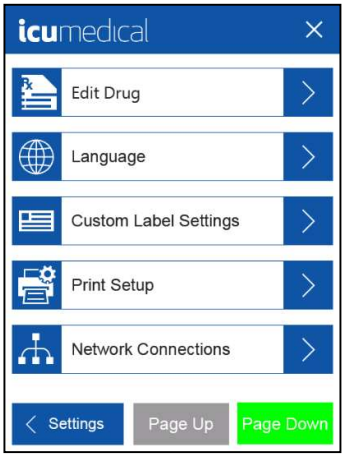
4. Press the Next button. Now you reach the calibration menu. Press the button at the top right of the touchscreen to access the settings and then select the advanced settings.





5. Enter the pin code for this area. The pin code will be sent to you by the ICU Medical service staff. Once pin is entered, you are in the menu sub-item of the advanced settings.





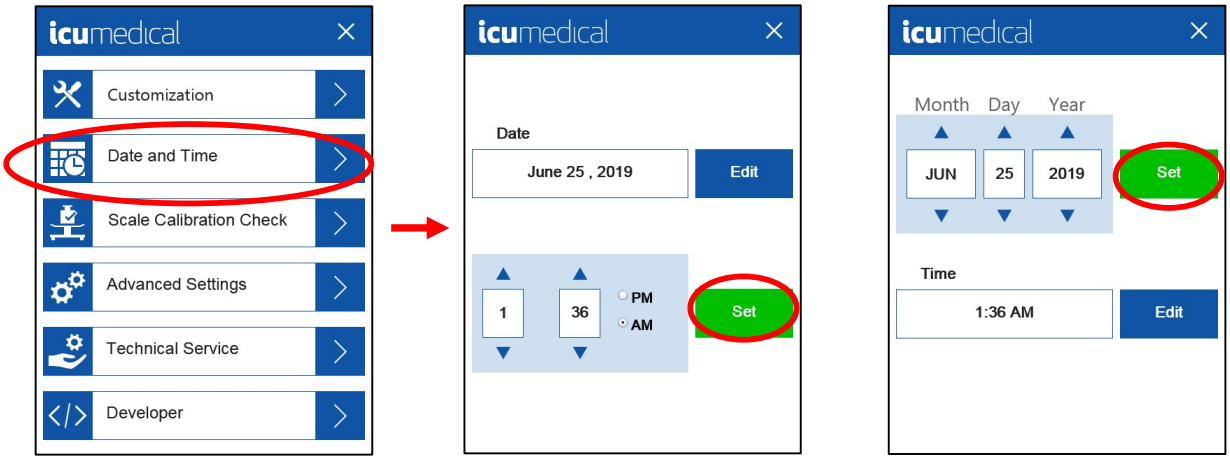
6. Please scroll down by pressing the "Page Down" button and select "User Login at Startup" to enable it.

Note: Once the green check mark is selected by the authorized user, the System must be rebooted before the user login will appear.

4.2 Date and Time

The user can update the date and time in the Diana Peristaltic Pump on the first page of the Settings Menu.

1. Enter the current date and/or time and press set



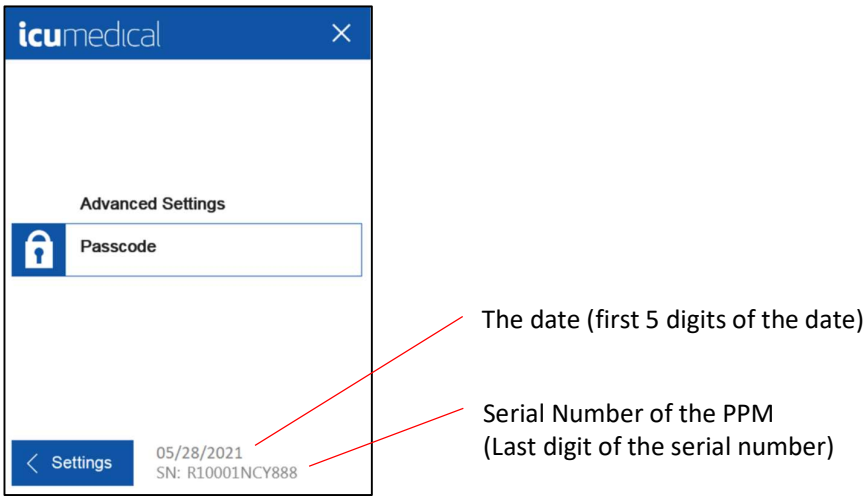
4.3 Advanced Settings

The Advanced Settings will allow the user to adjust various settings of the system. This menu is available only to authorized user and has a rotating passcode.

4.3.1 Rotating passcode

The rotating passcode is composed of three different components and must be recalculated by the user every day. The Requirements are: the Serial Number of the Diana Peristaltic Pump system, the current date (this is the rotating part) and the value for assigned to the the Advanced Settings options. The value assigned for Advanced Settings is 3.

1. The first component for choosing the rotating passcode is the current date. (the first 5 digits of the date).
2. The second component is the last digit of the serial number of the Diana Peristaltic Pump system.
3. The third and last 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 has to 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 unit
Y	Value for setting area (3 -> Advanced)

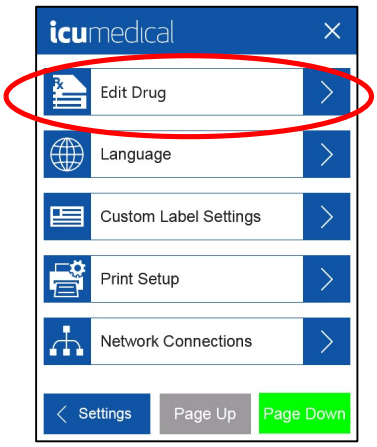
Example for calculating the passcode:
The digits which are marked in red are the digits that must be used in the rotaing passcode.

Date:	05/28/2021
Serialnumber 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).

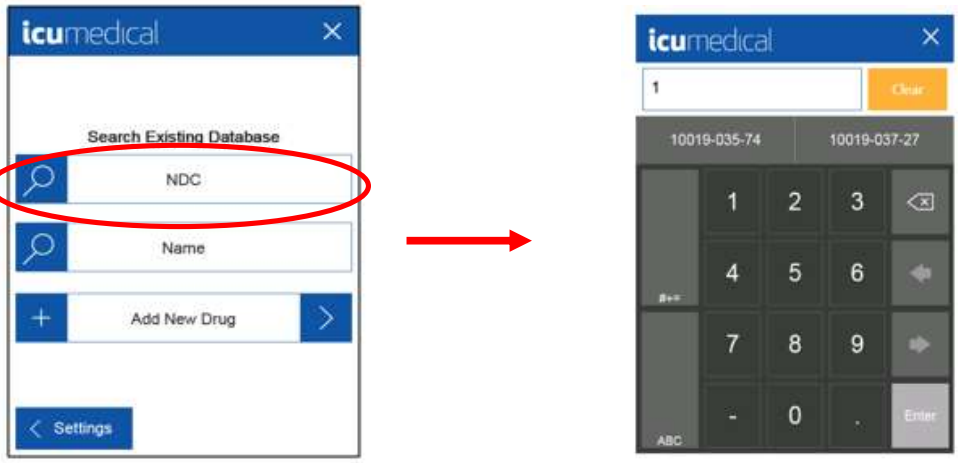
4.3.2 Edit Drug

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



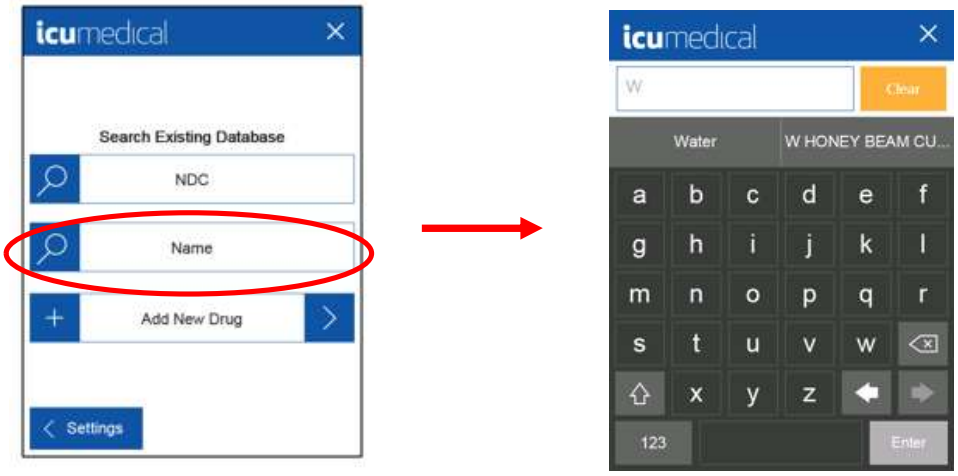
Users can search drugs by NDC or a drug name.

To search by NDC, select NDC option. Enter the NDC code and press "Enter".



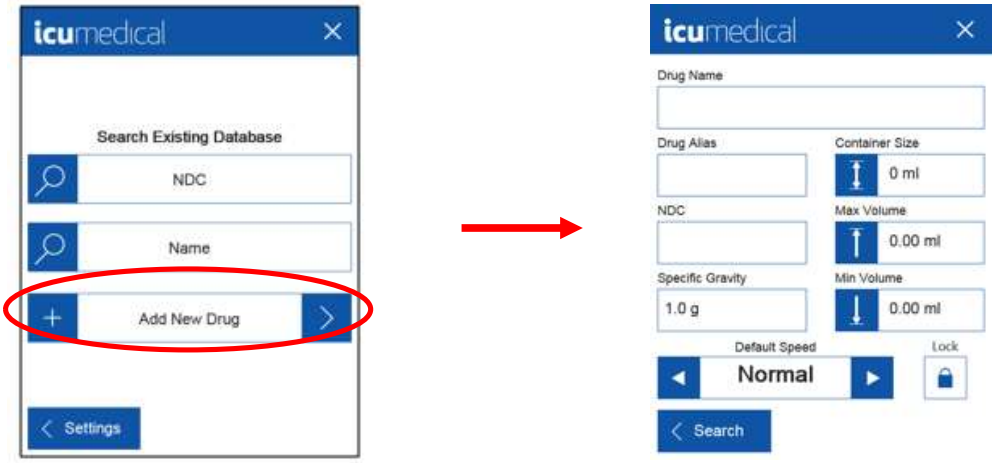
Note: As user enters NDC number, system will suggest the NDC number to autofill.

To search by name, select Name. Enter the name and press “Enter”.

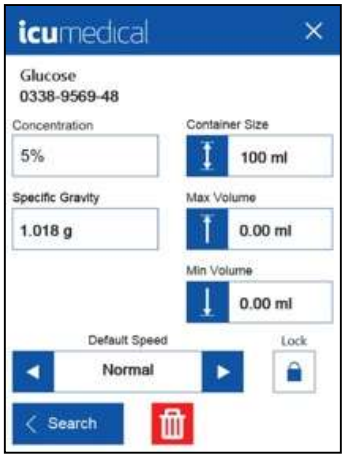


Note: As user enters the drug name characters, system will suggest the name to autofill.

If required drug does not exist in unit’s database, then user will need to add the new drug to the database. To add new drug, select “Add New Drug”. Enter the new drug information and press “Enter”.



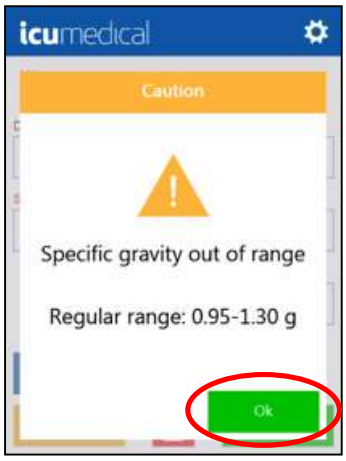
2. Once the drug is identified, add missing information if required, and verify the correct information is entered in the designated fields and press “Save”.



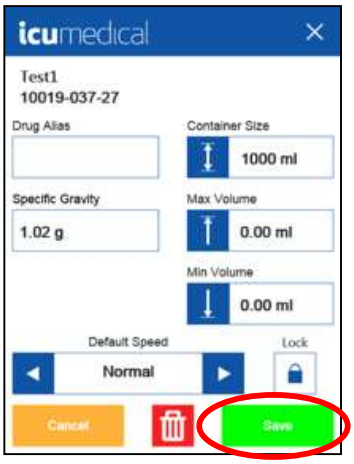
New Drug

Existing Drug

3. If a specific gravity is entered outside the value range defined in the system (0.95-1.30), the "Specific Gravity" field is highlighted in red. If the user continues and presses the “Save” button, a warning message appears which must be confirmed by pressing the "Ok" button. User will not be able to proceed further if correct Specific Gravity is not entered.



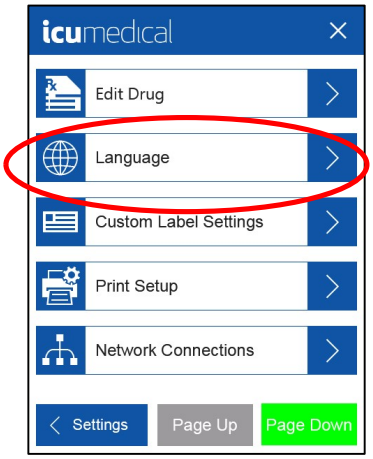
4. Enter a specific weight in the range 0.9 – 1.30 g and then press "Save". System will return to initial Edit Drug screen.



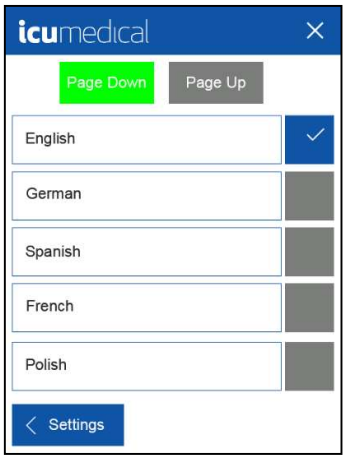
4.3.3 Language

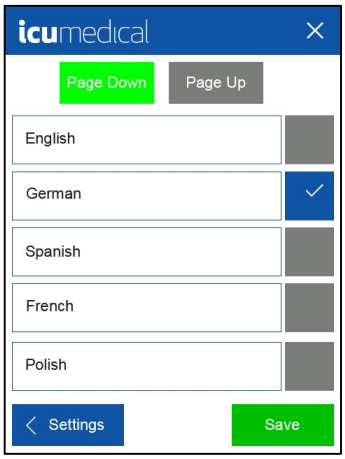
The Diana Peristaltic Pump has multiple interface languages that can be displayed. This menu allows a user to switch the language.

1. Select Language in the Advanced Settings menu.



2. Select the Language by pressing on the gray square next to the desired choice. Press Save to set the new language.

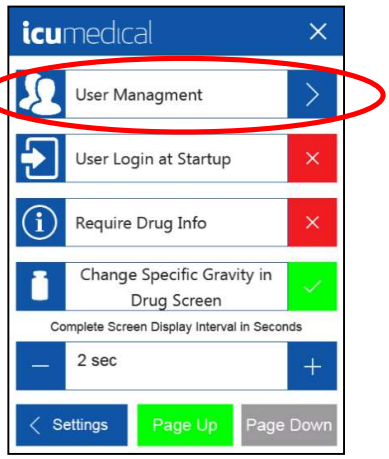




4.3.4 User Management

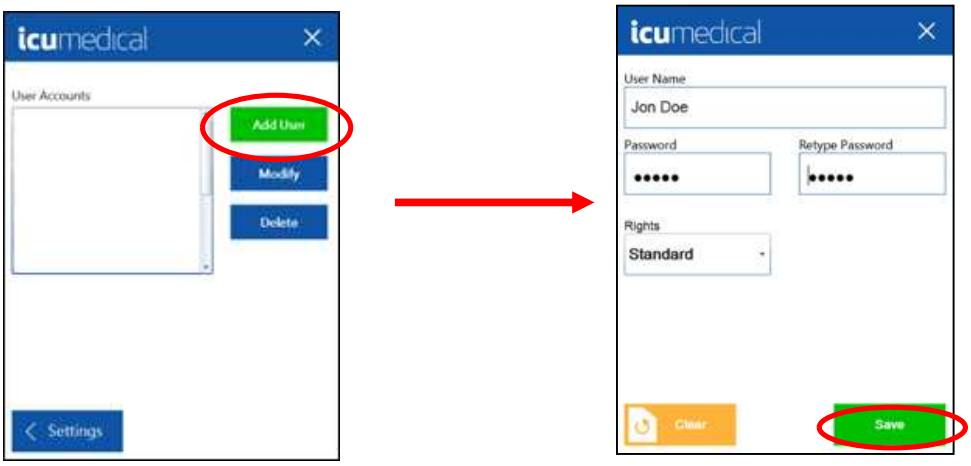
The administrator of this function can create individual users and assign users various permissions.

1. Select User Management in the Advance Settings section.



To create a new user:

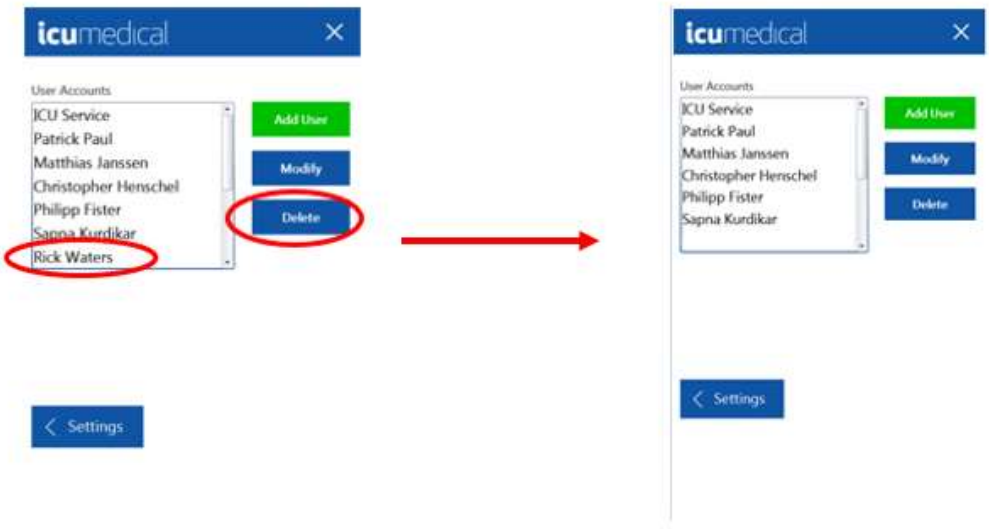
Press “Add User”. Enter the username, password, and rights (permissions level). Press “Save”.



Note: The administrator can choose between two access rights (Standard and Advanced) and assign this to the user. Only an advanced user has the ability to add new users to the system.

To modify a user:
Select an existing user and press “Modify” button. Once done with changes press “Save’.

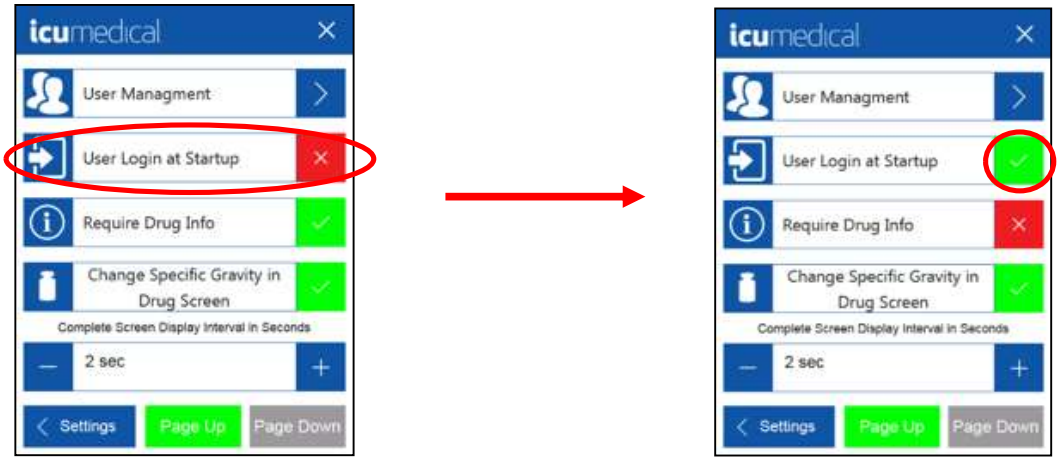
To delete a user:
Select an existing user and press “Delete” button. The user will be removed from the User Accounts list.



4.3.5 User Login at Startup

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

1. Select “User Login at Startup” in the Advanced Settings section.



2. Toggling between (✓) and (x) will require the system to either require User Login at Startup or not.

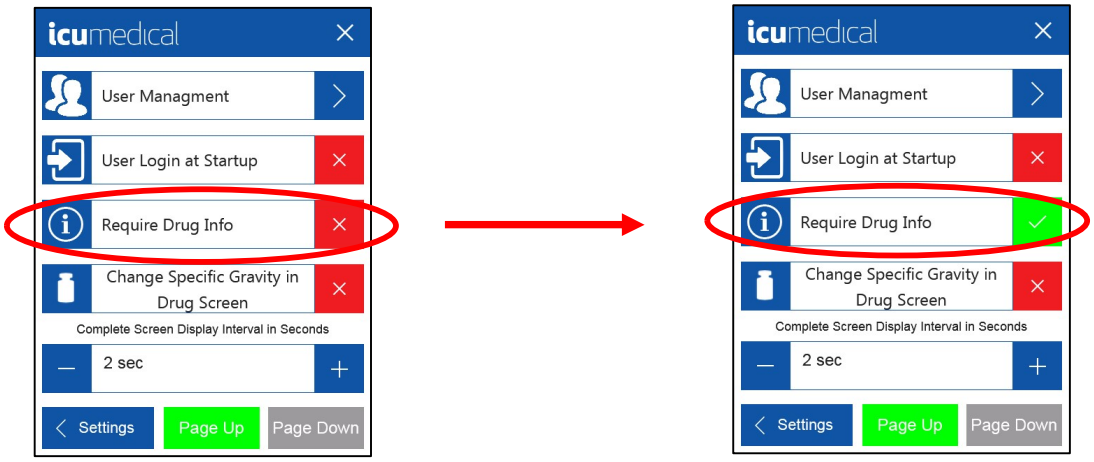
Note: When the green check mark is set by the authorized user, the user login will be required each time the unit is powered on.

4.3.6 Require Drug Information

The peristaltic pump 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”.

1. Select “Require Drug Info” in the advanced Setting section.



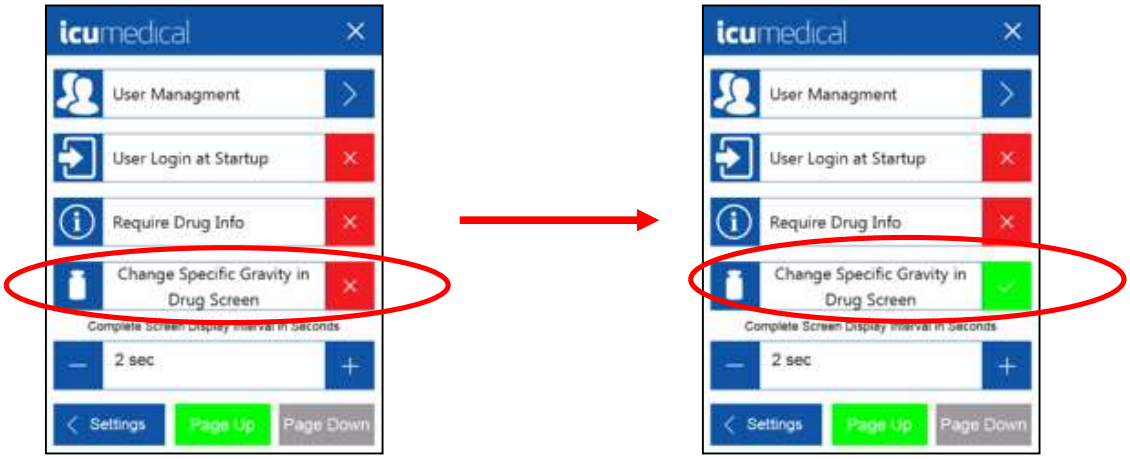
Drug Information is NOT required

Drug Information is required

4.3.7 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. Select Change Specific Gravity in Drug Screen in the Advanced Settings section.



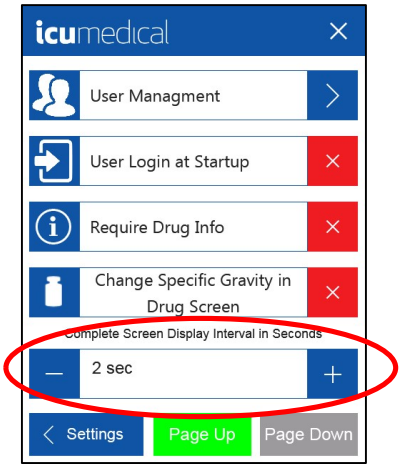
2. Toggling between (✓) and (x) will allow the change of specific gravity or not.

4.3.8 Complete Screen Display Interval in Seconds

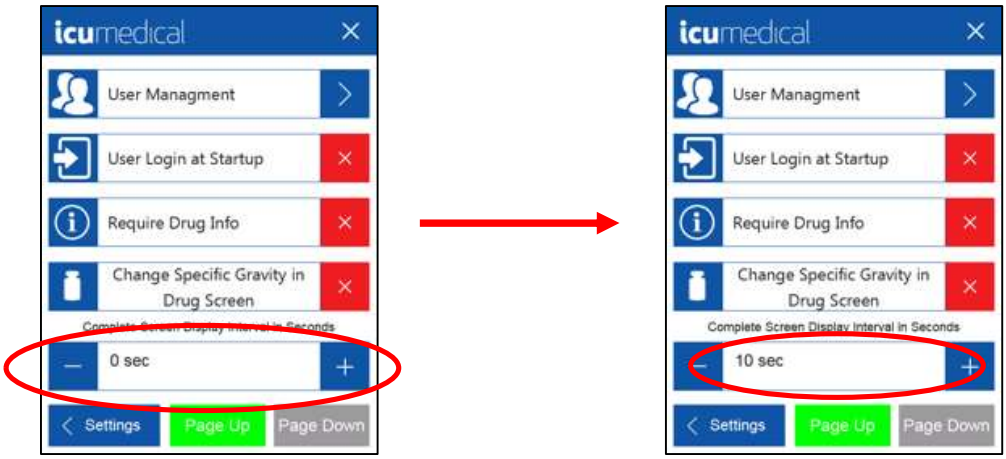
A timer can be set for how long the display of the finished filling operation should be displayed.

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

1. Find the field below the “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.



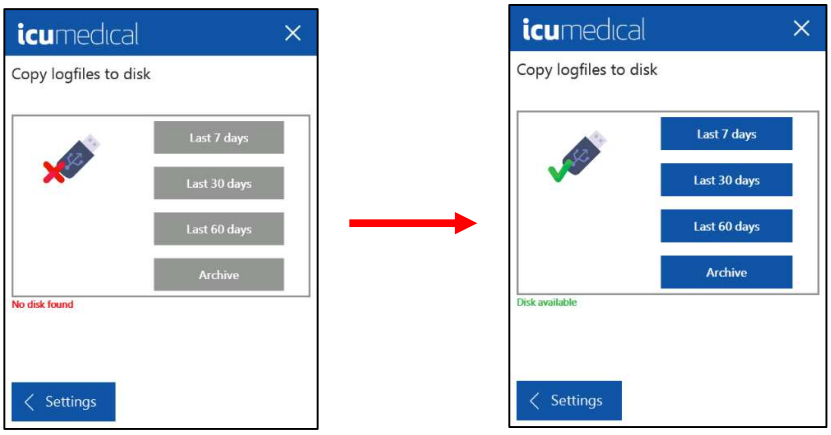
4.3.9 Logfiles

- Insert USB stick into adapter

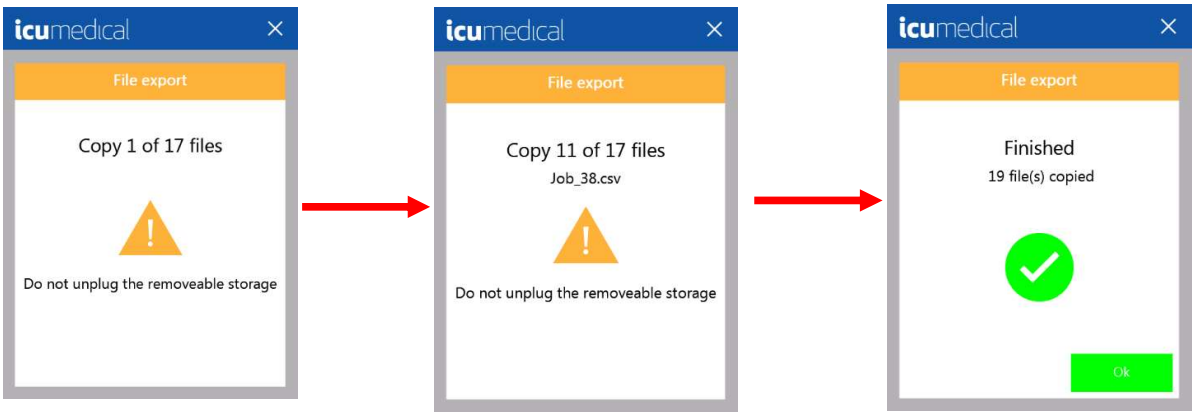
  Note: USB stick and adapter must be requested from ICU Service personnel

- Insert adapter into Peristaltic Pump USB port
- Select desired option (Last 7 days, Last 30 days, Last 60 days, Archive)
- Remove USB and adapter from pump after “Finished” message is displayed on unit

  Note: “Archive” will save all available log files

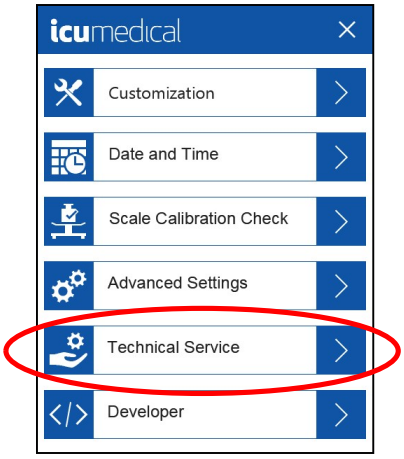


Note: System will display progress until log files are transferred to the USB stick



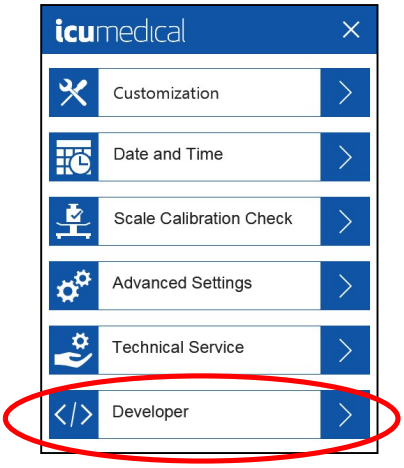
4.4 Technical Services

“Technical Service” Menu Item is for ICU Medical authorized personnel only.



4.5 Developer

“Developer” Menu Item is for ICU Medical authorized personnel only.



5.0 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 unit to ICU Medical Service department once a year for inspection and maintenance. Please contact your local ICU Medical representative or ICU Medical Service department for instructions.

5.1 Accuracy Specifications

Note: Verify Diana Peristaltic Pump accuracy performance before use to ensure it meets facility protocols.

Diana Peristaltic Pump accuracy with Water/Isopropyl Alcohol at a Slow-speed setting using ICU Medical Luer-based components, 16G needle, 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

Diana Peristaltic Pump accuracy with Dextrose 10%/Lipids at a viscosity-specific speed using ICU Medical Lipids tubing set (Luer-based):

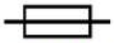
+/- 10% for volumes greater than or equal to 5 mL

Diana Peristaltic Pump can provide a sustained transfer rate (measured with Water) using ICU Medical tubing set:

0.7 L/min with Luer-based sets
0.6 L/min with 16G needle
0.2 L/min with 18G needle

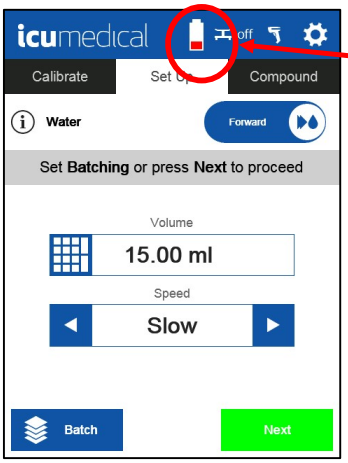
5.1.1 Envionmental Specifications

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 – 0.4 A 50 – 60 Hz
Electrical Fuse	 2X 2.0A . T, H 250V 5X20MM

5.2 Pulsating Battery Indicator

The pulsating battery indicator is a safety reminder to the user that the Peristaltic Pump Module has to returned to ICU Medical Service Team. The 3 Volt battery which is installed isn't providing the required power and has to be replaced.



If the battery has to be changed this icon starts flashing at top of display

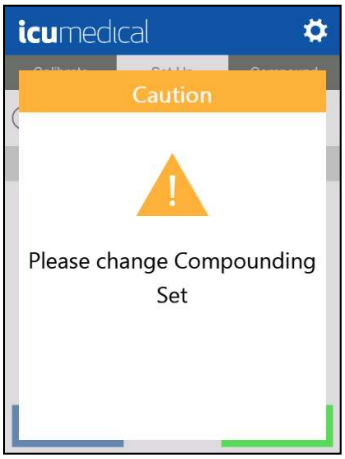
5.3 Fuse Replacement

The Peristaltic Pump uses two fuses located in the rear of the unit; fuses are a part of the Power Inlet (See Section 2.2 for illustration of location). Service on the fuses can be performed by the end-user (end-user buys the fuses from local hardware/electrical store). Fuse type to be used is ceramic fuse model number T2AH250V. Incorrect insertion of the fuses may result in no power to the unit.

1. Make sure the unit is powered-off and power cord is unplugged.
2. Using flat head screwdriver, 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 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 unit to to avoid damage to the fuse holder or Power Inlet.

5.4 Tubing Replacement

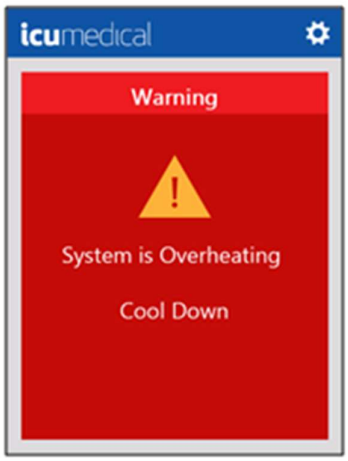
The system will display the warning shown below if a tubing set has compounded more than 60L of fluid. When the user replaces the tubing set, the workflow may continue.



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

5.5 Temperature Warning

In rare instances, the Diana Peristaltic Pump may indicate that the system is overheating. A common source of this issue is heavy use of the unit in short periods of time. To ensure proper temperature maintenance, a maximum limit of duty cycle, transfer volume and internal temperature has been placed in the unit software. Once the unit has reached one of these limits, a warning is displayed to the user.



The unit will be required to remain idle during the cooling phase. The unit will be ready for use after end of the cooling off period and the duty cycle will revert to the original state.

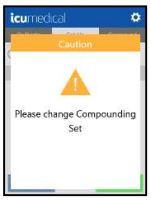
Note: During cooling off period, a user cannot operate the unit.

In some instances, the unit will instruct the user to power off the unit. The warning remains for the duration of the cooling process on the unit's display. Once the warning on the display is gone, the unit can be used again for further filling activities.

Run Time Variable	Setting
Maximum Run Time	8 Hours
Maximum transfer volume	240 Liters
Max Temperature Limit	55° C
Recommended Cool Down Period	30 minutes

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

5.6 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 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 to reduce the back pressure
	Using inline filter	Reduce speed to reduce back pressure
Tubing kicks out of the pump	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 unit
		Use “BX” series tubing
Pump display is dark		Check Power Cord and ensure connection
Unit providing alert to change compounding set 	Compounding set (tubing set) has been used to transfer 60 liters.	Replace tubing set.
Database Error Messages  	System malfunction.	Please contact ICU Medical Technical Support.

6.0 Unit Software Update

The folder “drp / update" can be found on the USB stick to update the Diana Peristaltic Pump.

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

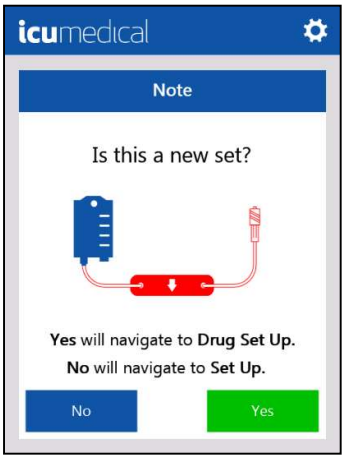
After the system has booted up, the prefabricated USB stick is plugged into the USB interface of the system (you will need the enclosed adapter cable). A selection window opens automatically. The window will allow the user to select which components should be updated. It is possible to perform a complete system 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 system automatically restarts. If the system update is also checked, a new window opens with a progress bar and with an indication of which file is currently being updated.

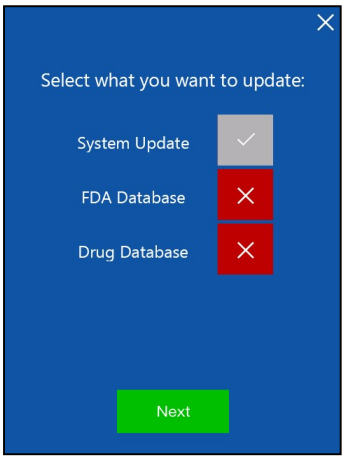
After the update has been successfully transferred, the system will restart and return to the setup screen.

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

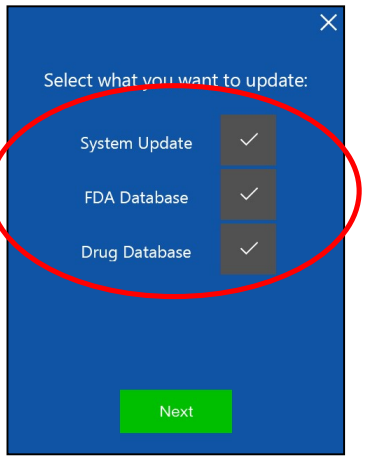
1. Turn on the system and wait for the system to completely power on.

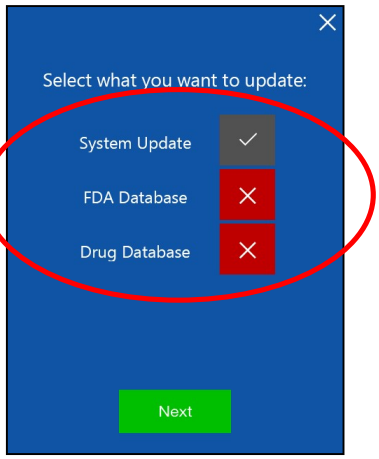


2. Insert the USB stick with the update on it into the designated port on the back of the roller pump (adapter cable required). The selection window will open automatically.



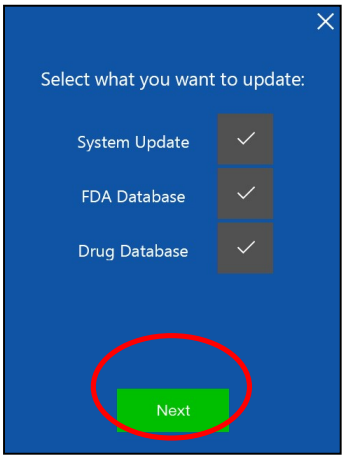
3. Follow instruction provided by ICU Medical service personnel and make the selection of which components need to be updated.



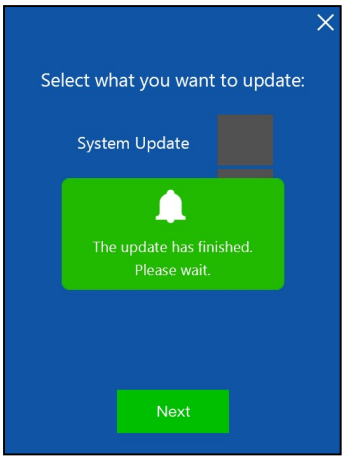


Note: Components marked with a red cross cannot be updated because they are not available on the USB stick.

4. Then press the "Next" button to start the update.

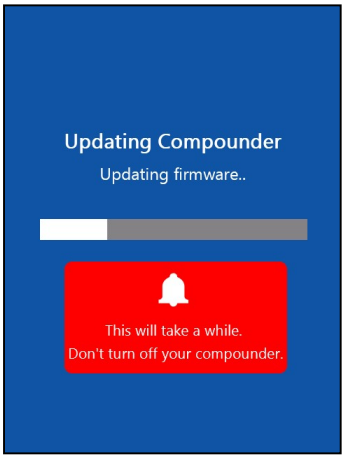


5. Once the system is updated, the following message will be displayed:

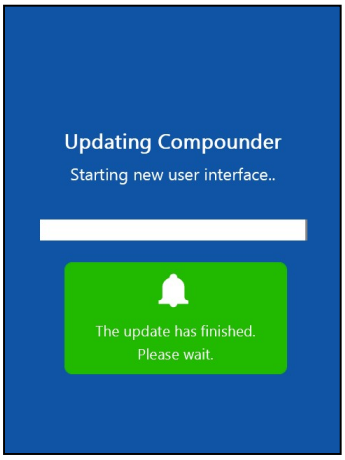


A progress bar indicates how far the update has progressed and which file is currently being updated.

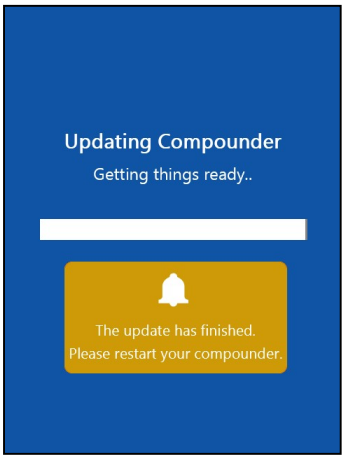
Note: This message is displayed to the user only if a firmware update is performed to prevent the system from being turned off by the user while the update is in progress.



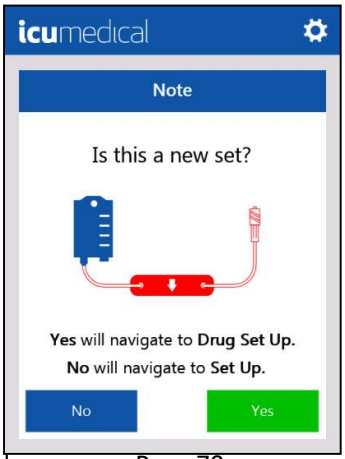
6. After completing the update (if no firmware update has been made), the user will receive a confirmation message that the update has been successfully completed. Then the system automatically restarts.



7. If a firmware update is executed, the user receives a message and the system must be restarted manually by pressing the on / off button. Switch the system off. Wait some seconds before you restart.



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



6.1 Duty Cycle

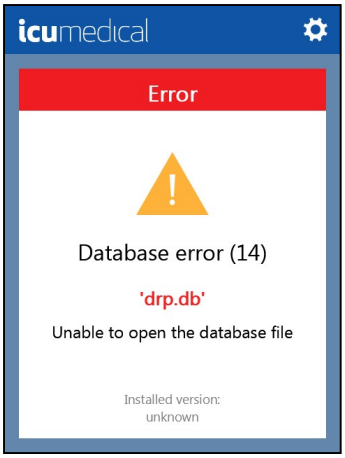
The maximum duty cycle of the unit is 8 hours. After 8 hours of continuous usage the system must be allowed to cool down for 30 minutes. The system cannot be used during this cooling-off period. The system is completely ready for use after expiration of the cooling-off period and the duty cycle will reset back to 8 hours.

7.0 Transport

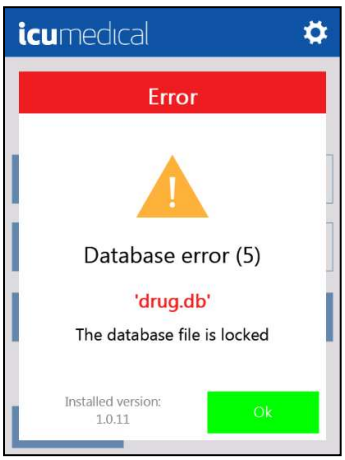
Please note that some metal parts may be warm after heavy use of the unit. The user should not use the unit for 30 minutes before transportation to allow the metal parts to cool. However, the unit should remain switched on during the cooling phase.

8.0 Database Error

This database error occurs when the Diana peristaltic pump module cannot read the database. The number in brackets indicates the error. You will find the error designation in the following list (see 8.1.1). 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 pressing the "OK" key and then follow up with the usual workflow. If you receive this error message, please contact a service employee in order to be able to correct this database error as quickly as possible.



8.1 List of 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 readonly 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 */
#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() */

9.0 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 you:

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

951 Calle Amanecer
San Clemente, CA 92673 USA

10.0 Warranty and Service Information

10.1 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 Peristaltic Pump or accessories.
- Unauthorized cleaning of the Peristaltic Pump or accessories.
- Transportation damages of any sort.
- Accident, fire, water, vandalism or causes other than ordinary usage.
- Misuse of the equipment or accessories.
- Disregard for 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 Systems

Switch off the power supply of the Peristaltic Pump. Spilled liquid and drops must be wiped promptly to avoid intrusion into the pump. Use only lint-free cloths or swabs with cleaning and disinfection solutions. Use no abrasives. Also clean the Diana peristaltic pump under the stainless steel plate, including rollers when the system is turned off.

In the following you find the recommended cleaning and disinfection Protocol:

Step 1 - Wipe the pump with 2% sodium hypochlorite (bleach) - Cleaning solution

Ingredient	**Lot**	**Lot**
Bleach (5.25% sodium hypochlorite)	190.5 ml	381 ml
Sterile water for rinsing (pour bottle)	309.5 ml	619 ml
TOTAL VOLUME	500 ml	1000 ml

Step 2 - Wipe the pump with 1% sodium thiosulfate off - Disable solution

Ingredient	**Amount when using (Sodium thiosulfate 10%)**	**Amount when using (Sodium thiosulfate 25%)**	
Sodium thiosulfate inj. (10% or 25%)	50 ml	20 ml	40 ml
Sterile water for rinsing (pour bottle)	450 ml	480 ml	960 ml
TOTAL VOLUME	500 ml	500 ml	1000 ml

Step 3 - Wipe the pump with sterile water - *wipe all surfaces to remove residues of bleach or sodium thiosulfate.*

Step 4 - With sterile isopropanol wipe - *wipe all surfaces prior to using the system for compounding of sterile products. Remaining residue can be removed with a sterile isopropanol wipe or lint-free sterile swab soaked with sterile water or sterile isopropanol.*

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:

1. Use new Tubing Set
2. Ensure Tubing Set is fully primed and properly calibrated
3. Identify the specific gravity of the liquid being tested
4. Use at least 150 mL output empty container for this test
5. Enter 100 mL and press Next
6. Without connecting the tubing set to the bag, place the empty container on scale
7. Tare scale with empty container
8. Attach the empty container Tubing Set
9. Press Start to initiate transfer
10. Remove Tubing Set
11. Enter the weight if the specific gravity is correct
12. Enter the actual volume into the Diana Peristaltic Module
13. Press Calibrate

With Graduated Cylinder:

1. Use new Tubing Set
2. Ensure Tubing Set is fully primed and properly calibrated
3. Use at least 150 mL output empty container for this test
4. Enter 100 mL and press Next
5. Place the distal end of the tubing set inside the graduated cylinder so that liquid will passed into the cylinder
6. Press Start to initiate transfer
7. Remove Tubing Set
8. Identify the volume transferred
9. Enter the actual weight into the Diana Peristaltic Module
   Note: Find the actual weight by multiply the volume inside Cylinder by the specific gravity of the liquid
10. Press Calibrate

Appendix C: Volumetric Calibration

The user can perform a volumetric calibration of the Diana Peristaltic Pump if no scale is available.

Note: The calibration process of the Peristaltic Pump is designed for and recommended to be performed using an external scale or the optional attached scale. Accuracy specifications are based on gravimetric calibration. Performing calibration without a scale, such as with an IV syringe, introduces additional variations. For IV syringes, these variations include–but are not limited to–the volumetric accuracy of the syringe, the "to deliver" intent of syringe markings and the "to contain" interpretation during syringe-based calibration, the compressibility of air in the syringe and the syringe plunger seal, the surface area of the syringe plunger seal, and the kinetic and static friction of the syringe plunger seal within the syringe barrel.

1. Turn the unit on.
2. Prepare source container and install tubing during initialization, if desired, for faster workflow.
    a. Heavy duty tubing (BX series) is recommended for high-backpressure processes such as filling elastomeric pumps or filling at high speeds against high restrictions like 18G or 20G needles. Tubing should be replaced after 60 L of liquid transfer in either direction.
3. Resolve any alerts.
    a. Always select "Yes" for "Is this a new set?" unless you intend to continue compounding without recalibrating. If you plan to calibrate, select "No." Failure to do so may cause the software to crash during priming or calibration in certain versions up to and including 2.0.0.5. The remainder of these instructions assume the user has selected "Yes."
    b. The unit will display the Drug Set Up screen.
4. Attach source container.
5. For a "No Drug Info" setup, leave Drug Name blank on Drug Set Up page, and Press the "Next" button.
    a. If preferred, select a Drug Name which is configured for 1.00 g/ml Specific Gravity.
    b. When using a syringe-based visual calibration process, always use 1.00g/ml Specific Gravity regardless of the actual specific gravity of the liquid to be transferred.
6. If desired, enter the volume of solution in the source container as "Container Volume."
    a. This is optional. Leaving the Container Volume at 0.0 ml will inactivate the "Source container is empty" alert. If a Container Volume is entered, the unit will alert "Source container is empty" when the unit predicts the source container will be empty based on the previous transfers.
7. Press the "Next" button.
    a. These instructions assume the user has selected "Yes" when prompted "Is this a new set?" The unit will display the Priming screen in the Calibration tab.
8. Make sure that the receiving (distal) end of the tubing set is connected to a destination container.
9. Press the "Prime" button.
    a. The unit displays the priming progress screen
    b. After priming, the unit will display the Calibration screen in the Calibration tab.
10. Attach a new, empty 50 ml syringe.
    a. Smaller syringes exhibit higher backpressure. A 50 ml syringe is recommended.
11. If desired, adjust the calibration volume.

12. If desired, adjust the speed.
    a. Each Diana Peristaltic Pump is validated to provide accuracy of ± 1% with water at Slow-speed setting with no restriction nor back pressure for volumes greater than or equal to 10 ml. Different liquid characteristics, speeds, restrictions, and back-pressures may exhibit different results. Verify Diana Peristaltic Pump accuracy performance before use to ensure it meets expectations when used according to facility protocols.
    b. Default speed can be set per Drug Name in Settings.
13. Press “Start.”
    a. The unit displays the calibration transfer progress screen
    b. After calibration transfer, the unit will display the Enter Measured Volume screen.
14. Visually determine the volume of liquid transferred to the 50 ml syringe.
15. Enter the determined volume as “Measured Weight.”
    a. The system is designed for calibration with an external scale. Syringe-based visual calibration requires defining Specific Gravity as 1.00 grams per milliliter and entering the determined volume as a weight in grams.
16. Press “Accept.”
    a. The unit displays the Enter Transfer Volume screen in the Set Up tab
17. Continue with transfer as described in the Manual.