Diana™ Compounding Workflow System

User Manual

DS2900

For use with Release V3.0

IFU0000481 (01, 2022-10)

icumedical
human connections

Diana™

Compounding Workflow System

Contents

Change History

Part Number	Description of Change
IFU0000481 (01,2022-10)	Initial Release

1. Introduction

1.1 Intended Use

The Diana™ Compounding Workflow System is a modular system which includes the Diana™ Syringe Pump (SPM). The SPM is intended to be used in a healthcare facility or approved 503B outsourcing facility. Use is to be supervised by a pharmacist and performed by pharmacy technicians trained in sterile compounding and the use of the system to dispense a specified quantity of hazardous and non-hazardous drugs from a set of source containers into a destination container or containers.

The SPM device is supplied in a calibrated condition. Servicing must only be performed by ICU Medical or its authorized agents.

Note: The system is NOT intended to screen, monitor, treat, diagnose, or prevent any specific condition or disease

Note: The system has no patient contact.

1.2 General Guidelines

Intended users/operators of the system are pharmacists and pharmacy technicians. The user 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 an as-needed basis. Users should have the ability to read and understand English, and should have reading vision of 20/32 or better

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 at all times.

1.3 Important Safety Precautions

- Read this User Manual carefully before using the Diana Syringe Pump System.
- DO NOT connect the unit directly to humans or animals.
- The Diana Syringe Pump System is designed for use in laminar airflow boxes, biological safety cabinets, gloveboxes, laminar airflow hoods and/or safety work benches in clean rooms.

Hazardous drug preparation should only be performed in containment primary engineering controls such as biological safety cabinets.

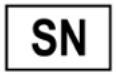
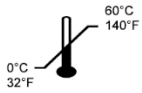
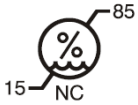
- The Diana Syringe Pump System should be installed in HIPAA compliant facilities.
- No modifications to the Diana Syringe Pump System are allowed. Do not modify in any way, otherwise there is a possibility of operator injury, impairment or damage to the unit.
- The Diana Syringe Pump System does not 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 the unit is damaged during operation, switch off immediately and disconnect from the power supply.
- If the Diana Syringe Pump System has observable sharp edges, contact an ICU Medical representative immediately.
- Do not place the Diana Syringe Pump on an unstable surface.
- Place the system components (including the syringe pump, tablets, printer, and scanner) on a level, clean, dry surface. Ensure space between components to allow appropriate air flow.
- The Bag Tray Assembly is designed to hold only one output container at a time.
- Do not use the Compounding System if enclosure is cracked or otherwise compromised.
- To avoid the potential for cross contamination between drugs, replace the Diana Cassette when a new medication is to be compounded. Also replace the Diana Cassette if the same Cassette has been installed on the machine for 24 hours.
- When using the Diana Syringe Pump System for reconstituting vials, care should be taken to ensure the vials remain upright at all times and ensure vials are not over-pressurized prior to connecting to the Syringe Pump.
- The Diana system does not measure the total volume of the output container , therefore the user is responsible to ensure that final volume of fluid in the output container after transfer will be within the volume range deemed acceptable by the output container manufacturer.
- If using a length of tubing between the outlet of the Diana Cassette outlet and the output container, the tubing must be primed prior to connection to the Diana Cassette on the Syringe Pump
- The Diana system only requires the user to input year and month of the drug expiration. DO NOT rely on the Diana system to warn users about drugs that expire prior to the end of the expiration month (example: July 2022 = July 31, 2022).
- The System should only be used with the manufacture-provided power cord (ICU Kit Number DS1902 , ICU Part Number: 826-11518-403).
- If power cord is damaged, stop using the system and unplug the cord from the power source.
- The Diana Syringe Pump System should only be connected to a properly grounded electrical supply outlet.

- Avoid routing the power cord across the floor where it can create a tripping hazard.
- Position the Diana Syringe Pump to provide easy access to its power plug (so that it can be disconnected from electrical supply in the event of an emergency).
- DO NOT use the Diana Cassette set if the sterile packaging has signs of damage. If the Diana Cassette's sterile packaging is damaged, replace it with a new one and discard the damaged one.
- Replace Diana Cassette after 10 preparations.
- Note: Follow the Diana Cassette labeling instructions.
- The maximum weight allowed on the bag tray or IV rod is 1.0kg (2.2lb).
- When the Diana Syringe Pump System is installed below a vertical flow HEPA filter, the area below the adjustable tray does not receive first air. Do not expose critical sites below the tray. Vial stoppers and needle ports exposed below the tray should be disinfected before accessing.
- Transport the Diana Syringe Pump only by use of its handles.
- At the end of service life, dispose of the syringe pump, accessories, and consumables by contacting ICU Medical for further information.
- During storage and use, avoid impacts and vibrations which could result in a malfunction of the Diana Syringe Pump System.
- Do not insert any body parts or foreign objects into the Diana Syringe Pump ports or openings.
- The System is not suitable for use in mobile equipment such as an ambulance.
- Avoid direct contact with liquids. If a spill occurs, quickly remove spilled liquids in accordance with the facility protocol.
- Follow facility procedures for the disposal of batteries, electronic components, Diana Cassettes, tubing, and container bags.
- Never immerse in liquids for cleaning purposes. Do not attempt to sterilize using mechanical or steam sterilization equipment.
- All cleaning of the Diana Syringe Pump System should be performed according to the detailed instructions in this manual.
- 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.
- This Compounding System may not be resold or exported without the manufacturer's written permission.
- Do not operate Compounding System in the presence of flammable substances, including anesthetics.
- Save the original Diana Syringe Pump System box and packaging. In the event that it needs to be sent in for servicing, return the Diana Syringe 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.

- Connection of the Diana Compounding Workflow System to the organization's computer IT-Network could result in previously unidentified risks to patients, operators, or third parties, and the organization making those connections must identify and control those risks.
- Portable and mobile RF communications equipment, such as cellular telephones, 2-way radios, Bluetooth™ devices, microwave ovens, in close proximity to the Diana Compounding Workflow System may affect wireless and wired communications and/or the operation of the system.
- External Radio Frequency Interference (RFI) or electromagnetic radiation may affect the safe operation of the Diana Compounding Workflow System. Ensure it is not being affected by electromagnetic interference from other devices being used in the vicinity of the Diana Compounding Workflow System.
- If hardware is not supplied by ICU Medical, we strongly recommend the use of virus checking software on the web server hardware that will be designated to host the Diana Web Server software and databases. However, we suggest you consider ignoring scanning directories where the datafiles reside or to ignore MDF and LDF type files. Updates or changes to the antivirus software after installation could affect the Diana Web Server application's performance. Please contact the ICU Medical Technical Support Center for information or assistance.

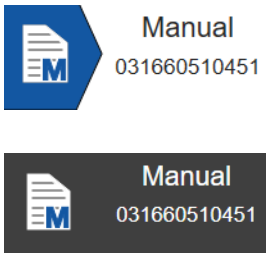
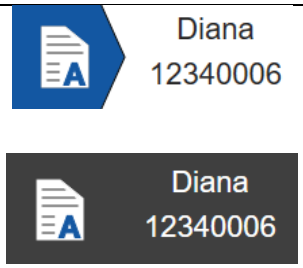
1.4 Glossary of Symbols

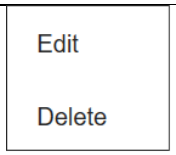
Symbol	Reference	Description
	ISO 7010 M002	Follow Instructions For Use
	IEC 60417-5032	Alternating Current
	ISO 7010 W001	Generic Safety Warning
	ISO 7010 W012	High Voltage Warning
	ISO 7010 W024	Fingers and other body parts do not come into contact with moving parts
	ISO 3864-2 Warning (Triangle)	Fingers and other body parts do not come into contact with moving parts
	15223-1 Fourth edition 2021-07 Ref # 5.1.1	Manufacturer

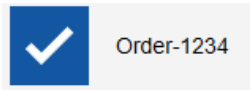
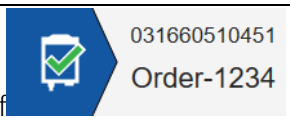
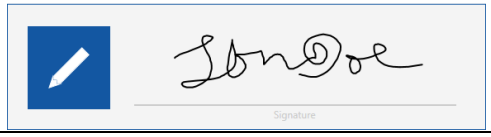
Symbol	Reference	Description
	ISO 15223-1: 2016 Ref # 5.1.7	Serial Number
	IEC 60417-5019	Connect an earth terminal to the ground
	IEC 60417 - 5534	Power plug
	47CFR, FCC Part 15 Subpart B, Class B	Compliant with FCC Class B limits
	IEEE 802.11ac-2013	Device Contains an RF Transmitter
	CSA 60601.1 IEC 60601-1 3rd Edition	Compliance, Safety, Accountability
	15223-1 Fourth edition 2021-07 Ref # 5.1.2	Authorized European Representative
	EN 60529: 2018	Protected from limited dust ingress & Protected from water spray less than 60 degrees from vertical.
	Directive 2012 / 19 / EU	Waste Electrical and Electronic Equipment Directive
	ISO 15223-1: 2016 Ref # 5.3.7	Temperature limitation
	ISO 15223-1: 2016 Ref # 5.3.8	Humidity limitation
	UN3481	Packaging Label for Lithium Battery

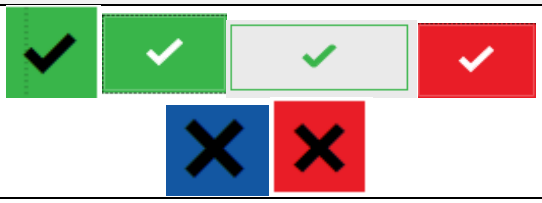
Symbol	Reference	Description
	ISO 15223-1: 2016 Ref # 5.4.2	Single use item marked

1.5 List of Symbols Used on the Operator and/or Pharmacist User Interface

Symbol	Description
	ICU Medical Logo. The user can tap the logo to access closing the application.
	Manual Tab when the tab is selected and is not selected.
	Automated Tab when the tab is selected and is not selected.
	Syringe Cassette is not connected to the Syringe Pump. Blinking icon means connect the Syringe Cassette to the Syringe Pump when the order is ready for processing.
	Input Vial is not connected to the Syringe Pump. Blinking icon means connect the Input Vial to the Syringe Pump when the order is ready for processing.
	Output Container is not connected to the Syringe Pump. Blinking icon means connect

Symbol	Description
	the Output Container to the Syringe Pump when the order is ready for processing.
	Barcode Scanner is not connected.
	Label Printer is not connected.
	Operator lost communication to the Web Server.
	SPM camera is not working.
	Logged In User. The user may press this icon to logout from the UI.
	Setting Icon. User may press this icon to access the configured settings of the application.
	User may press this photo button to take a picture using the tablet camera or connected barcode scanner.
	The user may press this icon to delete the captured picture.
	Pop-up for the user to edit or delete the information.
	Automated tab when the Syringe Pump is performing the delivery. (“12340006” represents the Syringe Pump Serial Number)
	Automated tab when the Syringe Pump is stopped during the delivery.
	Automated tab when the Syringe Pump has encountered an unrecoverable error.

Symbol	Description
	Automated tab when the Syringe Pump is not connected to the system.
	Automated tab when the Syringe Pump is rebooted.
	Order is waiting on the Operator application for the Pharmacist to validate the completed preparation.
 	Displaying amount of liquid Delivered and Specified for the order on the Verification/Validation screen.
	Displaying the Order on the Pharmacist Tablet for validation.
 	Signature screens for the pharmacist when accepting the preparation.
	Navigate Ascending/Descending lists up and down.
	Navigate Ascending/Descending lists up and down.
	Action icon to access the setting in the setting screen.
	Down arrow to select an option/value from the list.

Symbol	Description
	Select or Deselect an option.
	User may press this button to add/show the reconstitution protocol information on the Drug screen.

1.6 Replaceable Parts

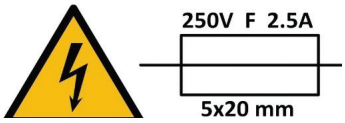
Part Name	ICU Part Number
Diana Compounding Workflow System	DS2900
Diana Syringe Pump	DS2000
Diana Workflow Management System	DS2100
Diana Workflow Management Software	DS2110
Diana Operator Tablet	DS2120
Diana Pharmacist Tablet	DS2130
Diana Tablet Stand Kit	DS2140
Diana Tablet Case	DS2141
Diana Tablet Stand	DS2142
Diana USB Bar Code Scanner Kit	DS2150
Diana USB Bar Code Scanner	**DS2151**
Diana USB C to USB A Adapter	**DS2152**
Diana USB Bar Code Scanner Cable	**DS2153**
Diana Wi-Fi Printer Kit	**DS2160**
Label Printer Paper Roll (Case)	**DS2161**
Diana Webserver	**DS2810**
Diana Router	**DS2820**
Diana Power Cord	**DS2010**

2. General Operation Information

2.1. Implementation and Maintenance

NOTE: All software and hardware iImplementation should be performed by an authorized ICU Medical representative or authorized agent. All maintenance work shall be completed by the manufacturer with the exception of routine cleaning (See Appendix A for details).

2.2. Environmental Specifications

Operating Temperature	+10°C to +40°C (50°F to 104°F)
Operating Humidity	0% to 60% (Non-condensing)
Operating Altitude	0 to 2000 meters (6562 feet) above sea level
Operating Light	30 to 1600 Lux
Storage Temperature	0°C to +60°C (32°F to 140°F)
Storage Humidity	0% to 90% (Non-condensing)
Storage Altitude	0 to 2000 meters (6562 feet) above sea level
Transportation Temperature	0°C to +60°C (32°F to 140°F)
Transportation Altitude	0 to 5000 meters (16405 feet) above sea level
Transportation Humidity	0% to 60% (Non-condensing)
Dimensions	21 x 34 x 25 (cm) 8.27 x 13.38 x 9.84 (inch)
Weight	5.6 kg (12.3 lbs)
Electrical Operating Power Range	100 – 240 V~ 0.8 – 0.4 A 50 – 60 Hz
Electrical Fuse	

Note: Operate the unit within the environmental specifications listed in the above table to ensure proper operation.

2.3. Performance Specifications

Minimum Fluid Delivery Volume	1 mL
Maximum Fluid Delivery Volume	1000 mL
Delivered Volume Accuracy of water from 5ml to 1000ml	+- 5%

Note: Fluid viscosity can affect system accuracy, see section 5.10 for details on making system adjustments to account for fluid viscosity

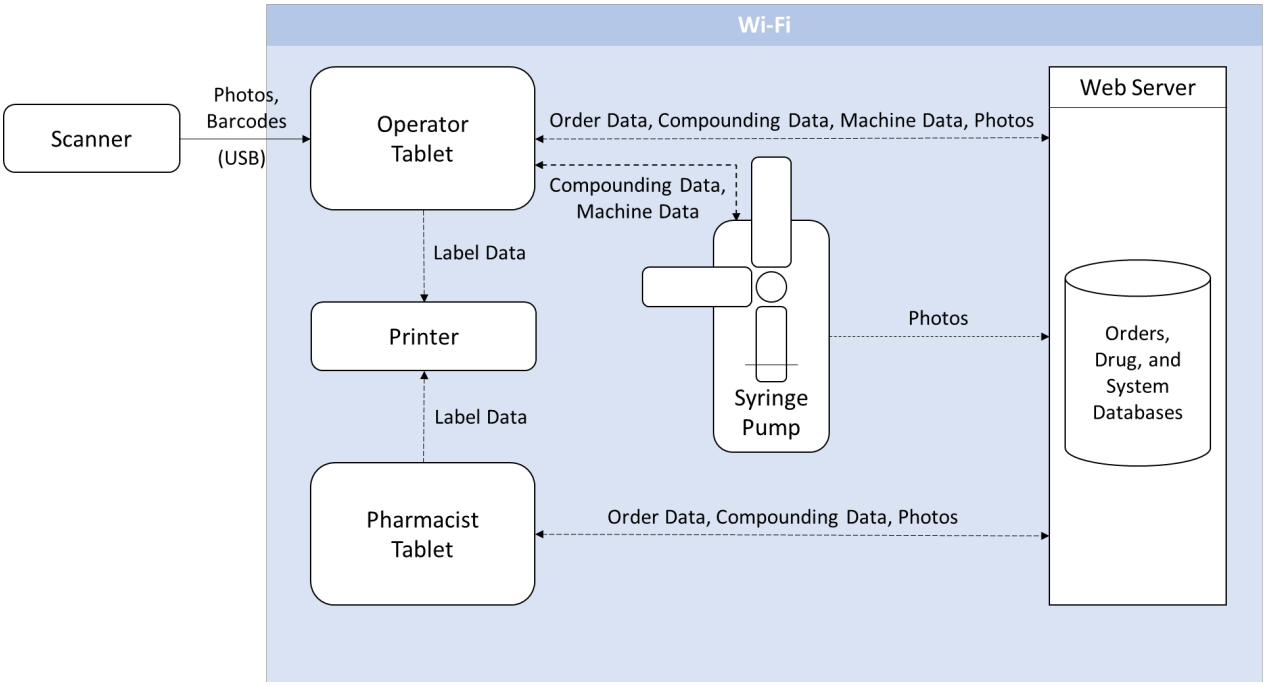
3. Diana Compounding Workflow System Overview

3.1. Components of the Diana Compounding Workflow System

The Diana Compounding Workflow System consists of multiple components that can communicate over a Wi-Fi network. The components are:

- Syringe Pump
- Operator Tablet
- Pharmacist Tablet
- Web Server
- Bar Code Scanner
- Printer

Additional Operator Tablets and Syringe Pumps can be added to the system to ensure that each facility has the right mix of hardware to fit their needs. Up to three Syringe Pumps can be configured to the same Operator Tablet. One Pharmacist Tablet can be associated with up to three Operator Tablets. Shown below is a system diagram of the Diana Compounding Workflow System.

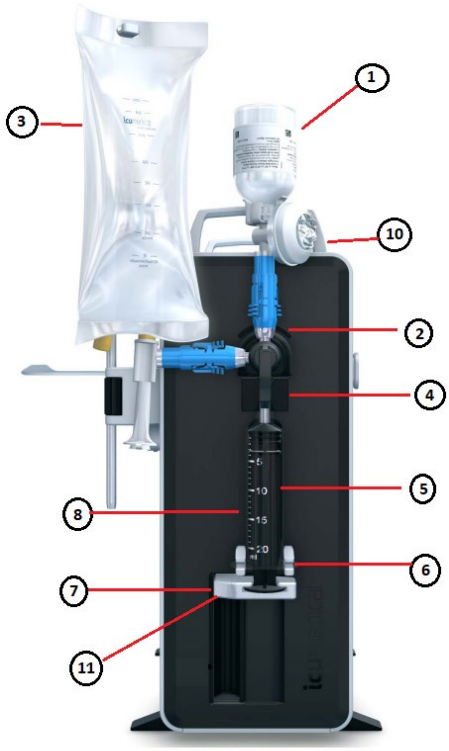


Term	Definition
Order Data	Data that describe the preparation to be compounded; e.g., order number, drug id, drug volume, etc.
Compounding Data	Data that describe the status and record of the compounding process; e.g., NDC, timestamps, approvals, etc.

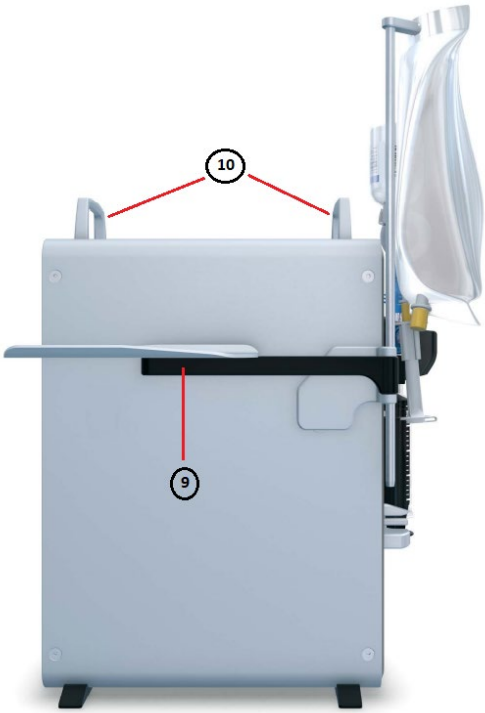
Term	Definition
Machine Data	Specific commands and parameters the Syringe Pump uses; e.g., carriage pushing and pulling speeds, transfer volumes, start and stop commands, sensor status, etc.
Photos	Photographs. Images captured by the Scanner, Operator Tablet, and/or Syringe Pump.

Component	Description
Syringe Pump	The component of the system that accepts commands that transfer fluid from the input container to the output container.
Operator Tablet	A tablet that has a software user interface running on Windows 10 OS, which provides the primary mechanism to the user (typically a pharmacy technician) to control the Diana Syringe Pump. A user can input order and drug information; initiate and verify a transfer; and print a label.
Pharmacist Tablet	A tablet that has a software user interface running on Windows 10 OS, which provides the user (typically a pharmacist) a way to validate the transferred order preparation. A user can review order, drug, and preparation information, and print a verification label.
Web Server	An essential component in the Diana ecosystem. It serves as the mediator between the remote SQL Server databases and the other components that require access to data, i.e. the Diana Syringe Pump, Operator, and Pharmacist software.
Bar Code Scanner	The scanner is tethered to the Operator Tablet to scan bar codes on input drug vials and take pictures, which increases the efficiency and accuracy of data being entered into the Diana System.
Printer	A component that is connected through wireless communication to the system that prints a label with information of the preparation that has been performed, which can be placed on the output container. When the preparation has been verified on the Pharmacist Software, an updated label with verification information will then be printed on the label to be placed on the output container. Note: Due to size limitations of the printed labels, labels printed for preparations that use 14 or more unique vials in a single preparation may have missing information on the label. Printed label information is for reference only.

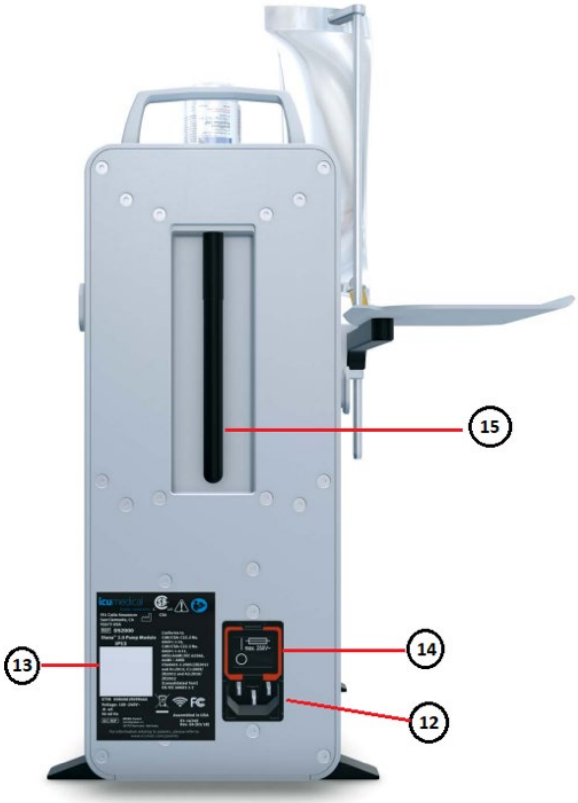
3.2. Views of the Diana Syringe Pump



Front of the Syring Pump Module



Left side of the Syringe Pump Module



Back of the Syringe Pump Module

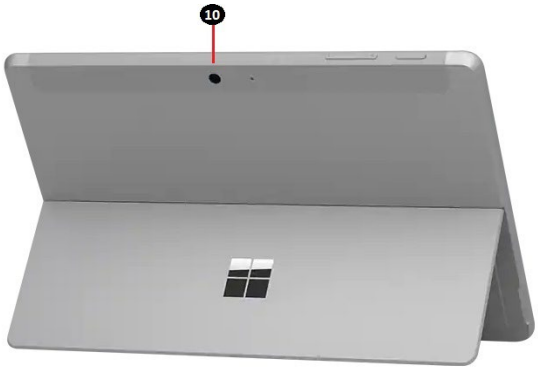
Right Side of the Syringe Pump Module

Item #	Component	Definition/Explanation
1.	Input Container	Typically a drug vial or IV bag. The input container is a fluid source with a compatible ICU Medical connector which can be attached to the Diana Cassette prior to a transfer.
2.	LED Status Lights	LED indicator lights (green and blue).
	GREEN	The Diana Syringe Pump is on and is currently selected by the Operator Software user interface.
	BLUE	The Diana Syringe Pump is powered on and is not selected by the Operator Software user interface
3.	Output Container	Typically an IV bag, CADD Cassette, empty sterile container, or vials. The output container is a receptacle with a compatible ICU Medical connector, which can be attached to the Diana Cassette prior to a transfer.
4.	Fluid Detection Sensor	Detects the presence of air or fluid in the fluid path of the Diana Cassette.
5.	Camera Window	A clear window that provides a transparent barrier for the Diana Camera to have a clear view of the Diana Cassette.
6.	Syringe Driver Pins	Used to hold the Diana Cassette in place during a transfer.
7.	Syringe Driver	A movable holder that is calibrated to the Diana Cassette. Upon initiation of a transfer, the driver moves the syringe plunger back to the location that correlates to the volume of fluid in the syringe. For transfers over the maximum volume of the syringe barrel, the Syringe Driver will cycle through multiple transfers until the desired volume is reached.
8.	Diana Cassette	Diana Cassette.
9.	Bag Holder	A tray on which the output container rests before, during, and after a transfer. The holder must be attached to the left cleat (as shown in the

		pictures above, Item 16). The tray has three positions available depending on the output container/adapter combination and operator preference. The Bag Holder can be used either with a Pin or IV Rod configuration. In the case of the IV Rod use, it can be adjusted up or down according to the IV bag size used.
10.	Handle	Handles used to lift and move the Diana Syringe Pump.
11.	Syringe Carriage	The main connection point of the Diana Cassette to the Diana Syringe Pump. It is vital to ensure the Diana Cassette is properly seated in the syringe carriage.
12.	Power Plug	Used to connect the Diana Syringe Pump using the provided power cord.
13.	Back Panel Label	Provides an indication of regulatory compliance. Provides details like manufacturer address, model number, IP53 rating, voltage rating, and serial number.
14.	Power Switch	Used to turn the Diana Syringe Pump On or Off.
15.	Wireless Antenna	Used to enhance the communication of the Diana Syringe Pump to the other components of the system.
16.	Cleat	Used to connect the bag holder to the Diana Syringe Pump.

3.3. Operator and Pharmacy Tablet

Tablet Front View



Tablet Rear View

USB Adapter

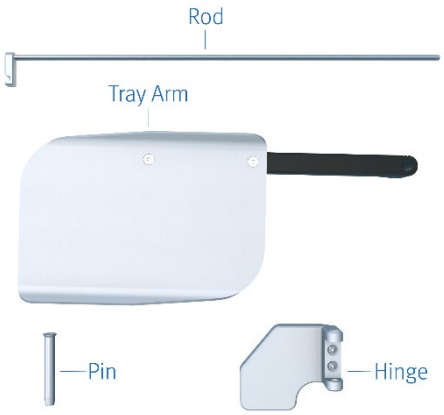
Item #	Component	Definition/Explanation
1.	Power Button	Used to turn the Operator/Pharmacist Tablets on and off.

2.	**Volume Buttons**	Used to increase/decrease the tablet volume sound.
3.	**Front Camera**	Used to take additional pictures of labels, input containers, patient orders, or other aspects of the transfer that can be photographed.
4.	**Studio Mics**	Microphone to capture the sound.
5.	**Headphone Jack**	Input for the headsets, earphones or headphones.
6.	**USB-C Port**	Industry-standard connector for connecting USB Cables.
7.	**Kickstand**	Tablet Stand.
8.	**Power Port**	Used to connect the Tablet to a power cord.
9.	**microSD Card Reader**	microSD card reader for transferring data.
10.	**Back Camera**	Used to take additional pictures of labels, input containers, patient orders, or other aspects of the transfer that can be photographed.

3.4. Bag Tray Assembly Instructions

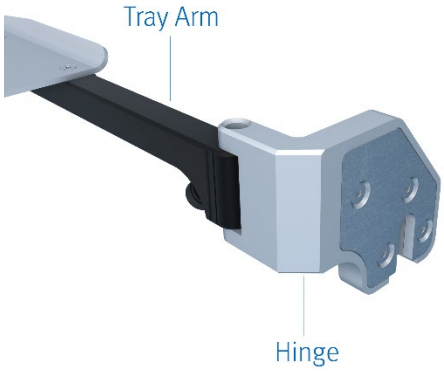
The Diana Syringe Pump comes with a Bag Tray Assembly consisting of a bag tray that can be assembled using either the provided Pin or Rod. The Rod may be used for holding the output containers during the transfer process. The Bag Tray Assembly instructions are below.

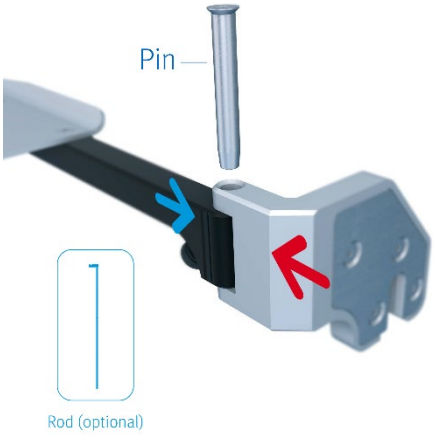
1. Remove the bag tray items from the box.

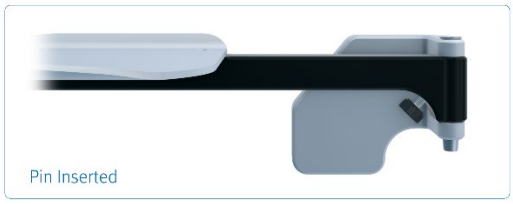


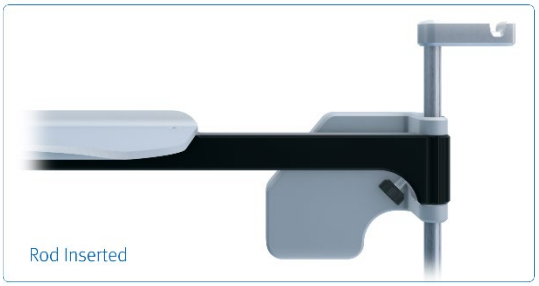
2. Insert the Screw in the Tray Arm, do not tighten.

3. Place the Tray Arm into the Hinge and insert either the Pin or the Rod in the hole. Note the orientation of the components. Light pressure on the Tray Arm, applied towards the Hinge, may be required to assist the insertion. If using the Rod, the Screw may be tightened to help support containers weighing more than 250 grams.

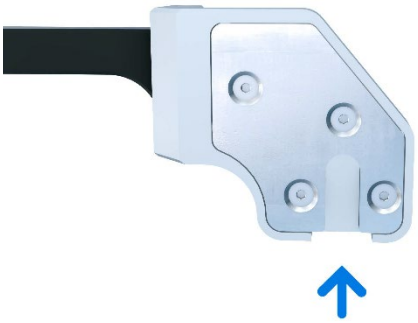








4. Connect the Bag Tray to the Syringe Pump, by attaching the bag tray Hinge to the left front cleat (see BLUE arrow below) by sliding the slot (see BLUE arrow below) in the Hinge over the cleat.



5. Push down on the Hinge until the cleat is no longer visible, this will seat the Hinge firmly on the cleat. To remove the hinge, tap from below and lift up.

6. The Tray Arm can be swiveled in 3 positions.

7. To change the Pin with the Rod or vice versa, the Tray Arm has to be placed in a perpendicular position and the screw loosened. Then the Pin must be pushed from below (blue arrow) and push on the Tray Arm in the direction shown below (red arrow) to release the spring pressure from internal retaining pins while pulling the Pin or the Rod out. While pushing on the Tray Arm towards the Hinge (red arrow), pull the Pin or Rod up and out. For a better grip on the top of the Pin, fist push the Pin up from below (blue arrow). Follow steps mentioned earlier to insert the desired component.

3.5. Tablet Stand Kit Assembly Instructions

Tablets have an optional Tablet Stand Kit. The Tablet Stand Kit assembly instructions are below.

1. The Tablet Stand Kit has these 3 components.

2. Install the Case onto the tablet. See business.otterproducts.com/pro-pack for guidance, your case is a Defender Series case.

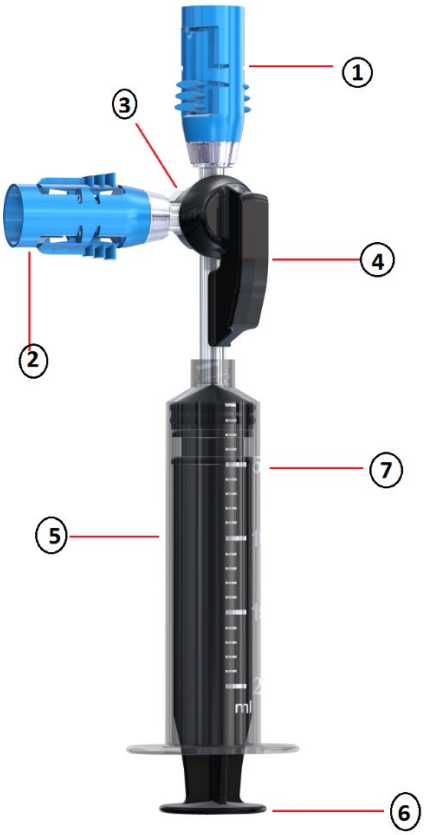
3. Attach the Gooseneck to the Suction Cup Base by screwing it into the cup's nut. Make it finger tight by hand only.

4. Bend the Gooseneck so the square points toward the user and the arrows on the square are pointing up.

5. On the back of the tablet case, there is a square frame that needs to be hooked on the top of the base square. Push the tablet down to lock (click) in place. The tablet can be rotated and attached on any side.

6. To attach the Suction cup to a surface, the orange plunger (See image in “1.” above) needs to be pushed a few times until the suction cup adheres to it. To remove – pull one of the rubber tabs on the lip of the suction cup.

3.6. Diana Cassette



Chemolock Cassette

Item #	Component	Definition/Explanation
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 fluid 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 fluid transfer.
3.	Cassette Stopcock	The Cassette Stopcock seats in the Syringe Carriage and is activated by the Diana Syringe Pump to transfer fluid.
4.	Cassette Handle	The Cassette Handle allows a user to easily insert the Cassette Stopcock into the Syringe Carriage.
5.	Syringe Barrel	The Syringe Barrel is the cylindrical tube that houses fluid while the syringe is pulling in and expelling fluid.
6.	Syringe Plunger	The Syringe Plunger can be pulled and pushed inside the Syringe Barrel to pull in and expel fluid.

7.	Syringe Graduated Volume Markings	The Syringe Graduated Volume Markings are indications on the Syringe Barrel that indicate to the user the measured volume of fluid held in the syringe barrel.

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

ICU Medical Part Number	Description
CL6000	Diana Cassette with Two Bonded ChemoLock™
CL6000-5	Diana Cassette with Two Bonded ChemoLock™ Adaptors, 5 Units

3.6.1. Cassette Installation

3.6.1.1. Make sure that the Diana Syringe Cassette package is not damaged. DO NOT use the Diana Cassette set if the sterile packaging has signs of damage.

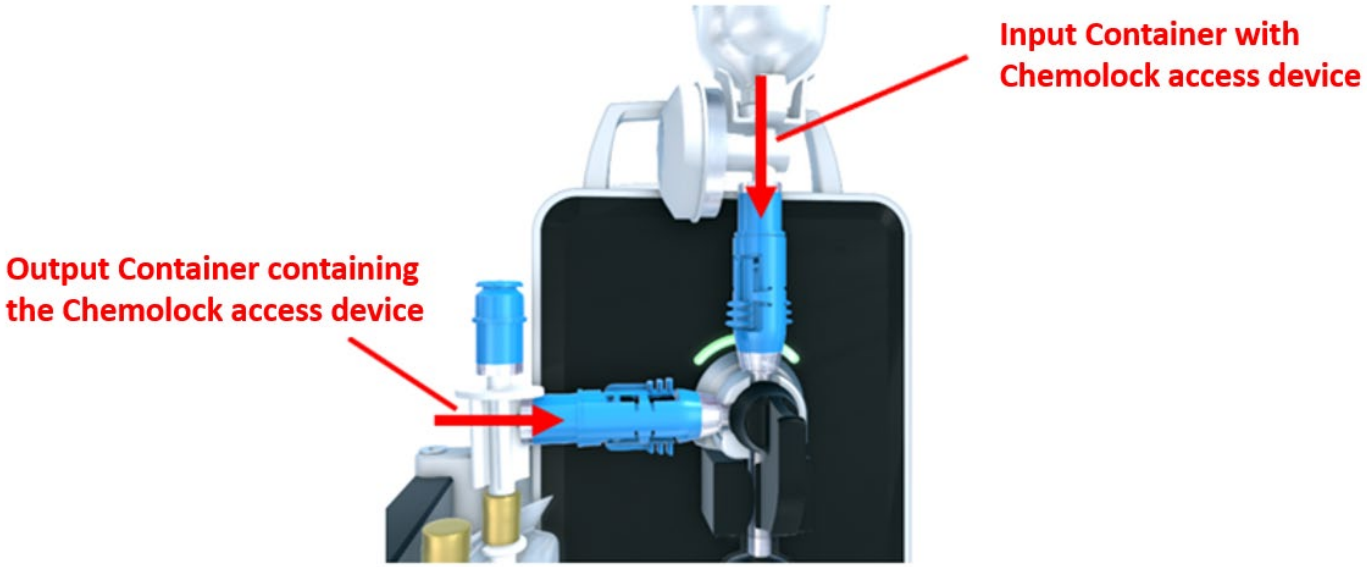
3.6.1.2. Open package and remove Diana Syringe Cassette. Make sure that the stop cock position is angled half way between the two ChemoLock connectors (see image below). If the stop cock is not in the correct position or any other defect or damage is seen on the Diana Syringe Cassette, do not use the cassette and dispose of it.

3.6.1.3. Slide the Syringe Cassette into the Diana Compounder making sure the Syringe Cassette is securely in place. The bottom of the syringe piston should be placed into the bracket at the bottom of the compounder during the installation process.

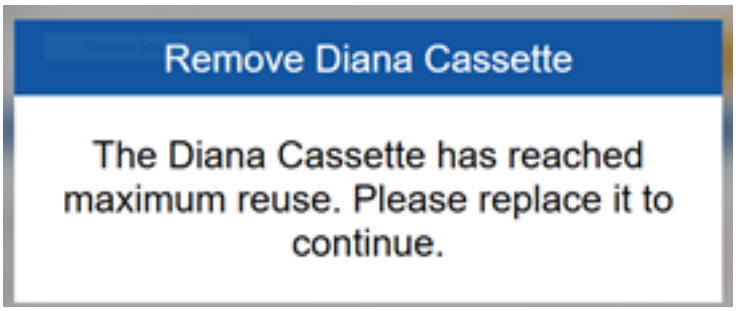
3.6.1.4. To Connect Drug Vial (Input Container) to Syringe Cassette: Invert vial containing the Chemolock vial access device to the vertical Chemolock connector on the Syringe Cassette.

Note: The Diana compounder is designed to detect air bubbles in the fluid being transferred. If air is detected in the fluid, the Diana compounder will prompt the user to use the reprime feature on the device to reprime the cassette. During the reprime workflow, the Diana compounder will automatically reduce the pull speed of the Diana compounder (to reduce the introduction of cavitation in the fluid). Use of input containers or access devices with restrictive flow paths may cause cavitation, thus the user may need to utilize the reprime function the cassette Diana compounder to reduce the operating speed of the device. See section 6.3.4 for more information on reprime.

3.6.1.5. To Connect Output Container to Syringe Cassette: Connect Output Container containing the Chemolock spike to the horizontal Chemolock connector on the Syringe Cassette.



Note: After 10 preparations of the Diana Cassette, the Operator Tablet will display the below warning message that can be cleared by replacing it with a new unused Diana Cassette.



3.7. Compatible Input and Output Connections

The Diana Syringe Cassette has integrated ChemoLock injectors for the input and output connection locations. Only ICU Medical ChemoLock components should be used to attach the input and output containers to the Diana Syringe Cassette.

System users should utilize the appropriate ChemoLock component based on the specifics of the transfer they will be performing.

3.8. SurfaceGo™ Tablets Settings

Refer to Microsoft SurfaceGo user manual for details about adjusting tablet settings

Latest user manual can be found at https://support.microsoft.com

4. Operation

4.1. Powering On the Devices

In order to communicate with all the components of the Diana system, the user must complete these steps in the following order.

Note(s): Make sure the Wi-Fi Router is Powered ON and the Diana Web Service is running on the Host Web Server System prior to turning on the Diana system components.

4.1.1. Powering ON the Diana Syringe Pump

1. Power ON the Diana Syringe Pump using the Power Switch on the back panel.

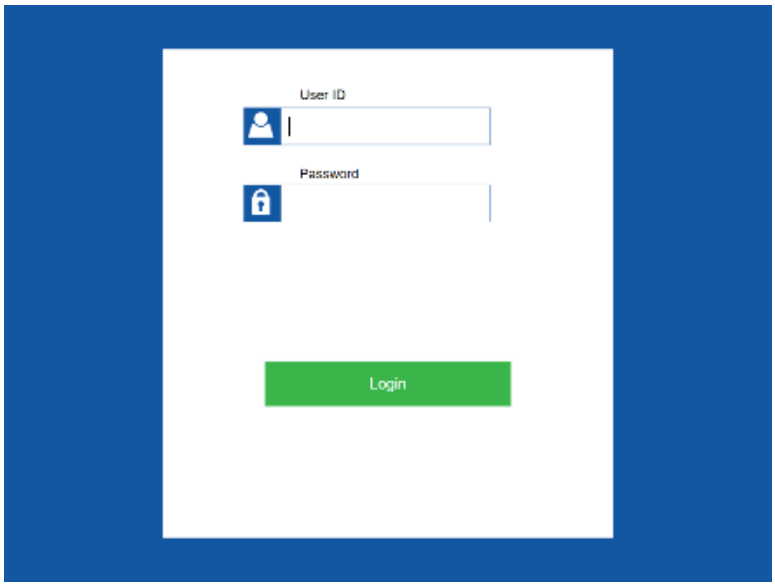
2. During Power ON, Diana Syringe Pump LED indicators flash blue and green continuously for a few seconds and then turn solid blue.

4.1.2. First Time Use of the Operator Tablet

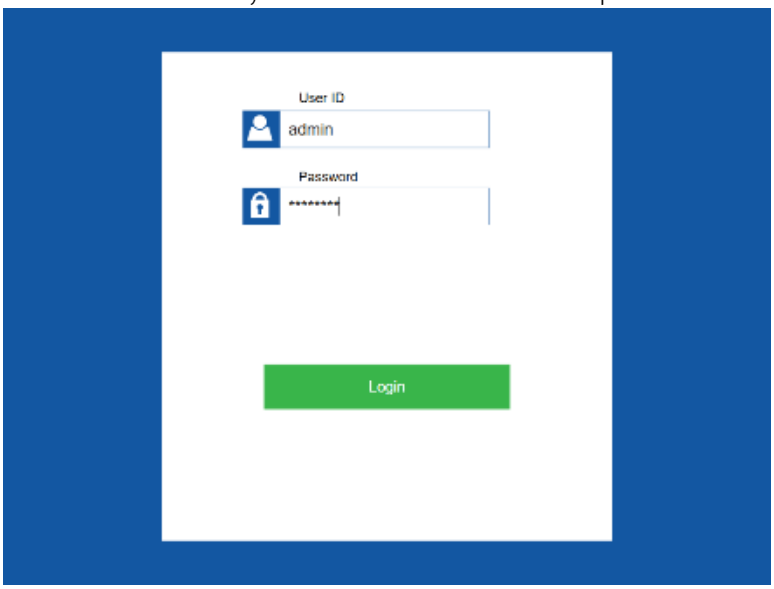
1. Power on the Operator Tablet by pressing the tablet's power button.

2. Operator Tablet automatically logs in to **Diana User** system account and displays the Operator application Login page.

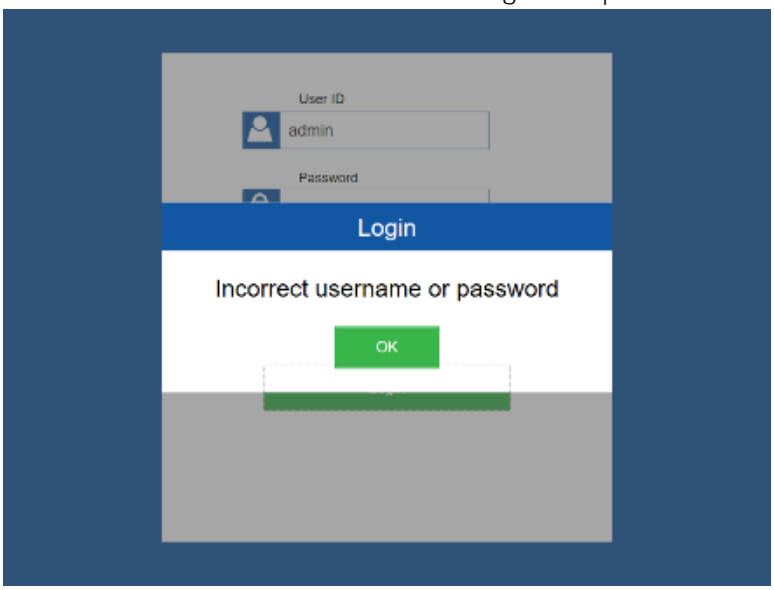
   Note: If the below screen is not displayed, contact ICU Service personnel for assistance.



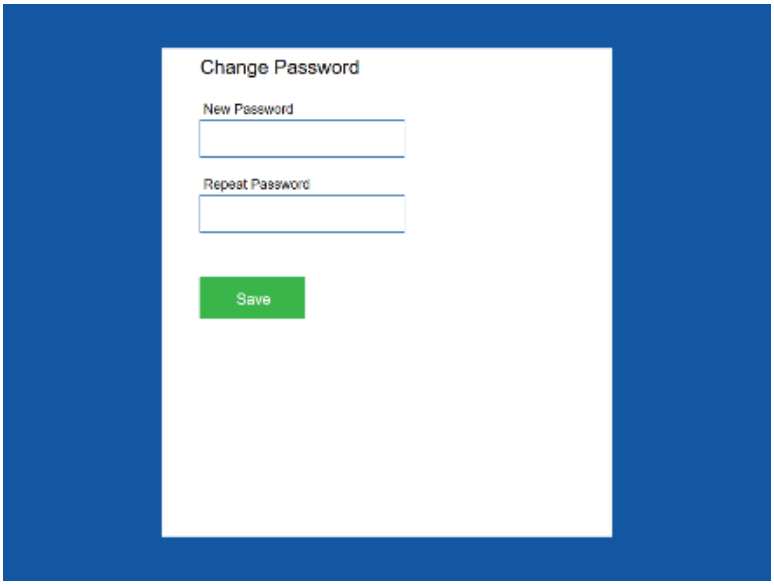
3. Enter the **User ID** and **Password** values.
   Note: Contact system administrator for the User credentials. See section 6.12 “Manage User Settings” for details on how the system administrator can set-up User credentials.

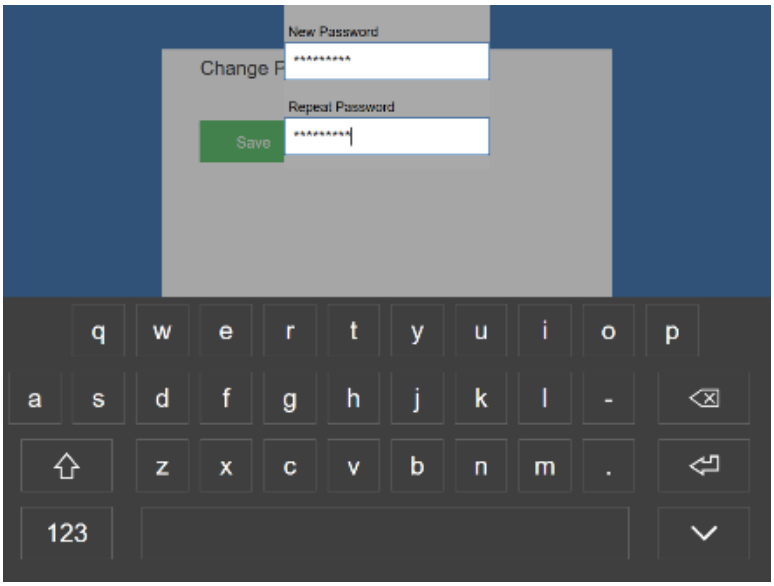


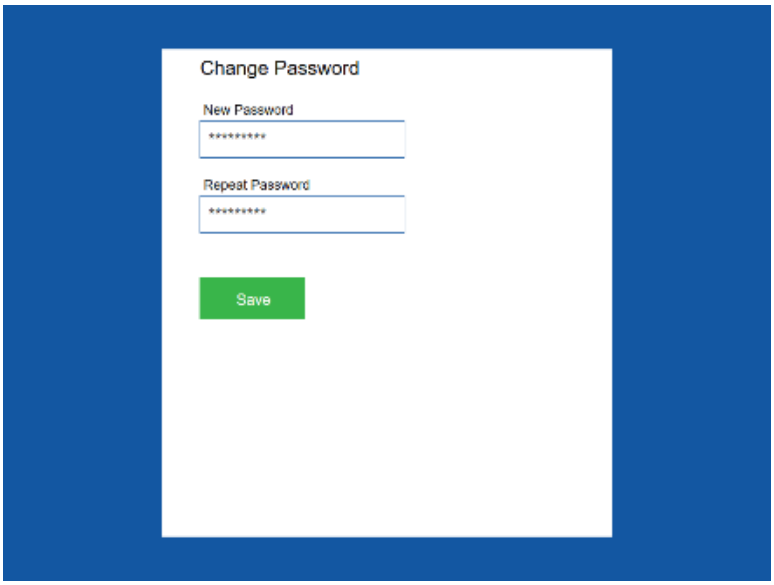
Note: If the entered User ID and Password values are incorrect, the following message displays. Contact system administrator if the user is unable to login with provided username and password.



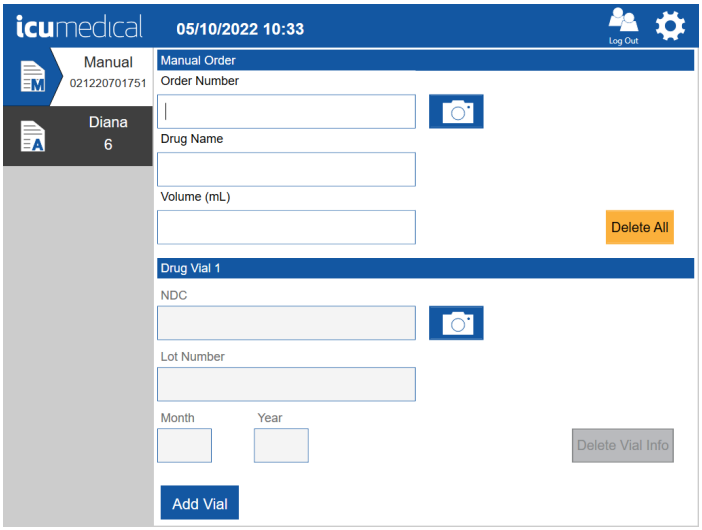
4. If the user is logging on to the system for the first time, the Operator application asks the user to change the default password. Change the default password.
   Note: Password values must consist of printable characters, cannot start or end with a whitespace character, and must contain at least one numeric character, one symbol character, and one upper-case text character. Password length must be between 8 and 21 characters.







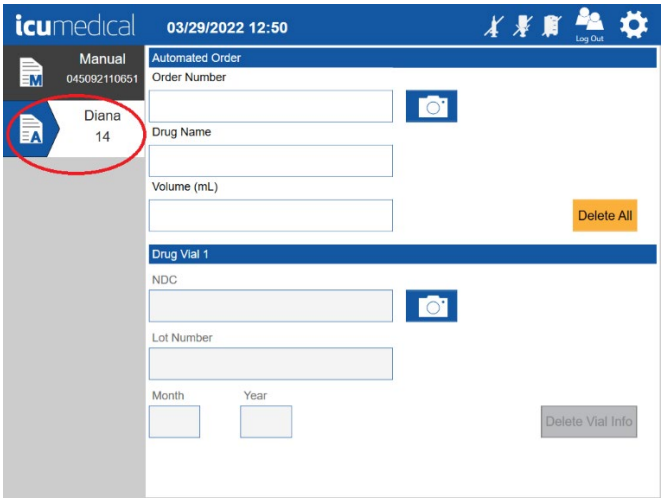
5. After the successful login the Order Entry Page for the Manual Tab of the XX is displayed.



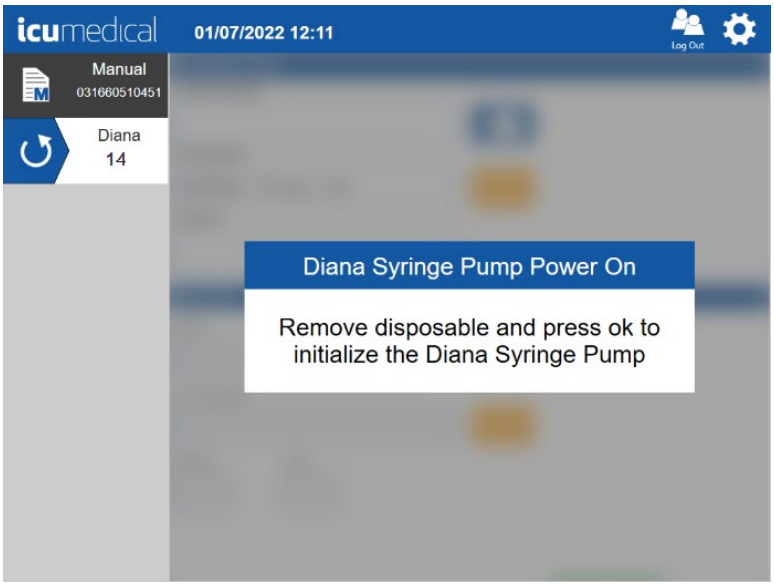
Manual ‹Operator Tablet Serial Number› Tab: The user uses this tab to enter order information to the system and manually transfers the drug from input vial to output container without using the Diana syringe pump. The technician can use the Manual workflow without using the Diana Syringe Pump. The example screen above shows the Manual Operator 021220701751.

Diana ‹Syringe Pump Serial Number› Tab: The user uses this tab to enter order information to the system and uses the Diana Syringe Pump to transfer the drug from input vial to output container. The example screen above shows the Diana 6 (“6” is the serial number for the Diana Syringe Pump).

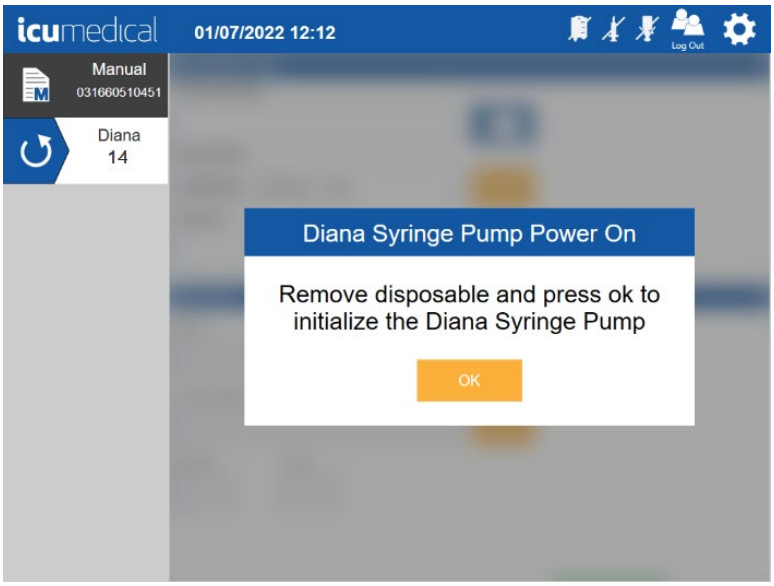
6. To proceed to Syringe Pump Module initialization: Select the connected **Diana ‹Syringe Pump Serial Number›** tab to display the Order Entry Page for the Diana Syringe Pump . The following screen is displayed.



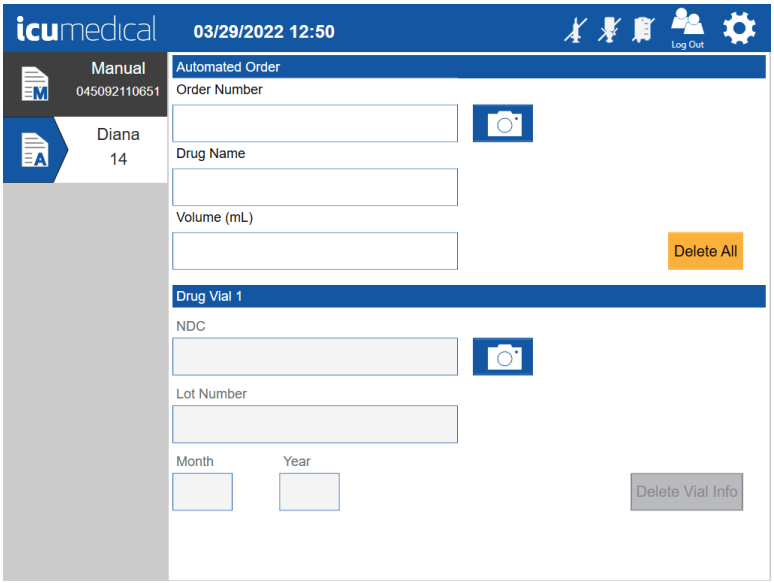
Note: Each time the Diana Syringe Pump is power cycled, if the user selected the Diana Automated tab, the Operator tablet software displays an initialization message. If there are disposables (Diana Cassette, input vial and/or output container) connected to the Diana Syringe Pump, the following screen displays.



If no disposables are connected the following screen displays. Remove the disposables if connected. Press the OK button once all disposables are disconnected.



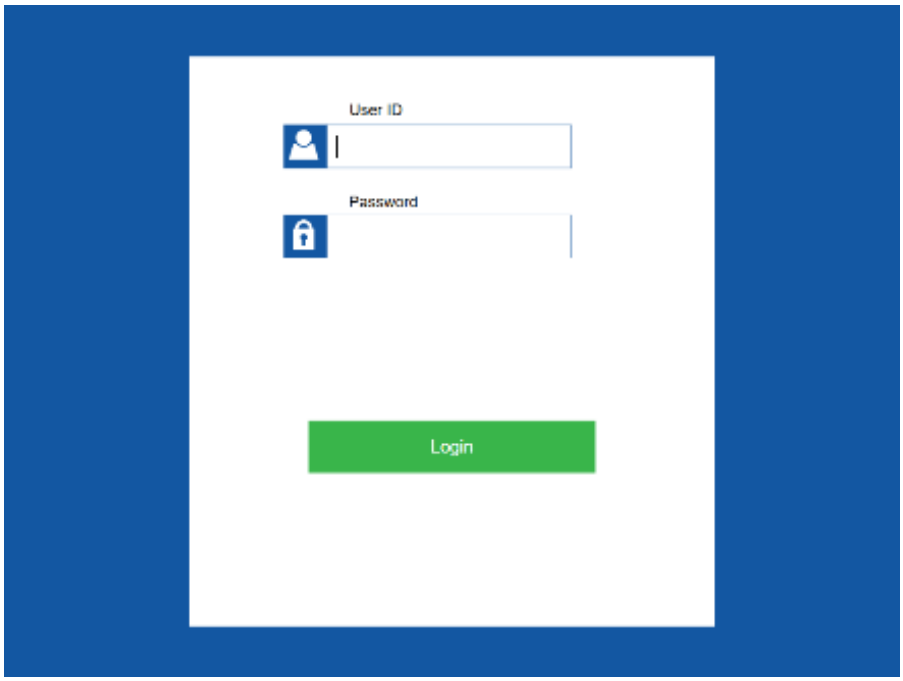
The system then initializes its moving parts to a home position. Once the initialization of the Diana Syringe Pump is done, the Order Details screen will display (see screen below).



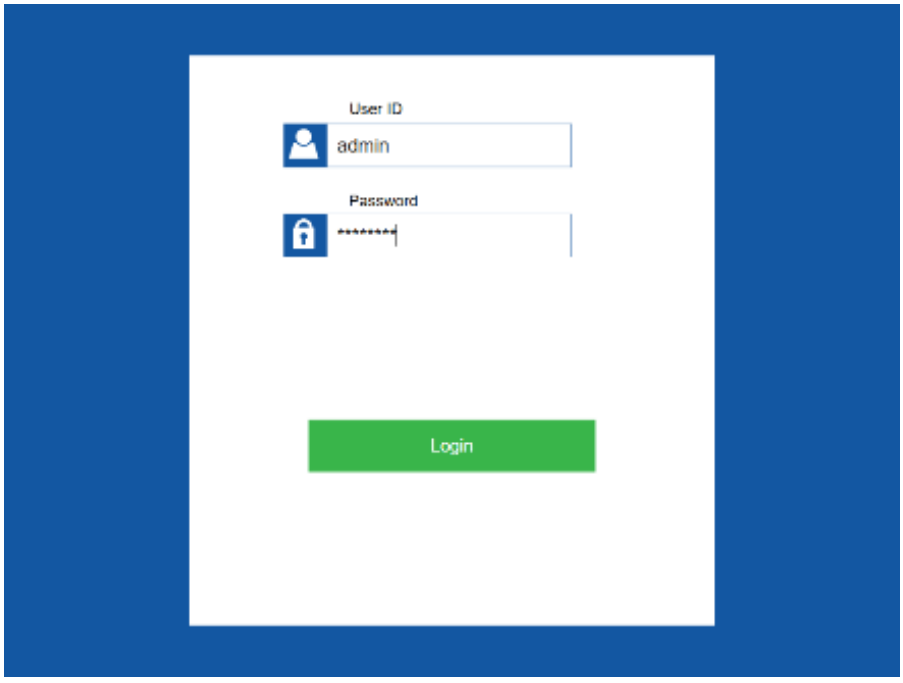
4.1.3. First Time Use of the Pharmacist Tablet

1. Power on the Pharmacist Tablet by pressing the tablet's power button.
2. Pharmacist Tablet automatically login to **Diana User** system account and display the Pharmacist application Login page.

   Note: If the below screen is not displayed, contact ICU Service personnel for assistance.



3. Enter the **User ID** and **Password** values.

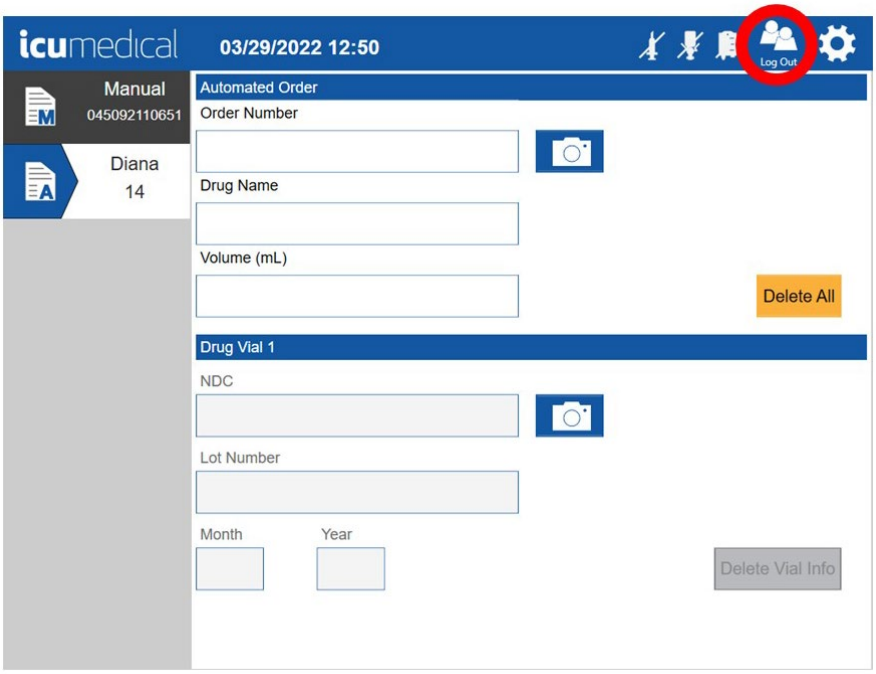


4. Once login successful the Pharmacist application displays the Application Home Screen. (see below).

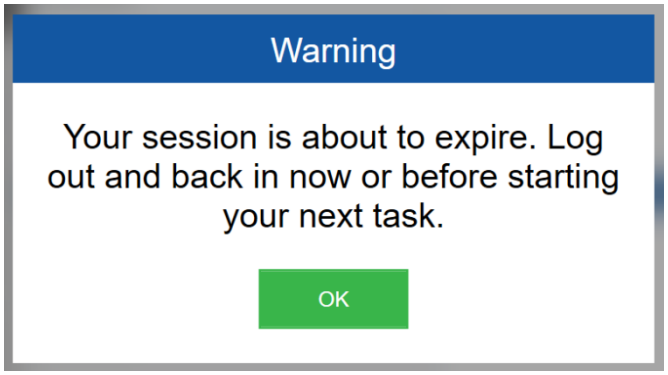
4.1.4 Sessions on Operator and Pharmacist Tablet Applications

By default, the sessions on the Operator and Pharmacist Tablet Application are set to require log out and log back in every 48 hours. The user will automatically be logged out of the Operator and Pharmacist Tablet Applications after 48 hours of use. After logging back into the application, the user can continue using the system.

The user can log out of the Application at any time during use by using the Log Out icon (circled in red below).



The warning message below will be displayed on the Application screen 1-minute before automatic log out. The system will automatically log out the user 1-minute after this message is displayed.

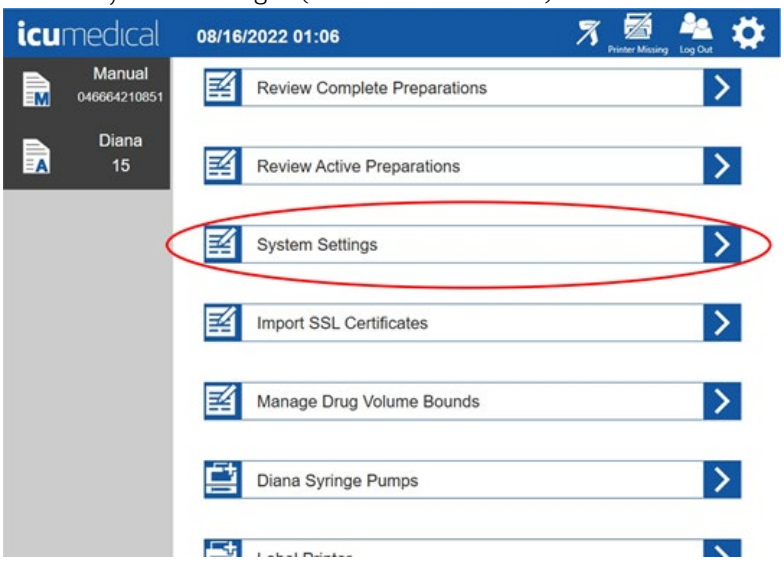


Note: If a preparation is in process when session log out is required, the SPM will pause the preparation. Once the user logs back into the Operator Application, the user can continue the preparation by pressing the Start icon on the Application.

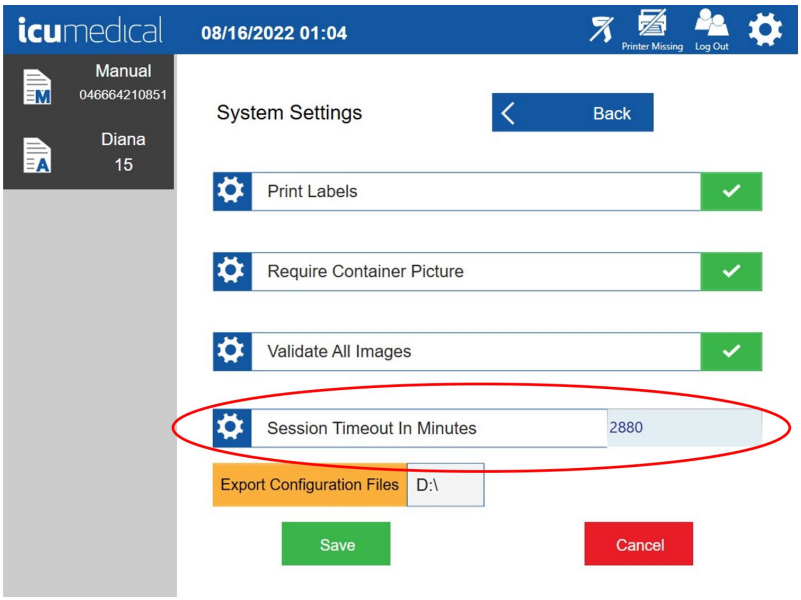
The user can change the session timeout from 10 minutes to 2880 minutes. To change the session timing, follow the steps below.

1. Click the  icon in the upper right-hand corner of the Operator Or Pharmacist Tablet Application. This will open the application settings screen.

2. Select “System Settings” (circled in RED below)

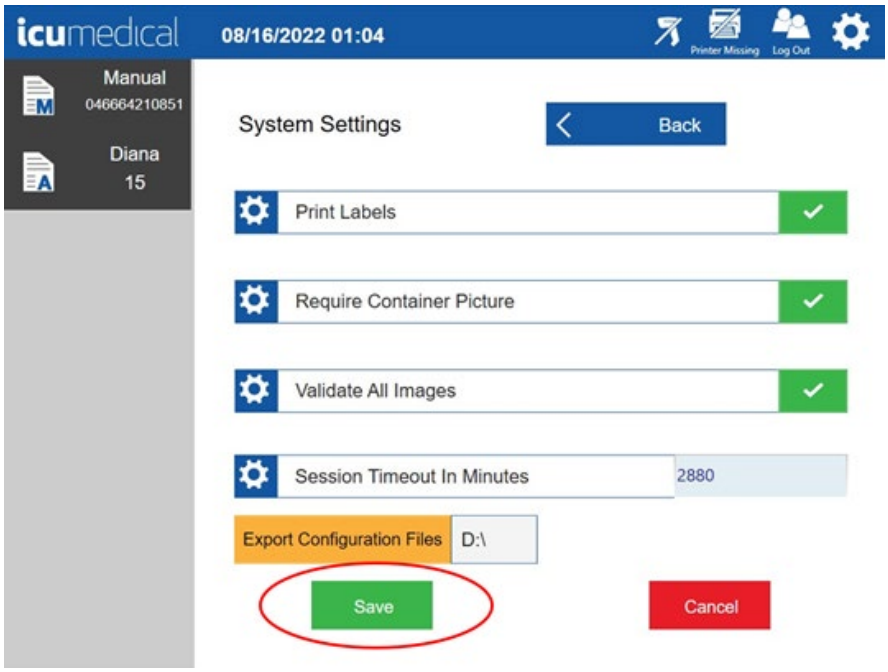


3. Use the touch screen on the tablet to scroll to the bottom of the page (swipe up on the touch screen) to expose the entry box for “Session Timeout in Minutes” (circled in RED below)



4. Update the time to match your desired time. Minimum time 10 minutes, maximum time 2880 minutes.

5. Click the Save icon on the bottom of the tablet screen (circled in RED below)



6. For changes to take effect, please restart the Webserver first. Then close and reopen the Operator and Pharmacist Applications. And lastly, power cycle the Syringe Pump Unit.

4.2. Shutting Down the components of the Diana Compounding Workflow System

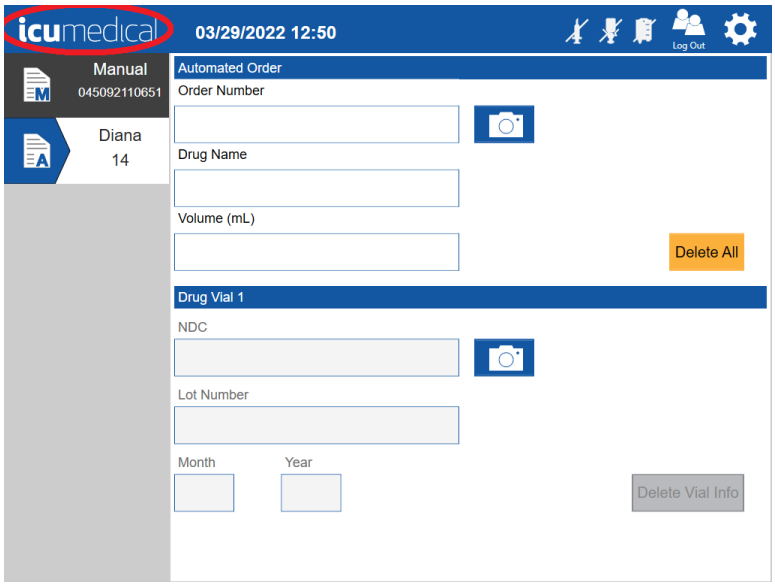
4.2.1. Powering OFF the Diana Syringe Pump

Power OFF the Diana Syringe Pump using the Power Switch on the back panel.

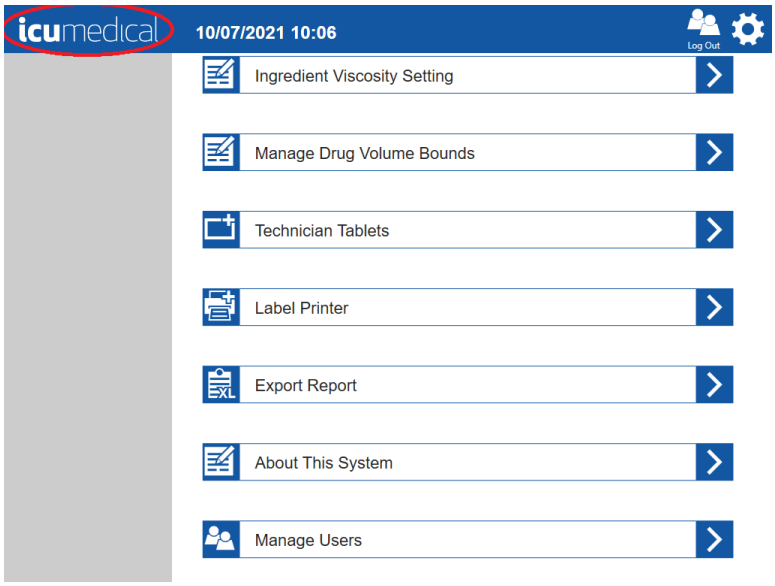
4.2.2. Powering OFF the Tablets

When the Operator or Phamacist application is opened follow the instructions to shutdown the Operator or Phamacist Tablet.

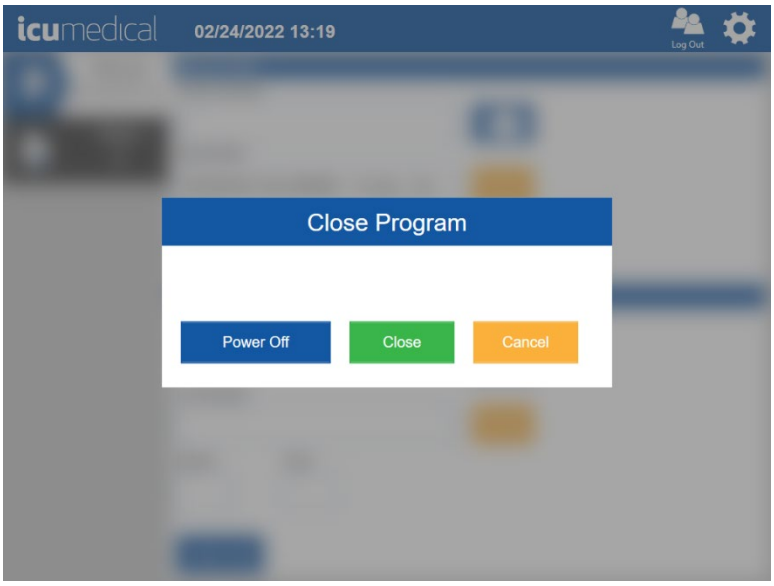
Make sure the user logged into the Operator or Pharmacist application. Tap on the Operator or Pharmacist application icumedical logo (top left corner). Operator or Pharmacist application displays the **Close Program** message to the user.



Operator Application Screen



Pharmacist Application Screen



Tap **Power Off** button to power OFF the Operator tablet or tap **Close** to close the program without powering off the tablet.

4.3. Workflow of the System

The Diana System provides the following workflows:

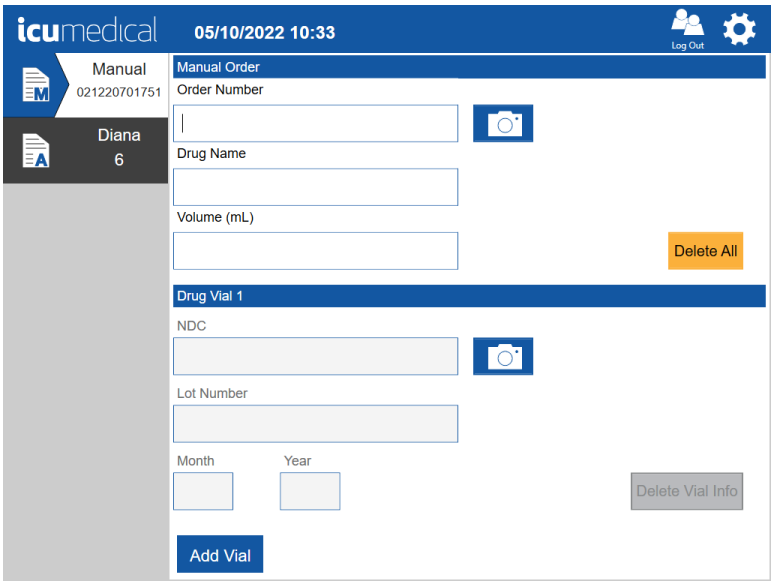
1. Manual Workflow
2. Automated Workflow

4.3.1. Manual Workflow

The Diana Operator Tablet user interface allows the user to add order preparation information manually into the Diana Compounding System. The user then manually compounds the desired medication(s) with the ordered amount and volume of medication(s) and diluent(s).

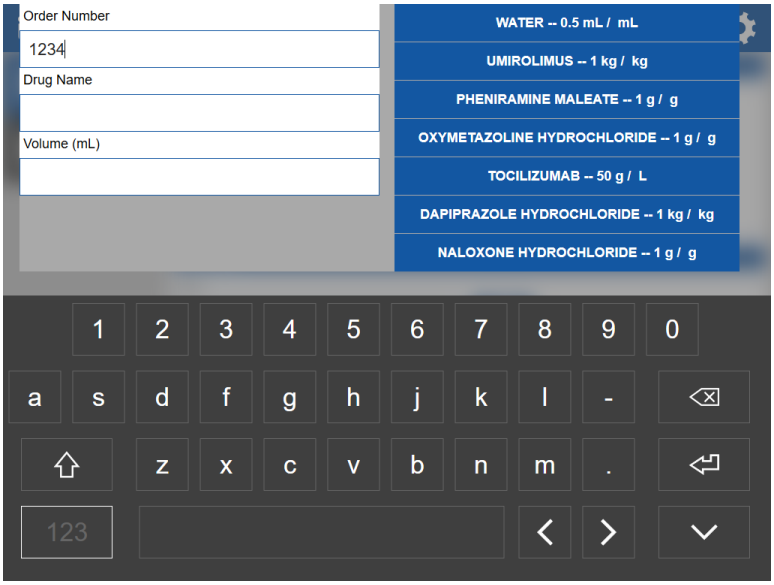
Note: This workflow can be used without the presence of a Diana Syringe Pump.

1. Select the **Manual** tab.



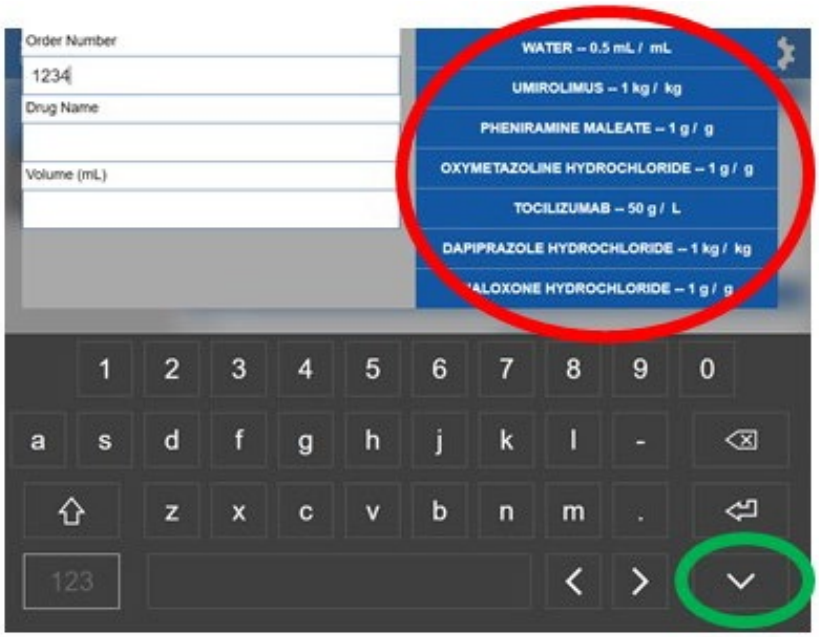
2. Tap on the **Order Number** text box and enter the **Order Number.**

   Note: If the Order Number is not provided in the Patient Order Form, enter zero for the Order Number.



   Note: The down arrow key (circled in green below) can be pressed to minimize the keyboard and exit this entry screen.

   Note: The right side displayed drug list (circled in red below) is a list of recently used drugs. This list will update as the user does preparations using the system.

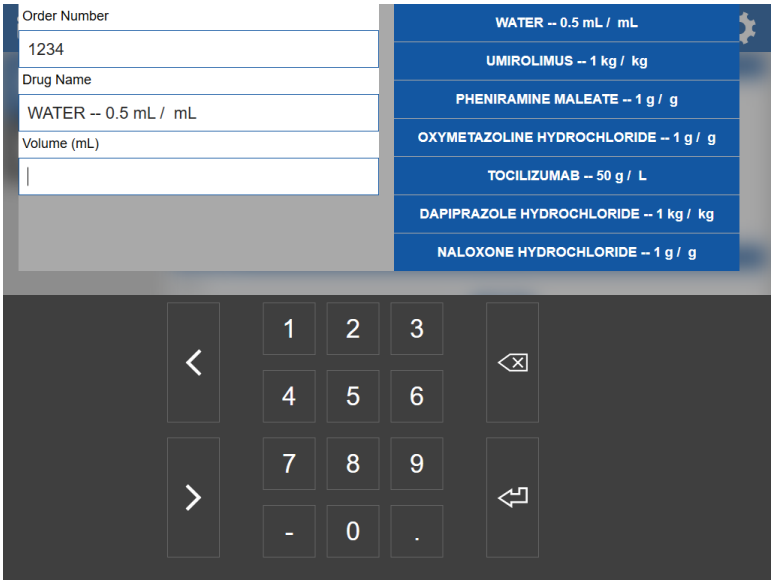


3. Next, tap the **Drug Name** text box. Use the on-screen keyboard to enter the drug name. As you type in the drug name, the software will automatically display the drug names in the system database starting with the typed letters. Once you find the drug name, select the drug by tapping the desired drug. If the user does not find the desired drug in the drop down menu, please refer to section 5.5 of this manual for details about creating a new drug.

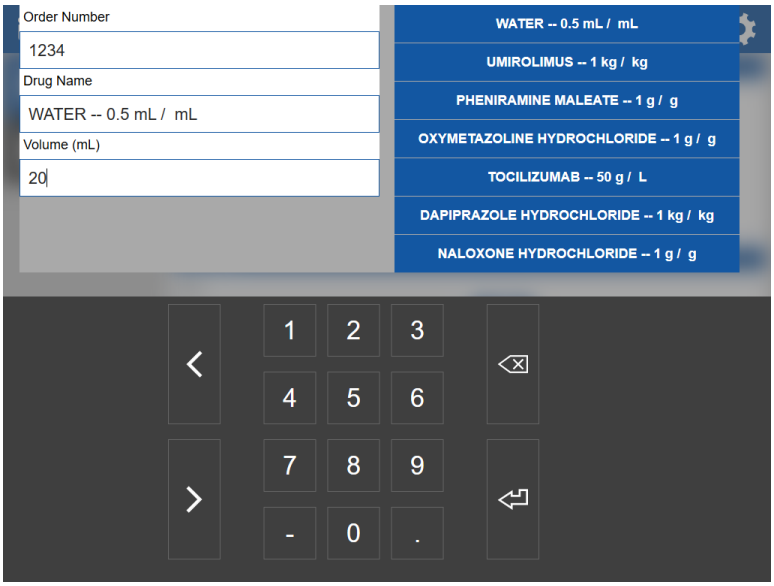
   Note: The user can select the drug on the right side (blue background) displayed drug list.

   Note: The drug name and concentrations are derived from the FDA database. Users must ensure they select the correct drug from the list.

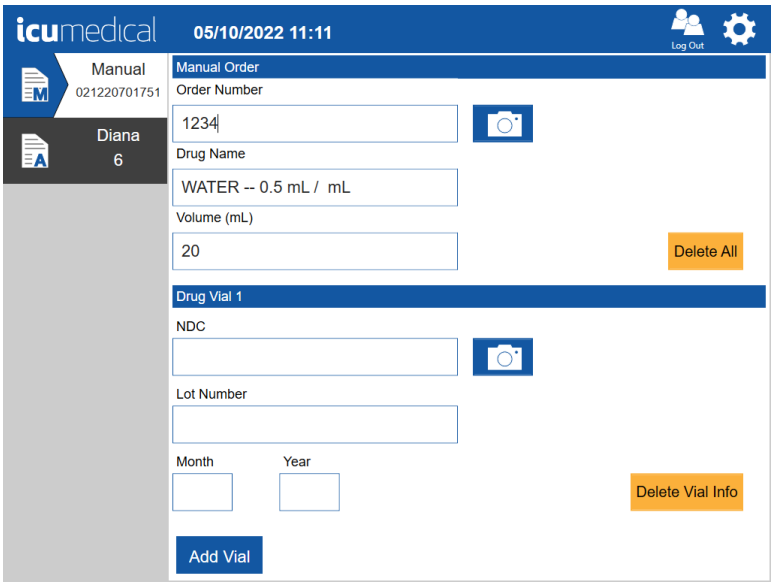
4. Next, tap the **Volume** text box and an onscreen numeric keypad will be displayed.



5. Use the numeric keypad to enter the volume (mL) of the medication to be transferred and tap the onscreen **Enter** key. The user may enter a value from 1 to 1000 mL. The system will accept values with up to two decimal places (example: 25.55 mL).



6. The drug information entered will display on the Order screen.



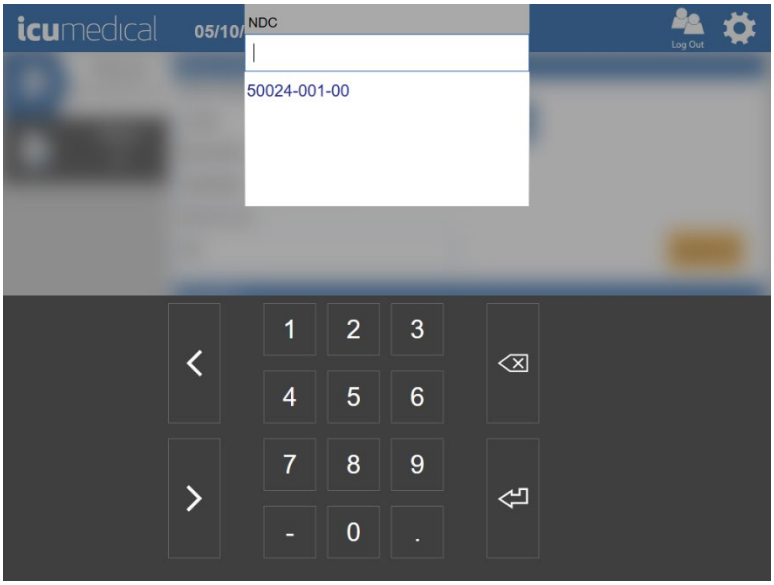
Note: "Delete Vial Info" button will clear the entered information below the Drug Vial 1 heading

Note: "Delete All" button will clear the all information entered on the order entry page

7. Next, to enter the input drug information, Enter Drug Vial 1 information by tapping on the **NDC** text box. The following screen displays for the user to select the desired NDC ID from the list. Select available **NDC** ID. The software will automatically display the NDC IDs in the system database. If the

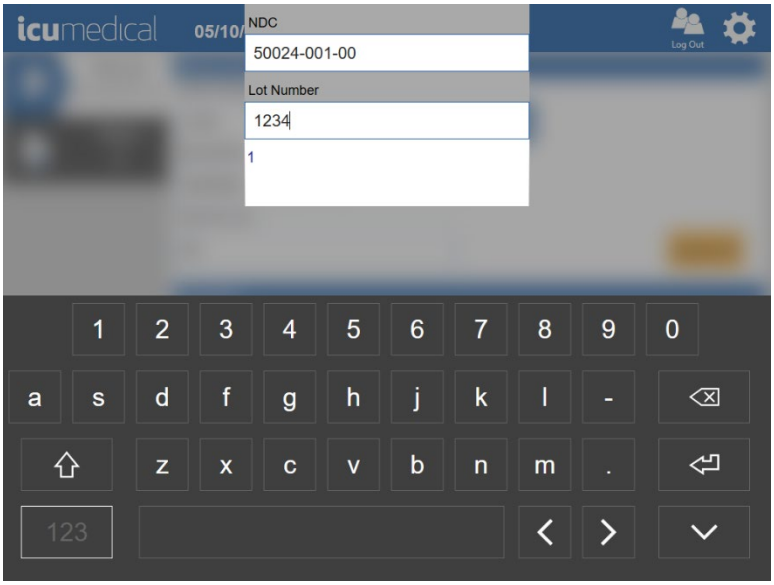
user does not find the desired drug NDC in the drop down menu, please refer to section 5.5 of this manual for details about creating a new drug.

Note: The user can use the connected barcode scanner to scan the NDC barcode from the input vial. To scan the input barcode, focus on the input vial label barcode, then press and hold the scanner trigger button.

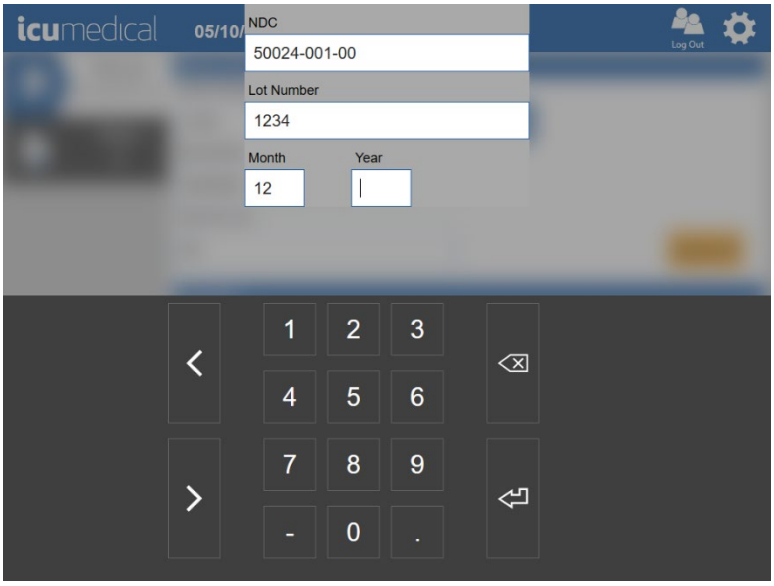


8. Tap on Lot Number text box. The following screen displays for the user to enter the lot number of the input vial. Lot number must be alpha-numeric and must be 20 characters or less.

   Note: If there are previously added Lot Numbers for the selected NDC, the software automatically displays a list of available Lot Numbers in the system for the user to select the Lot Number.

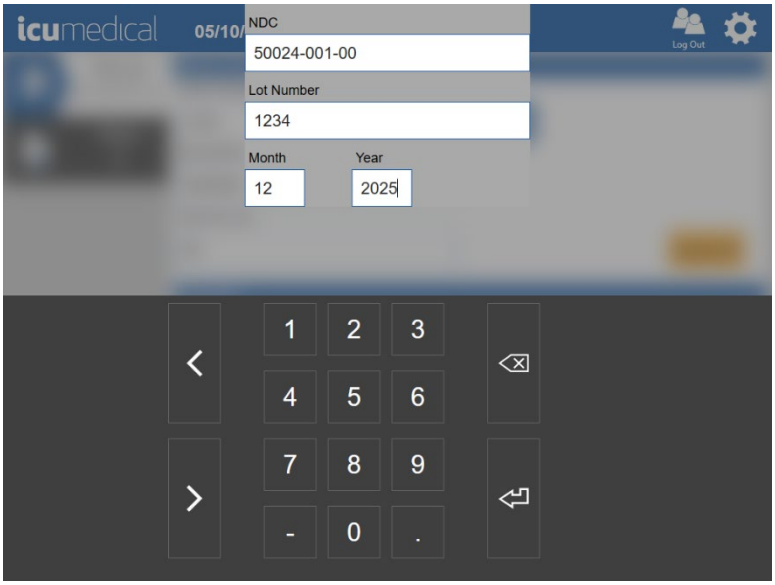


9. Add Expiration Date: Tap on **Month** text box. The following screen displays for the user to enter the Expiration Month of the input vial.



10. Tap on **Year** text box. The following screen displays for the user to enter the Expiration Year of the input vial.

    Note: If the user selects previously added Lot Number for the selected NDC, the software enters the **Month** and **Year** values automatically. The user can change the Month and Year values.

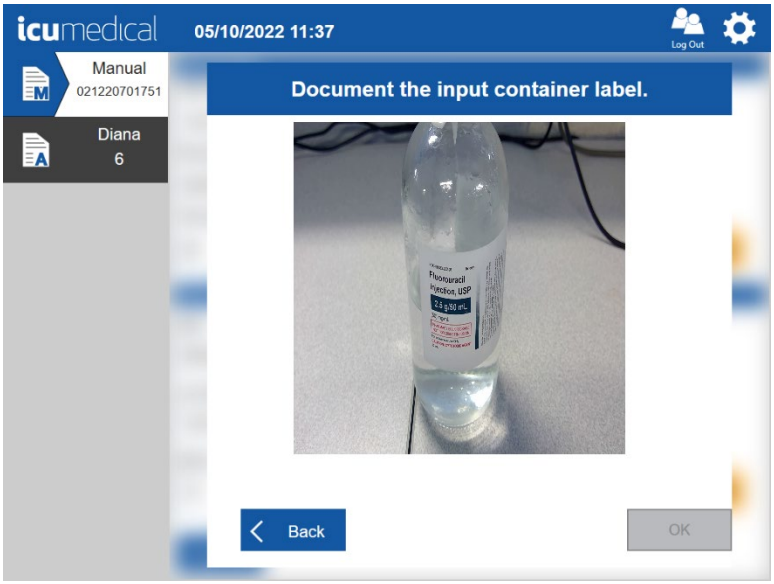


11. Tap onscreen **Enter**  button once the values are entered/selected.

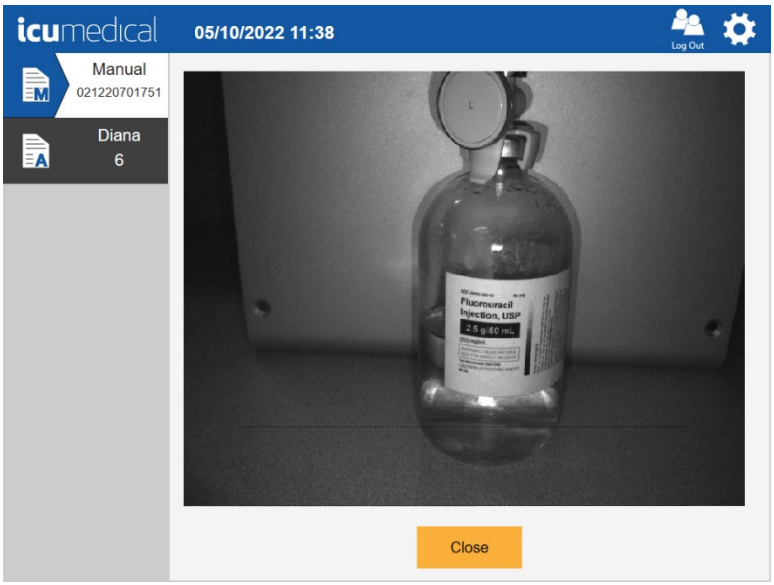
12. The software automatically displays the **Document the input container label** screen to allow the user to take a picture of the input container.

Notes:

a. The user must take a picture of the input container; otherwise, the software prevents the transfer process.
   Note: This feature can be disabled. Refer to the System Settings section.
b. To take a picture of the vial, a user may utilize the tablet camera or the barcode scanner. Take a picture of the label on the input vial which includes the NDC code, lot number, expiration date, drug name and concentration.
c. To take a picture using tablet camera, focus on the input vial label, and press Capture button.
d. To take a picture using the barcode scanner, focus on the input vial label, then press and hold the scanner trigger button.



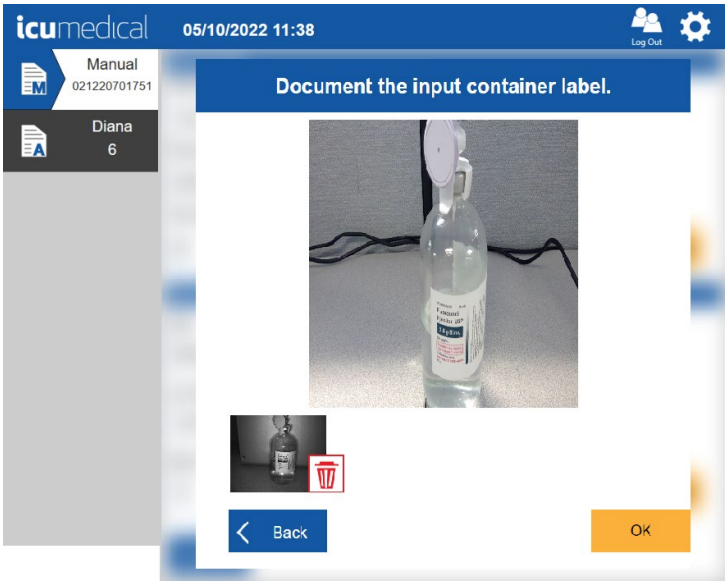
13. The software captures the picture and displays zoomed-in mode for the user to verify the captured picture is clear enough to see the content of the input vial.



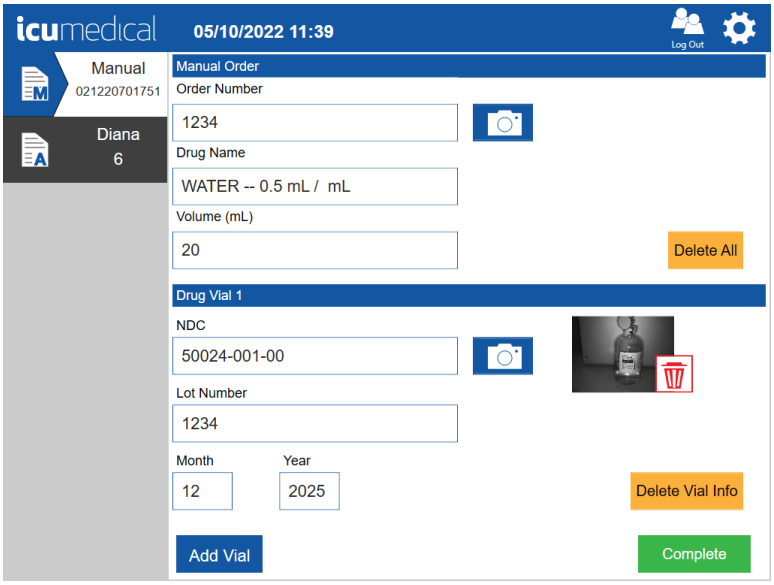
14. Tap the **Close** button.

    Note: The zoomed-in picture will automatically close within the configured time (in seconds) if the user does not tap the **Close** button. Refer to the **System Settings** section for setting up the **Photo Display Time in Seconds** time.

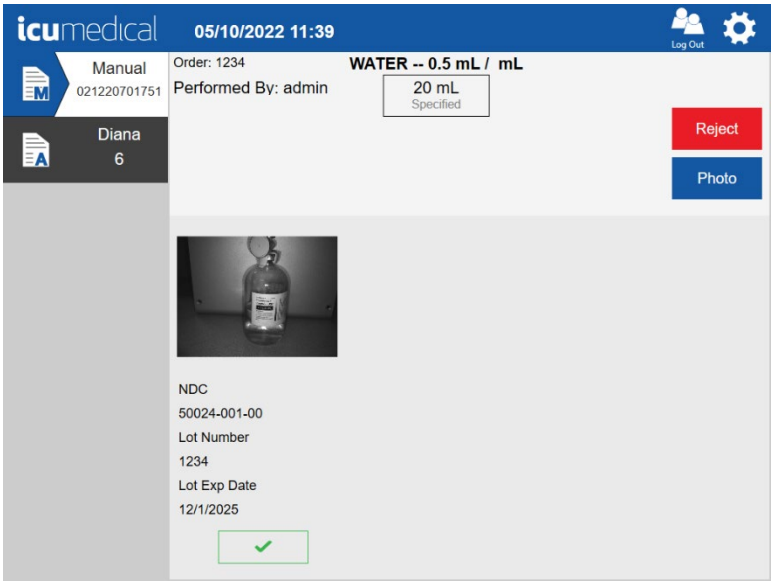
15. The software displays the captured picture on the screen. To remove a picture, tap the **Delete** icon next to the captured picture. Tap the **OK** button to save the picture(s).



16. Added vial information is displayed on the screen. The user may add additional Vials to the order by pressing the **Add Vial** button (follow the above steps for Adding NDC information). Tap the **Complete** button.



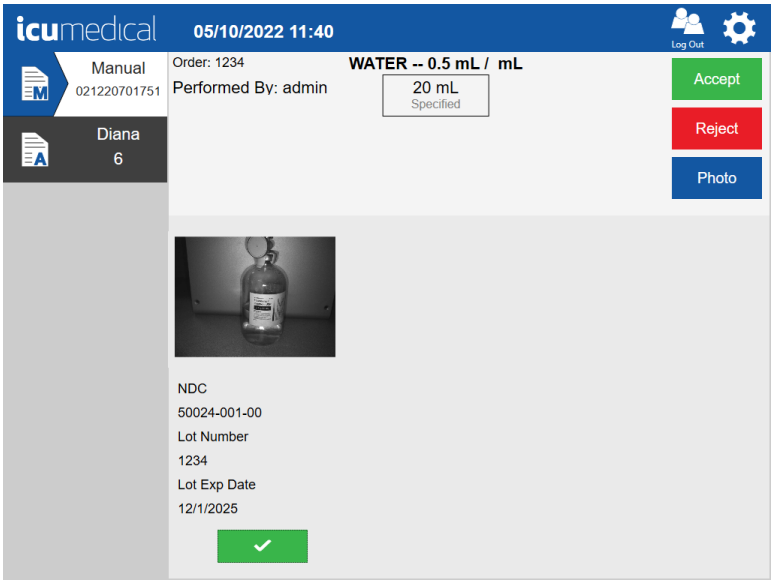
17. The verification screen will display with the entered information.



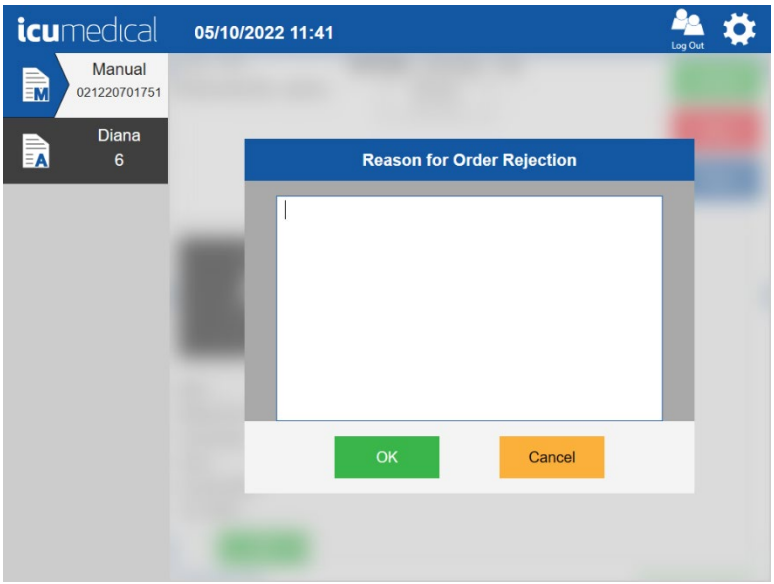
18. The user may then withdraw the desired amount of fluid from the vial. Tap the **Photo** button to capture the volume drawn to syringes.
19. Review the pictures on the verification screen by selecting the green check mark under each picture.

    Note: The UI interface displays the **Accept** button only when all the pictures are reviewed by the user. This feature can be disabled. Check in the **System Settings** section.

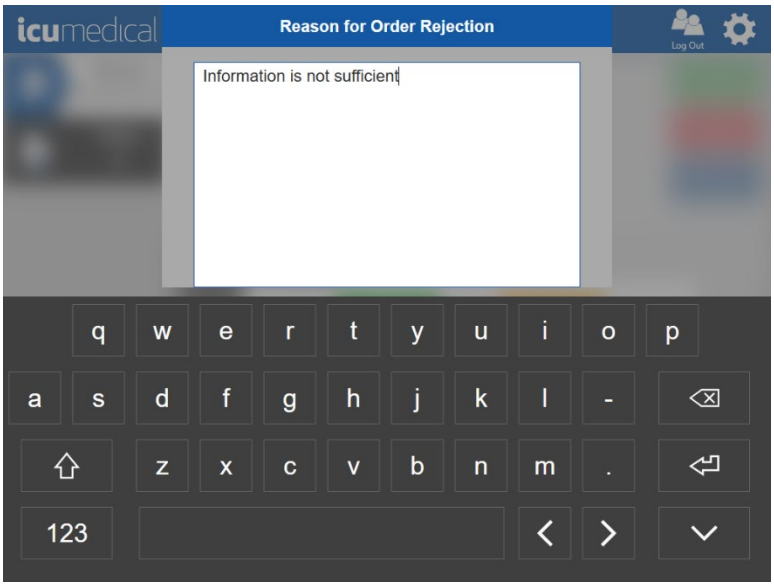
20. Choose the **Accept** or **Reject** buttons to either accept or reject the manual order.



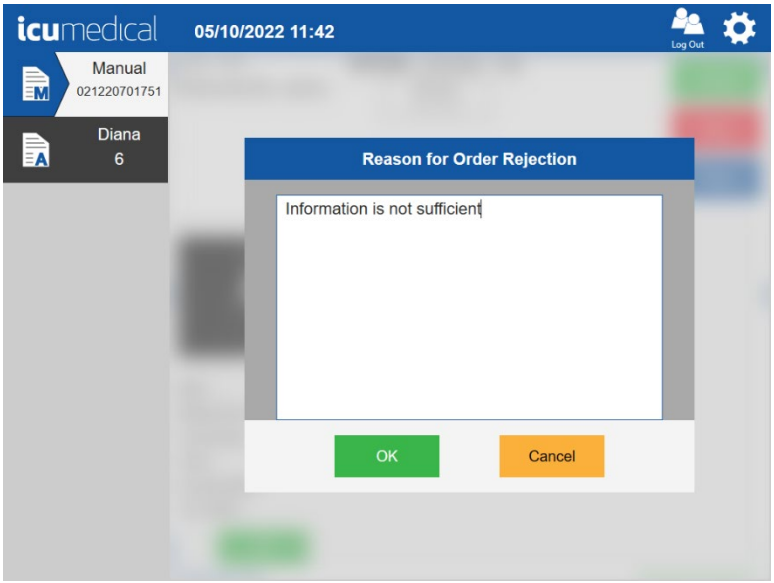
21. If the user rejects the order, the software provides a screen for the user to enter the reason for rejection.



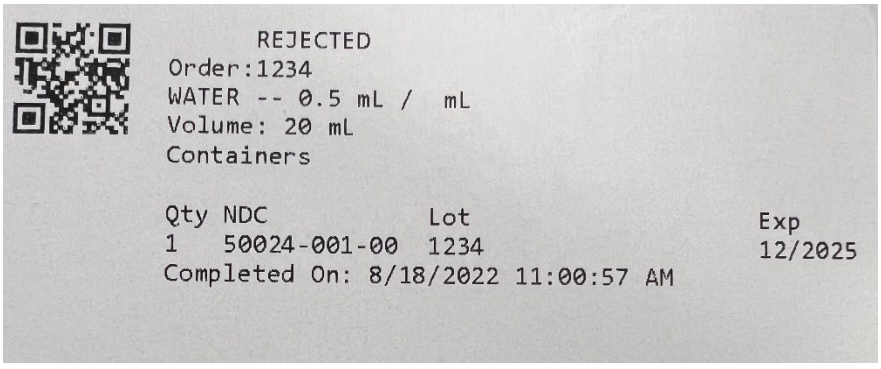
22. Tap on the **Reason** text area and enter the reason. Tap the Enter key. 



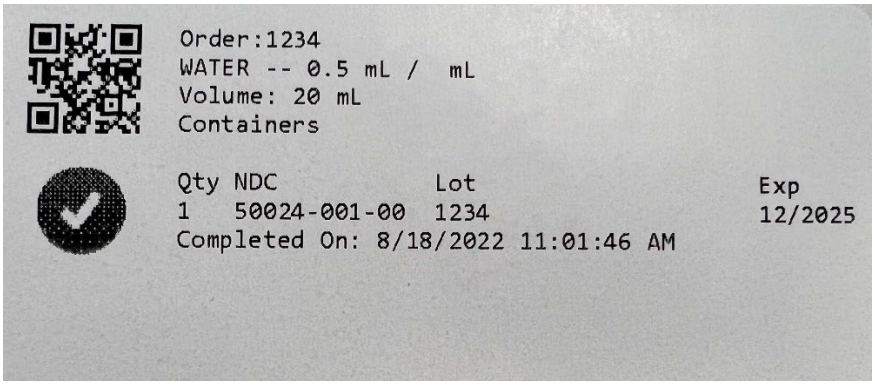
23. The following screen will display. Tap the **OK** button.



24. A label will print, which should immediately be placed on the output container.



25. If the user accepts the order, a label will print, which should immediately be placed on the **output container**.



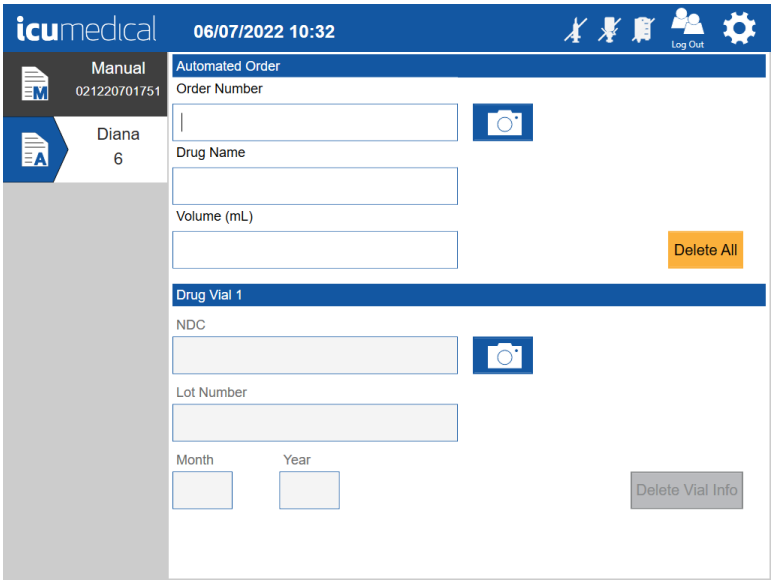
Note: Due to size limitations of the printed labels, labels printed for preparations that use 14 or more unique vials in a single preparation may have missing information on the label. Printed label information is for reference only.

26. Once the verification is done, the UI displays the Manual Order Details screen.

4.3.2. Automated Workflow

The Diana Operator application allows the user to transfer the fluid from the input vial to output container by using the connected Diana Syringe Pump.

1. Ensure the Operator application is communicating to the correct Diana Syringe Pump. Select the Diana Syringe Pump.



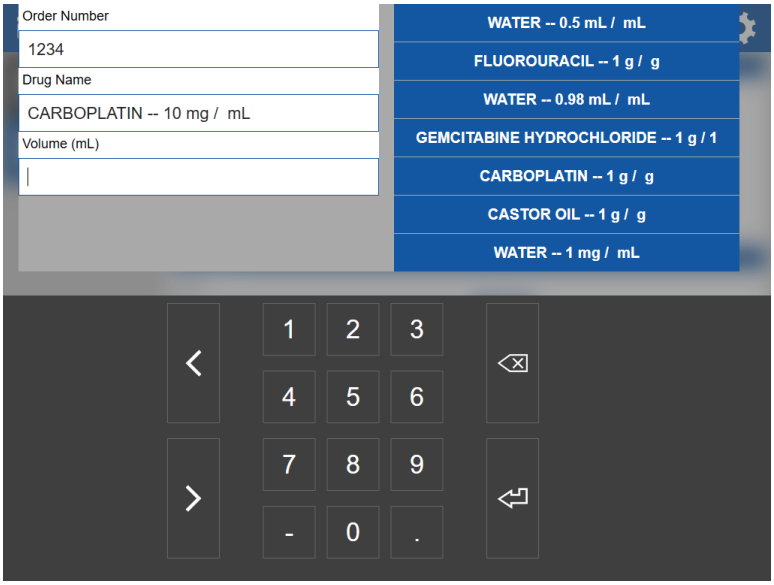
2. Tap on the **Order Number** text box and enter/select the information for **Order Number, Drug Name,** and **Volume.**

   Note: If the Order Number is not provided in the Patient Order Form, enter **0 (Zero)** for the Order Number.

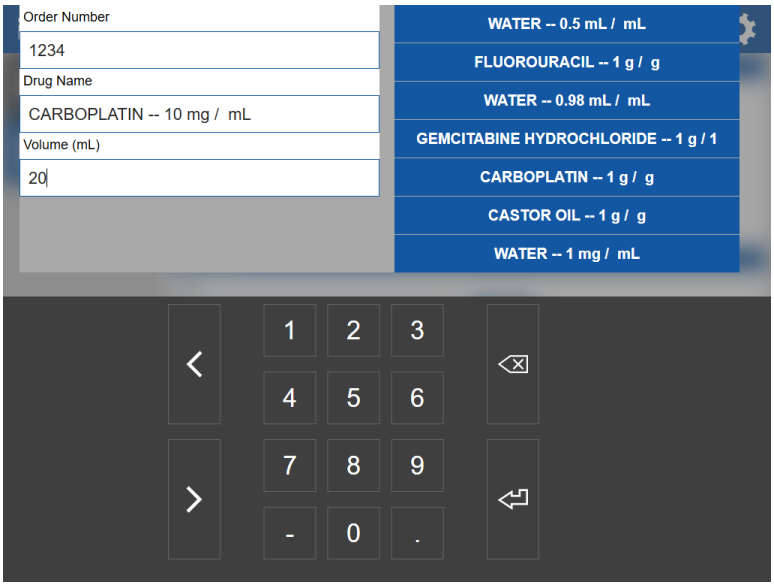
3. Next, tap the **Drug Name** text box. Use the on-screen keyboard to enter the drug name. As you enter the drug name, the software will automatically display the drug names starting with the typed letters. Once you find the drug name, select the drug by tapping the desired drug.

   Note: The user can select the drug on the right side displayed drug list.

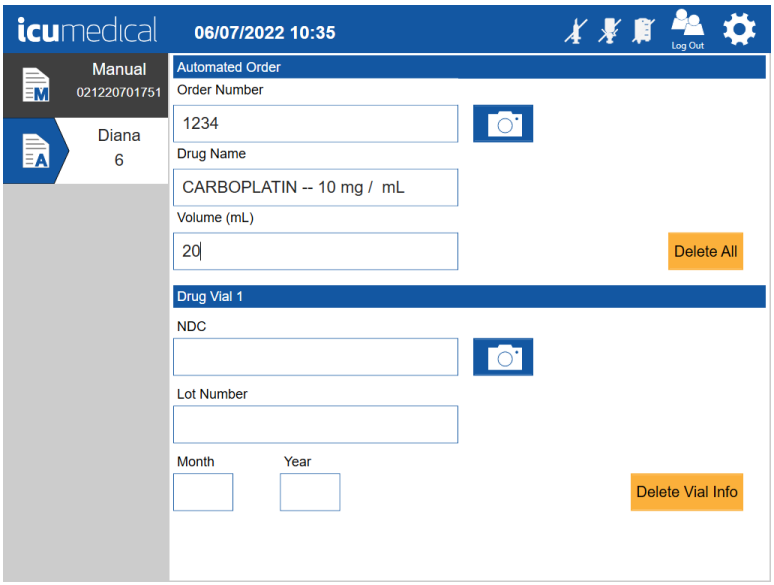
4. Next, tap the **Volume** text box and an onscreen numeric keypad will be displayed.



5. Use the numeric keypad to enter the volume in milliliters of the transfer and tap the onscreen **Enter** key. 

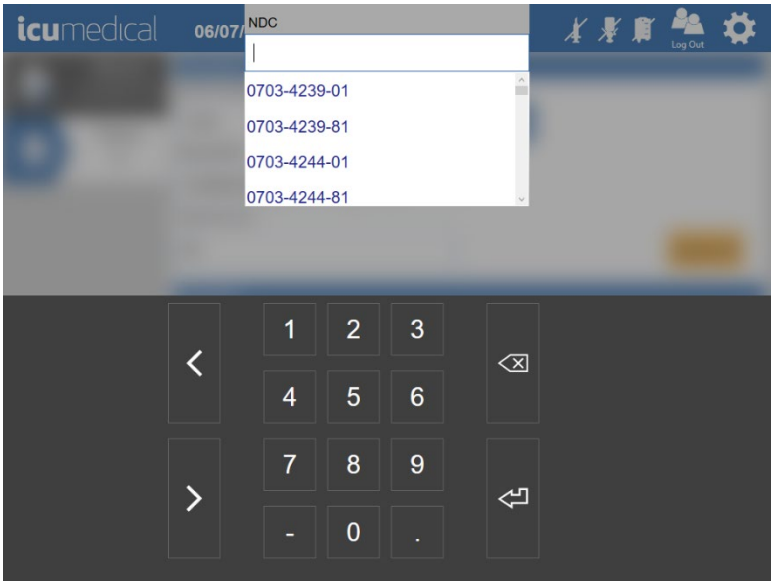


6. The information entered is displayed.



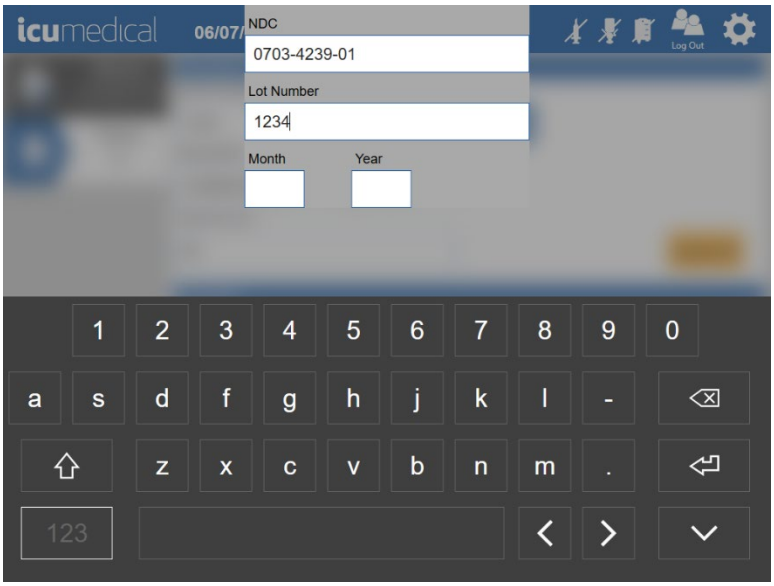
7. Tap on the **NDC** text box. The following screen allows the user to select the available NDC ID from the list. Select an available **NDC** ID.

   Note: The user can use the connected barcode scanner to scan the **NDC** barcode from the input vial.

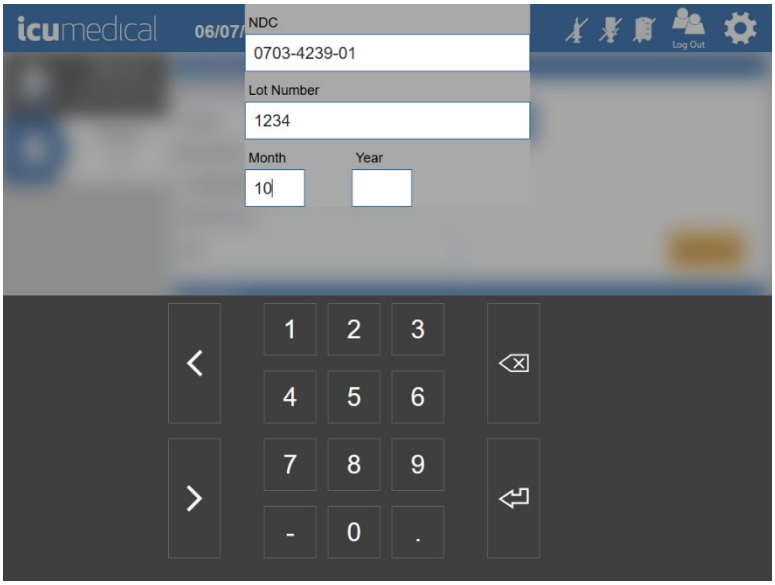


8. Tap on **Lot Number** text box. The following screen allows the user to enter the lot number of the input vial.

   Note: If there are previously added Lot Numbers for the selected NDC, the software automatically displays a list of available Lot Numbers in the system for the user to select the Lot Number.

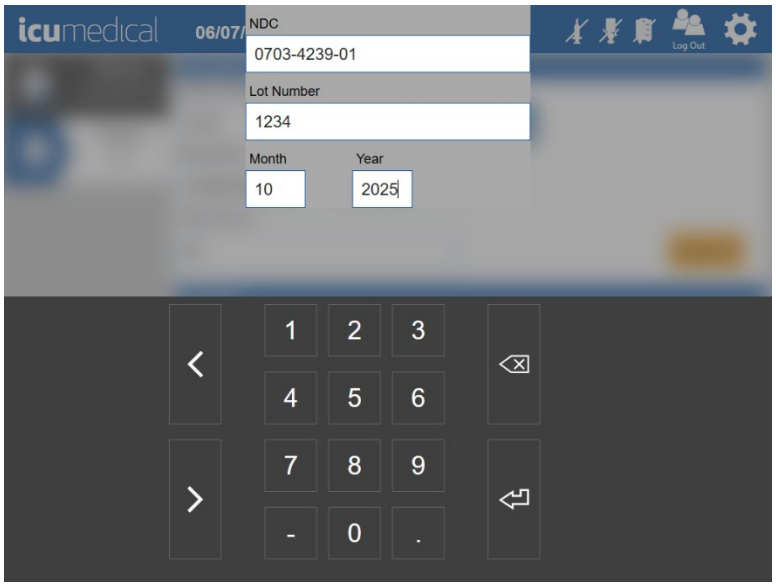


9. Tap on **Month** text box. The following screen allows the user to enter the Expiration Month of the input vial.



10. Tap on **Year** text box. The following screen allows the user to enter the Expiration Year of the input vial.

    Note: If the user selects a previously added Lot Number for the selected NDC, the software enters the **Month** and **Year** values automatically. The user can change the Month and Year values.



11. Tap onscreen **Enter**  button once the values are entered/selected.

12. The software automatically opens the **Document the input container label** screen to take the picture of the input container.

    Notes:

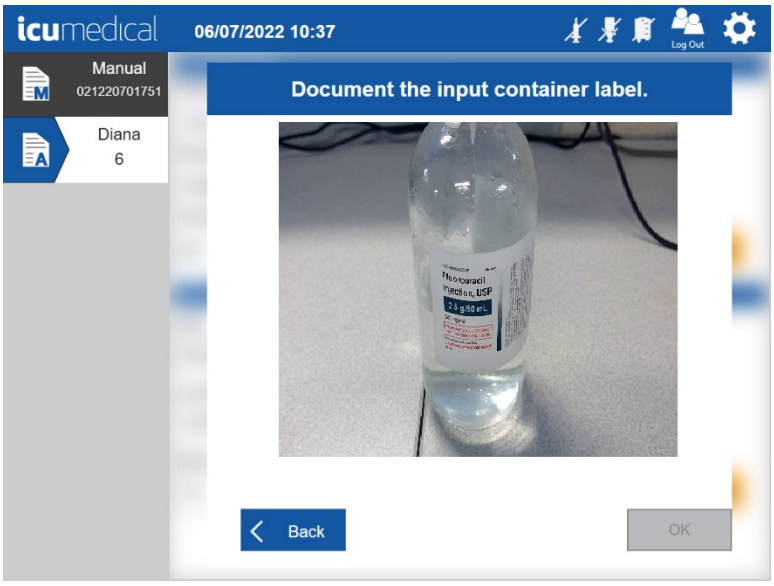
    a. The user must take a picture of the input container; otherwise, the software prevents the transfer process.

       Note: This feature can be disabled. Check in the **System Settings** section.

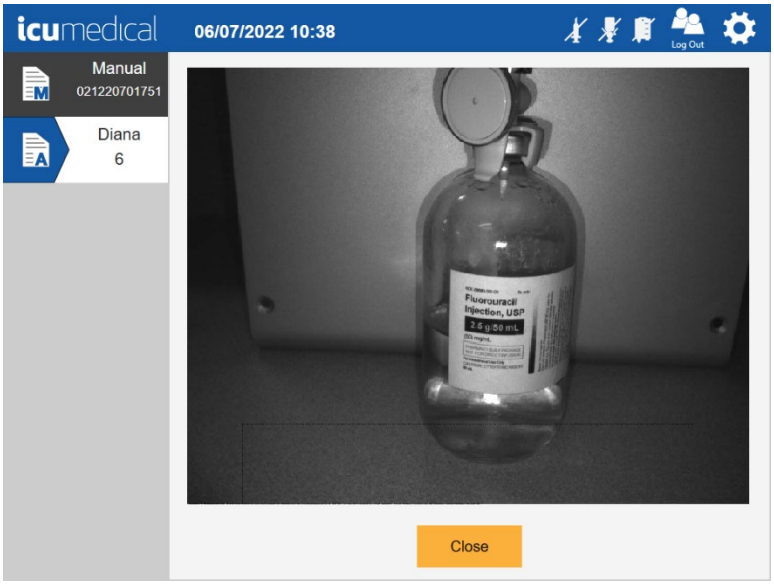
    b. To take a picture of the vial, a user may utilize the tablet camera or the barcode scanner. Take a picture of the label on the input vial which includes the **NDC code, lot number, expiration date, drug name and concentration**.

    c. To take a picture using the tablet camera, focus on the input vial label and press the **Capture** button.

    d. To take a picture using the **barcode scanner**, focus on the input vial label, press and hold the **scanner trigger** button.



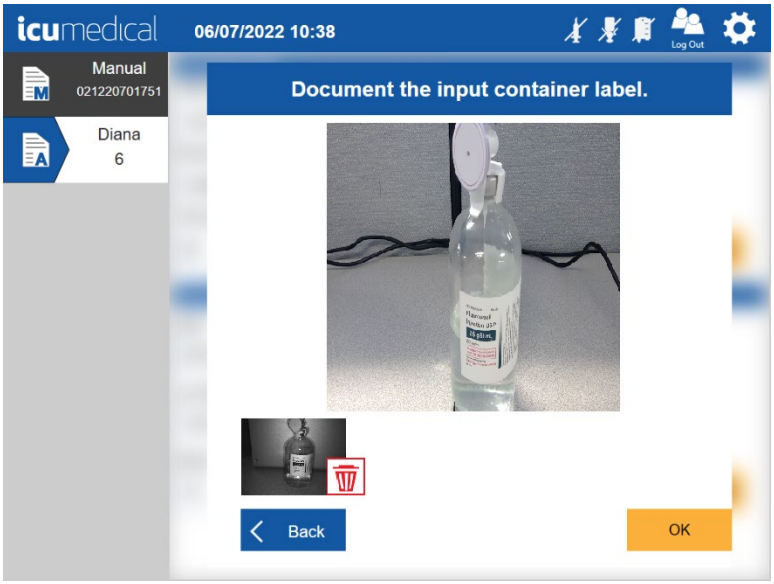
13. The software captures the picture and displays zoomed-in mode for the user to verify the captured picture is clear enough to see the content of the input vial.



14. Tap the **Close** button.

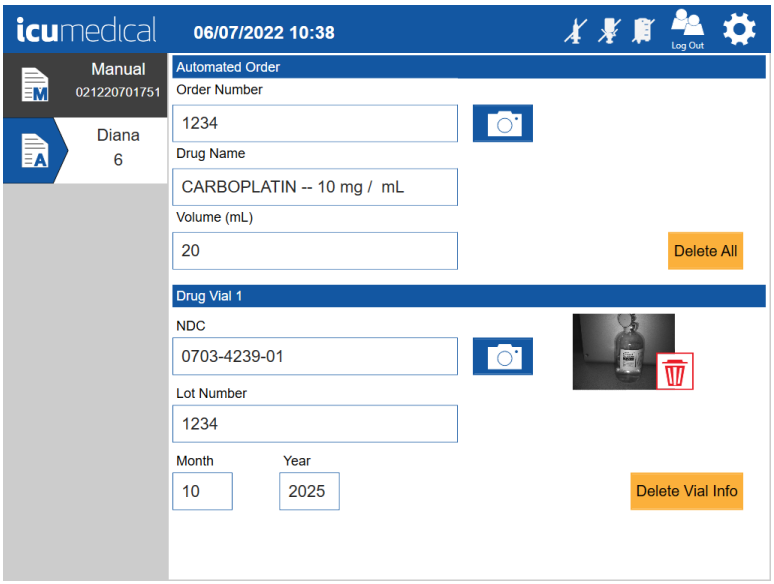
    Note: The zoomed-in picture will automatically close within the configured time (in seconds) if the user does not tap the **Close** button.

15. The captured picture displays on the screen. To remove a picture, tap the **Delete** icon next to the captured picture. Tap the **OK** button to save the picture(s).

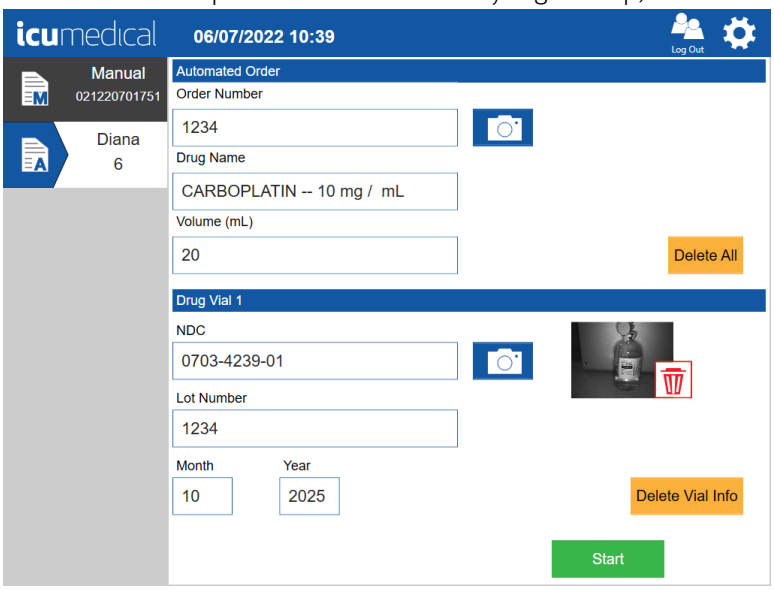


16. Added NDC information is displayed on the screen.

17. The software notifies (flashing **Diana Cassette, input vial** and **output container** icons on the tool bar) the user to connect the Diana Cassette, input vial, and output container to the Diana Syringe Pump.



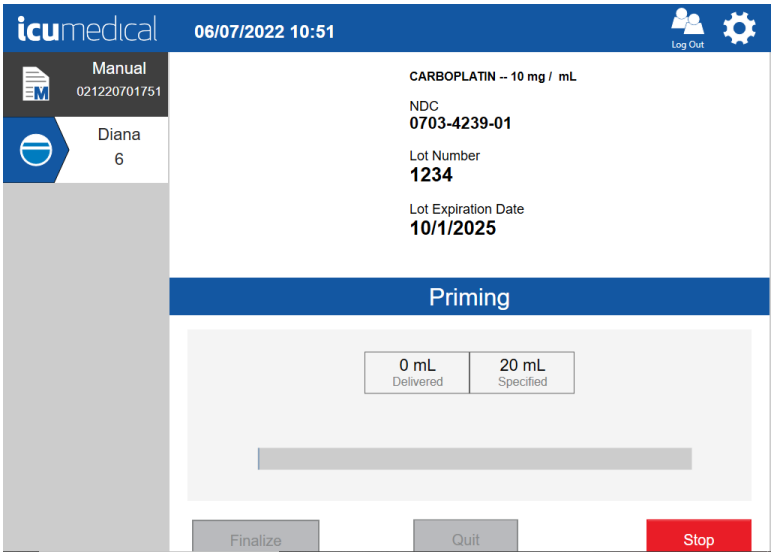
18. Once the user connects the disposables to the Diana Syringe Pump, the following screen displays:



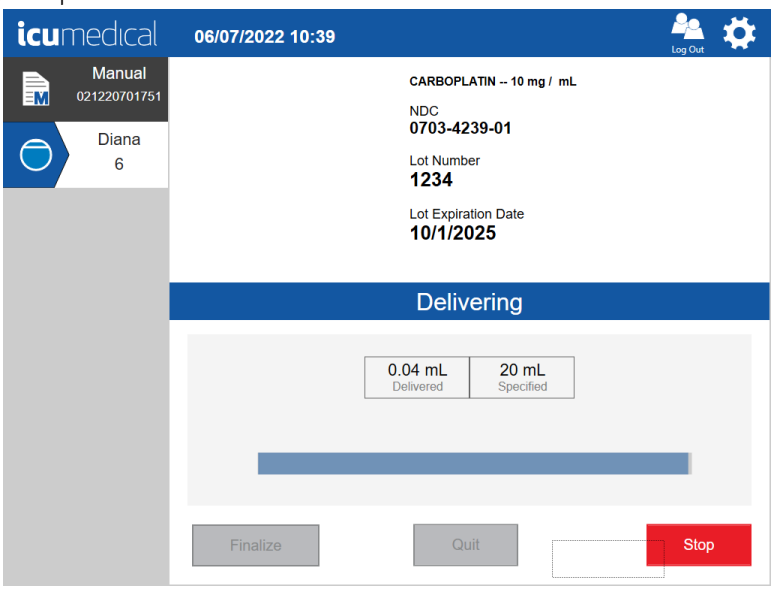
Note: Once the proper drug transfer information and pictures have been entered into the system, the system will now be in a state where it can begin a transfer.

Note: The Diana system does NOT monitor output container size, therefore the user is responsible to ensure that volume of fluid delivered into the output container is within the volume range deemed acceptable by the output container manufacturer

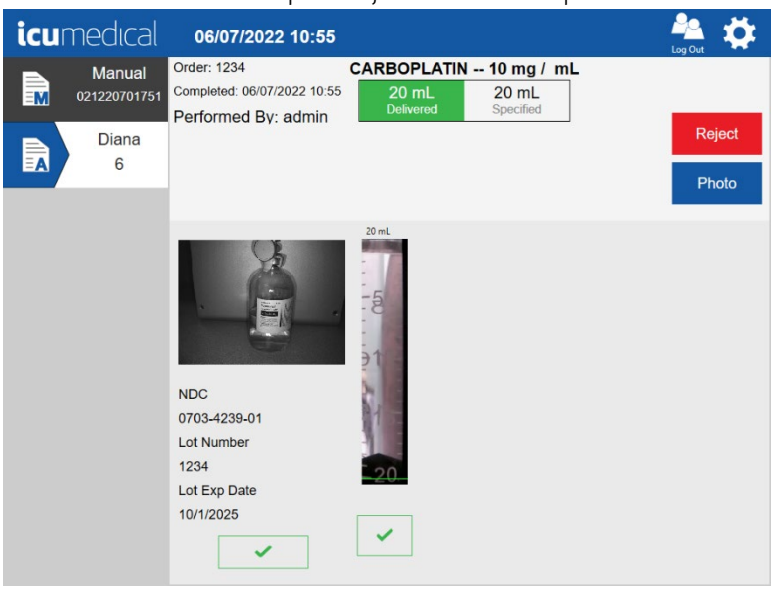
19. To initiate a transfer, tap the **Start** button. The Syringe Driver may draw a small volume of drug from the input vial and push it back into the input vial which will prime the disposables.



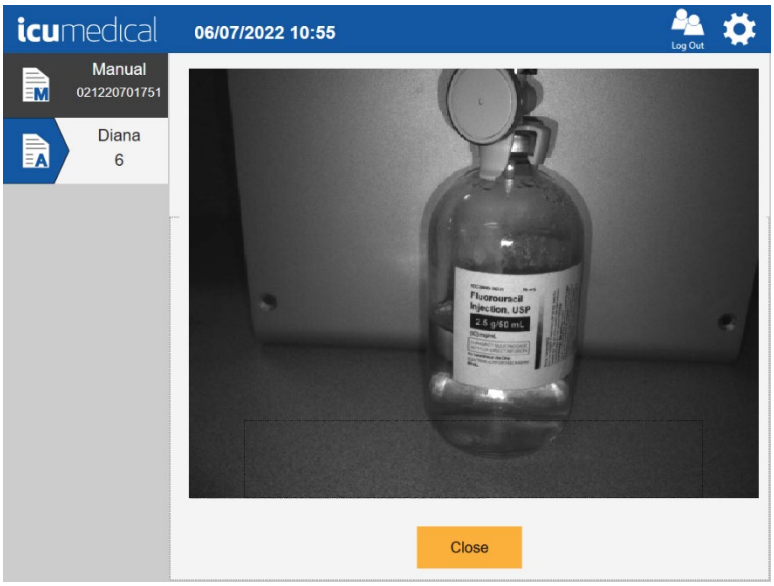
20. Once the fluid path has been primed, the Diana Syringe Pump will then draw the desired amount of fluid into the Diana Cassette. As the device is drawing fluid, the status bar (with a light blue color) on the Operator tablet will begin to fill. This provides a status to the user as to how far the transfer is from being complete.

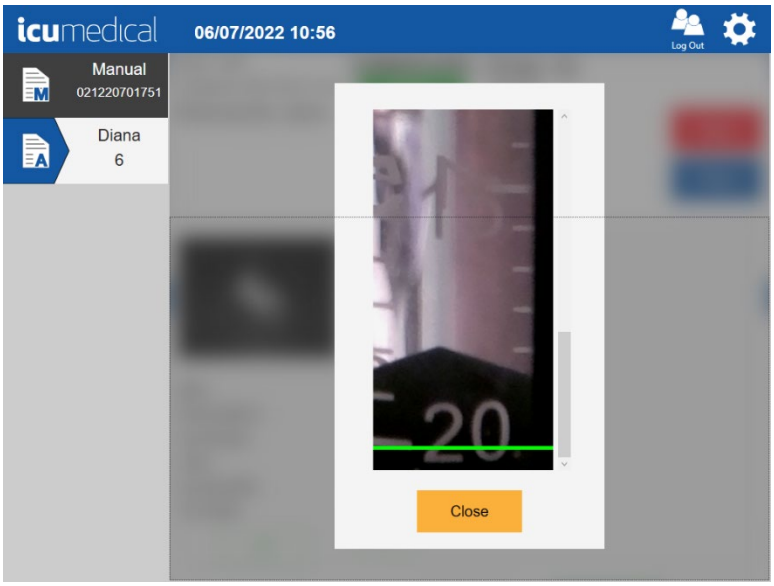


21. As the device is pushing fluid into the output container, the status bar will fill up (the light blue will fill up with a darker blue) accordingly. Additionally, a real-time indication of fluid transfer will be displayed on-screen providing the user with an indication of how much drug has been transferred into the bag.
22. Once the automated drug transfer process is completed, the Diana software GUI presents a verification screen to the user to accept or reject the transfer process.



23. The Diana software provides the user the ability to zoom in on the pictures (to zoom in on the photo, tap the photo).

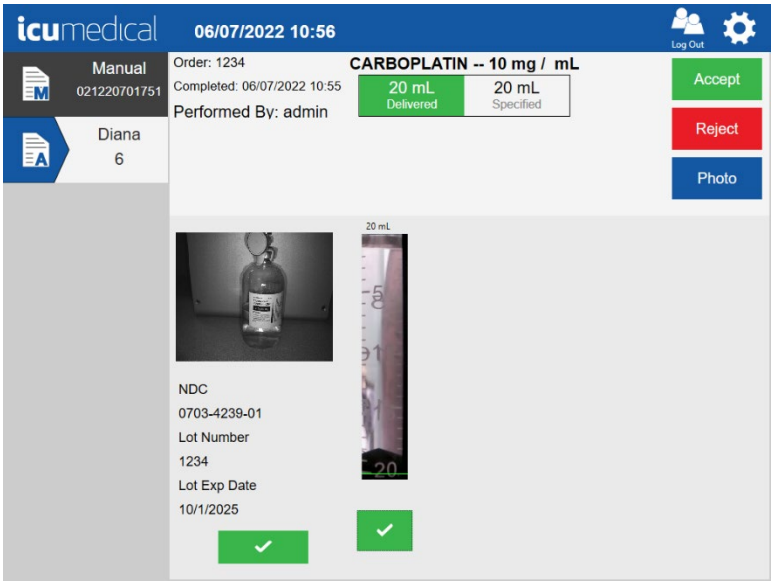




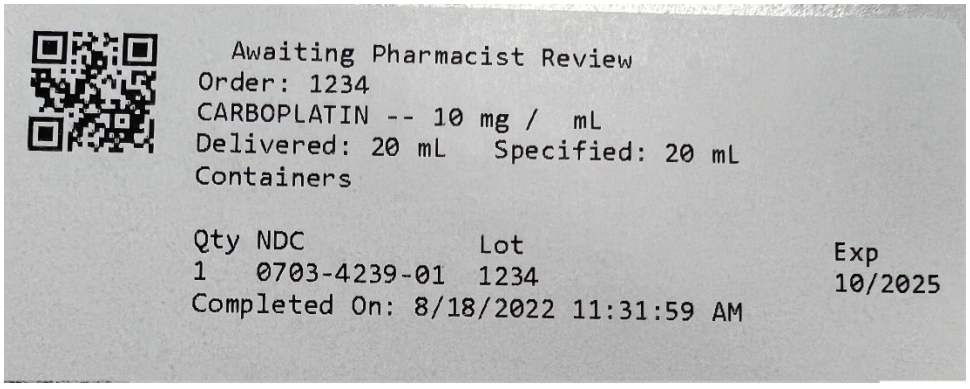
24. The user may take additional pictures by pressing the Photo button.

25. Review the pictures on the verification screen by selecting the green check mark under each picture.

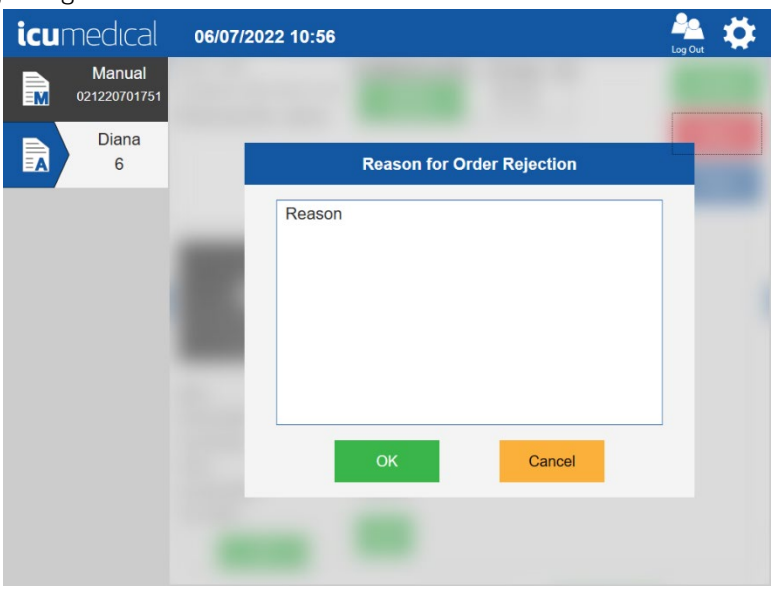
    Note: The UI interface displays the Accept button only when all the pictures are verified by the user. This feature can be disabled. Check in the System Settings section.

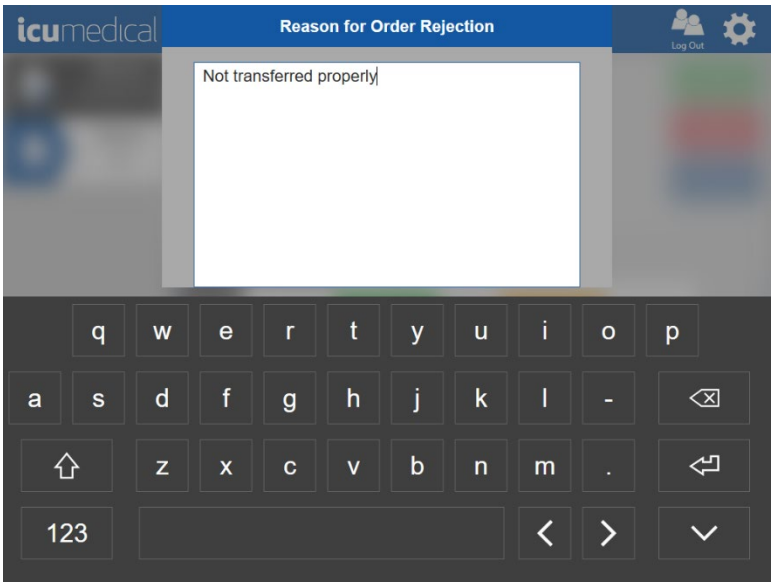


26. If the user accepts the transfer, a label will print, which should immediately be placed on the output container.

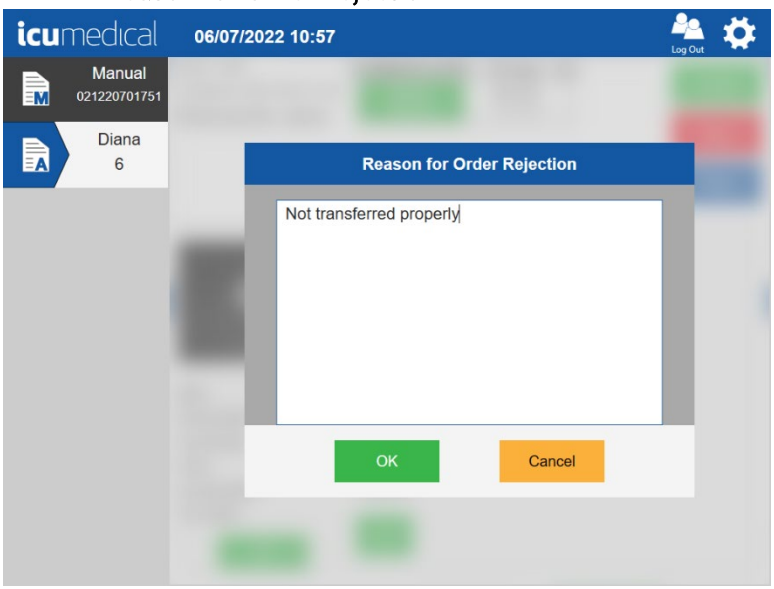


27. If the user rejects the transfer, the Diana software GUI presents a screen to the user to provide the reason for rejecting the transfer.

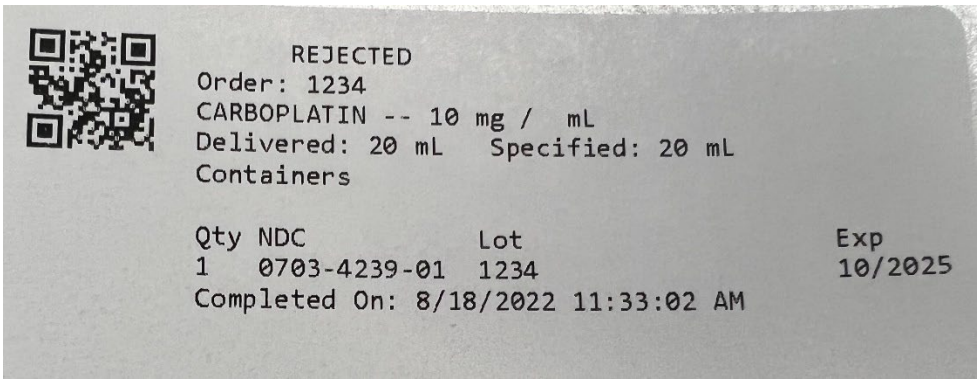




28. Tap **OK** button on the **Reason for Order Rejection** screen.



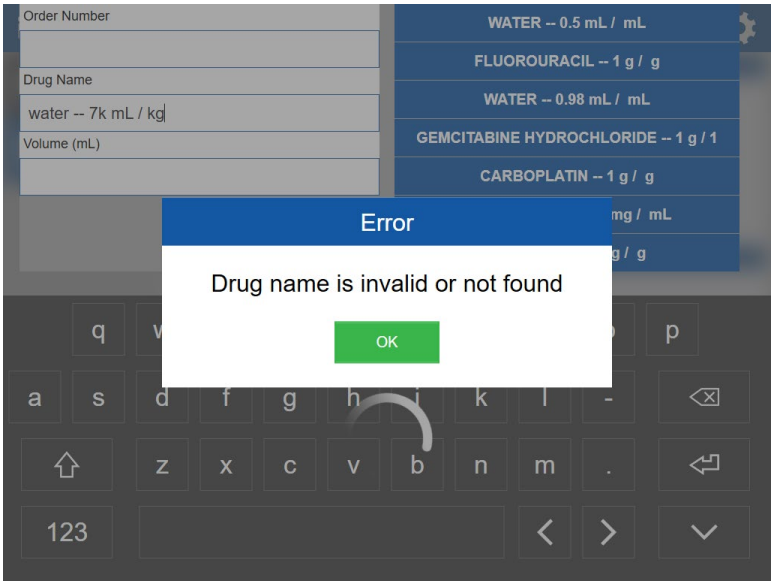
29. Once the user provides the reason, a label will print, which should immediately be placed on the output container.



4.3.2.1. Checking Drug Name for Verification

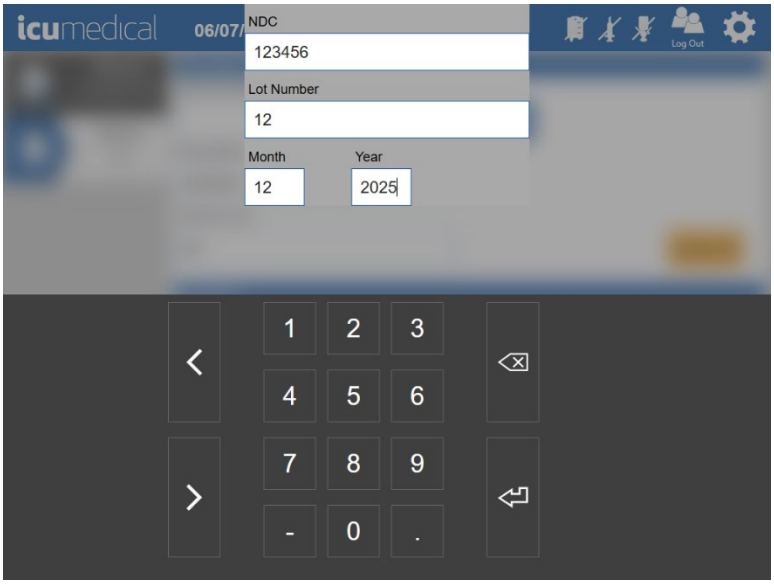
The Diana System software provides the ability to verify that the correct drug name has been entered before a transfer can take place. Once the desired drug name has been entered, the Diana System software will check the name of the drug against the list of drugs in the system database.

When the incorrect drug has been entered, an indication is displayed on the Operator application requiring the user to enter new drug information.



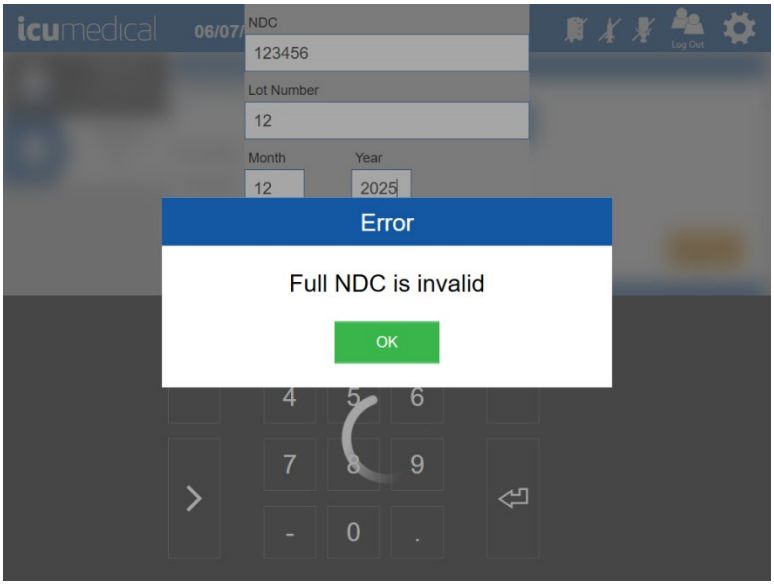
4.3.2.2. Checking the Drug NDC for Verification

The Diana System software provides the ability to verify that the correct Drug NDC has been entered or scanned before a transfer can take place. Once the desired Drug NDC has been entered or scanned, the Diana System software will check the Drug NDC against the list of drug NDC's on the system.

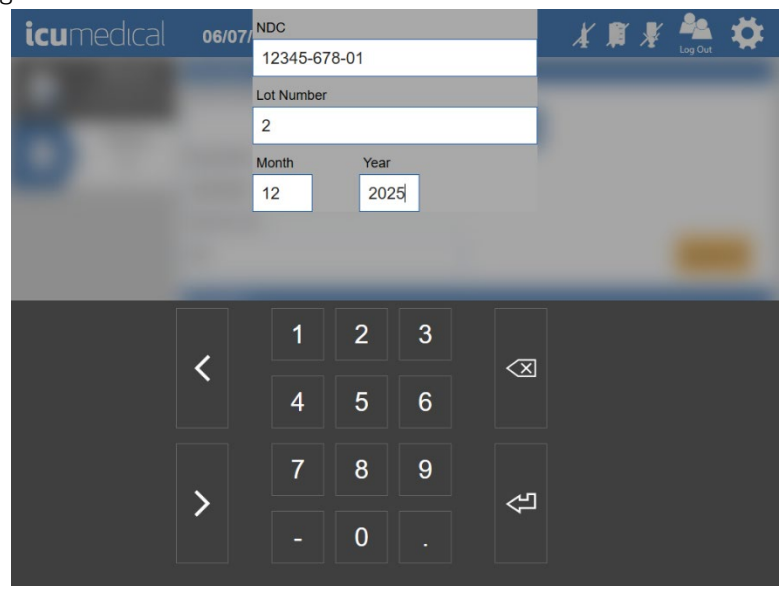


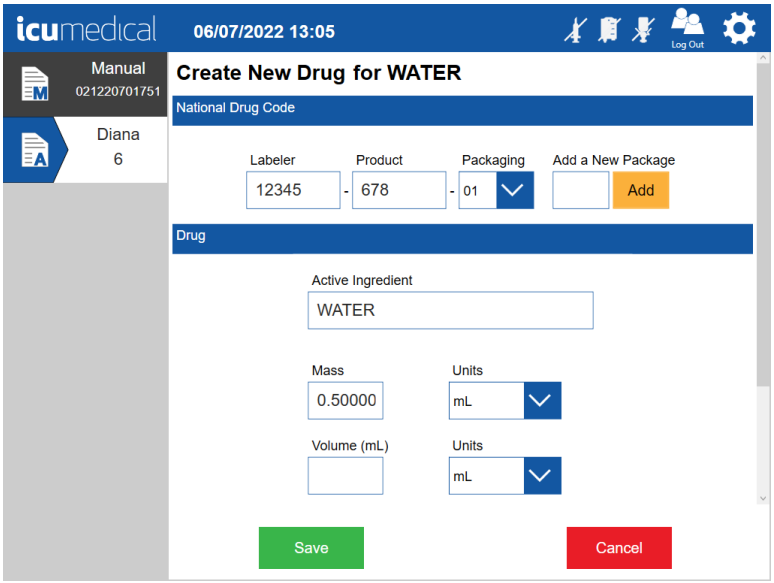
When the incorrect Drug NDC format has been entered or scanned, the Operator application displays a message to the user that the entered/scanned NDC is not a valid format.

Note: The Lot Number and Lot Expiration values also need to be entered prior to the operator software verifying if the NDC information is correct or not.



When the entered/scanned Drug NDC is in the correct format, but it is not associated with the entered Drug Name, the Operator application displays a New Drug screen for the user to add the drug information. The User can create a new Drug NDC for the Drug Name or select the option to cancel the drug creation.

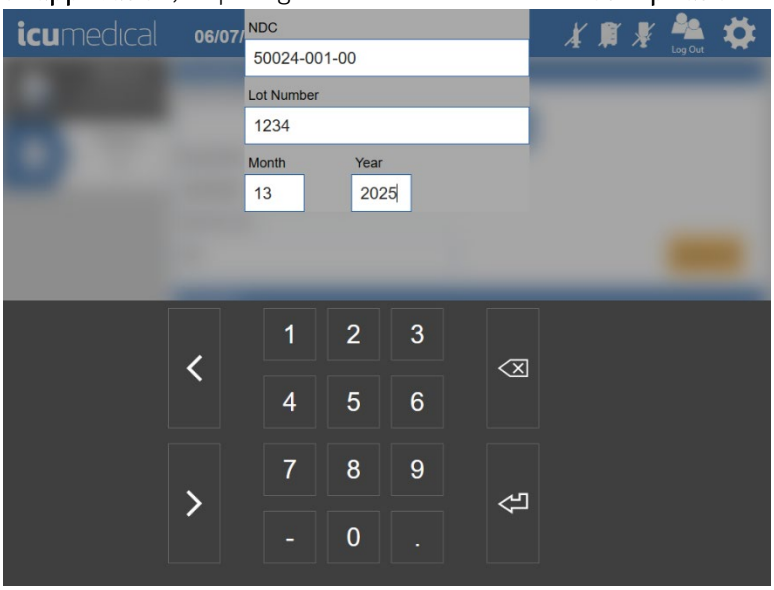


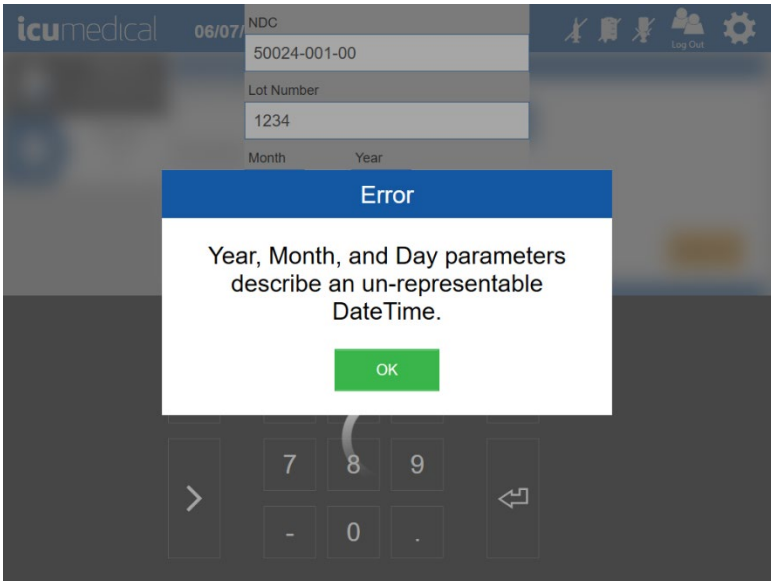


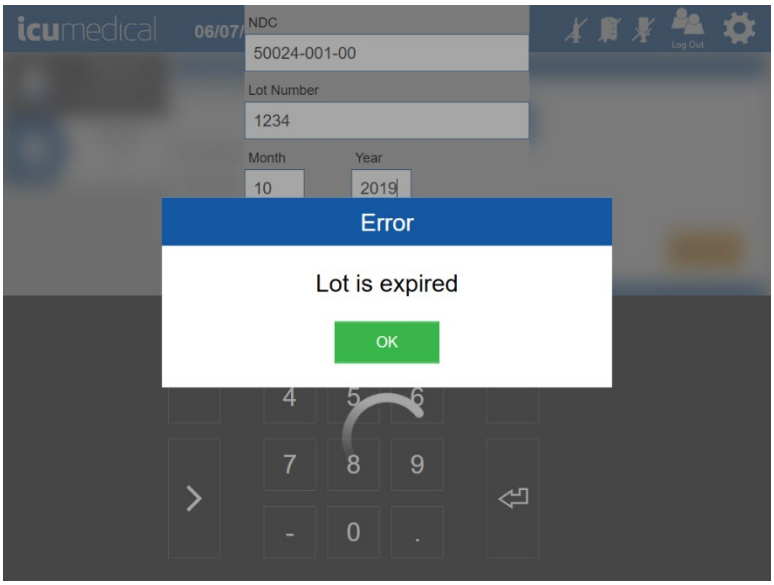
4.3.2.3. Checking the Lot Expiration Date for Verification

The Operator application provides the ability to verify that the correct **Lot Expiration Date** has been entered before a transfer can take place. Once the **Lot Expiration Date** has been entered , the Operator application will check the entered **Lot Expiration Date**.

When an incorrect **Lot Expiration Date** or **Expired Date** has been entered, an indication is displayed on the **Operator application**, requiring the user to enter a new **Lot Expiration Date**.







4.3.3. Validating a Transfer

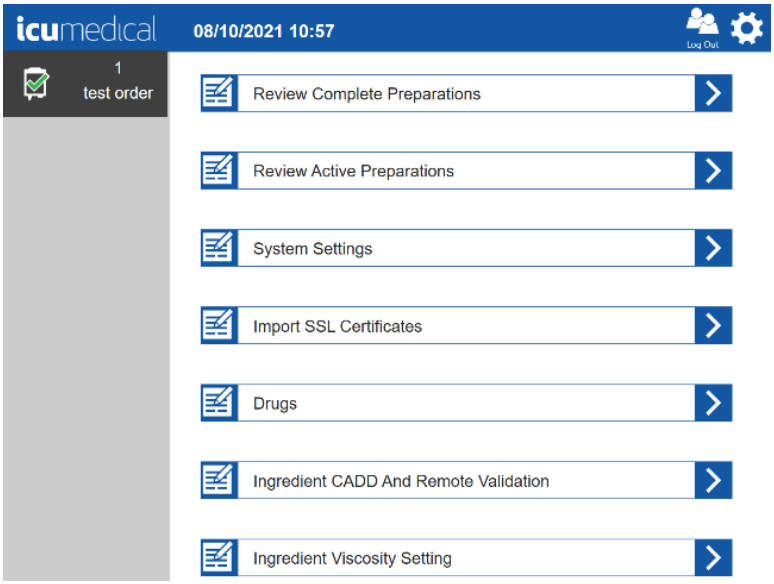
The Diana System has a Pharmacist Application that runs on the Pharmacist Tablet, allows preparations (manual or automated) to be validated by a pharmacy administrator. For the automated transfers the embedded camera inside the Diana Syringe Pump take pictures of the syringe in the pulled state before transferring into the output container and then send the transfer information along with the pictures of the transfer to the Operator Application. The Pharmacist Application will download the preparation, which includes the pictures taken by the operator application and the Diana Syringe Pump, and allows a pharmacist to verify the correct mixture took place without having to enter the clean room environment.

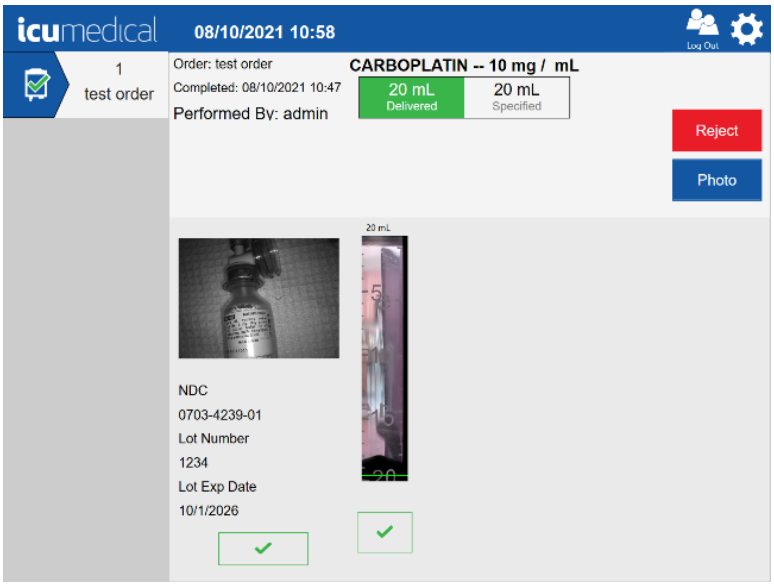
Once a transfer for certain drugs has been completed from the Operator application, the Pharmacist Application will display a transfer in the Pharmacist GUI with the patient order number on it.

The pharmacist has options to approve or reject the transfer.

4.3.3.1. Approving a Transfer

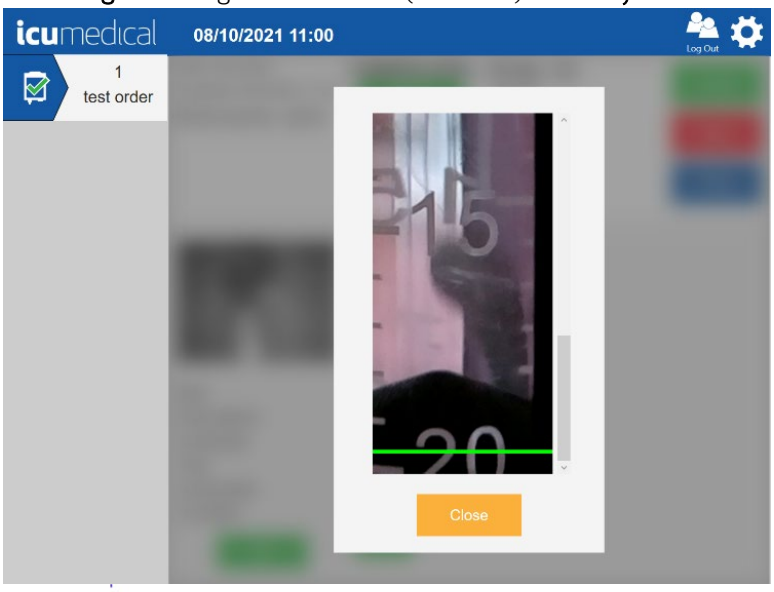
1. Tap the transfer with the corresponding preparation order to be validated.



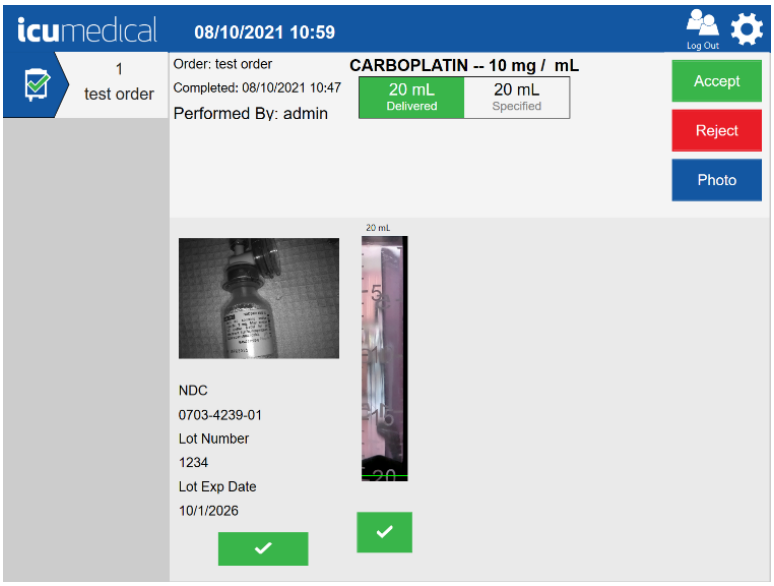


2. Review the information. Review each picture and tap the **green check mark** icon to approve each picture.

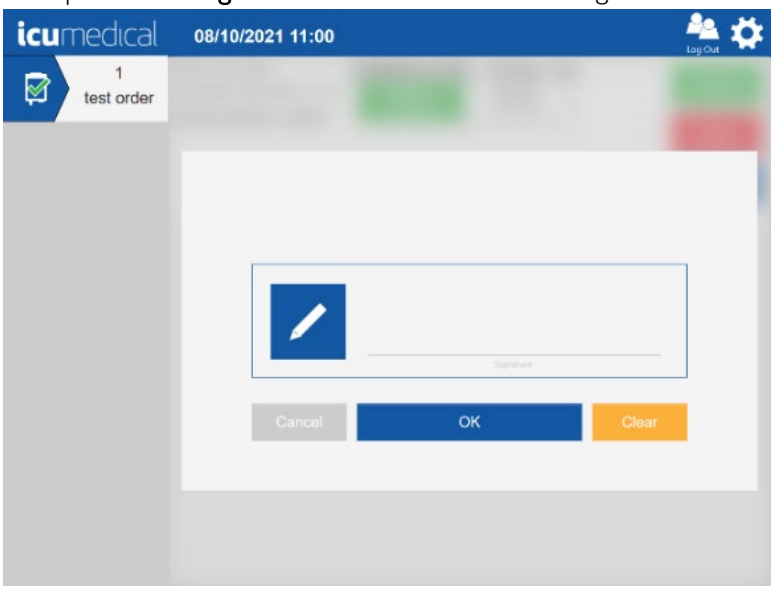
3. When all the pictures have been reviewed, the **Accept** button will display.
   Note: Displaying Accept button without validating the pictures can be possible when the **Validate All Images** settings is set to **Red** (Disabled) in the **System Settings**.



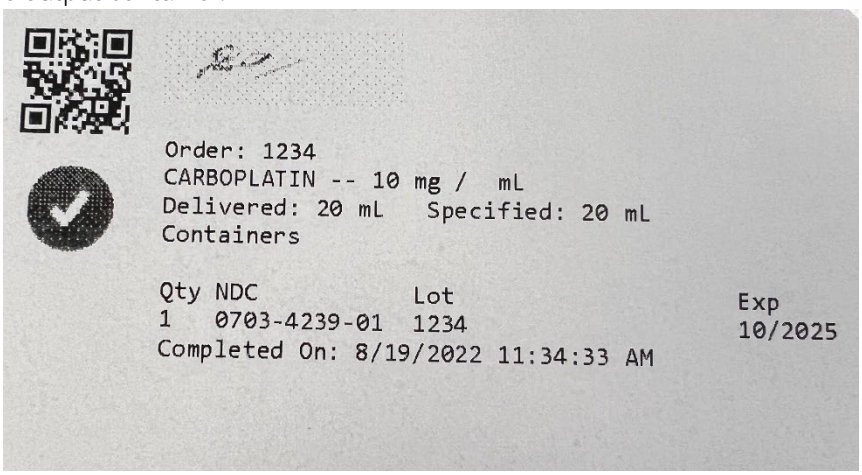
4. Touch the **Accept** button on the screen.



5. The software presents a **Signature** screen for the user to sign the transfer.

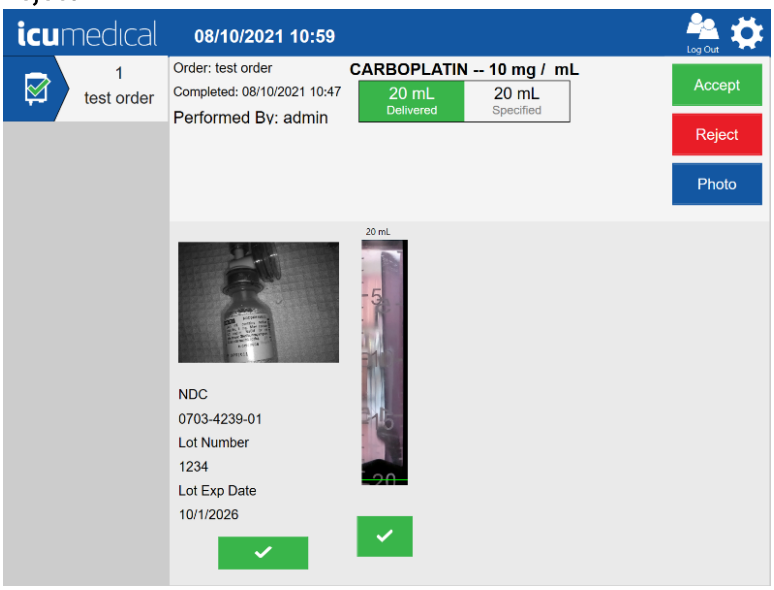


6. Once the pharmacist approves the transfer, a label will print, which should immediately be placed on the output container.

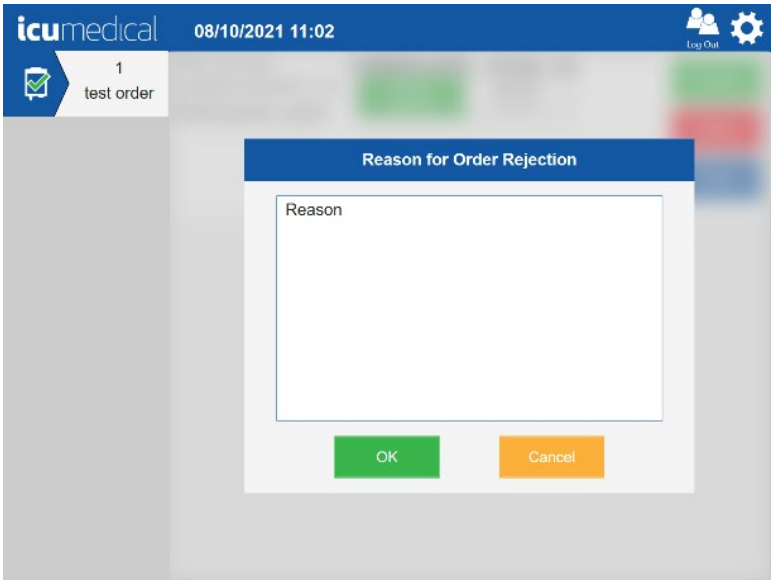


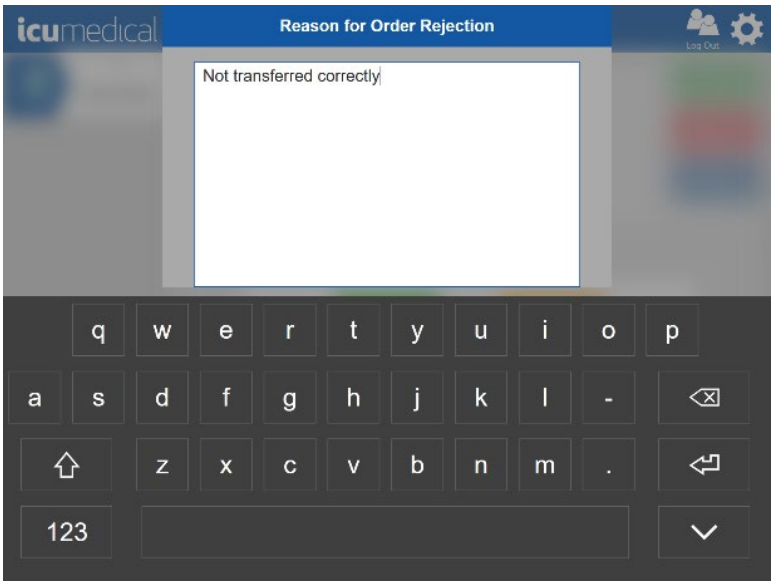
4.3.3.2. Rejecting a Transfer

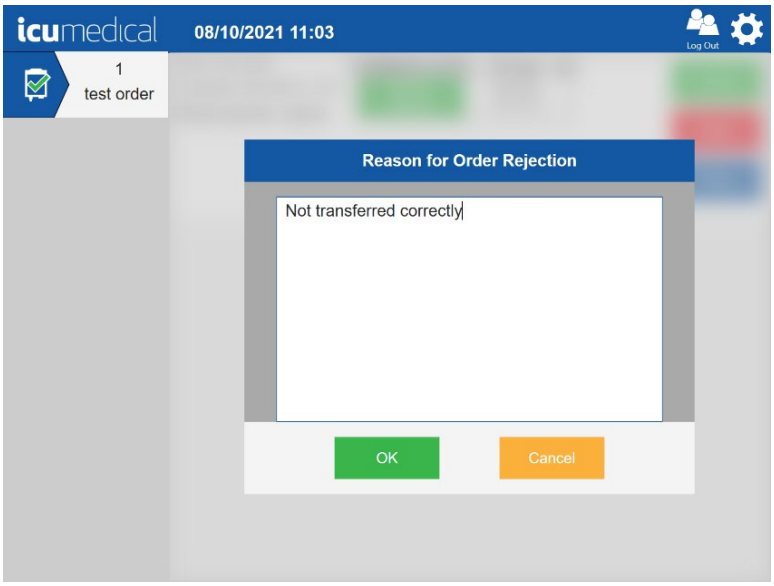
1. Tap the transfer with the corresponding preparation order to be validated.
2. Review the information.
3. Tap the **Reject** icon on the screen.



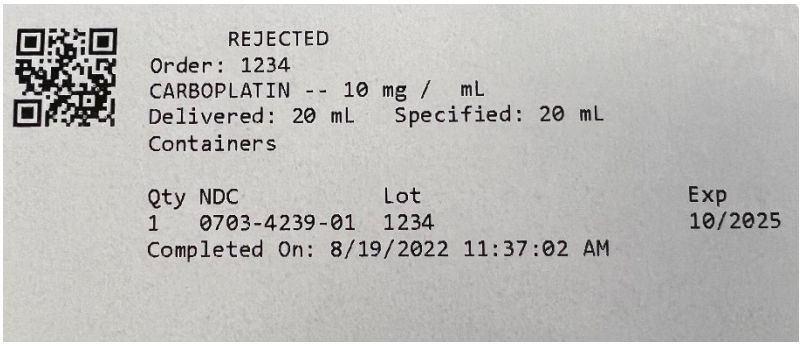
4. The software presents a **Reason for Order Rejection** screen for the user to provide the reason. Tap Reason area and enter the rejection reason. Tap on-screen Enter key and then tap OK button.







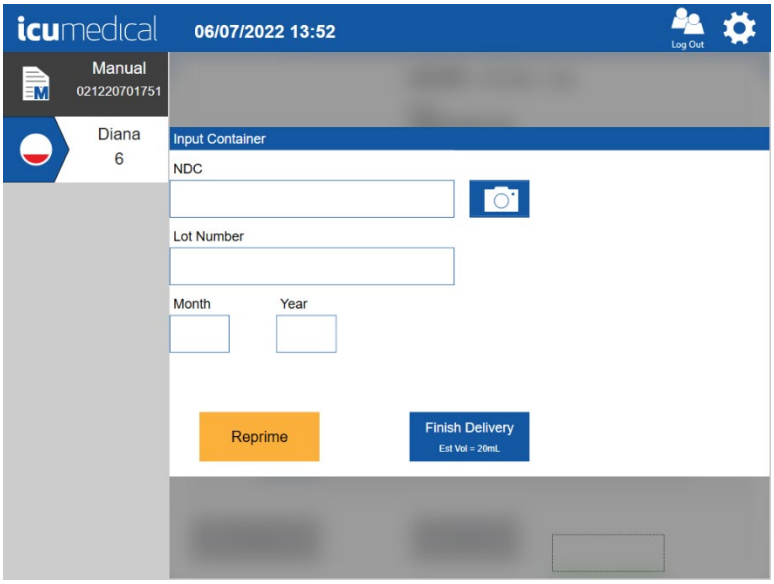
5. Once the pharmacist rejects the transfer, a label will print, which should immediately be placed on the output container.



4.3.4. Replacing the Empty Input Container

The Diana operator application notifies the user when an empty input container condition occurs. Follow the steps below to replace the empty input container.

1. When an empty input container condition occurs, the Diana operator application notifies the user.

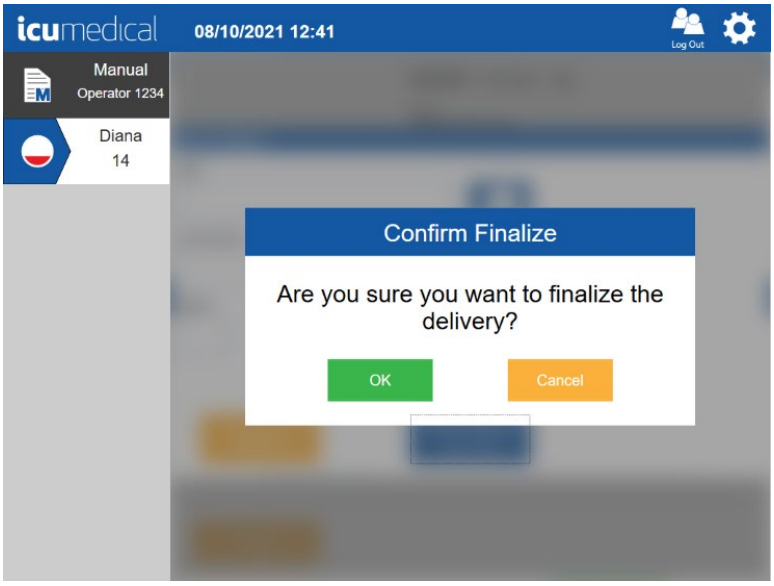


2. To replace the empty input container, proceed to **Step 3** in this section.

    a. User can choose **Reprime** (See above picture) if the input container is not empty.
    b. The user may choose to finalize the delivery process by tapping the **Finish Delivery** (See above picture) button.

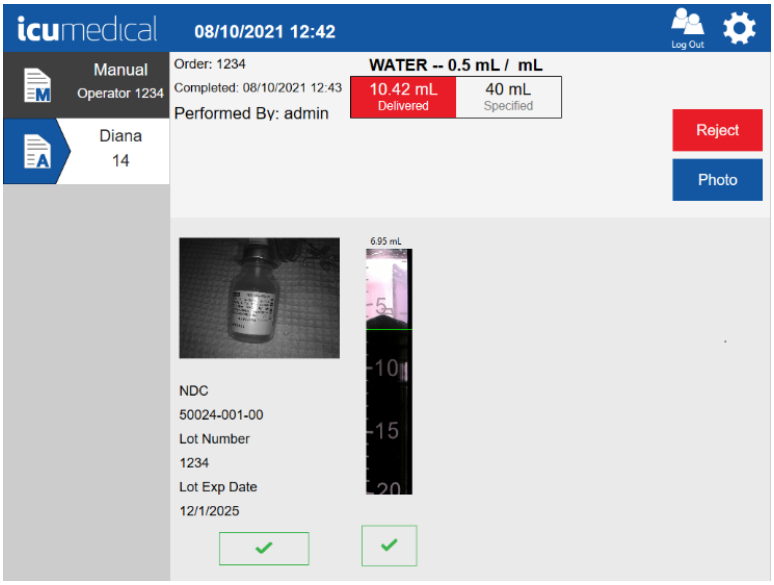
    Follow the steps below to Finalize the order without replacing the Empty Input Vial:

    i. The Diana Opeator application notifies the user to confirm the **Finalize** transfer process. The User can press the **Cancel** button to be taken back to the Empty Vial screen. Tap **OK** button to finalize the transfer process.



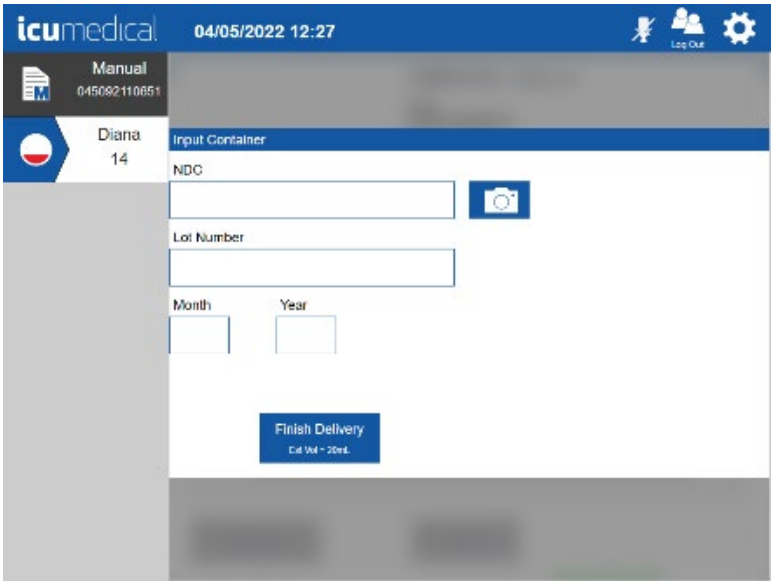
ii. The Diana Syringe Pump transfers the liquid from Diana Cassette to the output container and the verification screen displays to the user to accept or reject the transfer.

Note: Accept button displays when the user reviews and select the checkmarks under the pictures.

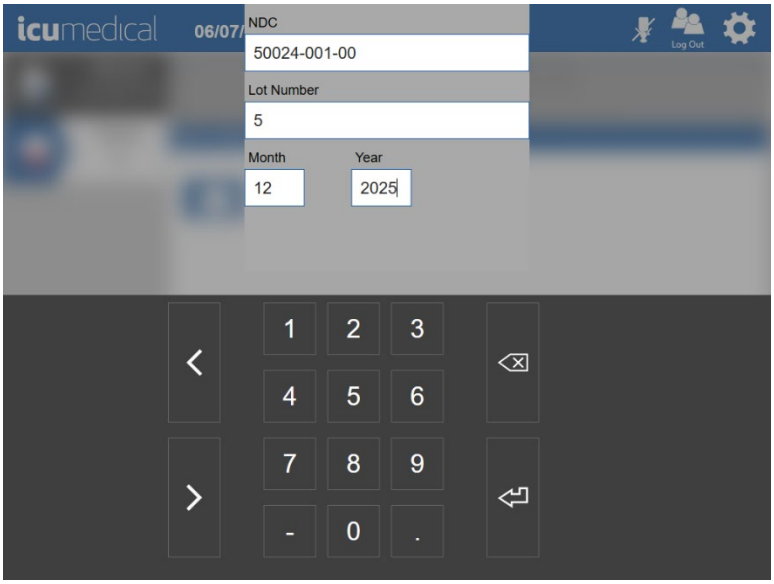


3. If the user wants to replace the input container, remove the empty input container. The following screen will display.

Note: Reprime button is not displayed once the user removes the empty input container.

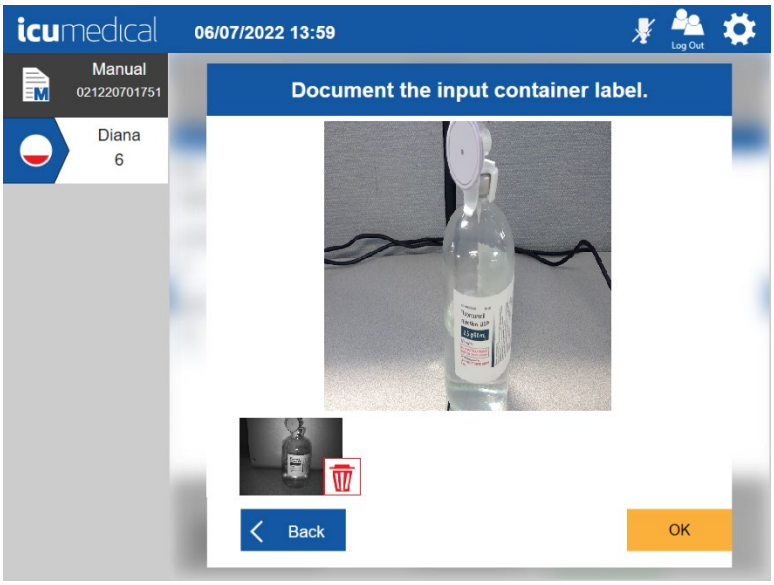


4. Enter/scan the new input container information. After entering the information, tap the onscreen keyboard **Enter** button. 

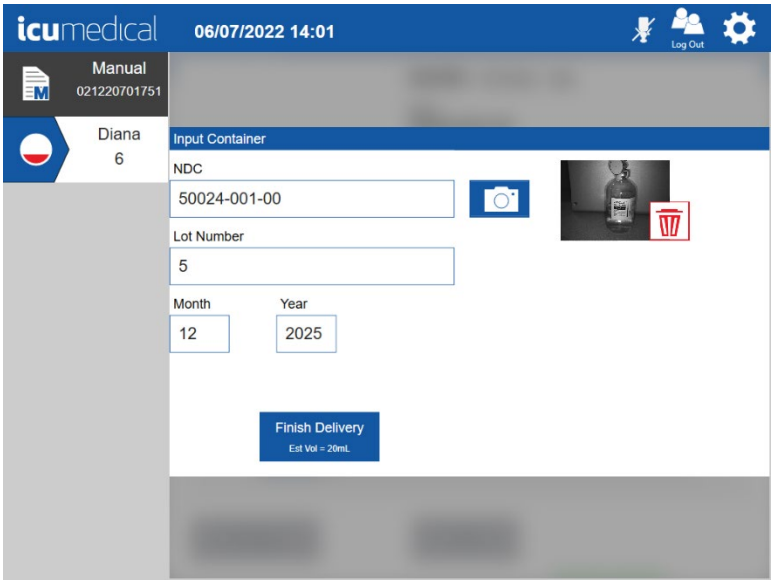


5. The software automatically opens the **Camera** Screen to take a picture of the input container.
   Note: The User must take the picture of the input container; otherwise, the software prevents the transfer process from progressing. To take a picture of the input container, a user may utilize the tablet camera or the barcode scanner.
6. Tap the **Capture** button. The operator application captures the picture and displays it on the screen.
   Note: The **Capture** button displays when the picture taking option is either Tablet Front or Tablet Rear in the System Settings. If the picture taking option is Scanner Video, only **OK** button displays.
7. To delete a picture, tap the **Delete** icon.

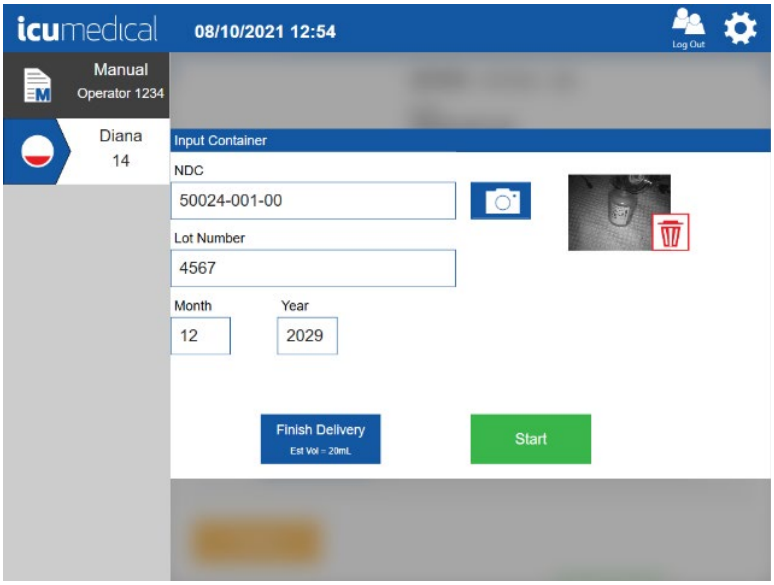
8. Tap the **OK** button to save the picture(s).

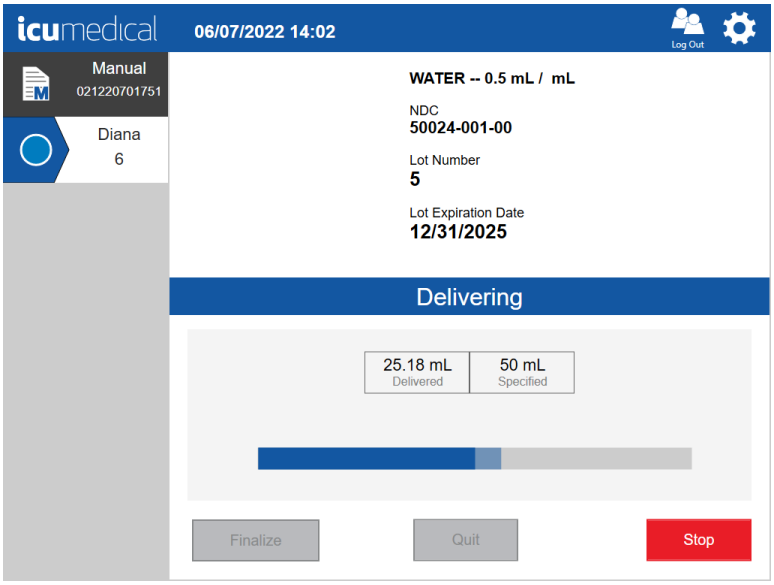


9. The Diana operator application prompts the user to attach the drug input container (blinking **input container** on the tool bar. See picture below).



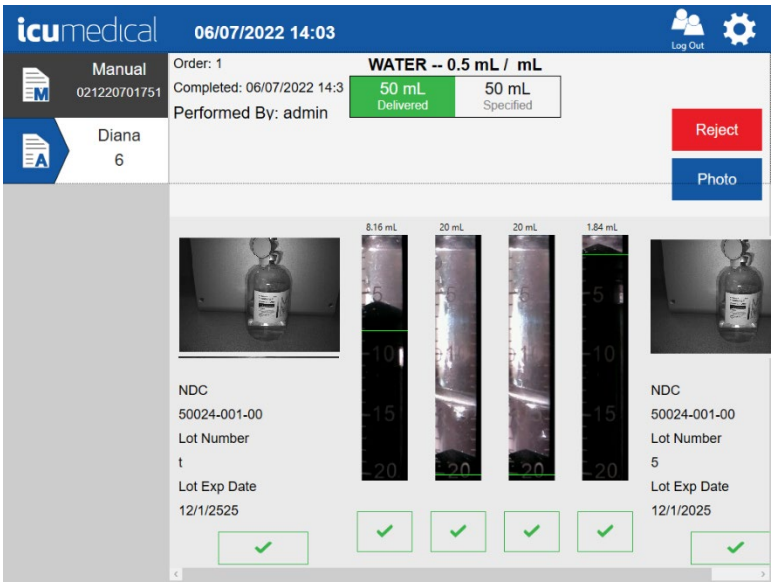
10. Connect the new input container to the Diana Cassette. The Diana operator application displays the following screen. Tap the **Start** button to continue the transfer process.



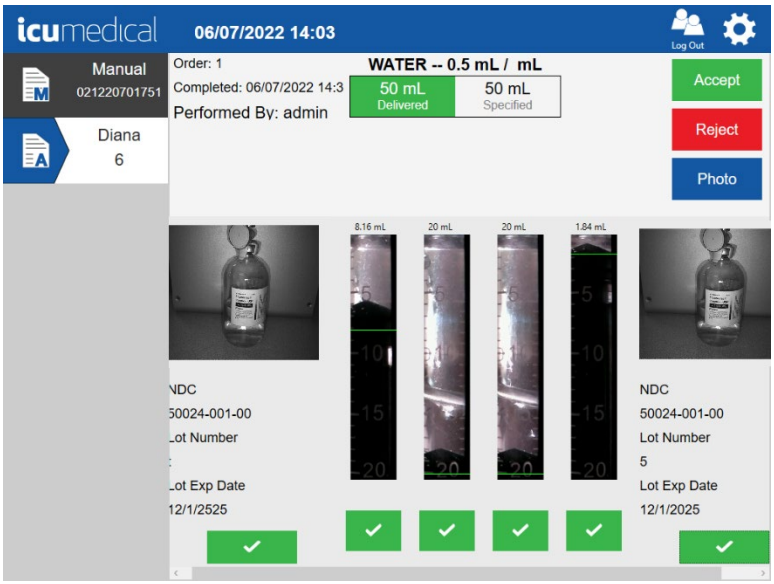


11. Once the delivery process completes, the Diana operator application provides a verification screen to user to verify the information.

    Note: The Diana operator application displays each input container's information on the verification screen.

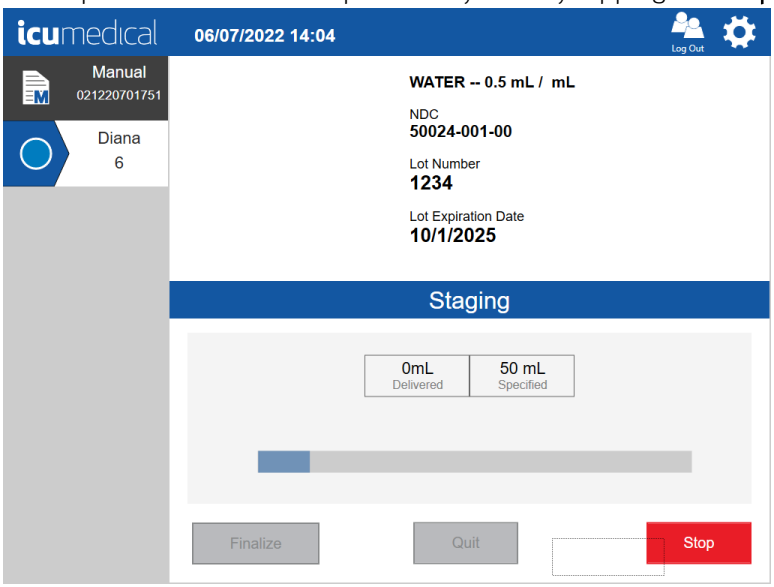


12. Review the pictures and Accept or Reject the preparation.

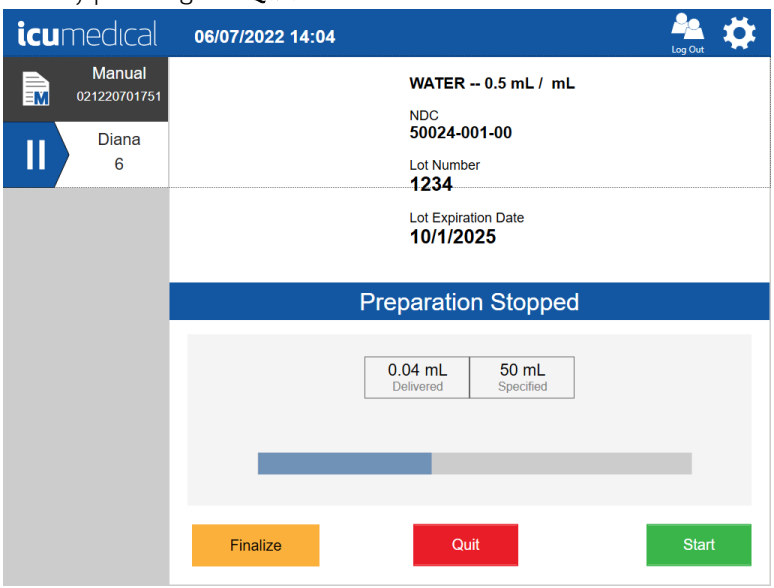


4.3.5. Interrupt Dispensing Process Using Stop

The compounding transfer process can be interrupted at any time by tapping the **Stop** button.

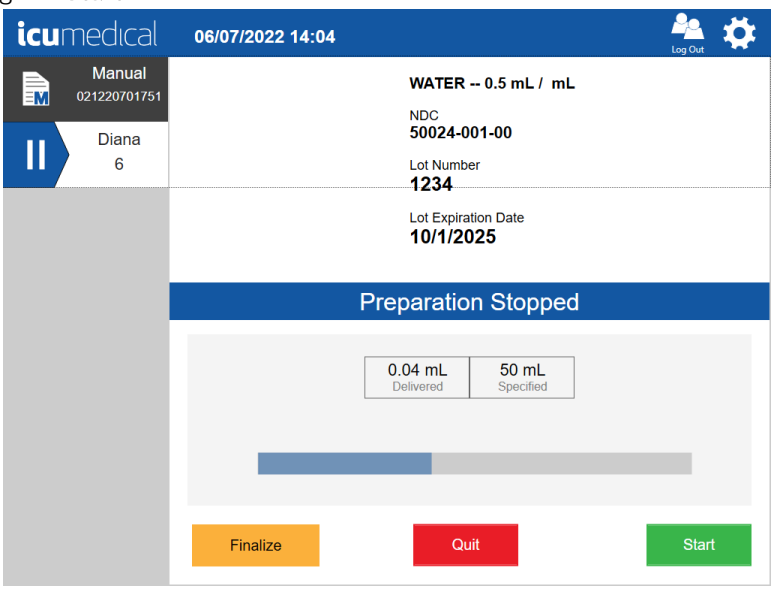


Once the user stops the transfer process, the Diana Operator application GUI presents options to the User to resume by pressing the **Start** button or finalize the delivery process by pressing the **Finalize** button or quit the delivery process by pressing the **Quit** button.

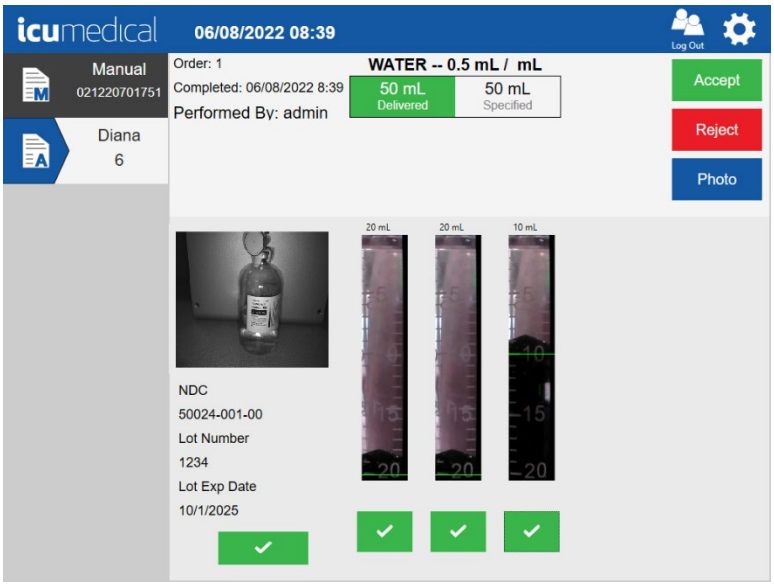


4.3.6. Resume After Stop

After the **Stop** button has been selected, the user can resume an interrupted compounding process without any errors by tapping the **Start** button.

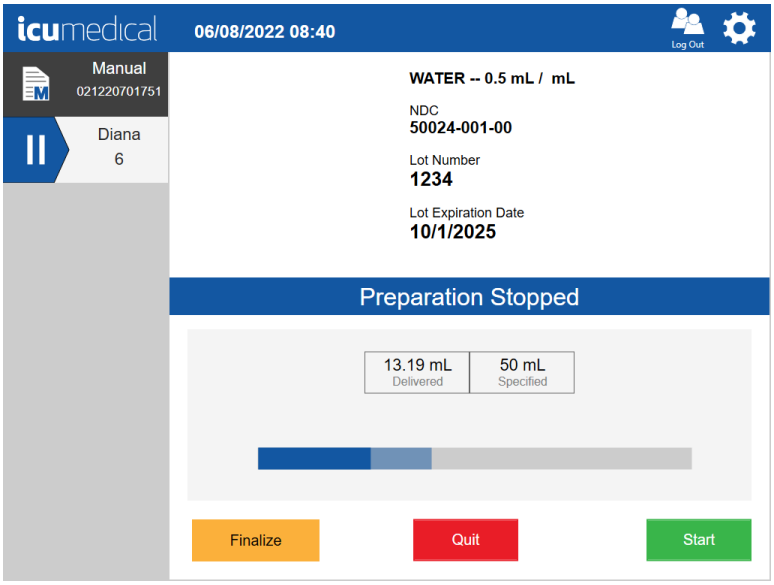


Once the user resumes the process; the Diana Operator application completes the drug transfer process and presents a verification screen to the user to accept or reject the transfer process.

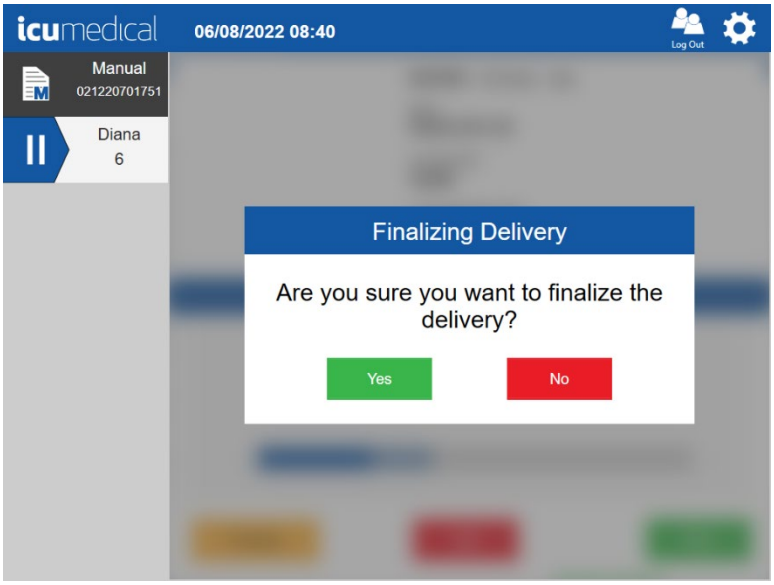


4.3.7. Cancel/Finalize the Delivery Process

Once the user stops the transfer process, the Diana Operator application presents options to the user to finalize the delivery process.

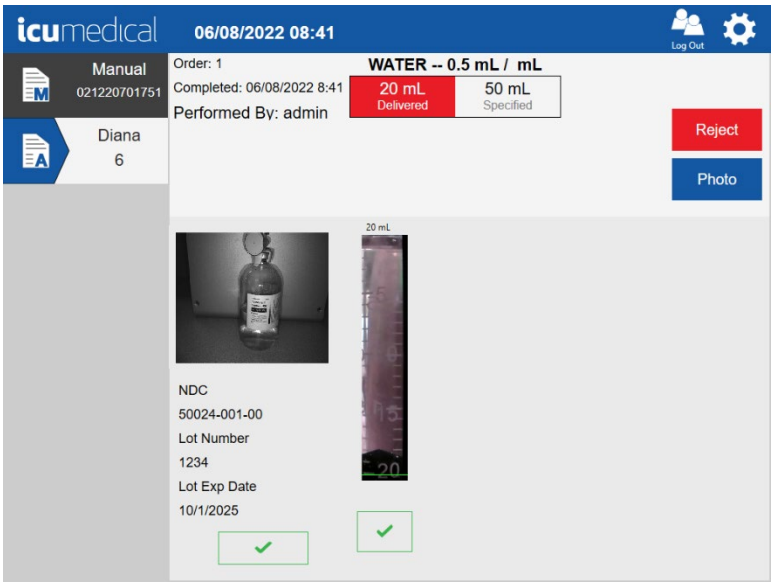


If the user finalizes the delivery process, the Diana Operator application prompts the user to confirm finalizing the delivery process.



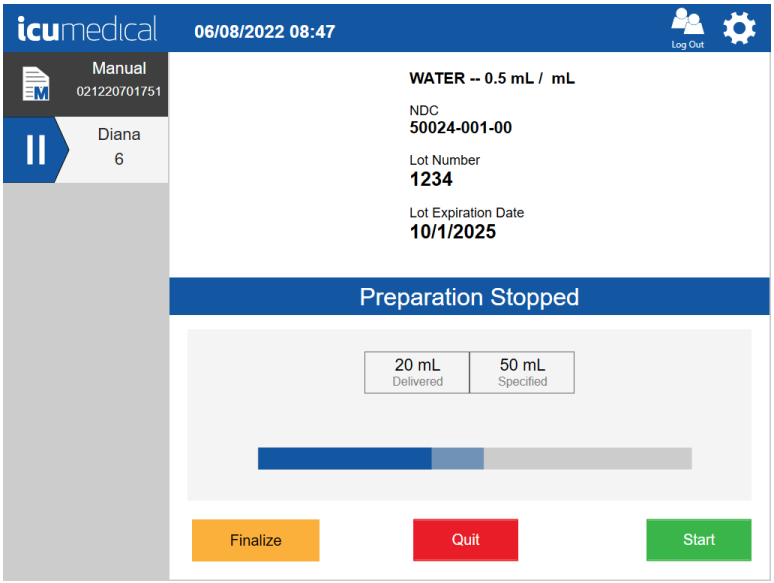
If the user taps the **Yes** button, the Diana Operator application GUI completes transferring the liquid from the Diana Cassette to the output container and presents a verification screen to the user to accept or reject the process.

Note: The Accept button displays when the user reviews and select the checkmarks under the pictures.

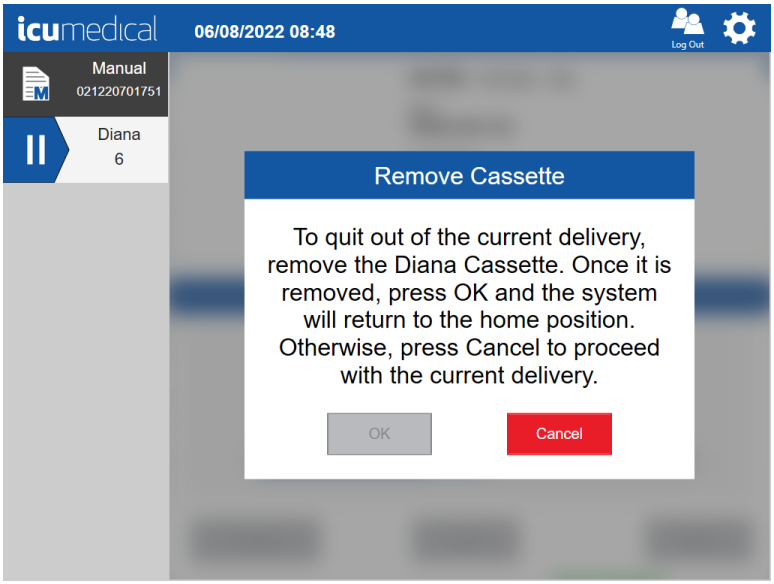


4.3.8. Quit the Delivery Process

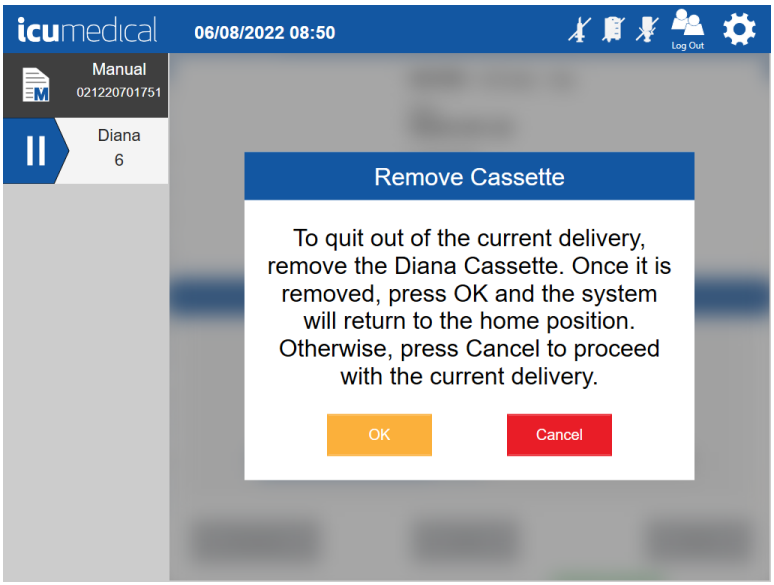
Once the user stops the transfer process, the Diana Operator application presents options to the user to quit the delivery process.



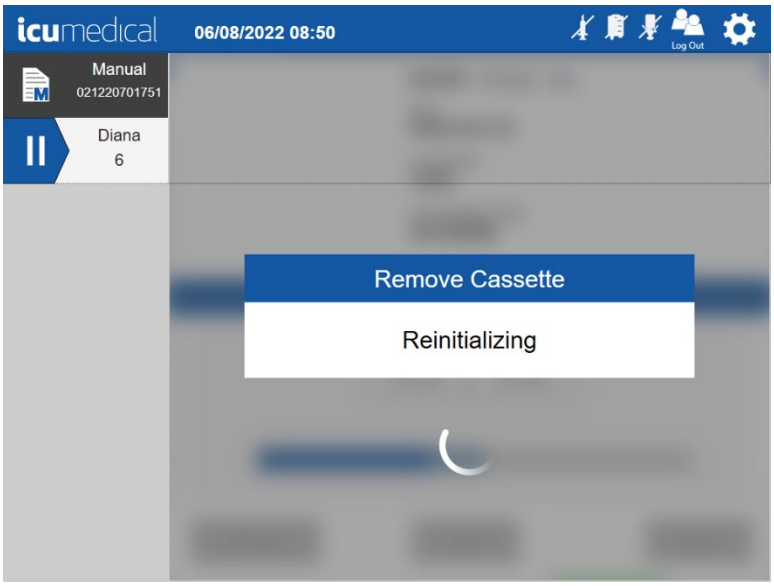
If the user is quitting the delivery process, the Diana Operator application instructs the user to remove the disposables, press OK, SPM goes through an initialization as if it were power cycled.



The user can tap the **Cancel** button to cancel the quitting process. If the user wants to quit the transfer process, the user has to remove the disposables from the compunder. The operator application enables the **OK** button.

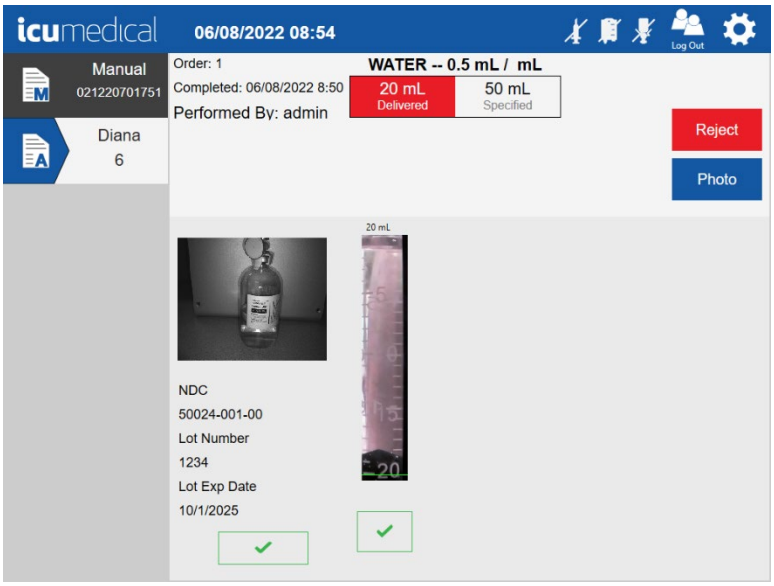


If the user taps the **OK** button, the Diana Compounder starts reinitialization process.



Once the reinitialization of the compounder completes, the Diana Operator application presents a verification screen to the user to accept or reject the process.

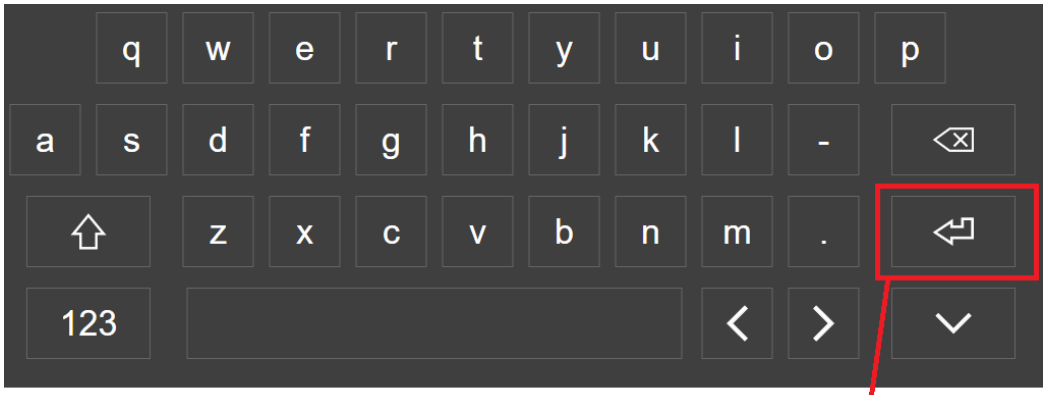
Note: The **Accept** button displays when the user reviews and select the checkmarks under the pictures.



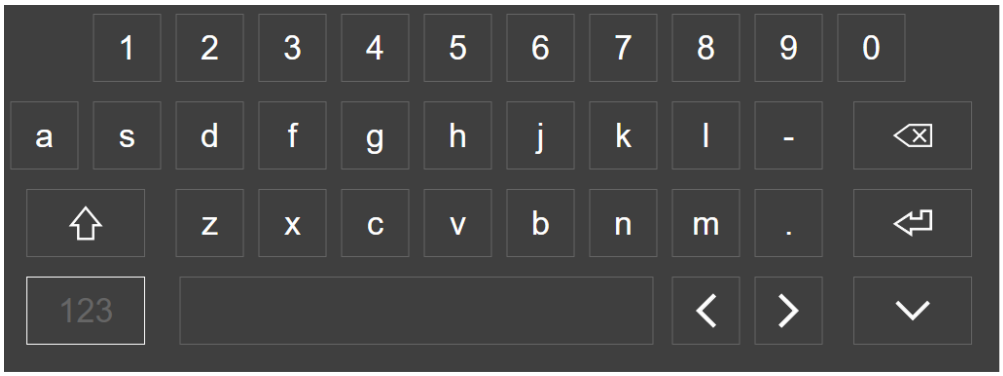
4.3.9. The Virtual Keyboard

An important part of the Diana Software User Interface is the virtual keyboard. The virtual keyboard is displayed when certain text boxes are touched or selected. These text boxes require some user input, such as entering an NDC (National Drug Code) or medication name. There are many uses for the virtual keyboard.

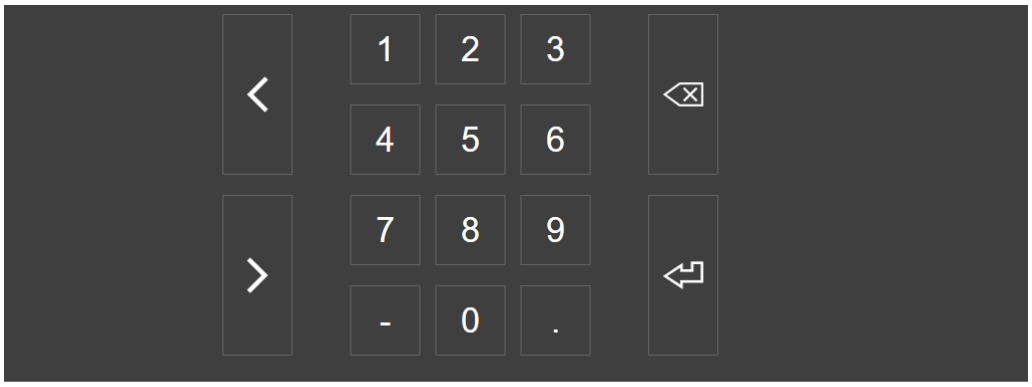
The virtual keyboard comes in two types: an alphanumeric keyboard and a numeric-only keypad. The numeric keypad is used when the input to the text box is restricted to numeric digits.



Virtual alphanumeric keboard



Virtual alphanumeric keyboard



Virtual numeric keyboard

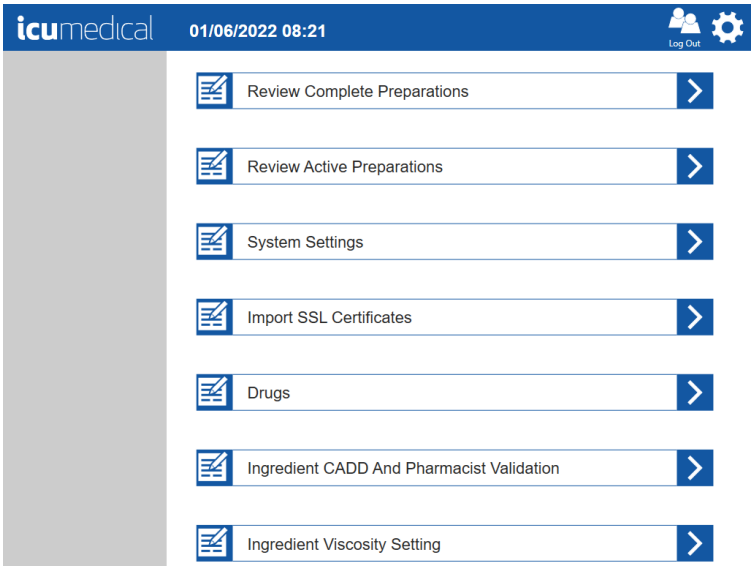
5. Tool Settings

Both the Diana Operator and the Pharmacist applications have user accessible settings. Some settings are available for both the Pharmacist and Operator applications, some are Pharmacist application only and some are Operator application only. Which settings are available is controlled by the tool settings configuration file. This file is created at implementation time and is not changeable by the user.

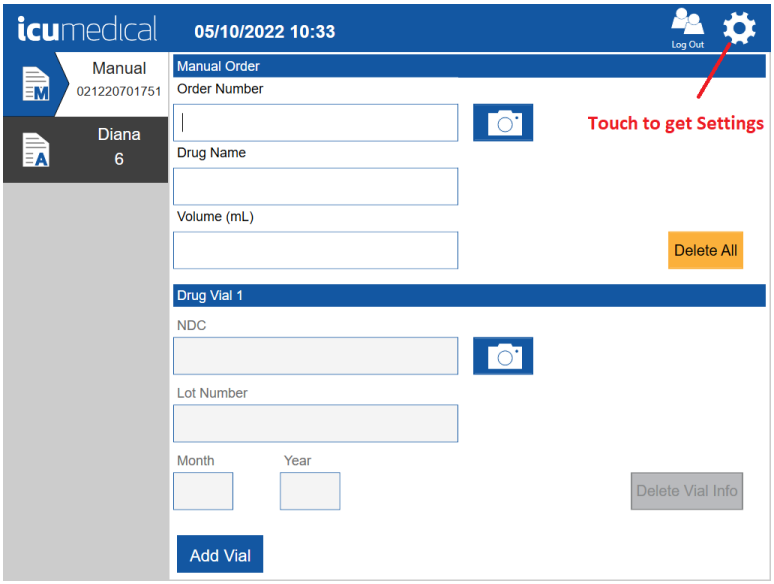
The table below shows the tool settings available on Diana Compounding Workflow System.

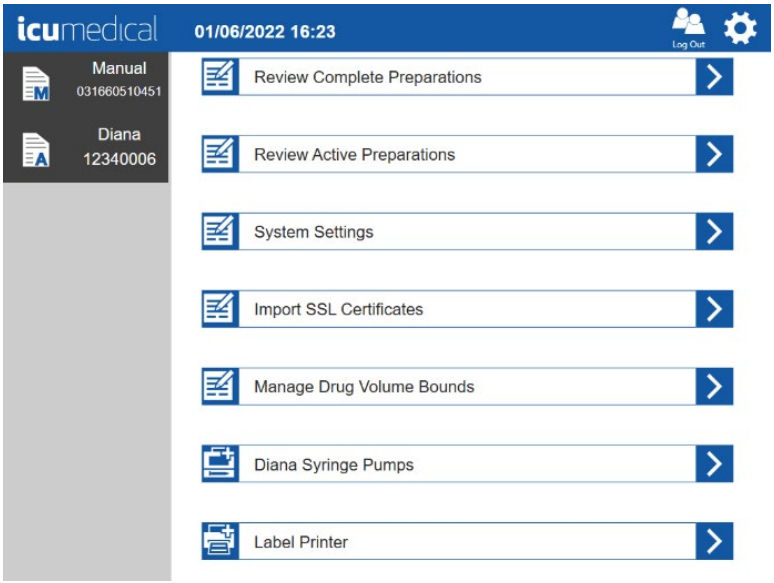
Tool Setting Name	Operator	Pharmacist
About This System	x	x
Review Complete Preparations	x	x
Review Active Preparations	x	x
Drugs		x
System Settings	x	x
Import SSL Certificates	x	x
Manage Drug Volume Bounds	x	x
Export Report	x	x
Export Logs	x	x
Label Printer	x	x
Diana Syringe Pumps	x	
Manage Users		x
Change Password	x	
Operator Tablets		x
Ingredient CADD And Pharmacist Validation		x
Ingredient Viscosity Setting		x

Settings on the Operator and Phamacist applications are displayed as a series of settings bars on the settings screen. The Pharmacist application startup screen displays the settings.



Getting to the settings for the Operator application, requires an additional step. To display the settings screen for the Operator application, the user must touch the gear icon in the upper right-hand corner of the Operator application main screen.

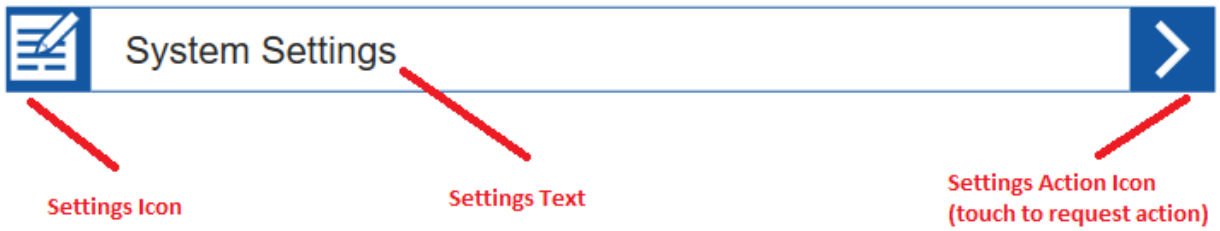




Both the Operator and the Pharmacist application settings screens are scrollable. There can be more settings than can be displayed at one time. Scrolling of the settings is simple; touch the screen in the settings area and drag up or down depending on the desired direction of scrolling.

The settings screen consists of several individual settings bars. Each setting bar has a descriptive icon on the left of the bar, text in the middle that briefly describes the associated setting and a settings action icon on the right of the bar. The settings action icon is a white colored right facing arrowhead against a blue background.

To launch any of the settings, touch the settings action icon of the desired settings bar.



Most settings screens have a Back button 

. Touching or selecting this button will return the display to the main settings screen.

5.1. Label Printer Setting

Contact ICU Service representative to assist in configuring printer.

Note: Due to size limitations of the printed labels, labels printed for preparations that use 14 or more unique vials in a single preparation may have missing information on the label. Printed label information is for reference only.

5.2. About This System Setting

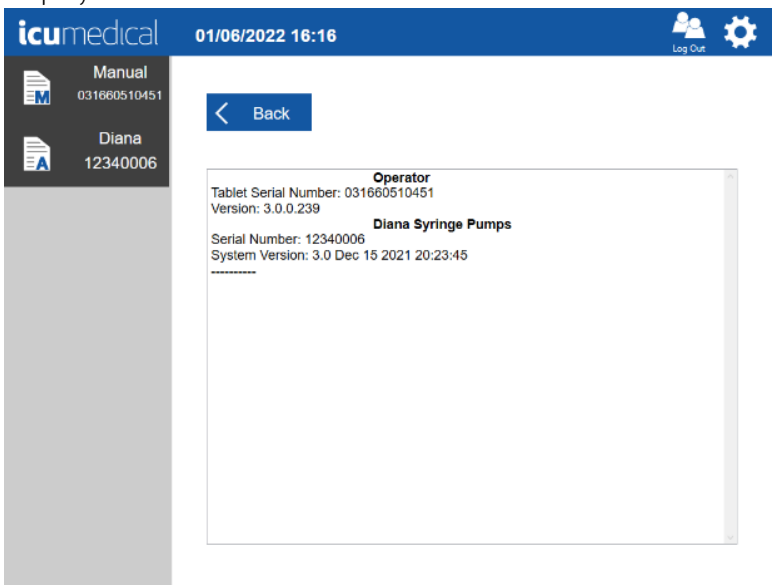
Touching the action icon of the About This System settings bar will display a screen that details the version and contents of the application.

1. Tap the Settings Icon
2. Tap the About This System setting action icon

The following information for the Operator and Pharmacist applications is displayed.

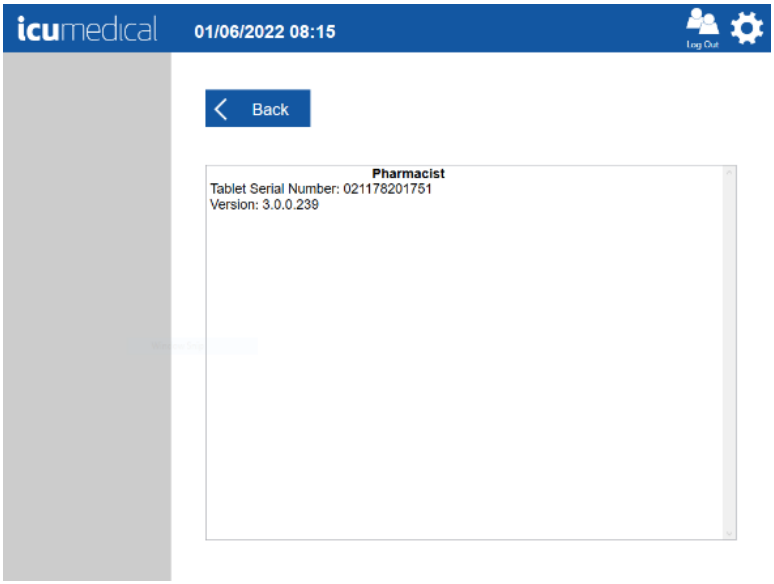
Operator:

- Tablet Serial Number
- Operator Application Version
- Diana Syringe Pump Serial Number
- Diana Syringe Pump System Version and Installed Date



Pharmacist:

- Tablet Serial Number
- Pharmacist Software Version



5.3. Operator Tablets Setting

The Diana Hazardous Drug Compounding System can have one or more operator tablets. The Pharmacist application (Pharmacist tablet) must know about them in order to properly communicate and coordinate user defined drugs and to validate preparations.

The Pharmacist application is configured at the factory to include all operator tablets associated with it, but over the lifetime of the system, the hosting clinic, hospital or pharmacy may add or replace some of the operator tablets. When that happens, the configuration of the Pharmacist application must be updated via the **Operator Tablets** setting.

This Operator Tablets setting option allows the user to do the following:

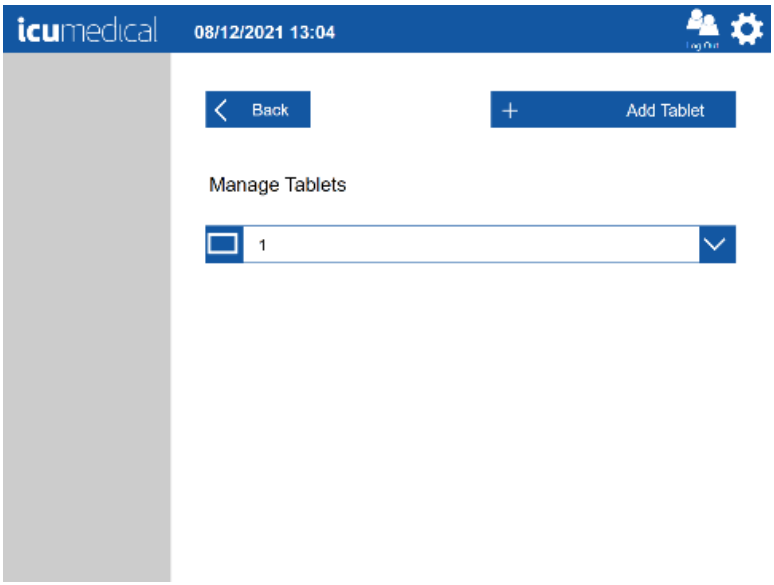
1. Add New Operator Tablet
2. Replace Existing Operator Tablet
3. Remove Operator Tablet

5.3.1. Add New Operator Tablet

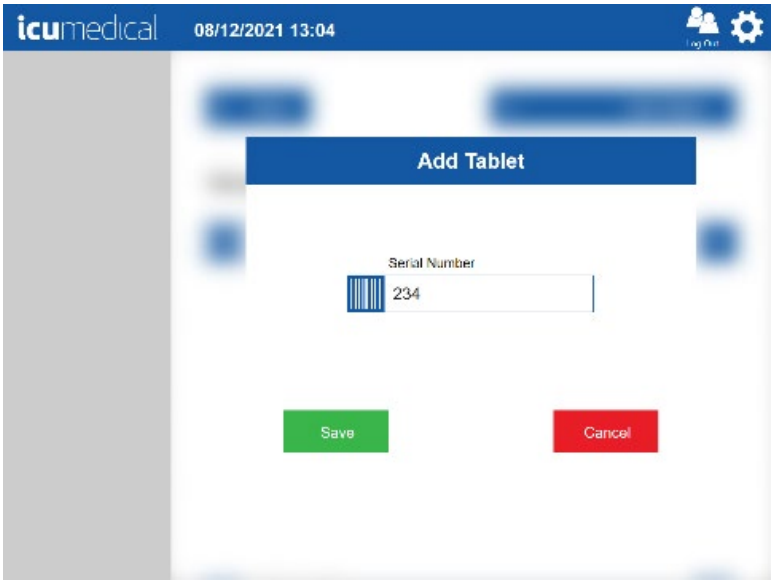
1. Tap **Settings** Icon
2. Tap **Operator Tablets** setting action icon

3. **Manage Tablets** screen is displayed

4. Tap the **Add Tablet** button in the **Manage Tablets** screen



5. Enter the Operator Tablet serial number in the **Add Tablet** pop-up window

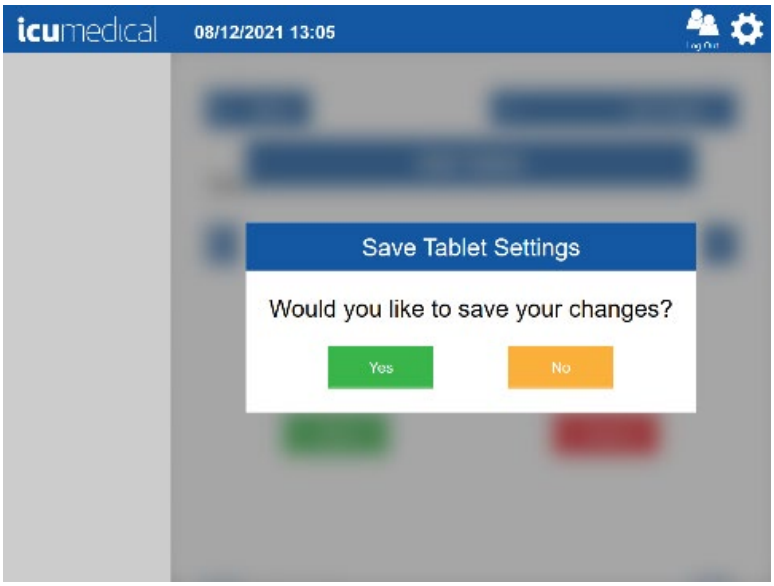


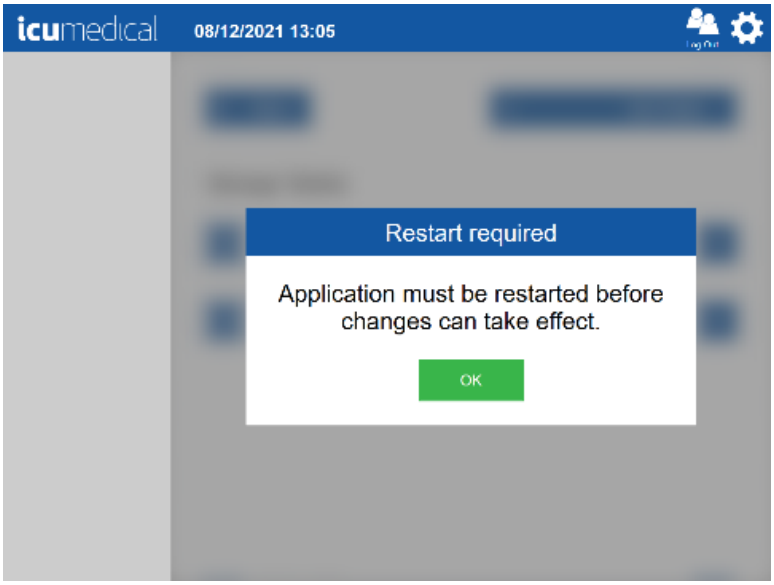
6. Tap the **Save** button

   Note: Tapping the **Cancel** button will return to the **Manage Tablets** screen without adding a new Operator Tablet to the system
7. Tap the **Yes** button on the **Save Tablet Settings** confirmation page

   Note: Tapping the **No** button will return to the **Add Tablet** pop-up window
8. Tap the **Ok** button on the **Restart Required** confirmation message pop-up window

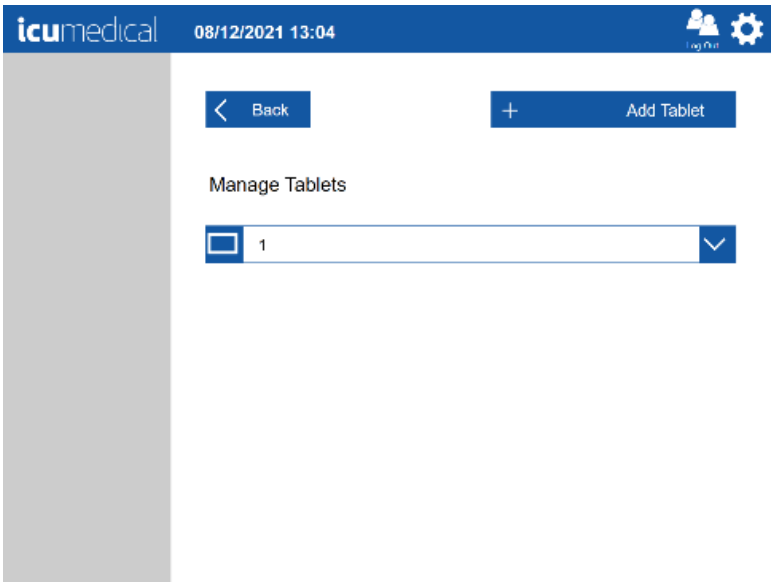
9. Restart the Operator application



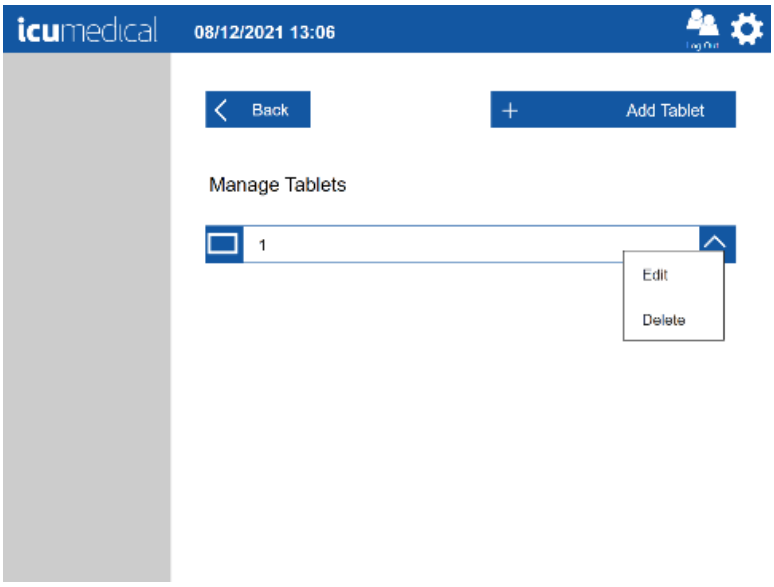


5.3.2. Replace Existing Operator Tablet

1. Tap the **Settings** Icon
2. Tap the **Operator Tablets** setting action icon

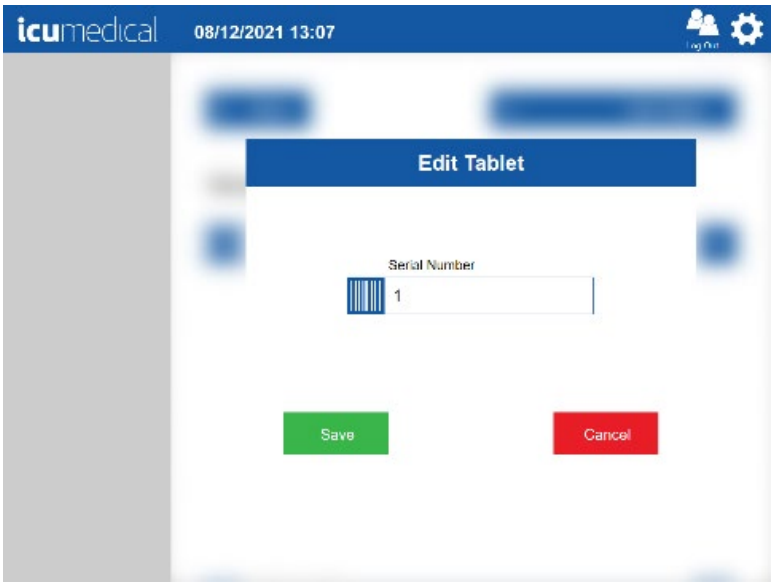


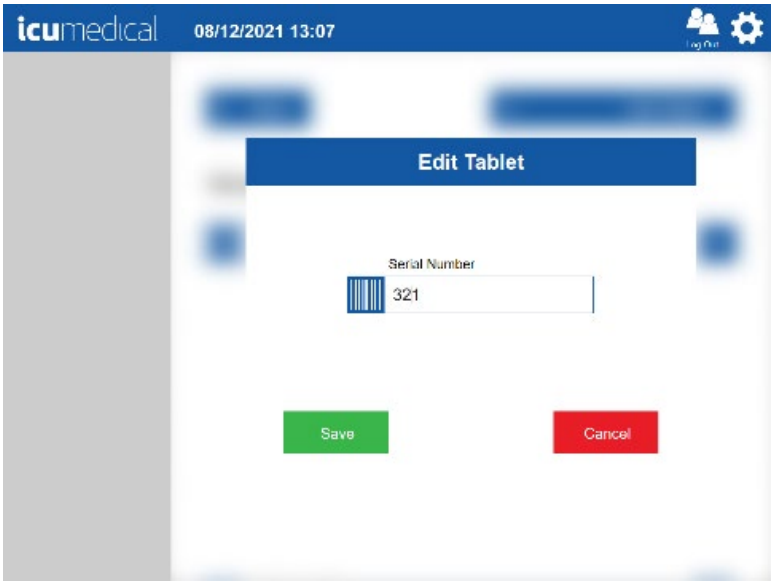
3. **The Manage Tablets** screen is displayed
4. Tap the action icon for the existing Operator tablet bar
5. A pop-up menu indicating **Edit** and **Delete** is displayed



6. To replace the Operator tablet, tap **Edit**

7. Change the Operator tablet serial number in the **Edit Tablet** pop-up window



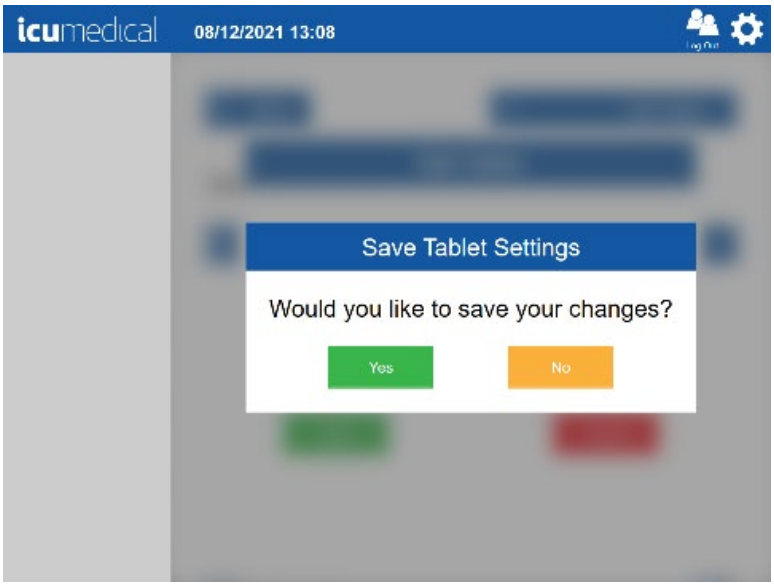


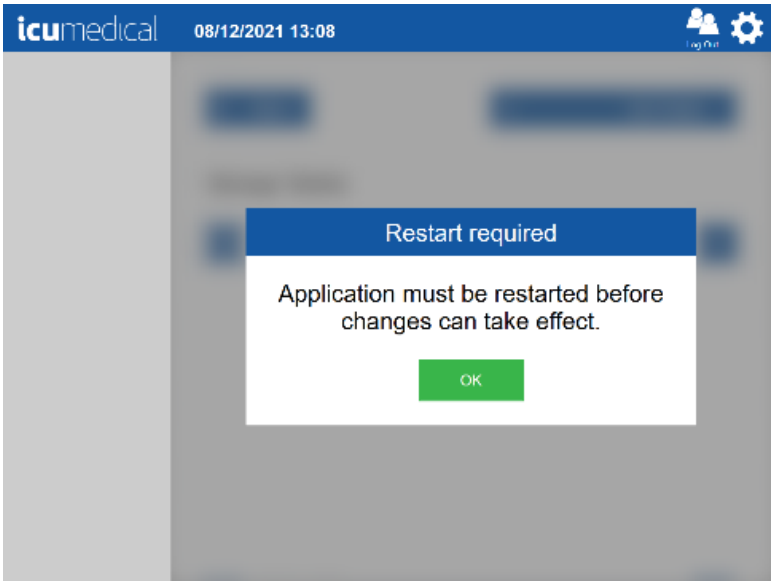
8. Tap the **Save** button

   Note: Tapping the **Cancel** button will return to the **Edit Tablet** screen without editing the existing Operator tablet serial number
9. Tap the **Yes** button on the **Save Tablet Settings** confirmation page

   Note: Tapping the **No** button will return to the **Edit Tablet** pop-up window
10. Tap the **Ok** button on the **Restart Required** confirmation message pop-up window

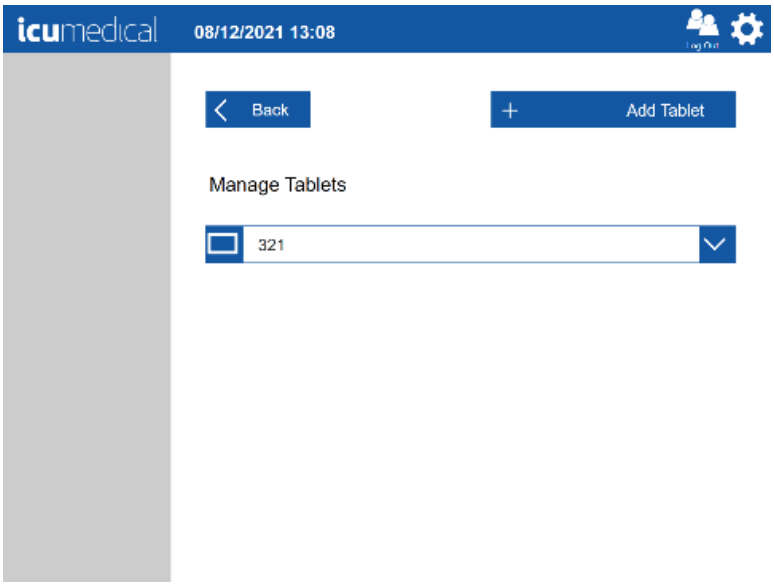
11. Restart the Operator application



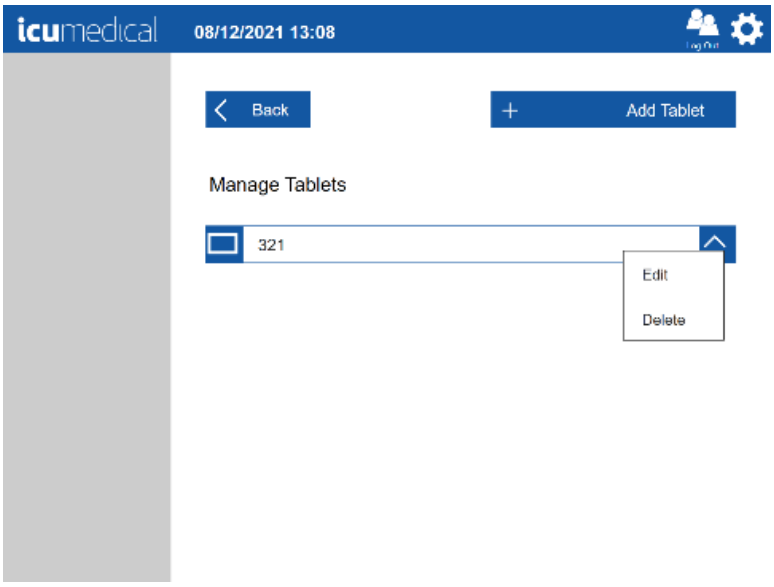


5.3.3. Remove Operator Tablet

1. Tap the **Settings** Icon
2. Tap the **Operator Tablets** setting action icon
3. **The Manage Tablets** screen is displayed



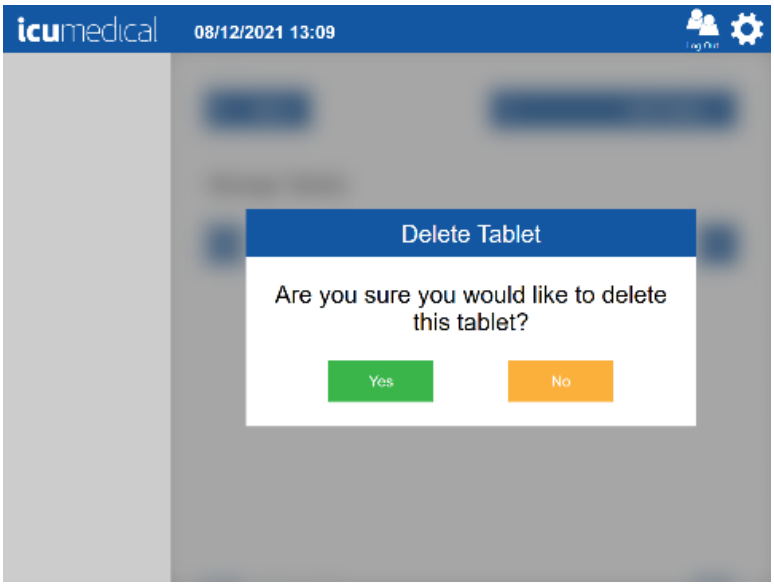
4. Tap the action icon for the existing Operator tablet bar
5. A pop-up menu indicating **Edit** and **Delete** is displayed

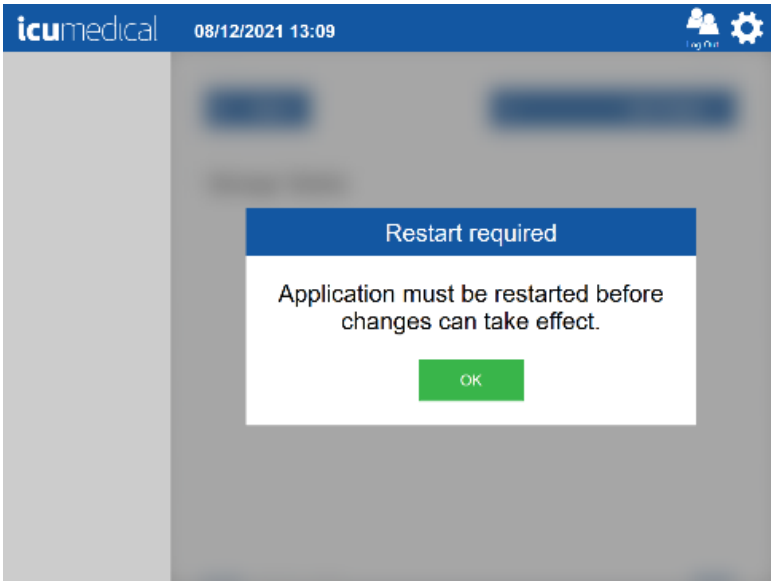


6. To remove the Operator tablet, tap the **Delete button**
7. Tap the **Yes** button on the **Delete Tablet** confirmation pop-up window

   Note: Tapping **No** button will return to the **Manage Tablets** screen pop-up

8. Restart the Operator application





5.4. Diana Syringe Pumps Setting

Contact ICU Service representative to assist in configuring Syringe Pumps.

5.5. Drugs Setting

Since both user defined, and FDA defined drugs are part of the Diana Automated Compounding System, the **Drugs** setting allows the user to do the following:

1. Create Drug
2. Edit Drug
3. Delete Drug

5.5.1. Create Drug

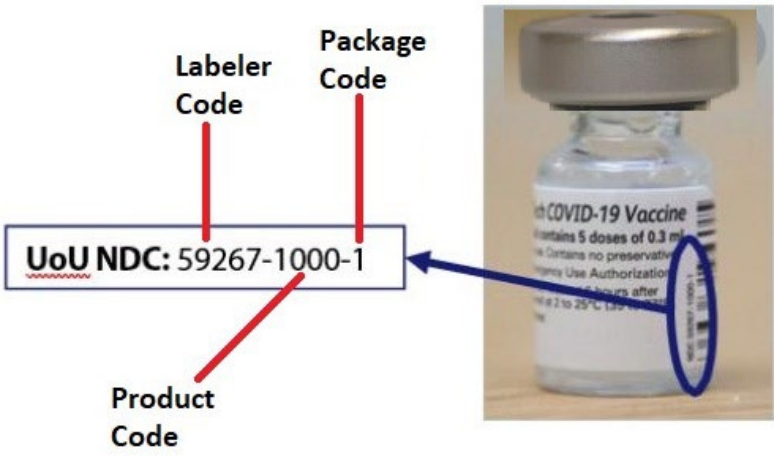
The System allows the user to create new user defined drugs and/or drug concentrations in to the system.

If the user wants to add a new drug (Drug ID aka NDC code) to an existing drug ingredient, follow the section **5.5.1.1 Create New Drug ID** section.

If the user wants to create a custom drug (Drug ID, custom drug name and concentration) follow the section **5.5.1.2 Create Custom Drugs** section.

If the user wants to create a custom, user definable mass and volume values (Drug ID and new concentration to an existing Drug Ingredient) for the drug follow the section **5.5.1.3 Create Custom Mass Volume For a Drug** section.

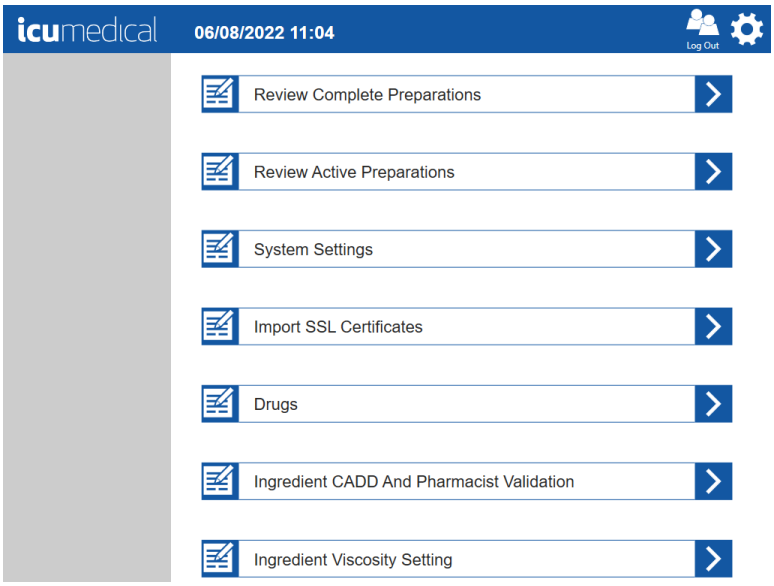
NDC Codes (Drug IDs) are printed on medication containers. They consist of three pieces: Labeler Code, Package Code, and Product Code as shown in the example below.



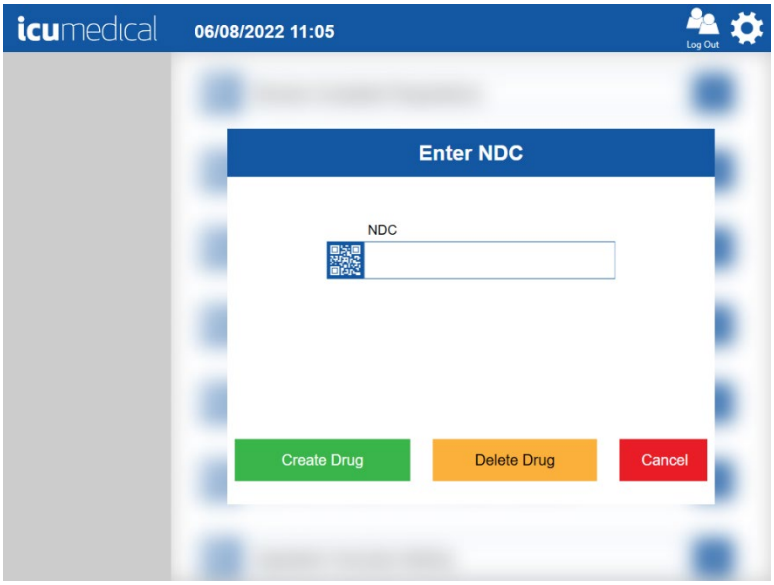
In the instructions that follow, the Labeler Code, Package Code, and Product Code values shown are just examples. Use the specific values for your drug.

5.5.1.1. Create Drug ID for a drug missing from the Library

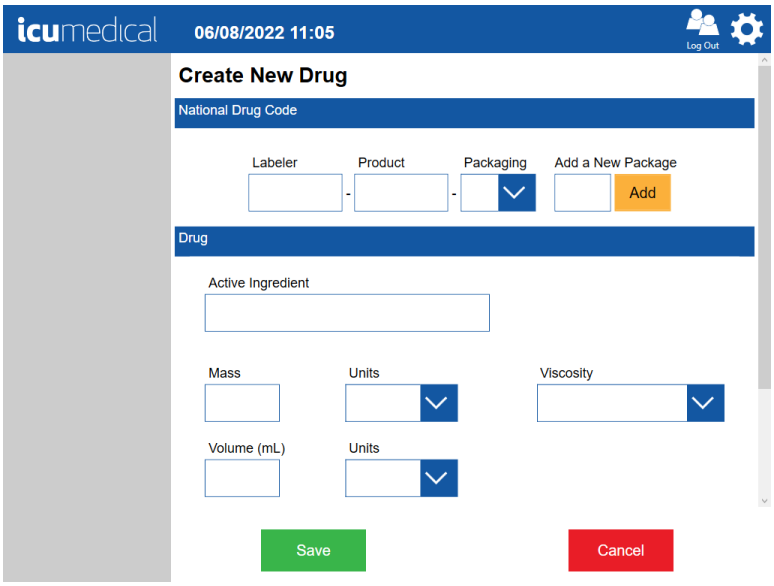
1. On the Pharmacist application tap the **Settings** icon
2. Tap the **Drugs** setting action icon



3. **The Enter NDC** window is displayed

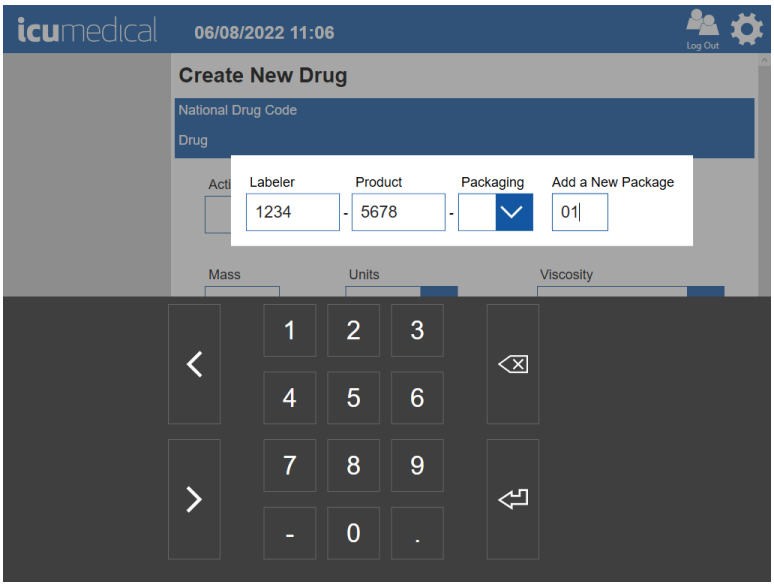


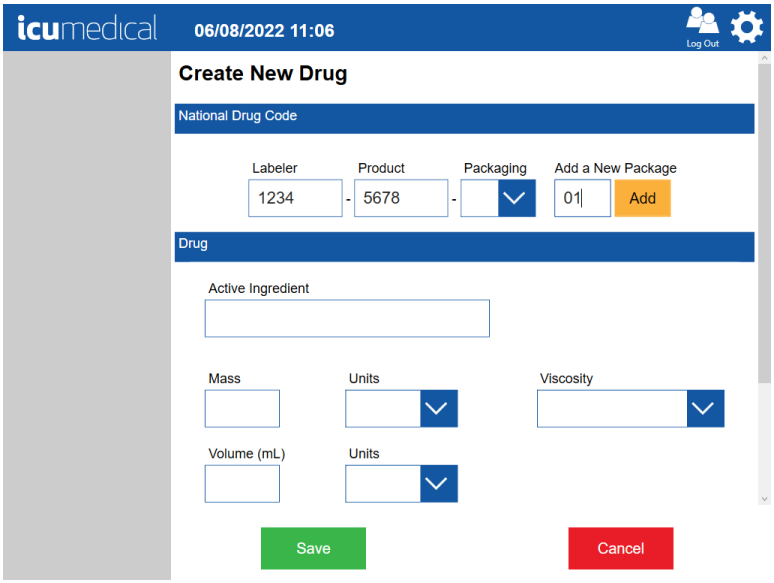
4. Tap **the Create Drug** button and the **Create New Drug** screen is displayed



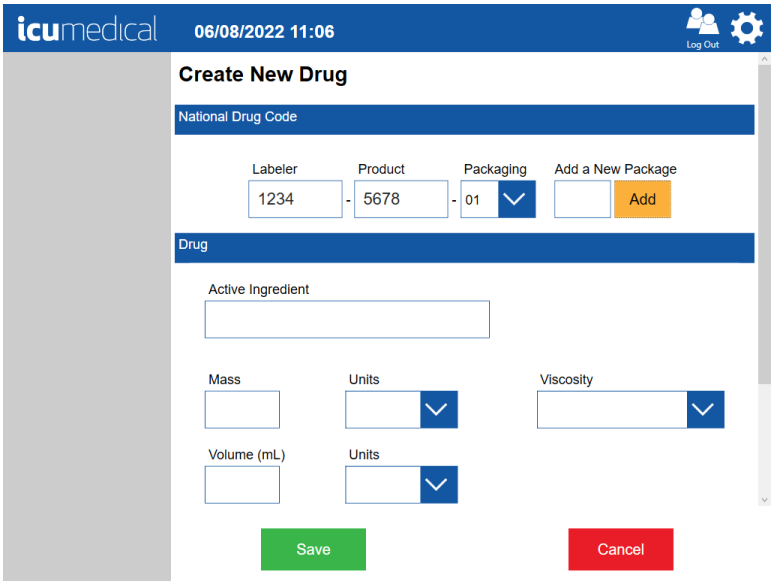
5. Tap the **Labeler** field and enter the values for **Labeler**, **Product** and **Add New Package** codes and then tap on-screen enter key

   Note: Need to tap on each field to enter the values

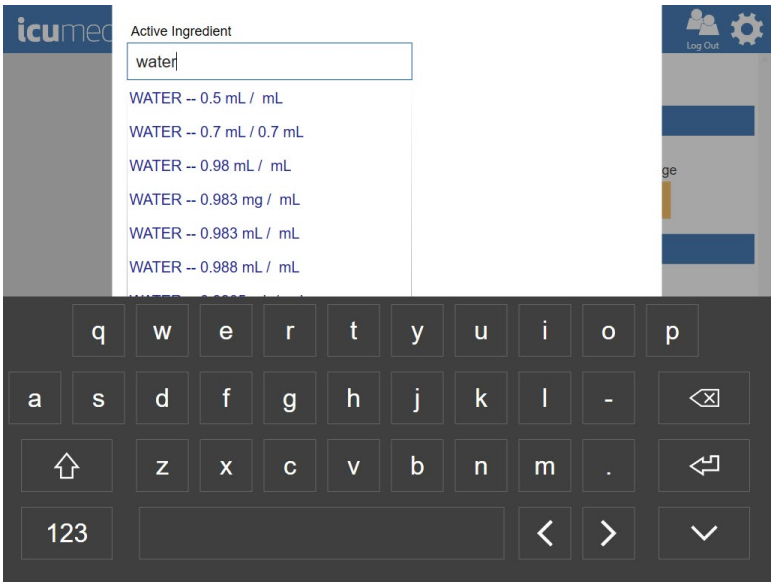




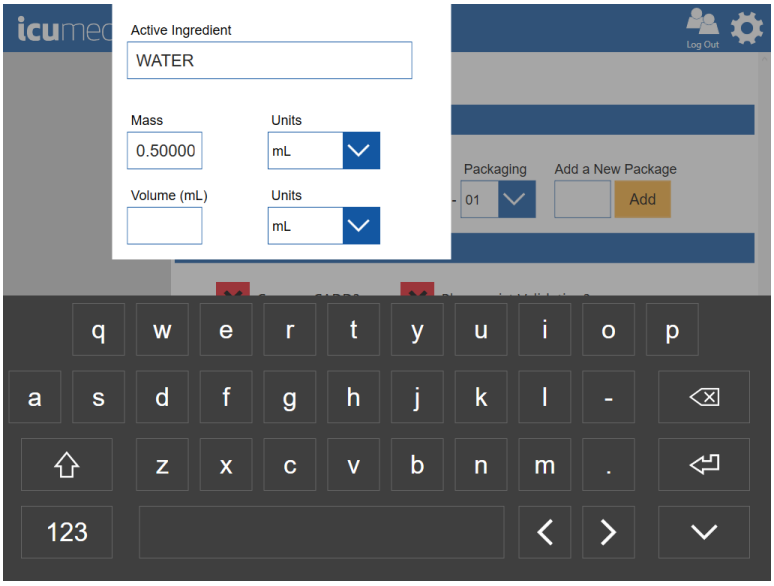
6. Tap the Add button. Entered new Package value is added to the Packaging dropdown list

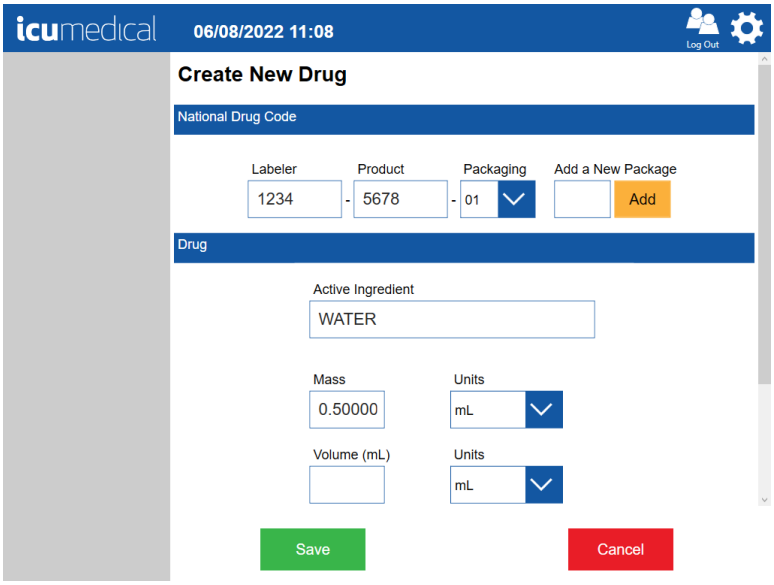


7. Tap the **Active Ingredient** field and type the first letter of the desired ingredient, and a list of ingredients starting with that letter will be displayed. Select the Ingredient from the list. The Application automatically enters the values for the following:
   a. **Active Ingredient**
   b. **Mass** value and **Mass** units
   c. **Volume** value and **Volume** units



8. Tap on-screen enter key

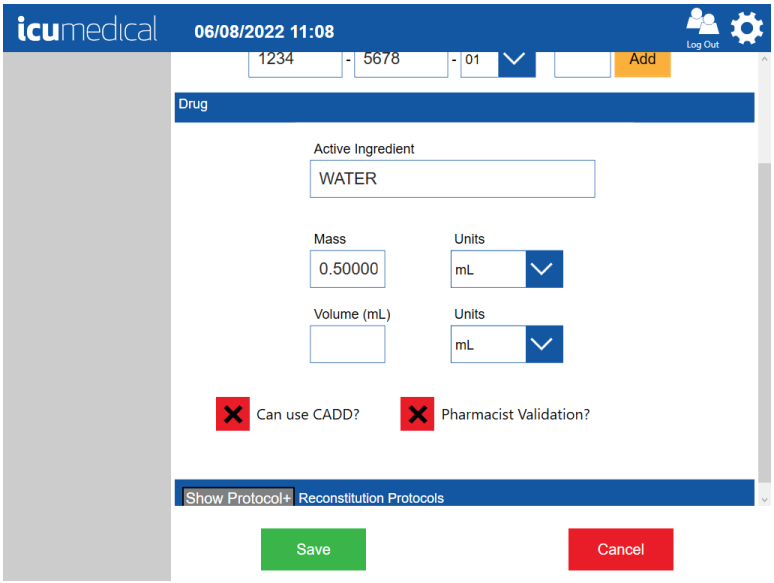




9. Choose the following if necessary for the NDC
   a. Select or Deselect Can use CADD?

b. Select or Deselect **Pharmacist Validation?**

Note: Scroll down to see the **CADD** and **Pharmacist Validation** options



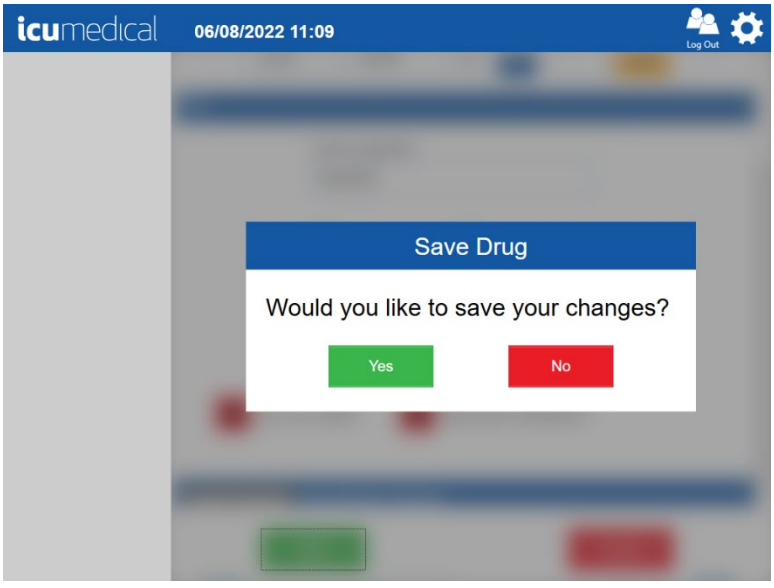
10. Tap the **Show Protocol+** button if the new drug requires Reconstitution Protocols

    Note: Refer to the Making a Reconstituted Drug section to view instructions for adding a Reconstitution protocol to a drug

11. Tap the **Save button** to add the new drug to the drug library or tap **Cancel** to cancel the new drug creation

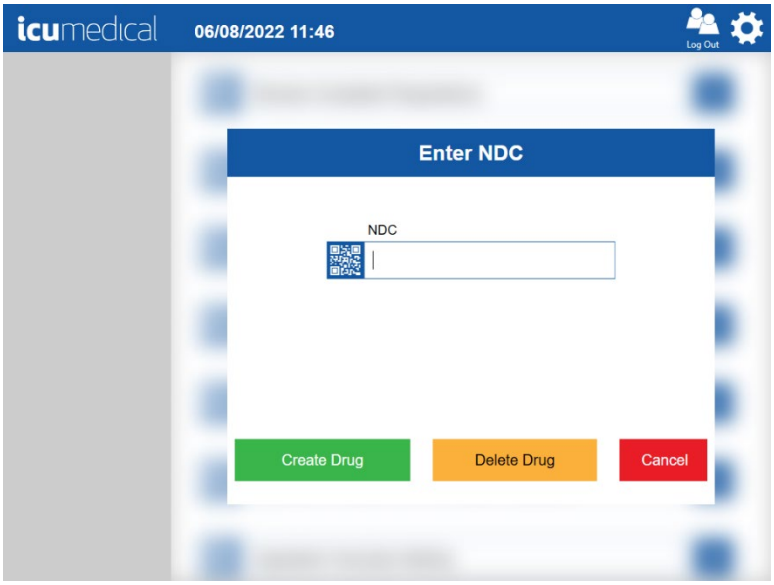
12. Tap the **Yes** button on the **Save Drug** confirmation page

    Note: Tapping the **No** button will return to the **Create New Drug** screen



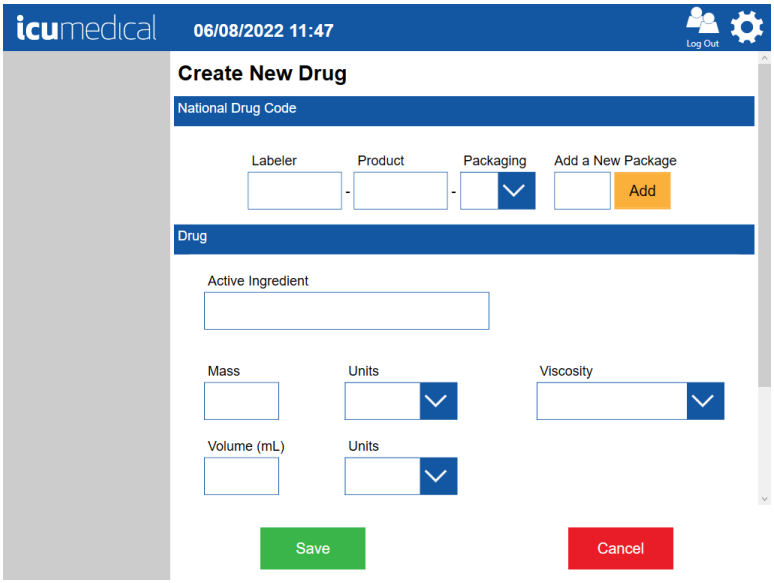
5.5.1.2. Create Custom Drugs (e.g., investigational drug)

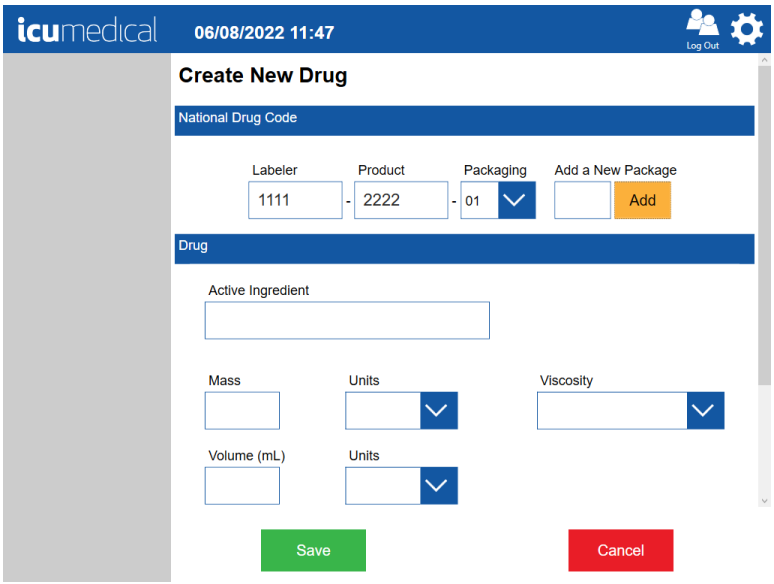
1. From the Pharmacist application, select the **Settings** icon.
2. Select **Drugs** option and on the **Enter NDC** screen tap **Create Drug** button.



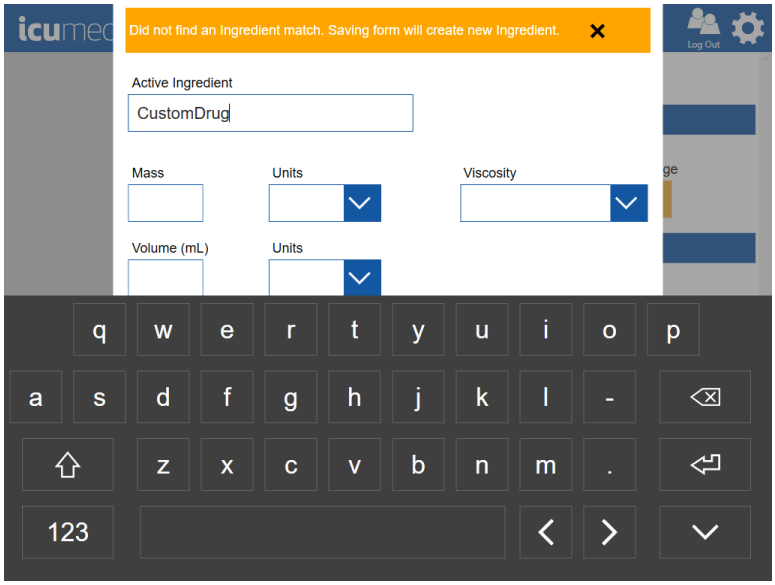
3. On the **Create New Drug** screen enter the following for the **National Drug Code** section and tap the **Add** button. Verify that the package is added to the Packaging list.
   Labeler -› **1111 (example; do not use an existing labeler code)**
   Product -› **2222 (example)**
   Add a New Package -› **01 (example)**

   Note: Labeler, Product, and Packge values must be entered for the newly created drug or it not be usable by the Diana system.





4. Tap on the **Active Ingredient** field and by using on-screen keyboard enter, for example, **CustomDrug**. Notice that Pharmacist application notifies "**Did not find an Ingredient match. Saving form will create new Ingredient**" banner message to the user.



5. Enter/Select the following values and tap on-screen **Enter** key once the values are entered/selected.

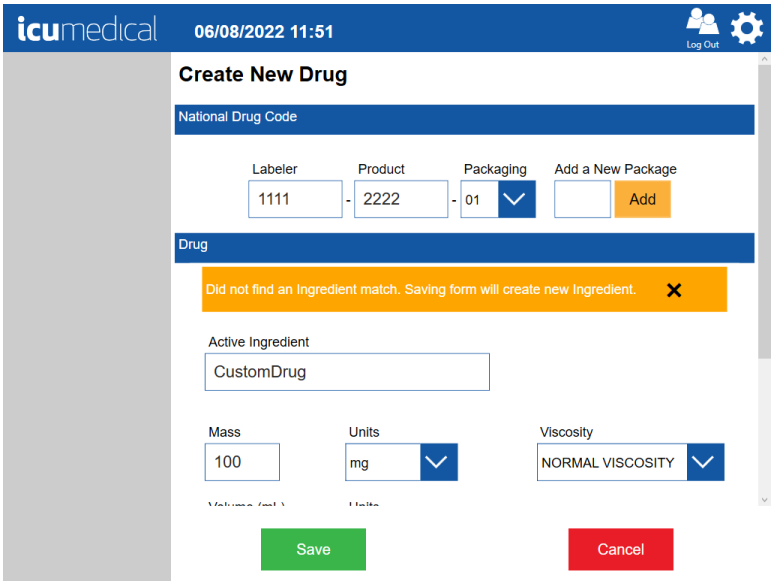
   Mass-› **100 (example)**

   Mass Units-›**mg (example)**

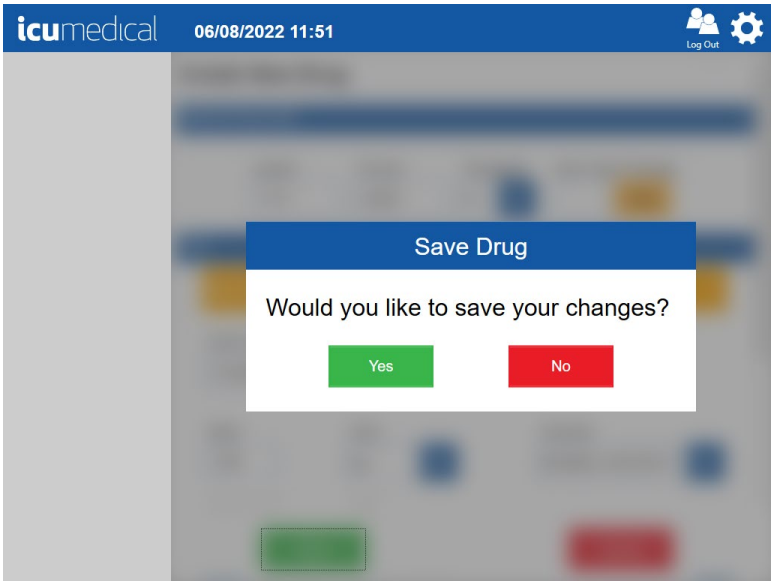
   Volume-› **100 (example)**

   Volume Units-› **mL (example)**

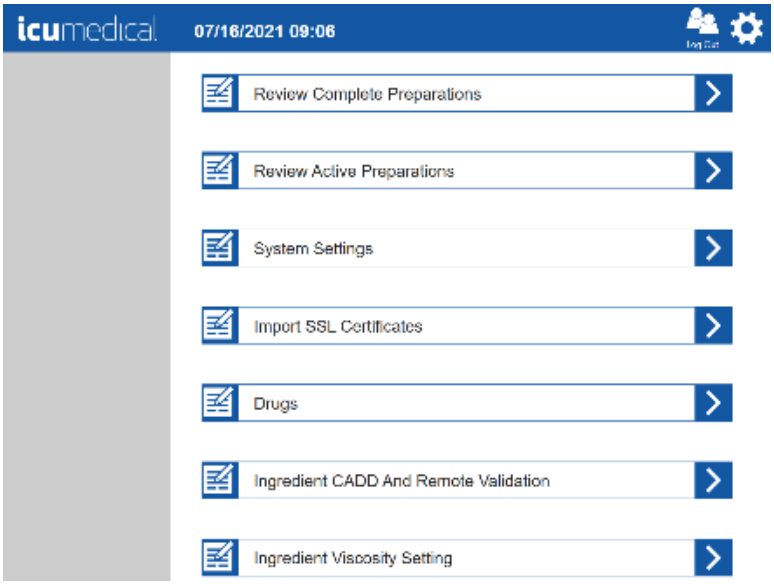
   Viscosity-› **NORMAL VISCOSITY (example)**



6. Tap the **Save** button on the **Create New Drug** screen. Press **Yes** on the **Save Drug** message.

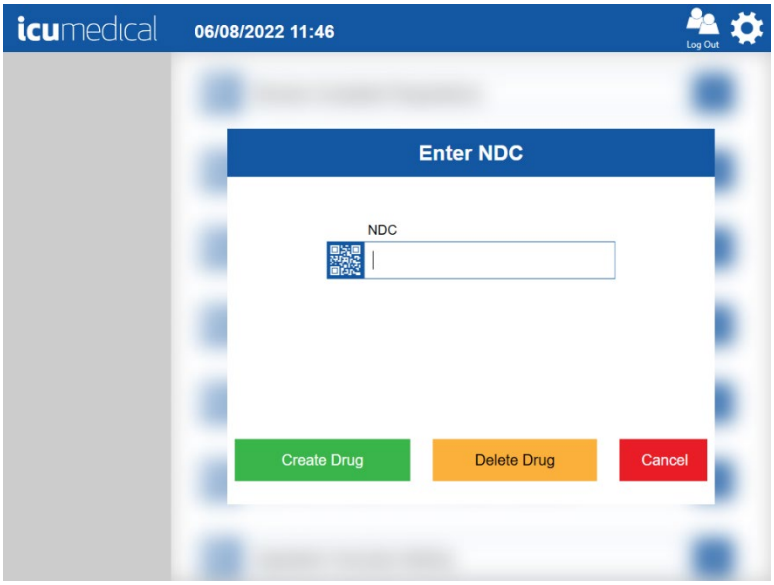


7. Pharmacist application displays the settings home screen after user manually adds the custom drug and diluent information into the Drug Library.



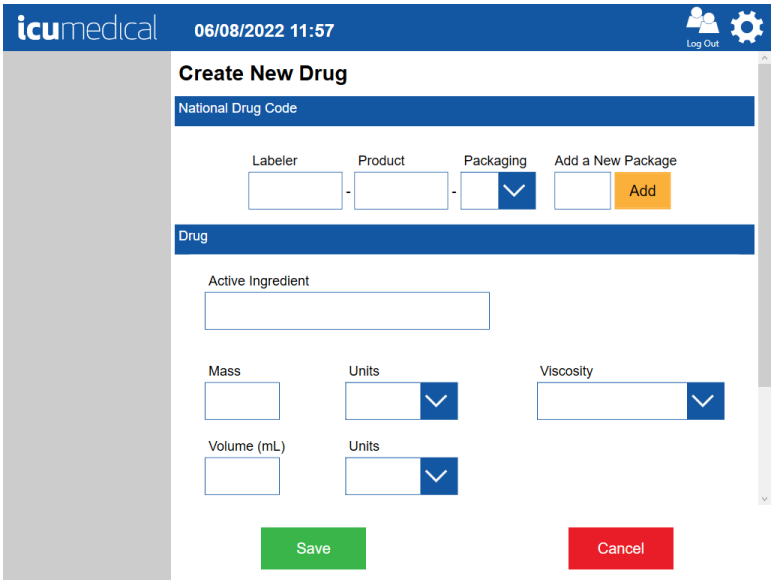
5.5.1.3. Create Custom Concentration For a Drug (e.g., special dilution)

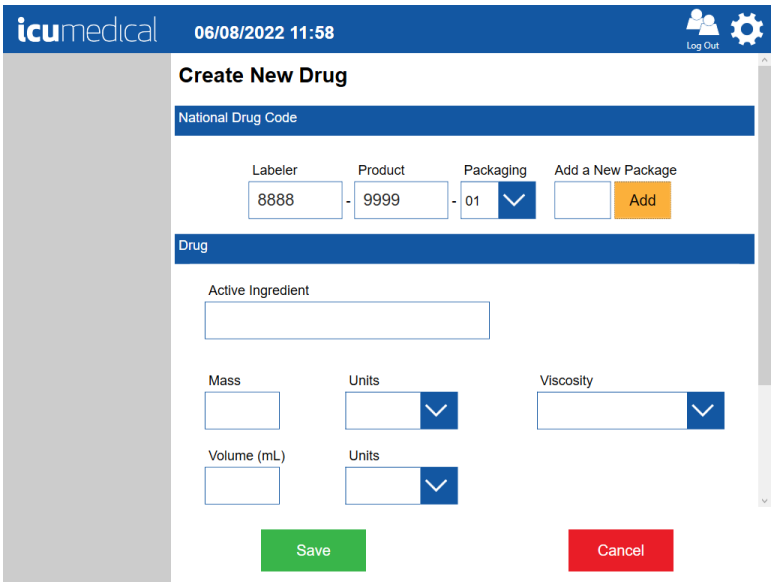
1. From the Pharmacist application, select the **Settings** icon.
2. Select **Drugs** option and on the **Enter NDC** screen tap **Create Drug** button.



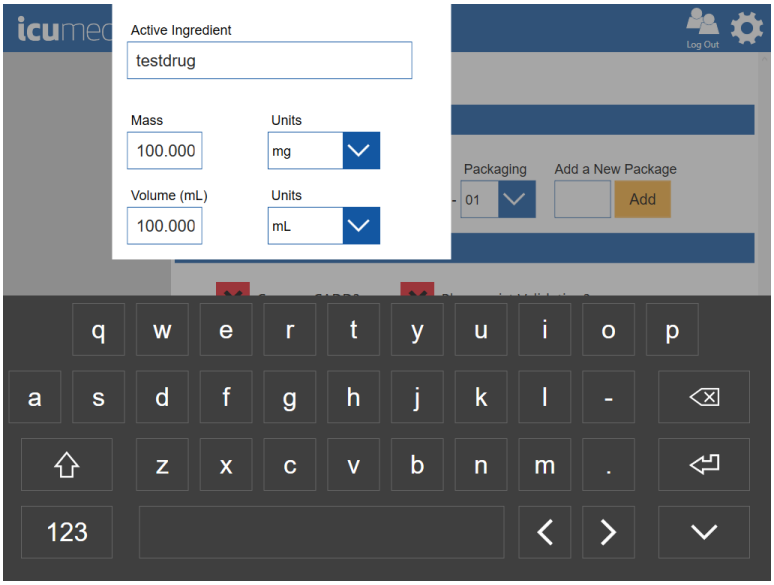
3. On the **Create New Drug** screen enter the following for the **National Drug Code** section and tap the **Add** button. Verify that the package is added to the Packaging list.
   Labeler -› **8888 (example; do not use an existing labeler code)**
   Product -› **9999 (example)**
   Add a New Package -› **01 (example)**

   Note: Labeler, Product, and Packge values must be entered for the newly created drug or it not be usable by the Diana system.



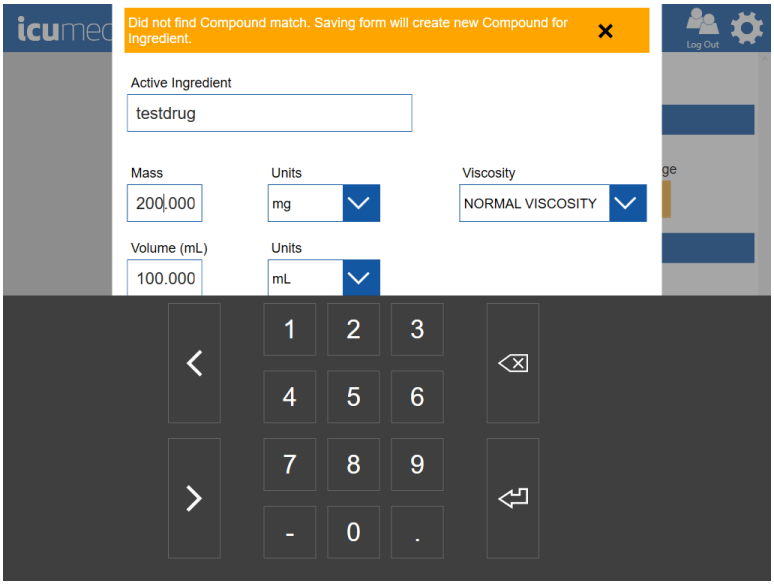


4. Tap on the **Active Ingredient** field and by using on-screen keyboard enter, for example, **TestDrug,** and select **TestDrug 100.0 mg / 100.0 mL**.

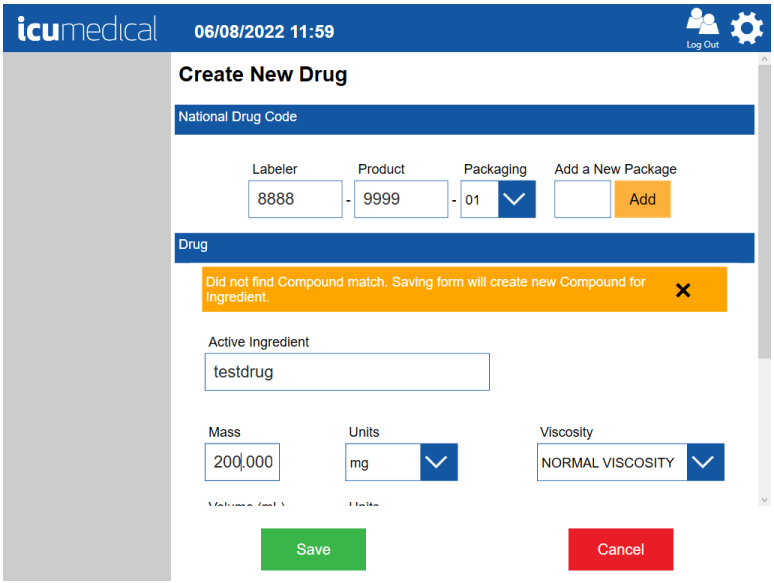


5. Verify that after selecting the compound, the **Mass, Volume** and **Units** values are automatically filled based on the selected Active Ingredient option.

6. Tap the Mass filed and change the value to **200.00**. Verify that Pharmacist application notifies "**Did not find an Compound match. Saving from will create new Compound for Ingredient**" banner message to the user.
Note: The values entered here in this manual is for example purpose only.

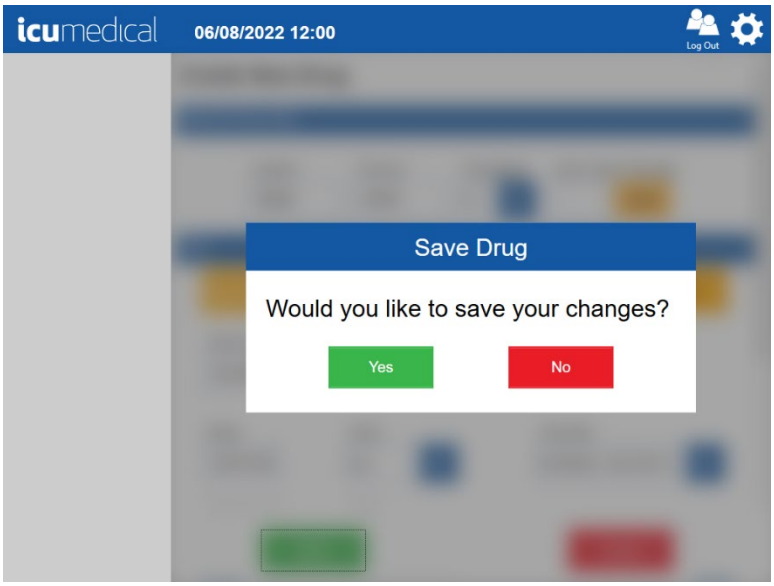


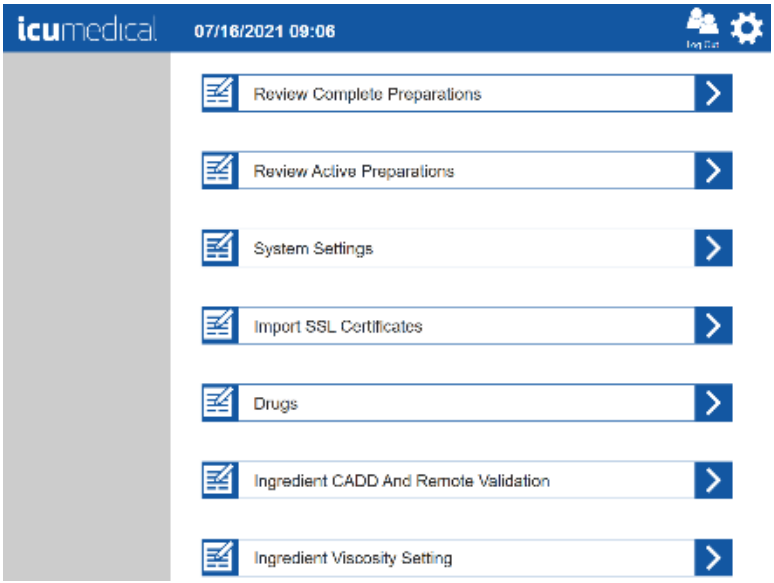
7. Tap on-screen **Enter** button and verify that the updated Mass volume is displayed.



8. Tap the **Save** button on the **Create New Drug** screen.

9. Press **Yes** on the **Save Drug** message and verify that the Pharmacist application displays the settings home screen after user manually adds the custom drug and diluent information into the Drug Library.





5.5.2. Edit Drug

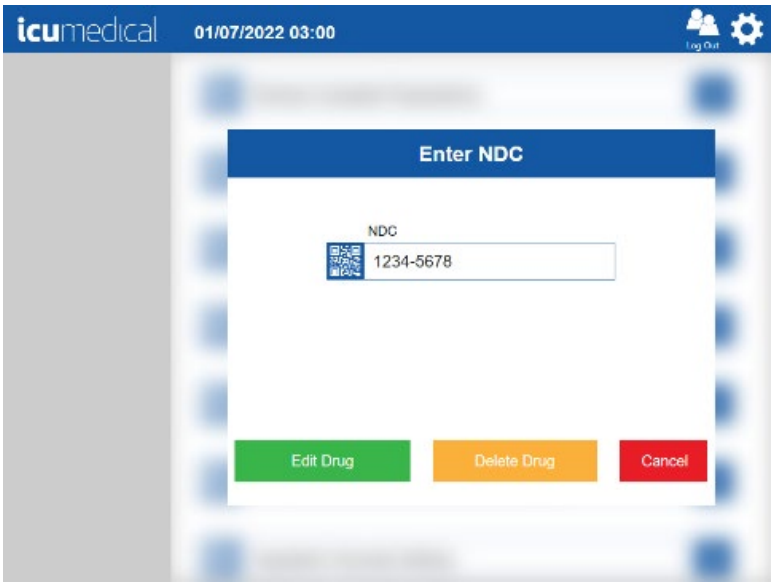
The System allows the user to update an existing drug concentration in the system.

Note: The System allows the user to update the following only:

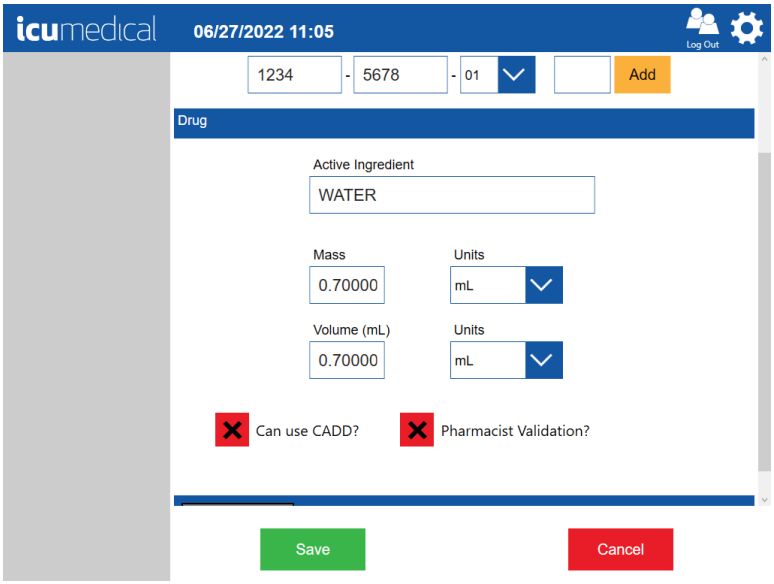
- Adding new package
- Select/Deselect **Pharmacist Validation?**

- Select/Deselect **Can use CADD?**
- Add **Reconstitution Protocol**

1. On the Pharmacist application tap the **Settings** Icon
2. Tap the **Drugs** setting action icon
3. On the **Enter NDC** pop-up window, tap the NDC field and enter the existing NDC ID and tap the **Edit Drug** button. Drug details screen displays



4. Enter/select the values for the following:
   a. Add a new package
   b. Select or deselect **Can use CADD?**
   c. Select or deselect **Pharmacist Validation?**



5. Tap the **Show Protocol+** if the new drug requires Reconstitution Protocols
6. Tap the **Save** button to update the drug information or tap **Cancel** to cancel the drug update

5.5.3. Disable Drug

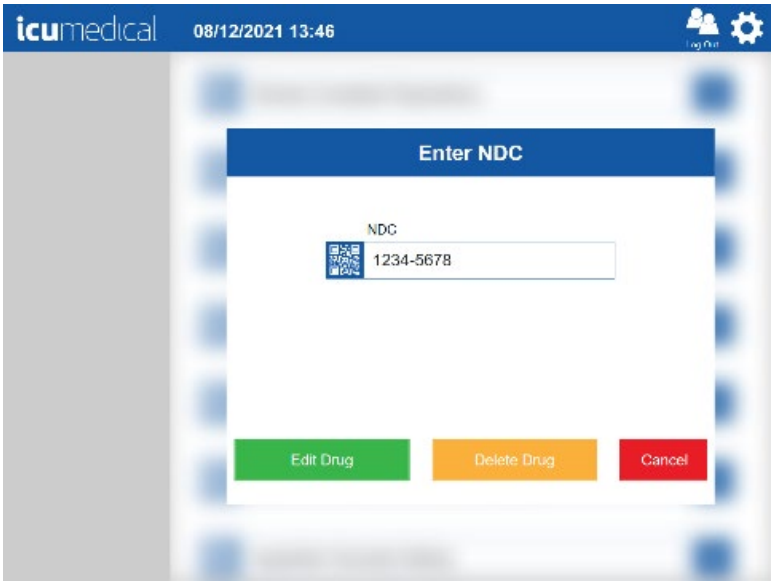
See Ingredient CADD And Pharmacist Validation Setting

5.5.4. Delete Drug

The System allows the user to delete an existing user created drug from the system.

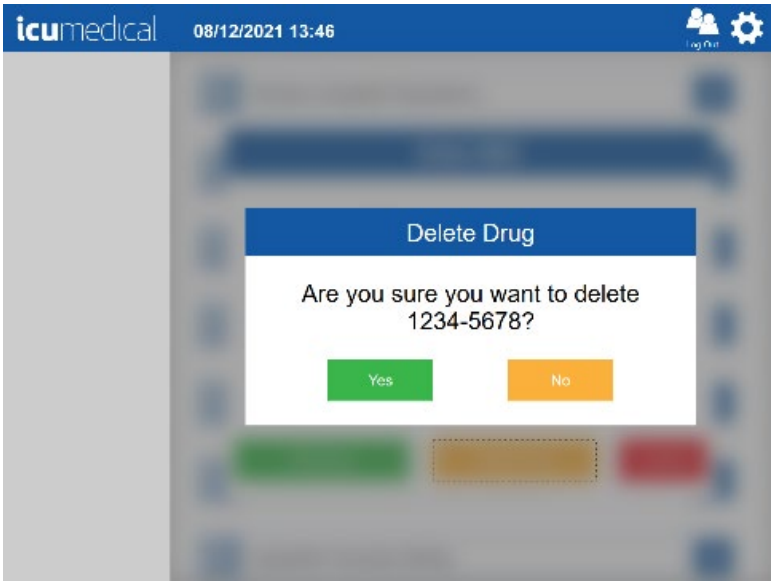
Note: The System does not allow to delete any FDA drugs.

1. On the Pharmacist application tap the **Settings** Icon
2. Tap the **Drugs** setting action icon
3. On the **Enter NDC** pop-up window, tap the NDC field and enter the existing NDC ID and tap the **Delete Drug** button

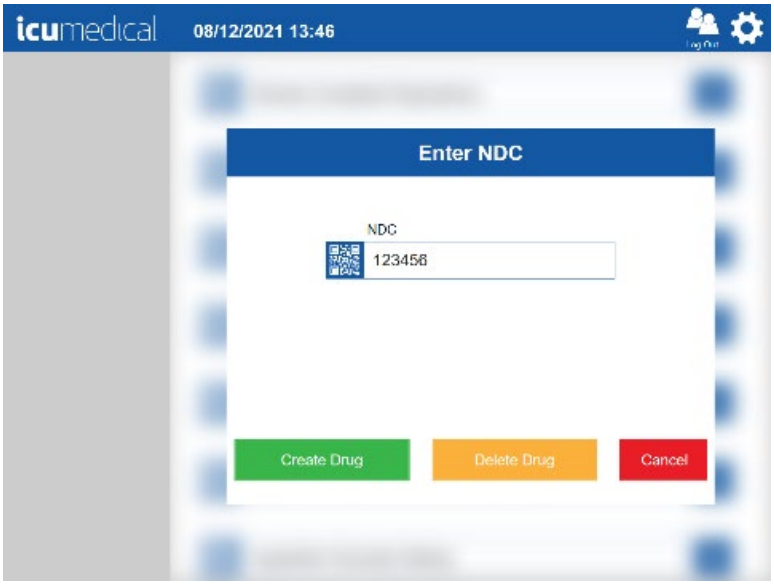


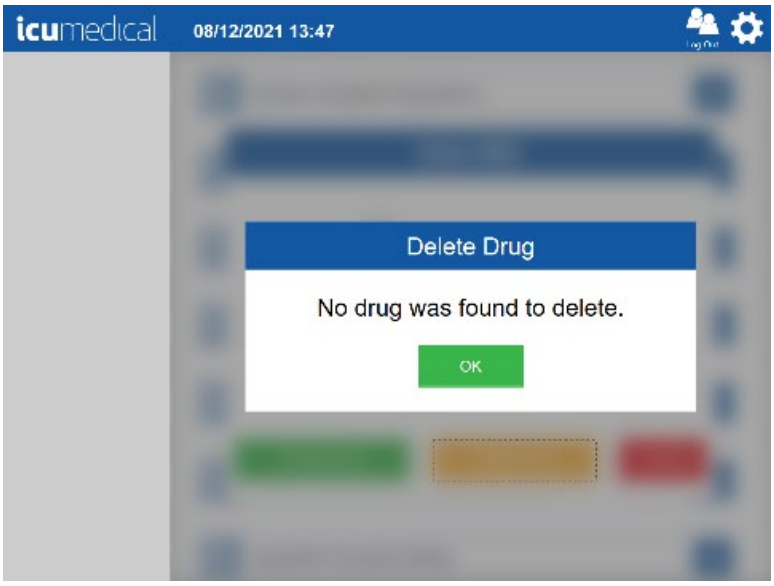
4. The System displays the confirmation screen for the user to confirm the delete with **Yes** or **No** option
5. Tap **Yes** to delete the drug

6. Tap **No** to cancel drug deletion



Note: If the NDC entered does not exist and the **Delete** button is touched, an error screen is displayed.

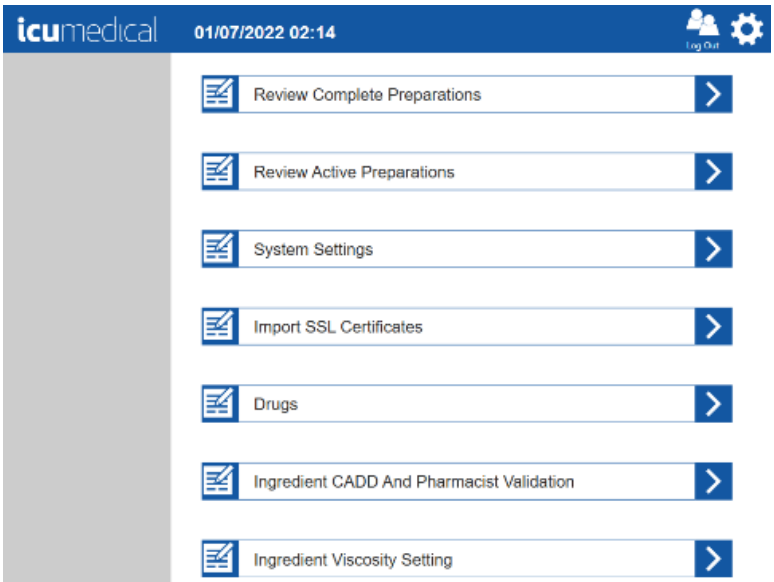




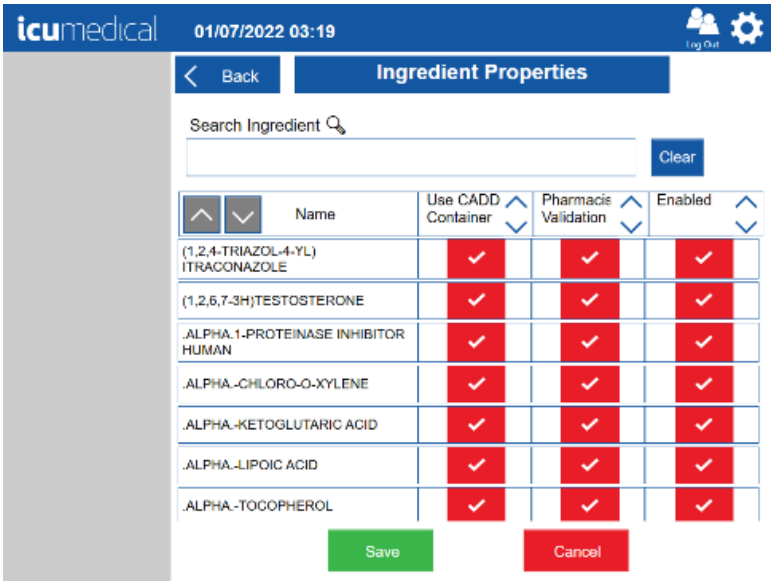
5.6. Ingredient CADD And Pharmacist Validation Setting

The various ingredients in the drug database can be enabled/disabled, set to require/not require a medication cassette container (e.g. CADD™) and set to require/not require Pharmacist validation. The **Ingredient CADD And Pharmacist Validation** setting allows the user to search for ingredients and change their associated values.

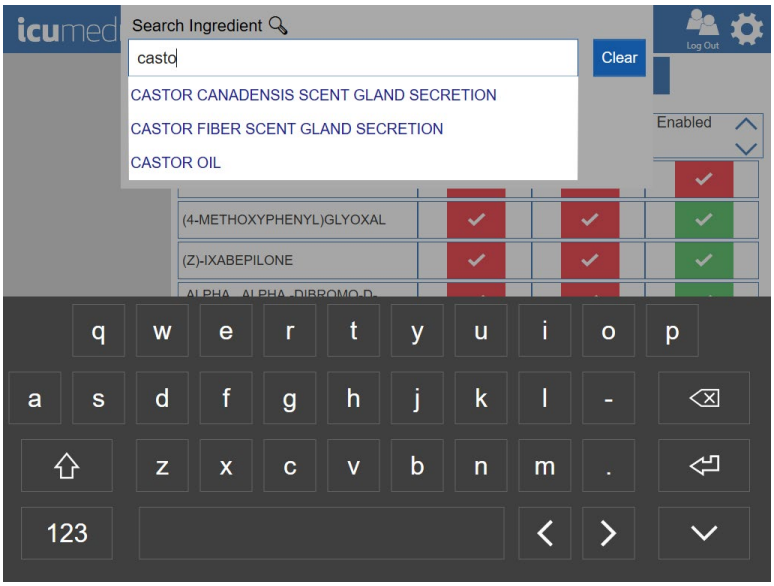
1. On the Pharmacist application tap the **Settings** Icon
2. Tap the **Ingredient CADD And Pharmacist Validation** setting action icon

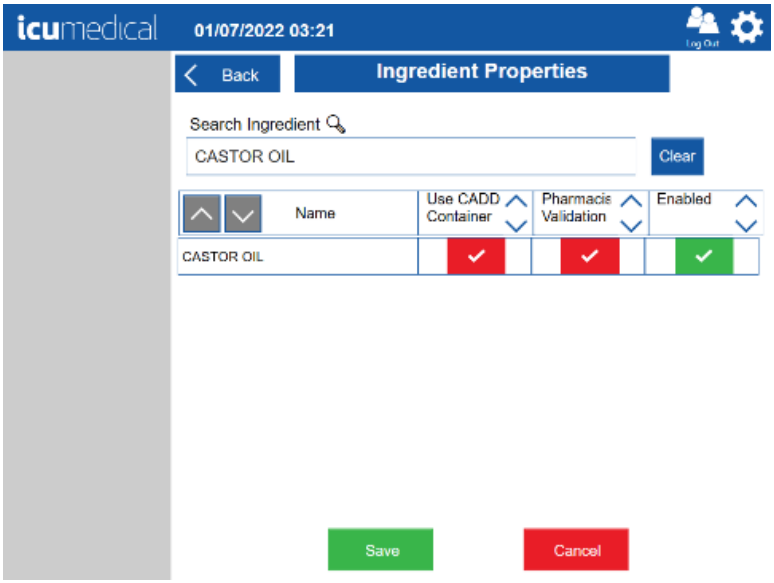


3. The **Ingredient Properties** screen is displayed



4. Tap the **Search Ingredient** text box and begin typing the ingredient name.
   Note: The system will display a drop-down list of ingredients that start with the character or characters entered in the text box. Select the desired item.





5. Check or uncheck the Use CADD Container field.
6. Check or uncheck the **Pharmacist Validation** field

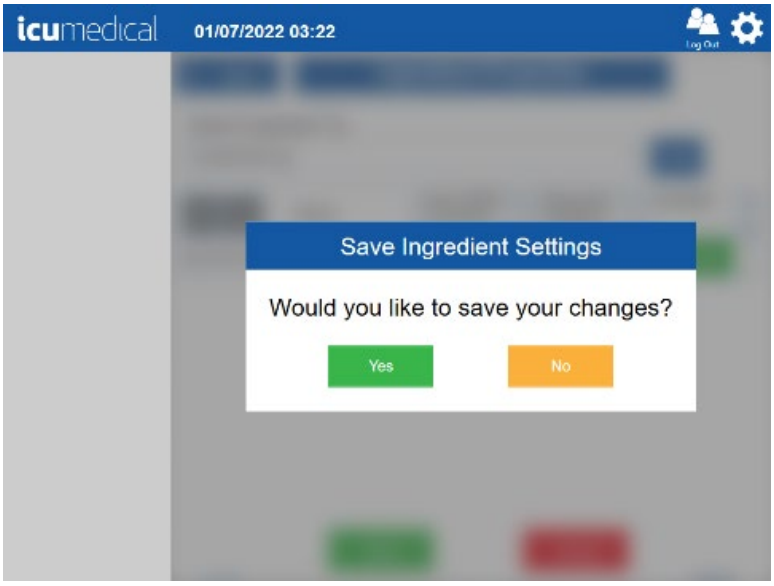
7. Check or uncheck the **Enabled** field

8. Tap the **Save** button

   Note: Tapping the **Cancel** button will return to the **Settings** screen without changing the Ingredient properties

9. Tap the **Yes** button on the **Save Ingredients Settings** confirmation page

   Note: Tapping the **No** button will return to the **Ingredient Properties** screen



5.7. Review Complete Preparations and Review Active Preparations Setting

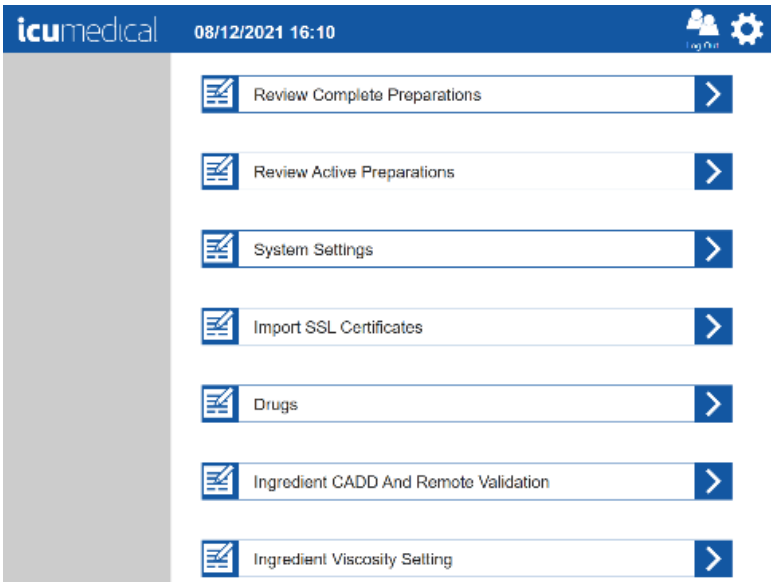
The Diana system keeps a record of every preparation created, starting from manufacture. These records include dates, times, results, images and other relevant data. These preparations can be reviewed on the application using the **Review Complete Preparations** setting.

Review Active Preparations contains the preparations that are currently active on the system. Active preparations are either in the **SPM Transferring** or **Compounding Drug** or **Need Operator Validation** or **Need Pharmacist Validation** states.

Review Active Preparations on the Operator application displays preparations in **SPM Transferring** or **Compounding Drug** or **Need Operator Validation** state.

Review Active Preparations on the Pharmacist application displays preparations in **SPM Transferring** or **Compounding Drug** or **Need Operator Validation** or **Need Pharmacist Validation** state.

To review preparations, touch the action icon of the **Review Complete Preparations** or **Review Active Preparations** bars.

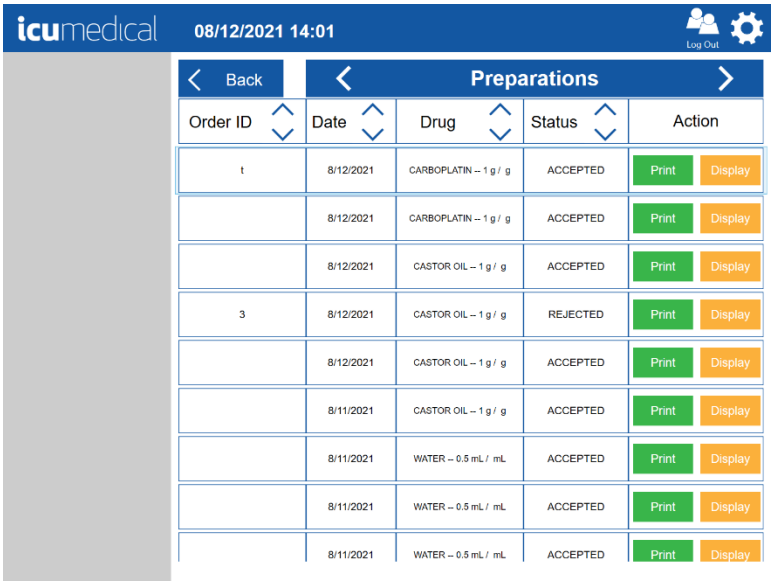


The **Review Complete Preparations** screen has one or more preparation records in a scrollable list. Each row in this list is a record. The list can be sorted in ascending or descending order by Order ID, Date, Drug (*i.e.*, substance and concentration) or Status by touching the up/down arrow icon next to the title of each column in the list.

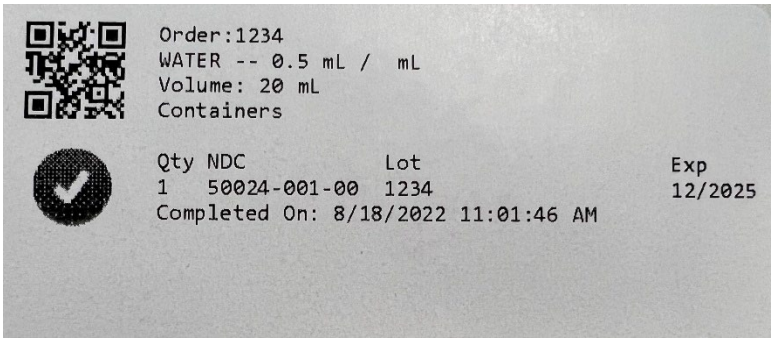
The following data is shown for each preparation: the order ID, the date of completion, the substance and concentration of the drug that was dispensed and the status of the preparation.

The rightmost column in this list is entitled Action. Each record has two buttons in this column; one is the **Print** button, and the other is the **Display** button.

If the **Display** button for a preparation record is touched, a screen that displays all of the images associated with this delivery, and other relevant information will be displayed. There may be one or more syringe pictures, depending on the amount of fluid delivered. There may be one or more vial pictures, zero or more miscellaneous pictures, and a signature image if the preparation was validated by the pharmacist.



Touching the **Print** button will print a label with a QR image and other relevant information for this preparation on the Diana System printer.

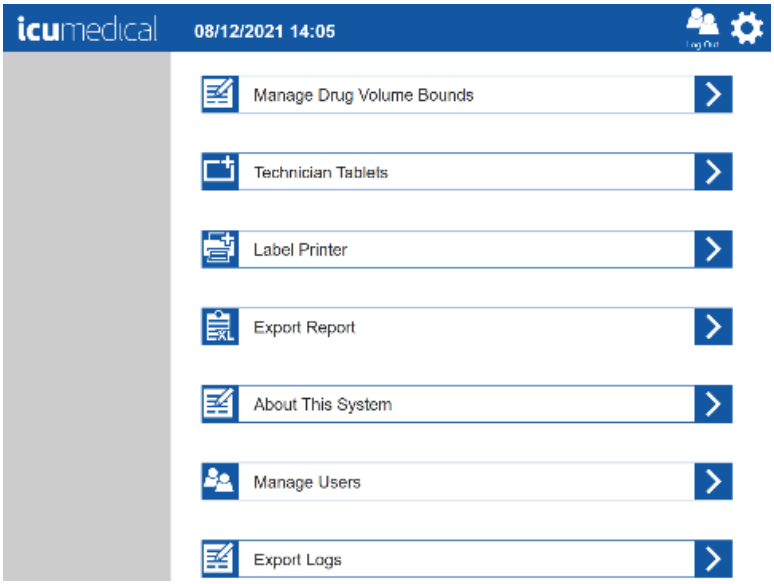


5.8. Export Report Setting

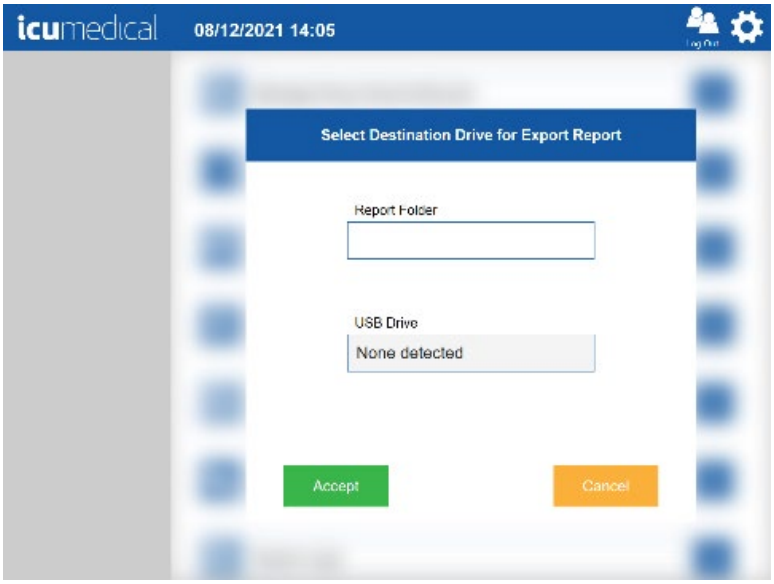
The Export Report setting allows the user to export all delivery/preparation information stored in the system to an external drive. Export Report setting is available in both Operator and Pharmacist applications.

1. Insert USB flash drive into the tablet's USB port
2. Tap the **Settings** Icon

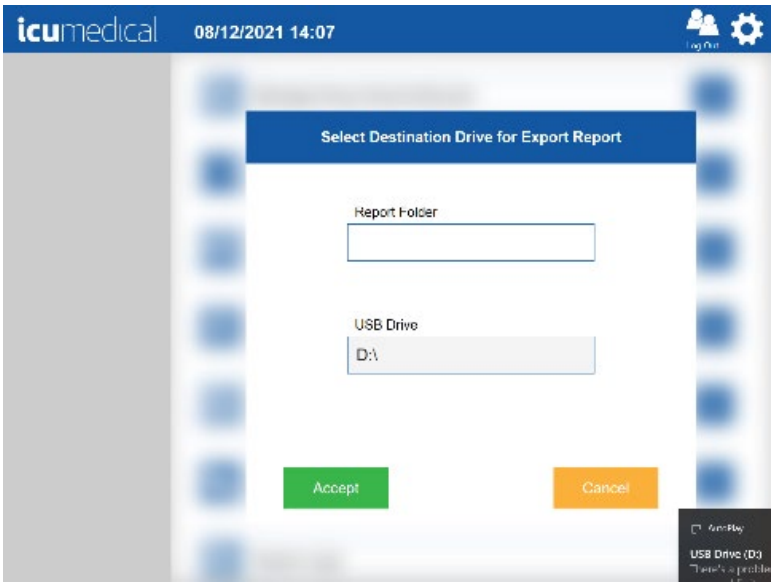
3. Tap the **Export Report** setting action icon

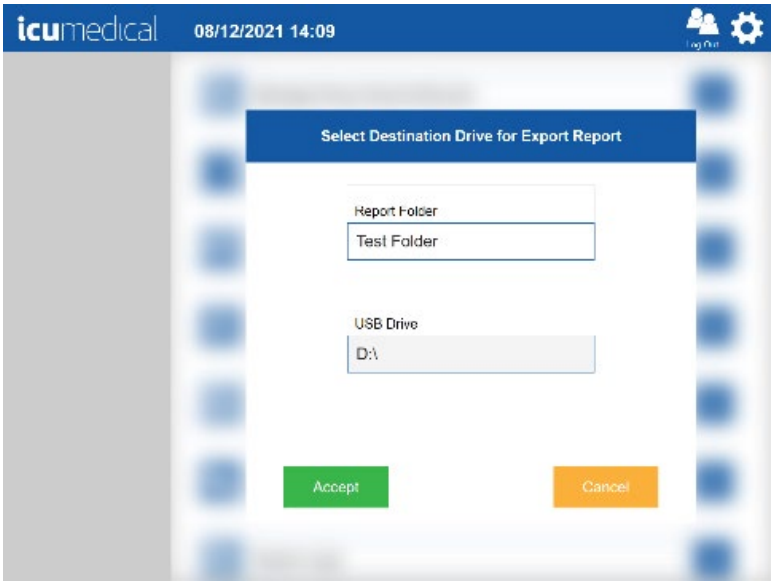


4. The **Select Destination Drive for Export Report** pop-up window is displayed



5. In the **Select Destination Drive for Export Report** pop-up window, enter the **Report Folder** name
Note: The Report Folder name should be a folder name on the root of the inserted USB drive. If this directory does not exist, it will be created



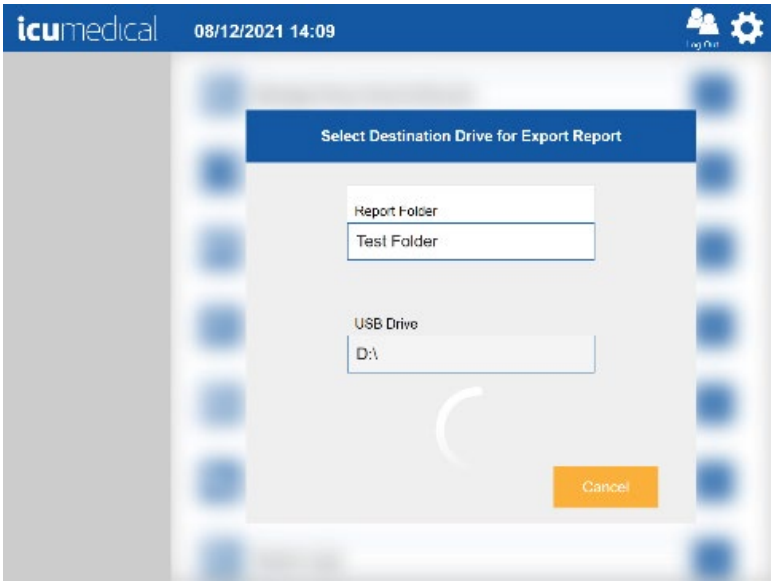


6. Tap the **Accept** button

   Notes:

   a. Tapping the **Cancel** button will return to the **Settings** screen

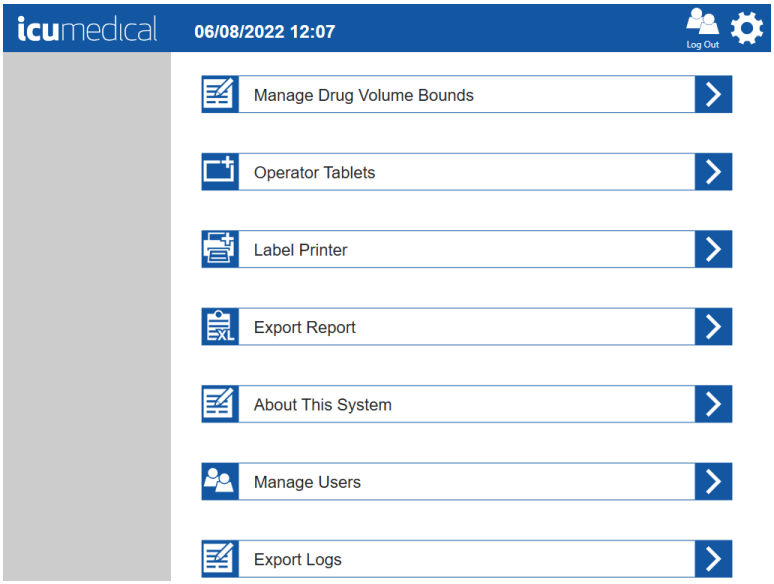
   b. If the USB flash drive was not inserted, the **No USB Drive** pop-up window will be displayed. Tap the **OK button** will return to the **Select Destination Drive for Export Report** pop-up window



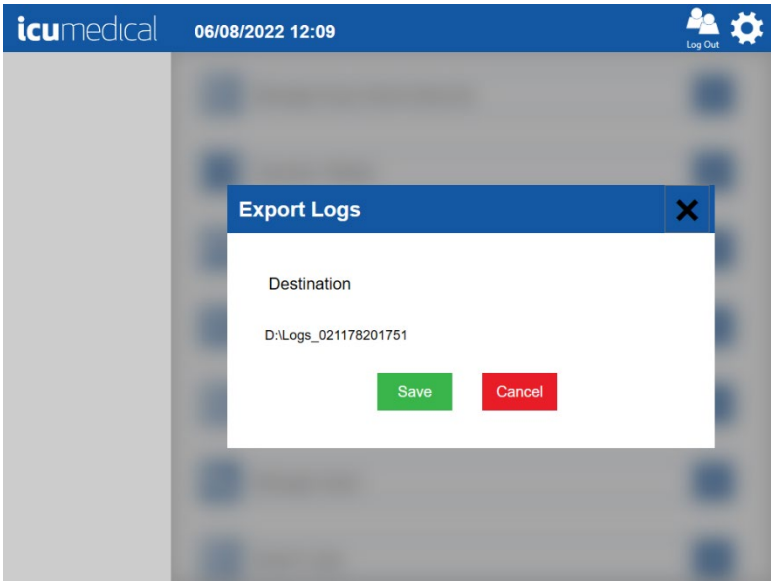
5.9. Export Logs Setting

The Export Logs setting allows the user to export the Operator or Pharmacist log files.

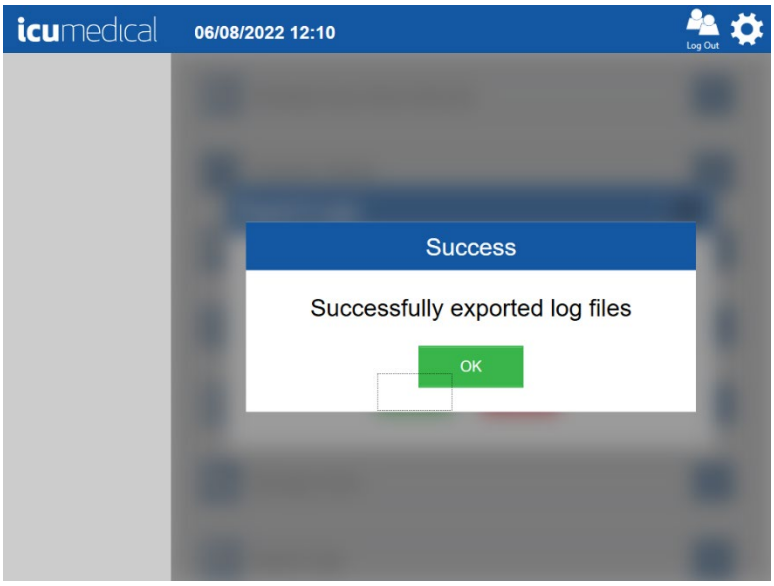
1. Insert a USB flash drive into the tablet's USB port
2. Tap the **Export Logs** setting action icon



3. The Export Logs pop-up window is displayed



4. In the **Export Logs** pop-up window, tap the **Save** button
   Note: Tapping the **Cancel** button will return to the **Settings** screen
5. Application displays successful export notification to the user



5.10. Ingredient Viscosity Setting

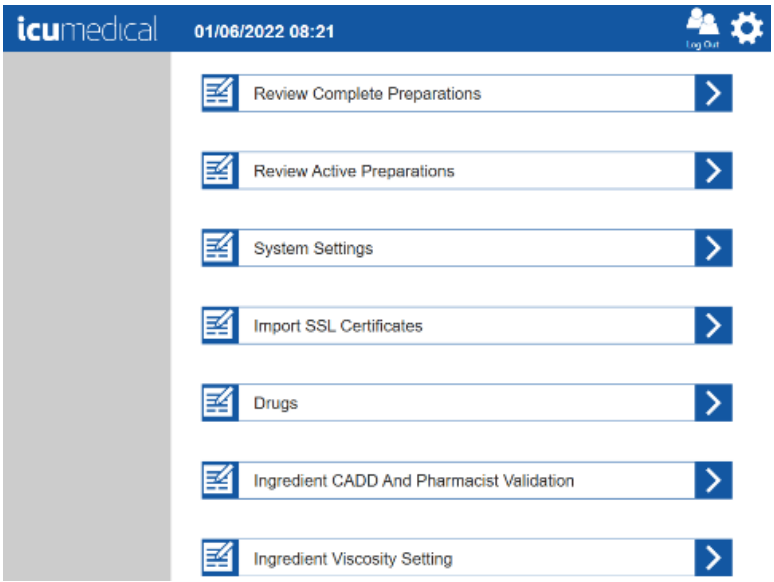
The viscosity of the drugs which can be compounded with the Diana Automated Compounding System can be based on water, various alcohols, and various oils or lipids. Each of these has a different viscosity. The

Diana Syringe Pump must know the viscosity of the drug solution or suspension being dispensed or it may not function correctly. Most drugs can use the “Normal” setting, but the user may find improved system performance by updating the viscosity setting to “High” for fluids with high viscosities.

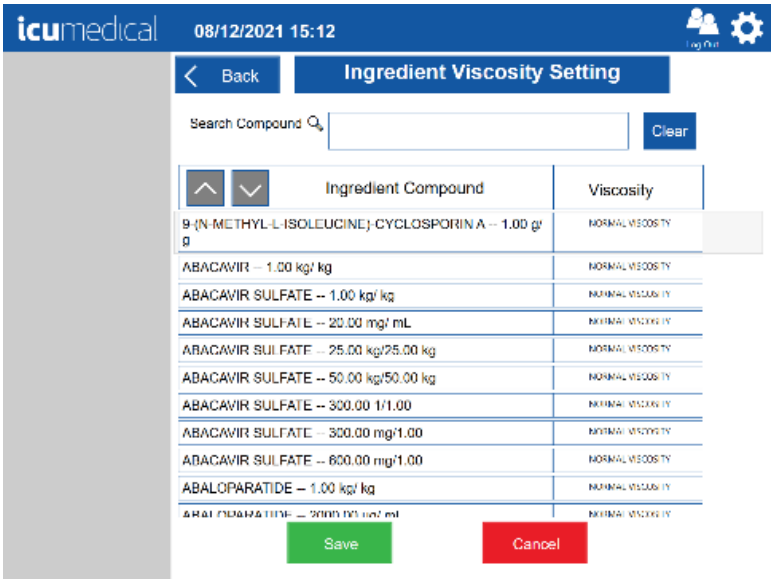
Note: System settings are defaulted to “Normal” for all drugs in the default database

The Diana Pharmacist application allows the user to change the viscosity setting for the drugs.

1. Tap the **Setting** Icon
2. Tap the **Ingredient Viscosity Setting** action icon

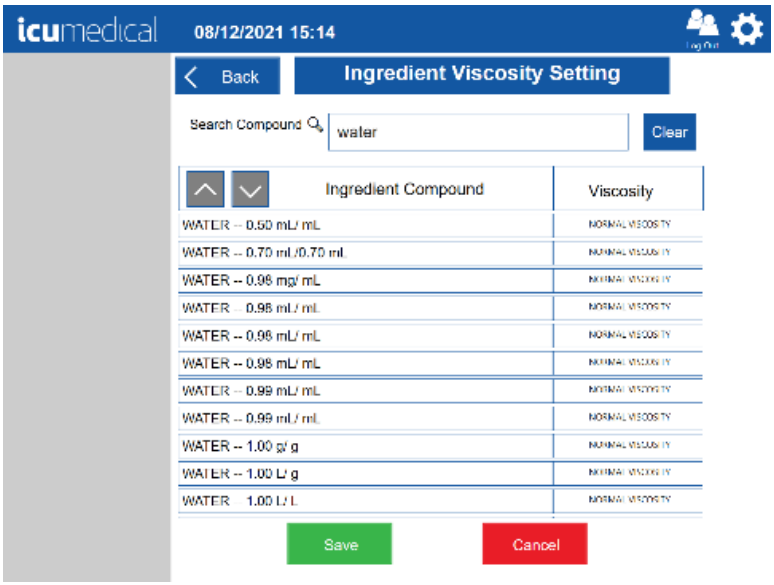


3. The **Ingredient Viscosity Setting** setting screen is displayed



4. Tap the **Search Compound** text box and type the compound name

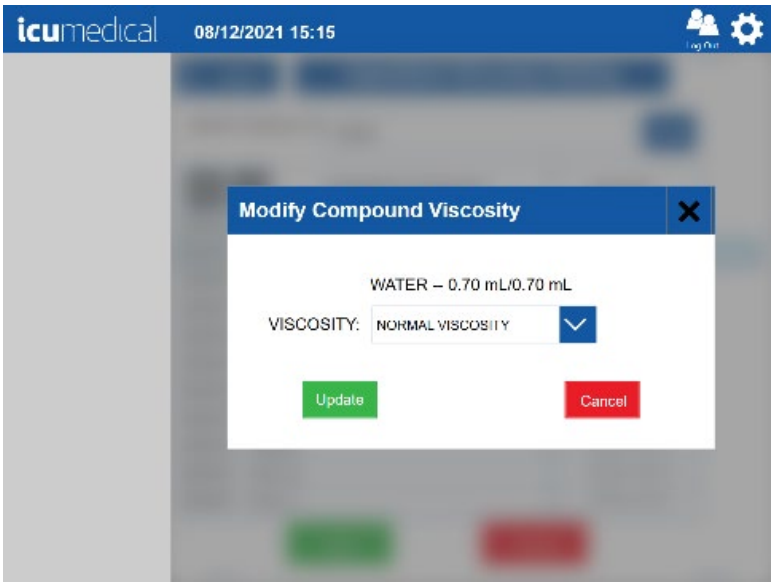
   Note: The system will display a drop-down list of ingredients which start with the character or characters entered in the box. Select the desired item

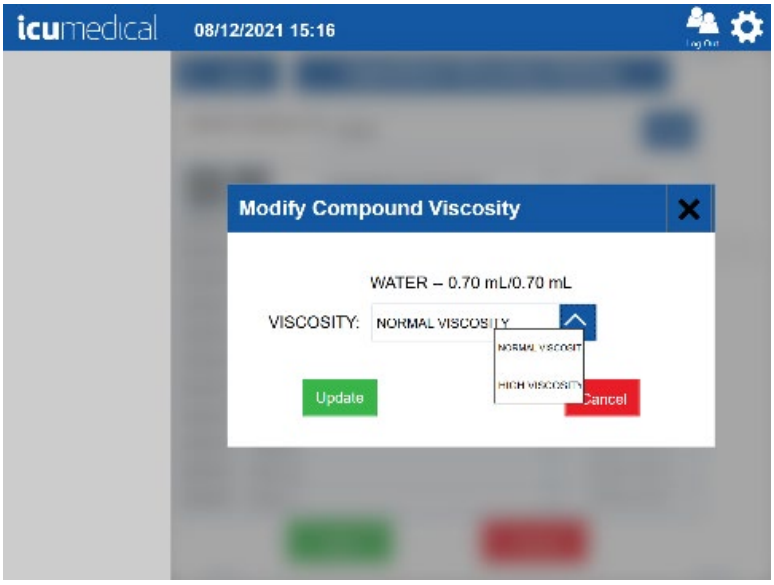


5. Select an **Ingredient Compound**
6. The **Modify Compound Viscosity** pop-up window will be displayed
7. Choose the Viscosity for the Ingredient from the drop down list

8. Tap the **Update** button

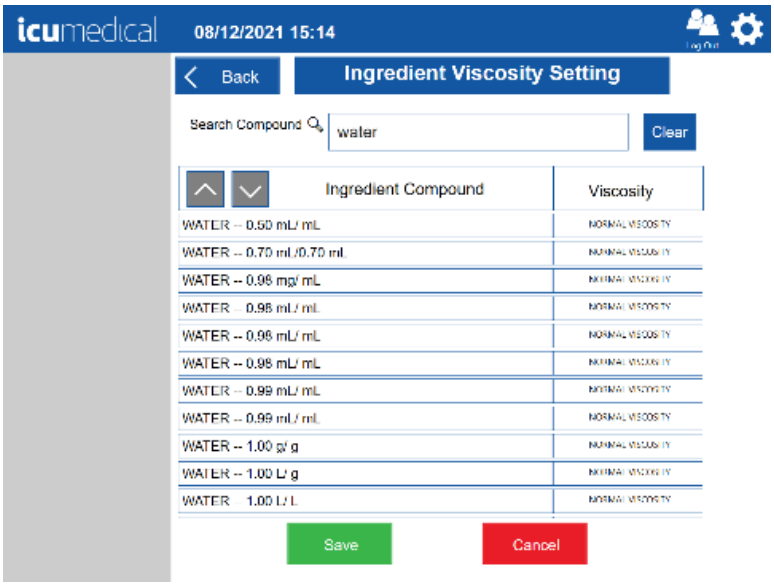
   Note: Tapping the **Cancel** button on the **Modify Compound Viscosity** pop-up window will return to the **Ingredient Viscosity Setting** setting screen without changing the viscosity for the compound



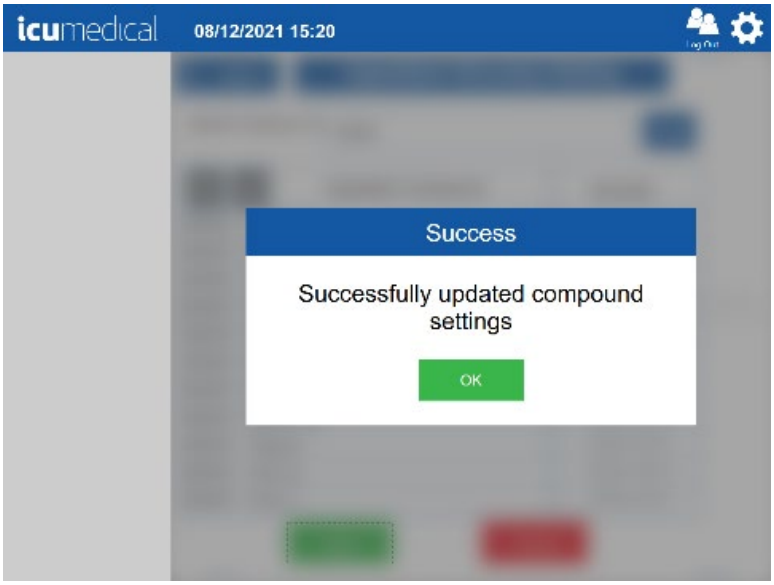


9. Tap the **Save** button on the **Ingredient Viscosity Setting** screen

   Note: Tapping the **Cancel** button on the **Ingredient Viscosity** setting screen will return to the **Settings** screen without changing the viscosity for the compound



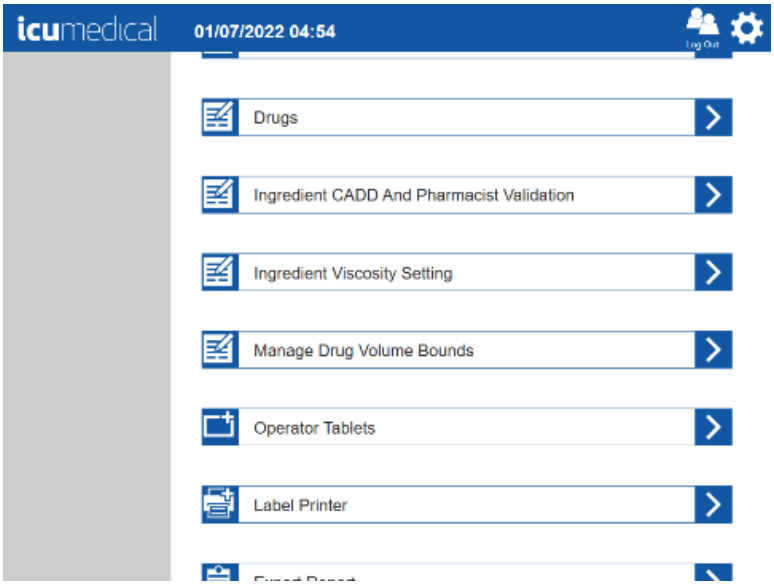
10. Tap the **OK** button on the **Success** confirmation page



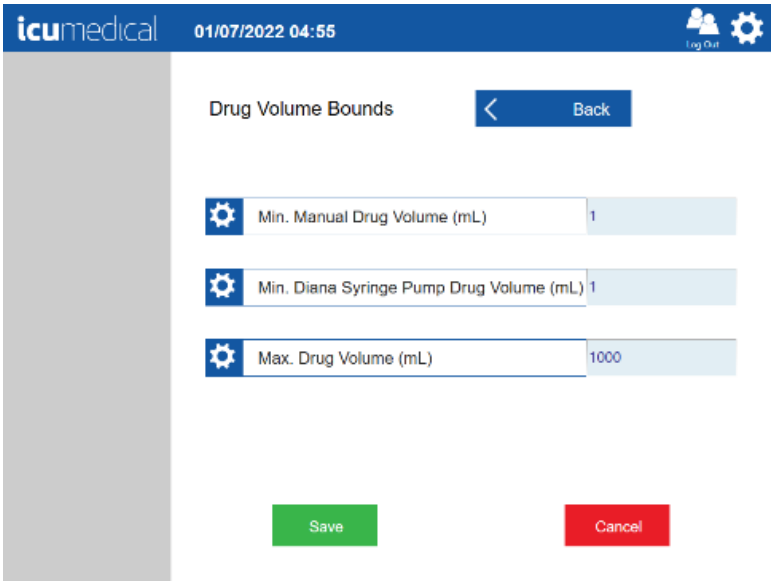
5.11. Manage Drug Volume Bounds Setting

The Manage Drug Volume Bounds setting allows the user to set the Minimum and Maximum drug volumes in milliliters the system will allow the user to transfer.

1. Tap the **Settings** Icon
2. Tap **the Manage Drug Volume Bounds** setting action icon



3. **The Drug Volume Bounds** setting screen is displayed

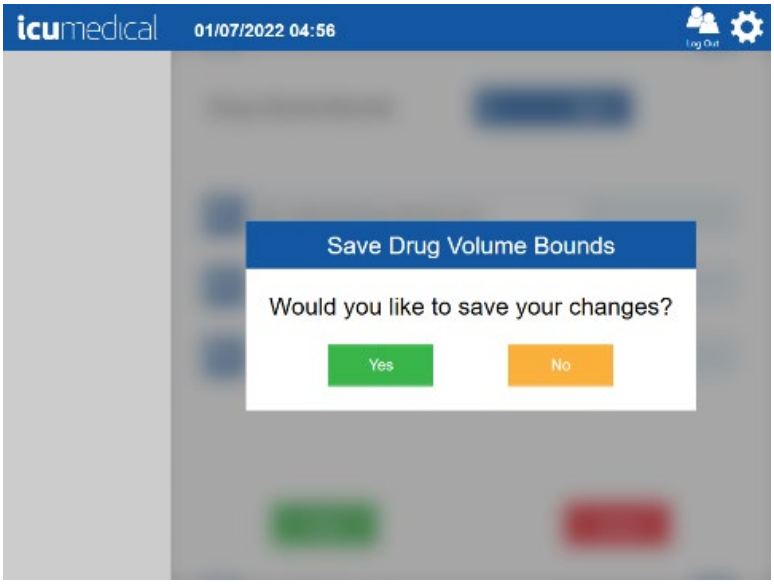


4. Change the desired Minimum or Maximum volume based on the site preference

Note: The volume bounds should be in between **1 mL** and **1000 mL**.

5. Tap the **Save** button
   Note: Tapping the Cancel button on the Drug Volume Bounds setting screen will return to the Settings screen without changing the values

6. Tap the **Yes** button on the **Save Drug Volume Bounds** confirmation pop-up window
   Note: Tapping the **No** button on the **Save Drug Volume Bounds** confirmation **pop-up window** will return to the **Drug Volume Bounds** setting screen



5.12. Manage Users Setting

The Manage Users setting in the Pharmacist application allows the administrator to manage users of the system.

This option allows the administrator to do the following:

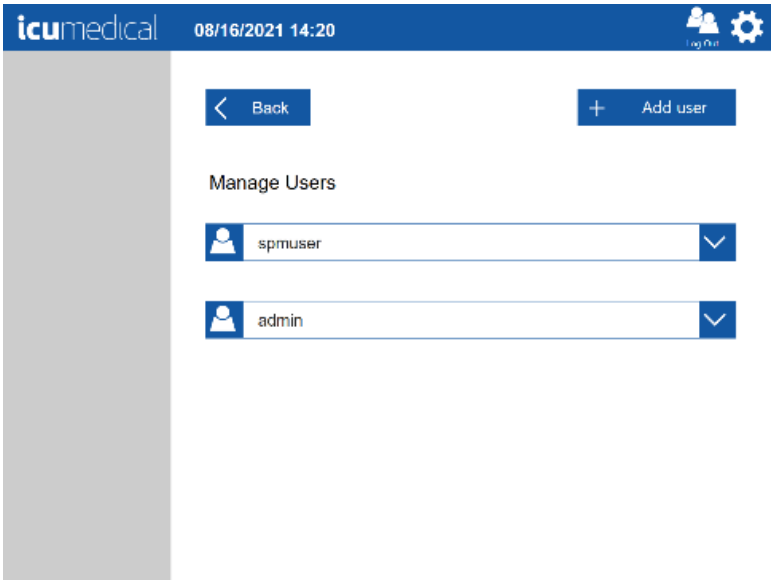
1. Add New User
2. Edit Existing User
3. Disable or Enable User or Reset Password

5.12.1. Add New User

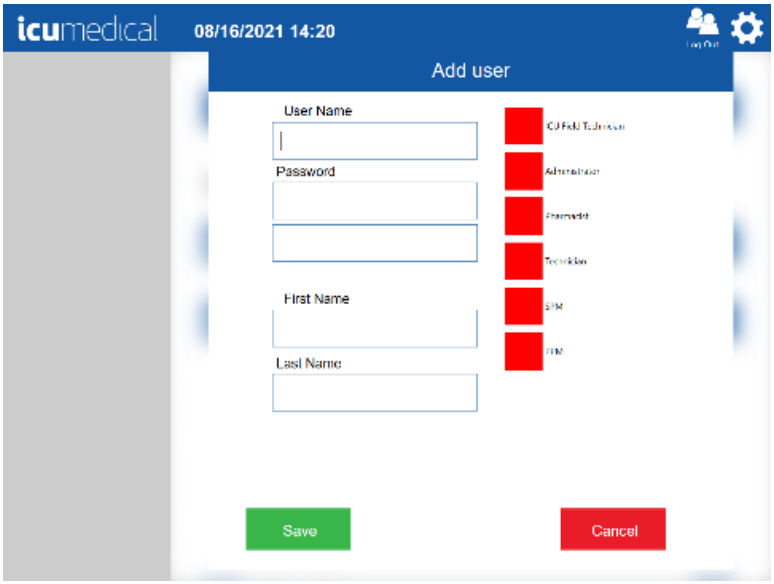
1. Tap the **Settings** Icon

2. Tap the **Manage Users** setting action icon

3. **The Manage Users** screen is displayed

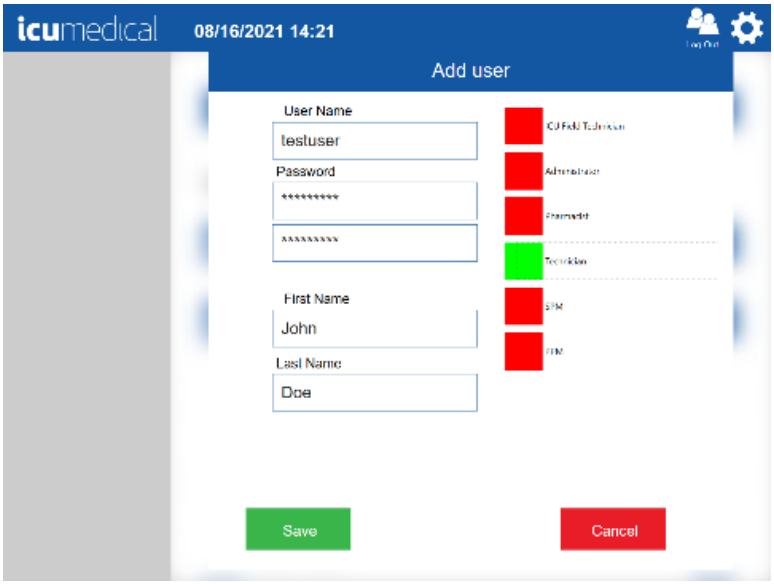


4. Tap the **Add user** button. The **Add User** screen is displayed



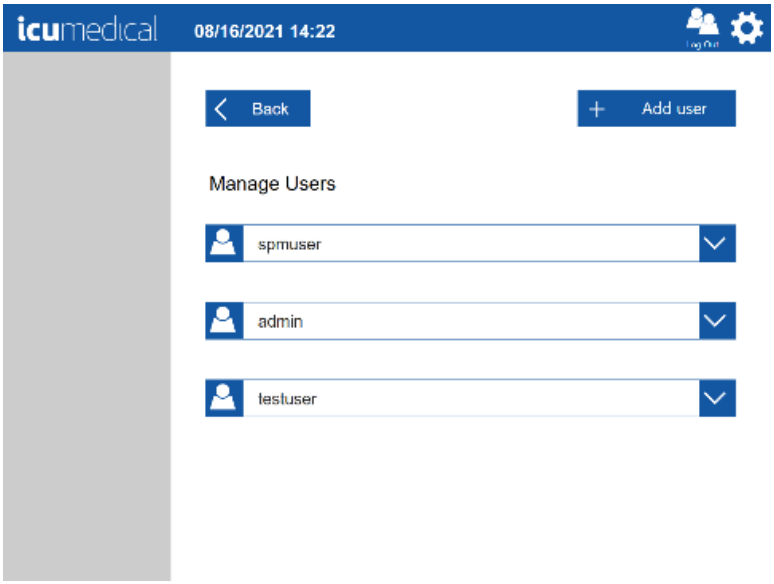
5. Enter values for all the fields and select appropriate roles for the user

   Note: Password values must consist of printable characters, cannot start or end with a whitespace character, and must contain at least one numeric character, one symbol character, and one upper-case text character. Password length must be between 8 and 21 characters.



6. Tap the **Save** button

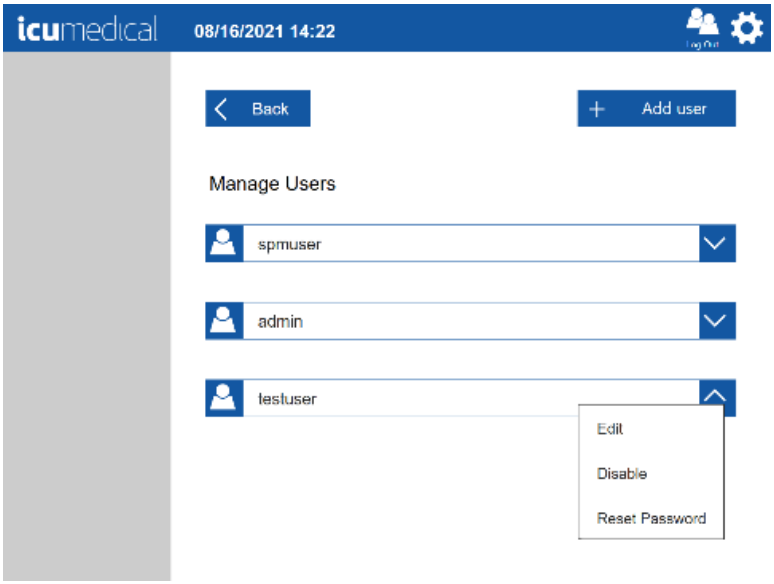
   Note: Tapping the **Cancel** button will return to the **Manage Users** screen without adding a new user to the system



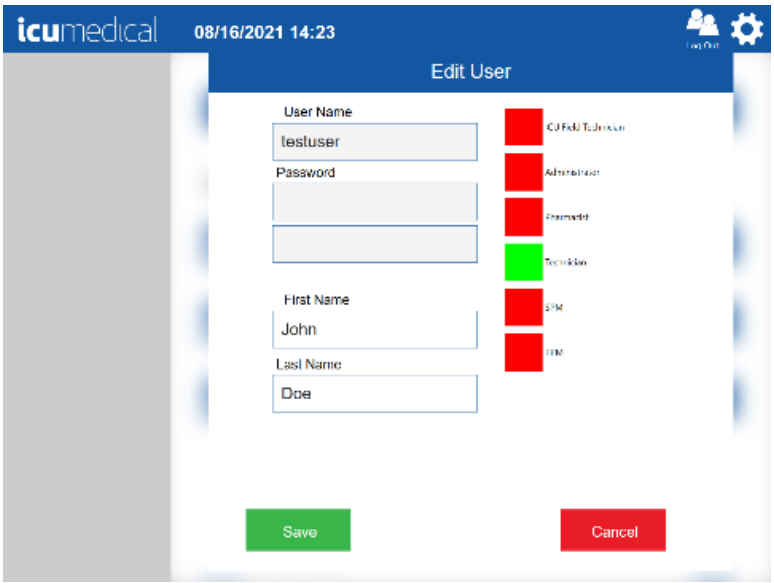
5.12.2. Edit Existing User

1. Tap the **Settings** Icon
2. Tap the **Manage Users** setting action icon
3. **The Manage Users** screen is displayed
4. Tap the action icon for the existing user bar

5. A pop-up menu indicating **Edit, Enable/Disable** and **Reset Password** is displayed

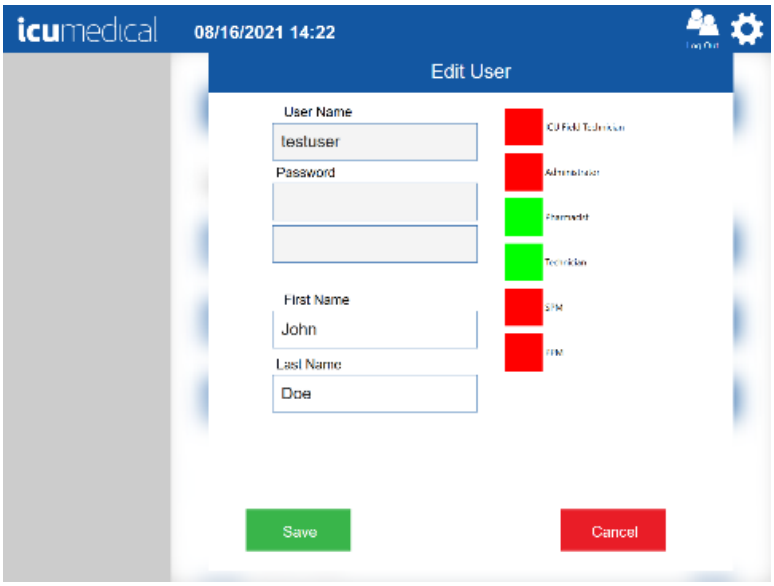


6. To edit the user, tap the **Edit button**
7. Change the values for the user in the **Edit User** pop-up window



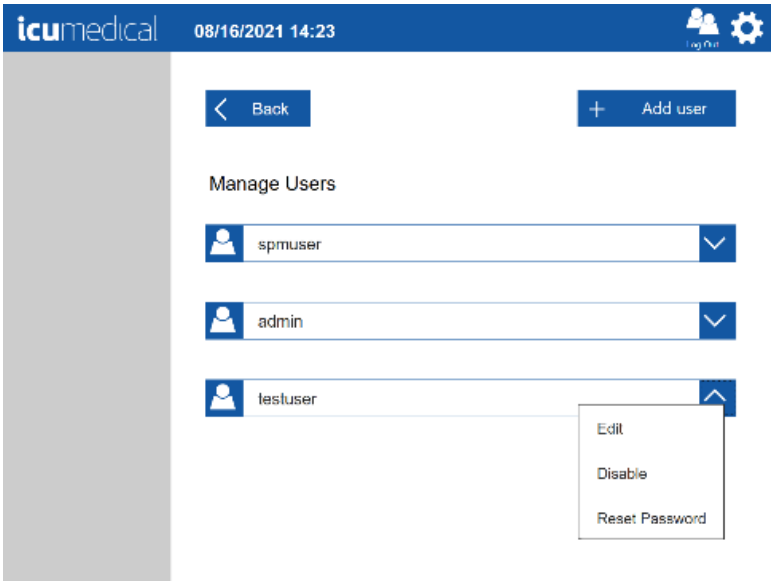
8. Tap the **Save** button

   Note: Tapping the **Cancel** button will return to the **Manage Users** screen without editing the existing user values

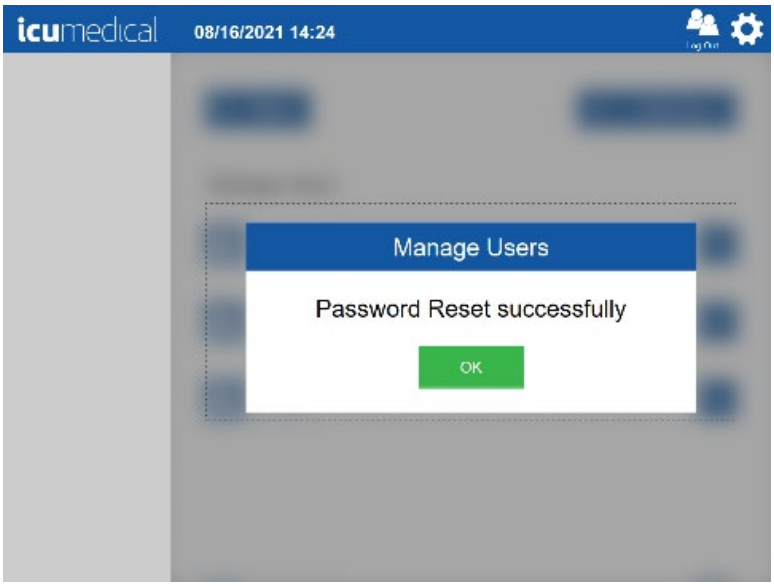


5.12.3. Disable or Enable User or Reset Password

1. Tap the **Manage Users** setting action icon
2. **The Manage Users** screen is displayed
3. Tap the action icon for the existing user bar
4. A pop-up menu indicating **Edit, Enable/Disable** and **Reset Password** is displayed



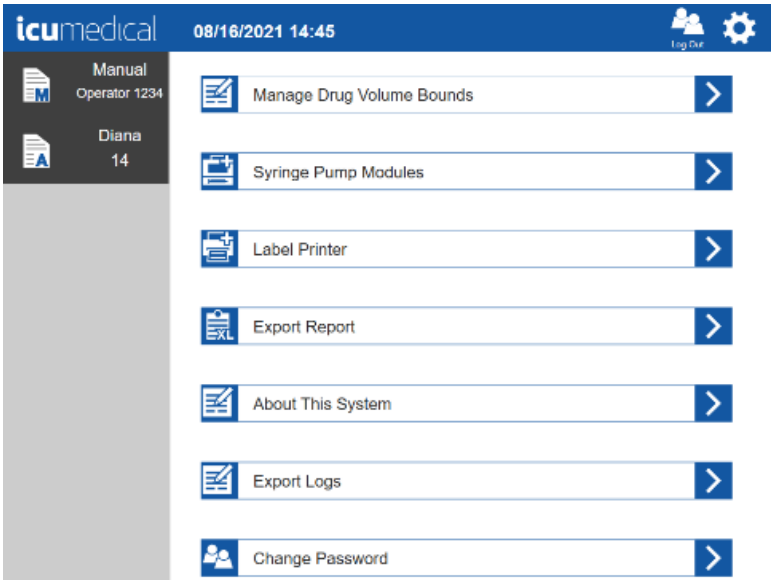
5. To disable the user, tap **Disable**
6. To enable the user, tap **Enable**
7. To reset the user password, tap **Reset Password**
8. Tap the **OK button** on the Manage Users **Password Reset successfully** message



5.13. Change Password Setting

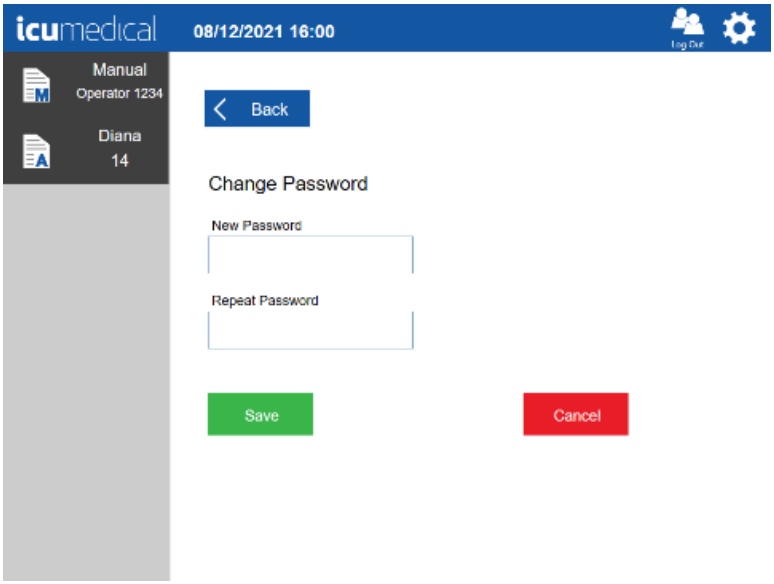
The Change Password setting in the Operator application allows the logged-in user to reset their password.

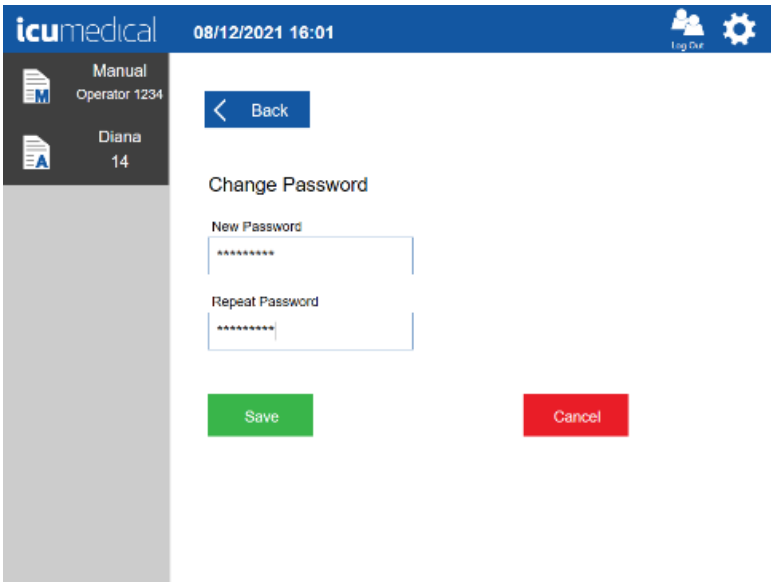
1. Tap the **Settings** Icon
2. Tap the **Change Password** setting action icon



3. The Change Password screen is displayed
4. Enter the new password

   Note: Password values must consist of printable characters, cannot start or end with a whitespace character, and must contain at least one numeric character, one symbol character, and one upper-case text character. Password length must be between 8 and 21 characters.





5. Tap the Save button

   Note: Tapping the Cancel button will return to the Settings screen without resetting the password

5.14. Import SSL Certificates

Contact ICU Service representative to configure this setting.

5.15. System Settings Setting

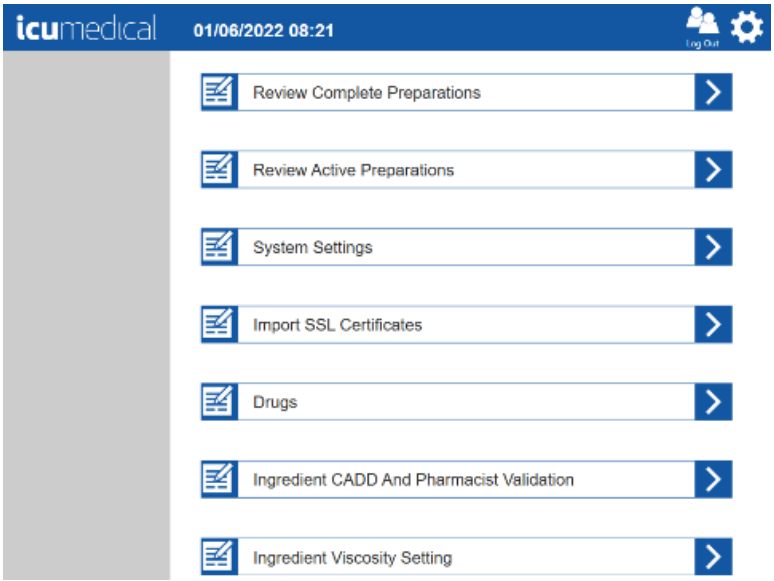
This setting allows the user to enter/select or enable/disable different options for the system. Scroll down to see all the System Settings options.

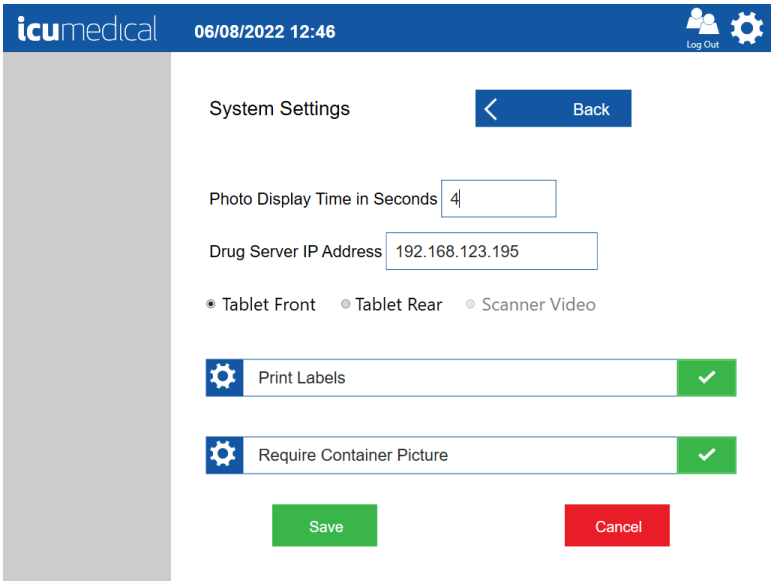
These are the settings available:

- Photo Display Time in Seconds
- Drug Server IP Address
- Camera Usage
- Print Labels
- Require Container Picture
- Validate All Images
- Session Timeout In Minutes
- Export Configuration Files

5.15.1. Photo Display Time in Seconds

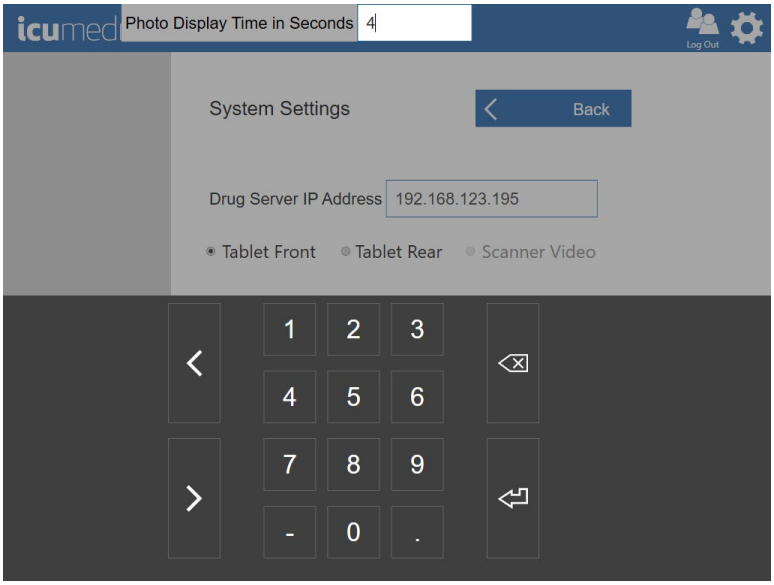
1. This setting allows the user to configure the default photo display time for pictures taken of the input vial or syringe during order preparation. This setting also applies to the photos taken while on the verification and validation screens.
2. Tap the **Settings** icon and tap the **System Settings** setting action icon

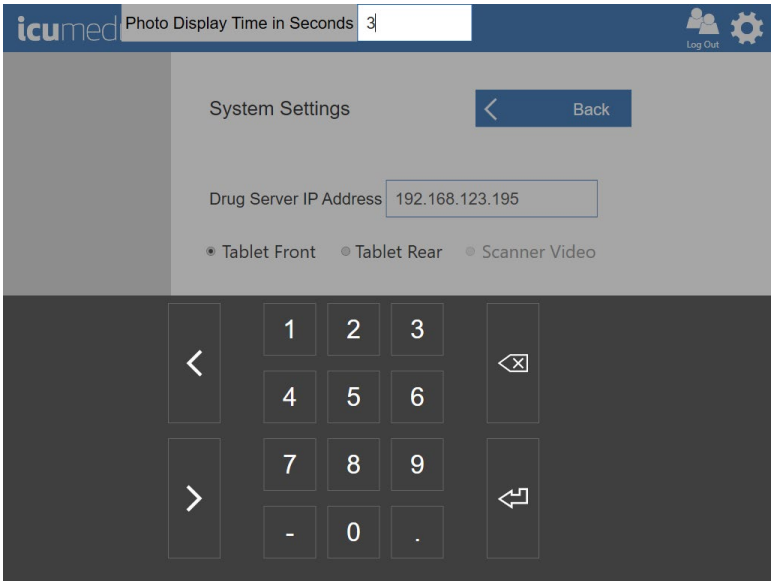


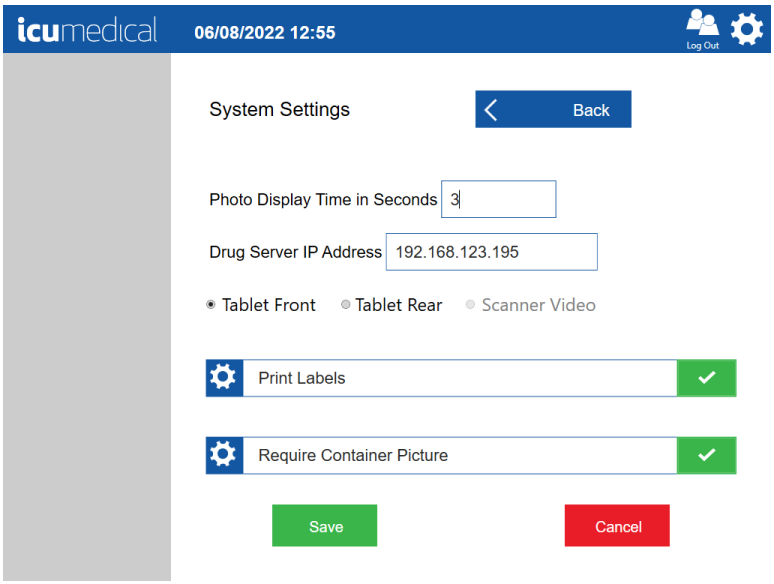


3. Tap the **Photo Display Time in Seconds** field

4. Enter time in seconds







5. Tap the **Save** button to save the changes or the **Cancel** button to cancel the changes

5.15.2. Drug Server IP Address

This shows the IP address of the Drug Server. Contact ICU Service representative to configure this setting.

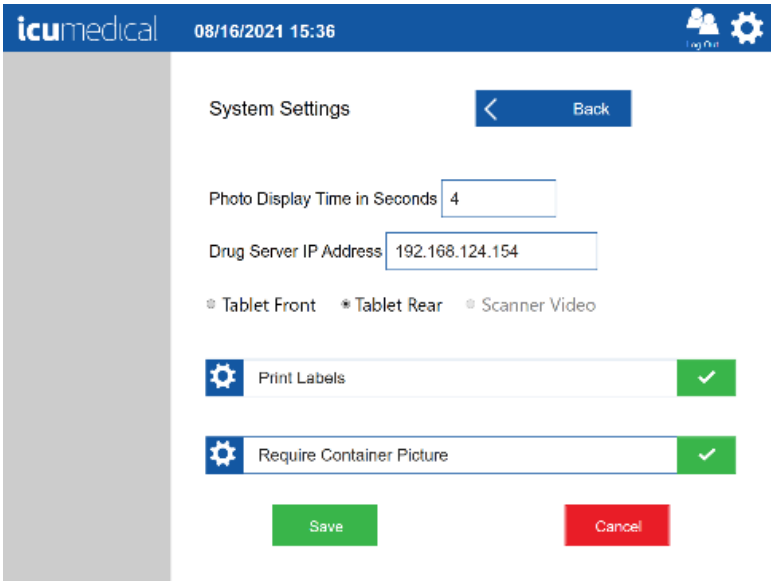
5.15.3. Camera Usage

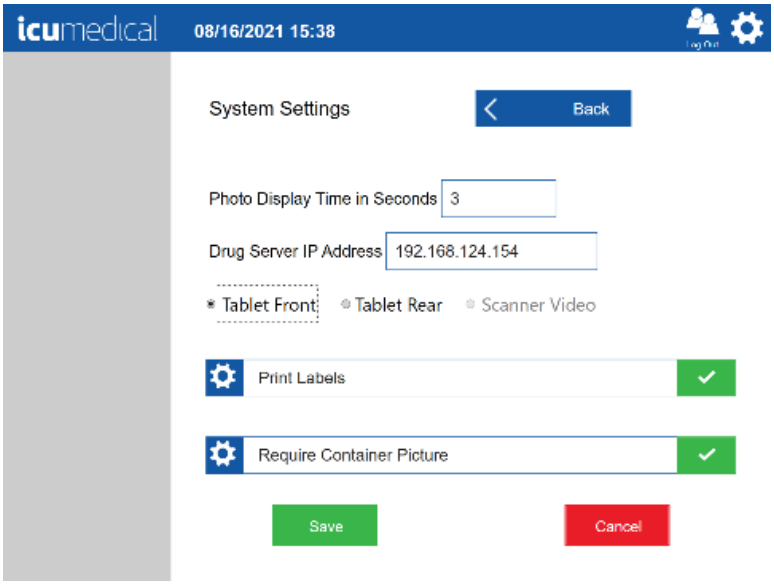
This setting allows the user to select which camera the Operator and Pharmacist applications uses to take pictures of the input vial or syringe during order preparation. This setting also applies to the pictures taken on the Verification and Validation screens.

Note: Pharmacist application does not have the barcode scanner configured, so the **Scanner Video** option is automatically disabled.

1. Tap the **Settings** Icon and tap the **System Settings** setting action icon
2. Select one of the following options below:
   a. Tablet Front
   b. Tablet Rear
   c. Scanner Video

3. Tap the **Save** button to save the changes or the **Cancel** button to cancel the changes



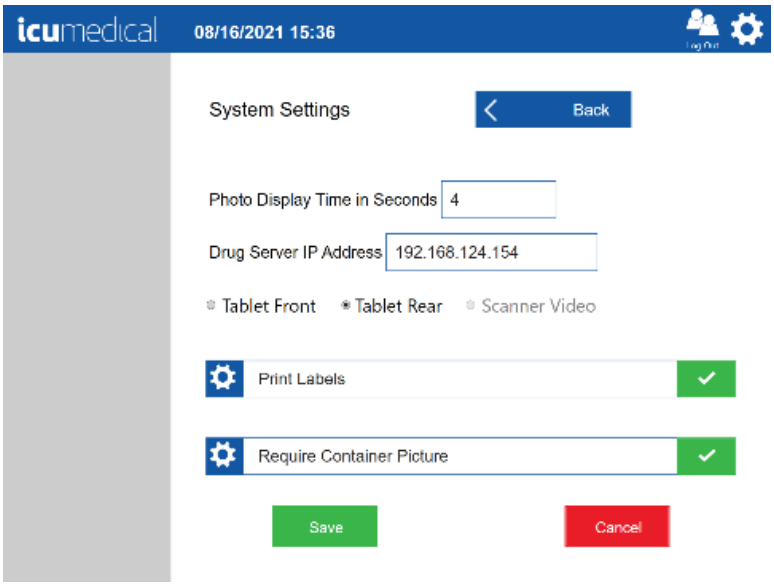


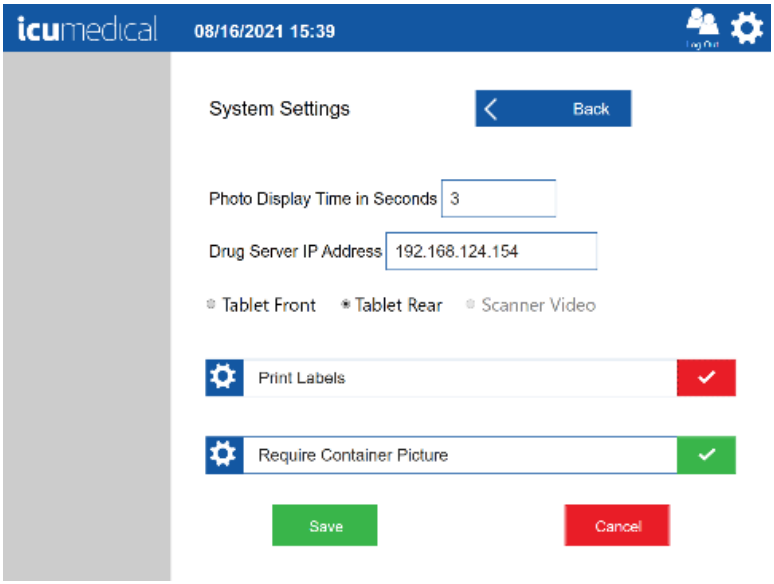
5.15.4. Print Labels

This setting allows the user to enable or disable automatic printing of the order completion label when the user accepts or rejects an order on the Verification or Validation screens.

1. Tap the **Settings** Icon and tap the **System Settings** setting action icon
2. Select/Deselect the **Print Labels** option

3. Tap the Save button to save the changes or the Cancel button to cancel the changes



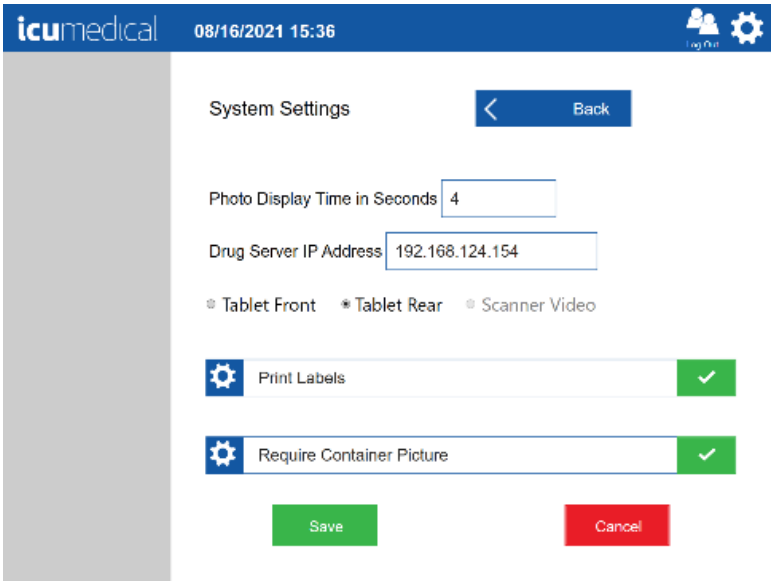


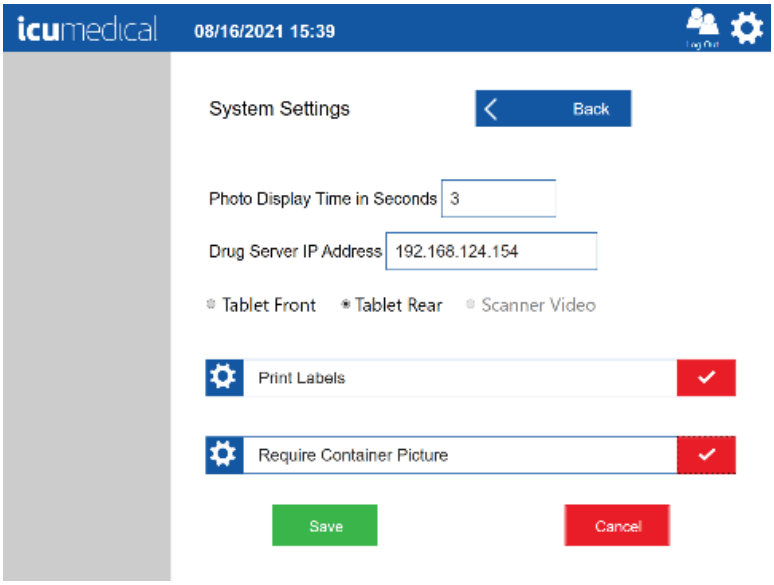
5.15.5. Require Container Picture

This setting allows the user to enable or disable the requirement to take input vial or Diana Cassette pictures in the Order Details screen before starting the preparation process.

1. Tap the **Settings** Icon and tap the **System Settings** setting action icon
2. Select/Deselect the **Require Container Picture** option

3. Tap the **Save** button to save the changes or the **Cancel** button to cancel the changes



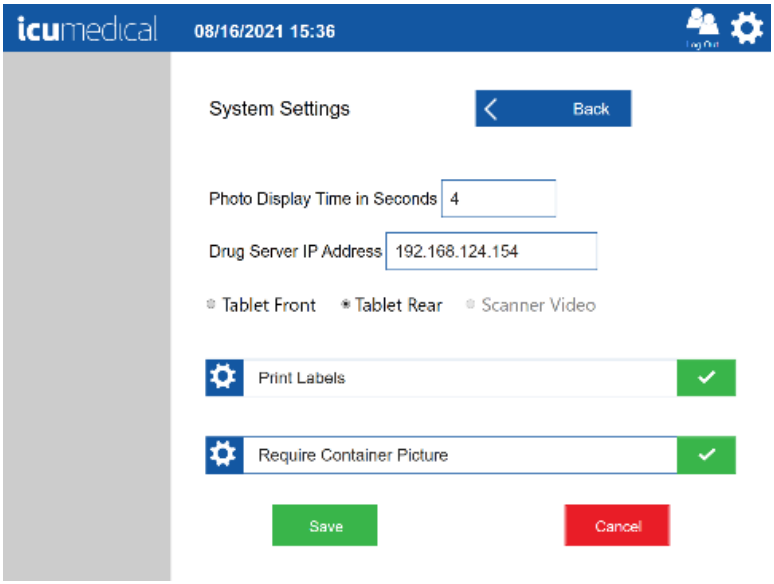


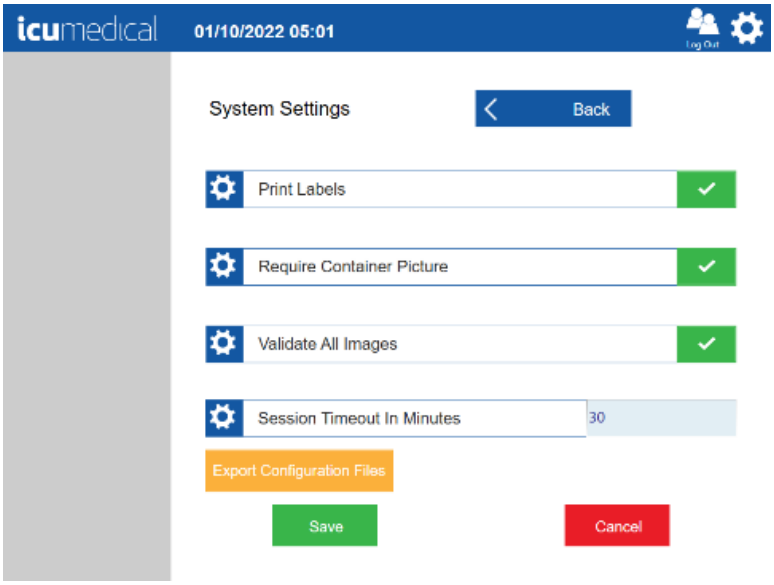
5.15.6. Validate All Images

This setting allows the user to enable or disable the requirement to validate the images on the Verification or Validation screens.

1. Tap the **Settings** Icon and tap the **System Settings** setting action icon
2. Select/Deselect the **Validate All Images** option

3. Tap the **Save** button to save the changes or the **Cancel** button to cancel the changes



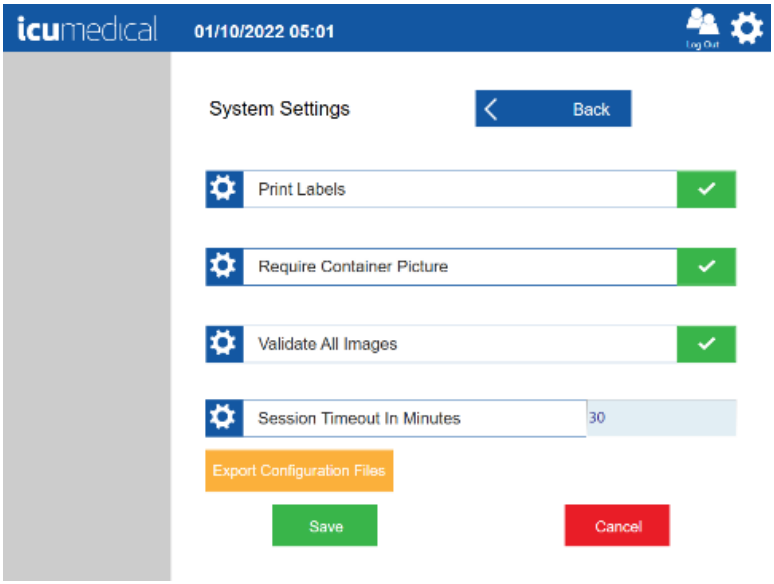


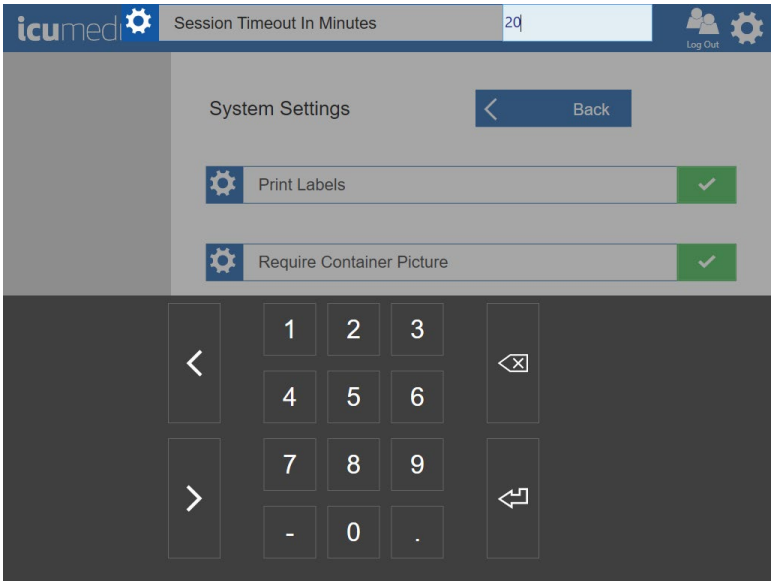
5.15.7. Session Timeout In Minutes

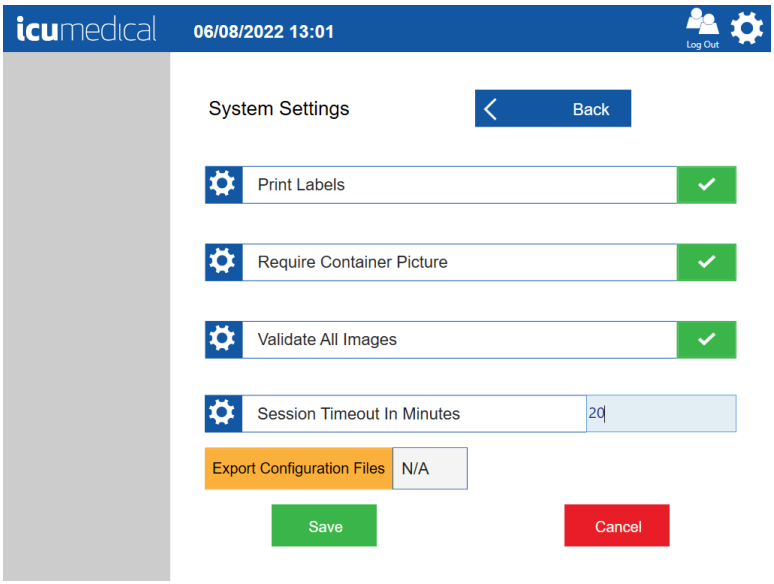
This setting allows the user to configure the user inactive session timeout in minutes.

1. Tap the **Settings** Icon and tap the **System Settings** setting action icon
2. Tap the **Session Timeout In Minutes** field
3. Change the time

4. Tap the **Save** button to save the changes or the **Cancel** button to cancel the changes





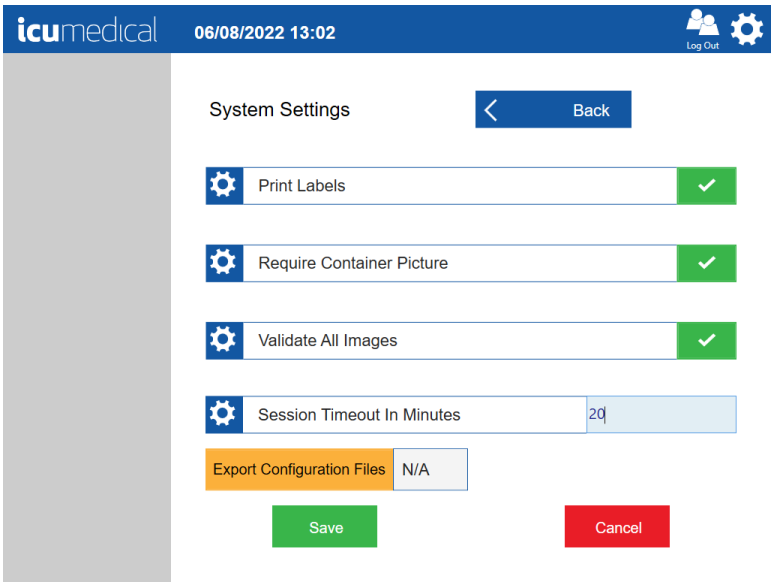


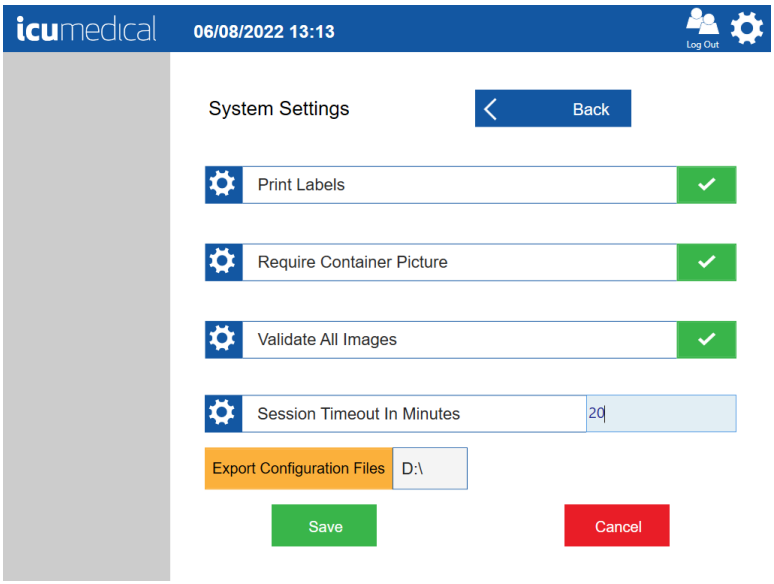
5.15.8. Export Configuration Files

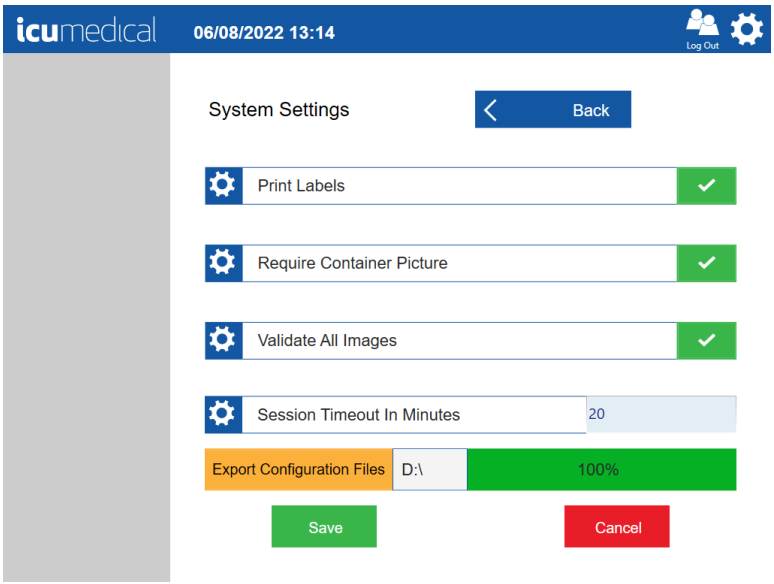
This setting allows the user to export the current operator/pharmacist tablet configuration files to an external USB drive.

1. Tap the **Settings** Icon and tap the **System Settings** setting action icon
2. Tap the **Export Configuration Files** button

   Note: If the external USB is not connected to the tablet, the application displays N/A next to the **Export Configuration Files** button. If the external USB is connected to the tablet, the application displays the USB drive letter next to the **Export Configuration Files** button
3. **100%** complete green bar is displayed after successful export of the configuration files







6. Warranty and Service Information

6.1. 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 the Diana Syringe Pump or accessories.
- Unauthorized cleaning of the Diana Syringe 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.

6.2. 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:

ICU Medical, Inc.
951 Calle Amanecer
San Clemente, CA 92673
(866).829.9025
https://www.icumed.com

Appendix A: Cleaning and Disinfection of the Diana Automated Compounding System

Switch off the Diana Syringe Pump and remove the Power cord from the Diana Syringe Pump.

The operator must wear proper protective equipment (PPE) when operating the System and adhere to facility protocols and standards for operating compounding equipment.

Do not attempt to sterilize or autoclave the Diana Automated Compounding System *under any circumstances.* All external parts are manufactured of stainless steel, aluminum, specially-coated aluminum, impact-proof polystyrene, or polyester.

Standard cleaning and disinfecting agents with an alcohol base can be used to clean and disinfect the device. *DO NOT* use radical-forming or peroxide-forming cleaning and disinfection agents or ketone based cleaning and disinfection agents unless listed below. Do not directly spray onto or moisten the connector sockets on the rear wall of the device. For removing severe soiling, check solvent solubility of plastic and other device parts and labels before attempting to clean with any solvents.

Approved cleaning and disinfection agents:

Agent	Concentrations (water solutions)
Isopropyl Alcohol	Equal or less than 70.0% w/w
Sodium Hypochlorite (bleach)	Equal or less than 2.0% 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

In many cases, cleaning the device with a lukewarm soap solution is the simplest and most gentle cleaning method. Gentle wiping and spraying of cleaning and disinfection agents are typically sufficient. The recommended cleaning and disinfecting protocol is provided below:

Step #1 – Wipe Device with 2% Sodium Hypochlorite (bleach) - Cleansing Solution

Ingredient	Amount	Amount
Bleach (5.25% sodium hypochlorite)	190.5 mL	381 mL
Sterile Water for Irrigation (pour bottle)	309.5 mL	619 mL

TOTAL VOLUME	500 mL	1000 mL

Step #2 – Wipe device with 1% Sodium Thiosulfate - Deactivating Solution

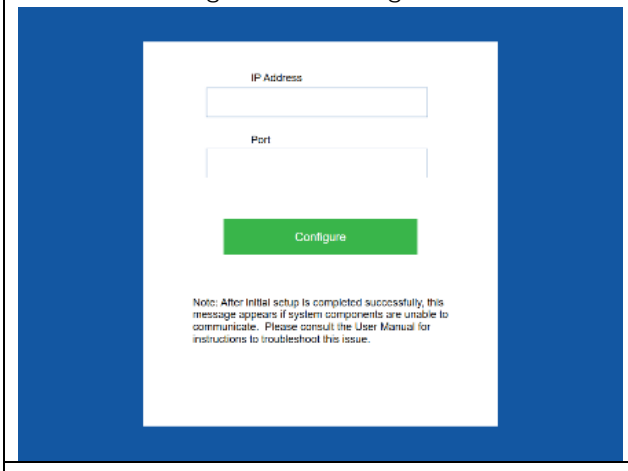
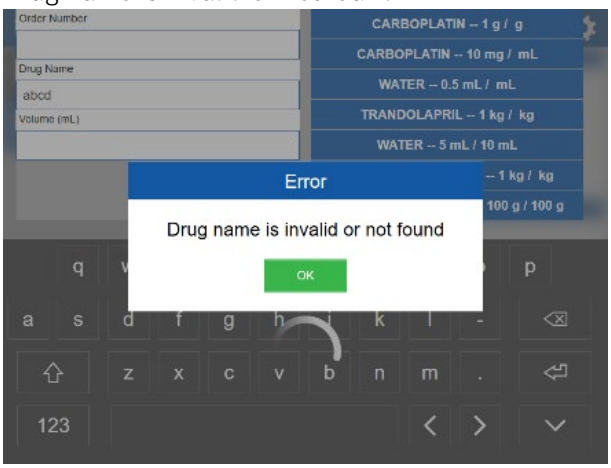
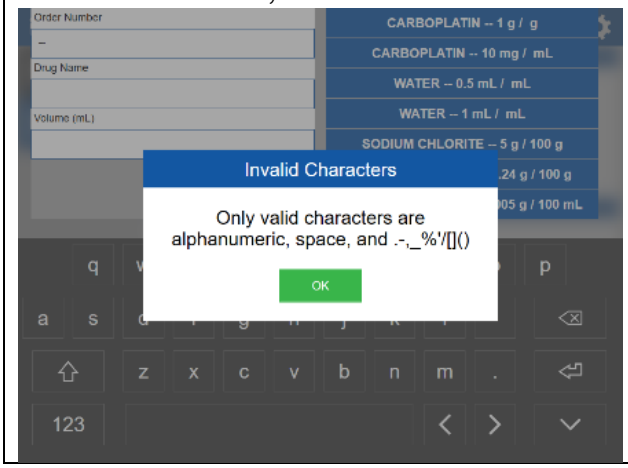
Ingredient	Amount Using (Na Thiosulfate 10%)	Amount Using (Na Thiosulfate 25%)	
Na Thiosulfate Inj. (10% or 25%)	50 mL	20 mL	40 mL
Sterile Water for Irrigation (pour bottle)	450 mL	480 mL	960 mL
TOTAL VOLUME	500 mL	500 mL	1000 mL

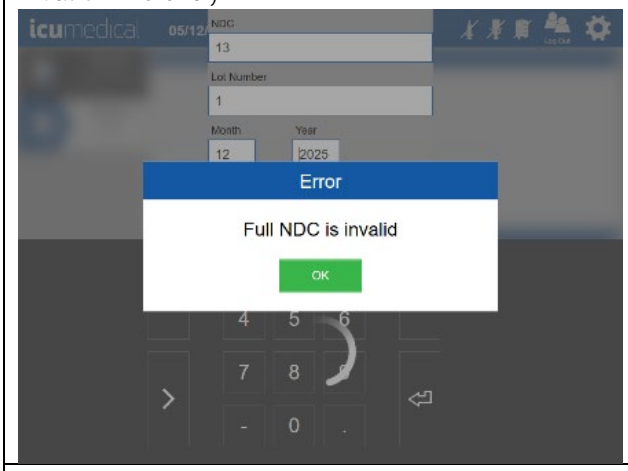
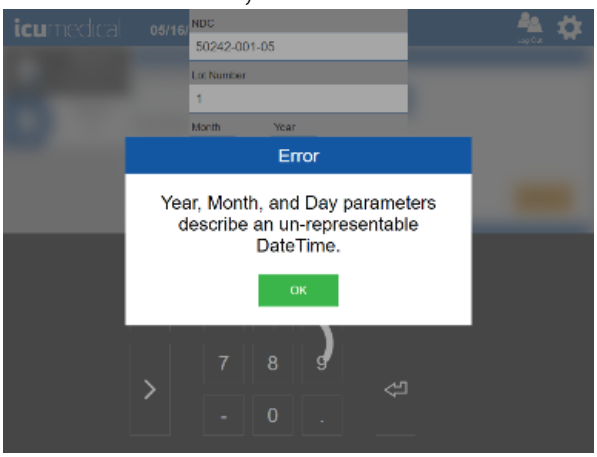
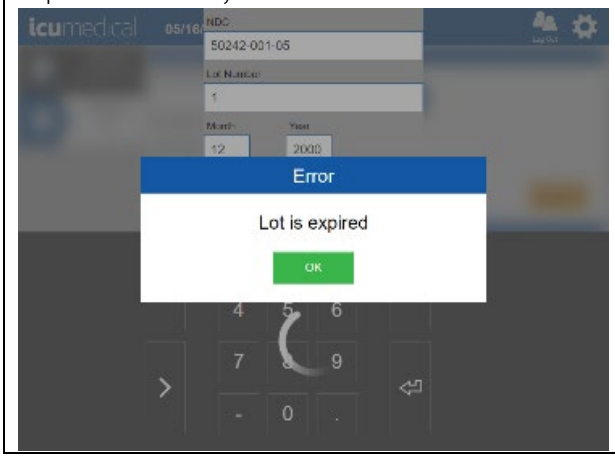
Step #3 – Wipe with Sterile Water - Wipe all surfaces to remove any residual bleach or Na thiosulfate.

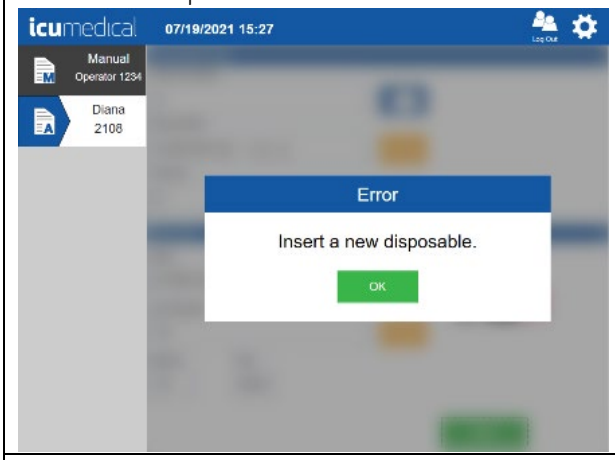
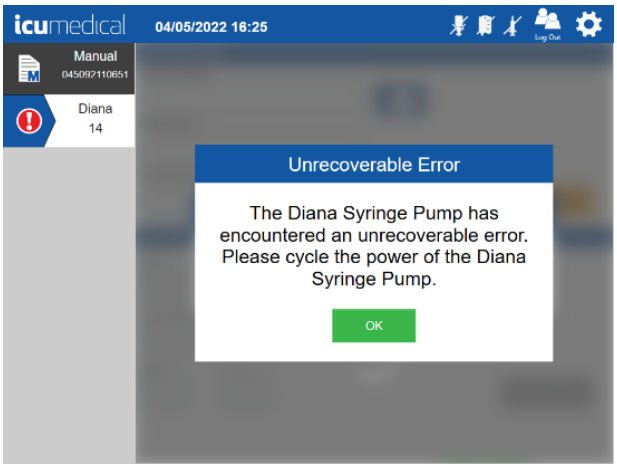
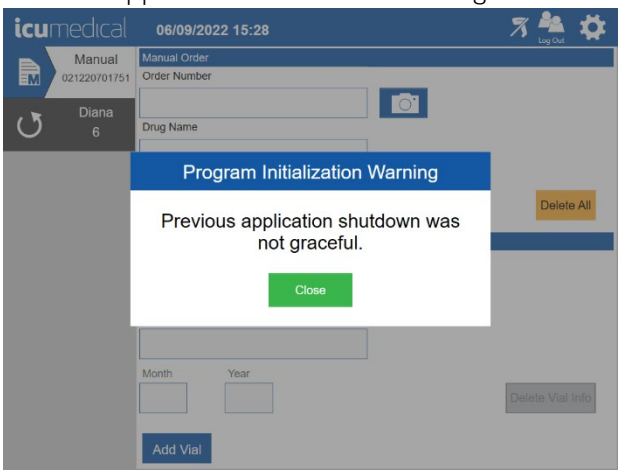
Step #4 – Wipe with Sterile Isopropyl Alcohol - Wipe all surfaces prior to use in compounding sterile products. Any remaining residue may be cleaned by using an alcohol swab, lint-free towel soaked in isopropyl alcohol, or a soap solution suitable for cleaning a biological safety cabinet.

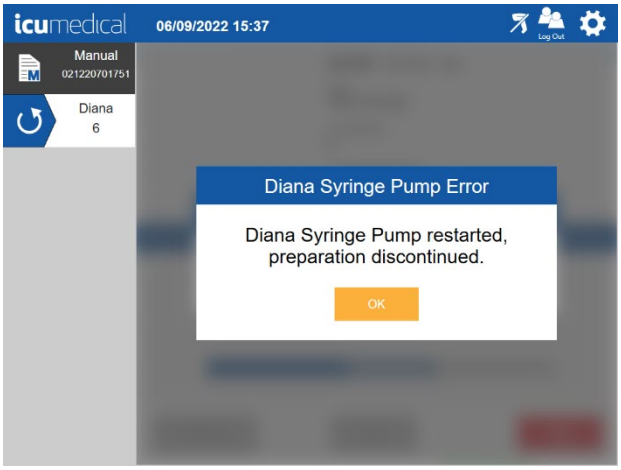
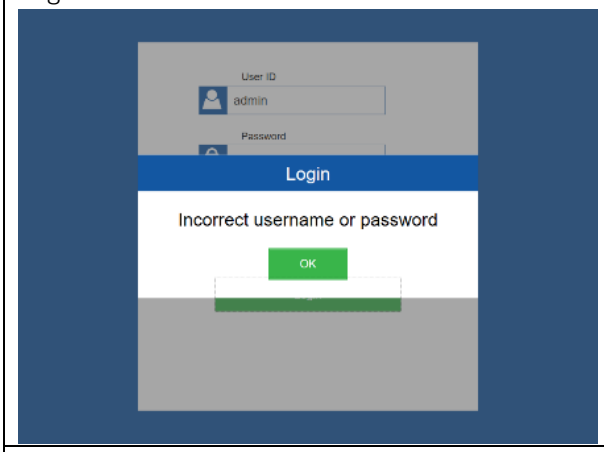
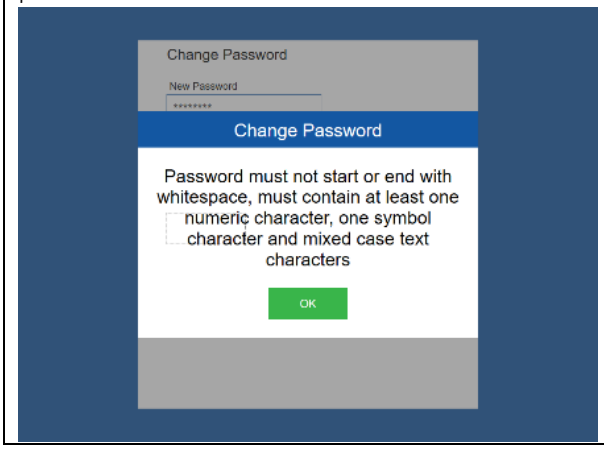
Step #5 – (optional cleaning) repeat steps 3 and4 two times each once per day from debris, wiping in top-down motion and discarding towels, followed by a dry and clean towel wipe in between each step. Carefully clean the sensors, syringe plunger pins, syringe carrier plunger, and stopcock holder (See picture below).

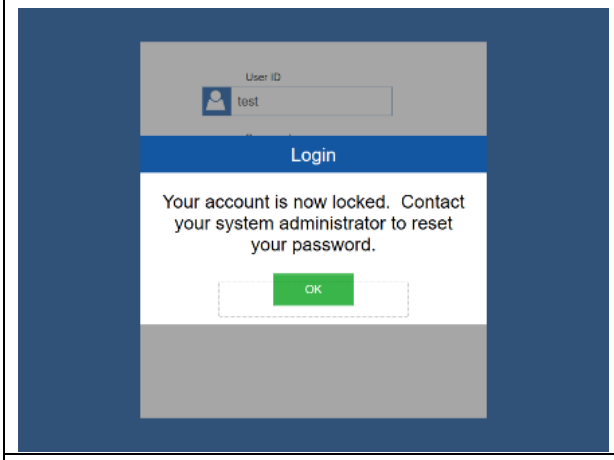
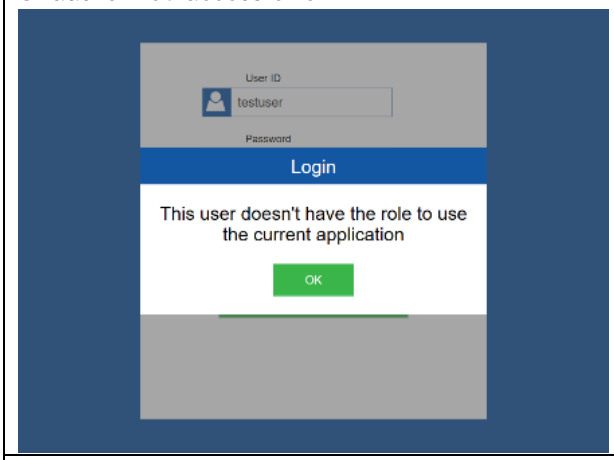
Appendix B: Troubleshooting and Maintenance

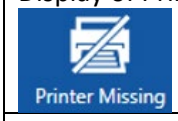
Description of Fault	Remedy
IP address configuration message 	Operator or Pharmacist tablet lost communication to the Web Server. Make sure that the Webserver computer is On and is connected to the configured Wi-Fi router. Restart the tablet and if the message reappears contact ICU service personnel.
Drug name is invalid or not found 	Make sure that the entered drug name is correct.
Invalid character entry 	Make sure that the entered value does not contain any special characters other than specified in the error message.

Invalid NDC entry 	Make sure that the entered/scanned drug ID (NDC) is correct.
Incorrect Month entry 	Make sure that the entered Month is correct.
Expired Date entry 	Make sure that the entered the date value is not expired. Check the date on the input vial. If it is expired discard the input vial and use a new unexpired input vial.

Insert New Disposable error 	Make sure that a new Diana Cassette (disposable) is installed on the Syringe Pump before proceeding with the drug transfer process
Motor movements error 	Examine the Syringe pump for any obstruction in the syringe carrier. Remove any obstructions found. Remove any attached disposables from the Syringe Pump. Restart the Syringe Pump.
Previous application shutdown was not graceful 	Tap the Close button and restart the application.

SPM restarted error message during the delivery process 	Remove the disposables from the SPM, press OK. The previous delivery status will be in Discontinue state.
Login error 	Make sure that the entered User ID and Password are correct.
Password entry error while setting up the user password 	Make sure that the entered password is in correct format.

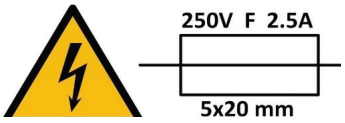
Account Locked 	If the account locked message is due to 5 consecutive failed login attempts. The user account should be unlocked by an Administrator from the Pharmacist application.
Unauthorized access error 	Make sure the user has the right access privileges.
 	Displaying amount of liquid Delivered and Specified for the order on the Verification/Validation screen. If the UI displays Delivered Box in Green, that means the delivered volume is within the range. If the UI displays Delivered Box in Red, that means the delivered volume is not within the range. User will either Accept or Reject the delivery based on the delivered volume
Display of SPM camera disconnected Icon on the tool bar 	Restart the Diana Syringe Pump. If the icon still displays, contact ICU service personnel.

Display of Barcode scanner not connected Icon on the tool bar 	Barcode Scanner is not connected. Make sure that the barcode is connected to the Operator tablet properly. If the icon still displays, contact ICU service personnel.
Display of Printer not connected Icon on the tool bar 	Label Printer is not connected. Make sure that the printer is turned on. If the icon still displays, contact ICU service personnel.
Display of Wi-Fi not connected Icon on the tool bar 	Operator lost communication to the Web Server. Make sure that the Webserver computer is On and is connected to the configured Wi-Fi router. If the icon still displays, contact ICU service personnel.

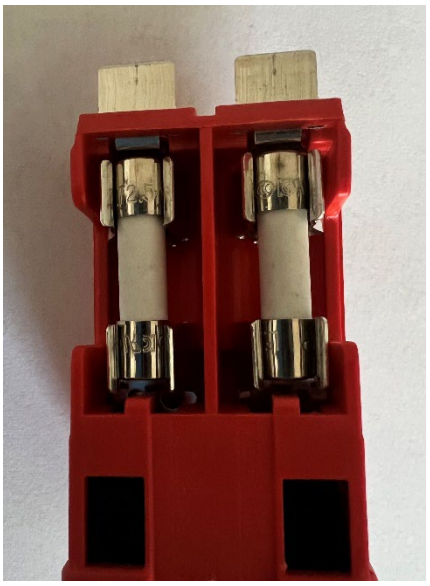
Fuse Replacement

Diana Syringe Pump uses two fuses located in the rear of the unit; fuses are a part of the power inlet module. Service on the fuses can be done by the end-user (end-user buy the fuses from local hardware/electrical store). Incorrect insertion of the fuses may result in no power to the unit.

1. Procure proper fuses (two per pump): F2.5A 250V, 5x20mm



2. Make sure the unit is powered-off and power cord is unplugged.
3. Using flat head screwdriver remove the power switch holder from power inlet module, by pulling the power switch holder carefully.
4. Remove the old fuse(s) from the power switch holder and replace with new fuse(s). It is recommended to replace both fuses at the same time.
5. Reinsert power switch holder back into power inlet module by gently pushing inside until it stops.



Appendix C: Accuracy Verification Protocol

1. Use **10 mL** input containers for this test.
2. Use a **100 mL** output IV bag for this test.
3. Use a new Diana Cassette.
4. Place the empty output IV bag on a scale.
5. Tare scale with empty IV bag (scale readability and repeatability should be to 0.001g)
6. Turn ON the Diana Syringe Pump.
7. Launch the Operator software.
8. Use the **Water** substances for Drug Name.
9. Perform a delivery of **5 mL**.
10. After dispensing is complete disconnect output IV bag.
11. Weigh the disconnected IV bag on previously tarred scale and record new weight.
12. Divide weight by 1 g/mL (density of water) to convert grams to mL's.
13. Record mL's after calculating density conversion.
14. Calculate % error.

    Calculate % error = Measured Fluid dispensed mL's – (Programmed volume mL's / Programmed volume mL's * 100)

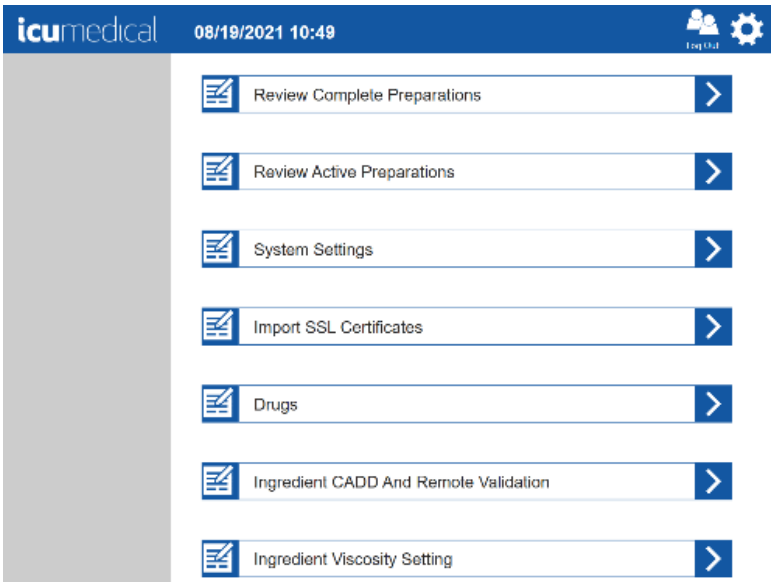
15. Repeat 3 tests for 5 mL.
16. Repeat 4 tests for 10 mL and 20 mL (Use **100 mL** input containers for this test).

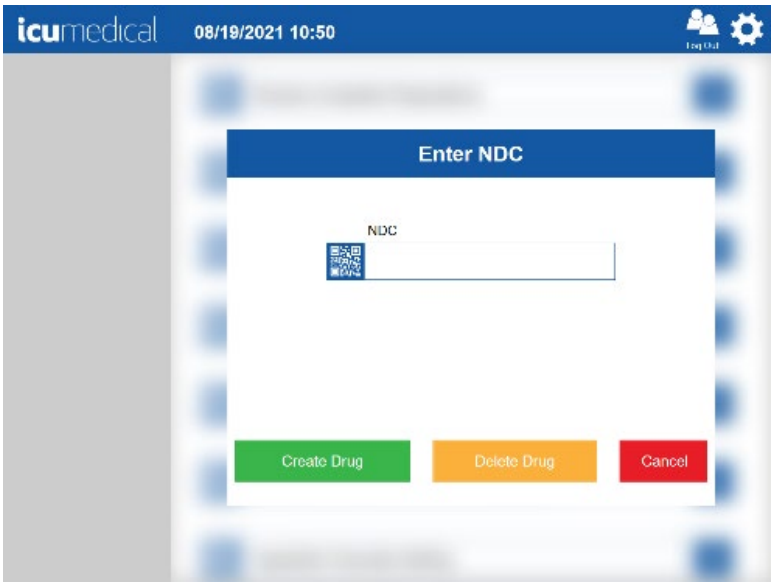
Appendix D: Making a Reconstituted Drug

A reconstitution protocol must be created for a drug. A reconstitution protocol defines the resulting drug and concentration after reconstitution and specifies the diluent and amount to use. This reconstitution protocol can then be associated with one or more drugs through their Drug Identifier (usually an NDC).

1. Adding Reconstitution Protocol to a Drug

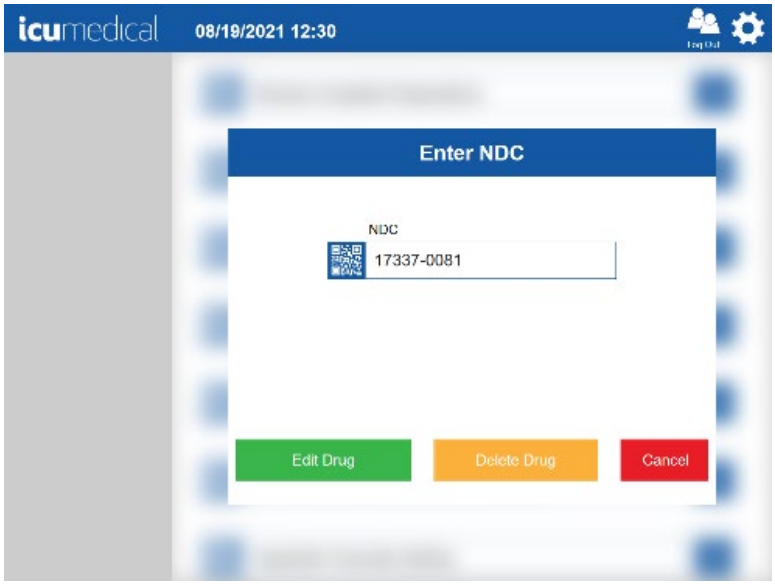
1. Open the Pharmacist application from the Pharmacist Tablet.
2. Choose the **Drugs** option from the settings. The screen below is displayed.



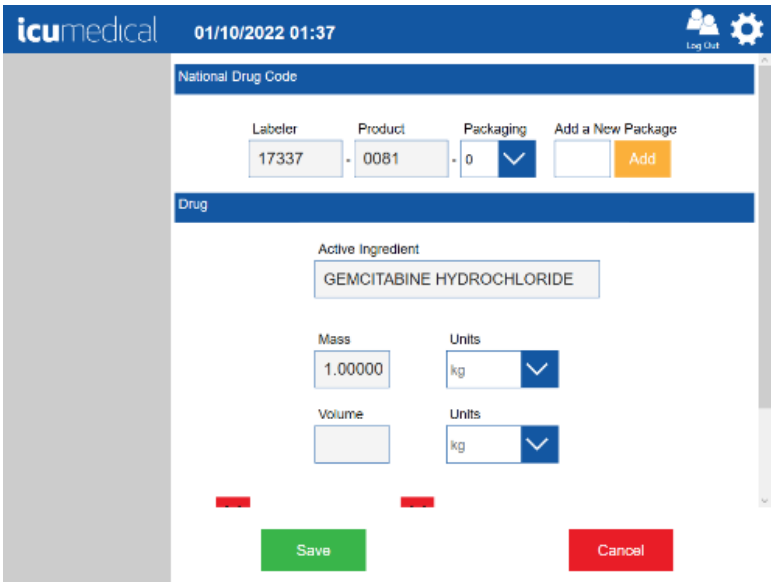


3. On the Enter NDC screen, enter the Drug ID for which the reconstitution protocol is being created.

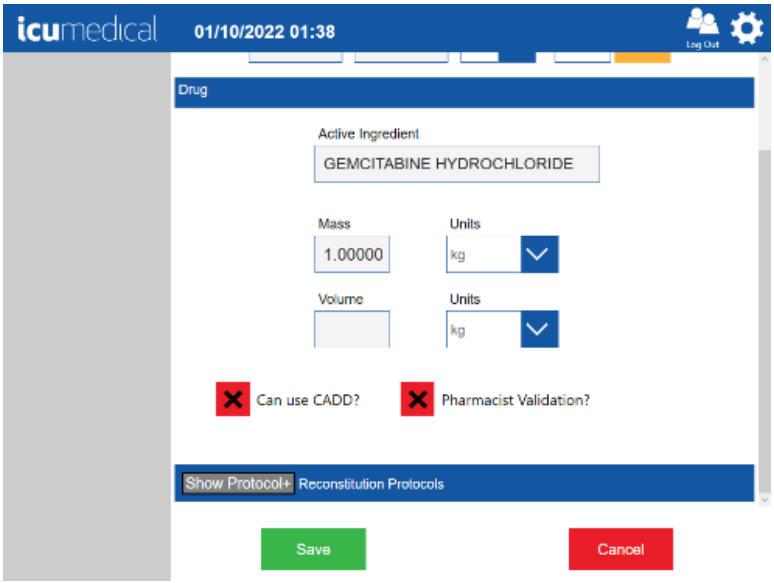
Note: If the Drug ID needs to be added to the Drugs database, refer to the Drugs settings section to create a new Drug ID.



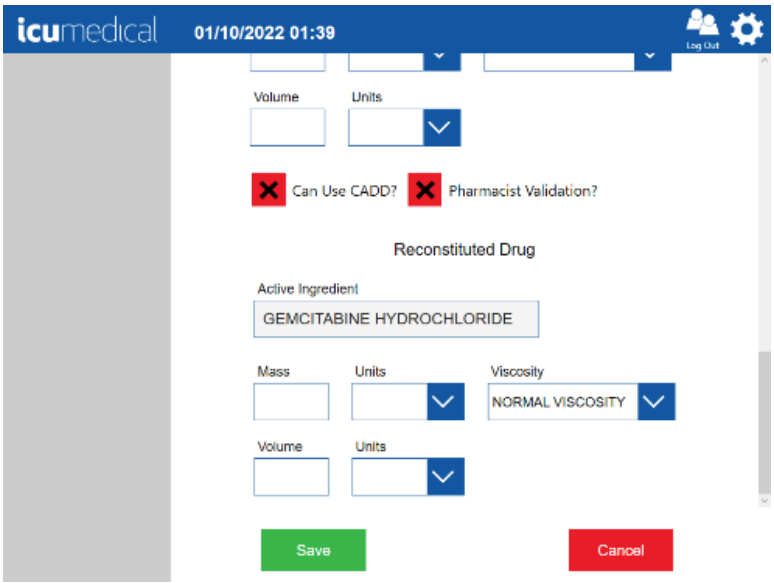
4. Tap **Edit Drug** from the **Enter NDC** screen. The Drug details screen is displayed.



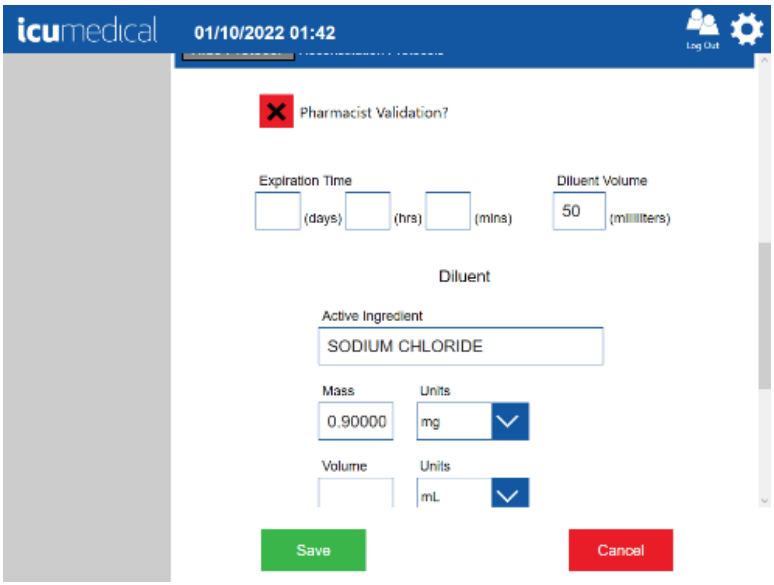
5. Scroll down the screen to see the **Show Protocol+** button.

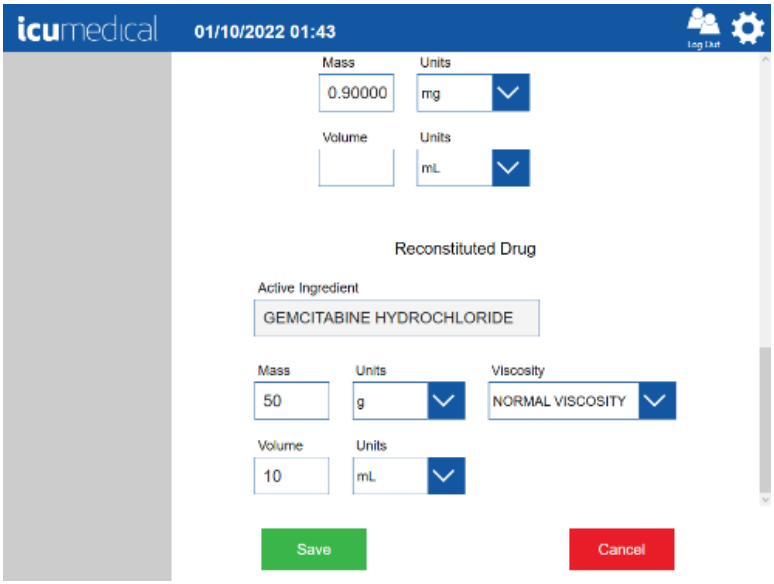


6. Tap the **Show Protocol+** button. Information related to Reconstitution Protocol for the drug is displayed.

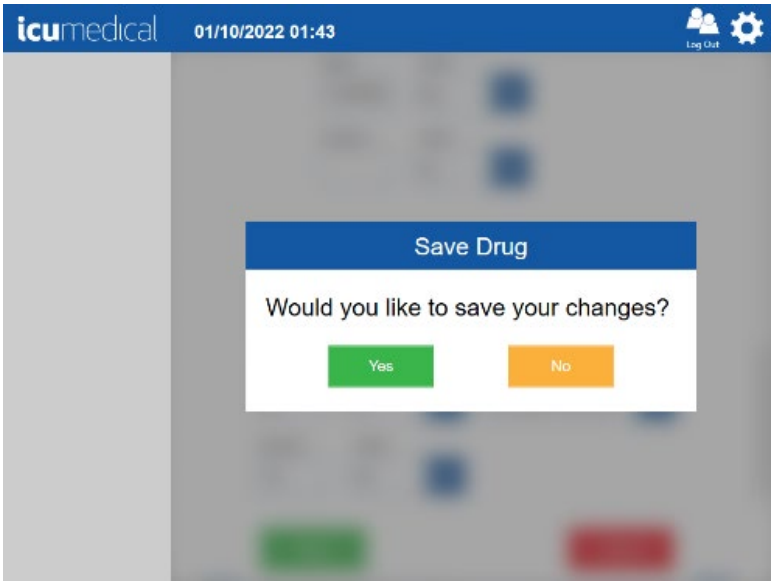


7. Add the information for **Diluent Volume**, **Diluent** and **Reconstituted Drug** sections.
Important Note: Follow the hospital instructions for adding the information for Diluent and Reconstituted Drug sections. The information in this section is for example purposes only.





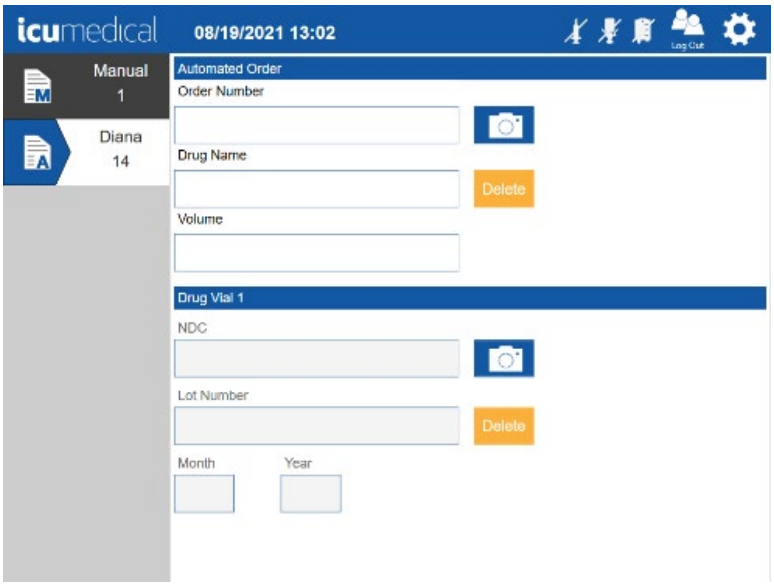
8. Once all the information is entered, tap the **Save** button.
9. Tap the **Yes** button on the **Save Drug** confirmation dialog.



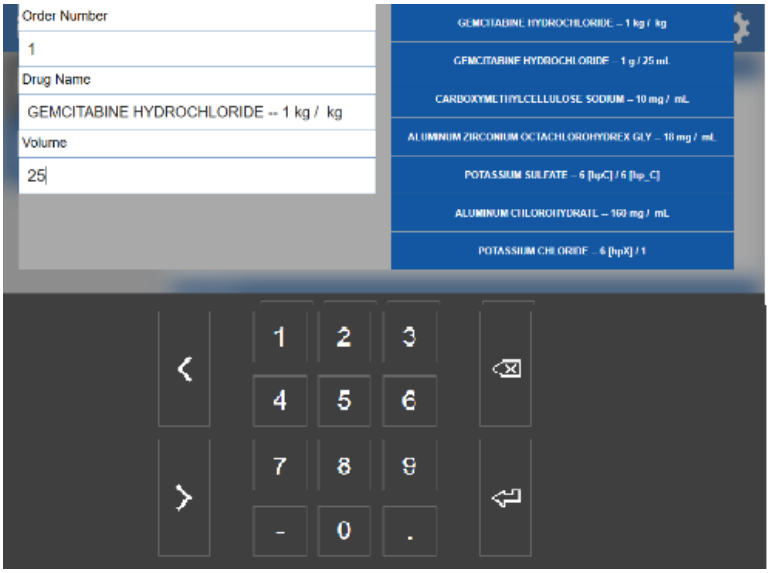
2. Making a Reconstitution Drug

Note: If using a length of tubing between the outlet of the Diana Cassette outlet and the output container, the tubing must be primed prior to connection to the Diana Cassette on the Syringe Pump

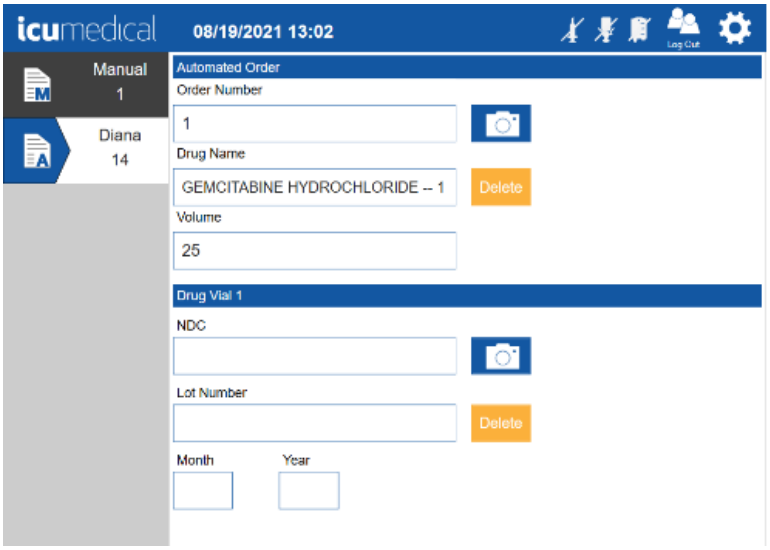
1. On the **Operator application**, select the connected Diana Syringe Pump.



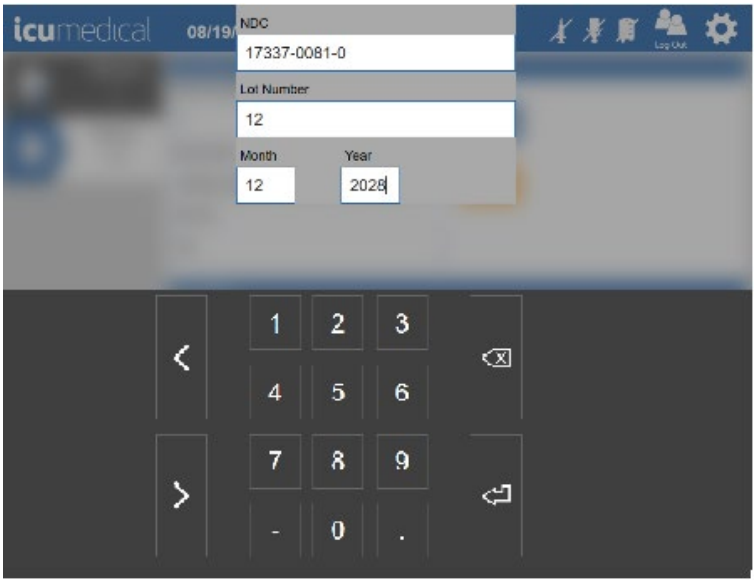
2. For the Drug Name enter/select the Reconstituted drug name.
3. Enter the **Order Number** and enter a value for the **Volume**.



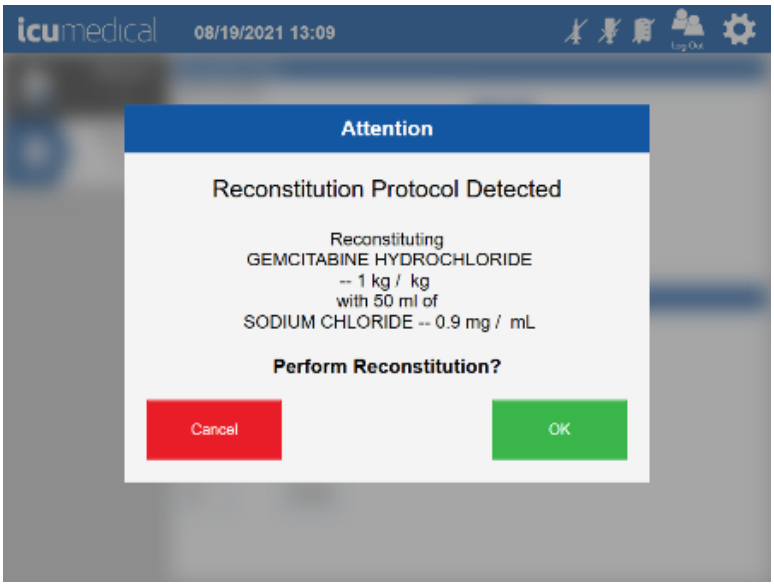
4. Tap the NDC field and select the NDC ID for which the reconstitution protocol was added.
   Note: The user must select the correct NDC ID in order to perform a reconstitution for the drug.



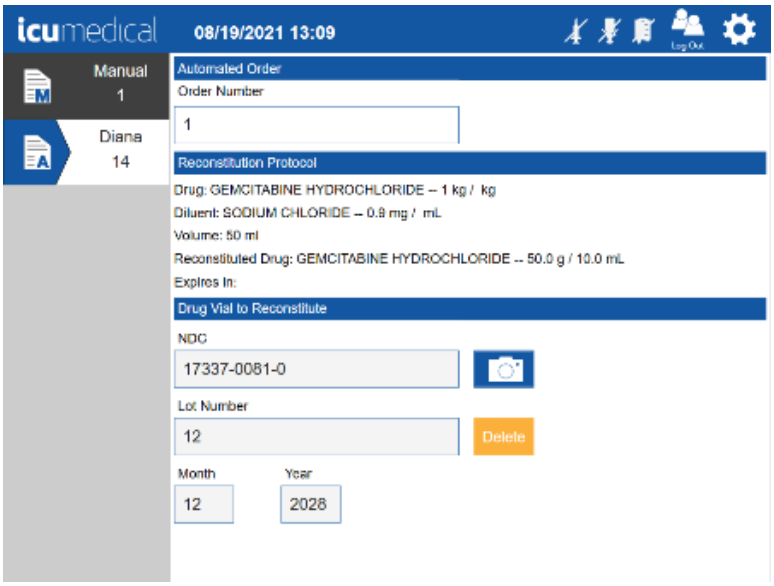
5. Enter the **Lot Number** and **Lot Expiration** details using keyboard and press **Enter** key.



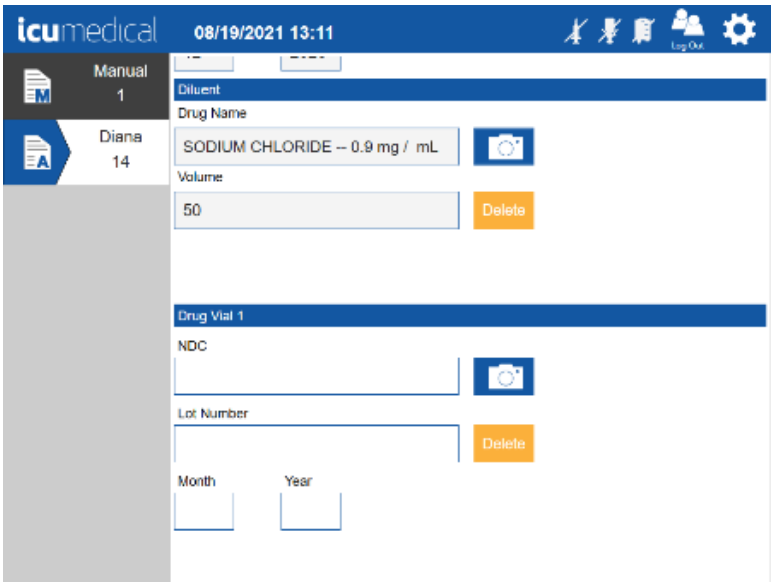
6. The Reconstitution Protocol Detected message is displayed. Tapping the OK button allows the user to perform the Reconstitution.
   Note:The user can choose the Cancel button to perform a normal delivery.



7. Tap the OK button on the confirmation message to proceed. Information related to Reconstitution Protocol is displayed.

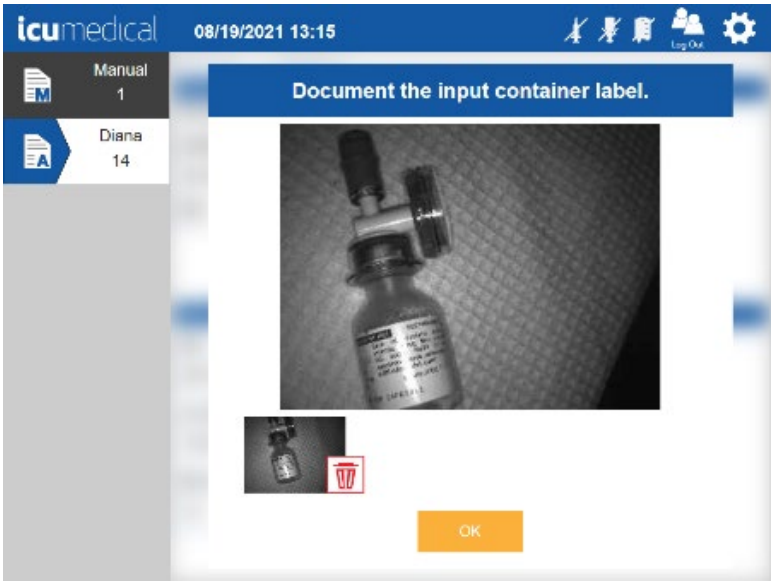


8. Scroll down to see the **Drug Vial 1** section, to add the drug vial.



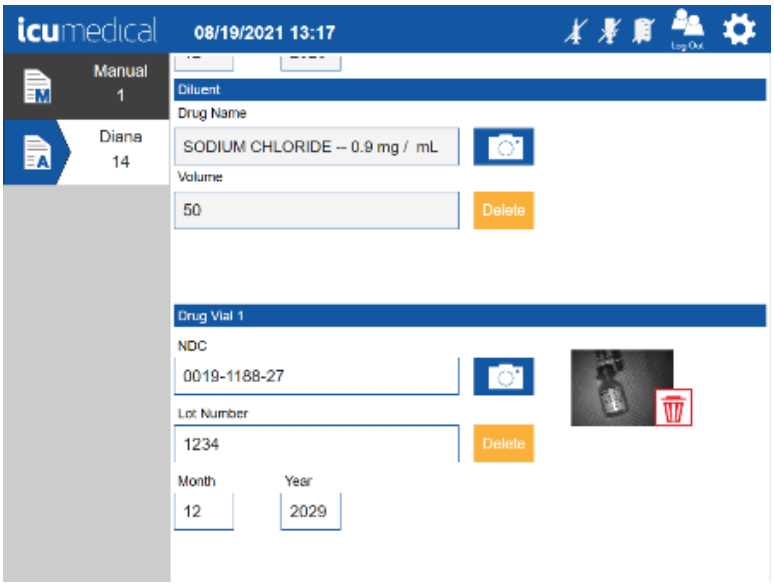
9. Tap the **NDC** field on the **Drug Vial 1** section and select the **NDC ID**, enter the **Lot Number** and **Lot Expiration** details.

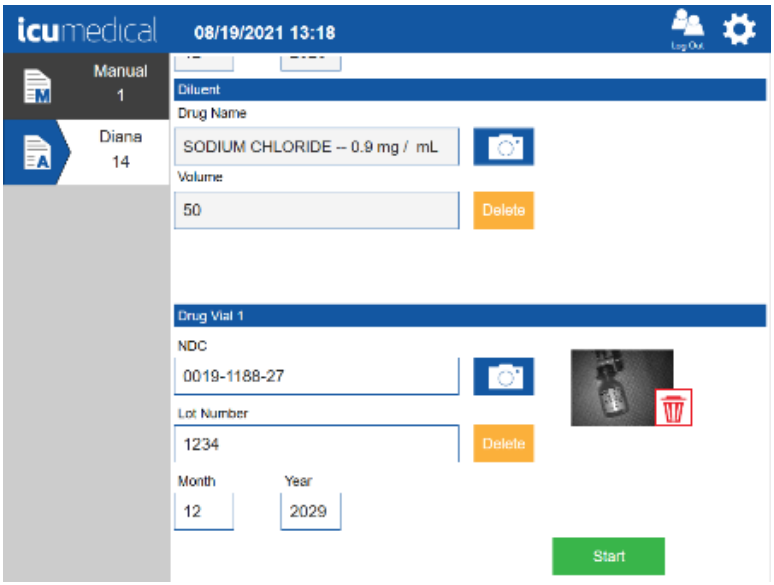
10. The Document the input container label screen is displayed to allow the user to take pictures. Capture the input vial pictures and tap the OK button.



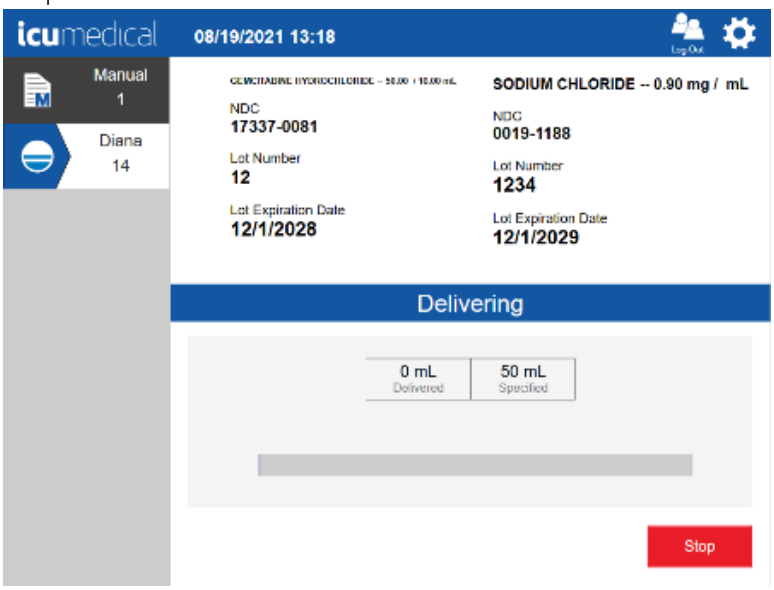
11. Insert the Diana Cassette and connect the input vial and output container.

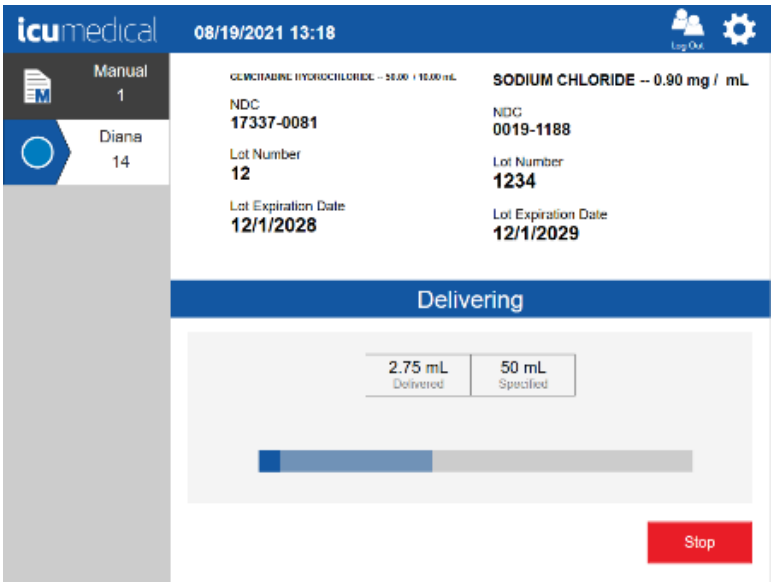
12. Process the order by tapping the Start icon.



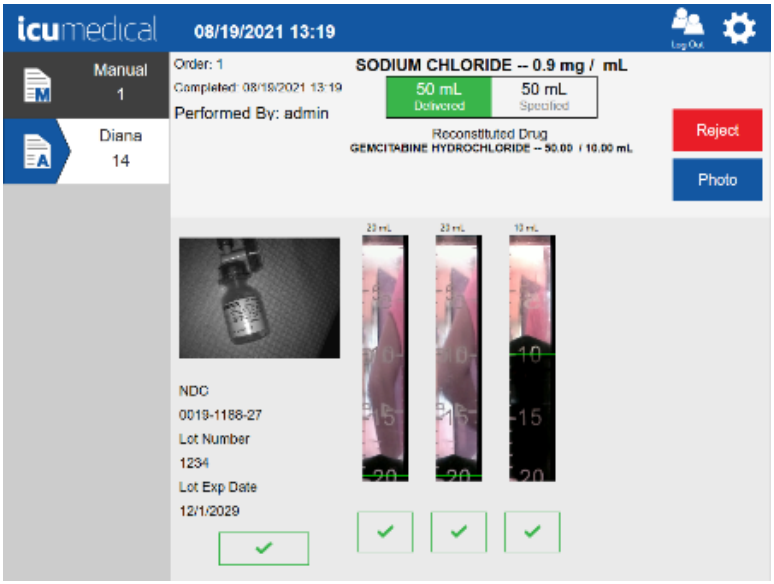


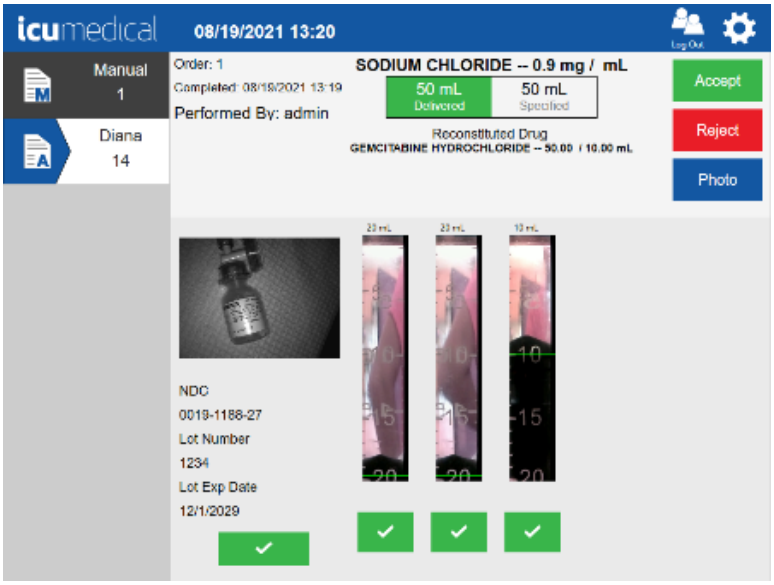
13. The System starts processing the order and displays the verification screen once the transfer process completes.





14. On the verification screen, review the pictures and the Reconstituted drug information and Accept/Reject the preparation.



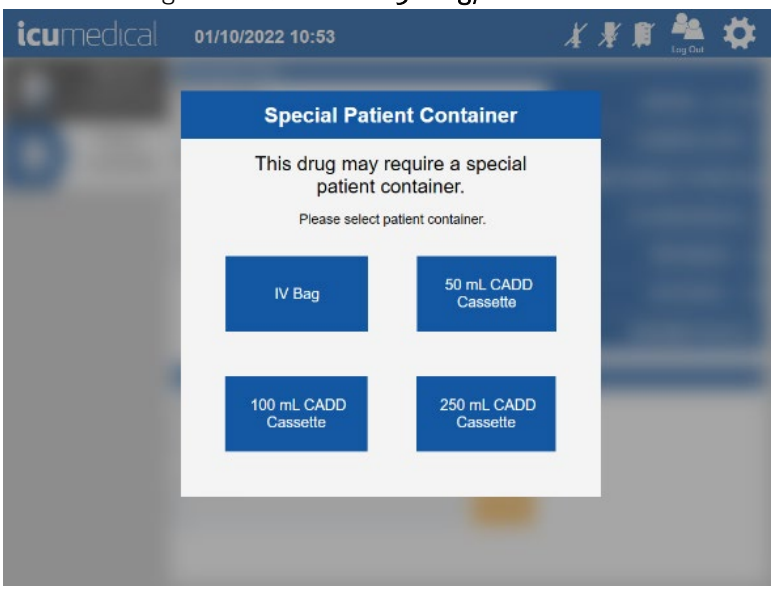


Appendix E: Special Output Container Identification and Selection

The Diana Automated Compounding System supports special output containers that require removal of air before transferring fluid into it. The drugs that needs special output containers are identified in the drug database through the **Ingredient CADD And Pharmacist Validation** tool setting.

1. CADD Cassette

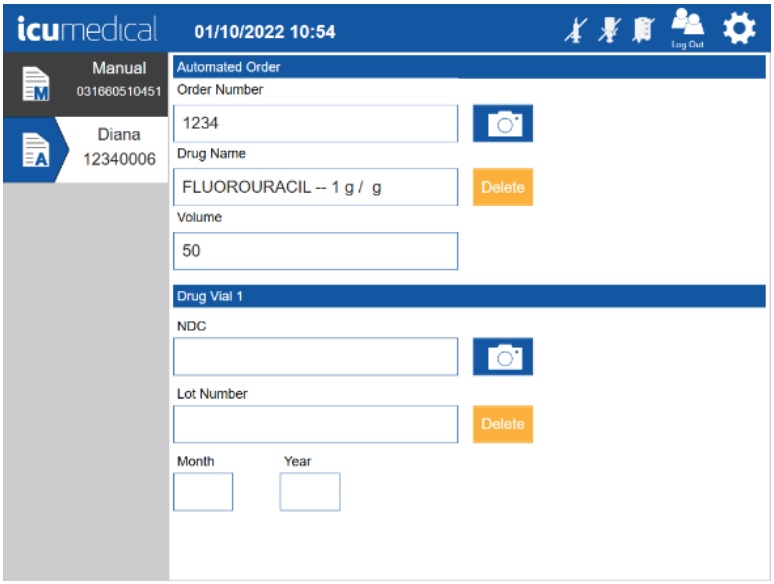
1. On the **Operator application**, select the connected Diana Syringe Pump and enter the order details. Once the information is entered on the **Order Screen** the following pop-up screen is displayed.
   Note: Here we are using **FLUOROURACIL—50 mg/1 mL**.

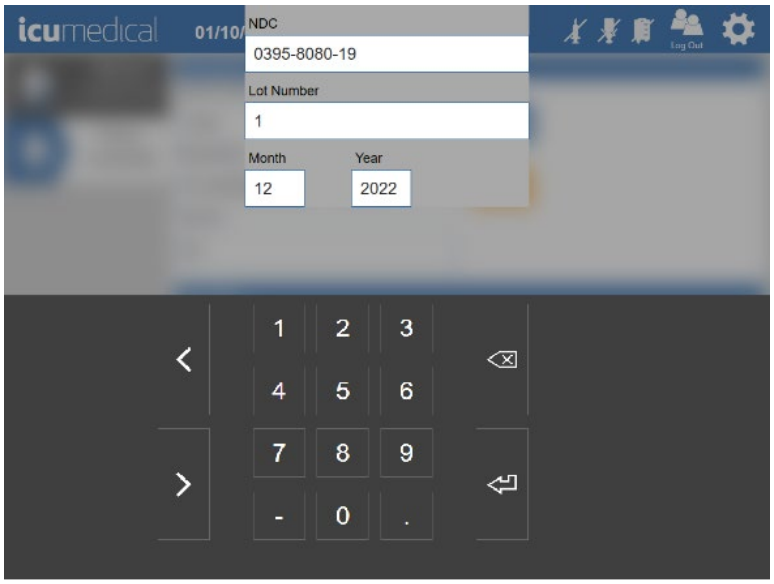


2. Select the appropriate patient container depending on the volume entered in the Order screen.

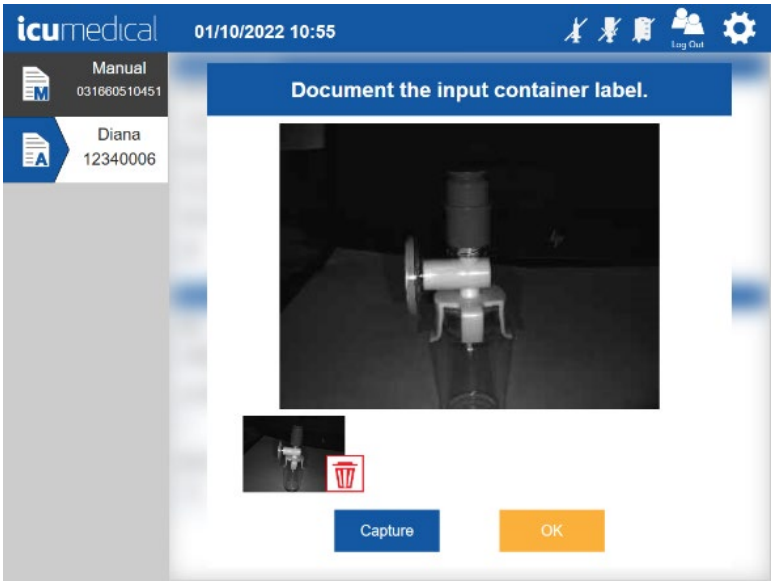
In this example 50 mL CADD Cassette selected.

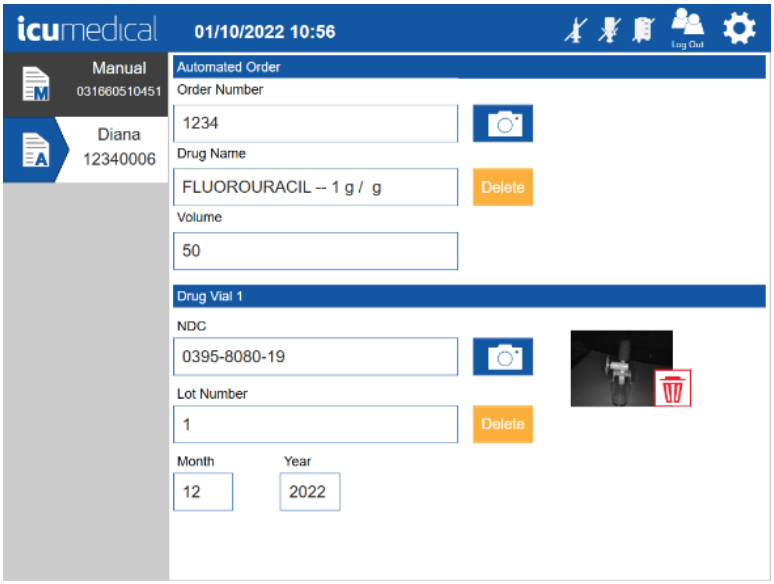
3. Tap the NDC field,enter the NDC details and tap on the virtual keyboard Enter key.



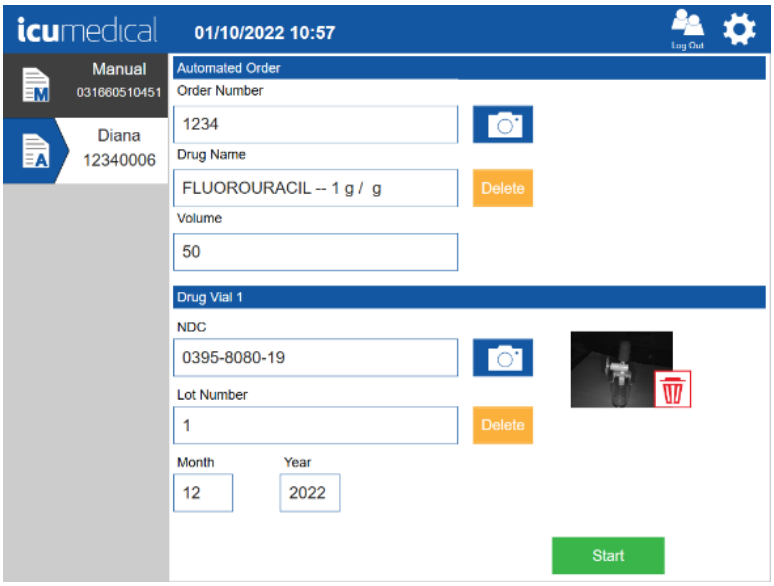


4. On the **Document the input container label** window, capture the input vial and tap the **OK** button. The System displays the order screen.

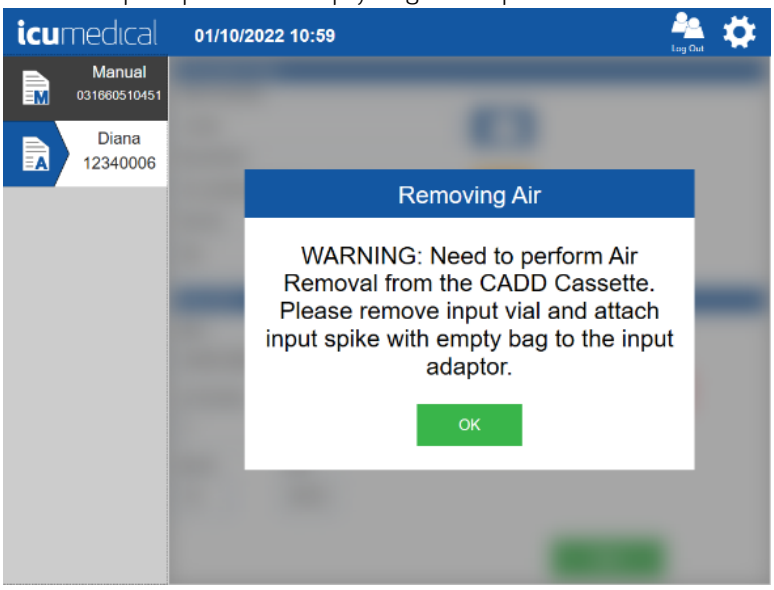


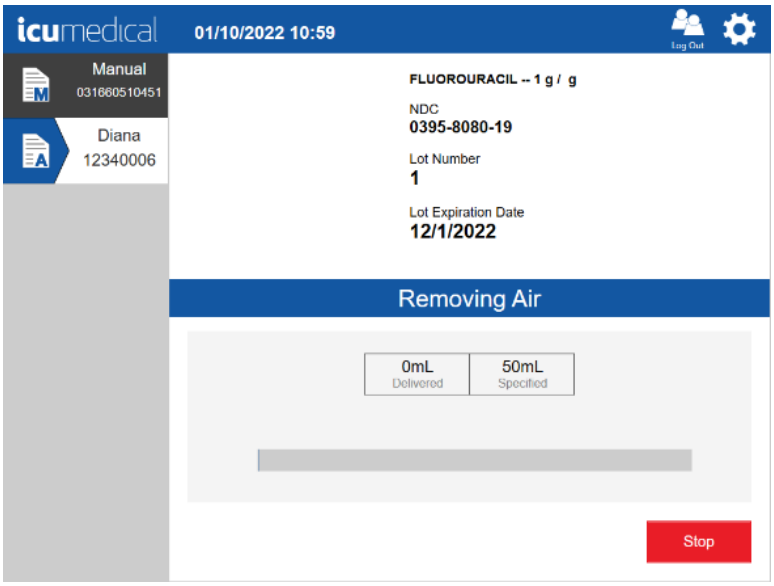


5. Connect the disposables and tap the **Start** button.

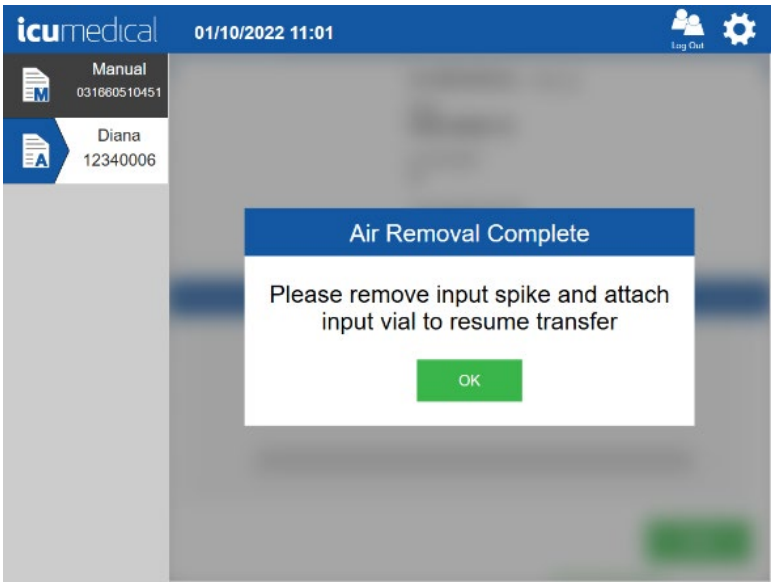


6. The Operator application displays a Removing Air notification asking the user to remove input vial and attach the input spike with empty bag to the input adapter. Remove the Input Vial and then connect the input spike with empty bag and tap OK button.

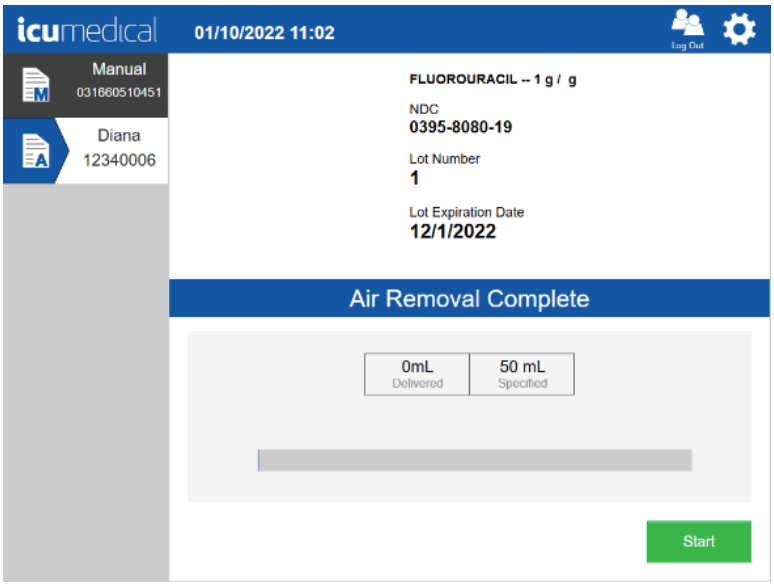




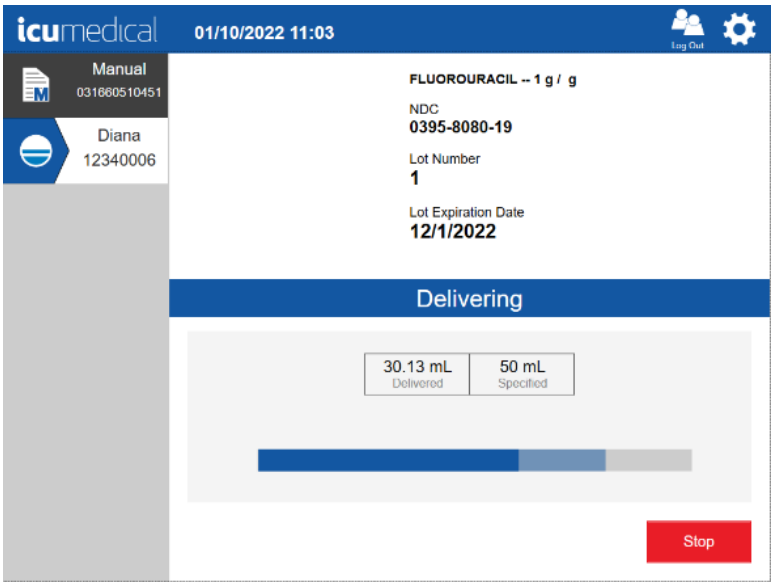
7. The system removes the air from the output container and displays the **Air Removal Complete** notification. Remove the **input spike** and waste bag and attach the **input vial**. Tap the **OK** button.

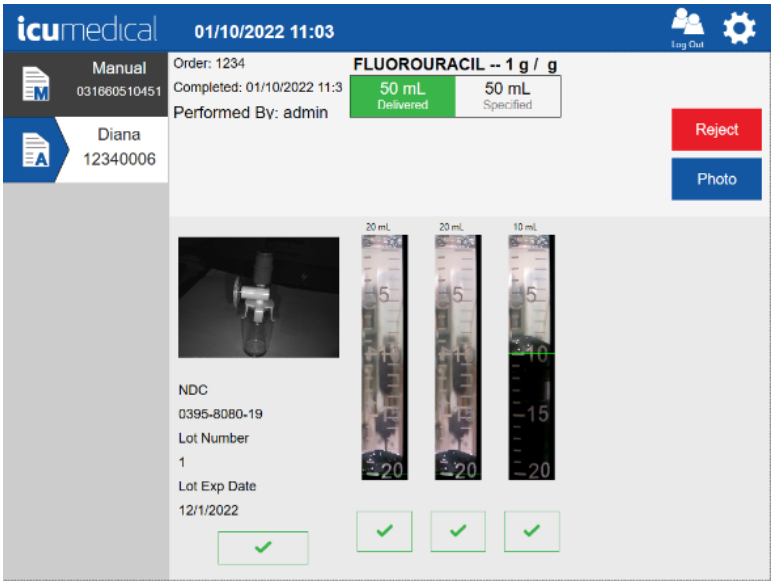


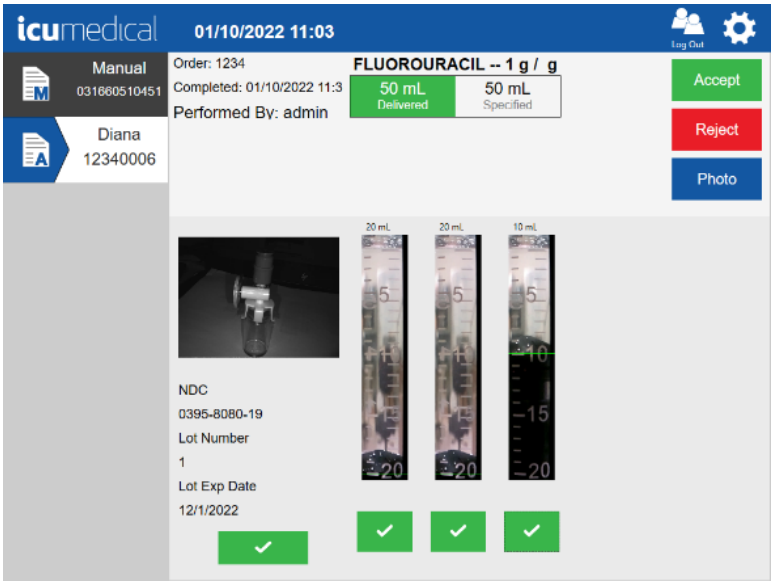
8. Tap the **Start** button to start the transfer process. The Diana Syringe Pump starts transferring the drug from the input vial to the output container.



9. Once the transfer process completes the system displays the verification screen for the user to confirm the transfer process. See the screens below. Review the pictures on the verification screen and tap the **Accept** or **Reject** button.






icumedical
01/10/2022 11:03
Log Out
Manual
031660510451
Diana
12340006
Order: 1234
Completed: 01/10/2022 11:3
Performed By: admin
FLUOROURACIL -- 1 g / g
50 mL
Delivered
50 mL
Specified
Accept
Reject
Photo
20 mL
20 mL
10 mL
NDC
0395-8080-19
Lot Number
1
Lot Exp Date
12/1/2022

Appendix F: Specialty Substances List

1. The following list of substances are set by default to requiring Pharmacist validation.

CHLORAMBUCIL	DOCETAXEL	PERTUZUMAB	LISINOPRIL
METHOTREXATE	PASIREOTIDE	GANCICLOVIR	HYDROXYUREA
METHYLTESTOSTERONE	LOMUSTINE	DEFERIPRONE	PROGESTERONE
CLONAZEPAM	OXCARBAZEPINE	DACTINOMYCIN	MEDROXYPROGESTERONE ACETATE
ACITRETIN	NILOTINIB	MECHLORETHAMINE	CYCLOSPORINE
CIDOFOVIR	NELARABINE	VALGANCICLOVIR	RIFAMPIN
VANDETANIB	BRENTUXIMAB VEDOTIN	BELINOSTAT	MISOPROSTOL
OXYTOCIN	BOSENTAN	DINOPROSTONE	ESTRADIOL
THIOGUANINE	CARBAMAZEPINE	FLOXURIDINE	TESTOSTERONE
MITOMYCIN	CAPECITABINE	THALIDOMIDE	TRETINOIN
OXALIPLATIN	CISPLATIN	IMATINIB	AMBRISENTAN
DECITABINE	SPIRONOLACTONE	TEMSIROLIMUS	VIGABATRIN
ROMIDEPSIN	NEVIRAPINE	APOMORPHINE	DUTASTERIDE
CARBOPLATIN	LIRAGLUTIDE	TRAMETINIB	TOPIRAMATE
ETOPOSIDE	CABERGOLINE	IXABEPILONE	AFATINIB
MYCOPHENOLIC ACID	COLCHICINE	GEMCITABINE	RIOCIGUAT
FLUCONAZOLE	PHENYTOIN	VEMURAFENIB	RISPERIDONE
THIOTEPA	ENTECAVIR	ZIPRASIDONE	FLUTAMIDE
PEMETREXED	DRONEDARONE	PALIFERMIN	BEXAROTENE
CLADRIBINE	MYCOPHENOLATE MOFETIL	DAUNORUBICIN	FINASTERIDE
CARMUSTINE	METHIMAZOLE	SORAFENIB	AZATHIOPRINE
FULVESTRANT	CYTARABINE	RASAGILINE	PROPYLTHIOURACIL
ENZALUTAMIDE	ERLOTINIB	GEMTUZUMAB OZOGAMICIN	PALIPERIDONE
LEUPROLIDE	IFOSFAMIDE	DACARBAZINE	PACLITAXEL
CLOFARABINE	MERCAPTOPURINE	DOXORUBICIN	VALRUBICIN
RIBAVIRIN	ALITRETINOIN	DEGARELIX	TEMOZOLOMIDE
BUSULFAN	MITOTANE	REGORAFENIB	DEXRAZOXANE
EXEMESTANE	DIETHYLSTILBESTROL	OSPEMIFENE	FLUOROURACIL
VORICONAZOLE	CETRORELIX	ABACAVIR	CARBIDOPA
TEMAZEPAM	BOSUTINIB	TOPOTECAN	CHLORAMPHENICOL
ESTROPIPATE	LEFLUNOMIDE	VISMODEGIB	ANASTROZOLE
POMALIDOMIDE	CRIZOTINIB	PENTETATE CALCIUM TRISODIUM	SIROLIMUS
EVEROLIMUS	CABAZITAXEL	ADO-TRASTUZUMAB EMTANSINE	PENTOSTATIN
TERIFLUNOMIDE	FINGOLIMOD	TRIPTORELIN	BORTEZOMIB
ZIDOVUDINE	PLERIXAFOR	FLUDARABINE	
MIFEPRISTONE	BLEOMYCIN	DABRAFENIB	
PRALATREXATE	FLUOXYMESTERONE	IDARUBICIN	
AXITINIB	MACITENTAN	LENALIDOMIDE	
AZACITIDINE	VORINOSTAT	CYCLOPHOSPHAMIDE	
LETROZOLE	MELPHALAN	DASATINIB	

2. **FLUOROURACIL** is configured by default to support use of a CADD cassette.