



Diana™

Hazardous Drug Compounding System

User Manual v1.3.x

Compatible with:

Diana Firmware v5.3x

Diana Display v5.3x

Needlefree > Easy to Use > Less Waste > Lower Cost

icumedical
human connections

Effective Date: 01 Aug 2016 Printed By: Date/Time:

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List of Contents

Description and Intended Use	3
Cautions and Warnings	5
Regulatory Compliance.....	6
General Operation Information	6
What to do in case of damage.....	7
Views of the System.....	8
Front and Rear of the System.....	8
Touchscreen Key Panel	9
Print Parameters.....	12
Setting up the System	13
Operation of the System	13
External Accessories.....	14
Connecting the External Liquid Sensor	14
Powering the System On.....	14
Installing Disposables for Channel One.....	16
Insertion of the 50 ml syringe into the syringe pump unit	19
Technical Data Specifications	38
Appendix A: Diana System Manager Software	39
Appendix B: Cleaning and Disinfecting the Diana System	41
Appendix C: List of Symbols Used on the Device.....	42
Appendix D: Troubleshooting.....	43

Introduction

This manual provides the user with basic information for operating the System. It documents all the usable functions and explains how to use them. The device is supplied in a calibrated condition. Servicing must only be performed by the manufacturer.

Because of continuing product improvements, prices and specifications are subject of change without notice. Changes to this manual, either in response to user input or to continuing product improvements, are accomplished through reissue. If in the normal use of this manual, errors, omissions, or incorrect data are noted, please contact ICU Medical, Inc. Customer Service or your local ICU Medical representative.

Description and Intended Use

The Diana Hazardous Drug Compounding System is a controller-regulated device which includes syringe pump units for preparing and filling hazardous drugs. Compatible vials, elastomeric pumps, and bags can be used as receiving containers. Desired Volumes can be selected for compounding. The central device contains a touchscreen display for entering data and for controlling the functions of the System. Entered data, and the status of the System are displayed as plain text or in diagrams.

It is important to follow the safety instructions to ensure proper functionality. Please refer to the Technical Data Specification Section of the manual for information on accuracy ranges for each channel of the device as they differ from the operating range of the device.

Preparation volumes in the range of 5 ml to 999.9 ml have been tested under different conditions. Please refer to the Technical Data Specification section in this manual for the accuracy range of the device before use. ICU Medical cannot ensure the accuracy of preparations under 5 ml.

In order to ensure system performance within the accuracy range provided herein, it is recommended that you initially test the accuracy of each drug at the clinical volumes before use.

Diana System Version Compatibility

Diana System, Model CH5300 and CL5300 (also known as ASN223 and ASN223CL in some countries), v1.3.x is compatible with:

- Diana Firmware v5.3x
- Diana Display v5.3x
- Diana Serial Switch v5.3x

The Diana System Model CH5300 and CL5300 are assembled by ICU Medical Inc. at its facilities 4455 Atherton Dr., Salt Lake City, Utah, U.S.A.

The Diana System Model ASN223 and ASN223CL are assembled by Neo Care GmbH D-58513 Ludenscheid Altenaer Str. 136, Germany. Neo Care is a wholly owned subsidiary of ICU Medical Inc.

Trademarks: ICU Medical, ICU Medical human connections, Diana, Clave, MicroClave, Y-Clave, and Spiros are trademarks of ICU Medical Inc. Clave, MicroClave, Y-Clave, ChemoLock and Spiros are registered in the United States patent and trademark office.

Customer Service

All functions of the System were checked before shipment.

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

U.S. & Canada ICU Medical, Inc.

1-866-829-9025
1-949-366-2183

ICU Medical Europe Italy

1-866-829-9025
1-949-366-2183

ICU Medical - NeoCare Germany

1-866-829-9025
1-949-366-2183

Medikus GmbH Austria

1-866-829-9025
1-949-366-2183

Other Locations

Record your local ICU Medical or distributor contact information here:

Name: _____

Phone: _____

Email: _____

General Safety Instructions

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



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

The System may not be resold or exported without the manufacturer's written permission.

In order to prevent injury while the System is operating, ensure that fingers and other body parts do not come into contact with moving parts.



Cautions and Warnings

- The system should only be used with the manufacturer provided power cords.
- Avoid impacts and vibration.
- Do not attempt to alter the System in any way.
- Transport only by use of the handle.
- Avoid direct contact with liquids. If a spill occurs, quickly remove liquids and hazardous drugs in accordance with the facility protocol.
- Never immerse in liquids for cleaning purposes. Do not attempt to sterilize using mechanical or steam sterilization equipment.
- If damaged during operation, switch off immediately and disconnect from the power supply.
- Ensure drug vial temperature is within 8-12°C of room temperature to minimize occurrence of condensation on cassette during compounding. Remove the required vials from the refrigerator and allow them to reach room temperature (about 30 minutes) prior to compounding to minimize occurrence of condensation on cassette.
- When using the Diana system with reconstituted vials, care should be taken to ensure the vial remains upright at all times and ensure vials are not over-pressurized prior to connecting to Channel One cassette.
- **WARNING:** Never connect directly to human beings or animals.
- **WARNING:** To avoid potential for cross contamination between drugs, only use cassettes and preparation sets for the same drug preparations and transfers.
- **WARNING:** Use new, sterile cassettes and adapters only. This reduces cross contamination of drugs and fluids, including but not limited to: penicillin and related agents, mutagenic agents, drugs with narrow therapeutic indexes, and high-potency drugs. Also reduces the severity of the associated clinical hazards that can result from contaminated and non-sterile fluid pathways.

Regulatory Compliance

The Diana System complies with the following standards:

- IEC 601-1:1988+A1:1991+A2:1995 Medical electrical equipment – Part 1: General requirements for Safety.
- IEC 601-1-4:1996 +A1:1999 Medical electrical equipment – Part 1: General requirements for Safety, Collateral Standard: Programmable Electrical Medical Systems (PEMS).
- IEC 60601-1-2, 3rd Edition: 2007 Medical Device EMC/EMI Compliance – Class A.
- CE mark meeting the applicable European Community EC directives
- The Diana System CH5300 and CL5300 are CSA certified for US and Canada,



CSA 601.1
MCN: 252357

General Operation Information

Before powering the system on, make sure the power cord is correctly connected back of the Diana unit and the wall outlet (110/220 Vac). After powering the device off, wait 10 seconds before powering on.

For three-phase electrical power system compatibility, connect the system to a center-tapped single phase branch of the electrical power service.

The start, stop and pause functions can be operated remotely by means of an additional foot-operated switch.

An established protocol should be developed to clean the System with commercially available cleaning and disinfection agents (see Appendix B: Cleaning and Disinfecting the Diana System).

Prime all disposables prior to using for drug compounding and patient preparation. Verify all connections and consumables are secure. The System is only compatible with ICU Medical supplied accessories and disposables. Do not use alternative disposables as this can affect the calibration, and fail to support accurate compounding and appropriate operation. Discard all Diana diluents sets, cassettes and syringe assembly units and all Oncology disposables within 24 hours of opening a sterile package unless otherwise specified in the specific product's user manual or directions for use.

Installation and Maintenance

The Diana system does not allow for any user installation or maintenance. All maintenance and installation must be performed by an authorized ICU Medical representative.

Before leaving the factory, every device is calibrated by the manufacturer and then verified to meet all specifications. All maintenance work should be completed by the manufacturer with the exception of routine cleaning. Customers should perform routine accuracy verification checks using the protocol described in Appendix E: Accuracy Verification Check Test Protocol and contact the manufacturer if any errors are observed outside the system specifications.

Customer should contact ICU Medical if any recalibration or maintenance is required. At minimum, customer should contact ICU Medical at least once per year to help determine if maintenance and calibration services are required.

What to do in case of damage

If the device is damaged during operation, or if the mains cable is damaged, switch the device off immediately and disconnect it from the power supply (socket).

Environmental Operating Conditions

Operating Temperature: +10°C to +40°C

Storage Temperature: 0°C to +60°C

Relative Humidity: 20% to 90% (Non-condensing)

The System is designed for use in laminar airflow boxes and/or safety work benches in clean rooms.

The System is not suitable for use in mobile equipment.

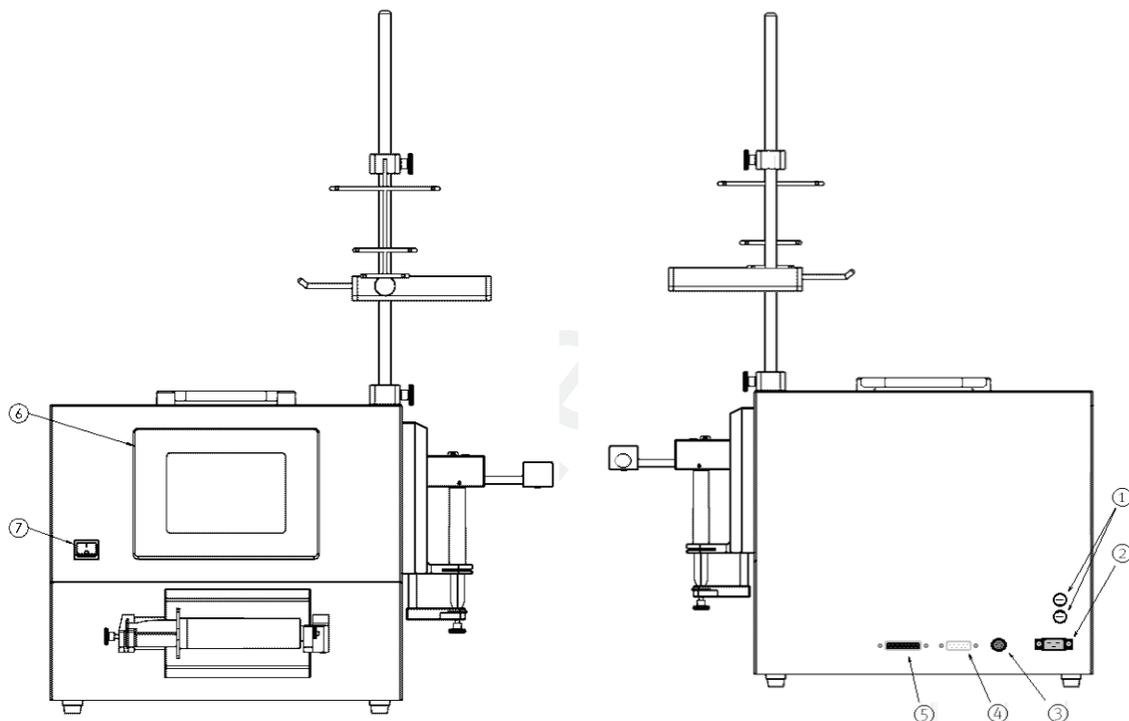
Views of the System

Views of the system throughout this manual highlight the use of a Diana Cassette with Spiros. Other versions of the Diana Cassette are also available. Please refer to the Diana Cassette Directions for Use for additional instruction.

The specification plate and the system interface for accessories and add-on devices are fitted on the back of the device (see illustration Front and Rear of the System). The on/off switch and the touchscreen display panel used for all System operations are fitted on the front of the device.

Installation of the external accessories on the device's central unit must only be carried out when the device is powered off.

Front and Rear of the System



1. 2 x 2AT fuses
2. Main power cord
3. Connection for foot pedal accessory
4. Connection to serial interface module for label printer and scanner
5. Connection for external liquid sensor
6. Touch function display
7. Power switch

Operation of the System

Touchscreen Key Panel

Diana utilizes an intuitive touchscreen approach for data entry. The programming screen is the default screen. Users are prompted to select a channel and scan an order number and/or a medication before programming volumes.

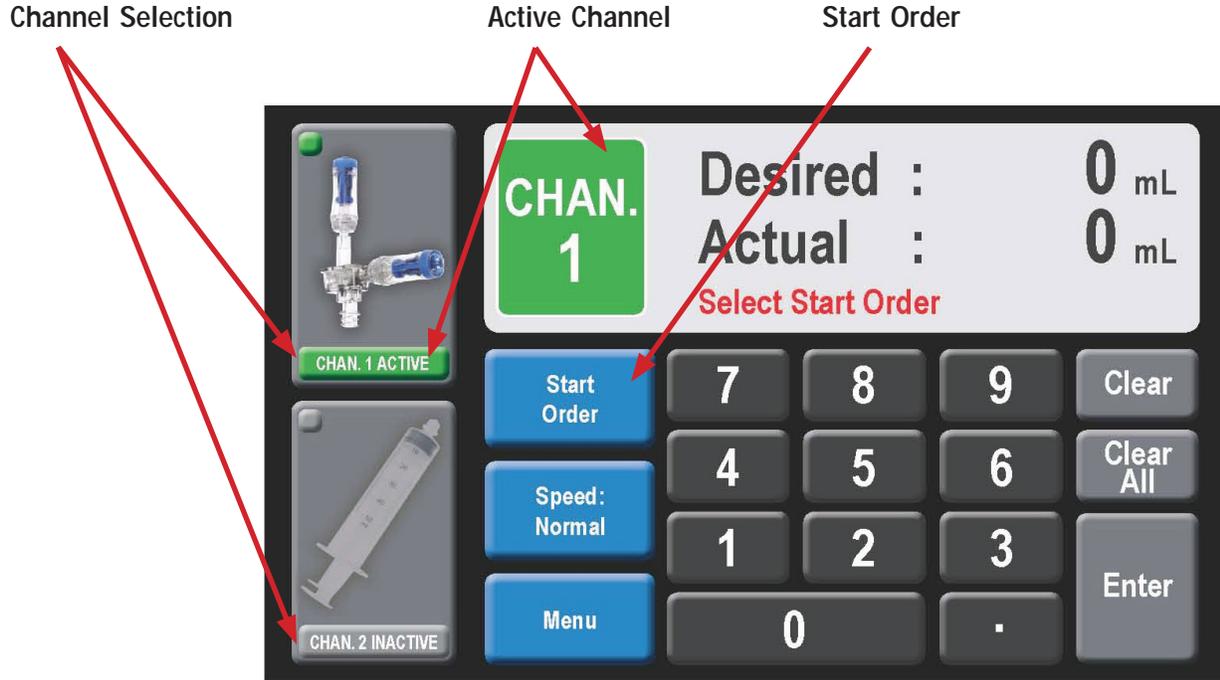


Illustration 1 - Programming screen

Accessing Standard Parameters

To access the standard parameter page select Menu button shown in the display below. Access to the standard parameters page is only possible when **channel one is selected and active channel displays CHAN 1 and the programmed volume (Desired ml) shows 0 ml**. The standard parameters are inaccessible when channel two is active.

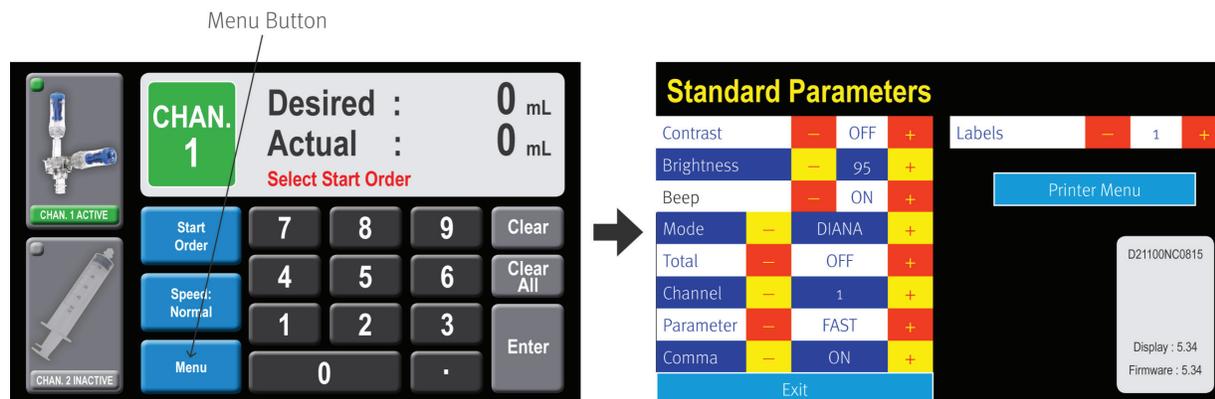


Illustration 2 - Access standard parameters page by selecting Menu Button on programming screen

Adjusting System and Syringe Speed Parameters

Selecting **Menu** when **CHAN 1** is active takes you to the **Standard Parameters** page, as shown in Illustration 3 -below. In this window you can change the beep from on to off as well as the brightness level

Diana offers the ability to change speed in the main Programming Screen, however, you can also change the speed for both channels in the Standard Parameters menu. To change speed, select **channel 1** for the 20 ml syringe pump motor or **channel 2** for the 50 ml syringe pump motor. Now you can select **Normal**, **Moderate**, or **Fast** speeds by selecting these values in the **Parameter** section. For viscous solutions and drugs (e.g. Paclitaxel) use **Normal** speed. To change the number of labels that are printed out with upon delivery completion, increase/decrease the number next to the Labels parameter. Leave this window with **Exit**, and the changed values are stored.



Illustration 3 - Standard parameters

Use of Moderate and Fast Speed should be reserved to non-viscous drugs and fluids.

Use *Normal* speed only when using viscous solutions and drugs (e.g. Paclitaxel).

Use *Normal* speed only when using multi-vial solutions (e.g. Methotrexate).

Use *Normal* speed when using the Genie vial access device equipped with a check valve.

Print Parameters

Users may change the Printer date/time, number of printed labels and print a test label by accessing the Print Parameters page. To access this page, select the Menu button and then the Printer button in the Standard Parameters menu. The Print Parameters screen will display as shown below in Illustration 4.

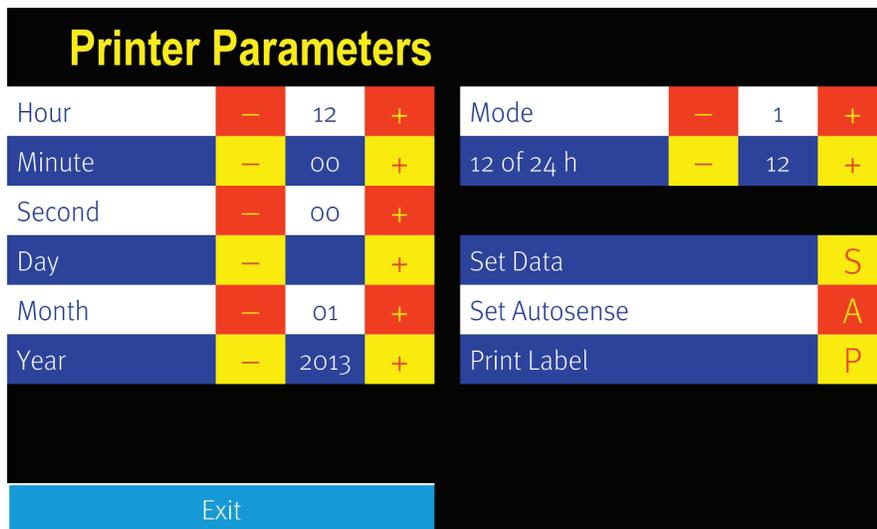


Illustration 4 - Print parameters

First, ensure Diana is connected to the printer. To test if the connection works, select '**P**' on the Print Label feature. Use the 12 or 24 hour clock to set the clock function accordingly, and use the hour, minute, and second functions to set the time. Likewise, use the day, month and year functions to set the calendar date. To save the date, select '**S**' to Set Data. Diana must be able to communicate to the printer to save the new settings on the printer.

To print a test label, select '**P**' on the Print Label feature. If the changes were saved you should see those changes reflected in the label printed.

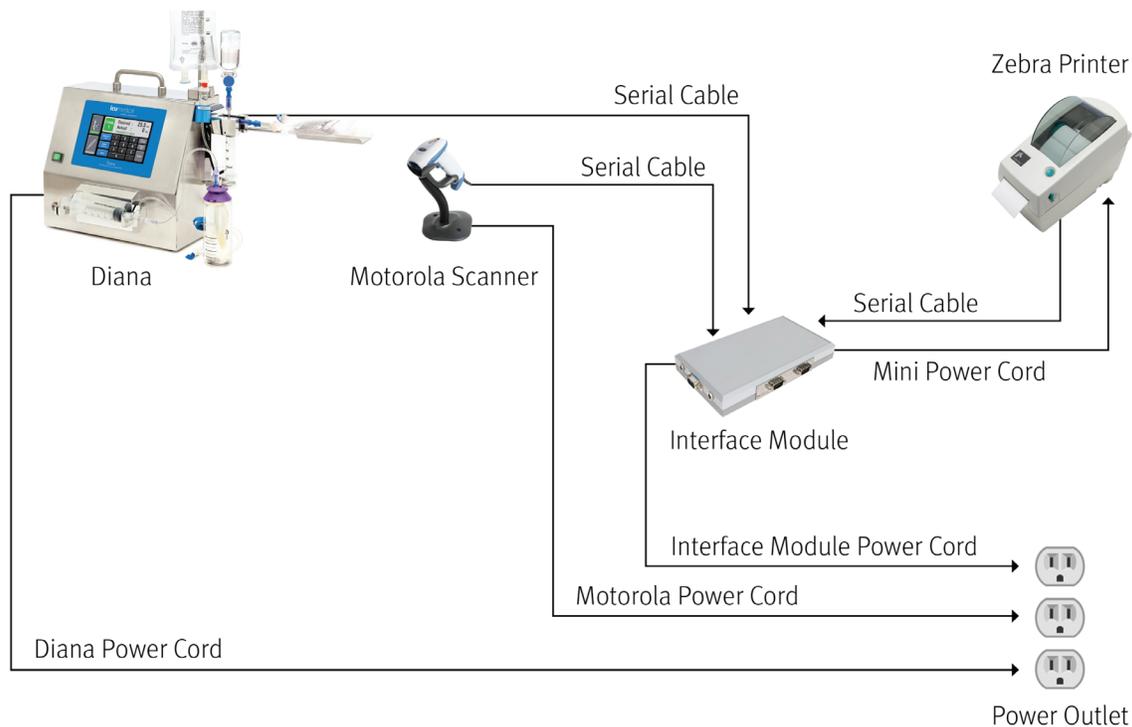
Mode 1 enables the Diana print feature. If Mode is selected to 0, then the Diana print feature is disabled. To re-enable printing, change Mode 0 to Mode 1. If printing is disabled after making this change, please check the connection or reset the baud rate on the printer using the Diana System Manager.

Other features:

- 12 or 24 h: mode of which kind of clock
- Set Date: Push **S** to transfer this data to setup printer
- Set Autosense: Push **A** to activate sensor in printer to detect when print labels have run out.
- Print label: Push **P** for to print one test label
- Labels: Push "+" or "-" to adjust the number of labels printed at the completion of a workflow sequence.
 - ▶ Diana can print up to 5 labels upon the completion of a compound.

Setting up the System

- How to connect the cables to Diana
- Barcode & Scanner



Operation of the System

All the components required for operation are integrated in the base unit.

The touch panel allows the operator to communicate with the System. The operator enters commands via the keypad, and the System acknowledges this by means of plain text in the display.

After powering the System on, the device first carries out a self-test. If an error is found during the self-test, the operator sees an error message. If the error is found to be in one of the two compounding channels, the relevant channel is displayed so that the operator can, if appropriate, remove the cause of the problem.

Readiness for operation is only displayed after the self-test has recognized that the device is functioning correctly.

External Accessories

Connection of the external accessories (e.g. foot pedal, external liquid sensor, serial interface module, scanner and printer) must only be performed when the device is powered off and the mains switch is not illuminated.

Connecting the External Liquid Sensor

During compounding with Channel 2, always use the external liquid sensor which is supplied with the System. It monitors the level of liquid in the drip chamber of the diluent supply line and automatically interrupts the compounding process before air is pushed into the receiving container.

The sensor must be connected to the FLC connector on the back of the device for correct operation. Insert the FLC connector into the receptacle on the rear of the System and hand-tighten, using the screws on the connector.

Liquid sensors in channel 1 are embedded into the Diana System. No further action is required to use.

Powering the System On

Before powering the System on, check to ensure that all the external connection devices and main power cord are secure.

When rebooting the system the user should wait 10 seconds before turning the Diana back ON to allow the device to properly initialize.

Connecting the Channel One Cassette to the syringe

- Use only the sterile and approved ICU Medical components with the Diana System and remove any air gap in the provided syringe before making the connection to the cassette.
- Screw the syringe all the way to the cassette collar to create a secure fitting and correct syringe-cassette length as shown in illustrations 5 and 6 below.
- Eliminate any visible gap between the syringe luer end and cassette collar as shown in Illustration 7.

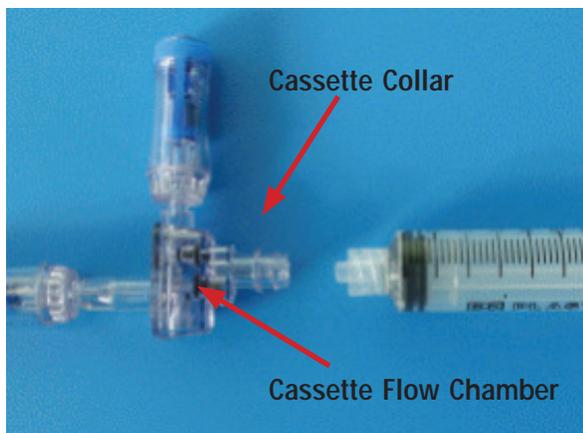


Illustration 5 - Cassette-Syringe Connection



Illustration 6 - Connected Cassette

Remove any air gap in syringe barrel before connecting the syringe to the cassette.



Illustration 7 - Eliminate any visible gaps

Eliminate any visible gap between the cassette collar and syringe luer end.

Installing Disposables for Channel One

When assembling the disposable items, follow this sequence:

1. Uncap syringe and remove any air gap in syringe barrel
2. Connect cassette flow chamber to the 20 ml syringe
3. Verify a secure and no gap “luer-to-collar” connection between the syringe and the cassette
4. Insert the assembled cassette and syringe unit into the syringe pump unit
5. Prepare the receiving container
6. Prepare the vial from which fluid is to be transferred
7. Connect the vial to the cassette in Channel
8. Connect the receiving container to the cassette

Effective

Insertion of the Syringe Cassette Unit



Illustration 8 – Cassette assembly insertion

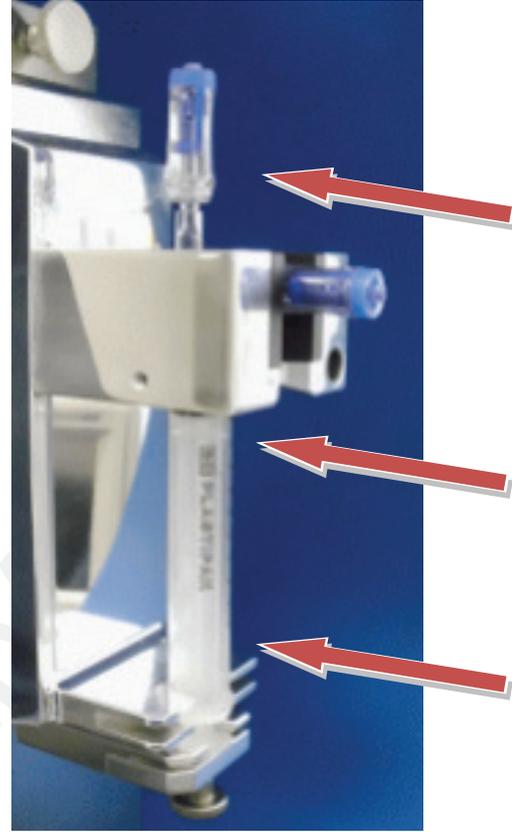


Illustration 9 – Cassette insertion

As shown in illustrations 8 and 9, push the syringe/cassette assembly unit in the direction of the arrows into the groove. When inserting the unit, ensure that the cassette engages fully, and a 'click' sound will be heard. In addition, verify the correct seat of the syringe piston in the lower holder of the pump unit. Fix the piston by turning the knurled screw lightly - do not over-tighten.

Knurled screw should be in unscrewed position before inserting and removing the syringe/cassette assembly unit.

Do not over-tighten knurled screw.

Priming Section

When using new cassettes in Channel 1, Diana will detect the lack of fluid and ask if a new cassette has been inserted. If so, select “Yes, Start Priming” and Diana will automatically prime the cassette before administering a fluid transfer.

Preparation of the Receiving Container

The following receiving containers can be used with the System:

- Infusion bag
- Semi-rigid plastic bottle
- Elastomeric pump

All the containers listed above need to be connected to the System disposables by means of the Clave®/MicroClave®/Y-Clave®/ChemoLock® Connector to ensure functionality. For correct handling of the device used with the receiving container, please refer to the Directions for Use included in each package.

Preparation of the Drug Vial

Access the drug vial using an approved Vial Access Device according to the Directions for Use.

Connection of the Drug Vial and Receiving Container to the System

Attach the vial and receiving container to the cassette by utilizing the ChemoClave or ChemoLock Closed System. See Cassette Directions for Use for additional instruction.

Ensure drug vial temperature is within 8-12°C of room temperature to minimize occurrence of condensation on cassette during compounding. Remove the required vials from the refrigerator and allow them to reach room temperature (about 30 minutes) prior to compounding to minimize occurrence of condensation on cassette.



Illustration 10 – Connected receiving container

Installing Diluent Set for Channel Two

When assembling the disposable items, follow this sequence:

1. Prime the diluent set prior to use.
2. Insert the 50 ml syringe into the syringe pump carriage.
3. Connect to the solution container, or use the spike to access.
4. Suspend the solution container.

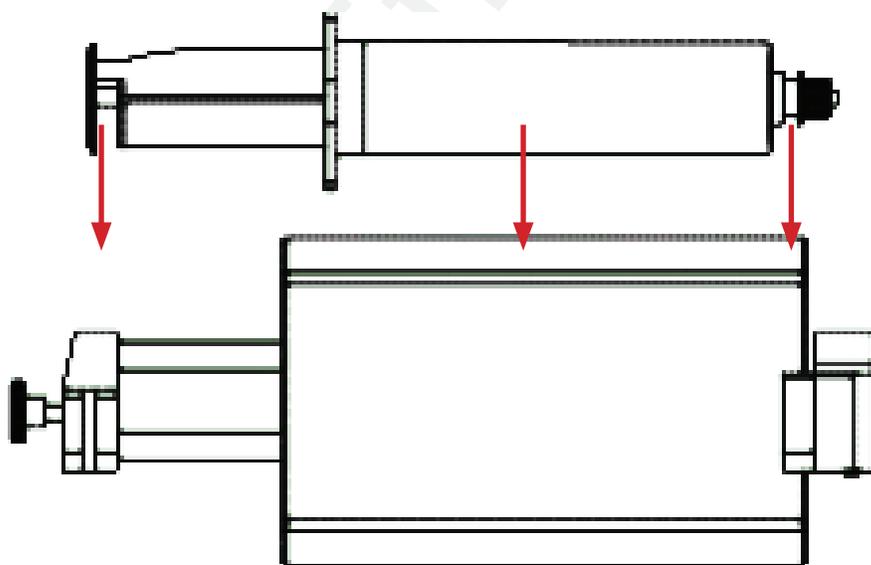
Ensure the diluent set fluid lines are not twisted or occluded before operating the Diana System.

Priming Channel Two

Channel Two must be hand primed before using. To hand prime, connect the diluent set to a source fluid container and receiving container and remove the syringe from the syringe pump carriage. Manually draw 20 ml fluid into the syringe from the source container. Hold the syringe vertically with the syringe facing upwards to allow air bubbles to escape through the syringe luer fitting. Press the liquid out from the syringe into the receiving container and dispose of the priming liquid waste. When the tubes and syringe are de-aerated, reinsert the syringe into the Channel Two syringe pump carriage. Discard priming fluid volume and if needed receiving container.

Insertion of the 50 ml syringe into the syringe pump unit

Align the groove of the syringe with the carriage and first insert to the rear, then press the front end into the mounting. Fix the syringe in position by means of the knurled screw. Fix the piston by turning the knurled screw lightly - do not over-tighten.



Drip Chamber and External Liquid Sensor Placement

The Channel Two drip chamber and the external liquid sensor help ensure consistent fluid flow and no air-in-line occurs between the source container and receiving container during dispensing.

As shown below in Illustration 11, fill the drip chamber to the top with fluid - minimizing the air gap - by squeezing the chamber when connected to the source container. After the drip chamber is full, slide the external liquid sensor as far up the drip chamber walls until snug and secure in place.



Illustration 11- Proper sensor placement

Fill the drip chamber to the top with fluid minimizing the air gap.

Slide the external liquid sensor as far up the drip chamber walls as possible.

Diana Compounding Workflow Sequence

The Diana System has a built-in workflow sequence that allows users to associate a fluid or drug with the active channel through a barcode interface, and then program desired dispense volumes for that channel. The Diana System workflow sequence is **initiated by pressing the “Start Order” button on the main screen** (and as shown below in Illustration 12):

1. Select Start Order
2. Scan the Patient Order Barcode
3. Scan the Medication Barcode label
4. Program Volume
5. Confirm
6. Press Start
7. Print Label

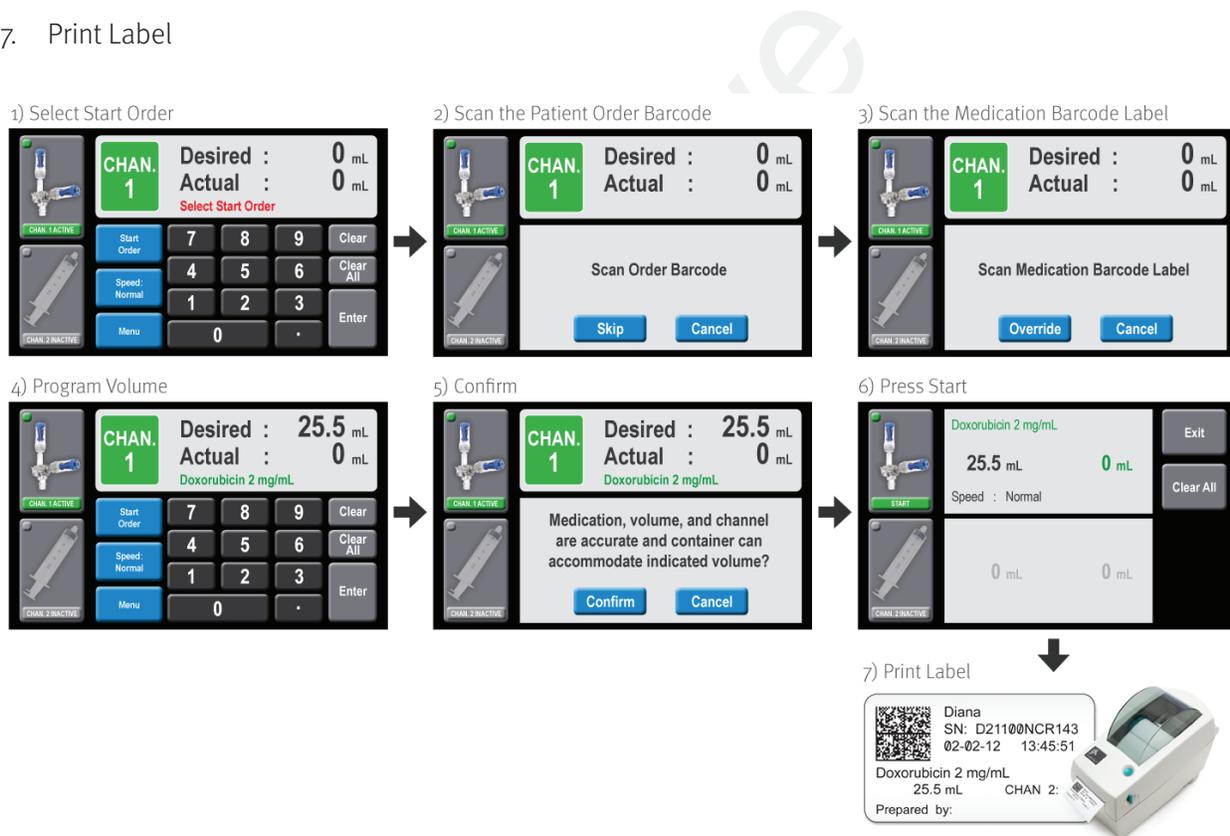


Illustration 12 - Diana compounding workflow sequence

- Regardless of Closed System used with the Diana System, the user interface will display a Diana cassette with Spiros male luer connection.
- Diana does not verify the patient order against the prescription in the Pharmacy Information System. Diana will embed the patient order number in the barcode on the printed label.

- Users may select “Skip” to bypass patient order scanning (Note: no barcode will print with the label).
- Users may select “Override” to bypass patient order scanning (Note: ‘override’ will be printed on the label).
- **Note: Care should be taken when Diana is ready to scan the patient order. The scanner may read other barcodes as patient orders if placed around the scanner.**

Scanning a Drug or Diluent

After the appropriate channel has been selected and a patient order has been scanned, a drug or diluent may be scanned using the connected barcode scanner. To scan a drug or diluent, follow the steps below:

- Place the vial under the barcode scanner
- Orient the container so that the barcode is facing the scanner

The Diana system will provide an audible feedback once the barcode has been successfully scanned and will display the active medication name in green on the main programming display.

If the drug or fluid scanned is not shown, users may select <override> (in the default list) to bypass drug selection (**Note: ‘<override>’ will be printed on the label.**)

The Diana barcode scanner is equipped to read 1D and 2D style bar codes.



Once medication has been scanned, the name of the active ingredient will appear on the Diana Screen (See Illustration 13 - Scanned Drug Display).

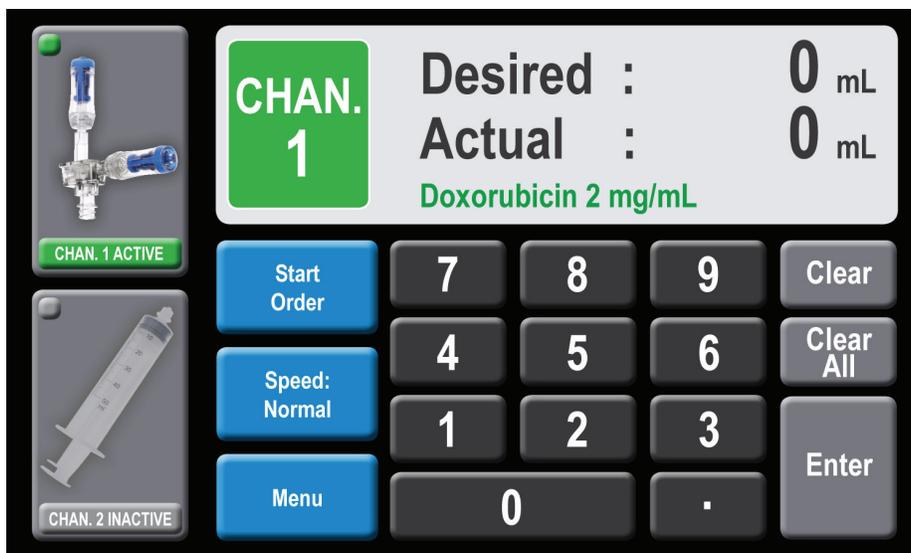


Illustration 13 - Scanned Drug Display

In cases where the drug has only one active ingredient, the concentration of the drug will appear.

In some cases, the name of the active ingredient had to be truncated to fit the Diana display. In this case, an indication that the name has been truncated will appear as "...". In other cases, Tall Man Lettering has been applied to the name to clearly identify the active ingredient. i.e. vinCRISStine Sul... 1 mg/mL

Programming Fluid Volume (ml values)

After the appropriate medication is scanned for the active channel, enter the ml value using **Numeric Keypad** and program volumes in range from 0.1 ml to 999.9 ml on the keypad (please refer to the accuracy range of the device in the Technical Data Specifications section of the manual). After each key is pressed the volume (ml value) which has been entered is shown in the upper line of the display for the selected channel. If errors are made during entry, the displayed value can be deleted by selecting the **CLEAR** key. Pressing the **CLEAR** key removes all volume entries. To delete both volume and medication entries select the **CLEAR ALL** key. To delete both volume and medication entries select the **CLEAR ALL** key. When the required value has been set, press **ENTER** to go to the next screen. Note: The decimal point selection is only displayed if a decimal number other than zero is entered afterwards. Do not enter values lower than 0.5 ml.

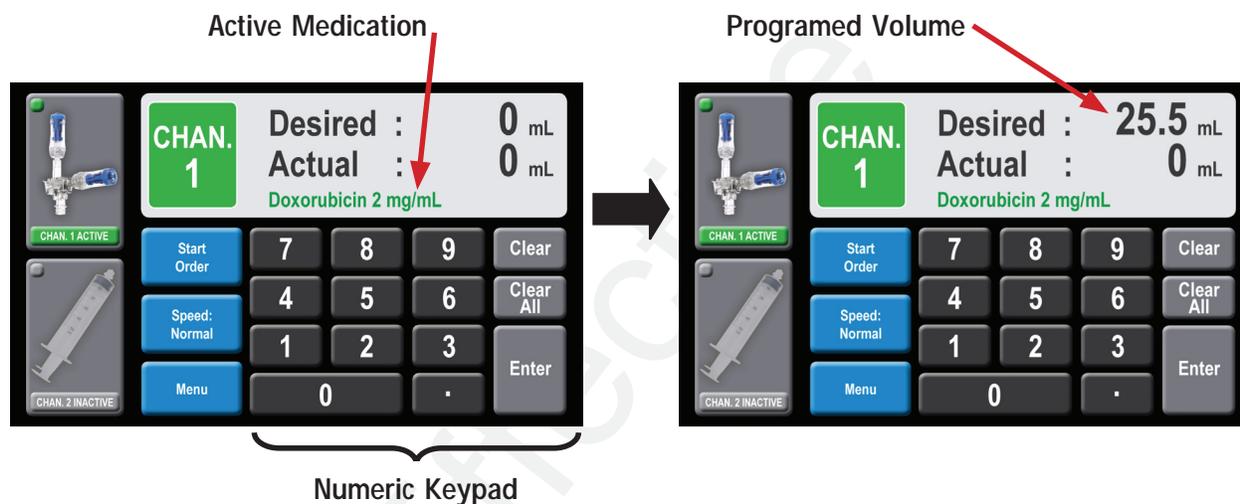


Illustration 14 – Programming fluid volume screen

Confirm Programming Values and Container

The Confirmation Screen (as shown below in Illustration 15) allows users to confirm or cancel programmed data before proceeding to the Start screen. Users must confirm correct medication, volume, and channel are accurate and that the container can accommodate the indicated volume before proceeding to start screen. If data is incorrectly shown or container is not able to accommodate, then press cancel to address.

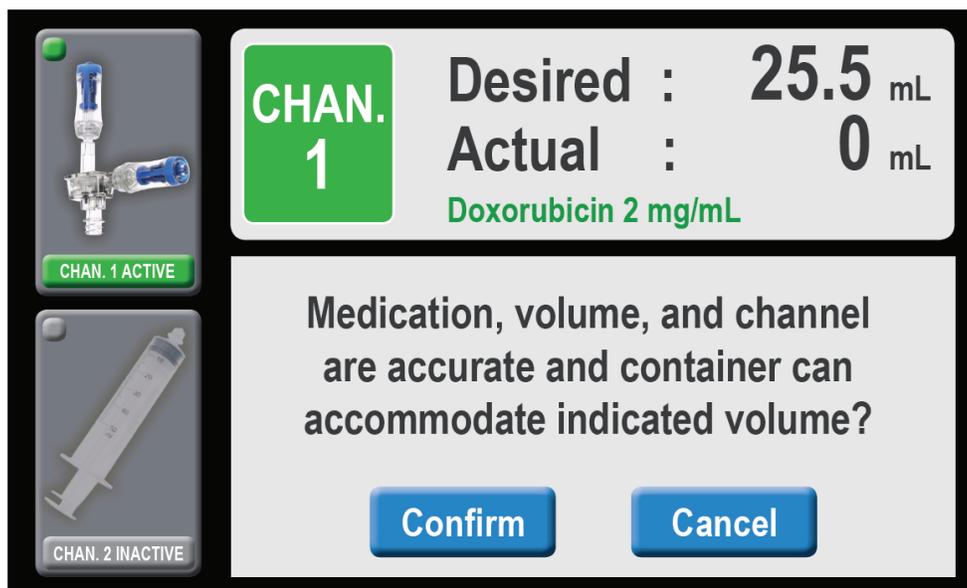


Illustration 15 – Confirmation Screen

Confirm correct medication, volume, and channel are accurate to ensure the system has received the correct input before starting.

Confirm the receiving container can accommodate the indicated volume before proceeding to start screen.

Select Cancel if data entry is incorrect or container is not able to accommodate the volume programmed.

Start Fluid Dispensing

After confirming medication, volume, speed, and channel are accurate and that the container can accommodate the indicated volume, initiate dispensing by selecting the **START** key for the desired channel. If any value is not correct, you may select Clear all to correct before starting.

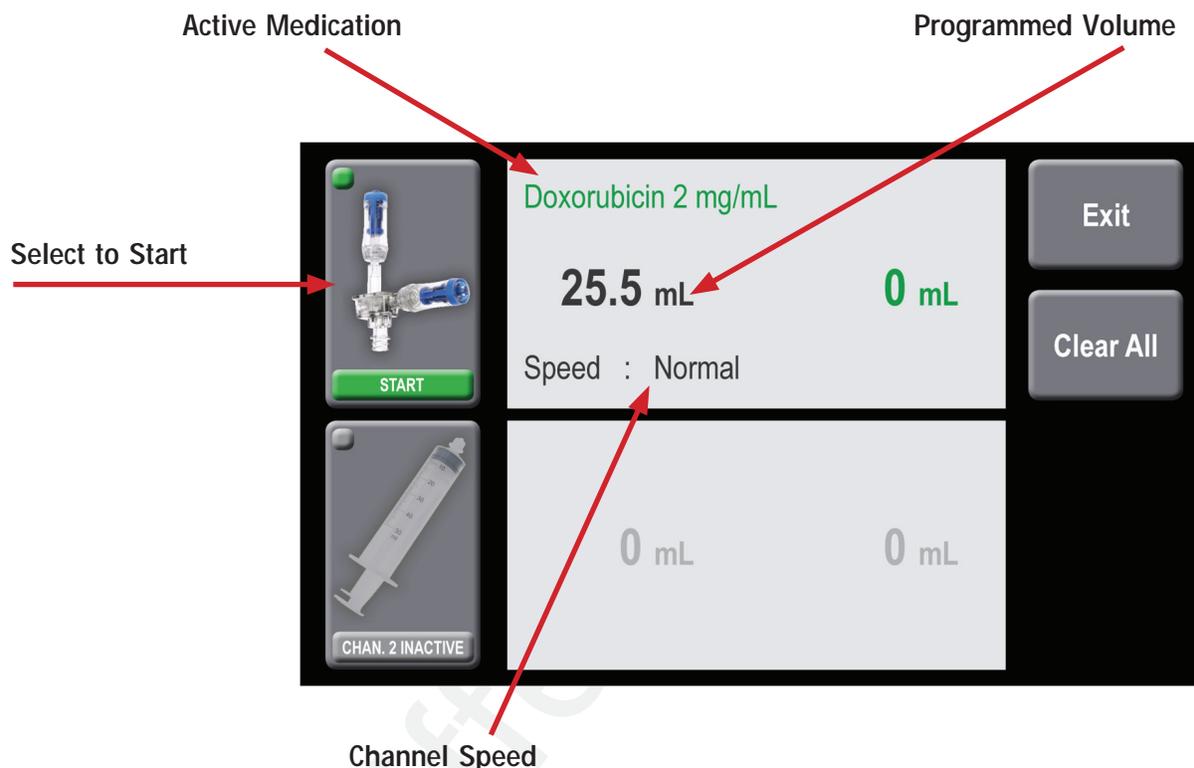


Illustration 16 - Start dispensing

The programmed value which has been entered is displayed to the right of the channel Start key. If you wish to change a value then you will need to select **CLEAR ALL** - deletes all previously entered data - and returns you to the initial programming screen. Selecting **Exit** will take you to a Locked Programming Screen (as shown in Illustration 19) where you may change speed only. **Note: In all cases, a programming value should only be entered for the channel which is currently active.**

Print Label

After dispensing is complete, the Diana system sends information to the printer, prompting a summary label of the compounding performed to be printed as shown in Illustration 17. Date and time may be changed (see Diana System Manager for more detail).

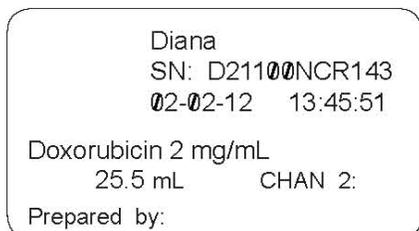
Successfully Scanned (medicine barcode) with Order Number Barcode



Manual Override with Order Number Barcode



Successfully Scanned (medicine barcode) with No Order Number Barcode



Manual Override with No Order Number Barcode

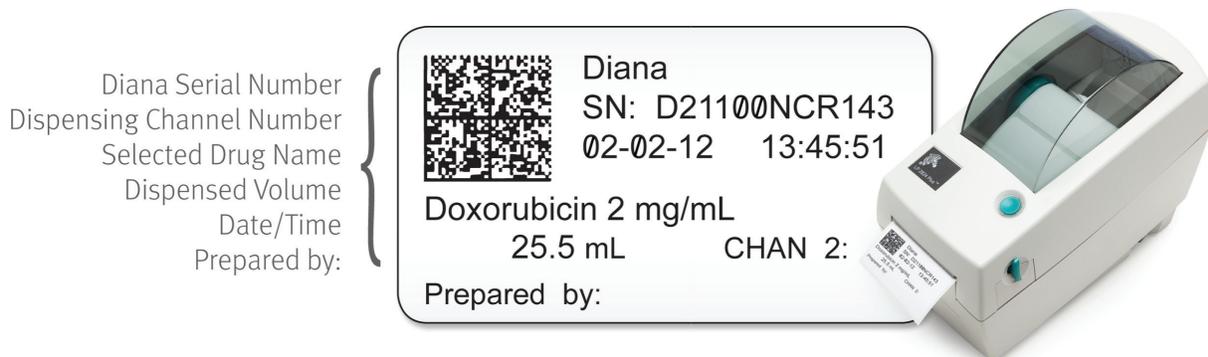
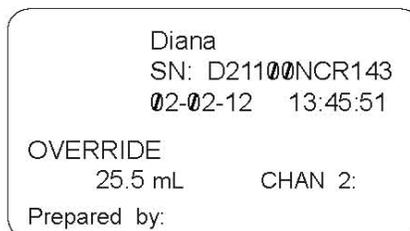


Illustration 17 - Print label

Note: The printed label can accommodate a signature or initials in the 'Prepared by' section.

Priming Section

Priming and Start Fluid Dispensing When Using a New Cassette

When a new cassette has been inserted and start fluid dispensing operation is initiated, the following message (Illustration 18) will display. The system is recognizing the new cassette and asking if you want to prime it. Press **Yes Start Priming** to automatically prime the cassette. If the cassette is already primed, press **No**, and start volume dispensing. After priming, users will need to reselect Start to initiate the dispensing of the programmed volume.

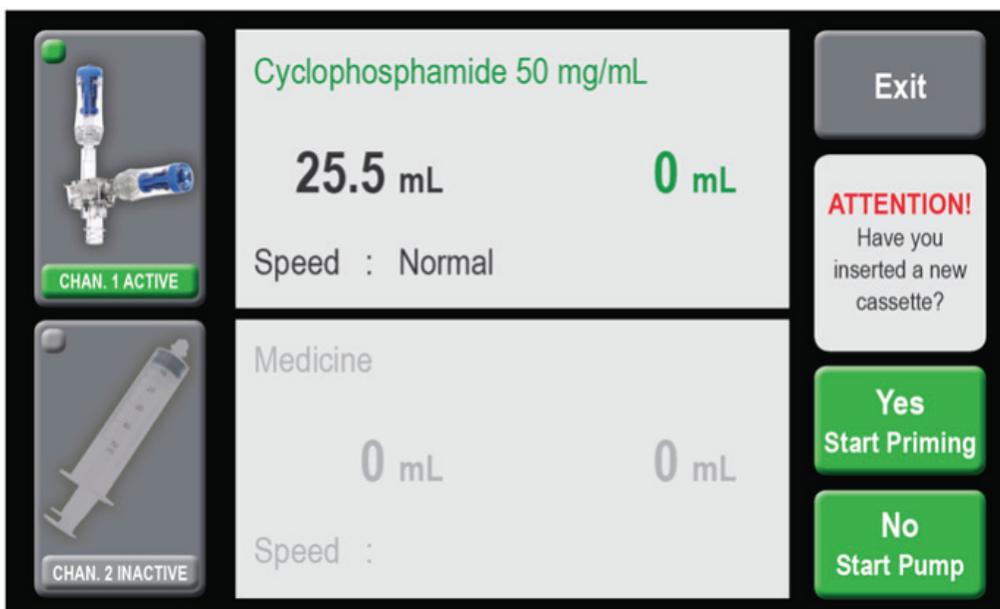


Illustration 18 - Priming channel one

After priming users will need to reselect **Start** to initiate the dispensing of the programmed volume.

Locked Programming Screen

After a channel has been programmed, confirmed and in a ready-to-start dispensing state, if a user selects Exit while in the Start page then this Locked Programming Screen (shown in illustration 19) is displayed.

All numeric keypad functions are disabled for the locked channel. As such, users may not program a locked channel, but the user may change the channel speed or review the confirmed data input and last actual volume dispensed on this page. To return to Start screen users must select **READY**. If a user wishes to change a value then you will need to select **CLEAR ALL** - deletes all previously entered data – to return to the initial programming screen and sequence.



Illustration 19 - Locked programming screen

Effective

Start Fluid Dispensing When Receiving Container Not Attached

If a receiving container is not attached to the Channel One cassette, illustration 20 is displayed. Attach the receiving container and continue the process by pressing *Resume*. In rare cases if fluid path between the Channel One cassette and the attached receiving container is obstructed, or if too much pressure builds up, then an icon will be displayed indicating that there is an error. Stop the compound (See Interrupt Dispensing Process Using All Stop), remove the cassette, reset the pump to its original position (See Reset After All Stop), then replace cassette and receiving container.

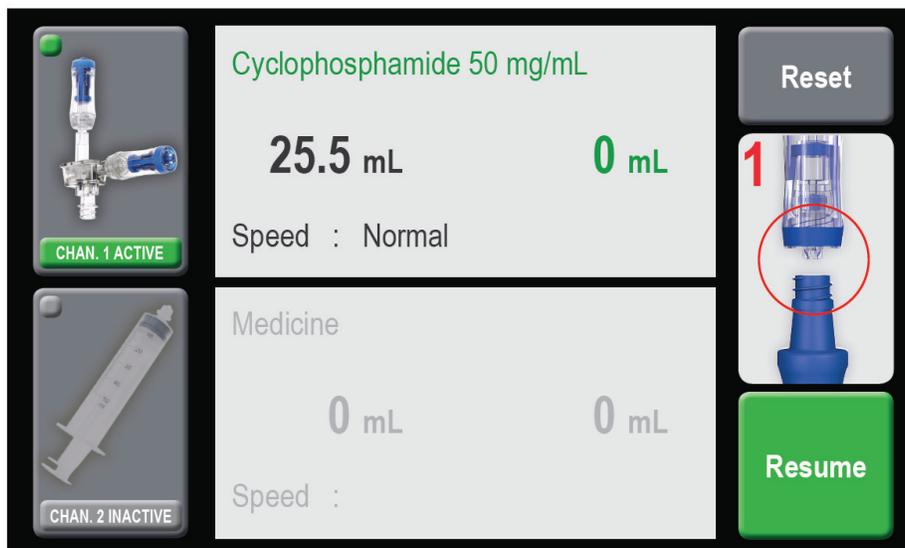


Illustration 20 - No container connected

Ensure all connections are secure and fluid path of the connected system is unobstructed before starting.

In rare cases if fluid path between the syringe and the attached receiving container is obstructed - or if too much pressure is built up in the cassette flow chamber - then an icon will be displayed indicating that there is an error. Stop the compound, remove the cassette, reset the pump to its original position, then replace cassette and receiving container. **If this occurs, the cassette and the patient's receiving container must be replaced.**

Operating Conditions

Illustration 21 is displayed during the fluid dispensing process. The entered volume parameters are shown in black and the current dispensed volume is shown in green and updates continuously during each syringe push to the receiving container. Operation stops when the programmed value is reached and two audible beeps are heard to express that the dispensing is complete. There is a brief pause following each dosing cycle while pressures equalize within the system and allow for the final delivery of fluid. Channel 1 processes 20 ml of fluid at a time, until the total entered dose is reached. For example, Channel 1 will cycle three times to deliver a 50 ml dose (20-20-10 sequence) and will pause on prompt Empty Vial during that sequence if a vial change is needed.

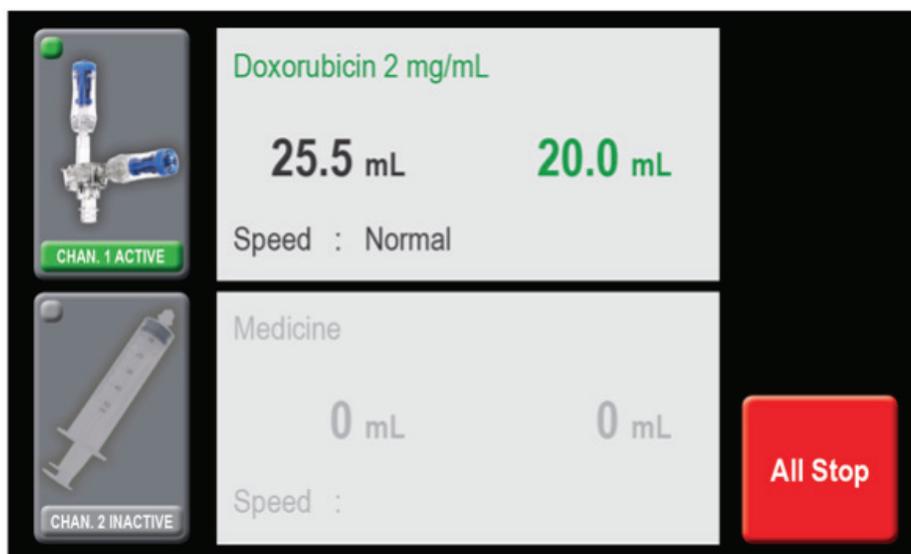


Illustration 21 - Operating conditions

It is not possible to enter and program new dispensing volumes or change syringe speed while a channel is actively dispensing fluid. New programming entries and speed changes can only occur after a dispensing process has finished.

Interrupt Dispensing Process Using All Stop

The compounding process can be interrupted at any time by pressing the **ALL STOP** key or any other part of the touchscreen panel as shown in Illustration 21 - Resume dispensing after ALL STOP

Press ALL STOP or any part of the display key to halt the syringe motor and interrupt dispensing of fluid after dispensing has started.

Resume After Dispensing After All Stop

After the *All STOP* key has been selected, the *Resume* Key (shown in Illustration 22) is displayed. Users may select *Resume* to resume dispensing. When the compounding process is interrupted via *All STOP*, the parameters do not change and users can resume an interrupted compounding process without any errors by pressing the *Resume* key.

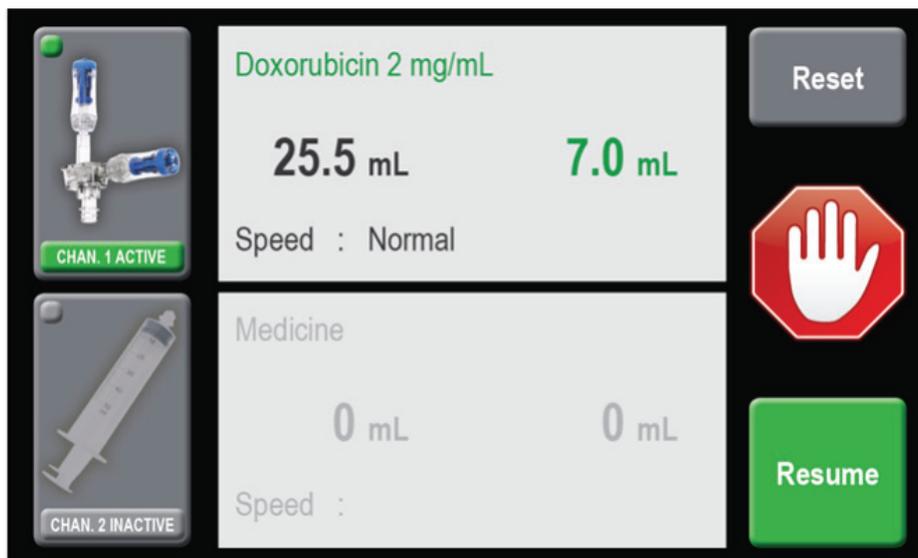


Illustration 22 - Resume dispensing after ALL STOP

Reset After All Stop

Users may also abort the dispensing process by selecting *Reset* - shown in Illustration 22 above. When *Reset* is chosen, the syringe pump will return to its home position – dispensing any fluid previously drawn by the syringe - into the receiving container without counting and displaying previously drawn volumes. Remove and discard any patient container and prepared solutions if *Reset* is selected. To avoid dispensing fluid during a reset, remove the cassette before pressing the *Reset* button.

If Users do not wish to abort the process, then *Resume* can be selected to continue dispensing where the process was left off.

After Reset, do not attempt to restart the patient preparation process after reset with same containers as receiving container volumes are not guaranteed to be accurate when the dispensing process is manually aborted by Reset.

Foot Pedal Operation

The dispensing process can be initiated by a foot pedal when connected by pressing the pedal to start the active channel. Pressing the foot pedal activates the dispensing process the same way as selecting Start. User may also stop the dispensing process by pressing the foot pedal as shown in illustration 23 below.

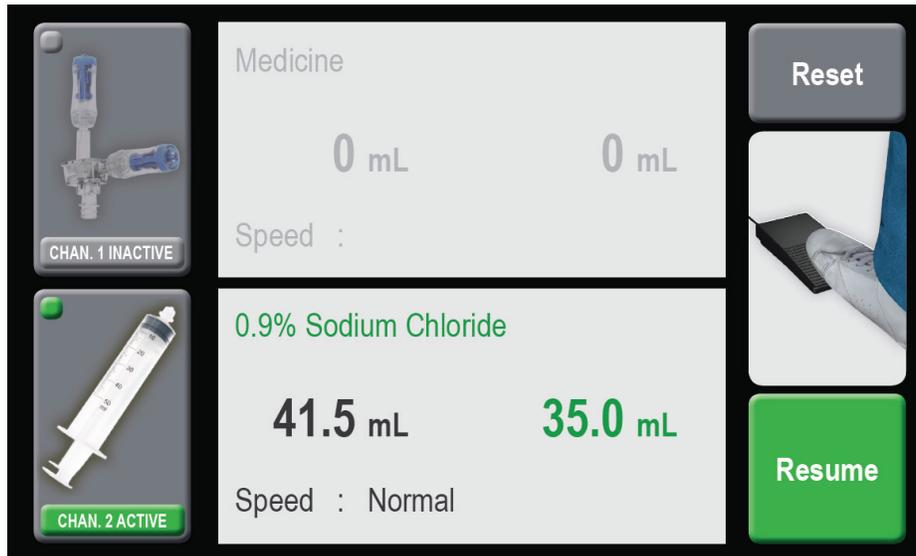


Illustration 23 - Foot pedal operation

Exchanging Empty Vials on Channel One Cassette

During compounding, a cassette sensor monitors the process to check whether liquid is being transferred to the syringe. If the sensor recognizes that there is air in the cassette, it initiates a bottle empty stop (Illustration 24). If the vial is not empty, an air bubble may have caused the stop. In this case, you can resume dispensing directly by pressing *Not Empty - Resume*. Multiple bottle empty stops may occur while the sensor is adjusting for the infusion solution.

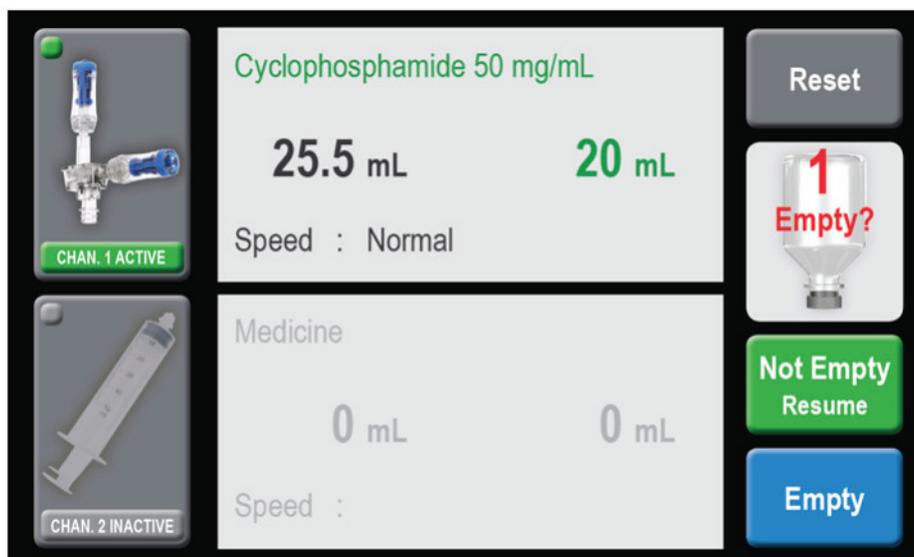


Illustration 24 - Empty vial

If the vial is empty, press *EMPTY* and illustration 25 will display. Scan and Exchange the next drug vial as necessary. Compounding can be resumed by pressing *Resume*. Air in the cassette will be purged when Resumed. If new scanned drug vial is not recognized, user may re-scan another vial or press <override> to continue compounding. If override is selected, then previously displayed Drug name medication on the screen will be deleted and replaced with Override on both the screen and the printed label.

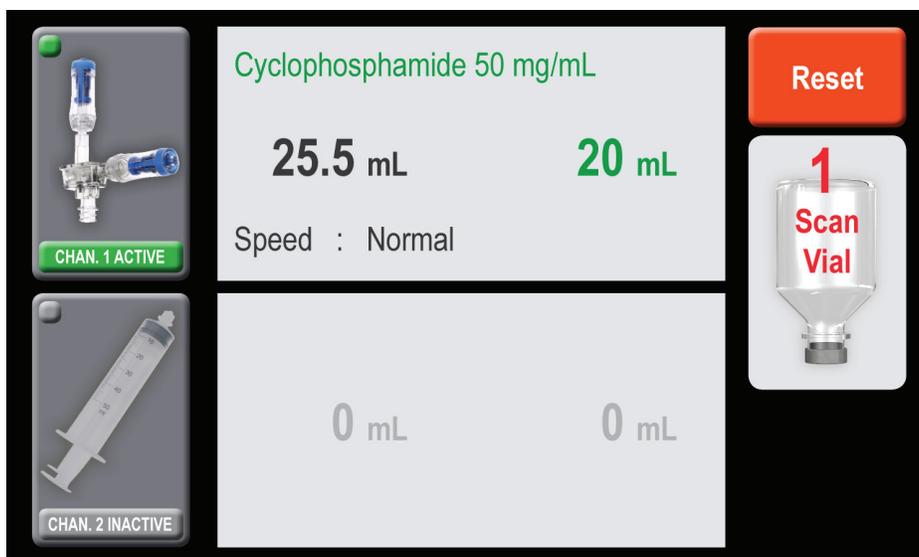


Illustration 25 - Exchange vial

Empty Fluid Sensor on Channel Two

If the drip chamber on the Channel Two diluent set runs dry, the liquid sensor stops operation and **Empty?** is displayed as shown in Illustration 26 below. Scan and replace the diluent or source fluid, refill the drip chamber completely full by squeezing the drip chamber, reconnect the external liquid sensor to top if drip chamber, and press *Resume* to continue.

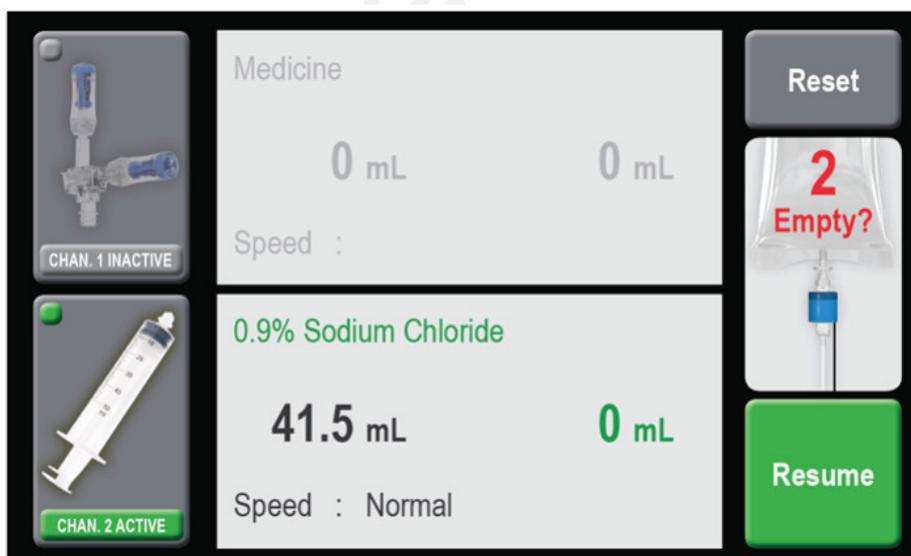


Illustration 26 – Channel Two Empty

System Reset

If one of the channels is subjected to a mechanical blockage, and the system is unable to compound, the system interrupts the process and Illustration 27 is displayed. Press the **Reset** key and illustration 28 will display to warn you and allow you to confirm reset – by pressing **Reset** again this allows the syringe pump to return to the starting position.

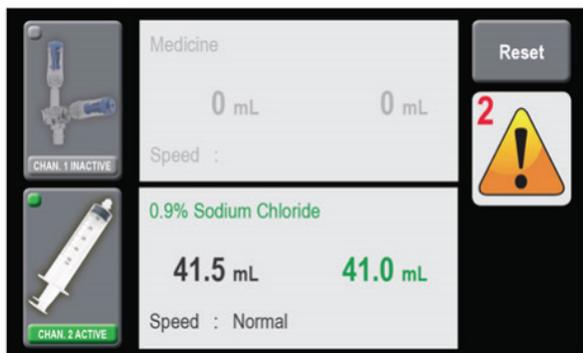


Illustration 27 - System reset

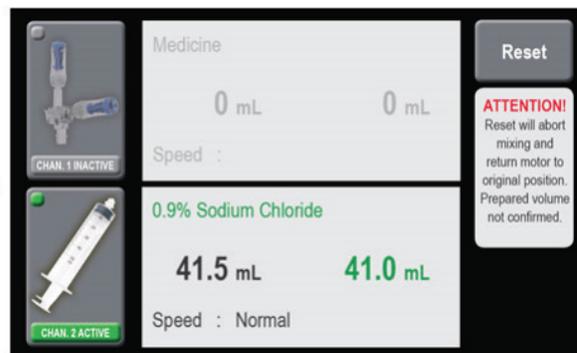


Illustration 28 - System reset confirm

After Reset, remove and discard all disposables and prepared solutions with the associated failed process. Do not attempt to restart the process after reset as volumes are not guaranteed to be accurate.

The reset screen will appear as follows (Illustration 29). If required for safety reasons, you can stop the Reset function at any time by means of the **Reset Stop** key and resume reset by means of the **Reset** key until the function has finished. After Reset, power-off the Diana system by means of the ON-OFF switch.

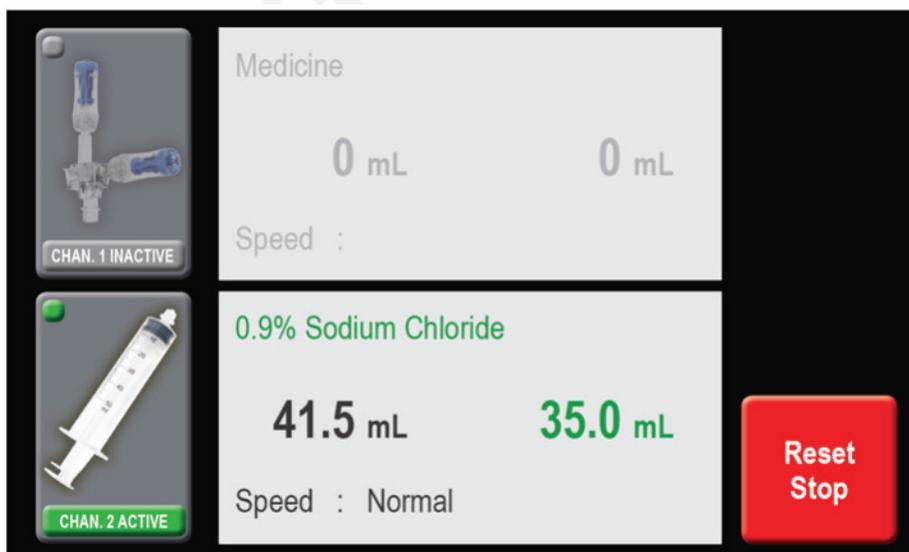


Illustration 29 – Reset stop

Eliminate any visible gap between the cassette collar and syringe luer end and remove air from syringe when attaching to cassette to help avoid reset situation.

Avoid applying pressure to syringe motor to help avoid reset situations.

After Reset, power-off the Diana system by means of the ON-OFF switch.

After Reset, do not attempt to restart the patient preparation process after reset with same containers as receiving container volumes are not guaranteed to be accurate when the dispensing process is manually aborted by Reset.

Effective

Technical Data Specifications

Description:	Diana Hazardous Drug Compounding System
Delivery rate Channel One:	normal: 25 $\frac{ml}{min}$; moderate: 40 $\frac{ml}{min}$; fast: 50 $\frac{ml}{min}$
Delivery rate Channel Two:	normal: 100 $\frac{ml}{min}$; moderate: 120 $\frac{ml}{min}$; fast: 130 $\frac{ml}{min}$
Dispensing Volume Increments:	0.1 ml
Operating range ¹ :	0.1 – 999.9 ml
Accuracy range ²	5 – 999.9 ml
Channel One Accuracy Range ^{3,4} :	
5-19.9 ml	+/- 1 ml
20-49.9 ml	+/- 3%
50-999.9 ml	+/- 2%
Channel Two Accuracy Range ^{3,5} :	
5-999.9 ml	+/- 3%
Power supply:	100-230 Volt, 50-60 Hz
Power consumption:	max. 60 VA
Dimensions:	W 44 x D 24 x H 34 cm
Weight:	13.8 kg
Noise Emission:	< 65dB(A)
Operating temperature:	+10°C to +40°C
Storage temperature:	0°C to +60°C
Relative Humidity:	20% to 90%

¹Operating range is the dispensing volume range a user can enter into the device as a desired volume to be dispensed.

²Accuracy range of the device is the dispensing volume range for which ICU Medical has validated the system accuracy.

³Accuracy Specification is published at 1 Standard Deviation. Standard Deviation is a statistical measurement of variation from the mean. +/- 1 Standard Deviation represents 68% of the expected data population, whereas +/- 2 Standard Deviations represents 95% of the expected data population.

⁴Accuracy determined based on using Diana at Normal speed using a variety drugs commonly found in an oncology pharmacy. For volumes greater than 5 ml after proper priming.

⁵Accuracy determined based on using Diana at Normal speed using a variety of diluents (water, 10% glucose/90% water, 20% lipid) commonly found in an oncology pharmacy. For volumes greater than 5 ml after proper priming.

In order to ensure system performance within the accuracy range provided, it is recommended that you initially test the accuracy of each drug at the clinical volumes before use.

Appendix A: Diana System Manager Software

The Diana System Manager enables users to configure the Zebra printer settings for use with Diana.

Installing the Diana System Manager Software

The Diana System Manager software requires no installer. The software program may be downloaded to your standard Windows PC with Windows 2007 or higher, and .NET 3.5 or higher.

To download the Diana System Manager software, we recommend creating a new file directory called 'Diana System Manager'. Select the files from the provided media and paste them into the directory. The Diana System Manager software can be started by simply double clicking the Diana System Manager executable file from within the directory.

Connecting and Configuring Printer with the Diana System Manager Software

To connect your computer with the Diana Systems Manager software to the printer, do the following:

1. Turn off the printer and disconnect the printer cables from Diana
2. Connect a 9-pin Male to 9-pin Female RS232 Serial cable (1:1) to your computers COM port and to the printer's RS232 port (**Note: you may also use the USB-to-RS232 adapter to make the connection to the computer**).
3. Turn on the printer.
4. Start the Diana System Manager software on your PC.

The Diana Systems System Manager software can configure date, time and reset the baud rate on supported printers. Printer configuration is managed by performing the following (and as shown in Illustration 30):

5. Select Printer Configuration Menu
6. Click Select and choose the appropriate COM Port
7. Enter desired date and time to set
8. Select desired date and time formats
9. Press Configure Printer to configure printer with desired settings
10. A Test Label will print confirming the desired settings selected

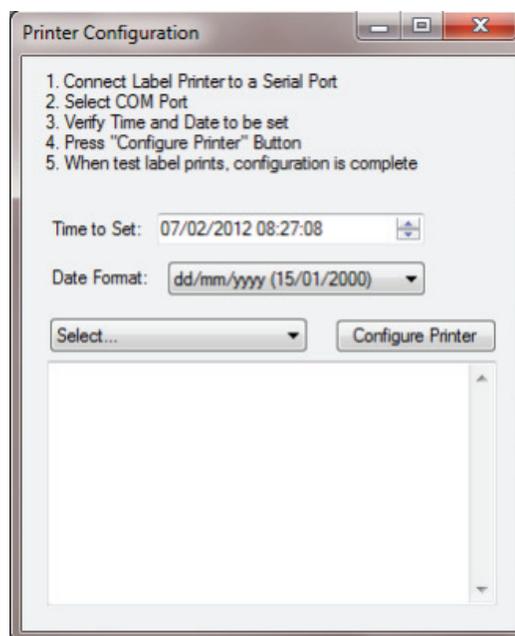
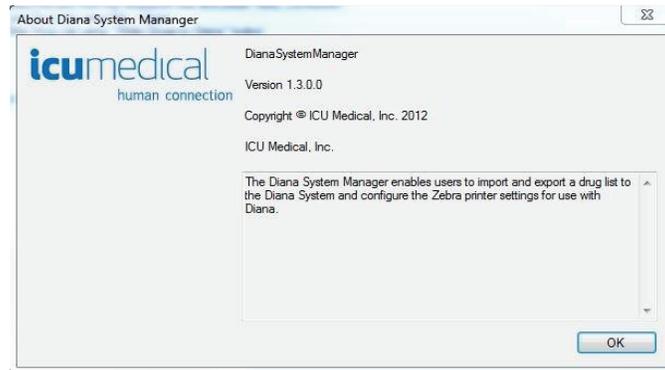


Illustration 30 – Printer configuration

About Box

The About Box allows users to find the version number for the Diana System Manager software installed on a user's computer. The Diana System Manager software v1.3.x.x is compatible with Diana v1.3 – firmware 5.3x and display v5.3x. To find the version of Diana Systems Manager select **Help >> About**.



Appendix B: Cleaning and Disinfecting the Diana System

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

Refer to the manufacturers cleaning instructions for the scanner and printer.

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. 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.

In many cases, cleaning the device with a lukewarm soap solution is the simplest and most gentle cleaning method. Gentle wiping and spraying cleaning and disinfection agents is 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)	190.5ml	381ml
Sterile Water for Irrigation (pour bottle)	309.5	619ml
TOTAL VOLUME	500ml	1000ml

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

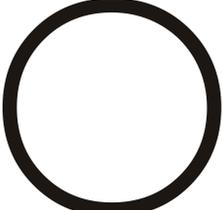
Ingredient	Amount Using (Na Thiosulfate 10%)	Amount Using (Na Thiosulfate 25%)	
Na Thiosulfate Inj (10% or 25%)	50ml	20ml	40ml
Sterile Water for Irrigation (pour bottle)	450ml	480ml	960ml
TOTAL VOLUME	500ml	500ml	1000ml

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 solutions suitable for cleaning a biological safety cabinet.

Step #5 – (optional cleaning) repeat steps #3-#4 two times each, wiping in top-down motion and discarding towels, followed by a dry and clean towel wipe in between each step.

Appendix C: List of Symbols Used on the Device

Symbol	Reference	Title
	IEC 60417-5032	Alternating Current
	IEC 60417-5036	Dangerous Voltage
	IEC 60417-5019	Protective Earth (Ground)
	ISO 7000-0434	Caution risk of danger or Attention, consult ACCOMPANYING DOCUMENTS
	IEC 60417-5007	“ON” (Power)
	IEC 60417-5008	“OFF” (Power)

Appendix D: Troubleshooting

Problems During Dosing	
Description of Fault	Remedy
Repeated "Empty Vial" message	<ul style="list-style-type: none"> ● Twist vial and ensure vial adapter spike is fully inserted into vial to remedy any septum tenting around vial spike. ● Replace Vial Adapter Spike
Wireless Scanner is not powering on	<ul style="list-style-type: none"> ● Contact ICU Technical Support for service
Air bubbles forming in syringe	<ul style="list-style-type: none"> ● Change speed parameter to normal. ● Use Genie vial adapter designed for Diana. ● Twist vial and ensure vial adapter spike is fully inserted into vial to remedy any septum tenting around vial spike.
Vacuum forming inside syringe	<ul style="list-style-type: none"> ● Change speed parameter to normal. ● Use Genie vial adapter designed for Diana. ● Twist vial and ensure vial adapter spike is fully inserted into vial to remedy any septum tenting around vial spike.
Air bubble introduced after new vial replaced	<ul style="list-style-type: none"> ● Tap vial to help dislodge any trapped air in vial spike. ● Prime new vial adapter fitting if needed. ● Consider using a set with drip chamber.
Channel 1 syringe continues to draw after vial has been emptied	<ul style="list-style-type: none"> ● If condensation is visible on cassette, replace cassette and let drug vial temperature reach within 8-12°C of room temperature. ● Check for debris on channel 1 Syringe pump carriage. ● Replace cassette. ● Contact ICU Technical Support for service.

Appendix D: Troubleshooting (continued)

Problems During Dosing	
Description of Fault	Remedy
Air flowing through diluent set lines	<ul style="list-style-type: none"> • Fill the drip chamber to the top with fluid minimizing the air gap. • Slide the external liquid sensor as far up the drip chamber walls. • Reduce speed as needed.
System Reset	<ul style="list-style-type: none"> • Remove any air gap in prior syringe before connecting to cassette. • Eliminate any visible gap between the cassette collar and syringe luer end. • Avoid applying pressure to movable portion of syringe motor platform when exchanging syringes.
Fluid seen dispensed back to source container instead of receiving container	<ul style="list-style-type: none"> • Exchange with new cassette and discard patient container.
Nothing is shown in the display after the device is switched on	<ul style="list-style-type: none"> • Switch the device off. Check to see if the device's fuse is faulty. Replace if necessary. • Check if mains power supply is functioning.
After switching on, one or more injection pumps are not in the home position	<ul style="list-style-type: none"> • Press the RESET key to return the device to its basic position
Liquid does not flow properly into the syringe pistons	<ul style="list-style-type: none"> • Check if the spike has been correctly connected.
FLC warning showing on power up	<ul style="list-style-type: none"> • Ensure external liquid sensor is connected properly.
Firmware does not boot-up on power-on	<ul style="list-style-type: none"> • Power system off, wait 10 seconds, then power-on.
Scanner not working or not scanning barcodes	<ul style="list-style-type: none"> • Check connectors. • Try with another barcode • Move scanner closer to barcode • Ensure scanner is targeting barcode.
Printer does not print labels	<ul style="list-style-type: none"> • Contact ICU Technical Support for service

Appendix D: Troubleshooting (continued)

Problems During Dosing	
Description of Fault	Remedy
Barcode not recognized by scanner	<ul style="list-style-type: none"> • Add drug to Diana System library using the Diana System Manager. • Press override to continue with Diana workflow sequence.
Black screen appears upon power up	<ul style="list-style-type: none"> • Power system off, wait 10 seconds, then power-on.

Effective

Appendix E: Accuracy Verification Check Test Protocol

Channel One Verification Test

1. Turn device on
2. Select Clear All
3. Select Menu button to go to Standard Parameters Page
4. On Standard Parameters Page, Change Speed 'Parameter' = Normal for CHAN 1
5. Spike Sterile Water vial (25 ml or 50ml vial size is ideal) with CH-70
6. Insert new cassette into Channel 1
7. Spike an empty 50 ml IV bag with suitable bag spike
8. Connect Sterile Water vial adapter to cassette
9. Attach empty receiving container IV bag to cassette
10. Pre-prime channel cassette and fluid pathway from fluid vial to bag spike
11. Remove IV bag and place empty receiving container IV bag on scale
12. Tare scale with empty IV bag (scale resolution should be to 0.001g)
13. Remove receiving container IV bag and connect to Diana Cassette
14. Program Volume (5 ml)
15. Select Sterile Water
16. Confirm volume and diluent
17. Press Start
18. After dispensing is complete disconnect IV bag
19. Weigh disconnected IV Bag on previously tarred scale and record new weight
20. Divide weight by 0.99802 g/ml (density of Sterile Water @ 21°C) to convert grams to ml's.
21. Record mL's after calculating density conversion.
22. Calculate % error

$$\text{Calculate \% Error} = \frac{(\text{Measured Fluid dispensed mL's} - \text{Programmed volume mL's})}{(\text{Programmed volume mL's} \times 100)}$$
23. Repeat 3x for 5 ml
24. Repeat 4x each for 20ml and 50 ml

If you observe >1 mL error at volumes =5 mL or >3% error at volumes =20 ml or >2% error at volumes =50 ml as a result of this on Channel One Verification Test, your Diana system may require recalibration. Contact your authorized ICU Medical Representative for further evaluation and more information about recalibration.

Channel Two Verification Test

1. Turn device on
2. Select Clear All
3. Select Menu button to go to Standard Parameters Page
4. On Standard Parameters Page, Change Speed 'Parameter' = Normal for CHAN 2
5. Spike Sterile Water bag and prime Channel two set and drip chamber and entire fluid pathway.
6. Insert fully primed set into Channel Two
7. Connect Sterile Water IV bag with suitable bag spike
8. Place empty receiving container IV bag on scale
9. Tare scale with empty IV bag (scale resolution should be to 0.001g)
10. Remove receiving container IV bag and connect to Channel 2 Set
11. Program Volume (5 ml)
12. Select Sterile Water
13. Confirm volume and diluent
14. Press Start
15. After dispensing is complete disconnect IV bag
16. Weigh disconnected IV Bag on previously tarred scale and record new weight
17. Divide weight by 0.99802 g/ml (density of Sterile Water @ 210C) to convert grams to ml's.
18. Record mL's after calculating density conversion.
19. Calculate % error

$$\text{Calculate \% Error} = \frac{(\text{Measured Fluid dispensed mL's} - \text{Programmed volume mL's})}{(\text{Programmed volume mL's} \times 100)}$$
20. Repeat 3x for 5 ml
21. Repeat 4x each for 25 ml and 50 ml

If you observe >3% error at volumes ≥ 5 mL as a result of this on Channel Two Verification Test, your Diana system may require recalibration. Contact your authorized ICU Medical Representative for further evaluation and more information about recalibration.

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DF-4925-EN Rev 02 (04/16)