SYMBOLS ON THE COMPOUNDER



Power button



Power light



Load cell



Display



Pump door must be closed to operate



Warning / Caution



USB port



Ethernet port



Reset button



Protective ground (earth) terminal



WARNING! USA Federal law restricts this device to sale, distribution, and use by or on order of a physician.



Fuse

TERMS IN THIS MANUAL



WARNING

Indicates a risk of personal injury or patient harm if the instructions are not followed



CAUTION

Indicates a risk of damage to equipment or data if the instructions are not followed

IMPORTANT! Provides important information

NOTE: Provides additional information

Tip! Provides a recommendation

In the electronic version of this manual, underlined text and Table of Contents entries provide hyperlinks to other sections.

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INTRODUCTION

The Baxter ExactaMix® 1200 Compounder is an automated pumping system that compounds multiple sterile ingredients into a finished solution in a single patient bag. Using a formula provided electronically or entered manually, the compounder withdraws a specified volume of each ingredient from its source container in a specified sequence, and pumps each ingredient into a patient bag. The finished solution is delivered to patients intravenously.

You can use the compounder to compound solutions such as:

- Total Parenteral Nutrition (TPN)
- Continuous Renal Replacement Therapy (CRRT)
- Cardioplegia
- Base solutions
- Epidurals



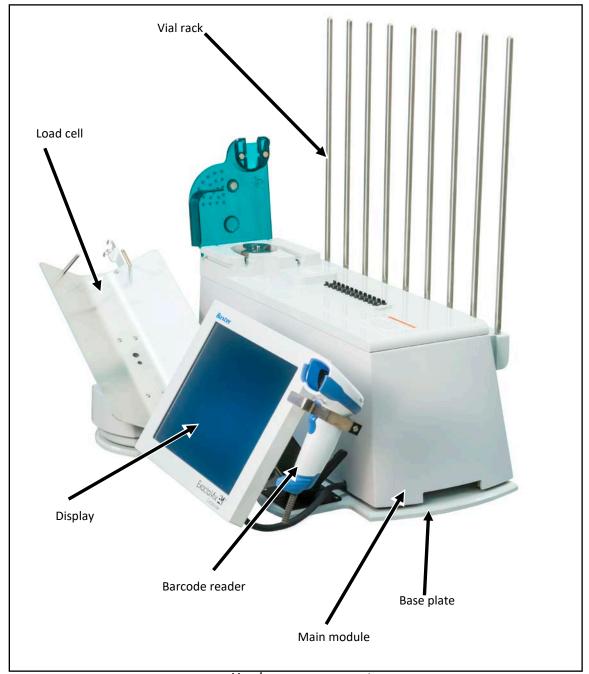
WARNING

The compounder software is not intended to replace the professional judgment or knowledge of a pharmacist or pharmacy technician.

COMPONENTS

HARDWARE COMPONENTS

The compounder consists of these main hardware components:



Hardware components

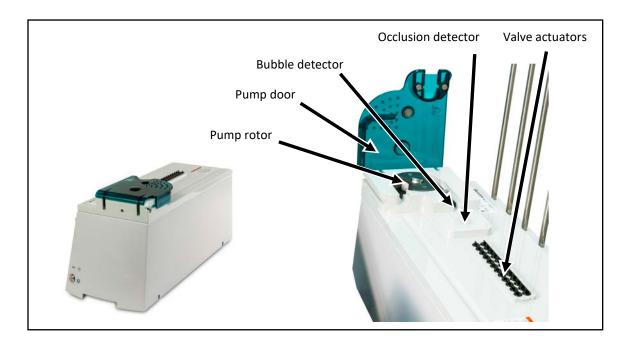
NOTE: The vial rack extension (optional) and the printer (North America only) are not shown.

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The main module contains the moving parts of the compounder, including these parts:

- The **valve actuators** open and close as needed to allow the delivery of individual ingredients. When the pump is paused, the valve actuators automatically close.
- The **occlusion detector** detects occlusions (blockages) in the tube between the source containers and the detector.
- The **bubble detector** detects air bubbles as they pass through the tube over the detector.
- The pump door allows access to the pump rotor.
- The **pump rotor** moves the fluid from the valve set to the destination bag.



Main module, with close-up view of the top

The **load cell** weighs each destination bag and sends this measurement back to the display, where calculations are performed. A 2,000 g calibration weight is provided with the compounder and used to calibrate the load cell.



Load cell

The **display** operates the compounder software and includes a touch screen for easy input. The bottom of the display contains four USB ports, which can be used to connect a barcode reader, keyboard, mouse, and printer or USB drive. The bottom of the display also contains one Ethernet port.



Display

The **barcode reader** is stored on the right side of the display. This reader is used to scan barcodes on the labels of source containers, inlets and patient bags.

Models of the barcode reader may vary.



Barcode reader

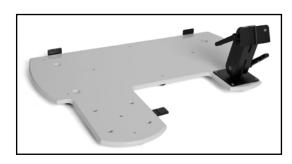
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The **vial rack** attaches to the main module. Adjustable **vial holders** and **syringe holders** attach to the vial rack.



Vial rack

The **base plate** is the common base on which the compounder's components sit.

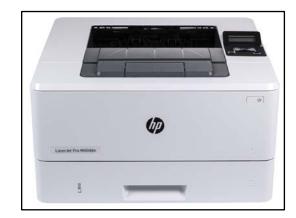


Base plate

The laser **printer**, used for printing reports and labels, can be connected directly to the compounder or to a network.

Models of the printer may vary.

The printer is available in North America only.



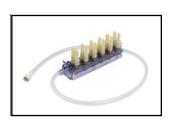
Printer

DAILY USE COMPONENTS

- The valve set is a sterile, multiple-port valve with an outlet tube attached. The valve body
 fits over the valve actuators on the compounder, protecting them from damage. The outlet
 tube attaches to the destination bag. For ordering information, refer to <u>Valve Sets</u> on
 Page 21.
- The **inlet** is a sterile tube with a spike or Luer end attached. The spike or Luer end attaches to a source container, and the other end attaches to a port on the valve set. The type of inlet that is used depends on the source container. For inlet types, descriptions and ordering information, refer to <u>Inlets</u> on Page 18.

NOTE: The valve set and inlets are collectively known as the tube set.

- The **destination bag** is a sterile container that holds the fluid pumped from the source containers. There are two main types of destination bags, which are available in different sizes. For bag types, descriptions and ordering information, refer to Bags on Page 19.
 - The patient bag is used for delivering the finished solution to a patient. This bag contains three ports for filling the bag, adding ingredients manually and delivering the finished solution.
 - The calibration bag is used for collecting any fluid that is not intended for a
 patient. For example, this type of bag is used while calibrating and priming the
 compounder. This bag contains only one port for filling the bag. The calibration
 bag is available in North America only.









Valve set

Inlet

Patient bag Calibration bag

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SOFTWARE

The display of the compounder has Baxter ExactaMix® 1200 Operating Software installed.

To comply with regulations of the United States Food and Drug Administration (FDA), the compounder has been validated and approved for use only with the software that Baxter Healthcare Corporation provides.

CAUTION



Do not install any software on the compounder—including operating system updates, antivirus software or firewall software—unless the software is provided by or approved in writing by Baxter. Installing any software not approved by Baxter may change the operating parameters, adversely affect the operation and create unsafe conditions. Installing this software voids the compounder's warranty.

License

The license to use the compounder software is granted to a single concurrent user on a single ExactaMix 1200 Compounder for the term of the equipment contract. Baxter retains ownership of the software. Distribution or copying of this software, other than for backup purposes, is expressly forbidden.

Permissions

The options that appear in the software depend on the permissions granted to the user. If you have questions about your permissions, contact your supervisor. For more information about setting up permissions, refer to <u>Setting Up the Users</u> on Page 124.

Navigation

On any screen or window that requires data entry, tapping a field displays an on-screen keyboard or number pad that allows you to enter characters.



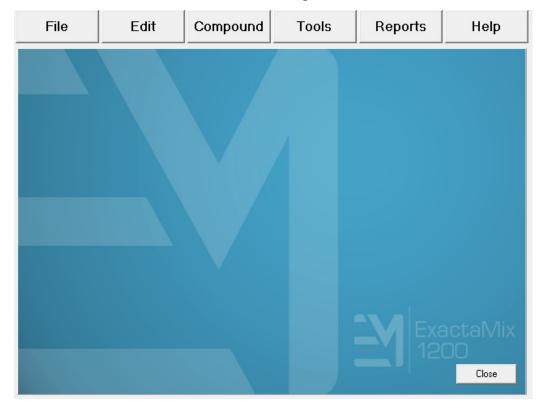


On-screen keyboard and number pad

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Menu Screen

The menu screen allows access to menus and settings.



Menu screen

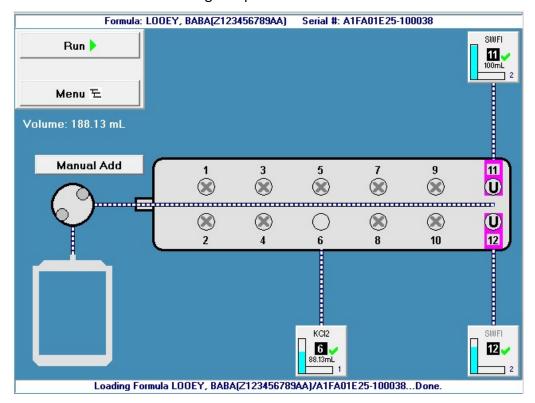
The menu screen has six tabs at the top. Tapping a tab displays a drop-down menu. Use the:

- **File** menu to manage formulas, log in or out of the software, exit the software, restart the compounder or shut down the compounder
- **Edit** menu to edit the configurations, formulary, ingredient groups, inlet information and bag information
- **Compound** menu to set up the compounder for operation, select a formula to compound and manage ingredients
- **Tools** menu to set up options related to the system, users, security, directories used for saving certain files and software maintenance
- **Reports** menu to view, print and export reports related to compounding and other device activity
- Help menu to view tutorials and information about the hardware and software

Tapping **Close** in the bottom right displays the pump screen (or a similar screen during the setup process). You can also display the pump screen by selecting certain functions, such as those on the **Compound** menu.

Pump Screen

The pump screen shows a diagram of the valve set. It is used during the compounding process. Similar screens are used during setup.

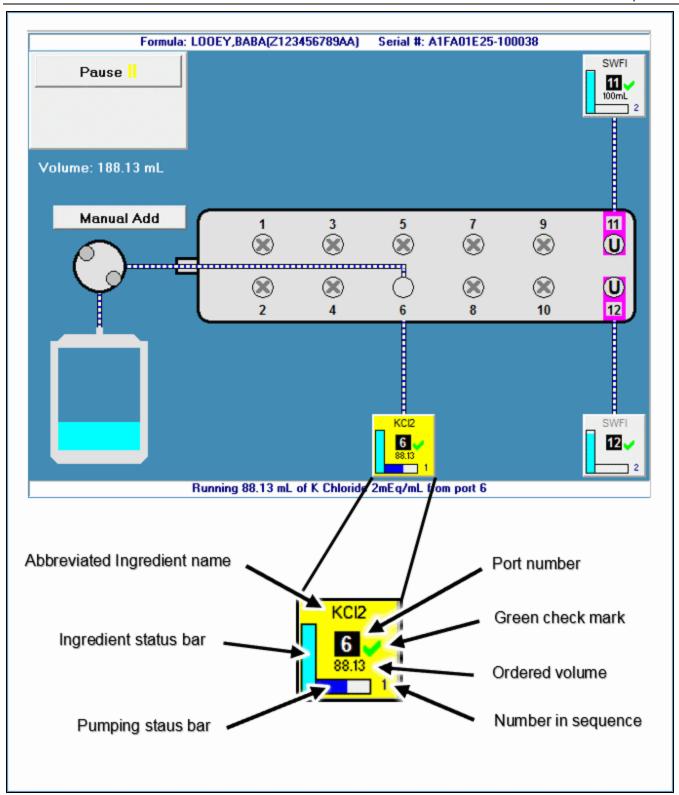


Pump screen at the start of the compounding process

The appearance of the pump screen changes slightly during various steps of the compounding process. However, the screen always includes these elements:

- The Formula: <formula name / patient name> and Serial#: <serial number> appear on the top of the screen.
- Buttons appear on the left side of the screen. Tapping **Run** starts the compounding process. Tapping **Menu** displays the menu screen.
- The total volume to be pumped for the order appears under the **Menu** button.
- A diagram of the valve set with numbered ports appears on the middle of the screen. Ports that:
 - o Have no ingredient attached have an X over them
 - Have an ingredient attached have an ingredient button connected
 - Have the Universal Ingredient attached are identified by a U
 - Make up an electronic Y-site are identified by colored highlighting

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Ingredient button

On the pump screen, each ingredient button includes:

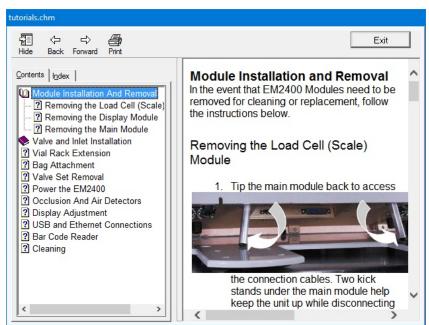
- The abbreviated ingredient name
- The port number
- A green check mark indicating that the inlet and port have been verified, or a red X indicating that they need to be verified
- The ordered volume of the ingredient
- A number indicating the ingredient's place in the compounding sequence
- A vertical bar showing how much of the ingredient remains in the container; during the compounding process, this bar decreases as the remaining volume decreases
- A horizontal bar showing how much of the ingredient is being used for the current order;
 during the compounding process, this bar increases as the pumped volume increases

When an ingredient is being pumped, its button becomes yellow. An animation shows fluid moving through the inlets and the outlet tube into the destination bag. Horizontal marks across an inlet represent fluid, indicating that this inlet has been primed.

Tutorials

The compounder software includes step-by-step tutorials about setting up the compounder. The tutorials refer to the Baxter ExactaMix® 2400 Compounder; however, this information also applies to the ExactaMix 1200 Compounder. To access the tutorials:

- 1. At the menu screen, tap Help > Tutorials.
- 2. At the tutorials window:
 - On the Contents tab, tap a topic to display the associated help content.
 - On the **Index** tab, enter and search for keywords.



Tutorials window

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FEATURES

SUMMARY OF FEATURES

The compounder:

- Accepts formulas created by order-entry software via 2D Formula Barcode/PAT/FRM file interface, or by direct entry on the compounder
- Uses barcodes on the source containers and inlets to promote proper setup
- Includes software with a Setup Wizard to guide you through the setup process
- Supports a maximum of 12 ingredients, source containers in volumes of 10–5,500 mL and destination bags in volumes of 125–5,000 mL
- Allows you to attach the same ingredient to more than one port, creating an electronic Ysite
- Allows you to specify the sequence in which ingredients are pumped
- Allows you to specify the accuracy limits for the finished solution
- Uses volumetric delivery, gravimetric verification and automatic calibration to help ensure delivery accuracy
- Uses a bubble detector and occlusion detector
- Can be immediately stopped by lifting the pump door
- Can track ingredient lot numbers and ingredient expiration dates
- Generates a MixCheck™ Report for each finished solution
- Can print reports and barcode labels at the compounder's printer
- Can be set up to communicate with the printer and the order-entry computer through a network

ORDER ENTRY

Order entry can be done through direct entry, refer to page 77, or by using separate orderentry software.

The ExactaMix operating software can communicate, via a network, with order-entry software on a separate computer. The order-entry software must produce both a .PAT/.FRM file and a corresponding barcode. Scanning the barcode at the compounder retrieves the .PAT/.FRM file.

Alternatively the order-entry software must be able to produce a formula label, containing the formula details in the 2D barcode. Scanning the 2D barcode loads the formula onto the compounder. For more information, refer to <u>Loading the Formula</u> on Page 75.

FORMULARY

The formulary is the list of ingredients, and associated products, which can be attached to the compounder.

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An ingredient is a solution of a specific chemical entity at a specific concentration regardless of container size, container type or manufacturer. One ingredient can have several associated products.

A product is an ingredient in a particular container size and type from a specific manufacturer. Several products can be associated to one ingredient group.

For example, in North America:

- Ingredient: Dextrose 70%
- Products:
 - o Hospira Dextrose 70%, 2000 mL bag
 - o Hospira Dextrose 70%, 1000 mL bag
 - o Hospira Dextrose 70%, 500 mL bottle
 - Baxter Dextrose 70%, 2000 mL bag
 - Baxter Dextrose 70% 1000 mL bottle

INGREDIENT GROUPS

An ingredient group is a list of chemically similar ingredients. For example:

• Ingredient Group: Phosphate

Ingredients: K Phos 3mM/mL, Na Phos 3mM/mL

Ingredient Group: Calcium

Ingredients: Ca Gluconate 10%, Ca Chloride 10%

Some ingredients can tolerate each others' presence in the finished solution, but must be separated during compounding to ensure that they do not mix within the common fluid pathway, or within the patient bag in the absence of sufficient volume. These ingredients are considered to be incompatible. For example, calcium and phosphate should not be mixed in their concentrated forms (in the absence of amino acids), or a precipitate will immediately result. The compounder will pump incompatible ingredients only if it can pump a user-specified volume of another ingredient between them.

Each ingredient group has a list of other groups with which it is incompatible. When ingredients are assigned to these groups, the software can detect formulas in which incompatible ingredients are not sufficiently separated.

UNIVERSAL INGREDIENT

When a patient bag is removed, approximately 25 mL of the last ingredient pumped remains in the common fluid pathway. This ingredient then becomes the first ingredient to enter the next patient bag when the next solution is compounded. Because this ingredient must be suitable for all formulas, it is called the Universal Ingredient (UI).

Each formula must include enough UI volume to allow a final flush, which flushes all the previous ingredients into the patient bag. Regardless of the total volume of the UI to be delivered, the compounder reserves enough UI volume to perform a final flush at the end of

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the compounding process. You can change the volume used for the final flush when creating a configuration.

The UI is specified by the facility and is typically water or dextrose.

CONFIGURATION

A configuration identifies the products that will be attached to the ports, the sequence in which they will be pumped, any allowable auto-additions, the ingredient and volume to use for any ingredient flushes, the Universal Ingredient and the volume to use for the final flush.

BARCODE VERIFICATION

WARNING



It is important to use a barcode reader for scanning labels during verification of the setup.

For the barcode verification to be effective, it is critical that the configuration be set up properly. For instructions, refer to <u>Attaching the New Ingredients and Inlets</u> on Page 47.

During daily setup, or when a source container must be replaced, the software guides you through a process of barcode verification. You scan a barcode label on each inlet and each source container to verify that the inlet is attached to the correct container.

Each inlet must be labeled with a barcode that identifies the port to which the inlet is attached. These barcode labels are packaged with the valve set. The compounder software can also generate a report that makes these labels available for printing.

Most source containers already have a manufacturer's barcode label attached. For containers that are filled or diluted in the pharmacy, the compounder software can also generate a report that makes these labels available for printing.

Tip! Baxter strongly recommends using the manufacturer's barcode whenever possible.

MEASUREMENT OF VOLUME AND WEIGHT

The compounder uses volumetric delivery to move fluid, with gravimetric verification to check the final weight of the destination bag. The compounder also performs an automatic calibration to maintain delivery accuracy.

Volumetric Delivery

The pump rotor moves as it pumps an ingredient into the destination bag. The amount of movement determines the volume that is delivered.

Automatic Calibration

The pump is calibrated with water. A flow factor associated with each ingredient adjusts the flow of that ingredient compared to the flow of water. The flow factor accounts for the ingredient's viscosity, the size and type of its source container, its inlet, its venting and other factors that affect its delivery. As a result, calibrating with water automatically calibrates the compounder for use with all the other ingredients.

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Every time the rotor pumps an uninterrupted delivery of 175 mL or more of water, the compounder automatically performs a calibration of the rotor movement. Automatic calibration maintains the rotor's accuracy and reduces the need for manual adjustments.

Gravimetric Verification

The compounder provides feedback about its delivery accuracy by weighing the finished solution and comparing that weight to the theoretical weight of a perfectly compounded solution. This theoretical weight is computed by this formula:

\(\sum_{\text{Ingredient}}\) \(\sum_{\text{Nolume}}\) \(\sum_{\text{Ingredient}}\) \(\sum_{\text{Nolume}}\) \(\sum_{\text{Ingredient}}\) \(\sum_{\text{Nolume}}\)

PRINTING OPTIONS

The printer is used for printing reports and creating labels for inlets and source containers. The printer can use standard 8.5 x 11 in. (21.6 x 28 cm) for reports and Avery® label sheets (70x25,4mm) (or comparable sheets) for inlet flags.

For using A4 paper, in the Options window, change the reports directory path to C:\Program Files\Baxter\Exacta-Mix 1200\Reports\A4. Refer to section <u>Setting Up Directories Option</u> on Page 122.

You can connect the printer to a:

- USB port on the display
- USB port on the order-entry computer, for use on a network
- Network via an Ethernet cable

The compounder software includes the printer drivers.



CAUTION

Use only Baxter-authorized printers with the compounder. Installing other printer drivers on the compounder voids the compounder's warranty.

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NETWORK CONNECTIVITY

You can connect the compounder, via an Ethernet cable, to a:

- Facility network
- Mini-net that is typically shared only with the order-entry computer and the compounder's printer

The compounder reaches out to the network only to retrieve .PAT/.FRM files, send print jobs and back up the database.

Baxter does not support network-related equipment, nor activities related to setting up or troubleshooting network connectivity for the compounder.

Tip! If you connect the compounder to a network, Baxter recommends taking precautions to minimize the compounder's exposure to cyber threats. For example, isolate the compounder behind a VLAN or use a router that acts as a firewall. For more information about network security, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

ORDERING SUPPLIES

Order supplies through your normal channels.

Baxter Customer Service at +1.800.567. 2292.



WARNING

Use only sterile inlets, bags and valve sets validated by Baxter.

INLETS

The following inlets are available worldwide.

Product	Order Number	Quantity / Case	For use with:	Standard Priming Volume	Minimum Priming Volume
Non-vented High- Volume Inlet	H938 173	25	Large-volume, vented or collapsible containers (such as bags of dextrose and water)	50–60 mL	25–30 mL
Vented High- Volume Inlet	H938 174	25	Large-volume, non-vented containers that require a spike to vent air into the container	50–60 mL	25–30 mL
Vented Micro- Volume Inlet	H938 175	25	Small-volume vials	5–6 mL	2.5–3 mL
Micro-Volume Inlet, with Large-Bore Spikes	H938 751	25	Small-volume bags or bottles that require a large-bore spike	5–6 mL	2.5–3 mL
Syringe Inlet	H938 176	25	60 mL Luer syringes (regardless of the volume they contain)	5–6 mL	2.5–3 mL

OEM inlets are sterile, bio-compatible, non-pyrogenic, non-DEHP and contain no natural rubber latex components.

NOTE: The compounder will automatically use the highest available value for the standard priming volume and half of that value for the minimum priming volume. However, you can adjust these priming volumes in the Inlet Editor. For instructions, refer to <u>Using the Inlet Editor</u> on Page 150.

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BAGS

The following bags are available in North America.

Product	Order Number	Quantity / Case	Notes
ExactaMix Empty EVA Container, 250 mL	H938 737	50	
ExactaMix Empty EVA Container, 500 mL	H938 738	50	
ExactaMix Empty EVA Container, 1000 mL	H938 739	50	
ExactaMix Empty EVA Container, 2000 mL	H938 740	50	
ExactaMix Empty EVA Container, 3000 mL	H938 741	50	
ExactaMix Empty EVA Container, 4000 mL	H938 142	50	
ExactaMix Empty EVA Container, 5000 mL	H938 143	50	
ExactaMix Empty EVA Container, dual chamber, 1500 mL	H938 901	42	
ExactaMix Empty EVA Container, dual chamber, 3000 mL	H938 905	42	
ExactaMix Empty EVA Calibration Bag, 1000 mL	H938 735	50	Can be used for functions other than calibration; refer to <u>calibration</u> bag on Page 6
Tamper-resistant add-port cap	H938 4858	100	Not compatible with dual-chamber bags

Baxter bags are sterile, bio-compatible, non-pyrogenic and contain no natural rubber latex components. These bags have a large-bore, threaded fill-port connector.

The following bags are available in European Countries

Product Code	Product Description	Film	Size (mL)	Qty/ Cs	Fill Port	Mfr
E1301-OD	EVA, TPN Bag, Internal Thread, 125 mL	EVA	125	50	Lg. Bore	B. Braun
E1302-OD	EVA, TPN Bag, Internal Thread, 250 mL	EVA	250	50	Lg. Bore	B. Braun
E1305-OD	EVA, TPN Bag, Internal Thread, 500 mL	EVA	500	50	Lg. Bore	B. Braun
E1310-OD	EVA, TPN Bag, Internal Thread, 1000 mL	EVA	1000	40	Lg. Bore	B. Braun
E1320-OD	EVA, TPN Bag, Internal Thread, 2000 mL	EVA	2000	35	Lg. Bore	B. Braun
E1330-OD	EVA, TPN Bag, Internal Thread, 3000 mL	EVA	3000	35	Lg. Bore	B. Braun
E1340-OD	EVA, TPN Bag, Internal Thread, 4000 mL	EVA	4000	30	Lg. Bore	B. Braun
E1350-OD	EVA, TPN Bag, Internal Thread, 5000 mL	EVA	5000	25	Lg. Bore	B. Braun
E1302-OD/5	EVA, TPN Bag, Internal Thread, 250 mL (5 pack)	EVA	250	50	Lg. Bore	B. Braun
E1305-OD/5	EVA, TPN Bag, Internal Thread, 500 mL (5 pack)	EVA	500	50	Lg. Bore	B. Braun
E1310-OD/5	EVA, TPN Bag, Internal Thread, 1000 mL (5 pack)	EVA	1000	40	Lg. Bore	B. Braun
E1305-OD/5	EVA, TPN Bag, Internal Thread, 500 mL (5 pack)	EVA	500	50	Lg. Bore	B. Braun
E1310-OD/5	EVA, TPN Bag, Internal Thread, 1000 mL (5 pack)	EVA	1000	40	Lg. Bore	B. Braun
E1320-OD/5	EVA, TPN Bag, Internal Thread, 2000 mL (5 pack)	EVA	2000	35	Lg. Bore	B. Braun
E1302-OV/5	B. Braun EVA TPN Bag, 250 mL (5 pack)	EVA	250	50	Lg. Bore	B. Braun
E1305-OV/5	B. Braun EVA TPN Bag, 500 mL (5 pack)	EVA	500	50	Lg. Bore	B. Braun
E1310-OV/5	B. Braun EVA TPN Bag, 1000 mL (5 pack)	EVA	1000	40	Lg. Bore	B. Braun
E1320-OV/5	B. Braun EVA TPN Bag, 2000 mL (5 pack)	EVA	2000	35	Lg. Bore	B. Braun
E1330-OV/5	B. Braun EVA TPN Bag, 3000 mL (5 pack)	EVA	3000	35	Lg. Bore	B. Braun
E2301OD	TPN BAG EVA 125 mL YELLOW	EVA	125	50	Lg. Bore	B. Braun
E2302OD	TPN BAG EVA 250 mL YELLOW	EVA	250	50	Lg. Bore	B. Braun
E2305OD	TPN BAG EVA 500 mL YELLOW	EVA	500	50	Lg. Bore	B. Braun
E23100D	TPN BAG EVA 1000 mL YELLOW	EVA	1000	40	Lg. Bore	B. Braun
E23200D	TPN BAG EVA 2000 mL YELLOW	EVA	2000	35	Lg. Bore	B. Braun
E23300D	TPN BAG EVA 3000 mL YELLOW	EVA	3000	35	Lg. Bore	B. Braun
E1301-OLPF	EVA TPN Bag, 125 mL (LL Fill Port)	EVA	125	50	Luer Lock	Diffuplast
E1302-OLPF	EVA TPN Bag, 250 mL (LL Fill Port)	EVA	250	50	Luer Lock	Diffuplast
E1305-OLPF	EVA TPN Bag, 500 mL (LL Fill Port)	EVA	500	50	Luer Lock	Diffuplast
E1310-OLPF	EVA TPN Bag, 1000 mL (LL Fill Port)	EVA	1000	40	Luer Lock	Diffuplast
E1320-OLPF	EVA TPN Bag, 2000 mL (LL Fill Port)	EVA	2000	35	Luer Lock	Diffuplast
E1330-OLPF	EVA TPN Bag, 3000 mL (LL Fill Port)	EVA	3000	35	Luer Lock	Diffuplast
E1340-OLPF	EVA TPN Bag, 4000 mL (LL Fill Port)	EVA	4000	30	Luer Lock	Diffuplast
E1350-OLPF	EVA TPN Bag, 5000 mL (LL Fill Port)	EVA	5000	25	Luer Lock	Diffuplast
E14010D	TPN BAG MULTILAYER 125 mL	EVA	125	50	Lg. Bore	Diffuplast
E1402OD	TPN BAG MULTILAYER 250 mL	EVA	250	50	Lg. Bore	Diffuplast
E1405OD	TPN BAG MULTILAYER 500 mL	EVA	500	50	Lg. Bore	Diffuplast
E14100D	TPN BAG MULTILAYER 1000 mL	EVA	1000	40	Lg. Bore	Diffuplast
E14200D	TPN BAG MULTILAYER 2000 mL	EVA	2000	35	Lg. Bore	Diffuplast
E14300D	TPN BAG MULTILAYER 3000 mL	EVA	3000	35	Lg. Bore	Diffuplast
E1440OD	TPN BAG MULTILAYER 4000 mL	EVA	4000	30	Lg. Bore	Diffuplast

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Baxter bags are sterile, bio-compatible, non-pyrogenic and contain no natural rubber latex components. These bags have a large-bore, threaded fill-port connector or a luer lock fill-port connector.

VALVE SETS

The following valve sets are available in North America.

Product	Order Number	Quantity / Case	Notes
EM1200 Valve Set	H938 792	10	Includes:
			 Numbered inlet labels with barcodes
			• 10 calibration bags (H938 735 3)

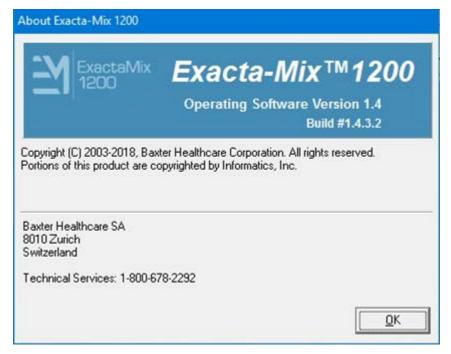
Baxter valve sets are sterile, bio-compatible, non-pyrogenic, non-DEHP and contain no natural rubber latex components.

GETTING HELP

Baxter Technical Services is available 24 hours/day, 7 days/week at 1.800.678.2292 or COtechsupport@baxter.com.

Before you call for technical support:

- At the menu screen, tap Help > About.
 The About window appears. It provides information about the hardware and software.
- 2. At the About window, identify the Operating Software Version and Build #.



About window

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INSTALLING THE COMPOUNDER

Your Baxter service provider will install the compounder at your site.

If you must reinstall the compounder or replace a component, verification tests must be performed before you use the compounder again. Contact Baxter Technical Services for assistance. Refer to <u>Getting Help</u> on Page 22.

To start, open the packaging, remove all the items and inspect them to make sure that they are not damaged.

WARNING



Do not use sharp objects to open the packaging. Personal injury could result.

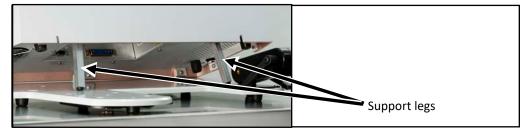
The compounder should be placed on a level and stable surface to prevent its modules from moving out of position. Always hold the modules as shown below to avoid dropping them.

- 1. Route the power cord out through the routing hole in the back of the main module.
- 2. Place the main module onto the base plate.



Placing the main module

- 3. Place the load cell to the left of the base plate.
- 4. Place the display to the right of the base plate.
- 5. Tip the main module back and extend the support legs.



Extending the support legs

NOTE: If the main module is near a wall, there may not be enough space behind the main module to tip it back. You can move the compounder forward by lifting the front of the base plate slightly and sliding it toward you.

WARNING

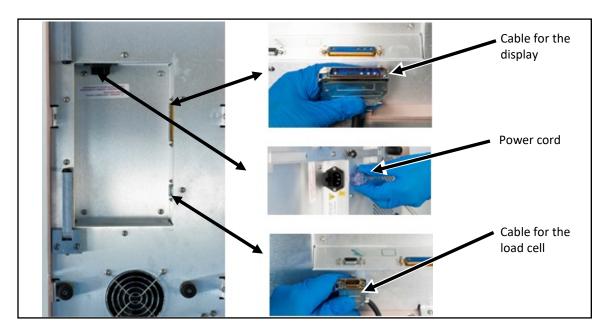


Using the support legs will reduce the possibility of pinching your hands when you connect the cord and cables.

The power cord must be unplugged from the main AC power source whenever you connect or disconnect the display and load cell.

The power cord must be positioned so that the plug is easily accessible.

- 6. Under the main module, connect the following cord and cables. Reach under the main module with your palm facing up.
 - a. Connect the power cord.
 - b. Connect the cable for the display. Squeeze the ends of the connector to unlock it, connect it, then release to lock it into place.
 - c. Connect the cable for the load cell. Squeeze the ends of the connector to unlock it, connect it, then release to lock it into place.



Connecting the cord and cables

NOTE: The above pictures depict ROHS unit plug placement. Plug locations for Non-ROHS units are slightly different.

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- 7. Retract the support legs so that the main module rests fully on the base plate.
- 8. Route the cables through the two routing holes, pushing any excess length of the cables through the holes.



Routing a cable

- 9. Install the load cell.
 - a. Place the load cell onto the base plate.
 - b. To lock the load cell, move the black lever back until it clicks into place.



Installing the load cell

10. Install the display onto the arm.

The white locking pin snaps into the locked position.



Installing the display

NOTE: You can remove the display by pulling the locking pin out to the unlocked position, then rotating the pin 90 degrees to keep it in this position while lifting the display.

- 11. Install the barcode reader.
 - a. Pull the arm that is behind the display out to the right.
 - b. Rotate the arm up and over toward you.
 - c. Pull the arm slightly to the right to lock it into place.



Rotating the arm

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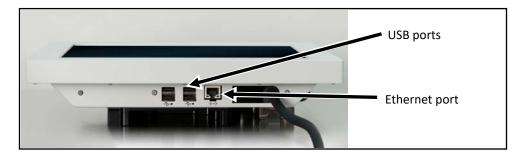
d. Place the barcode reader in the cradle with the trigger facing you to avoid accidental scanning.



Placing the barcode reader

- 12. Connect the USB cable from the barcode reader to a USB port on the bottom of the display.
- 13. If desired:
 - Connect the USB cable from the printer to a USB port on the display.
 - Connect an Ethernet cable to the Ethernet port on the display.

NOTE: To perform administrative work, you can also connect a keyboard and mouse to the USB ports on the display. The keyboard and mouse should not be connected during normal compounding operation.

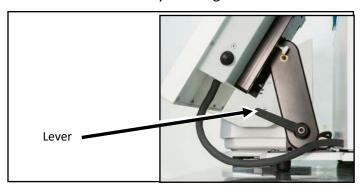


Ports on the display

- 14. Move the arm of the display to the desired position.
 - a. Unlock the lever on the right by rotating it forward.

NOTE: Pulling the lever slightly out to the right may make it easier to rotate.

- b. Adjust the arm of the display forward or backward.
- c. Lock the lever by rotating it backward.

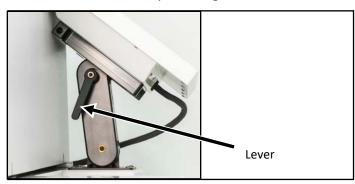


Lever on the right

- 15. Move the display to the desired position.
 - a. Unlock the lever on the left by rotating it backward.

NOTE: Pulling the lever slightly out to the left may make it easier to rotate.

- b. Adjust the display up or down.
- c. Lock the lever by rotating it forward.



Lever on the left

- 16. Check that the cables:
 - Are not kinked or pinched
 - Do not touch the base of the load cell
- 17. Plug the power cord into an uninterruptible power supply (UPS).

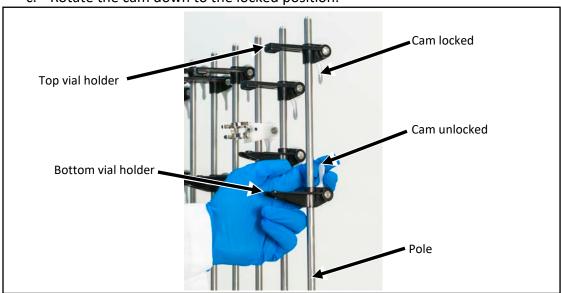
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18. Install the vial rack onto the back of the main module. On each end, slide the slot on the vial rack over the bolt on the main module.



Installing the vial rack

- 19. Install the vial holders in the desired locations on the vial rack.
- 20. Adjust the position of each top and bottom vial holder.
 - a. Rotate the cam up to the unlocked position.
 - b. Push the holder to the desired location on the pole.
 - c. Rotate the cam down to the locked position.

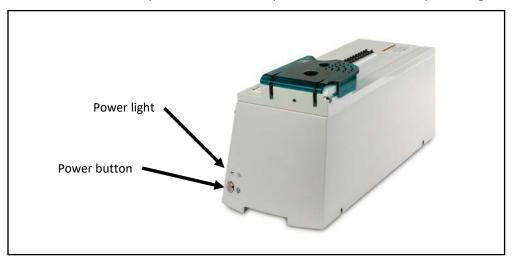


Adjusting the vial holders

STARTING UP, LOGGING IN AND OUT, AND SHUTTING DOWN

STARTING UP AND LOGGING IN

1. On the main module, press and hold the power button until the power light illuminates.



Power light and power button

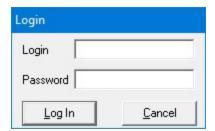
2. If the software does not start automatically, double-tap the **Exacta-Mix 1200** icon on the Windows® desktop.

Tip! Baxter recommends setting the software to start automatically. Contact Baxter Technical Services for assistance with setting up this feature. Refer to <u>Getting Help</u> on Page 22.



Icon

- 3. If the *Login* window appears:
 - a. Enter a **Login** name.
 - b. Enter a **Password**. (**NOTE**: Passwords are case-sensitive)
 - c. Tap Log In.



Login window

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Tip! Baxter recommends setting up each user with a unique login name and password. If the compounder is connected to a network, Baxter recommends that the compounder be logged in to the network automatically. For details, contact Baxter Technical Services. Refer to Getting Help on Page 22.

NOTE: To require each user to log in, refer to <u>General</u> on Page 120. To set up password expiration, refer to <u>Password Expiration</u> on Page 121.

When the software starts, it performs self-checks and briefly displays the following messages. Other messages may also appear. Do not cancel these operations.

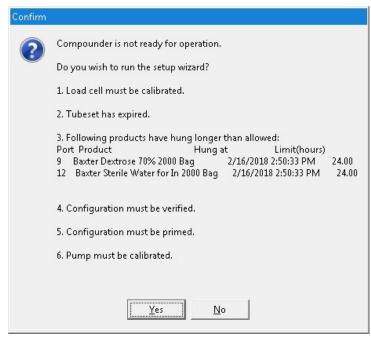


Messages that appear at startup

Next, the software may display a *Confirm* screen. Several styles of the *Confirm* screen may appear, but each includes this text: **Compounder is not ready for operation. Do you wish to run the setup wizard?** The screen also lists the conditions that prevent the compounder from being ready for operation. The screen appears if any of these conditions exist:

- The calibration of the load cell has expired.
- The calibration of the pump has expired.
- The tube set has expired.

NOTE: To set up the options for tube set expiration, refer to <u>Tube Set Expiration</u> on Page 116.



Confirm screen

- 4. If the *Confirm* screen appears:
 - o Tap **Yes** if you want to use the Setup Wizard now. For instructions on using the Setup Wizard, refer to Setting Up the Compounder on Page 34.
 - Tap No if you want to continue using the software in the current state.
 Tip! Baxter recommends always tapping Yes. If you tap No, you will be instructed to perform any required setup steps before compounding.

LOGGING OUT

When you have finished using the compounder, or another user needs to log in, you can log out of the software without shutting down the compounder.

At the menu screen, tap either:

- File > Logout
- Tools > Users > Change User

NOTE: The *Confirm* screen may appear if the compounder is not ready for operation. To set up the automatic logout option, refer to <u>Auto-Logout</u> on Page 120.

REBOOTING AND SHUTTING DOWN

Tip! Baxter recommends shutting down the compounder when you are finished using it. Baxter also recommends fully shutting down and starting up the compounder once a day, to allow the software to perform routine database maintenance at startup.

At the menu screen, tap File > Exit.
 The Exit Options window appears.



Exit Options window

IMPORTANT! The last two options shown above require Administration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.

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Operator Manual for the Baxter ExactaMix 1200 Compounder

- 2. Tap one of these options:
 - Shutdown the computer? to shut down the software and turn off the compounder
 - **Reboot the computer?** to shut down the software, turn off the compounder and restart the compounder
 - Log on as a different user? to log out and allow another user to log on
 NOTE: The Confirm screen may appear if the compounder is not ready for operation.
 - Minimize this application? to minimize the compounder software so that the Windows desktop is visible

NOTE: The compounder software remains active and can be maximized when needed.

- Exit program? to exit the compounder software
- 3. Tap **OK**.

NOTE: You cannot turn off any part of the compounder by pressing the power button on the main module. This button is used only to turn the power on.

CAUTION



You can reboot the display by pressing and holding the Reset button on the right side of the display. You can shut down the compounder (main module and display) by pressing and holding the power off button on the bottom right of the main module. However, either of these actions can corrupt the database. Do not press either of these buttons at any time other than when you are directed by Baxter Technical Services.

SETTING UP THE COMPOUNDER

ACCESSING THE SETUP WIZARD

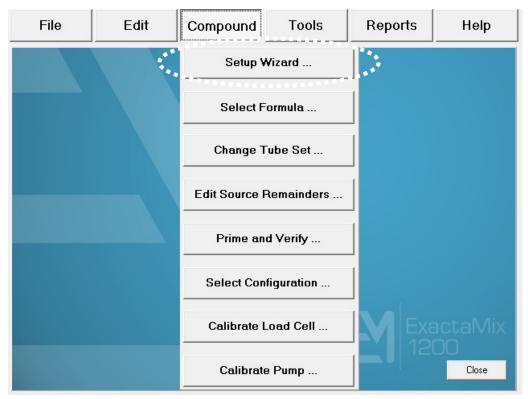
The Setup Wizard guides you through the setup process.

You can access the Setup Wizard in two ways:

- Tap **Yes** at the *Confirm* screen if it appears during startup.
- Tap **Compound > Setup Wizard** at the menu screen to access the Setup Wizard at any time.

NOTE: The **Compound** menu also includes options that allow you to perform individual steps of the setup process without completing the entire Setup Wizard.

Tip! Baxter recommends always using the Setup Wizard to guide you quickly through the necessary steps in the proper sequence.



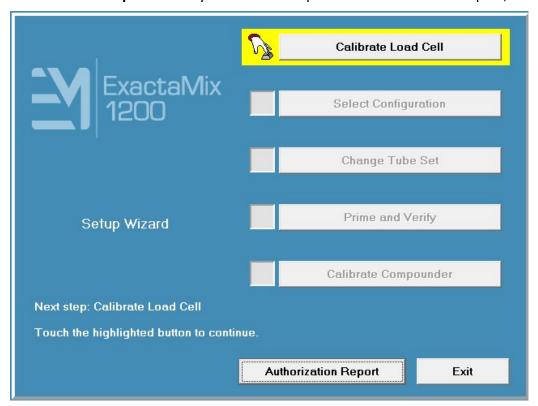
Menu screen, Compound menu

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IMPORTANT! These functions require Compounder permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.

The Setup Wizard guides you through these main steps:

- 1. Calibrate Load Cell guides you through calibrating the load cell.
- 2. **Select Configuration** allows you to select a configuration to use.
- 3. **Change Tube Set** guides you through installing a new tube set and new ingredients for the selected configuration.
- 4. **Prime and Verify** guides you (and an optional cosigner) through the process of priming the inlets and verifying the setup.
- 5. **Calibrate Compounder** calibrates the compounder's pump to ensure that it will deliver the intended volume of each ingredient.
- 6. **Authorization Report** allows you to view and print the Authorization Report, if desired.



Setup Wizard screen

CALIBRATING THE LOAD CELL

This procedure calibrates the load cell to ensure that it measures weight accurately.

The load cell must be calibrated:

- Daily when the calibration expires
- Using a 2,000 g weight that Baxter provides

Tip! Baxter recommends:

- Using gloves to handle the weight, to minimize the accumulation of oils and dust
- Storing the weight in its storage case

To calibrate the load cell:

1. At the Setup Wizard screen, tap Calibrate Load Cell.

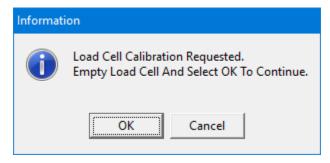


Setup Wizard screen, calibrating the load cell

NOTE: To calibrate the load cell without using the Setup Wizard, you can tap **Compound** > **Calibrate Load Cell** at the menu screen.

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The Load Cell Calibration Requested message appears.

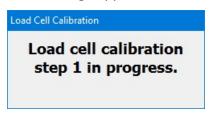


Message

IMPORTANT! If any items touch the load cell during the calibration, the calibration will not be accurate.

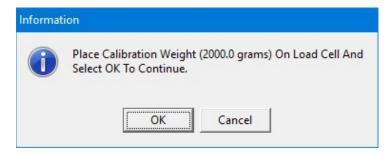
- 2. Make sure that:
 - There is no weight on the load cell.
 - There is nothing touching any part of the load cell (for example, there are no cables touching the base).
- 3. At the Load Cell Calibration Requested message, tap **OK**.

This message appears and then disappears:



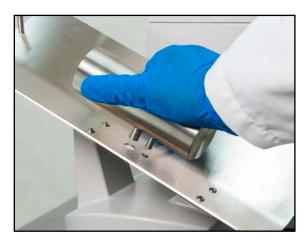
Message

The Place Calibration Weight message appears.



Message

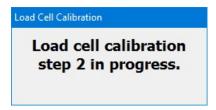
4. Place the 2,000 g weight on the load cell, aligning it with the holes in the load cell.



Aligning the calibration weight

- 5. Wait five seconds to allow the weight to stabilize.
- 6. At the Place Calibration Weight message, tap ${\bf OK}.$

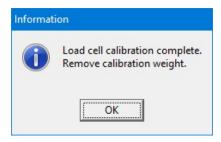
This message appears and then disappears:



Message

When calibration is finished, one of these results occurs:

- If you accessed the calibration procedure from the *Setup Wizard* screen, you return to that screen, and a check mark now appears next to **Calibrate Load Cell**.
- If you accessed the calibration procedure directly from the **Compound** menu, a *Load* cell calibration complete message appears.



Message

- 7. If the Load cell calibration complete message appears, tap **OK**.
- 8. Remove the calibration weight.

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SELECTING THE CONFIGURATION

The configuration identifies which ingredients are attached and at which ports on the compounder.

This procedure is required only if both of the following conditions exist:

- More than one configuration is available.
- You want to use a configuration that is different from the last one that was used.

The software automatically selects the last configuration that was used, and a check mark appears next to **Select Configuration**.

If you want to change the configuration:

1. At the Setup Wizard screen, tap Select Configuration.

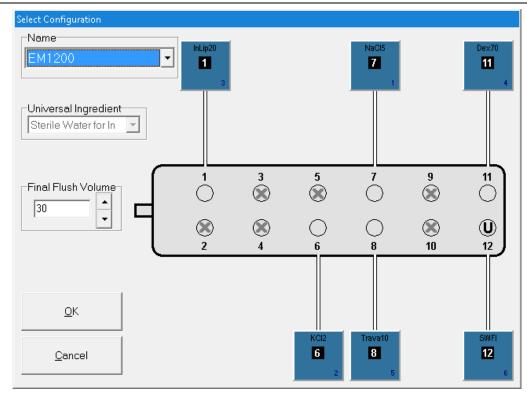


Setup Wizard screen, selecting the configuration

NOTE: To select the configuration without using the Setup Wizard, you can tap **Compound > Select Configuration** at the menu screen.

The Select Configuration screen displays the last configuration that was used.

- 2. In the **Name** list, select the desired configuration.
- 3. Tap **OK**.



Select Configuration screen

NOTE: When you select a different configuration, you may need to change the tube set, then prime and verify it.

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CHANGING THE TUBE SET

The tube set must be changed:

- When you select a different configuration, in some cases
- During the daily setup, if the tube set is expired

NOTE: To set up the options for tube set expiration, refer to <u>Tube Set Expiration</u> on Page 116.

WARNING

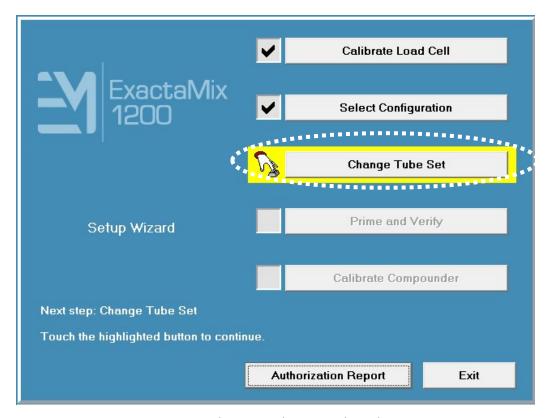


To maintain delivery accuracy, the tube set must be replaced after it has delivered 150 L of fluid or been installed for 24 hours, whichever comes first.

Check that the materials of the inlets, valves and bags are compatible with all ingredients used. Contact the *ingredient manufacturer* to confirm compatibility.

Checking the Tube Set Statistics

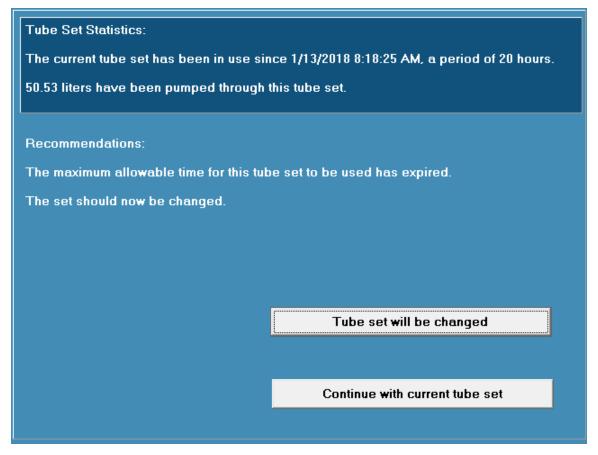
1. At the Setup Wizard screen, tap Change Tube Set.



Setup Wizard screen, changing the tube set

NOTE: To change the tube set without using the Setup Wizard, you can tap **Compound > Change Tube Set** at the menu screen.

A screen with tube set statistics and recommendations appears. The statistics show how long the current tube set has been installed and how much fluid has been pumped during that time. Based on the usage, the software recommends whether or not the tube set should be changed.



Tube set statistics and recommendations

- 2. Tap one of these options:
 - Tap **Tube Set will be changed**, then continue with <u>Removing the Expired Tube Set</u> and <u>Expired Ingredients</u> on Page 43.

NOTE: Selecting **Tube Set will be changed** resets the expiration counter for the tube set and resets the ingredient remainders (values in the software that represent the actual volume of fluid remaining in the source containers).

Tap Continue with current tube set.

NOTE: Selecting **Continue with current tube set** does not reset the expiration counter or the ingredient remainders.

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Removing the Expired Tube Set and Expired Ingredients



CAUTION

Do not remove the valve set until you have removed all the source containers. This precaution helps to prevent a dropped source container from damaging the valve actuators.

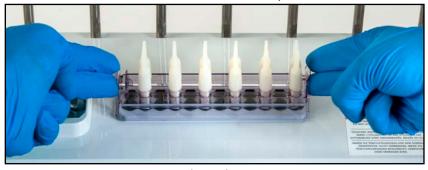


WARNING

The only time the rotor should be rotated manually is under "Tube Set Will Be Changed" or when the compounder is powered OFF. Turning the rotor at any other time while the compounder is powered on will result in a fault state error message.

If an expired tube set and expired ingredients are already installed:

- 1. Attach a calibration bag. Refer to Attaching the Calibration Bag on Page 73.
- 2. Remove one source container from the vial rack or hanger, and turn the container right side up.
- 3. Lower the container below the height of the valve set, and allow the fluid in the inlet to flow back into the source container.
- 4. Repeat the previous steps for each source container.
- 5. Press the tabs on the ends of the valve set, then lift to remove it.



Removing the valve set

NOTE: The appearance of the valve set may differ from the example shown above.

- 6. Turn the pump rotor counterclockwise to drain fluid from the common fluid pathway into the calibration bag.
- 7. Remove the calibration bag.
 - a. Remove the bag's fill port from the load cell's fill port holder.
 - b. Remove the bag from the load cell.
- 8. Discard the valve set and the attached calibration bag.
- 9. Discard the inlets, spikes and Ingredient(s) per the facility protocol.

Tip! Baxter recommends cleaning the compounder before installing a new valve set. Refer to <u>Cleaning the Compounder</u> on Page 101, and follow your facility's protocol.

Installing the New Valve Set



CAUTION

If the valve set is not installed properly, the compounder cannot be calibrated accurately.

1. Check that the valve actuators are not broken or damaged.









Normal

Damaged

Broken

Valve actuators



WARNING

Do not use the compounder if a valve actuator is broken or damaged. Patient harm can result. For assistance, contact Baxter Technical Services. Refer to Getting Help on Page 22.

2. Remove the valve set from the packaging.

NOTE: Always use aseptic technique when installing the valve set.

IMPORTANT! Check the expiration date on the valve set before installing it. Do not use a valve set that is past its expiration date.

- 3. Place the valve set onto the valve actuators.
- 4. Gently push the end tabs down and out until you hear a click on each end.



Installing the valve set

NOTE: The appearance of the valve set will differ from the example shown above, but the installation steps are the same.

5. Make sure that the valve set is installed securely by pulling up on both ends gently.



CAUTION

Once the valve set has been installed, do not attempt to remove it during operation.

6. Open the pump door.

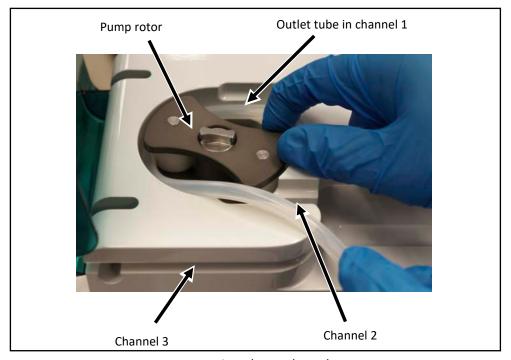
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V

WARNING

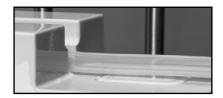
To avoid pinching your fingers, grasp the pump rotor from the top and rotate it counterclockwise, keeping your fingers away from other surfaces while moving the rotor.

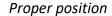
7. Route the outlet tube into channel 1, around the pump rotor and into channels 2 and 3 as shown. Move the pump rotor counterclockwise only. Do not pull or stretch the outlet tube.

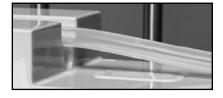


Routing the outlet tube

a. Make sure that the tube is in proper position at the bottom of channels 1 and 2.







Improper position

b. Make sure that the tube is in proper position against the wall around the pump rotor.

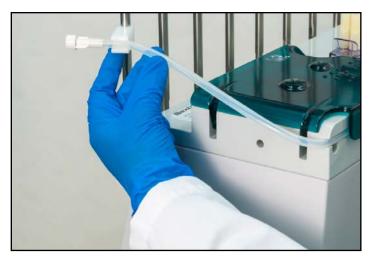




Proper position

Improper position

- 8. Close the pump door.
- 9. Connect the end of the outlet tube to the tube holder on the vial rack.



Connecting the outlet tube

Preparing the New Ingredients



WARNING

The compounder is not for use with non-sterile containers.

Source containers that can be used with the compounder are:

- Large-volume, vented or collapsible containers
- Large-volume, non-vented containers
- Small-volume vials
- 60mL Luer syringes

Tip! Baxter recommends using only sterile BD® 60 mL Luer syringes. If you plan to use a different type, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

1. Gather all the new ingredients.

Tip! Baxter recommends using the Authorization Report to quickly identify the ingredients needed for a specific configuration. For more information, refer to <u>Authorization Report</u> on Page 168.

2. Check that each source container has a barcode label attached.

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Tip! Baxter strongly recommends using the manufacturer's barcode whenever possible.

NOTE: For containers that are filled or diluted in the pharmacy, the Product Barcodes Report can make labels available for printing. For more information, refer to <u>Product Barcodes Report</u> on Page 179.

Attaching the New Ingredients and Inlets

Always use aseptic technique when attaching the ingredients and inlets.

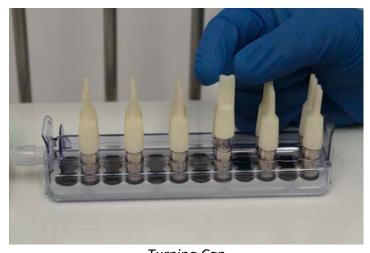
Follow all the steps of this process for one ingredient and inlet pair before continuing with the next pair. This practice helps to ensure that you attach the ingredients and inlets correctly.

Tip! To keep track of the steps, Baxter recommends working from left to right in the sequence of the port numbers (1, 2, 3 and so on). You might find it helpful to remember the main steps of this process (covered in more detail on the upcoming pages) by remembering the term iTASL, which signifies:

- 1. *identify* the port you are going to be working with by turning the cap.
- 2. **Touch** (tap) the ingredient button on the screen.
- 3. Attach the inlet to the port on the valve set.
- 4. **Spike** and hang the source container.
- 5. **Label** the inlet with the numbered barcode label.

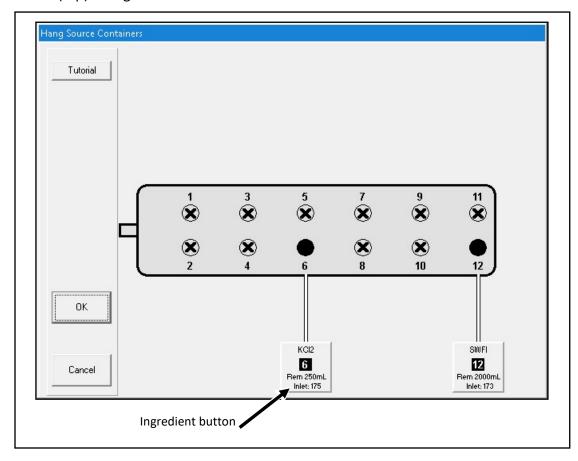
To attach an ingredient:

1. *identify* the port you are going to be working with by turning the cap.



Turning Cap

2. **Touch** (tap) its ingredient button on the screen.

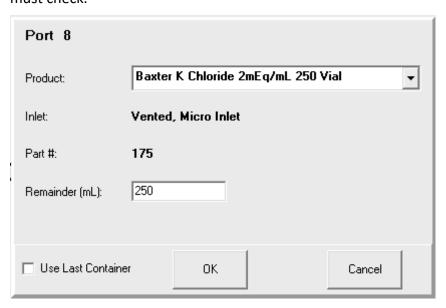


Hang Source Containers screen, no ingredients attached

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The ingredient detail window appears.

IMPORTANT! Always view the ingredient detail window. It includes details not visible on the ingredient button. For example, it includes the full product description, which you must check.



Ingredient detail window

- 3. At the ingredient detail window, review the information.
 - a. Check that the **Port** number is correct.
 - b. Check that the **Product** description matches the source container to be used.

NOTE: If desired, you can tap the arrow to the right of this field to see a list of similar products in the same ingredient group. If you select another product in this list, the **Inlet** type and **Part** # may change accordingly.

c. Check that the **Inlet** type and **Part** # are correct.

NOTE: The **Part** # shows the middle three digits of the complete part number. For a list of complete part numbers, refer to <u>Inlets</u> on Page 18. The complete part number also appears on the packaging materials for the inlet.

d. Check that the **Remainder (mL)** matches the current volume of the source container.

NOTE: When you attach a full, unopened container, the **Remainder (mL)** should equal the volume indicated on the container. When you attach a partially full container, change the **Remainder (mL)** to the actual volume in the container. Remainders on syringes should always be verified. The compounder will use this information to help track the volume used, to alert you when the container needs to be changed.

e. If required, enter or check the **Lot Number** and the **Expiration**.

NOTE: To set up these tracking options, refer to <u>Track Product Expiration Date</u> <u>and Lot Number</u> on Page 114.

WARNING

It is important to use the correct inlet type for the container. Using the incorrect inlet type can lead to occlusions and incorrect ingredient delivery, resulting in patient harm.

- 4. Attach the inlet to the port.
 - a. Locate the inlet type specified in the ingredient detail window.
 - b. Remove the inlet from its packaging materials and gently uncurl it. Do not pull or stretch the inlet.

WARNING



A kink in the tube, a plugged vent on a vial or bottle inlet or a plugged inlet spike can cause the compounder to deliver incorrect ingredient volumes, resulting in patient harm. After attaching the inlets, visually check that the tubes are not kinked or plugged.

- c. Check that the inlet is not kinked or plugged.
- d. On the valve set, locate the port number specified at the ingredient detail window.

Tip! To locate an odd-numbered port, Baxter recommends locating the next, even-numbered port in the front row. For example, to attach an inlet to port 3, look for port 4 in the front row and then attach the inlet to the port directly behind it (port 3). Avoid leaning over the compounder.

- e. Grasp the port cap with one hand, remove the port cap and immediately attach the inlet with your other hand.
- 5. **Spike** and hang the container.



CAUTION

The pictures and instructions on the following pages are for reference only. When spiking the container, use proper technique as identified by your facility's protocol.

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o To spike and hang a bag:

NOTE: To prevent dropping the bag, you can hang it on the hood hanger.

a. Turn the bag with its spike port facing down.
 NOTE: This step helps to reduce the possibility of air bubbles entering the inlet tube.

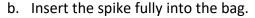


Turning

WARNING



Failure to insert the spike completely into the bag port may restrict flow and cause the delivery of incorrect ingredient volumes, resulting in patient harm.



- c. Rotate the spike 180° to prevent occlusions.
- d. Hang the bag on the hood hanger, if the bag is not already there.



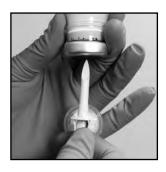
Inserting

Operator Manual for the Baxter ExactaMix 1200 Compounder

o To spike and hang a bottle:

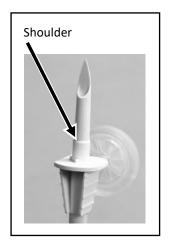
NOTE: To prevent dropping the bottle, you can hang it on the hood hanger.

a. Turn the bottle with its septum facing down.
 NOTE: This step helps to reduce the possibility of air bubbles entering the inlet tube.



Turning

b. Locate the shoulder of the spike.



Shoulder

c. Insert the spike fully into the bottle, up to the shoulder of the spike.

NOTE: Inserting the spike up to the shoulder helps ensure that the maximum amount of fluid and the minimum amount of air is withdrawn from the bottle.



Inserting

d. Hang the bottle on the hood hanger, if the bottle is not already there.



Hanging

Operator Manual for the Baxter ExactaMix 1200 Compounder

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- o To spike and hang a vial:
 - a. Turn the vial with its septum facing down.
 NOTE: This step helps to reduce the possibility of air bubbles entering the inlet tube.



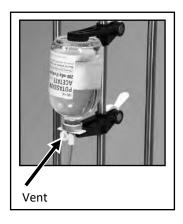
Turning

b. Insert the spike fully into the vial.



Inserting

- c. Push the bottom of the vial (now facing up) against the top holder. Make sure that the vent faces you.
 - **NOTE:** If the vent faces away from you (into the bottom vial holder), the air flow may be obstructed, causing an occlusion or limited flow. Also, the vial will not be seated securely.
- d. Slide the spiked end of the vial into the bottom vial h older.



Hanging

- o To spike and hang a syringe:
 - a. Turn the syringe with its Luer end facing down.
 NOTE: This step helps to reduce the possibility of air bubbles entering the inlet tube.

NOTE: Only syringes that have been verified by a pharmacist should be hung on the compounder.

b. Rotate the inlet onto the syringe.



Rotating

c. Hang the syringe on the vial rack by snapping the syringe flanges into the syringe holder.



Hanging

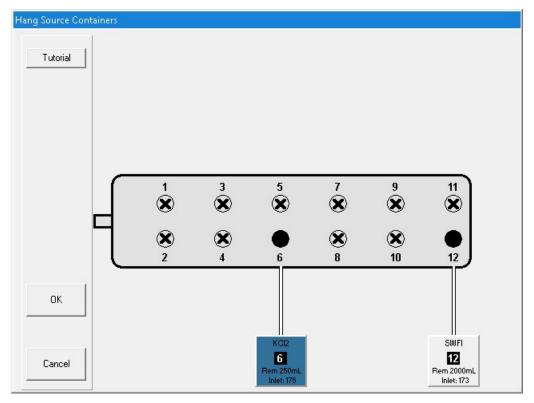
- 6. **Label** the inlet with the appropriate, numbered inlet barcode label that was packaged with the valve set. Attach the label close to the source container. The number on the label must match the number of the port to which the inlet is attached.
- 7. Check that the correct inlet is:
 - a. Attached to the correct ingredient and port
 - b. Labeled with the correct barcode label

Tip! Baxter recommends rotating the source container so that the barcode label faces you, for easy scanning during barcode verification.

8. At the ingredient detail window, tap **OK**.

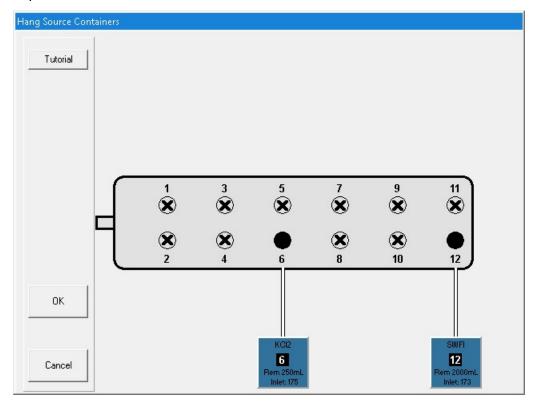
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At the *Hang Source Containers* screen, the color of the ingredient button becomes blue to indicate that the ingredient is attached and waiting to be primed.



Hang Source Containers screen, one ingredient attached

- Repeat the previous steps for all the ingredients you want to attach.
 When all the ingredient buttons are blue, you are finished changing the tube set.
- 10. Tap **OK**.



Hang Source Containers screen, all ingredients attached

If you started this procedure from the *Setup Wizard* screen, a check mark now appears next to **Change Tube Set** at the *Setup Wizard* screen.

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PRIMING AND VERIFYING

After the ingredients and inlets are attached, they must be primed and verified. This process includes scanning the barcodes on each container and inlet, priming the inlets and verifying the setup.

1. At the Setup Wizard screen, tap Prime and Verify.



Setup Wizard screen, priming and verifying

NOTE: To prime and verify without using the Setup Wizard, you can tap **Compound > Prime and Verify** at the menu screen.



WARNING

It is important to use a barcode reader for scanning labels during verification of the setup.

2. If your facility:

- Uses barcode verification, continue with <u>Verifying the Ingredient and Inlet Barcodes</u> on Page 58
- Does not use barcode verification, skip to <u>Priming the Inlets and Verifying the Setup</u> on Page 61

Verifying the Ingredient and Inlet Barcodes



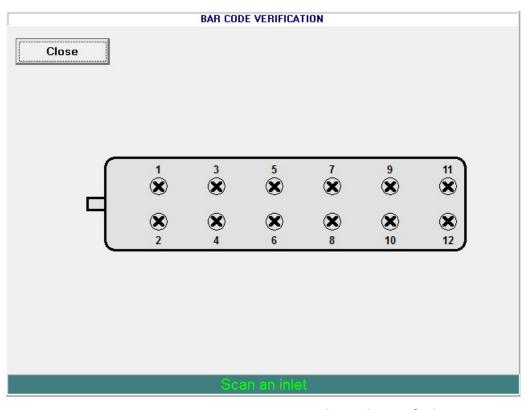
WARNING

For the barcode verification to be effective, it is critical that the configuration be set up properly. For instructions, refer to <u>Attaching the New Ingredients and Inlets</u> on Page 47.

IMPORTANT! This procedure requires barcode scanning to be enabled. To enable barcode scanning (and, if desired, to require it for verification), refer to <u>Barcode Reader</u> on Page 121.

Tip! Baxter recommends enabling barcode scanning at all times.

On the *BARCODE VERIFICATION* screen, the ports appear empty until the barcodes on the attached inlets and source containers are scanned.



BARCODE VERIFICATION screen, no barcodes verified

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WARNING

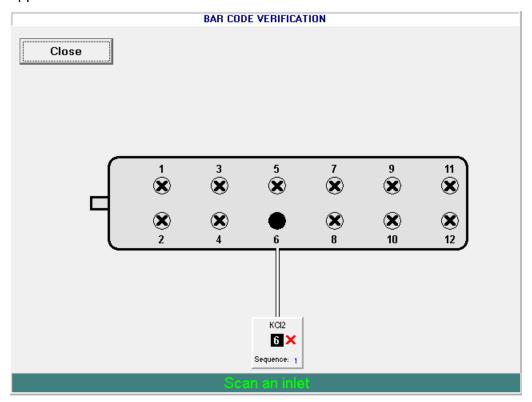


Scan only the barcodes attached to the inlet and the corresponding source container. *Do not scan unattached barcodes or old (used) containers.* Doing so may result in incorrect ingredient delivery, resulting in patient harm.

Tip! Baxter strongly recommends scanning from left to right (or from right to left) to prevent skipping any ports.

- 1. Scan the barcode label on an inlet.
- 2. Scan the barcode label on the corresponding source container.

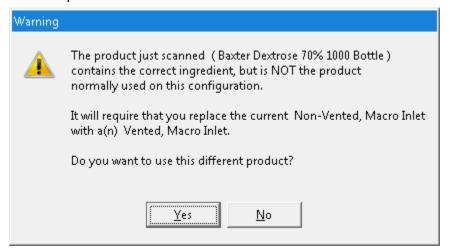
 If you scanned the correct source container, the corresponding ingredient button appears on the screen.



BARCODE VERIFICATION screen, one pair of barcodes verified

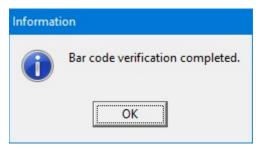
If you scanned an incorrect source container, the compounder beeps and displays **Incorrect scan, try again** at the bottom of the screen. Scan the correct source container.

If the scanned product is not the specific product identified in the configuration but is the same ingredient, a *Warning* message appears. Tap **Yes** if you want to use the scanned product.



Message

- 3. Repeat the previous steps until an ingredient button appears for each attached ingredient.
- 4. At the *Barcode verification completed* message, tap **OK**.



Message

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Priming the Inlets and Verifying the Setup

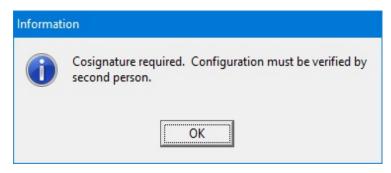
Usually, a cosigner must log in and verify the setup. Refer to your facility's protocol.

WARNING

It is important to have a cosigner independently verify the setup, to help ensure that the first user attached each ingredient's inlet to the correct port. Incorrect setup could result in patient harm.

IMPORTANT! The cosignature option requires Verification permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124. To require that a cosigner verify the setup, refer to <u>Cosignature</u> on Page 121.

- 1. Attach a calibration bag. Refer to Attaching the Calibration Bag on Page 73.
- 2. If the *Cosignature required* message appears, the cosigner should:
 - a. Тар **ОК**.



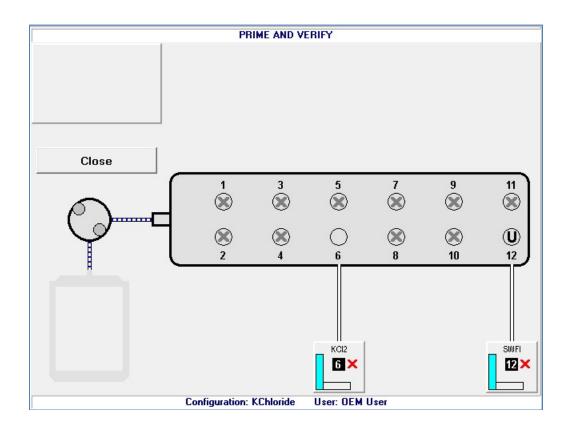
Message

- b. Enter a Login name.
- c. Enter a Password.
- d. Tap **Log In**, then continue with the next steps.



Cosignature window

When an X appears on the ingredient button, it indicates that priming and verification are needed.



PRIME AND VERIFY screen, no inlets primed

CAUTION



Do not prime calcium and phosphate ingredients consecutively. Interaction of these ingredients can cause a precipitate, which may block the common fluid pathway and require a replacement of the tube set.

If the configuration includes a lipid, you should prime the Universal Ingredient immediately after priming the lipid.

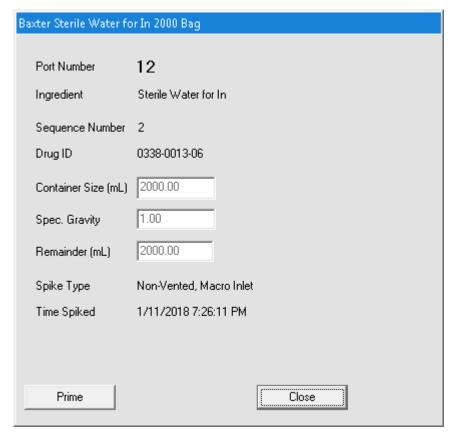
Always follow the configuration setup that Baxter recommends, and prime ingredients in the sequence of the port numbers (1, 2, 3 and so on).

Tip! Baxter recommends physically rotating each source container so that its product label faces you, for easy verification.

3. Tap an ingredient button.

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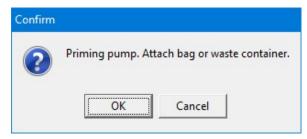
The ingredient detail window appears.



Ingredient detail window before priming

- 4. At the ingredient detail window, review the information.
 - a. Check that the product information in the title bar of the window is correct.
 - b. Check that the **Port Number** is correct.
 - c. Check that the **Ingredient** description matches the source container to be used.
 - d. Check that the **Remainder (mL)** matches the current volume of the source container to be used.
 - e. Check that the **Spike Type** (inlet type) is correct.
- 5. On the valve set, locate the port for this ingredient.
- 6. With your hand, hold the inlet that is attached to the port, and follow the inlet up to the source container.

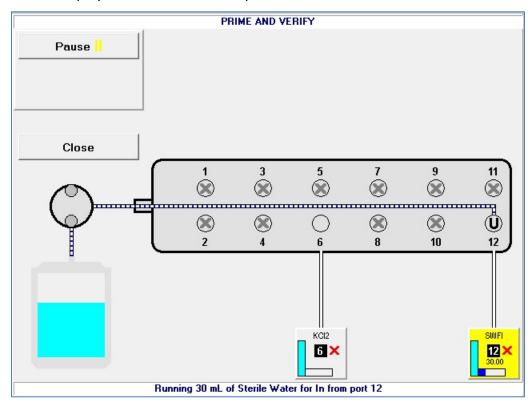
- 7. While continuing to hold the inlet near the source container:
 - a. Check that the number on the inlet label matches the port number.
 - b. Check that the product attached to the inlet matches the information on the screen.
 - c. At the ingredient detail window, tap **Prime**.
 - d. Check that a calibration bag is attached.
 - e. At the Priming pump message, tap **OK**.



Message

f. Watch and feel for fluid moving through the inlet that is in your hand.

When an ingredient is being primed, its button becomes yellow. The screen displays an animation of the process.



PRIME AND VERIFY screen, priming in progress

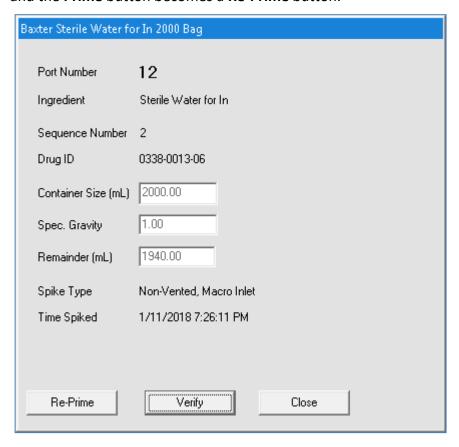
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WARNING

The ingredient must be attached to the proper port. Patient harm can occur if the location of an ingredient is incorrect.

- 8. If the fluid:
 - Does flow through the inlet that is in your hand, continue with the next step
 - Does not flow through the inlet that is in your hand, resolve any problems, check that the inlet is attached to the correct port and prime it again

After the inlet has been primed, the ingredient detail window includes a **Verify** button, and the **Prime** button becomes a **Re-Prime** button.

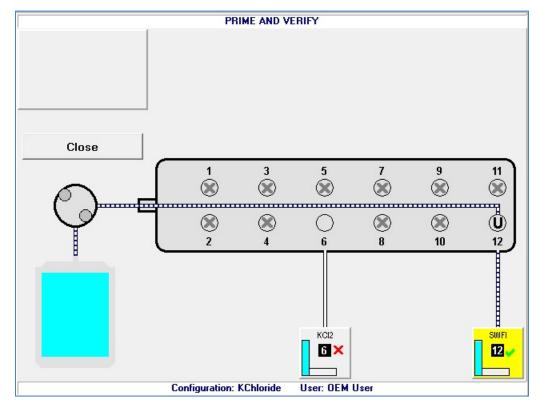


Ingredient detail window after priming

NOTE: The first prime uses the standard priming volume. Any subsequent primes use the minimum priming volume.

- 9. Check the inlet to be sure that it primed properly, leaving no air in the inlet tube. If necessary, tap **Re-Prime**.
- 10. When priming is finished:
 - a. Release the tube from your hand.
 - b. Tap **Verify** to confirm that the ingredient's inlet is attached to the correct port.

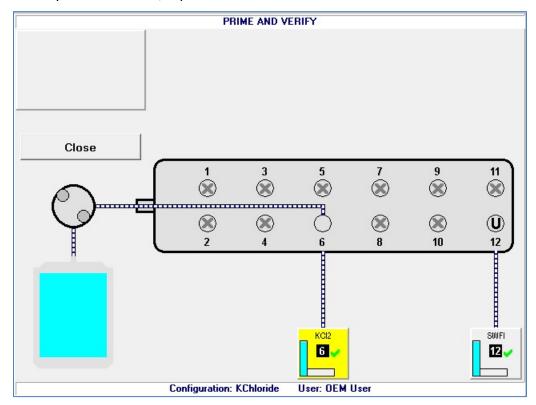
The connecting lines between the ingredient button and the port include horizontal marks, indicating that the ingredient has been primed. On the ingredient button, the red X becomes a green check mark, indicating that the ingredient has been verified.



PRIME AND VERIFY screen, one inlet primed and verified

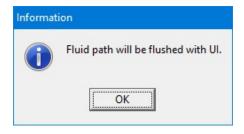
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- 11. Repeat steps 3–10 for all the attached ingredients. If the calibration bag becomes full, remove it and attach a new one. Refer to <u>Attaching and Removing the Calibration Bag</u> on Page 73.
- 12. When you are finished, tap Close.



PRIME AND VERIFY screen, all inlets primed and verified

13. At the Fluid path will be flushed with UI message, tap OK.



Message

The compounder flushes the common fluid pathway with the Universal Ingredient, and tests for proper function of the occlusion detector. If the test fails, you cannot continue compounding a solution. Refer to <u>Issues with the Occlusion Detector / "Flow Sensor"</u> on Page 204.

14. At the UI flush complete message, tap OK.



Message

If a cosigner was logged in, the software automatically logs out the cosigner and logs in the original user.

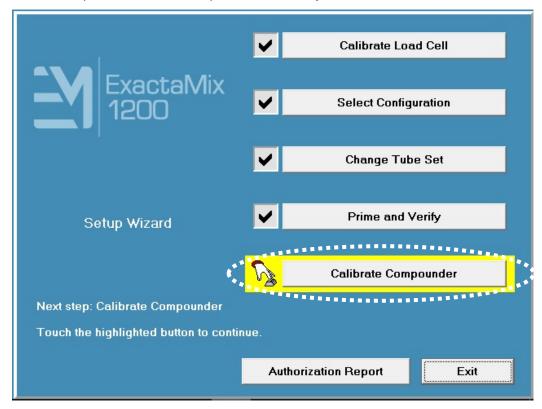
If you started this procedure from the *Setup Wizard* screen, a check mark now appears next to **Prime and Verify** at the *Setup Wizard* screen.

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CALIBRATING THE COMPOUNDER

This procedure calibrates the compounder's pump to ensure that it delivers the intended volume of each ingredient.

1. At the Setup Wizard screen, tap Calibrate Compounder.



Setup Wizard screen, calibrating the compounder

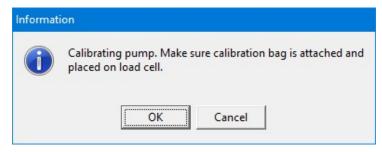
NOTE: You can calibrate the compounder at any time by tapping **Compound > Calibrate Pump** at the menu screen.



CAUTION

A calibration bag must be used during all priming/verifying and Universal Ingredient flushes.

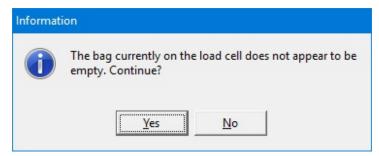
- 2. If a calibration bag is not already attached, attach it. Refer to <u>Attaching the Calibration</u> <u>Bag</u> on Page 73.
- 3. At the Calibrating pump message, tap **OK**.



Message

- 4. If the *Bag currently on the load cell does not appear to be empty* message appears, visually check the contents of the bag.
 - If the bag is empty, refer to <u>The bag currently on the load cell does not appear to be</u> empty on Page 203.
 - If the bag contains fluid, continue with the next step.
- 5. Check whether the bag has space for an additional 200 mL of fluid.
 - If the bag does not have space:
 - a. Tap No.
 - b. At the Operation Cancelled message, tap **OK**.
 - c. Remove the calibration bag. Refer to Removing the Calibration Bag on Page 73.
 - d. Attach an empty calibration bag. Refer to <u>Attaching the Calibration Bag</u> on Page 73.
 - e. Return to Step 1.
 - If the bag has space, tap Yes.

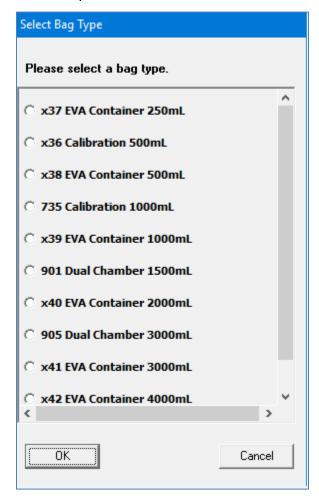
IMPORTANT! It is acceptable to calibrate the pump when the calibration bag contains fluid. However, the calibration procedure is the only time you should tap **Yes** at this message. Never tap **Yes** when compounding a solution into a patient bag.



Message

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- 6. At the Select Bag Type window:
 - a. Select the type of bag you are using.
 - b. Tap **OK**.



Select Bag Type window, sample North American version

IMPORTANT! If any items touch the load cell during the calibration, the calibration will not be accurate.

- 7. Make sure that:
 - There is no weight on the load cell.
 - There is nothing touching any part of the load cell (for example, there are no cables touching the base).

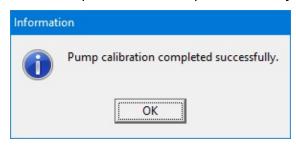
The compounder pumps 100 mL of water, checks the weight, makes any necessary adjustments to the movement of the pump rotor, pumps 100 mL again and checks the weight again. If the Universal Ingredient (UI) for the configuration is something other than water, the compounder automatically flushes the common fluid pathway with the identified UI.

This message appears and disappears:



Message

8. At the Pump calibration completed successfully message, tap **OK**.



Message

NOTE: If calibration fails, refer to Pump calibration failed on Page 201.

If you started this procedure from the *Setup Wizard* screen, a check mark now appears next to **Calibrate Compounder** at the *Setup Wizard* screen.

9. Remove the calibration bag. Refer to Removing the Calibration Bag on Page 73.

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ATTACHING AND REMOVING THE CALIBRATION BAG

Attach and remove the calibration bag when other procedures direct you to do so.

Attaching the Calibration Bag

Always use aseptic technique when attaching the bag.

- 1. Connect a sterile calibration bag to the outlet tube.
 - **Tip!** Baxter recommends connecting the bag to the outlet tube before attaching it to the load cell, to prevent twisting or straining the tube.
- 2. Attach the bag to the load cell. Place the holes in the corners of the bag over the guide pins on the load cell.
- 3. Route the bag's fill port through the load cell's fill port holder.
- 4. Make sure the outlet tube is curved, not twisted or kinked.





Attaching the calibration bag to the outlet tube and the load cell

Removing the Calibration Bag

Always use aseptic technique when removing the bag.

- 1. Remove the bag's fill port from the load cell's fill port holder.
- 2. Remove the bag from the load cell.
- 3. Clamp the bag's fill port.
- 4. Disconnect the outlet tube from the bag.
- 5. Connect the end of the outlet tube to the tube holder on the vial rack.
- 6. Cap the bag's fill port.
- 7. Discard the bag.

VIEWING THE AUTHORIZATION REPORT

When the setup steps are finished, the **Authorization Report** button becomes active at the *Setup Wizard* screen.

At the Setup Wizard screen, tap Authorization Report.



Setup Wizard screen, viewing the Authorization Report

NOTE: You can view the Authorization Report at any time by tapping **Reports > Authorization Report** at the menu screen.

For more information, refer to Authorization Report on Page 168.

To exit the Setup Wizard screen, tap Exit.

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USING THE COMPOUNDER

After you finish setting up the compounder, you are ready to load formulas and fulfill orders.

LOADING THE FORMULA

There are several methods for loading a formula onto the compounder. They are:

- Automatically loading a formula by scanning a barcode to retrieve the .PAT/.FRM file (recommended)
- Automatically loading a formula by scanning the 2D formula barcode containing formula details.
- Manually entering a formula through direct entry
- Manually selecting a saved formula

Tip! Baxter strongly recommends loading a formula by scanning a barcode, and using the manual entry or selection methods only when the barcode method fails. If the network connection to the order-entry computer fails, you can still load a formula by scanning a barcode. For instructions, refer to <u>Loading a Formula by Connecting a USB Drive</u> on Page 207.

NOTE: To enable barcode scanning (and, if desired, to require it for loading formulas), refer to <u>Barcode Reader</u> on Page 121.

Loading a Formula by Scanning a Barcode

Most facilities use this method.

IMPORTANT! This method requires:

- Order-entry software on a separate computer. This software must be able to produce both
 a .PAT/.FRM file and a corresponding label/report with a barcode. Both the .PAT/.FRM file
 and barcode must be compatible with the compounder. Alternatively, the software must
 also be able to produce a formula label, containing the formula details in the 2D barcode
 and the 2D formula barcode must also be compatible with the compounder. Baxter Abacus®
 TPN Calculation Software meets these requirements. For more information, contact Baxter
 Technical Services. Refer to Getting Help on Page 22.
- Network connection between the order-entry computer and the compounder
- Barcode reader at the compounder

The pharmacist creates an order in the order-entry software, which creates a .PAT/.FRM file that contains the patient information and the formula. A corresponding label with a barcode also prints at the same time. Alternatively, the order-entry software creates and prints a 2D Formula Barcode label which directly contains the patient information and the formula.

Typically, a technician applies this label to a new patient bag and brings the bag to the compounder. However, this process depends on your facility's protocol.

At the compounder:

- 1. Navigate to the pump screen.
- 2. Scan the barcode on the label of the patient bag.

The compounder retrieves the order through the network and populates the pump screen with the patient name, formula serial number and volume of each ingredient to be pumped. The compounder reads the code number of each ingredient in the formula and matches this number to one in the formulary. In the United States, the code number is usually the National Drug Code (NDC).

WARNING



The code number for each product in the formula must exactly match the code number for that product in the compounder's formulary. If a code number is assigned to one product in the order-entry software, and that number is assigned to a different product in the compounder's formulary, the compounder may pump the wrong ingredient, resulting in patient harm. It is the user's responsibility to ensure that code numbers are properly and consistently assigned in both systems.

NOTE: If any ordered ingredients are not in the configuration on the compounder, are not allowed as auto-additions or have a volume less than 0.2 mL, the compounder software will identify these ingredients as manual additions.

3. Continue with Fulfilling the Order (Basic Process) on Page 84.

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Entering a Formula through Direct Entry

Some facilities may use this method if the order-entry software is temporarily unavailable. With this method, you must manually enter the volume of each ingredient to create a new formula.

This process creates a formula with a unique ID, but it does not create a 2D Formula Barcode/.PAT/.FRM file or a corresponding label with a barcode.

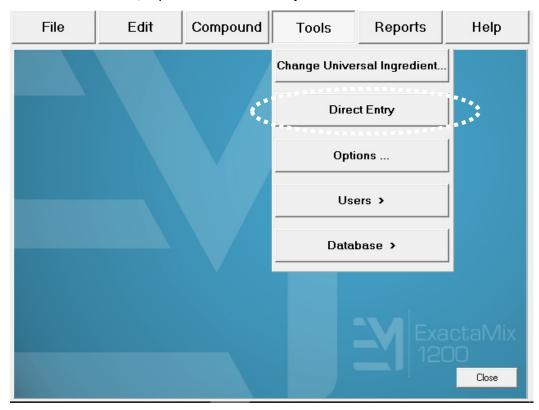


WARNING

Formulas entered directly into the compounder should be checked by a pharmacist. The compounder does not verify the formulas.

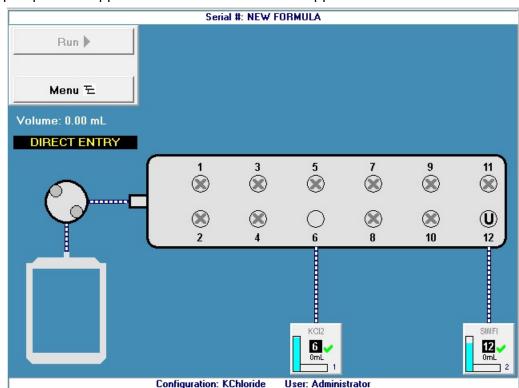
IMPORTANT! This function requires Formula Entry permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.

1. At the menu screen, tap Tools > Direct Entry.



Menu screen, Tools menu

NOTE: To stop using direct entry, you can tap **Tools > Cancel Direct Entry** at the menu screen.



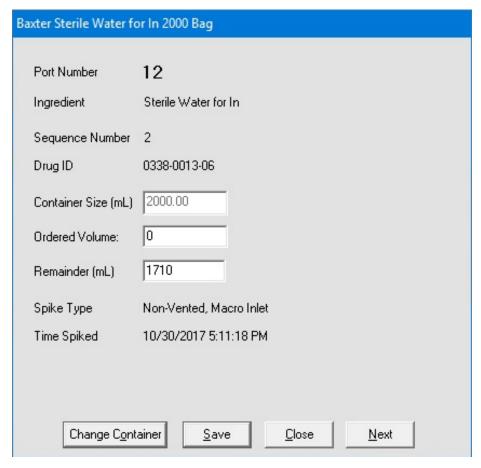
The pump screen appears. The text **DIRECT ENTRY** appears on the left side.

Pump screen during direct entry

- 2. Obtain the formula from the pharmacist. Refer to your facility's protocol.
- 3. Tap the ingredient button for the first ingredient in the formula.

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The ingredient detail window appears.



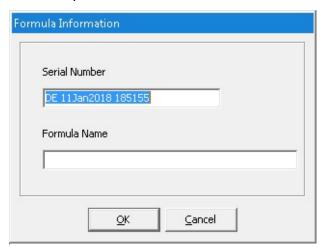
Ingredient detail window during direct entry

- 4. At the ingredient detail window:
 - a. Check that the **Ingredient** shown matches the ingredient ordered. Check its description, concentration and so on.
 - b. Enter the **Ordered Volume** of the ingredient to be delivered.
 - c. Tap **Save**, or tap **Next** to view the next ingredient detail window. The **Run** button becomes available on the pump screen.
- 5. Repeat steps 3–4 for each ingredient in the formula.
- 6. If you want to:
 - Use the formula now, continue with <u>Saving and Using a Direct-Entry Formula</u> on Page 80
 - Save the formula for using later, continue with <u>Saving a Direct-Entry Formula to Use</u> <u>Later</u> on Page 81

Saving and Using a Direct-Entry Formula

NOTE: For information about automatic unloading of formulas, refer to <u>Understanding</u> <u>Automatic Unloading of Formulas</u> on Page 84.

- 1. Attach the patient bag. Refer to Attaching the Patient Bag on Page 84.
- 2. At the pump screen, tap Run.
- 3. At the Formula Information window:
 - a. Enter a Formula Name.
 - b. If desired, enter a new Serial Number.Tip! Baxter recommends not changing the serial number.
 - c. Tap OK.



Formula Information window

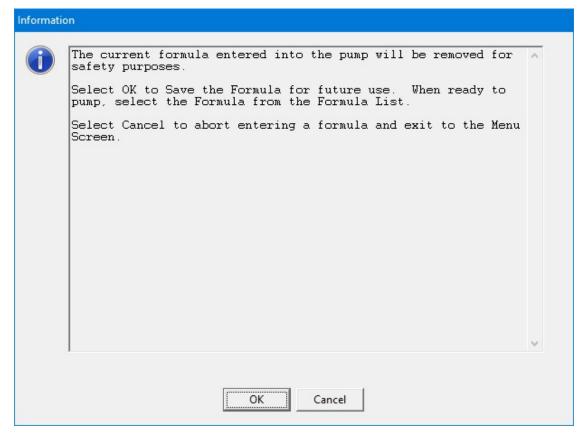
4. Continue with Compounding the Solution on Page 85.

NOTE: You do not need to tap Run again.

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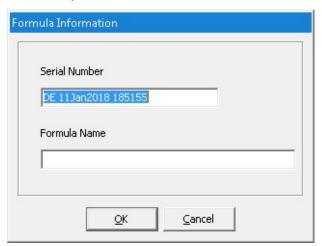
Saving a Direct-Entry Formula to Use Later

- 1. At the pump screen, tap Menu.
- 2. At the Information message, tap OK.



Message

- 3. At the Formula Information window:
 - a. Enter a Formula Name.
 - b. If desired, enter a new Serial Number.Tip! Baxter recommends not changing the serial number.
 - c. Tap **OK**.



Formula Information window

4. When you want to compound the solution, continue with <u>Selecting a Saved Formula</u> on Page 83.

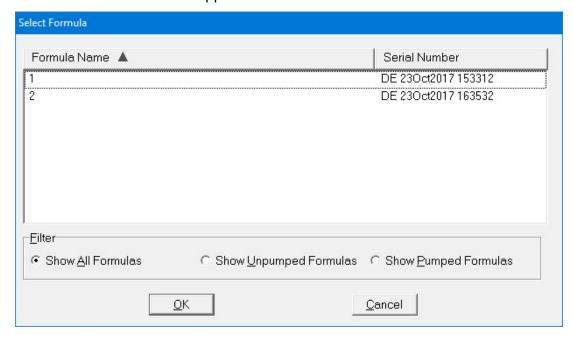
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Selecting a Saved Formula

Some facilities may use this method to select a saved formula, which has already been loaded onto the compounder through scanning a barcode or direct entry.

IMPORTANT! This function requires that formulas can be loaded without scanning barcodes. For more information, refer to <u>Barcode Reader</u> on Page 121.

At the menu screen, tap Compound > Select Formula.
 The Select Formula window appears.



Select Formula window

- 2. At the Select Formula window, tap one of these filter options:
 - Show All Formulas to view all the formulas that are stored
 - Show Unpumped Formulas to view all the formulas that have not been used for compounding
 - Show Pumped Formulas to view all the formulas that have been used for compounding

Tip! Baxter recommends selecting only **Show Unpumped Formulas**.

NOTE: You can tap **Formula Name** to sort by name or tap **Serial Number** to sort by number. Formulas are stored for a specified time period. To set up the storage of formulas, refer to Storage on Page 115.

- 3. Select a formula.
- 4. Tap **OK**.

The formula is loaded and appears on the pump screen.

5. Continue with Fulfilling the Order (Basic Process) on Page 84.

FULFILLING THE ORDER (BASIC PROCESS)

Understanding Automatic Unloading of Formulas

As a safety precaution, the software automatically unloads the formula in these two main situations:

• The software usually unloads the formula if you leave the pump screen after loading the formula and before starting the compounding process.

The message below, or one similar to it, appears and then automatically disappears.

The only exception is that the software does not unload the formula when you perform an auto-addition.

Information

Current formula entered into the pump will be removed for safety purposes. Rescan the formula when ready.

Message

 The software usually unloads the formula when compounding is finished, regardless of the outcome.

No message appears; however, you cannot use the formula for compounding again.

The only exception is that the software does not unload the formula when both of these conditions occur together:

- The solution limit is more than 1 and has not yet been met, or the solution limit is disabled. For more information, refer to <u>Solution Limit</u> on Page 122.
- Barcode scanning is not required to load a formula, but the formula was loaded through this method. For more information, refer to <u>Barcode Reader</u> on Page 121.

Attaching the Patient Bag

Always use aseptic technique when attaching the bag.

- 1. Connect a sterile patient bag to the outlet tube.
 - **Tip!** Baxter recommends connecting the bag to the outlet tube before attaching it to the load cell, to prevent twisting or straining the tube.
- 2. Attach the bag to the load cell. Place the holes in the corners of the bag over the guide pins on the load cell.
- 3. Route the bag's fill port through the load cell's fill port holder.
- 4. Make sure the outlet tube is curved, not twisted or kinked.

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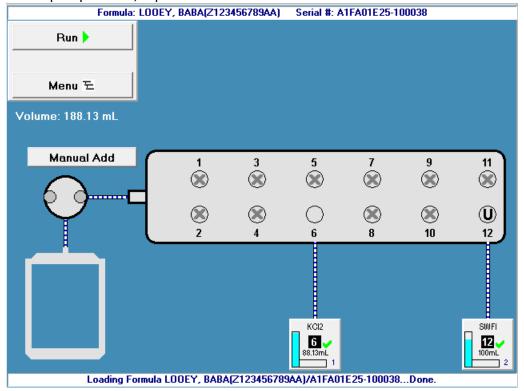


Attaching the patient bag to the outlet tube and the load cell

Compounding the Solution

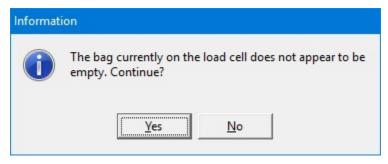
IMPORTANT! This function requires Compounder permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.

1. At the pump screen, tap Run.



Pump screen, ready to start compounding the solution

- 2. If the *Bag currently on the load cell does not appear to be empty* message appears, visually check the contents of the bag.
 - If the bag is empty, refer to <u>The bag currently on the load cell does not appear to be empty</u> on Page 203.
 - If the bag contains fluid:
 - a. Tap No.
 - b. At the Operation Cancelled message, tap **OK**.
 - c. Remove the bag. Refer to Removing the Calibration Bag on Page 73.
 - d. Attach an empty bag. Refer to Attaching the Patient Bag on Page 84.
 - e. Return to Step 1.



Message

WARNING

If you tap **Yes**, the compounder will reset the measured weight to zero, despite the fact that the bag contains fluid.



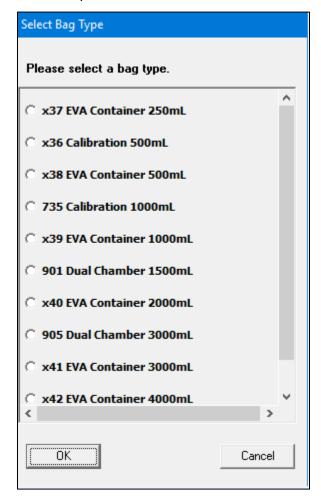
The finished solution may contain an unintended volume or ingredient, even if the final measured weight is within the acceptable range. This unintended volume or ingredient may result in patient harm.

The **Details** section of the MixCheck Report will indicate that you continued compounding despite the warning that the bag did not appear to be empty.

For instructions on how to handle a finished bag in this situation, refer to your facility's protocol.

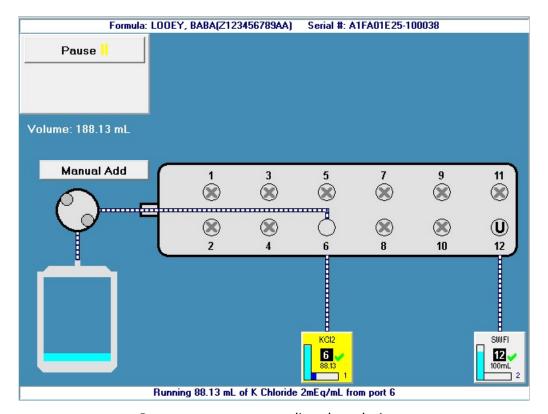
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- 3. At the *Select Bag Type* window:
 - a. Select the size of the bag you attached.
 - b. Tap **OK**.



Select Bag Type window, sample North American version

At the pump screen, the **Run** button becomes a **Pause** button. The compounder pumps each ingredient, one at a time, into the patient bag in the specified sequence and volume. When an ingredient is being pumped, its button becomes yellow.



Pump screen, compounding the solution

NOTE: For information about messages that might appear just before or during the compounding process, refer to <u>Fulfilling the Order (Additional Steps)</u> on Page 90. If you need to stop compounding temporarily, you can perform either of the following actions. The MixCheck Report will indicate that you performed the action.

- Tap Pause, then tap Resume to start compounding again.
- Open the pump door, then close the pump door and tap **Resume** to start compounding again.

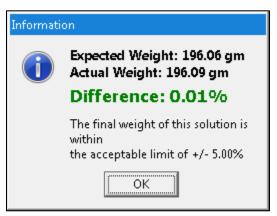
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When compounding is finished, a message displays this information about the patient bag:

- Expected weight
- o Actual weight
- o Difference
- Statement about whether or not the difference is acceptable

NOTE: If the difference is not acceptable, refer to <u>Issues with the Weight and Load Cell</u> on Page 202. The acceptable difference is typically set to \pm 5%. To change this setting, refer to Acceptable Weight Variances on Page 118.

4. At the message with information about the patient bag, tap **OK**.



Message

Removing the Patient Bag

Always use aseptic technique when removing the bag.

- 1. Remove the bag's fill port from the load cell's fill port holder.
- 2. Remove the bag from the load cell.
- 3. Clamp the bag's fill port.
- 4. Disconnect the outlet tube from the bag.
- 5. Connect the end of the outlet tube to the tube holder on the vial rack.
- 6. Cap the bag's fill port.

Completing the Order



WARNING

It is important to inspect the finished solution to make sure that it complies with standards.

- 1. Visually inspect the finished solution in the patient bag for precipitates and particulates. Follow your facility's protocol.
- 2. View and approve the MixCheck Report according to your facility's protocol. For instructions, refer to <u>MixCheck Report</u> on Page 162.
- 3. If necessary, perform any manual additions. Refer to <u>Performing a Manual Addition</u> on Page 92.

FULFILLING THE ORDER (ADDITIONAL STEPS)

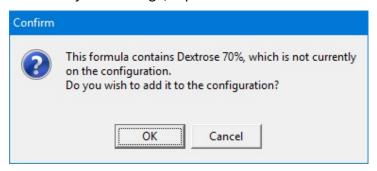
To complete some orders, you may need to perform additional steps along with the basic steps already explained. Interruptions to the compounding process may occur. These additions and interruptions are part of normal operation.

Performing an Auto-Addition

An auto-addition allows you to add an ingredient to the existing configuration temporarily, to fulfill the current order, instead of selecting a new configuration (which would require you to prime and verify all the inlets and ingredients).

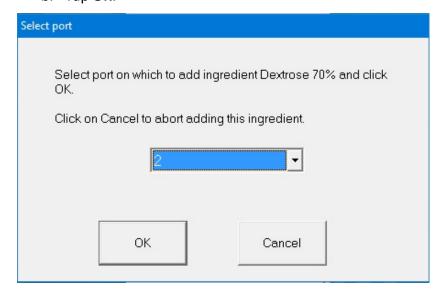
If the loaded formula includes an ingredient that is not attached to the compounder, but is identified as an allowable auto-addition in the formulary and the current configuration, a *Confirm* message appears.

1. At the Confirm message, tap OK.



Message

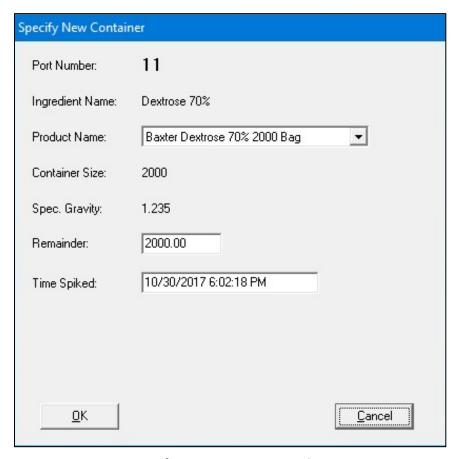
- 2. At the Select port window:
 - a. Select the port to which you will attach the ingredient.
 - b. Tap OK.



Select port window

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- 3. At the *Specify New Container* window:
 - a. Select the Product Name.
 - b. Tap **OK**.



Specify New Container window

- 4. Attach the new ingredient and inlet. Refer to <u>Attaching the New Ingredients and Inlets</u> on Page 47.
- 5. If you have already attached the patient bag, remove it. Refer to <u>Removing the Patient</u> <u>Bag</u> on Page 89.
- 6. Attach a calibration bag. Refer to Attaching the Calibration Bag on Page 73.
- 7. Prime and verify the new inlet and ingredient. Refer to <u>Priming and Verifying</u> on Page 57.
- 8. Remove the calibration bag. Refer to Removing the Calibration Bag on Page 73.
- 9. Attach the patient bag. Refer to Attaching the Patient Bag on Page 84.
 - **NOTE:** You can reattach the original patient bag.
- 10. Continue with compounding the solution. Refer to <u>Compounding the Solution</u> on Page 85.

NOTE: The formula is not unloaded from the pump screen.

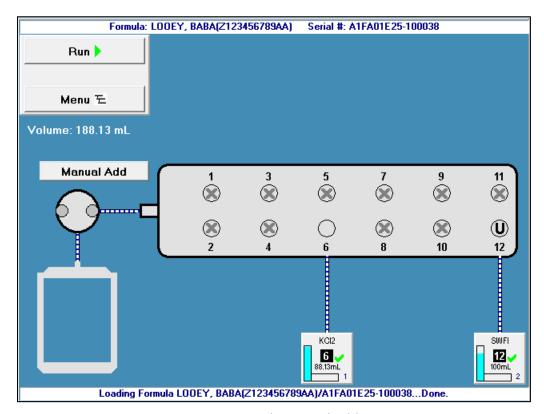
Performing a Manual Addition

A manual addition allows you to add an ingredient to the finished solution manually. This type of addition may be necessary when the loaded formula includes an ingredient that meets one or more of these conditions:

- It is not in the configuration.
- It is not identified as an allowable auto-addition.
- Its ordered volume is less than the 0.2 mL minimum required for use on the compounder.

If a formula loaded by scanning a barcode includes an ingredient that must be added manually:

• A **Manual Add** button appears on the left side of the pump screen. You can tap this button to view information about the ingredients that must be added manually.



Pump screen with manual addition

• The MixCheck Report includes a list of any ingredients that must be added manually. For more information, refer to MixCheck Report on Page 162.

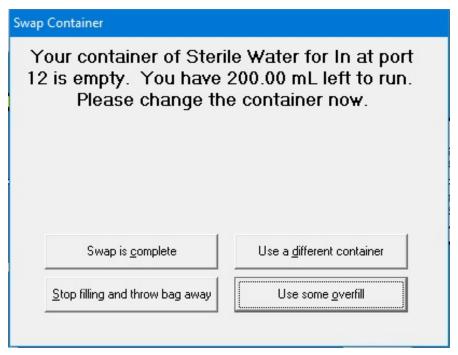
To add ingredients manually, follow your facility's protocol.

NOTE: To set the maximum volume allowed for a manual addition, refer to <u>Manual Add</u> on Page 118.

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Replacing a Source Container

If you are fulfilling a series of orders, an ingredient may become depleted and need to be replaced. When a formula is loaded and requires more ingredient volume than what remains in the source container, the vertical bar on the ingredient button flashes. You can replace the container now or start compounding. If you start compounding, the *Swap Container* window appears when the source container is almost empty.



Swap Container window

1. Check that the source container is appropriately depleted.

WARNING



If there is a large amount of fluid remaining in the source container, or if the container has emptied completely and forced air into the inlet, there may be a delivery problem. For assistance with troubleshooting, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

- 2. At the Swap Container window, tap one of these options:
 - Tap Swap is complete to replace the empty container with an exact match (same ingredient, container size, container type and manufacturer). Use aseptic technique to replace the source container.
 - Tap Use a different container to replace the empty container with the same ingredient from a different container size, container type or manufacturer. Use aseptic technique to replace the source container.

WARNING



The remainder value in the software must accurately represent the actual volume remaining in the source container. Change a remainder value only when you know the precise amount remaining in the source container. Incorrect remainder values can lead to bubbles, occlusions and under-delivery of an ingredient if its source container runs empty.

NOTE: Using a different container may require you to change and prime the inlet. Refer to <u>Attaching the New Ingredients and Inlets</u> on Page 47 and <u>Priming and Verifying</u> on Page 57.

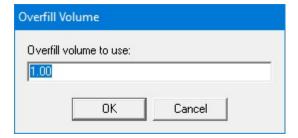
- Tap **Stop filling and throw bag away** to cancel the order. At the pump screen, tap **Stop** and follow the on-screen instructions.
- Tap **Use some overfill** to use the fluid remaining in the current container to complete the order. At the *Overfill Volume* window:
 - a. Enter the Overfill volume to use.



WARNING

Adjusting the value improperly in the **Overfill volume to use** field can lead to bubbles, occlusions and under-delivery of an ingredient if its source container runs empty.

b. Tap **OK**.



Overfill Volume window

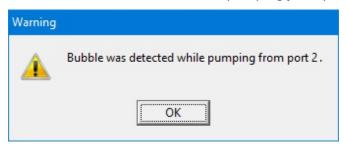
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Handling an Air Bubble

An air bubble can occur at any time, but it most frequently occurs after attaching a source container and priming the inlet. A bubble can be caused by an improperly spiked container, an empty container or incomplete priming.

When the bubble detector finds a bubble in the outlet tube over the detector, the compounding process stops and an alarm beeps. A message also appears.

1. At the Bubble was detected while pumping from port <port number> message, tap OK.



Message

IMPORTANT! A bubble in the common fluid pathway displaces the volume of one or more ordered ingredients, causing an under-delivery of these ingredients.

- 2. Determine the impact of the bubble:
 - a. Check the size of the bubble using the ExactaMix Bubble Chart (5300-0868) to determine the volume of fluid displaced.
 - b. If more than one bubble is present, evaluate each bubble and add the values together to determine the total volume of fluid displaced.
 - c. Identify all the ingredients pumped prior to the alarm, the ingredient pumped during the alarm and the volume of each ingredient ordered.

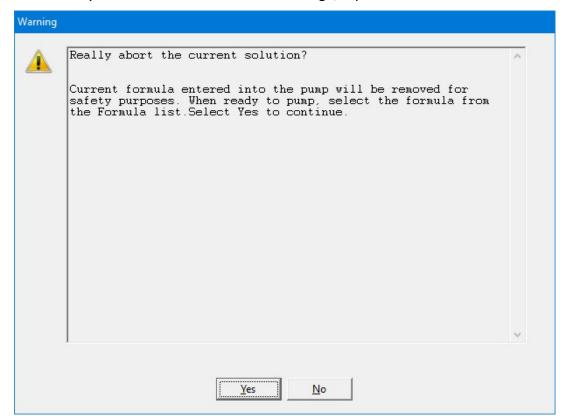
Tip! Baxter recommends that a pharmacist evaluate the clinical significance of bubbles encountered during the compounding process.

- Ask a pharmacist to determine if the displaced volume is clinically significant for any of the ingredients pumped. Assume that the total displaced volume applies to each ingredient ordered.
- 4. If the clinical significance:
 - Is acceptable, tap **Resume** at the pump screen to continue compounding the solution, and do not continue with the steps below
 - Is not acceptable, or cannot be determined, continue with the next step to cancel the order

Tip! Baxter recommends documenting all decisions according to your facility's protocol.

- 5. Immediately write a large "X" on the label of the patient bag.
- 6. At the pump screen, tap **Stop**.

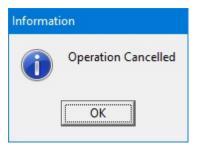
7. At the Really abort the current solution? message, tap Yes.



Message

The software unloads the formula.

8. At the Operation Cancelled message, tap **OK**.



Message

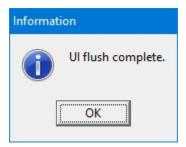
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9. At the Fluid path will be flushed with UI message, tap **OK**.



Message

- 10. Check that the fluid moves properly during the flush.
- 11. At the UI flush complete message, tap OK.



Message

- 12. Remove the bag. Refer to Removing the Patient Bag on Page 89.
- 13. Discard the bag.

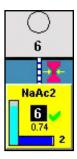
NOTE: To help reduce the occurrence of bubbles and make their detection more accurate, you can:

- Use proper technique to spike the containers. Refer to the steps for spiking a container, starting on Page 50.
- Re-prime any inlets that have visible bubbles. Refer to <u>Priming the Inlets and Verifying the</u> Setup on Page 61.
- Increase the priming volume in the configuration. Refer to <u>Adding or Editing a Configuration</u> on Page 133.
- Clean the channel over the bubble detector. Refer to <u>Cleaning the Compounder</u> on Page 101.
- Make sure that the outlet tube is in the proper position. It should be at the bottom of the channel over the bubble detector. Refer to Step 7a on Page 45.

Handling an Occlusion

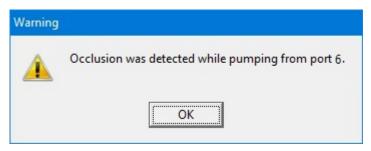
An occlusion can be caused by an empty syringe, stuck syringe plunger, kinked tube or other obstruction in the inlet.

When the occlusion detector detects that a vacuum was drawn, indicating an occlusion somewhere between the source container and the detector, the compounding process stops and an alarm beeps. A message appears, and a red occlusion symbol also appears near the ingredient button.



Occlusion symbol

- 1. Immediately write a large "X" on the label of the patient bag.
- 2. At the Occlusion was detected while pumping from port <port number> message, tap **OK**.

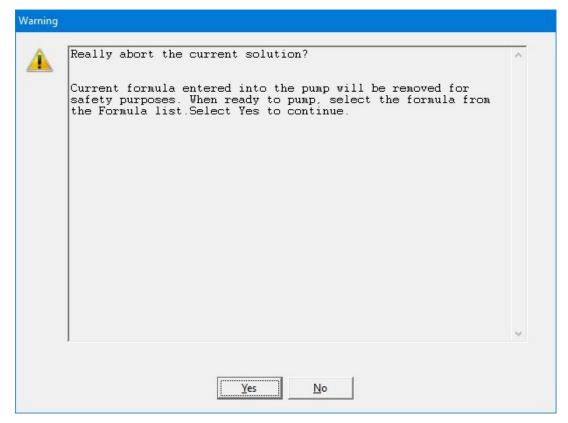


Message

3. At the pump screen, tap **Stop**.

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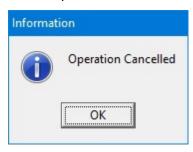
4. At the Really abort the current solution? message, tap Yes.



Message

The software unloads the formula.

5. At the *Operation Cancelled* message, tap **OK**.



Message

- 6. Check that:
 - Each syringe has fluid and its plunger is not stuck.
 - The appropriate inlet is used with each source container.
 - The inlets have no obstructions, kinks, tangles or plugs. If necessary, replace the inlets. Refer to <u>Changing the Tube Set</u> on Page 41.
 - The occlusion detector is not damaged or dirty.
 - The outlet tube is straight and flat on the occlusion detector.
- 7. At the Fluid path will be flushed with UI message, tap **OK**.



Message

- 8. Check that the fluid moves properly during the flush.
- 9. At the *UI flush complete* message, tap **OK**.



Message

- 10. Remove the bag. Refer to Removing the Patient Bag on Page 89.
- 11. Discard the bag.

Handling Other Interruptions and Errors

For more information about handling interruptions and errors, refer to <u>Troubleshooting</u> on Page 193.

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MAINTAINING THE COMPOUNDER

To keep the compounder in the best possible condition, perform these routine maintenance tasks:

- Calibrate the load cell
- Change the tube set
- Clean the compounder
- Calibrate the compounder
- Shut down and start up the compounder
- Back up and compact the database

CALIBRATING THE LOAD CELL

This procedure is usually performed as part of the daily setup.

For instructions, refer to <u>Calibrating the Load Cell</u> on Page 36.

CHANGING THE TUBE SET

This procedure is usually performed as part of the daily setup.

For instructions, refer to Changing the Tube Set on Page 41.

CLEANING THE COMPOUNDER

Clean the compounder when indicated by your facility's protocol. Use only these approved materials:

- Non-abrasive cloth
- Soap and water
- 70% isopropyl alcohol or another self-drying disinfectant
- Povidone iodine

Tip! Baxter recommends cleaning the compounder daily or whenever you change the tube set, or whenever there is a spill.

CAUTION

Cleaning is required to ensure that the compounder operates as intended. Failure to clean the compounder can impair its operation.



Do not immerse the compounder in liquid or use sodium hypochlorite solutions (for example, Clorox®).

Disassembling the compounder beyond what is needed for cleaning as described in this procedure voids the manufacturer's warranty.

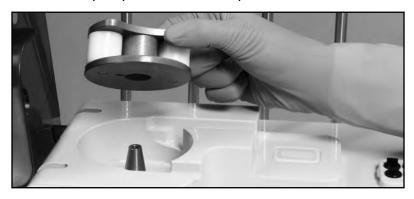
Power off the device during routine cleaning.

- 1. Shut down and turn off the compounder. Refer to <u>Rebooting and Shutting Down</u> on Page 32.
- 2. If the tube set is installed, remove and discard it. Refer to Removing the Expired Tube Set and Expired Ingredients on Page 43.
- 3. Open the pump door.
- 4. Remove and retain the thumbscrew and washer used to attach the rotor.



Removing the thumbscrew

5. Remove the pump rotor from the spindle.



Removing the pump rotor

- 6. Using the approved materials, clean the:
 - a. Pump rotor, making sure that the rollers spin freely
 - b. Pump rotor area
 - c. Channels near the pump rotor area
- 7. Install the:
 - a. Pump rotor, aligning the notch on the bottom of the rotor with the pin on the spindle
 - b. Washer and thumbscrew
- 8. Close the pump door.
- 9. Using the approved materials, clean the:
 - a. Valve actuators
 - b. Surface of the main module
 - c. Load cell
 - d. Poles and holders on the vial rack

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CALIBRATING THE COMPOUNDER

This procedure is usually performed as part of the daily setup.

For instructions, refer to <u>Calibrating the Compounder</u> on Page 69.

SHUTTING DOWN AND STARTING UP THE COMPOUNDER

Tip! Baxter recommends fully shutting down and starting up the compounder once a day, to allow the software to perform routine database maintenance at startup.

For instructions, refer to Starting Up, Logging In and Out, and Shutting Down on Page 30.

BACKING UP AND COMPACTING THE DATABASE

The compounder's database accumulates data related to solutions, formulas and logs. For example, the software records important device activity in a Blackbox log, which Baxter can access through the Blackbox Report when needed. The compounder stores this data for a specified time period. To set up the storage options, refer to <u>Storage</u> on Page 115.

When you shut down the software, the compounder automatically backs up the database. If required during troubleshooting, you can use the backup data to restore the software settings to an earlier state. When you start up the software, it notifies you if more than seven days have passed since the last backup occurred. In this situation, perform a manual backup.

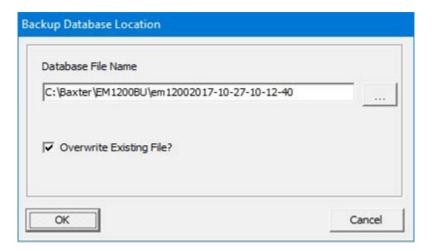
Tip! Baxter recommends performing a manual backup at least once a week or after changing the system settings.

You can also compact the database to reduce its space on the hard drive and keep the compounder operating efficiently. To set up the compaction options, refer to <u>Database Compaction</u> on Page 117.

Backing Up the Entire Database

This procedure backs up the entire database, including the Blackbox log.

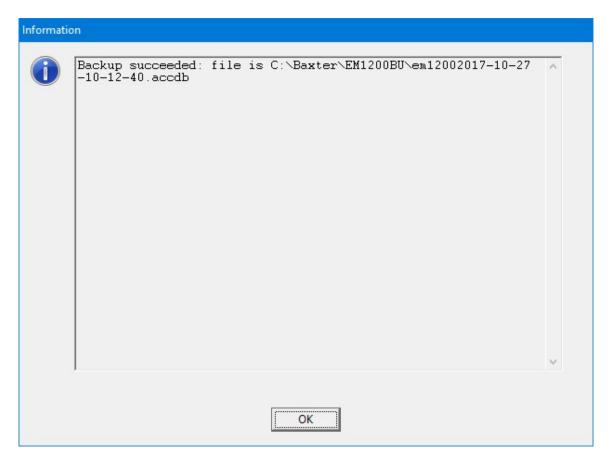
- 1. At the menu screen, tap **Tools > Database > Backup All**.
- 2. At the Backup Database Location window:
 - a. If desired, change the location of the backup by tapping the button to the right of the current location (not recommended).
 - b. If you want to:
 - Replace all the previous backup files to save space, select the Overwrite Existing File? check box
 - Keep the previous backup files, clear the **Overwrite Existing File?** check box
 - c. Tap **OK**.



Backup Database Location window

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3. At the Backup succeeded message, tap **OK**.

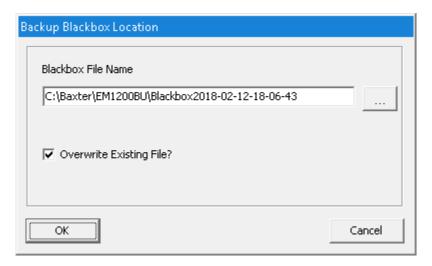


Message

Backing Up the Blackbox Log

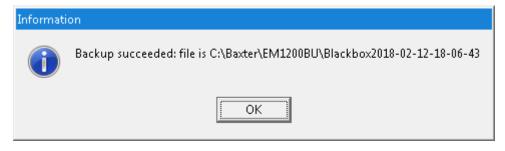
This procedure backs up only the Blackbox log.

- 1. At the menu screen, tap **Tools > Database > Backup Blackbox**.
- 2. At the *Backup Blackbox Location* window:
 - a. If desired, change the location of the backup by tapping the button to the right of the current location (not recommended).
 - b. If you want to:
 - Replace all the previous backup files to save space, select the Overwrite Existing File? check box
 - Keep the previous backup files, clear the **Overwrite Existing File?** check box
 - c. Tap OK.



Backup Blackbox Location window

3. At the Backup succeeded message, tap **OK**.

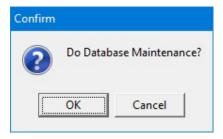


Message

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Compacting the Database

- 1. At the menu screen, tap **Tools > Database > Maintenance**.
- 2. At the Do Database Maintenance? message, tap **OK**.



Message

PERFORMING ADVANCED TASKS

Perform these tasks only when directed by Baxter Technical Services.

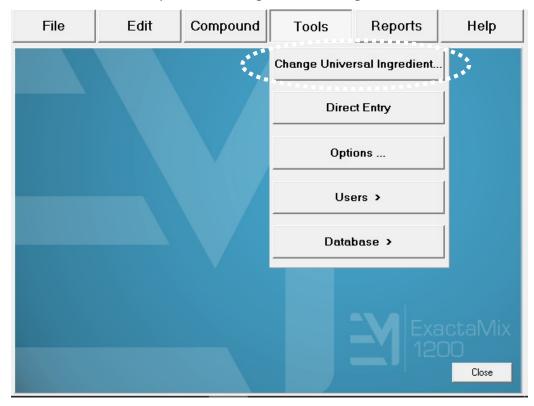
CHANGING THE UNIVERSAL INGREDIENT

IMPORTANT! This function requires Change Universal Ingredient permissions. For more information about user groups and permissions, refer to Setting Up the Users on Page 124.

To change the Universal Ingredient for the most recently used configuration when you are not in the process of compounding a solution, do the following procedure. To change the volume used for flushing after a UI change, refer to Flush Between UI Changes on Page 118.

If you are prompted to change the volume of the UI during the compounding process, refer to <u>Formula Conflict</u> on Page 199.

1. At the menu screen, tap **Tools > Change Universal Ingredient**.

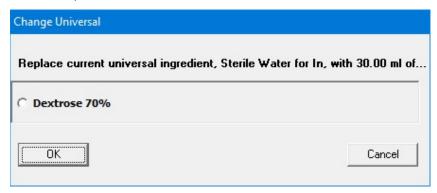


Menu screen, Tools menu

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A *Change Universal* window appears. It lists any ingredients that are available in the current configuration and have been specified as Universal Ingredients in the Formulary Editor. To specify the Universal Ingredients, refer to <u>Using the Formulary Editor</u> on Page 140.

- 2. At the Change Universal window:
 - a. Select the Universal Ingredient you want to use.
 - b. Tap **OK**.



Change Universal window

The compounder requires a flush of the new Universal Ingredient to clear the old Universal Ingredient from the common fluid pathway.

- 3. Attach a calibration bag. Refer to Attaching the Calibration Bag on Page 73.
- 4. At the Flushing with Universal Ingredient message, tap OK.



Message

The pump screen shows an animation of the flush.

- 5. When the *Completed flushing* message appears, remove the calibration bag. Refer to Removing the Calibration Bag on Page 73.
- 6. If you will continue with compounding a solution, attach a patient bag. Refer to Attaching the Patient Bag on Page 84.
- 7. At the Completed flushing message, tap **OK**.



Message

CHANGING THE INGREDIENT REMAINDERS

For each ingredient, the compounder tracks the volume that is used and the volume that remains in the source container (the remainder). If necessary, you can manually change each remainder shown in the software.

WARNING



The remainder value in the software must accurately represent the actual volume remaining in the source container. Change a remainder value only when you know the precise amount remaining in the source container. Incorrect remainder values can lead to bubbles, occlusions and under-delivery of an ingredient if its source container runs empty.

IMPORTANT! This function requires Compounder permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.

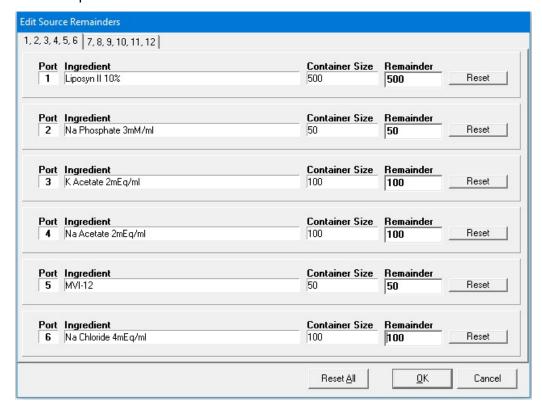
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- 1. At the menu screen, tap **Compound > Edit Source Remainders**.
- 2. At the Edit Source Remainders window:
 - a. For the desired ingredient, change the **Remainder** to correspond to the volume remaining in the container.

NOTE: You can tap **Reset** to change the remainder to its default value, or tap **Reset All** to change all the remainders to their default values at the same time.

Tip! Baxter does not recommend using **Reset All** unless the entire list of ingredients has been changed.

b. Tap OK.



Edit Source Remainders window

SETTING UP THE OPTIONS

IMPORTANT! These functions require Administration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.

NOTE: At any tab of the *Options* window:

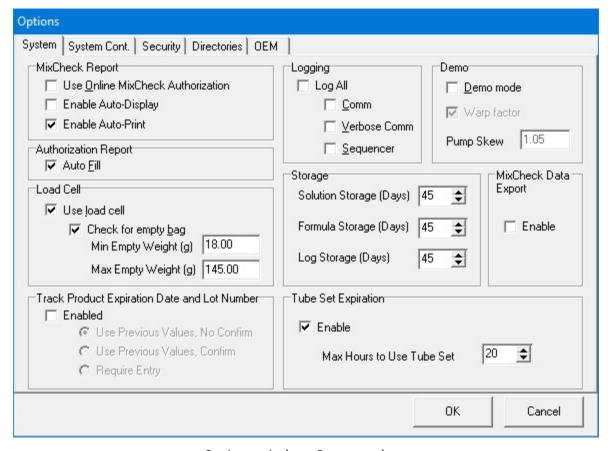
- Tapping **OK** saves the changes made on all the tabs and requires you to exit the software.
- Tapping **Cancel** closes the window without saving any changes.

SETTING UP THE SYSTEM OPTIONS

Use the **System** tab to set up the general system options.

To access the system options, tap **Tools > Options** at the menu screen.

At the Options window, the **System** tab is selected.

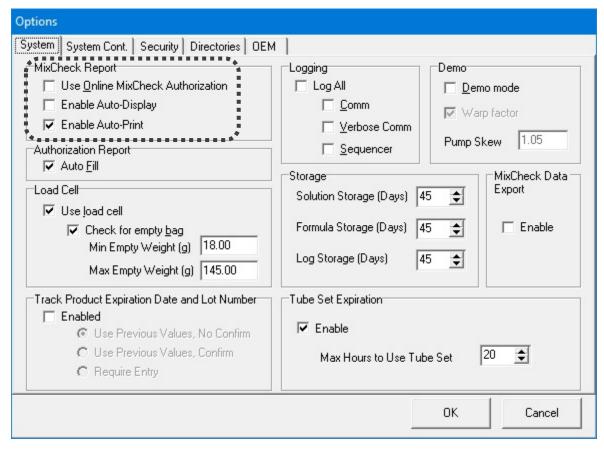


Options window, **System** tab

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MixCheck Report

The MixCheck Report is available after compounding is finished. For more information about the contents of this report, refer to MixCheck Report on Page 162.



Options window, **System** tab

By default the **Enable Auto-Print** is enabled. Ensure either one or both of the options **Enable Auto-Display** and **Enable Auto-Print** are selected; otherwise you get an error message. Use Online MixCheck Authorization is optional

- Select **Use Online MixCheck Authorization** if you want to require a qualified user to log in with a password to approve each MixCheck Report on the screen.
- Select **Enable Auto-Display** if you want the MixCheck Report to appear automatically on the display after compounding is finished.
- Select **Enable Auto-Print** if you want the MixCheck Report to print automatically after compounding is finished.

Authorization Report

The Authorization Report is available after the Setup Wizard is finished, or from the **Reports** menu. For more information about the contents of this report, refer to <u>Authorization Report</u> on Page 168.

Select **Auto Fill** if you want to make the **Assembled** and **Verified** columns of the report populate automatically with the name of the person who logged in to perform the task.

Load Cell

IMPORTANT! Baxter does not recommend changing these settings. Before changing any of these settings, contact Baxter Technical Services. Refer to Getting Help on Page 22.

Select **Use load cell** if you want to use the compounder's scale. This box should always be selected, except if the load cell is not functional and an external scale is available. If you select this check box, the following options become available.

Select **Check for empty bag** if you want to make the load cell check for the absence of a bag or the presence of a non-empty bag. If you select this check box, numbers appear in both of these fields:

- For **Min Empty Weight**, enter the minimum expected weight of an empty bag. If the load cell measures a weight less than this number at the start of compounding, a warning message indicates that a bag may not be attached to the load cell.
- For Max Empty Weight, enter the maximum expected weight of an empty bag. If the load
 cell measures a weight greater than this number at the start of compounding, a warning
 message indicates that the bag on the load cell may not be empty.

Tip! Baxter recommends selecting Check for empty bag.

Track Product Expiration Date and Lot Number

Select **Enabled** if you want to track the expiration date and lot number for every source container that is attached to the compounder. If you select this check box, these options become available:

- Select **Use Previous Values, No Confirm** if you want the compounder to use the previous date and lot number without requiring confirmation.
- Select **Use Previous Values, Confirm** if you want the compounder to use the previous date and lot number but require confirmation.
- Select **Require Entry** if you want the user to enter values each time a new container is attached.

Logging

IMPORTANT! Baxter does not recommend changing these settings.

Regardless of the **Logging** settings, the compounder stores records in a Blackbox log. For information about viewing the contents of this log, refer to <u>Blackbox Report</u> on Page 182.

In most cases, it is not necessary to change the **Logging** settings. Selecting any of these check boxes may cause the log to grow to a size that slows the performance of the software.

Demo

Demo mode uses a "virtual compounder" to simulate the compounder's operation. It can be used during training.

Select **Demo mode** if you want to enable demo mode. If you select this check box, these options become available:

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- Select Warp factor if you want to make the virtual compounder perform compounding operations faster than normal.
- For **Pump Skew**, enter a number. Entering a number other than **1.05** forces the virtual compounder to pump inaccurately, for training purposes.

NOTE: Operating in demo mode affects the ingredient remainders.

Tip! Do not use demo mode with ingredients attached.

Storage

The storage fields set the number of days that the database stores solution, formula and log (Blackbox) information. Information older than the specified storage period is purged when the software starts up.

You can increase or decrease these settings:

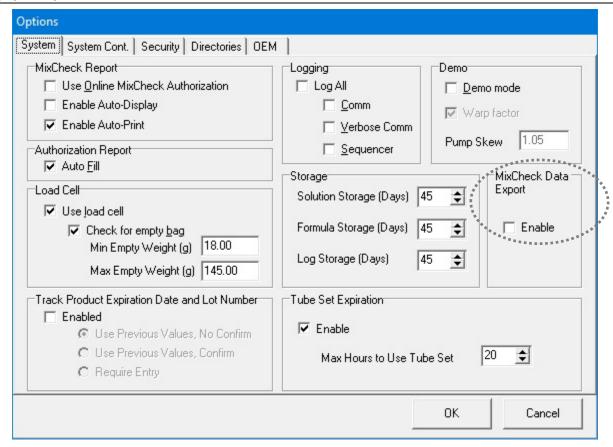
- For **Solution Storage (Days)**, enter the number of days that used formulas are available in the database.
- For **Formula Storage (Days)**, enter the number of days that unused formulas are available in the database.
- For **Log Storage (Days)**, enter the number of days that Blackbox information is available in the database.

Tip! Baxter recommends entering at least 45 days for each of these fields.

MixCheck Data Export

Select **Enable** if you want the compounder to export data directly to the Baxter DoseEdge® Pharmacy Workflow Manager.

For this feature, the DoseEdge system must be specified as the printer. For assistance with setting up printers, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.



Options window, System tab

Tube Set Expiration

IMPORTANT! Before changing any of these settings, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

Select **Enable** if you want the compounder to display a message when the tube set has been used longer than recommended.

For **Max Hours to Use Tube Set**, enter the maximum number of hours that the tube set should be used.

Tip! Baxter recommends entering 20 for the **Max Hours to Use Tube Set**, so that the tube set expires shortly before (instead of shortly after) the daily setup.

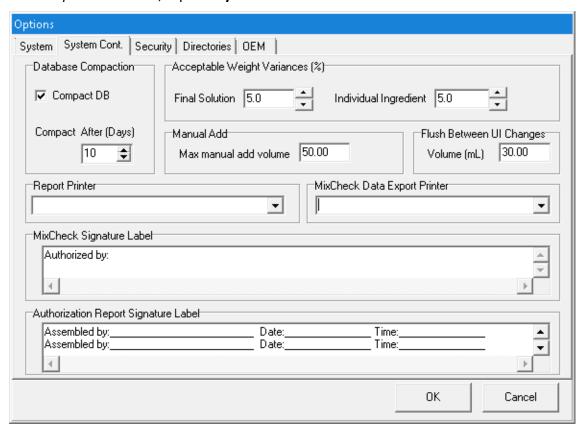
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SETTING UP THE SYSTEM (CONTINUED) OPTIONS

The **System Cont.** tab is a continuation of the **System** tab.

To access the continued system options:

- 1. At the menu screen, tap Tools > Options.
- 2. At the Options window, tap the System Cont. tab.



Options window, System Cont. tab

Database Compaction

IMPORTANT! Do not change these settings unless directed by Baxter Technical Services.

Select **Compact DB** if you want to make the compounder compact the database at startup.

Acceptable Weight Variances (%)

For **Final Solution**, enter the maximum acceptable difference between the expected and actual weight of the compounded solution. If any compounded solution has a weight outside this range, an alarm beeps and a message displays the results in red. The results also appear on the MixCheck Report.

For **Individual Ingredient**, enter the maximum acceptable difference between the expected and actual weight of each delivered ingredient. If any delivered ingredient has a weight outside this range, a message appears. The compounder weighs only ingredient deliveries of 100 mL or more.

Tip! Baxter recommends entering 5% for the **Final Solution** and 5% for the **Individual Ingredient**.

Manual Add

For **Max manual add volume**, enter the maximum volume allowed for a manual addition. If the volume of the formula ingredient exceeds this amount, a message appears, with options to add the ingredient manually or cancel compounding.

Flush Between UI Changes

For **Volume (mL)**, enter the final flush volume used to clear the common fluid pathway after changing the Universal Ingredient.

NOTE: A UI flush contains three deliveries with standard volumes of 50, 50 and 30 mL. Changing the **Volume** setting changes only the last of the three deliveries.

Report Printer

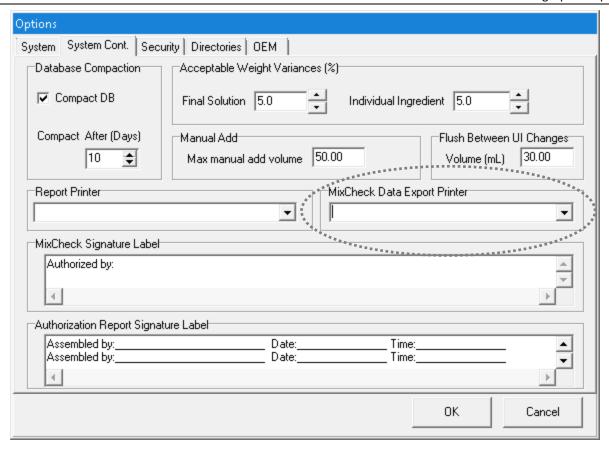
Select the printer used for printing reports.

MixCheck Data Export Printer

Select the printer used when sending MixCheck data to the DoseEdge system.

If **MixCheck Data Export** option (System tab) is enabled, application will display **MixCheck Data Export Printer** in System Cont. tab.

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Options window, System Cont. tab

MixCheck Signature Label

Enter text that you want to include at the bottom of the MixCheck Report.

Authorization Report Signature Label

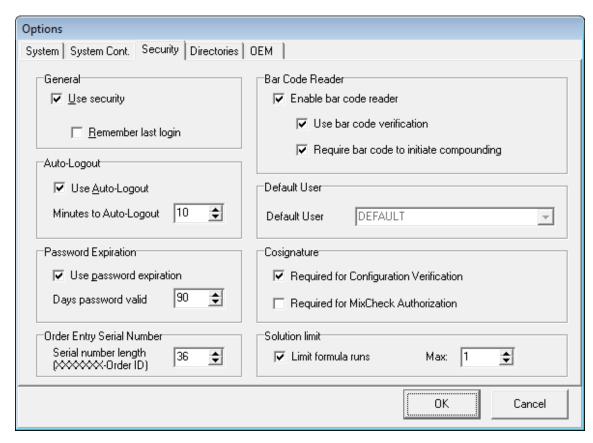
Enter text that you want to include about required signatures in the Authorization Report.

SETTING UP THE SECURITY OPTIONS

Use the **Security** tab to set the security features according to your facility's protocol.

To access the security options:

- 1. At the menu screen, tap Tools > Options.
- 2. At the Options window, tap the Security tab.



Options window, **Security** tab

General

Select **Use Security** if you want each user to sign in with a user ID and password.

Select **Remember last login** if you want the login box to populate automatically with the user ID of the last user who logged in. Only the user ID populates; the user must enter a password each time.

Auto-Logout

Select **Use Auto-Logout** if you want the current user to be logged out automatically after a period of inactivity.

For **Minutes to Auto-Logout**, enter the number of minutes after which the user is logged out.

Tip! Baxter recommends entering 10–15 for the **Minutes to Auto-Logout**.

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Password Expiration

Select **Use password expiration** to place an expiration date on each password, if your facility's protocol requires that user passwords must be changed on a regular basis.

NOTE: By default Use password expiration checkbox is checked.

For **Days password valid**, enter the number of days after which the password expires.

Tip! Baxter recommends entering 90 (or the number specified by your facility's protocol) for the **Days password valid**.

Order Entry Serial Number

For **Serial number length**, enter the number of maximum length of serial number for a formula file.

NOTE: If the Order Entry Serial Number is more than 36 characters, part of it may be truncated in the reports.

Barcode Reader

Select **Enable barcode reader** to allow the use of a barcode reader for scanning labels during verification of the setup and for loading formulas. If you select this check box, these options become available:

- Select **Use barcode verification** if you want to require the use of a barcode reader for scanning labels during verification of the setup.
- Select **Require barcode to initiate compounding** if you want to require the use of a barcode reader for loading formulas. If this box is selected, the user cannot manually select a saved formula.



WARNING

It is important to use a barcode reader for scanning labels during verification of the setup and for loading formulas.

NOTE: Compounder supports both 1D & 2D GS1 barcode formats. However to enable 2D barcode reading a 2D barcode reader (part number # 6500-0500) is needed.

Default User

If your facility does not require users to log in, select a **Default User** who is logged in automatically at startup.

Tip! Baxter does not recommend using this feature.

Cosignature

Select **Required for Configuration Verification** if you want to require a second user to log in and verify the configuration. If this option is not selected, the same user can set up and verify the configuration.

Tip! Baxter strongly recommends requiring a cosignature.

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Select **Required for MixCheck Authorization** if you want to require a second user to log in and verify the MixCheck Report on the screen after compounding.

Solution Limit

Select **Limit formula runs** if you want to limit the number of times a specific formula can be used for compounding.

For Max, enter the maximum of times an individual formula can be used.

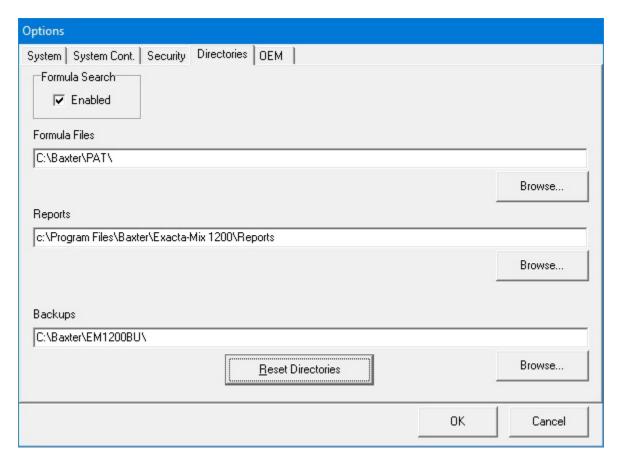
Tip! Baxter recommends entering 1 for the **Max**.

SETTING UP THE DIRECTORIES OPTIONS

Use the **Directories** tab to set the locations of formula files, reports and backups.

To access the directories options:

- 1. At the menu screen, tap Tools > Options.
- 2. At the *Options* window, tap the **Directories** tab.



Options window, **Directories** tab

3. If you want to allow users to retrieve formula files, select **Formula Search**.

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IMPORTANT! After initial installation, you should not need to change the locations of the directories. Do not tap **Reset Directories** unless directed by Baxter Technical Services. This button changes the locations of the directories from their current settings.

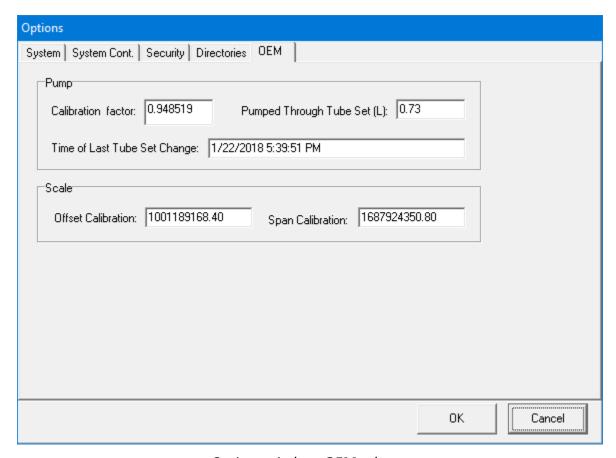
- 4. If you want to change the locations of the directories:
 - a. Tap Browse for Formula Files, Reports or Backups.
 - b. Select the location of the directory.

VIEWING THE OEM OPTIONS

You cannot edit the information on this tab; however, you may need to view it if directed by Baxter Technical Services.

To access the OEM options:

- 1. At the menu screen, tap Tools > Options.
- 2. At the *Options* window, tap the **OEM** tab.



Options window, **OEM** tab

SETTING UP THE USERS

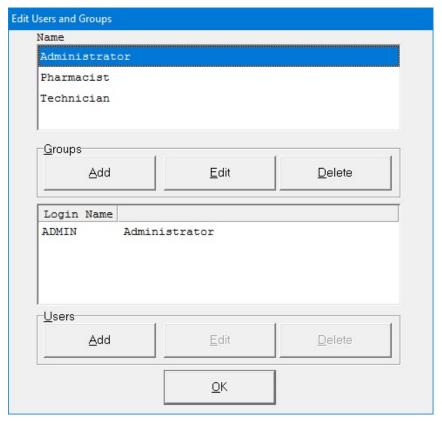
Each user must have an account so that the compounder can track activity. Users are assigned to groups that have the appropriate permissions to perform the required tasks.

WORKING WITH GROUPS

Adding or Editing a Group

IMPORTANT! These functions require Administration permissions.

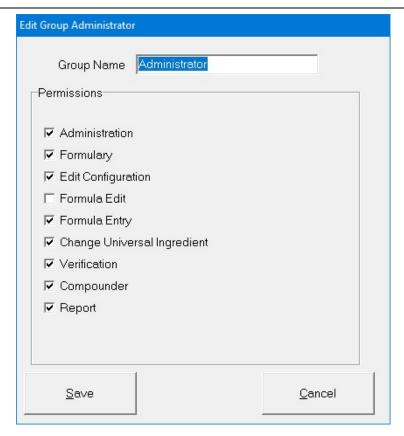
1. At the menu screen, tap **Tools > Users > Edit Users and Groups**.



Edit Users and Groups window

- 2. At the Edit Users and Groups window, in the top half, do one of these options:
 - Tap Add to add a group.
 The Add Group window appears.
 - Select the group you want to edit from the Name list, then tap Edit.
 The Edit Group <name> window appears.

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Edit Group <name> window

3. At the *Add Group* window or *Edit Group <name>* window, select the permissions for the group.

IMPORTANT! These permissions will apply to an entire group of users. You cannot assign unique permissions directly to a user; however, you can create a group that contains only one user.

Permissions	Allowed Functions	Baxter recommends assigning to:
Administration	 Access the Windows desktop Use Tools > Options 	Administrator
	Use Tools > Users > Edit Users and Groups	
	Use the Inlet EditorUse the Bag Inventory Editor	
Formulary	Use the Formulary Editor Use the Ingredient Group Editor	Administrator
Edit Configuration	Use the Configuration Editor	Administrator
Formula Edit	Increase the Universal Ingredient volume to satisfy the flush requirement (available in v 1.2 or older software versions only)	None*
Formula Entry	Create and save direct-entry formulas	Administrator and Pharmacist
Change Universal Ingredient	Change the Universal Ingredient without changing the configuration	Administrator, Pharmacist and Technician
Verification	 Perform cosignature authorization of the priming and verifying steps during setup Perform authorization and cosignature authorization of the MixCheck Reports 	Administrator and Pharmacist
Compounder	 Calibrate the load cell Select the configuration Change the tube set Prime the inlets Calibrate the compounder Compound the solution Edit the source remainders 	Administrator, Pharmacist and Technician
Report	 View reports Export reports Print reports (except MixCheck Report) 	Administrator, Pharmacist and Technician

^{*} Use of this permission for any user is discouraged. Because this permission allows a user to make changes to formulas, the clinical impact must be considered.

Tip! Baxter recommends having a pharmacist perform the verification.

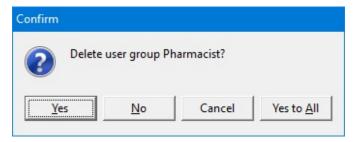
- 4. Tap **Save**.
- 5. At the *Edit Users and Groups* window, tap **OK**.

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Deleting a Group

IMPORTANT! This function requires Administration permissions.

- 1. At the menu screen, tap Tools > Users > Edit Users and Groups.
- 2. At the Edit Users and Groups window, in the top half:
 - a. Select the group you want to delete from the **Name** list.
 - b. Tap **Delete**.
- 3. At the *Delete user group <name>?* message, tap **Yes** to delete the group.



Message

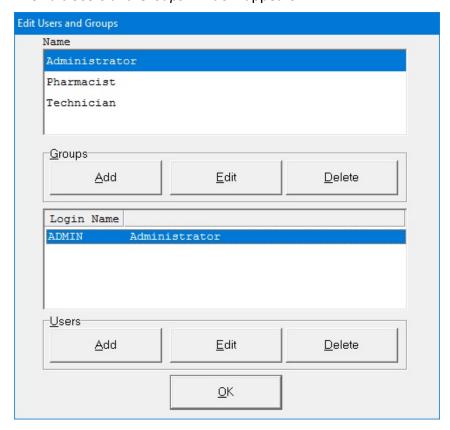
4. At the Edit Users and Groups window, tap **OK**.

WORKING WITH USERS

Adding or Editing a User

IMPORTANT! These functions require Administration permissions.

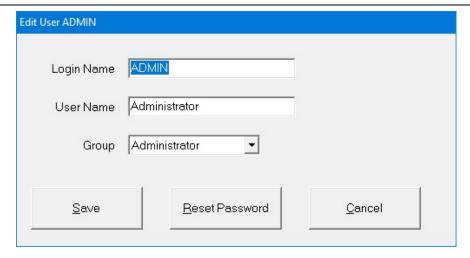
1. At the menu screen, tap **Tools > Users > Edit Users and Groups**. The *Edit Users and Groups* window appears.



Edit Users and Groups window

- 2. At the *Edit Users and Groups* window:
 - a. In the top half, select the group from the **Name** list.
 - b. In the bottom half, do one of these options:
 - Tap Add to add a user.
 - The *Add User* window appears.
 - Select the user you want to edit from the Login Name list, then tap Edit.
 The Edit User <name> window appears.

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Edit User <name> window

- 3. At the Add User window or Edit User <name> window:
 - a. Enter the **Login Name**.
 - b. Enter the User Name.

Tip! Baxter recommends using a short **Login Name** and full **User Name**.

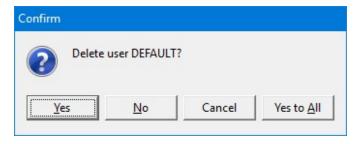
- c. Select the **Group** to which the user is assigned.
- d. Tap Save.
- 4. At the Edit Users and Groups window, tap **OK**.

NOTE: The password will be the same as the **Login Name** until the user logs in and changes the password. Baxter requires that new users change their passwords upon their first login attempt.

Deleting a User

IMPORTANT! This function requires Administration permissions.

- 1. At the menu screen, tap Tools > Users > Edit Users and Groups.
- 2. At the *Edit Users and Groups* window:
 - a. In the top half, select the group from the **Name** list.
 - b. In the bottom half, select the user you want to delete from the **Login Name** list, then tap **Delete**.
- 3. At the *Delete user <name>?* message, tap **Yes** to delete the user.



Message

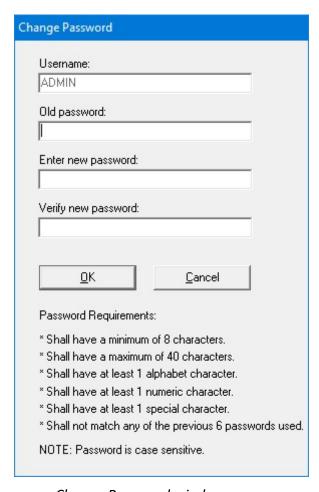
4. At the Edit Users and Groups window, tap **OK**.

Changing a Password

- 1. At the menu screen, tap **Tools > Users > Change Password**.
- 2. At the Change Password window:
 - a. Enter the Old password.
 - b. Enter the new password.
 - c. Enter the **new password** again to confirm it.
 - d. Tap OK.

IMPORTANT! Passwords are case-sensitive.

Baxter requires a new password shall be a minimum of 8 characters and a maximum of 40 characters. It shall contain at least 1 number, 1 alphabet, and 1 special character.

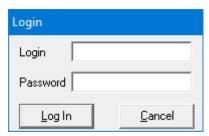


Change Password window

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Logging in as a Different User

- 1. At the menu screen, select **Tools > Users > Change User**.
- 2. At the *Login* window:
 - a. Enter a different **Login** name.
 - b. Enter the **Password**. (**NOTE:** Passwords are case-sensitive)
 - c. Tap Log In.



Login window

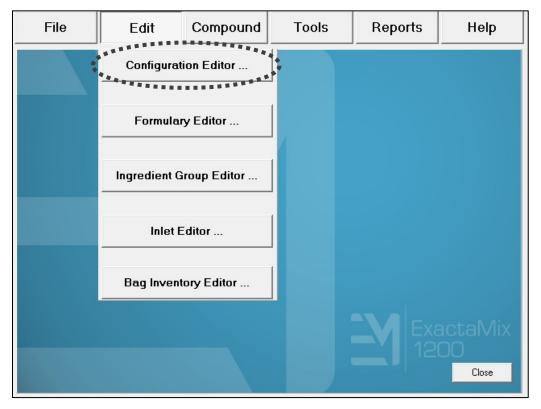
USING THE CONFIGURATION EDITOR

Use the Configuration Editor to manage the configurations.

IMPORTANT! These functions require Edit Configuration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124. Before making any changes in the Configuration Editor, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

IMPORTANT! The Configuration Editor is to be used only to create and manage non-active configurations. All changes to the Universal Ingredient of an active configuration must be made through the "Change Universal Ingredient" functionality described on Page 108.

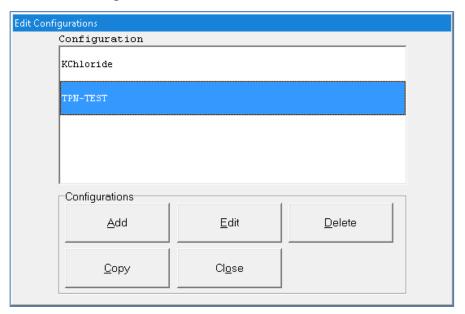
At the menu screen, tap **Edit > Configuration Editor**.



Menu screen, Edit menu

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The *Edit Configurations* window appears. It lists the available configurations and allows you to add, edit or delete configurations.



Edit Configurations window

ADDING OR EDITING A CONFIGURATION

WARNING

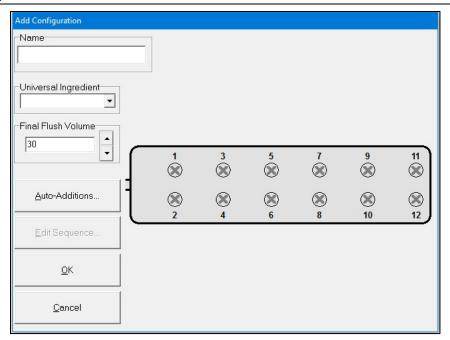


It is strongly recommended that installers / support services review and approve every new or edited configuration before it is placed into service.

Installers / support services are available for reviewing and approving all new and updated configurations. Refer to Getting Help on Page 19 for additional instruction.

- 1. At the Edit Configurations window, do one of these options:
 - Tap Add to add a configuration.
 - The Add Configuration window appears.
 - Select the configuration you want to edit, then tap **Edit**.
 - The *Edit Configuration <name>* window appears.
 - Select the configuration you want to copy, then tap **Copy**.
 - The Copy of <copied configuration name> window appears.

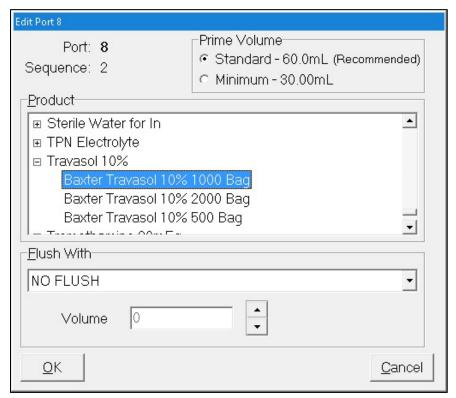
NOTE: You can use the **Copy** option to make minor edits to an existing configuration and save it with a new name.



Add Configuration window

- 2. Enter the Name of the configuration.
- 3. Tap a port.

The *Edit Port < number>* window appears.



Edit Port < number > window

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- 4. At the Edit Port < number > window:
 - a. Select the **Product** to associate with the port.

NOTE: For a product to appear in the list, it must first be in the formulary. Refer to <u>Using the Formulary Editor</u> on Page 140.

b. Select the **Prime Volume**. You can leave the standard volume that is automatically selected, or select the minimum volume.

Tip! Baxter recommends using the standard prime volume to ensure that the inlets are primed and any bubbles are removed.

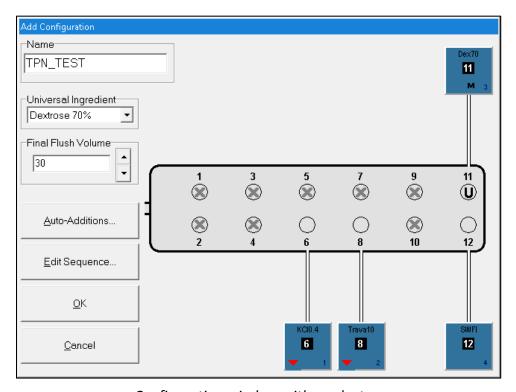
NOTE: The prime volume is used during setup of the compounder. This volume must be set for each product that is in each configuration. Auto-addition ingredients are always primed with the standard volume.

c. If the selected product requires an ingredient flush after it is delivered, select the flush ingredient in the **Flush With** list and set the flush volume in the **Volume** field.

NOTE: For example, to force a flush when lipids are pumped in a 3-in-1 bag, set the port with the appropriate flush ingredient and volume. Typically, the flush ingredient is the Universal Ingredient, but it can be any ingredient in the configuration and the formula. For an ingredient to appear in the **Flush With** list, it must first be specified as an allowable Universal Ingredient in the formulary. Refer to Using the Formulary Editor on Page 140.

- d. Tap **OK**.
- 5. Repeat Steps 3–4 for all the ports you want to use.

The configuration window now shows the product that is associated with each port. If you requested an ingredient flush for a product, the ingredient button includes a red downward arrow that represents the flush. If the ingredient is set to use the minimum prime volume, the ingredient button includes the letter M.



Configuration window with products

6. At the configuration window:

Select the Universal Ingredient.

NOTE: For the Universal Ingredient to appear in the list, it must first be in the configuration. Universal Ingredients must be assigned to ports 9–12; they cannot be assigned to ports 1–8. A port specified for the Universal Ingredient is labeled **U.** For commonly used ingredients such as the Universal Ingredient, you can set up an electronic Y-site.

b. Enter the Final Flush Volume.

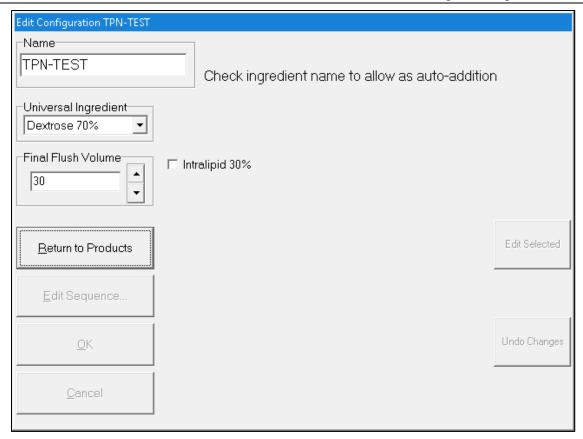
Tip! Each formula must include at least this volume of the Universal Ingredient. Baxter recommends using at least 30 mL. The minimum is 25 mL.

c. If you want to specify ingredients for auto-addition, tap **Auto-Additions**. Otherwise, skip to Step 8.

A list of ingredients that are available for auto-addition appears on the right side of the window.

NOTE: For the ingredient to be listed as available for auto-addition, it must first be specified as an allowable auto-addition in the formulary. Refer to <u>Using the Formulary Editor</u> on Page 140.

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Selecting auto-additions

- 7. To select auto-additions:
 - a. Select the check box for each desired ingredient.
 - b. To select a specific product or add an ingredient flush for the selected ingredient, tap **Edit Selected**.
 - c. When you are finished, tap **Return to Products**.
- 8. At the configuration window, tap **Edit Sequence**.

NOTE: This option is available only for existing configurations. If you do not edit the sequence (pumping order), the compounder will use the sequence of the port numbers (1, 2, 3 and so on).

Edit Configuration TPN-TEST Name-TPN-TEST Universal Ingredient Seq Ingredient Auto-Add K Chloride 0.4mEq/mL False Dextrose 70% 2 False Travasol 10% 3 Dextrose 70% False Final Flush Volume 4 Sterile Water for In-False • Auto-Additions.. Return to Products Undo OK <u>C</u>ancel

A sequential list of ingredients appears on the right side of the window.

Editing the sequence

- 9. To edit the sequence:
 - a. Select an ingredient, then use the arrows to move it up or down in the sequence.
 - b. When you are finished, tap **Return to Products**.
- 10. At the configuration window, tap **OK**.
- 11. At the *Edit Configurations* window, tap **Close**.



WARNING

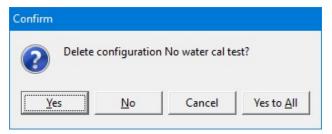
A Baxter pharmacist must approve every new or edited configuration before it is placed into service.

- 12. Print a Configuration Report for the new or edited configuration. Refer to <u>Configuration</u> Report on Page 175.
- 13. Contact Baxter Technical Services for instructions on sending the Configuration Report. Refer to <u>Getting Help</u> on Page 22.

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DELETING A CONFIGURATION

- 1. At the Edit Configurations window:
 - a. Select one or more configurations you want to delete.
 - b. Tap **Delete**.
- 2. At the *Delete configuration <name>?* message, tap:
 - Yes to delete the configuration
 - Yes to All to delete all configurations selected in the *Edit Configurations* window NOTE: If only one configuration is selected, only one will be deleted.



Message

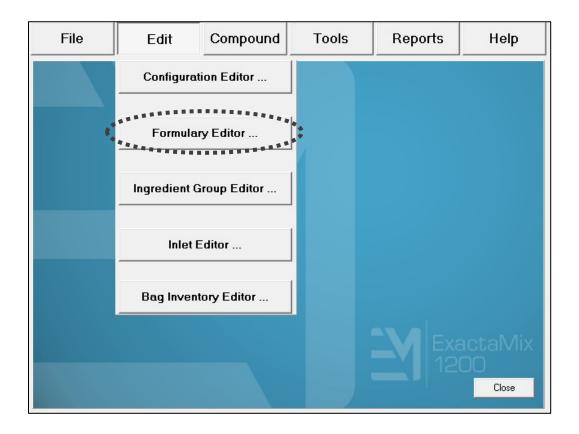
3. At the Edit Configurations window, tap Close.

USING THE FORMULARY EDITOR

Use the Formulary Editor to manage the ingredients and products in the formulary.

IMPORTANT! These functions require Formulary permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124. Before making any changes in the Formulary Editor, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

At the menu screen, tap **Edit > Formulary Editor**.

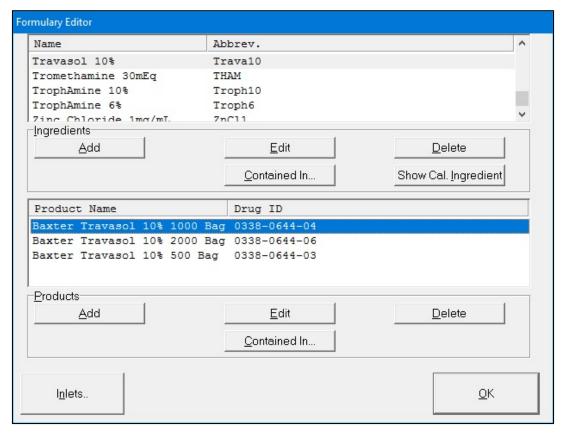


Menu screen, Edit menu

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The Formulary Editor window appears. The top list identifies the ingredients that can be included in a formula. The bottom list identifies each **Product Name**, with its **Drug ID**, that can be used for each ingredient type.

Tapping the **Inlets** button displays the Inlet Editor. For instructions on using this feature, refer to <u>Using the Inlet Editor</u> on Page 150.

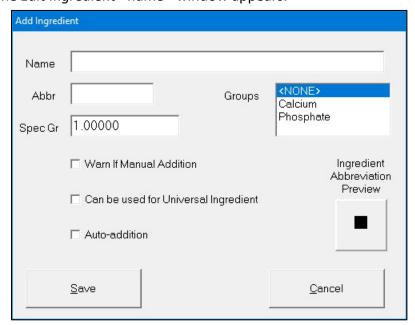


Formulary Editor window

WORKING WITH INGREDIENTS

Adding or Editing an Ingredient

- 1. At the *Formulary Editor* window, in the top half, do one of these options:
 - Tap **Add** to add an ingredient.
 - The Add Ingredient window appears.
 - Select the ingredient you want to edit from the Name list, then tap Edit.
 The Edit Ingredient <name> window appears.



Add Ingredient window

- 2. At the *Add Ingredient* window or *Edit Ingredient <name>* window:
 - a. Enter the Name.
 - b. Enter the Abbr (abbreviation).

NOTE: The information entered in the **Abbr** field will appear on the Ingredient Abbreviation preview and in the ingredient button on the pump screen.

- c. Enter the **Spec Gr** (specific gravity).
- d. In the **Groups** list, select the group to which the ingredient belongs. For more information, refer to <u>Using the Ingredient Group Editor</u> on Page 147.
- e. If desired, select one or more of these check boxes:
 - Warn If Manual Addition to make a message appear when a formula that includes this ingredient is used, but this ingredient is not in the current configuration
 - Can be used for Universal Ingredient to allow this ingredient to be used as a Universal Ingredient
 - Auto-addition to allow this ingredient to be added for temporary use at an open port
- f. Tap Save.

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Deleting an Ingredient

- 1. At the *Formulary Editor* window, in the top half:
 - a. Select one or more ingredients you want to delete from the **Name** list.
 - b. Tap **Delete**.
- 2. At the *Delete ingredient <name>?* message, tap:
 - Yes to delete the ingredient
 - Yes to All to delete all ingredients selected in the Formulary Editor window
 NOTE: If only one ingredient is selected, only one will be deleted.



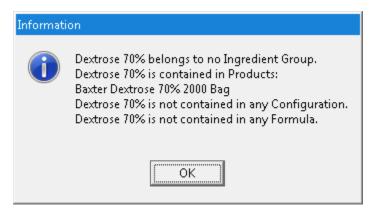
Message

Viewing an Ingredient's Usage Information

- 1. At the Formulary Editor window, in the top half:
 - a. Select the ingredient you want to view from the Name list.
 - b. Tap Contained In.

A message with the ingredient's current usage appears, including:

- The groups to which the ingredient belongs
- The products that contain the ingredient
- The configurations and formulas that contain the ingredient
- 2. At the Information message, tap OK.



Message

The Calibration Ingredient

The calibration ingredient is used for calibrating the compounder's pump.



WARNING

A sterile water product is required as the calibration ingredient.

If you think the calibration ingredient needs to be changed, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

Viewing the Calibration Ingredient

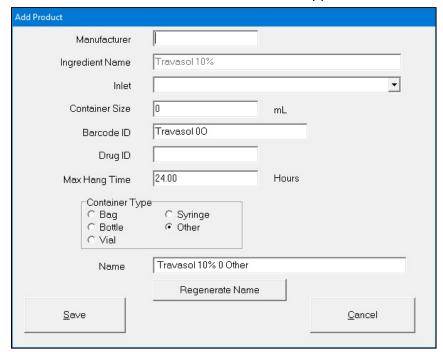
- 1. At the *Formulary Editor* window, in the top half, tap **Show Cal. Ingredient**. The calibration ingredient is highlighted.
- 2. Tap **OK**.

WORKING WITH PRODUCTS

Adding or Editing a Product

- 1. At the Formulary Editor window:
 - a. In the top half, select the ingredient from the **Name** list.
 - b. In the bottom half, do one of these options:
 - Tap Add to add a product.
 - The Add Product window appears.
 - Select the product you want to edit from the **Product Name** list, then tap Edit.

The *Edit Product <name>* window appears.



Add Product window

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- 2. At the Add Product window or Edit Product <name> window:
 - a. Enter the product's Manufacturer.

NOTE: The **Ingredient Name** field populates automatically with the ingredient name in the formulary. You cannot change this field.

WARNING

It is important to select the correct inlet type for the container. Selecting the incorrect inlet type can lead to occlusions and incorrect volume delivery, resulting in patient harm.

- b. Select the appropriate **Inlet** for the container. For information about the available inlet types, refer to <u>Inlets</u> on Page 18.
- c. Enter the Container Size.
- d. Scan the barcode to enter the Barcode ID.

NOTE: For items that do not have a Barcode ID from the manufacturer, you can enter the data manually.

Tip! Baxter recommends always using the barcode reader when possible.

WARNING



If a code number is assigned to one product in the order-entry software, and that number is assigned to a different product in the compounder's formulary, the compounder may pump the wrong ingredient. It is the user's responsibility to ensure that code numbers are properly and consistently assigned in both systems.

e. Enter the **Drug ID**.

NOTE: The Drug ID is used to identify products uniquely. In the United States, the Drug ID is usually the NDC.

f. Enter the Max Hang Time.

NOTE: This setting is the maximum amount of time the product can be attached to the compounder. The compounder displays a message if the product remains attached longer than the specified time.

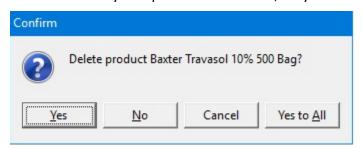
- g. Select the product's **Container Type**.
- h. If you want to change the **Name**, tap **Regenerate Name** or enter a new name.

NOTE: Based on the product information, the **Name** is generated automatically for new products. This name is used when the product's barcode is printed.

i. Tap **Save**.

Deleting a Product

- 1. At the Formulary Editor window:
 - a. In the top half, select the ingredient from the Name list.
 - b. In the bottom half, select one or more products you want to delete from the **Product Name** list, then tap **Delete**.
- 2. At the *Delete product <name>?* message, tap:
 - Yes to delete the product from the ingredient
 - Yes to All to delete all products selected in the Formulary Editor window
 NOTE: If only one product is selected, only one will be deleted.



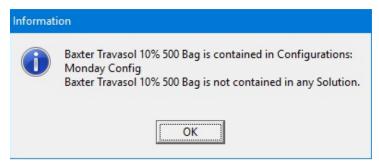
Message

Viewing a Product's Usage Information

- 1. At the Formulary Editor window:
 - a. In the top half, select the ingredient from the **Name** list.
 - b. In the bottom half, select the product you want to view from the **Product Name** list, then tap **Contained In**.

A message with the product's current usage appears, including:

- The configurations that contain the product
- The solutions that contain the product
- 2. At the *Information* message, tap **OK**.



Message

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USING THE INGREDIENT GROUP EDITOR

Use the Ingredient Group Editor to manage the ingredient groups, assign the products that are in the formulary to the correct groups and specify which groups are incompatible.

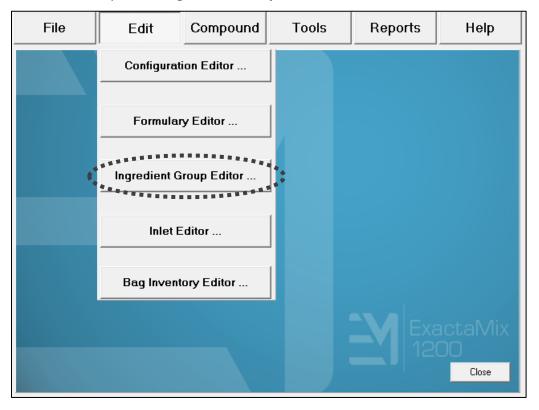
WARNING



Any calcium-containing products must be assigned to the calcium members group, and any phosphate-containing products must be assigned to the phosphate members group to ensure the software will warn users about formulas that may cause a precipitate in the tube set during the compounding process.

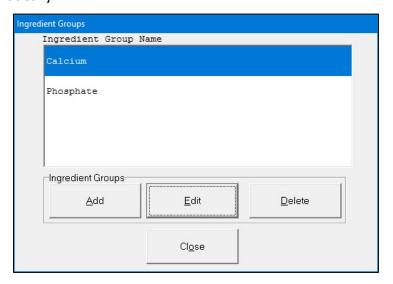
IMPORTANT! These functions require Formulary permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124. Before making any changes in the Ingredient Group Editor, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

At the menu screen, tap **Edit > Ingredient Group Editor**.



Menu screen, Edit menu

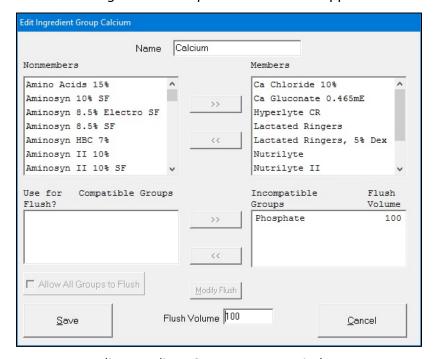
The *Ingredient Groups* window appears. It lists the available ingredient groups and allows you to add, edit or delete ingredient groups. **Calcium** and **Phosphate** groups are created automatically.



Ingredients Groups window

ADDING OR EDITING AN INGREDIENT GROUP

- 1. At the *Ingredient Groups* window, do one of these options:
 - Tap Add to add a new ingredient group.
 The Add Ingredient Group window appears.
 - Select the group you want to edit, then tap Edit.
 The Edit Ingredient Group <name> window appears.



Edit Ingredient Group <name> window

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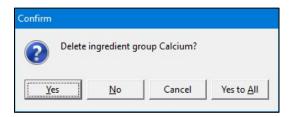
- 2. Enter the **Name** of the group.
- 3. Specify the members of this group.
 - To add an ingredient to this group:
 - a. Select the ingredient in the Nonmembers list.
 - b. Tap >> to move the ingredient to the **Members** list.
 - To remove an ingredient from this group:
 - a. Select the ingredient in the **Members** list.
 - b. Tap << to move the ingredient to the **Nonmembers** list.
- 4. Specify the groups that are incompatible with this group.
 - To make another group incompatible with this group:
 - a. Select the other group in the **Compatible Groups** list.
 - b. Enter a Flush Volume.

NOTE: The flush ingredient will be any ingredient that is not listed as incompatible.

- c. Tap >> to move the group to the **Incompatible Groups** list.
- To make another group compatible with this group:
 - a. Select the other group in the **Incompatible Groups** list.
 - b. Tap << to move the group to the **Compatible Groups** list.
- 5. To modify the flush volume for an incompatible group:
 - a. Select the group in the Incompatible Groups list.
 - b. Edit the Flush Volume.
 - c. Tap Modify Flush.
- 6. Tap Save.
- 7. At the *Ingredient Groups* window, tap **Close**.

DELETING AN INGREDIENT GROUP

- 1. At the *Ingredient Groups* window:
 - a. Select one or more ingredient groups you want to delete.
 - b. Tap **Delete**.
- 2. At the *Delete ingredient group <name>?* message, tap:
 - Yes to delete the ingredient group
 - Yes to All to delete all ingredient groups selected in the *Ingredient Groups* window
 NOTE: If only one ingredient group is selected, only one will be deleted.



Message

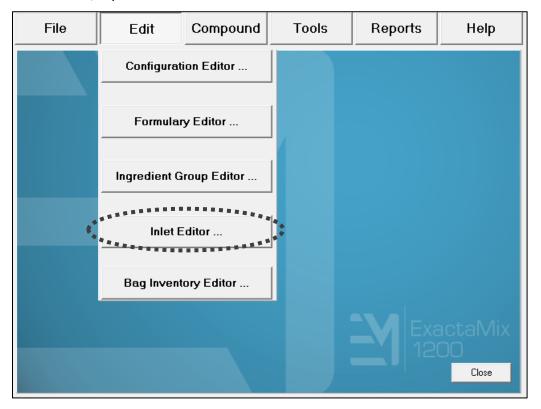
3. At the *Ingredient Groups* window, tap **Close**.

USING THE INLET EDITOR

The priming volume and pumping speed for inlets may differ depending on the inlet's spike and tube diameter. The Inlet Editor allows you to adjust the priming volumes for all the inlets.

IMPORTANT! These functions require Administration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124. Before making any changes in the Inlet Editor, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

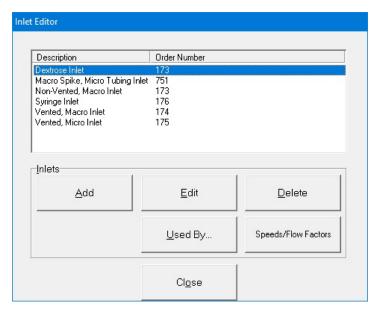
At the menu screen, tap **Edit > Inlet Editor**.



Menu screen, Edit menu

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The *Inlet Editor* window appears. It lists the available inlets and allows you to add, edit or delete inlets.



Inlet Editor window

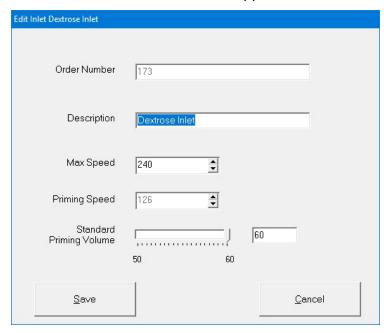
ADDING OR EDITING AN INLET

- 1. At the *Inlet Editor* window, do one of these options:
 - Tap Add to add a new inlet.

The Add Inlet window appears.

Select the inlet you want to edit, then tap Edit.

The *Edit Inlet <name>* window appears.



Edit Inlet <name> window

IMPORTANT! For the order number, description and recommended priming volume for each inlet, refer to Inlets on Page 18.

NOTE: Use of this function is not recommended without Baxter instruction.



WARNING

Modifying these settings without contacting Baxter Technical Services could result in ingredients over or under delivering and may cause patient harm.

- 2. At the Add Inlet window or Edit Inlet <name> window:
 - a. Enter the Order Number.
 - b. Enter the **Description**.



WARNING

The **Max Speed** and **Priming Speed** are set automatically. Do not change them unless directed by Baxter Technical Services.

c. If desired, edit the Standard Priming Volume.

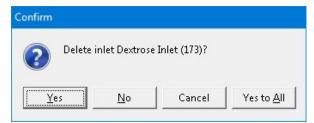
NOTE: The software will not allow you to set a **Standard Priming Volume** that is less than what Baxter recommends.

- d. Tap Save.
- 3. At the *Inlet Editor* window, tap **Close**.

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DELETING AN INLET

- 1. At the *Inlet Editor* window:
 - a. Select one or more inlets you want to delete.
 - b. Tap **Delete**.
- 2. At the *Delete inlet <name>?* message, tap:
 - Yes to delete the inlet
 - Yes to All to delete all inlets selected in the *Inlet Editor* window
 NOTE: If only one inlet is selected, only one will be deleted.



Message

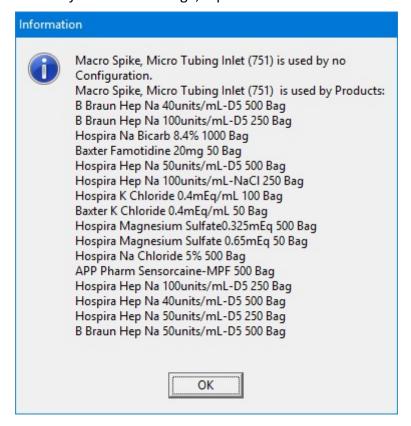
3. At the *Inlet Editor* window, tap **Close**.

VIEWING AN INLET'S USAGE INFORMATION

- 1. At the Inlet Editor window:
 - a. Select an inlet.
 - b. Tap Used By.

A message with the inlet's usage information appears.

2. At the Information message, tap OK.



Message

3. At the *Inlet Editor* window, tap **Close**.

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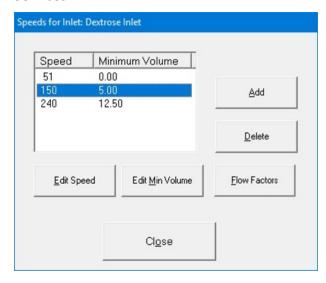
VIEWING AN INLET'S SPEEDS AND FLOW FACTORS

IMPORTANT! All the ingredients need flow factors prior to compounding. Contact Baxter Technical Services for adding/updating flow factors.

IMPORTANT! These settings affect the delivery volume, so they must be accurate. Do not make any changes unless directed by Baxter Technical Services. Baxter has determined the flow factors for all of the ingredients commonly used in TPN. If you think that a flow factor needs to be changed, or a flow factor for a new ingredient needs to be added, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

NOTE: Only the OEM user is able to view or edit the flow factors.

- 1. At the Inlet Editor window:
 - a. Select an inlet.
 - b. Tap **Speeds/Flow Factors**.
- 2. At the *Speeds for Inlet <name>* window, follow the instructions of Baxter Technical Services.



Speeds for Inlet <name> window

3. At the *Inlet Editor* window, tap **Close**.

USING THE BAG INVENTORY EDITOR

The Bag Inventory Editor allows you to manage the bags that are available for use on the compounder.

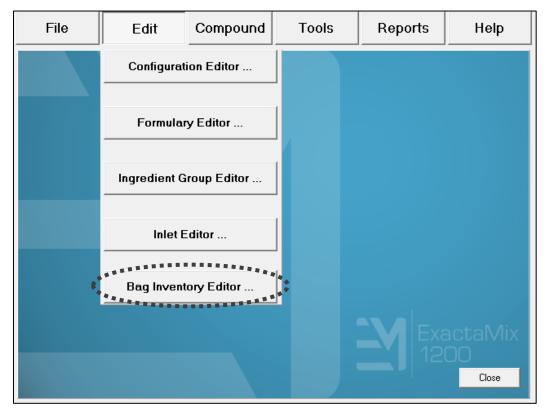


CAUTION

Before making any changes in the Bag Inventory Editor, contact Baxter Technical Services. Refer to Getting Help on Page 22.

IMPORTANT! These functions require Administration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124. Use only bags validated by Baxter for use with the compounder. For details, refer to <u>Bags</u> on Page 19. Using non-validated bags voids all manufacturer warranties. In addition, the accuracy of the finished solution will not be validated.

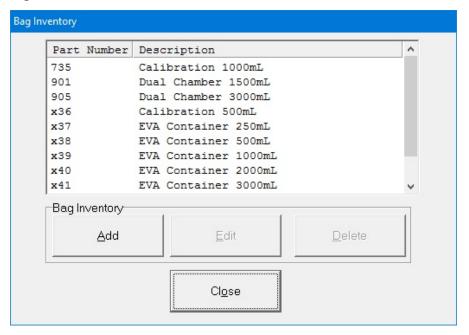
At the menu screen, tap Edit > Bag Inventor Editor.



Menu screen, Edit menu

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The *Bag Inventory* window appears. It lists the available bags and allows you to add, edit or delete bags.

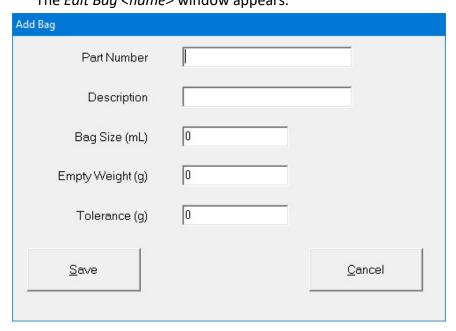


Bag Inventory window

ADDING OR EDITING A BAG

IMPORTANT! Before adding a bag, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

- 1. At the Bag Inventory window, do one of these options:
 - Tap Add to add a new bag.
 The Add Bag window appears.
 - Select the bag you want to edit, then tap Edit.
 The Edit Bag <name> window appears.



Add Bag window

- 2. At the *Add Bag* window or *Edit Bag <name>* window:
 - a. Enter:
 - Part Number
 - Description
 - Bag Size
 - Empty Weight
 - Tolerance

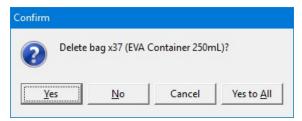
NOTE: You can obtain the empty weight and tolerance of approved bags from Baxter.

- b. If you are adding a new bag, enter other information as directed by Baxter.
- c. Tap **Save**.
- 3. At the Bag Inventory window, tap Close.

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DELETING A BAG

- 1. At the *Bag Inventory* window:
 - a. Select one or more bags you want to delete.
 - b. Tap **Delete**.
- 2. At the *Delete bag <name>?* message, tap:
 - Yes to delete the bag
 - Yes to All to delete all bags selected in the Bag Inventory window
 NOTE: If only one bag is selected, only one will be deleted.



Message

3. At the Bag Inventory window, tap Close.

USING REPORTS

The compounder offers standard reports that document compounding activity and support various utilities. All reports are formatted for printing on 8.5×11 in. $(21.6 \times 28 \text{ cm})$ paper or on A4 paper size of 70X25, 4mm (or comparable paper).

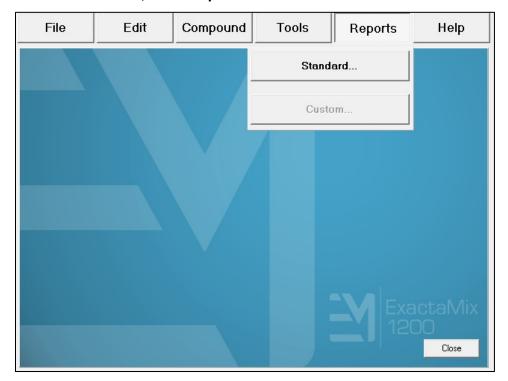
NOTE: For using A4 paper, refer to <u>Printing Options</u> on Page 16.

IMPORTANT! Viewing, printing and exporting reports requires Report permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.

NOTE: To select the printer used for printing reports, refer to Report Printer on Page 118.

To view reports:

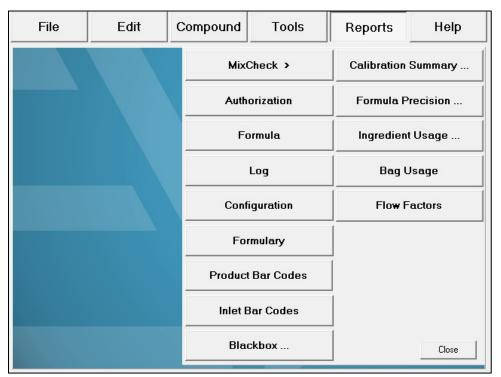
1. At the menu screen, select **Reports > Standard**.



Menu screen, Reports menu

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2. Select the report you want to view.

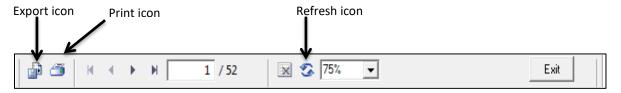


Standard reports

3. View the report. Refer to the instructions on the upcoming pages.

NOTE: The report screen may include scroll bars on the right side and/or the bottom. The top of the report screen may include these navigation options:

- o The print icon allows you to send the report to the specified printer.
- The export icon allows you to save the report to a USB drive.
- o The refresh icon generates the report again.
- o The percentage list controls the zoom.
- The arrows and the number field allow you to move to different pages of a multipage report.
- 4. When you are finished using the report, tap Exit.



Navigation options for reports

MIXCHECK REPORT

The MixCheck Report provides details about the compounding process for an order. It reports information including the expected bag weight, measured bag weight, ordered ingredients and volumes, and manual additions that are required.

Customizing MixCheck Reports

IMPORTANT! Authorization and cosignature authorization of this report require Verification permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.

The following options are available for customizing the MixCheck Report:

- To make this report display and/or print automatically after compounding, and/or allow onscreen authorization, refer to MixCheck Report on Page 113.
- To require a cosigner to authorize the MixCheck Report, refer to Cosignature on Page 121.
- To allow exporting of this report directly to the DoseEdge system, refer to <u>MixCheck Data Export</u> on Page 115.
- To specify signature-related text that you want to include at the end of the report, refer to MixCheck Signature Label on Page 119.

Using MixCheck Reports

WARNING



It is important to print a MixCheck Report for every order, then have a cosigner (pharmacist) view and approve the entire report, especially the **Formula Name**; **Expected Weight**, **Measured Weight** and **Difference**; **Manual Additions**; and **Details**.

For instructions on viewing and approving the MixCheck Report, refer to the following pages.

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			MixCheck TM Re	port			
Seri	mula Name al Number diguration			-	Date/Time User Elapsed Time	Administrator	:32PM
Expe	ected Weigh	nt (g): 205.05	Measured Weight (g):	195.38		Difference (%): -4	.72
Jser Co	omments:						
<u> Ianua</u>	al Addition	<u>s:</u>					
	ent Name			Vol (mL)	Added		
	ol 15% te Adult			40.08 50.64			
				20.04			
						Ordered	Volume
Port:	se 70% 11	Baxter Dextrose 70% 2000	Bag (seq 4)				30
K Chlo Port:	oride 0.4mI 6	Eq/ mL Baxter K Chloride 0.4mEq	/mL 60 Bag (seq 1)				35
Sterile Port:	Water for		2000 Pag (car 2)				45.54
2011.	12	Baxter Sterile Water for In	2000 Bag (seq 3)				45.54
Port:	12	Baxter Sterile Water for In	2000 Bag (seq 5)				30
						Total (mL):	75.5
Travas Port:	sol 10% 8	Baxter Travasol 10% 2000	Bag (seq 2)				55
Details							
Selec		3 EVA Container 5000mL.			Total (1	nL):	195.5
Occli Pump The	cted bag x4 lusion was d p door was		_		Total (1	mL):	195.5

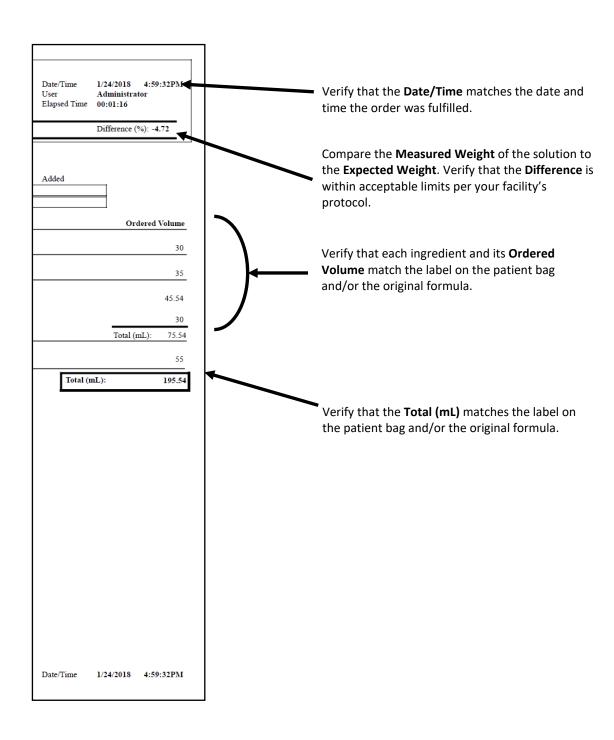
Sample MixCheck Report

Verify that the Formula Name $MixCheck^{TM}Report$ matches the patient name on the DOE, JOHN(5551212) Formula Name label on the patient bag. Serial Number A1FA01E41-5984912 Configuration TPN_TEST Expected Weight (g): 205.05 Measured Weight (g): 195.38 Verify that the Serial Number (unique for each order) matches the serial User Comments: number on the label of the patient Manual Additions: Ingredient Name Vol (mL) bag. Clinisol 15% 40.08 Infuvite Adult 50.64 If Manual Additions are listed: Dextrose 70% 1. Verify that they match the label on Port: 11 Baxter Dextrose 70% 2000 Bag (seq 4) the patient bag and/or the original K Chloride 0.4mEq/mL formula. Baxter K Chloride 0.4mEq/mL 60 Bag (seq 1) Port: 6 2. Add these ingredients to the Sterile Water for In Baxter Sterile Water for In 2000 Bag (seq 3) solution manually. Port: 12 3. Place your initials in the Added 12 Baxter Sterile Water for In 2000 Bag (seq 5) column. Travasol 10% Baxter Travasol 10% 2000 Bag (seq 2) Port: Evaluate the information in the **Details** Details: section to verify that the solution was Selected bag x43 EVA Container 5000mL. compounded properly. This section Occlusion was detected while pumping from port 6. lists any interruptions that occurred Pump door was open during delivery from port 8. Notify Pharmacist. The final weight of this solution is within the acceptable limit of +/- 5.00% while compounding, such as ingredient Authorized by: changes, ingredient replacements, occlusions, bubbles, pump pauses, pump door openings and other interruptions. In the signature-related section at the end of the report, follow your facility's protocol. Serial Number A1FA01E41-5984912 Page 1 of 1

Sample MixCheck Report (left side)

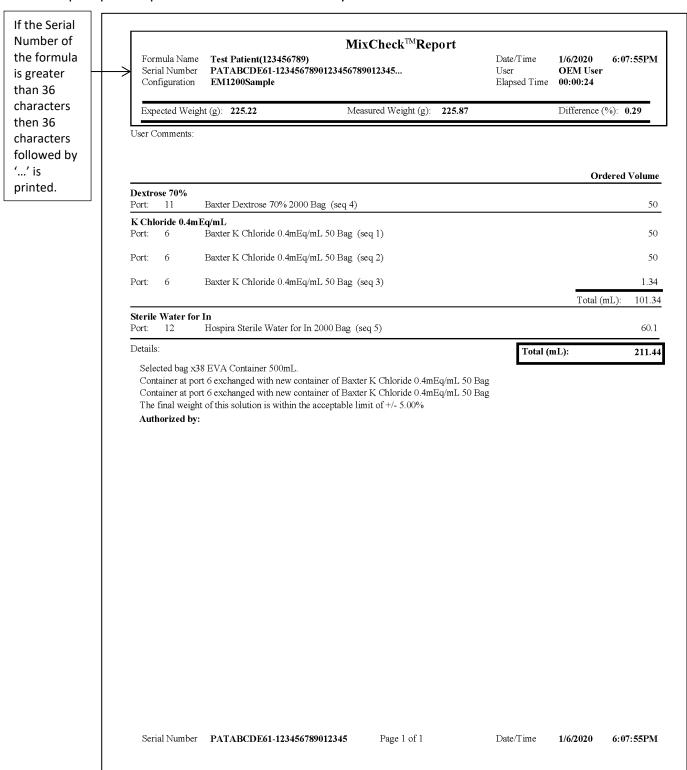
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Sample MixCheck Report (right side)

If the Serial Number of the formula file contains more than 36 characters then the MixCheck Report prints up to 36 characters followed by '...'.



Sample MixCheck Report

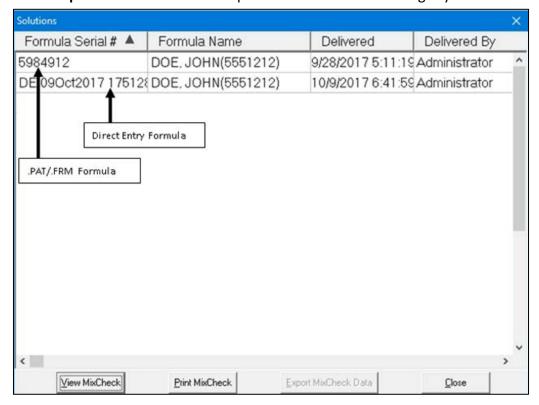
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Viewing Old MixCheck Reports

- 1. At the menu screen, tap Reports > MixCheck > Old MixCheck Data.
- 2. At the Solutions window:
 - a. Select a formula.
 - b. Tap one of these buttons:
 - View MixCheck to view the report on the screen
 - **Print MixCheck** to send the report to the assigned printer
 - Export MixCheck Data to export the data to the DoseEdge system



Solutions window

AUTHORIZATION REPORT

The Authorization Report contains information about the compounder setup, including:

 The user who set it up (in the Assembled column) and the optional cosigner who performed the verification (in the Verified column)

NOTE: Users can print the report and write their initials in these columns, or the software can be set up to populate these columns automatically.

• The ingredient name, port and inlet used during setup

The following options are available for customizing the Authorization Report:

- To require a cosigner to verify the setup, refer to <u>Cosignature</u> on Page 121.
- To make the **Assembled** and **Verified** columns populate automatically, refer to <u>Authorization Report</u> on Page 113.
- To specify signature-related text that you want to include at the end of the report, refer to <u>Authorization Report Signature Label</u> on Page 119.

To view the Authorization Report, tap **Reports > Standard > Authorization** at the menu screen.

Authorization Deport

				,	Autnorization Report		
Co	onfiguration:	TPN_TES	ST			Current user:	Administrator
ort Ingredient nan	<u>ne</u>	Inlet PN	Container (mL)	Remainder(mL) <u>Assembled</u>	Verified	Date / Time
K Chloride 0.4	mEq/mL	751	50	15.00	Administrator	OEM User	1/23/2018 6:25:00PN
Travasol 10%		173	2000	1945.00	Administrator	OEM User	1/23/2018 6:24:56PN
1 Dextrose 70%		173	2000	1870.00	OEM User	OEM User	1/23/2018 6:39:49PN
2 Sterile Water f	or In	173	2000	1924.46	Administrator	OEM User	1/23/2018 6:24:50PN
Part Number	Count						
173	3						
751	1						
Assembled by:			Date:	Ţ	ime:		
Assembled by:_ Checked by:_			Date: Date:	<u></u>	ime:		
onecked by			Date	'	e		

Sample Authorization Report

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FORMULA REPORT

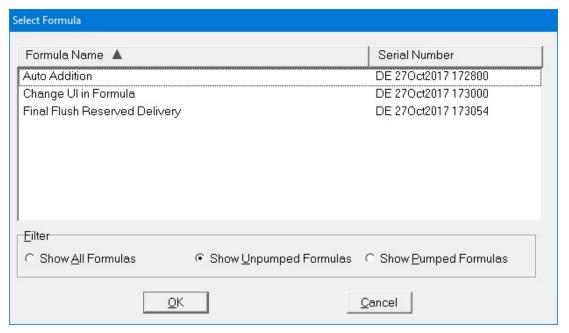
The Formula Report is a summary of a specific formula.

To view the Formula Report:

- 1. At the menu screen, tap **Reports > Standard > Formula**.
- 2. At the Select Formula window:
 - a. Select **Show All Formulas**, or select another filter to reduce the number of formulas displayed.

NOTE: You can tap **Formula Name** to sort by name or tap **Serial Number** to sort by number.

- b. Select a formula.
- c. Tap OK.



Select Formula window

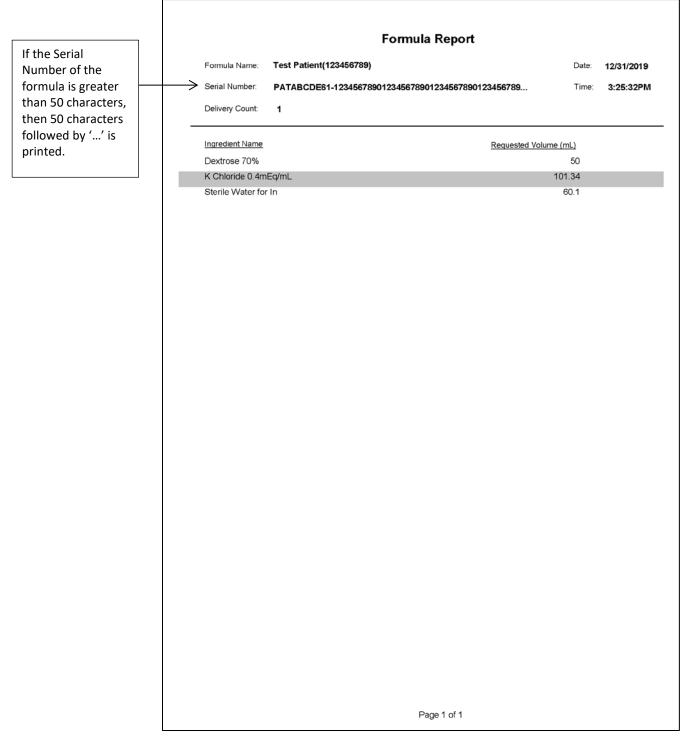
Formula Report Test Patient(123456789) Formula Name: Date: 12/31/2019 Serial Number: PATABCDE61-123456789012345678901234567890123456789... Time: 3:25:32PM Delivery Count: Ingredient Name Requested Volume (mL) Dextrose 70% 50 K Chloride 0.4mEq/mL 101.34 Sterile Water for In 60.1

Sample Formula Report

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If the Serial Number of the formula file contains more than 50 characters then the Formula Report prints up to 50 characters followed by '...'.



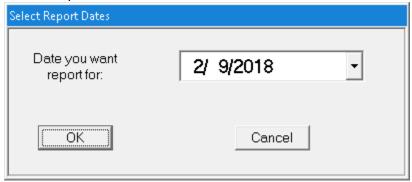
Sample Formula Report

LOG REPORT

The Log Report is a summary of the formulas that were used for compounding on a specific day.

To view the Log Report:

- 1. At the menu screen, tap Reports > Standard > Log.
- 2. At the Select Report Dates window:
 - a. Enter the date for the report.
 - b. Tap **OK**.



Select Report Dates window

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Log Report

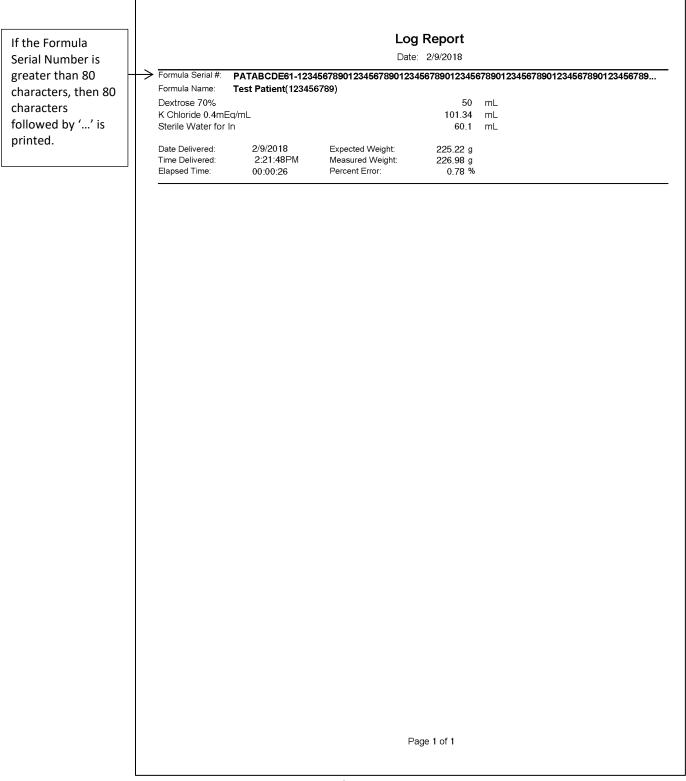
Date: 2/9/2018

		Date	. 2/9/2010		
Formula Serial #:	A1FA01E25-100038	Formula N	lame: LOOEY	, BAE	3A(Z123456789AA)
Dextrose 70%			8.08	mL	
K Chloride 0.4mE	Eq/mL		1.64	mL	
Sterile Water for	In		100	mL	
Travasol 10%			0.74	mL	
K Chloride 2mEq	ı/mL		88.13	mL	MANUAL ADD
Date Delivered:	2/9/2018	Expected Weight:	112.42 g		
Time Delivered:	3:18:31PM	Measured Weight:	112.65 g		
Elapsed Time:	00:00:13	Percent Error:	0.21 %		
Formula Serial #:	A1FA01E41-5984912	Formula N	lame: DOE, JO)NHC	5551212)
Dextrose 70%			30	mL	
K Chloride 0.4mE	Eq/mL		35	mL	
Sterile Water for	In		75.54	mL	
Travasol 10%			55	mL	
Clinisol 15%			40.08	mL	MANUAL ADD
Infuvite Adult			50.64	mL	MANUAL ADD
Date Delivered:	2/9/2018	Expected Weight:	205.05 g		
	0.40.50514	Managera d Waights	205.41 g		
Time Delivered:	3:19:58PM	Measured Weight:	205.419		

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Sample Log Report

If the Serial Number of the formula file contains more than 80 characters then the Log Report prints up to 80 characters followed by '...'.



Sample Log Report

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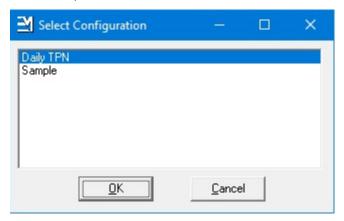
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CONFIGURATION REPORT

The Configuration Report provides information about a specific configuration.

To view the Configuration Report:

- 1. At the menu screen, tap **Reports > Standard > Configuration**.
- 2. At the Select Configuration window:
 - a. Select the configuration.
 - b. Tap **OK**.



Select Configuration window

Configuration Report

User:	Administrator	Time:	6:51:11PM
Configuration:	TPN_TEST	Date:	1/23/2018

Sequence	Port		Ingredient
1	6		K Chloride 0.4mEq/mL
2	8		Travasol 10%
3	11	U	Dextrose 70%
4	12		Sterile Water for In

[&]quot;U" marks the default universal ingredient for this configuration.

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Sample Configuration Report

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[&]quot;A" marks the allowed auto-addition ingredients for this configuration.

FORMULARY REPORT

The Formulary Report lists the ingredients that are included in the formulary. Only ingredients that may actually be mounted on the compounder should be in the formulary.

To view the Formulary Report, tap **Reports > Standard > Formulary** at the menu screen.

Date:

F۵	rmı	ılə	rv R	an	ort
гυ	THIL	ııa:	IV R	œD	oπ

Time: 2:44:28PM

5/10/2011

			<u> </u>	<u>Size</u>
Albumin 25%				
ZLB Albumin 25% 50 Vial	44206-251-05	175	1.07	50
ZLB Albumin 25% 100 Vial	44206-251-10	175	1.07	100
Aminosyn 10%				
Hospira Aminosyn 10% 500 Bag	0409-2291-03	173	1.03	500
Abbott Aminosyn 10% 500 Bag	0074-2991-03	173	1.03	500
Abbott Aminosyn 10% 1000 Bag	0074-2991-05	173	1.03	1000
Hospira Aminosyn 10% 1000 Bag	0409-2291-05	173	1.03	1000
Abbott Aminosyn 10% 1000 Bottle	0000-0000-19	174	1.03	1000
Hospira Aminosyn 10% 1000 Bottle	0409-0000-19	174	1.03	1000
Aminosyn 15%				
Hospira Aminosyn 15% 2000 Bag	0409-0000-18	173	1.05	2000
Abbott Aminosyn 15% 2000 Bag	0000-0000-18	173	1.05	2000
Aminosyn 8.5%				
Abbott Aminosyn 8.5% 500 Bottle	0000-0000-20	174	1.03	500
Hospira Aminosyn 8.5% 500 Bottle	0409-0000-20	174	1.03	500
Aminosyn HBC 7%				
Abbott Aminosyn HBC 7% 500 Bag	0074-4168-03	173	1.02	500
Hospira Aminosyn HBC 7% 500 Bag	0409-4168-03	173	1.02	500
Aminosyn II 10%				
Hospira Aminosyn II 10% 500 Bag	0409-4164-03	173	1.03	500
Abbott Aminosyn II 10% 1000 Bottle	0074-1090-05	174	1.03	1000
Abbott Aminosyn II 10% 500 Bag	0074-4164-03	173	1.03	500
Hospira Aminosyn II 10% 1000 Bottle	0409-1090-05	174	1.03	1000
Aminosyn II 15%				
Hospira Aminosyn II 15% 2000 Bag	0409-7122-07	173	1.05	2000
Abbott Aminosyn II 15% 2000 Bag	0074-7122-07	173	1.05	2000
Aminosyn II 8.5%				
Hospira Aminosyn II 8.5% 500 Bottle	0409-0000-21	174	1.03	500
Abbott Aminosyn II 8.5% 500 Bottle	0000-0000-21	174	1.03	500
Aminosyn PF 10%				
Hospira Aminosyn PF 10% 1000 Bag	0409-4179-05	173	1.03	1000
Abbott Aminosyn PF 10% 1000 Bag	0074-4179-05	173	1.03	1000
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Sample Formulary Report

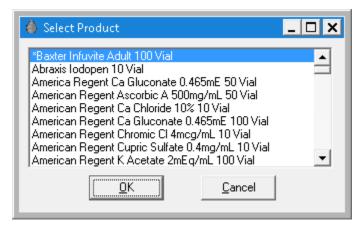
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PRODUCT BARCODES REPORT

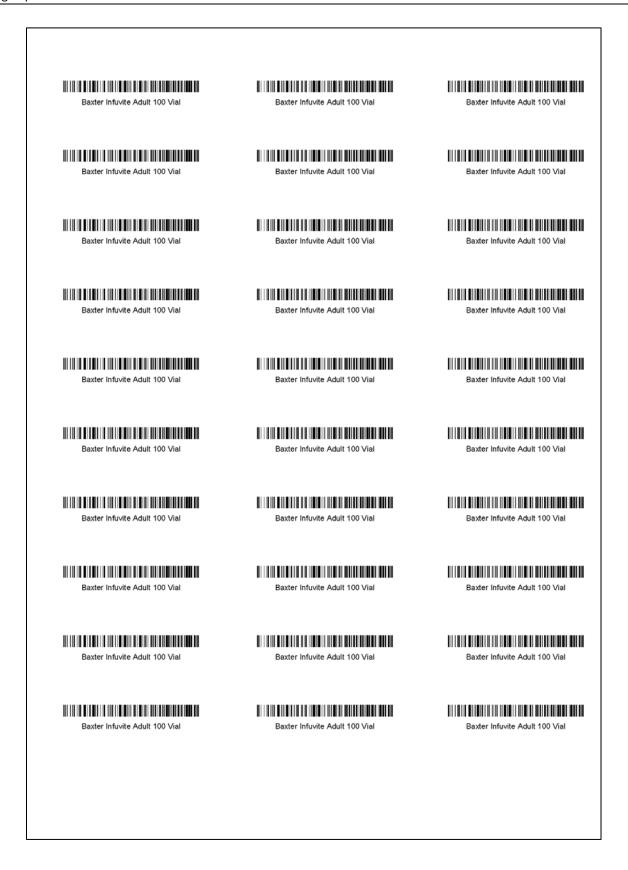
The Product Barcodes Report displays the barcodes for products that are in the formulary. You can print the report onto labels for use with products that do not have a manufacturer's barcode.

To view the Product Barcodes Report:

- 1. At the menu screen, tap **Reports > Standard > Product Barcodes**.
- 2. At the Select Product window:
 - a. Select the product.
 - b. Tap **OK**.



Select Product window



Sample Product Barcodes Report

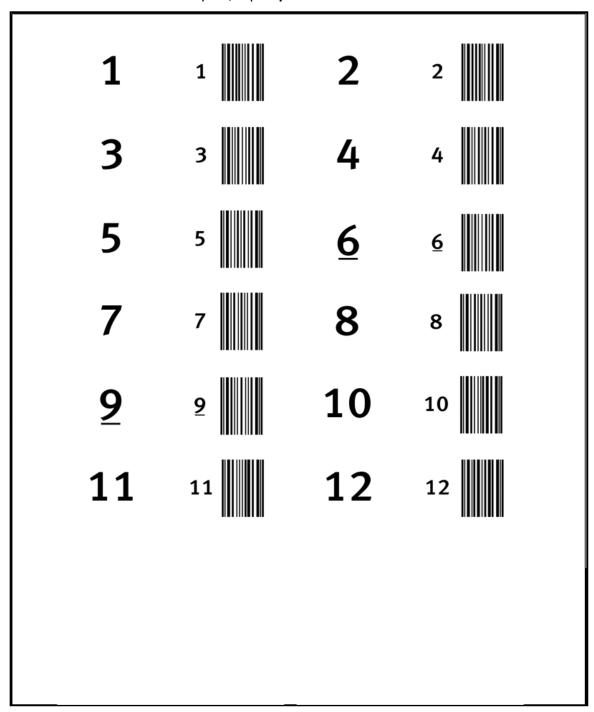
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INLET BARCODES REPORT

The Inlet Barcodes Report displays the barcodes for the inlets. You can print the report onto labels, in case you make a mistake during setup and need an extra barcode label.

To view the Inlet Barcodes Report, tap **Reports > Standard > Inlet Barcodes** at the menu screen.



Sample Inlet Barcodes Report

BLACKBOX REPORT

The Blackbox Report is a chronological list of all important system activity for a specific period of time. If necessary, Baxter may use this information for troubleshooting.

To view the Blackbox Report:

- 1. At the menu screen, select **Reports > Standard > Blackbox**.
- 2. At the Enter Begin and End Times window:
 - a. Enter the starting and ending times for the report.
 - b. Tap OK.



Enter Begin and End Times window

For assistance with reading this report, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

				Blackbox Report
Entry Date	Entry Time	<u>User Name</u>	Audit Category	Audit Message
8/21/2017	9:53:10PM	Initialization	Database	Opened database: C:\Baxter\Database\em1200.accdb
8/21/2017	9:53:10PM	Initialization	DB VERSION	DB VERSION get from database : 4
8/21/2017	9:53:11PM	Initialization	DB VERSION	DB VERSION get from database : 4
8/21/2017	9:53:11PM	Initialization	Startup	Using database C:\Baxter\Database\em1200.accdb
8/21/2017	9:53:11PM	Initialization	Startup	Application info: Product: EM1200, Build #1.4.3.2
8/21/2017	9:53:12PM	Initialization	Startup	Loading configuration MAN
8/21/2017	9:53:12PM	Initialization	Startup	Initiating Database Purge/Compaction
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Creating OPOSPacketComm
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Creating OPOS Driver
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: OPOS Driver Created
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Loading USB Scanner Driver
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Scanner Open successfully
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Scanner Claim successful
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Scanner set Enabled successful
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Scanner set DataEventEnabled successful
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Scanner set DecodeData successful
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Scanner is Idle
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Scanner Driver successfully loaded and initialized.
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Creating USBController
8/21/2017	9:53:15PM	Initialization	COMM	OPOS: Created USBController Object TJvHidDeviceController.
8/21/2017	9:53:15PM	Initialization	BARCODE	Created
8/21/2017	9:53:16PM	Initialization	PUMPSENT	0x0101
8/21/2017	9:53:16PM	Initialization	PUMPRCVD	0x0101
8/21/2017	9:53:17PM	Initialization	PUMPSENT	0x0102
8/21/2017	9:53:17PM	Initialization	PUMPRCVD	0x01020150554D502030303237
8/21/2017	9:53:17PM	Initialization	PUMP	FirmwareID: PUMP 0027
8/21/2017	9:53:17PM	Initialization	PUMPSENT	0x0115
8/21/2017	9:53:17PM	Initialization	PUMPRCVD	0x011500
8/21/2017	9:53:17PM	Initialization	PUMPSENT	0x0110
8/21/2017	9:53:17PM	Initialization	PUMPRCVD	0x01101000
8/21/2017	9:53:17PM	Initialization	PUMPSENT	0x0131
8/21/2017	9:53:17PM	Initialization	PUMPRCVD	0x0131648C0100E50C0000
8/21/2017	9:53:17PM	Initialization	PUMP	Life statistics: Revolutions=101476, Cycles=3301
8/21/2017	9:53:17PM	Initialization	FLOWSENT	0x0401
8/21/2017	9:53:17PM	Initialization	FLOWRCVD	0x0401
8/21/2017	9:53:18PM	Initialization	FLOWSENT	0x0402
8/21/2017	9:53:18PM	Initialization	FLOWRCVD	0x040201464C4F572030303237
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Sample Blackbox Report

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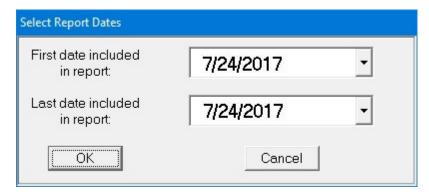
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CALIBRATION SUMMARY REPORT

The Calibration Summary Report summarizes the calibration processes for the pump and the load cell during a specific period of time. It also distinguishes between automatic and manual calibrations.

To view the Calibration Summary Report:

- 1. At the menu screen, tap **Reports > Standard > Calibration Summary**.
- 2. At the Select Report Dates window:
 - a) Enter the First and Last dates for the report.
 NOTE: The available dates are still limited by the amount of time this information is stored. For more information, refer to Storage on Page 115.
 - b) Tap OK.



Select Report Dates window

Calibration Summary Pump Calibration 7/24/2017 From: 7/24/2017 Type Result <u>Time</u> Cal Product User <u>Port</u> <u>Volume</u> 7/24/2017 3:38:05PM Manual using load cell Succeeded OEM User 0338-0013-08 12 200.00 **Load Cell Calibration** Time <u>User</u> Result 7/24/2017 3:29:17PM OEM User Succeeded Page 1 of 1

Sample Calibration Summary Report

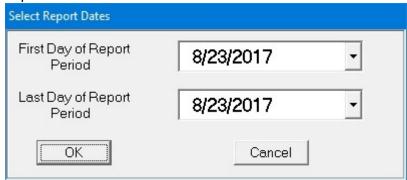
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FORMULA PRECISION REPORT

The Formula Precision Report summarizes the precision of the compounding process (how accurately the actual weight matched the expected weight) during a specific period of time.

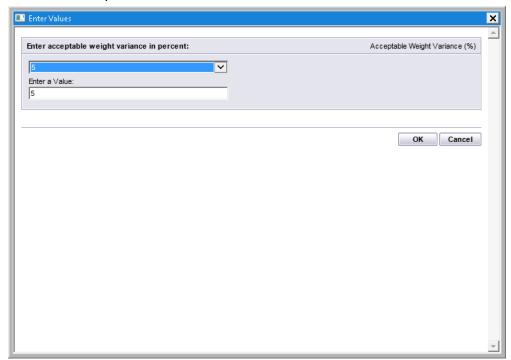
To view the Formula Precision Report:

- 1. At the menu screen, tap **Reports > Standard > Formula Precision**.
- 2. At the Select Report Dates window
 - a. Enter the First and Last dates for the report
 NOTE: The available dates are still limited by the amount of time this information is stored. For more information, refer to <u>Storage</u> on Page 115.
 - b. Tap OK.



Select Report Dates window

- 3. At the Enter Values window:
 - a. Select Acceptable Weight Variance (%) from the drop down list.
 - b. Tap **OK**.



Enter Values window

Formula Precision Summary 5/7/2019 To: 5/7/2

5/7/2019 From:

Acceptable Weight Variance: - 5.00% to 5.00%

Serial Number	Formula Name	<u>Delivered</u> <u>User</u>	Expected (g	Measured (g)	<u>%Variance</u>
5/7/2019 PATABCDE61-1 2345678901234 56789012345	Test Patient(123456789)	6:16:59PM Administrator	121.75	122.02	0.22

Summary:	Number of bags		
-5% + variance	0		
-4% to -4.99% variance	0	Maximum positive variance	0.22 %
-3% to -3.99% variance	0	Maximum negative variance	0.00 %
-2 % to -2.99% variance	0	waximum negative variance	0.00 70
-1% to -1.99% variance	0	Average variance	0.22 %
-0.01% to -0.99% variance	0	, worago variano	0.22 70
0% to 0.99% variance	1	Median variance	0.22 %
1% to 1.99% variance	0		
2% to 2.99% variance	0		
3% to 3.99% variance	0		
4% to 4.99% variance	0		
5% + variance	0		
Total Bags	1		
Bags within range	1		
Bags out of range	0		

Printed Date /Time: 5/7/2019 6:24:16PM Page 1 of 1

Sample Formula Precision Report

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If the Serial Number of the formula file contains more than 36 characters then the Formula Precision Report prints up to 36 characters followed by '...'.

If the Serial Number of the formula is greater than 36 characters then 36 characters followed by '...' is printed.

Formula Precision Summary

6:16:59PM Administrator

From: 5/7/2019

Serial Number Formula Name

PATABCDE61-1 Test Patient(123456789)

5/7/2019

To: **5/7/2019**

121.75

Expected (g) Measured (g) %Variance

0.22

122.02

Acceptable Weight Variance: - 5.00% to 5.00%

Delivered User

Summary:	Number of bags		
-5% + var	ance 0		
-4% to -4.99% var	ance 0	Maximum positive variance	0.22 %
-3% to -3.99% var	ance 0	Maximum negative variance	0.00 %
-2 % to -2.99% var	ance 0	aximam riaganta tahunoo	
-1% to -1.99% var	ance 0	Average variance	0.22 %
-0.01% to -0.99% vari	ance 0	, wordings variation	J.22 /
0% to 0.99% var	ance 1	Median variance	0.22 %
1% to 1.99% var	ance 0		
2% to 2.99% var	ance 0		
3% to 3.99% var	ance 0		
4% to 4.99% var	ance 0		
5% + var	ance 0		

Printed Date /Time: 5/7/2019 6:24:16PM Page 1 of 1

Total Bags

Bags within range

Bags out of range

1

1

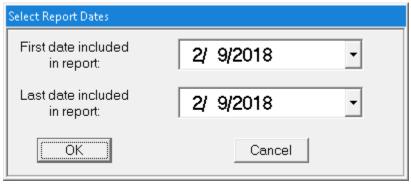
0

INGREDIENT USAGE REPORT

The Ingredient Usage Report summarizes the ingredient usage during a specific period of time. This report is used to manage inventory.

To view the Ingredient Usage Report:

- 1. At the menu screen, select **Reports > Standard > Ingredient Usage**.
- 2. At the Select Report Dates window:
 - a. Enter the First and Last dates for the report.
 - b. Tap **OK**.



Select Report Dates window

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Ingredient Name	From:	Ingredient Usage 2/9/2018 To:	2/9/2018 <u>Volume Used (ml)</u>	Containers
Formulary Ingredients				
Dextrose 70%			38.08	
Baxter Dextrose 70% 2000 Ba	g	0338-0719-06	38.08	1
K Chloride 0.4mEq/mL			36.64	
Baxter K Chloride 0.4mEq/mL	60 Bag	0338-0703-41	36.64	1
Sterile Water for In			195.54	
Baxter Sterile Water for In 200	0 Bag	0338-0013-06	195.54	1
Travasol 10%			55.75	
Baxter Travasol 10% 2000 Baç	J	0338-0644-06	55.75	1
Clinisol 15%			40.08	
nfuvite Adult			60.84	
K Chloride 2mEq/mL			88.13	
		Page 1 of 1		

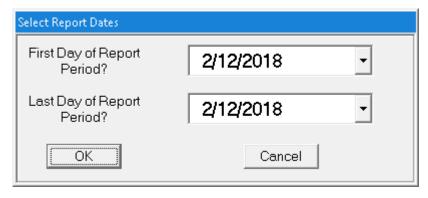
Sample Ingredient Usage Report

BAG USAGE REPORT

The Bag Usage Report summarizes the bag usage during a specific period of time. This report is used to manage inventory.

To view the Bag Usage Report:

- 1. At the menu screen, tap Reports > Standard > Bag Usage.
- 2. At the Select Report Dates window:
 - a. Enter the First date and Last date for the report.
 - b. Tap **OK**.



Select Report Dates window

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	Bag Usage		
	2/12/2018 2/1	2/2018	
Part Number	<u>Description</u>	Nu	mber Used
x41	EVA Container 3000mL.		1
		Total:	1

Sample Bag Usage Report

FLOW FACTORS REPORT

The Flow Factors Report lists the flow factors for all the ingredients in the current configuration.

To view the Flow Factors Report, tap **Reports > Standard > Flow Factors** at the menu screen.

NOTE: You do not need to view this report unless directed by Baxter Technical Services.

			Flow Factors		
Config	guration	n: TPN-TEST			
Date:		12/24/2019			
Time:		3:21:18PM			
<u>Port</u>	Seq	Product Name	Min Vol (mL)	Max Vol (mL)	Flow Factor
6	1	Baxter K Chloride 0.4mEq/mL 50 Bag			
			0.00	10.00	1.0400
			10.00	12,000.00	1.0180
9	2	Baxter Travasol 10% 2000 Bag			
			0.00	5.00	1.0370
			5.00	12.50	0.9990
			12.50	12,000.00	1.0090
11	3	Baxter Dextrose 70% 2000 Bag			
			0.00	5.00	1.0050
			5.00	12.50	1.0010
			12.50	12,000.00	1.0250
12	4	Baxter Sterile Water for In 2000 Bag			
			0.00	5.00	1.0150
			5.00	12.50	0.9770
			12.50	12,000.00	1.0010

Sample Flow Factors Report

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TROUBLESHOOTING

HANDLING INTERRUPTIONS AND ERRORS

If you encounter any of these interruptions or errors, take the suggested actions. If the issue persists, contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

Issues with the Barcodes

Issue / On-screen Text	Explanation	Suggested Actions
The label on the source	The barcode on the source	Check that the barcode on the source container is
container cannot be	container is not legible.	legible.
scanned.		
Text:		
Unable to scan		
The label on the source	The ingredient is not in	1. Check that the barcode on the source container
container cannot be	the formulary.	is legible.
scanned.		2. Check that the Barcode ID in the formulary is
		correct. Refer to <u>Adding or Editing a Product</u> on
Text:		Page 144.
Not in Formulary		3. If the ingredient is not in the formulary, add the
		ingredient. Refer to <u>Adding or Editing an</u>
		<u>Ingredient</u> on Page 142.
The label on the patient	The barcode reader does	1. Check that the green LED on the barcode
bag cannot be scanned.	not indicate that it is	reader illuminates when you scan a barcode.
	operational.	 If the LED does not illuminate, check that
		the cable for the barcode reader is
		connected properly to the display.
		 If the LED illuminates, reboot the
		compounder. Refer to Rebooting and
		Shutting Down on Page 32.
		2. Check that the barcode reader and its cable are
		not damaged.
		3. At the menu screen, tap Compound > Select
		Formula, then select the formula you need. If it
		is not listed, check that the Ethernet cable is
		connected properly to both the display and the
		order-entry computer. Then reboot the order-
		entry computer and the compounder. Refer to
		Rebooting and Shutting Down on Page 32.
No barcodes can be	The barcode reader does	Disconnect the cable for the barcode reader
scanned.	not indicate that it is	from the display, then reconnect this cable.
	operational.	2. Check that the barcode reader and its cable are
		not damaged.
		3. If the cables for the keyboard and mouse are
		connected to the display, disconnect these
		cables. Then reboot the compounder. Refer to
		Rebooting and Shutting Down on Page 32.
		4. Contact Baxter Technical Services for a barcode
		programming sheet. Refer to <u>Getting Help</u> on
		Page 22.

Issue / On-screen Text	Explanation	Suggested Actions
Text:	The .PAT/.FRM file is not	Correct the .PAT/.FRM file in the order entry
Unable to retrieve	available.	software, then print and scan a new barcode
formula for scanned		label.
barcode < Formula File		2. Check that the Ethernet cable is connected
Name> from the formula		properly to both the display and the order-
file directory <formula file<="" th=""><th></th><th>entry computer.</th></formula>		entry computer.
directory>. There may be		3. Reboot the compounder. Refer to Rebooting
an issue with network		and Shutting Down on Page 32.
connectivity, please		4. Check that the network is functioning.
reboot the compounder.		5. Check the path on both the order-entry
		computer and the compounder. Refer to
If the problem persists,		Setting Up the Directories Options on Page 122.
please contact Baxter		
Technical Services		
Text:	The 2D Formula Barcode	1. Correct the serial number of the 2D Formula
2D Formula Barcode serial	serial number does not	Barcode, then print and scan the new 2D
number (X) does not	meet the Order entry	Formula Barcode.
meet current Order Entry	specification	
specification and cannot		
be loaded.		
Text:	The 2D Formula Barcode	1. Correct the content of the 2D Formula Barcode,
The following formula	does not meet the Order	then print and scan the new 2D Formula
name or data is not	entry specification	Barcode.
supported.		
Contact the Order Entry		
System Administrator.		
Content: "%s"		
Text:	2D Formula Barcode serial	2. Either, correct the length of the serial number
2D Formula Barcode serial	number format (X) does	of the 2D Formula Barcode (Maximum up to
number format (X) does	not meet the configured	the value specified in the security tab), then
not meet the current	maximum serial number	print and scan the new 2D Formula Barcode
configured maximum	length, set in options	(or)
serial number length.	screen → security tab.	3. Increase the serial number length value in the
Refer to security tab in	The serial number length	options screen→security tab, such that the
options screen or contact	should be less than or	serial number length available in the 2D
the Order Entry systems.	equal to the value	Formula Barcode is lesser than or equal to the
	specified in the security	configured value in security tab.
	tab.	

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Issue / On-screen Text	Explanation	Suggested Actions
Text:	The 2D Formula Barcode	Correct the length of the Ingredient ID, it must
2D Formula Barcode	contains ingredient(s)	not exceed 20 characters.
contains the following	whose Ingredient ID(s)	2. Print the 2D Formula Barcode and scan the new
errors. So 2D Formula	exceeds the maximum	2D Formula Barcode.
Barcode (X) cannot be	allowable characters (20).	25 Formala Barcode.
loaded.	anowasie enaracters (20).	
1000001		
1) Following Ingredient		
ID(s) exceeds the		
maximum characters (20).		
, ,		
(%s)		
You must correct the		
Ingredient ID(s) then load		
the formula.	The 2D Fermin 1 D	4 Compatible law still 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Text: 2D Formula Barcode	The 2D Formula Barcode	1. Correct the length of the Ingredient Name, it
	contains ingredient(s) whose ingredient name(s)	must not exceed 25 characters. 2. Print the 2D Formula Barcode and scan the new
contains the following errors. So 2D Formula	exceeds the maximum	2. Print the 2D Formula Barcode and scan the new 2D Formula Barcode.
Barcode (X) cannot be	allowable characters (25).	2D Formula Barcode.
loaded.	allowable characters (23).	
loaded.		
1) Following manual		
Ingredient Name(s)		
exceeds the maximum		
characters (25).		
,		
(%s)		
You must correct the		
manual Ingredient		
Name(s) then load the		
formula.		
Text:	The 2D Formula Barcode	1. Correct the format of the Ingredient Volume, it
2D Formula Barcode	contains ingredient(s)	must be of the format (####.##). 2. Print the 2D Formula Barcode and scan the new
contains the following	whose ingredient volume does not meet the format	
errors. So 2D Formula Barcode (X) cannot be		2D Formula Barcode.
loaded.	(####.##).	
ioaucu.		
1) Following Ingredient		
Volume(s) does not meet		
the format (####.##).		
(%s)		
You must correct the		
Ingredient Volume(s)		
format then load the		
formula.		

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Issue / On-screen Text	Explanation	Suggested Actions
Issue / On-screen Text Text: 2D Formula Barcode contains the following errors. So 2D Formula Barcode (X) cannot be loaded.	Explanation The 2D Formula Barcode contains same ingredients appearing multiple times whose volumes are different.	 Suggested Actions Correct the Ingredient names having the same ingredient name multiple times. Print the 2D Formula Barcode and scan the new 2D Formula Barcode.
Ingredient (%s) appears multiple times, with volume (%d1) and volume(%d2)		
Text: Barcode reader (X): barcode contains an invalid Code 39 character.	The barcodes for formulas must use the Code39 symbology, which has a restricted character set.	 Reprint the barcode. Scan the barcode again.
Text: Barcode reader (X): barcode contains an invalid MOD43 check digit.	The barcodes for formulas must use the Code39 symbology with a MOD43 check digit appended.	 Reprint the barcode. Scan the barcode again.
Text: Barcode reader (X): invalid barcode or formula not available.	The barcode that was scanned does not match a formula.	 Check that the network settings are correct. Check that the Ethernet cable is connected properly to both the display and the orderentry computer. Check the database to ensure that the formula exists.

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Issues with the Formulas, Ingredients and Configurations

Issue / On-screen Text	Explanation	Suggested Actions
Text: This formula contains <ingredient name="">, which is not currently on the configuration. Do you wish to add it to the</ingredient>	The ingredient is an auto- addition ingredient.	Add the ingredient. Refer to <u>Performing an Auto-Addition</u> on Page 90.
configuration? Text: Configuration must be verified before compounding.	The configuration is not primed and verified.	Prime and verify the configuration. Refer to <u>Priming</u> and <u>Verifying</u> on Page 57.
Text: The following ports contain products that have been spiked longer than allowed. Port Product Time Spiked Allowed Hang Time (Hours) < list of products>.	One or more ingredients are expired.	 Tap Cancel. Check the expiration dates of all the ingredients. Change the container of each expired ingredient.
Text: Ingredient <ingredient name=""> must be manually added and its requested volume of <requested volume=""> mL exceeds the maximum manual add volume of <max add="" manual="" volume=""> mL.</max></requested></ingredient>	The ordered volume of the product exceeds the maximum volume for manual additions.	 Tap Cancel. Check that the Drug ID is correct and that it matches the code number from the order-entry software. Refer to Adding or Editing a Product on Page 144.
Text: Manual Add	The product is not included in the configuration, or its ordered volume is less than 0.2 mL. The product is included in the physical configuration, and its ordered volume is at least 0.2 mL, but it does not match any products in	Add the product manually. Refer to Performing a Manual Addition on Page 92. Check that the Drug ID is correct and that it matches the code number from the order-entry software. Refer to Adding or Editing a Product on Page 144.
Text: Swap Container: Your container of <ingredient name=""> is empty. You have <remaining volume=""> mL left to run. Please</remaining></ingredient>	the software configuration. The container is almost empty and needs to be replaced.	Check that the container is almost empty. If the container is almost empty, replace it. Refer to Replacing a Source Container on Page 93. If the container is not almost empty, check that
change the container now.		it is the correct container, and contact Baxter Technical Services. Refer to <u>Getting Help</u> on Page 22.

Issue / On-screen Text	Explanation	Suggested Actions
The OK button is not	The ingredient detail	Tap each ingredient button to view the details.
active on the Hang Source	windows have not been	Refer to Attaching the New Ingredients and Inlets on
Containers screen, and the	viewed.	Page 47.
ingredient buttons do not		
change to a blue color.		
During priming, the fluid	The inlet is not attached	Remove the source container from the vial rack
does not flow through the expected inlet.	to the proper port.	or hanger and turn it right-side-up, to prevent fluid from flowing.
		2. Remove the inlet from the incorrect port and
		attach it to the correct port.
		Return the source container to the vial rack or hanger.
Text:	The tube set needs to be	Attach a calibration bag and continue. Refer to
Flushing with Universal	flushed prior to	Attaching the Calibration Bag on Page 73.
Ingredient. Please attach	compounding.	
flush/calibration bag.		
Text:	There is not enough	1. Tap Cancel.
Formula Conflict:	ingredient flush between	2. Contact Baxter Technical Services. Refer to
Formula contains	incompatible ingredient groups.	Getting Help on Page 22.
incompatible ingredients	groups.	
with insufficient flush		
volume between them.		
First Ingredient:		
<ingredient name=""></ingredient>		
Second Ingredient:		
<ingredient name=""></ingredient>		
Required Flush: < required		
volume>		
Available Flush:		
<available volume=""></available>		

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Issue / On-screen Text	Explanation	Suggested Actions
Text:	The formula does not	WARNING
Formula Conflict:	contain the minimum	If you choose to Increase Ingredient
Additional < flush volume>	required Universal	Volume, the clinical impact should be
mL of < <i>Universal</i>	Ingredient.	considered. This option increases the
Ingredient> required for flush.		volume in the bag and is not part of the original order.
indsin.		Increasing the Universal Ingredient volume may change the overall formula ordered. Consult a pharmacist before compounding.
		IMPORTANT! This function requires Formula Edit
		permissions, which Baxter does not recommend using. For more information about user groups and permissions, refer to Setting Up the Users on Page 124.
		Tap one of these options:
		Tap Change UI To to change the Universal
		Ingredient to one that has the minimum volume
		required and does not have flush ingredient.
		Then tap OK and continue with the steps below.
		WARNING
		A calibration bag must be used during all Universal Ingredient flushes. You must replace the original patient bag with a calibration bag for the flush, then reattach the original patient bag. If this is not done, the patient bag could contain an unintended volume and/or ingredient.
		 If a patient bag is attached, remove it. Refer to Removing the Patient Bag on Page 89. Change the Universal Ingredient. Refer to Changing the Universal Ingredient on Page 108, starting at Step 2. Attach the patient bag. Refer to Attaching the Patient Bag on Page 84. Repeat the compounding process.
Text:	All ingredients need flow	Click Ok on the error message.
The requested product	factors prior to	Click Ok on the error message.
<pre><pre><pre><pre><pre><pre><pre><pre></pre></pre></pre></pre></pre></pre></pre></pre>	compounding.	2. Contact Baxter Technical Services for
be added to the		adding/updating flow factors.
configuration as the flow		
factors are not set up for		
the associated inlet <inlet< th=""><th></th><th></th></inlet<>		
name>.		
Please confirm the correct		
inlet is associated for this		
product or enter the		
correct flow factors for		
the requested product		
and associated Inlets.		
Contact Baxter Technical Services for help		

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Issue / On-screen Text Explanation	Suggested Actions
Text: Formula cannot be pumped. The following Products contain invalid flow factors: st of products> Please contact Baxter Technical Services to obtain the correct flow factors and for help to enter them All ingredients need flow factors prior to compounding. compounding. Plant Explanation All ingredients need flow factors prior to compounding. compounding.	 Click Ok on the error message. Contact Baxter Technical Services for adding/updating flow factors.

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Issues with the Calibration

On-screen Text	Explanation	Suggested Actions
Load cell not calibrated.	The load cell is not	1. Tap Yes.
Must calibrate to	calibrated.	2. Calibrate the load cell. Refer to <u>Calibrating the</u>
continue.		Load Cell on Page 36.
Span	The calibration of the load	1. Check that:
Calibration out	cell is out of range.	The load cell is level and locked into place.
of Range	, and the second	 There is nothing (for example, the outlet tube, bag or cable for the load cell) touching the pan or base of the load cell. There are no environmental factors (for example, fans) interfering with the load cell. Calibrate the load cell. Refer to Calibrating the Load Cell on Page 36. Read the on-screen messages carefully, and make sure that you do not place the calibration weight on the load cell too early.
The pump has not been	The pump is not	1. Tap Yes.
calibrated since the last	calibrated.	Calibrate the pump. Refer to <u>Calibrating the</u>
tube set change. This		Compounder on Page 69.
operation must be		
completed prior to		
pumping a solution.		
Would you like to		
calibrate the pump now?		
Pump calibration failed.	The calibration of the pump failed.	 Check that the valve set is installed properly. Refer to Installing the New Valve Set on Page 44. For the source container of water, check the following conditions. Refer to Attaching the New Ingredients and Inlets on Page 47. The correct inlet is used. The inlet is not kinked. The bag is spiked properly. Refer to Page 51. Clean any spills near the pump rotor. Refer to Cleaning the Compounder on Page 101. Calibrate the load cell. Refer to Calibrating the Load Cell on Page 36. Calibrate the pump. Refer to Calibrating the Compounder on Page 69.
Text: You have exceeded the maximum allowed calibration limit of 20000mL, the system will recalibrate now. Do you want to calibrate now?	Certain situations may prevent auto-calibration from happening. Therefore a manual calibration is required.	Click Yes Calibrate the pump. Refer to <u>Calibrating the Compounder</u> on Page 69

Issues with the Weight and Load Cell

On-screen Text	Explanation		Suggested Actions
Expected Weight:	The final bag weight is out	1.	Check that all the source containers are spiked
<pre><calculated weight=""> gm</calculated></pre>	of range.		properly. Refer to the steps for spiking a
			container, starting on Page 50.
Actual Weight: <actual< th=""><th>After the compounder</th><th>2.</th><th>Check that the pump rotor is clean. Refer to</th></actual<>	After the compounder	2.	Check that the pump rotor is clean. Refer to
weight> gm	delivers all the		Cleaning the Compounder on Page 101.
	ingredients, the weight of	3.	Check that the outlet tube is installed properly.
Difference: <weight< th=""><th>the patient bag differs</th><th></th><th>Refer to Installing the New Valve Set on</th></weight<>	the patient bag differs		Refer to Installing the New Valve Set on
difference>%	from the expected weight		Page 44.
	by more than the	4.	Calibrate the load cell. Refer to Calibrating the
The final weight of this	acceptable difference.		Load Cell on Page 36.
solution is outside of the		5.	Calibrate the pump. Refer to Calibrating the
acceptable limit of +/-5%			Compounder on Page 69.
		6.	Compound a large-volume solution with at
Possible Cause: Unknown			least 205 mL of water to make the compounder
			calibrate automatically.
Expected Weight:	An individual ingredient	1.	Check that all the ingredients and inlets are
<calculated weight=""> gm</calculated>	delivery is out of range.		correct.
	.6	2.	Check that the tube set is installed properly.
Actual Weight: <actual< th=""><th>After the compounder</th><th></th><th>Refer to <u>Installing the New Valve Set</u> on</th></actual<>	After the compounder		Refer to <u>Installing the New Valve Set</u> on
weight> gm	delivers an ingredient, the		Page 44 and Attaching the New Ingredients and
Difference and the	weight of the patient bag	_	Inlets on Page 47.
Difference: <weight< th=""><th>differs from the expected</th><th>3.</th><th>On the MixCheck Report, check for references</th></weight<>	differs from the expected	3.	On the MixCheck Report, check for references
difference>%	weight by more than the		to occlusions and bubbles. Refer to MixCheck
The final weight of this	acceptable difference.		Report on Page 162. Have a pharmacist check the accuracy.
solution is within the	The compounder checks	4.	Check that all the source containers are spiked
acceptable limit of +/-5%,	the weight after individual	4.	properly. Refer to the steps for spiking a
however some	ingredient deliveries over		container, starting on Page 50.
ingredients may not have	100 mL.	5.	Check that the pump rotor is clean. Refer to
delivered correctly.	100		Cleaning the Compounder on Page 101.
,		6.	Calibrate the load cell. Refer to <u>Calibrating the</u>
Possible Cause:			Load Cell on Page 36.
<ingredient name=""> is</ingredient>		7.	Calibrate the pump. Refer to <u>Calibrating the</u>
possibly <underweight <="" th=""><th></th><th></th><th>Compounder on Page 69.</th></underweight>			Compounder on Page 69.
overweight> by <weight< th=""><th></th><th>8.</th><th>Compound a large-volume solution with at</th></weight<>		8.	Compound a large-volume solution with at
error> grams			least 205 mL of water to make the compounder
			calibrate automatically.
		9.	Contact Baxter Technical Services to check that
			the flow factors are correct. Refer to Getting
			<u>Help</u> on Page 22.
Bag out of range	Dextrose is pumping too	1.	Check that there are no environmental factors
	quickly or slowly.		interfering with pumping dextrose.
			 Keep the room temperature stable.
			Always allow refrigerated dextrose to return
			to room temperature before using it.
		2.	Check that the source container is spiked
			properly. Refer to the steps for spiking a
			container, starting on Page 50.
		3.	Check that the correct inlet is assigned to
			dextrose in the formulary. Refer to Adding or
			Editing a Product on Page 144.

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On-screen Text	Explanation	Suggested Actions
The bag currently on the load cell does not appear to be empty.	Before pumping starts, the load cell detects that the destination bag contains fluid.	 If the bag is not empty, and you are: Compounding the solution, refer to Step 2 on Page 86 Calibrating the compounder, refer to Step 4 on Page 70 If the bag is empty: Tap No. At the Operation Cancelled message, tap OK. Remove the bag from the load cell. Refer to: Removing the Patient Bag on Page 89 Removing the Calibration Bag on Page 73 Calibrate the load cell. Refer to Calibrating the Load Cell on Page 36. If necessary, reattach the appropriate bag to the load cell. Refer to: Attaching the Patient Bag on Page 84 Attaching the Calibration Bag on Page 73
There does not appear to be a bag hung on the scale.	The load cell detects that the destination bag is not attached.	If the bag is not attached, attach the appropriate bag to the load cell. Refer to: • Attaching the Patient Bag on Page 84 • Attaching the Calibration Bag on Page 73 If the bag is attached: 1. Tap No. 2. Calibrate the load cell. Refer to Calibrating the Load Cell on Page 36.

Issues with the Pump

On-screen Text	Explanation	Suggested Actions
Pump was paused.	The pump was paused	If the pump was paused by tapping Pause , tap
	during normal operation.	Resume to continue compounding.
[Error: 01-13-002] Unable	The pump fault occurred.	1. At the pump screen, tap Stop and follow the
to start the pump		on-screen instructions.
because the pump is in a		2. Reboot the compounder. Refer to Rebooting
fault state.		and Shutting Down on Page 32.
Pump faulted. Unable to	A system fault or power	1. Write a large "X" on the label of the patient
close valve. Valve is	loss occurred.	bag, then remove and discard the bag.
moving.		2. Reboot the compounder. Refer to Rebooting
		and Shutting Down on Page 32.
Pump is in fault state and	A pump fault occurred.	Tap Yes to reset the pump.
must be reset before use.		
Reset the pump?		

Issues with the Occlusion Detector / "Flow Sensor"

NOTE: For all of these messages about the occlusion detector self-test, tapping **Cancel** displays a *Contact Baxter* message and disables your ability to compound a solution or calibrate the compounder.

On-screen Text	Explanation	Suggested Actions
The Occlusion Detector	The test failed, possibly	Contact Baxter Technical Services. Refer to Getting
Test failed.	because the detector	Help on Page 22.
Sensor failure.	malfunctioned or the tube	
	set was not installed	
Select OK to retry	properly.	
Select Cancel to exit		
The Occlusion Detector	The test failed because an	1. Tap Cancel.
Test failed.	air bubble was detected in	2. To help reduce the occurrence of bubbles and
Air detected in fluid	the common fluid	make their detection more accurate, refer to
pathway.	pathway.	the note on Page 97.
		, and the second
Select OK to Retry.		NOTE: To perform the test again, you must re-prime
Select Cancel to Exit.		at least one non-UI inlet and then exit the PRIME
		AND VERIFY screen.
The Occlusion Detector	The test did not finish	1. Close the pump door.
Test failed.	because the pump door	2. Tap OK . The test occurs again.
Pump door open.	was opened during the	
	test.	
Select OK to Retry.		
Select Cancel to Exit.		
The Occlusion Detector	The test did not finish	Tap OK . The test occurs again.
Test failed.	because the pump was	
Pump was paused.	paused during the test.	
Select OK to Retry.		
Select Cancel to Exit.		
The Occlusion Detector	The test failed for an	Tap OK . The test occurs again.
Test failed.	unknown reason.	
Select OK to Retry.		
Select Cancel to Exit.		
The Occlusion Detector	The test did not start	1. Tap Cancel.
Test did not run because	because an air bubble was	2. To help reduce the occurrence of bubbles and
the bubble test failed.	detected in the common	make their detection more accurate, refer to
	fluid pathway, or the	the note on Page 97.
	outlet tube was not	NOTE TO COLUMN 1
	installed properly.	NOTE: To perform the test again, you must re-prime
		at least one non-UI inlet and then exit the PRIME
C	The second of C. U. C.	AND VERIFY screen.
Cannot set flow sensor	The compounder failed to	Contact Baxter Technical Services. Refer to Getting
status:	set the status of the	Help on Page 22.
	occlusion detector when	
	starting to pump.	

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Other Issues

Issue / On-screen Text	Explanation	Suggested Actions
The compounder does not	The power cord or the	3. Press and hold the power button until the green
power up.	cable for the display is	LED is illuminated.
	disconnected.	4. Clean the power button.
		5. Check that the power cord is connected to the
		main module and the power source.
		6. Check that the cable for the display is
		connected properly to both the display and the
		main module.
	The power source is not	Connect the power cord to another power source.
	functional.	
The screen of the display	The cable for the display is	1. Check that the cable for the display is
does not respond to	disconnected.	connected properly to both the display and the
touch.		main module.
		Disconnect the cables for the mouse and leading the display.
The compounder connet	The network is temperarily	keyboard from the display.
The compounder cannot retrieve orders from the	The network is temporarily unavailable.	Loading a Formula by Connecting a USB drive. Refer to
order-entry computer.	unavanable.	Loading a Formula by Connecting a USB Drive on Page 207.
order-entry computer.	The barcode label for the	Contact Baxter Technical Services. Refer to Getting
	patient bag cannot be	Help on Page 22.
	printed.	THEID ON FURGE 22.
The MixCheck Report does	The printer is	Check that the printer is connected and turned on.
not print.	disconnected or turned	,
	off.	
	Printing was cancelled	Check that the MixCheck Report is available
	inadvertently.	when you print old MixCheck Reports. Refer to
	·	Page 162.
		Be aware that the message about the MixCheck
		Report being printed appears after you tap OK
		at the message about the final weight. If you
		quickly tap more than once, you might
		inadvertently tap Cancel Printing.
	The path to the printer is	Check the path to the printer. Refer to Setting Up
	not set up properly.	the Directories Options on Page 122.
Text:	An internal software error	Contact Baxter Technical Services. Refer to <u>Getting</u>
An unknown pump	occurred.	Help on Page 22.
error/valve error occurred	TI 20 5	
Text:	The 2D Formula	Create a new order in the order-entry software.
Bad file format	Barcode/.PAT /.FRM file	
	being read does not match	
Text:	the expected format. During the compounding	1. Tap Continue.
Cancellation in progress.	process, a necessary	Tap Continue. Write a large "X" on the label of the patient
Solution will need to be	container replacement	bag, then remove and discard the bag.
discarded. Continue?	was cancelled.	bug, then remove and discard the bag.
Text:	Compaction of the	Close the other program that is accessing the
Cannot open DB file X	database failed because	database.
exclusively	another program was	Try compacting the database again. Refer to
, 	accessing the database.	Compacting the Database on Page 107.
		3. Reboot the compounder. Refer to Rebooting
		and Shutting Down on Page 32.

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Issue / On-screen Text	Explanation	Suggested Actions
Text:	The database was	Contact Baxter Technical Services. Refer to Getting
Cannot open DB X after	compacted but cannot be	Help on Page 22.
compaction	opened. There may be a	
-	hard drive error or	
	database corruption.	
Text:	The pump failed to resume	Close the pump door.
Cannot resume:	compounding.	
Text:	The cable for the display is	Check that the cable for the display is connected
Compounder connection	disconnected or damaged.	properly to both the display and the main module,
not established. Must		and that the cable is not damaged.
connect to continue.		
Text:	A software error occurred.	Reconnect the cord and cables. Refer to Step 6 on
No Pump Device Assigned		Page 24.
Text:	A software error occurred.	Reconnect the cord and cables. Refer to Step 6 on
No Scale Device Assigned		Page 24.
Text:	A software error occurred.	Reconnect the cord and cables. Refer to Step 6 on
No Valve Device Assigned		Page 24.
Text:	A hardware	1. Shut down the compounder. Refer to Rebooting
Time out.	communication error	and Shutting Down on Page 32.
	occurred.	2. Check that the cord and cables are connected
		properly. Refer to <u>Installing the Compounder</u> on
		Page 23.
		3. Turn the compounder on. Refer to Starting <u>Up</u>
		and Logging In on Page 30.
Text:	The current database	Contact Baxter Technical Services. Refer to <u>Getting</u>
Unable to save current DB	cannot be saved. There	Help on Page 22.
	may be a hard drive	
	failure, missing directory,	
	network failure (if the	
	destination is on a	
	network drive) or issue	
Tarak	with permissions.	Debootable community D. C. J. D. J. J.
Text:	A port cannot be closed.	Reboot the compounder. Refer to Rebooting and
Valve is moving.	Packup failed due to	Shutting Down on Page 32.
Text:	Backup failed due to	If you are saving backups on a server confirm the
"Backup failed:	configured backup directory path is not	network connectivity.
' <configured backup="" path<="" th=""><th>available in the</th><th></th></configured>	available in the	
with Database name>' is	compounder.	If the problems till persists check the path of the
not a valid path. Make	compounder.	backup folder. Refer to <u>Setting Up the Directories</u>
sure that the path name is		Options on Page 122.
spelled correctly and that you are connected to the		· -
server on which the file		
resides"		
resides		

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LOADING A FORMULA BY CONNECTING A USB DRIVE

Some facilities may use this method if they use order-entry software but the network is temporarily unavailable.

IMPORTANT! This method requires:

- Formula Entry permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 124.
- Order-entry software on a separate computer. This software must be able to produce both a .PAT/.FRM file and a corresponding label with a barcode. Both the .PAT/.FRM file and barcode must be compatible with the compounder. Abacus software meets these requirements. For more information, or if a barcode cannot be printed, contact Baxter Technical Services. Refer to Getting Help on Page 22.
- USB drive

NOTE: Be sure that the USB drive is free of viruses.

• Barcode reader at the compounder

In the order-entry software, the pharmacist creates an order, which creates a barcode and the corresponding .PAT/.FRM file that contains the patient information and the formula. The pharmacist saves the order onto a USB drive. A corresponding label with the barcode prints at the same time. Typically, a technician applies this label to a new patient bag and brings it to the compounder. However, this process depends on your facility's protocol.

At the compounder:

- 1. Connect the USB drive to a USB port on the bottom of the display.
- 2. Set up the EXACTAMIX software to look for formula files on the USB drive. For instructions, refer to <u>Setting Up the Directories Options</u> on Page 122.

NOTE: The software will continue to look for formula files in this location until you change it back to the original location.

3. Scan the barcode on the label of the patient bag.

The compounder retrieves the order file from the USB drive and populates the pump screen with the name and volume of each ingredient to be pumped. The compounder reads the code number of each ingredient in the formula and matches this number to one in the formulary. In the United States, the code number is usually the NDC.

WARNING



The code number for each product in the formula must exactly match the code number for that product in the compounder's formulary. If a code number is assigned to one product in the order-entry software, and that number is assigned to a different product in the compounder's formulary, the compounder may pump the wrong ingredient. It is the user's responsibility to ensure that code numbers are properly and consistently assigned in both systems.

NOTE: If any ordered ingredients are not in the configuration on the compounder, are not allowed as auto-additions or have a volume less than 0.2 mL, the compounder software will identify these ingredients as manual additions.

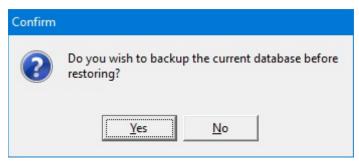
4. Continue with Fulfilling the Order (Basic Process) on Page 84.

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RESTORING THE DATABASE

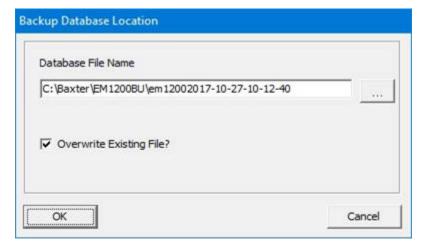
If certain types of issues occur, Baxter Technical Services may ask you to restore the database.

- 1. At the menu screen, tap **Tools > Database > Restore Database**.
- 2. At the Do you wish to backup message, if you:
 - Want to back up the current database before restoring, tap Yes and continue with the next step
 - Do not want to back up the current database before restoring, tap No and skip to step 5



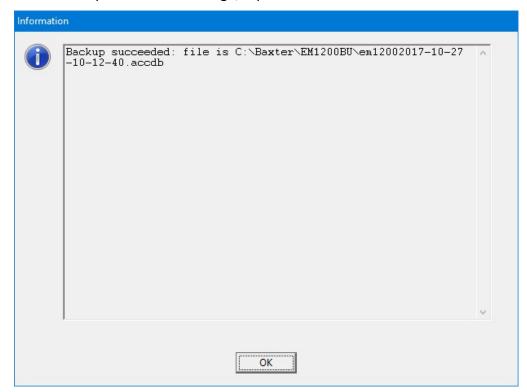
Message

- 3. At the Backup Database Location window:
 - a. If desired, change the location of the backup by tapping the button to the right of the current location (not recommended).
 - b. Check **Overwrite Existing File?** to replace the previous backup file.
 - c. Tap OK.



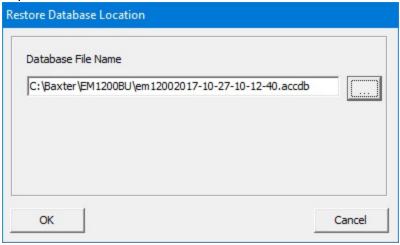
Backup Database Location window

4. At the Backup succeeded message, tap **OK**.



Message

- 5. At the Restore Database Location window:
 - a. If desired, change the location of the backup you want to restore by tapping the button to the right of it.
 - b. Tap **OK**.



Restore Database Location window

6. At the Database restored successfully message, tap **OK**.

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The compounder is now ready to use the restored database.



Message

NOTE: Upon login Baxter recommends resetting the directories to the correct path. Refer to section <u>Setting Up the Directories Options</u> on Page 122.

GLOSSARY

Use this glossary to help you understand any terms that may be unfamiliar.

Term	Definition			
acceptable weight variance	The percentage by which the final weight of the compounded solution,			
	or the weight of an ingredient delivery, is allowed to differ from the			
	expected weight. You can specify the variance.			
alarm	An audible tone that indicates an error state.			
auto-addition	An option that allows you to add an ingredient to the existing			
	configuration when needed, instead of selecting a new configuration			
	(which would require you to prime and verify all the inlets and			
	ingredients).			
backup	The process and result of saving database information to a location			
- Sacrap	other than the compounder.			
base plate	The common base on which the compounder's components sit.			
Blackbox data	The logged activities of the compounder, mainly based on the			
Blackbox data	communication between software, firmware and user actions.			
andionlogia				
cardioplegia	A specific combination of ingredients used to induce cardiac arrest			
	during cardiac surgery.			
common fluid pathway	The area from the port through the valve set to the destination bag. One			
	or more ingredients can be present in this area.			
compounder	The complete device with all of its hardware components and software,			
.,	excluding the tube set and bags.			
compound / compounding	The process of pumping ingredients into a patient bag.			
configuration	A designation of the products that will be attached to the ports, the			
	sequence in which they will be pumped, any allowable auto-additions,			
	the ingredient and volume to use for any ingredient flushes, the			
	Universal Ingredient and the volume to use for the final flush.			
Continuous Renal Replacement	A form of therapy to dialyze acute patients continuously, when these			
Therapy (CRRT)	patients cannot tolerate conventional dialysis.			
daily setup	The process of attaching all the ingredients for a specific configuration to			
	the compounder and preparing to compound solutions. Includes			
	priming, verification and calibration.			
daily use components	The disposable components (tube set) and destination bags.			
database	Information containing operating parameters, the formulary and other			
	definable variables to be used by the compounder.			
deliver / delivering	The act of pumping ingredients from a source container to the			
	destination bag.			
delivery	A single, measured volume of fluid that has been pumped into the			
•	destination bag.			
destination bag	A sterile container that holds the fluid pumped from the source			
	containers. It can be a patient bag (used for delivering the finished			
	solution to a patient) or a calibration bag (used for collecting any fluid			
	that is not intended for a patient).			
direct entry mode	A mode where you enter a formula manually by specifying the ingredient			
	and volume to be delivered from each port.			
display	The touch-screen display for the user interface. It mounts to the base			
	plate.			
disposables	See tube set.			
	A specific volume and concentration of an ingredient.			
dose	A specific volume and concentration of an ingredient.			

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Term	Definition		
electronic Y-site	A setup option that helps to improve the efficiency of pumping common		
creetrome i site	ingredients. When the first container of this ingredient has emptied, the		
	compounder continues pumping from the next container of this		
	ingredient.		
enhanced flush	Two intermediate flushes followed by the final flush.		
epidural	An injection into the epidural space of the spine for regional anesthesia.		
equivalent ingredient products			
equivalent ingredient products	Products of the same ingredient type that may have different container sizes, container types or manufacturers.		
final flush	A delivery of fluid that is pumped to clear all delivered ingredients from		
	the common fluid pathway, to ensure that these ingredients are fully		
	present in the finished solution. The fluid used for this flush is always the		
	Universal Ingredient. The standard volume is 30 mL, but it can be		
	changed.		
finished solution	The ingredients in the patient bag after compounding, including manual additions.		
flow factor	A value associated with each ingredient that compares the flow of that		
now ractor	ingredient to the flow of water. The flow factor accounts for the		
	ingredient's viscosity, the size and type of its source container, its inlet,		
	its venting and other factors that affect its delivery.		
fluid pathway	See common fluid pathway.		
flush	See final flush, ingredient flush or intermediate flush.		
formula	A recipe of ingredients to be compounded. Typically, it is created by the		
lomina	pharmacist, based on a prescription from a physician.		
formulan	The list of ingredients, and associated products, which can be attached		
formulary	to the compounder.		
in an annatible succes	·		
incompatible group	A group of ingredients that you identify as having interaction concerns		
to and discon	with other ingredients.		
ingredient	A solution of a specific chemical entity at a specific concentration,		
	regardless of the container size, container type or manufacturer. One ingredient can have several associated products.		
ingredient flush	A delivery of fluid that is pumped to clear the common fluid pathway		
ingredient nusn	between the delivery of certain ingredients that have interaction		
	concerns. The fluid used for this flush is usually the Universal Ingredient,		
	_		
ingradient group	but it can be any compatible ingredient in the configuration and formula.		
ingredient group	A list of chemically similar ingredients, used for defining incompatible		
initial setup	groups. The placement and assembly of the product components at the		
illitial Setup	customer facility by Baxter personnel.		
inlet	A sterile tube with a spike or Luer end attached. The spike or Luer end		
	attaches to a source container, and the other end attaches to a port on		
	the valve set.		
intermediate flush	A delivery of fluid that comes just before the final flush as part of an		
	enhanced flush. The fluid used for this flush is always the Universal		
	Ingredient, and it is pumped in two deliveries of 50 mL each.		
large-volume delivery	See macro ingredient.		
load cell	The component that holds the destination bag, weighs the compounded		
	solution and reports the measurement to the software. It mounts to the		
	base plate.		
macro ingredient	A generic term used to describe an ingredient that uses a large-bore inlet		
	and is delivered in volumes equal to or greater than 5 mL.		
main module	The component that contains the valve actuators, occlusion detector,		
	bubble detector, pump chamber and power supply. It mounts to the		
	base plate.		
	· '		

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Term	Definition			
maintenance	The act of performing scheduled or expected work on the compounder.			
	It does not include repairs or corrections due to product failure.			
manage	The act of creating, modifying, saving or deleting information within the			
	software.			
manual addition	A product that is added to the compounded solution manually, after			
	compounding has finished.			
message	Small on-screen window or other text that provides information or			
	instructions, but does not allow you to enter information. Pay attention			
	to the text, because some messages may include critical information.			
micro ingredient	A generic term used to describe an ingredient that uses a micro inlet and			
	is delivered in volumes less than 5 mL.			
National Drug Code (NDC)	A unique, three-segment number used in the United States to identify			
	drug products used by humans.			
occlusion	A blockage in the fluid pathway.			
OEM	Original Equipment Manufacturer i.e Baxter Healthcare			
outlet tube	The section of tube on the discharge side of the valve set. It connects the			
	valve set to the destination bag.			
.PAT file	A file, created in the order-entry software, which contains the patient			
	information and formula.			
.FRM file	An encrypted file, created in the order-entry software, which contains			
	the patient information and formula.			
2D Formula Barcode Label	A label, printed in the order-entry software, which contains the patient			
	information and formula along with the 2D Barcode.			
patient	The recipient of the finished solution.			
permissions	The privileges granted to groups of users to allow them to perform			
	specific functions.			
port	The interface between the valve set and the inlets for source containers.			
prime	To pump a small volume of an ingredient through an inlet, to remove air			
	bubbles from the inlet and prepare it for compounding the solution.			
privileges	See permissions.			
product	An ingredient in a particular container size and type from a specific			
	manufacturer. Several products can be associated with one ingredient.			
pump	A peristaltic device used to push fluid through the outlet tube.			
pump module	See main module.			
remainder	A value in the software that represents the actual volume of fluid			
	remaining in the source container.			
scale	See load cell.			
screen	A large on-screen window that takes up the full screen of the display.			
	Pay attention to the text, because some screens may include critical			
	information.			
sequence	The order in which ingredients are delivered to the destination bag.			
solution	The mixture of ingredients that have been compounded.			
small-volume delivery	See micro ingredient.			
source container	A container (bag, bottle, vial or syringe) that holds one ingredient.			
tolerance	The amount by which any characteristic (for example, dimensional,			
	chemical, physical or mechanical properties) may vary from that			
	specified.			
Total Parenteral Nutrition (TPN)	A form of intravenous therapy that requires multiple fluid ingredients to			
	be accurately compounded into a single solution to support a patient's			
	nutritional needs.			
tube set	The valve set and inlets.			

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Term	Definition			
Universal Ingredient (UI)	The ingredient that is used to flush the common fluid pathway. This			
	ingredient must be contained in the configuration and the formula being			
	compounded.			
unload	The precaution of removing a formula from the pump screen when you			
	navigate away from this screen. Unloading does not delete the formula			
	from the database.			
user accounts	The accounts that contain the user names, user permissions and other			
	attributes as determined by the facility.			
valve set	A sterile, multiple-port valve with an outlet tube attached. The valve			
	body fits over the valve actuators on the compounder, protecting them			
	from damage. The outlet tube attaches to the destination bag.			
variance	One measure of statistical dispersion, averaging the squared distance o			
	its possible values from the expected value (mean).			
volume	The physical amount of the ingredient that is delivered, typically in			
	milliliter (mL) units.			
window	An on-screen feature that provides information or instructions and			
	allows you to make choices or enter information. Pay attention to the			
	text, because some windows may include critical information.			

APPENDIX

SPECIFICATIONS

Display

	DY Display		
Dimensions and Weight:	Length: 12.2 in. (31 cm)		
	Width: 2.1 in. (5.3 cm)		
	Height: 9.6 in. (24.2 cm)		
	Weight: 8 lb (3.6 kg)		
Operating software:	Windows 10 IoT Enterprise 2016 LTSB		
CPU:	Intel Atom Z5xxP 1.1 Ghz		
Memory:	512 MB SDRAM and 2 GB SODIMM		
Screen:	XGA/VGA		
CD ROM:	None		
Ethernet:	10/100 Base-T Ethernet network		
	connectivity		
USB ports:	4 ports, USB 2.0 supporting USB 1.1/2.0		

The display supports the connection and use of a USB 1.1 keyboard and mouse.

Dimensions

Main module:	Length: 24 in. (61 cm)
	Width: 10 in. (25.4 cm)
	Height: 10 in. (25.4 cm)
Display:	Length: 11 in. (27.9 cm)
	Width: 5 in. (12.7 cm)
	Height: 9 in. (22.9 cm)
Load cell:	Length: 13 in. (33 cm)
	Width: 8 in. (20.3 cm)
	Height: 10 in. (25.4 cm)
Compounder,	Length: 30 in. (76.2 cm)
without vial rack:	Width: 19 in. (48.3 cm)
	Height: 12 in. (30.5 cm)
Compounder,	Length: 40 in. (101.6 cm)
with vial rack:	Width: 20 in. (50.8 cm)
	Height: 30 in. (76.2 cm)

Weight

Main module:	40 lb (18.14 kg)
Display:	10 lb (4.5 kg)
Load cell:	5 lb (2.3 kg)
Base:	13 lb (5.89 kg)
Vial rack:	9.5 lb (4.3 kg)
Compounder:	79 lb (35.83 kg)

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Electrical

Power:	100–240 V AC RMS, 50–60 Hz, 336 W			
Line cord:	3-prong detachable plug			
Fuse ratings:	F1—3 Amp, 2 AG, fast acting, 250 V			
 Pump driver PCA 	F1—2 Amp, 2 AG, fast acting, 250 V			
LRV PCA	F1—4 Amp, 5 x 20 mm, slow acting, 250 V			
 Power supply 	F2—4 Amp, 5 x 20 mm, slow acting, 250 V			
1.,	F3—3.15 Amp, 5 x 20 mm, fast acting, 250 V			
	F4—3.15 Amp, 5 x 20 mm, fast acting, 250 V			
	F5—6.3 Amp, 5 x 20 mm, fast acting, 250 V			

Performance

Accuracy:	± 0.03 mL at 0.2 mL;		
	± 0.03 mL at 0.4 mL;		
	± 0.06 mL at 1 mL;		
	± 5% at 10 mL and greater		
Dispensing of ingredients:	Increments of 0.01 mL		
Volume of source containers:	0.2-5,500 mL		
Volume of destination bags:	125–5,000 mL		
Maximum flow rate of water:	16.6 mL/second		
Maximum number of ingredients:	12		
Maximum capacity of vial rack:	12 (small-volume vials and 60 mL Luer syringes)		

Environmental Conditions

Operating temperature:	59–86°F (15–30°C)
Storage temperature:	32–147°F (0–64°C)
Maximum relative humidity:	10-80%
Maximum altitude:	Not to exceed 3,000 m
Main supply voltage fluctuation:	Not to exceed ±10%
Sound pressure level:	Not to exceed 85 dBA

For Indoor Use Only

ISO Class 5 (Class 100) cleanroom as defined in ISO 14644-1:1999

Class I Equipment (Grounded Type)

Installation (Over Voltage) Category II

Pollution Degree 2 Environment

The maximum circuit voltage of USB 1.1/2.0 is 5.0 V DC with a maximum current of 500 mA DC (all ports combined). Use only Baxter-supplied USB devices.

This equipment is intended for use in a "basic electromagnetic environment" as defined per IEC 61326; such as an office, pharmacy, or clinic. It is not intended to be used in an "industrial environment" or near equipment either sensitive to electromagnetic interference or near equipment that emits electromagnetic interference such as large electrical machinery or near MRI, CAT, Electrosurgical or Electrocautery or similar equipment. If you find that this equipment creates interference with other nearby equipment or is affected by other nearby equipment try changing the orientation or separation of each equipment to reduce the effect.

WEEE COMPLIANCE



- This symbol on a Baxter product or its packaging means that the product should not be disposed of with general waste. It is your responsibility to dispose of your waste equipment separately from the municipal waste stream. The correct disposal of your end-of-life equipment will help prevent potential negative consequences for the environment and human health.
- Baxter endeavors to reduce the environmental and human health effects of electrical and electronic equipment at the time it is being discarded and offers its EU customers details on to facilitate environmentally sound disposal of this equipment at: http://www.baxter.com/assets/europe/directives/weee/in

dex.html

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WARRANTY STATEMENT

Baxter Healthcare Corporation provides a limited warranty for the ExactaMix 1200 Compounder.

See your lease or purchase contract for details about the warranty.

If the equipment is under warranty, Baxter will replace the defective equipment. Equipment that is not under warranty can also be replaced, however, the customer is responsible for the cost of repairs and shipping.

Baxter Healthcare Corporation warrants that the ExactaMix 1200 Operating Software will perform as described in the operator manual, by the release notes with the currently released version and when operated on a properly configured computer using a properly configured load cell and barcode reader. Where there is a discrepancy between the manual and the operation of the software, Baxter Healthcare Corporation may, at its discretion, revise either the software or the text of the manual.

This software is intended solely for the operation of the ExactaMix 1200 Compounder for the preparation of compounded sterile formulas. It is not intended to replace the professional knowledge or judgment of a Registered Pharmacist in the preparation of such formulas.

No other warranties, whether express or implied, made by any representative or other agent of Baxter Healthcare Corporation shall be binding upon Baxter Healthcare Corporation. This is an exclusive warranty.