

# Baxter

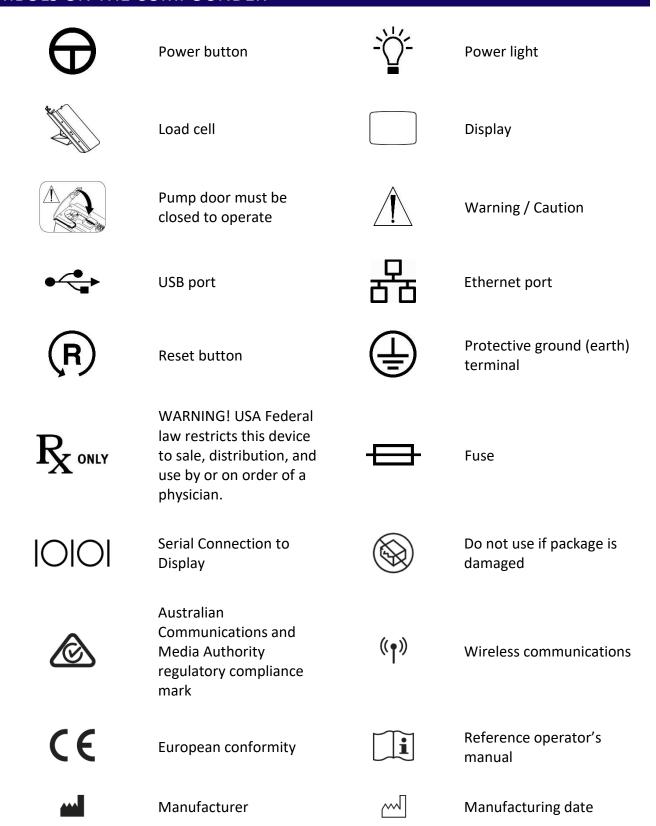
ExactaMix Pro

**AUTOMATED COMPOUNDER** 

EM2400
OPERATOR MANUAL



# SYMBOLS ON THE COMPOUNDER



**Operator Manual** 

ExactaMix Pro 2400 Compounder



**Humidity limitations** 



Temperature limitations



Not made with natural rubber latex



A separate waste collection is required for Waste of Electrical and Electronic Equipment (WEEE)



Catalogue number



Serial number



Taiwan National communication commission conformity



Underwriters Laboratory listed

# For use with the following product codes REF:

Main Module	EXACTA-M (RoHS compliant); 2400-M (non-RoHS)
Load Cell	EXACTA-LC (RoHS compliant); 2400-L (non-RoHS)
Display Module	EXM24DY; EXME24DY
Vial Rack	EXACTA-VS; EXACTA-VLS; EXACTA-VL; EXACTA-V
Base Plate	2400-B

All the refurbished product codes of above modules are also applicable to this manual.

# 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.

# TABLE OF CONTENTS

INTRODUCTION	1
COMPONENTS	2
Hardware Components	2
Daily Use Components	6
Software	6
License	6
Permissions	7
Navigation	7
Menu Screen	8
Pump Screen	9
Tutorials	. 11
FEATURES	. 12
Summary of Features	12
Order Entry	. 12
Formulary	13
Ingredient Groups	13
Universal Ingredient	13
Configuration	. 14
Barcode Verification	. 14
Measurement of Volume and Weight	. 14
Volumetric Delivery	14
Automatic Calibration	. 14
Gravimetric Verification	15
Printing Options	15
Network Connectivity	. 16
Valve Sets	. 17
Inlets	. 17
Bags	. 18
GETTING HELP	. 20
INSTALLING THE COMPOUNDER	. 22

STARTING UP, LOGGING IN AND OUT, AND SHUTTING DOWN	30
Starting Up and Logging In	30
Logging Out	31
Rebooting and Shutting Down	32
SETTING UP THE COMPOUNDER	33
Accessing the Setup Wizard	33
Calibrating the Load Cell	35
Selecting the Configuration	38
Changing the Tube Set	40
Checking the Tube Set Statistics	40
Installing the New Valve Set	42
Preparing the New Ingredients	44
Attaching the New Ingredients and Inlets	45
Priming and Verifying	54
Verifying the Ingredient and Inlet Barcodes	55
Priming the Inlets and Verifying the Setup	58
Calibrating the Compounder	65
Attaching and Removing the Calibration Bag	68
Attaching the Calibration Bag	68
Removing the Calibration Bag	69
Viewing the Authorization Report	69
USING THE COMPOUNDER	70
Fulfilling the Order (Basic Process)	70
Loading a Formula by Scanning a Barcode	70
Attaching the Patient Bag	71
Compounding the Solution	72
Removing the Patient Bag	75
Completing the Order	75
Understanding Automatic Unloading of Formulas	76
Other methods of Loading the Formula	77
Entering a Formula through Direct Entry	78
Saving and Using a Direct-Entry Formula	80

Saving a Direct-Entry Formula to Use Later	81
Selecting a Saved Formula	82
Fulfilling the Order (OTHER COMMON ACTIVITES)	83
Replacing a Source Container	83
Performing a Manual Addition	84
Handling an Air Bubble	85
Handling an Occlusion	88
Performing an Auto-Addition	90
Handling Other Interruptions and Errors	91
Removing the Expired Tube Set and Expired Ingredients	92
MAINTAINING THE COMPOUNDER	93
Calibrating the Load Cell	93
Changing the Tube Set	93
Cleaning the Compounder	93
Calibrating the Compounder	95
Shutting Down and Starting Up the Compounder	95
Backing Up and Compacting the Database	95
Backing Up the Entire Database	96
Backing Up the Blackbox Log	96
Compacting the Database	97
PERFORMING ADVANCED TASKS	98
Changing the Universal Ingredient	98
Changing the Ingredient Remainders	100
SETTING UP THE OPTIONS	101
Setting Up the System Options	101
MixCheck Report	102
Load Cell	103
Track Product Expiration Date and Lot Number	103
Logging	103
Demo	104
Storage	104
MixCheck Data Export	104

	Tube Set Expiration	105
	Setting Up the System (Continued) Options	106
	Database Compaction	106
	Acceptable Weight Variances (%)	106
	Manual Add	107
	Flush Between UI Changes	107
	Report Printer	107
	MixCheck Data Export Printer	107
	MixCheck Signature Label	107
	Authorization Report Signature Label	107
	Setting Up the Security Options	108
	Auto-Logout	108
	Password Expiration	108
	Order Entry Serial Number	109
	Barcode Reader	109
	Cosignature	109
	Solution Limit	109
	Setting Up the Directories Options	110
	Viewing the OEM Options	111
SYSTE	M SETTINGS	112
	Display	113
	Device Information	114
	Date & Time	114
	Turning on automatic date and time	115
	Changing region	115
	Turning on daylight savings time	116
	Language	116
	Ethernet	117
	Wi-Fi	117
	Firewall Settings	118
	Printer management	119

SETTING UP THE USERS	120
Working with Groups	120
Adding or Editing a Group	120
Deleting a Group	123
Working with Users	123
Adding or Editing a User	123
Deleting a User	125
Changing a Password	125
Logging in as a Different User	126
USING THE CONFIGURATION EDITOR	127
Adding or Editing a Configuration	128
Configuration Guidance	133
Example of a Standard Recommended Configuration	134
Deleting a Configuration	137
USING THE FORMULARY EDITOR	138
Working with Ingredients	140
Adding or Editing an Ingredient	140
Deleting an Ingredient	141
Viewing an Ingredient's Usage Information	141
The Calibration Ingredient	142
Viewing the Calibration Ingredient	142
Working with Products	142
Adding or Editing a Product	142
Deleting a Product	144
Viewing a Product's Usage Information	144
USING THE INGREDIENT GROUP EDITOR	145
Adding or Editing an Ingredient Group	146
Deleting an Ingredient Group	148
USING THE INLET EDITOR	149
Adding or Editing an Inlet	150
Deleting an Inlet	151
Viewing an Inlet's Usage Information	151

Viewing an Inlet's Speeds and Flow Factors	152
USING THE BAG INVENTORY EDITOR	154
Adding or Editing a Bag	155
Deleting a Bag	157
USING REPORTS	158
MixCheck Report	160
Customizing MixCheck Reports	160
Using MixCheck Reports	160
Using Online MixCheck Authorization	160
Authorization Report	165
Formula Report	167
Log Report	170
Configuration Report	173
Formulary Report	175
Product Barcodes Report	176
Inlet Barcodes Report	178
Blackbox Report	179
Calibration Summary Report	181
Formula Precision Report	183
Ingredient Usage Report	186
Bag Usage Report	188
Flow Factors Report	190
Custom Reports	191
TROUBLESHOOTING	192
Handling Interruptions and Errors	192
Issues with the Barcodes	192
Issues with the Barcode Scanner Holder	195
Issues with the Display Cable	195
Display has power but is not communicating with the main module	195
Issues with the Formulas, Ingredients and Configurations	196
Issues with the Calibration	200
Issues with the Weight and Load Cell	201

Issues with the Pump	202
Issues with the Occlusion Detector / "Flow Sensor"	203
Other Issues	204
Loading a Formula by Connecting a USB Drive	206
Restoring the Database	207
GLOSSARY	209
APPENDIX	212
Specifications	212
Display	212
Dimensions	212
Weight	212
Electrical	213
Performance	213
Environmental Conditions	213
WEEE Compliance	214
WI-FI COMPLIANCE	214
United States	214
Canada	214
Taiwan	215
WARRANTY STATEMENT	216

# INTRODUCTION

The Baxter **ExactaMix Pro** 2400 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.



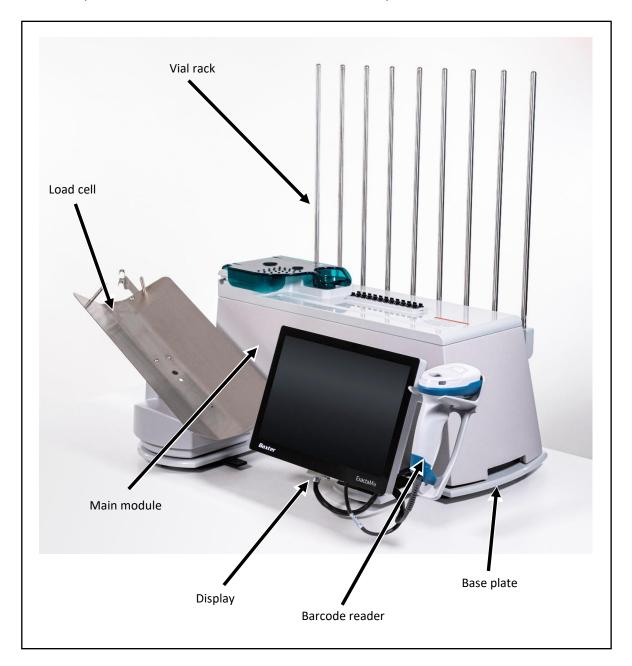
#### **WARNING**

Operators should be trained according to this manual before using the **ExactaMix Pro** compounder.

# **COMPONENTS**

#### HARDWARE COMPONENTS

The compounder consists of these main hardware components:



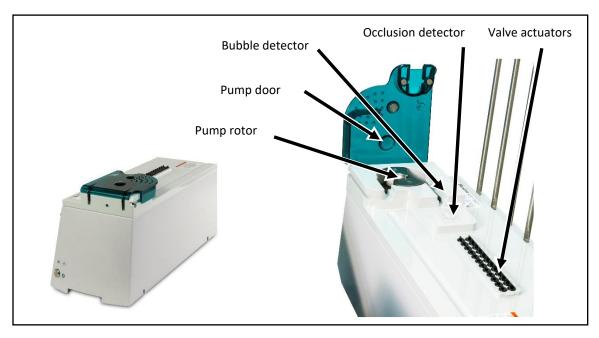
Hardware components

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

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

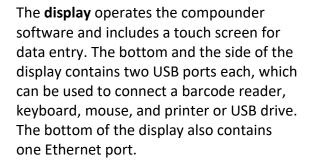
• The **valve actuators** open and close as needed to allow the delivery of individual ingredients. When the pump is paused, the valve actuators automatically close.

- 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 to the display, where calculations are performed. A 2,000 g calibration weight for use in calibrating the load cell is provided with the compounder.



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.

The barcode reader model may vary.

The barcode reader holder is attached to the right side of the display module. It stores the barcode reader when it is not in use.



Load cell



Display



Barcode reader



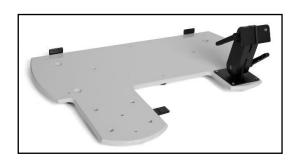
Barcode reader holder

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 are mounted.



Base plate

A laser **printer** (North America only), used for printing reports and labels, can be connected directly to the display or to a network.

Printer models may vary.



Printer

The display cable is a serial cable that provides communication between the main module and the display module.



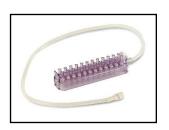
Display cable

#### 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 Valve Sets on page 17.
- 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 Inlets on page 17.

**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, available in different sizes. See <u>Bags</u> on Page 18 for bag descriptions and ordering information.
  - The patient bag is used for delivering the finished solution to a patient. This bag has 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. Such as while calibrating and priming the compounder. This bag has only
    one port for filling the bag. The calibration bag is available in North America only.









Valve set

Inlet

Patient bag

Calibration bag

#### **SOFTWARE**

Baxter **ExactaMix Pro** 2400 Operating Software is installed on the compounder display.

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.

#### License

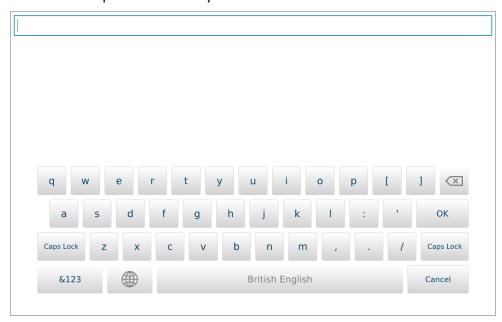
The license to use the compounder software is granted to a single concurrent user on a single **ExactaMix Pro** 2400 Compounder for the term of the equipment contract. Baxter retains ownership of the software. Distribution or copying of this software, other than for backup purposes, is expressly forbidden.

#### **Permissions**

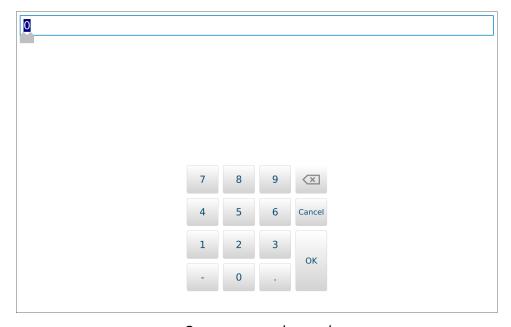
The options that appear in the software depend on the permissions granted to the user. If you have questions about your permissions, contact your supervisor. For more information about setting up permissions, refer to <u>Setting Up the Users</u> on Page 120.

#### **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



On-screen number pad

#### Menu Screen

The menu screen provides access to menus and settings.



Menu screen

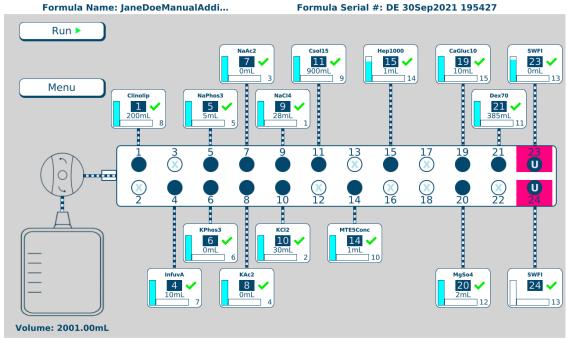
The menu screen has the following six options:

- **File** menu: allows formula management, software log in/logout/exit, compounder restart or compounder shutdown.
- **Edit** menu: for editing the configurations, formulary, ingredient groups, inlet information and bag information
- **Compound** menu: sets up the compounder for operation, selects a formula to compound and manage ingredients
- **Tools** menu: sets up options related to the system, users, security, directories used for saving certain files. and software maintenance.
- **Reports** menu: allows users to view, print and export reports related to compounding and other device activity.
- **Help** menu: provides tutorials and information about the hardware and software.

Tapping **Close** at 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.

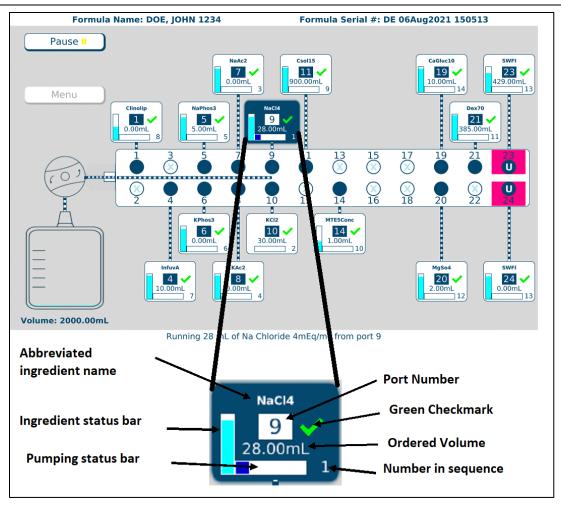


Loading Formula JaneDoeManualAddition/DE 30Sep2021 195427...Done.

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 at 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 in the middle of the screen.
   Ports that:
  - Have no ingredient attached have an X over them
  - o Have an ingredient attached have an ingredient button connected
  - o Have the Universal Ingredient attached are identified by a U
  - Make up an electronic Y-site are identified by colored highlighting



Ingredient button details

On the pump screen, each ingredient button includes:

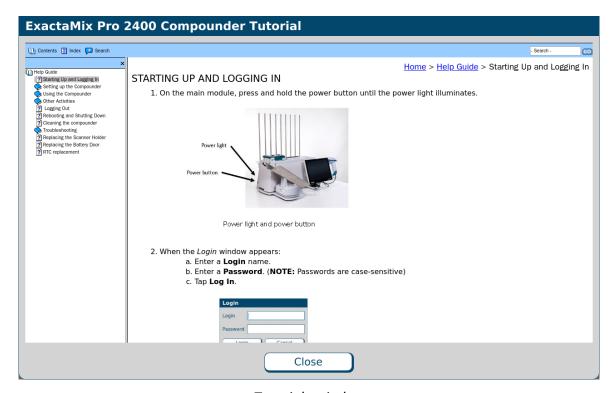
- The abbreviated ingredient name
- The port number
- A green check mark indicating that the inlet and port have been verified, or a red X indicating that they need to be verified.
- The ordered volume of the ingredient
- A number indicating the ingredient's place in the compounding sequence
- A vertical bar showing how much of the ingredient remains in the container. during compounding, 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 is shown in blue. 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. To view the tutorials:

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



Tutorials window

## **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 users through the setup process
- Supports a maximum of 24 ingredients, source containers in volumes of 10–5,500 mL and destination bags in volumes of 125–5,000 mL
- Allows attachment of the same ingredient to more than one port, creating an electronic Y-site
- Allows specification of the sequence in which ingredients are pumped
- Allows specification of 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 be set up to communicate with a printer
- Can print reports and barcode labels at the compounder's printer
- Can be set up to communicate with the order entry system through a wired or wireless network
- Allows users to identify facility specific ingredients in the formulary
- Allows authorization of MixCheck reports online

#### **ORDER ENTRY**

Order entry can be done through direct entry (see Page 78), or by using separate order-entry software.

The **ExactaMix Pro** compounder operating software can communicate, via a network, with order-entry software on a separate computer. The order-entry software must produce 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>Fulfilling the Order (Basic Process)</u> on Page 70.

#### **FORMULARY**

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

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. An ingredient can be made available or unavailable by authorized users.

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. When an ingredient is set to be unavailable, all associated products also become unavailable.

#### For example:

Ingredient: Dextrose 70%

Products:

Baxter Dextrose 70%, 2000 mL bag

Baxter Dextrose 70% 1000 mL bag

#### **INGREDIENT GROUPS**

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

• Ingredient group: Phosphate

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

• Ingredient group: Calcium

Ingredients: Ca Gluconate 10%, Ca Chloride 10%

Some ingredients can tolerate each other's 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 ingredients from incompatible ingredient groups 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 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 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 45.

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 associated 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.

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:

# $\Sigma$ (Volume<sub>Ingredient</sub> × Specific Gravity<sub>Ingredient</sub>)

#### PRINTING OPTIONS

The printer is used for printing reports and creating labels for inlets and source containers. The printer can use standard  $8.5 \times 11$  in. (21.6 x 28 cm) letter paper size for reports and **Avery** 6460 label sheets or equivalent for inlet labels.

To use A4 paper size, navigate to the *Options window* by selecting **Tools > Options**. Select the *directories* tab. Then in the report's section select Standard Report (A4 paper size) from the drop-down menu.

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.

#### **IMPORTANT!**

Use only Baxter-authorized printers with the compounder.

#### NETWORK CONNECTIVITY

You can connect the compounder via an Ethernet cable or wireless connection to a:

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

The compounder uses 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. Refer to Baxter **ExactaMix Pro**Cybersecurity Guide document for more information about network security or contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

#### **WARNING**

Cybersecurity is a shared responsibility. The following guidance should be considered during implementation and use of your **ExactaMix Pro** compounder. For further guidance, refer to the **ExactaMix Pro** Cybersecurity Guide which can be found at Baxter's Product Security website www.baxter.com/product-security.

- Physical access to the device should be limited to only authorized users
- Prepare and perform training for personnel, cautioning them against credential sharing
- Ensure that IT maintains cybersecurity of the facility's environment around the device by performing the following:
  - Network segmentation
  - Firewalling each network segment, limiting inbound and outbound connections
  - Scanning for unauthorized network access
  - Scanning for vulnerabilities and viruses

If you have discovered a potential vulnerability related to the **ExactaMix Pro** product, please report this information to productsecurity@baxter.com or call +1-888-887-0098 (if calling from the U.S.).



# **ORDERING SUPPLIES**

Order supplies through normal channels. For USA/Canada, you can contact Baxter Customer Service at +1.800.567.2292. For all other countries, find your local customer service contact details by visiting <a href="www.baxter.com/location-selector">www.baxter.com/location-selector</a>, selecting your location and using the contact link.



#### **WARNING**

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

#### **VALVE SETS**

The following valve sets are approved for the **ExactaMix Pro** compounder.

Product	Order Number	Quantity / Case	Notes
EM2400 Valve Set	H938 <b>724</b>	10	<ul> <li>Includes:</li> <li>Numbered inlet labels with barcodes</li> <li>10 calibration bags (H938735RS)</li> </ul>
EM2400 Valve Set— Except Calibration bags	H938 <b>724E</b>	10	Includes:  • Numbered inlet labels with barcodes

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

#### **INLETS**

The following inlets are approved for use on the **ExactaMix Pro** compounder.

Product	Order Number	Quantity / Case	For use with:	Standard Priming Volume	Minimum Priming Volume
Non-vented	H938 <b>173</b>	25	Large-volume, vented or collapsible	50–60	25–30 mL
High-Volume Inlet			containers (such as bags of dextrose and water)	mL	
Vented High-	H938 <b>174</b>	25	Large-volume, non-vented containers	50–60	25–30 mL
Volume Inlet			that require a spike to vent air into the container	mL	
Vented Micro- Volume Inlet	H938 <b>175</b>	25	Small-volume vials	5–6 mL	2.5–3 mL
Micro-Volume Inlet, with Large-Bore Spikes	H938 <b>751</b>	25	Small-volume bags or bottles that require a large-bore spike	5–6 mL	2.5–3 mL
Syringe Inlet	H938 <b>176</b>	25	50 or 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 149.

BAGS

The following empty bags are approved for the ExactaMix Pro compounder.

Product	<b>Product Code</b>	Quantity / Case	Notes
ExactaMix EVA Container, 250 mL	H938 <b>737</b>	50	N/A
ExactaMix EVA Container, 500 mL	H938 <b>738</b>	50	N/A
ExactaMix EVA Container, 1000 mL	H938 <b>739</b>	50	N/A
ExactaMix EVA Container, 2000 mL	H938 <b>740</b>	50	N/A
ExactaMix EVA Container, 3000 mL	H938 <b>741</b>	50	N/A
ExactaMix EVA Container, 4000 mL	H938 <b>742</b>	50	N/A
ExactaMix EVA Container, 5000 mL	H938 <b>743</b>	50	N/A
ExactaMix EVA Calibration Bag, 1000 mL	H938 <b>735</b>	50	Can be used for functions
			other than calibration; refer to
			calibration bag on Page 6.
EVA Dual Chamber Container, 1500 mL	H938901	42	250 mL upper chamber
			1250 mL lower chamber
EVA Dual Chamber Container, 3000 mL	H938905	42	500 mL upper chamber
			2500 mL lower chamber
EVA TPN BAG, INT THR, 250 mL	E3002OD	50	mfr. Haemotronic
EVA TPN BAG, INT THR, 250 mL (5 pack)	E3002OD5	50	mfr. Haemotronic
EVA TPN BAG, INT THR, 500 mL	E3005OD	50	mfr. Haemotronic
EVA TPN BAG, INT THR, 500 mL (5 pack)	E3005OD5	50	mfr. Haemotronic
EVA TPN BAG, INT THR, 1000 mL	E30100D	50	mfr. Haemotronic
EVA TPN BAG, INT THR, 1000 mL (5 pack)	E30100D5	50	mfr. Haemotronic
EVA TPN BAG, INT THR, 2000 mL	E30200D	30	mfr. Haemotronic
EVA TPN BAG, INT THR, 3000 mL	E30300D	30	mfr. Haemotronic
EVA TPN BAG, INT THR, 4000 mL	E30400D	30	mfr. Haemotronic
EVA TPN BAG, INT THR, 5000 mL	E30500D	30	mfr. Haemotronic
EVA TPN Bag, 125 mL (LL Fill Port)	E1301-OLPF	50	Luer Lock port; mfr. Diffuplast
EVA TPN Bag, 250 mL (LL Fill Port)	E1302-OLPF	50	Luer Lock port; mfr. Diffuplast
EVA TPN Bag, 500 mL (LL Fill Port)	E1305-OLPF	50	Luer Lock port; mfr. Diffuplast
EVA TPN Bag, 1000 mL (LL Fill Port)	E1310-OLPF	40	Luer Lock port; mfr. Diffuplast
EVA TPN Bag, 2000 mL (LL Fill Port)	E1320-OLPF	35	Luer Lock port; mfr. Diffuplast
EVA TPN Bag, 3000 mL (LL Fill Port)	E1330-OLPF	35	Luer Lock port; mfr. Diffuplast
EVA TPN Bag, 4000 mL (LL Fill Port)	E1340-OLPF	30	Luer Lock port; mfr. Diffuplast
EVA TPN Bag, 5000 mL (LL Fill Port)	E1350-OLPF	25	Luer Lock port; mfr. Diffuplast
EVA TPN BAG MULTILAYER 125 mL	E14010D	50	Lg. Bore port, mfr. Diffuplast
EVA TPN BAG MULTILAYER 250 mL	E1402OD	50	Lg. Bore port, mfr. Diffuplast
EVA TPN BAG MULTILAYER 500 mL	E1405OD	50	Lg. Bore port, mfr. Diffuplast
EVA TPN BAG MULTILAYER 1000 mL	E14100D	40	Lg. Bore port, mfr. Diffuplast
EVA TPN BAG MULTILAYER 2000 mL	E1420OD	35	Lg. Bore port, mfr. Diffuplast
EVA TPN BAG MULTILAYER 3000 mL	E14300D	35	Lg. Bore port, mfr. Diffuplast
EVA TPN BAG MULTILAYER 4000 mL	E1440OD	30	Lg. Bore port, mfr. Diffuplast
EVA TPN BAG MULTILAYER 5000 mL	E14500D	25	Lg. Bore port, mfr. Diffuplast

Product	Product Code	Quantity / Case	Notes
TPN EVA UV BAG 125mL with female connector	BX0001BP	150	Lg. Bore port, mfr. Valmed
TPN EVA UV BAG 250mL with female connector	BX0002BP	150	Lg. Bore port, mfr. Valmed
TPN EVA UV BAG 500mL with female connector	BX0003BP	150	Lg. Bore port, mfr. Valmed
TPN EVA UV BAG 1000mL with female connector	BX0004BP	125	Lg. Bore port, mfr. Valmed
TPN EVA UV BAG 2000mL with female connector	BX0005BP	80	Lg. Bore port, mfr. Valmed
TPN EVA UV BAG 3000mL with female connector	BX0006BP	80	Lg. Bore port, mfr. Valmed
TPN EVA UV BAG 4000mL with female connector	BX0007BP	60	Lg. Bore port, mfr. Valmed
TPN EVA UV BAG 5000mL with female connector	BX0008BP	50	Lg. Bore port, mfr. Valmed
TPN MULTILAYER BAG 125mL with female	BX0009BP	150	Lg. Bore port, mfr. Valmed
connector			
TPN MULTILAYER BAG 250mL with female	BX0010BP	150	Lg. Bore port, mfr. Valmed
connector			
TPN MULTILAYER BAG 500mL with female	BX0011BP	150	Lg. Bore port, mfr. Valmed
connector			
TPN MULTILAYER BAG 1000mL with female	BX0012BP	125	Lg. Bore port, mfr. Valmed
connector			
TPN MULTILAYER BAG 2000mL with female	BX0013BP	60	Lg. Bore port, mfr. Valmed
connector			
TPN MULTILAYER BAG 3000mL with female	BX0014BP	60	Lg. Bore port, mfr. Valmed
connector			
TPN MULTILAYER BAG 4000mL with female	BX0015BP	60	Lg. Bore port, mfr. Valmed
connector			
TPN MULTILAYER BAG 5000mL with female	BX0016BP	50	Lg. Bore port, mfr. Valmed
connector			

**ExactaMix** 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.

# **GETTING HELP**

Always contact Baxter Technical Support if you encounter any issues.

Baxter Technical Support can be contacted by emailing <a href="COtechsupport@baxter.com">COtechsupport@baxter.com</a> or calling 1.800.678.2292 (if from the U.S. or Canada). Regional Technical Support contact information can also be found by visiting www.baxter.com/location-selector, selecting your location and using the contact link.

Before you call for technical support, you will need your compounder's software version and build number. To obtain this information follow the instructions below.

- 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 Number.



About window

#### Alternatively,

**IMPORTANT!** These instructions require the user to have System Settings permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

- At the menu screen, tap Tools > System Settings.
   The System Settings window appears. It provides information about the hardware and software along with other operating system settings.
- **2.** Select the **Device Information** option in the left pane.
- 3. In the right pane, identify the **Software Version** and **Build Number**.



System Settings window

## INSTALLING THE COMPOUNDER

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

If you must reinstall the compounder, relocate the compounder or replace a component, verification tests must be performed before you use the compounder again. Contact Baxter Technical Support for assistance. Refer to <u>Getting Help</u> on Page 20.

**NOTE:** If a compounder needs to be moved to a new location, please contact Baxter Technical Support at least 30 days prior to the date of relocation.

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

**Tip!** Save the packaging material for future use in case the modules ever need to be shipped for technical service or repair.

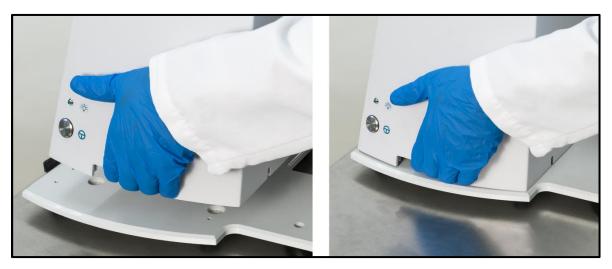
#### **WARNING**



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

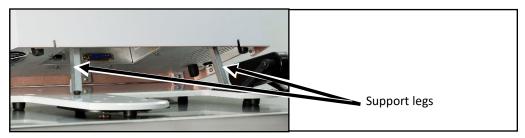
The compounder should be always placed on a level and stable surface to prevent the compounder or its individual modules from falling. Always hold the modules as shown below to avoid dropping them.

- 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 on the left of the base plate.
- **4.** Place the display on 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.

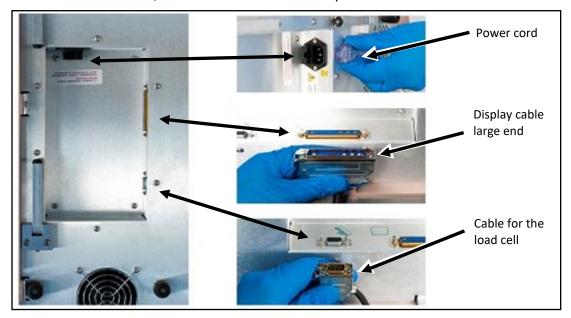
The power cord must be positioned so that the plug is easily accessible.



#### **CAUTION**

Ensure the system is fully powered down before disconnecting the display cable. Failure to unplug the power cord before disconnection of the display can result in the system becoming inoperable.

- **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 larger end of the display cable. Squeeze the ends of the connector to unlock it, connect it, and then release to lock it into place.
  - c. Connect the load cell cable. Squeeze the ends of the connector to unlock it, connect it, then release to lock it into place.

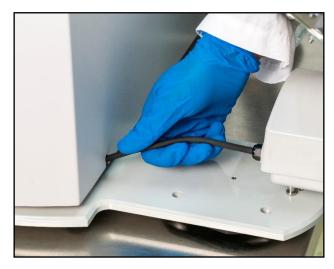


Connecting the cord and cables

**NOTE:** Connector locations may vary depending on the model.

- 7. Retract the support legs so that the main module rests fully on the base plate.
- **8.** Route the cables through the two routing cut-outs, pushing any excess cable length through the holes. Ensure cables are not pinched under the main module.

**IMPORTANT!** Ensure the cables are routed through their respective cut outs and not pinched under the main module.



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.** Display preparation:

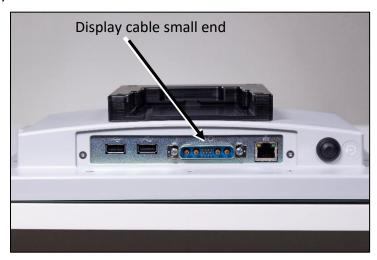
a. Place the display face down on a flat clean surface with the scanner side edge positioned flush to the edge of the workstation.



b. Position the scanner holder so that the two screw holes in the scanner holder align with the two threaded holes of the display.



- c. Use the supplied hardware and a 2.5 mm hex driver to secure the scanner holder to the display. Baxter recommends tightening to 4 in-lbs. (0.45 N·m) of torque. **IMPORTANT!** Do not over tighten.
- **11.** Attach the smaller end of the display cable to the connection on the bottom of the display.



**12.** Install the display onto the mounting arm.

The white locking pin snaps into the locked position.





*Installing the display* 

**NOTE:** To remove the display, pull the locking pin out to the unlocked position, then rotate the pin 90 degrees to keep it in this position while lifting the display.

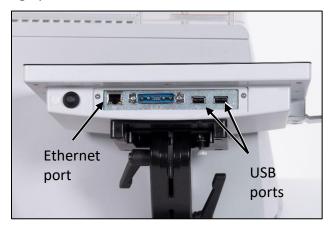
**13.** Place the barcode reader on the barcode reader holder with the trigger facing away from you.



Placing the barcode reader

- **14.** Connect the USB cable from the barcode reader to a USB port on the bottom of the display.
- **15.** If desired:
  - Connect the USB cable from the printer to a USB port on the display.
  - Connect a 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. Disconnect keyboard and mouse before starting normal compounding operation.



For Symbol definitions, refer to **Symbols** on **Page i** 

- **16.** Move the arm of the display to the desired position by doing the following:
  - 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

- 17. Move the display to the desired position by doing the following:
  - 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.

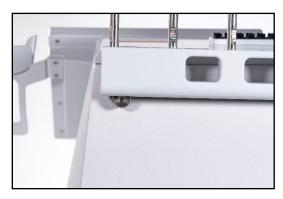


Lever on the left

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

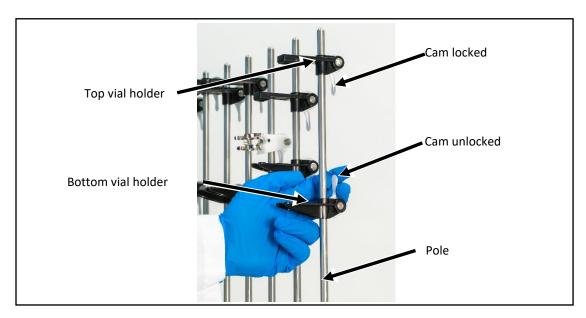
**NOTE:** Baxter recommends the **ExactaMix Pro** compounder be connected to an uninterruptible power supply (UPS) with battery backup. This will prevent power spikes and/or a hard shutdown of the device.

**20.** 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* 

- **21.** Install the vial holders in the desired locations on the vial rack.
- **22.** 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.

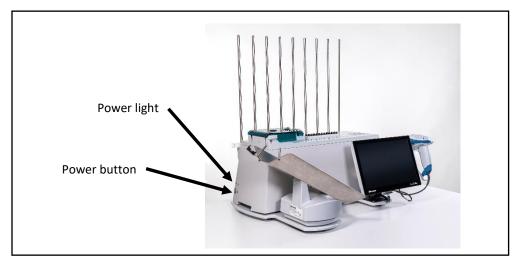


Adjusting the vial holders

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



Login window

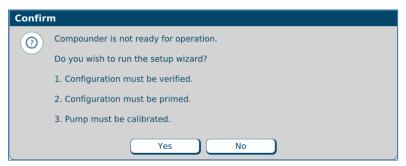
**Tip!** Baxter recommends setting up each user with a unique login name and password. If the compounder is connected to a network, Baxter recommends that the compounder be logged in to the network automatically. For details, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

**NOTE:** To require each user to log in, refer to <u>Setting Up the Security Options</u> on Page 108. To set up password expiration, refer to <u>Password Expiration</u> on Page 108.

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 105.



Confirm screen

- **3.** If the *Confirm* screen appears:
  - 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 33.
  - 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 Auto-Logout on Page 108.

#### 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.

1. At the menu screen, tap File > Exit.

The Exit Options window appears.



Exit Options window

- 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
- **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**



To reboot a nonresponsive display, press and hold the Reset button on the bottom left of the display. To shut down the compounder (main module and display), press and hold the power off button on the bottom right of the main module. However, either of these actions can corrupt the database. Do not press the Power or Reset buttons at any time unless directed to do so by Baxter Technical Support.

# SETTING UP THE COMPOUNDER

# ACCESSING THE SETUP WIZARD

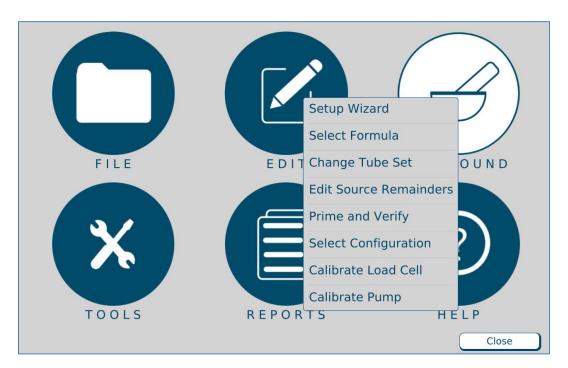
The Setup Wizard guides you through the setup process.

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.

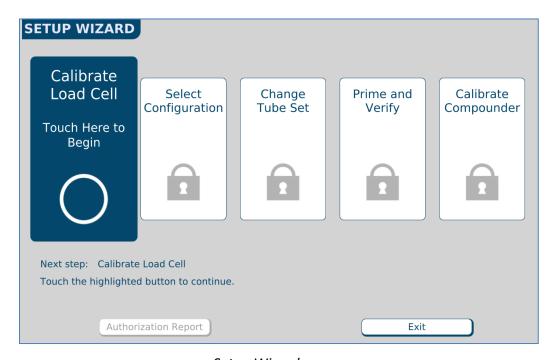


Menu screen, Compound menu

**IMPORTANT!** These functions require Compounder permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

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:

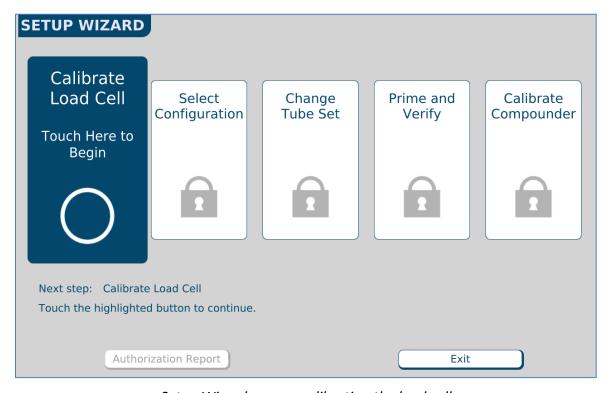
- Daily when the calibration expires
- Using a 2,000 g weight that Baxter provides

# 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:

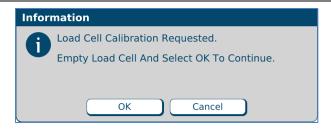
1. At the Setup Wizard screen, tap Calibrate Load Cell.



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.

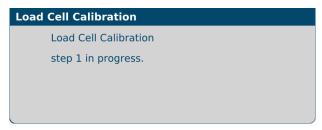
The Load Cell Calibration Requested message appears.



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.



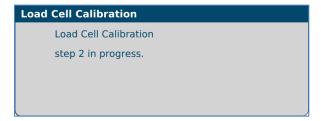
Message

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



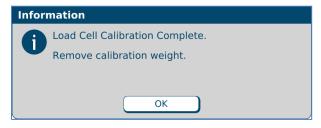
Aligning the calibration weight

- **5.** Wait five seconds to allow the weight to stabilize.
- **6.** At the *Place Calibration Weight* message, tap **OK**. This message appears and then disappears:



Message

When calibration is finished, a Load cell calibration complete message appears.



Message

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

# SELECTING THE CONFIGURATION

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

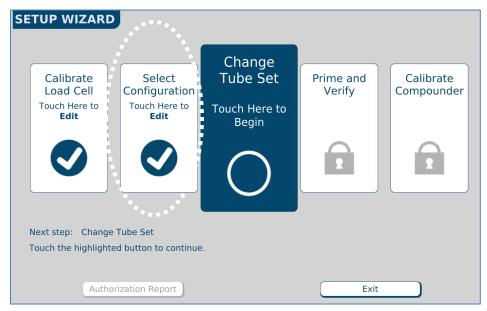
This procedure is required only if both of the following conditions exist:

- 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 in the **Select Configuration** portion of the *Setup Wizard*.

If you want to change the configuration:

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

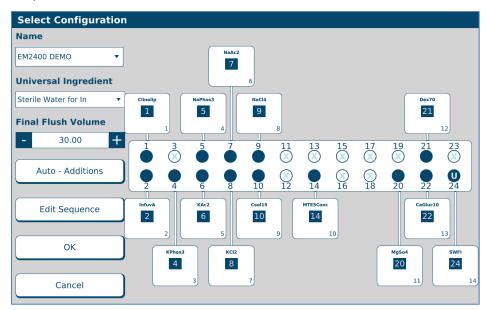


Setup Wizard screen, selecting the configuration

**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 most likely will need to change the tube set, then prime and verify it.

# 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 105.

#### **WARNING**

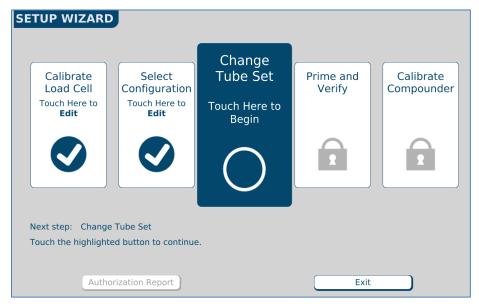


To maintain delivery accuracy, the tube set must be replaced after it has delivered 150 L of fluid or been installed for 24 hours, whichever comes first.

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**

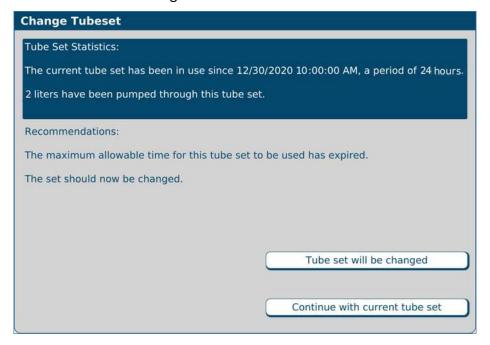
1. At the Setup Wizard screen, tap Change Tube Set.



Setup Wizard screen, changing the tube set

**NOTE:** To change the tube set without using the Setup Wizard, 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 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>Changing the Tube Set</u> on Page 93.

**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.

For removing the expired tube set and ingredients, refer to Removing the Expired Tube Set and Expired Ingredients on Page 92.

# **Installing the New Valve Set**



#### **CAUTION**

If the valve set is not installed properly, the compounder may not pump 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 Support. Refer to <u>Getting Help</u> on Page 20.

- **2.** Open the pump door.
- 3. 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.

- **4.** Place the valve set onto the valve actuators.
- 5. Push the end tabs down and out using your thumbs until you hear a click on each end.



*Installing the valve set* 

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

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



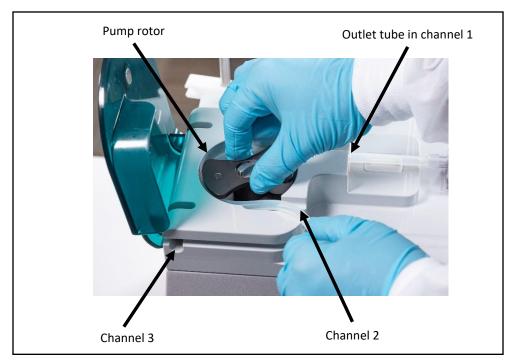
#### **CAUTION**

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

#### **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. *Tip!* Press down firmly on the silicone tubing to ensure contact with the bottom of the channel. This will ensure the tubing is properly seated in the bubble detector and over the occlusion detector.





**Proper position** 

Improper position

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



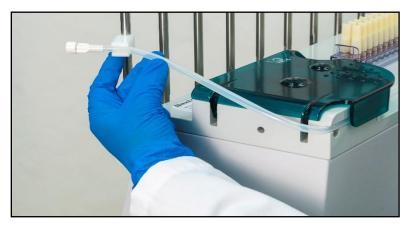


Proper position

Improper position

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

**Tip!** Optionally, you can attach the calibration bag to the outlet tube to avoid interference while connecting source containers.



Connecting the outlet tube

# **Preparing the New Ingredients**



# WARNING

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



#### **WARNING**

Review each drug product's safety profile before use.

Source containers that can be used with the compounder are:

- Large-volume, vented or collapsible containers
- Large-volume, non-vented containers
- Small-volume vials
- 50 or 60mL Luer syringes depending on brand

**Tip!** Baxter recommends using only sterile **BD** 50 mL Luer syringes. If you plan to use a different type, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

1. Gather all the new ingredients.

**Tip!** Baxter recommends using a configuration's previous Authorization Report at the end of attaching all the ingredients and inlets to quickly identify the ingredients needed for a specific configuration. For more information, refer to <u>Authorization</u> Report on Page 165.

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

**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 176.

**IMPORTANT!** Any container labeled with a barcode printed from **ExactaMix Pro** software should be verified and initialed by a pharmacist prior to connecting it to the compounder.

# 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 one end to the other in the sequence of the port numbers (example: 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.

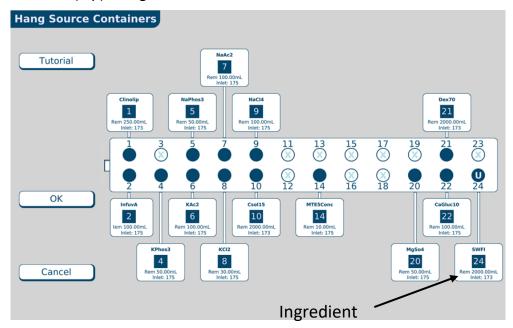
# To attach an ingredient:

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



Turning Cap

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



Hang Source Containers screen, no ingredients attached

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 last three digits of the complete part number. For a list of complete part numbers, refer to <u>Valve Sets</u> in Page 17. 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> and <u>Lot Number</u> on Page 103.

#### **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. This port should match the identified port in step 1.

**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.

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.

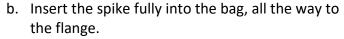


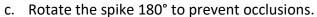
Turning

#### **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.





- d. Hang the bag on the hood hanger, if the bag is not already there.
- To spike and hang a bottle:

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



Inserting

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 into the septum of 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

- 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

 Insert the spike fully into the vial.
 IMPORTANT! Baxter recommends grasping the inlet alongside the vent as shown to ensure the vent does not get obstructed.



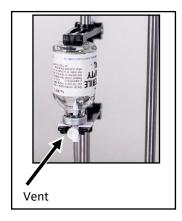
Inserting

c. Push the bottom of the vial (now facing up) against the top holder. Make sure that the vent faces you, is unobscured and is not dislodged.

**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 holder.

**NOTE:** In the event the inlet vent cap comes off of the inlet, discard the inlet and replace with a new one.



Hanging

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

**NOTE:** The flanges on the syringe should go into the slot between the spring clips on the syringe holder.



Rotating



Hanging

**6.** *Label* the inlet with the appropriate port numbered 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.

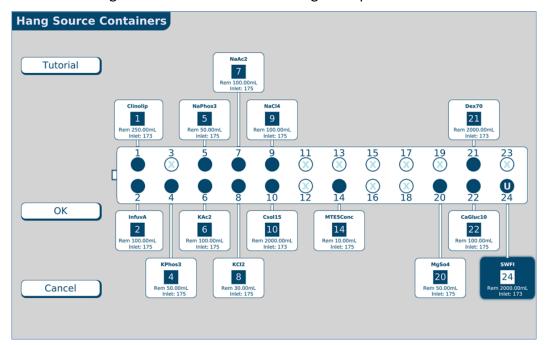
**Tip!** Baxter recommends placing the barcode label on the inlet tube about an inch (2.5cm) below the spike, so the user can see observe the fluid flowing.

- **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.

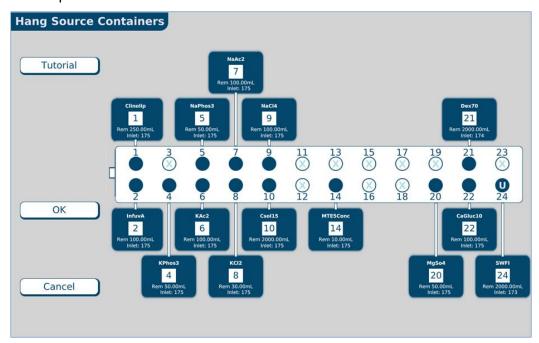
**8.** At the ingredient detail window, tap **OK**.

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

- **9.** 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**.



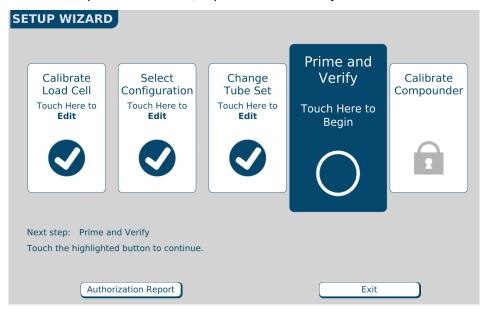
Hang Source Containers screen, all ingredients attached

If you started this procedure from the *Setup Wizard* screen, a check mark now appears in **Change Tube Set** portion of the *Setup Wizard* screen.

# 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 55.
  - Does not use barcode verification, skip to <u>Priming the Inlets and Verifying the Setup</u> on Page 58.

# **Verifying the Ingredient and Inlet Barcodes**



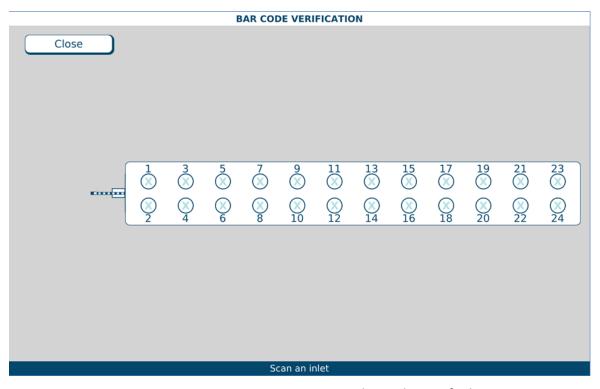
#### **WARNING**

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 45.

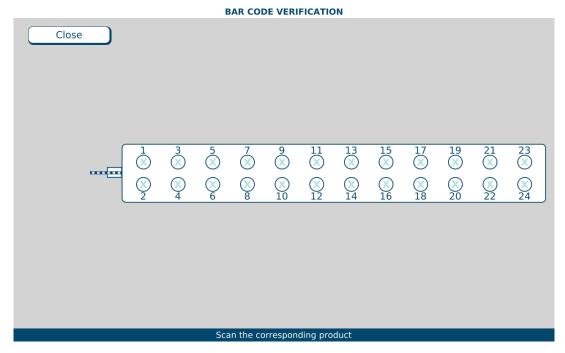
**IMPORTANT!** This procedure requires barcode scanning to be enabled. To enable barcode scanning (and, if desired, to require it for verification), refer to <u>Barcode Reader</u> on Page 109.

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



BARCODE VERIFICATION screen, Inlet scanned, asking to scan the corresponding product



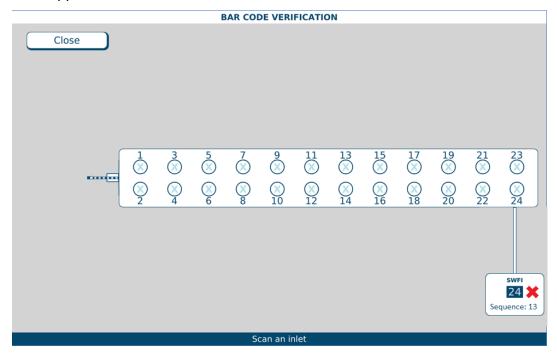
#### **WARNING**

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 ingredients or ports.

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

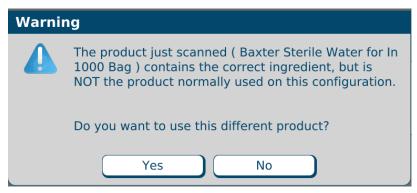
  If you scanned the correct source container, the corresponding ingredient button appears on the screen.



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.** After all inlets and ingredients are scanned successfully, the *Barcode verification completed* message will appear, tap **OK**.



Message

# 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 always 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.

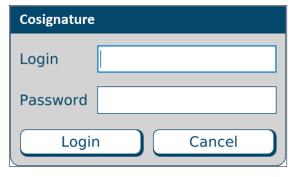
**IMPORTANT!** The cosignature option requires Verification permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120. To require that a cosigner verify the setup, refer to <u>Cosignature</u> on Page 109.

- **1.** Attach a calibration bag, if not already attached. Refer to <u>Attaching the Calibration Bag</u> on Page 68.
- **2.** If the *Cosignature required* message appears, the cosigner should:
  - a. Tap **OK**.



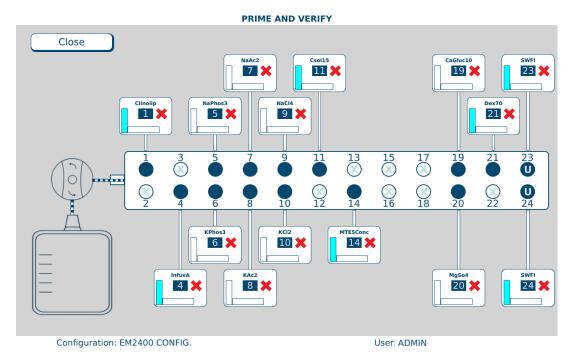
Message

- 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.

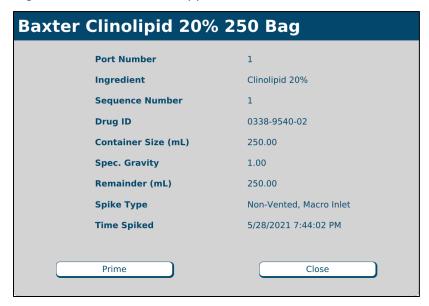
If the configuration includes a lipid, you should prime the Universal Ingredient immediately after priming the lipid.

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.

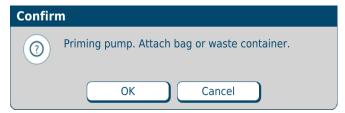
3. Tap an ingredient button.

The ingredient detail window appears.



Ingredient detail window before priming

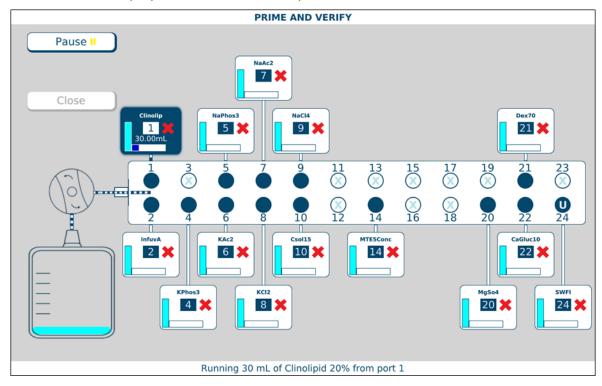
- **4.** At the ingredient detail window, review the information.
  - a. Check that the product information in the title bar of the window is correct.
  - b. Check that the **Port Number** is correct.
  - c. Check that the **Ingredient** description matches the source container to be used.
  - d. Check 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 one hand, hold the inlet that is attached to the port, and with the other hand, 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 blue. The screen displays an animation of the process.



PRIME AND VERIFY screen, priming in progress

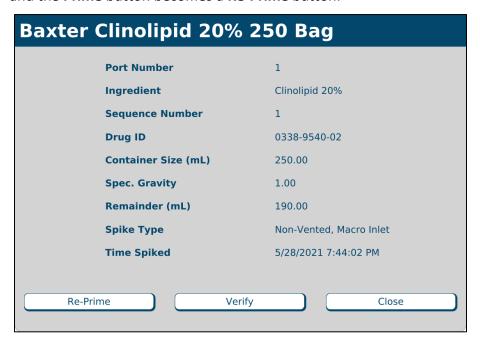


#### **WARNING**

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.

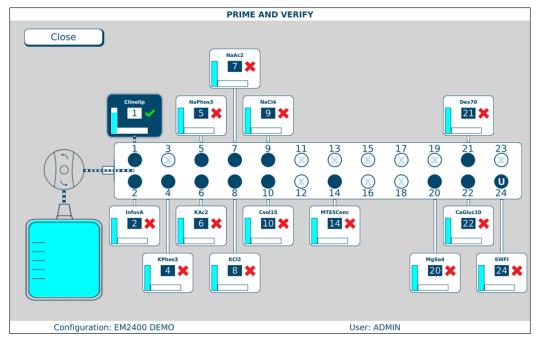


Ingredient detail window after priming

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

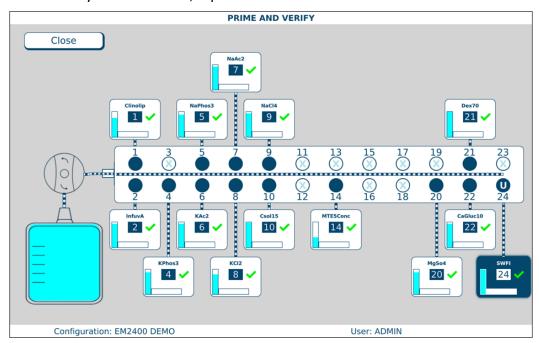
- **9.** Check the inlet to be sure that it primed properly, leaving no air in the inlet tube. If necessary, tap **Re-Prime**.
- 10. When priming is finished:
  - a. Release the tube from your hand.
  - b. Tap **Verify** to confirm that the ingredient's inlet is attached to the correct port.

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

- **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 68.
- 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 <a href="Issues with the Occlusion Detector">Issues with the Occlusion Detector</a> / "Flow <a href="Issues">Sensor</a>" on Page 203.

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



Message

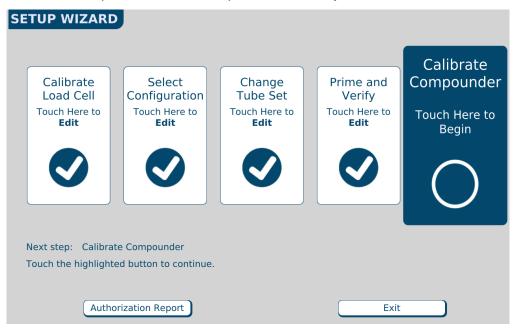
If a cosigner was logged in, the software automatically logs out the cosigner and logs in the original user.

If you started this procedure from the *Setup Wizard* screen, a check mark now appears in the **Prime and Verify** portion of the *Setup Wizard* screen.

# 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

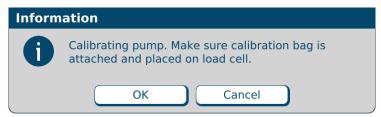
**NOTE:** You can calibrate the compounder at any time by tapping **Compound > Calibrate Pump** at the menu screen.



#### **CAUTION**

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

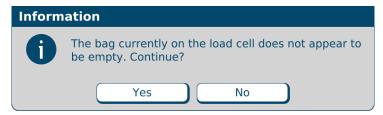
- **2.** If a calibration bag is not already attached, attach it. Refer to <u>Attaching the Calibration</u> Bag on Page 68.
- 3. At the Calibrating pump message, tap OK.



Message

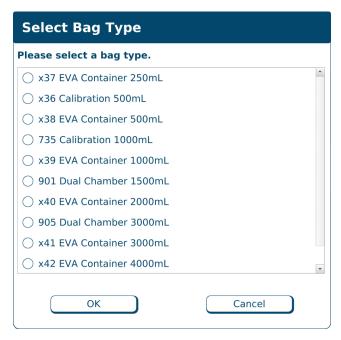
- **4.** If the *Bag currently on the load cell does not appear to be empty* message appears, visually check the contents of the bag.
  - If the bag is empty, refer to <u>The bag currently on the load cell does not appear to be</u> empty on Page 202.
  - If the bag contains fluid, continue with the next 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 69.
    - d. Attach an empty calibration bag. Refer to <u>Attaching the Calibration Bag</u> on Page 68.
    - 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

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



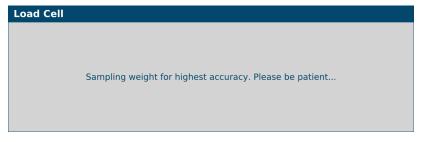
Select Bag Type window, sample North American version

**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 <u>Pump calibration failed</u> on Page 200.

If you started this procedure from the *Setup Wizard* screen, a check mark now appears in the **Calibrate Compounder** portion of the *Setup Wizard* screen.

9. Remove the calibration bag. Refer to Removing the Calibration Bag on Page 69.

# 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 twisting the bag onto the outlet tube before attaching the bag to the load cell to prevent twisting or straining of the connection.
- **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.

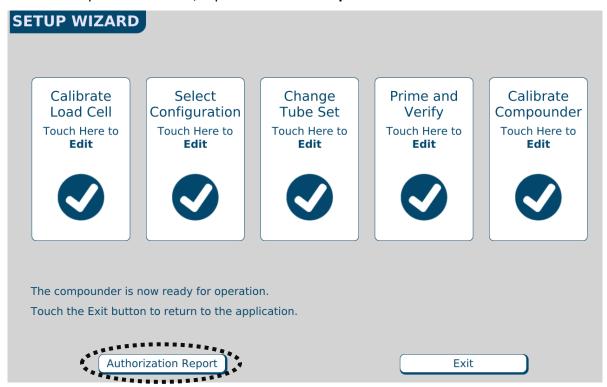
- 1. Remove the bag's fill port from the load cell's fill port holder.
- **2.** Remove the bag from the load cell.
  - **3.** Clamp the bag's fill port, unless the bag is not full and it will be used for other recalibrations.
  - 4. Disconnect the outlet tube from the bag.
  - **5.** Connect the end of the outlet tube to the tube holder on the vial rack.
  - **6.** Cap the bag's fill port.
  - 7. Discard the bag, or if not full, set aside the bag for re-calibration or flushing.

**NOTE:** If saving the bag, keep it in the hood to preserve aseptic.

# 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 165.

To exit the Setup Wizard screen, tap Exit.

# **USING THE COMPOUNDER**

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

# FULFILLING THE ORDER (BASIC PROCESS)

### 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. For more information, contact Baxter Technical Support. Refer to Getting Help on Page 20.
- · 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.

Baxter recommends the following process:

- 1. Attach the bag label to the patient bag.
- 2. Attach the patient bag to the compounder. Refer to Attaching the Patient Bag on page 71.
- Scan the barcode for the order.

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 Drug ID number of each ingredient in the formula and matches this number to one in the formulary. In the United States, the Drug ID number is usually the National Drug Code (NDC).

#### **WARNING**



The Drug ID number for each product in the formula must exactly match the Drug ID number for that product in the compounder's formulary. If a Drug ID 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 will pump the wrong ingredient, resulting in patient harm. It is the user's responsibility to ensure that Drug ID 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.

### **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 twisting the bag onto the outlet tube before attaching the bag to the load cell to prevent twisting or straining of the connection.
- 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.



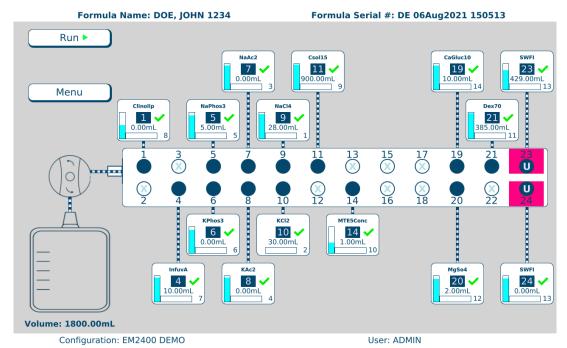


Attaching the patient bag to the outlet tube and the load cell

### **Compounding the Solution**

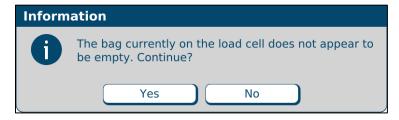
**IMPORTANT!** This function requires Compounder permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

**5.** At the pump screen, verify the patient's name and bag serial number at the top of the screen matches the name and serial number on the bag. If they match, tap **Run**.



Pump screen, ready to start compounding the solution

- **6.** If the message shown below 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 202.
  - If the bag contains fluid:
    - a. Tap No.
    - b. At the Operation Cancelled message, tap **OK**.
    - c. Remove the bag. Refer to Removing the Patient Bag on Page 75.
    - d. Attach an empty bag. Refer to Attaching the Patient Bag on Page 71.
    - 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.

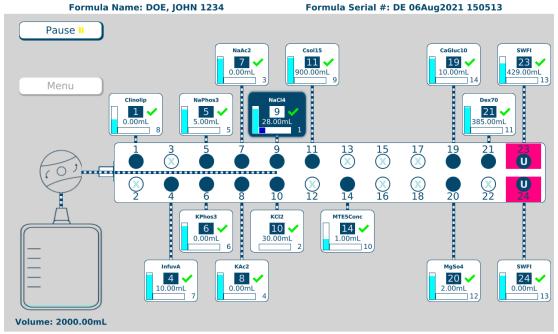
The **Details** section of the MixCheck Report will indicate that you continued compounding despite the warning that the bag did not appear to be empty. For instructions on how to handle a finished bag in this situation, refer to your facility's protocol.

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



Select Bag Type window

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 blue.



Running 28 mL of Na Chloride 4mEq/mL from port 9

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 (OTHER COMMON ACTIVITES)</u> on Page 83.

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.

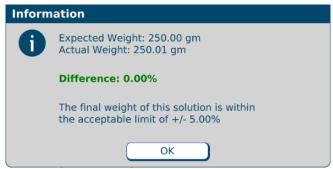
- Tap **Pause**, then tap **Resume** to start compounding again.
- Open the pump door, then close the pump door and tap **Resume** to start compounding again.

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

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

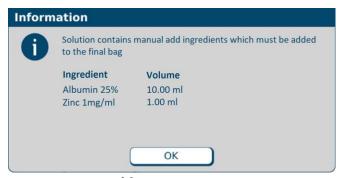
**NOTE:** If the difference is not acceptable, refer to <u>Issues with the Weight and Load Cell</u> on Page 201. The acceptable difference is typically set to  $\pm$  5%. To change this setting, refer to Acceptable Weight Variances on Page 106.

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



Message

**9.** If the selected formula contained manual add ingredients, the following message will appear as a reminder, 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. Clamp the bag's fill port according to facility protocol.
- 3. Remove the bag from the load cell.
- **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.** If necessary, perform any manual additions. Refer to <u>Performing a Manual Addition</u> on Page 84.
- **2.** Visually inspect the finished solution in the patient bag for precipitates and particulates. Follow your facility's protocol.
- **3.** View and approve the MixCheck Report according to your facility's protocol. For instructions, refer to MixCheck Report on Page 160.

Operator Manual

ExactaMix Pro 2400 Compounder

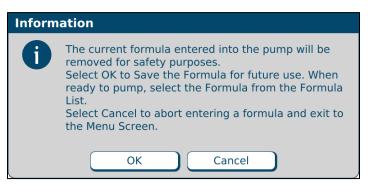
### UNDERSTANDING AUTOMATIC UNLOADING OF FORMULAS

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

• The software 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.



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 the following 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 109.
- 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 109.

**NOTE:** In the event there is a power interruption during compounding, upon restarting the compounder and initiating pumping, the formula will be unloaded and the system will perform a flush as follows:

- Power interruption during pumping prime and verify the open port, then flush occurs.
- Power interruption during idle state formula unloads, then flush occurs.

Write a large "X" on the label of the patient bag after the flush, then remove and discard the bag.

### OTHER METHODS OF 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 the 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 system fails, you can still load a formula by scanning a barcode. For instructions, refer to Loading a Formula by Connecting a USB Drive on Page 206.

**NOTE:** To enable barcode scanning (and, if desired, to require it for loading formulas), refer to <u>Barcode Reader</u> on Page 109.

# **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.

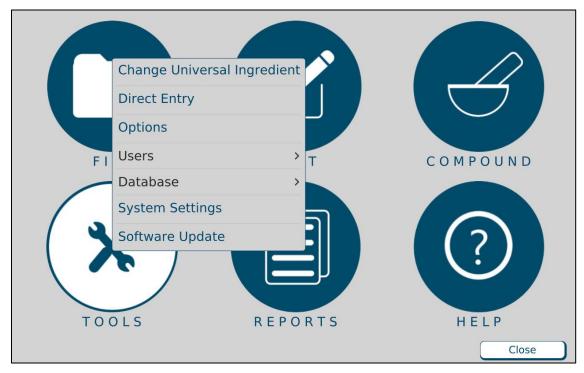


#### **WARNING**

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

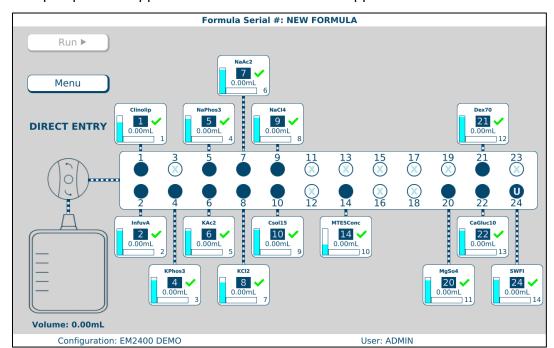
**IMPORTANT!** This function requires Formula Entry permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

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



Menu screen, Tools menu

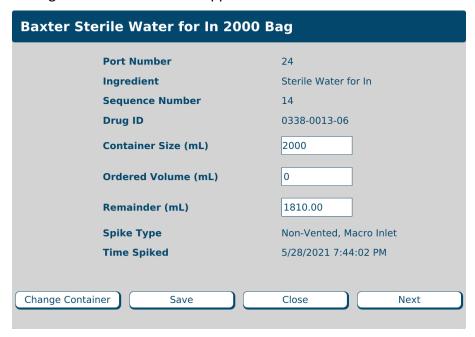
**NOTE:** To stop using direct entry, you can tap **Tools > Cancel Direct Entry** at the menu screen.



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. 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 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 76.

- 1. Attach the patient bag. Refer to Attaching the Patient Bag on Page 71.
- **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**.



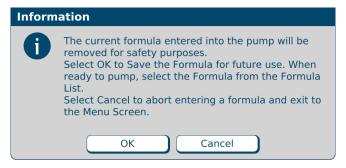
Formula Information window

4. Continue with Compounding the Solution on Page 72.

**NOTE:** You do not need to tap **Run** again.

## 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

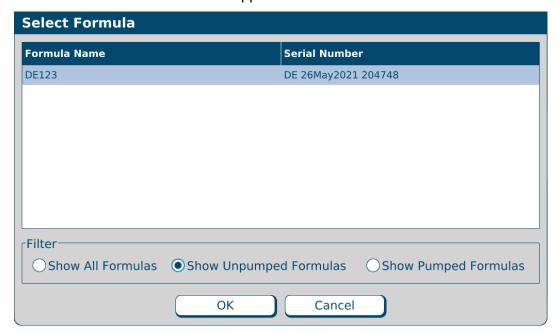
**4.** When you want to compound the solution, continue with <u>Selecting a Saved Formula</u> on Page 82.

### **Selecting a Saved Formula**

Some facilities may use this method to select a saved formula, which has already been loaded onto the compounder by 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 109.

**1.** 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 <u>Storage</u> on Page 104.

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

The formula is loaded and appears on the pump screen.

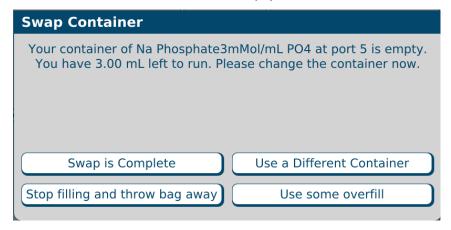
5. Continue with Fulfilling the Order (Basic Process) on Page 70.

# FULFILLING THE ORDER (OTHER COMMON ACTIVITES)

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.

# **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 Support. Refer to <u>Getting Help</u> on Page 20.

- 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.

**NOTE:** This is the recommended action.

#### 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 45 and <u>Priming and Verifying</u> on Page 54.

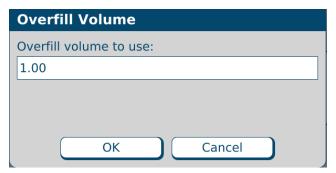
- Tap **Stop filling and throw bag away** to cancel the order. At the pump screen, tap **Stop** and follow the on-screen instructions.
- Tap **Use some overfill** to use the fluid remaining in the current container to complete the order. At the *Overfill Volume* window:
  - a. Enter the Overfill volume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

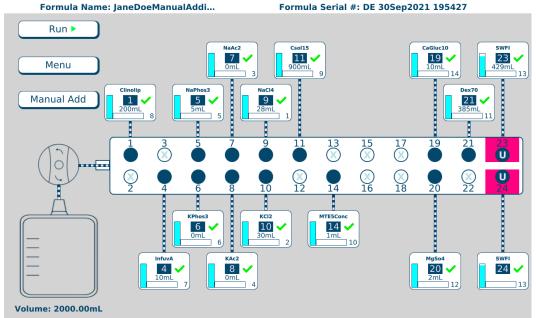
### **Performing a Manual Addition**

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.



Loading Formula JaneDoeManualAddition/DE 30Sep2021 195427...Done.

### 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 160.

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 107.

#### 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

**NOTE**: This does not mean that the bubble came from port 24. The bubble could have come from any of the previous ingredient deliveries.

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

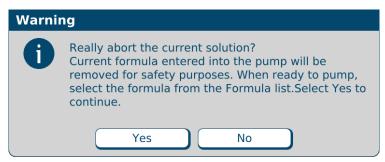
- **2.** Determine the impact of the bubble:
  - a. Check the size of the bubble using the EM2400 Bubble Chart to determine the volume of fluid displaced. Use the bubble chart to determine the size of the bubbles within the tube set.
  - b. If more than one bubble is present, evaluate each bubble and 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.

- **3.** 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

**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 75.
- **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 48.
- Re-prime any inlets that have visible bubbles. Refer to <u>Priming the Inlets and Verifying the Setup</u> on Page 58.
- Increase the priming volume in the configuration. Refer to Adding or Editing a Configuration on Page 128.
- Clean the channel over the bubble detector. Refer to <u>Cleaning the Compounder</u> on Page 93.
- 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 43.

#### **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.



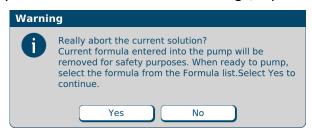
Occlusion symbol

- 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**.
- **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 40.
  - 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

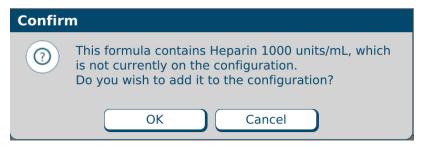
- **10.** Remove the bag. Refer to Removing the Patient Bag on Page75.
- 11. Discard the bag.

### **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).

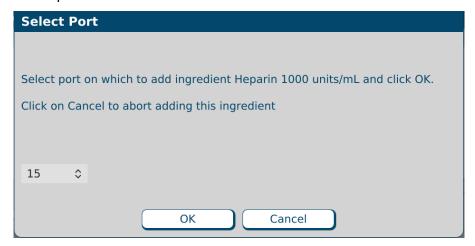
If the loaded formula includes an ingredient that is not attached to the compounder but is identified as an allowable auto-addition in the formulary and the current configuration, a *Confirm* message appears.

1. At the Confirm message, tap OK.



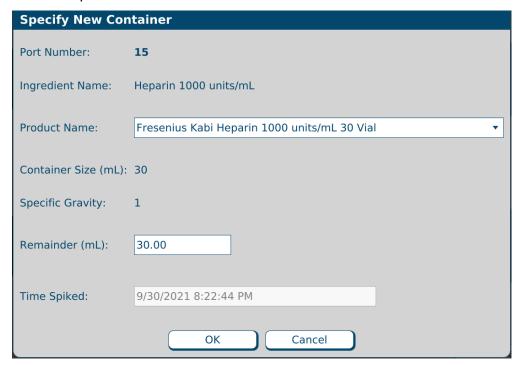
Message

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



Select port window

- **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 45.
- **5.** If you have already attached the patient bag, remove it. Refer to Removing the Patient Bag on Page 75.
- 6. Attach a calibration bag. Refer to Attaching the Calibration Bag on Page 68.
- **7.** Prime and verify the new inlet and ingredient. Refer to <u>Priming and Verifying</u> on Page 54.
- **8.** Remove the calibration bag. Refer to Removing the Calibration Bag on Page 69.
- 9. Attach the patient bag. Refer to Attaching the Patient Bag on Page 71.
  - **NOTE:** You can reattach the original patient bag.
- **10.** Continue with compounding the solution. Refer to <u>Compounding the Solution</u> on Page 72.

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

## **Handling Other Interruptions and Errors**

For more information about handling interruptions and errors, refer to <u>Troubleshooting</u> on Page 192.

#### REMOVING THE EXPIRED TUBE SET AND EXPIRED INGREDIENTS



#### **CAUTION**

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

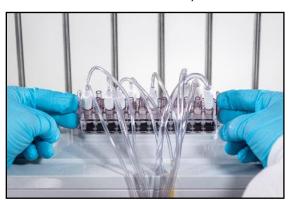


#### **WARNING**

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 68.
- 2. Place a waste container in front of the hood and align in front of the compounder.
- **3.** Remove one source container from the vial rack or hanger and turn the source container right side up.
- **4.** Lower the source container below the height of the valve set between the load cell and the display. Bags can be lowered directly into the waste container.
- **5.** Repeat the previous steps for each source container.
- 6. 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.

- 7. Turn the pump rotor counterclockwise while removing the outlet tube from the pump.
- 8. 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.
- **9.** Discard the valve set and the attached calibration bag into the waste container.
- **10.** Discard the inlets, spikes and Ingredient source container(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 93, and follow your facility's protocol.

# MAINTAINING THE COMPOUNDER

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

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

And perform these tasks regularly:

- Back up and compact the database (Baxter recommends Weekly)
- Clean the rotor (Baxter recommends Monthly)

## CALIBRATING THE LOAD CELL

This procedure is usually performed as part of the daily setup. For instructions, refer to Calibrating the Load Cell on Page 35.

### CHANGING THE TUBE SET

This procedure is usually performed as part of the daily setup. For instructions, refer to <u>Changing the Tube Set</u> on Page 40.

## 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

**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.

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

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

- **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 92.
- **3.** Open the pump door.
- **4.** Remove and retain the thumbscrew and washer used to attach the rotor.

**NOTE:** The rotor should be cleaned at least monthly, or when there are visible signs of contaminants.





Removing the thumbscrew

**5.** Remove the pump rotor from the spindle.



Removing the pump rotor

- **6.** Using the approved materials, clean the:
  - Pump rotor, making sure that the rollers spin freely. If rollers are not spinning freely, contact Baxter Technical Support.
  - Pump rotor area
  - Channels near the pump rotor area
- **7.** Install the:
  - Pump rotor, aligning the notch on bottom of the rotor with the pin on the spindle
  - Washer and thumbscrew
- 8. Close the pump door.
- **9.** Using the approved materials, clean the:
  - Valve actuators
  - Surface of the main module
  - Load cell
  - Poles and holders on the vial rack

### 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 65.

### 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 Storage on Page 104.

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 106.

#### **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

**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

## **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 Support.

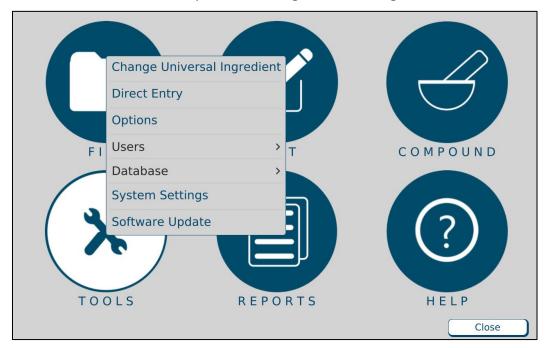
### CHANGING THE UNIVERSAL INGREDIENT

**IMPORTANT!** This function requires Change Universal Ingredient permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

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 107.

If you are prompted to change the volume of the UI during the compounding process, refer to <u>Formula Conflict</u> on Page 198.

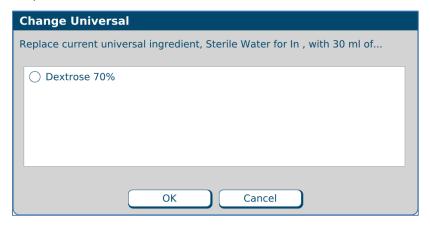
1. At the menu screen, tap Tools > Change Universal Ingredient.



Menu screen, Tools menu

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 138.

- 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 68.
- **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 69.
- **6.** If you will continue with compounding a solution, attach a patient bag. Refer to Attaching the Patient Bag on Page 71.
- **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 120.

- 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**.

Port	Ingredient	Container Size	Remaind	Reset
1	Clinolipid 20%	1000	940.00	Reset
4	Infuvite Adult	100	94.00	Reset
5	Na Phosphate3mMol/mL PO4	15	9.00	Reset
6	K Phosphate 3mMol/mL PO4	15	9.00	Reset
7	Na Acetate 2mEq/mL	100	94.00	Reset
8	K Acetate 2mEq/mL	50	44.00	Reset
9	Na Chloride 4mEq/mL	100	94.00	Reset
10	K Chloride 2mEq/mL	250	244.00	Reset
11	Clinisol 15%	2000	1940.00	Reset
14	Multitrace-5 Concentrate	10	4.00	Reset
19	Ca Gluconate 0.465mEq/mL	100	94.00	Reset
20	Magnesium Sulfate 4.06mEq	20	14.00	Reset
21	Dextrose 70%	2000	1940.00	Reset
23	Sterile Water for In	1000	820.00	Reset
24	Sterile Water for In	2000	1890.00	Reset

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 120.

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

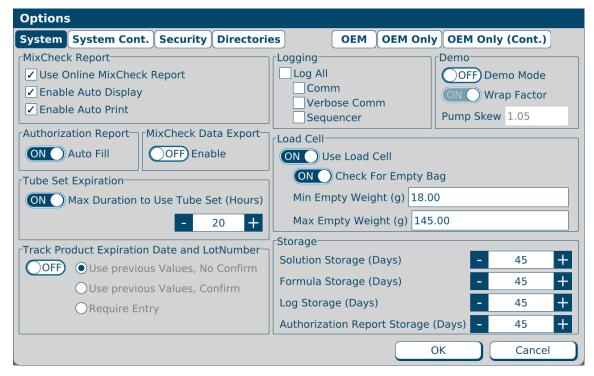
- Tapping OK saves the changes made on all the tabs and requires you to exit the software.
- Tapping Cancel closes the window without saving any changes.

## 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.

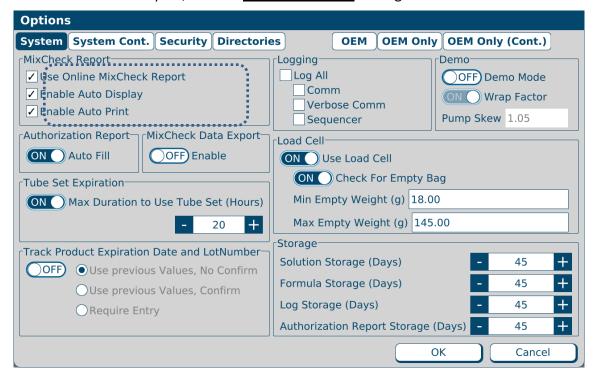
At the *Options* window, the **System** tab is selected.



Options window, System tab

### 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 160.



Options window, System tab

**Enable Auto-Print** is enabled by default. Ensure one or both of the options **Enable Auto-Display** and **Enable Auto-Print** are selected; otherwise, an error message results. **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. For details, refer to
  Using Online MixCheck Authorization on Page 160.
- 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 165.

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 Support. Refer to <u>Getting Help</u> on Page 20.

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 179.

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:

- 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:

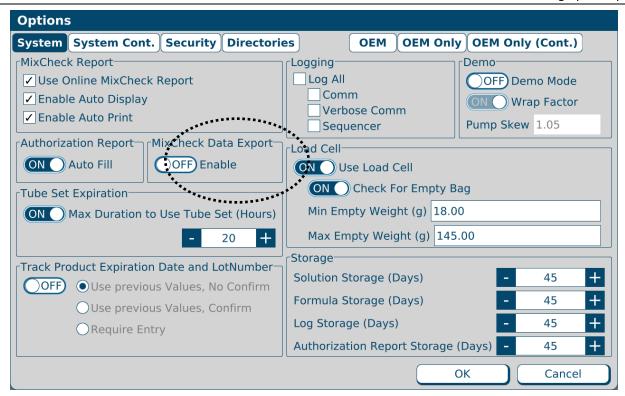
- For **Solution Storage (Days)**, enter the number of days that used formulas are available in the database.
- For **Formula Storage (Days)**, enter the number of days that unused formulas are available in the database.
- For **Log Storage (Days)**, enter the number of days that Blackbox information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

The minimum duration available for the above-mentioned storages are 30 days and maximum are 15 months. By default, all the above storage days are set to 45 days.

### **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 Support. Refer to <u>Getting Help</u> on Page 20.



Options window, System tab

## **Tube Set Expiration**

**IMPORTANT!** Before changing any of these settings, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

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 previous daily setup.

# 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 Support.

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.

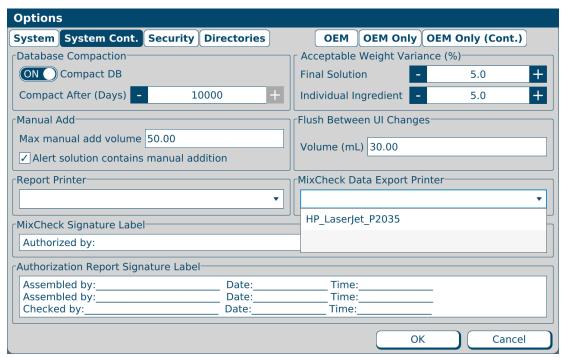
**NOTE:** A UI flush contains three deliveries with standard volumes of 50, 50 and 30 mL. Changing the **Volume** setting changes only the last of the three deliveries.

### **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, the application will display **MixCheck Data Export Printer** in the System Cont. tab.



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**

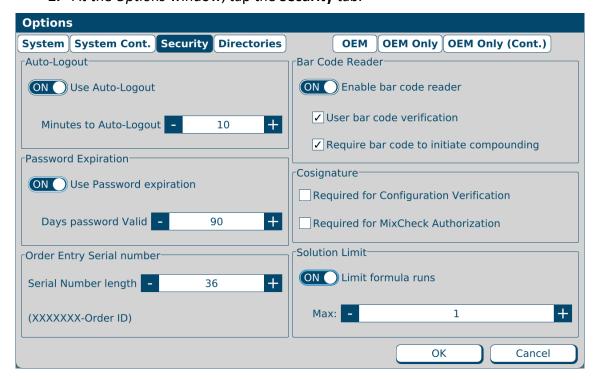
Enter text that you want to include about required signatures in the Authorization Report.

### 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

#### 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.

### **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, the **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 maximum number of characters allowed in the 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 and 2D GS1 barcode formats.

#### 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 co-signature.

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.

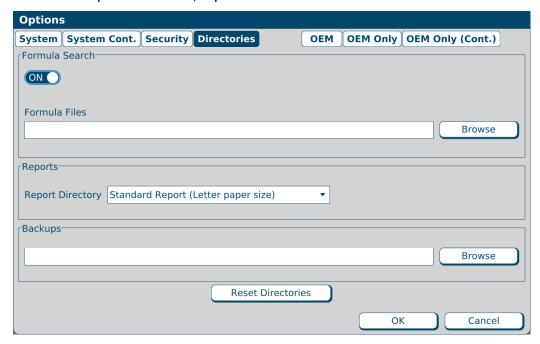
*Tip!* Baxter recommends entering 1 for the **Max**.

## SETTING UP THE DIRECTORIES OPTIONS

Use the **Directories** tab to set the locations of formula files 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

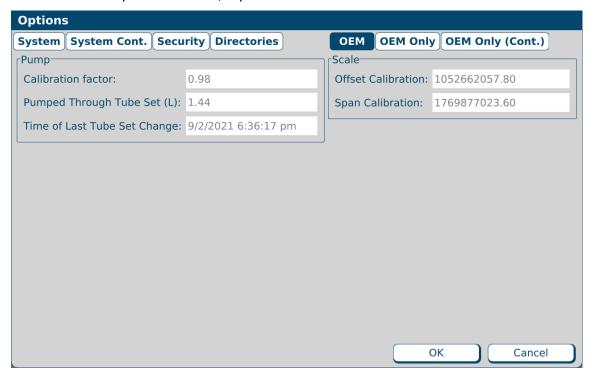
- 3. If you want to allow users to retrieve formula files, select Formula Search.
  IMPORTANT! After initial installation, you should not need to change the locations of the directories. Do not tap Reset Directories unless directed by Baxter Technical Support. This button changes the locations of the directories from their current settings.
- **4.** If you want to change the locations of the directories:
  - a. Tap Browse for Formula Files 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 Support.

To access the OEM options:

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



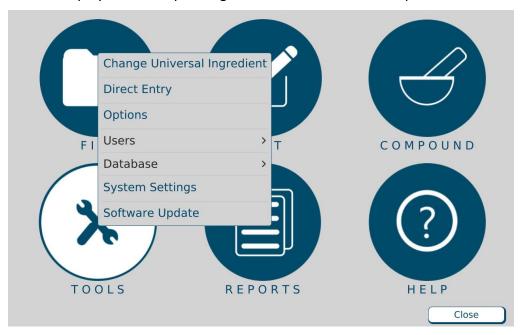
Options window, **OEM** tab

# **SYSTEM SETTINGS**

<u>IMPORTANT!</u> Access to these functions requires Administration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

To access system settings

- 1. At the main menu, tap Tools > System Settings
- **2.** In the left window pane, select a setting option of choice and the right window pane will display the corresponding information and editable options.



Tools options, Menu screen

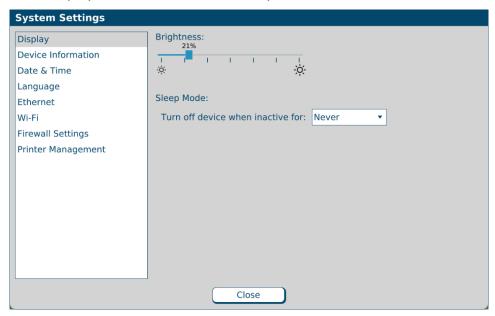
## **DISPLAY**

## **Brightness:**

The brightness of the display can be dimmed or brightened by adjusting the slider left or right between 0% and 100%.

## Sleep Mode:

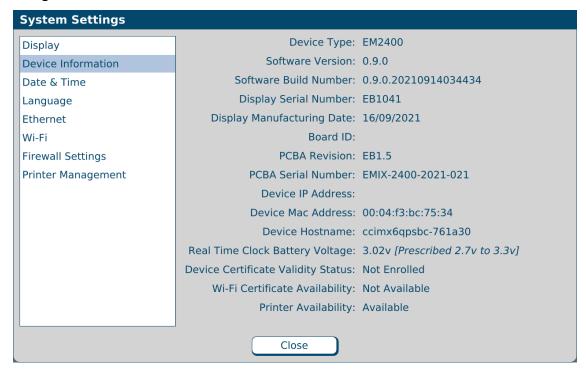
Sleep mode can be used to turn off the device after a period of inactivity. To adjust the inactivity period, tap the drop-down menu arrow and select a desired time or Never if you do not want the display to turn off due to inactivity.



Display screen, System Settings

## **DEVICE INFORMATION**

Device information provides information about the **ExactaMix Pro** display that can be helpful during service.



**Device Information screen** 

## DATE & TIME

**IMPORTANT!** These functions require System Settings permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

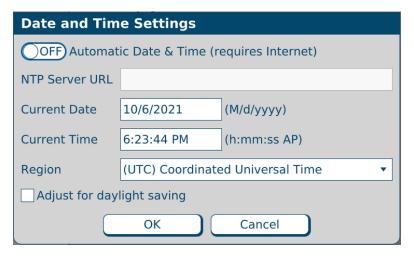
To change the date and time, select the **Edit** button on the *System Settings* screen. From this screen you can set time and date manually by entering the desired time or date in the fields, or use automatic time settings.



Date & Time screen

## Turning on automatic date and time

- 1. Connect the **ExactaMix Pro** display to an internet source.
- 2. Tap the toggle button so that it reads ON.
- 3. Enter an NTP Server URL into the box next to NPT Server URL.
- **4.** Tap **OK**.



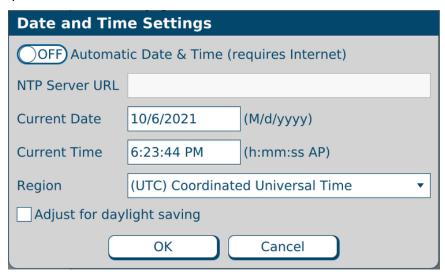
Date and Time Settings screen

## **Changing region**

- **1.** Tap the drop-down arrow in the box next to Region.
- 2. Select the desired region from the list.
- 3. Tap **OK**.

## Turning on daylight savings time

- **4.** After setting the time, check the box next to Adjust for daylight saving if the compounder is located in a region where Daylight Savings Time is observed.
- **5.** Tap **OK**.

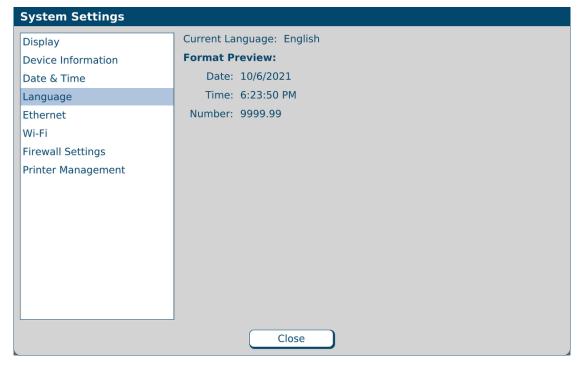


Date and Time Settings screen

## LANGUAGE

**IMPORTANT!** Access to these functions requires System Settings permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

To view/edit language settings, click the **Language** tab on the *System Settings* screen.



Language screen

## **ETHERNET**

**IMPORTANT!** Access to these functions requires Network Configuration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120,

To view/edit ethernet settings, click the **Ethernet** tab on the *System Settings* screen.

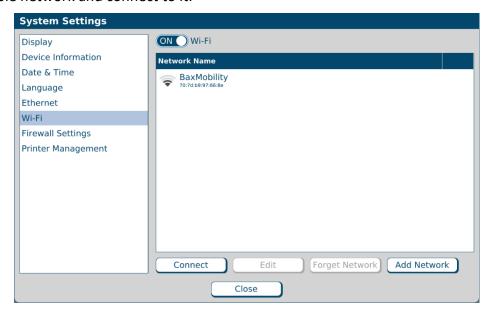


Ethernet screen

## WI-FI

**IMPORTANT!** Access to these functions requires Network Configuration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

To view/edit wi-fi settings click the **Wi-Fi** tab on the *System Settings* screen. Select the desired available network and connect to it.

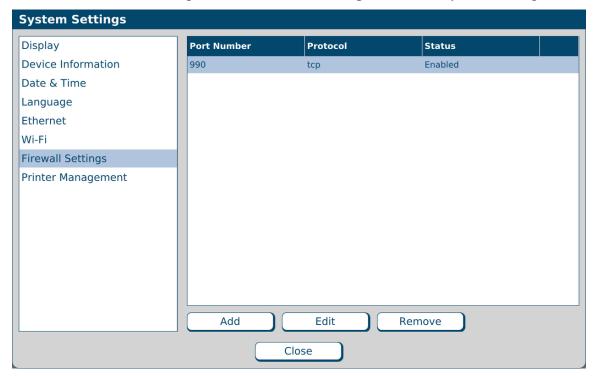


Wi-Fi Screen

## FIREWALL SETTINGS

**IMPORTANT!** Access to these functions requires Network Configuration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

To view/edit firewall settings click the **Firewall Settings** tab on the *System Settings* screen.



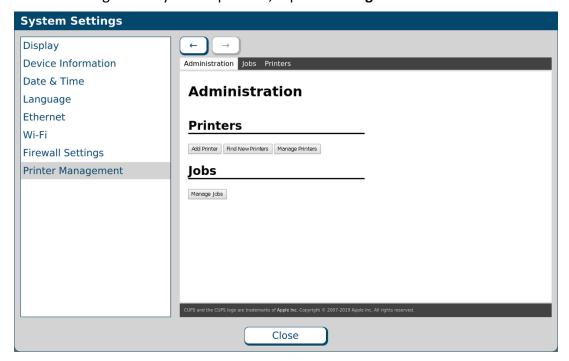
Firewall Settings screen

## PRINTER MANAGEMENT

**IMPORTANT!** Access to these functions requires Network Configuration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120.

To view/add/edit printer settings click the **Printer Management** tab on the *System Settings* screen.

- 1. To add a printer, tap the Add Printer button.
- 2. To find printers on the network, tap the **Find New Printers** button.
- 3. To manage already added printers, tap the Manage Printers button.



Printer Management screen

# SETTING UP THE USERS

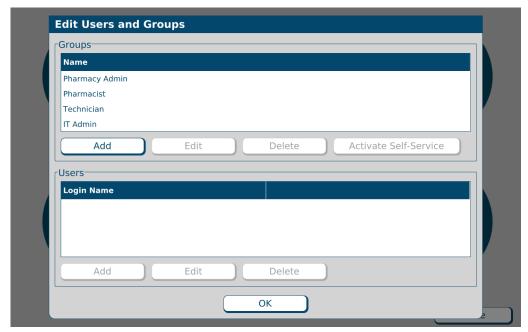
Each user must have an account so that the compounder can track activity. Users are assigned to groups that have the appropriate permissions to perform the required tasks.

## WORKING WITH GROUPS

## Adding or Editing a Group

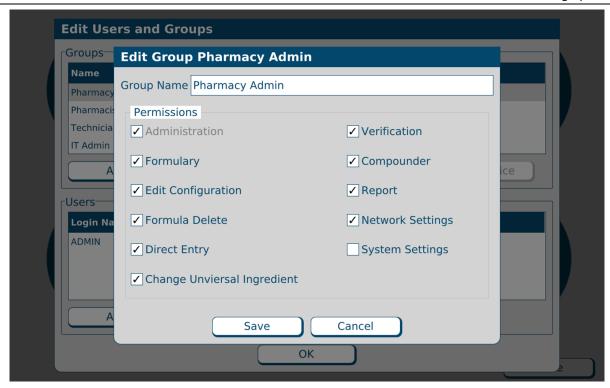
**IMPORTANT!** These functions require Administration permissions.

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.



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	Use Tools > Options     Use Tools > Users > Edit Users and Crouns	Pharmacy Admin and IT Admin
	<ul><li>Use Tools &gt; Users &gt; Edit Users and Groups</li><li>Use the Inlet Editor</li></ul>	11 Admin
	<ul> <li>Use the Bag Inventory Editor</li> </ul>	
	<ul> <li>Add / Update Flow Factors</li> </ul>	
	Update Date/Time	
	<ul> <li>Restore Database &amp; access device logs.</li> </ul>	
Formulary	Use the Formulary Editor	Pharmacy Admin
	Use the Ingredient Group Editor	
<b>Edit Configuration</b>	Use the Configuration Editor	Pharmacy Admin
Direct Entry	Create and save direct-entry formulas	Pharmacy Admin,
		Pharmacist and
		Technician

Permissions	Allowed Functions	Baxter recommends
		assigning to:
Formula Deletion	Delete a formula	Pharmacy Admin
Change Universal	Change the Universal Ingredient without changing the	Pharmacy Admin,
Ingredient	configuration	Pharmacist and
		Technician
Verification	<ul> <li>Perform cosignature authorization of the priming and</li> </ul>	Pharmacy Admin and
	verifying steps during setup	Pharmacist
	<ul> <li>Perform authorization and cosignature authorization</li> </ul>	
	of the MixCheck Reports	
Compounder	Calibrate the load cell	Pharmacy Admin,
	Select the configuration	Pharmacist and
	Change the tube set	Technician
	Prime the inlets	
	Calibrate the compounder	
	Compound the solution	
	Edit the source remainders	
Report	View reports	Pharmacy Admin, IT
	Export reports	Admin Pharmacist
	Print reports (except MixCheck Report)	and Technician
Network Settings	<ul> <li>Authentication type (username/password OR</li> </ul>	Pharmacy Admin and
	certificate based)	IT Admin
	<ul> <li>Username &amp; Password to access server share</li> </ul>	
	<ul> <li>Ethernet settings (enable/disable, automatic IP, static IP &amp; DNS)</li> </ul>	
	Wi-Fi settings (enable/disable, automatic IP, static IP)	
	& DNS)	
	Firewall settings (Allow/Reject ports, display	
	configured ports)	
	Wi-Fi security protocol parameters & certificates	
	(WEP, WPA2, WPA2-Enterprise)	
	<ul> <li>Configuration of paths for PAT/FRM files (Part of</li> </ul>	
	Options)	
	Select Print Report type	
	Export Report Location	
	Database and logs Backup Location	

*Tip!* Baxter recommends having a pharmacist perform the verification.

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

### **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

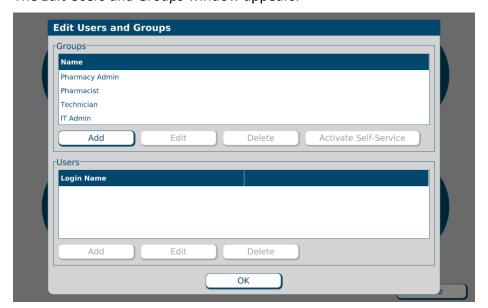
4. At the Edit Users and Groups window, tap OK.

## **WORKING WITH USERS**

## Adding or Editing a User

**IMPORTANT!** These functions require Administration permissions.

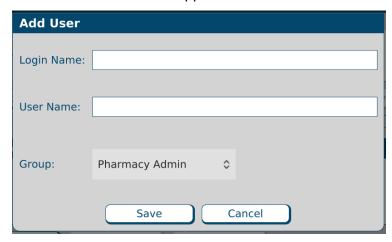
At the menu screen, tap Tools > Users > Edit Users and Groups.
 The Edit Users and Groups window appears.



Edit Users and Groups window

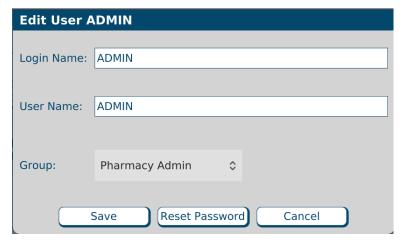
- **2.** At the *Edit Users and Groups* window:
  - a. In the top half, select the group from the **Name** list.
  - b. In the bottom half, do one of these options:
    - Tap **Add** to add a user.

The Add User window appears.



Add User window

Select the user you want to edit from the Login Name list, then tap Edit.
 The Edit User <name> window appears.



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

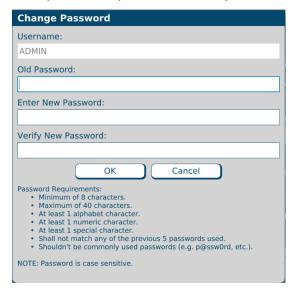
**4.** At the *Edit Users and Groups* window, tap **OK**.

### **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 that a new password shall be a minimum of 8 characters and a maximum of 40 characters. It shall contain at least 1 number, 1 alphabetic letter, and 1 special character. Also, it shall not match any of the previous 5 passwords or any commonly used passwords.



Change Password window

# 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 120. Before making any changes in the Configuration Editor, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

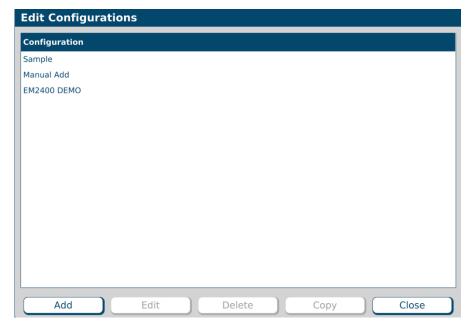
**IMPORTANT!** The Configuration Editor is to be used only to create and manage non-active configurations. All changes to the Universal Ingredient of an active configuration must be made through the <u>Changing the Universal Ingredient</u> functionality described on Page 98.

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



Menu screen, Edit menu

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 a Baxter Technical representative review and approve every new or edited configuration before it is placed into service.

Baxter Technical Support is available for reviewing and approving all new and updated configurations. Refer to <u>Getting Help</u> on Page 20 for additional instruction.

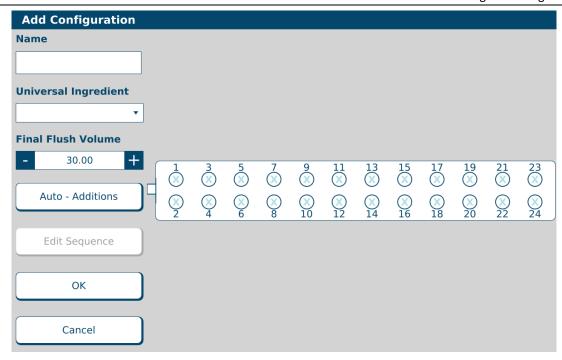
- **1.** At the *Edit Configurations* window, do one of these options:
  - Tap Add to add a configuration.

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 and then tap Copy.

The Copy of <copied configuration name> window appears.

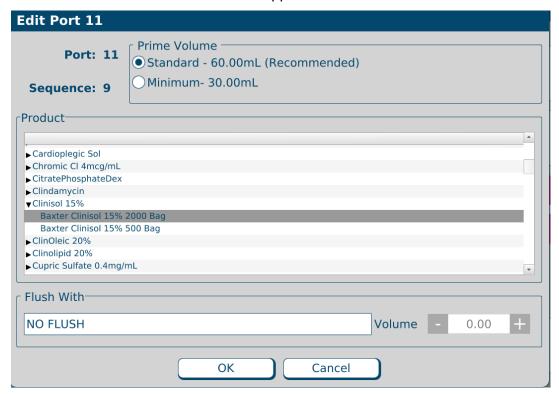
**NOTE:** You can use the **Copy** option to make minor edits to an existing configuration and save it with a new name.



Add Configuration window

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

The *Edit Port < number>* window appears.



Edit Port <number> window

- **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 and active. Refer to <u>Using the Formulary Editor</u> on Page 138.

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.

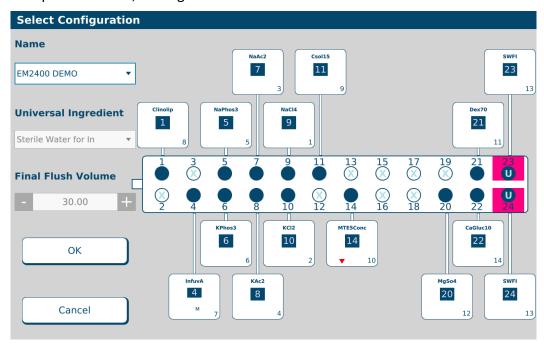
**NOTE:** The prime volume is used during setup of the compounder. This volume must be set for each product that is in each configuration. Auto-addition ingredients are always primed with the standard volume.

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 138.

- d. Tap **OK**.
- **5.** Repeat Steps 3 and 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:
  - a. 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 19–24; they cannot be assigned to ports 1–18. 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.

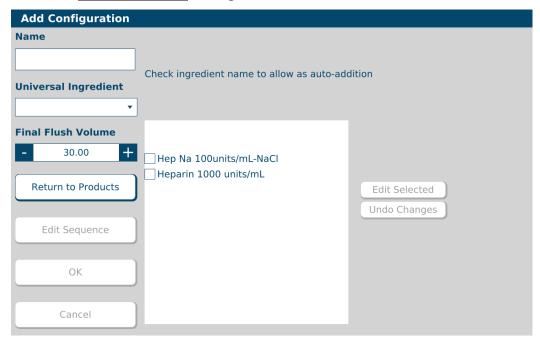
b. Enter the Final Flush Volume.

**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 138.



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 EM2400 DEMO Name EM2400 DEMO **Universal Ingredient** Auto-Add Seq Ingredient Sterile Water for In Na Chloride 4mEq/mL False Final Flush Volume K Chloride 2mEq/mL False 30.00 Na Acetate 2mEq/mL False Auto - Additions 4 K Acetate 2mEq/mL False 5 Na Phosphate3mMol/m... False **Return to Products** 6 K Phosphate 3mMol/m... False 7 Infuvite Adult False OK 8 Clinolipid 20% False 9 Clinisol 15% False Cancel

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 Configuration Report on Page 173.

## CONFIGURATION GUIDANCE

There are two primary guiding requirements for port placement and ingredient sequencing in a configuration:

- **1.** To minimize or eliminate opportunities for chemical interaction between concentrated ingredients
- 2. To maximize the efficiency of valve movement

In view of these requirements, there are certain ingredients that should never be placed on the compounder, and as a result must be added as a "manual add". These ingredients include:

- Iron-containing salts highly reactive and will cause lipid emulsions to crack
- Insulin adsorbs onto PVC tubing and causes unreliable drug delivery
- Albumin >10% this is a harvested blood protein whose behavior within the pumping system can be inconsistent due to the variant viscosity of the product.

Operator Manual

ExactaMix Pro 2400 Compounder

Every configuration requires a *Universal Ingredient* (UI), which is the ingredient that is in the common fluid path when pumping starts, and is the last ingredient pumped to clear the common fluid path when a preparation is complete. Typically, the UI is Sterile Water for Injection (SWFI), although it may be other ingredients such as dextrose or amino acids depending on the requirements of the order. The UI must be mounted on ports 19 or greater; preferably mounted on port 23 and/or 24. If not ports 23 or 24, the UI must be mounted as far back on the valve set as possible to ensure complete flushing of the entire valve set.

An Electronic Y-Site allows for the same ingredient to be mounted on more than one port and is generally used with the high-volume base components, such as SWFI or Dextrose.

An Auto Addition (AutoAdd) defines those ingredients designated in the formulary that are mounted only if and when they are needed.

The compounder does allow for unique customer applications. The standard configuration below can be modified provided that the potential for chemical interactions is taken into consideration and maximization of the efficiency of valve movement is achieved.

Not all ports must be used. Depending on the customer needs and the number of ingredients to be used, ports may be omitted from the configuration. These are noted as "OPEN" in the configuration table. It is recommended to position the omitted, unused ports between the ingredient groups to allow for future additions to the configuration.

**Example of a Standard Recommended Configuration** 

Sequence	Port	Ingredient	Comment
1	9	Sodium Chloride	-
2	8	Potassium Chloride	-
3	7	Sodium Acetate	-
4	6	Potassium Acetate	-
5	5	Sodium Phosphate	-
6	4	Potassium Phosphate	-
7	3	Multivitamins Pediatric	-
8	2	Multivitamins Adult	-
9	1	Lipids	-
10	10	Amino-Acid	AutoAdd
11	11	Amino-Acid	-
12	12	OPEN	-
13	13	Trace Elements Pediatric	-
14	14	Trace Elements Adult	-
15	15	Single Trace Element	-
16	16	Single Trace Element	-
17	17	Other TPN Drug	-
18	18	Other TPN Drug	-
19	21	Dextrose	-
20	19	L-Cysteine	-
21	20	Magnesium Sulfate	-
22	23	Sterile Water for Injection	UI, Y site
23	24	Sterile Water for Injection	UI, Y site
24	22	Calcium Gluconate	

The following offers information to support the recommended sequencing and port placement of the general categories of the standard recommended configuration.

## **Monovalent Salts:**

Sodium chloride, potassium chloride, sodium acetate, potassium acetate, sodium phosphate, and potassium phosphate are recommended to be sequenced first (1 through 6 in the above example) and mounted on ports 4 through 10. Preferably the phosphate containing ingredients are pumped after the other salts.

## Fat Soluble Ingredients (multivitamins and lipids):

Multivitamins are generally mounted on ports 3 through 5 and sequenced directly after the electrolytes.

Lipids are emulsions of oil and water, held in suspension by an anionic (negatively charged) surfactant.

Acidic ingredients will not be sequenced directly after lipids. Lipids have a very low specific gravity as compared to other ingredients. As lipids are "lighter" than other ingredients, they have the potential to "migrate" along the common fluid path. Because of this potential, it is recommended that lipids have a minimum of 4 ports separating the next sequenced ingredient. Lipids are recommended to be sequenced prior to the Aminos and are mounted on ports < 4.

## **Amino Acids:**

This is the first major flush. Amino acids, such as Travasol, Clinisol, Prosol and Premasol, are generally one of the larger ingredient volumes in a TPN formula. These can be used to dilute the other ingredients and minimize incompatibilities. It is recommended to sequence the Lipids prior to the amino acids to assist with the dilution of the Lipids.

## **Multi Trace Elements:**

Trace Elements, either a combination product such as Trace Elements-4 or Trace Elements-5, or individual elements such as zinc, chromium, copper and selenium are sequenced and mounted after the Amino Acids. The combination product, (Trace Elements-4 or Trace Elements-5), are preferably mounted on ports 13 or 14 and sequenced 13 or 14. The individual elements (e.g., zinc, chromium, copper, selenium), are preferably mounted directly after the combination products and before Other Drugs and Dextrose, preferably on ports 13 through 16 and sequenced 13 through 16.

## **Other TPN Ingredients:**

Include ingredients such as famotidine, ranitidine, heparin, and L-carnitine which are mounted and sequenced after the Trace Elements.

## Dextrose:

This is the second major flush. Dextrose is also one of the larger ingredient volumes in a TPN formula. It is mounted next to or immediately before SWFI and sequenced after the Trace Elements and Other Drugs to assure maximum dilution before Magnesium and Calcium products are pumped. This will minimize the inherent physical incompatibilities.

## **Divalent Salts - Magnesium:**

Di-valent cations also affect the stability of lipids. Magnesium and calcium are the most common of these found in a TPN formula. Magnesium should be mounted after the Trace Elements and Other TPN Ingredients groupings and sequenced after Dextrose and before SWFI to maximize dilution of the lipids.

## Sterile Water for Injection (SWFI):

This is the final major flush. Sterile water for injection is used to calibrate the compounder. Every configuration should require the presence of Sterile Water for Injection.

SWFI is mounted last and generally sequenced after the Magnesium products to maximize the dilution of the solution and flush the valve set prior to the addition of the Calcium product (the final ingredient).

## **Divalent Salts - Calcium:**

The interaction of calcium and phosphorus to form insoluble calcium phosphate is the most critical interaction to address. Calcium phosphate precipitates immediately in most aqueous solutions. It is the buffering provided by the amino acids in a TPN that permit small quantities of calcium and phosphorus to be mixed without forming a precipitate. The smaller the concentrations of calcium and phosphorus at the time they are mixed, the less likely it is that a precipitate will form. This condition occurs when Calcium is added last, with phosphate being diluted as much as possible in the TPN. On the EM2400 TPN Compounder, the phosphate-containing salts (sodium phosphate and potassium phosphate) are added early within the electrolyte group, generally sequenced < 10 and on ports < 10. The calcium salts are added last and mounted on port > 20, after the addition of amino acids; dextrose and water provide the maximum dilution of the phosphate salt.

## **Exceptions:**

L-cysteine and ascorbic acid are included in this group. However, these ingredients are highly acidic and may react with other ingredients.

L-cysteine is highly acidic (very low pH 1.4) and affects the stability of lipids ("cracking") as well as having undesirable interactions with other TPN ingredients, such as:

- Folic acid orange precipitate
- Cimetidine cysteine-cimetidine complex green in color
- Copper cysteine-copper complex green in color

Ascorbic acid reacts with copper and other heavy metals that are components of Trace Elements resulting in the degradation of the Ascorbic acid. Therefore, L-cysteine and Ascorbic acid are to be mounted at least 2 ports after the Trace Element group and sequenced directly after the Dextrose and before Magnesium group.

## **Non-TPN Ingredients:**

These ingredients include Anticoagulant Citrate Dextrose (ACD)/Citrate Phosphate Dextrose (CPD), Tromethamine (THAM), sodium bicarbonate, mannitol, lidocaine, and bupivacaine. These ingredients are not used in TPN but in the compounding of other non-TPN preparations.

The recommended practice is to set up a separate software configuration to accommodate the non-TPN use e.g., cardioplegia, Continuous veno-venous hemodialysis (CVVHD), epidurals. To avoid the potential for error, these ingredients should not be included in any TPN configuration, even as an Auto-Addition.

## **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 120. Before making any changes in the Formulary Editor, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

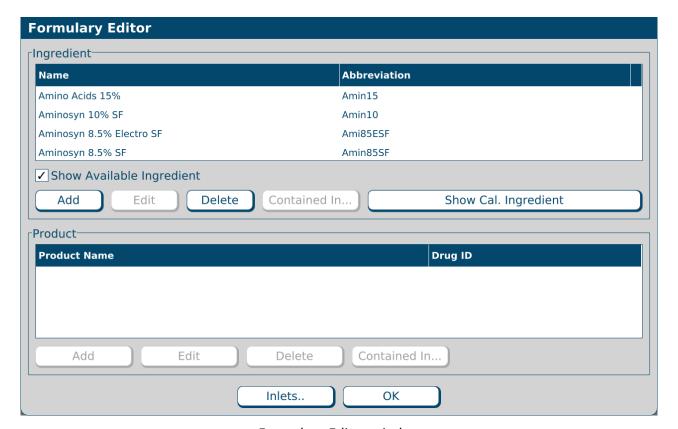
At the menu screen, tap **Edit > Formulary Editor**.



Menu screen, Edit menu

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 Using the Inlet Editor on Page 149.

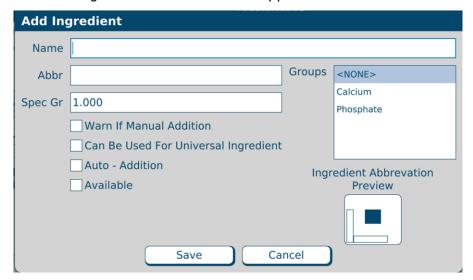


Formulary Editor window

## 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

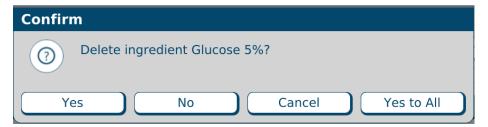
- **2.** At the *Add Ingredient* window or *Edit Ingredient <name>* window:
  - a. Enter the Name.
  - b. Enter the Abbr (abbreviation).

**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 145.
- 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**.

## **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.



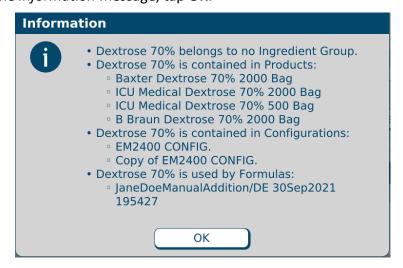
Message

## 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 Support. Refer to <u>Getting Help</u> on Page 20.

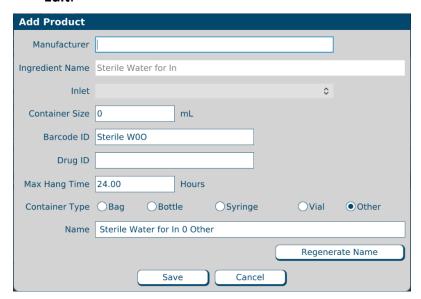
## **Viewing the Calibration Ingredient**

- **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.



Add Product window

- 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>Valve Sets</u> on page 17.
- 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 Drug ID 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 Drug ID 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.

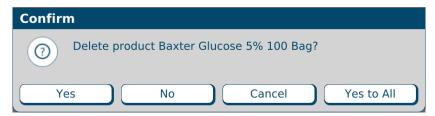
- g. Select the product's **Container Type**.
- h. If you want to change the **Name**, tap **Regenerate Name** or enter a new name.

**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.



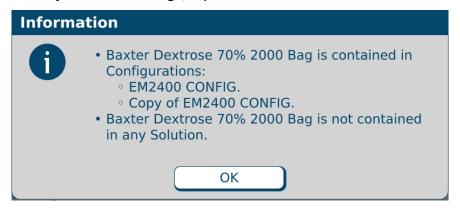
Message

## 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

# 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.

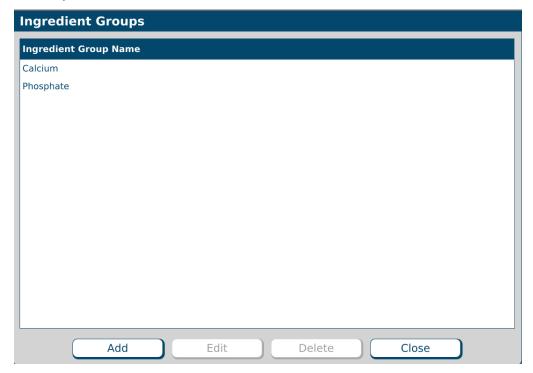
**IMPORTANT!** These functions require Formulary permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120. Before making any changes in the Ingredient Group Editor, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

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



Menu screen, Edit menu

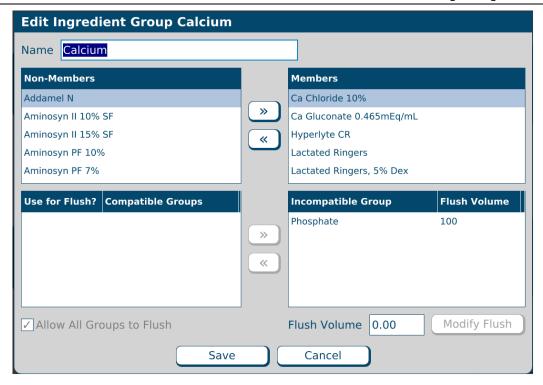
The *Ingredient Groups* window appears. It lists the available ingredient groups and allows you to add, edit or delete ingredient groups. **Calcium** and **Phosphate** groups are created automatically.



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

- **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.

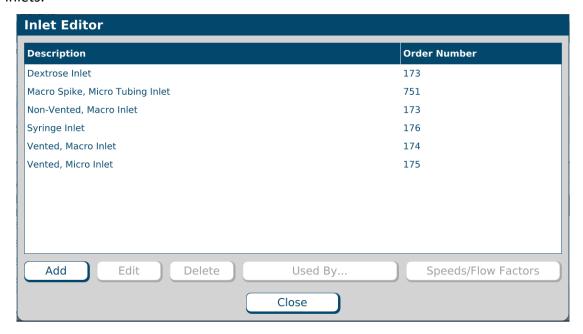
**IMPORTANT!** These functions require Administration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120. Before making any changes in the Inlet Editor, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

At the menu screen, tap Edit > Inlet Editor.



Menu screen, Edit menu

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



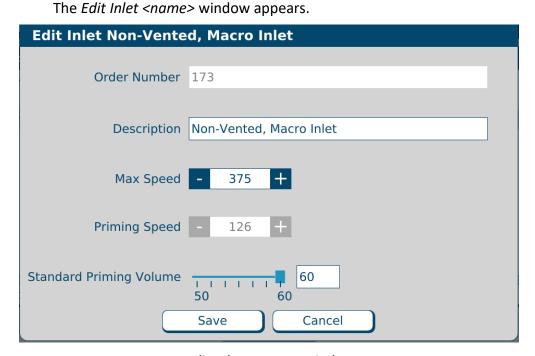
Inlet Editor window

## 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**.



Edit Inlet <name> window

**IMPORTANT!** For the order number, description and recommended priming volume for each inlet, refer to <u>Inlets</u> on Page 17.

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



### **WARNING**

Modifying these settings without contacting Baxter Technical Support 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 Support.

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**.

## **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

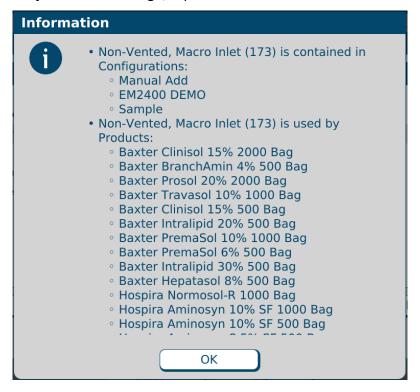
**3.** At the *Inlet Editor* window, tap **Close**.

## 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**.

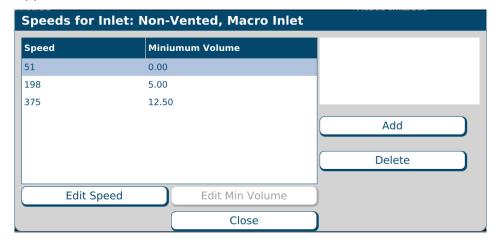
## VIEWING AN INLET'S SPEEDS AND FLOW FACTORS

**IMPORTANT!** All the ingredients need flow factors prior to compounding. Contact Baxter Technical Support 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 Support. Baxter has determined the flow factors for all 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 Support. Refer to <u>Getting Help</u> on Page 20.

**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 Support.



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 Support. Refer to <u>Getting Help</u> on Page 20.

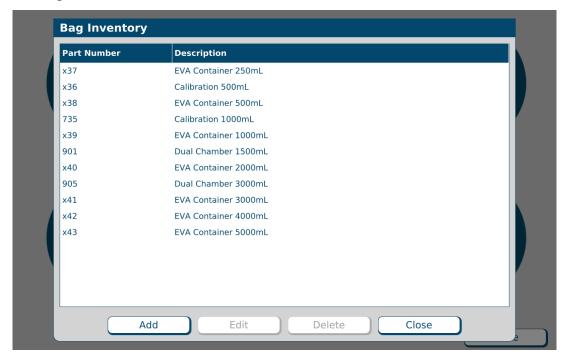
**IMPORTANT!** These functions require Administration permissions. For more information about user groups and permissions, refer to <u>Setting Up the Users</u> on Page 120. Use only bags validated by Baxter for use with the compounder. For details, refer to <u>Bags</u> on Page 18. Using non-validated 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

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



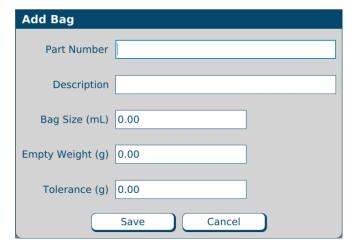
Bag Inventory window

## ADDING OR EDITING A BAG

**IMPORTANT!** Before adding a bag, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

- 1. At the Bag Inventory window, do one of these options:
  - Tap Add to add a new bag.

The Add Bag window appears.



Add Bag window

Select the bag you want to edit, then tap Edit.
 The Edit Bag <name> window appears.



Edit 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**.

## **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  $8.5 \times 11$  in.  $(21.6 \times 28 \text{ cm})$  paper or on A4 paper size of 70X25, 4 mm (or comparable paper).

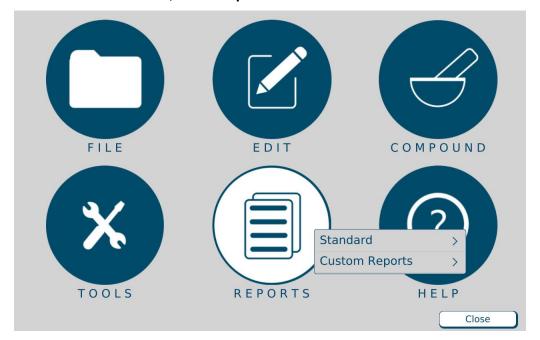
**NOTE:** To use A4 paper, refer to <u>Printing Options</u> on Page 15.

**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 120.

**NOTE:** To select the printer used for printing reports, refer to <u>Report Printer</u> on Page 107.

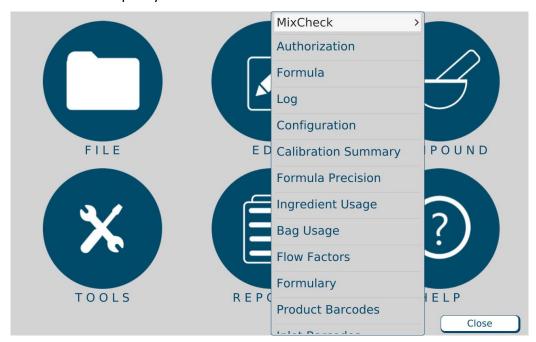
To view reports:

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



Menu screen, Reports menu

**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 button 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 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. This report can be exported in PDF format.

## **Customizing MixCheck Reports**

**IMPORTANT!** When using the Use Online MixCheck Authorization, 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 120.

The following options are available for customizing the MixCheck Report:

- To make this report display and/or print automatically after compounding, and/or allow on-screen authorization, refer to <u>MixCheck Report</u> on Page 102.
- To require a cosigner to authorize the MixCheck Report, refer to <u>Cosignature</u> on Page 109.
- To allow exporting of this report directly to the DoseEdge system, refer to MixCheck <u>Data Export</u> on Page 104.
- To specify signature-related text that you want to include at the end of the report, refer to <u>MixCheck Signature Label</u> on Page 107.

## **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.

## **Using Online MixCheck Authorization**

If "Auto-Display" and "Use Online MixCheck Authorization" are enabled in the options (**Menu > Tools > Options >** System tab **>** MixCheck Report), the MixCheck report will display automatically on the screen after compounding is completed. Go to step 2(b).

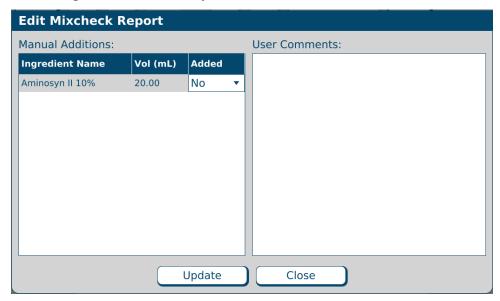
If the Use Online MixCheck Authorization option is enabled, "Review Unauthorized Solutions..." dropdown option is enabled under the MixCheck Report menu option:

- 1. At the menu screen, tap Reports > MixCheck > Review Unauthorized Solutions...
- 2. At the Solutions window:
  - a. Select a formula. The Report Preview MixCheck window appears.



MixCheck report preview

b. Click on **Update Manual Add & User Comments** to verify if all the Manual ingredients have been added by selecting YES/NO adjacent to the listed ingredient and click **Update**.



Update Manual Add & User Comments screen

- c. Tap one of these buttons on the Report Preview screen:
  - Accept to authorize the report
  - Postpone to save the report for later verification
  - Print to send the report to the assigned printer

## **MixCheck Report**

Formula Name **DOE,JANE(5678)** Date/Time **12/15/2021 03:35:10 pm** 

Serial Number 1CB881D-100184 User ADMIN

Configuration EM2400 CONFIG Elapsed Time 00:09:42

Expected Weight (g): 1,094.74 Measured Weight (g): 1,093.06 Difference (%): -0.15

## **Manual Additions:**

# Ingredient Name Vol (mL) Added Infuvite Adult 10.50 NO K Chloride 2mEq/mL 7.88 NO

## **Details:**

Selected bag x39 EVA Container 1000mL.

Container at port 1 exchanged with new container of Baxter Clinolipid 20% 500 Bag Container at port 23 exchanged with new container

of Baxter Sterile Water for In 2000 Bag The final weight of this solution is within the acceptable limit of +/- 5.00%

## **User Comments:**

				Order	ed Volume
Ca Glu	ıcon	ate 0.465mEq/mL			
Port:	19	Fresenius Kabi Ca Gluconate 0.465mEq/mL 50 Vial	Drug ID: 63323-360-03	Seq ( 11	22.58
Clinol	ipid :	20%			
Port:	1	Baxter Clinolipid 20% 500 Bag	Drug ID: 0338-9540-03	Seq ( 3 )	40.00
Port:	1	Baxter Clinolipid 20% 500 Bag	Drug ID: 0338-9540-03	Seq ( 4 )	91.25
					131.25
Dextr	ose 7	70%			
Port:	21	Baxter Dextrose 70% 2000 Bag	Drug ID: 0338-0719-06	Seq ( 7 )	210.00
K Pho	spha	ite 3mMol/mL PO4			
Port:	6	Hospira K Phosphate 3mMol/mL PO4 15 Vial	Drug ID: 0409-7295-01	Seq ( 2 )	1.75
Magn	esiur	n Sulfate 4.06mEg			
Port:	20	Fresenius Kabi Magnesium Sulfate 4.06mEq 50 Vial	Drug ID: 63323-642-50	Seq ( 8 )	0.52
Multit	race	-5 Concentrate			
Port:	14	*Am Reg MTE-5 ConC 10mL	Drug ID: 0517-8210-25	Seq ( 6 )	1.05
Na Ch	lorid	le 4mEq/mL			
Port:	9	APP Pharm Na Chloride 4mEq/mL 30 Vial	Drug ID: 63323-187-30	Seq ( 1 )	2.63
Sterile	e Wa	ter for In			
Port:	23	Baxter Sterile Water for In 2000 Bag	Drug ID: 0338-0013-06	Seq ( 9 )	150.00
Port:	24	Baxter Sterile Water for In 2000 Bag	Drug ID: 0338-0013-06	Seq ( 10	61.85
Port:	23	Baxter Sterile Water for In 2000 Bag	Drug ID: 0338-0013-06	Seq ( 12	30.00
					241.85
Travas	sol 1	0%			
Port:	12	Baxter Travasol 10% 1000 Bag	Drug ID: 0338-0644-04	Seq (5)	420.00

Authorized By:

Total (mL): 1,031.63

Date/Time 12/15/2021 03:35:10 pm

Sample MixCheck Report

Verify that the **Formula Name** matches the patient name on the label on the patient bag.

Verify that the **Serial Number** (unique for each order) matches the serial number on the label of the patient bag. If the Serial Number of the formula is greater than 36 characters then 36 characters followed by '...' is printed.

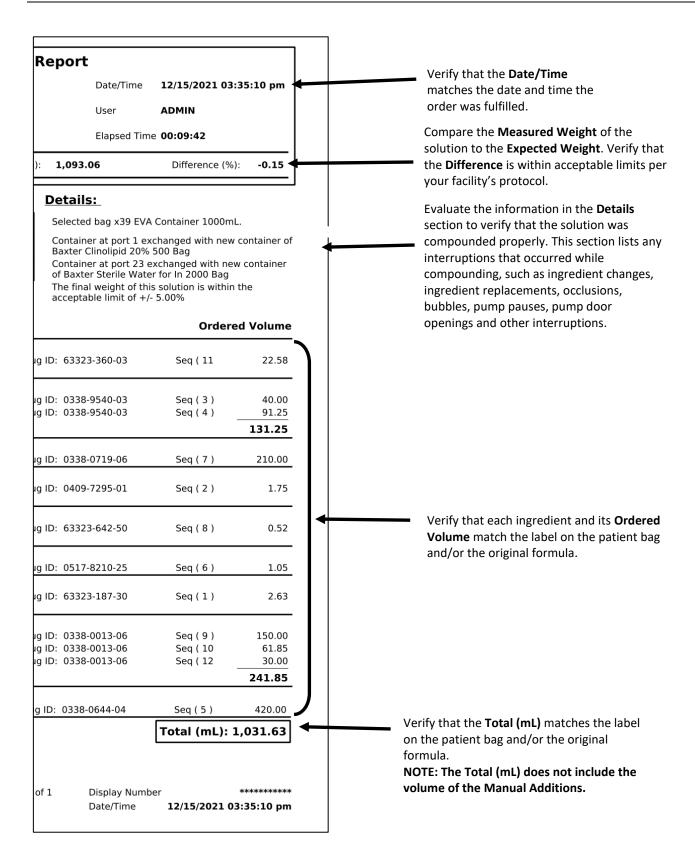
## If Manual Additions are listed:

- Verify that they match the label on the patient bag and/or the original formula.
- 2. Add these ingredients to the solution manually.
- 3. Place your initials in the **Added** column.

In the signature-related section at the end of the report, follow your facility's protocol.

#### **MixCheck** Formula Name DOE, JANE (5678) Serial Number 1CB881D-100184 Configuration EM2400 CONFIG Expected Weight (g): 1,094.74 Measured Weight (g Manual Additions: **Ingredient Name** Vol (mL) Added 10.50 NO Infuvite Adult K Chloride 2mEq/mL 7.88 NO User Comments: Ca Gluconate 0.465mEq/mL Port: 19 Fresenius Kabi Ca Gluconate Dru 0.465mEg/mL 50 Vial Clinolipid 20% Port: 1 Baxter Clinolipid 20% 500 Bag Dru Port: 1 Baxter Clinolipid 20% 500 Bag Dru **Dextrose 70%** Port: 21 Baxter Dextrose 70% 2000 Bag K Phosphate 3mMol/mL PO4 Port: 6 Hospira K Phosphate 3mMol/mL PO4 15 Magnesium Sulfate 4.06mEq Port: 20 Fresenius Kabi Magnesium Sulfate Dru 4.06mEq 50 Vial **Multitrace-5 Concentrate** Port: 14 \*Am Reg MTE-5 ConC 10mL Dru Na Chloride 4mEq/mL APP Pharm Na Chloride 4mEq/mL 30 Drι Port: 9 Vial Sterile Water for In Baxter Sterile Water for In 2000 Bag Dru Port: 23 Port: 24 Baxter Sterile Water for In 2000 Bag Dru Port: 23 Baxter Sterile Water for In 2000 Bag Dru Travasol 10% Port: 12 Baxter Travasol 10% 1000 Bag Dru **Authorized By:** Serial Number 1CB881D-100184 Page 1

Sample MixCheck Report (left side)



Sample MixCheck Report (right side)

## 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 109.
- To make the **Assembled** and **Verified** columns populate automatically, refer to <u>Authorization Report</u> on Page 102.
- 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 107.

You will be able to select a configuration for this report in the select configuration window.

To view the Authorization Report:

- 1. At the menu screen, tap Reports > Standard > Authorization.
- 2. At the Select Report Date window:
  - a. Enter the date for the report.
  - b. Tap **OK**.
  - c. This report can be exported in **PDF** format



Select Report Date window

	Authorization Report								
	Configura	Configuration: TPN-Test			•	Current user: Administrator			
Port	Ingredient name	Inlet PN	Container (mL)	Remainder(m	<u>L)</u>	Assembled	Verified	Date / Tim	ne
7	K Chloride 0.4mEq/m	L 751	50	44.00		Administrator	Pharmacist	11/13/2018 4:	12:38PM
9	Travasol 10%	173	1000	940.00		Administrator	Pharmacist	11/13/2018 4:	
19	Dextrose 70%	173	2000	1940.00		Administrator	Pharmacist	11/13/2018 4:	
24	Sterile Water for In	173	2000	1610.00		Administrator	Pharmacist	11/13/2018 4:	12:54PM
Pa	rt Number	Count							
_	173	3							
	751	1							
		•							
As	sembled by:		Date:		Time:				
	sembled by: necked by:		Date: Date:		Time: Time:				
	lecked by		Date		rime				
1									
Prin	nt Date / Time: 11/13/20	18 4:13:42PM				Page 1 of 1			

Sample Authorization Report

## **FORMULA REPORT**

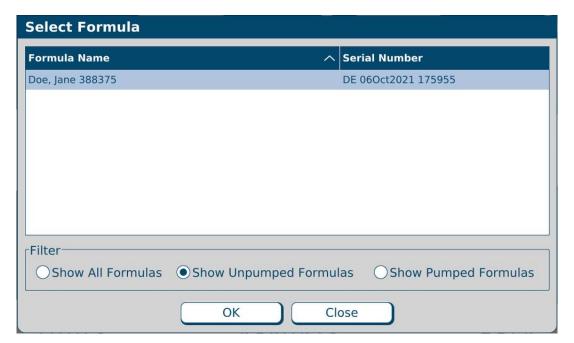
The Formula Report is a summary of a specific formula.

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**.
- d. This report can be exported in **PDF** format.



Select Formula window

## Formula Report

 Formula Name:
 DOE, JOHN(5551212)
 Date:
 12/22/2017

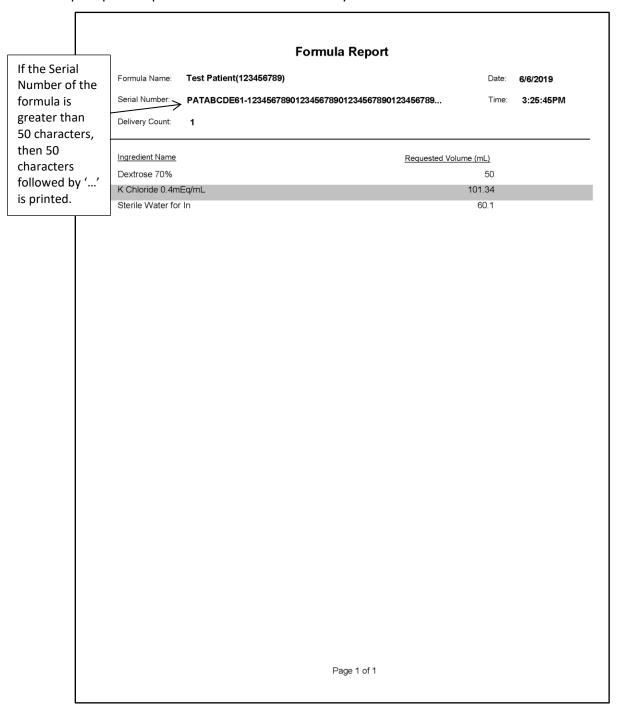
 Serial Number:
 A1FA01E32-5984912
 Time:
 1:05:14PM

Delivery Count: 1

In annualizat Name	
<u>Ingredient Name</u>	Requested Volume (mL)
Clinisol 15%	40.08
Dextrose 70%	50.72
Infuvite Adult	50.64
K Chloride 0.4mEq/	nL 55.64
Sterile Water for In	75.54

Page 1 of 1

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**.
  - c. This report can be exported in PDF, Excel and txt format



Select Report Dates window

# Log Report

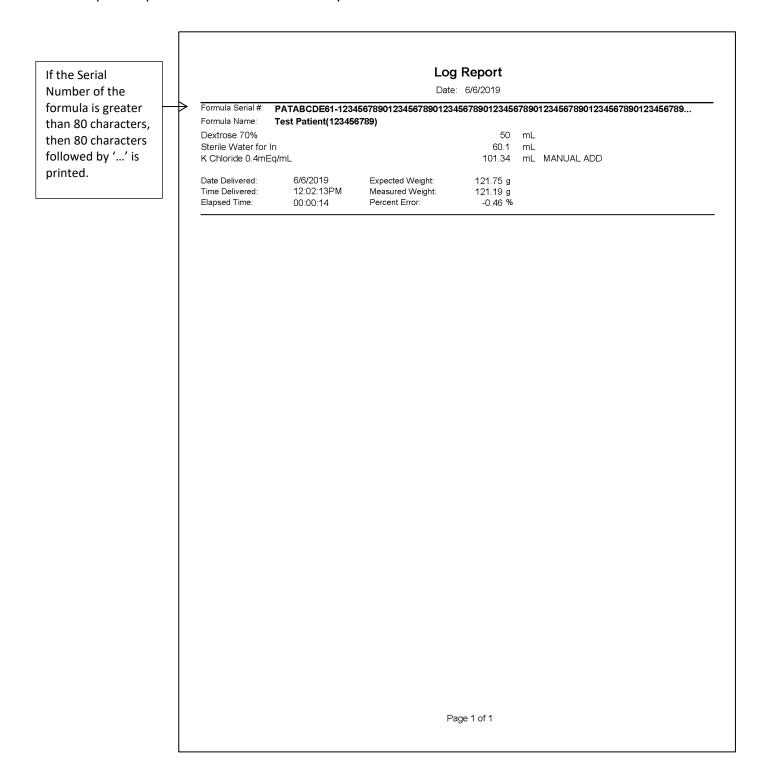
Date: 2/9/2018

		Date. 2	3/2010		
Formula Serial #:	A1FA01E25-100038	Formula Name	LOOEY	, BAE	BA(Z123456789AA)
Dextrose 70%			8.08	mL	
K Chloride 0.4m	Eq/mL		1.64	mL	
Sterile Water for	r In		100	mL	
Travasol 10%			0.74	mL	
K Chloride 2mE	q/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 Name	DOE, JO	OHN(	5551212)
Dextrose 70%			30	mL	
K Chloride 0.4m	Eq/mL		35	mL	
Sterile Water for	r In		75.54	mL	
Travasol 10%			55	mL	
OI: 1 1450/			40.08	mL	MANUAL ADD
Clinisol 15%			40.00		
Infuvite Adult			50.64	mL	MANUAL ADD
	2/9/2018	Expected Weight:			MANUAL ADD
Infuvite Adult	2/9/2018 3:19:58PM	Expected Weight: Measured Weight:	50.64		MANUAL ADD
Infuvite Adult  Date Delivered:			50.64 205.05 g		MANUAL ADD

Page 1 of 1

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 '...'.



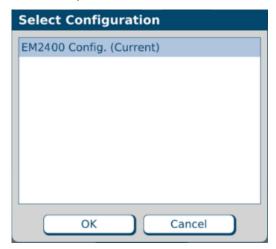
Sample Log Report

### **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**.
  - c. This report can be exported in **PDF** format.



Select Configuration window

# **Configuration Report**

Configuration:	EM2400 CONFIG	Date:	01/10/2022
User:	ADMIN	Time:	03:13:58 pm

Sequence	Port		Ingredient
1	9		Na Chloride 4mEq/mL
2	10		K Chloride 2mEg/mL
3	7		Na Acetate 2mEq/mL
4	8		K Acetate 2mEq/mL
5	5		Na Phosphate3mMol/mL PO4
6	6		K Phosphate 3mMol/mL PO4
7	4		Infuvite Adult
8	1		Clinolipid 20%
9	Auto-Add	A	Travasol 10%
10	11		Clinisol 15%
11	14		Multitrace-5 Concentrate
12	21		Dextrose 70%
13	20		Magnesium Sulfate 4.06mEq
14	23	U	Sterile Water for In
14	24	U	Sterile Water for In
15	19		Ca Gluconate 0.465mEq/mL

Page 1 of 1

Sample Configuration Report

<sup>&#</sup>x27;U' marks the default universal ingredient for this configuration.

<sup>&#</sup>x27;A' marks the allowed Auto Addition 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. This report can be exported in **PDF/Excel** format.

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

Forr	nulary Report			
Date: 10/4/2021				
Time: 7:37:07 PM				
Ingredient Name				Availability
<u>Product Name</u>	<u>Drug ID</u>	<u>Inlet</u>	Sp. Gravity	Size
Addamel N Fresenius Kabi Addamel N 10 Vial	63323-0143-97	751	1.10	No 10
Aminosyn II 10% SF Hospira Aminosyn II 10% SF 2000 Bag	0409-7172-17	173	1.03	No 2,000
Aminosyn II 15% SF Hospira Aminosyn II 15% SF 2000 Bag	0409-7171-17	173	1.05	No 2,000
<b>Aminosyn PF 10%</b> ICU Medical Aminosyn PF 10% 1000 Bag	0990-4179-05	173	1.03	No 1,000
Aminosyn PF 7% Hospira Aminosyn PF 7% 500 Bag	0409-4178-03	173	1.02	No 500
<b>Anticoagulant Na Citrate</b> Fenwal Anticoagulant Na Citrate 500 Bag	0942-9504-10	173	1.02	No 500
Ca Chloride 10% American Regent Ca Chloride 10% 10 Via I	0517-2710-25	175	1.06	No 10
Ca Gluconate 0.465mE Fresenius Kabi Ca Gluconate 0.465mE 10 Vial	63323-360-19	175	1.05	Yes 10
Fresenius Kabi Ca Gluconate 0.465mE 10 0 Vial	63323-360-61	175	1.05	100
Fresenius Kabi Ca Gluconate 0.465mE 50 Vial	63323-360-59	175	1.05	50
Cardioplegic Solution Baxter Cardioplegic Solution 1000 Bag	0338-0341-04	173	1.00	No 1,000
Clinimix 4.25/10  Baxter Clinimix 4.25/10 1000 Bag  Baxter Clinimix 4.25/10 2000 Bag	0338-1134-03 0338-1091-04	173 173	1.05 1.05	No 1,000 2,000
Clinimix 4.25/5  Baxter Clinimix 4.25/5 1000 Bag  Baxter Clinimix 4.25/5 2000 Bag	0338-1133-03 0338-1089-04	173 173	1.03 1.03	No 1,000 2,000
<b>Clinimix 5/15</b> Baxter Clinimix 5/15 1000 Bag Baxter Clinimix 5/15 2000 Bag	0338-1137-03 0338-1099-04	173 173	1.07 1.07	No 1,000 2,000
Clinimix 5/20  Baxter Clinimix 5/20 1000 Bag  Baxter Clinimix 5/20 2000 Bag	0338-1138-03 0338-1101-04	173 173	1.09 1.09	No 1,000 2,000
<b>Clinimix 6/5</b> Baxter Clinimix 6/5 1000 Bag	0338-0198-01	173	1.03	No 1,000
Baxter Cillilling 0/3 1000 Bay	0336-0196-01 Page 1 of 8	1/3	1.03	Ι,

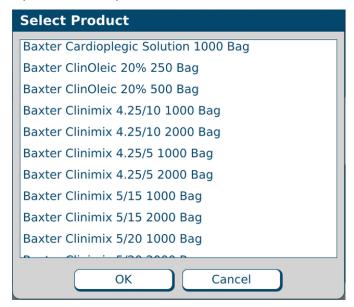
Sample Formulary Report

### PRODUCT BARCODES REPORT

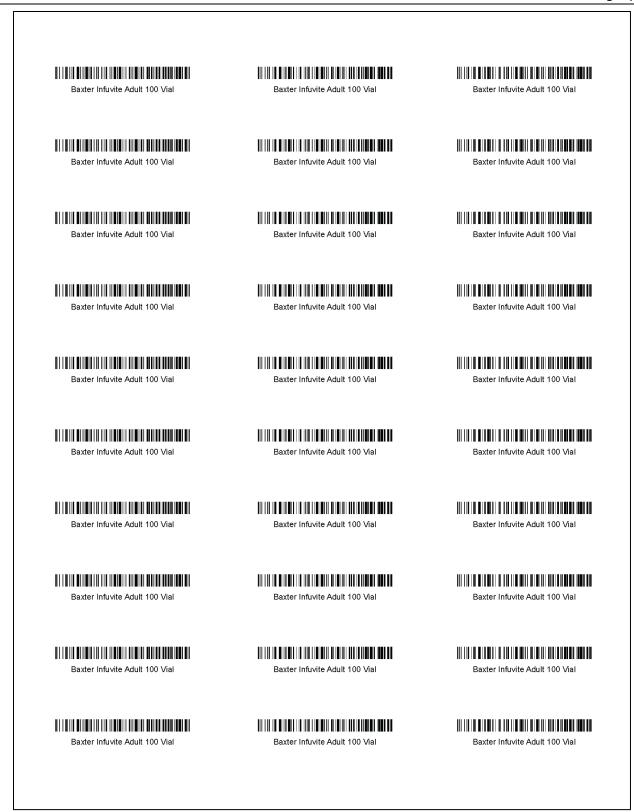
The Product Barcodes Report displays the barcodes for products that are in the formulary. You can print the report onto labels for use with products that do not have a manufacturer's barcode.

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**.
  - c. This report can be exported in PDF format



Select Product window

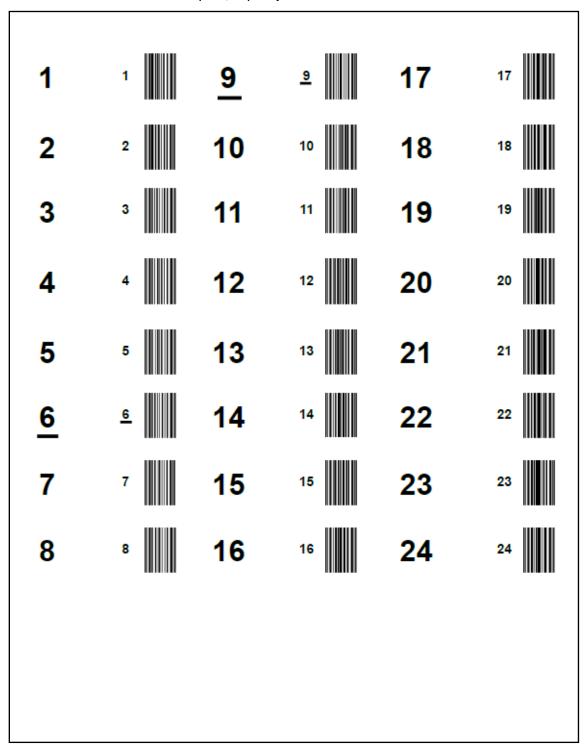


Sample Product Barcodes Report

### **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. This report can be exported in **PDF** format.

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



Sample Inlet Barcodes Report

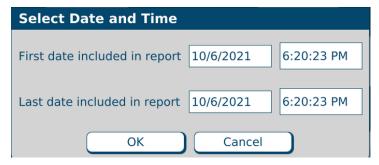
### **BLACKBOX REPORT**

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.

**NOTE:** Exporting the Blackbox report takes several minutes. Baxter recommends doing the export at the end of the day.

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**.
  - c. This report can be exported in **PDF** format.



Enter Begin and End Times window

For assistance with reading this report, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

Entry Date	Entry Time	User Name	Audit Category	Audit Message
12/15/2021	09:29:26 am	SYSTEM	VALVE	Port 17 acutations:0,Port 18 acutations:0,Port 19
12/15/2021	09:29:26 am	SYSTEM	VALVE	acutations:5,Port 20 acutations:2, Port 21 acutations:2,Port 22 acutations:0,Port 23
12/15/2021	00:20:26 25	CVCTEM	VALVECENT	acutations:7,Port 24 acutations:10, 0x0210
12/15/2021	09:29:26 am 09:29:26 am	SYSTEM SYSTEM	VALVESENT VALVERCVD	0x0210 0x0210FE000000
12/15/2021 12/15/2021	09:29:26 am	SYSTEM	SCALESENT	0x0310re000000
12/15/2021	09:29:26 am	0.0	SCALERCVD	0x0301 0x0301
12/15/2021	09:29:27 am	SYSTEM	SCALESENT	0x0301 0x0302
12/15/2021	09:29:27 am		SCALERCVD	0x03020 0x0302015363616C6530323134
12/15/2021	09:29:27 am	SYSTEM	SCALE	FirmwareID: Scale0214
12/15/2021	09:29:27 am	SYSTEM	SCALE	CompounderScaleMain::ScaleSequenceDone
12/15/2021	09:29:27 am	SYSTEM	SCALESENT	0x0311
12/15/2021	09:29:27 am	SYSTEM	SCALERCVD	0x0311 0x031100A08D1922
12/15/2021	09:29:27 am	SYSTEM	BELLSENT	0x0901
12/15/2021	09:29:27 am	SYSTEM	BELLRCVD	0x0901 0x0901
12/15/2021	09:29:29 am		BELLSENT	0x0902
12/15/2021	09:29:29 am	SYSTEM	BELLRCVD	0x0902 0x090201415544494F30343134
12/15/2021	09:29:29 am	SYSTEM	BELL	FirmwareID: AUDIO0414
12/15/2021	09:29:29 am	SYSTEM	GUI	GUIRESPINIT status is 0 and
12/13/2021	09.29.29 dill	3131614	301	O} tatus":false} tusMessage":"Request processing got failed"} s":0} :1} ome ready. "}}
12/15/2021	09:30:16 am	SYSTEM	SECURITY	LOGON attempted by password: Username admin (Password is empty)
12/15/2021	09:30:16 am	SYSTEM	SECURITY	LOGIN FAILED: Username admin
12/15/2021	09:30:37 am	SYSTEM	GUIINTERFACE	GetGroupNameByLoginName Error in UserGroupListModel
12/15/2021	09:30:37 am	SYSTEM	GUI	["maa.login",48, {"LoginName":"ADMIN","password":"************}]
12/15/2021	09:30:37 am	SYSTEM	MODEANDACCESS	LOGON attempted by password: ADMIN
12/15/2021	09:30:37 am	SYSTEM	Database	Opened database: /var/persist/database/em2400.d
12/15/2021	09:30:37 am	SYSTEM	CompDB	Configure SQLite busy timeout as 30000 ms -> Succeeded
12/15/2021	09:30:40 am	SYSTEM	CompDB	SQLITE rollback method set as WAL
12/15/2021	09:30:40 am	SYSTEM	MODEANDACCESS	LOGON successful for ADMIN
12/15/2021	09:30:40 am	ADMIN	GUI	REQUESTED TO ENABLE USB AFTER USER LOGIN
12/15/2021	09:30:40 am	ADMIN	USB	Enum: Attached Mass Storage (vid: 5118, pid: 16675, iclass: 8, isub-class: 6, iprotocol: 80)
12/15/2021	09:30:40 am	ADMIN	USB	Check device Mass Storage attached: Attached
12/15/2021	09:30:40 am	ADMIN	GUI	Mass storage is attached and enabling it.
12/15/2021	09:30:40 am	ADMIN	USB	Enable mass storage driver: ENABLED
12/15/2021	09:30:40 am	ADMIN	GUI	USB mass storage hot-plugin events has been subscribed.
12/15/2021	09:30:40 am	ADMIN	USB	Hotplugin monitoring thread started.
12/15/2021	09:30:40 am	ADMIN	USB	Subscription (Mass Storage: Attached) is complete
12/15/2021	09:30:40 am	ADMIN	USB	Subscription (Mass Storage: Detached) is complete
12/15/2021	09:30:40 am	ADMIN	GUI	Barcode reader hot-plugin events has been subscribed.
12/15/2021	09:30:40 am	ADMIN	USB	Subscription (Barcode Reader: Attached) is completed.
12/15/2021	09:30:40 am	ADMIN	USB	Subscription (Barcode Reader: Detached) is completed.
12/15/2021	09:30:40 am	ADMIN	GUI	HLA configurations: serial num = D1D2138037, mf date = 24/09/2021
12/15/2021	09:30:40 am	ADMIN	GUI	Formula files directory configured with USB path

Page 1 of 222

### Sample Blackbox Report

### 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 <a href="Storage">Storage</a> on Page 104.
  - b. Tap **OK**.
  - c. This report can be exported in **PDF** format.



Select Report Dates window

# **Calibration Summary**

### **Pump Calibration**

From: **6/27/2017** 

To: **6/27/2017** 

			1 10111. 072	.172017	10.	0/2//2017		
	<u>Time</u>	<u>Type</u>		Result				
_	<u>User</u>		Cal Product			<u>Port</u>	<u>Volume</u>	
6	6/27/2017							
	3:30:04AM	Auto-adjustment		Succeeded				
	Admir	istrator	0338-0013-29			24	602.24	
	3:30:37AM	Manual using load cell		Succeeded				
	Admir	istrator	0338-0013-29			24	200.00	

### **Load Cell Calibration**

<u>Time</u>	<u>User</u>	Result
6/27/2017		
2:52:34AM	Administrator	Succeeded

Page 1 of 1

### 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 date 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 <a href="Storage">Storage</a> on Page 104.
  - b. Select Acceptable Weight Variance (%) from the drop-down list.
  - c. Tap **OK**.
  - d. This report can be exported in **PDF** format.



Select Report Dates window

# Formula Precision Summary 12/22/2021 To: 12/22/2021

From:

Acceptable Weight Variance: - 5.00% to 5.00%

Serial Number	Formula Name	Delivered User	Expected (g)	Measured (g)	<u>%Variance</u>
12/22/2021					
A1FA01E32-598	DOE, JOHN(5551212)	1:00:52PM Administrator	194.83	193.88	-0.49

Summary:	Number of bags		
-5% + variance	0		
-4% to -4.99% variance	0	Maximum positive variance	0.49 %
-3% to -3.99% variance	0	Maximum negative variance	-1.40 %
-2 % to -2.99% variance	1	Maximum negative variance	1.40 %
-1% to -1.99% variance	1	Average variance	-0.49 %
-0.01% to -0.99% variance	1	, word <b>g</b> o variance	0.40 %
0% to 0.99% variance	1	Median variance	-0.49 %
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	4		
Bags within range	4		
Bags out of range	0		

Printed Date /Time: 12/22/2021 1:02:37PM Page 1 of 1 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 '...'.

**Formula Precision Summary** If the Serial From: 12/12//2021 12/12//2021 Acceptable Weight Variance: - 5.00% to 5.00% Number of the Serial Number Formula Name Delivered User Expected (g) Measured (g) %Variance formula is 12/12/2021 greater than 36 PATABCDE611 Test Patient(123456789) 2345678901234 12:02:13PM OEM User 121.75 121.19 -0.46 characters then 36 characters 56789012345. followed by '...' Summary: Number of bags is printed. -5% + variance 0 0.49 % Maximum positive variance -4% to -4.99% variance 0 -3% to -3.99% variance -1.40 % Maximum negative variance -2 % to -2.99% variance 1 -1% to -1.99% variance Average variance -0.49 % -0.01% to -0.99% variance 0% to 0.99% variance Median variance -0.49 % 1% to 1.99% variance 0 2% to 2.99% variance 3% to 3.99% variance 0 4% to 4.99% variance 0 5% + variance 0 **Total Bags** 4 Bags within range 4 Bags out of range Page 1 of 1 Printed Date /Time: 12/12/2021 3:16:36PM

Sample Formula Precision Report

### 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 date for the report.
  - b. Tap **OK**.
  - c. This report can be exported in **PDF/Excel** format.



Select Report Dates window

ngredient Name	From:	2/20/2018	edient Usage To:	2/20/2018 Volume Used (ml)	<u>Containers</u>
Formulary Ingredier	<u>ıts</u>				
Dextrose 70%				30.00	
Baxter Dextrose 70% 200	0 Bag		0338-0719-06	30.00	1
K Chloride 0.4mEq/m				35.00	
Baxter K Chloride 0.4mE	q/mL 50 B	ag	0338-0703-41	35.00	1
Sterile Water for In				75.54	
Baxter Sterile Water for I	n 5000 Ba	1	0338-0013-29	75.54	1
Travasol 10%	0 D		0220 0011 01	55.00	
Baxter Travasol 10% 100	) Bag		0338-0644-04	55.00	1
Manual Add Ingredi	<u>ciits</u>			40.08	
nfuvite Adult				50.64	

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 and Last date for the report.
  - b. Tap **OK**.
  - c. This report can be exported in **PDF/Excel** format.



Select Report Dates window

# Bag Usage 2/20/2018 --- 2/20/2018 Part Number Description Number Used EVA Container 1000mL. x39 Total: Page 1 of 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.

You will be able to select a specific configuration or all configurations on the screen for the Flow Factors Report. This report can be exported in **PDF** format.

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

Flow Factors							
Config	uration	n: TPN-TEST					
Date:		1/8/2020					
Time:		4:18:50PM					
<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	1.0040		
			10.00	12,000.00	1.9890		
9	2	Baxter Travasol 10% 1000 Bag					
			0.00	5.00	1.0030		
			5.00	12.50	0.9730		
			12.50	12,000.00	1.0050		
11	3	Baxter Dextrose 70% 2000 Bag					
			0.00	5.00	1.9870		
			5.00	12.50	1.9960		
			12.50	12,000.00	1.0220		
12	4	Baxter Sterile Water for In 5000 Bag					
			0.00	5.00	1.0020		
			0.00 5.00	5.00 12.50	1.9930 0.9640		
			12.50	12,000.00	1.9970		
			12.00	12,000100	10000		
		Pa	age 1 of 1				

Sample Flow Factors Report

### **CUSTOM REPORTS**

The custom reports can be created for your facility for a fee. For more information on custom reports, contact Baxter Technical Support. Refer to <u>Getting Help</u> on Page 20.

To view custom reports, select **Reports > Custom Reports**.



Menu screen, Reports menu

# 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 Support. Refer to <u>Getting Help</u> on Page 20.

### **Issues with the Barcodes**

Issue / On-screen Text	Explanation	Suggested Actions
The label on the source	The barcode on the source	1. Check that the barcode on the source container is
container cannot be	container is not legible.	legible.
scanned.		2. Follow the process to print the barcode through
		the ExactaMix software. Refer to Product Barcodes
Text:		Report on Page 176.
Unable to scan		
The label on the source	The ingredient is not in	Check that the barcode on the source container
container cannot be	the formulary.	is legible.
scanned.		2. Check that the <b>Barcode ID</b> in the formulary is
		correct. Refer to <u>Adding or Editing a Product</u> on
Text:		Page 142.
Not in Formulary		3. If the ingredient is not in the formulary, add the
		ingredient. Refer to Adding or Editing an
		<u>Ingredient</u> on Page 140.
The label on the patient	The barcode reader is not	Check that the green LED on the barcode
bag cannot be scanned.	operational.	reader illuminates when you scan a barcode.
		<ul> <li>If the LED does not illuminate, check that</li> </ul>
		the cable for the barcode reader is
		connected properly to the display.
		<ul> <li>If the LED illuminates, reboot the</li> </ul>
		compounder. Refer to <u>Rebooting and</u>
		Shutting Down on Page 32.
		2. Check that the barcode reader and its cable are
		not damaged.
		3. Contact Baxter Technical Support. Refer to
		Getting Help on Page 20.
No barcodes can be	The barcode reader is not	Disconnect the cable for the barcode reader
scanned.	operational.	from the display, then reconnect this cable.
		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 Support for a barcode
		programming sheet. Refer to <u>Getting Help</u> on
		Page 20.

Issue / On-screen Text	Explanation	Suggested Actions
Text:	The .PAT /.FRM file is not	1. Verify the .PAT/.FRM name exists in the Pat file
Unable to retrieve	available.	share. If not, correct the .PAT/.FRM file in the
formula for scanned		order entry software, then print and scan a
barcode <formula file<="" th=""><th></th><th>new barcode label.</th></formula>		new barcode label.
Name> from the formula		Check that the Ethernet cable is connected
file directory <formula file<="" th=""><th></th><th>properly to both the display and the order-</th></formula>		properly to both the display and the order-
directory>. There may be		entry computer.
an issue with network		3. Check that the network is functioning.
connectivity, please		4. Reboot the compounder. Refer to <u>Rebooting</u>
reboot the compounder.		and Shutting Down on Page 32.
		5. Check the path on both the order-entry
If the problem persists,		computer and the compounder. Refer to
please contact Baxter		Setting Up the Directories Options on Page 110.
Technical Support		
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"	00.5	2 61 611
Text:	2D Formula Barcode serial	Do one of the following:
2D Formula Barcode serial	number format (X) does	Correct the length of the serial number of the
number format (X) does	not meet the configured	2D Formula Barcode (Maximum up to the value
not meet the current	maximum serial number	specified in the security tab), then print and
configured maximum	length, set in options	scan the new 2D Formula Barcode
serial number length.	screen → security tab.	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.	

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

Issue / On-screen Text	Explanation		Suggested Actions
Text: 2D Formula Barcode	The 2D Formula Barcode contains same ingredients	1.	Correct the Ingredient names having the same ingredient name multiple times.
contains the following errors. So 2D Formula Barcode (X) cannot be loaded.	appearing multiple times whose volumes are different.	2.	Print the 2D Formula Barcode and scan the new 2D Formula Barcode.
Ingredient (%s) appears multiple times, with volume (%d1) and volume(%d2)			
Text:	The barcodes for formulas	1.	Reprint the barcode.
Barcode reader (X):	must use the Code39	2.	Scan the barcode again.
barcode contains an	symbology, which has a		
invalid Code 39 character.	restricted character set.		B :
Text:	The barcodes for formulas	1.	Reprint the barcode.
Barcode reader (X): barcode contains an	must use the Code39	2.	Scan the barcode again.
invalid MOD43 check	symbology with a MOD43		
digit.	check digit appended.		
Text:	The barcode that was	1.	Check that the network settings are correct.
Barcode reader (X):	scanned does not match a	2.	Check that the Ethernet cable is connected
invalid barcode or	formula.		properly to both the display and the order-
formula not available.			entry computer.
		3.	Check the database to ensure that the formula exists.

### **Issues with the Barcode Scanner Holder**

Issue / On-screen Text	Suggested Actions
Barcode scanner holder is loose and moves when picking up or putting back the scanner	Use a Philips screwdriver to tighten the two screws that secures the barcode scanner holder to the back of the display.  If problem persists, please call Baxter Technical Support.
Barcode scanner holder is broken	Call Baxter Customer Service to get a new barcode scanner holder. For contact details, refer to Help.
Missing Barcode scanner holder	Call Baxter Customer Service to get a new barcode scanner holder. For contact details, refer to Help.

# Issues with the Display Cable

Issue / On-screen Text	Suggested Actions
The display cable cannot be connected to the display	Make sure the smaller connector end of the cable is being used to plug into the display module. See the photos on page 24.  If problem persists, please call Baxter Technical Support.
The display cable cannot be connected to the main module	Make sure the larger connector end of the cable is being used to plug into the main module. See the photos on page 24.  If problem persists, please call Baxter Technical Support.
The display cable is damaged (connectors and/or insulation)	Call Baxter Technical Support to get a display cable. For contact details, refer to Help.
Display has power but is not communicating with the main module	Make sure the display cable connections are not loose. If problem persists, please call Baxter Technical Support.

# Issues with the Formulas, Ingredients and Configurations

Issue / On-screen Text	Explanation	Suggested Actions
Text:	The ingredient is an auto-	Add the ingredient. Refer to Performing an Auto-
This formula contains <ingredient name="">, which</ingredient>	addition ingredient.	Addition on Page 90.
is not currently on the		
configuration. Do you		
wish to add it to the		
configuration? Text:	The configuration is not	Prime and verify the configuration. Refer to Priming
Configuration must be	primed and verified.	and Verifying on Page 54.
verified before	printed and vernieur	and vernying on ruge on
compounding.		
Text:	One or more ingredients	1. Tap Cancel.
The following ports	are expired.	2. Check the expiration dates of all the
contain products that have been spiked longer		ingredients.  3. Change the container of each expired
than allowed. Port		ingredient.
Product Time Spiked		
Allowed Hang Time		
(Hours) < list of products>.		
Text:	The ordered volume of the	1. Tap Cancel.
Ingredient <ingredient name=""> must be manually</ingredient>	product exceeds the maximum volume for	<ol><li>Check that the <b>Drug ID</b> is correct and that it matches the Drug ID number from the order-</li></ol>
added and its requested	manual additions.	entry software. Refer to Adding or Editing a
volume of <requested< th=""><th></th><th>Product on Page 142.</th></requested<>		Product on Page 142.
volume> mL exceeds the		-
maximum manual add		
volume of <max manual<="" th=""><th></th><th></th></max>		
add volume> mL. Text:	The product is not	Add the product manually. Refer to Performing a
Manual Add	included in the	Manual Addition on Page 84.
	configuration, or its	Ğ
	ordered volume is less	
	than 0.2 mL.	
	The product is included in the physical configuration,	Check that the <b>Drug ID</b> is correct and that it matches the Drug ID number from the order-entry software.
	and its ordered volume is	Refer to Adding or Editing a Product on Page 142.
	at least 0.2 mL, but it does	neter to reading or Editing a Froduct
	not match any products in	
	the software	
Tauti	configuration.	Charlethat the apptain on its store at a country
Text: Swap Container: Your	The container is almost empty and needs to be	<ul> <li>Check that the container is almost empty.</li> <li>If the container is almost empty, replace it.</li> </ul>
container of <ingredient< th=""><th>replaced.</th><th>Refer to Replacing a Source Container on</th></ingredient<>	replaced.	Refer to Replacing a Source Container on
name> is empty. You	-1	Page 83.
have < remaining volume >		If the container is not almost empty, check
mL left to run. Please		that it is the correct container, and contact
change the container		Baxter Technical Support. Refer to <u>Getting</u>
now.		<u>Help</u> on Page 20.

Issue / On-screen Text	Explanation	Suggested Actions
The <b>OK</b> button is not active on the <i>Hang Source Containers</i> screen, and the ingredient buttons do not change to a blue color.	The ingredient detail windows have not been viewed.	Tap each ingredient button to view the details.  Refer to <u>Attaching the New Ingredients and Inlets</u> on Page 45.
During priming, the fluid does not flow through the expected inlet.	The inlet is not attached to the proper port.	<ol> <li>Remove the source container from the vial rack or hanger and turn it right-side-up, to prevent fluid from flowing.</li> <li>Remove the inlet from the incorrect port and attach it to the correct port.</li> <li>Return the source container to the vial rack or hanger.</li> </ol>
Text: Formula Conflict:	There is not enough ingredient flush between incompatible ingredient	<ol> <li>Tap Cancel.</li> <li>Verify ordered volume of flush ingredient is correct. If not, re-enter order.</li> </ol>
Formula contains incompatible ingredients with insufficient flush volume between them.	groups.	3. Contact Baxter Technical Support. Refer to Getting Help on Page 20.
First Ingredient: <ingredient name=""></ingredient>		
Second Ingredient: <ingredient name=""></ingredient>		
Required Flush: <required volume=""></required>		
Available Flush: <available volume=""></available>		

Issue / On-screen Text	Explanation	Suggested Actions
Text:	The formula does not	
Formula Conflict:	contain the minimum	WARNING
Additional <flush volume=""> mL of <universal ingredient=""> required for flush.</universal></flush>	required Universal Ingredient.	If you choose to Increase Ingredient  Volume, the clinical impact should be considered. This option increases the
		volume in the bag and is not part of the original order.
		Increasing the Universal Ingredient volume may change the overall formula ordered. Consult a pharmacist before compounding.
		Tap Change UI To to change the Universal Ingredient to one that has the minimum volume required and does not have flush ingredient, without increasing the ordered volume. 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.
		<ol> <li>If a patient bag is attached, remove it. Refer to Removing the Patient Bagon Page 75.</li> <li>Change the Universal Ingredient. Refer to Changing the Universal Ingredient on Page 98,</li> </ol>
		starting at Step 2.  3. Attach the patient bag. Refer to Attaching the Patient Bag on Page 71.  4. Repeat the compounding process.

Issue / On-screen Text	Explanation		Suggested Actions
Text:	•	1.	Tap <b>OK</b> on the error message.
The requested product	All ingredients need flow	2.	Contact Baxter Technical Support for
<pre><pre><pre><pre><pre><pre>cannot</pre></pre></pre></pre></pre></pre>	factors prior to		adding/updating flow factors.
be added to the	compounding.		
configuration as the flow			
factors are not set up for			
the associated inlet <inlet< th=""><th></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			
Support for help			
Text:	All ingredients need flow	1.	Tap <b>OK</b> on the error message.
Formula cannot be	factors prior to	2.	Contact Baxter Technical Support for
pumped. The following	compounding.		adding/updating flow factors.
Products			
contain invalid flow			
factors:			
<li><li>dist of products&gt;</li></li>			
Please contact Baxter			
Technical Support to			
obtain the			
correct flow factors and			
for help to enter them			
into the Formulary.			

### 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.	Calibrate the load cell. Refer to <u>Calibrating the</u>
continue.	canbratea.	Load Cell on Page 35.
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	cen is out of range.	· I
of Range		<ul> <li>There is nothing (for example, the outlet tube, bag or cable for the load cell) touching</li> </ul>
		the pan or base of the load cell.
		There are no environmental factors (for
		•
		example, fans) interfering with the load cell.
		2. Calibrate the load cell. Refer to <u>Calibrating the</u>
		Load Cell on Page 35. Read the on-screen
		messages carefully, and make sure that you do
		not place the calibration weight on the load cell
The access to the	The second is a second	too early.
The pump has not been	The pump is not	1. Tap Yes.
calibrated since the last	calibrated.	2. Calibrate the pump. Refer to <u>Calibrating the</u>
tube set change. This		Compounder on Page 65.
operation must be		
completed prior to		
pumping a solution.		
Would you like to		
calibrate the pump now?		
Pump calibration failed.	The calibration of the	3. Follow steps above for Span Calibration out of
rump cambration raneu.	pump failed.	·
	pump raneu.	Range. 4. For the source container of water, check the
		following conditions. Refer to Attaching the
		New Ingredients and Inlets on Page 45.
		i. The correct inlet is used.
		ii. The inlet is not kinked.
		iii. The bag is spiked properly (all the
		way up to the flange). Refer to
		Page 49.
		5. Clean any spills near the pump rotor. Refer to
		Cleaning the Compounderon Page 93.
		6. Calibrate the load cell. Refer to <u>Calibrating the</u>
		Load Cell on Page 35.
		7. Check that the valve set is installed properly.
		Refer to Installing the New Valve Set on
		Page 42.
		8. Calibrate the pump. Refer to <u>Calibrating the</u>
		Compounder on Page 65.
Text:	Too many bags have been	1. Click Yes
You have exceeded the	processed without	Calibrate the pump. Refer to <u>Calibrating the</u>
maximum allowed	meeting the 175 mL auto-	Compounder on Page 65.
calibration limit of	calibration threshold.	
20000mL, the system will	Therefore, a manual	
recalibrate now. Do you	calibration is required.	
want to calibrate now?	The second of the second	
	l	

# Issues with the Weight and Load Cell

On-screen Text	Explanation	Suggested Actions
Expected Weight:	The final bag weight is out	Check that all the source containers are spiked
<calculated weight=""> gm</calculated>	of range.	properly. Refer to the steps for spiking a
		container, starting on Page 48.
Actual Weight: <actual< th=""><th>After the compounder</th><th>2. Check that the outlet tube is installed properly.</th></actual<>	After the compounder	2. Check that the outlet tube is installed properly.
weight> gm	delivers all the	Refer to <u>Installing the New Valve Set</u> on
	ingredients, the weight of	Page 42.
Difference: < weight	the patient bag differs	3. Turn the spike on the SWFI ¼ turn then
difference>%	from the expected weight	Calibrate the pump. Refer to <u>Calibrating the</u>
	by more than the	<u>Compounder</u> on Page 65.
The final weight of this	acceptable difference.	4. Calibrate the load cell. Refer to <u>Calibrating the</u>
solution is outside of the		<u>Load Cell</u> on Page 35 the re-calibrate the pump.
acceptable limit of +/-5%		5. Check that the pump rotor is clean. Refer to
		Cleaning the Compounder_on Page 93.
Possible Cause: Unknown	A . 1	4 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Expected Weight:	An individual ingredient	Check that all the ingredients and inlets are
<calculated weight=""> gm</calculated>	delivery is out of range.	correct and spiked correctly with emphasis on
Actual Mainhte anatual	A ft a u t la a a a ua u a a u u d a u	the possible cause ingredient.
Actual Weight: <actual< th=""><th>After the compounder delivers an ingredient, the</th><th>2. Check that the valve set is installed properly.</th></actual<>	After the compounder delivers an ingredient, the	2. Check that the valve set is installed properly.
weight> gm	weight of the patient bag	Refer to <u>Installing the New Valve Set</u> on Page 42 and <u>Attaching the New Ingredients and</u>
Difference: <weight< th=""><th>differs from the expected</th><th>Inlets on Page 45.</th></weight<>	differs from the expected	Inlets on Page 45.
difference>%	weight by more than the	3. On the MixCheck Report, check for references
dijjerence 7/6	acceptable difference.	to occlusions and bubbles. Refer to MixCheck
The final weight of this	deceptable difference.	Report on Page 160. Have a pharmacist check
solution is within the	The compounder checks	the accuracy.
acceptable limit of +/-5%,	the weight after individual	4. Check that the pump rotor is clean. Refer to
however some	ingredient deliveries over	Cleaning the Compounder_on Page 93.
ingredients may not have	100 mL.	5. Calibrate the load cell. Refer to <u>Calibrating the</u>
delivered correctly.		Load Cell on Page 35.
,		6. Calibrate the pump. Refer to Calibrating the
Possible Cause:		Compounder on Page 65.
<ingredient name=""> is</ingredient>		7. Compound a large-volume solution with at
possibly < underweight /		least 205 mL of water to make the compounder
overweight> by <weight< th=""><th></th><th>calibrate automatically.</th></weight<>		calibrate automatically.
error> grams		8. Contact Baxter Technical Support to check that
		the flow factors are correct. Refer to <u>Getting</u>
		<u>Help</u> on Page 20.
Bag out of range	Dextrose is pumping too	1. Check that there are no environmental factors
	quickly or slowly.	interfering with pumping dextrose.
		<ul> <li>Keep the room temperature stable.</li> </ul>
		<ul> <li>Always allow refrigerated dextrose to return</li> </ul>
		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 48.
		3. Check that the correct inlet is assigned to
		dextrose in the formulary. Refer to <u>Adding or</u>
		Editing a Product on Page 142.

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 Compounding the Solution_Step 2 on Page 72.  Calibrating the compounder, refer to Calibrating the Compounder_ Step 4 on Page 65.
		If the bag is empty:  1. Tap No.  2. At the Operation Cancelled message, tap OK.  3. Remove the bag from the load cell. Refer to:  • Removing the Patient Bag_on Page 75  • Removing the Calibration Bag_on Page 69  4. Calibrate the load cell. Refer to Calibrating the Load Cell on Page 35.  5. If necessary, reattach the appropriate bag to the load cell. Refer to:  • Attaching the Patient Bag on Page 71  • Attaching the Calibration Bag on Page 68
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 71  • Attaching the Calibration Bag on Page 68  If the bag is attached:  • Tap No.  • Calibrate the load cell. Refer to Calibrating the Load Cell on Page 35.

# Issues with the Pump

On-screen Text	Explanation	Suggested Actions
[Error: 01-13-002] Unable	The pump fault occurred.	1. At the pump screen, tap <b>Stop</b> 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 <b>Yes</b> to reset the pump.
must be reset before use.		
Reset the pump?		

### Issues with the Occlusion Detector / "Flow Sensor"

**NOTE:** For all 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	1. Verify the outlet tube is lying flat along the top
Test failed.	because the detector	of the occlusion sensor and that the tubing is
Sensor failure.	malfunctioned or the tube	pushed all the way down into the bubble
	set was not installed	detector.
Select OK to retry	properly.	2. Contact Baxter Technical Support. Refer to
Select Cancel to exit		Getting Help on Page 20.
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 87.
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 <b>OK</b> . 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 <b>OK</b> . 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 <b>OK</b> . 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 87.
	outlet tube was not	NOTE: To perform the test and in view mount in a miles
	installed properly.	<b>NOTE:</b> To perform the test again, you must re-prime at least one non-UI inlet and then exit the <i>PRIME</i>
Cannot set flow sensor	The compounder failed to	AND VERIFY screen.
status:	The compounder failed to set the status of the	Contact Baxter Technical Support. Refer to Getting
status.		Help on Page 20.
	occlusion detector when	
	starting to pump.	

### **Other Issues**

Issue / On-screen Text	Explanation	Suggested Actions
The compounder does not power up.	The power cord or the cable for the display is disconnected.	<ol> <li>Check that the power cord is connected to the main module and the power source.</li> <li>Check that the cable for the display is connected properly to both the display and the main module.</li> <li>Press and hold the power button until the green LED is illuminated.</li> <li>Clean the power button.</li> </ol>
The screen of the display	The power source is not functional.  The cable for the display is	Connect the power cord to another power source.  1. Check that the cable for the display is
does not respond to touch.	not fully connected.	connected properly to both the display and the main module.
The compounder cannot retrieve orders from the order-entry computer.	The network is temporarily unavailable.	<ol> <li>Verify the order entry computer is powered on.</li> <li>Verify network connectivity. If the network is down, load the formula by connecting a USB drive. Refer to Loading a Formula by Connecting a USB Drive on Page 206.</li> </ol>
The MixCheck Report does not print.	The printer is disconnected or turned off.  Printing was cancelled inadvertently.	Check that the printer is connected and turned on.  The message about the MixCheck Report being printed appears after you tap <b>OK</b> at the message
	The path to the printer is	about the final weight. If you quickly tap more than once, you might inadvertently tap <b>Cancel Printing</b> . Reprint the report.  Check the path to the printer. Refer to Setting Up
Text:	not set up properly.  An internal software error	the Directories Options on Page 110.  1. Reboot the compounder.
An unknown pump error/valve error occurred	occurred.	Contact Baxter Technical Support. Refer to Getting Help on Page 20.
Text: Bad file format	The 2D Formula Barcode/.PAT/.FRM file being read does not match the expected format.	Create a new order in the order-entry software.
Text: Cancellation in progress. Solution will need to be discarded. Continue?	During the compounding process, a necessary container replacement was cancelled.	<ol> <li>Tap Continue.</li> <li>Write a large "X" on the label of the patient bag, then remove and discard the bag.</li> </ol>
Text: Cannot open DB file X exclusively	Compaction of the database failed because another program was accessing the database.	<ol> <li>Close the other program that is accessing the database.</li> <li>Try compacting the database again. Refer to Compacting the Database on Page 97.</li> <li>Reboot the compounder. Refer to Rebooting and Shutting Down on Page 32.</li> </ol>

Issue / On-screen Text	Explanation	Suggested Actions
Text:	The database was	Contact Baxter Technical Support. Refer to Getting
Cannot open DB X after	compacted but cannot be	Help on Page 20.
compaction	opened. There may be a	
-	hard drive error or	
	database corruption.	
Text:	The pump failed to	Close the pump door.
Cannot resume:	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
Time out.	communication error	Rebooting 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 22.
		3. Turn the compounder on. Refer to <u>Starting Up</u>
<del>-</del> .		and Logging In on Page 30.
Text:	The current database	Contact Baxter Technical Support. Refer to Getting
Unable to save current DB	cannot be saved. There	Help on Page 20.
	may be a hard drive	
	failure, missing directory, network failure (if the	
	destination is on a	
	network drive) or issue	
	with permissions.	
Text:	A port cannot be closed.	Reboot the compounder. Refer to Rebooting and
Valve is moving.		Shutting Down on Page 32.
Text:	Backup failed due to	If you are saving backups on a server confirm the
Backup failed:	either a network failure or	network connectivity.
' <configured backup="" path<="" th=""><th>an incorrect backup folder</th><th>,</th></configured>	an incorrect backup folder	,
with Database name>' is	path.	If the problem persists, check the path of the
not a valid path. Make		backup folder. Refer to Setting Up the Directories
sure that the path name		Options on Page 110.
is spelled correctly and		
that you are connected to		
the server on which the		
file resides		
Text:	For security purposes,	After your account is locked, you must wait at least
Your account has been	your account is locked	5 minutes before attempting another login.
locked because the	after 3 unsuccessful	
number of consecutive	consecutive attempts to	
log-in failures exceeded	login.	
the maximum allowed		

### 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 Setting Up the Users on Page 120.
- 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 Support. Refer to <u>Getting Help</u> on Page 20.
- 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 also 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 Pro** software to look for formula files on the USB drive. For instructions, refer to <u>Setting Up the Directories Options</u> on Page 110.

**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 Drug ID number of each ingredient in the formula and matches this number to one in the formulary. In the United States, the Drug ID number is usually the NDC.

#### **WARNING**



The Drug ID number for each product in the formula must exactly match the Drug ID number for that product in the compounder's formulary. If a Drug ID 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 Drug ID 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 70.

# RESTORING THE DATABASE

If certain types of issues occur, Baxter Technical Support 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**. 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 <u>Setting Up the Directories Options</u> on Page 110.

# GLOSSARY

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

Term	Definition
acceptable weight	The percentage by which the final weight of the compounded solution, or the
variance	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 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 communication
	between software, firmware and user actions.
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 /	The process of pumping ingredients into a patient bag.
compounding Configuration	A designation of the products that will be attached to the ports, the sequence in
Configuration	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	A form of therapy to dialyze acute patients continuously, when these patients
Replacement Therapy	cannot tolerate conventional dialysis.
(CRRT)	,
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	
Direct ontry mode	
Direct entry mode	
Display	
	• • • • • • • • • • • • • • • • • • • •
·	
Licotionic i ditt	
Enhanced flush	
Direct entry mode  Display Disposables Dose Electronic Y-site  Enhanced flush Epidural	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).  A mode where you enter a formula manually by specifying the ingredient and volume to be delivered from each port.  The touch-screen display for the user interface. It mounts to the base plate.  See tube set.  A specific volume and concentration of an ingredient.  A setup option that helps to improve the efficiency of pumping common ingredients. When the first container of this ingredient has emptied, the compounder continues pumping from the next container of this ingredient.  Two intermediate flushes followed by the final flush.  An injection into the epidural space of the spine for regional anesthesia.

Term	Definition
Equivalent ingredient	Products of the same ingredient type that may have different container sizes,
products	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 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
	pharmacist, based on a prescription from a physician.
Formulary	The list of ingredients, and associated products, that can be attached to the
	compounder.
Incompatible group	A group of ingredients that you identify as having interaction concerns 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 may have
	several associated products.
Ingredient flush	A delivery of fluid that is pumped to clear the common fluid pathway between the
	delivery of certain ingredients that have interaction concerns. The fluid used for
	this flush is usually the Universal Ingredient, but it can be any compatible
	ingredient in the configuration and formula.
Ingredient group	A list of chemically similar ingredients, used for defining incompatible groups.
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
Laura valvusa dalivami	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.
Magraingradiant	
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
main mounte	detector, pump chamber and power supply. It mounts to the base plate.
Maintenance	The act of performing scheduled or expected work on the compounder.
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
ivialidal addition	has finished.
Message	Small on-screen window or other text that provides information or instructions
	but does not allow entry of 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	A unique, three-segment number used in the United States to identify drug
(NDC)	products used by humans.
Occlusion	A blockage in the fluid pathway.
OEM	Original Equipment Manufacturer i.e., Baxter Healthcare
<del></del>	1 O

Term	Definition		
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, that contains the patient information		
	and formula.		
.FRM file	An encrypted file, created in the order-entry software, that contains the patient		
	information and formula.		
2D Formula Barcode	A label, printed by the order-entry software, that includes patient information and		
Label	formula and a 2D Barcode.		
Patient	The recipient of the finished solution.		
Permissions	The privileges granted to groups of users to allow them to perform specific		
	functions.		
Pop-up message	A temporary window that appears to notify the user that they need to take an		
	action.		
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.		
privilagas	· · · · · · · · · · · · · · · · · · ·		
privileges product	See <i>permissions</i> .  An ingredient in a particular container size and type from a specific manufacturer.		
product	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	Information window that occupies the entire display		
sequence	The order in which ingredients are pumped/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	A form of intravenous therapy that requires multiple fluid ingredients to be		
Nutrition (TPN)	accurately compounded into a single solution to support a patient's nutritional		
	needs.		
tube set	The valve set and inlets.		
Universal Ingredient (UI)	The ingredient that is used to flush the common fluid pathway. This ingredient		
	must be included 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		
valve set	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 of 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.		

# **SPECIFICATIONS**

# Display

Operating software:	Linux Yocto Project		
CPU:	Quad-core Arm® Cortex®-A9 1.2 GHz		
System on Module (SOM)	ConnectCore 6+ , Cortex®-A9		
Memory:	8 GB flash, 2 GB DDR3, 64 GB Micro SD card		
Screen Resolution:	WXGA (1280 x 800)		
Ethernet:	1 Gigabit Ethernet network connectivity		
USB ports:	4 ports, USB 2.0 supporting USB 1.1/2.0		
Wi-Fi Compatibility	IEEE 802.11 a/b/g/n/ac		
	For radio frequencies and power transmitted, refer to:		
	ConnectCore 6 Plus Hardware Reference Manual (digi.com)		
Barcode scanner holder	Length: 4.4 in. (11.3 cm)		
specifications	Width: 3.33 in. (8.5 cm)		
	Height: 7.4 in. (18.8 cm)		
	Weight: 0.14 lb (0.06 kg)		

The display supports the connection and use of a USB 1.1/2.0 keyboard and mouse.

## **Dimensions**

Main module:	Width: 24 in. (61 cm)
	Depth: 10 in. (25.4 cm)
	Height: 10 in. (25.4 cm)
Display:	Width: 11.5 in. (29.1 cm)
	Depth: 2.2 in. (5.5 cm)
	Height: 7.9 in. (20 cm)
Load cell:	Width: 13 in. (33 cm)
	Depth: 8 in. (20.3 cm)
	Height: 10 in. (25.4 cm)
Compounder,	Width: 33 in. (76.2 cm)
without vial rack:	Depth: 19 in. (48.3 cm)
	Height: 12 in. (30.5 cm)
Compounder,	Width: 41 in. (104 cm)
with vial rack:	Depth: 20 in. (50.8 cm)
(these may vary with vial	Height: 30 in. (76.2 cm)
rack size)	

# Weight

Main module:	40.0 lb (18.14 kg)
Display:	4.3 lb (1.95 kg)
Load cell:	5.1 lb (2.3 kg)
Base:	13.0 lb (5.89 kg)
Vial rack:	Less than or equal to 13.2 lb (6 kg)
Compounder	Approx. 75 lb (34 kg)

#### **Electrical**

Power:	100–240 V AC RMS, 50–60 Hz, 336 W	
Line cord:	Use only a Baxter approved line cord	
Display Cable:	Use only a Baxter approved display cable	
Fuse ratings:	EXACTA-M	
	There are two 4 AMP, 5x20mm, SLOW BLOW fuses located in the AC	
	power inlet connector under the EXACTA-M Main Module.	
	2400-M	
	There is no user accessible fuse on the 2400-M Main Module.	

#### 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:	24
Maximum capacity of vial rack:	16 (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.

**IMPORTANT!** In the event of an Electrostatic Discharge (ESD), a system shutdown may occur. Upon system restart, any in-progress formulations before the ESD event will be unloaded and the valve set will be flushed. See the Power Interruption information on page 76.

#### **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/index.html

# WI-FI COMPLIANCE

#### **United States**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC CAUTION: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC CAUTION: This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

#### Canada

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: 1. This device may not cause interference. 2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : 1. L'appareil ne doit pas produire de brouillage; 2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

for indoor use only

Pour usage intérieur seulement

Data transmission is always initiated by software, which is the passed down through the MAC, through the digital and analog baseband, and finally to the RF chip. Several special packets are

initiated by the MAC. These are the only ways the digital baseband portion will turn on the RF transmitter, which it then turns off at the end of the packet. Therefore, the transmitter will be on only while one of the aforementioned packets is being transmitted. In other words, this device automatically discontinues transmission in case of either absence of information to transmit or operational failure.

La transmission des données est toujours initiée par le logiciel, puis les données sont transmises par l'intermédiaire du MAC, par la bande de base numérique et analogique et, enfin, à la puce RF. Plusieurs paquets spéciaux sont initiés par le MAC. Ce sont les seuls moyens pour qu'une partie de la bande de base numérique active l'émetteur RF, puis désactive celui-ci à la fin du paquet. En conséquence, l'émetteur reste uniquement activé lors de la transmission d'un des paquets susmentionnés. En d'autres termes, ce dispositif interrompt automatiquement toute transmission en cas d'absence d'information à transmettre ou de défaillance.

This equipment complies with ISED radiation exposure limits set forth for an uncontrolled environment and meets RSS-102 of the ISED radio frequency (RF) Exposure rules as this equipment has very low levels of RF energy.

Cet équipement est conforme aux limites d'exposition aux rayonnements énoncées pour un environnement non contrôlé et respecte les règles d'exposition aux fréquences radioélectriques (RF) CNR-102 de l'ISDE puisque cet appareil a une niveau tres bas d'energie RF.

#### Taiwan

取得審驗證明之低功率射頻器材,非經核准,公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。 低功率射頻器材之使用不得影響飛航安全及干擾合法通信;經發現有干擾現象時,應 立即停用,並改善至無干擾時方得繼續使用。 前述合法通信,指依電信管理法規定作業之無線電通信。 低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

English Translation: Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to approved low power radio-frequency devices. The low power radio-frequency devices shall not influence aircraft security and interfere legal communications; If found, the user shall cease operating immediately until no interference is achieved. The said legal communications means radio communications is operated in compliance with the Telecommunications Management Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

應避免影響附近雷達系統之操作。

English Translation: The use of equipment near radar systems should be avoided.

高增益指向性天線只得應用於固定式點對點系統。

English Translation: High-gain directional antennas can be used only in fixed point-to-point systems.

# **WARRANTY STATEMENT**

Baxter Healthcare Corporation provides a limited warranty for the **ExactaMix Pro** 2400 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 Pro** 2400 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 Pro** 2400 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.















Baxter Healthcare Corporation One Baxter Parkway Deerfield, IL 60015 USA