# ExactaMix Pro Compounder

## Information Systems Environmental Requirements for Configuring the **ExactaMix Pro** Automated Compounder

**For use with the following product codes REF :**

| | |
|---|---|
| Main Module | EXACTA-M; 2400-M |
| Load Cell | EXACTA-LC; 2400-L |
| Display Module | EXM24DY; EXME24DY; EXM12DY; EXME12DY |
| 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 guide.*

Baxter

# TABLE OF CONTENTS

## 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.

**Intended Use** : The ExactaMix compounder is a pharmacy compounding device intended to be used to compound solution's such as :

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

This document contains information about the hardware and software environmental requirements for the compounder as well as the interfaces and configurations to support customer installations. It is intended to answer questions regarding the impact this system may have in a customer's information systems (IS) infrastructure. For cybersecurity information, please refer to the **ExactaMix Pro** Compounder Cybersecurity Guide.

This guide is applicable to the following compounders:

- **ExactaMix Pro** 1200 Compounder
- **ExactaMix Pro** 2400 Compounder

## EXACTAMIX PRO PHYSICAL SPACE REQUIREMENTS

Dimensions:

| | |
|---|---|
| **Main module:** | Width: 24 in. (61 cm)<br>Depth: 10 in. (25.4 cm)<br>Height: 10 in. (25.4 cm) |
| **ExactaMix Pro Display (including barcode scanner holder):** | Width: 11.5 in. (29.1 cm)<br>Depth: 2.2 in. (5.5 cm)<br>Height: 7.9 in. (20 cm) |
| **Load cell:** | Width: 13 in. (33 cm)<br>Depth: 8 in. (20.3 cm)<br>Height: 10 in. (25.4 cm) |
| **Compounder, without vial rack:** | Width: 33 in. (76.2 cm)<br>Depth: 19 in. (48.3 cm)<br>Height: 12 in. (30.5 cm) |
| **Compounder, with vial rack:**<br>(These may vary with vial rack size) | Width: 41 in. (104 cm)<br>Depth: 20 in. (50.8 cm)<br>Height: 30 in. (76.2 cm) |

Weight:

| | |
|---|---|
| **Main module:** | 40.0 lb (18.14 kg) |
| **ExactaMix Pro 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 (6.00 kg) |

## ELECTRICAL REQUIREMENTS

The **ExactaMix Pro** compounder has the following electrical requirements:

| | |
|---|---|
| **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** | **There are two 4 AMP, 5x20mm, SLOW BLOW fuses** |

There are some user-serviceable parts. If service is needed, please contact an authorized Baxter service professional.

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 if facility power interruptions occur. Baxter recommends a UPS Battery Backup that meets or exceeds the following minimums:

| **UPS Battery Backup Requirement** | |
|---|---|
| **Output Power Capacity** | **330Watts / 600VA** |
| **Output Voltage Range** | **100 to 240VAC** |
| **Frequency** | **50 to 60 Hz** |
| **Waveform** | **A sinewave or a stepped approximation of a sinewave** |
| **Surge Energy Rating** | **490 Joules** |

## DISPLAY PROPERTIES AND CONNECTIONS

| **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 b/g/n/ac** |
| **Barcode scanner holder specifications** | **Length: 4.4 in. (11.3 cm)**<br>**Width: 3.33 in. (8.5 cm)**<br>**Height: 7.4 in. (18.8 cm)**<br>**Weight: 0.14 lb (0.06 kg)** |

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

The **ExactaMix Pro** Compounder encrypts and stores all information using hardware cryptographic module (Cryptographic Accelerator and Assurance Module (CAAM)) to ensure that the data is protected when at-rest. The CAAM uses 256-bit AES-CCM and 256-bit AES-ECB ciphers.

The compounder has a projected capacitive type LCD touchscreen that supports use by single- or double-gloved users. The touchscreen does not require calibration.

## USB ACCESS

The **ExactaMix Pro** Compounder allows use of USB mass storage devices for database backups, exported reports, and for .PAT file transfer if there are network problems.

The use of USB storage devices presents a cybersecurity concern; such devices are a means to bring malware into the device. To prevent loading and running of unauthorized software from USB, the compounder is configured as follows:

- The USB controller is configured in HOST ONLY mode. In this mode, the **ExactaMix Pro** Compounder will not appear as a mass storage device to a computer connected to the compounder's USB ports.
- By default, the compounder's USB ports are configured only for human interface devices such as barcode scanner, printer, keyboard and mouse.
- In order to enable the USB ports to access a mass storage device, an authorized user must be logged into the device.

**Auto-play/Auto-run is disabled on USB mass storage devices.**

## NETWORK REQUIREMENTS

The **ExactaMix Pro** Compounder has an ethernet port or can use wireless to access files (.PAT files) on a shared drive with the order entry system. The ethernet port supports up to 1 Gigabit network connectivity and supports TCP/IP V4 protocols (RJ-45 ethernet socket needs to be located near the hood in the cleanroom to accommodate the ethernet network connection).

The **ExactaMix Pro** Compounder can securely read files on the network share using industry standard security protocols in conjunction with Baxter PKI infrastructure. The compounder uses the File Transfer Protocol Secure (FTPS) protocol. Secure protocols enforce using X509 digital certificates to mutually authenticate each other and encrypt the data in-transit. The **ExactaMix Pro** Compounder has a client certificate pre-installed. Baxter will provide tools and procedures to create and install a server certificate on the network share. This is the recommended approach for securing access to order entry system files by the **ExactaMix Pro** Compounder.

The **ExactaMix Pro** Compounder can populate order information electronically through the use of .PAT files generated by an order entry or EMR system. These .PAT files must meet the ExactaMix Pro specifications and are stored in a directory on the network that is shared with the order entry system and the **ExactaMix Pro** Compounder (i.e., shared drive). The service account that will be used to access the shared drive will need full control permissions to allow both the order entry system and **ExactaMix Pro** Compounder to read, write, modify and change the files within the directory.

The other method to allow file sharing between the Order Entry system and **ExactaMix Pro** Compounder is by using Usernames/Passwords. The compounder uses Common Internet File System (CIFS) to allow for Microsoft Windows interoperability.

**NOTE:** Users operating the **ExactaMix Pro** Compounder will need Network Configuration Permission. This permission is by default given to IT Admin and Pharmacy Admin user groups.

# EXACTAMIX PRO COMPOUNDER PORT USAGE

By default, all ports are closed except those listed in the table below.

| Services | UDP Ports | TCP Ports | Comment |
|---|---|---|---|
| **DNS** | **53** | **-** | **This port is open to connect to a Domain Name Server (DNS) which is used to resolve human readable web addresses to IP Addresses.** |
| **NTP** | **123** | **-** | **This port is open to use Network Time Protocol (NTP). This protocol will assure the compounder's clock is at the correct time.** |
| **DHCP Client** | **68** | **-** | **This port is used to communicate with the Dynamic Host Configuration Protocol (DHCP) server to request an IP Address for the device.** |
| **Secured File Transfer Service** | **-** | **990** | **This port is used to access the data from Windows share folder securely.** |

# WIRELESS NETWORK REQUIREMENTS

The **ExactaMix Pro** Compounder provides the ability to securely connect to wireless (Wi-Fi) networks using any of the security protocols listed below in the order of lower security to higher security:

- WEP (Wired Equivalent Privacy) – Requires the user to enter WEP keys. The compounder supports shared and open authentication mechanisms with key sizes of 40 bits and 104 bits.
- WPA2/WPA-PSK – Requires the user to enter a pre-shared key as passphrase.
- WPA2/WPA-Enterprise with 802.1x authentication – Extensible Authentication Protocols (EAP) are supported, such as EAP-TLS and EAP-TTLS, EAP-FAST, EAP-TTLS/PAP and EAP-TTLS/MSCHAPv2. Requires the user to enter Wi-Fi Client Certificate and Private Key to the compounder.

The Display supports Wi-Fi communication standards with their associated bandwidths:

- IEEE 802.11b/g/n/ac

The table below shows the minimum receive sensitivity for the different connection modes of the **ExactaMix Pro** Compounder. Use appropriately placed Access Points in order for the signal strength to be greater than these values.

**DIGI CONNECT CORE 6 Plus Module Receive Sensitivity**

| Mode | | 802.11b | | 802.11ga | | 802.11n | | 802.11ac | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Modulation | | DBPSK | CCK | BPSK-1/2 | 64QAM-3/4 | BPSK-1/2 | 64QAM-5/6 | BPSK-1/2 | 64QAM-5/6 | 256QAM-5/6 |
| | | 1 Mbps | 11 Mbps | 6 Mbps | 54 Mbps | MCS0 | MCS7 | MCS0 | MCS7 | MCS9 |
| 2.4 GHz | HT20 | -90 | -88 | -90 | -75 | -82 | -64 | -82 | -64 | - |
| | HT40 | - | - | - | - | -79 | -61 | -79 | -61 | -54 |

## PRINTER REQUIREMENTS

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

The printer can also use A4 paper 8.25 x 11.75 in. (21.0 x 29.7 cm).
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

**Network Printing Requires**

- Print permission on installed network printers for all authenticated users.

The compounder software includes the printer drivers.

Supported Printers:

- **HP** Laser jet printers
- **Brother** Laser printers
- **Epson** Laser jet printers
- **Lexmark** Laser jet printers

**IMPORTANT!**
Use only Baxter-authorized printers with the compounder.

## SOFTWARE INSTALLATION/ACTIVATION

The current design of the software does not allow the installation of software. Only Baxter certified software and/or patches may be installed with the assistance of a Baxter authorized Technician. The **ExactaMix Pro** Compounders are verified and validated solely with the software that was installed by Baxter.

## DATABASE COMPATIBILITY AND MIGRATION

The database for the **ExactaMix Pro** 2400 Compounder is not the same as the database for the **ExactaMix Pro** 1200 Compounder. Only restore a database for the appropriate 1200 or 2400 device. The compounder database is secured by SQLCipher (256-bit AES Encryption).

The **ExactaMix Pro** 2400/1200 Compounder database has a different format than the previous ExactaMix 2400/1200 Compounder database. An existing database from an older device must be migrated to the appropriate **ExactaMix Pro** 2400/1200 Compounder database format.

This migration process is only for the databases of ExactaMix 2400 with versions 1.10, 1.13, and 1.14 and the databases of ExactaMix 1200 with versions 1.0, 1.4, and 1.5. For other versions, consult with your Baxter authorized Technician. The Baxter authorized Technician will work with you to migrate the database to the current database format compatible with the **ExactaMix Pro** compounder.

**Note:** For the database of ExactaMix 2400 version 1.11, consult with your Baxter authorized Technician.

# EXACTAMIX PRO NETWORK CONFIGURATIONS

## PEER TO PEER CONFIGURATION

A Peer-to-Peer Configuration allows an Order Entry Workstation and the **ExactaMix Pro** Compounder that are not on a facility network to communicate on their own network. This can be setup using a cross-over cable between the Order Entry workstation and the **ExactaMix Pro** device. A shared folder will need to be setup on the Order Entry workstation to hold the .PAT files for the **ExactaMix Pro** Compounder. The customer is responsible for providing credentials to access their network and file share.

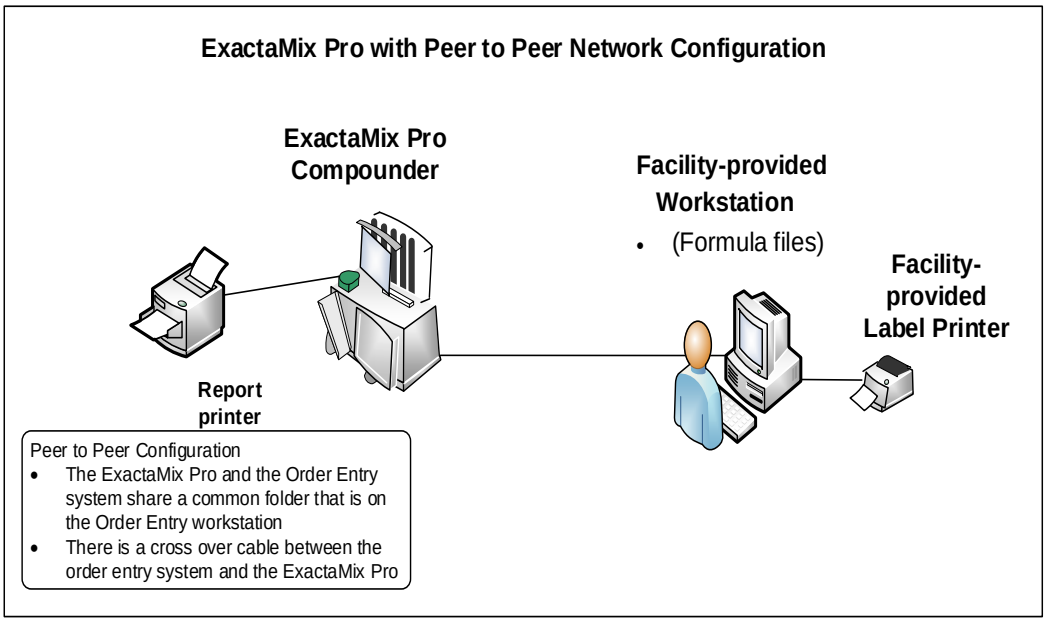


**Figure 1 – Peer to Peer**

## WIRED NETWORK CONFIGURATION

A wired network configuration allows the **ExactaMix Pro** Compounder to be on a facility's network. A shared folder will need to be set up on a network drive to hold the .PAT files for the compounder. The customer is responsible for providing credentials to access their network and file share.

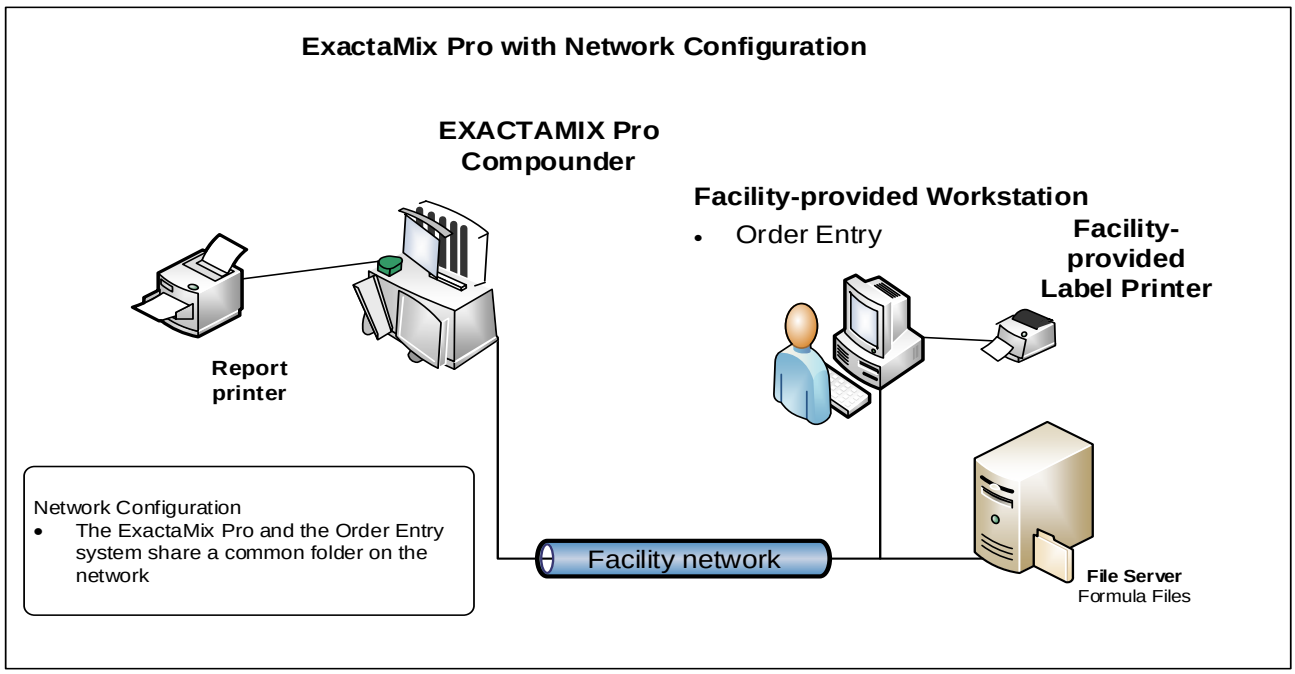


**Figure 2 – Wired Network**

## WIRELESS NETWORK CONFIGURATION

A wireless network configuration allows the compounder to be wirelessly connected to the facility's network. A shared folder will need to be set up on a network drive to hold the .PAT files for the compounder. The customer is responsible for providing credentials to access their network and file share.

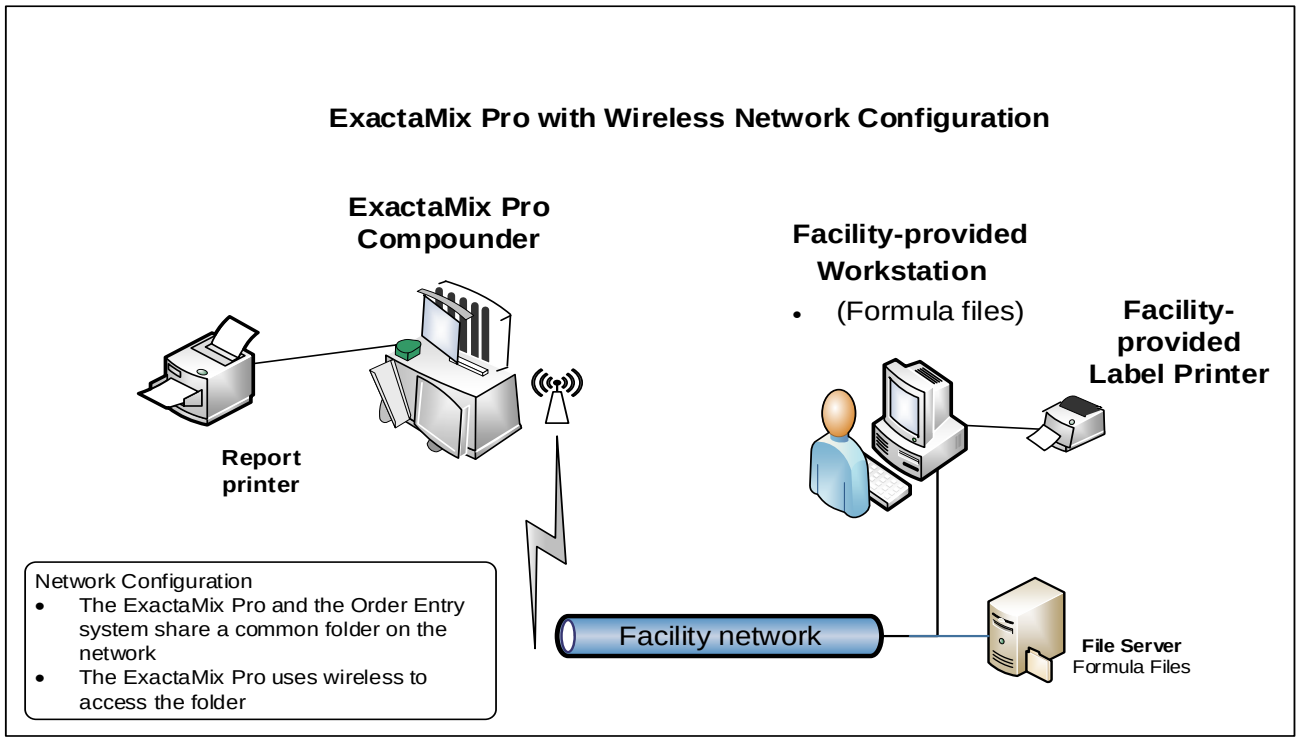


**Figure 3 – Wireless Network**

## MULTIPLE COMPOUNDERS VIA NETWORK CONFIGURATION

This configuration allows multiple compounders to be connected to a facility's network. The compounders can be connected wired or wirelessly. A shared folder will need to be set up on a network drive to hold the .PAT files, and each compounder must have access to this shared folder. The customer is responsible for providing credentials to access their network and file share. Each **ExactaMix Pro** Compounder can access only one shared folder. However, all compounders can access the same folder.

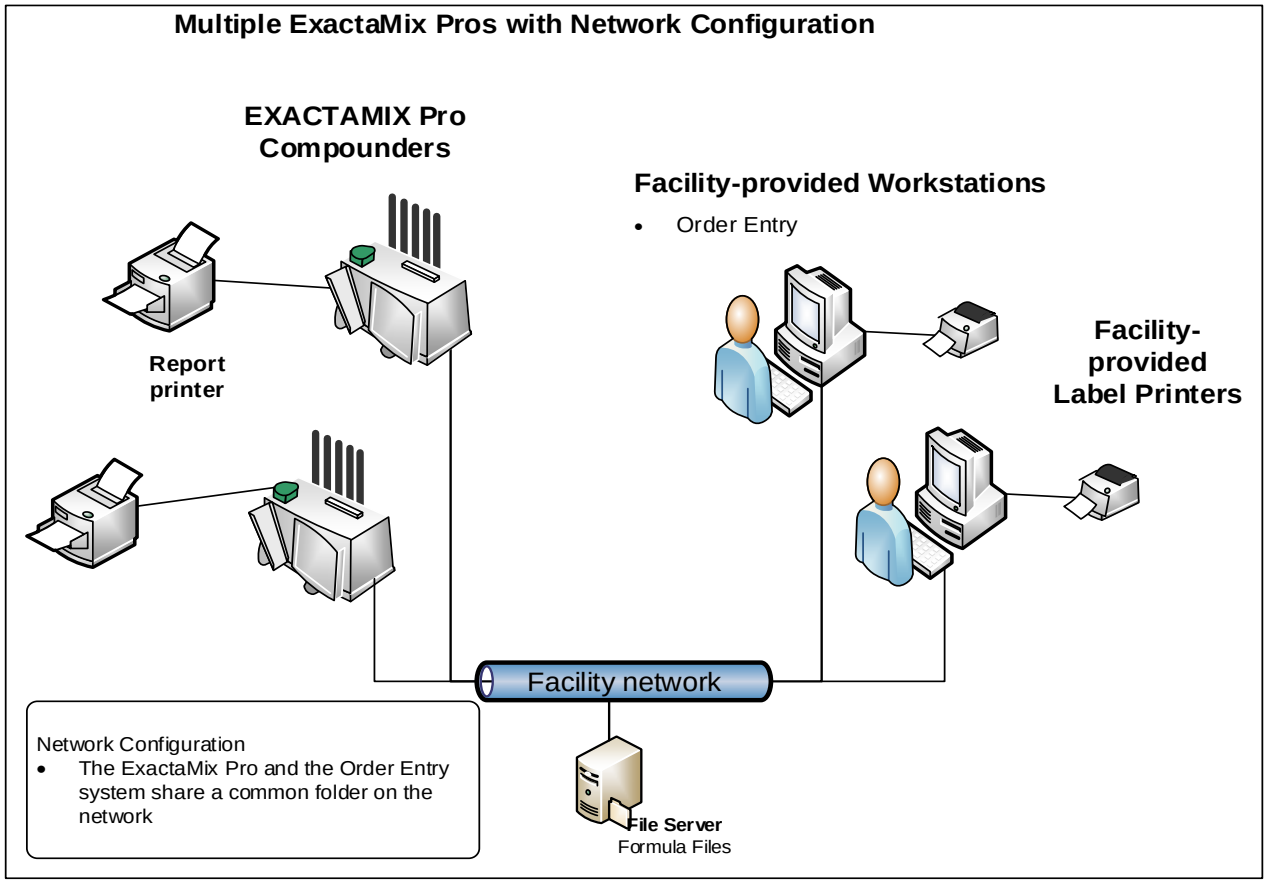


**Figure 4 – Multiple Compounder on Network**

## STAND-ALONE (EXACTAMIX PRO COMPOUNDER NOT ON NETWORK)

This configuration allows the compounder to not be connected to the facility's network or even connected with the Order Entry workstation. A shared folder for this configuration is not needed. The customer is responsible for providing credentials to access their network and file share. Your Order Entry system must be able to print a 2D Barcode on a label or on a report that contains the contents of the order. The **ExactaMix Pro** Compounder will read and then parse this 2D Barcode for the exact formula that will then be loaded into the compounder for filling. Please consult with your Baxter representative on which order entry software packages can produce this barcode.

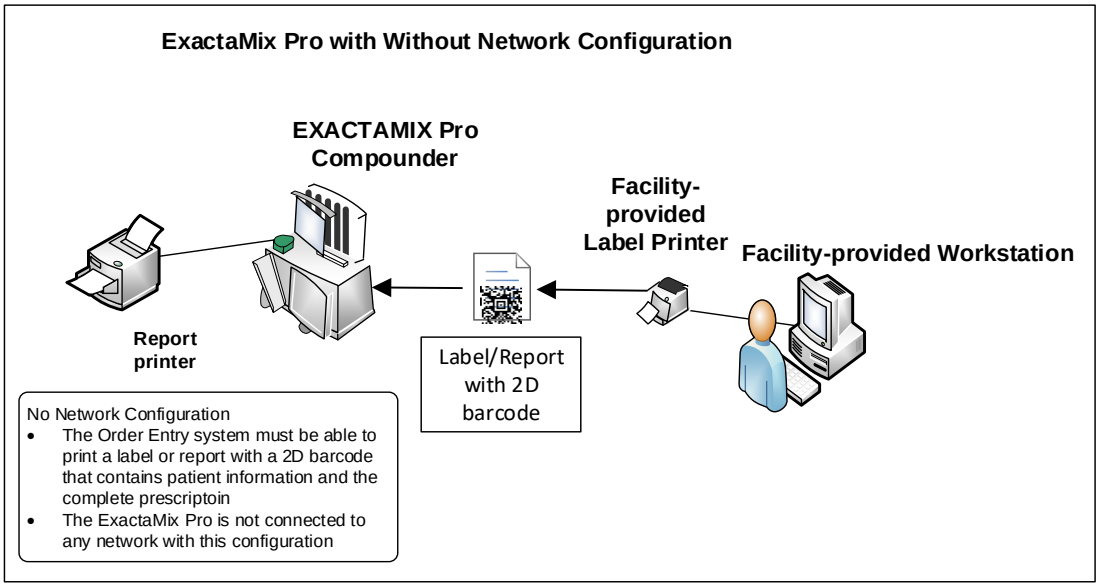


**Figure 5 – Stand Alone – No Network**

# BACKUPS

## PEER TO PEER CONFIGURATION BACKUPS

The Peer-to-Peer configuration has only the **ExactaMix Pro** Compounder and the facility's Order Entry workstation networked together. The compounder must be set up to automatically back up its database to the Order Entry workstation. A second option is to manually back up the database to a USB drive.

## NON-NETWORK CONFIGURATION BACKUPS

If the compounder is not connected to the network or to another workstation, then its database must be manually backed up to a USB drive.

## NETWORK AND MULTIPLE COMPOUNDER CONFIGURATION BACKUPS

The Network and Network with Multiple compounder configurations have the compounder on a facility's network with access to shared folders. The compounder must be configured to automatically back up the database to one of the shared folder locations. For the multiple compounder configuration, each compounder will need to be configured.

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015 USA

Baxter Healthcare Ltd.
Caxton Way, Thetford,
Norfolk IP24 3SE, United Kingdom
UK

℞ ONLY

The UKCA mark is not applicable to the following product codes EXM24DY, EXM24DYR, EXM12DY and EXM12DYR which are not available in United Kingdom.