



Photo courtesy of Baxter

Choosing an Automated Compounding Device

While automating pharmacy tasks brings with it many benefits, choosing the right technology to fit your needs can, at times, seem daunting.¹ Often, there are many diverse options to choose from—and automated compounding devices (ACDs) are no exception. Choosing the right ACD for your facility can enhance your practice, streamline the compounding process, assist with critical dose calculations, and provide an additional layer of medication safety. Choosing the wrong device can lead to staff frustration, therapy delays, and difficulties with other PN clinical services in your health system as a result of service delays.

The Basics

To determine the best ACD for your practice, you must first understand how they operate, as well as the differences between and limits of each device. ACDs use three types of measuring methods: gravimetric (weight-based), volumetric, or a combination of gravimetric and volumetric. Compounders can be further broken down into three categories based on the minimum volumes they can deliver and the number of components they can accommodate: macro, micro, or macro/micro. A “macro” device can deliver from 5.0 mL to >4 L, a “micro” device can deliver from 0.2 mL to >500 mL, and a “macro/micro” device can deliver 0.2 mL to 4 L. “Macro” devices are available with three to nine stations, “micro” devices are available with 10 stations and “macro/micro” devices are available with 12 to 24 stations. While all compounders will have a stated minimum measurable volume and accuracy range, they are generally more accurate at higher volumes. Each manufacturer includes complimentary order entry (OE) software that maximizes the effectiveness and efficiency of their ACD.

Gravimetric devices generally use a peristaltic pump mechanism. The volume delivered is calculated by dividing the weight delivered by the specific gravity of the ingredient. Gravimetric devices are not affected by running the source containers empty and delivering air into the final bag. These devices are calibrated using a manufacturer supplied reference weight.

Volumetric devices generally use both a peristaltic pump mechanism and a “stepper” motor to turn the pump mechanism. The device calculates the volume delivered by the precision of the delivery mechanism, internal diameter of the tubing, viscosity of the solution, and the diameter and length of the distal and proximal tubing. Delivery from these devices can be affected by many factors including variances in the tubing’s material, length, elasticity, and diameter; temperature, which affects solution viscosity and tubing size; ingredient head height; final bag height; and empty source components.

Monitoring and replacing source containers when they are empty will prevent the volumetric devices from delivering air in lieu of the ingredient to the final container. These devices have a limit to the volume that can be delivered before the set must be replaced and often generate the same amount of heat whether running or not because of the stepper motor’s operational characteristics.

Each ACD will have a stated delivery rate and accuracy. However, it is difficult to rely on these statements to compare ACDs, as the delivery rate is depend-



Photo courtesy of B. Braun

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ent upon the volume, number of ingredients, and container size of the source ingredients.

The Impact of USP <797>

USP General Chapter <797> mandates the calibration, verification, and documentation of all ACDs. Each device manufacturer validates the ACD per FDA guidelines, and the operator verifies the ACD prior to beginning compounding. USP <797> stipulates that “...compounding personnel shall keep a daily record of the accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant errors over time.”² This is especially crucial when compounding drugs with a narrow therapeutic index such as potassium chloride or small volume formulations intended for neonate patients.

While ACDs can improve the accuracy of the compounding process over traditional manual compounding methods, operators must be trained to use them properly.³ Compounding personnel need to fully understand all the functionalities and limits associated with using these devices in the compounding process.

Baxa Compounders

Baxa currently offers the Exacta-Mix 600, MicroMacro 12, MicroMacro 23, and the Exacta-Mix 2400 (EM2400) for the compounding of TPN, all of which use the Abacus order entry (OE) system. Each of these devices uses a volumetric pump to



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deliver ingredients and an independent gravimetric scale ensures accuracy. The Exacta-Mix 2400 automatically recalibrates whenever 175 mL or more of water is delivered.

Calibration for all Baxa systems requires a calibration weight and the user to pump solution into a container or bag to complete the calibration. Bar coding is used to verify ingredients, source lines, and final bags.

Except for the Exacta-Mix 2400, which includes a touch screen with a Microsoft Windows enabled control unit built into to compounder, the Baxa compounders require an external PC and electronic scale to run.

Baxter Compounders

Baxter offers the Automix 3+3 (macro six station), Automix 3+3 Accusource (macro six station), and Micromix (micro ten station) compounders, using Baxter's TPN Logix OE software. The Multitask Operating System (MOS) can also run the compounders but is no longer maintained or supported. The Automix 3 station device has been retired and Baxter no longer produces sets for the device.

All Baxter compounders are gravimetric devices. If the Logix OE software is not used, each volume and specific gravity (SPG) of the various macro ingredients for delivery into the final container must be manually programmed. The Logix OE software is required to use the Micromix compounder.

Baxter compounders run on various versions of Logix OE software and you should verify the particular software your device has installed. Baxter's Automix Compounders are able to deliver volumes starting at 10 mL. The Micromix Compounder will deliver down to 1.0 mL with a limit of 650 mL for all 10 stations. The sets for the Micromix Compounder have source line labels attached. Although Baxter compounders do not have bar coding implemented, the Automix 3+3 Accusource Compounder has the ability to "sense" source ingredients to prevent improper hanging of source solutions.

B. Braun Compounders

B. Braun's Pinnacle is a nine station gravimetric device (with nine and six stations disposable tubing sets) that delivers volumes starting at 5.0 mL. Bar coding is used to verify ingredients, source line, and final bags. The OE program, Pinnacle TPN Manager, is a browser based thin client design.

The software provides pooling calculations; one-step dual-chamber bag filling; ability to compound "3 in 1", "2 in 1," and dual chamber bags in any order

Minimum ACD System Requirements

- Warning limits for anions/cations
- Osmolarity warnings
- Overfill warnings when an order cannot be prepared in the volume specified
- TPN calcium/phosphate solubility tables
- Ability to add and set minimums and maximums for ingredients
- Positive identification of hanging solutions with NDC, lot #, expiry, and documentation of hang date and time
- Positive identification of patient orders
- Ability to batch a multiple bag order with a unique identifier for each bag that can be traced back to the compounding date and time
- Electrolyte pooling calculations and compounding
- Filling of dual-chamber IV bags from the compounder in one step (if applicable)
- No lipid "hazing"
- Ingredient usage reports
- A minimum of three patient types: adult, pediatric and neonate
- Ability to set up standard "formulas" for different referral sources
- Multi-user concurrent order entry
- A minimum of three user security access levels: administrator, pharmacist and technician
- Secure documentation for compounded bags and overrides
- HIPAA compliance
- Option to encrypt communication from order entry to the device
- Multi-compounder capability
- Network connection ability and WAN functionality
- No solution flushing required
- Ability to use multiple compounders for a single patient

(without lipid hazing); and Calcium Phosphate calculations that consider the reduced volume when using dual-chamber bags. Two or more of the devices can be used together, allowing for one device to make all of the pooling bags while the other does the compounding. The software calculates the actual specific gravity (SPG) of the pooling solution and uses that for compounding. The overfill volume of the pooling bag can be set to a specific volume to prevent excess waste.

Develop an RFP as an Evaluation Tool

Developing a detailed request for proposal (RFP) will guide the selection team and allow for standardization of data collection. The most successful nutrition support teams balance both the clinical and operational needs of the organization when formulating this document. To achieve your goal of increased accuracy and efficiency, look for a dependable device that can compound daily with minimal maintenance while providing fail-safe operation for patient safety. It should be easy to set-up and use, with minimal set assembly and labeling

requirements. Data collection and database queries should be automated. Positive identification for both source ingredients and final bags is important as is traceability of the compounding process and ingredients (including printable outputs). Lastly, it should be functional in all compounding environments, regardless of the engineering controls. (See Minimum ACD System Requirements on page 22)

When reviewing PN software systems, look for an option that will allow for multi-facility operation with centralized administration, the ability to create additional user access levels and patient types, and an easily loadable multi-user interface. The ability to view the status of individual orders and output information electronically is important. Also look for clear error codes and a robust error-checking database. Online training and help will make implementation easier.

The dependability of the vendor is also important, ask about their repair and replacement policy (especially the replacement turn-around time) and the depth of their technical support.

Conclusion

Although the decision to enhance your PN practice with the addition of an ACD may seem straightforward, careful consideration should be given to assure that the chosen device meets the key needs of the both the cleanroom staff and the clinical support team creating these PN formulations. Time taken at the start of the project to develop a comprehensive RFP encompassing the organization's clinical and operational needs will increase the overall satisfaction with the device when it is ultimately put into use. ■

References:

1. Adapted from the Baxa Technical Paper: Premix vs. Custom TPN – LS Diorio, DL Thomas – 2007 Baxa corporation available at: http://expert411.com/_wsn/page13.html
2. USP General Chapter <797>: www.USP.org
3. Crill CM, Hak EB, Helms RA. Accuracy of parenteral nutrition solutions compounded with automated systems and by hand. *Am J Health Syst Pharm.* 2005 Nov 15;62(22):2345-2348.



Lou Diorio, RPh, is a principal of LDT Health Solutions, Inc, a quality management consulting firm specializing in compounded sterile preparations and regional compounding solutions. The current Chair of APhA's APPM section of Administrative Practice and Management, Lou has practiced in and managed pharmacies in hospital, home care, and retail settings as well as an FDA registered compounding establishment. Lou can be reached at: LSDiorio@LDTRx.com.



David L. Thomas, RPh, MBA, is a principal of LDT Health Solutions, Inc. Mr. Thomas previously served as the director of information technology operations for SoluNet, LLC. He has also served as the manager of implementation and technology development for Baxter Healthcare and as the technology systems manager for Baxter's COMPASS Group. Before his 15-year tenure with Baxter, Dave held hospital practice and management positions. Dave is a graduate of St. Louis College of Pharmacy and can be reached at: DThomas@LDTRx.com.



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