LDT Health Solutions
PHARMACY CONSULTANTS

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B Braun Pinnacle® Pooling Considerations

Overview:

Total Parenteral Nutrition (TPN) "Pooling" is primarily used by home care pharmacists in settings where multiple days of TPN therapy are to be compounded and delivered to the patient's home. Pooling may also be used in facilities that have limited capabilities on the weekend and will prepare TPN doses for Friday, Saturday, and Sunday on Friday.

Pooling is the process of combining the volume needed of each ingredient into a single container for the entire batch. Each stable, compatible (non-reactive) additive ingredient plus an overfill volume (an overfill volume is utilized to compensate for any volume lost in the process) is combined into a pooling bottle/bag/container. An aliquot from the pooled container is then injected to each TPN bag by means of either of two methods: manual filling or automated compounder filling, where the pooled container is hung on the Automated Compounding Device (ACD) along with the base ingredients to prepare the patient specific batch of TPNs.

The manual method of producing a TPN dose could be done by combining the base components into the final container and then all of the micro-ingredients could be added using a needle and syringe. This would require that each individual additive ingredient be drawn up from each separate additive container and then injected into the additive port of the final container dose by dose.

Alternatively, pooling of these ingredients into a single container and then hanging this container on an ACD consists of delivering each base component into the final bag along with this aliquot of the pooled micro-ingredients (the pooled bag consists of each individual additive ingredient drawn up from each separate additive container per the total batch order volumes). Upon the addition of the base components, and the pooled micro-ingredients, the final bag is then removed from the ACD, the fill tubing is clamped off, and the injection port is sealed.

Pooling offers the following **advantages**:

1. **Reduce the number of "system breaks" (punctures) into the final bag.** Multiple ingredients are injected via one "system break" rather than each individual ingredient being injected independently. This can decrease the number of breaks by a factor of seven. Since touch contamination is a major concern during the compounding of any compounded sterile preparation (CSP), decreasing the number of "system breaks" (injections) in the production of TPN therefore decreases the likelihood of contamination.
2. **Reduce potential for "coring".** Multiple entries into the final bag by injection needles increases the potential for "coring" of the injection port material and the introduction of this foreign matter into the final dose.

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3. **Reduce the time required to check ingredients being added to each dose.** A release check is performed for the pooled additives as a single operation, rather than having to check the volume of each individual additive for each individual TPN dose.
4. **Reduce the time required to prepare multiple identical TPNs.** One injection is used to add multiple ingredients instead of individually injecting each ingredient.
5. **Increase consistency and accuracy of the ingredients being delivered via pooling of each individual additive into the TPN.** Manual syringe draw ups of each ingredient exhibit variations between individual bags.

Pooling has the following disadvantages:

1. Pooling utilizes an additional evacuated container or empty IV bag (the container that will hold the pool).
2. Increased ingredient waste because pooling volume must be increased to allow for line (tubing) losses and overfill for priming the automated compounding device (ACD).
3. More intricate calculations are required to determine pooling container's Specific Gravity (SPG) so that the ACD can properly deliver the required volume of fluid.
4. Two sets of overfill calculations are required- one, when final container has an overfill amount, and two the overfill fill to compensate for line loses because of the use of a pooling container.

History and Background:

Historically, home healthcare providers prepared and delivered up to 28 days of TPN therapy to a patient's location. Most providers did not calculate the pool's SPG and used an estimated pool SPG of 1.10 as a blanket factor for calculations. Depending on the combination of ingredients in the pool container, the estimated pool SPG led to variations in the amount of additives actually being delivered into the final container. Further variation was created by compounders adding incompatible ingredients such as phosphate salts to the sterile water container. Addition of these phosphate salts to the base sterile water container was done so that the phosphate salts would not have to be injected directly into the TPN final container. This would decrease the time required to prepare the patient specific batch. The addition of the phosphate salts to the base sterile water container created further variation due to the deviations in the actual volume present in the base commercially available containers of sterile water for injection. Additional variations were created by the practice of not accounting for (by subtracting) the additive volume when preparing the final TPN dose. This excess volume was used as the "overfill" to compensate for line losses when priming the patient's IV delivery pump. The patient's clinical lab values were then used to titrate the components to get the desired clinical outcome. As long as the facility's TPN preparation process remained fairly consistent, the patient did not have marked swings in their clinical lab values.

The combination of estimated pool SPG, variances in the addition of phosphate salts to the base sterile water container, and not compensating for the increased volume from the micro-

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ingredients led to the final TPN container being mislabeled. This variation from the label to what was actually in the final TPN dose could exceed 10% by volume and therefore be by FDA's (and most State Boards of Pharmacy) definition "adulterated."

Further complications occasionally arose when a patient was admitted to a hospital from a home care service or changed home healthcare providers preparing their TPN, since the labeled quantities were sometimes used as a basis for their initial TPN prescription order.

Discussion:

The primary consideration when combining the micro-ingredients of these CSPs into the pool container is to be absolutely certain that these ingredients are all compatible and stable as a combined mixture. This primary consideration makes the addition of Calcium and Phosphate salts to this pooled mixture mutually exclusive.

Secondarily, vigilance must be observed to assure the prevention of concentrated Calcium and Phosphate salts reacting within adjacent ACD source lines.

Another consideration of inclusion of micro-ingredients in the pool container is whether or not the ACD has sufficient additional stations for the hanging of common ingredients that are most often included into each TPN.

Micro-ingredients included in TPN pools are generally limited to the following:

1. Sodium Chloride (NaCl)
2. Sodium Acetate (NaAc)
3. Potassium Chloride (KCl)
4. Potassium Acetate (KAc)
5. Magnesium Sulfate (MgSO4)
6. Calcium Gluconate (CaGluc)
7. H-2 Antagonists (i.e. Pepcid [famotidine], Zantac [ranitidine], Tagamet [cimetidine]
8. MTE Products (MTE-4, MTE-5, etc.)
9. Zinc (Zn)
10. Copper (Cu)

Ingredients never recommended for inclusion into the pool container (whether because of compatibility or stability issues) are:

1. Sodium Phosphate (NaPO4)
2. Potassium Phosphate (KPO4)
3. Insulin
4. Heparin
5. MVI
6. Vitamin C (ascorbic acid)

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7. Thiamine
8. Cyanocobalamin (B-12)

Ingredients that are added immediately before administration by the patient or caregiver are excluded. These ingredients are usually excluded from the compounding of these CSPs because they are not generally stable over 24 hours and they can only be incorporated in this way. These additional patient additives are, but not limited to:

1. Insulin
2. Heparin
3. MVI
4. Vitamin C (ascorbic acid)
5. Thiamine (B-1)
6. Cyanocobalamin (B-12)

Regulatory Considerations:

Within the context of USP General Chapter <797>, TPN preparation is considered to be a medium risk CSP operation. By definition USP <797> Medium Risk CSPs have a maximum Beyond-Use Date (BUD) of nine (9) days if stored under refrigeration (and only 30 hours if kept at room temperature before administration). Therefore, in the absence of sterility testing, a facility now generally prepares a seven or eight day supply of TPN doses for the patient.

Considerations for the Pinnacle Compounder:

In order to determine the ingredients to be utilized for the pool container, an analysis of the ingredient volume, compatibility (physical & chemical), stability (physical & chemical), and available ACD stations on the Pinnacle Compounder must be performed.

Under **NO** circumstances should a Phosphate salt be combined into the micro-ingredient pool or hung on the Pinnacle compounder if Calcium is present on the Pinnacle Compounder. The danger is that a final TPN dose (container) could contain an insufficient fluid volume which would allow an insoluble precipitate of these salts to form. Insufficient fluid volume can be created when Calcium and Phosphate salts are added to the TPN dose (container) before the dextrose solution and/or sterile water is added. **This precipitate is insoluble and can result in patient harm if administered.**

Unstable ingredients should never be added to the pool. This can include but not limited to:

1. Insulin
2. Heparin
3. MVI
4. Vitamin C (ascorbic acid)
5. Thiamine
6. Cyanocobalamin (B-12)

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Ingredients that should be considered for hanging on the Pinnacle Compounder instead of being placed in the pool container are ingredients whose volumes routinely exceed 5.0 mLs. Under most regular applications these ingredients are, but not limited to:

1. Sodium Chloride (NaCl)
2. Sodium Acetate (NaAc)
3. Potassium Chloride (KCl)
4. Potassium Acetate (KAc)
5. Calcium Gluconate (CaGluc)

The larger volume ingredients should then be considered for inclusion on a Pinnacle Compounder station and not placed into the pool container. See "*LDT's BBraun Pinnacle Mixing Order*" Whitepaper for recommendations on how to properly sequence and hang these ingredients and pooling bag on the ACD.

Ingredients that should be considered to be placed into the pool are:

1. Magnesium Sulfate (MgSO4)
2. MTE Products (MTE-4, MTE-5, etc.)
3. Zinc (Zn)
4. Copper (Cu)

Any other ingredients must be evaluated for compatibility and stability (both physical & chemical) before they are considered to be added to the final TPN dose as part of the micro-ingredient pool such as H-2 Antagonists, (i.e. Pepcid® [famotidine], Zantac® [ranitidine], and Tagamet® [cimetidine]. Again, each drug item must be thoroughly evaluated before inclusion into the pool container.

Lastly, the BBraun Pinnacle Compounder TPN Manager™ software calculates the actual pool SPG, calculates the increased volume for the pool due to inclusion of overfill in the final TPN container, and calculates the overfill in the pooling container. Another advantage to the TPN Manager™ software is the ability to accommodate dual chamber TPN bags. The reduced volume, due to segregation of the lipids into the second chamber before combination, is considered in the determination of Calcium/Phosphate stability.

TPN Compounding Definitions and Concepts:

A complete knowledge of the following definitions, concepts, and caveats is needed in order to correctly perform TPN calculations and understand consequences of deviations from accepted calculations when modifying the TPN preparation process. These concepts are also important when switching from one methodology of calculations to another set of calculations based upon the patient's changing condition or the patient's clinical lab values. This is especially important when previous TPN calculations did not consider the additive component volumes as part of the ordered volume and a switch to an alternative software program is made that compensates for all of the components in the TPN. Issues that can be raised are deviations in the patient's lab values, the TPN bag running out solution during administration (i.e. additive volume was used

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for overfill), patient receiving the labeled prescription amount of ordered ingredients and suspecting mistakes in the alternative programs calculations.

Definitions:

Additive Solution: Any ingredient besides components considered to be Base Components. This can include but not be limited to Electrolytes, Vitamins, Trace Minerals, and Medications

Automated Compounding Device (ACD): Device used to prepare specific volumes of ingredients into a final container. Device may be gravimetric, volumetric, or a combination of the two

Base Component: Includes Amino Acid Solution, Dextrose, Lipids, and Sterile Water for Injection (SWFI)

Central Line: IV tubing inserted into a large blood vessel for continuous access to a central vein for administering fluids. A central line allows administration of more concentrated ingredients than can be administered via peripheral line. The high blood volume in the central vein dilutes the TPN solution.

Cyclic Rates: Used for the intermittent administration of a TPN. A cyclic rate allows the patient to be mobile between TPN administration times and can better replicate the normal feeding rhythms. The cyclic rate is usually specified as a starting rate and time period, administration rate and time period, and ending rate and time period. The starting and ending rate and time period give the patient's body time to adjust to the TPN administration. Normally, cyclic rates are used in home healthcare patents but can also be used in the hospital setting.

Final Container: IV bag that ingredients will be delivered to. This is the TPN dose that will be hung on the patient to deliver the specified nutritional components.

Infusion Period: Refers to the time over which a TPN is to be administered. This can be calculated when the Infusion Rate and Infusion Volume are known. When utilizing Cyclic Rates there are multiple Infusion Periods.

Infusion Rate: Volume of TPN to be administered in a given amount of time. This is normally expressed as mLs per hour. This can be calculated when the Infusion Period and Infusion Volume are known. When utilizing Cyclic Rates there are multiple Infusion Rates.

Infusion Volume: The dose volume to be administered. This value is expressed in mLs and this can be calculated when the Infusion Period and Infusion Rate are known. When utilizing Cyclic Rates there are multiple Infusion Volumes.

Ingredient: Refers to both Additive Solutions and Base Components

Minimum Possible Volume: Order method utilized for fluid restricted patients. This method makes the TPN as concentrated as possible and precludes the dosing using final percentages and all per units based on volume. "Q.S." (quantum sufficit) solution is not available using this option.

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Order Dose: Numerical amount of each ingredient to be contained in the TPN dose

Order Dose Units: Unit used to order an individual ingredient. For Base Components this can be, but are not limited to, final percentage, mLs, grams, grams of nitrogen, Kcal Protein, Kcal Dextrose, and Kcal of Lipids. For Additive Solutions units can be, but are not limited to, ampoules (amps), grams, milligrams, micrograms, mEqs, mMols, mLs, UNITS, and Vials. Final Percentage is not applicable for Base Components when ordering utilizing the Minimum Volume methodology. Dose Units are the numerator.

Order Per Units: Per Units are similar for Base Components and for Additive Solutions. These can be, but are not limited to, per per day, per mL, per 100mL, per 250mL, per 500mL, per Liter, per kilogram, per 100 kilogram, per pound, and per 100 pound. The weight units utilize the patient weight to determine the dosage. Per Units utilizing volume are not applicable when ordering utilizing the Minimum Volume methodology. Per Units is the denominator.

Patient Adds: Any Additive Solution added at time of administration by patient or patient care-giver. This is used for Additive Solutions that have a short expiry when added to the TPN. Examples are Insulin, Heparin, MVI, Vitamin C (ascorbic acid), Thiamine and Cyanocobalamin (B-12).

Peripheral Line: IV line inserted in the vascular periphery of the patient. The injection site can vary depending on the patient's age and where a line can be inserted. The osmolarity of the TPN determines whether or not the TPN can be administered via a Peripheral Line. Upper ranges vary from 900 to 1,100 mOsm/L depending on the patient type, current practice standards and policies at the institution. This type of venous access limits Dextrose concentration to less than 10% and usually to 5%.

Priming Loss: The volume lost when priming or flushing out of a source line for an ACD or an IV line on a patient pump

Q.S. (quantum satis, quantum sufficit): Latin phrase meaning a sufficient quantity. The Q.S. Base Component is SWFI. The volume calculated is the Ordered Volume minus the volume summation all of the TPN ingredient volume. Q.S. is not applicable when ordering by Minimum Volume method.

Overfill: Is the volume of solution to be included in a bag in excess of the ordered volume and is not intended to be administered. An overfill factor is determined and uniformly applied to all base components and additive solutions to maintain correct concentrations in the final solution. This results in a total volume that is the sum of the infusion volume ordered and the overfill volume. Overfill achieves three main purposes:

1. Provides extra volume in a TPN bag to prime the I.V. line.
2. Increases Additive Solution volumes so that they are measurable and deliverable. This method is especially important for neonate patients where the Infusion Volume is typically less than 100 mL to be delivered in 24 hours.
3. Provides a time cushion when a TPN dose is being administered over a 24 hour period.

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Overfill Warning (Dilutional Error): A situation in which an ordered TPN prescription can't be physically made in the Infusion Volume specified. This occurs when the sum of the volumes of the ingredients requested is greater than the requested Infusion Volume. Compounding of this solution will result in the patient not receiving the ordered prescription amounts. **This error cannot be ignored when preparing Neonatal TPNs.** This is not to be confused with Overfill.

Specific Gravity (SPG): The density of a substance relative to the density of water. Usually expressed as grams per 100mLs. SPG is an essential value when using ACDs weighing the amount of each ingredient to be delivered to the final container.

TPN Calculations:

Calculating TPN ingredient volumes is dependent upon the method being utilized for compounding. Regardless of the method used for compounding, considerations must be given, but are not limited to:

1. Overall TPN calculations
2. Ability to compound the TPN in the volume ordered
3. Overfill for final TPN container
4. Overfill for pooling solution
5. Specific Gravity (SPG) of the pooling solution
6. Line priming and waste volumes
7. Small ingredient volumes

TPN Sample Calculation Assumptions:

1. All TPN calculations will be based upon and reflect the actual TPN order.
2. Multiple TPN bags will be prepared for the prescription batch.
3. An ACD will used to prepare the TPN.
4. The final TPN container will have Overfill.
5. Prepared pool bag will be hung on the ACD.
6. Each pool ingredient weight will be calculated to three decimals.
7. SPG of Pooling Bag will be calculated to three decimal places using the summation of each ingredient weight divided by the summation of each ingredient volume.
8. A pooling bag will be prepared and hung on the ACD.
9. Pooling bag will use both ACD preparation and the manual drawing up of ingredients with syringes.
10. The pooling bag will contain Overfill to compensate for line losses and flushing.
11. All ingredient volume calculations will be rounded to two decimal places.
12. Calculation Methods (numerator):
    a. Ingredients ordered in final percentage
    ((Final Percentage/Source Percentage) * Infusion Volume) = Amount of Source Ingredient in mLs.
    b. Ingredient ordered in Kcals, grams. milligrams, micrograms, mEq, mMol, UNITS, vials and ampoules (Please Note: Ordered Amount and Source Concentration

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may not be in the same units.)
Ordered Amount/Source Concentration = Amount of Source Ingredient in mLs.

c. Ingredients ordered in mLs is the mLs amount to be used.

13. Calculation Methods per Units (denominator):
    a. Per Liter
    (Infusion Volume in mLs/1000 mLs)*Ordered Amount in mLs= Amount of Source Ingredient in mLs.
    b. Per 100ml (deciliter)
    (Infusion Volume in mLs/100mL)*Ordered Amount in mLs= Amount of Source Ingredient in mLs.
    c. Per Bag
    No conversion necessary
    d. Per kilogram
    Ordered Amount in mLs * Patient Weight = Amount of Source Ingredient in mLs.
    e. Per gram
    Ordered Amount in grams divided by the source concentration in decimal form. (A 10% source concentration would be 0.1.)
14. Phosphate will never be in the pooling bag.
15. ACD Volume Delivery Rounding Rules
    a. ≥100mL no decimal places
    b. ≥ 5.0 to < 100mL one decimal place
    c. <5.0mL two decimal places
16. Syringe Volume Delivery Rounding[i] Rules (BD Syringes)
    a. > 10mL no decimal places
    b. ≥ 3.0 to <= 10mL one decimal place (0.2mL decrements)
    c. ≥ 1.0 to < 3mL one decimal place (0.1mL decrements)
    d. <1.0mL two decimal places
17. Ingredient Concentrations and SPGs.

Ingredient	Concentration	SPG
Amino Acids	10%	1.032
Amino Acids	15%	1.046
Dextrose	70%	1.233
Lipids	20%	0.990
Lipids	30%	0.980
Sterile Water for Injection (SWFI)	N/A	1.000
Calcium Gluconate (CaGluc)	0.465mEq/mL	1.049
Famotidine Injection	10mg/mL	1.012

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Insulin	100UNITS/mL	1.000
Magnesium Sulfate (MgSO4)	4.0mEq/mL	1.222
MVI	1mL/mL	1.030
Potassium Acetate (KAc)	2mEq/mL	1.092
Potassium Acetate (KAc)	4mEq/mL	1.178
Potassium Chloride (KCl)	2mEq/mL	1.088
Potassium Phosphate (KPO4)	3mMol/mL	1.315
Sodium Acetate (NaAc)	2mEq/mL	1.080
Sodium Acetate (NaAc)	4mEq/mL	1.151
Sodium Chloride (NaCl)	2.5mEq/mL	1.097
Sodium Chloride (NaCl)	4mEq/mL	1.151
Sodium Phosphate (NaPO4)	3mMol/mL	1.278
Trace Elements	1mL/mL	1.018

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TPN Sample Order #1:

Patient Type:	Patient Weight	Infusion Rate	Infusion Period	Infusion Volume	Infusion Overfill	Final Volume	Pool Overfill	Batch Quantity
Adult	N/A	75 mL/Hour	24 Hours	1800 mL	100 mL	1900 mL	50 mL	7 Bags

Source Ingredient	Order	Per	Calculated Volume (mLs)	Deliverable Volume (mLs)	Calculated Volume with 100 mLs Overfill (mLs)	Deliverable Volume with 100 mLs Overfill Manual Adds (mLs)	Deliverable Volume with 100 mLs Overfill ACD Prepared Pool (mLs)	Deliverable Volume with 100 mLs Overfill Manually Prepared Pool (mLs)
Amino Acids 15%	5 %	Bag	600	600	633.33	633 **	633 **	633 **
Dextrose 70%	25 %	Bag	642.86	643	678.57	679 **	679 **	679 **
Lipids 30%	4 %	Bag	240	240	253.33	253 **	253 **	253 **
SWFI 1mL/mL	272.07 mL	Bag	272.07	272	287.19	287 **	287 **	287 **
Pool	N/A	N/A	N/A	N/A	N/A	N/A	27.9 **	27.9 **
NaCl 4mEq/mL *	20 mEq	Bag	5	5	5.28	5.2 ***	5.28 *	5.26 *
NaAc 4mEq/mL *	35 mEq	Bag	8.75	8.8	9.24	9.2 ***	9.25 *	9.25 *
CaGluc 0.465mEq/mL *	4.5 mEq	Bag	9.68	9.6	10.22	10 ***	10.23 *	10.28 *
MgSO4 4.06mEq/mL *	8 mEq	Bag	1.97	2	2.08	2.1 ***	2.08 *	2.06 *
Trace Elements 1mL/mL *	1 mL	Bag	1	1	1.06	1.1 ***	1.06 *	1.05 *
KPO4 3mMol/mL	20 mMol	Bag	6.67	6.6	7.04	7 ***	7 ***	7 ***
Famotidine 10mg/mL	20 mg	Bag	2	2	2.11	2.1 ***	2.1 ***	2.1 ***
MVI 1mL/mL	10 mL	Bag	10	10	10.56	11 ***	11 ***	11 ***
	Total Volume		1,800	1800	1900.01	1899.7	1900	1900
* Pool Component						** ACD *** Syringe	* Pool ** ACD *** Syringe	* Pool ** ACD *** Syringe

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TPN Sample Order #1 Pool Bag Volumes and SPGs:

Source Ingredient	ACD Prepared Pool		Manually Prepared Pool	
	Volume mLs	Weight Grams	Volume mLs	Weight Grams
NaCl 4mEq/mL *	46.4	53.406	46	52.946
NaAc 4mEq/mL *	81.2	93.705	81	93.474
CaGluc 0.465mEq/mL *	89.8	94.200	90	94.410
MgSO4 4.06mEq/mL *	18.3	22.363	18	21.996
Trace Elements 1mL/mL *	9.3	9.467	9.2	9.366
Total	245	273.141	244.2	272.192
	SPG	1.115	**SPG**	1.115

TPN Sample Order #1 Variance

Source Ingredient	Variance				
	ACD Bases Manual Syringe Ingredients	ACD Bases ACD Pool Manual Syringe Ingredients	ACD Bases Manual Pool Manual Syringe Ingredients	ACD Pool Using Generic 1.10 SPG for Pool	Manual Pool Using Generic 1.10 SPG for Pool
Amino Acids 15%	-0.1% **	-0.1% **	-0.1% **	N/A	N/A
Dextrose 70%	0.1% **	0.1% **	0.1% **	N/A	N/A
Lipids 30%	-0.1% **	-0.1% **	-0.1% **	N/A	N/A
SWFI 1mL/mL	-0.1% **	-0.1% **	-0.1% **	N/A	N/A
Pool	N/A	0.1%	0.1%	-1.3%	-1.3%
NaCl 4mEq/mL *	-1.5% ***	0.0% *	-0.4% *	-1.7%	-1.7%
NaAc 4mEq/mL *	-0.4% ***	0.1% *	0.1% *	-1.2%	-1.2%
CaGluc 0.465mEq/mL *	-2.2% ***	0.1% *	0.6% *	-0.8%	-0.8%
MgSO4 4.06mEq/mL *	1.0% ***	0.0% *	-1.0% *	-2.4%	-2.4%
Trace Elements 1mL/mL *	3.8% ***	0.0% *	-0.9% *	-1.9%	-1.9%
KPO4 3mMol/mL	-0.6% ***	-0.6% ***	-0.6% ***	N/A	N/A
Famotidine 10mg/mL	-0.5% ***	-0.5% ***	-0.5% ***	N/A	N/A
MVI 1mL/mL	4.2% ***	4.2% ***	4.2% ***	N/A	N/A
* Pool Component	** ACD *** Syringe	* Pool ** ACD *** Syringe	* Pool ** ACD *** Syringe		

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TPN Sample Order #2:

Patient Type:	Patient Weight	Infusion Rate	Infusion Period	Infusion Volume	Infusion Overfill	Final Volume	Pool Overfill	Batch Quantity
Adult	N/A	62.5 mL/Hour	24 Hours	1500 mL	75 mL	1575 mL	60 mL	7 Bags

Source Ingredient	Order	Per	Calculated Volume (mLs)	Deliverable Volume (mLs)	Calculated Volume with 75 mLs Overfill (mLs)	Deliverable Volume with 75 mLs Overfill Manual Adds (mLs)	Deliverable Volume with 75 mLs Overfill ACD Prepared Pool (mLs)	Deliverable Volume with 75 mLs Overfill Manually Prepared Pool (mLs)
Amino Acids 10%	70 Grams	Bag	700	700	735	735 **	735 **	735 **
Dextrose 70%	200 Grams	Bag	285.71	286	300	300 **	300 **	300 **
SWFI 1mL/mL	390.04 mL	Bag	390.04	390	409.54	410 **	410 **	410 **
Pool			N/A	N/A	N/A	N/A	116 **	116 **
NaCl 4mEq/mL *	90 mEq	Bag	22.5	23	23.63	24 ***	23.72 **	23.71 **
NaAc 2mEq/mL *	40 mEq	Bag	20	20	21	21 ***	21.06 **	21.05 **
KCl 2mEq/mL *	60 mEq	Bag	30	30	31.5	32 ***	31.59 **	31.57 **
KAc 2mEq/mL *	30 mEq	Bag	15	15	15.75	16 ***	15.73 **	15.72 **
CaGluc 0.465mEq/mL *	9.2 mEq	Bag	19.78	20	20.77	21 ***	20.79 **	20.78 **
MgSO4 4.06mEq/mL *	8 mEq	Bag	1.97	2	2.07	2.1 ***	2.07 **	2.13 **
Trace Elements 1mL/mL *	1 mL	Bag	1	1	1.05	1.1 ***	1.05 **	1.04 **
NaPO4 3mMol/mL	6 mMol	Bag	2	2	2.1	2.1 ***	2.1 ***	2.1 ***
Famotidine 10mg/mL	20 mg	Bag	2	2	2.1	2.1 ***	2.1 ***	2.1 ***
MVI 1mL/mL	10 mL	Bag	10	10	10.5	11 ***	11 ***	11 ***
	Total Volume		1500	1501	1575.01	1577.4	1576.21	1576.2
* Pool Component						** ACD *** Syringe	* Pool ** ACD *** Syringe	* Pool ** ACD *** Syringe

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TPN Sample Order #2 Pool Bag Volumes and SPGs:

Source Ingredient	ACD Prepared Pool		Manually Prepared Pool	
	Volume mLs	Weight Grams	Volume mLs	Weight Grams
NaCl 4mEq/mL *	178	204.878	178	204.878
NaAc 2mEq/mL *	158	170.640	158	170.640
KCl 2mEq/mL *	237	257.856	237	257.856
KAc 2mEq/mL *	118	128.856	118	128.856
CaGluc 0.465mEq/mL *	156	163.644	156	163.644
MgSO4 4.06mEq/mL *	15.5	18.941	16	19.552
Trace Elements 1mL/mL *	7.9	8.042	7.8	7.940
Total	870.4	952.857	870.8	953.366
	SPG	1.095	**SPG**	1.095

TPN Sample Order #2 Variance

Source Ingredient	Variance				
	ACD Bases Manual Syringe Ingredients	ACD Bases ACD Pool Manual Syringe Ingredients	ACD Bases Manual Pool Manual Syringe Ingredients	ACD Pool Using Generic 1.10 SPG for Pool	Manual Pool Using Generic 1.10 SPG for Pool
Amino Acids 10%	0.0%	0.0%	0.0%	N/A	N/A
Dextrose 70%	0.0%	0.0%	0.0%	N/A	N/A
SWFI 1mL/mL	0.1%	0.1%	0.1%	N/A	N/A
Pool	N/A	0.2%	0.2%	0.7%	0.7%
NaCl 4mEq/mL *	1.6%	0.4%	0.3%	0.8%	0.8%
NaAc 2mEq/mL *	0.0%	0.3%	0.2%	0.7%	0.7%
KCl 2mEq/mL *	1.6%	0.3%	0.2%	0.7%	0.7%
KAc 2mEq/mL *	1.6%	-0.1%	-0.2%	0.3%	0.3%
CaGluc 0.465mEq/mL *	1.1%	0.1%	0.0%	0.5%	0.5%
MgSO4 4.06mEq/mL *	1.4%	0.0%	2.9%	3.4%	3.4%
Trace Elements 1mL/mL *	4.8%	0.0%	-1.0%	-1.0%	-1.0%
NaPO4 3mMol/mL	0.0%	0.0%	0.0%	N/A	N/A
Famotidine 10mg/mL	0.0%	0.0%	0.0%	N/A	N/A
MVI 1mL/mL	4.8%	4.8%	4.8%	N/A	N/A
* Pool Component	** ACD *** Syringe	* Pool ** ACD *** Syringe	* Pool ** ACD *** Syringe		

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TPN Sample Order #3:

Patient Type:	Patient Weight	Infusion Rate	Infusion Period	Infusion Volume	Infusion Overfill	Final Volume	Pool Overfill	Batch Quantity
Adult	1.305	5 mL/Hour	24 Hours	120 mL	130 mL	250 mL	40 mL	7 Bags

Source Ingredient	Order	Per	Calculated Volume (mLs)	Deliverable Volume (mLs)	Calculated Volume with 130 mLs Overfill (mLs)	Deliverable Volume with 130 mLs Overfill Manual Adds (mLs)	Deliverable Volume with 130 mLs Overfill ACD Prepared Pool (mLs)	Deliverable Volume with 130 mLs Overfill Manually Prepared Pool (mLs)
Amino Acids 10%	2.5 Grams	kg	32.63	32.6	67.98	68 **	68 **	68 **
Dextrose 70%	14 %	Bag	24	24	50	50 **	50 **	50 **
SWFI 1mL/mL	46.29 mL	Bag	46.29	46.3	96.44	96.4 **	96.4 **	96.4 **
Pool			N/A	N/A	N/A	N/A	28.8 **	28.8 **
NaAc 2mEq/mL *	3 mEq	kg	1.96	2	4.08	4 ***	4.07 **	4.05 **
KCl 2mEq/mL *	3 mEq	kg	1.96	2	4.08	4 ***	4.07 **	4.05 **
KAc 2mEq/mL *	2 mEq	kg	1.31	1.3	2.73	2.7 ***	2.72 **	2.74 **
CaGluc 0.465mEq/mL *	32 mEq	L	8.26	8.2	17.21	17 ***	17.22 **	17.26 **
MgSO4 4.06mEq/mL *	0.25 mEq	kg	0.08	0.08	0.17	0.17 ***	0.17 **	0.17 **
Trace Elements 1mL/mL *	0.2 mL	kg	0.26	0.26	0.54	0.54 ***	0.54 **	0.55 **
KPO4 3mMol/mL	16 mMol	L	0.64	0.64	1.33	1.3 ***	1.3 ***	1.3 ***
MVI 1mL/mL	2 mL	kg	2.61	2.6	5.44	5.4 ***	5.4 ***	5.4 ***
	Total Volume		120	119.98	250	249.51	249.89	249.92
* Pool Component						** ACD *** Syringe	* Pool ** ACD *** Syringe	* Pool ** ACD *** Syringe

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TPN Sample Order #3 Pool Bag Volumes and SPGs:

Source Ingredient	ACD Prepared Pool		Manually Prepared Pool	
	Volume mLs	Weight Grams	Volume mLs	Weight Grams
NaAc 2mEq/mL *	34.3	37.044	34	36.720
KCl 2mEq/mL *	34.3	37.138	34	36.992
KAc 2mEq/mL *	22.9	25.007	23	25.116
CaGluc 0.465mEq/mL *	145	152.105	145	152.105
MgSO4 4.06mEq/mL *	1.4	1.711	1.4	1.711
Trace Elements 1mL/mL *	4.55	4.632	4.6	4.683
Total	242.45	257.817	242	257.327
	SPG	1.063	**SPG**	1.063

TPN Sample Order #3 Variance

	Variance				
Source Ingredient	ACD Bases Manual Syringe Ingredients	ACD Bases ACD Pool Manual Syringe Ingredients	ACD Bases Manual Pool Manual Syringe Ingredients	ACD Pool Using Generic 1.10 SPG for Pool	Manual Pool Using Generic 1.10 SPG for Pool
Amino Acids 10%	0.0%	0.0%	0.0%	N/A	N/A
Dextrose 70%	0.0%	0.0%	0.0%	N/A	N/A
SWFI 1mL/mL	0.0%	0.0%	0.0%	N/A	N/A
Pool	N/A	N/A	0.0%	3.3%	3.3%
NaAc 2mEq/mL *	-2.0%	-0.2%	-0.7%	2.7%	2.7%
KCl 2mEq/mL *	-2.0%	-0.2%	-0.7%	2.7%	2.7%
KAc 2mEq/mL *	-1.1%	-0.4%	0.4%	4.0%	4.0%
CaGluc 0.465mEq/mL *	-1.2%	0.1%	0.3%	3.8%	3.8%
MgSO4 4.06mEq/mL *	0.0%	0.0%	0.0%	5.9%	5.9%
Trace Elements 1mL/mL *	0.0%	0.0%	1.9%	5.6%	5.6%
KPO4 3mMol/mL	-2.3%	-2.3%	-2.3%	N/A	N/A
MVI 1mL/mL	-0.7%	-0.7%	-0.7%	N/A	N/A
* Pool Component	** ACD *** Syringe	* Pool ** ACD *** Syringe	* Pool ** ACD *** Syringe		

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TPN Sample Order #4:

Patient Type:	Patient Weight	Infusion Rate	Infusion Period	Infusion Volume	Infusion Overfill	Final Volume	Pool Overfill	Batch Quantity
Pediatric	27.7	60 mL/Hour	24 Hours	1440 mL	100 mL	1540 mL	50 mL	7 Bags

Source Ingredient	Order	Per	Calculated Volume (mLs)	Deliverable Volume (mLs)	Calculated Volume with 100 mLs Overfill (mLs)	Deliverable Volume with 100 mLs Overfill Manual Adds (mLs)	Deliverable Volume with 100 mLs Overfill ACD Prepared Pool (mLs)	Deliverable Volume with 100 mLs Overfill Manually Prepared Pool (mLs)
Amino Acids 10%	2.7 Grams	kg	747.9	748	799.84	800 **	800 **	800 **
Dextrose 70%	16 %	Bag	329.14	329	352	352 **	352 **	352 **
SWFI 1mL/mL	133.25 mL	Bag	133.25	133	142.5	143 **	143 **	143 **
Pool			N/A	N/A	N/A	N/A	233 **	233 **
NaAc 2mEq/mL *	9 mEq	kg	124.65	125	133.31	133 ***	133.13 **	133.1 **
KAc 2mEq/mL *	2.15 mEq	kg	29.78	30	31.85	32 ***	31.83 **	31.82 **
CaGluc 0.465mEq/mL *	1 mEq	kg	59.57	60	63.71	64 ***	63.66 **	63.65 **
MgSO4 4.06mEq/mL *	0.6 mEq	kg	4.09	4	4.37	4.4 ***	4.37 **	4.43 **
KPO4 3mMol/mL	0.5 mMol	kg	4.62	4.6	4.94	5 ***	5 ***	5 ***
Famotidine 10mg/mL	20 mg	Bag	2	2	2.14	2.1 ***	2.1 ***	2.1 ***
MVI 1mL/mL	5 mL	Bag	5	5	5.35	5.4 ***	5.4 ***	5.4 ***
	Total Volume		1440	1440.6	1540.01	1540.9	1540.49	1540.5
* Pool Component						** ACD *** Syringe	* Pool ** ACD *** Syringe	* Pool ** ACD *** Syringe

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TPN Sample Order #4 Pool Bag Volumes and SPGs:

Source Ingredient	ACD Prepared Pool		Manually Prepared Pool	
	Volume mLs	Weight Grams	Volume mLs	Weight Grams
NaAc 2mEq/mL *	962	1038.960	962	1038.960
KAc 2mEq/mL *	230	251.160	230	251.160
CaGluc 0.465mEq/mL *	460	482.540	460	482.540
MgSO4 4.06mEq/mL *	31.6	38.615	32	39.104
Total	1683.6	1811.275	1684	1811.764
	SPG	1.076	**SPG**	1.076

TPN Sample Order #4 Variance

Source Ingredient	Variance				
	ACD Bases Manual Syringe Ingredients	ACD Bases ACD Pool Manual Syringe Ingredients	ACD Bases Manual Pool Manual Syringe Ingredients	ACD Pool Using Generic 1.10 SPG for Pool	Manual Pool Using Generic 1.10 SPG for Pool
Amino Acids 10%	0.0%	0.0%	0.0%	N/A	N/A
Dextrose 70%	0.0%	0.0%	0.0%	N/A	N/A
SWFI 1mL/mL	0.4%	0.4%	0.4%	N/A	N/A
Pool	N/A	-0.1%	-0.1%	2.1%	2.1%
NaAc 2mEq/mL *	-0.2%	-0.1%	-0.2%	2.1%	2.1%
KAc 2mEq/mL *	0.5%	-0.1%	-0.1%	2.1%	2.1%
CaGluc 0.465mEq/mL *	0.5%	-0.1%	-0.1%	2.1%	2.1%
MgSO4 4.06mEq/mL *	0.7%	0.0%	1.4%	3.7%	3.7%
KPO4 3mMol/mL	1.2%	1.2%	1.2%	N/A	N/A
Famotidine 10mg/mL	-1.9%	-1.9%	-1.9%	N/A	N/A
MVI 1mL/mL	0.9%	0.9%	0.9%	N/A	N/A
* Pool Component	** ACD *** Syringe	* Pool ** ACD *** Syringe	* Pool ** ACD *** Syringe		

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Summary:

Careful consideration must be given when determining the ingredients to be included in the micro-ingredient pooling container of a TPN dose especially when the pooling container is to be hung on the Pinnacle® Compounder. The compatibility and stability (physical & chemical) of all the ingredients to be delivered by the ACD into the final TPN dose must be considered.

As stated, Calcium and Phosphate salts are mutually exclusive on the Pinnacle® Compounder. If Calcium products are hung on the Pinnacle® Compounder, Phosphate salts must NOT be hung on the Compounder and only added after the last base solution has been incorporated. The TPN should then be gently agitated to disperse the Calcium in the TPN dose to assure the proper mixing.

When converting to the Pinnacle® Compounding System, consideration must be given to all previous methods used to prepare TPNs. This is especially important when a "generic" SPG has been assigned to the pool container (bag), ingredient volume has not been included in the TPN volume, and other methods have been utilized to add the Phosphate salts. The Pinnacle® Compounding System will calculate and deliver the exact amounts ordered. Therefore, it should be noted that a patient moving from one method of preparation to another can have some swings in their clinical lab values. These deviations must be assessed and addressed by the clinicians responsible for the patient's care. Understanding exactly how and why your ACD is set-up, as well as assuring that it is consistently operated correctly, may give you a deeper understating into these occasional swings in laboratory values. It may not be that your ACD is inaccurate, but rather how previous calculations were utilized, and the compounding methods employed by your previous ACD delivering the final dose.

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[i] IS0 7886-1 - sterile hypodermic syringes for single use, IS0 7886-2 - sterile hypodermic syringes for single use in pumps and IS0 594-1 & 2 -conical fittings with 6% luer taper for syringes