QUALIFICATION OF A VOLUMETRIC AUTOMATED COMPOUNDING DEVICE TO OPTIMIZE THE PRODUCTION OF PARENTERAL NUTRITION BAGS.

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INTRODUCTION

Each year, the East group Hospital Pharmacy of Hospices Civils de Lyon produces more than **22,500 parenteral nutrition admixtures for home patients**. To guarantee the efficiency of such a production, a continuous optimization of manufacturing processes is necessary. To date, about two thirds of these bags are prepared using a volumetric automated compounding device (BAXA EM2400®). Electrolytes solutions are delivered using Baxter micro-volume tubing. In this context, we propose to evaluate the impact of increasing the tubing diameters on the accuracy of the analytical controls and secondarily, on the manufacturing time of parenteral nutrition bags.

Materials and Methods

Four "micro-volume" (ref.175) tubing connecting the electrolytes solutions (NaCl 20%, KCl 10%, sodium lactate 11.2% and magnesium sulfate 10%) were replaced by "high-volume" tubing (ref. 174).

An **operational qualification** was first carried out in two stages

- Determination of each electrolytes flow factors in the new configuration;
- Validation of the analytical controls on three series of six bags.

The compounder's **performance qualification** was then conducted on seven bags with "high volume" electrolytes and seven bags with "low volume" electrolytes.

The "micro-volume" configuration has been used as a reference method for these qualifications.

RESULTS

OPERATIONNAL QUALIFICATION → **PERFORMANCE QUALIFICATION**

1 — Determination of each electrolytes flow factors

A corrective index specific to "macro volumes" and to each electrolyte was calculated by an iterative method.

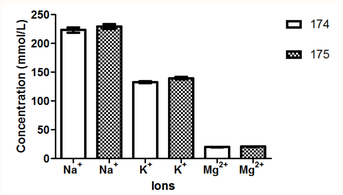
For each electrolyte, a mass of liquid was measured so as to correspond as closely as possible to the volume pumped by automated compounding device,. For each measure the value of the flow factor was adjusted.

The parameterization of this factor guarantees the accuracy of the volumes pumped during the manufacture of the bags.

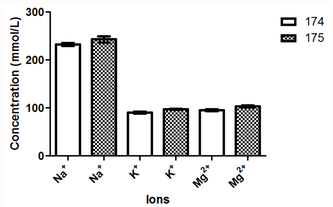
	Flow factors			
Pump speed	Na^+	K^+	Lactates	Mg^{2+}
240	1	0,99	1	0,9825
150	0,975	0,975	1	1
51	1,038	0,94	1,038	0,985

2 — Analytical validation on 3 sets of 6 electrolyte's bags

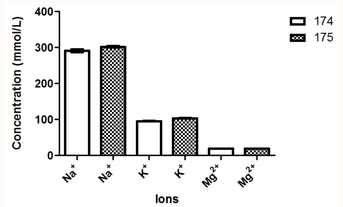
Low volumes of electrolytes (n=6)



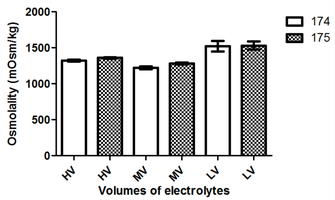
Medium volumes of electrolytes (n=6)



High volumes of electrolytes (n=6)

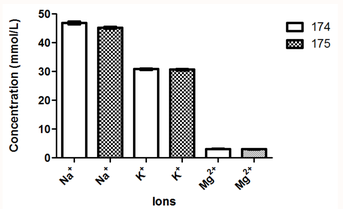


Osmolality

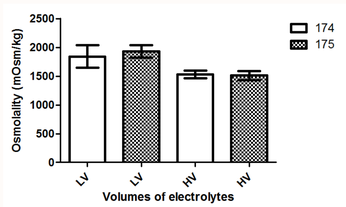


3 — Analytical validation on 2 sets of 7 "real bags"

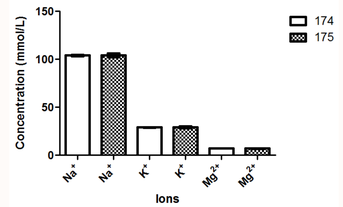
Bags with low volume of electrolytes (n=7)



Osmolality

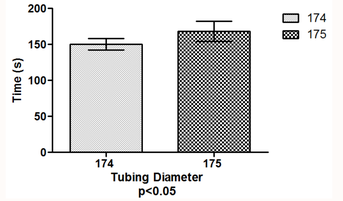


Bags with high volume of electrolytes (n=7)

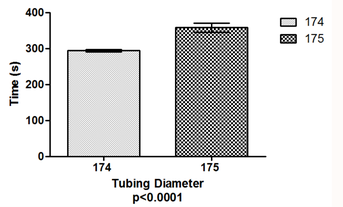


4 — Evaluation of production times

Bags with low volume of electrolytes (n=7)



Bags with high volume of electrolytes (n=7)



All electrolytic assays and osmolality measurements validate both types of qualification and are **as accurate as those found with the reference configuration**. In addition, the configuration change allows significant machine time savings in real conditions of use: on average, **18 seconds per bag of "small volume of electrolytes" (p <0.05) and 64 seconds per bag of "large volume electrolytes "(p <0.0001).**

CONCLUSION

This work validates a new, more efficient configuration and is in favor of its implementation in our manufacturing process. In the absence of regulations or specific recommendations regarding the qualification of volumetric automated compounding devices, this study constitutes a basis for future optimization studies.