NxSTAGE PUREFLOW SL CONDUCTIVITY TESTING

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INTRODUCTION

Safe and reliable conductivity testing is vital to hemodialysis treatment and helps prevent hemolysis. NxStage Pure Flow SL will perform conductivity testing prior to the use of each new batch of dialysate. If the parameter of 12.8 + 0.4 for Lactate dialysate is met, the machine will allow treatment to commence. If the parameter is not met, the machine will not allow treatment and drain the dialysate.

The purpose of this study is to demonstrate that conductivity obtained by the NxStage Pure Flow SL is equivalent to than obtained by manual testing for DaVita at Home patients.

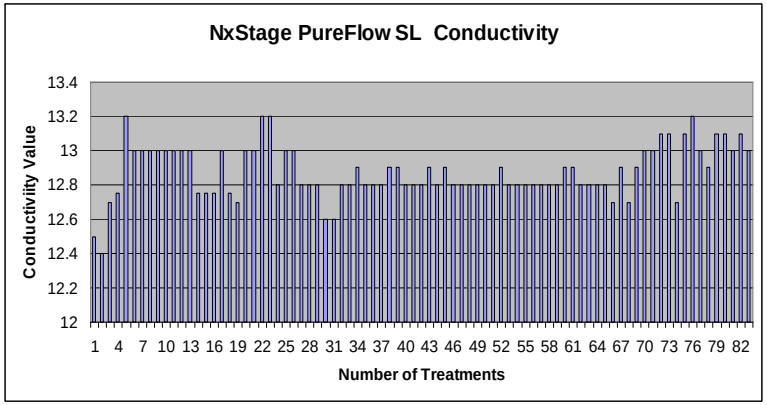
HYPOTHESIS

NxStage PureFlow SL will internally measure conductivity with each new batch of dialysate mixed. If the conductivity falls within stated parameters, the system will allow continuation of treatment. If the parameter is not met, the system requires a drain of the dialysate. There is no specific documentation numerically of the measurement provided to the care giver. This is an automatic recording with only pass or failed reading.

The hypotheses is that the NxStage PureFlow system accurately measures conductivity and maintains accuracy within +/- 0.2 mS/cm as stated in the PureFlow Users Guide. Also stated in the NxStage PureFlow Users Guide is the alarm point is +/- 5% of nominal value of formulation.

METHODS

As shown, each DaVita at Home patient was provided with the Myon L D meter and conductivity standard solution. The patient and partner were instructed regarding use of this equipment and standard solution, the hazards of performing dialysis with improper conductivity (such as hemolysis) and the proper documentation necessary to indicate performance of this testing. They were also required to perform return demonstrations regarding this training. The nursing staff monitored the results closely and maintained communication with the patients during this testing period. The testing period lasted 14 weeks with 4 patient participants.



RESULTS

There were 82 total results recorded (Figure). Of these, 2 were recorded less 12.6 mS/cm (12.4 mS/cm and 12.5 mS/cm, respectively) and 10 were recorded greater than 13.0 mS/cm (4 recordings at 13.2 mS/cm and 6 recording at 13.1 mS/cm). These measures were within 5% of the lower and upper limits of nominal conductivity. Accordingly, in each event no PureFlow system alarm was generated, and treatment was initiated.

CONCLUSIONS

- The results demonstrated that the NxStage PureFlow SL system, compared to the manual Myron L D meter, measures conductivity accurately.
- There were events of conductivity recorded beyond the variation of +/- 0.2mS/cm but these results did not produce failure alarm for conductivity.
- This study successfully proved the hypothesis showing that Home patients safely dialyzed using NxStage SL without using a manual meter.

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