

Human Factors Testing of the Quanta SC+ Hemodialysis System: An Innovative System for Home and Clinic Use



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INTRODUCTION & STUDY AIMS

- Despite being a less costly treatment, with potential quality of life and several key clinical parameter improvements, uptake rates of HHD are the lowest amongst all modality types.
- The Quanta SC+ Hemodialysis System was developed for home or facility use to provide patients with a system that is compact and simple to use, yet powerful enough to deliver acceptable dialysis adequacy by providing traditional high-flux, bicarbonate-based dialysis on a flexible schedule for patients.
- **The aim of this study was to assess safety and ease of use of SC+ with intended users.**

METHODS

- Human Factors Testing (HFT) involved a series of three, 2-hour training sessions for the Home Users and one 4.5-hour training session for the Healthcare Professionals.
- After the training sessions, there was a period of 3-9 days of training decay for the Home Users and 1-12 days with the Healthcare Professionals before the evaluation session was held, in a simulated home environment.
- During the evaluation session, each participant was observed and then scored according to the pre-specified criteria.
- A detailed study protocol was used to critically evaluate each participant in a standardized manner.

PARTICIPANT CHARACTERISTICS

Healthcare Professionals (n=17)

Renal Nurses (n=13)
Healthcare Assistants (n=4)

Mean Age 42.5 years (25-52)

Sex (% Females) 70.6%

Mean number of years of dialysis experience 9.6 years (1-19)

Home Users (n=15)

Caregivers (n=7)
Patients (n=8)

Mean Age 43.7 years old (19-76)

Sex (% Females) 46.7%

Mean number of years of dialysis experience 4.65 years (2 m-19 y)

SC+ BEFORE AND AFTER

Human Factors Testing influenced machine redesign



Pre HFT system

Post HFT system

RESULTS – SUMMARY OF RECORDED ERRORS FOR ALL 32 PARTICIPANTS (1,216 OPPORTUNITIES FOR ERROR)

	Close Call	Use Error
Task 1 – Turning on SC+	0	0
Tasks 2-4 – Selecting dialyses mode	0	0
Tasks 5-6 – Assembling consumables	0	0
Tasks 7-9 – Loading the blood line	1	2
Tasks 10-17 – Loading dialysate lines	0	2
Tasks 18-20 – Priming	0	0
Tasks 21-23 – Connecting the Patient	0	4
Task 24 – Starting treatment	0	0
Task 25 – Responding to low arterial pressure alarm	0	0
Task 26 – Responding to high venous pressure alarm	0	1
Task 27 – Responding to the air in the blood alarm	0	9
Tasks 28-31 – Ending treatment	0	3
Task 32 – Disposing of consumables	0	0
Task 33 – Manual washback	0	4
Tasks 34-38 – Comprehension of the instructions manual	0	3
Total	1	28

DISCUSSION

- Only 29 errors were observed in 1,216 opportunities for errors despite minimal training of healthcare professionals and patients.
- Errors that did occur were minor and attributed to initial lack of familiarity with the device overall.
- No use errors were linked to potential safety issues for patients.
- Issues highlighted in this study led to usability improvements for the SC+, including updates to the graphic user interface, improved colour coding of the consumables and clamps, better alarm handling and improvements to IFU and training documentation

CONCLUSIONS

- The SC+ Hemodialysis System is easy to use even with minimal training and a training decay period.
- A high-level of use safety will likely be achieved implementing this system, resulting in an optimal user experience.
- By taking human factors into consideration the design of SC+ will help to address systemic and patient barriers to wider HHD adoption.

LIMITATIONS

Cross-sectional observational study design; however, longitudinally clinical testing is ongoing.

DISCLOSURES

This study was funded by Quanta Dialysis Technologies Ltd.