HUMAN FACTORS TESTING OF THE QUANTA SC+ HAEMODIALYSIS SYSTEM: DEMONSTRATING EASE OF USE IN HEALTHCARE PRACTITIONERS AND PATIENTS WITH MINIMAL UPFRONT TRAINING

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Background

- Quanta Dialysis Technologies has developed SC+, a small, simple-to-use and versatile haemodialysis system designed for home and facility-based use. Following appropriate training, SC+ is intended for use by qualified healthcare professionals (HCPs) and patients/caregivers (lay users).
- The primary purpose of the human factors engineering (HFE) process is to determine how users interact with medical devices and how those interactions can be influenced by the user interface. The HFE process is designed to identify, reduce or eliminate design-related problems and to evaluate safe, effective use by intended users in intended use environments.

Hypothesis

- It is hypothesised that the SC+ haemodialysis system is simple, safe and easy-to-use for both HCP and lay users.

Method

- The HF validation study protocol was developed from FDA guidance (2016) and IEC 62366-1:2015 and consisted of four main phases: training, competency sign off, training decay and validation testing.
- User groups from both the United States and United Kingdom were trained and evaluated in their intended use environments; HCPs in a simulated clinical setting and lay users in a simulated home setting.
- Qualified nurse trainers structured and conducted participant training, representative of real-world use and a competency sign off was completed before validation testing.
- 15 HCPs were trained either individually or in pairs for 2 x 2-hour training sessions with a learning decay period of at least 23 hours separating each session.
- 10 lay users were trained individually for 3 x 3-hour training sessions and had an increased learning decay period of 24–48 hours between training sessions.
- Following sign off, participants were tested individually by a HF study moderator in use scenarios as defined by the approved validation protocol (Table 2). Each task completed by the participant was either recorded as a success, success with difficulty, close call, or use error.
- All use-errors were assessed for significance and safety.

Discussion

- Across all participants, the protocol defined a total of 8,100 opportunities for use error to occur.
- Despite minimal training and representative learning decay, only 180 use errors (2.2%) were observed and the vast majority of these were either test artefacts, non-safety related, or could not be mitigated further.
- Of the 180 use errors, only 4 were deemed significant and resulted in a User Manual update to enhance the readability and salience of warning and caution statements.
- Although the training structure was tailored for each user group based on real-world expectations, none of the 10 lay users required the full 9 hours of training to successfully pass competency sign off. The training time average for lay users was 6 hours 15 minutes, with the shortest training time recorded as 5 hours 20 minutes.
- Following training, 2 of the 15 HCPs required one additional training session to complete competency sign off, and both subsequently passed. The training time average for HCPs was 4 hours 16 minutes.

Results

- *Table 1* details the participant demographic (n=25) that made up the two user groups; HCPs and lay users.
- *Table 2* summarises the assessed use scenarios.
- All 25 participants completed 16 core use scenarios (2–8 and 10–18) as part of SC+ operation, alarm management, external cleaning and User Manual comprehension.
- The HCP user group also covered 2 additional use scenarios (1 and 9) to cover specific user tasks, not for lay user operation.
- Across the 18 use scenarios, HCPs and lay users were individually tested in 334 sub-steps and 309 sub-steps, respectively. This cumulated 8,100 opportunities for possible use error.
- *Chart 1* summarises the breakdown of use events captured during HF validation testing.
- There were a total of 180 use errors observed across both user groups; 153 use errors (1.9%) and 27 close calls (0.3%). 188 sub-tasks were 'not performed' due to a previous use error being committed which impacted later steps.

Healthcare Professionals *(n = 15)*	
Renal Nurses	6
Healthcare Assistants/Dialysis Techs	9
Mean Age	43y (25y – 61y)
Sex (% females)	73.3%
Mean number of years of dialysis experience	13.7y (1y – 36y)
Mean total training length for successful competency sign off	4hr 16min (4hr - 6hr)
Lay Users (n = 10)	
Patients	8
Caregivers	2
Mean Age	43y (20y - 63y)
Sex (% females)	30%
Mean number of years of dialysis experience	3.5y (7mo - 12y)
Mean total training length for successful competency sign off	6hr 15mins (5hr 20min - 7hr 20min)

Table 1: Participant Demographic

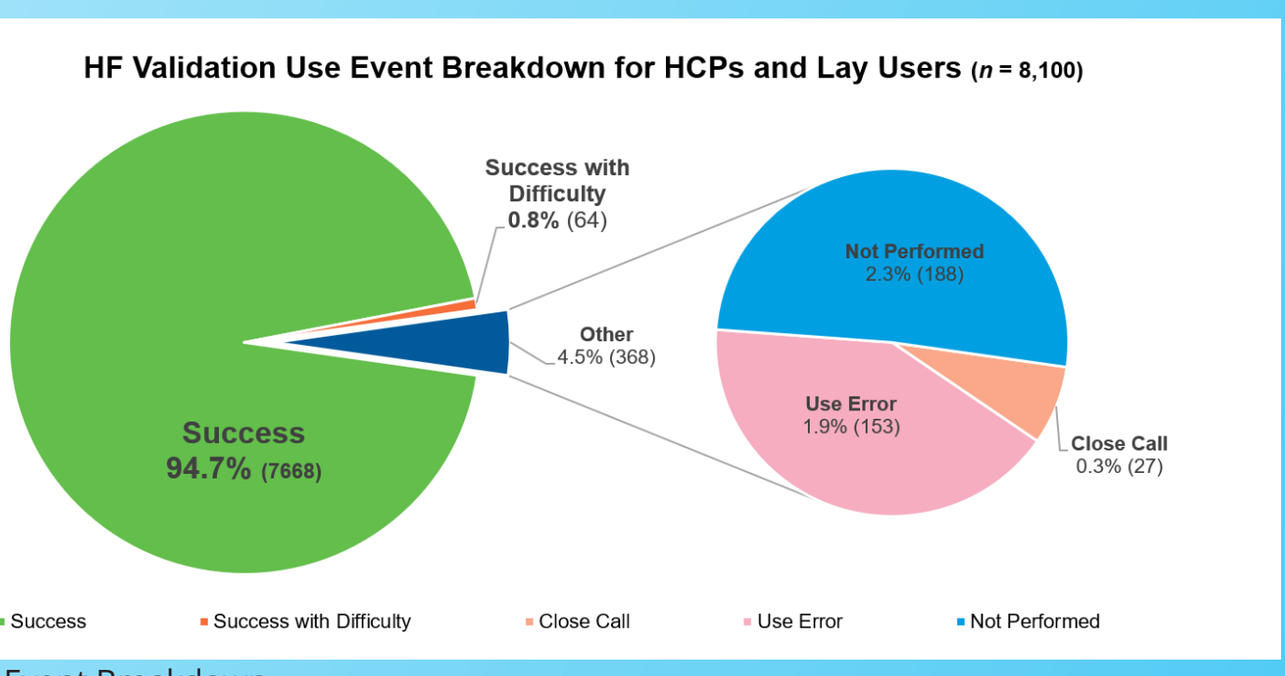

Chart 1: Use Event Breakdown

SC+ Use Scenario	Success	Success with Difficulty	Close Call	Use Error	Not Performed
1. Super User Settings (HCP only)	91.1%	0%	0%	8.8%	0%
2. Enter Treatment Settings	97.8%	0.6%	0.2%	1%	0.4%
3. Load Dialysate Cartridge	96.9%	1%	0%	1.9%	0.2%
4. Load Blood Tube Set	96.4%	1.3%	0.8%	1.4%	0.1%
5. Priming	96.9%	1.1%	0.3%	1.1%	0.6%
6. Patient Connect	91.3%	0.2%	0.3%	2.2%	6%
7. Changing Treatment Settings	96.4%	1.6%	0.4%	1.6%	0%
8. Manual Washback	94.0%	0.2%	0.2%	2.1%	3.5%
9. Prime Out (HCP only)	95.1%	0%	0%	0.4%	4.5%
10. Blood Pump Pressure High	92.9%	0.3%	0.3%	2.2%	4.3%
11. Air in Blood	91.7%	0.1%	0.4%	2.4%	5.4%
12. Dialyser/Drain Obstructed	94.0%	0.7%	1.3%	0.7%	3.3%
13. UF Paused	93.3%	1.3%	0.7%	2.0%	2.7%
14. Arterial Pressure Low	80.2%	0.6%	0.6%	3.7%	14.9%
15. Automatic Washback	96.3%	0.9%	0.6%	1.3%	0.9%
16. External Cleaning	92.8%	2.2%	0%	4.8%	0.2%
17. Hot Rinse	99.5%	0.5%	0%	0%	0%
18. Warnings and Caution Comprehension (User Manual)	98.5%	0.9%*	0%	0.7%*	0%

Table 2: Assessed Use Scenarios
* Subsequently addressed with User Manual updates

Conclusion

- The results of the HF testing demonstrate that HCPs and lay users successfully operated SC+ independently with a high level of use safety, despite minimal training and learning decay. The SC+ user interface is optimised for safe and effective use in accordance with FDA guidance and EU standards.

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SC+ is not yet FDA cleared and not yet available for sale in the USA

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