SC+ HAEMODIALYSIS SYSTEM: A NOVEL OPTIMISED APPROACH TO FLOW BALANCE AND FLUID REMOVAL DURING HAEMODIALYSIS

Clive Buckberry[1], Paul Komenda[1,2], Nicholas Hoenich[3], Mark Wallace[1], David Bond[1], John E. Milad[1]
[1]Quanta Dialysis Technologies Limited, Alcester, United Kingdom; [2]University of Manitoba, Winnipeg, Manitoba, Canada, [3]Newcastle University, Newcastle upon Tyne, United Kingdom

Background

- Accurate net fluid removal (NFR) to the patient's prescribed dry weight is a critical element in providing safe and effective haemodialysis. Too little NFR leaves patients overloaded with fluid and too much can result in serious risk of hypotension and cramping.
- The SC+ haemodialysis system, manufactured by Quanta Dialysis Technologies (*Figure 1*), is a small, simple-to-use and versatile device designed to improve patient access to home and facility-based haemodialysis.
- As dialyser designs have evolved, with an increasing range of UF coefficients (KuF) available to the clinician, it has become more important for dialysis machines to minimise errors in flow balance and NFR.
- Technical standards for haemodialysis machines define limits for the NFR error with and without UF as either 100 mL/hr or 400 mL/treatment irrespective of the treatment duration. However, this technical standard still leaves room for patient harm should they not hit their prescribed dry weight on a consistent basis.
- This poster describes the design, evaluation and performance of the flow balance and ultrafiltration (UF) module of SC+ to deliver clinically specified fluid removal across all conditions.

Figure 1: SC+ Haemodialysis System

Hypothesis

- It is hypothesised that the use of active system control and adaptive pumping will allow the fluid removal error to be minimised across a wider dynamic range of conditions likely to be encountered in the clinical setting.

Method

- The dialysate cartridge (*Figure 2*) has a number of passive and active design features to control flow and compliance within the pump system.
- A spectrum of tests to verify the performance of the SC+ haemodialysis system was conducted under a combination of the following conditions:
  - Dialyser KuF of 21 and 102 mmHg
  - Venous pressures of 50 and 250 mmHg
  - Dialysate flow rate of 300 and 500 mL/min
  - Room temperature of 15ºC and 32ºC (59ºF and 89.6ºF)
  - Atmospheric pressure of 800 and 1050 mbar
- Measurements of NFR error were made at different points over 4-hour treatments with samples taken at 30-minute intervals.

Results

- Results are plotted on *Figure 3.*
- The limits of each axis are set as defined in IEC 60601-2-16 (technical standard for haemodialysis machines at 100 mL/hr).
- A 3 sigma envelope is drawn and displayed around the results centred on the average and standard deviation.

	Average Error (mL/hr)	Standard Deviation (mL/hr)
NFR error without UF (flow balance)	1	19
NFR error with UF	13	20

Table 1: Net Fluid Removal Errors

- Over all the conditions described above, the NFR errors were as recorded in Table 1.

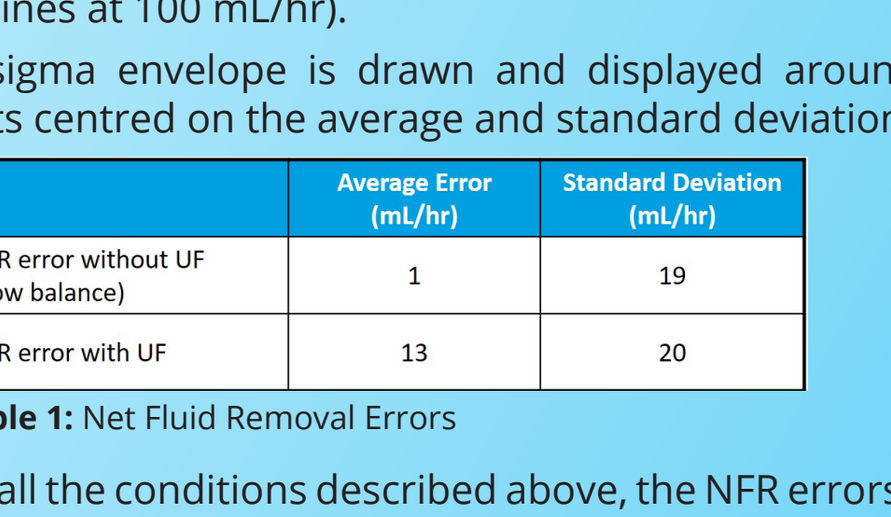

Figure 3: Net Fluid Removal Error Results

Discussion

- The results show that the NFR error is stable across a wide range of clinically relevant conditions.
- A 3 sigma envelope shows that 99.7% of all results will lie within acceptable limits with a further allowance of 1 sigma for any unexpected process variance in manufacture.
- The variation that does exist is partly explained by nominal variations in the dialyser used with each test

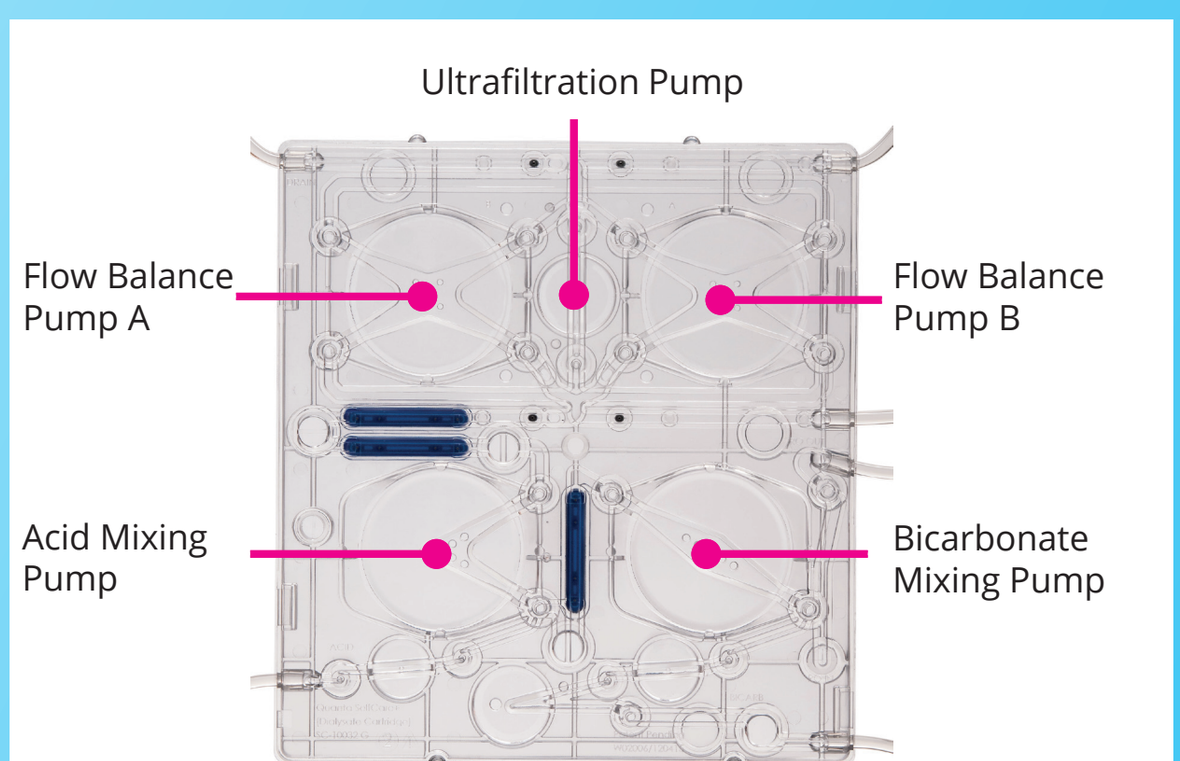

Figure 2 (a): SC+ Dialysate Cartridge

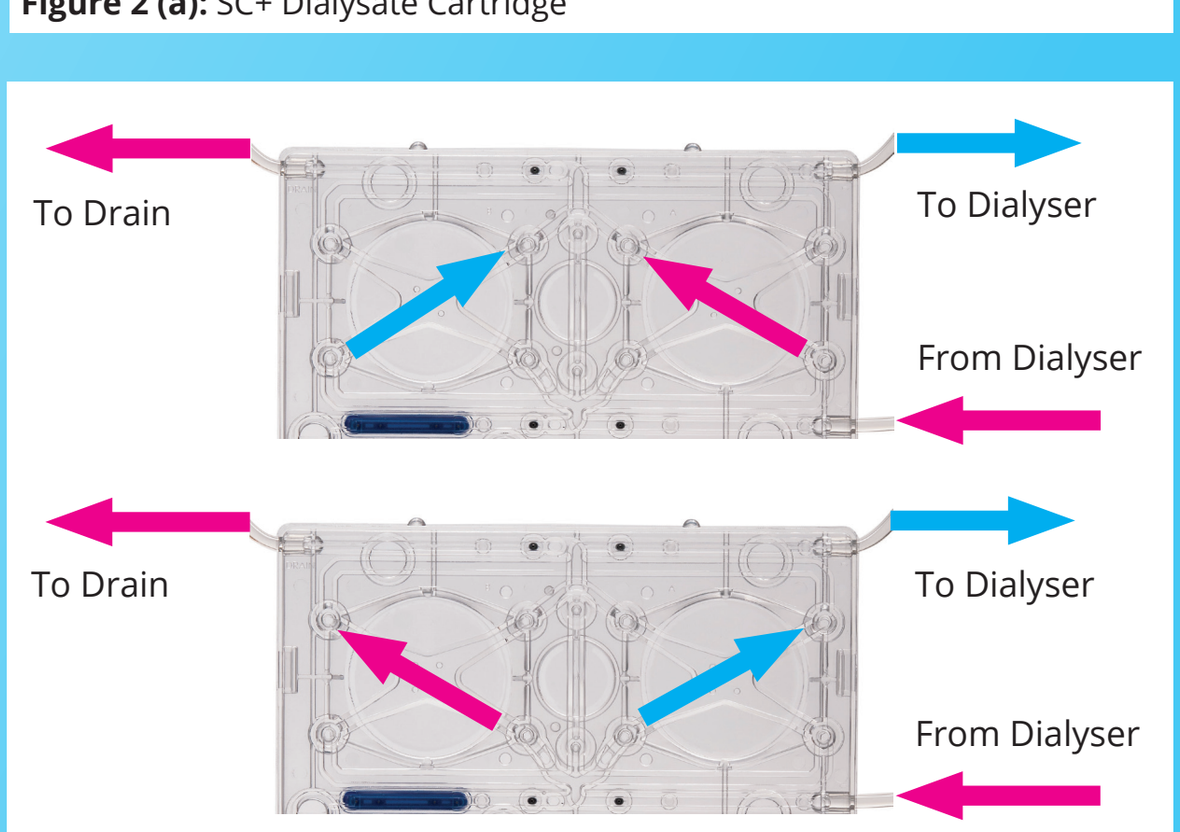

Figure 2 (b): Alternating Flow Path Through SC+ Dialysate Cartridge

Conclusion

- It has been demonstrated that SC+ is able to maintain highly accurate fluid management well within the limits required by technical standards under a range of clinically relevant parameters and patient safety limits.
- Additional prototype development is planned to extend the performance envelope further at flow rates up to 750 mL/min and for 12 hours' continuous operation.

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Email: enquiries@quantadt.com Tel: +44 (0) 1789 400 043

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