



Quanta Begins Study in US to support FDA Submission

Alcester, Warwickshire, UK, 7 August 2019: Quanta Dialysis Technologies Ltd (“Quanta” or the “Company”), a British medical technology company developing a personal haemodialysis system (SC+) for patient use in the clinic and the home, today announces that it has begun human factors testing of SC+ in the United States with Design Science, a leading specialist in medical device usability.

Human factors testing (HFT) is used to assess how intended users interact with a medical device in representative real-world conditions. The HFT study will be conducted in the US with end users representing a diverse range of age and ethnicity of the adult US population, to evaluate the safety and effective use of Quanta’s updated SC+ system. This represents an important step towards Quanta’s 510(k) submission to the FDA planned for later this year and, ultimately, US market entry.

From the beginning, SC+ has been designed with ease-of-use and patient safety as core attributes. Quanta has systematically applied state-of-the-art human factors engineering principles to develop a device that is simple and intuitive to operate, with the objective of empowering more patients to take control of their lives through self-care and home haemodialysis.

This study builds on earlier human factors testing conducted in the UK, as reported in Quanta’s previously published human factors paper in Hemodialysis International (click [here](#)).

John E. Milad, Chief Executive Officer of Quanta, said: *“We are delighted to be working with world-leading experts at Design Science on this important study that will help us bring SC+ to American patients and healthcare professionals. Results from this study will form an important part of our FDA submission strategy. Meanwhile, following the recently announced American Kidney Health Initiative, there has never been a stronger imperative for Quanta to bring SC+ to the US.”*

Katie Hansbro, Chief Executive Officer of Design Science, said: *“When we design usability studies during which users get to interact with novel medical technology, we are able to see first-hand how patients become excited by products with the potential to drastically improve their care experience. In all our work, we seek to amplify users’ needs to cultivate advancements in healthcare technology—and evaluating novel systems for companies like Quanta enables us to do that.”*

-ENDS-

For more information about Quanta, please contact:

Quanta

John E. Milad,
Chief Executive Officer

T: +44 (0)1789 400043
E: enquiries@quantadt.com

Consilium Strategic Communications

Amber Fennell / Matthew Neal / Lindsey Neville

T: +44 (0)203 709 5708
E: quanta@consilium-comms.com

About SC+

SC+ is a small, simple and powerful haemodialysis system designed to provide greater flexibility around where, when and how patients manage and receive their dialysis therapy. As a CE marked medical device, SC+ has been successfully piloted with the NHS, demonstrating clinical efficacy and performance compatible with traditional treatment regimens used in-centre. The innovative and patented technology behind SC+ is based on a design breakthrough that allows dialysate fluid management to be conducted on a small, lightweight, disposable cartridge. The small form factor and simple-to-use design of SC+ are intended to enable a broader range of users—including patients themselves—to manage dialysis therapy delivery across a wide range of settings—from the clinic to the home. Quanta will be launching SC+ in the UK later this year into a market that is increasingly seeking solutions to support patient self-care and home dialysis.

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

About Quanta

Quanta's mission is to improve the lives of dialysis patients through innovation. Quanta's lead product SC+ is designed to provide dialysis patients with greater choice, efficiency and empowerment in the delivery of their life-sustaining dialysis therapy. Quanta was founded in 2008 and is based in Alcester, UK.

For more information, please visit: www.quantadt.com.

About Design Science

Founded in 1991, Design Science was one of the first consultancies to focus on the person/product interface. Design Science has deep roots in those product categories where usability is mission critical. Although we have experience in commercial, industrial, and consumer products, we specialize in medical devices—cultivating a thorough understanding of the unique challenges associated with this domain. We conduct rigorous research through usability studies and field research (particularly contextual inquiry), developing a rich understanding of user needs and use-related hazards. In addition, we blend our in-house design, video, and human factors expertise to create instructional videos and user interfaces that optimize product usability. Design Science is based in Philadelphia, USA.

For more information, please visit: www.dscience.com.