



## Tablo® Hemodialysis System Receives FDA Clearance for Home Dialysis

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First new device cleared for home hemodialysis in 15 years

Hospital.  
Clinic.  
Home.



SAN JOSE, Calif.-(BUSINESS WIRE)- Outset Medical, a leading med tech innovator delivering first-of-its-kind technology into the growing global dialysis market, today announced the Food and Drug Administration (FDA) cleared the Tablo Hemodialysis System for patient use in the home. The new home clearance expands Tablo's existing labeled indication for use in acute and chronic care facilities, which for the first time enables healthcare providers the same dialysis machine from the ICU to the home.

Tablo enters the market at a critical time in the midst of the COVID-19 pandemic and renewed national focus on home dialysis for improving patient outcomes while lowering cost. In mid-2019, President Trump and United States Department of Health and Human Services Secretary Alex Azar announced an Executive Order to help Americans with kidney failure. A major component of the policy was ensuring 80% of all new dialysis patients start therapy at home or get transplanted by 2025. The emergence of COVID-19 further heightens the urgency for giving current in-center dialysis patients the option to treat at home.

"Tablo was designed to simplify dialysis, making it easier and more accessible for patients to take advantage of the safety, convenience and flexibility of dialyzing at home," said Outset Medical Chief Executive Officer, Leslie Trigg "We are proud to offer them this new, life-enhancing option, particularly in light of the COVID-19 related challenges dialysis patients and providers are experiencing."

Currently, more than 500,000 Americans undergo dialysis treatments three or more times each week, typically lasting four hours per treatment. Approximately 100,000 new patients start treatment annually. Yet only 12% receive it at home where they're more comfortable, productive and empowered.

### POSITIVE TRIAL RESULTS

A prospective, multicenter, home hemodialysis trial with 30 patients was completed in 2019 and confirmed the Tablo system is safe and effective for home use. The results were published in November 2019 in *Hemodialysis International*.

Troy Plumb, M.D., the principal study investigator and the Division Chief of Nephrology and Associate Professor of Medicine at the University of Nebraska Medical Center College of Medicine in Omaha, said, "My patients, colleagues and I are excited for Tablo to be available for home use. The trial made it clear the system is easy to learn and performs well in the home environment. I believe that Tablo will open up opportunities for patients to pursue home hemodialysis and take more control over their lives and care."

One of those patients is 62-year-old Texas resident and technology consultant Richard Crawford. He has had a kidney transplant that lasted 17 years and is currently on a transplant list. Over the years, he has had thousands of dialysis treatments at various centers as well as on home hemodialysis. He found using Tablo at home to be very intuitive, allowing him to dialyze while remaining productive during treatment.

"The home part of the Tablo trial only lasted eight weeks, but was eye opening," he said. "The system is extremely easy to set up and use, so I wasn't wasting hours on dialysis-related tasks. I was able to work at my desk during treatments, which was wonderful for my productivity. The system provided me with a new level of independence due to the ease of setup and maintenance. "When the trial ended and they had to pick up the Tablo, I tried talking them out of it. I really hated seeing it go."

Outset will begin a controlled rollout for home use at select sites over the coming months to ensure the highest level of training and support for Tablo home patients. This program will be balanced with the need to supply health systems, hospitals, and clinics with devices to support a surge of demand for dialysis treatments driven by COVID-19. More information about availability for patients and providers can be found at [www.outsetmedical.com](http://www.outsetmedical.com).

Tablo was designed in Silicon Valley to reduce the cost and complexity of dialysis care. Requiring only an electrical outlet and tap water to operate, the mobile Tablo system frees patients and providers from expensive clinic infrastructure. The machine's functionality enables it to serve as a dialysis clinic on wheels. Wireless data, sensor-based automation and an animated touchscreen make the system easy to learn and use. Leading health systems and medical centers across the U.S. use Tablo for hospital and clinic dialysis, and the U.S. Department of Health and Human Services (HHS) awarded a contract for the use of Tablo in communities hit by natural disasters.

### **Award Winning Technology**

Last April, Outset was a winner of the KidneyX Redesign Dialysis Competition, a partnership between the U.S. Department of Health and Human Services and the American Society of Nephrology to support innovative strategies for tackling kidney disease. Outset's winning concept marries data from Tablo's unique sensors and automation systems with physiologic data from the patient with an eye toward creating personalized dialysis treatments that improve patient outcomes.

Outset's Tablo System was also recently recognized with a Gold Edison Award in the medical patient experience category. The Edison Awards honor game-changing innovations at the forefront of new product and service development, marketing and human-centered design. Nominees were judged by a panel of more than 3,000 leading business executives including past award winners, academics and leaders in the fields of product development, design, engineering, science and medicine. Tablo received the top prize in its category, the Gold Award.

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### **Media Contact**

Kevin Knight  
206.451.4823  
[media@outsetmedical.com](mailto:media@outsetmedical.com)

### **About the Tablo Hemodialysis System**

Tablo is an FDA-cleared enterprise solution for dialysis, designed specifically to reduce the cost and complexity of dialysis across all care settings. Requiring only an electrical outlet and tap water to operate, the mobile Tablo system frees patients and providers from the burdensome infrastructure required to operate conventional dialysis machines. The machine's integrated functionality enables it to serve as a dialysis clinic on wheels and enables providers to standardize to a single platform that can be used across a wide spectrum of care settings. Wireless data, sensor-based automation and an animated touchscreen make the system easy to learn and use. Leading health systems and medical centers across the U.S. have adopted Tablo for hospital and clinic dialysis, and the U.S. Department of Health and Human Services (HHS) awarded a contract for the use of Tablo in communities hit by natural disasters.

### **About Outset Medical**

Outset Medical is dedicated to technology-driven service model innovation aimed at reducing cost and transforming the patient care experience. Outset's Tablo System is FDA-cleared for use in acute and chronic care settings. In addition to its acute and chronic care commercial expansion, the company has concluded a clinical trial to expand Tablo's labeled indication to include home use. For more information visit [www.outsetmedical.com](http://www.outsetmedical.com) and follow the company on Twitter at @OutsetMedical.