

# Human Factors Validation of the Tablo Hemodialysis System in Home Patients

Authors: Brittany Lim<sup>1</sup>, Elise Edson<sup>1</sup>, Cynthia D’Alessandri-Silva<sup>1</sup>, MD, Josh Schumacher<sup>1</sup>, BA, Michael Aragon<sup>1</sup>, MD

<sup>1</sup>Outset Medical, Inc. (San Jose, CA, USA)

## BACKGROUND

- Home hemodialysis (HHD) is a complex, lifesaving therapy for patients with end-stage kidney disease (ESKD).
- The high-level patient interaction needed to use devices safely and effectively while educating patients and care partners to administer dialysis at home requires significant training.
- This training can be facilitated by using more intuitive, patient-centered technology.
- The Tablo<sup>®</sup> Hemodialysis System (“Tablo”) is an all-in-one, easy-to-learn system indicated for clinic, hospital, and home settings. Features include a simplified user interface touchscreen GUI, coupled with images to assist users with system operation.
- Prior human factors (HF) validation testing of Tablo, showed a use error rate of 1.2%.

## OBJECTIVE

Report on the results of simulated use human factors validation testing on a recent software version of the Tablo System with patients in the home setting.

## METHODS

- Patients and their care partners (one pair considered a “participant”) were recruited to test the Tablo user interface in a simulated use home environment.
- Participants underwent two days of hands-on training to learn:
  - Device setup
  - Takedown
  - Monitoring of treatments
  - Device maintenance; and
  - Alarm resolution
- After a decay of at least 24 hours, participants performed all tasks without assistance from the trainer.
- Task performance (including use errors, close calls, and difficulties) were recorded, along with subjective interview and knowledge task assessments.

## RESULTS

- Fifteen (15) participants were recruited, consisting of: 6 who had prior HHD experience and 9 with no prior HHD or self-care experience
- A total of 5400 tasks were assessed across all participants. Of these:
  - 98.4% completed without difficulty
  - 0.7% completed with minor difficulty
  - 0.9% were classified as use errors, with none of these posing an unacceptable level of residual risk.
- 100% of participants reported confidence that they could use Tablo safely and effectively.



## CONCLUSION

- This human factors study demonstrates that after 2 days of standard training, Tablo is safe and easy to use for patients and their care partners in a simulated home environment regardless of prior experience with self-care.
- Recent software updates have further reduced the already low use error rate of Tablo.
- This data endorses prior reports of Tablo being easy to learn and use for patients and their care partners
- Results of this study may contribute to the high retention rates previously observed with the Tablo Hemodialysis System for home use.

**Table 1.** Participant User Task Assessments

Use Scenario	Scenario Title	Success	Difficulty	Close Call	Use Error	Total Tasks
1	Prepare System for Use	1289 (98.8%)	7 (0.5%)	1 (0.08%)	8 (0.6%)	1305
2	Connect Patient & Begin Treatment	176 (97.8%)	-	-	4 (2.2%)	180
3	Administer Treatment	1178 (98.2%)	8 (0.7%)	-	14 (1.2%)	1200
4	Complete Treatment, Disconnect Patient, Clean & Disinfect System	752 (98.3%)	6 (0.8%)	-	7 (0.9%)	765
5	Manual Blood Return	233 (97.1%)	6 (2.5%)	-	1 (0.4%)	240
6	Perform Routine System Maintenance	1444 (98.2%)	10 (0.7%)	-	16 (1.1%)	1470
7	User Manual and IFU Comprehension	120 (100%)	-	-	-	120
8	Miscellaneous Observations	120 (100%)	-	-	-	120
<b>Total</b>		<b>5312 (98.4%)</b>	<b>37 (0.7%)</b>	<b>1 (0.02%)</b>	<b>50 (0.9%)</b>	<b>5400</b>