

Ten thousand consecutive treatments using the Tablo Hemodialysis System in hospitals and clinics

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Background

The Tablo® Hemodialysis System is an all-in-one system cleared for use in clinic and hospital settings (Figure 1).

Features include an integrated water purification system, the ability to produce dialysate on demand, a simplified user interface, and two-way wireless connectivity that enables treatment records to automatically be uploaded to a cloud-based server for review by clinicians. Limited connectivity of existing traditional hemodialysis systems can make it difficult to track and trend treatment data and understand how well prescribed treatment parameters are being met.

This study reports on the clinical experience using Tablo in the clinic and hospital settings.

Objective

The objective of the study was to review 10,000 consecutive treatments across 24 sites on Tablo to evaluate the range of settings and treatment times most commonly used, as well as to demonstrate the utility of the wirelessly transmitted treatment data to track treatment metrics and potentially guide quality improvement.

Methods

Data on treatment prescription, clinically significant alarms (see Table 3), end treatment alarms, and treatment results for 10,000 dialysis treatments was collected using the Tablo system and real-time wireless data transmission to a cloud-based, HIPAA compliant platform.

Results

Ten thousand treatments were completed across 24 sites that are split between the hospital and clinic settings

Of the 10,000 treatments performed, 7720 completed at least 90% of the prescribed time. 1834 (18%) treatments were ended early by the user. 257 (2.6%) of treatments were terminated early due to end treatment alarms. Table 2 shows the detailed results by location and prescribed treatment time.

Table 2

Treatment results for the hospital and clinic settings

Treatment Parameter	Hospital IHD (≤ 6 hrs)	Hospital SLED (> 6 hrs)	Clinic IHD
Treatments Performed	4609	22	5369
Prescribed Tx Time (mean ± sd)	195.9 ± 33.6	483.4 ±69.9	221.0 ± 31.2
Actual Tx Time (mean ± sd)	166.5 ± 54.5	465.0 ± 42.5	211.0 ± 44.1
Prescribed Fluid Removed (mean ± sd)	2111.9 ± 972.8	3500.0 ± 2588.1	1960.8 ± 1192.9
Actual Fluid Removed (mean ± sd)	1815.8 ± 1073.6	3491.6 ± 2584.7	1852.5 ± 1205.7
% of Treatments within 10% of UF Goal	63.6%	86.4%	83.8%
Treatments Achieving 90% Prescribed Time (%)	3016 (65.4%)	18 (81.8%)	4686 (87.3%)
Treatments Ended Early by User (%)	1213 (26.3%)	5 (22.7%)	616 (11.5%)
Average # of Clinically Significant Alarms per Treatment	2.3		1.0

Chart 2

Shows the breakdown of end results of treatments in the hospital and the clinic

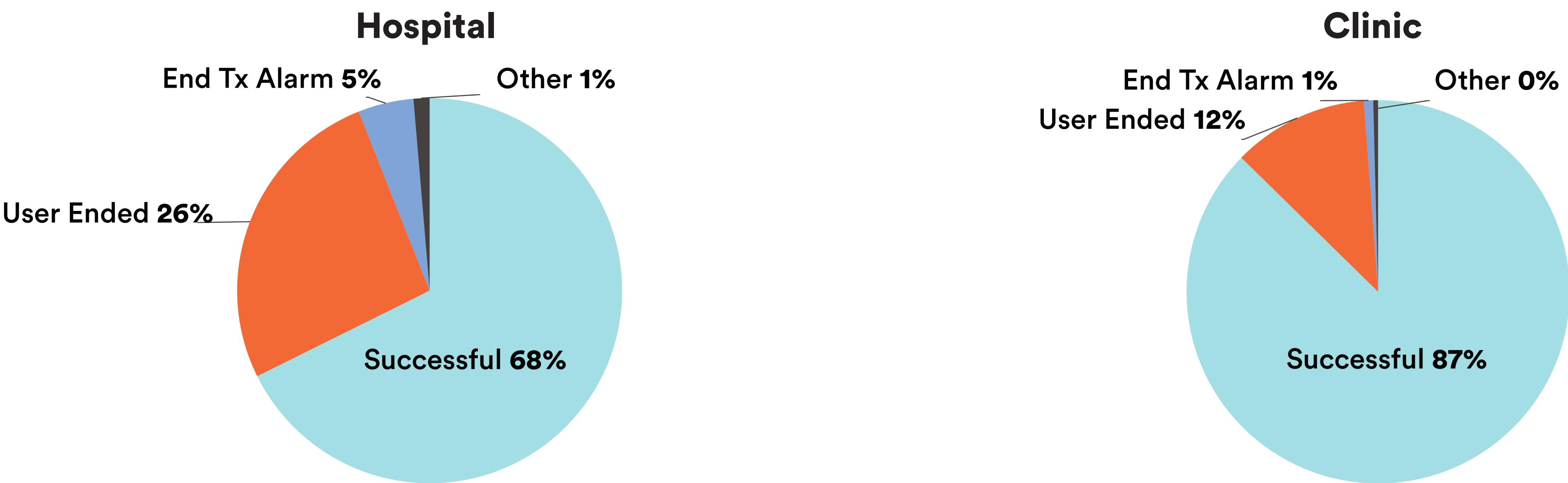


Table 3

Of the treatments that were ended by the user, the breakdown of reasons is below:

User Ended Reason	Hospital	Clinic
Treatment Related (i.e., access issues, clotting, system alerts)	81.3%	71.9%
Clinically Significant Alarms	31.1%	23.7%
• Venous pressure high	22.7%	17.4%
• Venous pressure low	6.6%	5.0%
• Low systolic BP	1.0%	0.5%
• Dialyzer blood leak	0.5%	0.2%
• Air in venous bloodline	0.2%	0.6%
Non-Treatment Related (i.e., logistics, patient choice)	16.9%	28.1%

Table 1

Setting	# of Sites	# of Treatments
Hospital	13	4,631
Clinic	11	5,369

Chart 1

Mean prescribed vs. achieved treatment time by location and treatment duration (min)

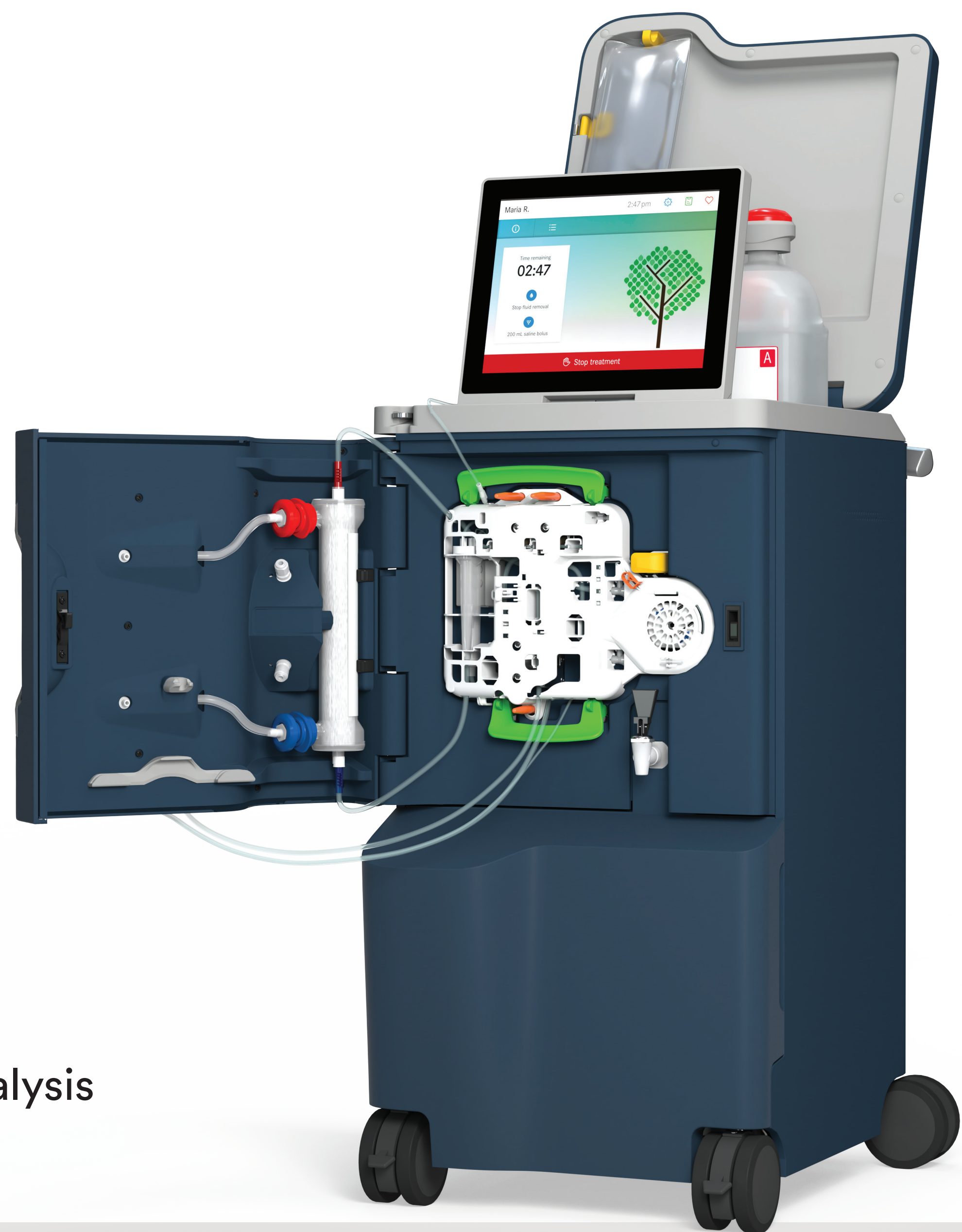
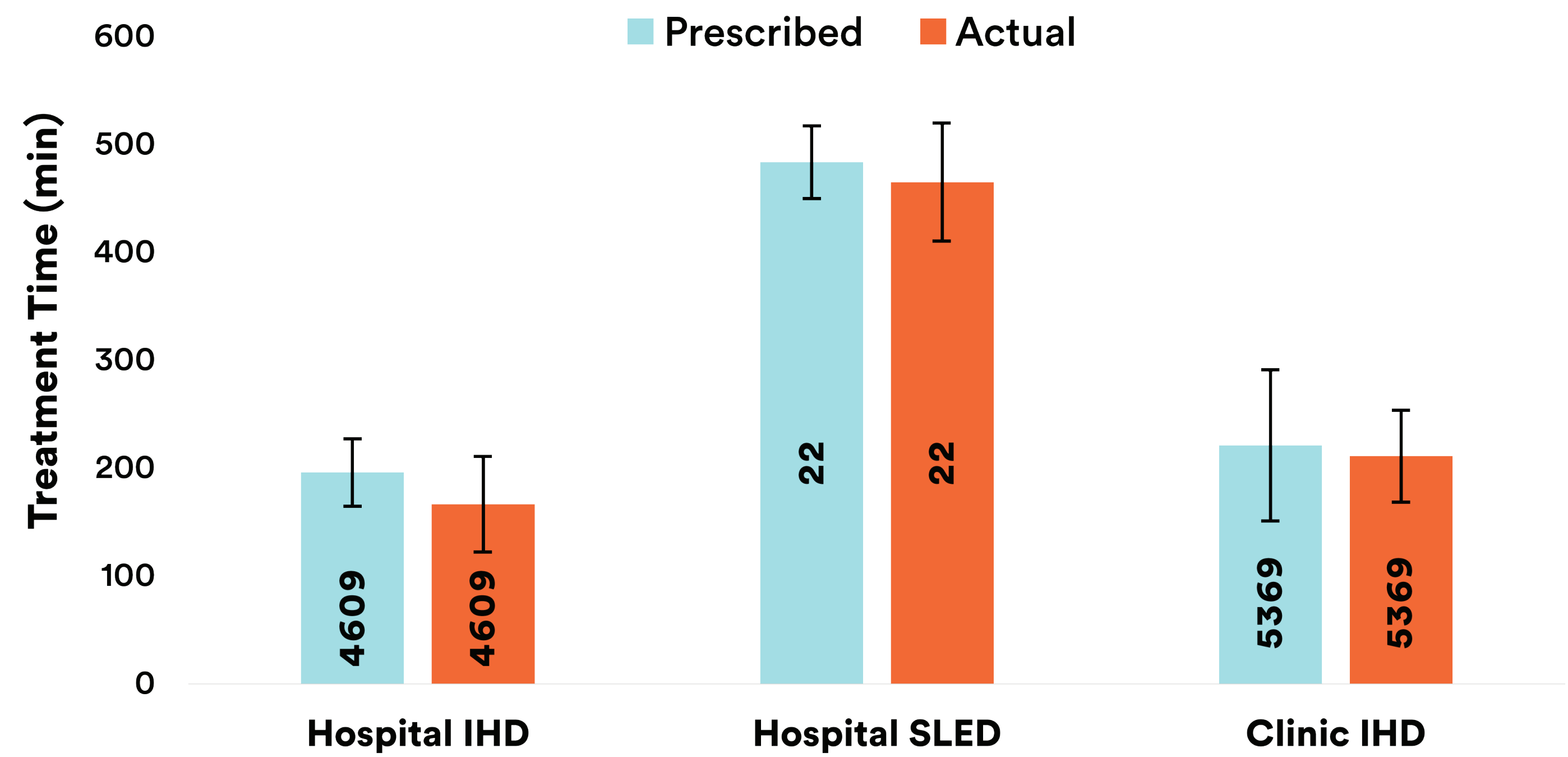


Figure 1.

Tablo Hemodialysis System

Summary

- Tablo has been successfully used across a wide range of treatment times and ultrafiltration rates in both the clinic and hospital settings.
- Tablo data suggests that dialysis treatments in the acute setting are terminated early by the user 2x more often than in the chronic setting and that the most common cause of early termination in BOTH settings is caused by the user ending the treatment early due to:
 - Clinically significant alarms (2.3 and 1.0 per treatment in the hospital and clinic settings)
 - Treatment related reasons (i.e., access issues, clotting, system alerts, etc.)
 - Non-Treatment related reasons (i.e., logistics, patient choice, etc.)
- End treatment alarms were rare and more likely to occur in shorter duration acute treatments.

Conclusion

- Tablo can successfully complete dialysis and ultrafiltration with minimal interruption from clinically significant alarms over a wide range of treatment times in both the acute and chronic environment.
- Tablo can facilitate review of robust treatment data sets via wireless data transmission utilizing Tablo's cloud-based, HIPAA compliant server to guide quality improvement programs in both the acute and chronic setting.
- In this data set, a quality improvement program focused on acute treatments and understanding reasons for user cancellation (e.g., access problems, interruption for other procedures, patient request, early achievement of treatment goals, etc.) could improve the overall success of prescribed metabolic and volume goals.
- This extensive clinical experience with Tablo confirms earlier reports of its successful use in smaller studies and highlights Tablo as a robust hemodialysis system for acute and chronic patient needs.

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