NxSTAGE®

Supplemental Quick Reference Guide

How to use this Supplemental Quick Reference Guide

This guide provides a **5-step** method for considering a variety of frequencies and treatment lengths, based on achieving a target weekly stdKt/V of 2.0, 2.5 or 3.0.

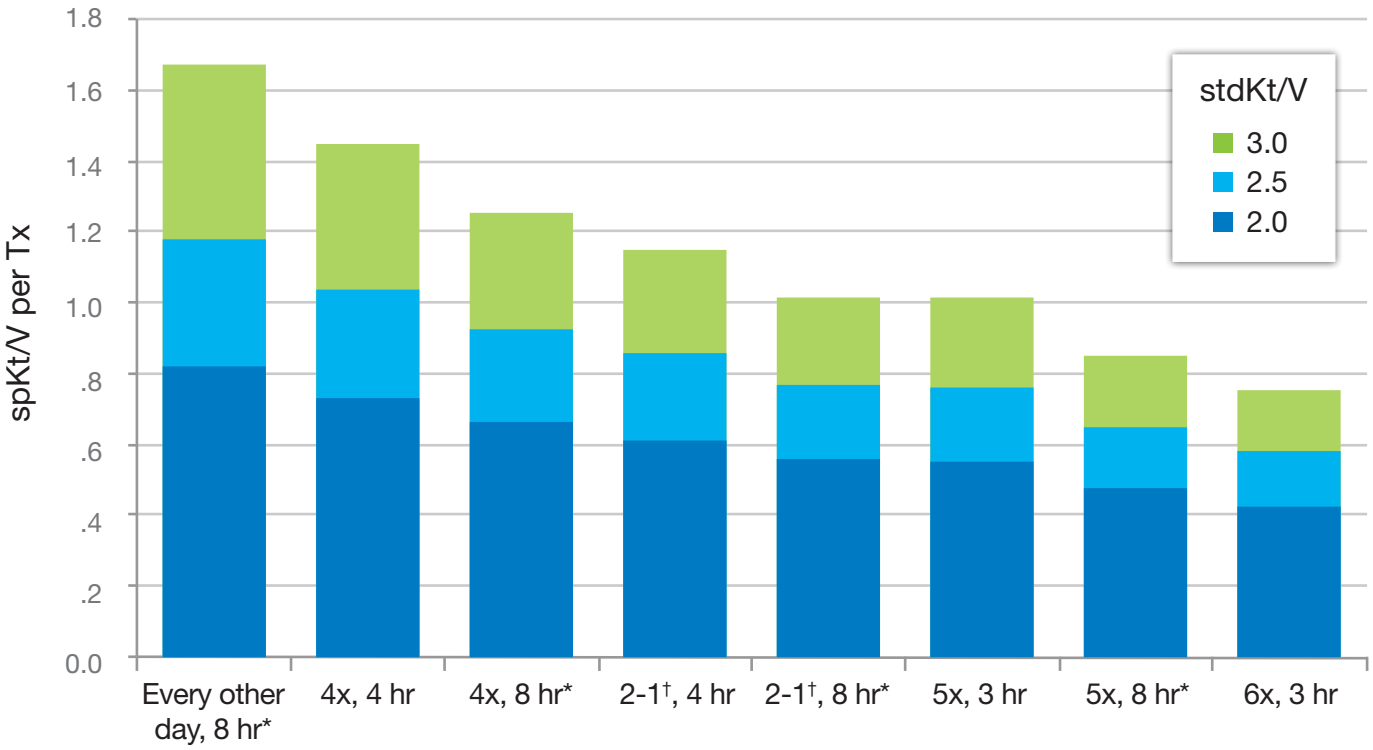
Step 1: Choose a frequency and duration best suited to the patient's lifestyle. This guide addresses 7 scenarios from every other day to 6 days a week.

Step 2: Select a target dose based on the outcome needs of the patient.

Step 3: Calculate the patient's body water volume.

Step 4: Choose the expected blood flow rate.

Step 5: Based on the selected schedule, target dose, body water volume and blood flow rate, identify the starting dialysate volume for the prescription. For patients using PureFlow™ SL, 35, 45 and 55 L volumes may be rounded up to the nearest SAK size (40, 50, or 60 L) for convenience.



* The NxStage System One is not specifically indicated for nocturnal use.

† 2-1 is a schedule of two dialysis days followed by one day off. It is approximatley 4.7 days per week.

Suggested Dialysate Volumes (L)

stdKt/V†	Blood Flow Rate (ml/min)	Body Water Volume (L)	Every Other Day, 8 hr*	4 x 4 hr	4 x 8 hr*	2-1 x 4 hr	2-1 x 8 hr*	5 x 3 hr	5 x 8 hr*	6 x 3 hr
2.0	300	30	25	25	20	20	20	20	20	20
		40	35	30	25	25	20	25	20	20
		50	40	40	35	30	25	30	25	20
		60	50	50	40	35	30	35	30	25
		70	55	-	45	40	35	50	35	30
	400	30	25	25	20	20	20	20	20	20
		40	35	30	25	25	20	25	20	20
		50	40	40	35	30	25	30	25	20
		60	50	45	40	35	30	35	30	25
		70	55	55	45	40	35	40	35	30
	500	30	25	25	20	20	20	20	20	20
		40	35	30	25	25	20	25	20	20
		50	40	35	35	30	25	30	25	20
		60	50	45	40	35	30	35	30	25
		70	55	55	45	40	35	40	35	30
2.5	300	30	35	35	30	25	20	25	20	20
		40	50	45	40	35	30	35	25	25
		50	60	-	45	45	35	50	35	30
		60	-	-	55	60	45	-	40	40
		70	-	-	-	-	50	-	45	60
	400	30	35	30	30	25	20	25	20	20
		40	50	45	40	35	30	35	25	25
		50	60	60	45	40	35	40	35	30
		60	-	-	55	50	45	60	40	40
		70	-	-	-	-	50	-	45	45
	500	30	35	30	30	25	20	25	20	20
		40	50	45	40	35	30	30	25	25
		50	60	55	45	40	35	40	35	30
		60	-	-	55	50	45	50	40	35
		70	-	-	-	60	50	-	45	45
3.0	300	30	50	50	40	35	30	35	25	25
		40	-	-	50	45	40	60	35	35
		50	-	-	-	-	50	-	45	50
		60	-	-	-	-	60	-	50	-
		70	-	-	-	-	-	-	60	-
	400	30	50	45	40	35	30	30	25	25
		40	-	-	50	45	40	45	35	30
		50	-	-	-	60	50	-	45	40
		60	-	-	-	-	55	-	50	55
		70	-	-	-	-	-	-	60	-
	500	30	50	45	40	35	30	30	25	25
		40	-	-	50	45	40	45	35	30
		50	-	-	60	55	45	60	45	40
		60	-	-	-	-	55	-	50	50
		70	-	-	-	-	-	-	60	-

† Weekly UF assumed to be 25% of body water, at a rate <= 10 ml/kg/hr
* The NxStage System One is not specifically indicated for nocturnal use.

Target duration not achievable at dialysate flow rates less than or equal to 12 L/hr.

Sample Patient Case

Patient

- Male
- 68 years old
- 163 cm tall
- 76 kg
- Diabetes, Hypertension
- AV fistula with buttonhole

Status

- Has been doing HHD at home with his wife for 9 months, his prescription is: 25 L, 6 days per week, 35% FF, 400 Qb.
- Tx time is 3:20 on average.
- His weekly standard Kt/V is 2.5.
- He and his wife are showing signs of burnout.

Options

- Watson formula gives a body water volume of 39 L. (Round up to 40 L to use the table.)
- The option table for 6 days, 3 hrs suggests 25 L therapy, consistent with his current prescription.
- The patient would like to dialyze fewer days, preferably for less time.
- A 4 day/week, 4 hour treatment can be delivered using 45 L of volume.

Conclusion

After discussion with the patient and partner, the decision is made to pursue 45 L, 4 hr therapy at a frequency of 4 days/week. As a result of this decrease in frequency, UF is expected to increase to 2 L per treatment. In addition, the cycler will need to be configured to allow a higher flow fraction, as explained in the next section.

Configuring the cycler

To configure the cycler for simple operation by the user, some healthcare providers use flow fraction (System Setting #1 on the System One cycler) to limit the combined dialysate and ultrafiltration pump rates. This is done in three steps (with specific values taken from the patient case at left).

1. Determine the estimated ultrafiltration rate per treatment. This must include the rinseback volume and interdialytic fluid intake. This total volume is then divided by the duration initially selected.

$$2\ \text{L} + 0.3\ \text{L} = 2.3\ \text{L}$$

$$2.3\ \text{L} / 4\ \text{hr} = 0.58\ \text{L/hr}$$

2. Determine the dialysate flow rate by dividing the prescribed dialysis fluid volume by the selected duration.

$$45\ \text{L} / 4\ \text{hr} = 11.25\ \text{L/hr}$$

3. Determine the flow fraction for patient convenience. This is the sum of the ultrafiltration and dialysate flow rates from the previous steps, divided by the blood flow rate (which must be converted to L/hr).

$$\frac{(0.58\ \text{L/hr} + 11.25\ \text{L/hr})}{\left(400\ \text{ml/min} \times \frac{60\ \text{min/hr}}{1{,}000\ \text{ml/L}}\right)} = 49\%$$

If the patient consistently achieves their target blood flow rate, this is a good way to cap the dialysate flow rate at the intended 11.25 L/hr. If blood flow rate varies from treatment to treatment, the flow fraction can be set to a high value (e.g. 200%) to remove it as a constraint and the patient can be trained to always set the flow rates to the same value (in this case, 0.58 L/hr and 11.25 L/hr). Flow fraction simply provides convenience for the patient when setting the pump speeds.

NOTE: Flow fraction is used only to constrain the dialysate flow rate used by the patient. There is no need to keep the flow fraction below a universal level (e.g. 40%); it is set as needed to allow the volumes on the facing page to be delivered in the intended length of therapy.

This document is meant to be used with *Prescribing Home Hemodialysis with the NxStage® System One™ QUICK REFERENCE GUIDE*, APM425. It provides additional details on the first two elements of a Physician Order as described in the Quick Reference Guide.

Background Formulas:

1. $V = \begin{cases} Male: 2.447 - 0.09516A + 0.1074H + 0.3362W \\ Female: -2.097 + 0.1069H + 0.2466W \end{cases}$

2. $$stdKt/V = \frac{\frac{10080\left(1-e^{-eKt/V}\right)}{t}}{\frac{1-e^{-eKt/V}}{spKt/V}+\frac{10080}{Nt}-1}$$

3. $$eKt/V = spKt/V\left(0.924 - \frac{0.395\times 60}{t}\right) + 0.056;\ eKt/V \leq spKt/V$$

4. $$K = \frac{Q_e(e^z-1)}{e^z-\frac{Q_e}{Q_d}}\left(1-\frac{Q_f}{Q_e}\right) + Q_f\ ;\quad z = K_0A\frac{\left(1-\frac{Q_e}{Q_d}\right)}{Q_e}$$

5. $$Q_e = Q_b(0.94 - 0.0022\mathrm{Hct})$$

1 Watson et al, Total body water volumes for adult males and females estimated from simple anthropometric measurements. Am J Clin Nutr 1980; 33(1):27-39.
2 National Kidney Foundation, KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1): 65
3 Leypoldt et al, Predicting treatment dose for novel therapies using urea standard Kt/V. Semin Dial 2004; 17(2):142-145.
4 Daugirdas et al, Solute-solver: a web-based tool for modeling urea kinetics for a broad range of hemodialysis schedules in multiple patients. Am J Kid Dis 2009; 54(5): 798-809
5 Gotch et al, Effective diffusion volume flow rates (Qe) for urea, creatinine, and inorganic phosphorus (Qeu, Qecr, QeiP) during hemodialysis. Sem Dial 2003; 16(6): 474-476

NxStage Medical has prepared this document as a convenient reference guide for physicians prescribing Home Hemodialysis (HHD) therapy with the NxStage System One.

This reference guide does not address the full range of topics (e.g., lab results, blood pressure management, fluid balance, etc.) critical for the overall management and ongoing monitoring of a patient on NxStage HHD therapy and should not be used as a substitute for the *NxStage System One User Guide*, *Hemodialysis Therapy Primer* (APM120), *Dialysate Preparation Primer* (APM231), other product labeling, clinical literature and physician judgment.

The data provided herein are for informational purposes only. Specific prescription parameters will vary by patient based on co-morbid conditions and individual response to therapy.

Physicians should routinely monitor patients for changes in condition (including blood pressure, weight, and laboratory values) that may necessitate a change in the patient's prescription or medications. The potential impact of more frequent hemodialysis on antihypertensive needs is well established. Because the patient's dry weight and fluid distribution may change over time, this factor should continue to be watched. Dry weight should be reassessed prior to increasing fluid removal targets due to the potential impact of improved nutrition.

NxStage Medical has prepared this document as an introduction; it does not address all topics critical for managing a patient on the NxStage therapy. It is always the physician's responsibility to ensure the appropriate prescription, therapy, and care plan for an individual patient.

Frequently Asked Questions

Why does blood flow rate not affect the suggested dialysate volume?

It does; however, for some prescriptions the effect is not readily apparent for two reasons. First, the prescription volumes are rounded up in 5 L increments. Therefore, a change in blood flow rate will change the precise volume required, but the rounded volumes may be the same (e.g. 21 L and 24.5 L will both be rounded up to 25 L in the table). Second, the effect of blood flow rate is diminished when the dialysate flow rate is slower than the blood flow rate. In traditional high-flow dialysis, blood flow rate is the constraining factor on clearance, so changing it will noticeably affect clearance. In low-flow dialysis (dialysis flow rate < blood flow rate), dialysate flow rate is the constraining factor, so blood flow rate changes have a lower impact on clearance.

Why can flow fraction be raised above 40%?

The flow fraction does not limit therapeutic outcomes. When dialysis is used at a lower flow fraction (<40%), the dialysis fluid is fully saturated with waste products. This saturation minimizes the amount of dialysis fluid that is needed to achieve a desired urea clearance. As flow fraction increases, dialysis fluid passes through the filter without absorbing its full potential of waste products. Therefore, as dialysis flow rate increases (and flow fraction exceeds 40%), more fluid must be used to achieve the same clearance. So flow fraction does not need to be a limiting factor in dialysis if fluid conservation is not the paramount concern.

What if I want to use a different schedule than is shown on the table?

The formulas provided in this brochure can be used to calculate an appropriate volume to use for any clearance target and schedule. The schedules and durations included in the table are not intended as recommendations; they represent a range of options that are calculated for your convenience.

Why isn't a conventional thrice-weekly schedule shown in the table of options?

The NxStage System One cycler can be used at whatever schedule is therapeutically appropriate; however, only a small number of example schedules are included in this document. Literature suggests that avoiding the two-day gap inherent in thrice-weekly dialysis improves mortality.[1] Please refer to other NxStage literature on the many benefits of more frequent home hemodialysis.

1 Zhang H et al, Dialysis outcomes and analysis of practice patterns suggests the dialysis schedule affects day-of-week mortality. Kidney Int 2012; 81(11): 1108-1115.

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