

**Instructions for HEMO Study Form 5.
Detailed Dialysis Information for a Kinetic Modelling Day**

Question 8a: BUN Measurements:

- 2 BUNs:** Pre + 15 (line disconnect) or 20 (sampling port) sec post inlet slow
- 3 BUNs:** Pre + immediate post inlet full + 15 (line disconnect) or 20 (sampling port) sec post inlet slow
- 6 BUNs:** Pre + 1 hr outlet full + 1 hr inlet full + 1 hr inlet slow + immediate post inlet full + 15 (line disconnect) or 20 (sampling port) sec post inlet slow
- 8 BUNs:** Pre + 1 hr outlet full + 1 hr inlet full + 1 hr inlet slow + immediate post outlet full + immediate post inlet full + 15 (line disconnect) or 20 (sampling port) sec post inlet slow + 30 min post

Note: The response to Question 8a at F4 and F36 should still be 7 (not 8), even though 8 BUNs are now being measured.

Question 9: Machine type:

<u>Fresenius</u>	<u>Baxter</u>	<u>Cobe</u>	<u>Althin Drake Willock</u>	<u>Braun</u>
1 = 2008D	5 = 550	7 = Centry 3	9 = System 1000	13 = 00131
2 = 2008E	6 = 1550	8 = Centry 2	10 = Althin TINA	14 = 7107005
3 = 2008H		11 = Cobe CX		
4 = 2008C		12 = Centry 3 Plus		
15 = 2008K				

Question 10: If the machine serial number is unknown, the question may be left blank

Question 11: See dialyzer type code list

Question 12: On first use report preprocessing sterilant

Question 13: On first use indicate if bleach was used in the preprocessing procedure

Question 15: Code list for Vascular Access type:

- | | |
|---|--|
| 1 = AV graft - forearm | 7 = Temporary venous catheter - femoral |
| 2 = AV graft - upper arm | 8 = Permacath - internal jugular or subclavian |
| 3 = AV graft - thigh | 9 = Permacath - femoral |
| 4 = AV fistula - forearm | 98 = Other |
| 5 = AV fistula - upper arm | |
| 6 = Temporary venous catheter -
internal jugular or subclavian | |

Question 16: Use of a membrane for the first time will have a reuse # of 0. Pre-processing only, does not constitute a re-use. Only count the number of times the dialyzer is used on a patient.

Question 32: A bolus is defined as > 50 cc.

Question 33: (Definition of Interruption Time):

Interruption time includes:

- 1) Any lowering of the blood flow rate greater than 50 ml/min
- 2) Any time when dialysate was in bypass
- 3) Any time in the middle of dialysis when either blood or dialysate flow rate was interrupted due to problems with needle placement, clotting, water pressure or other mechanical problems, etc.

Interruption time does **not** include:

- 1) Periods when the ultrafiltration rate was lowered, but when blood and dialysate flow rates were maintained.

Questions 34, 35, 36, 39, 40a and 41 DO NOT refer to the HEMO Study prescription report sent by the DCC, but rather to the actual dialysis unit treatment orders.

Question 38: If the blood flow at 30 minutes is not recorded, report the first blood flow recorded after 30 minutes into dialysis. If an interruption with zero blood flow takes place at 30 minutes enter the next blood flow after the interruption.

Question 41: Define any deviation between the dialysis unit prescribed dialysate flow and the flow actually delivered. Note that answers 1, 2, 3, and 4 assume interruptions in delivered flow, but answer 5 reflects a stable flow for the entire (to within 15 min) treatment.

Question 42: Answer 0 if the correct membrane was used, 1-3 if the incorrect membrane was used due to an error in following the dialysate unit prescription, and 4 if the incorrect membrane was used because the dialysate unit prescription deviated from the HEMO Study prescription report.

Question 51: Separate items for initial and final sodium and potassium concentrations in the dialysate are provided in case these are modified during dialysis. If these concentrations are not modified, leave the final concentrations blank. Only single concentrations for magnesium, calcium, and bicarbonate are presumed. If one of these did happen to be modified during dialysis, please enter the initial concentration.

Double Dialyzers - For questions 12, 13, 16, and 44 - refer to the SECOND dialyzer in the series.

For Additional Information on Filling Out Form 5, see Section 4.6 of the Manual of Operations.

HEMO Study Form 5. Detailed Dialysis Information for a Kinetic Modelling Day

This form is to be completed by the study coordinator and the dialysis unit technician on the **HEMO** kinetic modelling day sessions that may occur during Baseline and that occur every month during Follow-Up.

1. Patient Identification Number. _____
2. Patient Name Code _____
3. Dialysis Unit (from code list) _____
4. Date of dialysis session. ____/____/____
5. Visit Type _____
6. Week/Month Number _____
7. Day Number _____
8. a. Type of session (**1**=special 6-BUN Troubleshooting, **2**=2 BUNs; **3**=3 BUNs; **7**=8 BUNs, **8**= 10BUNs, **9**= Extra Baseline 2-BUN Session on Usual Rx) . . . _____
- b. Is the current modelling session a repeat of the previous modelling session due to > 15 min of interruptions or other problems? (0=No, 1=Yes) _____
- c. Is the current follow-up modelling session a make up session for a session missed during the preceding calendar month? (0=No, 1 = Yes) _____
(Only allowed in first 10 days of calendar month; Current month's modelling session should still be held).
- d. Specify the number of times a scheduled HEMO Study modelling session was scrubbed since the previous HEMO Study modelling session _____
9. Machine Type _____
10. Machine Serial Number _____
11. Dialyzer type (from code list). _____
12. What sterilant was applied to this dialyzer prior to the current use? _____
(0=none, 1=formaldehyde, 2=glutaraldehyde, 3=Renalin, 4=heat)
13. Was bleach applied to this dialyzer prior to the current use?
(0=no, 1=yes) _____
14. Patient target weight (estimated dry weight) (kg). _____

- 15. a. Current type of vascular access ____
- b. Has there been a surgical or radiological intervention to improve access function or a change in the type of access since the previous kinetic modelling session? (0=no, 1=yes) ____

16. Reuse # (if first use, enter 0). ____

- 17. a. How many dialysis treatments were completed in the dialysis unit during the week ^{*} preceding this session? ____
 2 = fewer than 3 treatments 4 = more than 3 treatments
 3 = exactly 3 treatments 9 = cannot be determined
^{*}The week prior to the current session consists of the 7 day period preceding (but not including) the day of the current session

- b. What was the interdialytic interval ^{*} prior to the current session? ____
 1 = 1 day 3 = 3 days
 2 = 2 days 4 = 4 or more days
 9 = cannot be determined

^{*} To illustrate, suppose the current session is on a Wednesday. Then the interdialytic interval is 1 day if the preceding dialysis was on Tuesday, 2 days if the preceding dialysis was on Monday, and 4 days if the preceding dialysis was on the previous Saturday

- 18. a. Start time (24-hour clock). ____:____
- b. End time (24-hour clock) ____:____

- 19. a. Start weight (kg) ____
- b. End weight (kg) ____

- 20. a. Start blood pressure (sitting). ____/____
- b. End blood pressure (sitting) ____/____
(Enter a code of 999 for palpated diastolic)
- c. Minimum blood pressure on run sheet (sitting) ____/____
(Specify systolic and diastolic blood pressure at time of minimum systolic blood pressure)

21a. Was isolated ultrafiltration performed at this dialysis session (0=No,1=Yes) ____

If yes, then indicate the following

- b. Amount of fluid removed during isolated ultrafiltration (ml) ____
- c. Start time of isolated ultrafiltration (24-hour clock) ____:____
- d. End time of isolated ultrafiltration (24-hour clock) ____:____

- 22a. Time of 60 minute BUN collection (24-hour clock) (if applicable) ___:___
- 22b. 30 minute post time (24-hour clock) (if applicable) ___:___
- 23. Actual time of dialysis by RTD clock, if available (minutes). ___ ___
Leave blank if machine does not have an RTD clock (see machine type)
- 24. Specify minimum (most negative) pre-pump pressure, if available (-)___ ___

Complications: for questions 25-30, code:
0 = No
1 = Yes, but not requiring saline, lowering of UF rate, or reduced blood flow
2 = Yes, requiring either saline, lowering of UF rate, or reduced blood flow

- 25. Hypotension? (Enter 0 or 2 Only) _____
- 26. Cramping? _____
- 27. Headache? _____
- 28. Light-headedness, dizziness, or faintness? _____
- 29. Nausea or vomiting? _____
- 30. Chest pain? _____
- 31. Did fever ($> 100^{\circ}\text{F}$, [i.e., $> 37.7^{\circ}\text{C}$]) occur during treatment? (0=no, 1=yes) ___
(Specify no if fever originated prior to treatment)
- 32. Was saline or any other bolus IV fluid administered during the last 15 minutes of
dialysis? (0 = no, 1 = yes) _____
- 33. Was total interruption time ≥ 15 minutes? (0=no, 1=yes) _____
- 34. Time of dialysis prescribed in the dialysis unit (minutes) ___ ___
- 35. Dialysis unit prescribed time in Question 34 delivered within 15 minutes: Status ___
0 = No problem, prescribed time was delivered 4 = No, due to technical problem
1 = No, due to patient symptoms (machine, water, power, etc.)
2 = No, due to cannulation/needle problem 5 = No, due to staff error
3 = No, due to patient refusal 6 = No, due to other
- 36. Blood flow prescribed in the dialysis unit (ml/min). ___ ___
- 37. Blood flow at 10 minutes (ml/min). _____
- 38. Blood flow at 30 minutes (ml/min) (Do not enter zero - see instructions). _____

48. Blood flow rate change times and new flows (24 hour clock):

Time	a.1. ____:____	b.1. ____:____	c.1. ____:____	d.1. ____:____	e.1. ____:____
Flow Rate (ml/min)	a.2. _____	b.2. _____	c.2. _____	d.2. _____	e.2. _____
Time	f.1. ____:____	g.1. ____:____	h.1. ____:____	i.1. ____:____	j.1. ____:____
Flow Rate (ml/min)	f.2. _____	g.2. _____	h.2. _____	i.2. _____	j.2. _____

Complete at the special F4 and F36 sub-study session with the 2 and 60 minute post-dialysis BUNs.

49. 60 minute post time (24-hour clock) (if applicable) _____:_____

Complete for all F4 and F36 sessions.

50. Specify the ultrafiltration rate indicated on the dialysis delivery system at 60 minutes into dialysis (L/hr) _____

51. Based on the dialysis run sheet, indicate the concentrations of the following substances in the dialysate (Leave final sodium and final potassium concentrations blank if these concentrations were not changed during dialysis.):

a) Initial Sodium (mEq/L) _____

b) Final Sodium (mEq/L) _____

c) Initial Potassium (mEq/L) _____

d) Final Potassium (mEq/L) _____

e) Magnesium (mEq/L) _____

f) Calcium (mEq/L) _____

g) Bicarbonate (mEq/L) _____

Complete at the special F4 or F36 sub-study session with the 2 and 60 minute post-dialysis BUNs.

52. Specify the actual number of seconds after the end of dialysis that the 2 min post sample was drawn (seconds) _____

201. Date this form completed ___/___/_____

202. Certification number of person completing this form _____

Clinical Center Use Only	
Date Form Entered ___/___/_____	Verified? _____
Person Entering this Form _____	