

TIME STUDY - Prepared For Baxter BioScience

A comparison of Bayer's BioSet product, Baxter's Baxject I and II devices, and the conventional vial-to-vial transfer with needles



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INTRODUCTION

We conducted a comparative-time study to look at four different techniques for reconstituting anti-hemophilic factor on July 27 and 28, 2005. This study helped us develop an understanding of the time involved to reconstitute Factor VIII (a task performed by hemophiliacs).

The research consisted of timing the reconstitution process for each of the four methods of reconstitution:

- BioSet
- Baxject I
- Baxject II
- Needles (Conventional vial-to-vial transfer with double-ended needle and filter needle)

METHODS

OVERVIEW

13 people participated in the research, which took place in a conference room at Baxter’s facilities in Round Lake, IL. 10 participants reconstituted single vials with each of the 4 methods and 3 participants reconstituted double vials with just BioSet and Baxject II.

Following training*, we asked each of the 10 single-vial participants to reconstitute 1 vial, 10 times, with each of the 4 methods (i.e., BioSet, Baxject I, Baxject II, and Needles). In addition, following training†, we asked each of the dual-vial participants to reconstitute 2 vials, 10 times, with each of the 2 methods (i.e., BioSet and Baxject II). At the end of each session, we asked the participants to complete a form with a series of related questions.

We used 4 cameras to record up to 4 participants per session and then reviewed the tapes to gather the timing data. The timing for each trial started when the participant received the instruction to start the reconstitution and ended when the participant placed the filled syringe on the table. ‡

* See page 7, for single-vial training procedure.

† See page 9, for dual-vial training procedure.

‡ See Appendix F, for detailed list of all the steps included in the timing.

PARTICIPANTS

Since the primary users of these reconstitution methods are males, Baxter recruited 9 men and 4 women as participants for the usability testing. While women are not afflicted with hemophilia, including a small number in this study was determined appropriate since women sometimes need to reconstitute Factor VIII for male dependants. Participants were a mix of Baxter's employees and employee referrals. We made every effort to insure that participants had equal experience (if any) with the different methods.

Age	Number of Participants (N = 10)
15 to 25	3
26 to 35	4
36 to 45	1
45 to 55	2
Gender	
Male	7
Female	3

Single-vial trials:

Age	Number of Participants (N = 3)
15 to 25	1
26 to 35	1
36 to 45	1
Gender	
Male	2
Female	1

Dual-vial trials:

PROCESS

Testing consisted of the following phases:

See appendix E for the complete protocol.

Single-vial trials:

1. Training (repeated for each method):

- a. Participants received written and verbal instructions for using one method. See appendix F for written and verbal instructions.
- b. Participants watched and listened to the researcher demonstrate that method.
- c. Researcher instructed the participants systematically as they performed the reconstitution.
- d. Researcher observed each of the participants perform the reconstitution without instruction and provided feedback at the end.

2. Researcher chose devices at random and placed one device with sufficient supplies on a table in front of each participant. Therefore, each participant in the room received a different device.

3. Researcher instructed each participant to reconstitute one vial, place the filled syringe on the table at completion, and wait for the other participants to finish.

4. After each of the participants reconstituted the first vial, the researcher repeat steps two and three an additional nine times.
5. Researcher rotated the devices on each table and repeat steps 2 through 4 until each participant completed 10 trials with each of the four devices.

Participants performed additional trials subsequent to a device failure or to making a mistake in the reconstitution procedure. See appendix C for a detailed list of disqualifiers.

Some of the accepted times include minor device failures or mistakes in the reconstitution procedure. Where applicable, notes indicating the device failure or procedural mistake accompany the recorded time. See appendix B for a complete list of included times.

Dual-vial trials:

1. Training (repeated for each method):

- a. Participants received written and verbal instructions for using one method. See appendix F for written and verbal instructions.
- b. Participants watched and listened to the researcher demonstrate that method.
- c. Researcher instructed the participants systematically as they performed the reconstitution.
- d. Researcher observed each of the participants perform the reconstitution without instruction and provided feedback at the end.

2. Researcher systematically varied the presentation order of the devices and placed one device with sufficient supplies on the table in front of each participant.

3. Researcher instructed each participant to reconstitute two vials, place the filled syringe on the table at completion, and wait for the other participants to finish. Participants pulled the solution, from both of the vials, into one 10 ml syringe.

4. After each of the participants completed the first trial, the researcher repeat steps two and three an additional nine times.
5. Researcher rotated the devices on each table and repeat steps 2 through 4 until each participant completed 10 trials with each of the two devices.

Participants performed additional trials subsequent to a device failure or to making a mistake in the reconstitution procedure.

MATERIALS

Single-vial trials used the following supplies for each method listed below:

BioSet

3ML GLASS SYRINGE (1)

- PRE-FILLED 2.5 ML OF WATER
- WITH DETACHED PLUNGER ROD

BioSet DRUG VIAL* (1)



BAXJECT I

ALCOHOL SWAB (1)

DRUG VIAL* (1)

WATER VIAL (1)

BAXJECT I DEVICE (1)

10ML B-D SYRINGE (1)



* All of the drug vials in this study contained powdered sugar as a substitute for Factor VIII.

MATERIALS

Single-vial trials used the following supplies for each method listed below (cont.):

BAXJECT II

ALCOHOL SWAB (1)

DRUG VIAL* (1)

WATER VIAL (1)

BAXJECT II DEVICE† (1)

10ML B-D SYRINGE (1)



NEEDLES

ALCOHOL SWAB (1)

DRUG VIAL* (1)

WATER VIAL (1)

DOUBLE-ENDED NEEDLE (1)

16-GAUGE FILTER NEEDLE (1)

10ML B-D SYRINGE (1)



* All of the drug vials in this study contained powdered sugar as a substitute for Factor VIII.

† Participants 9 and 10 used repackaged devices with rubber cement to hold packaging shut.
Their times were not significantly affected by this change.

MATERIALS

Double-vial trials used the following supplies for each method listed below:

BIOSET

3ML GLASS SYRINGE (2)

- PRE-FILLED 2.5 ML OF WATER
- WITH DETACHED PLUNGER ROD

BIOSET DRUG VIALS* (2)

10ML B-D SYRINGE (1)



BAXJECT II

ALCOHOL SWAB (1)

DRUG VIALS* (2)

WATER VIALS (2)

BAXJECT II DEVICES (2)

10ML B-D SYRINGE (1)



* All of the drug vials in this study contained powdered sugar as a substitute for Factor VIII.

TIMING RESULTS

Overall comparison of the four methods

BioSet time < Baxject II time < Baxject I time < Needles time

We considered the a priori chance of the mean (average) times for each participant resulting in a particular pattern, and labeled the time to prepare Factor VIII as follows: BioSet = A, Baxject II = B, Baxject I = C, and Needles = D. Therefore, the chance of the mean times for one participants resulting in $A < B < C < D$ should be 1 in 24. However, we observed this pattern for every single-vial participant in the study. This is akin to flipping a coin and obtaining 24 sequential heads when flipping the coin 24 times. In other words, it is highly unlikely that this pattern would occur simply due to chance.

Analysis of variance and descriptive statistics

In addition to the overall comparison of the 4 methods, we analyzed the data with descriptive statistics (e.g., means and standard deviations) and with analysis of variance (ANOVA) to test whether there was a statistically significant difference between sets of means.

We used the conventional threshold for statistical significance of .05. Thus, a finding was accepted as statistically significant (i.e., “real”) when its probability (“p” value) was less than .05, or 5 in 100. See appendix B for more detailed results for each of the participants.

SINGLE-VIAL TRIALS

BioSet was approximately 40% faster than Baxject II.

The mean time for BioSet was 35.5 seconds (SD = 12.2) while the mean time for Baxject II was 57.8 seconds (SD = 13.2). With a “p” value of less than 0.0001, this difference is statistically significant.

In addition, BioSet was significantly faster than both Baxject I and Needles.

Baxject II was approximately 13% faster than Baxject I.

The mean time for Baxject II was 57.8 seconds (SD = 13.2) while the mean time for Baxject I was 1 minute 7.1 seconds (SD = 13.2). With a “p” value of less than 0.0001, this difference is statistically significant.

Baxject II was also significantly faster than Needles.

Baxject I was approximately 16% faster than Needles.

The mean time for Baxject I was 1 minute 7.1 seconds (SD = 13.2) while the mean time for Needles was 1 minute 19.5 seconds (SD = 12.9). With a “p” value of less than 0.0001, this difference is statistically significant.

DUAL-VIAL TRIALS

BioSet was approximately 17% faster than Baxject II.

The mean time for BioSet was 1 minute 25.0 seconds (SD = 10.1) while the mean time for Baxject II was 1 minute 42.4 seconds (SD = 14.6). With a “p” value of less than 0.0001, this difference is statistically significant.

QUESTIONNAIRE RESULTS

Following are the main findings of the questionnaire. See appendix D for more detailed results for each of the participants.

SINGLE-VIAL TRIALS

Most of the participants indicated an overall preference for BioSet over the other three methods.

When asked to indicate which method they preferred the most, eight out of the ten participants listed BioSet and two participants listed Baxject II. Baxject I and Needles were ranked third and fourth, respectively.

Most of the participants ranked BioSet as the fastest method.

Nine of the ten participants ranked BioSet faster than the other three methods. When asked to indicate which of the four methods felt the fastest, only one participant ranked Baxject II as the fastest. Baxject I and Needles were ranked third and fourth, respectively.

Most of the participants listed Needles as their overall least preferred method.

Nine of the ten participants ranked Needles as their least preferred. However, one participant listed Baxject I as her least preferred method, indicating that she “put Baxject I last because the steps are hard to remember.”

DUAL-VIAL TRIALS

Two of the three participants indicated a preference for BioSet over Baxject II.

In addition, these two participants ranked BioSet as the fastest method. Only one of participants indicated a preference for Baxject II over BioSet and ranked Baxject II as the fastest method.

APPENDIX A: PARTICIPANT DEMOGRAPHICS

		Participant Number										
		TOTAL	1	2	3	4	5	6	7	8	9	10
SINGLE VIAL TRIALS												
1	Gender	10	1	1	1	1	1	1	1	1	1	1
	Male	7			1	1	1	1			1	1
	Female	3	1	1						1		
2	Age	10	1	1	1	1	1	1	1	1	1	1
	15 to 25	3			1	1	1					
	26 to 35	4	1					1		1		1
	36 to 45	1									1	
	45 to 55	2		1					1			
3	Baxter Employee	10	1	1	1	1	1	1	1	1	1	1
	Yes	7	1	1			1	1		1	1	1
	No	3			1	1			1			
DUAL VIAL TRIALS												
1	Gender	3	1	1	1							
	Male	2		1	1							
	Female	1	1									
2	Age	3	1	1	1							
	15 to 25	1		1								
	26 to 35	1	1									
	36 to 45	1			1							

APPENDIX B: TIME DATA

	A	B	C	D	E	F	G	H	I	J	K	L	M
1													
2	SINGLE-VIAL TRIALS												
3													
4		Participant Number											
5	BAXJECT I	1	2	3	4	5	6	7	8	9	10	Mean	SD
6	1	01:05.7	01:15.3	01:18.0	01:58.0	01:29.8	01:09.8	01:14.4	00:56.4	01:17.7	01:17.6	01:18.3	00:16.5
7	2	00:53.9	01:06.3	01:28.2	01:52.1	01:13.1	01:10.7	01:15.0	00:59.7	01:15.4	01:24.9	01:15.9	00:16.4
8	3	01:12.3	01:12.6	01:10.3	01:35.8	01:08.0	01:02.1	01:02.9	00:57.9	01:02.8	01:18.7	01:10.3	00:10.9
9	4	00:55.6	01:13.5	01:01.5	01:23.1	01:11.0	01:02.1	01:15.4	00:51.6	00:58.0	01:14.6	01:06.6	00:10.3
10	5	00:47.5	01:12.0	01:14.4	01:35.1	01:03.7	00:58.0	01:06.0	00:53.5	01:05.3	01:14.2	01:07.0	00:13.2
11	6	00:47.2	01:09.5	01:06.2	01:28.2	01:17.0	00:58.7	00:57.2	00:51.1	01:02.3	01:13.1	01:05.1	00:12.4
12	7	00:50.7	01:01.8	01:11.5	01:23.3	01:08.8	00:59.3	01:01.0	00:53.5	00:59.4	01:05.1	01:03.4	00:09.4
13	8	00:48.6	01:00.6	01:03.6	01:21.1	01:09.5	00:57.2	00:59.5	00:48.5	01:00.6	00:59.1	01:00.8	00:09.5
14	9	00:49.1	00:51.6	01:04.5	01:32.2	01:08.8	00:54.8		01:01.5	01:00.9	00:58.0	01:02.4	00:12.8
15	10	00:43.9	01:00.3	00:59.0	01:19.3	01:11.0	00:57.8		00:50.3	01:00.1	01:00.1	01:00.2	00:10.3
16	<i>Mean</i>	00:53.5	01:06.3	01:09.7	01:32.8	01:12.1	01:01.1	01:06.4	00:54.4	01:04.2	01:10.5	01:07.1	<i>X</i>
17	<i>SD</i>	00:09.0	00:07.6	00:08.8	00:13.1	00:07.1	00:05.3	00:07.5	00:04.3	00:06.8	00:09.3	<i>X</i>	00:13.2
18													
19		Participant Number											
20	BAXJECT II	1	2	3	4	5	6	7	8	9	10	Mean	SD
21	1	00:49.7	01:13.7	01:25.4	01:37.6	01:04.9	00:52.2	01:01.5	00:48.1	01:10.5	00:55.4	01:05.9	00:16.2
22	2	00:49.3	00:58.9	01:21.6	01:33.9	01:08.6	00:51.9	01:00.1	00:46.6	01:04.3	00:57.6	01:03.3	00:14.8
23	3	00:53.5	00:54.1	01:02.5	01:34.5	01:02.6	00:42.7	00:54.5	00:51.0	00:59.6	00:59.7	00:59.5	00:13.7
24	4	00:55.0	01:22.7	01:10.3	01:29.7	01:14.9	00:41.1	00:51.4	00:52.3	01:02.8	00:53.3	01:03.3	00:15.6
25	5	00:45.5	01:03.4	01:08.8	01:11.9	01:01.0	00:43.4	00:51.9	00:49.6	01:00.2	00:54.9	00:57.1	00:09.6
26	6	00:40.9	00:42.4	01:06.6	01:08.6	01:03.9	00:44.8	00:53.0	00:46.6	01:04.3	00:56.0	00:54.7	00:10.7
27	7	00:38.9	00:50.1	01:17.9	01:20.4	01:03.8	00:42.7	00:47.4	00:52.2	00:55.3	01:01.8	00:57.0	00:14.0
28	8	00:43.8	00:41.0	01:03.9	01:12.3	01:10.2	00:34.7	00:58.1	00:48.1	01:06.2	01:01.6	00:56.0	00:13.2
29	9	00:37.8	00:49.3	00:57.7	01:06.8	01:00.2	00:36.2	00:47.7	00:46.0	00:48.6	00:49.1	00:49.9	00:09.5
30	10	00:38.1	00:51.7	00:55.1	01:02.8	01:01.3	00:40.5	00:46.9	00:46.3	00:53.1	00:55.2	00:51.1	00:08.2
31	<i>Mean</i>	00:45.2	00:56.7	01:09.0	01:19.9	01:05.1	00:43.0	00:53.2	00:48.7	01:00.5	00:56.5	00:57.8	<i>X</i>
32	<i>SD</i>	00:06.4	00:13.3	00:10.0	00:13.1	00:04.7	00:05.7	00:05.3	00:02.4	00:06.6	00:03.9	<i>X</i>	00:13.2

APPENDIX B: TIME DATA

	A	B	C	D	E	F	G	H	I	J	K	L	M
33													
34		Participant Number											
35	BIOSET	1	2	3	4	5	6	7	8	9	10	Mean	SD
36	1	00:41.4	00:48.3	00:37.9	01:32.5	00:43.1	00:26.7	00:37.1	00:34.1	00:33.8	00:32.6	00:42.8	00:18.5
37	2	00:33.7	00:41.1	00:42.0	01:10.1	00:37.7	00:25.1	00:34.6	00:29.7	00:35.0	00:33.3	00:38.2	00:12.3
38	3	00:31.6	00:41.9	00:42.6	01:09.6	00:42.1	00:21.2	00:32.1	00:36.6	00:41.5	00:32.6	00:39.2	00:12.7
39	4	00:32.9	00:32.7	00:37.6	01:05.3	00:49.0	00:22.0	00:26.9	00:27.2	00:35.8	00:32.1	00:36.1	00:12.6
40	5	00:30.1	00:34.0	00:47.8	01:02.5	00:43.6	00:19.1	00:28.5	00:26.3	00:37.9	00:30.5	00:36.0	00:12.5
41	6	00:31.3	00:36.7	00:30.0	00:55.1	00:38.8	00:20.5	00:27.2	00:26.5	00:35.7	00:29.9	00:33.2	00:09.4
42	7	00:29.1	00:36.9	00:31.8	01:01.4	00:37.7	00:19.3	00:38.4	00:24.5	00:34.3	00:27.2	00:34.1	00:11.4
43	8	00:28.0	00:27.3	00:27.6	00:59.0	00:41.2	00:18.9	00:28.3	00:24.1	00:38.4	00:28.7	00:32.1	00:11.4
44	9	00:28.1	00:31.9	00:23.6	00:58.2	00:40.6	00:21.8	00:25.6	00:27.1	00:37.8	00:30.9	00:32.5	00:10.8
45	10	00:28.6	00:29.0	00:30.1	00:44.6	00:42.7	00:20.0	00:26.2	00:24.1	00:34.6	00:24.5	00:30.4	00:08.0
46	<i>Mean</i>	00:31.5	00:36.0	00:35.1	01:03.8	00:41.6	00:21.5	00:30.5	00:28.0	00:36.5	00:30.2	00:35.5	X
47	<i>SD</i>	00:04.0	00:06.4	00:07.7	00:12.5	00:03.3	00:02.6	00:04.7	00:04.3	00:02.4	00:02.8	X	00:12.2
48													
49		Participant Number											
50	NEEDLES	1	2	3	4	5	6	7	8	9	10	Mean	SD
51	1	01:35.6	02:22.4	02:05.3	02:15.6	01:51.3	01:20.8	01:32.5	01:05.5	01:35.1	01:40.4	01:30.9	00:16.0
52	2	01:20.3	02:07.2	01:46.4	01:49.6	01:43.0	01:18.4	01:26.6	01:11.1	01:39.3	01:25.9	01:27.4	00:12.1
53	3	01:20.0	01:39.8	01:36.2	02:00.1	01:27.1	01:10.7	01:27.9	01:07.2	01:30.4	01:28.7	01:22.0	00:10.2
54	4	01:25.2	01:27.0	01:28.2	01:33.5	01:36.8	01:09.1	01:20.2	00:57.5	01:33.9	01:29.5	01:21.2	00:15.4
55	5	01:15.9	01:29.1	01:40.6	01:30.9	01:31.9	01:07.3	01:17.2	01:15.0	01:24.7	01:24.5	01:20.1	00:08.7
56	6	01:17.7	01:21.6	01:40.3	01:41.3	01:35.0	01:03.2	01:15.9	01:05.5	01:26.2	01:21.6	01:17.9	00:12.2
57	7	01:04.0	01:23.8	01:29.8	01:40.2	01:28.9	01:06.5	01:14.8	00:57.5	01:25.0	01:22.6	01:15.9	00:12.0
58	8	01:17.6	01:12.8	01:25.6	01:10.7	01:25.9	01:03.5	01:24.4	00:56.5	01:22.9	01:15.8	01:14.8	00:12.2
59	9	01:12.3	01:25.1		01:15.8	01:29.6	01:01.6	01:14.0	00:55.5	01:22.4	01:09.6	01:12.1	00:12.7
60	10	01:11.3	01:17.5		01:25.2	01:27.2	01:04.3	01:13.3	00:57.1	01:26.8	01:10.3	01:13.2	00:12.1
61	<i>Mean</i>	01:18.0	01:34.6	01:39.0	01:38.3	01:33.7	01:08.5	01:20.7	01:02.8	01:28.7	01:22.9	01:19.5	X
62	<i>SD</i>	00:08.5	00:22.6	00:12.8	00:19.8	00:08.1	00:06.5	00:06.7	00:06.9	00:05.7	00:09.3	X	00:12.9

APPENDIX B: TIME DATA

	A	B	C	D	E	F	G	H	I	J	K	L	M
63													
64	DUAL-VIAL TRIALS												
65													
66		Participant Number							Participant Number				
67	BAXJECT II	1	2	3	Mean	SD		BIOSET	1	2	3	Mean	SD
68	1	02:10.7	01:42.9	02:16.6	02:03.4	00:18.0		1	01:28.9	02:01.7	01:34.3	01:41.6	00:17.6
69	2	01:53.1	01:59.1	02:03.4	01:58.5	00:05.2		2	01:25.4	01:39.5	01:23.4	01:29.4	00:08.7
70	3	01:44.4	01:38.5	02:07.7	01:50.2	00:15.4		3	01:26.7	01:34.1	01:27.3	01:29.4	00:04.1
71	4	01:35.9	01:31.0	01:58.6	01:41.8	00:14.7		4	01:19.8	01:34.3	01:25.4	01:26.5	00:07.3
72	5	01:34.9	01:23.3	01:57.8	01:38.6	00:17.6		5	01:14.8	01:33.8	01:17.0	01:21.8	00:10.4
73	6	01:37.4	01:32.9	01:47.6	01:39.3	00:07.5		6	01:22.4	01:19.5	01:25.5	01:22.5	00:03.0
74	7	01:34.7	01:28.5	01:43.7	01:35.6	00:07.7		7	01:12.1	01:28.1	01:23.6	01:21.3	00:08.2
75	8	01:30.4	01:26.8	01:35.5	01:30.9	00:04.4		8	01:14.1	01:22.3	01:18.5	01:18.3	00:04.1
76	9	01:35.3	01:36.2	01:37.5	01:36.3	00:01.1		9	01:11.4	01:24.7	01:21.5	01:19.2	00:06.9
77	10	01:25.1	01:23.0	01:38.6	01:28.9	00:08.4		10	01:12.3	01:17.3	01:30.3	01:20.0	00:09.3
78	<i>Mean</i>	01:40.2	01:34.2	01:52.7	01:42.4	X		<i>Mean</i>	01:18.8	01:31.5	01:24.7	01:25.0	X
79	<i>SD</i>	00:13.1	00:10.9	00:14.2	X	00:14.6		<i>SD</i>	00:06.7	00:12.8	00:05.2	X	00:10.1
80													
81													
82	ADDITIONAL SINGLE-VIAL TRIALS												
83													
84		Participant Num.							Participant Num.				
85	BAXJECT II	9	10	Mean	SD			BIOSET	9	10	Mean	SD	
86	1	01:01.1	00:46.3	00:53.7	00:10.5			1	00:37.5	00:27.4	00:32.5	00:07.1	
87	2	00:57.7	00:51.2	00:54.4	00:04.6			2	00:35.7	00:27.9	00:31.8	00:05.5	
88	3	00:54.2	00:45.6	00:49.9	00:06.1			3	00:30.3	00:27.5	00:28.9	00:02.0	
89	4	01:02.1	00:41.1	00:51.6	00:14.8			4	00:33.8	00:24.8	00:29.3	00:06.4	
90	5		00:46.5	00:46.5	#DIV/0!			5	00:34.4	00:24.7	00:29.5	00:06.9	
91	6	00:51.8	00:43.6	00:47.7	00:05.7			6	00:35.0	00:24.5	00:29.7	00:07.4	
92	7	00:54.4	00:44.2	00:49.3	00:07.2			7	00:32.8	00:28.4	00:30.6	00:03.1	
93	<i>Mean</i>	00:56.9	00:45.5	00:50.7	X			<i>Mean</i>	00:34.2	00:26.5	00:30.3	X	
94	<i>SD</i>	00:04.1	00:03.1	X	00:06.8			<i>SD</i>	00:02.3	00:01.7	X	00:04.5	

Comments:

Cell: H5 - Baxject I (single)
This participant made multiple mistakes and continued to make mistakes during the repeated trials. Researcher stopped repeating trials after recording 8 successes to conserve supplies and for later sessions.
Cell: E6 - Baxject I (single)
Flipped device before injecting air.
Cell: D7 - Baxject I (single)
Had trouble rotating valve.
Cell: E7 - Baxject I (single)
Forgot to fill syringe with air. Self corrected.
Cell: B8 - Baxject I (single)
Valve turned the wrong way, then self corrected.
Cell: E8 - Baxject I (single)
Flipped device before injecting air.
Cell: K8 - Baxject I (single)
Forgot to fill syringe with air. Self corrected.

Cell: E9 - Baxject I (single)
Flipped device before injecting air.
Cell: H9 - Baxject I (single)
Forgot to fill syringe with air. Self corrected.
Cell: D10 - Baxject I (single)
Picked up sugar to place it on top of water/device, then self corrected.
Cell: E10 - Baxject I (single)
Flipped device before injecting air.
Cell: J10 - Baxject I (single)
Vial slipped.
Cell: K10 - Baxject I (single)
Forgot to turn valve to original position.
Cell: E11 - Baxject I (single)
Flipped device before injecting air.
Cell: E12 - Baxject I (single)
Flipped device before injecting air.

Comments:

Cell: J12 - Baxject I (single)
Forgot to swirl.
Cell: E13 - Baxject I (single)
Flipped device before injecting air.
Cell: E14 - Baxject I (single)
Forgot to fill syringe with air. Self corrected.
Cell: I14 - Baxject I (single)
Took a personal break between trials 8 and 9.
Cell: C21 - Baxject II (single)
Asked question about process.
Cell: C21 - Baxject II (single)
Incomplete fluid transfer.
Cell: F24 - Baxject II (single)
Noticed slow fluid transfer.
Cell: K24 - Baxject II (single)
Forgot to place filled syringe on table and proceeded to empty syringe into cup. Time stopped after excess air was expelled and before syringe was emptied into cup.

Cell: H28 - Baxject II (single)
Had trouble opening BSII packaging.
Cell: J28 - Baxject II (single)
Noticed slow fluid transfer.
Cell: K28 - Baxject II (single)
Had trouble opening syringe.
Cell: C30 - Baxject II (single)
Incomplete fluid transfer.
Cell: C36 - BioSet (single)
Forgot to expel excess air from syringe.
Cell: E36 - BioSet (single)
Trouble disconnecting syringe.
Cell: E37 - BioSet (single)
Forgot to expel excess air from syringe.
Cell: J38 - BioSet (single)
Excessive air in syringe.

Comments:

Cell: H39 - BioSet (single)
Minimally swirled.
Cell: H43 - BioSet (single)
Forgot to swirl.
Cell: J43 - BioSet (single)
Plunger unscrewed during extraction of fluid.
Cell: H44 - BioSet (single)
Forgot to swirl.
Cell: C51 - Needles (single)
Needed brief instructions during trial.
Cell: D51 - Needles (single)
Trouble removing needle.
Cell: F51 - Needles (single)
Inverted vial before injecting air.
Cell: K51 - Needles (single)
Forgot to fill syringe with air. Self corrected.
Cell: C52 - Needles (single)
Accidentally removed needle from syringe while uncapping. Self corrected.

Cell: B54 - Needles (single)
Trouble remembering 2nd needle.
Cell: K55 - Needles (single)
Forgot to fill syringe with air. Self corrected.
Cell: C59 - Needles (single)
Trouble opening syringe.
Cell: H60 - Needles (single)
Vial slipped. Self corrected.
Cell: J68 - BioSet (dual)
Trouble opening 10 ml syringe.
Cell: J71 - BioSet (dual)
Opened BioSet before opening 10 ml syringe.
Cell: D72 - Baxject II (dual)
Forgot to swirl.
Cell: J76 - BioSet (dual)
Opened BioSet before opening 10 ml syringe.
Cell: B90 - Baxject II (single) - extra trial
Could not extract fluid from vial.

APPENDIX C: DISQUALIFIED TRIALS

As noted in the methods section, the researcher disqualified some of the trials and asked the participants to repeat them. Examples of disqualifying device failures or procedural mistakes include:

Baxject I (single-vial trials)

- A vial slipped off the table and was lost on the floor. The participant attempted to self-correct the situation by retrieving a new vial, but the trial time was impacted by a brief search for the missing vial on the floor. This procedural mistake disqualified one trial.
- Participant turned the valve incorrectly, after injecting air into the vial, and could not extract the solution from the vial. This procedural mistake disqualified three separate trials.
- Participant stopped to ask a question concerning the order of the procedure. This procedural mistake disqualified two trials.
- Participant inverted the connected vials and injected air with the solution vial on top. This procedural mistake disqualified one trial.
- Water failed to transfer to the drug vial, though the participant followed the correct procedure. This device failure disqualified three separate trials.

Baxter II (single-vial trials)

- Participant could not extract the solution from the vial, though the participant followed the correct procedure. This device failure disqualified one trial.
- Water failed to transfer to the drug vial, though the participant followed the correct procedure. This device failure disqualified five separate trials.

Baxter II (dual-vial trials)

- Water failed to transfer to the drug vial, though the participant followed the correct procedure. This device failure disqualified seven separate trials.
- Participant could not extract the solution from the vial, though the participant followed the correct procedure. This device failure disqualified one trial.
- Participant struggled to open the 10ml syringe. This device failure disqualified one trial.

BioSet (single-vial trials)

- Participant stopped to ask a question concerning excessive air in the syringe following extraction of the solution from the vial. This procedural mistake disqualified one trial.
- Participant could not extract the solution from the vial, though the participant followed the correct procedure. This device failure disqualified one trial.

BioSet (dual-vial trials)

- Participant failed to engage (i.e., press down on the pre-filled syringe until it clicks into place) the drug vial with the pre-filled syringe, and was unable to inject the water into the vial. This procedural mistake disqualified two separate trials.

Needles

- Participant stopped to ask a question concerning injection of air into the vial. This procedural mistake disqualified one trial.
- Water failed to transfer to the drug vial, though the participant followed the correct procedure. This device failure disqualified three separate trials.

APPENDIX D: FOLLOW-UP QUESTIONS

		TOTAL	Participant Number									
			1	2	3	4	5	6	7	8	9	10
SINGLE VIAL TRIALS												
1	Which method did you like the most/least?											
	Baxject I	10	1	1	1	1	1	1	1	1	1	1
	1 (most)	0										
	2	0										
	3	9	1	1	1	1	1	1			1	1
	4 (least)	1							1			
	Baxject II	10	1	1	1	1	1	1	1	1	1	1
	1 (most)	2				1			1			
	2	8	1	1	1		1	1		1	1	1
	3	0										
	4 (least)	0										
	BioSet	10	1	1	1	1	1	1	1	1	1	1
	1 (most)	8	1	1	1		1	1		1	1	1
	2	2				1			1			
	3	0										
	4 (least)	0										
	Needles	10	1	1	1	1	1	1	1	1	1	1
	1 (most)	0										
	2	0										
	3	1								1		
	4 (least)	9	1	1	1	1	1	1	1		1	1
	Comments											
	"I put Baxject I last because the inversion and lever process is not easy to use - hard to remember steps; yes, the needles has needles, but I didn't need to remember a lot with regards to order."	1								1		

APPENDIX D: FOLLOW-UP QUESTIONS

2	What did you like about each method?										
	Baxter I	10	1	1	1	1	1	1	1	1	1
	"No needles."	9	1	1	1		1	1	1	1	1
	"After multiple repetitions I felt more comfortable."	1									1
	"Easy to mix vials."	1			1						
	"The spike is covered."	1				1					
	Baxter II	10	1	1	1	1	1	1	1	1	1
	"Easy to use."	6		1	1		1		1	1	
	"No needles."	4					1		1	1	1
	"No need to prefill syringe with air."	2					1		1		
	"Automatic fluid transfer preferred over BJI."	1									1
	"Easier to use than BJI, but still more steps than with BioSet."	1	1								
	"Easy to fill syringe."	1				1					
	"Easy to mix vials."	1			1						
	"No lever to mess with."	1					1				
	BioSet	10	1	1	1	1	1	1	1	1	1
	"Easy to use."	5	1		1		1			1	
	"Least amount of steps."	4	1	1		1				1	
	"No needles."	3	1				1			1	
	"Least amount of parts."	2		1		1					
	"No alcohol."	2					1		1		
	"No vial caps or vials."	2							1		1
	"Feels cleaner - sterile from factory and no need to wipe."	1									1
	"Hard to mess up."	1							1		
	"No need to prefill syringe with air."	1					1				
	Needles	10	1	1	1	1	1	1	1	1	1
	Nothing / don't like	7	1	1			1	1	1		1
	"Very straightforward."	1							1		
	"Hard to mess up."	1							1		
	"Easy to put into the syringe."	1				1					
	"Less likely to get a mechanical problem."	1			1						

APPENDIX D: FOLLOW-UP QUESTIONS

3	What would you change about each method?										
	Baxject I	10	1	1	1	1	1	1	1	1	1
	"The position of the lever can be confusing."	4				1		1	1		1
	"Remove the lever."	3			1		1			1	
	"Simplify steps."	2	1				1				
	"A little hard to screw and unscrew."	1		1							
	"Difficult to open vial caps."	1									1
	"Difficult to remember 1/4 turn of valve at end."	1									1
	"It was difficult to remember to inject air."	1									1
	"There was too much play in water vial to spike (it felt like it would shoot off when injected with air)"	1									1
	"Vials tended to snap in crooked."	1									1
	Baxject II	10	1	1	1	1	1	1	1	1	1
	Nothing	6	1	1	1		1		1		1
	"Difficult to open vial caps."	1									1
	"Inverting to withdraw the solution."	1							1		
	"Reduce the number of steps."	1			1						
	"The packaging seemed difficult to remove and pulled off the blue cap once."	1					1				
	BioSet	10	1	1	1	1	1	1	1	1	1
	Nothing	5	1	1	1			1		1	
	"Didn't always hear snap at end of spiking w/ 5ml syringe."	2							1		1
	"Syringe needs bigger flange for a more comfortable injection."	2				1					1
	"The top/cap was difficult to remove."	2					1		1		
	"Syringe too small to retrieve all fluid."	1									1
	"The syringe was hard to hold."	1			1						
	Needles	10	1	1	1	1	1	1	1	1	1
	"Get rid of the needles."	7	1	1	1	1	1	1	1		
	"Make the needles smaller."	2	1	1							
	"Difficult to get all fluid out of the vial."	1									1
	"Difficult to open vial caps."	1									1
	"Find a way to minimize residual volume."	1					1				
	"I was worried about sticking myself."	1									1
	"It feels dirty to put my filled syringe inside the sharps container."	1									1
	"It's not intuitive to inject air into the vial."	1									1
	"Simplify steps."	1	1								
	"Use only one needle set."	1								1	

APPENDIX D: FOLLOW-UP QUESTIONS

4	Which method felt the fastest/slowest?											
	Baxter I	10	1	1	1	1	1	1	1	1	1	1
	1 (fastest)	0										
	2	0										
	3	9	1		1	1	1	1	1	1	1	1
	4 (slowest)	0										
	Not reported.	1		1								
	Baxter II	10	1	1	1	1	1	1	1	1	1	1
	1 (fastest)	2				1		1				
	2	7	1		1	1		1		1	1	1
	3	0										
	4 (slowest)	0										
	Not reported.	1		1								
	BioSet	10	1	1	1	1	1	1	1	1	1	1
	1 (fastest)	9	1	1	1	1	1	1		1	1	1
	2	1						1				
	3	0										
	4 (slowest)	0										
	Needles	10	1	1	1	1	1	1	1	1	1	1
	1 (fastest)	0										
	2	0										
	3	0										
	4 (slowest)	10	1	1	1	1	1	1	1	1	1	1
5	Additional comments?											
	None	5	1			1	1		1	1		
	"BioSet had the fewest steps which was good, but Baxter II was the easiest to use."	1			1							
	"Less chance for error with BioSet - for example, you can't start with the wrong vial."	1									1	

APPENDIX D: FOLLOW-UP QUESTIONS

DUAL VIAL TRIALS									
1	Which method did you like the most/least?								
	Baxter II	3	1	1	1				
	1 (most)	1		1					
	2 (least)	2	1		1				
	BioSet	3	1	1	1				
	1 (most)	2	1		1				
	2 (least)	1		1					
2	What did you like about each method?								
	Baxter II	3	1	1	1				
	"Easier package to open."	1	1						
	"Easy to understand and use properly."	1	1						
	"Easy to use."	1			1				
	"It seemed to be easier to use when combining two products."	1		1					
	BioSet	3	1	1	1				
	"Easy to use."	2	1		1				
	"Easy for anyone to use properly."	1	1						
	"I liked the prefilled syringe."	1			1				
	"Less supplies."	1	1						
3	What would you change about each method?								
	Baxter II	3	1	1	1				
	"Didn't work as reliably as BioSet."	1		1					
	"Nothing."	1			1				
	"Using the vials requires taking off the caps."	1		1					
	BioSet	3	1	1	1				
	"Change the syringe to plastic from glass."	1	1						
	"Nothing."	1			1				
	"Screwing on the plunger."	1		1					
	"Using two different syringes."	1		1					

APPENDIX D: FOLLOW-UP QUESTIONS

4	Which method felt the fastest/slowest?								
	Baxter II	3	1	1	1				
	1 (fastest)	1		1					
	2 (slowest)	2	1		1				
	BioSet	3	1	1	1				
	1 (fastest)	2	1		1				
	2 (slowest)	1		1					
5	Additional comments?								
	"BioSet would be even faster if you didn't have to switch the syringes."	1		1					
	"Both were very easy to use and better than taking the chance of getting stuck with a needle."	1			1				

APPENDIX E: PROTOCOL

OVERVIEW

This is a comparative-time study of four different techniques for reconstituting anti-hemophilic factor—Baxject I, Baxject II, Bayer BIO-SET, and conventional vial-to-vial transfer with needles.

PARTICIPANTS

Baxter will handle the recruitment effort and will use a mix of employees and employee referrals as participants. The participants will be tested in groups of four, or less, over a two-day period.

Single-vial trials - Twelve participants will reconstitute 40 vials (10 vials with each of the 4 devices)

Dual-vial trials - Four participants will reconstitute 40 vials in sets of 2 (20 vials with Baxject II and 20 vials with BioSet)

We may reuse four of the participants from the Single-vial trials for the Dual-vial trials of the study.

SCHEDULE (PROVISIONAL)

Wednesday, July 27, 2005	Thursday, July 28, 2005
9AM – 1PM Four participants,	9AM – 1PM Four participants,
1PM - 5PM Four participants	1PM - 5PM Four participants

METHODS

Videotapes and timing:

We will use four cameras to record up to four participants per session and then review the tapes back at the office to gather the timing data. Timing data for each trial starts when the participant receives directions to reconstitute a vial or vials and ends when the participant places the filled syringe on the table. We will provide all of the video and “raw data” to Baxter.

Statistics and findings:

We will analyze/summarize the data with descriptive statistics (means/ standard deviations, etc.) and with analysis of variance (ANOVA) to test whether or not there are significant differences between products in the time it takes for reconstitution.

Results to be provided in a short report that contains the timing data, the questionnaire data, and any suggestions that Design Science has for improving Baxject II. In addition, we will indicate which claims the data can support.

PROCEDURE

Single-vial trials:

1. Participants will receive instructions, watch a demonstration of each of the four methods (devices), and demonstrate use of each of the four methods.
2. The researcher will choose devices at random and place one device with sufficient supplies on a table in front of each participant. Each participant in the room will receive a different device.
3. The researcher will instruct each participant to reconstitute one vial and place the filled syringe on the table at completion.
4. After all of the participants have reconstituted the first vial, the researcher will repeat steps two and three an additional nine times.
5. The researcher will rotate the devices on each table and repeat steps 2 through 4 until each participant reconstitutes 10 vials with each of the four devices.

Dual-vial trials:

1. Participants will receive instructions, watch a demonstration of reconstituting two vials with each of the two methods (Baxter II and BioSet), and demonstrate use of each method.
2. The researcher will systematically vary the presentation order of the devices and place one device with sufficient supplies on the table in front of each participant.
3. The researcher will instruct each participant to reconstitute two vials and place the filled syringe on the table at completion.
4. After all of the participants have completed the first trial, the researcher will repeat steps two and three an additional nine times.
5. The researcher will rotate the devices on each table and repeat steps 2 through 4 until each participant reconstitutes 20 vials with each of the two devices.

Follow-up questions:

At the completion of each session, we will ask the participants to complete a few follow-up questions.

INTRODUCTION

(5 min.)

Thank you for coming.

We are from Design Science, a consulting company helping to run this study.

We have asked you here to help us evaluate four different methods (devices) of reconstituting anti-hemophilic factor. I will initially be showing you how to use each device, and when you are comfortable, I will ask you to use each one 10 times. Primarily, we want to see how long each method takes to reconstitute anti-hemophilic factor. In addition, we want to know how intuitive the devices are, what works, and what does not. If there is anything that does not make sense, we will try to improve it.

Here is what we plan to do during the 4 hr you are with us today:

1. A general rule: Please do not touch anything—none of the devices—until I give you a specific instruction. We have to go step-by-step, in a specific order.
2. Activities we will do:
 - a. I will ask you to reconstitute 10 vials with four different methods (devices).
 - b. At the end, I will ask you for your overall impressions.

3. Remember, we will not be testing your abilities.

- a. It is important not to rush; we want you to proceed through each task in a comfortable pace.
- b. If you have some trouble understanding something, the fault lies with its design—not with you.

Again, I will be giving you specific instructions. It is important that you proceed “step by step.”

FORMS

(5 min.)

Before we begin, we have some forms for you to sign.

- a. One is a non-disclosure form. Signing it means you promise not to tell anyone about devices you have seen today.
- b. The other is a video release. Signing it gives us permission to videotape this session, so long as none of the footage is ever made public.

INSTRUCTIONS/DEMONSTRATIONS

(20 min.)

Baxject I

Baxject II

BioSet

Needles

TRIALS

(3 hours)

[Note to researcher: Choose devices (at random for single-vial trials and systematically for dual-vial trials) and place one device with sufficient supplies on the table in front of each participant. Each participant in the room should receive a different device (when possible).]

Here is the first device you will use today. We will be timing each trial to see how long it takes the average person to reconstitute a vial with each device. Since we will be timing, please do not touch anything until I instruct you to do so. I will have all of you start together.

In a moment, I will ask you to start. When you finish filling the syringe, place the syringe on the table and wait for further instructions.

Each of you has received a different device to start with; so do not worry if the person next to you finishes before or after you do (different devices may require different amounts of time).

[After all of the participants have completed the first trial, repeat the process an additional nine times. Then, rotate the devices on each table and repeat again until each participant reconstitutes 10 vials (20 for dual-vial trials) with each of the devices.]

FOLLOW-UP QUESTIONS

(5 min.)

1. Overall, which method did you like the most and which did you like the least? Please rank the 4 methods from the one you like the most (1) to the one you like the least (4).

[most 1 2 3 4 least]

___ Baxject I ___ Baxject II ___ BioSet ___ Needles

Comments:

2. For each of the 4 methods, summarize for me what you liked about them.

Baxject I
Baxject II
BioSet
Needles

3. For each of the 4 methods, summarize for me what you would change if you could.

Baxject I
Baxject II
BioSet
Needles

4. Which method felt the fastest and which felt the slowest? Please rank the 4 methods from the fastest (1) to the slowest (4).

[fastest 1 2 3 4 slowest]

___ Baxject I ___ Baxject II ___ BioSet ___ Needles

Comments:

Do you have any additional feedback for us?

Comments:

That is the end of the session. Thank you for your time today.

APPENDIX F: VERBAL & WRITTEN INSTRUCTIONS

VERBAL INSTRUCTIONS

Also used by the researcher during demonstrations

BioSet (single-vial trials)

1. Open the drug vial by pressing both thumbs into the side of the cap. However, the cap may also be rotated if that feels easier.
2. Break-off the cap from the pre-filled syringe.
3. Attach the syringe to the drug vial.
4. Press down on the syringe, until it clicks into place, to engage the vial.
5. Attach the plunger to the pre-filled syringe.
6. Press down on the plunger to inject the water.
7. After the water transfers, swirl for 2-3 seconds. Do not wait for the powder to dissolve completely.
8. Invert the vial so the solution is on the top.
9. Pull back on the plunger to retrieve the solution.
10. Unscrew the syringe and expel any excess air while holding the syringe in an inverted position.
11. Place the filled syringe on the table and wait for everyone else to finish.

Baxject I (single-vial trials)

1. Open syringe packaging.
2. Remove caps from vials.
3. Open alcohol pack and swab the top of each vial.
4. Remove backing from packaging.
5. With the device still in the packaging, press the device down onto the water vial.
6. Lift, to remove the remaining packaging.
7. Invert the device/water vial and press the device down onto the drug vial.
8. After the water transfers, swirl for 2-3 seconds. Do not wait for the powder to dissolve completely.
9. Rotate the valve lever down towards the solution.
10. Fill the syringe with approximately 6ml of air.
11. Attach the syringe to the device and inject the air into the vial.

12. While holding the plunger in a depressed position, invert the vials so the solution is on the top.
13. Release the plunger and pull back to retrieve the solution.
14. While holding the plunger back, rotate the valve lever back to its original position.
15. Unscrew the syringe and expel any excess air while holding the syringe in an inverted position.
16. Place the filled syringe on the table and wait for everyone else to finish.

Baxject II (single-vial trials)

1. Open syringe packaging.
2. Remove caps from vials.
3. Open alcohol pack and swab the top of each vial.
4. Remove backing from packaging.
5. With the device still in the packaging, press the device down onto the water vial.
6. Lift, to remove the remaining packaging.
7. Invert the device/water vial and press the device down onto the drug vial.
8. After the water transfers, swirl for 2-3 seconds. Do not wait for the powder to dissolve completely.
9. Attach the syringe to the device.
10. Invert the vials so the solution is on the top.
11. Pull back on the plunger to retrieve the solution.
12. Unscrew the syringe and expel any excess air while holding the syringe in an inverted position.
13. Place the filled syringe on the table and wait for everyone else to finish.

Needles

1. Open syringe packaging.
2. Remove caps from vials.
3. Open alcohol pack and swab the top of each vial.
4. Rotate packaging on the double-ended needle and pull apart to expose the needle.
5. Press the needle down into the water vial.
6. Lift, to remove the remaining packaging.
7. Invert the needle/water vial and press the needle down into the drug vial.
8. After the water transfers, swirl for 2-3 seconds. Do not wait for the powder to dissolve completely.
9. Remove the water vial and place the double-ended needle into the sharps container.
10. Fill the syringe with approximately 6ml of air.
11. Rotate the packaging on the filter needle and pull apart to expose the connection part.

12. Attach the syringe to the needle.
13. Insert the needle and inject the air into the vial with the solution.
14. While holding the plunger in a depressed position, invert the vial so the solution is on the top.
15. Release the plunger and pull back to retrieve the solution. Tilting the vial may be necessary to remove the remaining solution, but do not worry about removing all of the solution.
16. Remove the needle from the vial and insert the needle into the "needle remover" on the sharps container. Rotate the syringe to unscrew the needle.
17. Expel any excess air while holding the syringe in an inverted position.
18. Place the filled syringe on the table and wait for everyone else to finish.

BioSet (dual-vial trials)

1. Vial 1

- a. Open the drug vial by pressing both thumbs into the side of the cap. However, the cap may also be rotated if that feels easier.
- b. Break-off the cap from the pre-filled syringe.
- c. Attach the syringe to the drug vial.
- d. Press down on the syringe, until it clicks into place, to engage the vial.
- e. Attach the plunger to the pre-filled syringe.
- f. Press down on the plunger to inject the water.
- g. After the water transfers, swirl for 2-3 seconds. Do not wait for the powder to dissolve completely.

2. Vial 2 - *repeat above procedure*

3. Extract solution

- a. Unscrew pre-filled syringe from vial 1 and attached 10 ml B-D syringe.

- b. Invert the vial so the solution is on the top.
 - c. Pull back on the plunger to retrieve the solution.
 - d. Repeat a through c for vial 2.
4. Unscrew the syringe and expel any excess air while holding the syringe in an inverted position.
5. Place the filled syringe on the table and wait for everyone else to finish.


Baxject II (dual-vial trials)

1. Open syringe packaging.
2. Remove caps from vials.
3. Open alcohol pack and swab the top of each vial.
4. Vial 1
 - a. Remove backing from packaging.
 - b. With the device still in the packaging, press the device down onto the water vial.
 - c. Lift, to remove the remaining packaging.
 - d. Invert the device/water vial and press the device down onto the drug vial.
 - e. After the water transfers, swirl for 2-3 seconds. Do not wait for the powder to dissolve completely.
5. Vial 2 - *repeat step 4*
6. Extract solution.
 - a. Attach the syringe to the first device.


- b. Invert the vials so the solution is on the top.
 - c. Pull back on the plunger to retrieve the solution.
 - d. Unscrew syringe and repeat a through c for vial 2.
7. Unscrew the syringe and expel any excess air while holding the syringe in an inverted position.
8. Place the filled syringe on the table and wait for everyone else to finish.

WRITTEN INSTRUCTION


Attachment 1
Instructions for Needle Reconstitution




- Remove one end of double needle cap.
- Insert exposed needle through center of diluent stopper.




- Remove case from needle.




- Insert exposed needle end through center of product stopper.
- Product vial vacuum draws diluent into vial.




- Swirl to dissolve powder.
- Determine dissolution time from diluent flow stop to essentially clear liquid.



- Hold for 2.5 to 3 hours at room temperature.
- Remove diluent vial; needle remains in product vial.
- Remove needle from product vial.



- Attach 100 filter needle to syringe; draw ~5ml air into syringe.
- Insert needle through center of stopper; inject air.




- Invert system; withdraw solution from stopper well.


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Instructions for BAXJECT NTD Use




- Peel off package lid without touching the inside.
- Do not remove the device from the package.




- With the diluent vial on a flat surface, turn the BAXJECT NTD package over and insert the transparent spike through the diluent stopper.
- Grip package edge and pull off the BAXJECT NTD.




- With the concentrate vial on a flat surface, turn the system over so diluent vial is on top and insert the white spike through the concentrate stopper.
- Vacuum draws the diluent into the concentrate vial.




- Swirl gently until product is completely dissolved.
- Hold for 2.5 to 3 hours at room temperature.



- Turn handle down towards the concentrate vial.
- Remove protector cap.



- Remove Luer protector if present. Pull syringe plunger back to approx. 25 ml.
- Connect syringe to hand Luer connector and push plunger in to pressurize system.



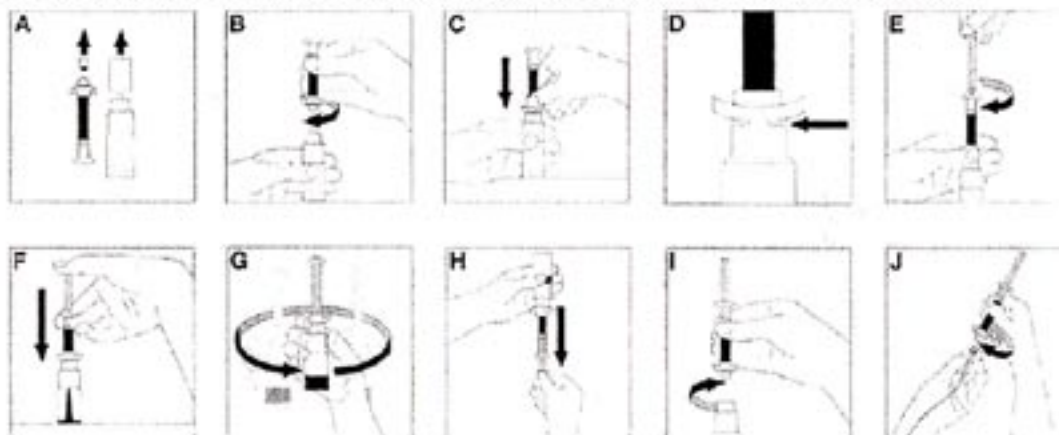
- Hold plunger in place while drawing system to have concentrate vial on top.
- Aspirate concentrate into the syringe.
- Hold plunger in extended position while turning handle to the closed (horizontal) position.
- Disconnect syringe.

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WRITTEN INSTRUCTION

1. Wash hands thoroughly using soap and warm water. Ensure you prepare the solution on a clean and dry surface.
2. Warm the unopened powder vial and the solvent syringe in your hands to approximately body temperature (do not exceed 37 °C). Wipe any observable moisture from the vial.
3. Remove the cap from the powder vial by gently moving it from side to side several times, whilst at the same time pulling upwards. Remove the stopper attached to the white cap from the syringe (A).
4. Gently screw the syringe on to the powder vial (B).
5. Place the vial on a rigid, non-slip surface and hold it firmly with one hand. Then, strongly press down the fingerplate near the syringe tip using your thumb and index finger (C) until the fingerplate meets the top edge of the Bio-Set. This indicates that the system is activated (D).
6. Connect the plunger rod to the syringe by screwing it into the rubber stopper (E).
7. Inject the solvent by slowly pushing the syringe's plunger down (F).
8. Dissolve the powder by gently swirling the vial. Do not shake the vial! Ensure that the powder is completely dissolved before use. Do not use solutions that contain visible particles or that are cloudy (G).
9. Invert vial/syringe and transfer the solution into syringe by drawing the plunger out slowly and smoothly (H). Ensure that the entire contents of the vial are drawn into the syringe.



WRITTEN INSTRUCTION

White = Factor

Clear = Water

BAXJECT II

Needleless Transfer Device

Instructions for Use

Preparation:
Bring vials to room temperature. Wash hands and put on gloves. Remove vial caps. Cleanse stoppers with alcohol swab and allow to dry.

Reconstitution

A

Peel off lid without touching the device.
DO NOT REMOVE DEVICE FROM PACKAGE.

B

Place vials on flat surface.
1. Turn device package over.
2. Press **DOWN** to insert the **CLEAR** spike through the water stopper.

C

Grip package at its edge and remove from device.
DO NOT TOUCH EXPOSED WHITE SPIKE.

D

1. Turn system over so **WATER** vial is on **TOP**.
2. Press **DOWN** to insert the **WHITE** spike through the **FACTOR** stopper.
(Note: Vacuum will draw the water into the factor vial.)

If water does not transfer, turn page over for recovery instructions. Otherwise continue to step E.

E

Swirl gently until factor is completely dissolved.
DO NOT SHAKE

F

1. Remove blue cap from device.
2. Remove syringe cap, if present.
3. Connect syringe to device.
DO NOT INJECT AIR

G

1. Turn system over so **FACTOR** vial is on top.
2. **SLOWLY** pull plunger back to transfer factor into syringe.
Disconnect syringe.

For multiple bottle pooling (use with large syringe):

- Mix all factor bottles as directed in steps A through E.
- Follow steps F and G to draw from each factor bottle into the large syringe.

Dispose of the Baxject II system as directed by your clinician.

Baxter