ASSESSMENT OF TESTING METHOD FOR CLOSED SYSTEM TRANSFER DEVICES ACROSS VAPOR RELEASE

Study Product:

B. Braun Onguard with Tevadaptor
BD PhaSeal™
CareFusion VialShield
Equashield by Equashield LLC
ICU Medical ChemoClave
ICU Medical ChemoLock

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Study Summary

Title	*ASSESSMENT OF TESTING METHOD FOR CLOSED SYSTEM TRANSFER DEVICES ACROSS VAPOR RELEASE*
Short Title	*Vapor Release Report*
Methodology	*Testing Based on NIOSH Proposed Vapor Testing*
Study Center(s)	*Nebraska Methodist Hospital*
Objectives	*To assess the 'Closeness' of various Closed System Transfer Devices across NIOSH Vapor Release Test*
Study Products	*B. Braun Onguard with Tevadaptor* *BD PhaSeal™* *CareFusion VialShield* *Equashield by Equashield LLC* *ICU Medical ChemoClave* *ICU Medical ChemoLock*

1 Introduction

Recently, the number of marketed Closed System Transfer Device (CSTD) models has increased. Interest in development of a CSTD performance test protocol originated from within the healthcare industry itself, with requests for an independently-developed containment test protocol. Additionally, in view of the upcoming USP-800 mandating the use of closed systems for administration, proper evaluation of CSTD connectors is essential since vast majority of administration procedures involves exclusively the use of CSTD connectors.

Several studies exist that evaluate the safety and efficacy data since the inception of Closed System Transfer Devices. Safety of CSTD is often shown by its ability to adhere to NIOSH definition of a CSTD. NIOSH defines a CSTD as a device that mechanically prohibits the transfer of environmental contaminants into a system and the escape of hazardous drug or vapor concentrations outside the system. NIOSH definition can be summarized that a device is a CSTD if it is Leak-proof and airtight. *Until November of 2015, a standard method of evaluation of the 'Airtightness' of a CSTD did not exist. NIOSH introduced a draft protocol titled, "A Vapor Containment Performance Protocol for Closed System Transfer Devices Used during Pharmacy Compounding and Administration of Hazardous Drugs." This protocol will test CSTDs per this draft protocol.*

2 Study Objectives

Objective of this study was to test 6 different CSTD devices to assess the testing method and how the results match up with CSTD manufacturer's claims of being able to contain alcohol and its vapor. CSTDs will be tested to the NIOSH vapor release protocol as per table below.

Table 1: CSTD Study Plan

CSTD Brand	NIOSH Vapor Test
Onguard	Y
PhaSeal	Y
VialShield	Y
Equashield	Y
ChemoClave	Y
ChemoLock	Y

3 Study Design

3.1 NIOSH Vapor Study

Vapor study was performed as per NIOSH draft Protocol CDC-2015-0075-003. The study involves simulation of dose preparation as prescribed in the protocol with 8 sets of device tested per CSTD user group. Total of 48 unique data points will be generated, 8 per CSTD type, in compliance with the protocol

4 Supplies Used

4.1 Supplies for NIOSH Vapor Study

Testing equipment:
In accordance to NIOSH Protocol including: analyzer Miran SapphIRe model 205B-XL; Secador® Techni-dome® 360 Vacuum Desiccator with (12-in) extension ring outfitted with glove ports and gloves; custom assembly of pipe system with filters, fittings for connecting and basis for test chamber.
In Addition, Miran SapphIRe field performance check kit Ref: CR014LG for span check and calibration.

Products used for testing:

Item	Product Code	Quantity
PhaSeal Vial Adaptor	P50	16
PhaSeal Syringe Adapter	N35	16
PhaSeal Bag Spike	C100	4
PhaSeal Patient Connector	C35	4
Equashield Vial Adaptor	VA-20/2	16
Equashield Syringe Unit	SU-60/2	16
Equashield Bag Spike	SA-1	4
Equashield Patient Connector	LL-1	4
ChemoClave Genie	CH-77	16
ChemoClave Spiros	CH2000S	16
ChemoClave Bag Spike	CH-12	4
ChemoClave Patient Connector	C1000	4
ChemoLock Vial Adaptor	CL-80	16
ChemoLock Syringe Adaptor	CL-2000S	16
ChemoLock Bag Spike	CL-12	4
ChemoLock Patient Connector	CL-2100	4
CareFusion VialShield	MV0520	16
CareFusion Texium	10012241-0500	16
CareFusion Bag Spike	10013365	4
CareFusion Patient Connector	2000E	4
Tevadaptor Vial Adaptor	412111	16
Tevadaptor Syringe Adaptor	412118	16
Tevadaptor Bag Spike	412113	4
Tevadaptor Patient Connector	412114	4
BD 60mL Syringe	309653	82
19 G Needle	305186	2
Baxter 500 mL 0.9% NaCl Bag	FE1323D	48
Amsino IV Tubing Set	108306	24
Vials with 50mL 70% IPA	-	96

5 Study Procedures

Each section below will outline specific procedures for each of the 3 components of this protocol.

5.1 Study Procedure for NIOSH Vapor Test

Span check / calibration performed using original Miran SapphIRe field performance check kit Ref: CR014LG, with Nitrous Oxide and Sulfur Hexafluoride gases.

Leak test for the test chamber was performed according to NIOSH protocol.

Before the start of each task, the background concentration of IPA vapor inside the room was measured and all testing starting conditions were created in accordance to NIOSH protocol, including ventilation and zeroing. A complete CSTD brand test evaluation included four repetitions of paired sequential tasks, identified as Task 1 and Task 2. Within each paired task repetition, Task 1 procedures were conducted first, followed by Task 2.

Task 1 procedure: Prepare 500 mL 0.9% sodium chloride IV bag with 90 mL of 70% IPA vials using 45 mL transfers
Summary Description of Task 1: To simulate reconstitution, withdraw 45 mL of 70% IPA from Vial 1 and inject into Vial 2 (for a total volume of 95 mL in Vial 2). Swirl the 70% IPA in Vial 2 to simulate reconstitution. Withdraw 90 mL of 70% IPA from Vial 2 in 45 mL increments using the two 60 mL syringes with syringe adapters (or connectors). Inject both the syringes into the 500 mL 0.9% sodium chloride IV bag through the bag adapter. Label the bag and place in a Ziploc bag.

Task 1 Procedures: Assemble the following supplies, and place into small supply trays for each test run:

- 2 × septum-capped vial containing 50 mL of 70% IPA, labeled 1 and 2
- 2 × 60 mL syringes, labeled 1 and 2
- 1 × 500 mL 0.9% sodium chloride IV bag
- 2 × CSTD vial adapters
- 2 × CSTD syringe adapters
- 1 × CSTD bag adapter

1. Place the supplies into the environmental test chamber, close chamber, and position spring-loaded hand clamps onto environmental test chamber to create a tight chamber seal.
2. Monitor and record every change in IPA detector reading for background IPA concentrations within the test chamber.
3. Record every change in IPA detector reading for each of the following CSTD use events:
   Event 1: Attaching vial adapters
Event 2: Mate 1st syringe with vial
Event 3: Removing alcohol from Vial 1
Event 4: Mate syringe 2 with vial 2
Event 5: Injecting alcohol from syringe 1 into Vial 2
Event 6: Withdrawing syringe 1 from Vial 2
Event 7: Withdrawing syringe 2 from vial 2
Event 8: Injecting syringe 1 into bag
Event 9: Injecting syringe 2 into bag
4. Attach one vial adapter to each of the two vials of 70% IPA. Pause for 30 seconds or until the IPA detector stabilizes to allow the instrument to detect to any leakage.
5. Attach one IV bag adapter to the administration port of one 500 mL 0.9% sodium chloride IV bag.
6. If specific CSTD (such as PhaSeal) requires, draw 45 mL of air into the 60 mL Syringe 1.
7. Attach one syringe adapter to 60 mL Syringe 1.
8. Mate the 60 mL Syringe 1 to 70% IPA Vial 1 using the CSTD connectors. Pause for 30 seconds or until the IPA detector stabilizes.

9. (Inject air into Vial 1 if specific CSTD, such as PhaSeal, requires); withdraw 45 mL of 70% IPA from Vial 1 and disconnect the syringe adapter from the vial adapter. BE SURE not to disconnect the syringe from the CSTD syringe adapter! Pause for 30 seconds or until the IPA detector stabilizes.
10. Set Vial 1 aside; it now contains 5 mL of 70% IPA.
11. Mate Syringe 1 containing 45 mL of 70% IPA to Vial 2 using the CSTD connectors. Pause for 30 seconds or until the IPA detector stabilizes.
12. Inject 45 mL of 70% IPA into Vial 2. If specific CSTD, such as PhaSeal, requires invert the vial and withdraw 45 mL of air from Vial 2 into the Syringe 1. There should be 95 mL of 70% IPA in Vial 2. Leave Syringe 1 connected. Pause for 30 seconds or until the IPA detector stabilizes.
13. Disconnect Syringe 1 from Vial 2. Pause 30 seconds or until the IPA detector stabilizes.
14. Swirl Vial 2.
15. Reconnect Syringe 1 to Vial 2 (if specific CSTD, such as PhaSeal, requires inject the 45 mL of air into Vial 2) and withdraw 45 mL of 70% IPA; disconnect Syringe 1 with the CSTD attached. Pause for 30 seconds or until the IPA detector stabilizes.
16. Mate the syringe adapter to the IV bag adapter; inject the 45 mL of 70% IPA. Pause for 30 seconds or until the IPA detector stabilizes.
17. Disconnect at the syringe adapter from the IV bag adapter and set the syringe aside. Syringe 1 will now contain no air and no liquid, and it is closed. Pause for 30 seconds or until the IPA detector stabilizes.
18. Select 60 mL Syringe 2, (if specific CSTD, such as PhaSeal, requires draw 45 mL of air into syringe) and attach the second syringe adapter.
19. Mate Syringe 2 with Vial 2 using the CSTD connectors. Pause for 30 seconds or until the IPA detector stabilizes.
20. If specific CSTD, such as PhaSeal, requires inject air into Vial 2 and withdraw 45 mL of 70% IPA using Syringe 2. Pause for 30 seconds or until the IPA detector stabilizes.
21. Disconnect syringe adapter from the vial adapter. Pause for 30 seconds or until the IPA detector stabilizes.
22. Mate Syringe 2 with the 500 mL 0.9% sodium chloride IV bag using the CSTD connectors; inject the 45 mL of 70% IPA. IV bag now contains 90 mL of IPA and a CSTD adapter (with overfill ~640 mL). Pause for 30 seconds or until the IPA detector stabilizes.
23. Remove Syringe 2 by disconnecting between the adapters (i.e., Syringe 2 and bag adapters). Pause for 30 seconds or until the IPA detector stabilizes.

Task 1 is now complete. Note the stop time, then open the environmental test chamber and remove all supplies and trays. Allow the IPA detector to stabilize to background before proceeding to Task 2.

Task 2: Prepare 45 mL 70% IPA in 60 mL syringes for IV push and Y-site administration

Summary Description of Task 2: Task 2 has two parts, simulating drug reconstitution followed by an IV push of the reconstituted drug. To simulate drug reconstitution, withdraw 45 mL of 70% IPA from Vial 3 and inject into Vial 4 (95 mL total volume in Vial 4). Swirl the 70% IPA in Vial 3 to simulate reconstitution then withdraw 90 mL of 70% IPA from Vial 4 in 45 mL increments using two 60 mL syringes with CSTD adapters. For simulating the IV push, inject each syringe dose into the Y-site of the IV tubing.

Task 2 Procedures: Prepare IV setup prior to administrating the IV dose to save space inside the environmental test chamber. Insert the bag spike on the IV administration tubing into the administration port of the IV bag. Close the roller clamp on the IV tubing. Attach one non vented luer lock cap to the end of the IV tubing to prevent IPA leakage.

Assemble the following supplies and place into small supply trays for each test run:

- 2 × 50 mL vials of 70% IPA, labeled 3 and 4
- 2 × 60 mL syringes, labeled 3 and 4
- 2 × CSTD vial adapters
- 2 × CSTD syringe adapters
- 1 × CSTD IV push adapter

- 1 × CSTD bag adapter
- 1 × 500 mL 0.9% sodium chloride IV bag. **Use a new bag; DO NOT use the same bag from Task 1.**
- IV administration tubing with at least one needleless Y-site
- Luer lock cap

1. Place the supplies into the environmental test chamber, close chamber, and position spring-loaded hand clamps onto environmental test chamber to create a tight chamber seal.
2. Monitor and record every change in IPA detector reading for background IPA concentrations within the test chamber.
3. Record every change in IPA detector reading for each of the following CSTD use events:
   Event 1: Attaching vial adapters

Event 2: Mate 1st syringe with vial
Event 3: Removing alcohol from Vial 1
Event 4: Mate syringe 2 with vial 2
Event 5: Injecting alcohol from syringe 1 into Vial 2
Event 6: Withdrawing syringe 1 from Vial 2
Event 7: Withdrawing syringe 2 from vial 2
Event 8: Injecting syringe 1 into IV line
Event 9: Injecting syringe 2 into IV line

4. Attach one vial adapter to each of the two vials of 70% IPA. Pause for 30 seconds or until the IPA detector stabilizes to allow the instrument to detect to any leakage.
5. Attach one IV bag adapter to one 500 mL 0.9% sodium chloride IV bag.
6. If specific CSTD, such as PhaSeal, requires draw 45 mL of air into 60 mL Syringe 3.
7. Attach one syringe adapter to this 60 mL Syringe 3.
8. Mate the 60 mL Syringe 3 to Vial 3 using the CSTD connectors. Pause for 30 seconds or until the IPA detector stabilizes.
9. (If specific CSTD, such as PhaSeal, requires inject air into Vial 3); withdraw 45 mL of 70% IPA from Vial 3 and disconnect the syringe adapter from the vial adapter. **BE SURE not to disconnect the syringe from the CSTD syringe adapter!** Pause for 30 seconds or until the IPA detector stabilizes.
10. Set Vial 3 aside—it now contains 5 mL of 70% IPA.
11. Mate Syringe 3 with 45 mL of 70% IPA to Vial 4 using the CSTD connectors. Pause for 30 seconds or until the IPA detector stabilizes.
12. Inject 45 mL of 70% IPA into Vial 4. If specific CSTD, such as PhaSeal, requires invert the vial and withdraw 45 mL of air from Vial 4 into the Syringe 3 (Syringe 3 now has 45 mL of air in it and there should be 95 mL of 70% IPA in Vial 4). Leave syringe connected. Pause for 30 seconds or until the IPA detector stabilizes.
13. Disconnect Syringe 3 from Vial 4. Pause 30 seconds or until the IPA detector stabilizes.
14. Swirl Vial 4.
15. Reconnect Syringe 3 to Vial 4 (If specific CSTD, such as PhaSeal, requires inject the 45 mL of air into Vial 4) and withdraw 45 mL of 70% IPA; disconnect Syringe 3 with the CSTD attached. This syringe now contains 45 mL of 70% IPA to administer later into the IV administration set. Pause for 30 seconds or until the IPA detector stabilizes.
16. If specific CSTD, such as PhaSeal, requires draw 45 mL of air into 60 mL Syringe 4 and attach the syringe adapter.
17. Mate Syringe 4 with Vial 4 using the CSTD connectors. Pause for 30 seconds or until the IPA detector stabilizes.
18. (If specific CSTD, such as PhaSeal, requires inject air into Vial 4)d withdraw 45 mL of 70% IPA using Syringe 4. Pause for 30 seconds or until the IPA detector stabilizes.
19. Disconnect syringe adapter from the vial adapter. Syringe 4 now contains 45 mL of 70% IPA to administer later into the IV administration set. Pause for 30 seconds or until the IPA detector stabilizes.
20. Check that the roller clamps on IV administration tubing are closed, including the ones to the Y-site and below.
21. Take the cover off the spike of the IV administration tubing and open the infusion port on the bag adapter of the 500 mL 0.9% sodium chloride IV bag.

22. Insert the tubing spike into the port of the bag adapter affixed to the 500 mL 0.9% sodium chloride IV bag. Pause for 30 seconds or until the IPA detector stabilizes.
23. Gently squeeze the 500 mL 0.9% sodium chloride IV bag to verify there is flow into the drip chamber.
24. Attach the IV push adapter into the Y-Site. Attach Syringe 3 dose (45 mL of 70% IPA in 60 mL syringe) with syringe adapter already connected (from step 14) to the push adapter. Pause for 30 seconds or until the IPA detector stabilizes.
25. Open all IV administration tubing roller clamps below the Y-site, and push the first "syringe dose" from Syringe 3 through the IV push adapter and tubing into the 500 mL 0.9% sodium chloride IV bag until the Syringe 3 is empty. Pause for 30 seconds or until the IPA detector stabilizes.
26. Remove Syringe 3 by disconnecting between the adapters (i.e., Syringe 3 and IV push adapters). Pause for 30 seconds or until the IPA detector stabilizes.
27. Select Syringe 4 for the second "syringe dose" (45 mL of 70% IPA in 60 mL syringe) with syringe adapter already connected (from step 18) and attach it to the push adapter. Pause for 30 seconds or until the IPA detector stabilizes.
28. Push the second "syringe dose" from Syringe 4 through the IV push adapter and tubing into the 500 mL 0.9% sodium chloride IV bag until the syringe is empty. Pause for 30 seconds or until the IPA detector stabilizes.
29. Remove Syringe 4 by disconnecting between the adapters (i.e., Syringe 4 and IV push adapters). Pause for 30 seconds or until the IPA detector stabilizes.
30. Close all IV administration tubing roller clamps.

Task 2 is now complete. Note the stop time, then open the environmental test chamber and remove all supplies and trays. Allow the IPA detector to stabilize to background before proceeding with repetitions of Task 1 and Task 2 for 4 replications for each brand of CSTD.

Test both Tasks for each CSTD brand.

6 Study Results

Of the 6 commonly marketed Closed System Transfer Devices that were tested only two passed the test, BD PhaSeal and Equashield, in terms of having vapor release below 0.3 ppm that is the below the detection level of the Miran analyzer. Remaining 4 CSTDs had vapor release above 1 ppm at various times in the drug manipulation process

7 Notes

As this study was performed to evaluate the NIOSH test methodology, the Onguard/Tevadaptor, an air-cleaning-system, was also tested. This was in attempts to understand first hand why this product category was excluded from the testing protocol.

Additionally, a new source of vapor release was discovered with certain CSTDs releasing vapor when spiking the vials with respective adapters. I switched operators for each device but the result remained consistent, regardless of how vials were spiked (gently or aggressively). I discovered that slightly pressurized vials detect leaks that otherwise would remain undetected. Drugs that come in vials in liquid or powder form for reconstitution may have additional pressure within the vials based on manufacturer specifications. Pressure variances are not noted on vials, and the altitude of reconstitution may further impact pressures (i.e., Omaha, NE, which is 1,090 feet above sea level, versus Denver, CO, which starts at 5,130 feet above sea level). This pressure can cause the drug to spray out from around the needle and vial stopper interface. In our testing this overpressure affected the outcome for certain CSTDs (see report) during spiking their adapter into the vial. The overpressure disappeared after the initial spiking into the expansion balloons that most of the tested CSTDs had. After the spiking there was no overpressure effect observed. Only Equashield vial adaptor and Genie (ICU ChemoClave) do not have an expansion chamber to expand into. The Genie CSTD continued to leak well after the pressure was gone, at every compounding step. Since the Genie device is severely leaky, routinely visible during the leakage test with 5-FU, the root cause analysis removed the overpressure effect as the cause of leakage. Note that temperature changes such as IPA making vials in cold clean room and executing the test in a warm conference room may contribute to pressure differentials.

8 Appendices

Appendix I: Data summary table for NIOSH Vapor Testing
Appendix II: CareFusion Raw Data
Appendix III: Equashield Raw Data
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Appendix VI: ChemoClave Raw Data
Appendix VII: Onguard /Tevadaptor Raw Data

Appendix I: Data Collection table for NIOSH Vapor Testing

Data Summary of NIOSH Vapor Testing					
Task	**CSTD Device**	**Number of Observations above 1 ppm**	**Mean Observations (ppm)**	**Peak Level (ppm)**	**Contributing Event to Peak Level contamination**
1	Equashield by Equashield, LLC	0	<0.3	0.2	Below Detection Limit
	PhaSeal by BD	0	<0.3	0.3	Below Detection Limit
	ChemoClave by ICU Medical	4	10.48	19.1	Withdrawing Syringe 2 from vial 2
	ChemoLock by ICU Medical	1	0.85	1.3	Injecting Syringe 2 into Bag
	VialShield by CareFusion	4	11	37.5	Injecting syringe 1 into bag
	Onguard/Tevadaptor by B.Braun	4	10.55	12.8	Injecting alcohol from syringe 1 into Vial 2
2	Equashield by Equashield, LLC	0	<0.3	0.2	Below Detection Limit
	PhaSeal by BD	0	<0.3	0	Below Detection Limit
	ChemoClave by ICU Medical	4	8.23	9.1	Removing Alcohol from Vial 1
	ChemoLock by ICU Medical	1	0.75	1.2	Attaching Vial Adaptor onto Vial
	VialShield by CareFusion	4	2.28	2.7	Attaching Vial Adaptor onto Vial
	Onguard/Tevadaptor by B.Braun	4	10.35	11.4	Injecting alcohol from syringe 1 into Vial 2

Appendix II: Equashield Raw Data

Task	Device	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6	Event 7	Event 8	Event 9
Task 1	1	-	-	-	-	0.1	-	-	-	0.1
	2	-	-	0.1	-	-	-	-	-	-
	3	-	-	-	-	-	-	-	-	-
	4	-	-	-	-	-	-	0.2	-	-
Task 2	1	-	-	-	-	-	-	-	0.1	-
	2	-	-	-	-	-	-	0.1	-	0.1
	3	0.1	-	-	-	-	-	-	0.1	-
	4	-	0.1	-	-	-	0.1	0.1	0.1	0.1

NOTE: Difference in PPM Reading is captured in the table above.

Event Description:
Event 1: Attaching vial adapters
Event 2: Mate 1st syringe with vial
Event 3: Removing alcohol from Vial 1
Event 4: Mate syringe 2 with vial 2
Event 5: Injecting alcohol from syringe 1 into Vial 2
Event 6: Withdrawing syringe 1 from Vial 2
Event 7: Withdrawing syringe 2 from vial 2
Event 8: Injecting syringe 1 into bag
Event 9: Injecting syringe 2 into bag

Appendix IV: PhaSeal Raw Data

Task	Device	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6	Event 7	Event 8	Event 9
Task 1	1	-	0.1	-	-	0	0.2	0.1	-	-
	2	-	0.1	-	-	0.1	0.2	-	-	-
	3	-	0.1	-	-	0.1	0.1	0.1	0.1	0.1
	4	-	0	-	-	0.1	0.1	-	-	-
Task 2	1	-	-	-	-	-	0.1	-	-	-
	2	-	-	-	-	0	0.1	-	-	-
	3	-	-	-	-	-	-	-	-	-
	4	-	0	-	-	0	0.1	-	-	-

NOTE: Difference in PPM Reading is captured in the table above.

Event Description:
Event 1: Attaching vial adapters
Event 2: Mate 1st syringe with vial
Event 3: Removing alcohol from Vial 1
Event 4: Mate syringe 2 with vial 2
Event 5: Injecting alcohol from syringe 1 into Vial 2
Event 6: Withdrawing syringe 1 from Vial 2
Event 7: Withdrawing syringe 2 from vial 2
Event 8: Injecting syringe 1 into bag
Event 9: Injecting syringe 2 into bag

Appendix V: ChemoLock Raw Data

Task	Device	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6	Event 7	Event 8	Event 9
Task 1	1	0.5					0.2	0.2		
	2	0.9		0.1			0.1			
	3	0.4					0.1			0.1
	4	0.1		0.1			0.1			
Task 2	1	1.2					0.3		0.1	
	2	0.3		0.1			0.1			
	3	0.5					0.1			0.1
	4	0.4		0.1					0.1	

NOTE: Difference in PPM Reading is captured in the table above.

Event Description:
Event 1: Attaching vial adapters
Event 2: Mate 1st syringe with vial
Event 3: Removing alcohol from Vial 1
Event 4: Mate syringe 2 with vial 2
Event 5: Injecting alcohol from syringe 1 into Vial 2
Event 6: Withdrawing syringe 1 from Vial 2
Event 7: Withdrawing syringe 2 from vial 2
Event 8: Injecting syringe 1 into bag
Event 9: Injecting syringe 2 into bag

Appendix VI: ChemoClave Raw Data

Task	Device	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6	Event 7	Event 8	Event 9
Task 1	1	-	-	2.1	-	5.6	-	-	-	-
	2	-	-	3.2	-	1.9	1.2	-	-	-
	3	-	-	1.1	-	2	4.5	-	-	-
	4	-	-	1	-	8.3	-	-	-	-
Task 2	1	-	-	8.9	-	-	-	-	-	-
	2	-	-	7.4	-	-	-	-	-	-
	3	-	-	13.9	-	-	-	-	-	-
	4	0.4	-	0.8	-	-	-	-	1	-

NOTE: Difference in PPM Reading is captured in the table above.

Event Description:
Event 1: Attaching vial adapters
Event 2: Mate 1st syringe with vial
Event 3: Removing alcohol from Vial 1
Event 4: Mate syringe 2 with vial 2
Event 5: Injecting alcohol from syringe 1 into Vial 2
Event 6: Withdrawing syringe 1 from Vial 2
Event 7: Withdrawing syringe 2 from vial 2
Event 8: Injecting syringe 1 into bag
Event 9: Injecting syringe 2 into bag

Appendix VII: Onguard/Tevadaptor Raw Data

Task	Device	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6	Event 7	Event 8	Event 9
Task 1	1	1.2	-	0.1	-	-	9.7	-	-	-
	2	1	-	-	-	-	8.7	-	-	-
	3	2.2	-	0.1	-	-	10.6	-	-	-
	4	0	-	0.1	-	-	9.1	-	-	-
Task 2	1	1.4	-	0.1	-	-	10	-	-	-
	2	1.1	-	0.1	-	-	9.4	-	-	-
	3	1.2	-	0.1	-	-	9.2	-	-	-
	4	1	-	0.2	-	-	8.8	-	-	-

NOTE: Difference in PPM Reading is captured in the table above.

Event Description:
Event 1: Attaching vial adapters
Event 2: Mate 1st syringe with vial
Event 3: Removing alcohol from Vial 1
Event 4: Mate syringe 2 with vial 2
Event 5: Injecting alcohol from syringe 1 into Vial 2
Event 6: Withdrawing syringe 1 from Vial 2
Event 7: Withdrawing syringe 2 from vial 2
Event 8: Injecting syringe 1 into bag
Event 9: Injecting syringe 2 into bag