



# An Evaluation of Potential Liquid/Aerosol Releases from a New Retractable Syringe

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## Abstract

*This study evaluated potential liquid and/or aerosol release from the use of a retractable syringe designed to prevent accidental needlesticks. This device includes a mechanism that retracts the needle into the syringe barrel upon depression of the plunger. During activation, the possibility exists for the release of blood and/or drug solution. The syringe was tested using radiolabeled bovine serum albumin (<sup>125</sup>I) to simulate human blood and tritiated water (<sup>3</sup>H) to simulate a drug solution, allowing for the quantification of potential releases.*

*Blood release as a result of the retraction mechanism was not detected, but indications of a simulated drug release were. The quantity of the simulated drug release was directly proportional to the gauge size of the needle and was unaffected by the syringe size. Users of this product might be cautioned against the possibility of a drug release when activating the needle retraction mechanism.*

## Introduction

It has been reported that on an average day in the United States, a health care worker reports an accidental needlestick every 39 seconds (Duesman & Ross, 1998). It is also estimated that another 66% of accidental needlesticks go unreported (Duesman & Ross, 1998; Goodman, 1997). Since as many as 20 different blood-borne pathogens can be transmitted through a single needlestick and 76% of health care workers' exposure to the human immunodeficiency virus (HIV) is from accidental needlesticks and sharps injuries, this has cre-

ated a great need for technological advances in medical equipment (Duesman & Ross, 1998).

Of the 20 different blood-borne pathogens that can be transmitted through an accidental needlestick, HIV and the hepatitis B virus (HBV) are of the greatest concern. Currently, the number of persons living with HIV and HBV is over 30.6 million and 350 million worldwide, respectively. Also, the odds of a health care worker contracting HIV or HBV after an infected needlestick are 1 in 250 and 1 in 20, respectively (Duesman & Ross, 1998).

Infection control experts have tried to modify health care worker behavior in order to reduce the risk of accidental needlesticks. Although these efforts have succeeded in raising awareness, the problem remains because the devices themselves are dangerous. In such situations, engineering controls may be effective (Goodman, 1997). However, while new technology may correct existing problems, it can sometimes create new problems as well.

The first attempt to modify the syringe involved using a sheath device, often called a "hood," that would slide over the needle after use (Anonymous, 1997a). The sheath type of safety device became problematic because operating the sheath required two hands and studies have shown that two-handed safety devices may raise the risk of needlestick injuries (Anonymous, 1997a; Okada, 1997).

The purpose of this study was to evaluate a new, retractable syringe technology, first produced in February 1997. This syringe is known as the VanishPoint<sup>®</sup> Syringe and is manufactured by Retractable Technologies, Inc. (Little Elm, TX) (Figure 1). The VanishPoint<sup>®</sup> Syringe utilizes a needle that automatically re-

tracts into the barrel after injection, greatly reducing the chance of an accidental needlestick and eliminating the hazards from recapping the needle (Anonymous, 1997b). Also, since the needle retracts inside the syringe, it is impossible to reuse that needle (Retractable Technologies, 1997). A recent report noted that once the needle is retracted it couldn't be accessed without crushing the entire syringe (Cahill, 1997). Since it has been reported that there are more than 1.3 million injection drug users in the United States alone (Retractable Technologies, 1997), this technology would effectively eliminate discarded disposable hypodermic needles that have supported drug use for many.

The retraction mechanism of the syringe is spring-operated and is activated by applying additional pressure to the plunger once it comes into contact with the base of the syringe. While this new syringe design ap-

pears to solve many problems, there is concern that the force of the mechanical retraction system may cause the release of a liquid or aerosol. This is a concern because the intended use of this syringe is for administering drugs. Therefore, if a liquid or aerosol is released, it could contain the drug being administered and possibly blood as well.

Although percutaneous transmission via needlestick is the most common route of exposure, and of most concern for health care workers, exposure to blood-borne pathogens may also occur through contact with the mucous membranes and any non-intact skin (Heinsohn & Jewett, 1995; Jacobson & Snyderman, 1989). This is important because while the total occupational risk of acquiring HIV is calculated at approximately 0.5%, the risk of HIV transmission through either mucous membrane or non-intact skin exposure has been determined to be approximately 0.1% (Jacobson

**Figure 1**

The VanishPoint<sup>®</sup> Syringe before (top) and after (bottom) retraction.



& Snyderman, 1989). In addition, blood-borne pathogens as well as some drugs may pose a toxicity hazard if an aerosol is produced and inhaled.

The aim of this research was to determine if the VanishPoint® Syringe creates a liquid and/or aerosol release by the activation of the retraction mechanism and, if it is determined that a liquid and/or aerosol is produced, to quantify the average release and the effect(s) of syringe and needle size.

## **Method**

The initial step to evaluate the potential for liquid or aerosol release was to estimate the release of liquids from within or on the needle during simulated use. To verify whether or not a release occurs during retraction, it was necessary to test the device using a substance that can be easily detected. Since there was concern about both a drug and blood release, two different radiolabeled substances were used to simulate and differentiate between the two materials. For this test, bovine serum albumin (BSA) labeled with  $^{125}\text{I}$  was used to simulate human blood to determine whether or not blood is possibly released due to the retraction mechanism of the syringe. A concentration of 1887  $\mu\text{Ci/ml}$  of BSA ( $^{125}\text{I}$ ) was obtained from ICN Biomedicals and Radiochemicals (Irvine, CA). Additionally, a 35  $\mu\text{Ci/ml}$  concentration of  $^3\text{H}_2\text{O}$  was used to simulate the drug retained in the syringe and was obtained from the University of Texas Health Science Center Radiation Safety Program (Houston, TX). These two products were chosen due to their ease of detection and because they were assumed to simulate actual materials that would be expected when used by a health care worker. Another advantage of these products is that they would also allow for the released materials to be quantified simultaneously by liquid scintillation counting. The  $^3\text{H}_2\text{O}$  utilized in this study is a beta-emitter and the BSA- $^{125}\text{I}$  is a gamma emitter. When the  $^3\text{H}$  decays, it ejects into its surroundings a beta particle that has kinetic energy between 0-20 keV with an average of 6 keV. When the  $^{125}\text{I}$  decays, it emits discrete packets of energy in the form of photons rather than particles and is detectable by the liquid scintillation counter in the kinetic energy range of 15-80 keV. One shortcoming of using liquid scintillation counting is a phenomenon known as quenching. *Quenching* is a term used to de-

scribe the impacts of various impediments within samples that affect light output or detection, and hence affect overall detection performance. The implications of possible quenching for this study are discussed below.

The method described below was chosen because it was believed that this method represents a worst-case exposure scenario for a health care worker. However, this is assuming that the health care worker would be activating the retraction mechanism of the syringe while the needle is outside the patient's body, which may not always be the case.

All work for this study was performed inside a chemical fume hood. A syringe was removed from its packaging and the needle was completely inserted into an inverted high-performance liquid chromatography vial fitted with a rubber septum and containing the labeled bovine serum albumin. The needle was removed from the vial without depressing the plunger of the syringe. This step allowed the needle to become coated with the bovine serum albumin to simulate blood from an injection. The tip of the needle was then placed just slightly into an open HPLC vial containing 1 ml of tritiated water. The 1 ml of tritiated water was drawn into the syringe and then expelled back into the HPLC vial. This procedure simulated drawing a drug into the syringe and its subsequent administration. As soon as the tritiated water was completely dispensed from the syringe, the needle was removed from the HPLC vial and placed inside a 7 ml scintillation vial and the mechanism to retract the needle was activated. Any bovine serum albumin or tritiated water expelled was assumed to be captured in the vial. The syringe was evaluated to ensure that the needle retracted as designed and then was discarded into a waste container labeled as radioactive waste. The scintillation vial was then filled with 1 ml EcoLume™ Liquid Scintillation Cocktail (ICN Biomedicals and Radionuclides) and placed into a Packard Tri-Carb Model 4640 scintillation counter (Downers Grove, IL) and counted for 1 minute. The above steps were repeated until the desired number of needle retractions was achieved.

Two detection discriminators, or channels, were set to accommodate the different energies of the radioisotopes used in the experimental protocol. Channel A was set for 0 to 20 keV for the  $^3\text{H}_2\text{O}$  beta emission, and Channel B was set for 0 to 70 keV to record the  $^{125}\text{I}$  emission. The  $^{125}\text{I}$  was quantified by

subtracting the results of Channel B from Channel A, since the majority of the events recorded in the 0 to 20 keV range were assumed to be from the decay of the  $^3\text{H}_2\text{O}$ . Due to the distinct radiation emission types, energies of these emitters, and small sample volume, quenching was not considered to significantly affect the results obtained in the counting channels established for this study. If quenching were to occur, the effects could be either an overall reduction in counts or a shifting of counts from the higher energy channel to the lower channel, thus impacting the ability to accurately quantify the amount of  $^3\text{H}$  versus  $^{125}\text{I}$ .

All waste, including any contaminated personal protective equipment, was treated as radioactive-contaminated waste and disposed of in accordance with regulatory requirements. After all waste was removed, the entire area was surveyed with a portable survey instrument to ensure that environmental contamination did not occur.

## Statistical Methods

A pilot study was initially conducted to determine if materials were released due to the syringe's retraction mechanism. The pilot study also provided an estimate of variability, which was used to calculate the sample size for the main study and which standardized the laboratory technique. The pilot study involved five samples for each syringe and gauge size as well as five background samples for each simulant, totaling 30 samples. Both the pilot study and the actual study used 3cc syringes with 20- and 25-gauge needles, and 5cc syringes with 20- and 22-gauge needles. These syringe and needle sizes are of interest because they represent the smallest and largest gauge sizes for each syringe size and are the syringe sizes most commonly used for drug administration. All but the 5cc 20-gauge needle had a 1-inch needle; this particular syringe had a 1.5-inch needle. To account for the difference in needle volume, the analytical results for this syringe were multiplied by  $2/3$  in order to make the data consistent and comparable with the other syringes. For the purpose of the calculations, only the adjusted data are used. Also, many of the BSA analytical results indicated a negative amount due to the method used to quantify the BSA. Since the amount of BSA present was not significantly different from zero, the number calculated was usually

negative due to the inherent measurement error of the liquid scintillation counter. Since a negative amount of radioactive material is not possible, negative differences were replaced with zero for the analysis. These results further support the notion that quenching did not occur since the release results in the average keV range were near zero. This is significant because if the release results are near zero in the average keV range, then the release outside of that range can be expected to be even smaller.

The gross data for both the pilot and main study were analyzed by the liquid scintillation counter in counts per minute (CPM). When mathematical operations are performed upon numbers generated from quantitative measurements, it is desirable to know the error of the calculated result, especially since errors can increase or propagate. One way to estimate this error is to utilize the Associated Error equation listed below. This equation was used to calculate the Associated Error (AE) for each sample (Shleien, 1992).

$$\text{Associated Error (AE)} = (\text{Count Rate} / \text{time})^{1/2}$$

Then, the CPM data and the calculated AE were converted to disintegrations per minute (DPM) with the following equation:

$$\text{DPM}^{15} = [(\text{CPM} - \text{BKG}) + (\text{AE})] / \text{EFF}$$

BKG is the average measured background value of the samples, and EFF is the detection efficiency of the liquid scintillation counter to detect a particular radioisotope. For  $^3\text{H}$  and  $^{125}\text{I}$ , efficiencies of 21% and 30% were used respectively. These are based on the quench curves developed for the scintillation counter that was used in this study. Then, to obtain the amount of activity present, the DPM calculations were converted to  $\mu\text{Ci}$  with the following equation:

$$\mu\text{Ci}^{15} = [(\text{DPM}) + (\text{AE})] / 2220000$$

(1  $\mu\text{Ci}$  is equal to  $2.22 \times 10^6$ )

The potential for generating a liquid or aerosol, as calculated by measuring the release of radiolabeled liquid materials, was determined by comparing the measured released radioactivity to the background laboratory results of the pilot study. Significance was evaluated by a two-tailed, two-sample, unequal variance *t*-Test for both the drug and blood simulants. The test evaluated whether a drug and/or blood simulant was expelled due to the retraction mechanism of the syringe.

To estimate the needed sample size for the main

study, an approximate analysis based only on one factor—syringe size—was considered.

focused on the drug simulant to answer the other specific aims of the study.

## Results

### Pilot Study Results

Table 1 presents an analysis of the analytical results generated from the pilot study, including the number of samples collected, mean, standard deviation, and the *t*-Test probability. The laboratory blanks and the results of the calculations for the mean and standard deviation in Table 1 are listed in units of activity ( $\mu\text{Ci}$ ). The AE for each sample was calculated and, since the AE results were so small, they were considered insignificant and were not included in Table 1.

For this study, a probability of less than 0.05 was considered statistically significant. Therefore, based on the *t*-Test probabilities of 0.000196 for the tritiated water and 0.269 for the BSA, a drug liquid/aerosol release was detected and a blood liquid/aerosol release was not. These results can be further extrapolated to mean that the retraction mechanism of the syringe has the potential to generate a drug release but not a blood release, which answers the first specific aim of the study of whether or not the VanishPoint® retraction mechanism creates a liquid/aerosol release. Based on these pilot study findings, the sample size calculation for the main study, as well as the main study itself, only

## Main Study Results

### Sample Size Calculation

To calculate the needed sample size for the main study, the drug simulant results from the pilot study in terms of syringe size, will be used in the following equation:

$$n = \frac{(\sigma_1^2 + \sigma_2^2)(z_{1-\alpha/2} + z_{1-\beta})^2}{(\mu_2 - \mu_1)^2}$$

Where:

- $n$  = sample size for each group
- $\sigma_1$  = standard deviation of the 3cc syringe pilot study results
- $\sigma_2$  = standard deviation of the 5cc syringe pilot study results
- $z_{1-\alpha/2}$  = 100(1- $\alpha$ /2) percentile of the standard normal distribution
- $z_{1-\beta}$  = 100(1- $\beta$ ) percentile of the standard normal distribution
- $\mu_1$  = mean of the 3cc syringe pilot study results
- $\mu_2$  = mean of the 5cc syringe pilot study results
- $\mu_1 = \mu_2$  = null hypothesis
- $\mu_1 \neq \mu_2$  = alternate hypothesis

**Table 1**  
Pilot Study Results for Tritiated Water and BSA

	<u>Tritiated Water</u>		<u>BSA</u>	
	<u>Actual</u>	<u>Blanks</u>	<u>Actual</u>	<u>Blanks</u>
<u># of Samples</u>	20	5	20	5
<u>Mean (<math>\mu\text{Ci}</math>)</u>	0.87	0.000030	0.0014	0.0000081
<u>Std Dev (<math>\mu\text{Ci}</math>)</u>	0.84	0.0000076	0.0054	0.0000051
<u>t-Test Prob</u>	0.000196		0.269	

While typical values for alpha and power are 0.05 and 0.8 respectively, this study will be more stringent and will use a power of 0.95 to increase the chance of detecting any significant differences that may be present between syringe and gauge sizes. Consequently,  $z_{1-\alpha/2} = z_{1-0.05/2} = z_{0.975} = 1.96$  and  $z_{1-\beta} = z_{1-0.95} = z_{0.05} = 1.645$  (Rosner, 1995). The needed sample size for the main study was calculated using the mean and standard deviation results from the pilot study that are listed in Table 2.

Using the sample size equation and the pilot study results in Table 2 yields the following resulting equation:

$$n = \frac{[(193573)^2 + (416602)^2](1.960 + 1.645)^2}{(632695 - 176514)^2}$$

$$n = 13.18 \cong 14$$

Therefore, to achieve 95% power to detect a significant difference between the two syringe sizes using a two-sided significant test with  $\alpha = 0.05$  will require a sample size of 14 syringes in each group. While there are only two groups (syringe sizes) in this analysis, there are two gauge sizes within each syringe size, so instead of dividing the sample size by two, each syringe and gauge size will use 14 samples, totaling 56 samples, to ensure maximum power is maintained. Additionally, 2 blank samples per syringe and gauge size, 8 total blank samples, will be analyzed to measure background levels and to ensure contamination does not occur. This brings the total number of samples needed for the actual study to 64, or 16 per group.

## Analysis

The laboratory technique and analytical analysis performed on the samples in the main study were consistent with the techniques utilized in the pilot

study. As in the pilot study, the AE results were so small that they were considered insignificant and were not included in Table 3. The second part of the study was to quantify the average release due to the retraction mechanism of the syringe. Consequently, the release results for each syringe and needle size were averaged to determine the overall quantity of tritiated water released, which was calculated to be 0.9580  $\mu\text{Ci}$  or 0.03 ml since the drug simulate had a concentration of 35  $\mu\text{Ci}/\text{ml}$ . Then, the mean and standard deviation for each syringe and gauge size were calculated, so that a *t*-Test could be performed to evaluate any effects due to the syringe and/or gauge size. These results in  $\mu\text{Ci}$  and associated probabilities are listed in Table 3.

Since the two different syringe sizes have a needle gauge size in common, (3cc/20 gauge versus 5cc/20 gauge) these syringe sizes can be compared using a two-tailed, two-sample, unequal variance *t*-Test to determine the effect of syringe size on the tritiated water release. Since the *t*-Test value for the 3cc/20 gauge and 5cc/20 syringe was 0.066, which is greater than 0.05, this indicates that the 1.8  $\mu\text{Ci}$  or 0.05 ml release associated with the 5cc/20 gauge syringe is not significantly greater than the 1.2  $\mu\text{Ci}$  or 0.03 ml release associated with the 3cc/20 gauge syringe. Therefore, the amount of tritiated water released from the retraction mechanism of the syringe was not significantly affected by syringe size. This is a logical conclusion since any remainder drug residue would mostly reside in the needle and not in the syringe.

Since each syringe size has two different needle gauge sizes, the effect of gauge size can be tested on both the 3cc and 5cc syringes. For the 3cc/25 gauge and 3cc/20 gauge sizes, the *t*-Test value is 0.0000000195, indicating that the 1.2  $\mu\text{Ci}$  or 0.03 ml release associated with the 3cc/20 gauge syringe is significantly greater

**Table 2**  
Pilot Study Tritiated Water Mean and Standard Deviation Results by Syringe Size

	3cc Syringe	5cc Syringe
# of Pilot Study Samples	10	10
Mean (cpm)	176514	632695
Standard Dev (cpm)	193573	416602

**Table 3**  
Overall Main Study Results by Each Syringe and Gauge Size

	<u>3cc 25g</u>	<u>3cc 20g</u>	<u>5cc 20g</u>	<u>5cc 22g</u>	<u>Blanks</u>
<u>N</u>	14	14	14	14	8
<u>Mean (μCi)</u>	0.013	1.2	1.82	0.76	0.000030
<u>StdDev (μCi)</u>	0.013	0.38	1.02	0.39	0.0000083
<u>t-Test Prob</u>	0.0000000195		0.00215		N/A
<u>t-Test Prob</u>	N/A	0.066		N/A	N/A

than the 0.013 μCi or 0.0004 ml release associated with the 3cc/25 gauge syringe. Furthermore, when comparing the 5cc/20 gauge and 5cc/22 gauge sizes, the *t*-Test value is 0.00215, which indicates that the 1.8 μCi or 0.05 ml release associated with the 5cc/20 gauge is significantly greater than the 0.76 μCi or 0.02 ml release associated with the 5cc/22 gauge size. Consequently, the amount of tritiated water released from the retraction mechanism of the syringe is significantly related to the gauge size of the needle for both the 3cc and 5cc syringes.

## Discussion

The primary aim of this study was to determine if the VanishPoint® Syringe has the potential for a drug and/or blood release due to the retraction mechanism of the syringe, which forcefully withdraws the needle into the syringe. Although other types of mechanical medical instruments have been shown to produce respirable and non-respirable blood aerosols (Jewett, Heinsohn, Bennett, Rosen, & Neuilly, 1992), prior to this study, apparently no data existed on the use of retractable syringes. The pilot study detected the indication of a drug release but not a blood release as a result of the syringe's retraction mechanism when using tritiated water as the drug simulant and BSA labeled with <sup>125</sup>I as the blood simulant.

The secondary aim of the study was to determine the average liquid/aerosol release and the effects, if any,

due to syringe and gauge size. Since the pilot study indicated that there was not a significant blood simulant release from the retraction mechanism of the syringe, the blood simulant was not included in the main study. The main study found that the average drug release was 0.9580 μCi or 0.03 ml and, statistically, was significantly affected by the gauge size of the needle but not by the syringe size itself. Therefore, it can be reasonably inferred that the larger the needle diameter (or lower numerical gauge number), the greater the volume of drug solution that may be released due to the retraction mechanism of the syringe.

The VanishPoint® Syringe offers advantages over the traditional syringe, which were discussed earlier. However, this study found a potential disadvantage associated with the syringe. This disadvantage was that the potential exists for a drug simulant release due to the needle retraction mechanism, which, depending upon the drug being administered, could be a major concern. Due to this finding, it might be useful to consider cautioning about the possibility of a drug release when activating the needle retraction mechanism and, consequently, warning about exercising caution when selecting the drug to be administered.

Since this was the first study of its kind, some limitations were encountered that should be considered in future studies. The potential quenching of the two isotopes could have been completely avoided had a

gamma counter been used to count the BSA  $I^{125}$  retraction results versus a scintillation counter. Second, it should be noted that this study focused on a worst-case exposure scenario, which means the health care worker would be activating the retraction mechanism of the syringe while the needle was outside of the patient's body. Third, the laboratory technique utilized in this study—inserting the needle into the blood simulant vial before the tritiated water vial—may have resulted in a “washing off” of some or all of the blood stimulant. This would have caused a reduction in both the quantity of simulated blood released by the syringe and the quantity detected by the liquid scintillation counter. This potential reduction of simulated blood could have contributed to the pilot study's insignificant detection of a blood simulant release.

Although releases of drug may occur when using this device, it is useful in reducing needlesticks and prevents the unwanted use of disposed needles. With enhanced education and proper training, the release of drug solution from the retraction of the needle should be minimized.

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