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(19) **United States**(12) **Patent Application Publication**  
**Baker et al.**(10) **Pub. No.: US 2014/0276430 A1**(43) **Pub. Date: Sep. 18, 2014**(54) **MEDICAMENT DELIVERY AND  
SIMULATION SYSTEM WITH A  
REMOVABLE DISPOSABLE CONTAINER  
FOR MEDICAMENT AND A ROTATABLE  
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der Pol**, Winter Garden, FL (US)(21) Appl. No.: **14/193,766**(22) Filed: **Feb. 28, 2014****Related U.S. Application Data**(63) Continuation of application No. 14/017,933, filed on  
Sep. 4, 2013.(60) Provisional application No. 61/788,033, filed on Mar.  
15, 2013.**Publication Classification**(51) **Int. Cl.***A61M 5/19* (2006.01)*A61M 5/32* (2006.01)*A61M 5/142* (2006.01)(52) **U.S. Cl.**CPC ..... *A61M 5/19* (2013.01); *A61M 5/14212*  
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(57)

**ABSTRACT**

In one embodiment of the invention, a container for storing a medicament prior to use is provided. The container includes a first housing for containing a medicament, a second housing, wherein the first housing is movable relative to the second housing, and an injection member associated with a lower portion of the first housing, wherein when the first housing moves relative to the second housing in a first direction to deliver the medicament, the injection member extends from the second housing traversing a first contaminant barrier disposed at a lower portion of the second housing. The first housing moves relative to the second housing in a second direction wherein the injection member is retracted into the second housing to prevent an unintentional contact with the injection member. In a further embodiment, an actuation mechanism for actuation of an injection includes a rotatable member.

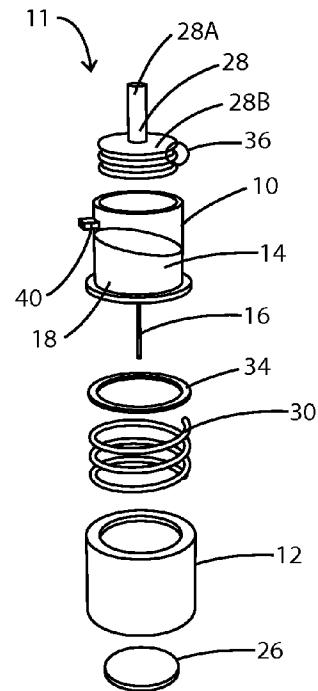
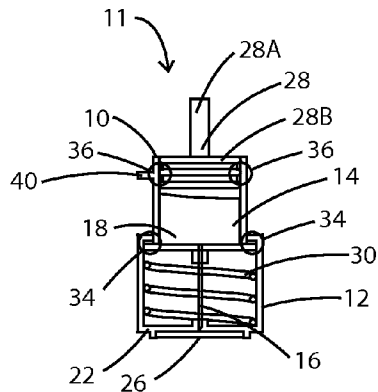


FIG. 1B

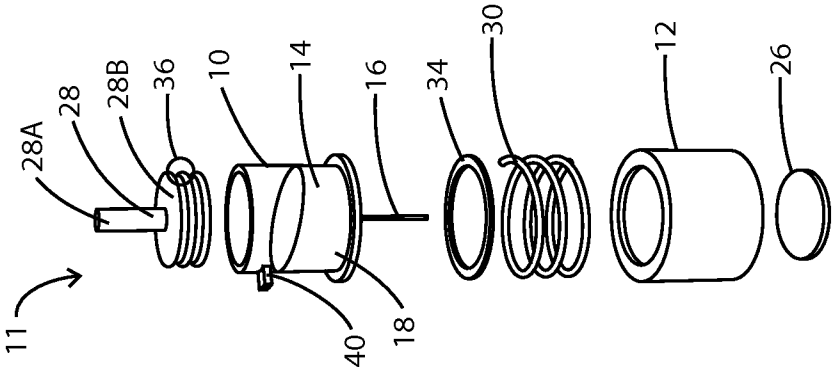


FIG. 1A

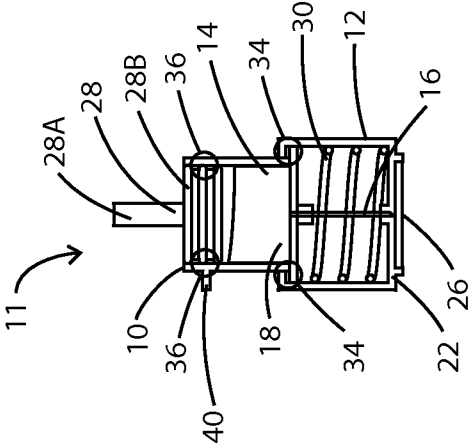


FIG. 2A

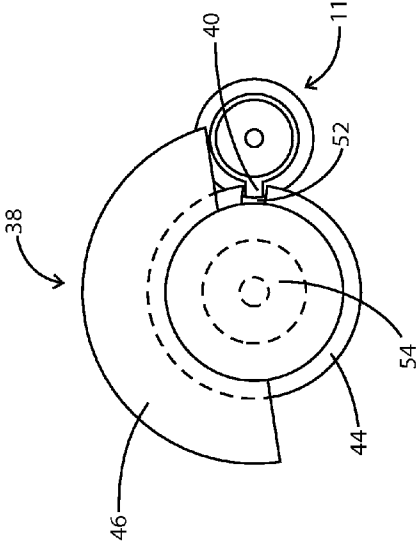


FIG. 2B

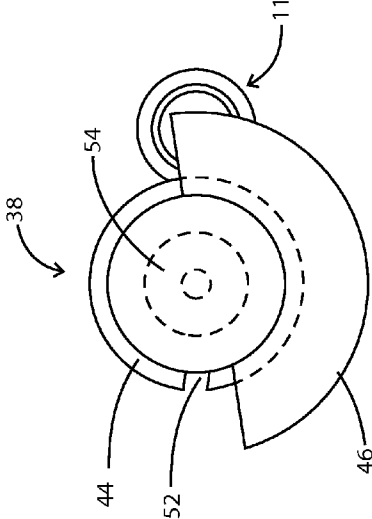


FIG. 2A'

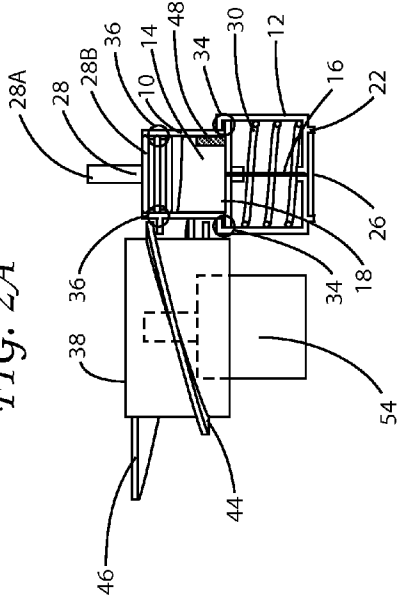


FIG. 2B'

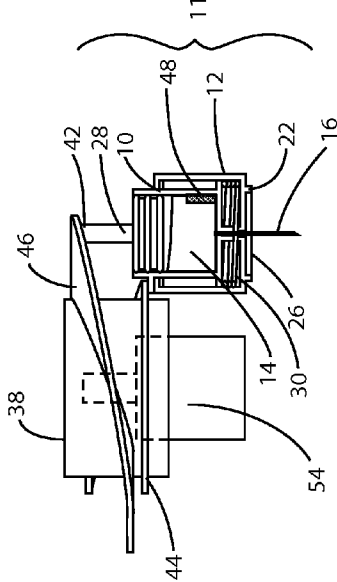


FIG. 2C

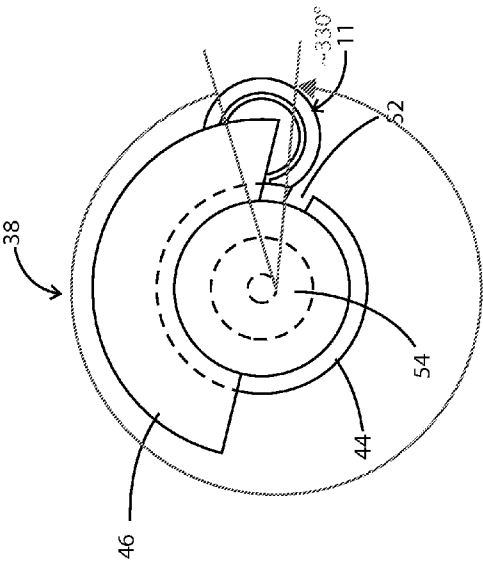


FIG. 2D

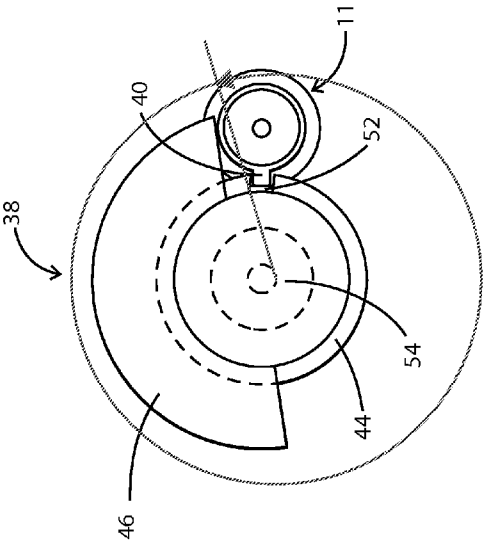


FIG. 2C'

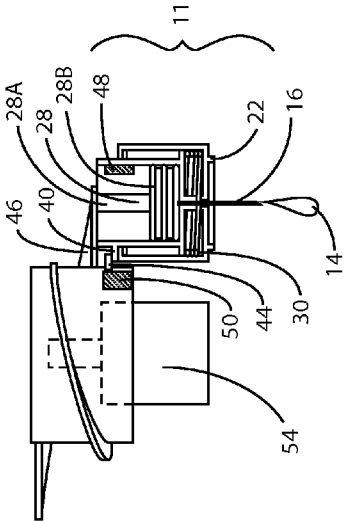
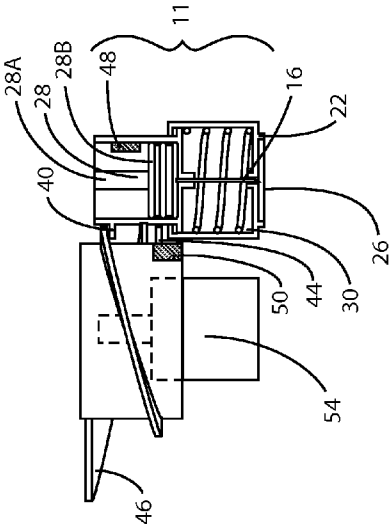


FIG. 2D'



**MEDICAMENT DELIVERY AND  
SIMULATION SYSTEM WITH A  
REMOVABLE DISPOSABLE CONTAINER  
FOR MEDICAMENT AND A ROTATABLE  
ACTUATION COMPONENT**

CROSS REFERENCE RELATED APPLICATIONS

**[0001]** This application is a continuation of U.S. Ser. No. 14/017,933 filed on Sep. 4, 2013 which claims priority to Provisional Application No. 61/788,033 filed on Mar. 15, 2013, the disclosure of which are incorporated herein by reference in their entirety.

BACKGROUND

**[0002]** Manual disposable syringe based devices have existed since the mid-1800's. These devices were designed for a single purpose of performing a subcutaneous injection through a hollow-bore needle affixed to the syringe device. Syringes are simple mechanical systems with no capability of refined fluid dynamics or ability to integrate advanced digital capabilities.

**[0003]** Auto-injection or "pen" devices have recently become increasingly popular for single dose or multi dose, at home self-administration. These auto-injection devices are primarily designed to accomplish two basic objectives: convenience and automation of drug delivery in an outpatient setting. These are typically mechanically spring-loaded devices that advance a plunger or rubber stopper to transfer medication via hollow-bore needle to a patient's tissues.

**[0004]** Auto-injection devices lack the ability to regulate whether the medication is actually delivered to the patient or whether it is delivered to a correct location. Most auto-injection devices fail to integrate advanced digital capabilities. A significant limitation is the inability of auto-injection devices to collect and transfer digital information from the device to other sources.

**[0005]** Injectable medications are required for a number of varying illnesses and diseases. A number of injectable medications require self-injection by a patient. Self-injection of a medicament using a device having a needle carries with it a certain stigma. Oftentimes patients are weary of injecting themselves for fear or anxiety related to failing to receive a complete dose of the medication, pain associated with injecting oneself with the needle, accidentally sticking oneself with the needle, and difficulties in adequately grasping the dosing mechanism to inject oneself, among other concerns.

**[0006]** Auto-injection devices are routinely used to provide a means for self-injecting certain medications. The size and operation of these auto-injection devices can often be daunting to a patient, whether they are injecting themselves for the first or they have injected themselves before. These fears and anxieties associated with the currently available self-injection devices, particularly the auto-injection devices, may result in the administration of an incomplete dose of a medicament, failure to administer any portion of the dose of a medicament, or accidentally sticking oneself with the needle of the device, which in some instances could lead to unwanted transmission of diseases if the needle is contaminated.

**[0007]** In some instances, after an auto-injection is complete, the contaminated needle is retracted within the auto-injection device or covered over by a needle guard or sheath and the entire auto-injection device is disposed of. Therefore, most auto-injectors currently available are single use auto-

injectors. These single use auto-injectors are costly and economically wasteful. Alternatively, there are injection devices which require a user to re-cap a needle after the injection is complete such that the disposable needle can be removed and discarded. These injection devices carry with them the risk of unwanted sticking of oneself during re-capping of the needle.

**[0008]** An additional concern exists with regard to injection devices, and in particular with regard to auto-injectors, where users with little or no medical knowledge or experience are injecting themselves or injecting others using these devices. Performing a medical treatment or test on oneself or others carries with it certain risks and often creates a level of anxiety for the user performing the treatment or test. It has proven beneficial in the medical field to practice various medical techniques including drug delivery, specifically where it relates to injections and other invasive drug delivery means prior to delivering the medications to a patient in need, and particularly in the case of self-administration of medications. Training devices are helpful in reducing anxiety associated with self administering medical treatment, as well as increasing efficiency and accuracy in providing the treatment to patients. Medical devices can be intimidating to use; the fear associated with giving oneself an injection, for example, can be traumatic. This fear is increased in persons with little or no experience in self-administration of medications. Consequently, devices to assist in training individuals to inject themselves or otherwise self-administer medication are beneficial in decreasing or preventing the anxiety associated with medicament delivery.

**[0009]** Therefore, there exists a need for an injection device which may be safely and efficiently used by patients without medical experience in preparing and self-injecting medications. Furthermore, a device which closely resembles a medicament delivery device that can be used to simulate an injection for training purposes would be highly beneficial.

BRIEF DESCRIPTION OF THE DRAWINGS

**[0010]** A more particular description briefly stated above will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments and are not therefore to be considered to be limiting of its scope, the embodiments will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

**[0011]** FIG. 1A provides a cross-sectional view of an embodiment of a container.

**[0012]** FIG. 1B provides an exploded view of the embodiment of the container in FIG. 1A.

**[0013]** FIGS. 2A-2D' illustrate an embodiment of a medicament delivery or injection simulation system and illustrate steps of the use of the embodiment of the system.

SUMMARY

**[0014]** In one embodiment, a container for storing a medicament prior to use is provided. The container includes a first housing for containing a medicament, a second housing, wherein the first housing may be movable relative to the second housing, and an injection member associated with a lower portion of the first housing. The container further includes when the first housing moves relative to the second housing in a first direction to deliver the medicament, the injection member extends from the second housing traversing

a first contaminant barrier disposed at a lower portion of the second housing, and the first housing moves relative to the second housing in a second direction the injection member may be retracted into the second housing to prevent an unintentional contact with the injection member.

**[0015]** In another embodiment, a medicament delivery or injection simulation system is provided. The medicament delivery or injection simulation system includes a container, and the container includes a first housing and a second housing, wherein the first housing may be movable relative to the second housing, and an injection member or an injection simulation member associated with a lower portion of the first housing. When the first housing moves relative to the second housing in a first direction, the injection member or injection simulation member extends from the second housing traversing a first contaminant barrier disposed at a lower portion of the second housing. When the first housing moves relative to the second housing in a second direction, the injection member or injection simulation member may be retracted into the second housing to prevent an unintentional contact with the injection member or injection simulation member. The medicament delivery or injection simulation system further includes an actuation mechanism associated with the container, wherein actuation mechanism drives the movement of the first housing and/or the second housing. In some embodiments, the actuation mechanism may include a motor.

**[0016]** In yet another embodiment, a container for storing a medicament prior to use is provided. The container includes a first housing for containing a medicament, a second housing, wherein the first housing is movable relative to the second housing, and an injection member associated with a lower portion of the first housing. The container further includes a plunger associated with the first housing, the plunger being movable relative to the first housing, wherein when the first housing moves relative to the second housing in a first direction to deliver the medicament, the injection member extends from the second housing traversing a first contaminant barrier disposed at a lower portion of the second housing, and wherein when the plunger moves relative to the first housing in a first direction, medicament is delivered through the injection member, and when the first housing moves relative to the second housing in a second direction the injection member is retracted into the second housing to prevent an unintentional contact with the injection member.

#### DETAILED DESCRIPTION

**[0017]** For the purposes of promoting an understanding of the principles and operation of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to those skilled in the art to which the invention pertains.

**[0018]** It is to be noted that the terms “first,” “second,” and the like as used herein do not denote any order, quantity, or importance, but rather are used to distinguish one element from another. The terms “a” and “an” do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item. The modifier “about” used in connection with a quantity is inclusive of the stated value and has the meaning dictated by the context. It is to be noted that all

ranges disclosed within this specification are inclusive and are independently combinable.

**[0019]** The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting. As used herein, the singular forms “a,” “an,” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. Furthermore, to the extent that the terms “including,” “includes,” “having,” “has,” “with,” or variants thereof are used in either the detailed description and/or the claims, such terms are intended to be inclusive in a manner similar to the term “comprising.” Moreover, unless specifically stated, any use of the terms first, second, etc., does not denote any order or importance, but rather the terms first, second, etc., are used to distinguish one element from another.

**[0020]** Notwithstanding that the numerical ranges and parameters setting forth the broad scope are approximations, the numerical values set forth in specific non-limiting examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements. Moreover, all ranges disclosed herein are to be understood to encompass any and all sub-ranges subsumed therein. As a non-limiting example, a range of “less than 10” can include any and all sub-ranges between (and including) the minimum value of zero and the maximum value of 10, that is, any and all sub-ranges having a minimum value of equal to or greater than zero and a maximum value of equal to or less than 10, e.g., 1 to 7.

#### DEFINITIONS

**[0021]** The term “associated” or “association”, as used herein, includes but is not limited to direct and indirect attachment, adjacent to, in contact with, partially or fully attached to, and/or in close proximity therewith. The term “in conjunction with” as used herein includes but is not limited to synchronously or near synchronous timing, the phrase may also include the timing of outputs, where one output directly follows another output. The term “value” as used herein, may refer to a specific value or a range of values.

**[0022]** The inventors have discovered many areas in which prior art injection devices and syringes are lacking, particularly in regard to certain safety and convenience features. While some safety syringes are provided with a retraction-type mechanism, such that after using the syringe the needle can be retracted into some kind of housing of the syringe; however, the syringe still requires removing a protective cap from the needle prior to injection. These prior art syringes present opportunities for unwanted sticking of oneself with the needle. These prior art syringes also present opportunities for contamination of the needle before it is injected into the skin of a user. Another area of the prior art that is lacking in efficiency includes where an auto injector is used for an injection, and the housing may be disposed of after a single use. It is not economically efficient to dispose of an auto injector after a single injection. Therefore, the inventors herein have identified a medicament containing container which solves many of these issues identified in the prior art.

**[0023]** The subject invention includes, in one embodiment, a medicament containing container which comprises a needle, wherein the medicament containing container may be configured to be received within an injection device. The medicament containing container comprises a needle and a safety guard and/or packaging such that the needle may be

protected and kept sterile until the container is inserted into the injection device in an embodiment. Upon insertion of the container into the injection device, the safety guard is removed and/or the packaging is opened such that the needle is positioned within the injection device for use upon injection by the user.

**[0024]** Following injection of the medicament contained within the medicament containing container, the needle automatically retracts into the medicament containing container such that a user cannot access the needle, in an embodiment. Thereafter, the empty container comprising the needle can be removed or extended from the injection device and disposed, leaving the injection device ready and able to receive another medicament containing container for the next injection, one embodiment. In one embodiment, placing the container into the injection device automatically opens the sterile packaging surrounding the needle portion and/or displaces the safety guard in preparation of the needle for injection. Therefore, the needle and the medicament maintain sterility until the container is inserted into the injection device prior to injection into the patient.

**[0025]** In one particular embodiment, a seal may be provided over the needle end of the container to protect the sterility of the container and the needle, prior to its use. During an injection, the needle punctures the seal and traverses the sealed container portion as it exits the proximal end of the injection device into the injection site of the patient.

**[0026]** Following use of the needle for injection, the needle may be retracted into the container such that the container can be safely removed from a reusable housing for disposal. The retraction of the needle into the container prevents unwanted and accidental needle sticks by the patient during the manipulation of the container between its removal from the housing and disposal in a sharps container. Furthermore, in order to comply with regulations regarding needle safety and proper disposal of needles, the retraction of the needle prevents it from being a danger to others, as the needle cannot be accessed once it is retracted within the container.

**[0027]** In one embodiment, the container may be a training (or injection simulation) container, in which an injection simulation member is provided in place of the needle for injection. The training container may be placed within the injection device to assist a user in learning to correctly use the device. The training container may be labeled as a training container, and may contain unique identification information on a portion of the container to identify it as a non-medicament containing container or training container. When the training container is placed within a housing for use, as will be described in greater detail below, the housing may include an information identification reader which identifies the container as a training container. The housing may be a reusable housing, in one embodiment.

**[0028]** In one embodiment, a medicament delivery system is provided. The medicament delivery system includes reusable housing, the reusable housing including an actuation mechanism and a receptacle for receiving a container. The actuation mechanism is provided for interacting with the container. The container may be provided for storing a medicament prior to use, the container includes a first housing for containing a medicament, a second housing, wherein the first housing may be movable relative to the second housing, and an injection member associated with a lower portion of the first housing. The container further includes wherein the actuation mechanism interacts with the container such that

the first housing moves relative to the second housing in a first direction the injection member may be extended from the second housing, traversing a first contaminant barrier, the plunger component moves relative to the first housing in a first direction to expel the medicament through the injection member, and the first housing moves relative to the second housing in a second direction such that the injection member may be retracted into the second housing to prevent an unintentional contact with the injection member. The container can be removed from the reusable housing post use and disposed of.

**[0029]** In a further embodiment, the actuation mechanism depresses the plunger component to deliver the medicament thorough the injection member after the injection member traverses the first contaminant barrier.

**[0030]** In a further embodiment the injection member traverses the first contaminant barrier and the plunger component may be depressed so as to deliver the medicament through the injection member. In a particular embodiment, the first contaminant barrier may be a membrane.

**[0031]** In still a further embodiment, a spring may be disposed between the first housing and the second housing such that when the first housing moves relative to the second housing in a first direction, the spring is biased, and when the medicament may be delivered from the injection member, the spring may be released and the injection member may be retracted into the second housing. In yet a further embodiment, the medicament delivery system further includes a second contaminant barrier between an upper portion of the second housing and a lower portion of the first housing to prevent contaminants from entering the second housing. In a further embodiment, a third contaminant barrier may be disposed between the plunger component and the first housing to prevent contaminants from entering the first housing and/or the medicament. Non-limiting examples of contaminant barriers include but are not limited to membranous materials or membranes. O-ring type membranes or contaminant barriers may be used in the second and third contaminant barrier positions, in non-limiting examples. A membrane may be used as a contaminant barrier in the first contaminant barrier position, in one non-limiting example.

**[0032]** In a further embodiment, the medicament delivery system is provided wherein the first housing includes a projection member that interacts with the actuation mechanism to cause the first housing to move relative to the second housing such that the injection member traverses the first contaminant barrier when the actuation mechanism is activated.

**[0033]** In another embodiment, the medicament delivery system is provided wherein when the actuation mechanism is activated, the actuation mechanism interacts with a portion of the first housing to move the first housing in a first direction relative to the second housing such that the spring is biased and the injection member traverses the first contaminant barrier.

**[0034]** The actuation mechanism can be activated in various ways. Depressing an actuation mechanism by turning a switch or by contact with a portion of the medicament delivery system, or by inserting the container into the housing, is one non-limiting example of activating an actuation mechanism, another non-limiting example of an actuation mechanism includes a motor.

**[0035]** In another embodiment of the medicament delivery system, the actuation mechanism may be a rotatable member.

The rotatable member includes a first threaded portion and a second threaded portion, in one embodiment, the second threaded portion provided to interact with the projection member such that when the actuation mechanism may be rotated in a first direction, the second threaded portion moves the projection member in a first direction relative to the second housing, such that the spring is biased and the injection member may be extended through the first contaminant barrier. In a further embodiment, the first threaded portion of the actuation mechanism may be provided to interact with the upper portion of the plunger component such that when the actuation mechanism may be rotated in a first direction, the first threaded portion moves the plunger component relative to the first housing in a first direction to expel the medicament through the injection member. In another embodiment, the second threaded portion contacts the projection member to move the first housing in a first direction relative to the second housing before the first threaded portion of the rotatable member contacts the upper portion of the plunger component to move the plunger component in a first direction relative to the first housing to dispel or deliver the medicament through the injection member.

**[0036]** In a further embodiment, the second threaded portion of the rotatable member includes an opening through which the projection member may be released, such that the first housing moves in a second direction relative to the second housing, to retract the injection member into the second housing. The rotatable member may be rotated by a motor or a torsion spring, or by hand in some embodiments, or a combination thereof, or any other means of rotation of the rotatable member known to those of skill in the art.

**[0037]** In an embodiment, the container comprises a unique identification information or a container information component including a unique identification information of the medicament contained within, whereby the identification information can be read by an identification reader or container information component reader. The rotatable member may include an identification reader, the reusable housing may include an identification reader and/or the actuation mechanism may include an identification reader, in an embodiment. The container information component and container information component reader may interact with one another such that information identified by the reader can be provided to the user. The information may be provided to a user on a display, or another visual communication device, or audibly provided to the user. The information may further be provided with a smell or a vibration, or by any other method of communication known in the art. The information may be provided, in a non-limiting example, by way of a bar code, or by a specific shape on the container which can be read by the reader to identify specific information about the medicament contained within the container. Such information may include the name and strength of the drug, the expiration date, dose, manufacturer's name, batch number, proper handling instructions (e.g., temperature storage conditions) among other information.

**[0038]** The container information component may further be designed to identify and record particular information regarding the container and the medicament stored within, such as the temperature at which the container has been maintained from the manufacturer through the delivery process in a non-limiting example. A log may be recorded by the system of the varying temperatures of the container and the medication by a module of the container so that a user can

identify if the container has been maintained at a proper temperature prior to use of the medicament. For this and other purposes, the container may include a power source such as a battery, in a non-limiting example. Therefore, medicaments which have not been maintained at the proper storage/handling temperature can be discarded. In instances where the container information component reader identifies information on the container information component, such as, information that the container may be housing an expired medication, the safety mechanism will prevent an activation of the actuation device, and therefore prevent injection of the expired medication into the user, in a non-limiting example.

**[0039]** In another embodiment, the medicament delivery system is provided wherein the actuation mechanism interacts with the plunger component such that the first housing to moves in a first direction relative to the second housing such that the injection member traverses the first contaminant barrier when the actuation mechanism is activated. In a further embodiment, the actuation mechanism may be a rotatable member, in one non-limiting example the rotatable member is an index cam. The rotatable member includes a first threaded portion, the first threaded portion provided to interact with an upper portion of the plunger component such that when the actuation mechanism is rotated in a first direction, the first threaded portion moves the first housing in a first direction relative to the second housing such that the spring is biased and the injection member may be extended through the first contaminant barrier.

**[0040]** In a further embodiment, thereafter, the actuation mechanism interacts with the plunger component such that the plunger component moves in a first direction relative to the first housing so as to expel the medicament through the injection member, and the first housing moves relative to the second housing in a second direction such that the injection member may be retracted into the second housing to prevent an unintentional contact with the injection member. When the actuation mechanism is activated, the first housing moves in a first direction relative to the second housing to extend the injection member through the first contaminant barrier before the plunger component moves in a first direction relative to the first housing to expel the medicament through the injection member and to a subject, in one embodiment. This can occur with only a first threaded portion which interacts with the plunger component.

**[0041]** The system operates in such a manner due in part at least to a difference in resistance between the movement of the first housing relative to the second housing and the extension of the injection member through the first contaminant barrier and the resistance between the movement of the plunger component relative to the first housing to dispel the medicament through the injection member. The first action will occur before the second as the system will take the path of least resistance. Thus, there is less resistance associated with the extension of the injection member through the first contaminant barrier and into the subject (i.e., movement of the first housing in a first direction relative to the second housing) than there is associated with the movement of the plunger component relative to the first housing to dispel the medicament through the injection member and into the subject.

**[0042]** In still a further embodiment, the first threaded portion includes an opening through which the projection member may be released, whereby the spring may be released,



such that the first housing moves in a second direction relative to the second housing, and the injection member retracts into the second housing.

**[0043]** The rotatable member can be rotated by a torsion spring or a motor, or a combination thereof. Those skilled in the art will appreciate that other forces and devices may be used to rotate the rotatable member in such a manner to depress the components of the device as described herein.

**[0044]** In another embodiment, a container for storing a medicament prior to use is provided. The container includes a first housing for containing a medicament, a second housing, wherein the first housing may be movable relative to the second housing, and an injection member associated with a lower portion of the first housing. The container further includes wherein when the first housing moves relative to the second housing in a first direction to deliver the medicament, the injection member extends from the second housing traversing a first contaminant barrier disposed at a lower portion of the second housing, and the first housing moves relative to the second housing in a second direction, the injection member is retracted into the second housing to prevent an unintentional contact with the injection member. In a further embodiment, a stopper may be associated with the first housing. The stopper may be movable relative to the first housing, whereby the medicament is delivered through the injection member upon movement of the first housing relative to the second housing in a first direction followed by movement of the stopper relative to the first housing in a first direction.

**[0045]** The container may be manually actuated by pressing down on the stopper, in one embodiment. Alternatively, in a non-limiting example, the container may be actuated with an actuation mechanism, wherein the actuation mechanism may be rotatable as an index cam, which may be activated manually via a torsion spring or by motor, gas, or compressed air, among other possible activation means known to those of skill in the art. Alternatively, the container may, itself, be actuated via a motor, gas or compressed air. Any other means of activation or actuation of the container to deliver medicament that are known to those of skill in the art are included herein.

**[0046]** In a further embodiment, the injection member traverses the first contaminant barrier and the stopper may be depressed so as to deliver the medicament through the injection member. In one embodiment, the first contaminant barrier may be a membrane. In another embodiment, the first contaminant barrier may include any material or device known to those of skill in the art to prevent unwanted contaminants from entering the device.

**[0047]** In a further embodiment, a spring may be disposed between the first housing and the second housing wherein when the first housing moves relative to the second housing in a first direction, the spring is biased, and after the medicament is delivered from the injection member, the spring may be released, and the injection member may be retracted into the second housing. This feature is beneficial, in one instance, to prevent unwanted sticking of oneself with the used injection member. After use of the device or container, the injection member is protected to allow disposal without accidental sticking of oneself with the injection member and prevention of potential contamination of oneself through contact with the injection member.

**[0048]** In a further embodiment, the container further includes a second contaminant barrier between the upper

portion of the second housing and the lower portion of the first housing to prevent contaminants from entering the second housing.

**[0049]** In another embodiment, the container further includes a third contaminant barrier between the first and second housing to prevent contaminants from entering the first housing and/or from being in contact with the medicament.

**[0050]** In a further embodiment, a medicament delivery and simulation system is provided, the system including a container, the container including a first housing, a second housing, wherein the first housing may be movable relative to the second housing and an injection member or an injection simulation member may be associated with a lower portion of the first housing. When the first housing moves relative to the second housing in a first direction, the injection member or injection simulation member extends from the second housing traversing a first contaminant barrier disposed at a lower portion of the second housing, and when the first housing moves relative to the second housing in a second direction the injection member or injection simulation member may be retracted into the second housing to prevent an unintentional contact with the injection member or injection simulation member. The medicament delivery and simulation system further includes an actuation mechanism in association with the container, wherein the actuation mechanism drives the movement of the first housing and/or the second housing. In a further embodiment, the actuation member comprises a motor. The actuation mechanism may include a motor, an index cam, a plunger component, or any manually or electrically activated actuation mechanism, in non-limiting examples. Other actuation mechanisms known to those of skill in the art are contemplated herein.

**[0051]** In a further embodiment, the medicament delivery and simulation system is provided wherein the first contaminant barrier is a membrane. In one embodiment, the container includes a medicament. In still a further embodiment, a stopper may be associated with the first housing, the stopper being movable relative to the first housing, whereby the medicament may be delivered through the injection member upon movement of the first housing relative to the second housing in a first direction followed by movement of the stopper relative to the first housing in a first direction.

**[0052]** In yet a further embodiment, the actuation member may be a motor which drives the movement of the stopper. In yet another embodiment of the medicament delivery and simulation system, the system further comprises a second contaminant barrier between an upper portion of the second housing and the lower portion of the first housing to prevent contaminants from entering the second housing. In still a further embodiment, a third contaminant barrier may be disposed between the stopper and the first housing to prevent contaminants from entering the first housing and/or the medicament, alternatively the stopper includes a third contaminant barrier or the stopper may be associated with the third contaminant barrier. In another embodiment, a shaft may be connected to the stopper.

**[0053]** In a further embodiment, the system includes a reusable housing having a receptacle for receiving the container. In still a further embodiment, the actuation mechanism is in the reusable housing.

**[0054]** In another embodiment, a medicament delivery system is provided, wherein the system may be configured to provide stepwise instructions for using the system to a user in

a particular sequence. The system includes a reusable housing, the housing comprising an actuation mechanism and a receptacle for receiving a container. The actuation mechanism is for interacting with the container, the reusable housing including a control interface, the control interface including at least one responsive member reactive to a user input. The housing includes a container for storing a medicament prior to use, the container including a first housing for containing a medicament, a second housing, wherein the first housing is movable relative to the second housing, a plunger component associated with the first housing, and an injection member associated with a lower portion of the first housing.

**[0055]** The system further includes a signal output component associated with the reusable housing component and circuitry associated with the reusable housing component configured to control a provision of the stepwise instructions to the user in the particular sequence. In one non-limiting example, the stepwise instructions are audibly provided to the user via the signal output component. The instructions can be a recording of any language providing verbal instructions. Alternatively, the instructions may be given with a series of sounds or beeps or other audible notifications to a user. In other embodiments, the instructions may be provided by one or a series of vibrations of the system or a scent or taste or temperature change of the system or the housing. Instructions may alternatively be provided visually, wherein a textual instruction may be provided or a pictorial or video-type instruction. Various lights may also be used to signal the stepwise instructions to a user via a series of lighted portions on the housing signaling the steps in which the system may be used, or any other lighted signaling manner as known by those of ordinary skill in the art. Any of these sounds, visual guides, vibrations, tastes or smells may be provided via the signal output component, in one embodiment.

**[0056]** Upon activation of the actuation mechanism, the actuation mechanism interacts with the container such that the first housing moves relative to the second housing in a first direction, the injection member may be extended from the second housing, traversing a first contaminant barrier, the plunger component moves relative to the first housing in a first direction to expel the medicament through the injection member, and the first housing moves relative to the second housing in a second direction such that the injection member may be retracted into the second housing to prevent an unintentional contact with the injection member. In one particular embodiment, a spring may be disposed between the first and second housings such that when the first housing moves relative to the second housing in a first direction, the spring is biased, and after the medicament is delivered from the injection member, the spring may be released and the injection member may be retracted into the second housing.

**[0057]** In a further embodiment, the first housing comprises at least a projection member that interacts with the actuation mechanism to cause the first housing to move relative to the second housing such that the injection member traverses the first contaminant barrier when the actuation mechanism is activated.

**[0058]** In still a further embodiment, when the actuation mechanism is activated, the actuation mechanism interacts with a portion of the first housing to move the first housing in a first direction relative to the second housing such that the injection member traverses the first contaminant barrier.

**[0059]** In yet a further embodiment, the actuation mechanism may be a rotatable member, the rotatable member may

include a first threaded portion and a second threaded portion, the second threaded portion provided to interact with the projection member such that when the actuation mechanism is rotated in a first direction, the second threaded portion moves the projection member in a first direction relative to the second housing such that the spring is biased and the injection member is extended through the first contaminant barrier. One skilled in the art in view of the teachings herein would understand that the first threaded portion could associate with a top portion or other portion of the first housing to move the first housing in a first direction relative to the second housing.

**[0060]** In another embodiment, the first threaded portion of the actuation mechanism is provided to interact with an upper portion of the plunger component such that when the actuation mechanism is rotated in a first direction, the first threaded portion moves the plunger component relative to the first housing in a first direction to expel the medicament through the injection member.

**[0061]** In yet another embodiment, the second threaded portion comprises an opening through which the projection member is released, whereby the spring is released, such that the first housing moves in a second direction relative to the second housing, and the injection member retracts into the second housing.

**[0062]** In another embodiment, the system may include a locking mechanism disposed adjacent to the first and/or second housing so as to prevent movement of the plunger component in a first direction relative to the first housing and the first housing in a first direction relative to the second housing when the locking mechanism is activated. In a further embodiment, insertion of the container into the receptacle of the reusable housing inactivates the locking mechanism. In another embodiment, removal of the container from the receptacle of the reusable housing activates the locking mechanism disposed adjacent to the second housing so as to prevent movement of the first housing in a first direction relative to the second housing and/or the second housing in a second direction relative to the first housing. The locking mechanism can be arranged in the system and device such that pre-delivery of the medicament or pre-simulation, the first and second housings cannot move relative to one another, and plunger component cannot move relative to first housing and post-delivery or post-simulation, the first and second housings cannot move relative to one another, but the plunger component may be freely movable, in one embodiment.

**[0063]** In still a further embodiment, the container can be removed from the reusable housing post use. In these embodiments, the housing may be reusable and the container may be removed after use and disposed. In an alternative embodiment, the system can be embodied as a single use system, wherein the entire housing is disposed after use. In certain single-use embodiments, the container may not be removed from the housing before disposal of the housing.

**[0064]** In a further embodiment, a medicament delivery system configured to provide stepwise instructions for using the system to a user in a particular sequence is provided. The system includes a housing component, the housing component comprising an actuation mechanism, the actuation mechanism for interacting with a container. The container for storing a medicament prior to use includes a first housing for containing a medicament, a second housing, wherein the first housing may be movable relative to the second housing, a plunger component associated with the first housing, and an injection member associated with a lower portion of the first

housing. The housing component may include a control interface which may include at least one responsive member reactive to a user input. The housing component may further include a signal output component associated therewith, and circuitry associated therewith, the circuitry configured to control a provision of the stepwise instructions to the user in the particular sequence. Upon activation of the system, the actuation mechanism interacts with the container such that the first housing moves relative to the second housing in a first direction the injection member may be extended from the second housing, traversing a first contaminant barrier, the plunger component moves relative to the first housing in a first direction to expel the medicament through the injection member, and the first housing moves relative to the second housing in a second direction such that the injection member may be retracted into the second housing to prevent an unintentional contact with the injection member.

**[0065]** In one particular embodiment, a spring may be disposed between the first housing and the second housing such that when the first housing moves relative to the second housing in a first direction, the spring is biased, and when the medicament is delivered from the injection member, the spring is released and the injection member may be retracted into the second housing.

**[0066]** In a further embodiment, the first housing comprises at least a projection member that interacts with the actuation mechanism to cause the first housing to move relative to the second housing such that the injection member traverses the first contaminant barrier when the actuation mechanism is activated.

**[0067]** In still a further embodiment, when the actuation mechanism is activated, the actuation mechanism interacts with a portion of the first housing to move the first housing in a first direction relative to the second housing such that the injection member traverses the first contaminant barrier.

**[0068]** In yet a further embodiment, the actuation mechanism may be a rotatable member, the rotatable member comprising a first threaded portion and a second threaded portion, the second threaded portion provided to interact with the projection member such that when the actuation mechanism is rotated in a first direction, the second threaded portion moves the projection member in a first direction relative to the second housing such that the spring may be biased and the injection member may be extended through the first contaminant barrier.

**[0069]** In another embodiment, the first threaded portion of the actuation mechanism may be provided to interact with an upper portion of the plunger component such that when the actuation mechanism is rotated in a first direction, the first threaded portion moves the plunger component relative to the first housing in a first direction to expel the medicament through the injection member.

**[0070]** In yet another embodiment, the second threaded portion comprises an opening through which the projection member is released, whereby the spring may be released, such that the first housing moves in a second direction relative to the second housing, and the injection member retracts into the second housing.

**[0071]** Turning to the Figures, FIG. 1A illustrates a cross-sectional view and FIG. 1B provides an exploded view of an embodiment of a container 11, the container 11 comprising a first housing 10, a second housing 12, an injection member 16 and a spring 30 disposed between a lower portion 18 of the first housing and a lower portion 22 of the second housing.

The container 11 further includes a first contaminant barrier 26 disposed at a lower portion 22 of the second housing. A plunger component 28 is provided associated with the first housing 10. The plunger component 28 may include a stopper 28B and a shaft 28A in an embodiment, as shown in FIGS. 1A-1B. A third contaminant barrier 36 is disposed between the plunger component 28 and the first housing 10 and prevents contaminants from entering the first housing 10 contacting a medicament 14 contained within the first housing 10. A second contaminant barrier 34 between the second housing 12 and the first housing 10 prevents contaminants from entering the second housing and contacting an inner portion of the second housing 12 and the injection member 16. The injection member 16 may be a needle in one embodiment. In another non-limiting embodiment, the injection member 16 may be an injection simulation member. A simulation or training container may be used in place of the container 11 and may be configured to cooperate with the actuation mechanism 38, wherein the injections simulation member is used in place of an injection member in the training or simulation container. A projection member 40 is provided in FIGS. 1A-1B, the projection member 40 can be used to interact with the actuation mechanism 38 as is described in more detail below. It will be apparent to those skilled in the art, in view of the teachings herein that, the projection member 40 is an optional feature, and is not required for operation of the container 11, depending on the type of actuation implemented.

**[0072]** In FIG. 1B, the second contaminant barrier 34 is embodied as an o-ring type seal, however, different types of contaminant barriers or seals can be used. This embodiment is provided for example only, and not in a limiting capacity. FIGS. 2A-2D' illustrate an embodiment of the device and system wherein the actuation mechanism 38 is a rotational member. In one non-limiting example, the rotational member can be an index cam. The actuation mechanism 38 includes a first threaded portion 46 and a second threaded portion 44, in one embodiment, provided to integrate with and provide movement of the various components of the container 11 to execute an injection or a simulated injection. In the Figures provided, the rotatable actuation mechanism 38 includes two threaded portions; however, one skilled in the art would appreciate that the same could be accomplished with only one threaded portion or with more than two threaded portions on the rotatable member 38. In the Figures shown herein, the rotational member is associated with a motor 54 provided, in an embodiment, to power or activate the rotational member or actuation mechanism 38.

**[0073]** FIG. 2A provides a top end view of a rotatable actuation mechanism 38 and a container 11 in a first position. Once the rotatable actuation mechanism 38 is activated, it is rotated in a first direction such that the second threaded portion 44, which interacts with a projection member 40 on the first housing 10 of the container 11 is moved in a first direction relative to the second housing 12 to bias the spring 30 and extend the injection member 16 through the first contaminant barrier 26 as demonstrated in FIGS. 2B and 2B'. As the rotatable actuation mechanism 38 continues its rotation in the first direction, a first threaded portion 46 comes in contact with the plunger component 28 and by continued rotation of the rotatable actuation mechanism 38 the plunger component 28 is moved in a first direction relative to the first housing 10 to deliver the medicament 14 through the injection member 16 and into the skin of a user as seen in FIGS. 2C and 2C'.

FIGS. 2C-2D show an opening 52 in the second threaded portion 44 whereby the projection member 40 is released to release the spring 30 such that the first housing 10 moves in a second direction relative to the second housing 12 so as to retract the injection member 16 into the second housing 12. In an embodiment, the unique identification information 48 is provided on the container 11, as can be seen in FIGS. 2A-2D' and the identification information reader 50 is provided on the actuation mechanism 38 as is shown in FIGS. 2C'-2D'. It should be borne in mind that all patents, patent applications, patent publications, technical publications, scientific publications, and other references referenced herein are hereby incorporated by reference in this application in order to more fully describe the state of the art to which the present invention pertains.

[0074] It is important to an understanding of the present invention to note that all technical and scientific terms used herein, unless defined herein, are intended to have the same meaning as commonly understood by one of ordinary skill in the art. The techniques employed herein are also those that are known to one of ordinary skill in the art, unless stated otherwise. For purposes of more clearly facilitating an understanding of the invention as disclosed and claimed herein, the preceding definitions are provided.

[0075] While a number of embodiments of the present invention have been shown and described herein in the present context, such embodiments are provided by way of example only, and not of limitation. Numerous variations, changes and substitutions will occur to those of skill in the art without materially departing from the invention herein. For example, the present invention need not be limited to best mode disclosed herein, since other applications can equally benefit from the teachings of the present invention. Also, in the claims, any means-plus-function and step-plus-function clauses are intended to cover the structures and acts, respectively, described herein as performing the recited function and not only structural equivalents or act equivalents, but also equivalent structures or equivalent acts, respectively. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the following claims, in accordance with relevant law as to their interpretation.

What is claimed is:

1. A container for storing a medicament prior to use, the container comprising:

- a first housing for containing a medicament;
- a second housing, wherein the first housing is movable relative to the second housing; and
- an injection member associated with a lower portion of the first housing;

wherein when the first housing moves relative to the second housing in a first direction to deliver the medicament, the injection member extends from the second housing traversing a first contaminant barrier disposed at a lower portion of the second housing, and when the first housing moves relative to the second housing in a second direction the injection member is retracted into the second housing to prevent an unintentional contact with the injection member.

2. The container of claim 1, further comprising a stopper associated with the first housing, said stopper being movable relative to the first housing, whereby the medicament is delivered through the injection member upon movement of the first

housing relative to the second housing in a first direction followed by movement of the stopper relative to the first housing in a first direction.

3. The container of claim 2, wherein the injection member traverses the first contaminant barrier and the stopper is depressed so as to deliver the medicament through the injection member.

4. The container of claim 1, wherein the first contaminant barrier is a membrane.

5. The container of claim 1, wherein a spring is disposed between the first and second housings such that when the first housing moves relative to the second housing in a first direction, the spring is biased, and after the medicament is delivered from the injection member the spring is released and the injection member is retracted into the second housing.

6. The container of claim 1, further comprising a second contaminant barrier between the second housing and the first housing to prevent contaminants from entering the second housing.

7. The container of claim 2, wherein the stopper is associated with a shaft.

8. The container of claim 2, wherein the stopper is associated with a third contaminant barrier.

9. The container of claim 8, wherein the third contaminant barrier prevents contaminants from entering the first housing and/or the medicament.

10. The container of claim 1, wherein the container does not comprise an actuation mechanism.

11. A medicament delivery or injection simulation system, comprising:

- a container, the container comprising a first housing and a second housing, wherein the first housing is movable relative to the second housing;

- an injection member or an injection simulation member associated with a lower portion of the first housing, wherein when the first housing moves relative to the second housing in a first direction, the injection member or injection simulation member extends from the second housing traversing a first contaminant barrier disposed at a lower portion of the second housing, and the first housing moves relative to the second housing in a second direction the injection member or injection simulation member is retracted into the second housing to prevent an unintentional contact with the injection member or injection simulation member; and

- an actuation mechanism associated with the container, wherein said actuation mechanism drives the movement of the first housing.

12. The medicament delivery or injection simulation system of claim 11, wherein the actuation mechanism comprises a motor.

13. The medicament delivery or injection simulation system of claim 11, wherein the first contaminant barrier is a membrane.

14. The medicament delivery or injection simulation system of claim 11, wherein the container comprises a medicament.

15. The medicament delivery or injection simulation system of claim 11, further comprising a stopper associated with the first housing, said stopper being movable relative to the first housing, whereby the medicament is delivered through the injection member upon movement of the first housing

relative to the second housing in a first direction followed by movement of the stopper relative to the first housing in a first direction.

**16.** The medicament delivery or injection simulation system of claim **15**, wherein the actuation mechanism comprises a motor that drives the movement of the stopper.

**17.** The medicament delivery or injection simulation system of claim **11**, further comprising a second contaminant barrier between an upper portion of the second housing and the lower portion of the first housing to prevent contaminants from entering the second housing.

**18.** The medicament delivery or injection simulation system of claim **15**, wherein a third contaminant barrier is disposed between the stopper and the first housing to prevent contaminants from entering the first housing and/or the medicament.

**19.** The medicament delivery or injection simulation system of claim **11**, further comprising a reusable housing, said reusable housing comprising a receptacle for receiving said container.

**20.** The medicament delivery or injection simulation system of claim **19**, wherein said actuation mechanism is in said reusable housing.

**21.** The medicament delivery or injection simulation system of claim **15**, further comprising a shaft connected to said stopper.

**22.** A container for storing a medicament prior to use, the container comprising:

- a first housing for containing a medicament;
- a second housing, wherein the first housing is movable relative to the second housing;
- an injection member associated with a lower portion of the first housing; and
- a plunger associated with the first housing, said plunger being movable relative to the first housing;

wherein when the first housing moves relative to the second housing in a first direction to deliver the medicament, the injection member extends from the second housing traversing a first contaminant barrier disposed at a lower portion of the second housing, and wherein when the plunger moves relative to the first housing in a first direction, medicament is delivered through the injection member, and when the first housing moves relative to the second housing in a second direction the injection member is retracted into the second housing to prevent an unintentional contact with the injection member.

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