IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRACCO DIAGNOSTICS INC. Plaintiff, v. JUBILANT DRAXIMAGE INC., JUBILANT PHARMA LIMITED, and JUBILANT LIFE SCIENCES Defendants.	)	Civil Action No.: _____ **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Bracco Diagnostics Inc. ("Bracco" or "Plaintiff"), by and through its undersigned counsel, files this Complaint against Defendants Jubilant DraxImage Inc., Jubilant Pharma Limited, and Jubilant Life Sciences (collectively, "Jubilant" or "Defendants") and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 9,814,826 ("the '826 patent"), 9,750,869 ("the '869 patent"), 9,750,870 ("the '870 patent"), 9,299,467 ("the '467 patent") and 9,299,468 ("the '468 patent") attached hereto as Exhibits A, B, C, D, and E respectively (collectively, "the patents-in-suit").

THE PARTIES

2. Bracco Diagnostics Inc. is a company organized and existing under the laws of Delaware, with a principal place of business at 259 Prospect Plains Road, Monroe Township, NJ 08831.

3. Upon information and belief, Jubilant DraxImage Inc. is a corporation organized and existing under the laws of Canada with its principal place of business at 16751 TransCanada Highway Kirkland, Québec, Canada H9H 4J4.

4. Upon information and belief, Jubilant DraxImage Inc. received FDA approval for the Ruby-Fill® rubidium-82 generator and elution system on September 30, 2016.

5. Upon information and belief, Jubilant Pharma Limited is a corporation organized and existing under the laws of Singapore, with its principal place of business at 6 Temasek Boulevard, #20-06 Suntec City Tower Four, Singapore 038986.

6. Upon information and belief, Jubilant Life Sciences is a corporation organized and existing under the laws of India, with its principal place of business at 1A, Sector 16A, Noida – 201301, Uttar Pradesh, India.

7. Upon information and belief, Jubilant DraxImage Inc. is a subsidiary of Jubilant Pharma Limited.

8. Upon information and belief, Jubilant Pharma Limited is a subsidiary of Jubilant Life Sciences.

9. Upon information and belief, Jubilant DraxImage Inc. is the manufacturer of the infringing strontium-rubidium radioisotope infusion system, which it sells under the tradename Ruby-Fill®. Jubilant DraxImage Inc. also filed a 505(b)(2) New Drug Application (NDA or 505(b)(2) NDA) No. 202153 to market and sell the infringing strontium-rubidium radioisotope infusion system (Ruby-Fill®) in the United States.

10. Upon information and belief, at least Jubilant Pharma Limited and Jubilant DraxImage Inc. actively participated in the development and regulatory approval process for the infringing strontium-rubidium radioisotope infusion system (Ruby-Fill®).

11. Upon information and belief, Jubilant Pharma Limited, Jubilant Life Sciences, and Jubilant DraxImage Inc. direct the manufacture and development of the Ruby-Fill® system that is the subject of NDA No. 202153, and directly or indirectly, derive substantial revenue from the sale of the Ruby-Fill® system and its components thereof.

12. Upon information and belief, Jubilant Pharma Limited, Jubilant Life Sciences, and Jubilant DraxImage Inc. are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of the infringing strontium-rubidium radioisotope infusion system (Ruby-Fill®) throughout the United States.

JURISDICTION AND VENUE

13. This action arises under the Patent Act, Title 35 of the United States Code, and is an action for patent infringement under § 271.

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

15. Upon information and belief, Jubilant DraxImage Inc. is engaged in the manufacturing, marketing, and sale of pharmaceutical products for the U.S. prescription drug market with products for sale in the United States, including in the state of New Jersey. According to Jubilant DraxImage Inc.'s website, it currently manufactures, markets, and/or sells pharmaceutical products in the United States, including, for example, DraxImage MAA, DraxImage DTPA, DraxImage I-131, Hicon, DraxImage MDP-25, DraxImage Sestamibi, Smart-Fill, and Ruby-Fill®.

16. This Court has personal jurisdiction over Jubilant DraxImage Inc. by virtue of the fact that, *inter alia*, Jubilant DraxImage Inc. has committed, aided, abetted, contributed to, and/or

participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271 that has led and/or will lead to foreseeable harm and injury to Plaintiff, including in the State of New Jersey.

17. Upon information and belief, Jubilant DraxImage Inc. is in the business of, *inter alia*, manufacturing and selling a strontium-rubidium radioisotope infusion system, which it sells under the tradename Ruby-Fill®, that are distributed throughout the United States, including in the State of New Jersey, through its own actions, and through the actions of its agents and affiliates, including.

18. Upon information and belief, Jubilant DraxImage Inc. participated and collaborated in the preparation, filing and seeking FDA approval of NDA No. 202153 for the Ruby-Fill® system, and participate and collaborate in the commercial manufacture, marketing offer for sale, and sale of the Ruby-Fill® system throughout the United States, including the State of New Jersey.

19. This Court also has personal jurisdiction over Jubilant DraxImage Inc. by virtue of the fact that, upon information and belief, *inter alia*, Jubilant DraxImage Inc. has availed itself of the rights and benefits of New Jersey law, and has engaged in systematic and continuous contacts with the State of New Jersey.

20. Therefore, this Court has personal jurisdiction over Jubilant DraxImage Inc. and because, *inter* alia: (a) Jubilant DraxImage Inc. is in the business of manufacturing drug products which it distributes, sells, and offers to sell, throughout the United States, including in New Jersey, and through the filing of 505(b)(2) NDA No. 202153, Jubilant DraxImage Inc. has sought approval to sell a product that infringes the patents-in-suit throughout the United States, including in New Jersey; (b) with knowledge of Bracco's CardioGen-82 system, Jubilant

DraxImage Inc. deliberately challenged intellectual property developed and held by Bracco, a Delaware company, in New Jersey; (c) upon information and belief, Jubilant DraxImage Inc. utilizes Jubilant Life Sciences (USA), Inc., a New Jersey based company, to assist in the sale and distribution of pharmaceutical products; (d) Jubilant DraxImage Inc. has offered to sell and sells, directly or indirectly, the Ruby-Fill® system throughout the United States and within New Jersey; (e) Jubilant DraxImage Inc.'s sales and offer for sales of the Ruby-Fill® system in the United States, has caused substantial injury to Bracco, a company headquartered within the District of New Jersey, and Jubilant DraxImage Inc. knows that Bracco has been injured by these action in New Jersey; (f) Jubilant DraxImage Inc. derives substantial revenue from products it ships to New Jersey as well as from products sold, used, or consumed within New Jersey; (g) Jubilant DraxImage Inc. regularly does and solicits business in New Jersey, and is engaged in a persistent, continuous, and systematic course of conduct in New Jersey.

21. Upon information and belief, Jubilant Pharma Limited, Jubilant Life Sciences, and Jubilant DraxImage Inc. are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of Ruby-Fill® systems throughout the United States, including into the State of New Jersey.

22. This Court has personal jurisdiction over Jubilant Pharma Limited and Jubilant Life Sciences because, *inter alia*, upon information and belief, Jubilant Pharma Limited and Jubilant Life Sciences, itself or in concert with and/or through its various subsidiaries, regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, demonstrating that Jubilant Pharma Limited and Jubilant Life Sciences has continuous and systematic contacts with the State of New Jersey.

23. Upon information and belief, Jubilant DraxImage Inc.'s acts of preparing and filing NDA No. 202153 were performed at the direction of, with the authorization of, and with the cooperation, participation, assistance and, at least in part, the benefit of Jubilant Pharma Limited and Jubilant Life Sciences. These are acts with real and injurious consequences giving rise to this infringement action, including the present commercial manufacture, use, and/or sale of the Ruby-Fill® system before the expiration of the patents-in-suit throughout the United States, including in this judicial district. Moreover, because Bracco has its principal place of business in New Jersey, these injuries and consequences are suffered in New Jersey. Therefore, Jubilant Pharma Limited, Jubilant Life Sciences, and Jubilant DraxImage Inc. together purposefully directed their activities towards the State of New Jersey. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic pharmaceutical companies business, Jubilant Pharma Limited, Jubilant Life Sciences, and Jubilant DraxImage Inc. reasonably anticipated being sued in New Jersey.

24. Therefore, this Court has personal jurisdiction over Jubilant Pharma Limited and Jubilant Life Sciences because, *inter alia*: (a) Jubilant Pharma Limited and Jubilant Life Sciences has purposefully directed its activities and the activities of Jubilant DraxImage Inc., its wholly owned subsidiary, at residents and corporate entities within the State of New Jersey; (b) the claims set forth herein as to Jubilant Pharma Limited and Jubilant Life Sciences arise out of or relate to those activities; (c) Jubilant Pharma Limited and Jubilant Life Sciences' contacts with the State of New Jersey (direct and/or indirect) are continuous and systematic; and (d) it is reasonable and fair for this Court to exercise personal jurisdiction over Jubilant Pharma Limited and Jubilant Life Sciences.

25. Additionally, this Court has personal jurisdiction over Jubilant DraxImage Inc. under Federal Rule of Civil Procedure 4(k)(2), because Jubilant DraxImage Inc. is organized under the laws of Canada.

26. Additionally, this Court has personal jurisdiction over Jubilant Life Sciences inter alia, under Federal Rule of Civil Procedure 4(k)(2), because Jubilant Life Sciences is organized under the laws of India.

27. Additionally, this Court has personal jurisdiction over Jubilant Pharma Limited inter alia, under Federal Rule of Civil Procedure 4(k)(2), because Jubilant Pharma is organized under the laws of Singapore.

28. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND FACTS

Bracco's NDA

29. Bracco is the holder of New Drug Application No. 19414 for CardioGen-82 (rubidium 82 generator).

30. CardioGen-82 is a closed system used to produce rubidium Rb 82 chloride injection for intravenous administration. Rubidium Rb 82 chloride injection is indicated by the U.S. Food and Drug Administration ("FDA") for Positron Emission Tomography ("PET") imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease. The resulting images allow a physician to evaluate the blood flow (perfusion) through the coronary arteries to the heart muscle, and thus diagnose whether any heart disease exists.

31. In 1989, the CardioGen-82 system became the first FDA approved generator-based Positron Emission Tomography ("PET") perfusion agent reimbursed for the evaluation of coronary artery disease.

32. The CardioGen-82 system infuses a radioactive nuclear medicine agent, rubidium-82 which is produced from its precursor strontium-82, for the purpose of imaging the heart to determine if the heart's blood supply is normal or not. By way of example, the existing CardioGen-82 system can be seen below (the actual generator is housed underneath in lead shielding):

33. Contained inside this cart is the rubidium generator:

The Patents-in-Suit

34. The ’826 patent is entitled “Integrated strontium-rubidium radioisotope infusion systems,” was duly and legally issued by the United States Patent and Trademark Office on November 14, 2017. A true and correct copy of the ’826 patent is attached to the Complaint as Exhibit No. A.

35. Bracco owns by assignment the entire right, title, and interest in the ’826 patent.

36. The ’869 patent is entitled “Integrated strontium-rubidium radioisotope infusion systems,” was duly and legally issued by the United States Patent and Trademark Office on September 5, 2017. A true and correct copy of the ’869 patent is attached to the Complaint as Exhibit No. B.

37. Bracco owns by assignment the entire right, title, and interest in the ’869 patent.

38. The ’870 patent is entitled “Integrated strontium-rubidium radioisotope infusion systems,” was duly and legally issued by the United States Patent and Trademark Office on September 5, 2017. A true and correct copy of the ’870 patent is attached to the Complaint as Exhibit No. C.

39. Bracco owns by assignment the entire right, title, and interest in the ’870 patent.

40. The ’467 patent is entitled “Radioisotope generator system including activity measurement and dose calibration,” was duly and legally issued by the United States Patent and Trademark Office on March 29, 2016. A true and correct copy of the ’467 patent is attached to the Complaint as Exhibit No. D.

41. Bracco owns by assignment the entire right, title, and interest in the ’467 patent.

42. The ’468 patent is entitled “Infusion system with radioisotope detector,” was duly and legally issued by the United States Patent and Trademark Office on March 29, 2016. A true and correct copy of the ’468 patent is attached to the Complaint as Exhibit No. E.

43. Bracco owns by assignment the entire right, title, and interest in the ’468 patent.

Defendants’ Infringing Activities

44. Defendants submitted an abbreviated new drug application (“ANDA”) to the U.S. Food and Drug Administration on June 18, 2010 to market a system Defendants described as the equivalent of CardioGen-82.

45. Due to variations in administration rates, the FDA reclassified the ANDA filing as a 505(b)(2) NDA. However, Defendants still relied on clinical studies that Bracco performed in submitting its proposed equivalent version of Bracco’s product.

46. Defendants represented to the FDA that the Ruby-Fill® system is a “pharmaceutical equivalent” to Bracco’s CardioGen-82.

47. Pharmaceutical equivalents are drug products in identical dosage forms intended for the same route of administration that: (1) contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; (2) do not necessarily contain the same inactive ingredients; and (3) meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. *See* 21 C.F.R. § 320.1(c).

48. Defendants received FDA approval for the Ruby-Fill® rubidium-82 generator and elution system on September 30, 2016 and began selling such units in the United States immediately thereafter.

49. Jubilant DraxImage Inc. manufactures and/or imports infringing strontium-rubidium radioisotope infusion systems and/or components thereof, including but not limited to rubidium-82 generators, under the tradename Ruby-Fill®, which are sold in the United States.

50. The Ruby-Fill® system is pictured below:

See http://www.draximage.com/products/us/ruby-fill/.

51. Upon information and belief, the Ruby-Fill® has been installed in, at least, three locations in the United States.

52. The Ruby-Fill® system utilizes a rubidium (Rb 82) generator. The Ruby-Fill® system pumps saline through the generator to elute rudibium-82 for injection into the patient. The rubidium (Rb 82) generator is a critical component to the overall Ruby-Fill® system, because it is the source of the rubidium-82. There is no use for Defendants rubidium (Rb 82) generator other than with the Ruby-Fill® system.

53. The Defendants unlawfully sell for importation, import, and/or sell after importation into the United States strontium-rubidium radioisotope infusion systems and components thereof that infringe the patents-in-suit.

54. Defendants manufacture the rubidium-82 generator, which is an essential component of the Ruby-Fill® system as it is the source of the rubidium-82 that is used in the rubidium-82 chloride for injection into patients. The FDA approved labeling for Ruby-Fill® states that this generator may be used "only with an appropriate, properly calibrated Elution

System (RUBY Rubidium Elution System) labeled for use with the generator." Defendants understand and intend that the rubidium-82 generator has no other approved use except as part of the infringing Ruby-Fill® system. Thus, Defendants encourage, recommend, and promote the use of its rubidium-82 generators as part of the infringing Ruby-Fill® system.

55. Through its infringing activities, Defendants have caused direct injury to Bracco throughout the United States and in New Jersey.

COUNT ONE – INFRINGEMENT OF THE '826 PATENT

56. Bracco repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

57. Defendants make, use, offer to sell, sells, and/or imports an infusion system to deliver a rubidium radioactive eluate (i.e., Ruby-Fill®) that infringes or induces or contributes to the infringement of one or more claims of the '826 patent.

58. The elements of claim 1 of the '826 patent are as follows:

> 1. A method of building an infusion system to deliver a rubidium radioactive eluate comprising:
>
> (a) installing a first shielding compartment, a second shielding compartment, and a shielded well on a platform of a cart, wherein:
>
> (i) the first shielding compartment has a first opening facing vertically upwardly,
>
> (ii) the first opening is configured for a strontium-rubidium radioisotope generator to be inserted into and removed from the first shielding compartment,
>
> (iii) the second shielding compartment has a second opening facing vertically upwardly,
>
> (iv) the second opening is configured for a waste bottle to be inserted into and removed from the second shielding compartment,
>
> (v) the first opening is located at a lower elevation than the second opening, and

> (vi) the shielded well is configured to receive an eluate reservoir that is configured to receive a sample of the rubidium radioactive eluate;
>
> (b) configuring a computer with a touch screen display for the infusion system to:
>
> (i) fill the eluate reservoir in the shielded well on-board the cart with the sample of the rubidium radioactive eluate by pumping saline from a saline reservoir into the strontium-rubidium radioisotope generator via a saline tubing line thereby generating the rubidium radioactive eluate that is discharged through an eluate tubing line,
>
> (ii) determine a strontium breakthrough test result on the sample of the rubidium radioactive eluate filled into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart, and
>
> (iii) not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

59. As shown below, Defendants do and will install a first shielding compartment, a second shielding compartment, and a shielded well on a platform of a cart when manufacturing the Ruby-Fill® system.

See Exhibit No. F at 1;

3.1 RUBY-FILL® RUBIDIUM RB 82 GENERATOR

The Generator always remains inside 1-inch-thick lead shielding. The handle must be removed before the lead cover can be removed. When the cover of the lead container is removed, only the fittings are exposed (see Fig. 3, Generator, Generator Handle & Lead Cover), which allows connection to the RUBY SET **via the RUBY CONNECTORS**. The Generator is a closed system and has Quick-Connect fittings which are plugged with metal caps for shipping (see Fig. 4, Generator Metal Caps). The inlet to the Generator is the male Quick-Connect and the outlet to the generator is the female Quick-Connect (see RUBY SET Installation, section 6.5). Once the Generator is expired there is no need to recap the Quick Connect fittings on the Generator with the metal caps.

Figure 3, Generator, Generator Handle & Lead Cover

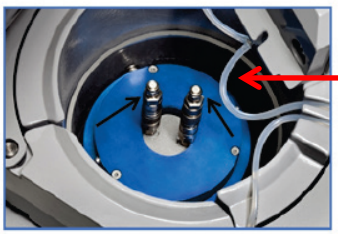


Figure 4, Generator Metal Caps

Id. at 10;

2.3 MAIN SYSTEM COMPONENTS

The main components of the RUBY Rubidium Elution System are (see Fig. 1, RUBY Rubidium Elution System, see Fig. 2, System Components):

1. Dose Calibrator
2. Waste Bottle
3. Pressure Transducer Holder and Connector
4. Pinch valves (four)
5. Photo Multiplier Tube (PMT)
6. Generator Well
7. Peristaltic Pump
8. Touch Screen Computer User Interface (not shown)
9. Removable Storage Compartment (not shown)

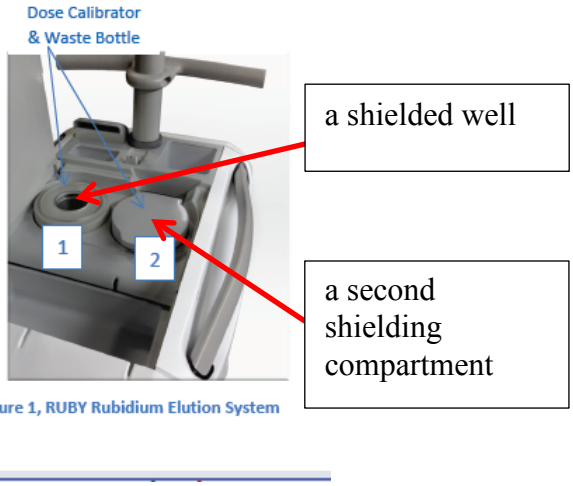


Figure 1, RUBY Rubidium Elution System

Id. at 9.

60. As shown below, the first shielding compartment of the Ruby-Fill® system has a first opening facing vertically upwardly.

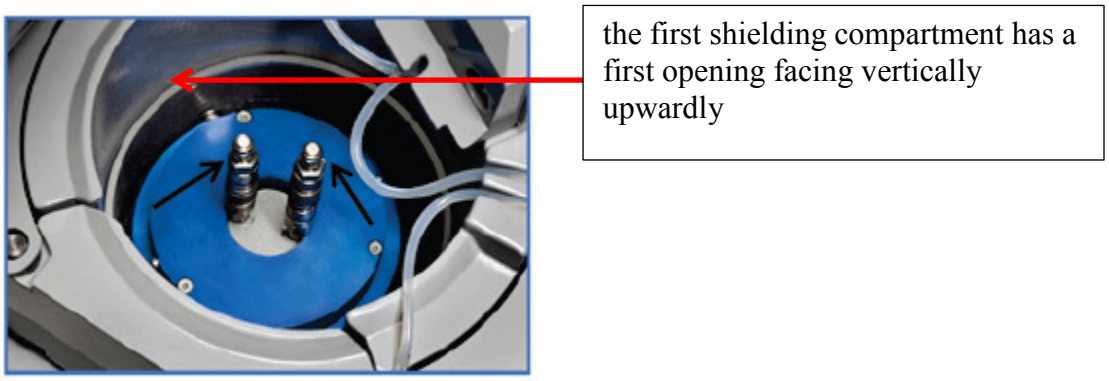


Figure 4, Generator Metal Caps

Id. at 10.

61. As shown below, the first opening of the Ruby-Fill® system is configured for a strontium-rubidium radioisotope generator to be inserted into and removed from the first shielding compartment.

6.6 INSTALLING THE NEW GENERATOR

Using the Generator handle, install a new Generator by inserting it carefully into the Generator well (see Fig. 37, Installing the New Generator). Remove the Generator handle, then the cover. Using aseptic techniques, remove the metal caps on the Generator and connect both RUBY CONNECTORS to the quick connects on the Generator, mating a male to a female quick connect. Make sure the tubing lines are in the grooves of the Generator lead well and close the Generator well lid promptly to avoid unnecessary exposure. The Generator packing slip is shipped with the Generator in a plastic pouch inside of the shipping container. Retrieve the packing slip, and on the Generator Setup screen, **step 5 under the Generator Installation and Setup** (Fig. 38, Generator Setup Screen) enter the lot number, strontium ratio (Sr-85/Sr-82), calibration date and expiration date.

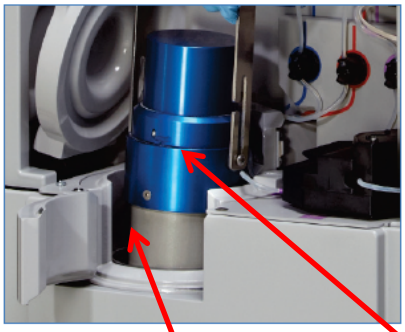


Figure 37, Installing the New Generator

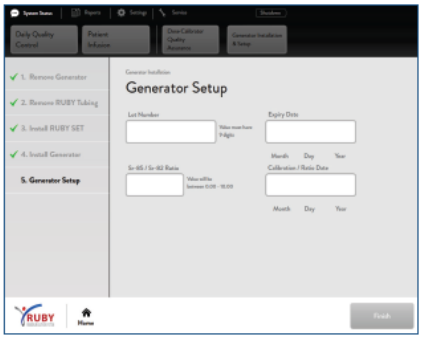


Figure 38, Generator Setup Screen

Save the Generator handle and cover with shipping container for use when removing the expired Generator and metal caps to recap the generator.

the first opening is configured for a strontium-rubidium radioisotope generator to be inserted into and removed from the first shielding compartment

a strontium-rubidium radioisotope generator

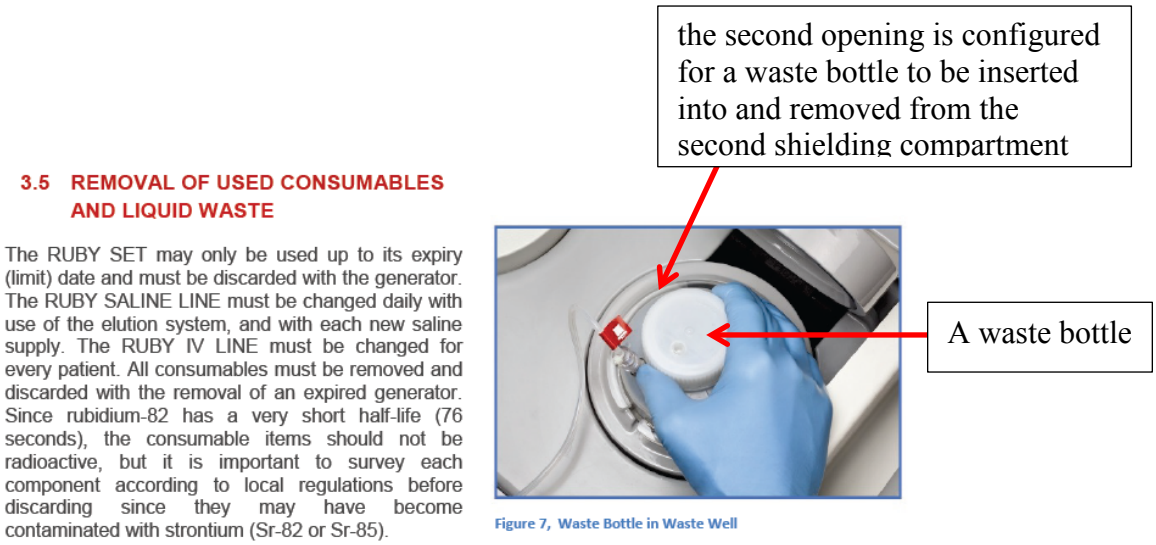
Id. at 34.

62. As shown below, the second shielding compartment of the Ruby-Fill® system has a second opening facing vertically upwardly.

Figure 7. Waste Bottle in Waste Well

Id. at 12.

63. As shown below, the second opening of the Ruby-Fill® system is configured for a waste bottle to be inserted into and removed from the second shielding compartment.



Id. at 12.

64. As shown below, the first opening of the Ruby-Fill® system is located at a lower elevation than the second opening.

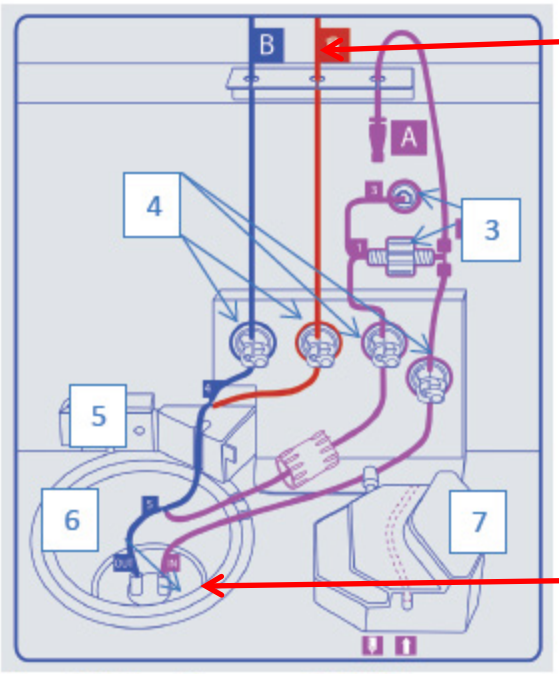


Figure 2, System Components (#3-#7)

Id. at 9.

65. As shown below, the shielded well of the Ruby-Fill® system is configured to receive an eluate reservoir that is configured to receive a sample of the rubidium radioactive eluate.

2.3 MAIN SYSTEM COMPONENTS

The main components of the RUBY Rubidium Elution System are (see Fig. 1, RUBY Rubidium Elution System, see Fig. 2, System Components):

1. Dose Calibrator
2. Waste Bottle
3. Pressure Transducer Holder and Connector
4. Pinch valves (four)
5. Photo Multiplier Tube (PMT)
6. Generator Well
7. Peristaltic Pump
8. Touch Screen Computer User Interface (not shown)
9. Removable Storage Compartment (not shown)

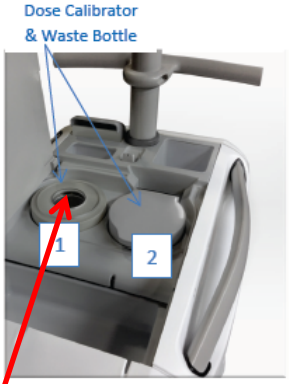


Figure 1, RUBY Rubidium Elution System

the shielded well is configured to receive an eluate reservoir that is configured to receive a sample of the rubidium radioactive eluate

Id. at 9;

> The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
> The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).
>
> Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.
>
> 1. Obtain a 50 ml sealed glass vial (with rubber stopper)
> 2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
> 3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
> 4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
> 5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
> 6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

See, e.g., id. at 42.

66. As shown below, the Ruby-Fill® system has a computer with a touch screen display for the infusion system.

Id. at 1.

67. As shown below, the Ruby-Fill® system can be configured to fill the eluate reservoir in the shielded well on-board the cart with the sample of the rubidium radioactive eluate by pumping saline from a saline reservoir into the strontium-rubidium radioisotope generator via a saline tubing line thereby generating the rubidium radioactive eluate that is discharged through an eluate tubing line.

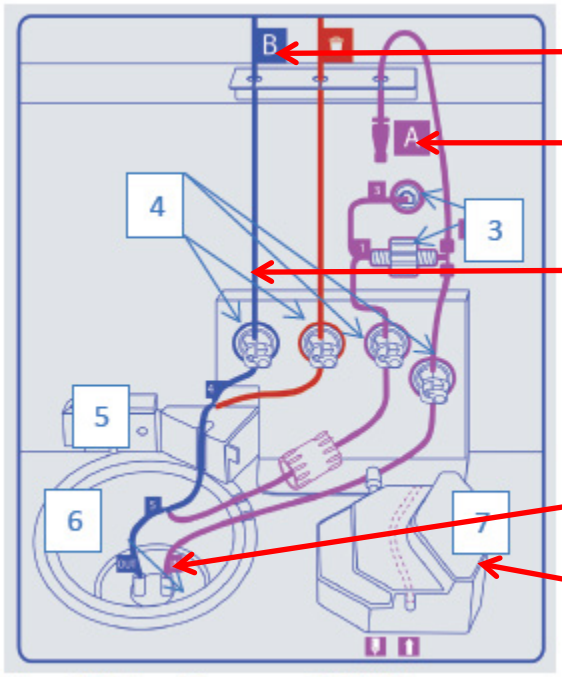


Figure 2, System Components (#3-#7)

to eluate reservoir in the shielded well on-board the cart

from a saline reservoir

an eluate tubing line

strontium-rubidium radioisotope generator

a pump for pumping saline from a saline reservoir into the strontium-rubidium radioisotope generator via a saline tubing line

Id. at 9;

6.1 DOSE CALIBRATOR QUALITY ASSURANCE

The RUBY Rubidium Elution System comes with an integrated dose calibrator. This dose calibrator is fully controlled using the system's software. To access the quality assurance mode, press Dose Calibrator Quality Assurance on the second row of the task bar and enter the required password. The control screen is displayed (see Fig. 26, Dose Calibrator Quality Assurance Screen). To perform the required quality assurance tests, such as Linearity, Geometry and Accuracy, an independent control screen is included to enable the operation and/or configuration of the dose calibrator in conventional mode (Table 2, Dose Calibrator Quality Assurance & Required Frequency of Performance). JDI personnel will complete all four quality assurance tests upon installation of the elution system. Users are responsible for performing Constancy daily (integrated into Daily Quality Control); Linearity quarterly and Accuracy annually.

Id. at 28;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

Id. at 42.

68. As shown below, the Ruby-Fill® system can be configured to determine a strontium breakthrough test result on the sample of the rubidium radioactive eluate filled into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart.

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

Id. at 42;

Figure 49, Flush, Calibration, and Breakthrough Screen

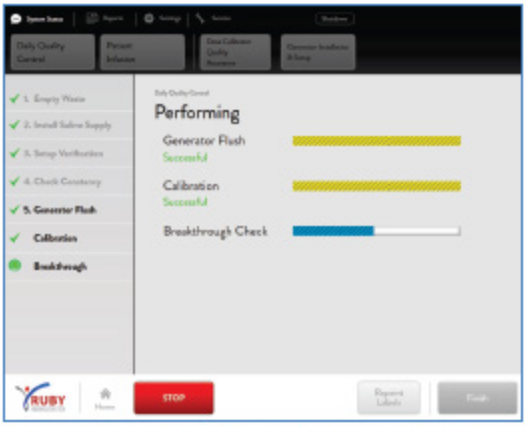


Figure 50, Performing Daily Quality Control (Flush and Calibration are completed and the Breakthrough Check is in progress)

Id. at 43.

69. As shown below, the Ruby-Fill® system can be configured to not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

System Error Message	Message Meaning	How to Troubleshoot
Sr Breakthrough Too High	The breakthrough limit level is reached. Patient infusions not allowed.	▪ Verify that the generator is not expired. ▪ Verify background activity fluctuations. ▪ Repeat radioactivity calibration and breakthrough check. ▪ Install a new generator.

Id. at 59;

The system can be used with four (4) patients before a Quality Control procedure must be performed if the breakthrough reaches an alert limit. If the user repeats the flush, the system counts this as a patient infusion.

- ≥ 50% of the USP limit* (see Table 3), the system does not allow the user to perform a patient infusion.
- Refer to Table 3 below for instructions to follow on Strontium Breakthrough results.

PASS < 20% of USP limits* (Green)	ALERT ≥ 20% and <50% of USP limits* OR 20L volume limit (Yellow)	FAIL ≥ 50% of USP limits* OR 30L volume limit (Red)
Breakthrough level is low.	Breakthrough level is increased.	Breakthrough level is approaching the allowable limit.
The Daily Quality Procedure (automated breakthrough test) is valid for a 24 hour period.	The Daily Quality Procedure (automated breakthrough test) is valid for 4 patients only.	The Daily Quality Control (automated breakthrough test) does not allow a sufficient margin of safety to continue the elutions (scans).
Proceed with use	Repeat an automated Daily Quality Control after every 4 patients (8 scans) and record the results Contact Jubilant DraxImage: 1-888-633-5343	The use of the RUBY-FILL® Rubidium Rb 82 Generator must be discontinued immediately. Contact Jubilant DraxImage: 1-888-633-5343
*USP limits: <0.02μCi of Sr-82/mCi of Rb-82; <0.2μCi of Sr-85/mCi of Rb-82		

Table 3: Strontium Breakthrough Results

Id. at 44.

70. Defendants infringe, contribute to the infringement of, and/or induce infringement of the '826 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by making, using, selling, offering for sale, and/or importing into the United States products covered by one or more claims of the '826 patent including, but not limited to, at least the Ruby-Fill® system.

71. Defendants directly infringe one or more claims of the '826 patent. Defendants make, use, sell, offer for sale, and/or import, in this District and elsewhere in the United States infringing products, such as the Ruby-Fill® system and thus directly infringes the '826 patent.

72. Defendant have had knowledge and notice of the '826 patent at least as early as the filing of this Complaint.

73. Defendants' infringement of the '826 patent has damaged and will continue to damage Bracco.

74. Defendants indirectly infringe the '826 patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Defendants' customers, in this District and elsewhere in the United States. For example, Defendants' customers directly infringe through their use of the inventions claimed in the '826 patent. Defendants induce this direct infringement through their affirmative acts of manufacturing, selling, distributing, instructing and/or otherwise making available the infringing products, such as the Ruby-Fill® system, and providing instructions, documentation, and other information to customers suggesting they use the infringing products, such as the Ruby-Fill® system in an infringing manner, including online technical support, marketing, product manuals, advertisements, and online documentation. As a result of Defendants' inducement, Defendants' customers use the infringing products, such as the Ruby-Fill® system in the way Defendants intend and directly infringe the '826 patent.

Defendants have performed and continue to perform these affirmative acts with knowledge of the '826 patent and with the intent, or willful blindness, that the induced acts directly infringe the '826 patent.

75. Defendants also indirectly infringes the '826 patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers, in this District and elsewhere in the United States. Defendants' affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, infringing products, such as the Ruby-Fill® system and causing these products to be manufactured, used, sold, and offered for sale contribute to Defendants' customers' use of the infringing products, such as the Ruby-Fill® system, such that the '826 patent is directly infringed. Defendants have performed and continue perform these affirmative acts with knowledge of the '826 patent and with intent, or willful blindness, that they cause the direct infringement of the '826 patent.

76. Defendants' infringement of the '826 patent will cause Bracco to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Bracco has no adequate remedy at law and, thus, a permanent injunction is appropriate to prohibit Defendants from infringing the '826 patent.

COUNT TWO – INFRINGEMENT OF THE '869 PATENT

77. Bracco repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

78. Defendants make, use, offer to sell, sells, and/or imports an infusion system to deliver a rubidium radioactive eluate (*i.e.*, Ruby-Fill®) that infringes or induces or contributes to the infringement of one or more claims of the '869 patent.

79. The elements of claim 1 of the '869 patent are as follows:

1. An infusion system on-board a cart comprising:

(a) a cabinet structure that comprises:

(i) a platform,

(ii) an exterior shell that extends upwardly above the platform and has a front side; a rear side; two sidewalls connecting the front side to the rear side; and a top surface; wherein the platform and the exterior shell collectively define an interior space of the cabinet structure and wherein the interior space of the cabinet structure is configured to receive a strontium-rubidium radioisotope generator having an inlet tubing port configured to receive saline and an outlet tubing port configured to discharge a rubidium radioactive eluate,

(iii) an opening through the exterior shell configured to provide access to the strontium-rubidium radioisotope generator within the interior space of the cabinet structure, and

(iv) an opening through the top surface of the exterior shell configured to provide access for inserting a waste bottle into or removing the waste bottle from the interior space of the cabinet structure;

(b) a computer with a touch screen display configured to receive an input from a user for controlling operation of the infusion system, wherein the touch screen display is mounted on a vertical post having a top end extending above the cabinet structure;

(c) a first shielding compartment in the interior space of the cabinet structure having a first opening facing vertically upwardly through which the strontium-rubidium radioisotope generator can be inserted into and removed from the first shielding compartment;

(d) a first door accessible via the opening through the exterior shell, the first door being configured to provide access to the first shielding compartment and to close over the first opening;

(e) a second shielding compartment having a second opening facing vertically upwardly through which the waste bottle can be inserted into and removed from the second shielding compartment;

(f) a second door accessible via the opening through the top surface of the exterior shell, the second door being configured to provide access to the second shielding compartment and to close over the second opening;

(g) wherein the first opening is located at a lower elevation than the second opening;

(h) a radioactivity detector positioned to measure radioactivity of the rubidium radioactive eluate flowing through an eluate tubing line in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator;

(i) a shielded well on-board the cart configured to receive an eluate reservoir, wherein the eluate reservoir is configured to receive a test sample; and

(j) wherein the computer of the infusion system is configured to:

(i) provide a stop button on the touch screen display to abort a function of the infusion system in response to a user input activating the stop button,

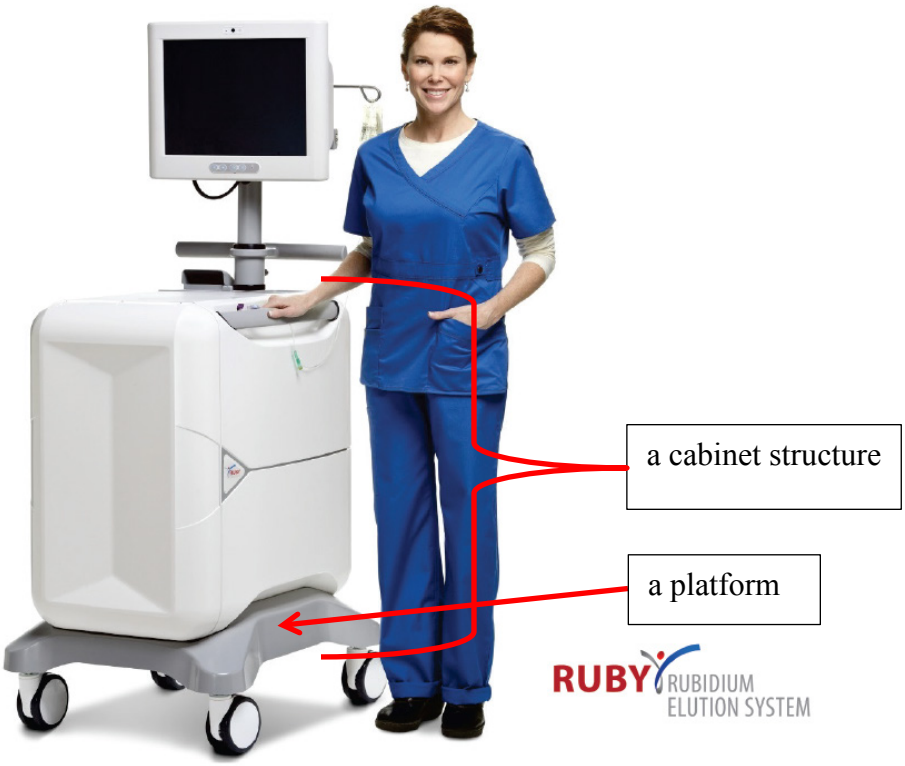
(ii) pump saline from a saline reservoir positioned outside of the interior space of the cabinet structure into the strontium-rubidium radioisotope generator through the inlet tubing port of the strontium-rubidium radioisotope generator thereby generating the rubidium radioactive eluate that is discharged through the outlet tubing port,

(iii) fill the eluate reservoir in the shielded well on-board the cart with the test sample of the rubidium radioactive eluate,

(iv) determine a strontium breakthrough test result on the test sample filled into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart, and

(v) not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

80. As shown below, the Ruby-Fill® infusion system has a cabinet structure that comprises a platform.

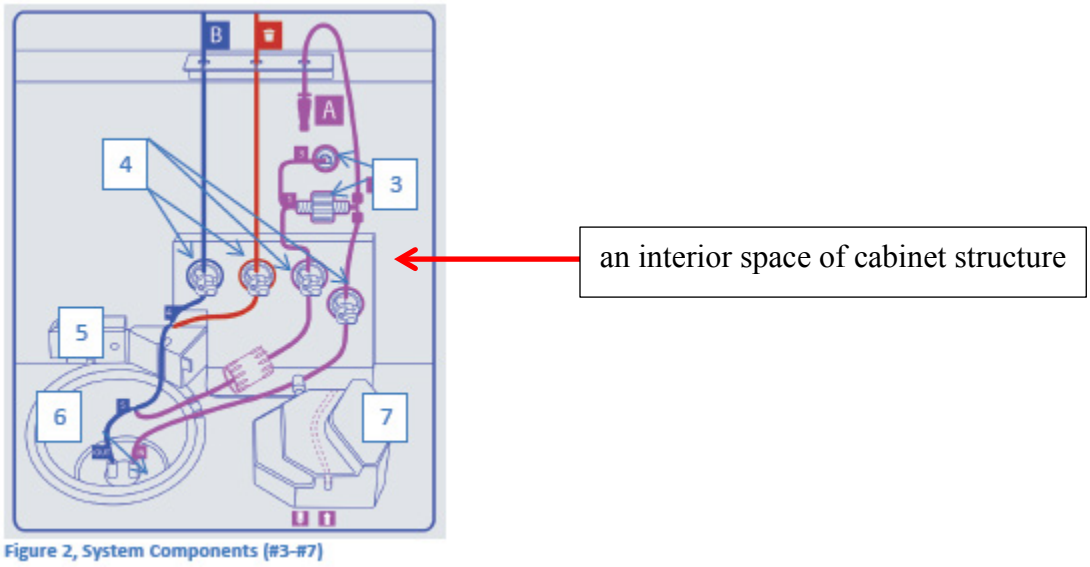


Id. at 1.

81. As shown below, the cabinet structure of the Ruby-Fill® infusion system has an exterior shell that extends upwardly above the platform and has a front side; a rear side; two sidewalls connecting the front side to the rear side; and a top surface.

Id. at 1.

82. As shown below, the platform and the exterior shell collectively define an interior space of the cabinet structure of the Ruby-Fill® infusion system.



See e.g., id. at 9.

83. As shown below, the interior space of the cabinet structure of the Ruby-Fill® infusion system is configured to receive a strontium-rubidium radioisotope generator having an inlet tubing port configured to receive saline and an outlet tubing port configured to discharge a rubidium radioactive eluate.

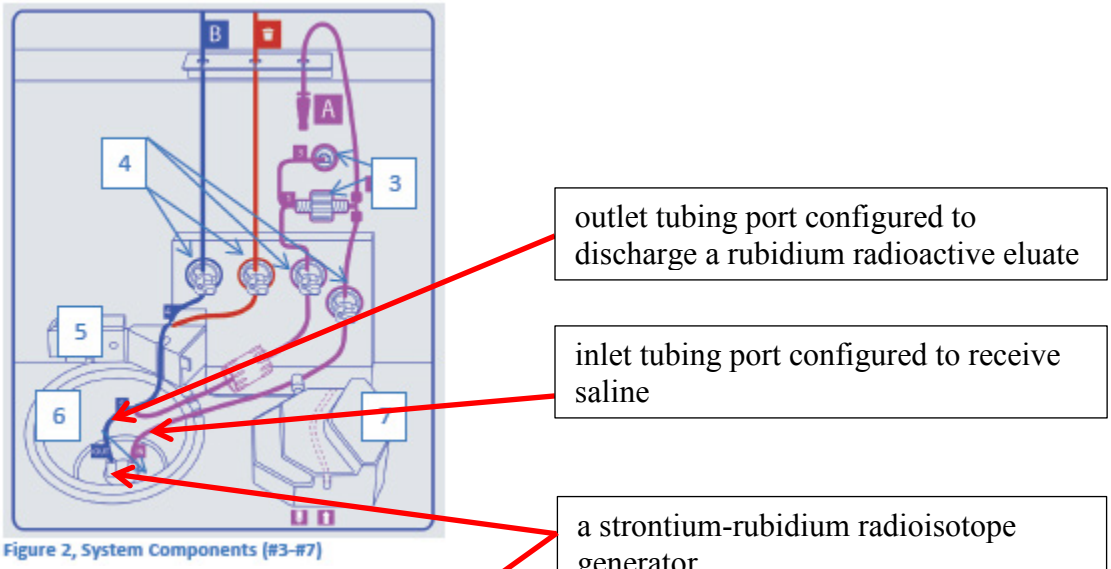


Figure 2, System Components (#3-#7)

Id. 21 at 9;

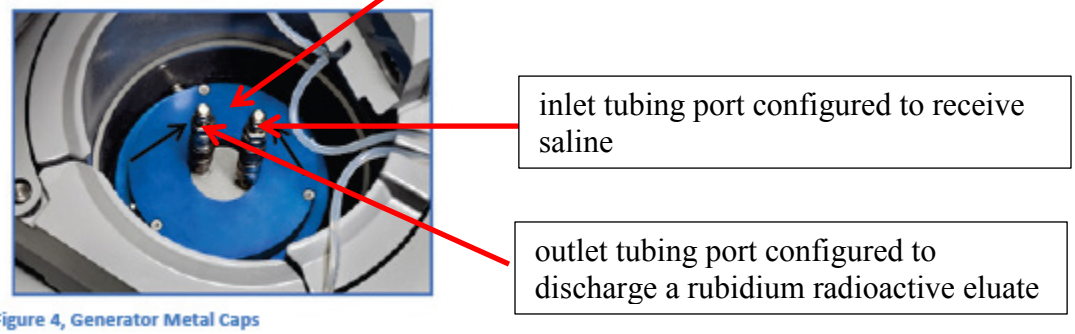
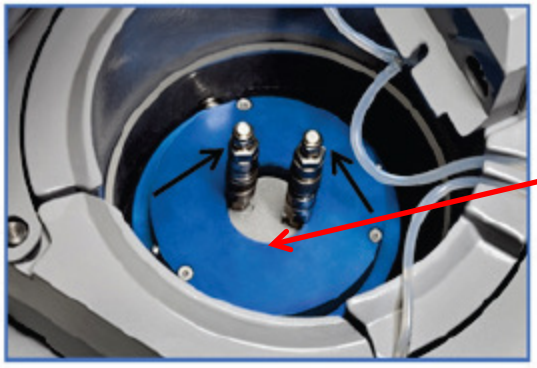


Figure 4, Generator Metal Caps

Id. at 10.

84. As shown below, the cabinet structure of the Ruby-Fill® infusion system has an opening through the exterior shell configured to provide access to the strontium-rubidium radioisotope generator within the interior space of the cabinet structure.



the strontium-rubidium radioisotope generator within the interior space of the cabinet structure

Figure 4, Generator Metal Caps

Id. at 10;

6.6 INSTALLING THE NEW GENERATOR

Using the Generator handle, install a new Generator by inserting it carefully into the Generator well (see Fig. 37, Installing the New Generator). Remove the Generator handle, then the cover. Using aseptic techniques, remove the metal caps on the Generator and connect both RUBY CONNECTORS to the quick connects on the Generator, mating a male to a female quick connect. Make sure the tubing lines are in the grooves of the Generator lead well and close the Generator well lid promptly to avoid unnecessary exposure. The Generator packing slip is shipped with the Generator in a plastic pouch inside of the shipping container. Retrieve the packing slip, and on the Generator Setup screen, **step 5 under the Generator Installation and Setup** (Fig. 38, Generator Setup Screen) enter the lot number, strontium ratio (Sr-85/Sr-82), calibration date and expiration date.

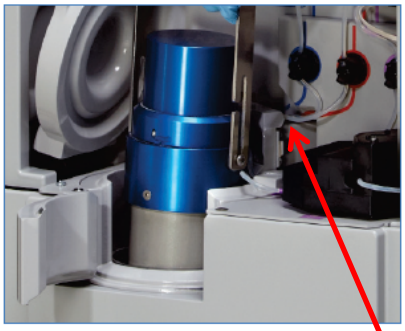


Figure 37, Installing the New Generator

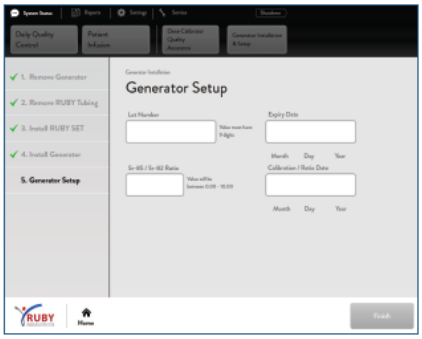


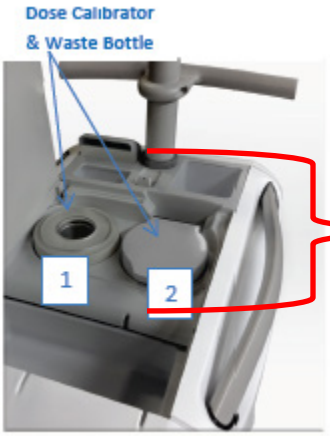
Figure 38, Generator Setup Screen

Save the Generator handle and cover with shipping container for use when removing the expired Generator and metal caps to recap the generator.

an opening through the exterior shell

Id. at 34.

85. As shown below, the cabinet structure of the Ruby-Fill® infusion system has an opening through the top surface of the exterior shell configured to provide access for inserting a waste bottle into or removing the waste bottle from the interior space of the cabinet structure.



an opening through the top surface of the exterior shell configured to provide access for inserting a waste bottle into or removing the waste bottle from the interior space of the cabinet structure

Figure 1, RUBY Rubidium Elution System

Id. at 9;

3.5 REMOVAL OF USED CONSUMABLES AND LIQUID WASTE

The RUBY SET may only be used up to its expiry (limit) date and must be discarded with the generator. The RUBY SALINE LINE must be changed daily with use of the elution system, and with each new saline supply. The RUBY IV LINE must be changed for every patient. All consumables must be removed and discarded with the removal of an expired generator. Since rubidium-82 has a very short half-life (76 seconds), the consumable items should not be radioactive, but it is important to survey each component according to local regulations before discarding since they may have become contaminated with strontium (Sr-82 or Sr-85).

Figure 7, Waste Bottle in Waste Well

Every quality control procedure and patient infusion creates liquid waste (located in either the shielded Waste Container and/or in the calibration vial). This radioactive solution must be discarded according to local regulations. Failure to empty the waste daily could cause the Waste Bottle to overflow into the Waste Well (see Fig. 7, Waste Bottle in Waste Well). If this occurs, remove the Waste Well liner and clean the Waste Well per site-specific procedures. Please consult your site's radiation safety officer (RSO).

a waste bottle

Id. at 12.

86. As shown below, the Ruby-Fill® system has a computer with a touch screen display configured to receive an input from a user for controlling operation of the infusion system, wherein the touch screen display is mounted on a vertical post having a top end extending above the cabinet structure.

Id. at 1.

87. As shown below, the Ruby-Fill® system has a first shielding compartment in the interior space of the cabinet structure having a first opening facing vertically upwardly through which the strontium-rubidium radioisotope generator can be inserted into and removed from the first shielding compartment.

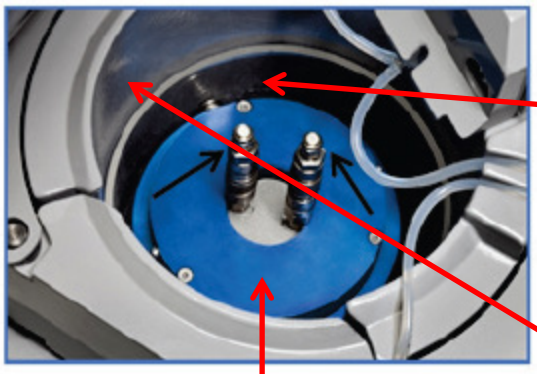


Figure 4, Generator Metal Caps

a first shielding compartment in the interior space of the cabinet structure having a first opening facing vertically upwardly through which the strontium-rubidium radioisotope generator can be inserted into and removed from the first shielding compartment

a first opening facing vertically upwardly

the strontium-rubidium radioisotope generator

Id. at 10;

6.6 INSTALLING THE NEW GENERATOR

Using the Generator handle, install a new Generator by inserting it carefully into the Generator well (see Fig. 37, Installing the New Generator). Remove the Generator handle, then the cover. Using aseptic techniques, remove the metal caps on the Generator and connect both RUBY CONNECTORS to the quick connects on the Generator, mating a male to a female quick connect. Make sure the tubing lines are in the grooves of the Generator lead well and close the Generator well lid promptly to avoid unnecessary exposure. The Generator packing slip is shipped with the Generator in a plastic pouch inside of the shipping container. Retrieve the packing slip, and on the Generator Setup screen, **step 5 under the Generator Installation and Setup** (Fig. 38, Generator Setup Screen) enter the lot number, strontium ratio (Sr-85/Sr-82), calibration date and expiration date.

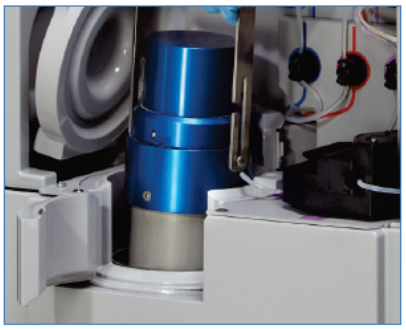


Figure 37, Installing the New Generator

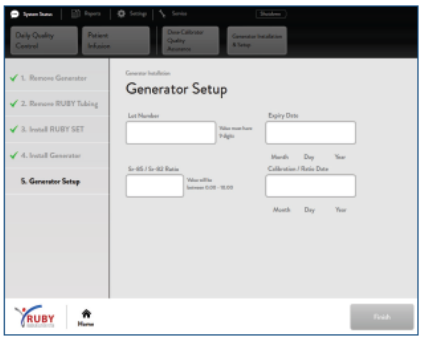


Figure 38, Generator Setup Screen

Save the Generator handle and cover with shipping container for use when removing the expired Generator and metal caps to recap the generator.

Id. at 34.

88. As shown below, the Ruby-Fill® system has a first door accessible via the opening through the exterior shell, the first door being configured to provide access to the first shielding compartment and to close over the first opening.

6.6 INSTALLING THE NEW GENERATOR

Using the Generator handle, install a new Generator by inserting it carefully into the Generator well (see Fig. 37, Installing the New Generator). Remove the Generator handle, then the cover. Using aseptic techniques, remove the metal caps on the Generator and connect both RUBY CONNECTORS to the quick connects on the Generator, mating a male to a female quick connect. Make sure the tubing lines are in the grooves of the Generator lead well and close the Generator well lid promptly to avoid unnecessary exposure. The Generator packing slip is shipped with the Generator in a plastic pouch inside of the shipping container. Retrieve the packing slip, and on the Generator Setup screen, **step 5 under the Generator Installation and Setup** (Fig. 38, Generator Setup Screen) enter the lot number, strontium ratio (Sr-85/Sr-82), calibration date and expiration date.

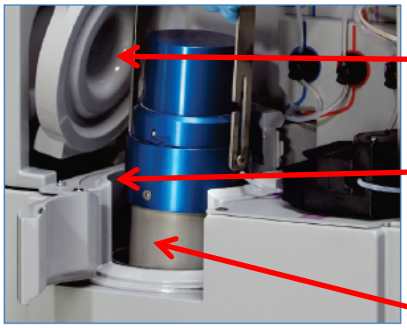


Figure 37, Installing the New Generator

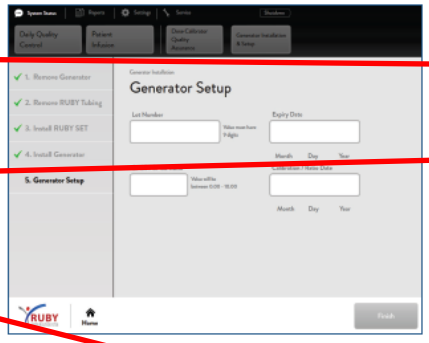


Figure 38, Generator Setup Screen

a first door

the first opening

the first shielding compartment

the opening through the exterior shell

Id. at 34.

89. As shown below, the Ruby-Fill® system has a second shielding compartment having a second opening facing vertically upwardly through which the waste bottle can be inserted into and removed from the second shielding compartment.

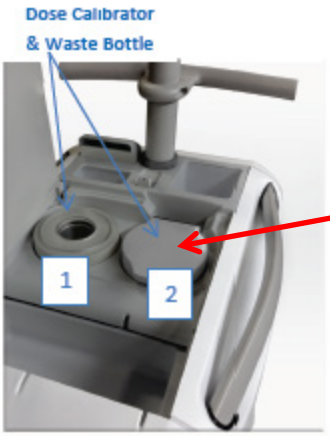


Figure 1, RUBY Rubidium Elution System

a second shielding compartment having a second opening facing vertically upwardly through which the waste bottle can be inserted into and removed from the second shielding compartment

Id. at 9;

3.5 REMOVAL OF USED CONSUMABLES AND LIQUID WASTE

The RUBY SET may only be used up to its expiry (limit) date and must be discarded with the generator. The RUBY SALINE LINE must be changed daily with use of the elution system, and with each new saline supply. The RUBY IV LINE must be changed for every patient. All consumables must be removed and discarded with the removal of an expired generator. Since rubidium-82 has a very short half-life (76 seconds), the consumable items should not be radioactive, but it is important to survey each component according to local regulations before discarding since they may have become contaminated with strontium (Sr-82 or Sr-85).

Figure 7, Waste Bottle in Waste Well

Every quality control procedure and patient infusion creates liquid waste (located in either the shielded Waste Container and/or in the calibration vial). This radioactive solution must be discarded according to local regulations. Failure to empty the waste daily could cause the Waste Bottle to overflow into the Waste Well (see Fig. 7, Waste Bottle in Waste Well). If this occurs, remove the Waste Well liner and clean the Waste Well per site-specific procedures. Please consult your site's radiation safety officer (RSO).

the waste bottle can be inserted into and removed from the second shielding compartment

Id. at 12.

90. As shown below, the Ruby-Fill® system has a second door accessible via the opening through the top surface of the exterior shell, the second door being configured to provide access to the second shielding compartment and to close over the second opening.

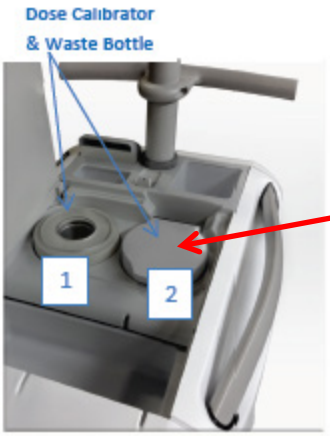


Figure 1, RUBY Rubidium Elution System

a second door accessible via the opening through the top surface of the exterior shell, the second door being configured to provide access to the second shielding compartment and to close over the second opening

Id. at 9;

3.5 REMOVAL OF USED CONSUMABLES AND LIQUID WASTE

The RUBY SET may only be used up to its expiry (limit) date and must be discarded with the generator. The RUBY SALINE LINE must be changed daily with use of the elution system, and with each new saline supply. The RUBY IV LINE must be changed for every patient. All consumables must be removed and discarded with the removal of an expired generator. Since rubidium-82 has a very short half-life (76 seconds), the consumable items should not be radioactive, but it is important to survey each component according to local regulations before discarding since they may have become contaminated with strontium (Sr-82 or Sr-85).

Figure 7, Waste Bottle in Waste Well

Every quality control procedure and patient infusion creates liquid waste (located in either the shielded Waste Container and/or in the calibration vial). This radioactive solution must be discarded according to local regulations. Failure to empty the waste daily could cause the Waste Bottle to overflow into the Waste Well (see Fig. 7, Waste Bottle in Waste Well). If this occurs, remove the Waste Well liner and clean the Waste Well per site-specific procedures. Please consult your site's radiation safety officer (RSO).

a second door

Id. at 12.

91. As shown below, the Ruby-Fill® system's first opening is located at a lower elevation than the second opening.

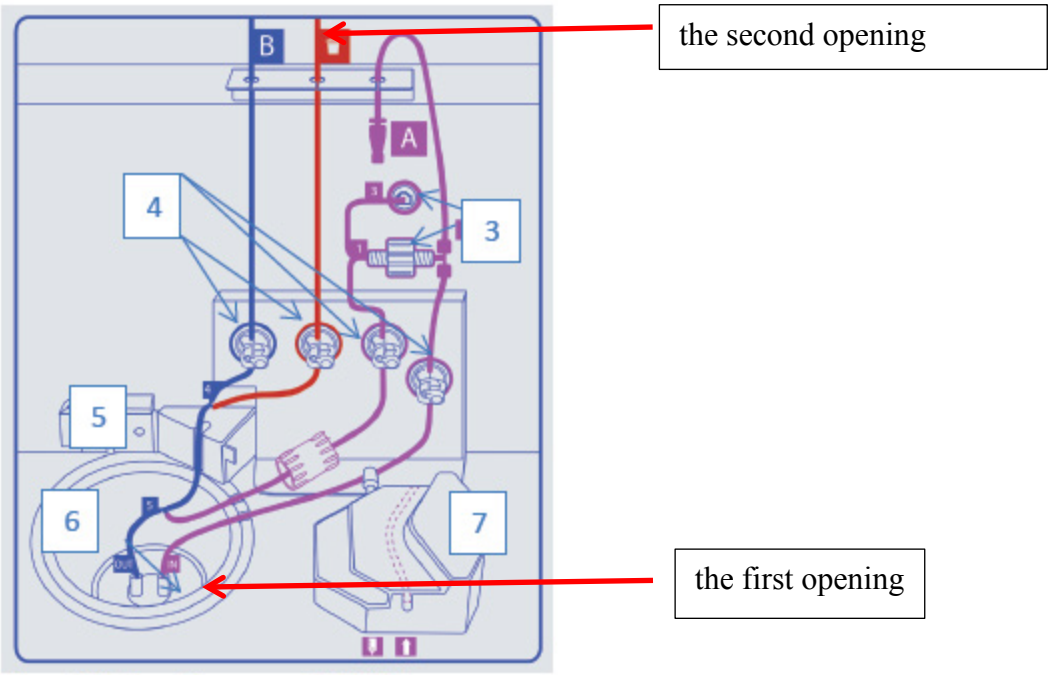


Figure 2, System Components (#3-#7)

Id. at 9.

92. As shown below, the Ruby-Fill® system has a radioactivity detector positioned to measure radioactivity of the rubidium radioactive eluate flowing through an eluate tubing line in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator.

System Error Message	Message Meaning	How to Troubleshoot
Radioactivity Counter Overlight	The radioactivity counter is exposed to light	▪ Verify that the radioactivity counter cover is closed.
Radioactivity Counter Failure	Error detected from the radioactivity counter	▪ Verify that the radioactivity counter cover is closed. ▪ Restart the system.
Radioactivity Counter Disconnected	Communication failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.
Radioactivity Counter Error	System detected a failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.
Radioactivity Counter Initialization Error	System detected a failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.

Id. at 59;

12. Insert line section between #4 and #5 into groove of the PMT, ensuring PMT door may be closed properly after tube placement (See Fig. 33, Installation of PMT portion of RUBY SET).

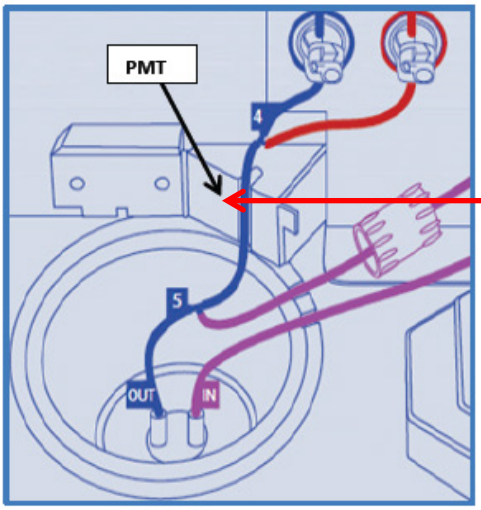


Figure 33, Installation of PMT portion of RUBY SET

a radioactivity detector positioned to measure radioactivity of the rubidium radioactive eluate flowing through an eluate tubing line in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator

Id. at 32.

93. As shown below, the Ruby-Fill® system has a shielded well on-board the cart configured to receive an eluate reservoir, wherein the eluate reservoir is configured to receive a test sample.

2.3 MAIN SYSTEM COMPONENTS

The main components of the RUBY Rubidium Elution System are (see Fig. 1, RUBY Rubidium Elution System, see Fig. 2, System Components):

1. Dose Calibrator
2. Waste Bottle
3. Pressure Transducer Holder and Connector
4. Pinch valves (four)
5. Photo Multiplier Tube (PMT)
6. Generator Well
7. Peristaltic Pump
8. Touch Screen Computer User Interface (not shown)
9. Removable Storage Compartment (not shown)

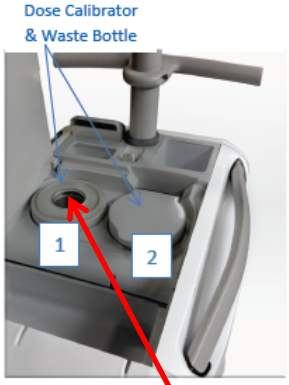


Figure 1, RUBY Rubidium Elution System

a shielded well on-board the cart configured to receive an eluate reservoir, wherein the eluate reservoir is configured to receive a test sample

Id. at 9;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

See, e.g., id. at 42.

94. As shown below, the Ruby-Fill® system has a computer for the infusion system.

2.2 SYSTEM DESCRIPTION

The RUBY Rubidium Elution System is a mobile cart that houses all of the components required for the infusion of Rubidium Chloride Rb 82 for Cardiac PET imaging. It is computer-controlled and allows for real-time monitoring of patient elutions.

The RUBY-FILL® Rubidium Rb 82 Generator provides an elution of Rubidium Chloride Rb 82 Injection which is indicated as an accessory to positron emission tomography (PET) imaging, for the assessment of myocardial perfusion to aid in the diagnosis of coronary artery disease. Rubidium Chloride Rb 82 Injection can be used when the patient is at rest and/or under pharmacologic stress conditions.

The RUBY Rubidium Elution System uses an intuitive and informative touch screen. The computer controlled, integrated system architecture allows for real-time monitoring of patient infusions. In the event of hardware failure or significant discrepancy of measurements from expected values, the software automatically terminates the elution and display the appropriate error message.

Id. at 8.

95. As shown below, the Ruby-Fill®'s computer can be configured to provide a stop button on the touch screen display to abort a function of the infusion system in response to a user input activating the stop button.

4.6 EMERGENCY TERMINATION OF PROCEDURE

The RUBY Rubidium Elution System has an emergency **Stop** button on the computer monitor screen that is available at any time during any function (see Fig. 8, Emergency Stop Button). If sudden termination of a procedure is necessary, press **Stop** and the pump will halt and all pinch valves will close. The patient can then be disconnected safely from the elution system until the situation is resolved.

No modification of this equipment is allowed. The system including the RUBY-FILL® Rubidium Rb 82 Generator should only be used by authorized trained personnel and in accordance with its intended use.

Clicking on the RUBY logo takes the user to a tool that recalibrates the PC Monitor. Refer to the **Troubleshooting** section for additional information about this tool.

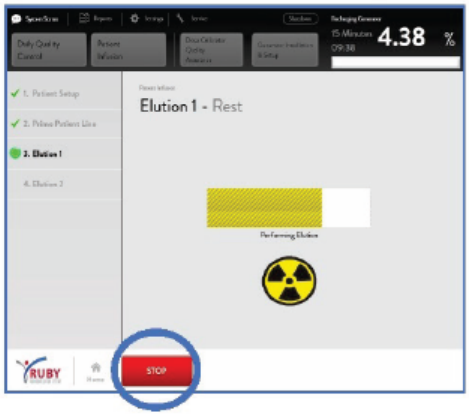


Figure 8, Emergency Stop Button

Id. at 15.

96. As shown below, the Ruby-Fill®'s computer can be configured to pump saline from a saline reservoir positioned outside of the interior space of the cabinet structure into the strontium-rubidium radioisotope generator through the inlet tubing port of the strontium-rubidium radioisotope generator thereby generating the rubidium radioactive eluate that is discharged through the outlet tubing port.

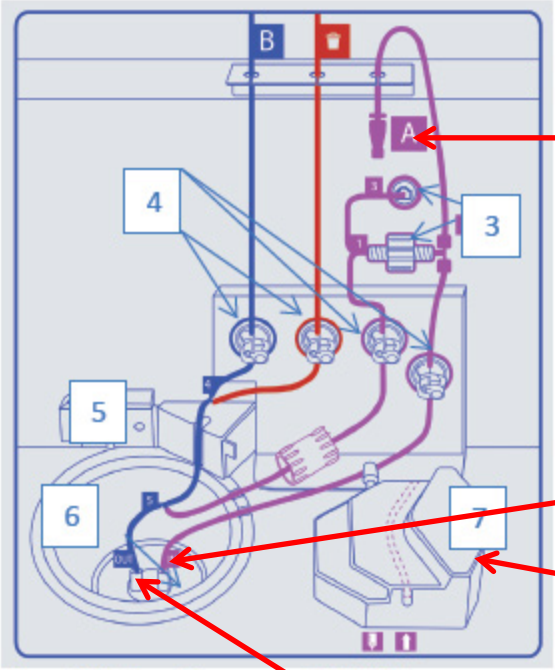


Figure 2, System Components (#3-#7)

From a saline reservoir

inlet tubing port of the strontium-rubidium radioisotope generator

a pump for pumping saline to inlet tubing of strontium-rubidium radioisotope generator

the outlet tubing port

Id. at 9;

3.4 SALINE BAGS, RUBY SALINE LINES, RUBY IV LINES

A bag of sterile 0.9% sodium chloride (additive free) injection, USP bag is installed by the user on the elution system to elute the generator. The saline bag hangs from a specially designed hook behind the computer screen (see Fig. 6, Saline Hook).

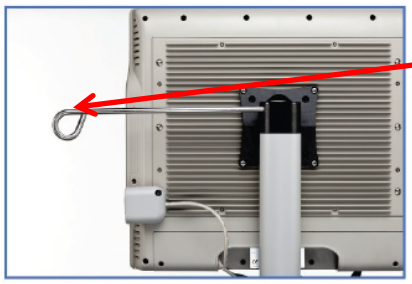


Figure 6, Saline Hook

The RUBY SALINE LINE connects the saline bag to the RUBY SET. The RUBY SALINE LINE is installed by the user through the pump in the elution system and is aseptically connected to the "A" end of the RUBY SET via a luer-lock connection (RUBY SALINE LINE Installation, section 6.7).

The RUBY SET terminates with a Luer-Lock fitting, "B" where the RUBY IV LINE is connected. An important feature of the RUBY IV LINE is an integrated 0.22 micron vented filter for increased patient safety (RUBY IV LINE Installation, section 6.8)

saline reservoir positioned outside of the interior space of the cabinet structure

Id. at 11;

6.7 INSTALLING THE 0.9% SODIUM CHLORIDE (ADDITIVE FREE) INJECTION, USP (SALINE SUPPLY) & RUBY SALINE LINE

A 0.9% sodium chloride (additive free) injection USP saline bag, RUBY SALINE LINE and RUBY IV LINE must be installed by the user to perform the Setup Validation in Daily Quality Control tab on the touchscreen monitor.

1. Visually inspect the RUBY SALINE LINE packaging for damage. Discard if damaged.
2. Using aseptic techniques, remove protective cap from saline bag and spike saline bag with the spike end of the RUBY SALINE LINE.
3. Ensure that the roller clamp is in the closed position on the RUBY SALINE LINE and hang the saline bag on the Saline hook.
4. Insert the RUBY SALINE LINE into the RUBY Rubidium Elution System via the keyhole on the right hand side of the system (see Fig. 39, RUBY SALINE LINE keyhole).
5. Open the pump by pulling lever **and** install the RUBY SALINE LINE into the pump (see Fig. 40, Installing RUBY SALINE LINE into Pump). Close the pump using the lever.
6. Using aseptic techniques, remove the protective cap of the RUBY SALINE LINE at point A and connect to the A portion of the RUBY SET (see Fig. 41, Attaching RUBY SALINE LINE to RUBY SET).
7. Open roller clamp on the RUBY SALINE LINE.
8. On the touch screen, select Pre-set Saline Volume (500mL or 1000ml) or Customized Saline Volume. The 0.9% USP saline bag must contain more than 50mL.
9. Change RUBY SALINE LINE with each new install of saline supply.

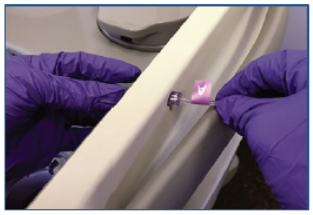


Figure 39, RUBY SALINE LINE Keyhole

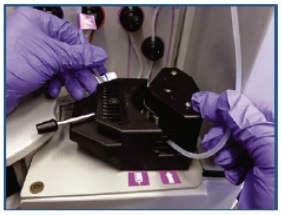


Figure 40, Installing RUBY SALINE LINE into Pump

Id. at 35;

7.2 INSTALL SALINE SUPPLY

Refer to INSTALLING THE 0.9% SODIUM CHLORIDE (ADDITIVE FREE) INJECTION, USP (SALINE SUPPLY) & RUBY SALINE IV LINE, section 6.7 (see Fig. 45, Install Saline Supply Screen).

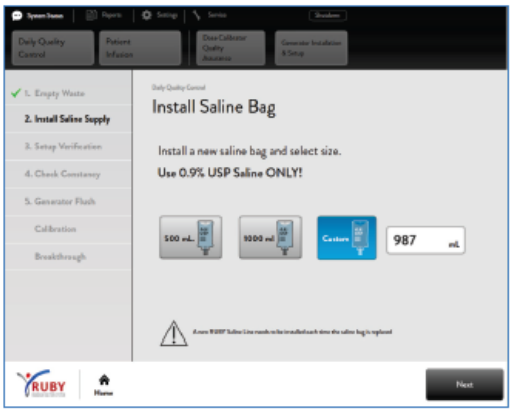


Figure 45, Install Saline Supply Screen

Id. at 39.

97. As shown below, the Ruby-Fill®'s computer can be configured to fill the eluate reservoir in the shielded well on-board the cart with the test sample of the rubidium radioactive eluate.

2.3 MAIN SYSTEM COMPONENTS

The main components of the RUBY Rubidium Elution System are (see Fig. 1, RUBY Rubidium Elution System, see Fig. 2, System Components):

1. Dose Calibrator
2. Waste Bottle
3. Pressure Transducer Holder and Connector
4. Pinch valves (four)
5. Photo Multiplier Tube (PMT)
6. Generator Well
7. Peristaltic Pump
8. Touch Screen Computer User Interface (not shown)
9. Removable Storage Compartment (not shown)

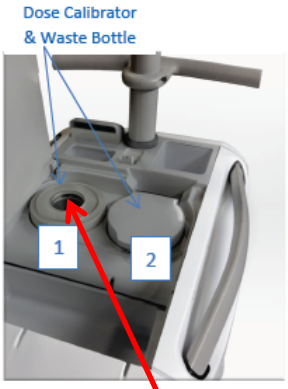


Figure 1, RUBY Rubidium Elution System

the shielded well on-board the cart with the test sample of the rubidium radioactive eluate

Id. at 9;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

See, e.g., id. at 42.

98. As shown below, the Ruby-Fill®'s computer can be configured to determine a strontium breakthrough test result on the test sample filled into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart.

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

Id. at 42;

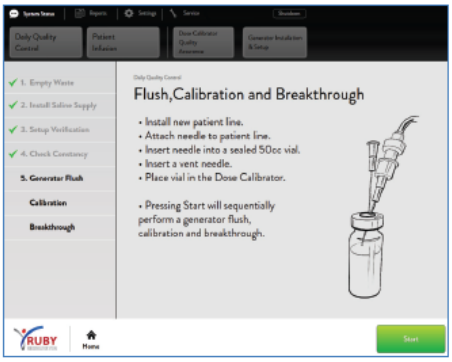


Figure 49, Flush, Calibration, and Breakthrough Screen

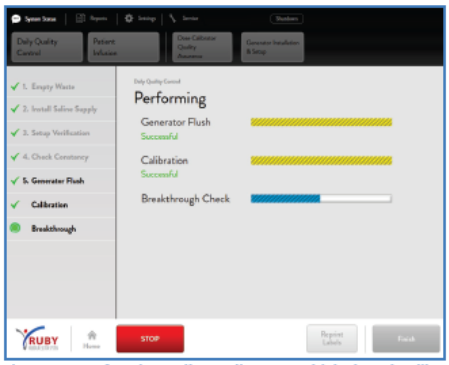


Figure 50, Performing Daily Quality Control (Flush and Calibration are completed and the Breakthrough Check is in progress)

The yellow progress bar indicates that a radioactive procedure is in progress and that radioactive solution is flowing through unshielded tubes. The user should remain at a safe distance from the elution system.

When the breakthrough check is complete, a label with the daily QC values automatically prints as configured in the settings. The user can either press Reprint Labels or press **Finish**.

When the user selects **Finish**, the Ready for Patient Infusion Screen appears (see Fig. 51, Ready for Patient Infusion Screen). This screen displays important information about the state of the elution system at a glance. The most important information displayed on this screen is:

- Breakthrough: Indicated as a percentage of the USP limit* (see Table 3), this field indicates the level of impurities calculated in the Daily Quality Control.
- Breakthrough History: The graph tracks the breakthrough levels for each day of use of the installed generator.
- Below the yellow line (<20% of USP limit*, see Table 3), the system can be used without any restriction on the number of infusions per Quality Control.
- An alert limit is reached when the reading is above the yellow line (≥ 20%) and below the red line (<50% of the USP limit*, see Table 3). Alert limits may be triggered by the following:
    - 20 L of saline eluted through the Generator.
    - or an eluate Sr-82 level of ≥0.004 µCi/mCi Rb-82. and ≤ 0.01 µCi/mCi Rb-82.
    - or an eluate Sr-85 level of ≥0.04 µCi/mCi and ≤ 0.1 µCi/mCi Rb-82.

Id. at 43.

99. As shown below, the Ruby-Fill®'s computer can be configured to not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

System Error Message	Message Meaning	How to Troubleshoot
Sr Breakthrough Too High	The breakthrough limit level is reached. Patient infusions not allowed.	▪ Verify that the generator is not expired. ▪ Verify background activity fluctuations. ▪ Repeat radioactivity calibration and breakthrough check. ▪ Install a new generator.

Id. at 59;

The system can be used with four (4) patients before a Quality Control procedure must be performed if the breakthrough reaches an alert limit. If the user repeats the flush, the system counts this as a patient infusion.

- ≥ 50% of the USP limit* (see Table 3), the system does not allow the user to perform a patient infusion.
- Refer to Table 3 below for instructions to follow on Strontium Breakthrough results.

PASS < 20% of USP limits* (Green)	ALERT ≥ 20% and <50% of USP limits* OR 20L volume limit (Yellow)	FAIL ≥ 50% of USP limits* OR 30L volume limit (Red)
Breakthrough level is low.	Breakthrough level is increased.	Breakthrough level is approaching the allowable limit.
The Daily Quality Procedure (automated breakthrough test) is valid for a 24 hour period.	The Daily Quality Procedure (automated breakthrough test) is valid for 4 patients only.	The Daily Quality Control (automated breakthrough test) does not allow a sufficient margin of safety to continue the elutions (scans).
Proceed with use	Repeat an automated Daily Quality Control after every 4 patients (8 scans) and record the results Contact Jubilant DraxImage: 1-888-633-5343	The use of the RUBY-FILL® Rubidium Rb 82 Generator must be discontinued immediately. Contact Jubilant DraxImage: 1-888-633-5343
*USP limits: <0.02μCi of Sr-82/mCi of Rb-82; <0.2μCi of Sr-85/mCi of Rb-82		

Table 3: Strontium Breakthrough Results

Id. at 44.

100. Defendants infringe, contribute to the infringement of, and/or induce infringement of the ’869 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by making, using, selling, offering for sale, and/or importing into the United States products covered by one or more claims of the ’869 patent including, but not limited to, at least the Ruby-Fill® system.

101. Defendants directly infringe one or more claims of the ’869 patent. Defendants make, use, sell, offer for sale, and/or import, in this District and elsewhere in the United States infringing products, such as the Ruby-Fill® system and thus directly infringes the ’869 patent.

102. Defendants have had knowledge and notice of the ’869 patent at least as early as the filing of this Complaint.

103. Defendants’ infringement of the ’869 patent has damaged and will continue to damage Bracco.

104. Defendants indirectly infringe the '869 patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Defendants' customers, in this District and elsewhere in the United States. For example, Defendants' customers directly infringe through their use of the inventions claimed in the '869 patent. Defendants induce this direct infringement through their affirmative acts of manufacturing, selling, distributing, instructing and/or otherwise making available the infringing products, such as the Ruby-Fill® system, and providing instructions, documentation, and other information to customers suggesting they use the infringing products, such as the Ruby-Fill® system in an infringing manner, including online technical support, marketing, product manuals, advertisements, and online documentation. As a result of Defendants' inducement, Defendants' customers use the infringing products, such as the Ruby-Fill® system in the way Defendants intend and directly infringe the '869 patent. Defendants have performed and continue to perform these affirmative acts with knowledge of the '869 patent and with the intent, or willful blindness, that the induced acts directly infringe the '869 patent.

105. Defendants also indirectly infringe the '869 patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers, in this District and elsewhere in the United States. Defendants' affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, infringing products, such as the Ruby-Fill® system and causing these products to be manufactured, used, sold, and offered for sale contribute to Defendants' customers' use of the infringing products, such as the Ruby-Fill® system, such that the '869 patent is directly infringed. Defendants have performed and continue to perform these affirmative acts with knowledge of the '869 patent and with intent, or willful blindness, that they cause the direct infringement of the '869 patent.

106. Defendants' infringement of the '869 patent will cause Bracco to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Bracco has no adequate remedy at law and, thus, a permanent injunction is appropriate to prohibit Defendants from infringing the '869 patent.

COUNT THREE – INFRINGEMENT OF THE '870 PATENT

107. Bracco repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

108. Defendants make, use, offer to sell, sells, and/or imports an infusion system to deliver a rubidium radioactive eluate (i.e., Ruby-Fill®) that infringes or induces or contributes to the infringement of one or more claims of the '870 patent.

109. The elements of claim 1 of the '870 patent are as follows:

> 1. A method of using an infusion system on-board a cart to deliver a rubidium radioactive eluate comprising:
>
> (a) installing a saline reservoir on the infusion system, wherein the infusion system comprises a platform and an exterior shell extending upwardly above the platform, and wherein the platform and the exterior shell collectively define an interior space of a cabinet structure;
>
> (b) placing the saline reservoir in fluid communication through a saline tubing line with an inlet tubing port of a strontium-rubidium radioisotope generator located in a first shielding compartment in the interior space of the cabinet structure, wherein the strontium-rubidium radioisotope generator further comprises an outlet tubing port configured to discharge the rubidium radioactive eluate, and wherein the first shielding compartment has a first opening facing vertically upwardly;
>
> (c) inserting a waste bottle into a second shielding compartment on-board the cart, wherein the second shielding compartment on-board the cart has a second opening facing vertically upwardly and being at a higher elevation than the first opening;
>
> (d) placing the waste bottle in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator

through an eluate tubing line, wherein a computer on-board the cart is configured to control the fluid communication between the waste bottle and the outlet tubing port, and wherein the computer has a touch screen display mounted on a vertical post with a top end extending above the cabinet structure;

(e) inserting an eluate reservoir in a shielded well on-board the cart;

(f) placing the eluate reservoir in fluid communication with the eluate tubing line, wherein the computer is further configured to control the fluid communication between the eluate reservoir and the eluate tubing line;

(g) pumping a sample of the rubidium radioactive eluate into the eluate reservoir in the shielded well on-board the cart;

(h) measuring a radioactivity of the sample of the rubidium radioactive eluate flowing through the eluate tubing line with a radioactivity detector on-board the cart while the sample of the rubidium radioactive eluate is flowing through the eluate tubing line;

(i) measuring a calibration radioactivity of the sample pumped into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart;

(j) comparing the radioactivity of the sample of the rubidium radioactive eluate flowing through the eluate tubing line measured by the radioactivity detector on-board the cart while the sample of the rubidium radioactive eluate is flowing through the eluate tubing line with the calibration radioactivity of the sample pumped into the eluate reservoir in the shielded well on-board the cart; and

(k) determining a strontium breakthrough test result on the sample pumped into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart, wherein the computer of the infusion system is further configured to not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

110. As shown below, the Ruby-Fill® user manual instructs the installation of a saline reservoir on the infusion system.

3.4 SALINE BAGS, RUBY SALINE LINES, RUBY IV LINES

A bag of sterile 0.9% sodium chloride (additive free) injection, USP bag is installed by the user on the elution system to elute the generator. The saline bag hangs from a specially designed hook behind the computer screen (see Fig. 6, Saline Hook).

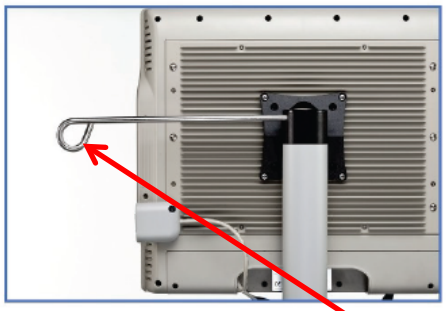


Figure 6, Saline Hook

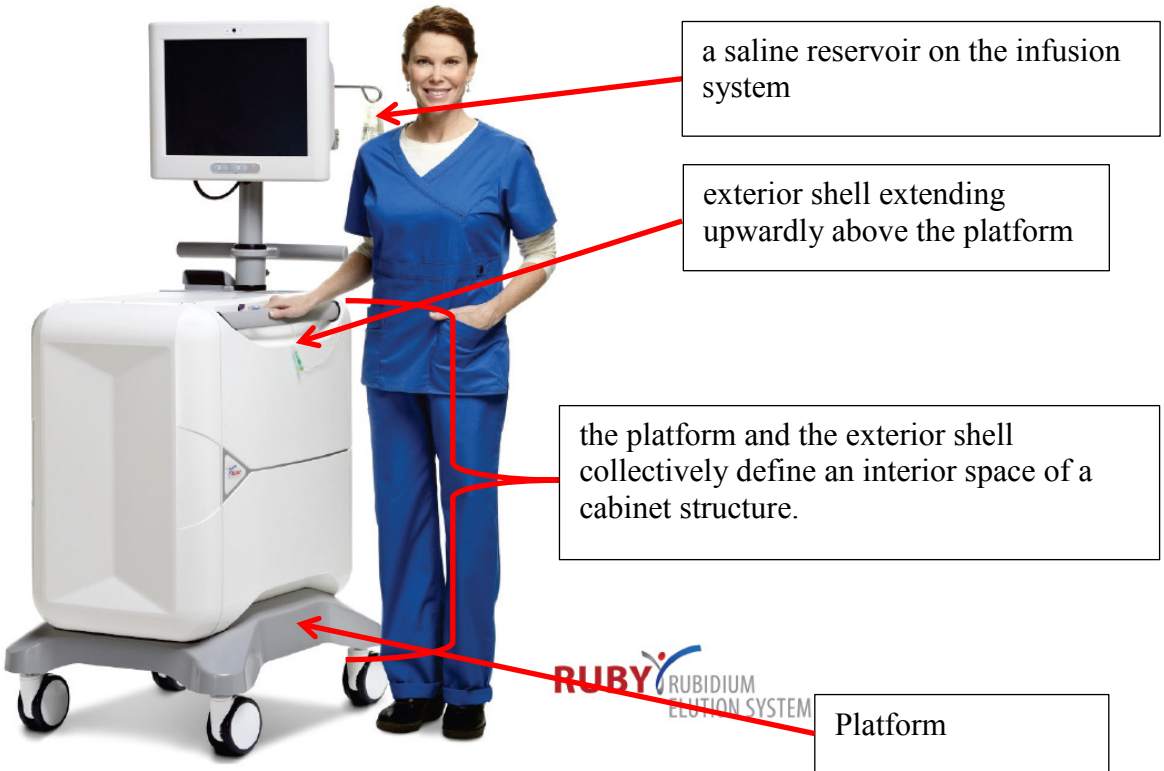
The RUBY SALINE LINE connects the saline bag to the RUBY SET. The RUBY SALINE LINE is installed by the user through the pump in the elution system and is aseptically connected to the "A" end of the RUBY SET via a luer-lock connection (RUBY SALINE LINE Installation, section 6.7).

The RUBY SET terminates with a Luer-Lock fitting, "B" where the RUBY IV LINE is connected. An important feature of the RUBY IV LINE is an integrated 0.22 micron vented filter for increased patient safety (RUBY IV LINE Installation, section 6.8)

installing a saline reservoir on the infusion system

Id. at 11.

111. As shown below, the Ruby-Fill® system comprises a platform and an exterior shell extending upwardly above the platform, and wherein the platform and the exterior shell collectively define an interior space of a cabinet structure.



Id. at 1;

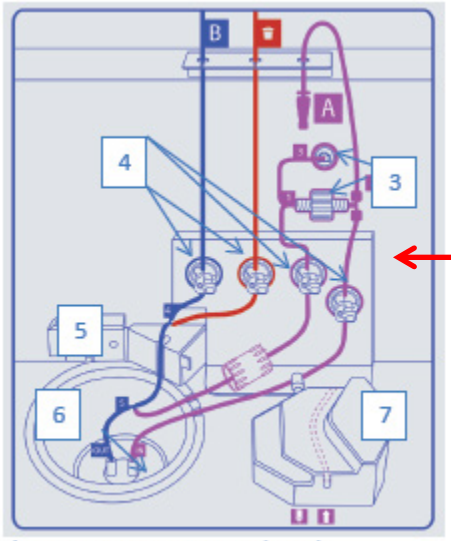


Figure 2, System Components (#3–#7)

an interior space of a cabinet structure

Id. at 9.

112. As shown below, the Ruby-Fill® user manual instructs placing the saline reservoir in fluid communication through a saline tubing line with an inlet tubing port of a strontium-rubidium radioisotope generator located in a first shielding compartment in the interior space of the cabinet structure, wherein the strontium-rubidium radioisotope generator further comprises an outlet tubing port configured to discharge the rubidium radioactive eluate, and wherein the first shielding compartment has a first opening facing vertically upwardly.

3.4 SALINE BAGS, RUBY SALINE LINES, RUBY IV LINES

A bag of sterile 0.9% sodium chloride (additive free) injection, USP bag is installed by the user on the elution system to elute the generator. The saline bag hangs from a specially designed hook behind the computer screen (see Fig. 6, Saline Hook).

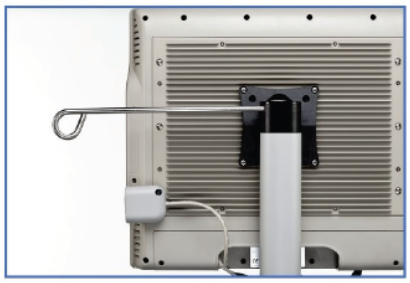


Figure 6, Saline Hook

The RUBY SALINE LINE connects the saline bag to the RUBY SET. The RUBY SALINE LINE is installed by the user through the pump in the elution system and is aseptically connected to the "A" end of the RUBY SET via a luer-lock connection (RUBY SALINE LINE Installation, section 6.7).

The RUBY SET terminates with a Luer-Lock fitting, "B" where the RUBY IV LINE is connected. An important feature of the RUBY IV LINE is an integrated 0.22 micron vented filter for increased patient safety (RUBY IV LINE Installation, section 6.8)

placing the saline reservoir in fluid communication through a saline tubing line with an inlet tubing port

Id. at 11;

6.7 INSTALLING THE 0.9% SODIUM CHLORIDE (ADDITIVE FREE) INJECTION, USP (SALINE SUPPLY) & RUBY SALINE LINE

A 0.9% sodium chloride (additive free) injection USP saline bag, RUBY SALINE LINE and RUBY IV LINE must be installed by the user to perform the Setup Validation in Daily Quality Control tab on the touchscreen monitor.

1. Visually inspect the RUBY SALINE LINE packaging for damage. Discard if damaged.
2. Using aseptic techniques, remove protective cap from saline bag and spike saline bag with the spike end of the RUBY SALINE LINE.
3. Ensure that the roller clamp is in the closed position on the RUBY SALINE LINE and hang the saline bag on the Saline hook.
4. Insert the RUBY SALINE LINE into the RUBY Rubidium Elution System via the keyhole on the right hand side of the system (see Fig. 39, RUBY SALINE LINE keyhole).
5. Open the pump by pulling lever **and** install the RUBY SALINE LINE into the pump (see Fig. 40, Installing RUBY SALINE LINE into Pump). Close the pump using the lever.
6. Using aseptic techniques, remove the protective cap of the RUBY SALINE LINE at point A and connect to the A portion of the RUBY SET (see Fig. 41, Attaching RUBY SALINE LINE to RUBY SET).
7. Open roller clamp on the RUBY SALINE LINE.
8. On the touch screen, select Pre-set Saline Volume (500mL or 1000ml) or Customized Saline Volume. The 0.9% USP saline bag must contain more than 50mL.
9. Change RUBY SALINE LINE with each new install of saline supply.

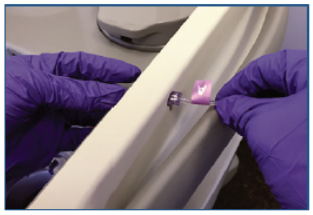


Figure 39, RUBY SALINE LINE Keyhole

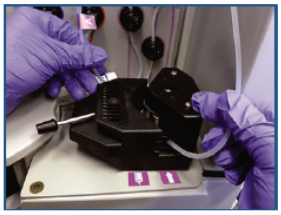
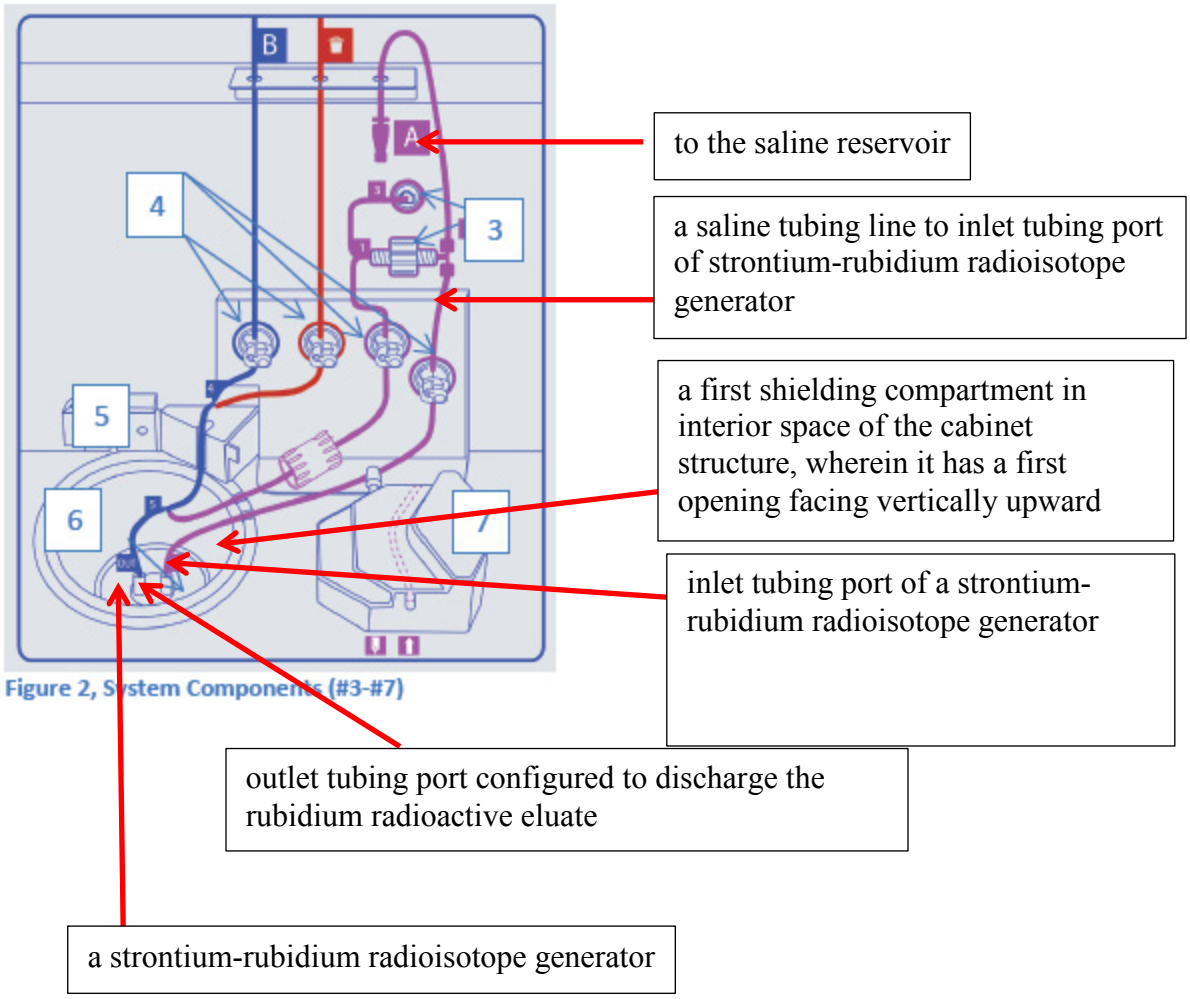


Figure 40, Installing RUBY SALINE LINE into Pump

placing the saline reservoir in fluid communication through a saline tubing line with an inlet tubing port of a strontium-rubidium radioisotope generator

Id. at 35;



Id. at 9.

113. As shown below, the Ruby-Fill® user manual instructs inserting a waste bottle into a second shielding compartment on-board the cart, wherein the second shielding compartment on-board the cart has a second opening facing vertically upwardly and being at a higher elevation than the first opening.

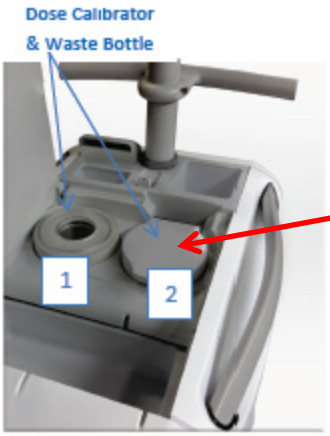


Figure 1, RUBY Rubidium Elution System

inserting a waste bottle into a second shielding compartment on-board the cart

Id. at 9;

3.5 REMOVAL OF USED CONSUMABLES AND LIQUID WASTE

The RUBY SET may only be used up to its expiry (limit) date and must be discarded with the generator. The RUBY SALINE LINE must be changed daily with use of the elution system, and with each new saline supply. The RUBY IV LINE must be changed for every patient. All consumables must be removed and discarded with the removal of an expired generator. Since rubidium-82 has a very short half-life (76 seconds), the consumable items should not be radioactive, but it is important to survey each component according to local regulations before discarding since they may have become contaminated with strontium (Sr-82 or Sr-85).

Figure 7, Waste Bottle in Waste Well

Every quality control procedure and patient infusion creates liquid waste (located in either the shielded Waste Container and/or in the calibration vial). This radioactive solution must be discarded according to local regulations. Failure to empty the waste daily could cause the Waste Bottle to overflow into the Waste Well (see Fig. 7, Waste Bottle in Waste Well). If this occurs, remove the Waste Well liner and clean the Waste Well per site-specific procedures. Please consult your site's radiation safety officer (RSO).

the second shielding compartment on-board the cart has a second opening facing vertically upwardly

Id. at 12;

7.1 EMPTY WASTE CONTAINER

To empty the liquid waste bottle, open the shielded lid and disconnect the tube from the bottle and discard the solution according to local regulations. Reinstall the waste bottle; making sure the tube is correctly installed to avoid leaks into the well. Close the lid and press **Next** on the Empty Waste Screen (see Fig.44, Empty Waste Screen).

Discard the waste solution according to local regulations and procedures for radioactive waste.

Failure to empty the waste daily could cause the waste bottle (1L fluid limit) to overflow into the waste well. If this occurs, remove the liner and clean waste well per site-specific procedures.

Figure 44, Empty Waste Screen

See also id. at 38;

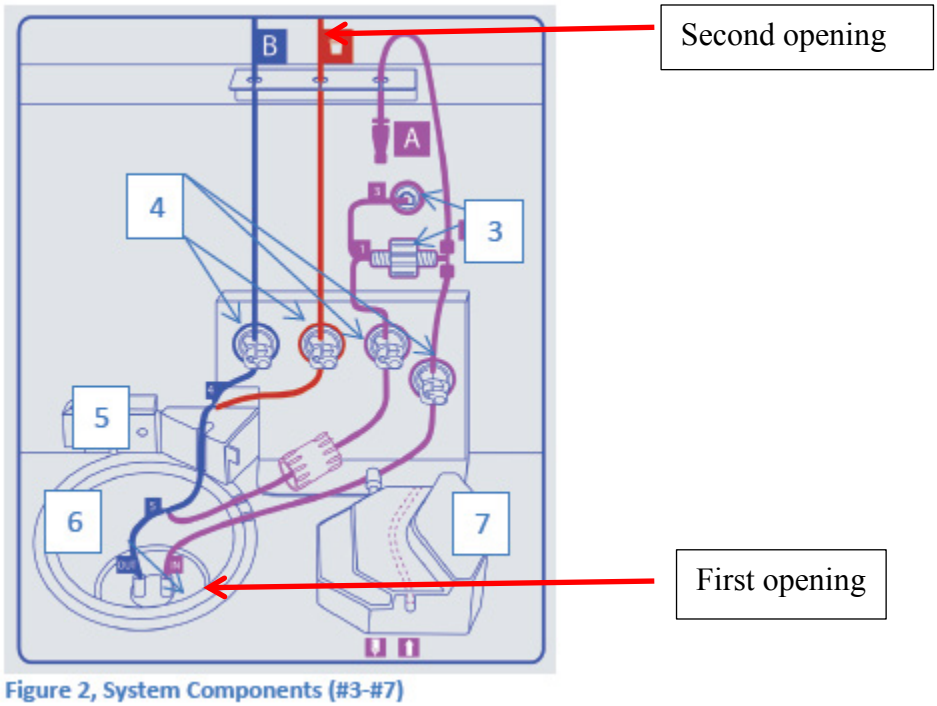


Figure 2, System Components (#3-#7)

Id. at 9 (second opening being at a higher elevation than the first opening);

114. As shown below, the Ruby-Fill® user manual instructs placing the waste bottle in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator through an eluate tubing line, wherein a computer on-board the cart is configured to control the fluid communication between the waste bottle and the outlet tubing port, and wherein the computer has a touch screen display mounted on a vertical post with a top end extending above the cabinet structure.

6.5 INSTALLING THE RUBY SET

11. Remove the protective cap and attach the Waste portion of tubing (next to the Red Trash Icon) to the Waste Bottle.

Id. at 31-32;

Figure 7, Waste Bottle in Waste Well

Id. at 12;

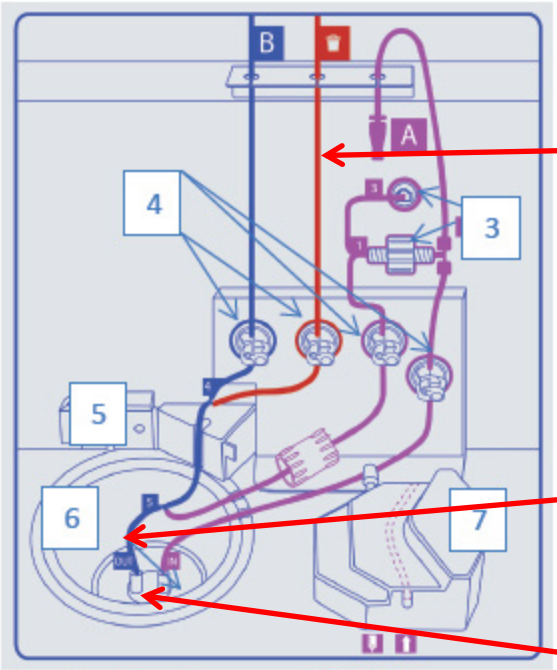


Figure 2, System Components (#3-#7)

the waste bottle in fluid communication with the outlet tubing port of the strontium-rubidium radioisotope generator through an eluate tubing line

the outlet tubing port of the strontium-rubidium radioisotope generator

the strontium-rubidium radioisotope generator

Id. at 9;

2.2 SYSTEM DESCRIPTION

The RUBY Rubidium Elution System is a mobile cart that houses all of the components required for the infusion of Rubidium Chloride Rb 82 for Cardiac PET imaging. It is computer-controlled and allows for real-time monitoring of patient elutions.

The RUBY-FILL® Rubidium Rb 82 Generator provides an elution of Rubidium Chloride Rb 82 Injection which is indicated as an accessory to positron emission tomography (PET) imaging, for the assessment of myocardial perfusion to aid in the diagnosis of coronary artery disease. Rubidium Chloride Rb 82 Injection can be used when the patient is at rest and/or under pharmacologic stress conditions.

The RUBY Rubidium Elution System uses an intuitive and informative touch screen. The computer controlled, integrated system architecture allows for real-time monitoring of patient infusions. In the event of hardware failure or significant discrepancy of measurements from expected values, the software automatically terminates the elution and display the appropriate error message.

Id. at 8;

a computer on-board the cart is configured to control the fluid communication between the waste bottle and the outlet tubing port, and wherein the computer has a touch screen display mounted on a vertical post with a top end extending above the cabinet structure

Id. at 1.

115. As shown below, the Ruby-Fill® user manual instructs inserting an eluate reservoir in a shielded well on-board the cart.

2.3 MAIN SYSTEM COMPONENTS

The main components of the RUBY Rubidium Elution System are (see Fig. 1, RUBY Rubidium Elution System, see Fig. 2, System Components):

1. Dose Calibrator
2. Waste Bottle
3. Pressure Transducer Holder and Connector
4. Pinch valves (four)
5. Photo Multiplier Tube (PMT)
6. Generator Well
7. Peristaltic Pump
8. Touch Screen Computer User Interface (not shown)
9. Removable Storage Compartment (not shown)

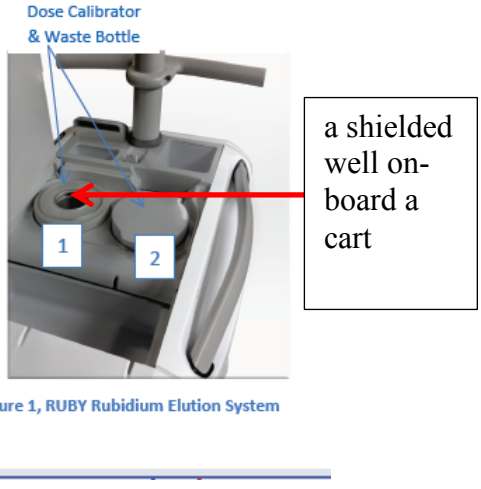


Figure 1, RUBY Rubidium Elution System

Id. at 9;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

See, e.g., id. at 42.

116. As shown below, the Ruby-Fill® user manual instructs placing the eluate reservoir in fluid communication with the eluate tubing line, wherein the computer is further configured to control the fluid communication between the eluate reservoir and the eluate tubing line.

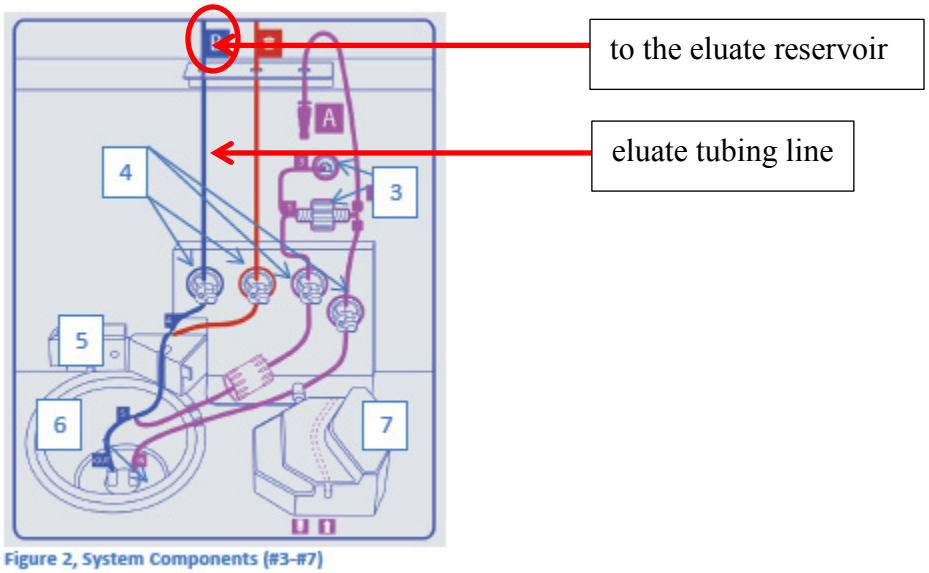


Figure 2, System Components (#3-#7)

Id. at 9;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

See, e.g., id. at 42 (placing the eluate reservoir in fluid communication with the eluate tubing line);

6.8 INSTALLING THE RUBY IV LINE

1. Visually inspect the RUBY IV LINE packaging for damage. Discard if damaged.
2. Using aseptic techniques, remove cap from B end of RUBY IV LINE and connect to B end of RUBY SET (see Fig. 42, Installing RUBY IV LINE).
3. A new RUBY IV LINE must be used for each patient.
4. The patient end of the RUBY IV Line (yellow sticker with patient icon) is connected to the patient.
5. Between Rubidium-82 Chloride injections (rest & stress) and if the RUBY IV LINE is disconnected from the patient, engage the clamp to close the line.
6. After each patient, and at the end of the day, remove and discard used RUBY IV LINE from the RUBY SET and discard according to local procedures for potentially biohazardous materials.

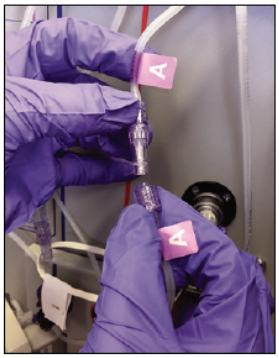


Figure 41, Saline Line to RUBY SET

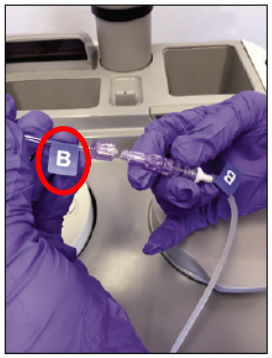


Figure 42, Installing RUBY IV Line

Id. at 36;

2.2 SYSTEM DESCRIPTION

The RUBY Rubidium Elution System is a mobile cart that houses all of the components required for the infusion of Rubidium Chloride Rb 82 for Cardiac PET imaging. It is computer-controlled and allows for real-time monitoring of patient elutions.

The RUBY-FILL® Rubidium Rb 82 Generator provides an elution of Rubidium Chloride Rb 82 Injection which is indicated as an accessory to positron emission tomography (PET) imaging, for the assessment of myocardial perfusion to aid in the diagnosis of coronary artery disease. Rubidium Chloride Rb 82 Injection can be used when the patient is at rest and/or under pharmacologic stress conditions.

The RUBY Rubidium Elution System uses an intuitive and informative touch screen. The computer controlled, integrated system architecture allows for real-time monitoring of patient infusions. In the event of hardware failure or significant discrepancy of measurements from expected values, the software automatically terminates the elution and display the appropriate error message.

the computer is further configured to control the fluid communication between the eluate reservoir and the eluate tubing line

Id. at 8.

117. As shown below, the Ruby-Fill® user manual instructs pumping a sample of the rubidium radioactive eluate into the eluate reservoir in the shielded well on-board the cart.

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

Id. at 42.

118. As shown below, the Ruby-Fill® user manual instructs measuring a radioactivity of the sample of the rubidium radioactive eluate flowing through the eluate tubing line with a

radioactivity detector on-board the cart while the sample of the rubidium radioactive eluate is flowing through the eluate tubing line.

System Error Message	Message Meaning	How to Troubleshoot
Radioactivity Counter Overlight	The radioactivity counter is exposed to light	▪ Verify that the radioactivity counter cover is closed.
Radioactivity Counter Failure	Error detected from the radioactivity counter	▪ Verify that the radioactivity counter cover is closed. ▪ Restart the system.
Radioactivity Counter Disconnected	Communication failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.
Radioactivity Counter Error	System detected a failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.
Radioactivity Counter Initialization Error	System detected a failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.

Id. at 59;

12. Insert line section between #4 and #5 into groove of the PMT, ensuring PMT door may be closed properly after tube placement (See Fig. 33, Installation of PMT portion of RUBY SET).

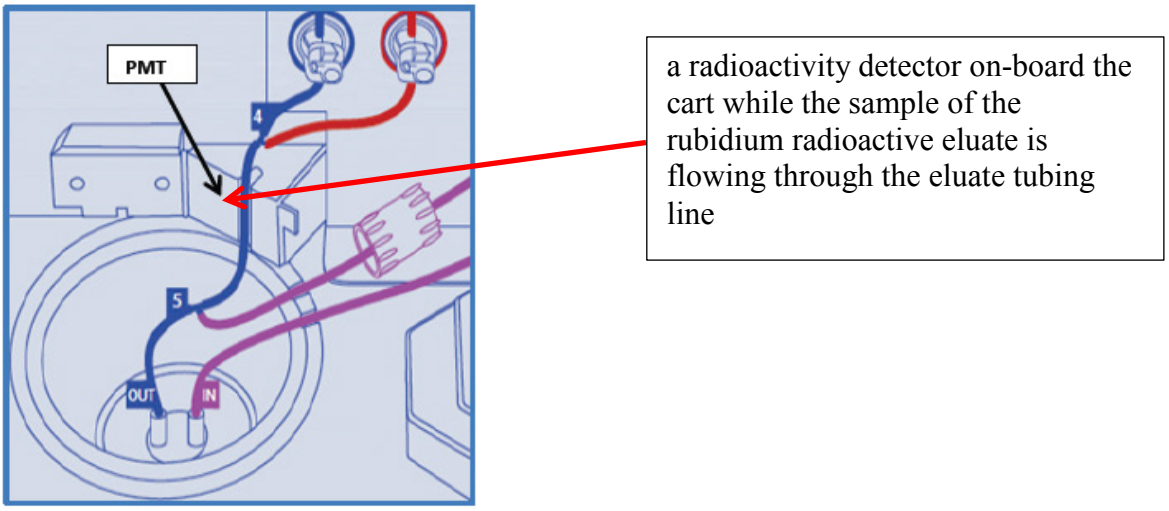


Figure 33, Installation of PMT portion of RUBY SET

Id. at 32.

119. As shown below, the Ruby-Fill® user manual instructs measuring a calibration radioactivity of the sample pumped into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart.

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

Id. at 42.

120. As shown below, the Ruby-Fill® user manual instructs comparing the radioactivity of the sample of the rubidium radioactive eluate flowing through the eluate tubing line measured by the radioactivity detector on-board the cart while the sample of the rubidium radioactive eluate is flowing through the eluate tubing line with the calibration radioactivity of the sample pumped into the eluate reservoir in the shielded well on-board the cart.

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

Id. at 42;

8. PATIENT INFUSIONS

In the event of hardware failure or significant discrepancy between measured and expected values, the software automatically terminates the elution and displays the appropriate error message.

Id. at 46, 49;

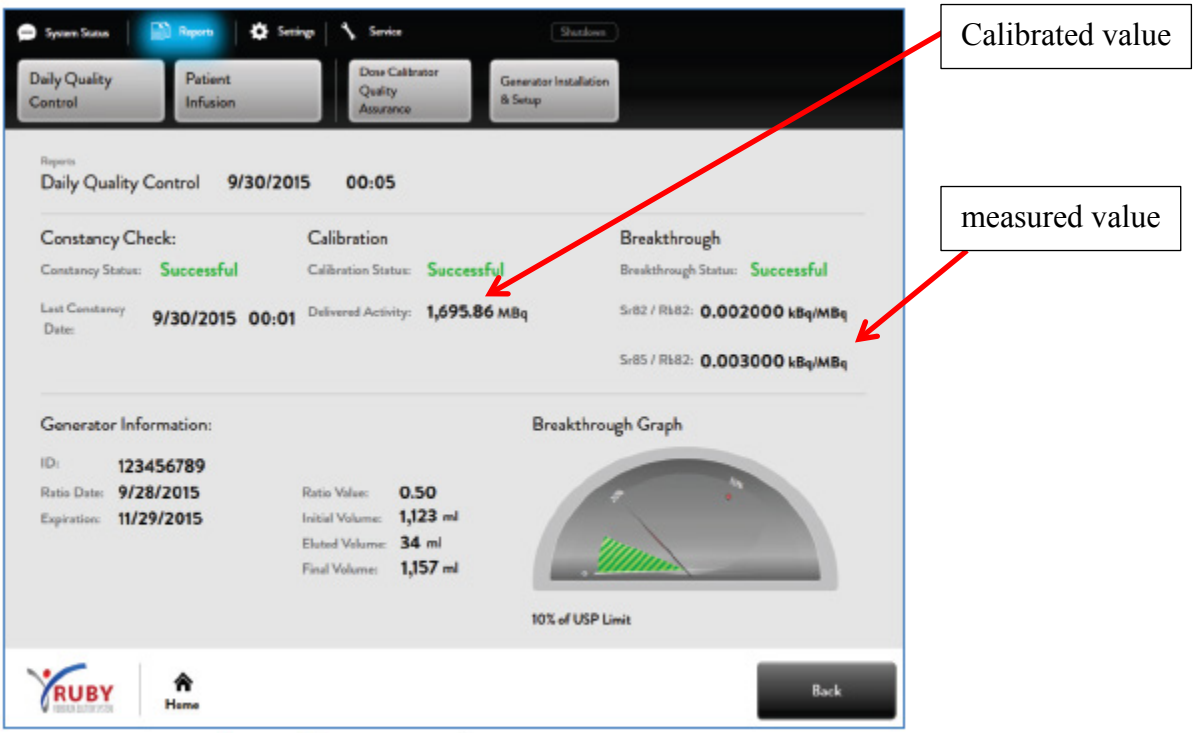


Figure 59, Daily Quality Control Report Screen

Id. at 51.

121. As shown below, the Ruby-Fill® user manual instructs determining a strontium breakthrough test result on the sample pumped into the eluate reservoir in the shielded well on-board the cart while the eluate reservoir remains in the shielded well on-board the cart, wherein the computer of the infusion system is further configured to not allow a patient infusion if the strontium breakthrough test result is greater than or equal to an allowed limit.

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

Id. at 42;

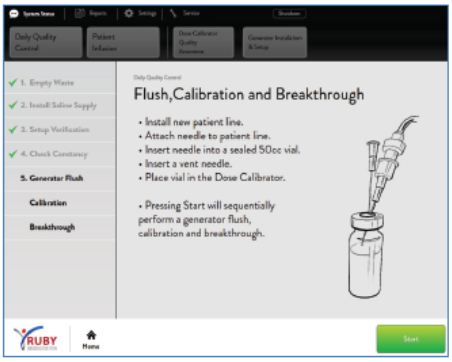


Figure 49, Flush, Calibration, and Breakthrough Screen

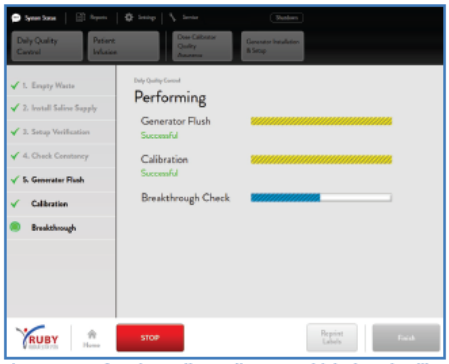


Figure 50, Performing Daily Quality Control (Flush and Calibration are completed and the Breakthrough Check is in progress)

The yellow progress bar indicates that a radioactive procedure is in progress and that radioactive solution is flowing through unshielded tubes. The user should remain at a safe distance from the elution system.

When the breakthrough check is complete, a label with the daily QC values automatically prints as configured in the settings. The user can either press Reprint Labels or press **Finish**.

When the user selects **Finish**, the Ready for Patient Infusion Screen appears (see Fig. 51, Ready for Patient Infusion Screen). This screen displays important information about the state of the elution system at a glance. The most important information displayed on this screen is:

- Breakthrough: Indicated as a percentage of the USP limit* (see Table 3), this field indicates the level of impurities calculated in the Daily Quality Control.
- Breakthrough History: The graph tracks the breakthrough levels for each day of use of the installed generator.
- Below the yellow line (<20% of USP limit*, see Table 3), the system can be used without any restriction on the number of infusions per Quality Control.
- An alert limit is reached when the reading is above the yellow line (≥ 20%) and below the red line (<50% of the USP limit*, see Table 3). Alert limits may be triggered by the following:
    - 20 L of saline eluted through the Generator.
    - or an eluate Sr-82 level of ≥0.004 µCi/mCi Rb-82. and ≤ 0.01 µCi/mCi Rb-82.
    - or an eluate Sr-85 level of ≥0.04 µCi/mCi and ≤ 0.1 µCi/mCi Rb-82.

Id. at 42-43;

System Error Message	Message Meaning	How to Troubleshoot
Sr Breakthrough Too High	The breakthrough limit level is reached. Patient infusions not allowed.	▪ Verify that the generator is not expired. ▪ Verify background activity fluctuations. ▪ Repeat radioactivity calibration and breakthrough check. ▪ Install a new generator.

Id. at 59;

The system can be used with four (4) patients before a Quality Control procedure must be performed if the breakthrough reaches an alert limit. If the user repeats the flush, the system counts this as a patient infusion.

- ≥ 50% of the USP limit* (see Table 3), the system does not allow the user to perform a patient infusion.
- Refer to Table 3 below for instructions to follow on Strontium Breakthrough results.

PASS < 20% of USP limits* (Green)	ALERT ≥ 20% and <50% of USP limits* OR 20L volume limit (Yellow)	FAIL ≥ 50% of USP limits* OR 30L volume limit (Red)
Breakthrough level is low.	Breakthrough level is increased.	Breakthrough level is approaching the allowable limit.
The Daily Quality Procedure (automated breakthrough test) is valid for a 24 hour period.	The Daily Quality Procedure (automated breakthrough test) is valid for 4 patients only.	The Daily Quality Control (automated breakthrough test) does not allow a sufficient margin of safety to continue the elutions (scans).
Proceed with use	Repeat an automated Daily Quality Control after every 4 patients (8 scans) and record the results Contact Jubilant DraxImage: 1-888-633-5343	The use of the RUBY-FILL® Rubidium Rb 82 Generator must be discontinued immediately. Contact Jubilant DraxImage: 1-888-633-5343
*USP limits: <0.02μCi of Sr-82/mCi of Rb-82; <0.2μCi of Sr-85/mCi of Rb-82		

Table 3: Strontium Breakthrough Results

Id. at 44.

122. Defendants infringe, contribute to the infringement of, and/or induce infringement of the '870 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by making, using, selling, offering for sale, and/or importing into the United States products covered by one or more claims of the '870 patent including, but not limited to, at least the Ruby-Fill® system.

123. Defendants directly infringe one or more claims of the '870 patent. Defendants make, use, sell, offer for sale, and/or import, in this District and elsewhere in the United States infringing products, such as the Ruby-Fill® system and thus directly infringes the '870 patent.

124. Defendants have had knowledge and notice of the '870 patent at least as early as the filing of this Complaint.

125. Defendants' infringement of the '870 patent has damaged and will continue to damage Bracco.

126. Defendants indirectly infringe the '870 patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Defendants' customers, in this District and

elsewhere in the United States. For example, Defendants' customers directly infringe through their use of the inventions claimed in the '870 patent. Defendants induce this direct infringement through their affirmative acts of manufacturing, selling, distributing, instructing and/or otherwise making available the infringing products, such as the Ruby-Fill® system, and providing instructions, documentation, and other information to customers suggesting they use the infringing products, such as the Ruby-Fill® system in an infringing manner, including online technical support, marketing, product manuals, advertisements, and online documentation. As a result of Defendants' inducement, Defendants' customers use the infringing products, such as the Ruby-Fill® system in the way Defendants intend and directly infringe the '870 patent. Defendants have performed and continue to perform these affirmative acts with knowledge of the '870 patent and with the intent, or willful blindness, that the induced acts directly infringe the '870 patent.

127. In addition, Defendants' prescribing information and user manual instructs and encourages end-users to use an infusion system on-board a cart to deliver a rubidium radioactive eluate. The affirmative instructions in the prescribing information and user manual for Defendants' Ruby-Fill® system will induce end users to practice the claims of the '870 patent because the instructions in the prescribing information and/or user manual will result in the Ruby-Fill® system being used in accordance with the steps of the claims. Defendants' Ruby-Fill® prescribing information and/or user manual encourages, recommends, and promotes use of the infringing method by end-users. Thus, Defendants intend, and will cause, end-users to practice at least claim 1 of the '870 patent.

128. Defendants also indirectly infringes the '870 patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers, in this

District and elsewhere in the United States. Defendants' affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, infringing products, such as the Ruby-Fill® system and causing these products to be manufactured, used, sold, and offered for sale contribute to Defendants' customers' use of the infringing products, such as the Ruby-Fill® system, such that the '870 patent is directly infringed. Defendants have performed and continue to perform these affirmative acts with knowledge of the '870 patent and with intent, or willful blindness, that they cause the direct infringement of the '870 patent.

129. Furthermore, there are no other substantial approved uses for Defendants' Ruby-Fill® system in the United States. Therefore, the manufacture and/or sale of Defendants' Ruby-Fill® system will contribute to and induce the infringement of at least claim 1 of the '870 patent by end users.

130. Defendants' infringement of the '870 patent will cause Bracco to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Bracco has no adequate remedy at law and, thus, a permanent injunction is appropriate to prohibit Defendants from infringing the '870 patent.

COUNT FOUR – INFRINGEMENT OF THE '467 PATENT

131. Bracco repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

132. Defendants make, use, offer to sell, sells, and/or imports an infusion system to deliver a rubidium radioactive eluate (*i.e.*, Ruby-Fill®) that infringes or induces or contributes to the infringement of one or more claims of the '467 patent.

133. The elements of claim 1 of the '467 patent are as follows:

1. A system comprising:

(a) a shielding assembly configured to contain a radioisotope generator that generates radioactive eluate via elution;

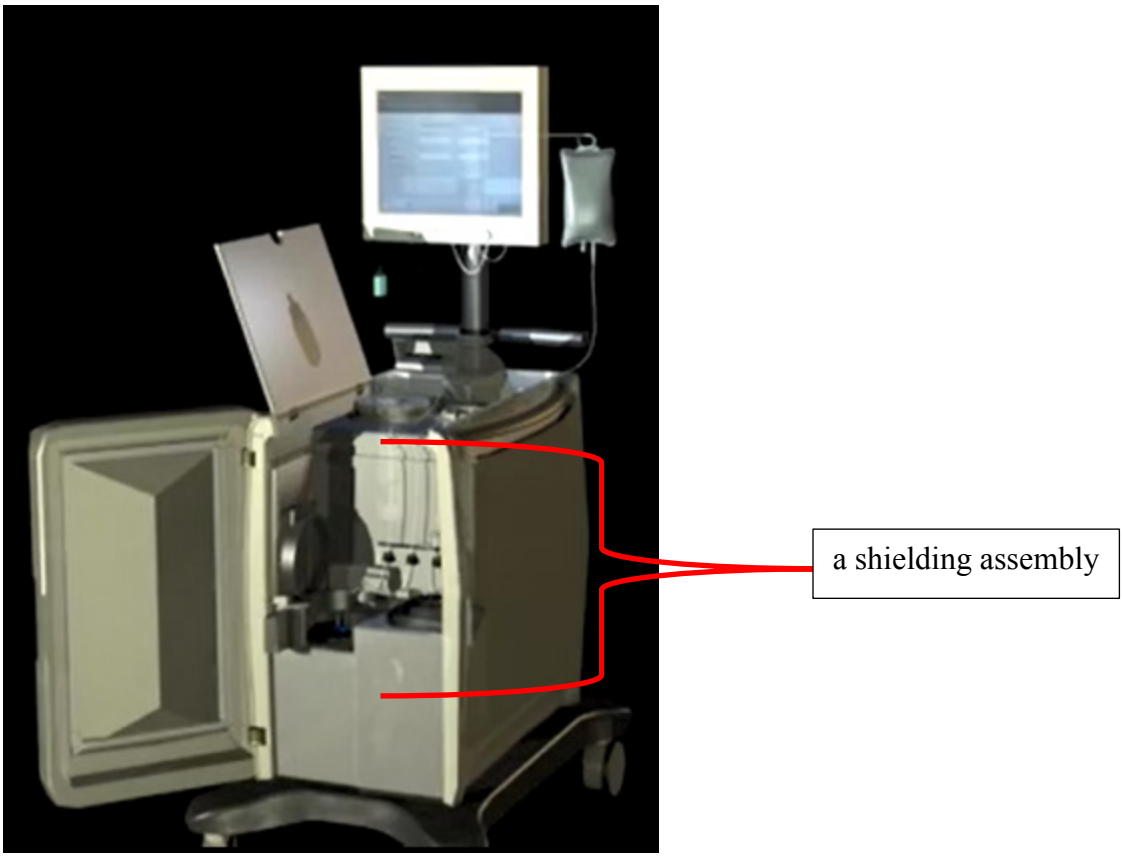
(b) a computer carried by the shielding assembly, wherein the computer is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing; and

(c) a dose calibrator electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing,

(d) wherein the computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results, and

(e) the computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

134. As shown below, the Ruby-Fill® infusion system has a shielding assembly configured to contain a radioisotope generator that generates radioactive eluate via elution.



Ruby-Fill® video file, previously available at http://www.draximage.com/

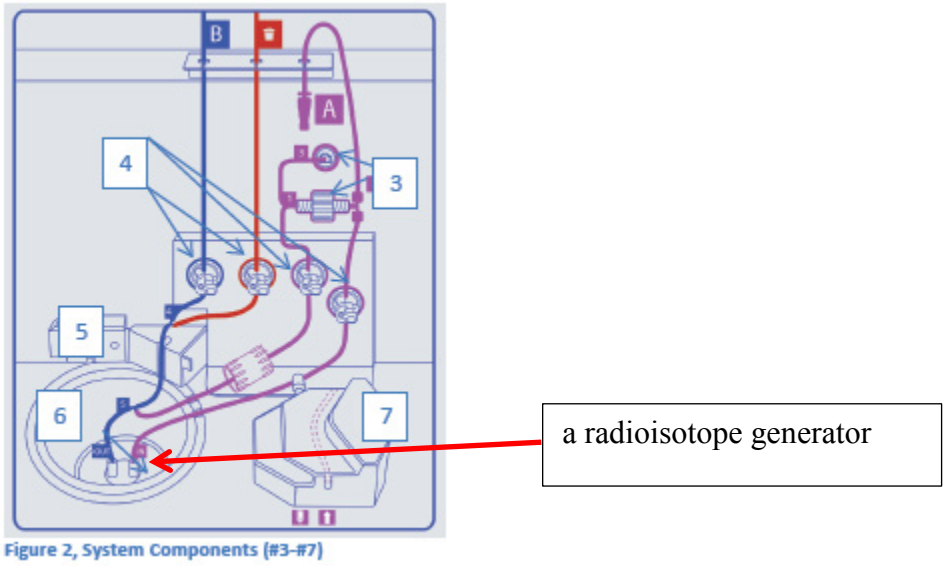


Figure 2, System Components (#3-#7)

See e.g., Exhibit No. F at 9;

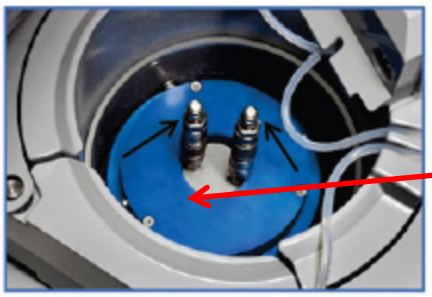


Figure 4, Generator Metal Caps

Id. at 10;

2.2 SYSTEM DESCRIPTION

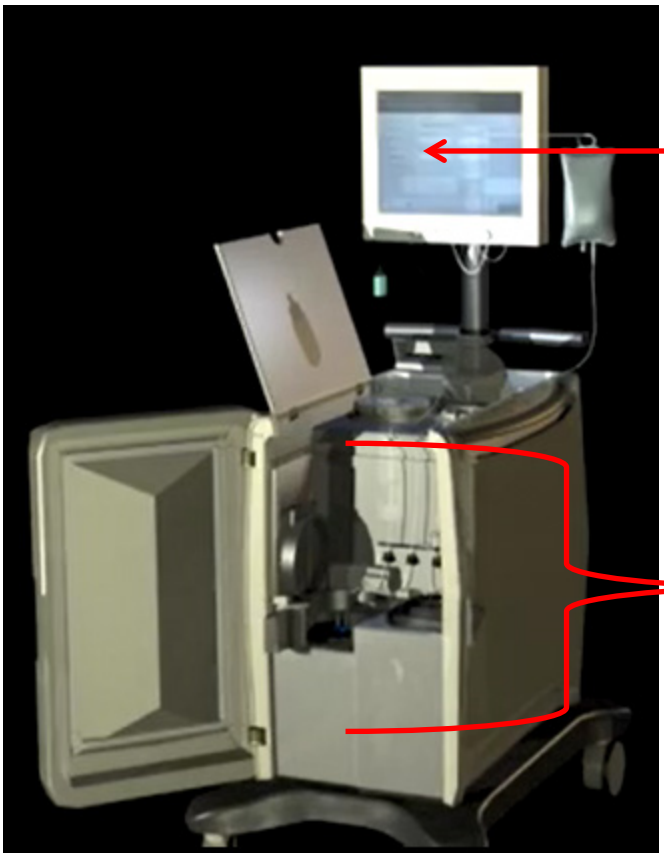
The RUBY Rubidium Elution System is a mobile cart that houses all of the components required for the infusion of Rubidium Chloride Rb 82 for Cardiac PET imaging. It is computer-controlled and allows for real-time monitoring of patient elutions.

The RUBY-FILL® Rubidium Rb 82 Generator provides an elution of Rubidium Chloride Rb 82 Injection which is indicated as an accessory to positron emission tomography (PET) imaging, for the assessment of myocardial perfusion to aid in the diagnosis of coronary artery disease. Rubidium Chloride Rb 82 Injection can be used when the patient is at rest and/or under pharmacologic stress conditions.

configured to generate radioactive eluate via elution

Id. at 8.

135. As shown below, the Ruby-Fill® infusion system has a computer carried by the shielding assembly, wherein the computer is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing.



Ruby-Fill® video file, previously available at http://www.draximage.com/;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

The word Successful (in green) appears next to each item as it is completed. This information is saved in the Daily QC report. If an error occurs, a red 'X' appears and that process is aborted. If this occurs, the user needs to repeat this process before proceeding to the next step (see Fig. 50, Performing Daily Quality Control).

configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing

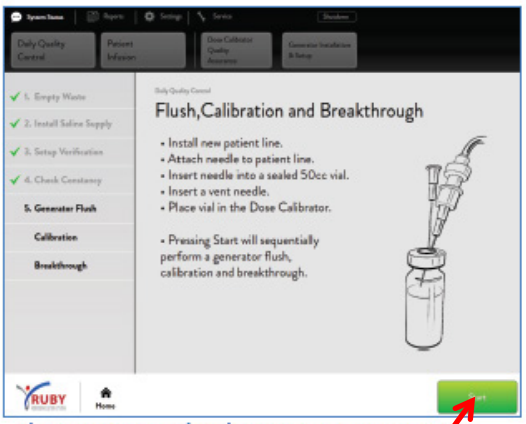


Figure 49, Flush, Calibration, and Breakthrough Screen

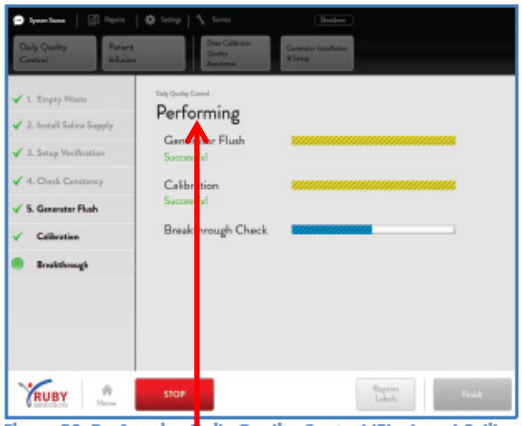


Figure 50, Performing Daily Quality Control (Flush and Calibration are completed and the Breakthrough Check is in progress)

configured to receive a user input

responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing

Exhibit No. F at 42-43.

136. As shown below, the Ruby-Fill® infusion system has a dose calibrator electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing.

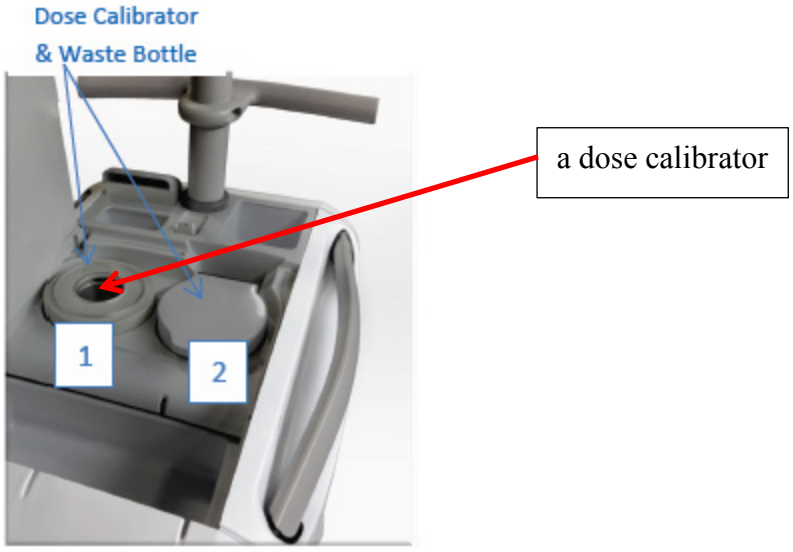


Figure 1, RUBY Rubidium Elution System

Id. at 9;

6. OPERATING THE SYSTEM

6.1 DOSE CALIBRATOR QUALITY ASSURANCE

The RUBY Rubidium Elution System comes with an integrated dose calibrator. This dose calibrator is fully controlled using the system's software. To access the quality assurance mode, press Dose Calibrator Quality Assurance on the second row of the task bar and enter the required password. The control screen is displayed (see Fig. 26, Dose Calibrator Quality Assurance Screen). To perform the required quality assurance tests, such as Linearity, Geometry and Accuracy, an independent control screen is included to enable the operation and/or configuration of the dose calibrator in conventional mode (Table 2, Dose Calibrator Quality Assurance & Required Frequency of Performance). JDI personnel will complete all four quality assurance tests upon installation of the elution system. Users are responsible for performing Constancy daily (integrated into Daily Quality Control); Linearity quarterly and Accuracy annually.

Dose Calibrator Quality Assurance Test	Required Frequency
Constancy	Upon Installation; Daily (integrated into Daily Quality Control procedure); following repair
Linearity	Upon installation; quarterly; following repair
Accuracy	Upon installation; annually; following repair
Geometry	Upon installation; following repair

Table 2, Dose Calibrator Quality Assuarance & Required Frequency of Performance

Required frequency of dose calibrator quality assurance tests may vary according to local regulations. Daily Dose Calibrator Constancy check is integrated into Daily Quality Control tab.

Id. at 28;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

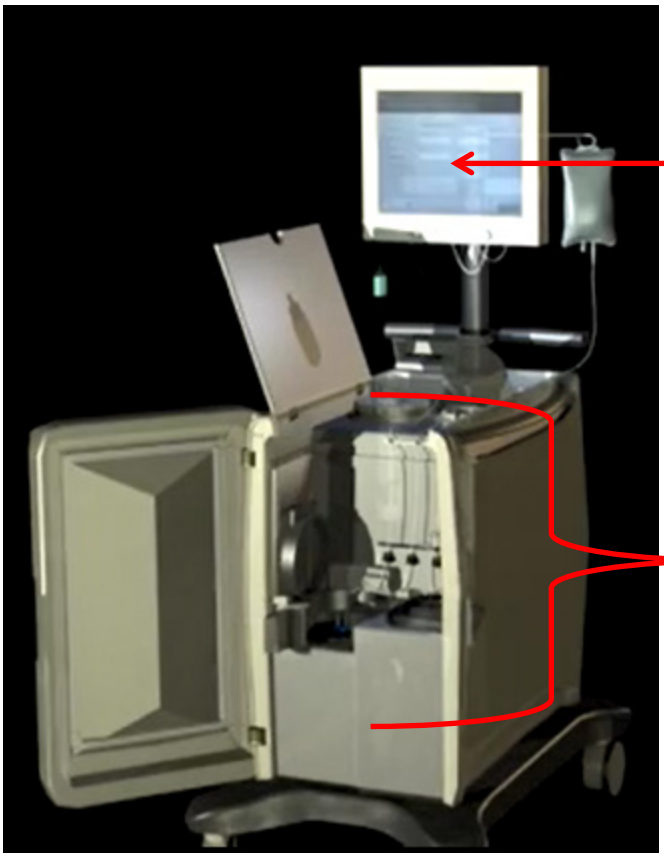
1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

The word Successful (in green) appears next to each item as it is completed. This information is saved in the Daily QC report. If an error occurs, a red 'X' appears and that process is aborted. If this occurs, the user needs to repeat this process before proceeding to the next step (see Fig. 50, Performing Daily Quality Control).

electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing

Id. at 42-43.

137. As shown below, Ruby-Fill®'s computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results.



Ruby-Fill® video file, previously available at http://www.draximage.com/;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

The word Successful (in green) appears next to each item as it is completed. This information is saved in the Daily QC report. If an error occurs, a red 'X' appears and that process is aborted. If this occurs, the user needs to repeat this process before proceeding to the next step (see Fig. 50, Performing Daily Quality Control).

configured to receive the activity data from the dose calibrator and calculate breakthrough test results

Exhibit No. F at 42-43;

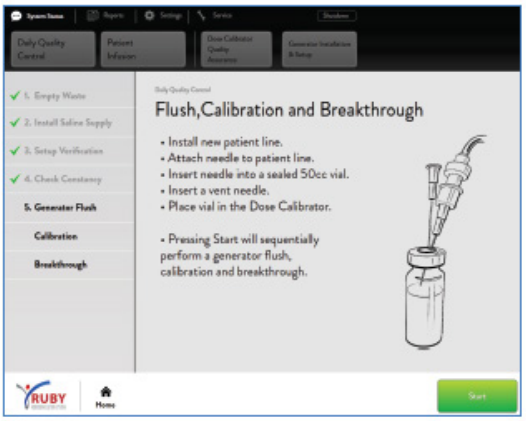


Figure 49, Flush, Calibration, and Breakthrough Screen

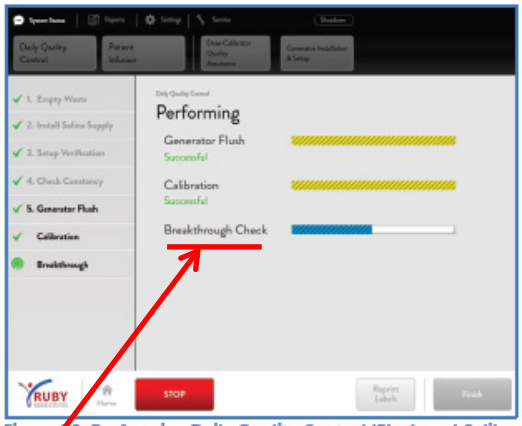


Figure 50, Performing Daily Quality Control (Flush and Calibration are completed and the Breakthrough Check is in progress)

configured to receive the activity data from the dose calibrator and calculate breakthrough test results

Id. at 42-43.

138. As shown below, Ruby-Fill®'s computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

System Error Message	Message Meaning	How to Troubleshoot
Sr Breakthrough Too High	The breakthrough limit level is reached. Patient infusions not allowed.	▪ Verify that the generator is not expired. ▪ Verify background activity fluctuations. ▪ Repeat radioactivity calibration and breakthrough check. ▪ Install a new generator.

Id. at 59;

The system can be used with four (4) patients before a Quality Control procedure must be performed if the breakthrough reaches an alert limit. If the user repeats the flush, the system counts this as a patient infusion.

- ≥ 50% of the USP limit* (see Table 3), the system does not allow the user to perform a patient infusion.
- Refer to Table 3 below for instructions to follow on Strontium Breakthrough results.

PASS < 20% of USP limits* (Green)	ALERT ≥ 20% and <50% of USP limits* OR 20L volume limit (Yellow)	FAIL ≥ 50% of USP limits* OR 30L volume limit (Red)
Breakthrough level is low.	Breakthrough level is increased.	Breakthrough level is approaching the allowable limit.
The Daily Quality Procedure (automated breakthrough test) is valid for a 24 hour period.	The Daily Quality Procedure (automated breakthrough test) is valid for 4 patients only.	The Daily Quality Control (automated breakthrough test) does not allow a sufficient margin of safety to continue the elutions (scans).
Proceed with use	Repeat an automated Daily Quality Control after every 4 patients (8 scans) and record the results Contact Jubilant DraxImage: 1-888-633-5343	The use of the RUBY-FILL® Rubidium Rb 82 Generator must be discontinued immediately. Contact Jubilant DraxImage: 1-888-633-5343
*USP limits: <0.02μCi of Sr-82/mCi of Rb-82; <0.2μCi of Sr-85/mCi of Rb-82		

Table 3: Strontium Breakthrough Results

Id. at 44.

139. Defendants infringe, contribute to the infringement of, and/or induce infringement of the '467 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by making, using, selling, offering for sale, and/or importing into the United States products covered by one or more claims of the '467 patent including, but not limited to, at least the Ruby-Fill® system.

140. Defendants directly infringe one or more claims of the '467 patent. Defendants make, use, sell, offer for sale, and/or import, in this District and elsewhere in the United States infringing products, such as the Ruby-Fill® system and thus directly infringes the '467 patent.

141. Defendants have had knowledge and notice of the '467 patent at least as early as the filing of this Complaint.

142. Defendants' infringement of the '467 patent has damaged and will continue to damage Bracco.

143. Defendants indirectly infringe the '467 patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Defendants' customers, in this District and

elsewhere in the United States. For example, Defendants' customers directly infringe through their use of the inventions claimed in the '467 patent. Defendants induce this direct infringement through their affirmative acts of manufacturing, selling, distributing, instructing and/or otherwise making available the infringing products, such as the Ruby-Fill® system, and providing instructions, documentation, and other information to customers suggesting they use the infringing products, such as the Ruby-Fill® system in an infringing manner, including online technical support, marketing, product manuals, advertisements, and online documentation. As a result of Defendants' inducement, Defendants' customers use the infringing products, such as the Ruby-Fill® system in the way Defendants intend and directly infringe the '467 patent. Defendants have performed and continue to perform these affirmative acts with knowledge of the '467 patent and with the intent, or willful blindness, that the induced acts directly infringe the '467 patent.

144. Defendants also indirectly infringe the '467 patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers, in this District and elsewhere in the United States. Defendants' affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, infringing products, such as the Ruby-Fill® system and causing these products to be manufactured, used, sold, and offered for sale contribute to Defendants' customers' use of the infringing products, such as the Ruby-Fill® system, such that the '467 patent is directly infringed. Defendants have performed and continue to perform these affirmative acts with knowledge of the '467 patent and with intent, or willful blindness, that they cause the direct infringement of the '467 patent.

145. Defendants' infringement of the '467 patent will cause Bracco to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Bracco

has no adequate remedy at law and, thus, a permanent injunction is appropriate to prohibit Defendants from infringing the '467 patent.

COUNT FIVE – INFRINGEMENT OF THE '468 PATENT

146. Bracco repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

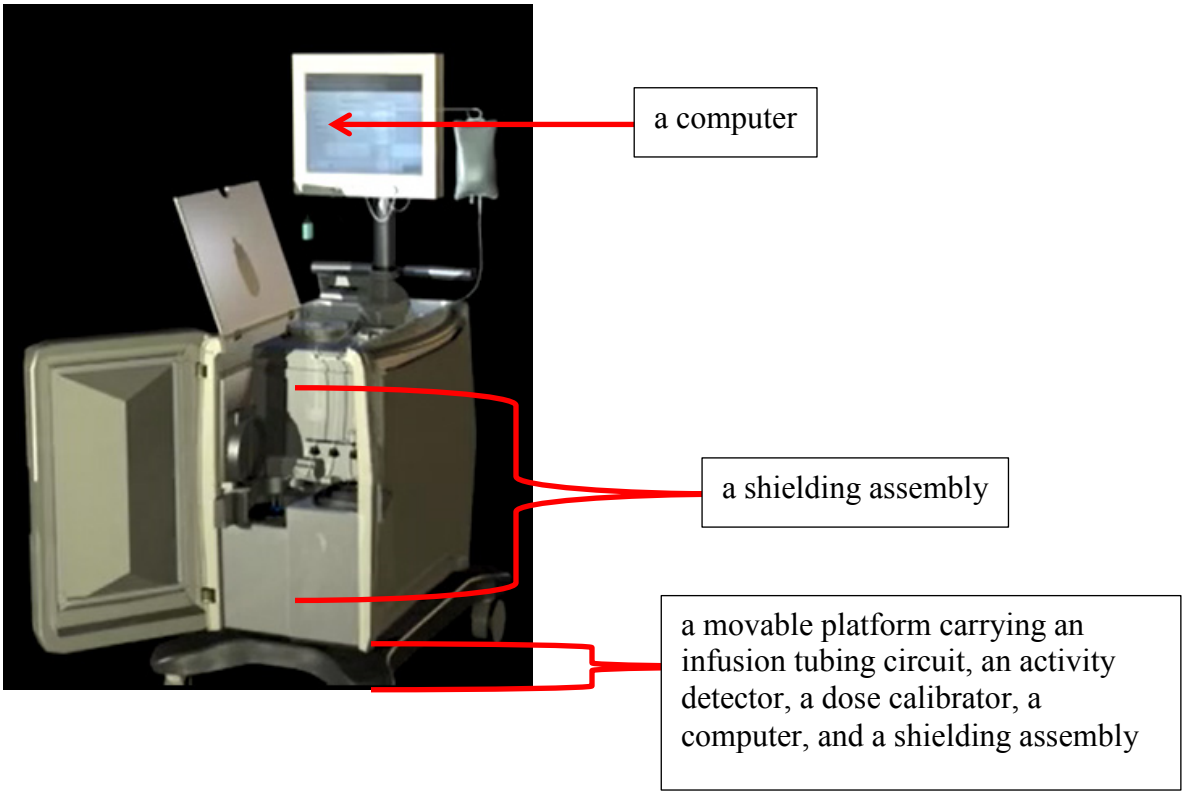
147. Defendants make, use, offer to sell, sells, and/or imports an infusion system to deliver a rubidium radioactive eluate (i.e., Ruby-Fill®) that infringes or induces or contributes to the infringement of one or more claims of the '468 patent.

148. The elements of claim 1 of the '468 patent are as follows:

> 1. A mobile radioisotope generator system comprising:
>
> (a) a movable platform carrying an infusion tubing circuit, an activity detector, a dose calibrator, a computer, and a shielding assembly containing a strontium/rubidium radioisotope generator configured to generate a radioactive eluate via elution of an eluant,
>
> (b) the infusion tubing circuit including a tubing line connected between the strontium/rubidium radioisotope generator and the dose calibrator and configured to supply a portion of radioactive eluate to the dose calibrator,
>
> (c) the activity detector being positioned downstream of the strontium/rubidium radioisotope generator and configured to measure an activity of the radioactive eluate flowing through the infusion tubing circuit, and
>
> (d) the computer being electronically coupled to the dose calibrator and configured to execute automated quality control testing using the dose calibrator,
>
> (e) wherein the computer is configured to determine an activity of strontium-82 and an activity of strontium-85 in the portion of radioactive eluate through automated quality control testing using the dose calibrator,
>
> (f) the computer is configured to control the mobile radioisotope generator system to deliver a dose of radioactive eluate to a patient during a patient infusion procedure, and

(g) the computer is further configured to prevent the patient infusion procedure if a quality control test result exceeds an allowable limit.

149. As shown below, The Ruby-Fill® infusion system has a movable platform carrying an infusion tubing circuit, an activity detector, a dose calibrator, a computer, and a shielding assembly containing a strontium/rubidium radioisotope generator configured to generate a radioactive eluate via elution of an eluant.



Ruby-Fill® video file, previously available at http://www.draximage.com/;

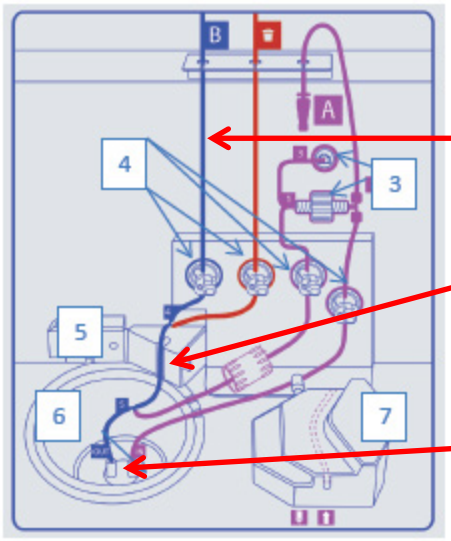


Figure 2, System Components (#3–#7)

an infusion tubing circuit

an activity detector

a strontium/rubidium radioisotope generator configured to generate a radioactive eluate via elution of an eluant

See e.g., Exhibit No. F at 9;

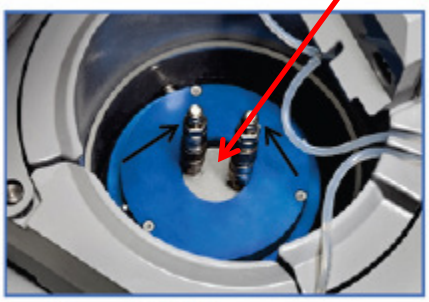


Figure 4, Generator Metal Caps

Id. at 10;

2.2 SYSTEM DESCRIPTION

The RUBY Rubidium Elution System is a mobile cart that houses all of the components required for the infusion of Rubidium Chloride Rb 82 for Cardiac PET imaging. It is computer-controlled and allows for real-time monitoring of patient elutions.

The RUBY-FILL® Rubidium Rb 82 Generator provides an elution of Rubidium Chloride Rb 82 Injection which is indicated as an accessory to positron emission tomography (PET) imaging, for the assessment of myocardial perfusion to aid in the diagnosis of coronary artery disease. Rubidium Chloride Rb 82 Injection can be used when the patient is at rest and/or under pharmacologic stress conditions.

Id. at 8;

configured to generate a radioactive eluate via elution of an eluant

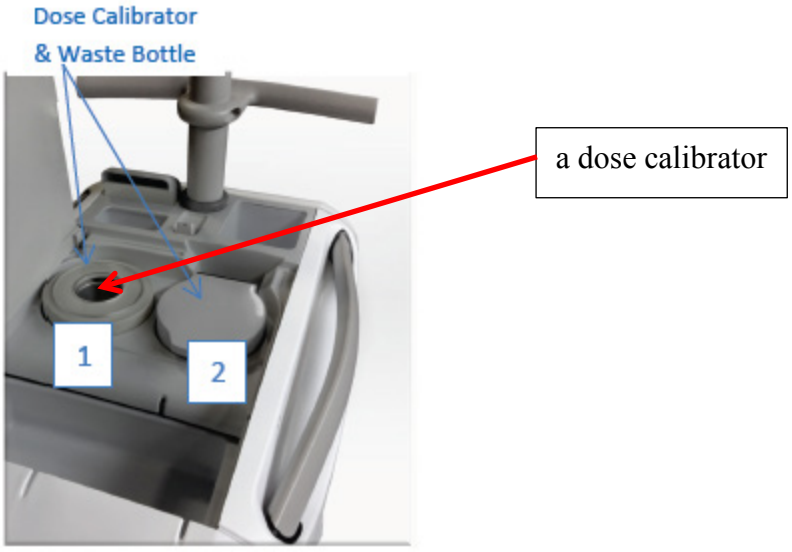


Figure 1, RUBY Rubidium Elution System

Id. at 9;

6. OPERATING THE SYSTEM

6.1 DOSE CALIBRATOR QUALITY ASSURANCE

The RUBY Rubidium Elution System comes with an integrated dose calibrator. This dose calibrator is fully controlled using the system's software. To access the quality assurance mode, press Dose Calibrator Quality Assurance on the second row of the task bar and enter the required password. The control screen is displayed (see Fig. 26, Dose Calibrator Quality Assurance Screen). To perform the required quality assurance tests, such as Linearity, Geometry and Accuracy, an independent control screen is included to enable the operation and/or configuration of the dose calibrator in conventional mode (Table 2, Dose Calibrator Quality Assurance & Required Frequency of Performance). JDI personnel will complete all four quality assurance tests upon installation of the elution system. Users are responsible for performing Constancy daily (integrated into Daily Quality Control); Linearity quarterly and Accuracy annually.

Dose Calibrator Quality Assurance Test	Required Frequency
Constancy	Upon Installation; Daily (integrated into Daily Quality Control procedure); following repair
Linearity	Upon installation; quarterly; following repair
Accuracy	Upon installation; annually; following repair
Geometry	Upon installation; following repair

Table 2, Dose Calibrator Quality Assurance & Required Frequency of Performance

Required frequency of dose calibrator quality assurance tests may vary according to local regulations. Daily Dose Calibrator Constancy check is integrated into Daily Quality Control tab.

Id. at 28.

150. As shown below, the infusion tubing circuit of the Ruby-Fill® infusion system includes a tubing line connected between the strontium/rubidium radioisotope generator and the dose calibrator and configured to supply a portion of radioactive eluate to the dose calibrator.

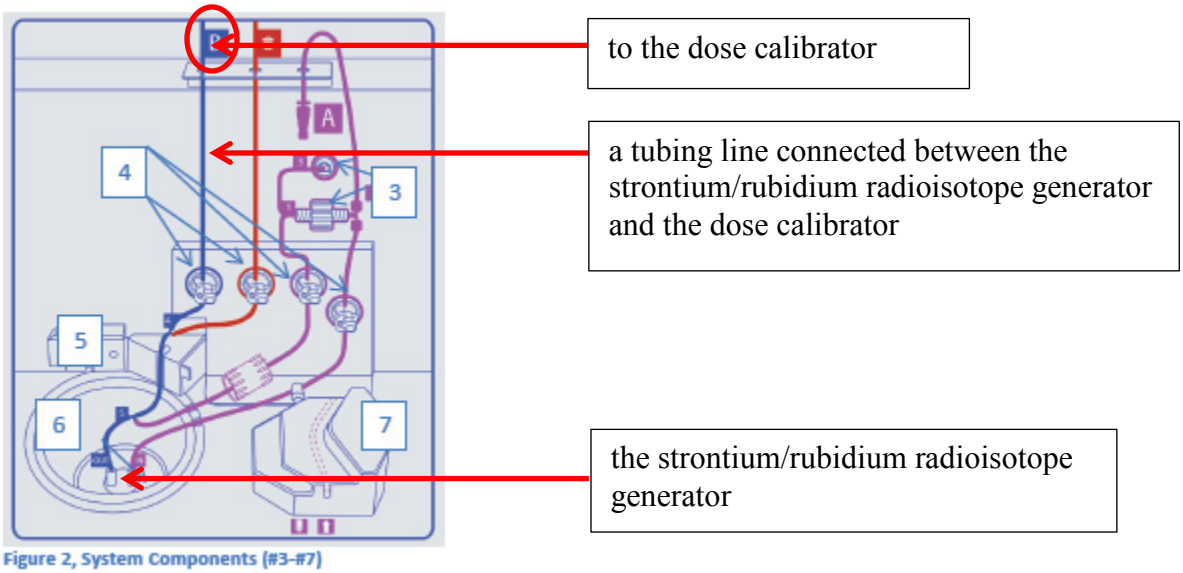


Figure 2, System Components (#3-#7)

Id. at 9;

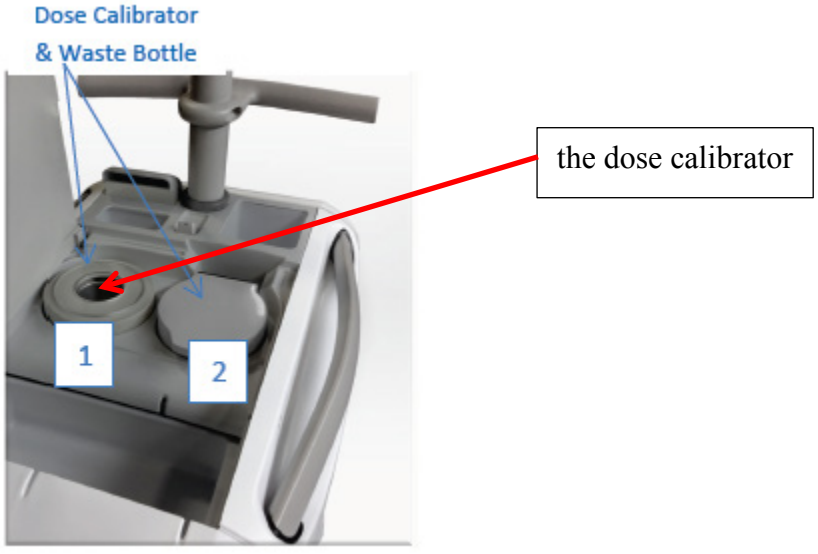


Figure 1, RUBY Rubidium Elution System

Id. at 9;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

See, e.g., id. at 42.

151. As shown below, the activity detector of the Ruby-Fill® infusion system being positioned downstream of the strontium/rubidium radioisotope generator and configured to measure an activity of the radioactive eluate flowing through the infusion tubing circuit.

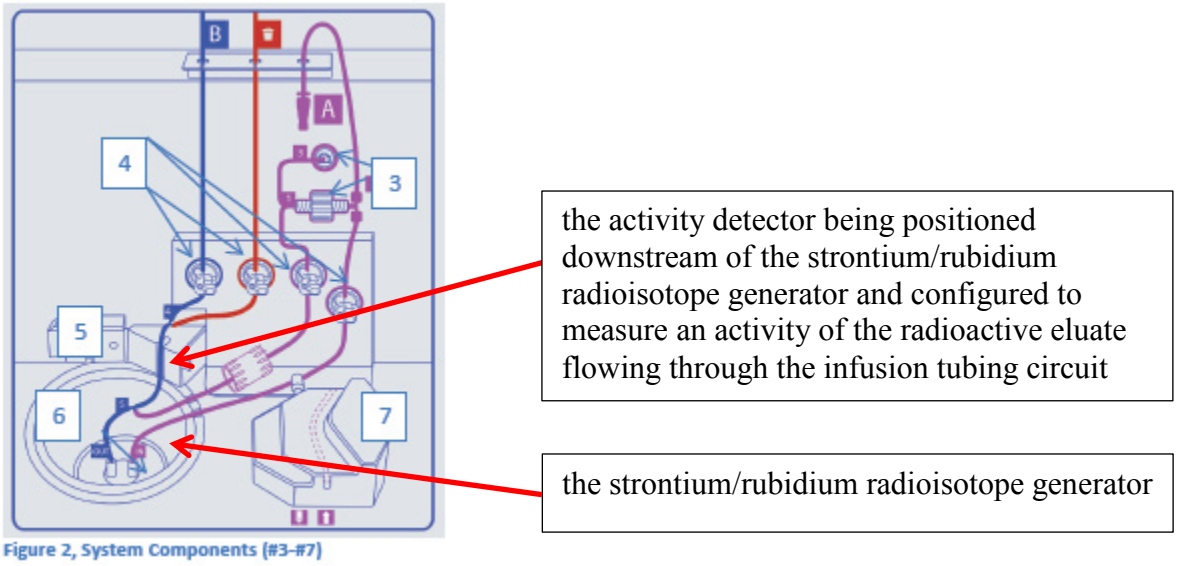


Figure 2, System Components (#3–#7)

Id. at 9;

System Error Message	Message Meaning	How to Troubleshoot
Radioactivity Counter Overlight	The radioactivity counter is exposed to light	▪ Verify that the radioactivity counter cover is closed.
Radioactivity Counter Failure	Error detected from the radioactivity counter	▪ Verify that the radioactivity counter cover is closed. ▪ Restart the system.
Radioactivity Counter Disconnected	Communication failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.
Radioactivity Counter Error	System detected a failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.
Radioactivity Counter Initialization Error	System detected a failure with the radioactivity counter	▪ Verify that the acquisition card cable is connected to the computer. ▪ Restart the system.

Id. at 59.

152. As shown below, the computer of the Ruby-Fill® infusion system being electronically coupled to the dose calibrator and configured to execute automated quality control testing using the dose calibrator.

Id. at 1;

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

The word Successful (in green) appears next to each item as it is completed. This information is saved in the Daily QC report. If an error occurs, a red 'X' appears and that process is aborted. If this occurs, the user needs to repeat this process before proceeding to the next step (see Fig. 50, Performing Daily Quality Control).

being electronically coupled to the dose calibrator and configured to execute automated quality control testing using the dose calibrator

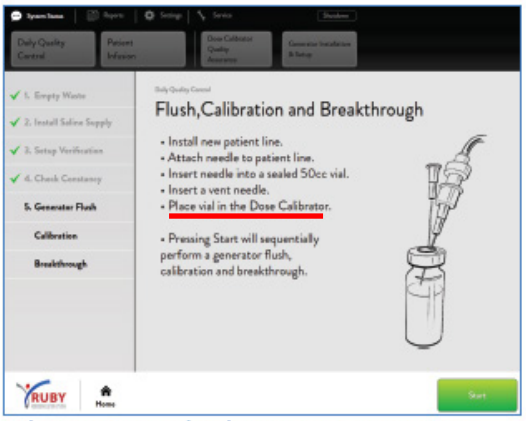


Figure 49, Flush, Calibration, and Breakthrough Screen

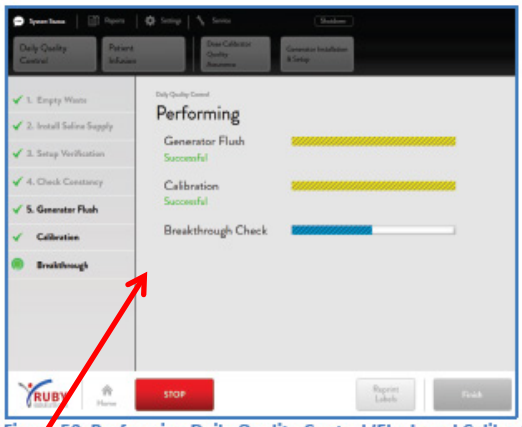


Figure 50, Performing Daily Quality Control (Flush and Calibration are completed and the Breakthrough Check is in progress)

automated quality control testing using the dose calibrator

Id. at 42-43.

153. As shown below, the computer of the Ruby-Fill® infusion system is configured to determine an activity of strontium-82 and an activity of strontium-85 in the portion of radioactive eluate through automated quality control testing using the dose calibrator.

The calibration process runs a measured amount (35mL) of saline through the Generator at a flow rate of 20 mL/min to deliver a calibrated sample. This calibrated sample is collected in a vial in the dose calibrator and measured to determine the activity. This activity will be used by the system to determine the activity available at this point in the life of the Generator and to measure the activity delivered in patient infusions.
The breakthrough test uses the sample produced during the calibration process. This portion of the Daily Quality Control takes 30 minutes, during which the Rb-82 decays completely, and the system assays the calibration sample and measures the amount of strontium-82 and strontium-85 present in the sample. This information is saved in the calibration report (refer to section 8.1, Reports).

Follow these steps before initiating Start for the Flush, Calibration and Breakthourgh.

1. Obtain a 50 ml sealed glass vial (with rubber stopper)
2. Aseptically install a RUBY IV LINE on the B needleless injection port of the RUBY SET
3. Aseptically install a sterile needle (20G) on the end of the RUBY IV LINE and insert into rubber stopper of glass vial
4. Insert a sterile vent needle (20G) into rubber stopper of glass vial
5. Place the vial into dose calibrator dipper and lower into the dose calibrator chamber
6. Press Start to begin the 50-minute procedure (see Fig. 49, Flush, Calibration, and Breakthrough Screen).

The word Successful (in green) appears next to each item as it is completed. This information is saved in the Daily QC report. If an error occurs, a red 'X' appears and that process is aborted. If this occurs, the user needs to repeat this process before proceeding to the next step (see Fig. 50, Performing Daily Quality Control).

the computer is configured to determine an activity of strontium-82 and an activity of strontium-85 in the portion of radioactive eluate through automated quality control testing using the dose calibrator

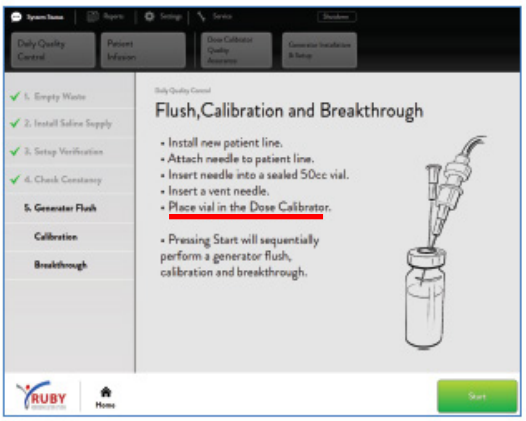


Figure 49, Flush, Calibration, and Breakthrough Screen

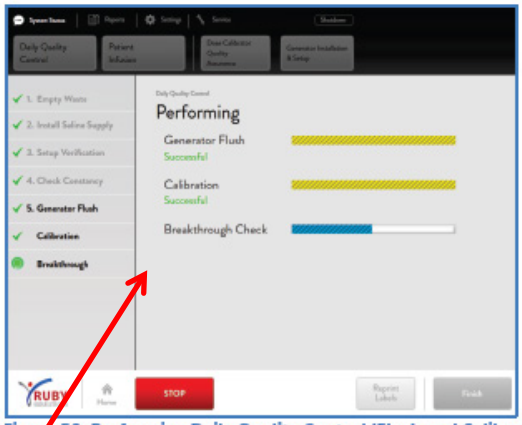


Figure 50, Performing Daily Quality Control (Flush and Calibration are completed and the Breakthrough Check is in progress)

automated quality control testing using the dose calibrator

Id. at 42-43.

154. As shown below, the computer of the Ruby-Fill® infusion system is configured to control the mobile radioisotope generator system to deliver a dose of radioactive eluate to a patient during a patient infusion procedure.

2.2 SYSTEM DESCRIPTION

The RUBY Rubidium Elution System is a mobile cart that houses all of the components required for the infusion of Rubidium Chloride Rb 82 for Cardiac PET imaging. It is computer-controlled and allows for real-time monitoring of patient elutions.

The RUBY-FILL® Rubidium Rb 82 Generator provides an elution of Rubidium Chloride Rb 82 Injection which is indicated as an accessory to positron emission tomography (PET) imaging, for the assessment of myocardial perfusion to aid in the diagnosis of coronary artery disease. Rubidium Chloride Rb 82 Injection can be used when the patient is at rest and/or under pharmacologic stress conditions.

The RUBY Rubidium Elution System uses an intuitive and informative touch screen. The computer controlled, integrated system architecture allows for real-time monitoring of patient infusions. In the event of hardware failure or significant discrepancy of measurements from expected values, the software automatically terminates the elution and display the appropriate error message.

Id. at 8;

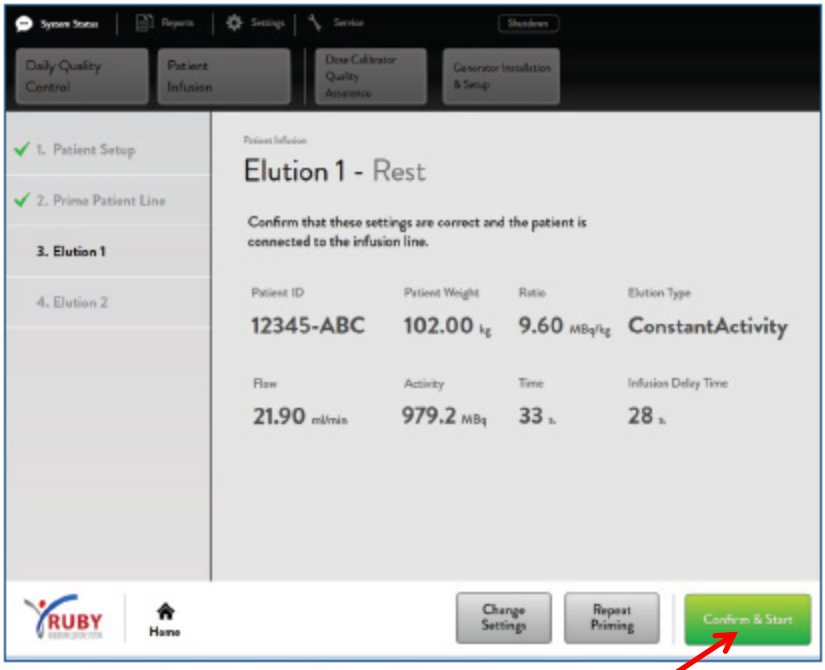


Figure 54, Elution Confirmation Screen

button for computer to control the delivery of a dose of radioactive eluate to a patient during a patient infusion procedure

Id. at 46-50.

155. As shown below, The Ruby-Fill®'s computer can be configured to prevent the patient infusion procedure if a quality control test result exceeds an allowable limit.

System Error Message	Message Meaning	How to Troubleshoot
Sr Breakthrough Too High	The breakthrough limit level is reached. Patient infusions not allowed.	▪ Verify that the generator is not expired. ▪ Verify background activity fluctuations. ▪ Repeat radioactivity calibration and breakthrough check. ▪ Install a new generator.

Id. at 59;

The system can be used with four (4) patients before a Quality Control procedure must be performed if the breakthrough reaches an alert limit. If the user repeats the flush, the system counts this as a patient infusion.

- ≥ 50% of the USP limit* (see Table 3), the system does not allow the user to perform a patient infusion.
- Refer to Table 3 below for instructions to follow on Strontium Breakthrough results.

PASS < 20% of USP limits* (Green)	ALERT ≥ 20% and <50% of USP limits* OR 20L volume limit (Yellow)	FAIL ≥ 50% of USP limits* OR 30L volume limit (Red)
Breakthrough level is low.	Breakthrough level is increased.	Breakthrough level is approaching the allowable limit.
The Daily Quality Procedure (automated breakthrough test) is valid for a 24 hour period.	The Daily Quality Procedure (automated breakthrough test) is valid for 4 patients only.	The Daily Quality Control (automated breakthrough test) does not allow a sufficient margin of safety to continue the elutions (scans).
Proceed with use	Repeat an automated Daily Quality Control after every 4 patients (8 scans) and record the results Contact Jubilant DraxImage: 1-888-633-5343	The use of the RUBY-FILL® Rubidium Rb 82 Generator must be discontinued immediately. Contact Jubilant DraxImage: 1-888-633-5343
*USP limits: <0.02μCi of Sr-82/mCi of Rb-82; <0.2μCi of Sr-85/mCi of Rb-82		

Table 3: Strontium Breakthrough Results

Id. at 44.

156. Defendants infringe, contribute to the infringement of, and/or induce infringement of the '468 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c) by making, using, selling, offering for sale, and/or importing into the United States products covered by one or more claims of the '468 patent including, but not limited to, at least the Ruby-Fill® system.

157. Defendants directly infringe one or more claims of the '468 patent. Defendants make, use, sell, offer for sale, and/or import, in this District and elsewhere in the United States infringing products, such as the Ruby-Fill® system and thus directly infringes the '468 patent.

158. Defendants have had knowledge and notice of the '468 patent at least as early as the filing of this Complaint.

159. Defendants' infringement of the '468 patent has damaged and will continue to damage Bracco.

160. Defendants indirectly infringe the '468 patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Defendants' customers, in this District and

elsewhere in the United States. For example, Defendants' customers directly infringe through their use of the inventions claimed in the '468 patent. Defendants induce this direct infringement through their affirmative acts of manufacturing, selling, distributing, instructing and/or otherwise making available the infringing products, such as the Ruby-Fill® system, and providing instructions, documentation, and other information to customers suggesting they use the infringing products, such as the Ruby-Fill® system in an infringing manner, including online technical support, marketing, product manuals, advertisements, and online documentation. As a result of Defendants' inducement, Defendants' customers use the infringing products, such as the Ruby-Fill® system in the way Defendants intend and directly infringe the '468 patent. Defendants have performed and continue to perform these affirmative acts with knowledge of the '468 patent and with the intent, or willful blindness, that the induced acts directly infringe the '468 patent.

161. Defendants also indirectly infringe the '468 patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers, in this District and elsewhere in the United States. Defendants' affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, infringing products, such as the Ruby-Fill® system and causing these products to be manufactured, used, sold, and offered for sale contribute to Defendants' customers' use of the infringing products, such as the Ruby-Fill® system, such that the '468 patent is directly infringed. Defendants have performed and continue to perform these affirmative acts with knowledge of the '468 patent and with intent, or willful blindness, that they cause the direct infringement of the '468 patent.

162. Defendants' infringement of the '468 patent will cause Bracco to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Bracco

has no adequate remedy at law and, thus, a permanent injunction is appropriate to prohibit Defendants from infringing the '468 patent.

DAMAGES

163. As a result of Defendants' acts of infringement, Bracco has suffered actual and consequential damages. However, Bracco does not yet know the full extent of the infringement and its extent cannot be ascertained except through discovery and special accounting. To the fullest extent permitted by law, Bracco seeks recovery of damages at least for lost profits, reasonable royalties, unjust enrichment, and/or benefits received by Defendants as a result of using misappropriated Bracco technology. Bracco further seeks any other damages to which Bracco is entitled under law or in equity.

DEMAND FOR JURY TRIAL

164. Bracco hereby demands a jury trial for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Bracco respectfully requests that this Court enter judgment in its favor as follows:

a. entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing Defendants' Ruby-Fill® system prior to the expiration of the patents-in-suit infringes, actively induces infringement, and/or contributes to the infringement of the patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c);

b. entry of judgment that Defendants' infringement of the patents-in-suit was willful, and that Defendants continued infringement of these patents is willful;

c. awarding Bracco actual damages in an amount sufficient to compensate Bracco for Defendants' infringement of the patents-in-suit until such time as Defendants ceases its infringing conduct;

d. awarding enhanced damages pursuant to 35 U.S.C. § 284;

e. awarding Bracco pre-judgment and post-judgment interest to the full extent allowed under the law, as well as its costs;

f. declaring that this is an exceptional case and awarding Bracco its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

g. ordering an accounting of damages for acts of infringement;

h. awarding Bracco its costs of suit; and

i. awarding such other equitable relief that may be requested and to which Bracco is entitled.

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Attorneys for Plaintiff

Dated: March 27, 2018