UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AESTHETIC MANAGEMENT PARTNERS, LLC AND
AESTHETIC MANAGEMENT PARTNERS, INC.,

Petitioners,

v.

HYDRAFACIAL LLC

Patent Owner.

Case No. IPR2025-01217
U.S. Patent No. 11,446,477

SECOND DECLARATION OF KARL R. LEINSING, MSME, PE

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: October 17, 2025

By: Karl R. Leinsing 2025.10.17 18:42:11 -04'00'

Karl R. Leinsing, MSME, PE

Aesthetic Management Partners, LLC et al v. HydraFacial
IPR2025-01217
HydraFacial Ex. 2004

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I. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

A. HydraFacial Is Entitled to a Presumption of a Nexus Between the Claimed Invention and the Objective Evidence of Secondary Considerations

1. I have been informed by counsel that a nexus is presumed between the claimed invention and the objective evidence of secondary considerations of non-obviousness when the product embodies the claimed invention and is coextensive with it.

2. I have been asked to evaluate whether certain of HydraFacial's products meet the limitations of the claims of the '477 Patent. Specifically, I have been asked to provide expert analysis on whether HydraFacial's Syndeo, Elite, Allegro, and Tower systems (collectively, "the HydraFacial Practicing Systems" or "HydraFacial Systems") embody the claims of the '477 Patent and are coextensive with them to establish a presumed nexus for purposes of secondary considerations. I have analyzed the relevant aspects of each of the HydraFacial Systems in light of the claims of the '477 Patent.

3. As set forth in detail below, it is my opinion that the HydraFacial Systems meet every limitation of the claims of the '477 Patent and therefore embody the claims. As I additionally explain below, it is my opinion that the HydraFacial Systems are coextensive with those claims.

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B. The HydraFacial Systems Meet Every Limitation of the Claims and therefore Embody the Claimed Invention

1. Practice of Claim 1

4. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of claim 1 of the '477 Patent.

5. Claim 1 recites as follows:

> 1. A skin treatment system comprising:
> a manifold system in communication with a first container and at least a second container, wherein each of the first container and the at least second container is configured to contain a treatment material, the manifold system being positioned in or on a console;
> a supply conduit placing the manifold system in fluid communication with a handpiece assembly;
> wherein the handpiece assembly comprises a working end having a skin contact surface;
> a vacuum source;
> a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the working end of the handpiece assembly during a skin treatment procedure; and
> at least one control to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly;
> wherein the vacuum source is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly to help remove waste from the hand piece assembly via the waste conduit and to help transfer at least one treatment material from the manifold system to the handpiece assembly.

I address each limitation of this claim below.

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a. 1[pre]: "A skin treatment system comprising:"

6. In my opinion, each of the Syndeo, Elite, Allegro, and Tower is "a skin treatment system:"

7. The Syndeo IFU, for example, describes the Syndeo as a "System [that] is intended to abrade (exfoliate) the upper layers of the Skin." Ex.2030 at 4. The Syndeo IFU also describes a step of the treatment by stating, "Place tip against skin to occlude and dab skin solution onto skin." *Id.* at 19.

8. I also confirmed that the Syndeo is "a skin treatment system" after examination of a Syndeo device. Below is a photo of the Syndeo device taken during my inspection of the device:

Ex. 2107 (Syndeo).

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9. The Elite System also meets this limitation. The Elite IFU, for example, describes the Elite as a "System [that] is intended to abrade (exfoliate) the upper layers of the skin." Ex. 2031 at 4; *see also* Ex. 2100.

10. I also confirmed that the Elite is "a system for treating skin" after examination of an Elite device. Below is a photo of the Elite device I inspected:

Ex. 2074.

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11. The Allegro IFU, for example, describes a system that is "intended to abrade the upper layers of the skin by operator controlled motion, in order to smooth the skin surface and improve the appearance of skin, i.e. fine lines and wrinkle." Ex. 2032 at 4.

12. I also confirmed that the Allegro is "a skin treatment system" after examination of an Allegro device. Below is a photo of the Allegro device I inspected:

Ex. 2075.

13. The Tower System also meets this limitation. The Tower Owner's Manual describes the Tower as a "revolutionary breakthrough in aesthetic

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technology" that performs a process that "removes dead skin cells and impurities while simultaneously infusing the new skin with cleansing, hydrating and moisturizing serums and antioxidants." Ex. 2125 at 3.

14. I also reviewed photographs and videos of a Tower device to confirm my understanding that the Tower is "a skin treatment system." An image from one of the videos I reviewed is shown below:

Ex. 2151 at 2

15. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

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b. 1[a]: "a manifold system in communication with a first container and at least a second container, wherein each of the first container and the at least second container is configured to contain a treatment material, the manifold system being positioned in or on a console"

16. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a manifold system in communication with a first container and at least a second container, wherein each of the first container and the at least second container is configured to contain a treatment material, the manifold system being positioned in or on a console."

17. The term "manifold" is common in the mechanical arts. A person of ordinary skill in the art would understand that a manifold is a pipe or closed space in a with multiple inlets and at least one outlet for passage of fluids. I have applied this ordinary meaning in my analysis below.

a. Syndeo

i. 1[a][i]: "a manifold system in communication with a first container and at least a second container"

18. In my opinion, the Syndeo includes "a manifold system in communication with a first container and at least a second container."

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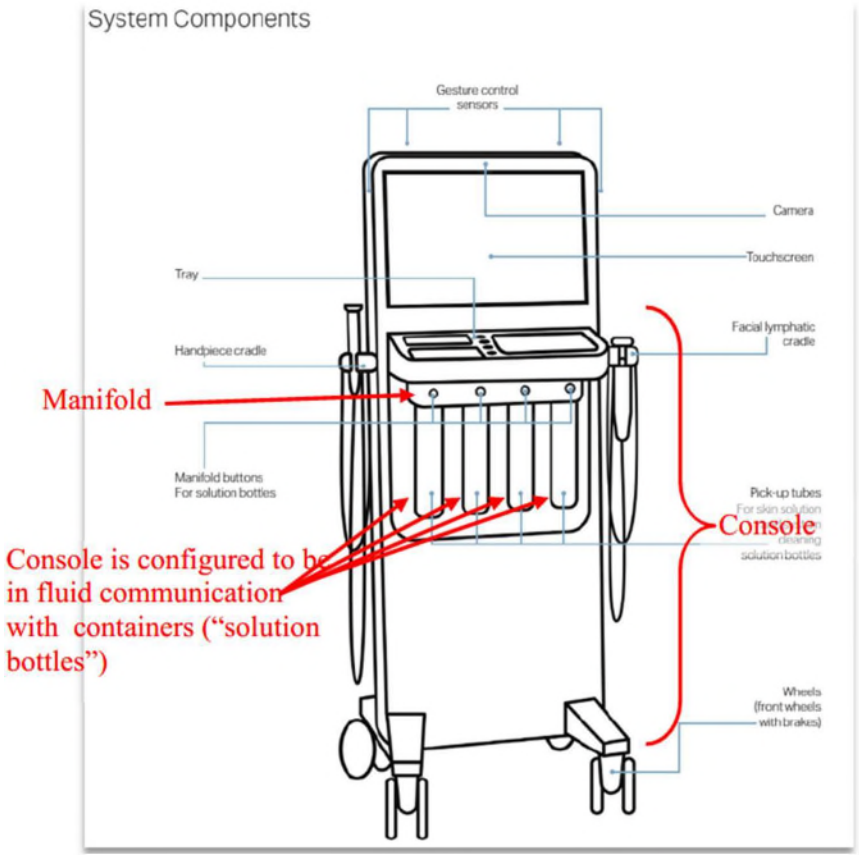
19. The Syndeo IFU contains an illustration of the console with system components. I have provided an annotated version of this illustration, identifying the location of the internal manifold system located within the console.



Ex. 2030 at 10.

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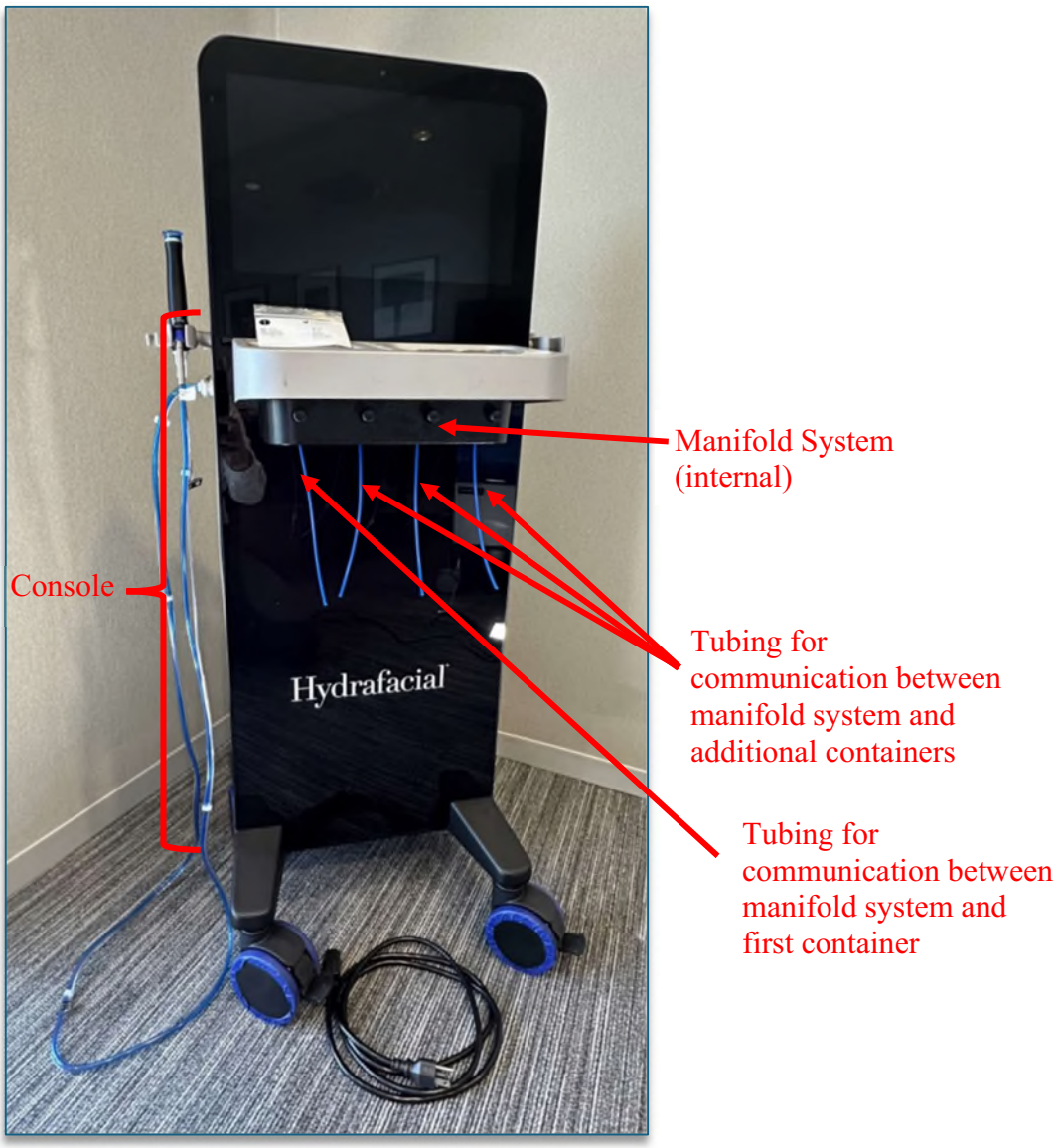
20. In addition, during my inspection of the Syndeo device, I confirmed that the Syndeo system includes an internal manifold system in the console of the device. An annotated photograph below shows the location of the internal manifold system in the console:



Ex. 2081 (Syndeo).

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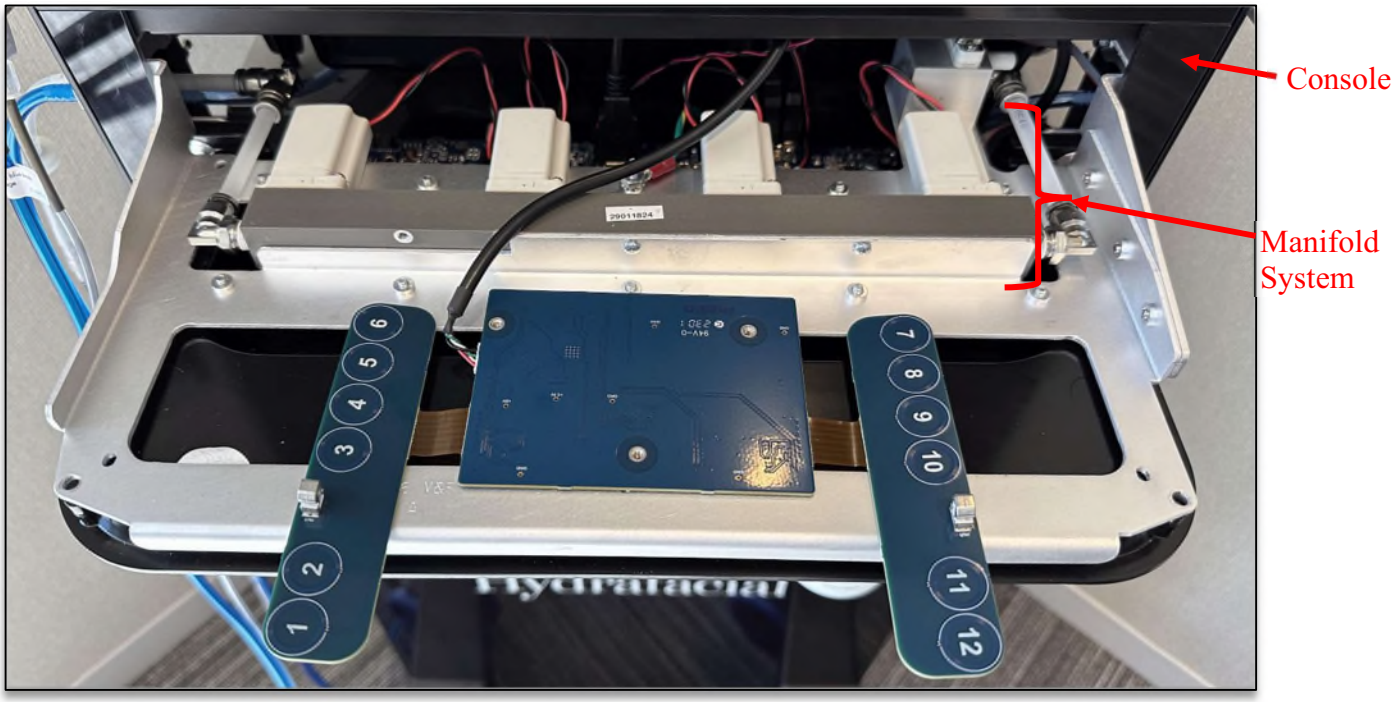
21. As part of my inspection of the Syndeo, I opened the console. In the console, I observed the internal manifold system located in the console. An annotated image of the manifold system in the console of the Syndeo system is included below:



Ex. 2085 (Syndeo).

22. As part of the disassembly of the Syndeo, I observed the manifold system in detail when removed from the console of the Syndeo system. The manifold system of the has a pipe or closed space with four inlets and one outlet for the passage of fluids. The below photo depicts the manifold system when removed from the Syndeo console.

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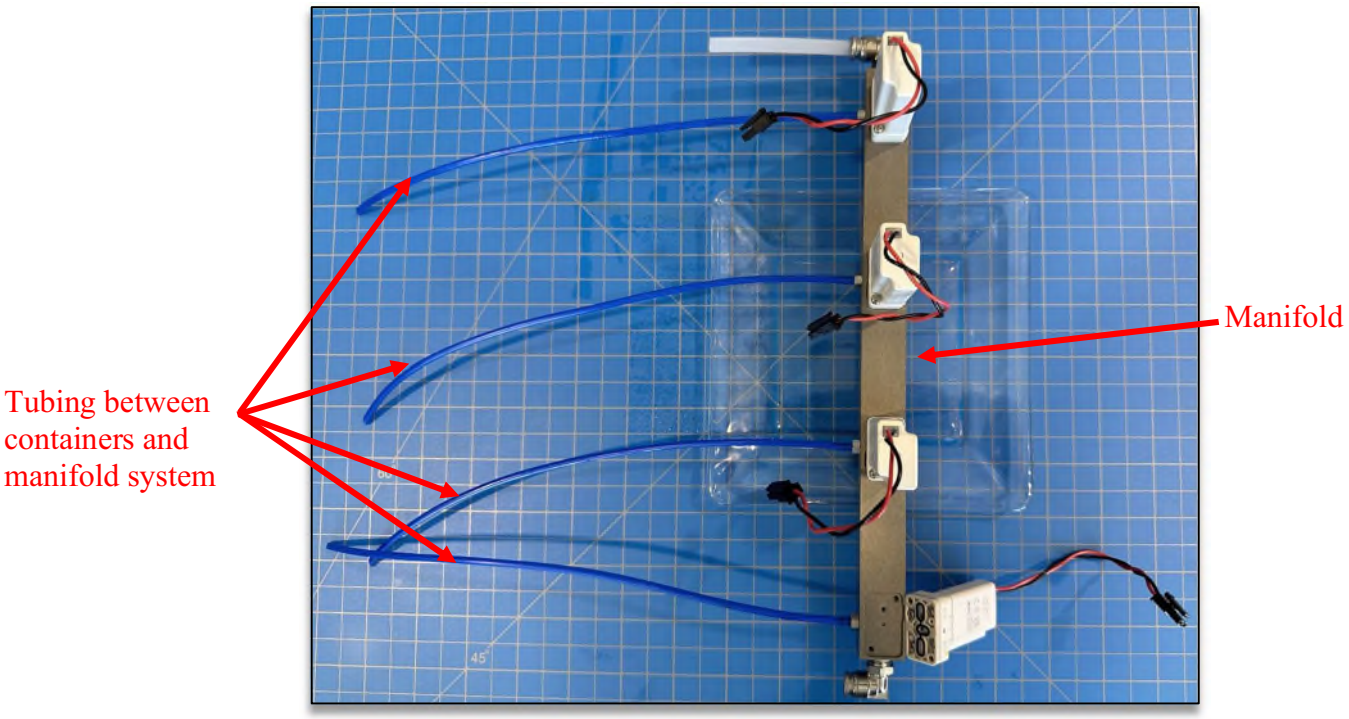

Ex. 2080 (Syndeo).

23. Accordingly, this limitation is satisfied by the Syndeo.

ii. 1[a][ii]: "wherein each of the first container and the at least second container is configured to contain a treatment material"

24. In my opinion, each of the first container and the at least second container of the HydraFacial Syndeo is configured to contain a treatment material.

25. The Syndeo IFU explains that the fluid containers connected to the console are configured to contain at least "treatment material" for use in "abrad[ing] (exfoliat[ing]) the upper layers of the skin." Ex. 2030 at 4. The Syndeo IFU further

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instructs a user to "[p]lace tip against skin to occlude and dab skin solution onto the skin" during a treatment procedure. *Id.* at 19.

26. In use, the Syndeo includes treatment material for use in each of the containers. For example, the Engineering Report Form for the Syndeo identifies "Activ-4," "Antiox+, Antiox-6," "Beta-HD," and "Rinse-away" as the serum containers which can be connected to the Syndeo console. The below image is excerpted from the Engineering Report Form. Thus, "Activ-4," "Antiox+, Antiox-6," "Beta-HD," and "Rinse-away," each corresponds to a container which may be connected to the Syndeo console.

Ex. 2113 at 2.

i. 1[a][iii]: "the manifold system being positioned in or on a console"

27. In my opinion, the HydraFacial Syndeo includes a manifold system that is positioned in or on a console.

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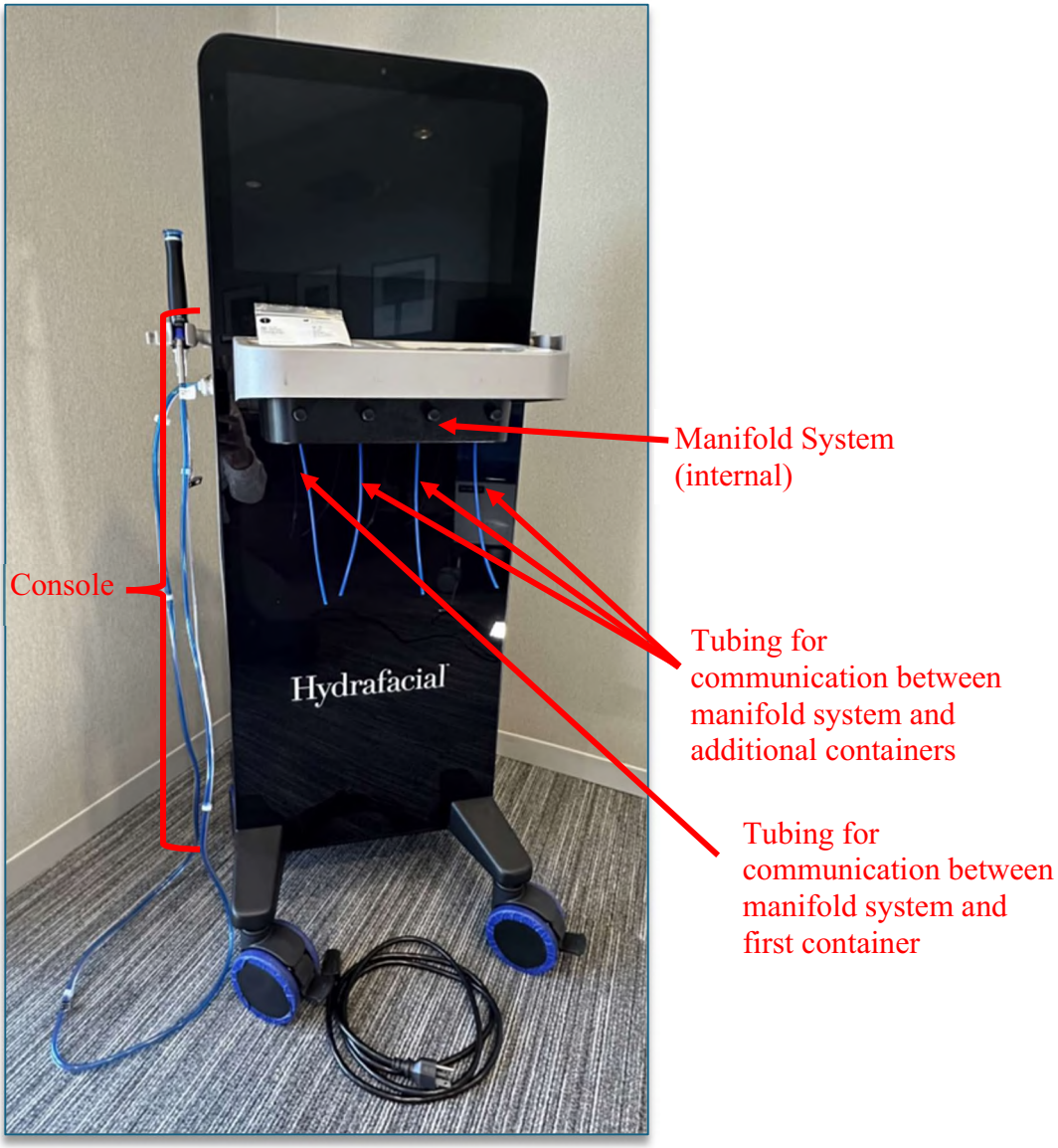
28. I have inspected the HydraFacial Syndeo and confirmed that the Syndeo device includes a manifold system positioned in the console of the device. An annotated photograph below shows the location of the internal manifold system in the console:



Ex. 2081 (Syndeo).

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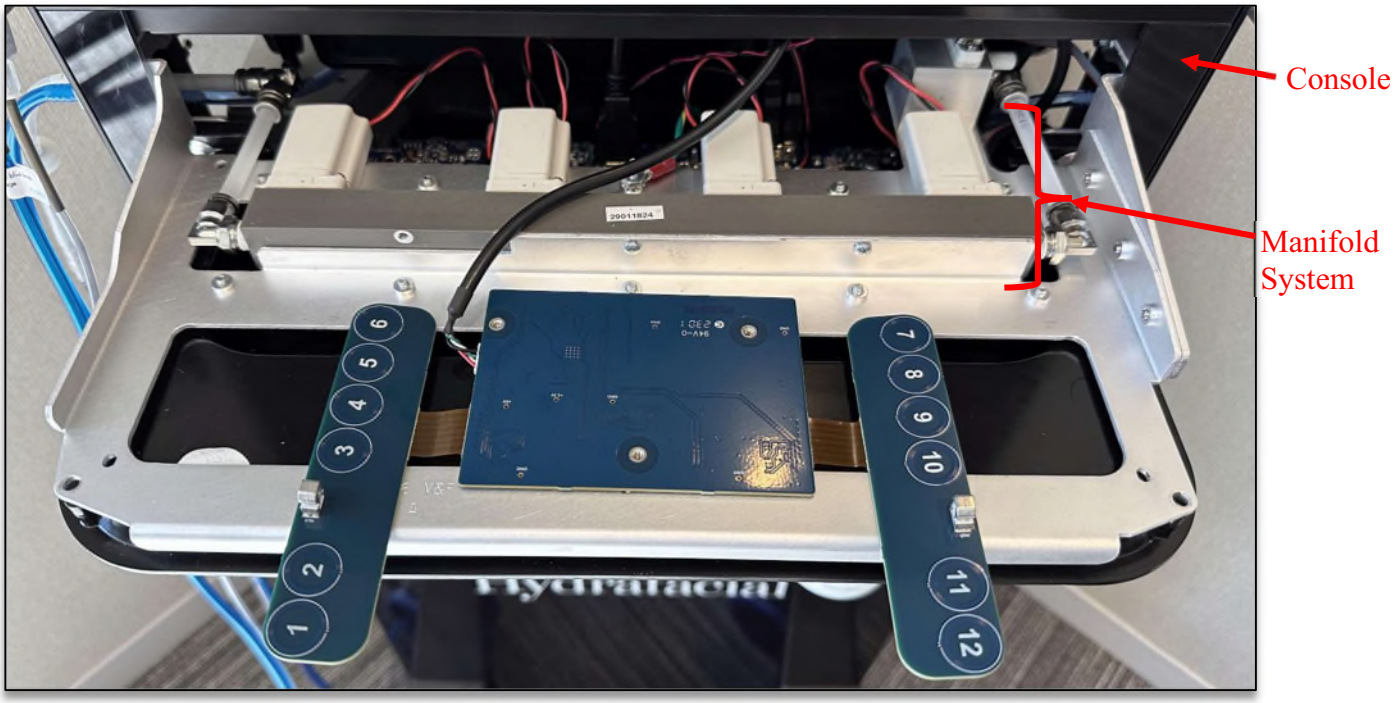
29. As part of my inspection of the Syndeo, I opened the console. In the console, I observed the manifold system located in the console. An annotated image of the manifold system in the console of the Syndeo system is included below:



Ex. 2085 (Syndeo).

30. The Syndeo IFU shows that the console includes a manifold system positioned in the console.

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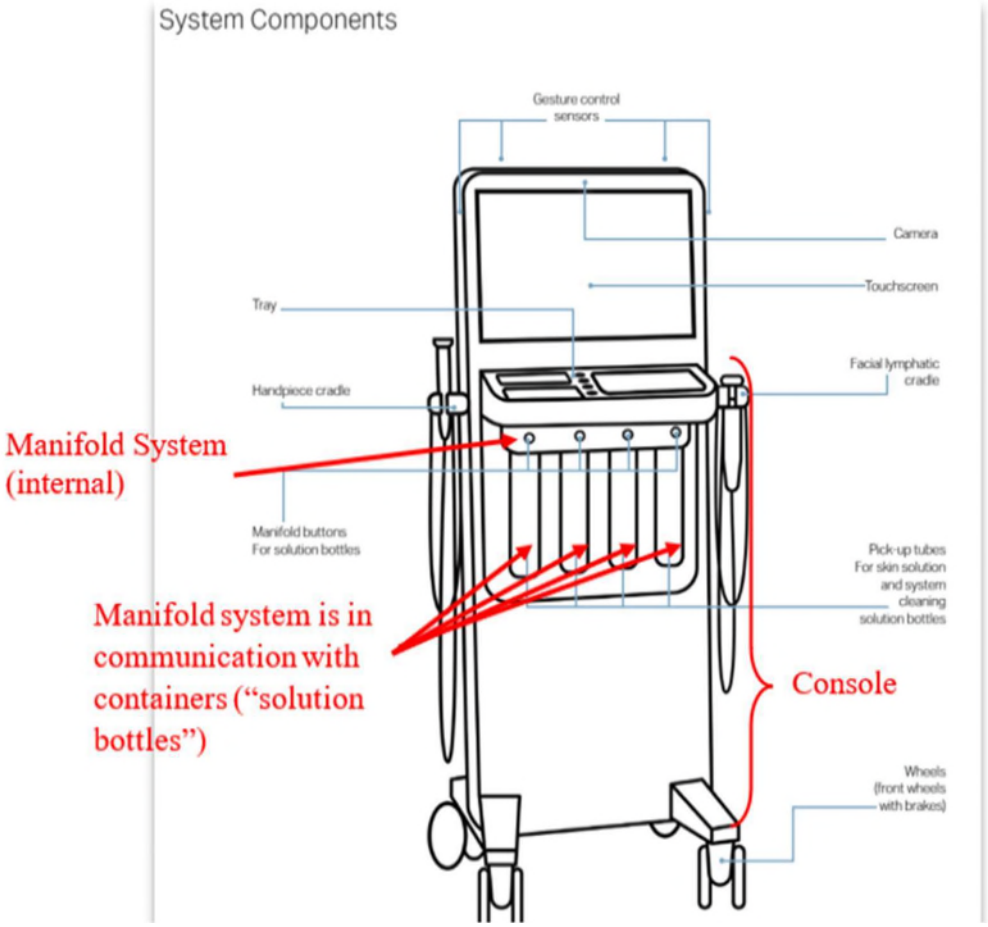

Ex. 2030 at 10.

31. Accordingly, this limitation is satisfied by the Syndeo.

b. Elite, Allegro, & Tower

i. 1[a][i]: "a manifold system in communication with a first container and at least a second container"

32. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a manifold system in communication with a first container and at least a second container."

33. The Elite IFU, Allegro IFU, and Tower Owner's Manual each contains an illustration of the console with system components. I have provided an annotated

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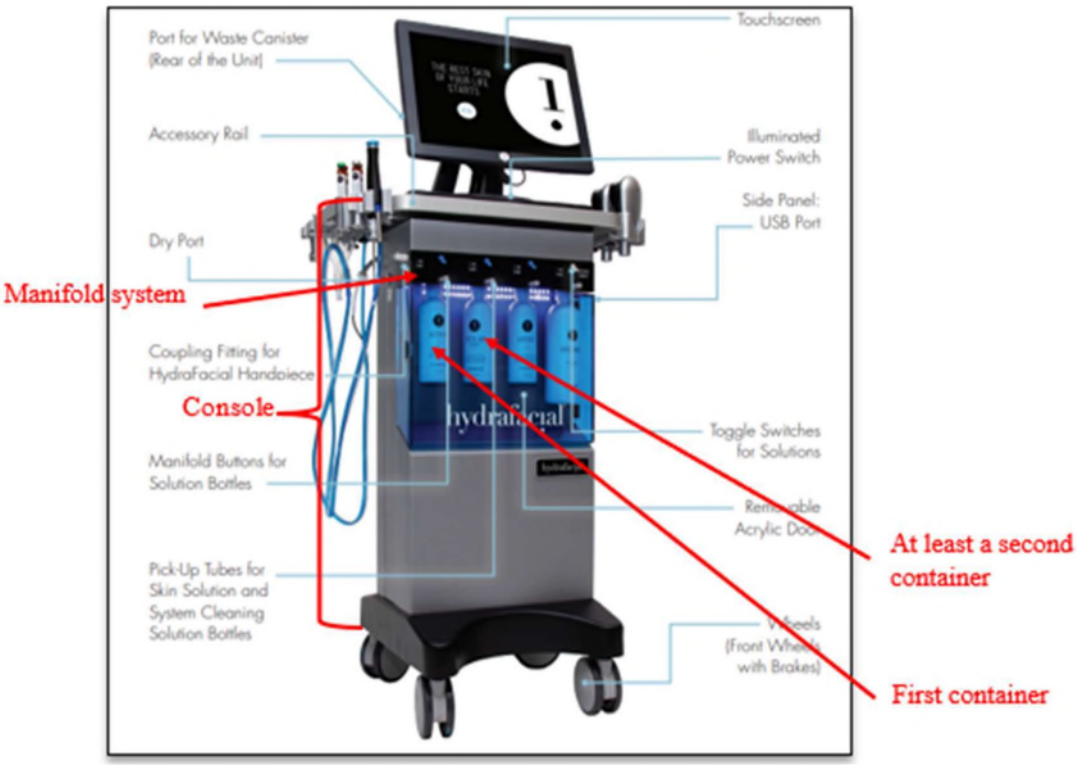
version of excerpts of these documents, identifying the location of the manifold system located within the console for each of the Elite, Allegro, and Tower:



Ex. 2031 at 10 (Elite IFU).

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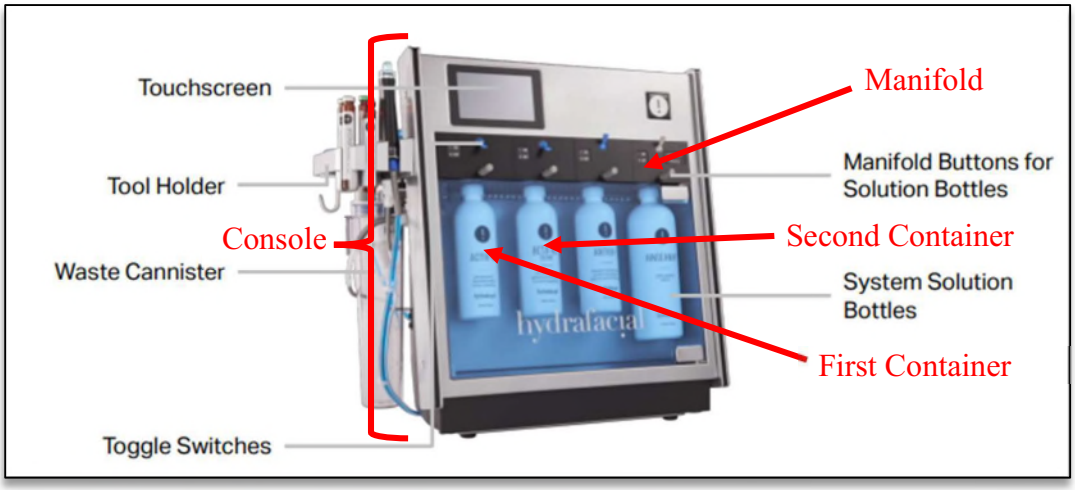

Ex. 2032 at 8 (Allegro IFU).

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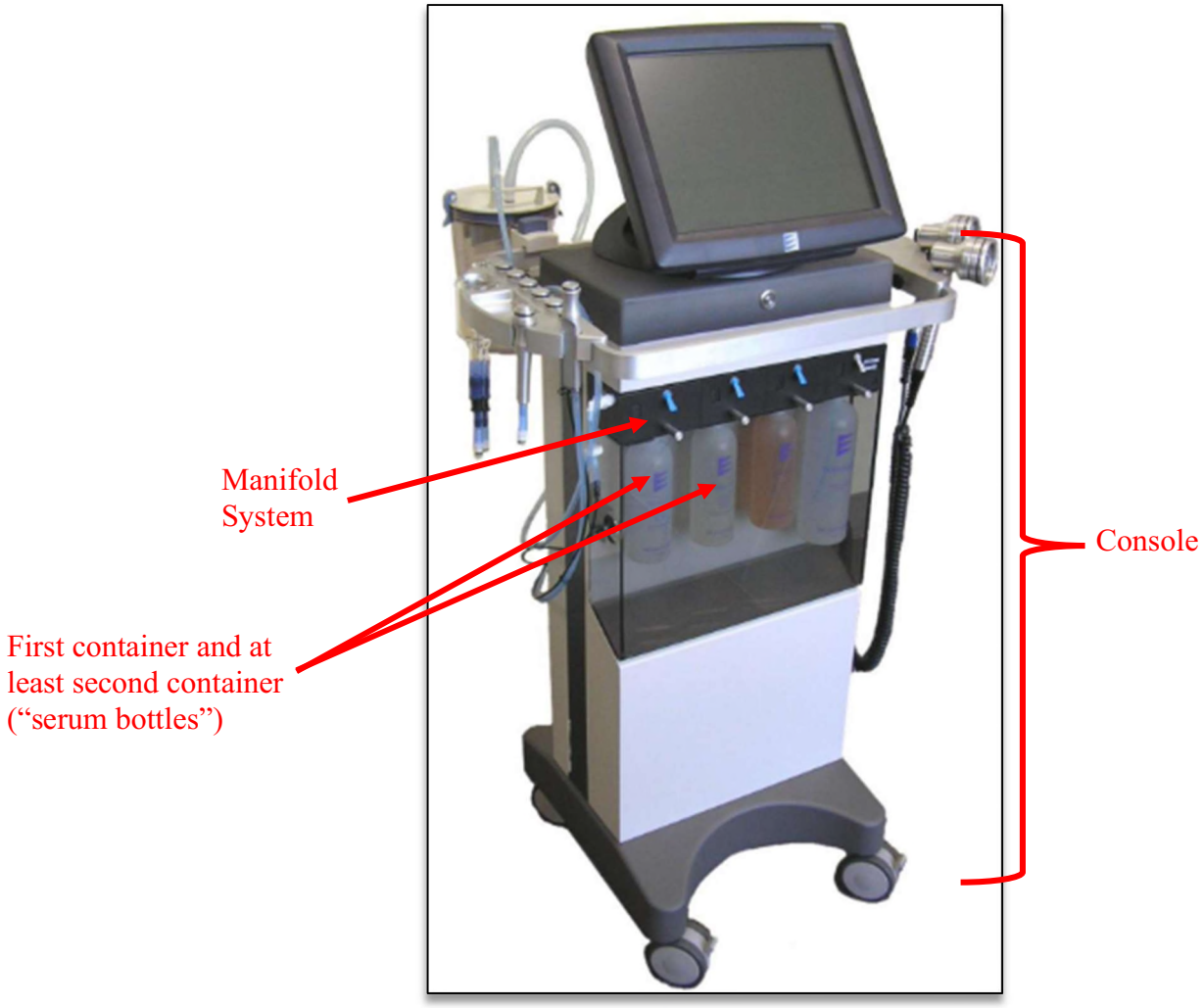

Ex. 2125 (Tower Owner's Manual). *See also id.* at 13 (Tower Owner's Manual identifying "manifold").

34. In addition, during my inspection of the Elite and Allegro devices, and review of photos and videos from the Tower, I confirmed that each system includes an internal block in the console of the device. Annotated photographs below shows the location of the manifold system in the console:

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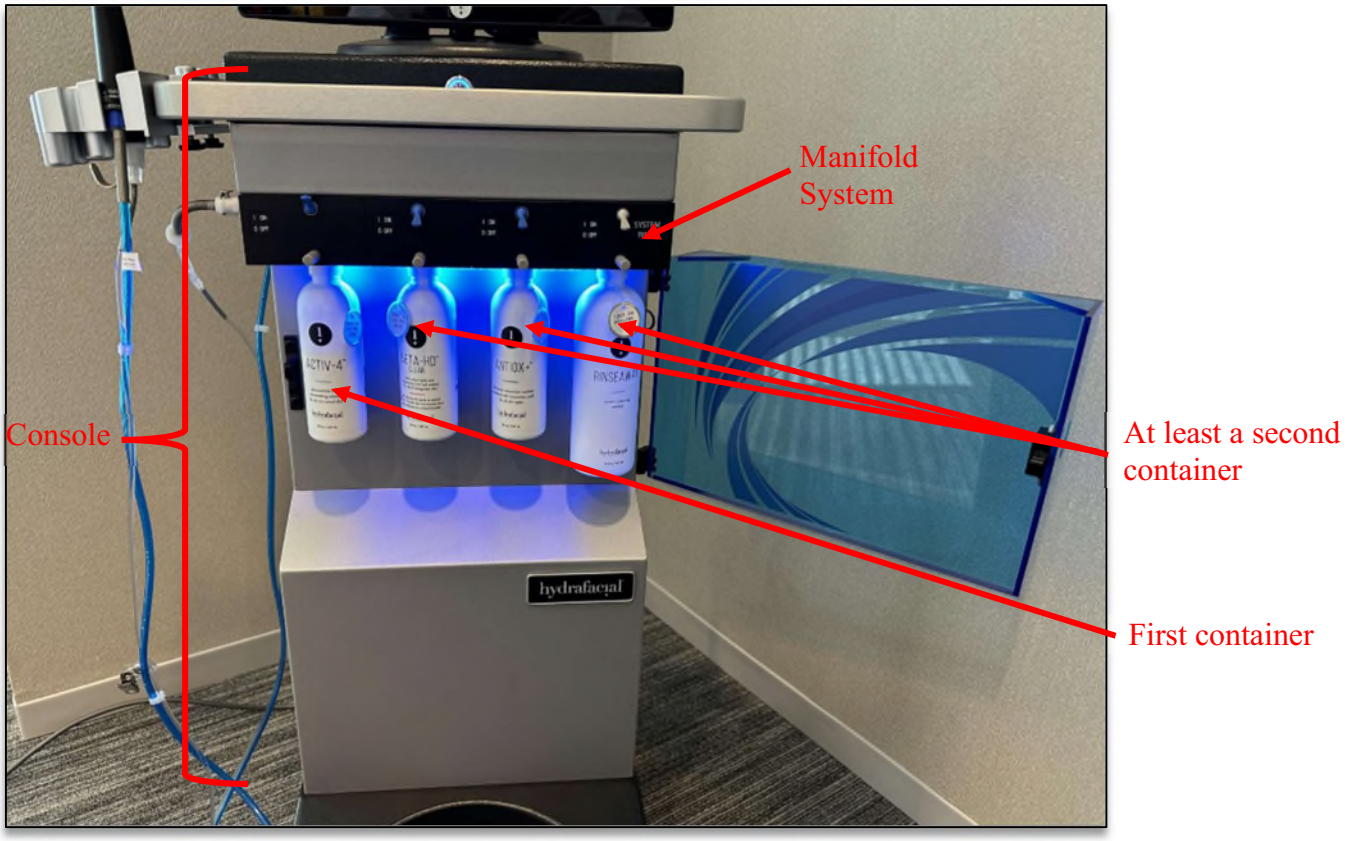
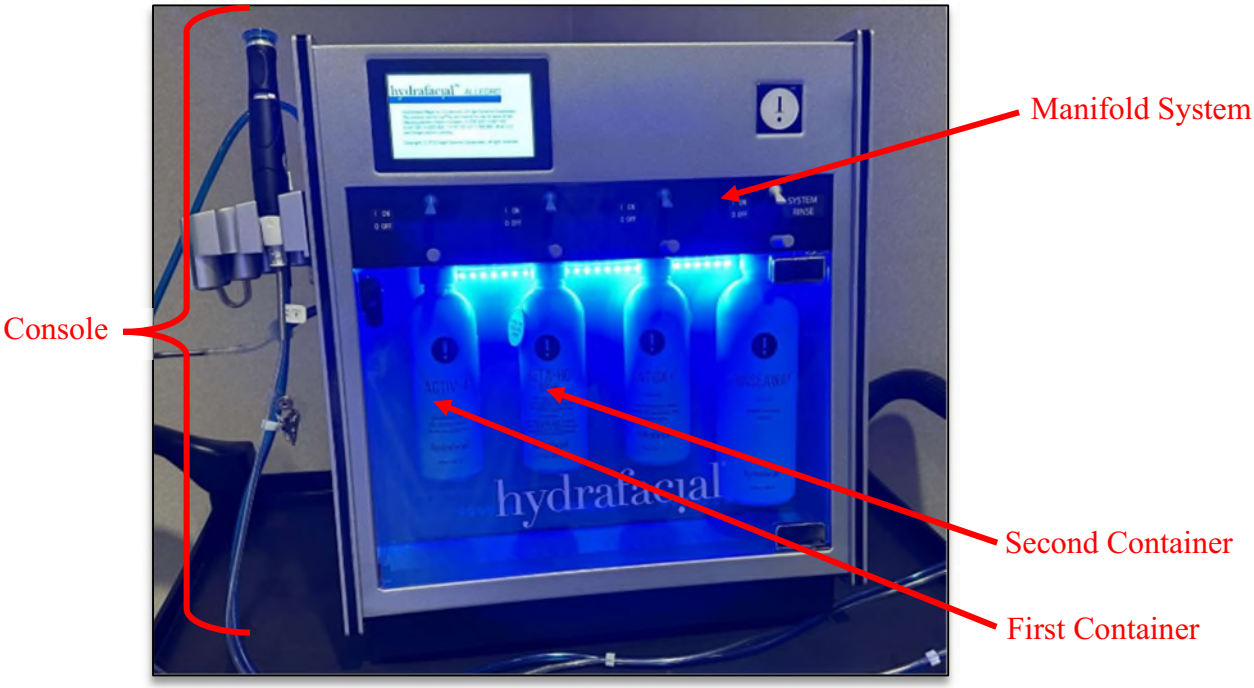


Ex. 2116 (Elite).



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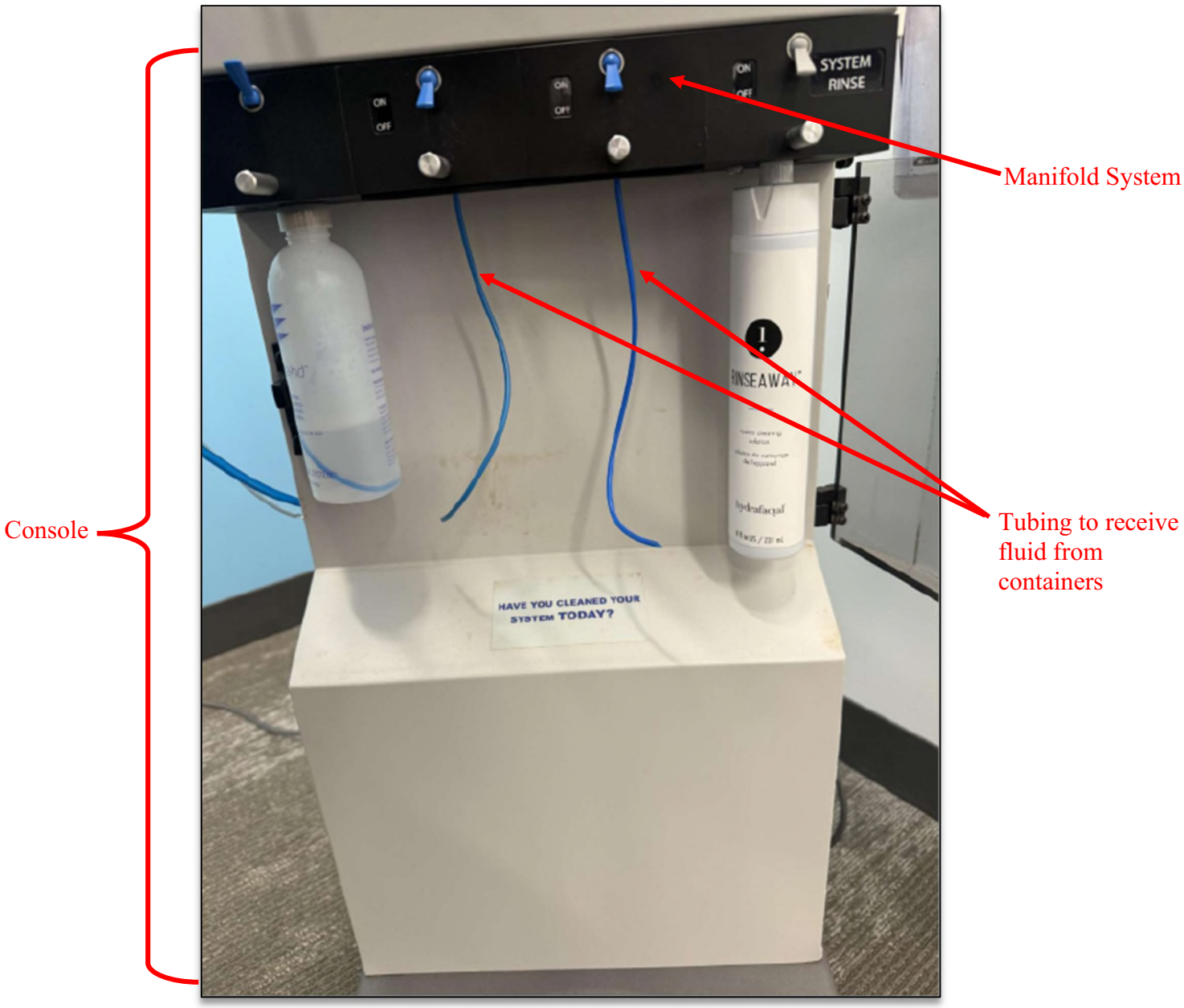
Ex. 2117 (Allegro).



Ex. 2118 (Tower).

35. As part of my inspection of the Elite and Allegro, I removed the manifold system from the console, and I observed the manifold system located in the console. I made similar observations from the images and videos of the Tower

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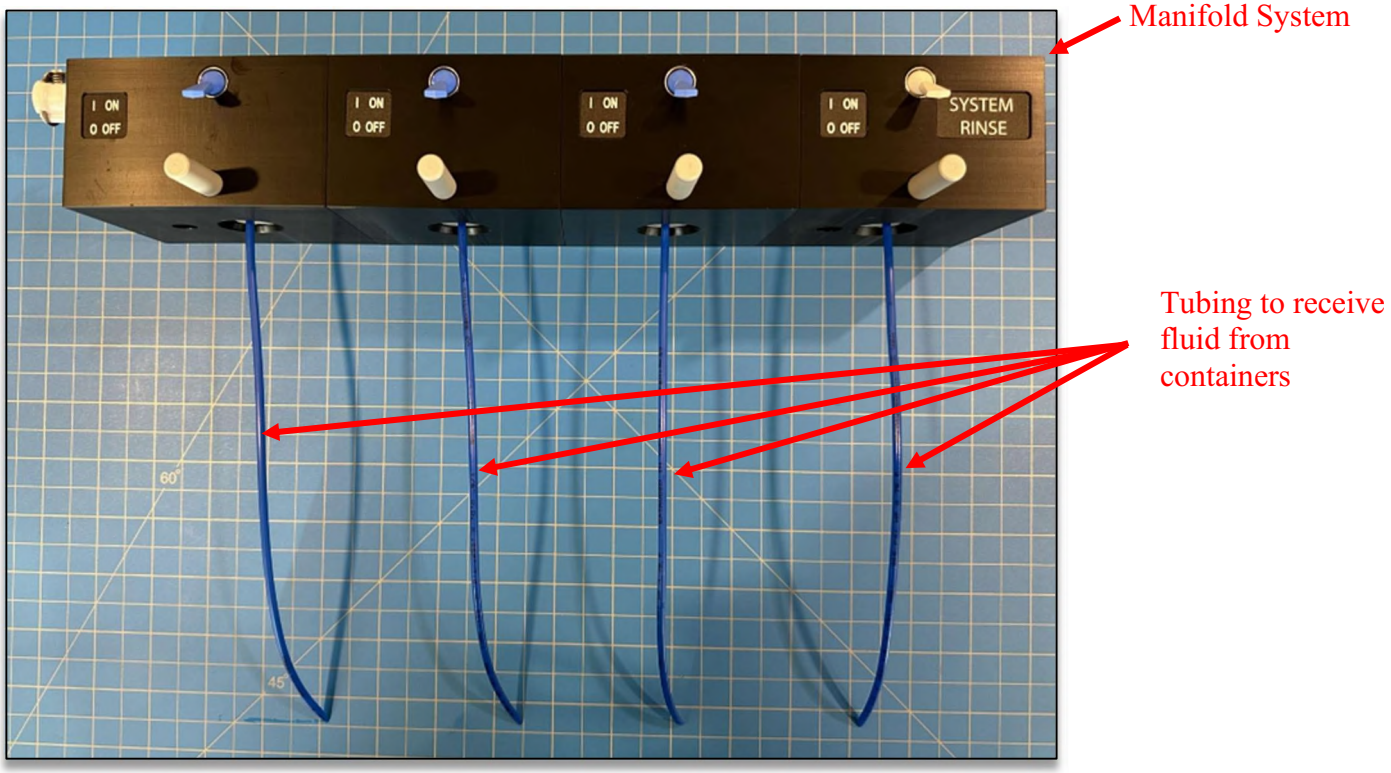
which I reviewed. The below photos accurately depict the manifold system of the

Elite, Allegro, and Tower, respectively when removed from the console:



Ex. 2094 (Elite).

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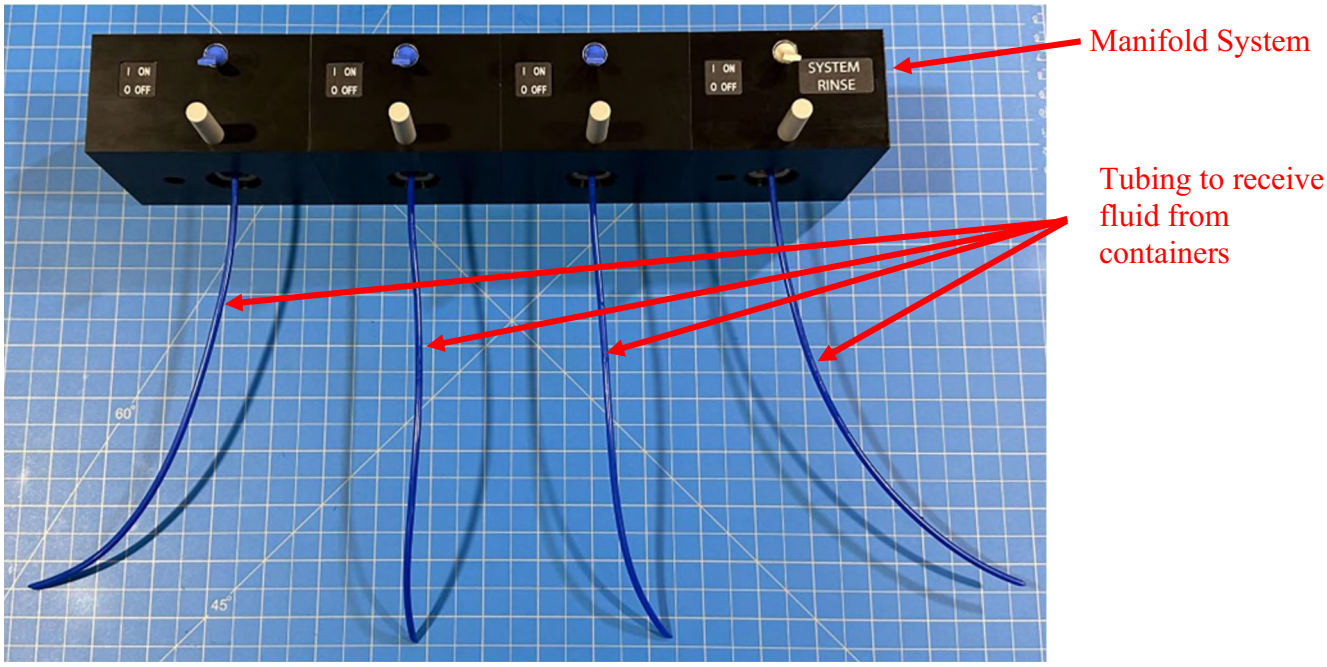

Ex. 2095 (Allegro).

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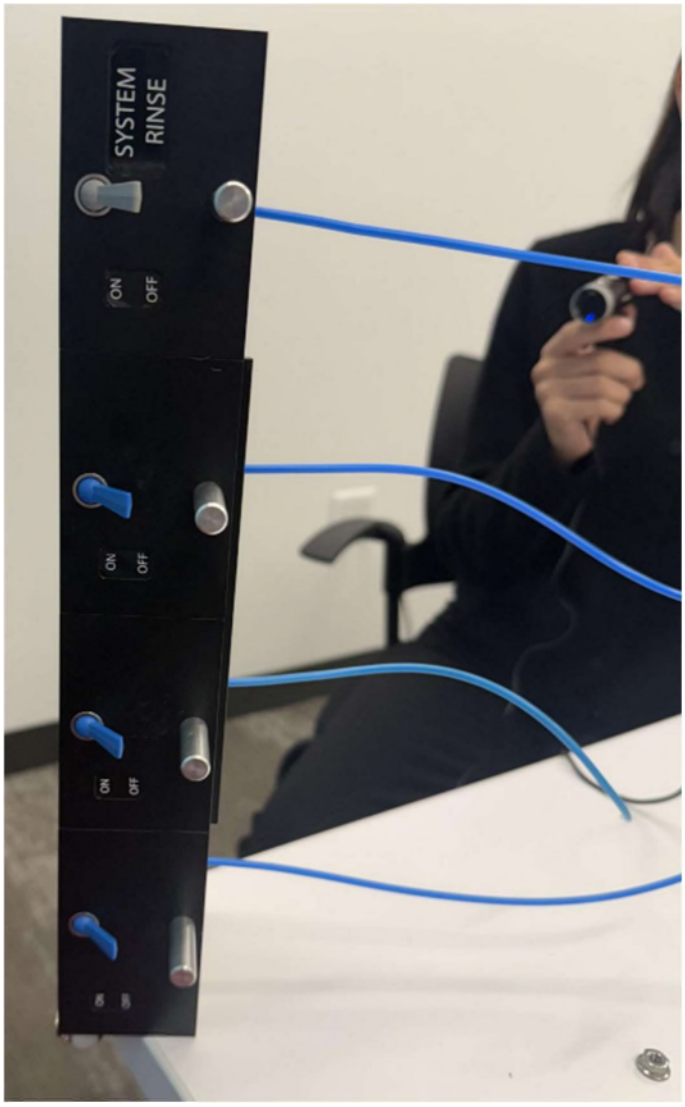

Ex. 2092 (Tower).

36. The technical specifications for the Elite reaffirms the existence of a manifold system in the console. As shown in the annotated technical drawing below, the HydraFacial Elite has a manifold system:

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Ex. 2099 at 265 (Elite).

37. Accordingly this limitation is satisfied by each of the Elite, Allegro, and Tower.

ii. 1[a][ii]: "wherein each of the first container and the at least second container is configured to contain a treatment material"

38. In my opinion, each of the first container and the at least second container of each of the Elite, Allegro, and Tower is configured to contain a treatment material.

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39. As explained in detail above, the user is instructed to connect a first container and at least one additional container to the console. *See* limitation 1[a][i]. In addition, as shown in the images below, each container which connects to the console for the Elite, Allegro, and Tower contains a different treatment material.

Ex. 2031 at 13 (Elite User Guide).

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Skin Solution Bottles

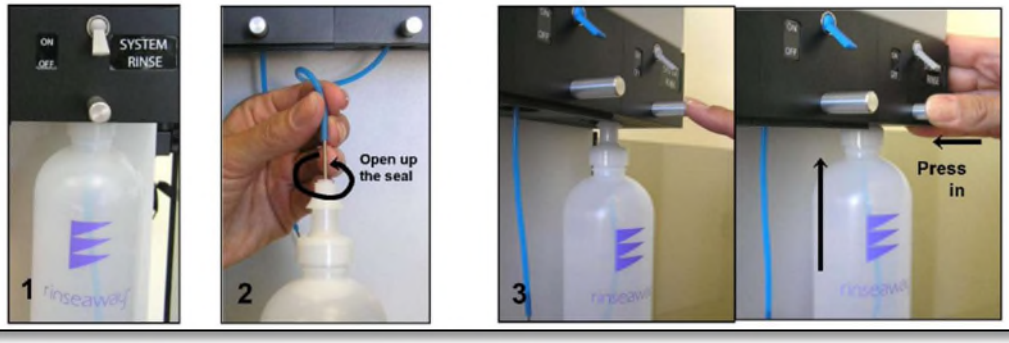
1. Open the front door. Remove the cap of the skin solution bottle and use the puncture tool to pierce the seal inside the bottle.
2. Press and hold each manifold button as you insert each bottle into the manifold, and then release the button.
   Note: The Rinseaway™ System Cleaning Solution should be installed in the manifold with the gray toggle switch labeled "SYSTEM RINSE".

3. The toggle switches control which skin solution bottle is being used. When a switch is in the ON position, fluid will be drawn from that bottle. When switched to the OFF position, no fluid will be drawn from the corresponding bottle.
   Note: Always keep the "SYSTEM RINSE" toggle switch (gray) off while performing procedures.

Ex. 2032 at 11 (Allegro IFU).

6) INSTALL SERUM BOTTLES

1. Please note that the Rinseaway™ System Cleaning Solution should be installed in the manifold with the ***gray*** toggle switch labeled "SYSTEM RINSE".
2. Open the front door. Remove the small top cap of the serum bottle and use the puncture pickup tube to pierce the seal inside the bottle. ***Enlarge the hole with the metal end.***
3. Press & hold each manifold button as you insert each bottle into the manifold, and then release the button.



Ex. 2125 at 13 (Tower Owner's Manual).

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40. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices this limitation.

iii. 1[a][iii]: "the manifold system being positioned in or on a console"

41. In my opinion, each of the Elite, Allegro, and Tower includes a manifold system that is positioned in or on a console.

42. For the same reason set forth in limitation 1[a][i], each of the Elite, Allegro, and Tower has a manifold system.

43. I have inspected the Elite and Allegro and reviewed photos and videos of the Tower and confirmed that each device includes a manifold system positioned in the console of the device. Annotated photographs below show the location of the manifold system for each device:

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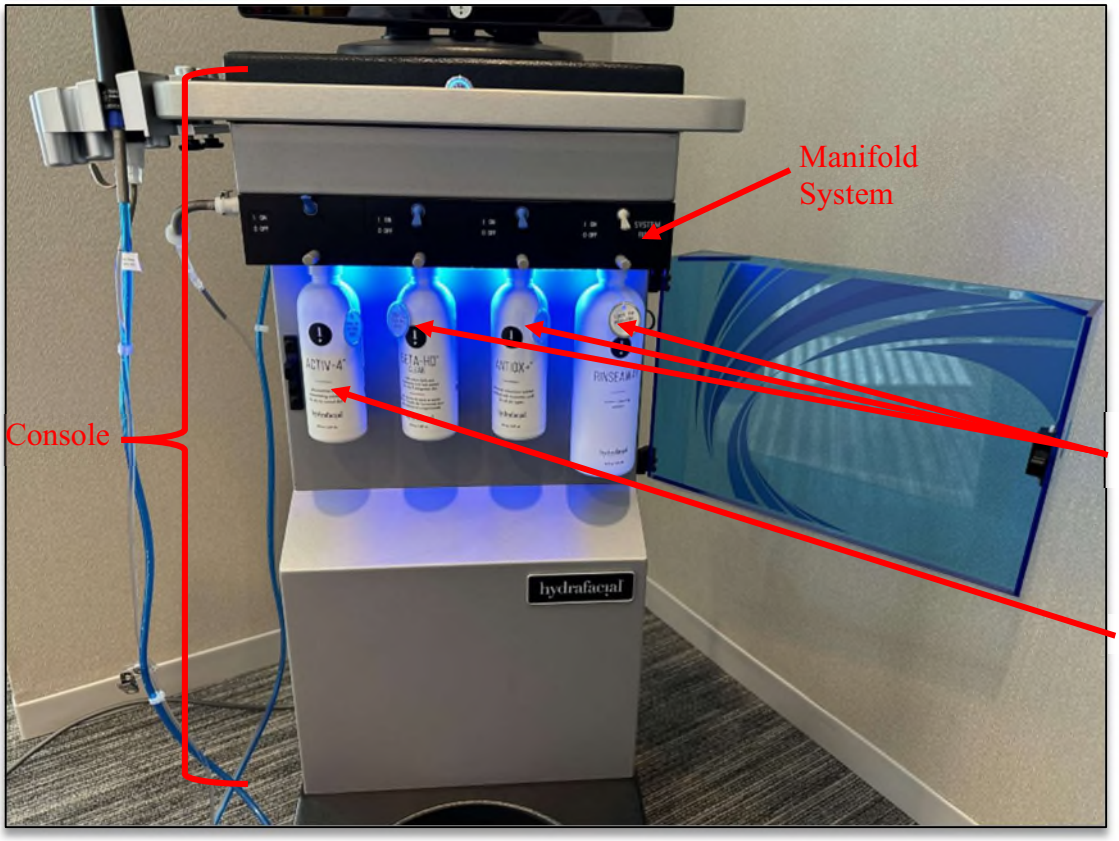
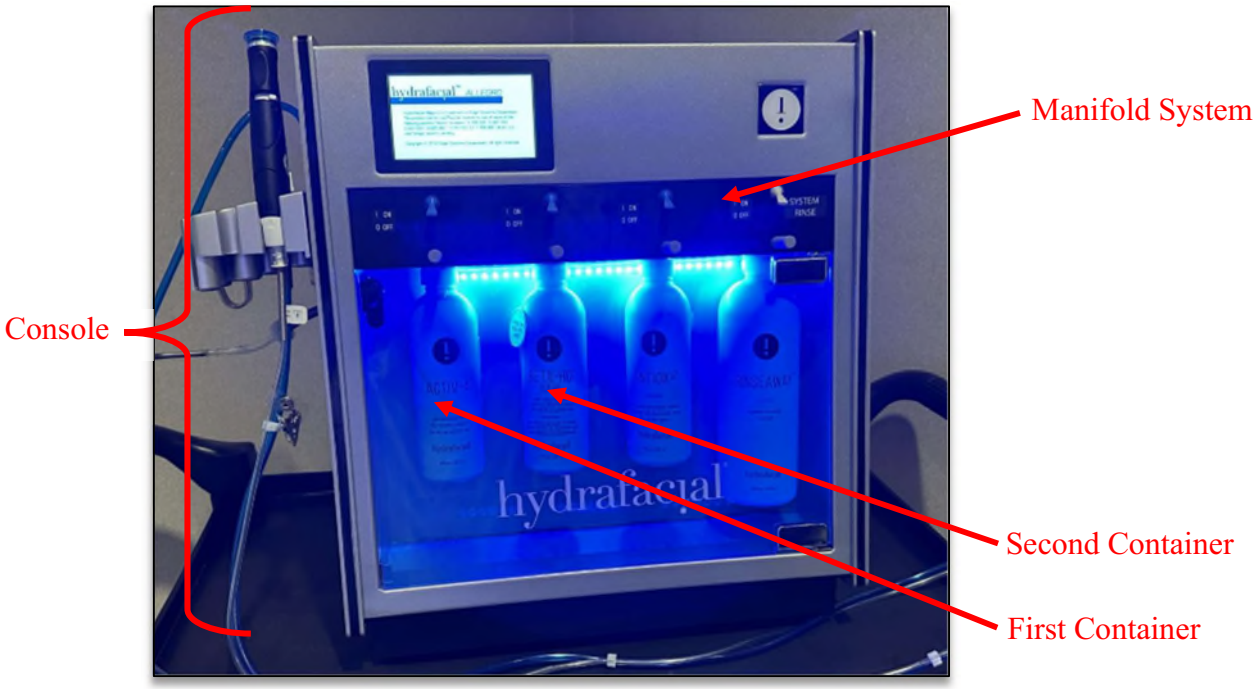


Ex. 2116 (Elite).



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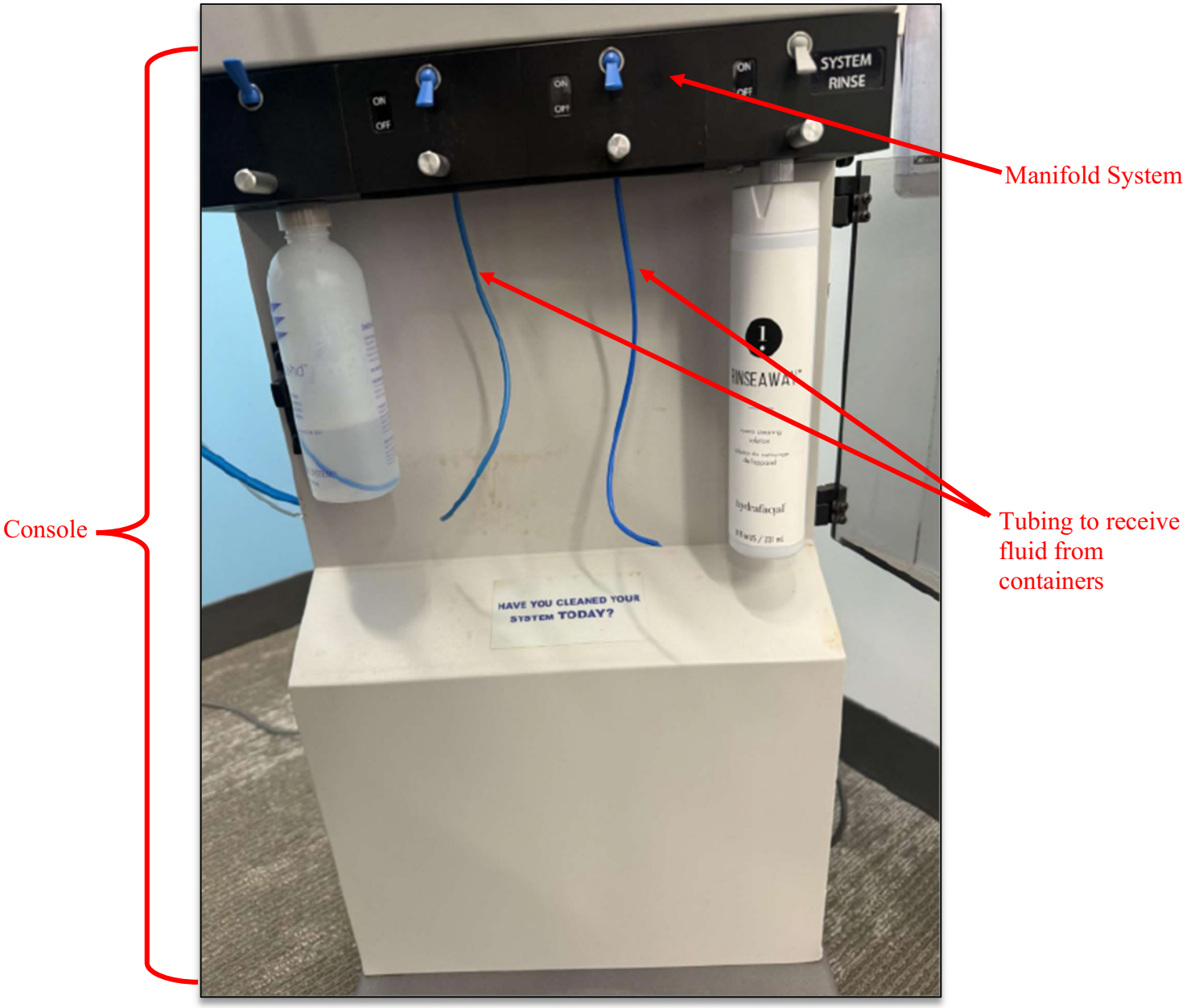
Ex. 2117 (Allegro).



Ex. 2118 (Tower).

44. The Elite IFU, Allegro IFU, and Tower Owner's Manual each contains an illustration of the console identifying the location of the manifold system located within the console for each of the Elite, Allegro, and Tower:

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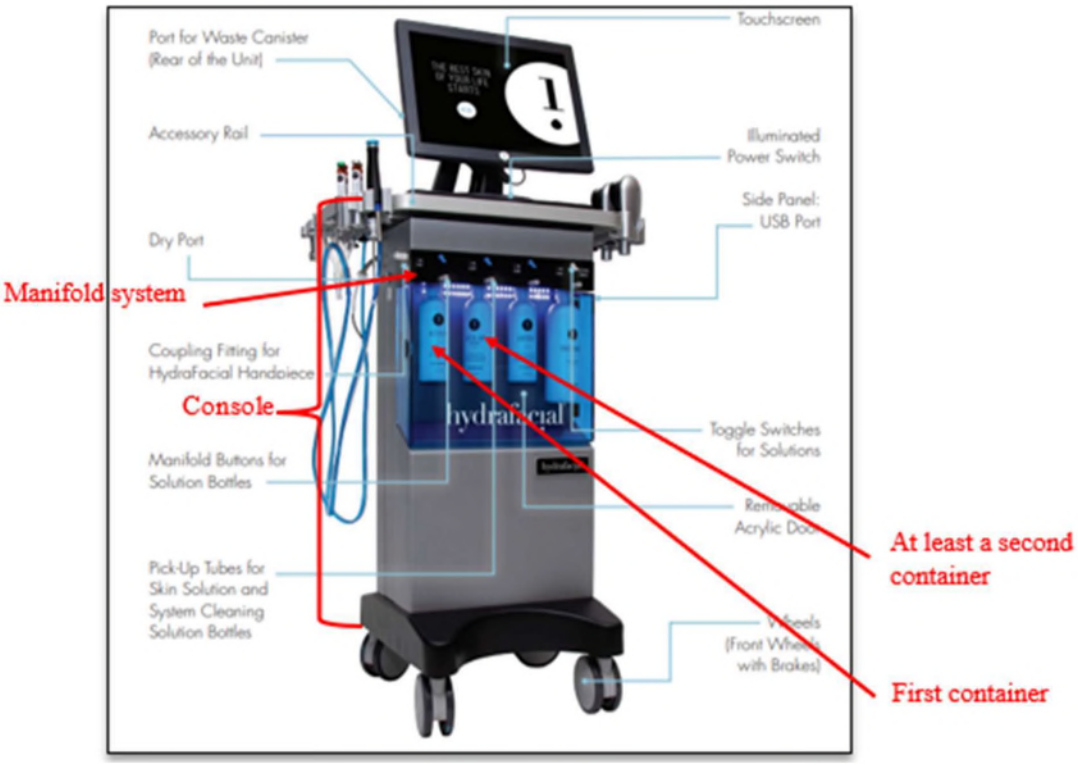
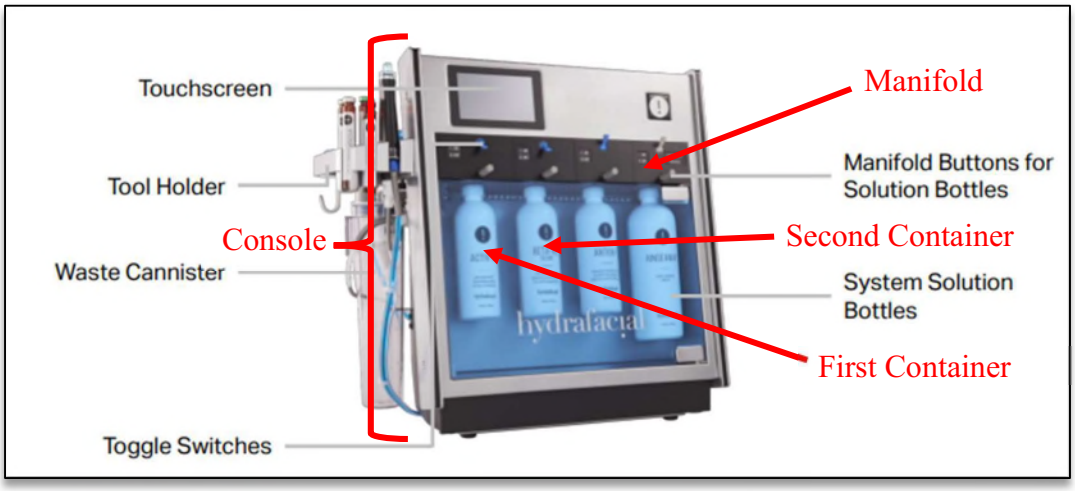


Ex. 2031 at 10 (Elite IFU).



Ex. 2032 at 8 (Allegro IFU).

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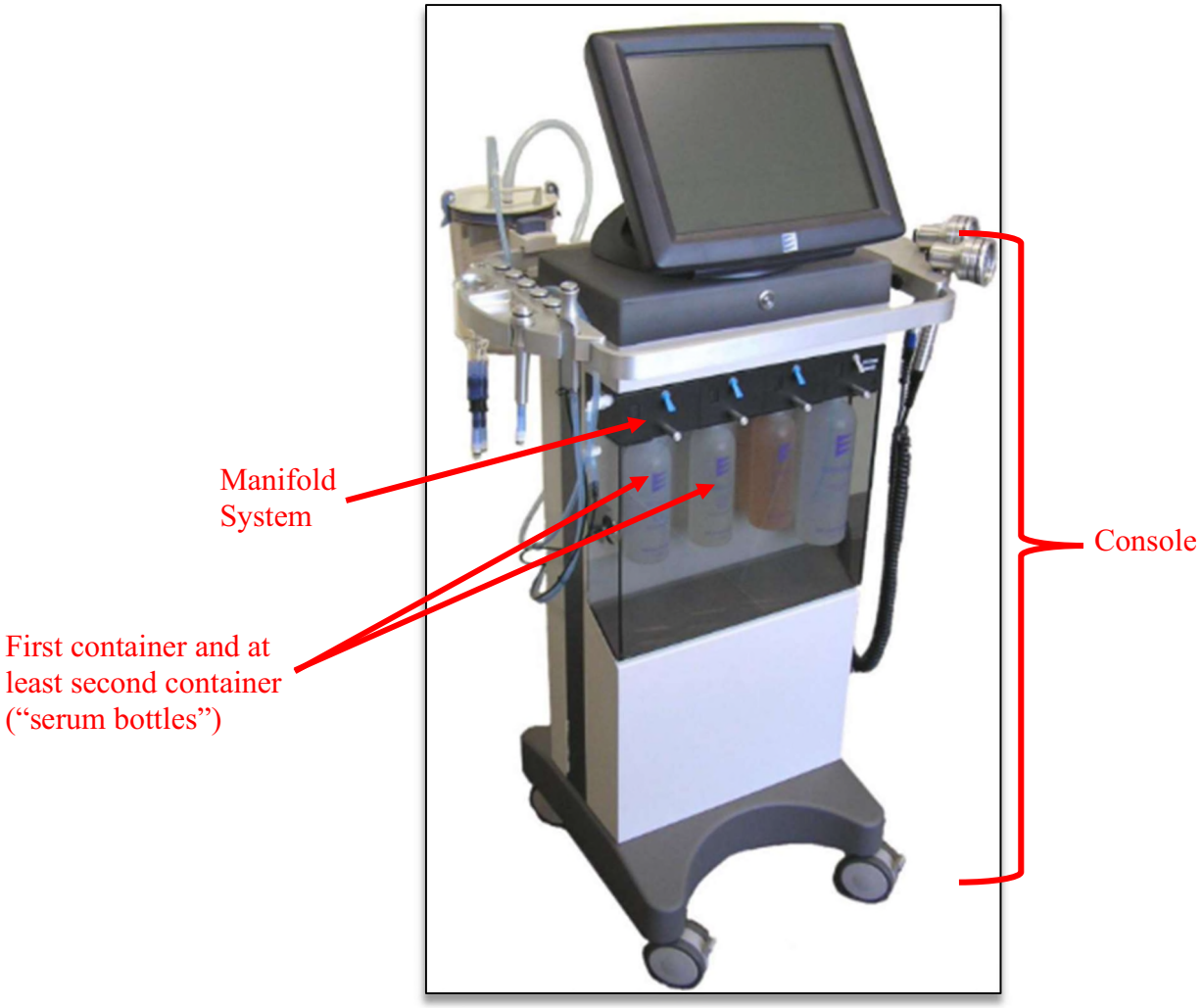

Ex. 2125 (Tower Owner's Manual). *See also id.* at 13 (Tower Owner's Manual identifying "manifold").

45. The technical specifications for each of the Elite and Tower reaffirm the existence of a manifold system in the console. As shown in the annotated technical drawing below, the HydraFacial Elite has a manifold system:

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Ex. 2099 at 265 (Elite).

46. Accordingly, each of the Elite, Allegro, and Tower practices this limitation.

c. 1[b]: "a supply conduit placing the manifold system in fluid communication with a handpiece assembly"

47. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a supply conduit placing the manifold system in fluid communication with a handpiece assembly."

48. During my inspection of each of the Syndeo, Elite, Allegro, and Tower, I observed that each included a handpiece assembly, as shown in the images below.

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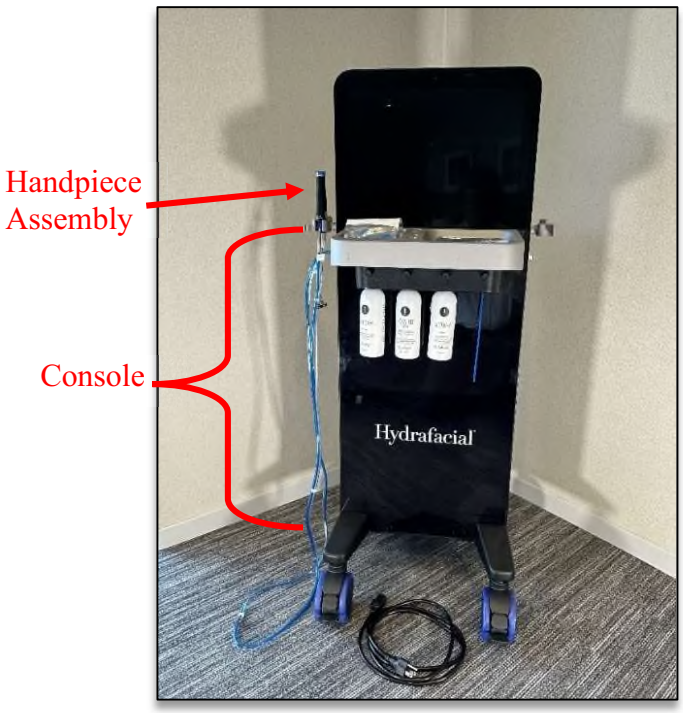

Ex. 2107 (Syndeo).

Ex. 2111 (Syndeo).

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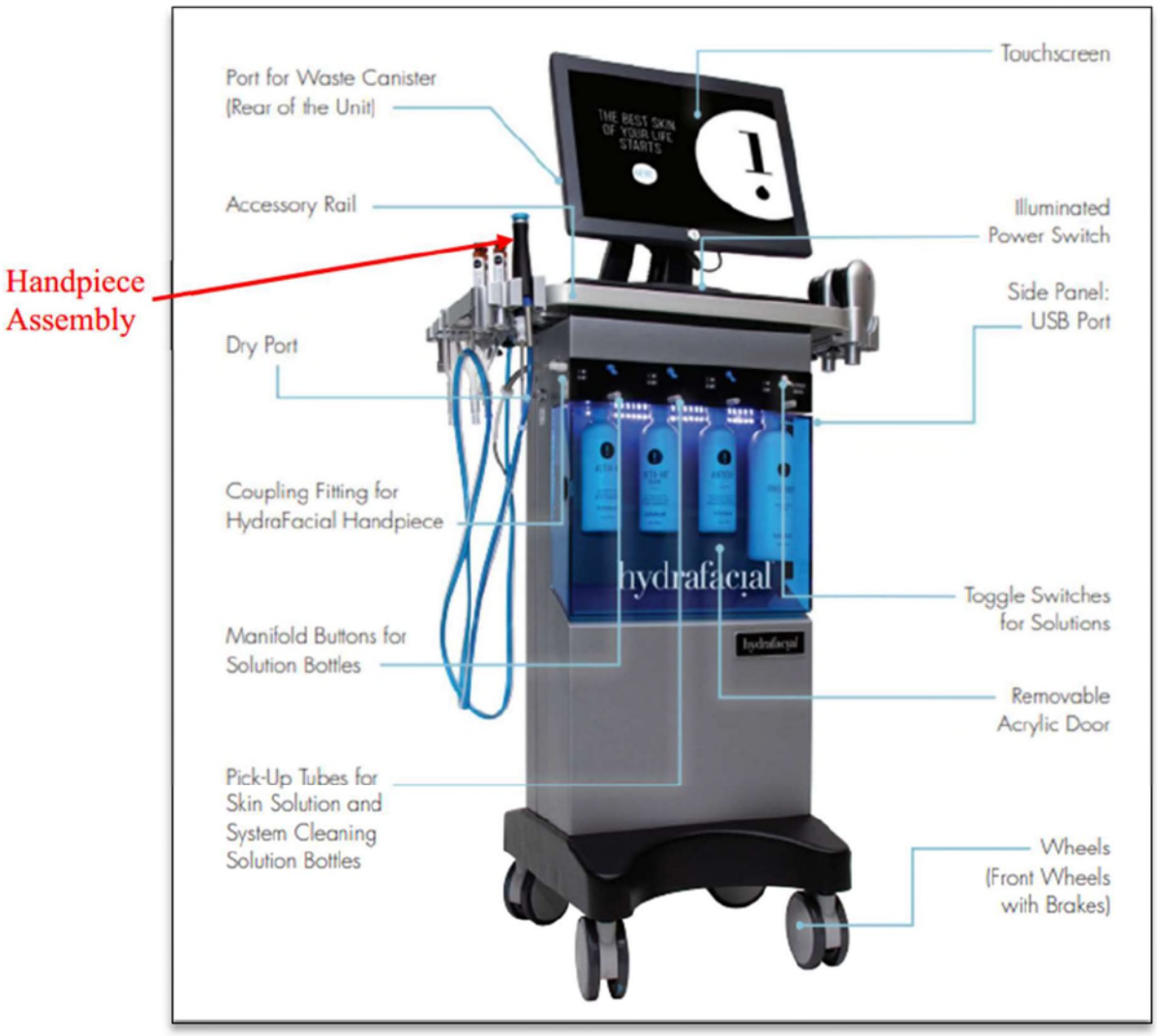
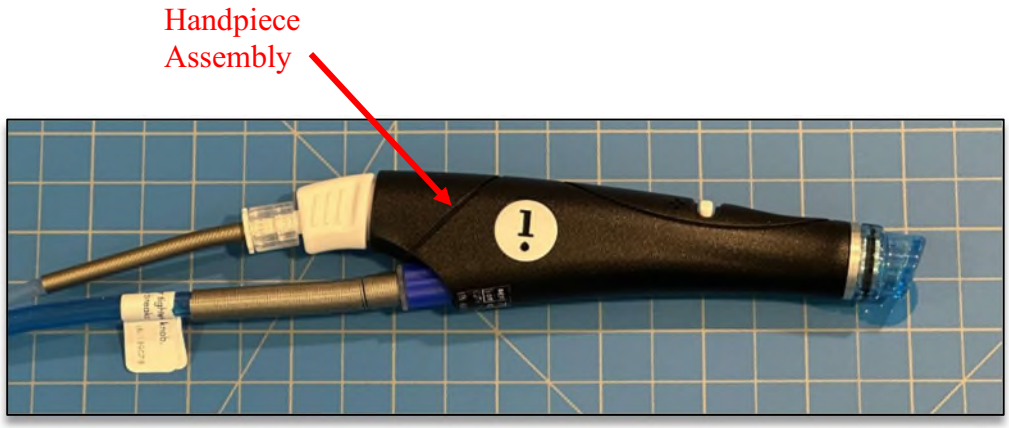


Ex. 2031 at 10 (Elite).



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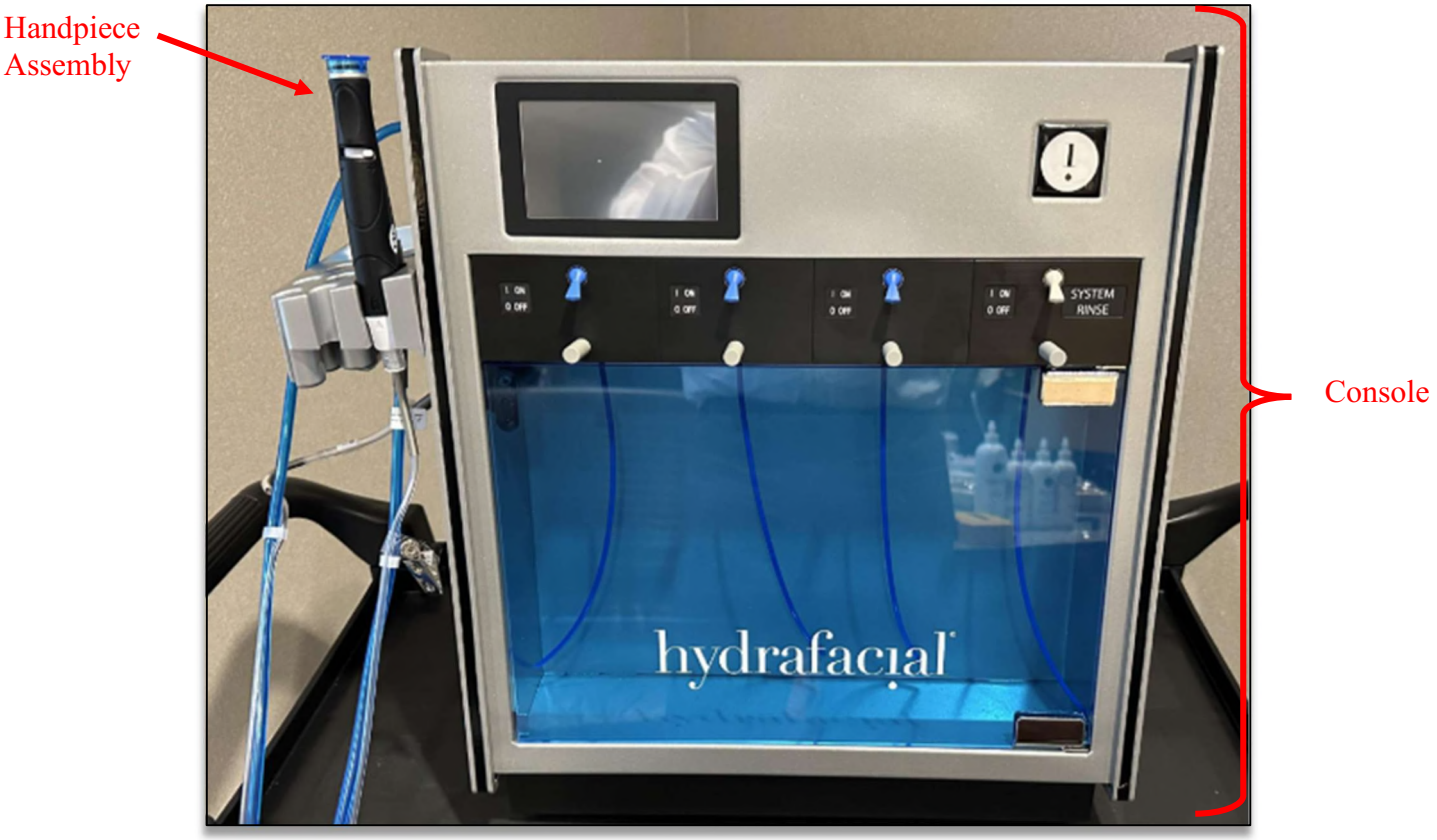
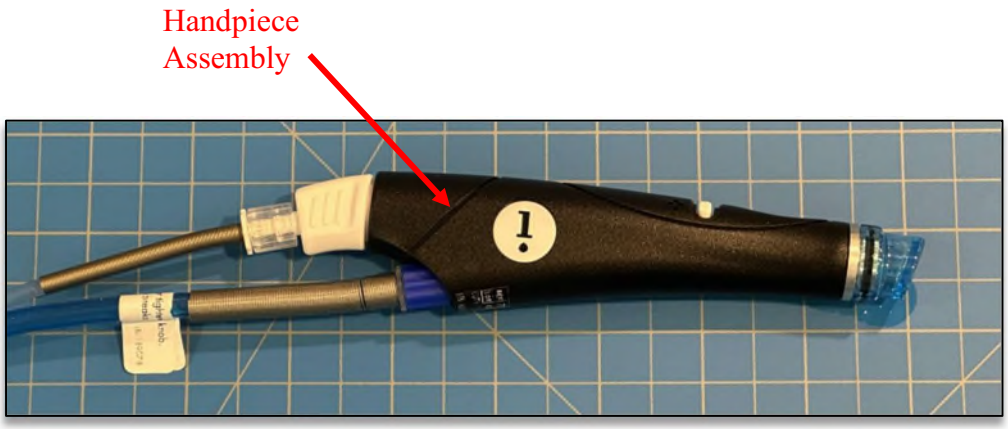
Ex. 2111 (Elite).



Ex. 2077 (Allegro).



Ex. 2111 (Allegro).

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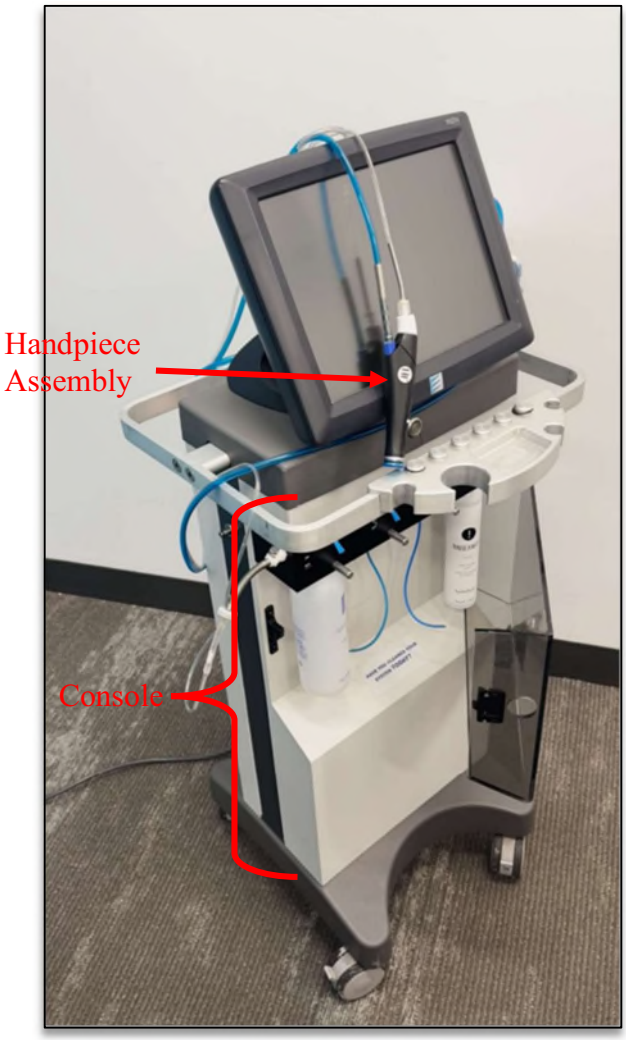

Ex. 2151 at 2 (Tower).

49. In addition, the Syndeo User Manual the Elite IFU, Allegro IFU, and Tower Design File History confirm that each of the four devices includes a handpiece assembly with a working end having a skin contact surface.

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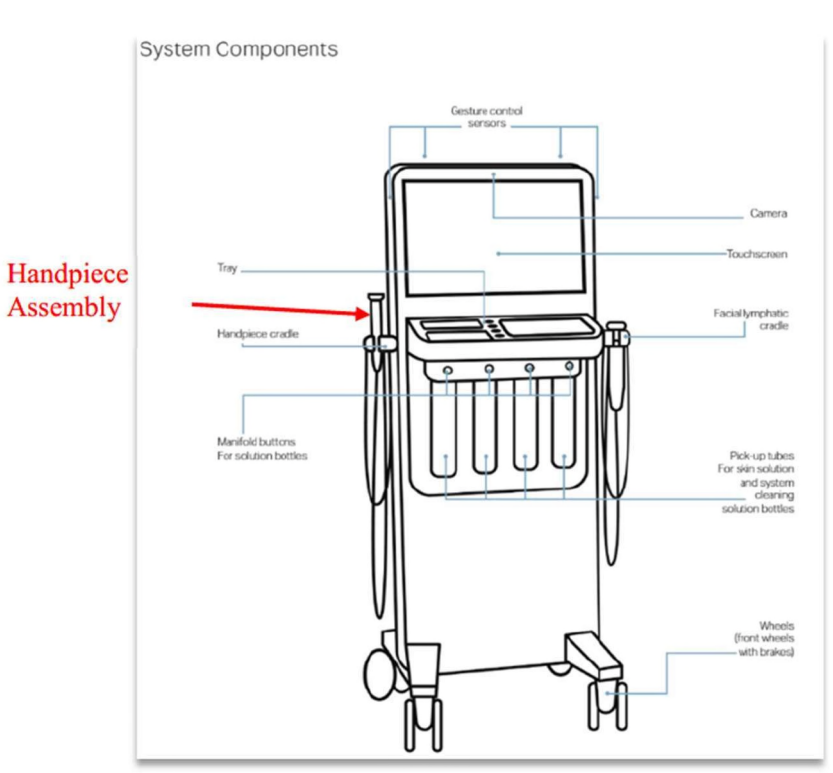

Ex. 2030 at 10 (Syndeo IFU). The Syndeo IFU explains that the handpiece is used to contact the skin tissue of a subject, instructing the user to "[p]lace a tip on the handpiece," and "[p]lace tip against skin to occlude and dab skin solution onto skin." *Id.* at 19.

50. During my inspection of each of the Syndeo, Elite, Allegro, and Tower, I observed that each has "a supply conduit placing the manifold system in fluid communication with a handpiece assembly."

51. My inspection of the Syndeo confirmed that this limitation is satisfied. As shown in the below photos, the supply conduit connects to the manifold system and extends from the manifold system to a coupling on the console. From the

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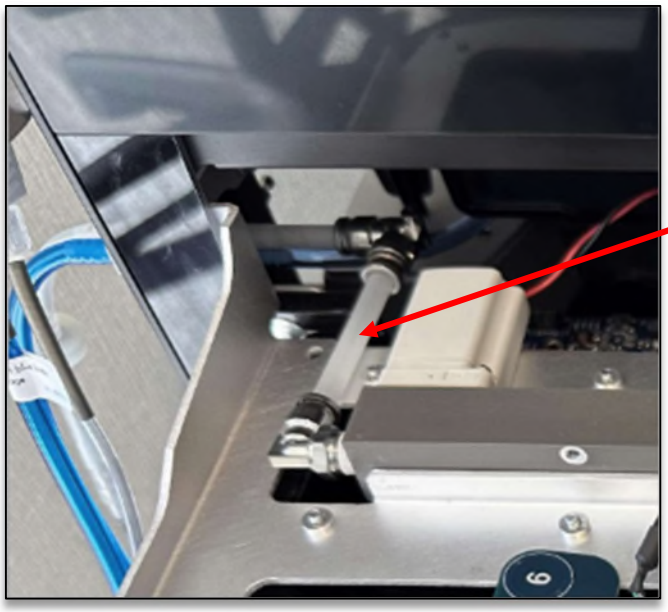
coupling, the supply conduit extends from the console to the handpiece assembly. As a result, the supply conduit places the manifold system in a state that makes the passage of fluid possible from the containers to the handpiece assembly.

Ex. 2085 (Syndeo).



Ex. 2085 (Syndeo).

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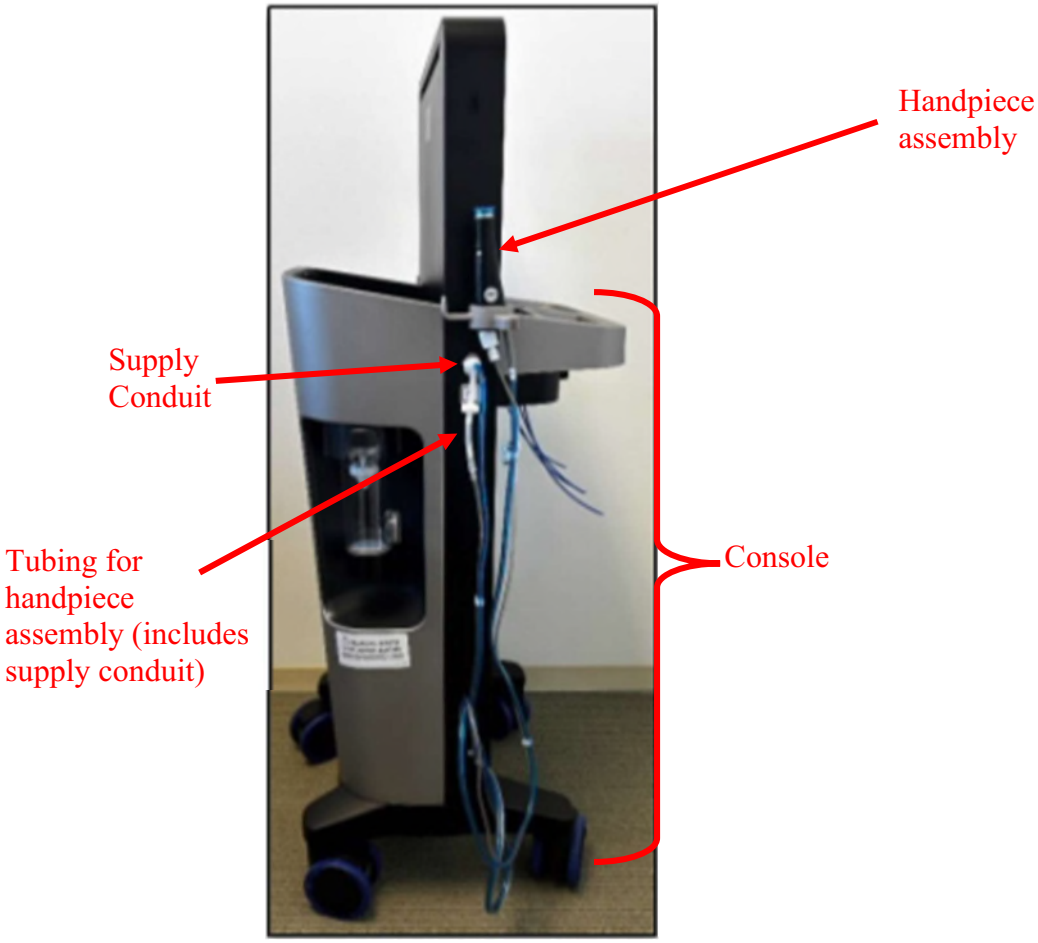

Ex. 2127 at 4 (Syndeo).

52. The fluid schematic for the Syndeo shows that the supply conduit connects the manifold system to the handpiece assembly and places the manifold system in a state that makes the passage of fluid possible from the containers to the handpiece assembly.

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Ex. 2114 (Syndeo).

53. The Syndeo IFU describes connecting a "Supply Line" between the handpiece assembly and the console, where the "Supply Line" serves as the supply conduit through which the manifold system is in fluid communication with the handpiece assembly.

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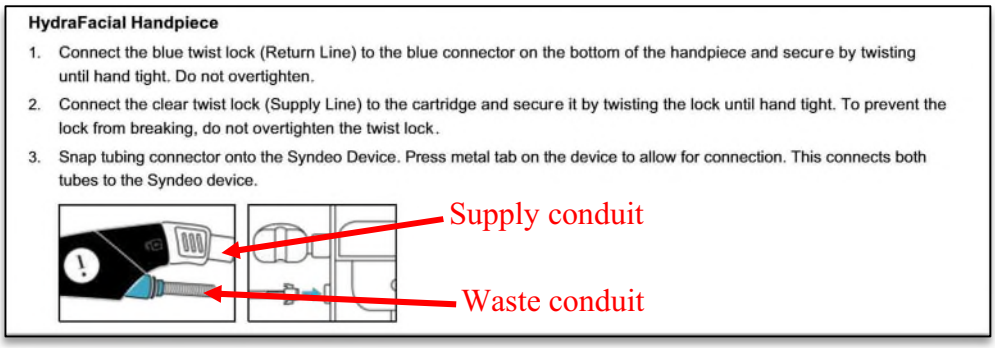

Ex. 2030 at 12 (Syndeo IFU).

54. My inspection of the Elite confirmed that this limitation is satisfied. As shown in the below photos, the supply conduit connects to the manifold system via a coupling on the console. From the coupling, the supply conduit extends from the console to the handpiece assembly. As a result, the supply conduit places the manifold system in a state that makes the passage of fluid possible from the containers to the handpiece assembly.

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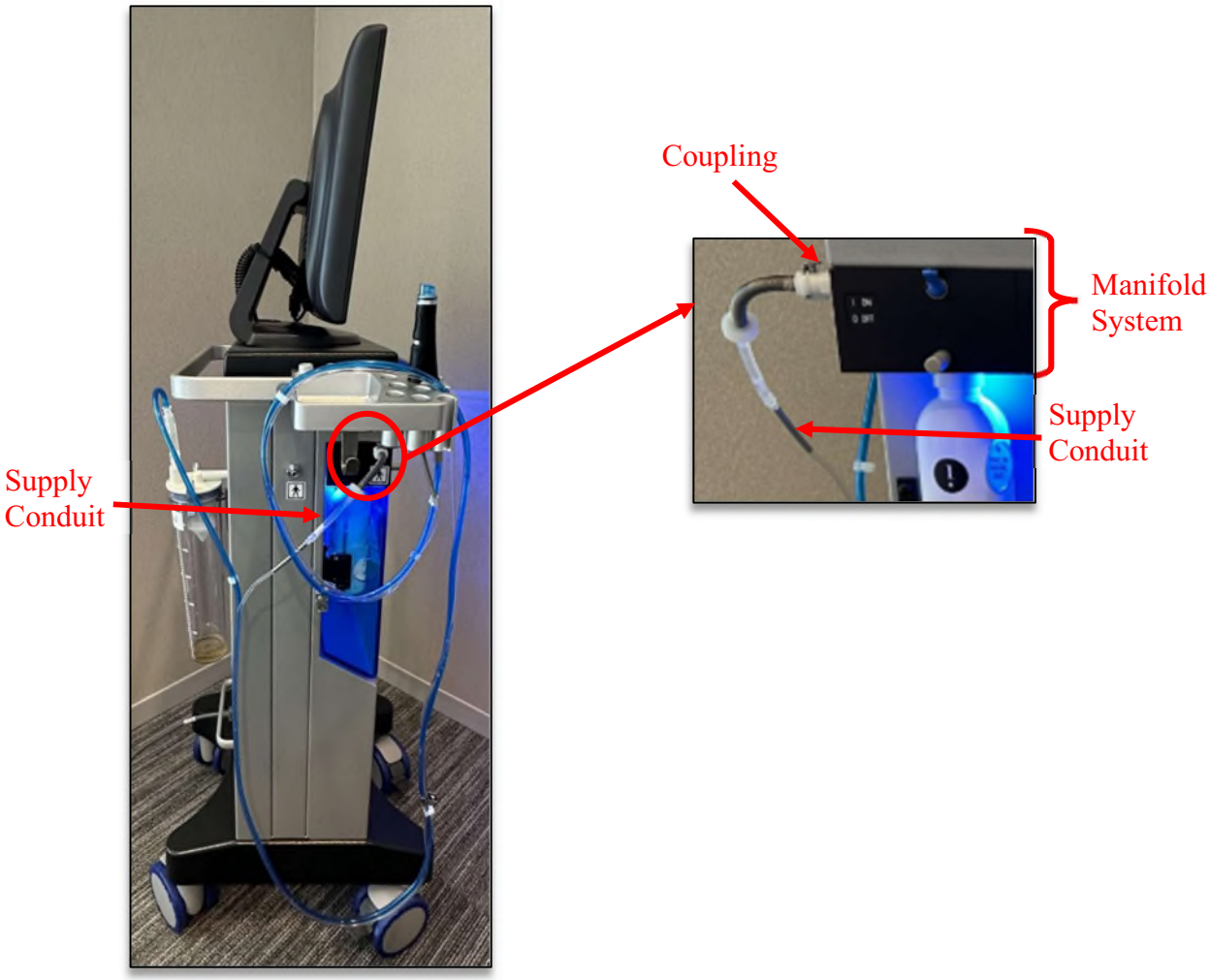

Ex. 2098 (Elite); 2116 (Elite).

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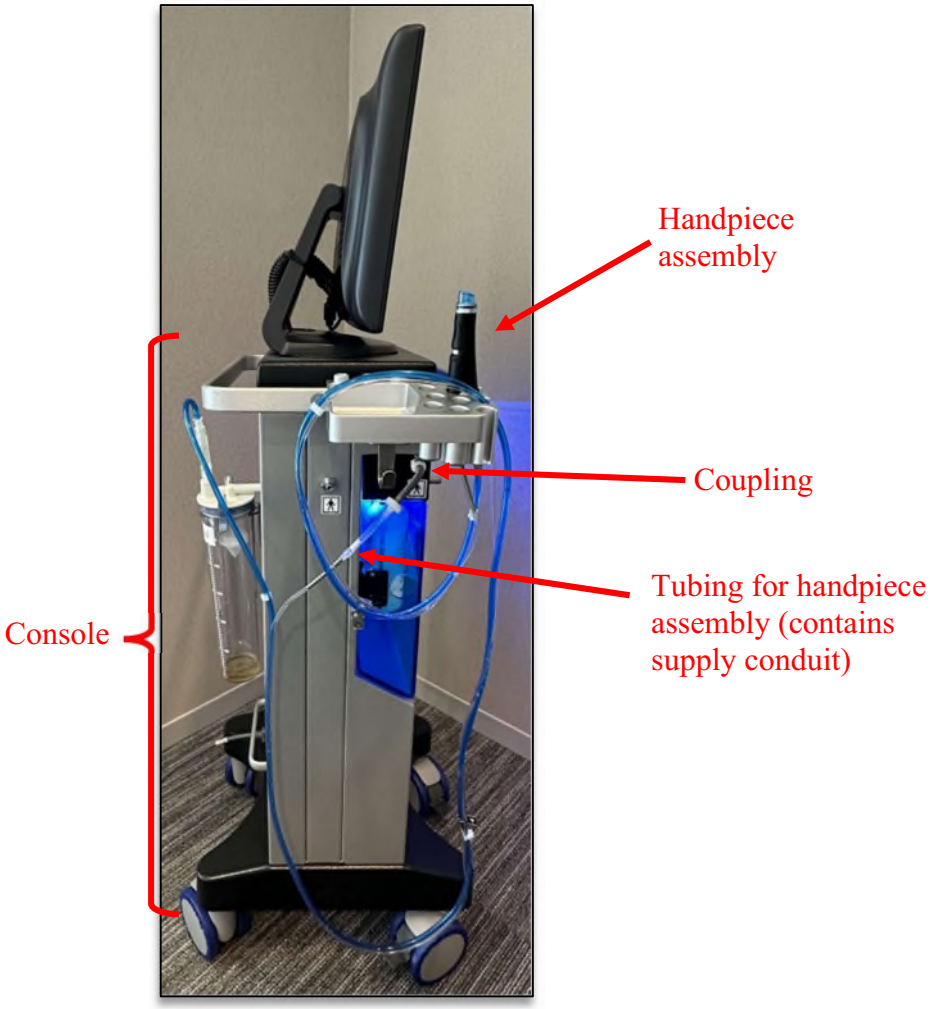
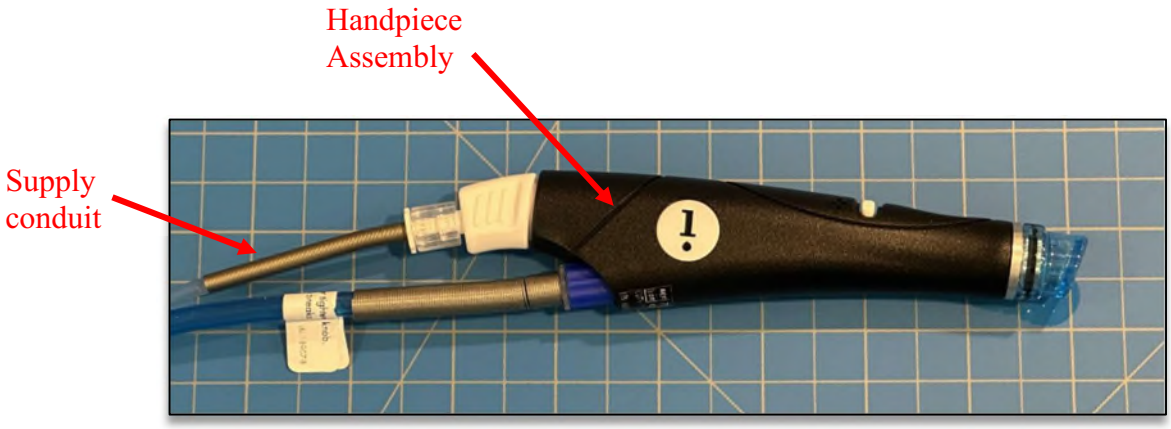


Ex. 2098 (Elite).



Ex. 2111 (Elite).

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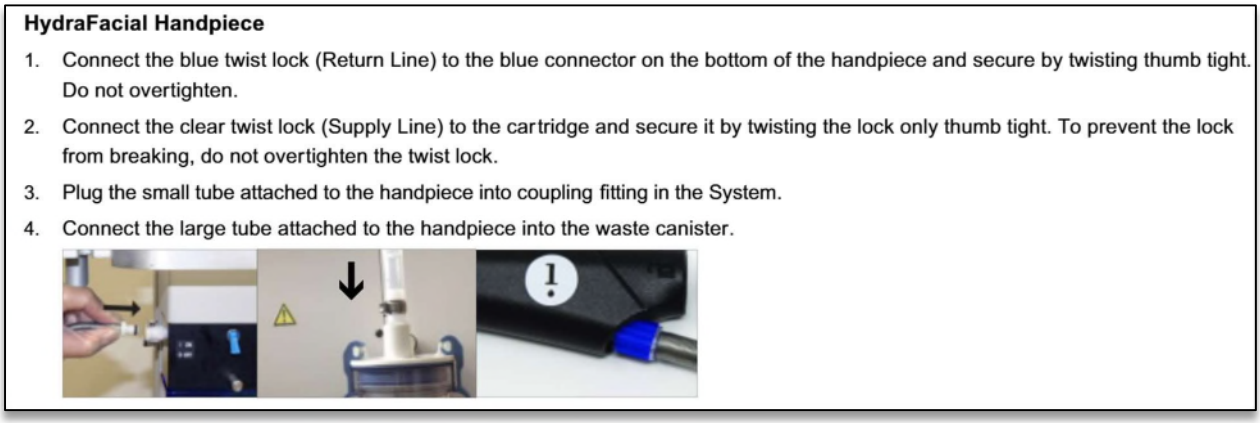
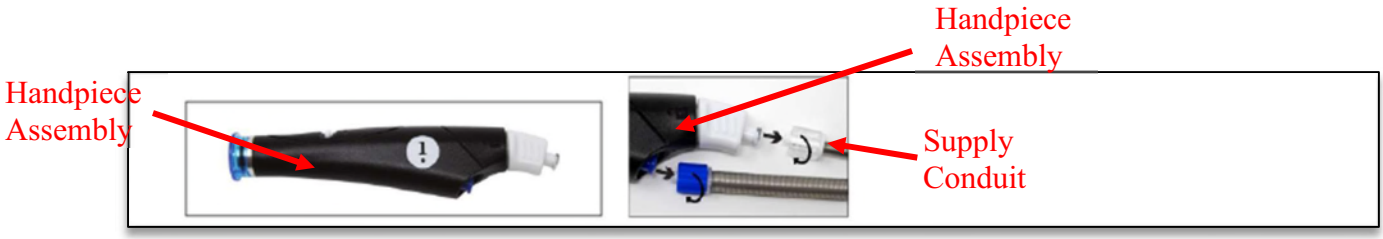
55. The Elite IFU describes connecting a "Supply Line" between the handpiece assembly and the console, where the "Supply Line" serves as the supply conduit through which the manifold system is in fluid communication with the handpiece assembly.



HydraFacial Handpiece

1. Connect the blue twist lock (Return Line) to the blue connector on the bottom of the handpiece and secure by twisting thumb tight. Do not overtighten.
2. Connect the clear twist lock (Supply Line) to the cartridge and secure it by twisting the lock only thumb tight. To prevent the lock from breaking, do not overtighten the twist lock.
3. Plug the small tube attached to the handpiece into coupling fitting in the System.
4. Connect the large tube attached to the handpiece into the waste canister.

Ex. 2031 at 12 (Elite IFU).



Ex. 2031 at 18.

56. My inspection of the Allegro confirmed that this limitation is satisfied. As shown in the below photos, the supply conduit connects to the manifold system and extends from the manifold system to a coupling on the console. From the coupling, the supply conduit extends from the console to the handpiece assembly.

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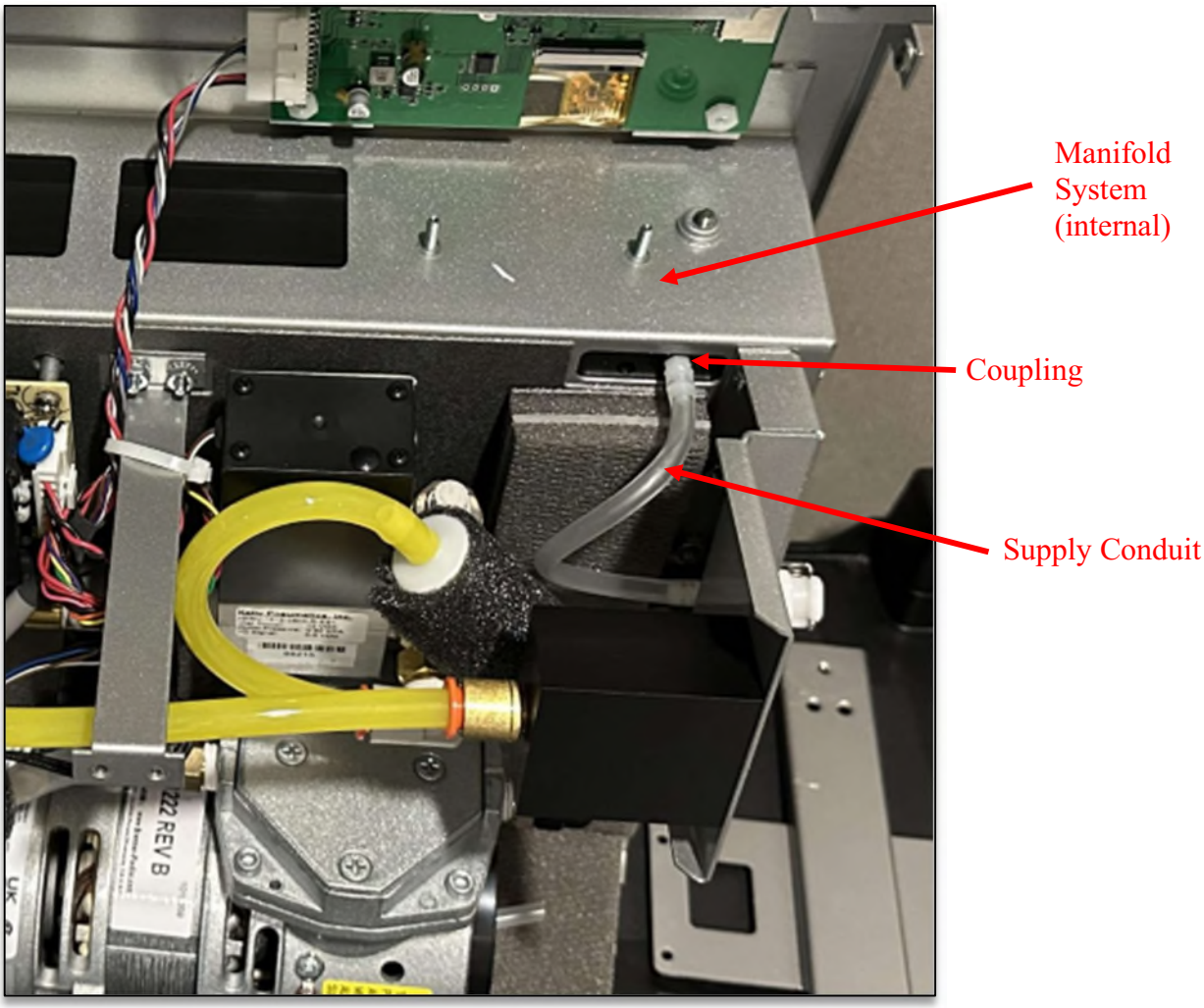
As a result, the supply conduit places the manifold system in a state that makes the passage of fluid possible from the containers to the handpiece assembly.



Ex. 2097 (Allegro).

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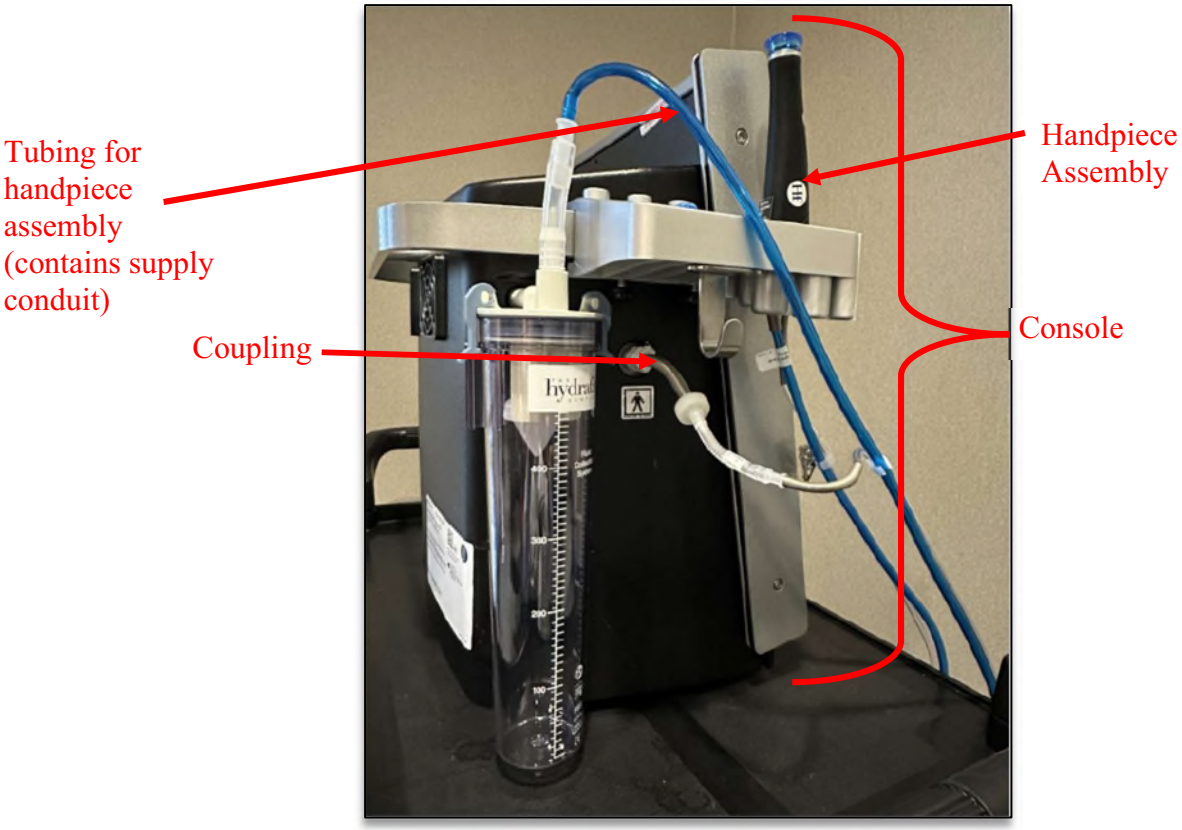
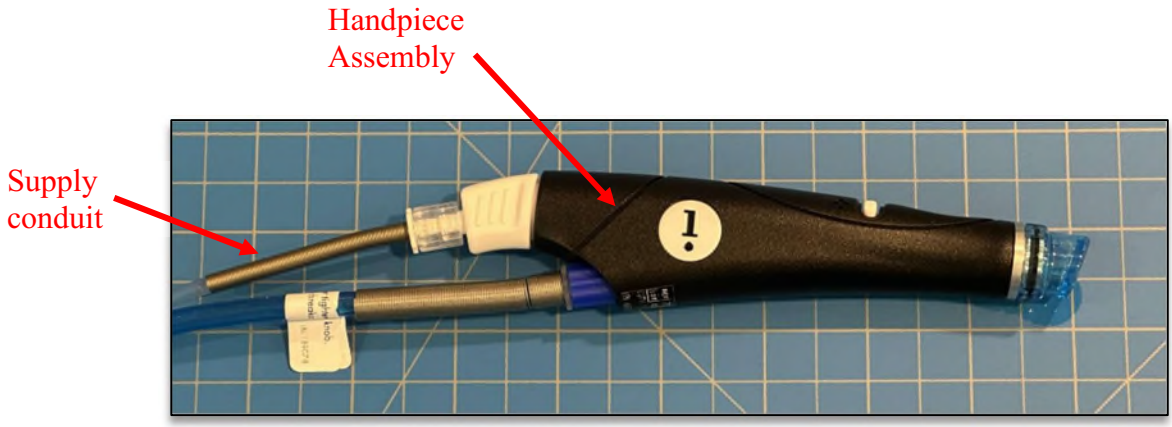


Ex. 2121 (Allegro).



Ex. 2111 (Allegro).

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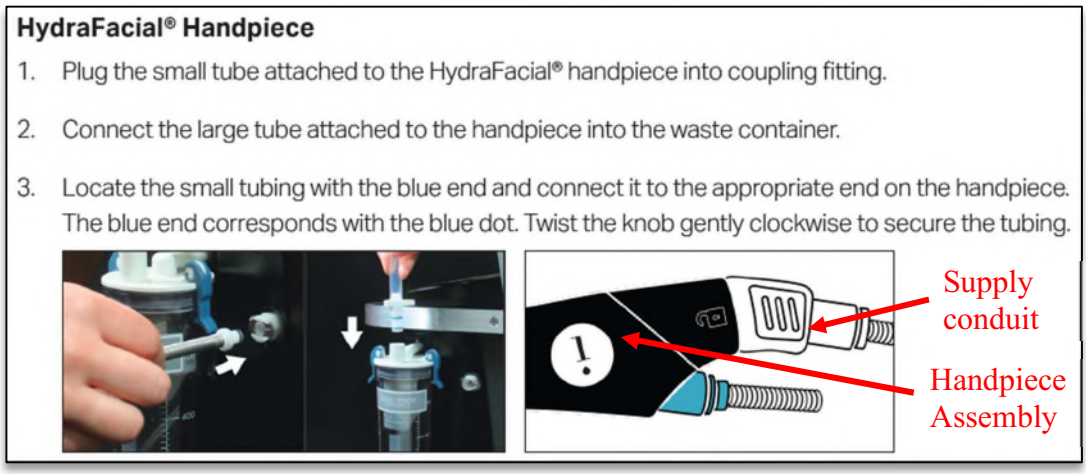
57. The Allegro IFU describes connecting a "small tube" between the handpiece assembly and the console, where the "small tube" serves as the supply conduit through which the manifold system is in fluid communication with the handpiece assembly.



Ex. 2032 at 9 (Allegro IFU).

58. My review of photos and videos of the Tower confirmed that this limitation is satisfied. As shown in the below photos, the supply conduit connects to the manifold system via a coupling on the console. From the coupling, the supply conduit extends from the console to the handpiece assembly. As a result, the supply conduit places the manifold system in a state that makes the passage of fluid possible from the containers to the handpiece assembly.

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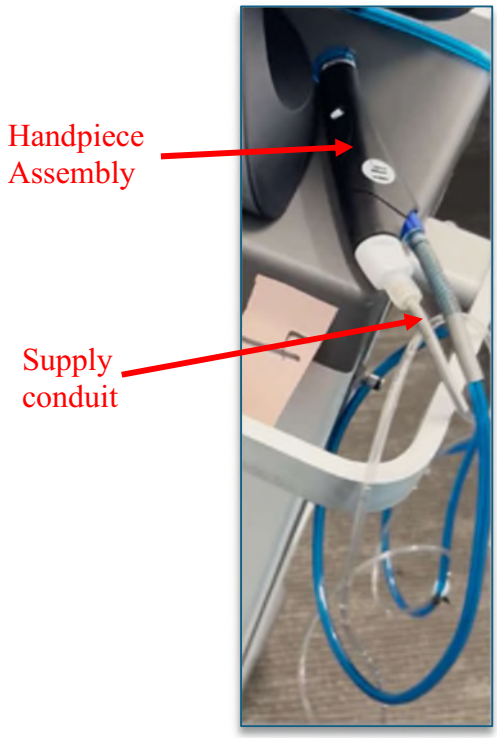
Ex. 2151 at 1 (Tower).



Ex. 2147 (Tower).

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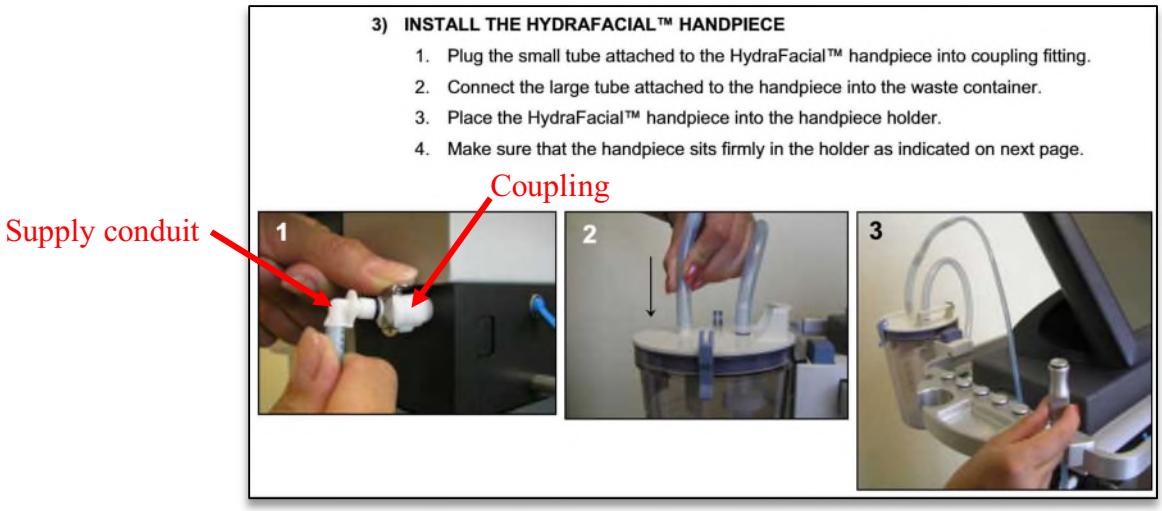
59. The Tower Owner's Manual describes connecting a "small tube" between the handpiece assembly and the manifold system, where the "small tube" serves as the supply conduit which places the manifold system in fluid communication with the handpiece assembly. The "small tube" connects the handpiece assembly to the manifold system via a coupling on the manifold system. The supply conduit extends from the manifold system in the console through tubing to the handpiece assembly via the coupling. The connection of the handpiece assembly to the manifold system via the coupling places the manifold system in fluid communication with the handpiece assembly.



Ex. 2033 at 10 (Tower Owner's Manual).

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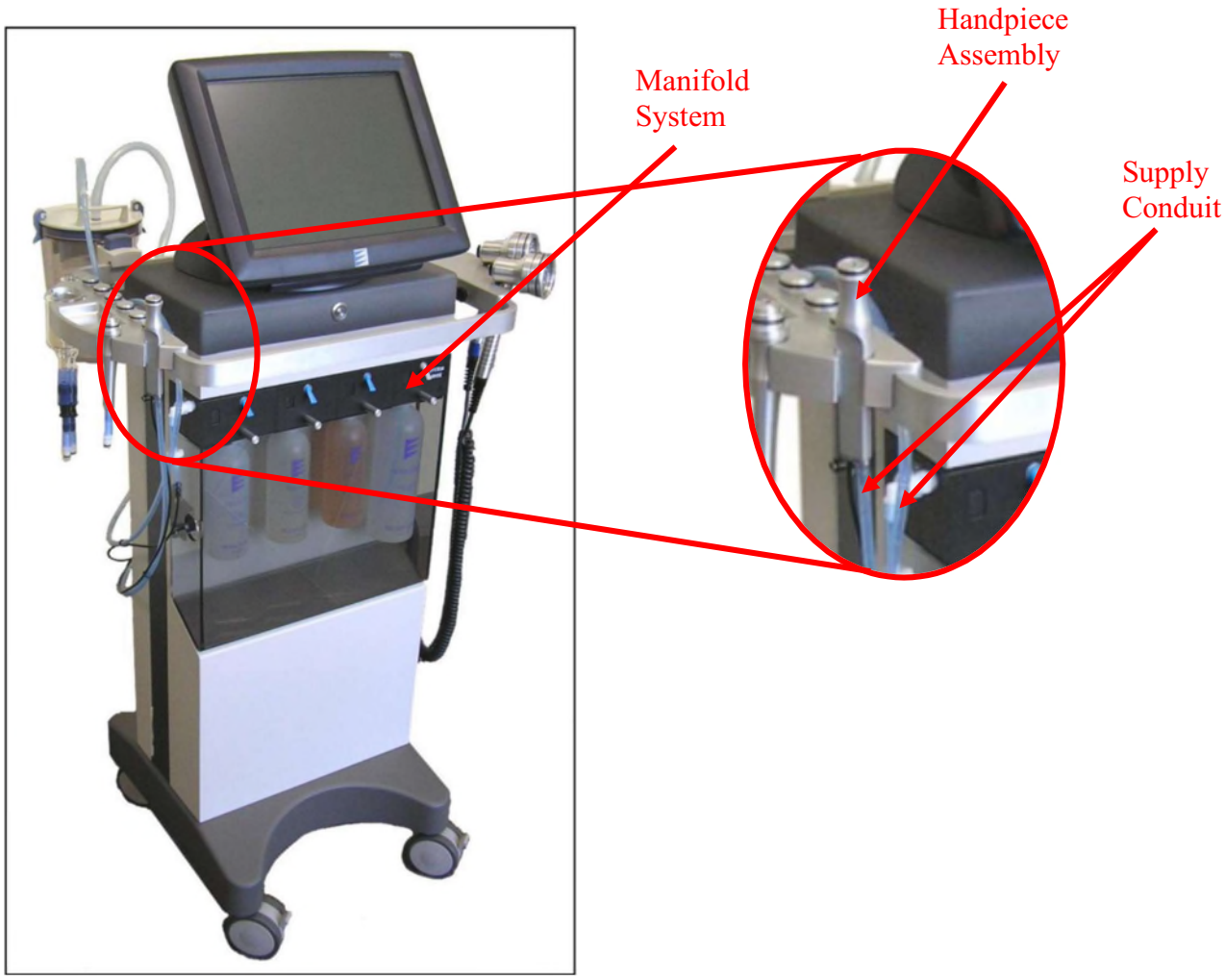

Ex. 2125 at 1 (Tower Owner's Manual)

60. Accordingly, this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

d. 1[c]: "wherein the handpiece assembly comprises a working end having a skin contact surface"

61. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has a "handpiece assembly" that "comprises a working end having a skin contact surface."

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62. For the same reasons set forth in limitation 1[c], each of the Syndeo, Elite, Allegro, and Tower has a "handpiece assembly."

63. In my opinion, each of the Syndeo, Elite, Allegro, and Tower also has a handpiece assembly that comprises a working end having a skin contact surface.

64. During my inspection of the Syndeo, Elite, and Allegro, I observed that each device has a handpiece assembly that comprises a working end having a skin contact surface.

Ex. 2111 (Syndeo)

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Ex. 2111 (Elite)

Ex. 2111 (Allegro).

65. For all four devices, in operation, the handpiece assembly is intended to be held in the hand and placed in contact with the skin, as confirmed by videos of the devices in operation. A screenshot from each of the videos shows the handpiece assembly with a working end with a skin contact surface in contact with skin tissue.

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From this, I concluded the handpiece assembly comprises a working end having a skin contact surface.

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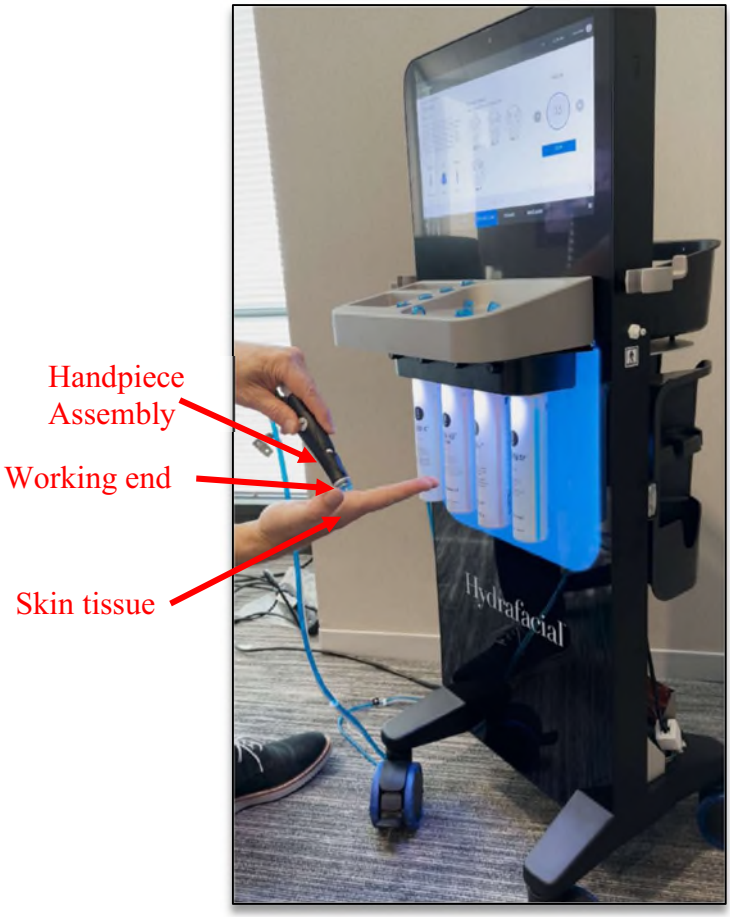
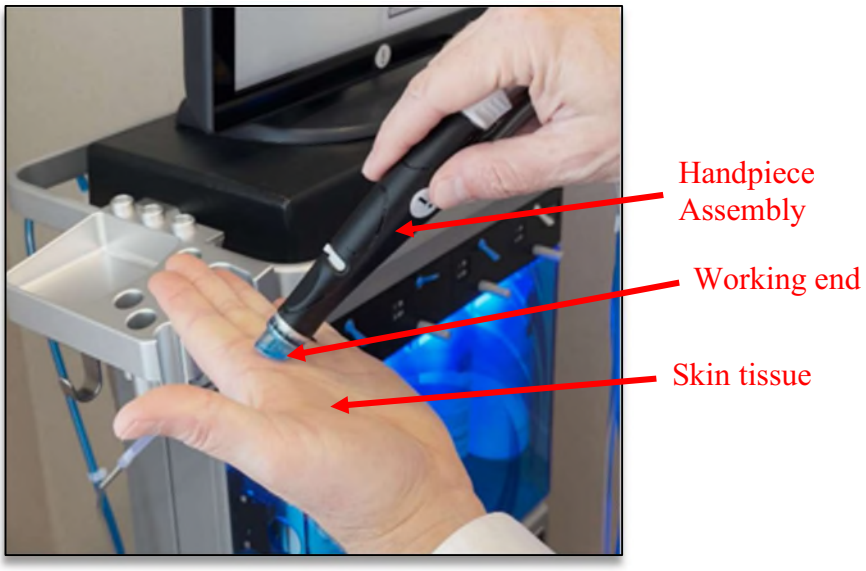


Ex. 2078 at 1 (Syndeo).



Ex. 2079 at 3 (Elite).

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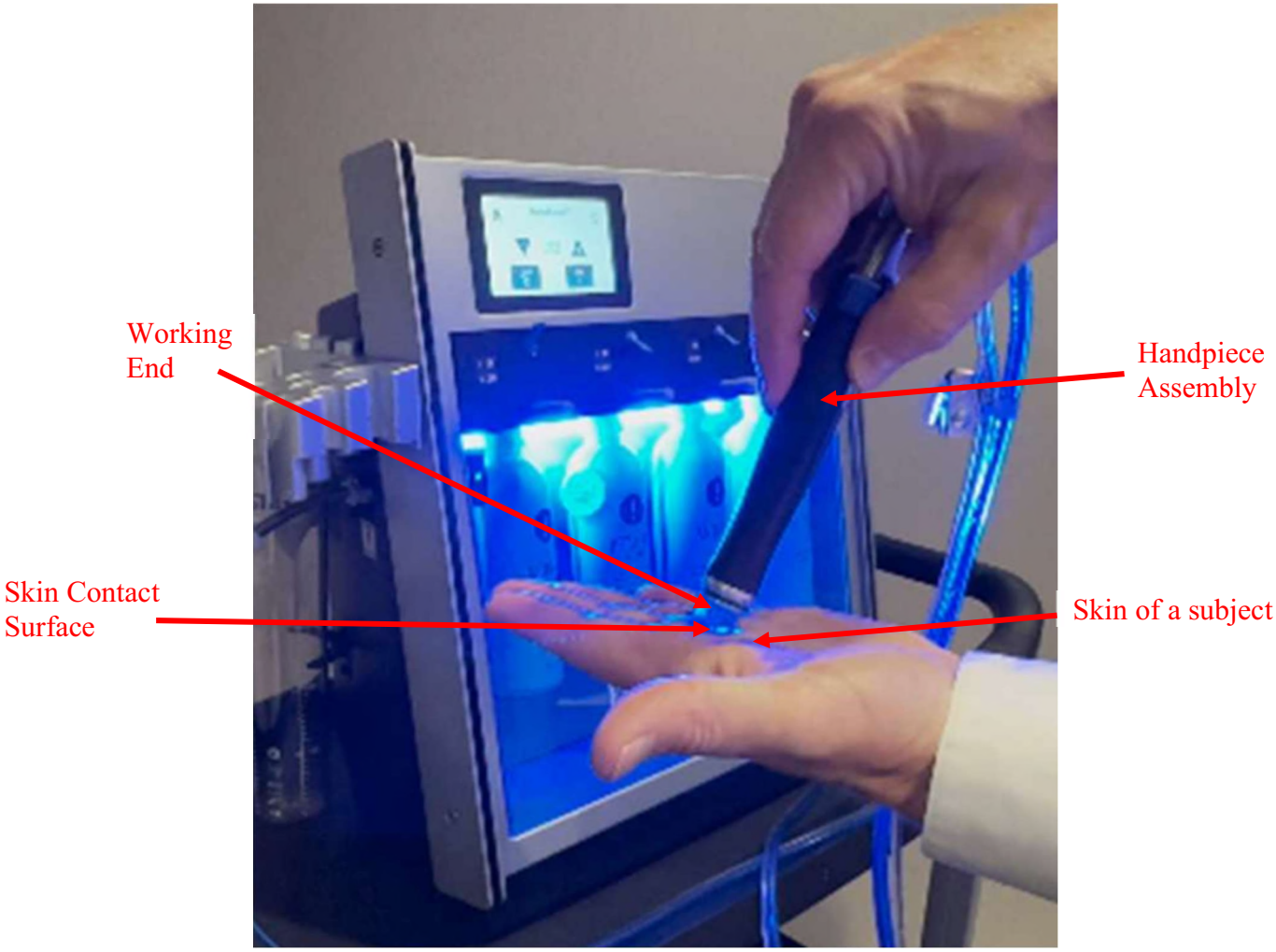

Ex. 2146 (Allegro).

66. Given the similarity between the Tower handpiece assembly and the handpiece assembly of the Syndeo, Allegro, and Elite, I have concluded that the Tower handpiece assembly has a working end with a skin contact surface for contacting skin, similar to the images above.

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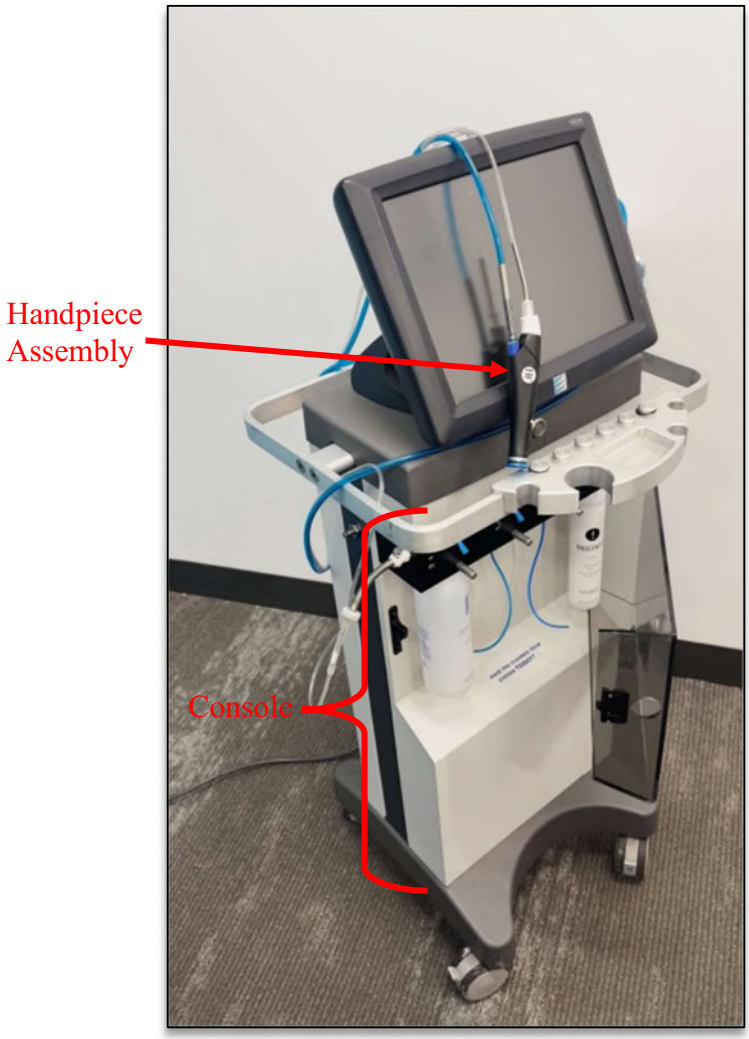

Ex. 2125 at 2 (Tower).

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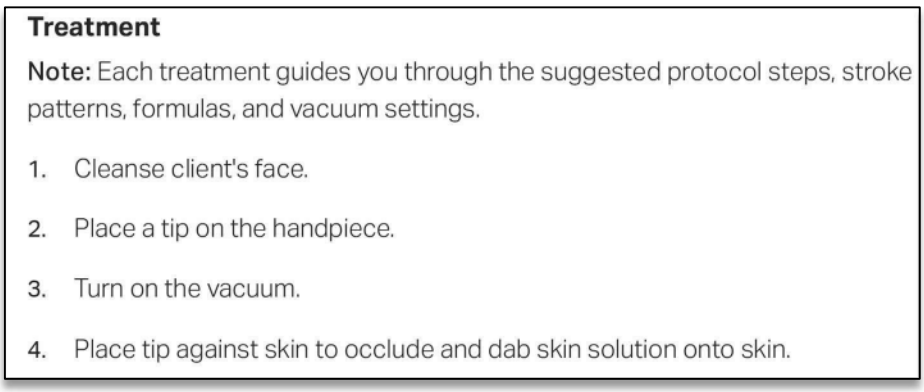
67. Each of the Syndeo IFU, Elite IFU, and Allegro IFU explains that the tip of the handpiece assembly is used to contact the skin surface of a subject.



Treatment

Note: Each treatment guides you through the suggested protocol steps, stroke patterns, formulas, and vacuum settings.

1. Cleanse client's face.
2. Place a tip on the handpiece.
3. Turn on the vacuum.
4. Place tip against skin to occlude and dab skin solution onto skin.

Ex. 2030 at 19 (Syndeo).

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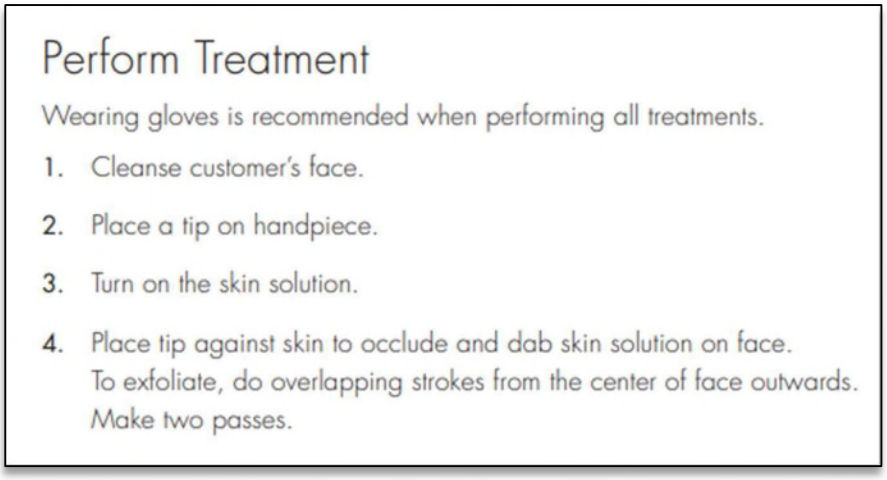

Perform Treatment

Wearing gloves is recommended when performing all treatments.

1. Cleanse customer's face.
2. Place a tip on handpiece.
3. Turn on the skin solution.
4. Place tip against skin to occlude and dab skin solution on face. To exfoliate, do overlapping strokes from the center of face outwards. Make two passes.

Ex. 2031 at 17 (Elite).

Hand Positioning

1. When applying the handpiece to the skin, place index finger over the indented surface.

Ex. 2034 at 7 (Allegro).

68. I understand that the Tower handpiece assembly was not available at the inspection of the device. Instead, a Syndeo handpiece assembly was used with the Tower. I understand that the Tower handpiece and the Syndeo handpiece function similarly and the handpiece assembly for each uses a tip that functions as a

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working end with a skin contact surface that contacts skin tissue. The Tower Owner's Manual shows the handpiece assembly with HydraPeel tips. The manual cautions a user that if there is "NO OR LOW FLUID FLOW," "[m]ake sure the plastic tip is firmly installed onto [the] HYDRAPEEL handpiece." Ex. 2125 at 18.

69. Accordingly, this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

e. 1[d]: "a vacuum source;"

70. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a vacuum source."

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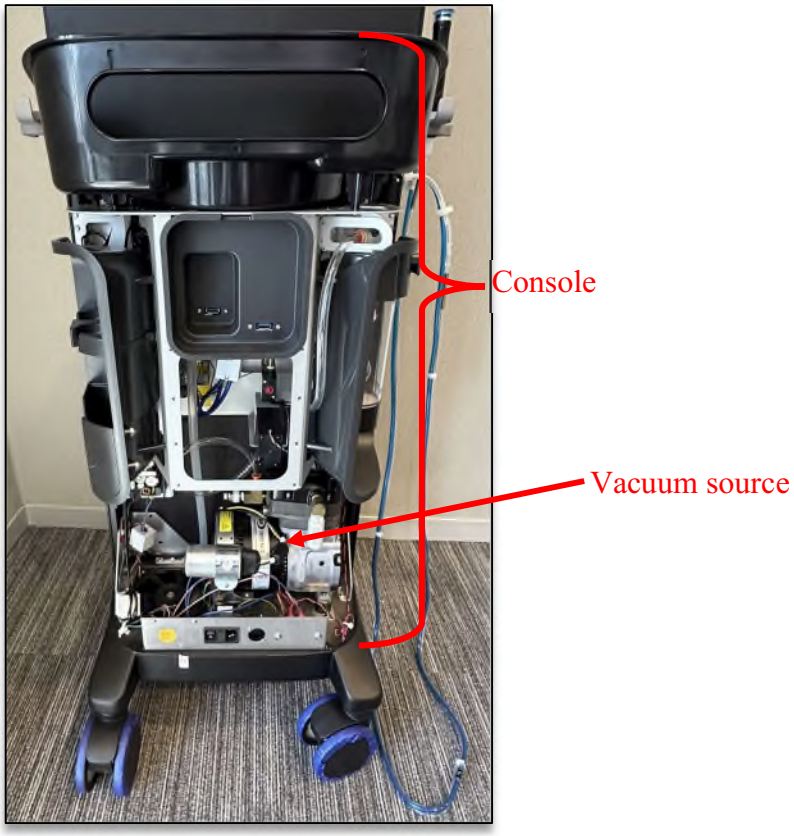
71. As shown in the images below, each of the Syndeo, Elite, Allegro, and Tower includes a vacuum source in the console:



Ex. 2109 (Syndeo).

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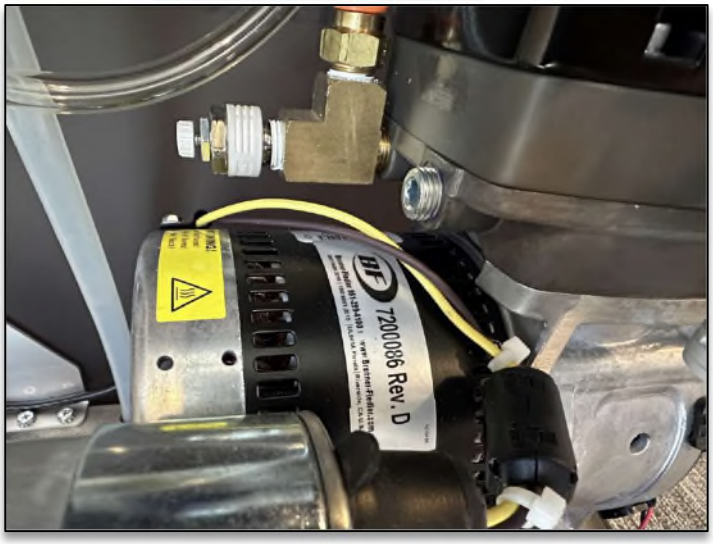
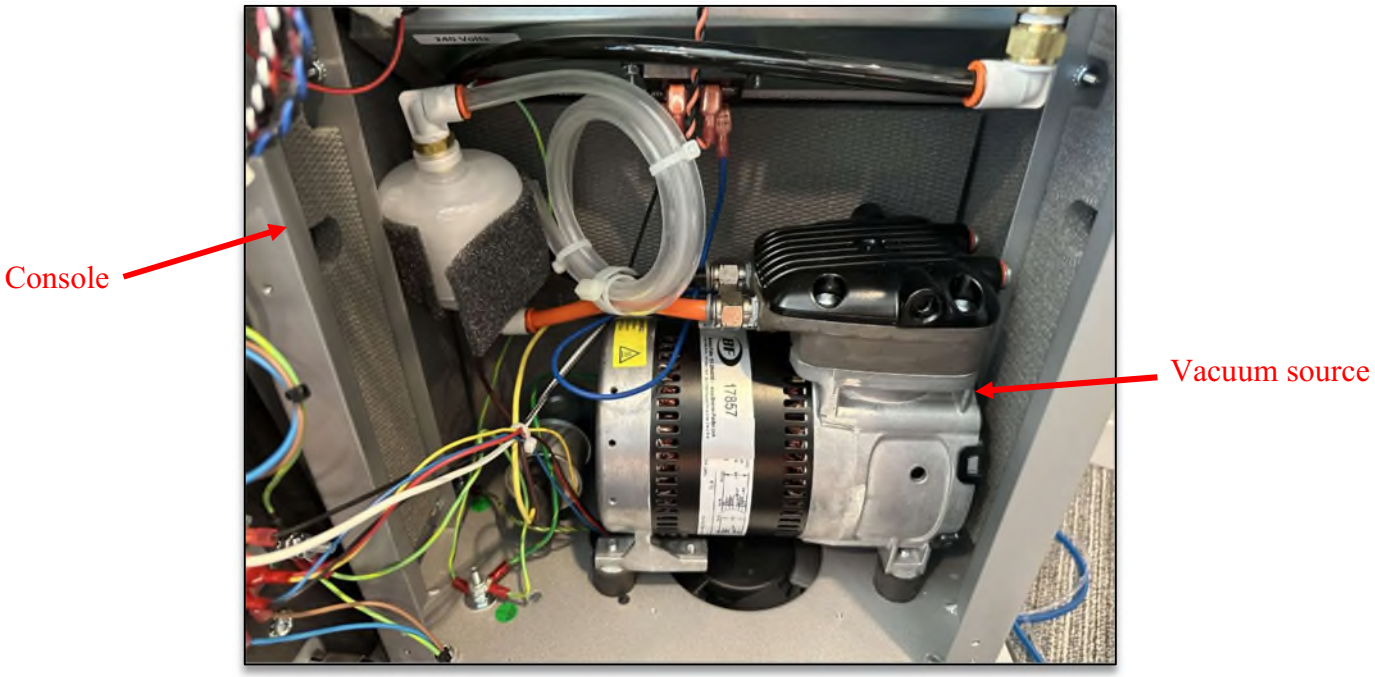


Ex. 2101 (Syndeo; vacuum source labeled as part number “7200086”).



Ex. 2102 (Allegro).

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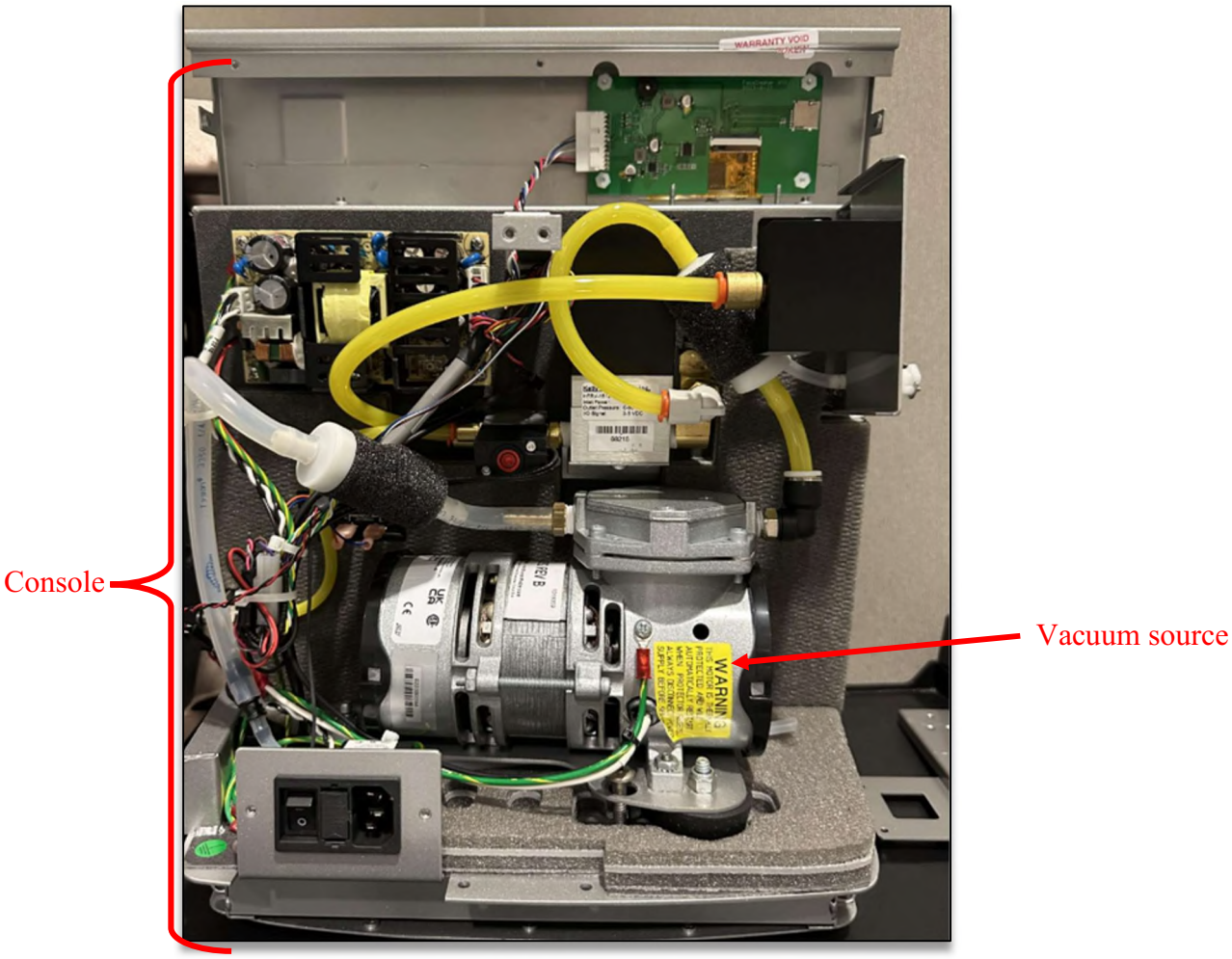

Ex. 2120 (Allegro).

72. The technical documents for each of the Syndeo, Elite, Allegro, and Tower confirm that a vacuum source is inside of the console. For example, the Syndeo, Elite, and Allegro IFUs describe turning the vacuum on and off and adjusting the vacuum:

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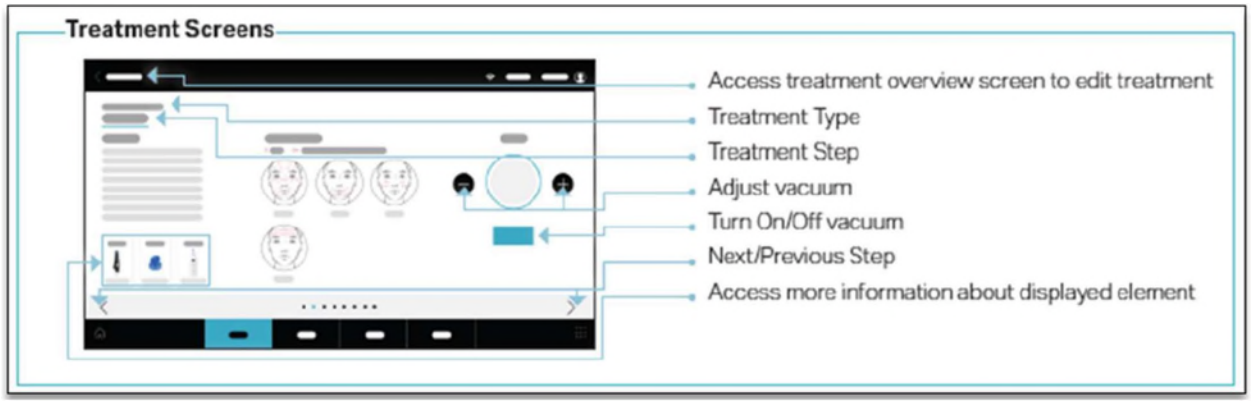
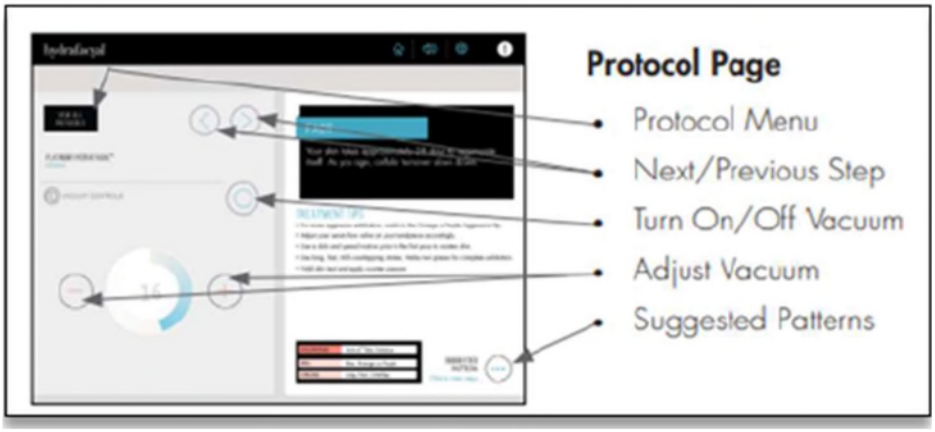
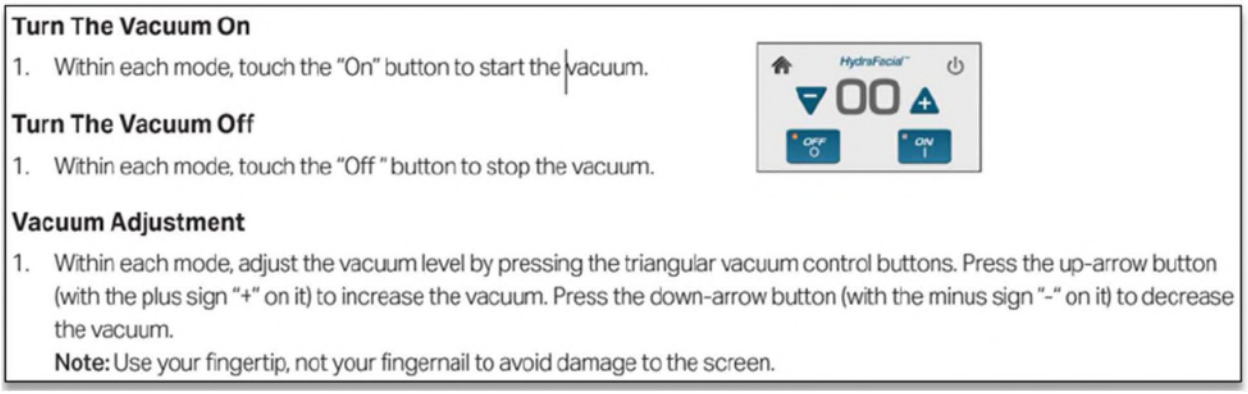


Ex. 2030 at 16 (Syndeo IFU).



Ex. 2031 at 16 (Elite User Guide).



Turn The Vacuum On

1. Within each mode, touch the "On" button to start the vacuum.

Turn The Vacuum Off

1. Within each mode, touch the "Off " button to stop the vacuum.

Vacuum Adjustment

1. Within each mode, adjust the vacuum level by pressing the triangular vacuum control buttons. Press the up-arrow button (with the plus sign "+" on it) to increase the vacuum. Press the down-arrow button (with the minus sign "-" on it) to decrease the vacuum.
   Note: Use your fingertip, not your fingernail to avoid damage to the screen.

Ex. 2032 at 13 (Allegro IFU).

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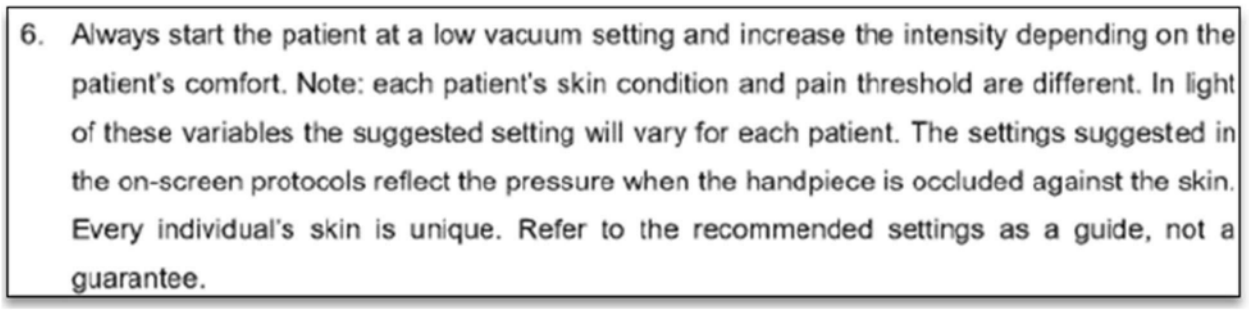
73. The Tower Owner's Manual similarly described having an adjustable vacuum:



6. Always start the patient at a low vacuum setting and increase the intensity depending on the patient's comfort. Note: each patient's skin condition and pain threshold are different. In light of these variables the suggested setting will vary for each patient. The settings suggested in the on-screen protocols reflect the pressure when the handpiece is occluded against the skin. Every individual's skin is unique. Refer to the recommended settings as a guide, not a guarantee.

Ex. 2033 at 3 (Tower Owner's Manual).

74. My inspection of each of the Syndeo, Elite, Allegro, and Tower devices (in person, via video, or via images) did not identify any external vacuum source, nor any ports to connect to an external vacuum source. Thus, it is my opinion that the console comprises the vacuum source.

75. Accordingly, it is my opinion that this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

f. 1[e]: "a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the working end of the handpiece assembly during treatment"

76. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a waste conduit in fluid communication with the handpiece assembly and the vacuum

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source to move waste away from the working end of the handpiece assembly during treatment."

77. For the same reasons set forth in limitation 1[c] and limitation 1[d], each of the Syndeo, Elite, Allegro, and Tower has a handpiece assembly with a working end.

78. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the working end of the handpiece assembly during treatment."

79. My inspection of the Syndeo confirmed that this limitation is satisfied. As shown in the below photos, a waste conduit extends from the vacuum source to the vacuum port for the waste container, from the vacuum port for the waste container to the waste container, from the handpiece port in the waste container to the coupling for the handpiece assembly, and from the coupling for the handpiece assembly to the handpiece assembly itself.

80. During my inspection of the Syndeo, I observed that the waste conduit comprises multiple tubing components that extend 1) between the vacuum source and a vacuum regulator; 2) between the vacuum regulator and a port for the waste container; 3) between the port of the waste container and the coupling for the

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handpiece tubing via the waste container, and 4) through the coupling for the handpiece assembly to the handpiece assembly itself. I have annotated the photos below using the numbering above to identify the tubing components the comprise the waste conduit.

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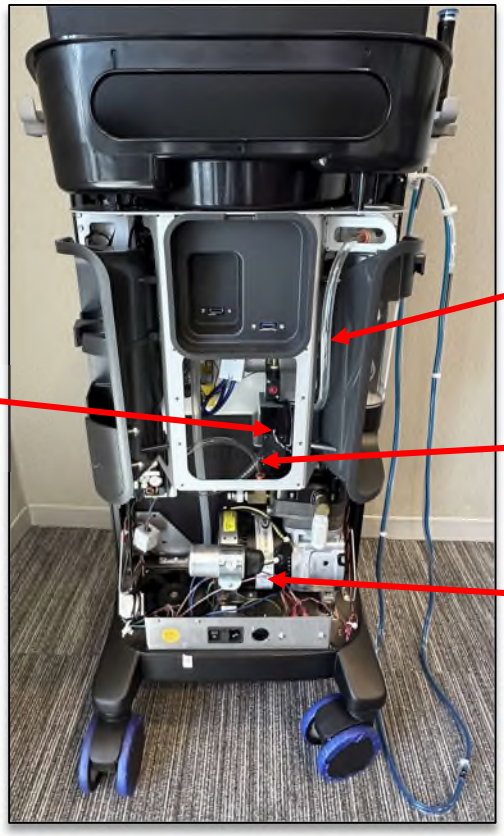
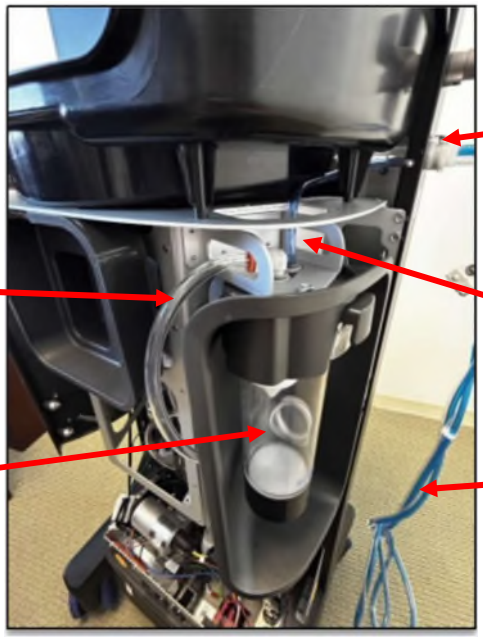


Ex. 2109 (Syndeo).



Ex. 2127 at 4 (Syndeo).

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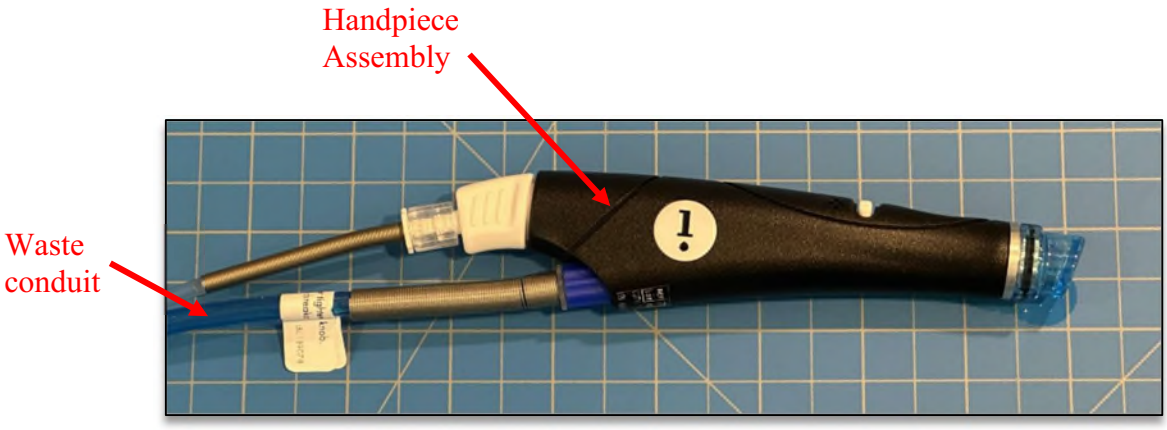
81. Below, I have identified waste conduit – 4) Handpiece Tubing (blue line), and the handpiece assembly that it connects to:



Ex. 2111 (Syndeo).

82. After the fluid exits the handpiece from the first conduit, the fluid goes through the handpiece to the second conduit via an opening in the main body of the handpiece, identified below:

Ex. 2127 at 2 (Syndeo).

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83. The waste conduit makes the passage of fluid possible from the handpiece assembly to the waste container using the vacuum source. I observed that, due to this fluid communication, when the vacuum source is activated and the handpiece assembly is contacting skin, a closed system is formed between a selected container and the vacuum source. Suction from the vacuum source, through the waste conduit, the handpiece assembly, the supply conduit, and the manifold system allows fluid to be drawn from the selected container and delivered to the skin, while used fluid and debris is simultaneously drawn away from the skin to the waste container.

84. The Syndeo IFU confirms the waste conduit is in fluid communication with the handpiece assembly and the vacuum source to move waste away from the working end of the handpiece assembly during treatment. The Syndeo IFU illustrates and describes a "Return Line." In the annotated illustration below the "Return Line" attaches to the handpiece. This "Return Line" serves as a portion of the waste conduit through which the handpiece assembly is in fluid communication with the vacuum source. For clarity, I have also labeled the supply conduit, which I describe in greater detail above.

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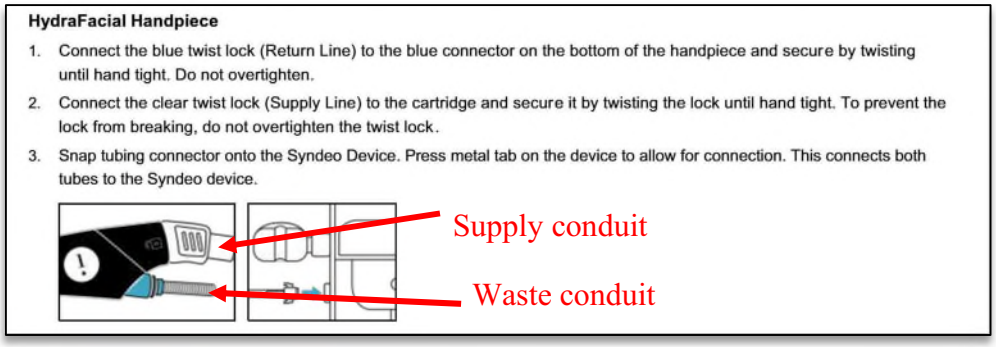
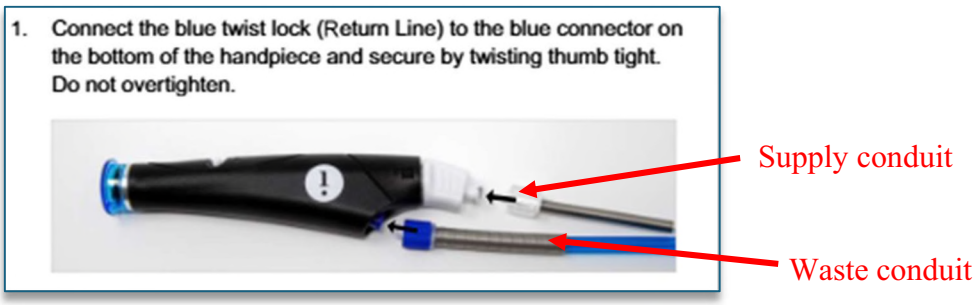


Ex. 2030 at 12 (Syndeo)

85. The Syndeo IFU describes the "Return Line" being connected between the handpiece and a waste container, labeled as the "waste canister." This waste container is, in turn, connected to and in fluid communication with the vacuum source in the console.



Ex. 2034 at 2 (Handpiece User Guide); *see also* Ex. 2030 at 22 (Syndeo IFU) ("Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister.")

86. The Syndeo fluid schematic also shows that the waste conduit is in fluid communication with the handpiece assembly and the vacuum source to move waste

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away from the working end of the handpiece assembly during treatment. Below, I have annotated the Syndeo fluid schematic to illustrate the flow path from the handpiece assembly, through the second waste, to the vacuum source.

Ex. 2114 (Syndeo).

87. My inspection of the Elite and Allegro, and review of images, videos, and documents for the Tower, confirmed that this limitation is satisfied. As shown in the below photos, a waste conduit extends from the vacuum source to the vacuum

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port for the waste container, from the vacuum port for the waste container to the waste container, from the handpiece port in the waste container to the coupling for the handpiece assembly, and from the coupling for the handpiece assembly to the handpiece assembly itself.

88. During my inspection of the Elite and Allegro, I observed that the waste conduit comprises multiple tubing components that extend 1) between the vacuum source and a vacuum regulator; 2) between the vacuum regulator and a port for the waste container; 3) between the port of the waste container and the coupling for the handpiece tubing via the waste container, and 4) through the coupling for the handpiece assembly to the handpiece assembly itself. I have annotated the photos below using the numbering above to identify the tubing components the comprise the waste conduit:

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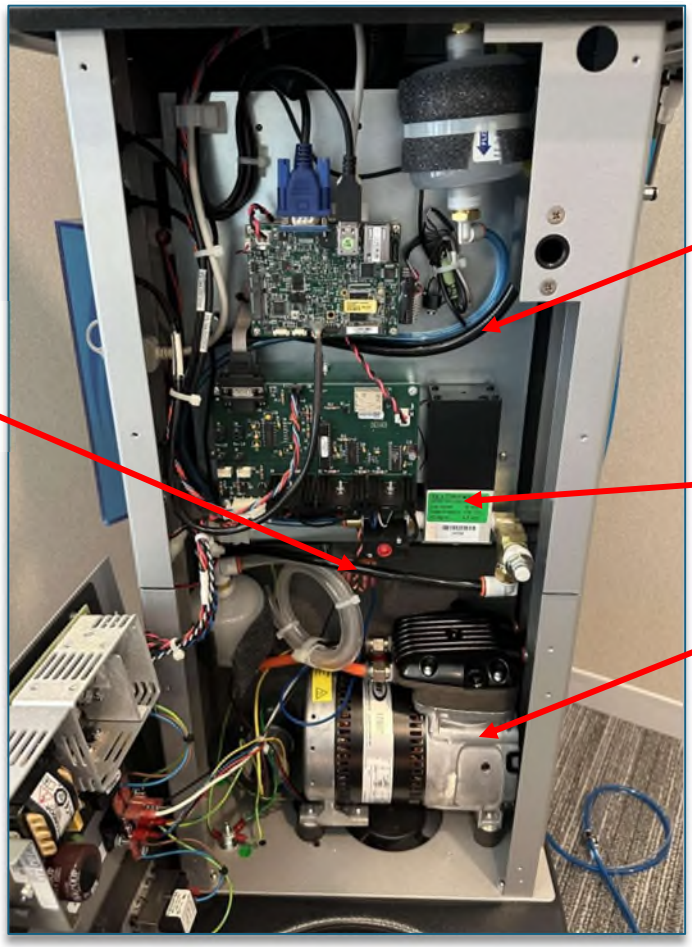

Ex. 2119 (Elite).

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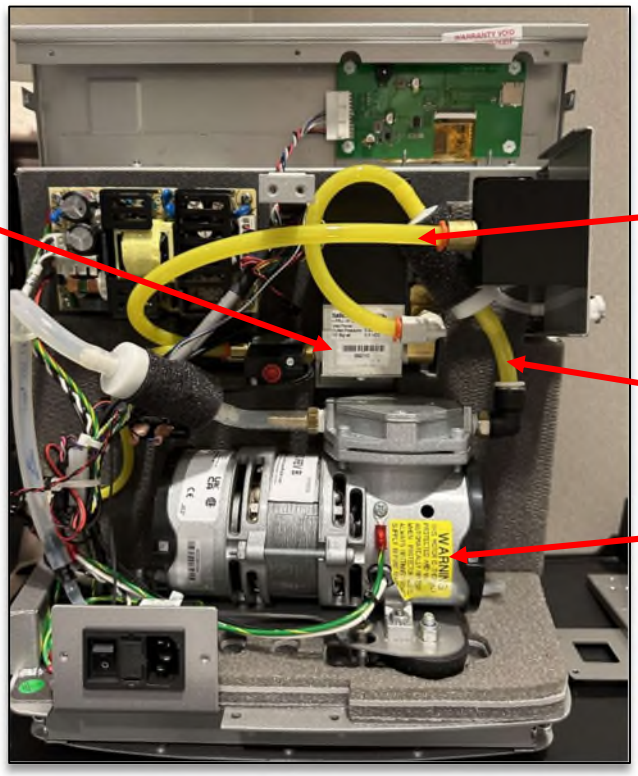
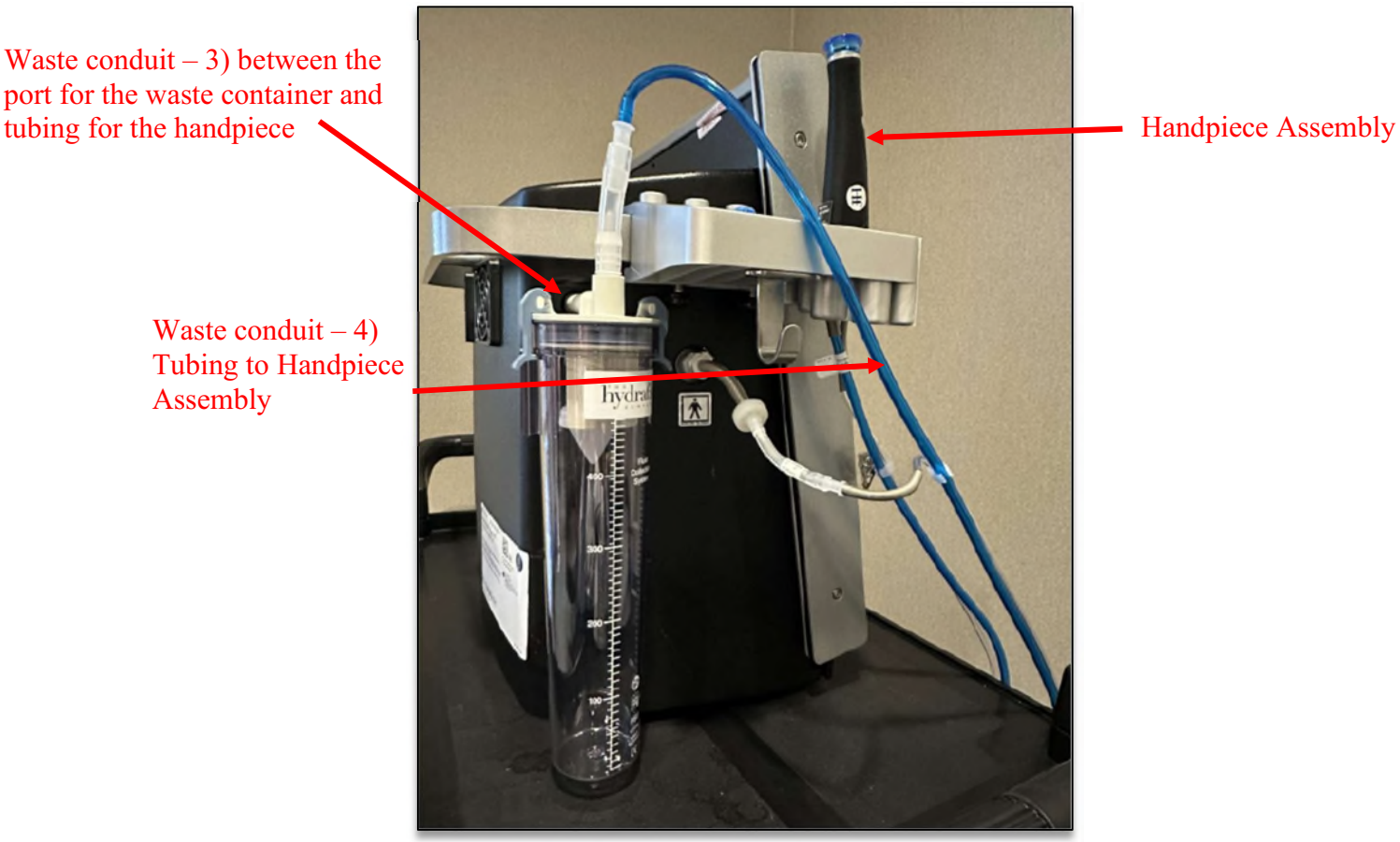
Ex. 2115 (Elite).



Ex. 2120 (Allegro).



Ex. 2121 (Allegro).

89. The Tower has the same second conduit comprised of multiple tubing components. Below, I have annotated image two images of the Tower Device. The first image identifies the handpiece, and the Second Conduit – 4) Tubing to Handpiece. The second image identifies the Second Conduit – 3) Between the Port for the Waste Container and Tubing for Handpiece.

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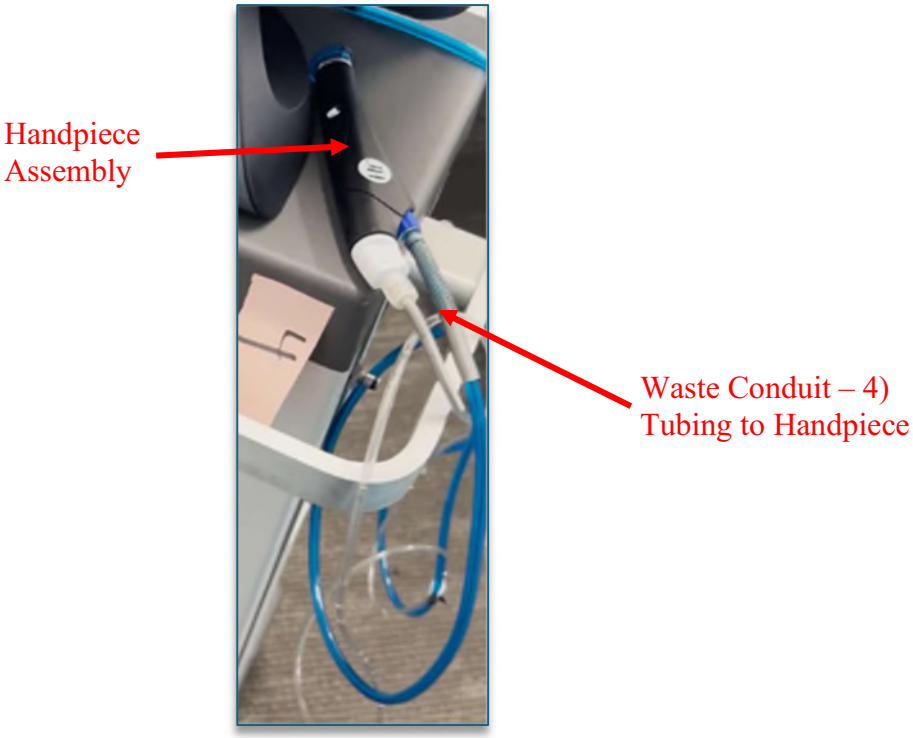
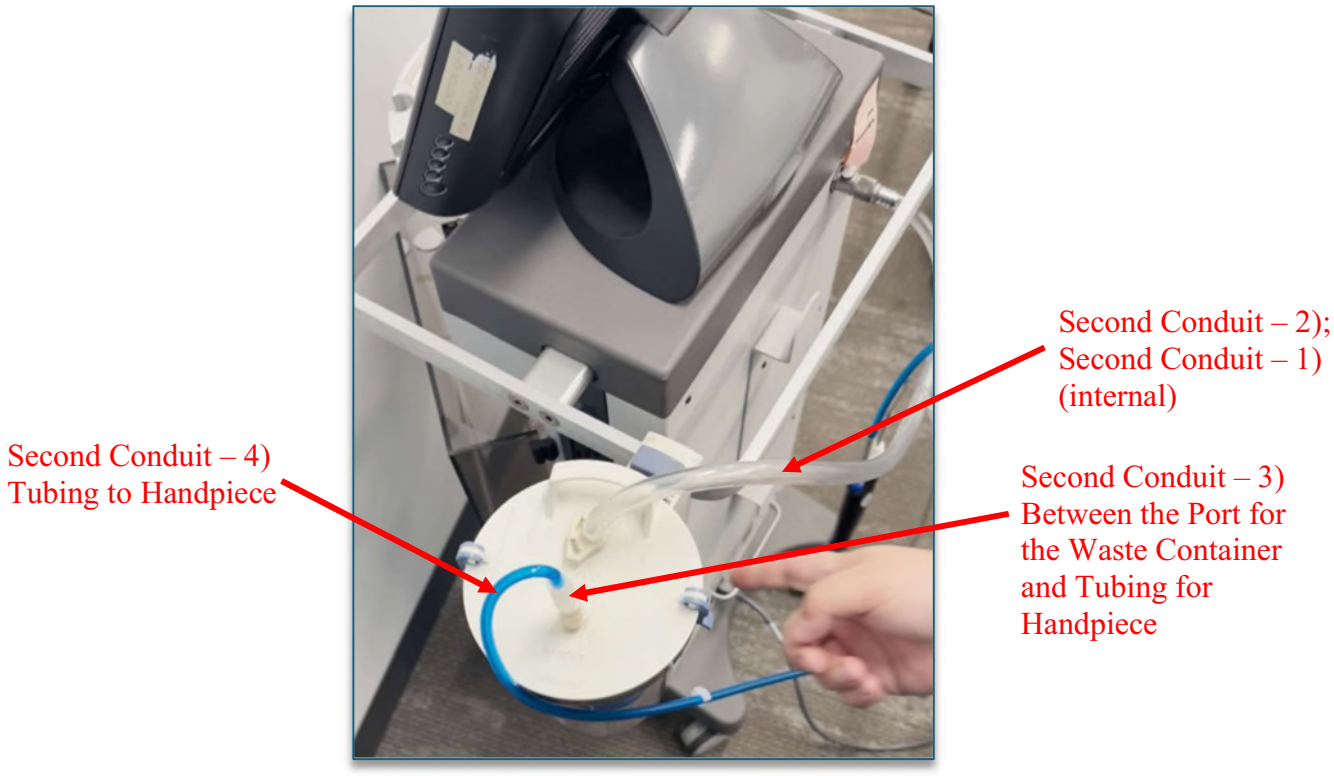


Ex. 2147 (Tower).



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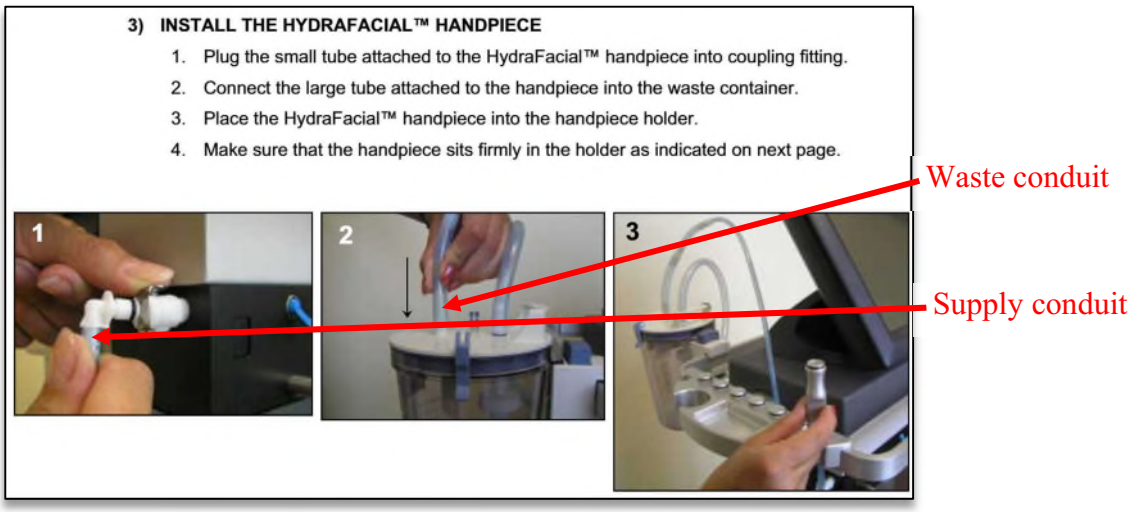
Ex. 2149 (Tower).

90. The Tower Owner's Manual confirm that the Tower has a handpiece assembly in fluid communication with the vacuum source through a waste conduit to move waste away from the working end of the handpiece assembly during treatment. In the Tower, the waste conduit – 4) Tubing to Handpiece) referenced in the image below as attaching to both the handpiece assembly and coupling, serves as a portion of the waste conduit through which the handpiece is in fluid communication with the vacuum source.



Ex. 2033 at 10 (Tower Owner's Manual). The waste conduit continues through the waste container and through a port for the waste container on the console, shown below:

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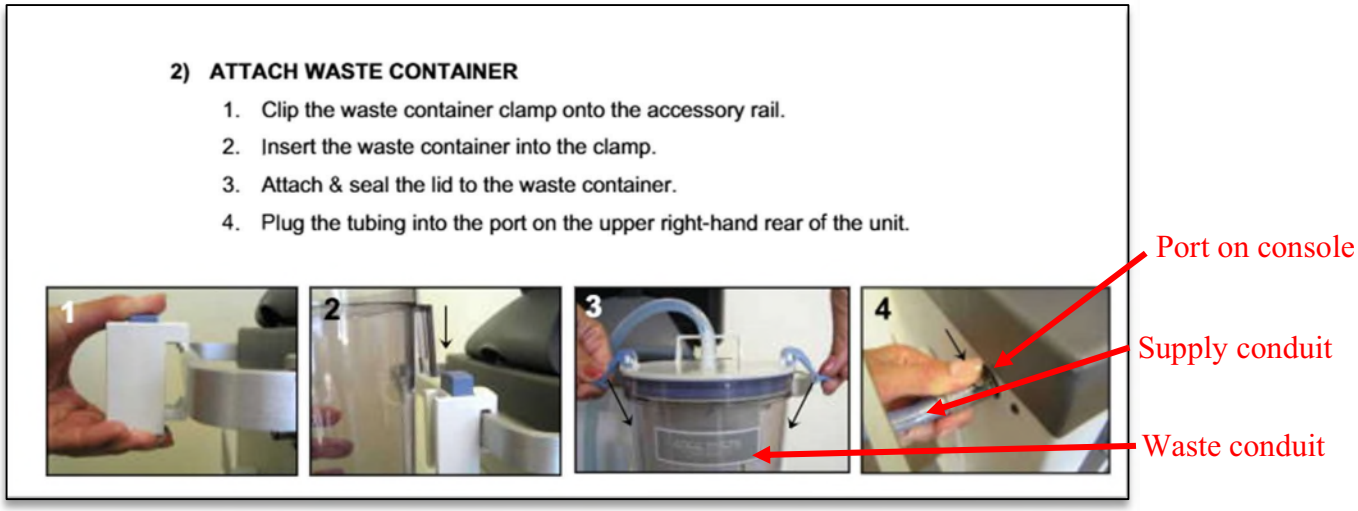
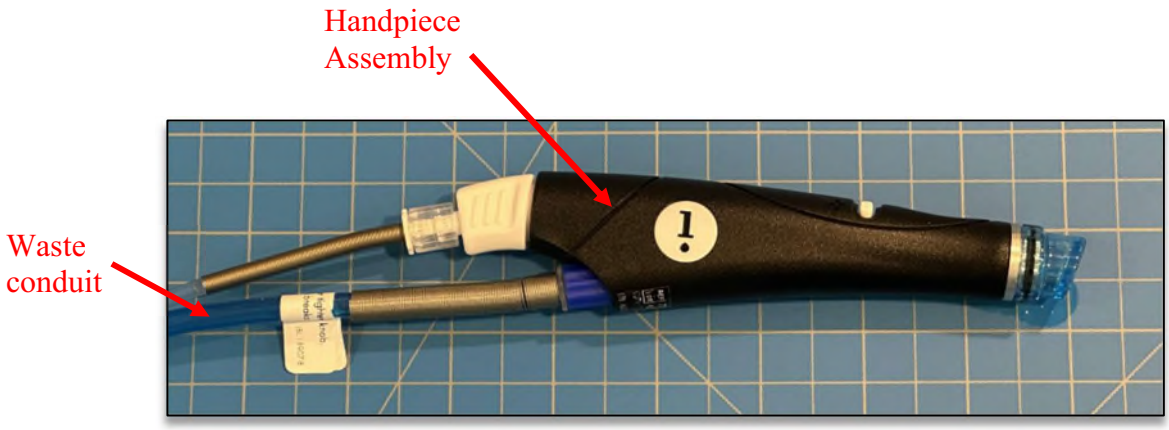


Ex. 2033 at 9 (Tower Owner's Manual). As shown in the image above, there is tubing connecting the vacuum source to the port of the waste container, thus placing the handpiece assembly in fluid communication with the vacuum source (Waste Conduit -2 and Waste Conduit -3).

91. Below, I have identified waste conduit – 4) Handpiece Tubing (blue line), and the handpiece assembly that it connects to for each of the Elite and Allegro devices:



Ex. 2111 (Elite).

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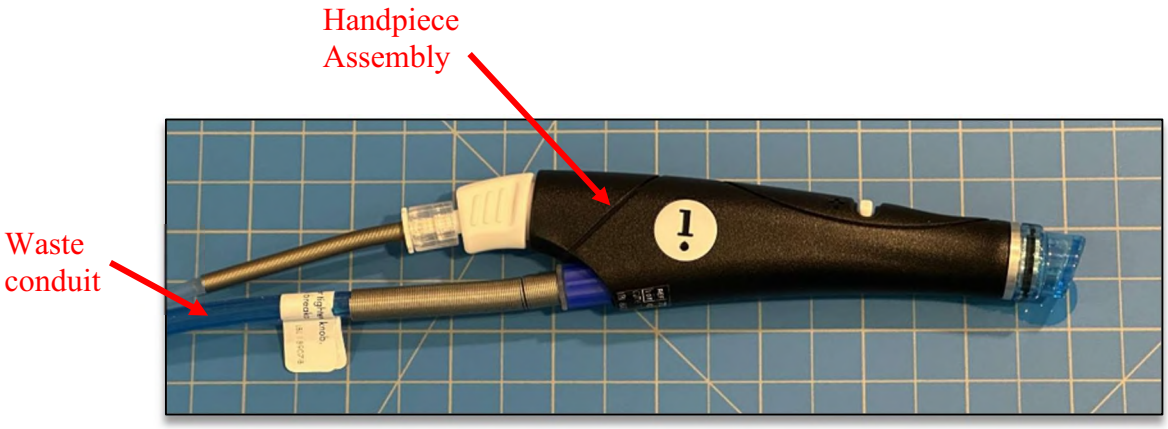
Ex. 2127 at 2 (Syndeo).



Ex. 2111 (Allegro).

92. My understanding is that the Tower handpiece functions similarly to the Syndeo handpiece that was available at the inspection and that the handpiece would have an opening that connects to the second conduit:

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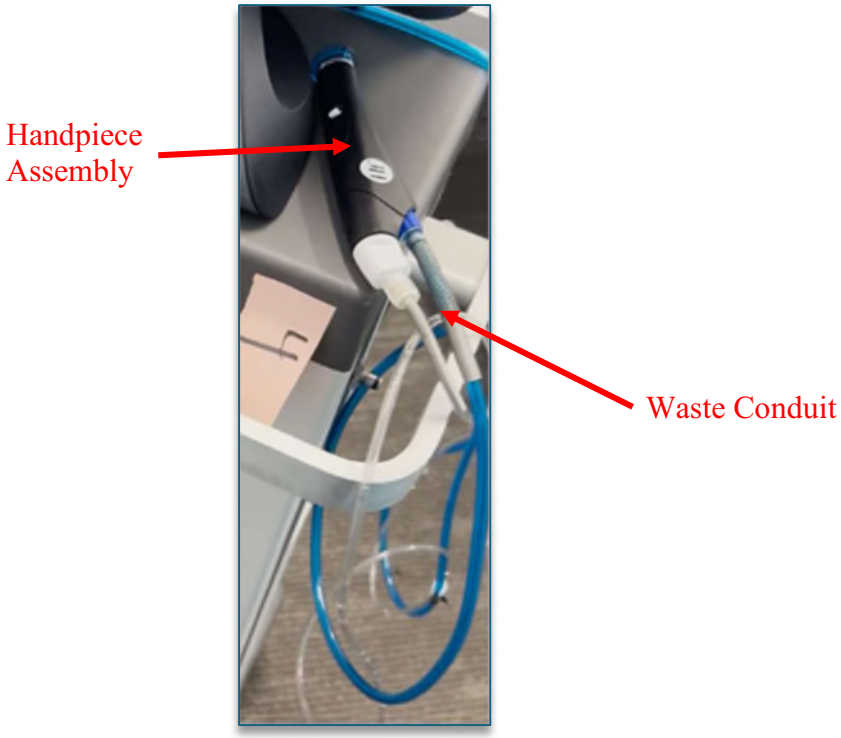

Ex. 2147 (Tower).

93. After the fluid reaches the tip, the fluid goes through the handpiece assembly to the waste conduit via an opening in the main body of the handpiece assembly. I have illustrated this on the Tower handpiece; however, both the Allegro and Elite have the same opening.

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Ex. 2106 (Tower).

94. The waste conduit places the handpiece assembly in fluid communication with the vacuum source. I observed for both the Elite and the Allegro, due to this fluid communication, when the vacuum source is activated and the handpiece assembly is contacting skin, a closed system is formed between a selected container and the vacuum source. Suction from the vacuum source, through the waste conduit, the handpiece, the supply conduit, and the manifold system allows fluid to be drawn from the selected container and delivered to the skin, while used fluid and debris is simultaneously drawn away from the skin to the waste container. Based on my review of video of the Tower with the cleaning cap on, it is my

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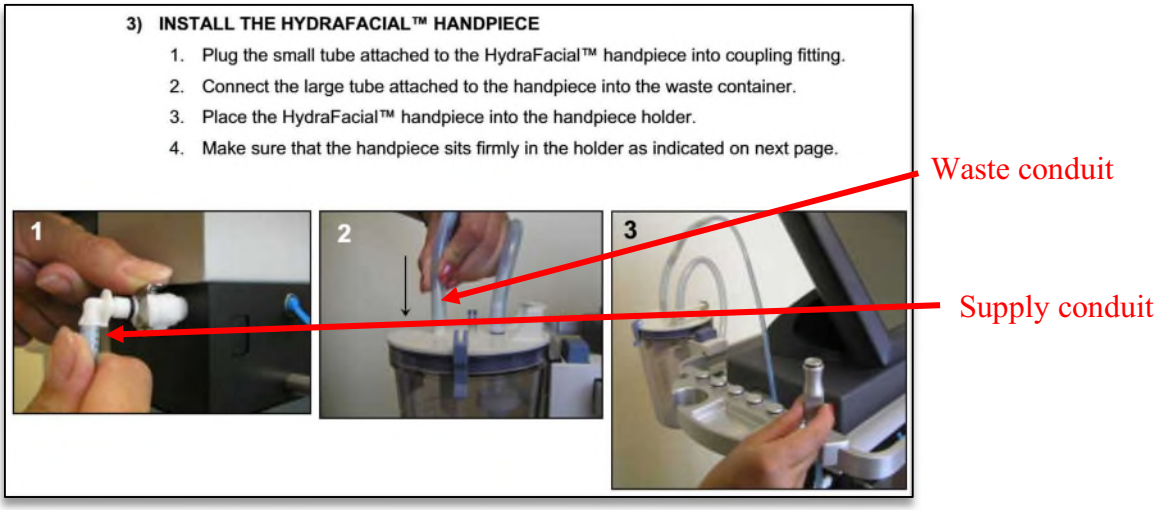
understanding that it operates the same as the Elite and Allegro when the handpiece assembly contacts the skin.

95. In the Tower, the waste conduit referenced in the image below as attaching to both the handpiece and coupling, serves as a portion of the waste conduit and is operatively coupled to the vacuum source.



Ex. 2033 at 10 (Tower Owner's Manual). The waste conduit continues through the waste container and through a port for the waste container on the console, shown below.

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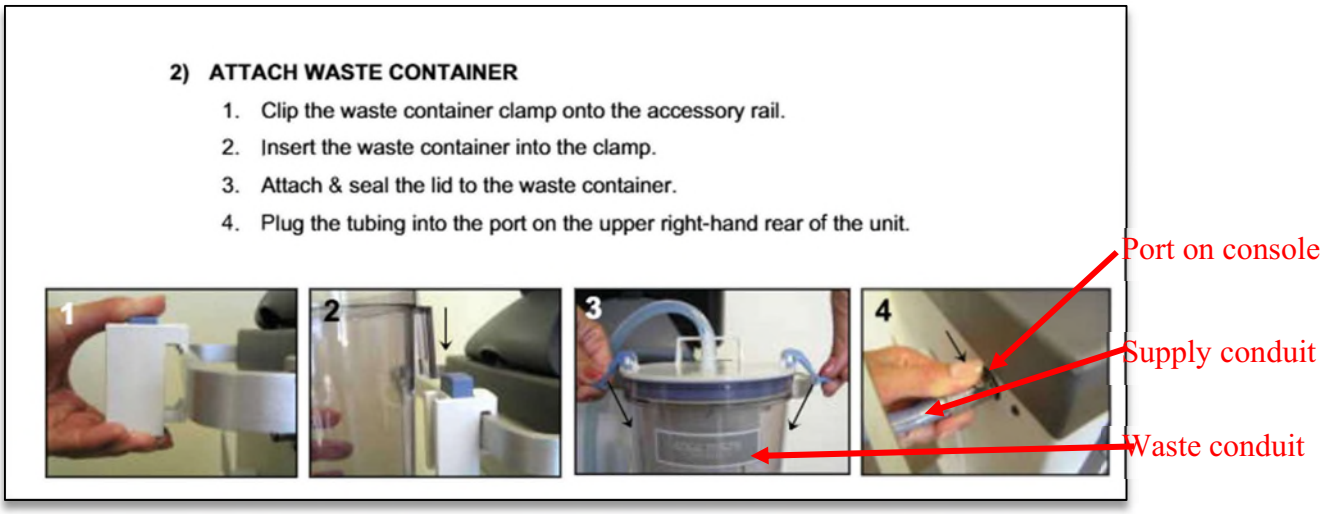

Ex. 2033 at 9 (Tower Owner's Manual). As shown in the image above, there is tubing connecting the vacuum source to the port of the waste container. Thus, a waste conduit in fluid communication with the handpiece assembly and the vacuum source moves waste away from the working end of the handpiece assembly during a skin treatment procedure.

96. The Elite IFU and Allegro IFU confirms each device has a handpiece assembly in fluid communication with the vacuum source through a waste conduit to move waste away from the working end of the handpiece assembly during treatment. The Elite IFU and Allegro IFU illustrates and describes a "Return Line." In the annotated illustrations below, the "Return Line" attaches to the handpiece assembly. This "Return Line" serves as a portion of the waste conduit through which the handpiece assembly is in fluid communication with the vacuum source. For

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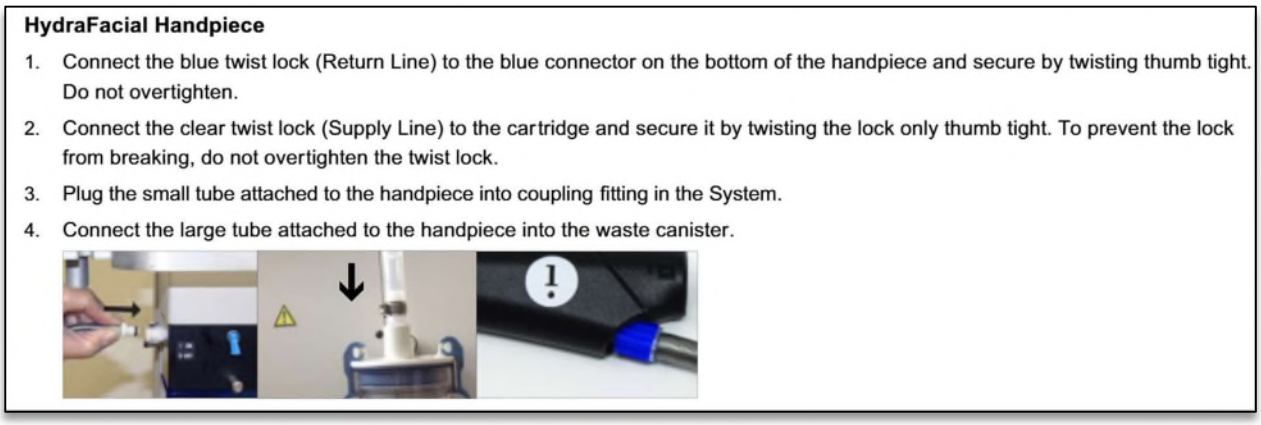
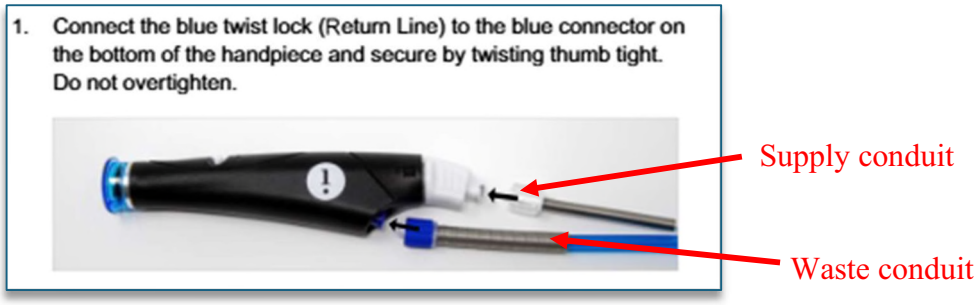
clarity, I have also labeled the supply conduit, which I describe in greater detail above.



Ex. 2031 at 12 (Elite)



Ex. 2034 at 2 (Handpiece User Guide); *see also* Ex. 2030 at 22 (Syndeo IFU) ("Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister.")

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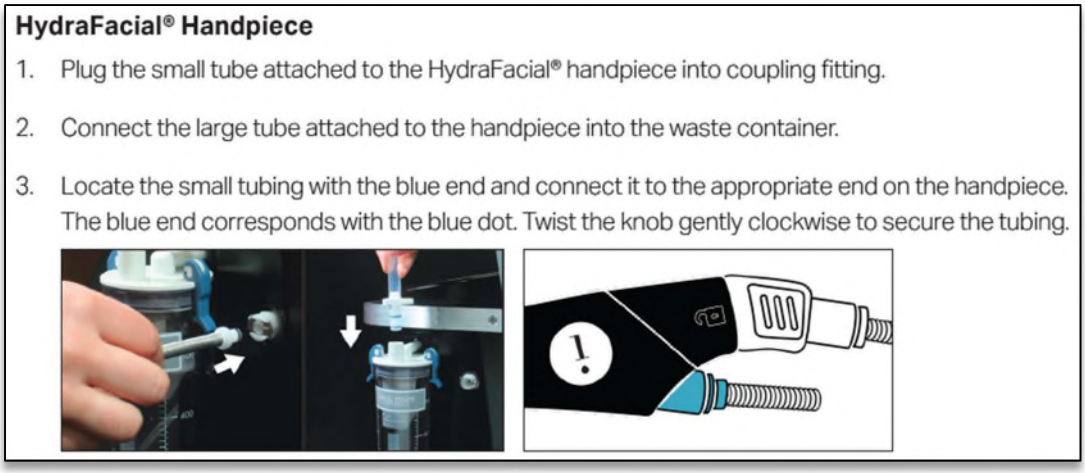
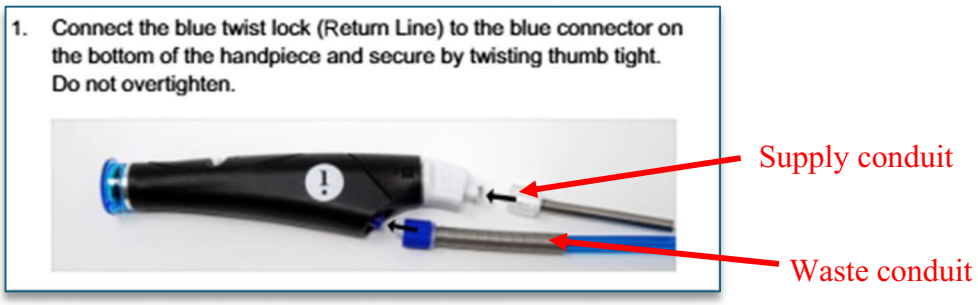


Ex. 2032 at 9 (Allegro).



Ex. 2034 at 2 (Handpiece User Guide); *see also* Ex. 2032 at 17 ("Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste cannister.")

97. Accordingly, this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

g. 1[f]: "at least one control to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly"

98. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "at least one control to permit control of a flow of treatment material from the first

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container and the at least second container through the supply conduit to the handpiece assembly."

99. For the same reasons set forth in limitation 1[b], each of the Syndeo, Elite, Allegro, and Tower has a handpiece assembly.

100. For the same reasons set forth in limitation 1[b], each of the Syndeo, Elite, Allegro, and Tower has a supply conduit that extends from the handpiece assembly to the manifold system, which is in fluid communication with the fluid containers (including the first and second fluid containers).

101. For the same reasons set forth in limitation 1[a][ii], each of the Syndeo, Elite, Allegro, and Tower has a first container and at least a second container that contains treatment material.

102. Further, in my opinion, each of the Syndeo, Elite, Allegro, and Tower has "at least one control to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly."

103. My inspection of the Syndeo confirmed that this limitation is satisfied. As shown in the below photos, the Syndeo system includes a manifold system in the console with tubing to receive treatment material from containers connected to the console. The manifold system is in fluid communication with tubing extending from

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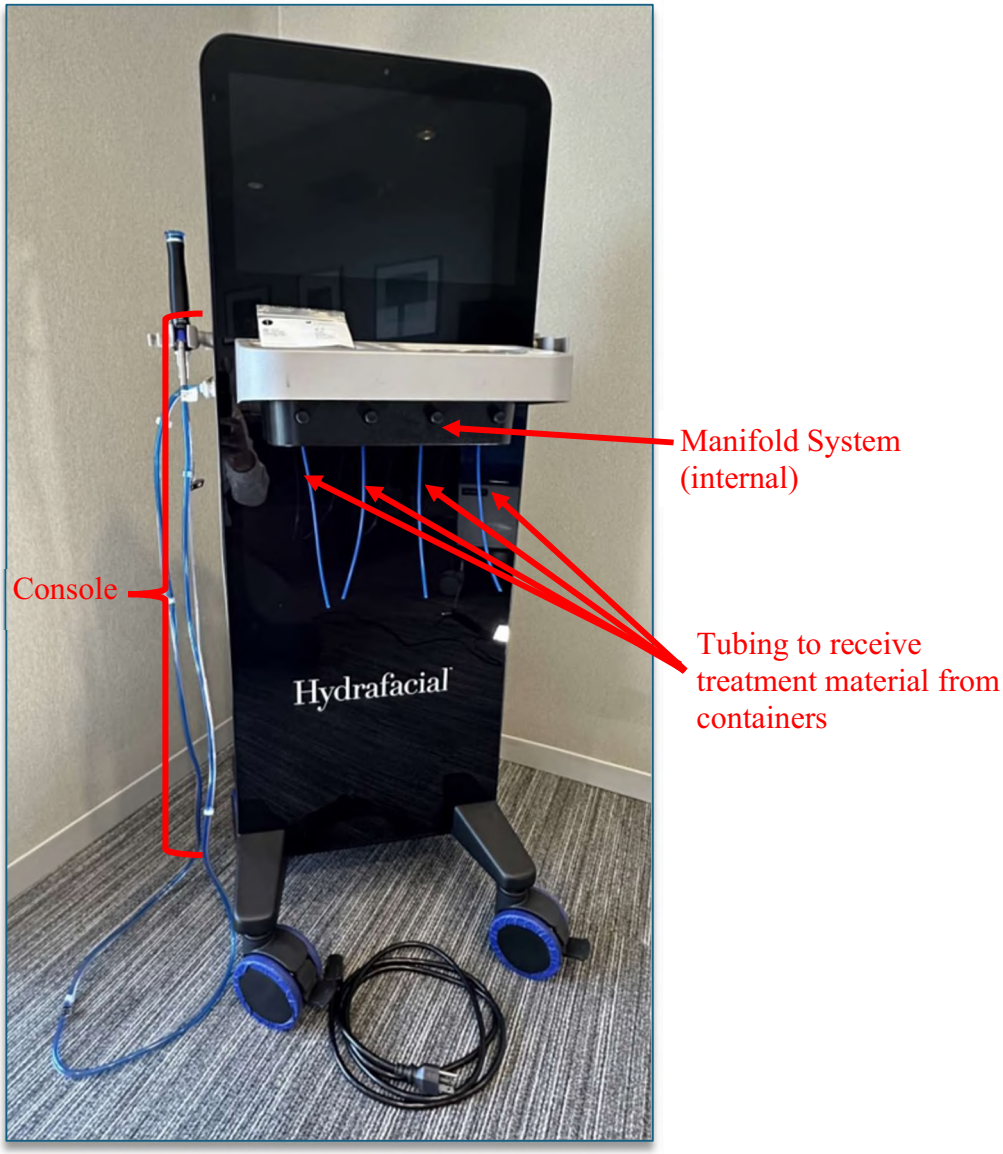
the manifold system. The manifold system is configured to receive treatment material, through the tubing, from the containers when the containers are connected



to the console.

Ex. 2081 (Syndeo).

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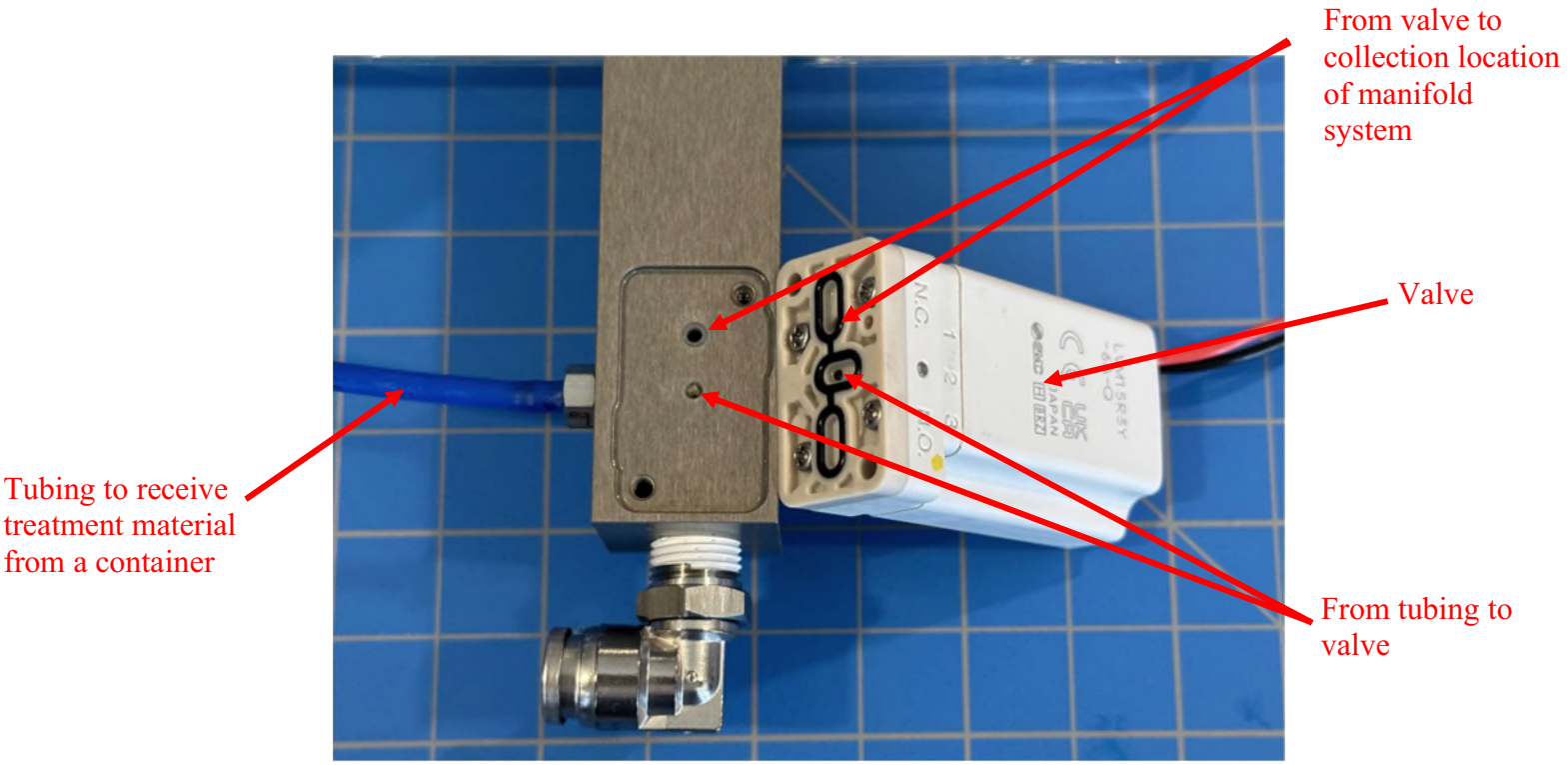
104. As part of my inspection of the Syndeo, I opened the console and took out the manifold system. I observed that the manifold system has tubing to receive fluid from containers extends to their respective valves that control which fluid reaches the outlet of the manifold based on which container a user selects. These valves can control the flow of treatment material from the first and second containers through the supply conduit to the handpiece assembly.



Ex. 2084 (Syndeo).

105. The Syndeo IFU explains that the HydraFacial Syndeo includes "solution bottle controls . . . located on the bottom of the screen within the treatment

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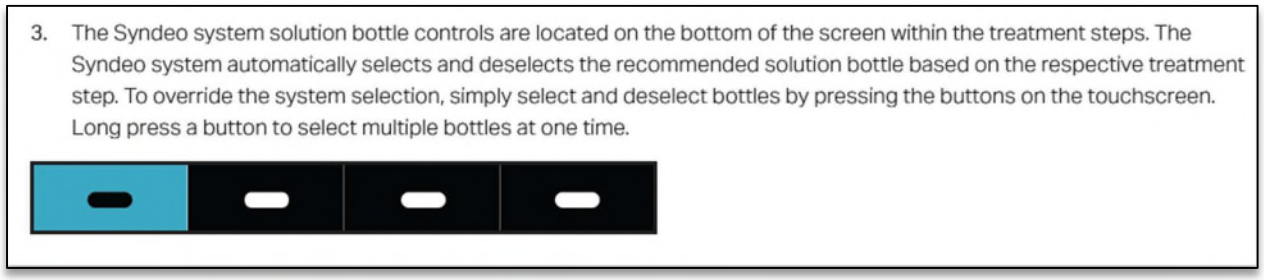
steps." Ex. 2030 at 14. It explains that the system "automatically selects and deselects the recommended solution bottle based on the respective treatment step."



Id. Thus, the HydraFacial Syndeo has at least one control to permit control of a flow of treatment material from the first container and the at least the second fluid container through the supply conduit to the handpiece assembly.

106. The Syndeo also has a flow control slider on the handpiece assembly to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly. As shown in the photo below, the handpiece assembly of the Syndeo has a slider that a user can move to control the flow of the treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly:

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Ex. 2130 (Syndeo).

The flow control slider operates by controlling a valve through which fluid from the block flows; when a user moves the slider in a direction indicating higher flow (towards the "+" sign), the valve of the flow control slider permits the passage of more fluid through the manifold system to the handpiece assembly. Conversely, moving the slider in a direction indicating reduced flow (towards the "-" sign) causes the valve to restrict the flow of fluid through the manifold system to the handpiece assembly.

107. The handpiece IFU also refers to a "flow control valve" that allows a user to adjust the rate of flow of fluids from the selected container, including the first container, to the handpiece during treatment.

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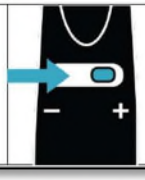
Flow Control Valve

- The flow control valve on the handpiece allows the user to adjust the rate of flow during the treatment.
- Turn the flow control valve toward the "+" sign to increase the serum flow or towards the "–" sign to decrease the flow.

- Set flow control valve to desired setting at each step of the treatment protocol. This may vary depending on the solution or serum being used.

Ex. 2034 at 5.

108. The Syndeo IFU states that low or no fluid flow may be caused by an issue with the flow control valve being closed. The IFU's resolution to this issue is to "[m]ake sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign."

Low or No Fluid Flow	Empty bottle	Make sure your skin solution bottle is not empty.
	Improper connection	Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister. Also, make sure that the lid is firmly attached to the waste canister.
	Tip is improperly installed	Make sure the tip is firmly installed onto the handpiece. Angled tips should face downwards in order to facilitate flow.
	Flow control valve is closed	Make sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign. 

Ex. 2030 at 22 (Syndeo).

109. My inspection of the Elite confirmed that this limitation is satisfied. As shown in the below photos, the Elite system includes a manifold system in the console with tubing to receive treatment material from containers connected to the

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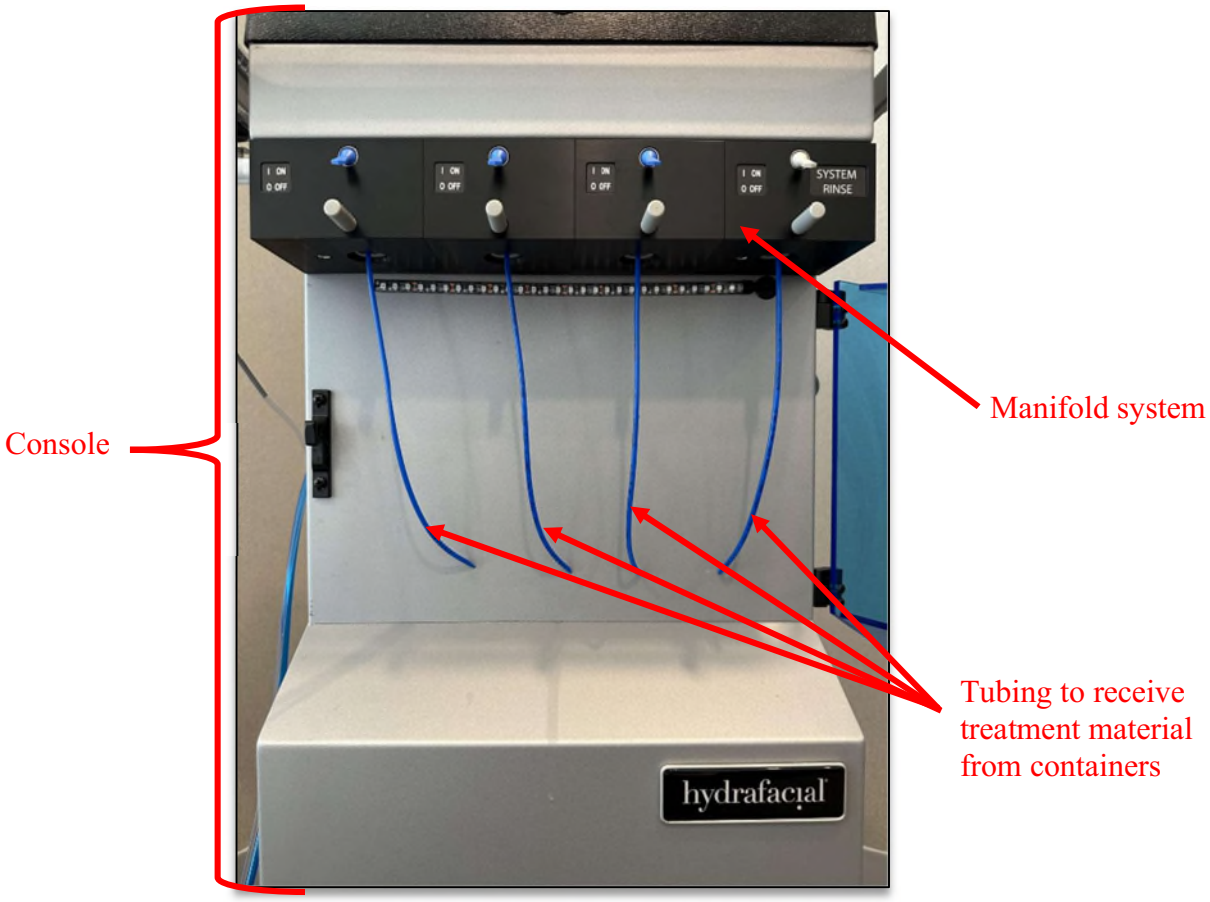
console. The manifold system is in fluid communication with tubing extending from the manifold system. The manifold system is configured to receive treatment material, through the tubing, from the containers when the containers are connected to the console.



Ex. 2135 (Elite).

110. As part of my inspection of the Syndeo, I opened the console and took out the manifold system. I observed that the manifold system has tubing to receive fluid from containers extends to their respective valves that control which fluid reaches the outlet of the manifold based on which container a user selects using

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switches. The switches control the vales that control the flow of treatment material from the first and second containers through the supply conduit to the handpiece assembly.

111. As shown in the drawing below, the manifold system of the HydraFacial Elite has valves that permit control of a flow of the treatment material from the first container and the at least second container.

Ex. 2099 at 265 (Elite)

112. The Elite IFU explains that the manifold system has "toggle switches" that "control which skin solution bottle is being used." Ex. 2031 at 14. It explains

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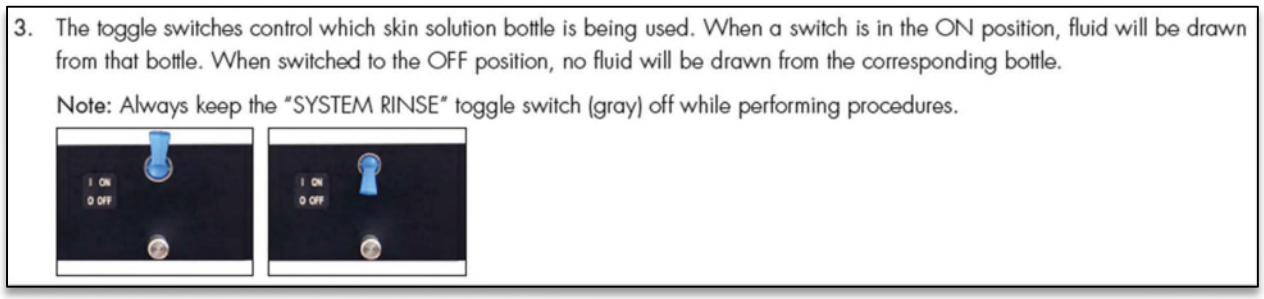
that "[w]hen a switch is in the ON position, fluid will be drawn from that bottle" and "[w]hen switched to the OFF position, no fluid will be drawn from the corresponding bottle." *Id.*



Id. Thus, the HydraFacial Elite has at least one control to permit control of a flow of treatment material from the first container and the at least the second fluid container through the supply conduit to the handpiece assembly.

113. The Elite also has a flow control slider on the handpiece assembly to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly. As shown in the photo below, the handpiece assembly of the Elite has a slider that a user can move to control the flow of the treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly. The flow control slider operates by controlling a valve through which fluid from the block flows; when a user moves the slider in a direction indicating higher flow

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(towards the "+" sign), the valve of the flow control slider permits the passage of more fluid through the manifold system to the handpiece assembly. Conversely, moving the slider in a direction indicating reduced flow (towards the "-" sign) causes the valve to restrict the flow of fluid through the manifold system to the handpiece assembly.

Ex. 2130 (Elite).

114. The handpiece IFU describes the "flow control valve" that allows a user to adjust the rate of flow of fluids from the selected container, including the first container, to the handpiece during treatment.

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Flow Control Valve

- The flow control valve on the handpiece allows the user to adjust the rate of flow during the treatment.
- Turn the flow control valve toward the "+" sign to increase the serum flow or towards the "–" sign to decrease the flow.

- Set flow control valve to desired setting at each step of the treatment protocol. This may vary depending on the solution or serum being used.

Ex. 2034 at 5.

115. The Elite IFU states that low or no fluid flow may be caused by an issue with the flow control valve being closed. The IFU's resolution to this issue is to "[m]ake sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign."

Low or No Fluid Flow	Toggle switch	Make sure the switch is on.
	Empty bottle	Make sure your skin solution bottle is not empty.
	Improper connection	Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister. Also, make sure that the lid is firmly attached to the waste canister.
	Tip is improperly installed	Make sure the tip is firmly installed onto the handpiece. Angled tips should face downwards in order to facilitate flow.
	Flow control valve is closed	Make sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign.

Ex. 2031 at 20 (Elite).

116. My inspection of the Allegro confirmed that this limitation is satisfied. As shown in the below photos, the Allegro system includes a manifold system in the

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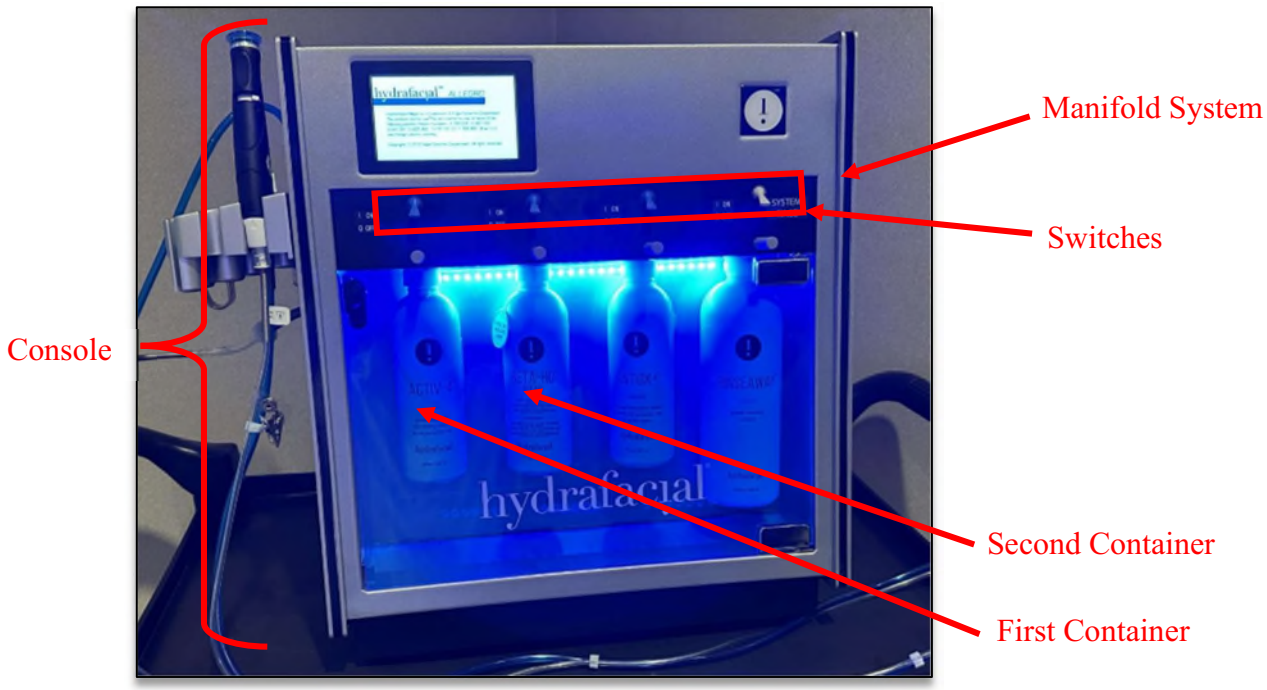
console with tubing to receive treatment material from containers connected to the console. The manifold system is in fluid communication with tubing extending from the manifold system. The manifold system is configured to receive treatment material, through the tubing, from the containers when the containers are connected to the console.



Ex. 2117 (Allegro).

117. As part of my inspection of the Allegro, I opened the console and took out the manifold system. I observed that the manifold system has tubing to receive fluid from containers extends to their respective valves that control which fluid reaches the outlet of the manifold based on which container a user selects using the

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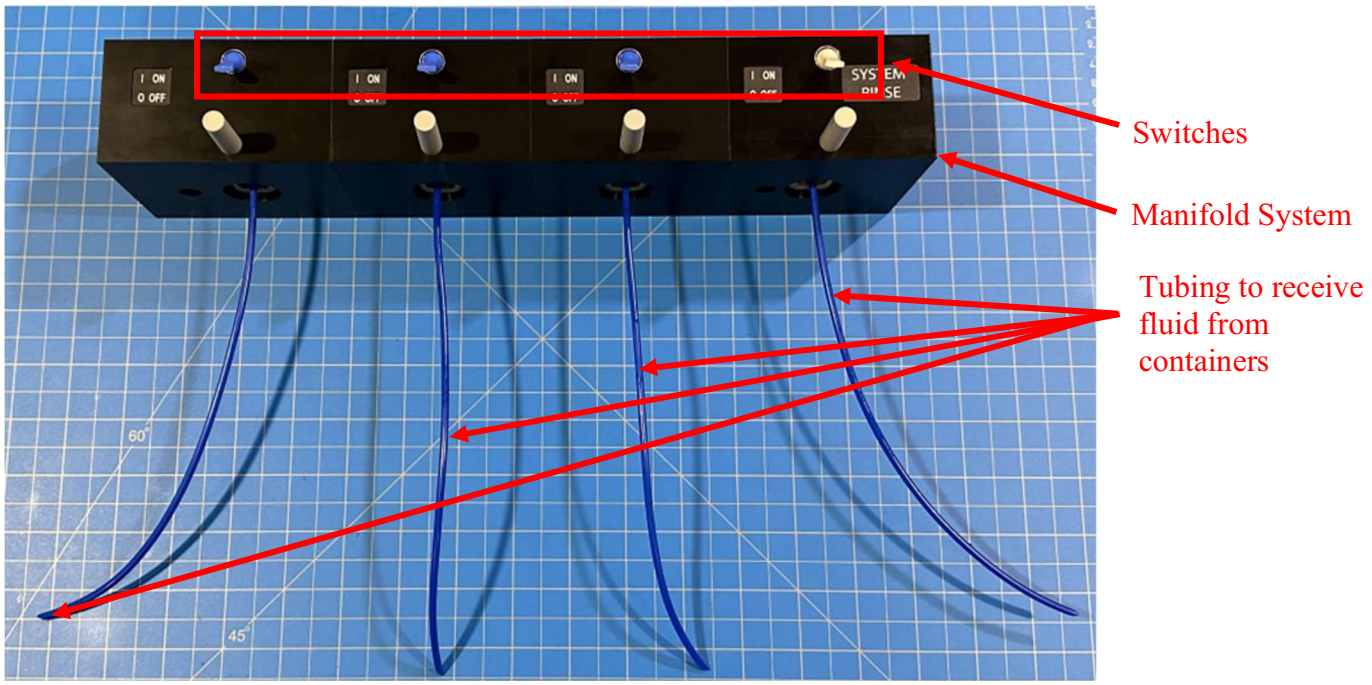
switches. The switches control the valves that control the flow of treatment material from the first and second containers through the supply conduit to the handpiece assembly.



Ex. 2095 (Allegro).

118. The Allegro IFU explains that a user may select which bottle (and thus which skin solution) used during treatment by using the toggle switches on the manifold system for each bottle. It further states that "[w]hen a switch is in the ON position, fluid will be drawn from that bottle" and "[w]hen switched to the OFF position, no fluid will be drawn from the corresponding bottle." Ex. 2031 at 14. Since these switches permit control of a flow from a switched ON container, the HydraFacial Allegro has at least one control to permit control of a flow of treatment

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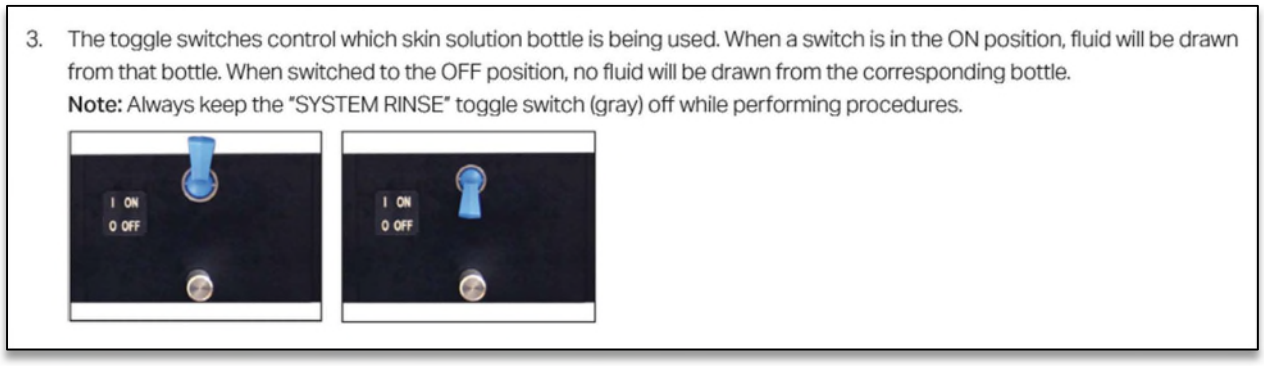
material from the first container and the at least second container through the supply conduit to the handpiece assembly.



Ex. 2031 at 14.

119. The Allegro also has a flow control slider on the handpiece assembly to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly. As shown in the photo below, the handpiece assembly of the Allegro has a slider that a user can move to control the flow of the treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly:

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Ex. 2130 (Allegro). The flow control slider operates by controlling a valve through which fluid from the block flows; when a user moves the slider in a direction indicating higher flow (right to the "+" sign), the valve of the flow control knob permits the passage of more fluid through the block. Conversely, moving the slider in a direction indicating reduced flow (left to the "-" sign) causes the valve to restrict the flow of fluid through the block. Movement of the slider fully towards the "-" sign fully restricts flow between the block and handpiece. Because each fluid flows through the block, the HydraFacial Allegro is configured to control a flow of the first treatment fluid contained in the first container to the handpiece through the block via the flow control slider.

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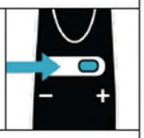
120. The Allegro IFU states that low or no fluid flow may be caused by an issue with the flow control valve being closed. The IFU's resolution to this issue is to "[m]ake sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign."

Low or No Fluid Flow	Toggle Switch	Make sure the switch is on.
	Empty bottle	Make sure your skin solution bottle is not empty.
	Improper connection	Make sure that your HydraFacial® handpiece is properly connected to the side of the skin solution station block, and to the waste container. Also, make sure that the lid is firmly attached to the waste container.
	Tip is improperly installed	Make sure the tip is firmly installed onto the handpiece. Angled tips should face downwards in order to facilitate flow.
	Flow control valve is closed	Make sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign. 
	Leak in the line	Check lines for any kinks or leaks. Repuncture bottle if needed.
	Faulty station	If using only one station at a time, turn current station off and try another station, if this corrects the problem please check on the previous station that internal bottle seal is completely broken and pick up assembly (metal portion) is fully submerged.
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.
	Waste canister is full	**Do not let the waste container fill above 450 mL.** If the container becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste container after each service.
	Clogging	Flush all stations thoroughly. Make sure the machine is cleaned after each service.
	Gray Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.
Too Much Fluid Flow	Flow control valve is opened too far	Make sure the flow control valve on the handpiece is not opened too far. The default setting for the flow control valve is 50% open. To decrease fluid flow, turn the flow control valve towards the – sign.
	Position of the machine	Place the unit on a sturdy stand or table that is 32" or less from the floor. The unit must be located lower than the treatment bed to prevent the skin solutions from siphoning out of the handpiece.

Ex. 2032 at 27 (Allegro).

121. My review of photos and videos of the Tower confirmed that this limitation is satisfied. As shown in the below photos, the Tower system includes a manifold system in the console with tubing to receive treatment material from

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containers connected to the console. The manifold system is in fluid communication with tubing extending from the manifold system. The manifold system is configured to receive treatment material, through the tubing, from the containers when the containers are connected to the console.

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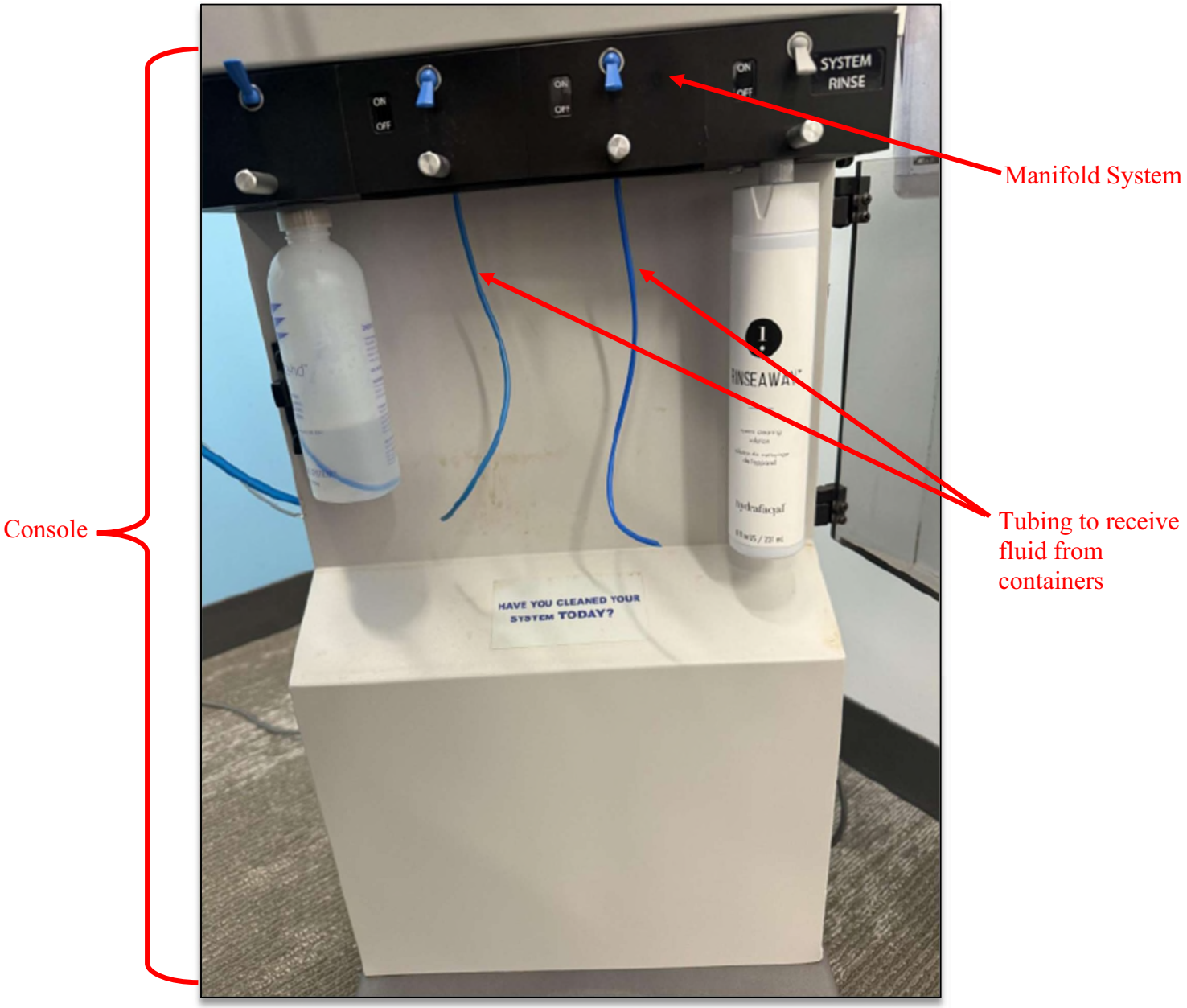

Ex. 2118 (Tower).

122. When the manifold system of the Tower is removed from the console, the manifold system has tubing to receive fluid from containers extends to their

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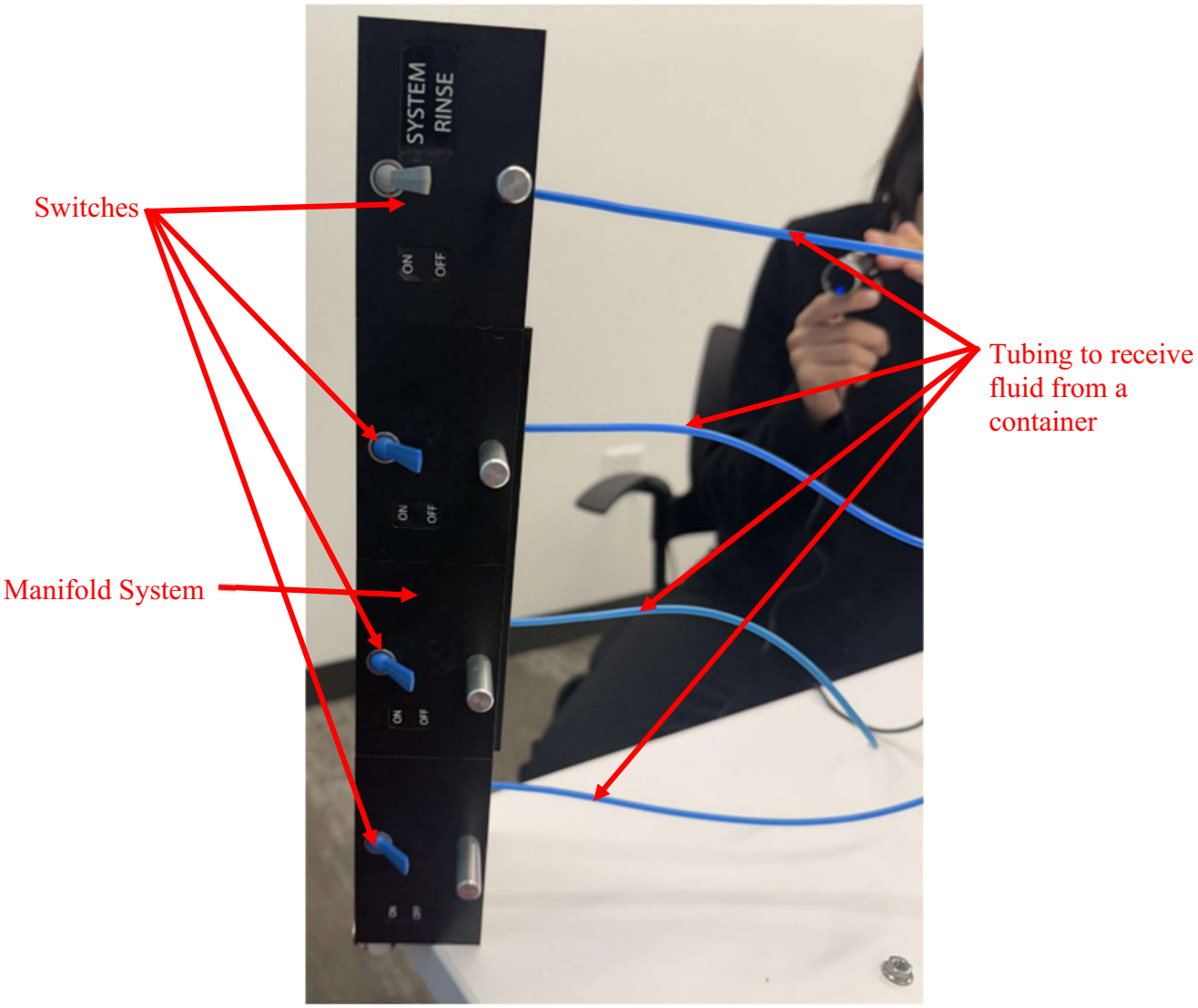
respective valves that control which fluid reaches the outlet of the manifold based on which container a user selects using switches. The switches control the vales that control the flow of treatment material from the first and second containers through the supply conduit to the handpiece assembly.



Ex. 2092 (Tower).

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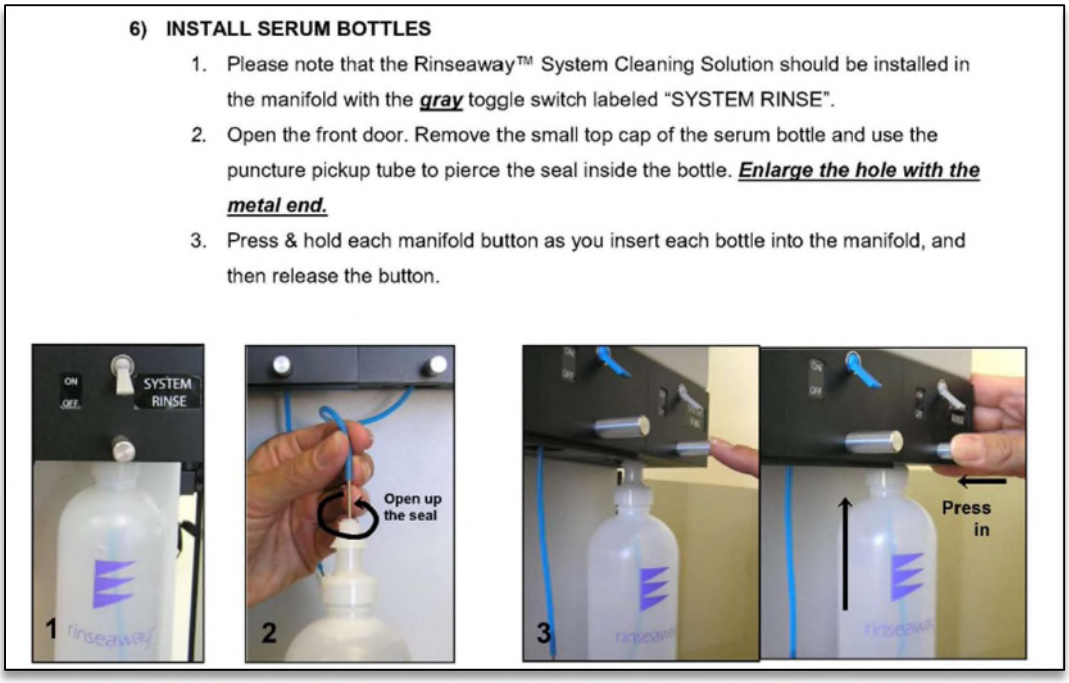
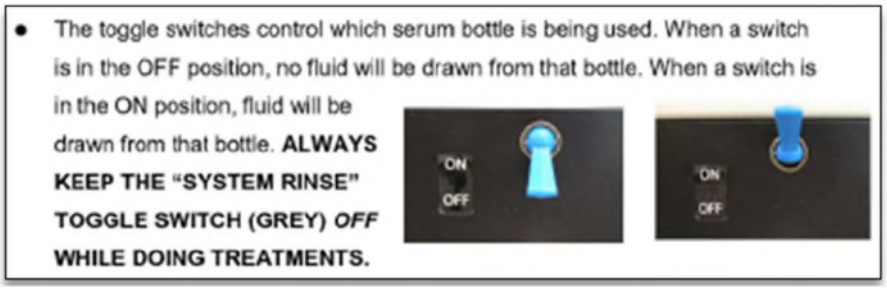
123. The Tower IFU describes connecting the containers, including the first container and the at least second container, to the manifold system such that the manifold system can control a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly. The manifold system has toggle switches that determine which container the manifold system will receive fluid from.



Ex. 2125 at 13 (Tower).



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Ex. 2033 at 13 (Tower).

124. Given the similarities between the Tower handpiece and Allegro and Elite handpieces, I have concluded that the Tower handpiece would similarly have a flow control slider on the handpiece assembly to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly.

125. Accordingly, this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

h. 1[g]: "wherein the vacuum source is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly to help remove waste from the handpiece assembly via the waste conduit and to help transfer at least one treatment material from the manifold system to the handpiece assembly."

126. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "wherein the vacuum source is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly to help remove waste from the handpiece assembly via the waste conduit and to help transfer at least one treatment material from the manifold system to the handpiece assembly."

127. As explained above, each of the Syndeo, Elite, Allegro, and Tower has: (1) a waste conduit in fluid communication with the handpiece assembly to remove waste away from a working end of the handpiece assembly during a skin treatment

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procedure; (2) a vacuum source; (3) a handpiece assembly with a working end with a skin contact surface that is in fluid communication with the manifold system via a supply conduit; and (4) a manifold system in communication with the first container and the at least a second container with treatment material.

128. For the same reasons set forth in limitation 1[b], each of the Syndeo, Elite, Allegro, and Tower has a handpiece assembly.

129. For the same reasons set forth in limitation 1[c], each of the Syndeo, Elite, Allegro, and Tower has a handpiece assembly with a working end.

130. For the same reasons set forth in limitation 1[a][ii], each of the Syndeo, Elite, Allegro, and Tower has a first container and at least a second container that contains treatment material.

131. For the same reasons set forth in limitation 1[d], each of the Syndeo, Elite, Allegro, and Tower has a vacuum source.

132. For the same reasons set forth in limitation 1[e], each of the Syndeo, Elite, Allegro, and Tower has a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the working end of the handpiece assembly during treatment.

133. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a vacuum source [that] is configured to create a suction force within the waste conduit

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and along the working end of the handpiece assembly to help remove waste from the handpiece assembly via the waste conduit and to help transfer at least one treatment material from the manifold system to the handpiece assembly."

134. A POSA would recognize that each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation under the plain and ordinary meaning of "help transfer."

135. Based on my observation of the Syndeo in operation, the suction force from the vacuum removes waste from the skin surface via the waste conduit that also draws treatment material from the first container or the at least a second container to the working end of the handpiece assembly via the supply conduit. The vacuum source works with multiple components of the Syndeo system to help transfer at least one treatment material from at least one container from the manifold system to the hand piece assembly. For example, the vacuum source works with the waste conduit, waste container, handpiece assembly, supply conduit, and manifold assembly to help transfer at least one treatment material from at least one container to the handpiece assembly. I observed that when the vacuum source is activated and the handpiece assembly is contacting skin, a closed system is formed between a selected container and the vacuum source to transfer a treatment material from a container to the handpiece assembly.

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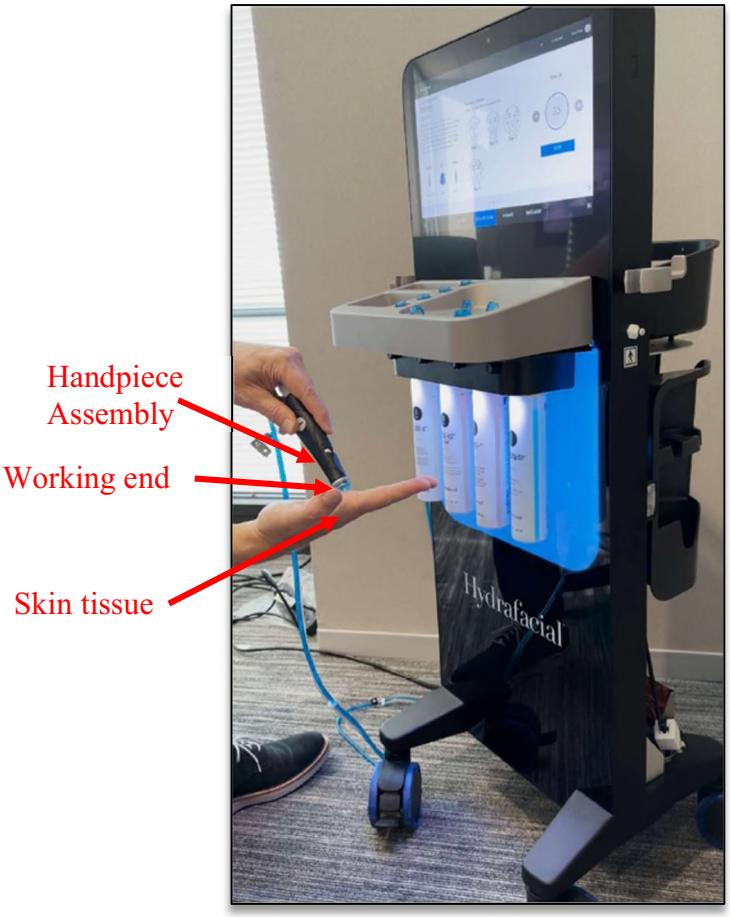

Ex. 2078 at 1 (Syndeo).

136. The Syndeo IFU instructs users to place the handpiece assembly against skin during treatment while the vacuum is on to occlude and dab skin solution onto the skin. By following these instructions, the vacuum source works with the waste conduit, waste container, handpiece assembly, supply conduit, and manifold assembly to help transfer at least one treatment material from at least one container to the handpiece assembly.

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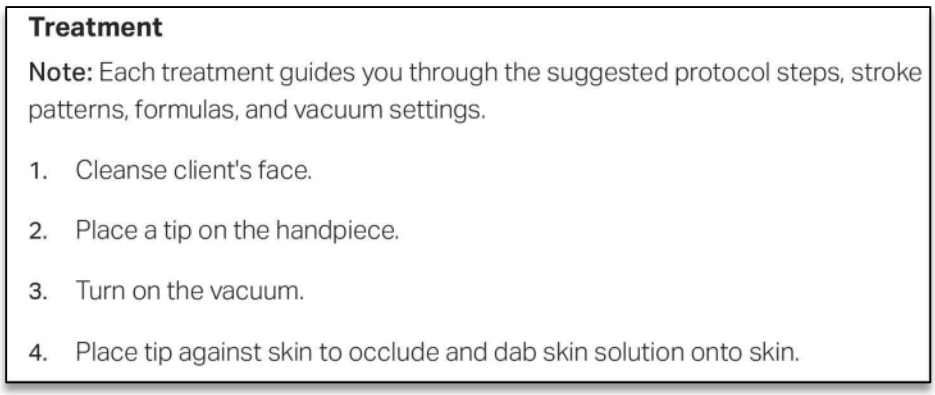

Treatment

Note: Each treatment guides you through the suggested protocol steps, stroke patterns, formulas, and vacuum settings.

1. Cleanse client's face.
2. Place a tip on the handpiece.
3. Turn on the vacuum.
4. Place tip against skin to occlude and dab skin solution onto skin.

Ex. 2030 at 19 (Syndeo).

137. The "Troubleshooting" section of the Syndeo IFU warns that, "[i]f the canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease." Ex. 2030 at 22. The recommended solution to this situation is to "[e]mpty the waste canister after each service." *Id.* Thus, the vacuum draws from either the first container or the second container to the handpiece assembly when the tip is pressed against skin.

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Low or No Fluid Flow	Leak in the line	Check lines for any kinks or leaks.
	Too many solution stations are on	Make sure you only have a maximum of two skin solution stations selected at one time.
	Faulty station	If using only one station at a time, deselect current station and try another station. If this corrects the problem please check on the previous station that the internal bottle seal is completely broken and pick up assembly (straw) is fully submerged. Repuncture the bottle if needed.
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.
	Waste canister is full	Do not let the waste canister fill above 450 mL. If the canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste canister after each service.
	Clogging	Flush all stations thoroughly. Make sure the System is cleaned after each service.
	Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.

Ex. 2030 at 22 (Syndeo).

138. Based on my observation of the Elite and Allegro in operation, for each system, the suction force from the vacuum removes waste from the skin surface via the waste conduit that also draws treatment material from the first container or the at least a second container to the working end of the handpiece assembly via the supply conduit. The vacuum source works with multiple components of each of the Elite and Allegro to help transfer at least one treatment material from at least one container from the manifold system to the hand piece assembly. For example, the vacuum source works with the waste conduit, waste container, handpiece assembly, supply conduit, and manifold assembly to help transfer at least one treatment material from at least one container to the handpiece assembly. For each of the Elite and Allegro, I observed that when the vacuum source is activated and the handpiece

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assembly is contacting skin, a closed system is formed between a selected container and the vacuum source to transfer a treatment material from a container to the handpiece assembly. Based on my review of video of the Tower with the cleaning cap on, it is my understanding that it operates the same as the Elite and Allegro when the handpiece assembly contacts the skin.

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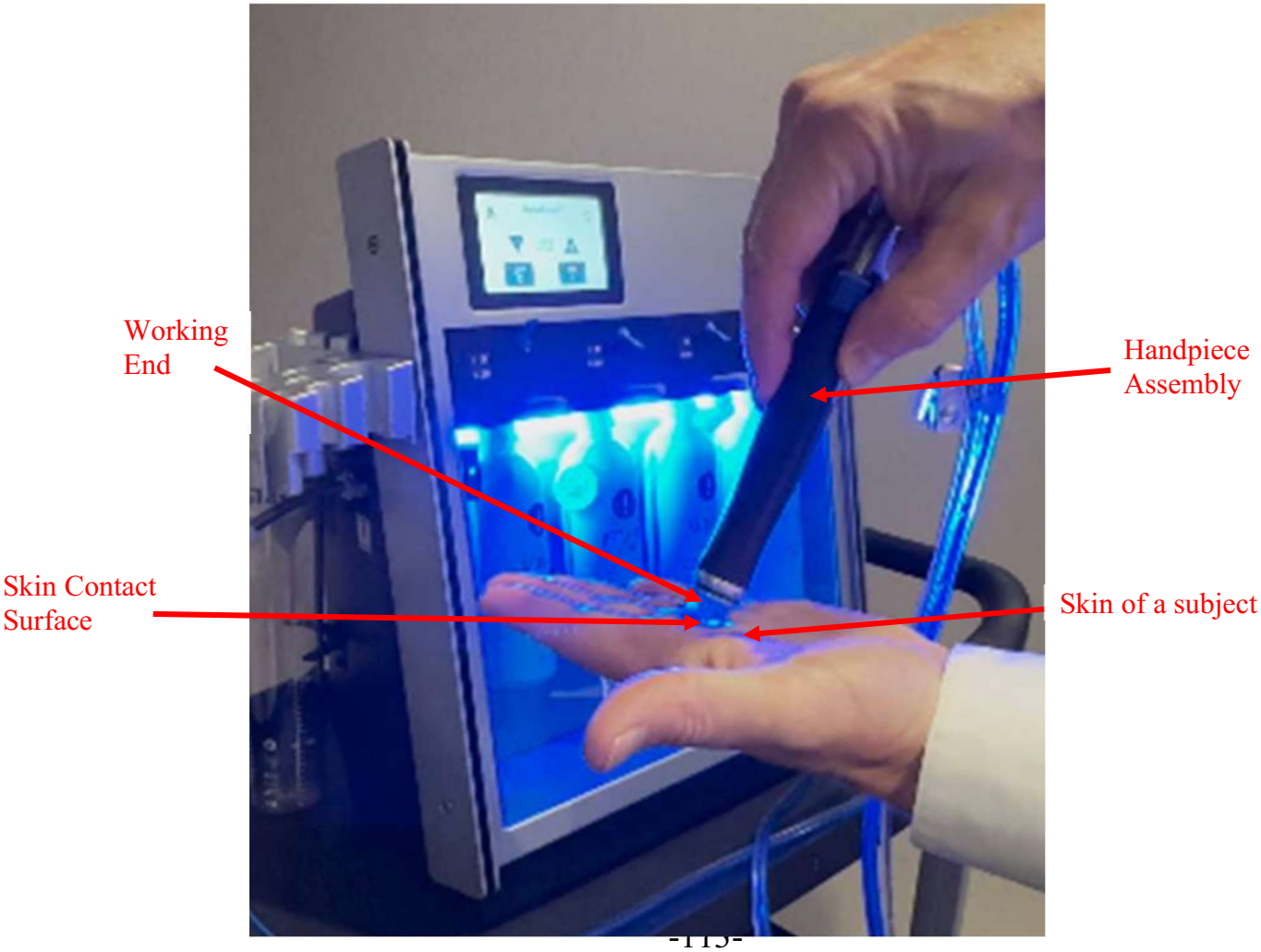
Ex. 2079 at 3 (Elite).



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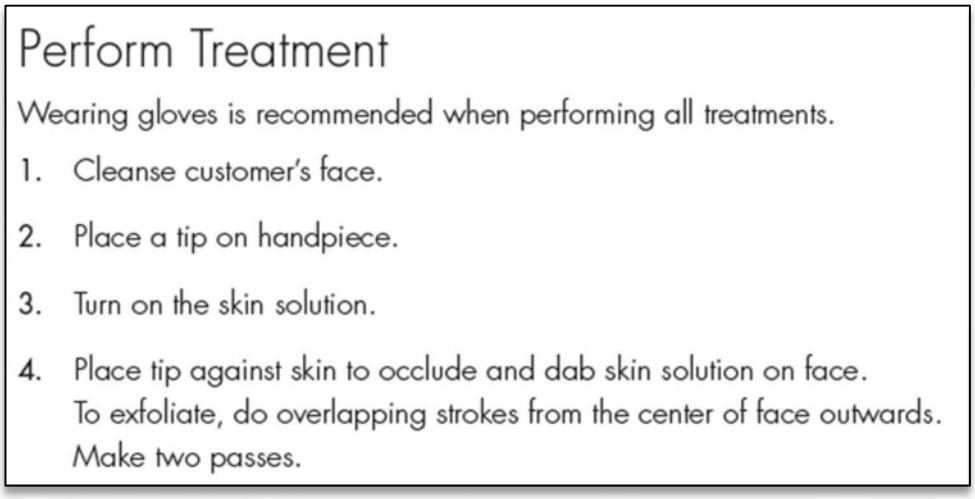
Ex. 2146 (Allegro).

139. The Elite IFU instructs users to place the handpiece assembly against skin during treatment while the vacuum is on to occlude and dab skin solution onto the skin. By following these instructions, the vacuum source works with the waste conduit, waste container, handpiece assembly, supply conduit, and manifold assembly to help transfer at least one treatment material from at least one container to the handpiece assembly.


Perform Treatment

Wearing gloves is recommended when performing all treatments.

1. Cleanse customer's face.
2. Place a tip on handpiece.
3. Turn on the skin solution.
4. Place tip against skin to occlude and dab skin solution on face. To exfoliate, do overlapping strokes from the center of face outwards. Make two passes.

Ex. 2031 at 17 (Elite).

140. The "Troubleshooting" section of the Allegro IFU and Elite IFU warns that, "[i]f the canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease." Ex. 2031 at 20; Ex. 2032 at 17. The recommended solution to this situation is to "[e]mpty the waste canister after each service." *Id*. Thus, the suction force generated by the vacuum

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source both helps remove waste from the hand piece assembly via the waste conduit and helps transfer at least one treatment material from the manifold system to the handpiece assembly.

Low or No Fluid Flow	Leak in the line	Check lines for any kinks or leaks.
	Too many solution stations are on	Make sure you only have a maximum of two skin solution stations on the ON position.
	Faulty station	If using only one station at a time, turn current station off and try another station. If this corrects the problem please check on the previous station that internal bottle seal is completely broken and pick up assembly (metal portion) is fully submerged. Repuncture bottle if needed.
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.
	Waste canister is full	Do not let the waste canister fill above 450 mL. If the canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste canister after each service.
	Clogging	Flush all stations thoroughly. Make sure the System is cleaned after each service.
	Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.

Ex. 2031 at 20 (Elite).

Low or No Fluid Flow	Toggle Switch	Make sure the switch is on.
	Empty bottle	Make sure your skin solution bottle is not empty.
	Improper connection	Make sure that your HydraFacial® handpiece is properly connected to the side of the skin solution station block, and to the waste container. Also, make sure that the lid is firmly attached to the waste container.
	Tip is improperly installed	Make sure the tip is firmly installed onto the handpiece. Angled tips should face downwards in order to facilitate flow.
	Flow control valve is closed	Make sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign.
	Leak in the line	Check lines for any kinks or leaks. Repuncture bottle if needed.
	Faulty station	If using only one station at a time, turn current station off and try another station, if this corrects the problem please check on the previous station that internal bottle seal is completely broken and pick up assembly (metal portion) is fully submerged.
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.
	Waste canister is full	**Do not let the waste container fill above 450 mL.** If the container becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste container after each service.
	Clogging	Flush all stations thoroughly. Make sure the machine is cleaned after each service.
	Gray Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.

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Ex. 2032 at 17 (Allegro).

141. Based on my observation of the Tower in operation, the suction force from the vacuum removes waste from the skin surface via the waste conduit that also draws treatment material from the first container or the at least a second container to the working end of the handpiece assembly via the supply conduit. The vacuum source works with multiple components of the Tower system to help transfer at least one treatment material from at least one container from the manifold system to the hand piece assembly. For example, the vacuum source works with the waste conduit, waste container, handpiece assembly, supply conduit, and manifold assembly to help transfer at least one treatment material from at least one container to the handpiece assembly. I observed that when the tip is pressed against the skin, the vacuum sources creates a suction force that draws treatment material from either the first container or the at least second container to the handpiece assembly while also removing waste away from the handpiece assembly.

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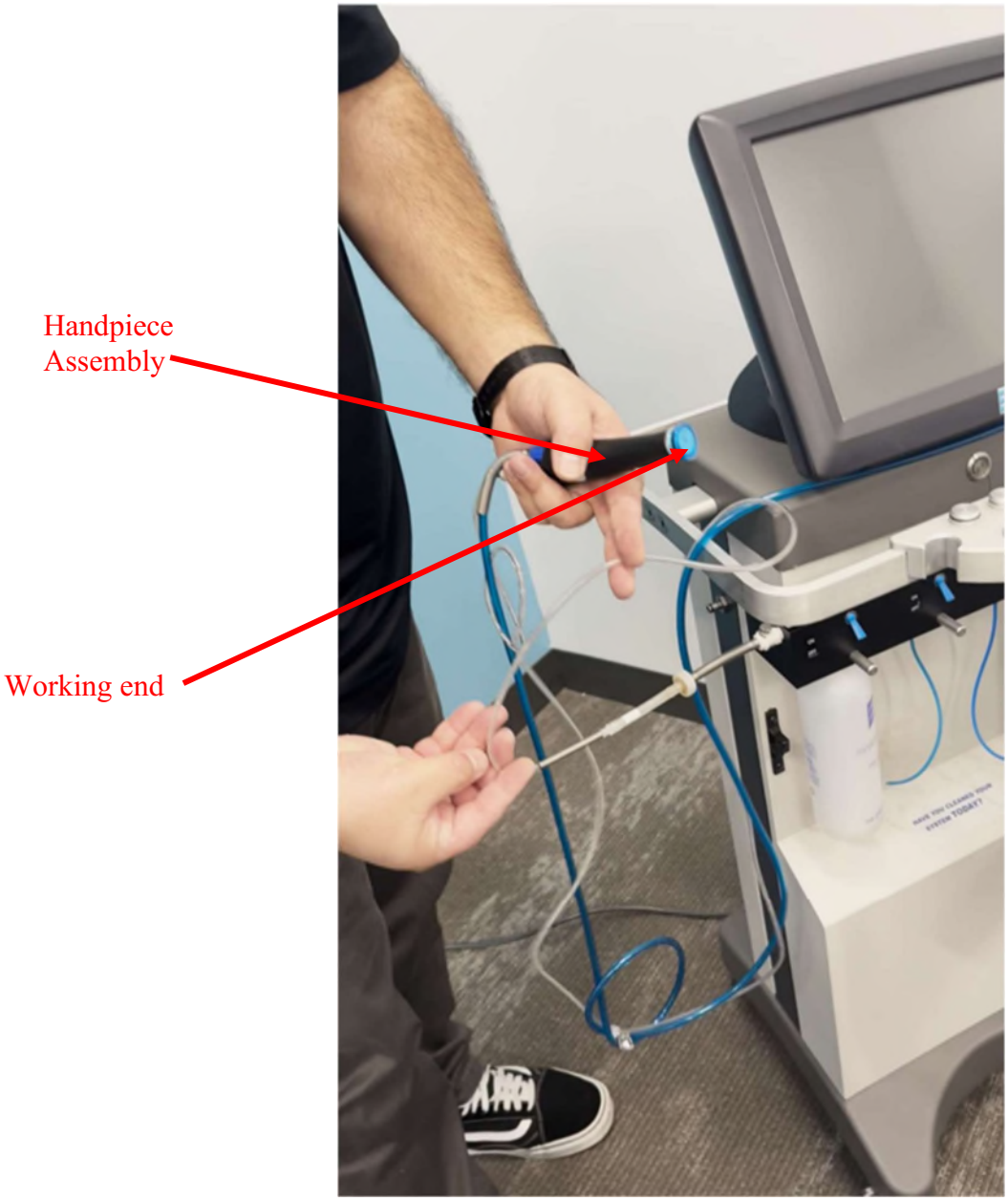

Ex. 2151 at 1 (Tower).

142. Accordingly, this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

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143. For all of these reasons, it is my opinion that each of the Syndeo, Elite, Allegro, and Tower practices Claim 1 of the '477 Patent.

2. Practice of Claim 2

144. Claim 2 of the '477 Patent recites: The system of claim 1, further comprising a computing device configured to control at least one function of the system. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

145. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 1, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "further comprising a computing device configured to control at least one function of the system."

a. Syndeo

146. As shown in the images below, the computing device of the Syndeo assists in operation of the touch screen of the Syndeo, which is used to select containers as well as treatment modes.

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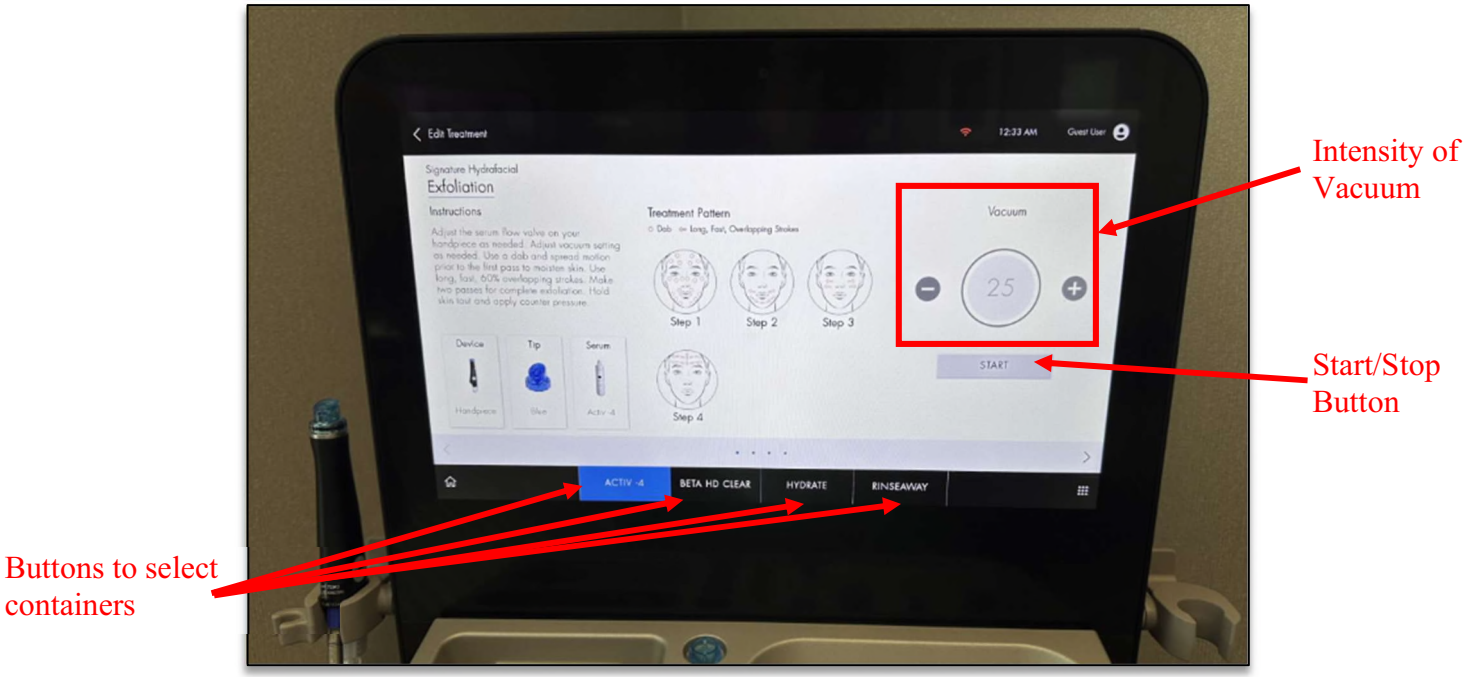

See Ex. 2128 (Syndeo). The above image was derived from a video showing the Syndeo in operation. In the video, the Syndeo touchscreen is visible, and displays options for controlling at least (1) the containers from which the solution dispensed through the handpiece will flow, (2) the start and stop functions for dispensing of a solution through the handpiece, and (3) the intensity of the vacuum generated by the vacuum source. *Id.*; *see also* Ex. 2087 at 2 (showing operation of Syndeo touchscreen to select container).

147. In addition, the Syndeo IFU confirms that the Syndeo has a "touchscreen" that "navigate[s] the system software." Ex. 2030 at 15. The Syndeo IFU states that a user can use the display screen (i.e. computing device) to control (1) the containers from which the solution dispensed through the handpiece will

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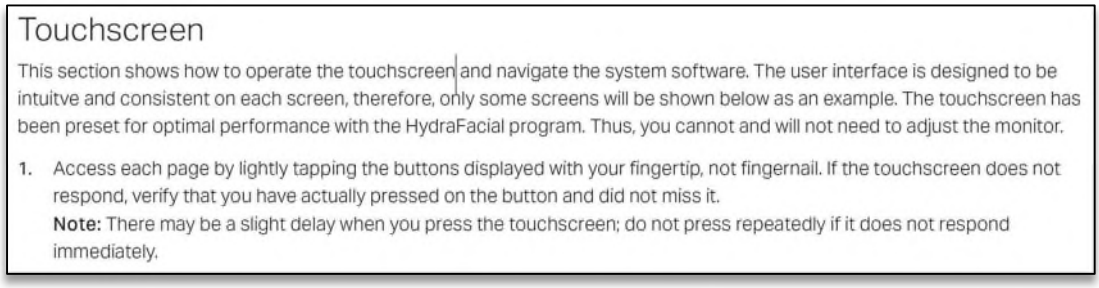
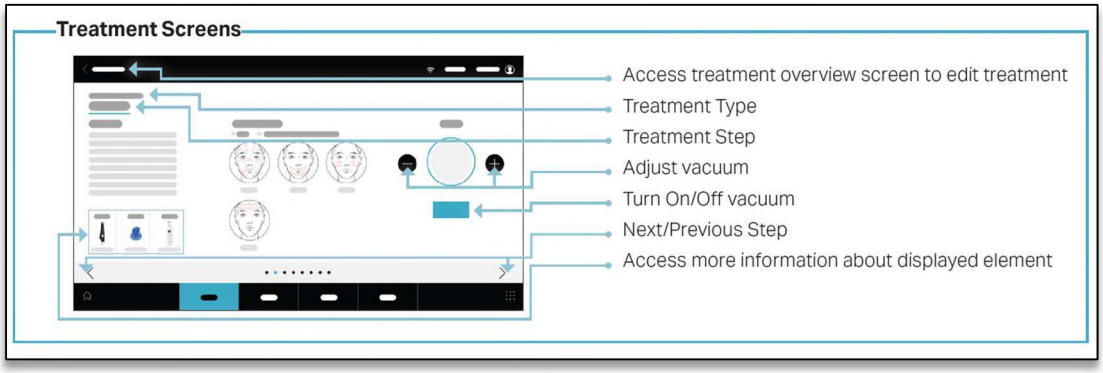
flow, (2) the start and stop functions for dispensing of a solution through the handpiece, and (3) the intensity of the vacuum generated by the vacuum source. *Id.*





Ex. 2030 at 15, 16.

a. Elite, Allegro, and Tower

148. As shown in the images below, the computing device of the Elite and Allegro assists in operation of the touch screen of the Elite and Allegro, which is used to select containers as well as treatment modes.

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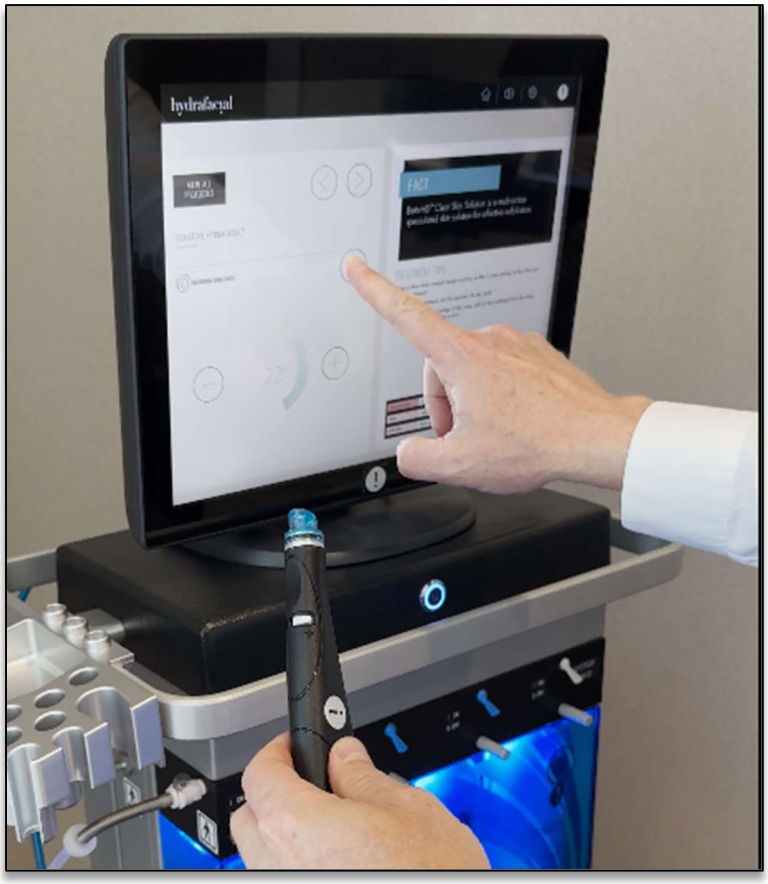

Ex. 2079 at 1.

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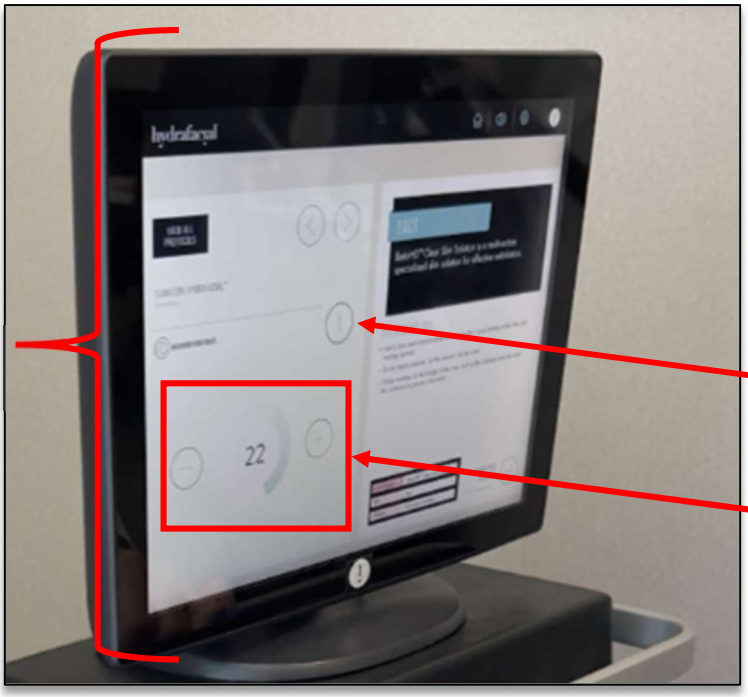
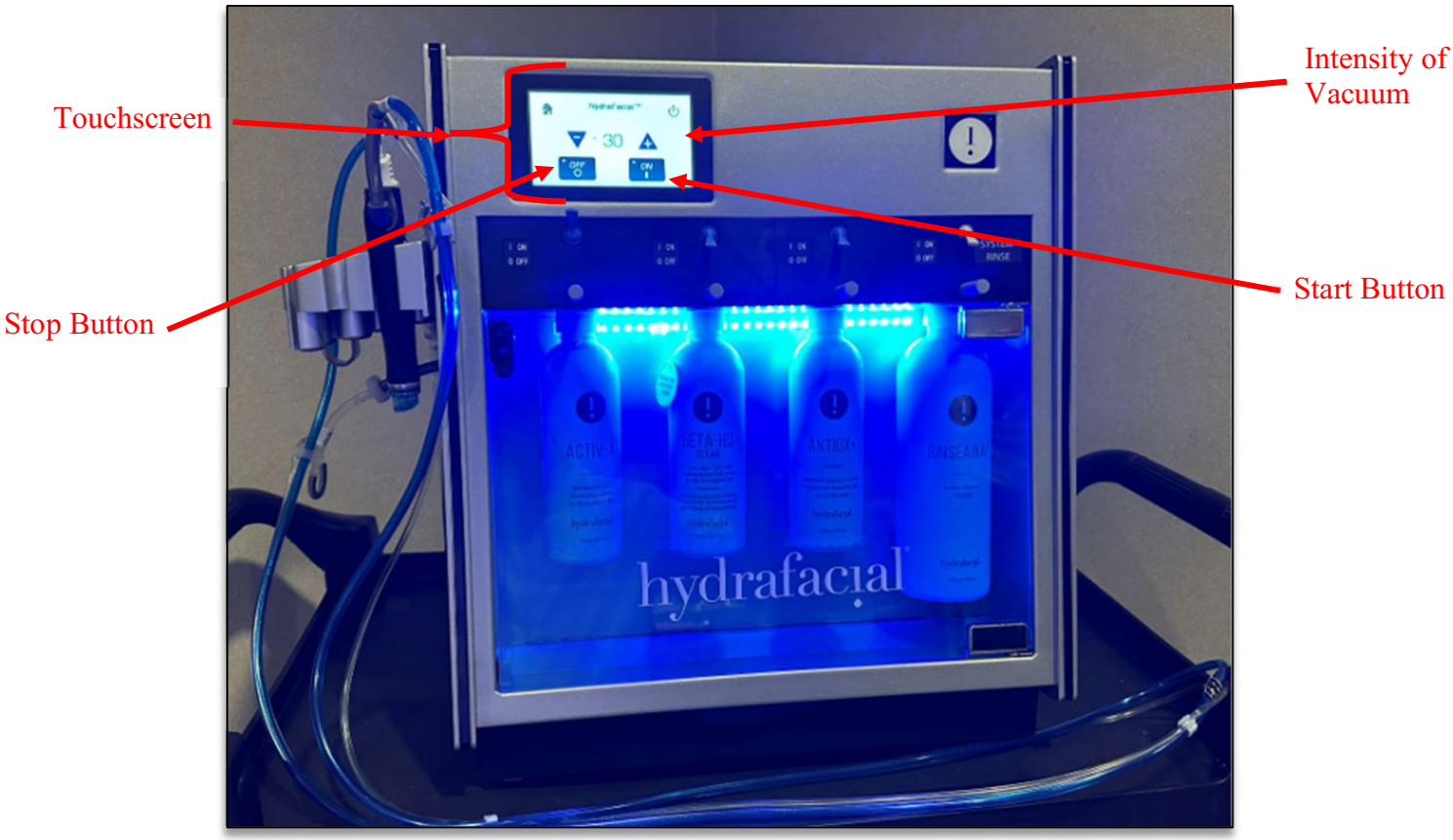


Ex. 2079 at 2.



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Ex. 2153 (Allegro).

149. In the above images, the Elite and Allegro touchscreen displays (ie., user input devices) are visible. Each touchscreen displays options for controlling at least (1) the start and stop functions for dispensing of a solution through the handpiece, and (2) the intensity of the vacuum generated by the vacuum source. See Ex. 2079 at 2 (Elite); Ex. 2153 (Allegro).

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150. In addition, the Elite IFU and the Allegro IFU confirms that the devices have a "touchscreen" that "navigate[s]" the software system. Ex. 2031 at 10 (Elite); Ex. 2032 at 8 (Allegro).

Ex. 2031 at 10 (Elite).

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Ex. 2032 at 8 (Allegro).

151. The Elite IFU and Allegro IFU each state that a user can use the touch screen to control at least (1) the start and stop functions for dispensing of a solution through the handpiece, (2) the intensity of the vacuum generated by the vacuum source, and (3) the desired protocol (Elite) or mode (Allegro). Ex. 2031 at 16 (Elite; Ex. 2032 at 12-13 (Allegro).

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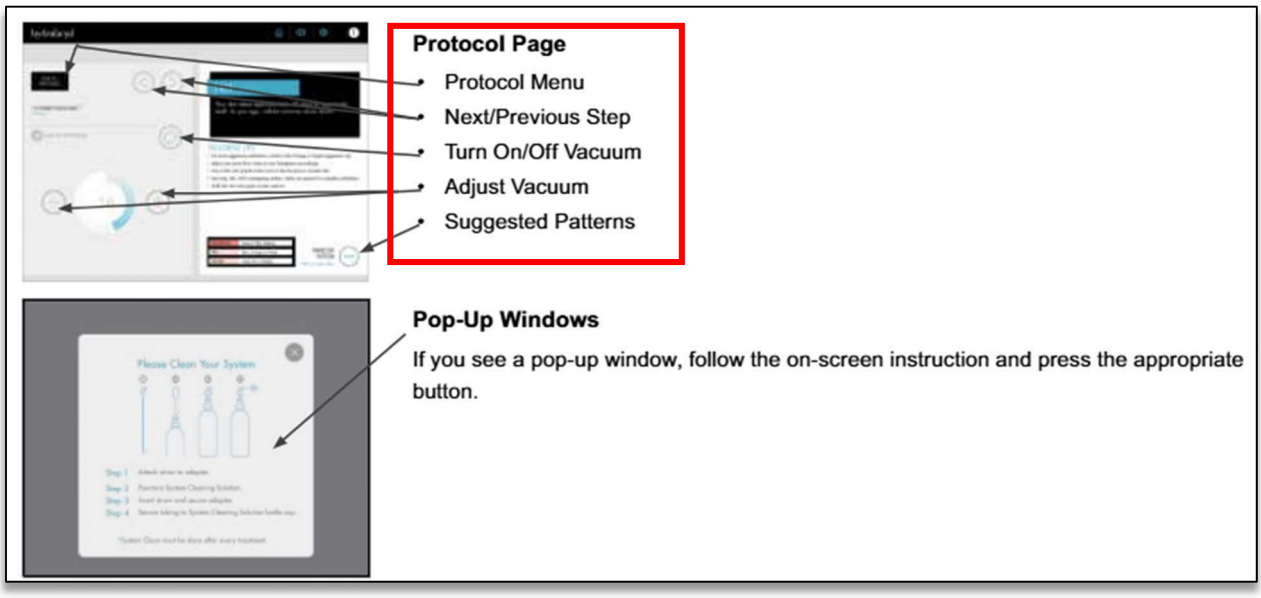

Ex. 2031 at 16 (Elite).

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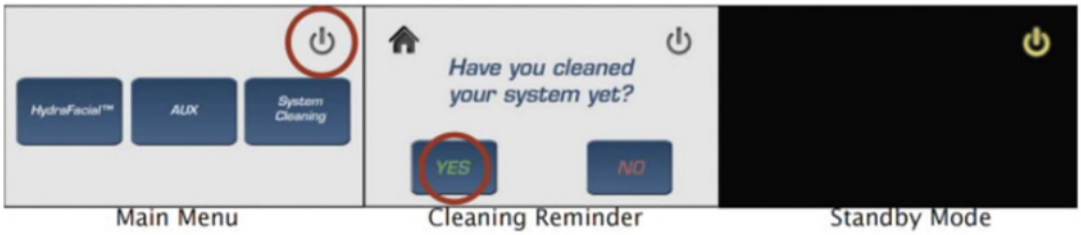
Standby Mode

1. Touch the power symbol on the top right corner of the screen to place the system into standby mode. A cleaning reminder will appear. If you have already cleaned your system, press the 'Yes' button to finish putting the system into standby mode. Remember to always clean your system before turning it off or placing it into standby.



Touchscreen Interface

1. Use your finger to operate the touchscreen interface. Simply touch any icon or button on the screen to invoke its function.

HydraFacial® MODE

1. From the Main Menu, touch the button indicating "HydraFacial®".

Auxiliary Mode

1. From the Main Menu, touch the button indicating "AUX".

System Cleaning Mode

1. From the Main Menu, touch the button indicating "System Cleaning".

Turn The Vacuum On

1. Within each mode, touch the "On" button to start the vacuum.

Turn The Vacuum Off

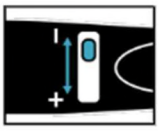
1. Within each mode, touch the "Off " button to stop the vacuum.

Vacuum Adjustment

1. Within each mode, adjust the vacuum level by pressing the triangular vacuum control buttons. Press the up-arrow button (with the plus sign "+" on it) to increase the vacuum. Press the down-arrow button (with the minus sign "-" on it) to decrease the vacuum.
   Note: Use your fingertip, not your fingernail to avoid damage to the screen.

Adjust Fluid Flow

1. Turn the flow control valve towards the + sign to increase fluid flow. Turn towards the - sign to decrease fluid flow.



Return To Main Menu

1. Touch the "Home" button to return to the Main Menu.

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Ex. 2023 at 12-13 (Allegro).

152. The Tower Owner's Manual discloses a similar touch screen where and "[m]ost of the controls for operating HydraFacial™ are accessed via the touch screen":

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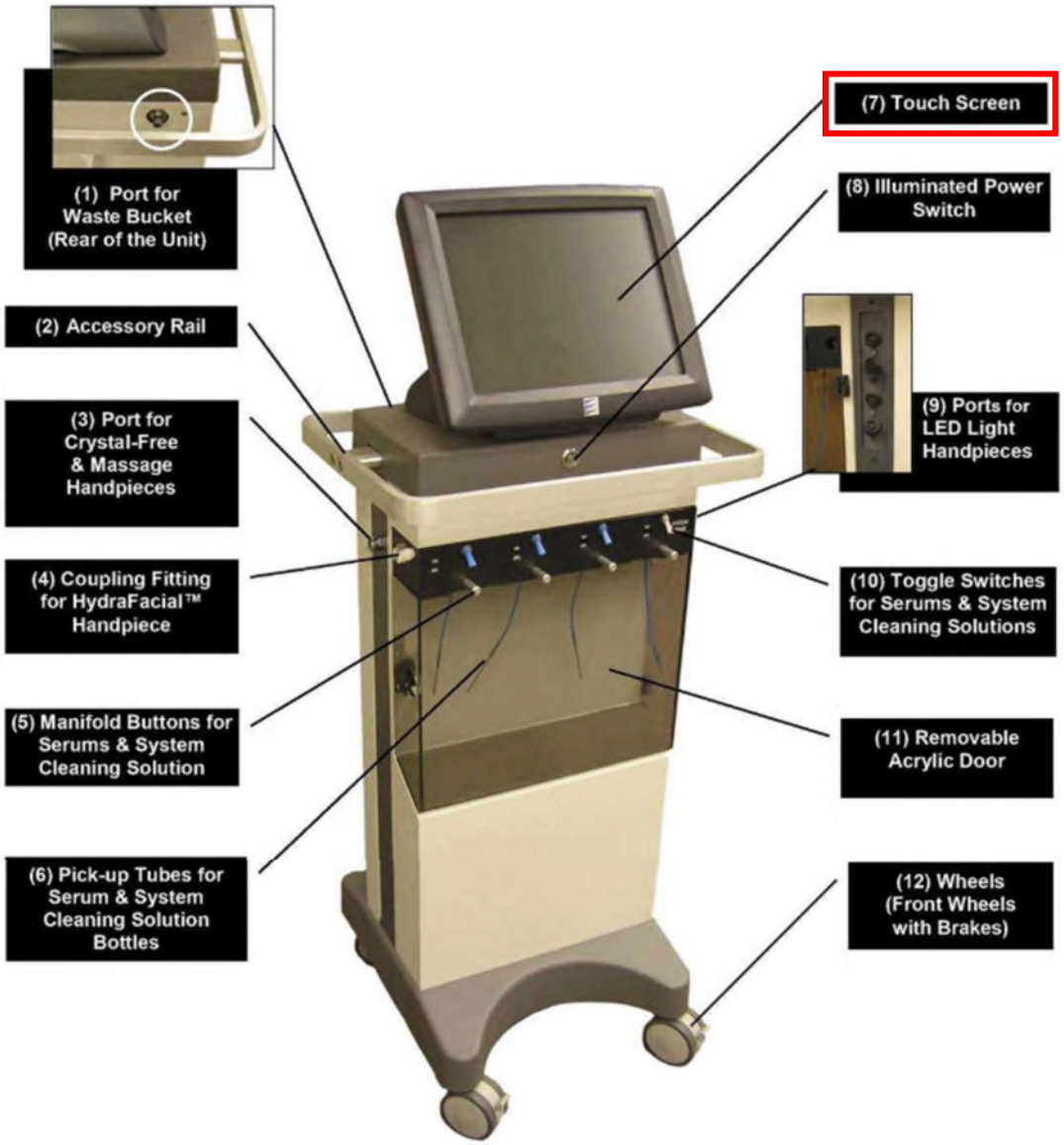

Ex. 2125 at 8.

Specifically, the Tower touchscreen includes display options for controlling at least (1) the start and stop functions for dispensing of a solution through the handpiece, and (2) the intensity of the vacuum generated by the vacuum source.

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153. Technical specifications for each of the Elite, Allegro, and Tower confirm each product has a computing device configured to control several functions of the system.

154. The electrical block diagram for the Elite/Tower shows that each has an "I/O Controller PCBA" that controls the "Vacuum Regulator," "3 Way Valve," and "Red/Blue LED Therapy":

Ex. 2100 at 17 (Elite and Tower).

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155. The electrical block diagram of the Allegro shows that the Allegro has a "I/O Controller PCBA" that controls, inter alia, the "Vacuum Regulator," "3 Way Valve," and "LCD Touch Screen."

Ex. 2100 at 18.

156. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of Claim 2 of the '477 Patent.

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3. Practice of Claim 3

157. Claim 3 of the '477 Patent recites: The system of claim 1, further comprising a user input device to facilitate control of a flow of treatment material from at least one of the first container and the at lease second container to the handpiece assembly. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

158. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 1, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "further comprising a user input device to facilitate control of a flow of treatment material from at least one of the first container and the at lease second container to the handpiece assembly."

159. As explained above in connection with Claim 2, the Syndeo includes a touchscreen that controls, *inter alia*, which container is selected for the flow of fluids to the handpiece. Because the touchscreen requires user input, the Syndeo has a user input device to select a flow of fluids from the first container and the at least one additional container to the handpiece.

160. As discussed above, each of the Elite, Allegro, and Tower includes toggles that the user must switch in order to select a flow of fluids from a container.

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See supra limitation 1[g]. Because the toggles require user input, the Tower has a user input device to select a flow of fluids from the first container and the at least one additional container to the handpiece.

161. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 3 of the '477 Patent.

4. Practice of Claim 4

162. Claim 4 of the '477 Patent recites: The system of claim 3, wherein the user input device comprises a touch screen. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

163. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of Claim 3, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "wherein the user input device comprises a touch screen."

164. As discussed above in connection with Claims 2 and 3, each of the Syndeo, Elite, Allegro, and Tower includes a user input device which comprises a touch screen.

165. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of Claim 4 of the '477 Patent.

5. Practice of Claim 5

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166. Claim 5 of the '477 Patent recites: The system of claim 1, further comprising a display. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

167. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 1, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "further comprising a display."

168. As discussed above in connection with Claim 2, each of the Syndeo, Elite, Allegro, and Tower includes a touchscreen, which is a display.

169. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of Claim 5 of the '477 Patent.

6. Practice of Claim 6

170. Claim 6 of the '477 Patent recites: The system of claim 1, wherein the manifold system is in fluid communication with at least four containers. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

171. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 1, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "wherein the

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manifold is configured to be placed in fluid communication with at least four fluid containers."

172. As discussed above in connection with limitation 1[a][i], the Syndeo, Elite, Allegro, and Tower includes a manifold configured to be placed in fluid communication with at least four fluid containers. *See* Ex. 2030; Ex. 2031; Ex. 2032, Ex. 2125 (each showing the Syndeo, Elite, Allegro, and Tower with four fluid containers in fluid communication with the manifold).

173. Accordingly, the Syndeo, Elite, Allegro, and Tower practices claim 6 of the '477 Patent.

7. Practice of Claim 7

174. Claim 7 of the '477 Patent recites: The system of claim 1, wherein the first container and the at least second container are configured to releasably couple to the manifold system. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

175. In my opinion, the Syndeo practices the limitations of claim 1, as explained above. In my opinion, the Syndeo further satisfies the limitation requiring "the first container and the at least second container are configured to releasably couple to the manifold system."

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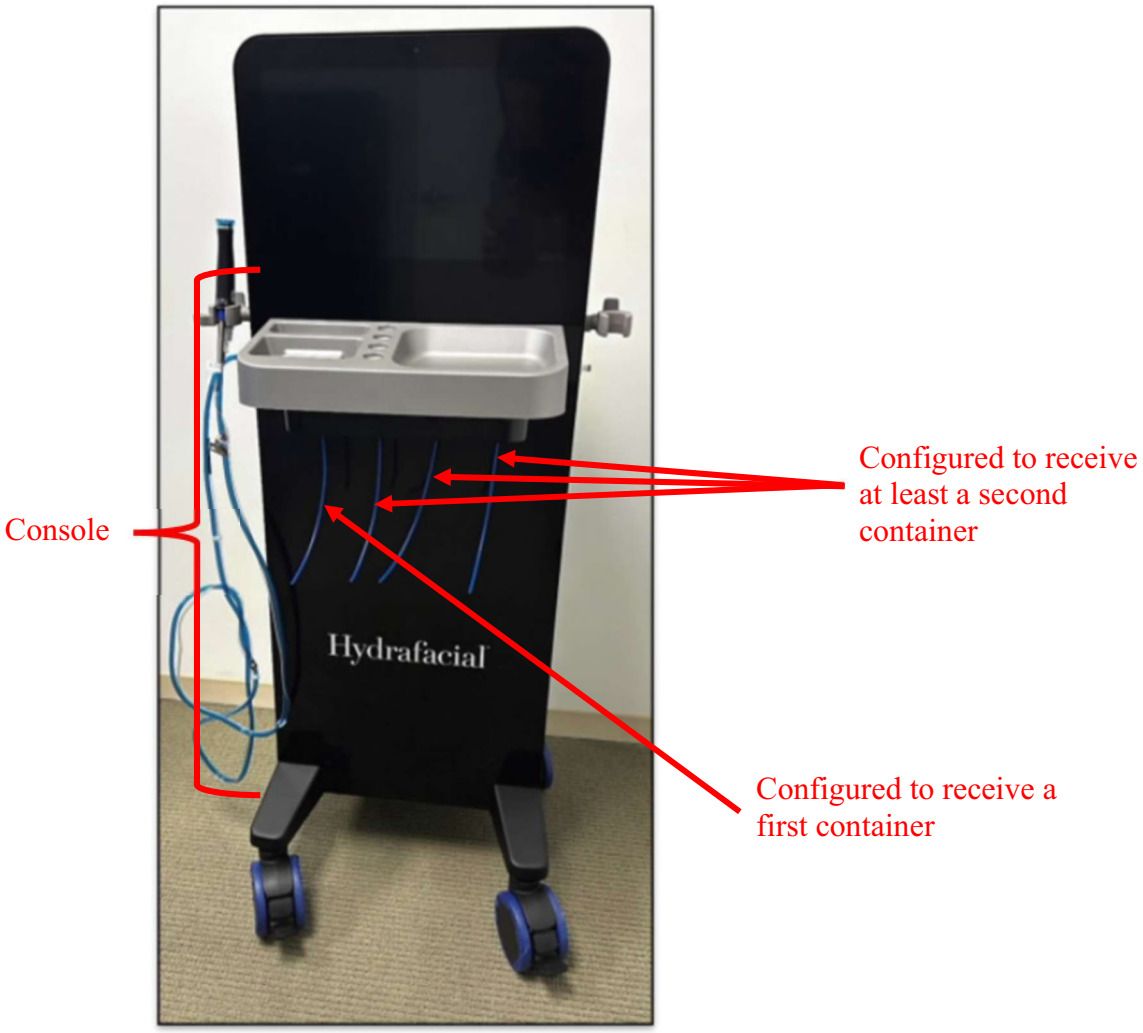
176. Based on my inspection of the Syndeo, I have determined that the first container and the at least second container are configured to releasably couple to the manifold system. The manifold system can receive the containers when a user aligns the container and then pushes the container up until it clicks in. When a user presses the corresponding button, the container is released from the manifold system.



Ex. 2127 Syndeo.

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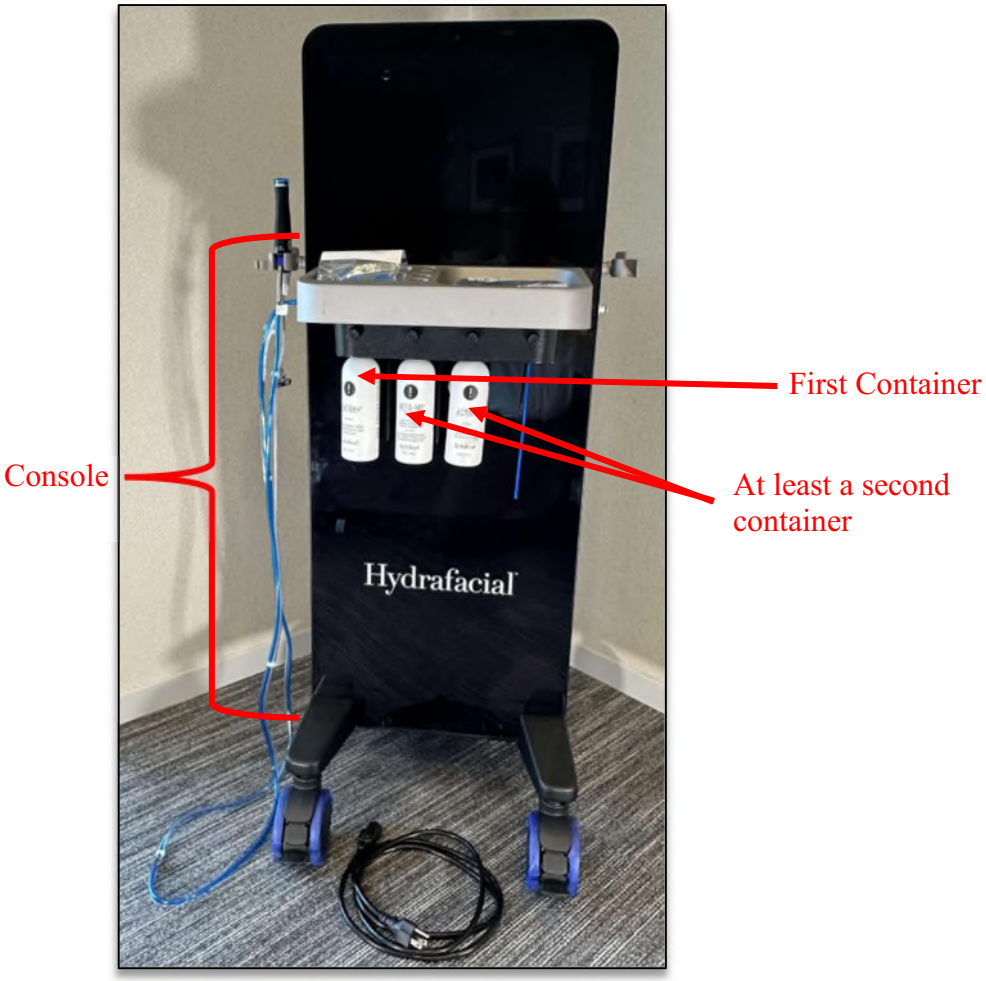
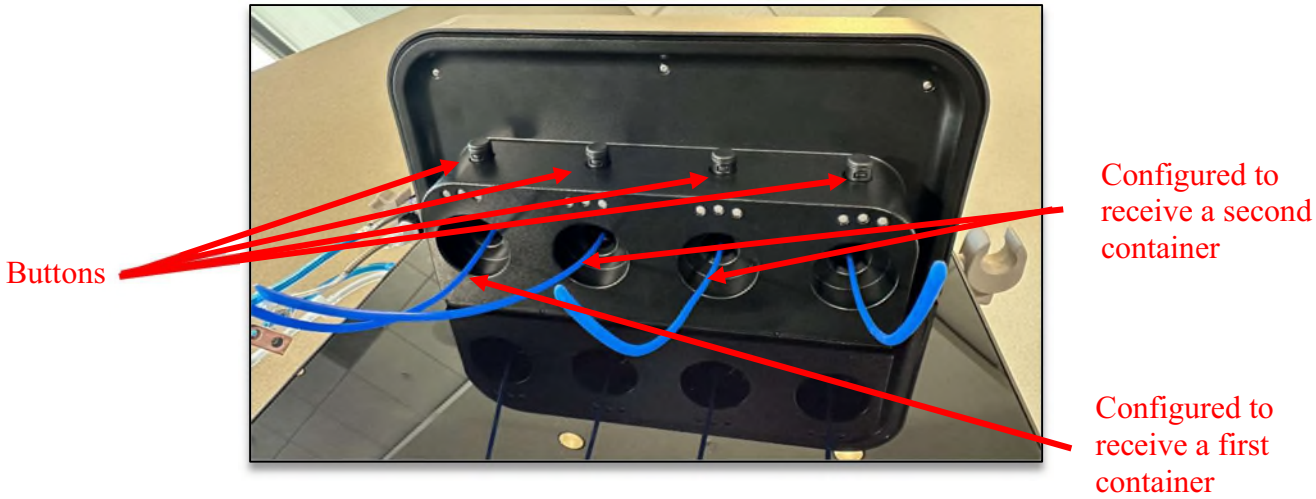


Ex. 2107 (Syndeo).



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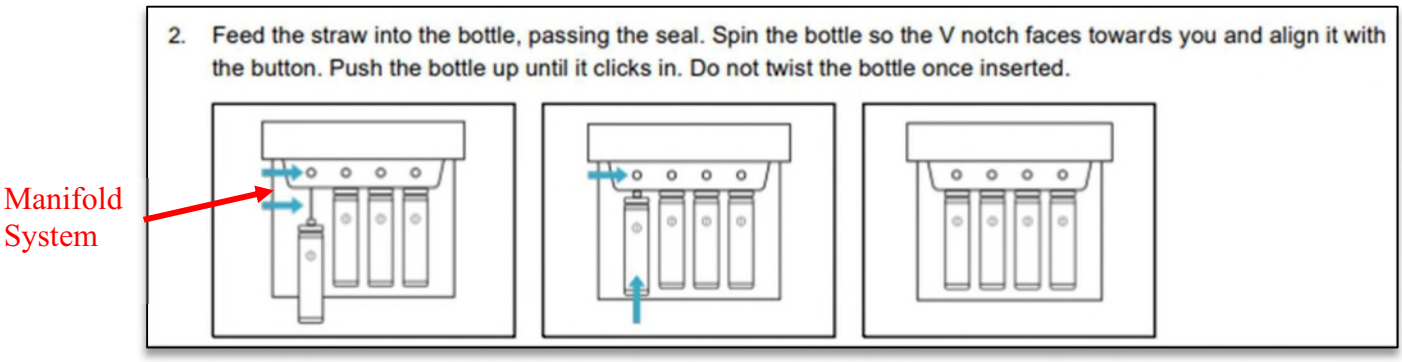
Ex. 2137 (Syndeo).

177. The Syndeo IFU describes connecting the containers (including the first and second containers), to the manifold system and pressing the buttons on the console when the containers are coupled to the manifold system to release the containers from the manifold system.



Ex. 2030 at 13 (Syndeo).

178. Based on my inspection of the Elite and Allegro devices, and review of photos and videos from the Tower, I determined that for each device, the first container and the at least second container are configured to releasably couple to the manifold system. The manifold system of each device can receive the containers when a user presses and holds the corresponding manifold button as each container is inserted and then releases the button when the container has been inserted. When a user presses the corresponding button, the container is released from the manifold system.

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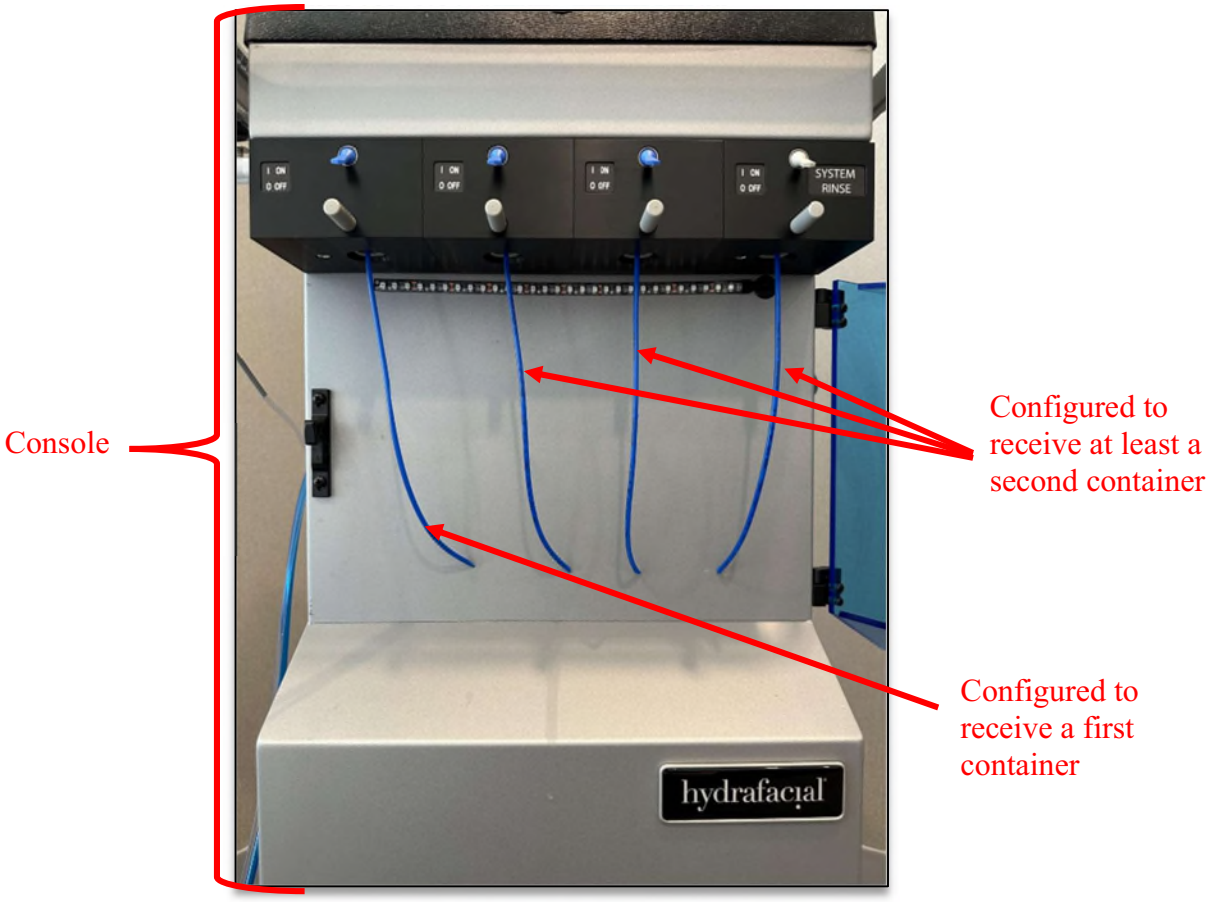

Ex. 2135 (Elite)

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Ex. 2116 (Elite).

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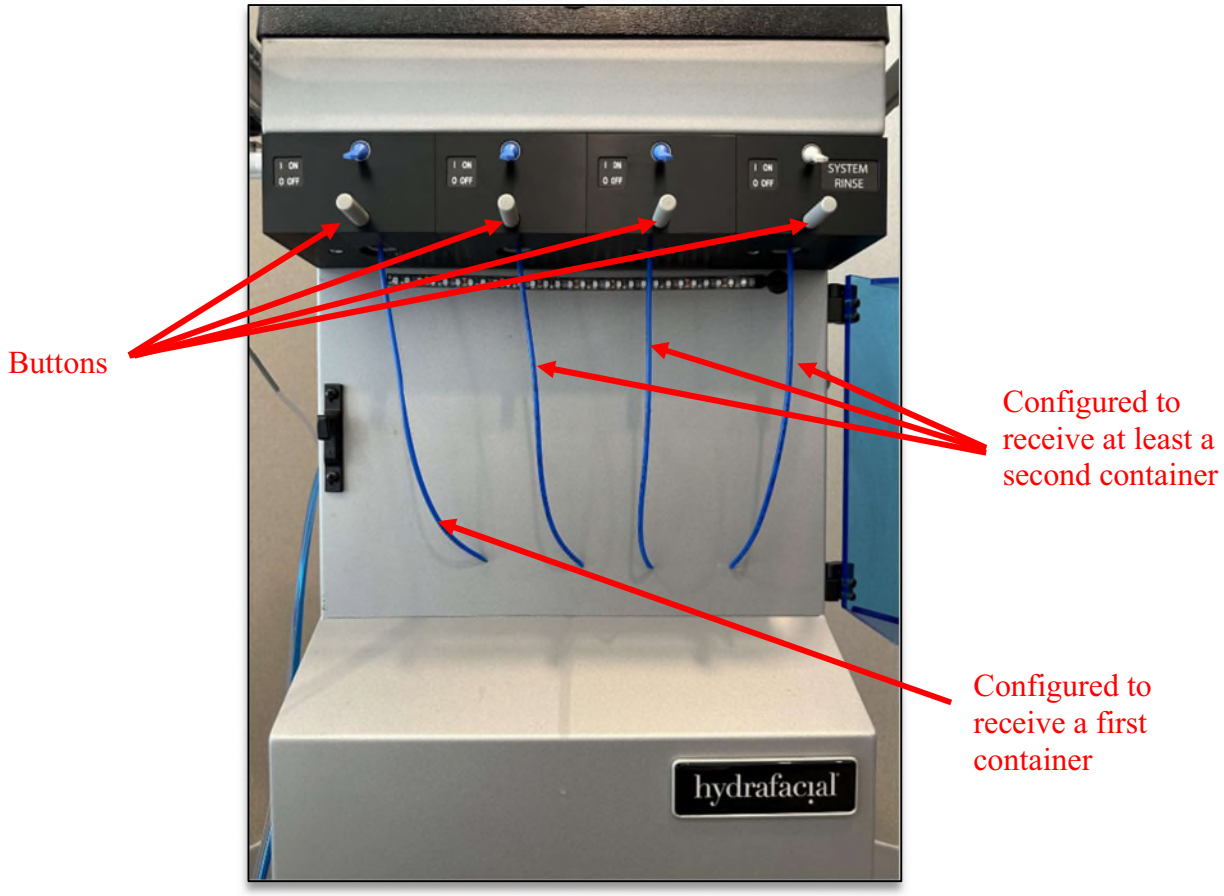

Ex. 2135 (Elite).

Ex. 2077 (Allegro).

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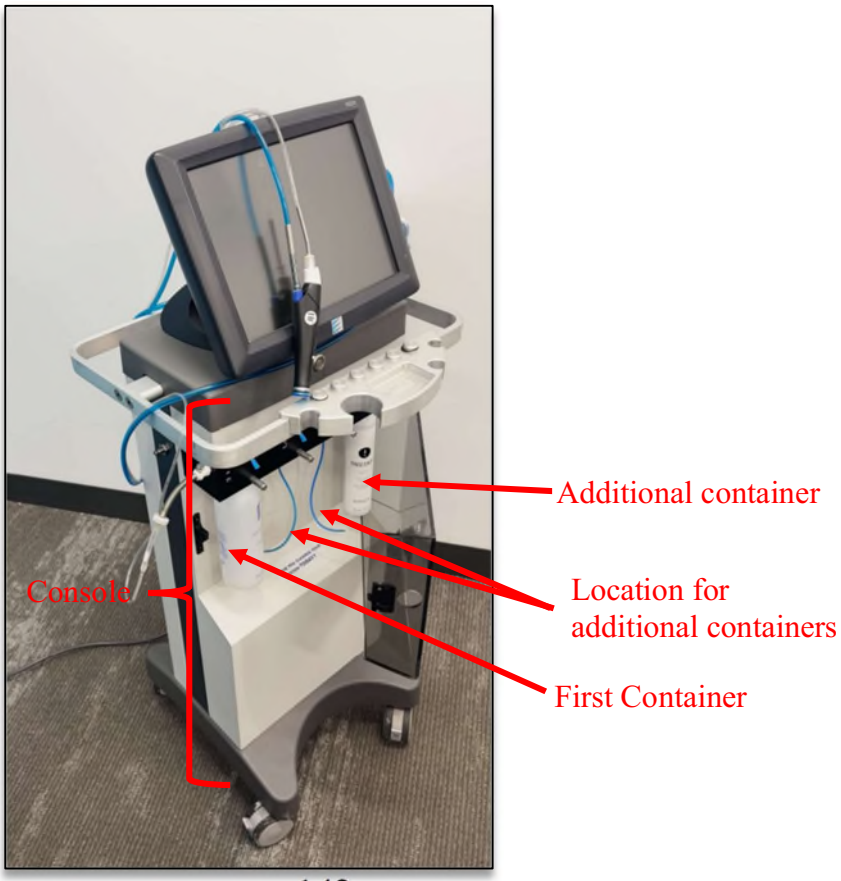
Ex. 2117 (Allegro).



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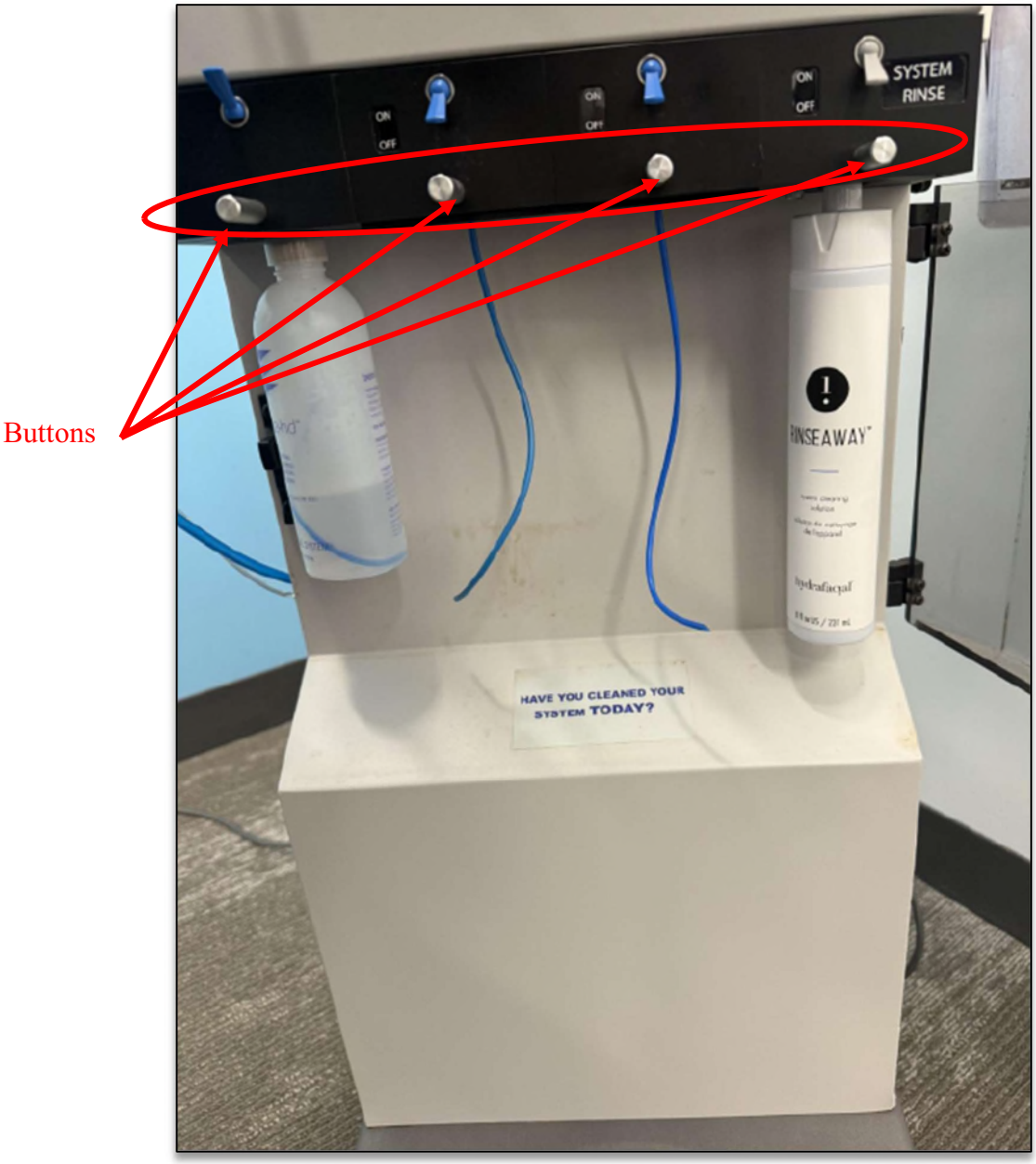
Ex. 2125 at 2 (Tower).



Ex. 2118 (Tower).

179. The Elite IFU and Allegro IFU describe connecting containers to the manifold system by pressing and holding holds the corresponding manifold button as each container is inserted and then releasing the button when the container has

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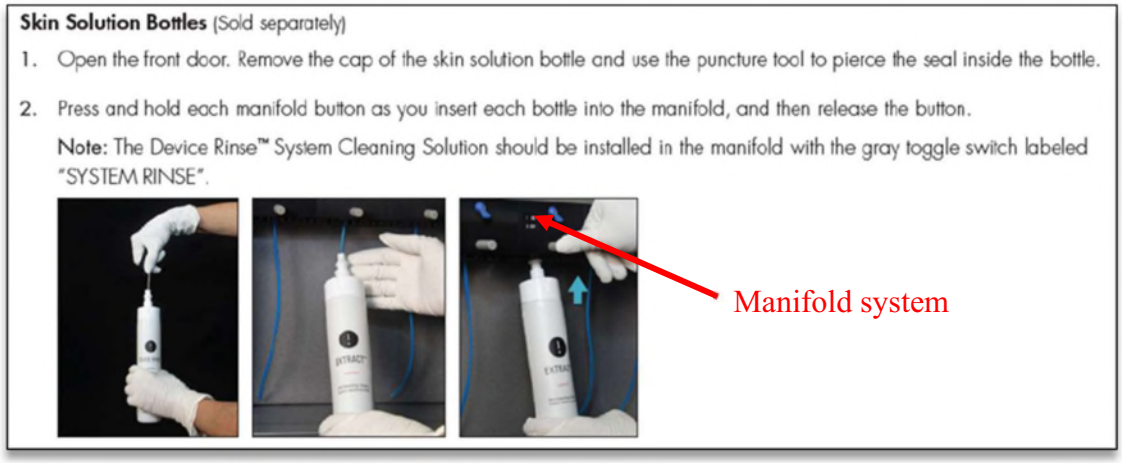
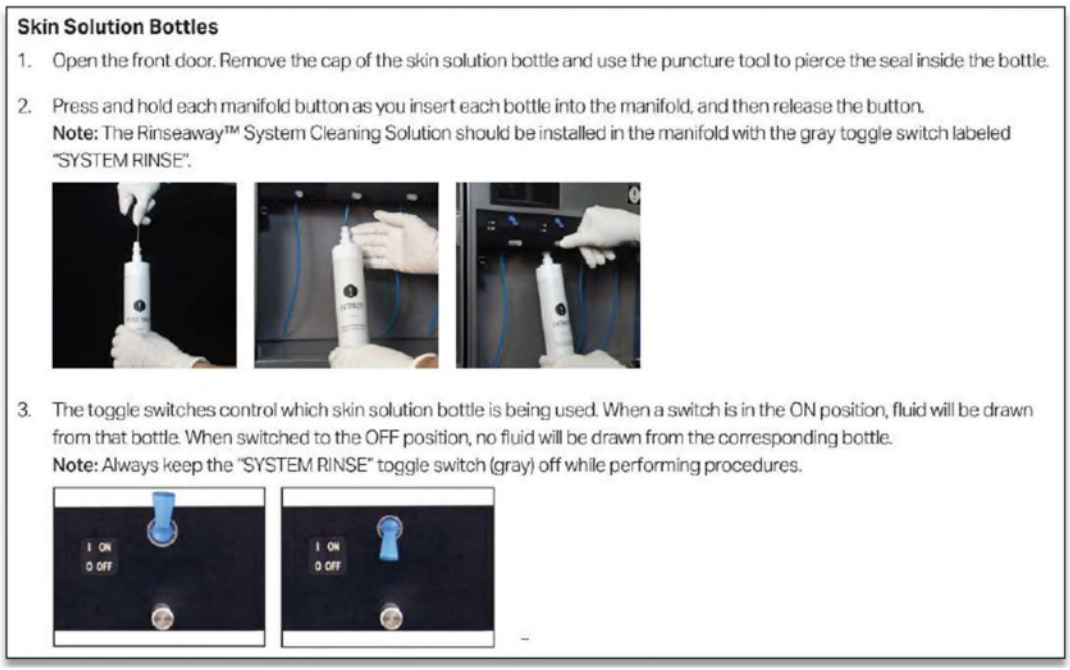
been inserted. Pressing the corresponding button on the manifold system when the container is coupled will release the container from the manifold system.



Ex. 2031 at 13 (Elite).



Ex. 2032 at 11 (Allegro).

180. The Tower Owner's Manual describes connecting containers to the manifold system by pressing and holding holds the corresponding manifold button

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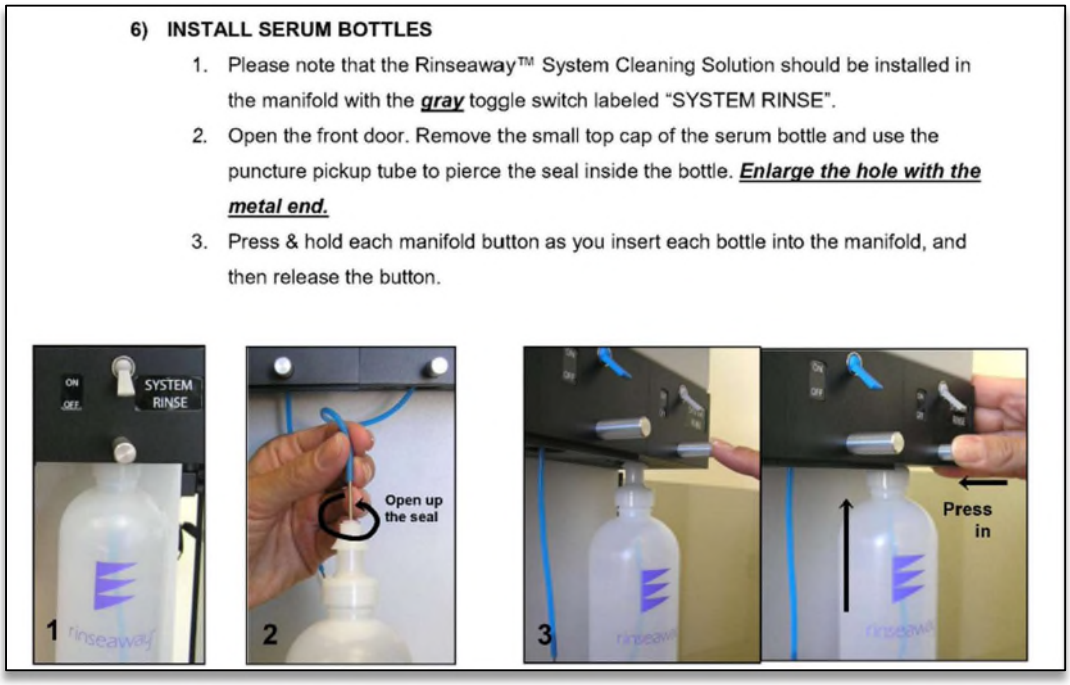
as each container is inserted and then releasing the button when the container has been inserted. Pressing the corresponding button on the manifold system when the container is coupled will release the container from the manifold system.



Ex. 2125 at 13 (Tower).

181. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 7 of the '477 Patent.

8. Practice of Claim 8

182. Claim 8 of the '477 Patent recites: The system of claim 1, wherein treatment materials from the first container and the at least second container are configured to be delivered to the supply conduit sequentially or simultaneously. In

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my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

183. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 1, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "wherein treatment materials from the first container and the at least second container are configured to be delivered to the supply conduit sequentially or simultaneously."

184. Each of the Syndeo, Elite, Allegro, and Tower can deliver treatment materials from the first container and the at least second container simultaneously.

185. For example, the Syndeo IFU explains that Syndeo includes "solution bottle controls . . . located on the bottom of the screen within the treatment steps." Ex. 2030 at 14 (Syndeo IFU). It explains that the system "automatically selects and deselects the recommended solution bottle based on the respective treatment step." The Syndeo can simultaneously deliver treatment material if a user performs a "long press" of a button "to select multiple bottles at one time." *Id.*

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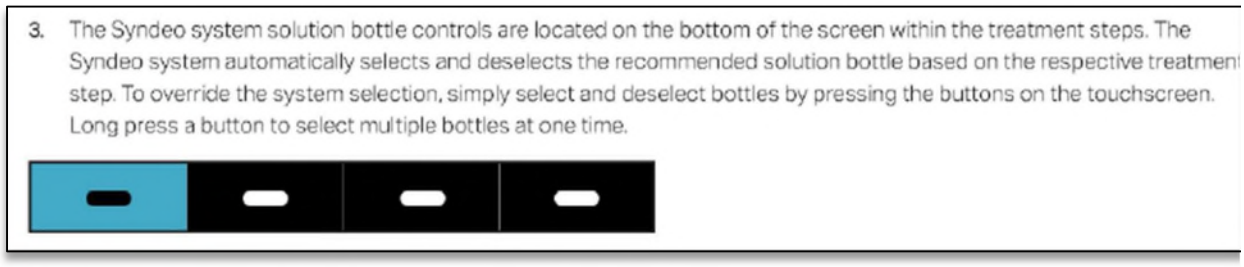
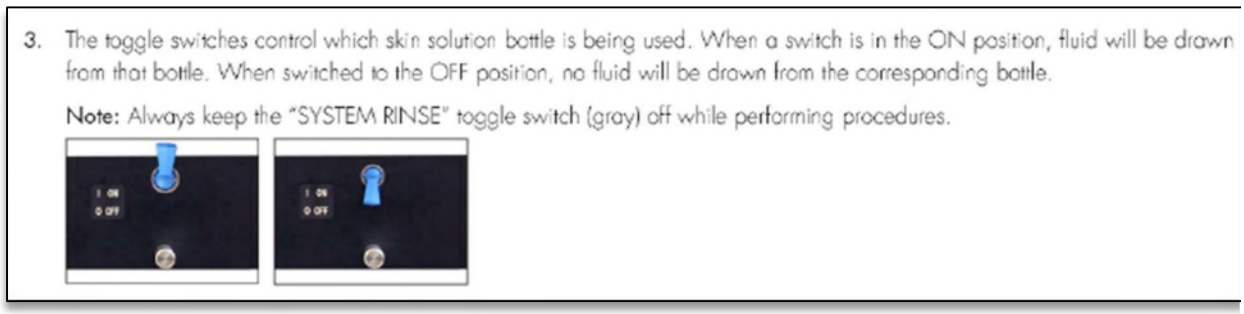


Ex. 2030 at 14 (Syndeo IFU).

186. The Elite IFU, Allegro IFU, and Tower Owner's Manual each explain that the "toggle switches" are used to control which skin solution bottle is being used. When a switch is in the "ON" position, fluid will be drawn from that bottle. Each of the Elite, Allegro, and Tower can simultaneously deliver treatment material if a user switches multiple toggle switches to "ON."



Ex. 2031 at 14 (Elite User Guide).

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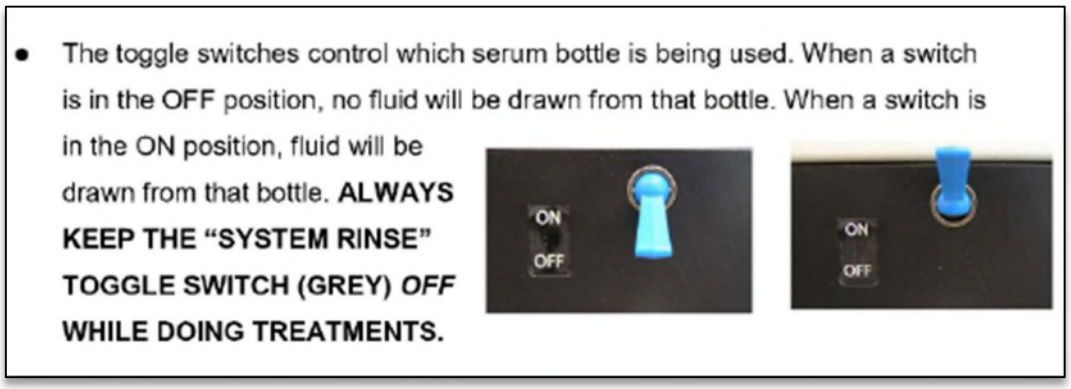
Ex. 2032 at 11 (Allegro IFU).



Ex. 2125 at 13 (Tower Owner's manual).

187. Each of the Syndeo, Elite, Allegro, and Tower can deliver treatment materials from the first container and the at least second container sequentially.

188. As discussed above, I have inspected each device and observed that in use, the user is able to select the treatment materials from the containers one after the other.

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189. Below is an excerpt from a video of the Syndeo in operation. The image shows the system is configured to deliver treatment materials contained in the first container and additional treatment materials from at the least the second container to the supply conduit one after another via a user selecting the appropriate container using the touch screen buttons.

Ex. 2078 at 3 (beginning treatment by delivering the first treatment fluid contained in the first container, then selecting a different container from which to draw fluid for treatment) (Syndeo).

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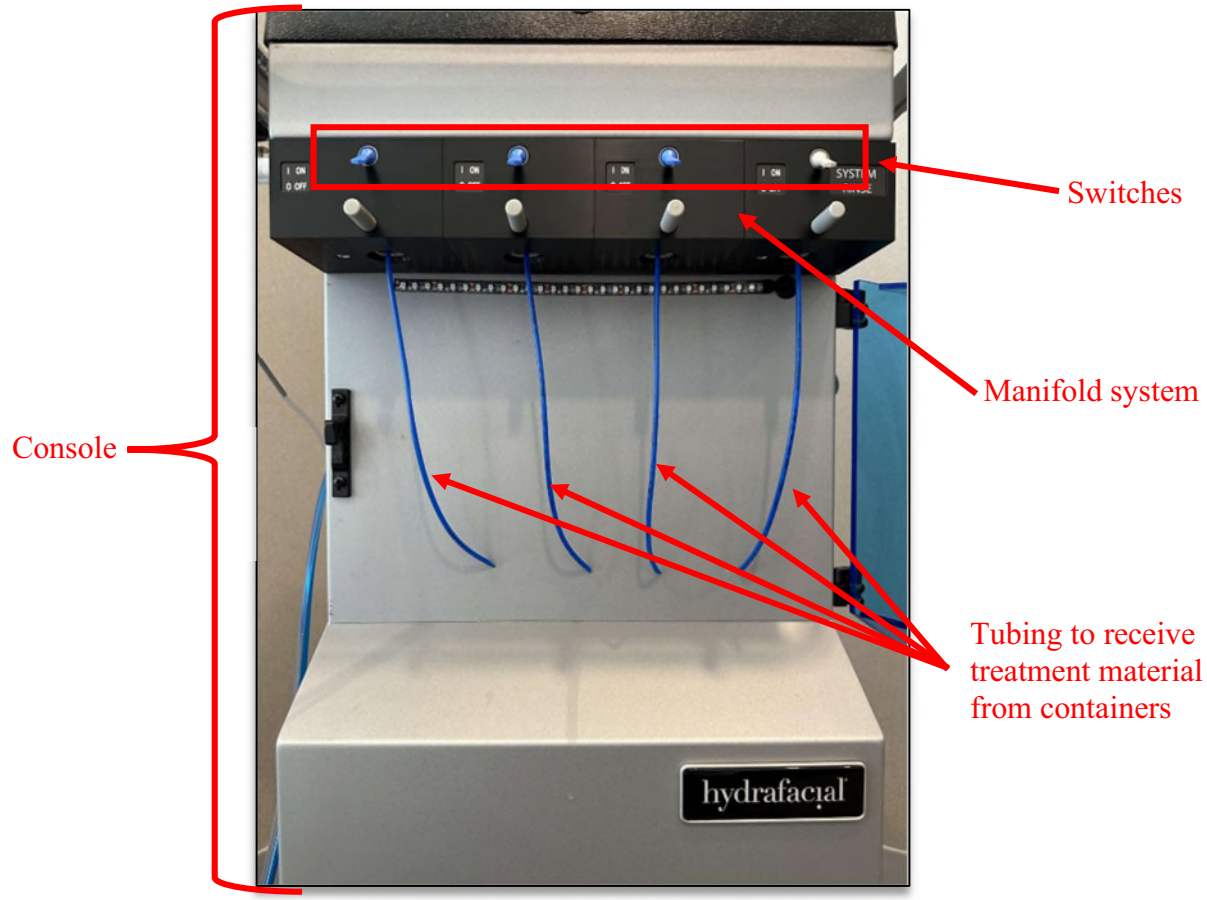
190. The images below show that the Elite and Allegro systems are each is configured to deliver treatment materials contained in the first container and additional treatment materials from at the least the second container to the supply conduit one after another via a user flipping the appropriate toggle switch.



Ex. 2135 (Elite).

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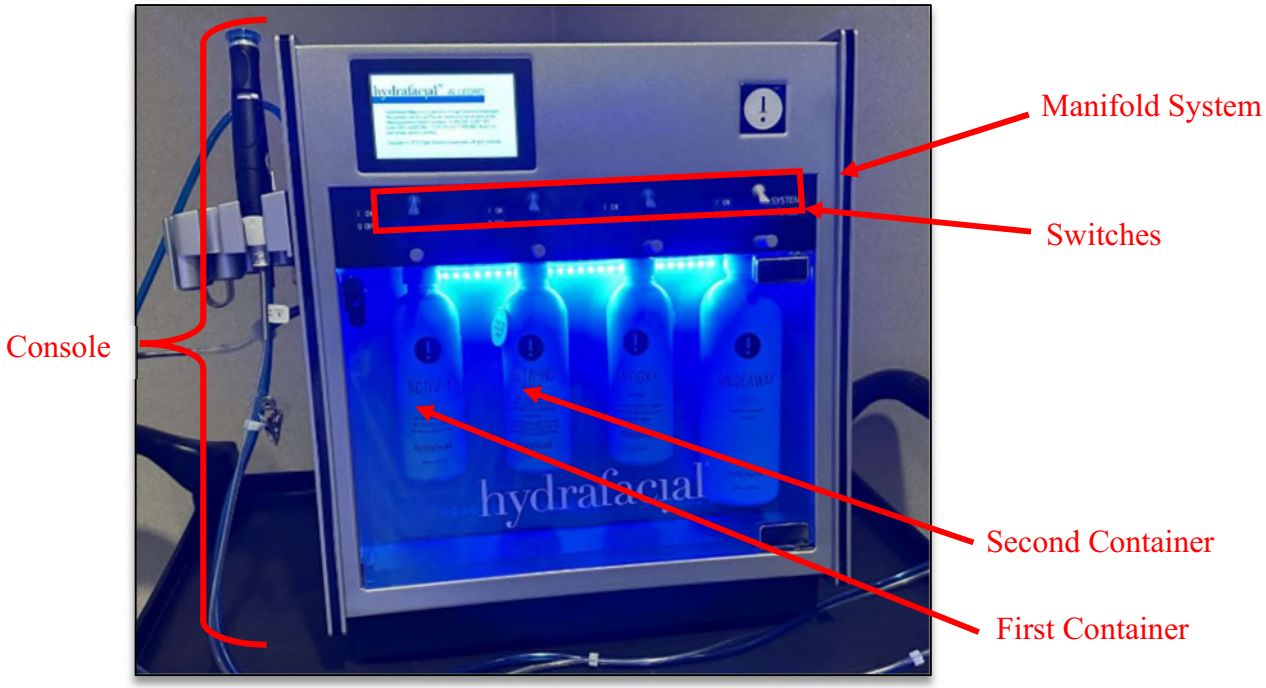

Ex. 2117 (Allegro).

191. The images below show that the Tower system is configured to deliver treatment materials contained in the first container and additional treatment materials from at the least the second container to the supply conduit one after another via a user flipping the appropriate toggle switch.

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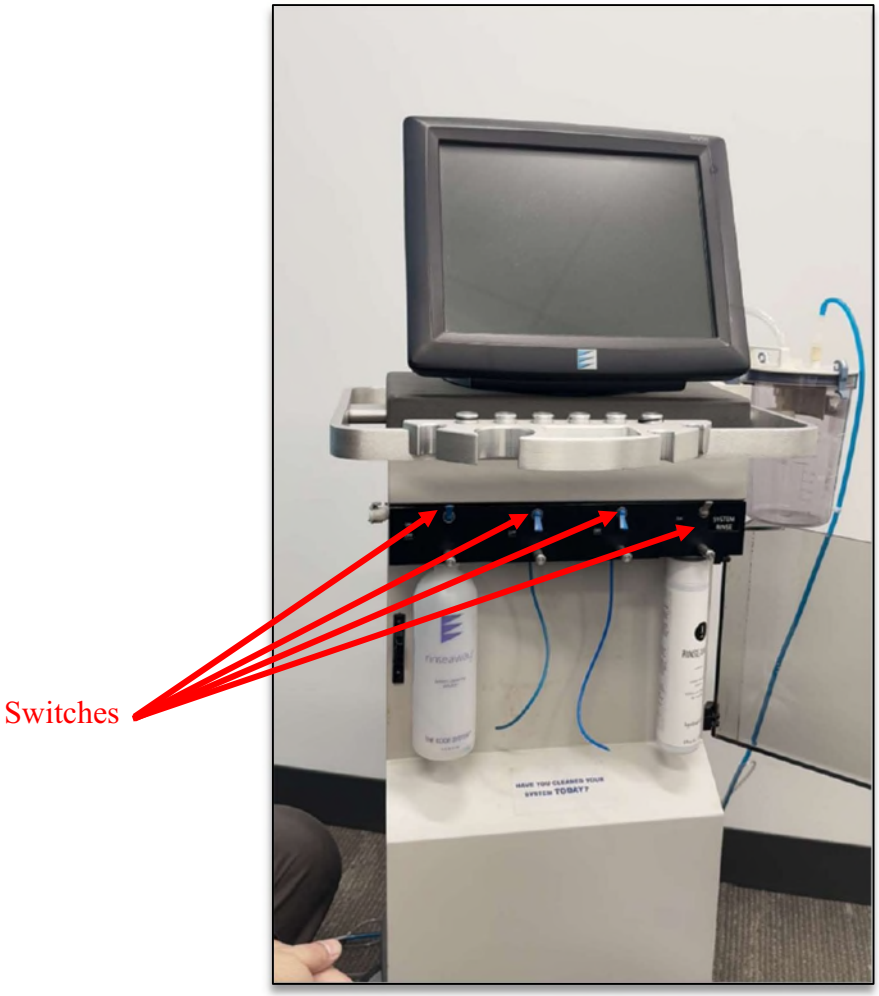

Ex. 2149 at 2 (Tower).

192. Technical documents for the Syndeo, Elite, Allegro and Tower confirm my opinions. For example, the Syndeo IFU provides further details regarding these containers and treatment fluids, and the delivery of fluids from the solution bottles. The Syndeo IFU explains that the Syndeo includes "solution bottle controls [] located on the bottom of the screen within the treatment steps.

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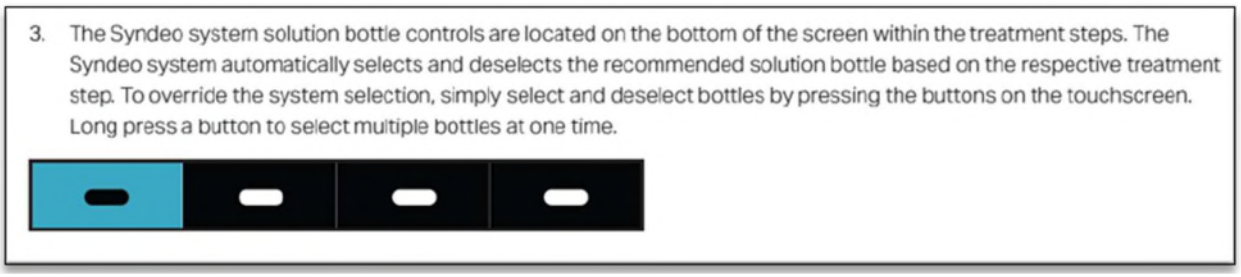

Ex. 2030 at 14 (Syndeo IFU).

193. The Syndeo IFU explains the Syndeo "automatically selects and deselects the recommended solution bottle based on the respective treatment step." *Id.* Based on this disclosure, a POSA would understand that the Syndeo is configured to deliver the treatment fluids to the handpiece sequentially "based on the respective treatment step." *Id.* The Syndeo IFU's troubleshooting section similarly describes the following scenario: "[i]f using only one station at a time, deselect current station and try another station." *Id.* at 22.

194. The Elite IFU, Allegro IFU, and Tower Owner's Manual each shows toggle switches on the console to control the delivery of the treatment fluids from the containers sequentially:

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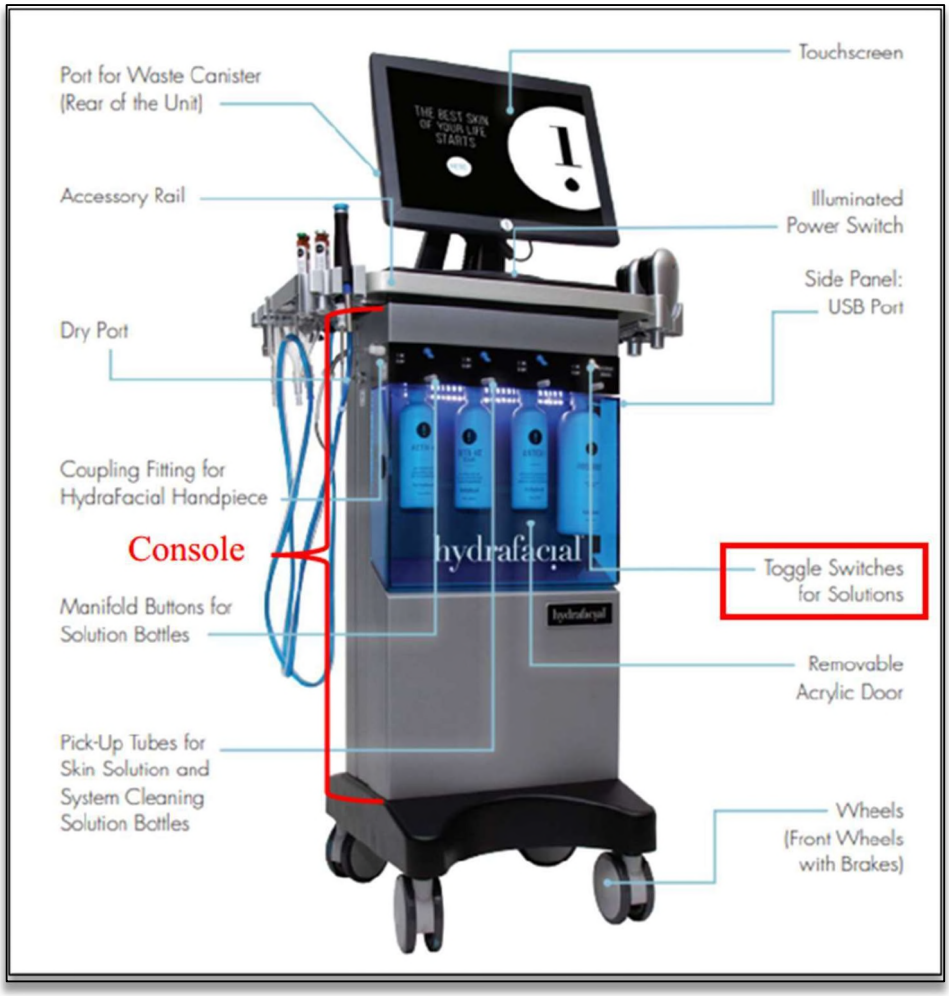

Ex. 2031 at 10 (Elite User Guide).

Ex. 2032 at 8 (Allegro IFU).

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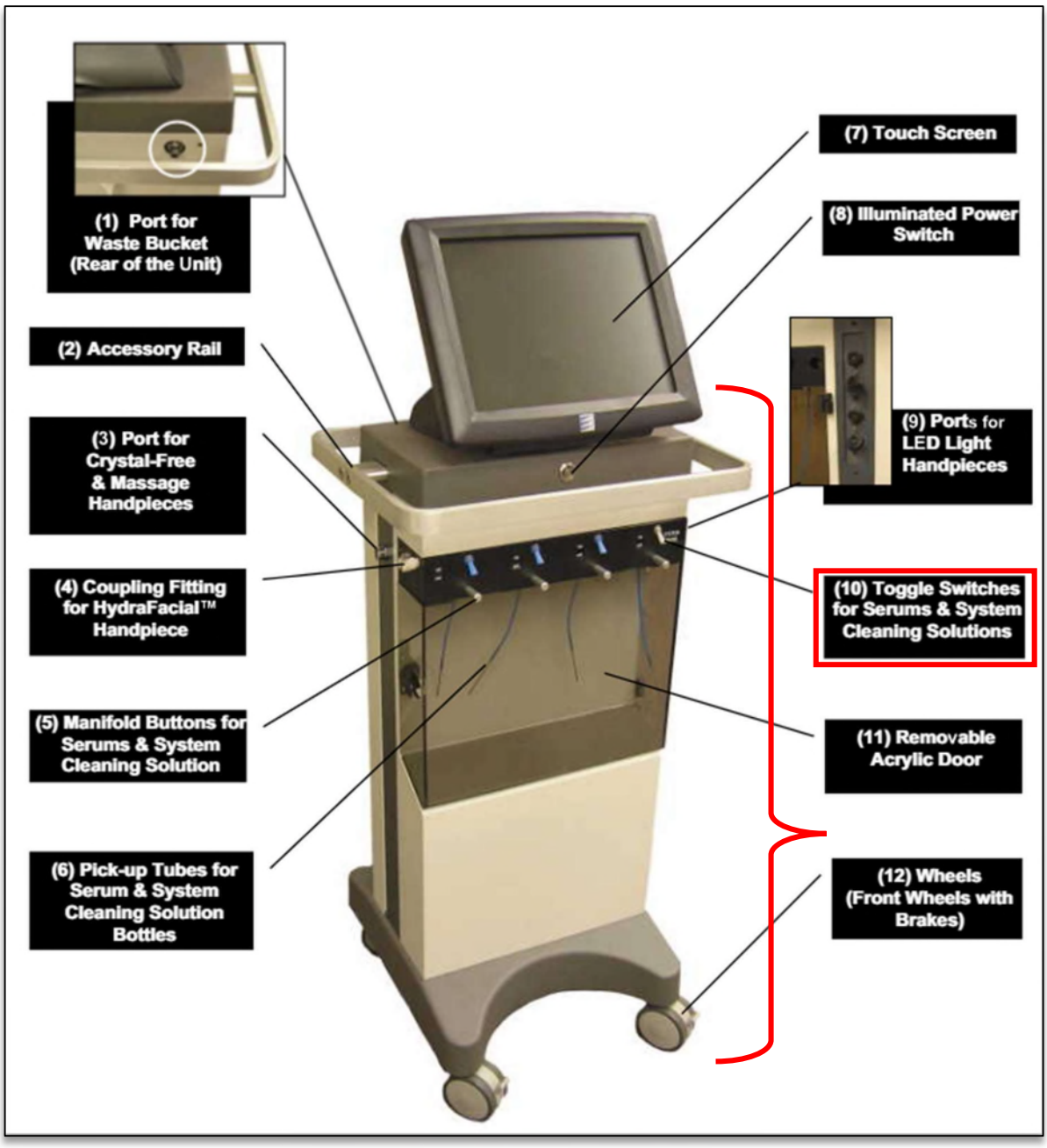

Ex. 2033 at 8 (Tower).

195. The Elite IFU explains that the "toggle switches [on the console] control which skin solution bottle is being used." Ex. 2031 at 14. It further states

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that "[w]hen a switch is in the ON position, fluid will be drawn from that bottle" and "[w]hen switched to the OFF position, no fluid will be drawn from the corresponding bottle." *Id.* Thus, for example, when the switch for the first container is ON and the switch for the at least one additional container is OFF, treatment fluid will be delivered to the handpiece from the first container only. Thereafter, when the switch for the first container is OFF and the switch for the at least one additional container is ON, treatment fluid will be delivered to the handpiece from the at least one additional container only. In this manner, through operation of the toggle switches, the system is configured to deliver the treatment fluids to the handpiece sequentially. Further, the Elite IFU's troubleshooting section describes the scenario, "[i]f using only one station at a time, turn current station off and try another station." *Id.* at 20.

196. The Allegro IFU contains similar disclosures. The Allegro IFU further explains that the "toggle switches control which skin solution bottle is being used. When a switch is in the ON position, fluid will be drawn from that bottle. When switched to the OFF position, no fluid will be drawn from the corresponding bottle." Ex. 2032 at 11. Thus, for example, when the switch for the first container is ON and the switch for the at least one additional container is OFF, treatment fluid will be delivered to the handpiece from the first container only. Thereafter, when the switch for the first container is OFF and the switch for the at least one additional container

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is ON, treatment fluid will be delivered to the handpiece from the at least one additional container only. In this manner, through operation of the toggle switches, the system is configured to deliver the treatment fluids to the handpiece sequentially. The Allegro IFU refers to the individual block components as "stations" and describes a troubleshooting scenario where, "[i]f using only one station at a time, turn current station off and try another station." *Id*. at 17.

197. The Owner's Manual for the Tower includes similar disclosures regarding the toggle switches. The Tower Owner's Manual explains that the "toggle switches control which serum bottle is being used. When a switch is in the OFF position, no fluid will be drawn from that bottle. When a switch is in the ON position, fluid will be drawn from that bottle." Ex. 2033 at 13. Thus, for example, when the switch for the first container is ON and the switch for the at least one additional container is OFF, treatment fluid will be delivered to the handpiece from the first container only. Thereafter, when the switch for the first container is OFF and the switch for the at least one additional container is ON, treatment fluid will be delivered to the handpiece from the at least one additional container only. In this manner, through operation of the toggle switches, the system is configured to deliver the treatment fluids to the handpiece sequentially. Further, the Tower Owner

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Manual's troubleshooting section describes the scenario, "[i]f using only one station at a time, turn current station off and try another station." *Id*. at 18.

198. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 8 of the '477 Patent.

9. Practice of Claim 9

199. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of claim 9 of the '477 Patent.

200. Claim 9 recites as follows:

> 9. A skin treatment system comprising:
> a manifold system in communication with at least two containers that are configured to be secured to the manifold system, wherein each of the at least two containers is configured to contain a treatment material;
> a handpiece assembly configured to contact a skin surface of a subject, wherein a supply conduit places the manifold system in fluid communication with the handpiece assembly;
> a vacuum source; and
> a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the handpiece assembly;
> wherein the system is configured to deliver at least one treatment material from at least one of the at least two containers to the handpiece assembly via the supply conduit using, at least in part, a vacuum created along a distal end of the handpiece assembly by the vacuum source.

I address each limitation of this claim below.

a. 9[pre]: "A skin treatment system comprising:"

201. Each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation for the same reasons set forth in limitation 1[pre].

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b. 9[a]: "a manifold system in communication with at least two containers that are configured to be secured to the manifold system, wherein each of the at least two containers is configured to contain a treatment material;"

202. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a manifold system in communication with at least two containers that are configured to be secured to the manifold system, wherein each of the at least two containers is configured to contain a treatment material."

203. For the same reasons set forth in limitation 1[a][i], the Syndeo has a manifold system in communication with at least two containers.

204. For the same reasons set forth in limitation 1[a][i], each of the Elite, Allegro, and Tower has a manifold system in communication with at least two containers.

205. For the same reasons set forth in claim 7, each of the Syndeo, Elite, Allegro, and Tower has containers that are configured to be secured to the manifold system. When the containers are connected to each of the Syndeo, Elite, Allegro, and Tower, the containers are secured to the manifold system. A user must press the button corresponding to each container to the container from the manifold system.

206. For the same reasons set forth in limitation 1[a][ii], each of the Syndeo, Elite, Allegro, and Tower has at least two containers configured to contain a treatment material.

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c. 9[b]: "a handpiece assembly configured to contact a skin surface of a subject, wherein a supply conduit places the manifold system in fluid communication with the handpiece assembly"

207. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a handpiece assembly configured to contact a skin surface of a subject, wherein a supply conduit places the manifold system in fluid communication with the handpiece assembly."

208. For the same reasons set forth in limitation 1[b], each of the Syndeo, Elite, Allegro, and Tower has a handpiece assembly.

209. For the same reasons set forth in limitation 1[b], each of the Syndeo, Elite, Allegro, and Tower has a supply conduit that places the manifold system in fluid communication with the handpiece assembly.

210. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has a handpiece assembly that is configured to contact a skin surface of a subject.

211. A POSA would recognize that each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation under the plain and ordinary meaning of "configured

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to contact a skin surface." The handpiece assembly of each of the Syndeo, Elite, Allegro, and Tower comprises the tip, which is configured to contact a skin surface.

212. During my inspection of the Syndeo, Elite, and Allegro, I observed that each device has a handpiece assembly that is configured to contact a skin surface. Each handpiece assembly has a tip that is used to contact a patient's skin surface.

Ex. 2111 (Syndeo).

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Ex. 2111 (Elite).

Ex. 2111 (Allegro).

213. For all four devices, in operation, the handpiece assembly is intended to be held in the hand and placed in contact with the skin, as confirmed by videos of the devices in operation. A screenshot from each of the videos shows the handpiece

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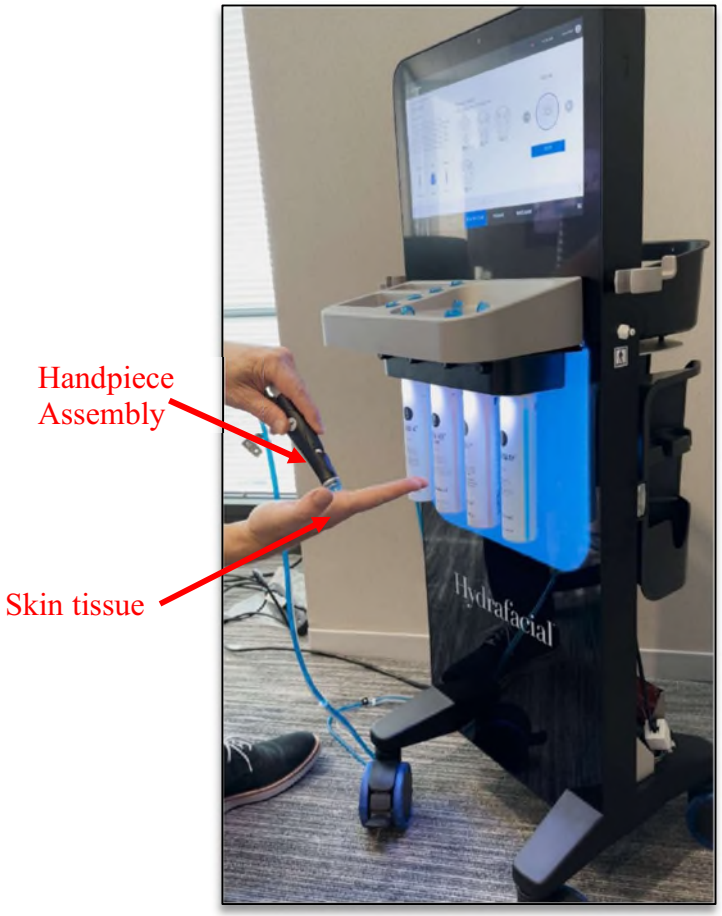
assembly with tip contacting the skin surface. From this, I concluded that the handpiece assembly is configured to contact a skin surface.



Ex. 2078 at 1 (Syndeo).

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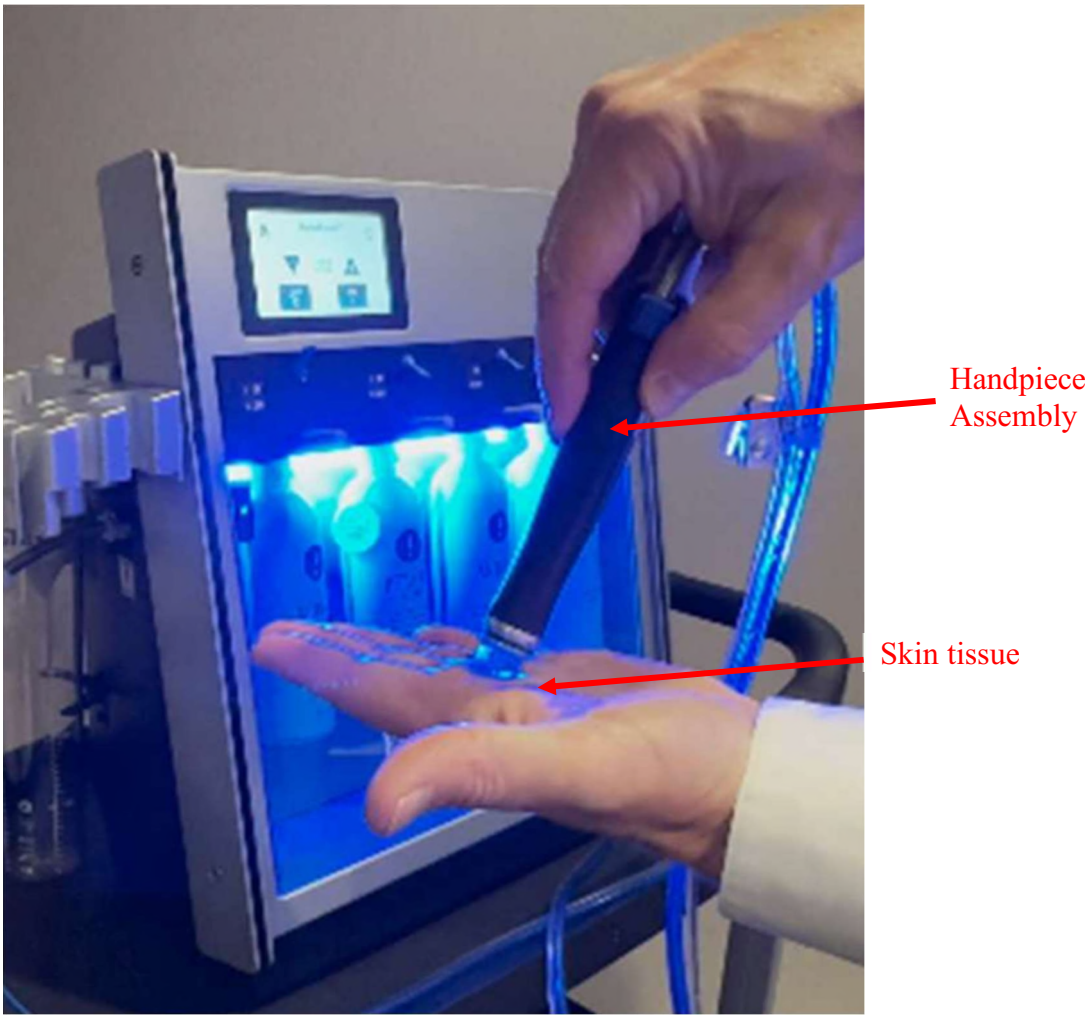
Ex. 2079 at 3 (Elite)



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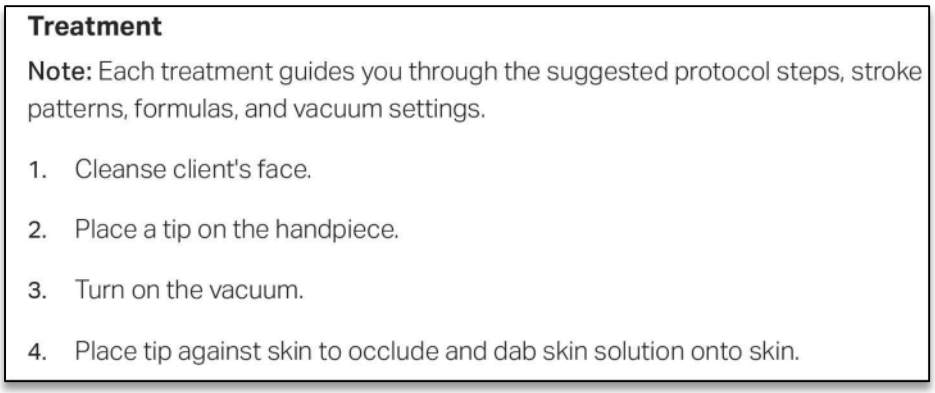
Ex. 2146 (Allegro).

214. Given the similarity between the Tower handpiece assembly and the handpiece assembly of the Syndeo, Allegro, and Elite, I have concluded that the Tower handpiece assembly is configured to contact a skin surface, similar to the images above.

215. Each of the Syndeo IFU, Elite IFU, and Allegro IFU explains that the tip of the handpiece assembly is used to contact the skin surface of a subject.

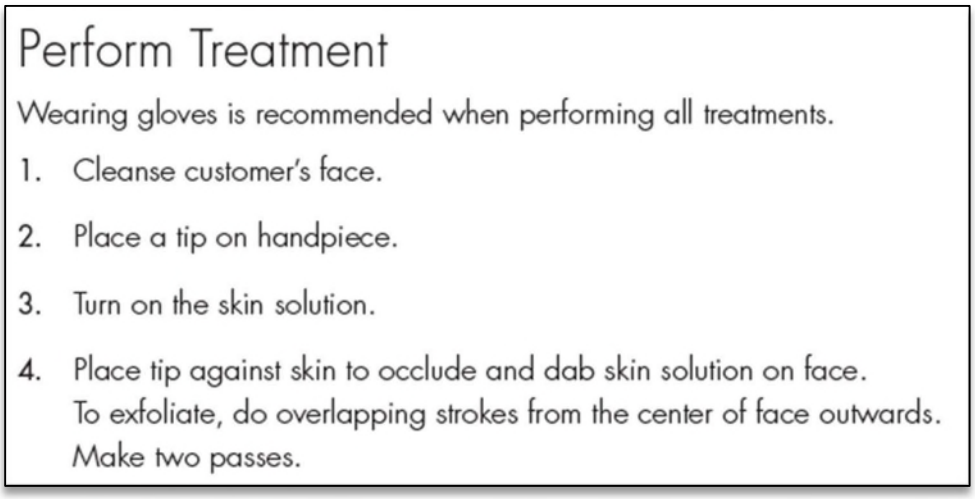


Treatment

Note: Each treatment guides you through the suggested protocol steps, stroke patterns, formulas, and vacuum settings.

1. Cleanse client's face.
2. Place a tip on the handpiece.
3. Turn on the vacuum.
4. Place tip against skin to occlude and dab skin solution onto skin.

Ex. 2030 at 19 (Syndeo).



Perform Treatment

Wearing gloves is recommended when performing all treatments.

1. Cleanse customer's face.
2. Place a tip on handpiece.
3. Turn on the skin solution.
4. Place tip against skin to occlude and dab skin solution on face. To exfoliate, do overlapping strokes from the center of face outwards. Make two passes.

Ex. 2031 at 17 (Elite).

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Ex. 2034 at 7 (Allegro).

216. I understand that the Tower handpiece assembly was not available at the inspection of the device. Instead, a Syndeo handpiece assembly was used with the Tower. I understand that the Tower handpiece and the Syndeo handpiece function similarly and the handpiece assembly for each uses a tip that functions as a working end with a skin contact surface that contacts skin tissue. The Tower Owner's Manual shows the handpiece assembly with HydraPeel tips. The manual cautions a user that if there is "NO OR LOW FLUID FLOW," "[m]ake sure the plastic tip is firmly installed onto [the] HYDRAPEEL handpiece." Ex. 2125 at 18.

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217. Accordingly, this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

d. 9[c]: "a vacuum source"

218. Each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation for the same reasons set forth in limitation 1[d].

e. 9[d]: "a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the handpiece assembly"

219. Each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation for the same reasons set forth in limitation 1[e].

f. 9[e]: "wherein the system is configured to deliver at least one treatment material from at least one of the at least two containers to the handpiece assembly via the supply conduit using, at least in part, a vacuum created along a distal end of the handpiece assembly by the vacuum source"

220. In my opinion, each of the Syndeo, Elite, Allegro, and Tower is "configured to deliver at least one treatment material from at least one of the at least two containers to the handpiece assembly via the supply conduit using, at least in part, a vacuum created along a distal end of the handpiece assembly by the vacuum source."

221. As explained above, each of the Syndeo, Elite, Allegro, and Tower has: (1) a manifold system in communication with at least two containers (2) at least two containers wherein each container is configured to contain treatment material, (3) a

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handpiece assembly configured to contact a skin surface of a subject, (4) a supply conduit that places the manifold system in fluid communication with the handpiece assembly, and (5) a vacuum source.

222. For the same reasons set forth in limitation 1[a][i], each of the Syndeo, Elite, Allegro, and Tower has a manifold system in communication with at least two containers.

223. For the same reasons set forth in limitation 1[a][ii], each of the Syndeo, Elite, Allegro, and Tower has a first container and at least a second container that contains treatment material.

224. For the set forth in limitation 9[b], each of the Syndeo, Elite, Allegro, and Tower has a handpiece assembly configured to contact a skin surface of a subject.

225. For the set forth in limitation 1[b], each of the Syndeo, Elite, Allegro, and Tower has a supply conduit that places the manifold system in fluid communication with the handpiece assembly.

226. For the same reasons set forth in limitation 1[d], each of the Syndeo, Elite, Allegro, and Tower has a vacuum source.

227. Based on my observation of the Syndeo, Elite, and Allegro in operation, for each system, a vacuum is created along the distal end of the handpiece assembly

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when the handpiece assembly is contacting a skin surface. After the vacuum is created along the distal end of the handpiece assembly, the vacuum source helps deliver treatment material from at least one of the at least two containers to the handpiece assembly via the supply conduit. For each of the Syndeo, Elite, and Allegro, I observed that when the vacuum source is activated and the handpiece assembly is contacting skin, a closed system is formed between a selected container and the vacuum source to transfer a treatment material from a container to the handpiece assembly. Based on my review of video of the Tower with the cleaning cap on, it is my understanding that it operates the same as the Elite and Allegro when the handpiece assembly contacts the skin.

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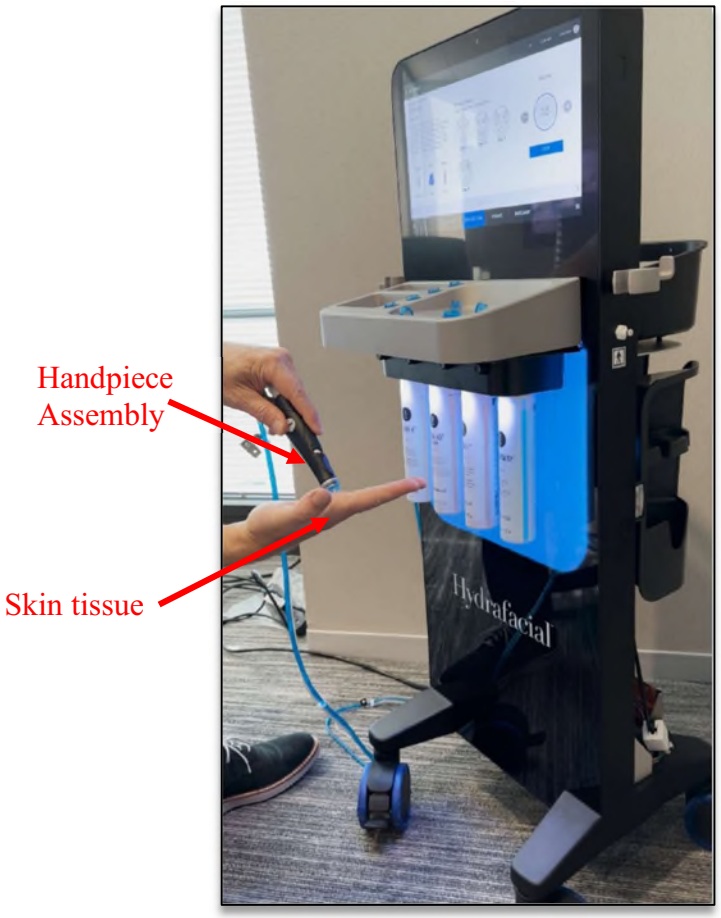

Ex. 2078 at 1 (Syndeo).

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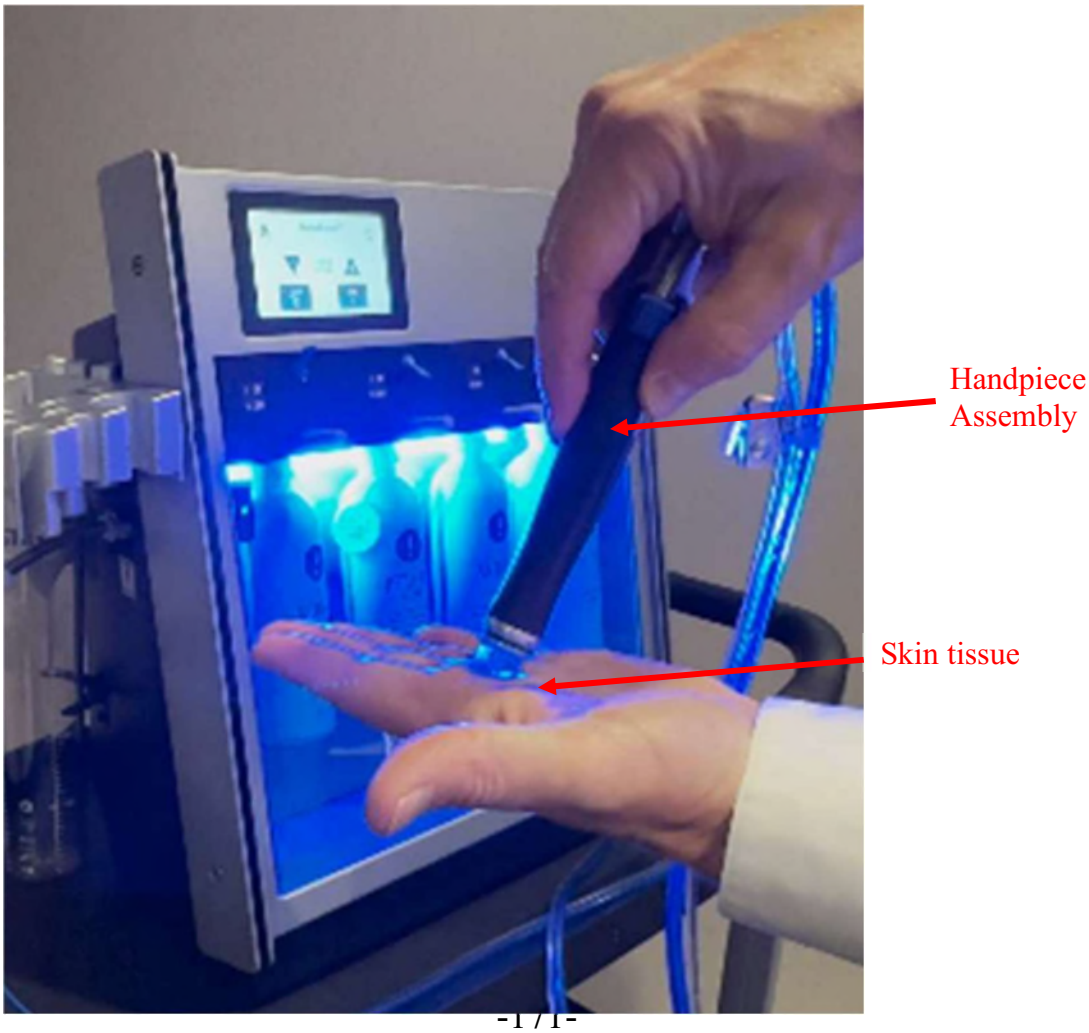
Ex. 2079 at 3 (Elite).



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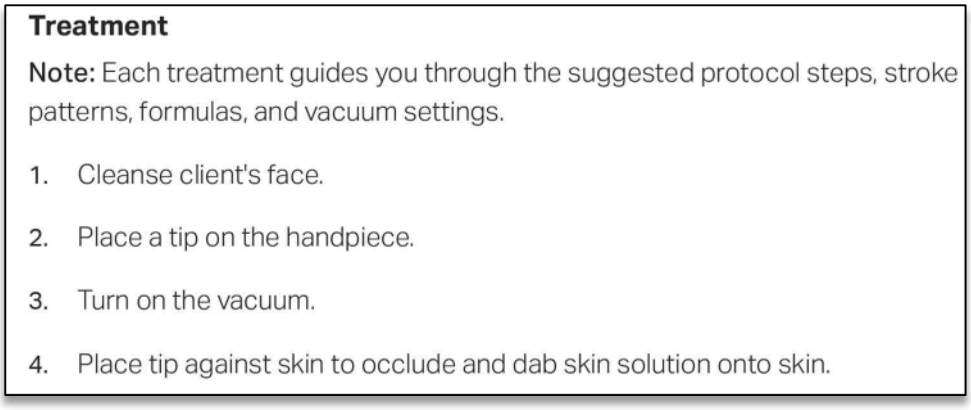
Ex. 2146 (Allegro).

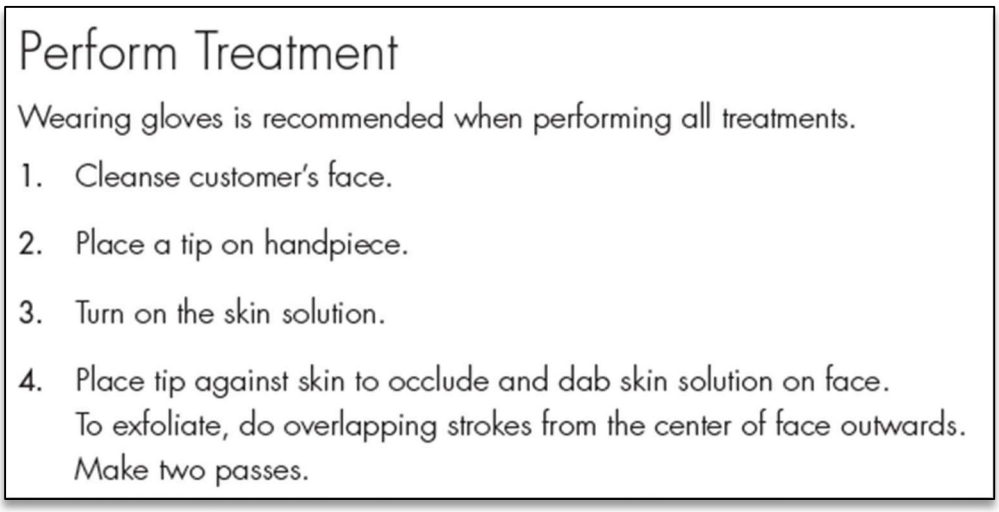
228. The Syndeo IFU and Elite IFU each instructs users to place the handpiece assembly against skin during treatment while the vacuum is on to occlude and dab skin solution onto the skin. By following these instructions, a vacuum is created along the distal end of the handpiece assembly by the vacuum source and the vacuum source helps deliver treatment material from at least one container to the handpiece assembly via the supply conduit


Treatment

Note: Each treatment guides you through the suggested protocol steps, stroke patterns, formulas, and vacuum settings.

1. Cleanse client's face.
2. Place a tip on the handpiece.
3. Turn on the vacuum.
4. Place tip against skin to occlude and dab skin solution onto skin.

Ex. 2030 at 19 (Syndeo).


Perform Treatment

Wearing gloves is recommended when performing all treatments.

1. Cleanse customer's face.
2. Place a tip on handpiece.
3. Turn on the skin solution.
4. Place tip against skin to occlude and dab skin solution on face. To exfoliate, do overlapping strokes from the center of face outwards. Make two passes.

Ex. 2031 at 17 (Elite).

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229. The "Troubleshooting" section of the Syndeo IFU, Allegro IFU, and Elite IFU each warns that "[i]f the canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease." Ex. 2030 at 22; Ex. 2031 at 20 (Elite); Ex. 2032 at 17 (Allegro). The recommended solution to this situation is to "[e]mpty the waste canister after each service." Id. Thus, the vacuum draws from either the first container or the second container to the handpiece assembly when the tip is pressed against skin.

Low or No Fluid Flow	Leak in the line	Check lines for any kinks or leaks.
	Too many solution stations are on	Make sure you only have a maximum of two skin solution stations selected at one time.
	Faulty station	If using only one station at a time, deselect current station and try another station. If this corrects the problem please check on the previous station that the internal bottle seal is completely broken and pick up assembly (straw) is fully submerged. Repuncture the bottle if needed.
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.
	Waste canister is full	Do not let the waste canister fill above 450ml. If canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste canister after each service.
	Clogging	Flush all stations thoroughly. Make sure the System is cleaned after each service.
	Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.

Ex. 2030 at 22 (Syndeo).

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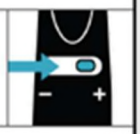
Low or No Fluid Flow	Leak in the line	Check lines for any kinks or leaks.
	Too many solution stations are on	Make sure you only have a maximum of two skin solution stations on the ON position.
	Faulty station	If using only one station at a time, turn current station off and try another station. If this corrects the problem please check on the previous station that internal bottle seal is completely broken and pick up assembly (metal portion) is fully submerged. Repuncture bottle if needed.
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.
	Waste canister is full	Do not let the waste canister fill above 450 mL. If the canister becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste canister after each service.
	Clogging	Flush all stations thoroughly. Make sure the System is cleaned after each service.
	Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.

Ex. 2031 at 20 (Elite).

Low or No Fluid Flow	Toggle Switch	Make sure the switch is on.
	Empty bottle	Make sure your skin solution bottle is not empty.
	Improper connection	Make sure that your HydraFacial® handpiece is properly connected to the side of the skin solution station block, and to the waste container. Also, make sure that the lid is firmly attached to the waste container.
	Tip is improperly installed	Make sure the tip is firmly installed onto the handpiece. Angled tips should face downwards in order to facilitate flow.
	Flow control valve is closed	Make sure the flow control valve on the handpiece is open. To increase fluid flow, turn the flow control valve towards the + sign. 
	Leak in the line	Check lines for any kinks or leaks. Repuncture bottle if needed.
	Faulty station	If using only one station at a time, turn current station off and try another station, if this corrects the problem please check on the previous station that internal bottle seal is completely broken and pick up assembly (metal portion) is fully submerged.
	Operator technique	Make sure that you are holding the handpiece correctly and not working against gravity or blocking the tubing.
	Waste canister is full	**Do not let the waste container fill above 450 mL.** If the container becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease. Empty the waste container after each service.
	Clogging	Flush all stations thoroughly. Make sure the machine is cleaned after each service.
	Gray Cartridge is loose	Make sure that the gray cartridge is properly inserted into the handpiece. The arrow on the cartridge should line up with the lock symbol.

Ex. 2032 at 17 (Allegro).

230. For all of these reasons, it is my opinion that each of the Syndeo, Elite, Allegro, and Tower practices Claim 9 of the '477 Patent.

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10. Practice of Claim 10

231. Claim 10 of the '477 Patent recites: The system of claim 9, wherein the manifold system is positioned in the console. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

232. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 9, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "wherein the manifold system is positioned in the console" for the same reasons set forth in limitation 1[a][iii].

233. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 10 of the '477 Patent.

11. Practice of Claim 11

234. Claim 11 of the '477 Patent recites: The system of claim 9, further comprising a computing device configured to control at least one function of the system. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

235. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 1, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "further

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comprising a computing device configured to control at least one function of the system."

236. For the same reasons set forth in Claim 2, each of the Syndeo, Elite, Allegro, and Tower comprises a computing device configured to control at least one function of the system.

237. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of Claim 11 of the '477 Patent.

12. Practice of Claim 12

238. Claim 12 of the '477 Patent recites: The system of claim 9, further comprising a user input device to facilitate control of a flow of treatment materials from at least one of the at least two containers to the handpiece assembly. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

239. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 9, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "further comprising a user input device to facilitate control of a flow of treatment materials from at least one of the at least two containers to the handpiece assembly" for the same reasons set forth above in Claim 3.

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240. For the same reasons set forth in Claim 2, each of the Syndeo, Elite, Allegro, and Tower comprises a computing device configured to control at least one function of the system.

241. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 12 of the '477 Patent.

13. Practice of Claim 13

242. Claim 13 of the '477 Patent recites: The system of claim 12, wherein the user input device comprises a touch screen. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

243. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 12, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "wherein the user input device comprises a touch screen" for the same reasons set forth above in Claim 4.

244. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 13 of the '477 Patent.

14. Practice of Claim 14

245. Claim 14 of the '477 Patent recites: The system of claim 9, wherein treatment materials from a first container and a second container are configured to

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be delivered to the supply conduit sequentially or simultaneously. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

246. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 9, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "wherein treatment materials from a first container and a second container are configured to be delivered to the supply conduit sequentially or simultaneously" for the same reasons set forth in claim 8.

247. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 14 of the '477 Patent.

15. Practice of Claim 15

248. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of claim 15 of the '477 Patent.

249. Claim 15 recites as follows:

> 15. A skin treatment system comprising:
> a manifold system in communication with at least two containers, wherein each of the at least two containers is configured to contain a treatment material;
> a handpiece assembly configured to contact a skin surface of a subject;
> a supply conduit placing the manifold system, and thus the at least two containers, in fluid communication with the handpiece assembly; and

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a waste conduit in fluid communication with the handpiece assembly and a vacuum source to move waste away from the handpiece assembly; and

wherein the system is configured to deliver treatment materials from at least one of the at least two containers to the handpiece assembly via the supply conduit using, at least in part, a vacuum created along a distal end of the handpiece assembly by the vacuum source.

I address each limitation of this claim below.

g. 15[pre]: "A skin treatment system comprising:"

250. Each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation for the same reasons set forth in limitation 1[pre].

h. 15[a]: "a manifold system in communication with at least two containers, wherein each of the at least two containers is configured to contain a treatment material"

251. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a manifold system in communication with at least two containers, wherein each of the at least two containers is configured to contain a treatment material."

252. For the same reasons set forth in limitation 1[a][i], the Syndeo has a manifold system in communication with at least two containers.

253. For the same reasons set forth in limitation 1[a][i], each of the Elite, Allegro, and Tower has a manifold system in communication with at least two containers.

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254. For the same reasons set forth in limitation 1[a][ii], each of the Syndeo, Elite, Allegro, and Tower has at least two containers configured to contain a treatment material.

i. 15[b]: "a handpiece assembly configured to contact a skin surface of a subject"

255. Each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation for the same reasons set forth in claim 9[b].

j. 15[c]: "a supply conduit placing the manifold system, and thus the at least two containers, in fluid communication with the handpiece assembly; and"

256. Each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation for the same reasons set forth in limitation 1[a][i] and limitation 1[b].

k. 15[d]: "a waste conduit in fluid communication with the handpiece assembly and a vacuum source to move waste away from the handpiece assembly; and"

257. Each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation for the same reasons set forth in claim 1[e].

l. 15[e]: "wherein the system is configured to deliver treatment materials from at least one of the at least two containers to the handpiece assembly via the supply conduit using, at least in part, a vacuum created along a distal end of the handpiece assembly by the vacuum source"

258. Each of the Syndeo, Elite, Allegro, and Tower satisfies this limitation for the same reasons set forth in limitation 9[e].

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259. For all of these reasons, it is my opinion that each of the Syndeo, Elite, Allegro, and Tower practices Claim 15 of the '477 Patent.

16. Practice of Claim 16

260. Claim 16 of the '477 Patent recites: The system of claim 15, wherein the manifold system is positioned in a console. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

261. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 15, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "wherein the manifold system is positioned in a console" for the same reasons set forth above in Claim 10.

262. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 16 of the '477 Patent.

17. Practice of Claim 17

263. Claim 17 of the '477 Patent recites: The system of claim 15, further comprising a computing device configured to control at least one function of the system. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

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264. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 15, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "further comprising a computing device configured to control at least one function of the system" for the same reasons set forth above in Claim 2.

265. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 17 of the '477 Patent.

18. Practice of Claim 18

266. Claim 18 of the '477 Patent recites: The system of claim 15, further comprising a user input device to facilitate control a flow of treatment materials from at least one of the at least two containers to the handpiece assembly. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

267. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 15, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "further comprising a user input device to facilitate control a flow of treatment materials from at least one of the at least two containers to the handpiece assembly" for the same reasons set forth above in Claim 3.

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268. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of Claim 18 of the '477 Patent.

19. Practice of Claim 19

269. Claim 19 of the '477 Patent recites: The system of claim 18, wherein the user input device comprises a touch screen. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

270. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 18, as explained above. In my opinion, each of the Syndeo, Elite, Allegro, and Tower further satisfies the limitation requiring "wherein the user input device comprises a touch screen" for the same reasons set forth above in Claim 4.

271. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 19 of the '477 Patent.

20. Practice of Claim 20

272. Claim 20 of the '477 Patent recites: The system of claim 15, wherein treatment materials from the first container and the at least second container are configured to be delivered to the supply conduit sequentially or simultaneously. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of this claim.

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273. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitations of claim 15, as explained above. In my opinion, the Syndeo further satisfies the limitation requiring "wherein treatment materials from the first container and the at least second container are configured to be delivered to the supply conduit sequentially or simultaneously" for the same reasons set forth above in Claim 8.

274. Accordingly, each of the Syndeo, Elite, Allegro, and Tower practices Claim 20 of the '477 Patent.

C. The HydraFacial Systems Are Coextensive with the Claims of the '477 Patent

275. I understand from counsel that to meet the coextensiveness requirement the patentee must demonstrate that the product is essentially the claimed invention and does not include critical unclaimed features. I also understand from counsel that the patentee is not required to show perfect correspondence between the claims and the product.

276. The HydraFacial Systems are coextensive with the claims of the '477 Patent for several reasons. First, Claim 1 is directed to skin treatment systems with specific key features including (1) multiple fluid containers; (2) a manifold system; (3) fluid communication between the fluid containers and manifold system; (4) fluid communication between a handpiece assembly (including a tip) and the manifold

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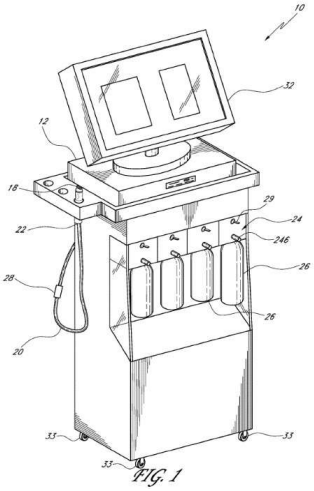
system; (5) a vacuum source, and (6) a waste container, and (7) fluid communication between the vacuum source and waste container and the handpiece assembly (including a tip). As I discussed in detail above, the HydraFacial Systems are skin treatment systems that include the key features recited in the claims.

277. Indeed, HydraFacial's Tower system was the originating multi-container system, first sold in 2005, and is reflective of the system depicted in the figures in the '477 patent, including Fig. 1 as shown below:

Tower Product	**'477 Patent, Fig. 1**
	

Ex. 2033 at 1; Ex. 1001, Fig. 1.

278. Second, the HydraFacial Systems do not contain other key or driving features that are not claimed. For example, although the HydraFacial Systems may include additional ancillary components, such as red and blue light therapy, these components are insignificant features. The HydraFacial Systems are primarily and

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extensively marketed as a hydrodermabrasion system, rather than light therapy devices. *See, e.g.*, Ex. 2038, Ex. 2039, Ex. 2040, Ex. 2041, Ex. 2042, Ex. 2043, Ex. 2044, Ex. 2045, Ex. 2046, Ex. 2047. I understand that any light therapy handpiece is insignificant to the HydraFacial Systems as they are unrelated to hydrodermabrasion. Thus, the features of the HydraFacial Systems that are significant are the features coextensive with the challenged Claims.

279. Third, the HydraFacial Systems do not include any critical unclaimed features. To the extent Petitioner argues, for example, that the tips or treatment solutions are critical features claimed by different patents that materially impact the HydraFacial Systems' functionality, I disagree. The tips are part of the handpiece/handpiece assembly. The claims recite, for example, "a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject" and "a handpiece configured to contact skin tissue of a subject." The patent specification makes clear that it is the handpiece/handpiece assembly, including the tip, that contacts the skin surface for treatment. See, e.g., '477 Patent at Figs. 1-4 and 5:42-46, 5:57-60, 6:44-45, 6:49-53, 7:50-54, 10:39-11:3, 19:25-28, 19:39-42.

280. Thus, in my opinion, because the HydraFacial Systems embody the claimed invention and are coextensive with the claims, HydraFacial is entitled to a presumption that there is a nexus between the claims of the '477 Patent and the

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secondary considerations of non-obviousness, including commercial success identified by Dr. Pallavi Seth and the copying I discuss below.

D. A Nexus Is Also Established by Comparison to HydraFacial's Nectre Product

281. I have been informed by counsel that a nexus may also be establish by showing that the evidence of secondary considerations is a direct result of the unique characteristics of the claimed invention.

282. I have been asked to provide expert analysis on whether HydraFacial's Nectre product, which was a single-container product embodies the claims of the '477 Patent and how it differs from the HydraFacial Systems. I have analyzed the relevant aspects of Nectre product in light of the '477 Patent claims. As set forth in detail below, it is my opinion that HydraFacial's Nectre product does meet every limitation of the claims of the '477 Patent because it lacks the claimed manifold that could receive fluid from multiple connected containers.

283. I understand that, in May 2008, HydraFacial launched a hydrodermabrasion system known as the HydraFacial Nectre ("Nectre"). See, e.g., Ex. 2035, Ex. 2036, Ex. 2037. I understand that HydraFacial stopped selling the Nectre in 2013. Like the Karasiuk prior art reference, and unlike the HydraFacial Systems, the Nectre was a single-container hydrodermabrasion system that lacked a

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block, fluid control member, or collection lumen that could receive fluid from multiple connected containers.

284. In my opinion, the Nectre meets each of the limitations of the challenged claims that are not dependent on the device having multiple containers connected to the manifold of the console. Below is an exemplary analysis of Claim 1 of the '477 Patent.

1. Exemplary Claim 1

285. Claim 1 recites as follows:

> 1. A skin treatment system comprising:
> a manifold system in communication with a first container and at least a second container, wherein each of the first container and the at least second container is configured to contain a treatment material, the manifold system being positioned in or on a console;
> a supply conduit placing the manifold system in fluid communication with a handpiece assembly;
> wherein the handpiece assembly comprises a working end having a skin contact surface;
> a vacuum source;
> a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the working end of the handpiece assembly during a skin treatment procedure; and
> at least one control to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly;
> wherein the vacuum source is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly to help remove waste from the hand piece assembly via the waste conduit and to help transfer at least one treatment material from the manifold system to the handpiece assembly.

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I address each limitation of this claim below.

a. 1[pre]: "A skin treatment system comprising:"

286. In my opinion, the Nectre is "A skin treatment system."

287. The Nectre User's Manual, for example, describes the Nectre as "a revolutionary breakthrough in aesthetic technology" and explains that it is "the next generation of exfoliation and skin rejuvenation." Ex. 2036 at 4. The User Manual identifies the Nectre as a "USA FDA Class I exempt device' where the intended use is "to perform dermabrasion (or exfoliation) using mechanical abrasion and water" and to "introduce[e] topic 'dermaceuticals' … during treatment." *Id.*

b. 1[a]: "a manifold system in communication with a first container and at least a second container, wherein each of the first container and the at least second container is configured to contain a treatment material, the manifold system being positioned in or on a console"

288. In my opinion, the Nectre does not disclose "a manifold system in communication with a first container and at least a second container, wherein each of the first container and the at least second container is configured to contain a treatment material."

289. As shown in the images and schematic below, the Nectre is only configured to receive a single container.

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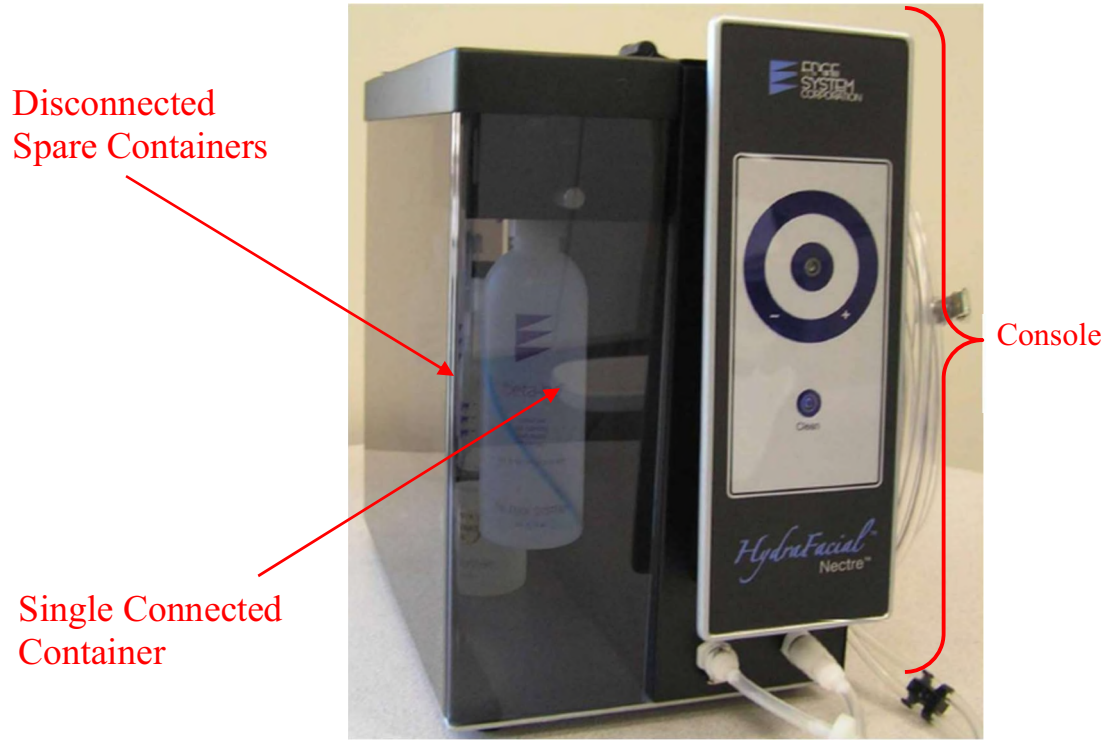

Ex. 2035 at 1 (Nectre Owner's Manual). [1]

[1] Although the User Manual and other documentation refer to a "manifold button" and a "manifold" in the device, a POSA would not recognize this structure as a manifold under the term's ordinary meaning since this structure is not a chamber or pipe with multiple inlets and cannot be configured to be in fluid communication with multiple fluid sources. Thus, as I explain in further detail herein, the Nectre device does not satisfy the "manifold system" limitation recited in the claims. I will, however, refer to this feature of the Nectre as a "manifold" to maintain consistency with the cited documentation, even though the structure does not qualify as a

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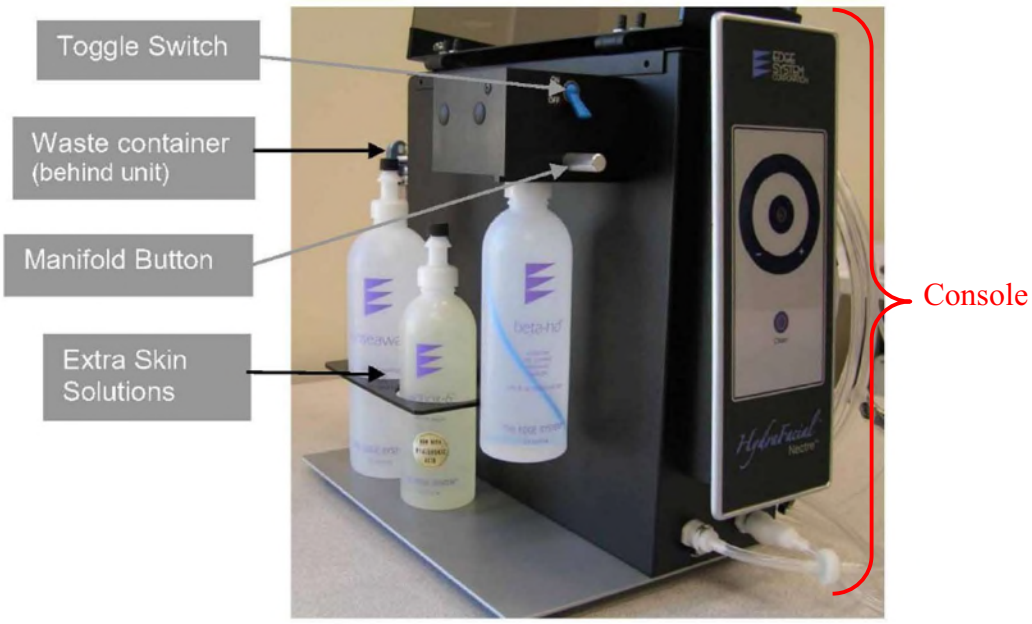

Ex. 2036 at 13 (Nectre User’s Manual).

manifold under the ordinary meaning as understood by the parties and Petitioners’ expert.

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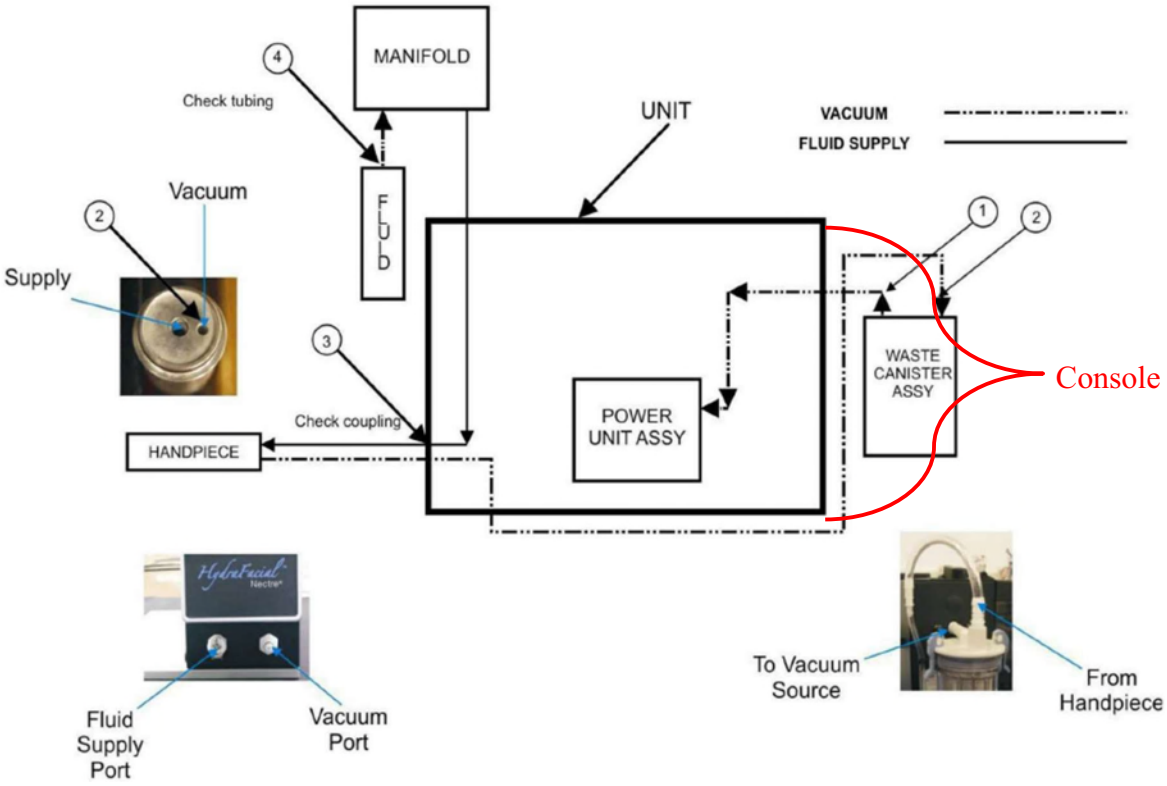

Ex. 2037 at 6 (Nectre Service Manual).

290. Users are instructed to connect the single container to the console, as shown below.

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4) INSTALL SKIN SOLUTION BOTTLES

1. Open the door on the side of the unit from the bottom.
2. Remove the small black cap off the skin solution bottle and use the puncture tool to pierce the seal inside the bottle. Move the tool in a circular motion to enlarge the opening in the seal so the pickup tube slides in easily.
3. Insert the pickup tube into the unsealed bottle.
4. Press & hold the manifold button and insert the bottle into the manifold, and then release the button. Be sure the bottle is securely attached before releasing it.
5. Place additional bottles of skin solution in the holders behind the skin solution port.

Ex. 2036 at 14 (Nectre User's Manual).

c. 1[b]: "a supply conduit placing the manifold system in fluid communication with a handpiece assembly;"

291. In my opinion, the Nectre includes a supply conduit placing what the Nectre documentation refers to as a manifold in fluid communication with a handpiece assembly. However, the Nectre does not have a manifold system as that term is understood by a person of skill in the art.

a. 1[b][i]: "a supply conduit;"

292. It is my opinion that the Nectre includes a supply conduit. As shown in the schematic and image below, a supply conduit extends from what the Nectre documentation refers to as a manifold to the handpiece assembly through a fluid supply port and internal manifold.

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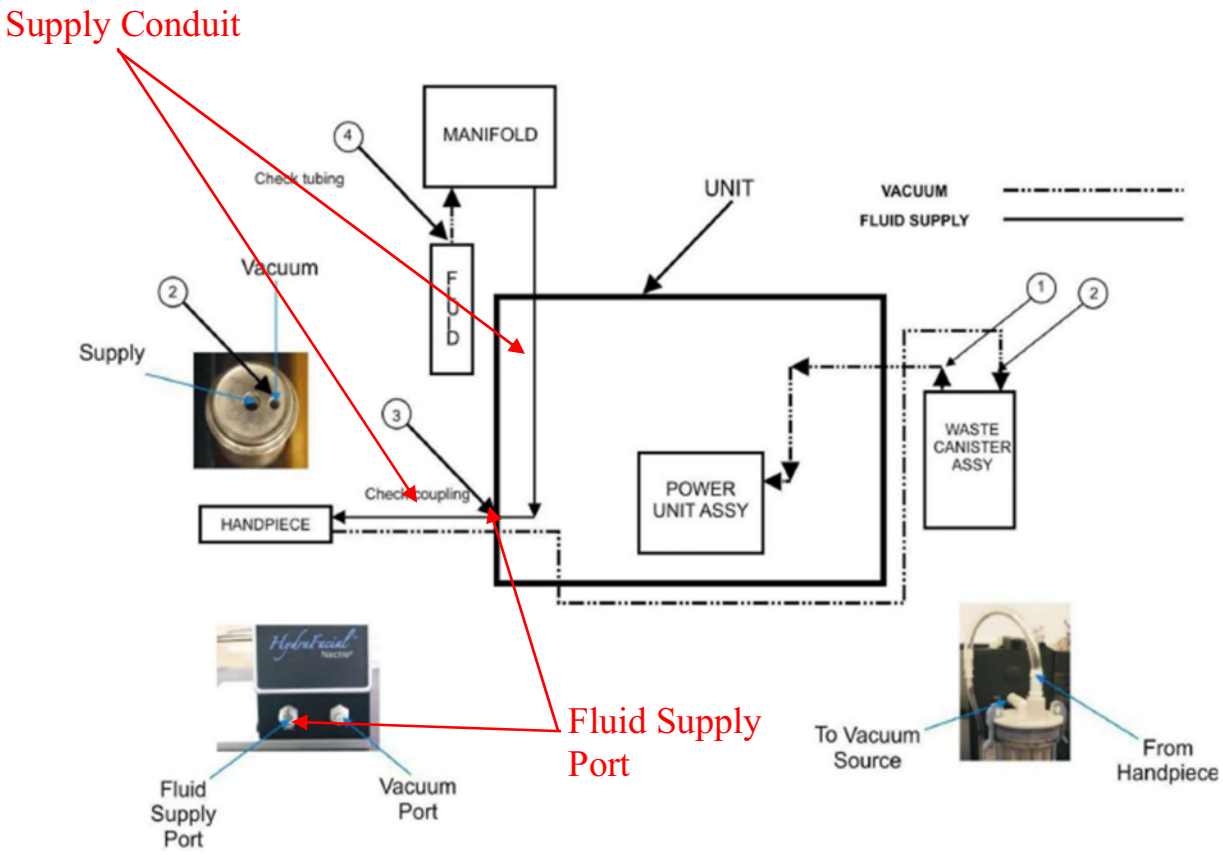

Ex. 2037 at 6 (Nectre Service Manual).

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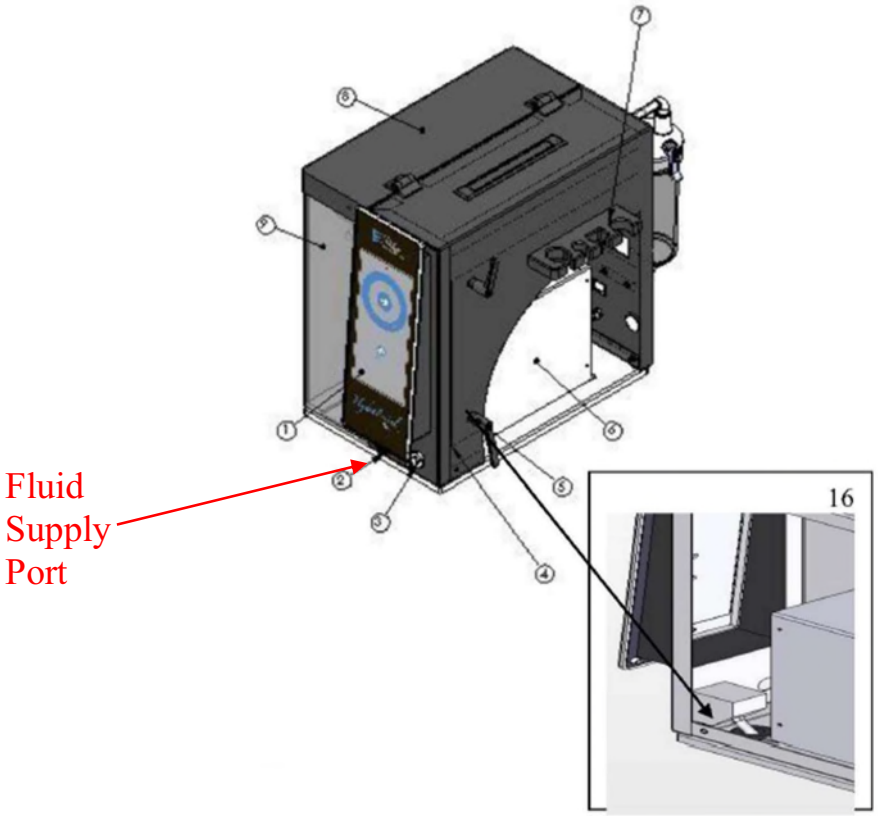
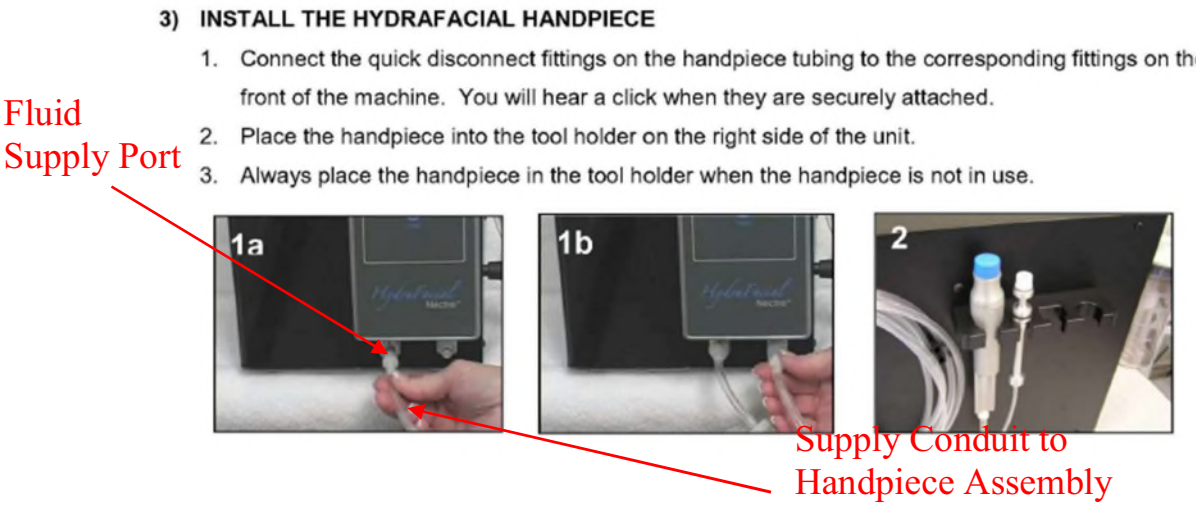


Id. at 7. The handpiece assembly is connected to the console and placed in fluid communication with what Nectre documentation refers to as the manifold system (and the container via the manifold system), through the fluid supply port.



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Ex. 2035 at 13 (Nectre Owner's Manual). The supply conduit extends from the fluid supply port to the handpiece assembly.

293. Accordingly, it is my opinion that the Nectre includes a "supply conduit."

b. 1[b][ii]: "placing the manifold system in fluid communication with"

294. As discussed above in limitation 1[b][i], when the handpiece assembly is connected, the Nectre system is placed in a state such that the passage of fluids from what the Nectre documentation refers to as a manifold to the handpiece assembly, via the supply conduit is possible. However, the Nectre does not include a manifold system.

295. Accordingly, it is my opinion that the Nectre meets this limitation with the exception of having the claimed manifold system.

c. 1[b][iii]: "a handpiece assembly"

296. In my opinion, the Nectre includes a handpiece assembly, as shown in the images below.

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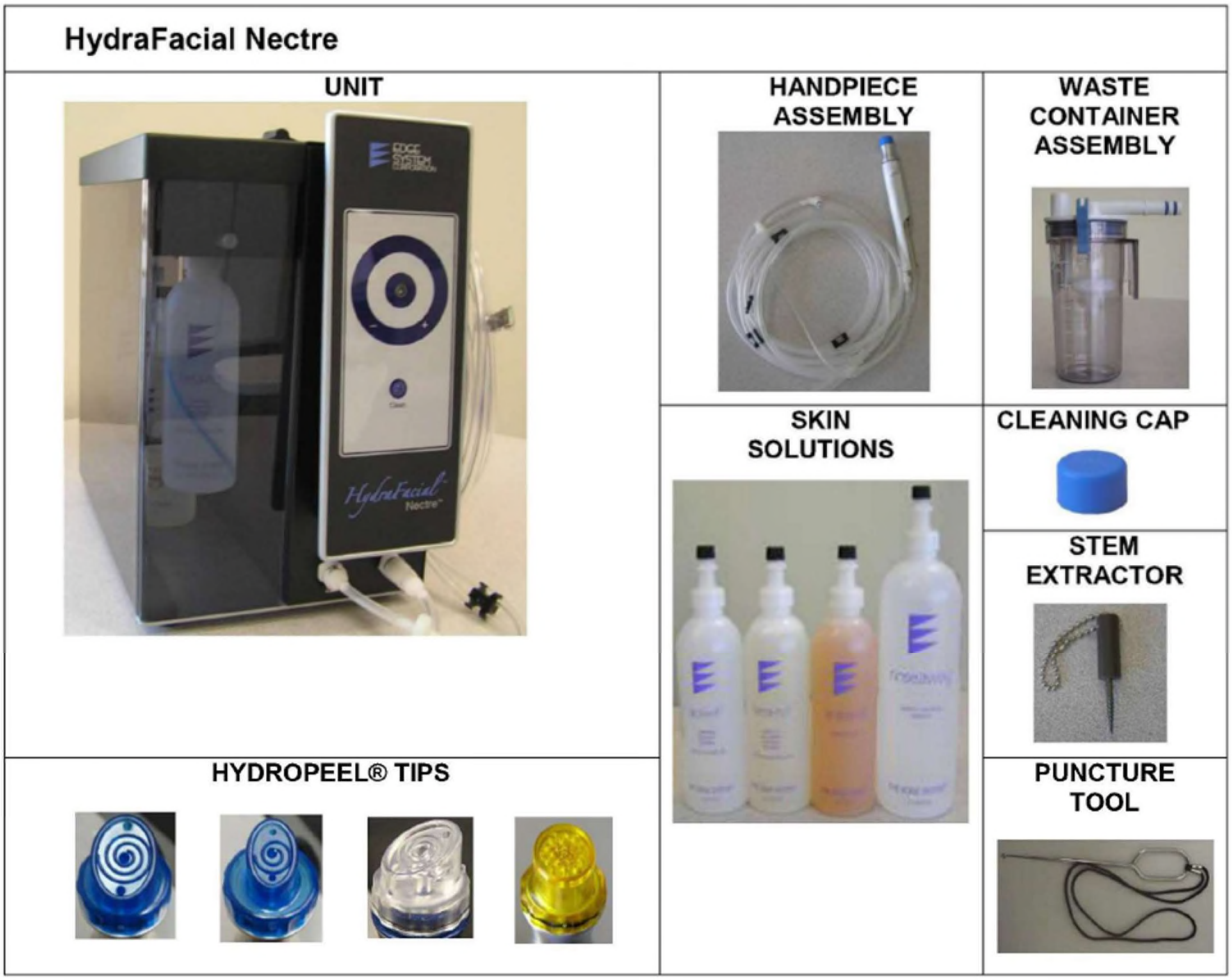

Ex. 2036 at 12 (Nectre User's Manual).

Increase flow
Counterclockwise

Decrease flow
Clockwise

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Ex. 2036 at 16 (Nectre User's Manual).

297. Accordingly, it is my opinion that the Nectre includes a "handpiece assembly" and satisfies this limitation with the exception of not having the claimed manifold system.

d. 1[c]: "wherein the handpiece assembly comprises a working end having a skin contact surface"

298. In my opinion, the Nectre includes a handpiece assembly comprising a working end having a skin contact surface.

299. As discussed above in limitation 1[b][iii], the Nectre includes a handpiece assembly, which in my opinion includes the tip. The patent specification makes clear that it is the handpiece/handpiece assembly, including the tip, that contacts the skin surface for treatment. *See, e.g.,* '477 Patent at Figs. 1-4 and 5:33-36, 5:47-51, 6:37-38, 6:42-46, 7:43-47, 10:31-62, 19:16-19, 19:30-33.

300. The Nectre User Manual confirms that the handpiece assembly, including the tip, is configured to contact skin tissue, instructing users to "[d]o a sensitivity test on the neck by the earlobe." Ex. 2036 at 7 (Nectre User's Manual); *see also supra* limitation 1[pre].

301. Accordingly, it is my opinion that the Nectre includes a handpiece assembly comprising "a working end having a skin contact surface."

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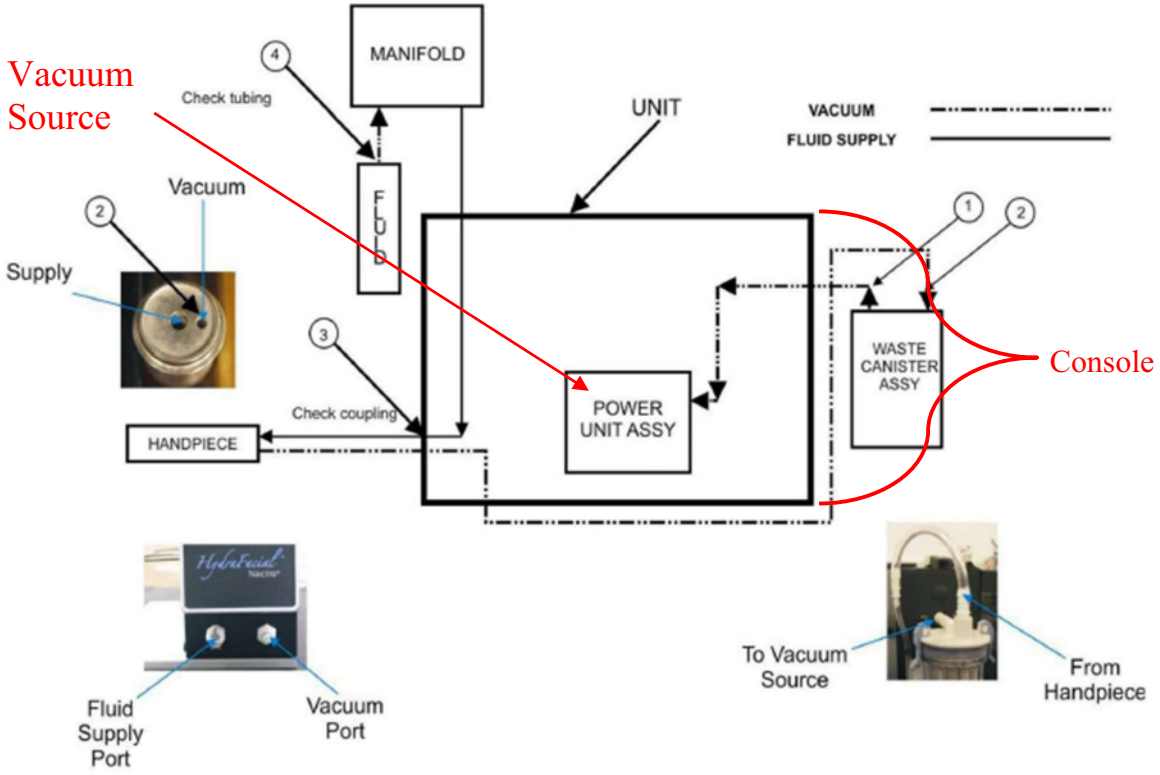
302. For these reasons, it is my opinion that this limitation is satisfied by the Nectre.

e. 1[d]: "a vacuum source"

303. In my opinion, the Nectre has a vacuum source.

304. As shown in the schematic below, the Nectre includes a vacuum source in the console.



Ex. 2037 at 6 (Nectre Service Manual).

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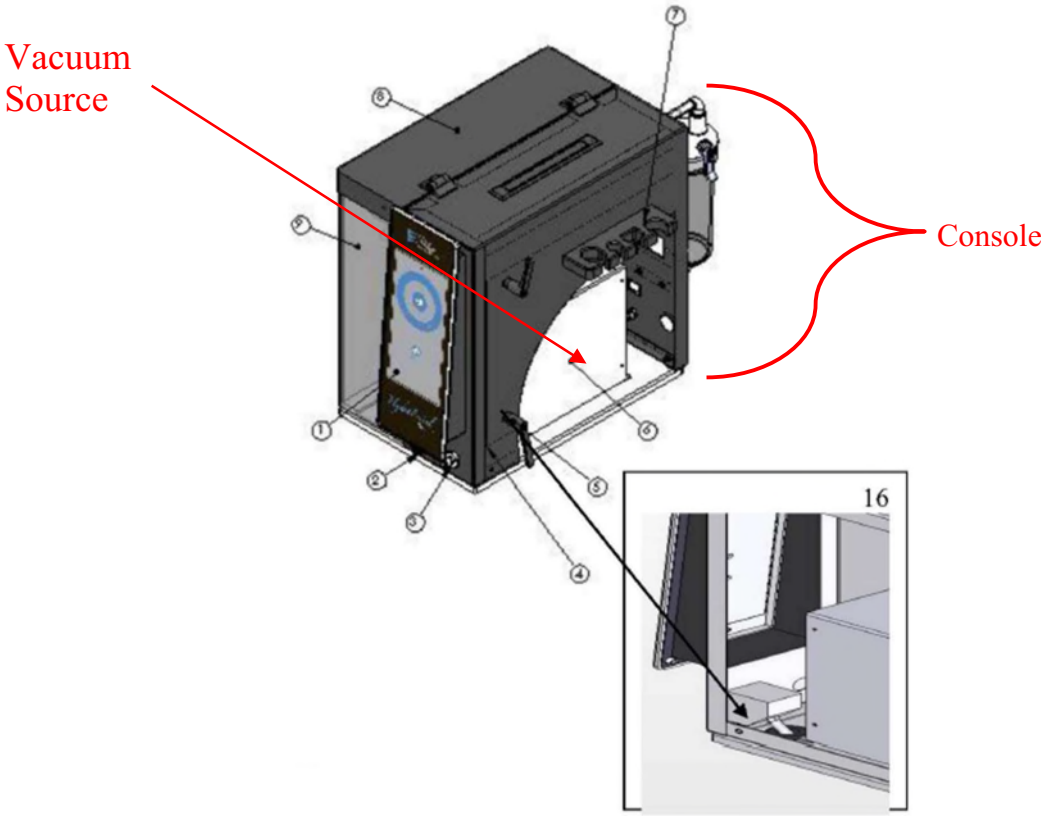

Id. at 7.

305. Accordingly, it is my opinion that this limitation is satisfied by the Nectre.

f. 1[e]: "a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the working end of the handpiece assembly during a skin treatment procedure; and"

306. In my opinion, the Nectre includes a waste conduit in fluid communication with the handpiece assembly and the vacuum source to move waste away from the working end of the handpiece assembly during a skin treatment procedure.

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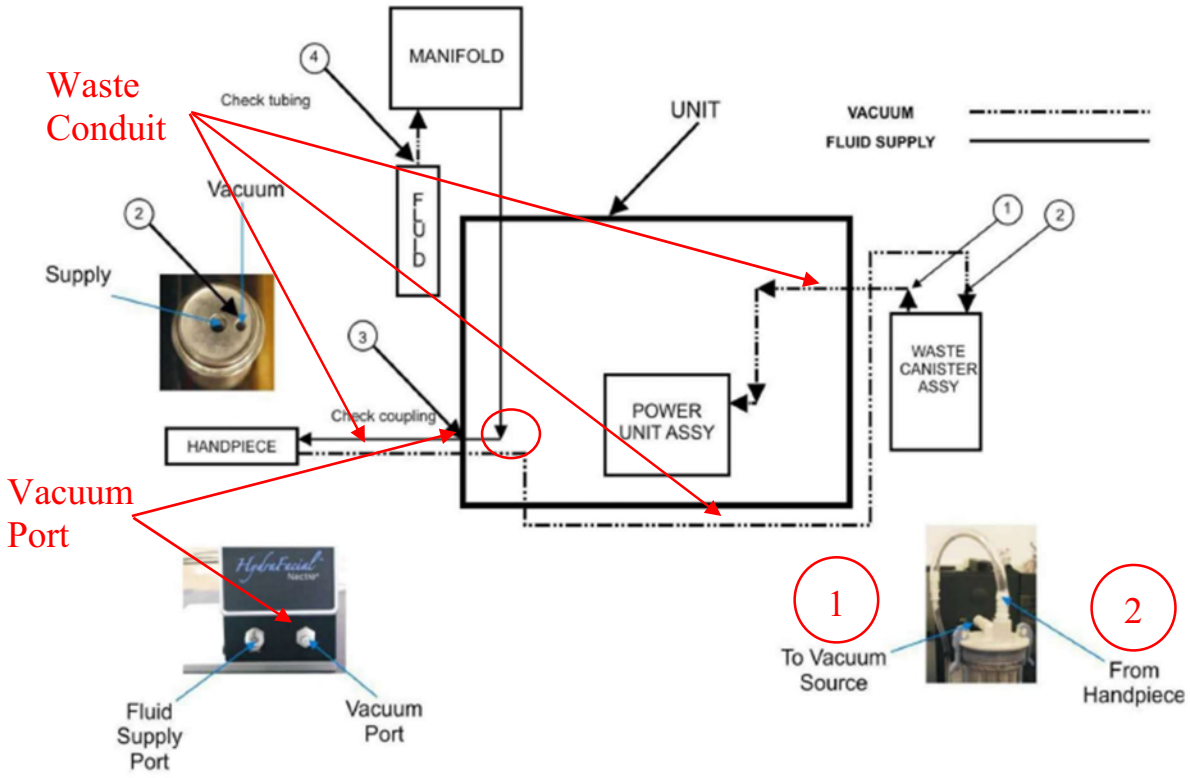
307. As shown in the below schematic, a waste conduit extends from the vacuum source to a vacuum port for the waste container, from the vacuum port for the waste container to the waste container, from the handpiece assembly port in the waste container to the vacuum port for the handpiece assembly, and from the vacuum port for the handpiece assembly to the handpiece assembly itself via what the Nectre documentation refers to as the internal manifold system and vacuum port.



Ex. 2037 at 6 (Nectre Service Manual).

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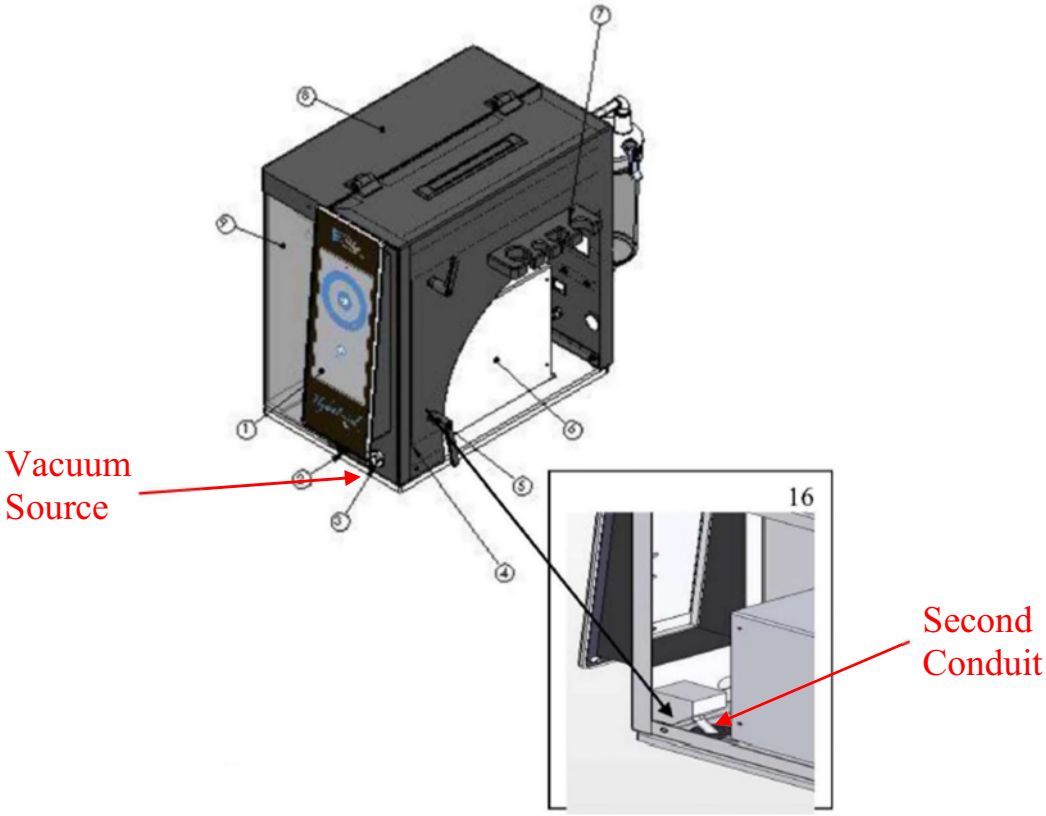

Id. at 7.

The handpiece assembly is connected to the console and placed in fluid communication with the waste conduit.

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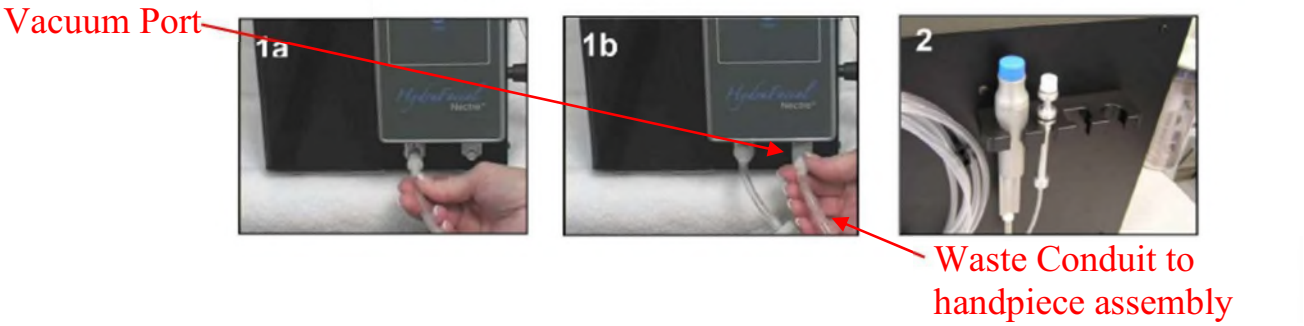
3) INSTALL THE HYDRAFACIAL HANDPIECE

1. Connect the quick disconnect fittings on the handpiece tubing to the corresponding fittings on the front of the machine. You will hear a click when they are securely attached.
2. Place the handpiece into the tool holder on the right side of the unit.
3. Always place the handpiece in the tool holder when the handpiece is not in use.



Ex. 2035 at 13 (Nectre Owner's Manual).

The waste conduit extends from the fluid supply port to the handpiece assembly. After the fluid exits the handpiece assembly to the skin surface, the used fluid and waste is suctioned into the handpiece assembly to the waste conduit via an opening in the main body of the handpiece assembly.

308. Due to the above-described fluid communication, when the vacuum source is activated and the handpiece assembly is contacting skin, a closed system is formed between a selected container and the vacuum source. Suction from the vacuum source, through the waste conduit, the handpiece assembly, the first conduit, and the block allows fluid to be drawn from the selected container and delivered to the skin, while used fluid and debris are simultaneously drawn away from the skin to the waste container.

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309. Accordingly, it is my opinion that this limitation is satisfied by the Nectre.

g. 1[f]: "at least one control to permit control of a flow of treatment material from the first container and the at least second container through the supply conduit to the handpiece assembly;"

310. In my opinion, the Nectre includes at least one control to permit control of a flow of treatment material from the single container through the supply conduit to the handpiece assembly.

311. As discussed in limitation 1[a] and 1[b], in the Nectre, fluid flows from the single container through the supply conduit to the handpiece assembly.

312. In addition, flow of treatment material from the single container to the handpiece assembly, via the supply conduit, could be controlled using, for example, the "Dial-a-Flow" adjustment knob on the handpiece assembly, as shown below.

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7) ADJUST SERUM FLOW

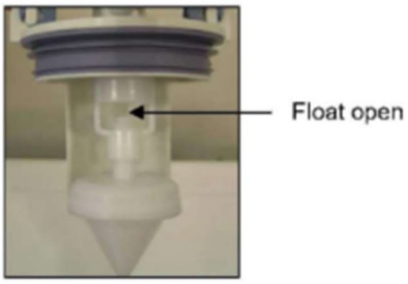
The handpiece has a built-in Dial-A-Flow™ adjustment for precision serum flow adjustment. The flow can be increased or decreased, as desired. The recommended starting point is the second to the smallest dot.

1. To **increase** serum flow, turn the Dial-A-Flow control **counterclockwise** toward the larger dots. Adjust as necessary.
2. To **decrease** serum flow, turn the Dial-A-Flow control **clockwise** toward the smaller dots. Adjust as necessary. Turning the control as far as it will go clockwise will stop all flow.

Note: If there is no vacuum or serum flow, be sure the float in the waste container is in the down position. (See page 16 for full troubleshooting instructions)

Increase flow
Counterclockwise

Decrease flow
Clockwise



Ex. 2035 at 15.

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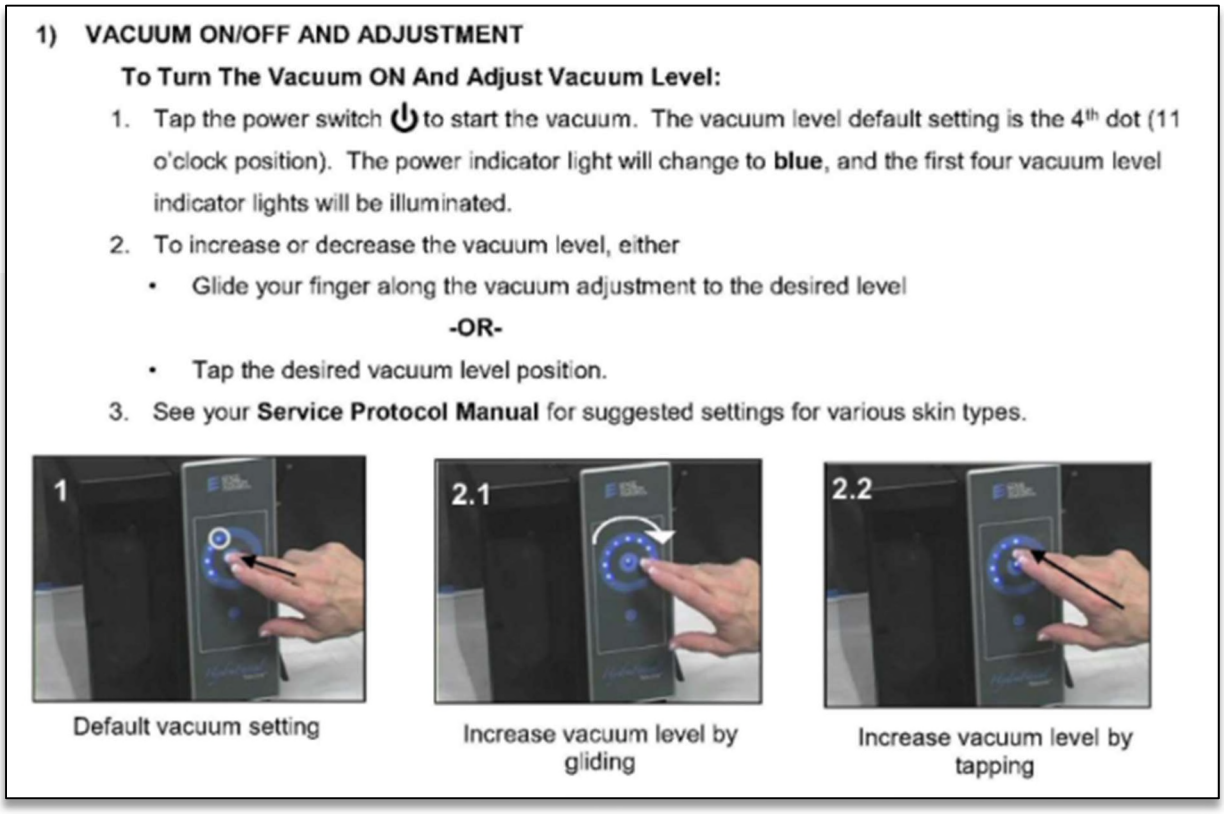
313. In addition, the Nectre can control flow of fluid by adjusting the vacuum level, and therefore adjusting the strength of the suction force within the closed loops system, thereby control flow of fluid, as shown below.



Id. at 17.

314. Accordingly, it is my opinion that this limitation, except to the extent it requires more than one container be connected to the system, is satisfied by the Nectre.

h. 1[g]: "wherein the vacuum source is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly to help remove waste from the handpiece assembly via the waste

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conduit and to help transfer at least one treatment material from the manifold system to the handpiece assembly."

315. In my opinion, the Nectre includes a vacuum source that is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly to help remove waste from the handpiece assembly via the waste conduit and to help transfer at least one treatment material from what the Nectre documentation refers to as the manifold system to the handpiece assembly.

316. As discussed above in limitation 1[d], Nectre includes a vacuum source. As discussed in limitation 1[e], the Nectre includes a waste conduit in fluid communication with the vacuum source and the working end of the handpiece assembly. As discussed in limitation 1[b][iii], the Nectre includes a handpiece assembly. As discussed in limitation 1[b], the Nectre includes a handpiece assembly in fluid communication with what the Nectre documentation refers to as a manifold. And, as discussed in limitation 1[a], the component the Nectre documentation describes as a manifold is in communication with a single treatment container.

a. 1[g][i]: "the vacuum source is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly"

317. As discussed above in limitation 1[e], the vacuum source creates a suction force within the waste conduit and along the working end of the handpiece assembly.

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b. 1[g][ii]: "to help remove waste from the handpiece assembly via the waste conduit"

318. The vacuum source helps remove waste from the handpiece assembly in several ways. For example, the vacuum source works in concert with the single fluid container, supply conduit, handpiece assembly, waste conduit, and waste container to form a closed loop system that allows suction force to form and remove waste from the handpiece assembly. *See supra* limitation 1[e].

319. Accordingly, the Nectre includes a vacuum source that is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly "to help remove waste from the handpiece assembly via the waste conduit."

c. 1[g][iii]: "and to help transfer at least one treatment material from the manifold system to the handpiece assembly"

320. The vacuum source helps transfer at least one treatment material from what the Nectre documentation refers to as the manifold to the handpiece assembly in several ways. For example, the vacuum source works in concert with the fluid containers, manifold system, supply conduit, handpiece assembly, waste conduit, and waste container to form a closed loop system that allows suction force to draw at least one treatment material from the fluid containers into what the Nectre

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documentation calls a manifold, and then from that component to the handpiece assembly via the supply conduit. *See supra* limitation 1[a] and limitation 1[b].

321. Accordingly, it is my opinion that the Nectre includes a vacuum source that is configured to create a suction force within the waste conduit and along the working end of the handpiece assembly "to help transfer at least one treatment material from" what the component the Nectre documentation calls a manifold "to the handpiece assembly."

322. For all of these reasons, it is my opinion that the Nectre meets the limitations of Claim 1 of the '477 Patent, with the exception of the limitations directed to the manifold system and having multiple containers connected to a manifold system.

323. For the same reasons (e.g., that Nectre lacks a manifold and that only a single container connects to the component the Nectre documentation refers to as a manifold), it is my opinion that the Nectre does not practice every element of claims 2-20.

E. There Is a Nexus Between the Commercial Success of the HydraFacial Systems and the '477 Patent Claims

324. I understand that another expert, Dr. Pallavi Seth, is offering opinions on the commercial success of the HydraFacial Systems. I am not a financial expert

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and offer no economic analyses related the commercial success of the HydraFacial Systems.

325. In connection with Dr. Seth's opinion on commercial success, I was asked to provide expert analysis on whether the HydraFacial Systems embody the claims of the '477 Patent and are coextensive with them to establish a presumed nexus. As I explained above, the HydraFacial Systems embody the claims of the '477 Patent and are coextensive with them, thus HydraFacial is entitled to the presumption of a nexus for the commercial success of the HydraFacial Systems.

326. Furthermore, in my opinion, the difference between the HydraFacial Systems and the Nectre is that the HydraFacial Systems are multi-container hydrodermabrasion systems (having a manifold of a console, waste conduit, and waste container) as opposed to the single-container hydrodermabrasion system found in the Nectre.

327. It is further my opinion that the multi-container HydraFacial Systems provide for easier and more efficient treatments (no need to pause treatment to change bottles), making the HydraFacial Systems more desirable. This is confirmed by the poor sales of the Nectre, which ultimately led to its discontinuation.[2]

[2] Discussion with Dr. Seth on 10/15/2025.

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328. To the extent Petitioners argue other components such as the tips are the driver of sales for the HydraFacial Systems, I disagree. First, the tips serve no purpose without the HydraFacial Systems. Also, the tips used in the Nectre are the same as those used in the HydraFacial Systems, and the Nectre experienced poor sales compared to the HydraFacial Systems, despite using the same tips. See, e.g., Ex. 2036, 12 (Nectre User Manual showing HydroPeel tips); Ex. 2032, 10 (Allegro IFU showing HydroPeel tips); Ex. 2031, 13 (Elite IFU showing HydroPeel tips).

329. Accordingly, it is my opinion that there is a nexus between the commercial success of the HydraFacial Systems and the claims of the '477 Patent directed to a multi-container system.

F. Copying

330. I understand from counsel that evidence a competitor has copied a product covered by a patent is strong evidence supporting nonobviousness.

331. HydraFacial became aware in 2014 that an individual named Rafael Newton Aguila ("Aguila") was selling a product under his own brand name, "HydraDerm," which was a near-exact copy HydraFacial's Tower product. Ex. 2005, 5-6.

332. As I explained above, the Tower embodies the challenged claims of the '477 patent, and Aguila's knockoff product wholesale copied those claimed features.

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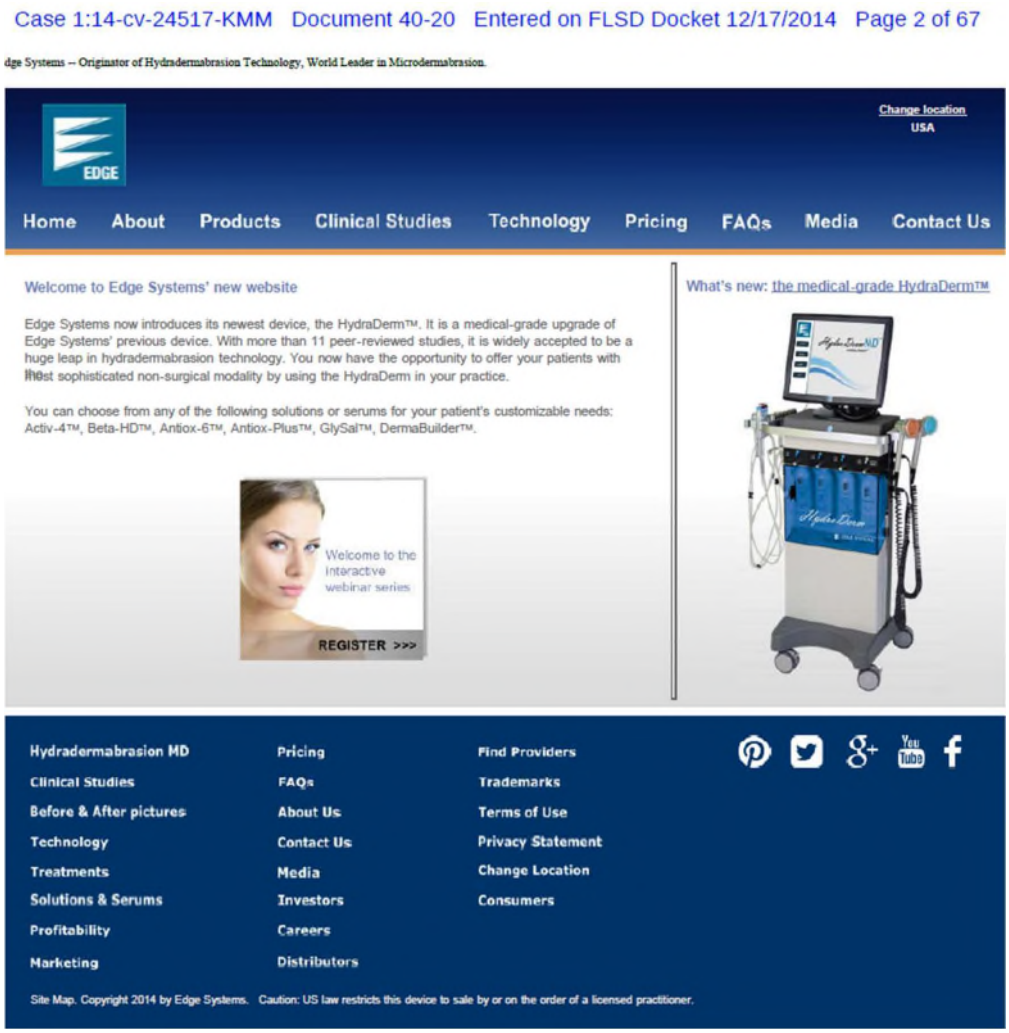
Aguila's own website confirmed he intended his "HydraDerm" product to look and function like the Tower.



Ex. 2154, 3 (attorney declaration attaching website printout); Ex. 2155, 2.

333. Aguila promoted his knockoff device as "the next generation in microdermabrasion technology due to the simultaneous dermal infusion of medicinal products and crystal-free exfoliation" and "the first medical device that

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uses the '4-in-1' technology of Cleansing, Exfoliation, Extraction, and Infusion." Ex. 2155, 4, 12.

334. On his website, Aguila included images of his knockoff "Hydraderm" having multiple treatment containers and emphasized the use of multiple treatment solutions. *Id.* Aguila also described the functionality of the components, including the "pneumatic action of the vacuum" and use of the handpiece to deliver treatments with the multiple solutions. *Id*., 7. In my opinion, these are the integrated treatment capabilities claimed in the '477 patent and embodied in the Tower.

335. I understand that HydraFacial brought a lawsuit against Aguila for patent infringement, trademark infringement, and trade dress infringement. Ex. 2005, 8-9. I understand that HydraFacial was granted an emergency motion for a temporary restraining order and a preliminary injunction against Mr. Aguila. See Ex. 2007 (Report and Recommendation on Prelim. Injunction); Ex. 2008 (Order Granting Prelim. Injunction).

336. I understand that later in the case the judge issued an order granting HydraFacial's motion for summary judgment. Ex. 2005 (Summary Judgment Order). In that order, the judge included a side-by-side comparison of Aguila's HydraDerm and HydraFacial's Tower:

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EDGE HYDRAFACIAL® PRODUCT

DEFENDANT'S ACCUSED PRODUCT

Ex. 2005, 6.

2. **The judge also described Aguila's copying of HydraFacial's Tower product this way:**

> Bootleg. Clone. Copycat. Imitation. Knock-off. Palm-Off. However one labels a peddled product that conspicuously capitalizes on another's intellectual property rights, this case presents the quintessential example.

Id., 1. The resemblance between Aguila's "HydraDerm" and the Tower was so close that Aguila was able to lure customers into thinking that the knockoff product was an authentic version of HydraFacial's Tower product. *Id.*, 7-8.

337. Based on my review of the evidence, including the images of Aguila's device, the statements on his website, the fact that multiple customers believed they had purchased a HydraFacial Tower, it is my opinion Aguila's device contained the same structural features—including a manifold, waste conduit, waste container and multiple treatment solution containers—integrated into the "HydraDerm" system.

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338. In my opinion, Aguila's blatant copying of the HydraFacial Tower is objective evidence that the claims of the '477 Patent would not have been obvious to a person of skill in the art. This blatant copying itself is direct proof of nexus between the secondary considerations of nonobviousness and the '477 Patent claims. Aguila's "HydraDerm" was a near-identical replica of the Tower, and, as I explained above, the Tower is coextensive with the claims of the '477 Patent.

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