

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

HYDRAFACIAL LLC,

Plaintiff,

v.

AESTHETIC MANAGEMENT PARTNERS, LLC
and AESTHETIC MANAGEMENT PARTNERS
INC.,

Defendants.

Case No. 2:24-cv-02480-JPM-tmp

**EXPERT DECLARATION OF KARL LEINSING, MSME, PE
IN SUPPORT OF HYDRAFACIAL LLC'S
MOTION FOR PRELIMINARY INJUNCTION**

I. BACKGROUND AND QUALIFICATIONS

1. My name is Karl Leinsing, and I am over 21 years of age and otherwise competent to submit this declaration (the “Declaration”) in support of Plaintiff HydraFacial LLC (“HydraFacial”)’s Motion for Preliminary Injunction against Defendants Aesthetic Management Partners, LLC and Aesthetic Management Partners, Inc. (collectively, the “Defendants” or “AMP”). I make this Declaration based on facts and matters within my own knowledge and on information provided to me by others. If called as a witness, I could and would competently testify to the matters set forth herein.

2. I understand that HydraFacial alleges that Defendants’ importation and sale of the hydrodermabrasion product the AquaFirmeXS (“the Accused Device”) infringes U.S. Patent No. 9,550,052 (the “’052 Patent”) and U.S. Patent No. 11,865,287 (the “’287 Patent”) (collectively, the “Asserted Patents”).

3. In forming my analysis and opinions, I relied on documents described herein as well as my own personal education, professional experience and knowledge of the art as it existed at the time the ’052 and the ’287 Patents were filed. I reserve the right to modify or expand my opinions if additional information is received.

4. In this expert declaration, I have been asked to review relevant materials and provide my expert opinion regarding whether claim 1 of the ’052 Patent and claim 22 of the ’287 Patent (collectively, “the Asserted Claims”) are infringed by the AquaFirmeXS. I have also been asked to provide my expert opinion as to whether the Asserted Claims are novel and non-obvious. I understand that these are a subset of the asserted claims for purposes of this motion for preliminary injunction, and that there are additional asserted claims and asserted patents in this case.

5. I am an independent expert and not an employee of any party or counsel to any party in this lawsuit.

6. I have summarized in this section my educational background, career history, and other qualifications relevant to this matter. I have also included a current version of my curriculum vitae as Appendix A.

7. I received a Bachelor of Science (B.S.) degree in mechanical engineering from the University of New Hampshire in 1988 and a Master of Science (M.S.) degree in mechanical engineering from North Carolina A&T State University in 1995. I am also licensed as a Registered Professional Engineer in the state of New Hampshire (License#: 11437).

8. I have been a medical device engineer since 1992 and have worked extensively with medical device pumps and disposables, including syringes, catheters, and valves of all types, since that date. I have extensive expertise in the mechanical design and manufacturing of medical devices. My areas of expertise include full-life cycle product development of medical devices, including conception, design, prototyping, manufacturing, testing, verification, validation, packaging, bioburden testing, sterility assurance testing, residual testing, biocompatibility, bacterial contamination testing, labeling, clinical trials, regulatory approval, marketing, and sales training.

9. Since 2006, I have been President of ATech Designs, Inc., where I have worked in the development of various medical devices and automated equipment that manufactures medical devices, including cardiovascular, surgical, intravenous, endoluminal, and percutaneous devices. More specifically, I have consulted in the development of various drug delivery devices, such as IV pumps, peritoneal dialysis pumps, auto-injectors, pen injectors, syringes, safety syringes, disinfecting caps, stop-cock valves, urinary catheter kits that include either bags or metered

containers, IV valves, catheter dressing designs that use a burst-type foil pouch that releases an antiseptic, subcutaneous ports, catheters, wound closure device, and knitting machine to make an endometrial ablation array that uses pneumatic valves, actuators, pressure/vacuum regulators.

10. Previously, from 2005-2006, I worked as a Director of Biomedical Engineering at Mitralign, Inc., developing implants for heart valve repair. From 2002 to 2005, I worked as a Manager of Design Engineering at ONUX Medical, Inc., developing fixation devices for abdominal aortic aneurysm repair as well as laparoscopic devices for stapling and sutures.

11. From 1992 to 2002, I worked as a Senior Principal Design Engineer at IVAC, which was a subsidiary of Eli Lilly & Company. There, I developed a number of medical drug infusion products, including disposable sets and components, IV tubing and syringe pump systems, injection systems, vial adapters, syringes, solution bags and containers, and needle-free valves for the delivery of drugs. My work involved both the conception and manufacturing of these devices, including both EtO and gamma irradiation sterilization of disposable medical devices such as syringes and male luer caps. During this time, I was the sole inventor of the SmartSite® Needle-Free Valve for intravenous infusion pumps and disposables. I was involved in the development of a dual-acting pen injector, capable of dispensing both long-term and short-term insulin, for Eli Lilly (parent company of my employer IVAC). In addition to my extensive involvement with the design team for the entire device, my work focused on the development of the disposable needle, valve mechanism, and adapters that attached to the distal end of the device.

12. I am a named inventor of over 41 patents, all of which relate to the medical device field. I have previously lectured on the product design and manufacturing process of medical devices. I was also named Chairman of the Medical Device and Manufacturing Conference in 2014 for the development process of medical devices.

13. A copy of my curriculum vitae, attached as [REDACTED] contains further details concerning my education, experience, publications, patents, awards, recognition, licenses, and other qualifications to render an expert opinion in this matter.

14. I am being compensated for my time in connection with this proceeding at my customary hourly rate of [REDACTED] per hour. My compensation is not dependent on the outcome of this proceeding. I have no personal or financial stake or interest in the outcome of this proceeding. I am not an employee, consultant, or contractor of HydraFacial.

15. I have personal knowledge of the matters set forth in this declaration and, if called upon as a witness, would testify competently thereto. I have used my education and my years of experience working in the field of mechanical engineering and medical device design, and my understanding of the knowledge, creativity, and experience of a person of skill in the art in performing the analysis expressed in this declaration.

II. PRIOR TESTIMONY

16. I have provided expert testimony in over twenty District Court litigations, ITC investigations, and State Litigations in the past four years, a list of which can be found in my curriculum vitae, attached hereto as [REDACTED]

III. MATERIALS REVIEWED

17. In forming the opinions expressed herein, I have considered the materials discussed in this declaration, including the '052 Patent and the '287 Patent. I also analyzed a sample of the AquaFirmeXS product, photographs and videos of which are included as exhibits.

18. Additionally, in forming my opinions, I have relied upon my education, training, and experience, along with my analysis of the Accused Device.

19. The opinions set forth in this report are based on the information of which I am aware to date. I reserve the right to supplement this report should additional information become available or should Defendants present new issues in response to this report.

IV. LEVEL OF SKILL IN THE ART

20. I have been informed that the definition of the level of skill possessed by the hypothetical person of ordinary skill in the art (“POSA”) is informed by several factors. These factors include the type of problems encountered in the relevant art, the prior art solutions to those problems, the rapidity with which innovations are made in the relevant art, the sophistication of the relevant technology, and the educational level of active workers in the field.

21. In my opinion, a person of ordinary skill in the art at the relevant time period, which I understand to be around the time of the earliest priority application of the ’052 and ’287 Patents, would have had a degree in science or engineering plus a minimum of three years of experience in the medical device industry. Alternatively, a product designer could have an additional two years of experience in the industry in lieu of a formal science or engineering degree. The person of ordinary skill would also consult with a physician as needed to understand the medical implications of the disclosed device, including the effect of the device on the skin.

V. APPLICABLE LEGAL STANDARDS

22. I am an engineer by training and profession. The opinions I express in this report involve application of my education, training, and technical knowledge and experience to the evaluation of the Accused Devices and the Asserted Claims.

23. Although I have extensive experience as an expert in patent matters, I am not an expert in patent law. Therefore, I have been advised by HydraFacial’s counsel of certain principles of patent law applicable in this action. I have applied these principles as appropriate in arriving at

the opinions set forth herein. The paragraphs below summarize these legal principles and my understanding of how these principles must be applied in forming my opinions.

A. Legal Principles

24. I have been informed by counsel that HydraFacial bears the burden of proving infringement of the Asserted Claims by a preponderance of the evidence. I understand this requires HydraFacial to show infringement of the Asserted Claims is more likely than not.

25. I understand that determination of patent infringement is a two-step process: first, a claim must be properly construed to determine its scope and meaning; and second the claim as properly construed must be compared to the accused product or process.

1. Claim Construction

26. I understand that claim construction is a matter of law for the Court. I also understand that any terms not construed by the Court receive their plain and ordinary meaning to a person of ordinary skill in the art at the time of the invention.

27. In forming my opinions in this case, I used the plain and ordinary meaning of each term to a person of ordinary skill in the art at the time of the invention.

28. I understand that there was an adjudication by the Administrative Law Judge in Inv. No. 337-TA-1408 entitled *Certain Hydrodermabrasion Systems and Components Thereof* regarding the construction of terms that are present in the Asserted Claims of the '052 and '287 Patents. I have been informed that this adjudication applied the plain and ordinary meaning of the claim terms and is not binding in the present suit.

2. Infringement

29. It is my understanding that there are two types of infringement: literal infringement and infringement under the doctrine of equivalents. I understand that, in order for a patent claim

to be literally infringed, each and every limitation of that claim must be present in the accused device.

30. I understand that, if a limitation is not literally present in the accused device, the claim may still be infringed under the doctrine of equivalents, if the accused device contains a substantial equivalent for the missing limitation. I understand that for a structure in the accused device to be an equivalent of a claim limitation that is literally missing, the structure in the accused device must be insubstantially different from the claim limitation. I also understand that one way of evaluating whether a structure is substantially different from a claim limitation is to determine whether the structure performs substantially the same function, in substantially the same way, to achieve substantially the same result as the limitation in question. I understand that this doctrine of equivalent analysis is known as the function, way, result test.

3. **Validity**

31. I understand from counsel that patents are presumed to be valid and that a party challenging the validity of a patent bears the burden of proving invalidity by clear and convincing evidence. I understand that “clear and convincing” means that the evidence is highly and substantially more likely to be true than untrue. In other words, Respondent must prove that it is highly probable that claim 1 of the ’052 Patent and claim 22 of the ’287 Patent are invalid. In evaluating the validity of the patent, I understand that each claim is to be evaluated independently.

a. **Anticipation**

32. It is my understanding that a claim is anticipated under 35 U.S.C. § 102¹ only if each and every element of the claimed invention is disclosed either expressly or inherently in a single prior art reference or embodied in a single prior art device or practice. In other words, I

¹ I understand that pre-AIA 35 U.S.C. § 102 applies to the ’052 and the ’287 Patent claims as the applicable priority date for the claims is prior to the March 16, 2013 effective date of the AIA.

understand that there must be no difference between the claimed invention and the disclosure of the prior art reference, as viewed by a person of ordinary skill in the art (“POSA”).

33. I also understand that a prior art reference does not anticipate a claim when it discloses multiple, distinct teachings that a person of ordinary skill in the art might somehow combine to achieve the claimed invention.

34. Finally, I understand that, in order to anticipate, a prior art reference must disclose the claimed invention as arranged in the claim, and that the disclosure must be enabling.

b. Obviousness

35. I understand that a patent claim may be invalid under 35 U.S.C. § 103 as being obvious if the claimed subject matter as a whole would have been obvious to a POSA at the time of the alleged invention. I also understand that an obviousness analysis takes into account the following factors, which are sometimes referred to as the *Graham* factors: (1) the scope and content of the prior art, (2) the differences between the claimed subject matter and the prior art, (3) the level of ordinary skill in the art at the time of the invention, and (4) “objective indicia of non-obviousness,” also referred to as secondary considerations of non-obviousness.

36. In determining the scope and content of the prior art, it is my understanding that it is appropriate to consider a prior art reference in an obviousness analysis if it falls within the field of the inventor’s endeavor or is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have come to an inventor’s attention in considering his or her problem.

37. To assess the differences between the prior art and the claimed subject matter, it is my understanding that 35 U.S.C. § 103 requires the claimed invention to be considered as a whole. This “as a whole” requires showing that one of ordinary skill in the art at the time of invention,

confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

38. I understand that a claim is not proved obvious merely by demonstrating that each of the individual claim elements was independently known. I understand that when a combination of references is relied upon to allege that a claimed invention would have been obvious, it is necessary to identify whether a reason existed at the time of the invention that would have prompted a POSA in the relevant field to combine the known prior art elements in the way the claimed invention does. I understand that an assessment of what a reference discloses or teaches—for purposes of an anticipation analysis or an obviousness analysis—must be conducted from the perspective of a POSA at the time of the invention. In other words, I understand that the mere fact that a possible arrangement existed in the prior art does not provide a reason that a POSA would have modified or combined teachings of the prior art. I further understand that a generic or conclusory analyses of motivations to combine are insufficient when they bear no relation to any specific combination of prior art elements from specific references and do not explain why a POSA would have combined them in the way the invention does.

39. I understand that, in addition to having reasons to modify or combine teachings of the prior art, the POSA must have a reasonable expectation of success in doing so. I also understand that a patent claim may be non-obvious where the inventors recognized and solved a problem that the prior art did not recognize. I have been informed that without knowledge of the problem, it would not have been obvious to undertake efforts to solve that problem. I understand that even an obvious solution does not render an invention obvious if the problem solved was previously unknown.

40. I understand that an assessment of what a reference discloses or teaches—for purposes of an anticipation analysis or an obviousness analysis—must be conducted from the perspective of a POSA at the time of the invention.

41. I understand that possible objective indicia of non-obviousness include considerations such as whether a product covered by the claims is commercially successful due to the merits of the claimed invention, whether there was a long felt need for the solution provided by the claimed invention, whether others failed to find the solution provided by the claimed invention, whether others copied the claimed invention, and whether there was acceptance by others of the claimed invention as shown by praise from others in the field.

42. I understand that, for the objective indicia of non-obviousness to have probative value, there must be a nexus between the merits of the claimed invention and the objective indicia of non-obviousness.

43. I understand that a nexus is presumed between the claimed invention and the objective evidence of secondary considerations of non-obviousness when a product embodies the claimed invention and is co-extensive with it.

c. Public Use

44. I understand that a patent claim may be invalid under 35 U.S.C. § 102(b) if the invention was publicly used more than one year prior to the invention's earliest priority date (the "critical date"). I understand that, in order to be an invalidating public use under 35 U.S.C. § 102(b), the invention must (1) be ready for patenting and (2) in public use.

45. I understand that factors the Federal Circuit has identified as being helpful in determining whether a use was public under the statute include the nature of the activity that occurred in public, the public access to and knowledge of the public use, whether there was any

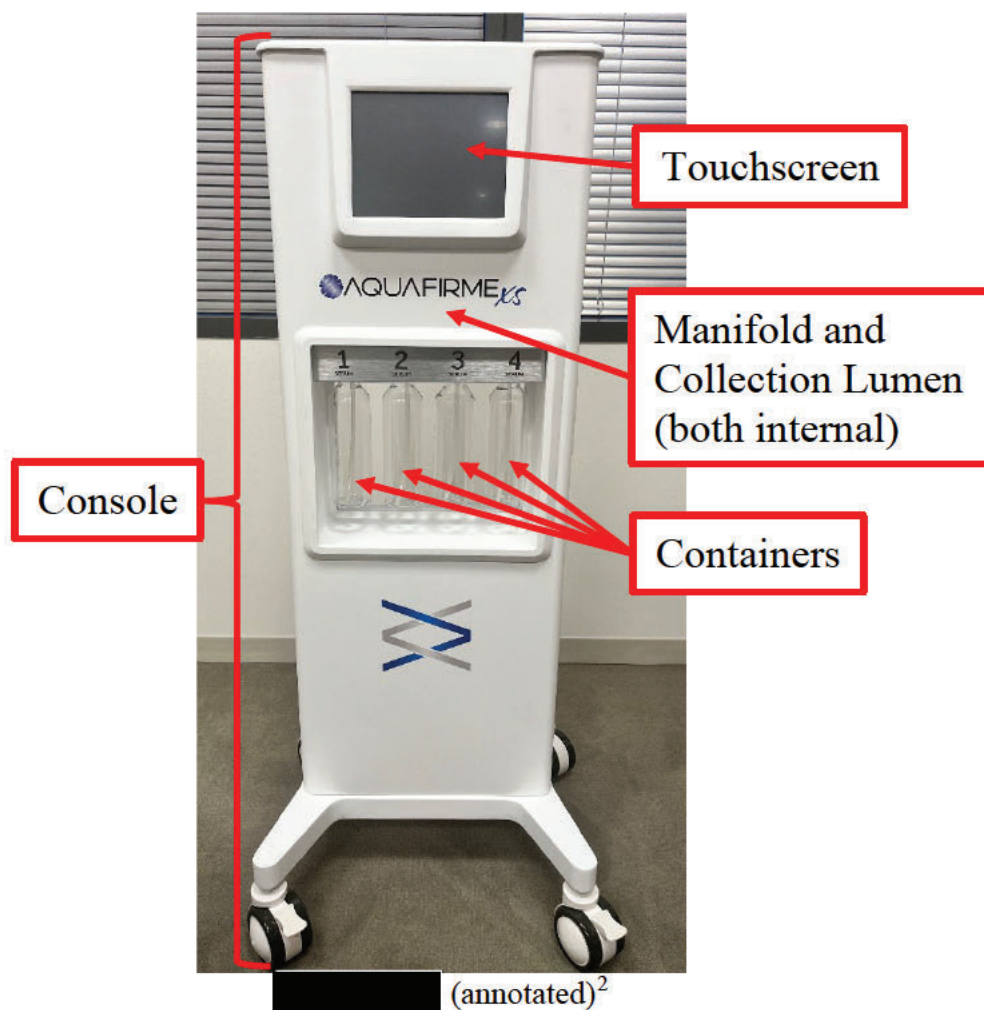
confidentiality obligation imposed on persons who observed the use. I further understand that the presence or absence of an express confidentiality agreement is not determinative of public use.

46. I understand that experimental use is an exception to the statute's public use restriction, and thus, is not an invalidating public use. I further understand that a use is experimental if the use is designed to (1) test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose. I understand that various factors are relevant to assessing whether or not a use is experimental, including: (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers. I further understand that an experimental use may be non-secret, but still remain a non-invalidating use.

47. I reserve the right to change or formulate new opinions if there is a material change in the law concerning patent infringement between now and the hearing.

VI. ACCUSED PRODUCT: THE AQUAFIRMEXS

48. I have inspected a sample of the accused product branded as the AMP AquaFirmeXS. That sample I analyzed is pictured below.



49. As shown above, the AquaFirmeXS comprises a computer display screen integrated into a console. The AquaFirmeXS includes four liquid containers (pictured) and a handpiece for a hydrodermabrasion treatment (not pictured) connected to the console. During my inspection, I observed that, during the operation of the AquaFirmeXS and when the handpiece of the AquaFirmeXS is contacting the skin, fluid is drawn from a selected fluid container to the tip of the handpiece, where the fluid contacts the skin. I further observed that used fluid is drawn away from the skin through the handpiece and into a waste container.

² All emphasis in textual quotations and color annotations and textual labels in figures has been added throughout, unless indicated to the contrary.

50. The AquaFirmeXS includes a handpiece/handpiece assembly, called the “EVO” handpiece, which is configured to contact a patient’s skin via a removable tip, shown below.



51. An isolated view of the handpiece body without its removable tip is shown below.



52. During my inspection of the handpiece without its removable tip, I observed a waste line through which fluid waste and debris is drawn away from the treatment area and to the waste container. I also observed a supply line which provides treatment fluid, drawn from the fluid containers, to the skin of a patient.

VII. GENERAL TECHNICAL DISCUSSION OF HYDRODERMABRASION

53. Hydrodermabrasion is a method of rejuvenating the skin by applying different fluid solutions to the skin to cleanse and exfoliate the skin surface, extract debris from pores, and thoroughly hydrate and moisturize the skin. It is a field that HydraFacial pioneered, as evidenced by the '052 and the '287 Patents. These systems are generally used by end users such as dermatologists, plastic surgeons, cosmetic physicians, and aestheticians at medical spas.

54. Hydrodermabrasion works by applying treatment fluids to a person's skin while simultaneously suctioning spent treatment fluid away from the skin and into a waste container. Systems that perform hydrodermabrasion, like those described by the '052 Patent and '287 Patent, have fluid containers connected to the system, such that the system allows the fluid containers to be in fluid communication with a handpiece through a supply conduit, which is applied to the skin of the user.

55. Hydrodermabrasion is distinguished from the old-style, previous field of microdermabrasion. Microdermabrasion is a method of removing the surface of the skin through mechanical rubbing or abrasion by a handpiece that usually emits a stream of sand or grit to wear away cell layers of the skin. One problem with microdermabrasion is that, as the grit wears away cell layers of the skin, so too does it remove moisture from the skin. Hydrodermabrasion solves this problem by using fluid sources and suction pressure instead of microdermabrasion's stream of sand or grit. This allows for a physical exfoliation of the skin from the suction pressure and textured tip of the handpiece, chemical exfoliation from the treatment solutions used as the fluid, and suction to lift dead skin cells off the surface.

VIII. BACKGROUND OF THE '052 PATENT AND '287 PATENT

56. The application that resulted in the '052 Patent was filed on April 28, 2015, and is a continuation of Application No. 13/267,554, filed on October 6, 2011, which is a continuation

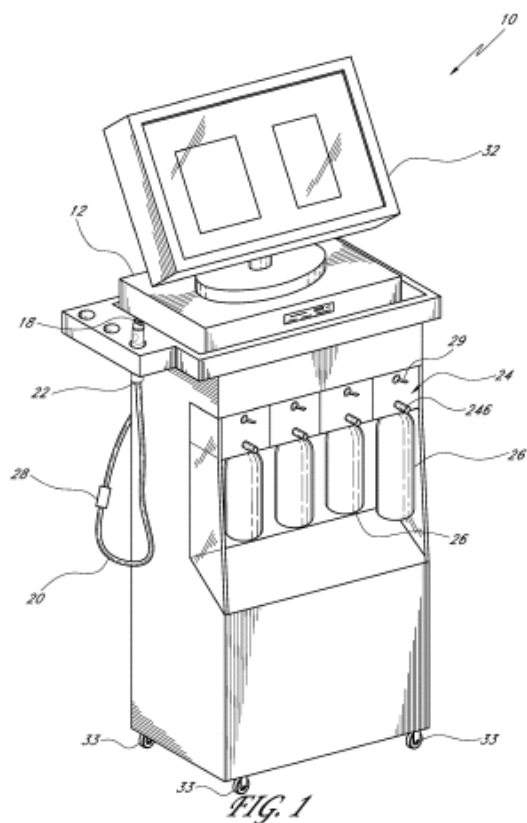
of application No. 11/392,348, filed on March 29, 2006, now Pat. No. 8,048,089. '052 Patent, cover page. The '052 Patent claims priority to provisional application No. 60/755,310, filed on December 30, 2005, and provisional application No. 60/764,668 filed on February 2, 2006. *Id.*

57. The application that resulted in the '287 Patent was filed on January 9, 2023, and is a continuation of Application No. 17/165,820, filed on February 2, 2021 and issued as Pat. No. 11,547,840, which is a continuation of Application No. 16/517,268, filed on Jul. 19, 2019 and issued as Pat. No. 11,446,477, which is a continuation of application No. 14/700,789, filed on April 30, 2015 and issued as Pat. No. 9,814,868, which is a continuation of application No. 13/267,554, filed on October 6, 2011 and issued as Pat. No. 9,474,886, which is a continuation of application No. 11/392,348, filed on March 29, 2006 and issues as Pat. No. 8,048,089. The '287 Patent claims priority to provisional application No. 60/764,668, filed on February 2, 2006, and provisional application No. 60/755,310, filed on December 30, 2005.

58. The claims of the '052 and '287 Patent are directed to skin treatment systems that operate in a wet mode, having multiple containers containing the treatment fluids to apply through the handpiece. *See, e.g.*, claim 1 of the '052 Patent; claim 22 of the '287 Patent. The '052 and '287 treatment system facilitates and automates the application of multiple treatment fluids to a person's skin via a handpiece while simultaneously suctioning spent treatment fluid away from the skin and into a waste container. '052 Patent at 5:51-5:57, 7:47-7:60.³ The user can select a desired treatment medium from multiple treatment-fluid containers (shown in the figure below). '052 Patent at 6:9-6:18, 15:49-51, 17:5-17:17. In one embodiment, the manifold system disclosed in the '052 Patent

³ Because the '287 Patent is a continuation of the '052 Patent, the two patents have identical specifications and thus only the '052 Patent specification is cited throughout this section. However, it is taken to be representative of both patents.

is a “manifold system 24 that holds containers 26 containing treatment fluids.” ’052 Patent at 14:26-28.



’287 Patent at Fig. 1; ’052 Patent at Fig. 1

IX. OPINIONS ON INFRINGEMENT

59. I have been asked to evaluate whether the accused product, Defendant’s AquaFirmeXS device, meets each limitation of claim 1 of the ’052 Patent, and meets each limitation of claim 22 of the ’287 Patent.

60. I have analyzed the relevant aspects of the AquaFirmeXS system in view of the Asserted Claims.

61. As set forth in detail below, it is my opinion that the AquaFirmeXS infringes the Asserted Claims, either literally or under the doctrine of equivalents.

62. If needed, I may provide a tutorial on the construction, use, and operation of the hydrodermabrasion functionality of the AquaFirmeXS system.

A. The AquaFirmeXS Practices Claim 1 of the '052 Patent

63. In my opinion, the AquaFirmeXS device meets each limitation of claim 1 of the '052 Patent.

64. Claim 1 recites as follows:

1. A system for performing a skin treatment procedure, the system comprising:
a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;
a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;
a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;
wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and
a vacuum source;
a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and
wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and
wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

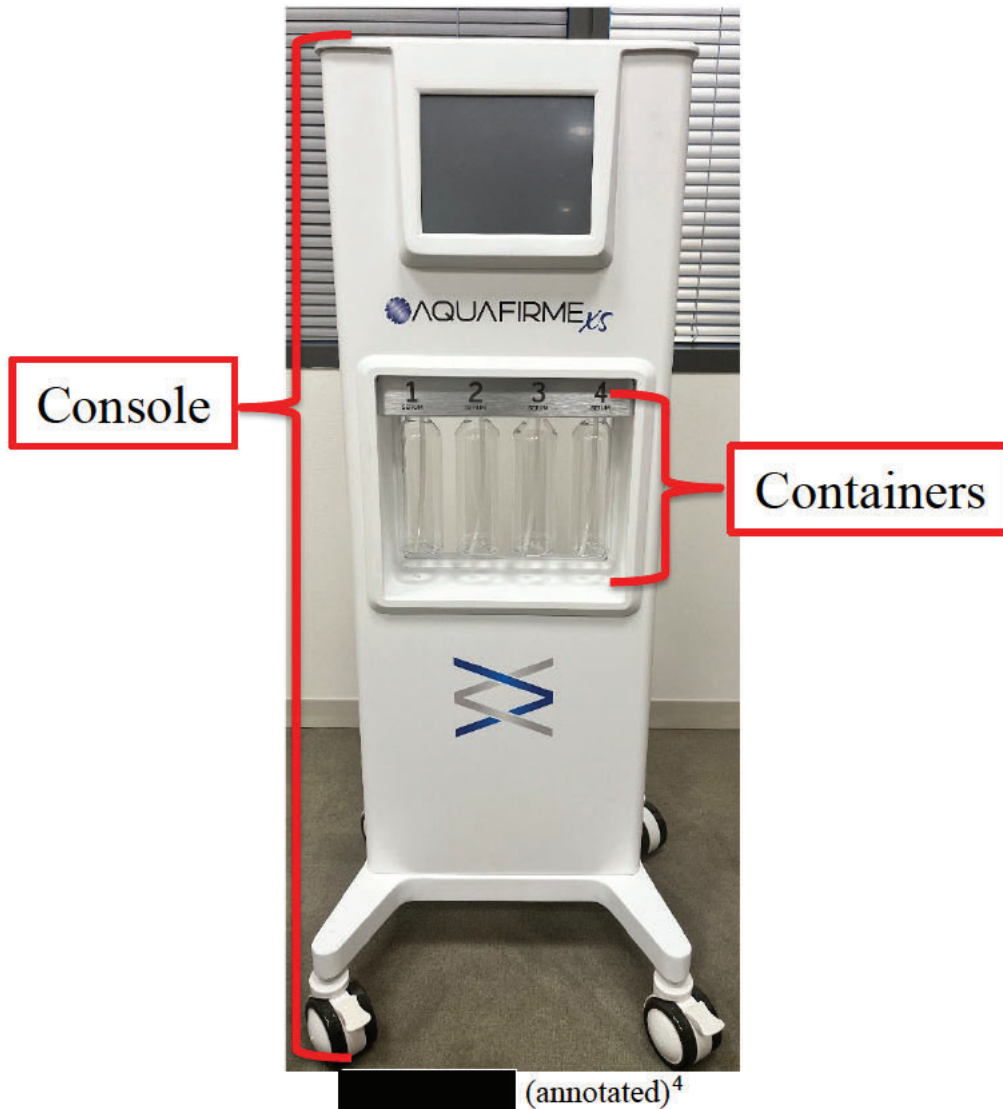
65. I address each limitation of this claim in the claim chart below. Unless further specified, the images are from Exhibit C and have been annotated for clarity.

CLAIM 1 OF THE '052 PATENT
Preamble 1[pre]: A system for performing a skin treatment procedure, the system comprising:
To the extent that the preamble is deemed to be a limitation, the AquaFirmeXS is a system for performing a skin treatment procedure.

AMP markets the AquaFirmeXS as a “facial treatment...ideal for treating poorly hydrated & undernourished skin.” **Dkt. 1-14** at 2. Spas using the AquaFirmeXS have marketed the AquaFirmeXS as “cleans[ing], exfoliat[ing], uplift[ing], and hydrat[ing] the skin.” **Dkt. 1-20** at 3 (describing vacuum suction for EVO handpiece); *see also* **Dkt. 1-10** at 10 (same for AquaFirme).

[a][i]: a console including a manifold,

AquaFirmeXS has a console including a manifold. For example, the console includes a closed space with multiple inlets and at least one outlet for passage of the treatment fluid, as shown below.



⁴ All emphasis in textual quotations and color annotations and textual labels in figures has been added throughout, unless indicated to the contrary.

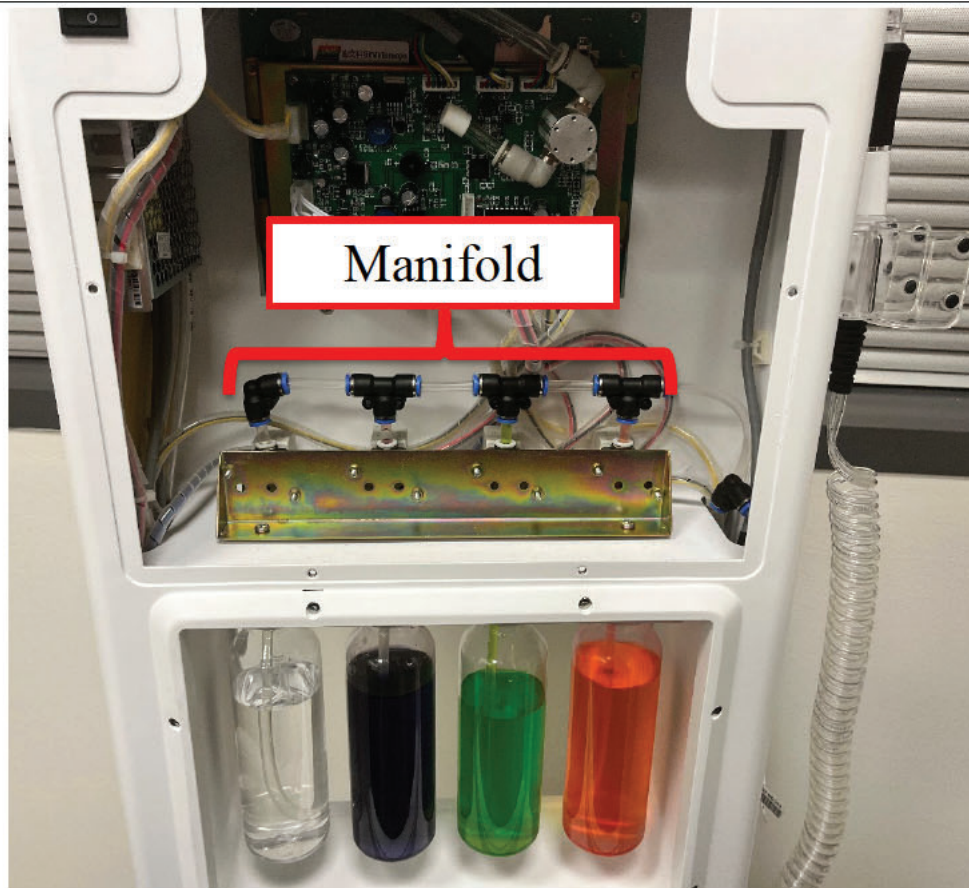
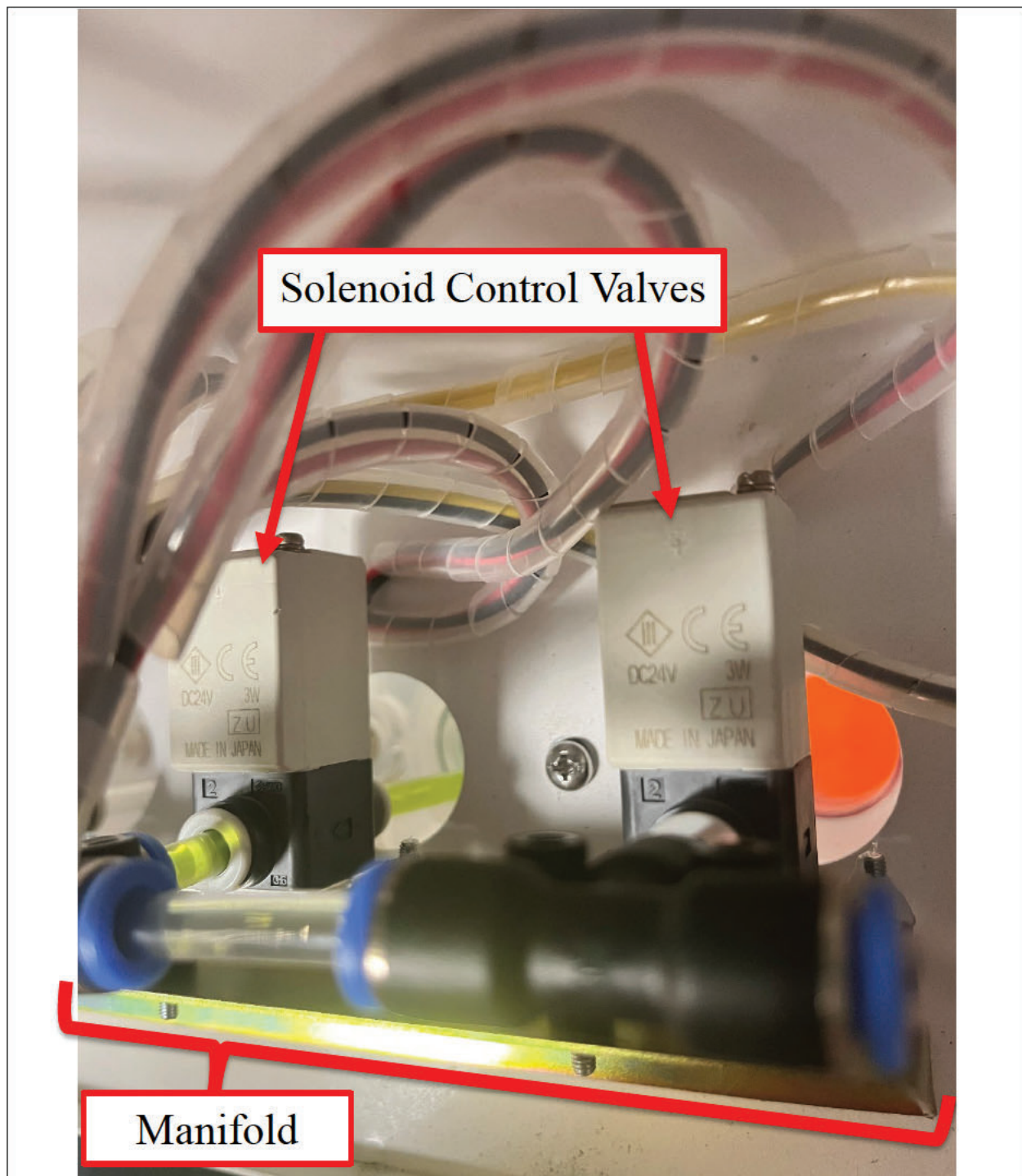


Exhibit C-22

**Exhibit C-25**

[a][ii] the manifold being in fluid communication with a first fluid container and at least a second fluid container,

The manifold of the AquaFirmeXS is in fluid communication with a first fluid container and at least a second fluid container. Tubing from the manifold extends downward into fluid containers, including the first fluid container and at least one additional fluid container, as shown in the images below.

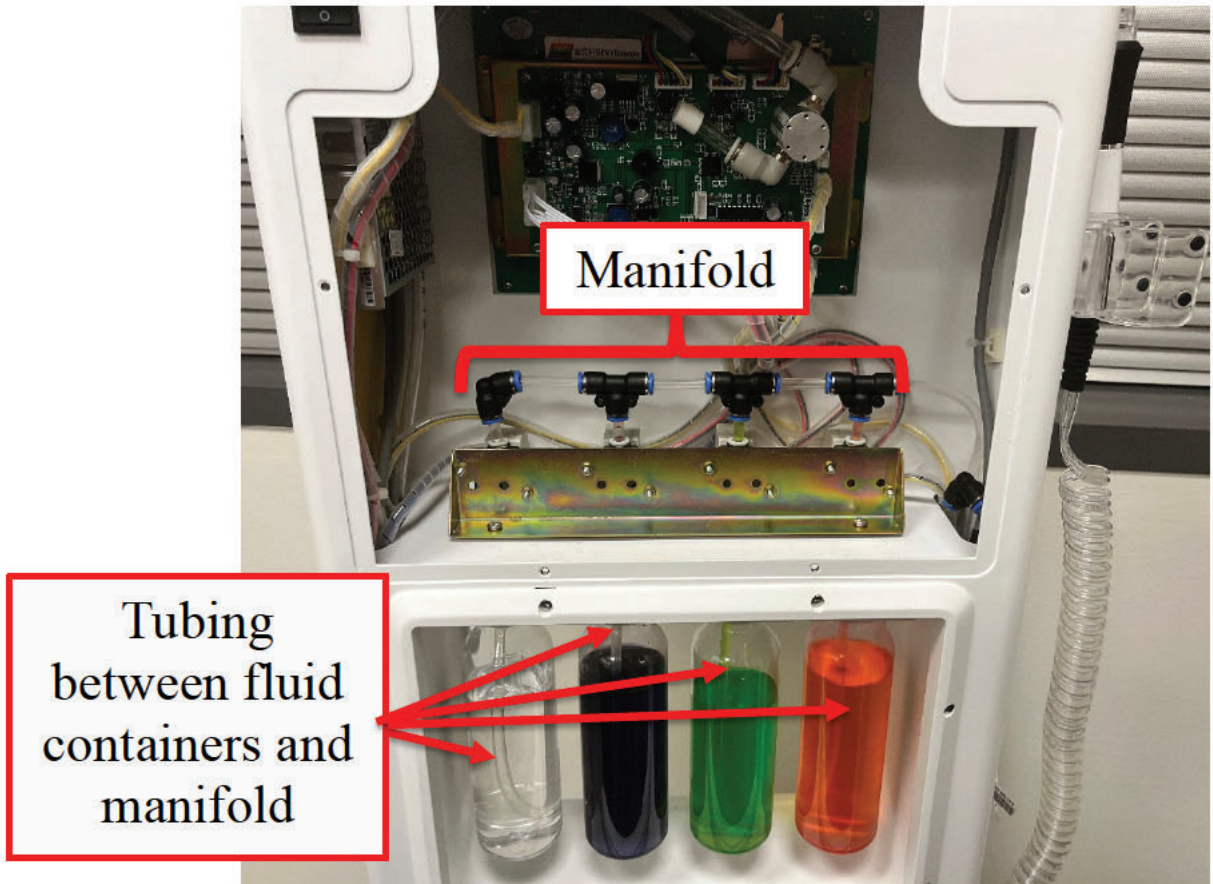
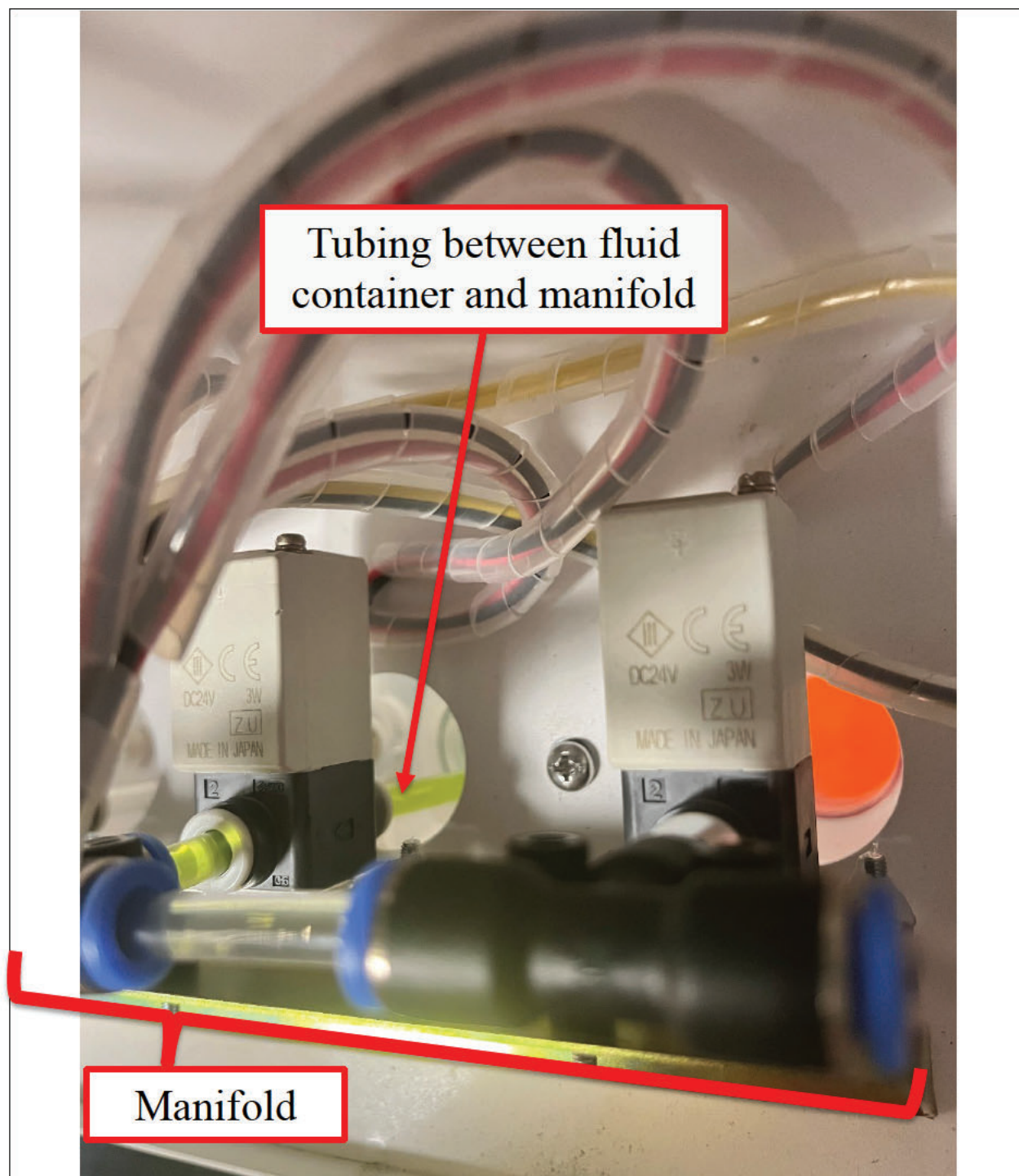


Exhibit C-22

**Exhibit C-25**

Under the section “How AquaFirme Works,” AMP’s website states that “EVO technology uses a combination of vacuum suction, spiral eddy movements and specially formulated solutions to cleanse, exfoliate, uplift and hydrate the skin, resulting in a fresh, youthful look. The EVO cosmetic treatment tip has been specially designed to allow for optimum cleaning and exfoliation of the skin, it also enables the nutrient-rich AquaFirme Solutions to be

absorbed by the skin.” **Dkt. 1-10; Dkt. 1-11.** The tubing extends from the manifold downward into the fluid containers, and the fluid in the selected container is delivered to the skin of a patient when coupled to the console, such that the manifold is in fluid communication with a first fluid container and at least a second fluid container.

The below images also show the manifold, removed from the rest of the console, in more detail.

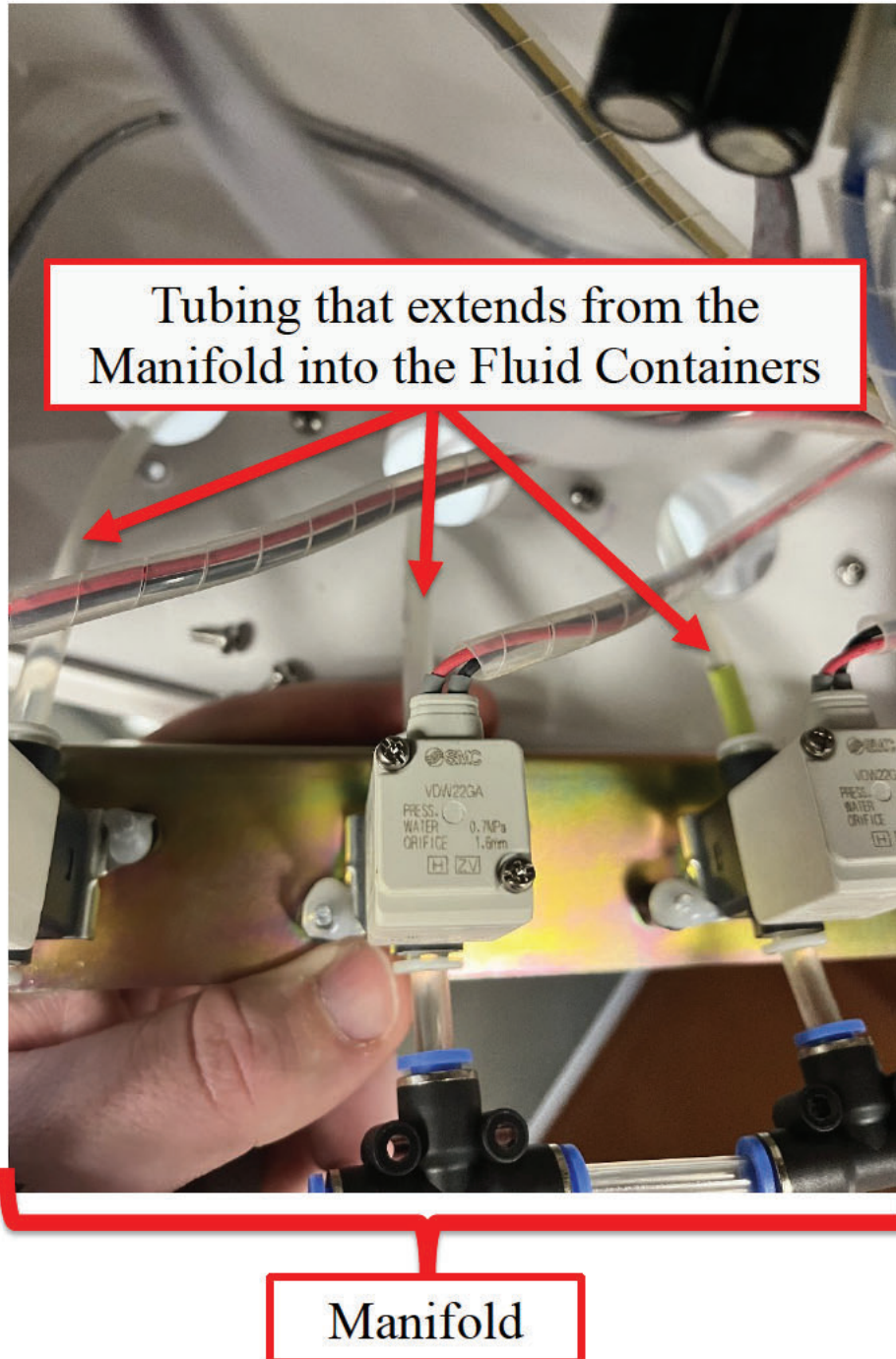


Exhibit C-58

The solenoid control valves pictured above have a part number of VDW22GA. They are SMC 24-volt direct current 3 watt solenoid valves with a pressure orifice of 0.7 MPa with 1.6mm orifice. As shown in the below image, taken from **Exhibit A-16**, the solenoid valves of the manifold assembly control the flow rate of fluids through the valve. *See Exhibit A-16* (showing further specifications for the solenoid valves).

Compact Direct Operated 2 Port Solenoid Valve *VDW Series*

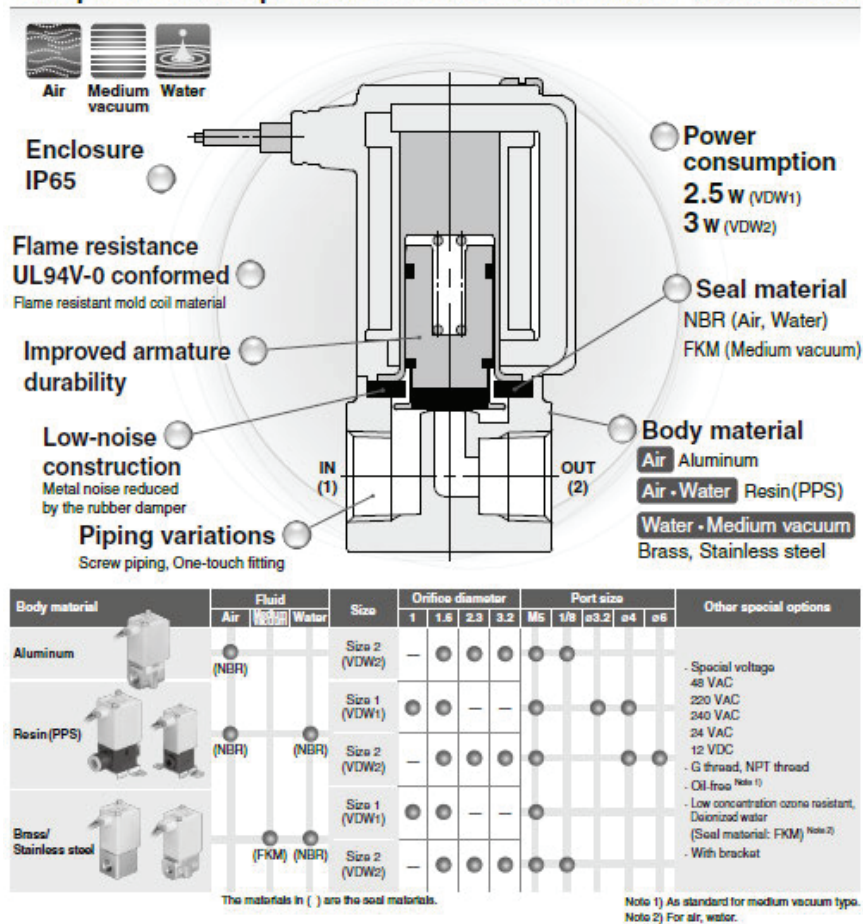


Exhibit A-16 at 2

[a][iii] the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;

The first fluid container and the at least the second fluid container of the AquaFirmeXS are configured to contain a treatment material for a skin treatment procedure, and the treatment material comprises a liquid.

Defendants advertise the AquaFirmeXS system as “utilizing our proprietary serums” to “cleanse, exfoliate, hydrate, and nourish the skin” when passed through the system’s handpiece. **Dkt. 1-9** at 2; *see also* **Dkt. 1-10** at 13; **Dkt. 1-11** at 2. The AquaFirmeXS uses “proprietary serums” during treatment, i.e. treatment solutions delivered to the skin, and the first fluid container and the at least the second fluid container are configured to contain such a liquid treatment material. *See* limitation 1[a][i], *supra* (showing the first fluid container and the at least the second fluid container on the console being configured to contain a liquid treatment material).

[b] a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

The AquaFirmeXS includes a handpiece assembly comprising a tip, and the tip is configured to contact a skin surface of a subject. The image below shows the handpiece assembly and tip



Exhibit C-32

I observed that the tip of the handpiece assembly is configured to contact skin, including the skin surface of a subject, as shown in the screenshot below from the **Exhibit C1** video:



Handpiece
Assembly

Skin Surface

Exhibit C-1 screenshot at 00:38

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Dkt. 1-21 at 2.

See also **Dkt. 1-10** at 10 (“The EVO cosmetic treatment tip has been specially designed to allow for optimum cleaning and exfoliation of the skin, it also enables the nutrient-rich AquaFirme Solutions to be absorbed by the skin.”).

[c] a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;

The AquaFirmeXS has a supply conduit that places the manifold in fluid communication with the handpiece assembly, as shown in the images below. The distal end of the supply conduit is configured to couple to the handpiece assembly, as shown below. The blue dashed line shows the communication path. *See also Dkt. 1-22* at 2 (showing tubing to handpiece assembly coupled to handpiece assembly).

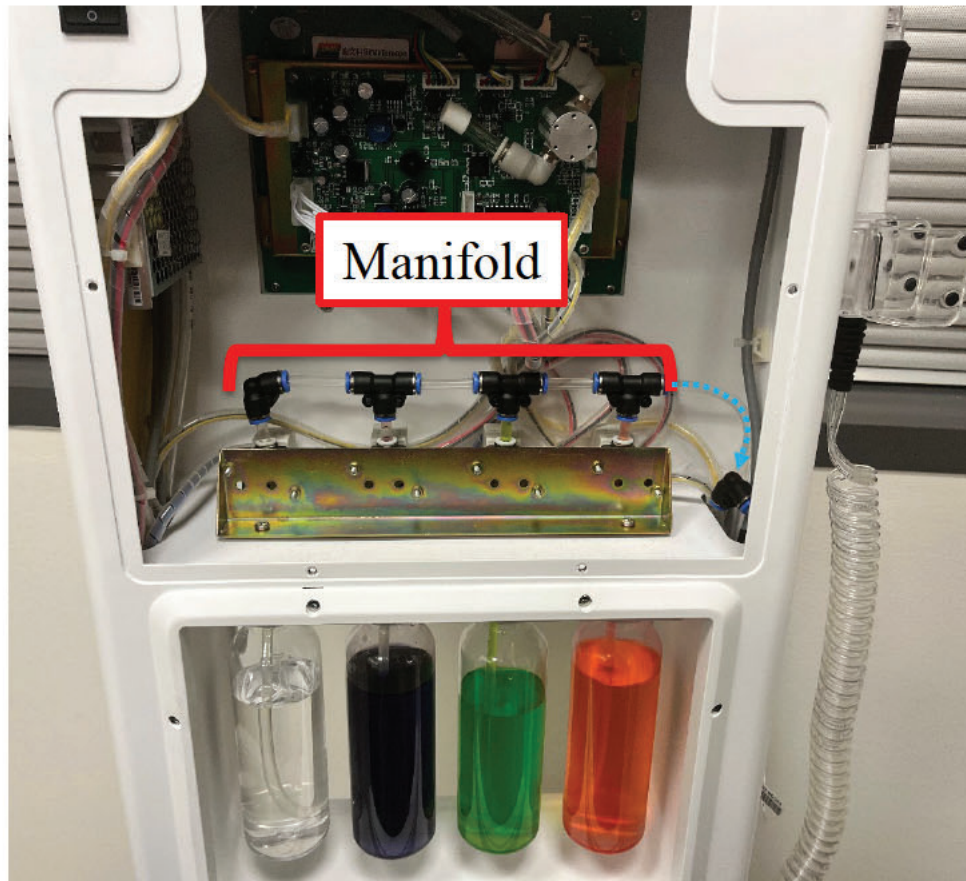


Exhibit C-22

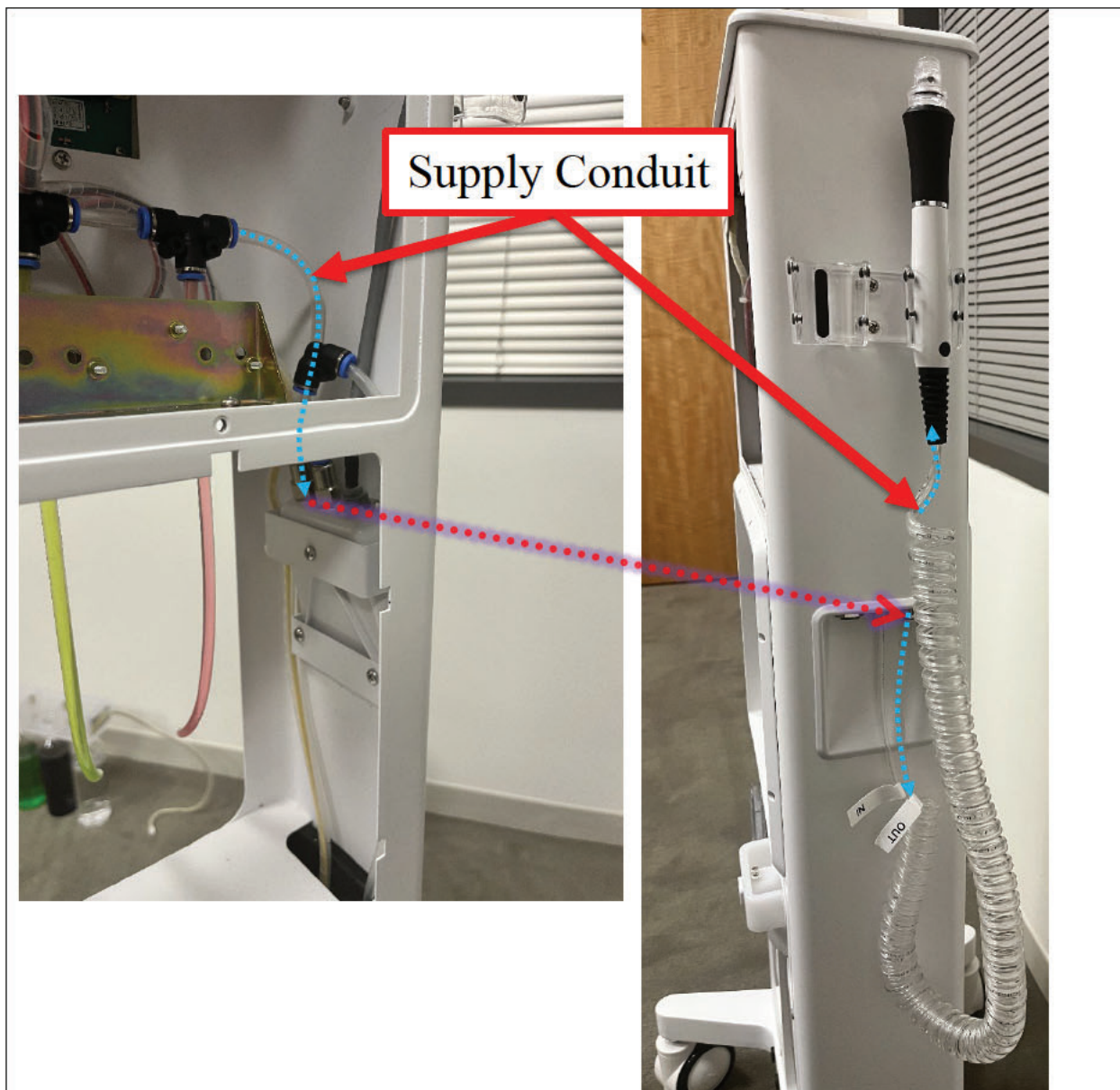


Exhibit C-42, Exhibit C-32.

This supply conduit is configured to couple to the handpiece assembly, as shown above.

**[d] wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit;
and**

The manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. *See* limitation 1[a][ii] above and 1[g] below (showing the ability to select different treatment materials from different fluid containers, as controlled by the manifold). The manifold controls the flow of treatment material via solenoid valves.

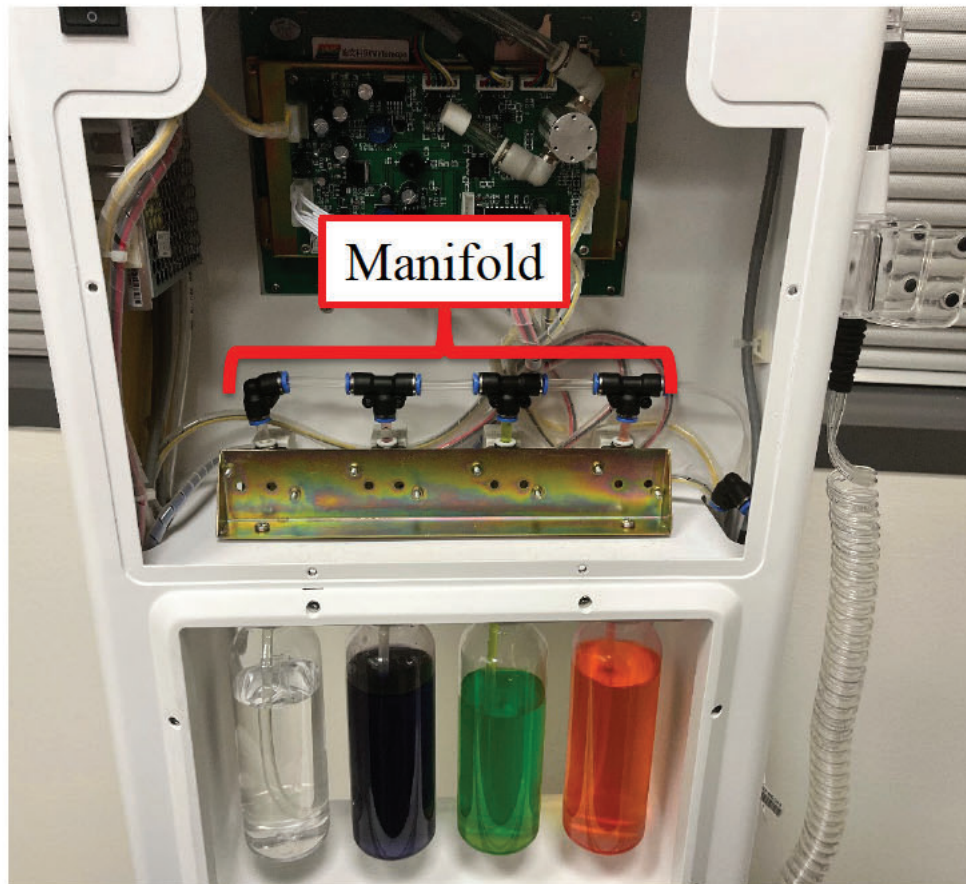
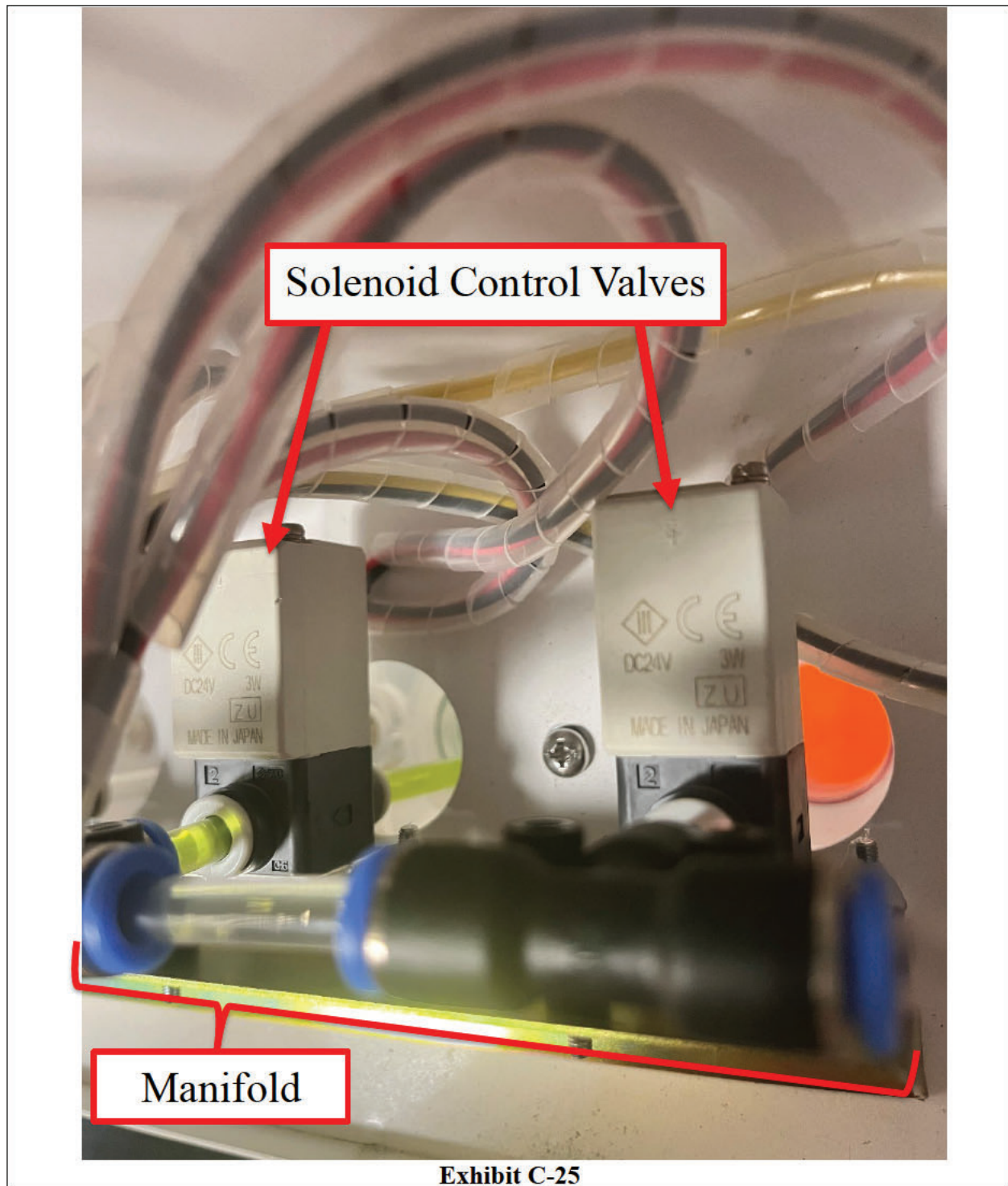


Exhibit C-22



[e] a vacuum source;

The AquaFirmeXS comprises a vacuum source. The images below show the vacuum source in the AquaFirmeXS.

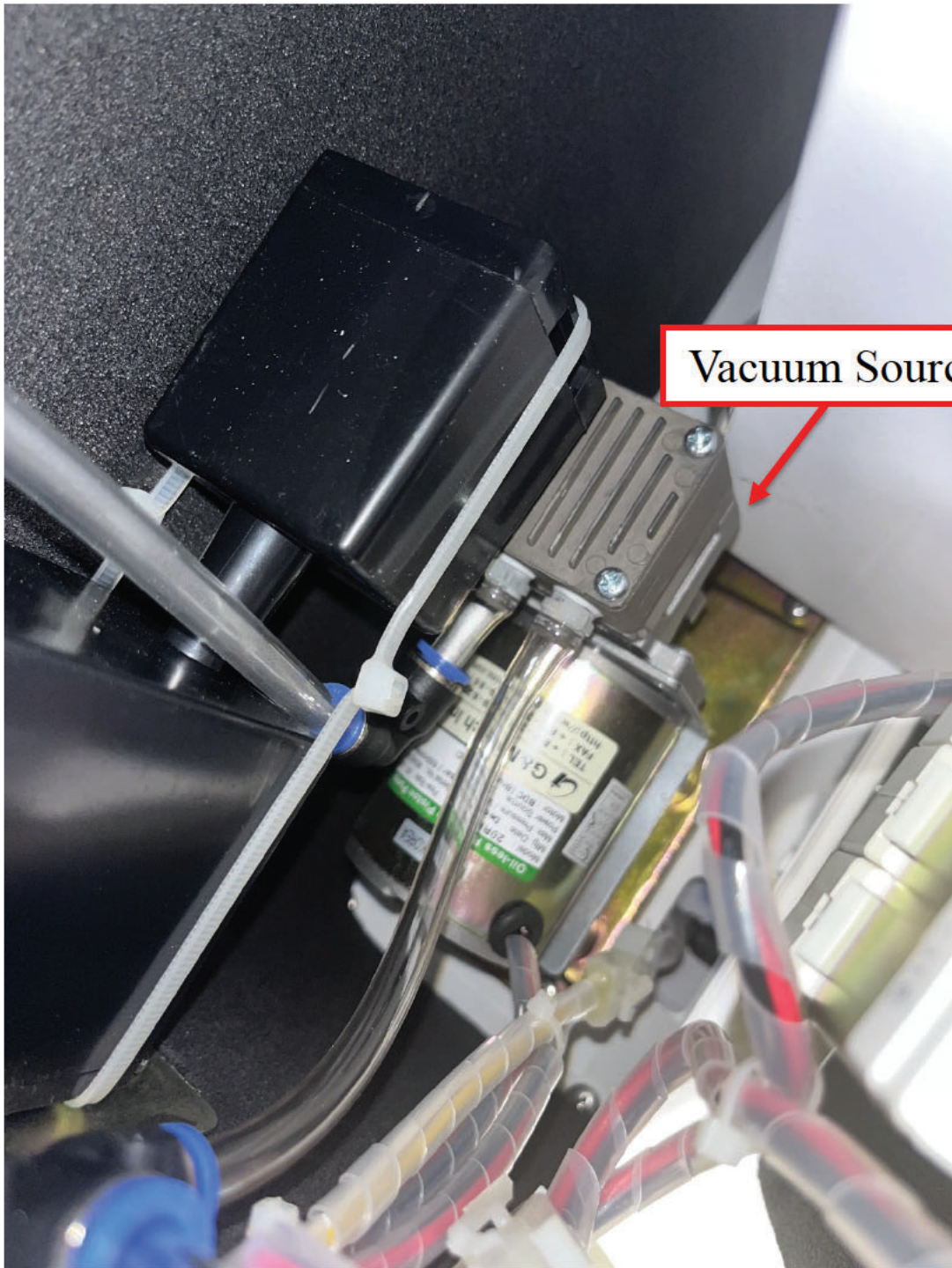


Exhibit C-49

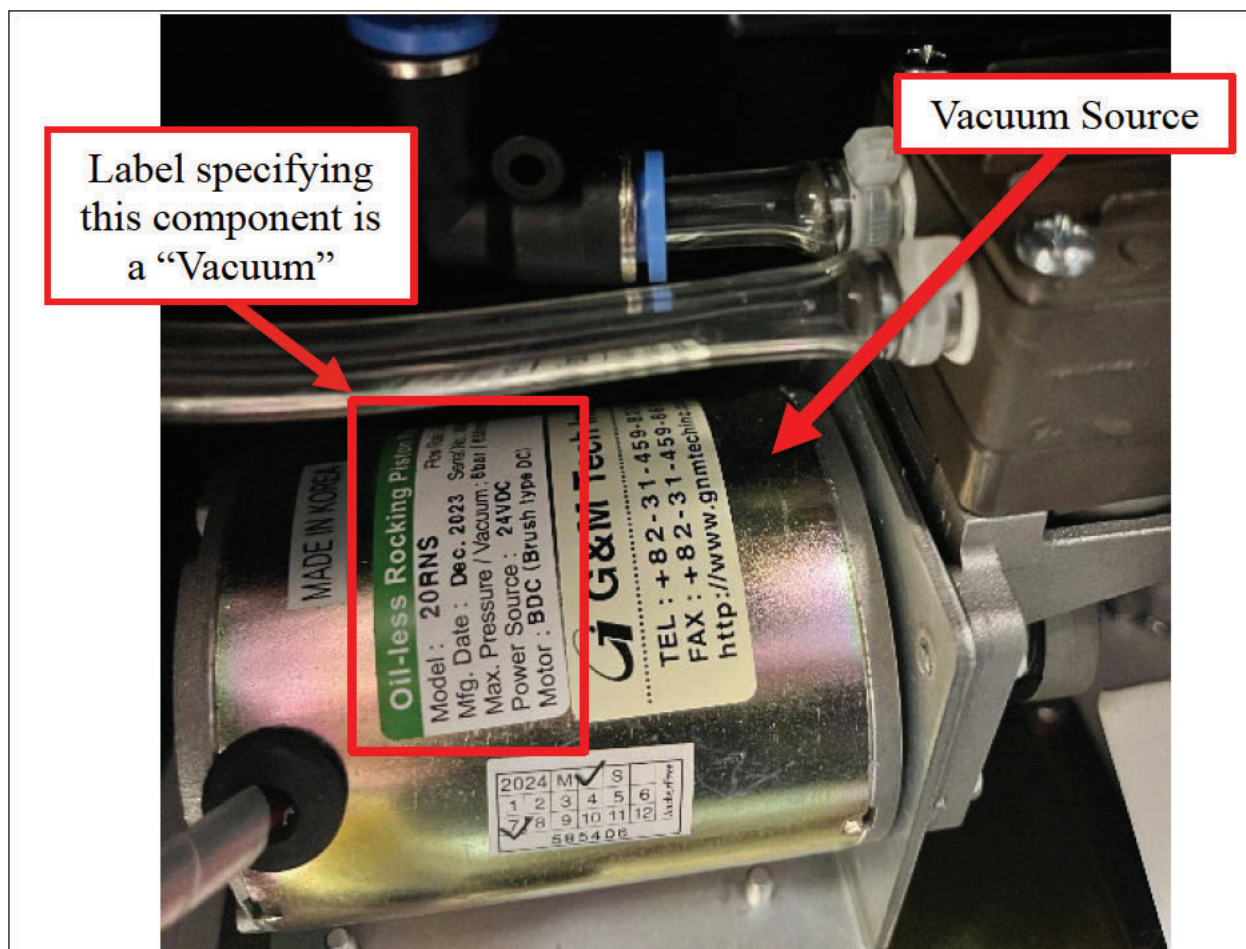


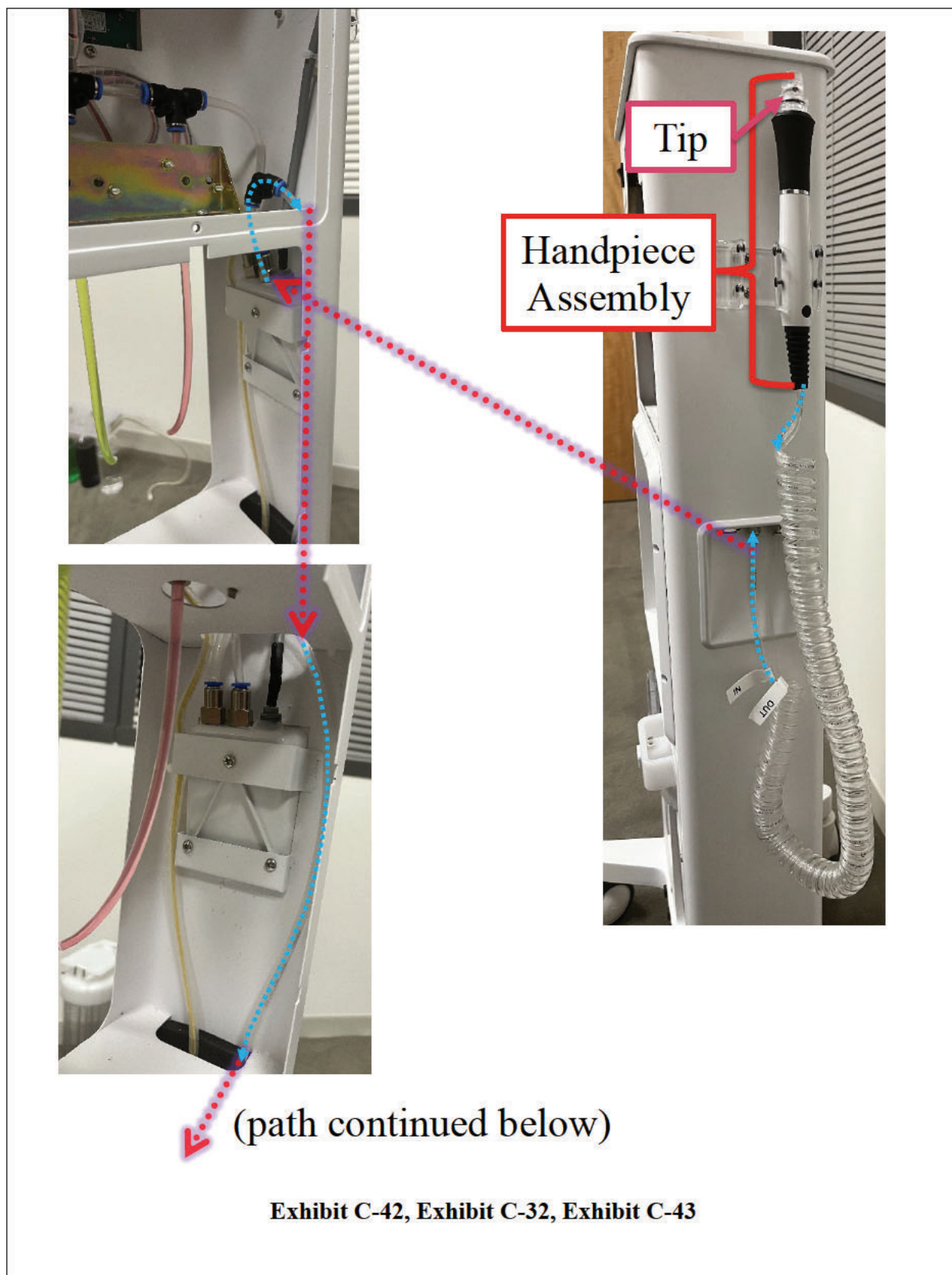
Exhibit C-59

The AquaFirmeXS uses "vacuum suction, spiral eddy movements and specially formulated solutions to cleanse, exfoliate, uplift and hydrate the skin." **Dkt. 1-14** at 2; *see also* **Dkt. 1-20**, **Dkt. 1-10** (describing vacuum suction in the system).

[f] a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and

As shown in the photos below, the AquaFirmeXS system has a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste during a skin treatment procedure. The waste conduit can include any of the conduits defined by the following or the combination of them all: (1) the tubing from the handpiece assembly to the port on the console for the handpiece assembly, (2) the tubing from the port for the handpiece to the waste container, (3) the tubing from the waste container to the air intake, and (4) the tubing from the air intake to the vacuum source. The images below show the fluid communication pathway of the waste conduit via light blue arrows.

The waste conduit is operatively coupled to the vacuum source. The image below shows the waste conduit highlighted in blue, and the suction force path via red arrows. *See also* limitation 1[b], *supra* (showing the tip of the handpiece assembly contacting skin).



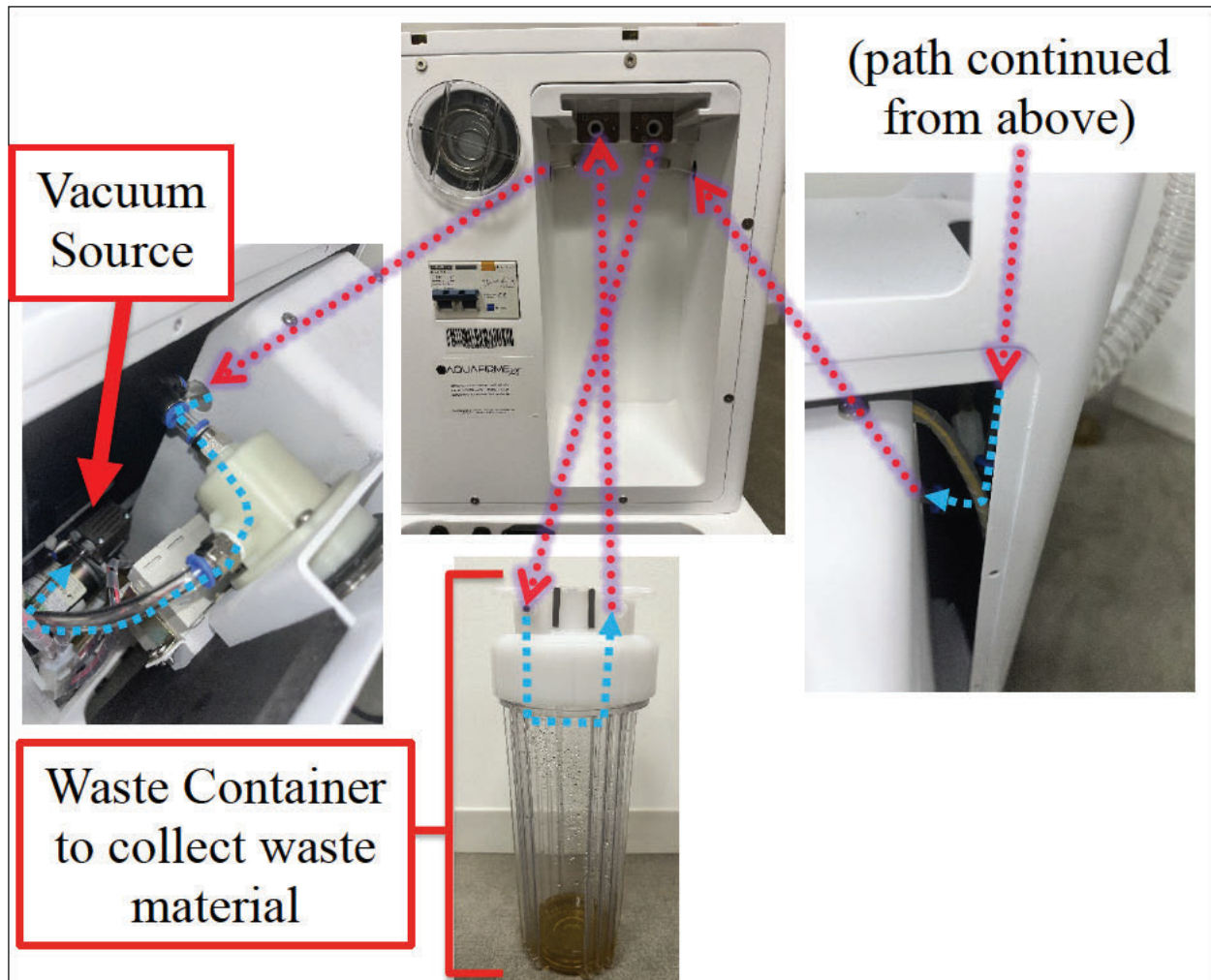


Exhibit C-46, Exhibit C-33, Exhibit C-45, Exhibit C-35.

Negative pressure draws waste material into the through-holes and out of the handpiece assembly into the waste container.

[g] wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and

The AquaFirmeXS is configured to permit a user to select the treatment material from the first fluid container or the second fluid container to be delivered through the supply conduit to the handpiece assembly. I observed that a user can select one of four containers for delivery of its contained treatment material through the supply conduit to the handpiece assembly. *See Exhibit C-1* (showing a user selecting the first fluid container and the at least second fluid container, and thus their contents, for delivery through the supply conduit to the handpiece assembly). Images of this selection are shown below.

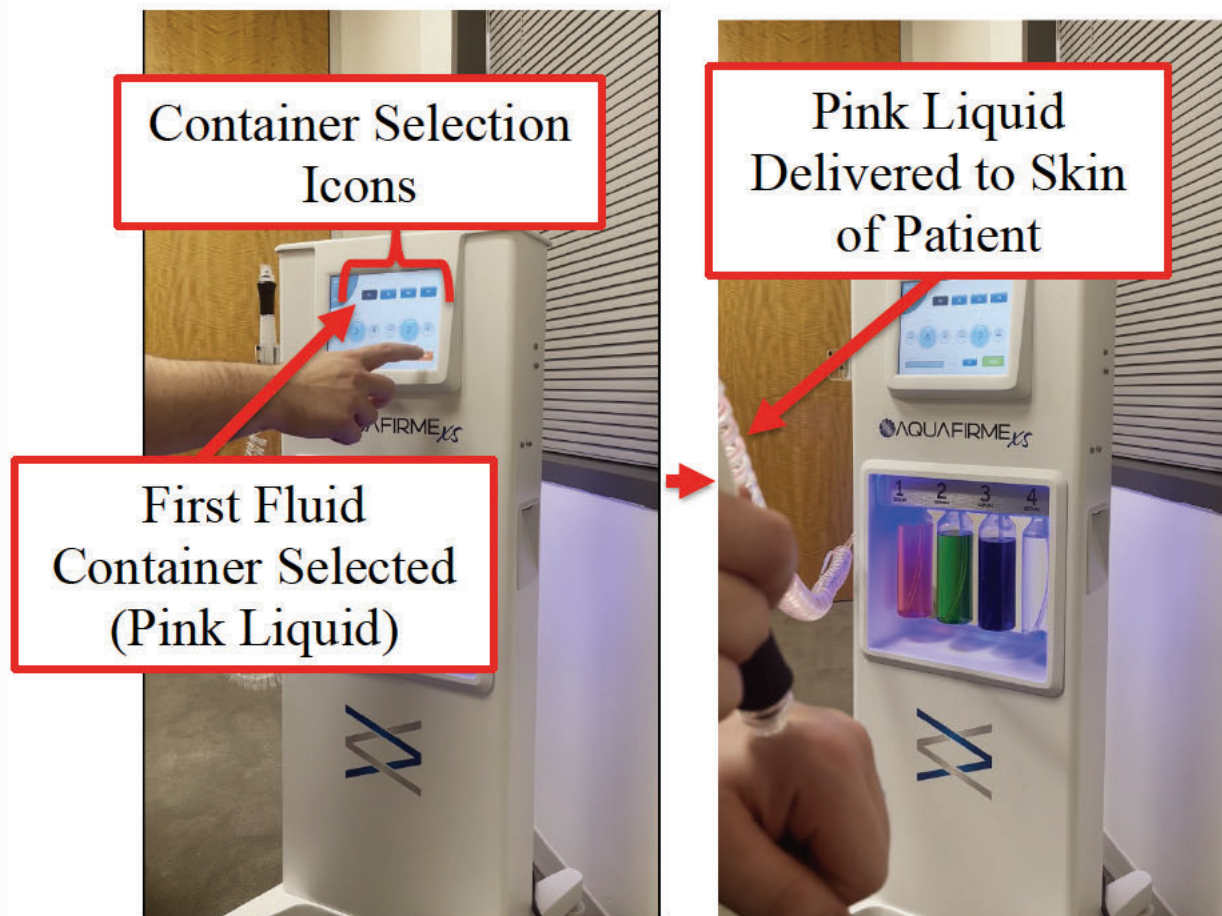


Exhibit C-2 screenshot at 00:04, 00:46

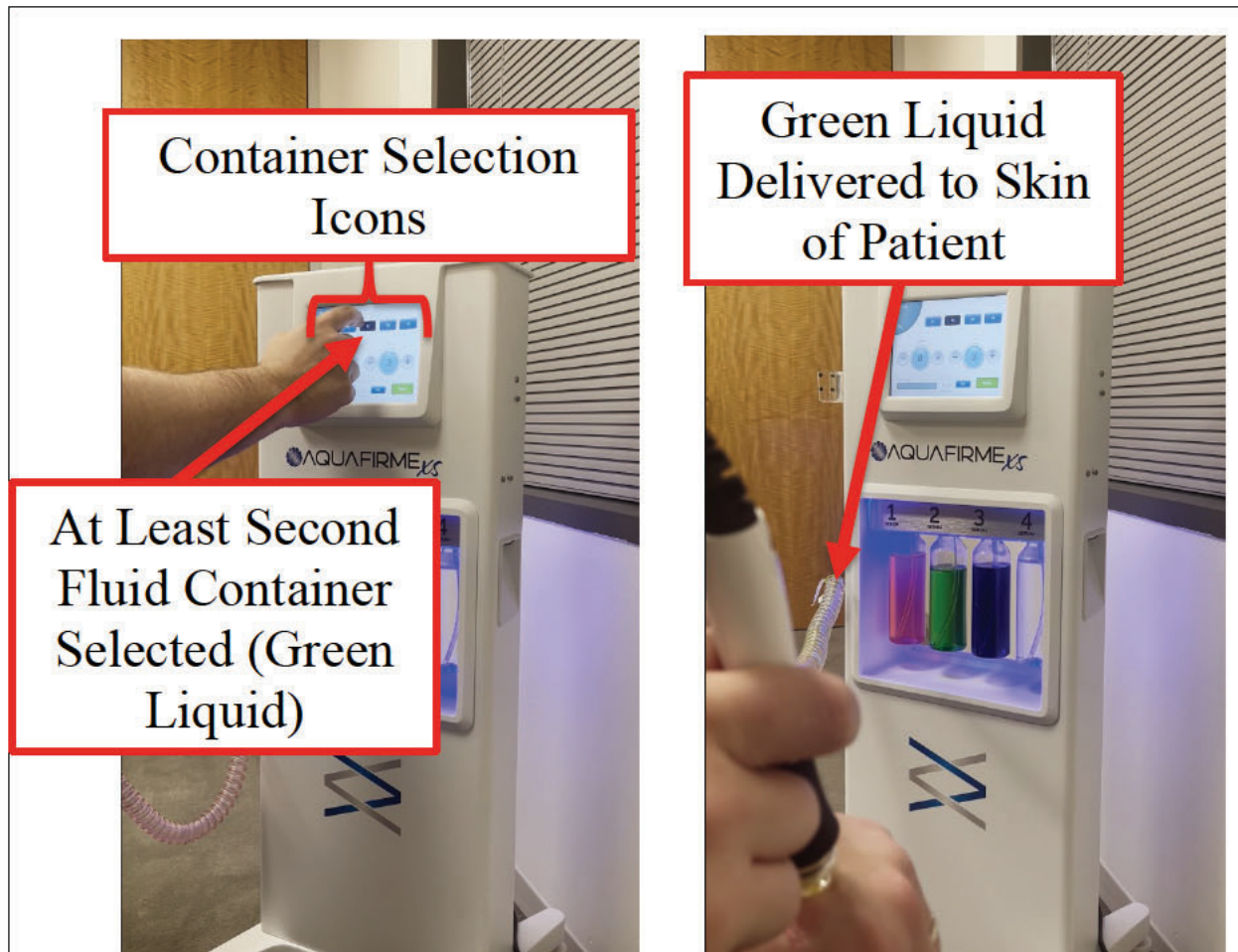
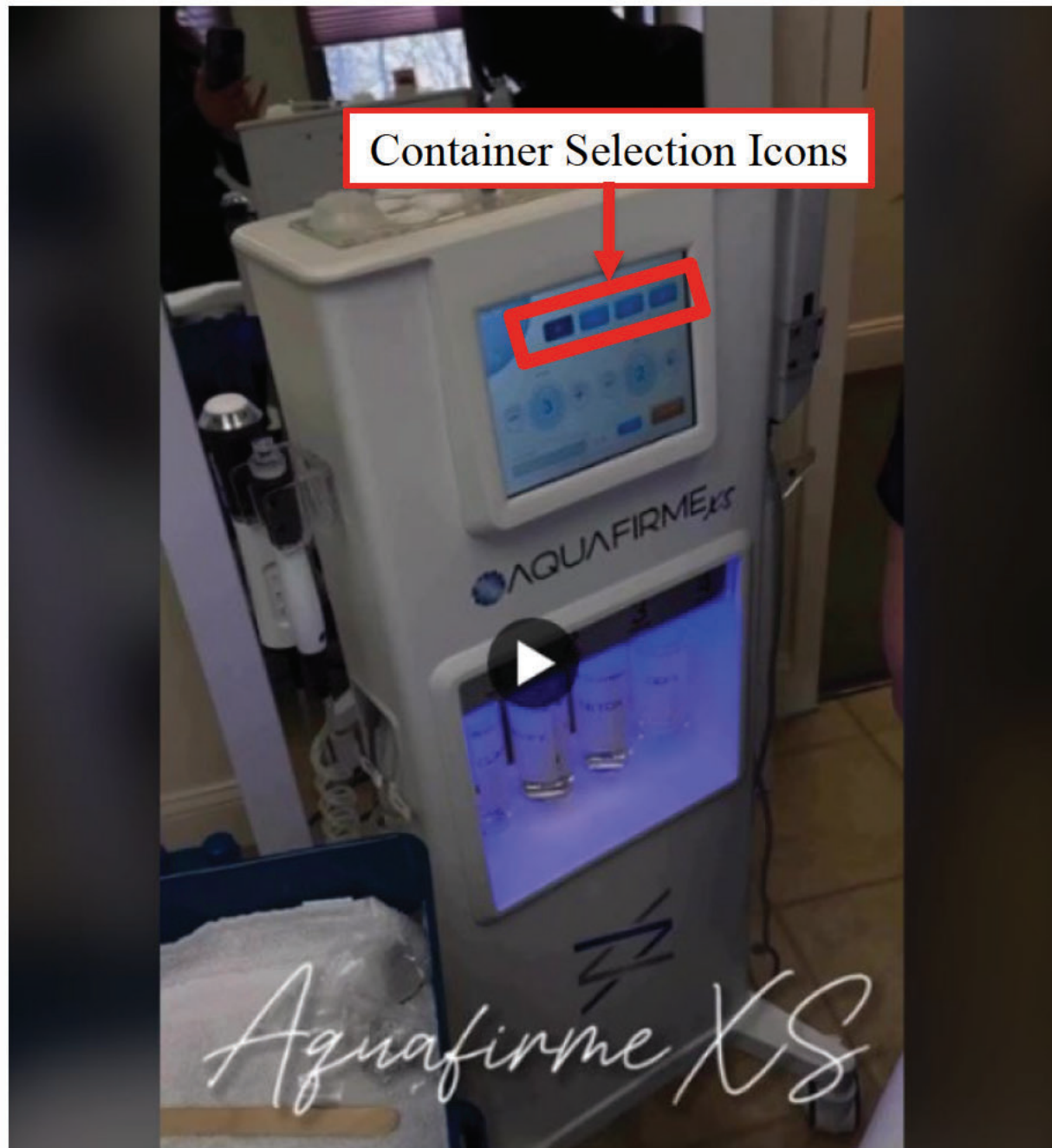


Exhibit C-2 screenshot at 01:11, 01:43

As shown in the images above, the user selects the first container from the computer display in the console, and the treatment materials within that first container are delivered to the user's skin. The user then selects the second container from the computer display in the console, and the treatment materials within the second container are delivered to the user's skin.

The screenshot of the AquaFirmeXS in use confirms the sequential delivery via selection of a fluid container.



Dkt. 1-13 at 2

[h] wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

When the AquaFirmeXS's vacuum source is activated and the hydrodermabrasion tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

I observed that the tip of the AquaFirmeXS handpiece assembly is configured to contact a skin surface of a subject during a skin treatment procedure to deliver a suction force to vacuum away debris while drawing and delivering the treatment solutions from the containers coupled to the manifold. *See also* limitation 1[f], *supra* (showing the suction force path). Screenshots of a video of the AquaFirmeXS in use show the tip in contact with my skin.

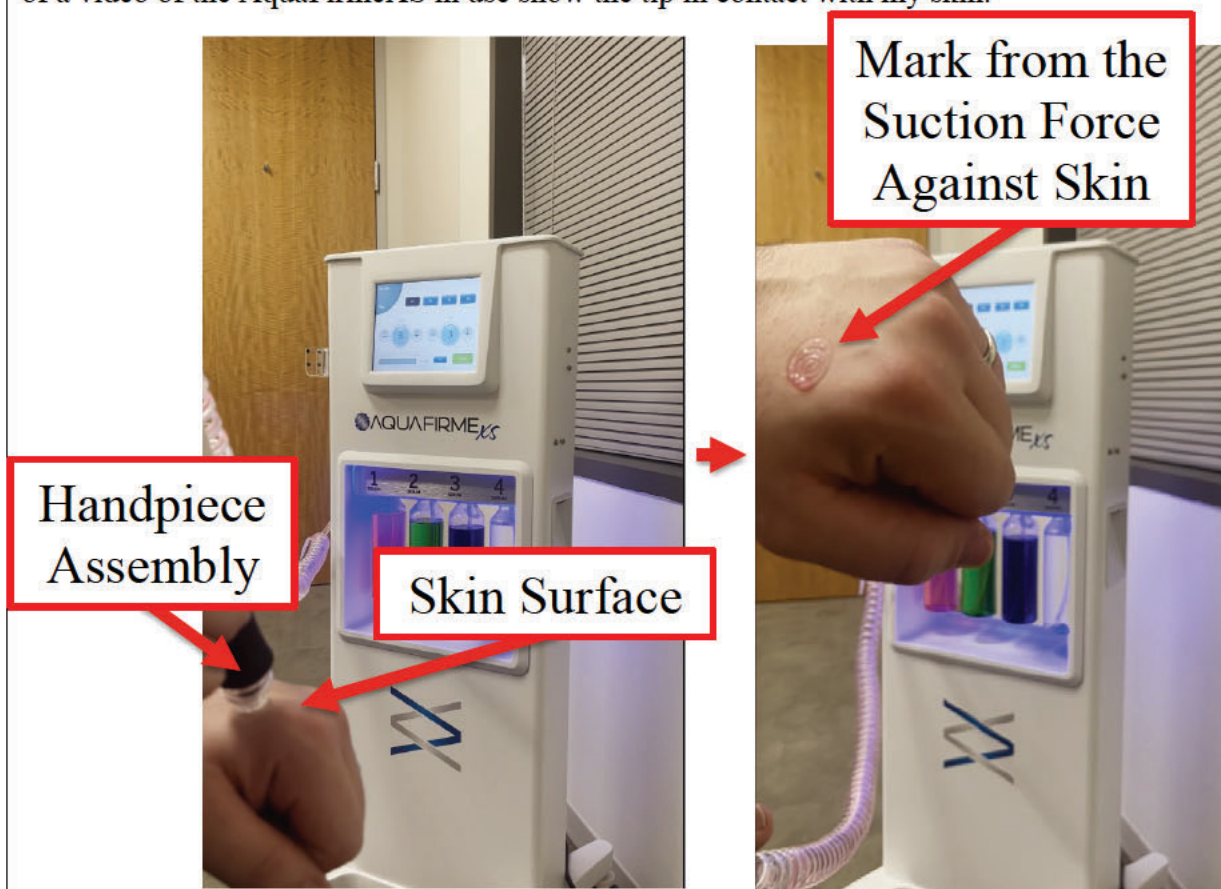


Exhibit C-2 screenshot at 00:46, 01:06

The AquaFirmeXS website says the AquaFirmeXS's "cosmetic treatment tip has been specially designed to allow for optimum cleaning and exfoliation of the skin, it also enables the nutrient-rich AquaFirmeXS Solutions to be absorbed by the skin." To accomplish this, the AquaFirmeXS "uses a combination of vacuum suction, spiral eddy movements and specially formulated solutions." **Dkt. 1-14** at 2; *see also* **Dkt. 1-20** at 3 (describing vacuum suction for EVO handpiece); **Dkt. 1-10** at 10 (same for AquaFirme).

B. The AquaFirmeXS Practices Claim 22 of the '287 Patent

66. In my opinion, the AquaFirmeXS device meets each limitation of claim 22 of the '287 Patent.

67. Claim 22 recites as follows:

22. A system for treating skin, the system comprising:
a console configured to receive a first container and at least one additional container;
a collection lumen configured to be in fluid communication with the first container and the at least one additional container when the first container and the at least one additional container are connected to the console; and
a handpiece having a working end, the working end of the handpiece being configured to contact skin tissue of a subject during use;
wherein the working end of the handpiece is configured to be placed in fluid communication with a vacuum source to create a suction force along a distal end of the handpiece when the vacuum source is activated and the handpiece is connected to the console and wherein the working end of the handpiece is configured to be placed in fluid communication with the first container or the at least one additional container through the collection lumen; and
a supply conduit that places the collection lumen in fluid communication with the working end of the handpiece when the handpiece is connected to the console;
wherein each of the first container and the at least one additional container includes treatment materials, and wherein treatment materials from the first container and the at least one additional container are configured to be delivered to the supply conduit sequentially when the first container and the at least one additional container are connected to the console.

68. I address each limitation of this claim in the claim chart below. Unless further specified, the images are from Exhibit C and have been annotated for clarity.

<u>CLAIM 22 OF THE '287 PATENT</u>
22[pre]: A system for treating skin, the system comprising:
To the extent that the preamble is deemed to be a limitation, the AquaFirmeXS is a system for treating skin. AMP markets the AquaFirmeXS as a “facial treatment...ideal for treating poorly hydrated & undernourished skin.” Dkt. 1-14 at 2. Spas using the AquaFirmeXS have marketed the AquaFirmeXS as “cleans[ing], exfoliat[ing], uplift[ing], and hydrat[ing] the skin.” Dkt. 1-20 at 3 (describing vacuum suction for EVO handpiece); <i>see also</i> Dkt. 1-10 at 10 (same for AquaFirme).

[a] a console configured to receive a first container and at least one additional container;

The AquaFirmeXS has a console configured to receive a first container and at least one additional container. *See* limitation 1[a], *supra*.

[b] a collection lumen configured to be in fluid communication with the first container and the at least one additional container when the first container and the at least one additional container are connected to the console; and

The AquaFirmeXS includes a collection lumen in the console configured to be in fluid communication with the containers when the containers are connected to the console. The below images show the collection lumen which extends within the tubes and connectors. Vertical tubing extends from the collection lumen into the containers with valves on each respective line as shown below. This tubing places the collection lumen in a state where the passage of fluid is possible between the containers and the collection lumen. As shown further below, the collection lumen is where fluid from each container passes before it is delivered to the handpiece for a skin treatment.

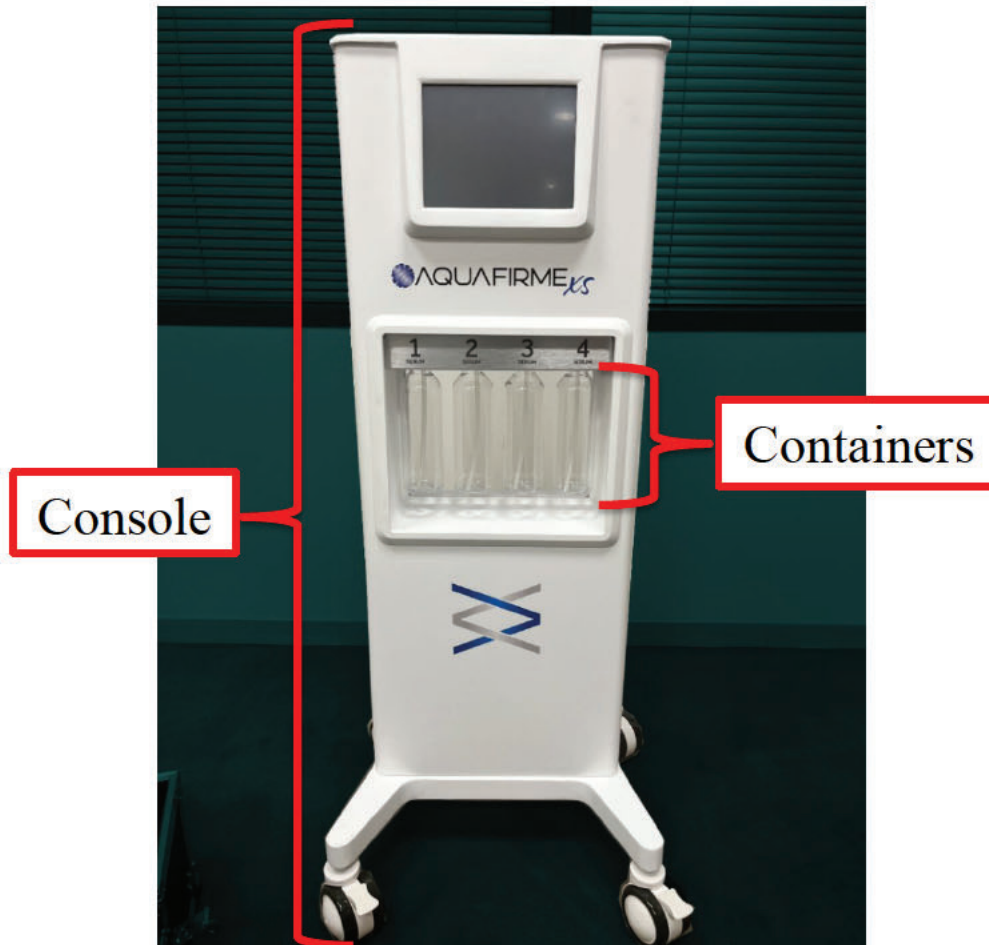
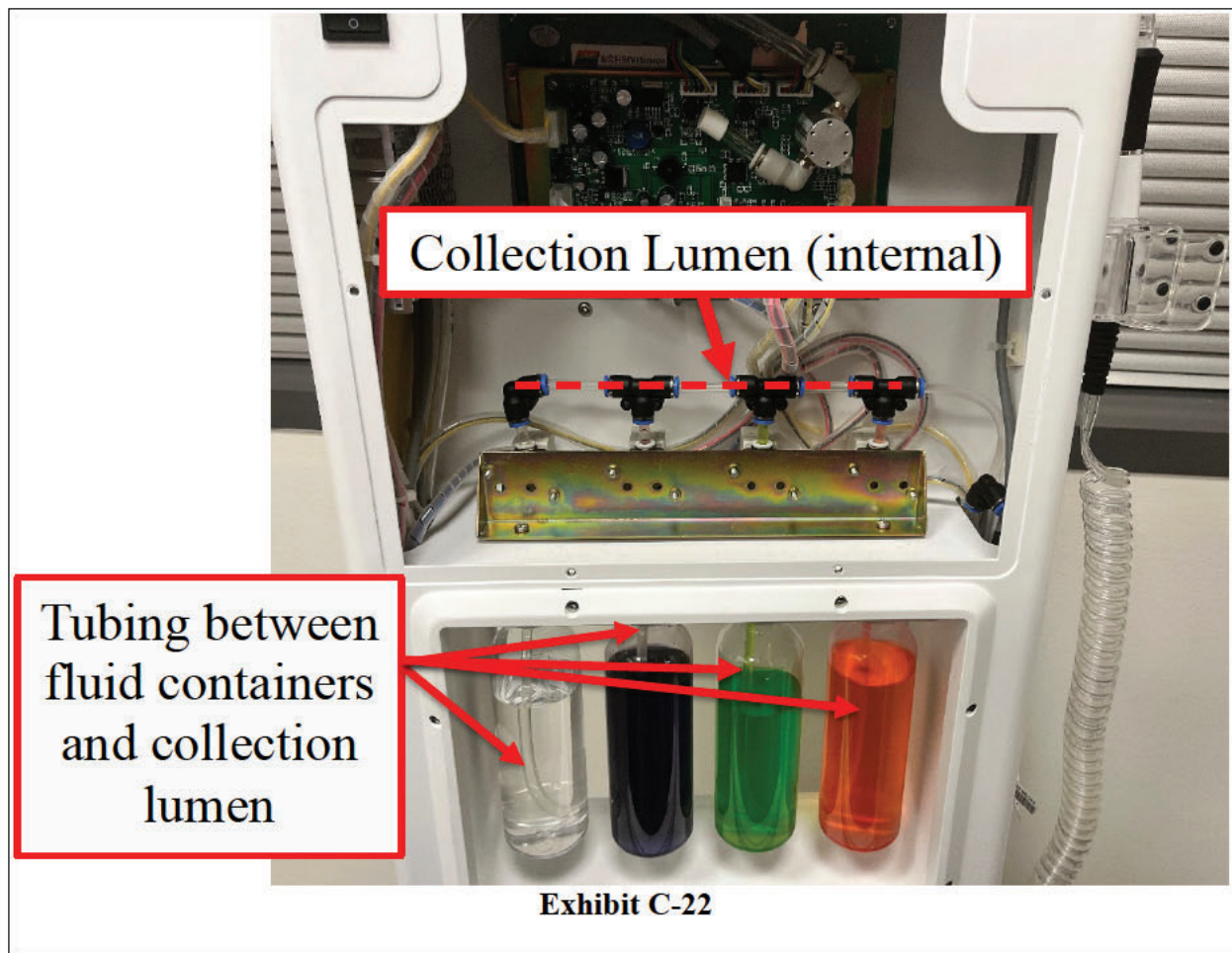
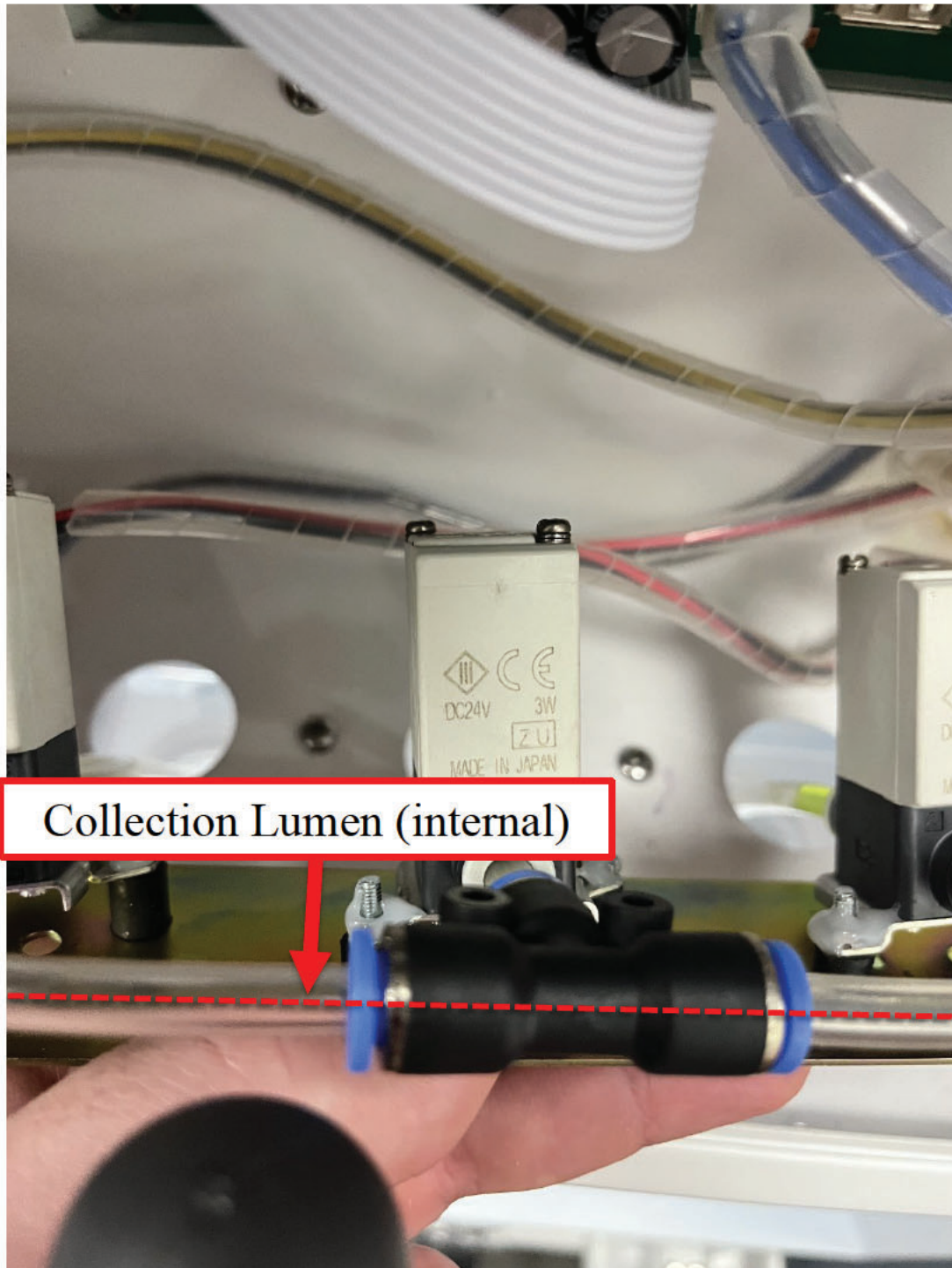


Exhibit C-16 (annotated)⁵

⁵ All emphasis in textual quotations and color annotations and textual labels in figures has been added throughout, unless indicated to the contrary.



**Exhibit C-57**

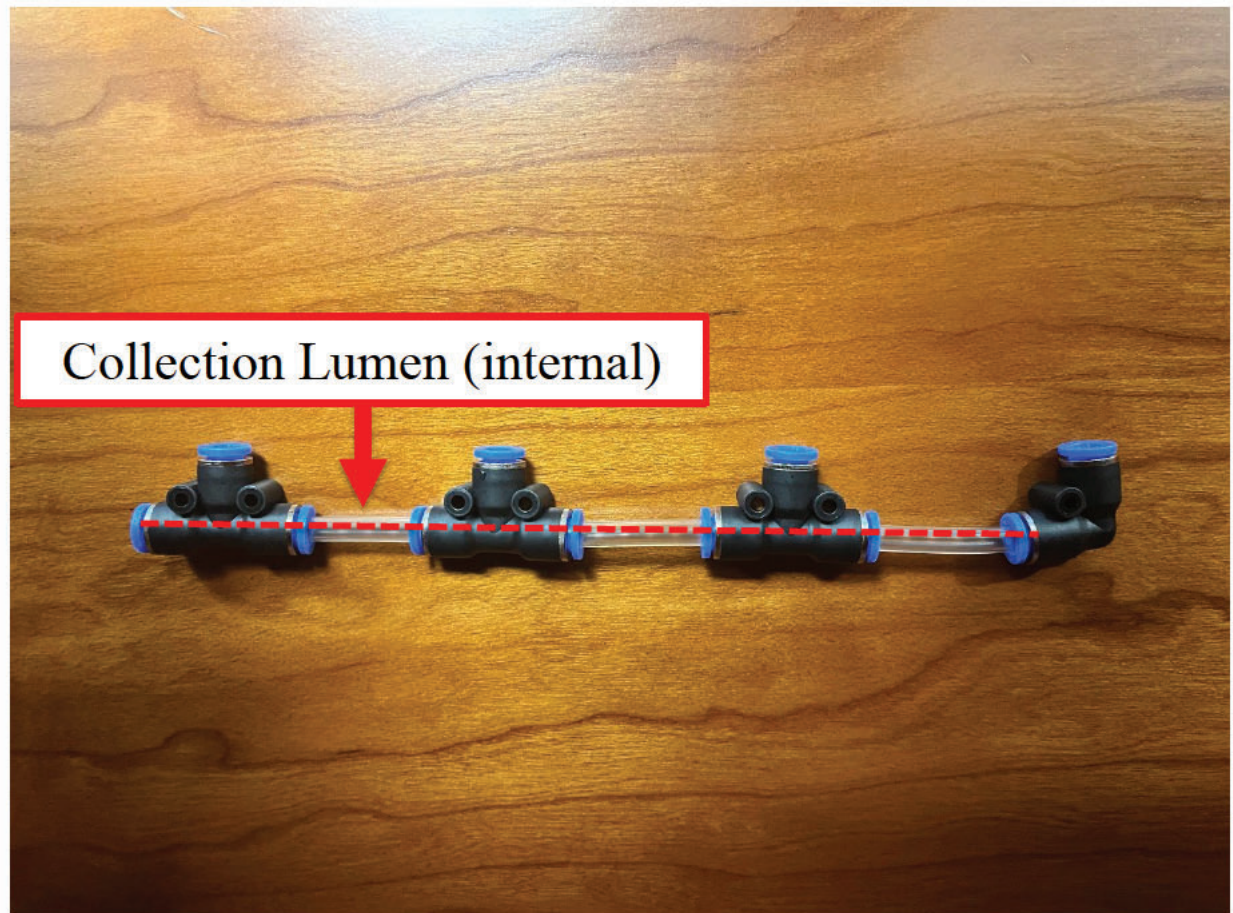


Exhibit C-53

**Exhibit C-54**

[c] a handpiece having a working end, the working end of the handpiece being configured to contact skin tissue of a subject during use;

The AquaFirmeXS has a handpiece with a working end, the working end of the handpiece configured to contact a patient's skin surface to perform the hydrodermabrasion treatment. *See* limitation 1[b], *supra*; *see also* **Dkt. 1-10** at 10 ("The EVO cosmetic treatment tip has been specially designed to allow for optimum cleaning and exfoliation of the skin, it also enables the nutrient-rich AquaFirme Solutions to be absorbed by the skin.").

The below images show the handpiece with a working end.

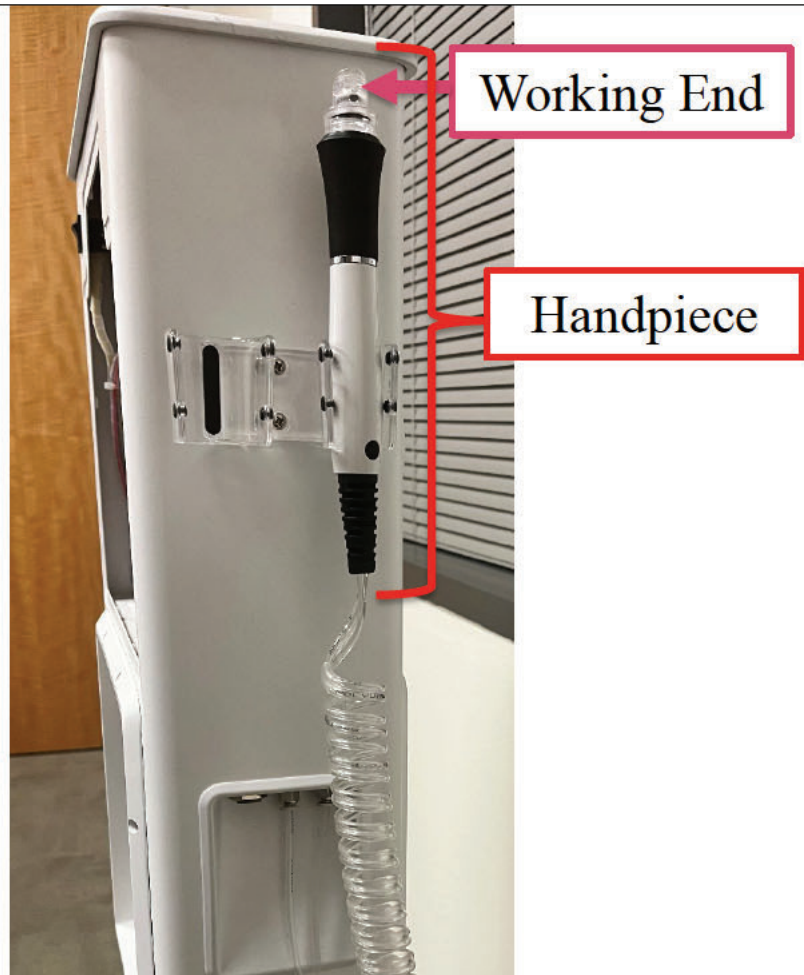
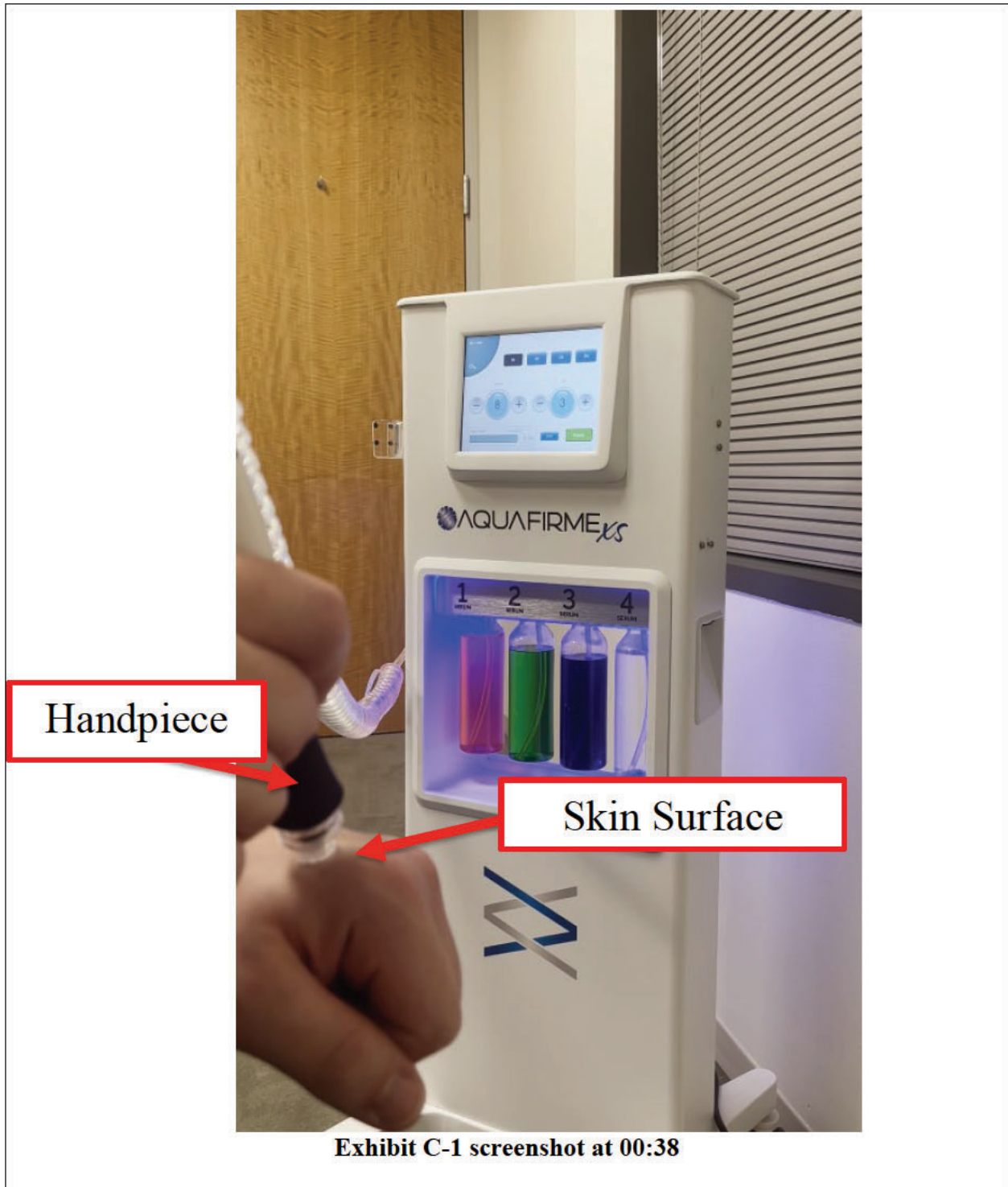


Exhibit C-32





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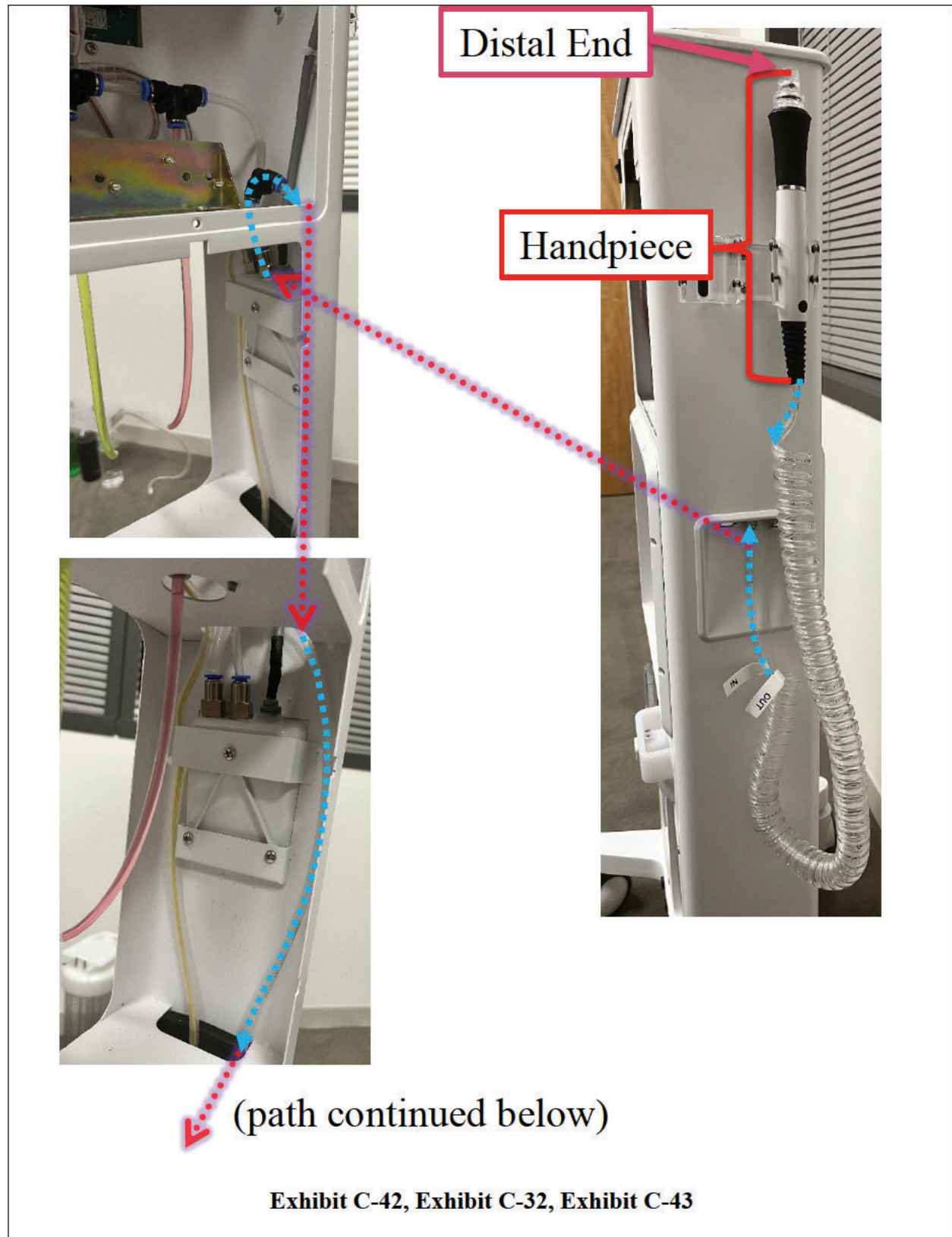


Dkt. 1-21 at 2.



[d][i] wherein the working end of the handpiece is configured to be placed in fluid communication with a vacuum source to create a suction force along a distal end of the handpiece when the vacuum source is activated and the handpiece is connected to the console and

The working end of the handpiece is configured to be in fluid communication with the vacuum source to create a suction force along the distal end of the handpiece as shown in the figures below. *See also* limitation 22[c], *supra* (showing the suction force of the vacuum source from the mark the handpiece leaves on the skin after contact).



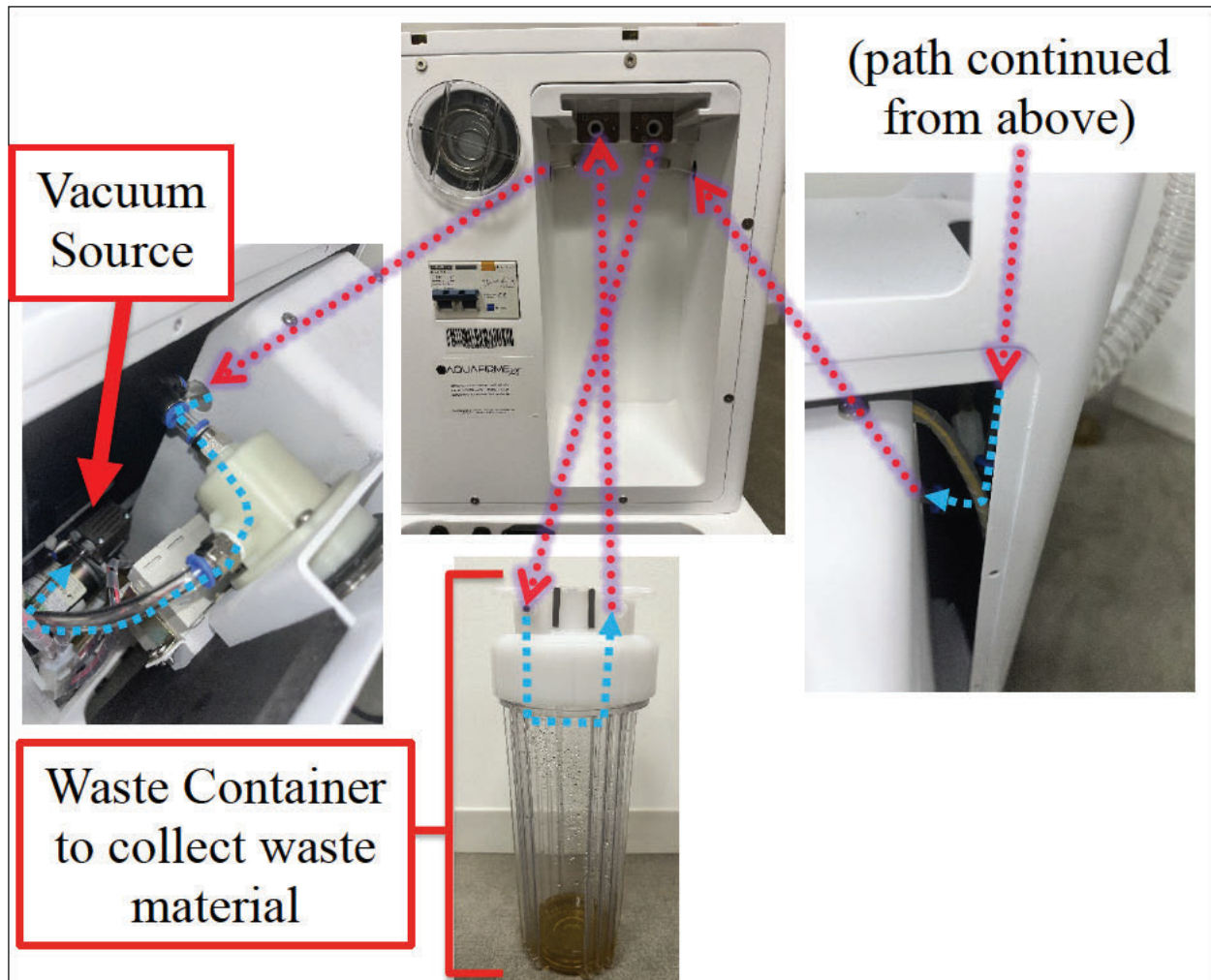


Exhibit C-46, Exhibit C-33, Exhibit C-45, Exhibit C-35.

Negative pressure draws waste material into the through-holes and out of the handpiece assembly into the waste container.

As further shown in the below images, the AquaFirmeXS includes a vacuum source. The AquaFirmeXS website explains that the AquaFirmeXS uses “vacuum suction, spiral eddy movements and specially formulated solutions to cleanse, exfoliate, uplift and hydrate the skin.” **Dkt. 1-14** at 2; *see also* **Dkt. 1-20**, **Dkt. 1-10** at 10 (describing vacuum suction in the systems). The images below show the vacuum source in the device.

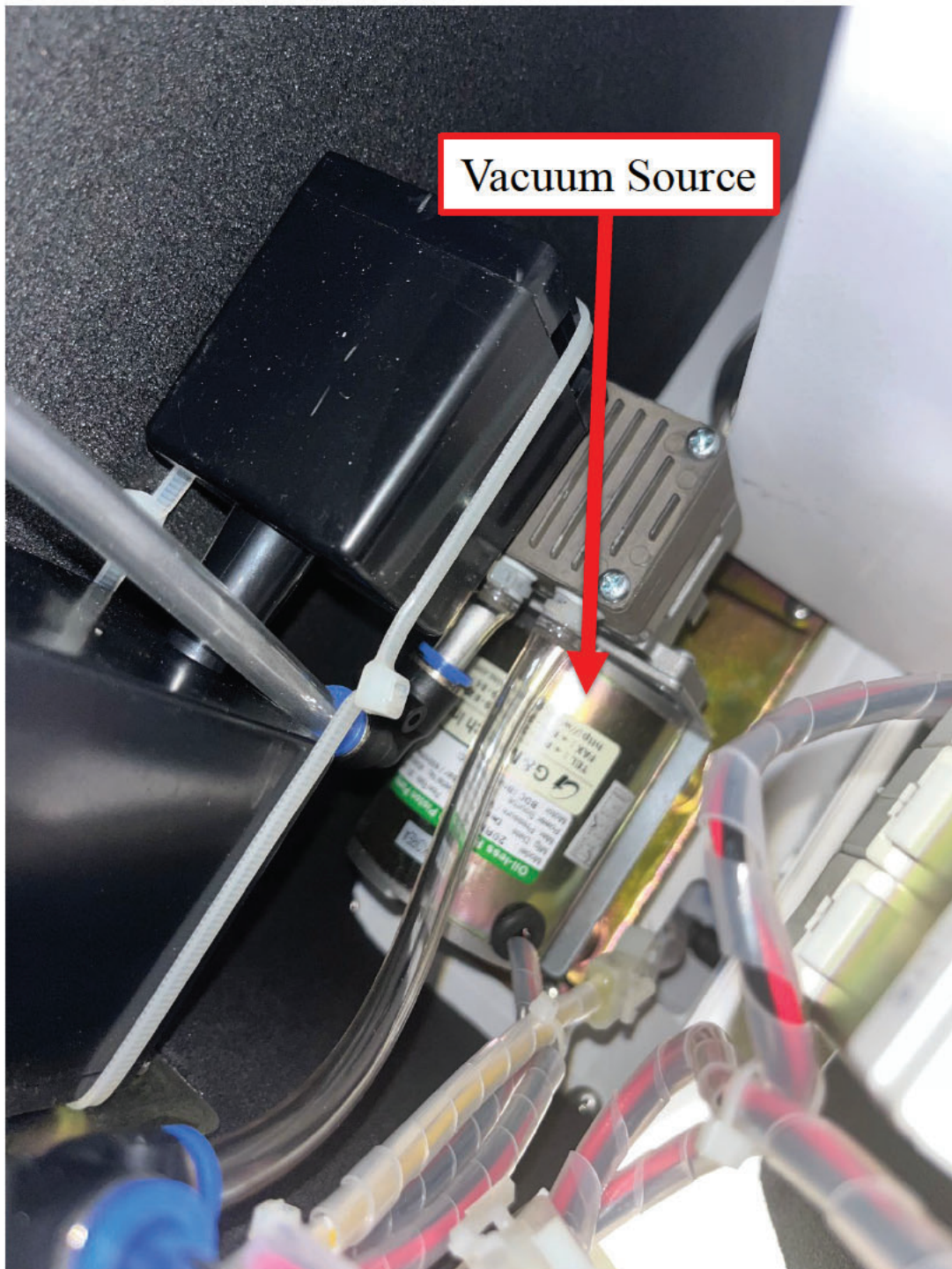


Exhibit C-49

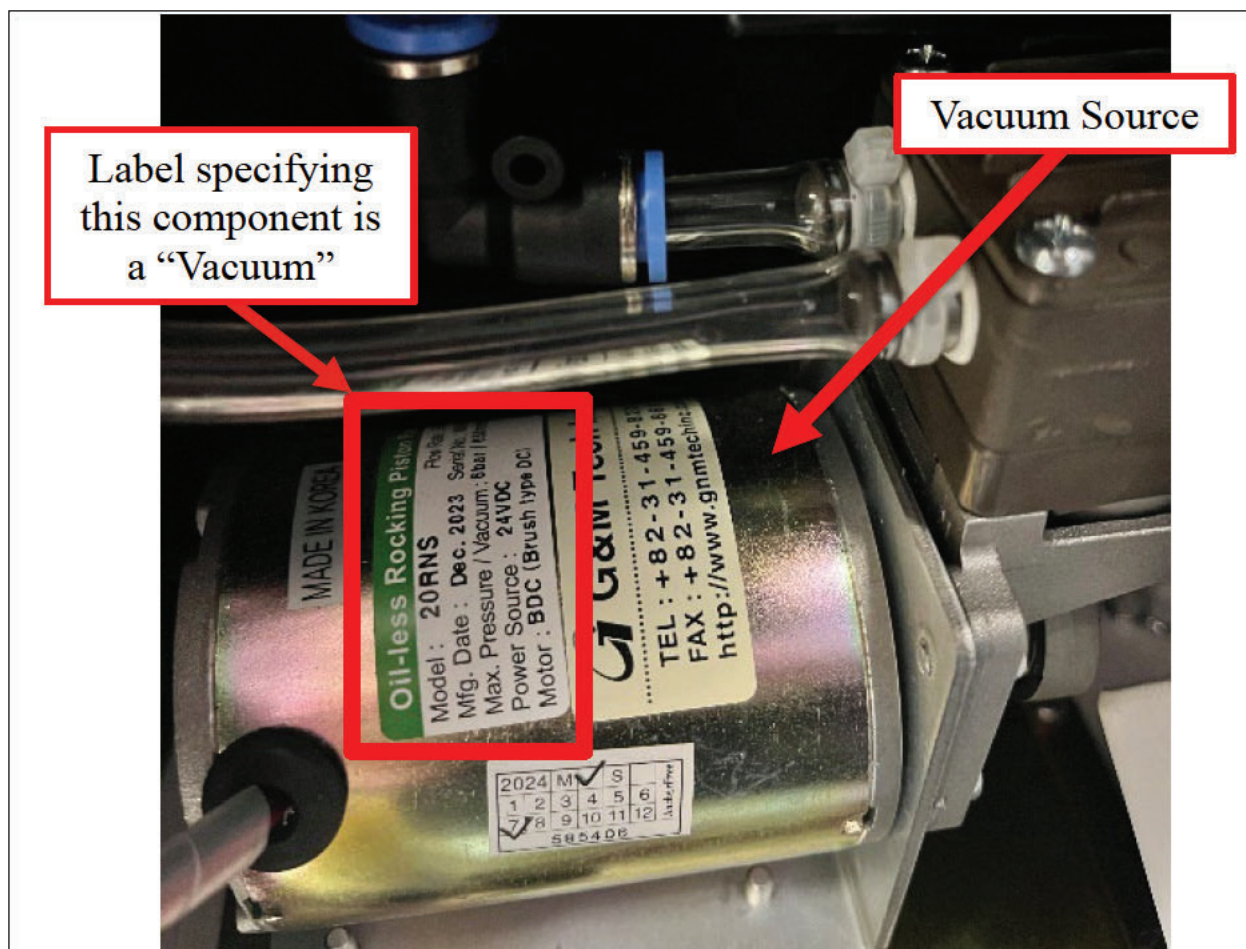


Exhibit C-59

As shown in the images below, the AquaFirmeXS handpiece working end is configured to create a suction force to remove waste while drawing and delivering the treatment solutions from the containers via the supply conduit.

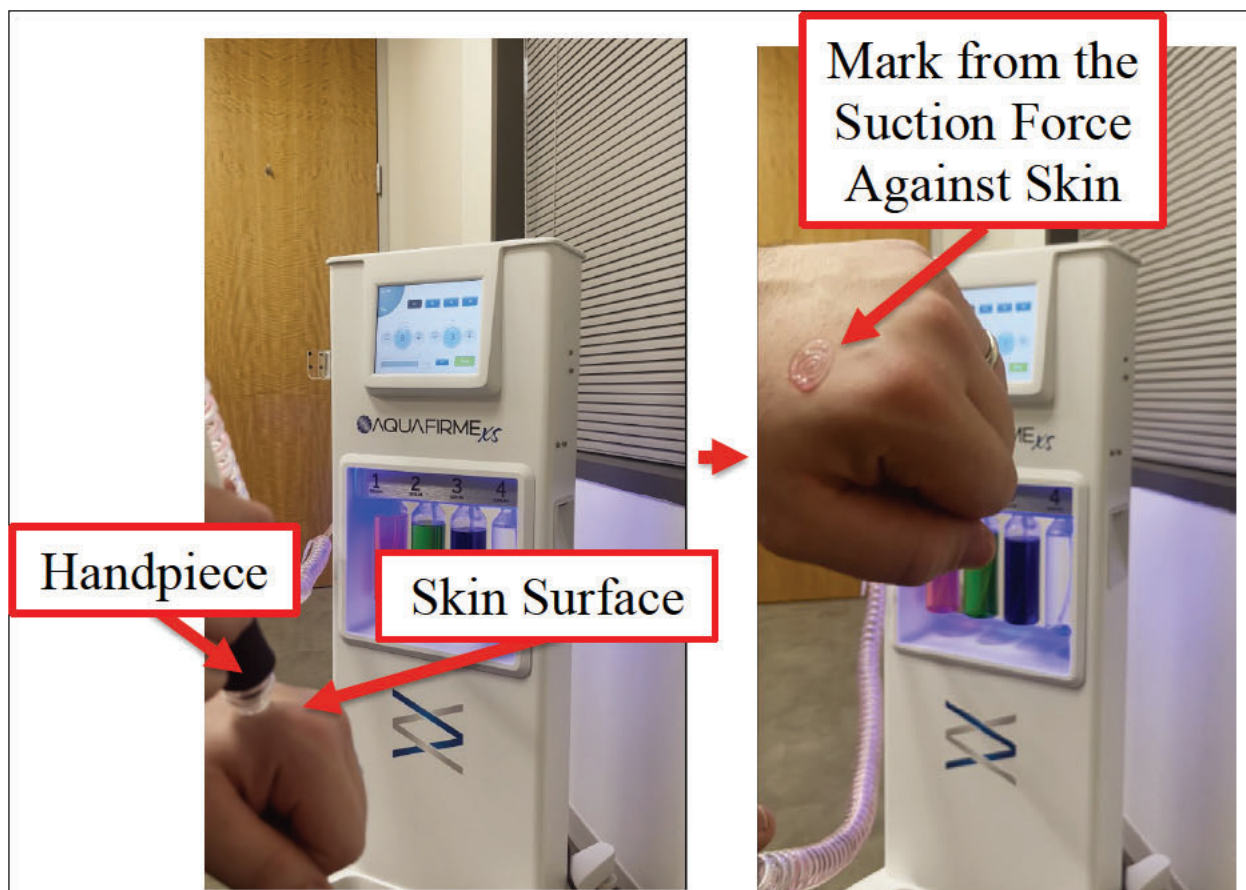
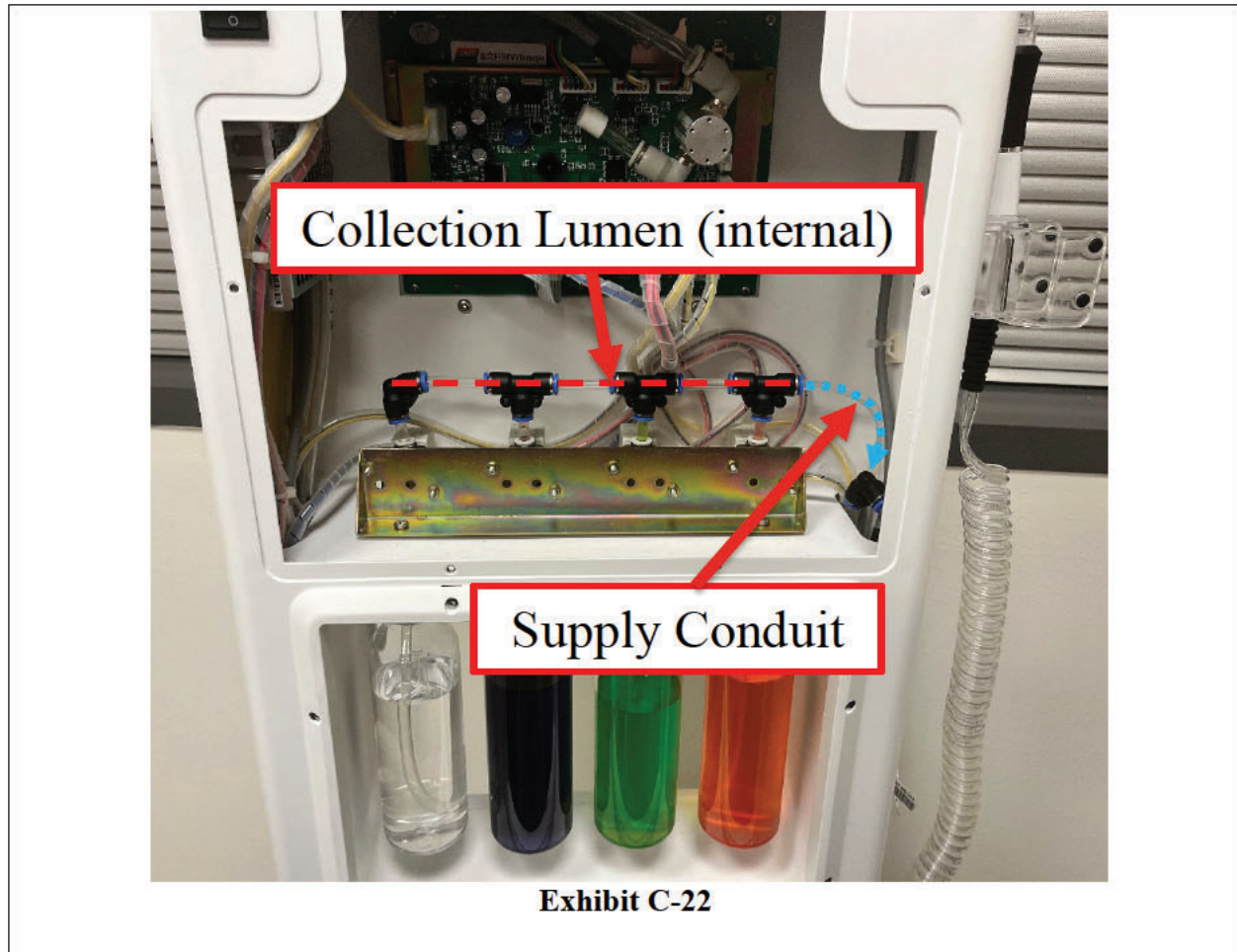


Exhibit C-2 screenshot at 00:46, 01:06

[d][ii] wherein the working end of the handpiece is configured to be placed in fluid communication with the first container or the at least one additional container through the collection lumen; and

The working end of the handpiece is configured to be placed in fluid communication with the fluid containers through the collection lumen, as shown in the images below.



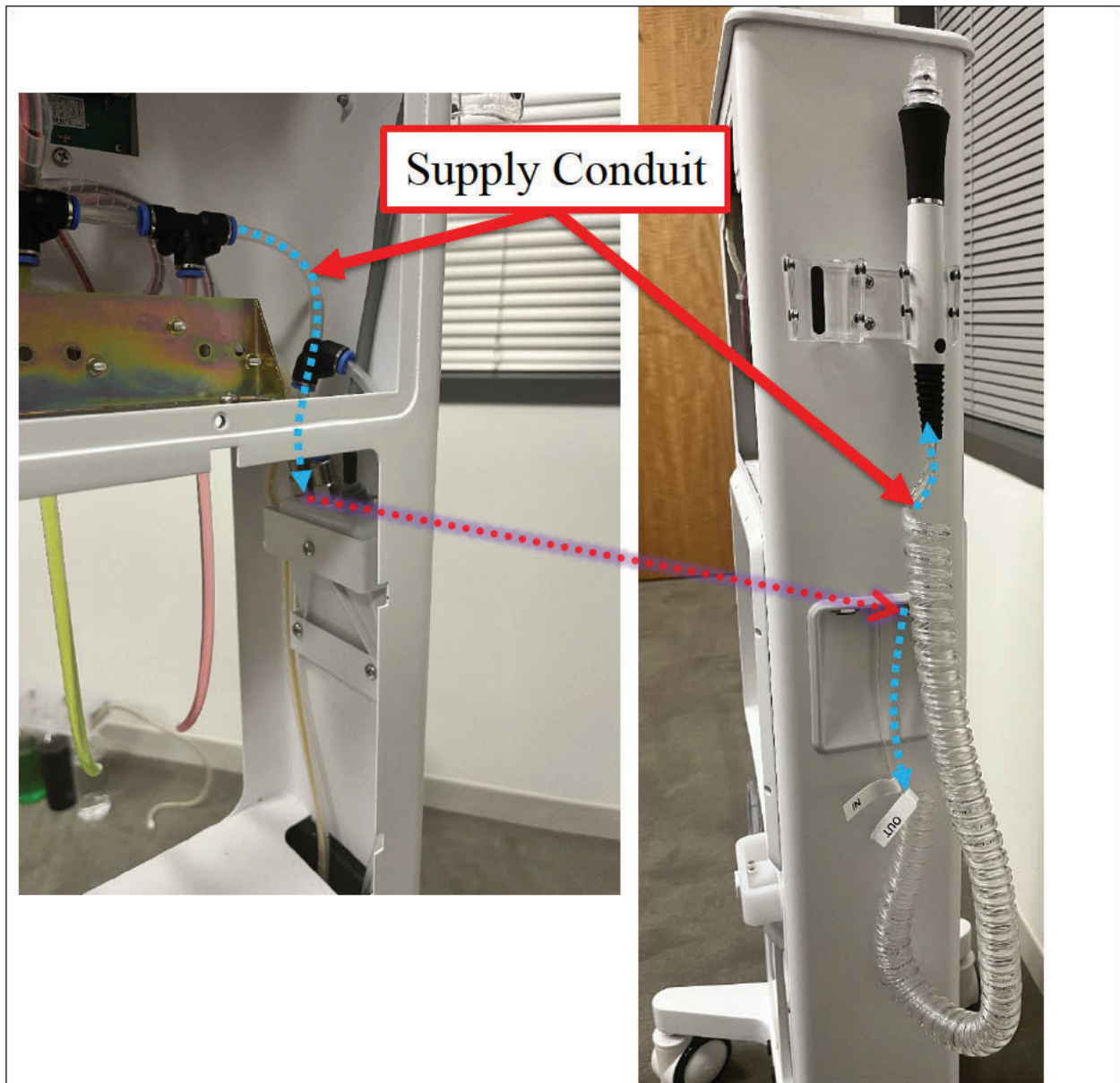


Exhibit C-42, Exhibit C-32.

This supply conduit is configured to couple to the handpiece assembly, as shown above.

[e] a supply conduit that places the collection lumen in fluid communication with the working end of the handpiece when the handpiece is connected to the console;

A supply conduit places the collection lumen in fluid communication with the working end of the handpiece, as shown below. *See also* limitation 22[d][ii] *supra*.



Exhibit C-22

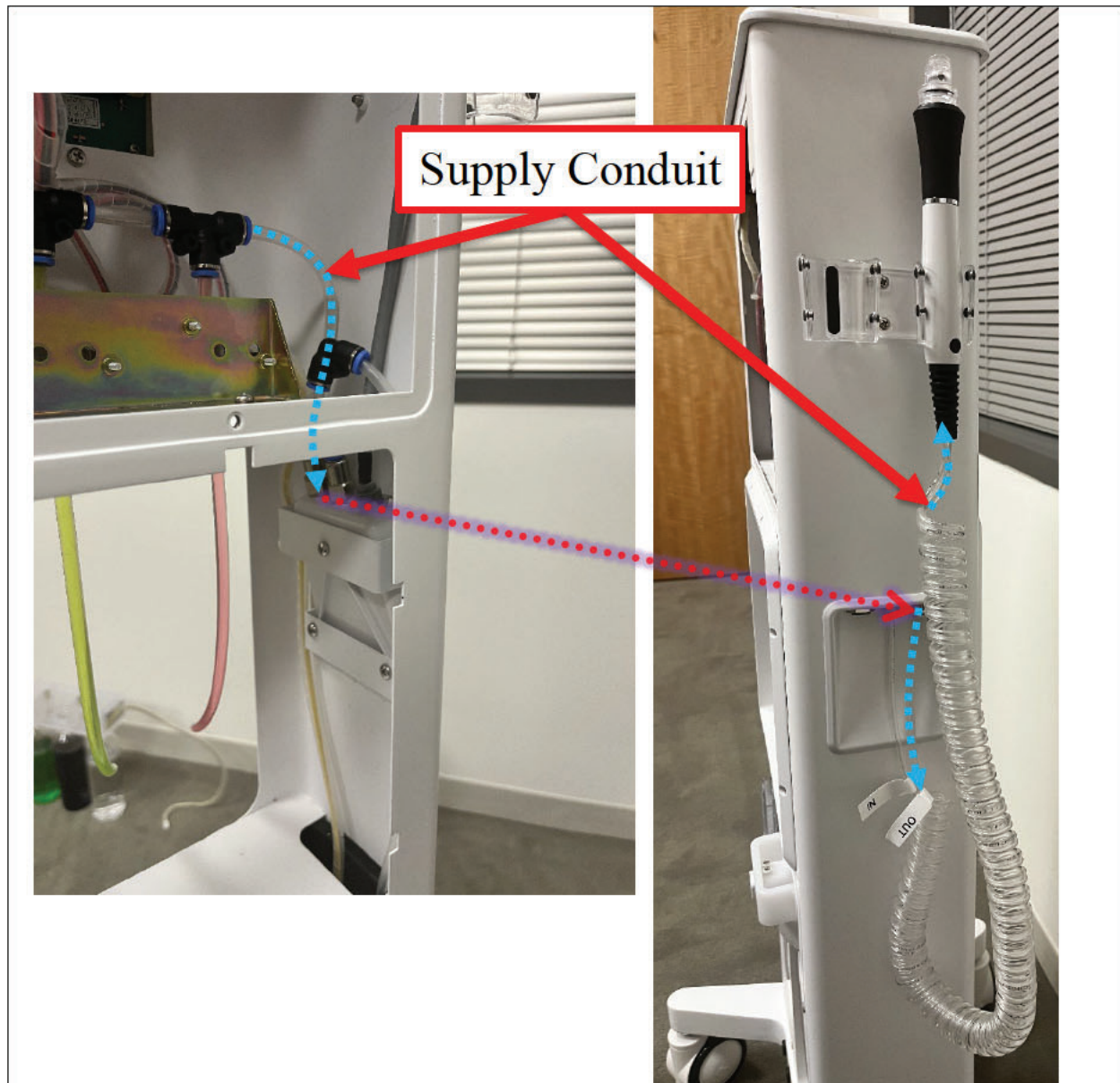


Exhibit C-42, Exhibit C-32.

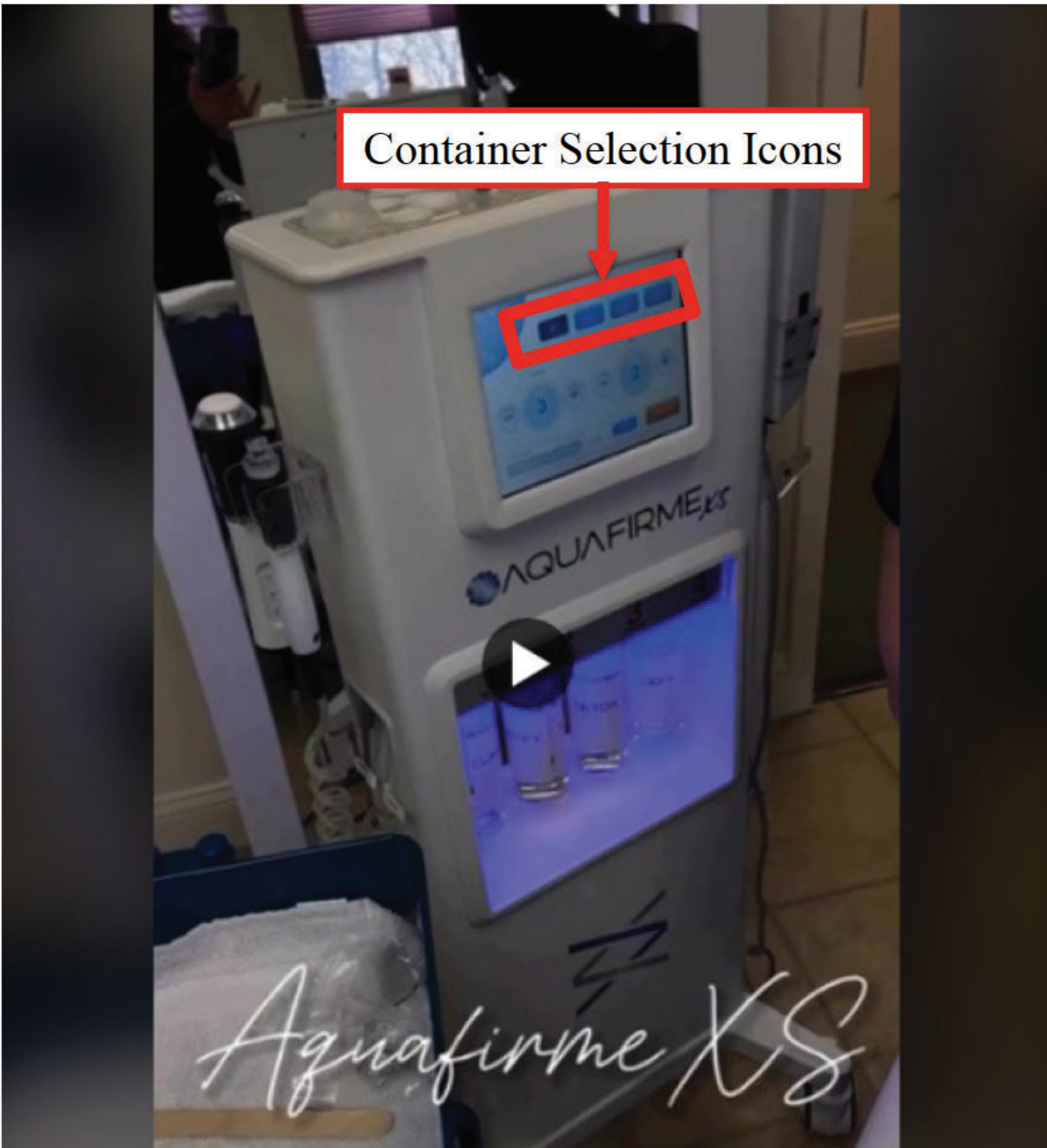
This supply conduit is configured to couple to the handpiece assembly, as shown above.

[f][i] wherein each of the first container and the at least one additional container includes treatment materials, and

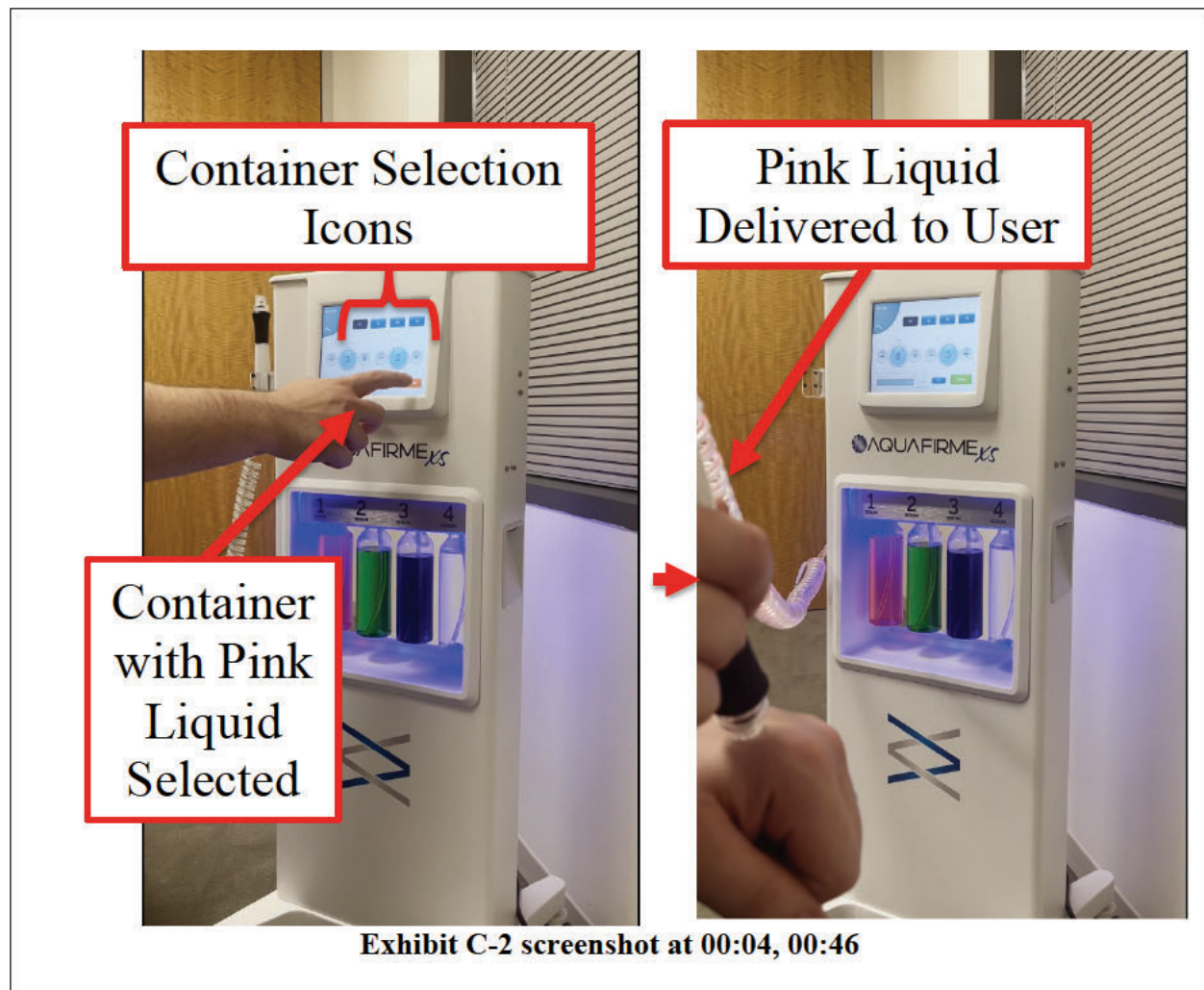
Defendants advertise the AquaFirmeXS system as “utilizing our proprietary serums” to “cleanse, exfoliate, hydrate, and nourish the skin” through the system’s handpiece’s cosmetic tip. **Dkt. 1-9** at 2; *see also* **Dkt. 1-10** at 13; **Dkt. 1-11** at 2. Because the AquaFirmeXS uses “proprietary serums,” i.e. treatment solutions delivered to the skin, the first fluid container and the at least the second fluid container are configured to contain a liquid treatment material. *See* limitation 22[a], *supra* (showing the first fluid container and the at least the second fluid container on the console being configured to contain a liquid treatment material).

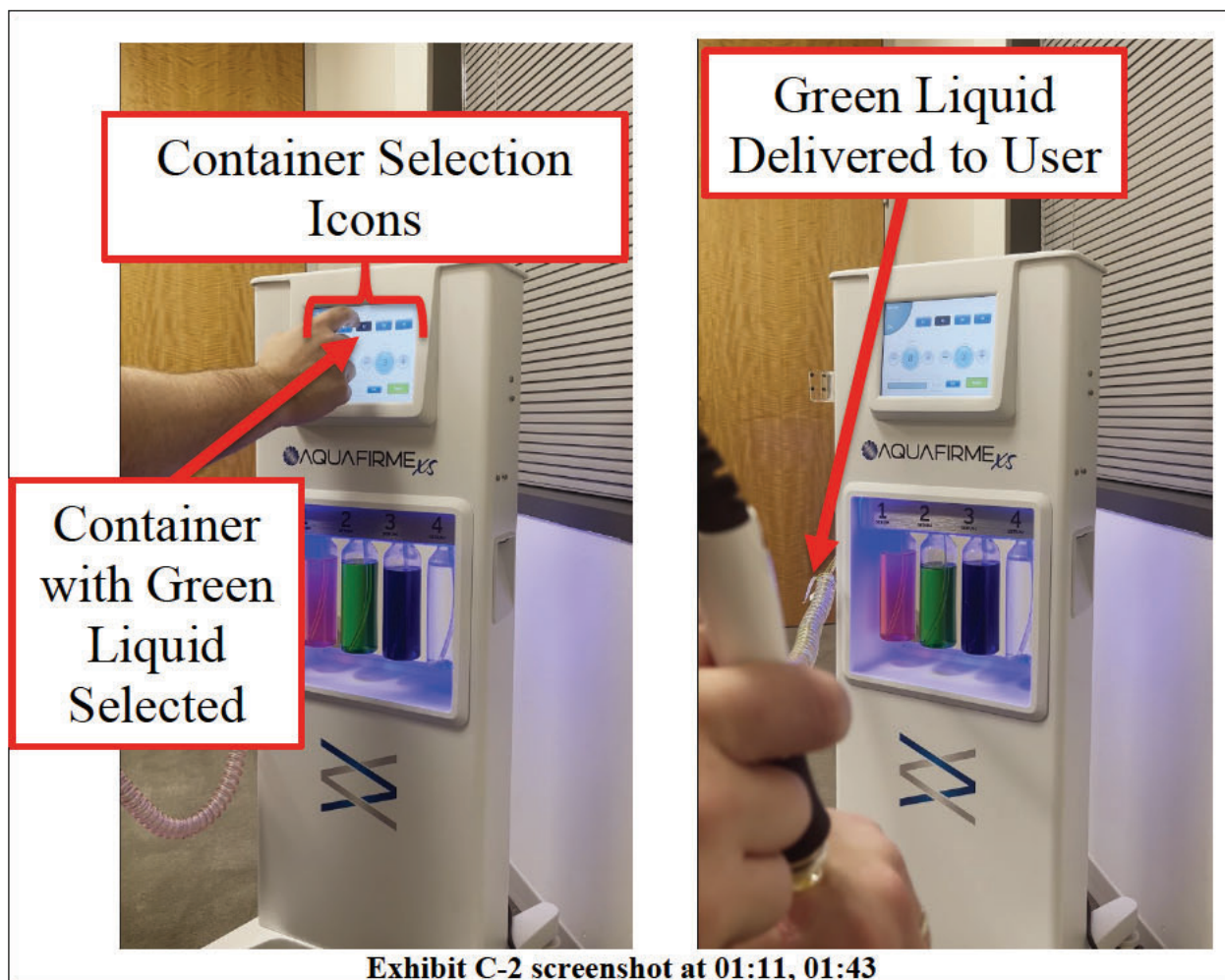
[f][ii] wherein treatment materials from the first container and the at least one additional container are configured to be delivered to the supply conduit sequentially when the first container and the at least one additional container are connected to the console.

As shown in the photos below, the AquaFirmeXS has an input device that permits a user to select the treatment material from the first fluid container or the second fluid container to be delivered through the supply conduit to the handpiece assembly sequentially. This occurs when a user selects a container for treatment via the container selection icons, as shown in the images below. *See also Dkt. 1-24* (displaying container selection icons).



Dkt. 1-13 at 2





X. OPINIONS ON VALIDITY

69. I have reviewed the following proceedings and associated materials challenging the validity of the '052 and '287 Patents based on an alleged lack of novelty and obviousness:

- IPR2024-01491 and its associated materials;
- IPR2025-00145 and its associated materials;
- IPR2025-00453 and its associated materials;⁶ and
- IPR2025-00445 and its associated materials.

⁶ I understand that the petition of IPR2025-00453 seeks to challenge U.S. Patent No. 11,446,477 (the "'477 Patent"). The '477 Patent claims priority to the application underlying the '052 Patent, and the '287 Patent claims priority to the application underlying the '477 Patent. For the sake of completeness, I address this petition with the others.

70. I understand that on April 11, 2025, the Board denied institution of the petition in IPR2024-01491 directed at the '287 Patent. I understand that on June 2, 2025, the Board granted institution of IPR2025-00145 which is also directed at the '287 Patent.

71. In the above cited proceedings, the petitioner contends that specific cited prior art references disclose systems that would allegedly anticipate or render obvious the claims of the '052 and '287 Patents. I disagree with these positions because none of the cited references in the proceedings teach systems that perform hydrodermabrasion as claimed by the '052 and '287 Patents.

72. I further understand that AMP has previously argued that the Asserted Claims of the Asserted Patents are invalid as obvious in view on numerous references. I address AMP's prior invalidity contentions and the contentions in the IPR petitions below, understanding that AMP has not argued these contentions or the contentions from the IPR petitions during the course of this litigation.

A. '052 Patent

73. In my opinion, Claim 1 of the '052 Patent is not invalid as anticipated or rendered obvious.

74. Claim 1 recites as follows:

1. A system for performing a skin treatment procedure, the system comprising:
a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;
a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;
a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;
wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and
a vacuum source;

a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

75. By way of example only and not an exhaustive list, none of the references cited by AMP or cited in the above proceedings teach the following limitations:

- “a console including a manifold, the manifold being in fluid communication with a first fluid container and at least a second fluid container, the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;” (claim 1 of the ’052 Patent);
- “wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit,” (claim 1 of the ’052 Patent).

76. For example, U.S. Patent Publication No. 2003/0093089 (“Greenberg”) was cited as a reference in IPR2024-01491 and IPR2025-00453, and U.S. Patent Publication No. 2003/0212415 (“Karasiuk”) was cited as a reference in all four IPRs.

77. Greenberg discloses a microdermabrasion machine that uses abrasive particles to abrade the skin. Greenberg is focused on “using abrasive particles of different sizes and/or type.” Appendix B (“Greenberg”) at ¶ 2. Accordingly, Greenberg’s machine in Fig. 1 has separate first

and second assemblies on either side, each with its own recovery container, supply container, and handle to separately drive particles of different sizes or type. *Id.* ¶ [0049].

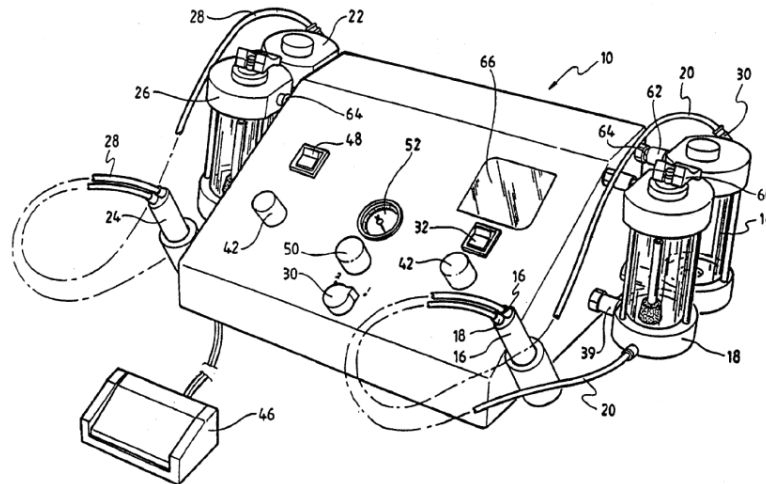


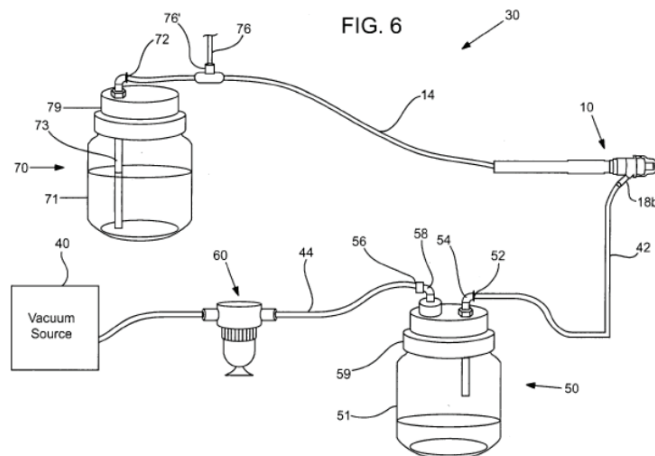
FIG 1

Appendix B (“Greenberg”) at Figure 1

78. Greenberg lacks a manifold in fluid communication with multiple containers and configured to control the flow of one of multiple skin-treatment containers to a handpiece. The machine disclosed in Greenberg draws spent abrasive particles into the recovery container, but for heavier abrasive particles, it also uses a compressor upstream of the bottles to propel the particles airborne. *Id.* at ¶¶ [0050]-[0051]. Other embodiments in Greenberg alter the number of supply containers, recovery containers, and handles, but none of the containers are designed for liquids or “wet” system. All Greenberg containers have tubes coming up from bottom and are incapable of drawing liquids from them. Hydrodermabrasion systems have tubes coming in from top of the containers. Greenberg discloses valves 106 and 108 (not manifolds) that work in tandem to select a container; however, such valves require an upstream positive pneumatic source for propelling particulates (and not a liquid material) to the handpiece. *Id.* at ¶ [0077]. In all instances, the machine uses only dry particles to abrade the skin (microdermabrasion and not hydrodermabrasion), and thus lacks “liquid” treatment materials. *See id.* at ¶¶ [0073]-[0076]

(describing particles used during treatment); ¶ [0085] (“Of course, great care needs to be taken to ensure that the particle[s] do not become too wet whereupon they will not be able to move freely through the apparatus but will stick to the container and the various tubes.”); ¶ [0070] (“provided that the particles are sufficiently dry and of suitable size, a whole range or organic particles may be used.”).

79. Karasiuk, as shown in the Figure 6 below, is a device that draws liquid from just one container during a treatment.



Appendix C (“Karasiuk”) at Figure 6

80. Karasiuk also lacks a manifold in fluid communication with multiple containers and configured to control the flow of one of multiple skin-treatment containers to a handpiece. Nothing in Karasiuk suggests separately storing and applying different treatment fluids in different containers in a single microdermabrasion treatment. At most, Karasiuk lists different solutions, suspensions, or compounds that can be contained “alone or in combination” in Karasiuk’s single reservoir 70. Appendix C (“Karasiuk”) at ¶ [0061]. Karasiuk further lacks any means, much less a manifold, for switching from reservoir 70 to any other source of liquid treatment material. Furthermore, Karasiuk teaches a breather line 76 and adjustable valve 78 (not shown) positioned

between the reservoir 70 and the handpiece 10, causing the vacuum source 40 to draw only air through tube 14, rather than draw material from the reservoir 70. *See id.* at ¶ [0059]. This arrangement makes the Karasiuk system inoperable for its intended purpose of drawing fluid to the device 10 and means that it is not enabled. Karasiuk's system is not enabled for placement of the adjustable breather line in other locations.

81. Additionally, a POSA would not have been motivated to combine or modify any of the references to achieve the claimed invention nor would a POSA have had a reasonable expectation of successfully combining or modifying the references. HydraFacial is the pioneer of the hydrodermabrasion field which owes its origin to HydraFacial and its patented technology.

82. I understand that Defendants have identified other references that purportedly challenge the validity of the '052 Patent, but Defendants have not offered specific reasons in support of how any of these references, alone or in combination with other references, anticipates or renders as obvious each limitation of any of the asserted claims of the '052 Patent. AMP's Resp. to Compl. and Not. of Invest. at 17, Inv. No. 337-TA-1416 (USITC October 10, 2024).

B. '287 Patent

83. In my opinion, Claim 22 of the '287 Patent is not invalid as anticipated or rendered obvious.

84. Claim 22 recites as follows:

22. A system for treating skin, the system comprising:
a console configured to receive a first container and at least one additional container;
a collection lumen configured to be in fluid communication with the first container and the at least one additional container when the first container and the at least one additional container are connected to the console; and
a handpiece having a working end, the working end of the handpiece being configured to contact skin tissue of a subject during use;
wherein the working end of the handpiece is configured to be placed in fluid communication with a vacuum source to create a suction force along a distal end of the handpiece when the vacuum source is activated and the handpiece is connected to the console and wherein the working end of the handpiece is configured to be placed

in fluid communication with the first container or the at least one additional container through the collection lumen; and
a supply conduit that places the collection lumen in fluid communication with the working end of the handpiece when the handpiece is connected to the console;
wherein each of the first container and the at least one additional container includes treatment materials, and wherein treatment materials from the first container and the at least one additional container are configured to be delivered to the supply conduit sequentially when the first container and the at least one additional container are connected to the console.

85. By way of example and not an exhaustive list, none of the cited references in this case or the above proceedings teach the following limitations:

- “a collection lumen configured to be in fluid communication with the first container and the at least one additional container when the first container and the at least one additional container are connected to the console;” (claim 22 of the ’287 Patent)
- “wherein each of the first container and the at least one additional container includes treatment materials, and wherein treatment materials from the first container and the at least one additional container are configured to be delivered to the supply conduit sequentially when the first container and the at least one additional container are connected to the console” (claim 22 of the ’287 Patent).

86. For example, as explained above with regard to the novelty of the ’052 Patent, Greenberg lacks a manifold, and it also lacks a collection lumen configured to be in fluid communication with one of multiple skin-treatment containers and wherein treatment materials from the containers are configured to be delivered to a handpiece. Greenberg does not disclose any embodiment having a collection lumen in fluid communication with multiple supply containers and a handpiece, and also in fluid communication with a vacuum source. Greenberg’s Fig. 5 embodiment lacks a vacuum source and instead relies on an upstream pressure source, such that valves 106 and 108 cannot meet the collection lumen limitation or the manifold limitation.

87. Further, as I explained above with regard to the '052 Patent, Karasiuk also lacks a manifold, and similarly lacks a collection lumen configured to be in fluid communication with one of multiple skin-treatment containers and wherein treatment materials from the containers are configured to be delivered to a handpiece. Karasiuk discloses only a single container.

88. Additionally, a POSA would not have been motivated to combine or modify any of the references to achieve the claimed invention nor have had a reasonable expectation of successfully combining or modifying the references. The secondary prior art references upon which these IPR petitions rely are from entirely different fields such as dental irrigation (Palmer) and jet dispensing for pharmaceutical administration (Trueba). A POSA would not have looked to either field to modify skin treatment devices, as the dental irrigation tool of Palmer shoots pulsed jets of fluid into a patient's mouth at a high velocity and pressure, U.S. Patent No. 5,199,604 at 2:52-56, 11:17-23; and both the jet dispensing tool of Trueba and the tool of Palmer rely on treatment liquids despite Greenberg teaching away from the use of fluids in its system. *Compare* U.S. Patent No. 6,684,880 (Trueba) at 7:9–14 *with* ¶ 80, *supra*. HydraFacial is the pioneer of the field of hydrodermabrasion and the automation of using multiple containers which owes its origin to HydraFacial and its patented technology.

89. I understand that Defendants have identified other references that purportedly challenge the validity of the '287 Patent, but Defendants have not offered specific reasons in support of how any of these references, alone or in combination with other references, anticipates or renders obvious each limitation of any of the asserted claims of the '287 Patent. AMP's Resp. to Compl. and Not. of Invest. at 17, Inv. No. 337-TA-1416 (USITC October 10, 2024).

C. Objective Indicia of Nonobviousness

90. The '052 and '287 Patents claim inventions with advantages and benefits that are unexpected and superior. The commercial success of Plaintiff's products practicing the Asserted

Claims when compared to hydrodermabrasion products that do not practice the Asserted Claims, as well as extensive copying by third parties, serves as objective evidence that the claims of the '052 and '287 Patents would not have been obvious.

1. *Nexus of Plaintiff's Products with the Asserted Claims*

91. In my opinion, HydraFacial's Syndeo®, Elite™, Allegro™, and Tower hydrodermabrasion systems (the "HydraFacial Systems") practice the Asserted Claims and are co-extensive with them to establish a presumed nexus.

92. I address how the Syndeo system practices each limitation of claim 1 of the '052 Patent in the claim chart below.

CLAIM 1 OF THE '052 PATENT
Preamble 1[pre]: A system for performing a skin treatment procedure, the system comprising:
<p>To the extent that the preamble is deemed to be a limitation, the HydraFacial Syndeo is a system for performing a skin treatment procedure.</p> <p><u>HydraFacial Syndeo IFUs</u></p> <p>The Syndeo IFU states "[t]he System is intended to abrade (exfoliate) the upper layers of the skin":</p>
<div style="border: 1px solid black; padding: 5px;"> <p>Intended Use</p> <p>The System is intended to abrade (exfoliate) the upper layers of the skin.</p> <p>Indication (related to the use of the device in the European Economic Area (EEA):</p> <ul style="list-style-type: none"> • Mild to moderate acne, i.e. acne vulgaris, comedonal acne (blackheads and whiteheads). • Superficial acne scarring. </div>
<p>Exhibit B2 at 4. The Syndeo IFU further describes a step of the treatment: "Place tip against skin to occlude and dab skin solution onto skin." <i>Id.</i> at 19.</p>

CLAIM 1 OF THE '052 PATENT**Photos of the HydraFacial Syndeo**

The photo below shows the HydraFacial Syndeo system.



Exhibit A1.

[a][i]: a console including a manifold,

The HydraFacial Syndeo is a system that comprises console including a manifold.

HydraFacial Syndeo IFUs

The Syndeo IFU shows the system having a manifold in the console at the location shown below.

CLAIM 1 OF THE '052 PATENT

System Components

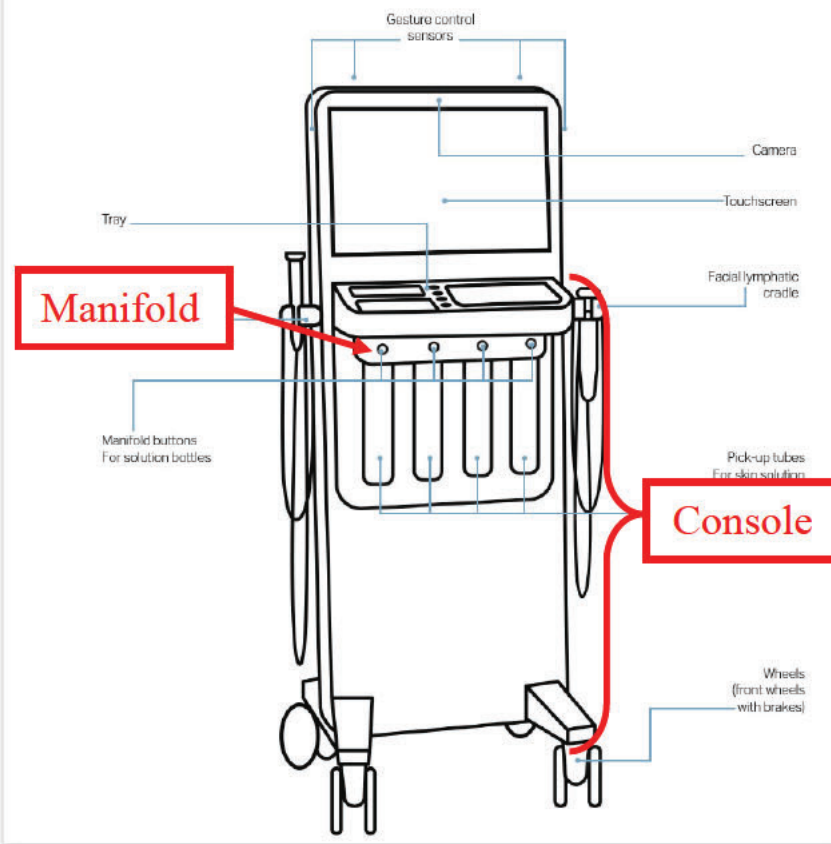
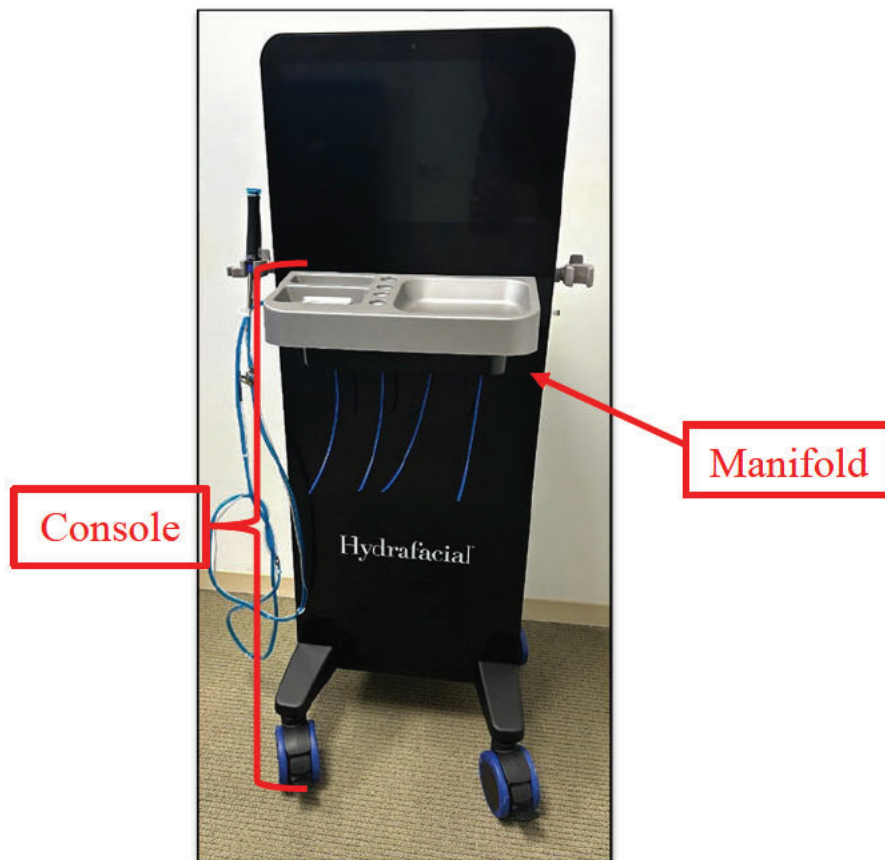


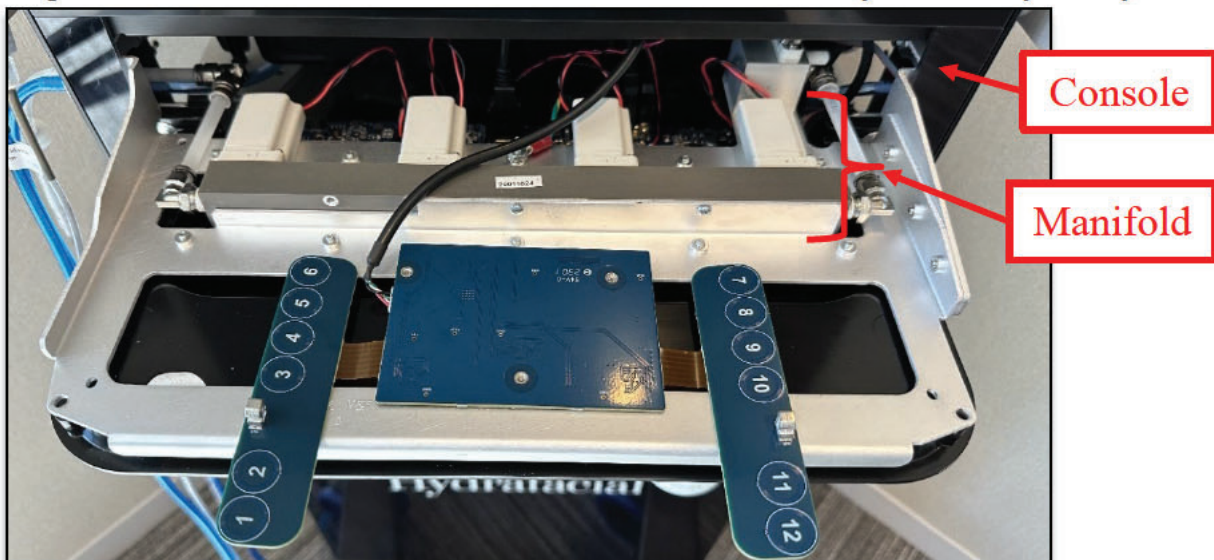
Exhibit B2 at 10.

Photos of HydraFacial Syndeo

The HydraFacial Syndeo system includes a manifold in the console:

CLAIM 1 OF THE '052 PATENT**Exhibit A2.**

The photo below further shows the manifold in the console of the HydraFacial Syneo system.

**Exhibit A3.**

CLAIM 1 OF THE '052 PATENT

The photo below shows the manifold removed from the console of the HydraFacial Syndeo system:

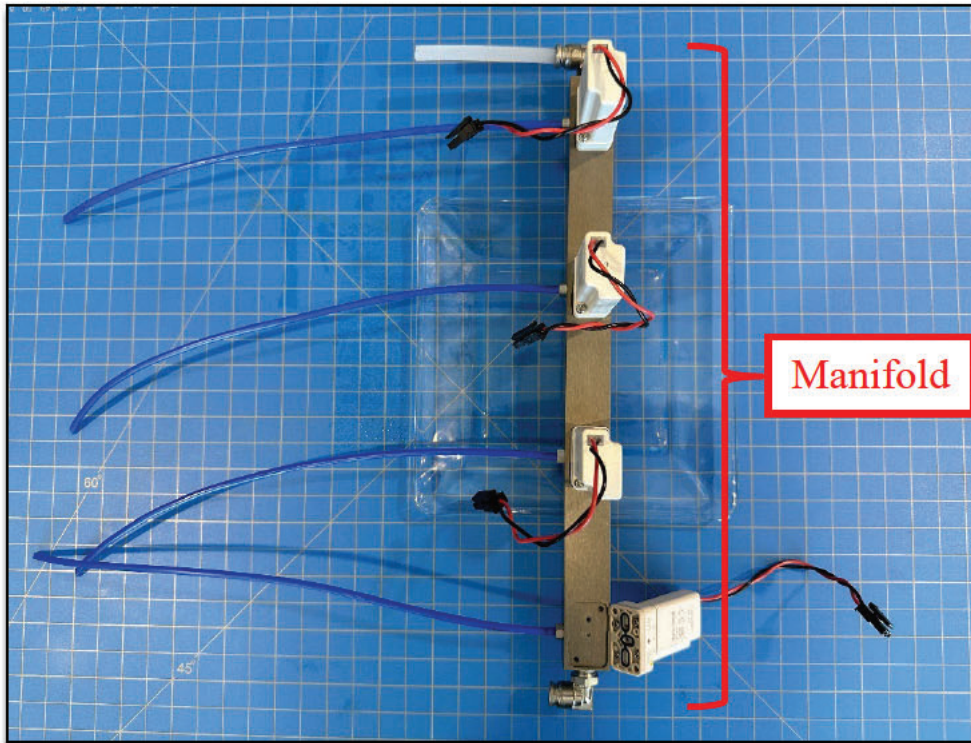


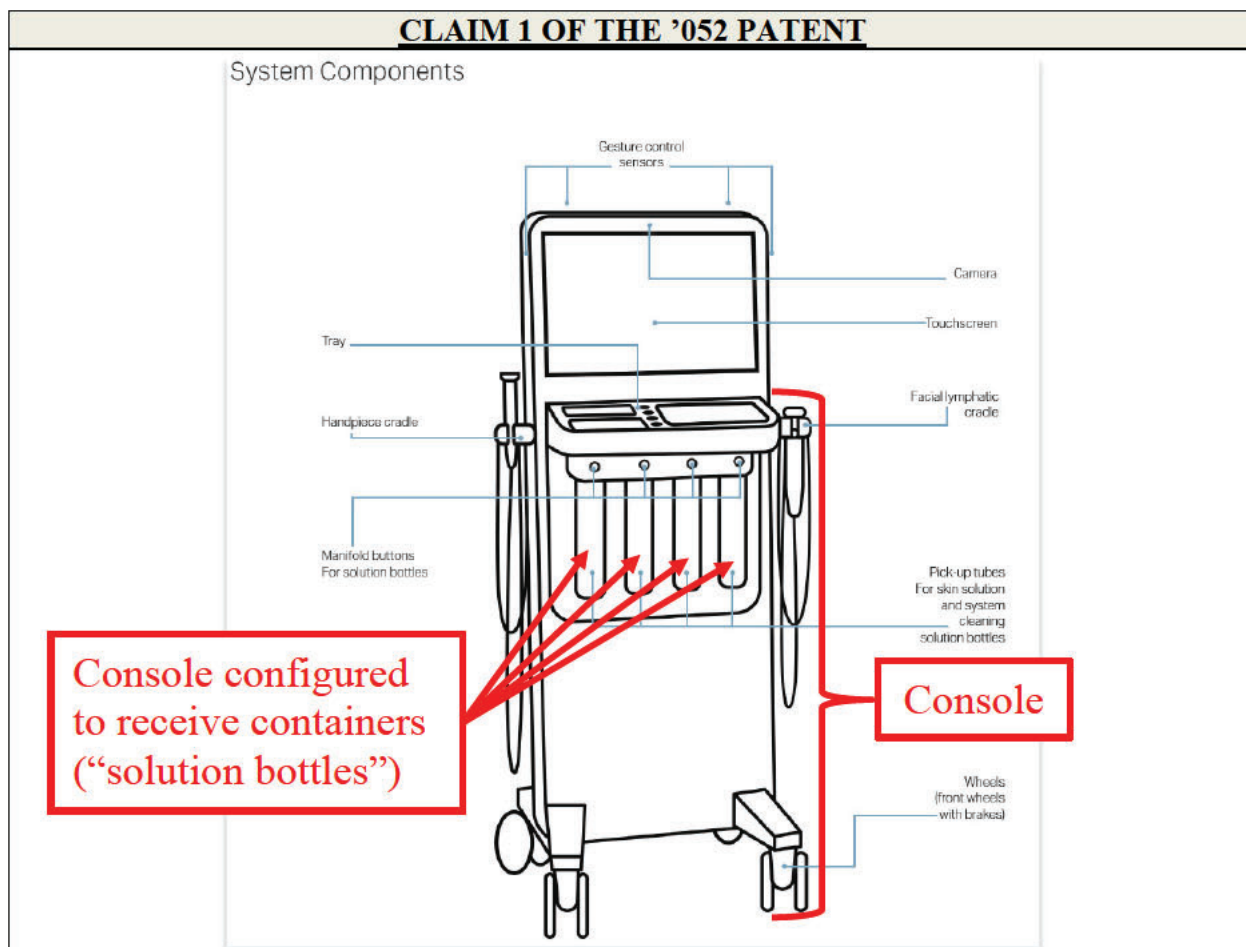
Exhibit A4.

[a][ii]: the manifold being in fluid communication with a first fluid container and at least a second fluid container,

The manifold of the HydraFacial Syndeo is in fluid communication with a first fluid container and at least a second fluid container.

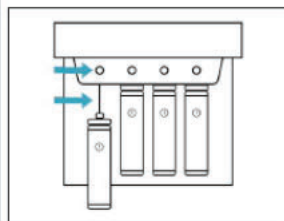
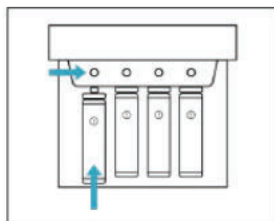
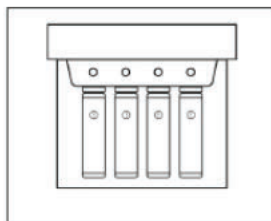
HydraFacial Syndeo IFUs

The Syndeo IFU depicts the system and console configured to receive a first fluid container and additional fluid containers (including the second container):

CLAIM 1 OF THE '052 PATENT**Exhibit B2** at 10.

The Syndeo IFU also describes connecting the containers (including the first and second containers) to the console such that the manifold is configured to receive fluid from the containers (including the first and second containers):

Feed the straw into the bottle, passing the seal. Spin the bottle so the V notch faces towards you and align it with the button. Push the bottle up until it clicks in. Do not twist the bottle once inserted.



Id. at 13. The Syndeo IFU explains that the HydraFacial Syndeo includes “solution bottle controls . . . located on the bottom of the screen within the treatment steps.” *Id.* at 14. It explains that the system “automatically selects and deselects the recommended solution bottle based on the respective treatment step.” *Id.* In this manner, the manifold is in fluid communication with the first fluid container and the at least the second fluid container.

CLAIM 1 OF THE '052 PATENT**Photos of HydraFacial Syndeo**

The photo below shows the HydraFacial Syndeo console configured to receive a first container and at least one additional container:

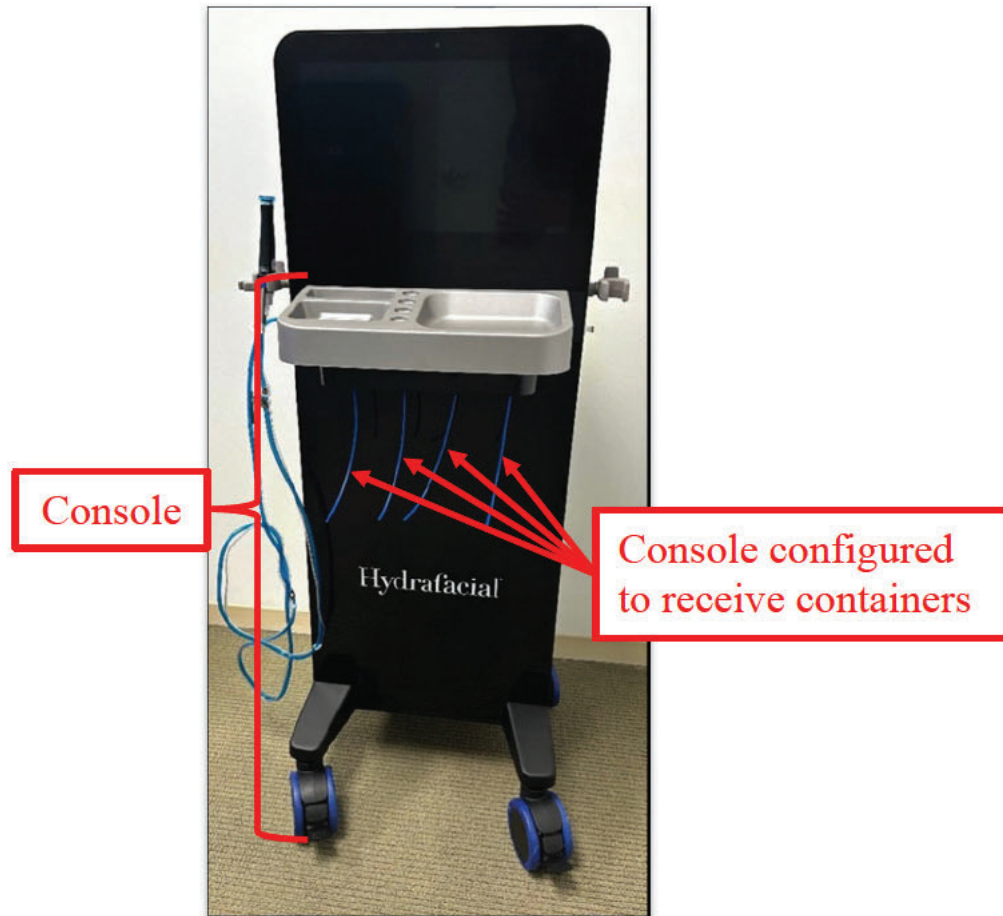


Exhibit A2. The manifold is in fluid communication the first container and at least the second container through tubing extending from the manifold. The manifold is configured to receive fluid, through the tubing, from the containers (including the first container) when the containers are connected to the console. As illustrated in the photo below, the tubing to receive fluid from containers extends to their respective serum valves that control which fluid reaches a lumen in the manifold based on which container a user selects.

CLAIM 1 OF THE '052 PATENT

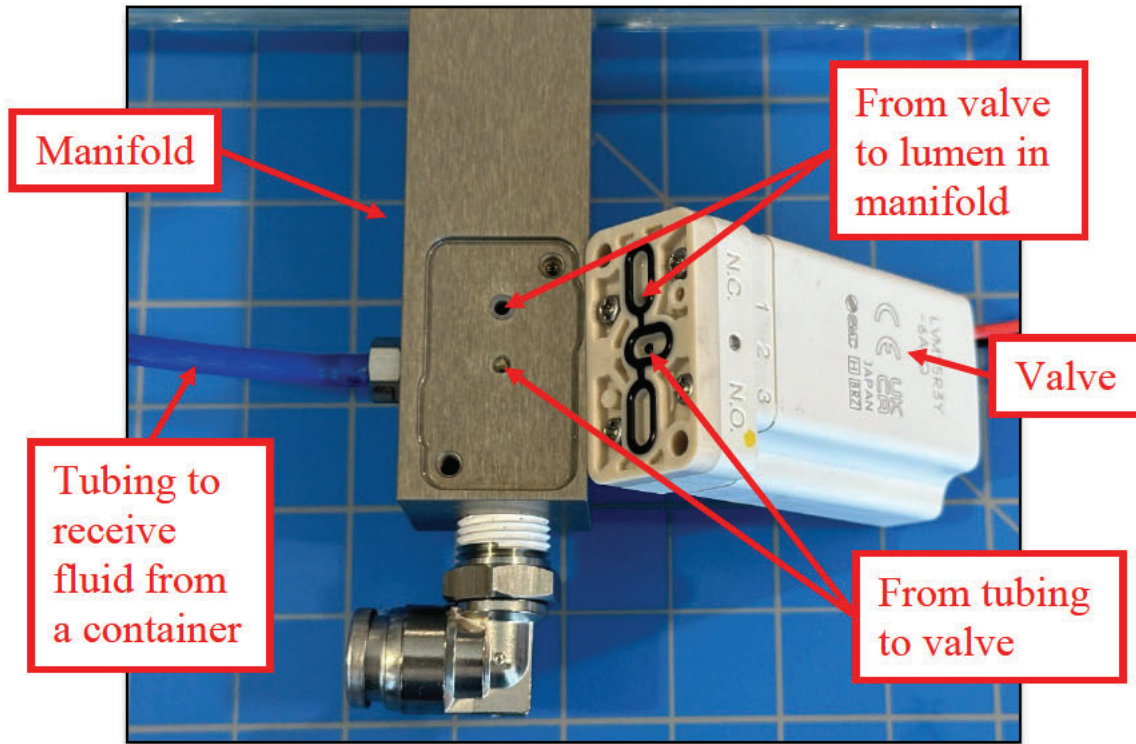


Exhibit A5.

[a][iii]: the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;

The first fluid container and the at least second fluid container of the HydraFacial Syndeo are configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid. *See* limitations 1[pre], [a], and [a][i], *supra* (describing “solution bottles” where placing the tip against skin “occlude[s] and dab[s] skin solution onto skin”).

[b]: a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

The HydraFacial Syndeo comprises a handpiece assembly comprising a tip, with the tip being configured to contact a skin surface of a subject.

HydraFacial Syndeo IFUs

The Syndeo IFU includes the figure below depicting the system comprising a handpiece assembly.

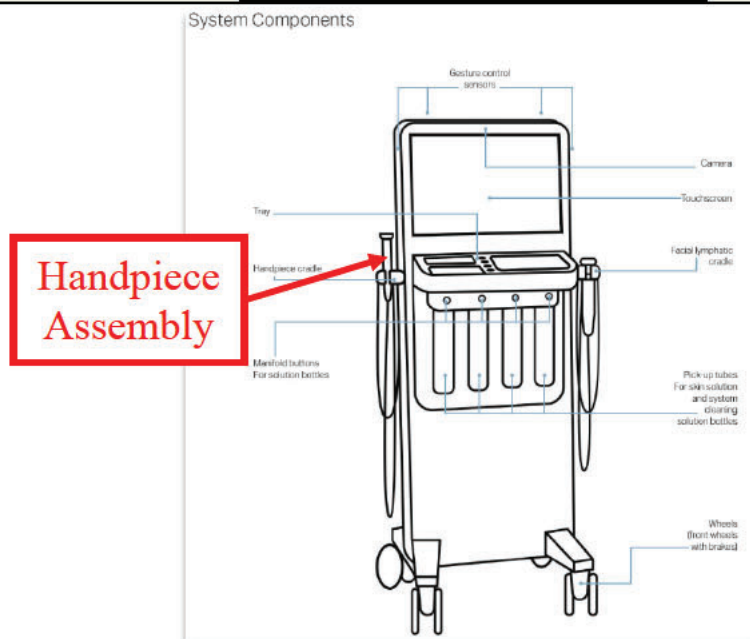
CLAIM 1 OF THE '052 PATENT

Exhibit B2 at 10. The Handpiece IFU explains that the handpiece assembly is “[d]esigned for use with patented HydroPeel™ tips.” **Exhibit B9** at 3.

The Syndeo IFU explains that the tip of the handpiece assembly contacts the skin surface of a subject during a treatment procedure:

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.

Exhibit B2 at 19.

Photos of HydraFacial Syndeo

The photos below show the HydraFacial Syndeo handpiece assembly with a tip configured to contact a skin surface of a subject.

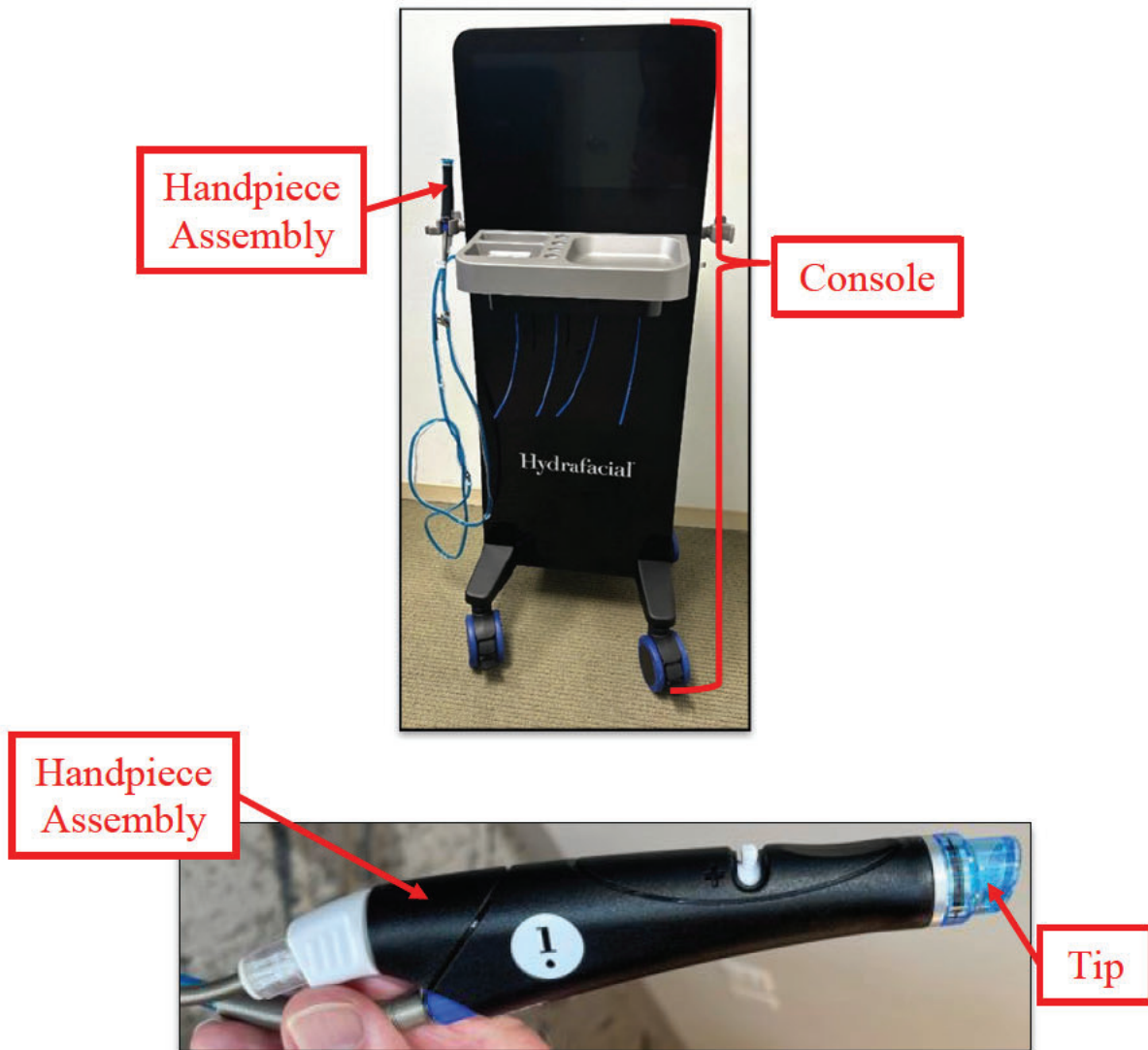
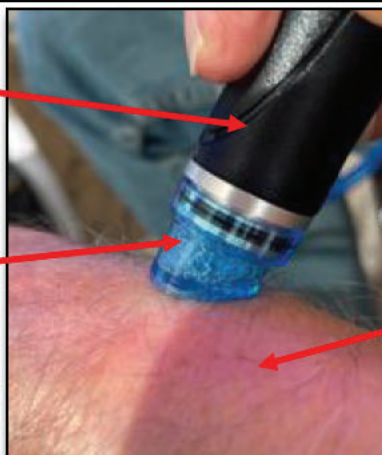


Exhibit A2. The photo below shows the handpiece assembly contacting the skin tissue of a subject during a treatment procedure.

CLAIM 1 OF THE '052 PATENT**Handpiece
Assembly****Tip****Skin tissue
of a subject****Exhibit A2.**

[c]: a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;

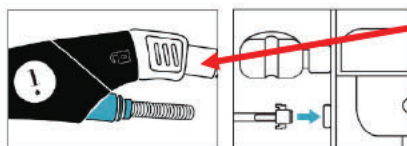
The HydraFacial Syndeo comprises a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein the distal end of the supply conduit is configured to couple to the handpiece assembly.

HydraFacial Syndeo IFUs

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 is in fluid communication with the handpiece assembly.

HydraFacial Handpiece

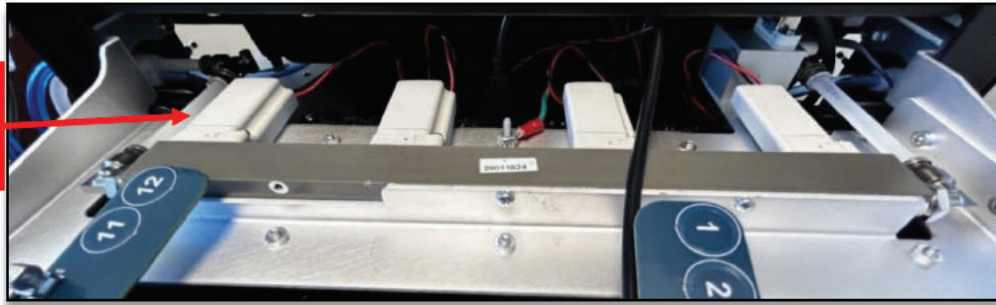
1. Connect the blue twist lock (Return Line) to the blue connector on the bottom of the handpiece and secure by twisting until hand tight. Do not overtighten.
2. Connect the clear twist lock (Supply Line) to the cartridge and secure it by twisting the lock until hand tight. To prevent the lock from breaking, do not overtighten the twist lock.
3. Snap tubing connector onto the Syndeo Device. Press metal tab on the device to allow for connection. This connects both tubes to the Syndeo device.

**Supply Conduit****Exhibit B2 at 12.****Photos of HydraFacial Syndeo**

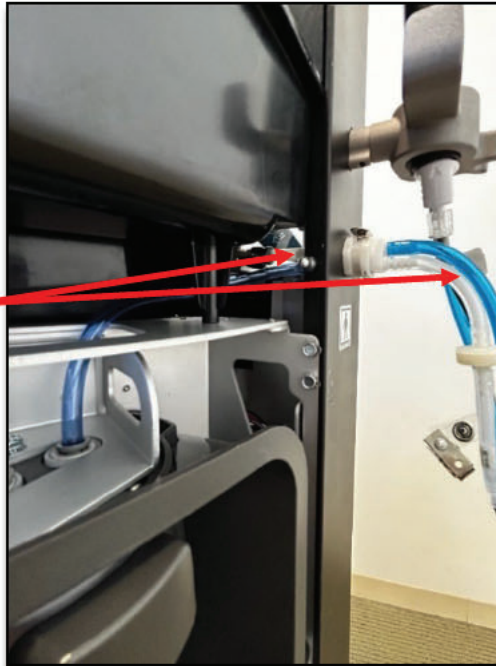
As shown in the photos below, the manifold of the HydraFacial Syndeo is in fluid communication with a handpiece assembly through the supply conduit via a coupling.

CLAIM 1 OF THE '052 PATENT

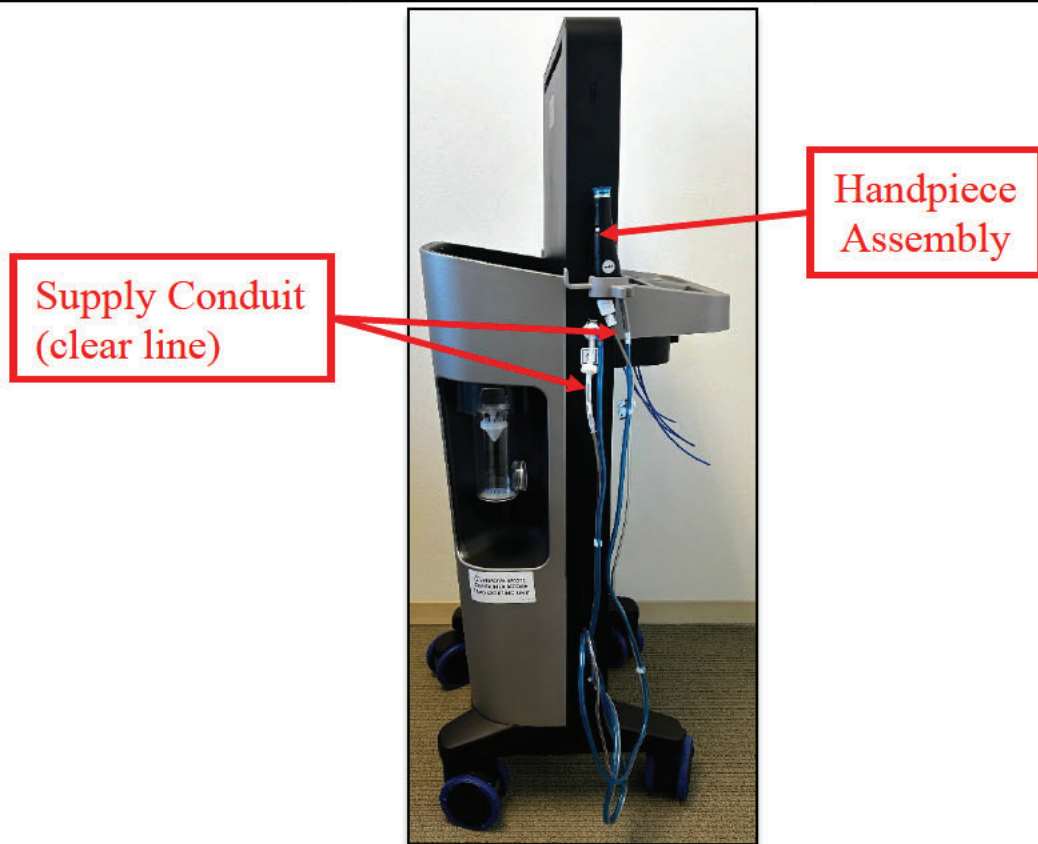
Supply
Conduit



Supply
Conduit

**Exhibit A2.**

The supply conduit extends from the manifold in the console through the tubing for the handpiece assembly via the coupling.

CLAIM 1 OF THE '052 PATENT**Exhibit A2.**

CLAIM 1 OF THE '052 PATENT

The tubing for the handpiece assembly contains the supply conduit. The supply conduit continues from the coupling on the console through tubing to the handpiece assembly. The fluid in the supply conduit runs to and through the handpiece itself to an opening on the handpiece assembly.



Supply Conduit



Opening from
Supply Conduit

Exhibit A2.

[d]: wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and

The manifold of the HydraFacial Syndeo is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

As described above, the supply conduit extends from the handpiece assembly to the manifold, which is in fluid communication with the fluid containers (including the first and second fluid containers). *See* limitation 1[c], *supra*. As explained below, the manifold in fluid communication with the fluid containers is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

HydraFacial Syndeo IFUs

The Syndeo IFU explains that the HydraFacial Syndeo includes “solution bottle controls . . . located on the bottom of the screen within the treatment steps.” **Exhibit B2** at 14. It explains that the system “automatically selects and deselects the recommended solution bottle based on the respective treatment step.”

CLAIM 1 OF THE '052 PATENT

3. The Syndeo system solution bottle controls are located on the bottom of the screen within the treatment steps. The Syndeo system automatically selects and deselects the recommended solution bottle based on the respective treatment step. To override the system selection, simply select and deselect bottles by pressing the buttons on the touchscreen. Long press a button to select multiple bottles at one time.



Id. In this manner, the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

Photos of HydraFacial Syndeo

As shown in the below screenshot from a video of the HydraFacial Syndeo in operation, the Syndeo can control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. This control occurs through the manifold.



See **Exhibit A7** (video at 0:03-0:25) (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). As shown in limitation 1[a][ii], the Syndeo has valves for each fluid line to the containers. During my inspection, I observed that the valves control the flow of treatment fluid through their respective fluid line to the handpiece assembly via the supply conduit.

CLAIM 1 OF THE '052 PATENT

[e]: a vacuum source;

The HydraFacial Syndeo comprises a vacuum source.

HydraFacial Syndeo IFUs

The Syndeo IFU illustrates and describes turning the vacuum on and off and adjusting the vacuum.

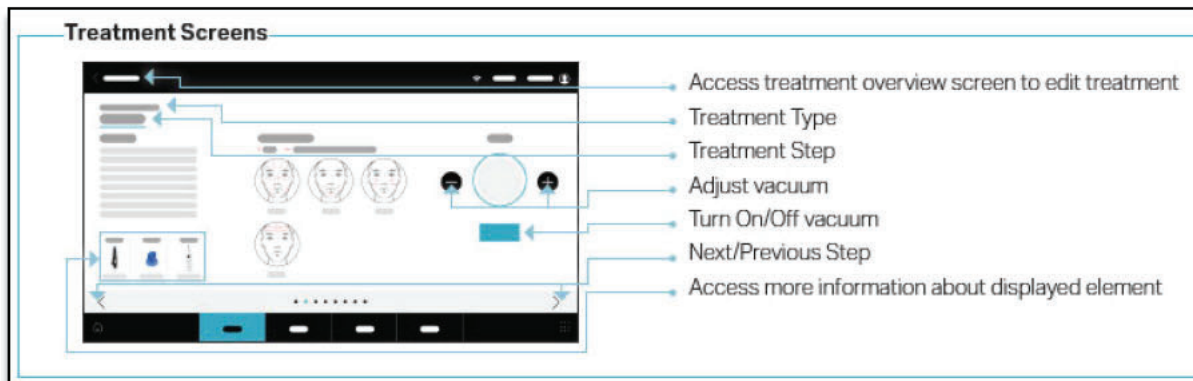
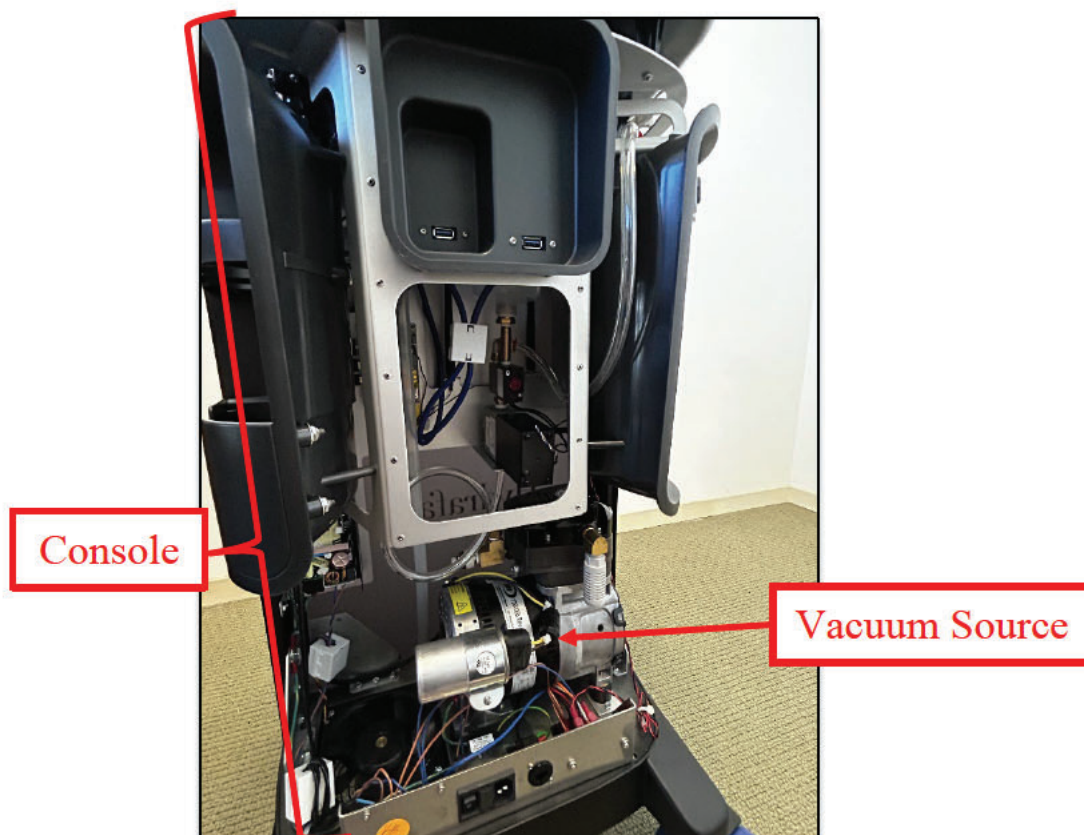


Exhibit B2 at 16.

Photos of HydraFacial Syndeo

The image below shows the vacuum source inside the HydraFacial Syndeo console.



CLAIM 1 OF THE '052 PATENT

Exhibit A2.

The below photo identifies the vacuum source having part number “7200086:”

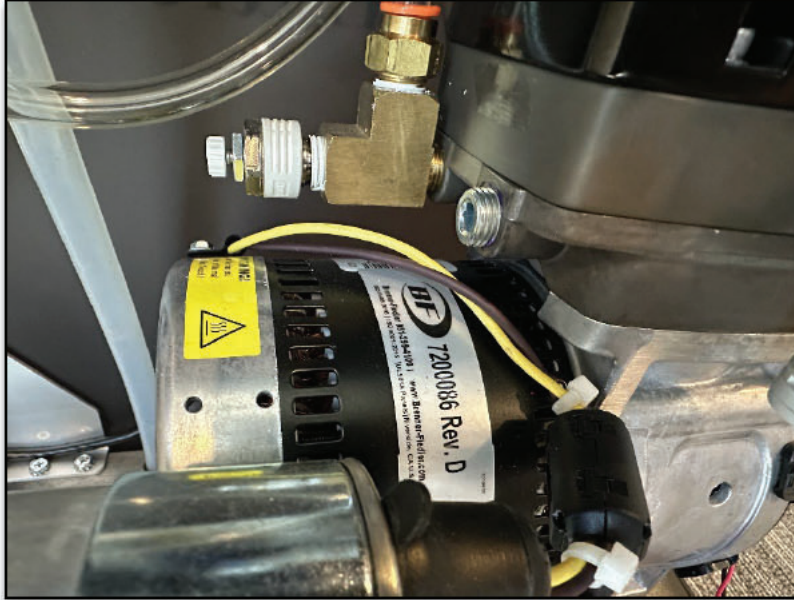


Exhibit A6.

[f]: a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and

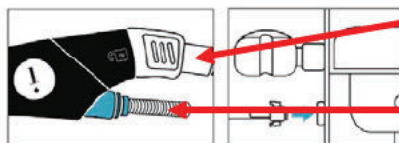
The HydraFacial Syndeo comprises a waste conduit in fluid communication with the tip of the handpiece assembly that removes waste away from a skin surface of a subject during a skin treatment procedure, where the waste conduit is operatively coupled to the vacuum source.

HydraFacial Syndeo IFUs

The Syndeo IFU illustrates and describes a “Return Line” attached to the handpiece assembly, wherein the Return Line which serves as a portion of the waste conduit through which the tip of the handpiece assembly is in fluid communication with the vacuum source (the “supply conduit” described above is also labeled for reference and clarity in the illustrations below).

CLAIM 1 OF THE '052 PATENT**HydraFacial Handpiece**

1. Connect the blue twist lock (Return Line) to the blue connector on the bottom of the handpiece and secure by twisting until hand tight. Do not overtighten.
2. Connect the clear twist lock (Supply Line) to the cartridge and secure it by twisting the lock until hand tight. To prevent the lock from breaking, do not overtighten the twist lock.
3. Snap tubing connector onto the Syndeo Device. Press metal tab on the device to allow for connection. This connects both tubes to the Syndeo device.

**Supply Conduit****Waste Conduit****Exhibit B2 at 12.**

The Handpiece IFU also describes the “Return Line” being connected between the handpiece assembly and a waste container (“waste canister”), which is, in turn, connected to and in fluid communication with the vacuum source in the console:

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.

**Supply Conduit****Waste Conduit**

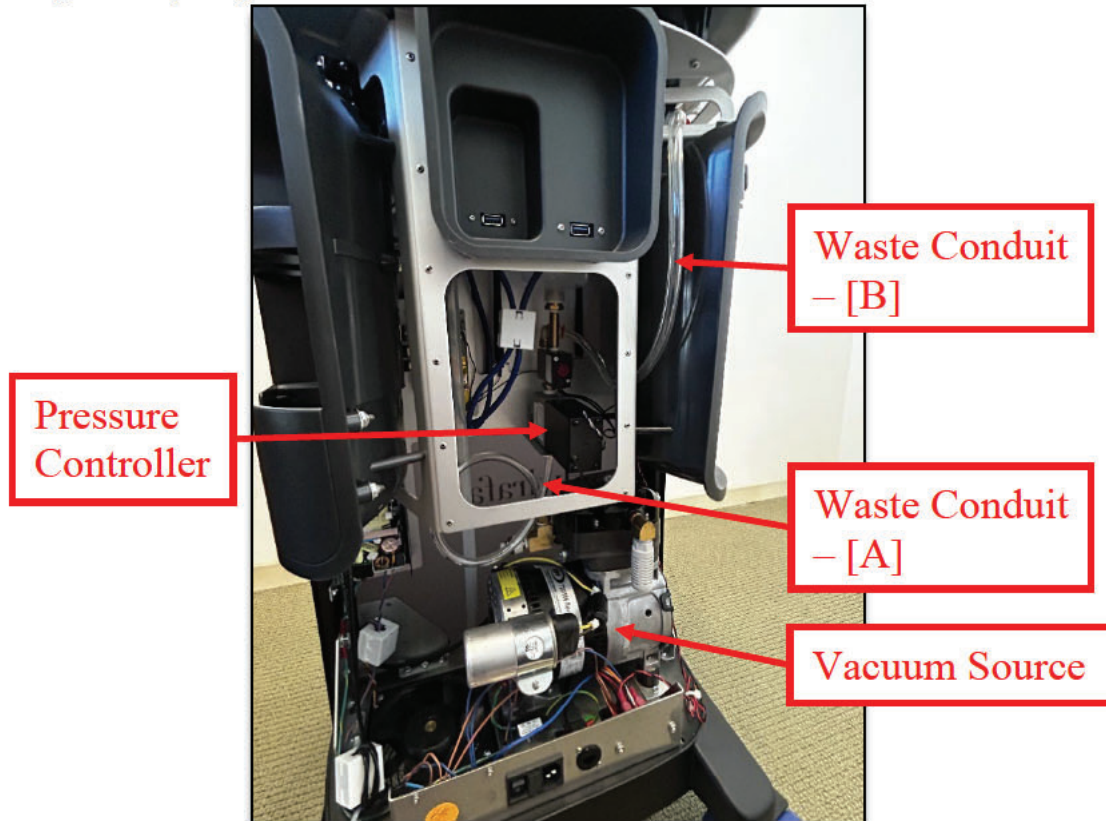
Exhibit B9 at 3; see also Exhibit B2 at 22 (“Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station manifold, and to the waste canister.”).

The handpiece assembly has a “vacuum opening” that is covered by the tip of the handpiece assembly, such that the handpiece assembly vacuums fluids through the tip and into the waste conduit:

**Exhibit B9 at 5.**

Photos of HydraFacial Syndeo

As shown in the photos below, the waste conduit comprises multiple tubing components that extend 1) between the vacuum source and a pressure controller [A]; 2) between the pressure controller and a port for the waste container [B]; 3) between the port of the waste container and the coupling for the handpiece assembly tubing via the waste container and tubing [C], and 4) between the coupling and the handpiece assembly [D]. The connection to the vacuum source operatively couples the waste conduit and the vacuum source.

**Exhibit A2.**

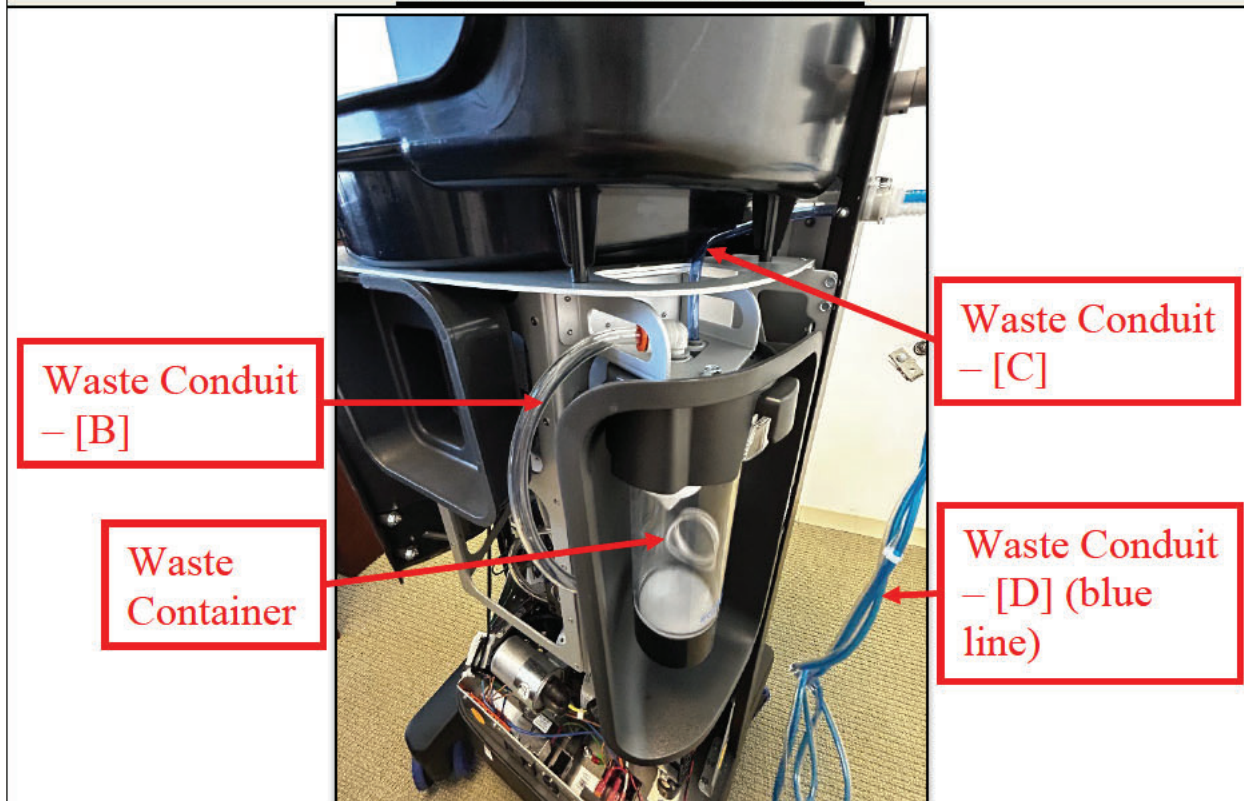
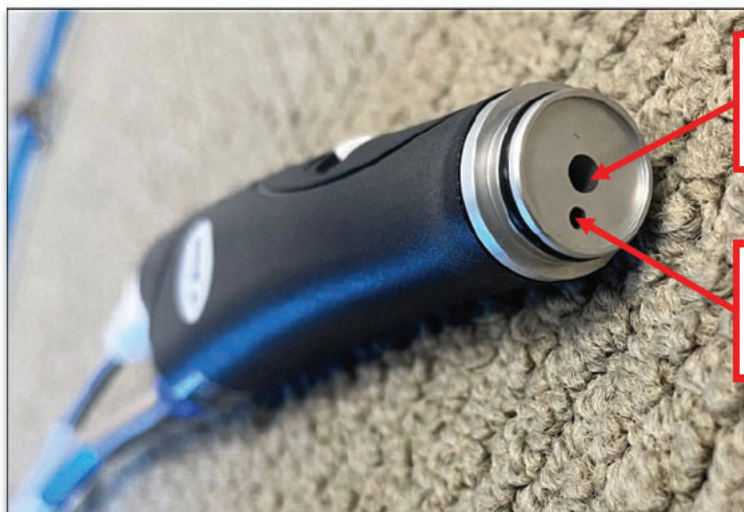
CLAIM 1 OF THE '052 PATENT

Exhibit A2. The tubing for the handpiece assembly contains the waste conduit. The waste conduit continues from the coupling on the console through tubing to the handpiece assembly. The fluid in the supply conduit runs through and away from the handpiece assembly itself via an opening on the handpiece assembly.



CLAIM 1 OF THE '052 PATENT



Opening from
Supply Conduit

Opening from
Waste Conduit

Exhibit A2.

[g]: wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and

The HydraFacial Syndeo is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.

As described above, the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. *See* limitations 1[a][i] and [d], *supra*. As described below, the HydraFacial Syndeo permits a user to select the treatment material to be delivered through the supply conduit to the handpiece assembly.

HydraFacial Syndeo IFUs

As explained by the Syndeo IFU, the user may select which bottle (and thus which skin solution) is used during treatment by selecting the bottles on the console screen:

3. The Syndeo system solution bottle controls are located on the bottom of the screen within the treatment steps. The Syndeo system automatically selects and deselects the recommended solution bottle based on the respective treatment step. To override the system selection, simply select and deselect bottles by pressing the buttons on the touchscreen. Long press a button to select multiple bottles at one time.

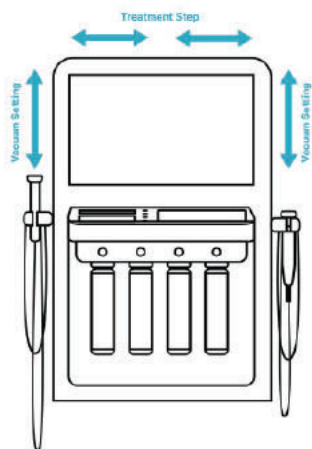


Exhibit B2 at 14.

The Syndeo IFU also allows a user to select the treatment step—and therefore the treatment material from the first fluid container or the at least second fluid container to be delivered—via “Gesture Control Functionality,” as shown in the image below.

CLAIM 1 OF THE '052 PATENT

Gesture Control Functionality



To minimize screen touching, gesture control functionality allows for intuitive and quick in-treatment navigation and vacuum control.

Treatment Step Navigation

- Navigate to the next step in a treatment: Wave your hand from **right to left** above one of the sensors.
- Navigate to the previous step in a treatment: Wave your hand from **left to right** above one of the sensors.

Vacuum Control

- Turn on the vacuum: Wave your hand from **bottom to top** over the sensor on the right or left side of the monitor.
- Subsequent waves from **bottom to top** over the sensor increases the vacuum level one point.
- Subsequent waves from **top to bottom** over the sensor decreases the vacuum level one point.

Id. at 17.

[h]: wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

When the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

As explained above, the HydraFacial Syndeo has (1) a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, (2) a vacuum source operatively coupled to the waste conduit, (3) a handpiece assembly with a tip that is configured to contact a skin surface of a subject during treatment, and (4) a manifold configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit to the handpiece assembly. *See* limitations 1[b], [c], [d], and [f], *supra*. As shown below, it is the same suction force that removes waste from the skin surface via the waste conduit that also draws treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

CLAIM 1 OF THE '052 PATENT**HydraFacial Syndeo IFUs**

The Syndeo IFU explains that the tip coupled to the handpiece assembly is placed against skin during treatment while the vacuum is on to occlude and dab skin solution onto the skin.

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.

Exhibit B2 at 19.

The “Troubleshooting” section of the Syndeo IFU warns that, “[i]f the canister becomes overfull, a builtin float will occlude the vacuum opening and skin solution flow through the handpiece will cease.” *Id.* 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.

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.



Id. at 22.

93. For all of these reasons, the HydraFacial Syndeo practices claim 1 of the '052 Patent.

94. I address how the Elite system practices each limitation of claim 1 of the '052 Patent in the claim chart below.

CLAIM 1 OF THE '052 PATENT

Preamble 1[pre]: A system for performing a skin treatment procedure, the system comprising:

To the extent the preamble is deemed to be a limitation, the HydraFacial Elite is a system for performing a skin treatment procedure.

HydraFacial Elite IFU

The Elite IFU indicates “[t]he System is intended to abrade (exfoliate) the upper layers of the skin”:

Intended Use

The System is intended to abrade (exfoliate) the upper layers of the skin.

Indication (related to the use of the device in the European Economic Area (EEA):

- Mild to moderate acne, i.e. acne vulgaris, comedonal acne (blackheads and whiteheads).
- Superficial acne scarring.

Exhibit B3 at 4. The Elite IFU further describes a step of the treatment: “Place tip against skin to occlude and dab skin solution on face.” *Id.* at 17.

Photos of HydraFacial Elite

The photo below shows the HydraFacial Elite system.



Exhibit A8.

CLAIM 1 OF THE '052 PATENT

[a][i]: a console including a manifold,

The HydraFacial Elite is a system that comprises console including a manifold.

HydraFacial Elite IFUs

The Elite IFU shows the system having a manifold on the console at the location shown below.

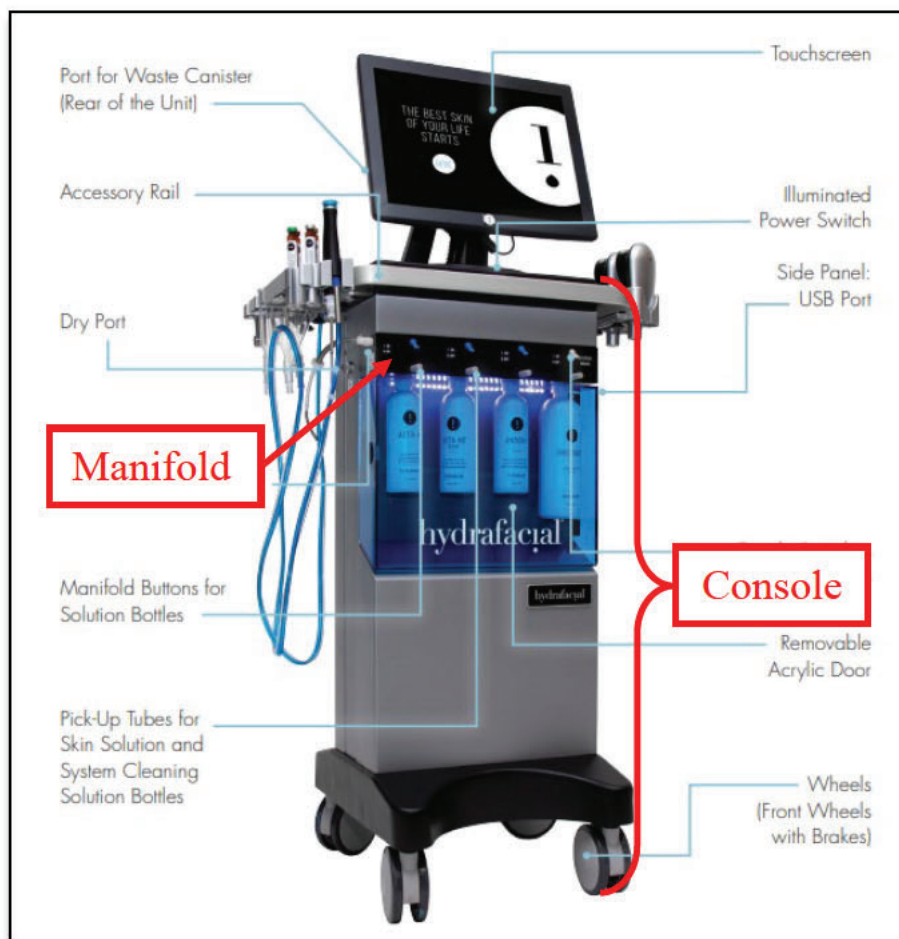
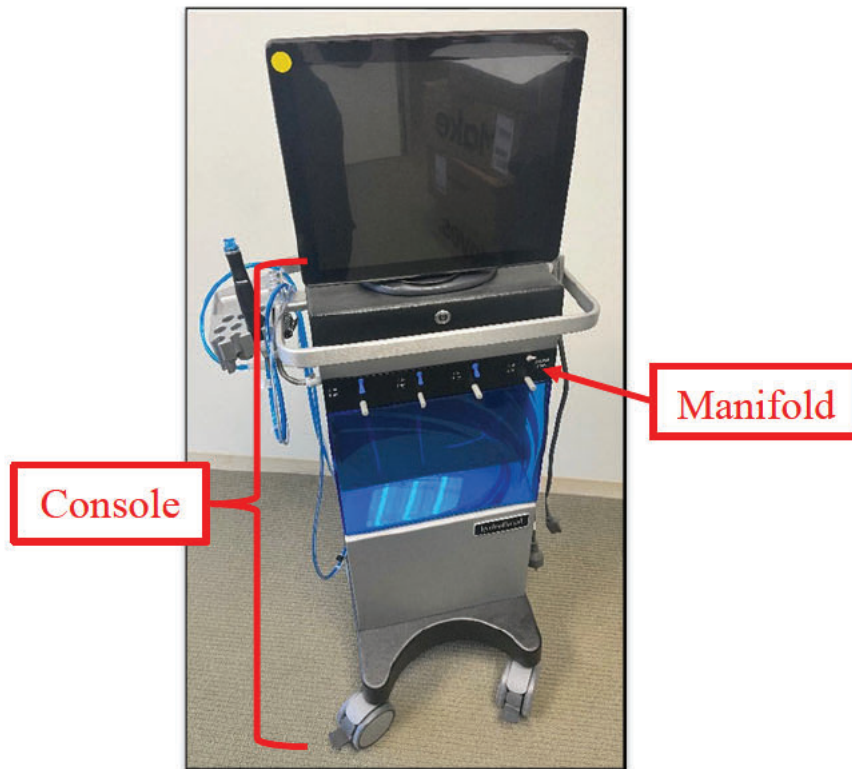


Exhibit B3 at 10.

Photos of HydraFacial Elite

The HydraFacial Elite system includes a manifold in the console:

CLAIM 1 OF THE '052 PATENT**Exhibit A8.**

[a][ii]: the manifold being in fluid communication with a first fluid container and at least a second fluid container,

The manifold of the HydraFacial Elite is in fluid communication with a first fluid container and at least a second fluid container.

HydraFacial Elite IFUs

The Elite IFU depicts the system and console configured to receive a first fluid container and additional fluid containers (including the second fluid container):

CLAIM 1 OF THE '052 PATENT

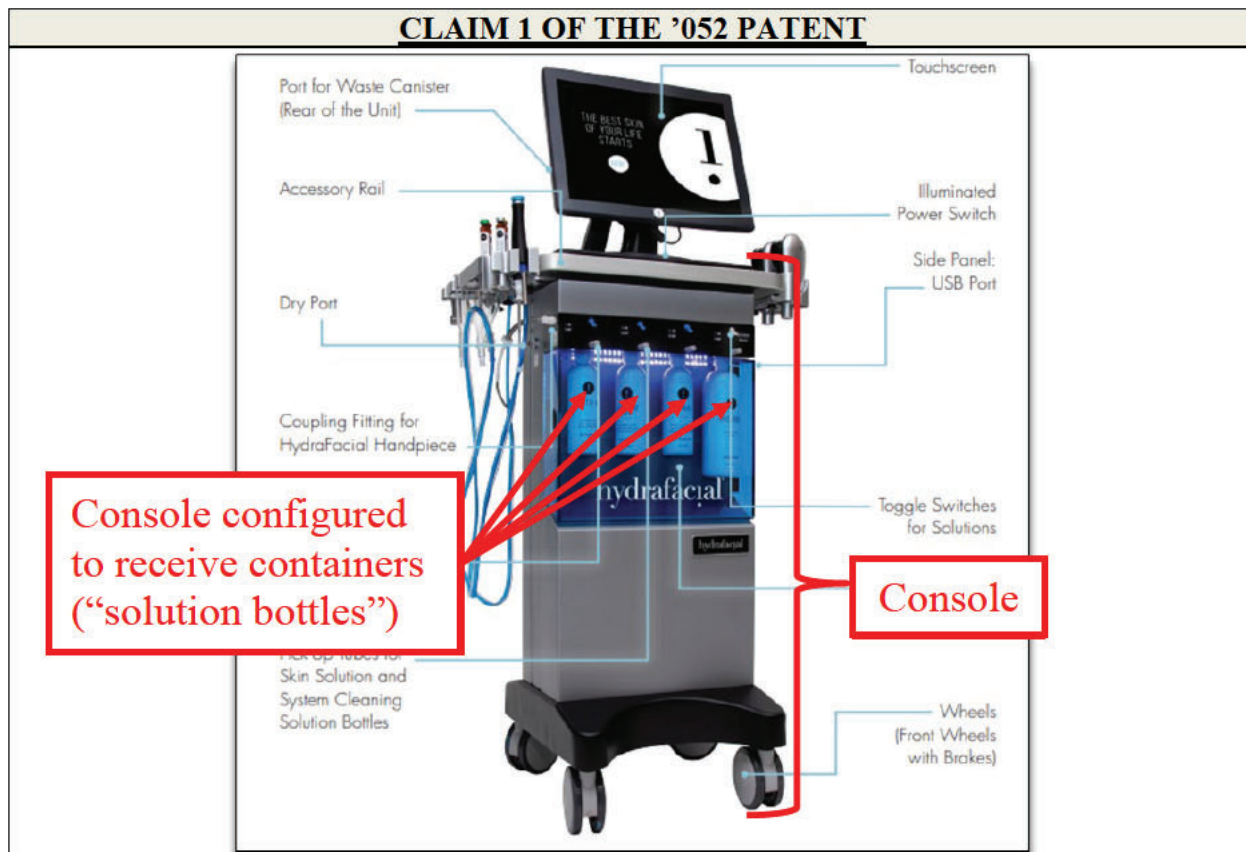


Exhibit B3 at 10.

The Elite IFU also describes connecting the fluid containers (including the first and second fluid containers) to the console such that the manifold is configured to receive fluid from the containers (including the first and second fluid containers):

Skin Solution Bottles (Sold separately)

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 Device Rinse™ System Cleaning Solution should be installed in the manifold with the gray toggle switch labeled "SYSTEM RINSE".



Exhibit B3 at 13.

CLAIM 1 OF THE '052 PATENT

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.



Id. at 14. The toggle switches on the manifold are used to select the fluid drawn from the fluid containers, including the first and second fluid containers, thereby putting the manifold in fluid communication with the first and second fluid containers.

Photos of HydraFacial Elite

Each of the individual components of the manifold is in fluid communication with tubing extending from the manifold. The manifold is configured to receive fluid, through the tubing, from the fluid containers (including the first and second fluid containers) when the containers are connected to the console.

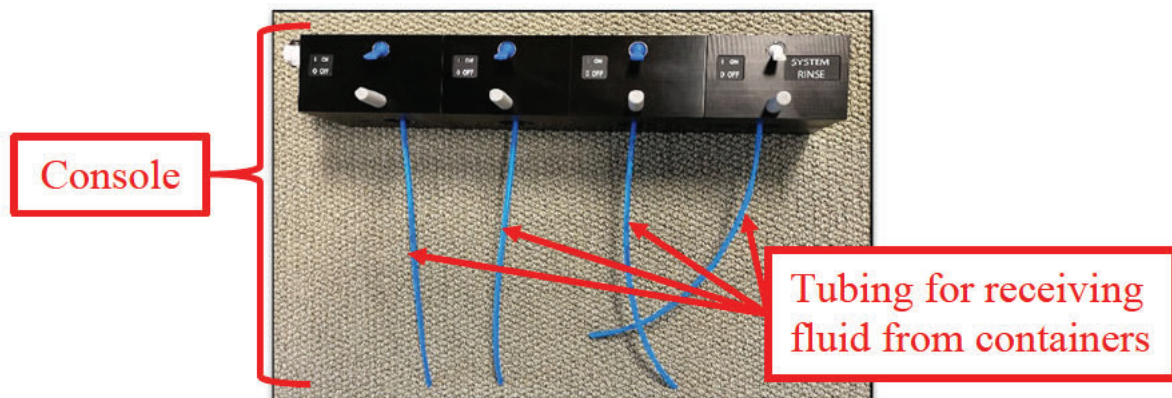


Exhibit A8.

[a][iii]: the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;

The first fluid container and the at least second fluid container of the HydraFacial Elite are configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid. *See* limitations 1[pre], [a], and [a][i], *supra* (describing “solution bottles” where placing the tip against skin “occlude[s] and dab[s] skin solution on face.”).

[b]: a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

The HydraFacial Elite comprises a handpiece assembly comprising a tip, with the tip being configured to contact a skin surface of a subject.

CLAIM 1 OF THE '052 PATENT

HydraFacial Elite IFUs

The Elite IFU includes the figure below depicting the system comprising a handpiece assembly.

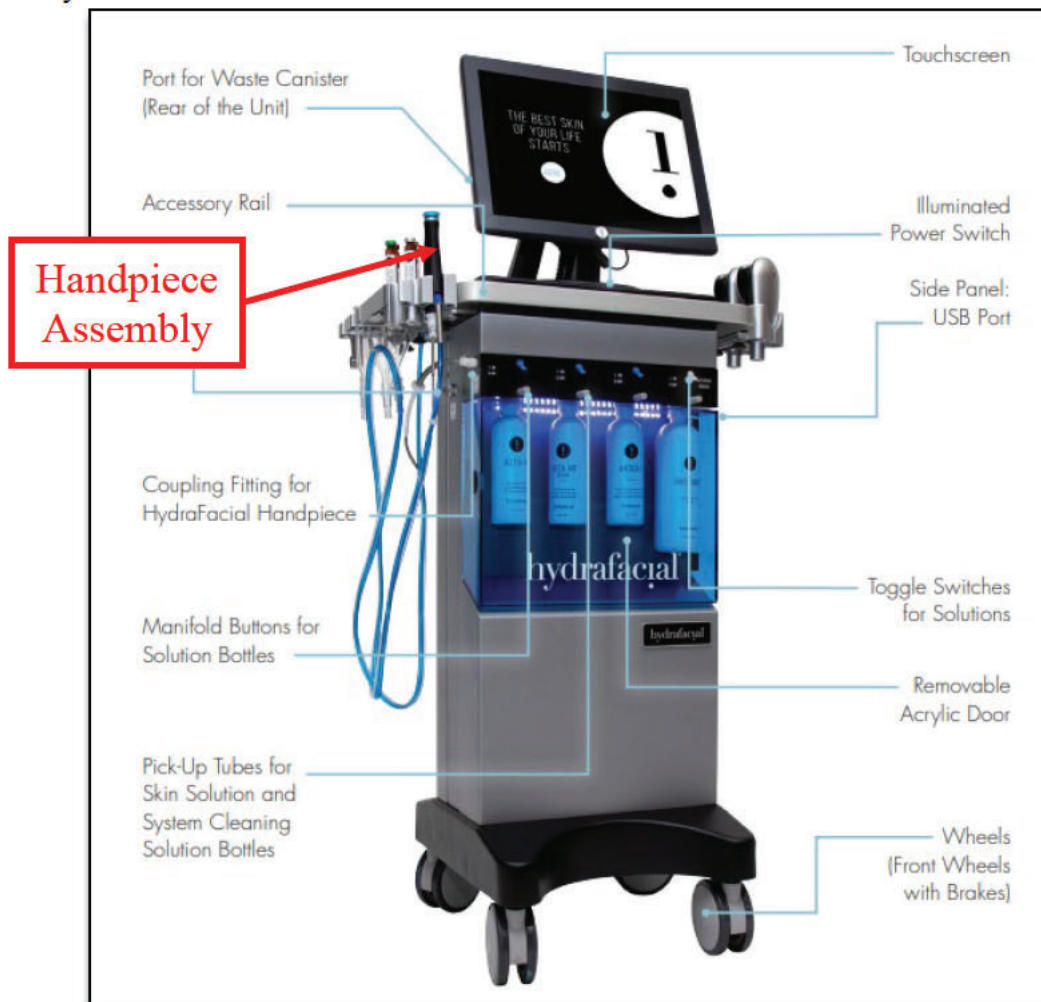
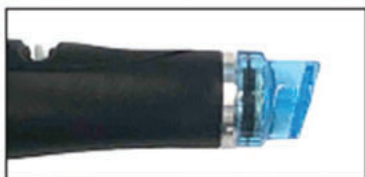


Exhibit B3 at 10.

The Elite IFU explains that the handpiece assembly should be used with a “HydroPeel Tip,” and that they tip should be placed against the skin “to occlude and dab skin solution on face.”

HydroPeel Tip

1. Align the HydroPeel tip and attach it to the handpiece.



CLAIM 1 OF THE '052 PATENT

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.

Exhibit B3 at 13, 17.

Photos of HydraFacial Elite

The photos below show the HydraFacial Elite handpiece assembly with a tip configured to contact a skin surface of a subject.

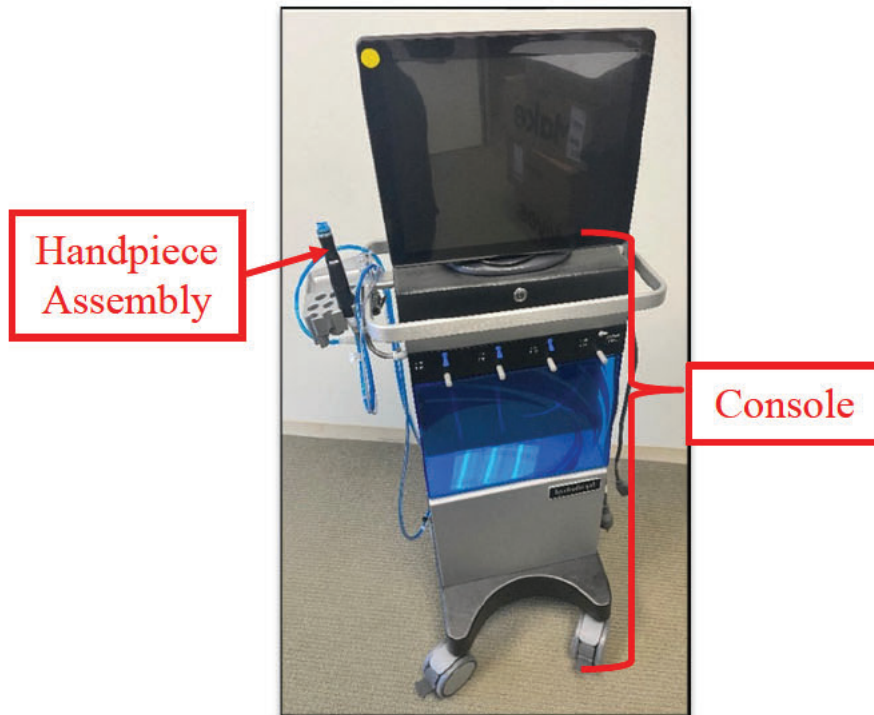


Exhibit A8.



Id.

CLAIM 1 OF THE '052 PATENT

The photo below shows the handpiece assembly contacting the skin tissue of a subject during a treatment procedure.

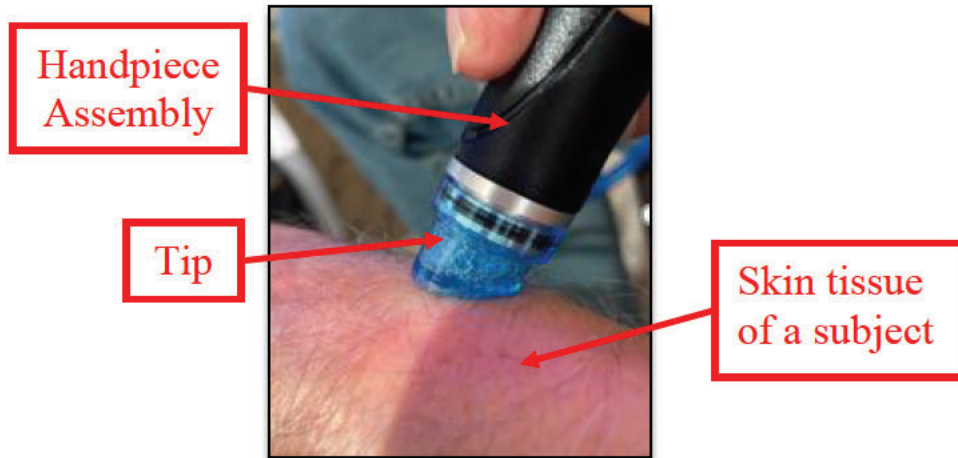


Exhibit A8.

[c]: a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;

The HydraFacial Elite comprises a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein the distal end of the supply conduit is configured to couple to the handpiece assembly.

HydraFacial Elite IFUs

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 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.

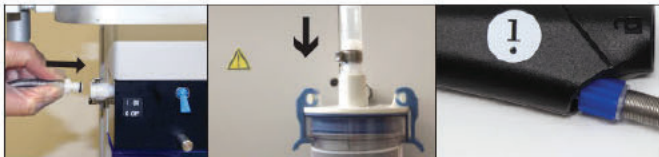
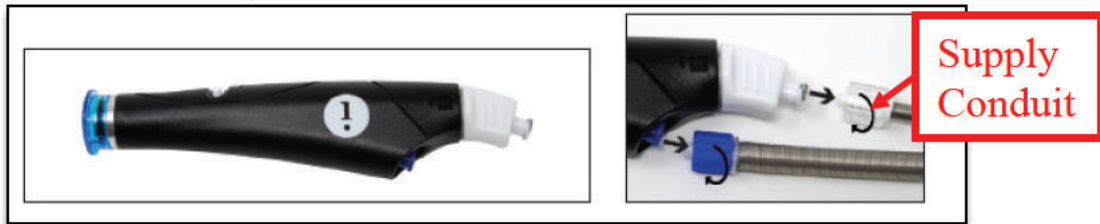


Exhibit B3 at 12.

CLAIM 1 OF THE '052 PATENT

Id. at 18. The Elite IFU further describes that a low or no fluid flow problem may be caused by an improper connection. The solution to this problem is to “[m]ake sure that your HydraFacial® handpiece is properly connected to the side of the skin solution station manifold [i.e., manifold], and to the waste canister. Also, make sure that the lid is firmly attached to the waste container.” *Id.* at 20.

Photos of HydraFacial Elite

As shown in the photos below, the manifold of the HydraFacial Elite is in fluid communication with a handpiece assembly through the supply conduit via a coupling.

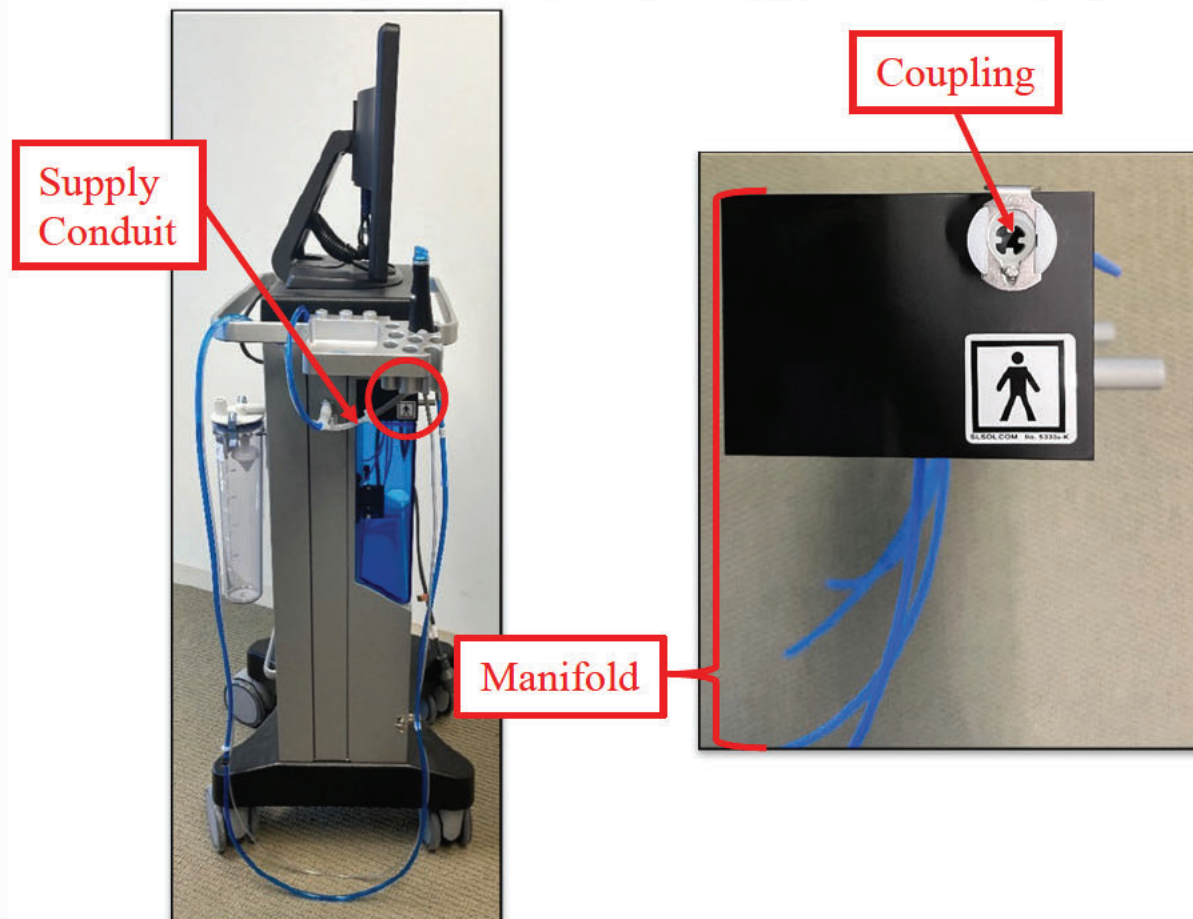
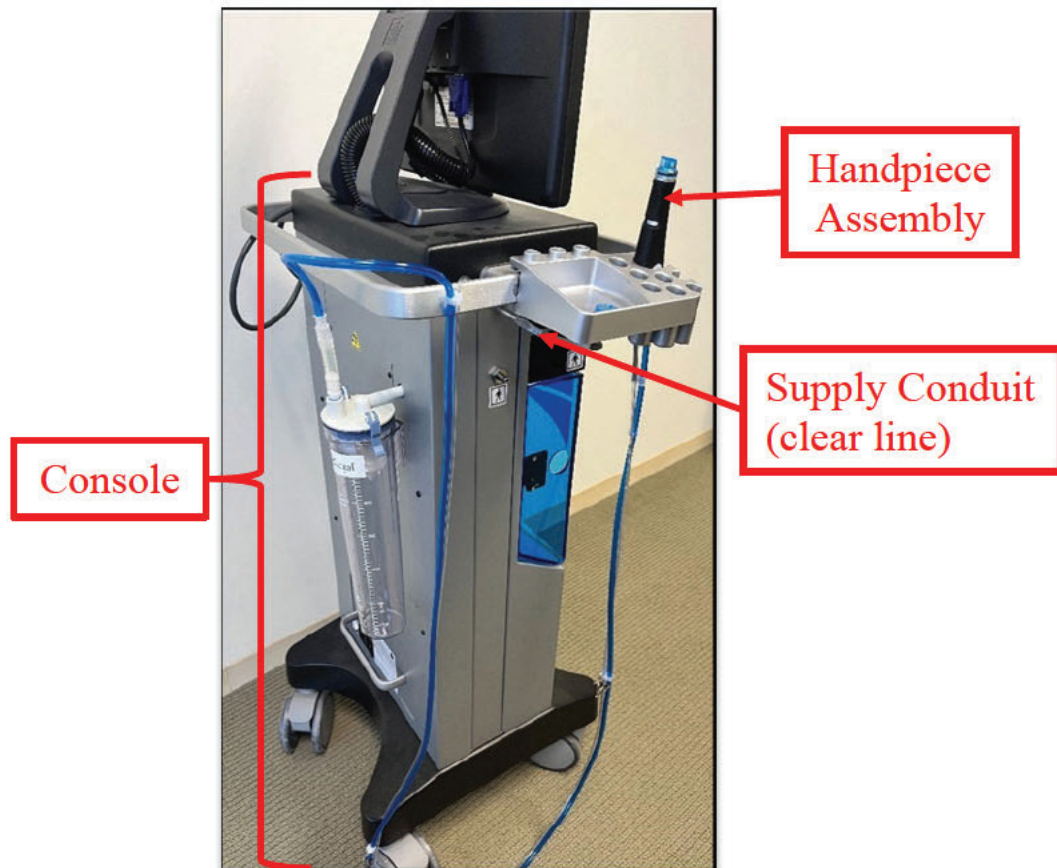


Exhibit A8.

CLAIM 1 OF THE '052 PATENT

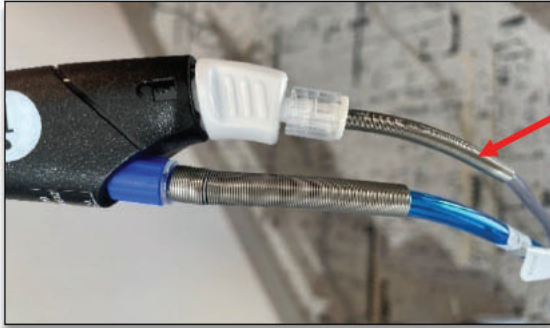
The supply conduit extends from the manifold in the console through the tubing for the handpiece assembly via the coupling.



Id.

CLAIM 1 OF THE '052 PATENT

The tubing for the handpiece assembly contains the supply conduit. The supply conduit continues from the coupling on the console through tubing to the handpiece assembly. The fluid in the supply conduit runs to and through the handpiece itself to an opening on the handpiece assembly.



Supply Conduit



Opening from
Supply Conduit

Exhibit A8.

[d]: wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and

The manifold of the HydraFacial Elite is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

As described above, the supply conduit extends from the handpiece assembly to the manifold, which is in fluid communication with the fluid containers (including the first and second fluid containers). *See* limitation 1[c], *supra*. As explained below, the manifold in fluid communication with the fluid containers is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

HydraFacial Elite IFUs

The Elite IFU shows toggle switches on the manifold system to control the flow of treatment material from the fluid containers:

CLAIM 1 OF THE '052 PATENT

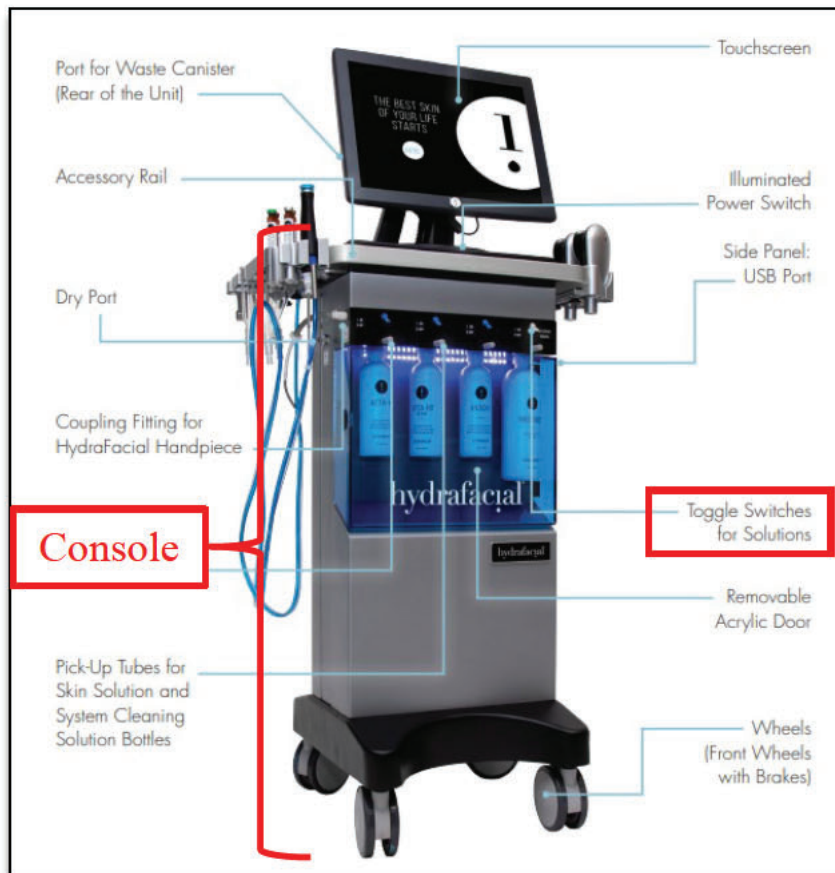


Exhibit B3 at 10. The Elite IFU explains that the “toggle switches [on the console] control which skin solution bottle is being used.” *Id.* at 14. It further states that “[w]hen a switch is in the ON position, fluid will be drawn from that bottle” and “[w]hen switched to the OFF position, no fluid will be drawn from the corresponding bottle.” *Id.* Thus, for example, when the switch for the first fluid container is ON and the switch for the at least the second fluid container is OFF, the manifold controls the flow of treatment material from both the first and second fluid containers by permitting flow from the first fluid container and restricting flow from the at least the second fluid container. Thereafter, when the switch for the first fluid container is OFF and the switch for the at least the second fluid container is ON, the manifold controls the flow of treatment material from both the first and second fluid containers by permitting flow from the at least the second fluid container and restricting flow from the first fluid container. In this manner, through operation of the toggle switches, the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. 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.

CLAIM 1 OF THE '052 PATENT**Photos of the HydraFacial Elite**

As shown in the image below, the manifold of the HydraFacial is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit via switches on the manifold system so that a user can select a fluid container from which to draw treatment material.

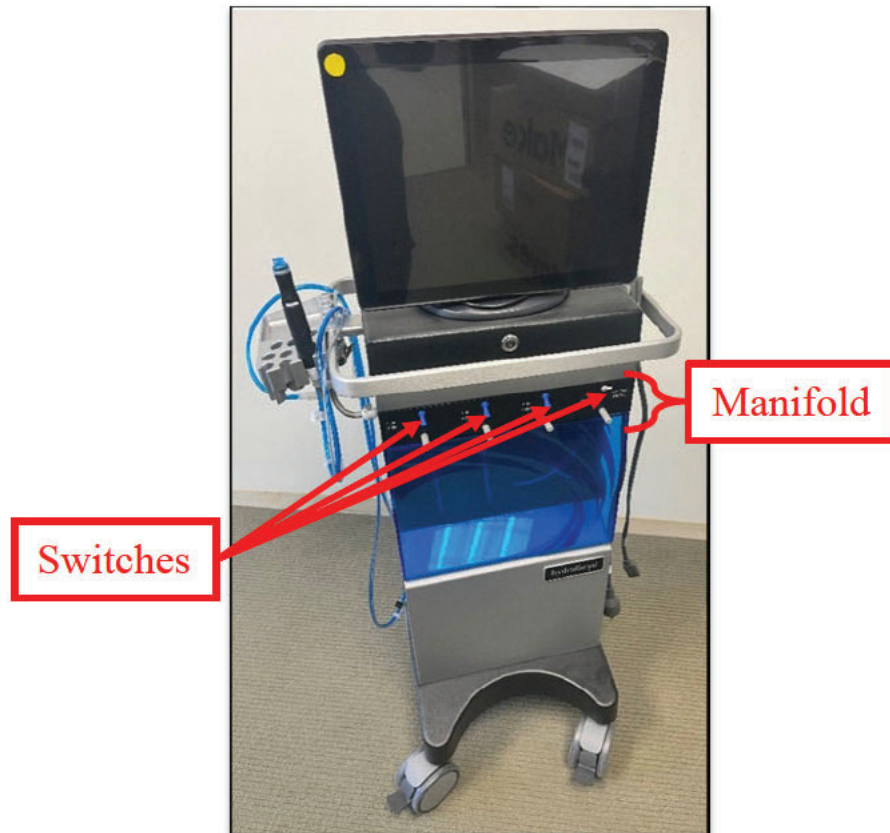


Exhibit A8.

[e]: a vacuum source;

The HydraFacial Elite comprises a vacuum source.

HydraFacial Elite IFUs

The Elite IFU illustrates and describes turning the vacuum on and off and adjusting the vacuum.

CLAIM 1 OF THE '052 PATENT

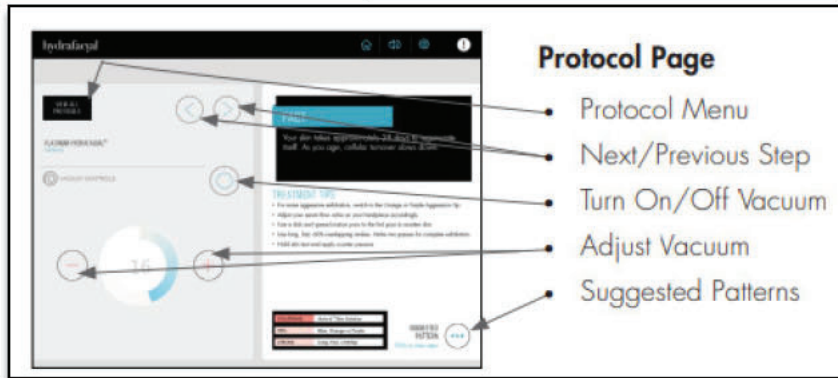


Exhibit B3 at 16.

Photos of HydraFacial Elite

The image below shows the vacuum source inside the HydraFacial Elite console.

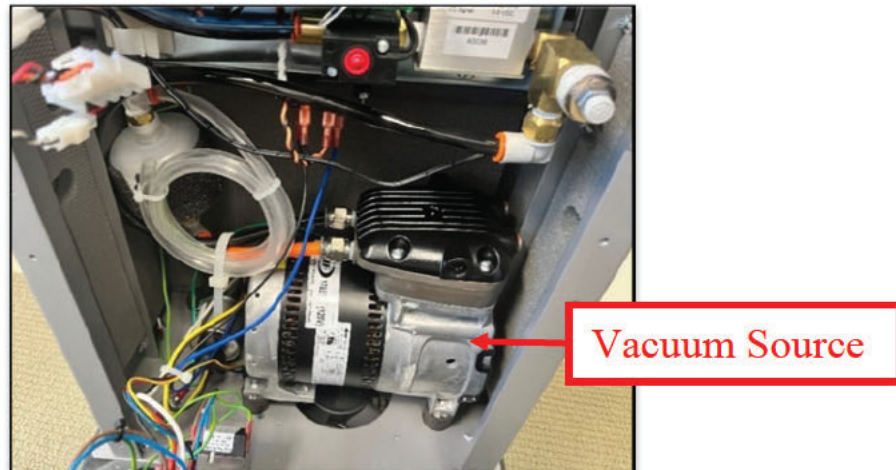


Exhibit A8.

[f]: a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and

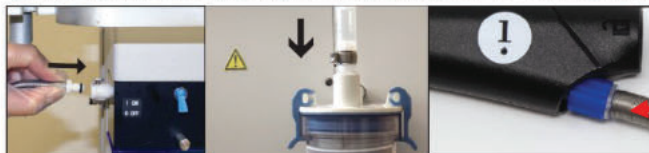
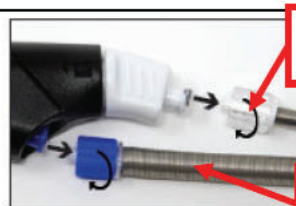
The HydraFacial Elite comprises a waste conduit in fluid communication with the tip of the handpiece assembly that removes waste away from a skin surface of a subject during a skin treatment procedure, where the waste conduit is operatively coupled to the vacuum source.

HydraFacial Elite IFUs

The Elite IFU illustrates and describes a “Return Line” attached to the handpiece assembly, wherein the Return Line which serves as a portion of the waste conduit through which the tip of the handpiece assembly is in fluid communication with the vacuum source (the “supply conduit” described above is also labeled for reference and clarity in the illustrations below).

CLAIM 1 OF THE '052 PATENT**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.

**Waste Conduit****Exhibit B3 at 12.****Supply Conduit****Waste Conduit****Exhibit B3 at 18.**

The Handpiece IFU also describes the “Return Line” being connected between the handpiece assembly and a waste container (“waste canister”), which is, in turn, connected to and in fluid communication with the vacuum source in the console:

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.

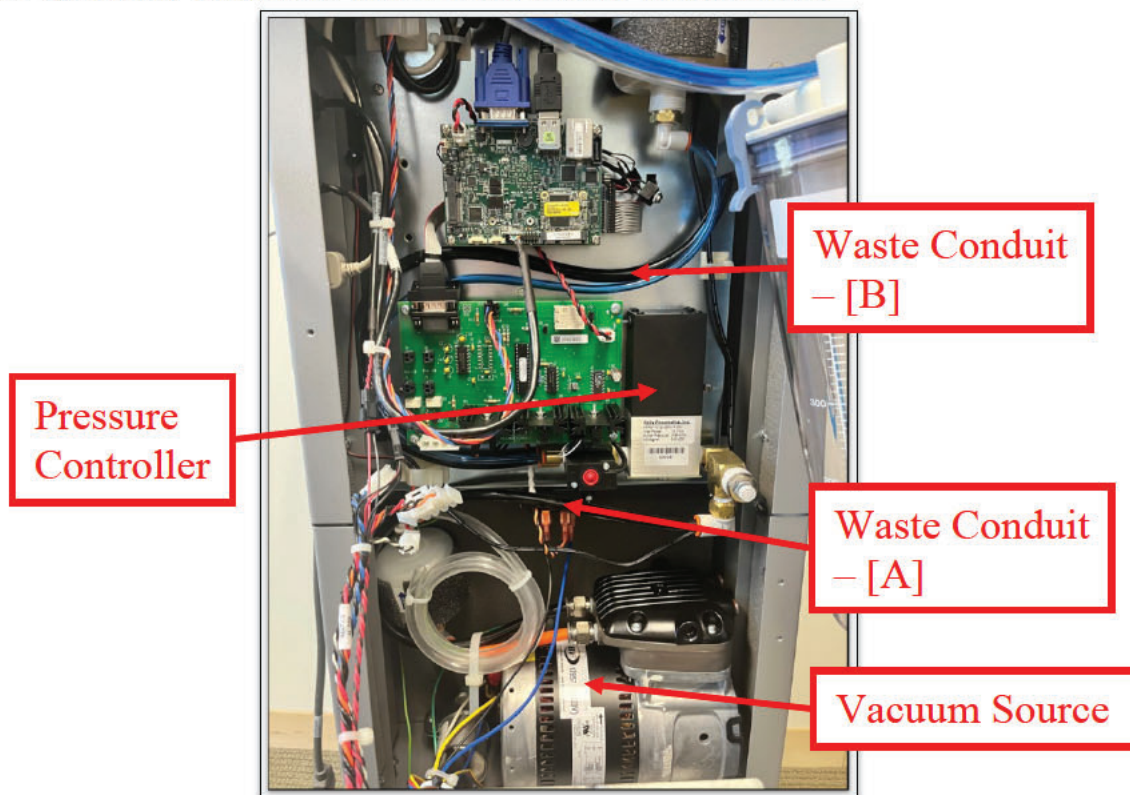
**Supply Conduit****Waste Conduit**

Exhibit B9 at 3; see also Exhibit B3 at 17 (“Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station manifold, and to the waste cannister.”).

The handpiece assembly has a “vacuum opening” that is covered by the tip of the handpiece assembly, such that the handpiece assembly vacuums fluids through the tip and into the waste conduit:

CLAIM 1 OF THE '052 PATENT**Exhibit B9 at 5.****Photos of HydraFacial Elite**

As shown in the photos below, the waste conduit comprises multiple black tubing components that extend 1) between the vacuum source and a pressure controller [A]; 2) between the pressure controller and a port for the waste container [B]; 3) between the port for the waste container and the tubing of the handpiece assembly via a waste container and tubing [C]; and 4) between the coupling and the handpiece assembly [D]. The connection to the vacuum source operatively couples the waste conduit and the vacuum source.

**Exhibit A8.**

The blue tubing for the handpiece assembly contains the waste conduit. The waste conduit continues from the port for the waste container on the console through the tubing to the handpiece assembly.

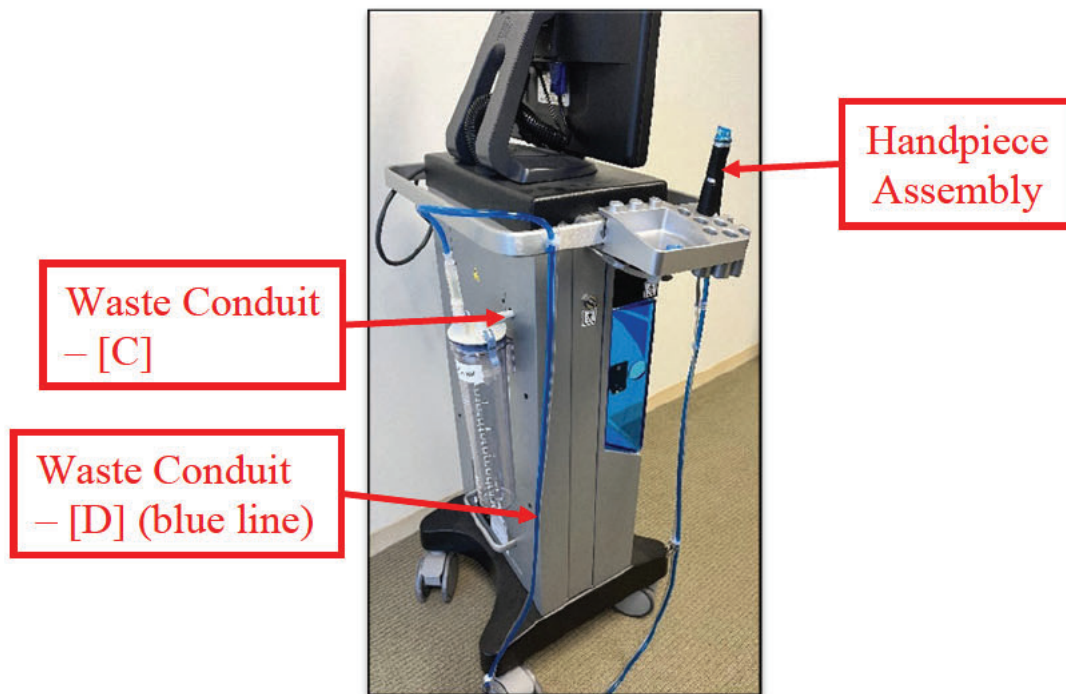
CLAIM 1 OF THE '052 PATENT

Exhibit A8. The fluid in the waste conduit runs through and away from the handpiece assembly itself via an opening on the handpiece assembly.



Exhibit A8.

CLAIM 1 OF THE '052 PATENT

[g]: wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and

The HydraFacial Elite is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.

As described above, the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. *See* limitations 1[a][i] and [d], *supra*. As described below, the HydraFacial Elite permits a user to select the treatment material to be delivered through the supply conduit to the handpiece assembly.

HydraFacial Elite IFUs

The Elite IFU explains that a user may select which bottle (and thus which skin solution) used during treatment by using the toggles on the manifold for each bottle.

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.

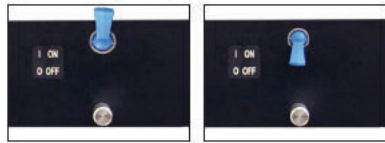


Exhibit B3 at 14. It further states that "[w]hen a switch is in the ON position, fluid will be drawn from that bottle" and "[w]hen switched to the OFF position, no fluid will be drawn from the corresponding bottle." *Id.* Since the user controls these switches, the HydraFacial Elite permits a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.

[h]: wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

When the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

As explained above, the HydraFacial Elite has (1) a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, (2) a vacuum source operatively coupled to the waste conduit, (3) a handpiece assembly with a tip that is configured to contact a skin surface of a subject during treatment, and (4) a manifold configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit

CLAIM 1 OF THE '052 PATENT

to the handpiece assembly. *See* limitations 1[b], [c], [d], and [f], *supra*. As shown below, it is the same suction force that removes waste from the skin surface via the waste conduit that also draws treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

HydraFacial Elite IFUs

The Elite IFU explains that the tip coupled to the handpiece assembly is placed against skin during treatment while the vacuum is on to occlude and dab skin solution onto the skin.

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.

Exhibit B3 at 16.

The “Troubleshooting” section of the 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.” *Id.* at 20. 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 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.



Id. at 20.

CLAIM 1 OF THE '052 PATENT

Photos of HydraFacial Elite

The screen capture below from a video of the Elite in use shows the handpiece assembly of the HydraFacial Elite contacting the skin tissue of a subject, thus drawing treatment material to the handpiece assembly while simultaneously removing waste from the skin surface.

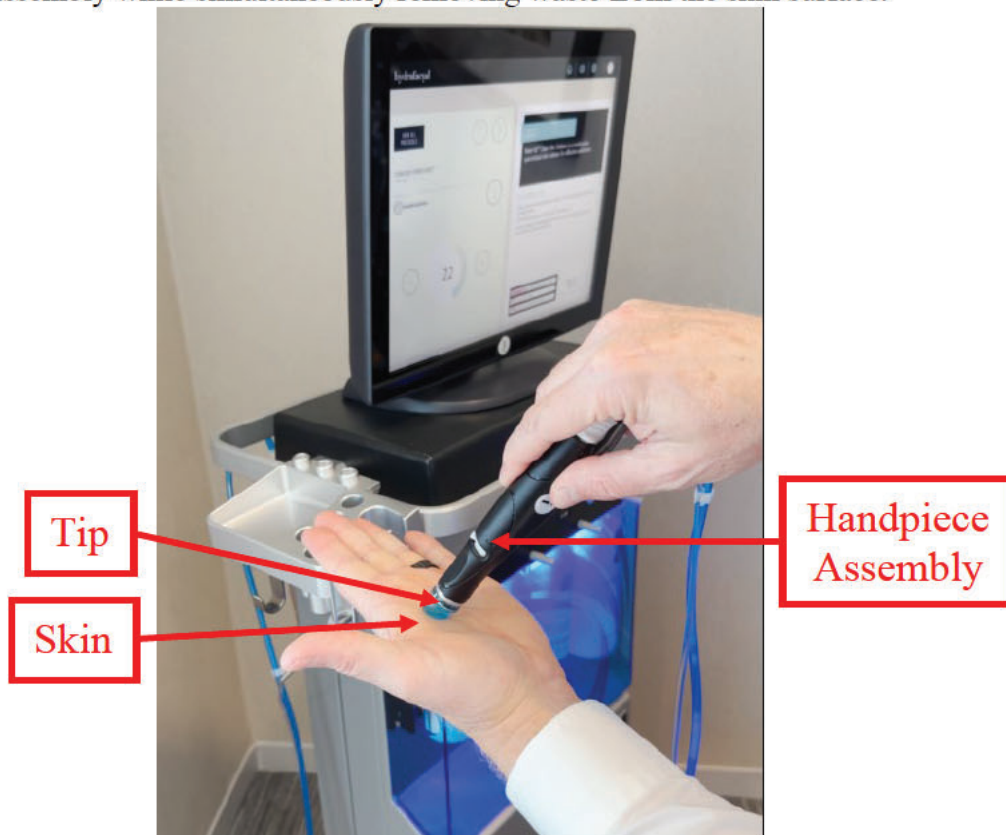


Exhibit A9 (see also video at 0:33–0:40).

95. For all of these reasons, the HydraFacial Elite practices claim 1 of the '052 Patent.

96. I address how the Allegro system practices each limitation of claim 1 of the '052 Patent in the claim chart below.

CLAIM 1 OF THE '052 PATENT

Preamble 1[pre]: A system for performing a skin treatment procedure, the system comprising:

To the extent that the preamble is deemed to be a limitation, the HydraFacial Allegro is a system for performing a skin treatment procedure.

CLAIM 1 OF THE '052 PATENT

HydraFacial Allegro IFUs

For example, the Allegro IFU indicates that the system 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 wrinkles.”

HydraFacial® mode:

The HydraFacial® Allegro™ system is a USA Food and Drug Administration (FDA) listed Class I exempt medical device; Class II medical device in Canada. Its intended use is 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 wrinkles. An additional feature is the capability of introducing topical skin solutions during the procedure.

Exhibit B4 at 4.

Photos of the HydraFacial Allegro

The photo below shows the HydraFacial Allegro system.

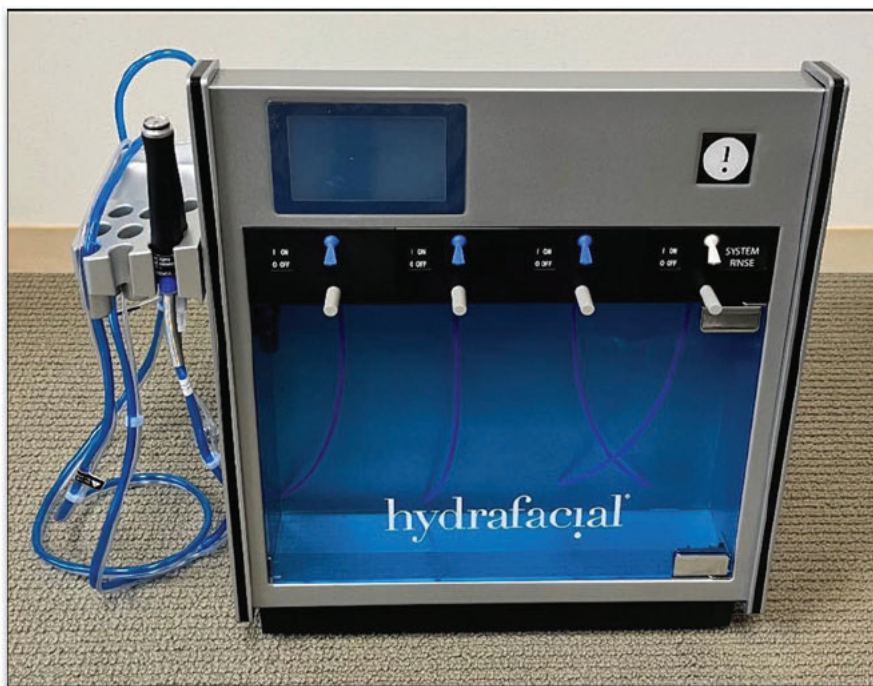


Exhibit A10.

CLAIM 1 OF THE '052 PATENT

[a][i]: a console including a manifold,

The HydraFacial Allegro is a system that comprises console including a manifold.

HydraFacial Allegro IFUs

The Allegro IFU shows the system having a manifold in the console at the location shown below.



Exhibit B4 at 8.

Photos of HydraFacial Allegro

The HydraFacial Allegro system includes a manifold in the console:



Exhibit A10.

CLAIM 1 OF THE '052 PATENT

[a][ii]: the manifold being in fluid communication with a first fluid container and at least a second fluid container,

The manifold of the HydraFacial Allegro is in fluid communication with a first fluid container and at least a second fluid container.

HydraFacial Allegro IFUs

The Allegro IFU depicts the system and console configured to receive a first fluid container and additional containers (including the second container) via the manifold:



Exhibit B4 at 8.

The Allegro IFU also describes connecting the fluid containers (including the first and second fluid containers) to the console such that the manifold is in fluid communication with the fluid containers (including the first and second fluid containers):

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.

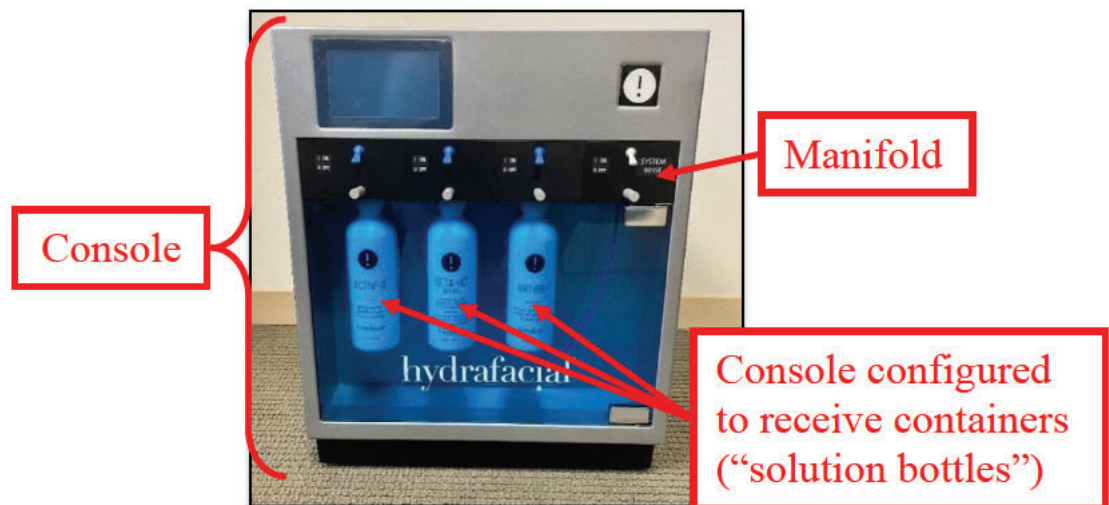
Note: Always keep the "SYSTEM RINSE" toggle switch (gray) off while performing procedures.



Id. at 11. The toggle switches on the manifold are used to draw fluid from the fluid containers, including the first and second fluid containers, thereby putting the manifold in fluid communication with the first and second fluid containers.

Photos of HydraFacial Allegro

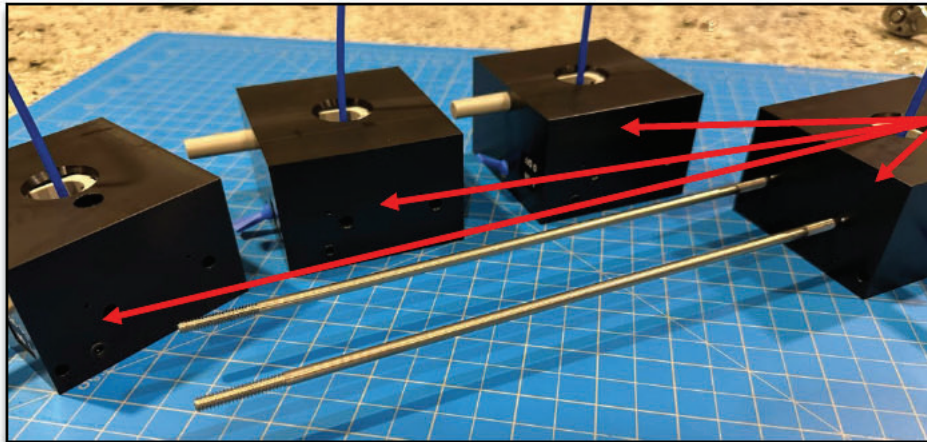
The HydraFacial Allegro system includes a manifold in the console, with the manifold receiving a first container and at least a second container:



CLAIM 1 OF THE '052 PATENT

Exhibit A10.

The manifold comprises individual components that are connected together through two bolts running through the manifold.



Manifold
Components

Exhibit A11.

Each of the individual components of the manifold is in fluid communication with tubing extending from the manifold. The manifold is configured to receive fluid, through the tubing, from the fluid containers (including the first and second fluid containers) when the containers are connected to the console.

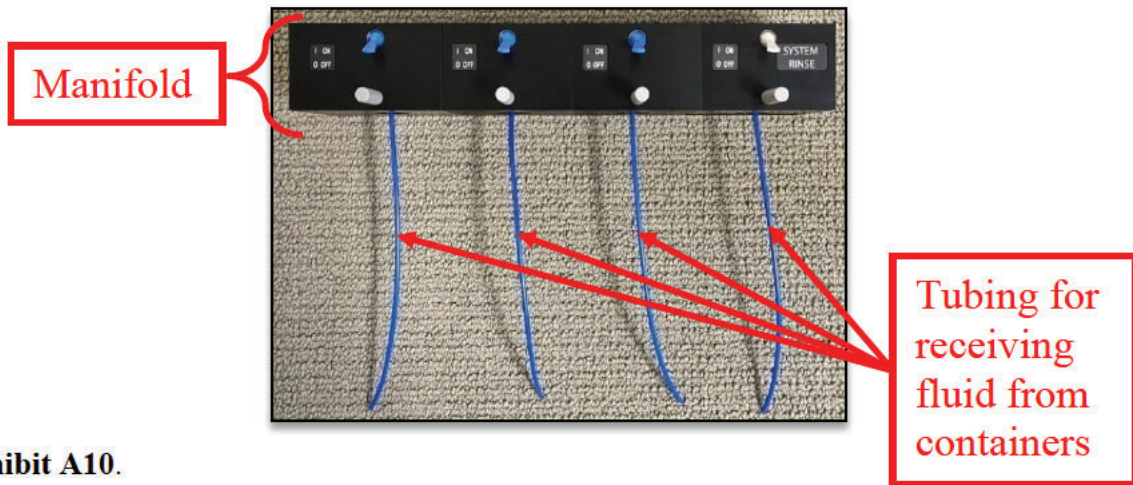


Exhibit A10.

[a][iii]: the first fluid container and the at least the second fluid container being configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid;

The first fluid container and the at least second fluid container of the HydraFacial Allegro are configured to contain a treatment material for a skin treatment procedure, wherein the treatment material comprises a liquid. *See* limitations 1[pre], [a], and [a][i], *supra* (describing “solution bottles” and “introducing topical skin solutions during the procedure.”).

CLAIM 1 OF THE '052 PATENT

[b]: a handpiece assembly comprising a tip, the tip being configured to contact a skin surface of a subject;

The HydraFacial Allegro comprises a handpiece assembly comprising a tip, with the tip being configured to contact a skin surface of a subject.

HydraFacial Allegro IFUs

The Allegro IFU includes the figure below depicting the system comprising a handpiece assembly.



Exhibit B4 at 7.

The Allegro IFU further describes attaching a “HydroPeel® tip” to the handpiece.



Id. at 10. The Allegro IFU further states that “If the [waste] container becomes overfull, a built-in float will occlude the vacuum opening and skin solution flow through the handpiece will cease.” *Id.* at 17. Thus, the handpiece assembly has a tip configured to contact a skin surface of a subject.

The Handpiece IFU explains that the handpiece assembly is “[d]esigned for use with patented HydroPeel™ tips,” and that the handpiece assembly contacts the skin surface of a subject during a treatment procedure:

CLAIM 1 OF THE '052 PATENT

Hand Positioning

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



Exhibit B9 at 3–4.

Photos of HydraFacial Allegro

The photos below show the HydraFacial Allegro handpiece assembly with a tip configured to contact a skin surface of a subject.

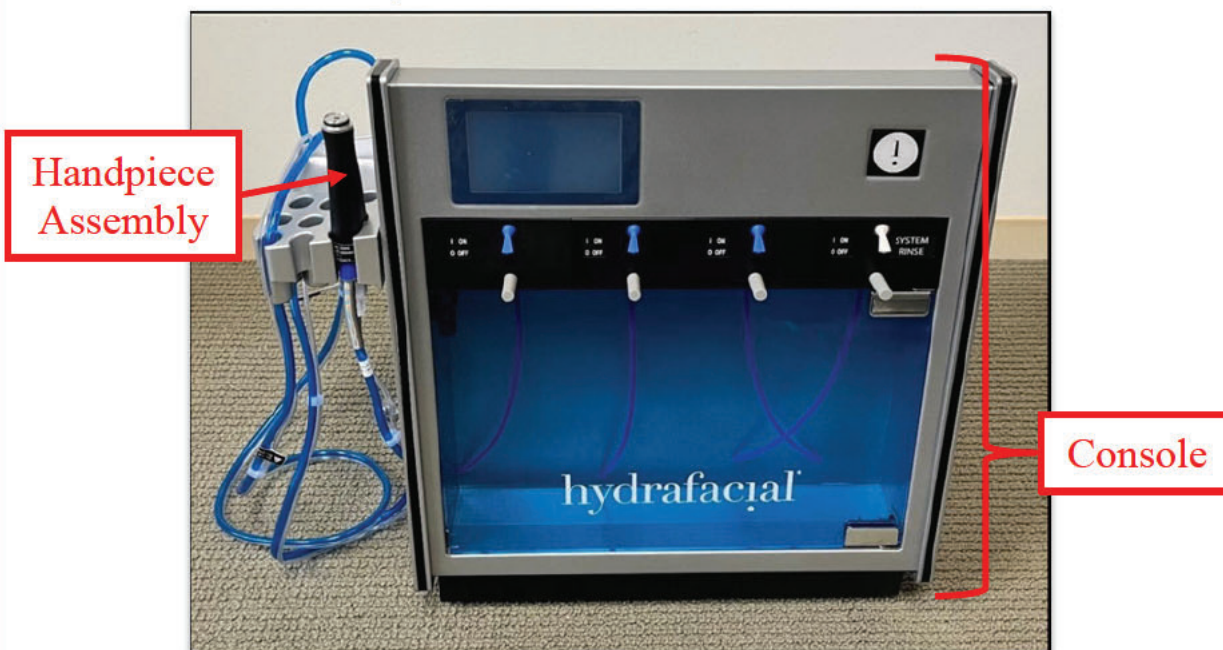


Exhibit A10.

A screenshot of a video of the HydraFacial Allegro in use shows the handpiece contacting the skin tissue of a subject.

CLAIM 1 OF THE '052 PATENT**Handpiece
Assembly****Skin Tissue**

Exhibit A12 (video at 0:07).

[c]: a supply conduit placing the manifold of the console in fluid communication with the handpiece assembly, wherein a distal end of the supply conduit is configured to couple to the handpiece assembly;

The HydraFacial Allegro has a supply conduit that places the manifold in fluid communication with the handpiece assembly when the handpiece assembly is connected to the console. Further, the distal end of the supply conduit is configured to couple to the handpiece assembly.

HydraFacial Allegro IFUs

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 is in fluid communication with the handpiece assembly.

CLAIM 1 OF THE '052 PATENT**HydraFacial® Handpiece**

1. Plug the small tube attached to the HydraFacial® handpiece into coupling fitting.
2. Connect the large tube attached to the handpiece into the waste container.
3. Locate the small tubing with the blue end and connect it to the appropriate end on the handpiece. The blue end corresponds with the blue dot. Twist the knob gently clockwise to secure the tubing.

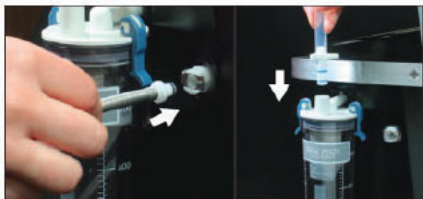
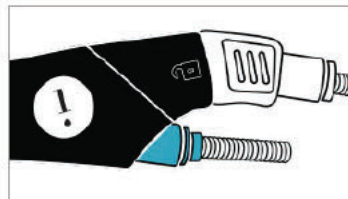
**Supply
Conduit**

Exhibit B4 at 9. The Allegro IFU further describes that a low or no fluid flow problem may be caused by an improper connection. The solution to this problem is to “[m]ake sure that your HydraFacial® handpiece is properly connected to the side of the skin solution station block [i.e., manifold], and to the waste container. Also, make sure that the lid is firmly attached to the waste container.” *Id.* at 17.

Photos of HydraFacial Allegro

As shown in the photos below, the manifold of the HydraFacial Allegro is in fluid communication with a handpiece assembly through a supply conduit via a coupling.

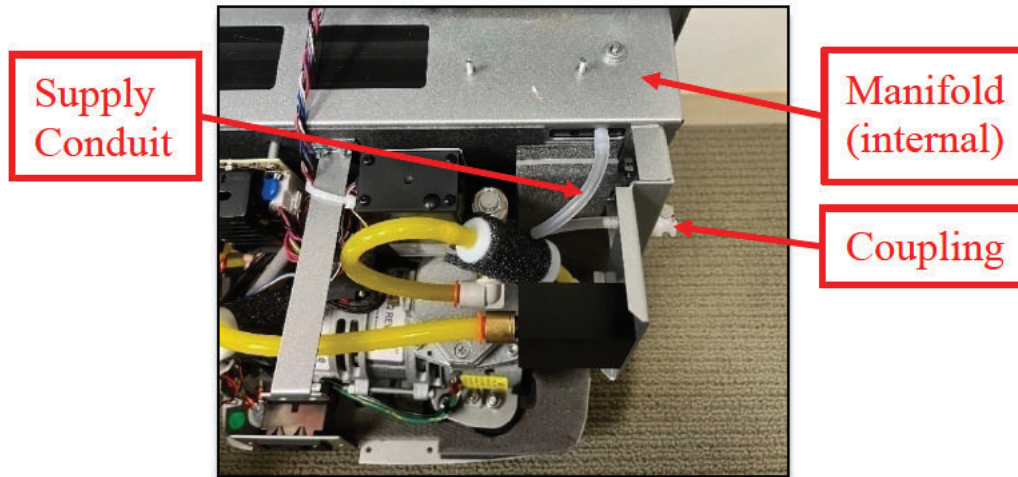


Exhibit A10.

The supply conduit extends from the manifold in the console through the tubing for the handpiece assembly via the coupling.

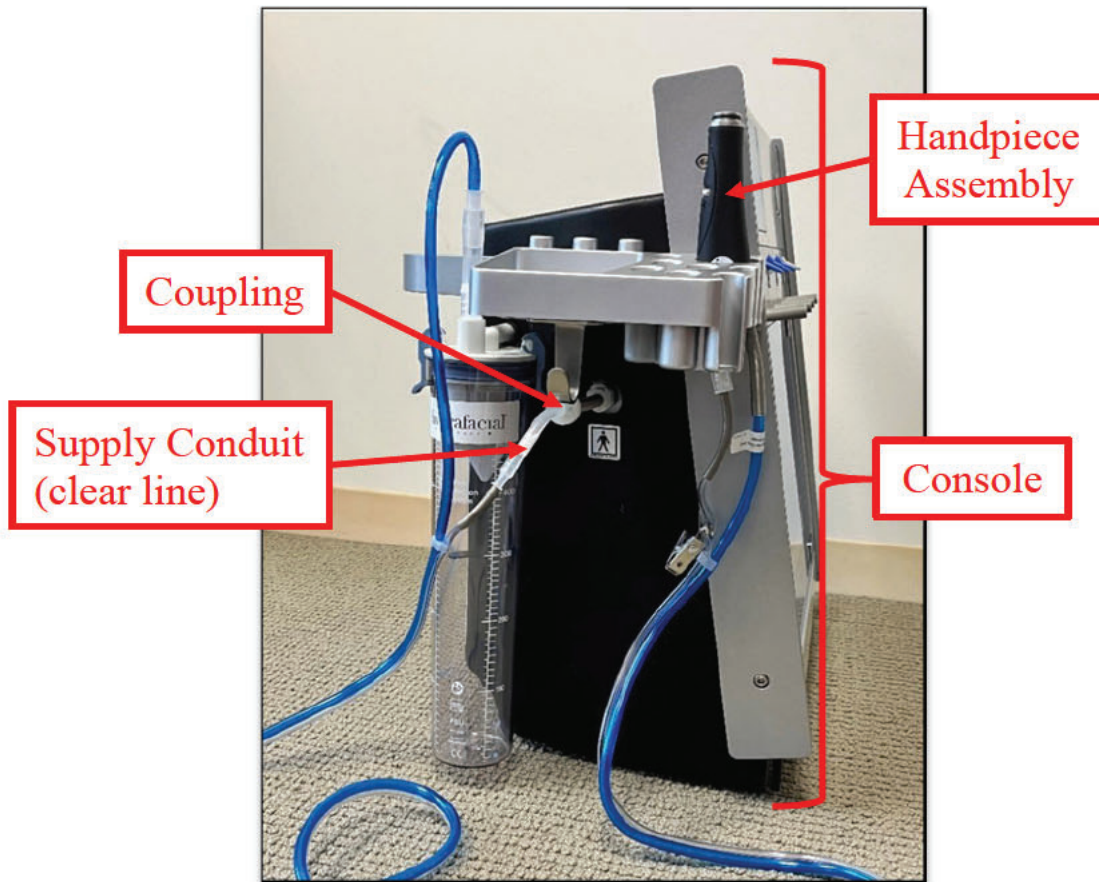
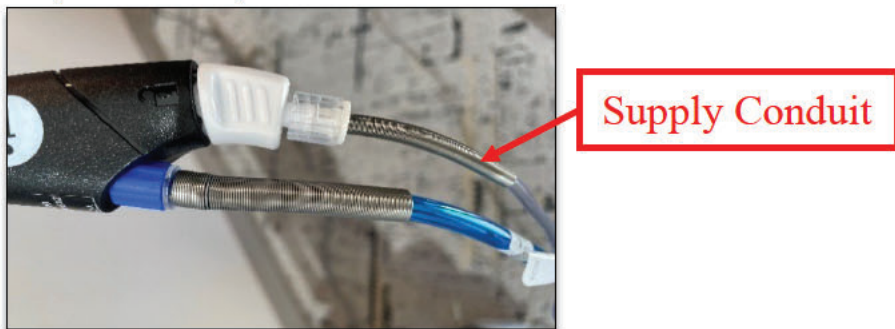


Exhibit A10.

The fluid in the supply conduit runs to and through the handpiece itself to an opening on the handpiece assembly.



CLAIM 1 OF THE '052 PATENT

Opening from
Supply Conduit

Exhibit A10.

[d]: wherein the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit; and

The manifold of the HydraFacial Allegro is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

As described above, the supply conduit extends from the handpiece assembly to the manifold, which is in fluid communication with the fluid containers (including the first and second fluid containers). *See* limitation 1[c], *supra*. As explained below, the manifold in fluid communication with the fluid containers is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

HydraFacial Allegro IFUs

The Allegro IFU shows toggle switches on the manifold to control the flow of treatment material from the fluid containers:

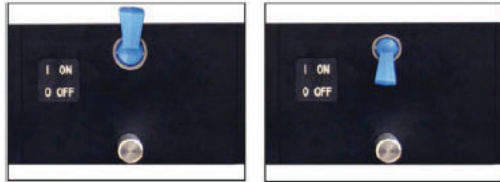


CLAIM 1 OF THE '052 PATENT

Exhibit B4 at 8. The Allegro IFU further explains that a user may select which bottle (and thus which skin solution) used during treatment by using the toggle switches on the manifold for each bottle.

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.

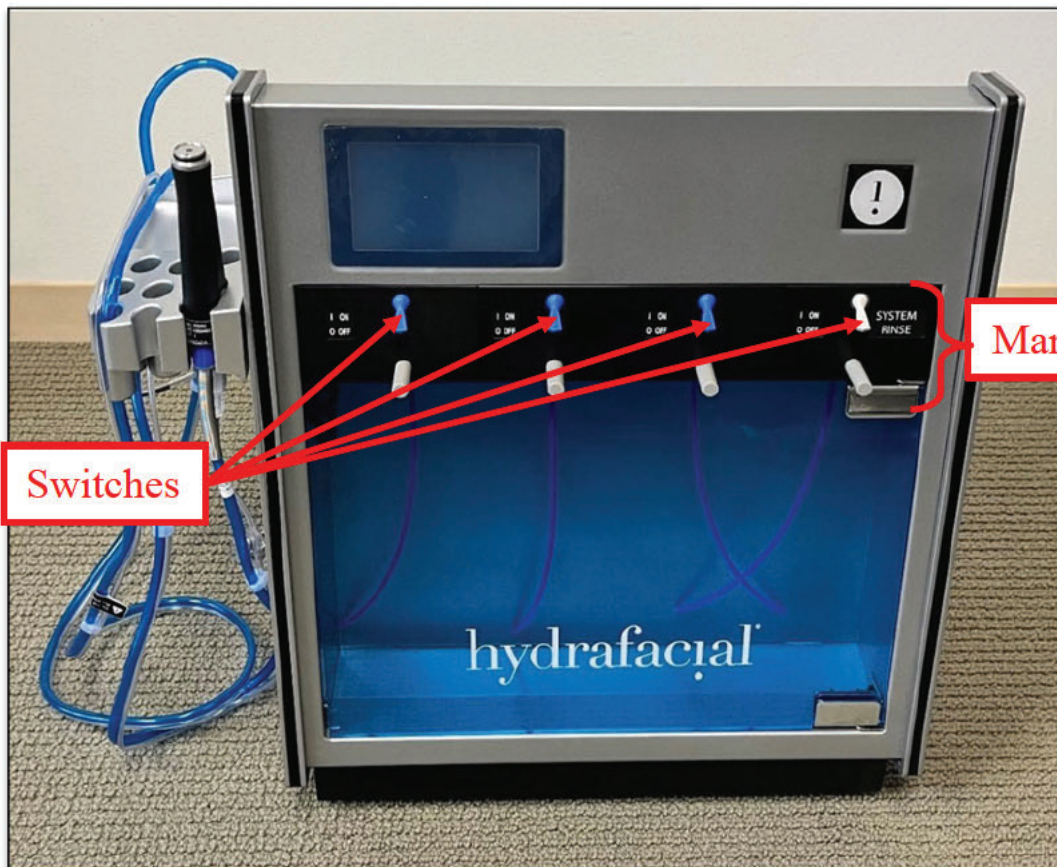
Note: Always keep the "SYSTEM RINSE" toggle switch (gray) off while performing procedures.



Id. at 11. 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.” *Id.* Thus, for example, when the switch for the first fluid container is ON and the switch for the at least the second fluid container is OFF, the manifold controls the flow of treatment material from both the first and second fluid containers by permitting flow from the first fluid container and restricting flow from the at least the second fluid container. Thereafter, when the switch for the first fluid container is OFF and the switch for the at least the second fluid container is ON, the manifold controls the flow of treatment material from both the first and second fluid containers by permitting flow from the at least the second fluid container and restricting flow from the first fluid container. In this manner, through operation of the toggle switches, the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit.

Photos of HydraFacial Allegro

As shown in the image below, the manifold of the HydraFacial is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit via switches on the manifold system so that a user can select a fluid container from which to draw treatment material.

CLAIM 1 OF THE '052 PATENT**Exhibit A10.****[e]: a vacuum source;**

The HydraFacial Allegro comprises a vacuum source.

HydraFacial Allegro IFUs

The Allegro IFU illustrates and describes turning the vacuum on and off and adjusting the vacuum.

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.

**Exhibit B4 at 13.**

CLAIM 1 OF THE '052 PATENT**Photos of HydraFacial Allegro**

The image below shows the vacuum source inside the HydraFacial Allegro console.

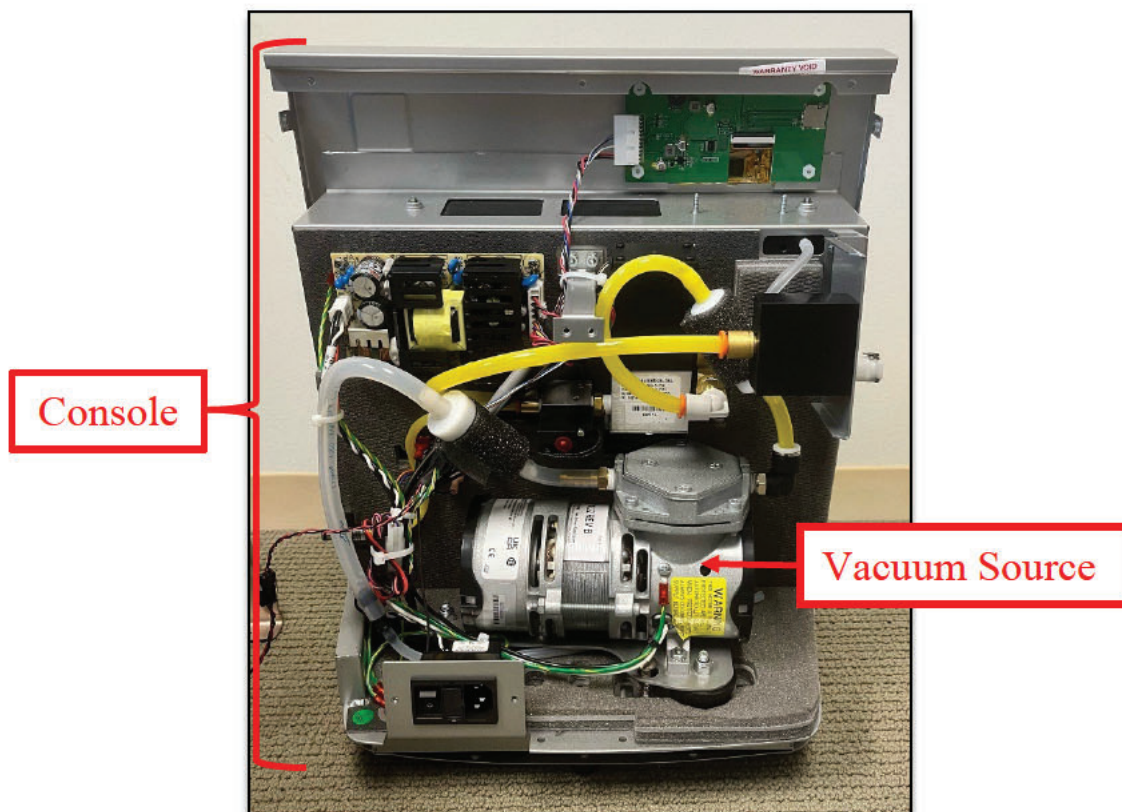


Exhibit A10.

[f]: a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source; and

The HydraFacial Allegro comprises a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, wherein the waste conduit is operatively coupled to the vacuum source.

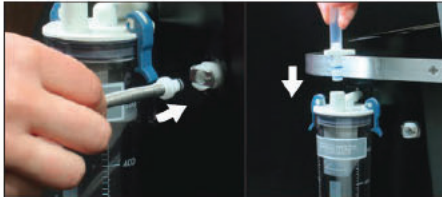
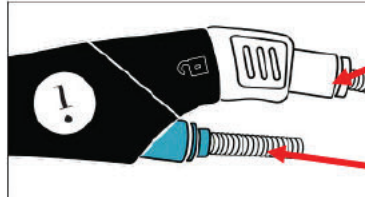
HydraFacial Allegro IFUs

The Allegro IFU illustrates and describes a “Return Line” attached to the handpiece assembly, wherein the Return Line which serves as a portion of the waste conduit through which the tip of the handpiece assembly is in fluid communication with the vacuum source (the “supply conduit” described above is also labeled for reference and clarity in the illustrations below).

CLAIM 1 OF THE '052 PATENT

HydraFacial® Handpiece

1. Plug the small tube attached to the HydraFacial® handpiece into coupling fitting.
2. Connect the large tube attached to the handpiece into the waste container.
3. Locate the small tubing with the blue end and connect it to the appropriate end on the handpiece. The blue end corresponds with the blue dot. Twist the knob gently clockwise to secure the tubing.



Supply Conduit

Waste Conduit

Exhibit B4 at 9.

The Handpiece IFU also describes the “Return Line” being connected between the handpiece assembly and a waste container (“waste canister”), which is, in turn, connected to and in fluid communication with the vacuum source in the console:

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.



Supply Conduit

Waste Conduit

Exhibit B9 at 3; see also Exhibit B4 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.”).

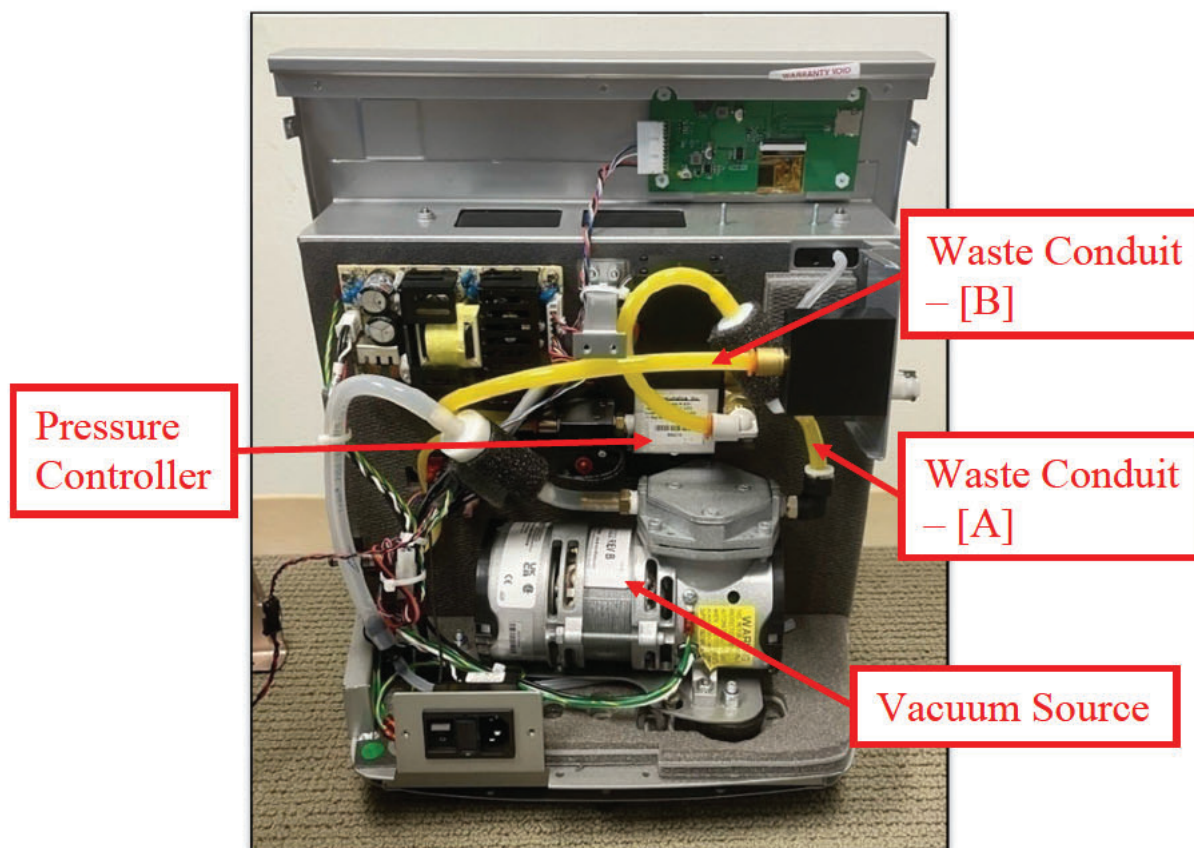
The handpiece assembly has a “vacuum opening” that is covered by the tip of the handpiece assembly, such that the handpiece assembly vacuums fluids through the tip and into the waste conduit:



Exhibit B9 at 5.

CLAIM 1 OF THE '052 PATENT**Photos of HydraFacial Allegro**

As shown in the photos below, the waste conduit comprises multiple tubing components that extend 1) between the vacuum source and a pressure controller [A]; 2) between the pressure controller and a port for the waste container [B]; 3) between the port for the waste container and the tubing of the handpiece assembly via a waste container and tubing [C]; and 4) between the coupling and the handpiece assembly [D]. The connection to the vacuum source operatively couples the waste conduit and the vacuum source.

**Exhibit A10.**

The blue tubing for the handpiece assembly contains the waste conduit. The waste conduit continues from the port for the waste container on the console through the tubing to the handpiece assembly.

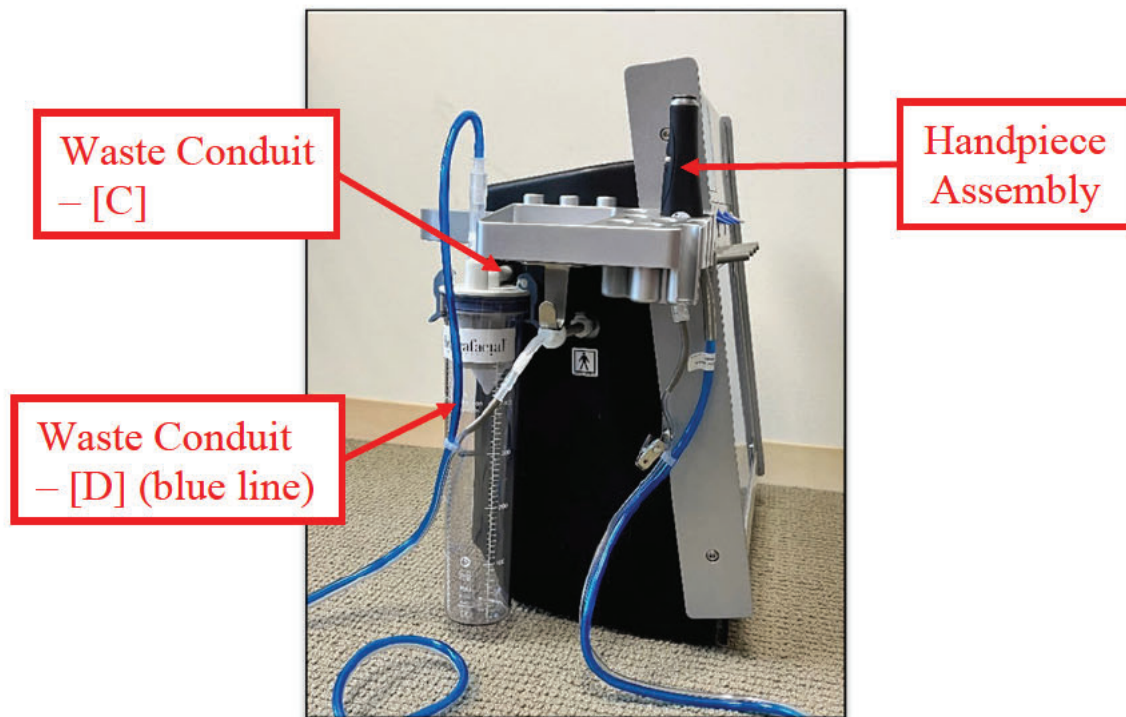
CLAIM 1 OF THE '052 PATENT

Exhibit A10. The fluid in the waste conduit runs through and away from the handpiece assembly itself via an opening on the handpiece assembly.



Exhibit A10.

CLAIM 1 OF THE '052 PATENT

[g]: wherein the system is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly; and

The HydraFacial Allegro is configured to permit a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.

As described above, the manifold is configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit. *See* limitations 1[a][i] and [d], *supra*. As described below, the HydraFacial Allegro permits a user to select the treatment material to be delivered through the supply conduit to the handpiece assembly.

HydraFacial Allegro IFUs

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 for each bottle.

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.



Exhibit B4 at 11. 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.” *Id.* Since the user controls these switches, the HydraFacial Allegro permits a user to select the treatment material from the first fluid container or the at least second fluid container to be delivered through the supply conduit to the handpiece assembly.

[h]: wherein, when the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

When the vacuum source is activated and the tip contacts the skin surface, a suction force is created within the waste conduit and along the tip, thereby removing waste from the skin surface via the waste conduit while drawing treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

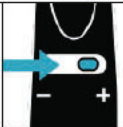
As explained above, the HydraFacial Allegro has (1) a waste conduit in fluid communication with the tip of the handpiece assembly to remove waste away from a skin surface of a subject during a skin treatment procedure, (2) a vacuum source operatively coupled to the waste conduit, (3) a handpiece assembly with a tip that is configured to contact a skin surface of a

CLAIM 1 OF THE '052 PATENT

subject during treatment, and (4) a manifold configured to control a flow of treatment material from the first fluid container and at least the second fluid container through the supply conduit to the handpiece assembly. *See* limitations 1[b], [c], [d], and [f], *supra*. As shown below, it is the same suction force that removes waste from the skin surface via the waste conduit that also draws treatment material from the first fluid container or the second fluid container to the tip via the supply conduit.

HydraFacial Allegro IFUs

The “Troubleshooting” section of the Allegro 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.” **Exhibit B4** at 17. The recommended solution to this situation is to “[e]mpty the waste canister after each service.” *Id.*

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.	

Id. Thus, the suction force generated by the vacuum 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.

97. For all of these reasons, the HydraFacial Allegro practices claim 1 of the '052 Patent.

98. I address how the Tower system⁷ practices each limitation of claim 1 of the '052 Patent in the claim chart below.

<u>CLAIM 1 OF THE '052 PATENT</u>
Preamble 1[pre]: A system for performing a skin treatment procedure, the system comprising:
To the extent that the preamble is deemed to be a limitation, the HydraFacial Tower is a system for performing a skin treatment procedure.
<p data-bbox="203 562 699 596"><u>HydraFacial Tower Owner's Manual</u></p> <p data-bbox="203 600 1377 743">The HydraFacial Tower's Owner's Manual indicates that the HydraFacial Tower is a "revolutionary breakthrough in aesthetic 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":</p> <div data-bbox="219 751 524 787" style="border: 1px solid black; padding: 5px;"> <p data-bbox="219 751 524 787">I. INTRODUCTION</p> <p data-bbox="219 821 1325 1058">Thank you for purchasing the HydraFacial MD™ System, a revolutionary breakthrough in aesthetic technology! The HydraFacial™ is the next generation of exfoliation and skin rejuvenation done simultaneously. The process removes dead skin cells and impurities while simultaneously infusing the new skin with cleansing, hydrating and moisturizing serums & antioxidants. The treatment is soothing, refreshing, non-irritating and very effective. You can have the utmost confidence in this high-end system manufactured by Edge Systems Corporation.</p> </div> <p data-bbox="203 1092 412 1125">Exhibit B5 at 3.</p>

⁷ The HydraFacial "Tower" system includes multiple models, including the HydraFacial Tower 120V, HydraFacial MD Tower 120V, HydraFacial Tower 240V, and HydraFacial MD Tower 240V (collectively referred to herein as the "HydraFacial Tower"). See **Exhibit B6** at 2. The HydraFacial Tower differs from its "MD"-branded counterpart via components that are not relevant as to whether such a product practices the Asserted Claims of the '287 Patent. Compare *id.* at 14–16 (bill of materials for "HydraFacial MD System, 120V") with *id.* at 61–63 (bill of materials for "HydraFacial System, 120V"); see also *id.* at 13 ("The Hydrafacial MD Tower System 120V {P/N 70143-02-01} will be used as a representative to validate all Tower System configurations. The only differences between the Hydra Facial MD Tower System 120V {P/N 70143-02-01} with the other configurations is the software and the wiring of the pump (120V Pump, 17857 / 240V Pump, 17858 [REDACTED]).

(emphasis added).