UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EUNSUNG GLOBAL CORP.,

Petitioners,

v.

HYDRAFACIAL LLC

Patent Owner.

Case No. IPR2024-01491
U.S. Patent No. 11,865,287

DECLARATION OF KARL R. LEINSING, MSME, PE

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

Dated: January 15, 2025 By: _____
Karl R. Leinsing, MSME, PE

Eunsung v. HydraFacial
IPR2024-01491
HydraFacial Ex. 2001

1. I, Karl Leinsing, am making this declaration at the request of Patent Owner HydraFacial LLC in the matter of the Inter Partes Review No. IPR2024-01491 of U.S. Patent No. 11,865,287 ("the '287 patent"). I understand that this declaration is being submitted in this proceeding as Exhibit 2001.

2. I am being compensated for my work in this matter at my standard hourly rate for consulting services. My compensation in no way depends on the outcome of this proceeding.

3. In addition to my own knowledge and expertise, I have reviewed and considered the following written materials in conducting the analyses and forming the opinions set forth in this declaration.

Exhibit or Paper No.	Description
2	Eunsung's Petition for Inter Partes Review
1001	U.S. Patent No. 11,865,287
1002	File History for U.S. Patent 11,865,287
1003	October 8, 2024 Declaration of Eric Simon
1004	U.S. Publication No. 2003/0212415 ("Karasiuk")
1005	U.S. Patent No. 5,199,604 ("Palmer")
1006	U.S. Publication No. 2003/0093089 ("Greenberg")
1008	U.S. Patent No. 6,684,880 ("Trueba")
2009	Declaration of Vipul Savsani

Exhibit or Paper No.	Description
2030	Hydrafacial Syndeo™ Instruction for Use (IFU), revised May 1, 2023
2031	HydraFacial MD™ Elite™ User Guide, revised November 1, 2023
2032	Hydrafacial™ Allegro MD Instructions for Use (IFU), revised November 06, 2023
2033	HydraFacial MD™ System Owner's Manual (Tower Owner's Manual) (2005)
2034	HydraFacial™ Handpiece User Guide, Revised February 19, 2020
2035	HydraFacial Nectre® System Owner's Manual, Revised May 14, 2008
2036	HydraFacial™ Nectre® System User Manual, Revised January 27, 2009
2037	HydraFacial™ Nectre® System Service Manual, Revised June 12, 2009
2038	Introducing . . . HydraFacial MD™ by Edge Systems Advertisement
2039	HydraFacial™ Rejuvenate Your "Microderm" Business! Advertisement (January/February 2006)
2040	HydraFacial™ Whole New Skin Advertisement
2041	My Life. My Time. My Skin HydraFacial MD™ Advertisement, Dated May 11, 2015
2042	Unique Patented HydraFacial MD® TECHNOLOGY Advertisement (2013)
2043	HYDRAFACIAL™ TOWER SYSTEM Advertisement (2020)

Exhibit or Paper No.	Description
2044	The Elite™ is the Latest HydraFacial System with Advancements to Ensure Your Practice's Success Advertisement (2020)
2045	EXPECT EVERYTHING: Introducing the Brand-New HydraFacial Elite Advertisement (2020)
2046	Expect Everything with the New HydraFacial Elite
2047	The Allegro™ System Advertisement (2020)

To the extent not listed above, I have also reviewed any other materials I discuss or cite herein.

I. QUALIFICATIONS AND PROFESSIONAL BACKGROUND

4. 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).

5. I have been a medical device engineer since 1992 and have worked extensively with medical device disposables, including syringes 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.

6. Since 2006, I have been President of ATech Designs, Inc., where I have worked in the development of various 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, among others. In many of these applications, vaporized hydrogen peroxide, ethylene oxide (EtO), gamma irradiation, autoclave, or E-beam sterilization methods were used to sterilize the medical devices.

7. Previously, from 2005 to 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.

8. 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 also 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.

9. 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.

10. 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.

11. My *curriculum vitae* lists additional information about my professional background and qualifications. Exhibit 2002 is a true and correct copy of my *curriculum vitae*.

II. RELEVANT LEGAL STANDARDS

12. I am an engineer by training and profession. The opinions I express in this declaration involve the application of my knowledge and experience to the evaluation of the ’287 patent and certain prior art to that patent. My knowledge of patent law is that of a lay person. Therefore, counsel for Patent Owner provided me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of the principles related to patentability that I must apply, and have applied, in conducting my analyses and reaching the opinions set forth in this declaration.

13. I understand that, in assessing the patentability of a patent claim, the Patent Office generally construes claim terms by giving them their ordinary and customary meaning, as they would have been understood by a person of ordinary skill in the art (“POSITA”) at the time of the invention in view of the intrinsic record

(patent specification and prosecution history). However, I understand that the inventors may, in the patent specification, expressly define a claim term to have a meaning that differs from the term's ordinary and customary meaning. I also understand that the inventors may disavow or disclaim certain claim scope, thereby departing from the ordinary and customary meaning, when the intrinsic record demonstrates that a clear and unambiguous disavowal or disclaimer has occurred. I understand that extrinsic evidence, such as relevant technical literature and dictionaries, may be useful in ascertaining how a POSITA would have understood a claim term, but the intrinsic record is the primary source for determining the meaning of claim terms. For the purposes of this review, and to the extent necessary, I have interpreted each claim term in accordance with the principles set forth in this paragraph.

14. It is my understanding that a claim is unpatentable as "anticipated" under 35 U.S.C. § 102 if a single prior art reference discloses every limitation of the claim, arranged as in the claim. I understand that a prior art reference does not anticipate a claim, however, when it discloses multiple, distinct teachings that a person of ordinary skill in the art might somehow combine to achieve the claimed invention. I understand that anticipation has not been alleged in the Petition, and, thus, is not at issue in this proceeding.

15. I understand that a claim is unpatentable under 35 U.S.C. § 103 if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art 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. Those objective indicia 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.

16. 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.

17. To assess the differences between 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" assessment 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.

18. I also understand that in an obviousness analysis, a patent challenger must demonstrate with evidence that a POSITA would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the POSITA would have had a reasonable expectation of success of doing so.

19. 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 POSITA at the time of the invention. In other words, a reference discloses or teaches a claim limitation if a POSITA would, at the relevant time, interpret the reference as expressly, implicitly, or inherently disclosing the claim limitation. I further understand that a reference does not need to use the exact language of the claim to disclose a claim limitation.

III. LEVEL OF ORDINARY SKILL IN THE RELEVANT ART

20. The relevant field of art is skin treatment, and more specifically apparatuses and methods of treating a person's skin, as described in the '287 Patent.

21. I understand that the level of ordinary skill in the art for the '287 patent is determined as of December 30, 2005, which is the earliest effective filing date of the patent. I also understand that Eunsung has not alleged that the '287 patent is not entitled to the December 30, 2005 effective filing date.

22. In my opinion, a POSITA for the '287 patent would have 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 POSITA 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.

23. I applied the above definition of a POSITA in my analysis set forth in this declaration. I understand the capabilities of a POSITA as of December 2005. In fact, I was a POSITA at the relevant time, although I had not at the relevant time consulted with a physician about the subject matter of the '287 patent. In connection with my analysis in this matter, I have consulted with Elliot Duboys, a medical practitioner with significant experience working with microdermabrasion and

hydrodermabrasion devices. Based on my training and experience, and my consultation with Dr. Duboys, I understand the level of knowledge and skill that a POSITA would have possessed in December 2005 and am familiar with what a POSITA would have understood regarding microdermabrasion and hydrodermabrasion at the relevant time.

24. I understand that Eunsung has proposed the following definition of a person of ordinary skill in the art (a "POSITA") with respect to the '287 patent:

> A person having ordinary skill in the art (POSITA) at the time of the alleged invention would have had an undergraduate degree (B.S.) in Mechanical Engineering or equivalent knowledge, training, or experience, with two years of work experience in the design of mechanical products, design of fluidic systems, and/or the design of devices intended for medical or cosmetological applications. Additional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above.

Pet., 2-3.

25. I agree with Dr. Duboys that Eunsung's definition of a POSITA ignores important knowledge of medical implications that would have been necessary for a POSITA to assess the obviousness of a proposed combination. Therefore, I disagree with Eunsung's definition.

26. Nevertheless, I alternatively applied Eunsung's definition of a POSITA and determined that my opinions are the same under either definition. Specifically,

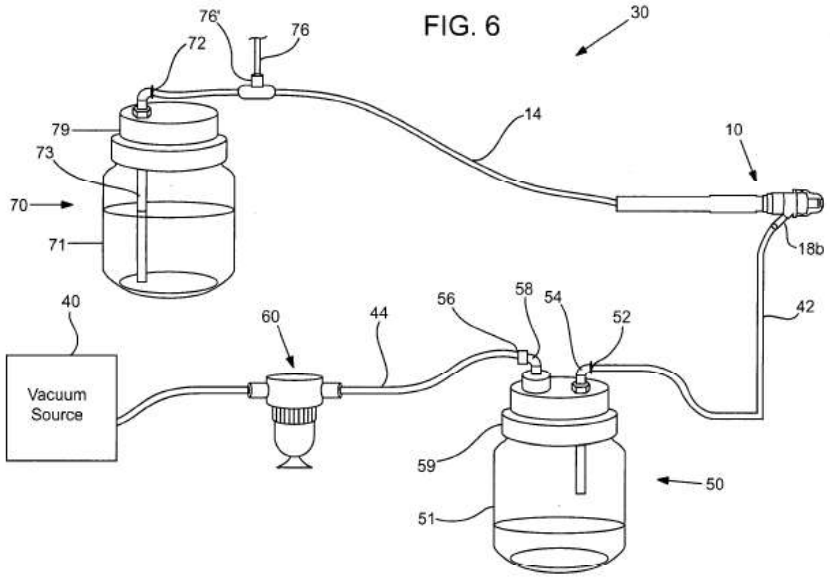
under either definition, the challenged claims of the ’287 patent would not have been obvious.

IV. CLAIM CONSTRUCTION

27. In my view, no express claim construction is necessary to assess the issues I was asked to analyze. I have applied the plain and ordinary meaning in view of the claim language, specification, and prosecution history to each claim term relevant to my analysis. However, I note that based on my discussion with Dr. Duboys, I understand he is of the opinion that the plain meaning of the terms “treatment fluid,” “treatment material,” and “fluid” in the claims do not include dry abrasive particles within their scope.

V. PATENTABILITY OVER THE KARASIUK GROUNDS

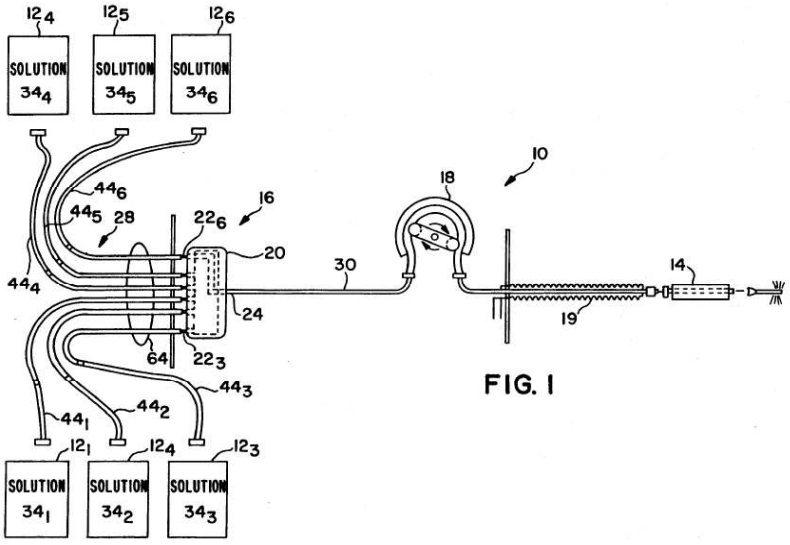
28. I was asked to assess certain technical issues related to whether the challenged claims would have been obvious over Karasiuk combined with other prior art, as more fully explained below. Eunsung relies on Karasiuk as its primary reference in Grounds 1A and 1B. In Ground 1A, Eunsung combines Karasiuk with Palmer to allege that all independent claims and some dependent claims would have been obvious. Pet., 1. As shown in Figure 6 below, Karasiuk is a microdermabrasion device that draws liquid from just one container during a microdermabrasion treatment.



EUNSUNG-1001, Fig. 6, [0014], [0020].

29. In my view, Karasiuk does not disclose a block for selectably connecting one of multiple skin-treatment containers to a handpiece. Nothing in Karasiuk suggests separately storing and applying different treatment fluids 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. *Id.*, [0061].

30. Palmer is an irrigation system used in periodontal procedures. EUNSUNG-1005, 1:10-15. As such, Palmer delivers a "pulsed jet" of treatment solution at constant pressure and substantially constant volumetric flow rate to the treatment area in the patient's mouth. Id., 11:17-23 (pressure of 25 psi and flow rate of 22-25 mL/minute). Palmer employs a peristaltic pump 18 located upstream of handpiece 14 to generate the pulsed jet of solution, as shown in Fig. 1.



Id., Fig. 1.

31. The handpiece sprays the pulsed jet directly at a treatment site in the patient's mouth to irrigate it with the needed solution. Id., 3:15-26. Unlike a microdermabrasion system, Palmer is a one-way irrigation system that lacks any mechanism to vacuum the spent solution from the patient's mouth and back through the handpiece.

32. Eunsung adds Trueba in Ground 1B for dependent claims having computing device limitations, and for a single limitation in claim 1 already addressed in Ground 1A. Pet., 53-56. Trueba involves a jet dispenser that combines Hewlett-Packard's inkjet technology with pharmaceutical administration. EUNSUNG-1008, 1:7-12.

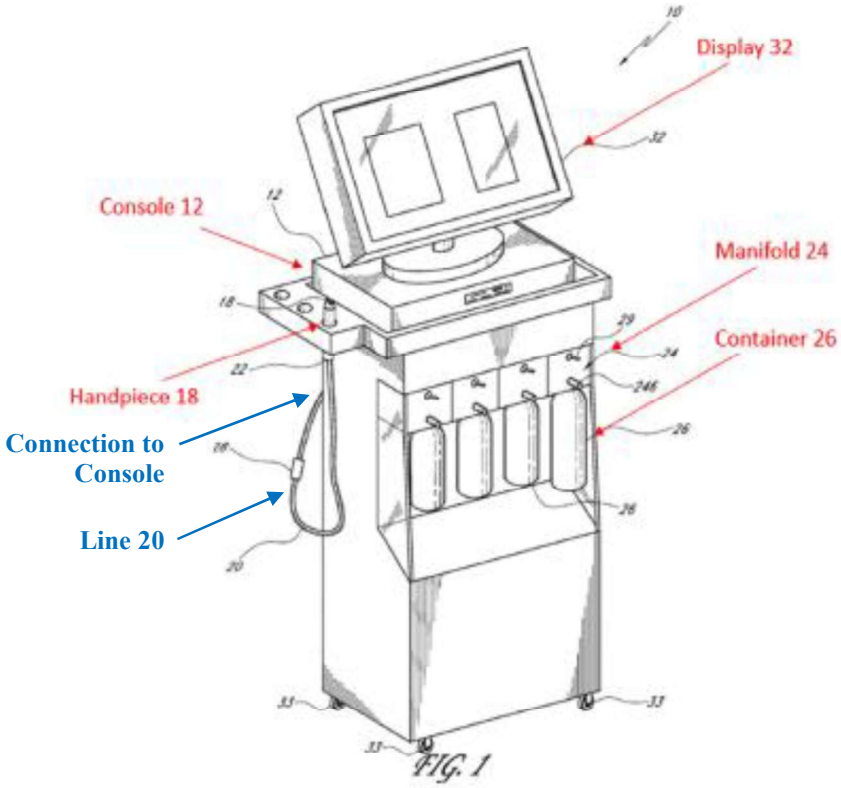
33. I was specifically asked to determine whether Karasiuk or Palmer discloses a handpiece connected to a console. Every claim of the '287 patent

requires a handpiece (or handpiece assembly) connected to the console during operation. See Limitations 1.3, 11.3, 22.4, 26.5, and 37.5. For example, Limitation 1.3 recites:

> wherein the block is: … configured to be in fluid communication with the handpiece through a first conduit ***when the handpiece is connected to the console***."

EUNSUNG-1001, 21:30-39. For the reasons explained below, in my opinion, neither Karasiuk nor Palmer discloses a handpiece connected to a console.

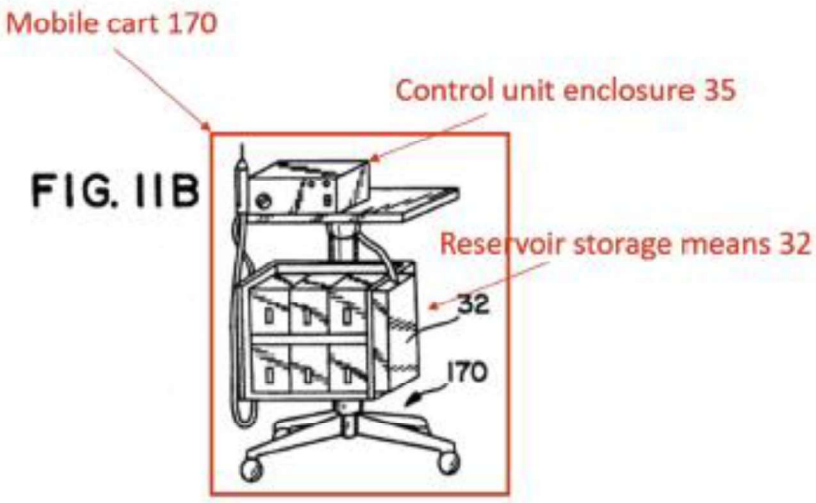
34. Referring to Fig. 1, the '287 patent explains that the "treatment system 10 includes a console 12 and a handpiece assembly 18 connected to the console 12 via a line 20." Id., 5:26-28. Eunsung's annotated Fig. 1 shows this configuration:



Pet., 3 ('287 patent, Fig. 1)[1]. The specification explains that "[t]he line 20 can comprise one or more conduits extending between the console 12 and the handpiece assembly 18." EUNSUNG-1001, 5:65-67.

35. In my opinion, Eunsung fails to show that either Karasiuk's or Palmer's handpiece is ever connected to a console. Eunsung relies on Palmer's mobile cart 170, illustrated below, for the console.

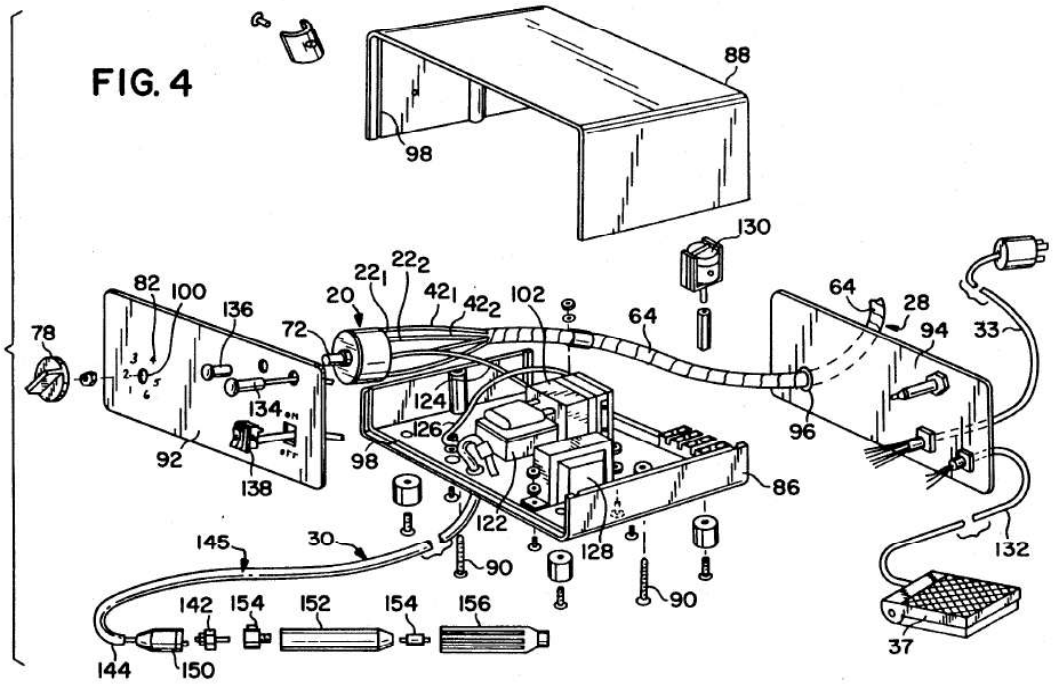
[1] Blue annotations to the figures were added by Patent Owner and the red annotations were added by Petitioner.



Palmer, FIG. 11B

Petition 7, 13 ("The Karasiuk-Palmer system includes a console in the form of, for example, 'mobile cart 170'") (emphasis by Eunsung).

36. However, Palmer's handpiece is not connected to mobile cart 170 in Palmer. Instead, Palmer's handpiece is connected by tubing to "control unit enclosure 35." EUNSUNG-1005, 5:16-20. Control unit enclosure 35 is a modular component in Palmer's system. *Id.*, 3:9-14. Fig. 4, shown below, is an exploded fragmentary view of control unit enclosure.



Id., Fig. 4, 4:19-21. Palmer explains that "[s]econd tubing means 30 couples the handpiece means 14 to the output of the pump within enclosure 35." *Id.*, 5:16-18.

37. Fig. 7 shows the connection of the handpiece means to the bottom portion of control unit enclosure 35 in more detail:

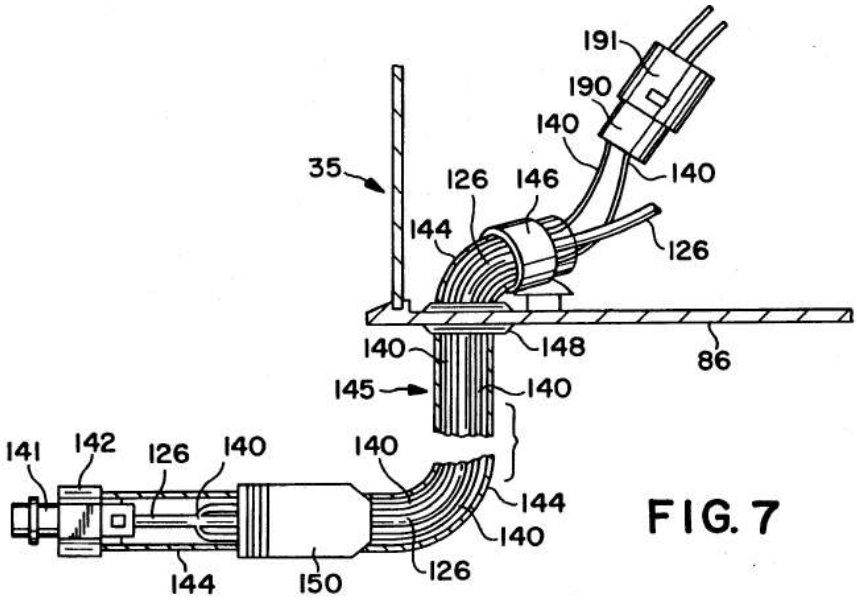
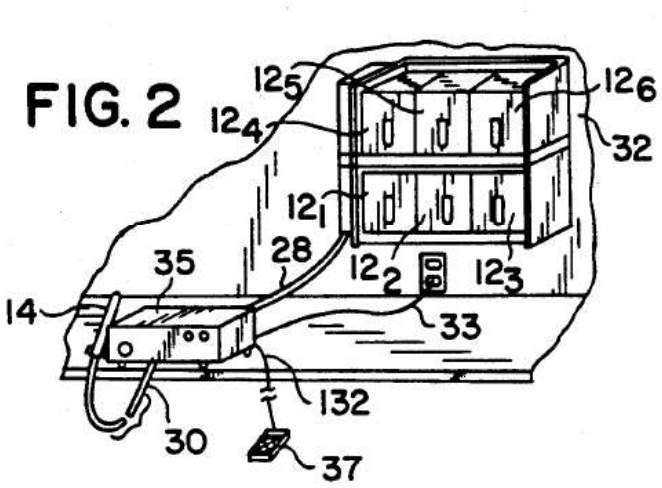


FIG. 7

Id., Fig. 7. Here, Palmer explains that "[t]he clear handpiece tubing assembly, designated 145, is clamped within enclosure 35 by a cable clamp 146 and passes through the bottom member 86 through a grommet 148." *Id.*, 9:37-40.

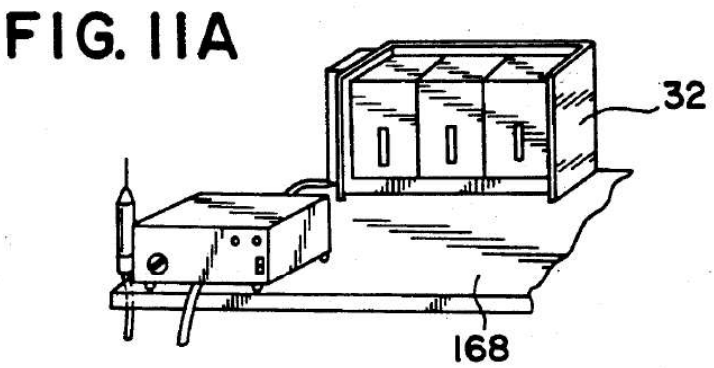
38. Palmer's control unit enclosure 35 and reservoir storage means 32 are modular components in Palmer's system. Palmer explains that the "modular means for storing solution reservoirs" and providing "substantial flexibility in setting up the system" are "the present invention." EUNSUNG-1005, 3:9-14. The system's modular configuration is an "advantage[] in the installation of the system." *Id.*, 9:58-10:2. To that end, Palmer describes placing the control unit enclosure 35 and reservoir storage means 32 in separate locations around the dental office. In each instance, handpiece means 14 is connected only to control unit enclosure 35.

39. Fig. 2 shows control unit enclosure 35 on a countertop with handpiece 14 attached, and reservoir storage means 32 hanging on the wall.



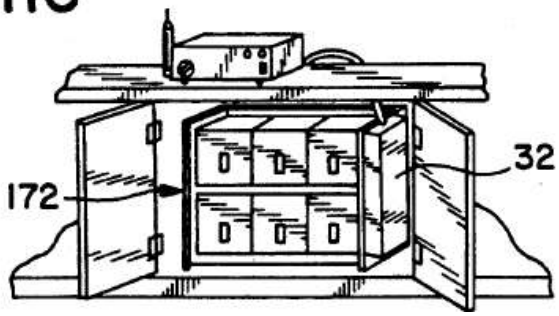
EUNSUNG-1005, Fig. 2, 5:10-13.

40. Fig. 11A shows both control unit enclosure 35 and reservoir storage means 32 on countertop 168.



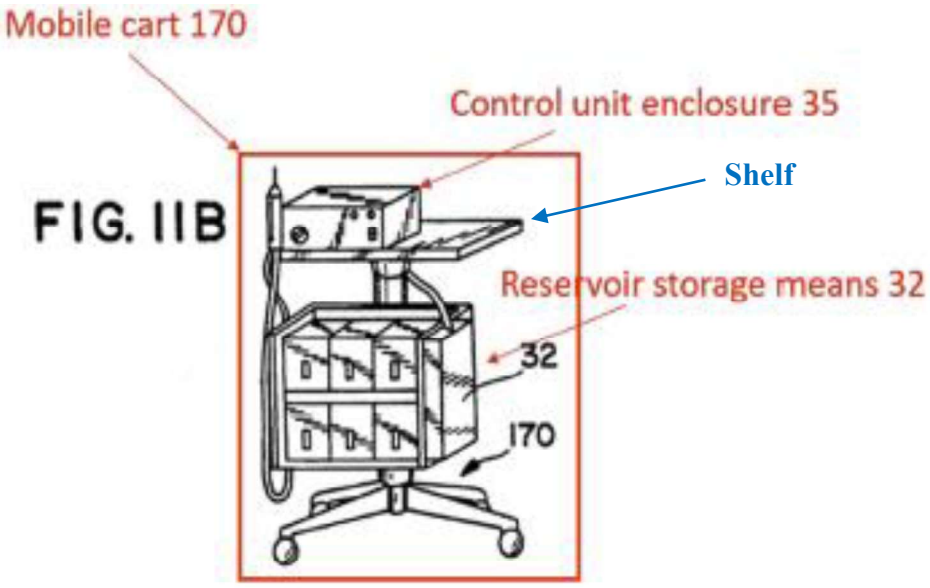
Id., Fig. 11A, 9:66-10:2. Fig. 11C shows reservoir storage means 32 "in a cabinet 172 underneath a counter," with control unit enclosure 35 on top of the counter.

FIG. IIC



Id., Fig. 11C, 9:66-10:2. Similarly, Fig. 11B, cited by Eunsung, shows Palmer's control unit enclosure 35 on a shelf on mobile cart 170 with the handpiece attached to control unit enclosure 35.

FIG. IIB



Palmer, FIG. 11B

41. Eunsung contends "a POSITA would have found obvious that Karasiuk's device 10 (handpiece) is connected to 'mobile cart 170' (console), as illustrated in Palmer." Pet., 21. However, Palmer's handpiece is never connected

to Palmer's mobile cart that Eunsung alleges is the console. And Eunsung never explains why or how a POSITA would have connected Karasiuk's handpiece to Palmer's mobile cart in light of Palmer's disclosure to the contrary. Eunsung points to Palmer's Fig. 11B, but, as discussed above, that figure actually confirms Palmer's handpiece is not connected to the mobile cart. Pet., 21. Eunsung's expert, Mr. Simon, repeats Eunsung's same argument nearly verbatim, without any additional evidence. EUNSUNG-1003, [113] ("a POSITA would have found it obvious that the handpiece (e.g., Karasiuk's device 10) is connected to the 'mobile cart 170' (console).").

42. In my opinion, because Eunsung failed to show its proposed combination of Karasiuk and Palmer has its handpiece connected to a console, the claims would not have been obvious over Karasiuk and Palmer.

VI. PRIOR ART PREVIOUSLY CONSIDERED BY THE PATENT OFFICE

43. I understand that the Board may reject an IPR petition that relies on "the same or substantially the same prior art or arguments previously … presented to the Office." I understand that an assessment of whether to deny the Petition on this basis involves legal analysis and an assessment of discretionary factors. I have not conducted such analysis or assessment or formed an opinion about the Board's ultimate exercise of discretion whether to deny the Petition on this basis. However,

I have been asked to assess some technical issues that I understand have a bearing on the Board's ultimate exercise of discretion.

44. I understand that a relevant issue is the similarity of prior art that the Examiner considered and the prior art Eunsung relies upon in the Petition. The prosecution history of the '287 patent shows that the Examiner considered the exact Karasiuk and Greenberg references that Eunsung relies upon as its primary references. EUNSUNG-1002, 229.

45. Eunsung relies on secondary reference Palmer, which discloses dental-irrigant containers, as allegedly suggesting multiple treatment containers and container-selection structure. In my opinion, that alleged disclosure is not materially different than the disclosure of Greenberg—which the Examiner considered—of a valve 108 that connects one of multiple containers to select from "different particles to use in a micro-dermabrasion machine."

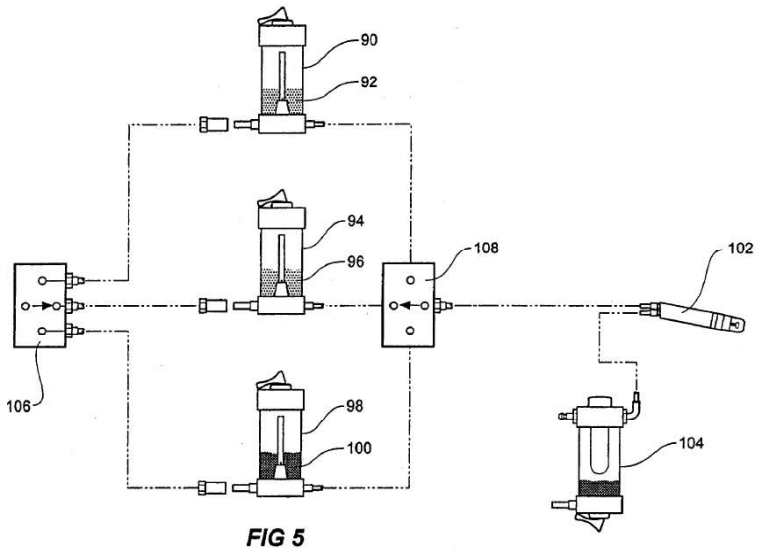


FIG 5

EUNSUNG-1006, Fig. 4, [0073]-[0077].

46. Indeed, in my view, Greenberg's containers are more closely related to the claimed invention than Palmer's. As explained by Dr. Duboys, Greenberg does not disclose the claimed invention, at least because its containers store dry particles rather than fluid. Greenberg's system is a microdermabrasion system, which sprays the dry abrasive particles at the patient's skin. But, unlike Palmer, Greenberg is at least in the field of microdermabrasion, which, while different than hydrodermabrasion (the system disclosed and claimed in the '287 patent), is more closely related than the unrelated field of dental irrigation. Thus, if it would have been obvious to combine Karasiuk with the disclosure of multiple treatment containers and container-selection structure to yield the claimed invention, the Examiner would have rejected the claims in view of Karasiuk and Greenberg. The Examiner's finding that the claims are patentable over Karasiuk and Greenberg shows that the claims are likewise patentable over Karasiuk and Palmer.

47. Eunsung relies on Trueba as a secondary reference for Grounds 1B and 2B. In my opinion, Trueba adds nothing of consequence to Grounds 1B and 2B because Eunsung does not allege that Trueba discloses the limitations missing from Karasiuk and Palmer (Ground 1B) or Greenberg (Ground 2B). Rather, Eunsung relies on Trueba as allegedly disclosing a computer interface with a touchscreen and a display for automatically controlling the device. The Examiner did not find the

claims patentable based on those computer-interface limitations. EUNSUNG-1002, 201-204. Indeed, in rejecting some claims, the Examiner found that Shadduck discloses a computer for device control and Duchon discloses a touchscreen and a display. *Id.*, 199-201. Eunsung does not rely on Trueba as allegedly disclosing anything the Examiner had not already found to be taught by the prior art applied during examination. Therefore, in my view, Trueba's teachings do not call into question the Examiner's patentability findings.

48. I also understand it is relevant whether Eunsung showed the Examiner erred in his evaluation of the asserted prior art. Eunsung asserts that "[t]o the extent Karasiuk and Greenberg were previously considered, the Examiner erred in overlooking the teachings cited in the Petition." Pet., 96. However, in my view, no evidence supports Eunsung's assertion. Upon reviewing the prosecution history, I found nothing that even suggests the Examiner overlooked, ignored, or misapplied the teachings of Karasiuk, Greenberg, or the other prior art of record. Indeed, in my view, a reasonable reading of the prosecution history is that the Examiner considered Karasiuk and Greenberg, along with the other prior art of record, and determined that the claims would not have been obvious over any combination of that art.

VII. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

49. I have been asked to evaluate whether the HydraFacial Syndeo, HydraFacial Elite, HydraFacial Allegro, and HydraFacial Tower[2] (collectively, "HydraFacial Systems") practice Claim 1 of the '287 Patent. In addition, I have been asked to provide expert analysis on whether the HydraFacial Systems embody Claim 1 of the '287 Patent and are coextensive with it to establish a presumed nexus.

50. I have analyzed the relevant aspects of each of the HydraFacial Systems in light of Claim 1 of the '287 Patent, and, as set forth in detail below, it is my opinion that each of the HydraFacial Syndeo, HydraFacial Elite, HydraFacial Allegro, and HydraFacial Tower practices Claim 1 of the '287 Patent, and are coextensive with this claim.

A. The HydraFacial Systems Meet Every Limitation of Claim 1 of the '287 Patent

51. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices every limitation of Claim 1 of the '287 Patent.

[2] 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").

52. Claim 1 recites as follows:

1. A system for treating skin, the system comprising:
a console configured to receive a first container and at least one additional container;
a handpiece configured to contact skin tissue of a subject; and
a block in the console, wherein the block is:
configured to selectively receive fluid from the first container when the first container is connected to the console;
configured to selectively receive fluid from the at least one additional container when the at least one additional containers is connected to the console; and,
configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console;
a vacuum source, wherein the console comprises the vacuum source; and
wherein the handpiece is configured to be in fluid communication with the vacuum source through a second conduit when the handpiece is connected to the console;
wherein when the handpiece, the first container, the at least one additional container and a waste container are each connected to the console, the first container contains a first treatment fluid, and the at least one additional container contains an additional treatment fluid, the handpiece is in fluid communication with the vacuum source and the waste container through the second conduit; and
the system is configured to deliver the first treatment fluid contained in the first container and the additional treatment fluid contained in the at least one additional container to the handpiece sequentially.

I address each limitation of this claim below.

1. "A system for treating skin, the system comprising:"

53. In my opinion, each of the Syndeo, Elite, Allegro, and Tower is "a system for treating skin."

54. The Syndeo IFU, for example, describes the Syndeo as a "System [that] is intended to abrade (exfoliate) the upper layers of the Skin." EX2030 at 4. The

Syndeo IFU also describes a step of the treatment by stating "Place tip against skin to occlude and dab skin solution onto skin." *Id.* at -19.

55. I also confirmed the Syndeo is "a system for treating skin" after examining a Syndeo device. Below is a photo[3] of the Syndeo device I inspected:



(Syndeo).

56. The Elite IFU describes the Elite as a "System [that] is intended to abrade (exfoliate) the upper layers of the skin." EX2031 at 4.

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

[3] All photos of the Syndeo, Allegro, and Elite are photos I personally took during inspections of each device. All photos of the Tower were provided by counsel and obtained at my direction.



(Elite).

58. The Allegro IFU describes a system that is "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." EX2032 at 4.

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



(Allegro).

60. The Tower Owner's Manual describes the Tower as 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." EX 2033 at 3.

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



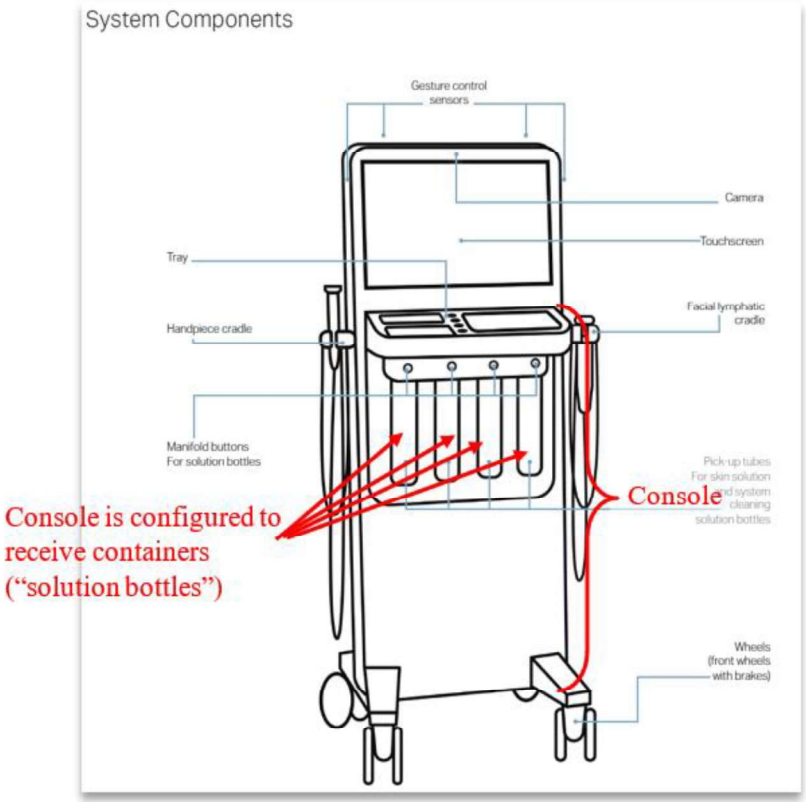
(Tower).

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

2. "a console configured to receive a first container and at least one additional container;"

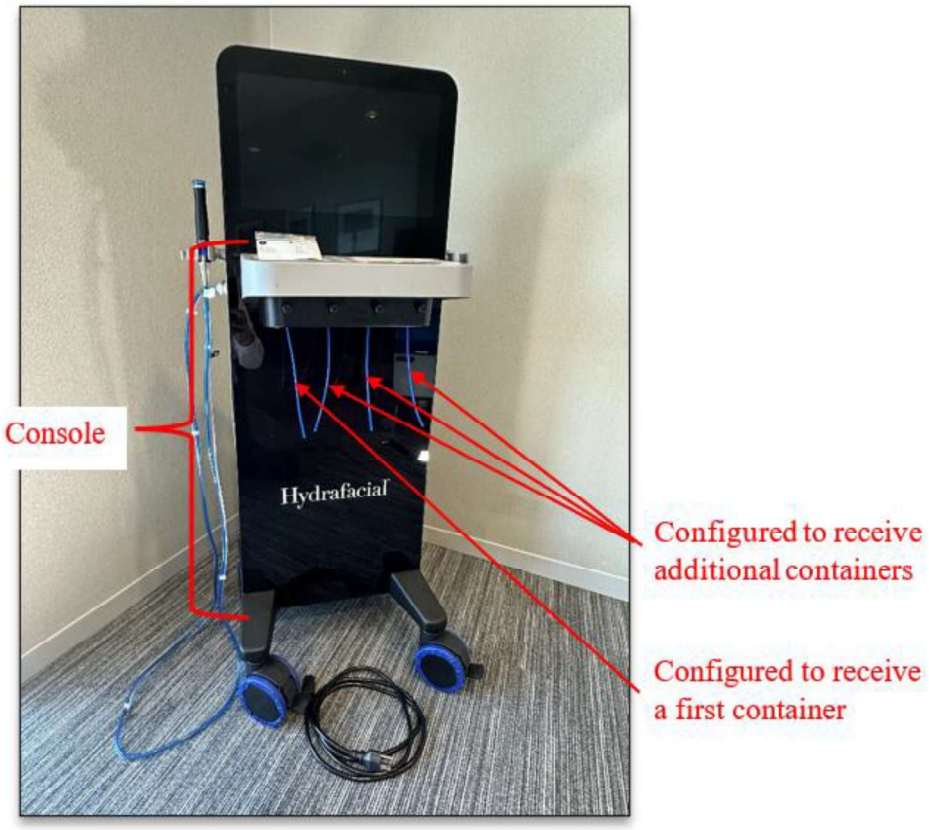
63. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a console configured to receive a first container and at least one additional container."

64. I have reviewed the Syndeo IFU, which depicts the Syndeo, including a console:

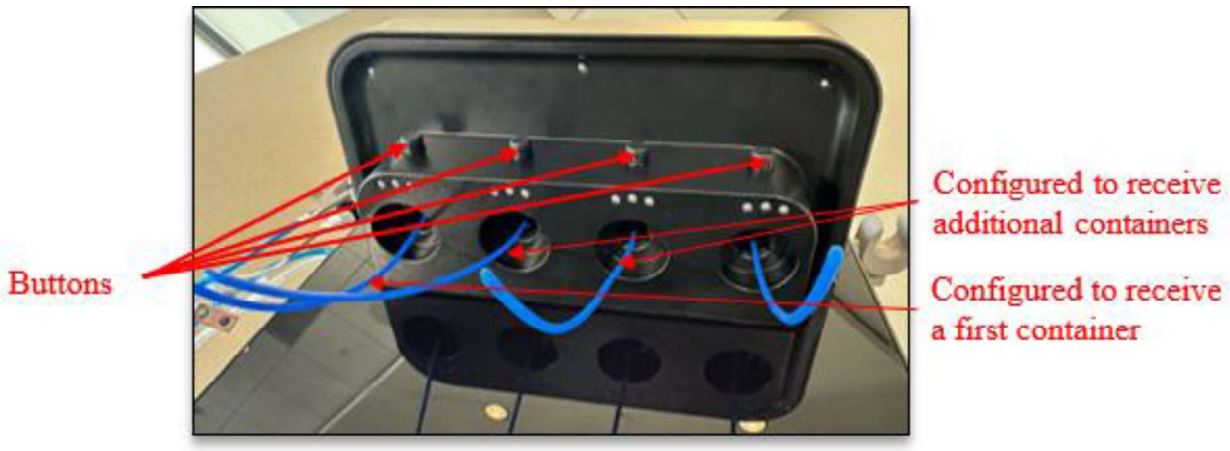


EX2030 at 10 (Syndeo). As can be seen in the image above, the console is configured to receive a first container, as well as two additional containers.

65. My inspection of the Syndeo confirmed the Syndeo has a console configured to receive a first container and at least one additional container. Below is an image of the Syndeo device I inspected, showing the Syndeo console configured to receive a first container and at least one additional container:

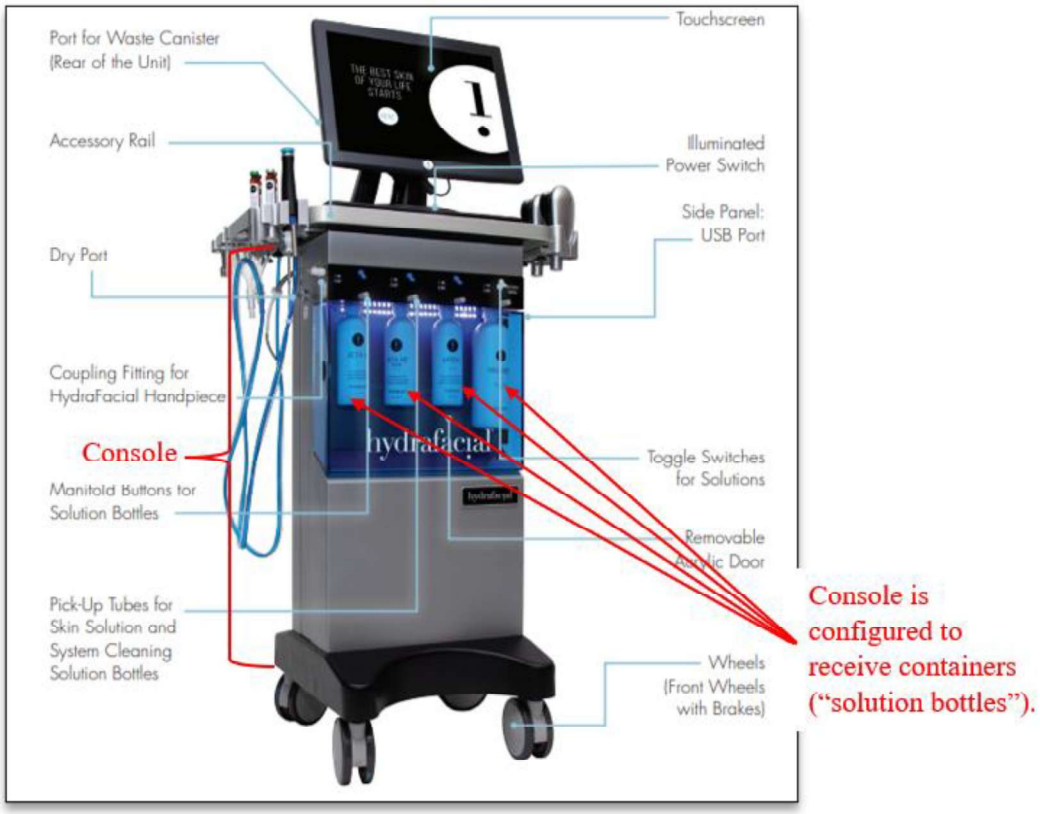


(Syndeo). The console can receive the containers when a user depresses buttons corresponding to respective containers.



66. I have also reviewed the Elite IFU, Allegro IFU, and Tower Owner's Manual, each of which depicts their respective device as a system and console

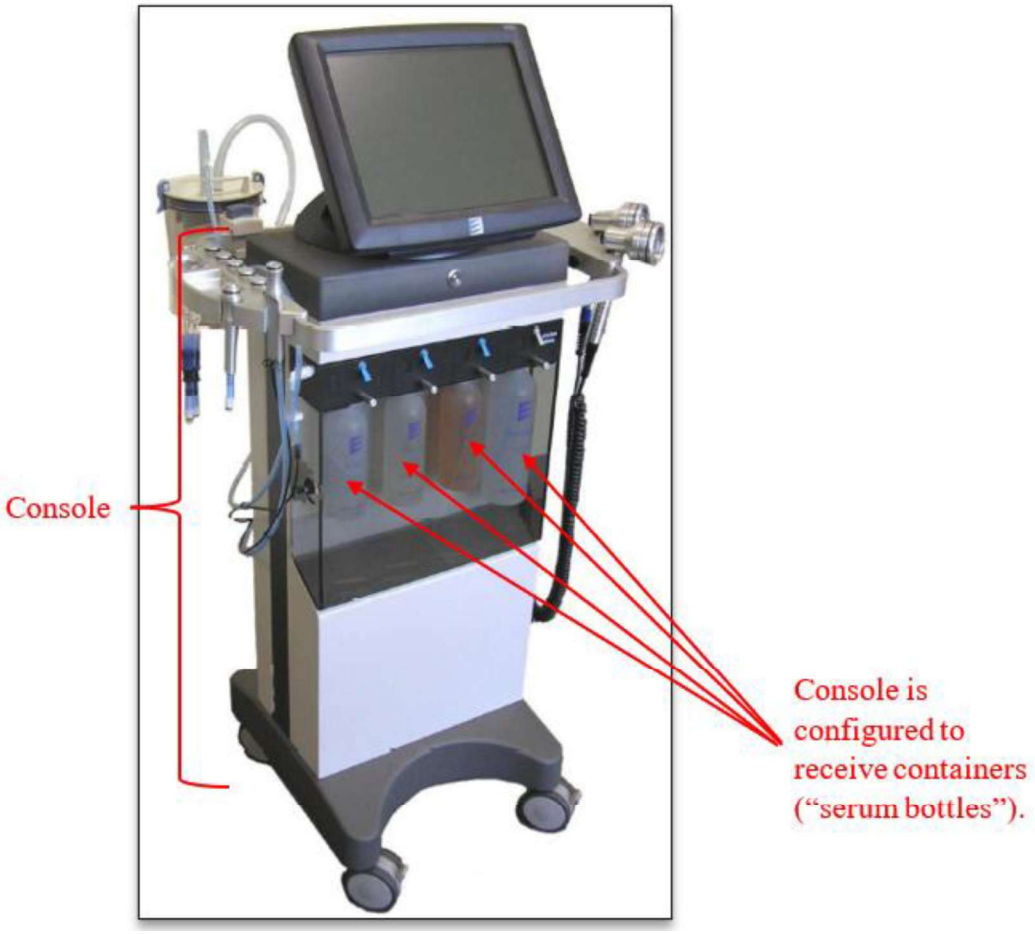
configured to receive a first container and additional containers. Annotated images from the Elite IFU, Allegro IFU, and Tower Owner's Manual are included below:



EX2031 at 10 (Elite).

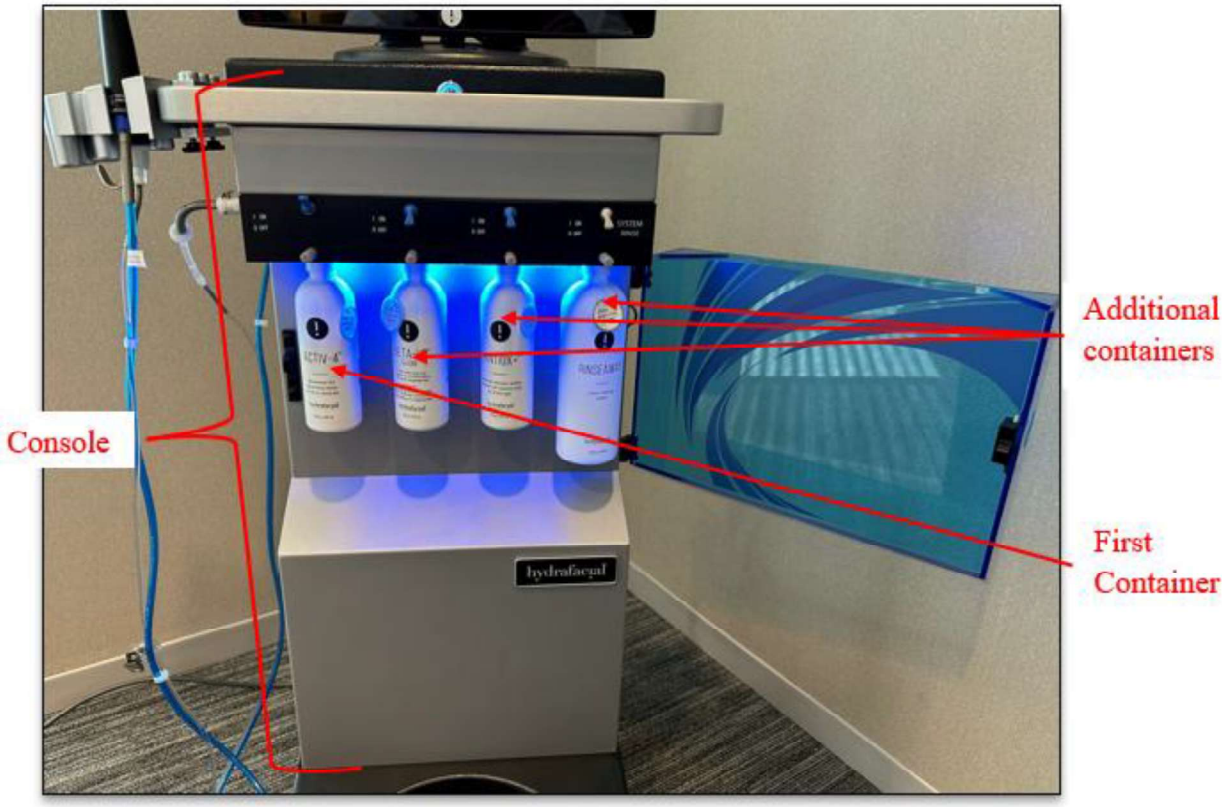


EX2032 at 8 (Allegro).

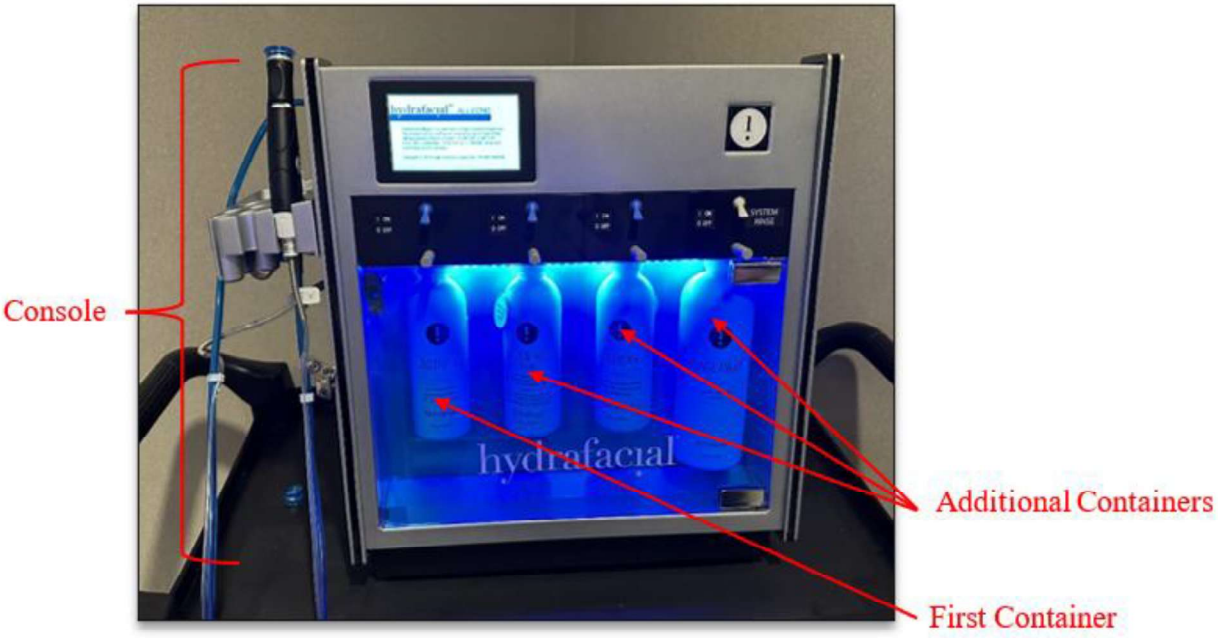


EX2033 at 1 (Tower).

67. My inspections of the Elite and Allegro confirmed that each has a console configured to receive a first container and at least one additional container. Below are images of the Elite and Allegro devices I inspected, showing the Elite and Allegro consoles, each configured to receive a first container and at least one additional container.

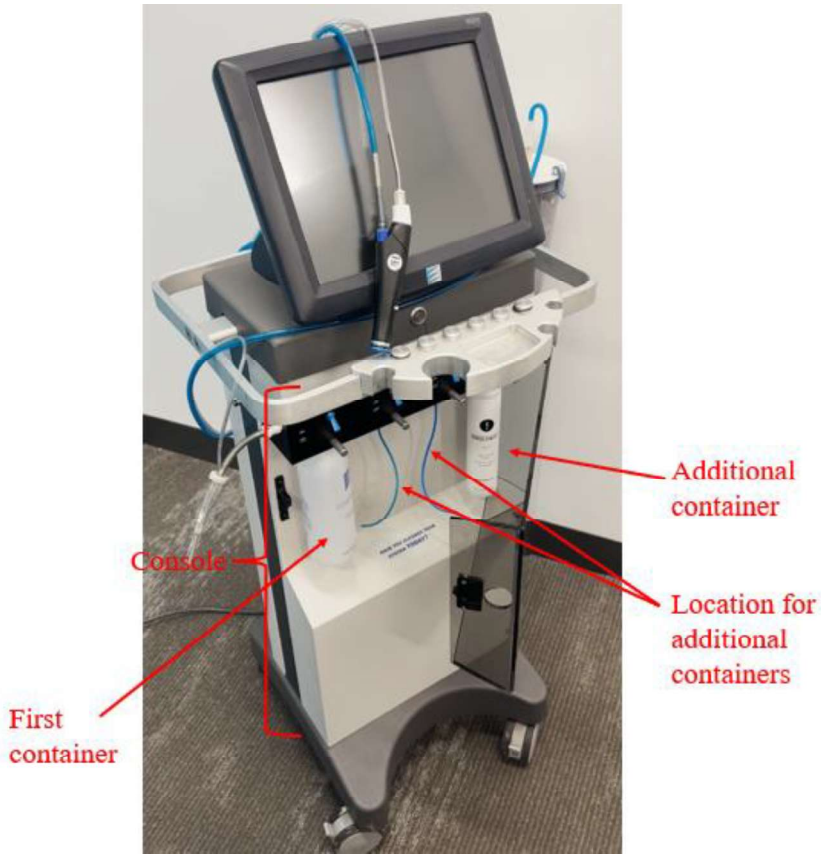

Additional containers
Console
First Container

(Elite).


Console
Additional Containers
First Container

(Allegro).

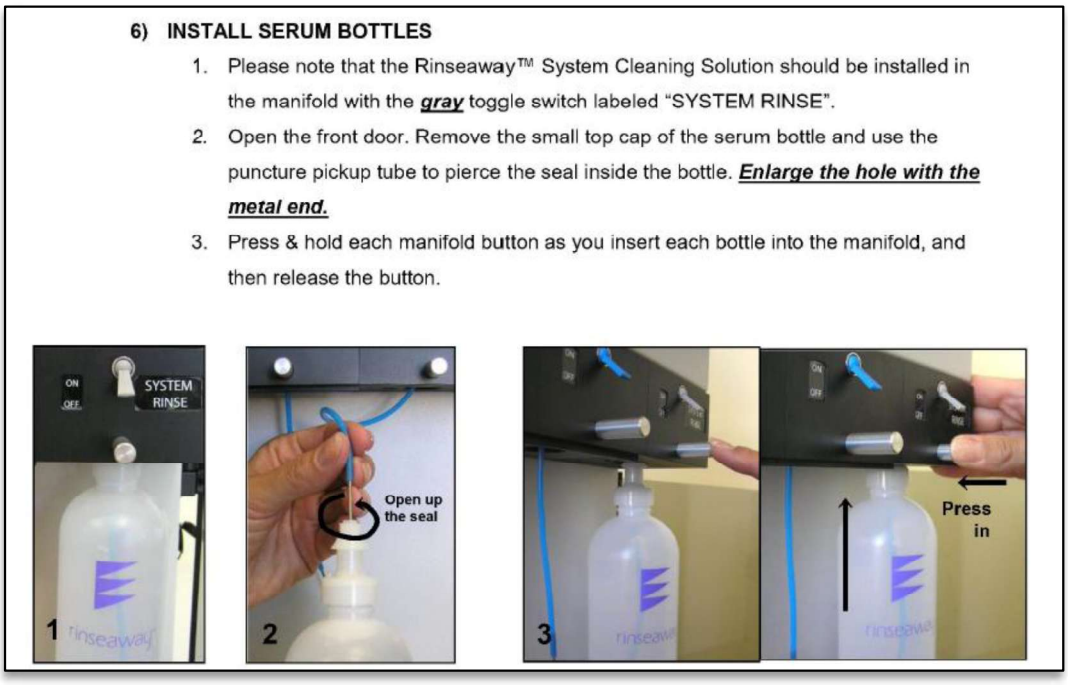
68. My review of videos and images of the Tower confirmed it has a console configured to receive a first container and at least one additional container. Below is an image of a Tower device, showing that the Tower is configured to receive a first container and at least one additional container:



(Tower).

69. As can be seen in the images above, the consoles for the Syndeo, Elite, Allegro, and Tower are each configured to receive a first container, as well as two additional containers.

70. Similarly, the Owner's Manual for the Tower provides guidance for how to "install" (connect) the serum bottles to the manifold [i.e. block], which is part of the console.



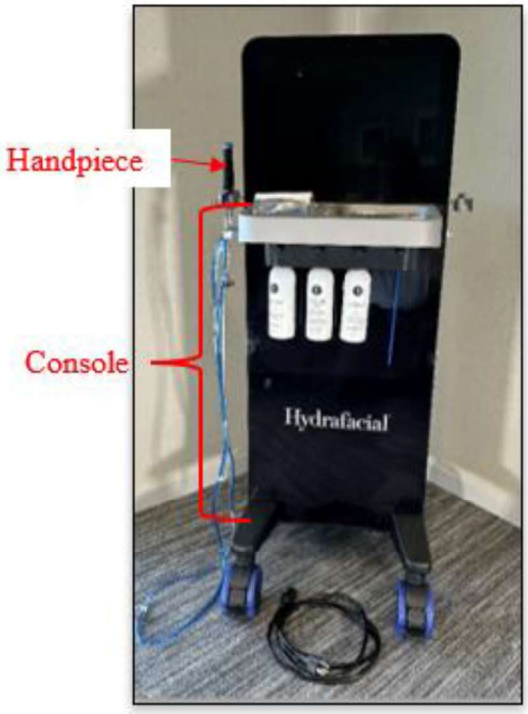
EX2033 at 13 (Tower).

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

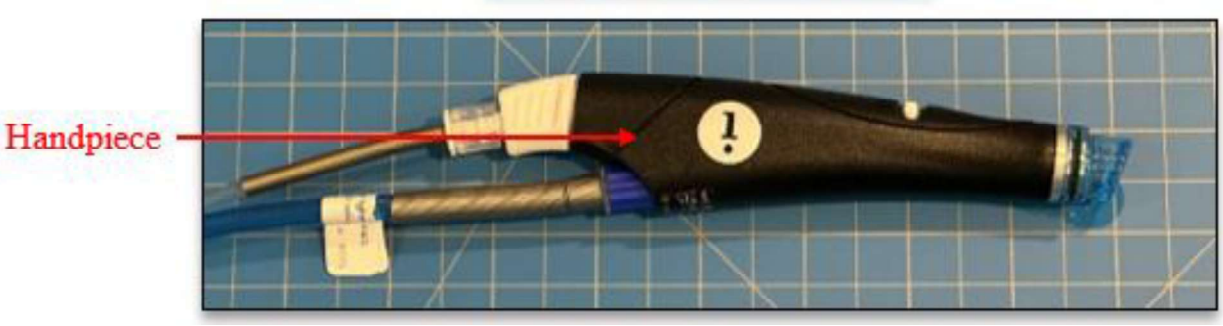
3. "a handpiece configured to contact skin tissue of a subject; and"

72. In my opinion, each of the Syndeo, Elite, Allegro, and Tower includes a "handpiece configured to contact skin tissue of a subject."

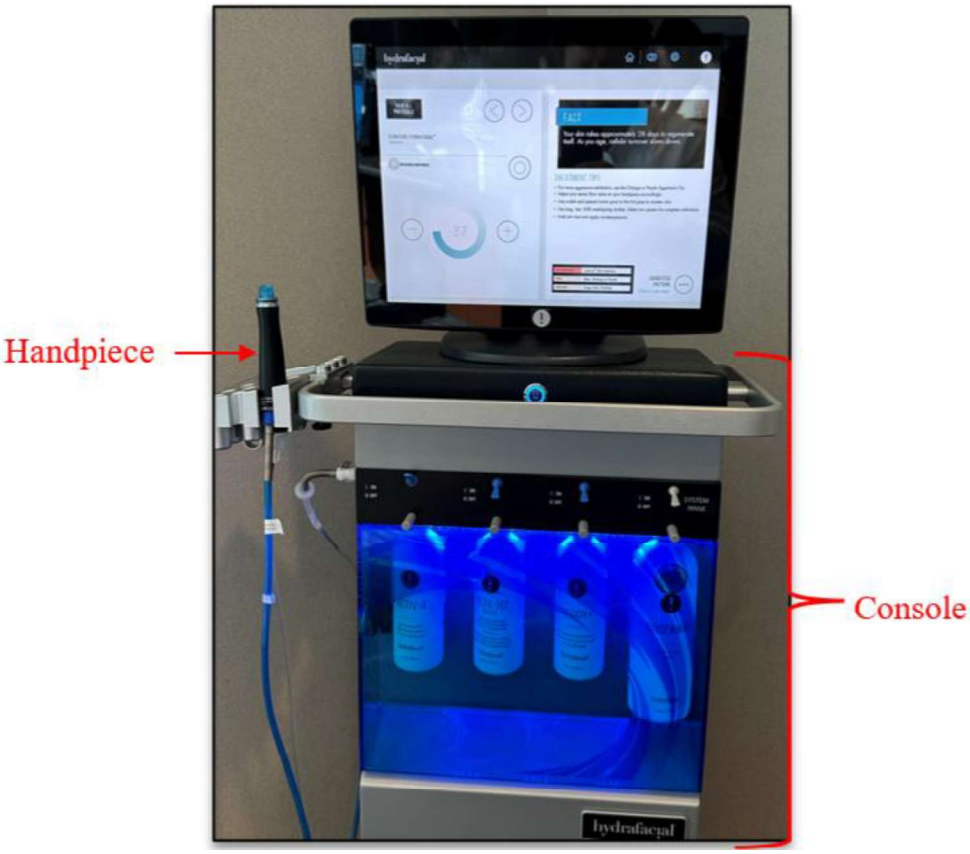
73. During my inspection of each of the Syndeo, Elite, Allegro, and Tower, I observed that each included a handpiece, as shown in the images below.



(Syndeo).



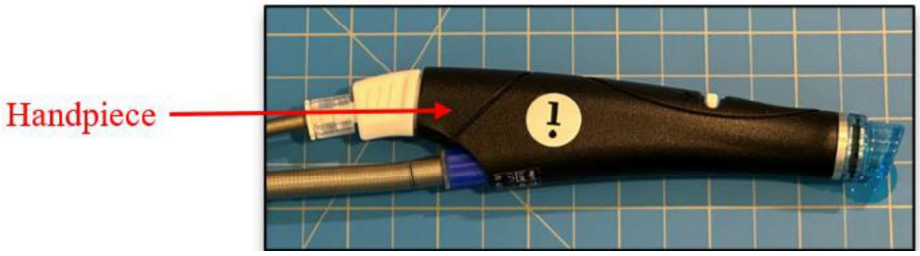
(Syndeo).


Handpiece
Console
hydrafacial

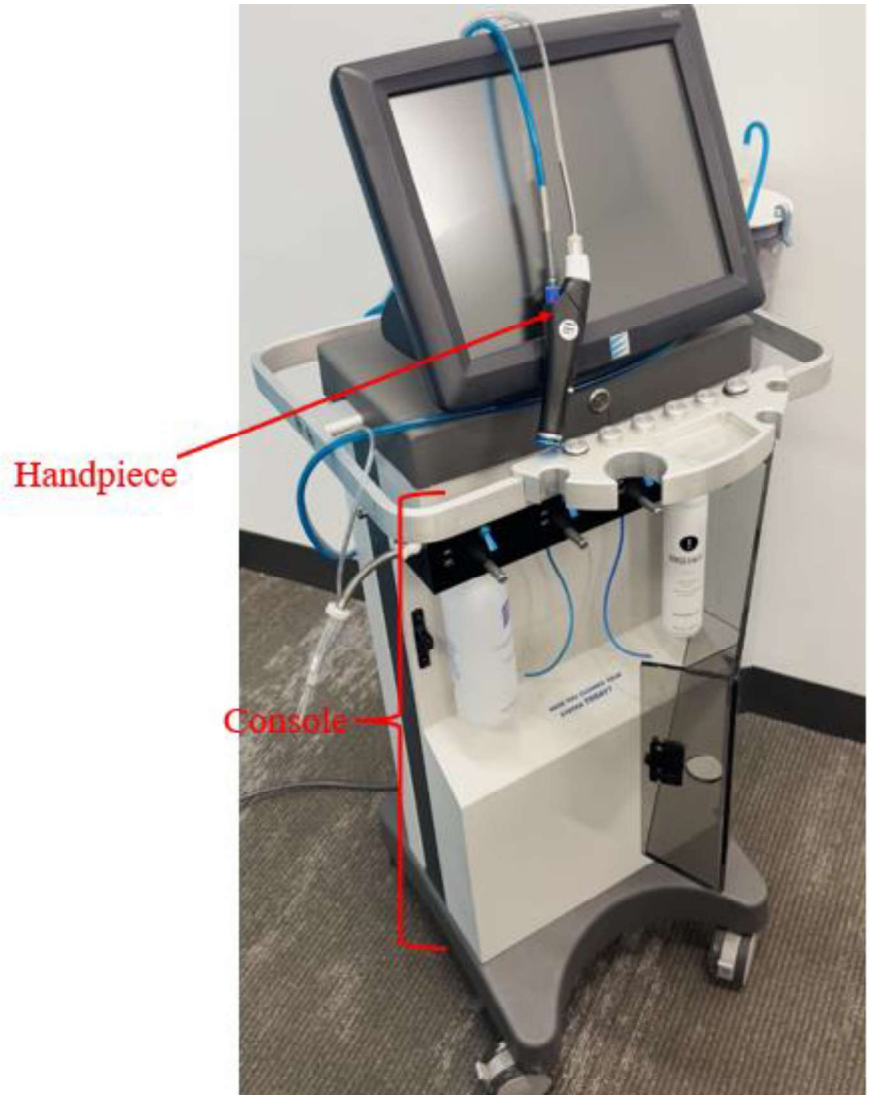
(Elite).


Handpiece
Console
SYSTEM RINSE
hydrafacial

(Allegro).

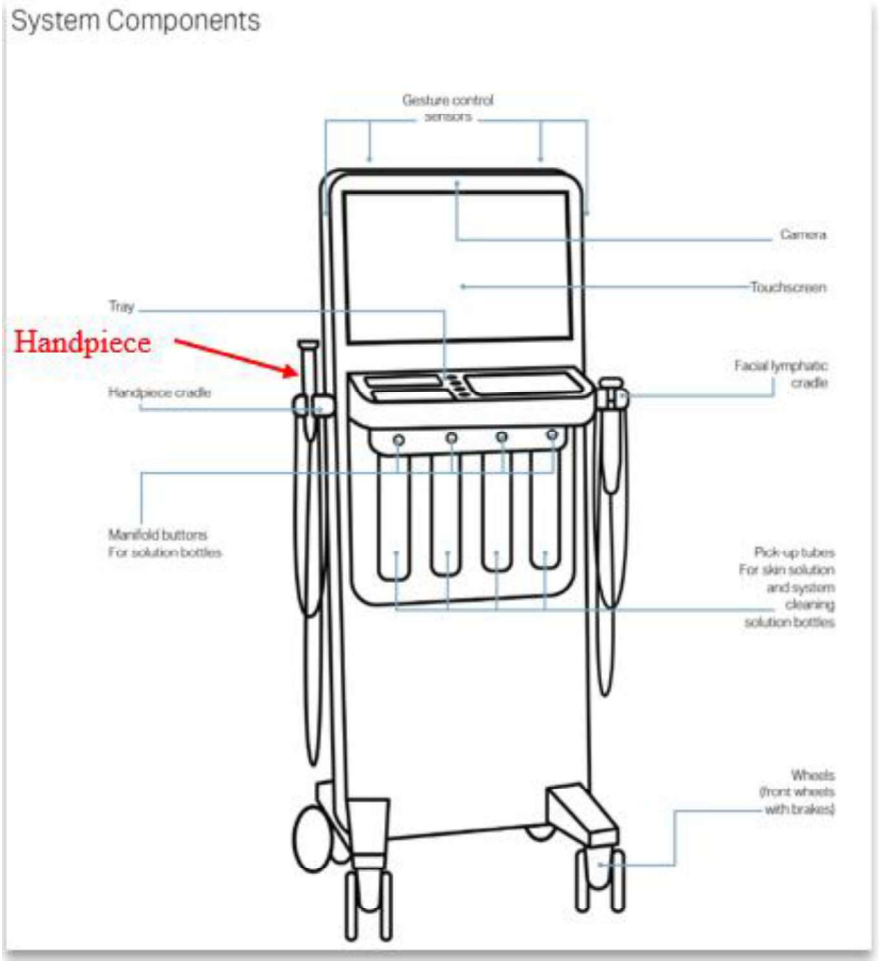


(Allegro).



(Tower).

74. In addition, the Syndeo User Manual, the Elite IFU, Allegro IFU, and Tower Owner's Manual confirm that each of the four devices includes a handpiece configured to contact skin tissue. For example, an image from the Syndeo User Manual is depicted below:



EX2030 at 10. The Syndeo IFU explains that the handpiece is used to contact the skin tissue of a subject, instructing the user to "[p]lace a tip on the handpiece," and "[p]lace tip against skin to occlude and dab skin solution onto skin." *Id.* at 19.

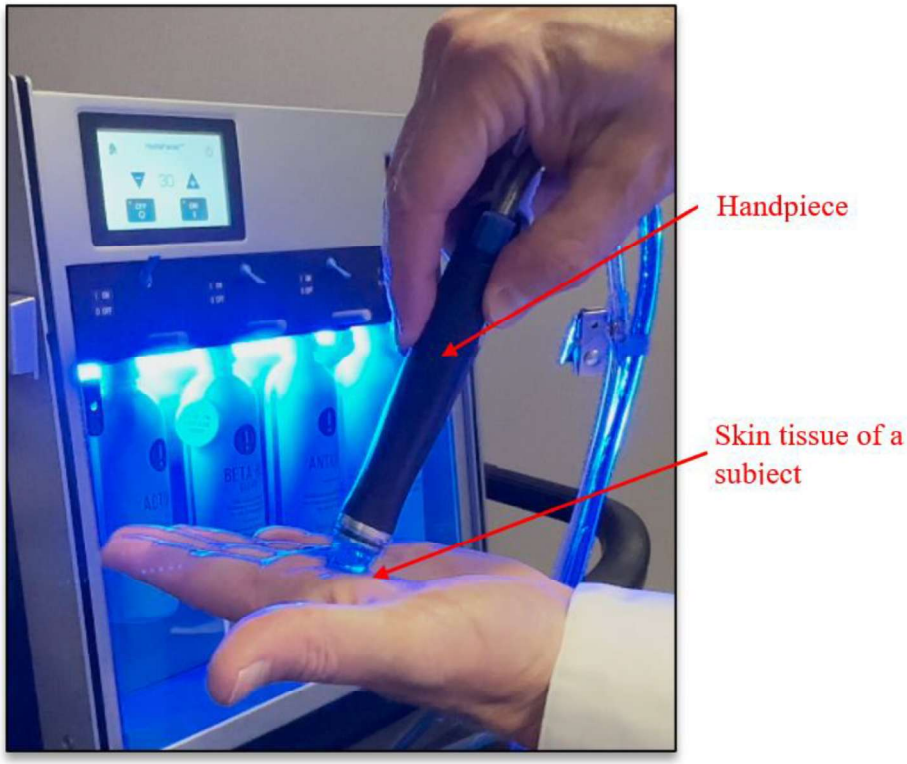
75. For all four devices, in operation, the handpiece is intended to be held in the hand and placed in contact with the skin, as confirmed by videos of the devices in operation. A screenshot from the video shows the handpiece in contact with skin tissue. From this, I concluded the handpiece is configured to contact skin tissue of a subject, as shown below.



(Syndeo).



(Elite).



(Allegro).

76. Given the similarity between the Tower handpiece and Allegro and Elite handpieces, I have concluded that the Tower handpiece would contact the skin tissue of a subject, similar to the images above.

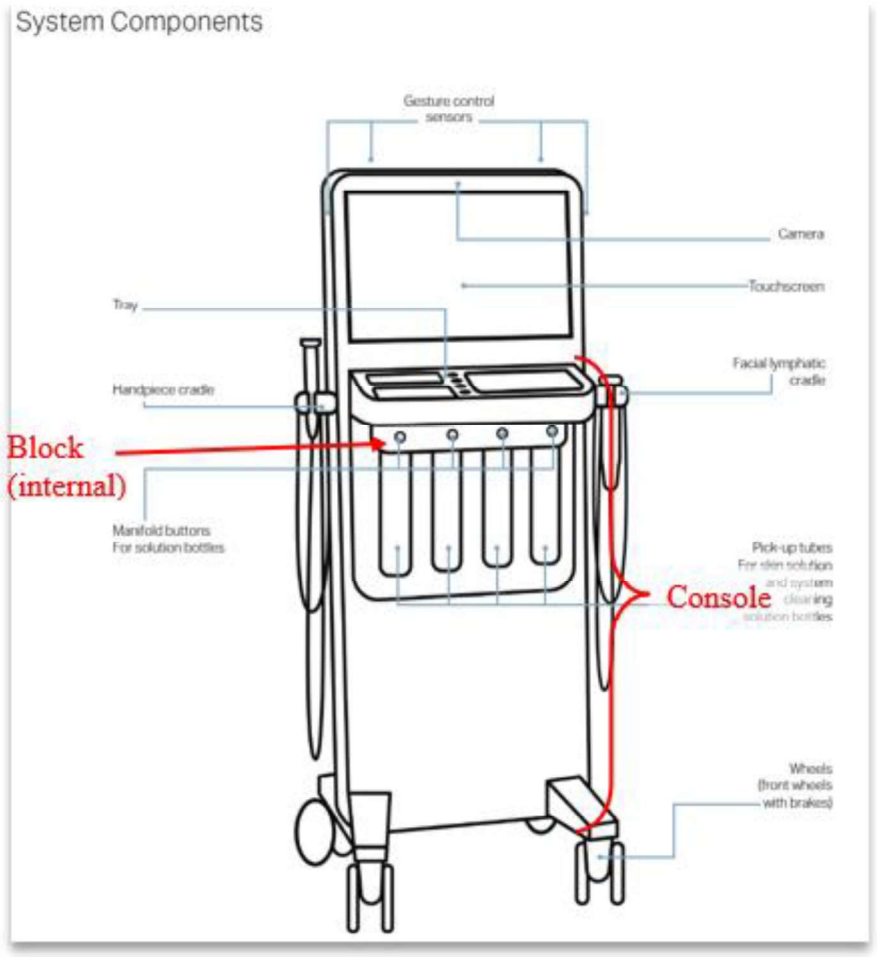
77. Accordingly, this limitation is satisfied by each of the Syndeo, Elite, Allegro, and Tower.

4. "a block in the console, wherein the block is:"

78. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a block in the console."

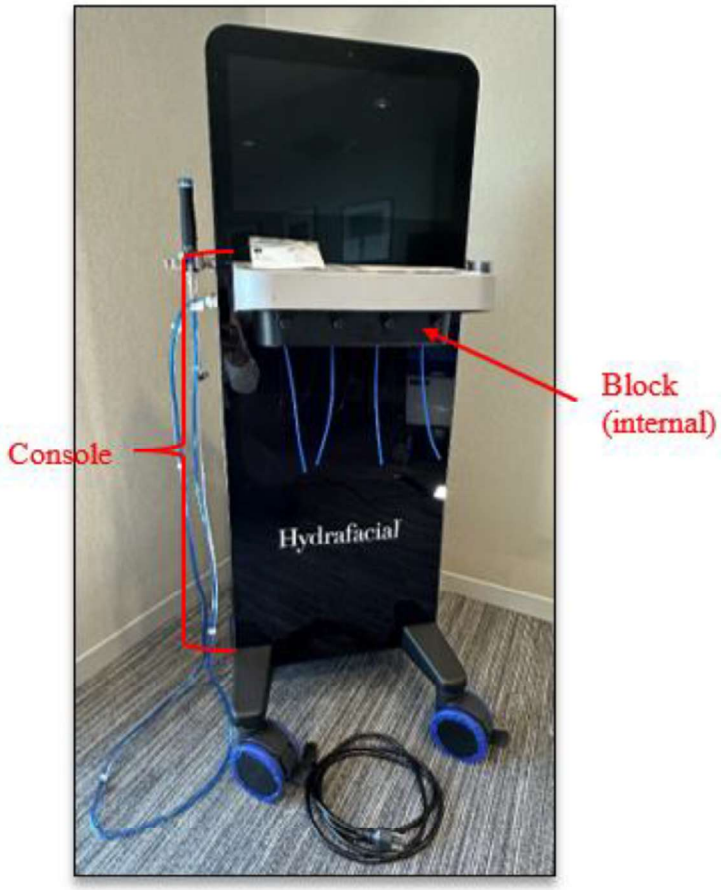
79. Section VII.A.4 discusses how the Syndeo meets this limitation and related sub-limitations (identified below in Section VII.A.4.a-c). Section VII.A.5 discusses how the Elite, Allegro, and Tower meet this limitation and related sub-limitations (identified below in Section VII.A.5.a-c).

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

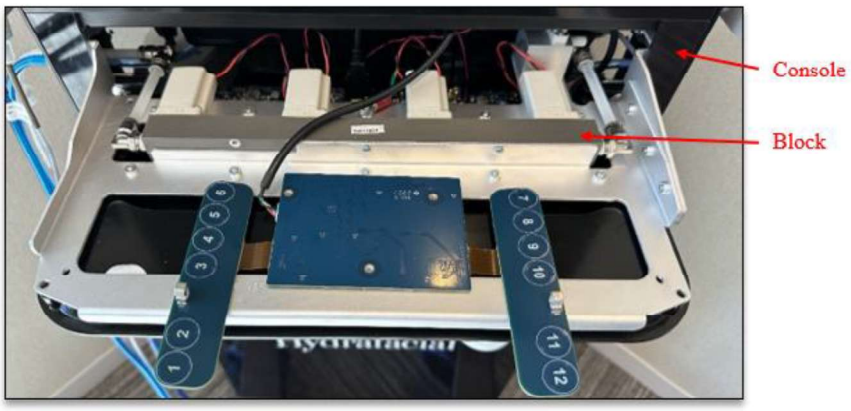


EX2030 at 10.

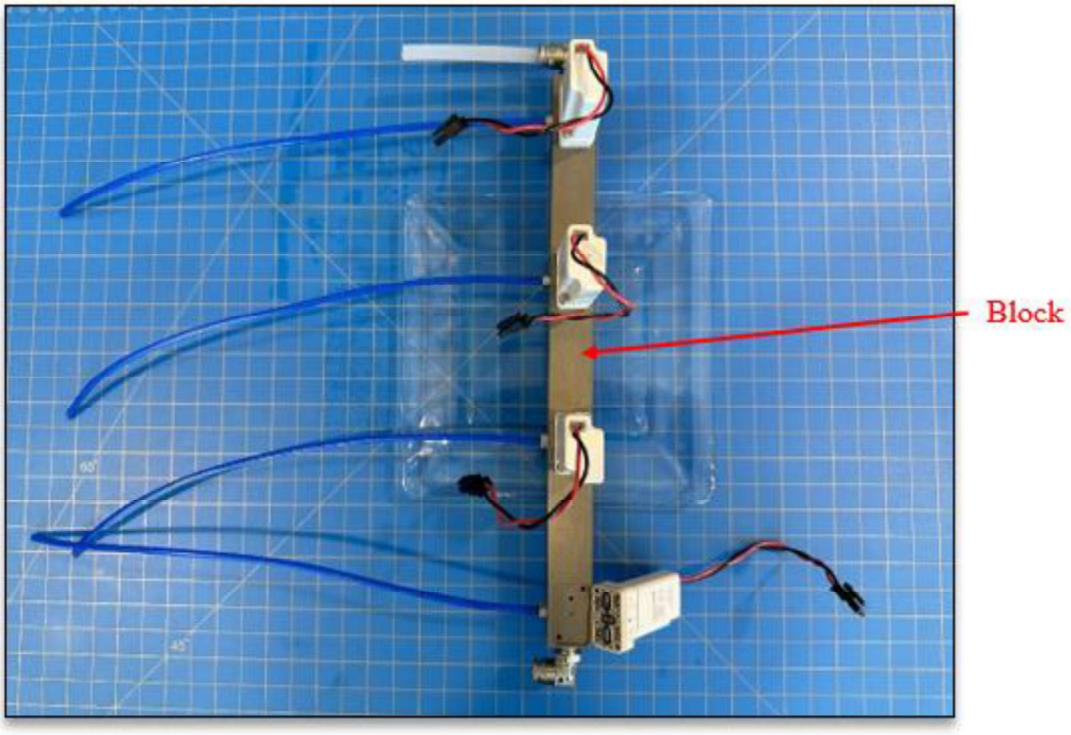
81. In addition, during my inspection of the Syndeo device, I confirmed the Syndeo system includes an internal block in the console of the device. An annotated photograph below shows the location of the internal block in the console:



82. As part of my inspection of the Syndeo, I opened the console. In the console, I observed the internal block located in the console – that is, a part with substantially flat sides. An annotated image of the block in the console of the Syndeo system is included below:



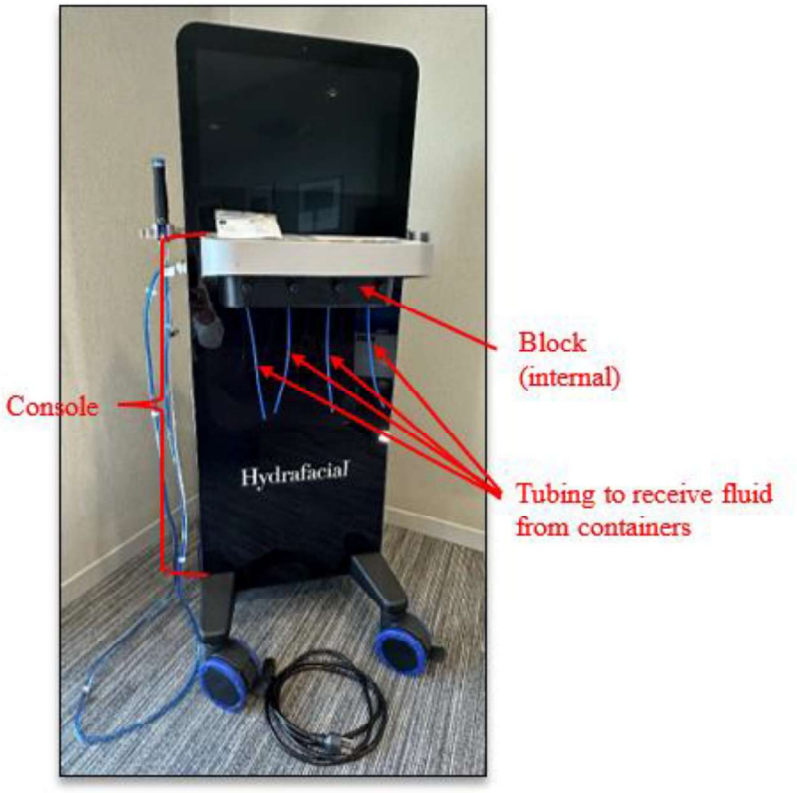
83. As part of the disassembly of the Syndeo, I observed the block in detail when removed from the console of the Syndeo system. The below photo depicts the block when removed from the Syndeo console.



a. <u>"configured to selectively receive fluid from the first container when the first container is connected to the console"</u>

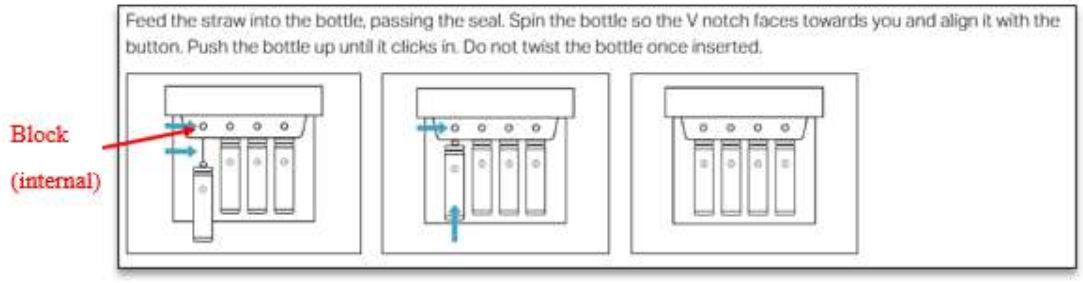
84. In my opinion, the Syndeo has "a block in the console that is configured to selectively received fluid from the first container when the first container is connected to the console."

85. My inspection of the Syndeo confirms that tubing extends from the "block" into the first container and additional container. The below images show the tubing which extends from the block into the first container and additional containers:



As can be seen in the above image, each container is connected to the console.

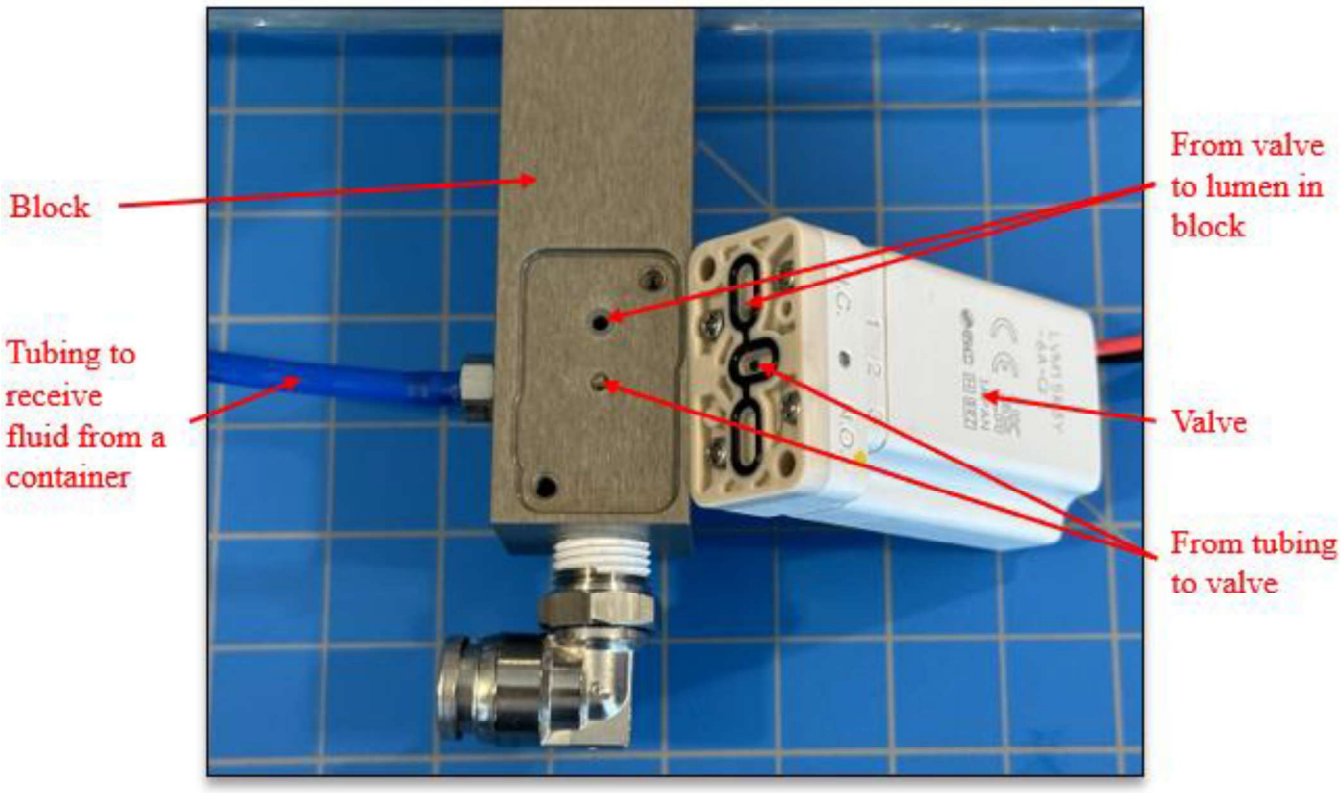
86. Images from the Syndeo IFU similarly confirm the connection between the block and the solution bottles:



EX2030 at 13. The Syndeo IFU explains the Syndeo includes "solution bottle controls [] located on the bottom of the screen within the treatment steps," and the system "automatically selects and deselects the recommended solution bottle based on the respective treatment step." *Id*. at 14.

87. An inspection of the block, separated from the console, provides additional insight regarding how the block is configured to selectively receive fluid from the first container when the first container is connected to the console. During my inspection, I observed the tubing which receives fluid from containers extends to their respective serum valves. The serum valves control which fluid reaches a lumen in the block based on which container a user selects. I have provided an annotated image below depicting how the tubing connects to the block, and the

necessary components, including the valve and lumen, which render the block configured to receive fluid from the containers.



88. A POSA would have understood that the tubing shown in the image above allows the block to selectively receive fluid from the first container (or one of the additional containers), when the first container (or additional container) is connected to the console. I note that the selected container must be connected to the console in order to complete the closed system, as the vacuum suction will draw fluid through the tubing, though the block, and through the handpiece to the skin.

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

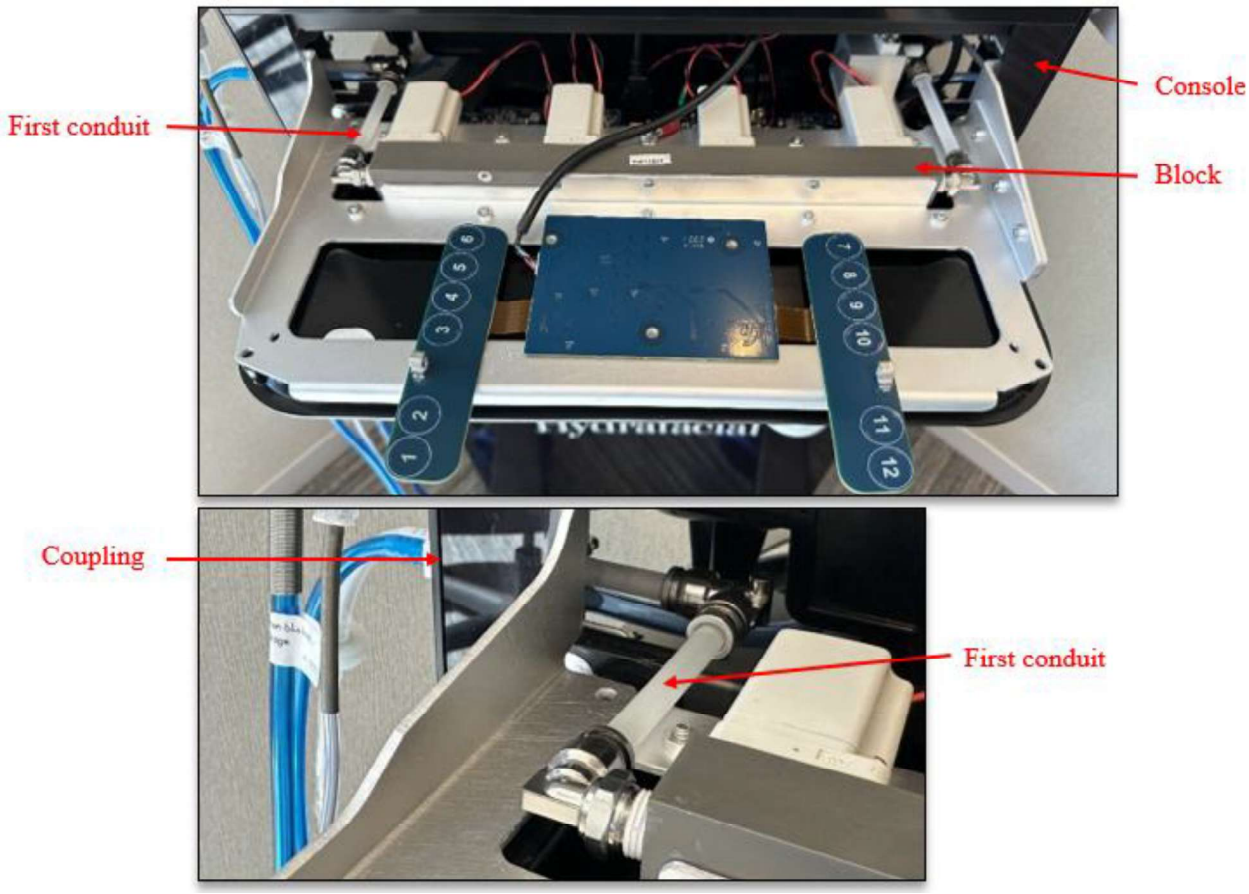
b. <u>configured to selectively receive fluid from the at least one additional container when the at least one additional containers is connected to the console; and</u>

90. This limitation is satisfied by the Syndeo for the same reasons set forth in Section VII.A.4.a above.

c. <u>configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console</u>

91. In my opinion, the Syndeo has "a block in the console that is configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console."

92. Based on my inspection of the Syndeo, I have determined that the block is in fluid communication with the handpiece through a first conduit, as shown in the images below. As shown in the images below, the first conduit extends from the block, where it eventually meets a coupling location.



The first conduit continues through the tubing to the handpiece itself.



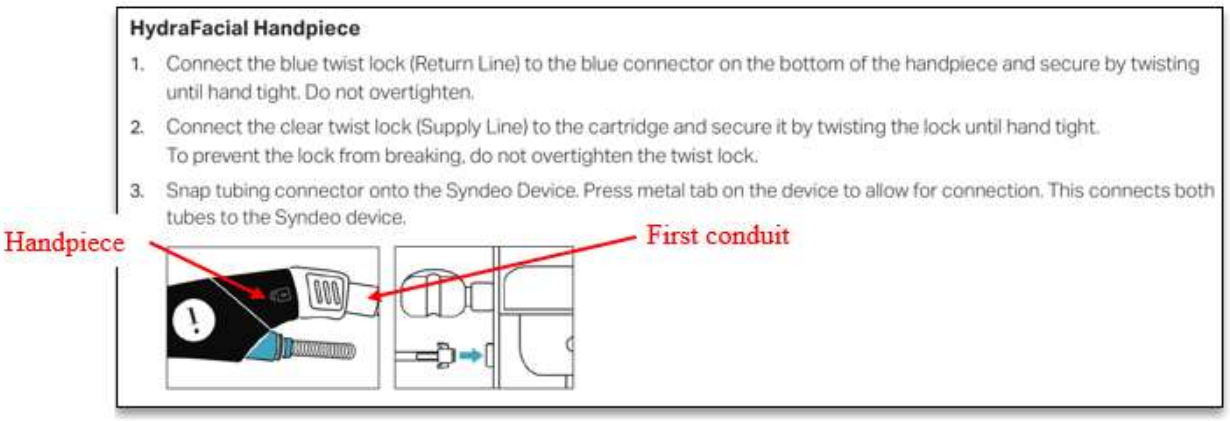
93. As illustrated above, the tubing that connects to the handpiece contains the first conduit. This first conduit continues through the handpiece, to an opening in the main body of the handpiece. As designed, fluid flows from the containers, through the block and first conduit (including through the handpiece) and ultimately through the opening in the main body of the handpiece.



94. The block is "selectively in fluid communication" through this first conduit in two ways. First, by selectively attaching a container. When a selected container is disconnected, the circuit cannot be completed and "fluid communication" ceases to exist between the block and the handpiece. Second, the handpiece can be selectively detached from the console. When detached, the circuit cannot be completed and "fluid communication" again ceases to exist between the block and the handpiece.

95. The Syndeo IFU confirms my understanding that the Syndeo has a block in the console that is configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console.

96. The Syndeo IFU describes connecting the "Supply Line" between the handpiece and the console. I have annotated an image from the IFU below, identifying the handpiece and first conduit, and showing the supply line that connects the handpiece to the console.



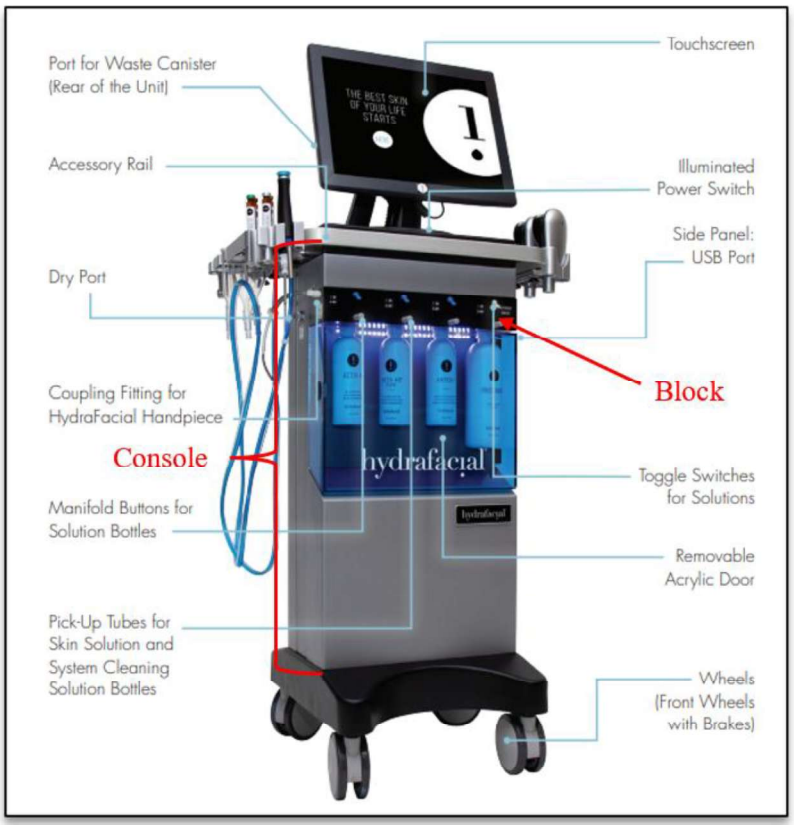
EX2030 at 12.

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

98. Section VII.A.5 below explains how the Elite, Allegro, and Tower similarly meet the limitation and sub-limitations discussed above for the Syndeo (*see* Section VII.A.4).

5. "a block in the console, wherein the block is:"

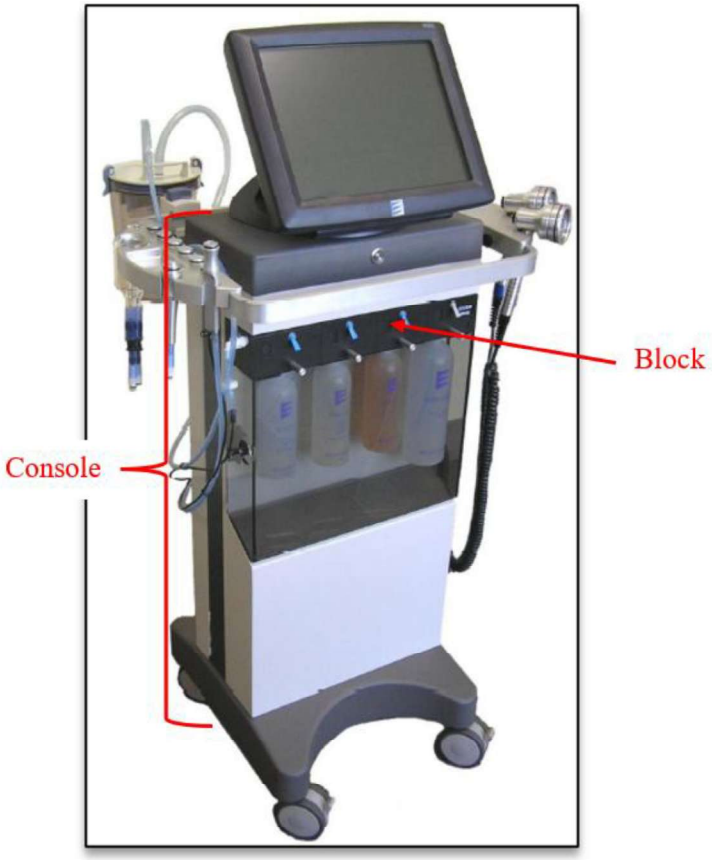
99. The Elite IFU, Allegro IFU, and Tower Owner's Manual each contains an illustration of the console with system components. I have provided an annotated version of excerpts of these documents, identifying the location of the internal block located within the console for each of the Elite, Allegro, and Tower:



EX2031 at 10 (Elite).

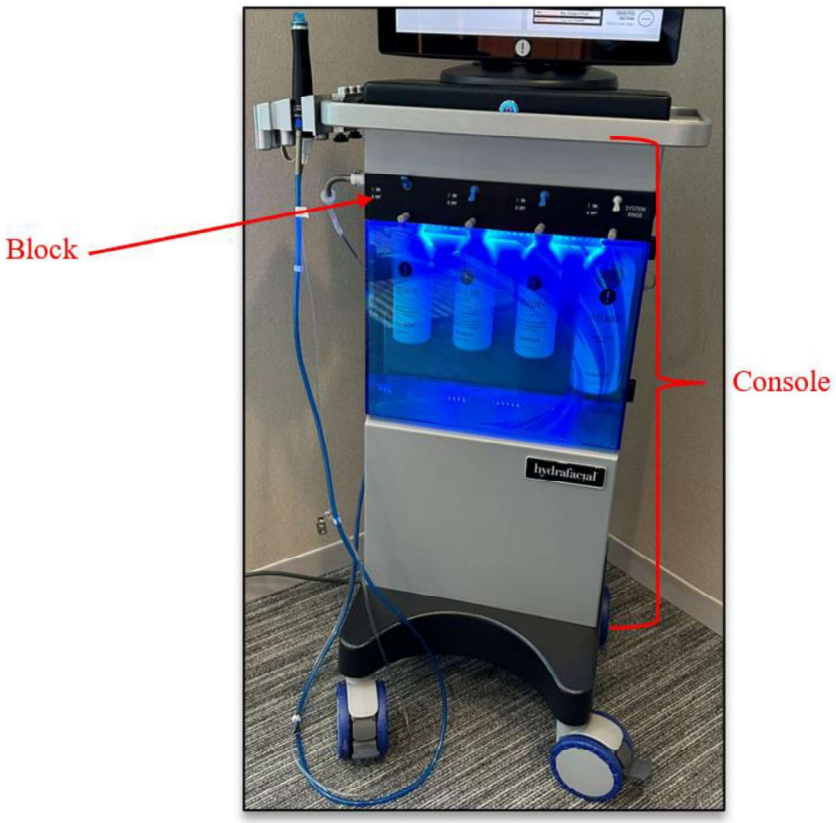


EX2032 at 7 (Allegro).



EX2033 at 1 (Tower); *see also id.* at 13 (Tower Owner's Manual referring to the Block as the "manifold").

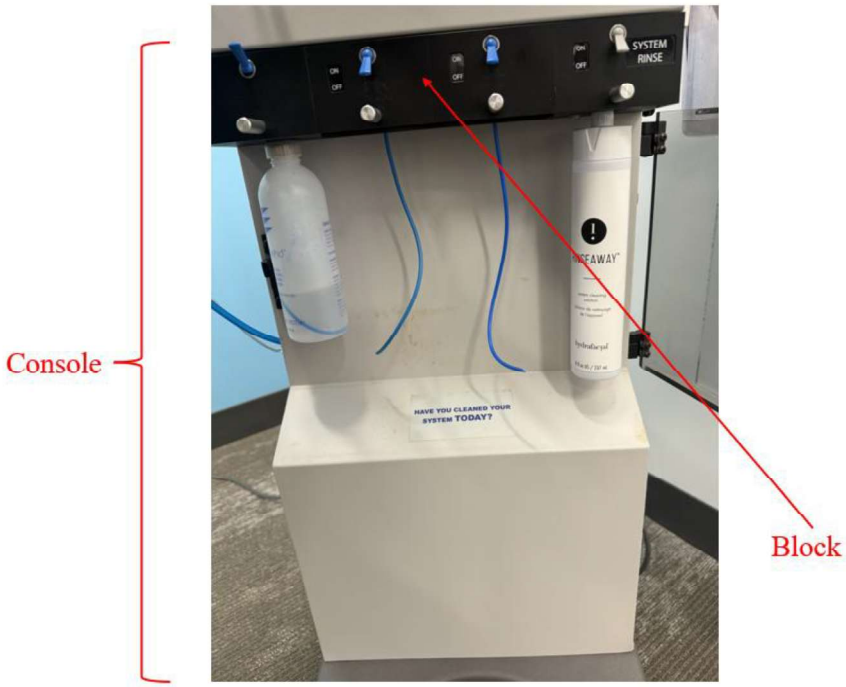
100. In addition, during my inspection of the Elite and Allegro devices, and review of photos and videos from the Tower, I confirmed that each system includes an internal block in the console of the device. Annotated photographs below show the location of the internal block in the console:



(Elite).

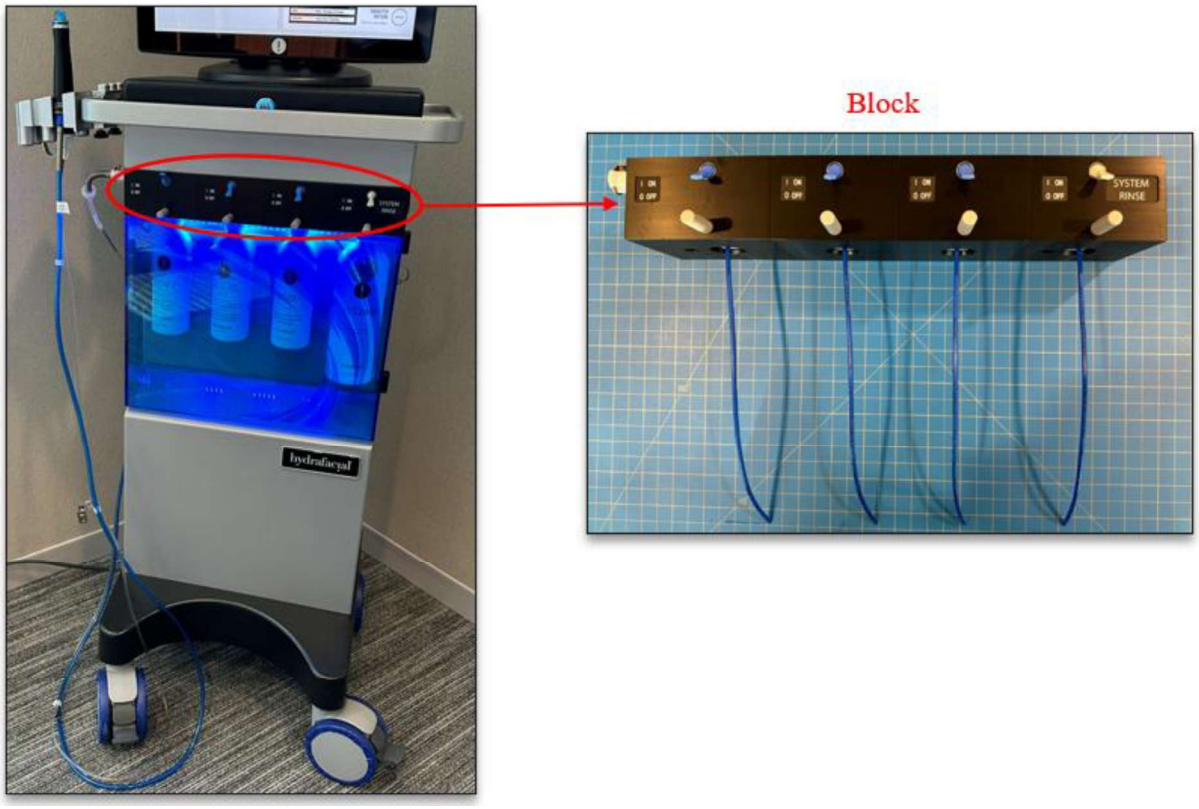


(Allegro).

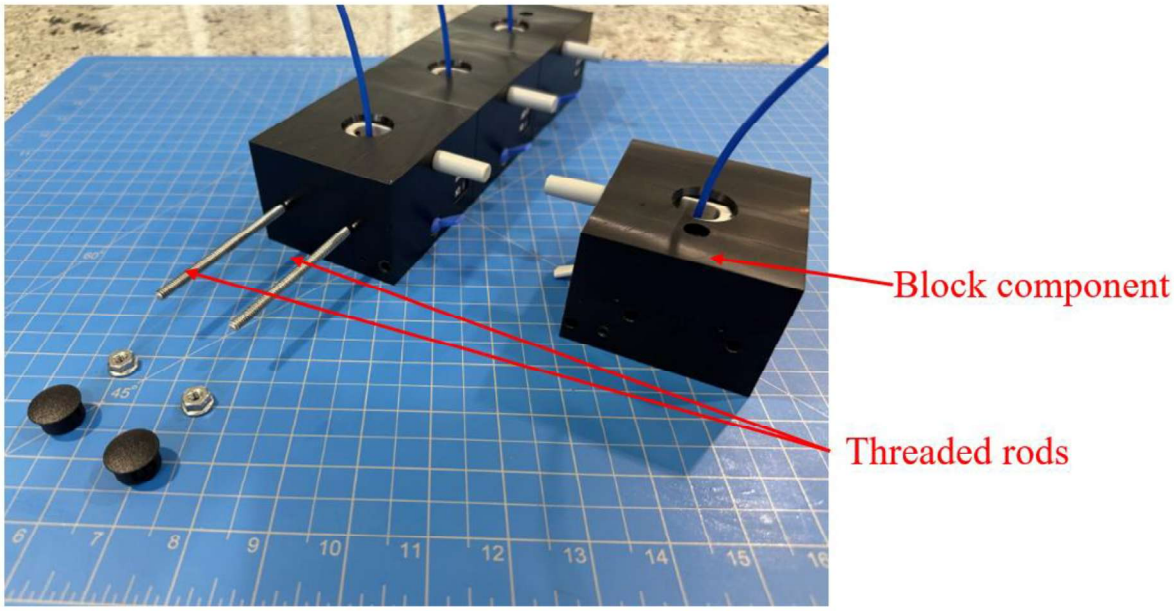


(Tower).

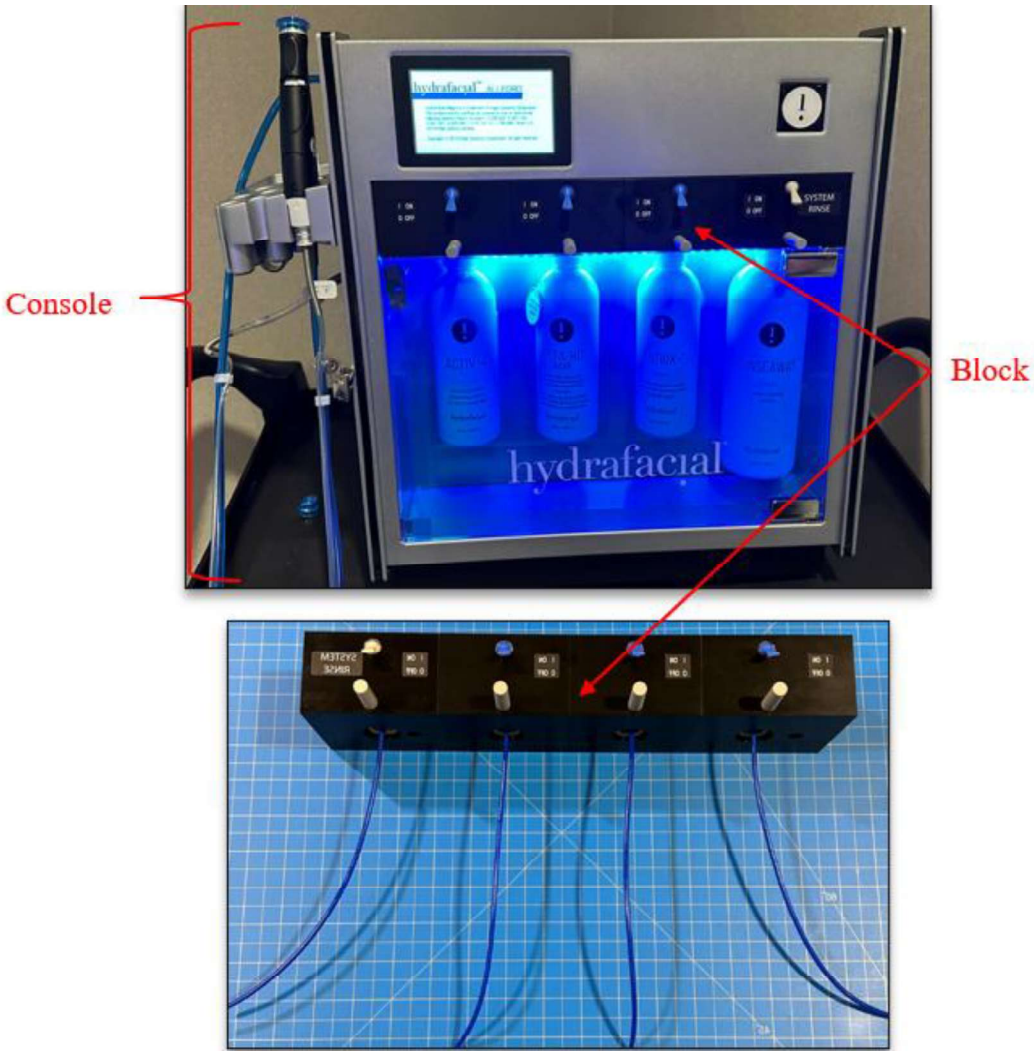
101. As part of my inspection of the Elite and Allegro, I removed the block from the console, and I observed the internal block– that is a part with substantially flat sides. I made similar observations from the images and videos of the Tower which I reviewed. The below photos accurately depict the block of the Elite, Allegro, and Tower, respectively when removed from the console:



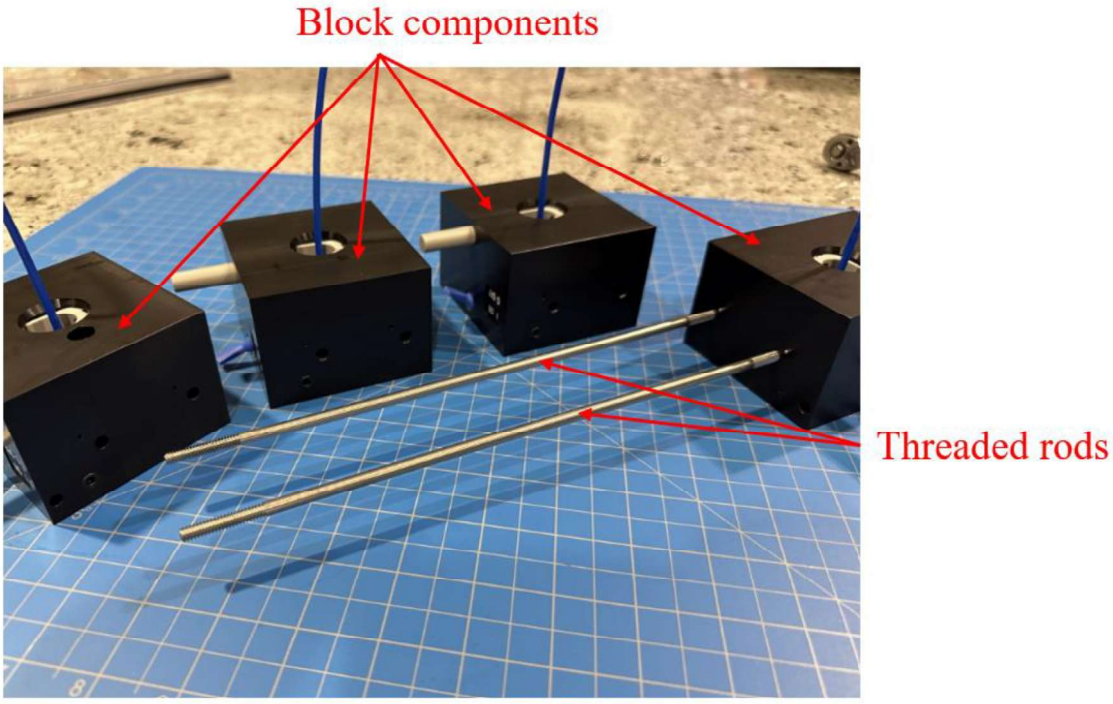
(Elite).



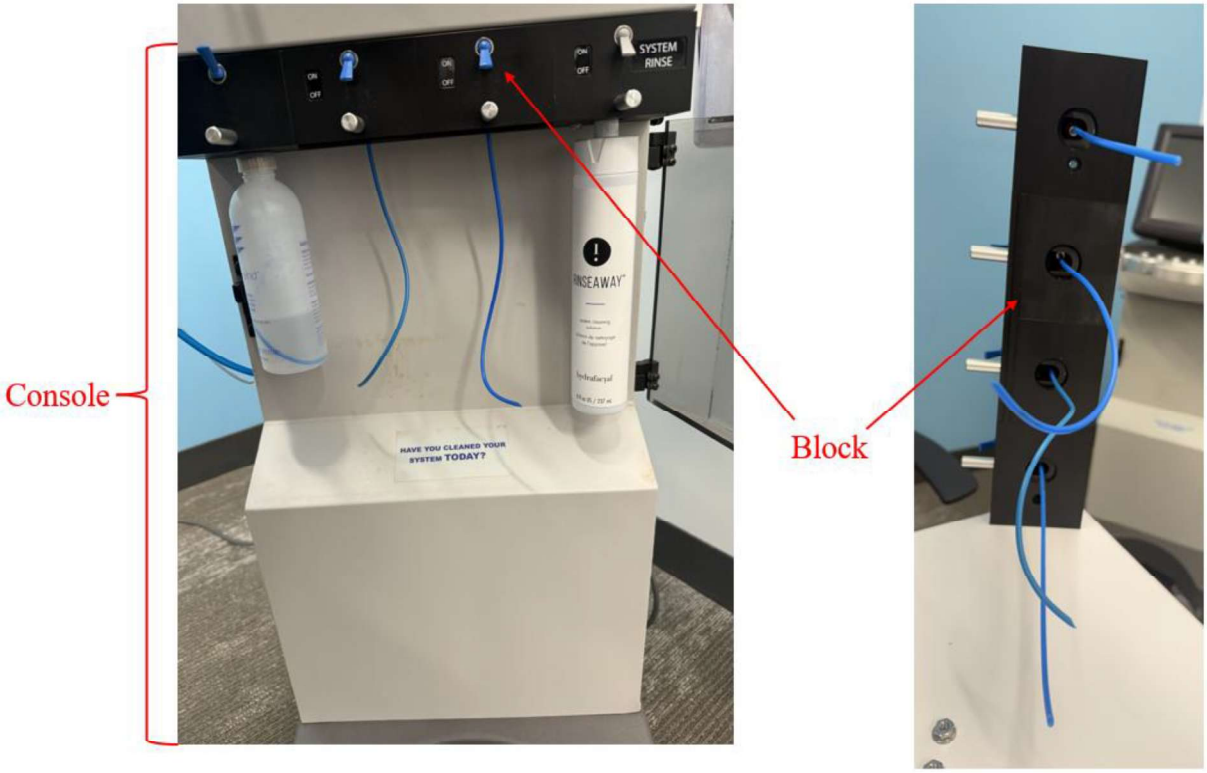
(Depicting Elite block comprised of individual components connected by two threaded rods running through the components).



(Allegro).



(Depicting Allegro block comprised of individual components that are connected together through two threaded rods running through the block).



(Tower).

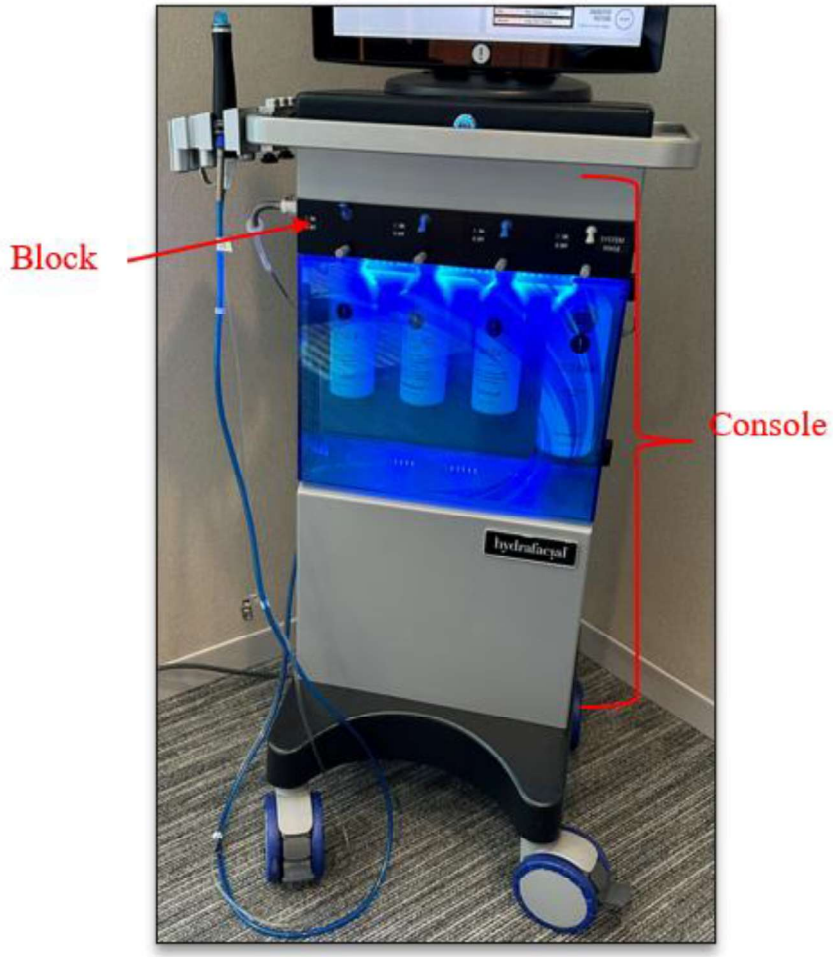
102. Accordingly, this limitation is satisfied by each of the Elite, Allegro, and Tower.

a. <u>"configured to selectively receive fluid from the first container when the first container is connected to the console"</u>

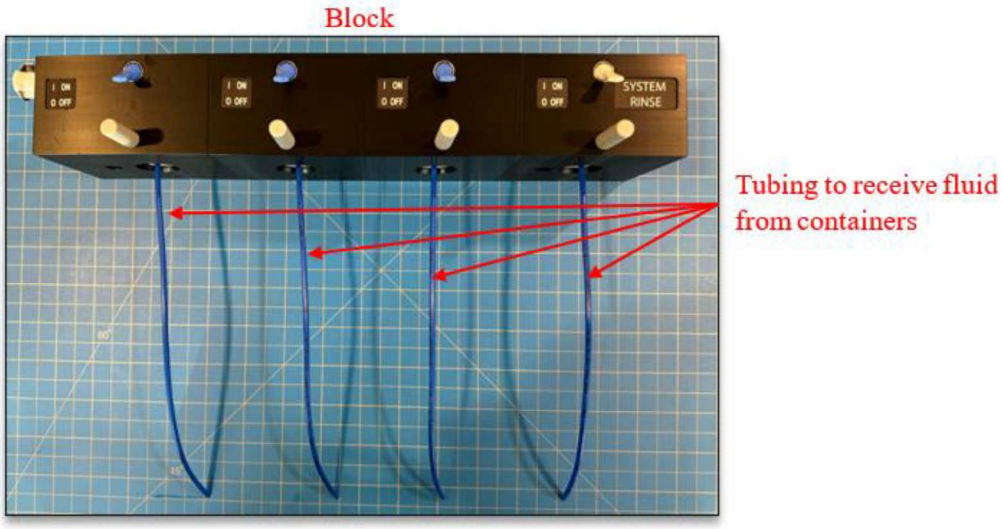
103. In my opinion, the each of the Elite, Allegro, and Tower has "a block in the console that is configured to selectively received fluid from the first container when the first container is connected to the console."

104. My inspection of the Elite and Allegro, and review of images and videos of the Tower, confirms that tubing extends from the "block" into the first

container and additional container. The below images show the tubing which extends from the block into the first container and additional containers:



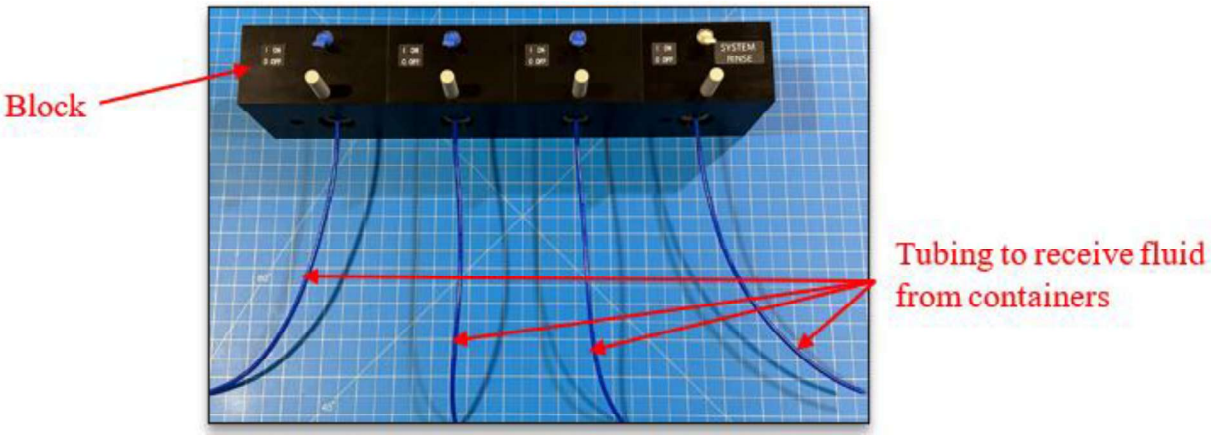
(Elite).



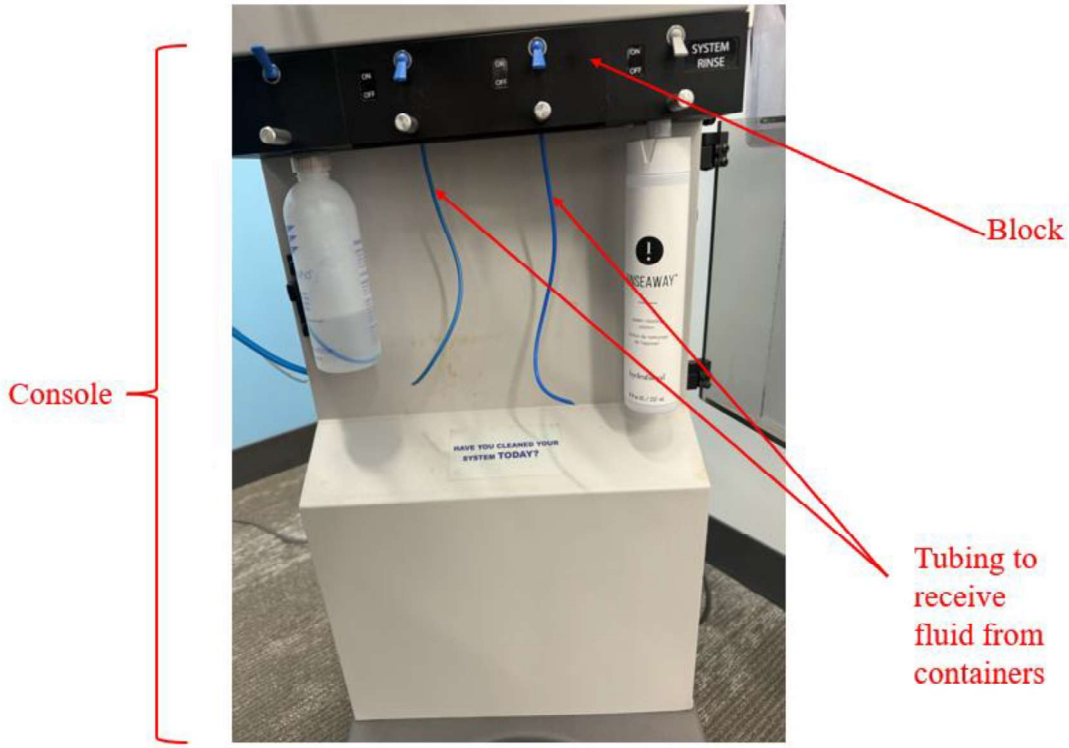
(Elite).



(Allegro).



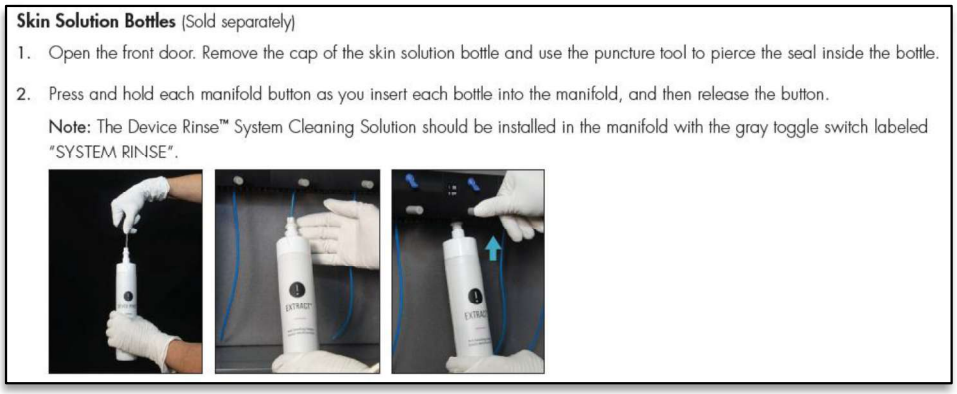
(Allegro).



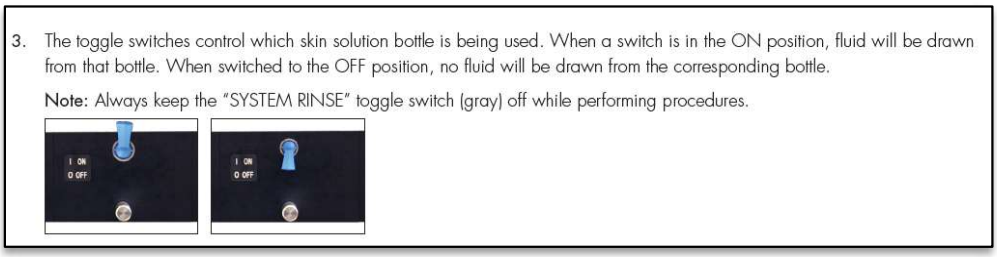
(Tower).

105. As can be seen in the above image, for each of the Elite, Allegro, and Tower, multiple containers are or can be connected to the console.

106. The Elite IFU, Allegro IFU, and Tower Owner's Manual similarly confirm the connection between the block and the solution bottles. Specifically, each describes connecting the containers, including the first container, to the console such that the block is configured to selectively receive fluid from the containers:



EX2031 at 13 (Elite).



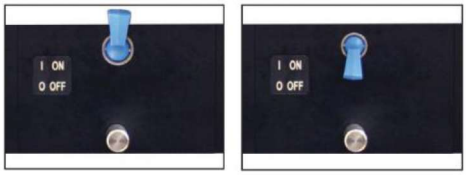
EX2031 at 14 (Elite).

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".



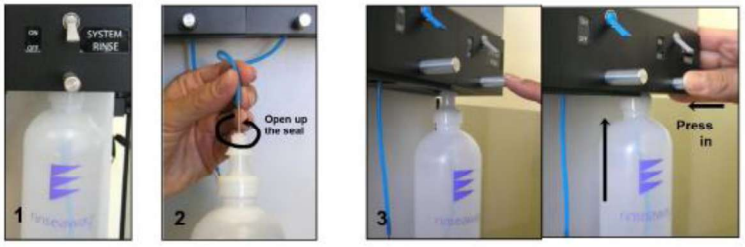
3. The toggle switches control which skin solution bottle is being used. When a switch is in the ON position, fluid will be drawn from that bottle. When switched to the OFF position, no fluid will be drawn from the corresponding bottle.
   Note: Always keep the "SYSTEM RINSE" toggle switch (gray) off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



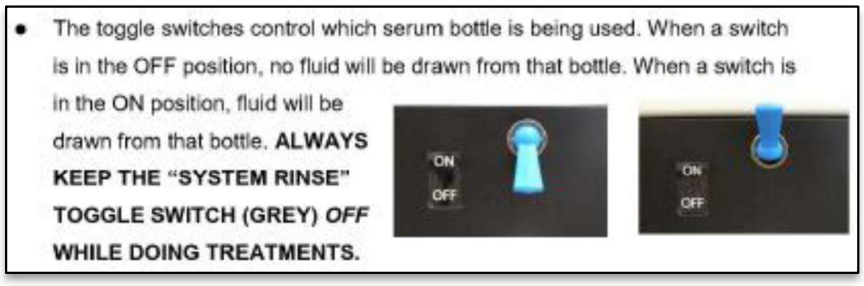
EX2032 at 11 (Allegro).

6) INSTALL SERUM BOTTLES

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



EX2033 at 13 (Tower).



EX2033 at 13 (Tower).

107. A POSA would have understood that the tubing shown in the image above allows the block to selectively receive fluid from the first container (or one of the additional containers), when the first container (or additional container) is connected to the console. I note that the selected container must be connected to the console in order to complete the closed system, as the vacuum suction will draw fluid through the tubing, though the block, and through the handpiece to the skin.

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

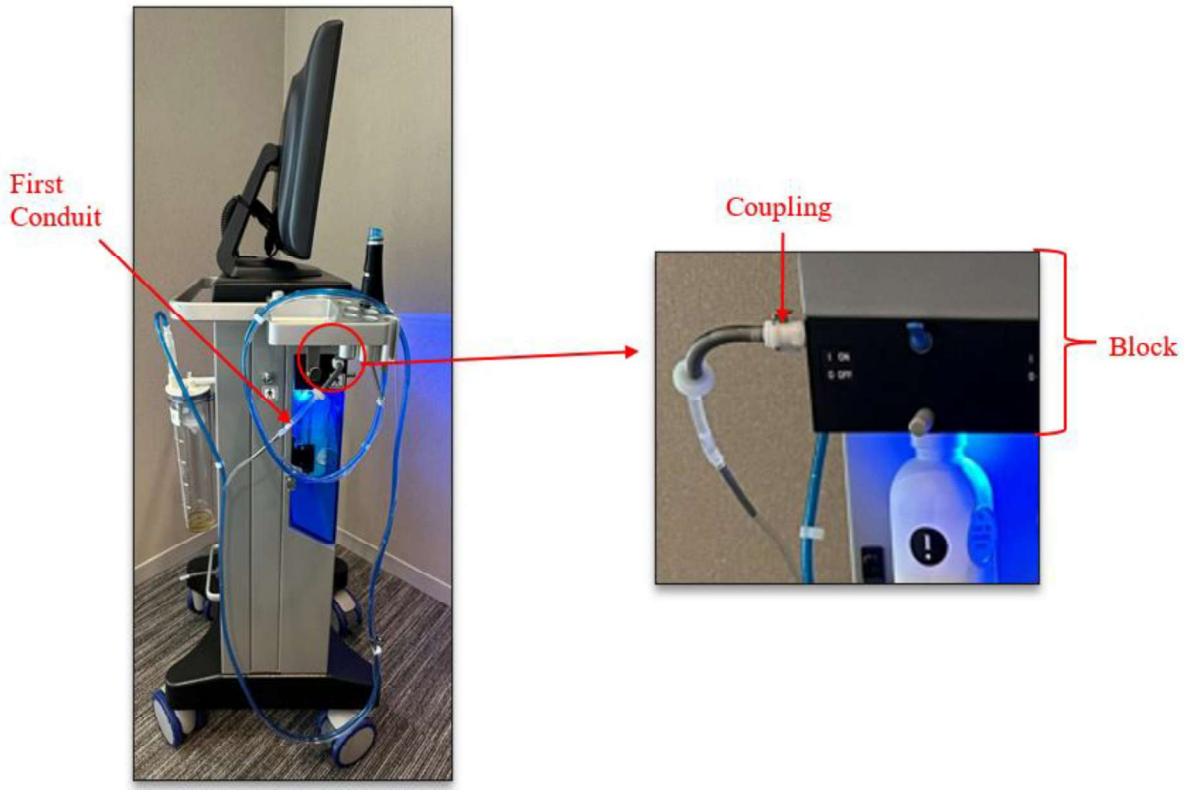
b. <u>configured to selectively receive fluid from the at least one additional container when the at least one additional containers is connected to the console; and</u>

109. This limitation is satisfied by each of the Elite, Allegro, and Tower for the same reasons set forth in Section VII.A.5.a., above.

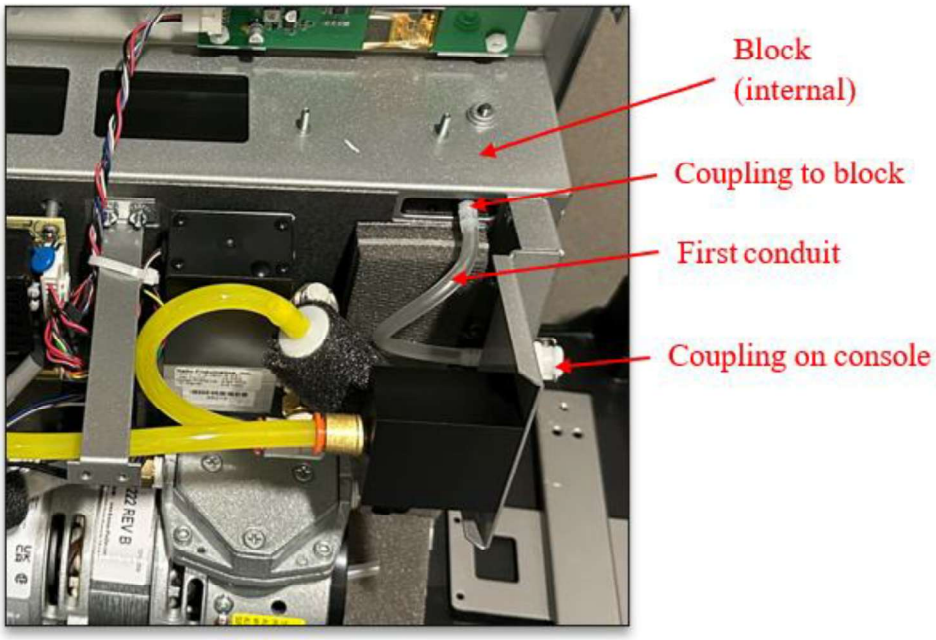
c. <u>configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console</u>

110. In my opinion, each of the Elite, Allegro, and Tower has "a block in the console that is configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console."

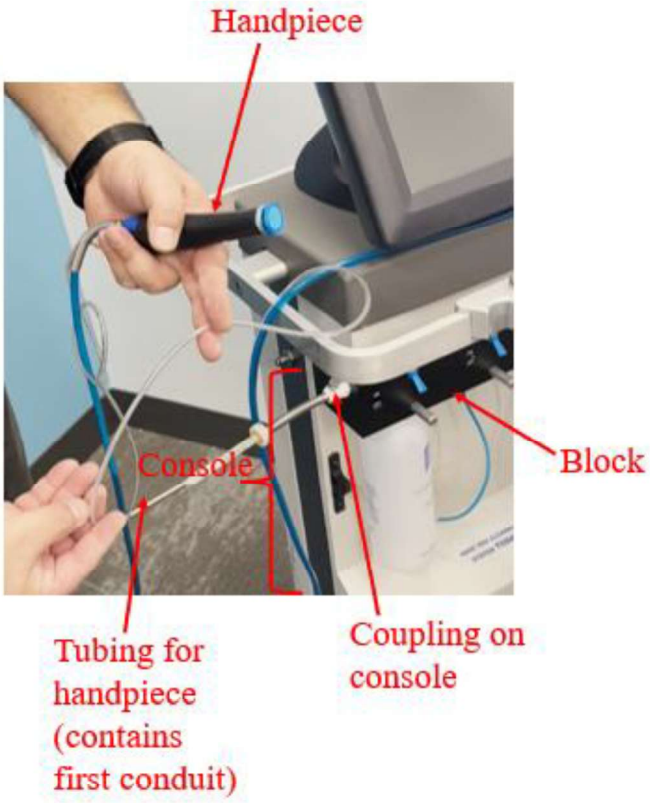
111. Based on my inspection of the each of the Elite and Allegro, review of image and videos of the Tower, and review of technical documents, I have determined that for each of the Elite, Allegro, and Tower, the block is in fluid communication with the handpiece through a first conduit. As shown in the images below, for each device, the first conduit extends from the block, where it eventually meets a coupling location:



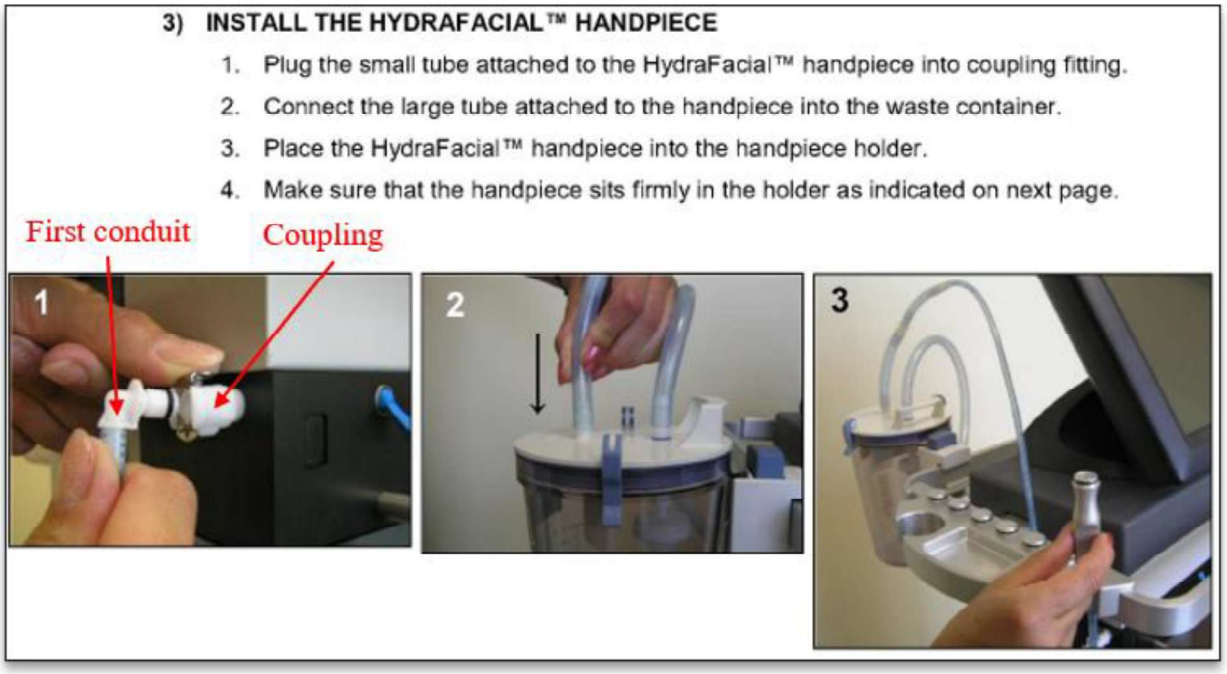
(Elite).


Block
(internal)
Coupling to block
First conduit
Coupling on console

(Allegro).

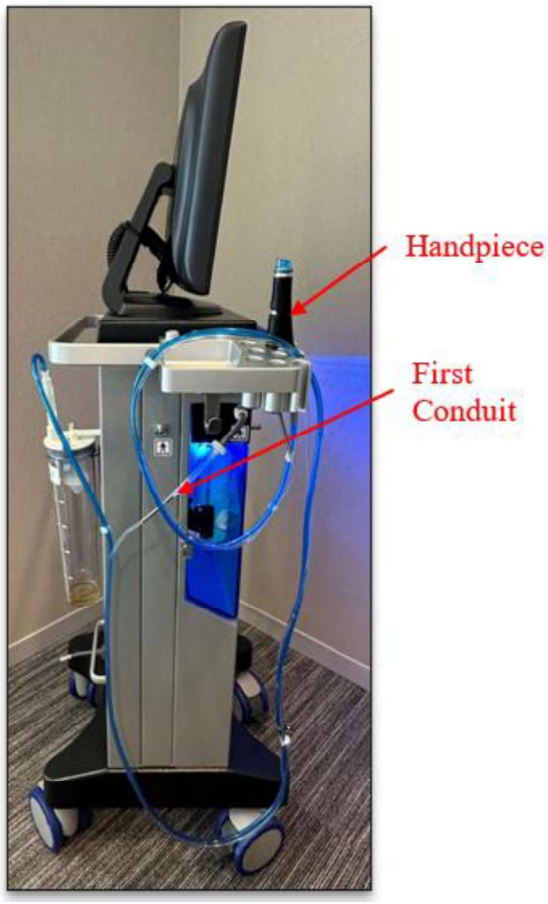

Handpiece
Console
Block
Tubing for
handpiece
(contains
first conduit)
Coupling on
console

(Tower).

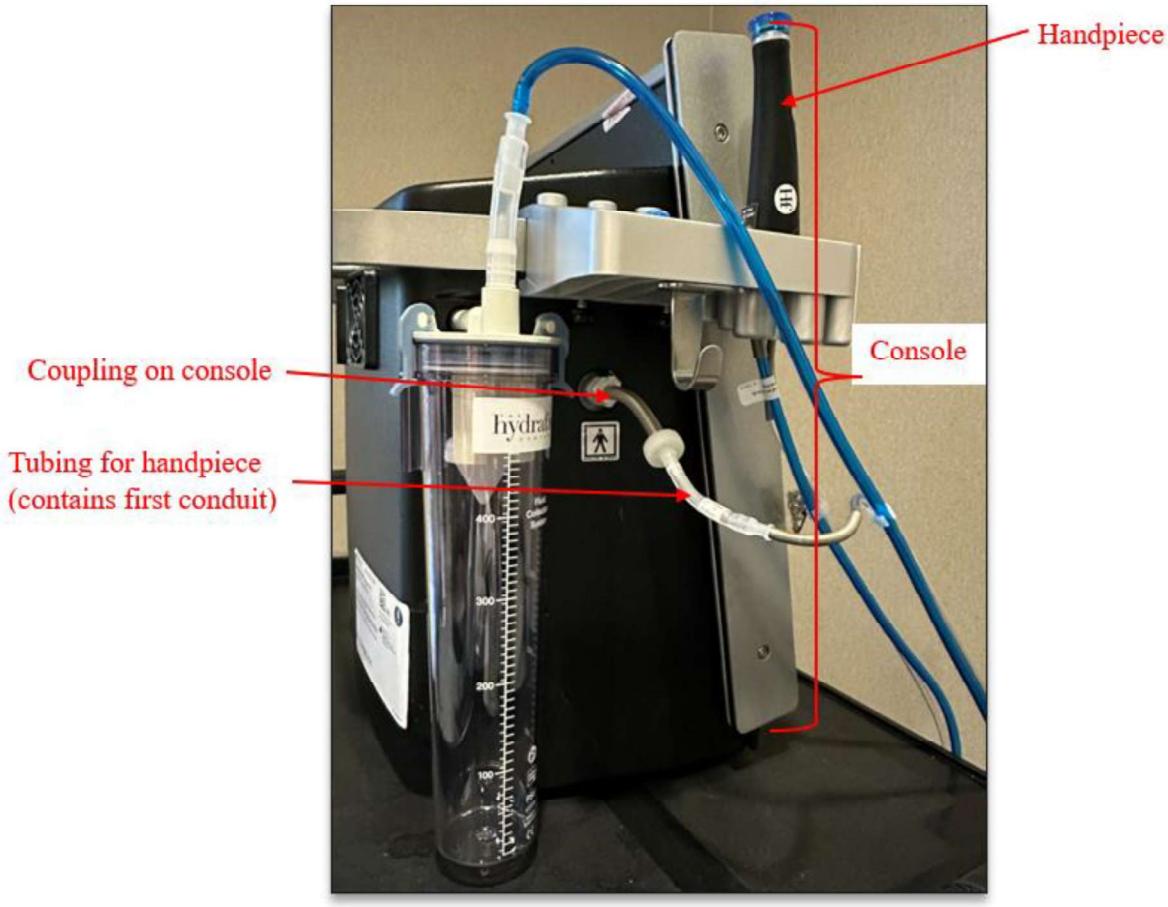


EX2033 at 10 (Tower).

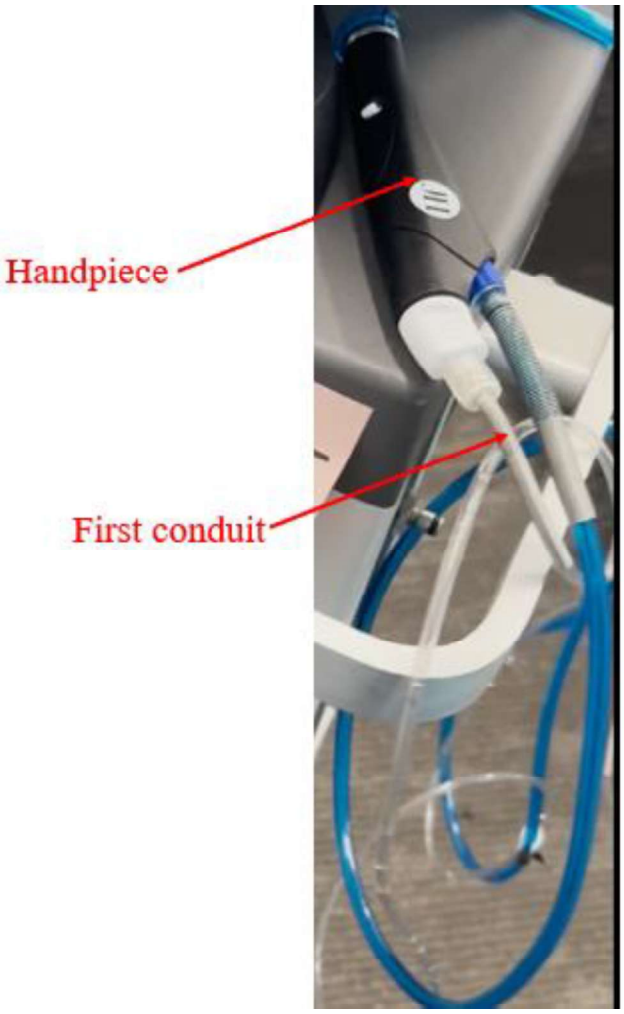
112. Then, for each device, the identified first conduit continues from the coupling on the console through the tubing to the handpiece itself:



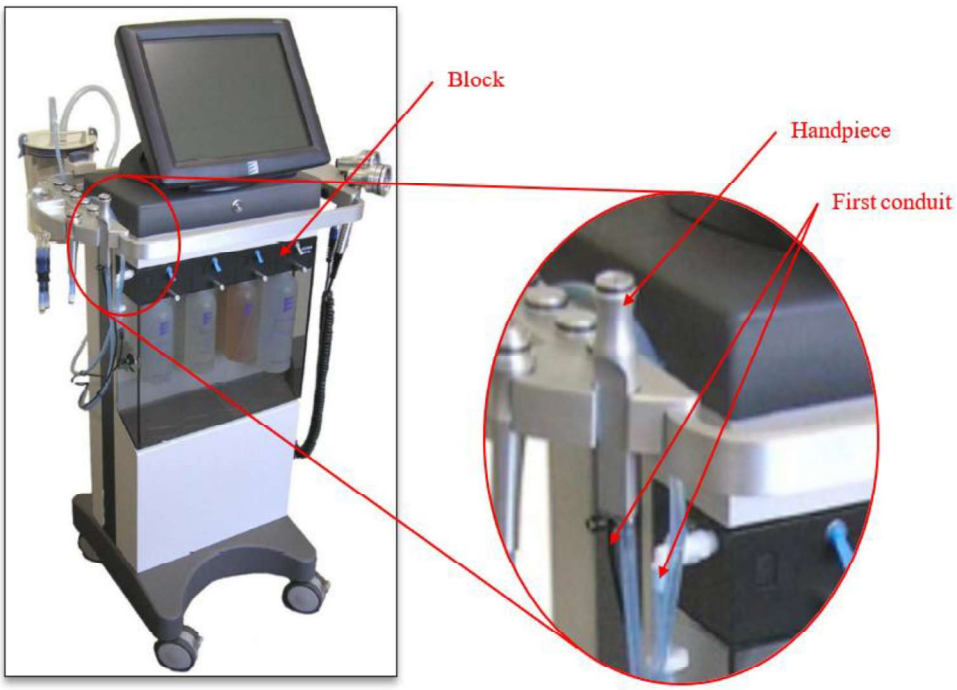
(Elite).


Handpiece
Console
Coupling on console
Tubing for handpiece
(contains first conduit)

(Allegro).

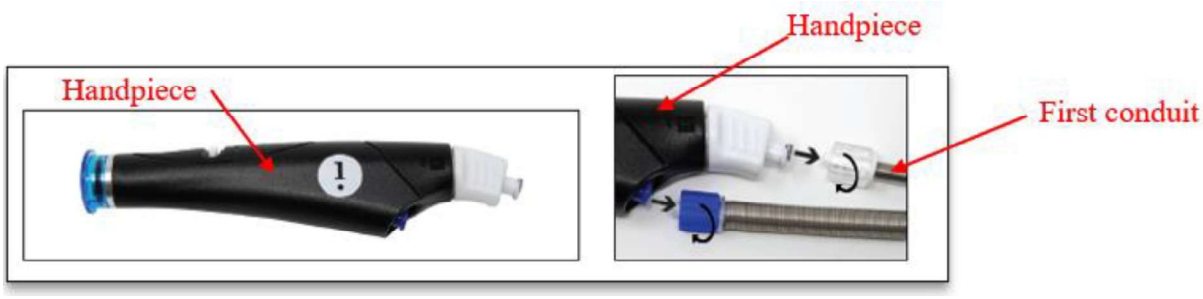


(Tower).



EX2033 at 1 (Tower).

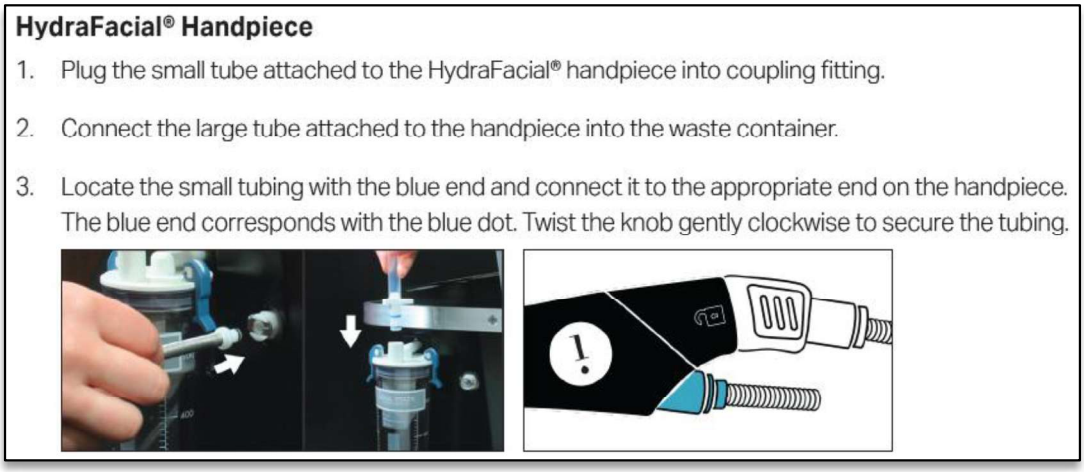
113. As illustrated above, the tubing that connects each of the Elite, Allegro, and Tower to the handpiece contains the first conduit. This first conduit continues through the handpiece, to an opening in the main body of the handpiece. As designed, fluid flows from the containers, through the block and first conduit (including through the handpiece) and ultimately through the opening in the main body of the handpiece.



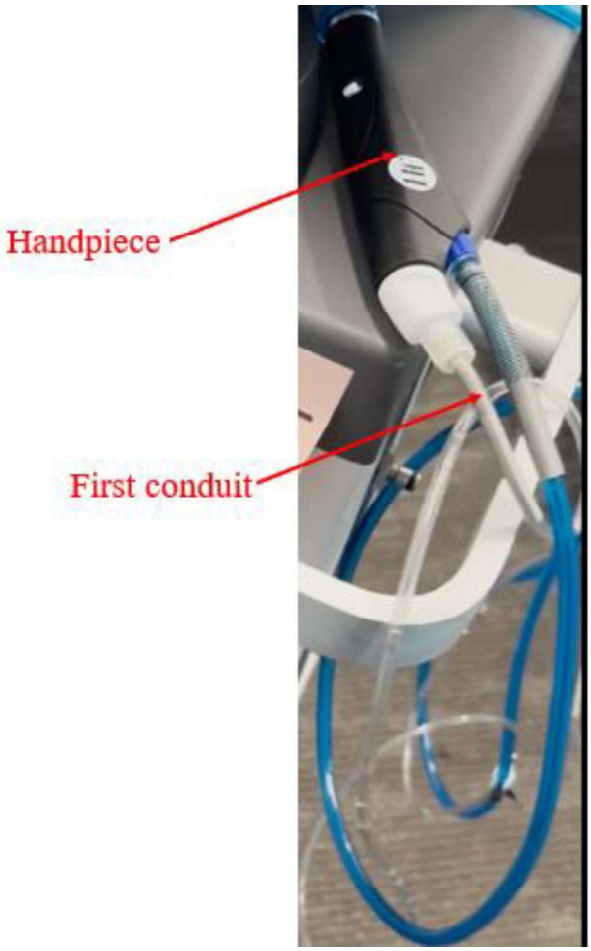
EX2031 at 18 (Elite).



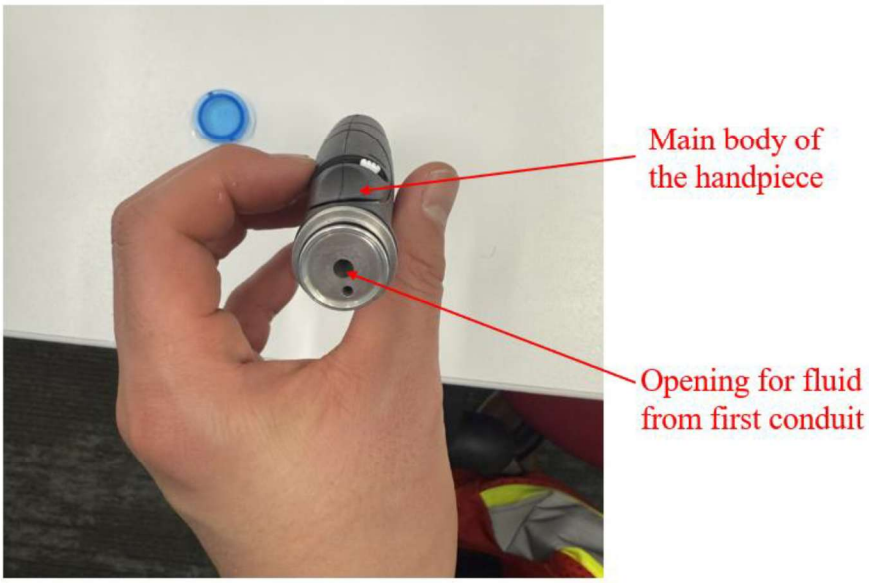
(Allegro).



EX2032 at 9 (Allegro).


Handpiece
First conduit

(Tower).


Main body of the handpiece
Opening for fluid from first conduit

(Tower).

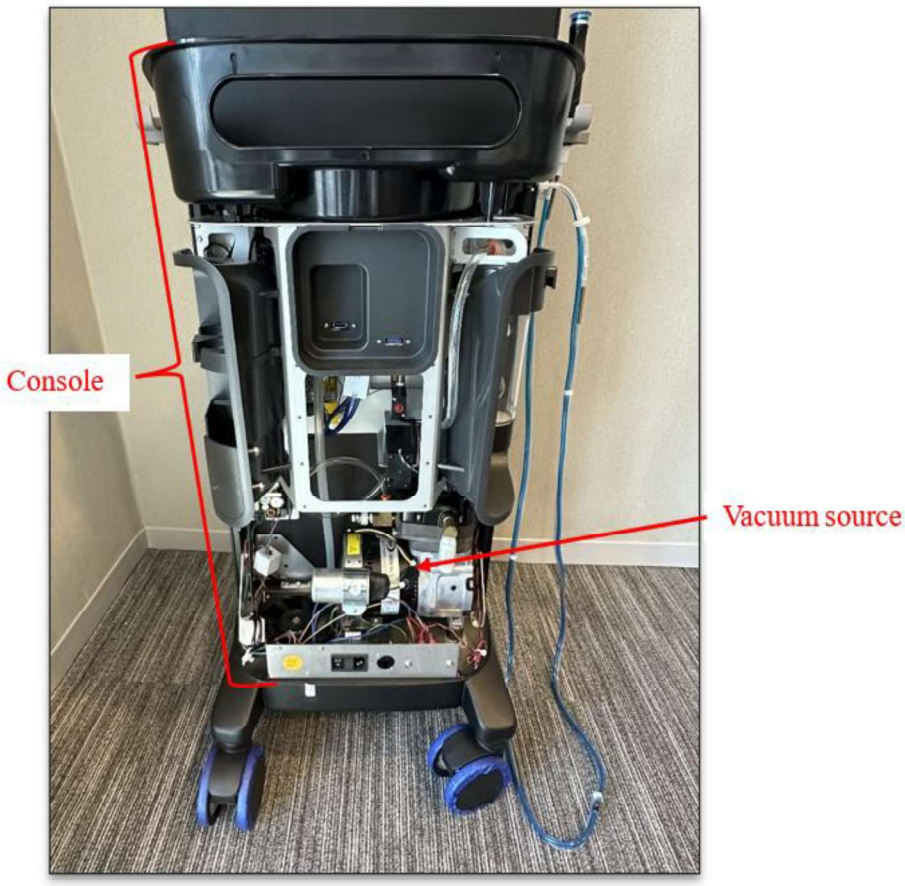
114. The block for each of the Elite, Allegro, and Tower devices is "selectively in fluid communication" through this first conduit in two ways. First, by selectively attaching a container. When a selected container is disconnected, the circuit cannot be completed and "fluid communication" ceases to exist between the block and the handpiece. Second, the handpiece can be selectively detached from the console. When detached, the circuit cannot be completed and "fluid communication" again ceases to exist between the block and the handpiece.

115. Accordingly, this limitation is satisfied by the Elite, Allegro, and Tower.

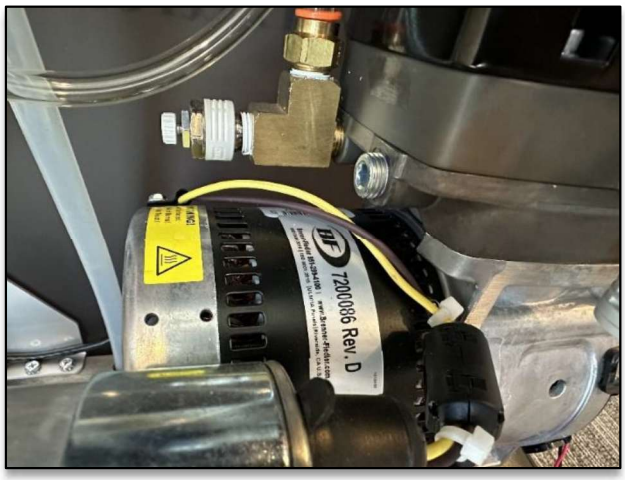
6. "a vacuum source, wherein the console comprises the vacuum source; and"

116. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has "a vacuum source, wherein the console comprises the vacuum source."

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



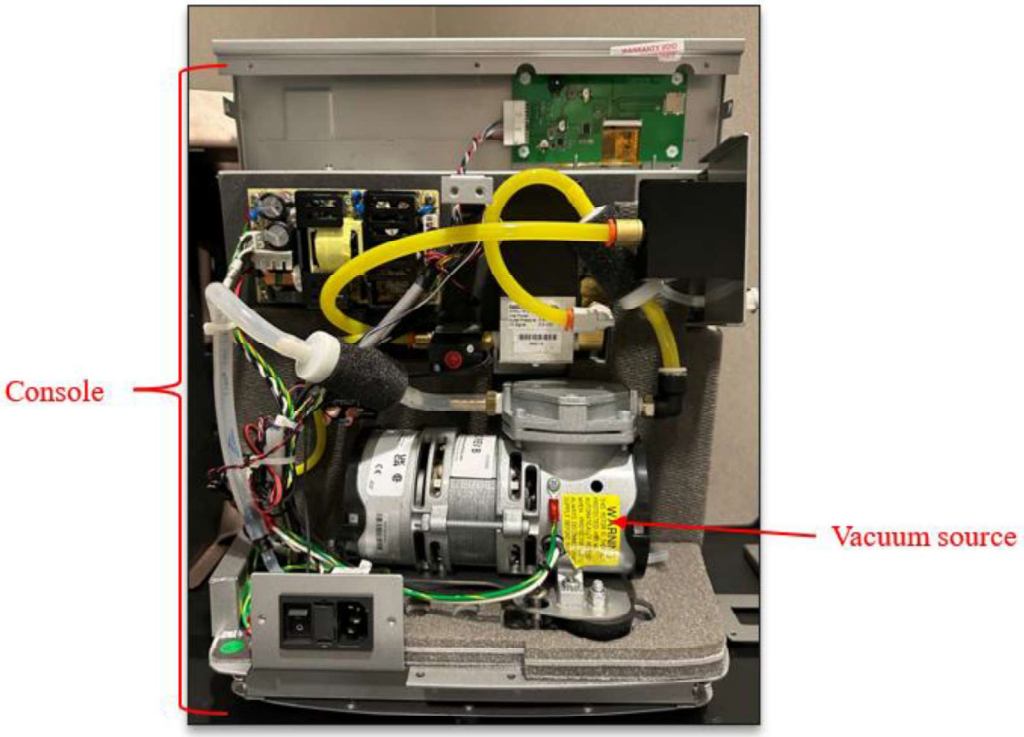
(Syndeo).



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



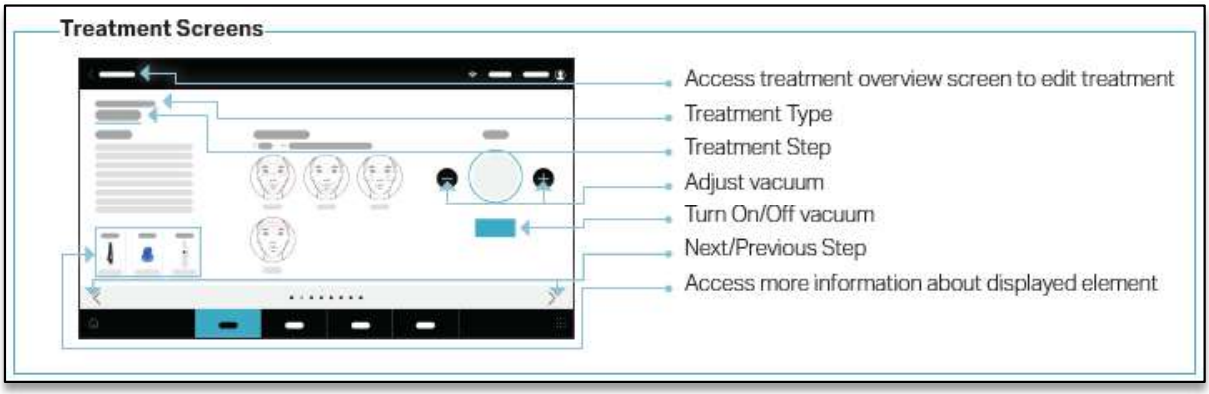
(Allegro).



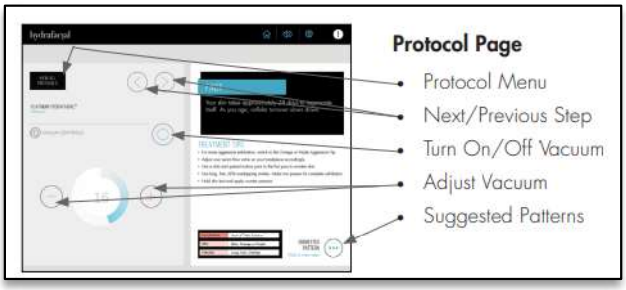
(Allegro).

118. Technical documents for each of the Syndeo, Elite, Allegro, and Tower confirm that a vacuum source is inside of the console. For example, the Syndeo,

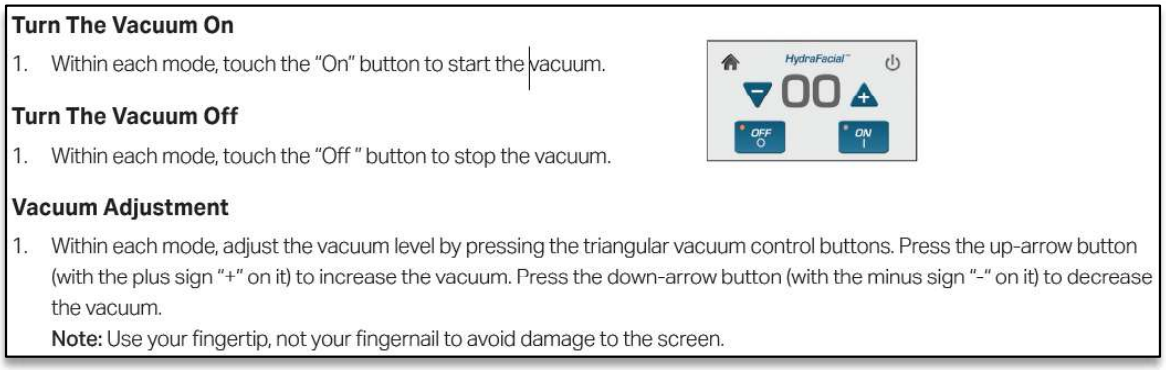
Elite, and Allegro IFUs describe turning the vacuum on and off and adjusting the vacuum:



EX2030 at 16 (Syndeo).

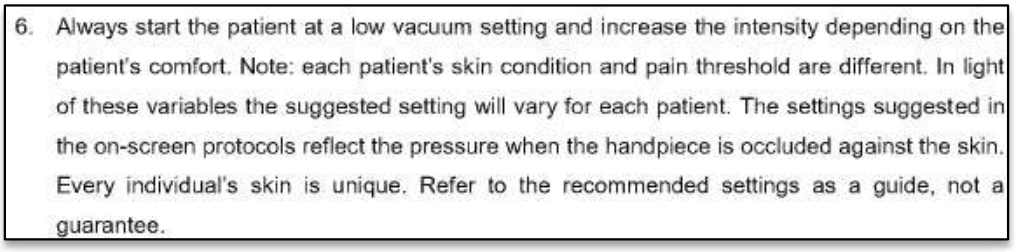


EX2031 at 16 (Elite).



EX2032 at 13 (Allegro).

119. The Tower Owner's Manual similarly describes having an adjustable vacuum:



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

EX2033 at 3 (Tower).

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

121. I understand that Cartessa contends that the vacuum is separate from any alleged console. It appears that Cartessa is narrowly reading the claim to require that the console itself is the vacuum source. I disagree with such a reading of the claim language. The console, or the body of the system, includes a vacuum source as described above.

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

7. wherein the handpiece is configured to be in fluid communication with the vacuum source through a second conduit when the handpiece is connected to the console;

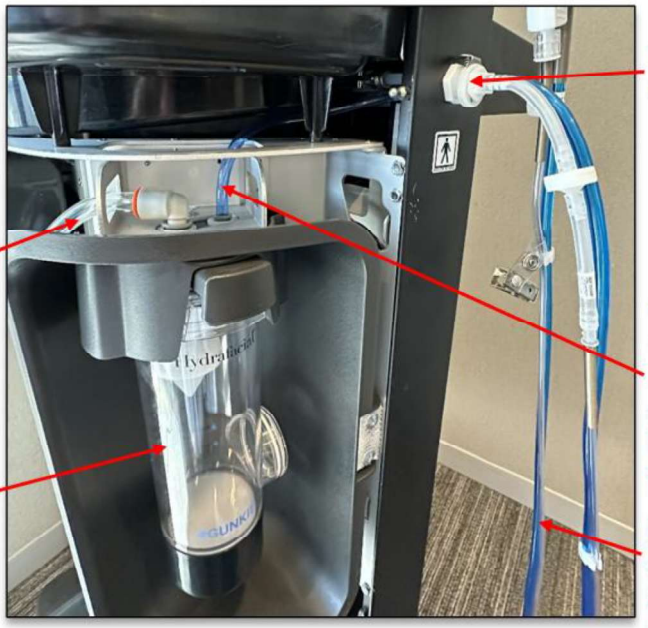
123. In my opinion, each of the Syndeo, Elite, Allegro, and Tower has a "handpiece [that] is configured to be in fluid communication with the vacuum source through a second conduit when the handpiece is connected to the console."

a. <u>Syndeo</u>

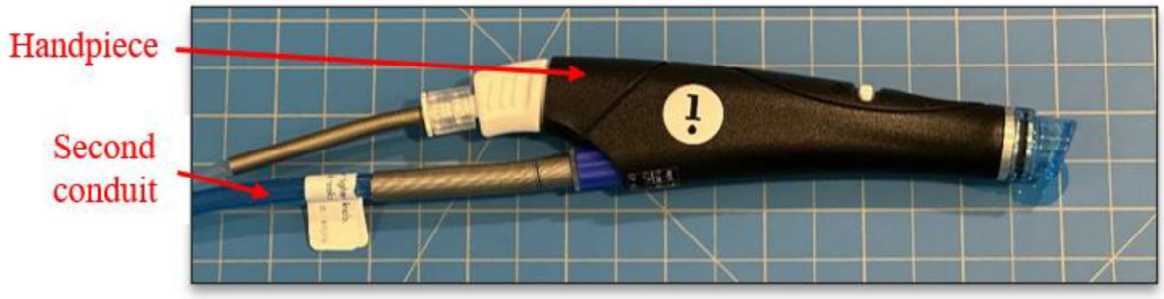
124. My inspection of the Syndeo confirmed that this limitation is satisfied. As shown in the below photos, a second conduit extends from the vacuum source to the vacuum port for the waste container, from the vacuum port for the waste container to the waste container, from the handpiece port in the waste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

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

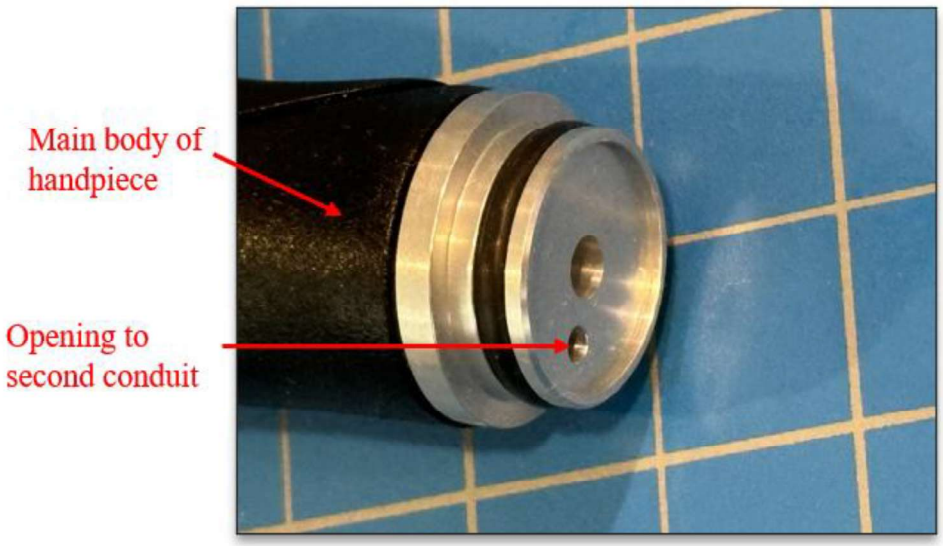

Second conduit – 2) between the vacuum regulator and the port for the waste container
Vacuum Regulator
Second conduit – 1) between the vacuum source and the vacuum regulator
Vacuum source


Handpiece Coupling
Second conduit – 2) between the vacuum regulator and the port for the waste container
Second conduit – 3) between the waste container and the handpiece coupling
Waste Container
Second conduit – 4) Handpiece Tubing (blue line)

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



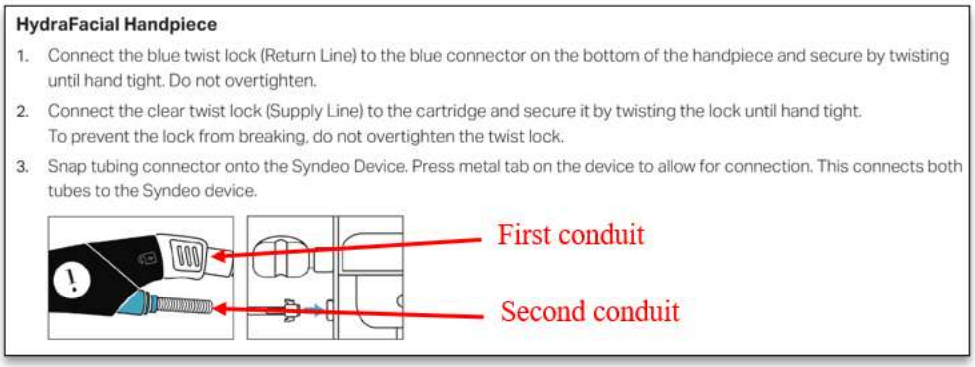
127. After the fluid exits the handpiece from the first conduit, the fluid goes through the handpiece to the second conduit via an opening in the main body of the handpiece, identified below:



128. The Second Conduit places the handpiece in fluid communication with the vacuum source. I observed that, due to this fluid communication, when the vacuum source is activated and the handpiece is contacting skin, a closed system is

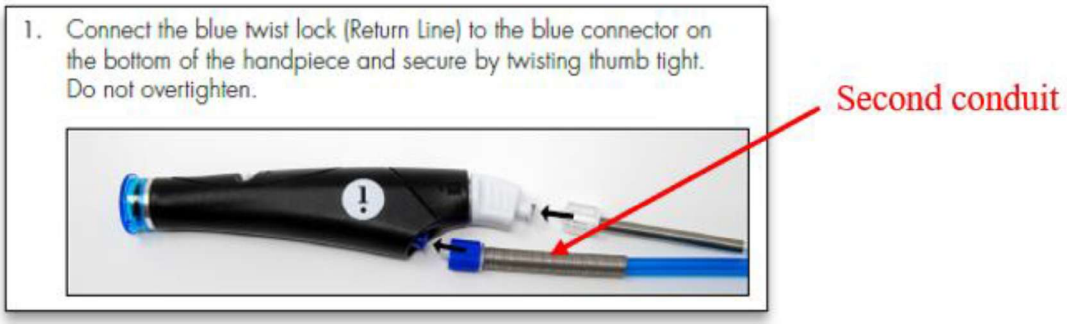
formed between a selected container and the vacuum source. Suction from the vacuum source, through the second conduit, the handpiece, the first conduit, and the block allows fluid to be drawn from the selected container and delivered to the skin, while used fluid and debris is simultaneously drawn away from the skin to the waste container.

129. The Syndeo IFU confirms the Syndeo handpiece is configured to be in fluid communication with the vacuum source through a second conduit when the handpiece is connected to the console. The Syndeo IFU illustrates and describes a "Return Line." In the annotated illustration below the "Return Line" attaches to the handpiece. This "Return Line" serves as a portion of the second conduit through which the handpiece is in fluid communication with the vacuum source. For clarity, I have also labeled the first conduit, which I describe in greater detail above in section VII.A.4.



EX2030 at 12.

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



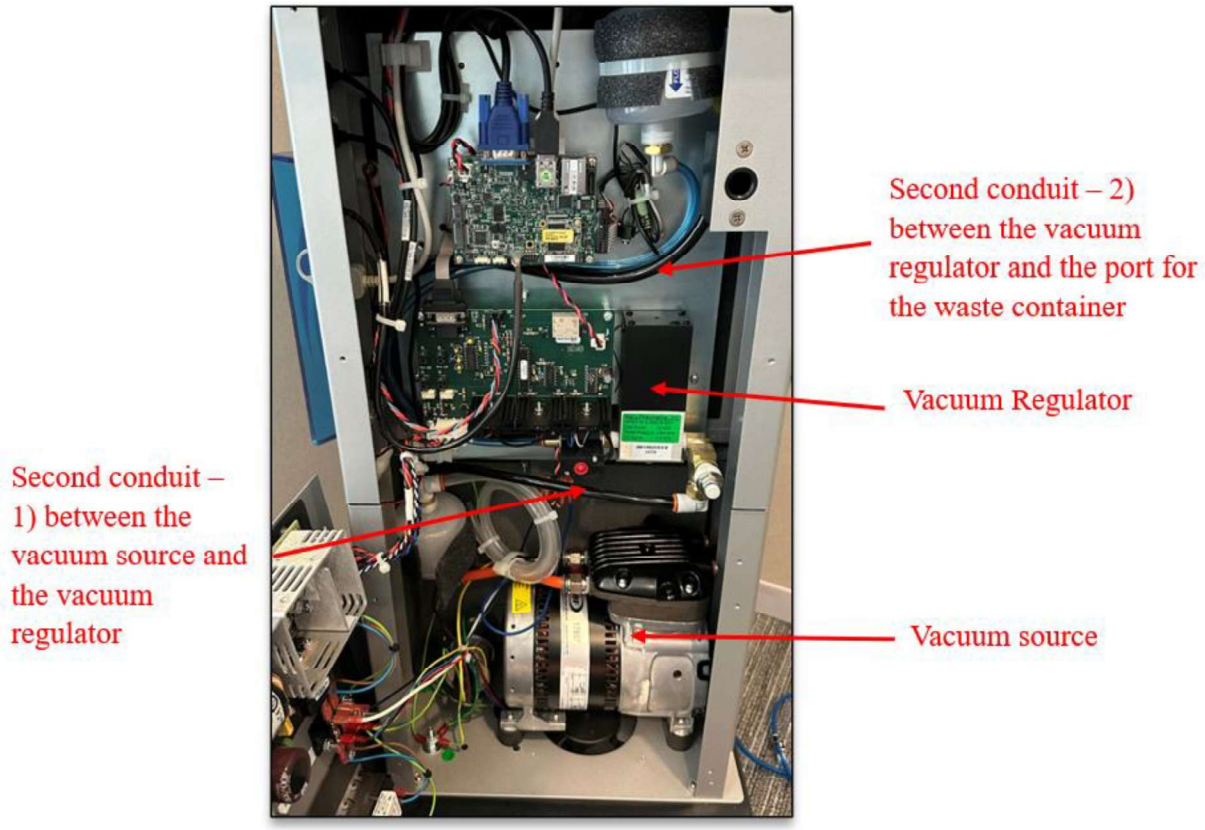
EX2034 at 3; *see also* EX2030 at 22 ("Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister.").

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

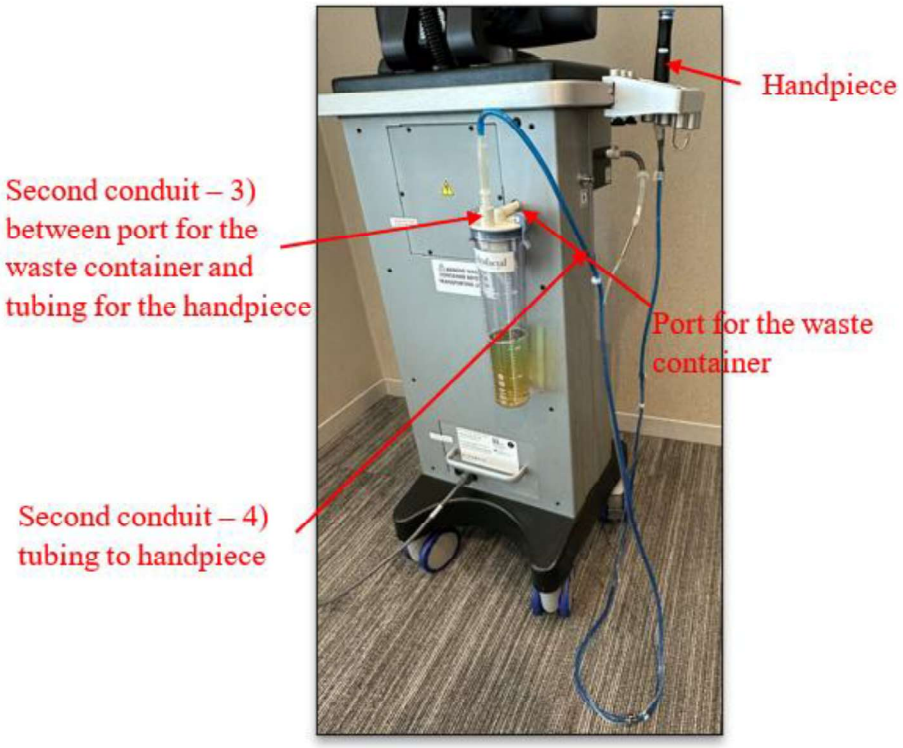
b. <u>Elite, Allegro, & Tower</u>

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

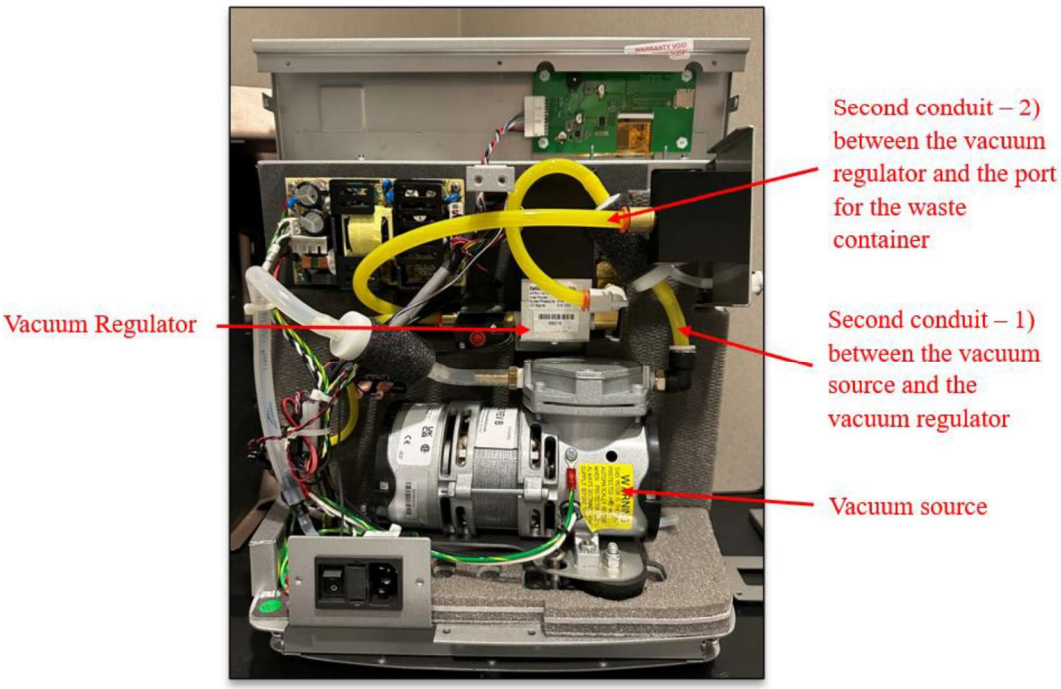
133. During my inspection of the Elite and Allegro, I observed that the second conduit comprises multiple tubing components that extend 1) between the vacuum source and a vacuum regulator; 2) between the vacuum regulator and a port for the waste container; 3) between the port of the waste container and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



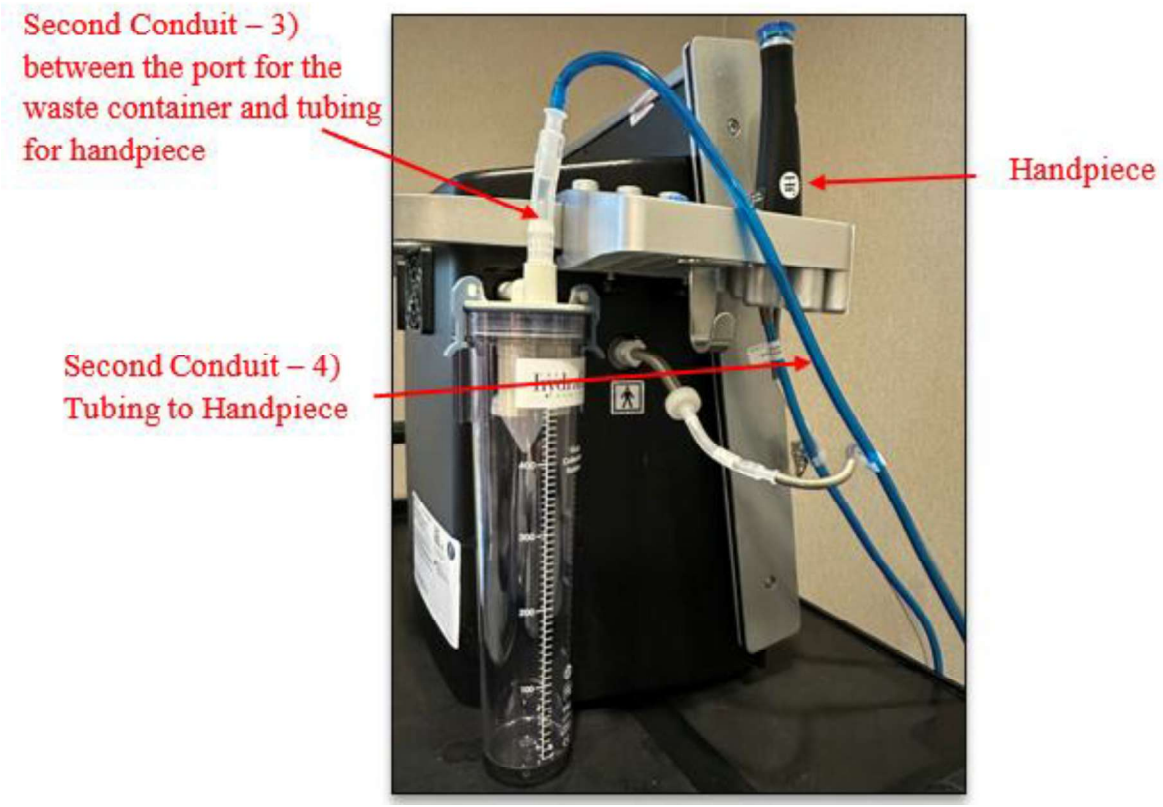
(Elite).


Handpiece
Second conduit – 3) between port for the waste container and tubing for the handpiece
Port for the waste container
Second conduit – 4) tubing to handpiece

(Elite).

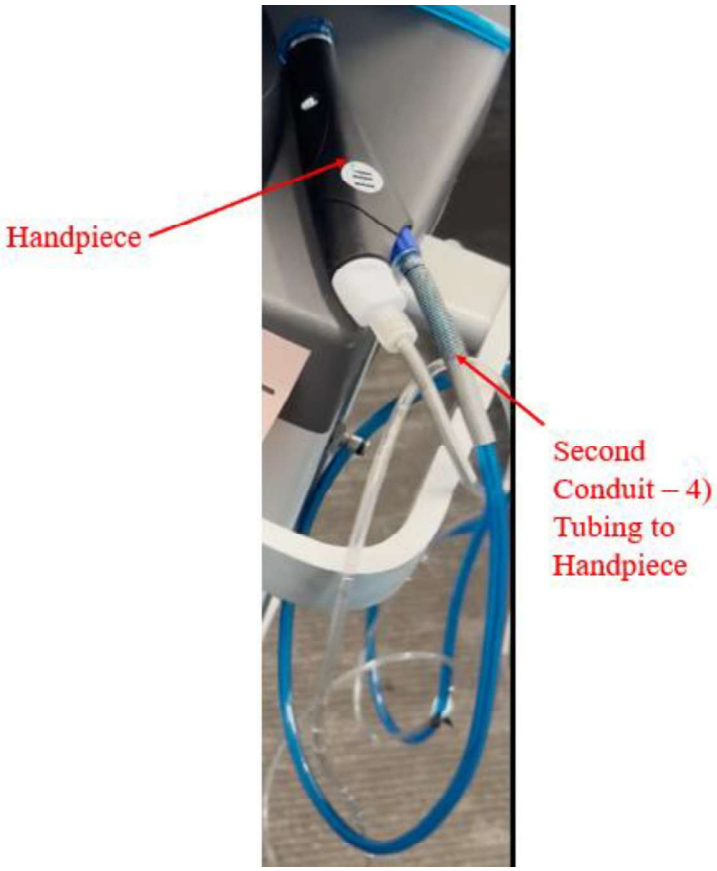

Second conduit – 2) between the vacuum regulator and the port for the waste container
Vacuum Regulator
Second conduit – 1) between the vacuum source and the vacuum regulator
Vacuum source

(Allegro).

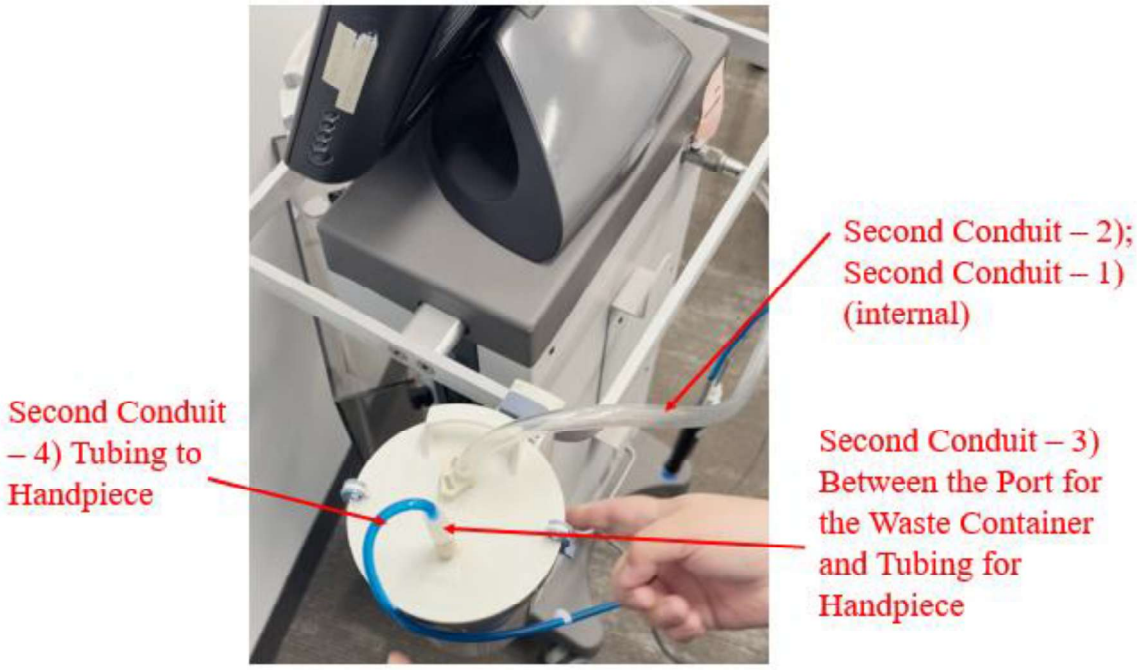


(Allegro).

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

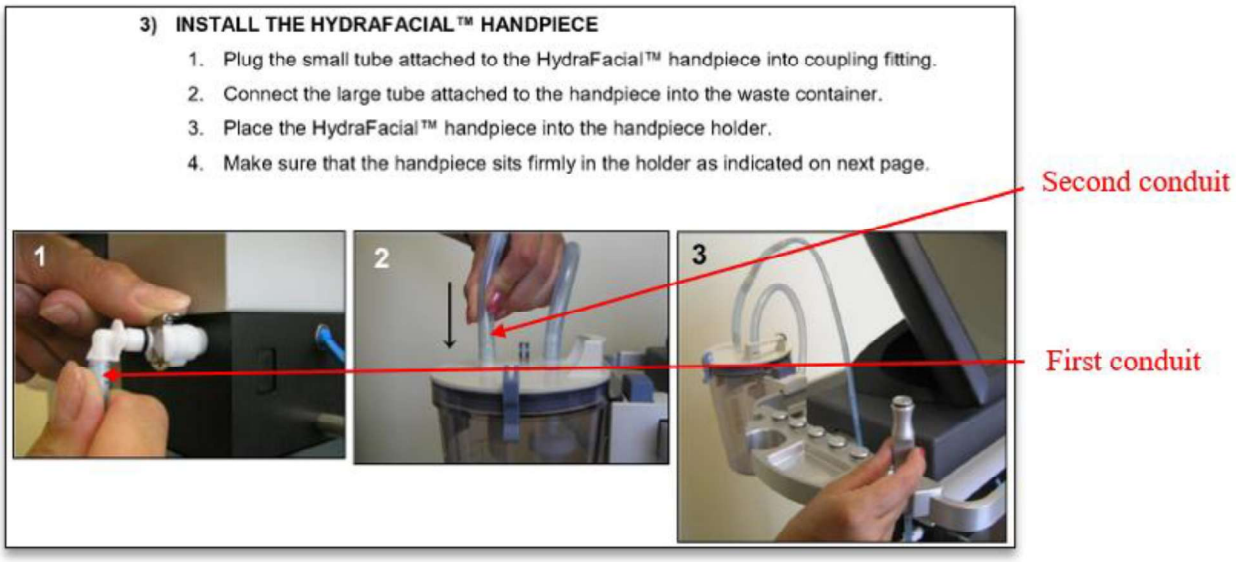

Handpiece
Second Conduit – 4) Tubing to Handpiece

(Tower).

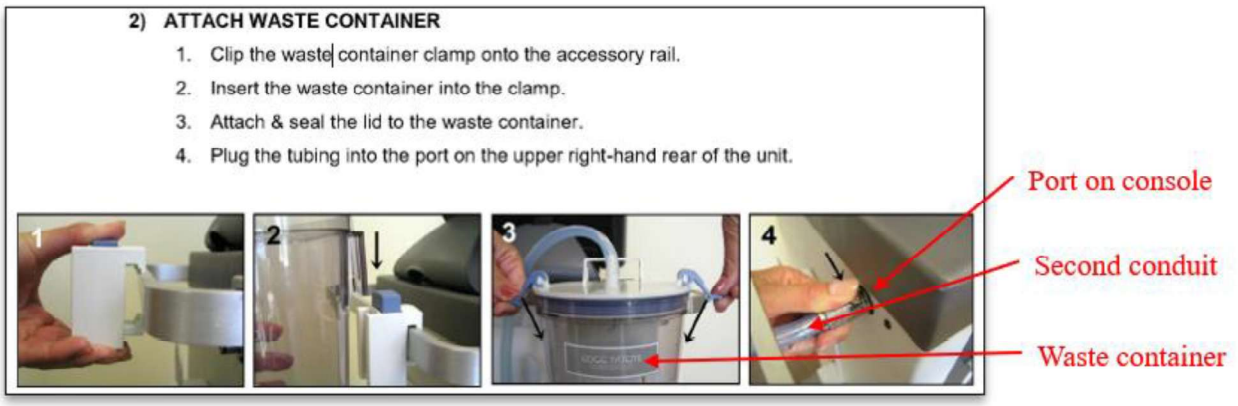


(Tower).

135. In the Tower, second conduit – 4) Tubing to Handpiece) referenced in the image below as attaching to both the handpiece and coupling, serves as a portion of the second conduit through which the handpiece is in fluid communication with the vacuum source.



EX2033 at 10 (Tower). The second conduit continues through the waste container and through a port for the waste container on the console, shown below:



Id. at -654 (Tower). As shown in the image above, there is tubing connecting the vacuum source to the port of the waste container, thus placing the handpiece in fluid communication with the vacuum source (Second Conduit -2 and Second Conduit -3).

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

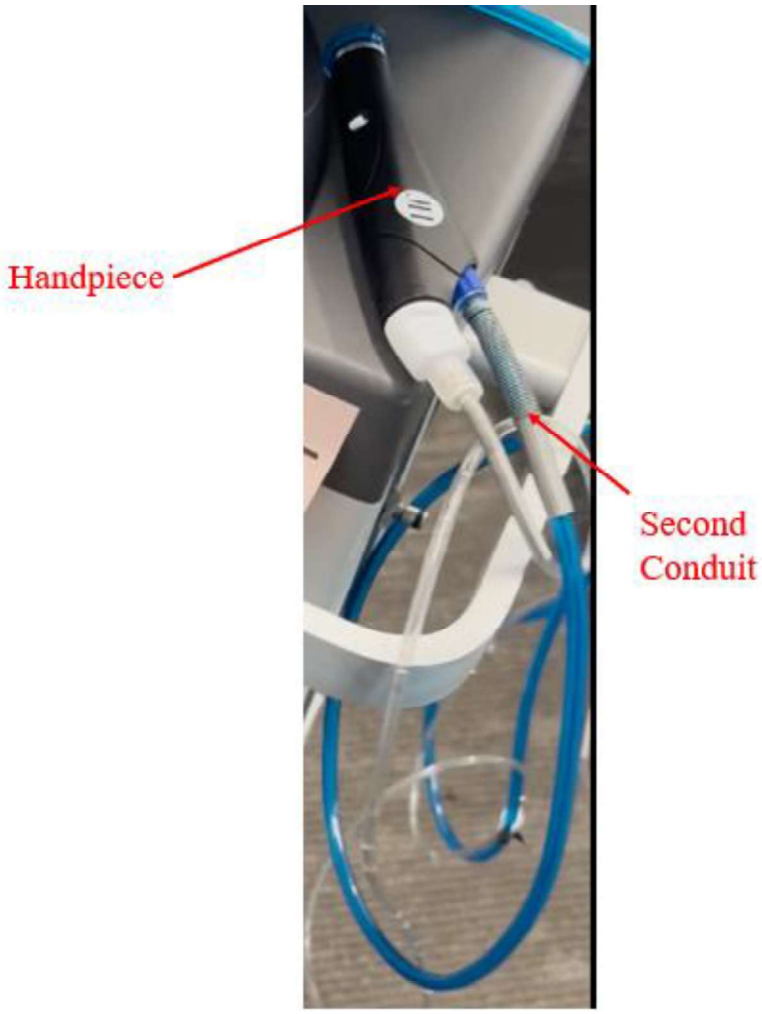


(Elite).



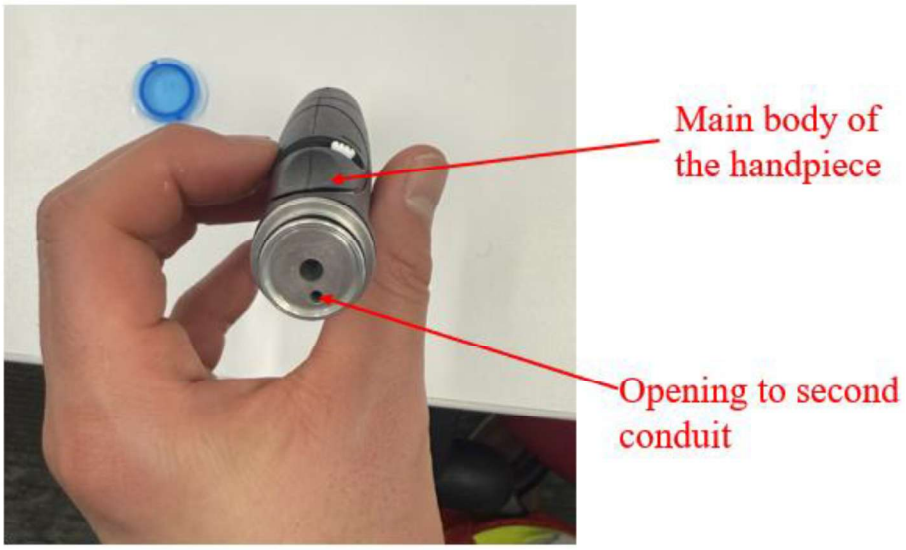
(Allegro).

137. From examining images of the handpiece of the Tower, I have determined that a functioning Tower device would have a similar second conduit connected to the handpiece:



(Tower).

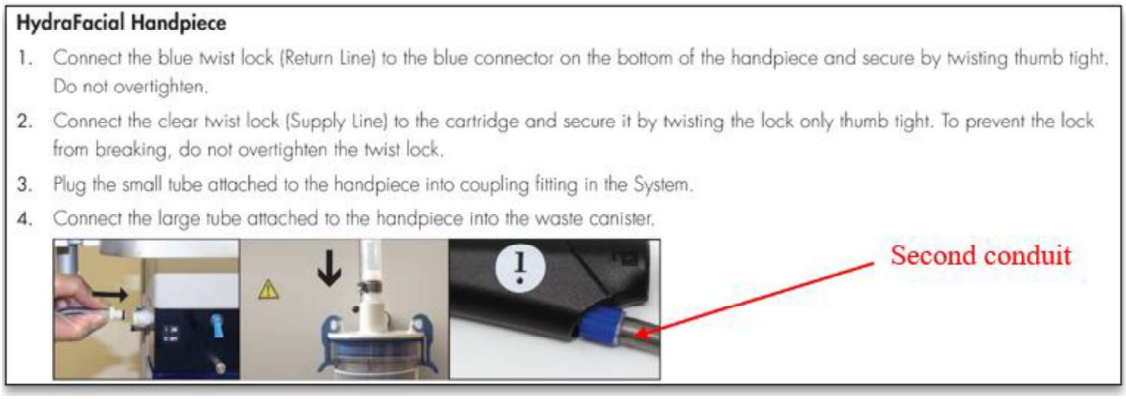
138. After the fluid exits the handpiece from the first conduit, the fluid goes through the handpiece to the second conduit via an opening in the main body of the handpiece. I have illustrated this on the Tower handpiece; however, both the Allegro and Elite have the same opening.



(Tower).

139. The Second Conduit places the handpiece in fluid communication with the vacuum source. I observed for both the Elite and the Allegro, due to this fluid communication, when the vacuum source is activated and the handpiece is contacting skin, a closed system is formed between a selected container and the vacuum source. Suction from the vacuum source, through the second conduit, the handpiece, the first conduit, and the block allows fluid to be drawn from the selected container and delivered to the skin, while used fluid and debris is simultaneously drawn away from the skin to the waste container. Based on my review of video of the Tower with the cleaning cap on, it is my understanding that it operates the same as the Elite and Allegro when the handpiece contacts the skin.

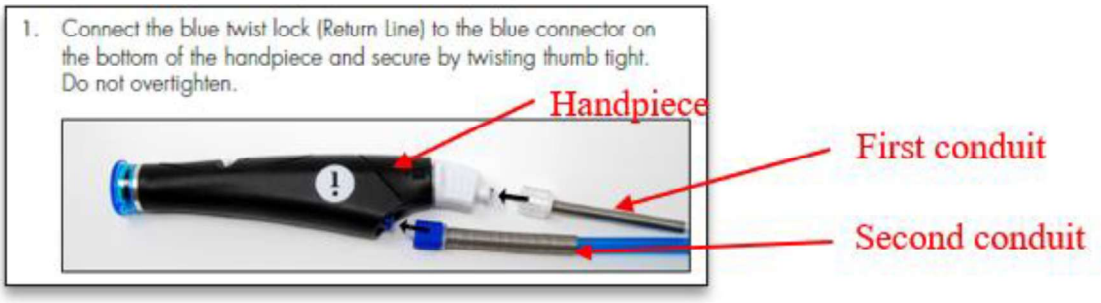
140. The Elite IFU and Allegro IFU confirms each device has a handpiece configured to be in fluid communication with the vacuum source through a second conduit when the handpiece is connected to the console. The Elite IFU and Allegro IFU illustrates and describes a "Return Line." In the annotated illustrations below, the "Return Line" attaches to the handpiece. This "Return Line" serves as a portion of the second conduit through which the handpiece is in fluid communication with the vacuum source. For clarity, I have also labeled the first conduit, which I describe in greater detail above in Section VII.A.5.



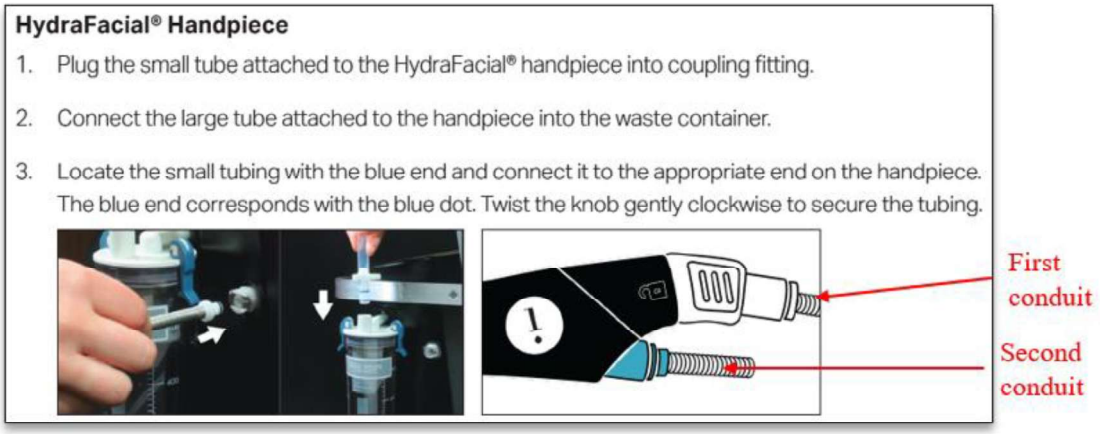
EX2031 at 12 (Elite).



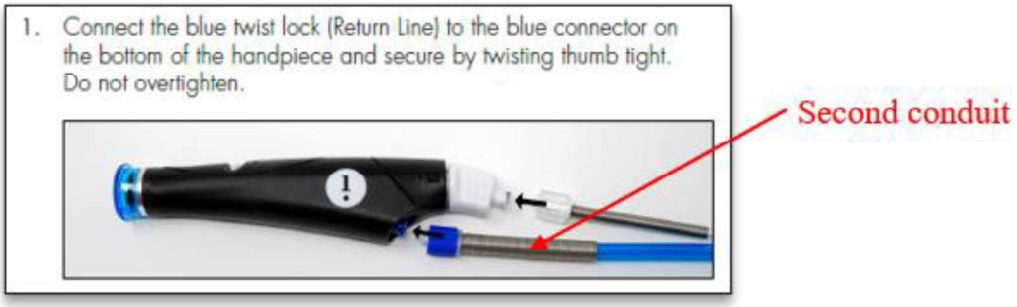
EX2031 at 18 (Elite).



EX2034 at 3 (Elite); *see also* EX2031 at 20 ("Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister.").



EX2032 at 9 (Allegro).



EX2034 at 3 (Allegro); *see* EX2032 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.").

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

8. wherein when the handpiece, the first container, the at least one additional container and a waste container are each connected to the console, the first container contains a first treatment fluid, and the at least one additional container contains an additional treatment fluid, the handpiece is in fluid communication with the vacuum source and the waste container through the second conduit; and

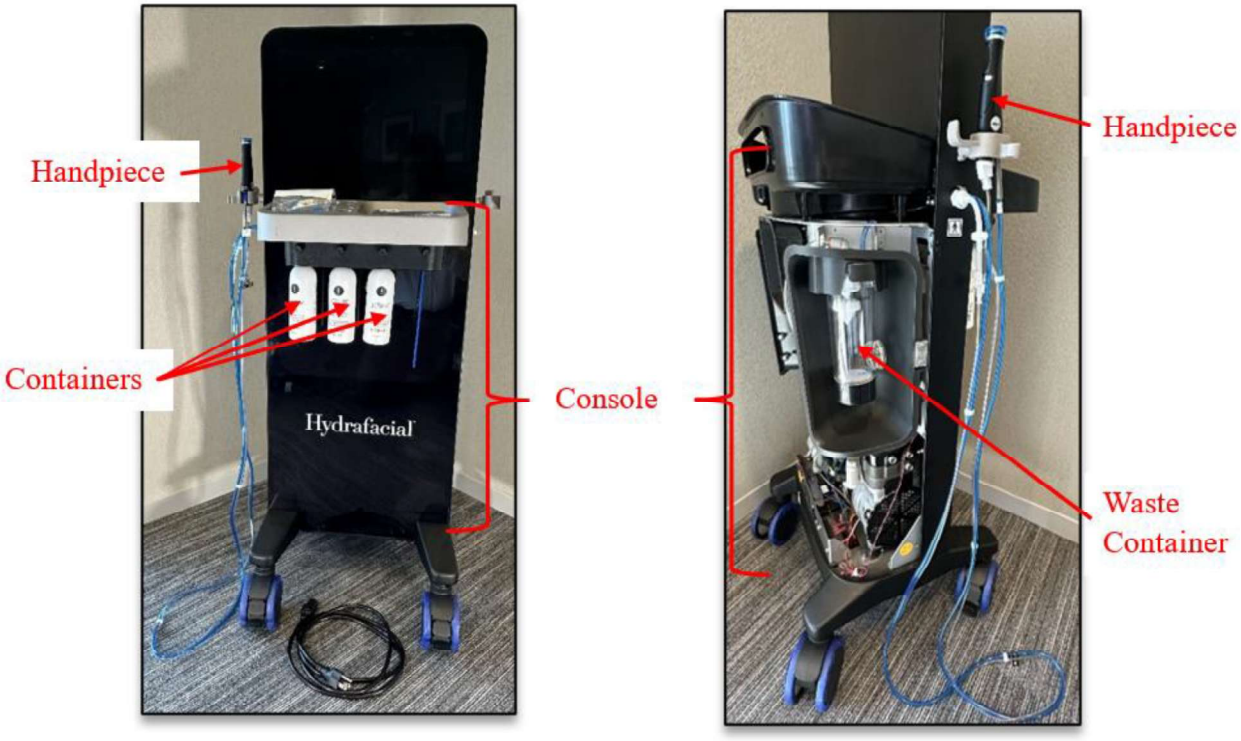
142. In my opinion, each of the Syndeo, Elite, Allegro, and Tower practices the limitation "wherein when the handpiece, the first container, the at least one additional container and a waste container are each connected to the console, the first container contains a first treatment fluid, and the at least one additional container contains an additional treatment fluid, the handpiece is in fluid communication with the vacuum source and the waste container through the second conduit."

a. <u>Syndeo</u>

143. I have inspected the Syndeo and determined that when each of the handpiece, the first container containing a first fluid treatment, the at least one additional container containing an additional fluid treatment, and a waste container

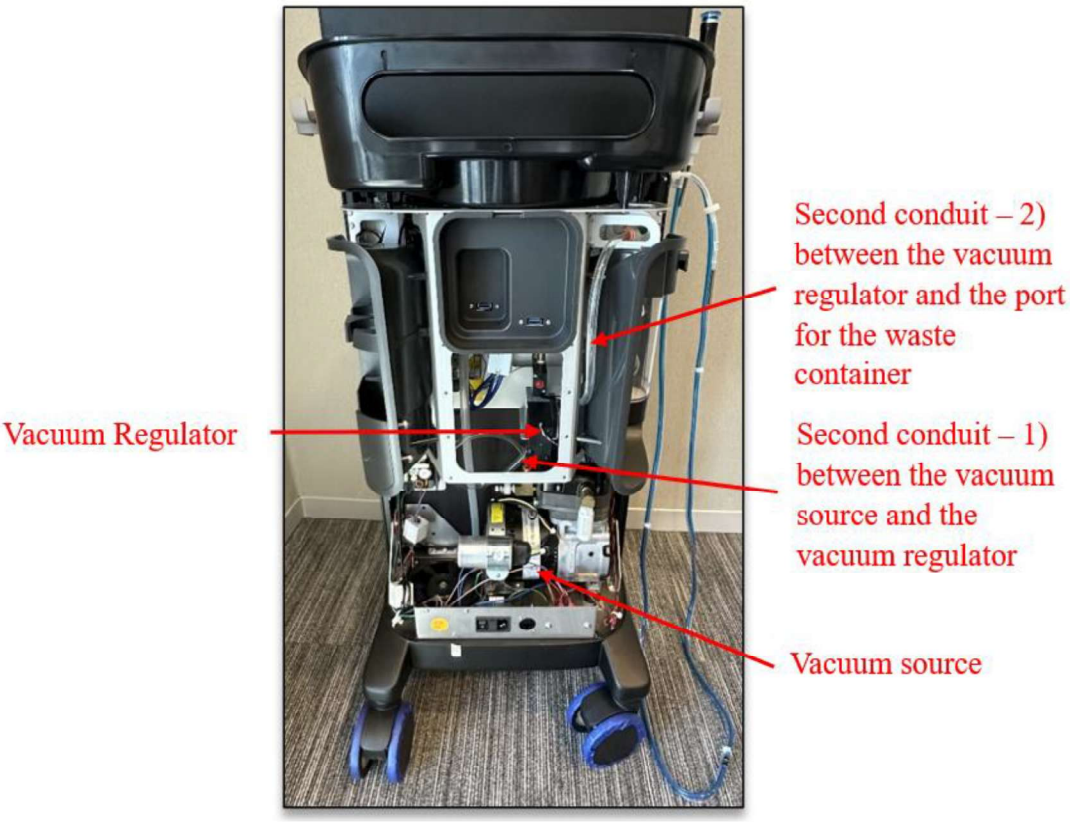
are connected to the console, the handpiece is in fluid communication with the vacuum source and the waste container through the second conduit.

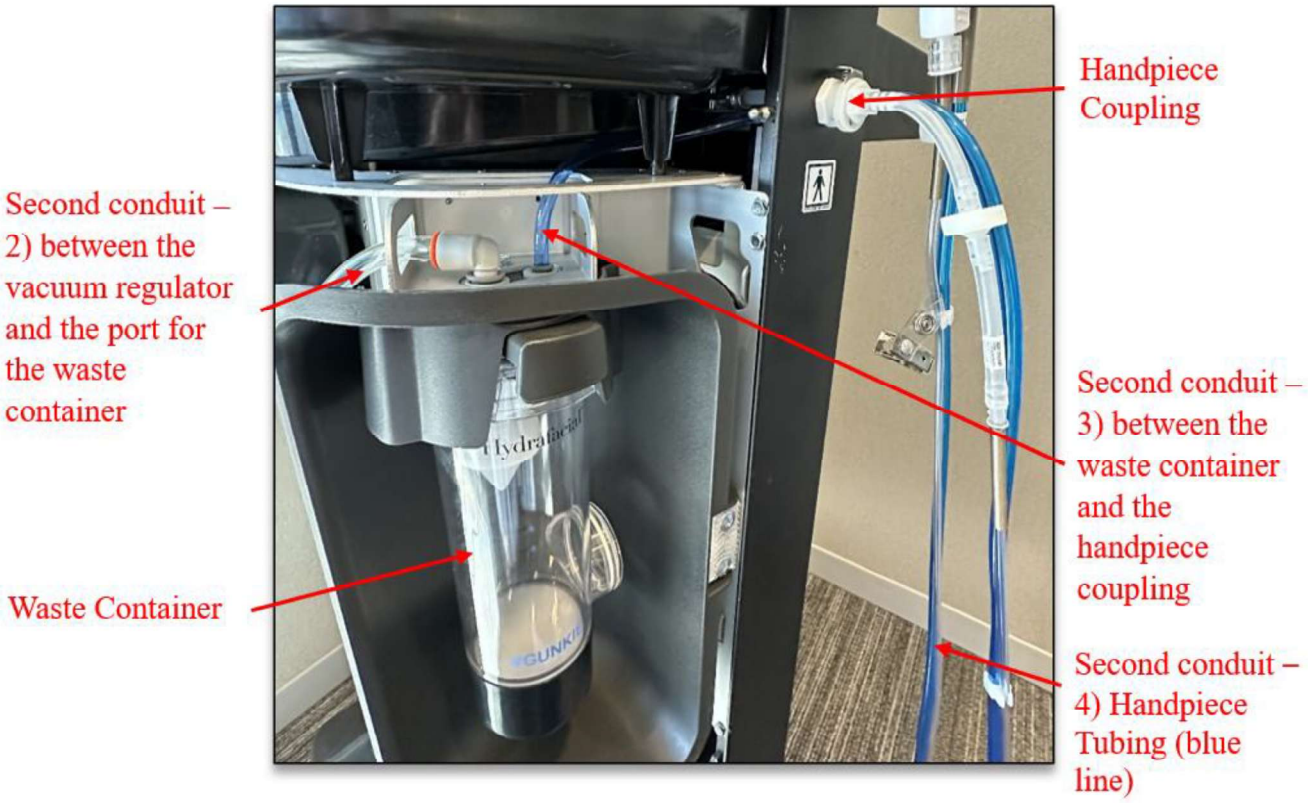
144. In the two images below, the waste container is shown to be connected to the rear of the console, the handpiece is shown to be connected to the console via tubing, and the first container (as well as each additional container) is attached to the console:



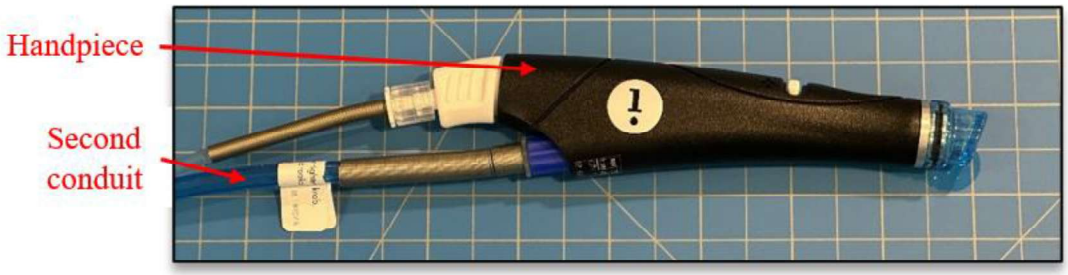
145. As explained above, the second conduit comprises multiple tubing components that extend, *inter alia*, between a port of the waste container and the coupling for the handpiece tubing via the waste container and tubing, and through

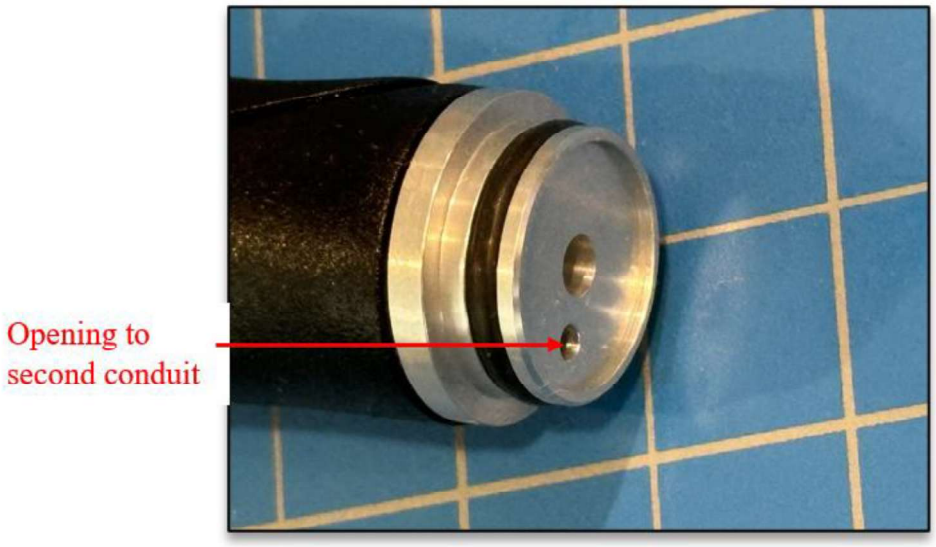
the coupling for the handpiece to the handpiece itself. The images below identify portions 1), 2), 3), and 4) of the second conduit:



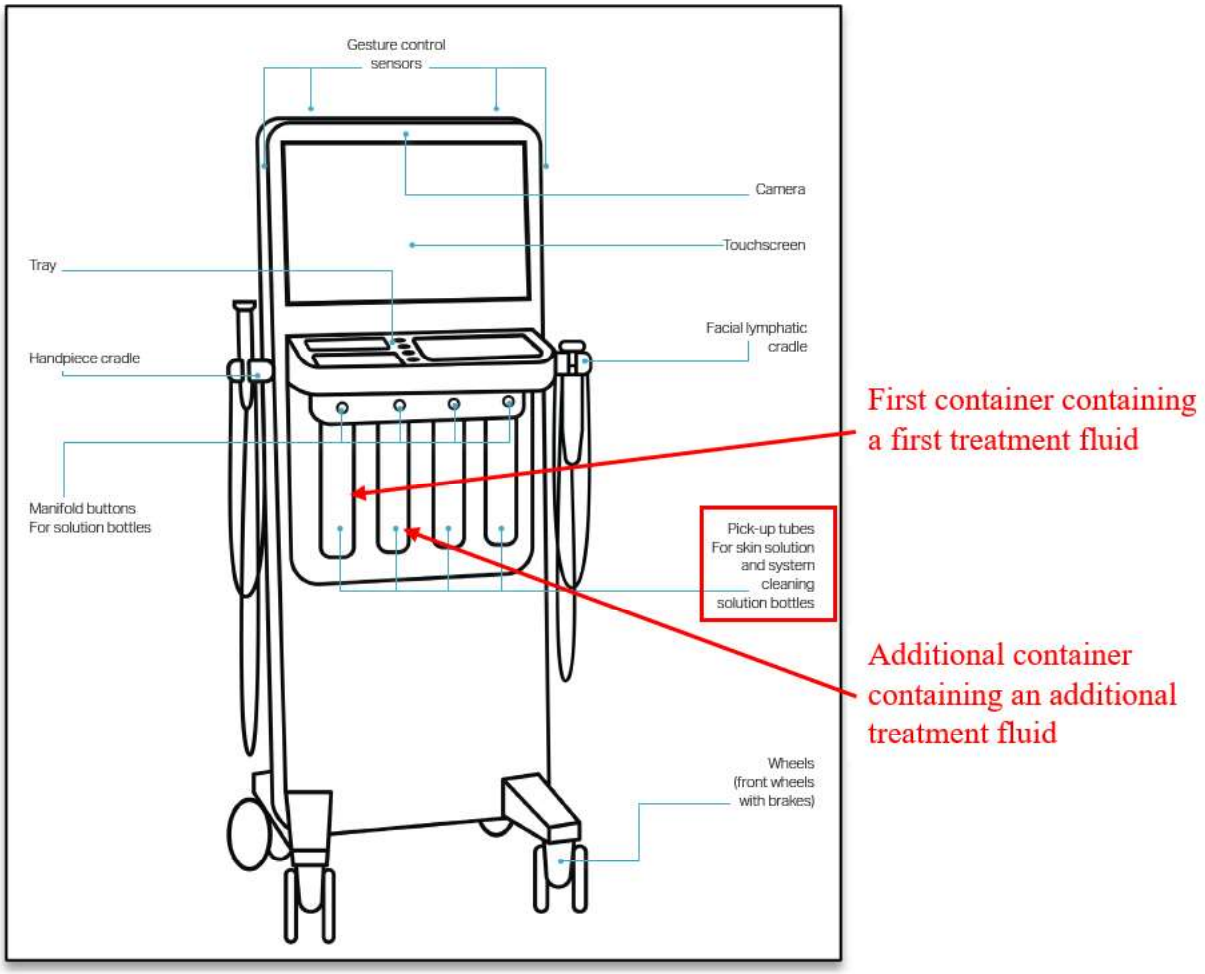


As discussed above, and illustrated in the annotated images below, treatment fluid flows through the first conduit contained in the Syndeo handpiece to the second conduit via an opening in the main body of the handpiece.





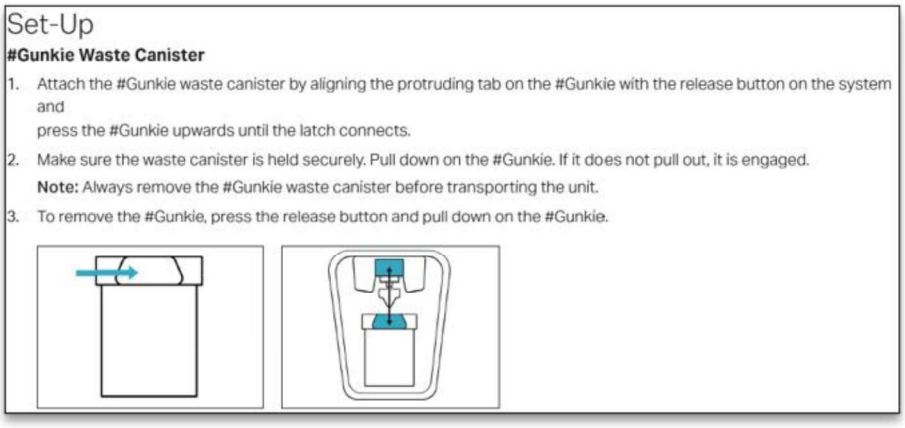
146. The Syndeo IFU further describes placing solutions in the appropriate containers. For example, the Syndeo IFU explains that the bottles inserted into the Syndeo console each contain a "skin solution." I have annotated, for clarity, an image from the Syndeo IFU showing the console with a first and additional container, each containing a different treatment fluid:



EX2030 at 10; *see also id*. at 13 ("Remove the cap of the skin solution bottle and use the puncture tool to pierce the seal inside the bottle."); *id*. at 7 ("Always use solution when performing abrasion. Performing the treatment without skin solutions could result in discomfort to the client."); *id*. at 14 ("The Syndeo system automatically selects and deselects the recommended solution bottle based on the respective treatment step."); *id*. at 22 ("Make sure your skin solution bottle is not empty.")

147. When the above conditions (fluid containers have fluid and are connected to the console, handpiece is connected to the console, waste container is connected to the console) are satisfied the handpiece of the Syndeo is in fluid communication with the vacuum source and the waste container through the second conduit.

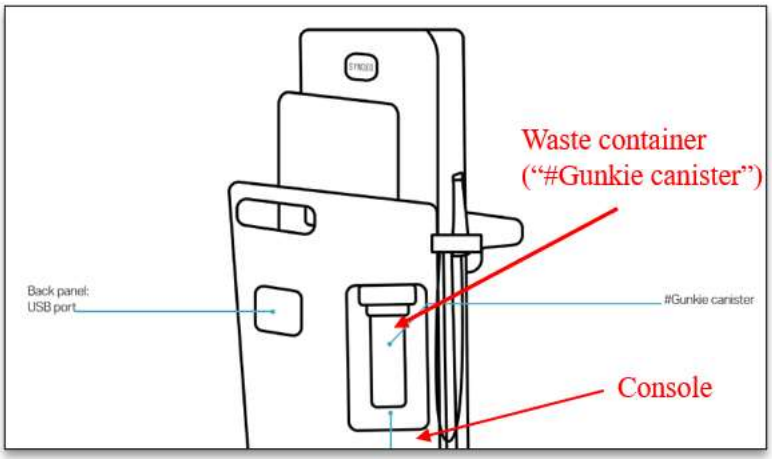
148. As explained in Section VII.A.6. above, the handpiece is in fluid communication with the vacuum source through the second conduit. The handpiece is also in fluid communication with the waste container through the second conduit. As shown in the image below, the Syndeo includes a waste container ("#Gunkie Waste Canister") connected to the console. The image below, excerpted from the Syndeo IFU, illustrates attaching the waste container to the console of the Syndeo system.



EX2030 at 12. The Syndeo IFU also describes that the handpiece is connected, through the Return Line, to the waste container ("waste canister"). EX2030 at 22

("Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister."); *id.* ("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.").

149. The Syndeo IFU also includes the figure below, which I have annotated for clarity, depicting the system having a waste container attached to the console:



Id. at 11.

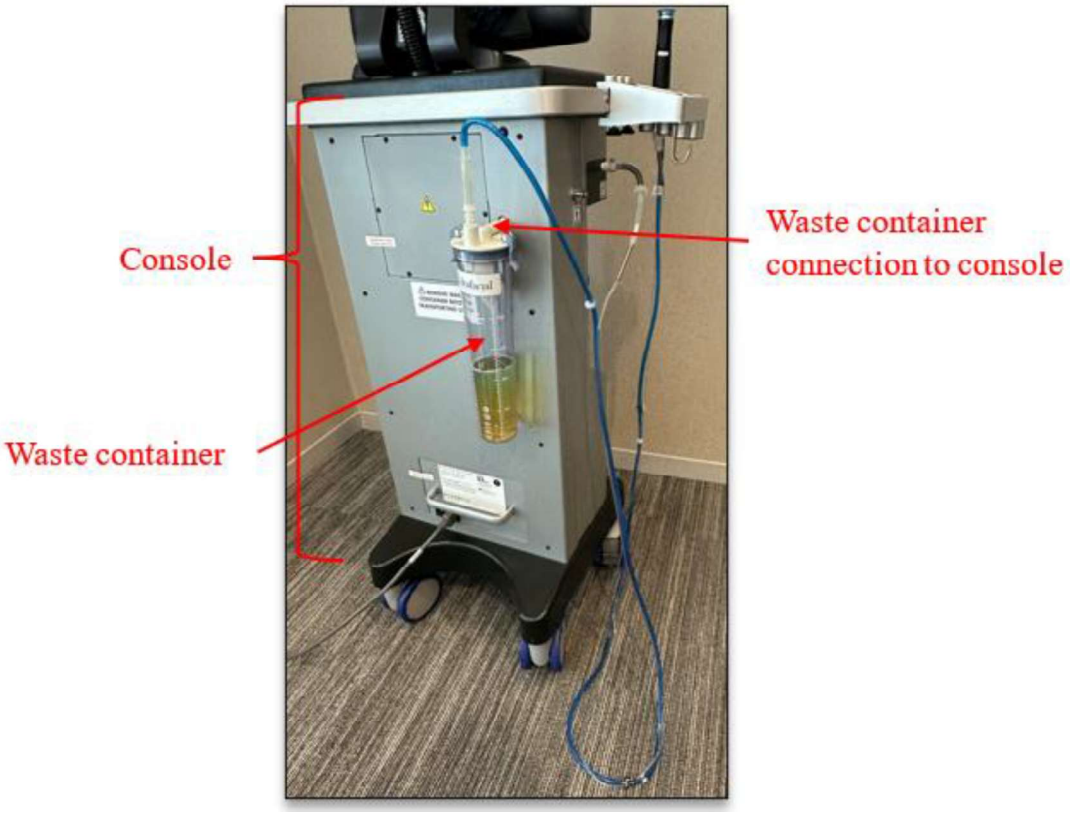
150. I also observed the fluid communication between the handpiece and the vacuum source and waste container during my examination of the Syndeo. When the vacuum source was activated and the handpiece placed in contact with skin, vacuum suction force passed from the vacuum source through the waste container and to the handpiece, where it could be felt against the skin.

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

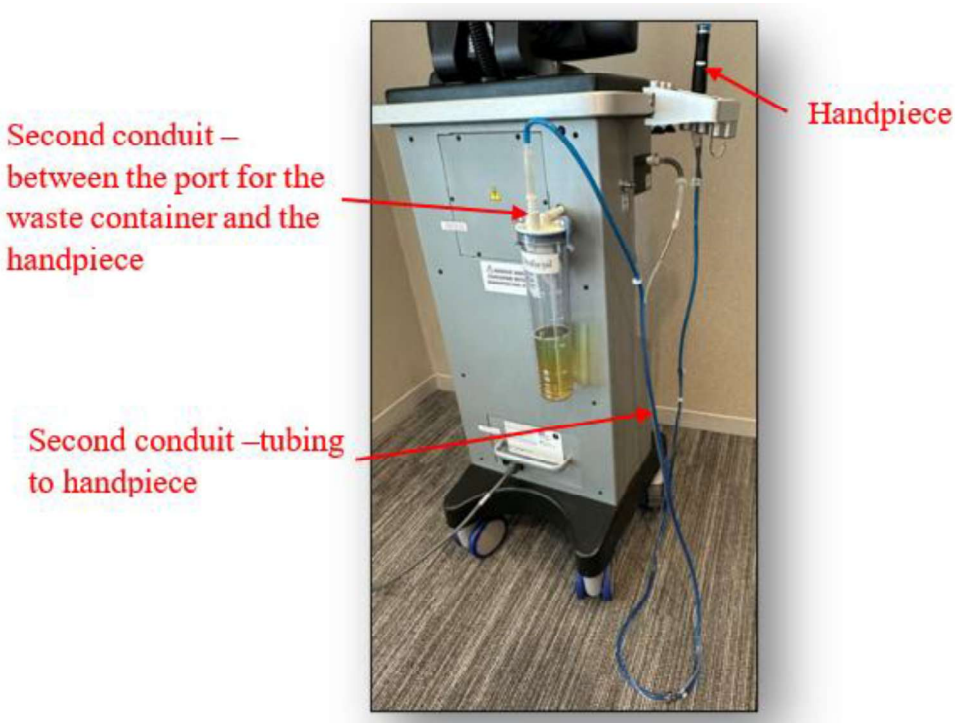
b. Elite, Allegro, and Tower

152. I have inspected the Elite, Allegro, and Tower and determined that when each of the handpiece, the first container containing a first fluid treatment, the at least one additional container containing an additional fluid treatment, and a waste container are connected to the console, the handpiece is in fluid communication with the vacuum source and the waste container through the second conduit.

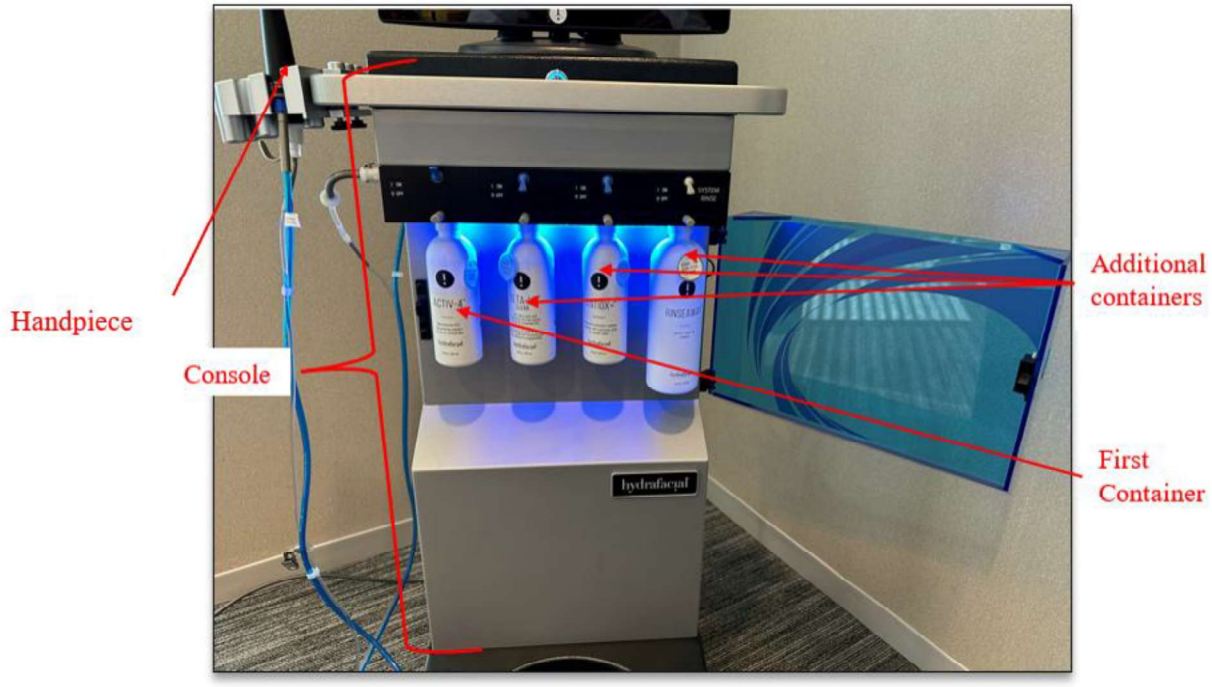
153. In the images below, the waste container is shown to be connected to the rear of the console, the handpiece is shown to be connected to the console via tubing, and the first container (as well as each additional container) is attached to the console:


Console
Waste container
connection to console
Waste container

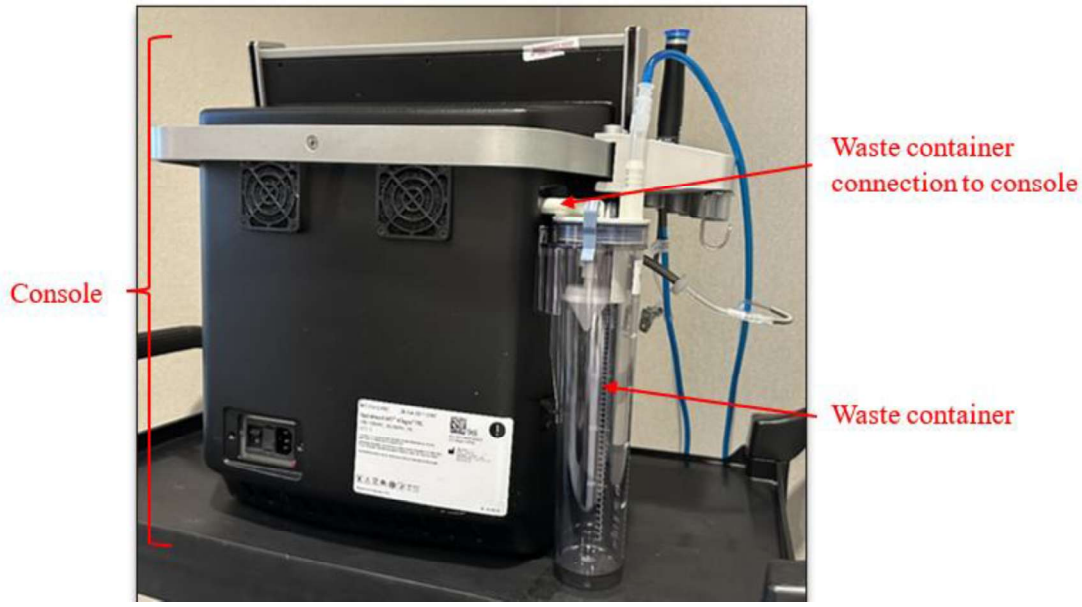
(Elite).


Handpiece
Second conduit –
between the port for the
waste container and the
handpiece
Second conduit –tubing
to handpiece

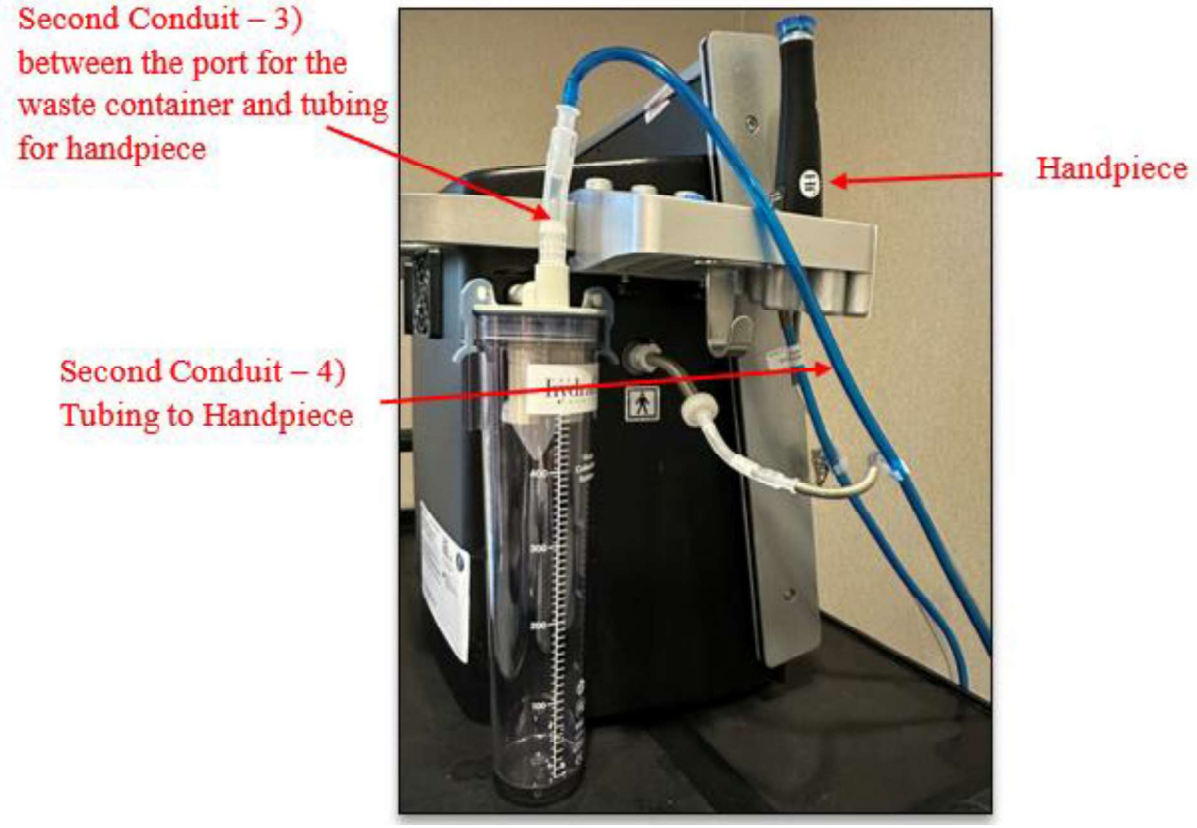
(Elite).



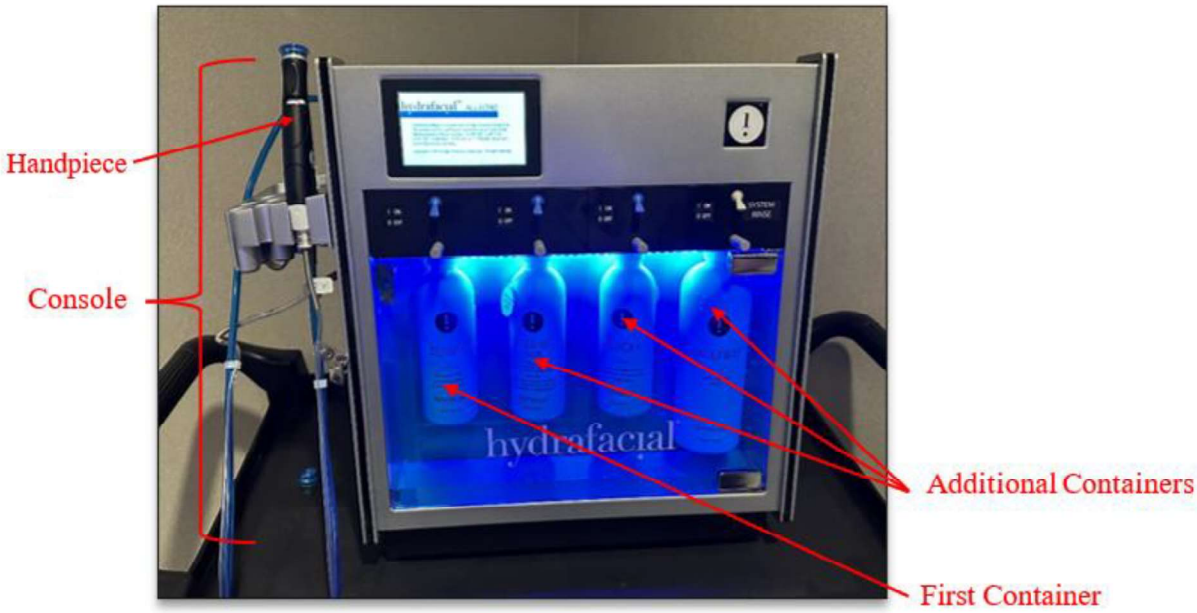
(Elite).



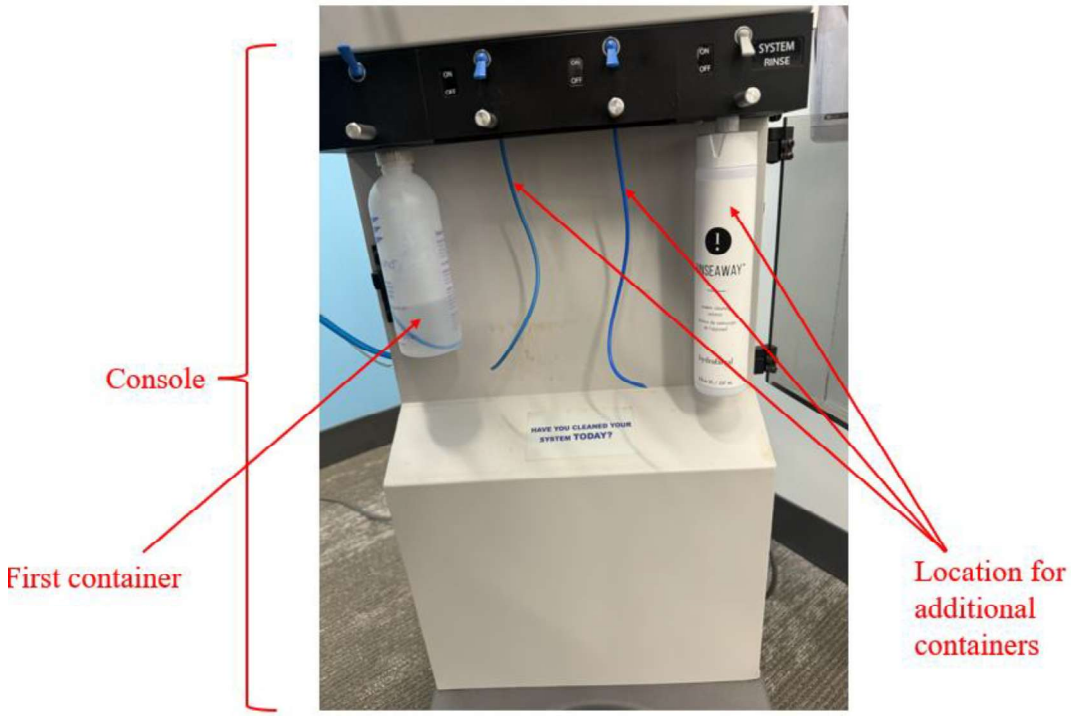
(Allegro).


Second Conduit – 3) between the port for the waste container and tubing for handpiece
Handpiece
Second Conduit – 4) Tubing to Handpiece

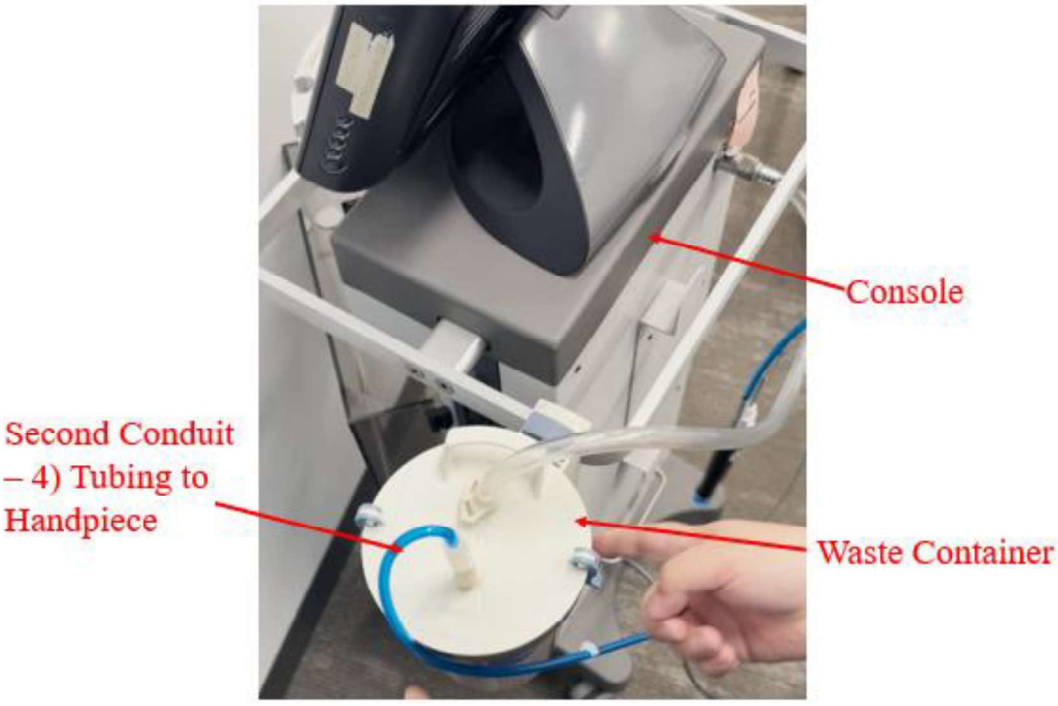
(Allegro).


Handpiece
Console
hydrafacial
Additional Containers
First Container

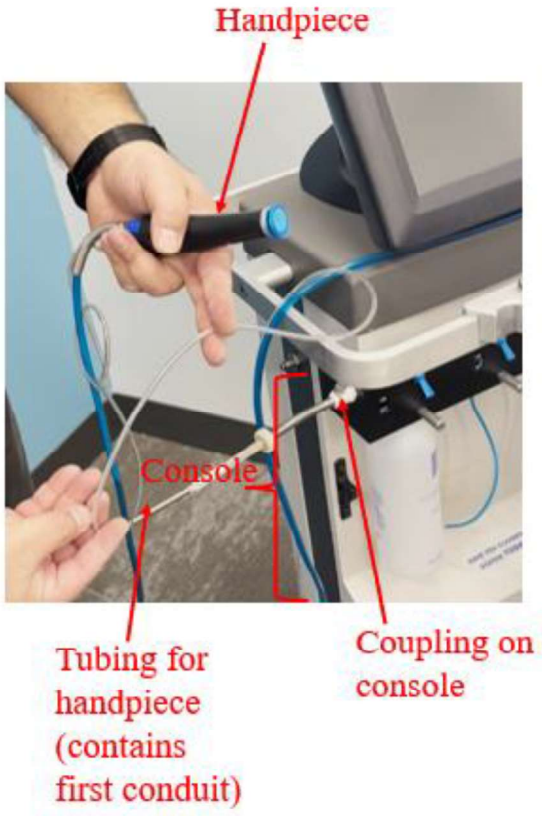
(Allegro).



(Tower).

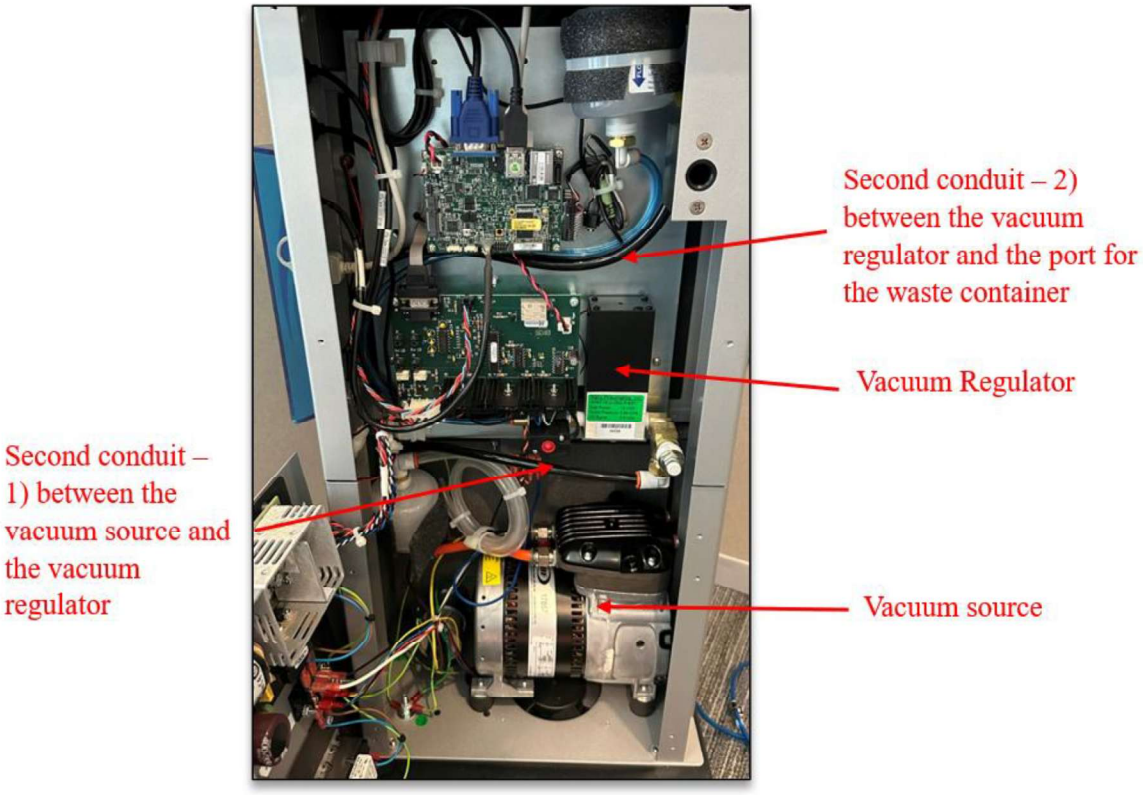

Console
Second Conduit – 4) Tubing to Handpiece
Waste Container

(Tower).

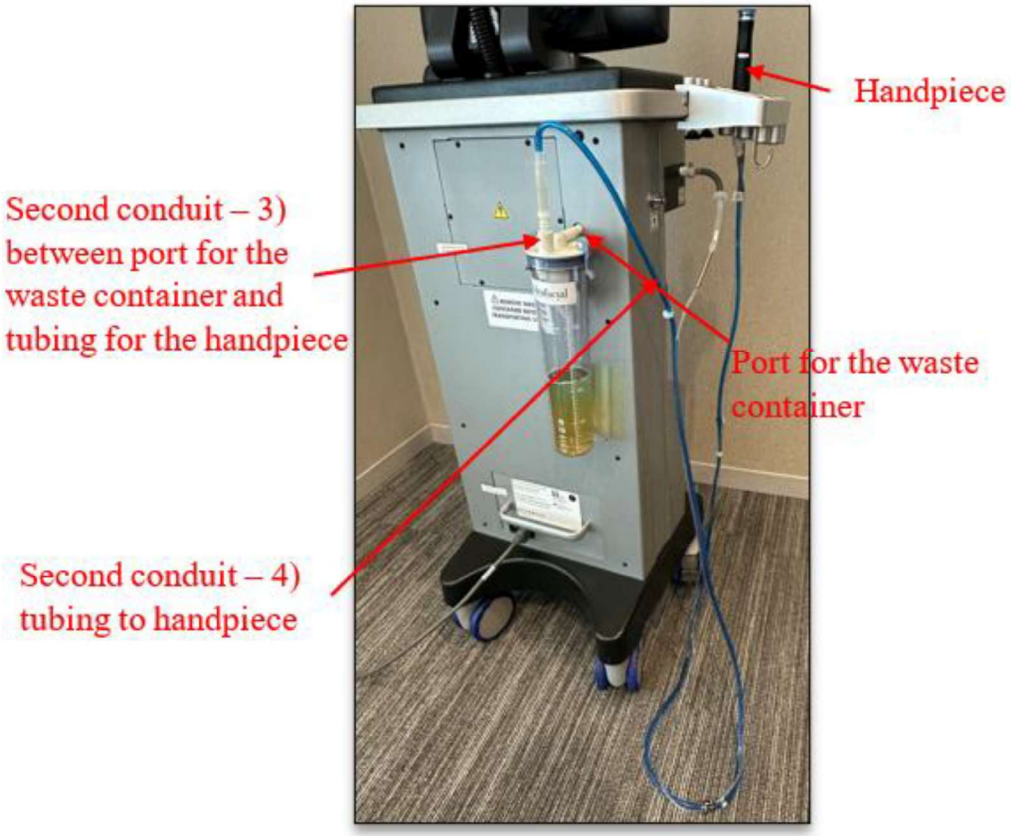


(Tower).

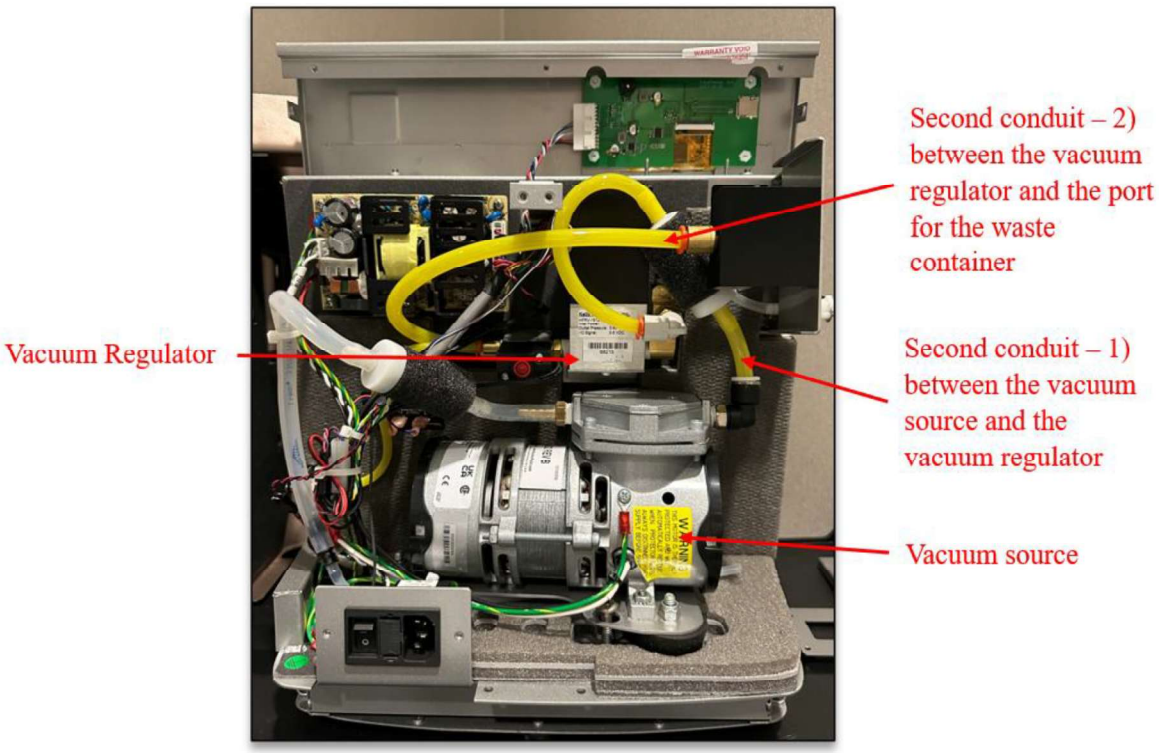
154. As explained above, the second conduit comprises multiple tubing components that extend, *inter alia*, between a vacuum source and the coupling for the handpiece tubing via the waste container and tubing, and through the coupling for the handpiece to the handpiece itself. The images below identify portions 1), 2), 3), and 4) of the second conduit for the Elite and Allegro:


Second conduit – 2) between the vacuum regulator and the port for the waste container
Vacuum Regulator
Second conduit – 1) between the vacuum source and the vacuum regulator
Vacuum source

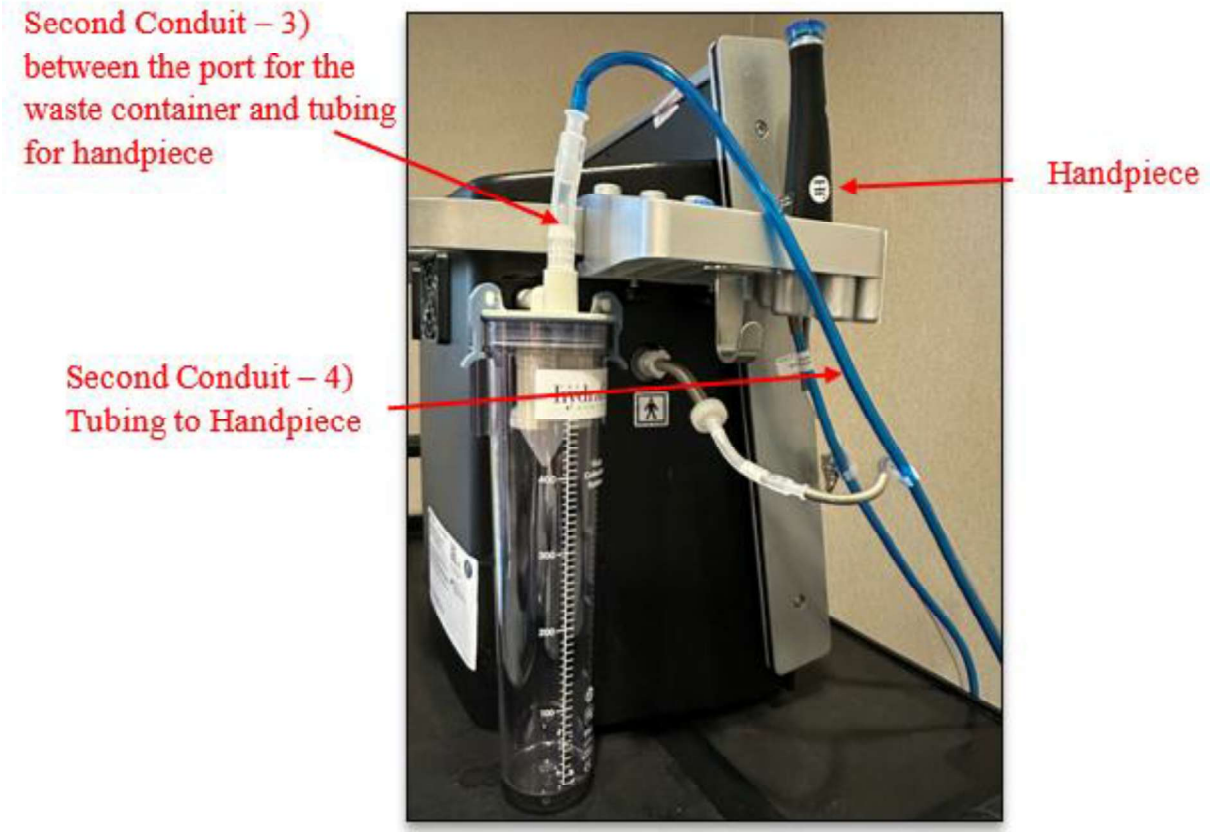
(Elite).


Handpiece
Second conduit – 3) between port for the waste container and tubing for the handpiece
Port for the waste container
Second conduit – 4) tubing to handpiece

(Elite).


Second conduit – 2) between the vacuum regulator and the port for the waste container
Vacuum Regulator
Second conduit – 1) between the vacuum source and the vacuum regulator
Vacuum source

(Allegro).



(Allegro). The Tower has the same second conduit comprised of multiple tubing components. *See supra* Section VII.A.7.b.

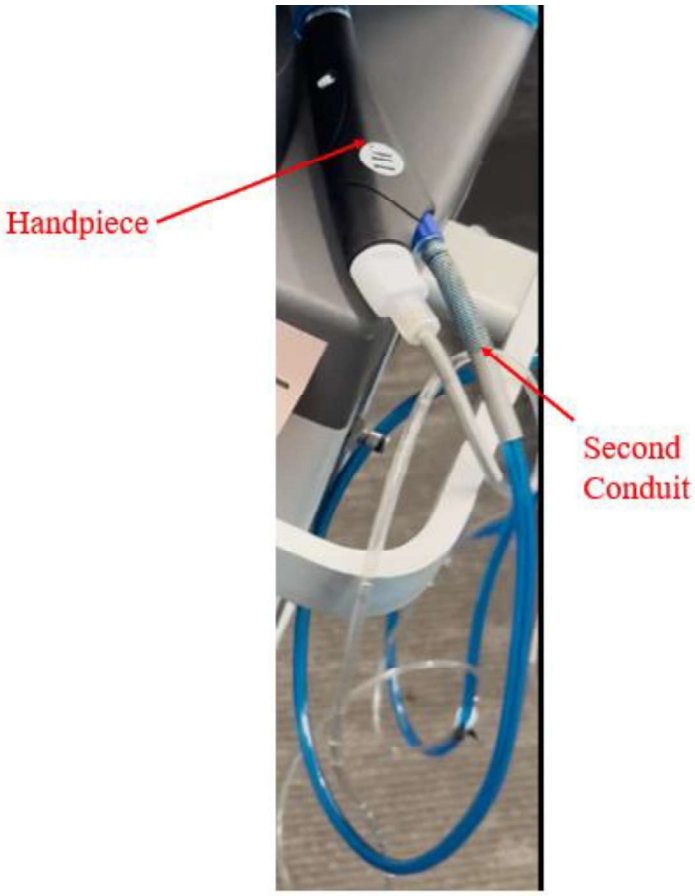
155. As discussed above, and illustrated in the annotated images below, treatment fluid flows through the first conduit contained in the Elite, Allegro, and Tower handpiece to the second conduit via an opening in the main body of the handpiece.



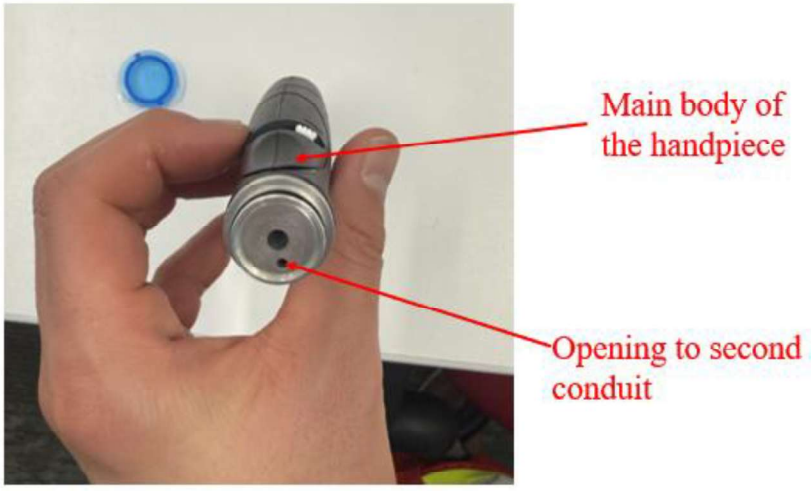
(Elite).



(Allegro).


Handpiece
Second
Conduit

(Tower).


Main body of
the handpiece
Opening to second
conduit

(Tower).

156. As explained in detail above, the user is instructed to connect the handpiece to the console for each device. *See supra* Section VII.A.7.b. The user is also instructed to connect a first container and at least one additional container to the console. *See supra* Section VII.A.5.

157. When the above conditions (fluid containers have fluid and are connected to the console, handpiece is connected to the console, waste container is connected to the console) are satisfied the handpiece of each of the Elite, Allegro, and Tower is in fluid communication with the vacuum source and the waste container through the second conduit.

158. As explained in Section VII.A.7.b. above, the handpiece is in fluid communication with the vacuum source through the second conduit. The handpiece is also in fluid communication with the waste container through the second conduit. As explained above, the handpiece for each of the Elite, Allegro, and Tower is in fluid communication with the waste container through the second conduit – 3) (Return line). Section VII.A.7.b.

159. Additionally, the Elite IFU describes that the handpiece is connected, through the Return Line, to the waste container ("waste canister"). EX2031 at 20 ("Make sure that your HydraFacial handpiece is properly connected to the side of the skin solution station block, and to the waste canister."); *id*. ("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.").

160. Similarly, the Allegro IFU describes that the handpiece is connected, through the second conduit, to the waste canister. EX2032 at 17 ("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."); *Id.* ("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.").

161. The Tower functions the same, for the reasons stated above. *See supra* Section VII.A.7.b.

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

9. "the system is configured to deliver the first treatment fluid contained in the first container and the additional treatment fluid contained in the at least one additional container to the handpiece sequentially."

163. In my opinion, each of the Syndeo, Elite, Allegro, and Tower is "configured to deliver the first treatment fluid contained in the first container and the additional treatment fluid contained in the at least one additional container to the handpiece sequentially."

164. As discussed above, I have inspected each device and observed that in use, the user selects a fluid container from the system menus in order to treat a patient with that fluid.

165. For example, below is an excerpt from a video of the Syndeo in operation. The image shows the system is configured to deliver treatment fluid contained in the first container and additional treatment fluid contained in an additional container to the handpiece sequentially via a user selecting the appropriate container from which to draw treatment fluid.



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

166. Similarly, the images below show the Elite and Allegro systems are configured to deliver treatment fluid contained in the first container and additional treatment fluid contained in an additional container to the handpiece sequentially via a user selecting the appropriate container from which to draw treatment fluid.

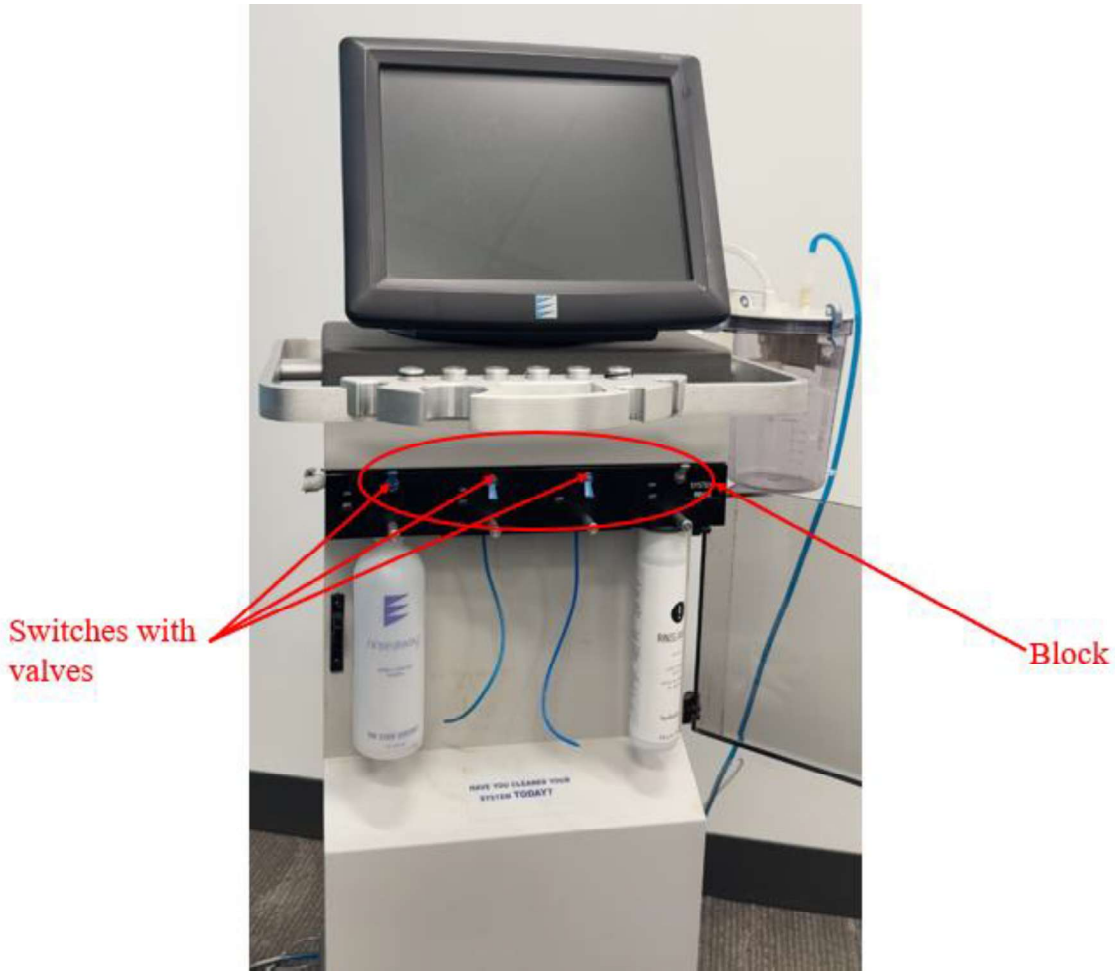


(Elite).



(Allegro).

167. Finally, the images of the Tower below show the system is configured to deliver treatment fluid contained in the first container and additional treatment fluid contained in an additional container to the handpiece sequentially via a user selecting the appropriate container from which to draw treatment fluid, consistent with the Elite and Allegro devices.



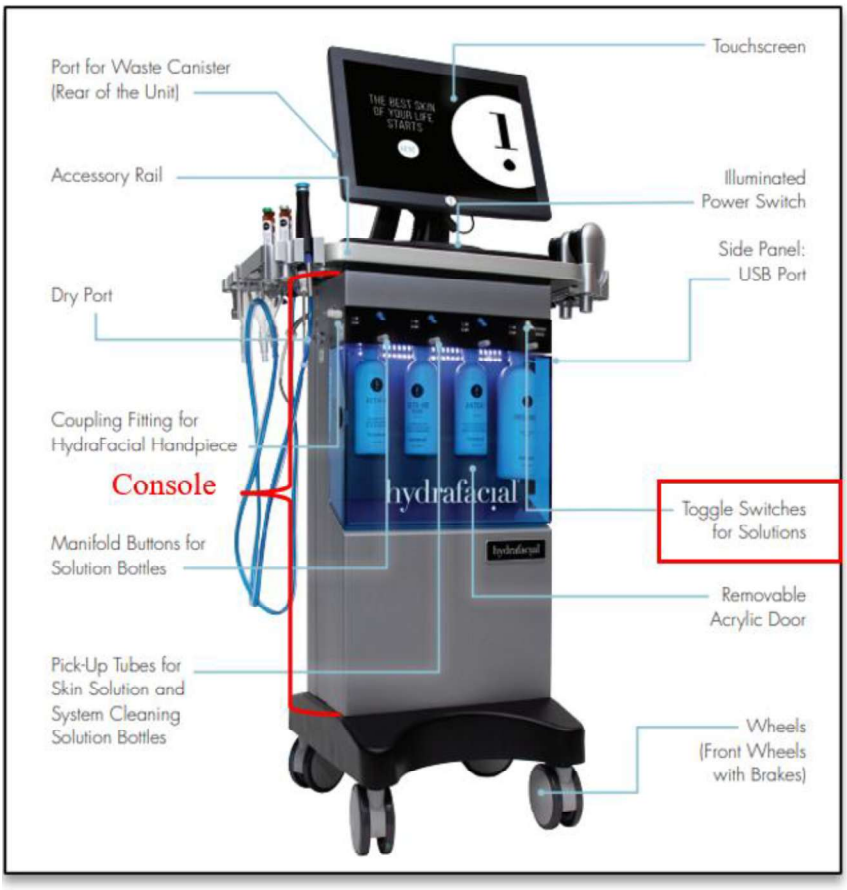
(Tower).

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



EX2030 at 14. The Syndeo IFU explains the Syndeo "automatically selects and deselects the recommended solution bottle based on the respective treatment step." *Id.* Based on this disclosure, a POSA would understand that the Syndeo is configured to deliver the treatment fluids to the handpiece sequentially "based on the respective treatment step." *Id.* The Syndeo IFU's troubleshooting section similarly describes the following scenario: "[i]f using only one station at a time, deselect current station and try another station." *Id*. at 22.

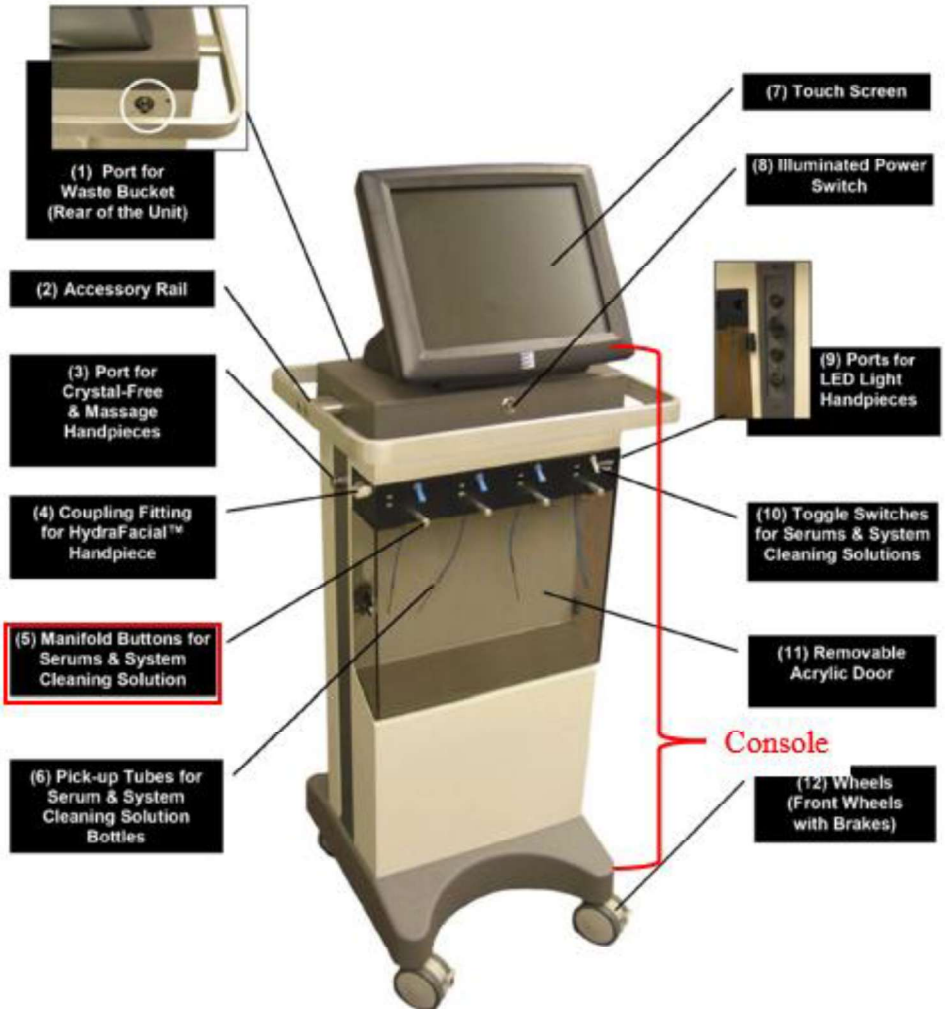
169. The Elite IFU, Allegro IFU, and Tower Owner's Manual each shows toggle switches on the console to control the delivery of the treatment fluids from the containers sequentially:



EX2031 at 10 (Elite).



EX2032 at 8 (Allegro).



EX2033 at 8 (Tower).

170. The Elite IFU explains that the "toggle switches [on the console] control which skin solution bottle is being used." EX2031 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 container is ON and the switch for the at least one additional container is OFF, treatment fluid will be

delivered to the handpiece from the first container only. Thereafter, when the switch for the first container is OFF and the switch for the at least one additional container is ON, treatment fluid will be delivered to the handpiece from the at least one additional container only. In this manner, through operation of the toggle switches, the system is configured to deliver the treatment fluids to the handpiece sequentially. Further, the Elite IFU's troubleshooting section describes the scenario, "[i]f using only one station at a time, turn current station off and try another station." *Id.* at 20.

171. The Allegro IFU contains similar disclosures. The Allegro IFU further explains that the "toggle switches control which skin solution bottle is being used. When a switch is in the ON position, fluid will be drawn from that bottle. When switched to the OFF position, no fluid will be drawn from the corresponding bottle." EX2032 at 11. Thus, for example, when the switch for the first container is ON and the switch for the at least one additional container is OFF, treatment fluid will be delivered to the handpiece from the first container only. Thereafter, when the switch for the first container is OFF and the switch for the at least one additional container is ON, treatment fluid will be delivered to the handpiece from the at least one additional container only. In this manner, through operation of the toggle switches, the system is configured to deliver the treatment fluids to the handpiece sequentially. The Allegro IFU refers to the individual block components as "stations" and

describes a troubleshooting scenario where, "[i]f using only one station at a time, turn current station off and try another station." *Id*. at 17.

172. The Owner's Manual for the Tower includes similar disclosures regarding the toggle switches. The Tower Owner's Manual explains that the "toggle switches control which serum bottle is being used. When a switch is in the OFF position, no fluid will be drawn from that bottle. When a switch is in the ON position, fluid will be drawn from that bottle." EX2033 at 8. Thus, for example, when the switch for the first container is ON and the switch for the at least one additional container is OFF, treatment fluid will be delivered to the handpiece from the first container only. Thereafter, when the switch for the first container is OFF and the switch for the at least one additional container is ON, treatment fluid will be delivered to the handpiece from the at least one additional container only. In this manner, through operation of the toggle switches, the system is configured to deliver the treatment fluids to the handpiece sequentially. Further, the Tower Owner Manual's troubleshooting section describes the scenario, "[i]f using only one station at a time, turn current station off and try another station." *Id*. at 18.

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

174. For all of these reasons, it is my opinion that each of the Syndeo, Elite, Allegro, and Tower practices Claim 1 of the '287 Patent.

B. The HydraFacial Systems Are Co-Extensive With the Claims

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

176. I have been asked to provide expert analysis on whether the Syndeo, Allegro, Elite, and Tower each embodies claim 1 of the ’287 Patent and is coextensive with claim 1, sufficient to establish a presumed nexus. As discussed in Section VII.A., above, the Syndeo, Allegro, Elite, and Tower are all multi-container systems having a claimed block, fluid control member, and collection lumen embodying claim 1 of the ’287 Patent.

177. Further, the Syndeo, Elite, Allegro, and Tower are coextensive with the Claim 1 for several reasons. First, Claim 1 is directed to skin treatment systems with specific key features including (1) multiple fluid containers, (2) a block, (3) fluid communication between the fluid containers and the block (4) fluid communication between a handpiece and the block (5) a vacuum source, (6) a waste container, and (7) fluid communication between the vacuum source and waste container and the handpiece. As discussed in detail above in Section VII.A., the Syndeo, Elite, Allegro, and Tower are skin treatment systems that include the key features recited in the claims.

178. Second, the Syndeo, Elite, Allegro and Tower do not contain other key or driving features that are not claimed. For example, these systems may include red and blue light therapy handpieces. However, the systems are primarily and extensively marketed as a hydrodermabrasion system, rather than light therapy devices. *See, e.g.*, EX2038 (Tower), EX2039 (Tower), EX2040 (Tower), EX2041 (Tower), EX2042 (Tower), EX2043 (Tower), EX2044 (Elite), EX2045 (Elite), EX2046 (Elite), EX2047 (Allegro). I understand from Dr. Duboys[4] that the red and blue light therapy handpieces are insignificant to the Syndeo, Elite, Allegro, and Tower, as they are unrelated to hydrodermabrasion and the effects could be achieved using less expensive machines. *See, e.g.,* EX2015 (handheld red, blue and infrared light treatment device sold for $299, available at https://www.celluma.com/products/celluma-pod). Thus, the features of the Syndeo, Elite, Allegro, and Tower that are significant are the features coextensive with Claim 1 of the '287 Patent.

179. Thus, in my opinion, a nexus is presumed between the secondary considerations and the Syndeo, Elite, Allegro, and Tower.

[4] Discussions with Dr. Duboys on 1/09/2025

C. Independent of the Presumption, a Nexus Exists Between the Objective Indicia and the '287 Patent Claims

1. The Nectre Was HydraFacial's Single-Container Hydrodermabrasion System

180. I understand that, in May 2008, HydraFacial launched a hydrodermabrasion system known as the HydraFacial Nectre ("Nectre"). *See, e.g.,* EX2035, EX2036, EX2037. I understand that HydraFacial stopped selling the Nectre in 2013. Unlike the Tower, Elite, Allegro, and Syndeo, the Nectre was a single-container hydrodermabrasion system that lacked a block that could receive fluid from multiple connected containers.

181. In my opinion, the Nectre meets the limitations of Claim 1 that are not dependent on the device having multiple containers connected to the console and having a block. Below is an analysis of Claim 1 of the '287 Patent.

Exemplary Claim 1

182. Claim 1 recites as follows:

> 1. A system for treating skin, the system comprising:
> a console configured to receive a first container and at least one additional container;
> a handpiece configured to contact skin tissue of a subject; and
> a block in the console, wherein the block is:
> configured to selectively receive fluid from the first container when the first container is connected to the console;
> configured to selectively receive fluid from the at least one additional container when the at least one additional containers is connected to the console; and,

configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console;

a vacuum source, wherein the console comprises the vacuum source; and

wherein the handpiece is configured to be in fluid communication with the vacuum source through a second conduit when the handpiece is connected to the console;

wherein when the handpiece, the first container, the at least one additional container and a waste container are each connected to the console, the first container contains a first treatment fluid, and the at least one additional container contains an additional treatment fluid, the handpiece is in fluid communication with the vacuum source and the waste container through the second conduit; and

the system is configured to deliver the first treatment fluid contained in the first container and the additional treatment fluid contained in the at least one additional container to the handpiece sequentially.

I address each limitation of this claim below.

a. <u>"A system for treating skin, the system comprising:"</u>

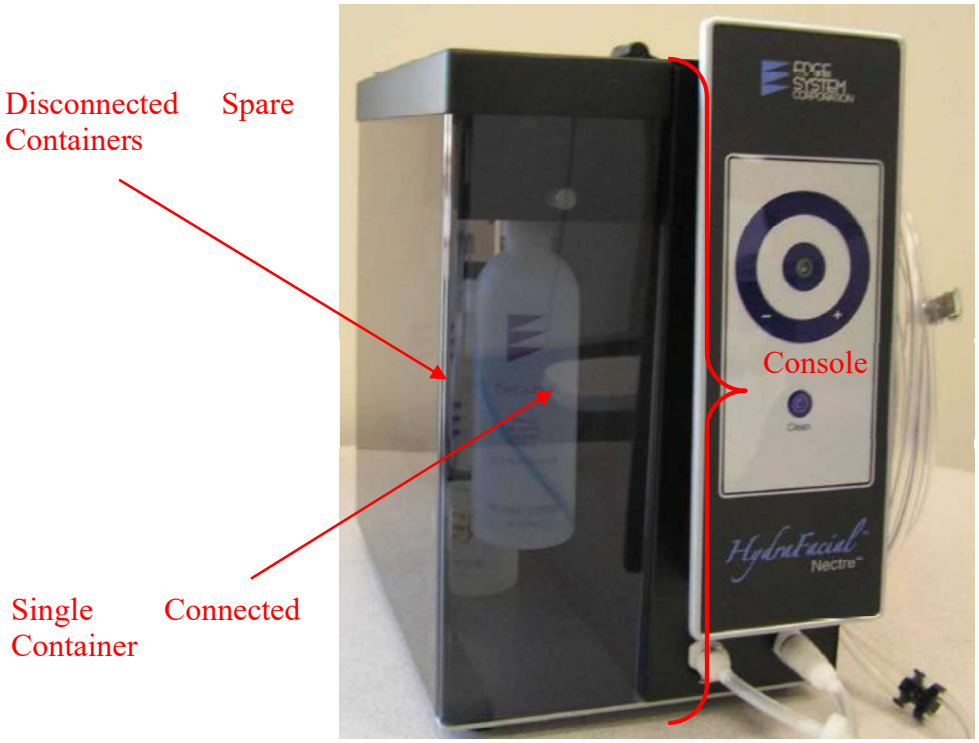
183. In my opinion, the Nectre is "a system for treating skin."

184. The Nectre User's Manual describes the Nectre as "a revolutionary breakthrough in aesthetic technology" and explains that it is "the next generation of exfoliation and skin rejuvenation." EX2036 at 4. The User Manual identifies the Nectre as a "USA FDA Class I exempt device" where the intended use is "to perform dermabrasion (or exfoliation) using mechanical abrasion and water" and to "introduce[e] topic 'dermaceuticals' . . . during treatment." *Id*.

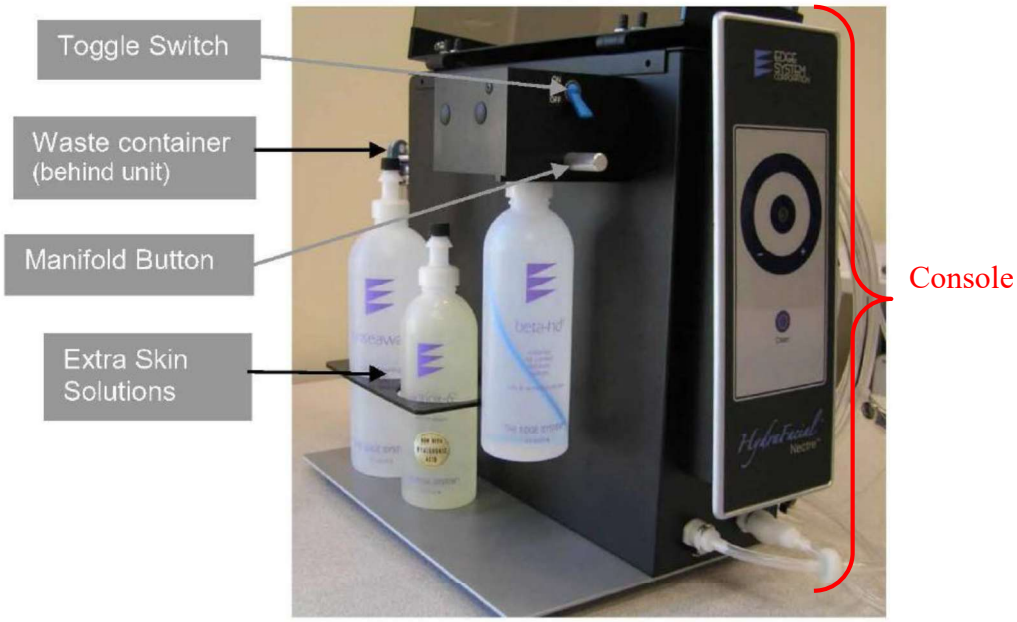
b. <u>"a console configured to receive a first container and at least one additional container;"</u>

185. In my opinion, the Nectre has "a console configured to receive a first container," but not "at least one additional container."

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

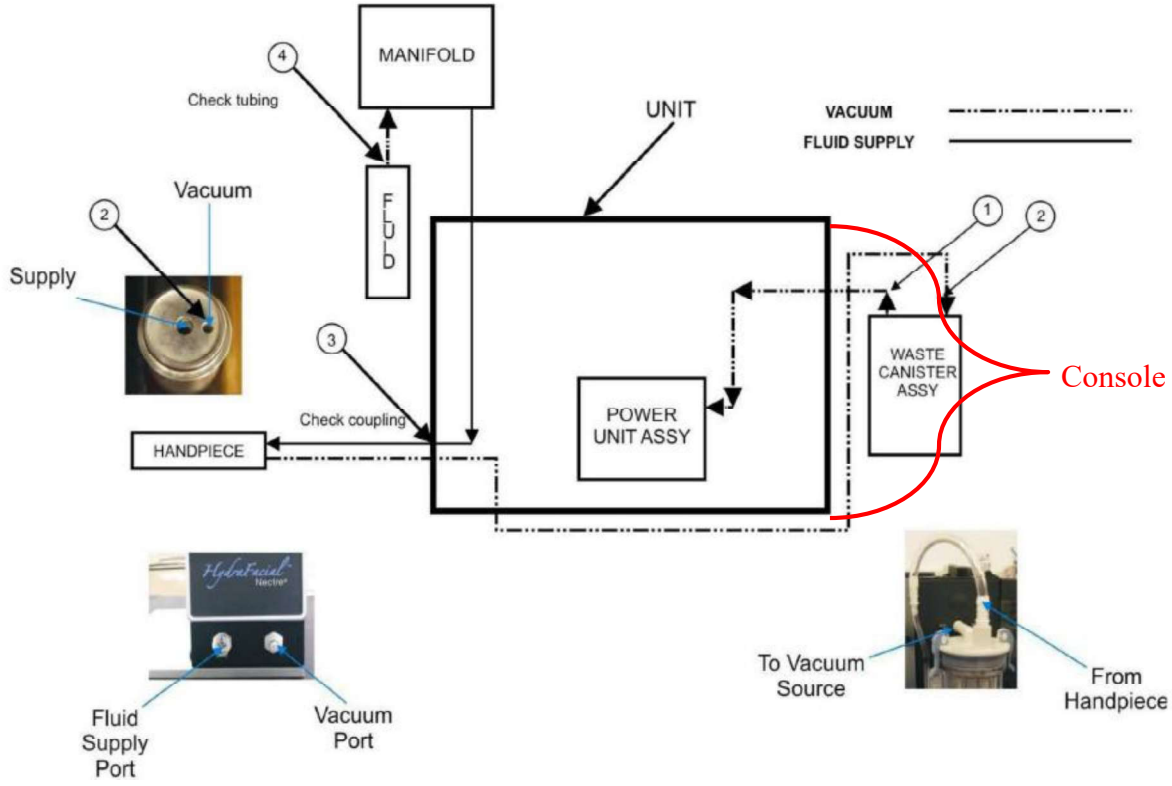


EX2035 at 1.



EX2036 at 11.

187. Schematics for the Nectre confirm that only a single fluid container may be connected to the console at a time.



EX2037 at 6.

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

4) INSTALL SKIN SOLUTION BOTTLES

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

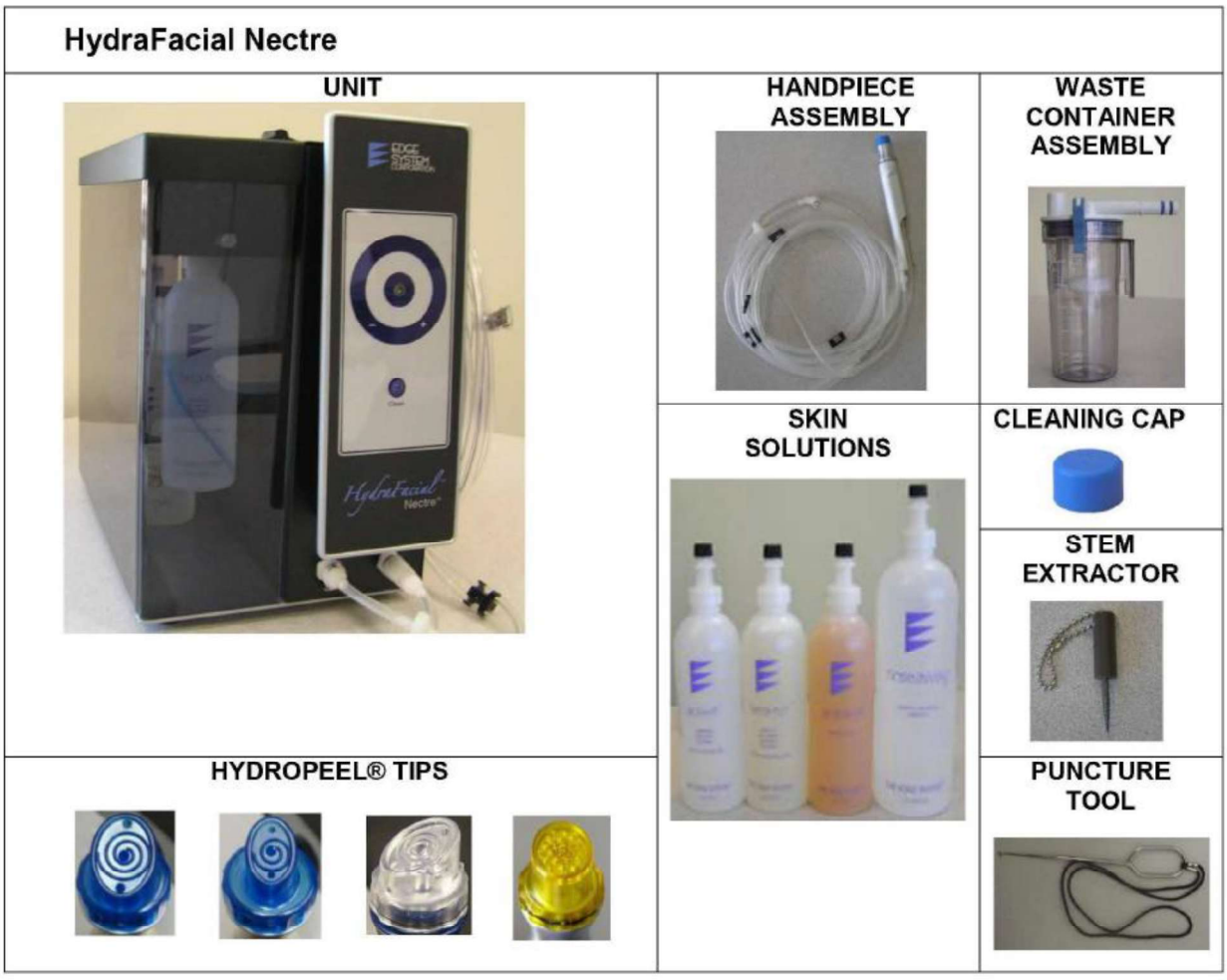


EX2036 at 12.

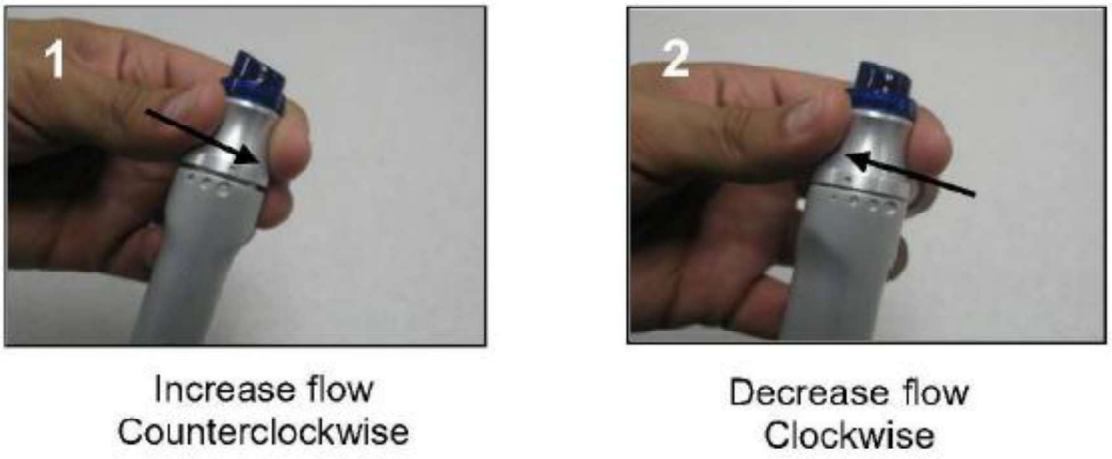
c. <u>"a handpiece configured to contact skin tissue of a subject; and"</u>

189. In my opinion, the Nectre has "a handpiece configured to contact skin tissue of a subject."

190. The Nectre includes a handpiece, as shown in the images below.



EX2036 at 12.



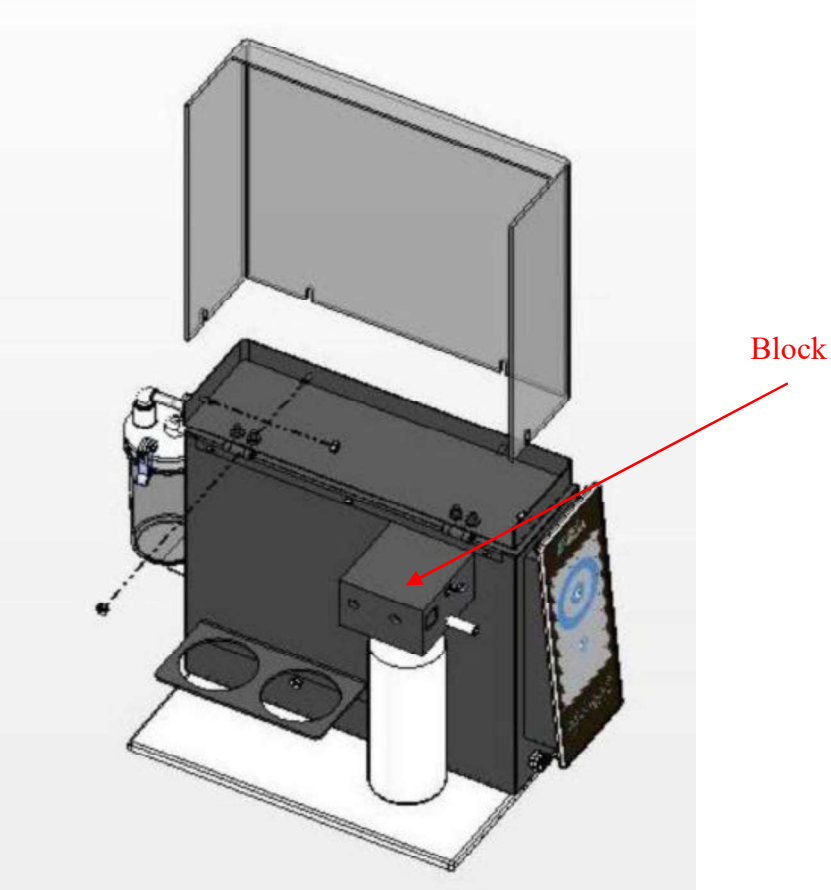
EX2036 at 16.

191. In addition, the User Manual confirms that the handpiece configured to contact skin tissue, instructing users to "[d]o a sensitivity test on the neck by the earlobe[.]" EX2036 at 7; *see also supra* at Section VII.C.1.a.

d. <u>"a block in the console, wherein the block is:"</u>

192. In my opinion, the Nectre includes a "block in the console" meeting sub-elements (i) and (iii), but not meeting sub-element (ii).

193. The Nectre Service Manual contains an illustration of the console with certain system components. I have provided an annotated version of this illustration, identifying the location of the internal block located within the console.

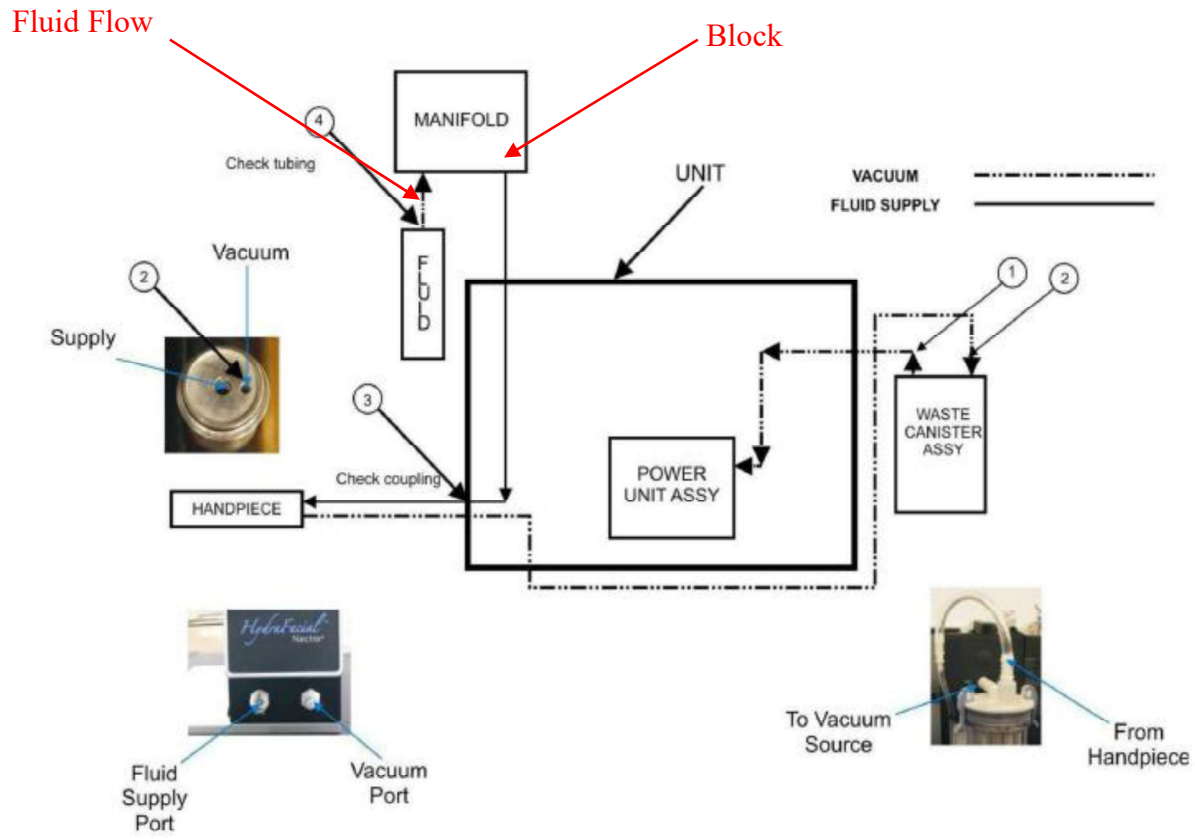


EX2037 at 12.

i. <u>"configured to selectively receive fluid from the first container when the first container is connected to the console"</u>

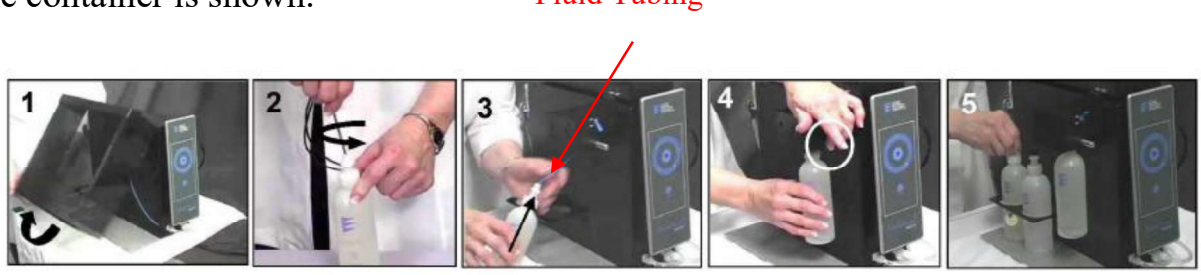
194. In my opinion, the Nectre has "a block in the console that is configured to selectively received fluid from the first container when the first container is connected to the console."

195. The below schematic shows how the block receives fluid from the first (only) fluid container in the Nectre.



EX2037 at 6.

196. In addition, as discussed above, users are instruction to connect the container to the console. In the below images, tubing extending from the block into the container is shown.



EX2036 at 12.

ii. <u>configured to selectively receive fluid from the at least one additional container when the at</u>

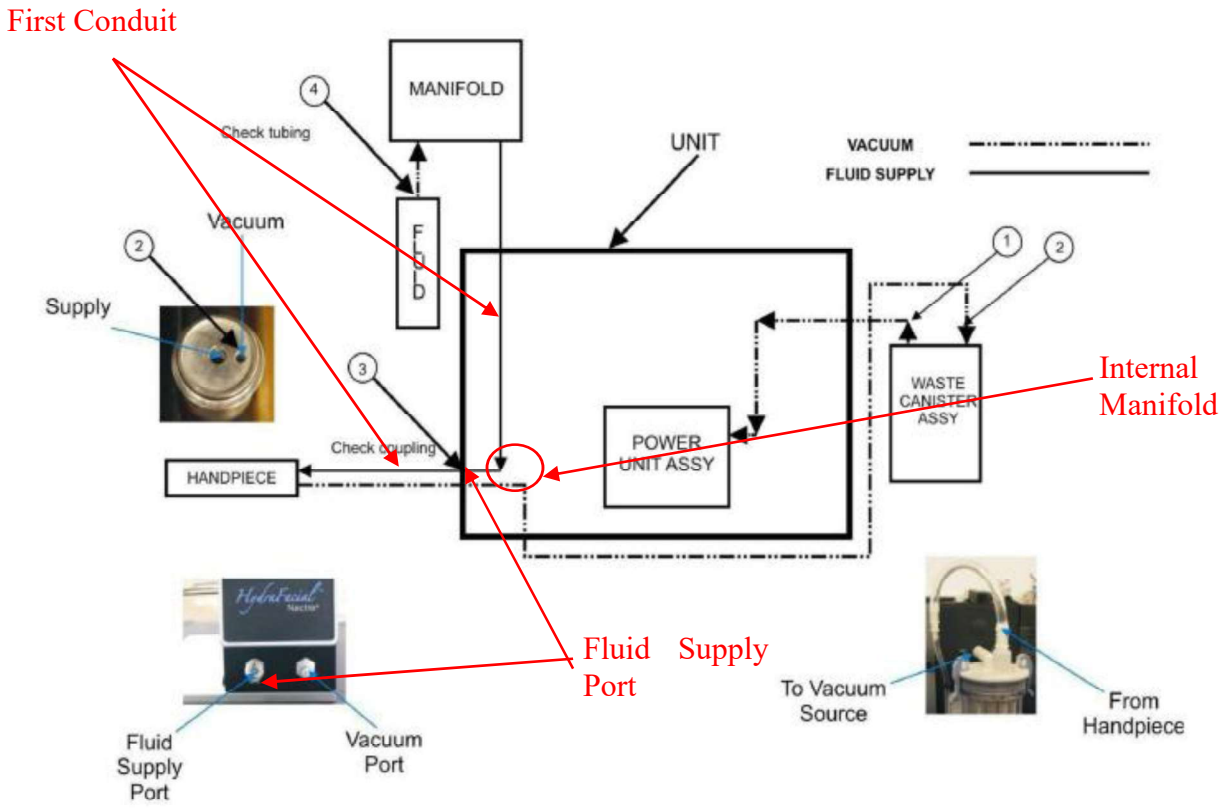
least one additional containers is connected to the console; and

197. The Nectre only allows for a single container to be connected to the console, and therefore does not meet this limitation.

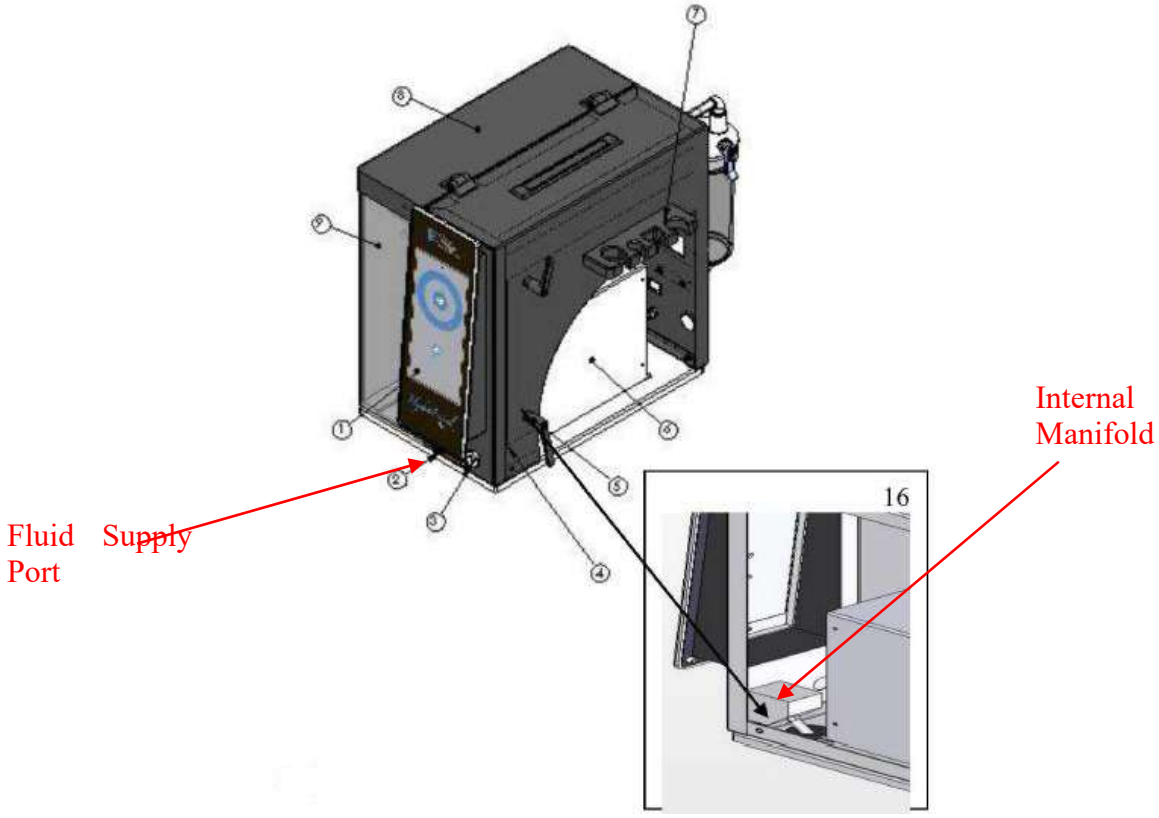
iii. configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console

198. In my opinion, the Nectre has "a block in the console that is configured to selectively be in fluid communication with the handpiece through a first conduit when the handpiece is connected to the console."

199. As shown in the schematic and image below, a first conduit extends from the block to the handpiece through a fluid supply port and internal manifold.

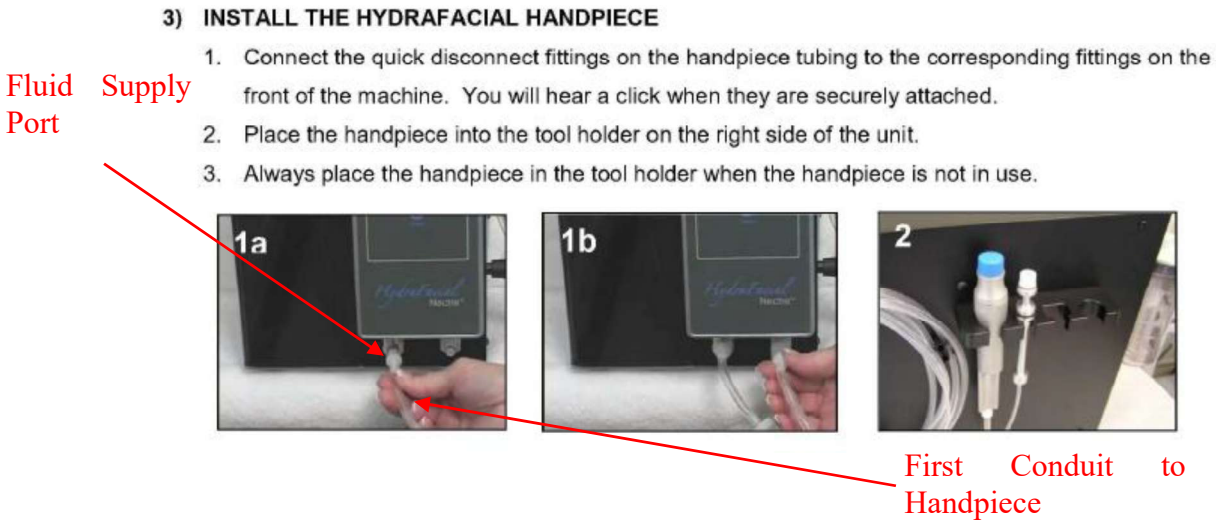

First Conduit
MANIFOLD
Check tubing
UNIT
VACUUM
FLUID SUPPLY
Vacuum
Supply
FLUID
WASTE CANISTER ASSY
Internal Manifold
POWER UNIT ASSY
Check coupling
HANDPIECE
Fluid Port
Supply
To Vacuum Source
From Handpiece
Fluid Supply Port
Vacuum Port

EX2037 at 6.



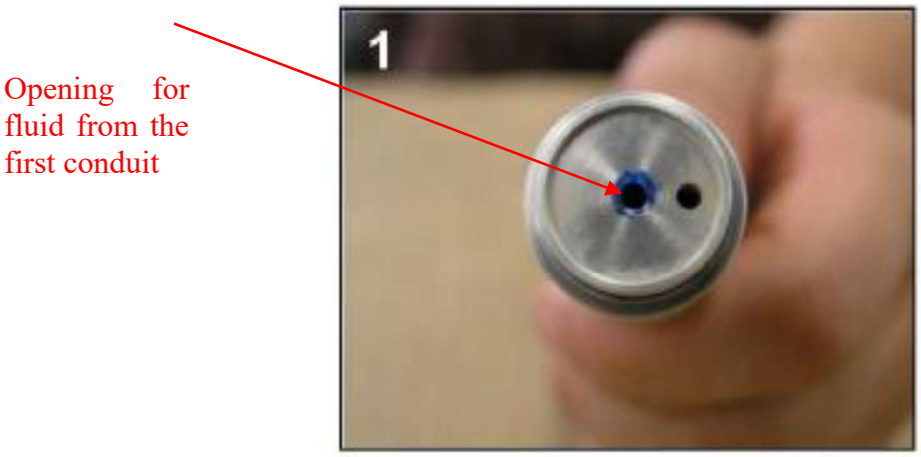
Id. at 7.

200. The handpiece is connected to the console and placed in fluid communication with the block (and the container via the block), through the fluid supply port.



EX2035 at 13.

201. The first conduit extends from the fluid supply port to the handpiece.



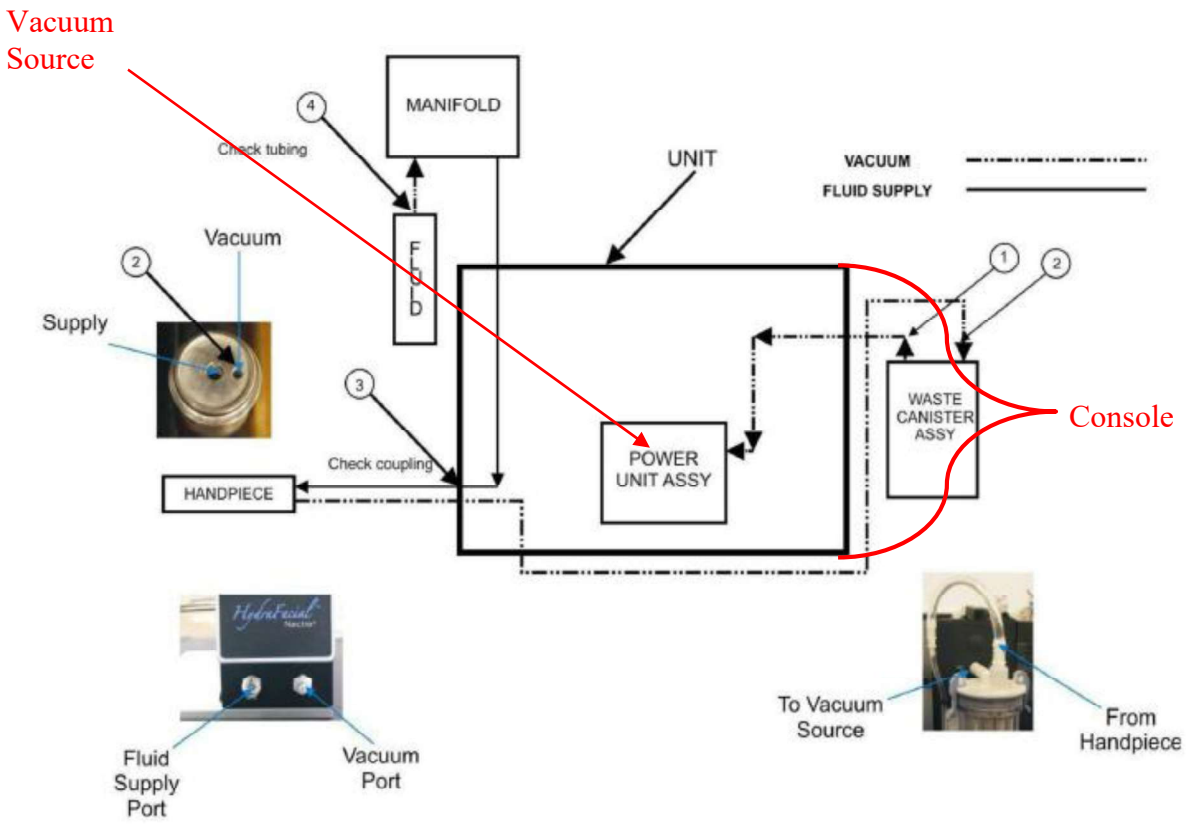
202. The block is "selectively in fluid communication" through this first conduit in two ways. First, by selectively attaching the container. When a selected container is disconnected, the circuit cannot be completed and "fluid communication" ceases to exist between the block and the handpiece. Second, the handpiece can be selectively detached from the console. When detached, the circuit

cannot be completed and "fluid communication" again ceases to exist between the block and the handpiece.

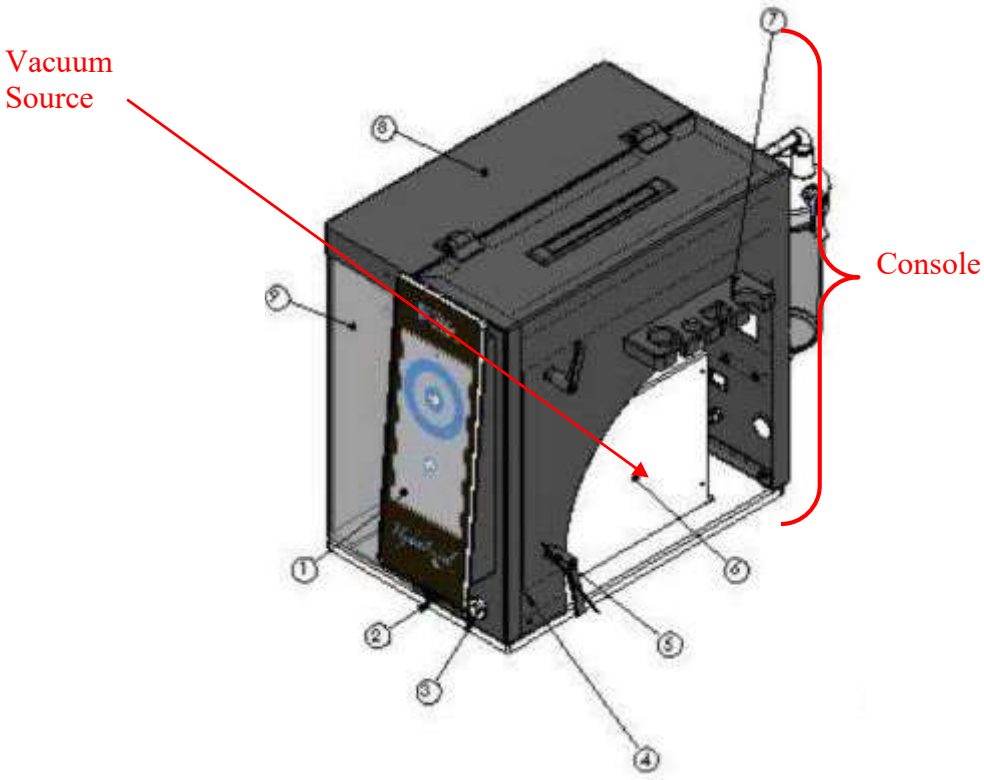
e. <u>"a vacuum source, wherein the console comprises the vacuum source; and"</u>

203. In my opinion, the has "a vacuum source, wherein the console comprises the vacuum source."

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



EX2037 at 6.



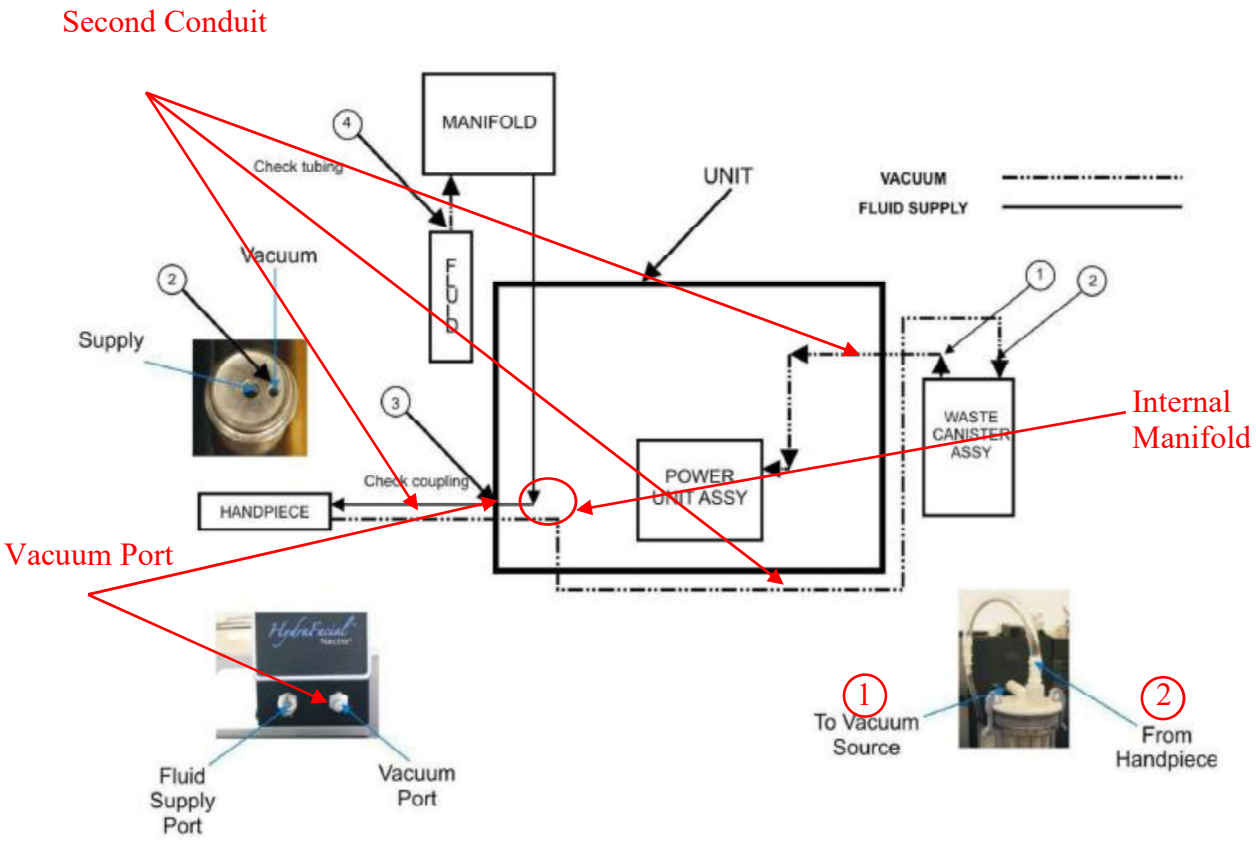
Id. at 7.

f. <u>wherein the handpiece is configured to be in fluid communication with the vacuum source through a second conduit when the handpiece is connected to the console;</u>

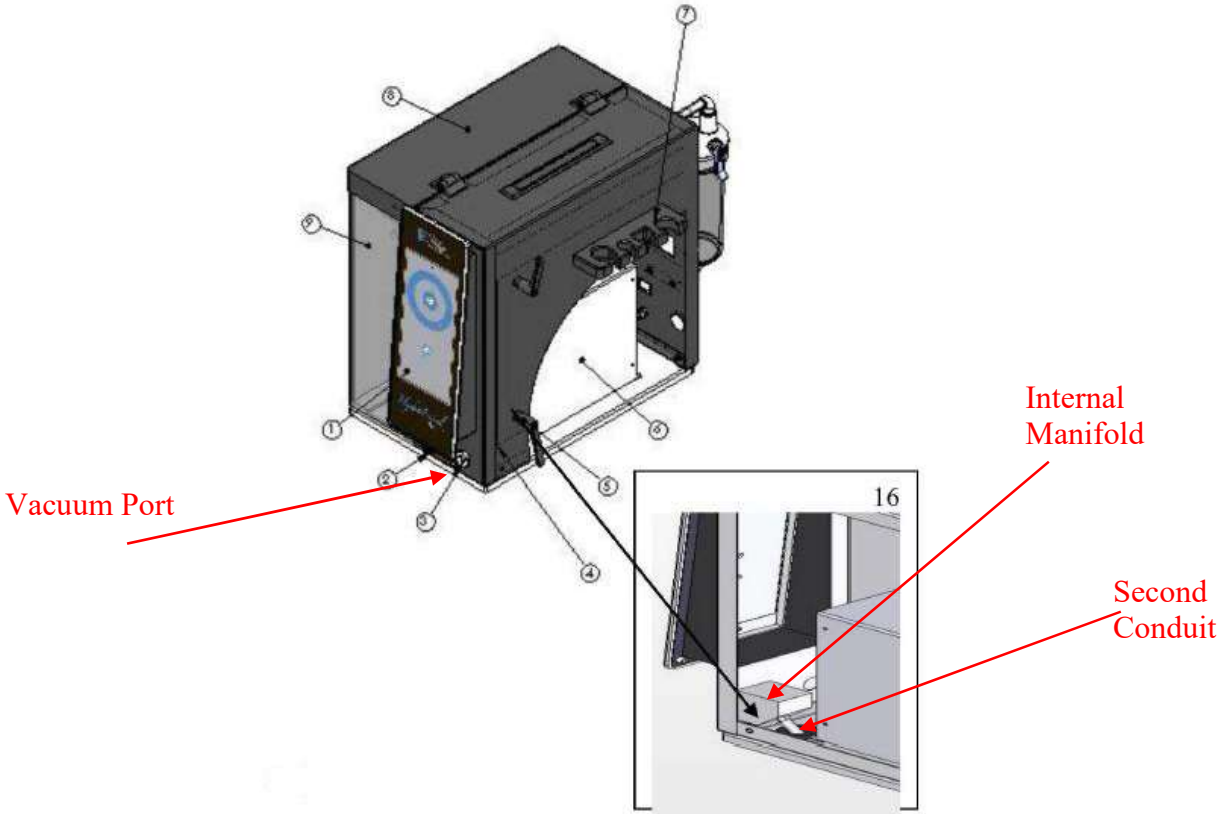
205. In my opinion, the Nectre has a "handpiece [that] is configured to be in fluid communication with the vacuum source through a second conduit when the handpiece is connected to the console."

206. As shown in the below schematic, a second conduit extends from the vacuum source to a vacuum port for the waste container, from the vacuum port for the waste container to the waste container, from the handpiece port in the waste

container to the vacuum port for the handpiece, and from the vacuum port for the handpiece to the handpiece itself via the internal manifold and vacuum port.

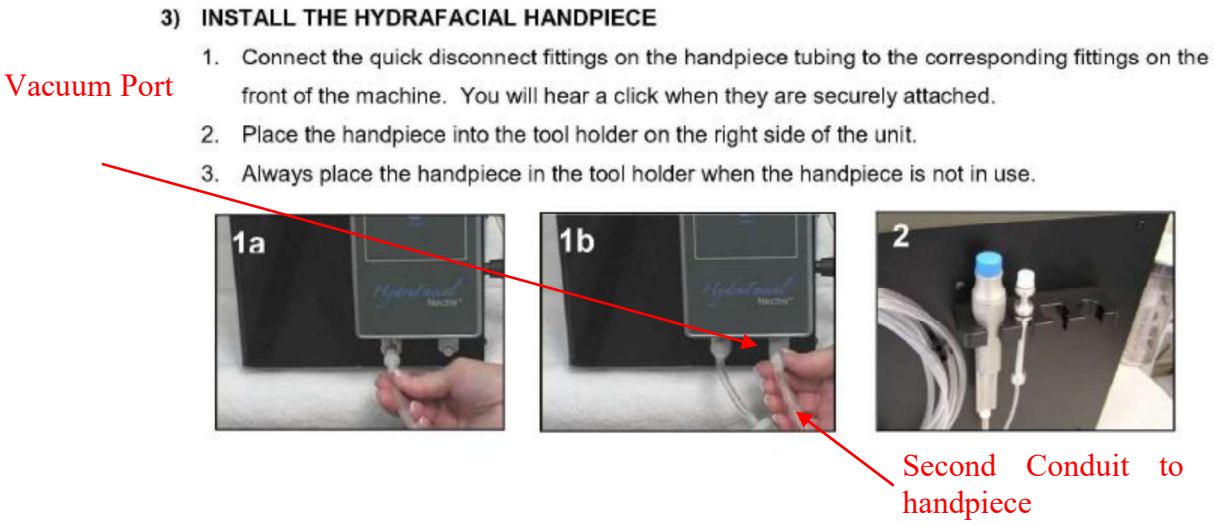


EX2037 at 6.



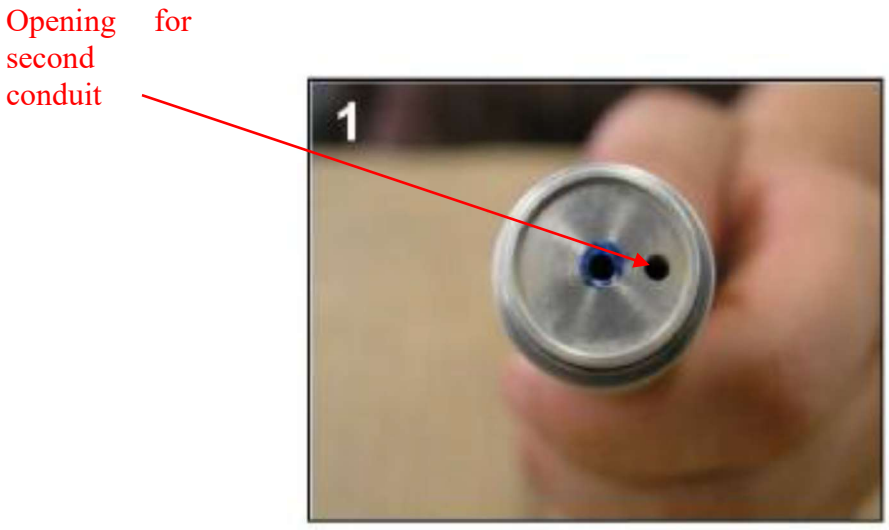
Id. at 7.

207. The handpiece is connected to the console and placed in fluid communication with the vacuum source through the vacuum port and waste container, via the second conduit.



EX2035 at 13.

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



209. Due to the above-described fluid communication, when the vacuum source is activated and the handpiece is contacting skin, a closed system is formed

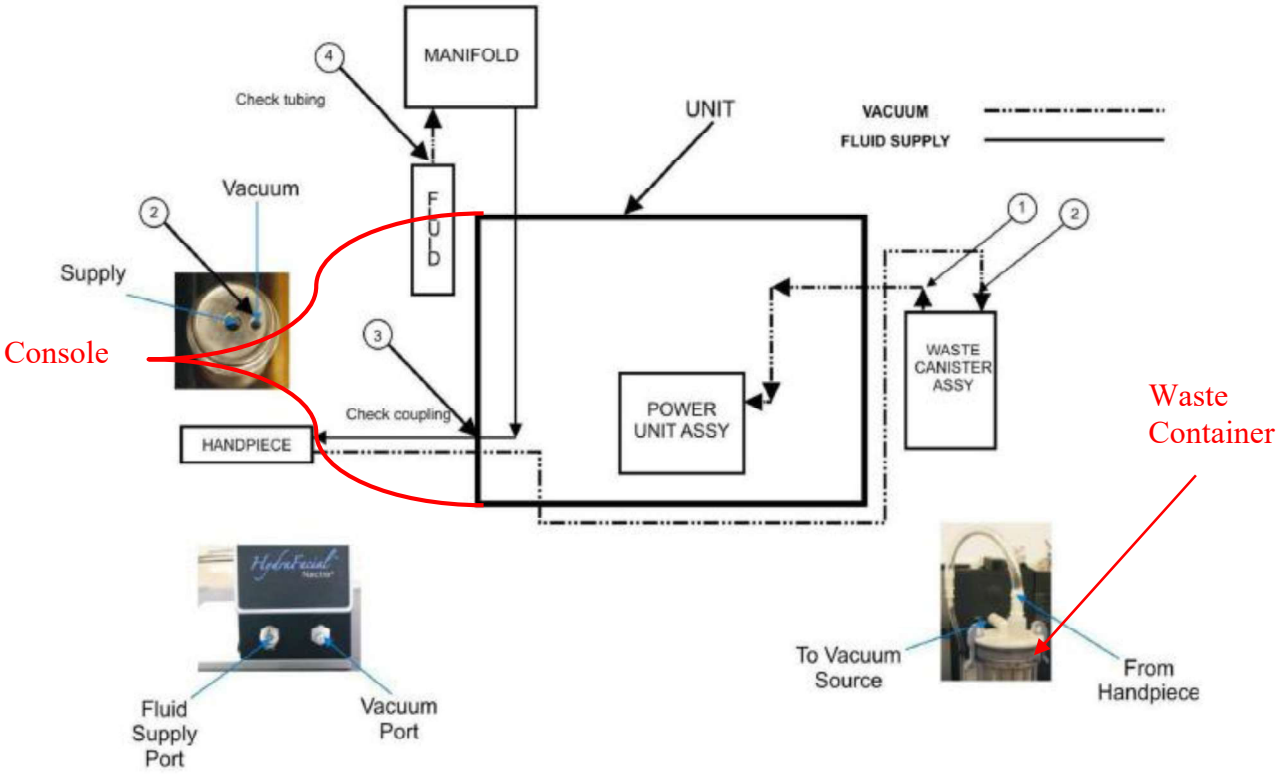
between a selected container and the vacuum source. Suction from the vacuum source, through the second conduit, the handpiece, the first conduit, and the block allows fluid to be drawn from the selected container and delivered to the skin, while used fluid and debris is simultaneously drawn away from the skin to the waste container.

> **g. <u>wherein when the handpiece, the first container, the at least one additional container and a waste container are each connected to the console, the first container contains a first treatment fluid, and the at least one additional container contains an additional treatment fluid, the handpiece is in fluid communication with the vacuum source and the waste container through the second conduit; and</u>**

210. In my opinion, the Nectre practices the limitation "wherein when the handpiece, the first container, the at least one additional container and a waste container are each connected to the console, the first container contains a first treatment fluid, and the at least one additional container contains an additional treatment fluid, the handpiece is in fluid communication with the vacuum source and the waste container through the second conduit," with the exception that the Nectre lacks "the at least one additional container."

211. As discussed above, the first (only) container and the handpiece are connected to the console. *See supra* Sections VII.C.1.b and VII.C.1.d. In addition,

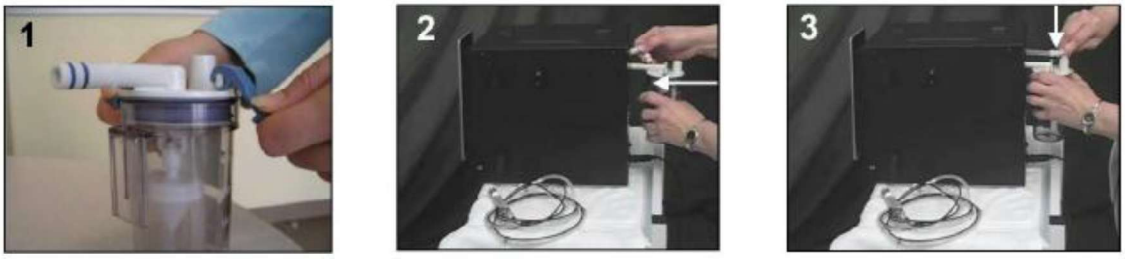
as shown in the schematic and image below, the waste container is connected to the console via ports and tubing (first and second conduits).



EX2037 at 6.

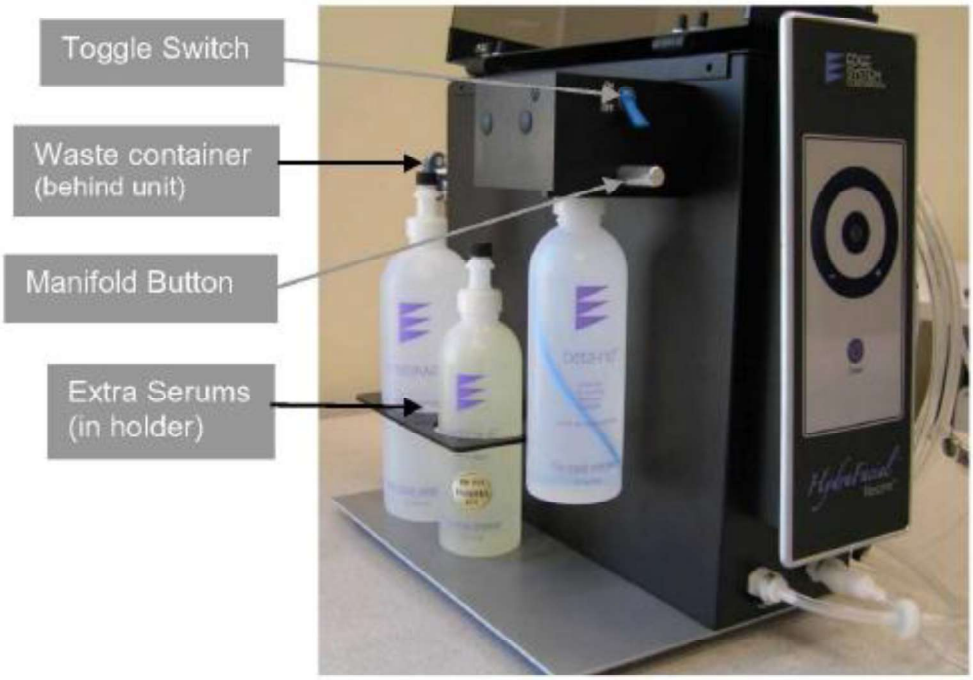
2) ATTACH WASTE CONTAINER

1. Firmly close both clips on the waste container lid.
2. Attach the waste container by inserting the connector on the lid into the port at the back of the unit.
3. Pull the tubing connector at the back of the unit, and insert it into the port on the lid of the waste container. Make sure the waste container is attached to the unit securely.



EX2035 at 12.

212. In use, the Nectre includes treatment fluids for use in the container. For the image below shows the connected container, as well as the additional detached containers with serums (e.g., beta-hd and Antiox-6).



EX2035 at 12.

213. When the above conditions (fluid container has fluid and is connected to the console, handpiece is connected to the console, waste container is connected to the console) are satisfied the handpiece of the Nectre is in fluid communication with the vacuum source and the waste container through the second conduit. *See supra* Section VII.C.1.d.

h. <u>"the system is configured to deliver the first treatment fluid contained in the first container and the additional treatment fluid contained in the at least one additional container to the handpiece sequentially."</u>

214. As discussed above, the Nectre only includes a single container containing treatment fluid, and therefore does not meet this limitation.

215. For all of these reasons, it is my opinion the Nectre meets the limitations of Claim 1 of the ’287 Patent literally or under the doctrine of equivalents, with the exception of limitations directed to having multiple containers connected to the console (or fluid control member) and having a block, fluid control member and collection member.

216. For the same reasons (e.g. that only a single container connects to the console or fluid control member), it is my opinion that the Nectre does not practice every element of claims 2-6, 8-12, 14, 16-19, 22-26, 30-32, 34-37, 39, 41-43, and 45.

2. Nexus Between the HydraFacial System’s Commercial Success and ’287 Patent Claims

217. In my opinion, the difference between the Syndeo, Elite, Allegro, and Tower Systems, and the Nectre is the multi-container hydrodermabrasion system (having a block, fluid control member, and collection lumen) found in the Syndeo, Elite, Allegro, and Tower, as opposed to the single-container hydrodermabrasion system found in the Nectre.

218. It is further my opinion that the multi-container system allows for easier and more efficient facials (no need to pause treatment to change bottles), making the Syndeo, Elite, Allegro, and Tower more desirable. This is confirmed by the poor sales of the Nectre compared to the multi-container systems, and I understand the

poor sales led to the Nectre being discontinued. *See* EX2009 (Declaration of Vipul Savsani) at ¶¶ 7-8.

219. Accordingly, it is my opinion that there is a nexus between the commercial success of the HydraFacial Systems and the claims of the ’287 Patent directed to a multi-container system.