EXHIBIT 14

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

ALIGN TECHNOLOGY INC., Plaintiff, v. CLEARCORRECT OPERATING LLC, CLEARCORRECT HOLDINGS, INC., INSTITUTE STRAUMANN AG & STRAUMANN USA, LLC, Defendants.	Case No. 6:24-CV-00187-ADA-DTG [redacted]
CLEARCORRECT OPERATING LLC, CLEARCORRECT HOLDINGS, INC. & STRAUMANN USA, LLC, Counterclaim-Plaintiffs, v. ALIGN TECHNOLOGY INC., Counterclaim-Defendant.	

OPENING EXPERT REPORT OF DR. MAUREEN VALLEY

[redacted]

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I. INTRODUCTION

1. I have been retained by Align Technology, Inc. ("Align") to provide opinions in the above-captioned case. I understand that Align has alleged that Defendants ClearCorrect Operating LLC, ClearCorrect Holdings, Inc., Institut Straumann AG, and Straumann USA, LLC (collectively, "ClearCorrect" or "Defendants") have infringed patents assigned to Align. I have been asked to investigate and provide opinions as to (1) whether the DentalWings Virtuo Vivo scanner system infringes U.S. Patent No. 10,791,936 (the "'936 Patent" or "Scanner Patent"), (2) whether the Straumann SIRIOS scanner system infringes the '936 Patent, (3) whether Align's iTero scanner system practices the '936 Patent, (4) objective indicia of non-obviousness for U.S. Patent Nos. 8,038,444 (the "'444 Patent" or "Treatment Planning Patent"), 10,973,613 (the "'613 Patent"), 11,154,384 (the "'384 Patent"), 11,648,090 (the "'090 Patent"), and 11,648,091 (the "'091 Patent") as well as the '936 Patent. I have also been asked to provide a background on the fields of dentistry and orthodontics based on my expertise.

2. I submit this Report in compliance with Federal Rule of Civil Procedure 26(a)(2). I reserve the right to supplement or amend this Report pursuant to Rule 26(e) and as otherwise provided if additional information becomes available. I also reserve the right to respond to any opinions raised in ClearCorrect's expert reports. I expect to testify at trial regarding the opinions in this Report and any supplemental reports that I may prepare for this case. For trial, I may prepare and rely on demonstratives to show aspects of my opinions at trial. I may address other materials at trial if asked to do so.

[redacted]

II. EXPERIENCE AND QUALIFICATIONS

3. I have provided a summary of my experience and qualifications below. A copy of my most recent curriculum vitae is attached as Appendix A. A list of my prior expert witness testimony is attached as Appendix C.

4. In 1987, I earned a Bachelor of Arts Degree in Biology from the University of California, Santa Barbara. In 1992, I earned a Doctor of Medicine in Dentistry Degree from Harvard School of Dental Medicine and a Master of Public Health Degree from Harvard School of Public Health. Additionally, in 1994, I earned a Master of Science Degree and a Certificate in Orthodontics from Northwestern University School of Dentistry.

5. Since 1999, I have maintained my current dental license from the California Board of Dental Examiners. I have been a practicing dental professional since 1987, and a practicing orthodontist since 1994. From 2007 to 2022, I owned my own orthodontic private practice in San Rafael, California. I am currently an orthodontist for an orthodontic/pediatric/oral surgery dental service organization called Kids Care Dental and Orthodontics in Lodi, California. In my career, I have been involved in the treatment and care of approximately 10,000 patients, including approximately 2,500 patients using aligners.

6. For over twenty years, I was a member of numerous professional organizations, including the California Association of Orthodontists, the California Dental Association, the American Association of Orthodontists, and the American Dental Association.

7. I was an Adjunct Clinical Professor in the Department of Orthodontics at the Harvard School of Dental Medicine, and an Associate Professor and Graduate Clinic Director in the Department of Orthodontics at the University of the Pacific Arthur A. Dugoni School of Dentistry. I also have experience as an educational consultant where I created course content for

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Align Technology presentations, and as a speaker where I taught Invisalign® certification and advanced courses for dentists and orthodontists, both nationally and internationally. I have received honors and awards, including the Arthur A. Dugoni School of Dentistry Faculty Recognition Award.

III. SUMMARY OF OPINIONS

8. I understand that Align is asserting that Defendants' DentalWings Virtuo Vivo intraoral scanner system and the Straumann SIRIOS intraoral scanner system infringe Claims 1, 4-6, 8-12, and 17 of the '936 Patent.

9. I understand that Align is asserting that Defendants' ClearCorrect system infringes the following patent claims:

a. Claims 1, 6-9, 12-14, 18, and 20 of the '613 Patent.

b. Claims 1, 2, 4, 6, 7, 10, 11, and 21 of the '384 Patent.

c. Claims 1, 3, and 10 of the '090 Patent.

d. Claims 1, 4, 6, 10, 11, and 18 of the '091 Patent.

e. Claims 1, 2, 5, 6, 11-12, 14, 39, and 40 of the '444 Patent.

10. U.S. Patent No. 10,973,613, 11,154,384, 11,648,090, and 11,648,091 are referred to collectively as the "Materials Patents."

11. I was asked by Align's counsel to provide certain opinions regarding ClearCorrect's infringement of the '936 Patent. I was also asked by Align's counsel to provide background on the fields of dentistry and orthodontics regarding clear aligner materials and treatment planning based on my expertise. I was further asked by Align's counsel to provide opinions regarding the objective indicia of non-obviousness for all Asserted Patents. I was not asked to provide any opinions regarding infringement of the Treatment Planning Patent or the

[redacted]

Materials Patents. In preparing these opinions, I have considered Align's amended complaint, ClearCorrect's answer, the Asserted Patents, the file histories of the Asserted Patents, the Court's claim construction order, Align's final infringement contentions, the documents cited in Align's final infringement contentions, and transcripts of depositions taken in this case. I have inspected the DentalWings Virtuo Vivo intraoral scanner system, the Straumann SIRIOS intraoral scanner system, and the Align iTero Element intraoral scanner system. The full list of materials that I considered in preparing this report is attached as Appendix B.

12. In summary, I conclude that:

a. The DentalWings VirtuoVivo intraoral scanner system infringes claims 1, 4-6, 8-12, and 17 of the '936 Patent.

b. The Straumann SIRIOS intraoral scanner system infringes claims 1, 4-6, 8-12, and 17 of the '936 Patent.

c. The Align iTero intraoral scanner system practices claims 1, 4-6, 8-12, and 17 of the '936 Patent.

d. There is a nexus between the claims of the Asserted Patents and the evidence of objective indicia of non-obviousness. The evidence of objective indicia of non-obviousness includes commercial success, industry praise, copying by competitors, unexpected results, and failure of others.

IV. RETENTION AND COMPENSATION

13. I am being compensated for my work in this matter at a rate of $550 per hour (or $650 per hour for testimony) plus expenses, which are my customary rates for consulting and

[redacted]

expert work. My compensation is in no way tied to the outcome of this case or to the content of this declaration.

V. LEGAL STANDARD

14. I understand that the following legal standards apply to matters that I address herein from a technical perspective.

15. I am not a legal expert and offer no legal opinions in this report.

A. PERSON OF ORDINARY SKILL IN THE ART FOR U.S. PATENT NO. 10,791,936.

16. I am not a lawyer but understand that the law requires that the meaning of terminology and disclosures in a patent are considered from the perspective of a person having ordinary skill in the pertinent art at the time of the alleged invention, which may be assumed to be the effective filing (priority) date on which the patent owner relies. I understand that the effective filing date of the '936 Patent is July 19, 2010.

17. I understand that some of the factors that may be considered in determining the level of ordinary skill in the art include (1) educational level and any specialties of the patent applicants; (2) types of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; (6) educational level and any specialties of active workers in the field; and (7) the nature of any testing described in the patent (and skills required of those doing such testing).

18. Based on the above, it is my opinion that a person of ordinary skill in the art ("POSITA") as of the effective filing date of the '936 Patent would have been part of an interdisciplinary team. This team would have included (1) at least one member with a university degree in computer, electrical, or mechanical engineering, or a related field, and at least two years of work experience in software development or 3D imaging of physical structures; and

[redacted]

optionally, (2) a member with a university degree related to dentistry (*e.g.*, DDS, DMD) with at least two years of experience in dentistry or orthodontics.

B. INFRINGEMENT OF U.S. PATENT NO. 10,791,936

1. Direct Infringement

19. I understand that for an accused infringer to directly infringe, the accused infringer must make, use, offer to sell, or sell within the United States, or import into the United States, the patented invention.

20. I understand that in order to prove direct infringement, the accused product, system, or method must meet each and every limitation of at least one asserted patent claim. If even one claim limitation is missing, there is no direct infringement of that claim.

21. I understand that the patentee must show that it is more likely than not that the accused infringer infringes a claim.

22. I understand that a claim can be directly infringed two different ways: (1) literal infringement and (2) infringement under the doctrine of equivalents.

23. I understand that literal infringement occurs when each and every limitation of the asserted claim is found in the accused product or method exactly as claimed. To determine if an accused product or method literally infringes, I understand that the accused product or method must be compared to the claim to determine whether every requirement of the claim is included in the accused product or method. If the accused product or method does not include every requirement of the claim, the accused product or method does not literally infringe the claim.

24. I understand that even if an accused product or method does not literally infringe, it may still infringe under the doctrine of equivalents. I understand that under the doctrine of equivalents, a claim limitation is satisfied if the accused element performs substantially the same function, in substantially the same way, to achieve substantially the same results as the claimed

[redacted]

limitation. I understand that the doctrine of equivalents is applied on an element-by-element basis, not to the invention as a whole, and is subject to legal limitations, such as prosecution history estoppel.

25. I understand that direct infringement for a method claim requires that all the steps of the claimed method are performed. I also understand that a single entity must perform every step of the method claim, either directly or through attribution. I understand that direct infringement may be found where one party exercises direction or control over others who perform some steps, or where multiple actors operate together as a joint enterprise.

2. Indirect Infringement

26. I understand that an accused infringer can indirectly infringe by inducing infringement or contributing to infringement.

27. For a finding of induced infringement, I understand that the accused infringer must actively and knowingly induce a third-party to infringe a claim. I understand that the patentee must show that the third-party directly infringed the patent claim. I understand the patentee must also show that the accused infringer knew of the asserted patent and knew or was willfully blind that the induced acts constituted direct infringement. I understand the patentee must prove that the accused infringer took affirmative steps to encourage, aid, or cause the infringing conduct.

28. I understand that affirmative acts to induce infringement may include providing instructions, technical support, product manuals, training materials, marketing materials, or other communications that encourage or instruct customers or end users to perform the infringing acts.

29. For a finding of contributory infringement, I understand that accused infringer must sell, offer to sell, or import a component of the patented invention. I understand that the component of the patented invention must constitute a material part of the invention and be

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especially made or adapted for use in an infringing manner. I understand that the component cannot be a staple article or commodity of commerce suitable for substantial non-infringing uses. I also understand that the accused infringer must have the knowledge that the component is made for use in an infringing product or method. Like inducement, I understand that contributory infringement requires proof of an underlying act of direct infringement.

C. OBJECTIVE INDICIA OF NON-OBVIOUSNESS OR SECONDARY CONSIDERATIONS

30. I understand that there are certain objective indicia or secondary considerations that may tend to show that a claimed invention would not have been obvious to a person of ordinary skill in the art. These include, for example, commercial success, industry praise, copying by competitors, long-felt but unsolved needs, unexpected results, and failure of others, . I further understand that there must be a relationship, or nexus, between any objective indicia and the novelty of the claimed invention.

D. CLAIM CONSTRUCTION

31. I understand that claim construction is the process of determining the meaning and scope of the asserted patent claims. I understand that various principles govern how a court determines how a person of ordinary skill in the art would understand the meaning and scope of patent claims and terminology therein. Some of these principles are set forth below.

a. **Intrinsic evidence**. I understand that intrinsic evidence includes the claim language itself, the specification of the patent, and the prosecution history. I understand that the claim language is the starting point for claim construction. I understand that the specification must also be considered when construing the claims. However, I also understand that the specification may describe specific

[redacted]

embodiments, and courts avoid importing limitations from preferred embodiments into the claims unless the patentee has clearly expressed an intent to limit the claims in that manner. I understand that the prosecution history (which I understand to mean the written record describing the process by which the applicant obtained the patent) may also inform claim construction by showing how the patent applicant and the United States Patent and Trademark Office understood the invention, including whether the patent applicant made clear statements limiting the scope of the claims to reach allowance.

b. **Ordinary meaning**. I understand that claims are generally given their ordinary meaning unless the patentee has acted as a lexicographer by explicitly defining a term or has clearly disclaimed or limited the cope of claims during prosecution.

c. **Extrinsic evidence**. I understand that courts may also consider extrinsic evidence, such as expert testimony, technical dictionaries, and treatises, to assist in understanding the meaning of a claim term. Extrinsic evidence may be used to provide context or background but is generally considered less reliable than intrinsic evidence and cannot contradict the clear meaning of the intrinsic evidence.

32. I understand that the Court entered a claim construction order construing the claims of the Asserted Patents on June 5, 2025.[1] In forming my opinions, I used the Court's construction of the claim terms as summarized below. For terms without a construction from the

[1] ECF No. 185.

[redacted]

Court, to the extent necessary to render my opinions, I interpreted the term as a person of ordinary skill in the art would at the time that each patent was filed in view of the claim language, specification, and prosecution history. Below are the Court's constructions for each patent.

a. **'444 Patent:** I understand that the Court construed "through at least one of staggering and roundtripping of at least one dental object" to be the "[p]lain and ordinary meaning which includes 'by staggering or roundtripping at least one dental object."[2] I understand that the Court construed "an optimal number of stages for the order of movement of the dental objects" to be "[t]he largest number of minimum stages needed to place the patient's teeth in their final, desired position."[3] I understand that the Court construed "mid-line shift pattern" to be the plain and ordinary meaning.[4]

b. **'936 Patent:** I understand that the Court construed "replace [replacing] at least a portion of the [removed] surface portion of the model [. . .] using the received second scan data [at least a portion of the second scan data]" as "[register] / [registering] the [received] second scan data with a retained portion of the model after removing the scan data of the removed surface portion."[5] I understand that the

[2] *Id.* at 3.
[3] *Id.*
[4] *Id.* at 4-5.
[5] *Id.* at 10.

[redacted]

Court construed "second scan data of the patient's teeth" as the plain and ordinary meaning.[6]

VI. TECHNICAL BACKGROUND

A. Overview of Dental Procedures

1. Restorative Dentistry

33. A patient may see a dentist or an orthodontist for many different reasons. Two important areas are "restorative" dentistry and teeth-straightening.[7]

34. Restorative dentistry is the branch of dental practice concerned with the diagnosis, prevention, and treatment of diseases and conditions that affect the structure, function, and integrity of teeth and supporting oral tissues.[8] Its primary objective is to restore damaged or missing teeth to proper form, function, and aesthetics, thereby preserving oral health and enabling normal chewing, speech, and appearance. [9]

35. Restorative dentistry addresses tooth structure that has been compromised by dental caries (tooth decay), fracture, wear, developmental defects, trauma, or disease, as well as tooth loss resulting from these conditions.[10] Treatment may involve restoring individual teeth, replacing missing teeth, or rehabilitating larger segments of the dentition. [11]

36. Restorative dental procedures are among the most frequently performed dental treatments across adult populations in many countries.[12] A substantial proportion of adults exhibit untreated dental caries (tooth decay), which often progress to structural damage requiring

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[6] *Id.*
[7] *Dentist*, Cleveland Clinic, https://my.clevelandclinic.org/health/articles/24448-dentist.
[8] *Restorative Dentistry*, Cleveland Clinic, https://my.clevelandclinic.org/health/treatments/10924-dental-restorations.
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] Ctrs. for Disease Control & Prevention, Nat'l Ctr. for Health Stats., *FastStats—Oral and Dental Health* (last reviewed June 26, 2025), https://www.cdc.gov/nchs/fastats/dental.htm.

[redacted]

restorative intervention such as crowns or inlays.[13] According to data from the U.S. Centers for Disease Control and Prevention (CDC), untreated dental caries affect a sizeable fraction of adults across age groups, with approximately one-quarter of adults ages 20–64 exhibiting untreated decay.[14]

37. Tooth loss remains a prevalent clinical condition that drives the demand for restorative therapies including dental implants.[15] Estimates suggest that millions of Americans are missing one or more teeth, and this unmet need increases with age.[16] Older adults are significantly more likely to experience edentulism or partial tooth loss, which contributes to the demand for implant-supported restorations and other prosthetic solutions.[17]

38. Restorative dentistry encompasses a wide range of procedures, varying in complexity depending on the extent of tooth damage or loss. Common restorative treatments include:

- **Direct restorations**, such as fillings, which repair localized loss of tooth structure using materials including composite resin or amalgam.[18]

[13] *Id.*; *Dental Caries (Tooth Decay) in Adults (Ages 20 to 64 Years)*, National Institute of Dental & Craniofacial Research (ALGN04807772); *Oral Health Surveillance Report*, Ctrs. for Disease Control & Prevention (ALGN04807744); Elani, H.W., et al., *Trends in Dental Implant Use in the U.S. 1999-2016, and Projections to 2026*, J. Dental Rsrch. (2018) (ALGN04807737).
[14] Ctrs. for Disease Control & Prevention, Nat'l Ctr. for Health Stats., *FastStats—Oral and Dental Health* (last reviewed June 26, 2025), https://www.cdc.gov/nchs/fastats/dental.htm.
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] Am. Dental Ass'n, *Materials for Direct Restorations* (last visited Jan. 5, 2026), https://www.ada.org/resources/ada-library/oral-health-topics/materials-for-direct-restorations; Am. Dental Ass'n - MouthHealthy, *Dental Filling Options* (last visited Jan. 5, 2026), https://www.mouthhealthy.org/all-topics-a-z/dental-filling-options.

[redacted]

- **Indirect restorations**, such as crowns, inlays, and onlays, which are fabricated outside the mouth and bonded or cemented to prepared teeth to restore strength, shape, and function.[19]
- **Fixed prosthodontic restorations**, including bridges, which replace one or more missing teeth by anchoring artificial teeth to adjacent natural teeth or implants.[20]
- **Implant-supported restorations**, in which dental implants are surgically placed into the jawbone and used to support crowns, bridges, or full-arch prostheses.[21]
- **Full-mouth rehabilitation**, which may combine multiple restorative approaches to address extensive tooth wear, loss, or functional impairment.[22]

39. Successful restorative dentistry depends on accurate assessment of tooth anatomy, occlusion (the way teeth contact during function), and the spatial relationship between teeth and surrounding structures.[23] Restorations must be precisely designed to fit the patient's dentition, distribute forces appropriately, and integrate with existing teeth and restorations.[24] Inadequate planning or imprecise execution can result in complications such as restoration failure, discomfort, bite imbalance, or damage to adjacent teeth.[25]

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[19] Am. Dental Ass'n, *Materials for Indirect Restorations* (last visited Jan. 5, 2026), https://www.ada.org/resources/ada-library/oral-health-topics/materials-for-indirect-restorations
[20] T. Johnson et al., *FIXED PROSTHODONTICS*, Basics of Dental Technology (2015).
[21] Am. College of Prosthodontists, *White Paper: Definitions of Implant Dental Prostheses*, https://www.prosthodontics.org/assets/1/7/ACP_White_Paper-Definitions_of_Implant_Dental_Prostheses.pdf
[22] *See* Am. Dental Ass'n, *Glossary of Dental Terms* (last visited Dec. 24, 2025), https://www.ada.org/publications/cdt/glossary-dental-terms.
[23] A. Aldowish et al., *Occlusion and Its Role in the Long-Term Success of Dental Restorations: A Literature Review – Introduction*, Cureus (2024), https://www.cureus.com/articles/313041-occlusion-and-its-role-in-the-long-term-success-of-dental-restorations-a-literature-review
[24] *Id.*
[25] *Id.*

[redacted]

40. Advances in dental imaging, impression techniques, and digital workflows have increasingly enhanced the precision and predictability of restorative procedures by enabling detailed visualization, planning, and fabrication of restorations tailored to individual patients.[26]

2. Orthodontics

41. There are several options a dentist or an orthodontist can offer to a patient who is interested in orthodontics, *i.e.*, treating irregularities of their teeth (especially of alignment and occlusion[27]) and jaws. These options include traditional wire and bracket "braces" and clear aligners.[28] Many different companies sell braces, clear aligners, or both. I am familiar with the range of treatment options available.

a. Wire-and-Bracket Braces

42. Wire-and-bracket braces involve brackets which are bonded to the patient's teeth surfaces and/or bands which are cemented around the patient's teeth. The brackets and bands have a central slot into which a single continuous archwire can be threaded. The archwire is a thin main metal wire which threads through the bracket and band slots and is secured using ligature ties (small elastic bands or wires) or by closing the bracket's built-in door (in self-ligating braces). The archwire, which is held firmly in the bracket slots against the teeth, applies gentle, continuous force to gradually move the teeth. This wire acts as a track, and as it's adjusted or returns to its "memory" shape, it moves the teeth. [29] Auxiliaries such as elastic bands

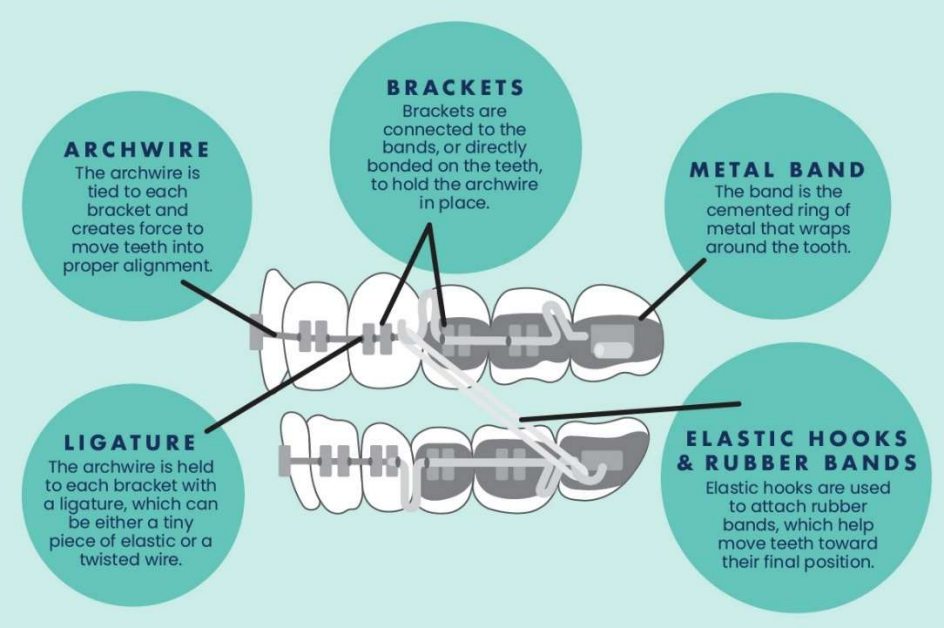
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[26] *Id.*; Align Tech., Inc., Form 10-K for FY 2024, at 6.
[27] "Occlusion" is defined as the way the teeth meet when the lower jaw (mandible) and upper jaw (maxilla) come together. McNeill C. Occlusion: what it is and what it is not. J Calif Dent Assoc. 2000 Oct;28(10):748-58. PMID: 11326518; Crest + Oral B Dental Care, *An Overview of Dental Anatomy – Occlusion* (last visited Jan. 5, 2026), https://www.dentalcare.com/en-us/ce-courses/ce500/occlusion.
[28] Am. Ass'n of Orthodontists, *Orthodontic Treatments* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/; Am. Ass'n of Orthodontists, *Braces* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/braces/; Am. Ass'n of Orthodontists, *Aligners* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/aligners/; River Falls Orthodontics, *Explaining the Different Parts of Braces* (last visited Dec. 24, 2025), https://www.riverfallsortho.com/explaining-the-different-parts-of-braces/.
[29] *Id.*

[redacted]

connect different parts of the braces (like top to bottom, or back to front) to apply pressure that braces alone can't to correct bite issues, align jaws, and straighten teeth more effectively.[30] Various other auxiliaries, including coils and elastic power chains may be used, depending on the clinical context and treatment goals. [31]

43. An image illustrating the different parts of braces is below (borrowed from the River Falls Orthodontics website).[32]



44. Once the braces are placed, an orthodontist will make small ongoing adjustments to the archwires, ligature ties, elastic bands, and/or other auxiliaries to create forces that move the patient's teeth closer to an approximated idealized position in the orthodontist's mind.[33]

45. As treatment with wire-and-bracket braces progresses, orthodontists commonly change archwires over time, moving from more flexible wires used during initial alignment to

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[30] *Id.*
[31] *Id.*
[32] River Falls Orthodontics, *Explaining the Different Parts of Braces*, https://www.riverfallsortho.com/explaining-the-different-parts-of-braces/.
[33] Am. Ass'n of Orthodontists, *Braces* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/braces/.

[redacted]

stiffer wires used during finishing and detailing.[34] In the finishing (final) phase of fixed orthodontic treatment, orthodontists typically transition to stiffer rectangular stainless steel or beta-titanium archwires to maximize expression of the bracket prescription and allow precise control over final tooth position, torque, angulation, and occlusal relationships.[35] These finishing wires are selected because of their rectangular shape and increased size reduces excess space between the wire and the inside of the bracket slot, enabling more accurate transmission of prescribed movements and facilitating detailed corrections that are difficult to achieve with more flexible initial alignment wires.[36]

46. Orthodontic treatment with braces can be described as "reactive," because it does not involve pre-planned treatment planning and tooth positioning.[37] This reactive type of treatment involves ongoing assessments of the patient's tooth positions by the orthodontist who then makes decisions regarding the next step in adjusting the braces.[38] After one adjustment, the orthodontist will allow a few weeks to pass, and then evaluate how the patient's tooth positions have changed in response.[39] The orthodontist will then make a further adjustment and allow a few more weeks to pass, and then again evaluate the patient's tooth positions.[40] This step-by-step process is repeated until the orthodontist is satisfied with the patient's tooth positions.[41]

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[34] Am. Ass'n of Orthodontists, *Archwires* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/archwires/; Proffit et al., *Contemporary Orthodontics* (6th ed. 2019).
[35] *Id.*
[36] *Id.*
[37] Proffit et al., *Contemporary Orthodontics*, at 384–390.
[38] Am. Ass'n of Orthodontists, *Braces* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/braces/.
[39] *Id.*
[40] *Id.*
[41] *Id.*; Proffit et al., *Contemporary Orthodontics* (6th ed. 2019).

[redacted]

b. Clear Aligners

47. "Clear aligners" are another option for patients interested in orthodontic treatment. They are also a form of orthodontic appliances designed to reposition teeth through the application of controlled, incremental mechanical forces. [42] Unlike traditional braces treatment which use brackets and wires, clear aligner treatment consists of a series of removable, transparent plastic trays ("aligners") that are custom-fabricated for an individual patient.[43] The first version of the Invisalign System launched in September 1998 after receiving FDA clearance for the treatment of malocclusion in patients with permanent dentition.[44]

48. Each aligner is manufactured from a medical-grade thermoplastic material and is designed to fit closely over the patient's teeth.[45] Clear aligners are typically worn for approximately 20 to 22 hours per day and are removed by the patient for eating, drinking, and oral hygiene.[46]

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[42] Chishti, M., & Phan, L. (2009). *Methods for correcting tooth movements midcourse in treatment* (Patent No. 7,578,674B2); Am. Ass'n of Orthodontists, *Aligners* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/aligners/; Align Tech., Inc., The Invisalign System (last visited Jan. 5, 2026), https://www.aligntech.com/solutions.

[43] *Id.*; Ziuchkovski, J. P., Fields, H. W., Johnston, W. M., & Lindsey, D. T. (2008). *Assessment of perceived orthodontic appliance attractiveness*. American Journal of Orthodontics and Dentofacial Orthopedics, 133(4), S68-S78; Boyd, R. L. (2008). *Esthetic orthodontic treatment using the Invisalign appliance for moderate to complex malocclusions*. Journal of dental education, 72(8), 948-967.

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[45] Zhang, N. et al., *Preparation and Characterization of Thermoplastic Materials for Invisible Orthodontics*, 30 DENTAL MATERIALS J. 954, 955–56 (2011); Am. Ass'n of Orthodontists, *Aligners* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/aligners/; Align Tech., Inc., *Five Facts About Clear Aligner Therapy* (Mar. 13, 2025), https://d1dtcx9hvyki7y.cloudfront.net/assets/Five+Facts+About+Clear+Aligner+Therapy.09.30.21.pdf.

[46] Am. Ass'n of Orthodontists, *Aligners* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/aligners/; Align Tech., Inc., Five Facts About Clear Aligner Therapy (Mar. 13, 2025), https://d1dtcx9hvyki7y.cloudfront.net/assets/Five+Facts+About+Clear+Aligner+Therapy.09.30.21.pdf.; INVISALIGN, *Invisalign Treatment Process – How Does the Invisalign® Treatment Work?* (last visited Dec. 24, 2025), https://www.invisalign.com/how-it-works; INVISALIGN, *Invisalign Aligners FAQs – What Is Invisalign Treatment?* (last visited Dec. 24, 2025), https://www.invisalign.com/frequently-asked-questions.

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49. Clear aligner treatment begins with the collection of digital or physical records of the patient's dentition, which may include intraoral scans or polyvinyl siloxane (PVS) impressions.[47]

50. Intraoral scans are captured with an intraoral scanner (*e.g.*, Align's iTero, the DentalWings Virtuo Vivo, or Straumann's SIRIOS).[48] Intraoral scanners are handheld optical devices that capture images as they are passed over the teeth and surrounding soft tissues.[49]

51. These records are used to create a three-dimensional digital model of the patient's teeth, typically encompassing the entire dental arch—that is, the curved arrangement of teeth within the upper or lower jaw.[50] Using specialized software, a sequence of incremental tooth movements intended to achieve a desired final alignment is planned to move the teeth from their initial positions to a predetermined final position or alignment.[51]

52. This treatment paradigm was advanced by Align's Invisalign system (using its proprietary treatment planning software, TREAT) which plans the entire course of treatment in advance.[52] Align makes the proposed treatment plan available to the treating doctor for review

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[47] *Id.*; Align Tech., Inc., *Five Facts About Clear Aligner Therapy* (Mar. 13, 2025), https://d1dtcx9hvyki7y.cloudfront.net/assets/Five+Facts+About+Clear+Aligner+Therapy.09.30.21.pdf.

[48] *See generally* Align Tech., Inc., *iTero Element 5D Intraoral Scanner User Manual* (2022) (ALGN00020792) at -822; Align Tech., Inc., *iTero Lumina Pro User Manual* (2024) (ALGN00338426) at -455; Align Tech., Inc., *iTero Manual Repository* (ALGN04795010) https://guides.itero.com/; iTERO, Our Scanners, https://itero.com/our-solutions.

[49] *See generally* Align Tech., Inc., *iTero Element 5D Intraoral Scanner User Manual* (2022) (ALGN00020792) at -822; Align Tech., Inc., *iTero Lumina Pro User Manual* (2024) (ALGN00338426) at -455; Align Tech., Inc., *iTero Manual Repository* (ALGN04795010) https://guides.itero.com/; iTERO, Our Scanners, https://itero.com/our-solutions.

[50] *See generally* Align Tech., Inc., *iTero Element 5D Intraoral Scanner User Manual* (2022) (ALGN00020792) at -822; Align Tech., Inc., *iTero Lumina Pro User Manual* (2024) (ALGN00338426) at -455; Align Tech., Inc., *iTero Manual Repository* (ALGN04795010) https://guides.itero.com/; iTERO, Our Scanners, https://itero.com/our-solutions; Align – iTero; https://www.aligntech.com/solutions/itero_scanner.

[51] *Id.*; *see also* STRAUMANN, *Straumann SIRIOS* (last visited Jan. 5, 2026), https://www.straumann.com/en/dental-professionals/digital/equipment/io-scanners/sirios.html (ALGN01637370).

[52] INVISALIGN, *Invisalign Treatment Process – How Does the Invisalign® Treatment Work?* (last visited Dec. 24, 2025), https://www.invisalign.com/how-it-works; INVISALIGN, *Invisalign Aligners FAQs – What Is Invisalign Treatment?* (last visited Dec. 24, 2025), https://www.invisalign.com/frequently-asked-questions; [redacted]

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and approval through ClinCheck Pro, which first launched on February 1, 2014.[53] In May 2020, Align launched ClinCheck Pro 6.0.[54]

53. ClinCheck allows doctors to upload scans of their patients' teeth and view a detailed, interactive 3D visualization of a patient's current dentition and projected tooth movements throughout treatment.[55] Doctors can review and revise proposed treatment plans and submit prescriptions for Invisalign.[56] The patients' initial tooth positions are evaluated, final tooth positions are determined, and a series of intermediate, incremental tooth positions necessary to move the teeth at predefined rates and distances are calculated.[57] These calculations are designed to avoid collisions between teeth, minimize interference with adjacent teeth and soft tissues, and remain consistent with the biological requirements of orthodontic tooth movement and the patient's physiology.[58]

54. Based on this digital treatment plan, a corresponding series of clear, removable aligners is custom-manufactured, with each aligner representing a small, planned change in tooth position relative to the previous stage.[59] Patients are typically instructed to wear each aligner for a specified period—often one to two weeks—before progressing to the next aligner in the series.[60]

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[53] Align Form 10-K for the Year Ended December 31, 2024, p. 5-6.
[54] *Id.*
[55] *Id.*; INVISALIGN, *ClinCheck® Pro Software* (last visited Jan. 5, 2026), https://www.invisalign.com/provider/align-digital-platform/clincheck.
[56] *Id.*
[57] *Id.*; '444 patent at 3:54–61.
[58] *Id.*; Tuncay, O.C., *The Invisalign System* (CC_ALGN_00003900) at -971, -019–026.
[59] Am. Ass'n of Orthodontists, *Aligners* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/aligners/.
[60] *Id.*; Align Tech., Inc., *Five Facts About Clear Aligner Therapy* (Mar. 13, 2025), https://d1dtcx9hvyki7y.cloudfront.net/assets/Five+Facts+About+Clear+Aligner+Therapy.09.30.21.pdf; INVISALIGN, *Invisalign Treatment Process – How Does the Invisalign® Treatment Work?* (last visited Dec. 24, 2025), https://www.invisalign.com/how-it-works; INVISALIGN, *Invisalign Aligners FAQs – What Is Invisalign Treatment?* (last visited Dec. 24, 2025), https://www.invisalign.com/frequently-asked-questions

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55. The aligner applies forces to the clinical crowns of the teeth (the visible portions of the teeth above the gumline) to achieve the intended incremental movement.[61] The patient then advances sequentially through the aligner series until the planned final tooth positions are reached.[62]

56. Because clear aligner treatment is planned entirely in advance and relies on aligners that closely approximate the unique geometry of a patient's teeth throughout the dental arch, precision in aligner design and fit is critical.[63] Even small inaccuracies in the fit of an aligner can alter the forces applied to individual teeth.[64] Such errors may accumulate from one aligner to the next, potentially resulting in unintended tooth movement, interference between teeth or soft tissue, failure of subsequent aligners to seat properly, interruption of treatment, and/or patient discomfort.[65]

57. Accordingly, each clear aligner treatment plan must be custom designed for the individual patient using high-resolution data that accurately represents the patient's actual tooth geometries and positions at the initial, successive, and final stages of treatment.[66] From this data, a complete set of custom aligners is manufactured to achieve the planned orthodontic outcomes.[67]

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[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *See* J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 3, 6–9 (2017) (ALGN02808426); Wheeler, T.T. et al., *Effect of aligner material on orthodontic tooth movement*, J Aligner Orthodontics 1(1):21–27 (2017) (ALGN02821971).
[65] *See* J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 3, 6–9 (2017) (ALGN02808426); Wheeler, T.T. et al., *Effect of aligner material on orthodontic tooth movement*, J Aligner Orthodontics 1(1):21–27 (2017) (ALGN02821971).
[66] J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 6–9 (2017) (ALGN02808426); Am. Ass'n of Orthodontists, *Aligners* (last visited Dec. 24, 2025), https://aaoinfo.org/treatments/aligners/; Align Tech., Inc., *Five Facts About Clear Aligner Therapy* (Mar. 13, 2025), https://d1dtcx9hvyki7y.cloudfront.net/assets/Five+Facts+About+Clear+Aligner+Therapy.09.30.21.pdf.
[67] *Id.*

[redacted]

i. Aligner Materials

58. Material selection is a critical factor in the performance and clinical effectiveness of clear aligner orthodontic treatment.[68] Clear aligners function by delivering controlled mechanical forces to teeth over extended periods of wear, and the nature, magnitude, and consistency of those forces are directly influenced by the physical and mechanical properties of the aligner material.[69] Properties such as elasticity, stiffness, stress relaxation, and durability affect how forces are generated, maintained, and transmitted from the aligner to the teeth throughout each stage of treatment.[70]

59. Because clear aligner treatment relies on a sequence of pre-manufactured appliances, rather than real-time adjustment by the clinician, the material must perform predictably in the oral environment.[71] Even small variations in force delivery caused by material behavior can alter the rate or direction of tooth movement, reduce treatment accuracy, or cause aligners to lose effectiveness before the intended wear period has concluded.[72]

60. Early clear aligner systems generally used single-layer thermoplastic materials, such as Align Technology's EX30 material.[73] These materials were formed from a single homogeneous polymer layer and were selected primarily for transparency, formability, and patient comfort.[74] While effective for producing removable orthodontic appliances, single-layer

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[68] J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 4-7 (2017) (ALGN02808426); [redacted]

[71] J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 4–7 (2017) (ALGN02808426); [redacted] G.D. Gardner, et al., *Wear comparison of thermoplastic materials used for orthodontic retainers*, Am. J. Orthodontics & Dentofacial Orthopedics, 124(3), 294-297 (2003).

[73] [redacted] N. Zhang, et al., *Preparation and characterization of thermoplastic materials for invisible orthodontics*. Dental Materials J., 30(6), 954-959 (2011); Ryokawa, H., et al., *The mechanical properties of dental thermoplastic materials in a simulated intraoral environment*. Orthodontic Waves, 65(2), 64-72 (2006).

[redacted]

materials exhibited limitations in their mechanical performance over time, including force decay, deformation, and reduced ability to maintain consistent orthodontic forces during wear.[75]

61. As clear aligner therapy expanded to address increasingly complex orthodontic movements, these material limitations became more significant.[76] Single-layer materials could lose force relatively quickly due to stress relaxation and creep, resulting in less predictable tooth movement and a greater reliance on refinements or additional aligners to achieve the desired outcomes.[77]

62. In response to these limitations, aligner materials evolved toward more advanced, multilayer constructions.[78] Multilayer materials are engineered by combining layers with different mechanical properties, allowing the material to balance competing requirements such as flexibility, resilience, and strength.[79]

63. Align's SmartTrack is an example of a later-generation, multilayer aligner material developed to improve the predictability and effectiveness of clear aligner treatment.[80]

[redacted]

SmartTrack was "designed specifically for the Invisalign system to achieve more predictable orthodontic treatments."[82]

[redacted]

[78] Zhang, N. et al., *Preparation and Characterization of Thermoplastic Materials for Invisible Orthodontics*, 30 DENTAL MATERIALS J. 954, 956–59 (2011).

[79] *Id.*

[80] J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 6–8 (2017) (ALGN02808426); [redacted] Align Tech., Inc., *About Us*, https://www.aligntech.com/about.

[redacted]

[82] *Material Solution Jointly Developed by Align Technology & Covestro to be Showcased at K 2019 Plastics Trade Fair*, Align (ALGN04796266).

[redacted]

64. The multilayer structure allows SmartTrack to better maintain its shape and mechanical properties under continuous intraoral conditions, including exposure to temperature changes, moisture, and repeated insertion and removal. As a result, the aligner is better able to apply sustained, gentle forces that more closely match the planned tooth movements specified in the digital treatment plan.[83]

65. The ability of an aligner material to deliver consistent, well-controlled forces is directly related to the precision of tooth movement. Materials that lose force too quickly or deform unpredictably may fail to move teeth as intended, leading to incomplete movements, unintended tipping or rotation, or difficulty seating subsequent aligners. These issues can compound over a series of aligners, undermining the accuracy of the overall treatment plan.[84]

66. By contrast, multilayer materials such as SmartTrack provide an advantage over earlier single-layer materials by enabling more precise and effective translation of digitally planned tooth movements into clinical results. Improved force consistency reduces variability between planned and actual tooth movement, enhances aligner tracking, and decreases the likelihood that small errors will accumulate across successive treatment stages.[85]

67. In summary, advances in aligner material design—from early single-layer thermoplastics to multilayer materials like SmartTrack—have played a significant role in improving the predictability, precision, and effectiveness of clear aligner orthodontic treatment.[86]

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[83] ALGN00339664; Morton et al., J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 7–9 (2017) (ALGN02808426); Ryokawa, H., et al., *The mechanical properties of dental thermoplastic materials in a simulated intraoral environment*. Orthodontic Waves, 65(2), 66-69 (2006).
[84] ALGN00339664; Morton et al., J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 7–9 (2017) (ALGN02808426); Ryokawa, H., et al., *The mechanical properties of dental thermoplastic materials in a simulated intraoral environment*. Orthodontic Waves, 65(2), 66-69 (2006).
[85] ALGN00339664; Morton et al., J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 7–9 (2017) (ALGN02808426); Ryokawa, H., et al., *The mechanical properties of dental thermoplastic materials in a simulated intraoral environment*. Orthodontic Waves, 65(2), 66-69 (2006).
[86] *Id.*; ALGN00000387-410; '613 Pat., 1:61-2:26.

[redacted]

ii. Benefits of SmartTrack Material

68. Benefits of the SmartTrack material ([redacted]) have been evaluated through Align's internal testing and clinical pilot studies, as well as published clinical literature comparing SmartTrack to Align's prior single-layer EX30 material.[87] At a high level, these studies have shown more consistent force delivery over the typical wear period, with slower force decay; higher clinical expression of planned tooth movements; greater average tooth movement toward planned positions; and improved patient comfort.[88]

69. For example, in a peer-reviewed patient survey conducted during the transition to SmartTrack, patients who experienced both single-layer EX30 and multilayer SmartTrack reported statistically significant reductions in pain intensity, pain duration, and pressure upon insertion with SmartTrack compared to EX30.[89] While this study was not designed to measure "accuracy" of tooth movement, reductions in discomfort are clinically relevant because clear aligner therapy depends on consistent wear, and improved comfort can reduce barriers to compliance with prescribed wear times.[90]

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[87] *See* A.-K. Bräscher et al., *Patient survey on Invisalign® treatment comparing the SmartTrack® material to the previous aligner material*, J Orofacial Orthopedics 77:432–438 (2016); Invisalign, SmartTrack Technical Data Reference Report (Sept. 12, 2012); *SmartTrack Technical Data Reference Report*, Invisalign (ALGN00000387); Bichu, Y.M., et al., *Advances in Orthodontic Clear Aligner Materials*, Bioreactive Materials (2023) (ALGN04787023); *Materials for Clear Aligners—A Comprehensive Exploration of Characteristics and Innovations: A Scoping Review*, Applied Sciences (ALGN04787052).

[88] A.-K. Bräscher et al., *Patient survey on Invisalign® treatment comparing the SmartTrack® material to the previous aligner material*, J Orofacial Orthopedics 77:432–438 (2016); Invisalign, SmartTrack Technical Data Reference Report (Sept. 12, 2012); *SmartTrack Technical Data Reference Report*, Invisalign (ALGN00000387); Bichu, Y.M., et al., *Advances in Orthodontic Clear Aligner Materials*, Bioreactive Materials (2023) (ALGN04787023); *Materials for Clear Aligners—A Comprehensive Exploration of Characteristics and Innovations: A Scoping Review*, Applied Sciences (ALGN04787052); [redacted]

[89] A.-K. Bräscher et al., *Patient survey on Invisalign® treatment comparing the SmartTrack® material to the previous aligner material*, J Orofacial Orthopedics 77:432–438 (2016).

[90] *Id.*; K. Miller et al., *A Comparison of Treatment Impacts Between Invisalign Aligner and Fixed Appliance Therapy During the First Week of Treatment*, 131 Am. J. Orthod. Dentofacial Orthop. 302.e1 (2007).

[redacted]

70. The effect of aligner material on orthodontic tooth movement has also been examined in controlled in vivo studies. In a randomized, blinded clinical investigation, identical tooth movements were programmed and delivered using aligners fabricated from either EX30 or SmartTrack.[91] The study found that SmartTrack produced a significantly greater amount of orthodontic tooth movement over the observation period than EX30.[92] This finding indicates that, under controlled conditions, SmartTrack more effectively translates programmed movement into achieved movement than the earlier single-layer material.[93]

71. Additional clinical and engineering analyses attribute SmartTrack's performance advantages to the material's elastic recovery and stress-relaxation behavior in intraoral conditions, which govern whether an aligner continues to apply effective orthodontic forces as it seats, stretches over malocclusions, and is worn over time.[94] These analyses show that SmartTrack's elasticity allows the aligner to stretch and then return close to its original shape to apply force more consistently, and that its force retention under intraoral stress-relaxation testing is substantially higher than earlier single-layer EX30 (41% for SmartTrack versus 12% for EX30 after 24 hours at 37°C water and 5% strain), supporting improved maintenance of planned forces throughout the wear period.[95]

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[91] Wheeler, T.T. et al., *Effect of aligner material on orthodontic tooth movement*, J Aligner Orthodontics 1(1):21–27 (2017) (ALGN02821971).
[92] *Id.*
[93] *Id.*
[94] J. Morton, et al., *Design of the Invisalign system performance*, SeminOrthod. 23:3–11 (2017) (ALGN02808426); [redacted]; ALGN00006176 at -6839.
[95] ALGN00794838.

[redacted]

73. In summary, peer-reviewed clinical studies and Align's internal studies support that SmartTrack provides measurable advantages over EX30 in several respects.[99] These include reduced patient-reported discomfort during aligner wear, greater orthodontic tooth movement under controlled in-vivo conditions, and improved accuracy of certain programmed movements—particularly transverse expansion—in retrospective clinical cohorts.[100] Overall, the scientific literature supports the conclusion that SmartTrack represents a clinically meaningful advancement over the earlier EX30 aligner material.

B. Use of Multilayer Materials in Clear Aligners

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[96] [redacted]

[97] *See* ALGN00794771.

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[99] A.-K. Bräscher et al., *Patient survey on Invisalign® treatment comparing the SmartTrack® material to the previous aligner material*, J Orofacial Orthopedics 77:432–438 (2016); Wheeler, T.T. et al., *Effect of aligner material on orthodontic tooth movement*, J Aligner Orthodontics 1(1):21–27 (2017) (ALGN02821971).; Invisalign, SmartTrack Technical Data Reference Report (ALGN00000387).

[100] A.-K. Bräscher et al., *Patient survey on Invisalign® treatment comparing the SmartTrack® material to the previous aligner material*, J Orofacial Orthopedics 77:432–438 (2016); Wheeler, T.T. et al., *Effect of aligner material on orthodontic tooth movement*, J Aligner Orthodontics 1(1):21–27 (2017) (ALGN02821971).; Invisalign, SmartTrack Technical Data Reference Report (ALGN00000387).

[redacted]

74. Multilayer materials have become the standard for treating patients with clear aligners.

75. Bay Materials manufactures Zendura FLX, which is a multilayer material that (I understand from Dr. Reitman) infringes the Asserted Claims of the Materials Patents.[101]

76. Zendura FLX is used by other major clear aligner manufacturers, including [redacted]

77. Zendura FLX is branded and sold by Ormco as "TruGEN" as part of Ormco's Spark Clear Aligner System by Ormco.[103] Ormco's Spark Clear Aligner system also includes a single-layer material, branded as "TruGEN XR."[104] [redacted]

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79. For braces, finishing is the final stage of braces treatment.[110] A "finishing wire" is used during the finishing stage of treatment.[111] Whereas earlier in treatment, doctors use a more flexible wire, such as those made of nickel titanium, to generate more significant tooth movements.[112] In the finishing stage, use a more rigid wire, such as those made of stainless steel, to create the small refined movements necessary at this point to complete a patient's treatment.[113] In the finishing stage, the doctor is makes small detailed bends in the rigid finishing wire, which result in the final tooth movements. In a typical treatment, four to five (if not more) different wires are used. Only one of the four to five wires in a typical treatment is a finishing wire. In my experience, the finishing wire is used for at most 20-25 percent of the overall treatment.

80. Clear aligner treatment progresses similarly to braces treatment.[114] Typically, the majority of tooth movements are made in the initial phase of treatment. In the final phase of treatment, small, fine-tuning movements are made to ensure that a patient's teeth have reached the desired final position.[115]

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[110] S.R. Srinivasan, S. Sundareswaran, *Finishing and detailing in Orthodontics – The guidelines, methods and philosophies – A comprehensive review*, IOSR J. of Dental and Medical Sciences, Apr. 2021, at 56.
[111] *Id.* at 57.
[112] MPOrthodontics, *What Are Orthodontic Braces Made Of? A Complete Guide*, https://mpbraces.com/what-are-orthodontic-braces-made-of-a-complete-guide/ ("Initial wires often use NiTi allow for gentle, continuous pressure").
[113] *Id.*
[114] Wright Orthodontics, *Your Guide to Successful Growth Guidance Orthodontic Treatment*, https://wrightortho.com/growth-guidance-orthodontic-treatment/.
[115] *Id.*

[redacted]

81. Based on my experience with both braces and clear aligners, I would expect that, at most, 20-25 percent of Ormco's Spark aligners are made of TruGEN XR. The remaining 75-80 percent of Spark aligners would be made of TruGEN. I reach this conclusion because TruGEN XR is designed to operate like the finishing wires used in braces treatment, which are typically 20-25 percent of the overall treatment time. Further, clear aligner treatment follows a similar course as braces treatment, with major tooth movement taking place in the initial phase of treatment, and small, finishing movements taking place at the end of treatment.

C. Overview of Dental Imaging Options

82. Three-dimensional dental imaging is used to capture hard and soft tissues in the oral cavity.[116] Dental imaging is used for diagnostic and assessment purposes, for restorative and implant treatments in dentistry, and for treatment planning, fixed and removeable appliance manufacturing (including aligners) in orthodontics.[117]

83. Capturing hard and soft tissues in the oral cavity for dental assessment has evolved over time from exclusively manual, analog methods using impression materials, to digital imaging using intraoral scanners.[118] Traditional physical impressions were time-consuming, uncomfortable, prone to distortion, and introduced cumulative errors at multiple stages of the orthodontic workflow.[119] Although intraoral scanning technology emerged as a

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[116] Invisalign, *Invisalign® Digital Treatment Experience* (last visited Jan. 5, 2026), https://www.invisalign.com/how-it-works/invisalign-digital-experience; Invisalign, *Invisalign® Frequently Asked Questions – How Invisalign Treatment Works* (last visited Jan. 6, 2026), https://www.invisalign.com/frequently-asked-questions; *see also* Am. Dental Ass'n, *Dental radiographs - Benefits and safety* (Sept. 2011), https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/for_the_dental_patient_sept_2011.pdf.

[117] Align Technology, Inc., iTero Element 5D Intraoral Scanner User Manual at 1–3 (2022); Align Technology, Inc., iTero Lumina Pro User Manual at 7, 12–13 (2024).

[118] *Id.*; T. Miyazaki, et al., *A Review of Dental CAD/CAM: Current Status and Future Perspectives*, Dental Materials Journal 28(1):44–56 (2009); A. Sharma et al., *History of materials used for recording static and dynamic occlusal contact marks: a literature review.* J Clin Exp Dent (2013).

[119] Lione, R., et. al., *Accuracy, Time, and Comfort of Different Intraoral Scanners: An In Vivo Comparison Study*, Applied Sciences (2024) (ALGN04787043), Singh, R., et al., *Accuracy and Clinical Performance of Intraoral*

[redacted]

potential solution, published studies and reviews identified limitations including inconsistent accuracy, workflow inefficiencies, and difficulty reliably capturing complete images, particularly in orthodontic applications requiring high precision.[120]

84. Historically, dental assessment relied primarily on direct visual examination, supplemented by basic mechanical tools.[121] One example is the use of articulating paper for assessing functional contacts between upper and lower teeth. When held between opposing teeth, it would identify occlusal contacts when the patient was asked to bite their teeth together.[122] While somewhat useful for assessing functional contacts, articulating paper provided limited precision and reproducibility and no three-dimensional record of tooth geometry or spatial relationships.[123]

85. In the past, to create physical records of tooth shape and position, clinicians were limited to using impression materials placed in trays that were inserted into the patient's mouth to capture a negative mold of the teeth and surrounding hard and soft tissues. These impressions were then poured with dental stone to produce positive plaster models. Impression materials have evolved over time. While alginate was once the material of choice for impression taking, polyvinyl siloxane (PVS) has become increasingly popular for better accuracy.[124]

Scanners Compared to Conventional and Extraoral Impressions: An Umbrella Review, Cureus (2025) (ALGN04787066).

[120] Lione, R., et. al., *Accuracy, Time, and Comfort of Different Intraoral Scanners: An In Vivo Comparison Study*, Applied Sciences (2024) (ALGN04787043), Singh, R., et al., *Accuracy and Clinical Performance of Intraoral Scanners Compared to Conventional and Extraoral Impressions: An Umbrella Review*, Cureus (2025) (ALGN04787066).

[121] T. Miyazaki, et al., *A Review of Dental CAD/CAM: Current Status and Future Perspectives*, Dental Materials Journal 28(1):44–56 (2009); Lione, R., et. al., *Accuracy, Time, and Comfort of Different Intraoral Scanners: An In Vivo Comparison Study*, Applied Sciences (2024) (ALGN04787043), Singh, R., et al., *Accuracy and Clinical Performance of Intraoral Scanners Compared to Conventional and Extraoral Impressions: An Umbrella Review*, Cureus (2025) (ALGN04787066).

[122] A. Sharma et al., *History of materials used for recording static and dynamic occlusal contact marks: a literature review.* J Clin Exp Dent (2013).

[123] *Id.*

[124] *Id.*; Align Form 10-K for the Year Ended December 31, 2024, p. 6.

[redacted]

86. The advent of digital intraoral scanners marked a fundamental shift in dental imaging.[125] Rather than taking an impression for capturing physical structures in the oral cavity to create a physical model, intraoral scanners use cameras to image the intraoral cavity.[126] These images are then processed into a three-dimensional digital model of the dentition and surrounding areas.[127] This digital representation can be viewed, manipulated, stored, and transmitted without the need for physical materials or stone models.[128]

87. Digital scanning offers several advantages over traditional impression techniques.[129] It reduces patient discomfort associated with impression trays and materials, eliminates distortions caused by material shrinkage or deformation, and improves reproducibility by reducing turnaround times from partner labs and the number of remakes needed.[130] Digital models also facilitate integration with computer-aided design and manufacturing (CAD/CAM) systems, enabling more precise and efficient fabrication of dental and orthodontic appliances.[131]

88. Modern intraoral scanning systems include software tools that allow clinicians to edit digital scan data to correct incomplete or distorted regions without restarting the entire scan.

[redacted] The Eraser function was conceived to address common

[125] Align Technology, Inc., *iTero Element 5D Intraoral Scanner User Manual* at 1–2 (2022).
[126] Align Technology, Inc., *iTero Lumina Pro User Manual* at 7–8 (2024).
[127] *Id.*; Align Technology, Inc., *iTero Element 5D Intraoral Scanner User Manual* at 1–2 (2022).
[128] *Id.*; '936 Patent at 19:9–14; Align Tech., Inc., iTero Manual Repository (last visited Jan. 6, 2026), https://guides.itero.com/; iTERO, Our Scanners (last visited Jan. 6, 2026), https://itero.com/our-solutions.
[129] T. Miyazaki, et al., *A Review of Dental CAD/CAM: Current Status and Future Perspectives*, Dental Materials Journal 28(1):44–56 (2009).
[130] *Id.*; Ryokawa, H., et al., *The mechanical properties of dental thermoplastic materials in a simulated intraoral environment*. Orthodontic Waves, 65(2), 64-72 (2006).
[131] *See* Invisalign, *Invisalign Digital Experience*, https://www.invisalign.com/how-it-works/invisalign-digital-experience; iTero, *Our Solutions*, https://itero.com/our-solutions
[redacted]

[redacted]

scanning problems such as food, saliva, blood, soft tissue interference, or other changes in dentition that occur during the preparation of a crown.[133] Once the tooth is prepared, the margin lines of the tooth must be visible, clean, and dry for a good scan.[134] Accordingly, the ability to scan the prepared tooth quickly before more saliva or blood emerges, or to re-scan the tooth after removing said saliva or blood, and to further check the quality of the new scan before proceeding with the case, is beneficial in ensuring that the crown preparation is successful. Additionally, the patient's discomfort during the procedure can be minimized by shortening the time for the scan.

89. The Eraser function allows a clinician to mark a region of the scan and replace the data with new scan data.[135] Align added the Eraser functionality to its intraoral scanner software, which was first released for use in the iTero in scanner software version 4.0 in 2011.[136] By permitting localized scan and replace rather than full rescans, the Eraser function improves workflow efficiency, reduces patient chair time, and enhances the accuracy of digital models used for treatment planning and appliance fabrication.[137]

90. The Eraser function is used frequently in both dentistry and orthodontic applications. In both applications, the Eraser function is used to remove unwanted material, such as food, saliva, blood, and soft tissue, which obscures the patient's teeth in the initial scan.[138] This enables the dentist from having retake the entire scan again. The Eraser function is also used during dental procedures, such as a crown preparation.[139] The Eraser function may be used

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[133] *Id.* at 259:8-14.
[134] *See id.* at 57:20-58:11.
[135] *Id.* at 142:16-20; 259:14-18.
[136] Align Tech., Inc., Form 10-Q (Aug. 8, 2011); ALGN00423711; ALGN00423713; ALGN04795136; [redacted] ALGN00423713; Redacted - Privileged [redacted] :20; ALGN00423711; ALGN00423713; ALGN04795136; ALGN00000956; ALGN00000962; ALGN00414950; ALGN00423713; [redacted].
[redacted]

[redacted]

to capture a pre-operation image of the patient's teeth.[140] After the operation is completed, the Eraser function will be used to remove the patient's tooth that has been modified during the operation, and the dentist will rescan the tooth.[141] This will produce a post-operation image without requiring the dentist to rescan the entire arch.[142] The Eraser function may also be used by a dentist during a dental procedure if additional modification is required on a tooth.[143] For example, if a tooth has been prepared for a crown preparation, the dentist may take a first scan of the tooth and determine that the crown-prepped tooth does not have adequate occlusal clearance to install a crown. In that case, the dentist will remove additional material from the crown-prepped tooth, and they can use the Eraser to rescan only the portion of the crown-prepped tooth that has been reduced.

91. The Eraser function can also be used in orthodontic applications when a patient's tooth has been modified.[144] For example, an orthodontist may take an initial scan of a patient's teeth and then discover that an unwanted attachment is still in place. The orthodontist will polish off the attachment and then use the Eraser function to rescan only the modified tooth. As another example, the orthodontist may perform enameloplasty of certain teeth, which involves removing small amounts of tooth enamel to improve the shape, size, or length of teeth to fix minor imperfections, such as chips or sharp edges. After performing the enameloplasty, the orthodontist can use the Eraser function to rescan the modified tooth without having to rescan the entire arch. In my experience in orthodontics, we use the Eraser tool in approximately 50 percent of the scans performed.

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[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] *Id.*

[redacted]

D. Overview of Treatment Planning for Clear Aligners

3. Invisalign® Treatment Planning

92. As described above, Align's patented technology uses a series of custom incremental aligners.[145] Each aligner in a series of aligners corresponds to one stage or segment of the overall orthodontic treatment plan for straightening the patient's teeth.[146] The patient wears each aligner for approximately one to two weeks, until the patient's teeth have adequately repositioned to the tooth arrangements corresponding to the cavities in that aligner, which may be viewed as a three-dimensional computer image.[147] The patient then replaces the current aligner with the next in the series.[148]

93. Traditional brackets and wires ("braces") generally apply force across the entire set of teeth at the same time.[149] Aligners, however, apply selective forces to individual teeth and these forces can be controlled to occur at particular stages in the treatment plan.[150] Thus, the treatment plan can be designed so that at each stage only certain teeth move while others stay in place.[151] This results in a more targeted and efficient force delivery system.[152] Teeth that are not

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[145] INVISALIGN, *Invisalign Treatment Process, How Does the Invisalign® Treatment Work?*, https://www.invisalign.com/how-it-works; INVISALIGN, *Invisalign Aligners FAQs – What Is Invisalign Treatment?*, https://www.invisalign.com/frequently-asked-questions.
[146] *Id.*; INVISALIGN, *Invisalign Aligners FAQs – What Is the Treatment Process?*, https://www.invisalign.com/frequently-asked-questions.
[147] *Id.*
[148] *Id.*
[149] River Falls Orthodontics, *Explaining the Different Parts of Braces*, https://www.riverfallsortho.com/explaining-the-different-parts-of-braces/; Am. Ass'n of Orthodontists, Archwires, https://aaoinfo.org/treatments/archwires/.
[150] Chishti, M., & Phan, L. (2009), *Methods for correcting tooth movements midcourse in treatment* (Patent No. 7,578,674B2); Ziuchkovski, J. P., Fields, H. W., Johnston, W. M., & Lindsey, D. T. (2008). *Assessment of perceived orthodontic appliance attractiveness*. American Journal of Orthodontics and Dentofacial Orthopedics, 133(4), S68-S78; Boyd, R. L. (2008). *Esthetic orthodontic treatment using the Invisalign appliance for moderate to complex malocclusions*. Journal of dental education, 72(8), 948-967; Am. Ass'n of Orthodontists, *Aligners*, https://aaoinfo.org/treatments/aligners/; INVISALIGN, *Invisalign Aligners FAQs – How Will Invisalign Treatment Straighten My Teeth?*, https://www.invisalign.com/frequently-asked-questions
[151] INVISALIGN, *Invisalign® Digital Treatment for Aligners*, https://www.invisalign.com/how-it-works/invisalign-digital-experience
[152] *See id.*; INVISALIGN, *Invisalign Aligners FAQs – How Will Invisalign Treatment Straighten My Teeth?*, https://www.invisalign.com/frequently-asked-questions

[redacted]

selected to move during a given stage can function as anchors to keep the aligner in place as it applies resilient force to the teeth selected to move.[153]

94. Align uses computer technology and three-dimensional imaging.[154] One aspect of Align's inventions involves the computer generation of a plurality of successive digital data sets based on an initial digital data set representing an initial tooth arrangement and a final digital data set representing a desired tooth arrangement.[155] The plurality of successive digital data sets represents a series of successive tooth arrangements progressing from the initial tooth arrangement to the final tooth arrangement.[156]

95. Align's technology is utilized to assist in the development of an orthodontic treatment plan and the computer implemented fabrication of a series of aligners proceeding from initial to final.[157] Because every patient's teeth and bite are unique and each aligner in the series corresponds to a different tooth arrangement in the overall treatment plan, each aligner must be custom manufactured for the individual patient and stage of treatment.[158] Fabrication of unique and highly specific aligners on a commercially viable scale, therefore, presents significant obstacles that Align's technology overcomes.

96. Align's Invisalign system reflects decades of sustained research and development. Align has invested more than $2 billion to build and refine the system, with annual research and development spending now exceeding $250 million.[159] That investment supports a global team

[153] *See id.*
[154] Align Form 10-K for the Year Ended December 31, 2024, p. 6.
[155] *See* INVISALIGN, *Invisalign® Digital Treatment for Aligners*, https://www.invisalign.com/how-it-works/invisalign-digital-experience.
[156] *Id.*
[157] INVISALIGN, *Invisalign Aligners FAQs – What Is the Treatment Process?*, https://www.invisalign.com/frequently-asked-questions.
[158] *Id.*
[159] Align Form 10-K for the Year Ended December 31, 2024

[redacted]

of material scientists, biomechanical engineers, software engineers, clinicians, and other specialists dedicated to advancing every stage of orthodontic care.[160]

4. Orthodontic Tooth Movements

97. There are many ways that teeth may be displaced, and therefore, many ways that teeth may be moved during orthodontic treatment, subject to biological and spatial constraints that limit both the speed and order of movement.[161] Determining the speed and sequence of tooth movement matters because moving teeth too quickly can result in devitalization (tooth death), detachment, or additional problems.[162] The planned order of movement must also avoid collisions or obstructions between teeth that would prevent proper, safe, and effective treatment.[163] A common concern is when the teeth have a "mid-line" displacement or "shift."[164] The dental mid-line refers to an imaginary vertical line passing between the two central incisors of the upper arch and the two central incisors of the lower arch, while the facial midline is an imaginary vertical reference line that divides the face into right and left halves.[165]

98. These constraints are illustrated by common midline-shift cases. When a patient's upper and/or lower dental midline is displaced—such that one arch is shifted laterally (sideways) relative to the opposing arch or to the facial midline—correcting the mid-line requires moving the affected teeth sideways until the dental midline aligns with the intended reference, whether that reference is the opposing dental midline or the facial midline.[166] For example, if the center

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[160] *Id.*
[161] Lidia Galán-Lopez et al., *A Systematic Review of the Accuracy and Efficiency of Dental Movements with Invisalign®*, 49 KOREAN J. ORTHOD. 140, 142–49 (2019).
[162] *See* Invisalign, *Oral Health*, https://www.invisalign.com/why-invisalign/oral-health.
[163] *Id.*
[164] *See* Align Tech., Inc., *What Invisalign® Treatment Can Treat — Midline Discrepancy*, INVISALIGN, https://www.invisalign.com/provider/invisalign-solutions/what-invisalign-treats
[165] *Id.*
[166] Lidia Galán-Lopez et al., *A Systematic Review of the Accuracy and Efficiency of Dental Movements with Invisalign®*, 49 KOREAN J. ORTHOD. 140, 145–47 (2019).

[redacted]

of the lower teeth is shifted too far to the right, correcting that shift requires moving the front lower teeth toward the left in the dental arch.[167] [redacted]

VII. THE PATENTS IN SUIT

A. Summary of the Inventions

100. Together, the Patents-in-Suit are directed to different components of the Invisalign System. The '613, '384, '090, and '091 Patents are directed to materials for use in dental appliances. The patents relate to a multilayer material with specific material properties that are advantageous for the movement of teeth. The '444 Patent is directed to improvements in treatment planning. The '444 Patent covers a system and method for receiving electronic representations of the patient's teeth in their initial and final positions and determining an order of movement of the teeth from initial to final positions using one or more movement patterns, including staggering or round-tripping of teeth, such that the teeth avoid colliding with or obstructing each other.

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[167] John Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 3, 6–9 (2017).

[redacted]

[redacted]

101. The ’936 Patent is directed to improvements in scanner functionality, in particular, an “Eraser” function that is particularly useful in restorative procedures and orthodontic treatment. More specifically, the ’936 patent describes the benefits of using and manipulating three-dimensional virtual representations of the intraoral cavity. Traditionally, the intraoral cavity of a patient can be studied by making a physical plaster model of that patient’s intraoral cavity. Virtual representations enable a dental practitioner to consider approaches for dealing with a variety of dental problems, including the design of prostheses, dental brackets, and aligners. For example, the computer model of a patient’s teeth may be manipulated to provide machining data to manufacture a prosthesis or a dental appliance. However, the computer model is based on the 3D data collected from an intraoral scan, and sometimes, some portions of the scan are inaccurate due to the presence of one or more of saliva, blood, lubricant, debris, etc. The inventor of the ’936 patent recognized that a method for modifying a 3D virtual model of the intraoral cavity would be useful. In particular, the ability to modify a 3D virtual model would improve the accuracy and precision of intraoral scanning, which in turn, would reduce the need for rescanning or re-taking a plaster impression of a patient’s teeth. The ’936 Patent describes the “3D virtual model” in broad terms that include “virtual model,” “digital model,” “3D numerical entity,” “computer model,” “3D digitized data,” and “3D representation.”

102. The ’936 patent describes methods of receiving a first set of scan data collected by an intraoral scanner and using that data to generate a model of the patient’s teeth. A user may then define a portion of that model to remove and replace. The intraoral scanner then collects a second set of scan data, which can be used to replace the removed portion and generate a new model of the patient’s teeth.[171]

[171] *See* ’936 Patent at 3:26-37.

[redacted]

103. The ’936 patent describes several embodiments of the invention. In Embodiment A, a user may “correct” a portion of a virtual model of dental surface by rescanning a portion of the model.[172] First, a first 3D virtual model of a physical part is created using a scanner. The virtual model is displayed to the user, so that the user may check the model. A portion of the first model is deleted or otherwise removed, resulting in a modified first virtual model. A second virtual model representing the previously deleted portion is created using a scanner. The second virtual model is then manipulated in the computer stem to register it onto the modified first virtual model. Identifying surface data from the second virtual model may be useful to align with corresponding parts of the modified first virtual model. In this aligned position, the second virtual model can be stitched into the modified first virtual model. The remainder of the second virtual model, including the identifying information may be discarded.

104. Embodiment B describes a way for a user to obtain a virtual model of the intra oral cavity, even with an artifact obscuring some of the initial scan.[173] A user need only delete the portion that is a removable artifact, which may be temporarily obscuring part of the dental services, such as a scan body or impression abutment, from the first virtual model.

105. Embodiment C describes a use in orthodontics, such as the preparation of a crown or bridge. ’936 patent at 16:15-17:12. In this scenario, a user may be preparing a dental preparation and checking that it is suitable for its intended use and can continue modifying the dental preparation until it is deemed suitable for its intended use. The dental practitioner can then rescan the area including the removed/modified teeth and replace the parts of the original virtual model corresponding to these teeth.

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[172] ’936 patent at 14:45-15:36.
[173] ’936 patent at 15:37-16:14.

[redacted]

106.

B. CLAIMS

1. '613 Patent

107. I have reproduced below asserted claim 1 of the '613 Patent.

1. A method of making a dental appliance for positioning a patient's teeth, the method comprising:

providing a sheet comprising three or more polymer layers, the three or more polymer layers comprising:

a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and

a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D;

providing a positive model of the patient's teeth in a target position; and

fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

2. '384 Patent

108. I have reproduced below asserted claim 1 of the '384 Patent.

1. A dental appliance for positioning a patient's teeth from a first arrangement toward a second arrangement, the dental appliance comprising:

a plurality of tooth-receiving cavities shaped to receive and resiliently reposition the patient's teeth from the first arrangement toward the second arrangement;

three or more polymer layers, the three or more polymer layers comprising:

a hard polymer layer comprising a co-polyester and having a flexural modulus greater than about 150,000 psi; and

a soft polymer layer comprising a thermoplastic polyurethane elastomer and having an elongation at break of greater than about 200%, and a hardness from about 60 A to about 85 D.

3. '090 Patent

[redacted]

109. I have reproduced below asserted claim 1 of the ’090 Patent.

1. A method of making a multilayer dental aligner for repositioning a patient’s teeth from a first arrangement toward a second arrangement, the method comprising:

providing a multilayer sheet comprising three polymer layers, the three polymer layers comprising:

a first layer consisting of a co-polyester, the co-polyester having a flexural modulus greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and

a second layer consisting of a thermoplastic polyurethane elastomer, the thermoplastic polyurethane elastomer having an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and

a third layer;

wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer;

providing a mold;

thermoforming the multilayer sheet over the mold to form a plurality of tooth-receiving cavities configured to receive and reposition the patient’s teeth from the first arrangement toward the second arrangement; and

trimming excess material from the thermoformed multilayer sheet to form the multilayer dental aligner.

4. ’091 Patent

110. I have reproduced below asserted claim 1 of the ’091 Patent.

1. A multilayer sheet comprising:

a first layer containing a single polymer, wherein the single polymer of the first layer is a co-polyester, and wherein the first layer has a flexural modulus greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and

a second layer containing a single polymer, wherein the single polymer of the second layer is a thermoplastic polyurethane elastomer, and wherein the second layer has an ultimate tensile strength of greater than 5000 psi, an

[redacted]

elongation at break of greater than 200%, and a hardness of 60A to 85D; and

a third layer;

wherein the first layer has an elastic modulus greater than the second layer; and

wherein the multilayer sheet is incorporated into an orthodontic appliance.

5. '444 Patent

111. I have reproduced below asserted claim 1 of the '444 Patent.

1. A computer-implemented method for staging the movement of a plurality of dental objects, the method comprising:

receiving, at a host computer, an electronic representation of each dental object of the plurality of dental objects in relation to one another;

receiving, by the host computer, an electronic representation of a desired final position for each respective dental object; and

determining, by the host computer, an order of movement for each respective dental object such that the dental objects avoid colliding with or obstructing each other on their respective routes from said initial position to said desired final position through at least one of staggering and round-tripping of at least one dental object.

6. '936 Patent

112. I have reproduced below asserted claim 1 of the '936 Patent.

1. A system for scanning a patient's teeth for a dental procedure, the system comprising:

a hand-held intraoral scanner; and

a computer readable medium including instructions that when executed by a computer system, cause the computer system to:

receive first scan data of the patient's teeth from the hand-held intraoral scanner;

display, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth;

receive user input defining a portion of the model to be removed;

remove, from the displayed model, a removed surface portion of the model to be removed according to the user input;

[redacted]

receive second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity;

replace at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity; and

output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the received second scan data.

VIII. SUMMARY OF THE PATENTED PRODUCTS

113. As explained above, the Invisalign System involves three primary components: intraoral scanning, treatment planning, and clear aligners. First, a 3D model is generated from an intraoral scan. The scan is used in digital treatment planning to create clear aligners.

114. It is my opinion that the iTero scanner practices at least Claim 1 of the '936 Patent. At a high level, the iTero scanner allows a user to scan a patient's teeth with a handheld scanner, remove any unwanted portions of the scan using an Eraser tool on the display attached to the handheld scanner, and rescan and replace the removed portions.

115. I understand from Dr. Singh that Align's TREAT software practices the inventions claimed in the Asserted Claims of the '444 Patent.

116. I understand that the '613, '384, '091, and '090 Patents (the "Materials Patents") claim various multilayer materials for use in orthodontic appliances. I understand from Dr. Maureen Reitman that the specific properties claimed in the Materials Patents are important and directly related to the ability of a clear aligner to exert constant, gentle force over the teeth. I further understand that these material properties lead to the benefits seen with SmartTrack over other single-layer aligner materials.

[redacted]

IX. SUMMARY OF THE ACCUSED PRODUCTS

117. Like the Invisalign System, treatment with ClearCorrect clear aligners involves three primary components: intraoral scanning, treatment planning, and clear aligners. First, a 3D model is generated from an intraoral scan. The scan is used in digital treatment planning to create clear aligners.

118. It is my opinion that the SIRIOS and Virtuo Vivo scanner systems infringe the Asserted Claims of the ’936 Patent.

119. I understand from Dr. Singh that ClearCorrect’s STAGE software infringes the Asserted Claims of the ’444 Patent.

120. I understand from Dr. Reitman that Zendura FLX infringes the Asserted Claims of the Materials Patents.

X. INFRINGEMENT ANALYSIS

A. THE VIRTUO VIVO INTRAORAL SCANNER SYSTEM INFRINGES THE ASSERTED CLAIMS OF U.S. PATENT NO. 10,791,936

121. As explained below, the Virtuo Vivo intraoral scanner system[174] practices each limitation of claims 1, 4-6, 8-12, and 17 of the ’936 Patent, either literally or under the doctrine of equivalents. This analysis is based on my review of the ’936 Patent, publicly available technical documentation, product literature, and operation of the Virtuo Vivo scanner system, as well as my education, training, and experience in dental imaging systems.

[174] The Virtuo Vivo intraoral scanner, as used in my report, refers generally to Virtuo Vivo scanners since April 2019. I understand that the Virtuo Vivo included the eraser functionality in April 2019. [redacted]

[redacted]

1. Infringement of Claims 1, 4-6, and 8 of the '936 Patent

a. Claim 1

i. 1[Pre]: "A system for scanning a patient's teeth for a dental procedure, the system comprising:"

122. The Virtuo Vivo scanner system is a system for scanning a patient's teeth for dental procedures within the meaning of Claim 1. The Virtuo Vivo is an intraoral scanning system specifically designed to capture digital three-dimensional representations of a patient's dentition and surrounding oral structures.[175] These scans are used in connection with a variety of dental procedures, including restorative dentistry, orthodontic treatment planning, and the fabrication of dental appliances.[176] The Virtuo Vivo scanner is used chairside by dental professionals to obtain accurate digital models of a patient's teeth, which are then used downstream in dental workflows such as diagnosis, treatment planning, and manufacturing of restorations or orthodontic appliances.[177] Accordingly, the Virtuo Vivo satisfies the claim preamble requirement of being a "system for scanning a patient's teeth for a dental procedure."[178]

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[175] *Virtuo Vivo, Intraoral Scanner* ("Scanner Brochure") at 4, Straumann (2023), https://www.straumann.com/content/dam/media-center/digital/en/documents/brochure/product-information/490.710-en_low.pdf (ALGN00015015); [redacted]

[176] *Id.* at 9 ("Planning services . . . grow and develop your practice by leveraging the full potential of our digital treatment planning and manufacturing services;" "Orthodontic treatments . . . Excite your patients and expand your treatment portfolio with clear aligners – the removable, and nearly invisible orthodontics treatment. Virtuo Vivo integrates directly for smooth and easy case submission to our ClearCorrect services;" "Surgical Planning & Production . . . Plan your implant case, design and manufacture your surgical guides as well as the temporary prosthetics;" "Dental Lab Partners . . . Reduce the lead time with your labs and share the digital impression with your Dental Lab Partner of choice. Virtuo Vivo is an open system for direct connection and communication."); [redacted]

[178] *See also Virtuo Vivo Intraoral Scanner*, Straumann (CC_ALGN_00106137); *Intraoral Scanner User Manual*, Dental Wings (CC_ALGN_03166785).

[redacted]

123. I inspected the Virtuo Vivo scanner on October 6 and 7, 2025. Below are images of the Virtuo Vivo packaging, product numbers, and the Virtuo Vivo scanner, which is connected to a laptop. As shown below, the system includes a scanner, which captures three-dimensional images of the patient's teeth. The images are displayed on the accompanying laptop. Accordingly, the Virtuo Vivo satisfies the claim preamble requirement of being a "system for scanning a patient's teeth for a dental procedure."

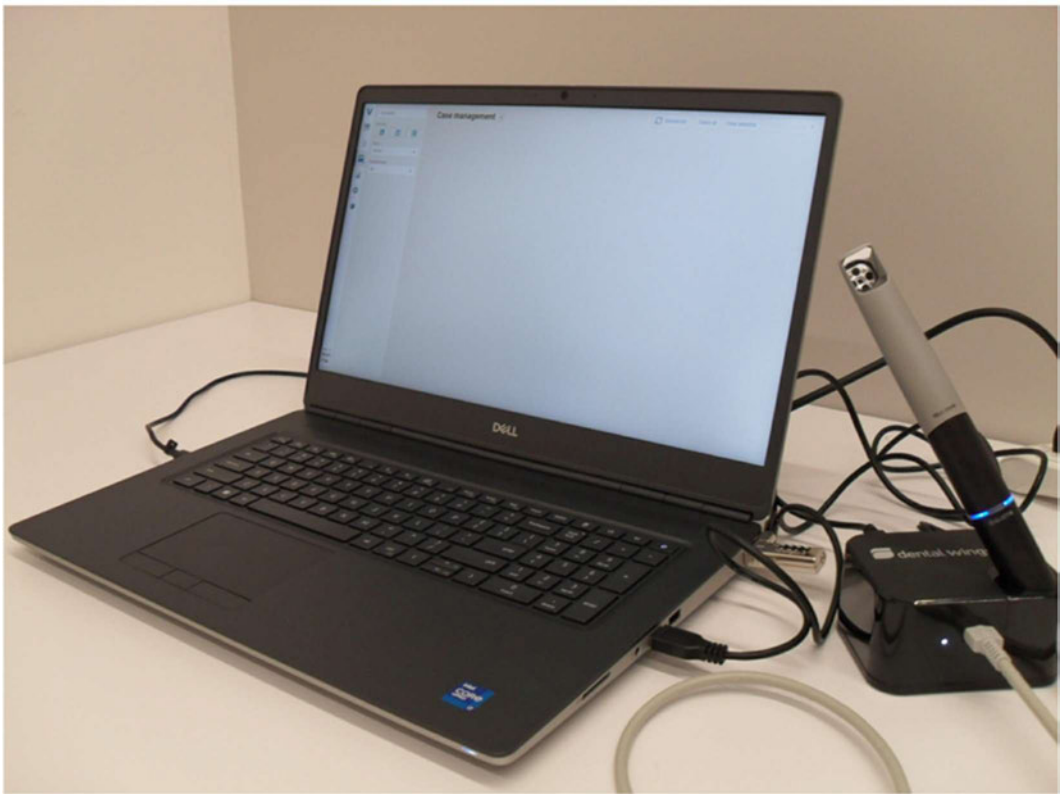


CC_EXEC_00000653



[redacted]

CC_EXEC_00000676



CC_EXEC_00000657

[redacted]



CC_EXEC_00000660

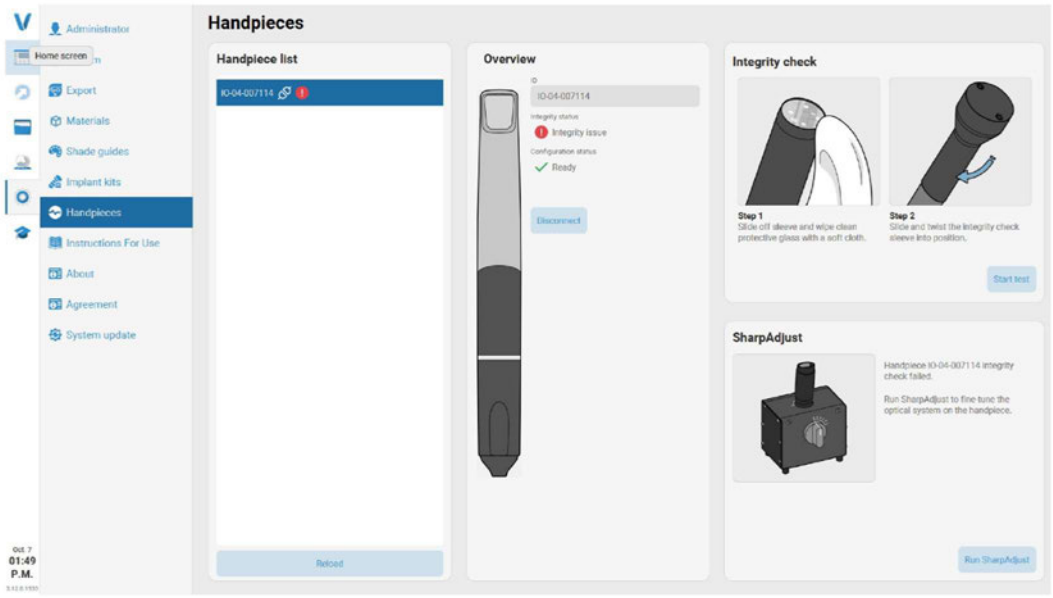


CC_EXEC_00000675

[redacted]

ii. 1[a]: "a hand-held intraoral scanner"

124. The Virtuo Vivo scanner system satisfies Claim 1[a]. The Virtuo Vivo scanner is a hand-held intraoral scanner.[179] The Virtuo Vivo scanner includes a portable scanning device that a dental professional holds in their hand and places in the patient's mouth (intraorally) to capture surface data of the teeth and surrounding intraoral structures (*e.g.*, gums).[180] Advertising for the Virtuo Vivo describes the devices as a "small and lightweight handpiece" that "is ergonomically designed for a pen-like grip."[181] This scanning device is referred to as a handpiece as shown below.



CC_EXEC_00000477

[redacted]

[180] (ALGN00015015) at -018 ("It all starts with a great scanner").
[181] *Virtuo Vivo Intraoral Scanner*, Straumann (CC_ALGN_00106137) at -141.

[redacted]

125. During normal operation, the clinician moves the Virtuo Vivo scanner over the teeth and surrounding gums while the device acquires optical scan data.[182] As described in the materials for the Virtuo Vivo scanner, the device "is a dental 3D scanner intended to be used to digitally record topographical characteristics of teeth and surrounding tissues."[183]

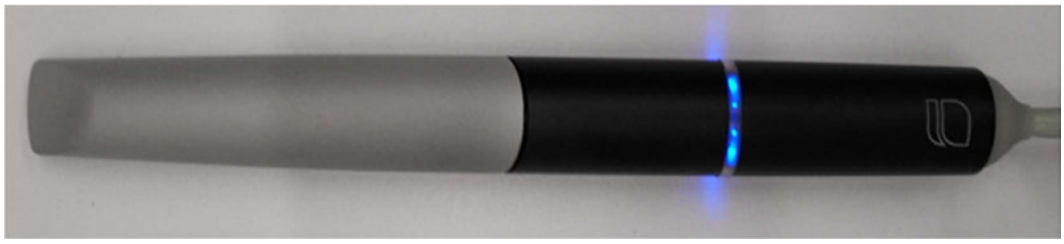
126. Below are images of the Virtuo Vivo scanner I inspected. To test the Virtuo Vivo scanner, I used the device to create a three-dimensional image of the teeth of a typodont, which is a realistic model of the human mouth, teeth, gums, and palate.[184] handholding the scanning device with my hand, I was able to maneuver it to capture images of the teeth and gums of the typodont. Accordingly, the Virtuo Vivo satisfies the requirement of a "hand-held intraoral scanner."



CC_EXEC_00000661

[182] *Virtuo Vivo Intraoral Scanner*, Straumann (CC_ALGN_00106137) at -141 ("Teeth and soft tissue are scanned from multiple orientations simultaneously, capturing difficult-to-see areas with minimal effort"); *Intraoral Scanner User Manual*, Dental Wings (CC_ALGN_03166785) at -790 ("The Intraoral Scanner is a dental 3D scanner intended to be used digitally to record topographical characteristics of teeth and surrounding tissues. The system produces 3D scans for use in computer-assisted design and manufacturing of dental restorations.").
[183] *Intraoral Scanner User Manual*, Dental Wings (CC_ALGN_03166785) at -790.
[184] As a note, some of the teeth on this typodont had attachments for aligner treatment purposes.

[redacted]



CC_EXEC_00000666



CC_EXEC_00000662

iii. 1[b][i]: "a computer readable medium including instructions that when executed by a computer system, cause the computer system to:'

127. The Virtuo Vivo scanner system satisfies Claim 1[b][i]. The Virtuo Vivo scanner system includes a computer with installed software, a monitor and a hand-held intraoral scanner equipped with optical sensors.[185] The Virtuo Vivo is sold in two product versions, a cart and a laptop.[186] Both versions include a computer system as shown below,[187] which is used "to run the

[185] *Intraoral Scanner User Manual*, Dental Wings (CC_ALGN_03166785) ("The Intraoral Scanner consists of a computer with embedded software, a monitor, and a handpiece equipped with optical sensors"); *see also id.* at -790 ("The Intraoral Scanner [] is delivered in two product variants . . . The delivery contains all components necessary to run the Intraoral Scanner as intended;"); *id.* at -794 ("The device is compatible with the Intraoral Scanner software application version 3.0 and higher"); *id.* at -788, -795 (restricting access to software); *id.* at -802 (showing components of the system, including scanner, screen, handpiece, laptop); *id.* at -835 ("Software applications . . . Intraoral Scanner software application included"); [redacted]

[186] [redacted]

[187] *Intraoral Scanner User Manual*, Dental Wings (CC_ALGN_03166785) at -833; [redacted]

[redacted]

Virtuo Vivo software that processes the data generated by the scanner and generate the 3D model for exporting."[188]

Technical data		
Type/Model	**DW-IO-001 (cart)**	**DW-IO-100 (laptop)**
LED risk group (acc. IEC 62471)	Exempt[1]	
Laser class (acc. IEC 60825)	Class 1	no laser
Protection class (acc: IEC 60529)	IPXO (noncritical area - no protection)	
Protection class (electrical)	Class 1 Equipment; Basic insulation, relies on an earth for protection. The earth connection is achieved with a 3-conductor mains cable ending in a 3-prong AC connector which shall be plugged into a corresponding AC outlet.	Class 2 Equipment: Double insulated electrical equipment which does not require a safety connection to earth for protection.
Pollution Degree	2; Normally only non-conductive pollution occurs. Temporary conductivity caused by condensation is to be expected.	
Mode of operation	Continuous	
Computer / operating system	Integrated high-performance computer storage for 8000 cases Dedicated high-end graphic card Windows 10 operating system Integrated gesture and voice recognition modules	Minimum requirements[2] **Memory:** 16 GB DDR4 at 2400 MHz **Processor:** Intel® Core™ i7-8750H **Graphic card:** NVIDIA GeForce GTX 1060 with 6 GB GDDR5 **Hard disk:** 256 GB SSD **Webcam**
	21" multi-touch screen	17" screen

128. Both the cart and laptop versions of the Virtuo Vivo scanner system include software for operation of the Virtuo Vivo scanner as shown below.[189]

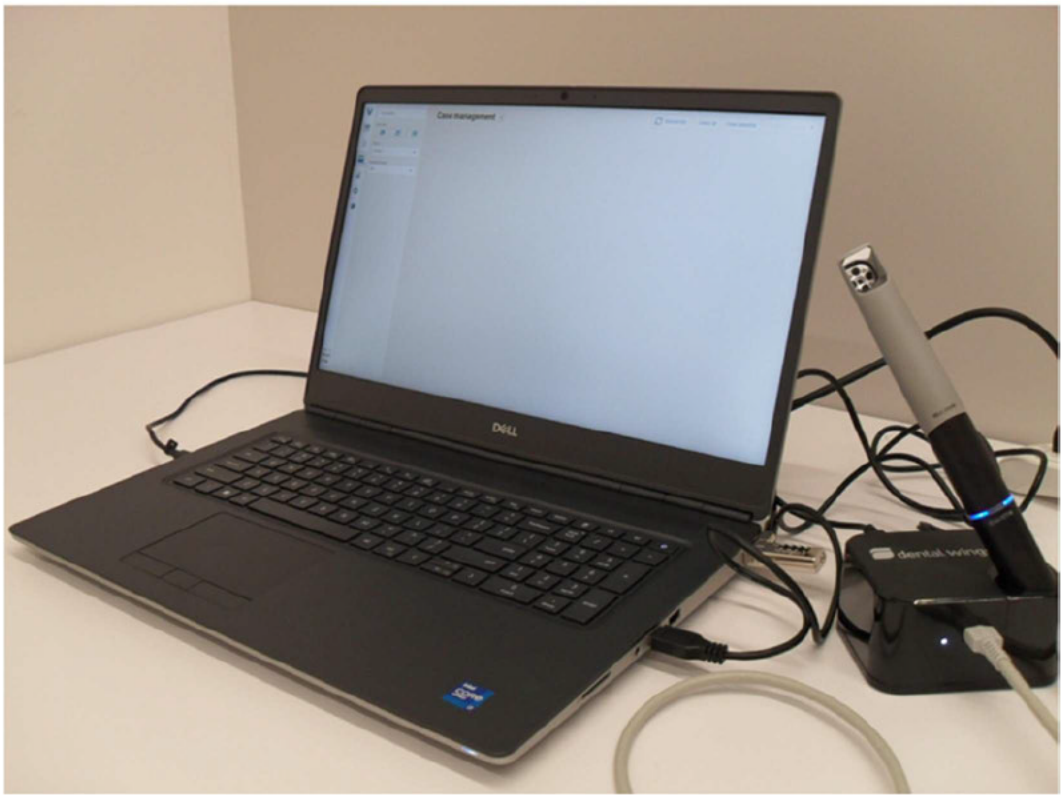
[redacted]

[189] *Id.* at -788.

[redacted]

Software applications	Included	Optional
Intraoral Scanner software application	x	

129. Below is an image of the laptop attached to the Virtuo Vivo scanner I inspected.



CC_EXEC_00000657

130. The laptop included the Virtuo Vivo scanner software. Below is an image of the Virtuo Vivo laptop screen which is running the scanner software discussed in more detail below. The laptop is attached to the Virtuo Vivo scanner device I inspected.

[redacted]



CC_EXEC_00000404

131. As shown above, the Virtuo Vivo scanner has a computer readable medium that includes instructions that can be executed by a computer system. Accordingly, the Virtuo Vivo scanner system satisfies Claim 1[b][i].

iv. 1[b][ii]: "receive first scan data of the patient's teeth from the hand-held intraoral scanner"

132. The Virtuo Vivo scanner system satisfies Claim 1[b][ii]. During operation of the Virtuo Vivo scanner system, the computer receives first scan data of the patient's teeth from the hand-held intraoral scanner.[190] For example, during a pre-preparation workflow, the scanner can take a pre-preparation scan. The software reads scan data from the sensor during the "Upper Pre-Preparation" or "Lower Pre-Preparation" steps.[191]

[redacted]

[191] Dental Wings, *Pre Preparation Workflow,* at 0:46, https://www.youtube.com/watch?v=TsOMsxjWTUk (ALGN00015010); [redacted]

[redacted]



133. The scan data is stored [redacted]

134. When I inspected the Virtuo Vivo scanner, I performed two tests using this scanner. To simulate a patient's oral cavity with teeth and gums, I used a dental typodont. A dental typodont is a realistic, articulated model of the human mouth (teeth, gums, palate) used by dental students, hygienists, and professionals for hands-on practice and training on procedures like fillings, crowns, orthodontics, and hygiene techniques before working on real patients. These models often feature replaceable plastic teeth that screw into place, soft rubber or silicone gums, and adjustable hinges to simulate jaw movement. One of the typodonts I used in my testing of the Virtuo Vivo and SIRIOS scanner systems included attachments on the surface of the teeth, which are used in clear aligner treatment. The attachments appear as small, raised bumps on the surface of the teeth.

[redacted]

[redacted]

135. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris often found on or between patients' teeth when they receive an intraoral scan. The debris could be food, plaque, tarter, blood, saliva, lubricant from the dental drill, waste material from working on a dental site, or any other foreign material that obscures a tooth's surface.[193]

136. For this test, I scanned both the upper and lower dental arches of the typodont using the Virtuo Vivo scanner. The Virtuo Vivo scanner software running on the laptop "receive[d] first scan data of the patient's teeth from the hand-held intraoral scanner." The three images shown below are different views of the first scan of the upper arch, which includes the upper left first molar with the debris (toothpaste).



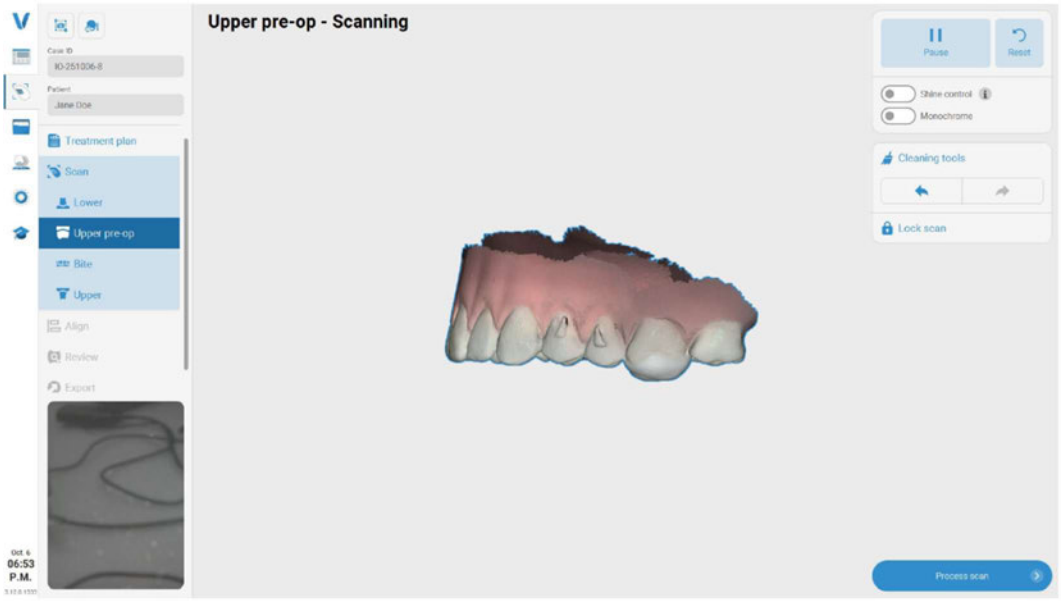
CC_EXEC_00000473

[193] '936 Patent at 2:1-5 (describing materials that can obscure a tooth's surface).

[redacted]



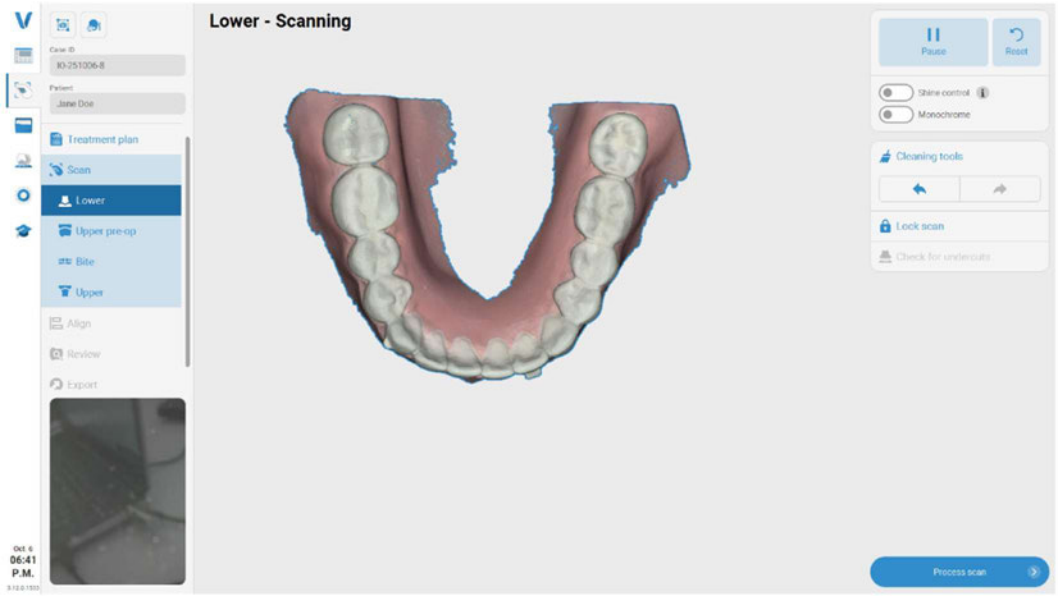
CC_EXEC_00000470



CC_EXEC_00000471

137. The image shown below is a first scan of the lower arch for the first test I performed.

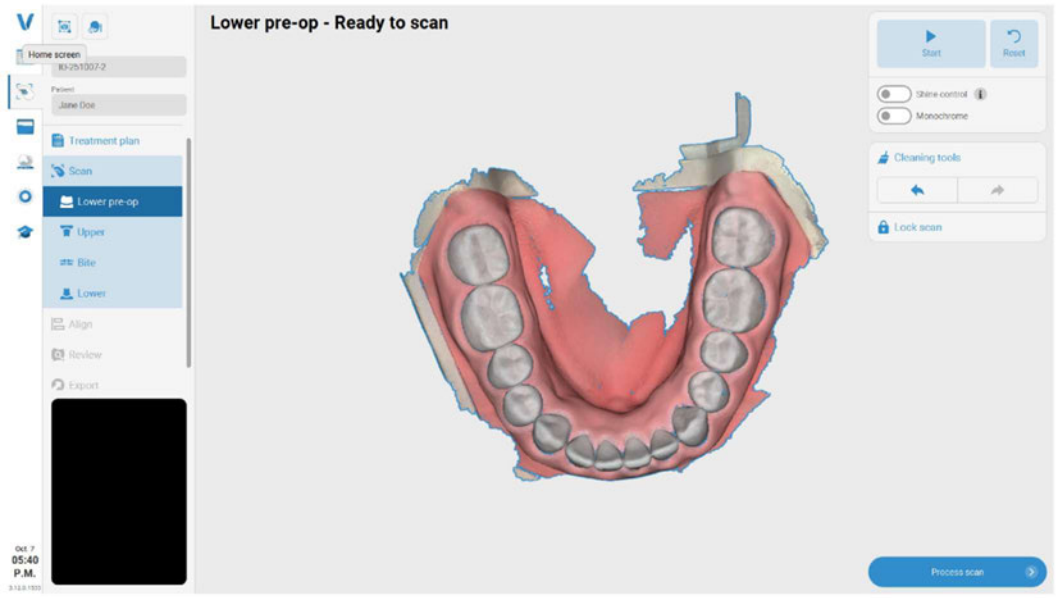
[redacted]



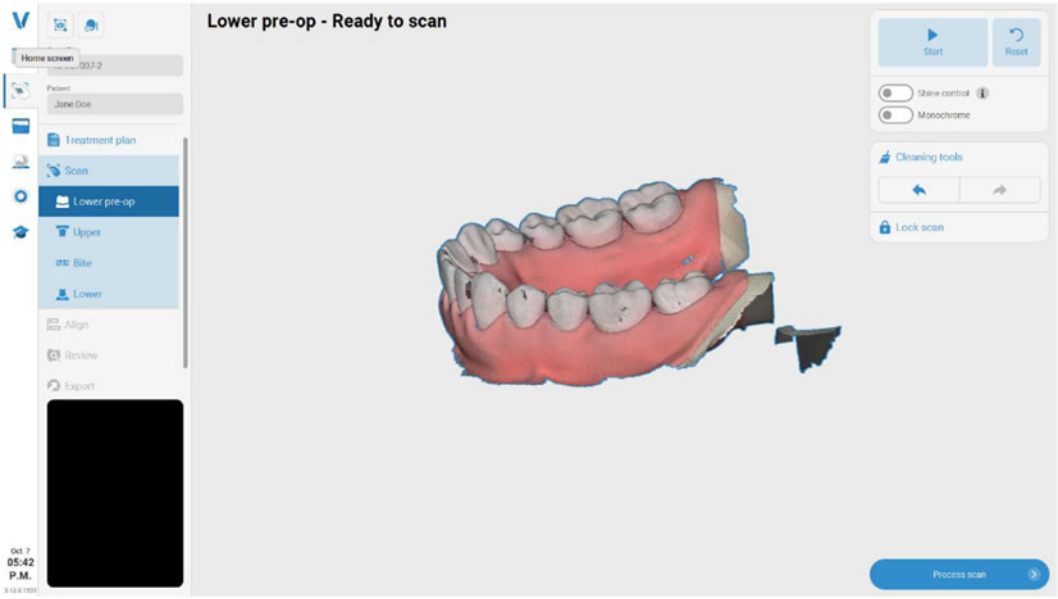
CC_EXEC_00000455

138. I also performed a second test using the Virtuo Vivo scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the Virtuo Vivo scanner system for a crown preparation or other dental procedure. For the first scan, the typodont's original tooth, that was later to be replaced with a crown-prepped version of the tooth, was in place to simulate capturing a pre-operation image of this tooth and all the patient's other teeth in the lower dental arch. The Virtuo Vivo scanner software running on the laptop "receive[d] first scan data of the patient's teeth from the hand-held intraoral scanner." The three images shown below are different views of the first scan of the lower arch before the crown preparation operation.

[redacted]

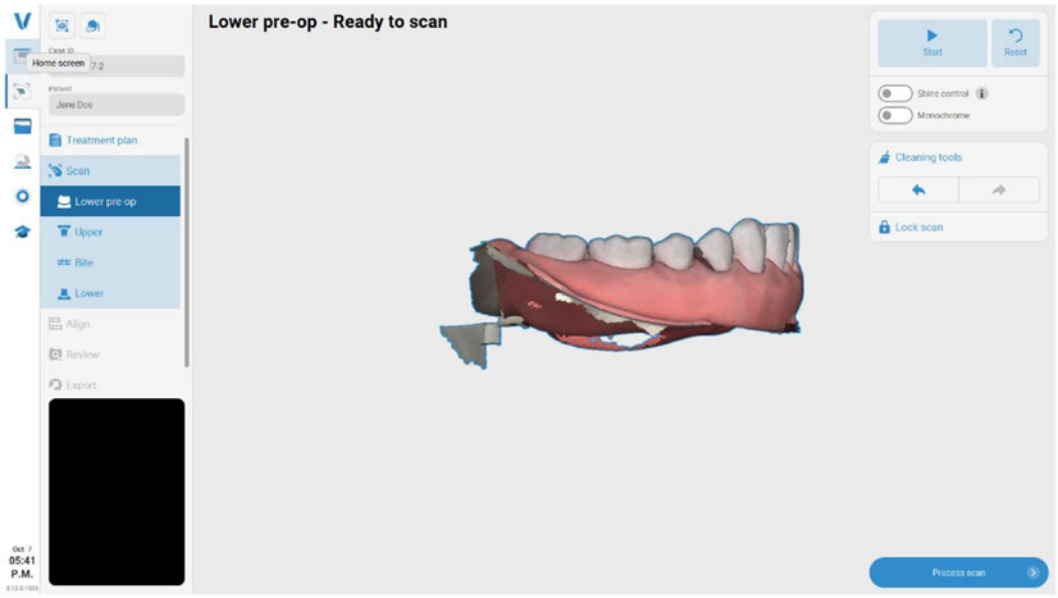


CC_EXEC_00000548



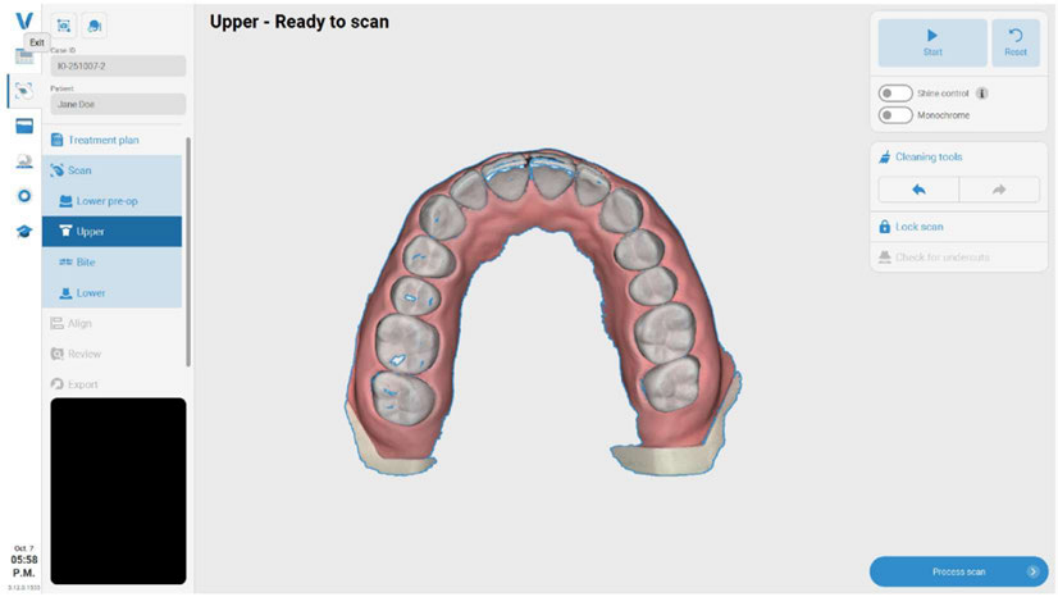
CC_EXEC_00000549

[redacted]



CC_EXEC_00000550

139. The image shown below is of the first scan of the upper arch for the second test I performed.



CC_EXEC_00000584

140. As shown above, the computer receives first scan data of the typodont simulated patient's teeth from the Virtuo Vivo hand-held intraoral scanner. I also understand from Dr.

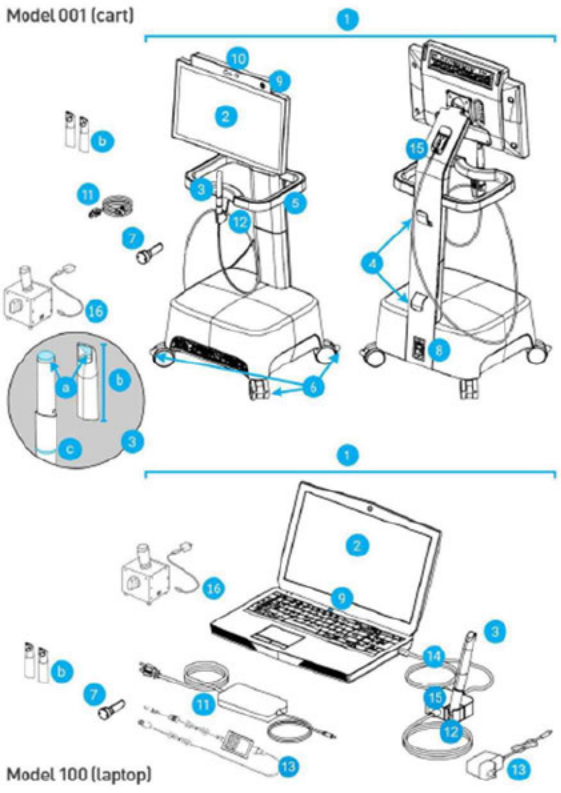
[redacted]

Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim limitation. Accordingly, the Virtuo Vivo scanner system satisfies Claim 1[b][ii].

v. 1[b][iii]: "display, to a display, a model of the patient's teeth wherein the model of the patient's teeth is based on the received first scan of the patient's teeth

141. The Virtuo Vivo scanner system satisfies Claim 1[b][iii]. The Virtuo Vivo scanner connects wirelessly to a computer system, which has a display. Both the cart and laptop configurations of the Virtuo Vivo include a screen display, as shown below.[194]

Parts identification



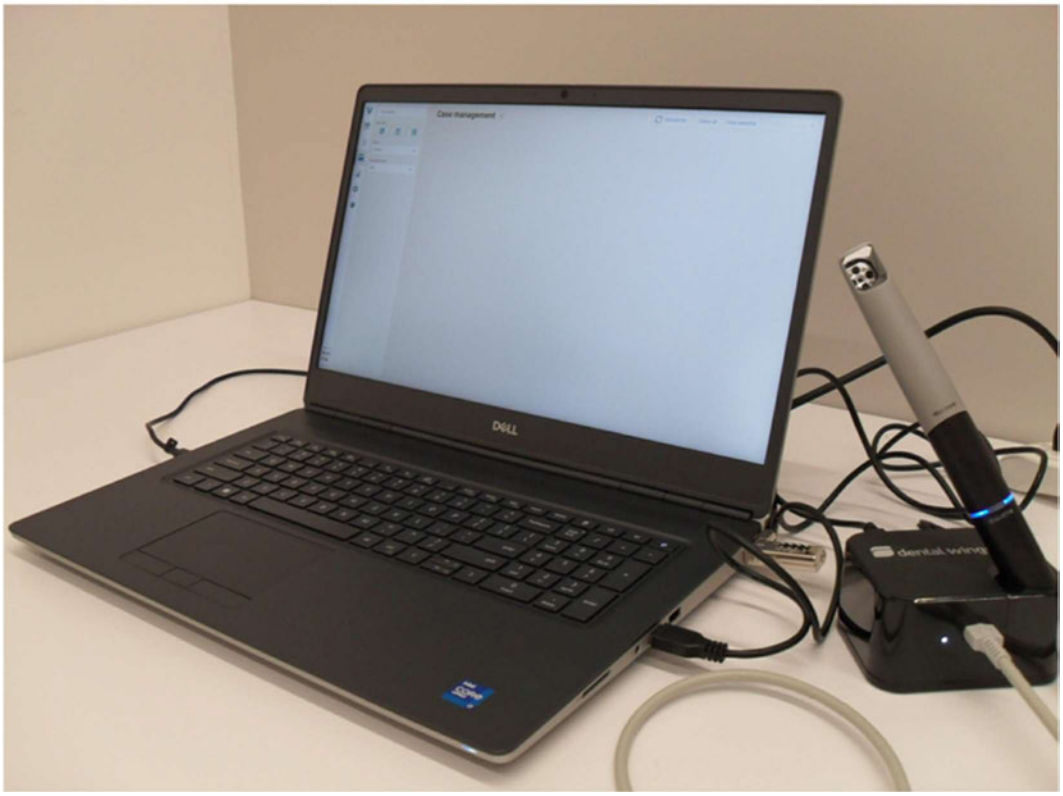
1. Scanner
2. Screen
3. Handpiece
   a. optics
   b. sleeve
   c. light ring
4. Cable hook
5. Handle
6. Wheel lock
7. Integrity-check sleeve
8. Power switch
9. Power button
10. Gesture/voice recognition module
11. Power cord/power supply
12. Holder
13. Handpiece connector power supply
14. USB cable
15. Handpiece connector
16. SharpAdjust

Figure 4: Identification of the scanner parts

[194] *Intraoral Scanner User Manual*, Dental Wings (CC_ALGN_03166785) at -802; [redacted]

[redacted]

142. When I inspected the Virtuo Vivo scanner, it was connected to a laptop with a display screen, as shown below.



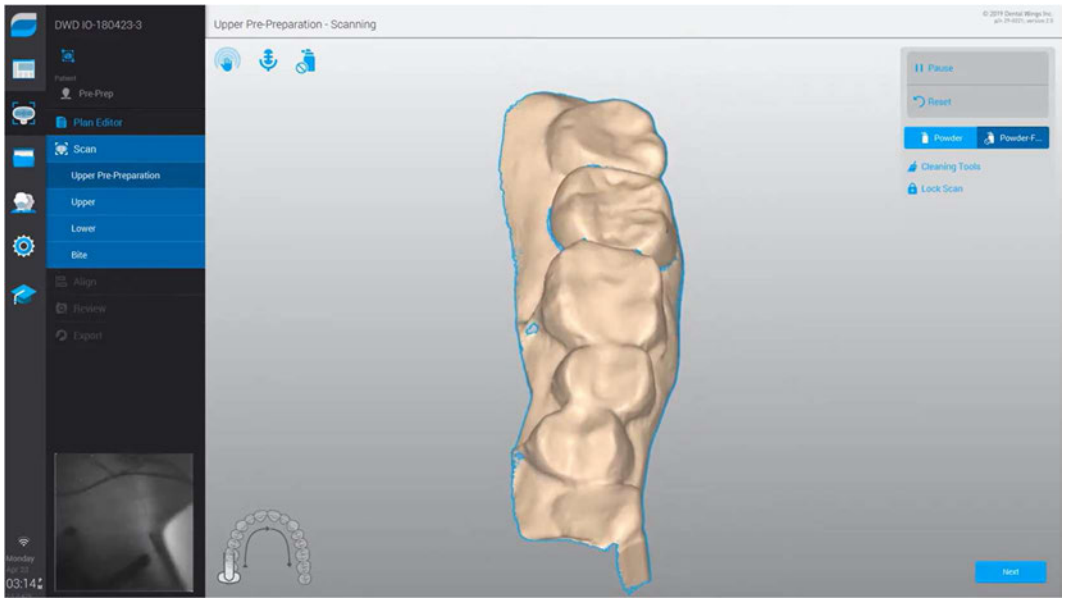
CC_EXEC_00000657

143. Both the laptop version and the cart version of the Virtuo Vivo scanner system generates a digital model of the patient's teeth based on the received first scan data read from the intra-oral scanner and displays that model on the system's display.[195] As shown in the Virtuo

[redacted]

[redacted]

Vivo tutorial video below, the displayed model visually represents the scanned dentition and is derived directly from the scan data captured by the scanner.[196]



144. When I inspected the Virtuo Vivo scanner, I performed a first test using the scanner and typodont to simulate a patient's teeth. I performed this test to simulate the workflow of the Virtuo Vivo scanner system when a removable unwanted element is obscuring part of the dental surface of a patient's teeth. To the upper left first molar of the typodont, I added toothpaste to simulate debris on or between a patient's teeth. The three images below are different views of the first scan of the teeth in the upper arch with debris on the upper left first molar and a first scan of the teeth in the lower arch. These images were displayed on the laptop attached to the Virtuo Vivio scanner.

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[196] Dental Wings, *Pre Preparation Workflow*, at 1:19, https://www.youtube.com/watch?v=TsOMsxjWTUk (ALGN00015010) (showing the display of a virtual model based on the received first scan data); *see also* Straumann, *Straumann® Virtuo Vivo™*, at 1:09, https://www.youtube.com/watch?v=UMDvQYrJIhE (ALGN00015033) (showing a laptop displaying the model based on the received first scan data); [redacted]

[redacted]

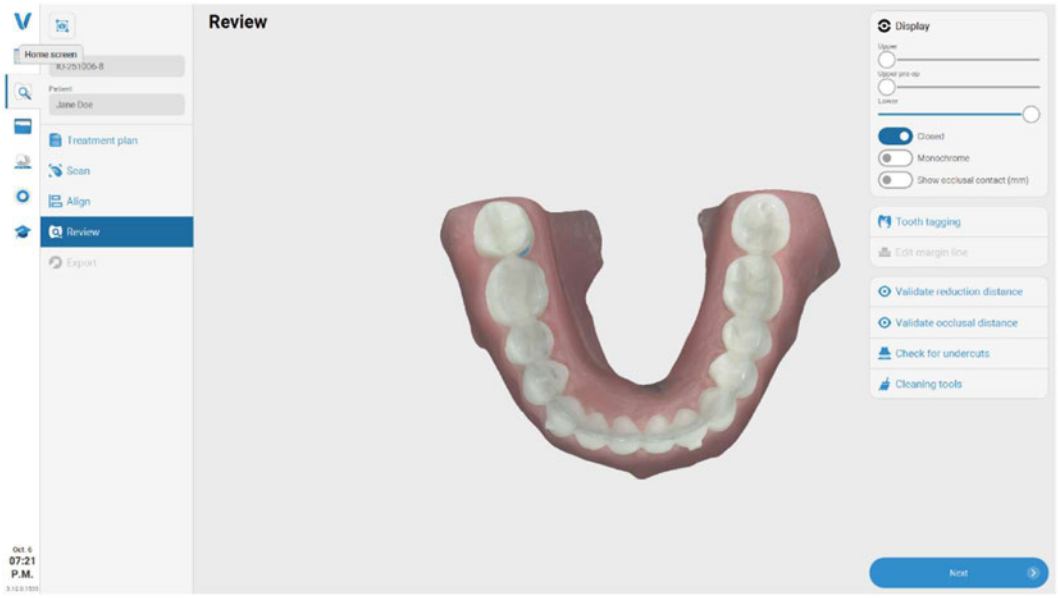


CC_EXEC_00000446



CC_EXEC_00000445

[redacted]



CC_EXEC_00000440

145. When I inspected the Virtuo Vivo scanner, I also performed a second test using the scanner and typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the Virtuo Vivo scanner system for a crown preparation or other dental procedure. The image below shows the first scan of the pre-operation teeth in the upper arch and the scan of the teeth in the lower arch. These images were displayed on the laptop screen attached to the Virtuo Vivo scanner.

[redacted]



CC_EXEC_00000560

146. As shown above, the Virtuo Vivo scanner system has a display, to a display, a model of the patient's teeth wherein the model of the patient's teeth is based on the received first scan of the patient's teeth. I also understand from Dr. Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim limitation. Accordingly, the Virtuo Vivo scanner system satisfies Claim 1[b][iii].

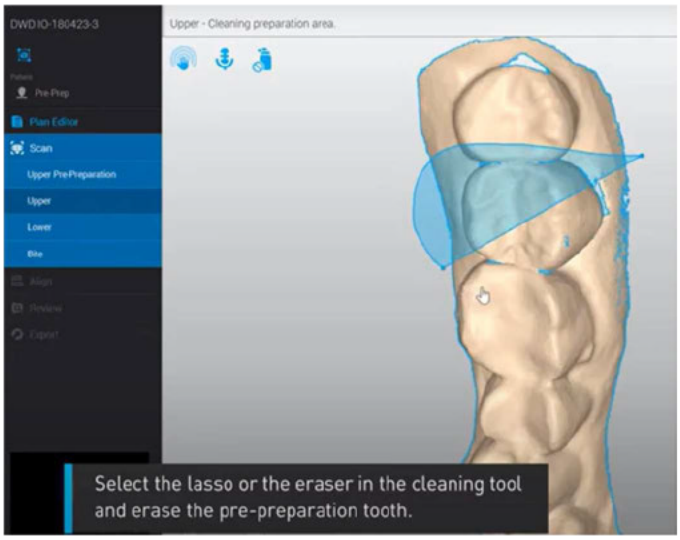
vi. 1[b][iv]: "receive user input defining a portion of the model to be removed"

147. The Virtuo Vivo scanner system satisfies Claim 1[v][iv]. The Virtuo Vivo software provides a user interface that allows the user to interact with the displayed digital model. Specifically, the software has tools which allow the user to select and remove scan data from the digital model. Through this interface, the user can select either the "Lasso" tool function or the "Eraser" tool function for targeted selection and deletion of scan data before rescanning.[197] The Lasso tool "allows [a user] to identify on the screen an area of the scan the

[197] [redacted].

[redacted]

user would like to remove," defining the portion of the scan to remove.[198] The Eraser tool also allows a user to remove a portion of the scan by dragging the eraser over the scan to remove the portion under the eraser.[199] The user may use the Lasso or Eraser tool to remove debris not desirable in the scan or rescan after a tooth has been modified.[200] For example, the user can select the Lasso tool and draw a closed shape around a portion of the patient's teeth. The shape divides the model into two portions. The portion of the model inside the closed shape will be removed. The portion of the model outside the closed shape will be kept.[201]



148. When I inspected the Virtuo Vivo scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the Virtuo Vivo scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper

[redacted]

[201] Dental Wings, *Pre Preparation Workflow*, at 1:41, https://www.youtube.com/watch?v=TsOMsxjWTUk, (ALGN00015010) (showing the process of selecting a portion of the virtual model); [redacted]

[redacted]

left first molar of the typodont to simulate debris on or between a patient's teeth. I then selected the Lasso tool and used the mouse of the laptop to draw a circle around the tooth with the simulated debris, selecting the portion of the model that I wanted to be removed. The image shown below is the first scan of the upper arch with the upper left first molar that has debris on it before I used the Lasso tool.



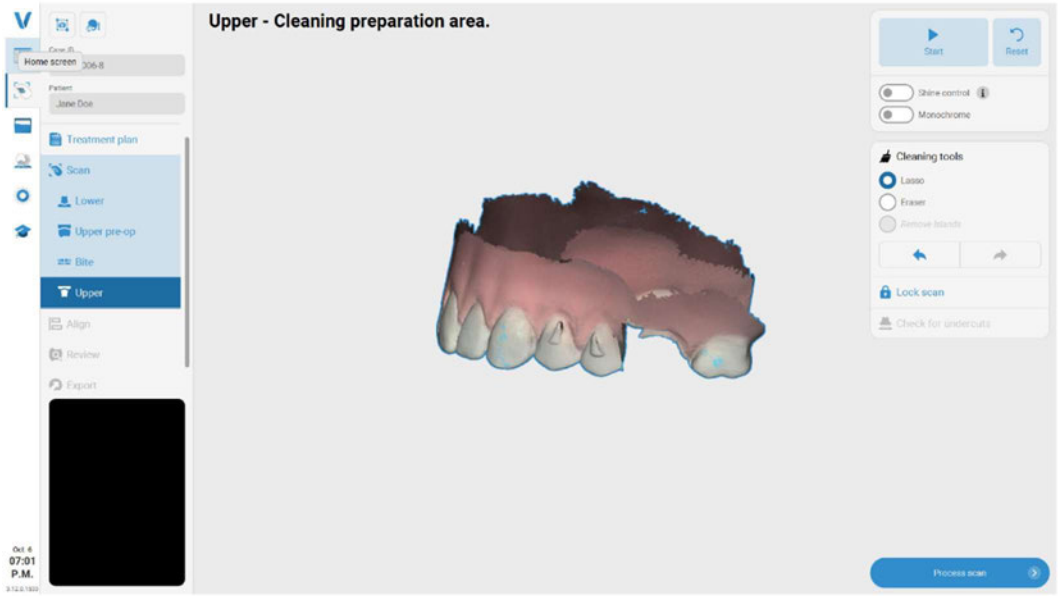
CC_EXEC_00000458

149. The three images below are different views of the first scan of the upper arch after I used the Lasso tool to define the upper left first molar tooth with debris. The portion of the model inside the closed shape was removed while the portion of the model outside the closed shape was kept.

[redacted]

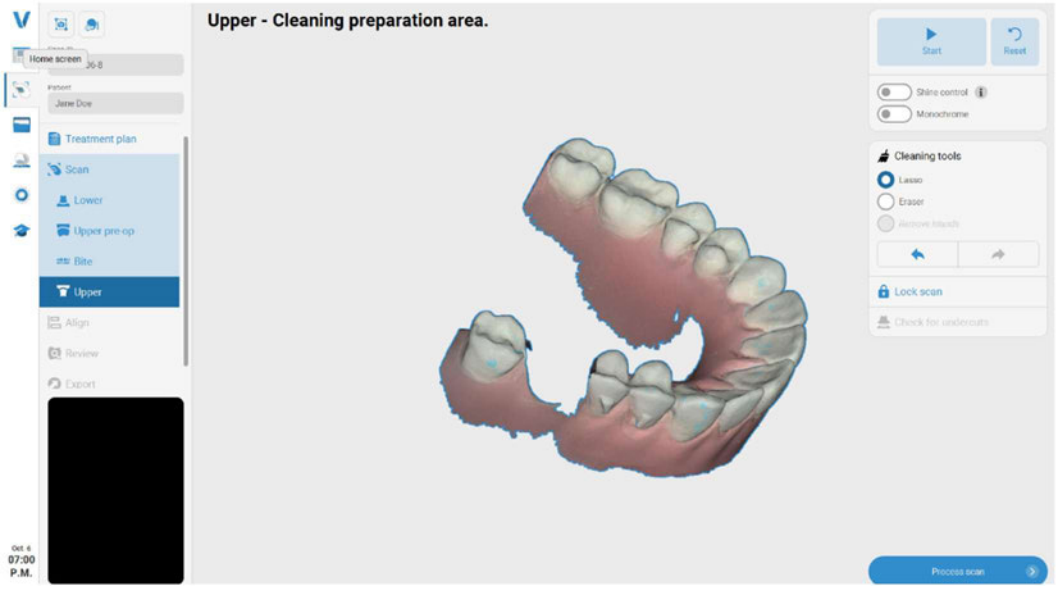


CC_EXEC_00000460



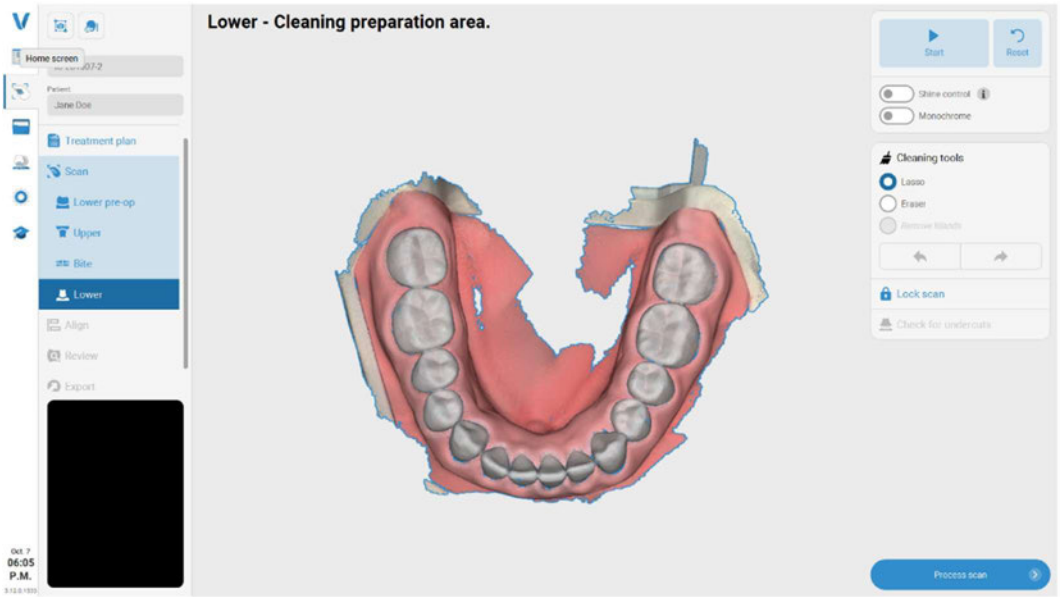
CC_EXEC_00000459

[redacted]



CC_EXEC_00000462

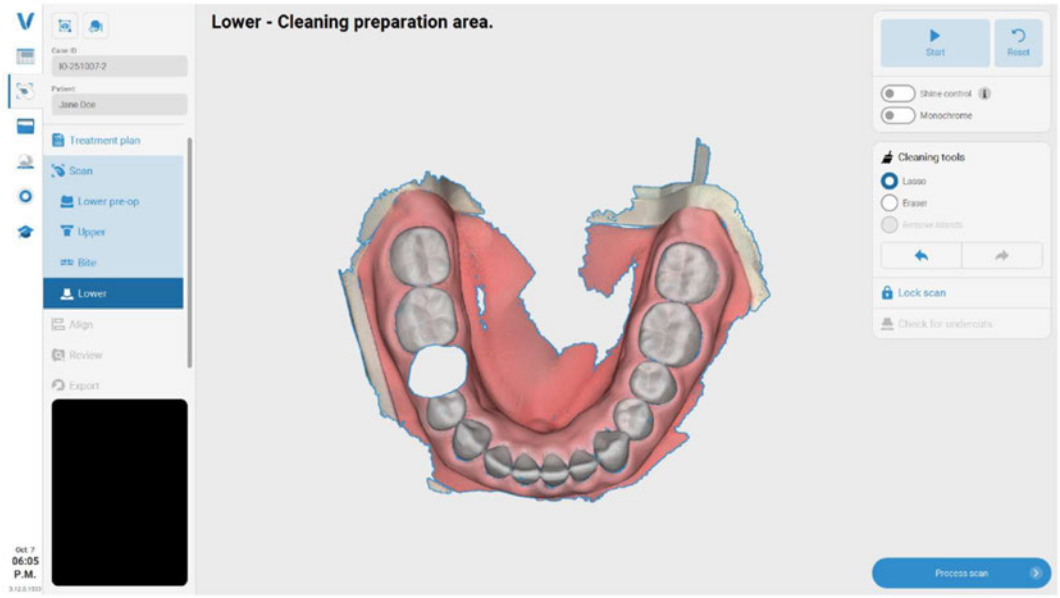
150. For the second test of the Virtuo Vivo scanner using this scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the Virtuo Vivo scanner system for a crown preparation or other dental procedure. In this test, I selected the lower right first premolar tooth for the crown preparation. The image shown below is the first scan in the lower arch before I used the Lasso tool to select the lower first premolar tooth.



[redacted]

CC_EXEC_00000537

151. The three images shown below are different views of the first scan of the lower dental arch after I selected and used the Lasso tool to indicate on the display screen the portion of the model (*i.e.*, the lower left first premolar) that I wanted to be removed.



CC_EXEC_00000544



CC_EXEC_00000553

[redacted]



CC_EXEC_00000552

152. As shown above, the Virtuo Vivo scanner system receives user input defining a portion of the model to be removed. I also understand from Dr. Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim limitation. Accordingly, the Virtuo Vivo scanner system satisfies Claim 1[b][iv].

vii. 1[b][v]: "remove, from the displayed model, a removed surface portion of the model to be removed according to the user input"

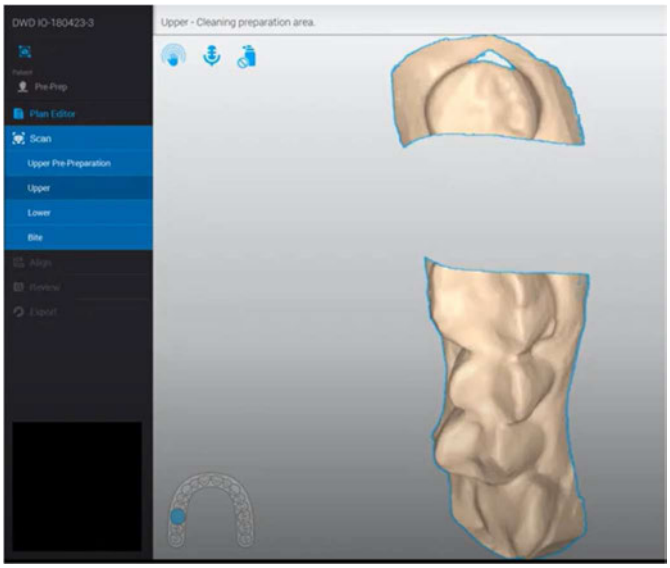
153. The Virtuo Vivo scanner system satisfies Claim 1[b][v]. After receiving the user input defining a portion of the model to be removed (*i.e.*, using either the Lasso or Eraser tool), the Virtuo Vivo scanner system removes this portion from the displayed digital model.[202] As a

202

[redacted]

[redacted]

result, the displayed model no longer includes the portion of the model that was selected by the user to be removed, as shown in the image below.[203]



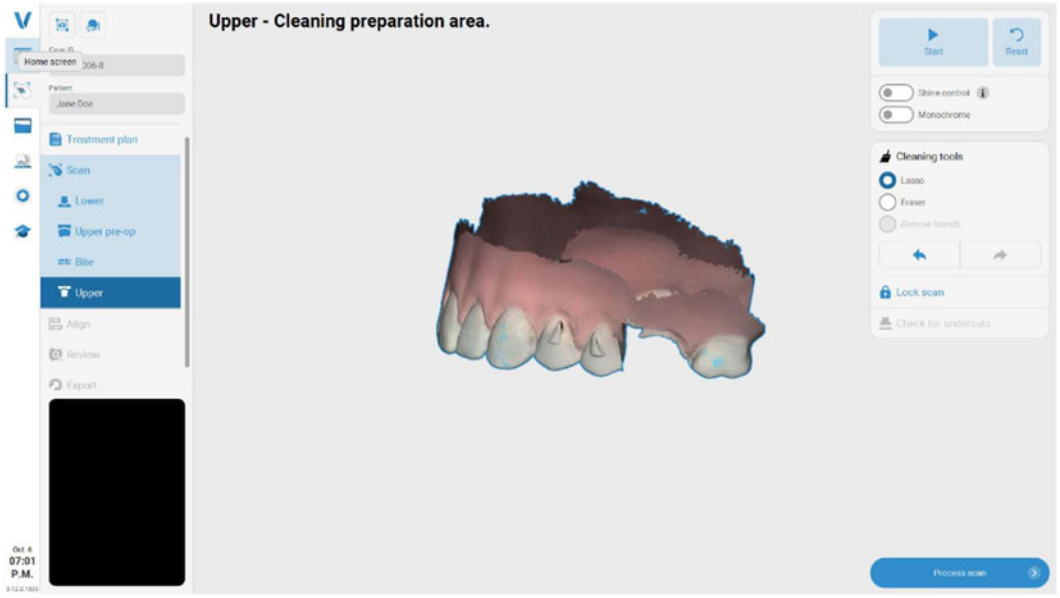
154. When I inspected the Virtuo Vivo scanner, I used it to perform two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the Virtuo Vivo scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris. In this test, using the mouse of the laptop, I selected the Lasso tool to define the portion of the model to be removed from the first scan, *i.e.*, the tooth with debris. The three images shown below are different views of the first scan after I used the Lasso tool to identify the portion of the model to be removed.

[203] Dental Wings, *Pre Preparation Workflow*, at 1:47, https://www.youtube.com/watch?v=TsOMsxjWTUk, (ALGN00015010) (showing the displayed model with a defined portion of the model removed); [redacted]

[redacted]

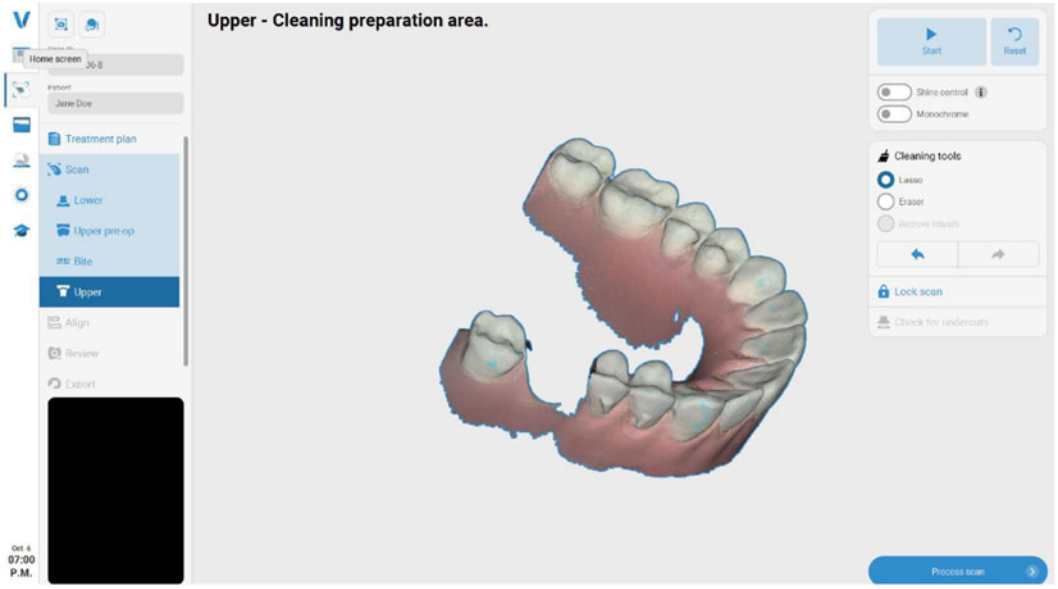


CC_EXEC_00000460



CC_EXEC_00000459

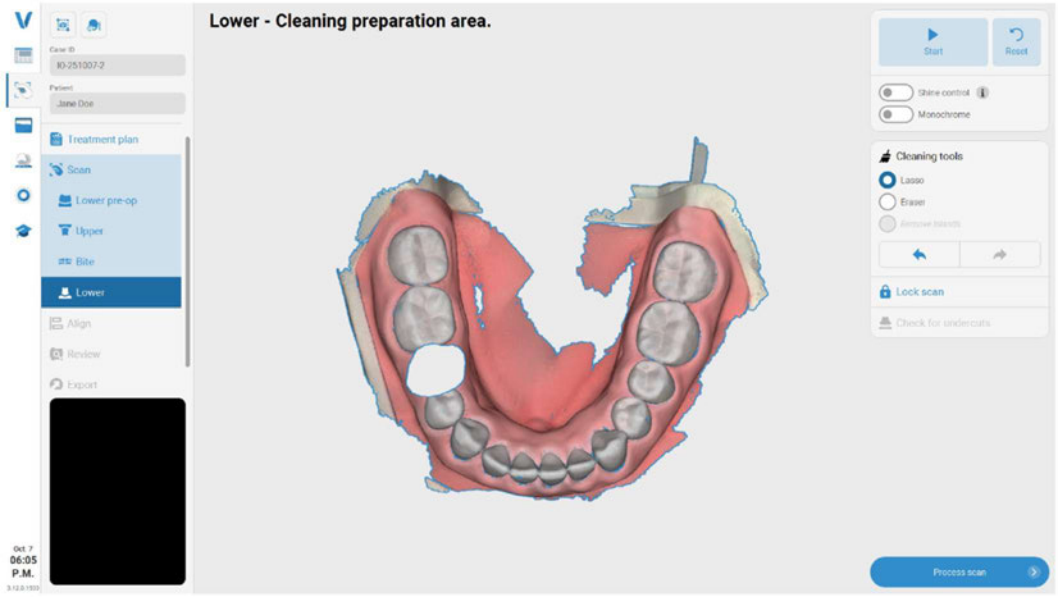
[redacted]



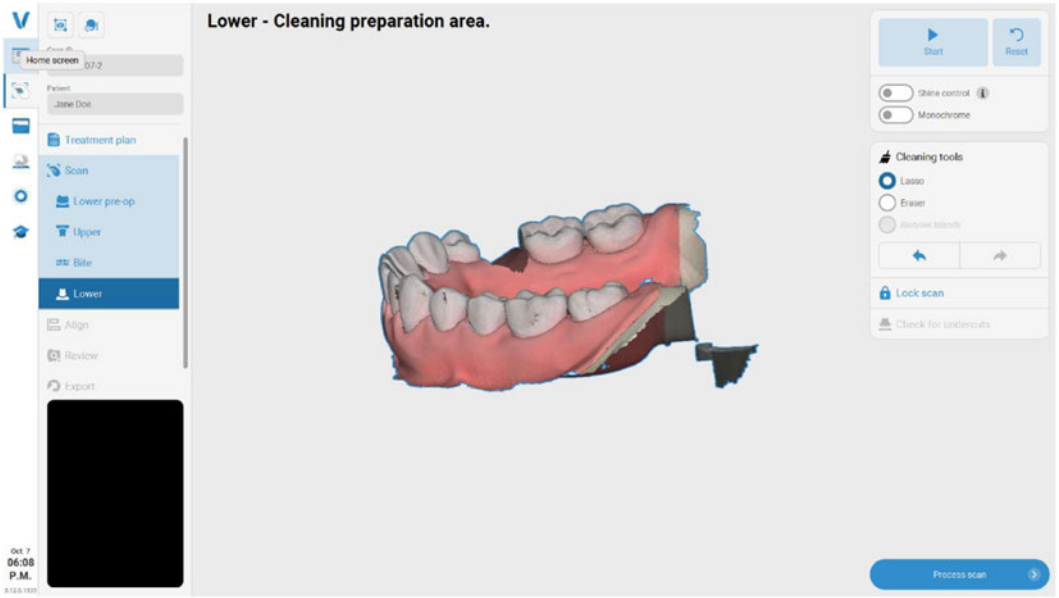
CC_EXEC_00000462

155. When I inspected the Virtuo Vivo scanner, I also used it and the typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the Virtuo Vivo scanner system for a crown preparation or other dental procedure. In this test, using the mouse of the laptop, I selected the Lasso tool and defined the portion of the model to be removed, which was the lower right second premolar. The three images shown below are different views of the first scan after I used the Lasso tool.

[redacted]



CC_EXEC_00000544



CC_EXEC_00000553

[redacted]



CC_EXEC_00000552

156. As shown above, the Virtuo Vivo scanner system removes, from the displayed model, a removed surface portion of the model to be removed according to the user input. I also understand from Dr. Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim limitation. Accordingly, the Virtuo Vivo scanner system satisfies Claim 1[b][v].

viii. 1[b][vi]: receive second scan data of the patient's teeth from the hand-held intraoral scanner, the scan data including surface data of a physically changed portion of the patient's intraoral cavity"

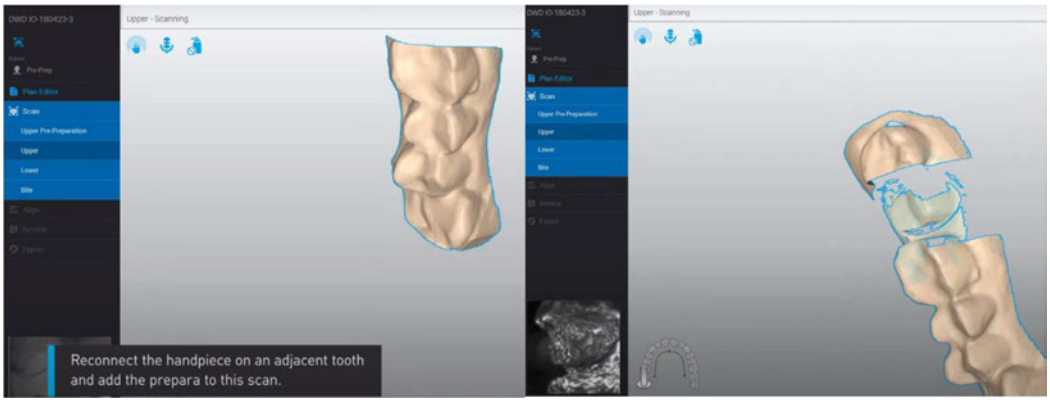
157. The Virtuo Vivo scanner system satisfies Claim 1[b][vi]. The Virtuo Vivo scanner system is capable of receiving additional scan data after the initial scan, including second scan data captured by the same hand-held intraoral scanner.[204] This second scan data may include

204 [redacted]

[redacted]

surface data of a portion of the patient's intraoral cavity that has physically changed since the first scan.

158. For example, in the Virtuo Vivo instructional video referenced throughout my report, a patient's tooth undergoes a dental procedure that results in the tooth being physically changed after the first scan and before the second scan.[205] The second 3D intraoral scan data, taken after the physical change has occurred to the patient's tooth, includes the surface data of the physically changed portion.[206] Screenshots from the video, below, show the user obtaining second scan data of a physically changed tooth.[207]



159. When I inspected the Virtuo Vivo scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the Virtuo Vivo scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste on the upper left first molar to simulate debris. In this test, I selected this tooth with debris to be removed from the first scan using the Lasso tool. Then I physically removed the toothpaste from the

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[205] Dental Wings, *Pre Preparation Workflow*, at 1:54-1:59, https://www.youtube.com/watch?v=TsOMsxjWTUk, (ALGN00015010) (showing the steps of receiving second scan data, including surface data of a physically changed part of the patient's mouth); [redacted]

[207] Dental Wings, *Pre Preparation Workflow*, at 1:54-1:59, https://www.youtube.com/watch?v=TsOMsxjWTUk, (ALGN00015010).

[redacted]

typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. The three images shown below are different views of the second scan of the teeth in the upper arch which included the tooth that once had toothpaste (debris) but then was removed. The image was received by the computer connected to the Virtuo Vivo scanner (which I held in my hand) of the second scan of the tooth, which is the physically changed portion of the patient's intraoral cavity.



CC_EXEC_00000464



[redacted]

CC_EXEC_00000463

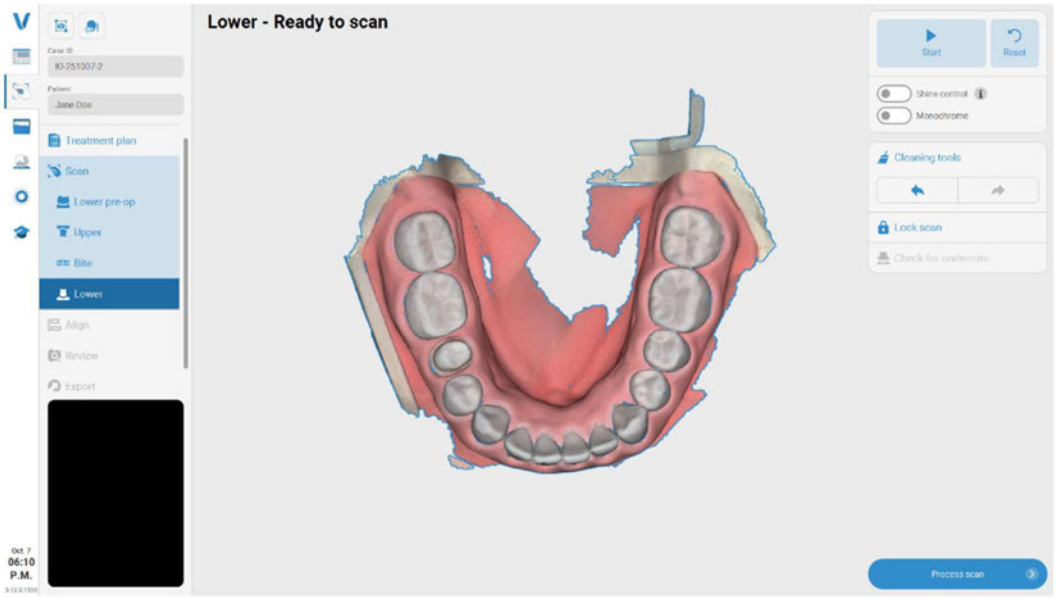


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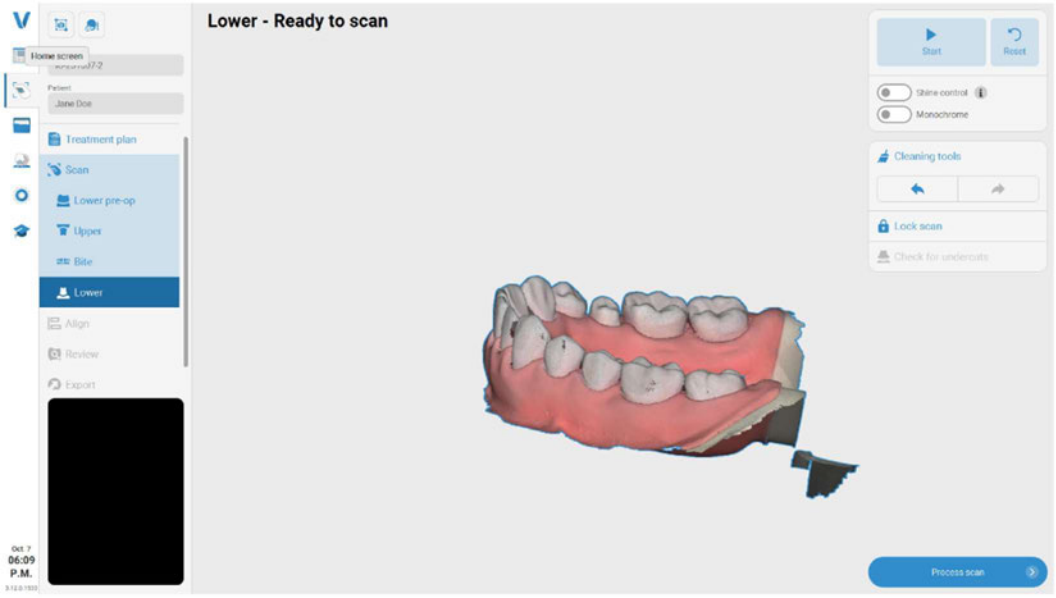
160. When I inspected the Virtuo Vivo scanner, I performed a second test using the scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the Virtuo Vivo scanner system for a crown preparation or other dental procedure where a tooth modification occurs. In this test, I selected on the display screen the tooth (*i.e.*, the lower right second premolar) that was going to be removed and replaced with a modified version of the tooth, one that had undergone a crown preparation procedure. On the typodont, I physically removed the pre-operation tooth with a post-operation crown prepped tooth. Next, I rescanned the post-operation crown prepped tooth. The three images shown below are different views of the second scan of the teeth in the lower arch which included the crown prepped lower right second premolar tooth. The images were received by the computer connected to the Virtuo Vivo scanner (which I held in my hand) of the second scan of the prepped tooth, which is the

[redacted]

physically changed portion of the patient's intraoral cavity.



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[redacted]



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161. As shown above, the Virtuo Vivo scanner system receives second scan data of the patient's teeth from the hand-held intraoral scanner, the scan data including surface data of a physically changed portion of the patient's intraoral cavity. I also understand from Dr. Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim limitation. Accordingly, the Virtuo Vivo scanner system satisfies Claim 1[b][vi].

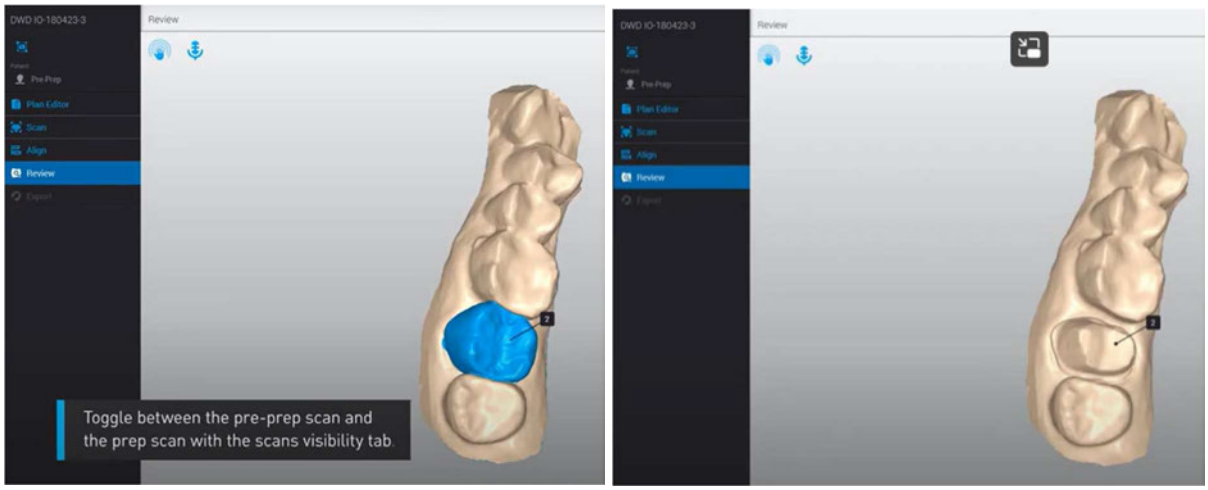
ix. 1[b][vii]: "replace at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity"

162. The Virtuo Vivo scanner system satisfies Claim 1[b][vii]. The Virtuo Vivo scanner system uses the received second scan data to replace at least a portion of the surface data that was previously removed from the model. The system integrates updated surface information

[redacted]

corresponding to the physically changed portion of the patient's intraoral cavity into the existing model framework.[208]

163. For example, the Virtuo Vivo instructional video referenced throughout my report shows a modified 3D model that combines the first and second scan data.[209] On the left, the area before removal of the identified surface portion is shown in blue.[210] On the right, the 3D model after the system replaces the identified and removed surface portion with the second scan data.[211]



164. When I inspected the Virtuo Vivo scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the Virtuo Vivo scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris. After scanning the upper dental arch with the toothpaste on the tooth, I used the mouse of the laptop to select this tooth to be removed from the

[redacted]

[209] Dental Wings, *Pre Preparation Workflow*, at 4:12 (left) and 4:21 (right), https://www.youtube.com/watch?v=TsOMsxjWTUk. (ALGN00015010) (showing replacing at the removed scan data of a physically changed portion with the second scan data).
[210] *Id.*
[211] *Id.*

[redacted]

first scan using the Lasso tool. Then I physically removed the toothpaste from the tooth and rescanned the tooth. Below are three different views of the same image after the first scan of the tooth with debris was replaced with the received second scan data of the tooth without the debris.



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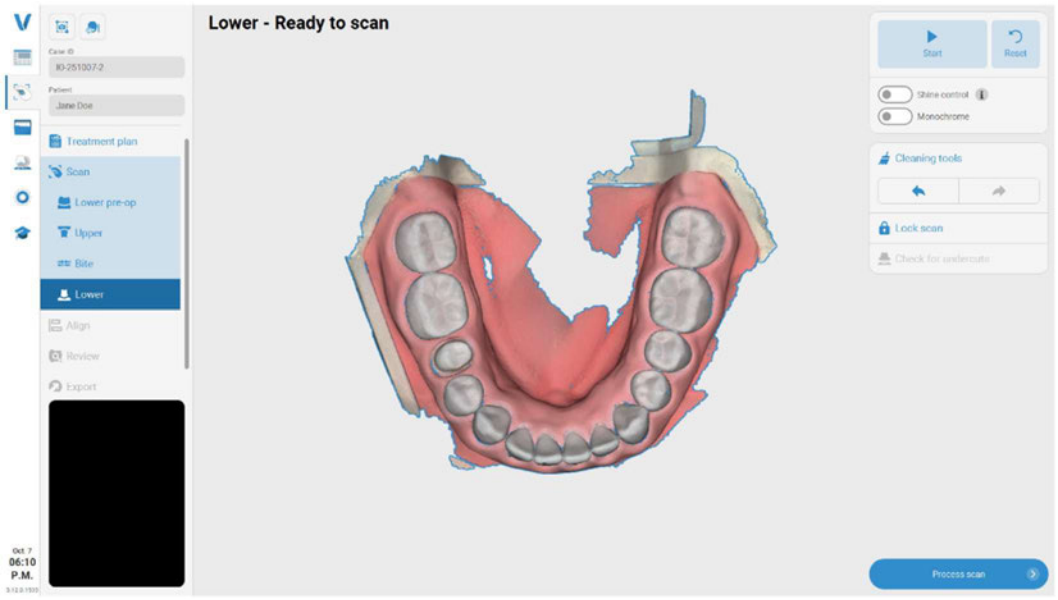
[redacted]



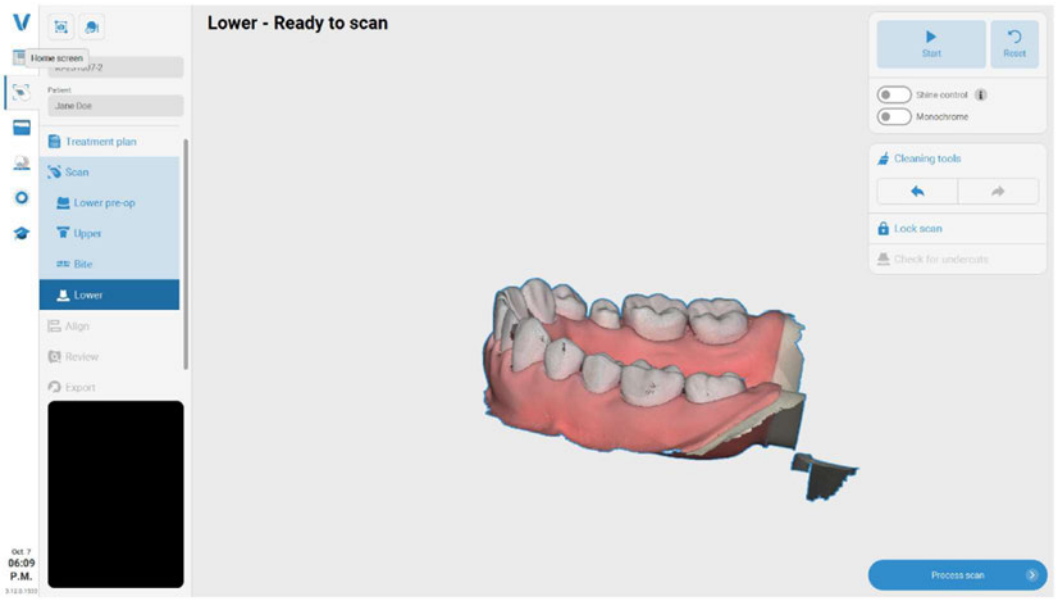
CC_EXEC_00000465

165. I also performed a second test using the Virtuo Vivo scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the upper dental arch with the pre-operation tooth, I used the mouse of the laptop to select this tooth so that it would be removed from this first scan using the Lasso tool. I then replaced the typodont pre-operation tooth with a typodont post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are three different views of the same image after the first scan of the pre-operation tooth was replaced with the received second scan data of the post-operation crown preparation tooth.

[redacted]



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[redacted]



CC_EXEC_00000569

166. As shown above, the Virtuo Vivo scanner system replaces at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity. I also understand from Dr. Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim limitation. Accordingly, the Virtuo Vivo scanner system satisfies Claim 1[b][vii].

x. 1[b][viii]: "output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the second scan data."

167. The Virtuo Vivo scanner system satisfies Claim 1[b][viii]. Following replacement of the removed surface portion using the second scan data, the Virtuo Vivo scanner system outputs the updated digital model to the display, as shown above. The displayed 3D model reflects the incorporation of the new scan data into the previously removed region.

168. When I inspected the Virtuo Vivo scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the

[redacted]

upper left first molar of the typodont. I performed this test to simulate debris on or between the patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan using the Lasso tool. Then I removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. The first image below is an image of the output to the display of the model of the patient's upper arch after the removed surface portion was replaced by the second scan. The second image below is an image of the model of the patient's upper arch before the removed surface portion was replaced by the second scan.



CC_EXEC_00000442

[redacted]



CC_EXEC_00000446

169. I also performed a second test using the Virtuo Vivo scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the lower dental arch with the pre-operation tooth, I selected this tooth so that it would be removed from this first scan using the Lasso tool. I then replaced the typodont pre-operation tooth with a typodont post-

[redacted]

operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth.



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CC_EXEC_00000559

170. As shown above, the Virtuo Vivo scanner system outputs, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the second scan data. Accordingly, the Virtuo Vivo scanner system satisfies Claim 1[b][viii].

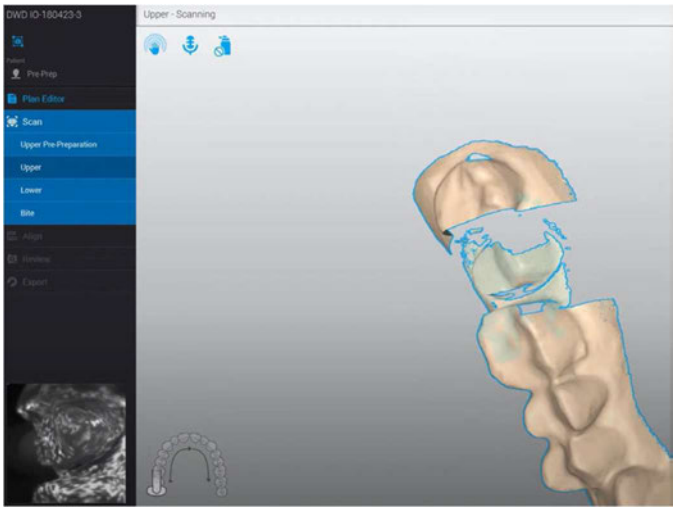
[redacted]

b. Claim 4

i. "The system of claim 1, wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to register the received second scan data with the model."

171. The Virtuo Vivo scanner system satisfies Claim 4. As described in connection with Claim 1[b][vii], the Virtuo Vivo software replaces removed surface portions of a digital dental model using subsequently acquired scan data.[212] In performing this replacement, the system aligns and spatially registers the second scan data with the existing model so that the new surface data corresponds correctly to the remaining portions of the model.[213]

172. For example, the Virtuo Vivo instructional video referenced throughout my report shows Virtuo Vivo software aligning the second scan data with the existing model.[214]



173. When I inspected the Virtuo Vivo scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the

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[212] [redacted]

[214] Dental Wings, *Pre Preparation Workflow*, at 1:54-1:59, https://www.youtube.com/watch?v=TsOMsxjWTUk (ALGN00015010) (showing the process of aligning the second scan data with the existing model).

[redacted]

upper left first molar of the typodont. I performed this test to simulate debris on or between a patient's teeth. In this test, I first scanned the upper arch which included the left first molar with toothpaste on it. Then I selected the tooth with debris to be removed from the first scan using the Lasso tool. After I selected the tooth with the debris for removal, I removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. Below are three different views of the same image showing that the Virtuo Vivo scanner system replaced the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model.

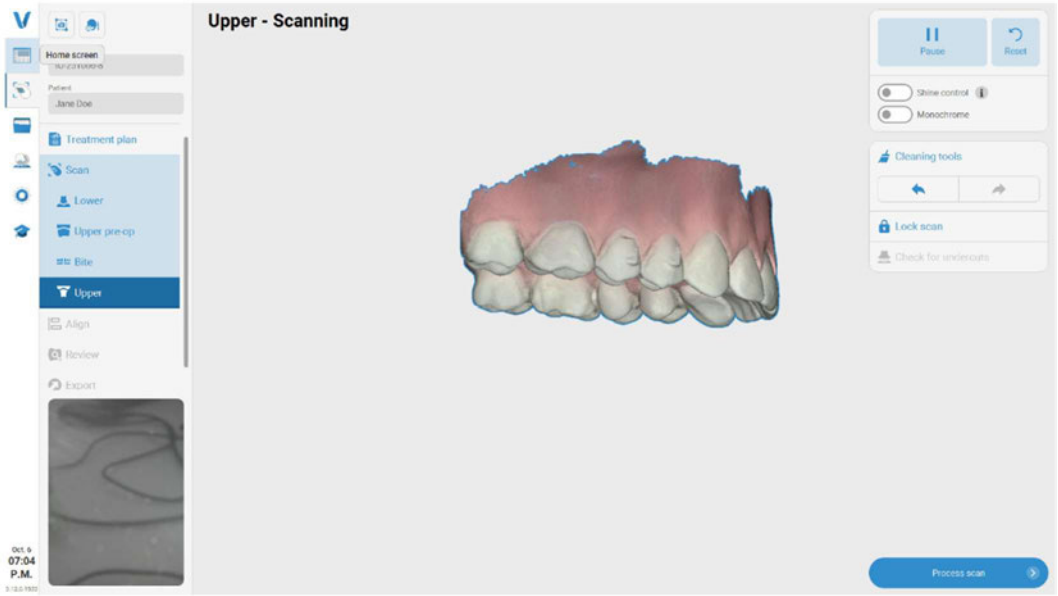


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[redacted]



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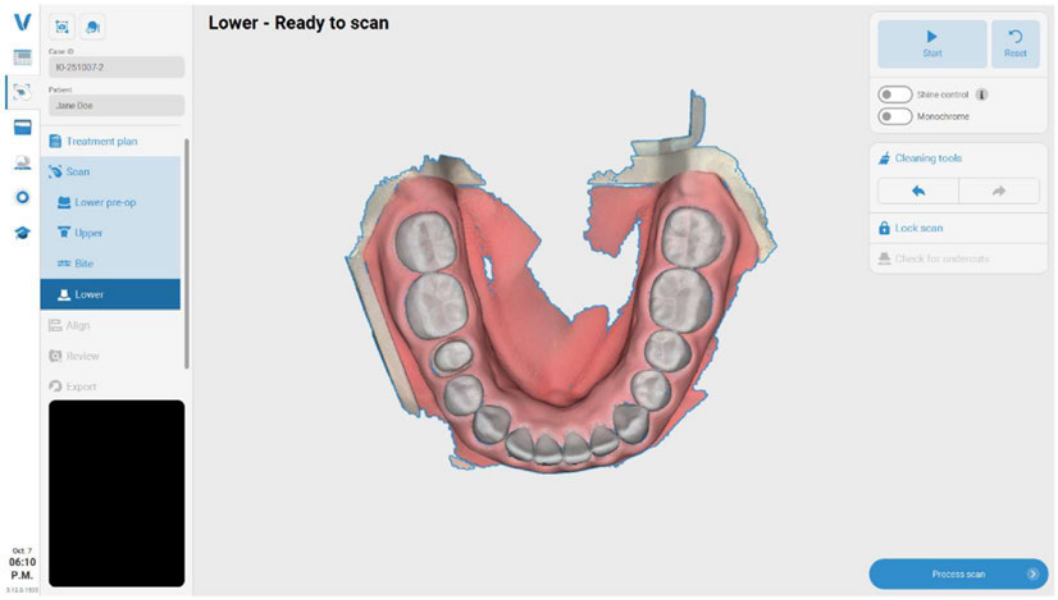
CC_EXEC_00000465

174. I also performed a second test using the Virtuo Vivo scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the lower dental arch

[redacted]

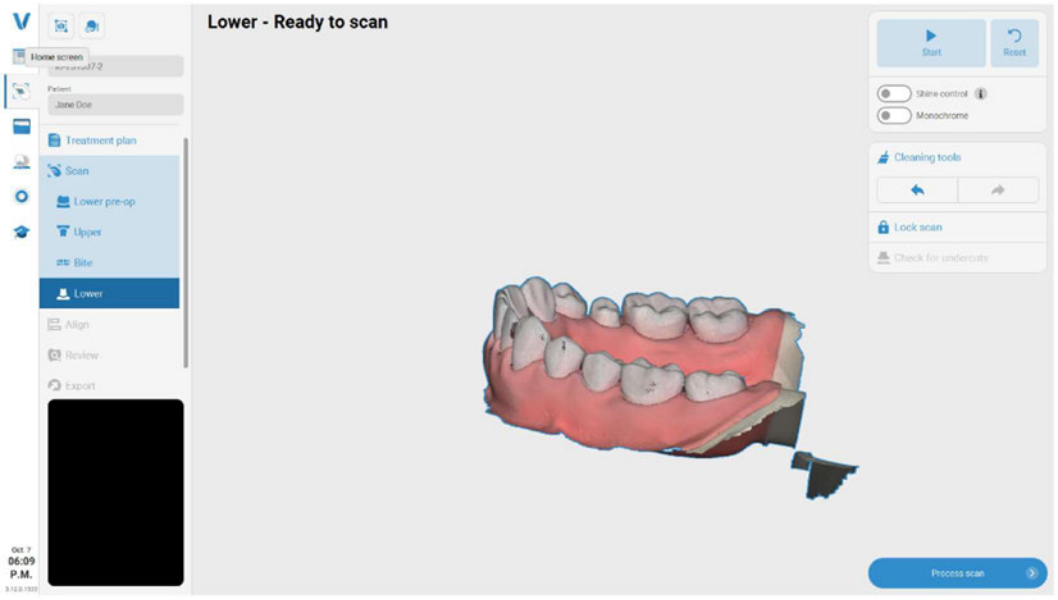
with the pre-operation tooth, I selected this tooth so that it would be removed from this first scan using the Lasso tool. Then I replaced the typodont pre-operation tooth with the post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are images showing that the Virtuo Vivo scanner system replaced the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model.

175.



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[redacted]



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176. As shown above, the Virtuo Vivo scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model. I also understand from Dr. Singh that the Virtuo

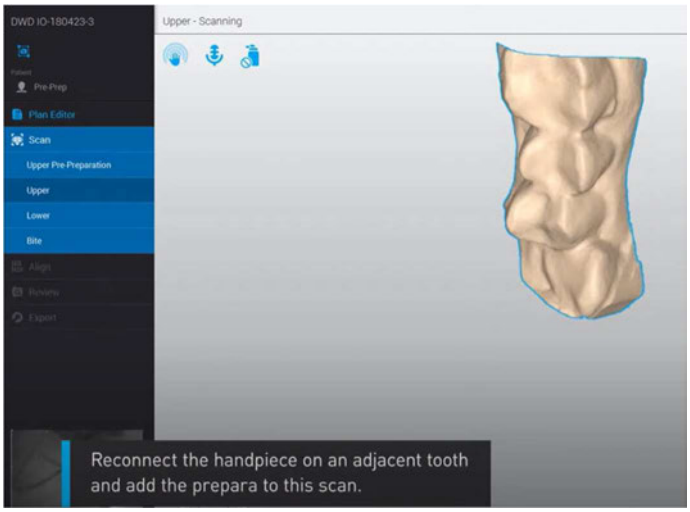
[redacted]

Vivo source code confirms that the Virtuo Vivo software performs this claim. Accordingly, the Virtuo Vivo scanner system satisfies Claim 4.

c. Claim 5

i. "The system of claim 4, wherein the received second scan data is registered with the model by aligning identifying data of the received second scan data with corresponding parts of the model."

177. The Virtuo Vivo scanner system satisfies Claim 5. The Virtuo Vivo software aligns the data between the first and second scans to replace portions of the model.[215] The Virtuo Vivo software registers the second scan of the physically modified tooth against the existing model by aligning the second scan of the "adjacent tooth" against the first scan of that same tooth.[216]



178. When I inspected the Virtuo Vivo scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the

[215] Dental Wings, *Pre Preparation Workflow*, at 1:55, https://www.youtube.com/watch?v=TsOMsxjWTUk (ALGN00015010) (showing the process of registering the received second scan data with the model by aligning the second scan data with the corresponding parts of the model based on the first scan data), [redacted]

[redacted]

upper left first molar of the typodont. I performed this test to simulate debris on or between a patient's teeth. In this test, I first scanned the upper arch which included the left first molar with toothpaste on it. Then I selected the tooth with debris to be removed from the first scan using the Lasso tool. After I selected the tooth with debris to be removed, I removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. Below are three different views of the same image showing that the Virtuo Vivo scanner system registered the second scan data by identifiable features in the second scan data with corresponding parts of the existing digital model.



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[redacted]



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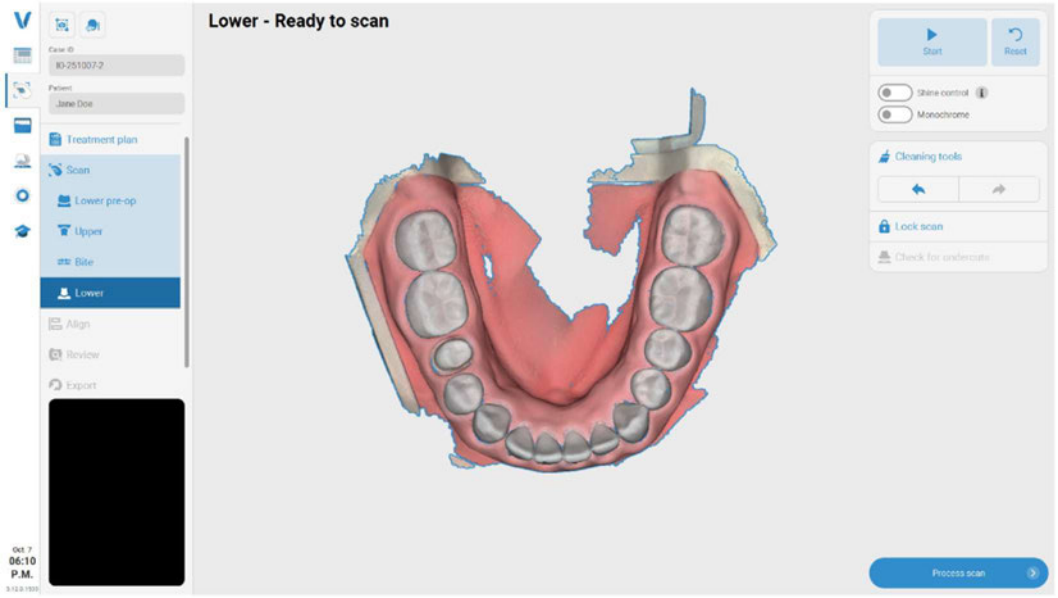


CC_EXEC_00000465

179. I also performed a second test using the Virtuo Vivo scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the lower dental arch

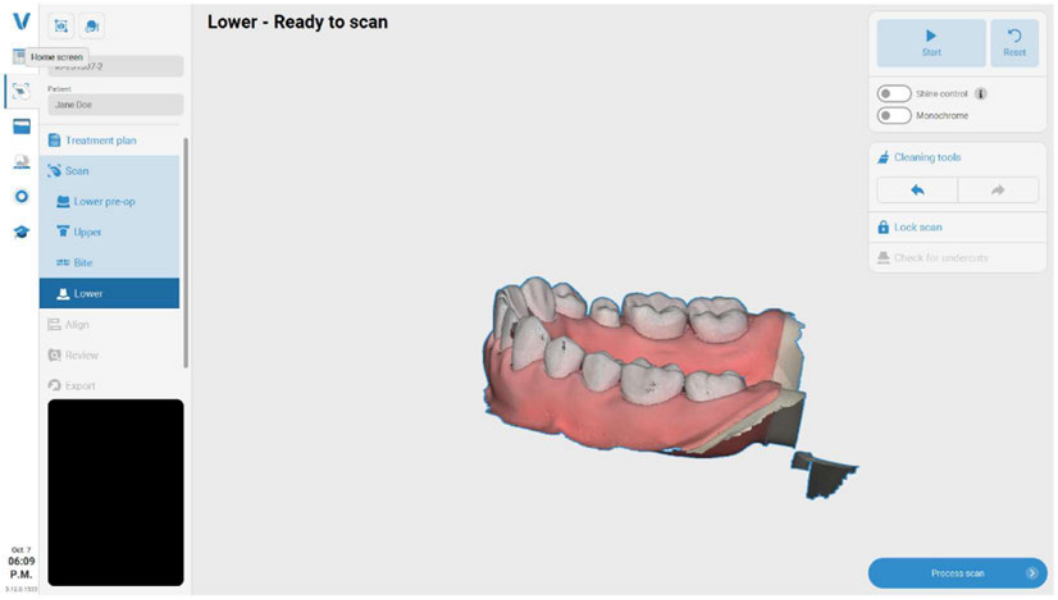
[redacted]

with the pre-operation tooth, I selected this tooth so that it would be removed from this first scan using the Lasso tool. Then I replaced the typodont pre-operation tooth with the post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are images showing that the Virtuo Vivo scanner system registered the second scan data by identifiable features in the second scan data with corresponding parts of the existing digital model.



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[redacted]



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180. As shown above, the Virtuo Vivo scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model. I also understand from Dr. Singh that the Virtuo

[redacted]

Vivo source code confirms that the Virtuo Vivo software performs this claim. Accordingly, the Virtuo Vivo scanner system satisfies Claim 5.

d. Claim 6

i. "The system of Claim 5, wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further stitch a portion of the received second scan data with the model."

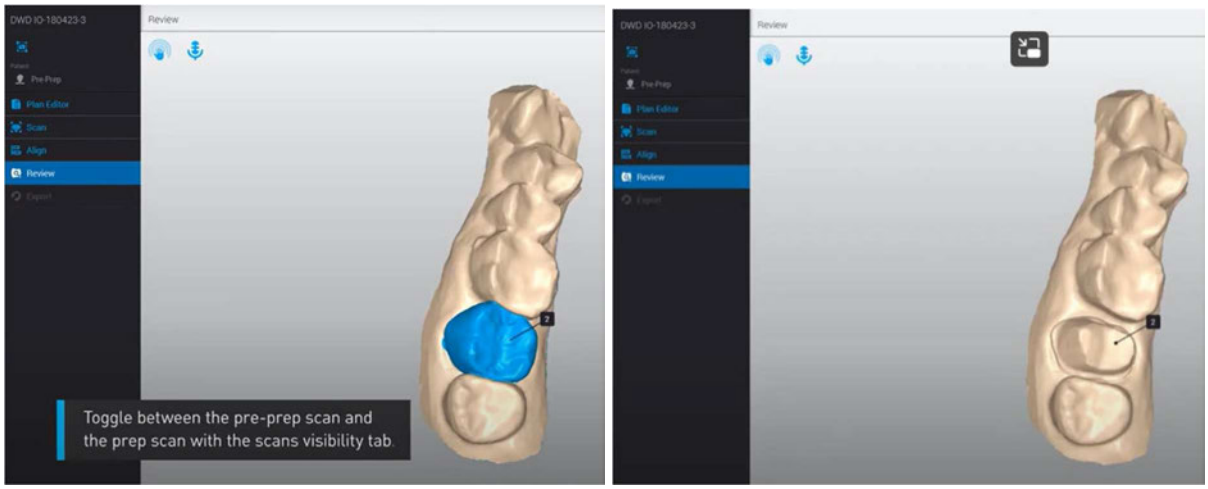
181. The Virtuo Vivo scanner system satisfies Claim 6. In addition to registering the second scan data with the existing model, I understand from Dr. Singh that the Virtuo Vivo software further stitches the new scan data into the model. I understand from Dr. Singh that stitching refers to the process of merging or blending overlapping surface data from the second scan with the existing model so as to create a continuous and coherent surface representation.

182. The Virtuo Vivo scanner system performs this stitching to ensure a seamless transition between the previously retained portions of the model and the newly added surface data. This stitching step is part of the replacement process and is necessary to produce a usable, unified digital model. As a result, the Virtuo Vivo scanner system includes instructions to stitch a portion of the received second scan data with the model, thereby satisfying Claim 6.

183. For example, the Virtuo Vivo scanner instructional video referenced throughout my report shows Virtuo Vivo software stitching a portion of the received second scan data with the model. On the left, the area before removal of the identified surface portion is shown in blue.[217] On the right, the 3D model after the system replaces the identified and removed surface portion with the second scan data.[218]

[217] *Id.*
[218] *Id.*

[redacted]



184. When I inspected the Virtuo Vivo scanner, I used it to perform a first test with toothpaste added to the upper left first molar of the typodont simulate debris on or between a patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan using the cut tool. Then I removed the toothpaste from the tooth. Next, I rescanned the tooth that I removed the toothpaste from. Below are images showing that the Virtuo Vivo scanner system stitched a portion of the received second scan data with the existing model.



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[redacted]



CC_EXEC_00000463

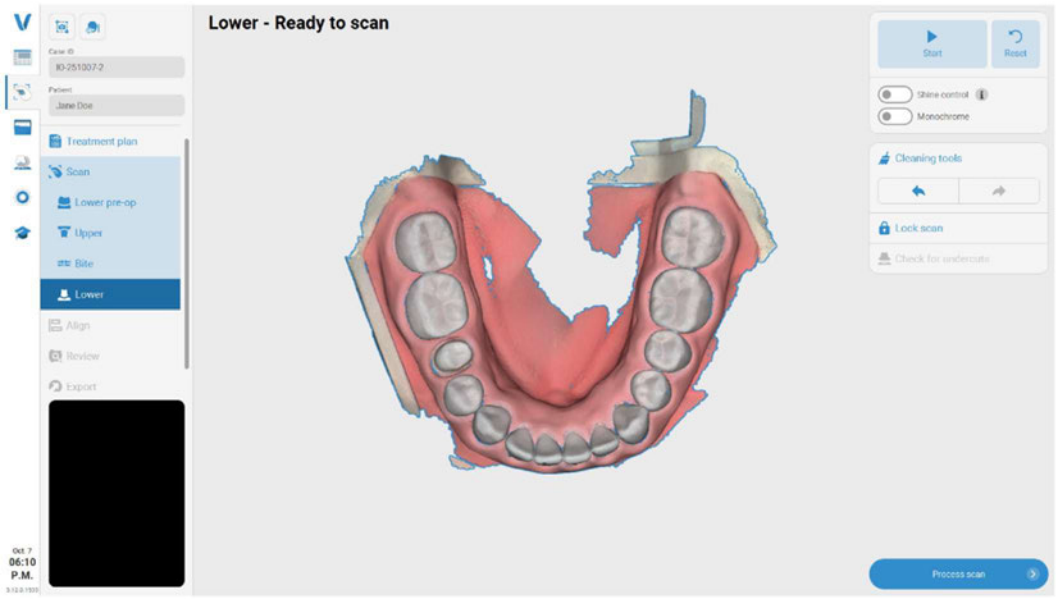


CC_EXEC_00000465

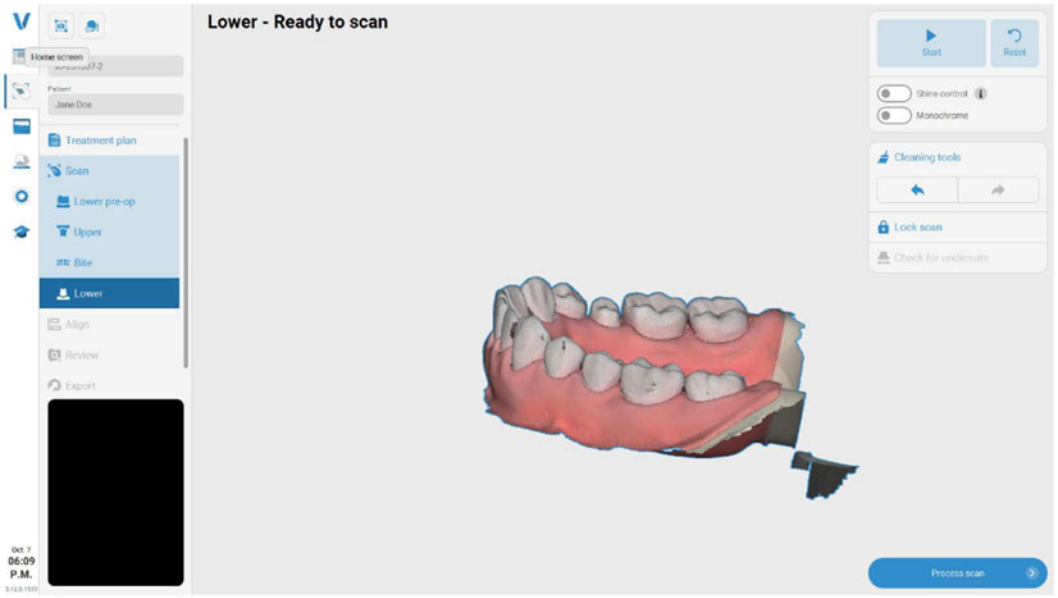
185. When I inspected the Virtuo Vivo scanner, I also used it to perform a second test with a crown preparation tooth to simulate the workflow for a crown preparation or other dental procedure. In this test, I selected the lower right second premolar as the tooth that was going to be replaced with a crown preparation tooth. Then I replaced the tooth with the post-operation

[redacted]

crown preparation tooth. Next, I rescanned the post-operation crown preparation tooth. Below are images showing that the Virtuo Vivo scanner system stitched a portion of the received second scan data with the existing model.



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[redacted]



CC_EXEC_00000569

186. As shown above, the Virtuo Vivo scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further stitch a portion of the received second scan data with the model. I also understand from Dr. Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim. Accordingly, the Virtuo Vivo scanner system satisfies Claim 6.

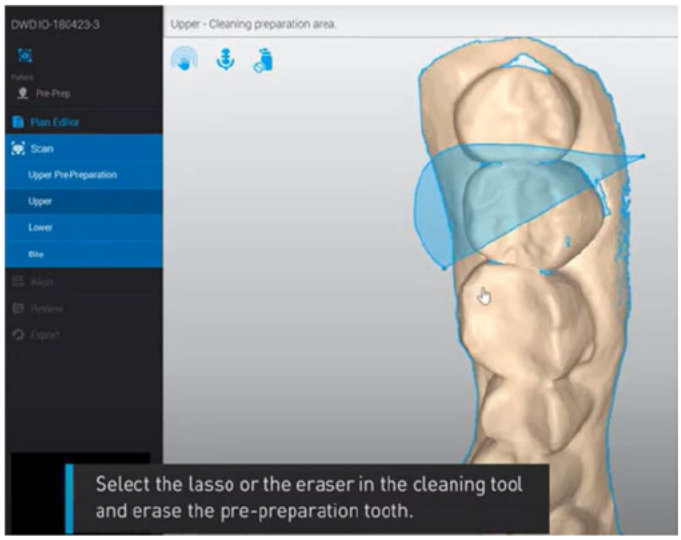
e. Claim 8

i. "The system of claim 1, wherein the computer readable medium further includes instructions that when executed by the computer system, cause the computer system to: mark, on the displayed model, the user input defined portion, after receiving the user input and before removing the removed surface portion of the model."

187. The Virtuo Vivo scanner system satisfies Claim 8. As discussed above in Claim 1[b][iv], the Virtuo Vivo software allows a user to define a portion of the displayed model for removal. As shown in the images above and reproduced below, the user draws a shape

[redacted]

around the portion of the displayed model for removal.[219] After receiving this user input and before actually removing the surface portion, the system visually marks or highlights the selected region on the displayed model.[220]



188. When I inspected the Virtuo Vivo scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris on or between a patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan using the Lasso tool. Below is an image of the start screen for the Lasso tool.

[219] Dental Wings, *Pre Preparation Workflow*, at 1:41, https://www.youtube.com/watch?v=TsOMsxjWTUk, (ALGN00015010) (showing the process of selecting a portion of the virtual model); [redacted]

[220] Dental Wings, *Pre Preparation Workflow*, at 1:41, https://www.youtube.com/watch?v=TsOMsxjWTUk, (ALGN00015010).

[redacted]



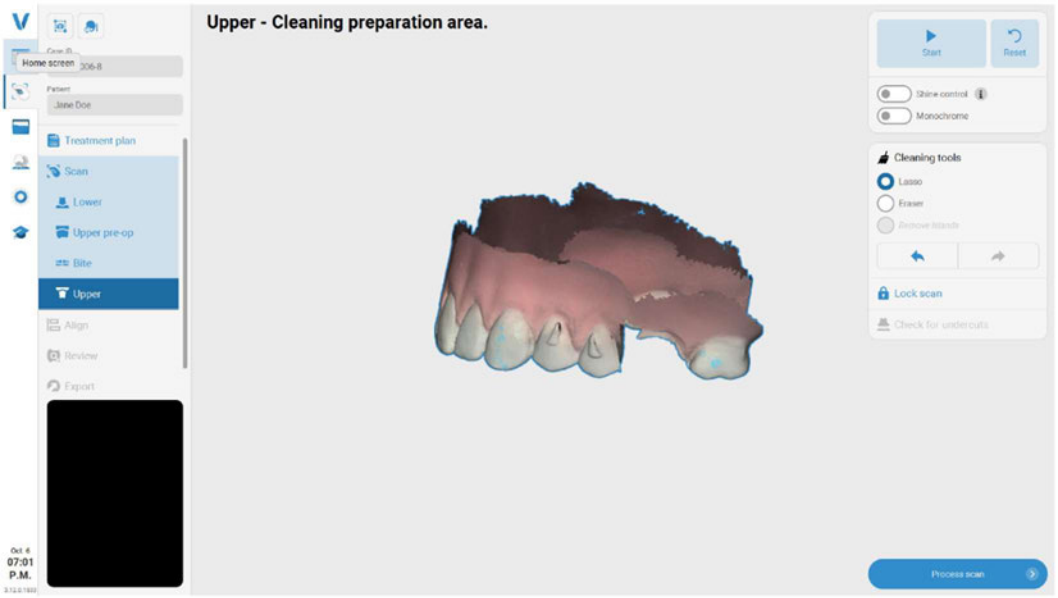
CC_EXEC_00000458

189. Below are images of the software after I used the Lasso tool to mark the tooth with debris.

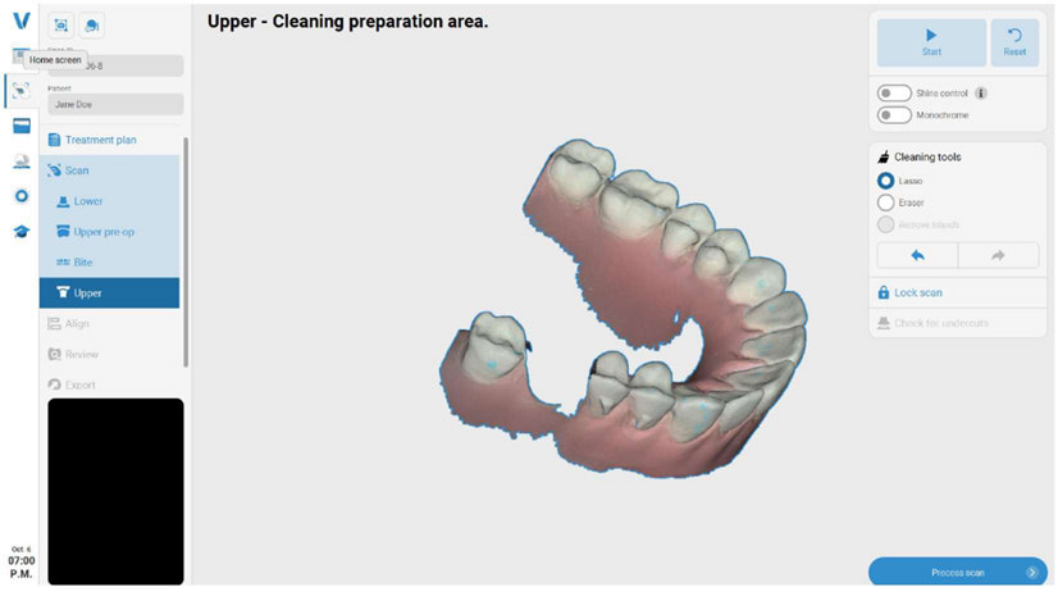


CC_EXEC_00000460

[redacted]



CC_EXEC_00000459

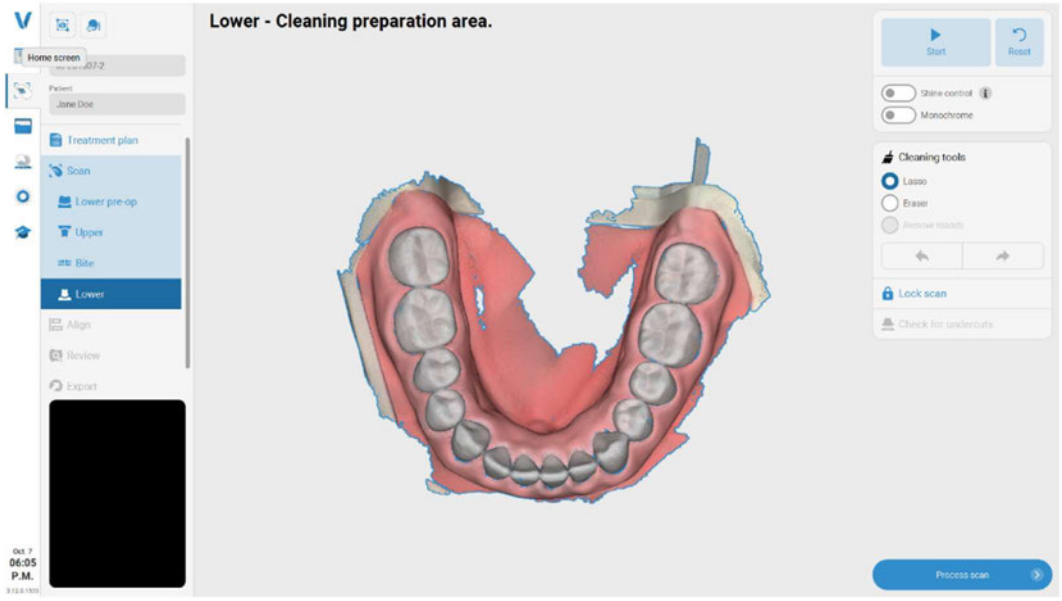


CC_EXEC_00000462

190. I also performed a second test using the Virtuo Vivo scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the lower dental arch

[redacted]

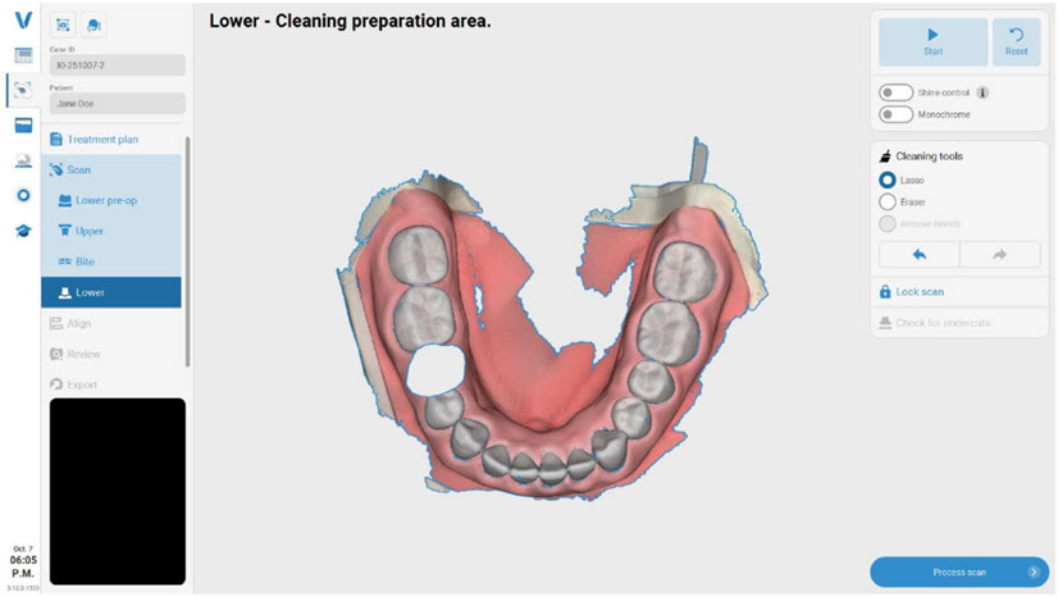
with the pre-operation tooth, I selected this tooth so that it would be removed from this first scan using the Lasso tool. Then I replaced the typodont pre-operation tooth with the post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below is an image of the start screen for the Lasso tool.



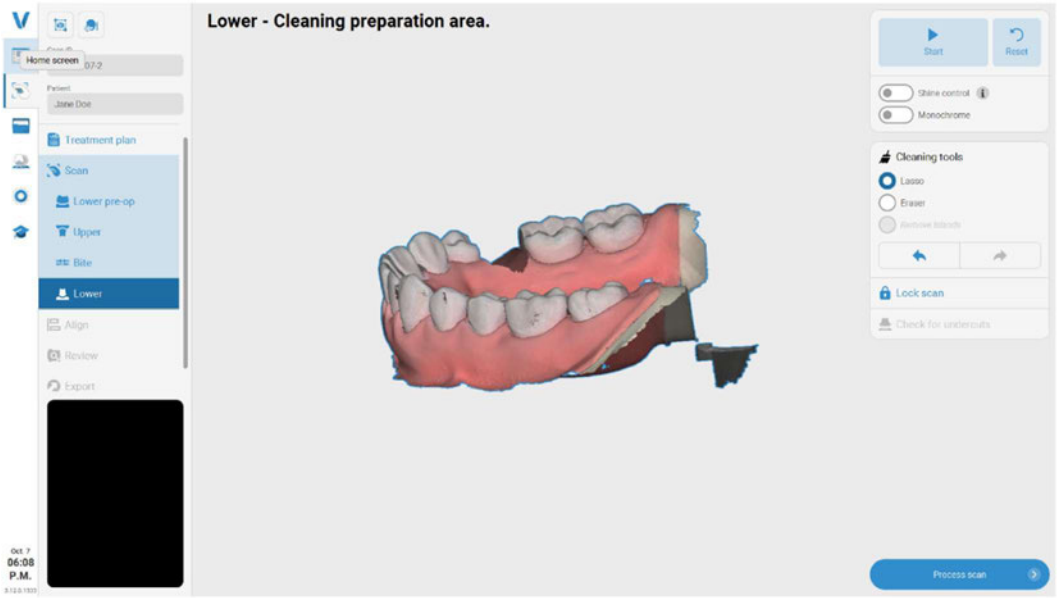
CC_EXEC_00000537

191. Below are images of the software after I added the mark to cut the tooth that was going to be replaced with the crown preparation tooth

[redacted]



CC_EXEC_00000544



CC_EXEC_00000553

[redacted]



CC_EXEC_00000552

192. As shown above, the Virtuo Vivo scanner system marks, on the displayed model, the user input defined portion, after receiving the user input and before removing the removed surface portion of the model. I also understand from Dr. Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim. Accordingly, the Virtuo Vivo scanner system satisfies Claim 8.

2. Infringement of Claims 9-12

a. Claim 9

i. Preamble: "A method for scanning a patient's teeth for a dental procedure, the method comprising:"

193. Users of the Virtuo Vivo can perform a method for scanning a patient's teeth for a dental procedure" as set forth in claim 9, for the same reasons as set forth above in my discussion of Claim 1[pre], incorporated here by reference.

[redacted]

ii. 9[a]: "receiving first scan data of the patient's teeth from a hand-held intraoral scanner"

194. During operation of the Virtuo Vivo scanner system, a user can perform a method of receiving first scan data of the patient's teeth from a hand-held intraoral scanner, as set forth in my discussion of Claim 1[b][ii], incorporated here by reference.

iii. 9[b]: "displaying, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth"

195. The Virtuo Vivo scanner system displays, to a display, a model of the patient's teeth based on the received first scan data of the patient's teeth, as set forth in my discussion of Claim 1[b][iii] above, incorporated here by reference.

iv. 9[c]: "receiving user input via the displayed model demarcating a portion of the model to be retained and a surface portion of the model to be replaced"

196. As set forth in my discussion of Claim 1[b][iv], set forth above and incorporated herein by reference, the Virtuo Vivo software provides a user interface that allows the user to interact with the displayed digital model. Through this interface, the user can provide input defining a portion of the model to be removed. The surface portion that is not removed is retained.

v. 9[d]: "receiving second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity"

197. As set forth in my discussion of Claim 1[b][vi] above, and incorporated herein by reference, the Virtuo Vivo scanner system is capable of receiving additional scan data after the initial scan, including second scan data captured by the same hand-held intraoral scanner. This second scan data may include surface data of a portion of the patient's intraoral cavity that has

[redacted]

physically changed since the first scan, such as a tooth that has been prepared or modified. The Virtuo Vivo scanner system therefore satisfies Claim 9[d].

vi. 9[e]: "replacing at least a portion of the surface portion of the model to be replaced according to the user input using at least a portion of the second scan data of the patient's teeth including the physically changed portion"

198. As set forth above in my discussion of Claim 1[b][vii] above, and incorporated here by reference, the Virtuo Vivo scanner system uses the received second scan data to replace at least a portion of the surface data that was previously removed from the model. The system integrates updated surface information corresponding to the physically changed intraoral region into the existing model framework. This functionality satisfies Claim 9[e].

vii. 9[f]: "outputting, to the display, the model of the patient's teeth with the at least the portion of the surface portion replaced using the second scan data"

199. As set forth above in my discussion of Claim 1[b][viii], and incorporated herein by reference, following replacement of the removed surface portion using the second scan data, the Virtuo Vivo scanner system outputs the updated digital model to the display. The displayed model reflects the incorporation of the new scan data into the previously removed region. Accordingly, the Virtuo Vivo scanner system satisfies Claim 9[f].

b. Claim 10

i. "The method of claim 9, further comprising marking an area on the displayed model associated with the received user input."

200. As discussed with respect to Claim 1[b][iv] and Claim 8 set forth above and incorporated herein by reference. The Virtuo Vivo software allows a user to define a portion of the displayed model for removal, and the area is visually marked.

[redacted]

c. Claim 11

i. "The method of claim 9, wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data comprises registering the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model."

201. Using the Lasso or Eraser tool in the Virtuo Vivo scanner system satisfies Claim 11, for the same reasons as set forth above with respect to Claim 5, incorporated herein by reference.

d. Claim 12

i. "The method of claim 11, wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data further comprises stitching the at least the portion of the second scan data with the model."

202. Using the Lasso or Eraser tool in the Virtuo Vivo satisfies Claim 12, for the same reasons as set forth with respect to Claim 6, set forth above and incorporated herein by reference.

3. Infringement of Claim 17

a. Claim 17

i. Preamble: "A system for intraorally scanning a patient's teeth for a dental procedure, the system comprising:"

203. The Virtuo Vivo is a system for intraorally scanning a patient's teeth for a dental procedure within the meaning of Claim 17 for the same reasons as set forth in my discussion above regarding Claim 1[pre], incorporated herein by reference.

ii. 17[a]: "a hand-held intraoral scanner"

204. The Virtuo Vivo includes a hand-held intraoral scanner for the same reasons as set forth with respect to Claim 1[a] in my discussion above, incorporated herein by reference.

[redacted]

iii. 17[b][i]: "a computer readable medium including instructions that when executed by a computer system, cause the computer system to"

205. The Virtuo Vivo scanner system includes a computer readable medium including instructions that are executed by the computer system and cause the computer system to perform the remaining limitations of Claim 17, as set forth in my discussion above regarding Claim 1[b][i], incorporated herein by reference.

iv. 17[b][ii]: "receive first scan data of the patient's teeth from the hand-held intraoral scanner"

206. The Virtuo Vivo scanner system receives first scan data of the patient's teeth from the hand-held intraoral scanner, as set forth above in my discussion above regarding Claim 1[b][ii], incorporated herein by reference.

v. 17[b][iii]: "display, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth"

207. The Virtuo Vivo scanner system displays a model of the patient's teeth based on the received first scan data of the patient's teeth, as set forth in my discussion above regarding Claim 1[b][iii], incorporated herein by reference.

vi. 17[b][iv]: "receive user input defining a portion of the model to be removed"

208. The Virtuo Vivo receives user input that defines a portion of the model that should be removed, as set forth in my discussion above regarding Claim 1[b][iv], incorporated herein by reference.

vii. 17[b][v]: "after receiving the user input, remove, from the displayed model, a removed surface portion of the model to be removed according to the user input"

209. For the same reasons as set forth in my discussion above regarding Claim 1[b][v], incorporated herein by reference, after receiving user input defining a portion of the model to be

[redacted]

removed, the Virtuo Vivo scanner system removes the identified surface portion from the displayed digital model. As a result, the displayed model no longer includes the removed surface region.

viii. 17[g]: "after removing the portion of the model, receive second scan data of the patient's teeth from the hand-held intraoral scanner"

210. As set forth above in my discussion of Claim 1[b][vi], incorporated herein by reference, after removing a portion of the model, the Virtuo Vivo scanner system can receive second scan data of the patient's teeth from the hand-held intraoral scanner.

ix. 17[h]: "register the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model"

211. As set forth above in my discussion of Claim 5, incorporated herein by reference, the Virtuo Vivo scanner system aligns identifying data from the second scan with corresponding parts of the model.

x. 17[i]: "replace at least a portion of the removed surface portion of the model using at least a portion of the received second scan data of the patient's teeth"

212. As set forth above in my discussion of Claim 1[b][vii], incorporated herein by reference, the Virtuo Vivo scanner system replaces a portion of the removed surface of the model with the data from the second scan of the patient's teeth.

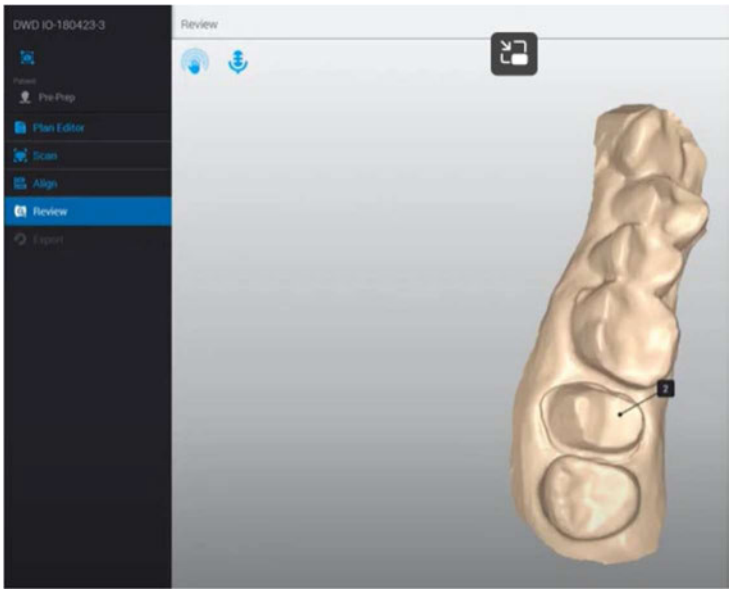
xi. 17[j]: "discarding a remainder of the second scan data, including the identifying data, after registering the second scan data with the model"

213. The Virtuo Vivo scanner system satisfies Claim 17[j]. After registering the second scan data with the existing model and using the relevant portions of that data for replacement, the Virtuo Vivo software does not retain unused portions of the second scan data, including identifying or alignment data that is no longer needed once registration has been

[redacted]

completed. In normal operation, only the surface scan data incorporated into the final model is preserved, while the remaining scan data that is not used in the replacement process is discarded.

214. For example, in the Virtuo Vivo instructional video referenced throughout my report, it shows that the remainder of the received second scan, including the identifying surfaces, is discarded. [221] As shown below, the stitched model includes only the portion of the second scan showing the tooth labeled "2." All that is left is the first scanned portion and the replaced portion of the second scan.[222]



215. When I inspected the Virtuo Vivo scanner, I used it to perform a first test with toothpaste added to the upper left first molar of the typodont to simulate debris on or between a patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan using the Lasso tool. Then I removed the toothpaste from the tooth. Next, I rescanned the tooth that I removed the toothpaste from. The first image below is an image showing the final image

[221] Dental Wings, *Pre Preparation Workflow*, at 4:21, https://www.youtube.com/watch?v=TsOMsxjWTUk. (ALGN00015010).
[222] *Id.*

[redacted]

after the second scan. The remainder of the second scan data has been discarded, leaving only the second scan data for the portion of the first scan that was removed. The second image below is an image of the model of the patient's teeth before the removed surface portion was replaced by the second scan.



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CC_EXEC_00000446

[redacted]

216. When I inspected the Virtuo Vivo scanner, I also used it to perform a second test to simulate the workflow of the Virtuo Vivo scanner system for a crown preparation or other dental procedure. In this test, I selected the lower right second premolar as the tooth that was going to be replaced with a crown preparation tooth. Then I replaced the tooth with the post-operation crown preparation tooth. Next, I rescanned the post-operation crown preparation tooth. The first image below is an image shows the final image after the second scan. The remainder of the second scan data has been discarded, leaving only the first scan data and second scan data for the portion of the first scan that was removed. The second image below is an image of the model of the patient's teeth before the removed surface portion was replaced by the second scan.



CC_EXEC_00000560

[redacted]



CC_EXEC_00000559

217. As shown above, the Virtuo Vivo scanner system discards a remainder of the second scan data, including the identifying data, after registering the second scan data with the model. I also understand from Dr. Singh that the Virtuo Vivo source code confirms that the Virtuo Vivo software performs this claim limitation. Accordingly, the Virtuo Vivo scanner system satisfies Claim 17[j].

xii. 17[k]: "output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the received scan data"

218. As set forth in my discussion of Claim 1[B][viii], set forth above and incorporated herein by reference, after the removed surface portion has been replaced using the second scan data, the Virtuo Vivo software outputs the updated digital model to a display. The displayed model reflects the integration of the second scan data into the previously removed region and presents the user with a revised, complete representation of the patient's dentition.

[redacted]

B. THE STRAUMANN SIRIOS INTRAORAL SCANNER INFRINGES THE ASSERTED CLAIMS

219. As explained below, the SIRIOS intraoral scanner[223] practices each limitation of Claims 1, 4-6, 8-12, and 17 of the '936 Patent. This analysis is based on my review of the '936 Patent, publicly available technical documentation, product literature, and operation of the SIRIOS scanner system, as well as my education, training, and experience in dental imaging systems.

1. Infringement of Claims 1, 4-6, and 8 of the '936 Patent

a. Claim 1

i. 1[Pre]: "A system for scanning a patient's teeth for a dental procedure, the system comprising:"

220. The SIRIOS scanner is a system for scanning a patient's teeth for dental procedures within the meaning of Claim 1. The SIRIOS scanner is an intraoral scanning system specifically designed to capture digital three-dimensional representations of a patient's dentition and surrounding oral structures.[224] These scans are used in connection with a variety of dental procedures, including restorative dentistry, orthodontic treatment planning, and the fabrication of dental appliances.[225]

---

[223] The SIRIOS intraoral scanner, as used in my report, refers generally to SIRIOS X3 and ST 200E. I understand that the software for SIRIOS X3 is identical to the ST 200E, including the cut tool discussed in my report. *See* [redacted]

[224] *Straumann SIRIOS*, Straumann (ALGN01637370) at -372 ("Redefine ease of use with our intraoral scanning solution").

[225] *Id*. at -372 ("Straumann SIRIOS features a smart design and offers a flexible scanning strategy, empowering you to adapt to various clinical situations"), -375 (Referring to implant, full-arch, surgical planning, and orthodontic workflows); *Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -326 ("The Straumann SIRIOS™ Intraoral Scanner . . . is a digital optical scanning device used to obtain digital impressions of hard and soft tissues such as teeth, gingiva, and mucous membranes by means of oral scanning, for the purpose of oral restoration and orthodontic treatment of malocclusion.*"); Straumann SIRIOS X3 Instruction Manual*, Straumann (CC_ALGN_03167466) at -493 (same); [redacted]

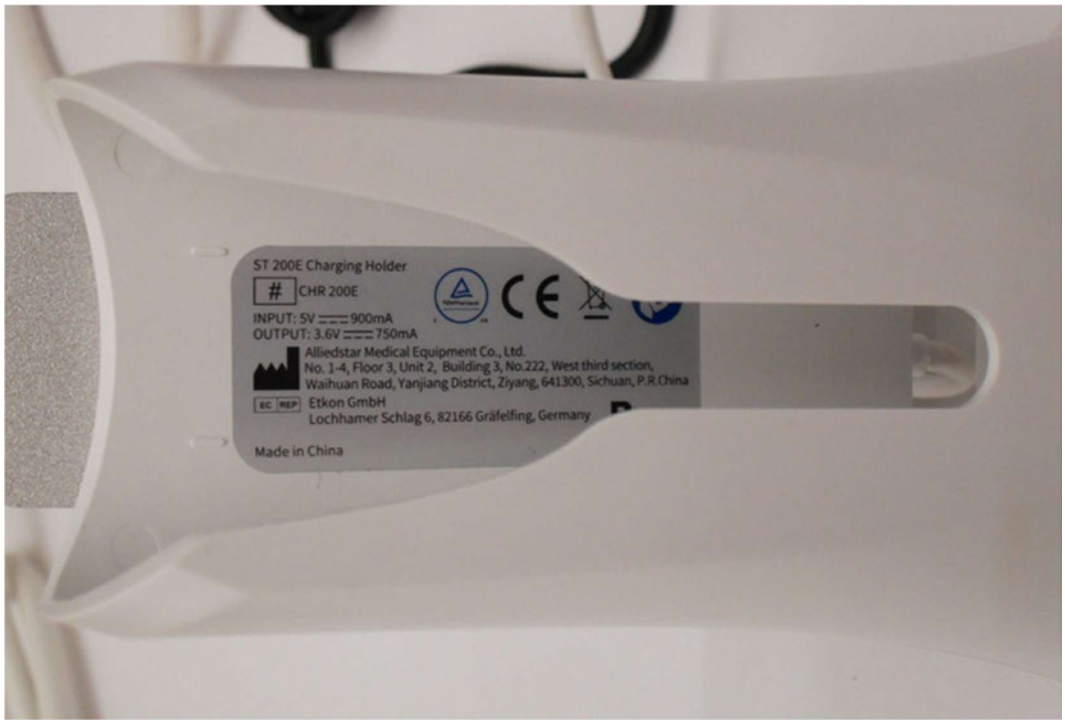
[redacted]

221. I inspected the SIRIOS scanner on October 6 and 7, 2025. Below are images of the product packaging, product numbers, and the SIRIOS scanner, which is connected to a laptop. As shown below, the system includes a scanner, which captures three-dimensional images of the patient's teeth. The images are displayed on the accompanying laptop. Accordingly, the SIRIOS satisfies the Claim preamble requirement of being a "system for scanning a patient's teeth for a dental procedure."



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[redacted]



CC_EXEC_00000693



CC_EXEC_00000698

[redacted]



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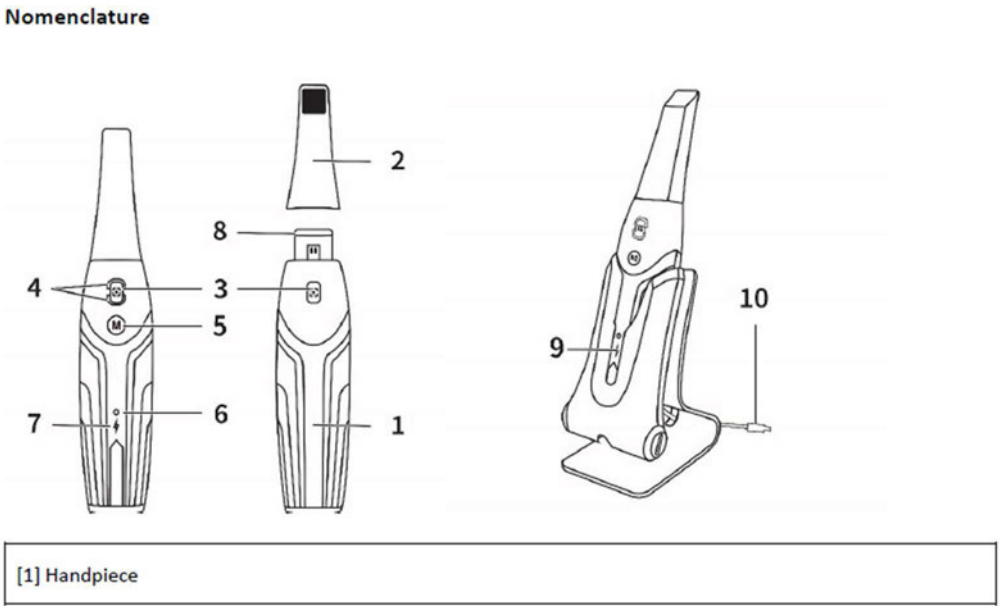
ii. 1[a]: "a hand-held intraoral scanner"

222. The SIRIOS scanner system satisfies Claim 1[a]. The SIRIOS scanner is a hand-held intraoral scanner.[226] The SIRIOS scanner includes a portable scanning device that a dental professional holds in their hand and places in the patient's mouth (intraorally) to capture surface data of the teeth and surrounding intraoral structures (*e.g.*, gums).[227] This portion of the scanner is referred to as the "handpiece."[228]

[redacted]

[227] *Straumann SIRIOS*, Straumann (ALGN01637370) at —372-73 ("the wireless scanner combines cutting-edge technology with an ergonomic pen-grip design").
[228] *Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -327; *Straumann SIRIOS X3 Instruction Manual*, Straumann (CC_ALGN_03167466) at -494.

[redacted]



During normal operation, the clinician moves the SIRIOS scanner over the teeth and surrounding gums while the device acquires optical scan data.

223. Below are images of the SIRIOS scanner I inspected. To test the SIRIOS scanner, I used the device to create a three-dimensional image of the teeth of a typodont, which is a physical dental model which simulates the teeth and gums of a human mouth. Holding the scanning device with my hand, I was able to maneuver it to capture images of the teeth and gums of the typodont. Accordingly, the SIRIOS satisfies the requirement of a "hand-held intraoral scanner."

[redacted]

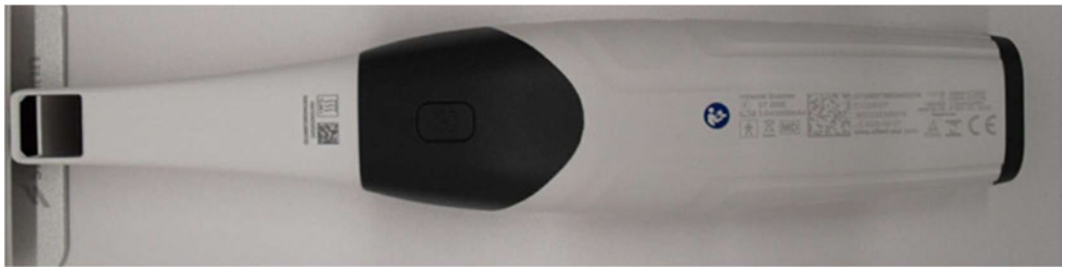


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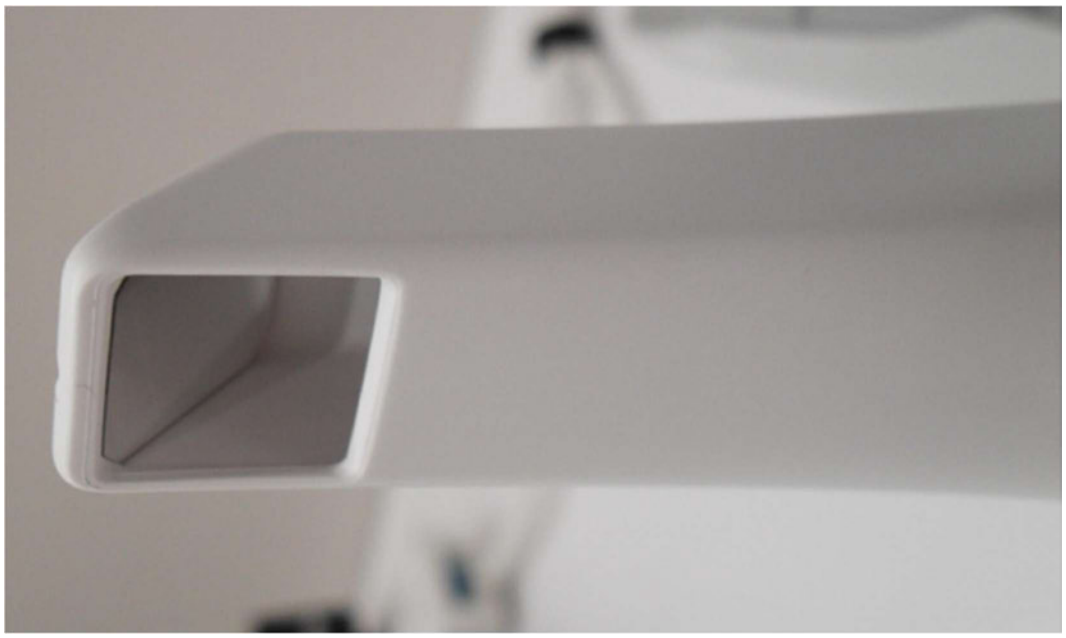


CC_EXEC_00000694

[redacted]



CC_EXEC_00000696



CC_EXEC_00000703

iii. 1[b][i]: "a computer readable medium including instructions that when executed by a computer system, cause the computer system to:'

224. The SIRIOS scanner system satisfies Claim 1[b][i]. The SIRIOS scanner system includes a computer with installed software, a monitor, and a hand-held intraoral scanner equipped with optical sensors.[229] The laptops and desktops used with the SIRIOS scanner

[229] *SIRIOS Review – Straumann Makes a Comeback in the IOS Market*, Institute of Digital Dentistry (ALGN01637330) at -338 ("The Straumann SIRIOS utilizes the same wireless technology as the Alliedstar AS200E, relying on a TP-LINK wireless adapter that connects to the laptop via a USB 3.0. Straumann Claims a reliable range of up to 7 meters from the connection hub."); [redacted]

[redacted]

include computer memory and software.[230] Below are the technical specifications for laptops and desktops used with the SIRIOS scanner.[231]

Minimum System Requirements of Laptop	**Processor:** 10th Generation Intel® Core™ i7-10750H or AMD Ryzen™ 7 4700U **Memory:** 16 GB **Graphics Card:** NVIDIA GeForce GTX 1650 4 GB **Disk:** 512 GB SSD **Operating System:** Win 10 (build 18362+) / Win 11, 64 bit **Others:** USB 3.0 Port **Optional:** Touch Screen
Minimum System Requirements of Desktop	**Processor:** 9th Generation Intel® Core™ i5-9600 or AMD Ryzen™ 5 2600 **Memory:** 16 GB **Graphics Card:** NVIDIA GeForce GTX 1650 4 GB **Disk:** 512 GB SSD **Operating System:** Win 10 (build 18362+) / Win 11, 64 bit **Others:** USB 3.0 Port **Optional:** Touch Screen

225. Below is an image of the laptop attached to the SIRIOS scanner I inspected.

[redacted] *Straumann SIRIOS X3 Instruction Manual*, Straumann (CC_ALGN_03167466) at -524 (listing the technical specifications required for laptops and desktops used with the SIRIOS X3 scanner, including the requirement for 32 GB of memory); [redacted]

[231] *Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -358; *see also Straumann SIRIOS X3 Instruction Manual*, Straumann (CC_ALGN_03167466) at -524.

[redacted]

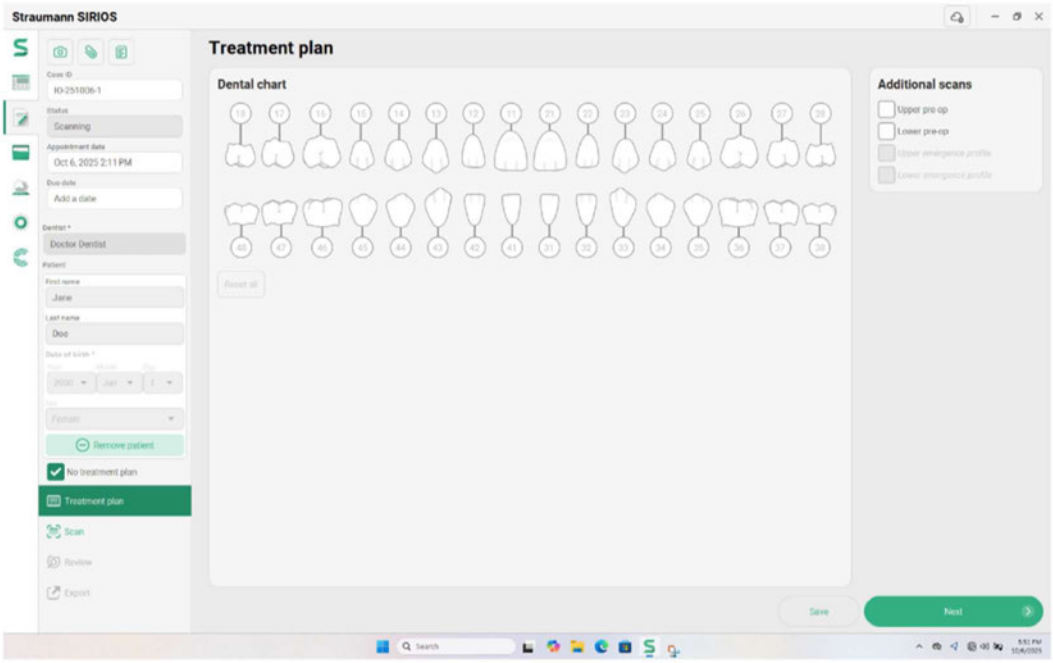


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226. The computer used with the SIRIOS scanner includes the SIRIOS scanner software.[232] Below is an image of SIRIOS laptop screen which is running the scanner software discussed in more detail below. The laptop is attached to the SIRIOS scanner device I inspected.

[redacted]

[redacted]



CC_EXEC_00000268

227. As shown above, the SIRIOS scanner has a computer readable medium that includes instructions that can be executed by a computer system. Accordingly, the SIRIOS scanner system satisfies Claim 1[b][i].

iv. 1[b][ii]: "receive first scan data of the patient's teeth from the hand-held intraoral scanner"

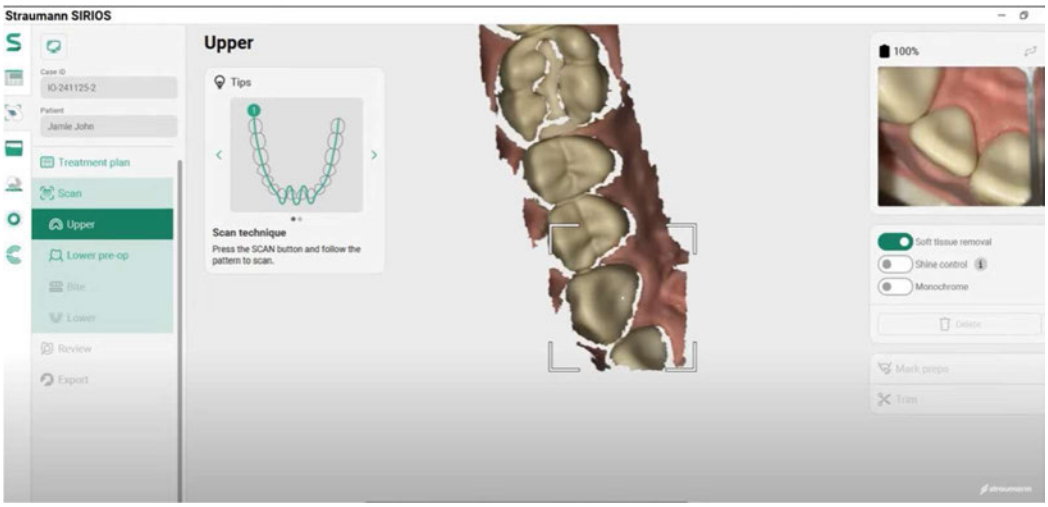
228. The SIRIOS scanner system satisfies Claim 1[b][ii]. During operation of the SIRIOS scanner system, the computer receives first scan data of the patient's teeth from the hand-held intraoral scanner.[233] For example, a user can obtain a first scan from the intraoral scanner in a Crown & Pre-Op Workflow, as shown in Straumann's training videos.[234] The SIRIOS software reads scan data of the patient's teeth from the sensor in the scanner during the

[redacted]

[234] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 1:06; https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352) (showing the steps of receiving first scan data).

[redacted]

Upper or Lower pre-op steps. As the user scans the teeth, the three-dimensional model of the teeth appears on the display screen within the SIRIOS software.[235] Below is an image of the display screen within the SIRIOS software.[236]



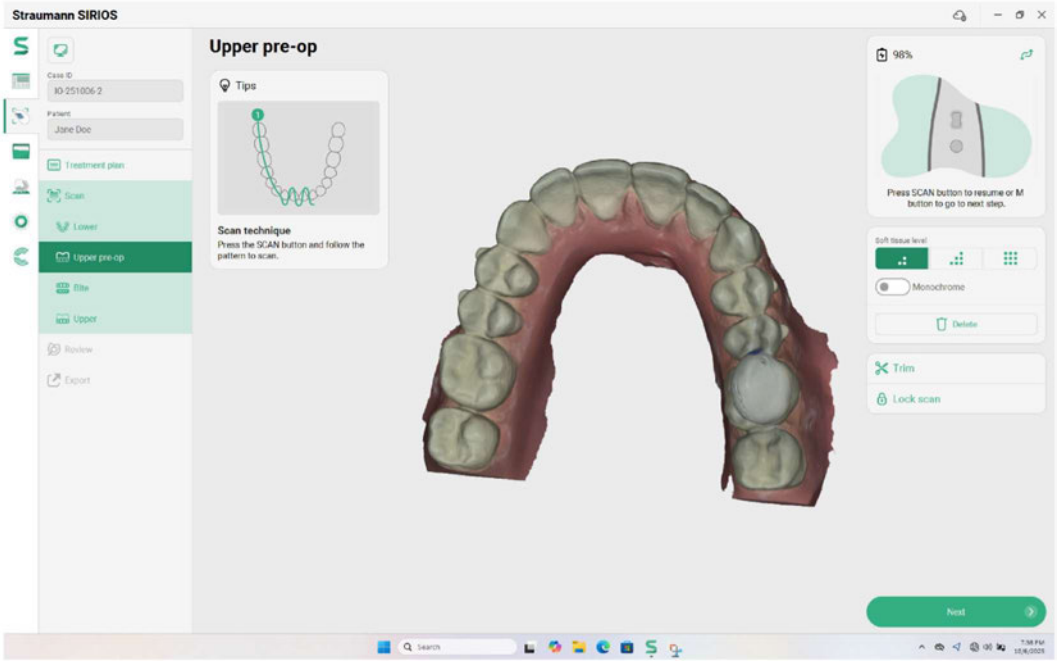
229. When I inspected the SIRIOS scanner, I performed two tests using this scanner. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris often found on or between patients' teeth when they receive an intraoral scan. The debris could be food, plaque, tarter, blood, saliva, lubricant from the dental drill, waste material from working on a dental site, or any other foreign material that obscures a tooth's surface.[237]

230. For this test, I scanned both the upper and lower arches of the typodont using the SIRIOS scanner. The SIRIOS scanner software running on the laptop "receive[d] first scan data of the patient's teeth from the hand-held intraoral scanner." The three images shown below are

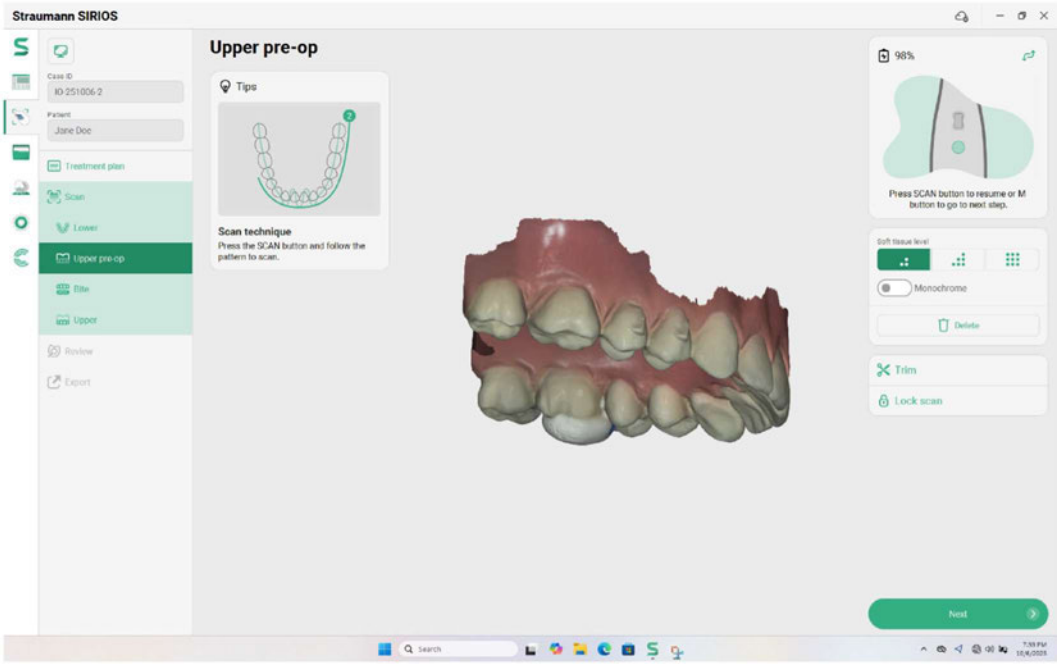
[235] *Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -340 (describing the process of starting a scan); *Straumann SIRIOS X3 Instruction Manual*, Straumann (CC_ALGN_03167466) at -505 (same).
[236] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 1:06; https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352).
[237] '936 Patent at 2:1-5 (describing materials that can obscure a tooth's surface).

[redacted]

different views of the first scan of the upper arch, which include the upper left first molar tooth with the debris (toothpaste).

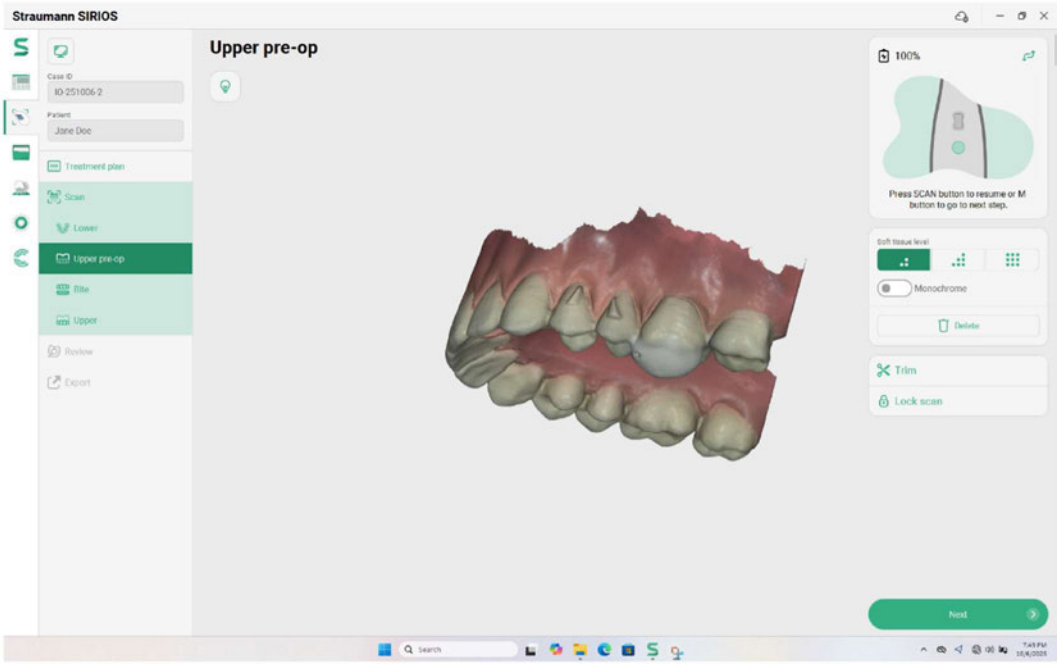


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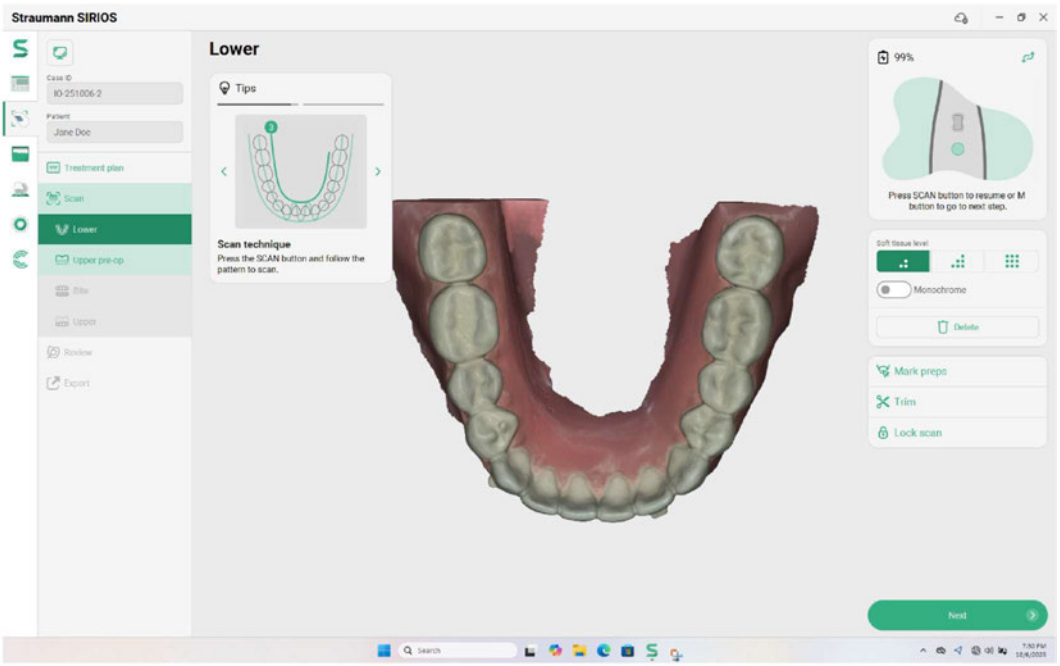
CC_EXEC_00000297

[redacted]



CC_EXEC_00000301

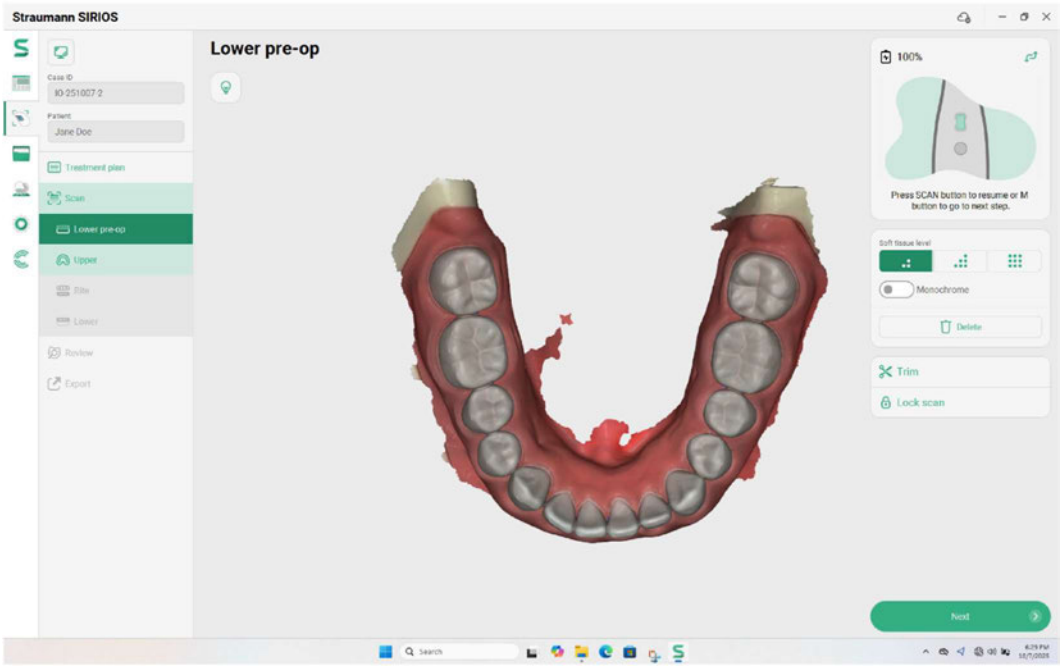
231. The image shown below is a first scan of the lower arch for the first test I performed.



CC_EXEC_00000280

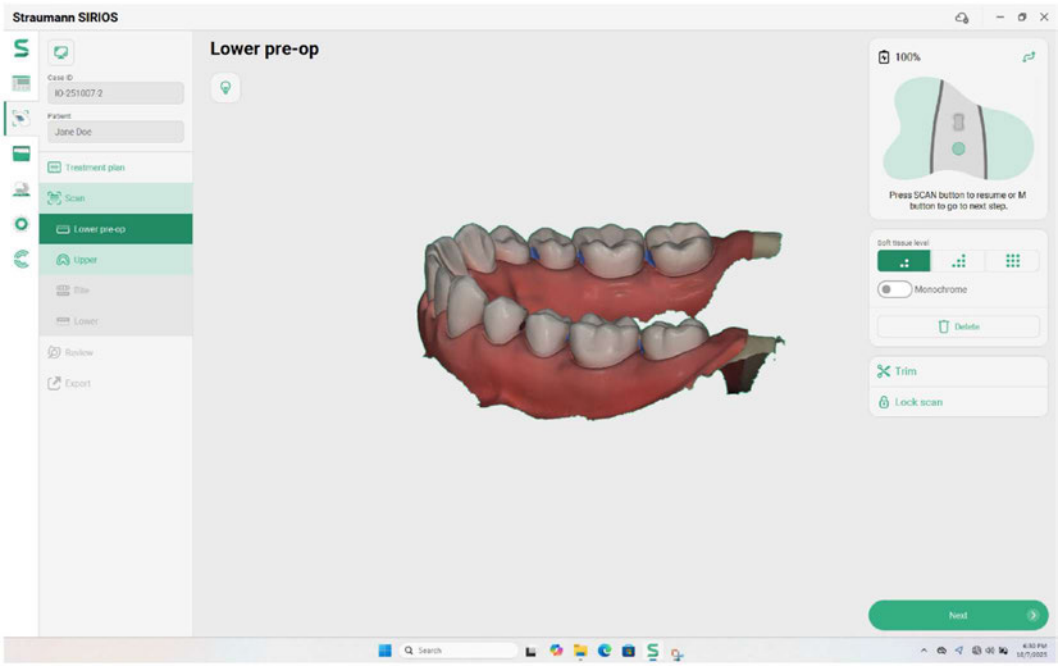
[redacted]

232. I also performed a second test using the SIRIOS scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the SIRIOS scanner system for a crown preparation or other dental procedure. For the first scan, the typodont's original tooth, that was later to be replaced with a crown-prepped version of the tooth, was in place to simulate capturing a pre-operation image of this tooth and all the patient's other teeth in the lower dental arch. The SIRIOS scanner software running on the laptop "receive[d] first scan data of the patient's teeth from the hand-held intraoral scanner." The three images shown below are different views of the first scan of the lower arch before the crown preparation operation.

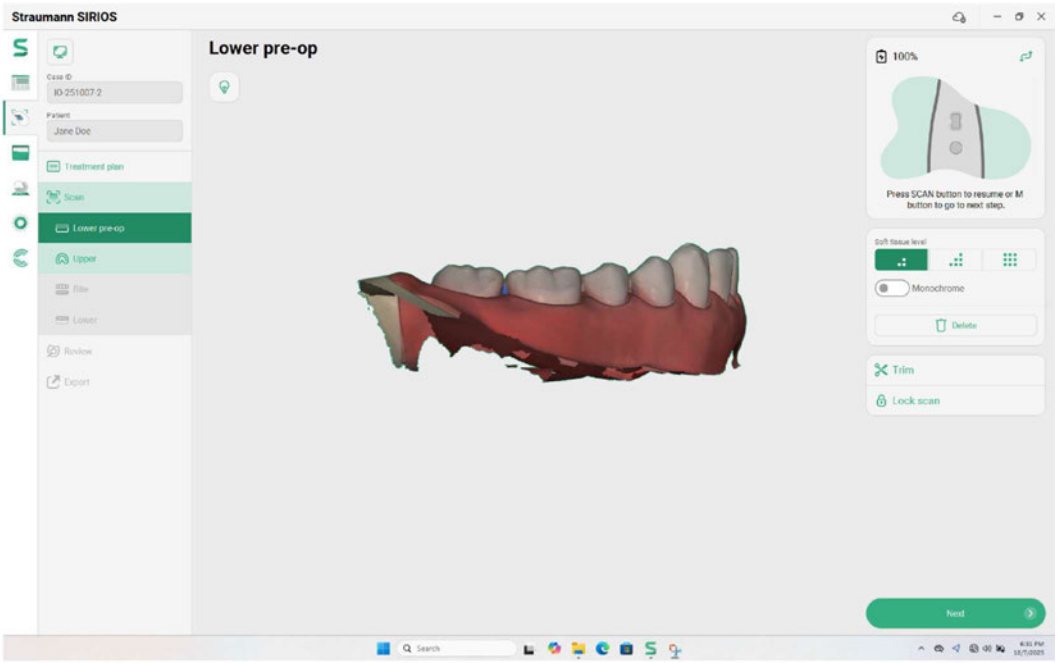


CC_EXEC_00000351

[redacted]



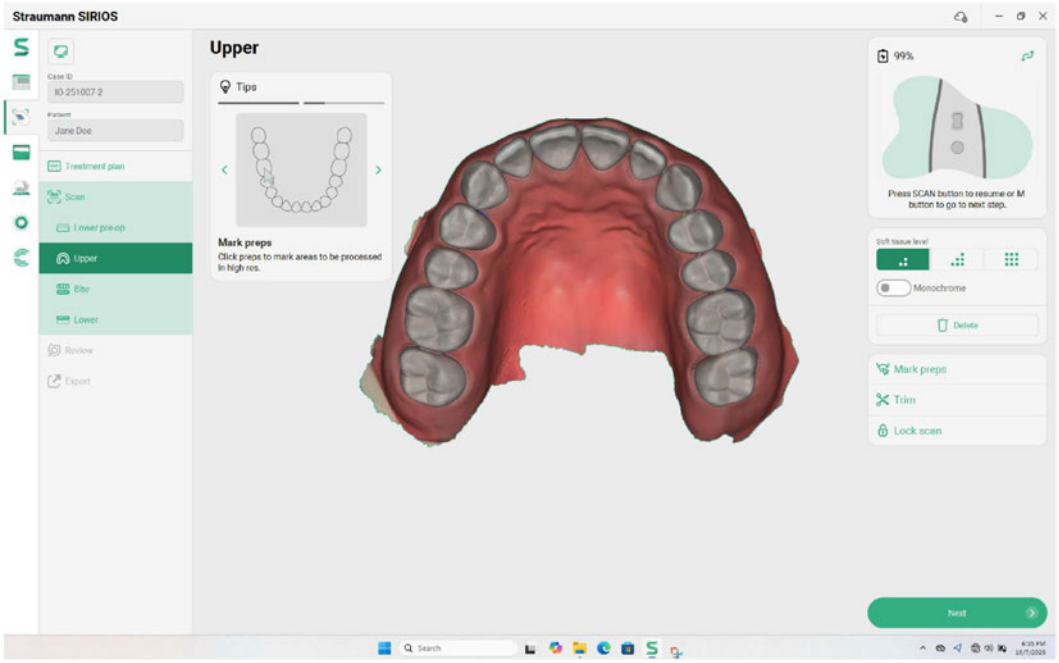
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CC_EXEC_00000353

233. The images shown below are of the first scan of the upper arch.

[redacted]



CC_EXEC_00000379

234. As shown above, the computer receives first scan data of the typodont simulated patient's teeth from the SIRIOS hand-held intraoral scanner. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim limitation. Accordingly, the SIRIOS scanner system satisfies Claim 1[b][ii].

v. 1[b][iii]: "display, to a display, a model of the patient's teeth wherein the model of the patient's teeth is based on the received first scan of the patient's teeth

235. The SIRIOS scanner system satisfies Claim 1[b][iii]. The SIRIOS scanner connects wireless to a computer system, which has a display.[238] When I inspected the SIRIOS scanner, it was connected to a laptop with a display screen, as shown below.

[redacted].

[redacted]

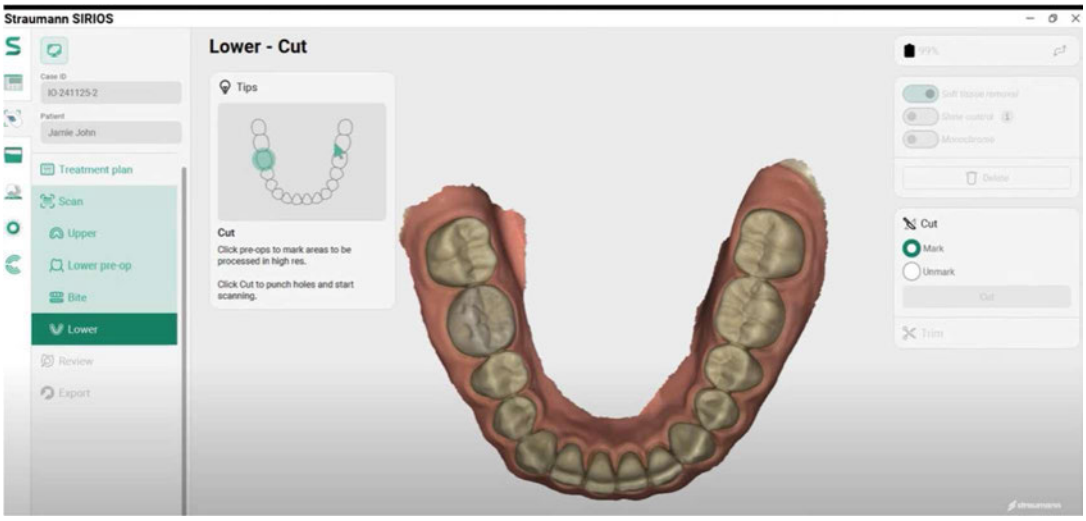


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236. The SIRIOS scanner system generates a digital model of the patient's teeth based on the received first scan data read from the intraoral scanner and displays that model on the system's display. The display screen displays the virtual model based on the first scan data that is received.[239] Below is an image of the virtual model within the SIRIOS scanner software.[240]

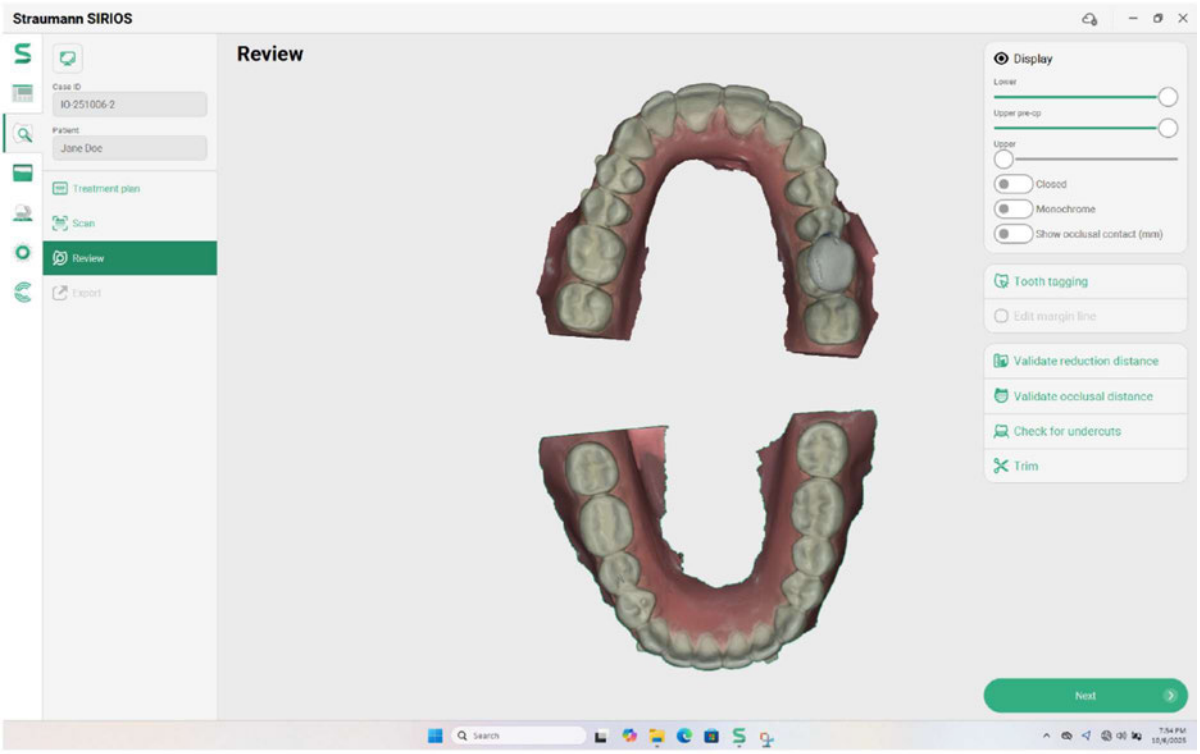
[239] *SIRIOS Brochure*, Straumann, https://www.straumann.com/content/dam/mediacenter/straumann/en/documents/brochure/product-information/490.950-en_low.pdf (ALGN01637353);
[240] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 1:06; https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352); [redacted]

[redacted]



237. When I inspected the SIRIOS scanner, I performed a first test using the scanner and typodont to simulate a patient's teeth. I performed this test to simulate the workflow of the SIRIOS scanner system when a removable unwanted element is obscuring part of the dental surface of a patient's teeth. To the upper left first molar of the typodont, I added toothpaste to simulate debris on or between a patient's teeth. The three images below are different views of the first scan of the teeth in the upper arch with debris on the upper left first molar and a first scan of the teeth in the lower arch. These images were displayed on the laptop attached to the SIRIOS scanner.

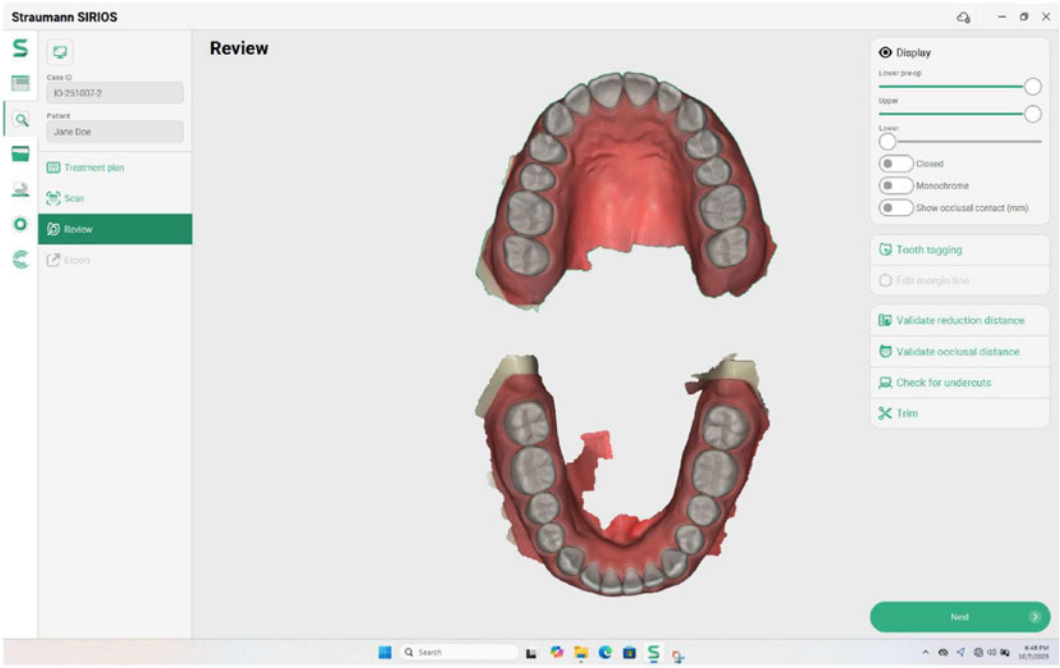
[redacted]



CC_EXEC_00000286

238. When I inspected the SIRIOS scanner, I also performed a second test using the scanner and typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the SIRIOS scanner system for a crown preparation or other dental procedure. The image below shows the first scan of the pre-operation teeth in the upper arch and the scan of the teeth in the lower arch. These images were displayed on the laptop screen attached to the SIRIOS scanner.

[redacted]



CC_EXEC_00000368

239. As shown above, the SIRIOS scanner system has a display, to a display, a model of the patient's teeth wherein the model of the patient's teeth is based on the received first scan of the patient's teeth. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim limitation. Accordingly, the SIRIOS scanner system satisfies Claim 1[b][iii].

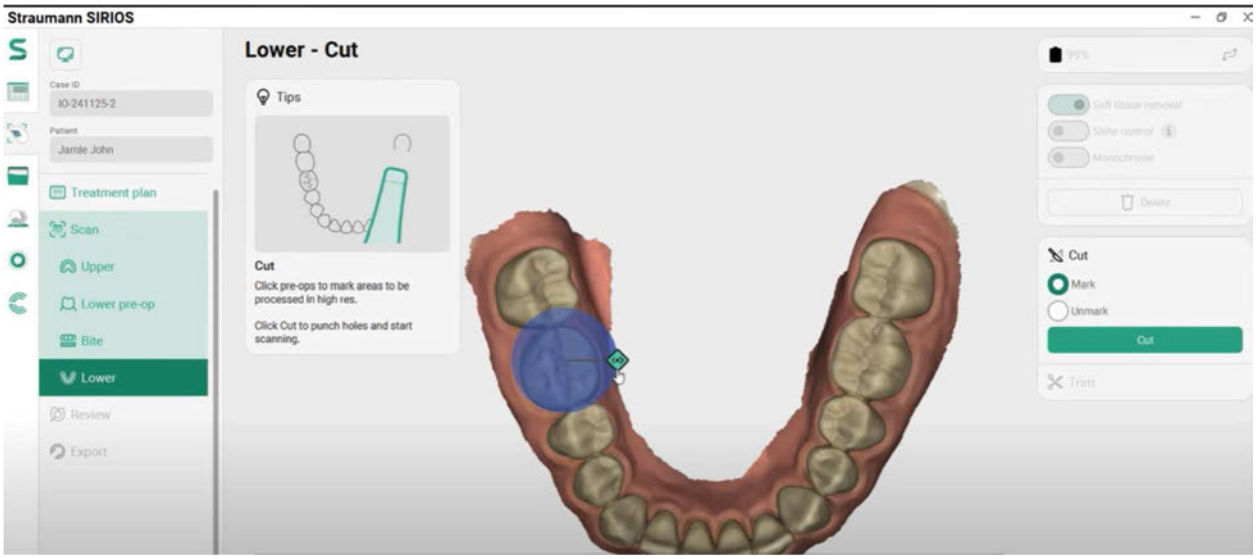
vi. 1[b][iv]: "receive user input defining a portion of the model to be removed"

240. The SIRIOS scanner system satisfies Claim 1[b][iv]. The SIRIOS software provides a user interface that allows the user to interact with the displayed digital model. Through this interface, the user can provide input defining a portion of the model to be removed. The user provides input using the "Cut" selection tool.[241] The user uses a "mark" to draw a

[241] *Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -351 (explaining that if there are discrepancies or overlapping areas in the scan, the user can "[u]se the Cut tool to eliminate mismatched data and excess tissue");

[redacted]

closed shape around a portion of the patient's teeth.[242] The shape divides the model into two portions. The portion of the model inside the closed shape will be removed. The portion of the model outside the close shape will be kept. Below is an image of the mark applied within the cut selection tool.[243]



241. When I inspected the SIRIOS scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the SIRIOS scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris on or between a patient's teeth. I then selected the cut tool and used the mouse of the laptop to draw a circle around the tooth with the simulated debris,

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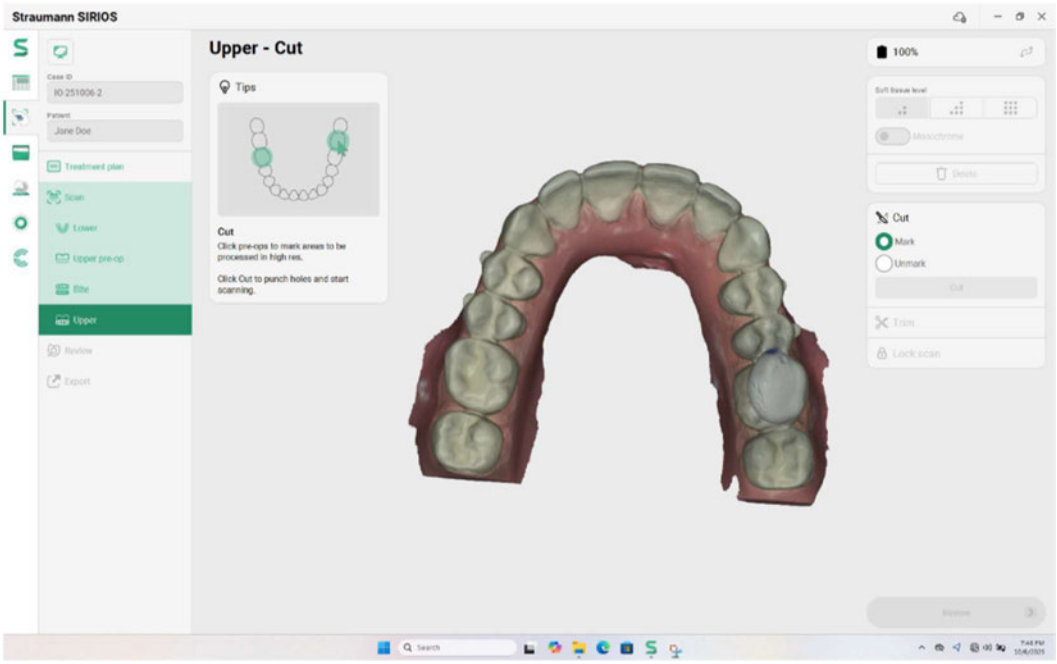
[redacted]

[242] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 1:57, https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352) ("Mark the preparation using the Cut tool. You can enlarge the mark cylinder by using the green handle."); [redacted]

[243] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:08, https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352) (showing the process of selecting a portion of the virtual model);

[redacted]

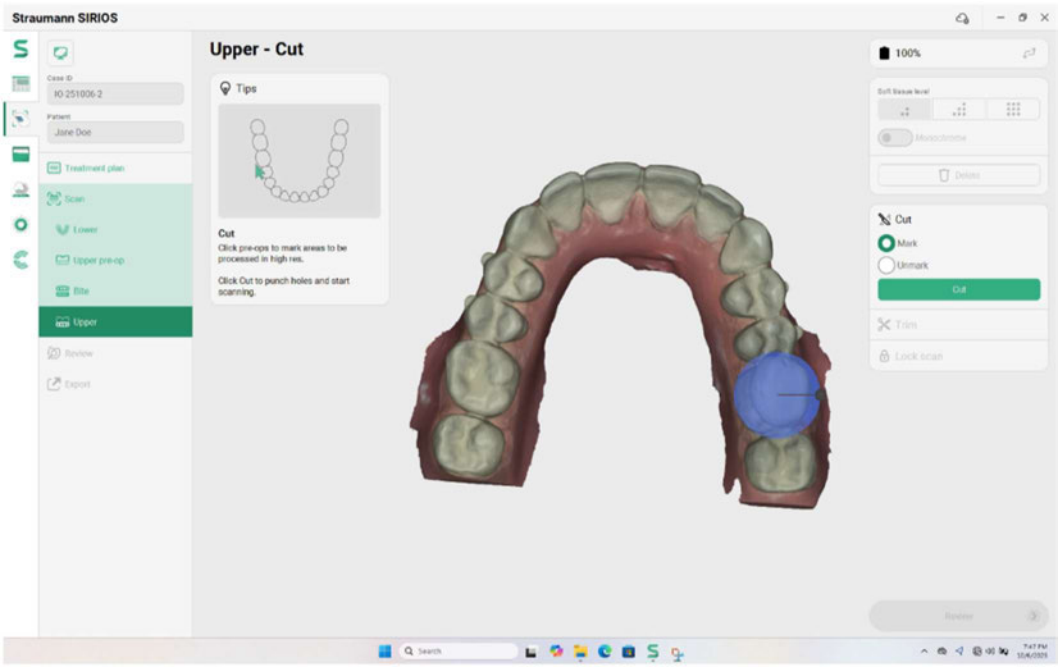
selecting the portion of the model that I wanted to be removed. The image shown below is the first scan of the upper arch with the upper left first molar that has debris on it before I used the cut tool.



CC_EXEC_00000294

242. The image below shows first scan of the upper arch after I used the cut tool to mark the upper left first molar tooth with debris. The portion of the model inside the mark was subsequently removed while the portion of the model outside the mark was kept.

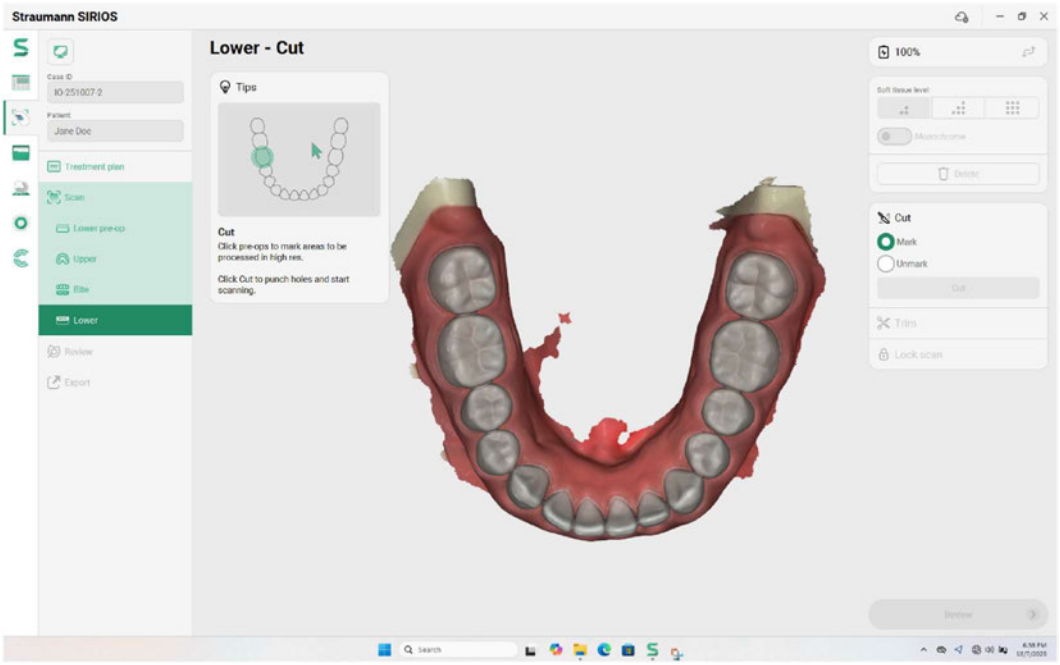
[redacted]



CC_EXEC_00000271

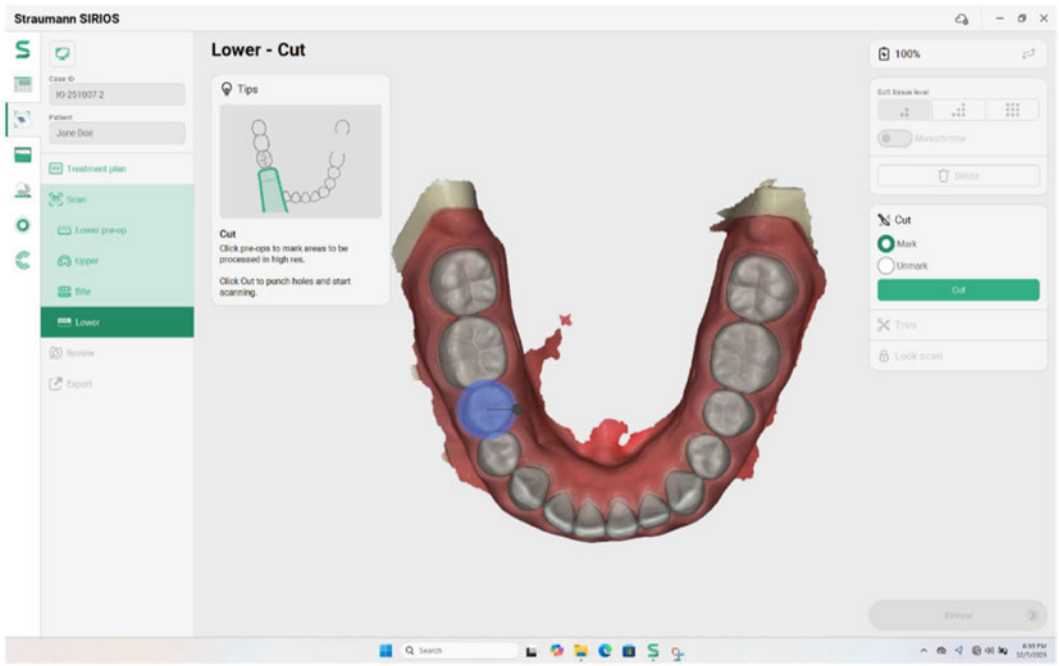
243. For the second test of the SIRIOS scanner using this scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the SIRIOS scanner system for a crown preparation or other dental procedure. In this test, I selected the lower first premolar tooth for the crown preparation. The image shown below is the first scan in the lower arch before I used the cut tool to select the lower first premolar tooth.

[redacted]



CC_EXEC_00000343

244. The image below shows the first scan of the lower dental arch after I selected and used the cut tool to indicate on the display screen the portion of the model (*i.e.*, the lower left first premolar) that I wanted to be removed.



[redacted]

CC_EXEC_00000354

245. As shown above, the SIRIOS scanner system receives user input defining a portion of the model to be removed. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim limitation. Accordingly, the SIRIOS scanner system satisfies Claim 1[b][iv].

vii. 1[b][v]: "remove, from the displayed model, a removed surface portion of the model to be removed according to the user input"

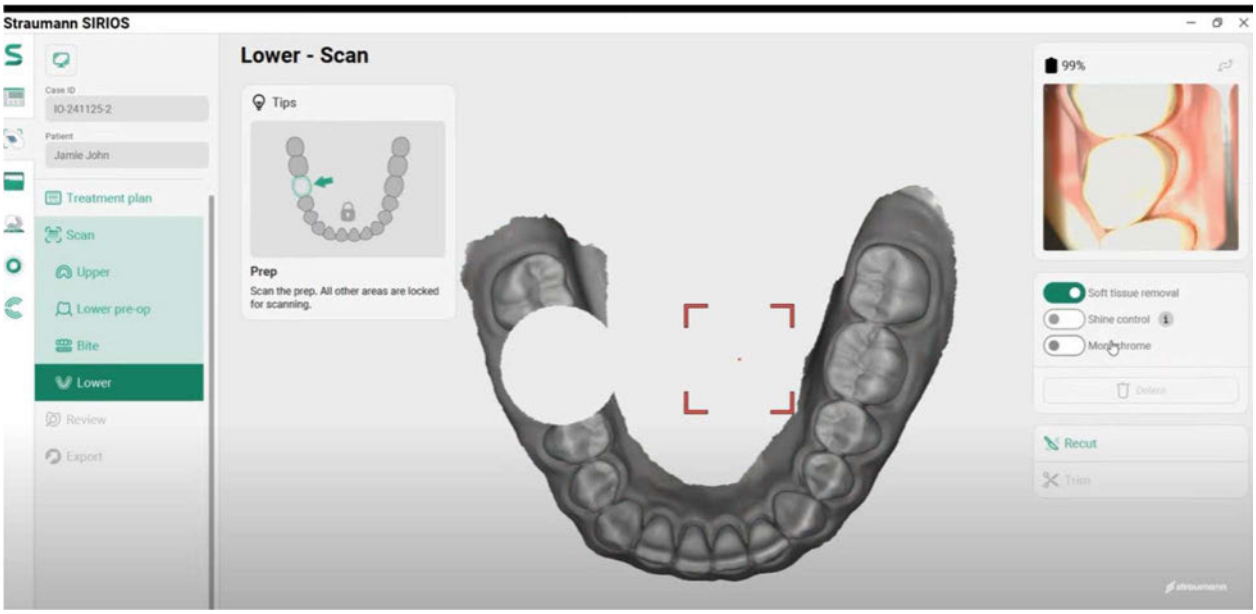
246. The SIRIOS scanner system satisfies Claim 1[b][v]. After receiving the user input defining a portion of the model to be removed (*i.e.*, the cut selection tool), the SIRIOS scanner system removes this portion from the displayed digital model.[244] As a result, the displayed model no longer includes the portion that was selected by the user to be removed.[245] Below is an image of the cut tool applied.[246]

[redacted]

[245] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:16 (https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9) (ALGN01637352) (showing the displayed model after a defined portion of the model is removed); *see also Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -351 (explaining that if there are discrepancies or overlapping areas in the scan, the user can "[u]se the Cut tool to eliminate mismatched data and excess tissue").

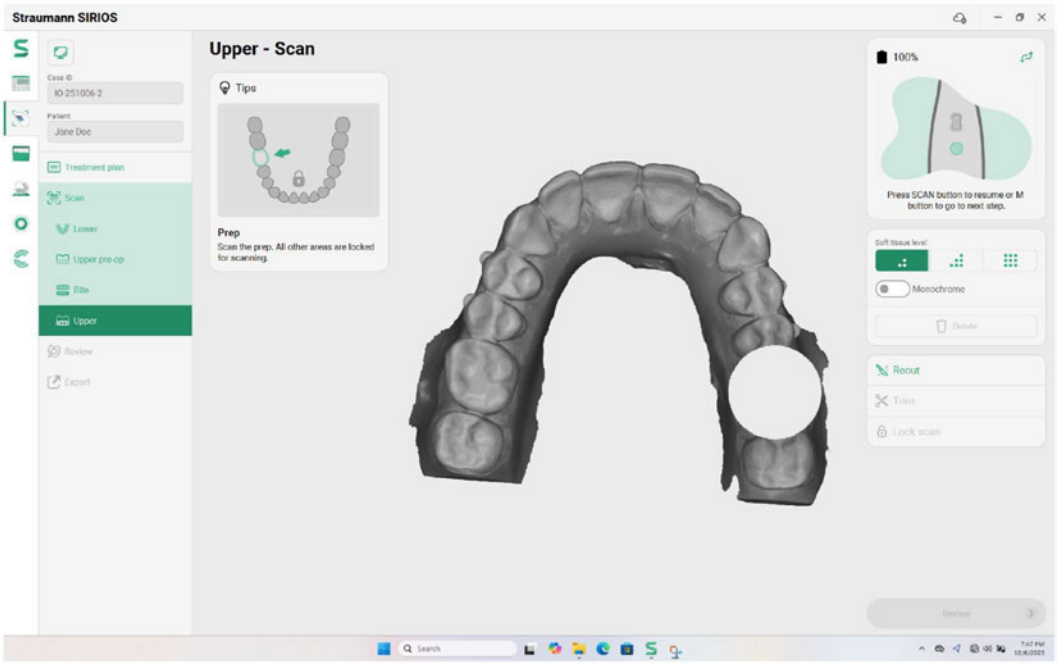
[246] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:16 (https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9) (ALGN01637352)

[redacted]



247. When I inspected the SIRIOS scanner, I used it to perform two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the SIRIOS scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris. In this test, using the mouse of the laptop, I selected the cut tool to define the portion of the model to be removed from the first scan, *i.e.*, the tooth with debris. The image below shows the first scan after I used the cut tool to identify the portion of the model to be removed.

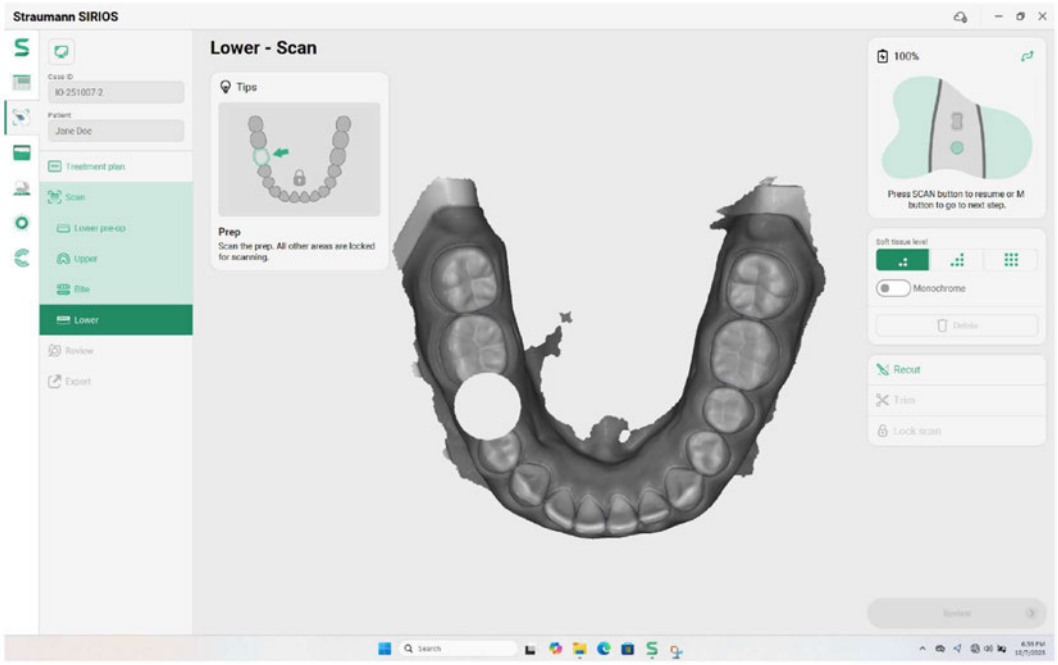
[redacted]



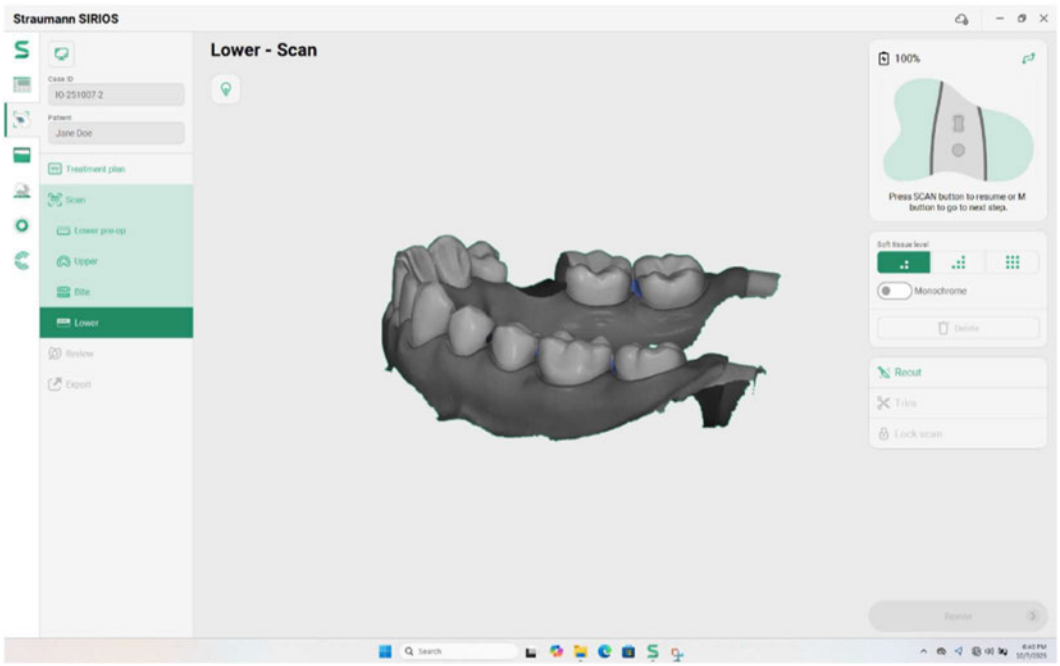
CC_EXEC_00000283

248. When I inspected the SIRIOS scanner, I also used it and the typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the SIRIOS scanner system for a crown preparation or other dental procedure. In this test, using the mouse of the laptop, I selected the cut tool and defined the portion of the model to be removed, which was the lower right second premolar. The three images shown below are different views of the first scan after I used the cut tool.

[redacted]

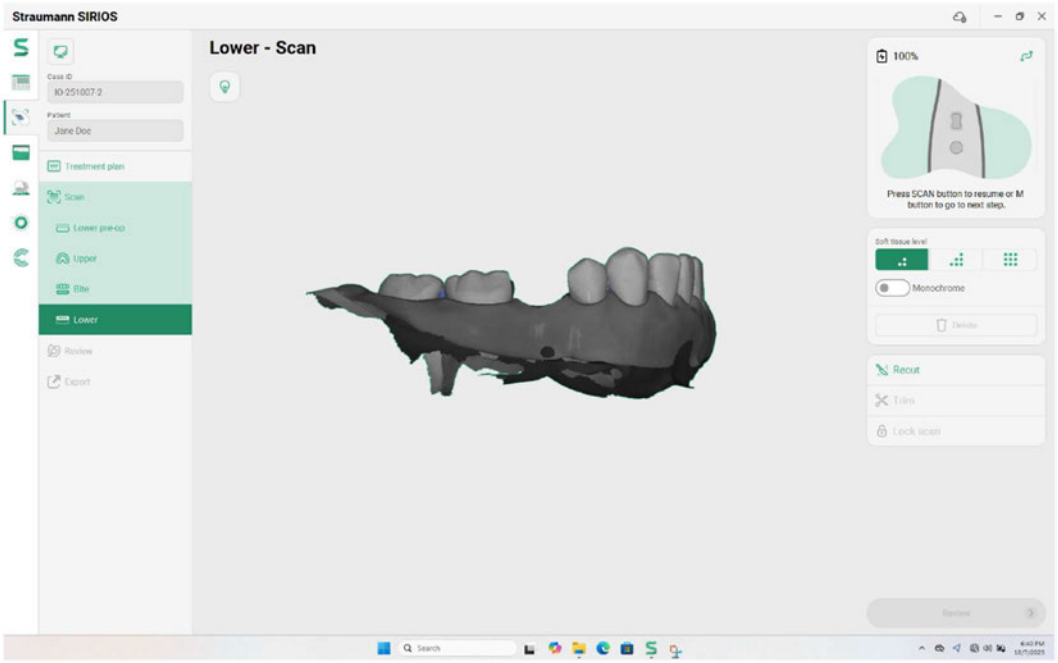


CC_EXEC_00000340



CC_EXEC_00000341

[redacted]



CC_EXEC_00000342

249. As shown above, the SIRIOS scanner system receives user input defining a portion of the model to be removed. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim limitation. Accordingly, the SIRIOS scanner system satisfies Claim 1[b][v].

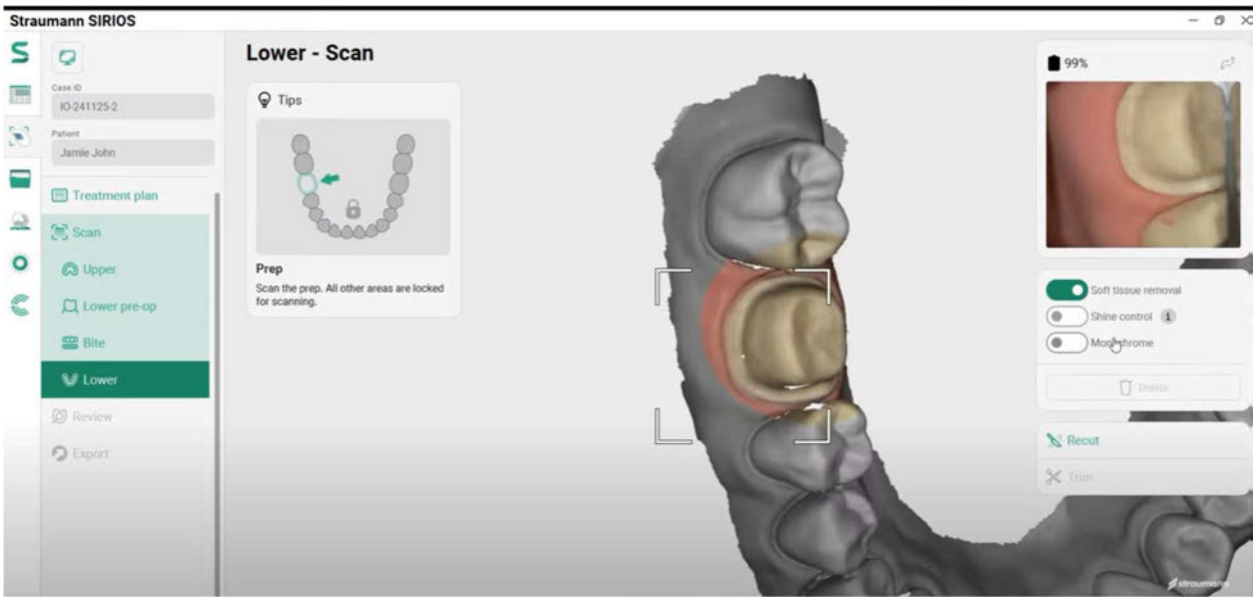
viii. 1[b][vi]: receive second scan data of the patient's teeth from the hand-held intraoral scanner, the scan data including surface data of a physically changed portion of the patient's intraoral cavity"

250. The SIRIOS scanner system satisfies Claim 1[b][vi]. The SIRIOS scanner system can receive additional scan data after the initial scan, including second scan data captured by the same hand-held intraoral scanner.[247] This second scan data may include surface data of a portion of the patient's intraoral cavity that has physically changed since the first scan.

[redacted]

[redacted]

251. For example, in the SIRIOS instructional video referenced throughout my report, a patient's tooth undergoes a dental procedure that results in the tooth being physically changed after the first scan and before the second scan. The second 3D intraoral scan data, taken after the physical change has occurred to the patient's tooth, includes the surface data of the physically changed portion. Screenshots from the video, below, show the user obtaining second scan data of a physically changed tooth.[248]

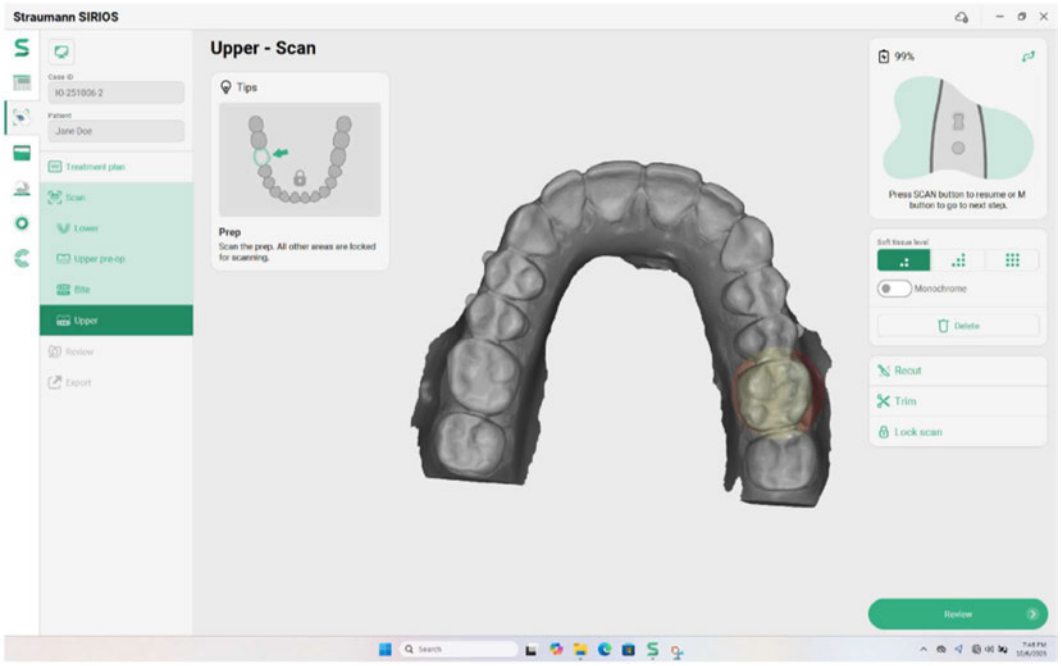


252. When I inspected the SIRIOS scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the SIRIOS scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste on the upper left first molar to simulate debris. In this test, I selected this tooth with debris to be removed from the first scan

[248] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:19, https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9) (ALGN01637352) (showing the process of receiving second scan data including surface data of a physically changed portion of the patient's intraoral cavity); *see also Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -351 (explaining that if there are discrepancies or overlapping areas in the scan, the user can "[u]se the Cut tool to eliminate mismatched data and excess tissue, then conduct a rescan").

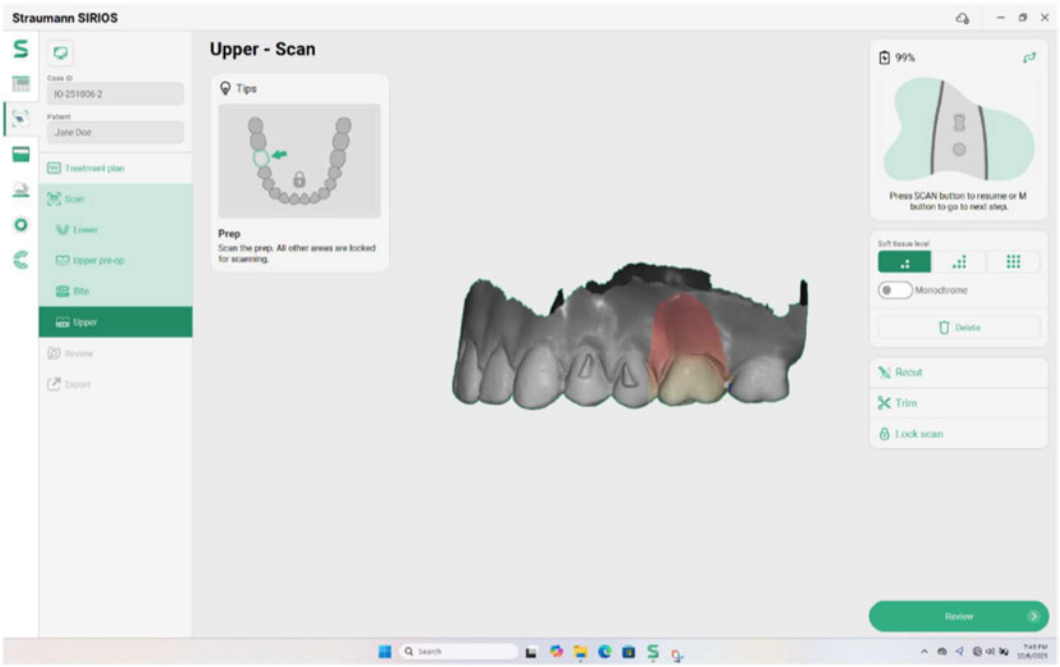
[redacted]

using the cut tool. Then I physically removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. The three images shown below are different views of the second scan of the teeth in the upper arch which included the tooth that once had toothpaste (debris) but then was removed. The image was received by the computer connected to the SIRIOS scanner (which I held in my hand) of the second scan of the tooth, which is the physically changed portion of the patient's intraoral cavity.

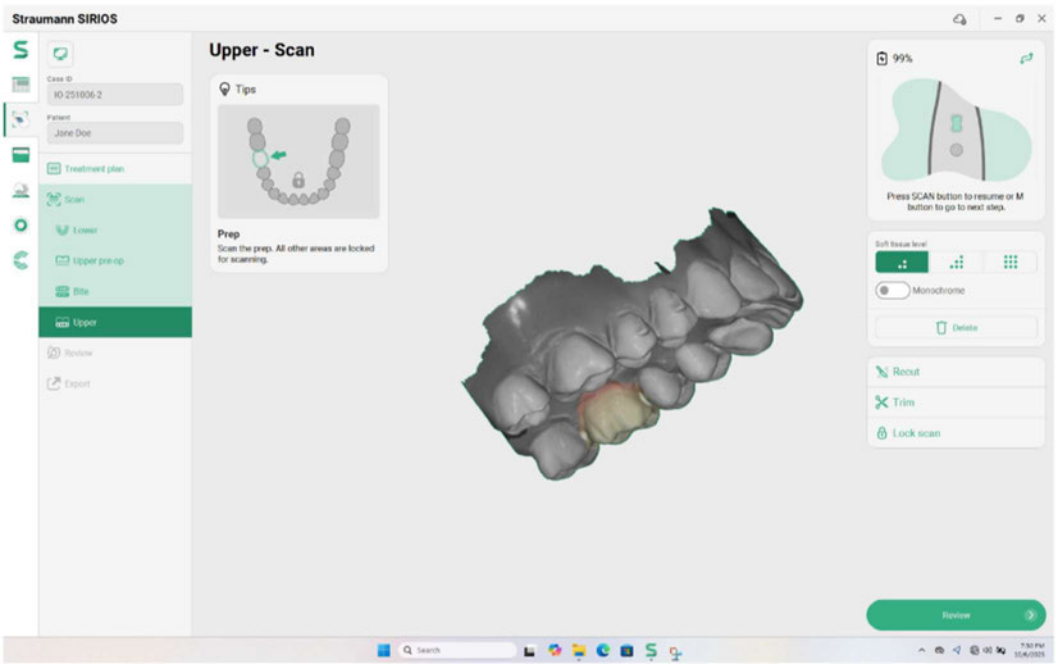


CC_EXEC_00000289

[redacted]



CC_EXEC_00000290

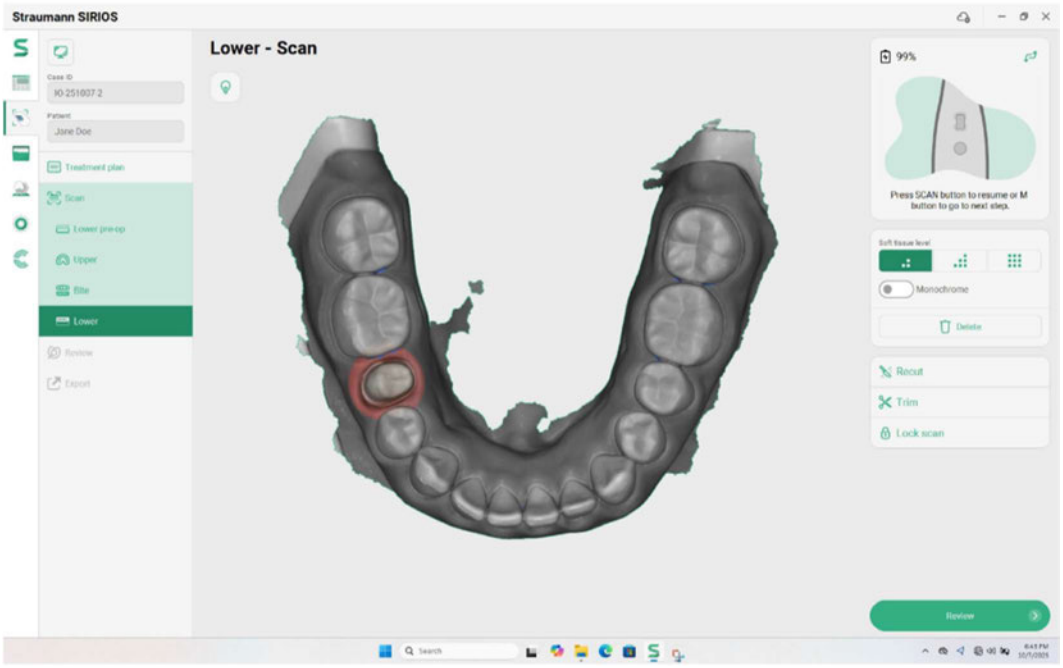


CC_EXEC_00000291

253. When I inspected the SIRIOS scanner, I performed a second test using the scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the

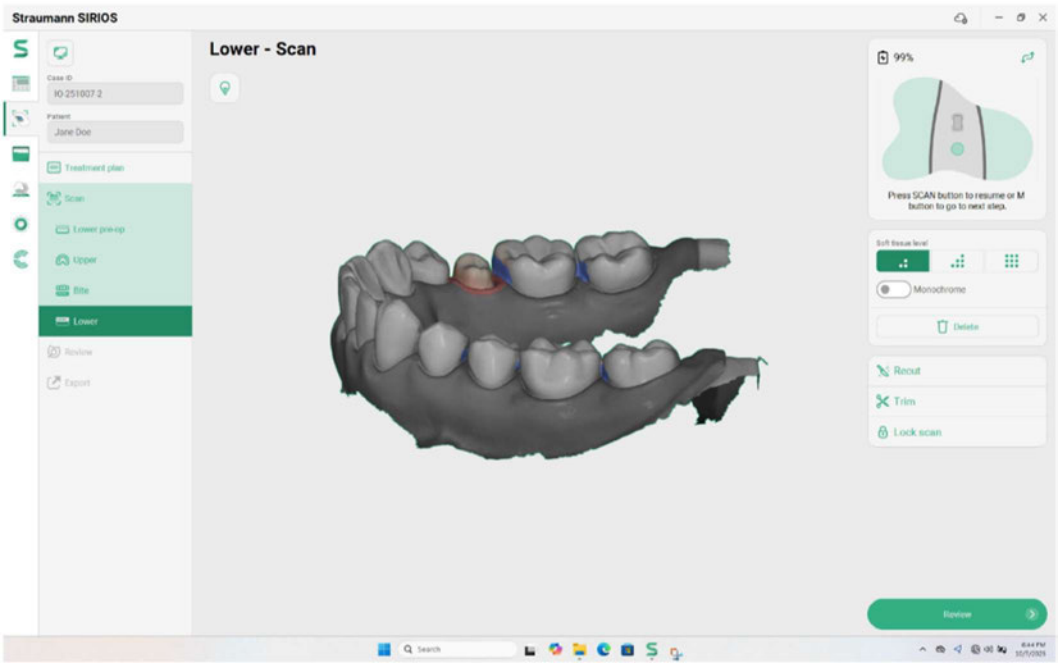
[redacted]

workflow of the SIRIOS scanner system for a crown preparation or other dental procedure where a tooth modification occurs. In this test, I selected on the display screen the tooth (*i.e.*, the lower right second premolar) that was going to be removed and replaced with a modified version of the tooth, one that had undergone a crown preparation procedure. On the typodont, I physically removed the pre-operation tooth with a post-operation crown prepped tooth. Next, I rescanned the post-operation crown prepped tooth. The three images shown below are different views of the second scan of the teeth in the lower arch which included the crown prepped lower right second premolar tooth. The images were received by the computer connected to the SIRIOS scanner of the second scan of the prepped tooth, which is the physically changed portion of the patient's intraoral cavity.

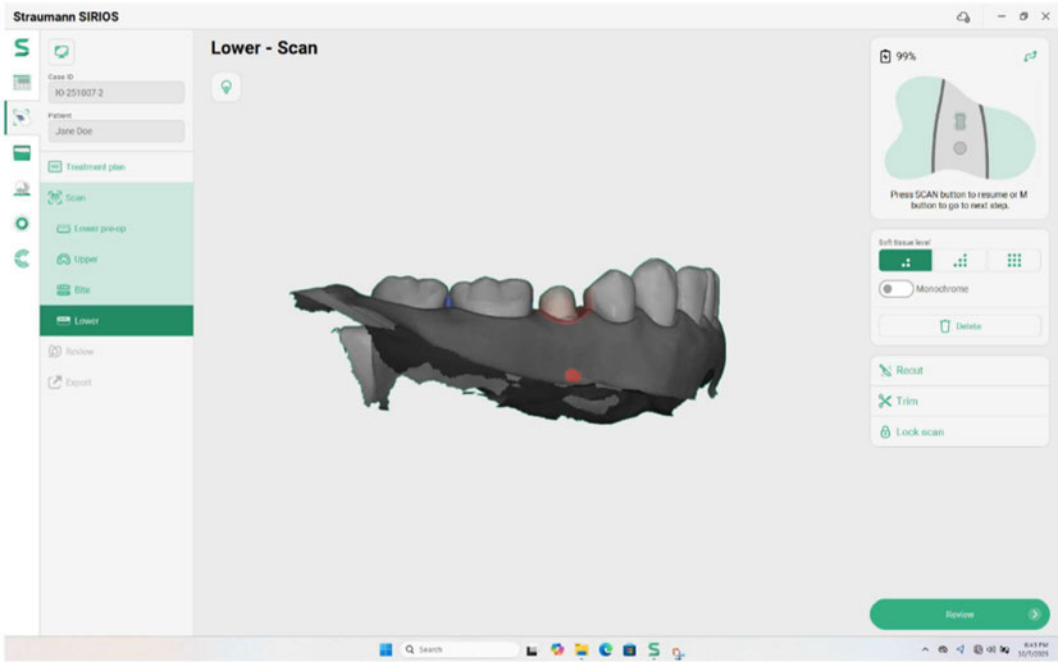


CC_EXEC_00000360

[redacted]



CC_EXEC_00000361



CC_EXEC_00000362

254. As shown above, the SIRIOS scanner system receives second scan data of the patient's teeth from the hand-held intraoral scanner, the scan data including surface data of a

[redacted]

physically changed portion of the patient's intraoral cavity. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim limitation. Accordingly, the SIRIOS scanner system satisfies Claim 1[b][vi].

ix. 1[b][vii]: "replace at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity"

255. The SIRIOS scanner system satisfies Claim 1[b][vii]. The SIRIOS scanner system uses the received second scan data to replace at least a portion of the surface data that was previously removed from the model.[249] The system integrates updated surface information corresponding to the physically changed portion of the patient's intraoral cavity into the existing model framework.[250]

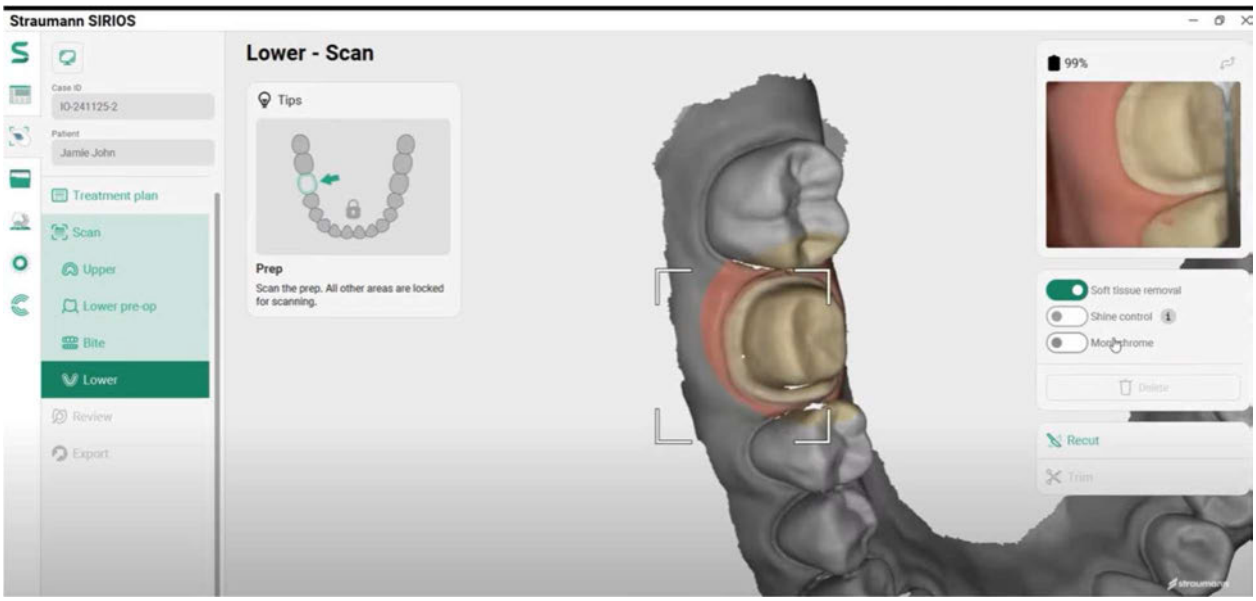
256. For example, the SIRIOS instructional video referenced throughout my report shows a modified three-dimensional model that combines the first and second scan data.[251] The image shows the three-dimensional model's modified scan after the system replaced the removed surface portion with the received second scan data. The first scan is shown in black and white in

[redacted]

[251] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:19 (https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9) (ALGN01637352); *see also Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -351 (explaining that if there are discrepancies or overlapping areas in the scan, the user can "[u]se the Cut tool to eliminate mismatched data and excess tissue, then conduct a rescan").

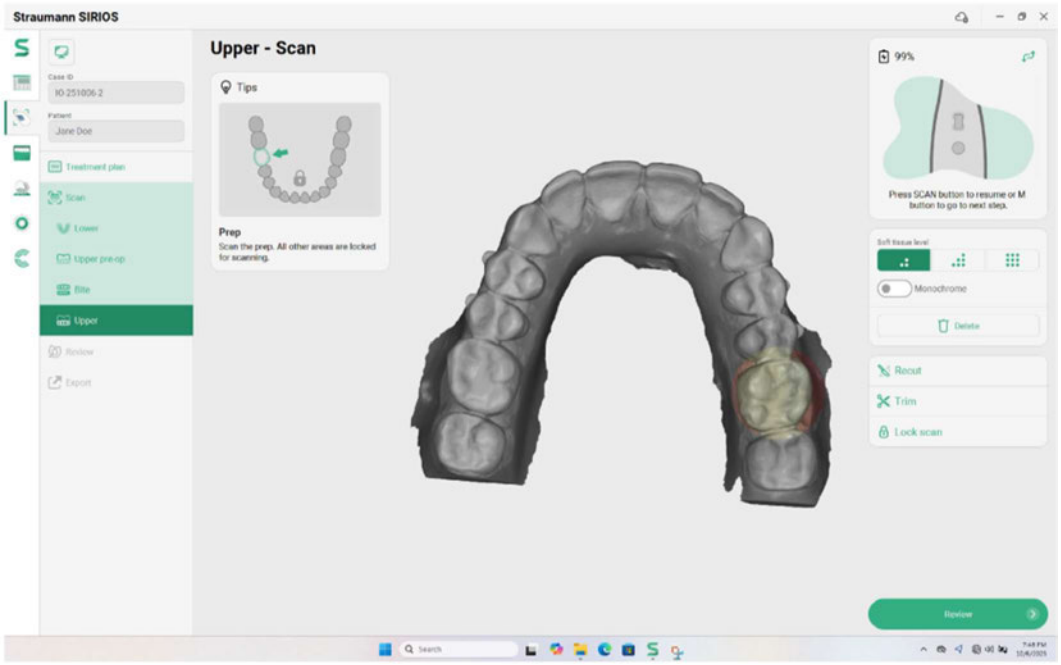
[redacted]

the image below. It shows the scan data received in the second scan in color.

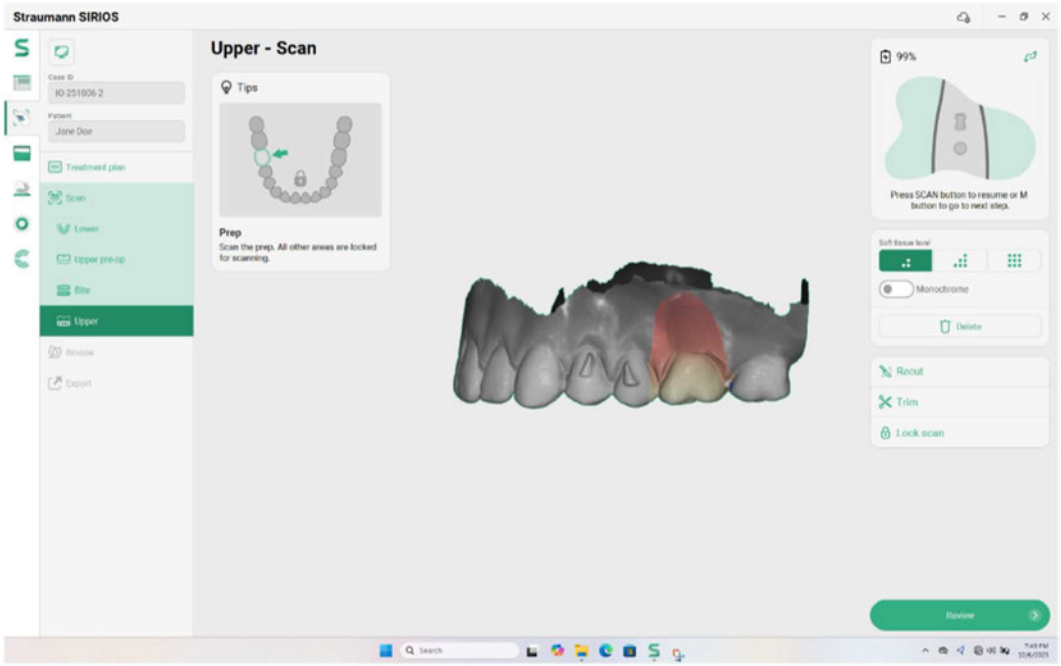


257. When I inspected the SIRIOS scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the SIRIOS scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris. After scanning the upper dental arch with the toothpaste on the tooth, I used the mouse of the laptop to select this tooth to be removed from the first scan using the cut tool. Then I physically removed the toothpaste from the tooth and rescanned the tooth. Below are three different views of the same image after the first scan of the tooth with debris was replaced with the received second scan data of the tooth without the debris.

[redacted]

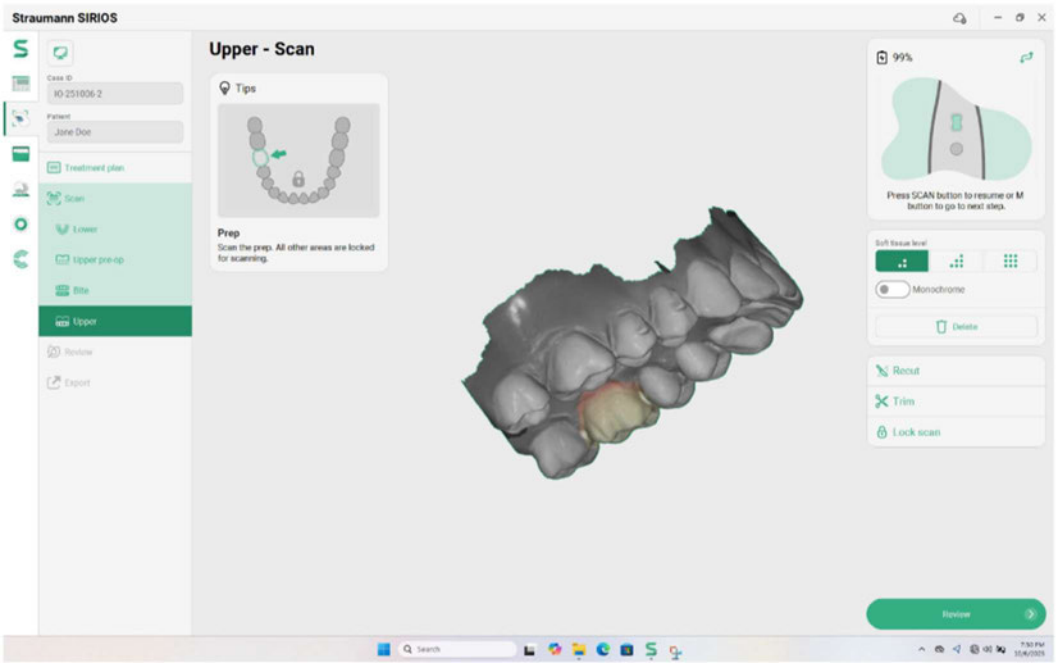


CC_EXEC_00000289



CC_EXEC_00000290

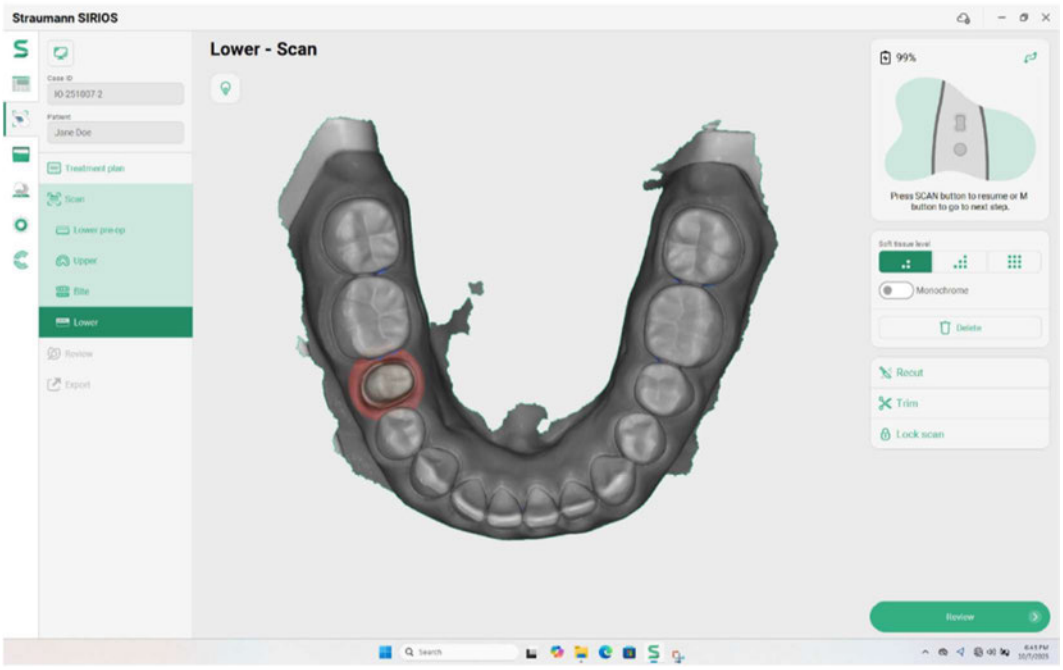
[redacted]



CC_EXEC_00000291

258. I also performed a second test using the SIRIOS scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the upper dental arch with the pre-operation tooth, I used the mouse of the laptop to select this tooth so that it would be removed from this first scan using the cut tool. I then replaced the typodont pre-operation tooth with a typodont post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are three different views of the same image after the first scan of the pre-operation tooth was replaced with the received second scan data of the post-operation crown preparation tooth.

[redacted]

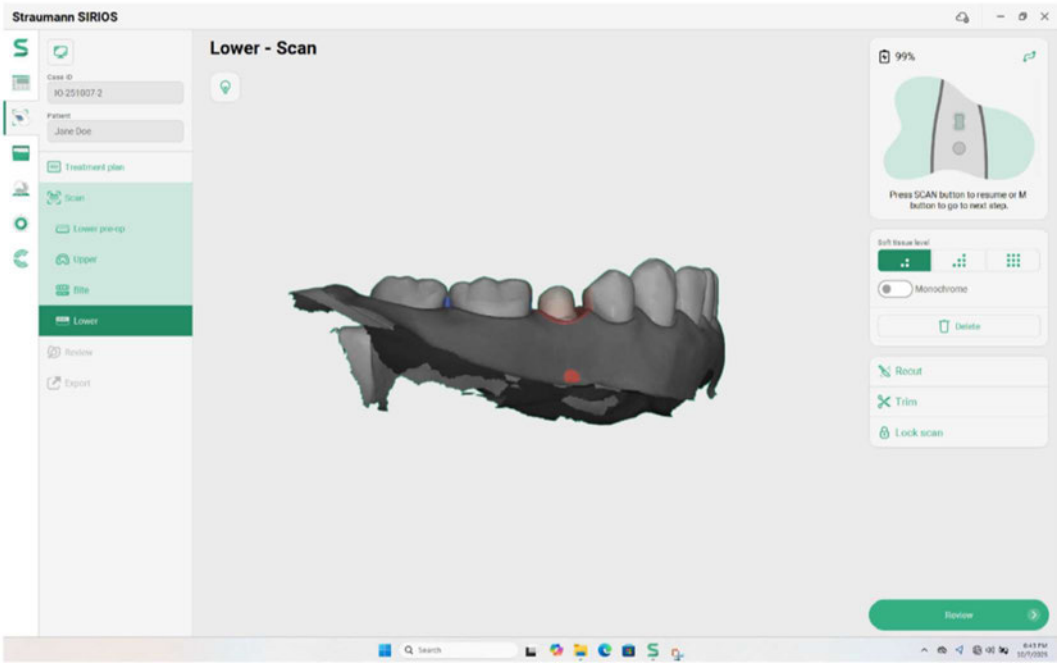


CC_EXEC_00000360



CC_EXEC_00000361

[redacted]



CC_EXEC_00000362

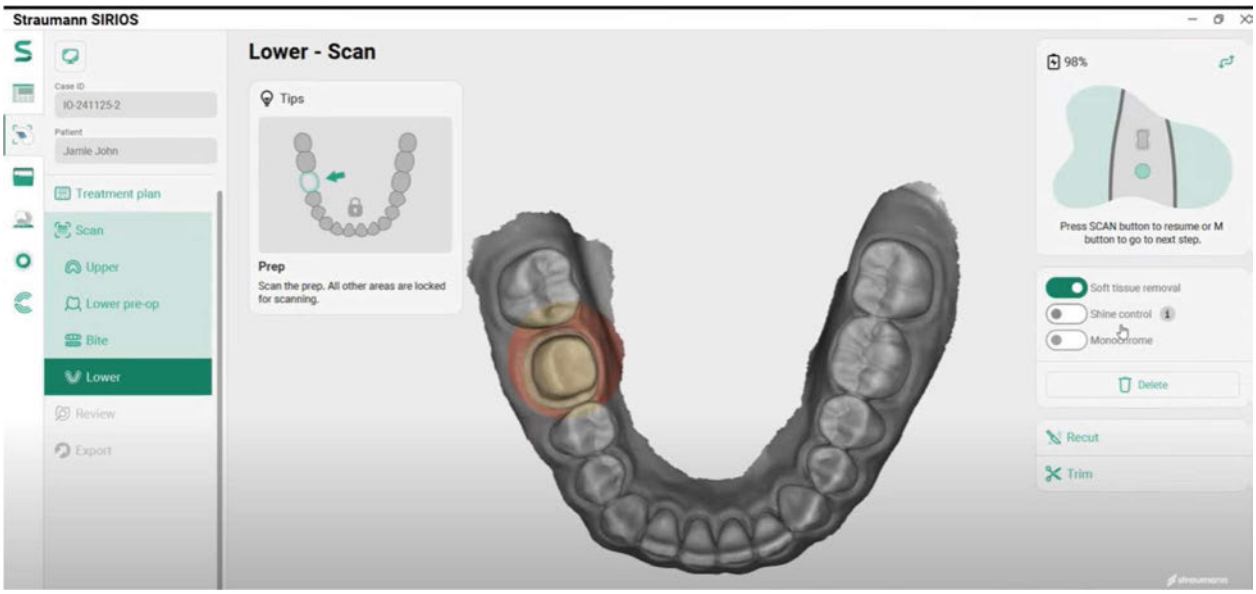
259. As shown above, the SIRIOS scanner system replaces at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim limitation. Accordingly, the SIRIOS scanner system satisfies Claim 1[b][vii].

x. 1[b][viii]: "output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the second scan data."

260. The SIRIOS scanner system satisfies Claim 1[b][viii]. Following replacement of the removed surface portion using the second scan data, the SIRIOS scanner system outputs the

[redacted]

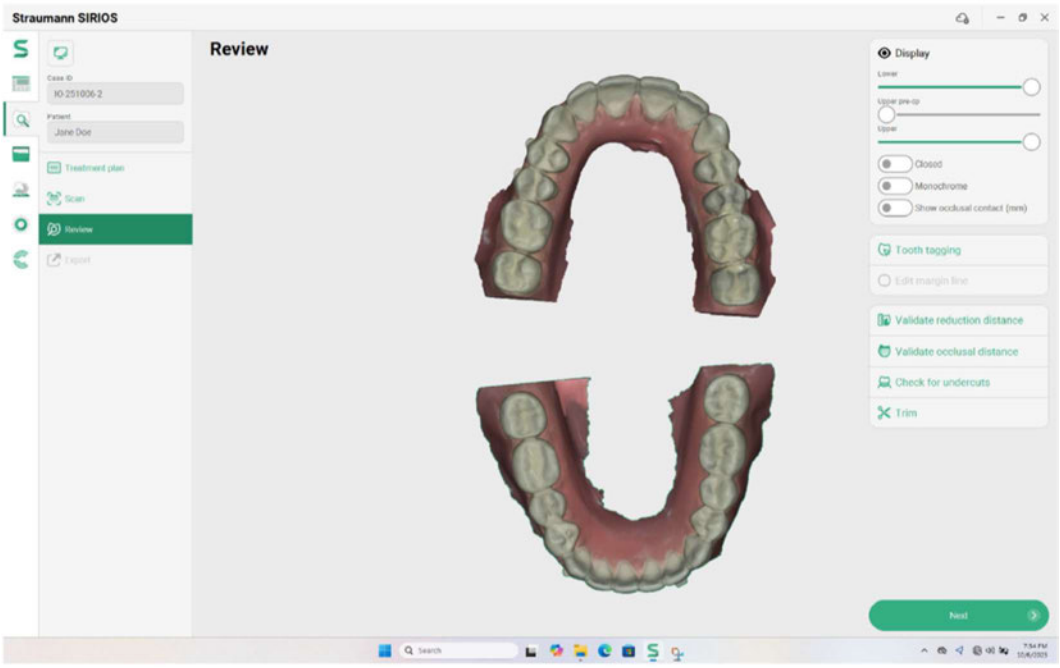
updated digital model to the display. The displayed 3D model reflects the incorporation of the new scan data into the previously removed region, as shown below.[252]



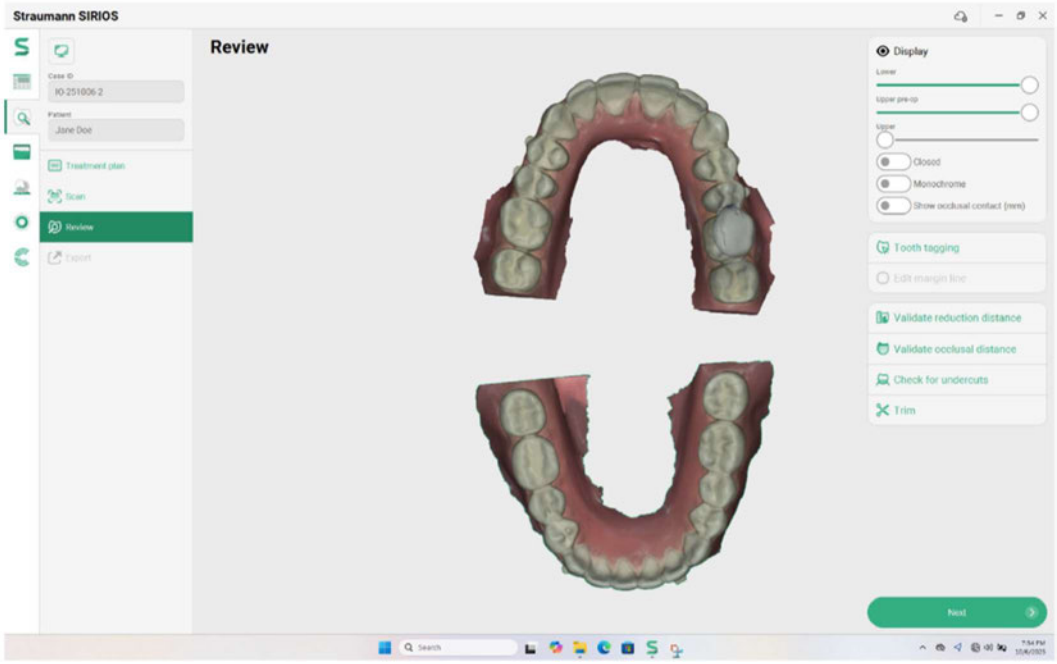
261. When I inspected the SIRIOS scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris on or between the patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan using the cut tool. Then I removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. The first image below is an image of the output to the display of the model of the patient's upper arch after the removed surface portion was replaced by the second scan. The second image below is an image of the model of the patient's upper arch before the removed surface portion was replaced by the second scan.

[252] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:33 (https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9) (ALGN01637352); *see also Instructions*, Straumann SIRIOS (CC_ALGN_03169301) at -351 (explaining that if there are discrepancies or overlapping areas in the scan, the user can "[u]se the Cut tool to eliminate mismatched data and excess tissue, then conduct a rescan").

[redacted]



CC_EXEC_00000285

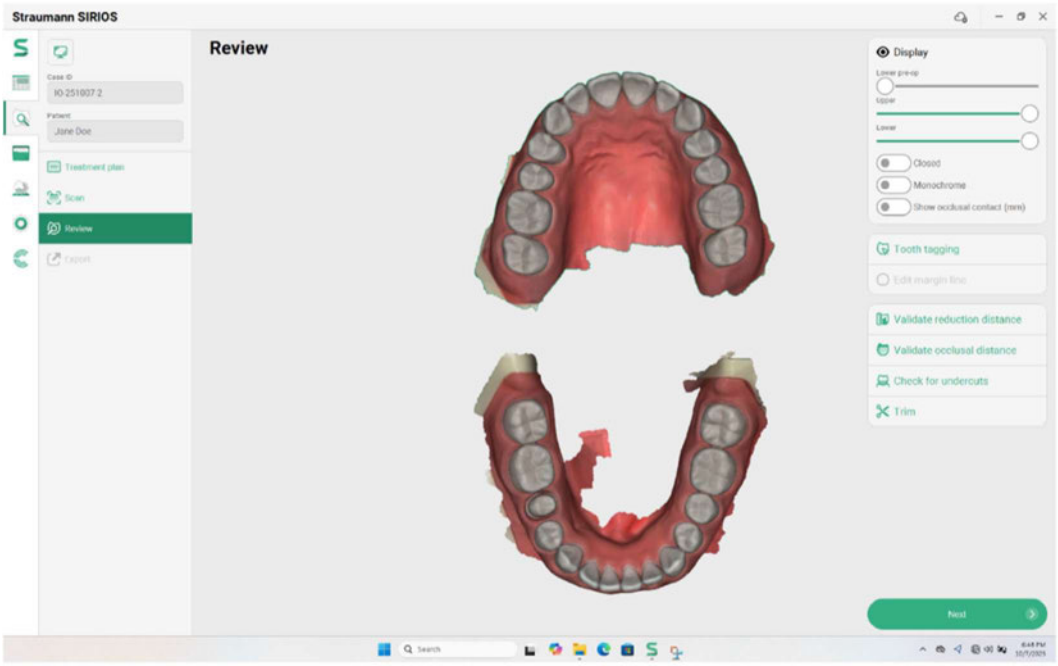


CC_EXEC_00000286

262. I also performed a second test using the SIRIOS scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation

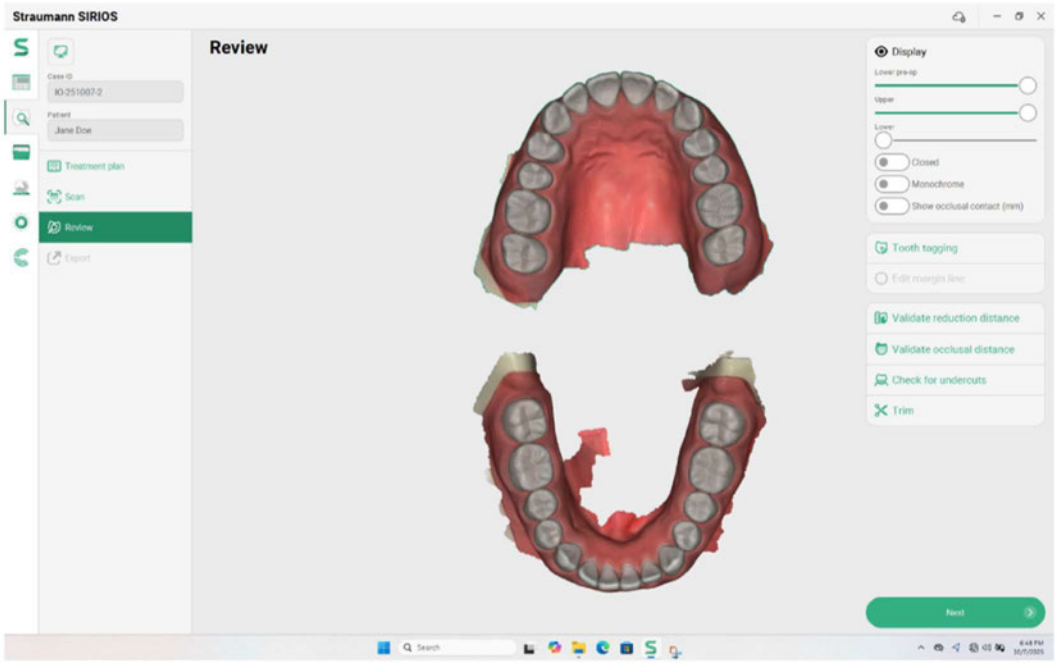
[redacted]

or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the lower dental arch with the pre-operation tooth, I selected this tooth so that it would be removed from this first scan using the cut tool. I then replaced the typodont pre-operation tooth with a typodont post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth.



CC_EXEC_00000367

[redacted]



CC_EXEC_00000368

263. As shown above, the SIRIOS scanner system outputs, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the second scan data. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim limitation. Accordingly, the SIRIOS scanner system satisfies Claim 1[b][viii].

b. Claim 4

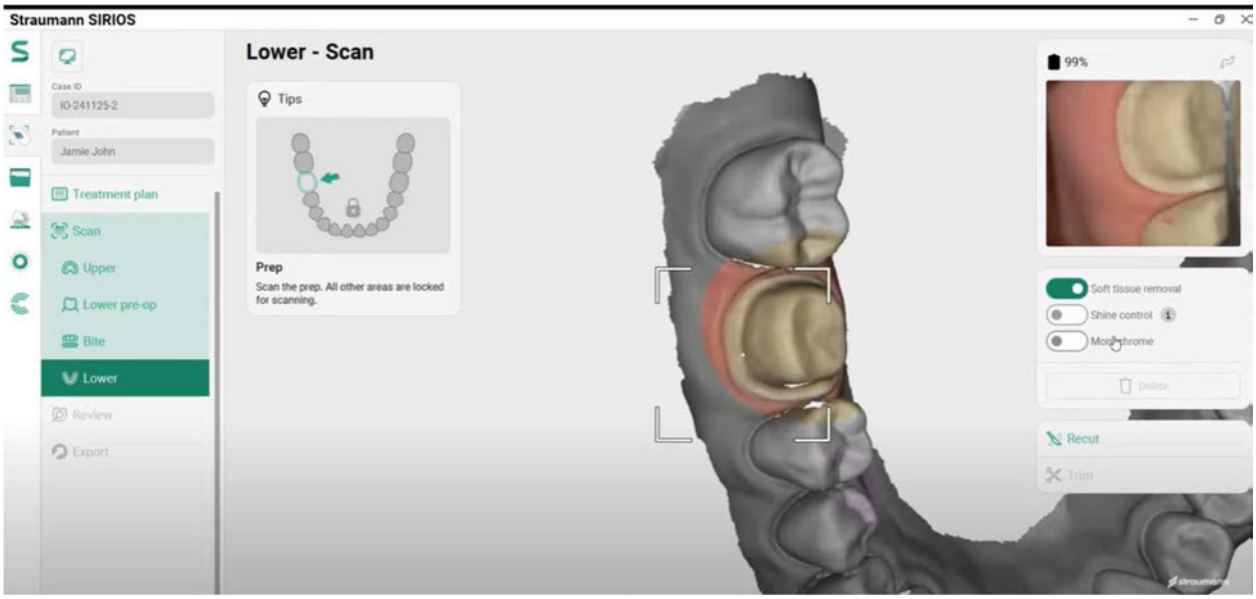
i. "The system of Claim 1, wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to register the received second scan data with the model."

264. The SIRIOS scanner system satisfies Claim 4. As described in connection with Claim 1[b][vii], the SIRIOS software replaces removed surface portions of a digital dental model using subsequently acquired scan data. In performing this replacement, the system aligns the

[redacted]

second scan data with the existing model so that the new surface data corresponds correctly to the remaining portions of the model.[253]

265. For example, the SIRIOS scanner instructional video referenced throughout my report shows SIRIOS software aligning the second scan data with the existing model.[254]



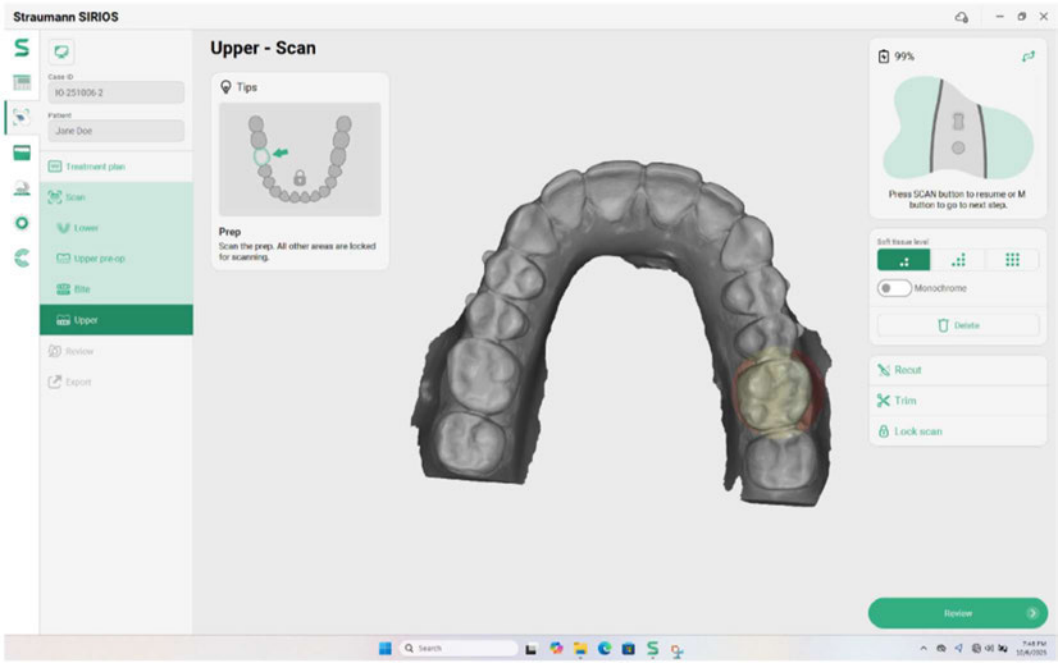
266. When I inspected the SIRIOS scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris on or between a patient's teeth. In this test, I first scanned the upper arch which included the left first molar with toothpaste on it. Then I selected the tooth with debris to be removed from the first scan using the cut tool. After I selected the tooth with debris to be removed, I removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. Below are three

[redacted]

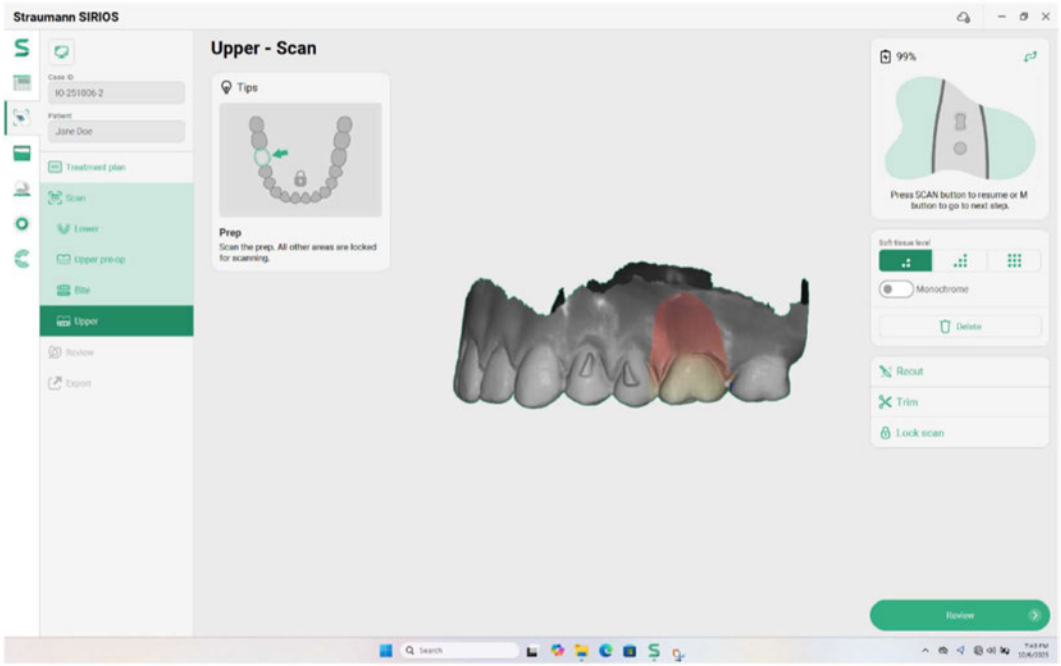
[254] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:19. https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352).

[redacted]

different views of the same image showing that the SIRIOS scanner system replaced the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model.

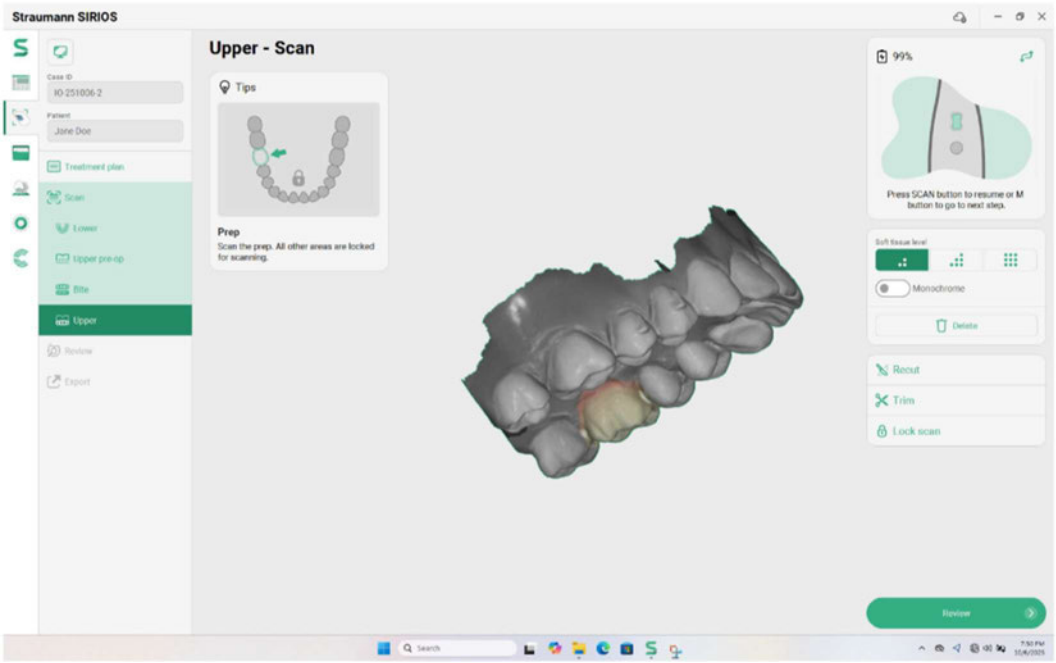


CC_EXEC_00000289



[redacted]

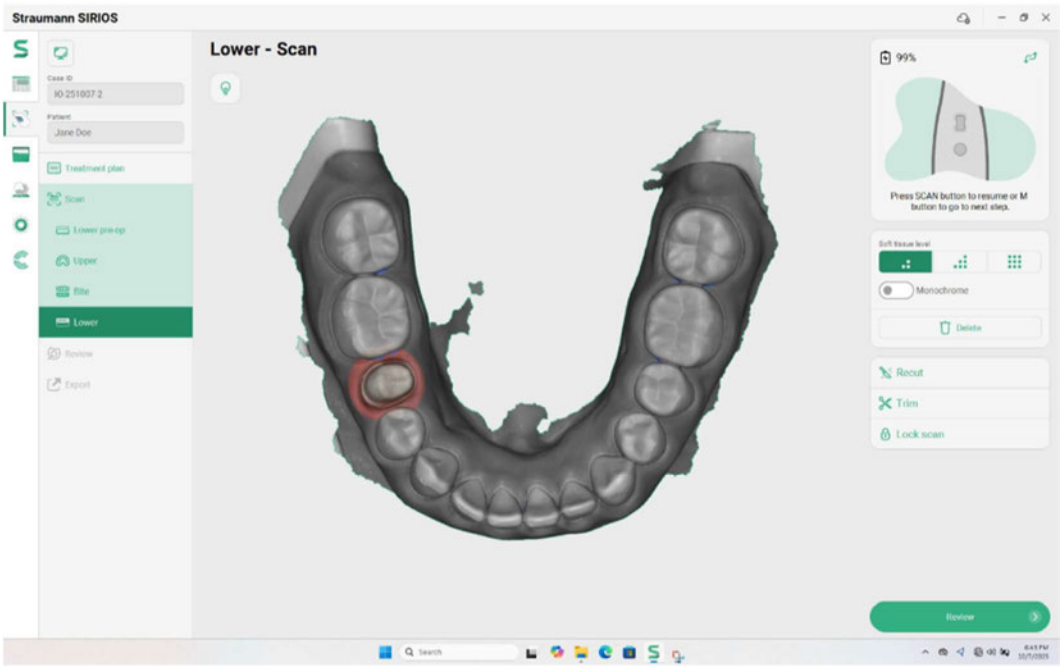
CC_EXEC_00000290



CC_EXEC_00000291

267. I also performed a second test using the SIRIOS scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the lower dental arch with the pre-operation tooth, I selected this tooth so that it would be removed from this first scan using the cut tool. Then I replaced the typodont pre-operation tooth with the post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are images showing that the SIRIOS scanner system replaced the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model.

[redacted]

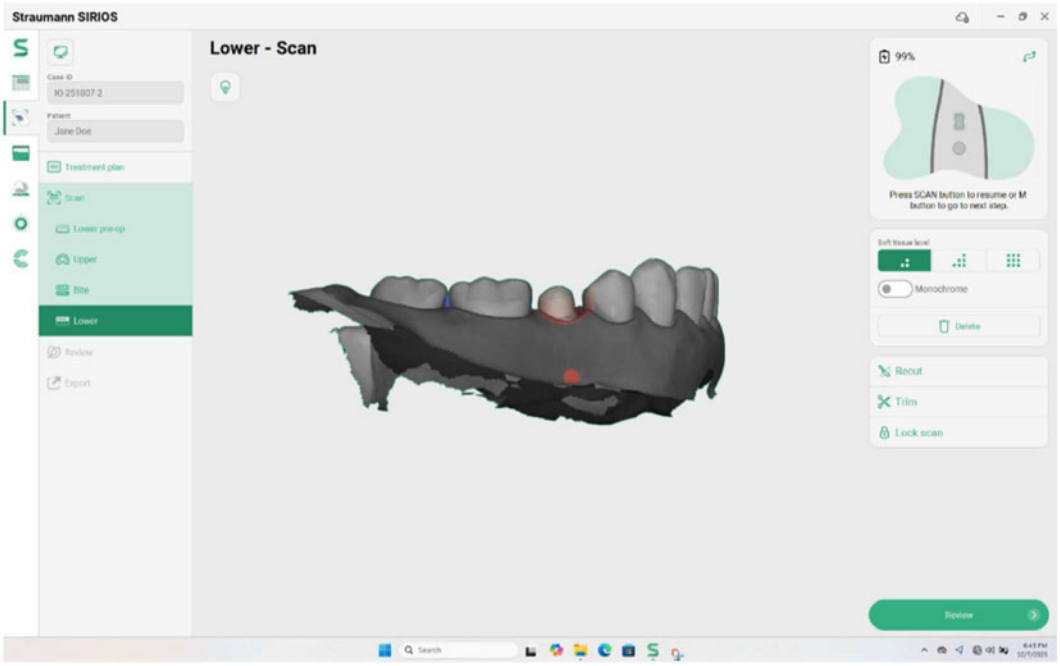


CC_EXEC_00000360



CC_EXEC_00000361

[redacted]



CC_EXEC_00000362

268. As shown above, the SIRIOS scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim. Accordingly, the SIRIOS scanner system satisfies Claim 4.

c. Claim 5

i. "The system of Claim 4, wherein the received second scan data is registered with the model by aligning identifying data of the received second scan data with corresponding parts of the model."

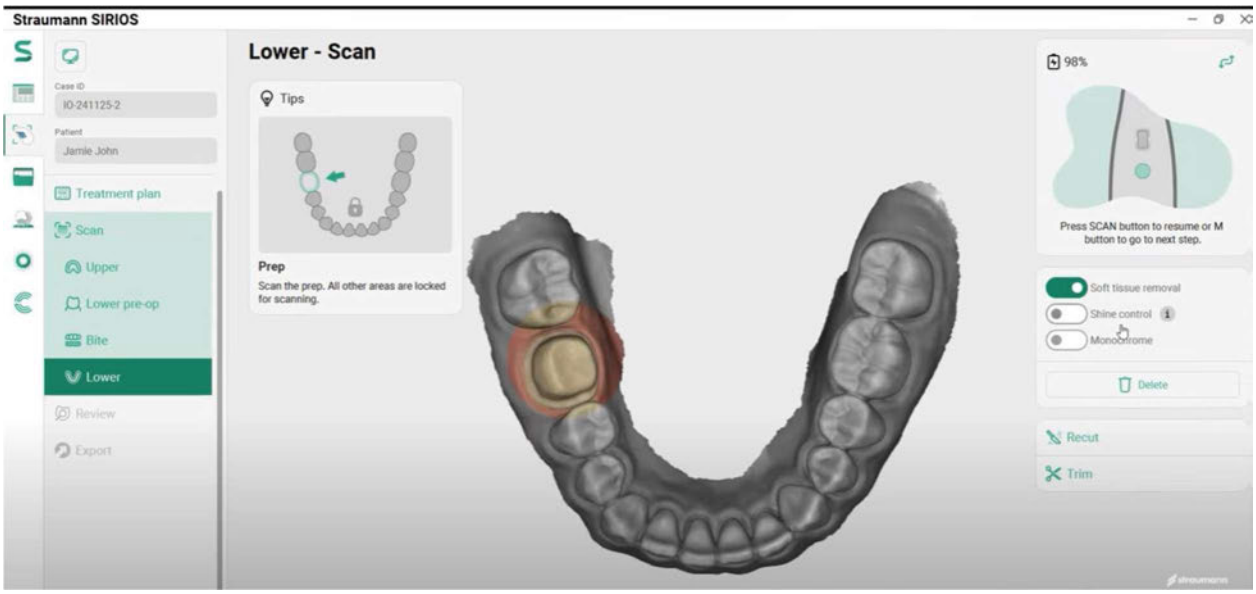
269. The SIRIOS scanner system satisfies Claim 5. When registering second scan data with an existing model, the SIRIOS software appears to align identifiable features or data points

[redacted]

in the second scan data—such as overlapping surface geometry, contours, or other distinguishing characteristics—with corresponding parts of the existing digital model.[255]

270. This alignment of identifying data enables the system to determine how the new scan data corresponds spatially to the previously captured model. By matching these identifying features, the SIRIOS scanner system ensures that the second scan data is accurately positioned relative to the existing model before replacement occurs. This process falls within the requirement of registering scan data "by aligning identifying data … with corresponding parts of the model," as recited in Claim 5.

271. For example, the SIRIOS scanner instructional video referenced throughout my report shows SIRIOS software aligning the second scan data with the existing model.[256]

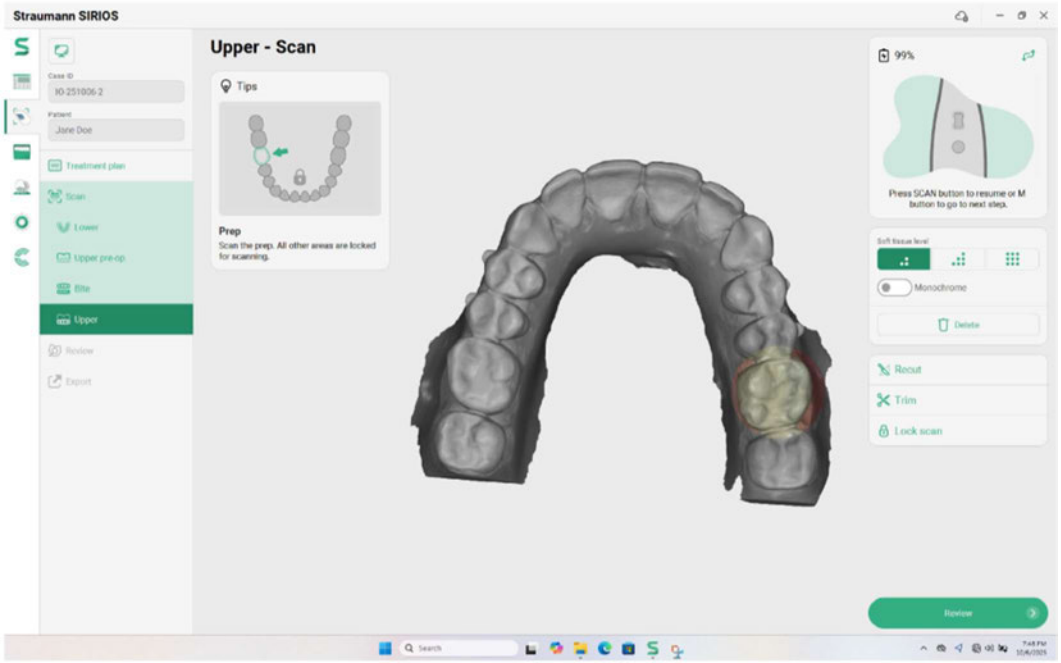


[redacted]

[256] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:19, https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352).

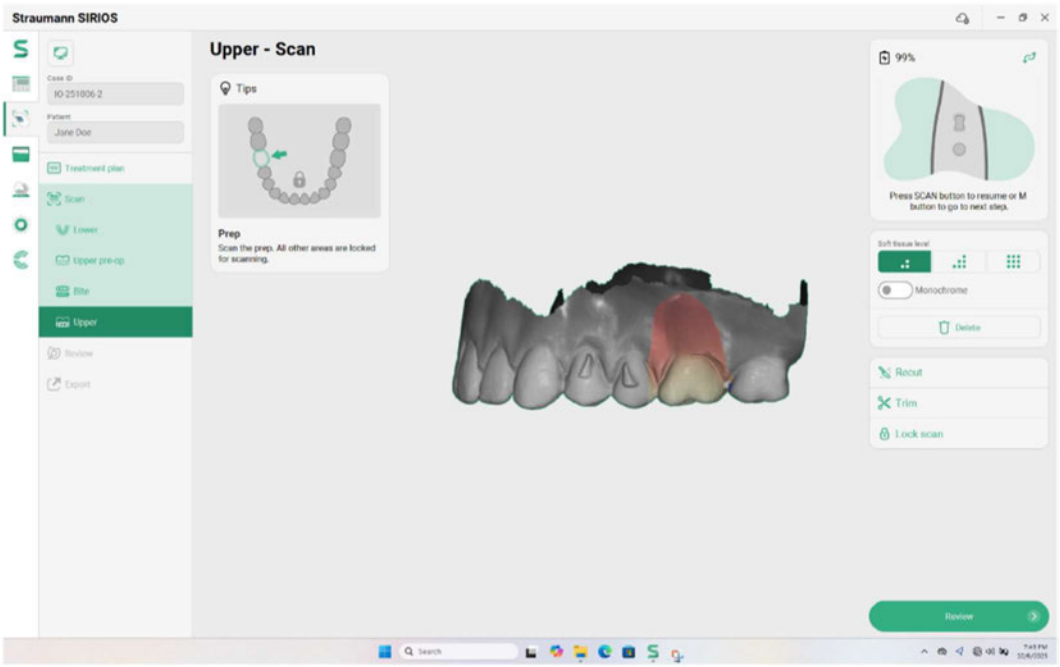
[redacted]

272. When I inspected the SIRIOS scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris on or between a patient's teeth. In this test, I first scanned the upper arch which included the left first molar with toothpaste on it. Then I selected the tooth with debris to be removed from the first scan using the cut tool. After I selected the tooth with debris to be removed, I removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. Below are three different views of the same image showing that the SIRIOS scanner system registered the second scan data by identifiable features in the second scan data with corresponding parts of the existing digital model.

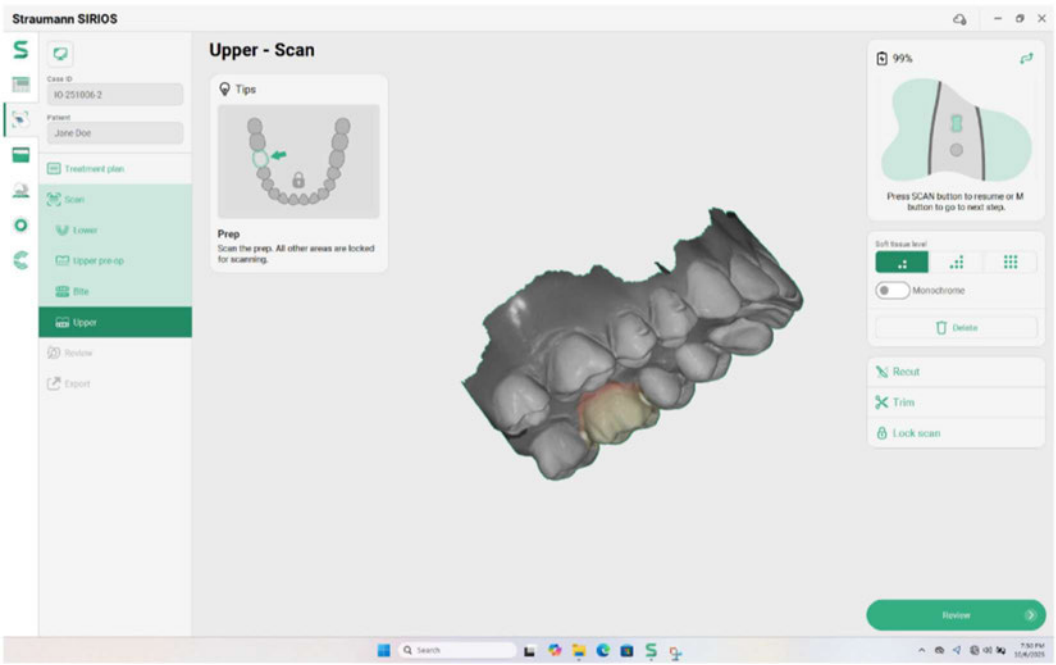


CC_EXEC_00000289

[redacted]



CC_EXEC_00000290

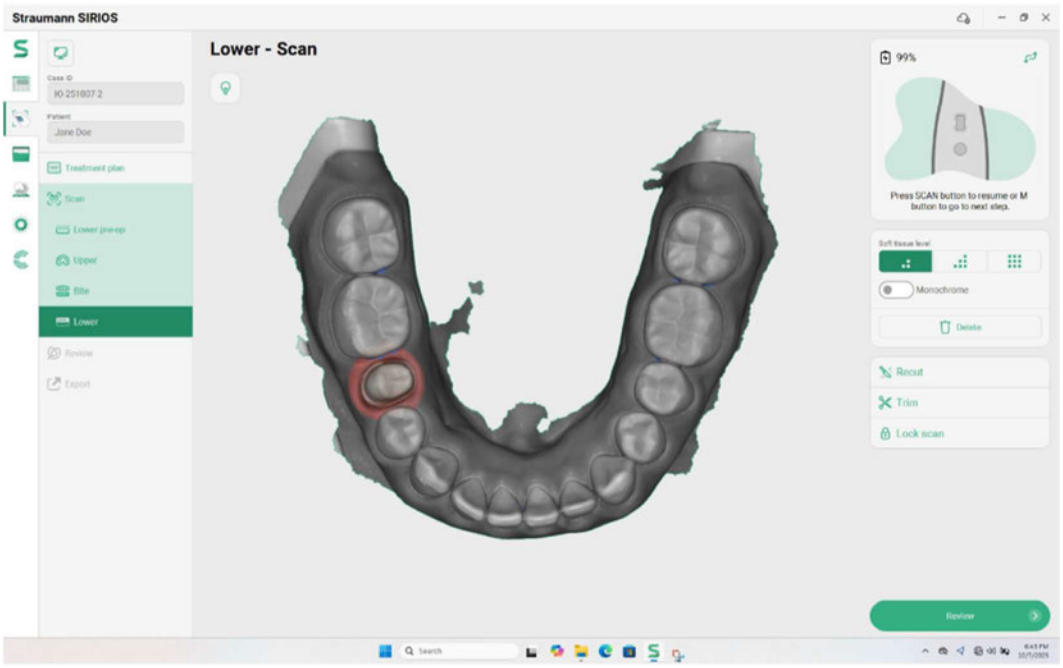


CC_EXEC_00000291

273. I also performed a second test using the SIRIOS scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation

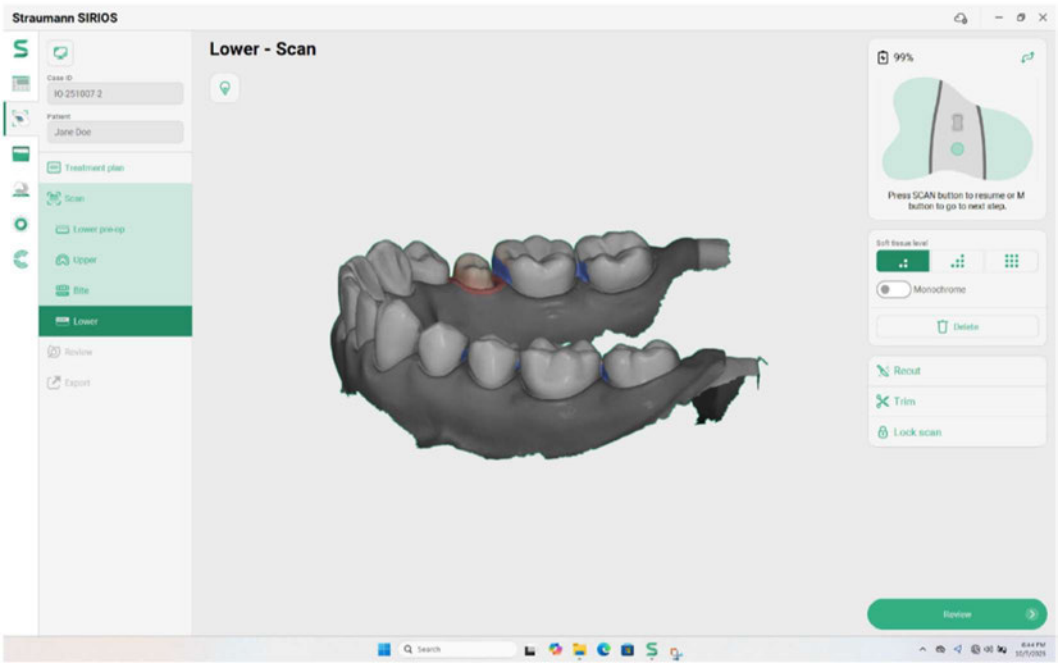
[redacted]

or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the lower dental arch with the pre-operation tooth, I selected this tooth so that it would be removed from this first scan using the cut tool. Then I replaced the typodont pre-operation tooth with the post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are images showing that the SIRIOS scanner system registered the second scan data by identifiable features in the second scan data with corresponding parts of the existing digital model.

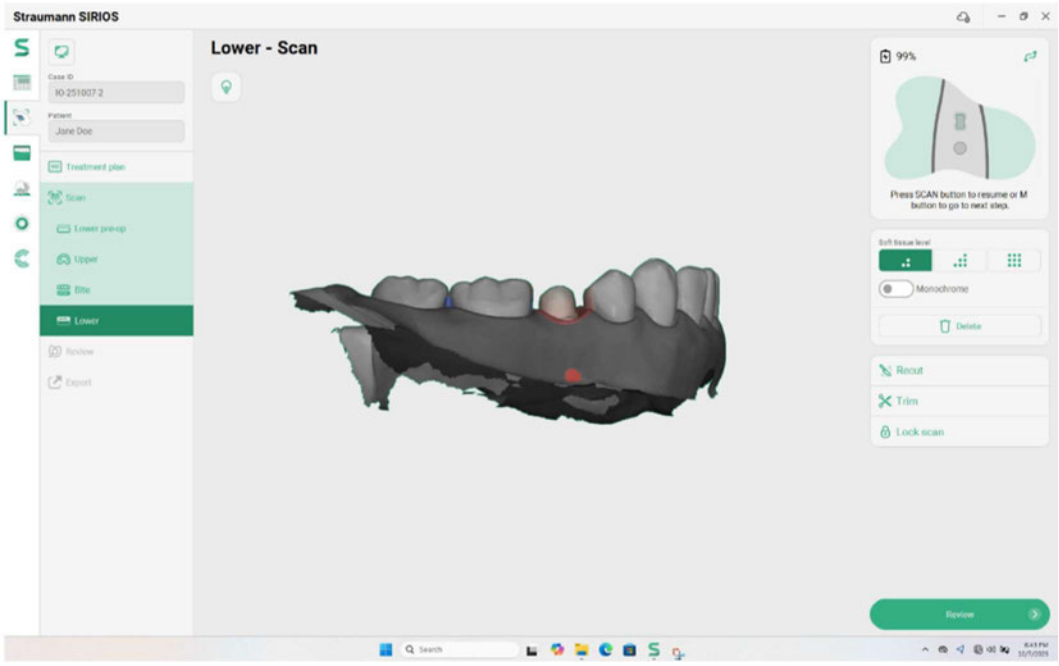


CC_EXEC_00000360

[redacted]



CC_EXEC_00000361



CC_EXEC_00000362

274. As shown above, the SIRIOS scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data by registering the

[redacted]

received second scan data with the model. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim. Accordingly, the SIRIOS scanner system satisfies Claim 5.

d. Claim 6

ii. "The system of Claim 5, wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further stitch a portion of the received second scan data with the model."

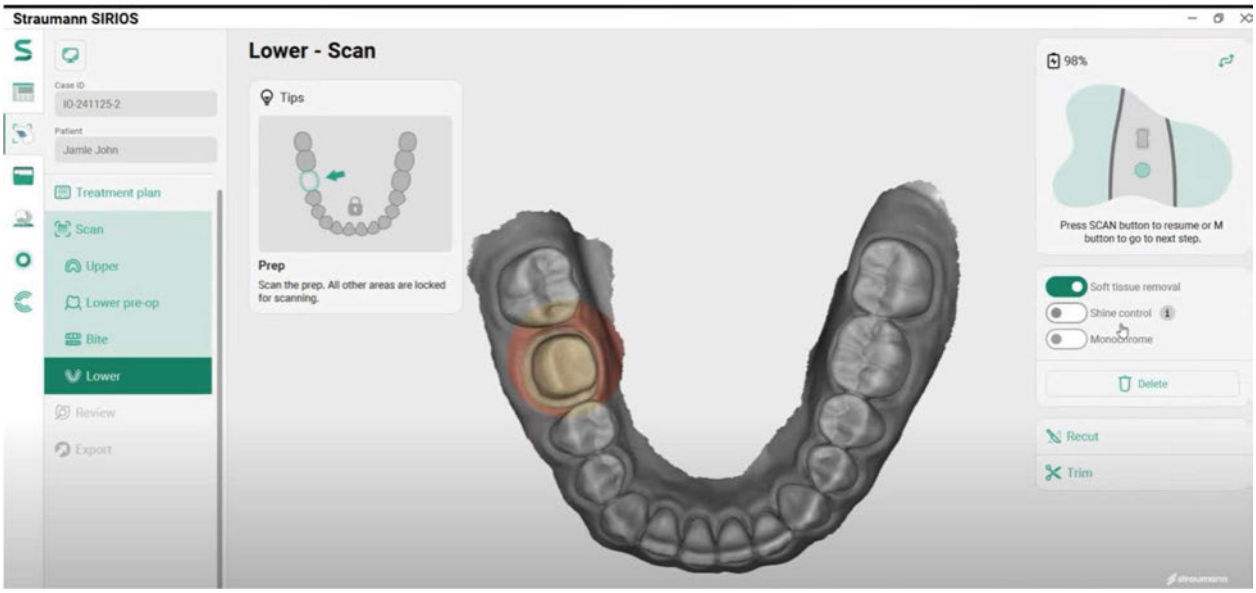
275. The SIRIOS scanner system satisfies Claim 6. In addition to registering the second scan data with the existing model, the SIRIOS software further stitches the new scan data into the model. Stitching refers to the process of merging or blending overlapping surface data from the second scan with the existing model so as to create a continuous and coherent surface representation.

276. The SIRIOS scanner system performs this stitching to ensure a seamless transition between the previously retained portions of the model and the newly added surface data. This stitching step is part of the replacement process and is necessary to produce a usable, unified digital model. As a result, the SIRIOS scanner system includes instructions to stitch a portion of the received second scan data with the model, thereby satisfying Claim 6.

277. For example, the SIRIOS scanner instructional video referenced throughout my report shows SIRIOS software stitching a portion of the received second scan data with the model.[257]

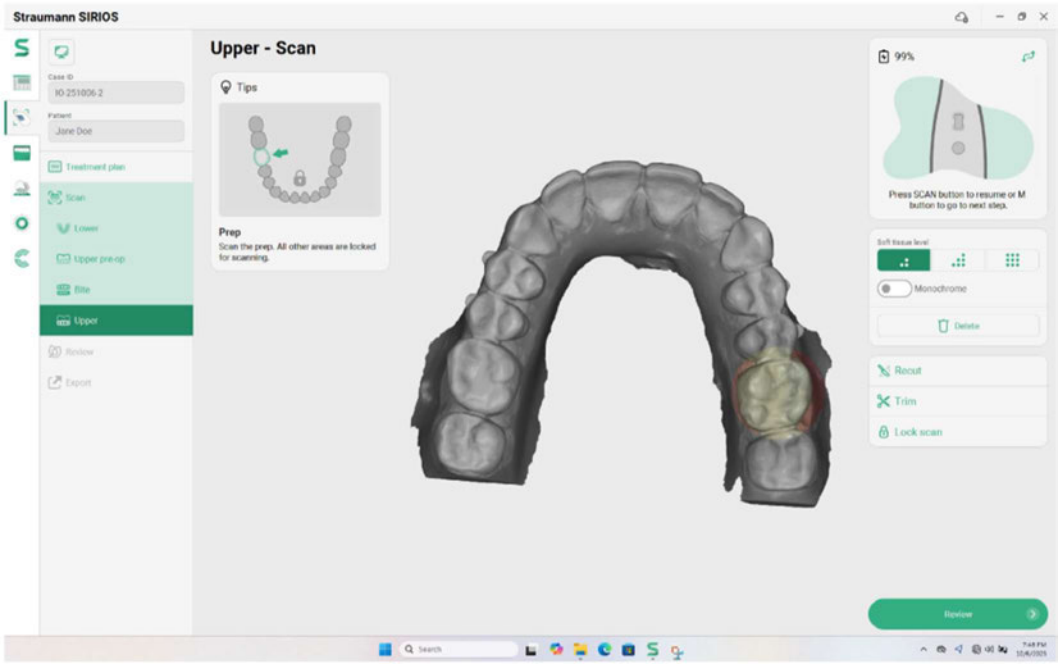
[257] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:33, https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352).

[redacted]

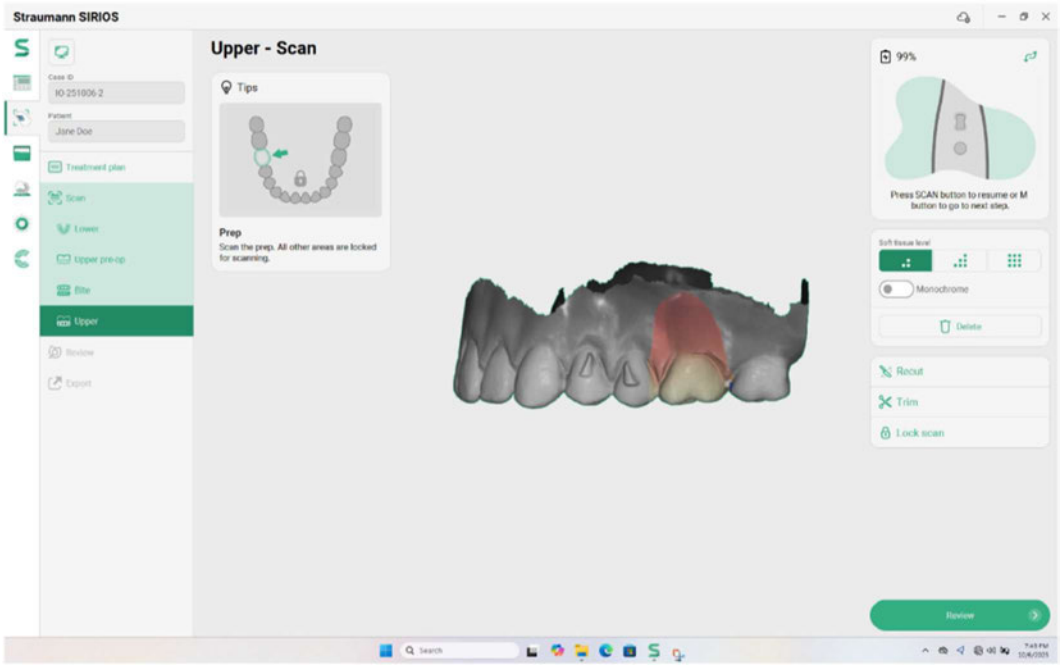


278. When I inspected the SIRIOS scanner, I used it to perform a first test with toothpaste added to one tooth on the upper arch of the typodont to simulate debris on or between a patient's teeth. In this test, I selected the upper left first molar as the tooth with debris to be removed from the first scan using the cut tool. Then I removed the toothpaste from the tooth. Next, I rescanned the tooth that I removed the toothpaste from. Below are images showing that the SIRIOS scanner system stitched a portion of the received second scan data with the existing model.

[redacted]

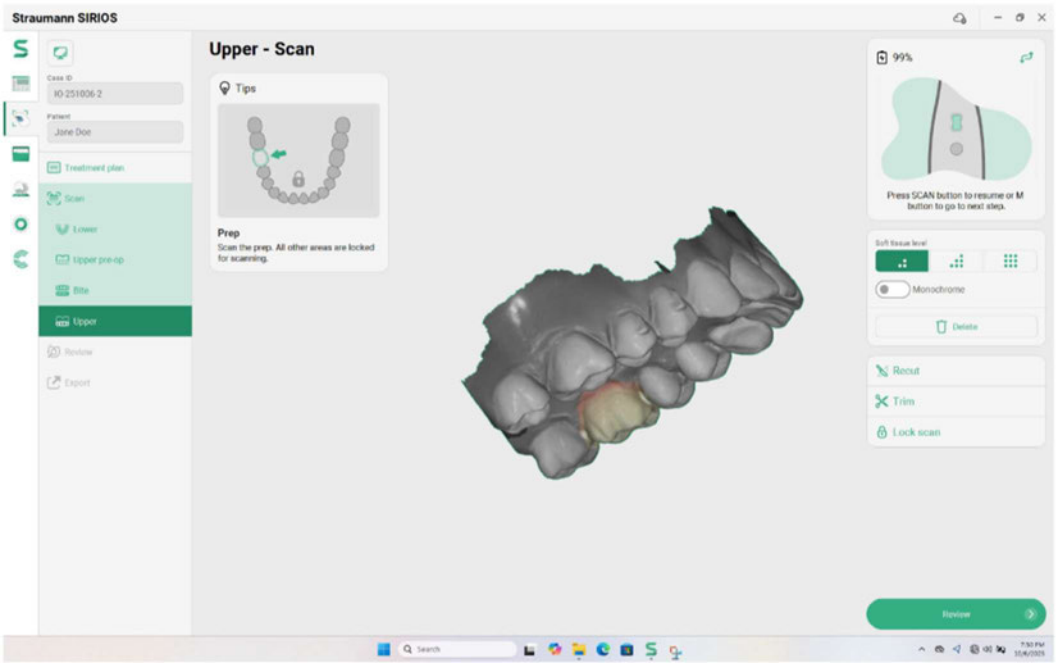


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CC_EXEC_00000290

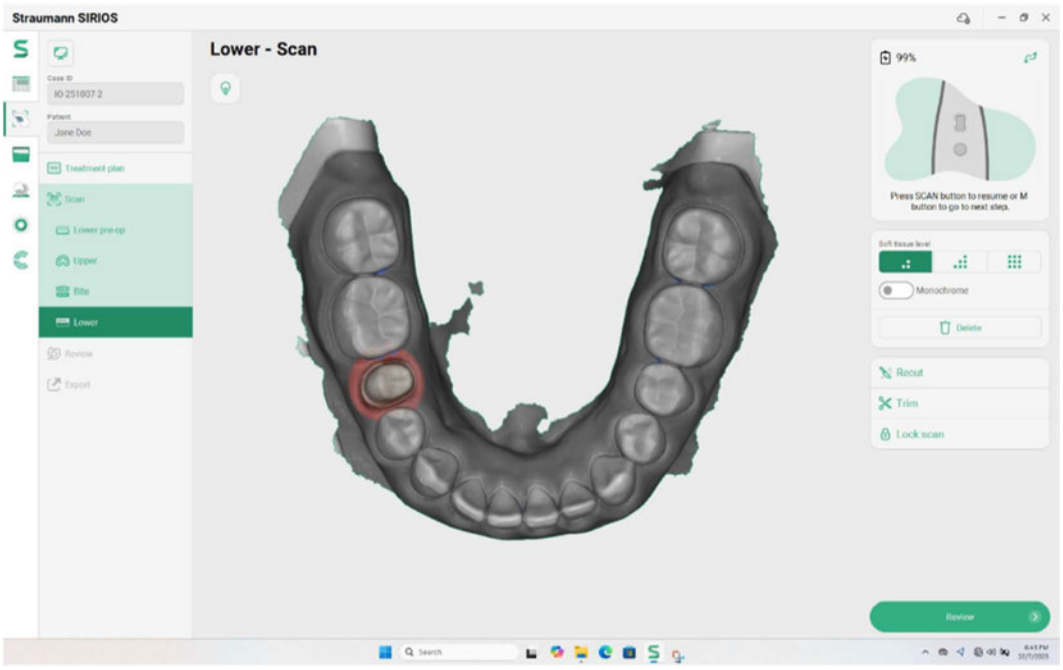
[redacted]



CC_EXEC_00000291

279. When I inspected the SIRIOS scanner, I also used it to perform a second test with a crown preparation tooth to simulate the workflow for a crown preparation or other dental procedure. In this test, I selected the lower right second premolar as the tooth that was going to be replaced with a crown preparation tooth. Then I replaced the tooth with the post-operation crown preparation tooth. Next, I rescanned the post-operation crown preparation tooth. Below are images showing that the SIRIOS scanner system stitched a portion of the received second scan data with the existing model.

[redacted]

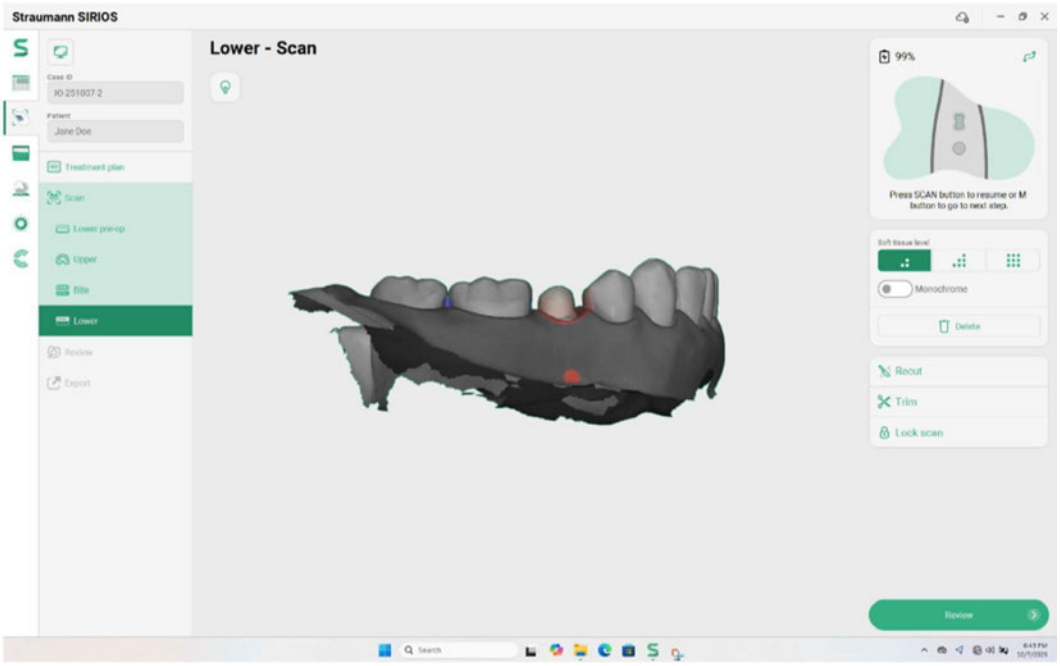


CC_EXEC_00000360



CC_EXEC_00000361

[redacted]



CC_EXEC_00000362

280. As shown above, the SIRIOS scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further stitch a portion of the received second scan data with the model. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim. Accordingly, the SIRIOS scanner system satisfies Claim 4.

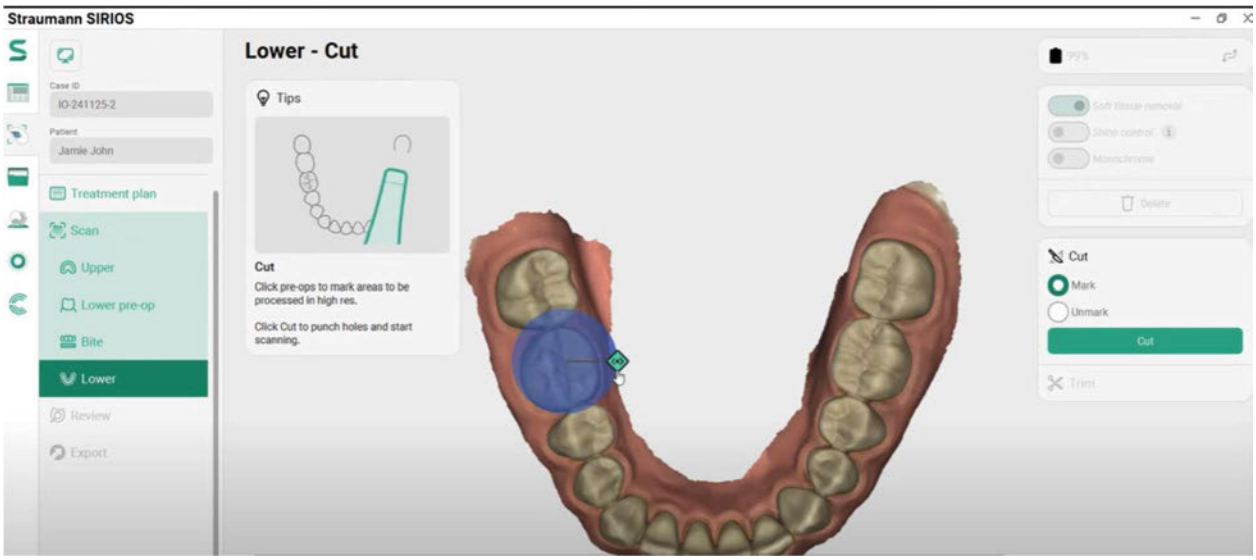
e. Claim 8

iii. "The system of Claim 1, wherein the computer readable medium further includes instructions that when executed by the computer system, cause the computer system to: mark, on the displayed model, the user input defined portion, after receiving the user input and before removing the removed surface portion of the model."

281. The SIRIOS scanner system satisfies Claim 8. As discussed above for Claim 1[b][iv], the SIRIOS software allows a user to define a portion of the displayed model for removal. As shown in the images above and reproduced below, the user draws a shape around the portion of the displayed model for removal. After receiving this user input and before

[redacted]

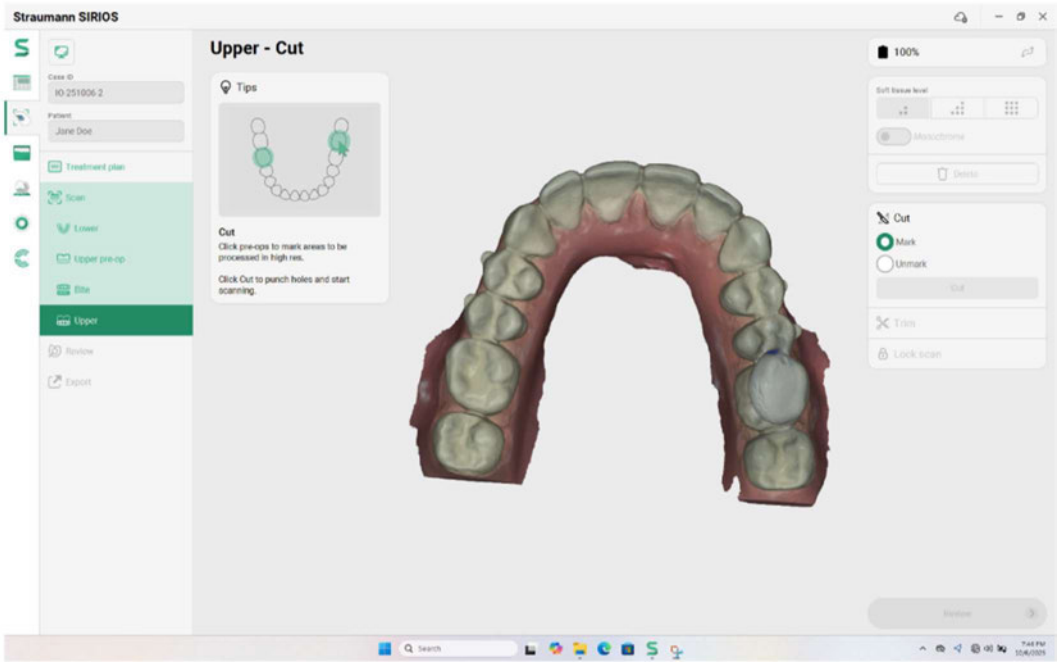
actually removing the surface portion, the system visually marks or highlights the selected region on the displayed model, as shown below.[258]



282. When I inspected the SIRIOS scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris on or between a patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan using the cut tool. Below is an image of the start screen for the cut tool.

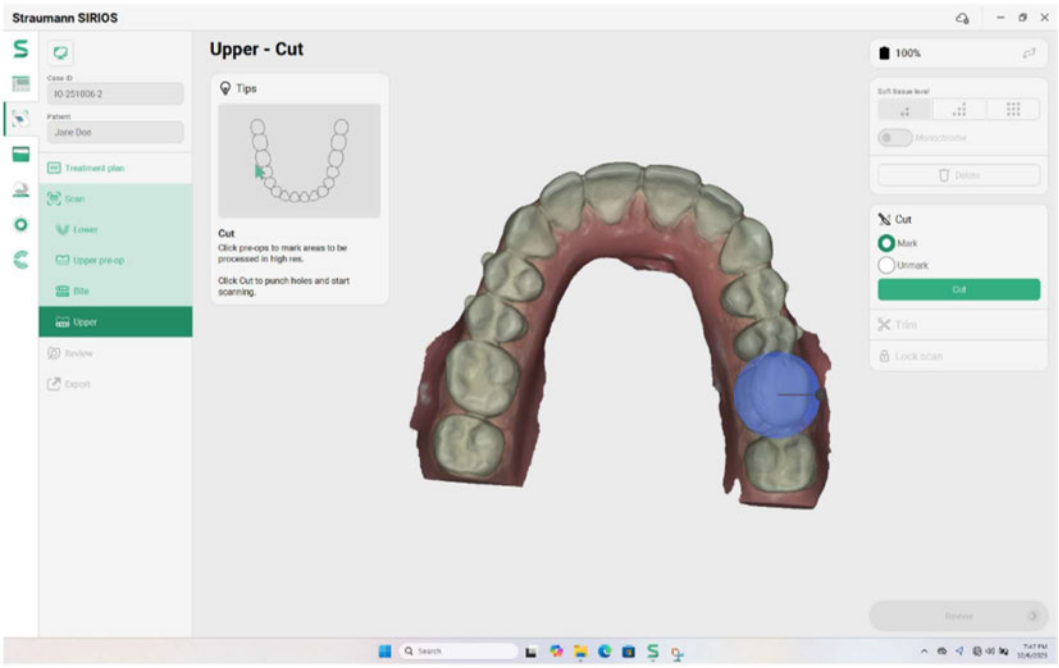
[258] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:08, https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352) (showing the process of selecting a portion of the virtual model).

[redacted]



CC_EXEC_00000294

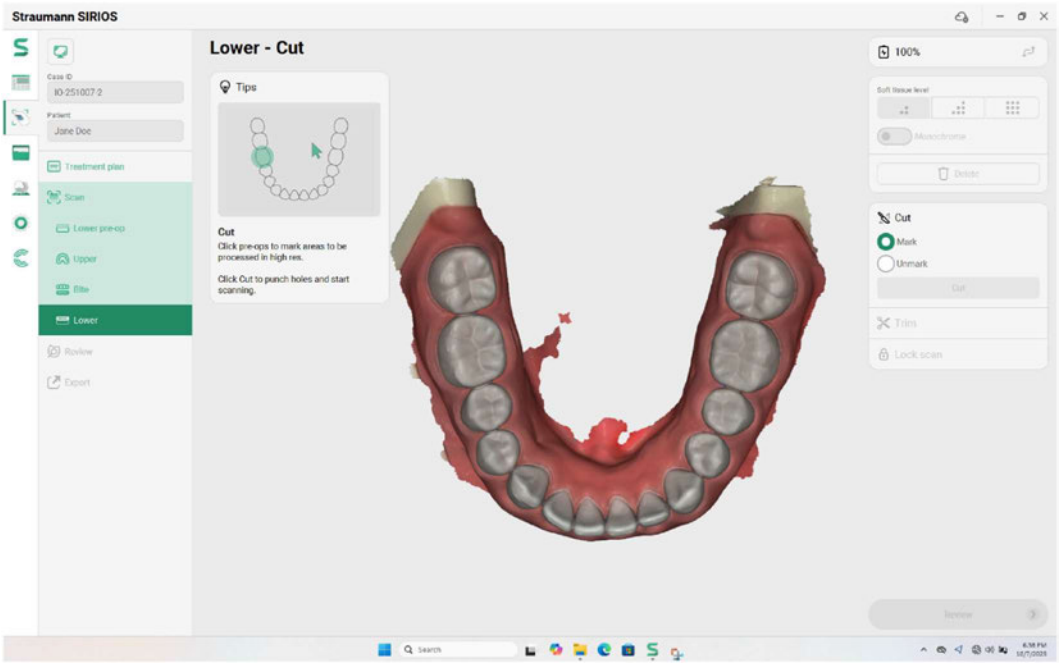
283. Below is an image of the software after I added the mark to cut the tooth with debris.



CC_EXEC_00000271

[redacted]

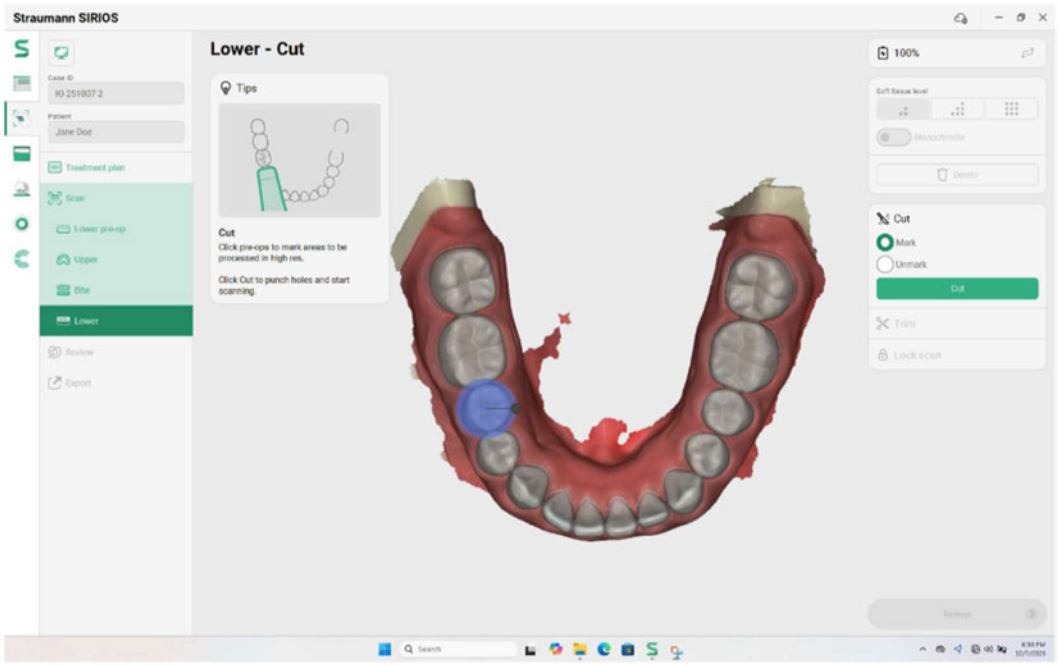
284. I also performed a second test using the SIRIOS scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the lower right second premolar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the lower dental arch with the pre-operation tooth, I selected this tooth so that it would be removed from this first scan using the cut tool. Then I replaced the typodont pre-operation tooth with the post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below is an image of the start screen for the cut tool.



CC_EXEC_00000343

285. Below is an image of the software after I added the mark to cut the tooth that was going to be replaced with the crown preparation tooth.

[redacted]



CC_EXEC_00000354

286. As shown above, the SIRIOS scanner system marks, on the displayed model, the user input defined portion, after receiving the user input and before removing the removed surface portion of the model. I also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim. Accordingly, the SIRIOS scanner system satisfies Claim 8.

2. Infringement of Claims 9-12

f. Claim 9

i. Preamble: "A method for scanning a patient's teeth for a dental procedure, the method comprising:"

287. Users of the SIRIOS can perform a method for scanning a patient's teeth for a dental procedure" as set forth in Claim 9, for the same reasons as set forth above in my discussion of Claim 1[pre], incorporated here by reference. The SIRIOS scanner system therefore satisfies Claim 9[pre].

[redacted]

ii. 9[a]: "receiving first scan data of the patient's teeth from a hand-held intraoral scanner"

288. During operation of the SIRIOS scanner system, a user can perform a method of receiving first scan data of the patient's teeth from a hand-held intraoral scanner, as set forth in my discussion of Claim 1[b][ii], incorporated here by reference. The SIRIOS scanner system therefore satisfies Claim 9[a].

iii. 9[b]: "displaying, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth"

289. The SIRIOS scanner system displays, to a display, a model of the patient's teeth based on the received first scan data of the patient's teeth, as set forth in my discussion of Claim 1[b][iii] above, incorporated here by reference. The SIRIOS scanner system therefore satisfies Claim 9[b].

iv. 9[c]: "receiving user input via the displayed model demarcating a portion of the model to be retained and a surface portion of the model to be replaced"

290. As set forth in my discussion of Claim 1[b][iv] above, and incorporated herein by reference, the SIRIOS software provides a user interface that allows the user to interact with the displayed digital model. Through this interface, the user can provide input defining a portion of the model to be removed. The surface portion that is not removed is retained. The SIRIOS scanner system therefore satisfies Claim 9[c].

v. 9[d]: "receiving second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity"

291. As set forth in my discussion of Claim 1[b][vi] above, and incorporated herein by reference, the SIRIOS scanner system is capable of receiving additional scan data after the initial scan, including second scan data captured by the same hand-held intraoral scanner. This second

[redacted]

scan data may include surface data of a portion of the patient's intraoral cavity that has physically changed since the first scan, such as a tooth that has been prepared or modified. The SIRIOS scanner system therefore satisfies Claim 9[d].

vi. 9[e]: "replacing at least a portion of the surface portion of the model to be replaced according to the user input using at least a portion of the second scan data of the patient's teeth including the physically changed portion"

292. As set forth above in my discussion of Claim 1[b][vii], and incorporated here by reference, the SIRIOS scanner system uses the received second scan data to replace at least a portion of the surface data that was previously removed from the model. The system integrates updated surface information corresponding to the physically changed intraoral region into the existing model framework. This functionality satisfies Claim 9[e].

vii. 9[f]: "outputting, to the display, the model of the patient's teeth with the at least the portion of the surface portion replaced using the second scan data"

293. As set forth above in my discussion of Claim 1[b][viii], and incorporated herein by reference, following replacement of the removed surface portion using the second scan data, the SIRIOS scanner system outputs the updated digital model to the display. The displayed model reflects the incorporation of the new scan data into the previously removed region. Accordingly, the SIRIOS scanner system satisfies Claim 9[f].

g. Claim 10

i. "The method of Claim 9, further comprising marking an area on the displayed model associated with the received user input."

294. As discussed with respect to Claim 1(b)(iv) and Claim 8 set forth above and incorporated herein by reference, the SIRIOS software allows a user to define a portion of the displayed model for removal, and the area is visually marked.

[redacted]

h. Claim 11

i. "The method of Claim 9, wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data comprises registering the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model."

295. Using the cut tool in the SIRIOS scanner system satisfies Claim 11, for the same reasons as set forth above with respect to Claim 5, incorporated herein by reference.

i. Claim 12

i. "The method of Claim 11, wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data further comprises stitching the at least the portion of the second scan data with the model."

296. Using the cut tool in the SIRIOS satisfies Claim 12, for the same reasons as set forth with respect to Claim 6, set forth above and incorporated herein by reference.

3. Infringement of Claim 17

j. Claim 17

i. Preamble: "A system for intraorally scanning a patient's teeth for a dental procedure, the system comprising:"

297. The SIRIOS scanner system is a system for intraorally scanning a patient's teeth for a dental procedure within the meaning of Claim 17 for the same reasons as set forth in my discussion above regarding Claim 1[pre], incorporated herein by reference.

ii. 17[a]: "a hand-held intraoral scanner"

298. The SIRIOS scanner system includes a hand-held intraoral scanner for the same reasons as set forth with respect to Claim 1[a] in my discussion above, incorporated herein by reference.

[redacted]

iii. 17[b][i]: "a computer readable medium including instructions that when executed by a computer system, cause the computer system to"

299. The SIRIOS scanner system includes a computer readable medium including instructions that are executed by the computer system and cause the computer system to perform the remaining limitations of Claim 17, as set forth in my discussion above regarding Claim 1[b][i], incorporated herein by reference.

iv. 17[b][ii]: "receive first scan data of the patient's teeth from the hand-held intraoral scanner"

300. The SIRIOS scanner system receives first scan data of the patient's teeth from the hand-held intraoral scanner, as set forth above in my discussion above regarding Claim 1[b][ii], incorporated herein by reference.

v. 17[b][iii]: "display, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth"

301. The SIRIOS scanner system displays a model of the patient's teeth based on the received first scan data of the patient's teeth, as set forth in my discussion above regarding Claim 1[b][iii], incorporated herein by reference.

vi. 17[b][iv]: "receive user input defining a portion of the model to be removed"

302. The SIRIOS scanner system receives user input that defines a portion of the model that should be removed, as set forth in my discussion above regarding Claim 1[b][iv], incorporated herein by reference.

vii. 17[b][v]: "after receiving the user input, remove, from the displayed model, a removed surface portion of the model to be removed according to the user input"

303. For the same reasons as set forth in my discussion above regarding Claim 1[b][v], incorporated herein by reference, after receiving user input defining a portion of the model to be

[redacted]

removed, the SIRIOS scanner system removes the identified surface portion from the displayed digital model. As a result, the displayed model no longer includes the removed surface region.

viii. 17[g]: "after removing the portion of the model, receive second scan data of the patient's teeth from the hand-held intraoral scanner"

304. As set forth above in my discussion of Claim 1[b][vi], incorporated herein by reference, after removing a portion of the model, the SIRIOS scanner system can receive second scan data of the patient's teeth from the hand-held intraoral scanner.

ix. 17[h]: "register the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model"

305. As set forth above in my discussion of Claim 5, incorporated herein by reference, the SIRIOS scanner system aligns identifying data from the second scan with corresponding parts of the model.

x. 17[i]: "replace at least a portion of the removed surface portion of the model using at least a portion of the received second scan data of the patient's teeth"

306. As set forth above in my discussion of Claim 1[b][vii], incorporated herein by reference, the SIRIOS scanner system replaces a portion of the removed surface of the model with the data from the second scan of the patient's teeth.

xi. 17[j]: "discarding a remainder of the second scan data, including the identifying data, after registering the second scan data with the model"

307. The SIRIOS scanner system satisfies Claim 17[j]. After registering the second scan data with the existing model and using the relevant portions of that data for replacement, the SIRIOS software does not retain unused portions of the second scan data, including identifying or alignment data that is no longer needed once registration has been completed. In normal

[redacted]

operation, only the surface data incorporated into the final model is preserved, while remaining scan data that is not used in the replacement process is discarded.

308. For example, in the SIRIOS instructional video referenced throughout my report, it shows that the remainder of the received second scan, including the identifying surfaces, is discarded. As shown below, the stitched model includes only the portion of the second scan showing the circled tooth. All that is left is the first scanned portion and the replaced portion of the second scan.[259]

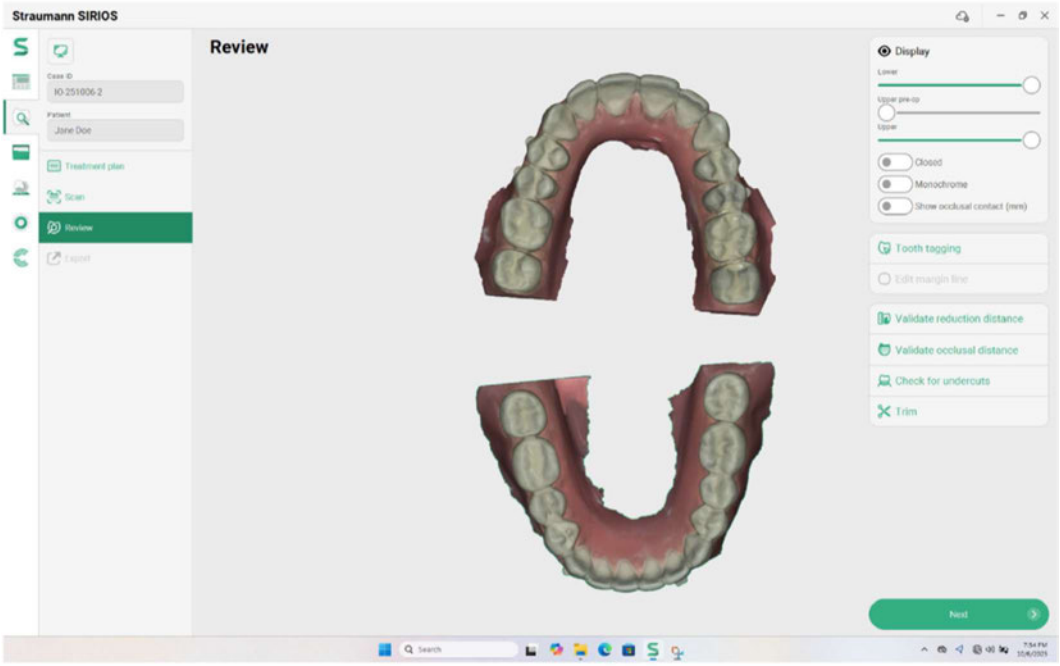


309. When I inspected the SIRIOS scanner, I used it to perform a first test with toothpaste added to the upper left first molar of the typodont to simulate debris on or between a patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan

[259] Straumann, *Crown & Pre-Op Workflow*, YouTube, at 2:42, https://www.youtube.com/watch?v=Qum4DelCCCk&list=PLK_7Ubh5GY2dpHApV1k3b7bXOJhdvTFEU&index=9 (ALGN01637352).

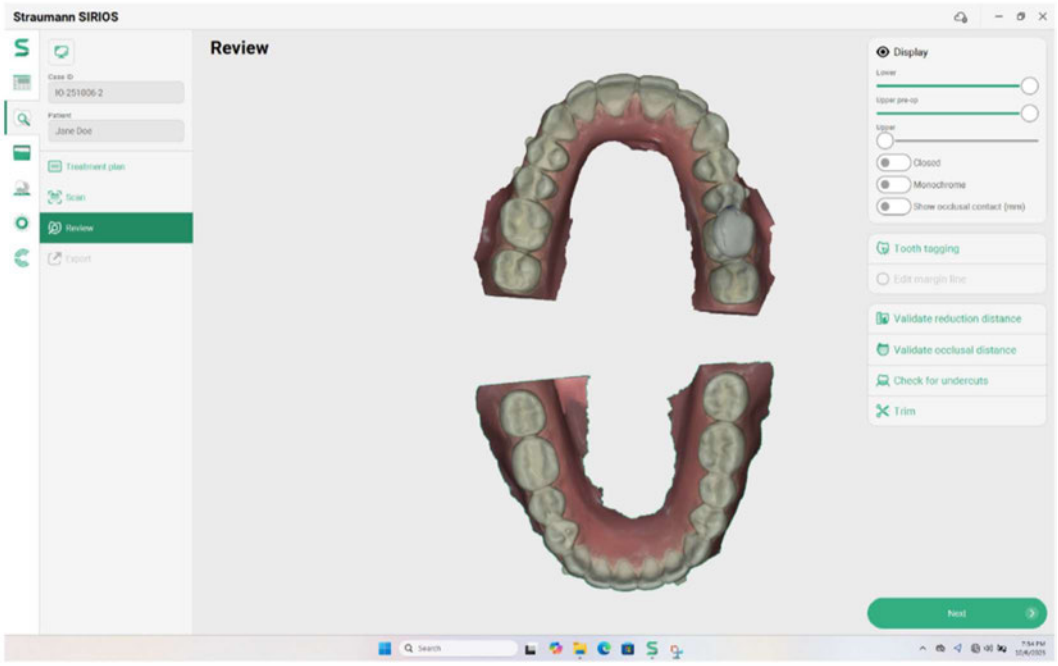
[redacted]

using the cut tool. Then I removed the toothpaste from the tooth. Next, I rescanned the tooth that I removed the toothpaste from. The first image below is an image showing the final image after the second scan. The remainder of the second scan data has been discarded, leaving only the first scan data and second scan data for the portion of the first scan that was removed. The second image below is an image of the model of the patient's teeth before the removed surface portion was replaced by the second scan.



CC_EXEC_00000285

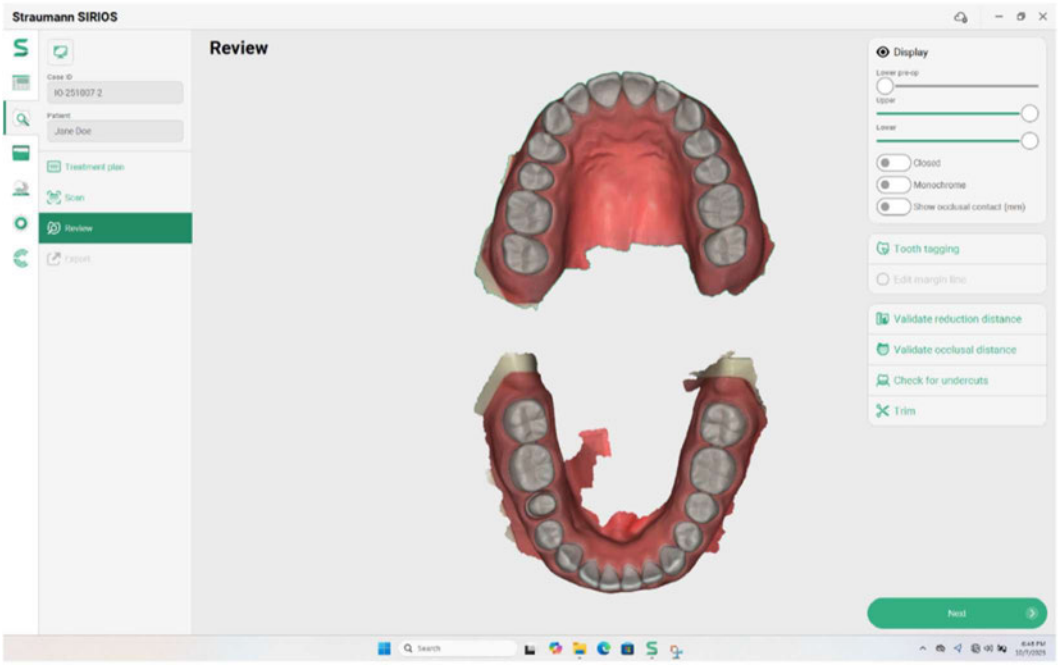
[redacted]



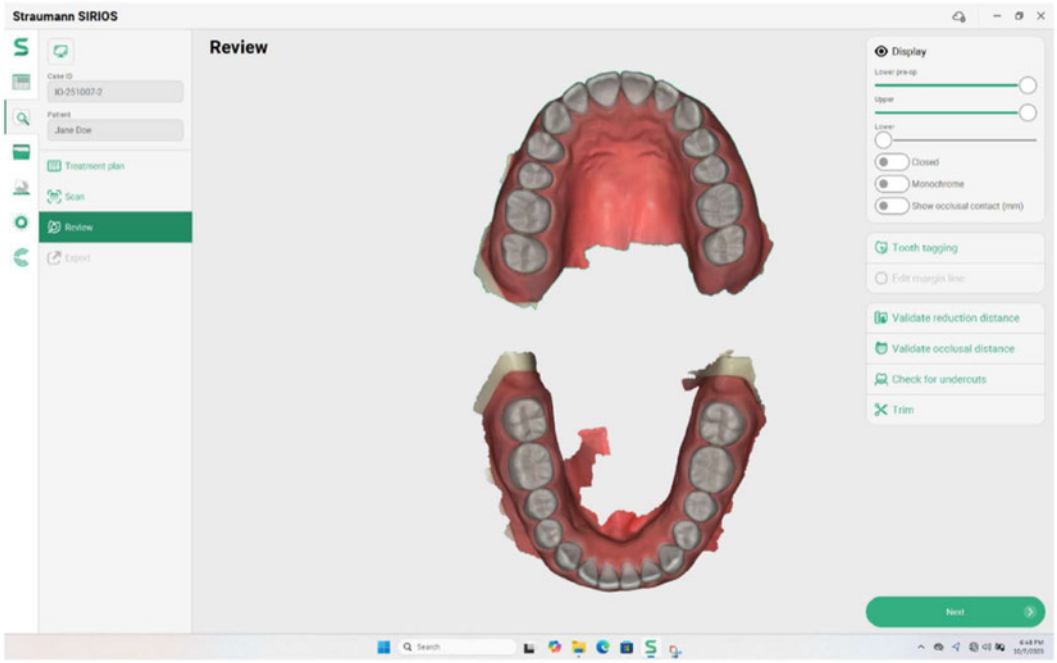
CC_EXEC_00000286

310. When I inspected the SIRIOS scanner, I also used it to perform a second test to simulate the workflow for a crown preparation or other dental procedure. In this test, I selected the lower right second premolar as the tooth that was going to be replaced with a crown preparation tooth. Then I replaced the tooth with the post-operation crown preparation tooth. Next, I rescanned the post-operation crown preparation tooth. The first image below is an image showing the final image after the second scan. The remainder of the second scan data has been discarded, leaving only the second scan data for the portion of the first scan that was removed. The second image below is an image of the model of the patient's teeth before the removed surface portion was replaced by the second scan.

[redacted]



CC_EXEC_00000367



CC_EXEC_00000368

311. As shown above, the SIRIOS scanner system discards a remainder of the second scan data, including the identifying data, after registering the second scan data with the model. I

[redacted]

also understand from Dr. Singh that the SIRIOS source code confirms that the SIRIOS software performs this claim limitation. Accordingly, the SIRIOS scanner system satisfies Claim 17[j].

xii. 17[k]: "output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the received scan data"

312. As set forth in my discussion of Claim 1[B][viii] above, and incorporated herein by reference, after the removed surface portion has been replaced using the second scan data, the SIRIOS software outputs the updated digital model to a display. The displayed model reflects the integration of the second scan data into the previously removed region and presents the user with a revised, complete representation of the patient's dentition.

C. THE iTERO INTRAORAL SCANNER EMBODIES THE ASSERTED CLAIMS OF U.S. PATENT NO. 10,791,936

313. As explained below, the iTero intraoral scanner[260] practices each limitation of Claims 1, 4-6, 8-12, and 17 of the '936 Patent. This analysis is based on my review of the '936 Patent, publicly available technical documentation, product literature, and operation of the iTero system, as well as my education, training, and experience in dental imaging systems.

1. iTero Practices Claims 1, 4-6, and 8 of the '936 Patent

a. Claim 1

i. 1[Pre]: "A system for scanning a patient's teeth for a dental procedure, the system comprising:"

314. The iTero scanner system is a system for scanning a patient's teeth for dental procedures within the meaning of Claim 1. The iTero scanner is an intraoral scanning system specifically designed to capture digital three-dimensional representations of a patient's dentition

[260] The iTero intraoral scanner, as used in my report, refers generally to each version of the iTero since version 4.0, when the "Eraser" feature was first released, unless otherwise specified. Redacted - Privileged [redacted]

[redacted]

and surrounding oral structures.[261] These scans are used in connection with a variety of dental procedures, including restorative dentistry, orthodontic treatment planning, and the fabrication of dental appliances.[262] The iTero scanner system comes in different configurations. For example, it comes as a wheel-stand cart system, as shown below.[263]

[261] *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -361 ("The iTero Element 5D Plus Lite systems are intraoral scanners with the following features and intended use: The optical impression (CAD/CAM feature of the scanner is intended/indicated for use to record the topographical images of teeth and oral issue. . . .iTero software is used with the iTero scanner in capturing 3D digital impression of teeth, oral soft tissue and structures, and bite relationship."); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at- 247 ("iTero Lumina is an intraoral scanner intended to record and display the topographical images of teeth, oral tissue, and bite relationship."); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -585 ("iTero Element 5D and iTero Element 5D Plus Imaging Systems are intraoral scanners intended to provide optical impression (CAD/CAM) features and 3D digital impressions of teeth, oral soft tissue, structure and bite relationship."); *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -133 ("The iTero Element 2, iTero Element Flex and iTero Element 2 Plus systems are intraoral scanners with the following features and intended use: The optical impression (CAD/CAM) feature of the scanner is intended/indicated for use to record the topographical images of teeth and oral tissue. . . . iTero software is used with the iTero scanner in capturing 3D digital impression of teeth, oral soft tissue and structures, and bite relationship.").

[262] *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -361("Data generated from iTero may be used in conjunction with the production of dental devices (e.g., aligners, braces, appliances, etc.) and accessories."); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -247 ("Data generated from iTero Lumina may be used in conjunction with the production of dental devices."); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -585 ("Data generated from iTero may be used in conjunction with the CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories."); *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -133 ("Data generated from iTero may be used in conjunction with the production of dental devices (e.g. aligners, braces, appliances, etc.) and accessories.").

[263] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -134; *see also id.* at -136; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -587; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -248; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -362.

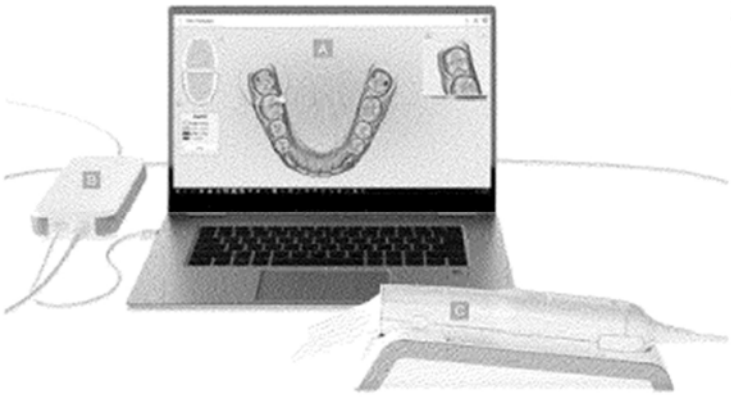
[redacted]



A Full HD touch screen
B Power switch
C Power LED
D Wand
E Cradle
F Wheel base

Figure 1: Front view of the iTero Element 2 intraoral scanner

315. The iTero scanner system is also sold as a laptop configuration, with an accompanying laptop that the iTero scanner is connected to, as shown below.[264]



A Laptop touch screen
B iTero Element Flex hub
C Wand and cradle

Figure 3: iTero Element Flex intraoral scanner

[264] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -135; *see also iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -588.

[redacted]

316. The iTero scanner system is also sold as a mobile configuration, with an accompanying touch-screen computing unit, as shown below.[265]



A Full HD touch-screen computing unit

B Wand

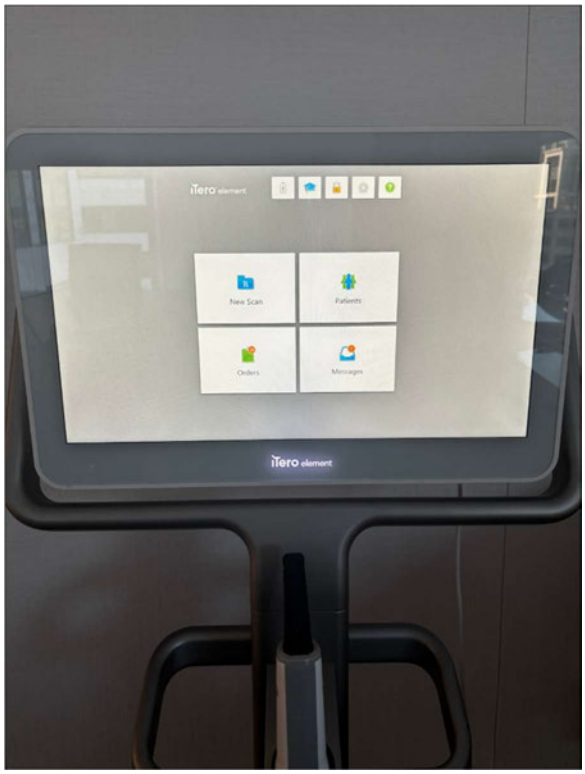
C Cradle

Figure 6: Front view of the iTero Element 2 Plus mobile-configuration intraoral scanner

317. I inspected the iTero scanner on November 17, 2025. Below are images showing the iTero scanner cart system. As shown below, the system includes a scanner, which captures three-dimensional images of the patient's teeth. The images are displayed on the accompanying display screen attached to the cart. Accordingly, the iTero satisfies the claim preamble requirement of being a "system for scanning a patient's teeth for a dental procedure."

[265] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN0336102) at -137; *see also iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -249; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -363.

[redacted]



ALGN04783323



ALGN04783324

[redacted]



[NEED TO PRODUCE]

ii. 1[a]: "a hand-held intraoral scanner"

318. The iTero scanner system satisfies Claim 1[a]. The iTero scanner is a hand-held intraoral scanner. The iTero scanner includes a portable scanning device that a dental professional holds in their hand and places in the patient's mouth (intraorally) to capture surface

[redacted]

data of the teeth and surrounding intraoral structures (*e.g.*, gums).[266] Below is a diagram of the iTero scanner, referred to as a "wand."[267]



A Protective sleeve
B Side buttons: Scan on/off
C Light ring
D Air vents
E Wand cable with USB connector

Figure 5: iTero Lumina wand

319. During normal operation, the dental professional holds the iTero scanner in their hand and moves the iTero scanner over the patient's teeth and surrounding gums while the device acquires optical scan data, as shown in the image below.[268]

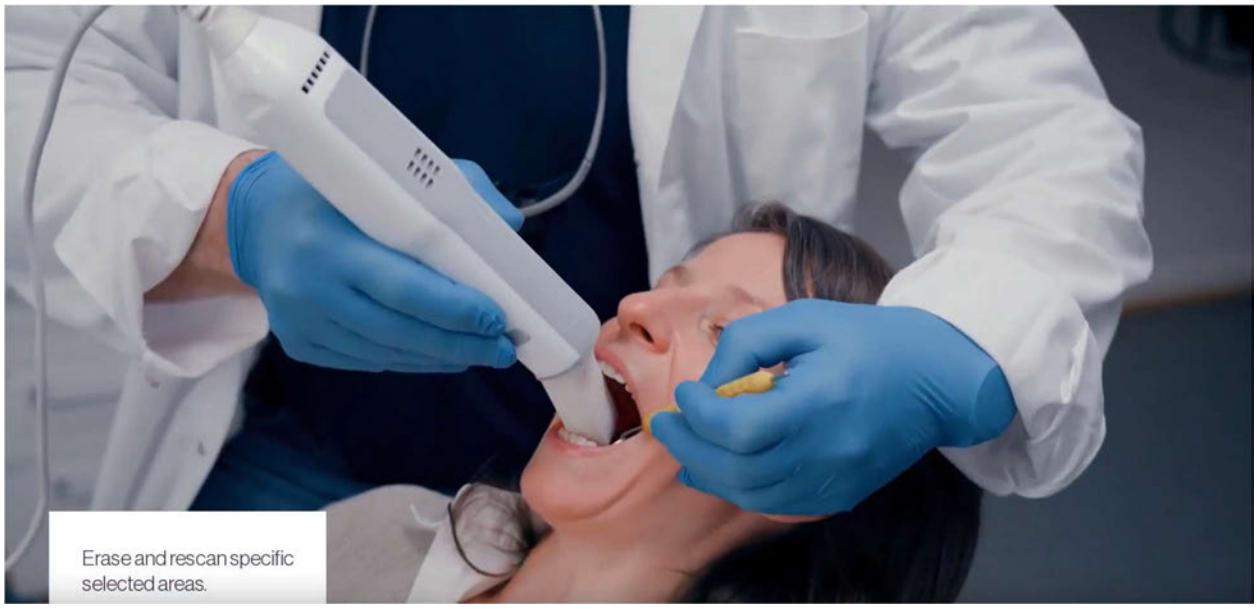
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[266] *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -361 ("The iTero Element 5D Plus Lite systems are intraoral scanners with the following features and intended use: The optical impression (CAD/CAM feature of the scanner is intended/indicated for use to record the topographical images of teeth and oral issue. . . .iTero software is used with the iTero scanner in capturing 3D digital impression of teeth, oral soft tissue and structures, and bite relationship."); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at- 247 ("iTero Lumina is an intraoral scanner intended to record and display the topographical images of teeth, oral tissue, and bite relationship."); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -585 ("iTero Element 5D and iTero Element 5D Plus Imaging Systems are intraoral scanners intended to provide optical impression (CAD/CAM) features and 3D digital impressions of teeth, oral soft tissue, structure and bite relationship."); *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -133 ("The iTero Element 2, iTero Element Flex and iTero Element 2 Plus systems are intraoral scanners with the following features and intended use: The optical impression (CAD/CAM) feature of the scanner is intended/indicated for use to record the topographical images of teeth and oral tissue. . . . iTero software is used with the iTero scanner in capturing 3D digital impression of teeth, oral soft tissue and structures, and bite relationship.").

[267] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -138; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -591; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -364.
[267]

[268] *How to use the Eraser tool: iTero Element intraoral scanners guide*, YouTube (ALGN04788767); *see also iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -371 (showing an individual holding the iTero scanner); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -255 (same); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -607 (same); *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -149 (same).

[redacted]



320. Below are images of the iTero scanner system I inspected. To test the iTero scanner, I used the device to create a three-dimensional image of the teeth of a typodont. Holding the scanning device with my hand, I was able to maneuver it to capture images of the teeth and gums of the typodont. Accordingly, the iTero scanner system satisfies the requirement of a "hand-held intraoral scanner."



[redacted]

[NEED TO PRODUCE]



ALGN04783325

iii. 1[b][i]: "a computer readable medium including instructions that when executed by a computer system, cause the computer system to:'

321. The iTero scanner system satisfies Claim 1[b][i]. As discussed above, the iTero scanner system comes in multiple models: (1) wheel-stand cart system; (2) a laptop configuration; and (3) a mobile configuration. *See supra* ¶¶ X-Y. Each of these models include a computer readable medium including instructions that complete the following steps. For example, the wheel-stand cart system includes a monitor and computing system.[269] The laptop

[269] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -132 ("The iTero Element 2 wheel-stand configuration scanner offers an all-in-one system available on a monitor with a fully interactive, touch screen display and an easy-to-use wand."), -147 (showing the "Full HD touch-screen computing unit" of the wheel-stand configuration), -149 (same); *see also iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -584, -605, -607; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -253, -255; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN000021339) at -362, -369.

[redacted]

configuration is used with a laptop computer.[270] The mobile configuration includes a touch screen computing unit.[271] iTero scanner software is used with all iTero scanner models to "captur[e] 3D digital impressions of teeth, oral soft tissue and structures, and bite relationship."[272] The iTero scanner software "controls the processing of the data, facilitating the integration of data, and exporting of the data for CAD/CAM fabrication of dental restorations, orthodontic devices, abutments, and accessories."[273] The wheel-stand cart system and the mobile configuration are both provided with the iTero scanner software installed.[274] The user installs the software on the laptop configuration.[275] Therefore, the iTero scanner system meets Claim 1[b][i].

322. Below is an image of the computing unit attached to the wheel-stand cart system I inspected.

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[270] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -132 ("iTero Element Flex is a wand-only configuration with any laptop that meets our minimum system requirements. . . ."); *see also iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -584.

[271] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -137 (showing the "Full HD touch-screen computing unit" of the mobile configuration"), -152-56 (same); *see also iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -590, -610-14; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -249, -258-62; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -363, -372-76.

[272] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -133; *see also iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -361.

[273] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -133; *see also iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -361.

[274] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -145; [redacted]

[275] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -145; ALGN00447520 at -602.

[redacted]



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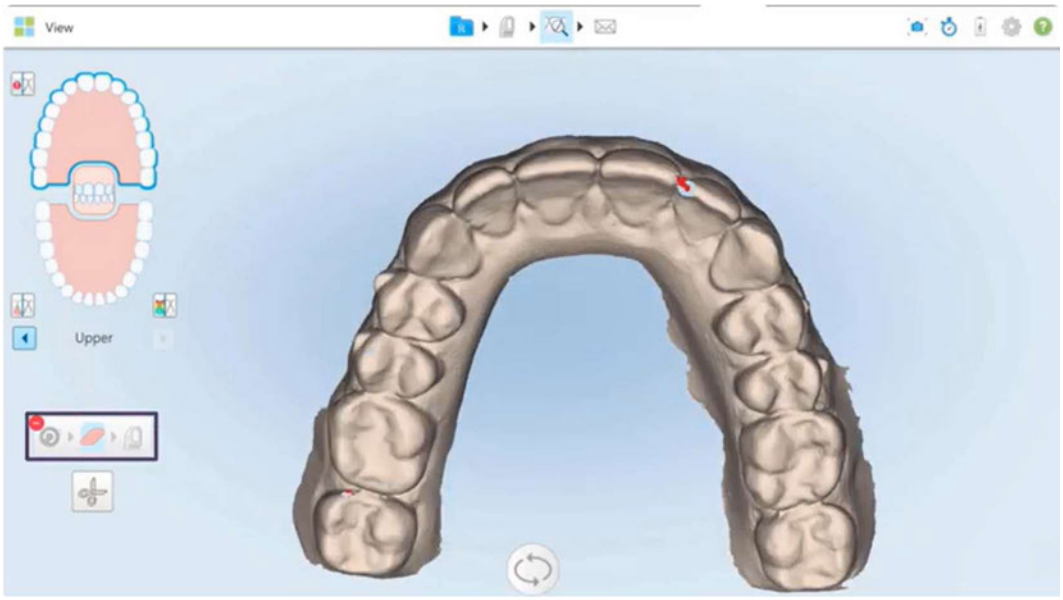
iv. 1[b][ii]: "receive first scan data of the patient's teeth from the hand-held intraoral scanner"

323. The iTero scanner system satisfies Claim 1[b][ii]. During operation of the iTero scanner system, the computer receives first scan data of the patient's teeth from the hand-held

[redacted]

intraoral scanner. For example, before using the iTero Eraser tool, the dental professional takes a first scan of the patient's teeth.[276]

324. Below is an example of a first scan using an iTero scanner from an iTero tutorial video.[277]



325. Below is another example of a first scan as shown in another iTero tutorial video.[278] The image below is in the context of a crown preparation, in which the dental professional uses the first scan to determine if the crown preparation has sufficient clearance.

[276] *How to use the Eraser tool: iTero Element intraoral scanners guide*, YouTube (ALGN04788767) at 0:52*; iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.19.
[277] *How to use the Eraser tool: iTero Element intraoral scanners guide*, YouTube (ALGN04788767), at 0:52.
[278] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.19.

[redacted]

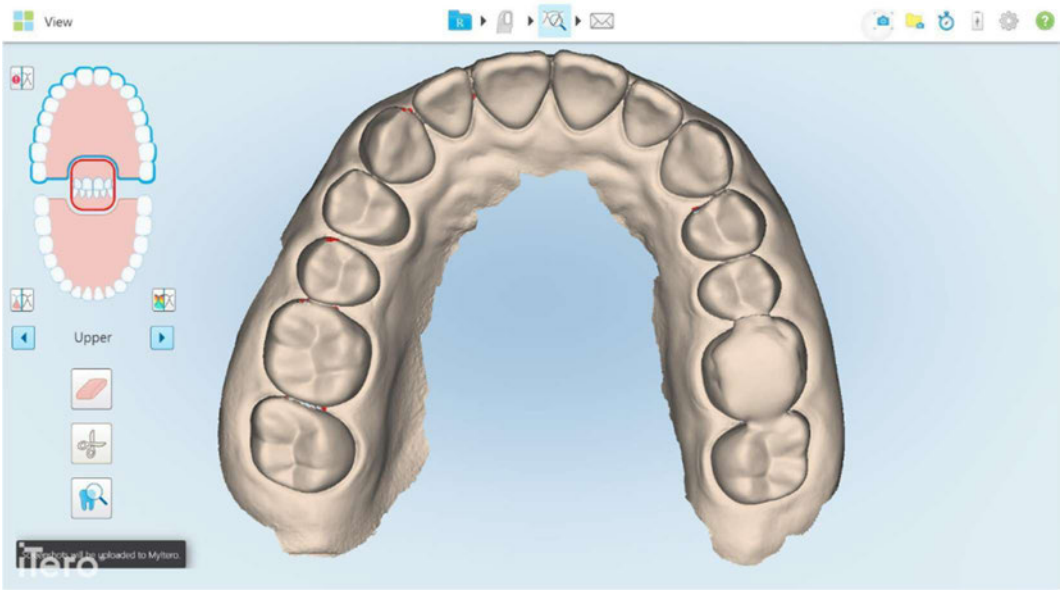


326. When I inspected the iTero scanner system, I performed two tests using this scanner. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris often found on or between patients' teeth when they receive an intraoral scan. The debris could be food, plaque, tarter, blood, saliva, lubricant from the dental drill, waste material from working on a dental site, or any other foreign material that obscures a tooth's surface.[279]

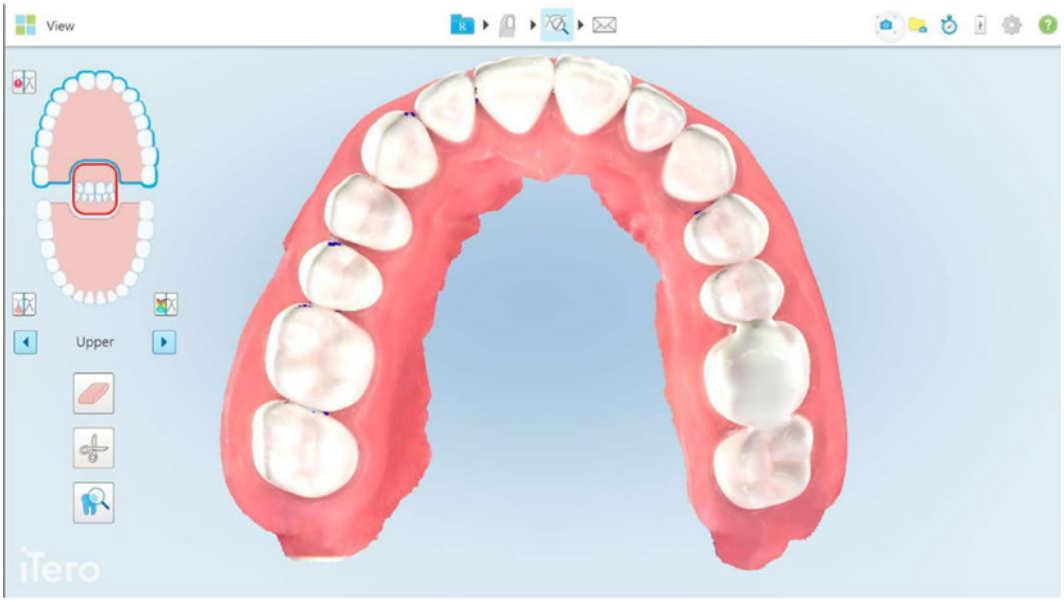
327. For this test, I scanned both the upper and lower arches of the typodont using the iTero scanner. The iTero scanner software running on the laptop "receive[d] first scan data of the patient's teeth from the hand-held intraoral scanner." The three images shown below are different views of the first scan of the upper arch, which included the upper left first molar tooth with the debris (toothpaste).

[279] '936 Patent at 2:1-5 (describing materials that can obscure a tooth's surface).

[redacted]

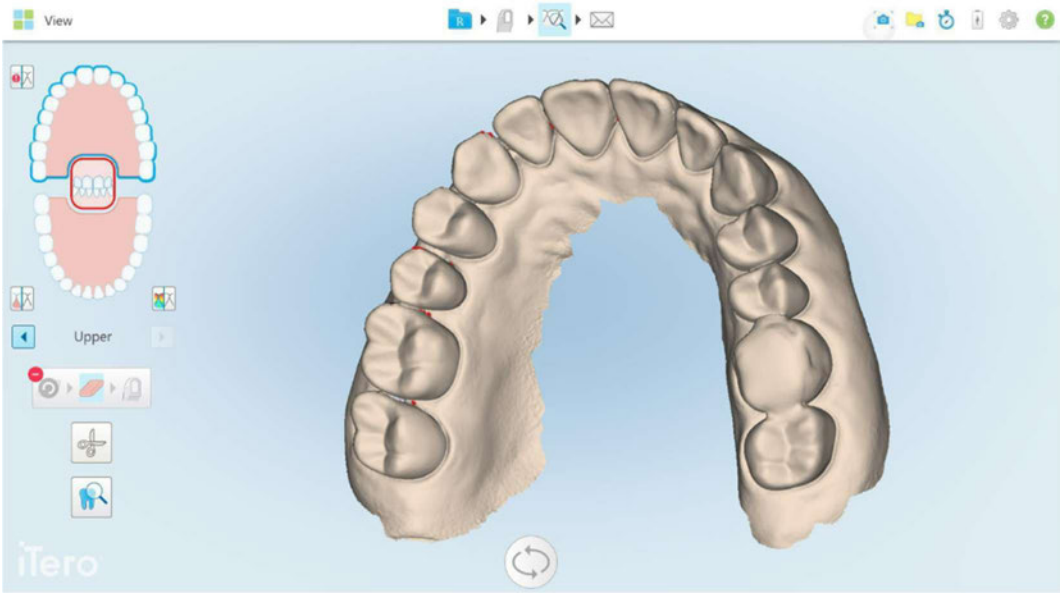


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[redacted]



ALGN04783407

328. The image shown below is a first scan of the lower arch for the first test I performed.

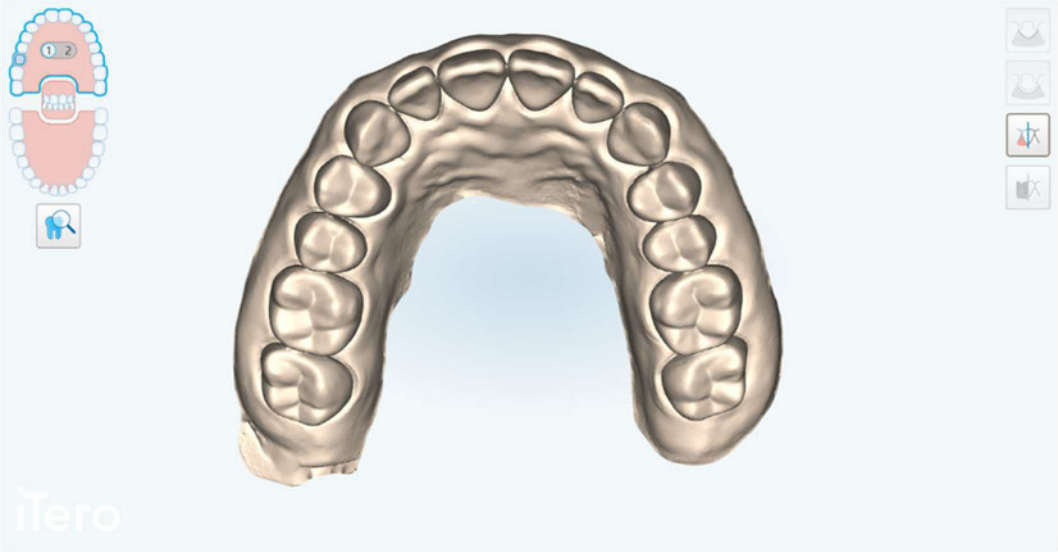


ALGN04783443

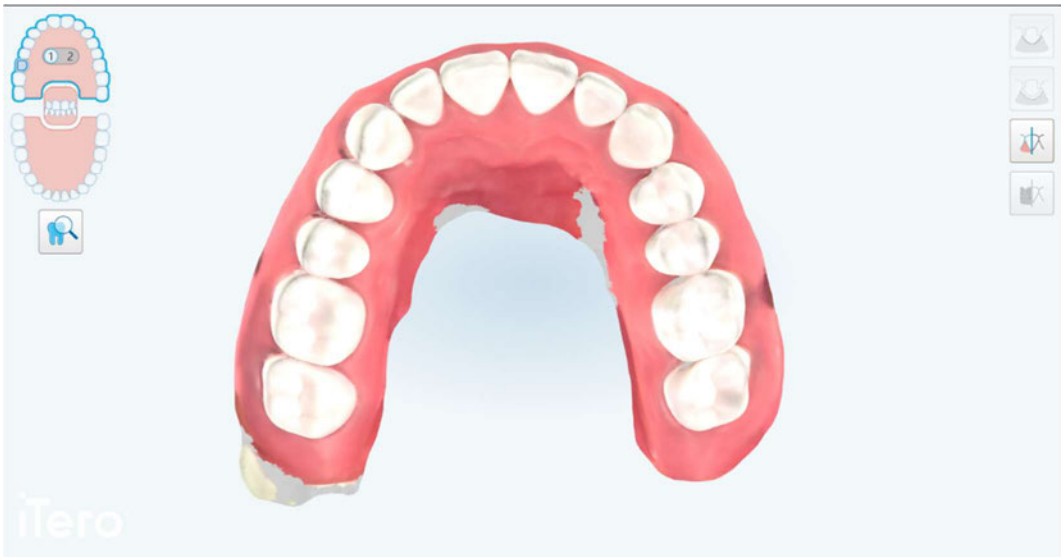
329. I also performed a second test using the iTero scanner system and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the iTero scanner system for a crown preparation or other dental procedure. For the first scan, the

[redacted]

typodont's original tooth, that was later to be replaced with a crown-prepped version of the tooth, was in place to simulate capturing a pre-operation image of this tooth and all the patient's other teeth in the upper dental arch. The iTero scanner software running on the laptop "receive[d] first scan data of the patient's teeth from the hand-held intraoral scanner." The six images shown below are different views of the first scan of the upper arch before the crown preparation operation.

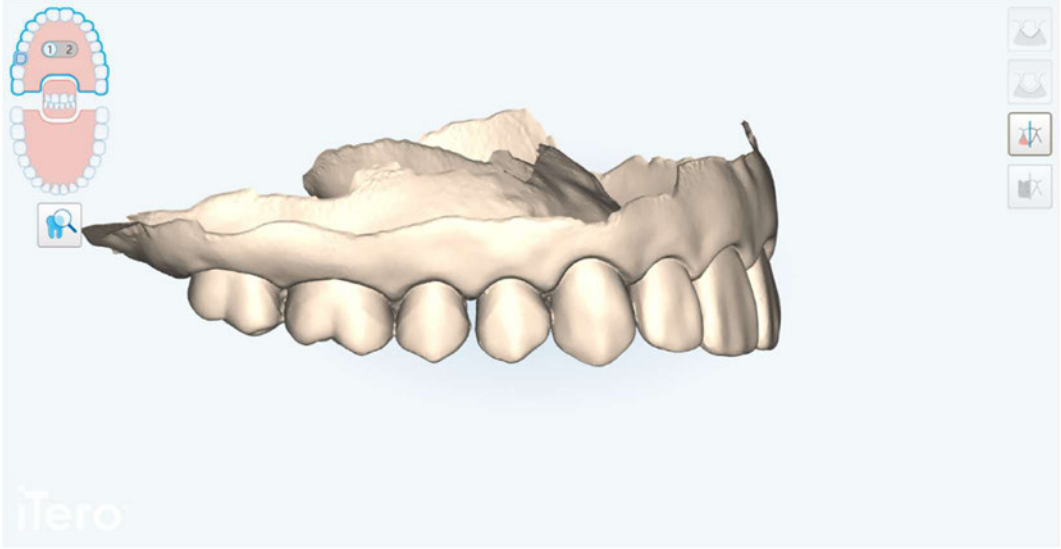


ALGN04783354



[redacted]

ALGN04783356

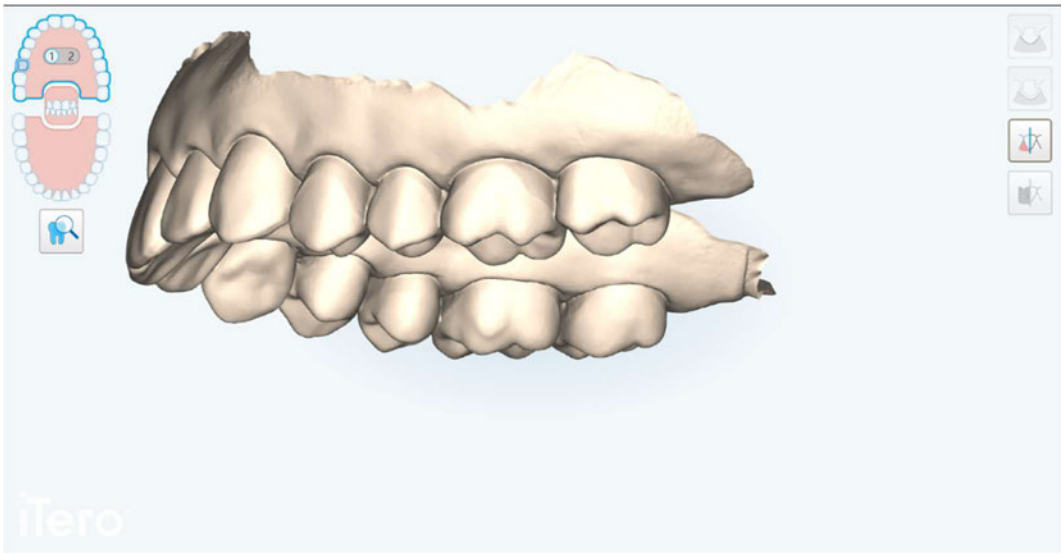


ALGN04783348

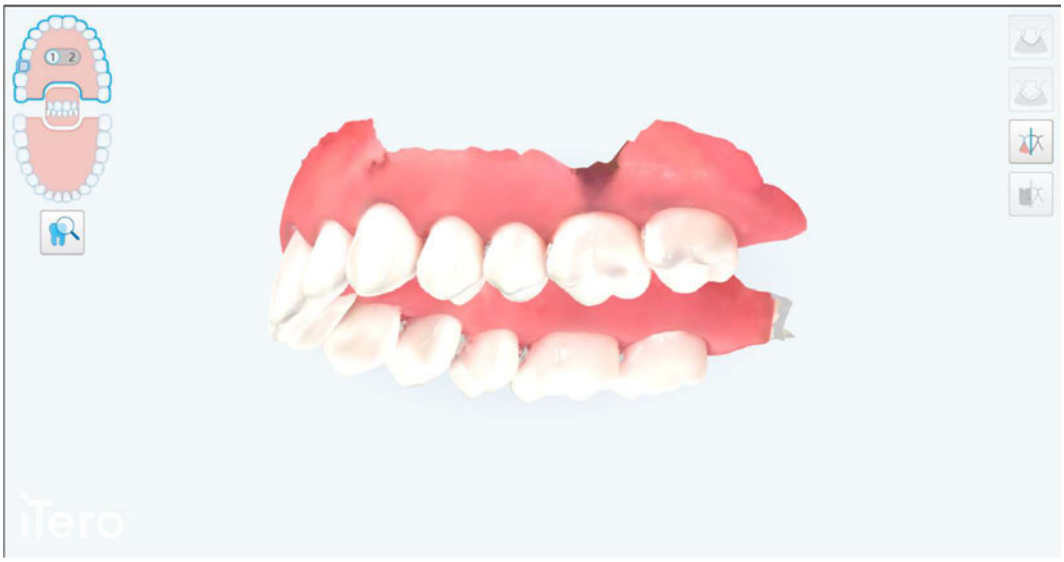


ALGN04783362

[redacted]



ALGN04783345



ALGN04783363

330. The images shown below are of the first scan of the lower arch.

[redacted]



ALGN04783490

331. As shown above, the computer receives first scan data of the typodont simulated patient's teeth from the iTero hand-held intraoral scanner. Accordingly, the iTero scanner system satisfies Claim 1[b][ii].

v. 1[b][iii]: "display, to a display, a model of the patient's teeth wherein the model of the patient's teeth is based on the received first scan of the patient's teeth"

332. The iTero scanner system satisfies Claim 1[b][iii]. As discussed above, the iTero scanner system comes in multiple models: (1) wheel-stand cart system; (2) a laptop configuration; and (3) a mobile configuration. *See supra* ¶¶ X-Y. Each of these models include a display. For example, the wheel-stand cart system includes "a monitor with a fully interactive, touch-screen display," as shown below.[280]

[280] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -132, -134, -335; *see also iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -584, -587, -815; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -246, ,-248, -420; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -361-62, -551.

[redacted]



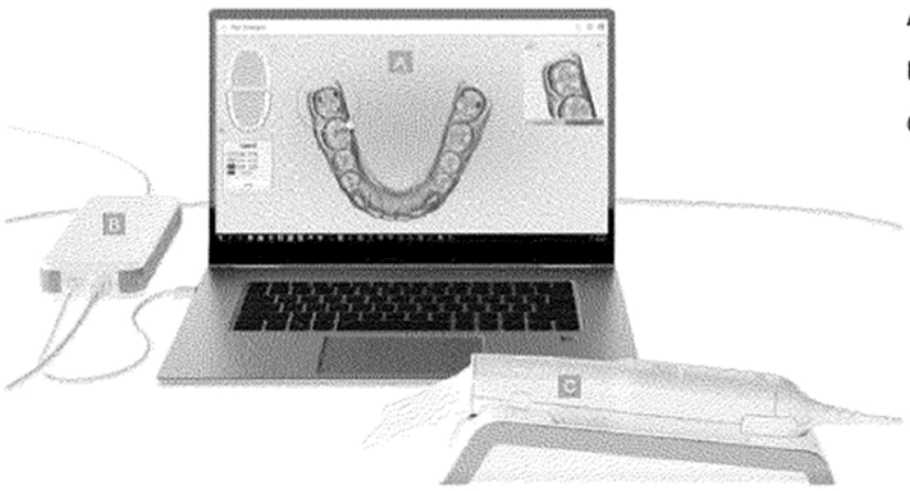
A Full HD touch screen
B Power switch
C Power LED
D Wand
E Cradle
F Wheel base

Figure 1: Front view of the iTero Element 2 intraoral scanner

333. The laptop configuration includes a laptop with a display, as shown below.[281]

[281] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -132; -135; -336; *see also iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -584, -588, -816.

[redacted]



A Laptop touch screen
B iTero Element Flex hub
C Wand and cradle

Figure 3: iTero Element Flex intraoral scanner

334. The mobile configuration also includes a "touch-screen display," as shown below.[282]



A Full HD touch-screen computing unit
B Wand
C Cradle

Figure 6: Front view of the iTero Element 2 Plus mobile-configuration intraoral scanner

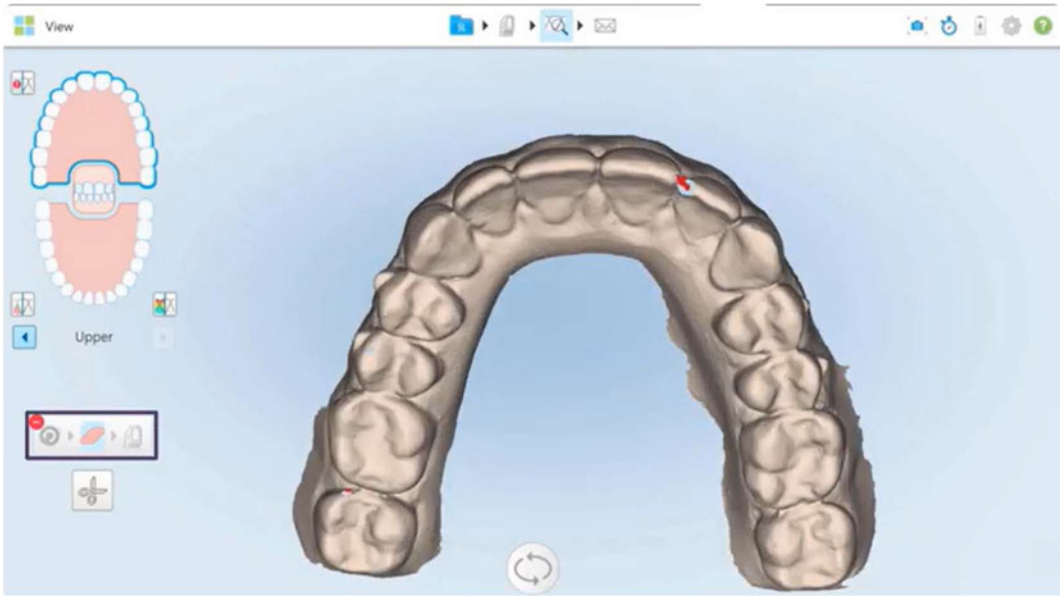
335. The iTero scanner system generates a digital model of the patient's teeth based on the received first scan data read from the intraoral scanner and displays that model on the

[282] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -132, -137, -338; *see also iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -584, -590, -818; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -246, -249, -420; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -361, -363, -551.

[redacted]

system's display. As a dental professional scans a patient's teeth, a three-dimensional model of the patient's teeth appears on the display.[283] Once the dental professional completes the scan, it is processed and the processed model of the patient's teeth is displayed on the iTero scanner system's display.[284]

336. Below is an example of the iTero scanner system's display displaying the first scan as shown in an iTero tutorial video.[285]

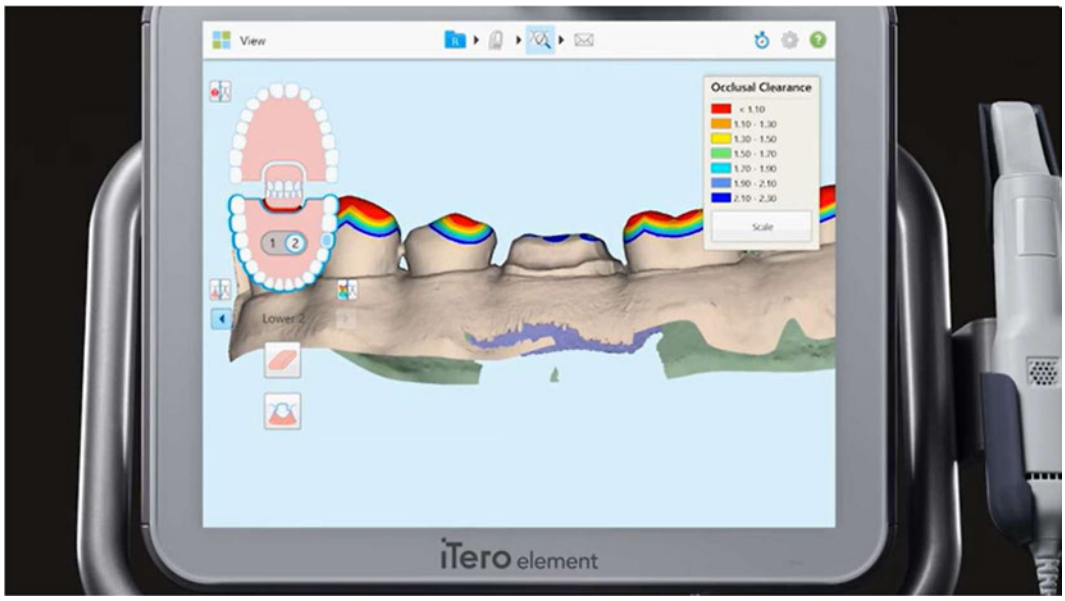


337. Below is another example of an iTero scanner system display displaying the first scan shown in another iTero scanner tutorial video.[286] The image below is in the context of a

[283] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -248-52; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -714-18; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -334-40; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -461-69.
[284] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -254-55 ("After the post-processing stage is complete, you can inspect the model in high resolution to ensure that sufficient anatomy has been captured, and that the model is accurate and complete."); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -722-23; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -343-44; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -468-69.
[285] *How to use the Eraser tool: iTero Element intraoral scanners guide*, YouTube (ALGN04788767) at 0:52.
[286] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.19.

[redacted]

crown preparation, in which the dental professional uses the first scan to determine if the crown preparation has sufficient clearance.



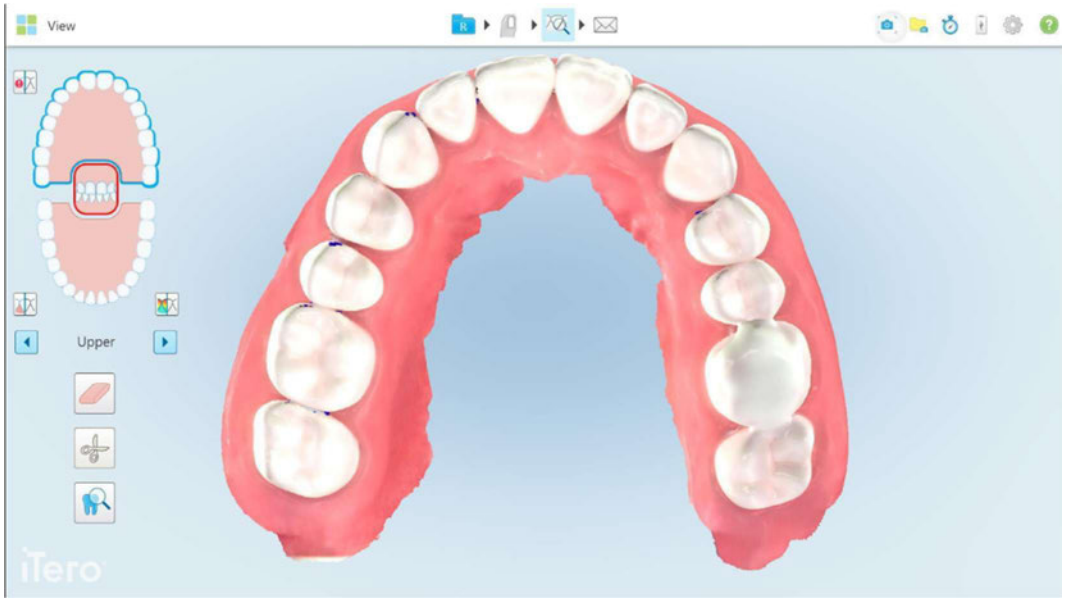
338. Below is an image of the iTero scanner system that I inspected.



ALGN04783323

[redacted]

339. When I inspected the iTero scanner, I performed a first test using the scanner and typodont to simulate a patient's teeth. I performed this test to simulate the workflow of the iTero scanner system when a removable unwanted element is obscuring part of the dental surface of a patient's teeth. To the upper left first molar of the typodont, I added toothpaste to simulate debris on or between a patient's teeth. The three images below are different views of the first scan of the teeth in the upper arch with debris on the upper left first molar and a first scan of the teeth in the lower arch. These images were displayed on the monitor attached to the iTero scanner.



ALGN04783403

[redacted]



ALGN04783443

340. When I inspected the SIRIOS scanner, I also performed a second test using the scanner and typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the SIRIOS scanner system for a crown preparation or other dental procedure. The image below shows the first scan of the pre-operation teeth in the upper arch and the scan of the teeth in the lower arch. These images were displayed on the laptop screen attached to the SIRIOS scanner.



[redacted]

ALGN04783356



ALGN04783490

341. As shown above, the iTero scanner system has a display, to a display, a model of the patient's teeth wherein the model of the patient's teeth is based on the received first scan of the patient's teeth. Accordingly, the iTero scanner system satisfies Claim 1[b][iii].

vi. 1[b][iv]: "receive user input defining a portion of the model to be removed"

342. The iTero scanner system satisfies Claim 1[b][iv]. The iTero software provides a user interface that allows the user to interact with the displayed digital model.[287] Through this interface, the user can use the Eraser tool.[288] The Eraser tool allows the user to provide an input

[287] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -254 (describing different functionality the user can use when viewing the scan, including the Eraser tool); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -722 (same); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -343-44 (same); *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -468-69 (same).

[288] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -254 (describing different functionality the user can use when viewing the scan, including the Eraser tool); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -722 (same); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -343

[redacted]

defining a portion of the three-dimensional model of the patient's teeth to be removed.[289] The Eraser tool allows the user to draw a shape around the portion of the patient's tooth that should be removed.[290] The shape divides the model into two portions: (1) the portion of the model within the closed shape, which will be removed, and (2) the portion of the model outside the closed shape, which will be kept.[291] Below is an example of the user-defined shape created using the Eraser tool.[292]

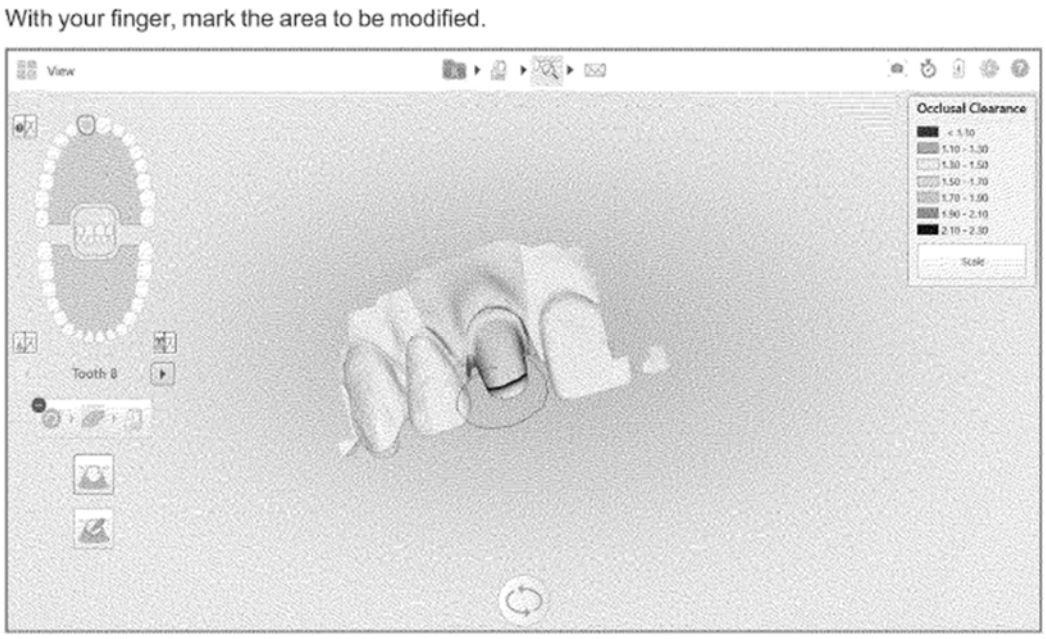


Figure 181: Mark the area to be modified

(same); *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -469 (same);

[redacted]

[289] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -292-94; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -761-63; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -379-82; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -507-09.

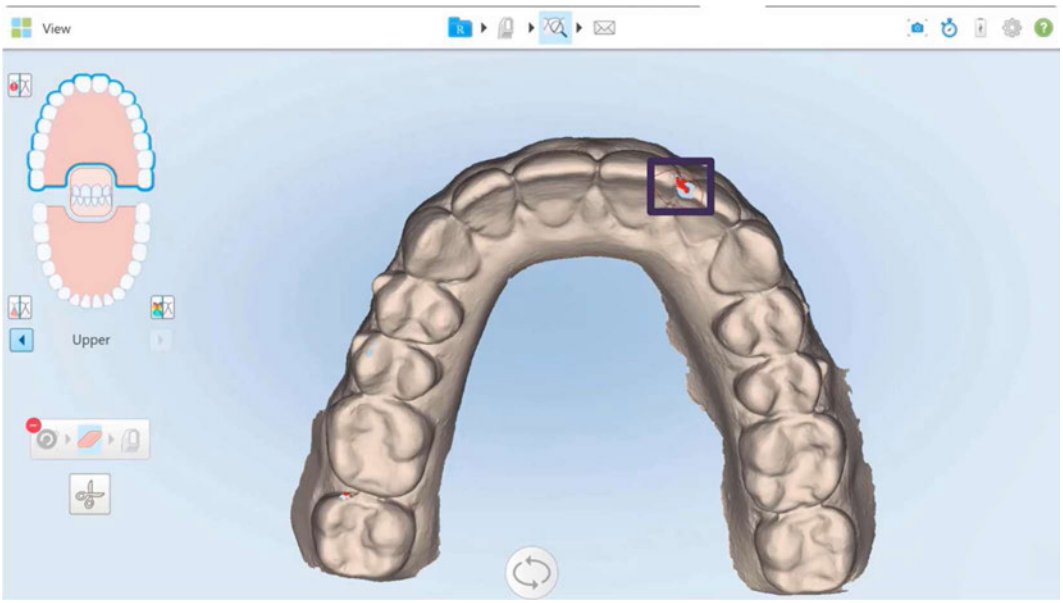
[290] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -293; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -762; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -380; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -508.

[291] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -293; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -762; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -380; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -508.

[292] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -293.

[redacted]

343. Below is an example of a user using the iTero Eraser tool to define a portion of the model to be removed, as shown in an iTero scanner tutorial video.[293]



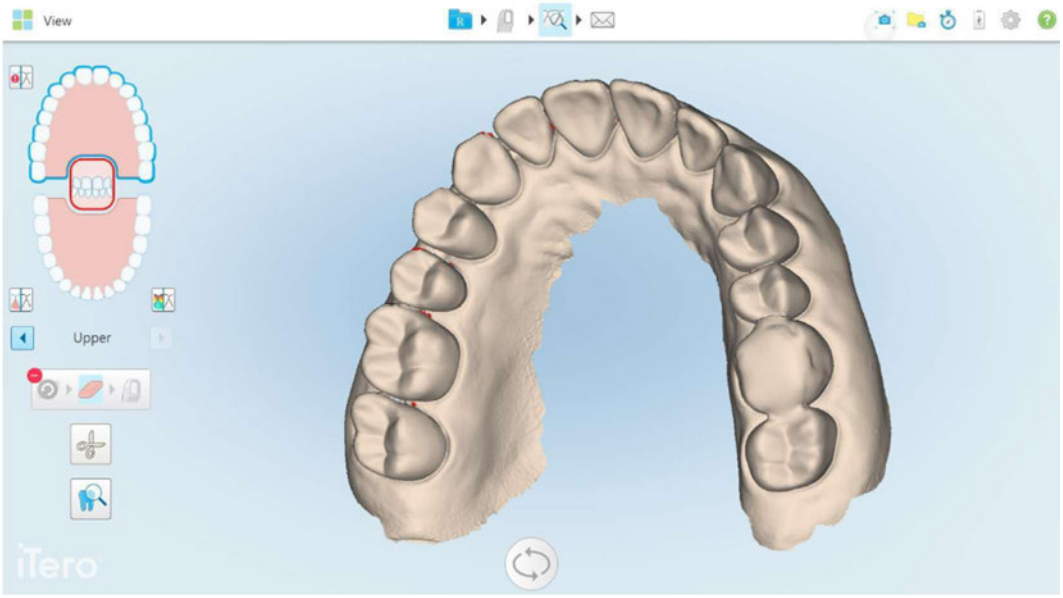
344. Below is another example of a user using the iTero Eraser tool to define a portion of the model to be removed, as shown in another iTero scanner tutorial video.[294]



[293] *How to use the Eraser tool: iTero Element intraoral scanners guide*, YouTube (ALGN04788767) at 0:51.
[294] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.27.

[redacted]

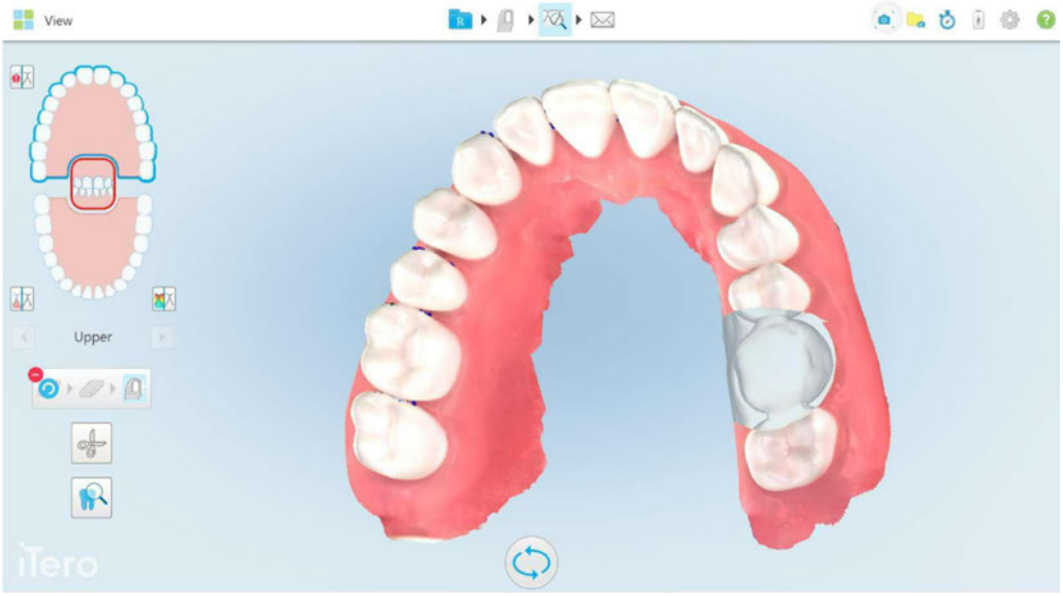
345. When I inspected the iTero scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the iTero scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris on or between a patient's teeth. I then selected the Eraser tool and used my finger on the touch-screen monitor to draw a circle around the tooth with the simulated debris, selecting the portion of the model that I wanted to be removed. The image shown below is the first scan of the upper arch with the upper left first molar that has debris on it before I used the Eraser tool.



ALGN04783407

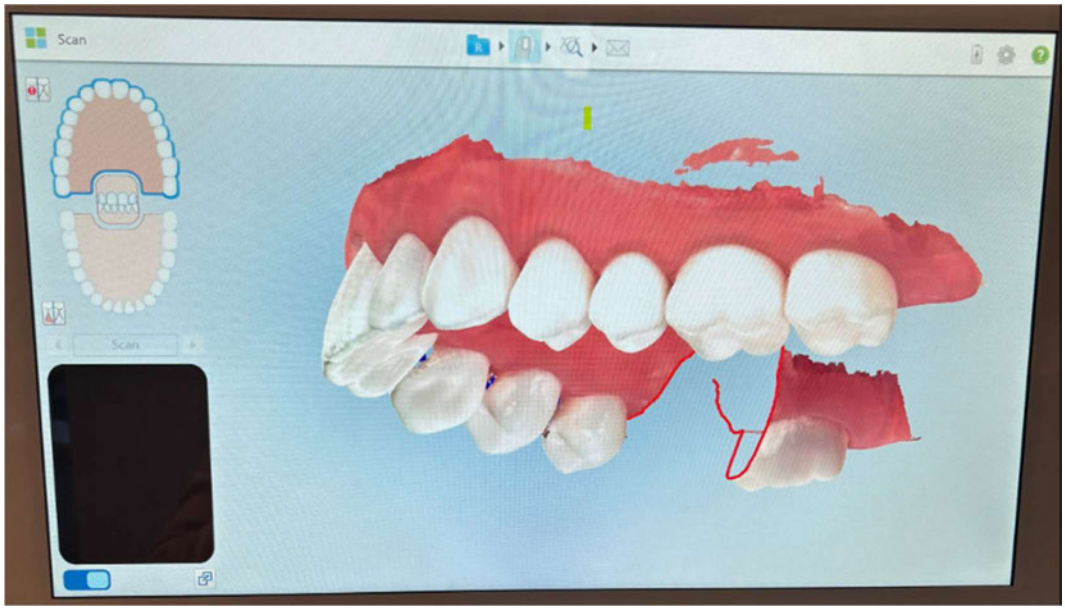
346. The image below shows the first scan of the upper arch after I used the Eraser tool to mark the upper left first molar tooth with debris. The portion of the model inside the shape I drew with the Eraser tool was removed while the portion outside of the shape I drew with the Eraser tool was kept.

[redacted]



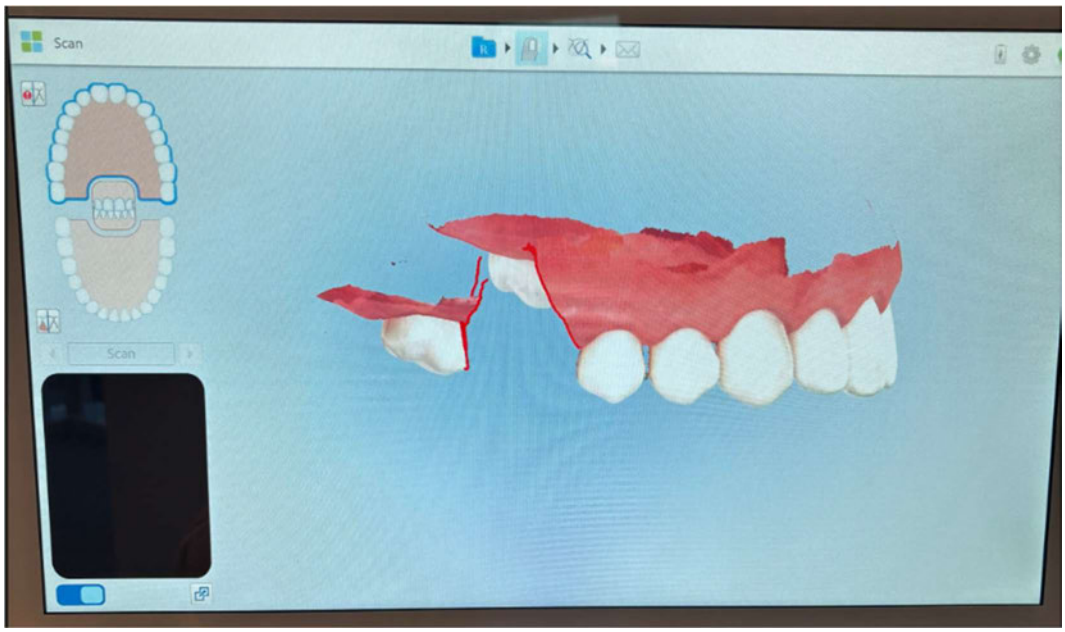
ALGN04783410

347. For the second test of the iTero scanner using this scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the iTero scanner system for a crown preparation or other dental procedure. In this test, I selected the upper right first molar tooth for the crown preparation. The image shown below is the first scan in the lower arch after I used the Eraser tool to select the upper right first molar tooth.



[redacted]

ALGN04783327



ALGN04783326

348. As shown above, the iTero scanner system receives user input defining a portion of the model to be removed. Accordingly, the iTero scanner system satisfies Claim 1[b][iv].

vii. 1[b][v]: "remove, from the displayed model, a removed surface portion of the model to be removed according to the user input"

349. The iTero scanner system satisfies Claim 1[b][v]. After receiving the user input defining a portion of the model to be removed (*i.e.*, the Eraser), the iTero scanner system removes this portion from the displayed digital model.[295] As a result, the displayed model no

[295] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -293; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -762; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -381; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -508.

[redacted]

longer includes the portion that was selected by the user to be removed, as shown in the image below.[296]

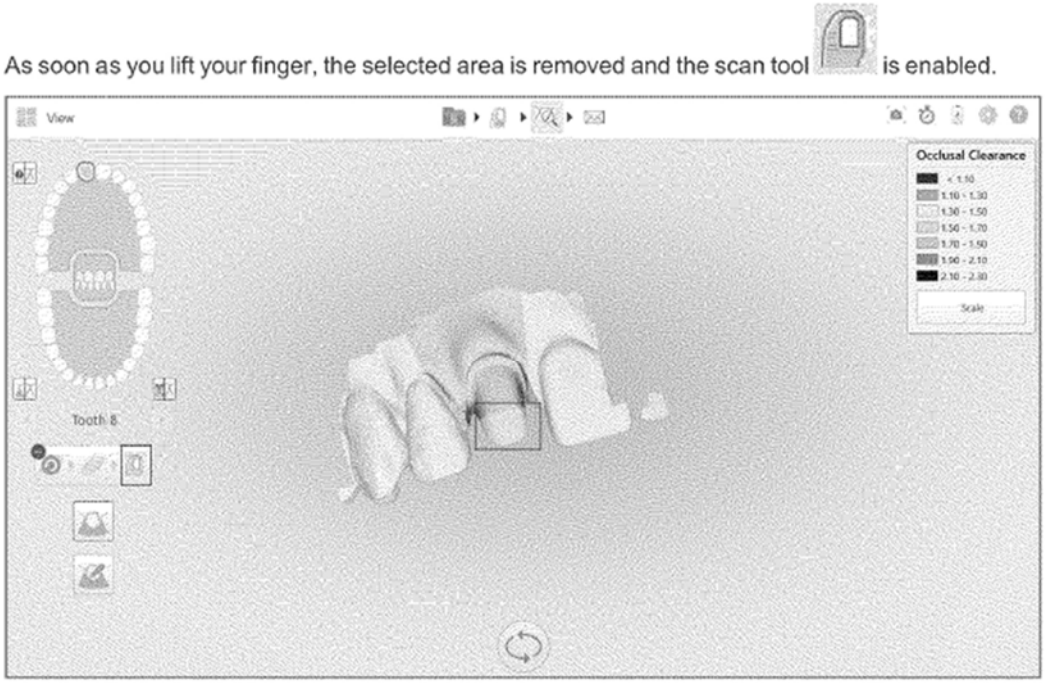
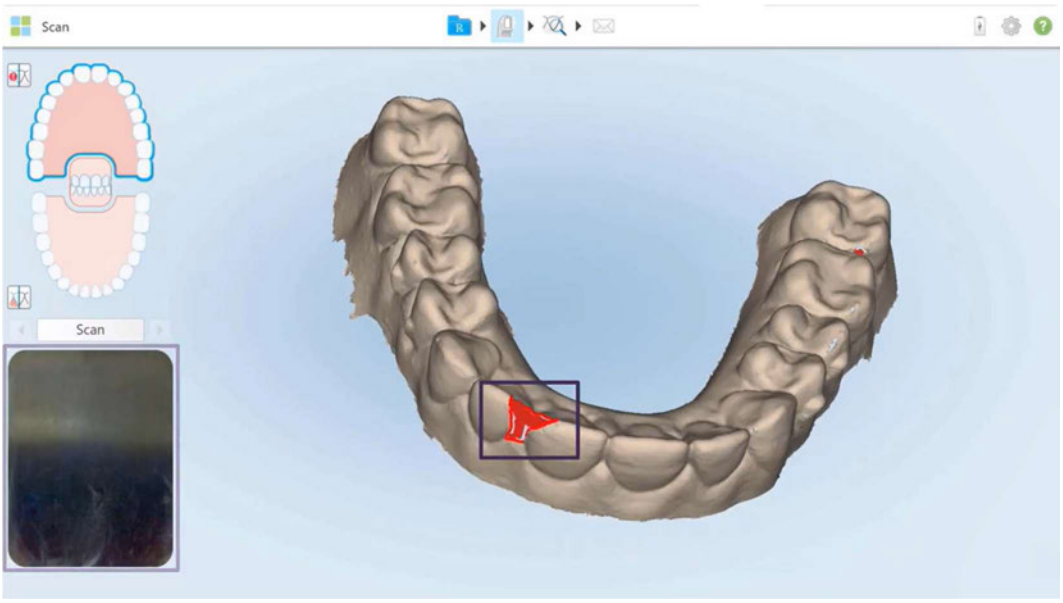


Figure 182: Selected area removed, and scan tool enabled

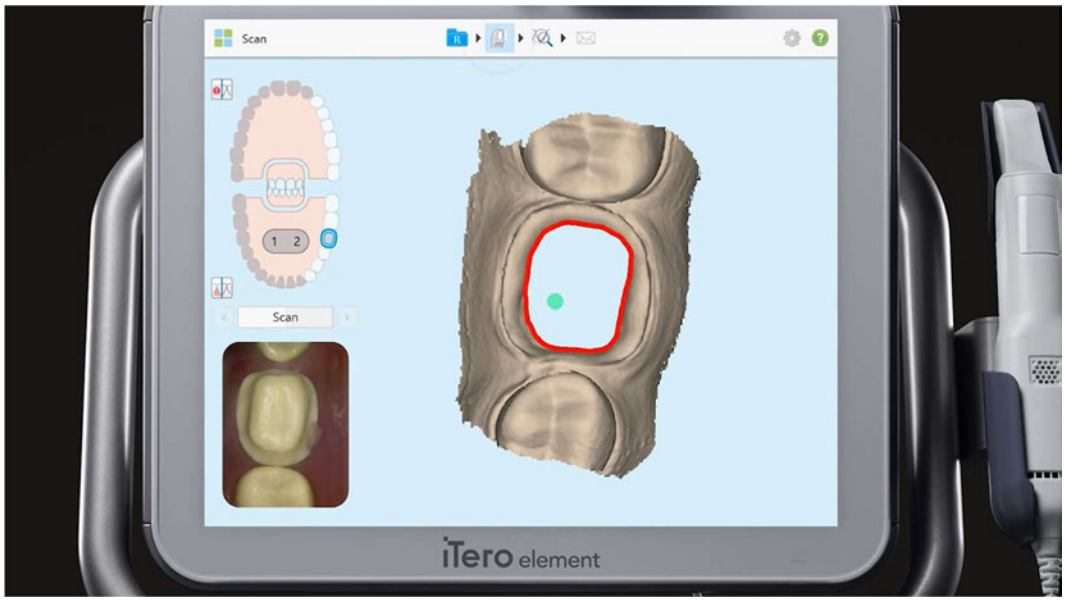
350. Below is an example of a user using the iTero Eraser tool to remove a portion of the model, as shown in an iTero scanner tutorial video.[297]

[296] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -293; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -762; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -381; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -508.
[297] *How to use the Eraser tool: iTero Element intraoral scanners guide*, YouTube (ALGN04788767) at 1:05.

[redacted]



351. Below is another example of a user using the iTero Eraser tool to define a portion of the model to be removed, as shown in another iTero scanner tutorial video.[298]



352. When I inspected the iTero scanner, I used it to perform two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the

[298] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.41.

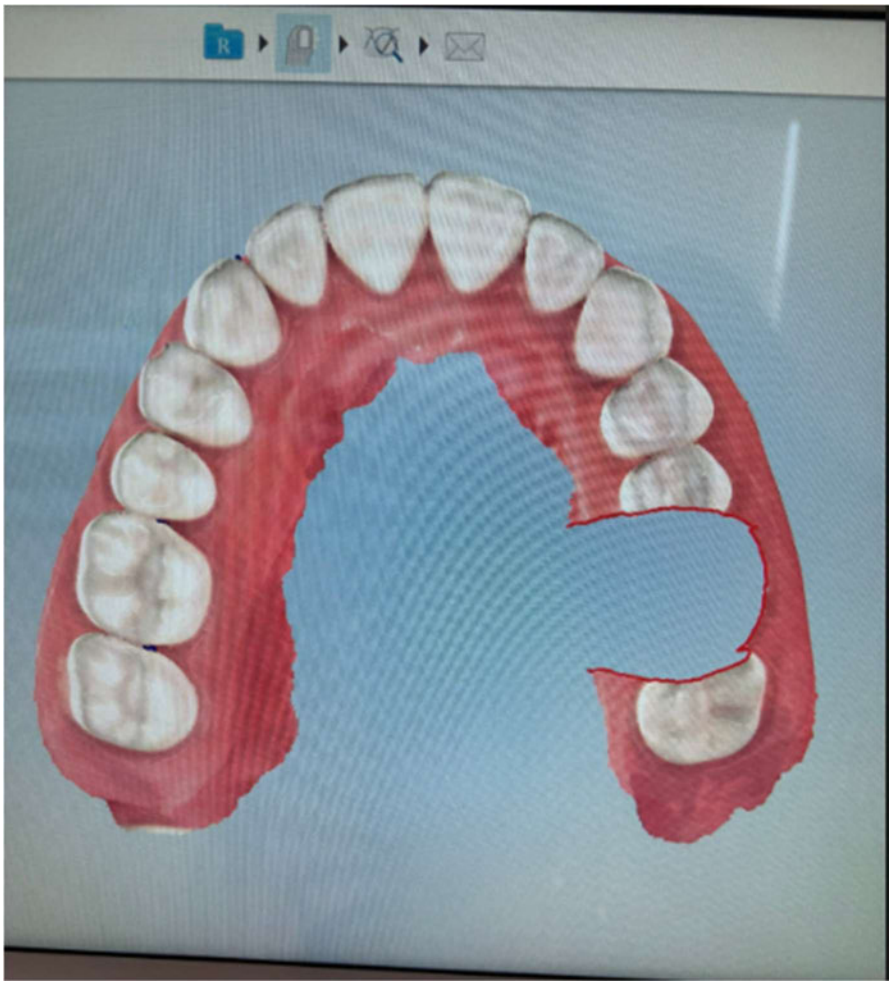
[redacted]

workflow of the iTero scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris. In this test, using my finger on the touch-screen monitor, I selected the Eraser tool to define the portion of the model to be removed from the first scan, *i.e.*, the tooth with debris. The two images shown below are different views of the first scan after I used the Eraser tool to identify the portion of the model to be removed.



ALGN04783410

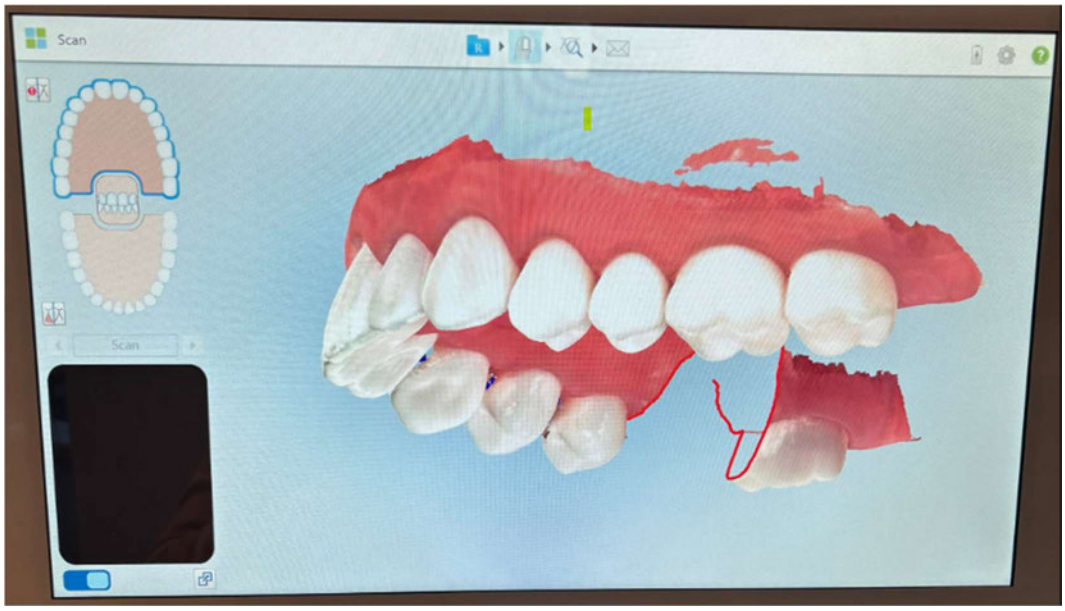
[redacted]



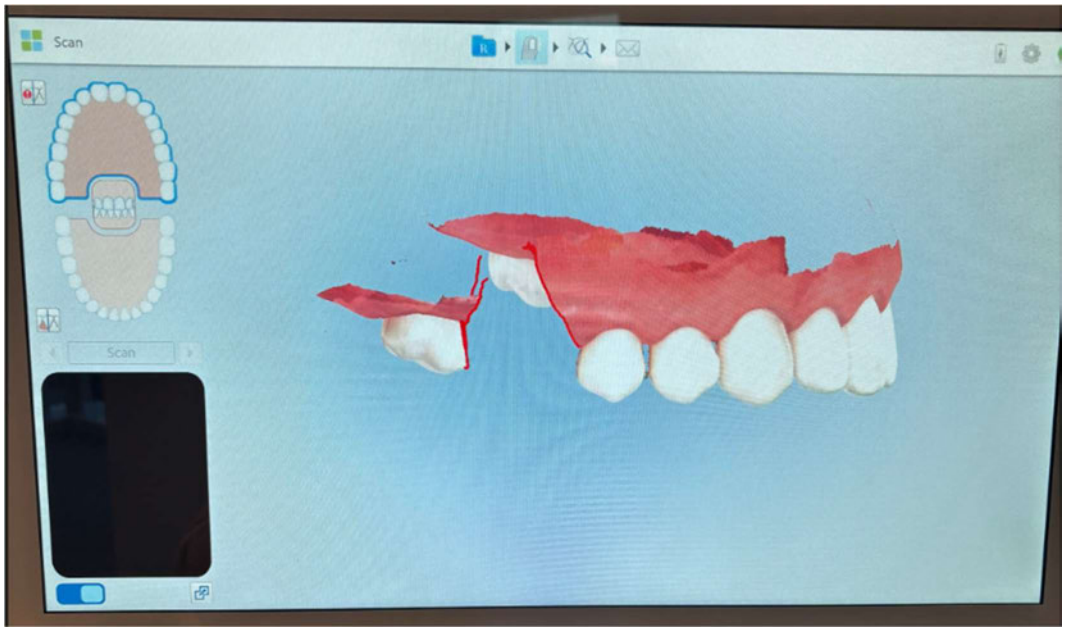
ALGN04783319

353. When I inspected the iTero scanner, I also used it and the typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the iTero scanner system for a crown preparation or other dental procedure. In this test, using my finger on the touch-screen monitor, I selected the Eraser tool and defined the portion of the model to be removed, which was the upper right first molar tooth. The two images shown below are different views of the first scan after I used the Eraser tool.

[redacted]



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ALGN04783326

[redacted]

viii. 1[b][vi]: receive second scan data of the patient's teeth from the hand-held intraoral scanner, the scan data including surface data of a physically changed portion of the patient's intraoral cavity"

354. The iTero scanner system satisfies Claim 1[b][vi]. The iTero scanner system is capable of receiving additional scan data after the initial scan, including second scan data captured by the same hand-held intraoral scanner.[299] This second scan data may include surface data of a portion of the patient's intraoral cavity that has physically changed since the first scan.[300] Below is an image from an iTero scanner manual describing the steps of using the Eraser tool, including rescanning the deleted area.[301]

[299] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -294 (discussing receiving additional scan data after the Eraser tool is used to remove a portion of the scan); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -763 (same); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -382; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -509.

[300] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -294 (discussing receiving additional scan data after the Eraser tool is used to remove a portion of the scan); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN00337552) at -763 (same); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -382; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -509.

[301] *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -382.

[redacted]

4. Tap  to return to Scan mode and rescan the deleted area.

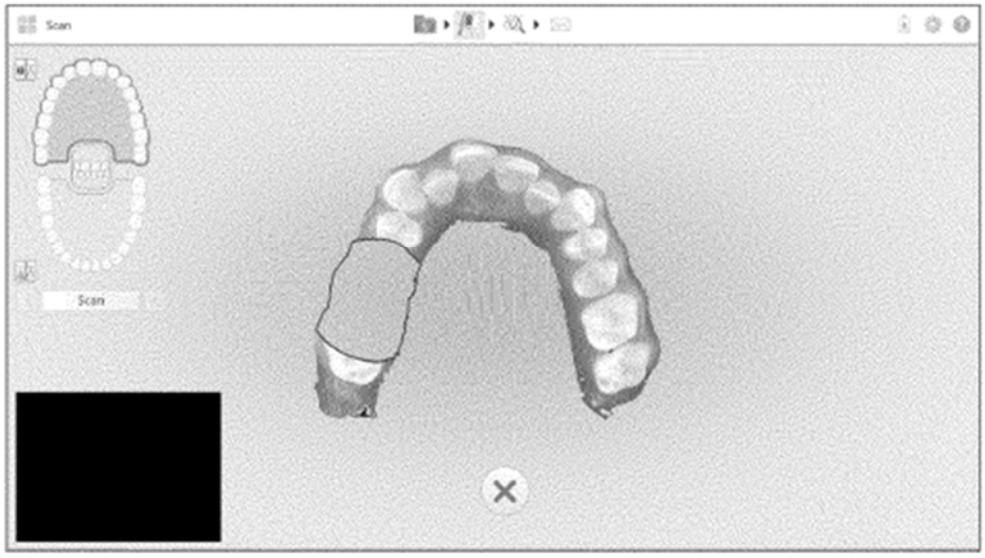
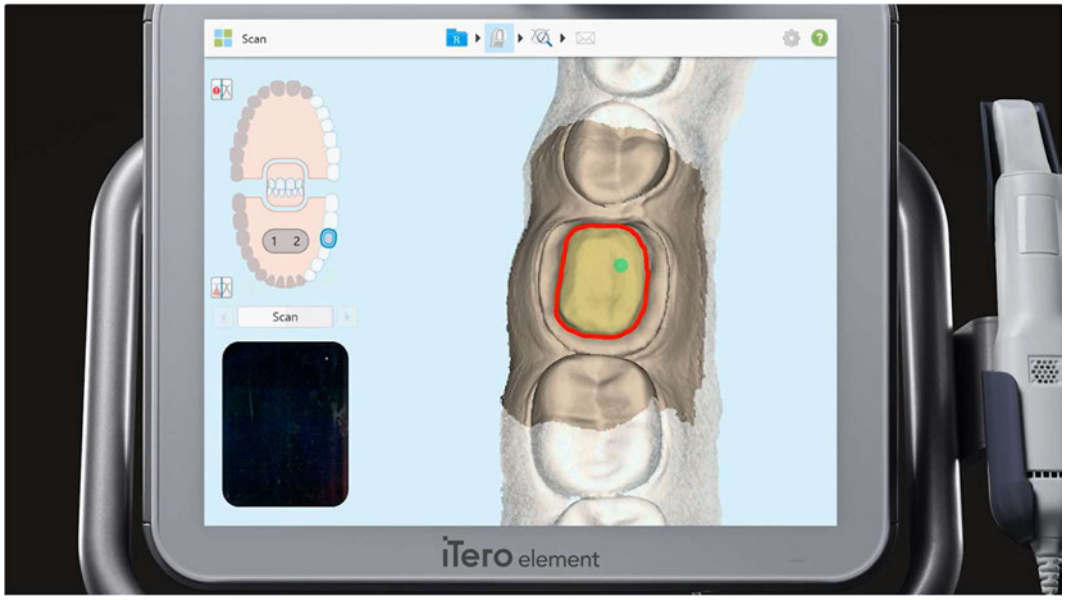


Figure 154: Deleted area to be rescanned

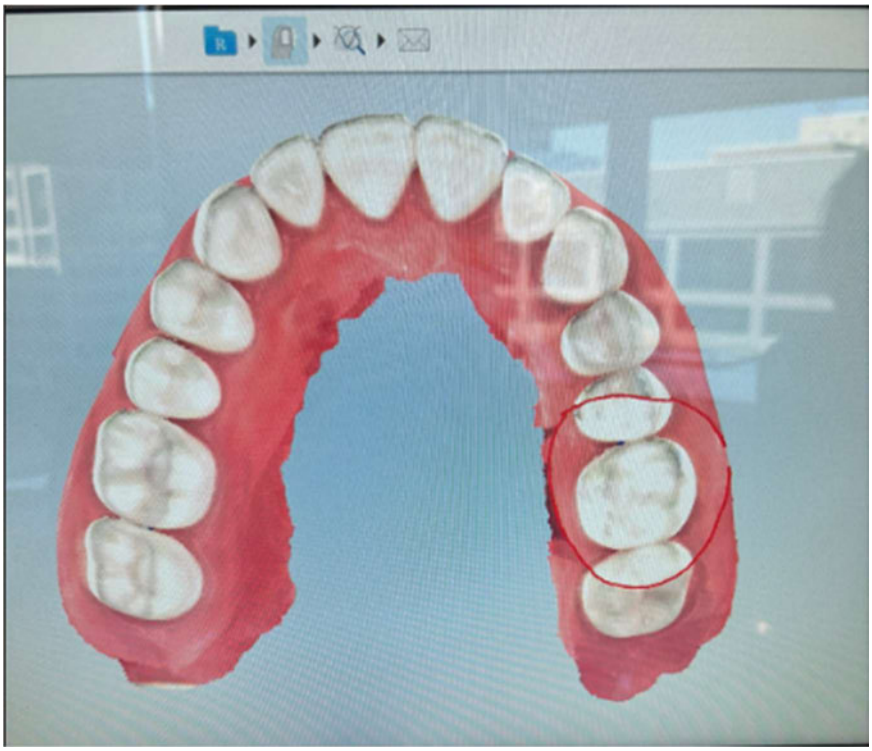
355. Below is an example of a user using the iTero Eraser tool to rescan the removed portion of the model, as shown in an iTero scanner tutorial video.[302]



[302] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.41.

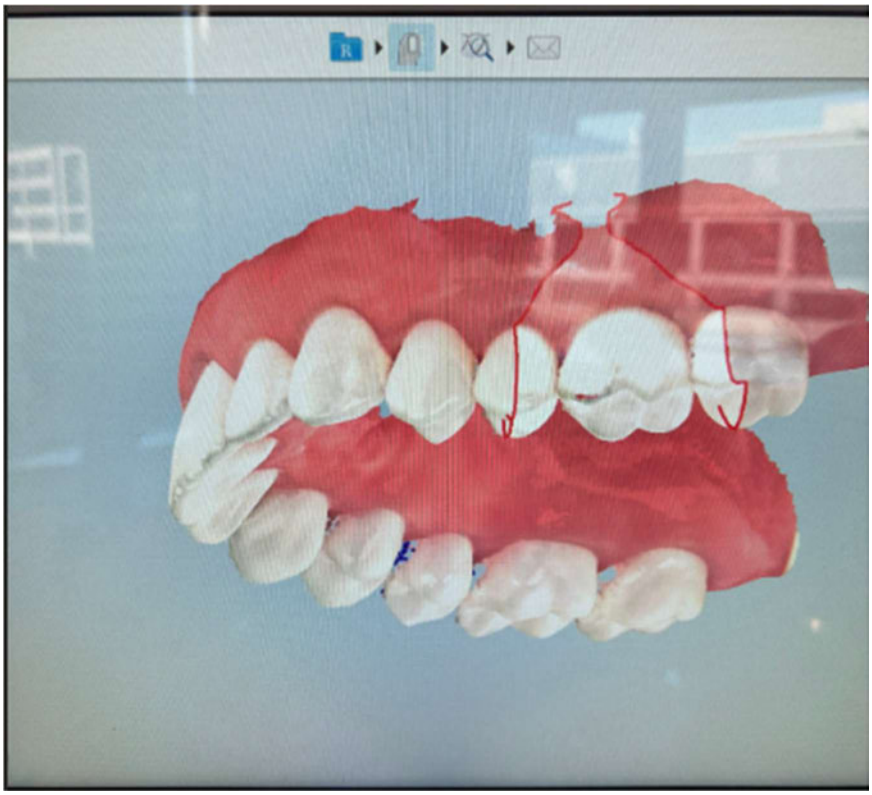
[redacted]

356. When I inspected the iTero scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the iTero scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste on the upper left first molar to simulate debris. In this test, I selected this tooth with debris to be removed from the first scan using the Eraser tool. Then I physically removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. The three images shown below are different views of the second scan of the teeth in the upper arch which included the tooth that once had toothpaste (debris) but then was removed. The image was received by the monitor connected to the iTero scanner of the second scan of the tooth, which is the physically changed portion of the patient's intraoral cavity.

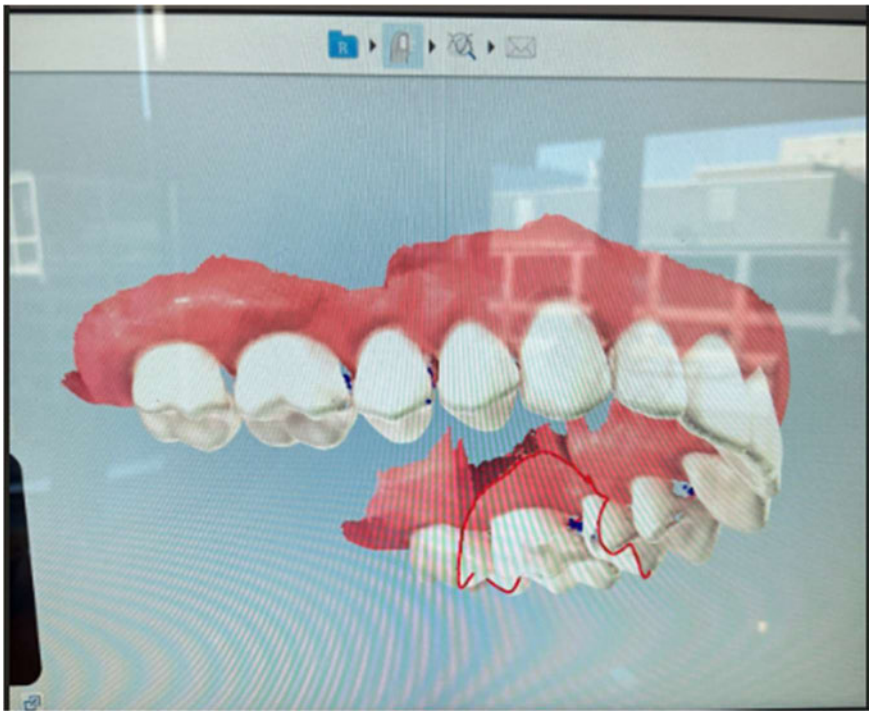


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[redacted]



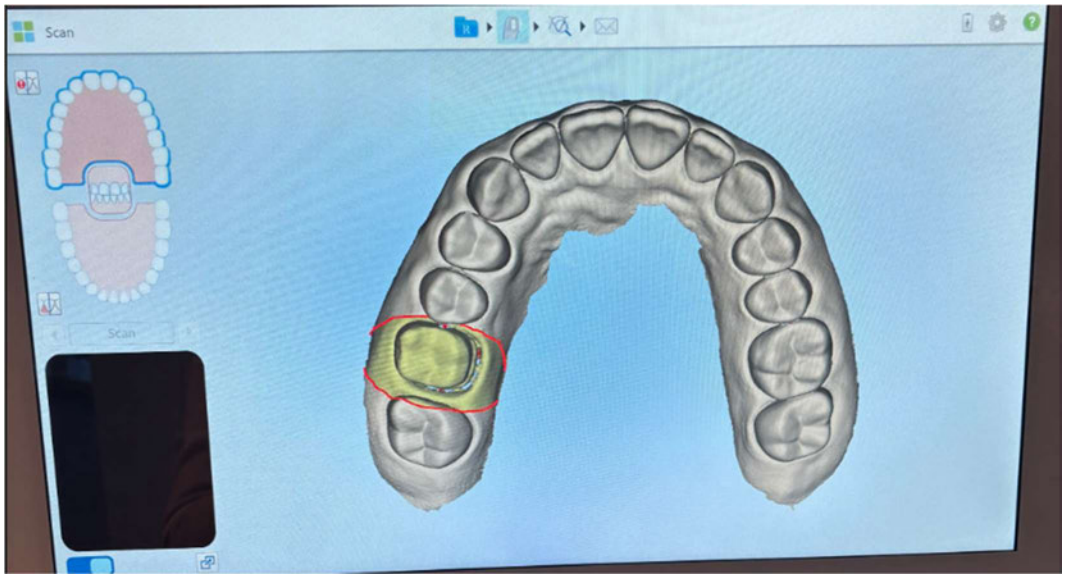
ALGN04783320



ALGN04783322

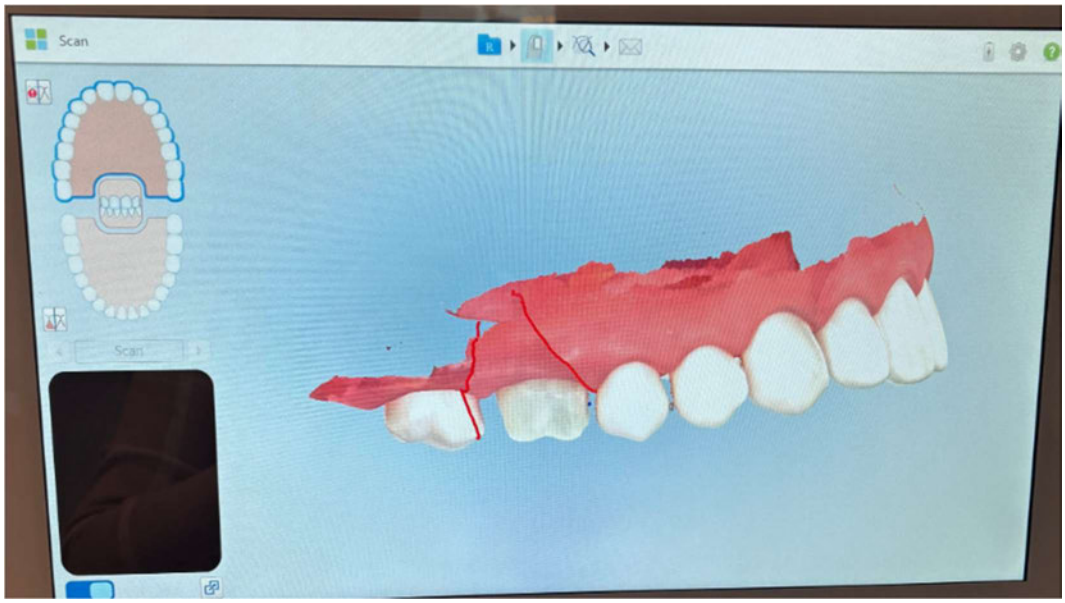
[redacted]

357. When I inspected the iTero scanner, I performed a second test using the scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the iTero scanner system for a crown preparation or other dental procedure where a tooth modification occurs. In this test, I selected on the display screen the tooth (*i.e.*, the upper right first molar) that was going to be removed and replaced with a modified version of the tooth, one that had undergone a crown preparation procedure. On the typodont, I physically removed the pre-operation tooth with a post-operation crown prepped tooth. Next, I rescanned the post-operation crown prepped tooth. The three images shown below are different views of the second scan of the teeth in the lower arch which included the crown prepped upper right first molar tooth. The images were received by the monitor attached to the iTero scanner of the second scan of the prepped tooth, which is the physically changed portion of the patient's intraoral cavity.

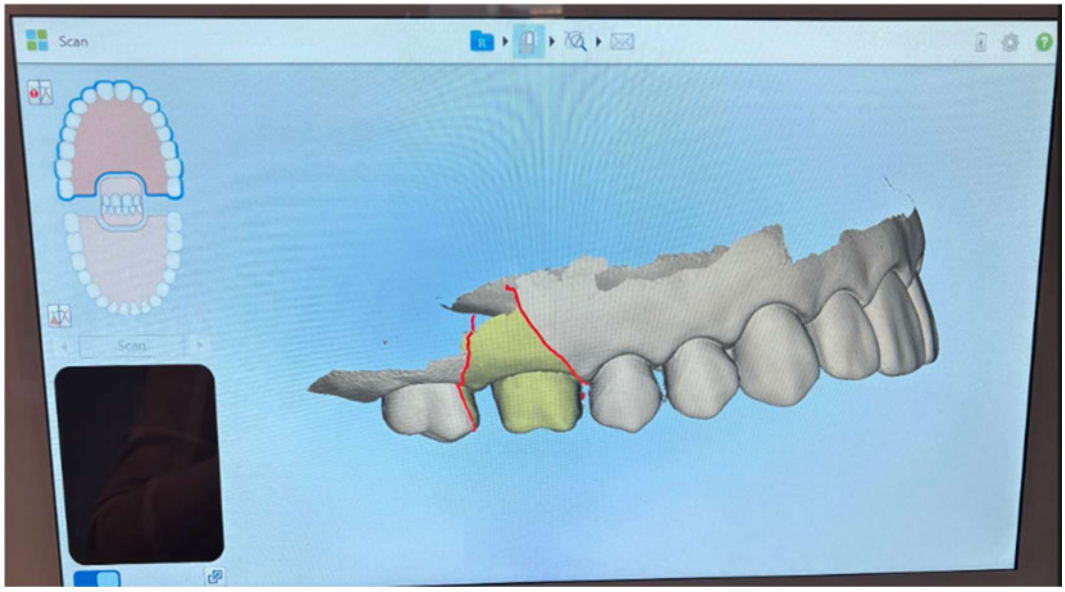


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[redacted]

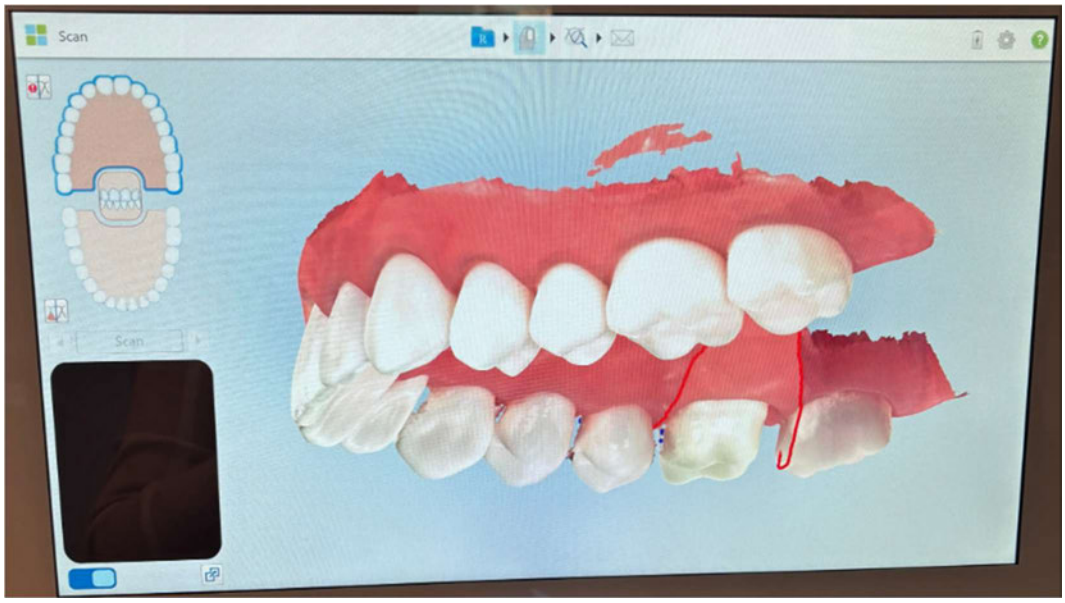


ALGN04783330

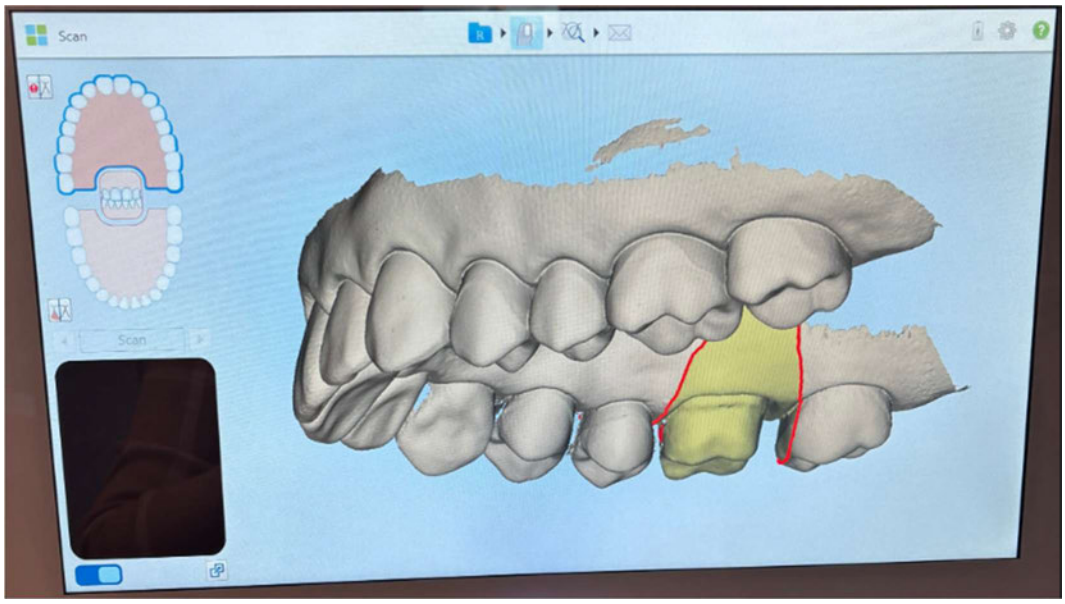


ALGN04783329

[redacted]



ALGN04783331



ALGN04783332

358. As shown above, the iTero scanner system receives second scan data of the patient's teeth from the hand-held intraoral scanner, the scan data including surface data of a physically changed portion of the patient's intraoral cavity. Accordingly, the iTero scanner system satisfies Claim 1[b][vi].

[redacted]

ix. 1[b][vii]: "replace at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity"

359. The iTero scanner system satisfies Claim 1[b][vii]. The iTero scanner system uses the received second scan data to replace at least a portion of the surface data that was previously removed from the model.[303] The system integrates updated surface information corresponding to the physically changed portion of the patient's intraoral cavity into the existing model framework.[304]

360. For example, one of the iTero tutorial videos referenced throughout my report shows a modified 3D model that combines the first and second scan data.[305] The image below shows the first scan in off-white and the second scan in yellow.[306]

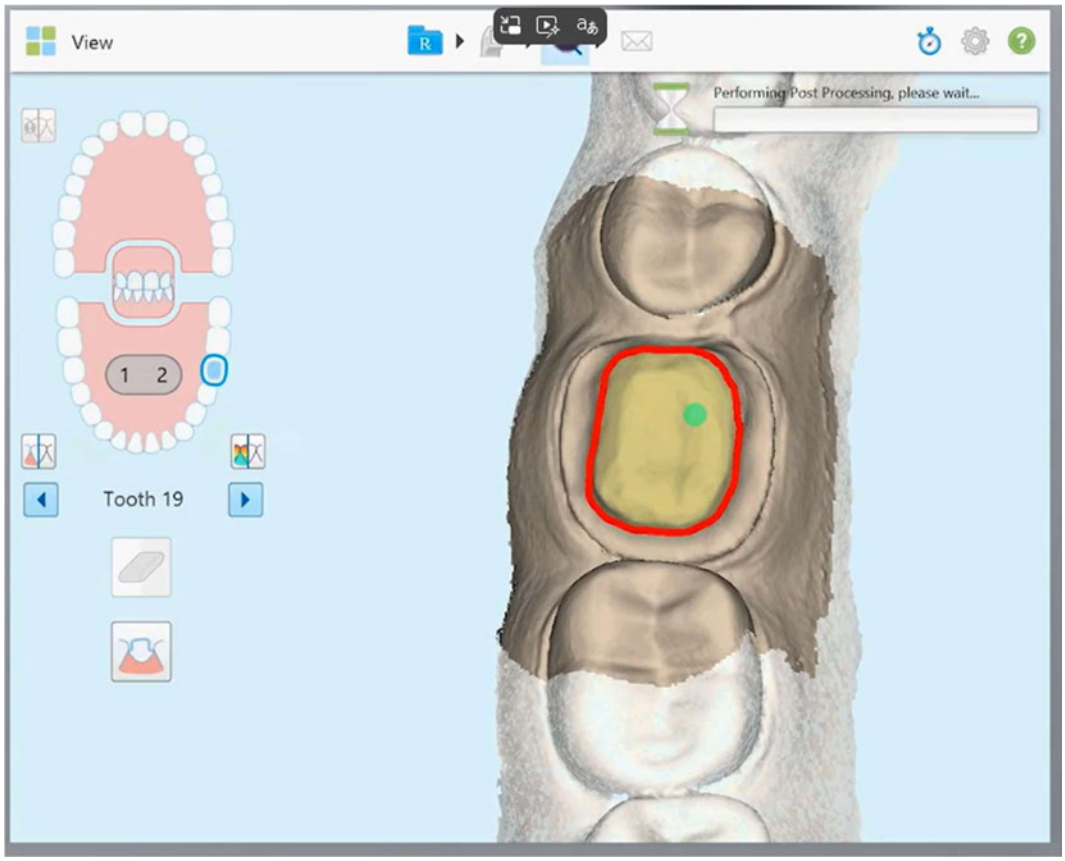
[303] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -292 (describing the Eraser tool as "enab[ling a user] to erase a selected area of the scanned model and then rescan only the erased area"); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN0337552) at -761 (same); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -379 (same); *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -507 (same).

[304] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -292-94; *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN0337552) at -761-63; *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -379-82; *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -507-09; [redacted]

[305] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.51.

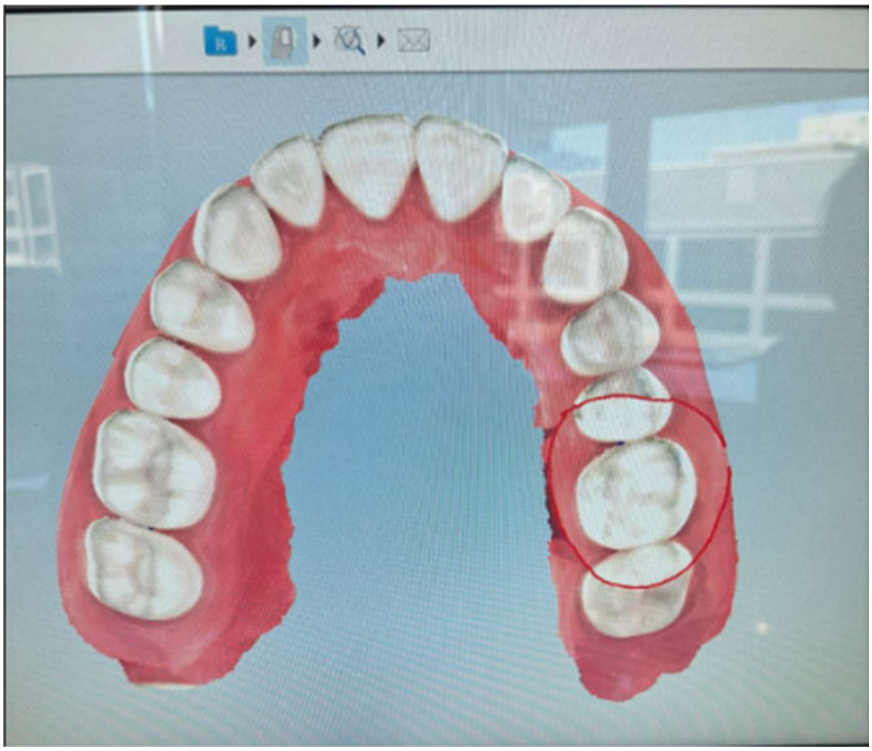
[306] *Id.*

[redacted]

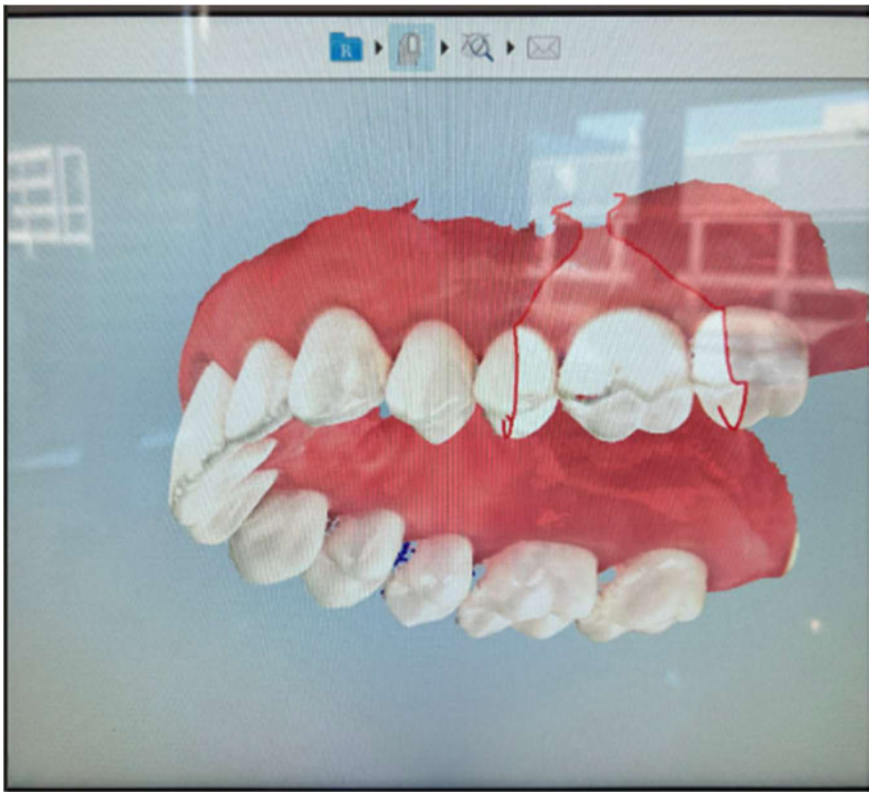


361. When I inspected the iTero scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the iTero scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris. After scanning the upper dental arch with the toothpaste on the tooth, I used my finger on the touch-screen monitor to select this tooth to be removed from the first scan using the Eraser tool. Then I physically removed the toothpaste from the tooth and rescanned the tooth. Below are three different views of the same image after the first scan of the tooth with debris was replaced with the received second scan data of the tooth without the debris.

[redacted]

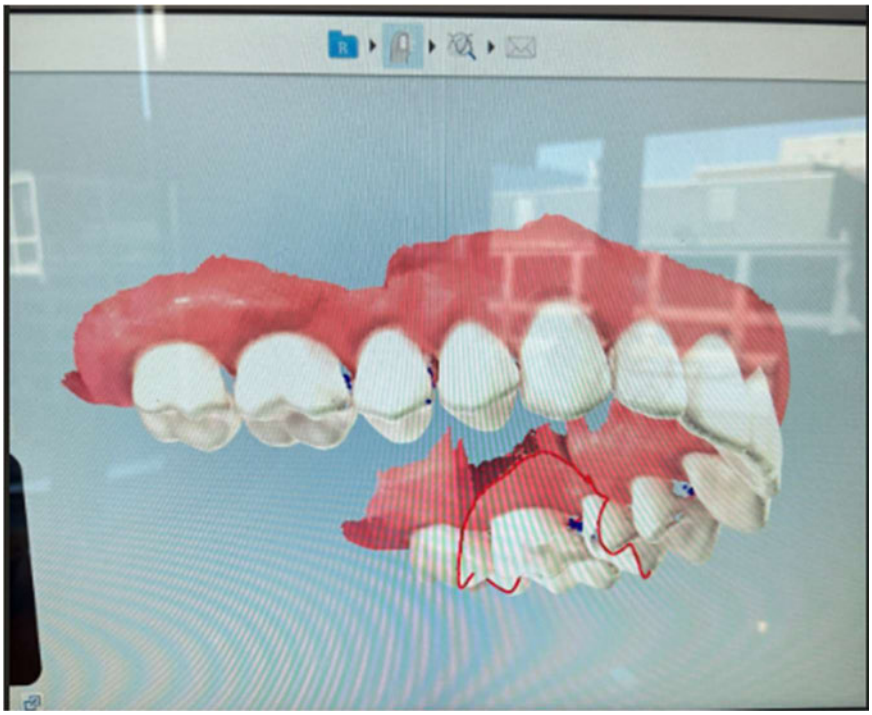


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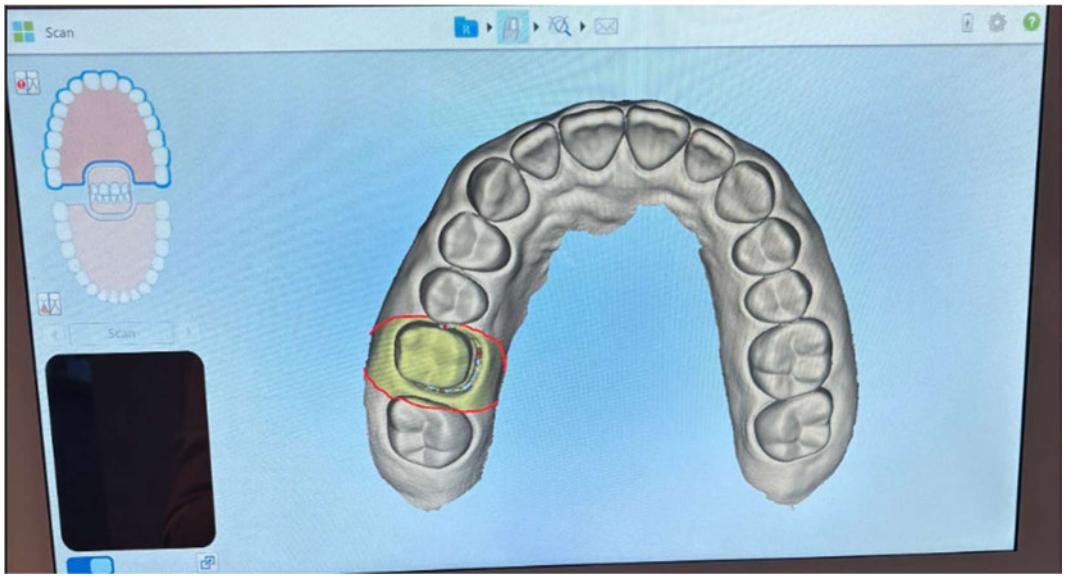
[redacted]



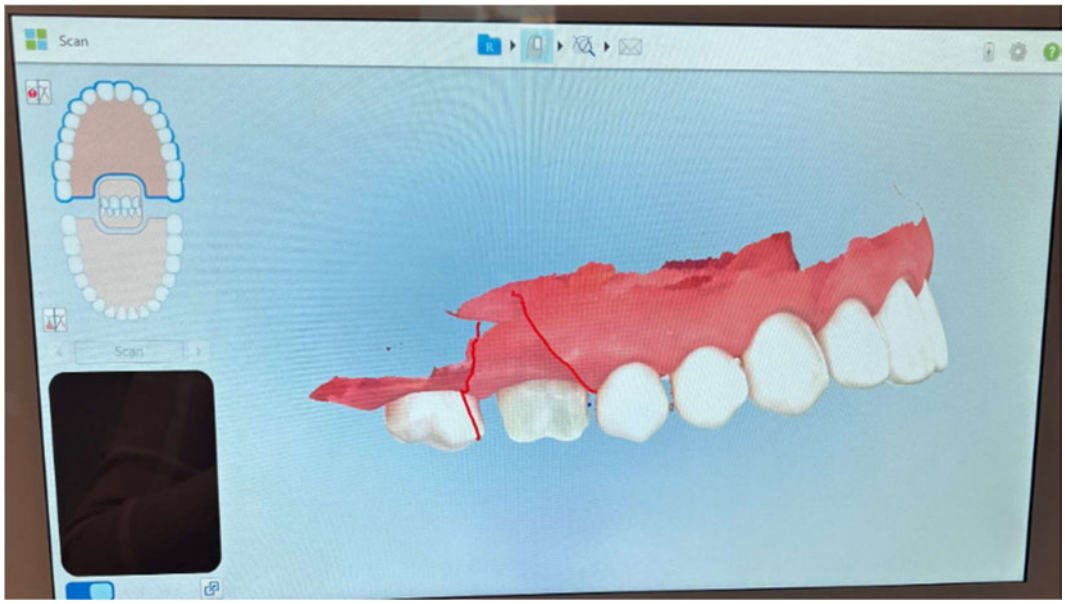
ALGN04783322

362. I also performed a second test using the iTero scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the upper right first molar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the upper dental arch with the pre-operation tooth, I used my finger on the touch-screen monitor to select this tooth so that it would be removed from this first scan using the Eraser tool. I then replaced the typodont pre-operation tooth with a typodont post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are five different views after the first scan of the pre-operation tooth was replaced with the received second scan data of the post-operation crown preparation tooth.

[redacted]

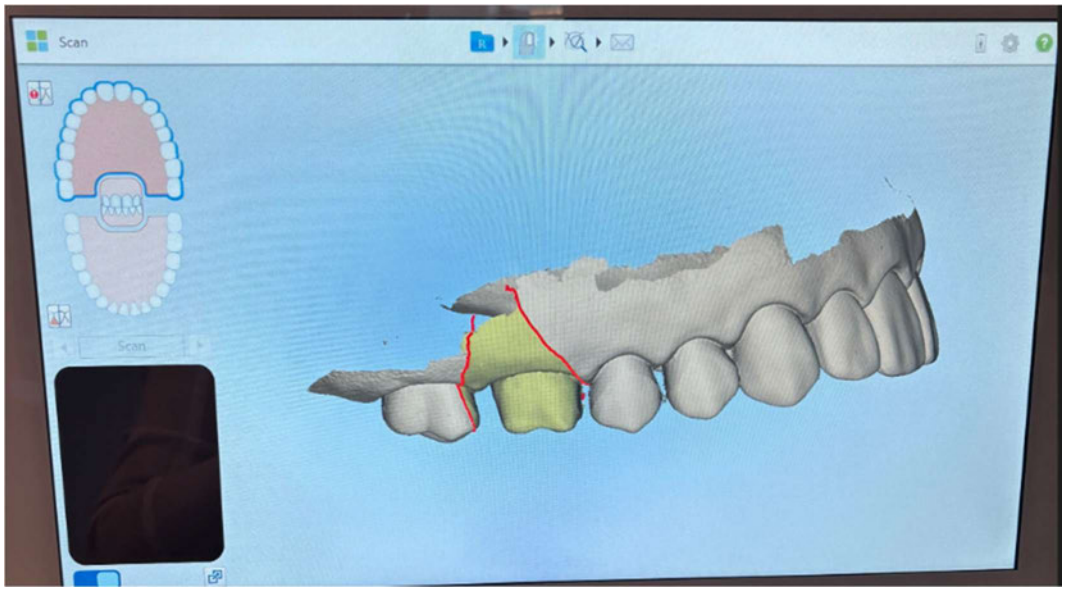


ALGN04783328

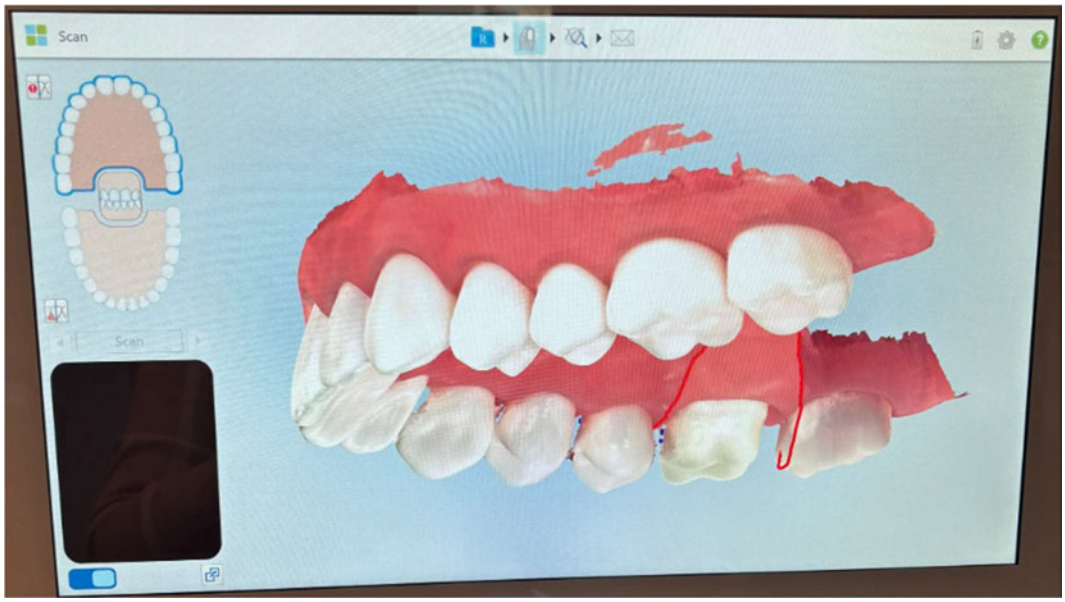


ALGN04783330

[redacted]

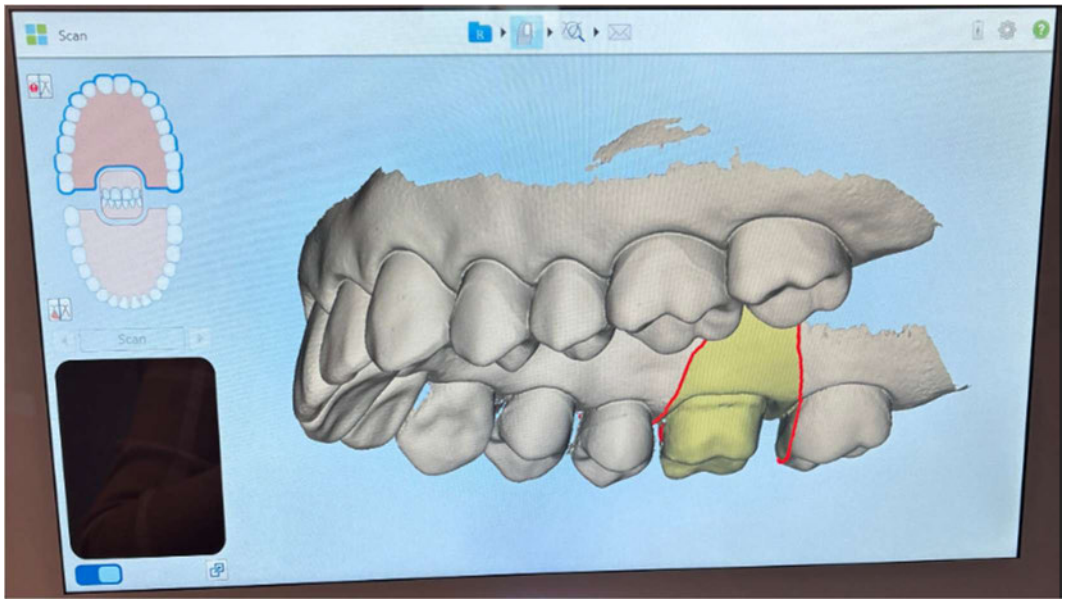


ALGN04783329



ALGN04783331

[redacted]



ALGN04783332

363. As shown above, the iTero scanner system replaces at least a portion of the removed surface portion of the model using the received second scan data of the patient's teeth including surface data of a physically changed portion of the patient's intraoral cavity. Accordingly, the iTero scanner system satisfies Claim 1[b][vii].

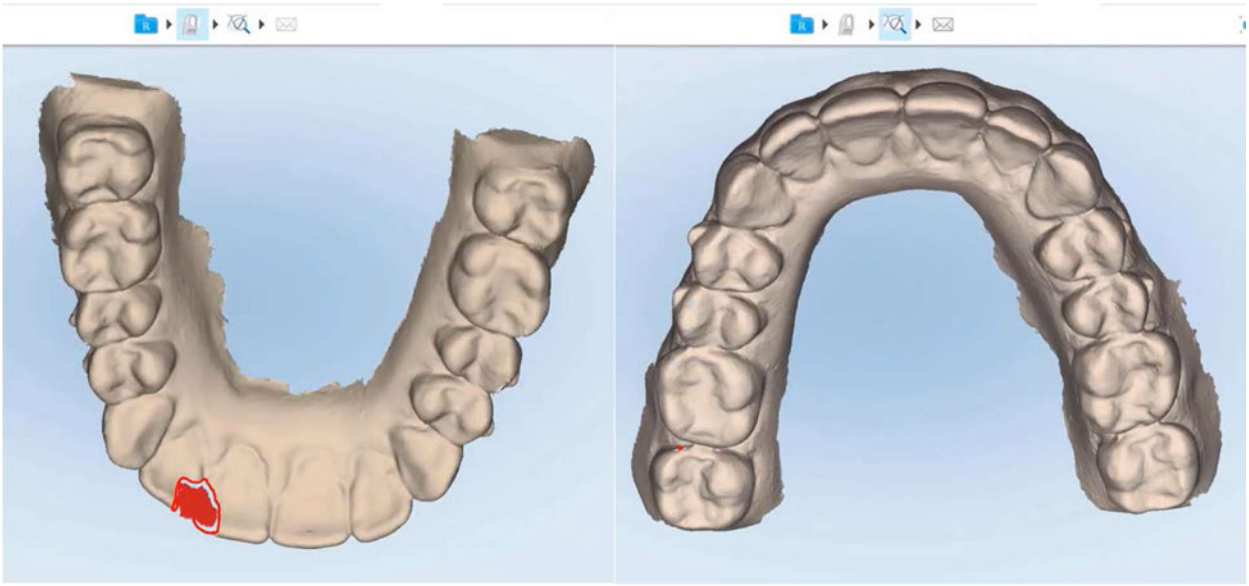
x. 1[b][viii]: "output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the second scan data."

364. The iTero scanner system satisfies Claim 1[b][viii]. Following replacement of the removed surface portion using the second scan data, the iTero scanner system outputs the updated digital model to the display. For example, below are two images of a digital model displayed in one of the iTero tutorial videos.[307] The image on the left is the model of the patient's teeth after the Eraser tool had been used to remove a portion of the first scan. The

[307] *How to use the Eraser tool: iTero Element intraoral scanners guide*, YouTube (ALGN04788767) at 1:04, 1:13.

[redacted]

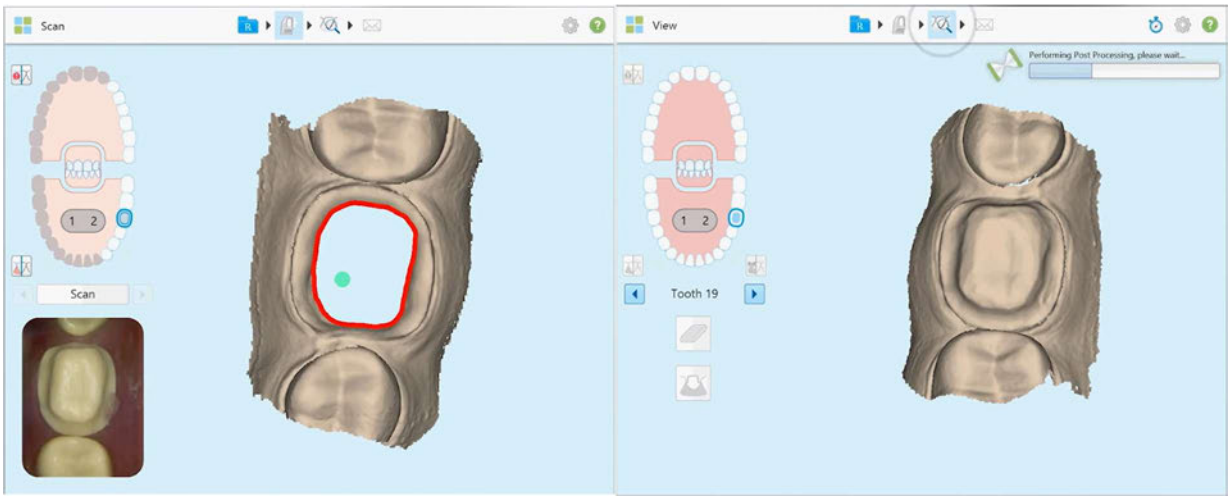
image on the right reflects the incorporation of the new scan data into the previously removed region.



365. As another example, below is another example of a digital model output, as shown in another iTero tutorial video.[308] The image on the left is after the Eraser tool has been applied to remove a portion of the scan. The image on the right is the digital model output displayed after the portion of the removed surface portion has been replaced using the second scan data.

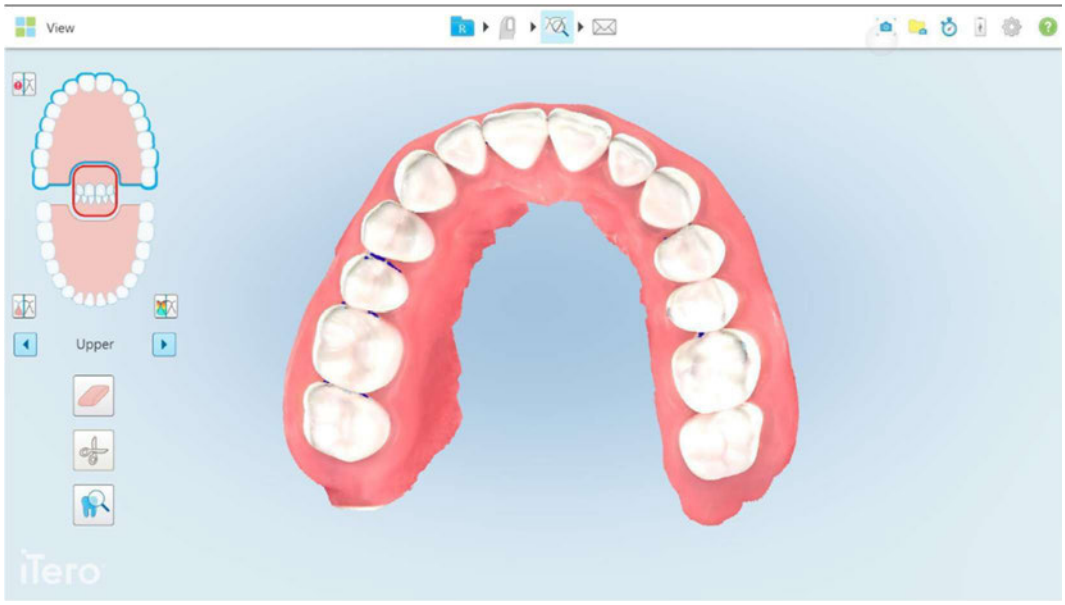
[308] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0:41, 0:54.

[redacted]

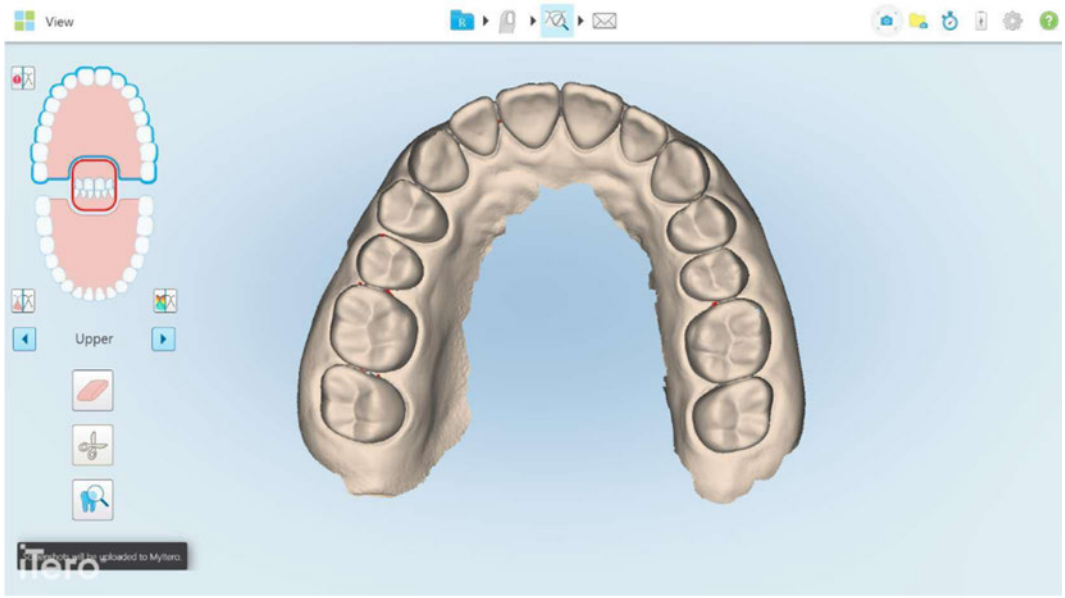


366. When I inspected the iTero scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont. I performed this test to simulate debris on or between the patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan using the Eraser tool. Then I removed the toothpaste from the typodont tooth. Next, I rescanned the tooth that I removed the toothpaste from. The first image below is an image of the output to the display of the model of the patient's upper arch after the removed surface portion was replaced by the second scan. The second image below is an image of the model of the patient's upper arch before the removed surface portion was replaced by the second scan.

[redacted]

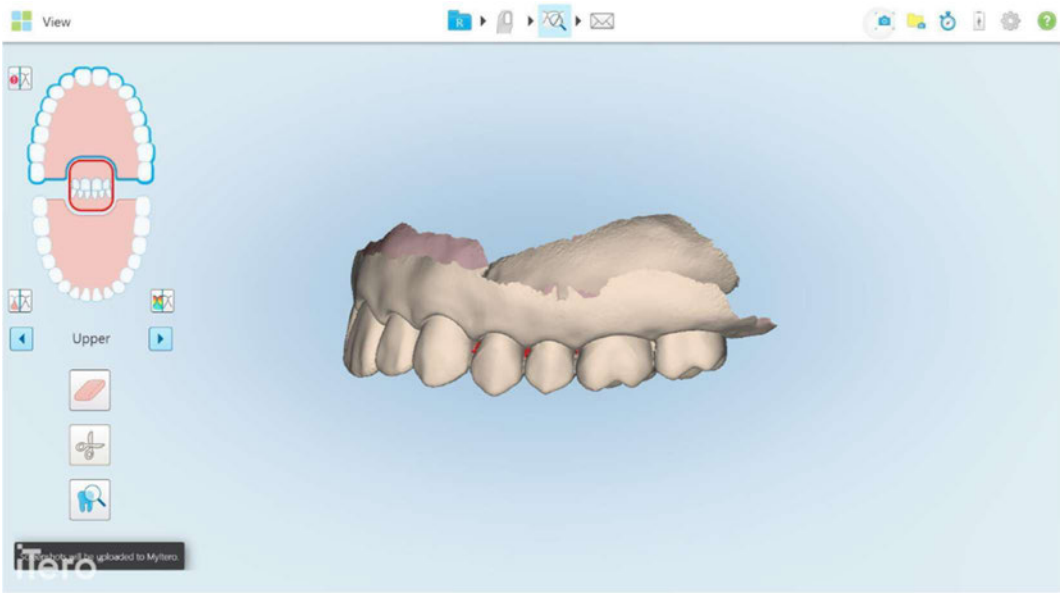


ALGN04783412

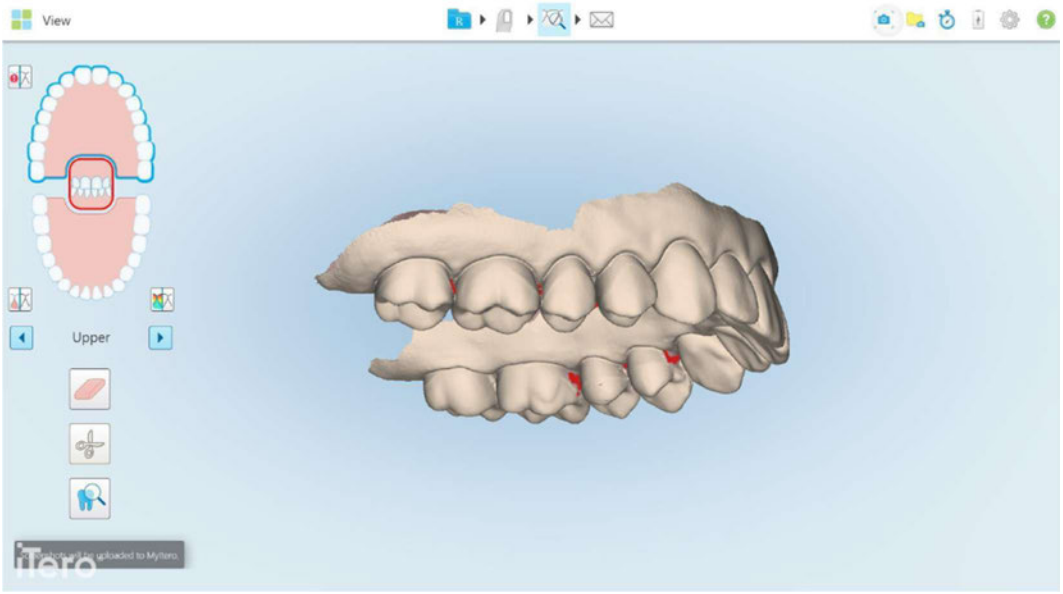


ALGN04783416

[redacted]



ALGN04783420

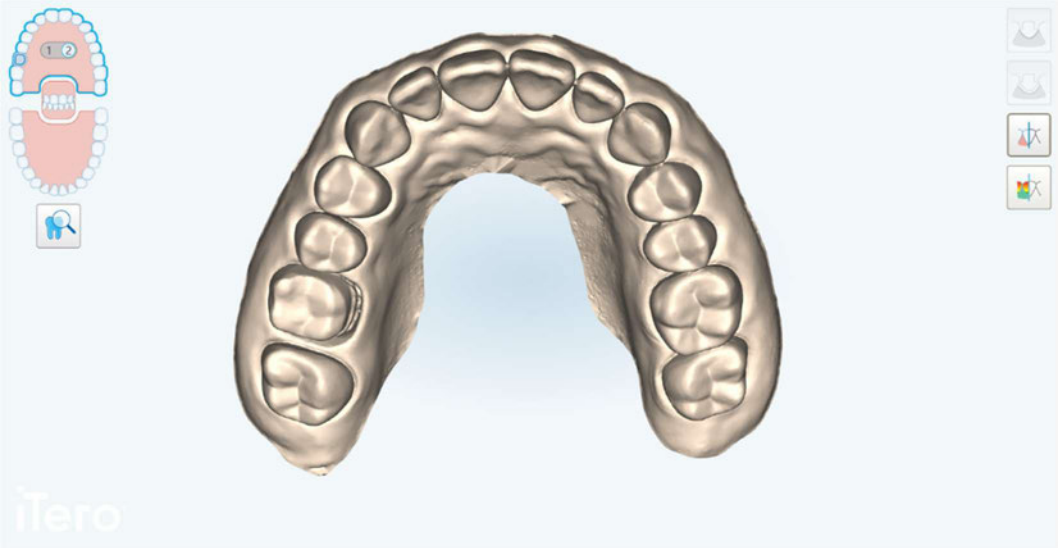


ALGN04783430

367. I also performed a second test using the iTero scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the upper right first molar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the upper dental arch with the pre-

[redacted]

operation tooth, I selected this tooth so that it would be removed from this first scan using the Eraser tool. I then replaced the typodont pre-operation tooth with a typodont post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth.

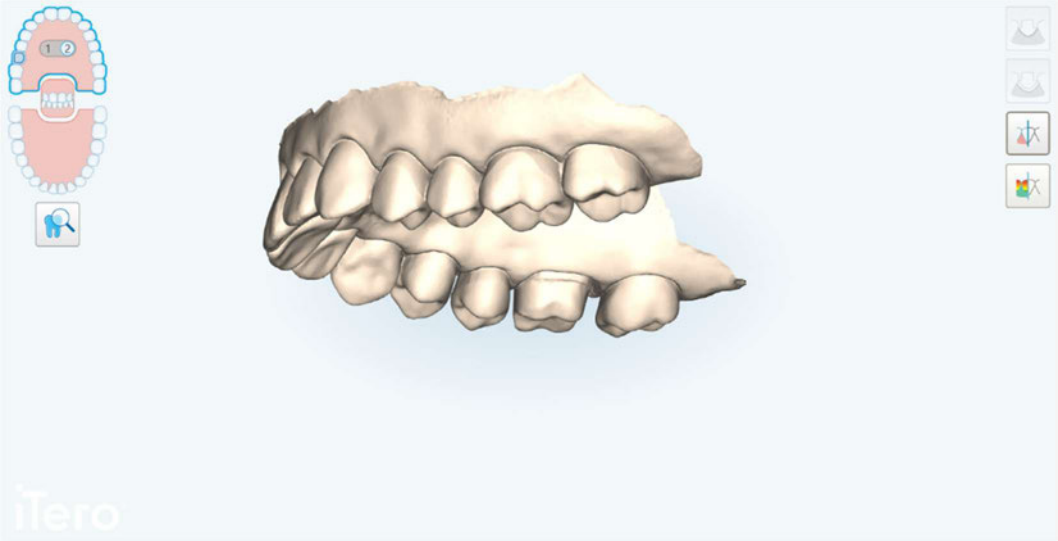


ALGN04783352



ALGN04783365

[redacted]

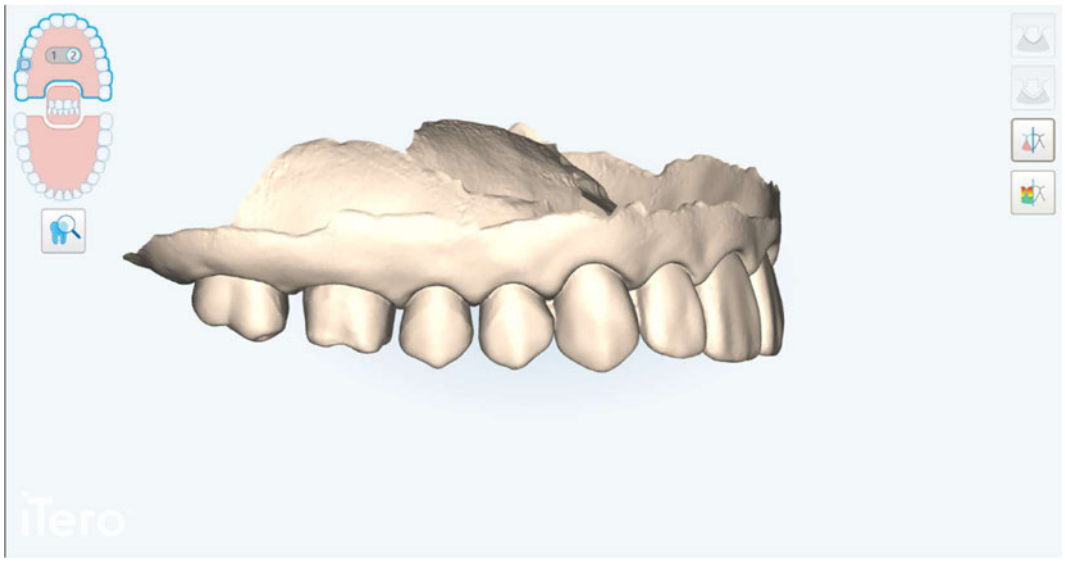


ALGN04783341



ALGN04783360

[redacted]



ALGN04783350

368. As shown above, the iTero scanner system outputs, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the second scan data. Accordingly, the iTero scanner system satisfies Claim 1[b][viii].

b. Claim 4

i. "The system of Claim 1, wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to register the received second scan data with the model."

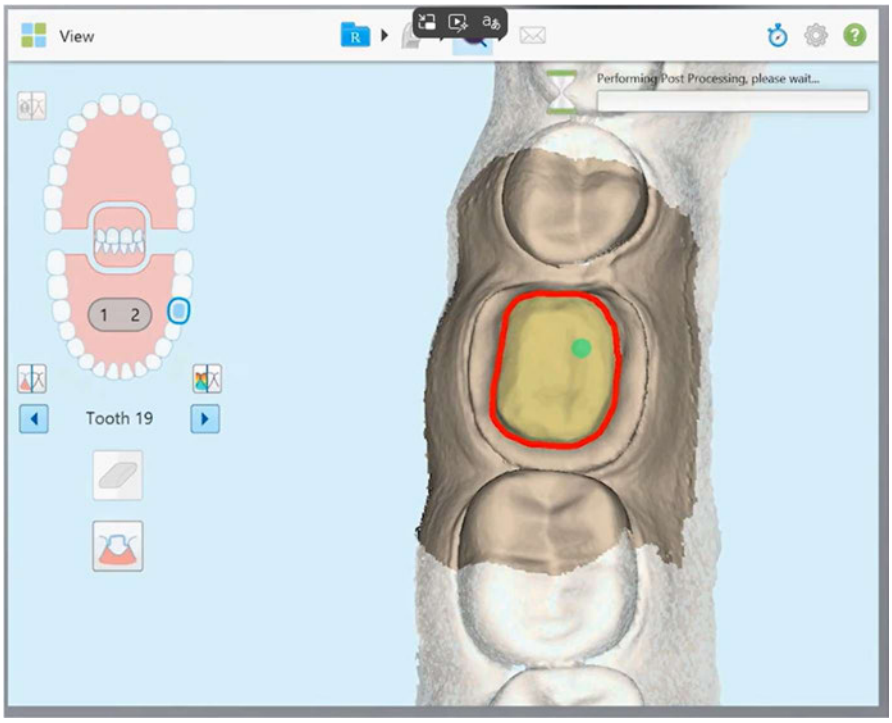
369. The iTero scanner system satisfies Claim 4. As described in connection with Claim 1[b][vii], the iTero software replaces removed surface portions of a digital dental model using subsequently acquired scan data.[309] In performing this replacement, the system aligns and

[309] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -292 (describing the Eraser tool as "enab[ling a user] to erase a selected area of the scanned model and then rescan only the erased area"); *iTero Element™ 5D and iTero Element™ 5D Plus Imaging Systems User Manual*, Align (ALGN0337552) at -761 (same); *iTero Lumina™ Intraoral Scanner User Manual*, Align (ALGN00338216) at -379 (same); *iTero Element™ 5D Plus Lite Intraoral Scanner User Manual*, Align (ALGN00021339) at -507 (same).

[redacted]

spatially registers the second scan data with the existing model so that the new surface data corresponds correctly to the remaining portions of the model.[310]

370. For example, an iTero tutorial video shows iTero software registering the second scan data with the existing model.[311]



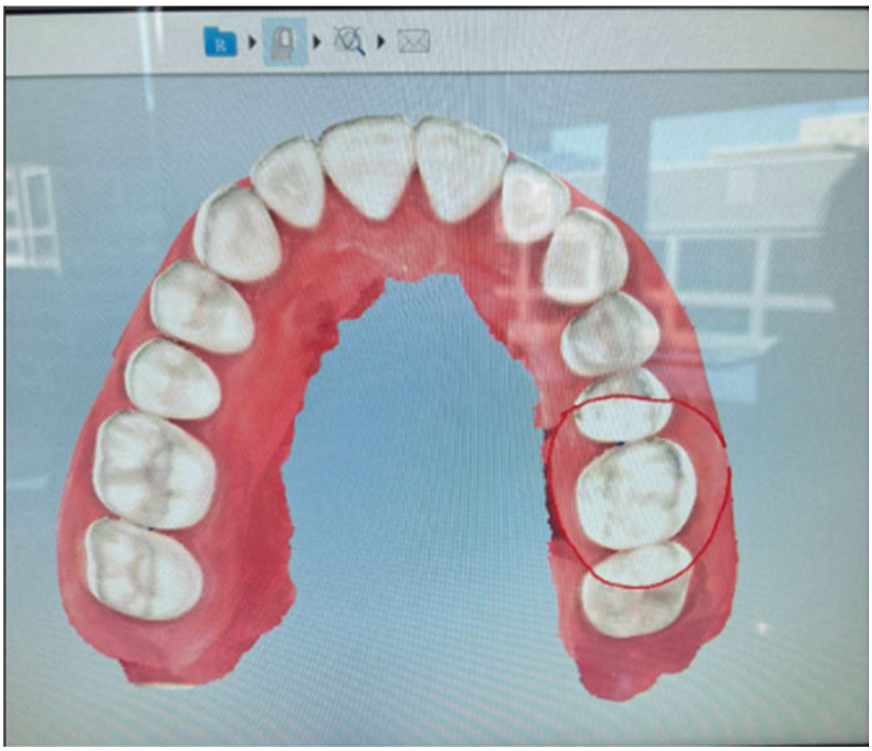
371. When I inspected the iTero scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the iTero scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris. After scanning the upper dental arch with the toothpaste on the tooth, I used my finger on the touch-screen monitor to select this tooth to be removed from the first scan using the Eraser tool. Then I physically removed the toothpaste from the tooth and

[redacted]

[311] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.51.

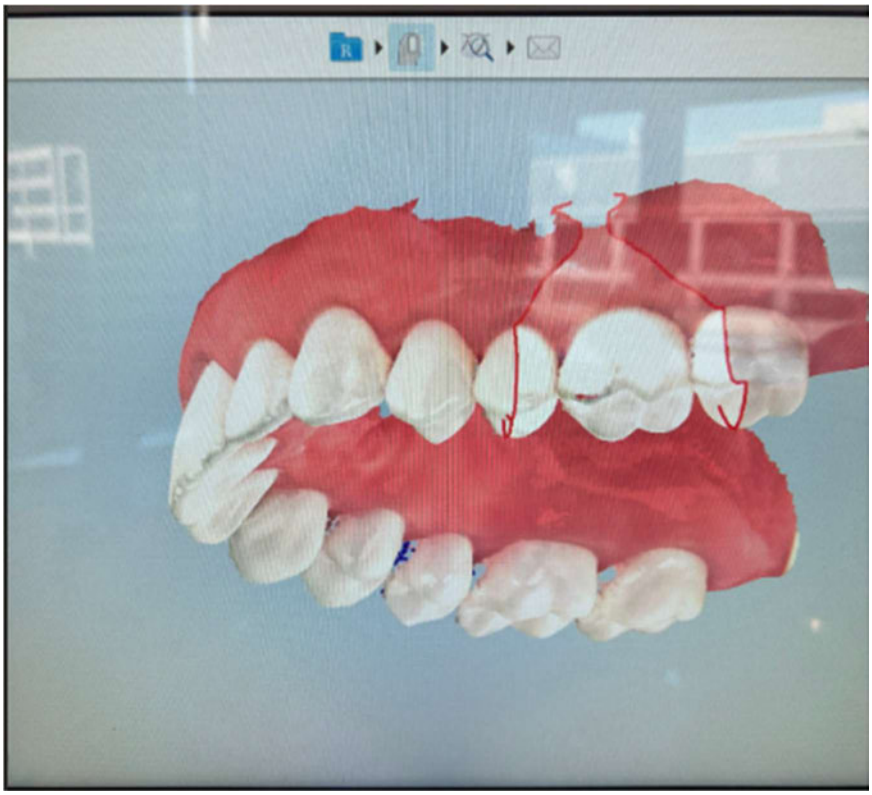
[redacted]

rescanned the tooth. Below are three different views of the same image showing that the iTero scanner system replaced the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model.

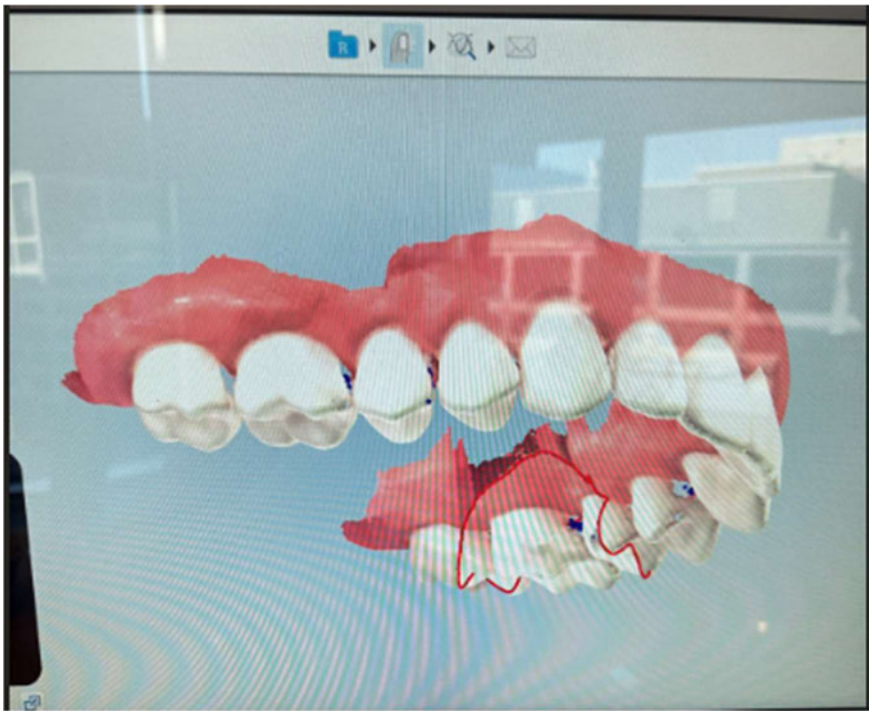


ALGN04783321

[redacted]



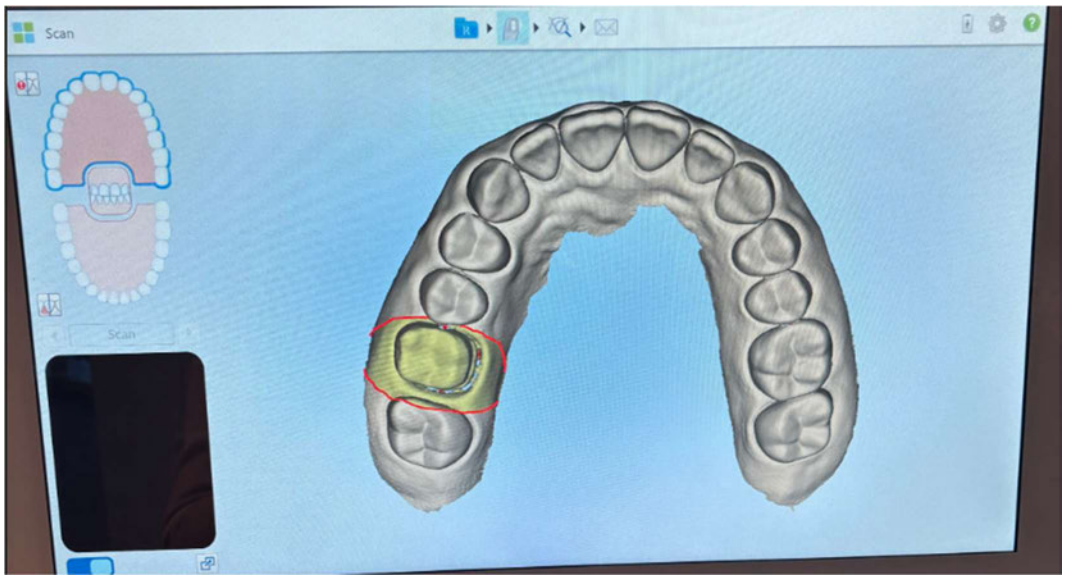
ALGN04783320



ALGN04783322

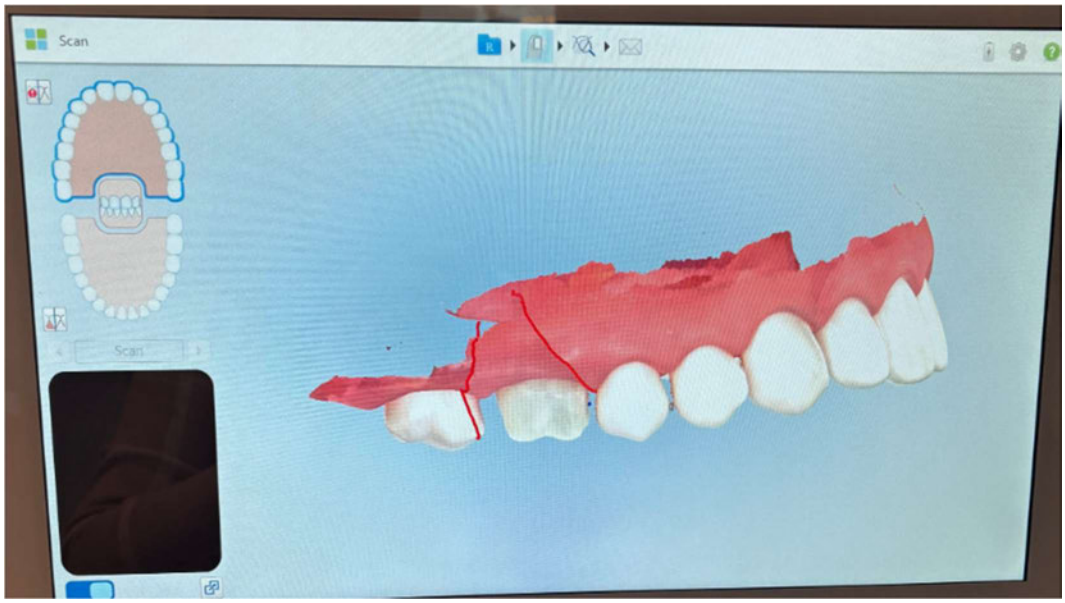
[redacted]

372. I also performed a second test using the iTero scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the upper right first molar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the upper dental arch with the pre-operation tooth, I used my finger on the touch-screen monitor to select this tooth so that it would be removed from this first scan using the Eraser tool. I then replaced the typodont pre-operation tooth with a typodont post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are images showing that the iTero scanner system registered the second scan data by identifiable features in the second scan data with corresponding parts of the existing digital model.

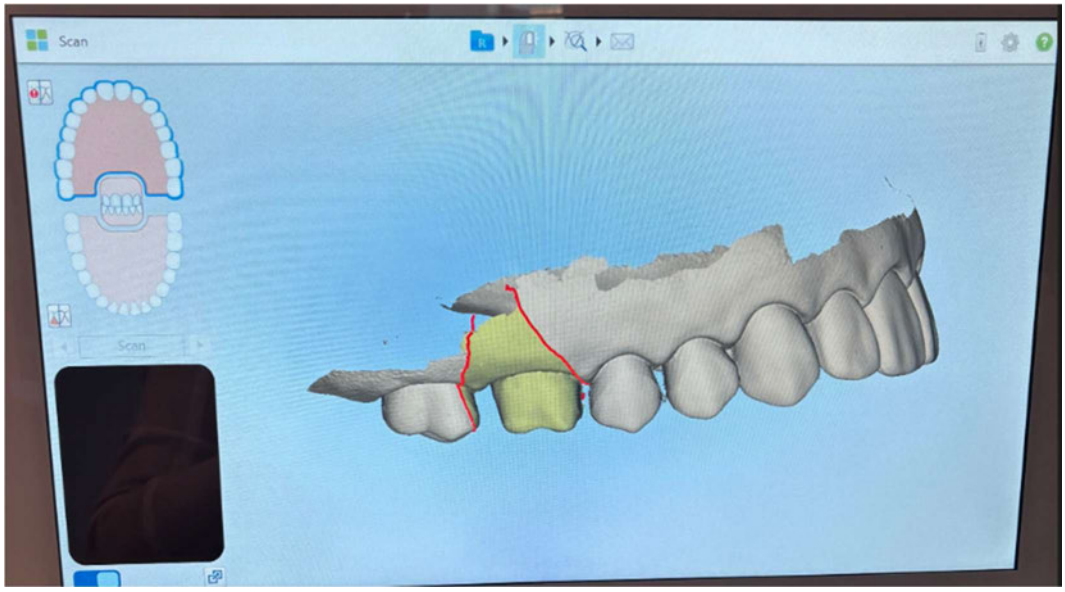


ALGN04783328

[redacted]

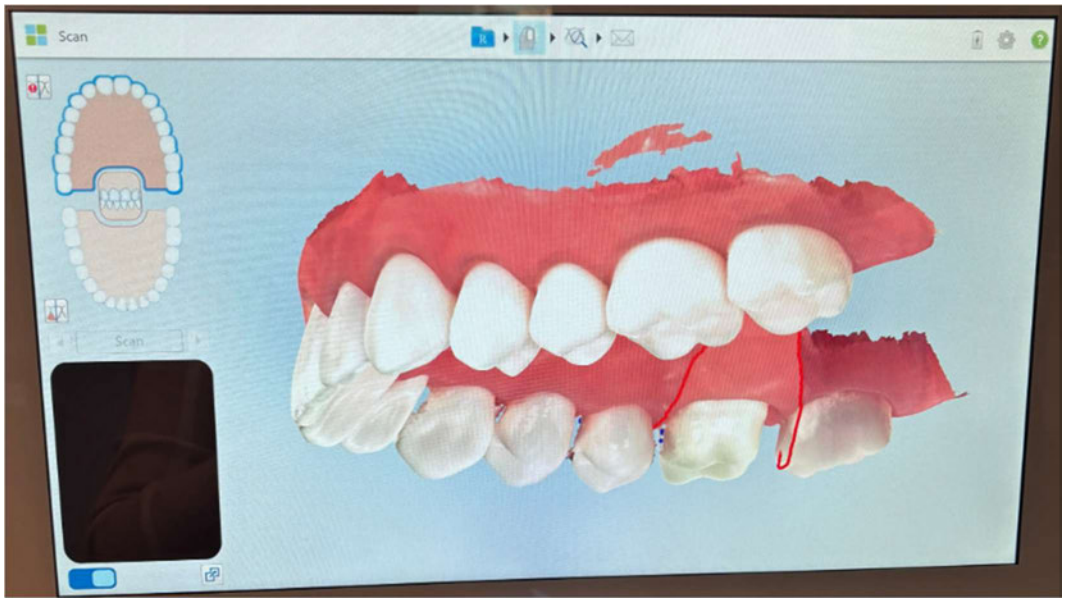


ALGN04783330

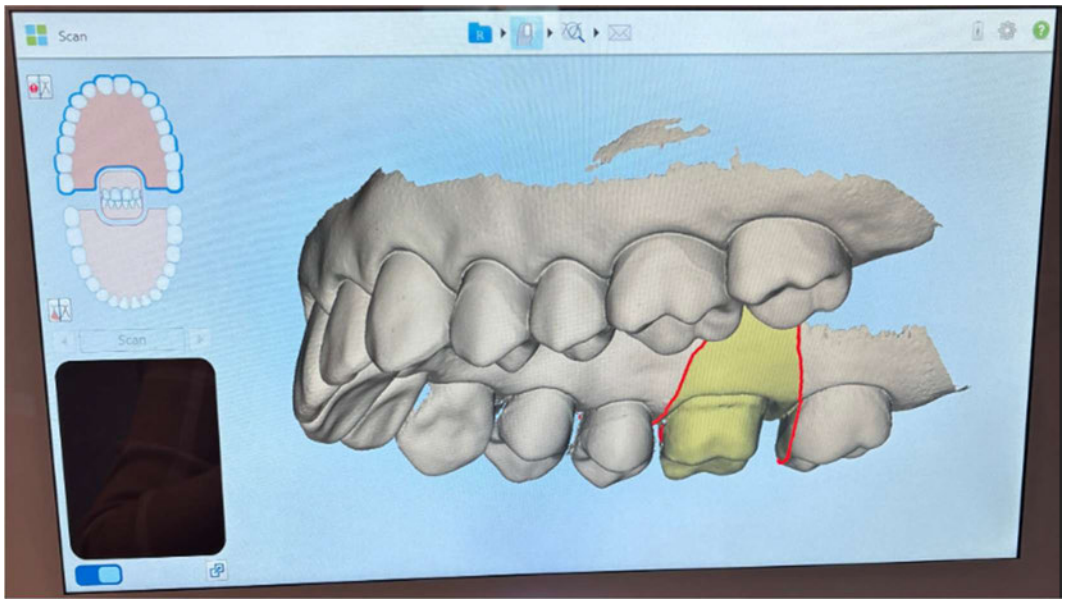


ALGN04783329

[redacted]



ALGN04783331



ALGN04783332

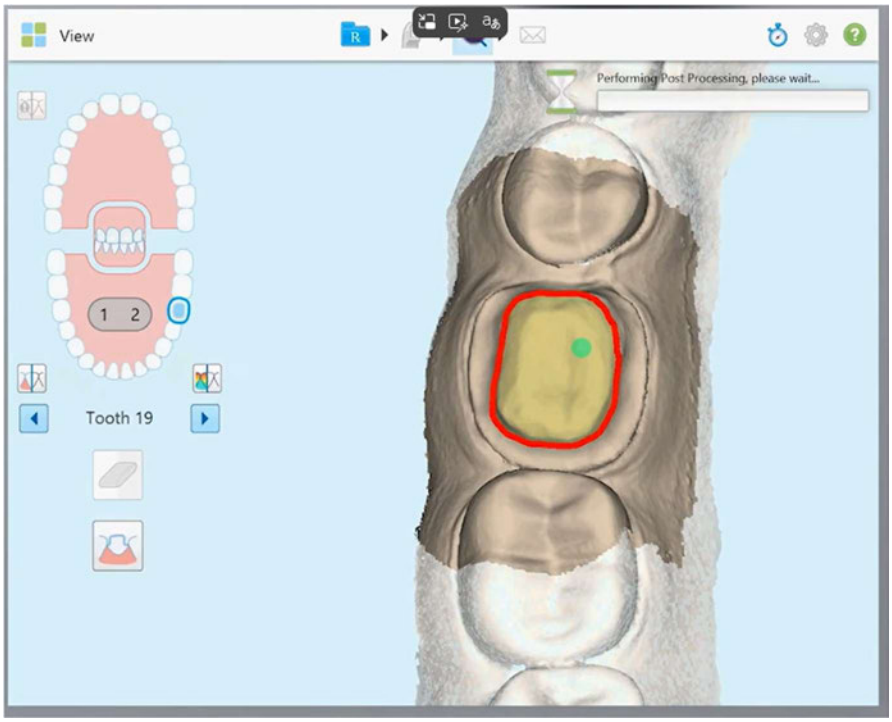
373. As shown above, the iTero scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model. Accordingly, the iTero scanner system satisfies Claim 4.

[redacted]

c. Claim 5

i. "The system of Claim 4, wherein the received second scan data is registered with the model by aligning identifying data of the received second scan data with corresponding parts of the model."

374. The iTero scanner system satisfies Claim 5. The iTero software aligns the data between the first and second scans to replace portions of the model.[312] For example, an iTero tutorial video shows iTero software registering the second scan data with the existing model.[313]



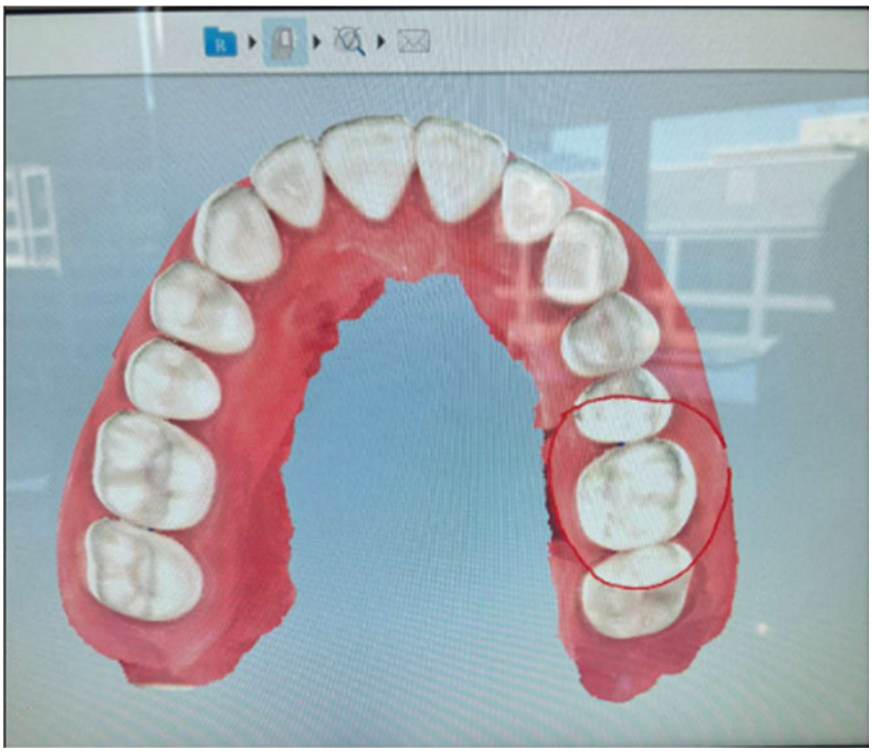
375. When I inspected the iTero scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the iTero scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of

[redacted]

[313] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124), at 0.51.

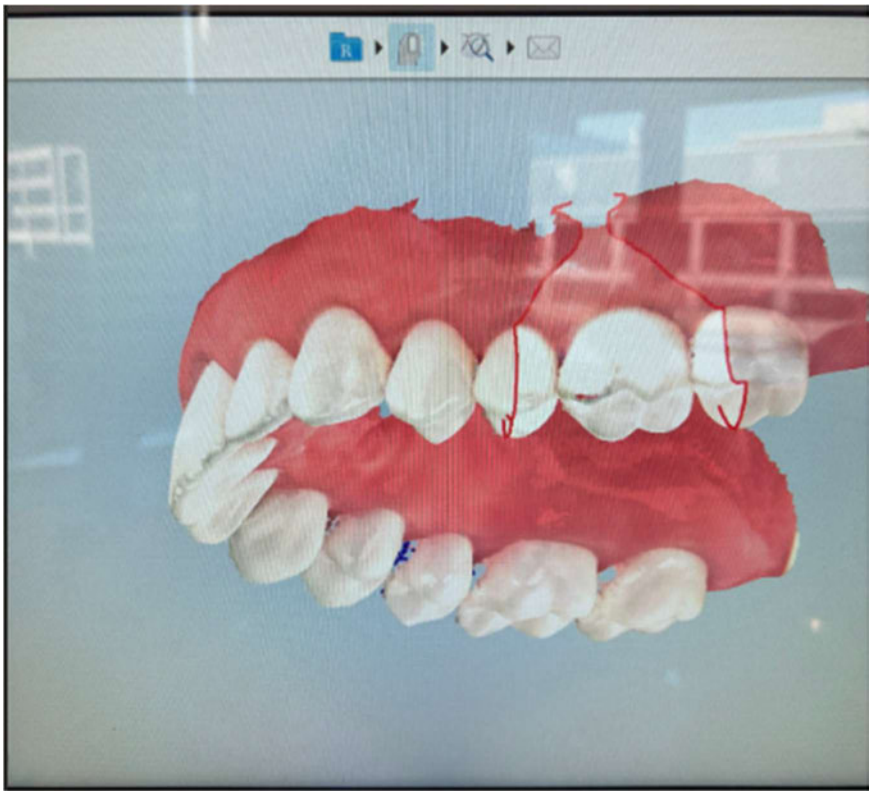
[redacted]

the typodont to simulate debris. After scanning the upper dental arch with the toothpaste on the tooth, I used my finger on the touch-screen monitor to select this tooth to be removed from the first scan using the Eraser tool. Then I physically removed the toothpaste from the tooth and rescanned the tooth. Below are three different views of the same image showing that the iTero scanner system registered the second scan data by identifiable features in the second scan data with corresponding parts of the existing digital model.

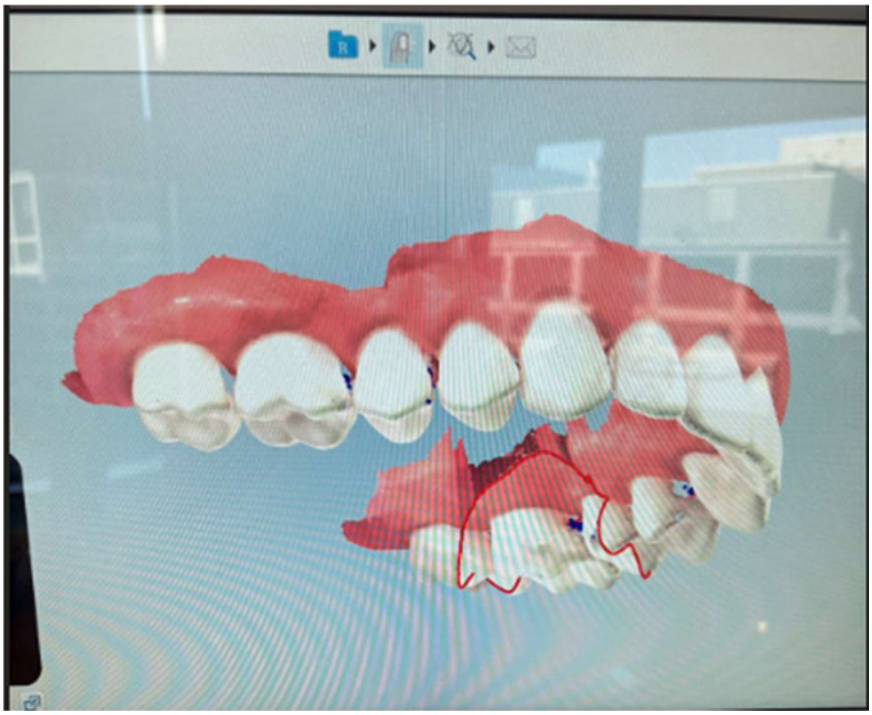


ALGN04783321

[redacted]



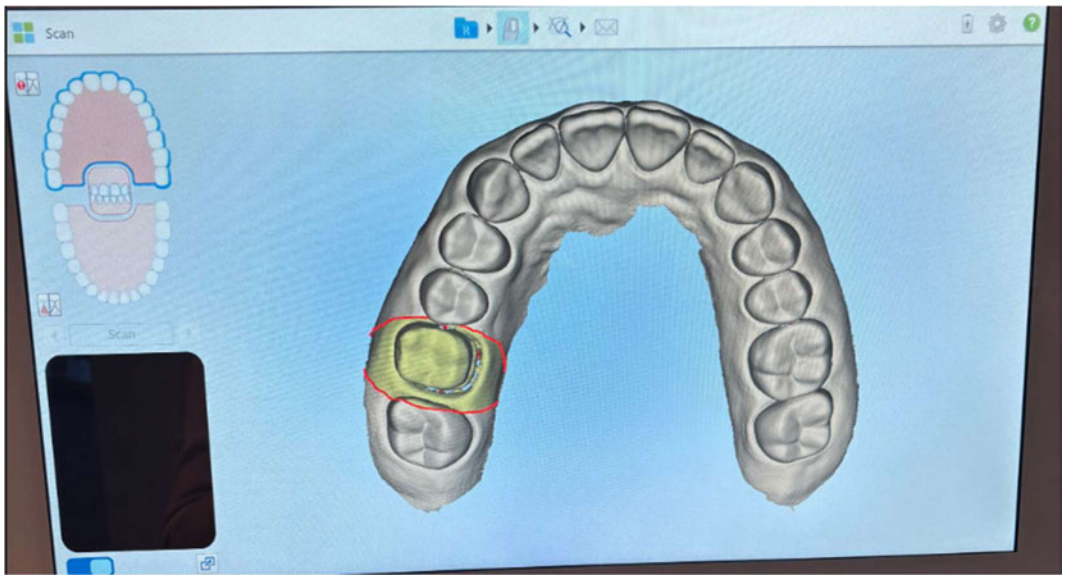
ALGN04783320



ALGN04783322

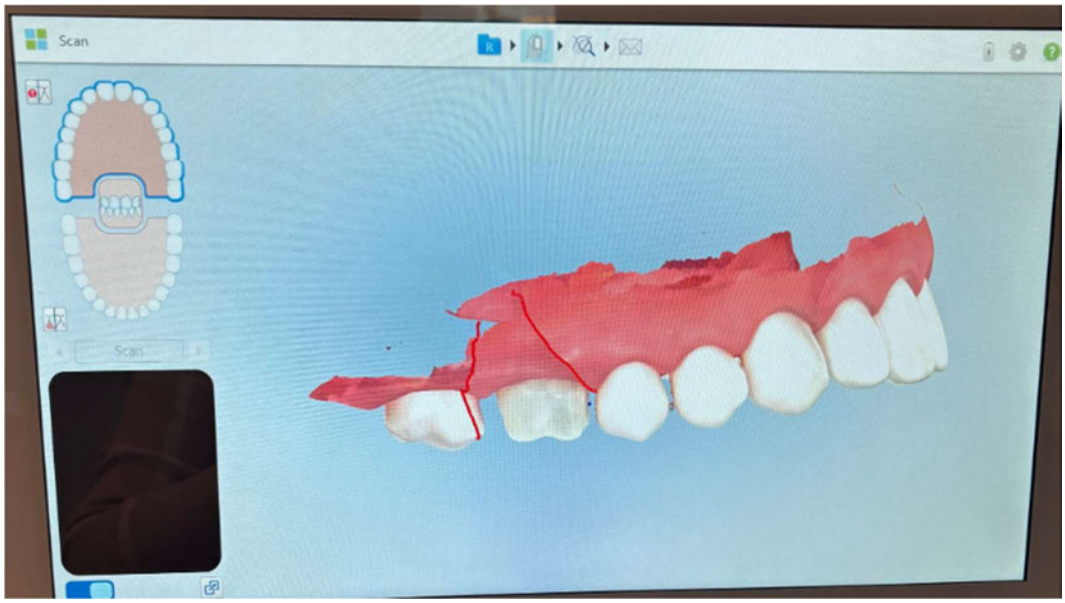
[redacted]

376. I also performed a second test using the iTero scanner and a typodont to simulate a patient's teeth. I performed this test to simulate the workflow for a crown preparation or other dental procedure. In this test, I chose the upper right first molar typodont tooth as the tooth that would be modified with a crown preparation. After scanning the upper dental arch with the pre-operation tooth, I used my finger on the touch-screen monitor to select this tooth so that it would be removed from this first scan using the Eraser tool. I then replaced the typodont pre-operation tooth with a typodont post-operation crown preparation tooth. Next, I rescanned just the post-operation crown preparation tooth. Below are images showing that the iTero scanner system replaced the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model.

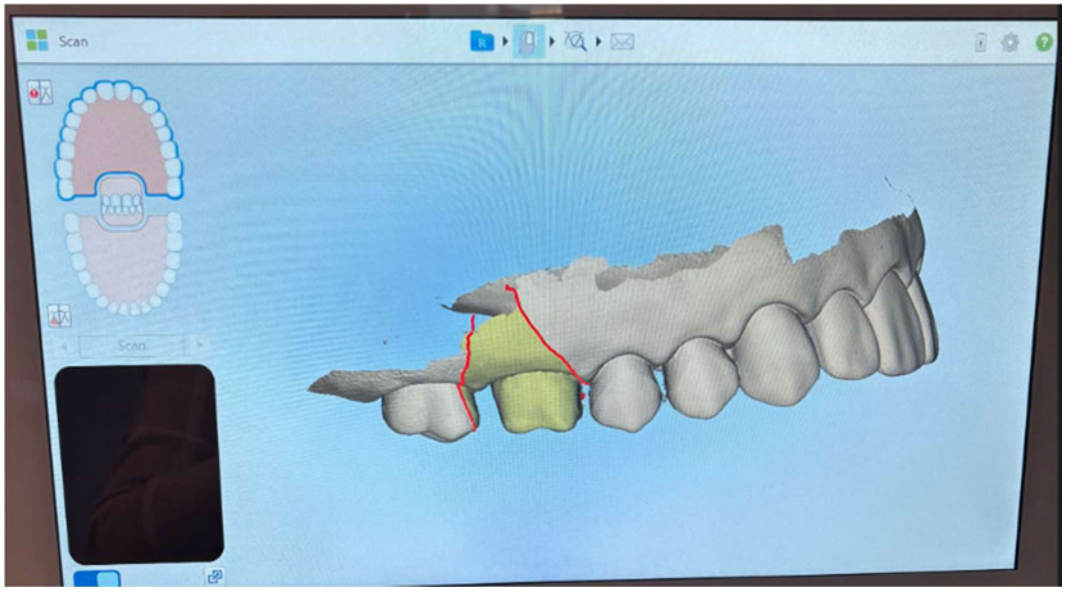


ALGN04783328

[redacted]

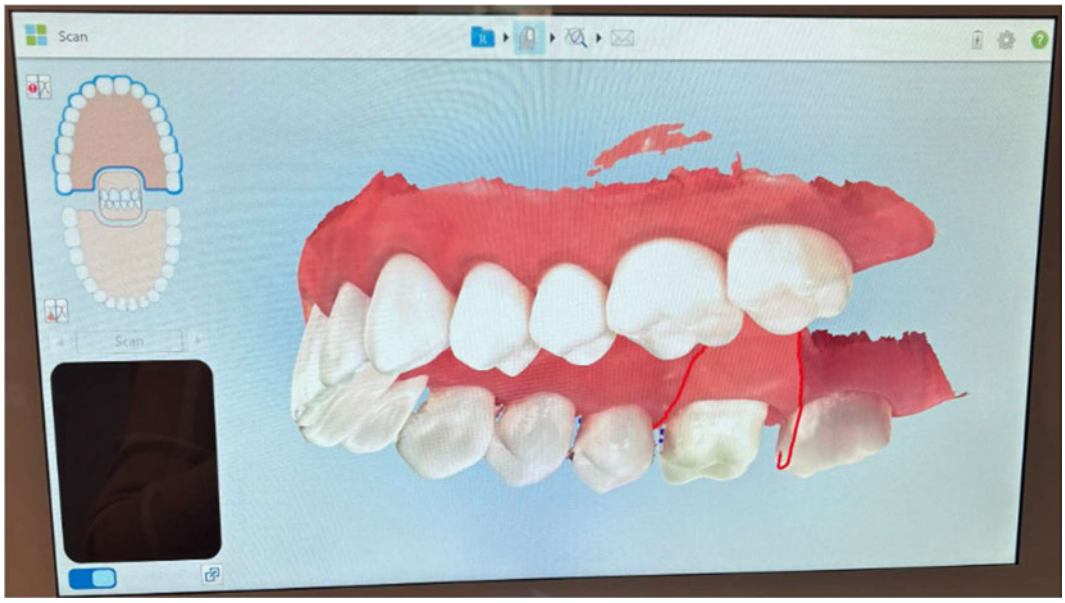


ALGN04783330

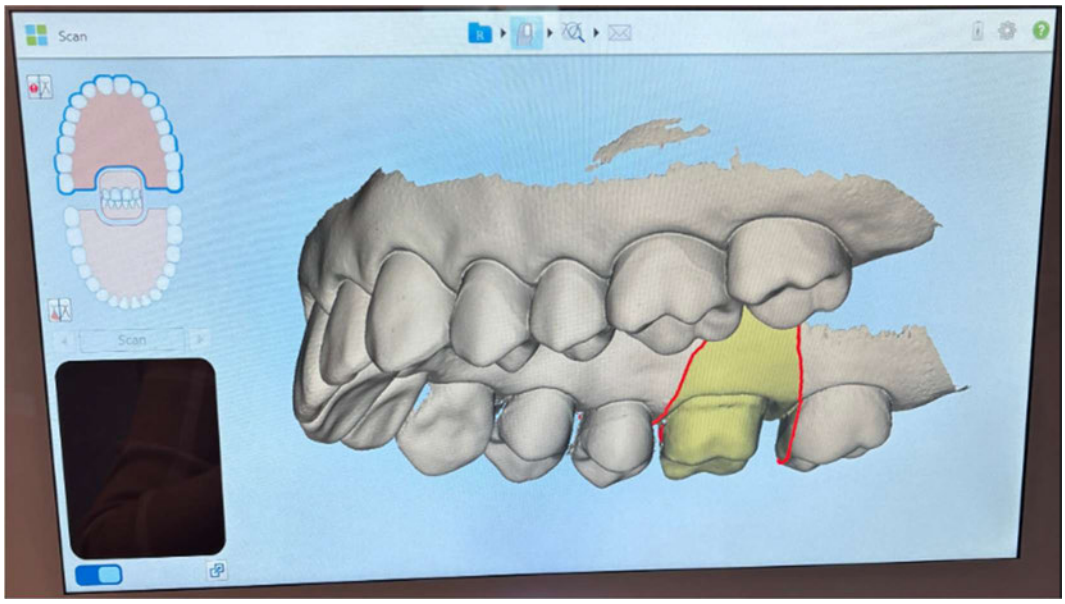


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[redacted]



ALGN04783331



ALGN04783332

377. As shown above, the iTero scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data by registering the received second scan data with the model. Accordingly, the iTero scanner system satisfies Claim 5.

[redacted]

d. Claim 6

i. "The system of Claim 5, wherein the instructions to replace the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further stitch a portion of the received second scan data with the model."

378. The iTero scanner system satisfies Claim 6. In addition to registering the second scan data with the existing model, the iTero scanner software further stitches the new scan data into the model.[314] Stitching refers to the process of merging the overlapping surface data from the second scan with the existing model.[315]

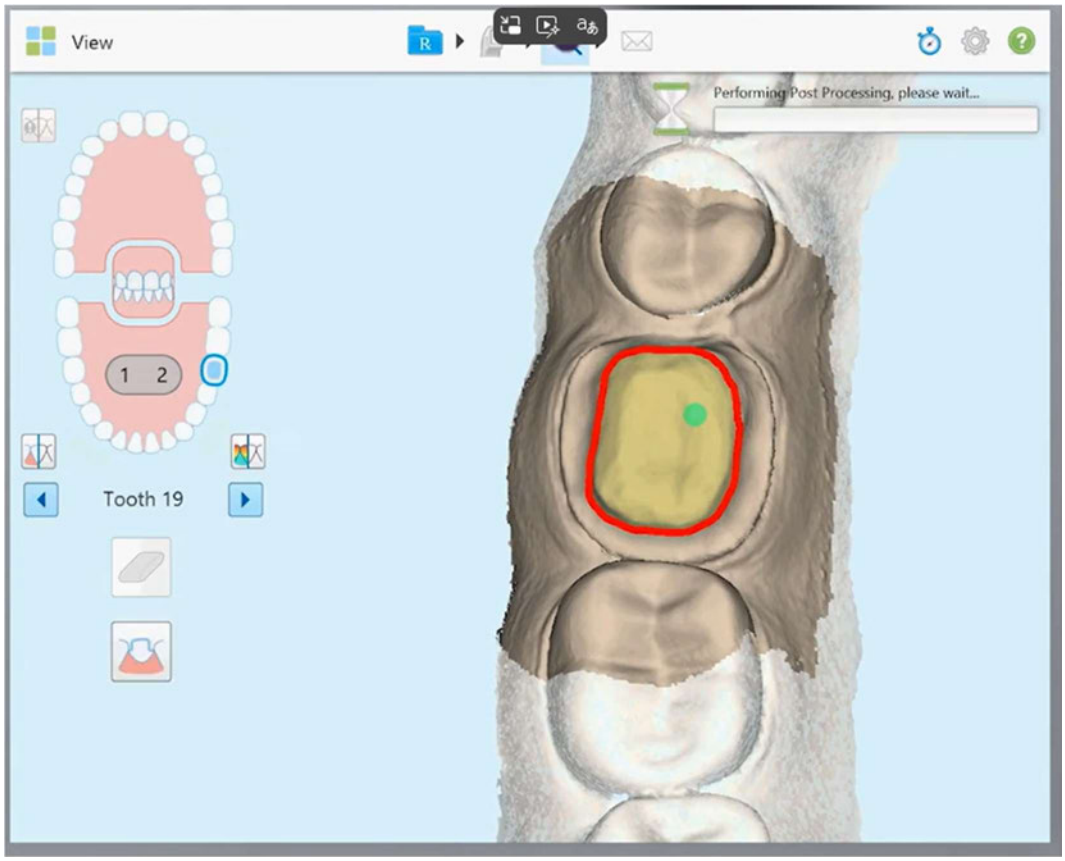
379. The iTero scanner system performs this stitching to ensure a seamless transition between the previously retained portions of the model and the newly added surface data. This stitching step is part of the replacement process and is necessary to produce a usable, unified digital model. As a result, the iTero scanner system includes instructions to stitch a portion of the received second scan data with the model, thereby satisfying Claim 6.

380. For example, an iTero scanner tutorial video shows iTero software stitching a portion of the received second scan data with the model.[316]

[redacted]

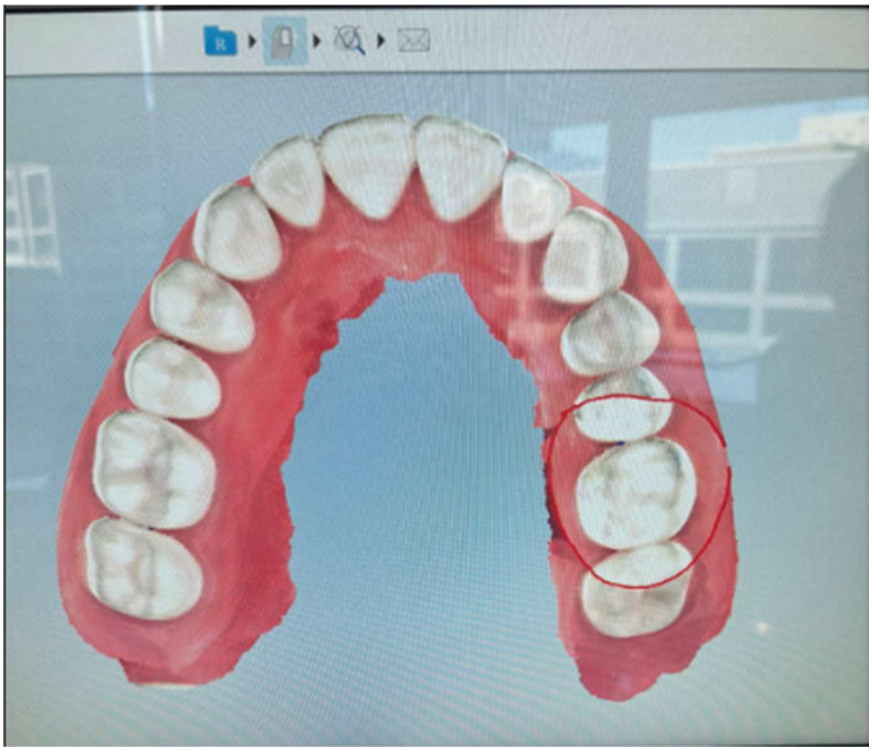
[316] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.51.

[redacted]

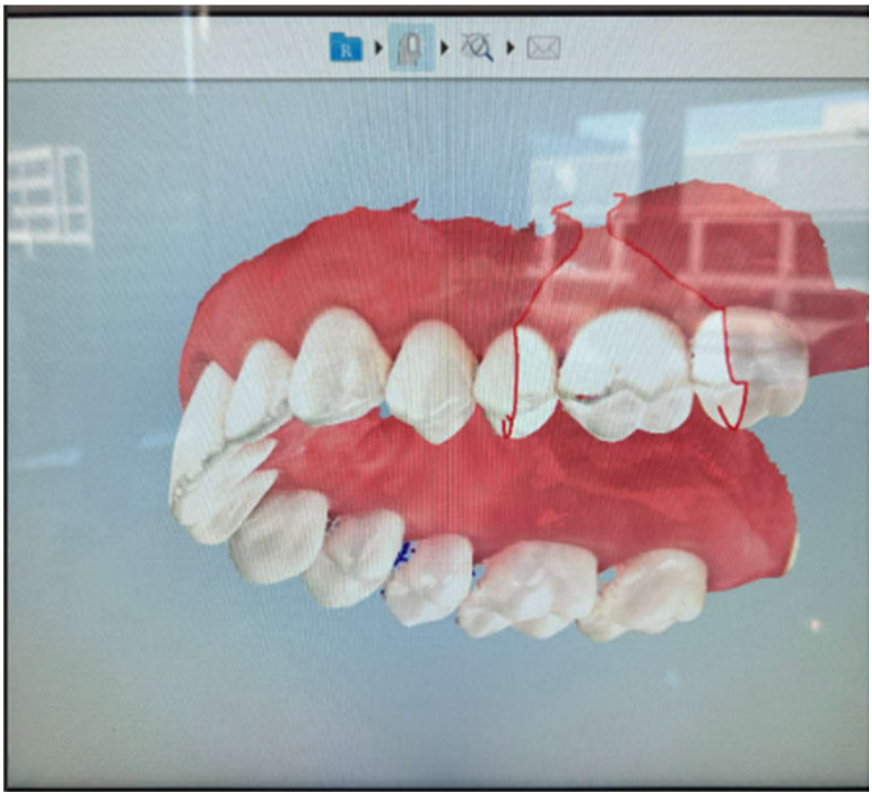


381. When I inspected the iTero scanner, I used it to perform a first test with toothpaste added to the upper left first molar tooth to simulate debris on or between a patient's teeth. In this test, I selected the tooth with debris to be removed from the first scan using the Eraser tool. Then I removed the toothpaste from the tooth. Next, I rescanned the tooth that I removed the toothpaste from. Below are images showing that the iTero scanner system stitched a portion of the received second scan data with the existing model.

[redacted]

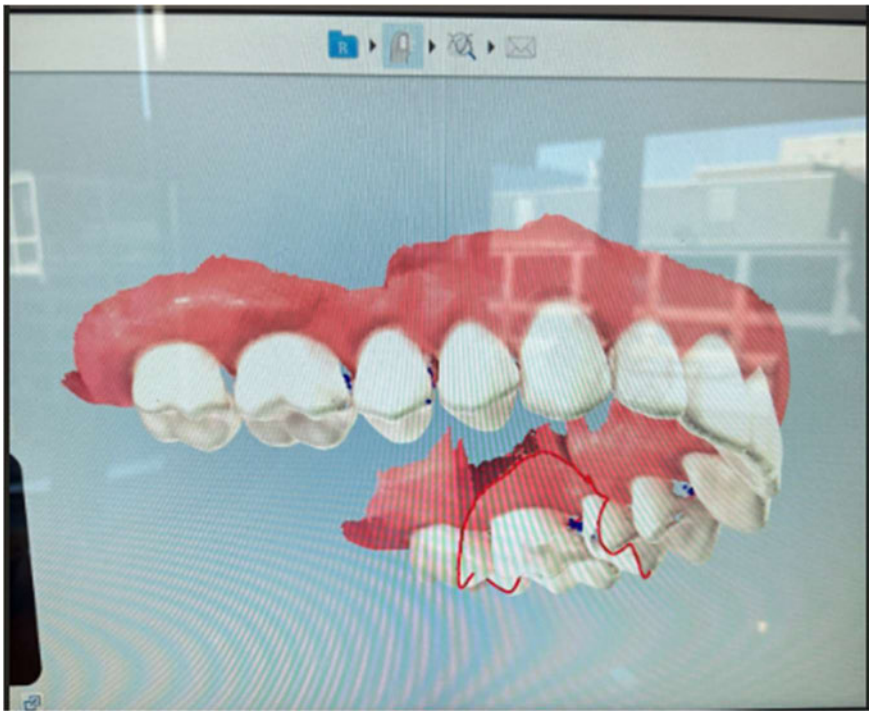


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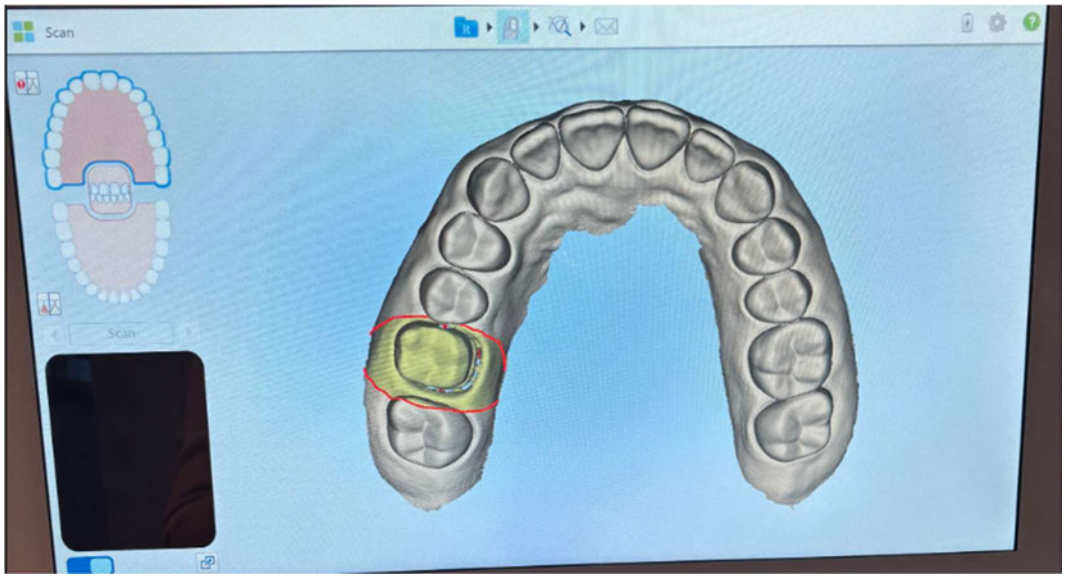
[redacted]



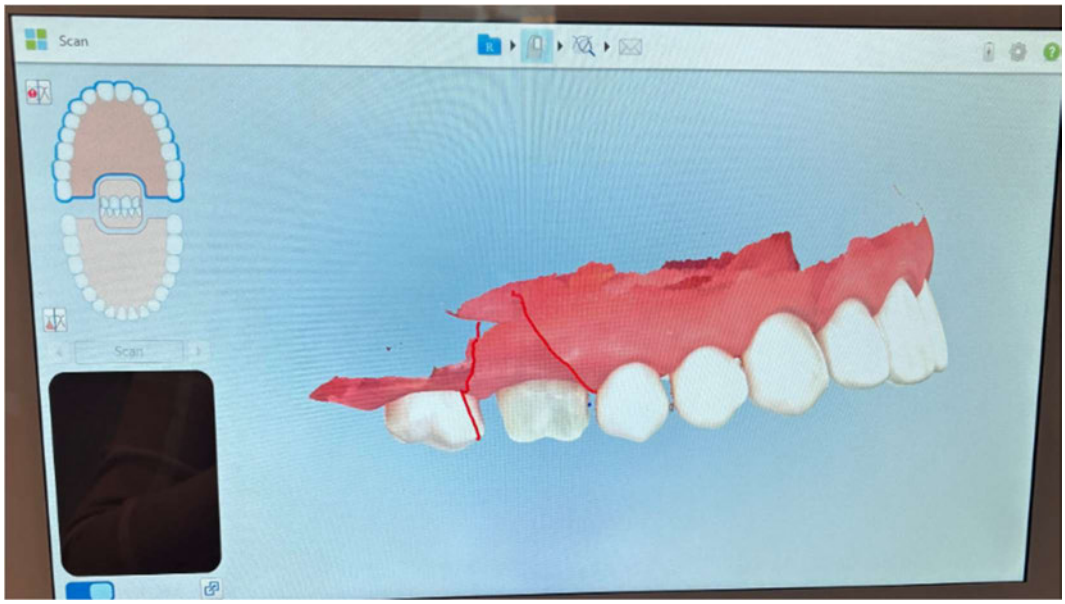
ALGN04783322

382. When I inspected the iTero scanner, I also used it to perform a second test with a crown preparation tooth to simulate the workflow for a crown preparation or other dental procedure. In this test, I selected the upper right first molar as the tooth that was going to be replaced with a crown preparation tooth. Then I replaced the tooth with the post-operation crown preparation tooth. Next, I rescanned the post-operation crown preparation tooth. Below are images showing that the iTero scanner system stitched a portion of the received second scan data with the existing model.

[redacted]

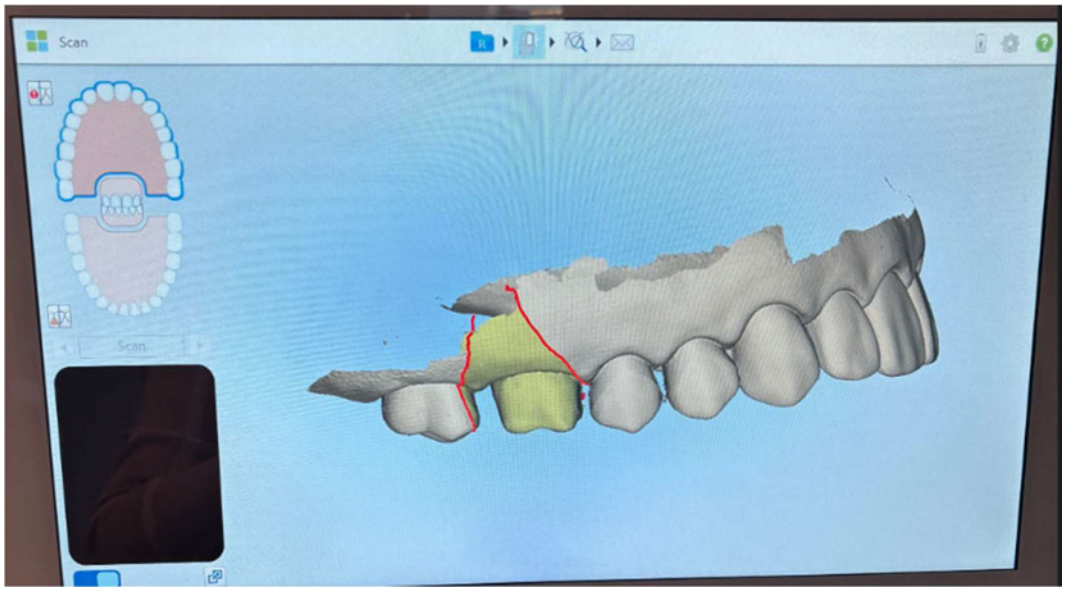


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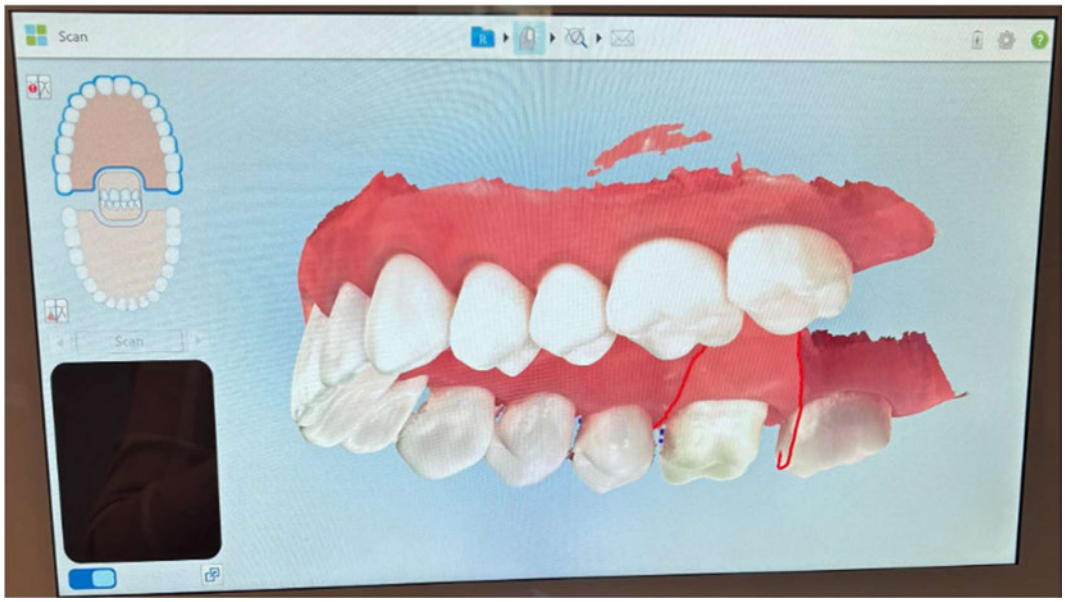


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[redacted]

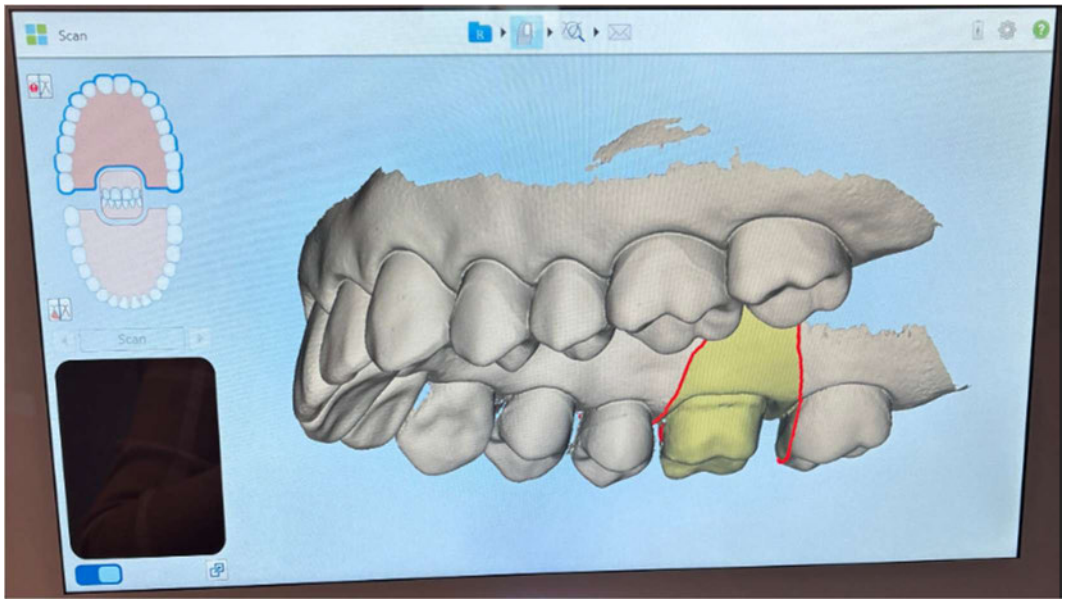


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ALGN04783331

[redacted]



ALGN04783332

383. As shown above, the iTero scanner system replaces the at least the portion of the removed surface portion of the model using the received second scan data comprise instructions to further stitch a portion of the received second scan data with the model. Accordingly, the iTero scanner system satisfies Claim 4.

e. Claim 8

i. "The system of Claim 1, wherein the computer readable medium further includes instructions that when executed by the computer system, cause the computer system to: mark, on the displayed model, the user input defined portion, after receiving the user input and before removing the removed surface portion of the model."

384. The iTero scanner system satisfies Claim 8. As discussed above for Claim 1[b][iv], the iTero software allows a user to define a portion of the displayed model for removal. As shown in the images above and reproduced below, the user draws a shape around the portion of the displayed model for removal. After receiving this user input and before

[redacted]

actually removing the surface portion, the system visually marks or highlights the selected region on the displayed model, as shown in the iTero manual below.[317]

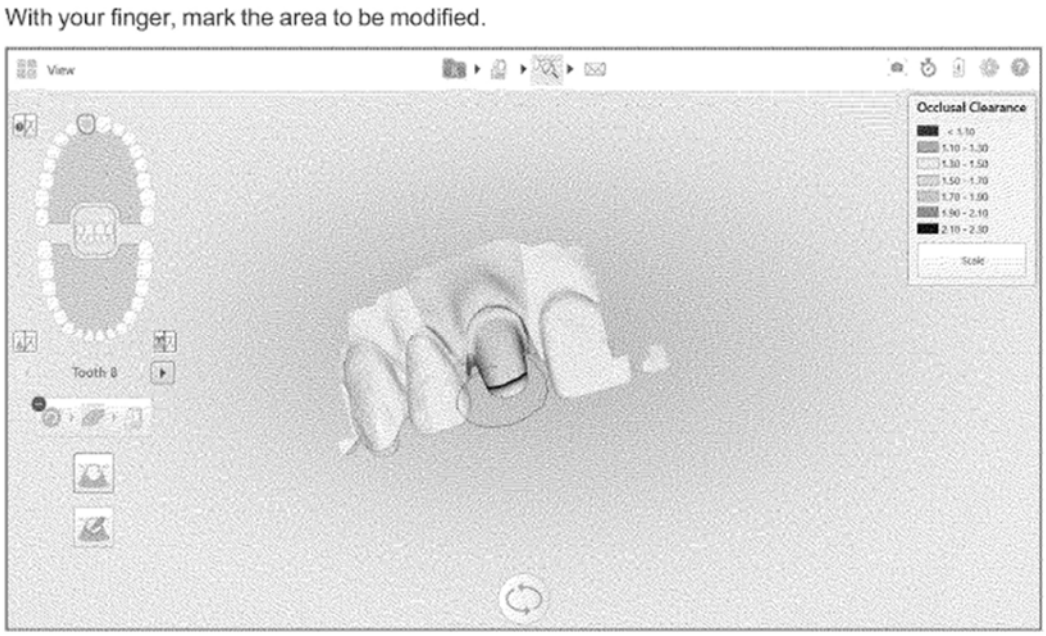


Figure 181: Mark the area to be modified

385. Below is another example of a user using the iTero Eraser tool to define a portion of the model to be removed, as shown in another iTero scanner tutorial video.[318]

[317] *iTero Element™ 2, iTero Element™ Flex, iTero Element™ 2 Plus Intraoral Scanners User Manual*, Align (ALGN00336102) at -293.

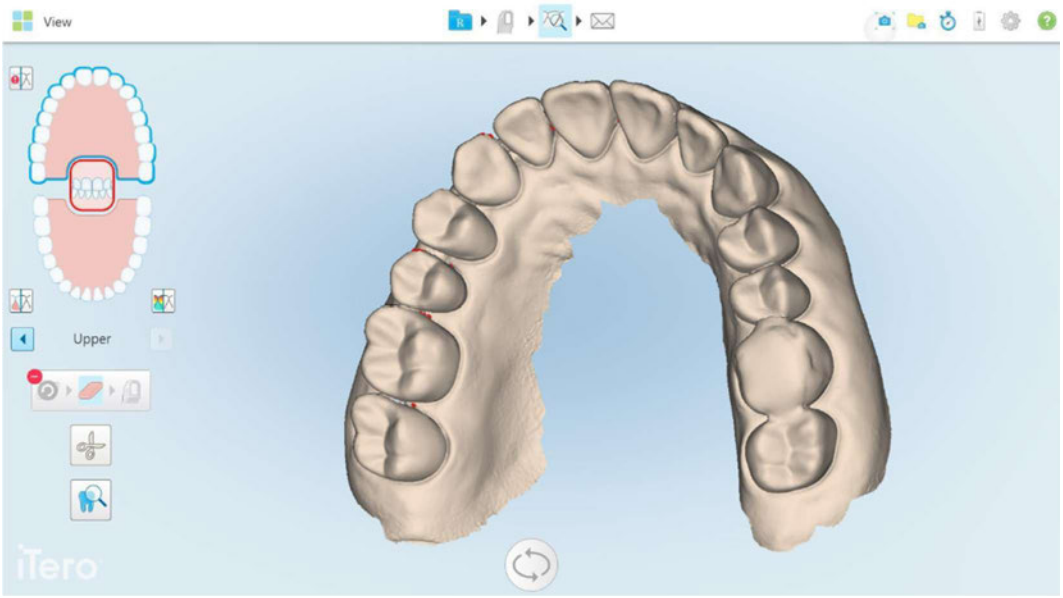
[318] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124) at 0.27.

[redacted]



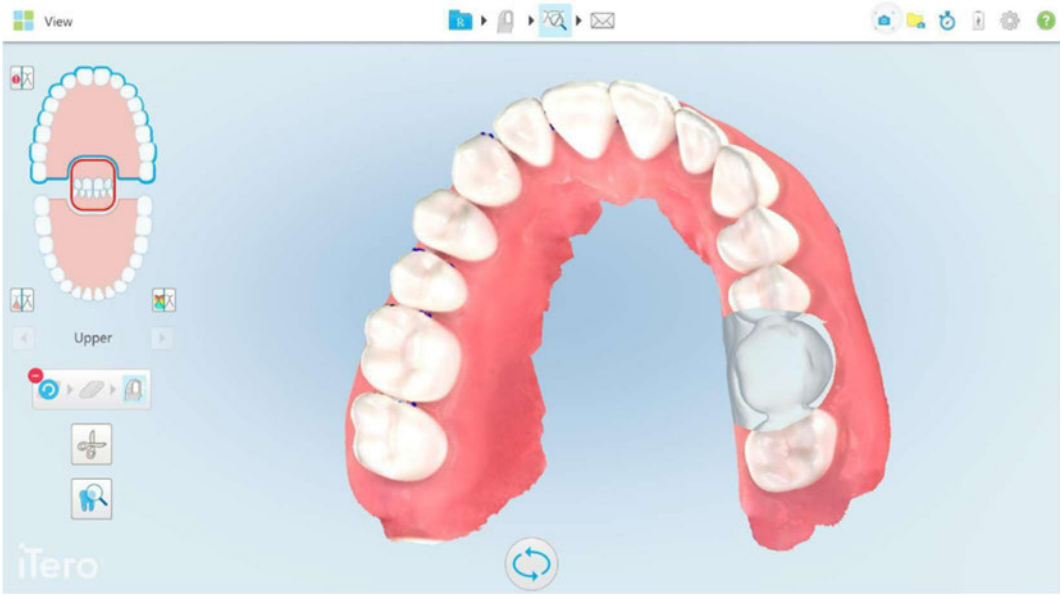
When I inspected the iTero scanner, I performed two tests using this scanner and a typodont to simulate a patient's teeth. I performed the first test to simulate the workflow of the iTero scanner system when a removable unwanted element is obscuring part of the dental surfaces of a patient's teeth. For the first test, I added toothpaste to the upper left first molar of the typodont to simulate debris on or between a patient's teeth. I then selected the Eraser tool and used my finger on the touch-screen monitor to draw a circle around the tooth with the simulated debris, selecting the portion of the model that I wanted to be removed. The image shown below is the first scan of the upper arch with the upper left first molar that has debris on it before I marked the tooth with the Eraser tool.

[redacted]



ALGN04783407

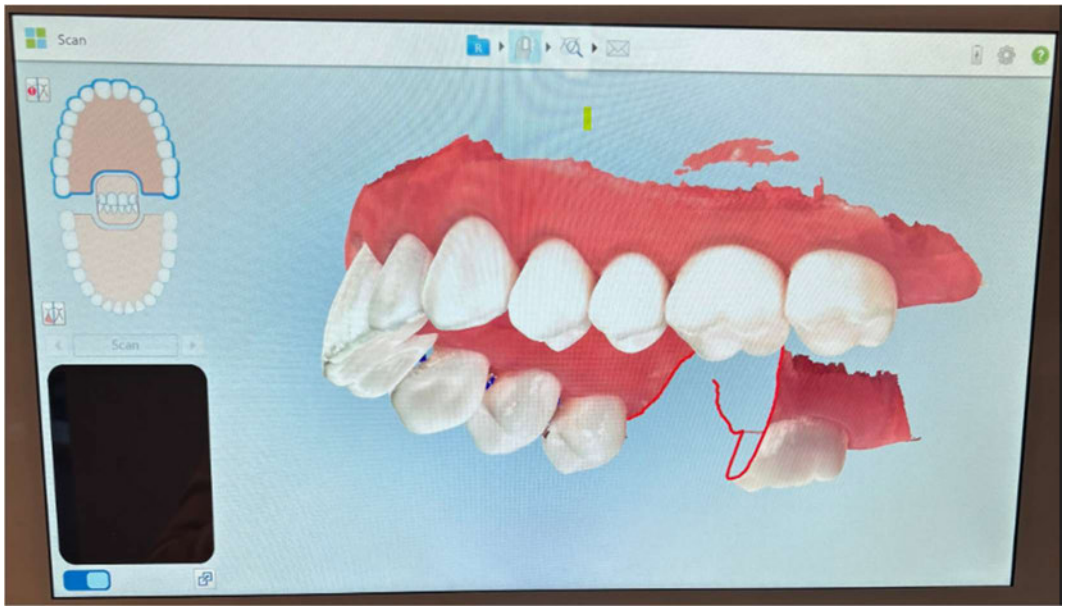
386. The image below shows first scan of the upper arch after I used the Eraser tool to mark the upper left first molar tooth with debris. The portion of the model inside the shape I drew with the Eraser tool was removed while the portion outside of the shape I drew with the Eraser tool was kept.



[redacted]

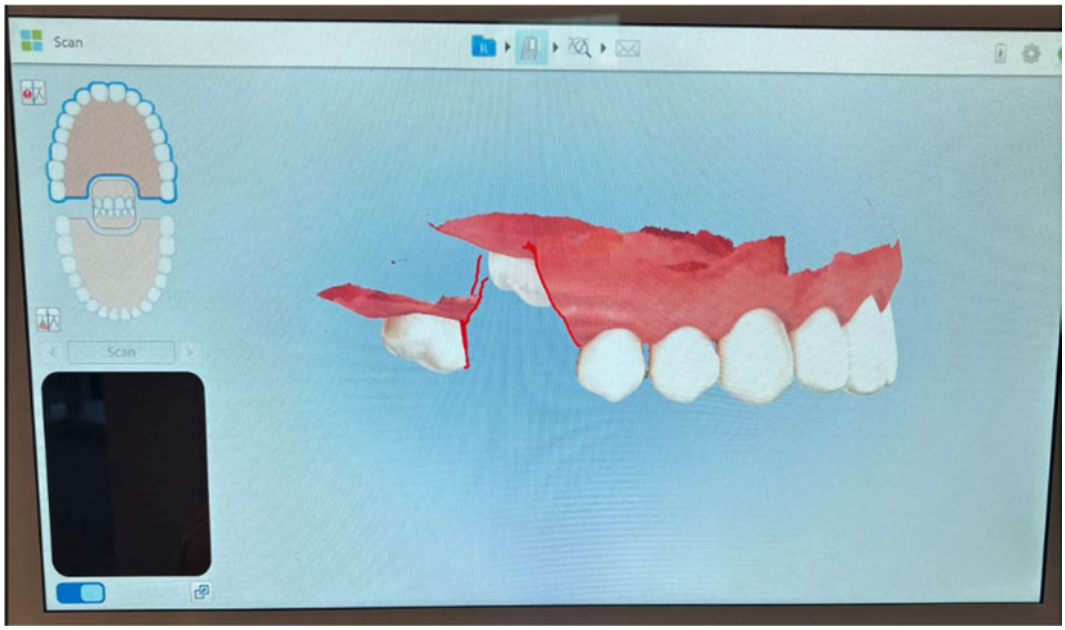
ALGN04783410

387. For the second test of the iTero scanner using this scanner and a typodont to simulate a patient's teeth. I performed the second test to simulate the workflow of the iTero scanner system for a crown preparation or other dental procedure. In this test, I selected the upper right first molar tooth for the crown preparation. The image shown below is the first scan in the lower arch after I used the Eraser tool to select the upper right first molar tooth for removal.



ALGN04783327

[redacted]



ALGN04783326

388. As shown above, the iTero scanner system marks, on the displayed model, the user input defined portion, after receiving the user input and before removing the removed surface portion of the model. Accordingly, the iTero scanner system satisfies Claim 8.

2. iTero Practices Claims 9-12

a. Claim 9

i. Preamble: "A method for scanning a patient's teeth for a dental procedure, the method comprising:"

389. Users of the iTero scanner system can perform a method for scanning a patient's teeth for a dental procedure" as set forth in Claim 9, for the same reasons as set forth above in my discussion of Claim 1[pre], incorporated here by reference.

ii. 9[a]: "receiving first scan data of the patient's teeth from a hand-held intraoral scanner"

390. During operation of the iTero scanner system, a user can perform a method of receiving first scan data of the patient's teeth from a hand-held intraoral scanner, as set forth in my discussion of Claim 1[b][ii], incorporated here by reference.

[redacted]

iii. 9[b]: "displaying, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth"

391. The iTero scanner system displays, to a display, a model of the patient's teeth based on the received first scan data of the patient's teeth, as set forth in my discussion of Claim 1[b][iii] above, incorporated here by reference.

iv. 9[c]: "receiving user input via the displayed model demarcating a portion of the model to be retained and a surface portion of the model to be replaced"

392. As set forth in my discussion of Claim 1[b][iv], set forth above and incorporated herein by reference, the iTero software provides a user interface that allows the user to interact with the displayed digital model. Through this interface, the user can provide input defining a portion of the model to be removed. The surface portion that is not removed is retained.

v. 9[d]: "receiving second scan data of the patient's teeth from the hand-held intraoral scanner, the second scan data including surface data of a physically changed portion of the patient's intraoral cavity"

393. As set forth in my discussion of Claim 1[b][vi] above, and incorporated herein by reference, the iTero scanner system is capable of receiving additional scan data after the initial scan, including second scan data captured by the same hand-held intraoral scanner. This second scan data may include surface data of a portion of the patient's intraoral cavity that has physically changed since the first scan, such as a tooth that has been prepared or modified. The iTero scanner system therefore satisfies Claim 9[d].

vi. 9[e]: "replacing at least a portion of the surface portion of the model to be replaced according to the user input using at least a portion of the second scan data of the patient's teeth including the physically changed portion"

394. As set forth above in my discussion of Claim 1[b][vii] above, and incorporated here by reference, the iTero scanner system uses the received second scan data to replace at least

[redacted]

a portion of the surface data that was previously removed from the model. The system integrates updated surface information corresponding to the physically changed intraoral region into the existing model framework. This functionality satisfies Claim 9[e].

vii. 9[f]: "outputting, to the display, the model of the patient's teeth with the at least the portion of the surface portion replaced using the second scan data"

395. As set forth above in my discussion of Claim 1[b][viii], and incorporated herein by reference, following replacement of the removed surface portion using the second scan data, the iTero scanner system outputs the updated digital model to the display. The displayed model reflects the incorporation of the new scan data into the previously removed region. Accordingly, the iTero scanner system satisfies Claim 9[f].

b. Claim 10

i. "The method of Claim 9, further comprising marking an area on the displayed model associated with the received user input."

396. As discussed with respect to Claim 1[b][iv] and Claim 8 set forth above and incorporated herein by reference. The iTero scanner software allows a user to define a portion of the displayed model for removal, and the area is visually marked.

c. Claim 11

i. "The method of Claim 9, wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data comprises registering the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model."

397. Using the Eraser tool in the iTero scanner system satisfies Claim 11, for the same reasons as set forth above with respect to Claim 5, incorporated herein by reference.

[redacted]

d. Claim 12

i. "The method of Claim 11, wherein replacing the at least the portion of the surface portion of the model to be replaced according to the user input using at least the portion of the second scan data further comprises stitching the at least the portion of the second scan data with the model."

398. Using the Eraser tool in the iTero scanner system satisfies Claim 12, for the same reasons as set forth with respect to Claim 6, set forth above and incorporated herein by reference.

3. iTero Practices Claim 17

a. Claim 17

i. Preamble: "A system for intraorally scanning a patient's teeth for a dental procedure, the system comprising:"

399. The iTero scanner system is a system for intraorally scanning a patient's teeth for a dental procedure within the meaning of Claim 17 for the same reasons as set forth in my discussion above regarding Claim 1[pre], incorporated herein by reference.

ii. 17[a]: "a hand-held intraoral scanner"

400. The iTero scanner system includes a hand-held intraoral scanner for the same reasons as set forth with respect to Claim 1[a] in my discussion above, incorporated herein by reference.

iii. 17[b][i]: "a computer readable medium including instructions that when executed by a computer system, cause the computer system to"

401. The iTero scanner system includes a computer readable medium including instructions that are executed by the computer system and cause the computer system to perform the remaining limitations of Claim 17, as set forth in my discussion above regarding Claim 1[b][i], incorporated herein by reference.

[redacted]

iv. 17[b][ii]: "receive first scan data of the patient's teeth from the hand-held intraoral scanner"

402. The iTero scanner system receives first scan data of the patient's teeth from the hand-held intraoral scanner, as set forth above in my discussion above regarding Claim 1[b][ii], incorporated herein by reference.

v. 17[b][iii]: "display, to a display, a model of the patient's teeth, wherein the model of the patient's teeth is based on the received first scan data of the patient's teeth"

403. The iTero scanner system displays a model of the patient's teeth based on the received first scan data of the patient's teeth, as set forth in my discussion above regarding Claim 1[b][iii], incorporated herein by reference.

vi. 17[b][iv]: "receive user input defining a portion of the model to be removed"

404. The iTero receives user input that defines a portion of the model that should be removed, as set forth in my discussion above regarding Claim 1[b][iv], incorporated herein by reference.

vii. 17[b][v]: "after receiving the user input, remove, from the displayed model, a removed surface portion of the model to be removed according to the user input"

405. For the same reasons as set forth in my discussion above regarding Claim 1[b][v], incorporated herein by reference, after receiving user input defining a portion of the model to be removed, the iTero scanner system removes the identified surface portion from the displayed digital model. As a result, the displayed model no longer includes the removed surface region.

[redacted]

viii. 17[g]: "after removing the portion of the model, receive second scan data of the patient's teeth from the hand-held intraoral scanner"

406. As set forth above in my discussion of Claim 1[B][vi], incorporated herein by reference, after removing a portion of the model, the iTero scanner system can receive second scan data of the patient's teeth from the hand-held intraoral scanner.

ix. 17[h]: "register the second scan data with the model by aligning identifying data of the second scan data with corresponding parts of the model"

407. As set forth above in my discussion of Claim 5, incorporated herein by reference, the iTero scanner system aligns identifying data from the second scan with corresponding parts of the model.

x. 17[i]: "replace at least a portion of the removed surface portion of the model using at least a portion of the received second scan data of the patient's teeth"

408. As set forth above in my discussion of Claim 1[b][vii], incorporated herein by reference, the iTero scanner system replaces a portion of the removed surface of the model with the data from the second scan of the patient's teeth.

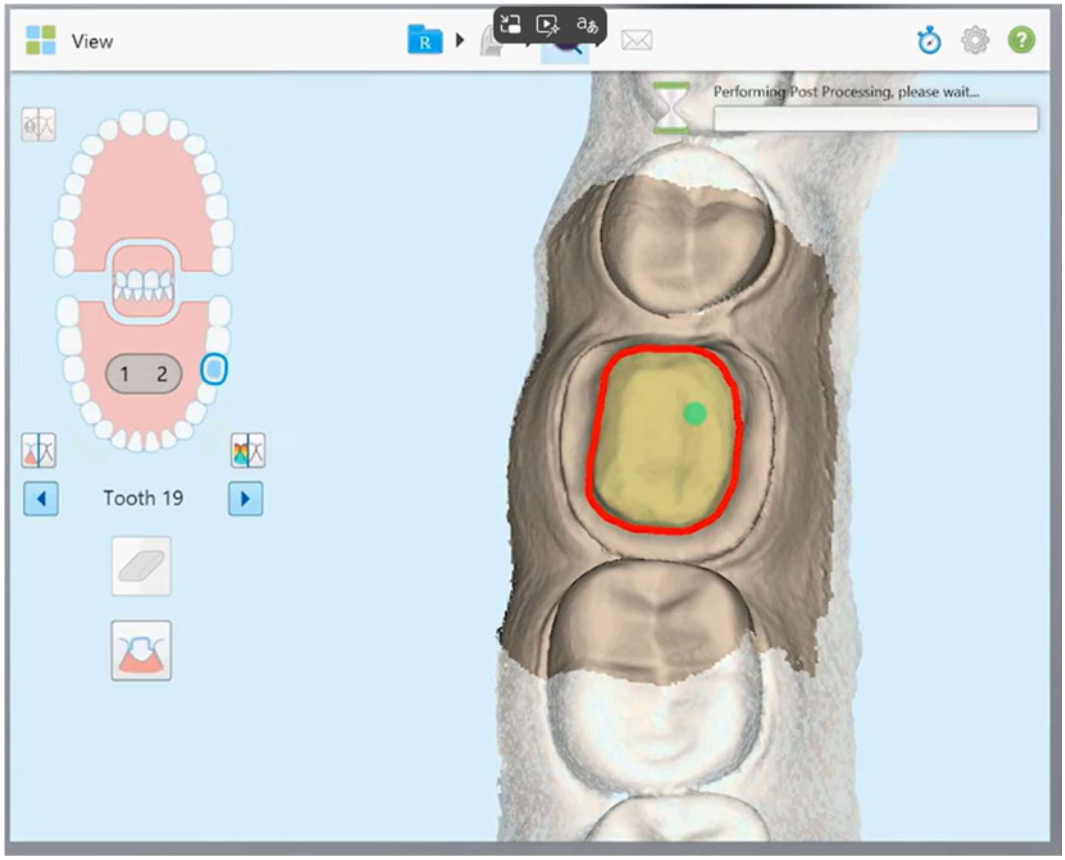
xi. 17[j]: "discarding a remainder of the second scan data, including the identifying data, after registering the second scan data with the model"

409. The iTero scanner system satisfies Claim 17(j). After registering the second scan data with the existing model and using the relevant portions of that data for replacement, the iTero software does not retain unused portions of the second scan data, including identifying or alignment data that is no longer needed once registration has been completed. In normal

[redacted]

operation, only the surface data incorporated into the final model is preserved, while remaining scan data that is not used in the replacement process is discarded.[319]

410. For example, one of the iTero tutorial videos shows a modified 3D model that combines the first and second scan data.[320] The image below shows the first scan in off-white and the second scan in yellow.[321] The yellow second scan data is only present for the portion of the first scan that was removed.



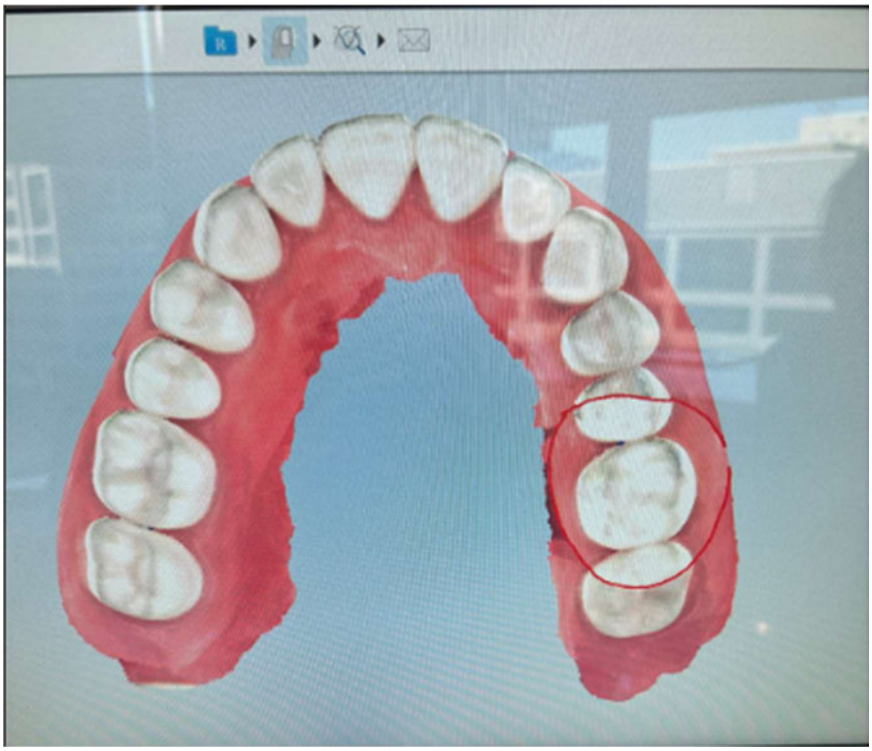
411. When I inspected the iTero scanner, I used it to perform a first test with toothpaste added to the upper left first molar of the typodont to simulate debris on or between a patient's

[redacted]

[320] *iTero Scanner Tutorial: Using the Eraser Tool*, YouTube (ALGN04795124), at 0.51.
[321] *Id.*

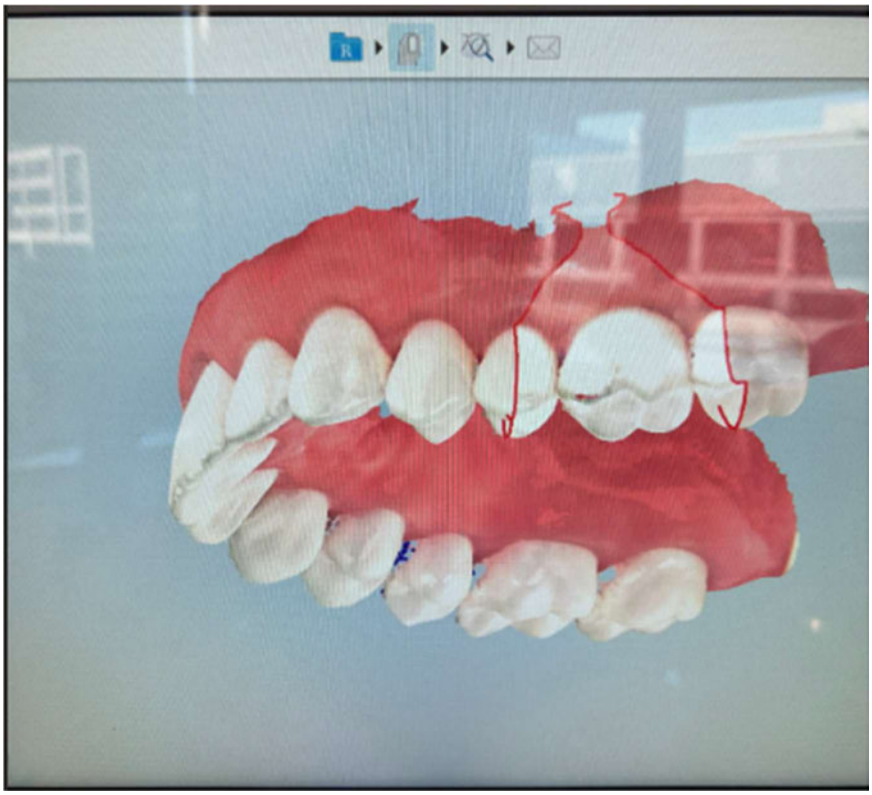
[redacted]

teeth. In this test, I selected the tooth with debris to be removed from the first scan using the Eraser tool. Then I removed the toothpaste from the tooth. Next, I rescanned the tooth that I removed the toothpaste from. The images below show that only the second scan data displayed is that of the removed portion of the first scan, circled in red.

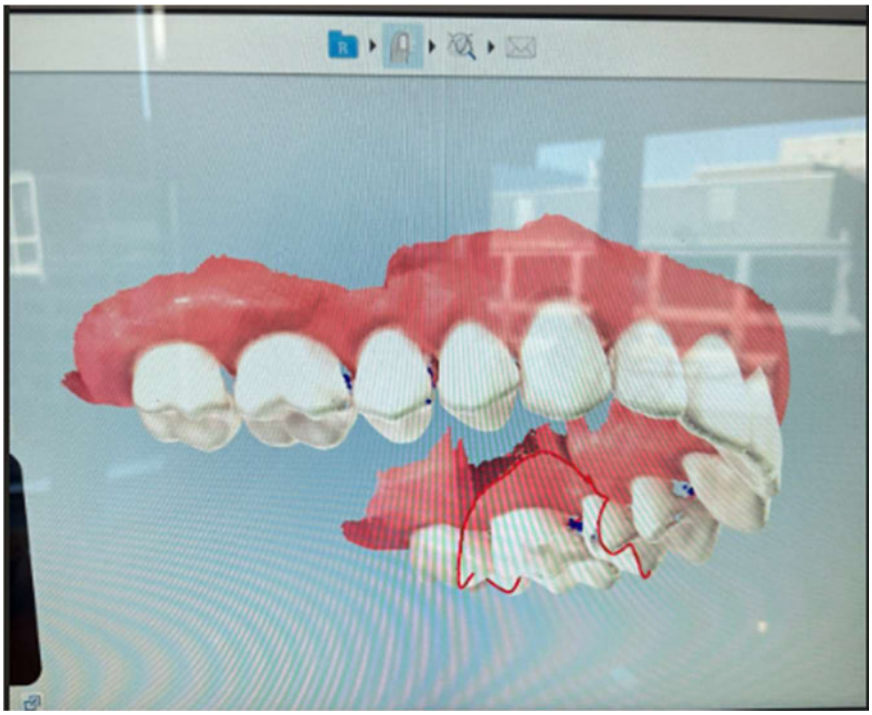


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[redacted]



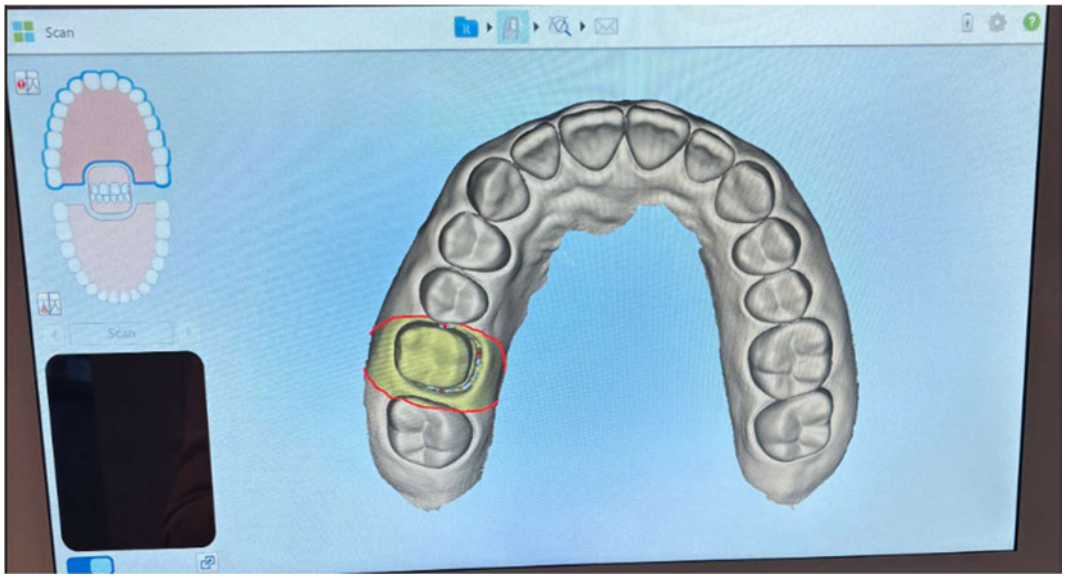
ALGN04783320



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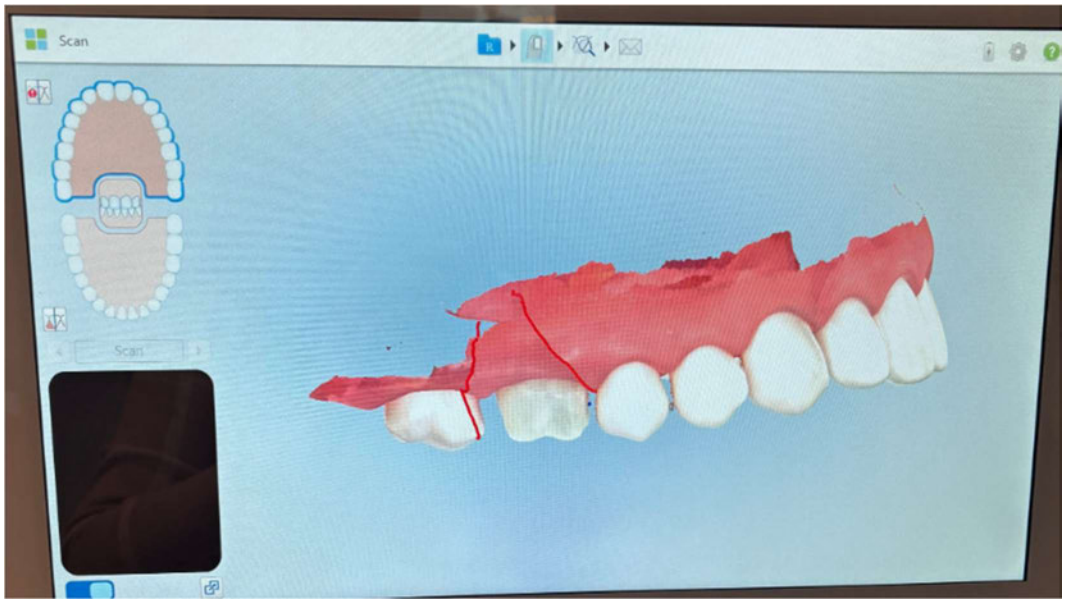
[redacted]

412. When I inspected the iTero scanner, I also used it to perform a second test to simulate the workflow for a crown preparation or other dental procedure. In this test, I selected the upper right first molar as the tooth that was going to be replaced with a crown preparation tooth. Then I replaced the tooth with the post-operation crown preparation tooth. Next, I rescanned the post-operation crown preparation tooth. The second scan filled in the removed portion of the first scan. The remainder of the second scan data has been discarded, leaving only the second scan data for the portion of the first scan that was removed. The images below show that only the second scan data displayed is that of the removed portion of the first scan, circled in red.

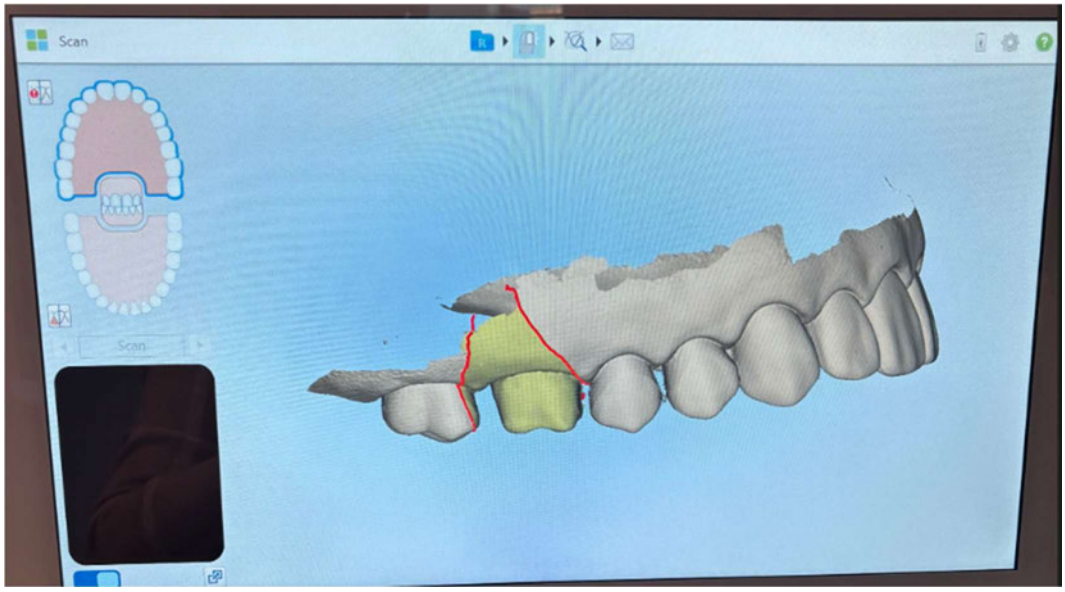


ALGN04783328

[redacted]

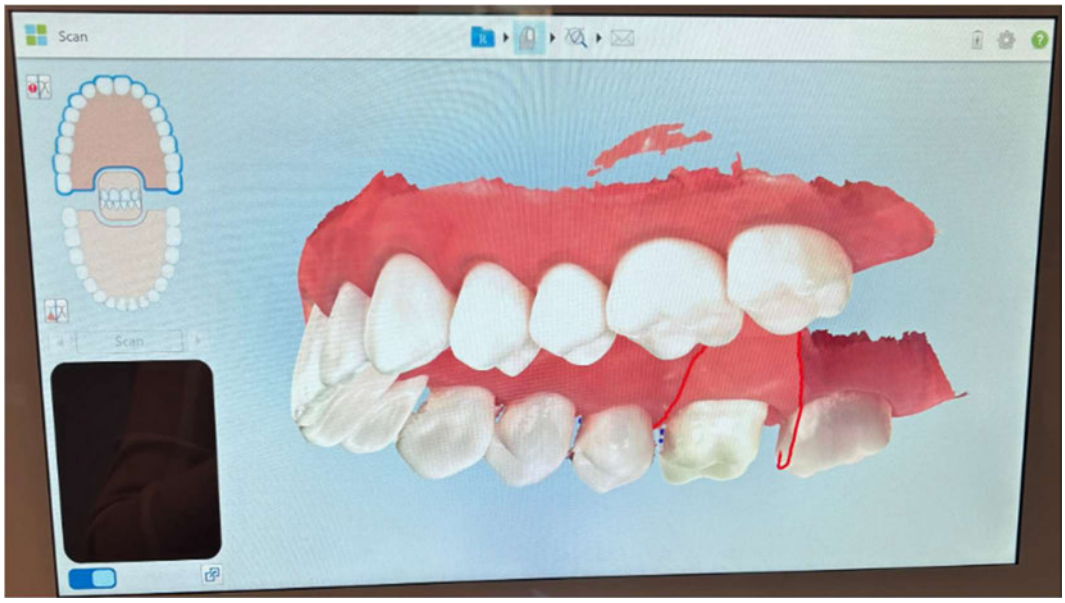


ALGN04783330

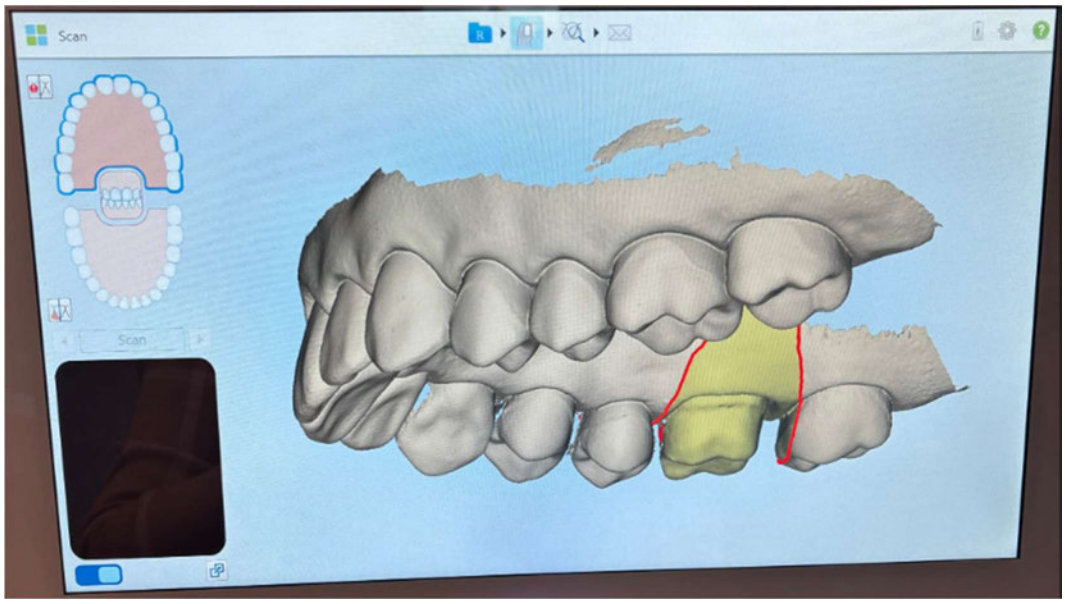


ALGN04783329

[redacted]



ALGN04783331



ALGN04783332

[redacted]

xii. 17[k]: "output, to the display, the model of the patient's teeth with the portion of the removed surface portion replaced using the received scan data"

413. As set forth in my discussion of Claim 1[b][viii], set forth above and incorporated herein by reference, after the removed surface portion has been replaced using the second scan data, the iTero software outputs the updated digital model to a display. The displayed model reflects the integration of the second scan data into the previously removed region and presents the user with a revised, complete representation of the patient's dentition.

XI. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

A. The Exemplary Align Products Practice the Asserted Patents

414. In my opinion, there exists a nexus between the Claims of the Asserted Patents and the evidence of secondary considerations of non-obviousness below. As explained in Section X.C of my Opening Report, I conclude that Align's iTero scanners practice the asserted Claims of the '936 Patent.

415. I understand from Dr. Singh that Align's TREAT software practices the asserted Claims of the '444 Patent.

416. I understand from Dr. Reitman that Align's SmartTrack material practices the asserted Claims of the Materials Patents.

417. As explained above, Align's clear aligner treatment comprises multiple steps.

418. First, a patient meets with their doctor, who takes impressions of the patient's oral cavity.[322] The doctor may use Align's iTero scanner for this step, which, as I explained above, practices the asserted Claims of the '936 Patent or uses PVS impressions. I have personal experience using Align's iTero scanners.

[322] https://www.invisalign.com/how-it-works

[redacted]

419. Second, the doctor prepares a custom treatment plan.[323] This is accomplished through ClinCheck, Align's doctor-facing treatment planning software.[324] I have personal experience using Align's ClinCheck software. [redacted] Technicians use TREAT to generate a Final Assessment Report and verify that the case has been set up with tooth movements according to the clinical protocol.[326] I understand from Dr. Singh that TREAT practices the asserted Claims of the '444 Patent.

420. Third, the Align clear aligners are manufactured, sent to the doctor, and used by the patient.[327] These aligners are crafted from SmartTrack material.[328] I understand from Dr. Reitman that SmartTrack practices the asserted Claims of the Materials Patents.

421. Use of Align's clear aligners require multiple steps. In my opinion, the proprietary technology that goes into each step is valuable in ensuring the product functions as expected. For example, iTero scanners are used to scan the patient's mouth, TREAT software is used to construct a treatment plan, and the SmartTrack material is used to create the clear aligners themselves.

B. Commercial Success

1. Align's SmartTrack Aligners

422. Align's SmartTrack aligners have been commercially successful. Align has treated millions of patients with its SmartTrack aligners and sold over a billion dollars in Invisalign aligners. In 2013, Align reported clear aligner net revenues of $166.2 million and

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[323] https://www.invisalign.com/how-it-works
[324] https://www.invisalign.com/provider/align-digital-platform/clincheck
[redacted]
[326] *Id.*
[327] https://www.invisalign.com/how-it-works
[328] *Id.*

[redacted]

shipped 111,130 cases.[329] In 2014, Align reported clear aligner net revenues of $186.4 million and 126,900 Invisalign cases.[330] In 2015, Align reported over $800 million clear aligner net revenues and 583,200 cases.[331] In 2016, Align reported clear aligner net revenues of $251.5 million.[332] In 2017, Align reported Q4 Invisalign volume was up 34.2% and $364.2 million in clear aligner net revenues, and 255,000 Invisalign cases.[333] In 2018, Align reported clear aligner revenues of $445.6 million and over 338,000 Invisalign case shipments.[334] In 2019, Align reported $543.6 million in clear aligner net revenues and 413,700 Invisalign cases.[335] In 2020, Align reported clear aligner net revenues of over $700 million, and 568,000 Invisalign case shipments.[336] In 2021, Align reported over $800 million in clear aligner net revenues and over 630,000 Invisalign case shipments.[337] In 2022, Align reported clear aligner revenues of over $3 billion dollars.[338] In 2023, Align also reported over $3 billion in clear aligner revenues.[339] In 2024, Align that over 19.5 million patients used its clear aligners, and, again, over $3 billion in clear aligner revenues.[340] In the third quarter of 2025, Align reported $805.8 million in clear aligner revenues.[341] Align's commercial success and number of patients treated show that its aligners are widely adopted. As an expert in the field of orthodontics, I confirm that Align's clear aligners continue to be a top choice for doctors and patients.

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[329] ALGN04804337 at -41.
[330] ALGN04796846 at -49.
[331] https://investor.aligntech.com/static-files/8a81b0bc-3d30-48f2-af7e-127b81d32702
[332] ALGN04804385 at -88.
[333] ALGN04804423 at -26.
[334] https://investor.aligntech.com/static-files/435e8014-c9b8-4e21-a24e-c4d912621e3e
[335] ALGN04796916 at -19.
[336] ALGN04796405 at -09.
[337] https://investor.aligntech.com/static-files/0693b31f-169f-4b25-a906-a5f685012e7f
[338] https://investor.aligntech.com/static-files/ec1352f8-cd7a-4781-b45f-e09a4f9e9bb7
[339] ALGN04796571 at -89.
[340] ALGN04796671 at -85.
[341] ALGN04796764 at -75.

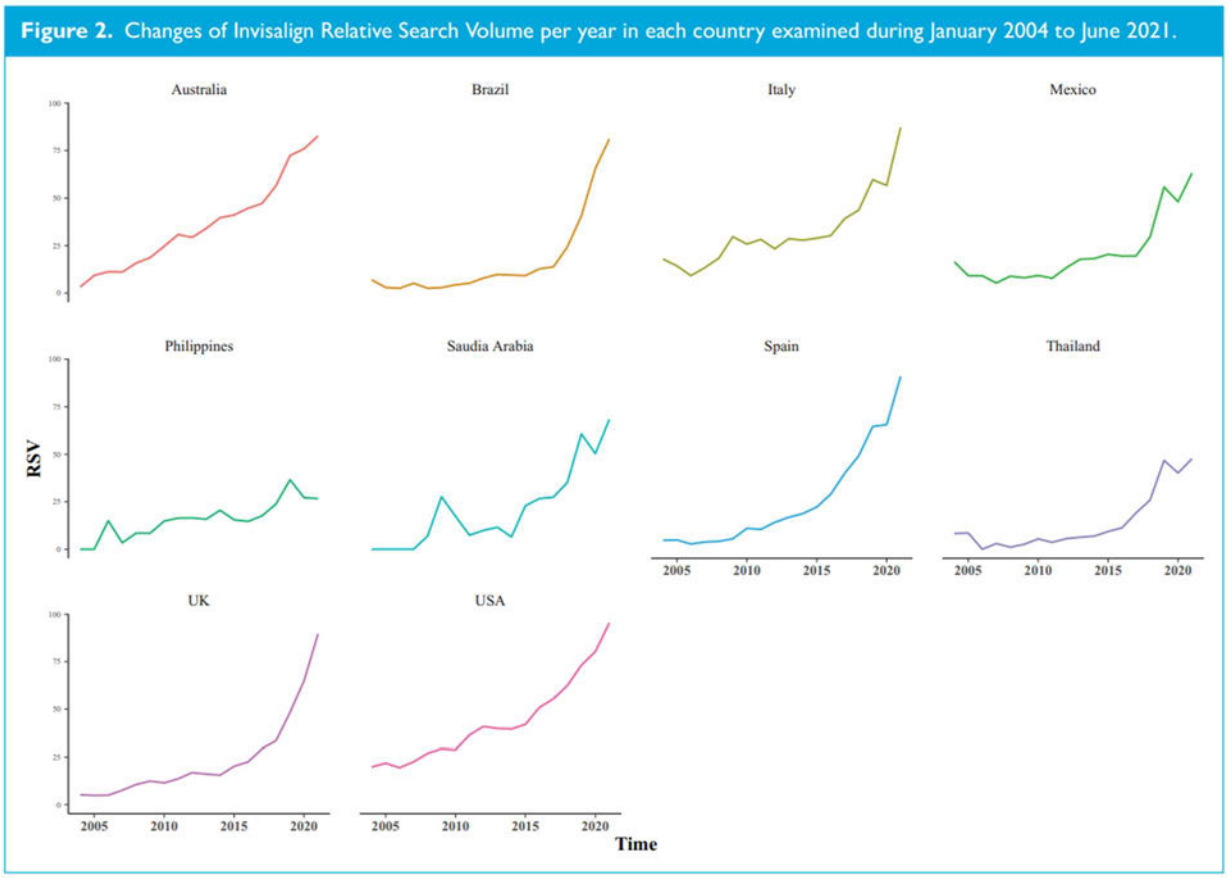
[redacted]

423. Third parties have recognized the commercial success of Align's clear aligners. For example, Forbes magazine recognized that Align was a "Billion-Dollar Orthodontics Business Built with Plastic and Patents."[342] As the article explains, one of the biggest advantages of Align is its patent portfolio, including covering "the type of plastic that's worn in patient's mouth to the software orthodontists use to plan out teeth movements." [343] In my opinion, these advantages relate to, respectively, the Materials Patents and the '444 Patent.

424. I expect the commercial success of Align's clear aligners will continue to grow, particularly as it expands to other countries. A 2023 study, for example, reported on the increasing public interest in Align's clear aligners in the United States and abroad.[344] In all ten survey countries, interest in Align's clear aligners trended almost uniformly upwards, with minor decreases attributed to the 2020 COVID-19 pandemic.

[342] https://www.forbes.com/sites/michelatindera/2017/04/25/out-of-silicon-valley-a-billion-dollar-orthodontics-business-built-with-plastic-and-patents/.
[343] *Id.*
[344] https://pure.rug.nl/ws/portalfiles/portal/788196852/livas-et-al-2022-public-interest-in-invisalign-in-developed-and-developing-countries-a-google-trends-analysis.pdf.

[redacted]



425. In my opinion, this demonstrates commercial success of Align's technology.

426. The commercial success of Align's aligners is attributable to the claimed features of the asserted claims of the Materials Patents. I understand from Dr. Maureen Reitman that the claimed features related directly to improved functionality, including force delivery, durability, and tooth movement predictability. Further, the clinical evidence shows that the claimed SmartTrack material enabled treatment of more complex malocclusions, improved on-track treatment rates, and faster and more predictable clinical outcomes. These features help drive clinical adoption and commercial success of Align's products, because effective treatment of

[redacted]

complex malocclusions, improved on-track treatment rates, and faster and more predictable clinical outcomes are important to doctors and patients.[345]

2. Align's iTero Scanners

427. Align's iTero scanners are also widely used and commercially successful. In 2013, Align reported scanner and CAD/CAM net revenues of $12.1 million.[346] In 2014, Align reported scanner and services net revenues of $12.2 million.[347] In 2015, Align reported $45.3 million in scanner and services net revenue.[348] In 2016, Align reported scanner and services revenue of $41.7 million.[349] In 2017, Align reported scanner and services revenues of $57.1 million.[350] In 2018, Align reported $88.4 million in scanner and services revenues.[351] In 2019, Align reported scanner and services revenue of $106.2 million.[352] In 2020, Align reported imaging systems and CAD/CAM services revenues of $133.8 million.[353] In 2021, Align reported imaging systems and services revenue of $215.9 million.[354] In 2022, Align reported total systems and services revenues of $662.1 million.[355] In 2023, Align reported total systems and services revenues of $662.9 million.[356] In 2024, Align reported total systems and services

[345] Livas, C., et al., *Public Interest in Invisalign in Developed and Developing Countries*, J. Orthodontics (2023) (ALGN04786993); Michela Tindera, Out of Silicon Valley, A Billion-Dollar Orthodontics Business Built With Plastics and Patents, Forbes (2023) (ALGN04787002); Bichu, Y.M., et al., *Advances in Orthodontic Clear Aligner Materials*, Bioreactive Materials (2023) (ALGN04787023); Cenzato, N., *Materials for Clear Aligners—A Comprehensive Exploration of Characteristics and Innovations: A Scoping Review*, Applied Sciences (ALGN04787052).
[346] ALGN04804337 at -41.
[347] ALGN04796846 at -49.
[348] https://investor.aligntech.com/static-files/8a81b0bc-3d30-48f2-af7e-127b81d32702
[349] ALGN04804385 at -88.
[350] ALGN04804423 at -26
[351] https://investor.aligntech.com/static-files/435e8014-c9b8-4e21-a24e-c4d912621e3e
[352] ALGN04796916 at -19.
[353] ALGN04796405 at -09.
[354] https://investor.aligntech.com/static-files/0693b31f-169f-4b25-a906-a5f685012e7f
[355] https://investor.aligntech.com/static-files/ec1352f8-cd7a-4781-b45f-e09a4f9e9bb7
[356] ALGN04796571 at -89.

[redacted]

revenues of $768.9 million.[357] In the third quarter of 2025, Align reported scanner and services revenue of $189.9 million.[358]

428. In my opinion, this success is based in part on the invention claimed in the '936 Patent. The Eraser tool, as described above, is an important tool is used frequently in both dentistry and orthodontic applications and allows dentists and orthodontists to more effectively and efficiently treat their patients.

3. Align's TREAT Software

429. I understand from Dr. Singh that Align's TREAT software, and in particular the claimed invention, help Align technicians create treatment plans more precisely and accurately. The treatment plan is an important part of clear aligner treatment. In my opinion, obtaining accurate and precise treatment plans is valuable to doctors and to patients. Accurate treatment planning is a feature I care about in my practice, and it helps patients because it can help the patient achieve better results and set clear expectations for treatment.[359] Therefore, in my opinion, a portion of Align's success in selling clear aligners is based, in part, on the beneficial features of Align's TREAT software.

C. Industry Praise

430. Align's technology has received wide industry praise.[360]

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[357] ALGN04796671 at -85.
[358] ALGN04796764 at -75.
[359] https://onedentalsf.com/blog/the-role-of-technology-in-invisalign-aligners-things-to-know-about
[360] *See, e.g.*, ALGN00020526-28, ALGN00020535-38, ALGN00020545-48, ALGN00020552-70, ALGN00020578-80, ALGN00020586-91, ALGN00020599, ALGN00020611-15, ALGN00020662-70; ALGN00020529-34, ALGN00020539-44, ALGN00020549-51, ALGN00020553-70, ALGN00020575-77, ALGN00020581-99, ALGN00020611-15, ALGN00020622-27, ALGN00020652-61, ALGN00020680-84.

[redacted]

431. Align's clear aligners have received several accolades. For example, *Dentaltown* gave Align the 2021 award for best "Clear Aligner System."[361] Align won again in 2023.[362] *Dentistry Today* recognized Align's Invisalign system as a top dental product in 2020.[363] *Dentaltown* is a respected trade publication in the dentistry space and has been widely used in the dental profession for over 20 years. Likewise, *Dentistry Today* is another respected trade publication in the dental industry and has been for over 30 years.

432. More specifically, third-party articles have praised SmartTrack. SmartTrack, which as I explained earlier, practices the asserted Claims of the Materials Patents. For example, *Dentaltown*, in recognizing Align's clear aligner system as the best in the industry, specifically noted that "Using SmartTrack material, . . . Invisalign treatment options address a range of simple to complex cases."[364] *Dentaltown* recognized that Algin's "patented SmartTrack aligner material" was "designed to deliver more gentle, constant force to improve control of tooth movements."[365] In an article by DrBicuspid, clinicians specifically reported that that in using SmartTrack, "the teeth track better, so the patients who were compliant with wearing their aligners are having much less to do in case refinement. The teeth seem to be following the proposed plan with better detail."[366] Similarly, *Bite Magazine* reported that "[c]ompared to conventional aligner materials . . . [t]he flexible SmartTrack material also more precisely conforms to tooth morphology, attachments, and interproximal spaces to improve control of tooth movement throughout treatment."[367]

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[361] ALGN00020526.
[362] ALGN00020552.
[363] ALGN00020586.
[364] ALGN00020535.
[365] *Id.*
[366] https://www.drbicuspid.com/dental-specialties/orthodontics/invisible-aligners/article/15366582/new-invisalign-material-promises-better-tracking
[367] https://www.bitemagazine.com.au/smarttrack/

[redacted]

433. Likewise, third-party articles have praised iTero scanners, which as I explained earlier, practice the asserted Claims of the '936 Patent. For example, *Dentaltown* gave Align's iTero scanners the best "Digital impressioning" system award in 2021-2023.[368] *Dentistry Today* recognized Align's iTero Element 2 and iTero Element 5D as top dental products in 2020.[369] Other third-party praise of iTero includes orthodontic marketing agency Neon Canvas, which recognized the iTero Element as the "Best Digital Scanner" in 2023.[370]

434. In my opinion, this demonstrates industry praise of Align's technology.

D. Copying by Competitors

435. Align's technologies have been copied by Align's competitors.

436. Several 510(k) applications suggest copying by Align's competitors. I understand that each entity that wants to market certain medical devices in the United States without going through a Premarket Approval application must submit a 510(k) to the FDA. A 510(k) application must include a demonstration that the applicant's medical device is "substantially equivalent" to another device legally marketed in the United States.

437. ClearCorrect has submitted at least two 510(k)s that refer to Align's clear aligners as a "substantially equivalent" device. In 2008, ClearCorrect pointed to the "Align System" as "substantially equivalent" to the "ClearCorrect System."[371] In 2022, ClearCorrect again pointed to the "Align System" as "substantially equivalent" to the "ClearCorrect System."[372] These 510(k) submissions show that ClearCorrect continuously referenced and relied on Align's innovations in developing its products.

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[368] ALGN00020529; ALGN00020539; ALGN00020549;
[369] ALGN00020586; ALGN00020581.
[370] ALGN00020680.
[371] ECF No. 1-10.
[372] ECF No. 1-12.

[redacted]

438. ClearCorrect's 2022 510(k) submission shows that ClearCorrect was referencing key Align technologies. For example, ClearCorrect confirmed that its "Aligner Material" was "[i]dentical" to Align's.[373] In 2022, Align's clear aligners were made of SmartTrack, which as I explained above, practices the asserted claims of the Materials Patents. Further, ClearCorrect confirmed that its "Treatment Planning Software" was "[i]dentical" to Align's.[374] In 2022, Align's treatment software was TREAT, which as I explained above, practices the asserted claims of the '444 Patent.

439. ClearCorrect's documents also show that ClearCorrect copied Align's SmartTrack materials to develop its multilayer material, Zendura FLX, which I understand from Dr. Reitman infringes the asserted claims of the Materials Patents.

440. For example, [redacted]

441. [redacted]

[373] *Id.* at 8.
[374] *Id.* at 9.

[redacted]

[redacted]

443. Other Align competitors also submitted 510(k)s for clear aligners that use the Zendura FLX material. For example, Ormco submitted a 510(k) that claims that Ormco's Spark Aligner System, using Zendura FLX material, is "substantially equivalent" to the Invisalign clear aligners.[380]

444. In my opinion, this demonstrates copying of Align's technology.

E. Unexpected Results

445. Align's materials inventions have produced unexpectedly better clinical results for patients.

446. Patients treated with Align's SmartTrack clear aligners, which embody one or more claims of those patents, achieve better outcomes compared to patients treated with prior, single-layer EX30 clear aligners.[381] The SmartTrack plastic's combination of hard and soft plastics increases aligner durability and stress relaxation properties relative to single-layer plastics like EX30.[382] SmartTrack aligners also move teeth faster[383] and are better able to apply sustained, gentle forces that more closely match the planned tooth movements specified in the digital treatment plan than prior EX30 aligners.[384] I reviewed the declaration of Dr. Chunhua

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[redacted]

[381] *See, e.g.*, ALGN00006176 at 6844-47.

[382] J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 3, 3-11 (2017) ([redacted]

[383] Wheeler, T.T. et al., *Effect of aligner material on orthodontic tooth movement*, J Aligner Orthodontics 1(1):21–27 (2017) (ALGN02821971).

[384] ALGN00339664; J. Morton et al., *Design of the Invisalign System Performance*, 23 SEMINARS IN ORTHODONTICS 3, 7–9 (2017) (ALGN02808426); Ryokawa, H., et al., *The mechanical properties of dental thermoplastic materials in a simulated intraoral environment*. Orthodontic Waves, 65(2), 66-69 (2006).

[redacted]

Li.[385] Dr. Li explained the development of SmartTrack, which as I explained above, practices the asserted Claims of the Materials Patents. Several clinical studies comparing Align's prior material to SmartTrack demonstrated unexpectedly superior clinical performance in several respects.

447. For example, one five-month clinical study compared treatment progress between users using SmartTrack ("SmartTrack Cohort") and a control cohort. The study evaluated whether actual tooth movements tracked the digitally planned movements specified in the treatment plan. Patients were placed into one of three groups based on the measured movement of teeth: On-Track, Off-Track, or Cannot Match. Patients were assigned to On-Track if the measured tooth movement matched the target tooth movement to within a predetermined degree of variance, based on the conclusion of the treating doctor or on direct analysis of data from doctor-submitted impressions. Patients with tooth movement falling outside this range were classified as Off-Track. Patients far outside the range were classified as Cannot Match. The SmartTrack Cohort exhibited approximately 26 percent more on-track patients than the control group, 17 percent fewer off-track patients, and 34 percent fewer Cannot Match patients.[386]

448. Align also conducted a retrospective analysis of 110,000 cases, 58,000 using SmartTrack and 52,000 using the prior Align material.[387] This experiment measured tooth movement predictability, which was based on how closely a patient's teeth followed the expected treatment plan. The SmartTrack cohort showed a 75 percent improvement in tooth movement

[385] ALGN00006176 at -6839-50; [redacted]
[386] ALGN00006176 at -6844.
[387] *Id.* at -6845.

[redacted]

predictability over the control group.[388] Tooth movement predictability allows for more accurate planning of a patient's treatment.

449. Dr. Li considered these clinical results unexpected.[389] I agree. I would not expect that one in four more patients would be kept on track in their treatment plan simply by changing the material of clear aligners. A 25 percent improvement in on track patients marks a substantial improvement in treatment outcomes. I also would not expect a 75 percent improvement in tooth movement predictability solely by changing the material of clear aligners. Indeed, Dr. Li explained that these clinical results were so striking that Align nearly completely adopted SmartTrack material within months.[390]

450. In my opinion, this demonstrates unexpected results of Align's technology.

F. Long-Felt But Unsolved Need

451. In general, as of the relevant time, those in the art recognized a need to improve dental technologies in order to overcome challenges that limited the treatment effectiveness, predictability, patient comfort, and to enable the successful treatment of more complex cases using clear aligners and digital orthodontics workflows. These challenges constrained the types of cases that could be treated reliably with aligners and imposed practical limitations on orthodontic treatment planning and appliance fabrication.

452. With respect to aligner materials, the orthodontic literature consistently documents that early and prior-generation clear aligner materials exhibited fundamental mechanical shortcomings. In particular, single-layer thermoplastic materials—while effective for producing removable orthodontic appliances—their mechanical properties degraded over

[388] *Id.* at 6845.
[389] *Id.* at 6846.
[390] *Id.*

[redacted]

time, resulting in rapid stress decay, insufficient durability, deformation, and reduced predictability and limited control of orthodontic tooth movement or the ability to maintain consistent orthodontic forces during wear.[391] Single-layer and early polymer systems have historically been unable to deliver sustained and consistent orthodontic forces, particularly under intraoral thermal, chemical, and mechanical stresses.[392] As further documented in the literature, stress relaxation and force decay, especially during the first hours of wear, were problems in conventional thermoplastic materials, resulting in reduced predictability and diminished efficacy.[393]

453. At the same time, there existed a long-felt need for more accurate, efficient, and patient-tolerant digital workflows for orthodontic treatment planning and appliance fabrication. Traditional physical impressions were time-consuming, uncomfortable for patients, prone to distortion, and vulnerable to cumulative errors at multiple stages of the orthodontic workflow.[394] Although intraoral scanning technology emerged as a potential solution, early technology did not resolve these issues. Published studies identified ongoing problems with accuracy, efficiency, and difficulty reliably capturing complete intraoral images, particularly in orthodontic applications requiring high precision.[395]

454. Align's Invisalign clear aligners made from the multilayer SmartTrack material, which embody at least the asserted claims of the Materials Patents, address the documented

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[391] *See, e.g.*, *Materials for Clear Aligners—A Comprehensive Exploration of Characteristics and Innovations: A Scoping Review*, Applied Sciences (ALGN04787052); [redacted]
[392] *Id.*; ALGN04787023.
[393] *See, e.g.*, ALGN04787023, *Materials for Clear Aligners—A Comprehensive Exploration of Characteristics and Innovations: A Scoping Review*, Applied Sciences (ALGN04787052).
[394] *See, e.g.*, ALGN04787043, ALGN04787066.
[395] *Id.*

[redacted]

problems of rapid stress decay, durability degradation, and reduced predictability.[396] Likewise, Align's iTero scanners, which embody at least the asserted claims of at least the '936 Patent, address the documented need for accurate, efficient, and comfortable digital workflows.[397]

455. Accordingly, the Asserted Patents satisfied long-felt and unresolved needs in the orthodontic field.

G. Failure of Others

456. I have reviewed Align's responses to ClearCorrect's Interrogatory No. 16, and I agree that Align's competitors in the clear aligner space failed to independently develop materials capable of achieving the clinical performance provided by Align's SmartTrack material.

457. For example, after Align transitioned to its three-layer SmartTrack aligners, Bay Materials did not offer a comparable multilayer aligner material until ClearCorrect and its affiliates undertook efforts to replicate the structure and performance of Align's SmartTrack material. I understand that those efforts included testing simulated constructions designed to achieve similar force-retention and durability characteristics, which ultimately led to the development of a three-layer material later marketed as Zendura FLX.

[396] *See, e.g.*, ALGN04787023, *Materials for Clear Aligners—A Comprehensive Exploration of Characteristics and Innovations: A Scoping Review*, Applied Sciences (ALGN04787052).
[397] *See, e.g.*, ALGN04787043, ALGN04787066.

[redacted]

Executed in Elk Grove, CA on this 6th day of January, 2026.

Maureen Valley

Maureen Valley, DMD, MPH, MS