



Align Technology Announces Availability of Restorative Capabilities on Its Next Generation iTero Lumina™ Intraoral Scanner and New iTero Lumina™ Pro Dental Imaging System

March 6, 2025

Next-generation iTero Lumina solutions with comprehensive capabilities provides transformative solutions for general practitioner (“GP”) dental practices to enable diagnostic, restorative, and multidisciplinary ortho-restorative workflows — including Near Infra-Red Imaging (NIRI) technology in the iTero Lumina Pro dental imaging system.

- Builds on 20+ years of expertise in restorative dentistry and the success of the proprietary iTero Multi-Direct Capture™ technology initially launched in February 2024 for clinical orthodontic needs.
- Powered by iTero Multi-Direct Capture™ technology with 3x larger field of view¹, and maximum capture distance of 25mm², designed to scan 2x faster² and simplify the capture of challenging areas for dentures, palates, edentulous spaces, and other complex cases.
- Facilitates the capture of all case types and supports highly efficient workflows.
- Superior full jaw clinical accuracy compared to tested intraoral scanners³ - iTero Lumina™ solutions enable predictable and repeatable first-time restoration fit⁴ from single unit crowns to removable prosthetics.
- iTero Lumina™ scans are within accuracy threshold of photogrammetry¹ (the highest standard for prosthetic planning) for full-arch implant restorations⁵ - captured in one single scan.
- Outstanding simplicity and highly efficient workflow with capture of single unit crowns to full arch preparations in a single pass.
- iTero Lumina™ solutions offer up to 5 capabilities in one device and one scan.
- Elevated patient experiences thanks to quick and comfortable scanning⁹, for exceptional care.

SAN JOSE, Calif. & TEMPE, Ariz. & PETACH TIKVA, Israel--(BUSINESS WIRE)--Mar. 6, 2025-- Align Technology, Inc. (NASDAQ: ALGN) a leading global medical device company that designs, manufactures, and sells the Invisalign® System of clear aligners, iTero™ intraoral scanners, and exocad™ CAD/CAM software for digital orthodontics and restorative dentistry, today announced the addition of restorative capabilities to its next generation iTero Lumina™ intraoral scanner (without iTero Near Infra-Red Imaging (NIRI) technology) and the new iTero Lumina™ Pro dental imaging system (with iTero NIRI technology), to enable efficient restorative and multidisciplinary ortho-restorative workflows and support diagnostic of interproximal caries above the gingiva, helping GP dentists reach new levels of practice efficiency and growth while delivering exceptional clinical outcomes.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20250306102381/en/>



iTero™ Lumina intraoral scanner (Photo: Business Wire)

Initially launched in February 2024, the iTero Lumina™ intraoral scanner delivers faster scanning speed², higher accuracy³, superior visualization⁸, and a more comfortable scanning experience.⁹

The enhanced capabilities of the iTero Lumina solutions provide outstanding scanning experience and performance, optimal for the simplest to the most challenging restorative cases. These capabilities are complemented by simplified restorative workflows that include the capture of single unit dental crowns to full dental arch with multiple preparations in a single pass, with a wave of an iTero Lumina wand.

- **Practice efficiency and growth: Effortless scanning experience and optimized workflows that simplify patient record taking and minimize chair time and footprint**
 - Capture simple to complex cases and extraoral appliances and material in one uninterrupted movement and without the need to scan each individual preparation from multiple preparation cases.
 - Experience versatility and efficiency with up to 5 capabilities in one device for less footprint in the practice, designed to reduce maintenance time and cost and enable the full automation of daily tasks from scanning to patient communication and lab collaboration: 1) photorealistic 3D models, 2) HD intraoral camera, 3) aid in interproximal caries detection with NIRI technology⁷, 4) photorealistic scans that eliminate the need for intraoral photos for Invisalign® case submission⁸ and 5) that are within comparable thresholds of photogrammetry¹¹, all in one single scan.
 - Simplify multiple treatment planning by using previous patient scans for all procedures within the treatment plan. No need to re-scan the patient and add chair time to your workflow.
- **Exceptional clinical outcomes: Superior clinical accuracy³**
 - Achieve predictable and repeatable first-time restoration fit⁵ from single unit crowns to removable prosthetics,

thanks to superior full-jaw accuracy compared to tested intraoral scanners³ and scans that are within accuracy threshold of photogrammetry for full-arch implant restorations⁴ - the highest standard for prosthetic planning captured in one single scan.

- Provide comprehensive patient data to your lab at once, including multi-bite and articulation information, to enable the design of optimal restorations and appliances.

- **Elevated staff and patient experience:**

- Offer a quick and comfortable experience⁹ for patients.
- Increase patient engagement and understanding with a modern and customized experience based on patient-centric views of their oral health condition.¹⁰

"We are excited to announce that the upgraded iTero Lumina™ scanner and new iTero Lumina™ Pro dental imaging system can now help doctors deliver exceptional restorative outcomes with the wave of a wand," said Karim Boussebaa, Align Technology executive vice president and managing director for the iTero scanner and services business. "The iTero Lumina™ solutions include superior 3D and 2D visualizations, to augment and amplify oral health assessment and communication using the Align™ Oral Health Suite, designed to increase patient engagement and understanding of their oral health condition."

Dr. Karla Soto, GP dentist and Align® Faculty member with a practice in Boca Raton, Florida, added, "The iTero Lumina scanner excels in the traditionally challenging scans with long spans, like full arch implant restorations or even edentulous areas. The amount of data and tissue it can capture is outstanding, making what was once a challenge, an easy, fast, and comfortable procedure for me, my team, and my patients."

Current iTero Lumina™ scanner owners will receive the new software which includes restorative and diagnostic support capabilities (without iTero NIRI technology) starting April via direct software update, following regulatory clearance in their countries.

The iTero Lumina™ Pro dental imaging system in cart and mobile configurations is commercially available in the United States, Canada, Australia, New Zealand, Japan, Hong Kong, Singapore, and Vietnam.

The iTero Lumina™ scanner cart and mobile configuration is commercially available in the United States, Canada, European Union countries, United Kingdom, Northern Ireland, South Africa, Kenya, Ghana, Australia, New Zealand, Japan, Hong Kong, India, Singapore, Vietnam, Korea, Taiwan, and Thailand.

The iTero Lumina™ scanner and iTero Lumina™ Pro dental imaging system are expected to be available pending regulatory approvals in other locations throughout 2025. Please contact your sales rep to find out when iTero Lumina solutions are available in your location.

1. Compared to the field of view of the iTero Element™ 5D dental imaging system, when the iTero Lumina™ intraoral scanner's scanning distance is 12 mm. Data on file at Align Technology, as of November 15, 2023.
2. Compared to the iTero Element™ 5D dental imaging system with tolerance AVE=±0.1 operating at a working distance from 0-20 mm. Data on file at Align Technology, as of November 15, 2023.
3. Based on bench testing conducted using ADA/ANSI 132 standard Model simulating "long distance accuracy (full jaw measurement)" in July 2024. Method: Comparative test to evaluate full arch accuracy (global accuracy), repeatability and reproducibility of intraoral scanners as described in ADA standard 132 [2015]; Sample definition: 3 operators performed 30 repetitive scans with each tested scanner.; Sample size: n=90 (3x30) scans for each scanner tested; Tested scanners: iTero Lumina; Trios 5; CS3800; Medit i700; Allied Star; Results: The accuracy of iTero Lumina is significantly higher than that of all 4 other scanners; with a reduction of total error ranging from 0.11% to 0.46%. Accuracy was defined as the accumulated average error + STD of all measurements specified in the standard. Data on file at Align Technology, as of August 26, 2024.
4. Based on bench testing conducted in June 2024 according to ADA/ANSI 132 standard requirements for long distance full jaw accuracy (average error =0.03% - 0.24% < 0.25%), crown accuracy (average error =0% - 0.9% < 1%) and inlay accuracy specimens (average error =0% - 0.4% < 1%). Data on file at Align Technology, as of August 26, 2024.
5. Based on bench testing conducted in January 2025 according to ISO 20896-2:2023 vs. Ground truth: Imetric icam 4D Photogrammetry system; Sample size: n=10; 5 upper arch model (All-on-6) and 5 lower arch model (All-on-4). Thresholds were defined as Horizontal error <50µm; Vertical error <30µm & Angular deviation < 0.4o.
6. Based on clinical data collected in January 2024 of n=15 subjects who participated in a clinical study with iTero Lumina™ intraoral scanner. Data reviewed by Invisalign trained practitioners (Orthodontists and GPs) in conjunction with Align clinical team. Data on File at Align Technology, as of January 31, 2024. Can not be used to imply that intraoral photographs may not be needed for practice patient records.
7. iTero NIRI technology is available on iTero Lumina Pro™ imaging system.
8. For Invisalign record-taking cases only. Based on a survey in September 2023 of n=22 users who participated in a global limited market release, working with iTero Lumina™ intraoral scanner for an average period of 6 months, representing both Invisalign trained general practitioners, orthodontists and their staff in NA, EU and APAC, who were presented with a 4 point level of agreement scale from strongly agree to strongly disagree with the following statement: "iTero Lumina™ intraoral scanner 3D model's superior 3D model eliminates the need to take intraoral photos." and "iTero Lumina™ intraoral scanner 3D model's superior 3D model boosts patient engagement." *Data on file at Align Technology, as of November 15, 2023.

9. Compared to iTero Element™ 5D imaging system wand. Data on file at Align Technology, as of November 15, 2023.
10. Based on assessing intraoral topographical images of hard and soft tissues and NIRI images.
11. Based on bench testing conducted in January 2025 according to *ISO 20896-2:2023* vs. Ground truth: Imetric icam 4D Photogrammetry system; Sample size: n=10; 5 upper arch model (All-on-6) and 5 lower arch model (All-on-4). Thresholds were defined as Horizontal error <50µm; Vertical error <30µm & Angular deviation < 0.4°. This claim is only relevant to specific markets, not including EU at this stage.

About Align Technology, Inc.

Align Technology designs and manufactures the Invisalign® System, the most advanced clear aligner system in the world, iTero™ intraoral scanners and services, and exocad™ CAD/CAM software. These technology building blocks enable enhanced digital orthodontic and restorative workflows to improve patient outcomes and practice efficiencies for over 271.6 thousand doctor customers and is key to accessing Align's 600 million consumer market opportunity worldwide. Over the past 28 years, Align has helped doctors treat approximately 19.5 million patients with the Invisalign System and is driving the evolution in digital dentistry through the Align™ Digital Platform, our integrated suite of unique, proprietary technologies and services delivered as a seamless, end-to-end solution for patients and consumers, orthodontists and GP dentists, and lab/partners. Visit www.aligntech.com for more information.

For additional information about the Invisalign System or to find an Invisalign doctor in your area, please visit www.invisalign.com. For additional information about the iTero digital scanning system, please visit www.itero.com. For additional information about exocad dental CAD/CAM offerings and a list of exocad reseller partners, please visit www.exocad.com.

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