Instruction For Use - Relu® Cloud 3.3, rev 1 (US)

AI-powered automation for dental CAD workflows

Table of contents

1 Introduction

Dear valued user,

Thank you for choosing **Relu® Cloud** — our AI-powered software platform built to help dental professionals deliver faster, more scalable, and more consistent care. Your decision to use our technology marks an important step in the digital transformation of dentistry, where automation and precision work hand in hand.

At **Relu**, we are committed to reshaping dental workflows through intelligent software. Relu® Cloud enables dental labs and clinicians to streamline their design processes using artificial intelligence and rule-based logic. The platform automatically processes intraoral scans, CBCT data, and facial scans to generate **pre-fabrication design aid** such as custom trays, mouthguards, bite base plates, retainers, and implant surgical guides.

Each design workflow is structured as a **modular service**, representing a specific task (e.g., segmentation, implant planning & surgical guide, custom trays). These services come with preset configurations that users can adapt to meet specific clinical or lab protocols, allowing for rapid, repeatable, and high-quality results.

Relu® **Cloud** is a **cloud-based solution**, meaning no software installation or special hardware is needed. The interface is accessible via a secure web portal, with role-based user permissions, audit trails, and state of the art cybersecurity remediations. Credits are only consumed upon case submission, and our refund policy ensures that you only pay for clinically valuable outcomes.

To further support performance and collaboration, the platform includes built-in quality control tools: an interactive 3D viewer, sculpting interface, model inspection features, and secure file-sharing capabilities.

Whether you're scaling your lab's output or adopting in-house 3D workflows in a clinic, Relu®**Cloud** adapts to your needs. We're proud to support your journey toward intelligent dental design — and we're here to be a trusted partner every step of the way.

Thank you for choosing Relu.

Sincerely,

The Relu Team

> **i** Relu® Cloud within Relu Automate
>
> Relu® Cloud is the regulated medical device delivered as part of the **Relu Automate** product. Relu Automate is the (non-medical) trade name under which Relu markets its broader platform — user and organization management, ordering and file handling, integrations and automation, and a collection of non-medical dental-laboratory services

— within which Relu® Cloud provides the medical device functions described in this document. General platform usage (accounts, services dashboard, file upload, ordering, billing, and the non-medical lab services) is documented in the **Relu Automate User Manual**.

2 Device Description

MD	Relu® Cloud, version 3.3
	July 2026
	Relu BV, Kolonel Begaultlaan 1a/5, 3012 Leuven, Belgium
UDI	(01)05419980224521(8012)3.3.0
Customer Support	support@relu.ai
Website	www.relu.ai
	https://relu.ai/documents/relu-cloud-us-v3-3-ifu
Rx Only	This device is intended for use by qualified healthcare professionals.

The Relu® Cloud software bill of materials can be made available on request. Please contact customer support for more information.

© 2026 Relu – All rights reserved.

The Relu® Cloud is a software application that allows trained health care professionals to use medical images for:

1. Visualization
2. Collaboration
3. Measurements & annotations
4. Image Processing (segmentation, registration, fusion, modelling)
5. Treatment planning

6. Export (images, measurements, annotations, models, 3D files)

The web application can be further used for measurements, diagnosis, monitoring, treatment planning, design, modeling, and reporting

The use of Relu® Cloud is limited to implantology, restorative dentistry, and other general dentistry devices. Relu® Cloud is NOT intended to be used for maxillofacial surgery, nor orthognathic surgery, nor designing any related devices.

2.1 Intended Use

Relu® Cloud is a software system intended to assist dental professionals in:

(1) generating digital three-dimensional models of a patient's teeth and jaws from dental or medical imaging data;

(2) supporting user-driven planning activities related to dental implant procedures;

(3) supporting digital workflows for the design of patient-specific endosseous dental implant surgical guides; and

(4) supporting digital modeling and editing workflows for the design of custom dental devices like protective occlusal mouthguards, custom trays, bite base plates, and directly printed retainers, without therapeutic, diagnostic, or mandibular repositioning claims.

The software enables the export of digital designs in industry-standard file formats (e.g., STL) for fabrication according to user-defined workflows.

Relu® Cloud is intended for use by qualified dental professionals in clinical or laboratory environments.

Relu® Cloud does not perform patient-specific fabrication of physical devices and does not generate automated diagnostic or therapeutic decisions.

2.2 Indications for use

Relu® Cloud is a software program for the management, transfer, and analysis of oral and maxillofacial image information, and can be used to provide design input for dental solutions. It displays and enhances digital images from various sources to support the treatment planning. It stores and provides these images within the system or across computer systems at different locations.

2.3 Contraindications

If the digital model of the patient or treatment planning on the model does not correspond to clinical findings and physical examination, it shall not be used for further purposes.

Use is contraindicated where input data quality prevents accurate anatomical representation, where significant patient motion artifacts are present, or where anatomical correspondence between modalities cannot be verified.

IOS–CBCT registration requires dentate regions to be present. Fully edentulous cases are not supported.

2.4 Target Population

The patient population is including, but not limited to the following:

Parameter	**Scope**
Age	Age 21 and older. For Implant treatments, patients with fully developed permanent teeth.
Gender	All
Ethnicity	All
Treatment needs	Dentistry and Implantology

2.5 Intended user

The Relu® Cloud can be used by the following user groups after required training. The web app must be used in conjunction with expert clinical judgment. Users must be aware of automation bias — the tendency to over-rely on AI-generated suggestions — and must exercise independent clinical judgment when reviewing all AI proposals generated by the system. See Section 5 for guidance.

1. Technical profiles: dental technicians, clinical engineers, design engineers.
2. Clinical profiles: dentists, dental assistants, dental specialists, orthodontists and implantology.

Users fabricating patient-specific devices based on Relu® Cloud generated and exported 3D designs are responsible to ensure they operate under applicable regulatory clearance.

> ⚠ Caution
>
> Federal law restricts this device to sale by or on the order of a dentist.

2.6 Intended environment

The Relu® Cloud is a software and requires a recent computer. The application is intended to be used in dental practice, dental lab or equivalent.

2.7 Device lifetime

Relu® Cloud is classified as Software as a Medical Device (SaMD). Relu defines the expected lifetime of Relu® Cloud as the period during which it will be actively maintained to ensure continued performance, safety, and compliance. During this period, Relu commits to delivering timely security patches, performance updates, and regulatory compliance updates as needed, and at a minimum, every two years or sooner based on emerging risks or vulnerabilities.

3 Performance specification and constraints

For performance, the medical device allows to accurately visualize, model and measure objects and geometries up to the resolution of the raw input data. No higher accuracy than the input data can be achieved.

For measurements, the device is able to measure up to the voxel resolution for volume data (e.g., CBCT, CT) and up to the triangle resolution for mesh data (e.g., STL, PLY). The degree of accuracy of the measurement function is therefore the same as the degree of accuracy of the raw input data.

For safety, the results of the application are always subject to the decision of the clinician, therefore being inherently safe.

Algorithm performance has been verified and validated and is documented in the device's verification and validation records. Performance is dependent on input data quality and adherence to the validated acquisition parameter ranges described in Section 6.5.

3.1 CBCT Segmentation

- Input: CBCT Scan (3D Volume)
- Output: A mask indicating where each structure is present in the image (3D Volume).
- Limitations: The structure must be present in the provided image to generate a proposal. Performance depends on input data quality (see Section 6.5 for validated acquisition parameter ranges). The masks must be reviewed before use.

Information presented to the user:

Users are presented with the information in a highlighted format on a scan viewer. The segmentation area is highlighted for the user's review and adjustment. There are no applicable units in this process.

Level of User Interaction:

The required interaction for the user is at the final step, the user must review whether the anatomy is correctly indicated.

3.2 IOS Segmentation

- Input: Intra Oral Scan (3D Mesh)
- Output: A Mask on the faces of the mesh indicating which tooth is present where on the Mesh. The mask on the teeth is according to the FDI number, all non-teeth elements (gingiva, base) are classified as background.
- Limitations: Masks must be reviewed before use. Performance depends on input data quality.

Information presented to the user:

Users are presented with the information in a highlighted format on a scan viewer. The segmentation area is highlighted for the user's review and adjustment. There are no applicable units in this process.

Level of user interaction:

The required interaction for the user is at the final step, the user must review whether the anatomy is correctly indicated.

3.3 Registration

- Input: Intra Oral Scan (3D Mesh) & CBCT (3D Volume) or Facial Scan (3D Mesh) & CBCT (3D Volume)
- Output: A transformation matrix that transforms the mesh to the coordinate system of the CBCT
- Limitations:

- For Intra Oral Scan and CBCT: The algorithm relies on teeth being present in the CBCT and IOS to perform the registration; edentulous cases are not supported. The algorithm is designed for registering data from the same patient at similar times, and does not accommodate changes such as newly added bridges, crowns, or recently extracted/moved teeth. Performance depends on input data quality (see Section 6.5).
- For Facial Scan and CBCT: The algorithm relies on the face being visible in the CBCT; this implies that only large FOVs are supported by the algorithm. Performance depends on input data quality.

Information presented to the user:

Users are presented with the information in a highlighted format on a scan viewer. They can review the overlay of the mesh on the CBCT.

Level of user interaction:

The required interaction for the user is at the final step, the user must review whether the anatomy is correctly indicated.

3.4 Implant planning

- Input: CBCT (3D Volume) & Intra Oral Scan (3D Mesh, optional), treatment parameters (implant libraries to use, teeth to extract, guide options, etc.)
- Output:
  1. Information about all placed implants: position, size, as well as implant object library ID
  2. Information about all placed wax-ups: position, size, as well as implant object library ID
  3. Information about all placed sleeves: position, size, as well as implant object library ID
  4. Guide meshes (one per IOS)
  5. Base models (one per IOS): original IOS with base
  6. Emergent profile models (one per jaw): original IOS with any crown that belongs to "teethToExtract" virtually extracted
  7. Temporary crown meshes (one per requested temporary crown): generated from the wax-up, abutment, and margin line

Limitations & scope:

Performance depends on input data quality (see Section 6.5).

The scope for the automatic implant & crown planning algorithm is:

1. Single units and maximum 4 singles side by side
2. Bridges maximum of 4 elements: 1 or 2 pontics and 2 pilar implants
3. Second molars will be proposed if opposing is present or proposed
4. Sinus lifting and bone grafting cases for the above implants (implants will be shown in the final proposed position):
    1. Sinus Lift (Smaller Augmentation) of maximum 4 mm
    2. Bone grafting needed:
        1. Lateral Grafting (Horizontal Deficiency): maximum of 6 mm total width (to fit a minimum 3 mm diameter)
        2. Vertical Grafting (Apical Deficiency): maximum 4 mm total height (to fit a minimum 8 mm length).

The quality of the implant & crown proposal for cases outside of this scope is not guaranteed.

The scope for the automatic guide design algorithm is:

1. We currently only support tooth-supported guides. One side of the implant can be edentulous, in this case the guide will rest on the gingiva.
2. Scan quality: the IOS scan shall be of good quality, with no holes or missing data, artefacts or other issues.
3. The scan must represent the situation of the patient at the time of the surgery. If any changes occurred or will occur to the dentition of the patient before the surgery (teeth movement, loss, or other), a newer scan shall be taken and used.
4. The adjacent teeth of the implant site shall not be mobile
5. Minimum arch coverage:
    1. For single implant cases, the IOS shall capture at least 2 adjacent teeth on either side of the implant side (or equivalent amount of gingiva). 3 adjacent teeth is recommended for better stability.
    2. For multiple implants, it is recommended to include a full arch scan for better stability.

The quality of the guide proposal for cases outside of this scope is not guaranteed.

A model of the IOS is provided together with the guide when exporting it. The user shall use this model to verify the correctness of the model (fit with the teeth, etc.)

Information presented to the user:

Users are presented with the planned implants & waxups in the viewer, on top of the 2D CBCT views, and in a 3D view with all segmented structures.

Level of user interaction:

The required interaction for the user is at the final step, the user must review whether the implant planning is correct, and adapt where necessary.

3.5 Summary of AI algorithm validation testing

3.5.1 Summary of performance data

Utilizing FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" the Proposed Device, Relu® Cloud underwent appropriate software verification and validation. This includes verification against defined requirements and validation against user needs. End-user validation and bench testing were performed. User testing demonstrated no critical defects impacting the intended use.

The geometric and functional correctness of surgical guides generated by the Relu Engine Automatic Guide Generation algorithm was assessed via bench testing. The deterministic, rule-based algorithm generates patient-specific surgical guides from a user-approved implant plan, and the generated guides were evaluated against predefined acceptance criteria covering sleeve positioning and dentition fit. Quantitative results demonstrate that the algorithm reliably produces geometrically correct surgical guides across a representative range of clinical configurations. Quantitative bench testing was performed on 71 surgical guides (from 49 patients) encompassing 182 implant sleeves, spanning upper and lower jaws with 1–8 sleeves per guide and 5–15 teeth per guide. Each guide was evaluated against seven geometric acceptance tests using a mesh tolerance of 0.030 mm. All surgical guides met the acceptance criteria.

The accuracy of the facial scan registration within the subject device, Relu Engine Facial Registration module, was assessed via bench testing. The algorithm aligns an optical facial scan to the (CB)CT coordinate system, and registration accuracy was evaluated both qualitatively and quantitatively by comparing algorithm output against expert reference annotations. Quantitative results demonstrate registration accuracy suitable for its intended visualization purpose. Quantitative bench testing was performed by computing surface distance metrics between the algorithm's registered facial scan and an expert-established ground truth registration across a dataset of 20 clinical scans. For each sample, Root Mean Square Error (RMSE) and Maximum Error were calculated as distances in mm between the two registered surfaces. Registration accuracy was assessed as the mean and standard deviation of each metric, and evaluated against predefined acceptance thresholds using one-sided 95% confidence intervals. The testing met the acceptance criteria.

In conclusion, all performance testing demonstrated device performance and substantial equivalence to the predicate device.

3.5.2 AI model performance testing

Relu® Cloud uses AI models to perform segmentation of various anatomical features and to assist in the placement of implants during surgical planning. The algorithms are trained on qualified ground truth data. Quantitative accuracy testing of the AI models was performed using mIOU and RMSE. Segmentations are validated identical to predicate K233925 Relu

Creator with n=25, with an additional equivalence test for US population of n=25 for this new submission. Implant planning and registration are validated with n=50 with 50% US population, where n represents the amount of unique patient cases and their corresponding imaging scans.

Implant planning performance was assessed across seven metrics using a Friedman three-way non-parametric test comparing Expert–Expert (EE), AI–Expert A (AI-A), and AI–Expert B (AI-B) deviation distributions. All metrics pass the acceptance criteria.

Segmentation and registration results:

Model	Cases (N)	Acceptance Criteria	Result
Dentition	25	mIoU 85%	0.92
IOS Dentition	25	IOU $>$ 0.90	0.97
Mandible	25	IOU $>$ 0.90	0.94
Mandibular Canal	25	Recall $>$ 0.80	0.95
Sinus	25	IOU $>$ 0.86	0.94
Skull	25	IOU $>$ 0.80	0.87
Pharynx	25	IOU $>$ 0.83	0.88
Registration	50	RMSE $<$ 0.5mm	0.297mm

Implant planning — scalar and angular agreement (Bland-Altman 95% LOA):

Metric	EE 95% LOA	AI vs Exp A 95% LOA	AI vs Exp B 95% LOA	AI equivalent to EE
Implant Radius (mm)	[-0.33, 0.16]	[-0.38, 0.18]	[-0.53, 0.17]	TRUE
Implant Height (mm)	[-2.24, 2.50]	[-2.09, 2.32]	[-2.90, 3.39]	TRUE
Implant Axis Angle (°)	[-6.52, 6.98]	[-8.65, 5.54]	[-10.21, 7.55]	TRUE
Implant-Waxup Gap (mm)	[-2.48, 2.60]	[-1.91, 1.17]	[-2.45, 1.85]	TRUE
Waxup Axis Angle (°)	[-9.54, 8.99]	[-10.97, 10.05]	[-12.06, 10.18]	TRUE

Implant planning — positional metrics (pairwise mean deviation and SD):

Metric	EE Mean (SD)	AI vs Exp A Mean (SD)	AI vs Exp B Mean (SD)	AI equivalent to EE
Implant Coronal Distance (mm)	1.01 (0.69)	1.32 (0.50)	1.39 (0.57)	TRUE
Implant Apical Distance (mm)	1.66 (1.00)	1.95 (0.73)	2.14 (0.95)	TRUE

3.5.3 AI ground truth and data independence

Data for training, tuning, and internal testing is obtained from a total of 243 different providers. Additionally the validation dataset was sourced from approximately 110 providers. Datasets are produced by highly-trained experts and verified by feedback loops of expert review and manual editing and correction. Medical segmentations and implant planning are produced on clinical cases by expert operators with an established track record.

Training labels for all algorithms are created through a structured annotation workflow managed by Relu's Clinical Data Manager, following documented anatomical definitions and standardized labeling protocols. For testing, annotator independence from the training process is maintained through independent verification or independent annotation, depending on the algorithm. Segmentation test labels were independently reviewed and verified by two qualified clinical reviewers from KU Leuven (OMFS-IMPATH), supervised by Prof. Dr. R. Jacobs, who had no involvement in training data creation. The review covered all 237 test cases across nine structures and identified zero major issues. For implant planning, test labels were annotated from scratch by an independent expert not involved in training annotation, with each case verified by a second independent clinician. The US-specific validation dataset was labeled entirely by independent external clinicians with no involvement in training, each verified by a second clinician.

Data independence between the training and validation datasets is established at multiple levels. Scan-level uniqueness is guaranteed by design through voxel-value hashing, ensuring no identical scan appears in both datasets. Provider-level separation is guaranteed through unique provider identifiers maintained in the source database, ensuring that all scans from a given dental practice appear exclusively in either the training or the validation set.

Patient-level independence cannot be guaranteed by design, as the anonymized dataset does not retain persistent patient identifiers across scans acquired at different time points. To address this, a dedicated post-hoc analysis was conducted. The analysis employed a two-stage similarity detection approach. In Stage 1, segmentation volumes were compared across all training-validation scan pairs, and pairs falling within a threshold volume difference were flagged for further review. In Stage 2, the top flagged pairs per anatomical structure were evaluated using a geometric framework comprising IoU (spatial overlap), HD95 (surface distance), and side-by-side visual inspection for morphological confirmation. Across all structures,

geometric similarity scores remained well below the levels expected for same-patient anatomy. The highest observed IoU was 0.760 (maxillary sinus), substantially below the approximately 0.95 threshold characteristic of same-patient scans. These results demonstrate that no patient overlap between the training and validation datasets was detected.

Additionally, variability at the provider level has been analyzed over the 243 different providers. No independence on the site level can be guaranteed, however proxies to site independence have been studied to cover full site variability, including different scanner manufacturers as well as acquisition parameters.

4 Installation and maintenance updates

The device does not require installation, as it operates entirely through a web-based interface. Updates are deployed automatically to ensure the user always accesses the latest validated version of the software. The updated version will be made available directly through the user's web browser upon accessing the medical device.

Information regarding version updates, including release notes and relevant instructions, will be communicated to the user via **Intercom** on the Relu® Cloud platform.

5 Warnings and precautions

⚠ Input data formats

The device is meant to be used with CBCT scans and/or Intra Oral and/or Facial Scans. Scanning protocols are left to the discretion of the user; however, we recommend that industry standards are referenced and followed and are selected to be appropriate for the intended use.

⚠ Input data quality

Relu® Cloud must be used with high quality input data. Poor quality input data (motion artifacts, metal artifacts, truncated field of view, low resolution) can result in inaccurate results generated by Relu® Cloud. See Section 6.5 for validated acquisition parameter ranges.

Image orientation

The 3D and 2D visualization must always be verified by a trained user on left–right orientation before any further use, to see that the images are not mirrored.

Tooth-numbering system

Relu® Cloud supports both the **FDI (ISO 3950)** and the **Universal** tooth-numbering systems. Before identifying a tooth, planning a treatment, or acting on a surgical report or drilling protocol, the trained user must verify which tooth-numbering system is active and confirm it is the one they intend to use. When Relu® Cloud is used embedded in a third-party application, the host application may set the tooth-numbering system for that session; users must take particular care to confirm the active system in such embedded contexts. Misreading the tooth number can lead to treatment at the wrong site.

Review proposals before use

Automatic results and design proposals provided by Relu®, including segmentations, alignments, implant planning, implant libraries (including implant-sleeve offset, drill lengths, related parameters), surgical guides, mouthguards, crowns and other AI-based dental designs, must always be independently verified by the trained user prior to export, production, or clinical use. Where available, third party surgical protocols, catalogs, and user manuals must be consulted. The automatic proposals are generated using parameters set by the user. The scope of options & editing given enable the user to shape the design freely; thus, responsibility for the final result lies with the user.

Adhere to IT system requirements

Relu® Cloud must be used on computer equipment that adheres to the specified system requirements. Inferior computer hardware can result in slow response and failure.

Cybersecurity precautions

Relu® Cloud must be accessed with individual user accounts. Shared logins are prohibited. Users are expected to take adequate measures to mitigate cybersecurity risks on local hardware and data, including installation of security updates, two-factor authentication, and appropriate user access management.

For trained professionals only

Relu® Cloud shall only be used by trained dental professionals. We recommend that all users participate in digital training offered by Relu and read the user manual section thoroughly. The AI proposals must always be verified by the trained user before any further use.

Automation bias

Automation bias is the tendency to over-rely on AI-generated outputs while reducing independent verification, even when the automated result is incorrect. This effect has been documented in trained clinical professionals across multiple domains (Lyell and Coiera, J Am Med Inform Assoc, 2017).
Users of Relu® Cloud must be aware that automation bias can affect their review of AI-generated proposals and must take active steps to counteract it. In particular:

- **All AI-generated results are proposals only.** Segmentations, implant positions, wax-ups, sleeves, surgical guides, and related outputs must be independently verified by the trained user before any clinical use. Accepting a proposal without independent evaluation constitutes a misuse of the device.
- **Do not approve a treatment plan without actively reviewing it.** The 3D planning viewer must be used to inspect implant positions, angulations, and proximity to anatomical structures before proceeding. Approval without opening and rotating the 3D view is insufficient.
- **All in-app warnings must be read and understood.** Do not dismiss or proceed past a safety warning; such as a nerve proximity alert or implant safety zone violation, without understanding why it was triggered and evaluating the clinical significance. Warnings are displayed in the 3D viewport and CT cross-sections to support this review.
- **The approval dialog requires explicit acknowledgment** that the user has reviewed the plan, is authorized to approve it, and understands that AI outputs require verification before clinical use. This step must not be treated as a formality.
- **If active warnings are present at the time of approval,** a red warning banner is shown in the approval dialog. The user must resolve or consciously accept each warning with full clinical justification before proceeding.
- **The export notice is a final reminder** that results are proposals requiring verification before clinical use. It should be read at each export.

Relu® Cloud includes system-level safeguards to support independent verification: a mandatory 3D viewer, deterministic safety warnings that operate independently of the

AI, a mandatory approval and consent workflow, and a verification notice at export. These safeguards are designed to mitigate automation bias but do not replace the user's independent clinical judgment.

Exports verification

Any exports made with the applications must be verified for accuracy with the images visualized in the web application or another trusted software before any further use. The user is responsible for ensuring that the designs (e.g. mouthguard, implant surgical guide) are correct and adapted for the patient & his treatment. The user is also responsible for choosing the parameters of the design (thickness, design offset, etc.) that are adapted for his fabrication workflow. The user is responsible for ensuring that the produced devices are robust, safe, and clinically fit.

Object recomputation

Any modification to implant planning invalidates an existing surgical guide. The guide must be recomputed and re-verified before export or clinical use. Any modification to the mouthguard outline invalidates an existing mouthguard. The mouthguard must be recomputed and re-verified before export or clinical use.

Caution when images are edited simultaneously

Relu® Cloud supports multiple users editing imported images. However, the software does not support simultaneous modifications of the same case. Users must review their results carefully before exporting to ensure they are not overwritten by others.

Generic implant libraries

Users are responsible for ensuring that any generic implant, i.e. a generic cylinder for which the dimensions can be fully defined by the user, used within the software is clinically appropriate. Relu is not responsible for the accuracy, suitability, or safety of any user-defined or generic implant.

Implant library compatibility

The software allows flexible treatment planning, including the use of different implant libraries for implants, surgical kits, sleeves, and abutments. The software displays recommended OEM combinations, along with the corresponding sleeve offsets, drill lengths, and other parameters. If you select non-recommended combinations, the software will

not make assumptions about compatibility, sleeve offsets, or drill lengths.
You are solely responsible for verifying: the validity of any non-recommended kit–sleeve combination, the correct drill lengths, sleeves, spoons, and offsets, and the consistency of all planning parameters with the manufacturer's official library and surgical protocols.
You must always review and confirm the software's proposals, including sleeve-implant combinations, sleeve offsets, drill lengths, and drill offsets, against the manufacturer's official data before clinical use.

⚠ In-app warnings

The software automatically performs safety and consistency checks and displays in-app warnings for detected issues. Always review and understand all warnings before using the results in a clinical context. Proceed with caution and verify all relevant parameters as appropriate.

⚠ Fabricating patient-specific devices

In the US, the physical surgical guide for endosseous dental implant placement is a medical device. Please contact a third-party medical device manufacturer registered and listed in compliance with FDA regulatory requirements to manufacture the physical surgical guide for endosseous dental implant placement or to purchase a validated milling/printing system to create the physical implant surgical guide at an on-site location. For more information, please contact your local regulatory agency for information regarding the regulatory status and requirements related to the manufacture of implant surgical guides and other patient specific devices designed by Relu® Cloud.
More specific, FDA considers these devices being medical devices classified under 21 CFR 872.3980, which have regulatory requirements for Device Establishment Registration and Listing (see 21 CFR Part 807) and following Quality Systems regulations (see 21 CFR Part 820).

⚠ Fabricating mouthguards

In the US, the physical mouthguard is a medical device. Please contact a third-party medical device manufacturer registered and listed in compliance with FDA regulatory requirements to manufacture the physical mouthguard or obtain a 510(k) clearance to fabricate mouthguards. For more information, please contact your local regulatory agency for information regarding the regulatory status and requirements related to the manufacture of mouthguards designed by Relu® Cloud.
More specific, FDA considers these devices being medical devices, which have regulatory requirements for Device Establishment Registration and Listing (see 21 CFR Part 807) and following Quality Systems regulations (see 21 CFR Part 820).

Fabricating custom trays

In the US, the physical custom tray is a medical device. Please contact a third-party medical device manufacturer registered and listed in compliance with FDA regulatory requirements to manufacture the physical custom tray or to purchase a validated milling/printing system to create the physical custom trays at an on-site location. For more information, please contact your local regulatory agency for information regarding the regulatory status and requirements related to the manufacture of custom trays designed by Relu® Cloud.
More specific, FDA considers these devices being medical devices classified under 21 CFR 872.6880, which have regulatory requirements for Device Establishment Registration and Listing (see 21 CFR Part 807) and following Quality Systems regulations (see 21 CFR Part 820).

Fabricating bite base plates

In the US, the physical bite base plate (record base) is a medical device. Please contact a third-party medical device manufacturer registered and listed in compliance with FDA regulatory requirements to manufacture the physical bite base plate or to purchase a validated milling/printing system to create the physical bite base plates at an on-site location. For more information, please contact your local regulatory agency for information regarding the regulatory status and requirements related to the manufacture of bite base plates designed by Relu® Cloud.
More specific, FDA considers these devices being medical devices classified under 21 CFR 872.6880, which have regulatory requirements for Device Establishment Registration and Listing (see 21 CFR Part 807) and following Quality Systems regulations (see 21 CFR Part 820).

Fabricating direct printed retainers

In the US, the physical dental retainer is a medical device. Please contact a third-party medical device manufacturer registered and listed in compliance with FDA regulatory requirements to manufacture the physical retainer or to purchase a validated milling/printing system to create the physical retainers at an on-site location. For more information, please contact your local regulatory agency for information regarding the regulatory status and requirements related to the manufacture of retainers designed by Relu® Cloud.
More specific, FDA considers these devices being medical devices, which have regulatory requirements for Device Establishment Registration and Listing (see 21 CFR Part 807) and following Quality Systems regulations (see 21 CFR Part 820).

6 Technical requirements & operating conditions

Recommended Requirements for Relu® Cloud:

6.1 Internet

Type	Requirements
Internet Speed	>50 Mbit/s upload / download (Relu® Solutions requires a stable internet connection. Interruptions during upload may result in errors.)

6.2 Hardware

Type	Requirements
Device	Desktop, laptop
CPU	8 Cores: Intel i7, Ryzen 7, Apple M chips
GPU	8 GB VRAM
RAM	16 GB
Memory type	SSD
Free Disk Space	10 GB
Display	1920 x 1080 pixels (Full HD)

6.3 Software

Type	Requirements
Operating System	Windows 11, MacOS 15, Ubuntu 24.04 (or later)
Browser	Chrome v138 (or later)

6.4 Data

Type	Requirements
CBCT	Size: < 1 GB. Format: .dcm (DICOM), .nii, .vti, .nrrd

Type	Requirements
Digital Impression	Size: < 200 MB. Format: .stl, .ply, .obj, .drc, .dcm (3Shape format). No fully edentulous cases
Facial Scanner	Size: < 200 MB. Format: .stl, .ply, .obj. Facial scan should include nose and mouth

6.5 CBCT Acquisition Parameter Ranges used in verification and validation

Parameter	Validated Range
Field of View (FOV)	>= 4 x 8 x 8
Voxel Size	0.1 – 0.5mm
Scanner Manufacturers Represented	Multiple vendors including but not limited to Planmeca, Morita, NewTom, Ray, Carestream, LargeV
Tube Voltage (kVp)	70 - 150
Tube Current (mA)	1-175

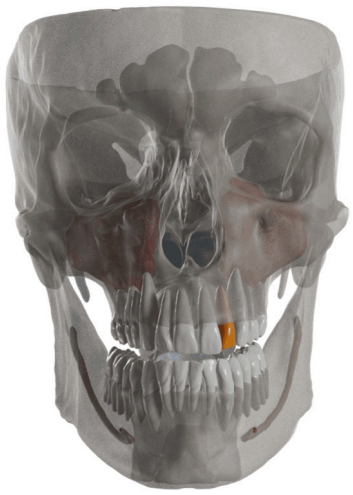
The CBCT datasets used during verification and validation included the acquisition parameter ranges listed above. Use of scans acquired with substantially different acquisition settings may affect the quality of automated proposals and may require additional user review and refinement.

7 Services

This Instructions for Use covers the **medical device services**. Account creation, the services dashboard, file upload, ordering, order management, team & billing, and session security are common to the whole Relu Automate platform and are documented in the **Relu Automate User Manual**.

The following medical device services are available on the Relu platform. Each is described in its own section below — its overview, order creation (inputs, outputs, and configurable parameters), and order reviewing & editing.

7.1 CBCT Segmentation & Alignment Service



> **Warning**
>
> Cases must remain within the validated clinical scope (see Section 3 - Performance specification and constraints). Cases exceeding this scope are not guaranteed.

7.1.1 Overview

The **Segmentation & Alignment Service** is a medical service that automatically generates **anatomical segmentations** from patient scans and aligns data from **multiple modalities** (such as CBCT, intra-oral, and facial scans).

The generated results can then be **reviewed, adjusted, and exported** in the **Advanced Editor** before being used for further planning or exported for downstream workflows.

7.1.2 Order creation

7.1.2.1 Inputs

- **CBCT (3D Volume, DICOM)** – required for full segmentation functionality.
- **Intra-oral scans (3D Mesh, STL/PLY/OBJ)** – optional, can be aligned to CBCT.
- **Facial scan (3D Mesh)** – optional, only one facial scan can be provided per order. Supported format is **OBJ**, optionally with associated texture files (.MTL and .PNG). A **ZIP archive** containing these files is accepted.

7.1.2.2 Outputs

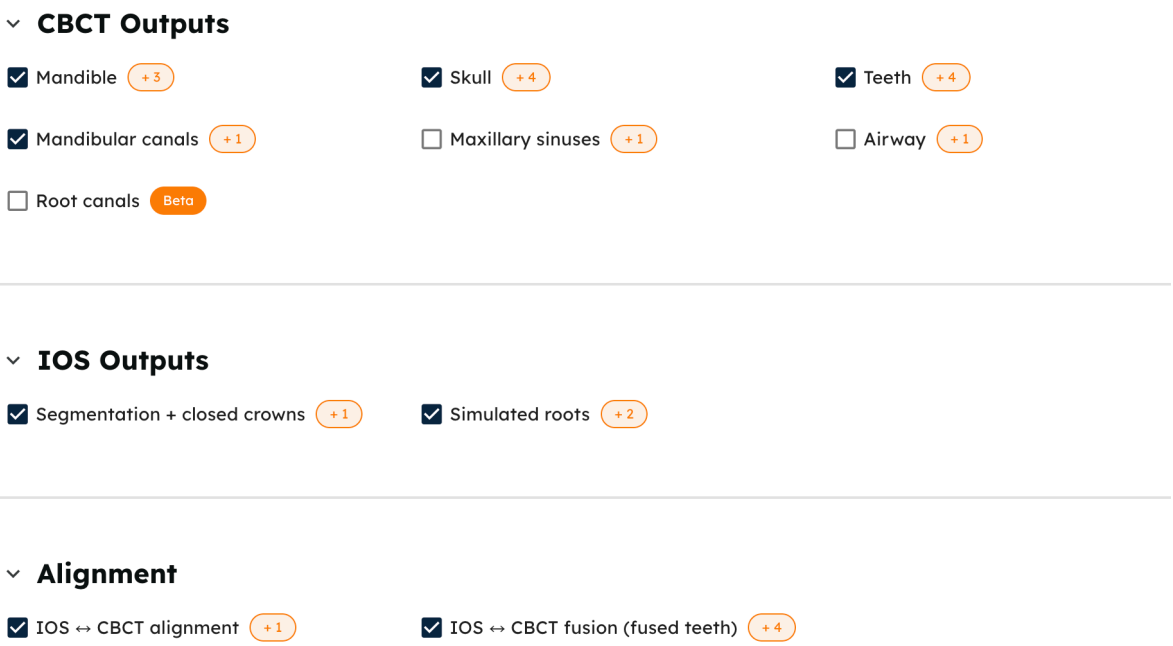
Depending on the uploaded input scans, the following outputs can be generated:

- Segmentation of dental and maxillofacial structures: maxilla, mandible, teeth (crowns and roots), mandibular canals, maxillary sinuses, and airway
- Gingiva segmentation from intra-oral scan
- Fused teeth combining crown data from intra-oral with root data from CBCT
- Closed intra-oral crowns
- Aligned intra-oral scans
- Aligned facial scan
- Panoramic arches for panoramic projection

7.1.2.3 Parameters

You can select which outputs are generated and tune a few advanced settings. As with other services, these can be **saved as a preset** for reuse.

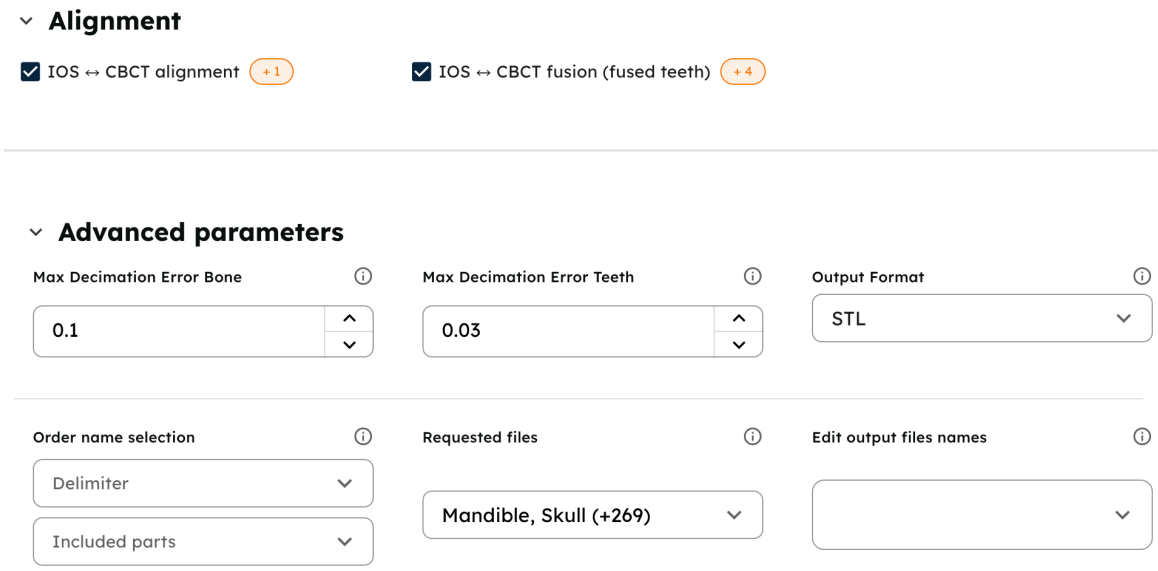
Output selection



- **CBCT Outputs** — choose which CBCT structures to segment: Mandible, Skull, Teeth, Mandibular canals, Maxillary sinuses, Airway, and Root canals (Beta).
- **IOS Outputs** — Segmentation + closed crowns, and Simulated roots.

- **Alignment** — IOS CBCT alignment, and IOS CBCT fusion (fused teeth).

Advanced parameters



- **Max Decimation Error Bone** (default 0.1) and **Max Decimation Error Teeth** (default 0.03) — control the mesh decimation tolerance for bone and teeth surfaces.
- **Output Format** — the file format of the exported meshes (e.g. STL).
- **Order name selection** — define a **delimiter** and **included parts** to derive the order name from the uploaded file names.
- **Requested files** — select which output files are generated.
- **Edit output file names** — customise the names of the generated output files.

7.1.3 Order reviewing & editing

7.1.3.1 Editor overview

You can visualise, edit, and validate results such as anatomical segmentations, implant positions, and surgical guides.

The editor app combines automation and manual control — automatically generating clinical proposals while allowing you to inspect, refine, and approve them with powerful visual and editing tools.

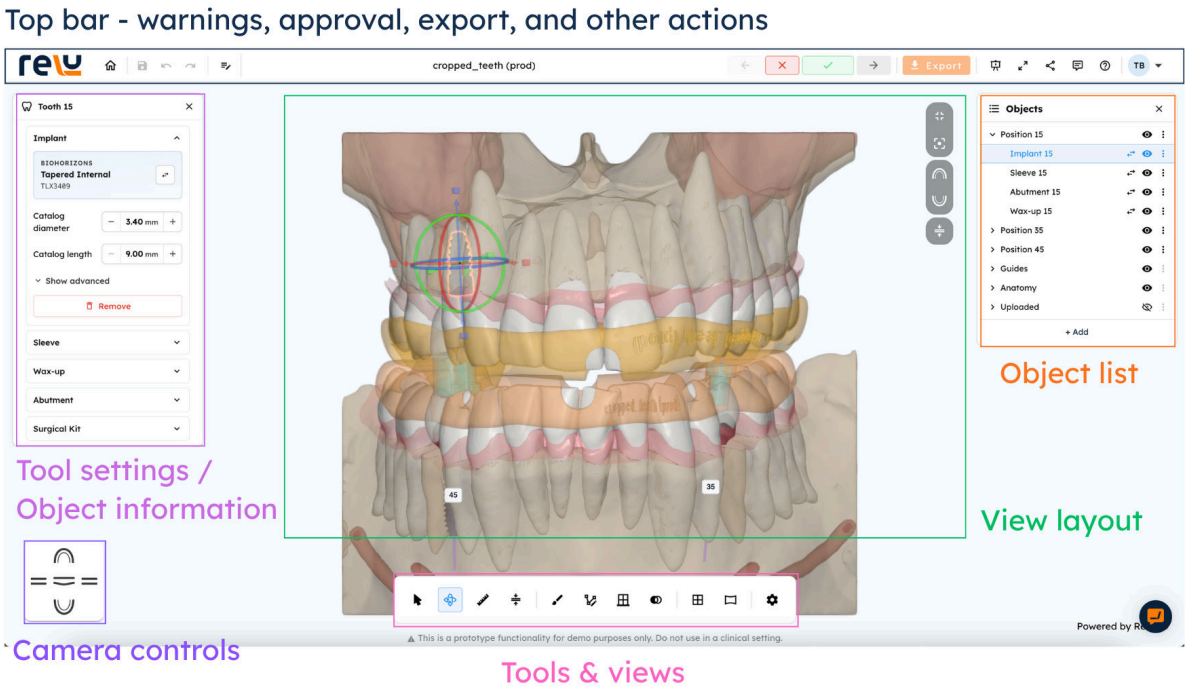
The steps, tools, and data you'll see depend on the **service** used to create the order (e.g. *CBCT Segmentation & Alignment* or *Implant Planning*) and on the **input scans** you uploaded.

The **Implant Planning & Surgical Guide Service** builds directly on top of the **CBCT Segmentation & Alignment Service**. That means all tools and data available in the latter are also available in Implant Planning.

Modes

The editor can operate in two modes:

- **Review & Adjustment Mode:** used for verifying and refining proposals without altering base anatomical data. This is the default mode in which the Editor is opened.
- **Advanced Edit Mode:** enables detailed, step-by-step editing of the workflow stages that led to the final result (e.g. segmentation, matching, panoramic projection). All manual edits are saved. To open this mode, click **Advanced Edit** in the top bar.



The image above shows the general structure of the user interface. It can be divided into 6 main areas:

Top bar — Main Application Actions

The top bar contains the main actions of the application, along with any active warnings. Available actions include:

- Home

- Undo / Redo
- Save
- Report Issue
- Help
- Approve Treatment (for implant workflows)
- Switch to Advanced Edit Mode
- Fullscreen
- Share
- Open Comments
- Profile actions such as Logout

> **Warning**
>
> Always review warnings before exporting or using results in any way.

Steps

Accessible only in **Advanced Edit Mode**, the Steps panel allows you to navigate between the different workflow stages (e.g. *IOS–CBCT Matching*).

Each step focuses on one task — for example, alignment, segmentation, or inspection — and displays only the tools, data, and views relevant to that task.

The number and type of steps depend on the selected service and the data you uploaded.

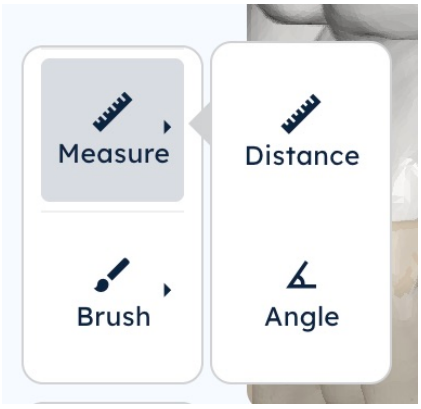
Tools & Views

This bar includes three sections: **Tools**, **Views**, and **Comments**.

Tools

Tools are used to inspect and modify results. Some tools have multiple options (indicated by a small arrow).

Hover over the icon to see the list, then click to activate a tool — only one tool can be active at a time.



Views

Views determine what you see in the **View Layout**.

Only one type of view can be active at a time, but each may have multiple configuration options.

Comments

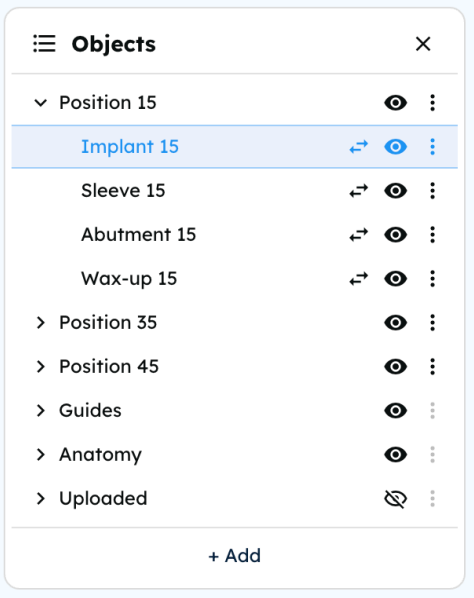
Toggle the comments panel to collaborate directly within an order. Comments are visible to all users who have access to that order.

Object List

The **Object List** lists all data used in the active step:

- **Input Files:** Original CBCT, intra-oral, or facial scans uploaded by the user, listed under the **Uploaded** section.
- **Outputs:** AI-generated or user-edited results such as segmentations, implants, abutments, crowns, and guides.

Clicking an object selects it and opens a panel with details and context-specific actions.



You can hide or show objects using the **eye icon**, and adjust transparency by hovering over it.

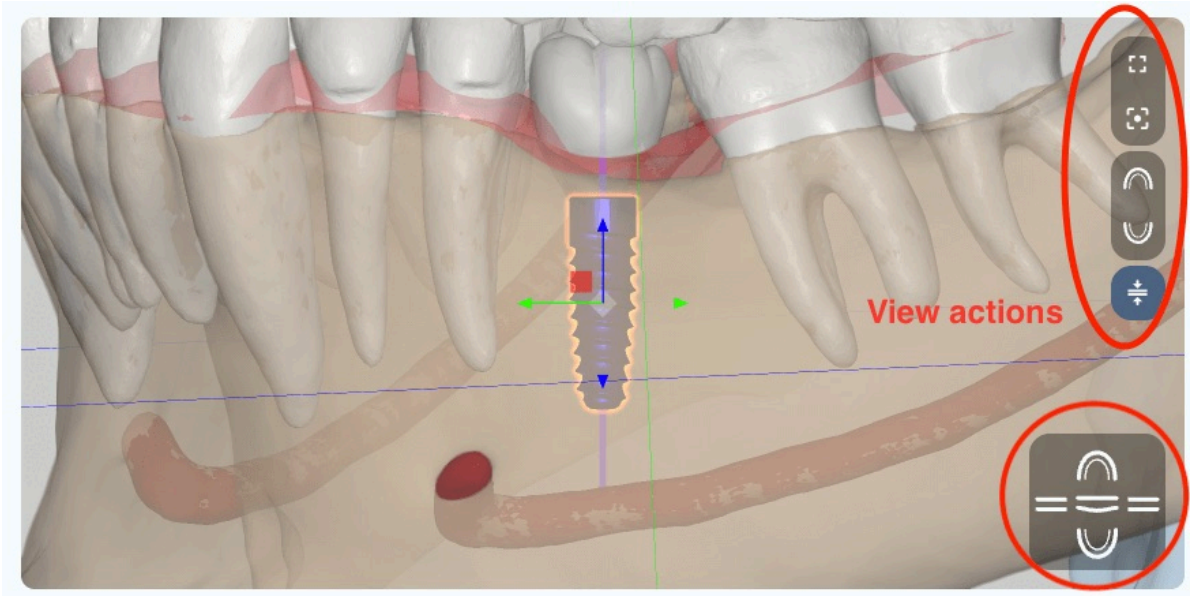
Minimise the Object List sidebar by clicking the arrow at its top left to give more space to the View Layout.

View Layout

This is where you explore your scans and planning results.

Multiple views can be opened at once or switched to fullscreen mode.

The available views will depend on the uploaded input data, selected service, and current step.



When hovering over a view, you'll see view-specific actions. All views share the following:

1. **Fullscreen / Exit fullscreen** – expand or restore the view.
2. **Reset view** – resets the camera to its default position.

3D View

Displays 3D objects such as segmentations, implants, and input scans.

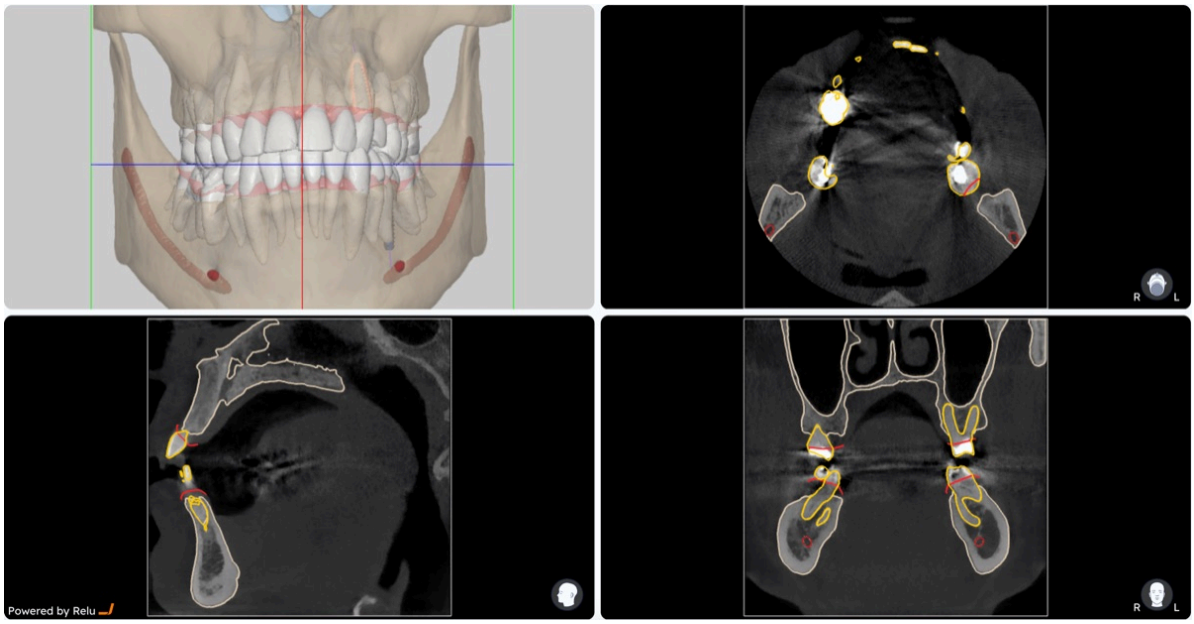
Controls:

- Drag → pan
- Right-click + drag → rotate
- Click object → select
- Click empty space → deselect

Additional actions:

- Hide either the upper or lower jaw.
- Jump to a predefined viewpoint (Top, Front, Left, Right, or Bottom).
- Toggle **Occlusion / Open Mouth** (only if both IOS scans are available).

2D CBCT Views



Visualise the CBCT volume through **axial**, **sagittal**, and **coronal** slices.

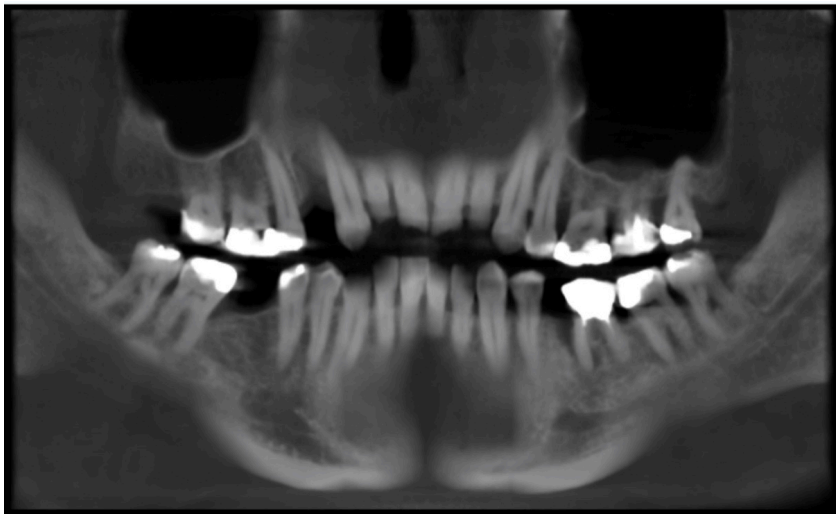
Controls:

- Ctrl + drag → pan
- Ctrl + scroll → zoom
- Click → move crosshairs in other views
- Scroll → navigate through slices

Additional options:

- **Snap to Object** – centres views on the selected item.
- Adjust **Brightness** and **Contrast**.

Panoramic projection view



Shows a 2D projection of CBCT slices along the panoramic arch.

You can edit this arch in **Advanced Edit → Panoramic Arches**.

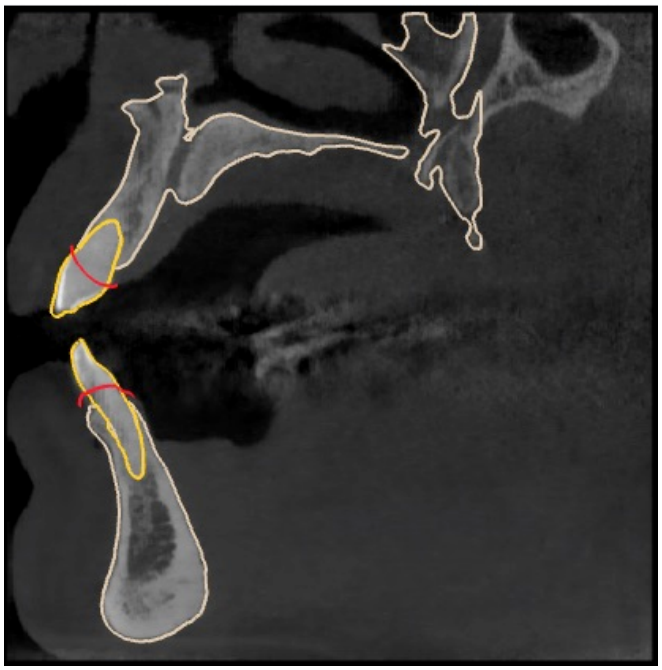
Controls:

- Ctrl + drag → pan
- Ctrl + scroll → zoom
- Scroll → expand the arch

Options:

- Choose **Upper** or **Lower** arch.
- Adjust **Brightness / Contrast**.
- Control the **number of slices** used for the projection.

Panoramic reslice view



Displays a cross-section that follows the panoramic arch.

Controls:

- Ctrl + drag → pan
- Ctrl + scroll → zoom
- Scroll → move along the arch

Options:

- Adjust **Brightness / Contrast**.

Help

Click the **Help** bubble to contact Relu's customer support team directly from within the application.

Feedback & Refunds

At Relu, we value your feedback. It helps us continuously improve our AI and software.

Click the **feedback** icon in the top bar.

You can choose between:

- Submitting general feedback, or

- Requesting a refund (if no clinical value could be extracted from the order).

Refund requests are subject to review by a Relu Administrator. For details, refer to the **End-User License Agreement (EULA)**.

Dependent Objects & Re-computation

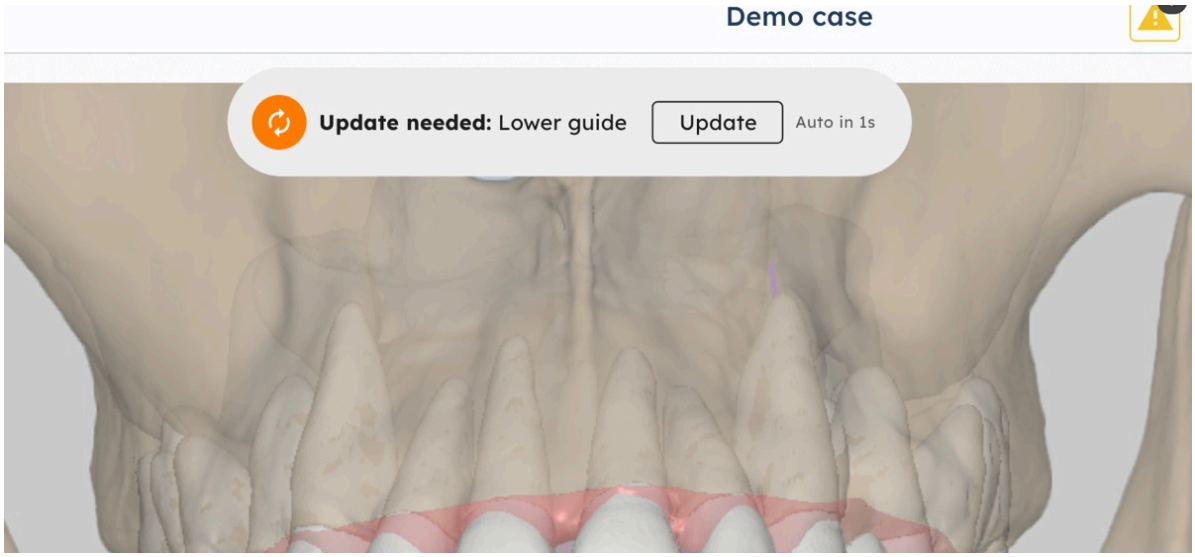
Certain objects depend on others (for example, a surgical guide depends on sleeves, or a segmentation mask on its mesh surface). When one object changes, the related object must be **recomputed**.

The software continuously tracks these dependencies and automatically triggers re-computation when needed. You can also do this manually.

A **sync icon** next to each object in the list shows its current computation status:

- Orange: re-computation needed
- Rotating blue: in progress
- Green: up to date
- Red: failed

If the object is visible in the current view, a popup will appear allowing you to manually trigger the re-computation.



During re-computation, **exports are temporarily disabled** to ensure only up-to-date data is used.

7.1.3.2 Segmentation & Alignment editing

The **Segmentation & Alignment** steps form the foundation of all workflows.

These steps:

- Provide **AI-assisted anatomical segmentation** of CBCT data
- Allow **alignment** of intra-oral and facial scans

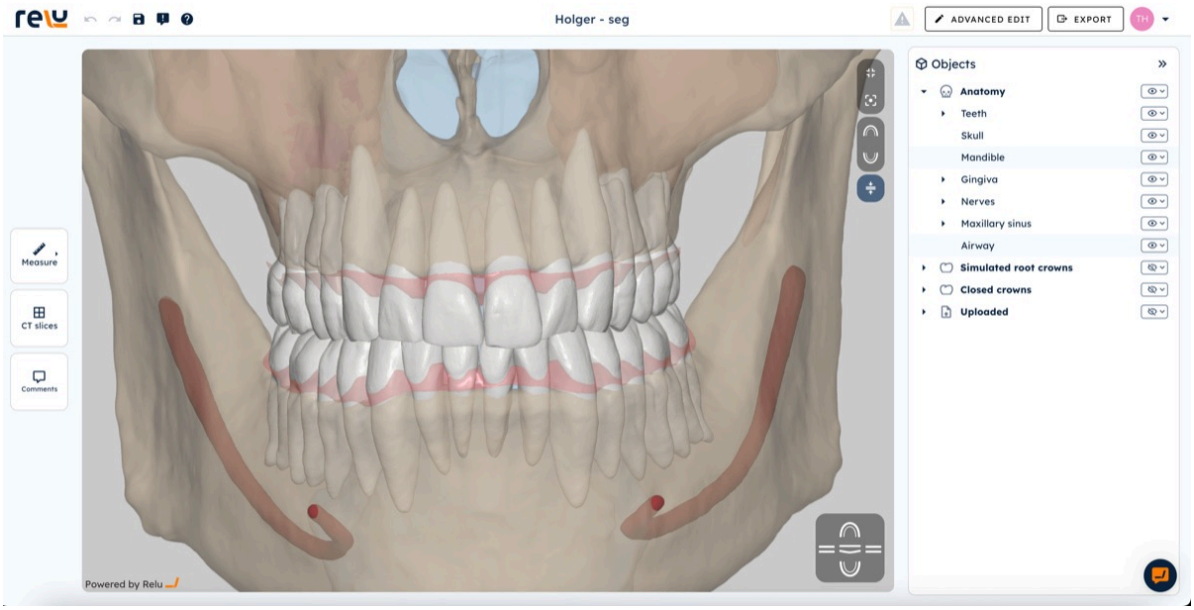
They appear in both:

- **Segmentation Service**, and
- **Implant Planning Service**, since implant planning builds directly upon these results.

You can export the results to use in other software or as part of larger clinical workflows.

For details, see Section 7.1.3.3.

Review & Adjustment Mode



When you open an order of the **Segmentation & Alignment** service, the application starts in the **Inspection Step**.

Depending on the uploaded scans, the following data are displayed:

- **Fused teeth** (if available): intra-oral crowns merged with CBCT roots
- If no fused teeth: **CBCT teeth** or **IOS closed crowns**
- **CBCT segmentations** (maxillary complex, mandible, nerves, etc.)

- **Gingiva** from the intra-oral scan
- All **uploaded input scans**

The goal of this step is to **review all automatic results** and decide whether they are ready for export or need manual correction.

If something looks incorrect, click **Advanced Edit** in the top bar to open the editing workflow.

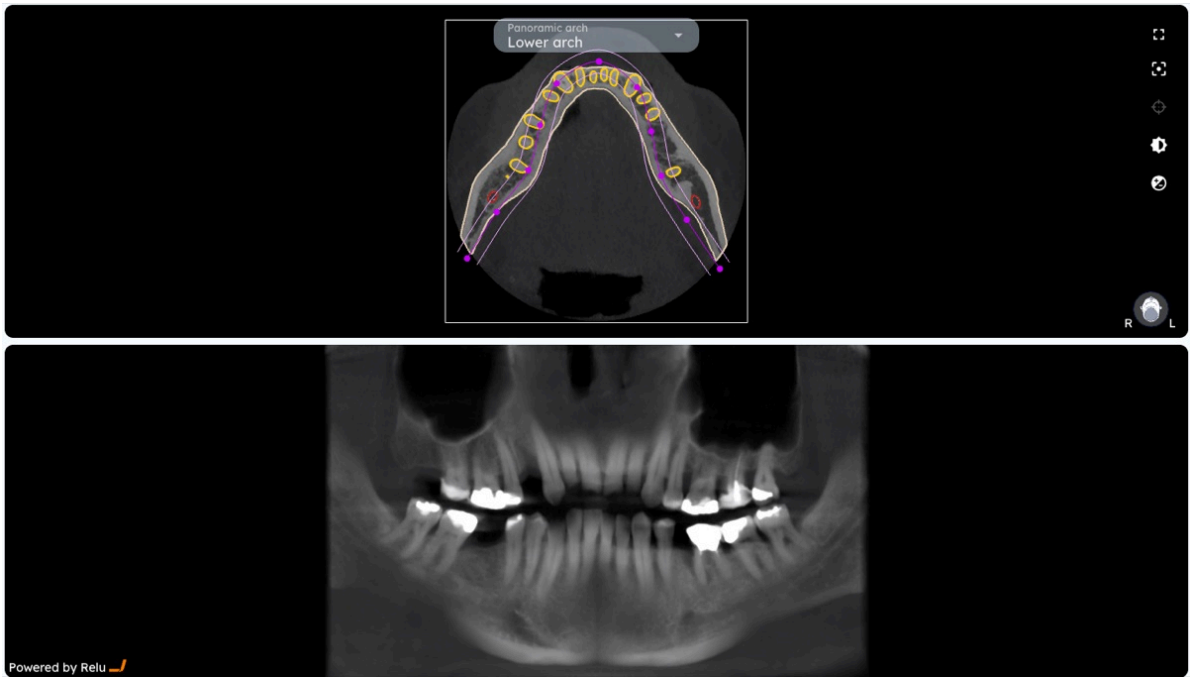
If everything looks good, click **Export** to proceed.

Advanced Edit Mode

When you switch to **Advanced Edit Mode**, additional steps appear depending on your uploaded data.

These steps allow you to manually adjust or refine the automatic AI results.

Panoramic Curves Step



The **Panoramic Curves Step** lets you **view and adjust** the dental arch trajectory proposed by the AI.

This curve defines how panoramic projections and reslice views are generated. Two curves are automatically proposed:

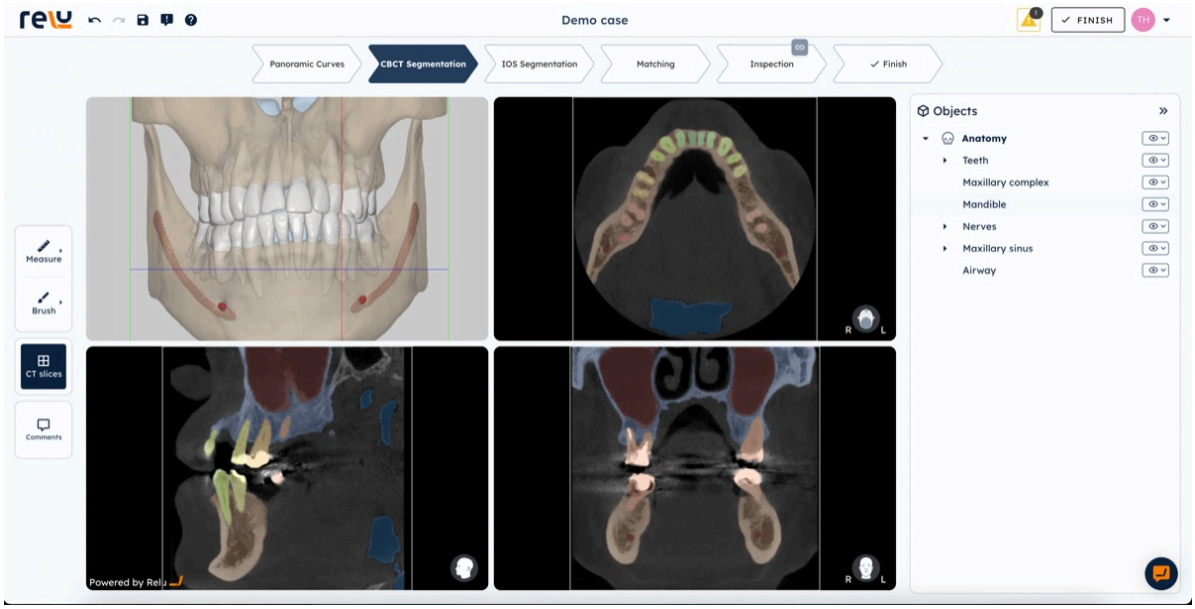
- One for the **upper** jaw
- One for the **lower** jaw

You can:

- Edit both curves by dragging their **purple control points** directly in the top view (overlaid on the CBCT axial slice)
- Adjust the **thickness** of the curve
- Switch between **upper** and **lower** curves
- Immediately see changes in the **panoramic projection view**

> **Warning**
>
> Accurate panoramic curves are essential for correct implant visualisation and treatment-planning accuracy.

CBCT Segmentation Step



The **CBCT Segmentation Step** displays and allows refinement of **AI-generated anatomical segmentations** (e.g. bone, teeth, nerves).

Segmentations appear as **colored masks** over the 2D CBCT slices. You can use the **Brush Editing Tool** to modify these masks. **To edit:**

1. Select the **Brush Tool** in the toolbar.
2. Select the object to edit from the **Object List**.

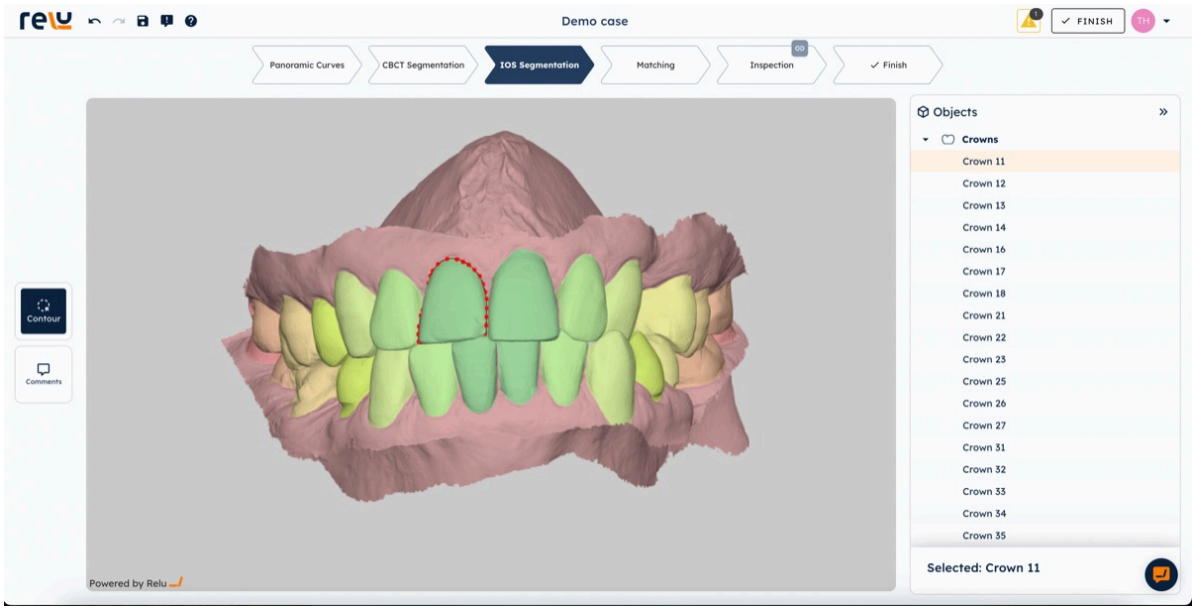
3. Adjust the brush settings:
    - **Mode** – Add or Remove
    - **Size** – Brush diameter
    - **Depth** – Slice depth (how many slices are affected)

When you edit a segmentation mask:

- Its **3D mesh (surface representation)** will need to be **recomputed** (done automatically after a short delay or triggered manually).
- If you edit **teeth segmentation** in an order containing an IOS, the **fused teeth** will also be recomputed.

> **Note**
>
> Before proceeding, validate that: segmentation boundaries match CBCT anatomy, mandibular canal and sinus contours are accurate, and bony structures are continuous and free of artefacts.

IOS Segmentation Step



The **IOS Segmentation Step** lets you review and edit the segmentation of **teeth crowns** in intra-oral scans.

Segmented teeth are displayed in color on the IOS surface. To edit a crown:

1. Activate the **3D Contour Tool**.

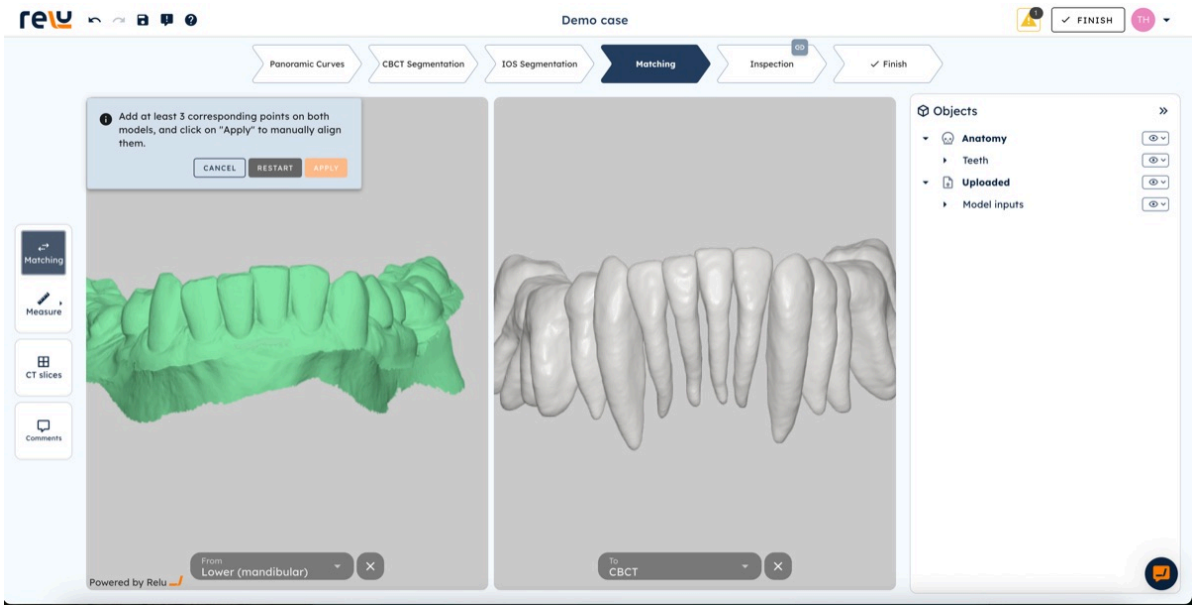
2. Select the crown from the **Object List**.
3. Adjust its outline by moving the **control points** of the contour.

When you edit a crown segmentation:

- The associated **closed crown** and **fused tooth** will automatically require re-computation.

> **Note**
>
> Before proceeding, validate that: gingiva and teeth margins are accurately segmented, and there are no holes, missing data, or overlaps between surfaces.

IOS–CBCT Matching Step



The **Matching Step** allows you to refine the **automatic registration** of the intra-oral and/or facial scans with the CBCT dataset.

To edit:

1. Activate the **Matching Tool**.
    - The 3D view will split into two windows: one showing the **source** object, one showing the **target**.
2. Use the selection panel at the bottom of the views to choose which objects are used for registration.

3. Refine the alignment with **Point-Based Matching**:
    - Select **at least three corresponding points** on both the source and target datasets.
    - Click **Apply** in the blue top-left panel to compute the optimal alignment.

For the CBCT, the software uses the **segmented teeth** as reference points.

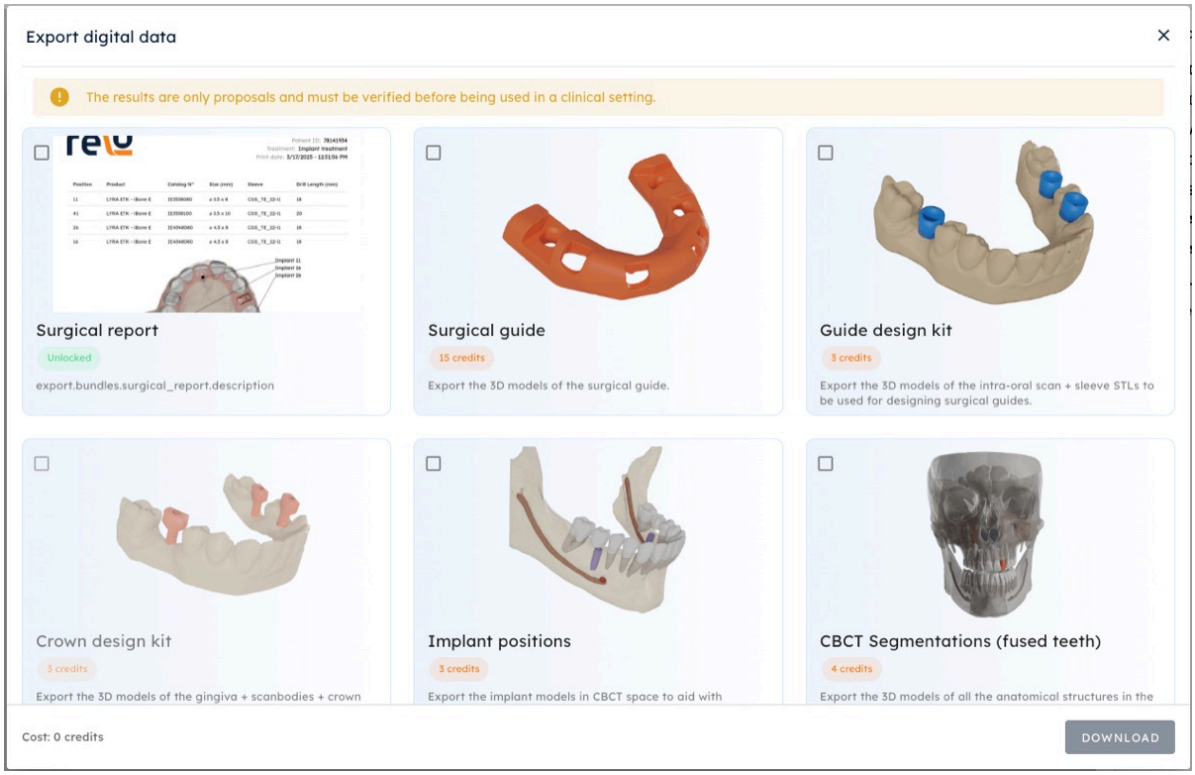
Use the 2D CT slices to evaluate alignment — intra-oral and facial scan cross-sections are shown directly on top.

Changing this alignment will affect the **fused teeth** and **surgical guide**, both of which will need re-computation.

> ⚠ Warning
>
> Accurate alignment is critical for precise implant positioning and surgical-guide design.

7.1.3.3 Export

> ⚠ Warning
>
> The trained professional is responsible for final validation of **fit, stability, and accuracy** of all exported outputs.



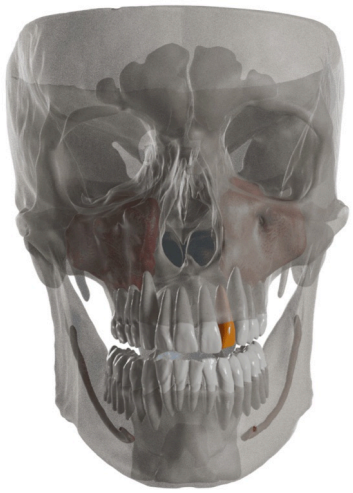
- **Approval required:** To export an implant treatment plan, the plan must first be **approved** by an authorized user. Click **Approve treatment** (top-right) and confirm authorization.
  - After approval, the plan is locked for editing. Approval can be **reverted** if changes are required.
- **Recomputation status:** If any change affects implant position/orientation/size, sleeve parameters, or guide design, the software **automatically recomputes** dependent elements (sleeves, guides, models).
  - While recomputation is active, **exports are disabled** and the UI indicates *Recomputation in progress*. Exports re-enable when status is **Up to date**.
- **Object availability:** Export options are only available when the **necessary objects exist** (e.g., the *Surgical guides* export appears only if at least one guide is present).

> **Note**
>
> Unless otherwise noted, files are provided in STL format. Reports are provided as PDF.

As noted above, certain bundles might not be available depending on the objects that are present in the editor. For CBCT Segmentation & Alignment orders, only the Segmentations bundle is available.

Some exports require **credits** to unlock. You pay **once per export type per case**; after unlocking you may re-download the same export type as often as needed.

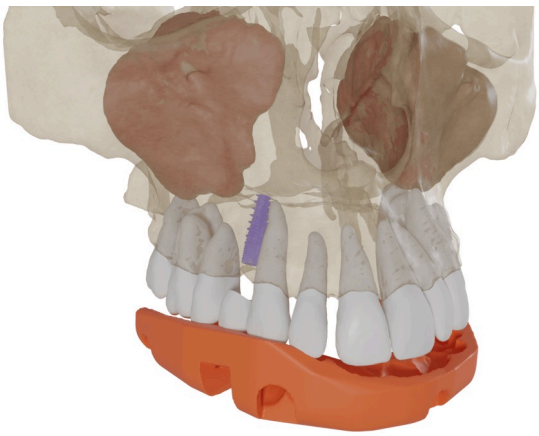
Segmentations



Includes STLs of automatically segmented anatomical structures:

- **Teeth**
- **Bone** (skull & maxillary complex)
- **Mandibular canals (nerves)**
- **Maxillary sinuses**
- …

7.2 Implant Planning & Tooth-Supported Guide Service



> **Warning**
>
> Cases must remain within the validated clinical scope (see Section 3 - Performance specification and constraints). Cases exceeding this scope are not guaranteed.

7.2.1 Overview

The **Implant Planning & Tooth-Supported Guide Service** builds directly on the **Segmentation & Alignment Service**, which provides the anatomical segmentation of the CBCT and the alignment of the intra-oral scan (IOS).

This service automatically generates a **proposed implant treatment plan** for the patient based on the provided input parameters.

The proposal includes **implants**, **virtual wax-ups**, **temporary crowns, abutments** and **sleeves**, as well as a **tooth-supported surgical guide** generated from these components.

The complete treatment plan and surgical guide can be **reviewed, refined, and exported** using the **Advanced Editor**.

> **Warning**
>
> All automatic results are proposals only. They must always be reviewed and verified by a qualified professional before any clinical use.

7.2.2 Order creation

7.2.2.1 Inputs

- **CBCT (3D Volume, DICOM)** – required.
- **Intra-oral scans (3D Mesh, STL/PLY/OBJ)** – optional, but required to generate a surgical guide model. Will be automatically aligned to the CBCT.
- **Facial scan (3D Mesh)** – optional, only one facial scan can be provided per order. Supported format is **OBJ**, optionally with associated texture files (.MTL and .PNG). A **ZIP archive** containing these files is accepted.

7.2.2.2 Outputs

The generated outputs include all the outputs from the CBCT Segmentation & Alignment service. Additionally, depending on the uploaded input data, the following results may be automatically generated:

- **Implant treatment proposal:** Includes automatic placement of **implants**, **sleeves**, **abutments**, **wax-ups**, and other implant-related objects.
- **Surgical guide and base models:** Automatic generation of a **tooth-supported surgical guide** and corresponding **base models**, enabling verification of the guide's fit on the dentition.
- **Emergence-profile models:** One model per jaw, representing the original intra-oral scan with the relevant teeth virtually extracted to define the emergence profile.
- **Temporary crowns:** Automatically generated based on the wax-ups, abutments, and defined margin lines.
- **Surgical report and patient passport:** Automatically generated documentation containing implant details, component information, and traceability data. A **drilling protocol** is also generated when the implant's library provides one for the selected surgical kit.

7.2.2.3 Parameters

As with other services, these parameters can be **saved as a preset** for easy reuse in future orders.

Please note that **treatment-specific parameters** are not saved in presets, as they are unique to each patient.

Treatment Details

You can define several **treatment parameters** that the AI will take into account when planning the implant treatment.

Automatic Implant & Crown Proposal

You can choose to let the AI **automatically propose implants and crowns in edentulous areas**.

When this option is enabled, the AI will detect edentulous sites and propose appropriate implants and crowns automatically—no need to manually define each position.

> **Note**
>
> Implant placement in areas where teeth must first be extracted always needs to be explicitly specified.

Visual Tooth Selector

Use the **visual tooth selector** to define where the AI should plan implants, crowns, and temporary crowns:

1. Select the **restoration type**: *Implant & Crown*, or *Pontic* (crown without implant).
2. Under **Implants / Crowns**, click the **tooth numbers** that correspond to the desired restoration sites.
3. Under **Temporary crowns**, click an implant-and-crown site to additionally request a **temporary crown** for that site (click again to clear it). Temporary crowns are billed per unit; pontic sites cannot have a temporary crown.
4. To remove an implant or crown, click the **"X" icon** next to it or click the same tooth number again.

Implant System

Here you can define the **implant system**, **surgical kit**, and **sleeves** that will be used for planning and guide generation.

The AI will only select components from the specified libraries, though you can modify them later in the **Advanced Editor**.

The **procedure type** controls whether a surgical guide is generated and which sleeve type applies. Options: **Free-handed** (no guide, no sleeves), **Pilot guide** (default; pilot sleeves), **Fully guided** (guided sleeves), and **2Ingis guide**.

You must specify the following parameters:

- **Implant manufacturer**
- **Implant product line**
- **Surgical kit**
- **Sleeve product line**

- **Abutment product line** — the abutment line used for all planned implants in the order. Choose a specific line, or leave it on **Any**, in which case the system selects an anatomically appropriate abutment per tooth automatically. You can override the abutment per tooth later in the **Advanced Editor**.

If your preferred system is not available, you can select the **Generic** system.

Some libraries are marked as:

- **Non-mesh** – placeholder geometry is used (not manufacturer-validated).

> ⚠ Warning
>
> Use *generic* and *non-mesh* libraries with care. It is your responsibility to verify that these components are compatible with your clinical instruments and workflow.

Advanced Parameters

You can configure advanced guide design parameters that influence how the **surgical guide pre-fabrication design aid** is generated, such as:

1. **Mesh thickness** (mm): defines the wall thickness of the mesh. Thicker meshes are more rigid.
2. **Design offset** (mm): compensates for dimensional tolerances in downstream fabrication. A small positive offset slightly enlarges internal dimensions to improve fit.

7.2.3 Order reviewing & editing

The Implant Planning service builds directly on the Segmentation & Alignment service. The **editor overview** and the **segmentation & alignment editing** described under that service (see Section 7.1.3) apply here as well; this section covers the implant-specific planning, surgical-guide, and export functionality.

The **Implant Planning Service** extends the segmentation workflow with **AI-assisted implant planning** and **surgical guide generation**.

When you open an order, the system provides an automatic proposal of:

- **Anatomy segmentation**: bone, teeth, nerves, etc.
- **Wax-up / crown** position and size
- **Dental implant** positions and size from the requested implant library
- **Sleeve** positions and catalogue numbers from the requested sleeve library
- **Temporary crowns** (when requested), based on the wax-up, abutment, and margin line
- **Tooth-supported surgical guide** model, based on the sleeves

Just like in the **Segmentation & Alignment** service, you can further refine segmentation and alignment via **Advanced Edit Mode**. For details, see the Segmentation & Alignment section above.

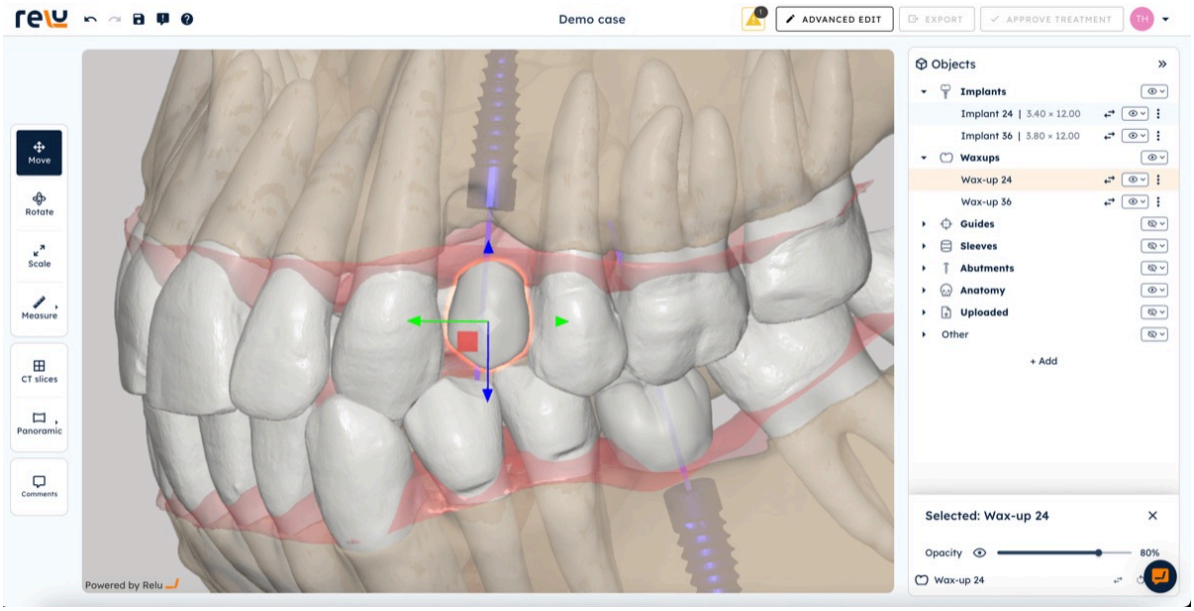
This service blends **automatic proposals** with **full manual control** over implant parameters, libraries, wax-ups, sleeves, and guide settings.

All automatic results must be **reviewed and approved by a trained dental professional** before export or clinical use.

You can export results for use in other software or as part of larger clinical workflows. See Section 7.1.3.3 for more information.

7.2.3.1 Implant planning

Virtual Wax-ups



Use **virtual wax-ups** to plan implants in a **top-down** manner, taking the intended restoration into account. The AI automatically places and scales a wax-up for each implant, based on neighbouring teeth.

You can edit **position**, **orientation**, and **size** of any wax-up in both **2D** and **3D** views:

- **3D View**: use the **transform tool** (the *orbit* icon) — a single gizmo that lets you move, rotate, and scale the object. Drag the **arrows** to move, the **circles** to rotate, and the **square** handles to scale.

- **2D Views**: use handles — **green squares** (scale), **red circles** (rotate), or drag to move.

Additional actions are available from the **menu** in the Object List:

- Delete the wax-up
- Change the **crown type** (e.g., incisor)
- **Reset** to the original AI position

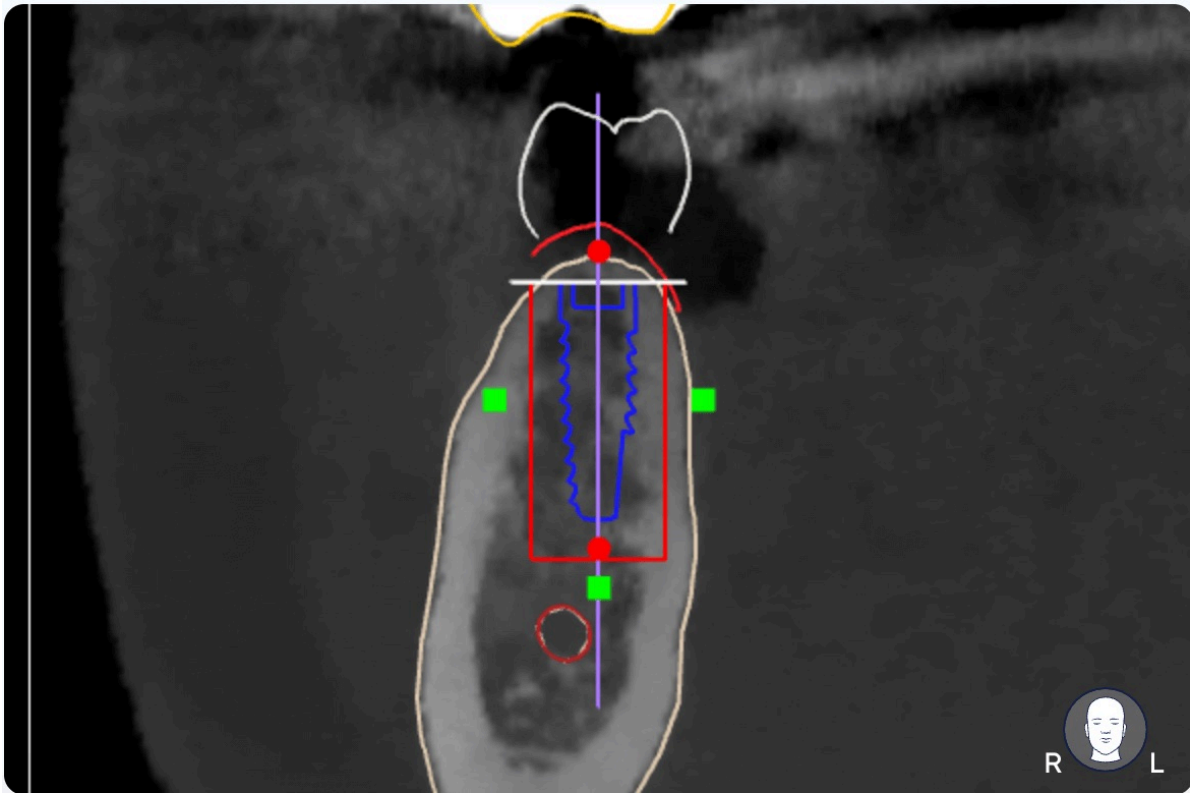
Implants

The AI proposes **implant positions** and selects **sizes** from the requested library, considering the associated crown, available space, nerves/sinuses, and other safety constraints.

You can edit implants in 2D & 3D using the same tools as for crowns. In the 2D view, choose whether rotations are around the **apex** or the **implant top**.

When you **resize**, the software picks a size from the **same product line** as the current implant.

Safety visualisation in 2D views

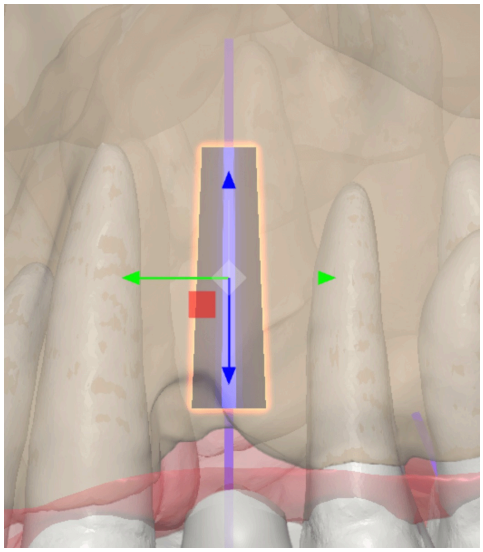


- The **safety zone** around the implant is shown in **red** (default: **1.5 mm** lateral, **2.0 mm** apical). You can increase these margins in **Settings**.
- A **white line** indicates the **bone level**, useful for positioning **tissue-level** implants.

Libraries & info

- Switch the **implant library** by clicking the **swap** button (the *swap-horizontal* icon) next to the implant in the Object List (filter by manufacturer and product line).
- Select an implant to view details like **catalogue length**, **intra-osseous length**, etc.
- For multi-unit restorations, use **Make parallel** to align selected implants.

Generic Implant Libraries



You can also use **generic implants** (you define all dimensions) when a specific implant is not in our standard library.

> ⚠ Warning
>
> You are responsible for confirming that any generic implant is clinically appropriate and compliant with applicable regulations. Relu is not responsible for the suitability, accuracy, or safety of user-defined implants.

Abutments

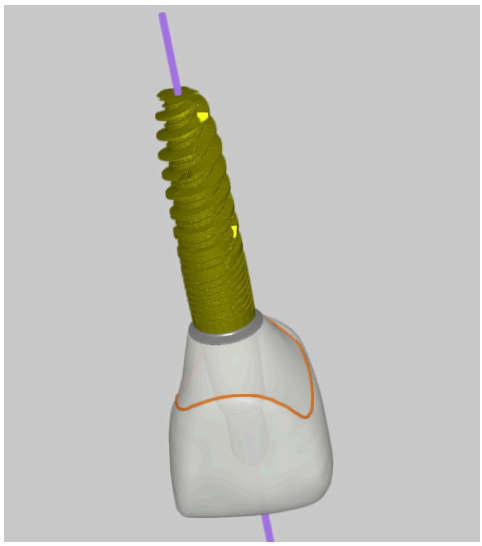
You can add different **abutment** types to implants (e.g., **scanbodies**, **Ti-base**, **temporary**).

Use the **Add** button at the bottom of the Object List (see Adding Implant Objects Manually below).

The software automatically selects a **compatible abutment** for the chosen implant. You can switch it via **Select from Library** in the Object List (filter by manufacturer and product line).

If you later **switch implants**, compatibility is **re-checked** automatically and the abutment is **updated** if needed.

Temporary Crowns

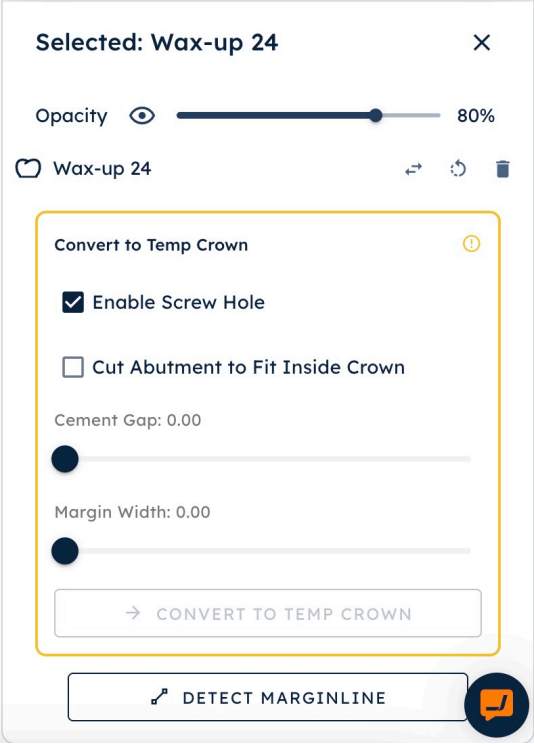


You can generate **temporary crowns** based on:

- the **virtual crown** (wax-up),
- the **abutment**, and
- a **margin line** defined on the IOS (required).

First, enable the feature in **Settings**. Then, when a wax-up is selected, additional tools and options appear:

- **Margin Line Tool** – edit the margin line by **moving, adding, or removing** control points.
- **Temporary Crown Generation Settings** (Object List):



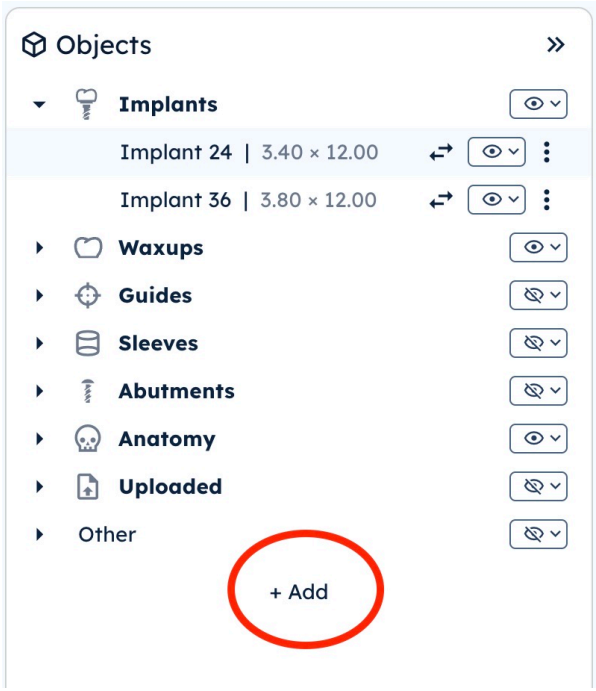
- **Screw hole** – enable for screw-retained crowns
- **Cut abutment to fit inside crown**
- **Cement gap** – clearance between abutment and crown interior
- **Margin width** – distance between the margin line and crown start

When ready, click **Convert to temp crown** to generate.

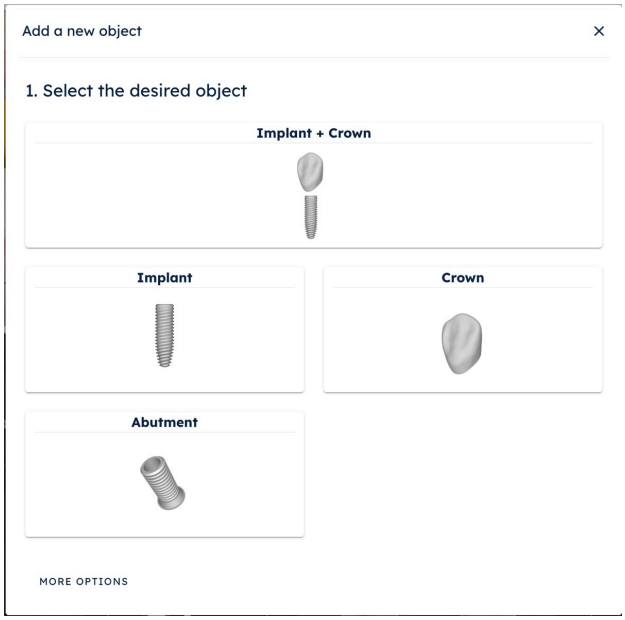
> **Note**
>
> Temporary crown generation isn't supported for all library abutments. If unsupported for your current abutment, a warning will appear.

Adding Implant Objects Manually

You can manually add implant objects using **Add** in the Object List.



Choose the **object type** (implant, crown, abutment, etc.):



Then select the **location** where you want to place it.

> **Note**
>
> You can't add an implant or crown where one already exists. Abutments can only be added where an implant already exists.

7.2.3.2 Surgical guides

Surgical guides are generated directly from your implant plan.

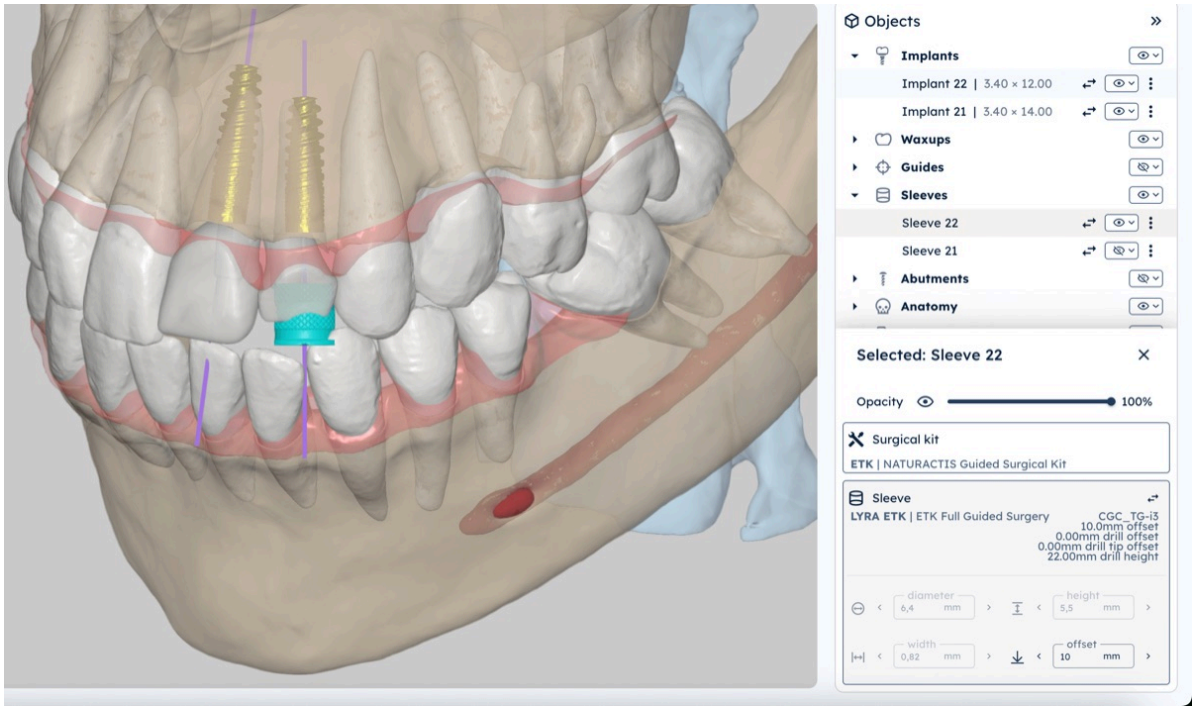
They support both **automatic** and **manual** creation of **tooth-supported guides**, ensuring sleeves are precisely positioned relative to planned implants.

Guides are automatically **re-computed** when sleeve changes, maintaining consistency across the workflow.

You can configure guide design parameters — e.g., **guide thickness**, **design offset**.

The generated guide mesh can also be **manually refined** with the sculpt, outline, and window tools — see *Editing the guide mesh* below.

Sleeves & Surgical Kits



The surgical guide is designed to position the **drilling sleeves** accurately relative to each implant. This positioning depends on three main factors: **the implant**, **the surgical kit**, and **the sleeve**.

Relu supports both **fully guided** and **pilot drilling** workflows.

The AI automatically proposes and positions the sleeves according to the parameters defined during order creation. You can manually modify the **sleeve type** and its **offset**.

Each sleeve remains linked to its corresponding implant; if the implant moves, the sleeve position updates automatically to maintain the correct offset.

When switching implants, the software verifies that the selected sleeve and offset are compatible with the new implant.

If they are not, the system will automatically replace them with a valid combination.

Each implant can use its own **surgical kit**; if you switch to an implant incompatible with the current kit, the software automatically switches to a compatible kit (or warns if none exists).

> **i** Key terminology
>
> - **Sleeve offset:** Distance between the top of the sleeve and the implant's bone level.
> - **Drill offset:** Fixed offset added on top of the sleeve during surgery (e.g., due to a drill spoon).
> - **Drill tip offset:** Additional drilling depth below the implant apex (distance between implant tip and osteotomy bottom).
> - **Implant intra-osseous length:** Portion of the implant within the bone. This may differ from the total implant length (e.g., for tissue-level implants).
> - **Drill length:** Total drill length = drill offset (if using a recommended kit–sleeve combination) + sleeve offset + implant intra-osseous length + drill tip offset (if applicable).

We recommend using **only manufacturer-approved surgical kit–sleeve combinations**.

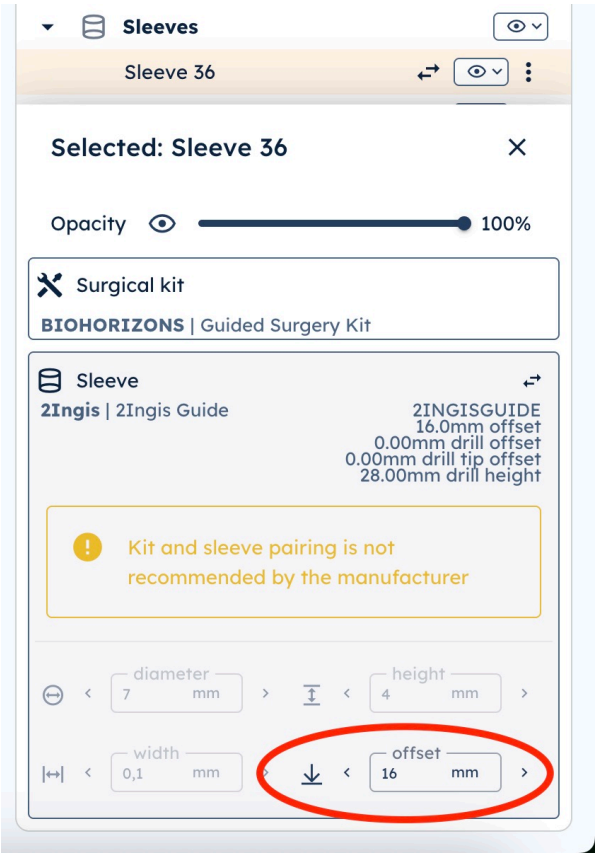
> **⚠** Warning
>
> You are responsible for verifying the validity of any non-recommended kit–sleeve combinations, including the correct drill lengths, spoons, and offsets. Relu does **not** make assumptions for non-recommended combinations. For non-recommended combinations, the **drill offset** and **drill tip offset** are considered **0 mm**. Use non-recommended combinations **at your own risk**.

The software restricts sleeve offsets to the valid range defined by the selected kit–sleeve combination. You can exceed this range if desired; however, doing so may mean that the **longest**

drill in the kit will not reach full depth, requiring part of the osteotomy to be performed **free-hand**.

You can change the sleeve library by selecting **"Select from Library"** in the **Object List**. In the selection dialog, you will see which sleeves are **recommended** for the chosen surgical kit and implant.

You can modify the sleeve offset by selecting the sleeve in the **Object List** and using the arrows next to the offset parameter. Detailed information about **drill length** and **surgical kit compatibility** is also displayed here.



Generic Surgical Kit & Sleeves

If your preferred surgical kit or sleeve library is not yet integrated in Relu, you can use **generic** kits and sleeves. The generic surgical kit defines drills ranging from **6.0 mm to 30.0 mm**, in **0.1 mm increments**. The generic sleeve allows **manual definition** of all sleeve parameters.

> ⚠ Warning
>
> You are responsible for confirming that any **generic surgical kit** or **user-defined sleeve** is **clinically appropriate** and **compliant with applicable regulations**. Relu is **not responsible** for the suitability, accuracy, or safety of user-defined or generic components.

> ⚠ Warning
>
> Proper sleeve positioning relative to the implant is **critical to patient safety**. Incorrect sleeve height or offset can result in improper drilling depth or implant placement.

Surgical Guide Design

An **initial surgical guide proposal** is automatically generated when opening the order. The guide is created based on the **sleeve types and positions**, as well as the **guide design parameters** (e.g., thickness, design offset) defined during order creation.

Whenever changes are made to sleeves — whether by moving an implant, adjusting the offset, or switching the sleeve library — the software automatically marks the corresponding guide as **requiring re-computation**. The user needs to trigger re-computation of the guide.

Abutments

Abutments are placed automatically and shown by default in the viewer. To change an abutment, open the **Abutment Library** dialog and select a different one; abutments that are anatomically preferred for the selected tooth are tagged **Recommended**. You can filter the library by manufacturer and product line.

You can also manually adjust guide design parameters by selecting the guide in the **Object List** and triggering a **re-computation**. See Section 7.2 for which parameters can be set.

By default, these values are taken from the **parameters set during order creation**.

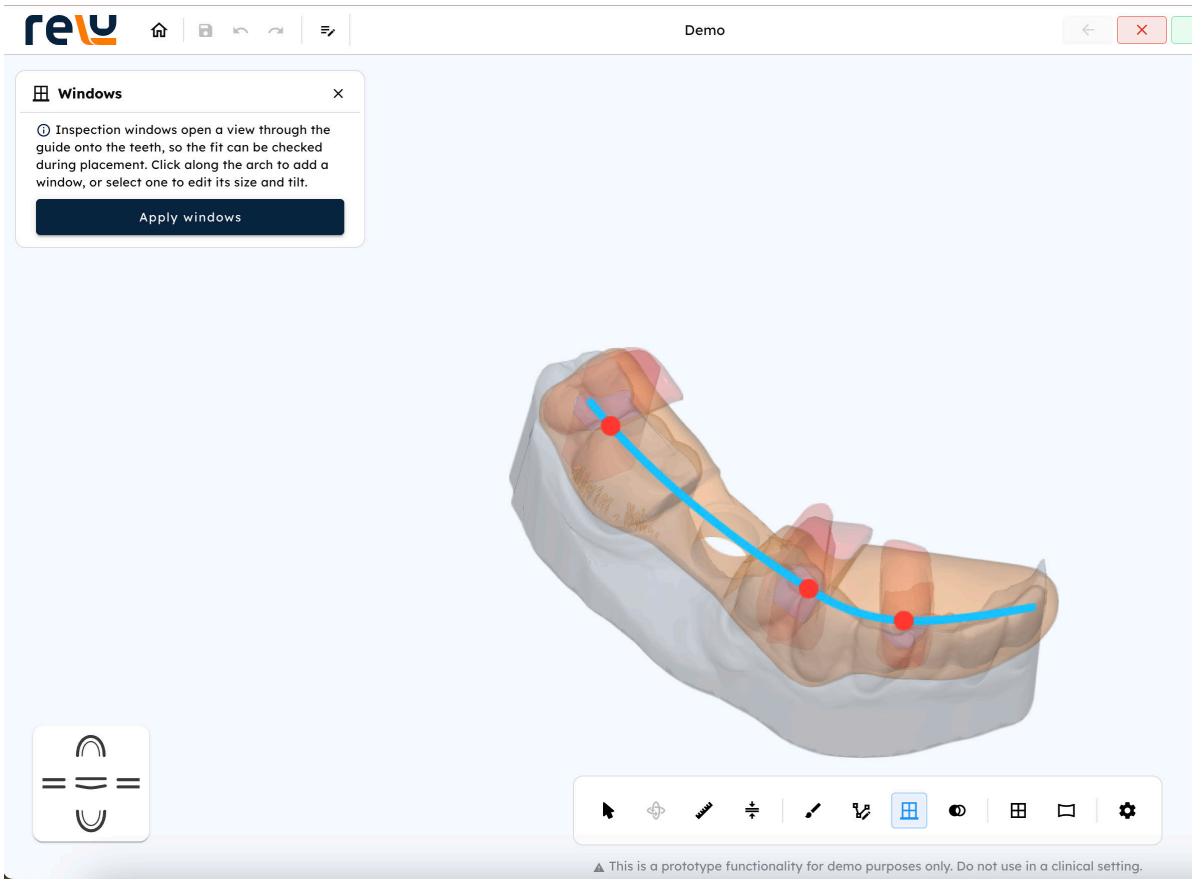
> **Note**
>
> Guide re-computation runs in the cloud and can take a few minutes. You can safely close or navigate away from the page — the computation will continue in the background.

Editing the guide mesh

The surgical guide mesh can be edited directly in the Advanced Editor with three tools:

- **Sculpt** — add, remove, or smooth guide material with a brush. The tool works the same way as the sculpting tool described in Section 7.3.3.6 (modes and brush settings).
- **Outline** — edit the guide outline, then trigger a **Recompute** to regenerate the guide from the new outline. The tool works the same way as the line adaptation tool described in Section 7.3.3.5 (Points mode, Trace mode, and Redraw).
- **Window** — add and adjust inspection windows in the guide.

Window tool



Inspection windows open a view through the guide onto the teeth, so the fit can be checked during placement. Click along the arch to add a window, or select an existing one to edit its **size** and **tilt**. Click **Apply windows** to regenerate the guide with the new windows.

If you prefer to finish the guide in third-party software, you can still download the guide mesh or use the **"Guide Design Kit"** export bundle.

> **Warning**
>
> The provided guide serves as a **pre-fabrication design aid.** The optimal parameters depend on multiple factors, including your **fabrication workflow & environment**, and **clinical preferences**. Always **validate and refine** these parameters for your specific workflow. Before surgery, verify the guide fit on the provided **intra-oral model**.

7.2.3.3 Validation & approval

Before any outputs (such as surgical guides or exported STL files) can be generated, the **treatment plan must be approved** by an authorized user. Click **Approve Treatment**

(top-right) and confirm authorization.

Once approved, the plan becomes **locked for editing**. Approval can be **reverted** if modifications are required.

Prior to approval, the user must review all aspects of the treatment plan, including:

- Implant positions and angulations
- Sleeve–implant relationships
- Surgical guide design and fit
- Any other anatomical or mechanical constraints

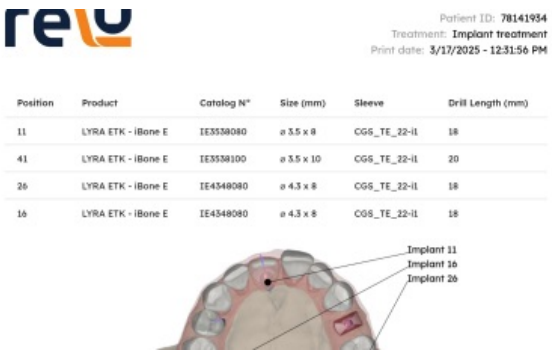
In addition, all **software-generated warnings** must be reviewed. These warnings are automatically triggered by internal safety checks designed to help identify potential clinical or mechanical risks:

- **Distance to nerve canal**: alerts when the planned implant breaches or approaches the minimum safety margin to the mandibular nerve canal. The user must ensure compliance with clinical guidelines and patient-specific anatomy.
- **Distance between planned implants**: alerts when two planned implants are positioned closer than the minimum recommended inter-implant distance, which may compromise bone integrity or prosthetic design.
- **Non-recommended sleeve–implant combination**: Triggered when a sleeve is used with an implant for which the manufacturer does not provide official compatibility data. The system will allow planning flexibility, but the user must confirm that the combination is mechanically and clinically suitable.
- **Non-recommended surgical kit–sleeve combination**: alerts when a sleeve is paired with a surgical kit that does not match the manufacturer's recommended configuration. The user must verify the drill diameters, sleeve inner diameter, and physical compatibility before surgery.
- **Generic libraries**: alerts when **generic components** (implant, sleeve, or surgical kit) are used. Generic libraries allow custom-defined dimensions and are not linked to a real manufacturer. The user is responsible for confirming that these dimensions and mechanical characteristics correspond to the actual components used clinically.

7.2.3.4 Export

The export prerequisites and mechanics are the same as for the Segmentation & Alignment service (see Section 7.1.3.3). The following additional bundles are available for implant-planning orders:

Surgical reports



Patient ID: 78141934
Treatment: Implant treatment
Print date: 3/17/2025 - 12:31:56 PM

Position	Product	Catalog N°	Size (mm)	Sleeve	Drill Length (mm)
11	LYRA ETK - iBone E	IE3538080	ø 3.5 x 8	CGS_TE_22-I1	18
41	LYRA ETK - iBone E	IE3538100	ø 3.5 x 10	CGS_TE_22-I1	20
26	LYRA ETK - iBone E	IE4348080	ø 4.3 x 8	CGS_TE_22-I1	18
16	LYRA ETK - iBone E	IE4348080	ø 4.3 x 8	CGS_TE_22-I1	18

Exports up to **three PDFs**:

1. **Surgical report:** Images of the surgical plan plus detailed descriptions of all implants (library, size, position) to support surgery and parts ordering.
2. **Patient passport:** Implant identifiers and space to attach manufacturer stickers for long-term traceability.
3. **Drilling protocol** *(included only when the implant's library provides a protocol for the selected surgical kit)*: per-implant implant information (position, manufacturer, model, diameter, length, surgical kit), the site-preparation drill sequence with color-coded steps, implant-placement details, and a per-kit **maximum recommended speed & torque** table, together with the surgical-kit image. Tooth numbering follows the active FDI/Universal setting and the report carries your organization logo.

Surgical guides

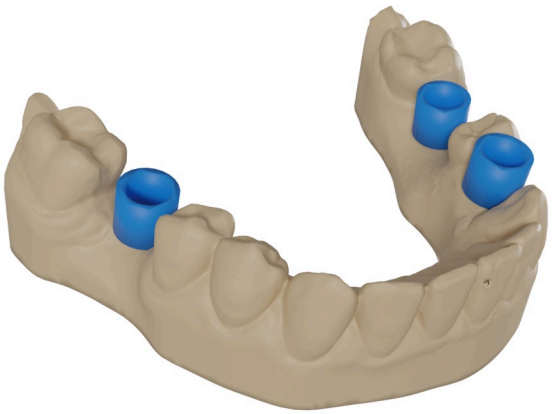
Exports 3D design STLs of:

1. **Wax-ups**
2. **Surgical guides** (tooth-supported)

3. **Guide models** (IOS with base; relevant teeth virtually extracted) for **fit verification** of the guide

> **Note**
>
> Surgical guide exports are only available when the guide is Up to date. If re-computation is required, the export is blocked until completed.

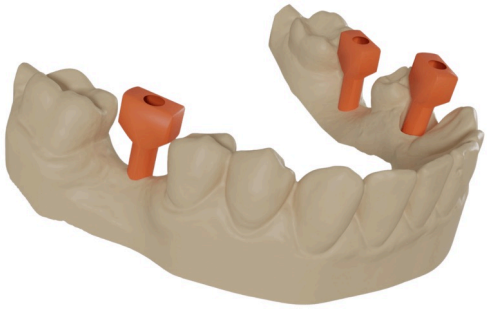
Guide design kit



For users who wish to design their own guide in third-party software while preserving planned geometry. Exports:

1. **Sleeve placeholders** (cylinders matching sleeve dimensions; originals are not distributed for IP reasons)
2. **Guide models** (IOS with base; relevant teeth virtually extracted)

Crown design kit

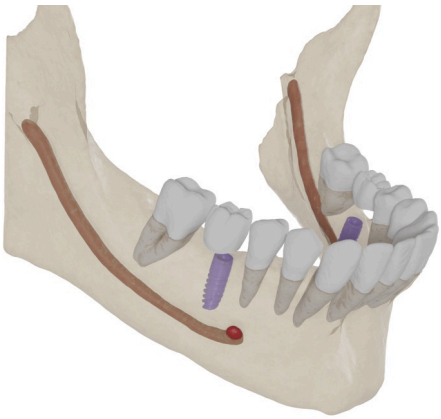


For temporary/final restoration design in third-party software. Exports:

1. **Wax-ups**
2. **Scanbodies**
3. **Emergence profile models** (IOS with relevant teeth virtually extracted, preserving emergence profiles)
4. **Guide models** (IOS with base; relevant teeth virtually extracted)

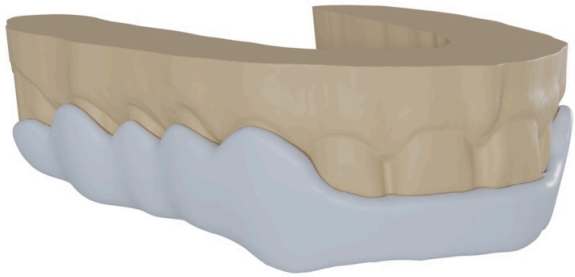
> **Note**
>
> Availability depends on implant libraries with integrated scanbodies manufacturers.

Implant positions



Exports **implant geometries in CBCT space** as STLs (cylindrical placeholders with the same key dimensions, not OEM models).

7.3 Mouthguard Service



7.3.1 Overview

The Mouthguard Design Service within Relu® Cloud supports the digital design of protective occlusal mouthguards based on dental surface models derived from intraoral scan (IOS) data. The service assists dental professionals and dental laboratories in preparing digital mouthguard designs for downstream fabrication.

The service is limited to protective occlusal coverage and is **not** intended for therapeutic treatment, orthodontic applications, mandibular repositioning, or clinical diagnosis.

7.3.2 Order creation

7.3.2.1 Inputs

- **Intra-oral scans (3D Mesh, STL/PLY/OBJ)** – required to provide the scans of both the lower & upper jaws, representing dental arches with erupted teeth suitable for occlusal coverage.

7.3.2.2 Outputs

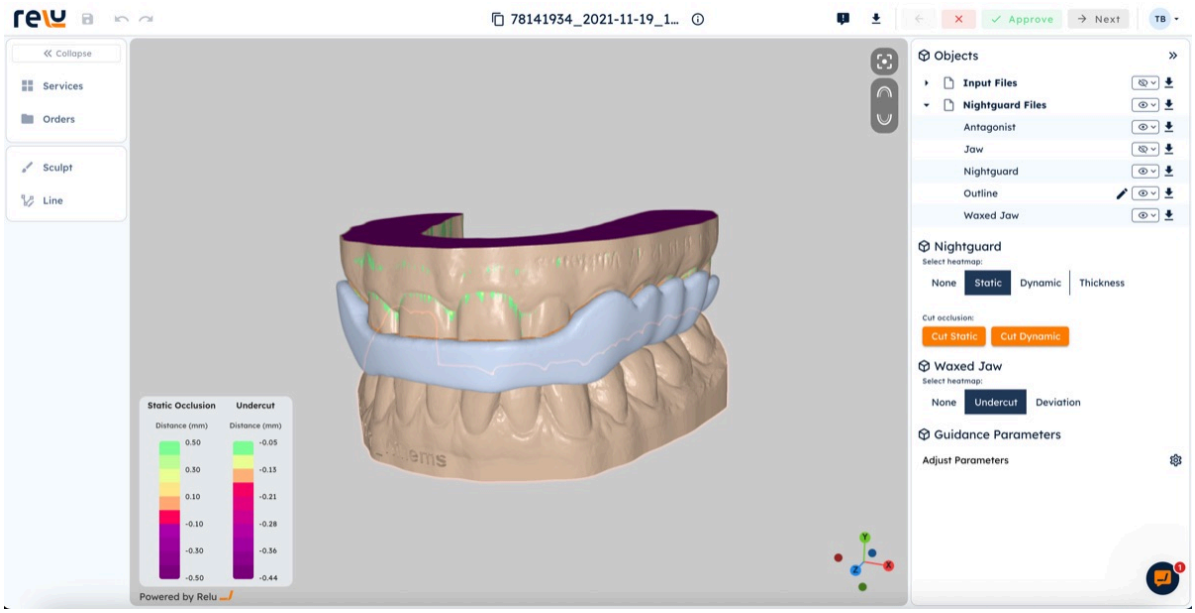
- **Mouthguard**
- **Mouthguard outline**
- **Waxed jaw**

7.3.2.3 Parameters

Parameters include:

1. **Minimum mesh thickness** (mm): defines the minimum wall thickness of the mesh. Thicker meshes are more rigid.
2. **Design offset** (mm): compensates for dimensional tolerances in downstream fabrication. A small positive offset slightly enlarges internal dimensions to improve fit.
3. **Guidance Angles & Ranges:** controls how the software simulates jaw movements to shape the occlusal guidance surfaces of the mouthguard.
4. **Impression Region:** for flat night guards, restricts the static-impression cut to **Anterior & Posterior** (default), **Anterior Only**, or **Posterior Only**.

7.3.3 Order reviewing & editing



7.3.3.1 Overview

After the mouthguard design is generated, the user reviews and refines the result in the Relu® Standard Editor. This page covers the **mouthguard-specific** review and editing tools. For general viewer controls (navigation, hiding/showing objects, downloading files, etc.), see Section 7.1.3.1.

Direct printed retainers are also built on the night-guard pipeline, but offer a more limited set of editing tools; they are covered separately in Section 7.6.3.

7.3.3.2 Objects Panel — Mouthguard Layers

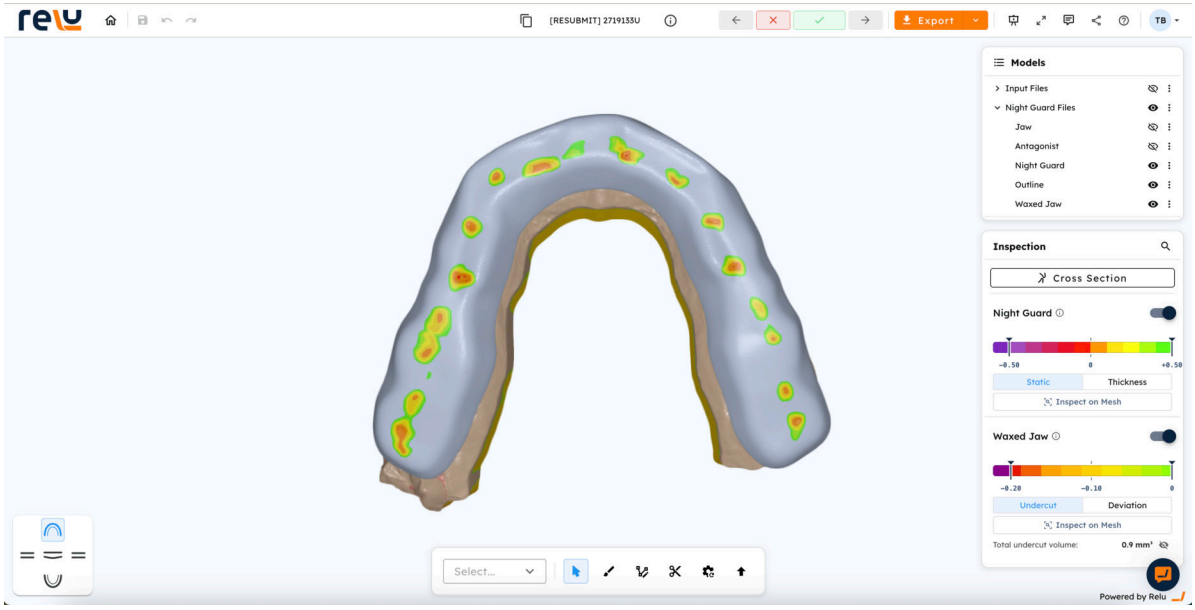
The Objects panel (right side) lists the following layers under **mouthguard Files**:

Layer	Description
Antagonist	The opposing jaw geometry used for occlusion analysis.
Jaw	The jaw scan on which the mouthguard is designed.
Outline	The boundary line defining the extent of mouthguard coverage. Editable via the Line tool.
Mouthguard	The generated mouthguard geometry.
Waxed Jaw	The waxed-up jaw model used as the basis for mouthguard generation.

Each layer can be toggled visible/hidden and downloaded individually using the eye and download icons.

7.3.3.3 Heatmap Visualizations

The viewer provides color-coded heatmap overlays to help assess design quality. Heatmaps are available for two objects: the **Mouthguard** and the **Waxed Jaw**.



Mouthguard Heatmaps

Select a heatmap under the **Mouthguard** section in the right panel:

Heatmap	What it shows
None	No heatmap — shows the plain mouthguard geometry.
Static	Distance between the mouthguard surface and the opposing jaw in static occlusion. Warm/red colors indicate areas closer than the target; green indicates areas at or above the target distance.
Dynamic	Distance map based on simulated dynamic jaw movements (protrusion, laterotrusion).
Thickness	Material thickness of the mouthguard.

Waxed Jaw Heatmaps

Select a heatmap under the **Waxed Jaw** section:

Heatmap	What it shows
None	No heatmap — shows the plain waxed jaw geometry.
Undercut	Visualizes undercut depth relative to the insertion direction. Helps assess retention characteristics.
Deviation	Shows deviation between the waxed jaw and the original scan geometry.

Reading the Color Legend

The color legend is displayed in the bottom-left corner of the viewer. It shows two scales:

- **Static Occlusion**
- **Undercut**

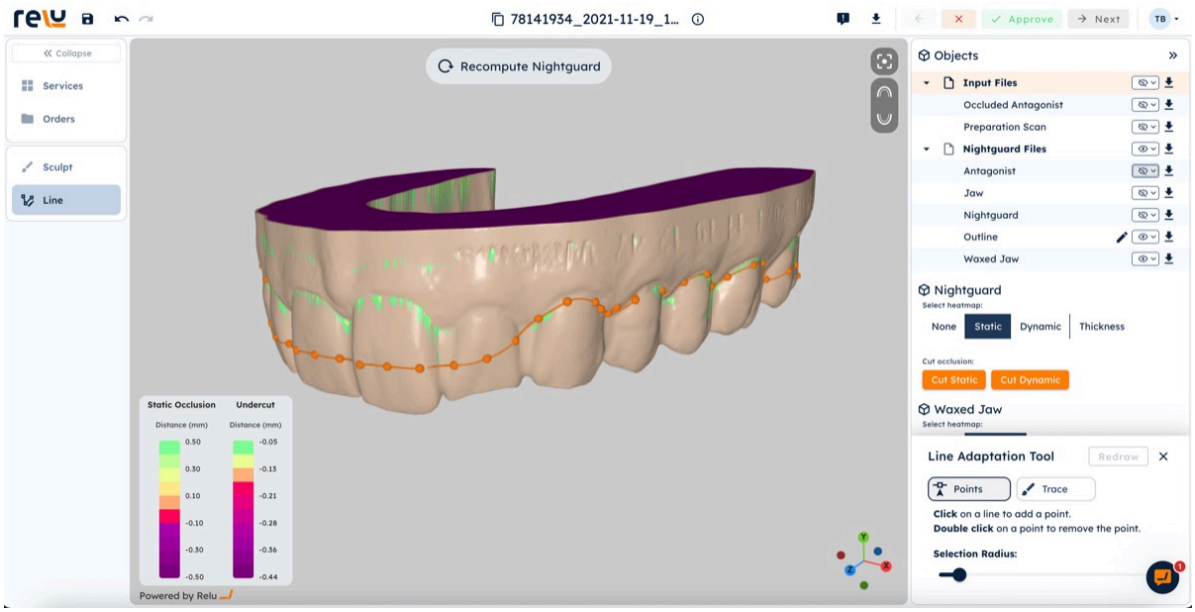
When the **Undercut** heatmap is active on the Waxed Jaw, a **Total undercut volume** readout is shown, with a toggle to **show / hide per-region volume annotations**.

7.3.3.4 Cut Occlusion

Two buttons in the mouthguard section allow automated removal of occlusal interferences:

Action	Description
Cut Static	Removes mouthguard material that interferes with the opposing jaw in static occlusion.
Cut Dynamic	Removes mouthguard material that interferes during simulated dynamic jaw movements.

7.3.3.5 Outline Editing — Line Adaptation Tool



The **Line** tool (left sidebar) opens the **Line Adaptation Tool**, which allows editing of the mouthguard outline — the boundary that defines where the mouthguard covers the teeth.

Points Mode

The default mode. The outline is displayed with orange control points along its path.

- **Click** on the outline to add a new control point.
- **Double-click** on an existing point to remove it.
- **Drag** a point to reposition it and reshape the outline.
- **Selection Radius** — adjusts how close your click needs to be to the line to register.

Trace Mode

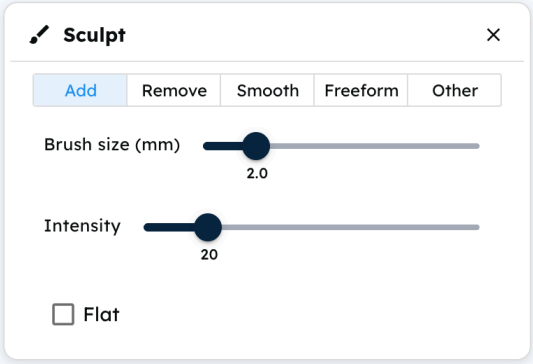
Allows freehand redrawing of a section of the outline by tracing a new path directly on the model.

Redraw

The **Redraw** button allows you to start from scratch to draw the outline.

> **Note**
>
> Once you're done with adapting the outline of the mouthguard, you need to trigger a recomputation of the mesh by using the "Recompute" button.

7.3.3.6 Sculpting Tool



The **Sculpt** tool (left sidebar) opens the **Sculpting Tool**, which allows direct manipulation of the mouthguard surface geometry.

Modes

The mode is selected from the tabs at the top of the panel; each mode defines how the brush affects the surface:

Mode	Description
Add	Adds material to the surface under the brush.
Remove	Removes material from the surface under the brush.
Smooth	Smooths the surface under the brush, reducing irregularities.

Mode	Description
Freeform	Pushes or pulls the surface freely for targeted, localized adjustments.
Other	Additional operations, selectable from a dropdown: **Flatten** (flattens the surface under the brush) and **Patch** (fills holes / patches the surface).

Brush Settings

- **Brush size (mm)** — controls the diameter of the sculpting brush (default 2.0 mm).
- **Intensity** — controls the strength of each stroke (default 20).
- **Flat** — when enabled, applies the brush with a flattening behavior rather than following the surface curvature.

The sculpting cursor is shown as an orange circle on the model surface. Adjust brush size and intensity to achieve fine or broad modifications.

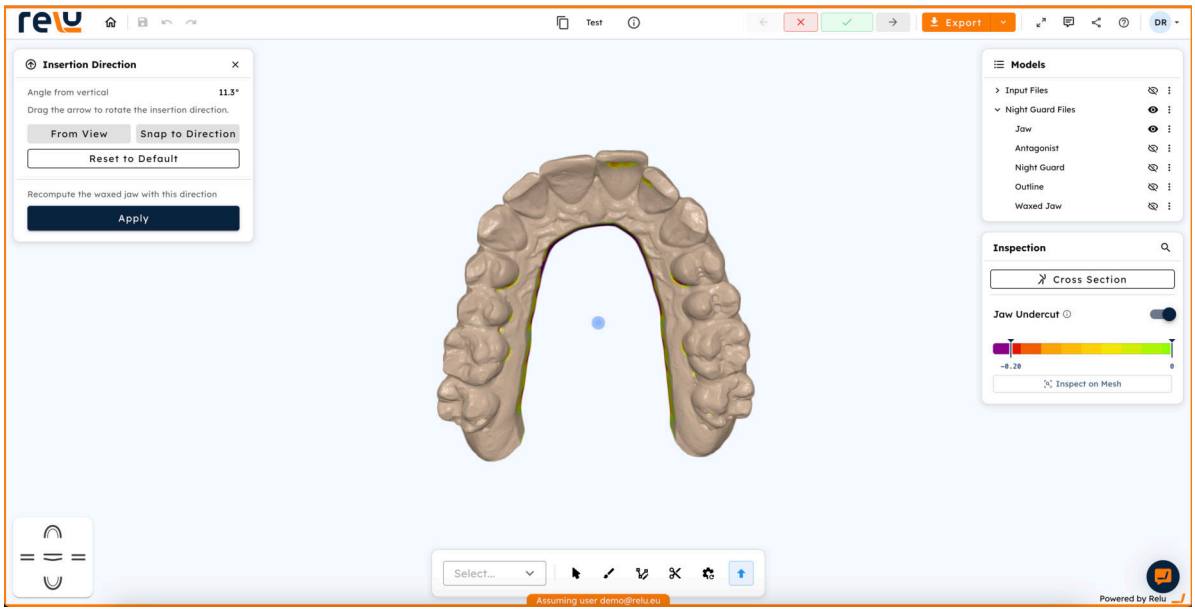
Night Guard Options

When using the **Remove** or **Smooth** mode on the night guard, two toggles are available:

- **Sculpt wax only** — restricts edits to the wax layer.
- **Enforce minimum thickness** — prevents thinning the night guard below its minimum thickness.

7.3.3.7 Insertion Direction & Follow-Anatomy Splints

The **insertion direction** used for undercut computation can be set with an interactive **gizmo** in the viewer; adjusting it updates the undercut heatmap and the waxing accordingly.



The **Insertion Direction** panel shows the **angle from vertical** and lets you set the direction **From View**, **Snap to Direction**, or **Reset to Default**; click **Apply** to recompute the waxed jaw with the chosen direction.

Anatomy night guard types (Anatomy Upper / Anatomy Lower) follow the antagonist anatomy; for these, the bite-opening and several mesh parameters do not apply.

7.3.3.8 Guidance Parameters

The **Guidance Parameters** section (visible in the right panel when scrolled down) allows adjustment of occlusal guidance settings directly in the review view. Click **Adjust Parameters** to modify guidance angles and ranges.

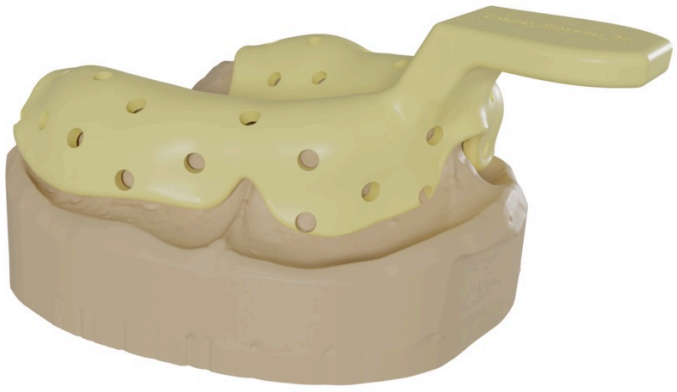
7.3.3.9 Approval & Export

Once review and adjustments are complete:

1. Verify the design using the available heatmaps (static occlusion, thickness, undercut).
2. Click **Approve** (green button, top-right) to confirm the design.
3. The approved mouthguard design is exported as a digital file (e.g., STL) for downstream fabrication.

If the design is not satisfactory, click the **X** button to reject and return to the order. You can ask for a refund.

7.4 Custom Tray Service



7.4.1 Overview

The Custom Tray Design Service within Relu® Cloud supports the digital design of custom trays intended for use as impression or fabrication aids within dental laboratory and clinical workflows. The service assists users in preparing digital tray designs for downstream fabrication.

The service is limited to the design of digital tray geometries and is **not** intended for diagnosis, treatment planning, or clinical decision-making.

7.4.2 Order creation

7.4.2.1 Inputs

- **Intra-oral scan (3D Mesh, STL/PLY/OBJ)** – required. Scan of either the lower or upper jaw.

7.4.2.2 Outputs

- **Custom tray**
- **Custom tray outline**
- **Model**

7.4.2.3 Parameters

Parameters include:

1. **Minimum mesh thickness** (mm): defines the minimum wall thickness of the mesh. Thicker meshes are more rigid.
2. **Design offset** (mm): compensates for dimensional tolerances in downstream fabrication. A small positive offset slightly enlarges internal dimensions to improve fit.
3. **Add Implant Holes [BETA]** (off by default): when enabled, adds implant holes of a configurable **Implant Hole Diameter (mm)** (default 10.0).
4. **Add Spacer Blocks** (off by default): adds blocks that prevent seating the tray too deep, of a configurable **Spacer Block Diameter (mm)** (default 4.0).

7.4.3 Order reviewing & editing

7.4.3.1 Overview

After the custom tray design is generated, the user reviews and refines the result in the Relu® Standard Editor. This page covers the **custom tray-specific** review and editing tools. For general viewer controls (navigation, hiding/showing objects, downloading files, etc.), see Section 7.1.3.1. For details on the **Sculpting Tool** and **Line Adaptation Tool**, which work the same way across services, see Section 7.3.3.6 and Section 7.3.3.5.

The same tools also apply to **Bite Plate Base** results, which are built on the custom-tray pipeline. The Bite Plate Base is generated with wax-rim retention and no handle; the Sculpt, Line, and Abutment tools work the same way.

7.4.3.2 Objects Panel — Custom Tray Layers

The Objects panel (right side) lists the following layers under **Output Files**:

Layer	Description
Upper Custom Tray	The generated custom tray for the upper jaw (if uploaded).
Lower Custom Tray	The generated custom tray for the lower jaw (if uploaded).

Each layer can be toggled visible/hidden and downloaded individually using the eye and download icons.

7.4.3.3 Editing Tools

The custom tray editor provides four tools in the left sidebar:

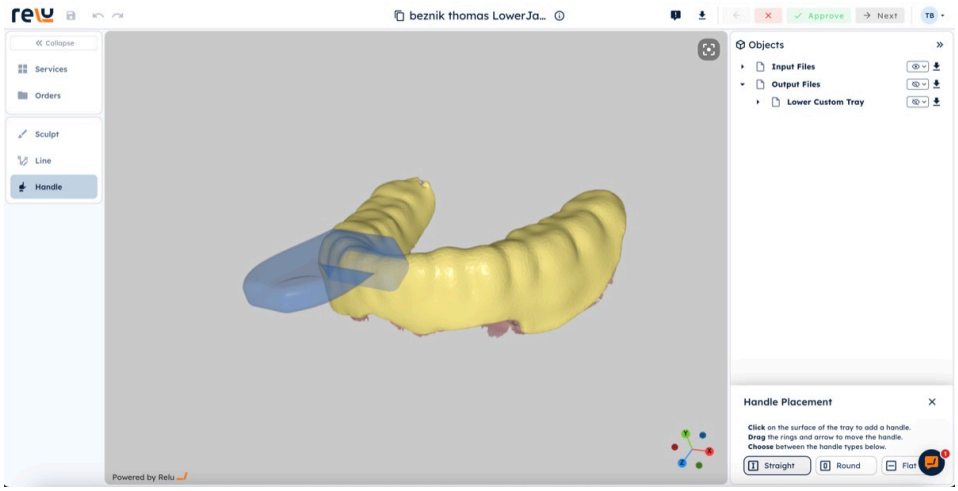
Sculpt

Opens the **Sculpting Tool** for direct manipulation of the tray surface. Works identically to the mouthguard sculpting tool — see Section 7.3.3.6 for details on modes (Add, Remove, Smooth, Freeform, Other) and brush settings.

Line

Opens the **Line Adaptation Tool** for editing the tray outline — the boundary that defines the extent of tray coverage. Works identically to the mouthguard line tool — see Section 7.3.3.5 for details on Points mode, Trace mode, and Redraw.

Handle



Opens the **Handle Placement** tool, which is specific to the custom tray service. This tool allows the user to position and configure the tray handle directly on the 3D model.

- **Click** on the surface of the tray to place a handle.
- **Drag** the rings and arrow to reposition and reorient the handle.
- **Choose** between handle types:

Type	Description
Straight	A straight handle extending from the tray surface.
Round	A rounded handle shape.
Flat	A flat handle shape.
Pawn	A pawn-shaped handle.
No Handle	Removes the handle from the tray.

- **Size** — use the size slider to scale the handle (default **1.0×**).

Abutment

Opens the **Abutment Locations** tool. Click on the jaw surface to place an abutment; drag the body to move it and the orange handle to rotate. Each placed abutment is listed and can be removed. For a selected abutment you can set its **Diameter (mm)** (4–20 mm) and preview the cross-section; click **Apply** to recompute the tray with the abutment holes.

7.4.3.4 Approval & Export

Once review and adjustments are complete:

1. Click **Approve** (green button, top-right) to confirm the design.
2. The approved custom tray design is exported as a digital file (e.g., STL) for downstream fabrication.

If the design is not satisfactory, click the **X** button to reject and return to the order.

7.5 Bite Plate Base Service

7.5.1 Overview

The Bite Plate Base Service supports the digital design of a **bite plate (record base)** from an upper and/or lower jaw scan, for use in registering and transferring the patient's bite. It is built on the Custom Tray generation pipeline, run with bite-plate-specific defaults (wax-rim retention, handle removed, drainage holes locked off).

The service is limited to the design of digital bite plate geometries and is **not** intended for diagnosis, treatment planning, or clinical decision-making.

7.5.2 Order creation

7.5.2.1 Inputs

- **Intra-oral scan (3D Mesh, STL/PLY/OBJ)** – required. Scan of the upper and/or lower jaw.

7.5.2.2 Outputs

Per jaw, the following can be generated:

- **Bite plate** and its **outline**
- **Base model**
- **Waxed (undercut) model**
- **Simple-tray reference**

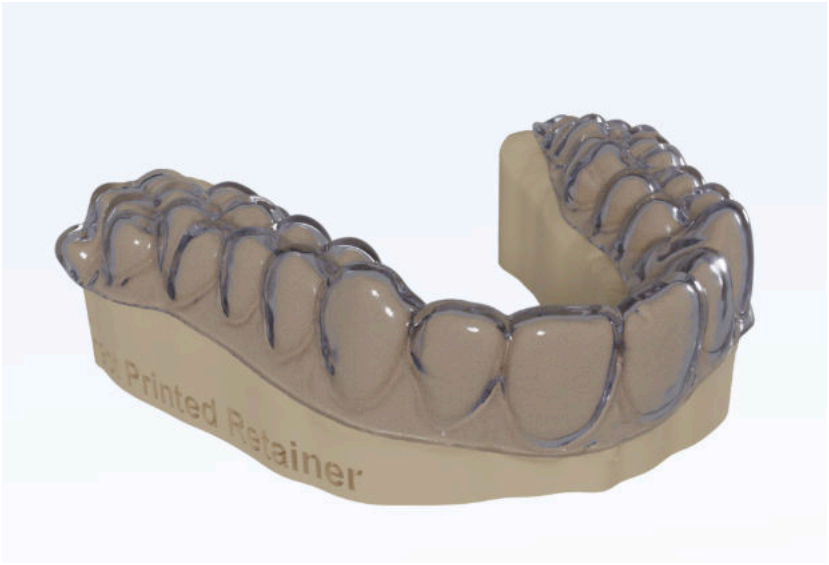
7.5.2.3 Parameters

Parameters include a configurable plate **thickness** (default 2.5 mm), **impression gap**, **distance to the vestibular fold**, **allowed undercut**, and **base height / infill**. The palate can optionally be excluded ("upper as horseshoe"), jaws can be predicted per scan, and the order name can be engraved.

7.5.3 Order reviewing & editing

Bite plates are reviewed and edited with the same tools as custom trays (the Bite Plate Base is generated with wax-rim retention and no handle). See Section 7.4.3 for the review & editing functionalities.

7.6 Direct Printed Retainers Service



7.6.1 Overview

The Direct Printed Retainers Service supports the digital design of **retainers intended to be printed directly** (rather than thermoformed) from an upper and/or lower jaw scan. It is built on the mouthguard generation pipeline, run with retainer-specific defaults (thinner wall, scalloped edge, tighter tooth offset).

The service is limited to the design of digital retainer geometries and is **not** intended for diagnosis, treatment planning, or clinical decision-making.

7.6.2 Order creation

7.6.2.1 Inputs

- **Intra-oral scan (3D Mesh, STL/PLY/OBJ)** – required. Scan of the upper and/or lower jaw.

7.6.2.2 Outputs

Per jaw, the following can be generated:

- **Retainer**
- Optional **jaw model** and **waxed model**

7.6.2.3 Parameters

Parameters include the **edge type** (scalloped / straight), **distance to the tooth surface** (default 0.15 mm), **thickness** (default 1.0 mm), and **distance to the gingival edge** (default 1.0 mm), alongside shared model options (base type / reinforcement, engraving, retainer waxing, bracket-and-wire removal, impression cleaning, trimline).

7.6.3 Order reviewing & editing

After the direct printed retainer is generated, the user reviews and refines the result in the Relu® Standard Editor. For general viewer controls (navigation, hiding/showing objects, downloading files, etc.), see Section 7.1.3.1.

Unlike the mouthguard and custom tray, the retainer offers a **more limited set of editing tools**: it can only be adapted with the **Sculpting Tool** — the line, handle, and abutment-placement tools do not apply.

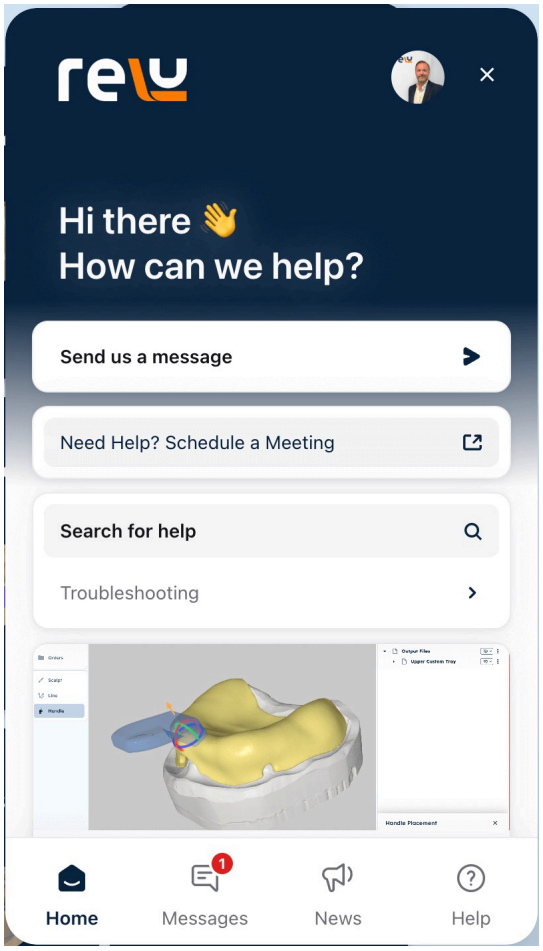
The sculpting tool works the same way as for the other appliances; see the **Sculpting Tool** (Section 7.3.3.6) for details on the modes (Add, Remove, Smooth, Freeform, Other) and brush settings.

> **Note**
>
> After adapting the retainer, verify the result before approving and exporting it for fabrication.

8 Help & Customer Support

Need help? Relu provides multiple support channels to assist you effectively.

8.1 Live chat via Intercom



For immediate assistance, you can use the live chat feature available within the Relu platform. Simply click the **chat icon** located in the bottom-right corner of your screen. Relu's virtual assistant will guide you through common questions or issues, and if needed, you can request to be connected to a human support agent during regular business hours.

8.2 Knowledge base

Browse articles, how-to guides, and troubleshooting steps at:

- help.relu.ai
- Also accessible through the platform's chat widget

8.3 Direct Email Support

If you are unable to resolve your issue through the chat widget or the online documentation, you can contact our support team directly via email at **support@relu.ai**. Be sure to include the email address associated with your Relu account, the case ID (if applicable), and a brief description of the problem you're experiencing. This will help our team respond more quickly and accurately to your request.

8.4 Feedback & Improvements

Your feedback plays a vital role in improving the Relu platform. If an output does not meet your expectations, you can use the **"Feedback"** option directly within the 3D Viewer to flag the issue and request a refund if needed. Alternatively, you're welcome to share suggestions or ideas for improvement via the chat widget or by emailing our support team through support@relu.ai.

8.5 Patient Data Storage

The Relu® Cloud software follows the HIPAA and GDPR guidelines for data protection. Patient data is anonymised, and encrypted both at rest and in-transit.

You can find more information about our privacy & security controls in our Trust Center, and more information about the protection of your privacy and personal data in our Privacy Policy.

8.6 Disposal

If the company decides the Relu® Cloud product is discontinued, this will be announced via e-mail 6 months in advance. The user must migrate all of its data from the Relu® Cloud.

All data is retained for a period of 10 years after the product is withdrawn from the market. After this date, all data is deleted according to industry standards/ privacy regulations.

8.7 Incident Reporting

If you become aware of an information security event or incident, possible incident, imminent incident, unauthorized access, policy violation, security weakness, or suspicious activity, then please immediately report the information using one of the following communication channels:

- Email privacy@relu.eu information or reports about the event or incident

Reporters shall act as a good witness and behave as if they are reporting a crime. Reports must include specific details about what has been observed or discovered.

Any serious incident related to the software must be reported without undue delay to Relu BV and to the competent authority of the Member State in which the incident occurred. The contact details of the competent authority can be found via the following URL: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human.

8.8 Explanation of Symbols

The following table lists ISO 15223-1 compliant symbols that are used in information provided with the Relu® Cloud device and their meaning.

Symbol	Meaning
	Indicates the item is a medical device
	Indicates the date when the medical device was manufactured
	Indicates a carrier that contains unique device identifier information
	Indicates the medical device manufacturer
	Indicates the need for the user to consult the electronic instructions for use
CE 1912	Symbol indicating that the product is conform the requirements of this European Regulation. The number 1912 indicates the reference code assigned to the notified body that issues the CE certificate for this product.