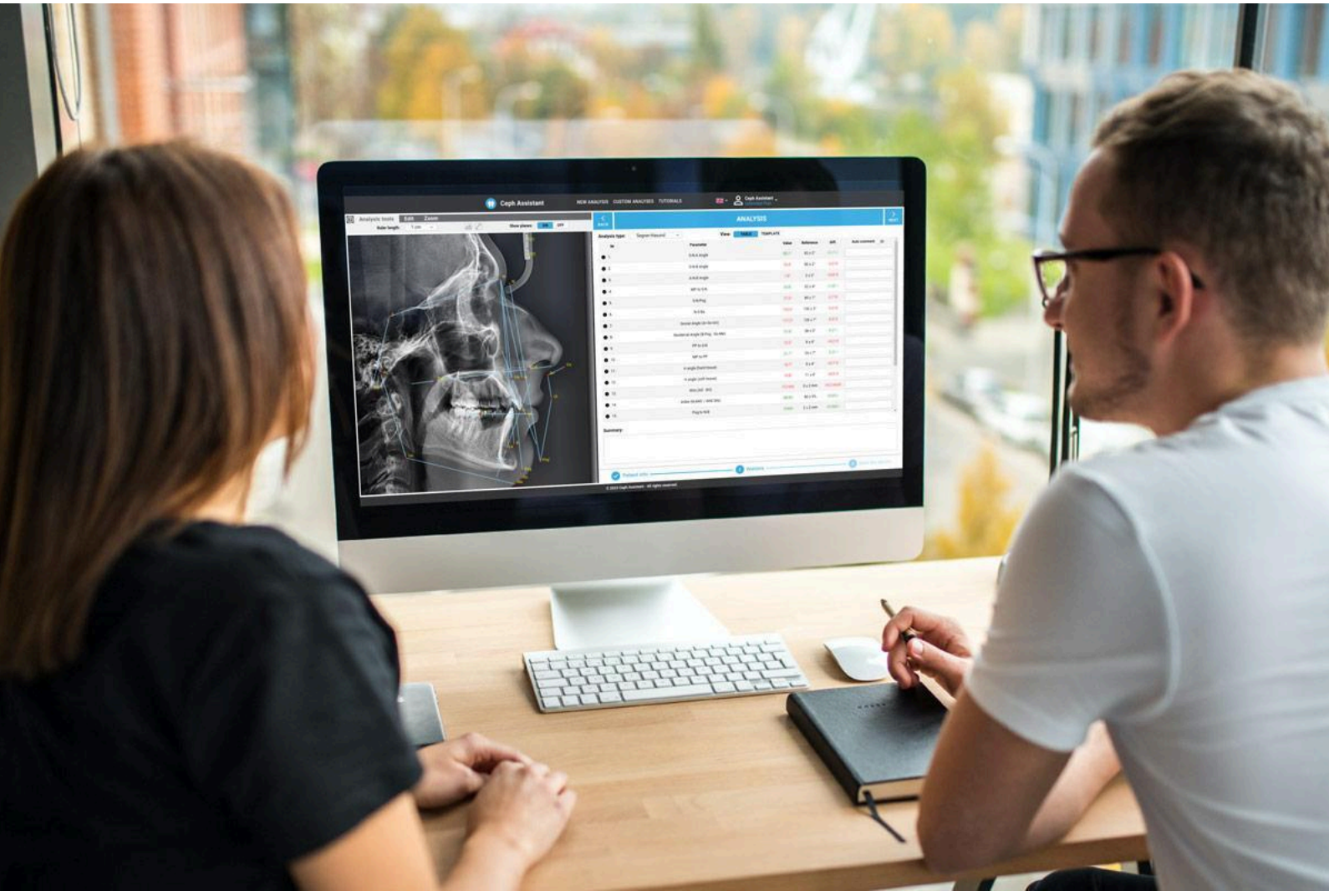
Ceph Assistant - AI-assisted orthodontic analysis software

Instructions for Use



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1. Purpose and Scope

Ceph Assistant is a web-based, AI-assisted software intended for use by trained and licensed dental professionals involved in orthodontic diagnosis, treatment planning, treatment monitoring, and follow-up. The software incorporates artificial intelligence (AI) technology to automatically detect anatomical landmarks from previously acquired dental and craniofacial images and scans provided by users. These AI-generated landmarks are subsequently processed using conventional software algorithms to calculate cephalometric measurements and generate analysis results. The software supports orthodontic and dentofacial analysis through automated and semi-automated functions, including landmark detection, measurement calculation, visualization, and report generation, based exclusively on previously acquired dental and craniofacial images and scans provided by users.

Ceph Assistant processes multiple image and scan modalities commonly used in orthodontics, including two-dimensional radiographic images, two-dimensional facial photographs, three-dimensional facial surface scans, and three-dimensional intraoral scans. The software does not perform image acquisition and does not interface with, control, or modify imaging hardware. All uploaded data must be acquired outside the software using appropriate, clinically validated imaging equipment and protocols in accordance with applicable clinical standards and regulations.

The software is designed to assist clinicians by providing AI-generated landmark suggestions and calculated measurements derived from user-supplied data. These outputs are intended to support, but not replace, professional clinical evaluation. All landmarks, measurements, visualizations, and reports generated by Ceph Assistant must be reviewed, verified, and, where necessary, adjusted by the user prior to clinical interpretation or use.

Ceph Assistant does not provide autonomous diagnosis, treatment planning, or treatment decisions. The software does not recommend specific therapies or clinical actions. Final responsibility for the interpretation of results, diagnostic conclusions, and treatment decisions remains solely with the qualified dental professional using the software.

The software is intended for professional use only and is not designed for direct patient use.

❗ For professional use only by trained and licensed dental professionals.
❗ Ceph Assistant does not acquire images or control imaging hardware; all data must be obtained externally using appropriate clinical equipment.
❗ All AI-generated landmarks, measurements, and reports must be reviewed and approved by the user before clinical use.
❗ The software does not provide diagnosis, treatment planning, or treatment recommendations.
❗ Final clinical interpretation and decision-making remain the sole responsibility of the user.

2. Intended Users

Ceph Assistant is intended for use exclusively by trained and licensed dental professionals who are qualified and legally authorized to acquire, interpret, and evaluate orthodontic and dentofacial imaging as part of clinical care. Intended users include, but are not limited to:

- **Licensed dentists** with appropriate education and clinical training in orthodontics, dentofacial analysis, or related diagnostic procedures.
- **Orthodontists** who routinely perform cephalometric, facial, and dental analyses for diagnosis, treatment planning, treatment monitoring, and outcome evaluation.
- **Other trained dental professionals** (e.g., dental specialists, radiologists specialized in cephalometric imaging and analysis, or clinicians in supervised training programs) who are authorized under applicable local laws and institutional policies to interpret orthodontic imaging and related measurements.

Intended users are expected to possess:

- Formal education in dental or craniofacial anatomy and orthodontic principles;
- Clinical experience with radiographic and photographic orthodontic records;
- The ability to critically assess image quality, landmark placement, and measurement validity;
- Knowledge of applicable clinical standards, ethical obligations, and data protection requirements.

Ceph Assistant is designed as a professional decision-support tool and assumes that users are capable of independently validating all software outputs. The software does not replace professional training, clinical expertise, or clinical responsibility.

Ceph Assistant is **not intended for use by patients**, lay users, or untrained personnel. It must not be used for self-diagnosis, self-treatment planning, or any purpose outside a professional clinical environment.

User access to Ceph Assistant is limited to individually authorized users. Accounts and authentication credentials are personal and must not be shared, transferred, or disclosed to any third party. Each user is responsible for maintaining the confidentiality of their login information and ensuring that the software is accessed only under their direct control.

If a user becomes aware of or suspects unauthorized access, credential disclosure, or account compromise, they must immediately change their password and notify Ceph Assistant. Shared accounts or unauthorized access constitute misuse and fall outside the intended use of the software.

Ceph Assistant is designed for interactive use exclusively through its validated graphical user interface (GUI). The software must not be accessed, operated, or controlled through automated scripts, bots, robotic process automation, headless browsers, or other programmatic means that bypass or simulate user interaction with the user interface. Use of the software without direct user interaction through the official UI falls outside the intended use and constitutes misuse.

❗ For use only by trained and licensed dental professionals.
❗ Users must be qualified to assess image quality, landmark placement, and analysis validity.
❗ All results must be independently reviewed and validated by the user.
❗ Not intended for patients, lay users, or self-diagnosis.
❗ Use of the software through its graphical user interface (GUI) is restricted to professional clinical environments only.

3. Product Description

Ceph Assistant is delivered as a cloud-based **Software-as-a-Service (SaaS)** solution that is accessed through a supported web browser. The software does not require local installation, dedicated hardware, or manual software updates. All core functionalities are provided through a secure online environment, ensuring that users always operate the most current validated version of the software.

Software updates are deployed centrally by the manufacturer and become available automatically to users through the web application. Users are not required to download or install software or firmware. Where an update materially affects device functionality or requires user awareness, users are informed through the application and/or other manufacturer communication channels. Only manufacturer-authorized software versions deployed through the official Ceph Assistant web application are supported.

Ceph Assistant is designed to support orthodontic and dentofacial analysis by combining automated, AI-assisted functions with user-controlled verification and adjustment tools. The software processes user-uploaded images and scans to generate landmark suggestions, measurements, visual overlays, and structured reports, while maintaining clinician oversight at every step.

The software includes the following AI-assisted analysis modules:

- **2D lateral cephalometric X-ray analysis**, supporting both conventional lateral cephalometric radiographs and CBCT-derived two-dimensional lateral images.
- **2D profile photo analysis** for soft-tissue profile evaluation.
- **2D frontal facial photo analysis** for facial proportion, symmetry, and alignment assessment.
- **2D smile photo analysis**, based on frontal facial images captured during a natural smile, supporting aesthetic and functional evaluation of the dentofacial region.
- **Extraoral 3D face scan analysis**, utilizing three-dimensional surface scans of the face for spatial landmark detection and measurement.
- **Intraoral 3D scan analysis**, based on maxillary and mandibular intraoral scans for dental arch and tooth-related measurements, and assessment of the relationships between the upper and lower dental arches.

All modules are built on a **unified workflow**, consisting of data upload, optional patient information entry, AI-assisted landmark detection, user review and adjustment, and report generation. This consistent workflow ensures predictable operation across modalities while allowing module-specific requirements and quality criteria to be applied where necessary.

Ceph Assistant does not modify original image or scan data and does not perform image acquisition. The software operates exclusively on user-supplied files and preserves the integrity of the uploaded data throughout the analysis process.

The modular architecture of Ceph Assistant allows clinicians to use individual analysis modules independently or in combination, depending on clinical needs. Outputs from different modules may be reviewed separately and documented as part of the patient record, subject to user validation.

The table below summarizes the primary functions of Ceph Assistant, identifying whether each function is performed using artificial intelligence (AI), conventional software, or manual (user-controlled) actions.

Function	**Technology**	**User involvement**
Image upload	Conventional software	User-controlled
Analysis module and type selection	Conventional software	User-controlled
Initial landmark detection and placement	Artificial Intelligence (AI)	Automatic
Landmark review and editing	Manual	User-controlled
Measurement calculation, comments and visual representations of the outputs	Conventional software	Automatic
Review and interpretation	Manual	User-controlled
PDF generation	Conventional software	Automatic

Table: Classification of AI-based, conventional, and manual software functions

Ceph Assistant monitors relevant events in system logs to support security monitoring and investigation. Depending on the detected condition, the system may reject or terminate the affected operation and notify the user through the application.

❗ The software processes only user-uploaded images and scans and does not acquire or modify original image or scan data.
❗ Each analysis module must be used only with the appropriate imaging modality, supported human anatomical structures, and input data that meet the module-specific quality requirements.
❗ Final responsibility for selecting analysis modules, reviewing outputs, and documenting results remains with the user.
❗ The final clinical interpretation of the automatic outputs and treatment decisions remain the responsibility of the qualified healthcare professional.

4. System Requirements

Ceph Assistant is provided as a web-based Software-as-a-Service (SaaS) solution. Proper system configuration and internet connectivity are required to ensure correct operation, data integrity, and acceptable performance. The user is responsible for ensuring that the system used to access Ceph Assistant meets the minimum requirements described below.

4.1 Hardware Requirements

- The following hardware specifications are recommended for optimal performance:
- Desktop or laptop computer with a modern **x64-based processor**
- **Minimum 8 GB RAM** (16 GB recommended when working with large image files or 3D scans)
- Graphics processing capability sufficient to support hardware-accelerated rendering in modern web browsers
- Display resolution of **1920 × 1080 pixels or higher** recommended for accurate visualization and landmark verification
- Mobile devices and tablets are not recommended for routine clinical use due to limitations in screen size, input precision, and performance.

4.2 Operating System Requirements

Ceph Assistant can be accessed on common desktop operating systems that support modern web browsers, including Microsoft Windows (current supported versions). The software does not require installation of additional plugins or standalone applications.

4.3 Supported Web Browsers

Ceph Assistant can be accessed on common web browsers, including Google Chrome (version 150.0.7871.187 or later). Other browsers or outdated versions may result in reduced functionality, degraded performance, or unsupported behavior.

4.4 Network and Internet Requirements

As a cloud-based solution, Ceph Assistant requires a stable internet connection.

- Recommended internet connection speed: **≥ 5 Mbps**
- Continuous connectivity is required during image upload, analysis processing, and report generation
- Ceph Assistant communicates with its cloud infrastructure through encrypted HTTPS connections over TCP port 443. Organizational firewalls, proxy servers, and other network security controls should be configured to permit this communication and must not interfere with secure application traffic.

Interruptions in network connectivity during active operations may result in incomplete uploads or analysis errors. Users should ensure a stable network environment when working with patient data.

Ceph Assistant uses HTTPS network communication to securely transfer supported input data to Ceph Assistant and generated outputs from Ceph Assistant. No other communication method or device-specific communication protocol is used or required for the intended operation of the software.

All user communication is outbound HTTPS (TLS) on TCP port 443. Traffic is bidirectional only as HTTPS request and response. Organizational firewalls should allow outbound TCP 443 to the endpoints below and should not intercept or downgrade TLS.

Port	**Direction (from user system)**	**Function**	**Approved endpoints**
TCP 443	Outgoing	Web application	https://app.cephassistant.com, https://www.cephassistant.com
TCP 443	Outgoing	Application API	https://backend-prod.cephassistant.com
TCP 443	Outgoing	Read of uploaded files and reports	https://cephprod.blob.core.windows.net
TCP 443	Outgoing	Subscription payment and customer billing portal	https://js.stripe.com, https://api.stripe.com, https://checkout.stripe.com, https://billing.stripe.com
TCP 443	Outgoing	Application error telemetry.	https://4d2f02aefd874bc39d3481ae0784347b@o4503908355473408.ingest.sentry.io

Table: Network communication

For an optional API integration, the service may send an outbound HTTPS request to a webhook address configured by that authenticated integrator. That address is the only approved destination for that flow. The integrator is responsible for accepting it.

4.5 Cybersecurity Requirements and Recommendations

To help ensure the secure operation of Ceph Assistant within the intended clinical environment, users should implement the following cybersecurity measures:

- Use a supported operating system and web browser with the latest security updates installed.
- Protect the host computer with up-to-date anti-malware software.

- Enable and maintain an appropriately configured firewall in accordance with the organization's IT security policies.
- Use strong, unique passwords that comply with the password requirements presented during user registration in the Ceph Assistant interface.
- Do not share user credentials between individuals.
- Restrict access to authorized users only.
- Use a secure and trusted internet connection when accessing Ceph Assistant.
- Do not install unsupported browser extensions or software that could interfere with normal operation of the application.
- Users should log out of Ceph Assistant after each session to reduce the risk of unauthorized access to patient data and user accounts.
- If a suspected cybersecurity vulnerability, credential compromise, unauthorized access or other security incident is detected, users should discontinue the affected operation, notify their responsible IT/security personnel, and contact Ceph Assistant for further assistance.
- Ceph Assistant is a centrally managed SaaS solution and does not include a shipped hardware device or user-configurable local software installation. Security-relevant application settings, including server-side access controls, logging, and security monitoring parameters, are configured and maintained by the manufacturer and cannot be modified by users. Users are responsible only for the security configuration of their local access environment, including the operating system, browser, anti-malware protection, firewall settings, network security, and account credentials. Users should not disable endpoint protection or firewall controls, bypass browser security warnings, share credentials, or use unsupported software or browser configurations, as these changes may increase cybersecurity risk. Passwords can be reset through the supported password-reset function if credential compromise is suspected.

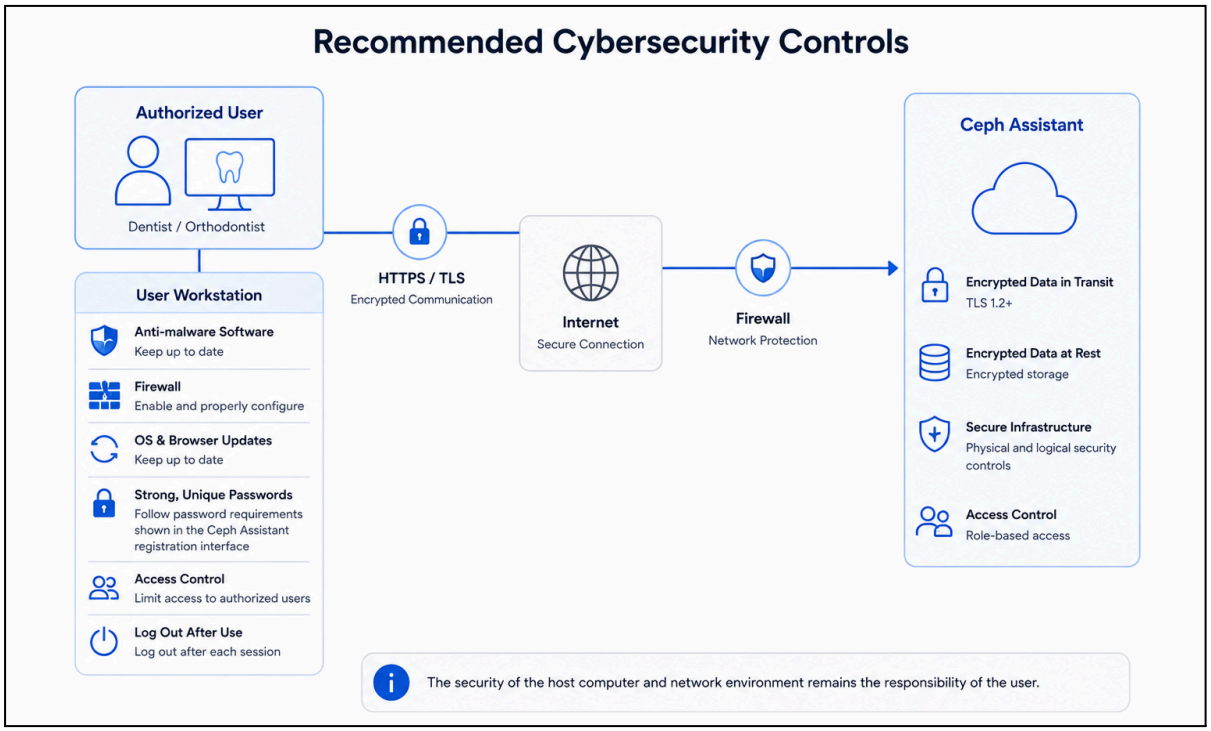


Figure: Recommended cybersecurity controls

4.6 Data Storage and Local Environment

The workstation used to access Ceph Assistant should be located in a controlled clinical environment, such as a lockable consultation room or office, where physical access is restricted to authorized personnel. Ceph Assistant does not require local data storage for core functionality. Generated reports are downloaded and stored locally according to the user's browser and operating system settings. Users are responsible for managing downloaded files in accordance with applicable data protection and record-keeping regulations. All locally stored patient data and downloaded reports should be protected against unauthorized access in accordance with the physical security measures of the controlled clinical environment described above.

4.7 Performance Considerations and Limitations

System performance may vary depending on:

- Size and resolution of uploaded images and scans
- Complexity of the selected analysis module
- Available system memory and processing resources
- Network latency and bandwidth

Large files, particularly 3D scans, may require additional processing time. The user should allow sufficient time for uploads and analyses to complete before initiating subsequent operations.

❗ Ceph Assistant requires a supported web browser and a stable internet connection to operate correctly.
❗ The user is responsible for ensuring that their hardware, operating system, and browser meet the minimum system requirements.
❗ Mobile devices and tablets are not recommended for routine clinical use due to limitations in screen size, input precision, and performance.
❗ The security of the host computer and network environment remains the responsibility of the user.

4.8 SBOM

A software bill of materials (SBOM) for Ceph Assistant is maintained in SPDX 2.3 JSON format. Separate files cover the web application, application service, and inference component, including relevant third-party and operating-system dependencies.

A software bill of materials (SBOM) for Ceph Assistant is maintained in SPDX 2.3 JSON format. Separate files cover the web application, application service, and inference component, including relevant third-party and operating-system dependencies.

The SBOM is maintained by the Ceph Assistant development team and is used together with automated security controls, including SAST, container scanning, and dependency scanning. Dependencies and known vulnerabilities are continuously monitored as part of the software development and maintenance process.

Because Ceph Assistant is deployed centrally, users do not patch or update software components locally. Identified vulnerabilities and dependency updates are assessed by the manufacturer and addressed through centrally deployed updates as appropriate.

4.9 Protection of critical functionality

Critical function of Ceph Assistant is authenticated analysis of user-supplied images and scans and generation of a report that the user reviews. That function is available only through an authenticated session over HTTPS. The user cannot enable or disable device ports or server-side security controls. There is no local installation and no offline mode.

If connectivity, authentication, or server-side security controls are unavailable, the operation is refused and no analysis result is produced. Controls that protect this behavior are:

- Access is limited to registered users.
- Passwords must be 8 to 255 characters and must pass the strength check shown at registration and password change.
- Access tokens expire after 60 minutes.
- Logout invalidates the session refresh token.
- Rate limiting applies to abuse-sensitive operations.
- All user traffic uses TLS.
- Access control, logging, and network exposure are maintained by the manufacturer.
- Software updates are deployed centrally.

All outputs still require review by the qualified user before clinical use.

4.10 Backup and restore of authenticated configuration

Device configuration consists of the account profile and analysis settings, custom analyses, and report branding. It is stored only in the user's authenticated cloud account. It is not stored as a file on the workstation. The user cannot export or import a configuration package.

The manufacturer stores this configuration in the production database and keeps restorable backups of that database. If service configuration must be recovered, the manufacturer restores it from those backups.

An authenticated user recovers access by signing in at https://app.cephassistant.com. If the password is lost, the user requests a reset link to the registered email address, sets a new password, and signs in. Configuration for that account is then available again. Password reset does not erase configuration. Downloaded PDF reports are the user's local copies and are not device configuration.

4.11 Retention and recovery by an authenticated user

Device configuration is retained for the life of the user account. Only that authenticated user can recover it. After sign-in, the user can view and change profile and analysis settings, custom analyses, and report branding.

Those changes remain in the account after logout. If access is lost, the authorized user recovers it through the password-reset message sent to the registered email address, then signs in. Credentials are individual and must not be shared. The manufacturer does not recover configuration for a person who cannot authenticate as that user.

4.12 Forensic evidence and security logs

Ceph Assistant records security-relevant events in manufacturer-operated logs. Logs are not created or stored on the user workstation. Users cannot view, delete, or reconfigure them.

Security logs are written as one JSON object per line. Each record includes an ISO-8601 timestamp, severity, event type, outcome, software version, and a correlation identifier. Where the user is authenticated, a user identifier is included. Records do not contain passwords or uploaded images or scans. Logged events include authentication success and failure, session token issuance and rejection, logout, password change, password reset request and outcome, and rejected access attempts.

Logs are collected into the manufacturer's log system and retained for 30 days. They are then deleted. Customers do not receive a continuous log feed. The JSON format can be used by the manufacturer's security monitoring tools. After a suspected security incident, an authenticated account holder, or their security contact, may request the relevant log summary from Ceph Assistant support while the records are still inside the 30-day retention period.

Application error reports sent to the error-monitoring service are separate from this security log and are not a forensic record of security events.

4.13 End of support and end of life

Ceph Assistant is provided only as the current centrally deployed version. Users do not install or keep older versions. Cybersecurity support, including monitoring, vulnerability remediation, and security updates, is provided for that deployed version for as long as the service is marketed.

The supported user environment is a current desktop operating system and the browser listed in 4.3. Older browsers are outside supported use.

Before cybersecurity support ends, Ceph Assistant will give account holders written notice at least 6 months in advance, by the registered email address and by a notice in the application. The notice will state the end-of-support date and the end-of-life date. After end of support, no further security updates will be provided. After end of life, the service will be discontinued and accounts will be decommissioned as described in Section 4.14. Third-party services used by the device are covered by the manufacturer's vulnerability management while the device is supported.

4.14 Secure decommissioning

Ceph Assistant is a cloud-based software device and has no hardware that requires return or sanitization. Decommissioning consists of closing the user account and deleting the associated data.

Upon a verified account closure request, access is revoked and the data associated with the account is deleted in accordance with the Ceph Assistant Privacy Policy and Data Processing Agreement. Records that must be retained by law, such as invoices, may be kept for the required retention period.

Records that must be kept by law, such as invoices, may be retained for the required period. Those records are not used to operate the device. The user remains responsible for deleting PDF reports and other files already downloaded to local computers, and for clearing browser site data for Ceph Assistant on those computers. After closure, sign-in and previous analysis or report links for that account no longer provide access.

5. Access, Account, and Login

Ceph Assistant is accessed through a secure web-based account system. User authentication, account management, and subscription handling are required to ensure appropriate access control, data protection, and service availability.

5.1 Account Registration

To create a new user account:

1. Navigate to **www.cephassistant.com** using a supported web browser.
2. Select **REGISTER**.
3. Complete the registration form by providing the following required information:
    a. Email address (entered twice for verification)
    b. Password (entered twice for verification)
    c. User name (e.g., clinician name)
    d. Dental office or clinic name (optional)
4. Review and accept the following mandatory agreements:
    a. Data Processing Agreement
    b. Terms of Use
    c. Privacy Policy
5. Optionally opt in to receive the Ceph Assistant newsletter.

Upon successful registration, the user account is created and associated with the provided email address. The email address serves as the unique account identifier and cannot be changed after registration.

Optional profile elements, such as clinic name and branding, may appear on generated reports if provided.

5.2 Login

Registered users may access Ceph Assistant by selecting **LOGIN** on the website and entering:

- Registered email address
- Password

If a user forgets their password, the **Forgot Password** function may be used to request a password reset link, which is sent to the registered email address. Password reset requires access to the registered email account.

5.3 Profile Management

After logging in, users may manage their account settings through the **Profile** section. Available options include:

5.3.1 Subscription

- Subscription plans are available in accordance with the information published at **www.cephassistant.com/pricing**.
- Subscription management and online payments are handled via a secure third-party payment provider (Stripe).
- Users may view current subscription status, upgrade or downgrade plans, and manage payment methods, subject to applicable terms.

5.3.2 Account Information

Users may update:

- User name
- Dental office or clinic name

The registered email address associated with the account cannot be modified.

5.3.3 Billing Information

Users may manage billing details for individual or company accounts, including:

- Billing type (individual or company)
- Name or company name
- Country
- Postal/ZIP code
- City
- Address
- VAT number (if applicable)

Billing information is used exclusively for invoicing and subscription management purposes.

5.3.4 Password Management

Users may change their password by providing:

- Current password
- New password (entered twice for verification)

Password changes take effect immediately upon confirmation.

5.3.5 Language Settings

Users may select and change the application language from the available options. Language preferences apply to the user interface and generated reports where supported.

5.4 API Access and Third-Party Integrations

Ceph Assistant may be accessed through application programming interfaces (APIs) by third-party systems or integrators, subject to separate technical and contractual arrangements.

When Ceph Assistant is integrated via API:

- The integrating party is responsible for ensuring that all end users of the integrated solution have accepted the applicable **Terms of Use**, **Data Processing Agreement**, and **Privacy Policy** of Ceph Assistant.
- The integrating party is responsible for ensuring that Ceph Assistant is used **in accordance with the Instructions for Use (IFU)** and for communicating relevant usage limitations, warnings, and responsibilities to end users.
- The integrating party must provide the service to its users in compliance with these agreements, the Instructions for Use, and all applicable data protection, medical device, and healthcare regulations.

API requests may generate **publicly accessible links** to analyses or reports. The integrating party:

- May share such links at its own discretion and responsibility;
- Is solely responsible for controlling access to and distribution of generated links;
- Bears full responsibility for any sharing of links that deviates from Ceph Assistant's default security settings.

Ceph Assistant is not responsible for unauthorized access, data exposure, misuse, or non-compliant use resulting from API integrations, including the sharing of API-generated links or use of the software outside the scope defined in this Instructions for Use.

❗ Access to Ceph Assistant requires a registered user account and authenticated login.
❗ The registered email address is the unique account identifier and cannot be changed after registration.
❗ Users are responsible for maintaining the confidentiality of their login credentials and email account used for password recovery.
❗ API integrations and any sharing of API-generated links are the sole responsibility of the integrating party.
❗ Ceph Assistant is not responsible for unauthorized access, data exposure, or misuse resulting from API integrations or shared links.

6. General Analysis Workflow (All Modules)

All supported analysis modules in Ceph Assistant follow the same standardized and structured workflow. This unified workflow is designed to ensure consistency, traceability, and user control across all modalities, while allowing modality-specific requirements to be applied where relevant.

6.1 Create a New Analysis

To begin an analysis, the user selects **NEW ANALYSIS** from the main navigation menu. This action initiates a new analysis session and prepares the system to receive user input.

The user must then **select the appropriate analysis module** corresponding to the type of image or scan to be analyzed (e.g., lateral cephalometric X-ray, profile photo, frontal photo, smile photo, extraoral 3D face scan, or intraoral 3D scan). Selecting the correct module is essential to ensure that the correct landmark sets, measurements, and processing logic are applied.

6.2 Upload Image or Scan Data

The user uploads a previously acquired image or scan file using the **UPLOAD** function or drag-and-drop functionality where available. Only files that meet the accepted format, size, and quality requirements for the selected module can be uploaded.

Once uploaded, the image or scan is displayed in the analysis canvas. The original file is not modified by the software.

6.3 Image Visualization and Display Adjustments

To support accurate review and landmark verification, Ceph Assistant provides visualization tools that may be used prior to or during analysis, depending on the selected module:

- Adjustment of **brightness**, **contrast**, and **light intensity** (if supported by the module)
- Enabling or disabling visual layers such as **planes**, **tracing**, **teeth**, **grid**, or **segmentation**

These tools allow the user to reduce visual clutter and focus on specific anatomical structures. Display adjustments affect visualization only and do not alter the underlying image data. The listed visualization elements cannot be directly modified; however, they may be enabled or disabled by the user at any time. The decision to rely on or disregard these visual elements remains solely the responsibility of the user.

6.4 Patient Information Entry

The user may enter patient-related information to support documentation and reference value selection. Entry of patient information is optional but recommended.

Typical patient information includes:

- Patient identifier
- Sex/gender
- Date of birth
- Treatment stage (e.g., before, during, after treatment)

Certain analyses may use age-, and gender-specific reference values. Therefore, entering the patient's date of birth and sex/gender is recommended to enable selection of the most appropriate reference dataset. If this information is not provided, default reference values will be used.

6.5 AI-Based Landmark Detection and Measurements

After data upload and optional patient information entry, the user initiates automated processing. The system performs **AI-based landmark detection and measurement calculations** appropriate to the selected module.

If the selected module supports calibration (e.g., radiographic analyses):

- The user must ensure that a physical ruler or calibration reference object with a millimeter scale is properly positioned during X-ray acquisition, clearly visible in the resulting image, and aligned parallel to the X-ray image plane without tilting toward or away from it. The user is responsible for verifying the visibility and correct positioning of the calibration reference before performing the analysis.
- The ruler must be correctly placed and calibrated to establish accurate linear measurements.
- The length of the ruler can be adjusted during the calibration process.

The user must also **select an analysis type**, either from the standard analysis types available within the software or from previously created custom analyses tailored to specific clinical needs.

6.6 Review and Manual Adjustment

All AI-based landmark positions, measurements and comments are presented as suggestions and must be reviewed by the user. The user may also add their own comments and write a custom summary to document their observations and findings. To support landmark verification, the user may also select the Template View function to display an annotated sample image. This feature is provided solely as a visual reference to illustrate the typical anatomical localization of landmarks based on scientific literature and is intended for informational purposes only.

The user may:

- Verify and adjust landmark positions
- Execute **custom linear and angular measurements**
- Select and place points on the image using the left mouse button

To support detailed inspection, the user may utilize navigation tools:

- **Zoom in** by scrolling or by dragging a selection box with the right mouse button
- **Zoom out** by scrolling or by performing a double right mouse click

These tools enable precise refinement of landmark placement and measurement accuracy.

6.7 Confirmation and Report Generation

Once the user has completed review and any necessary adjustments, the analysis may be finalized.

The user can generate and download a **PDF report** containing:

- Analysis results
- Verified landmarks and measurements
- Selected visual attachments
- Entered patient information (if provided)

If a **harmony box** is included in the report attachments, the user must review and adjust the harmony box parameters in the harmony box settings prior to finalizing the report.

The generated PDF report reflects the final, user-verified state of the analysis.

6.8 Workflow Consistency Across Modules

Differences between analysis modules relate only to:

- Accepted file formats
- Modality-specific quality and acquisition requirements

The overall workflow structure, user responsibilities, and verification steps remain consistent across all supported modalities.

6.9 Creating and Managing Custom Analyses

Ceph Assistant allows users to create **custom cephalometric analyses** by combining and organizing parameters from standard cephalometric analysis types. Custom analyses are intended to support clinic- or clinician-specific reporting preferences and can be reused across future cases. Upon user request, Ceph Assistant may also assist in creating a custom analysis configuration; however, such assistance is provided as a service and does not replace the user's responsibility for reviewing, validating, and approving the final custom analysis. The creation, configuration, scientific validity, and clinical use of custom analyses are the sole responsibility of the user, including in cases where Ceph Assistant assists in creating a custom analysis at the user's specific request; Ceph Assistant does not verify whether user-defined parameter selections, combinations, or interpretations are supported by scientific literature or appropriate for the intended clinical purpose.

6.9.1 Step 1 — Collect Parameters from Standard Analysis Types

Review the list of available **standard analysis types**, and elect a standard analyses to access their available parameters.

Standard analyses provide a broad library of parameters (e.g., angular, linear, proportional, and derived values). The user should identify parameters that are relevant for the intended clinical or documentation purpose.

6.9.2 Step 2 — Select Parameters, Set Properties, and Define Order

1. Choose the parameters to include in the custom analysis.
2. Configure the **properties** of each selected parameter where supported (e.g., displayed name, reference value presentation, and visibility in the report).
3. Arrange the selected parameters in the desired **order** to define the layout and structure of the custom analysis output.

The parameter order will determine how results are presented to the user and how they appear in the exported report.

6.9.3 Step 3 — Save and Name the Custom Analysis

1. Save the configured parameter set as a custom analysis.
2. Assign a clear, meaningful, and distinctive **name** to the custom analysis (e.g., clinic protocol name, clinician name, or a specific treatment workflow).

Saved custom analyses can be selected in the same way as standard analysis types and may be used for future analyses.

6.9.4 Editing and Deleting Custom Analyses

Custom analyses may be managed by the user through the custom analysis management area. Depending on account permissions and configuration, users may:

- Edit a custom analysis by adding/removing parameters, adjusting parameter properties, or changing parameter order;
- Rename an existing custom analysis;
- Delete a custom analysis that is no longer needed.

Users should ensure that changes to custom analyses are intentional, as edits may affect future analyses that use the updated configuration.

❗ The correct analysis module must be selected to ensure appropriate landmarks, measurements, and processing logic are applied.
❗ Only files that meet the required format, size, and quality criteria can be analyzed.
❗ All AI-based landmark positions, measurements, comments are suggestions and must be reviewed and can be adjusted by the user before finalization.
❗ Accurate calibration is the user's responsibility when required, including correct placement and adjustment of the reference ruler.

❗ Finalized reports reflect the user-verified state of the analysis, and the user is responsible for validating all report contents. Intermediate results are not intended for the use of this software and must not be relied upon before user approval of the final report.

❗ The scientific validity and the use of all custom analyses, including those created with Ceph Assistant assistance at the user's request, remain solely the user's responsibility.

7. Input Data Requirements

Ceph Assistant supports multiple image and scan modalities commonly used in orthodontic and dentofacial analysis. The accuracy and clinical relevance of AI-assisted landmark detection and measurements are directly influenced by the quality, orientation, and completeness of the uploaded data. For this reason, careful adherence to the input data requirements described in this section is essential.

This section defines both **general input requirements**, which apply to all supported modules, and **modality-specific requirements**, which address the unique characteristics and limitations of individual image and scan types.

7.1 General File Requirements (All Modules)

Unless otherwise specified for a given analysis module, the following general requirements apply to all uploaded files:

- **Maximum file size:**
  - Images: 150 MB per file.
  - Scans: 30 MB per file to ensure processing.
- **Accepted file types:** Determined by the selected analysis module. Uploading unsupported file formats will prevent analysis.
- **Minimum resolution (2D images):** 1500 × 1500 pixels. Images below this resolution may not provide sufficient anatomical detail for reliable landmark detection.
- **Recommended resolution (2D images):** 2000 × 2000 pixels or higher to ensure optimal visualization and measurement accuracy.
- **Maximum resolution (2D images):** Larger images may increase processing time without improving analytical accuracy. Images exceeding 10 MB will be automatically resized before processing.
- **3D scan quality:** Three-dimensional scans must have sufficient mesh density to accurately represent anatomical structures. Meshes must be free from visible holes, surface discontinuities, excessive smoothing, or distortion that could obscure landmarks.
- **Minimum patient age:** The device is intended for use only in patients aged 7 years or older.

Uploaded files should be provided in their **original, unaltered form**. Excessive compression, rescaling, cropping, filtering, or geometric transformation may degrade image fidelity and adversely affect analysis results. Images and scans that have been modified in a way that alters anatomical proportions should not be used. **Image files should contain the data only, without any additional padding, header or borders.**

7.2 Privacy, Anonymization, and Data Protection

To comply with data protection regulations and ethical standards, uploaded images and scans must not contain embedded patient-identifiable information such as patient name, date of birth, identification numbers, or clinic identifiers, unless explicit patient consent has been obtained and documented. Uploading images that allow the identification of a person without appropriate consent is strictly prohibited.

For facial photographs and textured three-dimensional face scans, anonymization is required unless the patient has provided explicit consent permitting the processing of identifiable facial data. The user is solely responsible for ensuring that all uploaded data complies with applicable data protection laws and institutional policies and bears all liability arising from any breach of these requirements.

❗ The accuracy and clinical relevance of analysis results depend directly on the quality, orientation, and completeness of the uploaded images and scans.
❗ Only files that comply with the specified format, size, and resolution requirements should be used for analysis.
❗ Poor image quality, incorrect positioning, missing calibration references, or incomplete scans may result in unreliable or unusable results.
❗ Uploaded data must comply with applicable data protection and anonymization requirements, unless explicit patient consent has been obtained.
❗ The user is responsible for ensuring that all module-specific input requirements are met before initiating analysis.
❗ Screenshots, compressed, incorrectly cropped images, photographs of displays, or otherwise modified image files should not be uploaded, as these may significantly reduce analysis reliability and accuracy.

7.3 Module-Specific Input Requirements

The following subsections describe the detailed input requirements for each supported analysis module. These requirements must be met in addition to the general file requirements described above.

7.3.1 2D Lateral Cephalometric X-ray Analysis (Including CBCT-derived 2D Images)

Accepted file formats:

- image/jpeg
- image/png
- image/bmp

Supported sources:

- Conventional lateral cephalometric radiographs
- CBCT-derived two-dimensional lateral images only if high resolution and the full cranium and a calibration object are visible

Specific requirements:

- The image must represent a true lateral projection of the craniofacial structures.
- The patient must be positioned in a natural head position at the time of image acquisition.

- A visible physical ruler or calibration object of known length must be present on the upper right side of the image, with a clearly readable millimeter scale. The ruler or calibration object must be properly positioned during X-ray acquisition, aligned parallel to the imaging plane, and must not be tilted toward or away from it. The user is responsible for verifying its correct positioning and visibility.
- The image must be acquired at a 1:1 scale without geometric distortion, stretching, or perspective alteration.
- No patient-identifiable data may be visible within the image.
- The image must show a right-facing facial profile.

Technical acquisition requirements:

- The image must be taken using a distant source with nearly parallel X-ray beams.
- The distance between the X-ray tube focus and the patient's median sagittal plane must be 1.5 meters.
- The distance between the patient's median sagittal plane and the film must be 20 cm.
- Standard exposure settings must be applied.
- The median sagittal plane must be parallel to the film.
- The Frankfurt horizontal plane must be horizontal.
- The central ray must be perpendicular to the patient's median sagittal plane.
- The central ray must be perpendicular to the film and directed toward the external auditory canal.
- Lips and soft tissues must be in a natural, relaxed position. Lips must be closed.
- Dental arches must be in centric occlusion.

Not evaluable images:

- Blurred radiographs, whether digital or film-based.
- Radiographs that were not digitally acquired but instead scanned or photographed from film.
- Images where the portion of the cranium required for landmark measurements is not visible.
- Images taken with the mouth open or not in occlusion.
- Left-facing profile images are not recognized by the models; only right-facing profiles are supported.
- All metallic objects must be removed from the head and neck area (e.g., earrings, hair clips, removable prostheses); if not removed, certain regions may be non-evaluable.

❗ Only true lateral cephalometric images with a right-facing facial profile are supported. Left-facing profiles and incorrectly oriented images must not be used.
❗ A clearly visible physical ruler or calibration object with a readable millimeter scale must be present in the upper right area of the image. It must be properly aligned parallel to the imaging plane without tilting toward or away from it. Incorrect calibration may affect measurement accuracy.
❗ Images must be clear, geometrically undistorted, and include all anatomical structures required for the selected analysis. Blurred, cropped, stretched, or otherwise distorted images must not be used.
❗ Images must be acquired with the patient correctly positioned. Incorrect positioning or occlusion may affect the reliability of the analysis.
❗ Only high-resolution, two-dimensional lateral images derived from CBCT that meet all applicable anatomical visibility and calibration requirements are supported.

❗ CBCT-derived lateral images must comply with the same quality, orientation, and calibration requirements as conventional lateral cephalometric X-rays. Only two-dimensional images derived from CBCT data are supported; volumetric CBCT datasets are not accepted.
❗ Radiographs must meet the specified technical acquisition requirements. Photographs or scans of conventional radiographic films are not supported.

7.3.3 2D Profile Photo Analysis

Accepted file formats:

- image/jpeg
- image/png
- image/bmp
- image/heic

Specific requirements:

- The image must show a right-facing facial profile.
- The photograph must be taken with a camera equipped with an appropriate lens and flash, avoiding distortion-causing modes.
- The patient must be positioned in a natural head position; the Frankfurt horizontal plane should be perpendicular to the vertical plane.
- The mouth must be closed with a neutral facial expression.
- Lighting must be even and sufficient; shadows, glare, and overexposure must be avoided.
- Facial structures must be clearly visible and in focus.
- Only the head and neck region (from the neck upward) should be visible.
- The image must be straight and not rotated or tilted.
- The image must be captured at an appropriate distance to avoid perspective distortion.
- Hair must be tucked behind the ears so the face is fully visible.
- The patient must not have facial hair (e.g., beard or mustache) that could over anatomical landmarks required for analysis.

❗ This modality complements diagnostic evaluation; however, it is important to emphasize that combined analysis of lateral photographs, cephalometric radiographs (skeletal structure), and dental impressions (dentition) ensures the most accurate treatment planning. The interval between related diagnostic images must not exceed three months.
❗ The facial image must be anonymized unless explicit patient consent has been obtained.
❗ Only photographs showing a right-facing facial profile are supported. Left-facing profiles and incorrectly oriented images must not be used.
❗ The patient must be positioned in a natural head position, with the mouth closed and a neutral facial expression. Incorrect positioning or facial expressions may affect the reliability of the analysis.
❗ Photographs must be clear, properly focused, and captured under sufficient, even lighting. Images affected by shadows, glare, overexposure, or blurring must not be used.

❗ Photographs must be captured at an appropriate distance using suitable camera settings to avoid perspective distortion. Rotated, tilted, or geometrically distorted images must not be used.
❗ All facial anatomical structures required for the selected analysis must be clearly visible. Hair, facial hair, or other obstructions must not cover the anatomical landmarks.

7.3.4 2D Frontal Facial Photo Analysis

Accepted file formats:

- image/jpeg
- image/png
- image/bmp
- image/heic

Specific requirements:

- The image must be captured in a true frontal orientation.
- The photograph must be taken with an appropriate lens and flash, avoiding distortion-causing modes.
- The facial expression must be neutral, with the mouth closed.
- The patient's eyes must be directed toward the camera.
- Lighting must be even and sufficient.
- Facial features must be clearly visible and in focus.
- Only the head and neck region should be visible.
- The image must not be rotated or tilted.
- Perspective distortion must be avoided.
- Hair must be tucked behind the ears and the Tr (Trichion) landmark must be clearly visible on the image.
- The patient must not have facial hair (e.g., beard or mustache) that could cover anatomical landmarks required for analysis.

❗ This modality complements diagnostic evaluation; however, it is important to emphasize that combined analysis of lateral photographs, cephalometric radiographs (skeletal structure), and dental impressions (dentition) ensures the most accurate treatment planning. The interval between related diagnostic images must not exceed three months.
❗ The facial image must be anonymized unless explicit patient consent has been obtained.
❗ Only photographs captured in a true frontal orientation are supported. Rotated, tilted, or incorrectly oriented images must not be used.
❗ The patient must have a neutral facial expression, with the mouth closed and eyes directed toward the camera. Incorrect positioning or facial expressions may affect the reliability of the analysis.
❗ Photographs must be clear, properly focused, and captured under sufficient, even lighting. Images affected by shadows, glare, overexposure, or blurring must not be used.
❗ Photographs must be captured using appropriate camera settings and distance to avoid perspective distortion. Geometrically distorted images must not be used.

❗ All facial anatomical structures required for the selected analysis must be clearly visible, including the Tr (Trichion) landmark. Hair, facial hair, or other obstructions must not cover the anatomical landmarks.

7.3.5 2D Smile Photo Analysis

Accepted file formats:

- image/jpeg
- image/png
- image/bmp
- image/heic

Specific requirements:

- The image must be a true frontal photograph captured during a natural smile.
- The photograph must be taken with an appropriate lens and flash, avoiding distortion-causing modes.
- Lighting must be even and sufficient.
- Facial structures and teeth must be clearly visible and in focus.
- Only the head and neck region (from the neck upward) should be visible.
- The image must be straight and not rotated or tilted.
- Perspective distortion must be avoided.
- The upper anterior teeth must be clearly visible.
- The maxillary central incisors (teeth 11 and 21) must be present for correct algorithm operation. The dentition must be permanent (not mixed dentition), to ensure correct labeling.
- To evaluate the smile line accurately, the patient must not grimace.
- The patient must not have facial hair (e.g., beard or mustache) that could cover anatomical landmarks required for analysis.
- Foreign materials or objects present on the tooth surface (e.g., orthodontic appliances such as braces) may adversely affect segmentation quality and the accuracy of analysis results.
- The dentition must be permanent (adult dentition). Mixed or primary dentition is not supported and may result in incorrect tooth identification and analysis.
- Any missing permanent teeth must be indicated by the user prior to analysis to ensure correct tooth labeling and accurate evaluation.

❗ This modality complements diagnostic evaluation; however, it is important to emphasize that combined analysis of lateral photographs, cephalometric radiographs (skeletal structure), and dental impressions (dentition) ensures the most accurate treatment planning. The interval between related diagnostic images must not exceed three months.
❗ The facial image must be anonymized unless explicit patient consent has been obtained.
❗ If required teeth are missing or not visible, this must be indicated by the user during the workflow.
❗ Only true frontal photographs captured during a natural smile are supported. Rotated, tilted, or incorrectly oriented images must not be used.

❗ The patient must display a natural smile without grimacing. Unnatural facial expressions may affect the accuracy of smile line evaluation.
❗ Photographs must be clear, properly focused, and captured under sufficient, even lighting. Images affected by shadows, glare, overexposure, or blurring must not be used.
❗ Photographs must be captured using appropriate camera settings and distance to avoid perspective distortion. Geometrically distorted images must not be used.
❗ All facial and dental anatomical structures required for the selected analysis must be clearly visible, particularly the upper anterior teeth. Facial hair or other obstructions must not cover the anatomical landmarks.
❗ The maxillary central incisors (teeth 11 and 21) must be present and clearly visible for correct algorithm operation and tooth identification.
❗ Only permanent dentition is supported. Primary or mixed dentition must not be used, as it may result in incorrect tooth identification and unreliable analysis results.
❗ Any missing permanent teeth must be indicated by the user before performing the analysis to ensure correct tooth labeling and evaluation.
❗ Foreign materials or objects on tooth surfaces, including orthodontic appliances such as braces, may affect tooth segmentation quality and the accuracy of analysis results.

7.3.6 Extraoral 3D Face Scan Analysis

Accepted file formats:

- Scan files:
  - .obj
  - .stl
  - .ply
- Texture files:
  - Image/jpeg
  - Image/png
  - image/bmp

Specific requirements:

- The scan must capture the full facial surface with a neutral facial expression.
- The patient’s eyes should be open during scanning.
- The facial surface must be complete, without holes or distortions.
- Only the head and neck region (from the neck upward) should be visible.
- The 3D model must be correctly oriented in space.
- A reliable, distortion-free, noise-free, and high-quality 3D scan must be used.
- Extraoral scan acquisition is required.
- The patient must not have facial hair (e.g., beard or mustache) that could cover anatomical landmarks required for analysis.

- Uploaded extraoral 3D face scans must be clean and represent a single continuous surface mesh of the facial anatomy. Scans containing multiple disconnected components, holes, or fragmented regions are not supported and may lead to inaccurate or invalid analysis results.

❗ If texture data is included, anonymization or explicit patient consent is required.
❗ Only extraoral 3D face scans capturing the complete facial surface with a neutral facial expression are supported. The patient's eyes should be open during scanning.
❗ The 3D model must be correctly oriented in space. Incorrect orientation may affect landmark identification and the reliability of the analysis.
❗ Scans must be high-quality, complete, and free from distortions, excessive noise, holes, or missing anatomical regions. Incomplete or distorted scans must not be used.
❗ Uploaded 3D face scans must represent a single continuous surface mesh of the facial anatomy. Scans containing multiple disconnected components, holes, or fragmented regions are not supported and may result in inaccurate or invalid analysis results.
❗ All facial anatomical structures required for the selected analysis must be clearly visible. Facial hair or other obstructions must not cover the anatomical landmarks.
❗ Only scans acquired using an extraoral 3D scanning method are supported. Scans obtained using other acquisition methods must not be used.

7.3.7 Intraoral 3D Scan Analysis

Accepted file formats:

- Scan files:
  - .obj
  - .stl
  - .ply
- Texture files:
  - Image/jpeg
  - Image/png
  - image/bmp

Specific requirements:

- Each analysis must include a maxillary and mandibular scan, and at minimum a first occlusion reference.
- The uploaded scans must be provided in a true frontal orientation, aligned in their natural anatomical position. Incorrect scan orientation may lead to inaccurate segmentation and analysis results.
- Intraoral scan acquisition is required.
- The scan must cover the full dental arch.
- Tooth anatomy must be clearly visible and free from artifacts.
- The scan must allow accurate detection of dental arch curvature and include a partial scan of the palate for reliable orthodontic evaluation.

- If a manually created physical impression or model is digitized, the operator is responsible for ensuring no distortion between transition areas.
- Uploaded intraoral scans must be clean, and consist of a single continuous mesh for both the maxillary and mandibular scans. Scans containing multiple disconnected components, holes, or fragmented regions are not supported and may lead to inaccurate or invalid analysis results.
- Foreign materials or objects present on the tooth surface (e.g., orthodontic appliances such as braces, or scanning artifacts) may adversely affect segmentation quality and the accuracy of analysis results.

❗ Missing teeth and the presence of primary teeth, must be indicated by the user during the workflow to ensure accurate labeling and correct interpretation of results.
❗ Please note that dental fillings and anatomical variations may affect the performance of the AI, especially during cusp point detection. Please always verify the detected points manually.
❗ Each analysis must include both maxillary and mandibular scans, along with at least one occlusion reference. Missing or incorrect occlusion data may affect the accuracy of the analysis.
❗ The uploaded scans must be correctly oriented and aligned in their natural anatomical position. Incorrect orientation or alignment may lead to inaccurate tooth segmentation and analysis results.
❗ Only scans acquired using an intraoral 3D scanning method are supported. Scans obtained using other acquisition methods must meet the specified requirements.
❗ Scans must cover the complete dental arches, with all required tooth anatomy clearly visible and free from distortions, excessive noise, or scanning artifacts. Incomplete or distorted scans must not be used.
❗ The scans must allow accurate detection of dental arch curvature and include a partial scan of the palate for reliable orthodontic evaluation.
❗ Both maxillary and mandibular scans must consist of a single continuous surface mesh. Scans containing multiple disconnected components, holes, or fragmented regions are not supported and may result in inaccurate or invalid analysis results.
❗ Foreign materials or objects on tooth surfaces, including orthodontic appliances such as braces, may affect tooth segmentation quality and the accuracy of analysis results.
❗ When digitizing physical impressions or dental models, the operator must ensure that no geometric distortions are introduced, particularly at transition areas.

7.3.8 VTO

Accepted file formats:

- image/jpeg
- image/png
- image/bmp

Specific requirements:

- If a profile photograph is also uploaded, both the cephalometric image and the profile photograph must belong to the same patient.

- If a profile photograph is also uploaded, the two images must have been acquired within three months of each other.
- No major anatomical or treatment-related changes must have occurred between the two image acquisitions, if applicable.
- If a profile photograph is also uploaded, both images must have been captured from the same angle and with a consistent head position.
- The VTO functionality must be used for visualization purposes only and must not be used for surgical planning.
- Treatment decisions or treatment-related conclusions must not be based solely on the VTO output.
- Any facial visualization generated by the VTO must be regarded as a visual projection only and must not be interpreted as an accurate prediction or guarantee of the patient's future appearance or individual soft tissue response to treatment.
- The healthcare professional must ensure the appropriate creation and use of the generated patient image, if any, and must inform the patient about the nature and limitations of the visualization.
- The healthcare professional must select and use the VTO approach appropriate for the intended clinical context.

All additional requirements applicable to lateral cephalometric X-ray analysis (Section 7.3.1) and 2D profile photo analysis (Section 7.3.3) also apply.

❗ The VTO functionality is intended for visualization purposes only and is not intended for surgical planning.
❗ No treatment decisions or treatment-related conclusions should be based solely on the VTO output.
❗ The facial image generated by the VTO does not fully represent the actual future appearance of the patient; it is a visual projection only.
❗ The software does not predict or guarantee how an individual patient’s soft tissues will change in response to treatment.
❗ The creation and use of the generated patient image are the responsibility of the healthcare professional. The healthcare professional is also responsible for appropriately informing the patient about the nature and limitations of the generated visualization.
❗ Different VTO approaches may be available. The healthcare professional is responsible for selecting and using the method considered appropriate for the intended clinical context.

8. Human-in-the-Loop Design and User Responsibility

Ceph Assistant is designed as a **human-in-the-loop** clinical decision-support system. Artificial intelligence is used to assist the user by providing automated landmark suggestions, measurements, and visualizations; however, the software does not operate autonomously and does not replace professional judgment. At all stages of use, the trained dental professional remains actively involved in the analysis process and retains full responsibility for verifying, correcting, and approving all outputs generated by the software.

8.1 Role of Artificial Intelligence

Ceph Assistant utilizes AI-based algorithms only to **detect calibration and anatomical landmarks** based on uploaded images and scans, which is the basis of:

- Calculation of angular, linear, and proportional measurements;
- Generation of visual overlays and structured analysis outputs.

All AI-generated results are **proposed suggestions only**. The software does not determine clinical relevance, diagnose conditions, or recommend treatment options.

8.2 Mandatory User Review and Verification

Before any analysis results can be used for clinical interpretation or documentation, the user must:

- Review all automatically placed landmarks;
- Verify the anatomical correctness of landmark positions;
- Adjust landmarks where necessary to reflect true anatomical structures;
- Review all calculated measurements for plausibility and consistency.

The software provides interactive tools that allow the user to move, refine, or override any AI-generated landmark or measurement.

8.3 Manual Adjustment and Measurement Tools

Ceph Assistant provides manual tools that enable the user to:

- Select and reposition landmarks using direct interaction;
- Create additional custom linear and angular measurements;
- Add or adjust reference points as needed to support individual clinical workflows.

These tools are available across supported modalities and allow the clinician to tailor the analysis to specific diagnostic or documentation needs.

8.4 Confirmation and No-Change Notification

If the user completes an analysis without modifying any AI-generated landmarks or measurements, Ceph Assistant may present a **confirmation notification** reminding the user to verify that all results have been reviewed.

This notification is intended to support user awareness and does not imply that changes are required in every case. The responsibility for confirming the correctness of results remains with the user regardless of whether modifications were made.

8.5 Clinical Responsibility and Limitations

Ceph Assistant does not provide autonomous diagnosis, treatment planning, or clinical decision-making. The software does not replace professional training, experience, or responsibility.

The user is solely responsible for:

- Interpreting analysis results;
- Determining clinical relevance;
- Making diagnostic and treatment decisions;
- Ensuring compliance with applicable clinical, regulatory, and ethical requirements.

Ceph Assistant must be used strictly in accordance with this Instructions for Use. Use outside the defined scope, or without appropriate user review, may result in inaccurate or misleading outcomes.

❗ Ceph Assistant is a human-in-the-loop decision-support system and does not operate autonomously.
❗ All AI-generated landmarks, measurements, and visualizations are suggestions only and require mandatory user review and approval.
❗ The user is responsible for verifying anatomical correctness of all landmarks and measurements.
❗ Ceph Assistant does not provide diagnosis or treatment decisions, and full clinical responsibility remains with the user.

9. Warnings and Precautions

Ceph Assistant is a professional clinical decision-support software intended to assist trained dental professionals in orthodontic and dentofacial analysis. The following warnings and precautions must be carefully reviewed and observed to ensure safe and appropriate use of the software.

9.1 General Warnings

- Ceph Assistant **does not acquire images** and does not control or validate imaging hardware. Image acquisition quality, patient positioning, and imaging protocols are entirely the responsibility of the user.
- Ceph Assistant **does not provide autonomous diagnosis, treatment planning, or clinical decisions**. All outputs generated by the software are intended to support, but not replace, professional clinical judgment.
- All AI-generated landmarks, measurements, and visualizations must be **reviewed, verified, and approved by the user** prior to any clinical interpretation or use.
- Failure to review and validate results may lead to inaccurate conclusions or inappropriate clinical decisions.

9.2 Image and Data Quality Precautions

- Poor image or scan quality (e.g., low resolution, motion blur, incorrect orientation, incomplete anatomy, excessive noise, or distortion) may result in inaccurate landmark detection and measurements.
- Uploaded images or scans that do not meet the input requirements specified in this Instructions for Use should not be used for analysis.
- Incorrect calibration of radiographic images, including improper ruler placement or inaccurate ruler length specification, may result in incorrect linear measurements.

9.3 Use of AI-Assisted Results

- AI-generated outputs represent algorithmic suggestions based on statistical models and training data and may not be appropriate for all patients or anatomical variations.
- The user must not rely solely on AI-generated results without independent verification.
- Manual adjustment of landmarks and measurements may be necessary to reflect true anatomical structures.

9.4 Modality-Specific Precautions

- For radiographic analyses, ensure correct patient positioning and the presence of a visible calibration object before initiating analysis.
- For facial photographs, improper lighting, facial expression, head rotation, or perspective distortion may compromise analysis accuracy.

- For three-dimensional scans, incomplete surface capture, mesh artifacts, or incorrect orientation may limit the reliability of results.
- For intraoral scans, missing teeth or scanning artifacts must be correctly indicated by the user to avoid misinterpretation.

9.5 Data Protection and Privacy Precautions

- Users are responsible for ensuring that uploaded data and the platform, network, and devices used to access Ceph Assistant comply with applicable data protection, cybersecurity, anonymization and patient consent requirements.
- Sharing reports or API-generated public links are performed at the user's or integrating party's own responsibility.
- It is the integrating party's responsibility to ensure that all integrations with Ceph Assistant, including data transmission and API communication are implemented and maintained through secure measures and in compliance with applicable requirements.

9.6 Software Limitations and Foreseeable Misuse

- Ceph Assistant must be used strictly in accordance with this Instructions for Use.
- Use by untrained personnel, patients, or for purposes outside orthodontic and dentofacial analysis constitutes misuse.
- The software should not be used as the sole basis for clinical decision-making.

Failure to observe these warnings and precautions may result in inaccurate analysis outcomes or inappropriate clinical use.

❗ Ceph Assistant does not acquire or validate images, and image quality, patient positioning, and calibration are the sole responsibility of the user.
❗ All AI-generated landmarks, measurements, and visualizations must be reviewed and approved by the user before clinical use.
❗ Poor image or scan quality, incorrect orientation, or improper calibration may result in inaccurate analysis results.
❗ AI-assisted outputs are suggestions only and must not be relied upon without independent clinical verification.
❗ Ceph Assistant must not be used as the sole basis for diagnosis, treatment planning, or clinical decision-making.
❗ Users are responsible for compliance with data protection, anonymization, and patient consent requirements when uploading or sharing data.
❗ Use of the software outside the Instructions for Use or by untrained personnel constitutes misuse and may lead to misleading outcomes.

10. Data Handling and Privacy

Ceph Assistant processes user-uploaded images, scans, and related metadata solely for the purpose of providing the functionalities described in this Instructions for Use, including analysis, visualization, and report generation.

10.1 Data Processing Principles

All data processing activities within Ceph Assistant are governed by the **Terms of Use**, **Data Processing Agreement (DPA)**, and **Privacy Policy** available on the Ceph Assistant website. These documents define the scope, purpose, and legal basis of data processing, as well as the rights and obligations of users and the service provider.

Ceph Assistant processes data in accordance with applicable data protection laws and regulations. The software is designed to process only the data necessary to perform the requested analysis and does not use uploaded data for autonomous decision-making.

10.2 Data Storage and Retention

Uploaded images, scans, and generated analysis results may be temporarily stored on secure servers to enable processing, review, and report generation. Data retention periods, storage locations, and deletion policies are defined in the applicable Terms of Use, Privacy Policy and Data Processing Agreement.

Users are responsible for managing downloaded reports and ensuring that locally stored files are handled, stored, and shared in compliance with applicable legal and institutional requirements.

10.3 Access Control and Security

Access to Ceph Assistant is restricted to authenticated users. Account-based access control mechanisms are used to prevent unauthorized access to uploaded data and generated results.

When API integrations are used, access control and data sharing responsibilities are allocated as described in Section 5.4. The user or integrating party is responsible for managing access to API-generated public links and for ensuring that such links are shared in accordance with applicable laws and security expectations.

10.4 User Responsibilities

The user is responsible for:

- Ensuring that uploaded data is lawfully obtained and that appropriate patient consent has been secured;
- Complying with anonymization requirements where applicable;

- Using Ceph Assistant in accordance with this Instructions for Use and applicable data protection regulations;
- Managing the distribution and storage of exported reports and shared links.

Ceph Assistant does not verify the legality of uploaded data or the adequacy of patient consent. Responsibility for compliance with data protection and privacy obligations remains with the user.

❗ Users are responsible for ensuring that uploaded data is lawfully obtained and that appropriate patient consent has been secured.
❗ Ceph Assistant does not verify anonymization status, patient consent, or legal compliance of uploaded data.
❗ Use of API integrations and sharing of API-generated links are the responsibility of the user or integrating party.

11. Support and Additional Resources

Ceph Assistant provides access to support resources intended to assist users in the correct and effective use of the software.

Support materials and contact information are available through:

- In-application help and guidance features;
- The Ceph Assistant website, including documentation, and general information.

Users are encouraged to consult available support resources if questions arise regarding software operation, workflow, or technical issues. Support services are intended to assist with software-related matters only and do not provide clinical advice or interpretation of analysis results.

12. Indications

- Intended for use as AI-assisted software to support analysis of dental and craniofacial images and scans.
- Intended to assist qualified users in identifying anatomical landmarks.
- Intended to support measurement of anatomical structures.
- Intended to support visualization of anatomical relationships.
- Intended to assist in orthodontic assessment workflows.
- Intended to support treatment planning activities.
- Intended to assist in documentation and reporting.
- Intended to provide decision-support information to qualified users.

13. Contraindications

- Not intended for use as a standalone diagnostic tool.
- Not intended to replace professional clinical judgment.
- Not intended for autonomous clinical decision-making.
- Not intended for use by untrained or unauthorized persons.
- Not intended for direct patient use.
- Not intended for self-diagnosis or self-treatment.
- Not intended for use outside professional clinical settings.
- Not intended for image acquisition.
- Not intended to process data that do not meet quality requirements.
- Not intended for use with incomplete or unsuitable input data.
- Not intended for use without user review and verification of outputs.
- Not intended to be relied upon without independent clinical assessment.
- Not intended for use outside the defined intended purpose.
- Not intended for use with unsupported file formats or modalities.
- Not intended for use when data protection requirements are not met.
- Not intended for use without appropriate patient consent where required.
- Not intended for use in violation of applicable regulations or professional standards.
- Not intended for use through unauthorized access methods or non-validated interfaces.
- Not intended for any purpose that may compromise patient safety or data integrity.

14. Device labeling



Figure: Ceph Assistant - label