AUGMEDIT

Lumi Prepare and Lumi Segment – Instructions For Use

Contents

1 Introduction

This document provides the instructions for use of Lumi Prepare and Lumi Segment (tradename "LumiNe Lite"). The Lumi Web Application contains Lumi Segment to generate 3D models from medical image data of the head, as well as Lumi Prepare for preoperative investigation of medical scans and 3D models of anatomical and pathological structures of the head. The Lumi HoloLens 2 Application contains Lumi Prepare with tools for virtual surgical treatment planning.

Detailed step-by-step instructions can be found in the User Guide accessible via https://www.lumi.cloud/.

2 Intended Purpose

Lumi Prepare is intended for the preoperative investigation of medical scans and 3D models of anatomical and pathological structures of the head, with capabilities for shape editing of the 3D models and virtual surgical treatment planning, both on 2D displays and in Augmented Reality. Lumi Segment is intended to generate 3D models from medical image data of the head, utilizing AI algorithms for automatic segmentation as well as manual segmentation functionalities. These models can be used for preoperative investigation of potential surgical treatment steps in conjunction with Lumi Prepare.

3 Indications for Use

Lumi Prepare is intended to be used by qualified surgeons, surgical residents, or medical professionals authorized by a hospital to review or prepare medical imaging data for surgical procedures. Lumi Segment is intended to be used specifically by qualified neurosurgeons, neurosurgical residents, or medical professionals authorized by a hospital to review or prepare medical imaging data for neurosurgical procedures.

Each user must be trained before use (see 19. Training requirements).The software is not intended for diagnostic use. All pathology visualized or segmented with the software must pertain to conditions that have been previously diagnosed.

Lumi Prepare supports the conversion of Magnetic Resonance Imaging (MRI) and/or Computed Tomography (CT) scans of adult patients into 3D models. Supported imaging types include:

- Contrast-enhanced T1 MRI scans (T1c Segmentation Function).
- Non-contrast-enhanced CT scans (CTnc Segmentation Function, Manual Segmentation).
- Contrast-enhanced CT scans (Manual Segmentation).

The T1c Segmentation Function is indicated for use in patients with a single intracranial contrast-enhancing tumor diagnosed by a neuroradiologist or neurosurgeon. The tumor must meet the following criteria:

- Minimum volume of 2.0 cc (0.1 in^3) and maximum volume of 100 cc (6.1 in^3).
- Minimum diameter of 15 mm (0.6 inches) and maximum diameter of 75 mm (3.0 inches) in any direction.

4 Intended Users

Lumi Prepare and Lumi Segment are intended to be used by a qualified surgeon, surgical resident, or medical professionals.

5 Intended Patient Population

Lumi Prepare and Lumi Segment are intended for use in adult patients aged 18 and older with cranial pathology, regardless of sex, ethnicity, or race.

6 Intended Clinical Benefits

The intended clinical benefit of Lumi Prepare and Lumi Segment is defined as an improvement in surgeons' spatial insight into the relevant anatomy and pathology prior to a neurosurgical procedure.

7 Contra-indications for use

- Diagnostic purposes
- Patients under 18 years of age
- Use during intraoperative surgical steps

8 Warnings

To minimize risks in case of a potential data breach, ensure that no unnecessary patient health information or identifiable meta-data is included when uploading scans. Always verify that the data you use is properly anonymized and/or limited to what is relevant for the procedure.

The output data provided by Lumi Prepare and Lumi Segment must be subject to careful expert assessment. Segmentations should thereby always be verified by a qualified user in Lumi Prepare and Lumi Segment by outline analysis on the source medical image, since false positive and negative segmentation regions can occur. The user is responsible for the adequate evaluation of the results.

The segmentation functions that create 3D Models from 2D data do only support the usage of T1 Magnetic Resonance Images (MRI) or Computer Tomography (CT) images.

It is recommended to use the software within a hardware and/or a network environment in which cybersecurity controls have been implemented including anti-virus and use of firewall.

It is not permitted to manually position the hologram over a real patient in a clinical setting. Doing so may create the false impression of image-guided navigation and could lead to unsafe use of the device.

When using Lumi Prepare, be aware that the review adds approximately 2–5 minutes to the pre-incision phase; ensure that total pre-incision time remains within 60 minutes and that prophylactic measures are administered at the correct moment.

9 Precaution

- Next to these Instructions for Use, also consult the User Guide before using Lumi Prepare and Lumi Segment.
- Confirm the created 3D Patient using the verification workflow to avoid relying on an incorrect 3D Patient for preoperative surgical planning.
- In case of device failure, immediately disconnect and contact technical support of Augmedit B.V.

10 Disclaimers

- The manufacturer assumes no liability for any failure or delay in performance caused by events beyond its reasonable control, including but not limited to natural disasters, power outages, or government restrictions.
- The manufacturer assumes no responsibility for errors, injuries or damages resulting from use by untrained or unauthorized personnel.
- The manufacturer has implemented cybersecurity measures in accordance with industry standards to protect user data. However, the manufacturer assumes no liability for damages resulting from unauthorized access, data breaches, or cybersecurity attacks beyond its reasonable control.
- The manufacturer assumes no responsibility for issues arising from the use of outdated software.
- The performance of Lumi Prepare and Lumi Segment depends on the hardware and environmental conditions as defined in Sections 17. Facility Requirements and Restrictions and 24.2 Hardware Requirements and Restrictions. The manufacturer does not guarantee accuracy, reliability or functionality on systems that do not meet the specified minimum requirements or are used in non-recommended settings.
- The user is responsible for ensuring that the software is updated to the latest version as provided by the manufacturer. Failure to do so may result in suboptimal performance or increased risk of errors for which the manufacturer assumes no liability.
- Lumi Prepare is intended to be used by qualified surgeons, surgical residents, or medical professionals authorized by a hospital to review or prepare medical imaging data for surgical procedures. Lumi Segment is intended to be used specifically by qualified neurosurgeons, neurosurgical residents, or medical professionals authorized by a hospital to review or prepare medical imaging data for neurosurgical procedures. The manufacturer assumes no liability for any injuries, damages, or losses resulting from improper use, misuse, or use beyond the intended purpose of this device.

11 Adverse Device Effects

Unknown within the Intended Purpose, as Lumi Prepare and Lumi Segment have not been released yet.

12 Device Deficiencies

Unknown within the Intended Purpose, as Lumi Prepare and Lumi Segment have not been released yet.

13 Limitation

- Not for diagnostic use; only for pre-diagnosed conditions and preoperative planning.

- Software may only be operated by the intended users (see Section 3. Indications for Use).
- Anonymized data only; no patient-identifiable information allowed.
- Limited to adult patients (aged 18 and older).
- Use of Lumi Segment requires specific scan types: contrast-enhanced T1 MRI scans, contrast-enhanced CT scans, or non-contrast enhanced CT scans.
- Tumor segmentation limited to specific size and volume criteria.

14 Performance Characteristics

The following performance characteristics of Lumi Prepare have been demonstrated in technical testing and clinical evaluations:

14.1 Technical Performance

User interaction times

- Adding a pointer: average 1 minute
- Drawing and opening functions: average 3 minutes
- Moving scan slices: average 1 minute
- Opening a 3D Patient from Lumi Web on Lumi HL2: average 1 minute 20 seconds
- Uploading and anonymizing DICOM images: less than 3 minutes

Segmentation functions

- T1c Segmentation: rapid execution time, suitable for routine clinical use

Quantitative imaging performance (Dice score / Hausdorff Distance)

- CT – Brain: Dice 0.988; HD95 1.1 mm
- CT – Skin: Dice 0.991; HD95 5.9 mm
- CT – Skull: Dice 0.991; HD95 3.4 mm
- CT – Ventricles: Dice 0.942; HD95 2.5 mm
- MRI (T1c) – Brain: Dice 0.967; HD95 3.9 mm
- MRI (T1c) – Skin: Dice 0.990; HD95 3.9 mm
- MRI (T1c) – Tumor: Dice 0.857; HD95 15.4 mm
- MRI (T1c) – Ventricles: Dice 0.912; HD95 6.0 mm

Measurement Functions (Calculation Functions Accessory v1.1.8)

- Lines and trajectories can be virtually planned and measured in Lumi. Measurements are expressed in millimeters (mm). Based on verification with reference models, the margin of error is within ±3 mm.
- The volumetric measurement function provides quantitative results expressed in cubic centimeters (cc). Based on verification with reference models, the margin of error is within ±0.05 cc.

14.2 Clinical Performance (based on Legacy Lumi MDD device and Lumi Prepare studies)

Surgical plan modification

- Across five prospective studies (n=196 patients), Lumi informed modifications to the surgical plan in ~14% of cases (95% CI 10–20%).
- Modification rates varied by procedure type: highest in extracranial–intracranial bypass (70%) and carotid endarterectomy (39%), lower in MCA aneurysm clipping (8%), posterior fossa oncology (14%), and heterogeneous cranial series (3%).
- No adverse outcomes were attributed to Lumi-related plan modifications.

Workflow time impact

- Preparation time (outside the operating room): typically 17–39 minutes depending on procedure type.
- Preoperative review time (inside the operating room): typically 1.6–5 minutes.
- In one large series (n=107), total surgical preparation time under anesthesia was slightly shorter with Lumi (48 ± 17 min) compared with matched conventional planning (52 ± 17 min).

Outcome-related findings

- In EC–IC bypass and MCA aneurysm cohorts, Lumi was associated with fewer intra-operative vessel complications and fewer revisions, although sample sizes were small.
- No Serious Adverse Device Effects (SADEs) have been reported across published studies, complaint analyses, and retrospective surveys.

14.3 Safety-Related Characteristics

- No SADEs or ADEs have been observed to date with Lumi Prepare or its legacy MDD device.
- Known limitations include:
    - Visualization of very small structures (<1 mm vessels, cranial nerves) depends on scan resolution and contrast, and may be incomplete.
    - Occasional image noise or low-quality scans can result in case exclusions (~5–10%).
    - Minor in-room time overhead (≈2–5 minutes) is possible but has not been associated with measurable increases in surgical-site infection risk when standard prophylaxis is followed.
    - Potential distractions (e.g., hologram repositioning, connectivity issues) are mitigated through training and fallback workflows.

15 Preparatory Steps

15.1 Lumi account setup

Users need to setup their Lumi account before they can access the Lumi Web Application and Lumi HL2 Application. Users receive their account information and instructions to setup their account by email. If needed, digital or on-site assistance is provided.

15.2 HL setup and install Lumi HL2 Application

Users need to setup their HoloLens 2 and install the Lumi HL2 Application on their HoloLens 2. Users receive setup instructions in a separate email from the email containing their account information. If needed, digital or on-site assistance is provided.

15.3 Eye calibration

The HoloLens 2 uses eye-tracking technology to provide the interaction with the virtual environment and correct for eventual movement of the HoloLens 2 on the head. As part of the HoloLens 2 set-up the eye calibration step is mandatory.

16 Maintenance

Lumi Prepare and Lumi Segment are periodically updated to include the latest features, bug fixes, and security vulnerability patches, ensuring optimal performance and compliance with current standards. In case of issues - either resource health or unusual activities or potential security incidents - an automatic email notification is sent out to Augmedit B.V.

17 Facility requirements and restrictions

17.1 Environment restrictions

In case Lumi Prepare is used in combination with the HoloLens 2 stable light levels are preferable for optimal performance. However the HoloLens 2 can be used in in dark environment (20 Lux), ambient lightning environment (600 Lux, e.g. outpatient clinic) and operation room (>600 Lux). Lumi Prepare and Lumi Segment can be used in the following environments with the following features:

Environment	**Allowed Lumi Prepare and Lumi Segment features**
Clinic	All
Hospital: office	All
Operation room without patient	All
Operation room with patient awake AND no sterile field in operation room	All
Operation room with patient under anaesthesia OR any sterile field	• Only use visualization features • Do not use joint session • Maintain a safe distance of at least 1.5 meters from the patient and/or sterile field

For a stable placement of 3D models, displayed on the HoloLens 2, the following conditions are recommended:

- Create a free working space of at least 0.15 meter in front of the user. Optimal working distance is between 0.5 and 1.5 meters in front of the HoloLens 2.
- Lumi Prepare and Lumi Segment is indicated for use in indoor areas with walls. Tables, floors and ceilings improve stable placement of 3D models.

- Scan the use environment by gently look around in the room. The device will automatically learn the shape of the room and this will facilitate a stable placement of 3D models.
- Limit moving objects (e.g. walking persons) in front of the HoloLens 2.
- Avoid fast movement or shaking of the HoloLens 2.
- For optimal luminance uniformity and spatial resolution, set the brightness of the HoloLens 2 to a comfortable level rather than using the maximum or minimum settings.

17.2 IT network restrictions

When operating the Lumi Web Application and Lumi HL2 Application, the computer or HoloLens 2 must be connected to a local network that meets the following specifications:

- Connection Security: Use a secure WiFi connection from the computer or HoloLens 2 to the local network, protected with a strong security profile as WPA2-Enterprise
- Network Access Rules: Allow outbound traffic from the computer or HoloLens 2 VLAN/subnet for TCP port 443 (HTTPS) to the following endpoints:
    - Lumi Backend:
        - Europe: *.lumi.cloud
        - US: *.us.lumi.cloud
    - Microsoft Authentication Servers: *.login.microsoftonline.com
    - Monitoring Services: *.applicationinsights.azure.com
    - Microsoft Services for Updates and Store Access: *.microsoft.com, *.windowsupdate.com, *.delivery.mp.microsoft.com, *.store.microsoft.com, *.msftconnecttest.com, *.msftncsi.com, *.hololens.com
- Performance: Provide a minimum network bandwidth per computer or HoloLens 2 device of 20 Mbps download and 5 Mbps upload
- Time Synchronization: Configure the network to provide access to a reliable NTP server for time synchronization and allow outbound UDP traffic on port 123 from the HoloLens 2 to the NTP server

The only intended information flow between Lumi and other software or systems using the local IT network is in case of an integration with the hospital's Picture Archiving and Communication System (PACS). In this case, Lumi receives medical imaging data in DICOM format from the PACS over the hospital's IT network. The flow is unidirectional:

- Source: PACS within the hospital network
- Destination: Lumi Backend for processing and secure delivery to the Lumi
- Protocol: Transfer occurs using a secure, encrypted connection (TLS over HTTPS)
- Purpose: To import patient medical imaging data into Lumi for visualization in AR
- No inbound connections to the PACS are initiated by Lumi; all transfers are initiated from within the PACS environment under hospital control

Failure of the IT Network to provide the required characteristics and services may result in hazardous situations that could impact patient care, data integrity, or clinical workflow. The following list outlines the hazardous situations associated with the IT Network:

- Using Lumi on a device connected to unsecured or weakly secured WiFi network may lead to compromised system security potentially causing a data breach.
- Using Lumi on a device connected to network with misconfigured firewall rules allowing unintended inbound access may lead to compromised system security potentially causing a data breach.
- Using Lumi on a device connected to network with insufficient bandwidth or high latency may cause delayed visualization of AR content leading to user discomfort.
- Using Lumi on a device connected to network without reliable NTP server may cause inconsistent timestamps in patient records and application logs leading to difficulty in audit logs or incident investigation.
- Failure to regularly apply software updates or patches can lead to unpatched security vulnerabilities increasing the risk of cyberattacks, software instability, or unauthorized access causing a data breach.
- Attempting to connect to the Lumi Web Application or Lumi HL2 Application without internet connection or with ports that are blocked results in users being unable to connect to Lumi which disrupts the clinical workflow and leading to user discomfort.

Please note that in the unlikely event of a successful cyberattack resulting in a data breach, Lumi system employs measures designed to protect patient data through encryption and anonymization. All personally identifiable health data is encrypted using industry-standard algorithms and stored separately from identifying metadata. This layered approach significantly limits the potential for meaningful data exposure.

18 Accessory and combination

Lumi Prepare and Lumi Segment support the Microsoft HoloLens 2 as Augmented Reality Head Mounted Device (AR HMD).

- Manufacturer: Microsoft Corporation, Redmond, WA, USA
- Product name: Microsoft HoloLens 2 Mixed Reality Headset
- Model no: NJX-000xx (xx depends on the region)

19 Training requirements

Authorized users must be trained before using Lumi Prepare and Lumi Segment for their intended purpose. Training is provided during training sessions, which are provided in a(n) (online) meeting, using slide decks and screen sharing.

Users are evaluated on the understanding of the training sessions by personnel of Augmedit B.V. before they independently start using Lumi Prepare and/or Lumi Segment.

20 Qualification requirements

Lumi Prepare and Lumi Segment can be operated exclusively by the intended users who meet the following criteria:

- Users of Lumi Prepare must be a qualified surgeon, surgical resident, or medical professional authorized by a hospital to review or prepare medical imaging data for surgical procedures.

- Users of Lumi Segment must be a qualified neurosurgeon, neurosurgical resident, or medical professional authorized by a hospital to review or prepare medical imaging data for neurosurgical procedures.

Users must complete manufacturer-provided training on Lumi Prepare and Lumi Segment.

21 Consulting healthcare professionals

N/A

22 Serious incident reporting

In the event of a serious incident directly related to an Augmedit B.V. medical device, it must be reported to Augmedit B.V. within 24 hours of detection. Users can do so by contacting their Augmedit representative by phone, email, or by emailing support@augmedit.com. Augmedit B.V. will assess and handle the incident according to regulatory requirements. A final Manufacturer Incident Report (MIR) will be prepared within the required timeframe. The final report will be submitted to the Competent Authorities in the relevant Member States. This ensures compliance with incident reporting obligations.

23 Special Handling and Storage

N/A

24 Device Information

24.1 Installation Statement

Lumi Prepare and Lumi Segment are cloud-based. As such, there is no physical installation required.

24.2 Hardware requirements and restrictions

Lumi Prepare and Lumi Segment are cloud-based and can be used via a web browser on any computer with internet connection and/or a Microsoft HoloLens 2 Mixed Reality Headset with access to the Microsoft Store.

24.3 Software requirements and restrictions

Computer and browser settings to support security:

- Supported web browsers and operating system include:
  - Google Chrome (version 90.0.4430 and later) running on Windows 10 and later
  - Microsoft Edge (version 83.0.0 and later) running on Windows 10 and later
  - Mozilla Firefox (version 78.10 and later) running on Windows 10 and later
- Do not use Lumi Referenced on unsupported or end-of-life operating systems
- Enable automatic browser updates to maintain security
- The computer's firewall must be enabled at all times
- Allow outbound traffic from the computer VLAN/subnet for TCP port 443 (HTTPS) to the endpoints stated in 14.2 IT Network Restrictions
- Ensure antivirus software is active and updated automatically
- Connect the computer only to secure networks (WPA2-protected WiFi or wired Ethernet)

If the computer hardware, OS, or browser is upgraded:

1. Verify OS and security settings as described above
2. Test the Lumi Web Application's connectivity and functionality before clinical use

HoloLens 2 platform settings to support security:

- Minimum supported HL2 Operating System version: Windows Holographic 23H1 or later
- Do not use Lumi Referenced on unsupported or end-of-life OS versions
- Allow outbound traffic from the HoloLens 2 VLAN/subnet for TCP port 443 (HTTPS) to the endpoints stated in 17.2 IT Network Restrictions
- Connect the HoloLens 2 only to secure networks (WPA2-protected WiFi)
- The HL2 does not run a user-facing antivirus app to install or run scans, but malware risks are reduced because apps must come from trusted sources like the Microsoft Store or enterprise deployment channels

If the HL2 OS is upgraded:

1. Verify OS and security settings as described above
2. Test the Lumi HL2 Application's connectivity and functionality before clinical use

24.4 Installation instructions

Users need to setup their Lumi account and the HoloLens 2, and install the Lumi HL2 Application. Instructions include setting up the Lumi account, configuring the Lumi account to be used on a HoloLens 2, adding the Lumi account to the HoloLens 2, signing in on the HoloLens 2 and installing the Lumi HL2 Application. Detailed step-by-step instructions are provided by email and can be found in the User Guide accessible from https://www.lumi.cloud/.

24.5 Installation Verification

The installation is considered successful if the following conditions are met:

1. The user can successfully sign in to https://www.lumi.cloud/, upload patient data, and view the uploaded patients.
2. The user can successfully sign in to the Lumi HL2 application and view the patient data.

This ensures both the cloud-based platform and the application on the HoloLens 2 are functioning as intended.

24.6 Critical dependencies

N/A

24.7 Configuration requirements

- A stable and reliable internet connection is essential to access both the Lumi Web platform and the Lumi HL2 application.
- Running eye calibration for each user is essential for reliable visualization of the stereoscopic images.

24.8 System interface requirements and restrictions

User configuration

Only users with accounts provided by Augmedit B.V. can use Lumi Prepare and Lumi Segment. Users can access Lumi Prepare and Lumi Segment with a personal Lumi account.

Segmentation functionalities

For the conversion of 2D image data into 3D structures of the head, the following functionalities may be used:

- MRI T1 Segmentation Function (T1cSF): This function transforms contrast enhanced T1-weighted MR images (MRI-T1) of the head into 3D models of the skin, brain, and ventricles. Lumi Segment's T1cSF can thereby be used for tumor segmentation only in case of a single intracranial contrast enhancing tumor, diagnosed by a neurosurgeon or a neuroradiologist, with a minimal volume of 2.0 cc (0.1 in^3) and a minimal diameter in any direction of 15 mm (0.6 inch), and a maximum volume of 100cc (6.1 in^3) and a maximal diameter in any direction of 75 mm (3.0 inch). CT non-contrast Segmentation Function (CTncSF): This function transforms non-contrast enhanced CT Scans of the head into 3D Models of the skin, skull, brain, and the ventricles.
- Manual Segmentation Function: In the 3D Viewer, Scans can be visualized as 2D slices, based on the various gray values of the anatomical and pathological structures. Using a slider, the user can adjust the thresholds, thereby selecting which parts of the Scan are displayed. A specific section of the Scan can also be isolated using sliders to focus on a particular area. All modifications are directly visualized as a preview in the 3D Viewer. Once the user has made the correct selections and adjusted the settings, the software can transform the 3D preview into an actual 3D Model.

Results have to be evaluated and approved by the user using outline functions on the source medical imaging. Users can adjust and remove segmentation results. The assigned labels can be renamed by the user.

The following requirements apply for the MRI T1 Segmentation Function (T1cSF).

Image type:	T1 MRI with contrast of the cranium from the vertex to at least the foramen magnum level and maximally to the C2 level.
Slices per series:	Minimum 100 slices per series with a maximum slice thickness and slice interval of 2 mm.

The following requirements apply for the CTnc Segmentation Function (CTncSF).

Image type:	CT scan without contrast of the cranium from the vertex to at least the foramen magnum level and maximally to the C2 level.
Slices per series:	Minimum 100 slices per series with a maximum slice thickness and slice interval of 2 mm.

The following requirements apply for the Manual Segmentation Function:

Image type:	CT or MR images of the cranium

Slices per series:	Minimum 104 slices per series with a maximum slice thickness and slice interval of 2.5 mm.

The visualization of the image data and the output representations are based on the data quality and resolution of the original image data series. In case of poor image contrast, resolution, scan artifacts (such as patient movement) or other image related defects or inaccuracies, this can lead to inaccurate results.

Planning tools

- 3D models can be marked within Lumi Prepare to enhance insight of the user during pre-operative planning.
- 3D models can be (partially) removed out within Lumi Prepare to enhance insight of the user during pre-operative planning.
- Lines, pointers, spheres, and planes can be added within Lumi Prepare to support the user during pre-operative planning.

Detailed descriptions and step-by-step instructions are available in the User Guide.

24.9 Start-up procedure

Before using the Lumi HL2 Application for the first time, the HoloLens 2 should be properly fitted to the user's head. A secure and stable fit ensures comfort, enhances usability, and helps prevent AR-related side effects such as headaches and neck strain. Additionally, running eye calibration is mandatory for all users. If eye calibration restart is needed, it is possible to start it manually from the Settings menu. Detailed descriptions and step-by-step instructions are available in the User Guide.

24.10 Shutdown procedure

Lumi Web Application
When users finish using the Lumi Web Application, they must ensure they sign out of the application and lock their computer screen to maintain the security and confidentiality of sensitive data.

Lumi HL2 Application
When users finish using the Lumi HL2 Application, they must ensure they close the application. Users can do so following these steps:

1. Open the hand menu by facing the palm toward the HoloLens 2.
2. Select "Exit Application" from the menu options.
3. When prompted, confirm by selecting "Yes" to close the application.
4. In the 3D interface displaying the Augmedit logo, select the "Close" button to complete the process.

24.11 Operating instructions

Brightness Settings

For optimal luminance uniformity and spatial resolution, we recommend users setting the brightness to a comfortable level rather than using the maximum or minimum settings. The brightness level of the HoloLens 2 can be adjusted between 10% and 100% using the buttons on the left side.

HoloLens 2 Cleaning Instructions

To clean the HoloLens 2, users have to follow these instructions:

1. Remove any dust by using a dry, lint-free microfiber cloth to gently wipe the surface of the device.
2. Lightly moisten the cloth by using medical 70% isopropyl alcohol, and then use the moistened cloth to gently wipe the surface of the device.
3. Let the device dry completely.

To clean the brow pad, users have to follow these instructions:

1. Use water and a mild, antibiotic soap to moisten a cloth, and then use the moistened cloth to wipe the brow pad.
2. Let the brow pad dry completely.

Discomfort

- If users are prone to motion sickness, get migraine headaches, or have an inner ear disorder, users might be at increased risk of discomfort.
- Having an interpupillary distance (IPD) outside the optimal range for the device might increase discomfort. IPD is the distance between the center of the pupils of the two eyes. Devices might work best for users whose IPD falls within the average range for adults: 57 mm to 71 mm.
- Users need good binocular vision to view stereoscopic 3D content. If users have a binocular vision disorder, such as strabismus, eye misalignment, or crossed or wandering eye, viewing 3D content isn't comfortable.
- Some people might have a pre-existing binocular vision disorder that they're not aware of until they try viewing 3D content. Users should consider consulting an eye doctor if they aren't able to view 3D content clearly and comfortably.

If users experience discomfort, users should stop using HoloLens 2 and rest until they feel better. Sitting still in a well illuminated environment can help speed recovery from disorientation. If users feel disoriented, avoid activities that require balance, coordination, or other capabilities until they recover. Users must ensure the display is properly calibrated. Users must take note of the type of content they were viewing and other aspects of the situation in which the discomfort occurred so they can adjust or ease into the situation next time. People differ in the time they take to adapt. Users should consider taking more frequent or longer breaks. If symptoms are severe or persist, users should consult a doctor. Viewing AR is not known to harm vision development or cause binocular vision disorders.

Versions and Updates

The Lumi Web Application automatically checks for new versions and installs updates automatically whenever a newer version is available. No user action is required.

The Lumi HL2 Application does not update automatically. When a new version is available, users receive a notification in the Lumi HL2 Application. This notification includes a direct link to the official store, where the latest version can be downloaded and installed.

Augmedit B.V. is responsible for all updates to Lumi Prepare and Lumi Segment, which are automatically deployed in the cloud environment and Microsoft Store once they have been approved, tested, verified, and validated according to the specified regulations and standards.

The software version number can be found in the "About" section of the 3D viewer, accessible via both the Lumi Web Application and the HoloLens 2 Application. Daily backups of configurations and data are created and managed through Azure Backup Vault, with the backup data being immutable to prevent unauthorized changes. Administrators can restore configurations and data using these backups.

24.12 Security Options

To ensure comprehensive protection, the following cybersecurity measures are implemented:

- **Access Control and User Session Management:** SSL connection is enforced with TLS 1.2, furthermore users are automatically logged out of the website after 60 minutes of inactivity.
- **Anti-malware:** Lumi Prepare and Lumi Segment uses Azure's built-in security features, including Microsoft Defender for Cloud, to protect against malware and other threats.
- **Audit logfiles:** Lumi Prepare and Lumi Segment collects logfiles on both user and system level to capture activities and events that occur within Lumi Prepare and Lumi Segment. These logfiles are monitored and reviewed to detect unauthorized access, security breaches, or unusual activities.
- **Data Encryption:** Data at rest and Cached data is AES-256 encrypted.
- **Data Transmission Security:** Data in transit is encrypted using HTTPS with TLS 1.2.
- **Firewalls:** Network security is enforced via Azure's Virtual Networks, IP whitelisting, and Network Security Groups (NSGs) to control inbound and outbound traffic.
- **Levels of authorization:** Authorized clinical Users can access designated asset groups according to their authorized Role-Based Access Control (RBAC) permissions.
- **Login in HoloLens 2:** Users can login in the HoloLens 2 with their username and password. This can be changed to login with a pin code or with the use of biometric authentication (iris scan).
- **Password requirements for Administrators:** Password policies adhere to Azure's standards, requiring among others MFA for access to critical systems by administrators.
- **Security event detection:** The LumiNE software uses Microsoft Defender for Cloud and Azure Monitor to detect and respond to anomalies. Alerts are configured for unusual access patterns and other security events. This also includes alerts for Multi-Logins and suspicious activities.
- **Sharing:** In the Multiplayer functionality, stereoscopic image displays can be shared between multiple users. The data in transit is encrypted using HTTPS with TLS 1.2.

24.13 Failure

Microsoft Defender for Cloud is enabled for all resources and checks log files and resource health. In the event of security failures, unusual activities, or potential security incidents, an e-mail notification is sent out to alert the designated security team. The security team investigates the unusual activity or potential security incident and reports to the Information Security Manager of Augmedit B.V. Appropriate precautionary measures are implemented as necessary to address and mitigate any security issues.

24.14 Decommissioning

Decommissioning is not strictly necessary, since the app is linked to a user account and becomes unusable without valid login credentials. Users could manually deinstall the Lumi HL2 App, by following these steps:

- Open Start Menu: On the HoloLens 2, say "Start" or use the Windows button to open the Start Menu.
- Find the App: Locate the app that should be removed in the list of installed apps.
- Select the App: Press and hold the app icon until a context menu appears.
- Uninstall: Select Uninstall from the menu.
- Confirm: Follow the on-screen instructions to confirm the removal of the app.

The app will be uninstalled from your HoloLens 2, freeing up storage space and removing its data. This includes any cached encrypted files.

All remaining decommissioning actions are performed by Augmedit under controlled internal procedures (e.g., deactivating the user account and patient group in Azure DevOps). For any questions regarding decommissioning or data retention, users may contact support@augmedit.com.

25 Messages

The following non self-explanatory system messages, error messages, and fault messages are generated by Lumi Prepare and Lumi Segment:

No.	Type	Platform	Message/Display	Cause	Actions
1.	Error	Lumi Web Application	"Error occurred"	- User unauthorized - Asset not found - Another user updated this item	- Refresh the Lumi Web Application and try again - Sign out and sign in again - Contact Augmedit B.V. support by using the 'Report Feedback' button in the Lumi Web Application, email support@augmedit.com, or by phone
2.	Warning	Lumi HL2 Application	"Your battery level is xx%"	The battery level of the XR glasses is below 25%	Charge the XR glasses until a higher battery level is reached
3.	Error	Lumi Web Application	"Scan upload failed"	The upload of the DICOM scan to Lumi.cloud failed	- Refresh the Lumi Web Application and try again - Contact Augmedit B.V. support by using the 'Report Feedback' button in the Lumi Web Application, email support@augmedit.com, or by phone
4.	Error	Lumi Web Application	"3D Model upload failed"	The upload of the 3D Model to Lumi.cloud failed	- Refresh the Lumi Web Application and try again - Contact Augmedit B.V. support by using the 'Report Feedback' button in the Lumi Web Application, email support@augmedit.com, or by phone

No.	Type	Platform	Message/Display	Cause	Actions
5.	Warning	Lumi Web Application	"You have made unsaved changes to the hologram"	The user tries to close the 3D Patient with unsaved changes	Choose one of the following options: - Save changes - Discard changes - Cancel
6.	Warning	Lumi HL2 Application	"You have unsaved changes, are you sure you want to close the hologram?"	The user tries to close the 3D Patient with unsaved changes	Choose one of the following options: - Cancel - Save and close - Close
7.	Warning	Lumi HL2 Application	"A newer version of the Lumi HL2 App is available, install it via the Microsoft Store"	The user has an outdated version of the Lumi HL2 Application installed and should update it to the newest version in the Microsoft Store on the HL2	Go to the Microsoft Store on your HL2, click on 'Installed Apps', search for 'Augmedit Lumi' and click on 'Update'

26 Website

All information described in this IFU can be found in the User Guide and in our e-IFU, accessible from https://www.lumi.cloud/.

27 Regulation and standards

Lumi Prepare and Lumi Segment have been designed to comply with the following applicable regulations and standards:

Regulations

EU Medical Device Regulation	Regulation EU 2017/745 of 25 May 2017
EU 2021/2226	Electronic instructions for use of medical devices - Requirements under new Implementing Regulation
EU 2025/1234	Amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form

Standards

EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
EN/IEC 62304:2006/A1:2015	Medical device software – Software life cycle processes
IEC 82304-1:2016	Health software — General requirements for product safety
EN/IEC 62366-1:2015 + A1:2020	Medical devices — Part 1: Application of usability engineering to medical devices
EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer

EN-ISO/IEC 27001:2022	Information security, cybersecurity and privacy protection — Information security management systems — Requirements
NEN 7510-1:2017	Information security in healthcare — Part 1: Management systems (Dutch national standard)

28 Electronic IFU Compliance and Access

28.1 Request Paper IFU

These Instructions for Use are supplied in electronic form. The user is able to request a paper form of the Instructions for Use at no extra cost by emailing to support@augmedit.com. The user will receive the paper form maximum 7 calendar days after the request.

28.2 Risk Assessment

A comprehensive risk assessment has been conducted to consider risks associated with:

a) Knowledge and experience of the intended users in particular regarding the use of the device and user needs;
b) Characteristics of the environment in which the device will be used;
c) Knowledge and experience of the intended user of the hardware and software needed to display the instructions for use in electronic form;
d) Access of the user to the reasonably foreseeable electronic resources needed at the time of use;
e) Performance of safeguards to ensure that the electronic data and content are protected from tampering;
f) Safety and back-up mechanisms in the event of a hardware or software fault, particularly if the instructions for use in electronic form are integrated within the device;
g) Foreseeable medical emergency situations requiring the provision of information in paper form;
h) Impact caused by the temporary unavailability of the specific website or of the internet in general, or of their access in the healthcare institution as well as the safety measures available to cope with such a situation;
i) Evaluation of the period within which the instructions for use shall be provided in paper form at the user's request;
j) Assessment of the website's compatibility displaying the electronic instructions for use with different devices which could be used to display those instructions.
k) Assessment of the website's compatibility displaying the electronic instructions for use with different devices which could be used to display those instructions.

28.3 Information about Updates and Safety Notifications

In case of a critical safety update or change in the IFU, the user will be made aware of this update or change by a notification displayed on https://www.lumi.cloud/.

28.4 Emergency Instructions

In case the electronic IFU is unavailable or impaired, users can request a paper form of the IFU by emailing to support@augmedit.com.

28.5 Retention Period eIFU

The eIFU shall be retained and made available to users indefinitely.

28.6 Language Accessibility

The eIFU can be requested in all required official languages of the Union as determined by each Member State where Lumi is available. The user will receive the eIFU in the requested language maximum 7 calender days after the request.

29 Manufacturer

This product is manufactured and sold by:

Augmedit B.V.
Galerij 15
1411 LH Naarden
The Netherlands
Tel. +31 617 1010 94
support@augmedit.com
www.augmedit.com

30 Glossary

Symbol	Title	Description	Meaning
	Manufacturer	Indicates the Medical Device Manufacturer	Augmedit B.V. Galerij 15 1411 LH Naarden The Netherlands +31 617 1010 94 support@augmedit.com www.augmedit.com
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	Caution, please consult the Instructions For Use and/or the accompanying documentation Safety sign ISO 7000-0434A
 https://www.lumi.cloud/	Consult the (electronic) Instructions For Use	Indicates the need for the user/operator to consult the (electronic) Instructions For Use	-

Symbol	Title	Description	Meaning
	Date of manufacture	Indicates the date when the medical device was manufactured	Date on which the software version was released Example: Date of manufacture: DD-MMM-YYYY
	Medical device	Indicates the item is a medical device	-
	Model number	Indicates the model number or type number of a product	Example: Software version number: Lumi 2.x.x.x
	CE marking	The CE conformity marking shall consist of the initials 'CE' as defined in the MDR	Indicates manufacturer declaration that the product complies with the general safety and performance requirements of the relevant European health, safety and environmental protection legislation. Notified Body: Scarlet NB B.V. NB number: 3022
	Unique device identifier	Indicates a carrier that contains unique device identifier information	Example: Basic UDI-DI Lumi *(01)12345678901234 *Illustrative only, not an actual UDI