



Lumi Referenced – Instructions For Use

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1 Introduction

This document provides the instructions for use of Lumi Referenced (tradename "LumiNE Elite").

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

2 Intended Purpose

Lumi Referenced is intended to aid in the intra-operative surgical steps of placing an External Ventricular Drain (EVD). Herein, the device visualizes with Augmented Reality the Scan and 3D Models of the skin, skull, brain, ventricles, and drain in relation to each other during this procedure. While using Lumi Referenced, standard surgical indications and techniques for ventricular drain placement are maintained, ensuring compatibility with established clinical workflows. The device works in conjunction with Lumi Segment and Lumi Prepare to ensure accurate segmentation and preoperative planning, offering enhanced anatomical insight and support throughout the procedure.

3 Indications for Use

Lumi Referenced is intended to aid in the surgical steps for external ventricular drain (EVD) placement in adult patients aged 18 years or older with symptomatic accumulation of cerebrospinal fluid (CSF) within the cerebral ventricles.

4 Intended Users

Lumi Referenced is intended to be used by qualified neurosurgeons, neurosurgical residents, or medical professionals authorized by a hospital to aid in the surgical steps for external ventricular drain (EVD) placement. Every user must be trained before use (see Section 19. Training requirements).

5 Intended Patient Population

Lumi Referenced is intended for use in adult patients aged 18 years or older who require placement of an external ventricular drain due to symptomatic accumulation of cerebrospinal fluid (CSF) within the cerebral ventricles, regardless of sex, ethnicity, or race.

6 Intended Clinical Benefits

The intended clinical benefit of Lumi Referenced is defined as a reduction in the risk of EVD misplacement.

7 Contra-indications for use

- Diagnostic purposes
- Patients under 18 years of age

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 Referenced must be subject to careful expert assessment. Trajectory planning and registration should thereby always be verified by a qualified user in Lumi Referenced. The user is responsible for the adequate evaluation of the results.



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.

9 Precautions

- Confirm the created 3D Patient using the verification workflow to avoid relying on an incorrect model.
- Attach the reference device securely to the patient's nose and forehead to prevent inaccurate drain visualization due to misalignment.
- Calibrate the reference device carefully to prevent inaccurate drain visualization due to visual offset.
- Check and confirm the planned drain trajectory to avoid deviations from the intended target.
- Complete each EVD workflow with a single user on a properly calibrated HoloLens 2, and do not hand over the HoloLens 2 during the procedure to prevent instability or crashes.
- Disconnect the HoloLens 2 immediately in case of failure and contact Augmedit B.V. technical support.

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 Referenced 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 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.
- The software is intended for use only by a neurosurgeon, neurosurgical resident, or medical professional qualified by a hospital to review and prepare medical imaging data for surgical 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 Referenced has not been released yet and no clinical results have been obtained to date.

12 Device Deficiencies

Unknown within the Intended Purpose, as Lumi Referenced has not been released yet.

13 Limitation

- Not for diagnostic use; only for pre-diagnosed conditions.
- Software may only be operated by qualified neurosurgeons, neurosurgical residents, or medical professionals authorized by a hospital to review and prepare medical imaging data for surgical procedures.
- Anonymized data only; no patient-identifiable information allowed.
- Limited to adult patients (aged 18 and older).

14 Performance Characteristics

The following clinical and technical performance characteristics of Lumi Referenced have been demonstrated in technical testing and evaluations in realistic phantoms. Please note that no patient results have been obtained until date.

14.1 Clinical Performance

Placement quality

- Lumi Referenced assisted EVD placements achieved 57.6% Kakarla Grade I (optimal) accuracy, compared to 37.3% with freehand.
- Malpositions (Kakarla Grade III) were reduced (21.2% with AR vs 40.7% freehand).
- AR use was associated with ~2.3-fold higher odds of achieving an optimal placement.

14.2 Technical Performance

Measurement Functions

- 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.

Placement accuracy

- Fiducial registration error averaged 3.8 mm.
- Lumi Referenced use reduced distance-to-target compared to freehand (8.1 mm vs 12.1 mm).
- EVD angular inaccuracy was lower using Lumi Referenced (6.2° vs 9.2°).
- Depth error was lower using Lumi Referenced (3.1 mm vs 4.2 mm).
- These differences were statistically significant, indicating improved placement precision compared with freehand.

Operating time

- Lumi Referenced use added on average ~7 minutes compared to the freehand EVD procedure.

- In emergencies, if planning is performed in-room, an estimated additional operative time of up to 12 minutes may be incurred. This value is derived from simulation studies using phantoms and was not derived from real time clinical data. Actual additional time may vary depending on varying clinical factors, such as case complexity.
- A modest learning effect was observed, with performance stabilizing after ~5 AR procedures.

14.3 Safety-Related Characteristics

- Distraction and workflow: Occasional unintended menu activations, pointer drift, or interface occlusions were observed. In simulation studies these did not influence task completion rate (>90% success).
- Inaccuracy risks: While phantom testing shows clear accuracy benefits over freehand, real-world factors (e.g., hair, skin mobility, workflow interruptions) may influence results.
- Infection risk: Based on published correlations between operative-time prolongation and infection risk in neurosurgical procedures, the estimated additional operative time could correspond to an estimated 0.15–0.6 percentage point increase in infection risk compared with freehand baselines (5–10%). These values are literature-based and were not based on clinical data for Lumi Referenced directly, This increase is considered minimal when standard sterile precautions and antibiotic protocols are followed.

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 Referenced is 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

Lumi Referenced is used in combination with the HoloLens 2 which requires stable light levels for optimal performance. 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 Referenced can be used in the following environments with the following features:

| Environment | Allowed Lumi Referenced features |
|---|--|
| Operation room with patient under anaesthesia | <ul style="list-style-type: none">• All• Do not use joint session |

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 Referenced 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.
- If you observe unstable tracking of the reference marker, adjust the operating room lighting to prevent it from shining directly onto the marker. This adjustment will enhance the stability of the reference marker's tracking.

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 Referenced supports 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 region)

19 Training requirements

Authorized users must be trained before using Lumi Referenced for their intended purpose. The training session is provided in an online meeting and starts with an extensive explanation and walk through of the complete



intraoperative workflow of Lumi Referenced using a slide deck and a standardized introduction video. Next, users practice the intraoperative workflow on a phantom model.

Users are evaluated on the understanding of the training sessions by personnel of Augmedit B.V. before they independently start using Lumi Referenced.

20 Qualification requirements

Lumi Referenced can be operated exclusively by the intended users who meet the following criteria:

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

Users must complete manufacturer-provided training on the device.

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, mail, or by emailing support@augmedit.com. Augmedit B.V. will assess and handle the incident according to regulatory requirements. A Final Incident Report 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 Referenced is cloud-based. As such, there is no physical installation required for the preoperative phase. During the intraoperative phase a set of tools is used consisting of the following parts:

- Head device: the head device helps users to connect a reference marker to the patient's head. The device allows users to rotate the Reference Marker into the desired position. Users can apply or change markers onto the head device without the need for further adjustments after fixation.
- Reference Marker: A 5x5cm marker which a laser engraved pattern. The Lumi software recognizes the marker and tracks the position and rotation in order to track the position of the patient.
- Pointer tool: equipped with a marker, the pointer tool can be used to indicate anatomical features on the patient to establish a reference.

The tools are provided by the manufacturer. No installation by the manufacturer is required for the tools.

24.2 Hardware requirements and restrictions

Lumi Referenced is cloud-based and can be used on a Microsoft HoloLens 2 Mixed Reality Headset with access to the Microsoft Store.

24.3 Software requirements and restrictions

Lumi Referenced is cloud-based and can be used on a Microsoft HoloLens 2 Mixed Reality Headset.

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.

Required HoloLens 2 configuration for intraoperative use

For optimal performance and to reduce the risk of workflow interruption during intraoperative use, the following HoloLens 2 system settings are required:

- Hologram Management: navigate to *Settings* → *System* → *Holograms* and ensure that the option 'Automatically remove all holograms in Mixed Reality home when device shuts down' is enabled. This prevents residual hologram clutter and supports stable initialization of new workflows.
- Battery Settings: navigate to *Settings* → *System* → *Battery* and ensure the option 'Turn battery saver on automatically at' is set to 'Never'.
Battery saver may reduce device performance, which can affect AR visualization quality.
- Power & Sleep Settings: navigate to *Settings* → *System* → *Power & Sleep* and set 'On batter power, turn off after' to at least 1 hour or 'Never'.
 - Note: Using 'Never' may fully drain the battery if the device is left on unintentionally. In such cases, store the HoloLens connected to a charger when not in use.
 - Important safety note: do not set 'When plugged in, turn off after' to 'never' while the device is connected to a charger. This configuration prevents the device from shutting down automatically, may cause excessive heat generation, and can damage the HoloLens 2.

Additionally, regularly check for available HoloLens 2 updates and install them as needed. To check this navigate to *Settings* → *Update & Security* → *Windows Update* and select 'Check for updates'. If an update is available, it will start downloading the new version. After the download is complete, select the 'Restart Now' button to trigger the installation.

If the HoloLens 2 Operation System is updated:

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

Lumi Referenced works in conjunction with Lumi Segment and Lumi Prepare to ensure accurate segmentation and preoperative planning, offering enhanced anatomical insight and support throughout the procedure.

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.
- Securely attaching the reference device with reference marker to the patient's nose and forehead is crucial to ensure an accurate and stable projection of the 3D Patient onto the patient, which is essential for precise visualization of the drain trajectory.
- Securely assessing and, when needed, calibrating, the accuracy of the reference marker tracking is crucial to ensure an accurate and stable projection of the 3D Patient onto the patient, which is essential for precise visualization of the drain trajectory.

24.8 System interface requirements and restrictions

User configuration

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

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, they 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 Referenced, 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.

EVD Procedure Instructions

To perform the EVD Procedure with AR visualization, users should follow the steps below:

1. Confirm indication for EVD using imaging and clinical characteristics.
2. Confirm absence of contra-indications.
3. Digitally transfer CT from Picture Archiving and Communication System (PACS) to Lumi Prepare.
4. Automatically segment skin, skull, brain and ventricles from CT using Lumi Web.
 - **Note:** Use only 3D models automatically or manually segmented from the uploaded DICOM by Lumi's segmentation algorithms to create a 3D Patient for the EVD procedure. Externally created or modified 3D models are not supported in Lumi Referenced and may compromise the accuracy of the holographic visualization and EVD procedure.
5. Plan the EVD trajectory.
6. Plan anatomical landmarks on the 3D Patient.
7. Position patient in supine position.
8. Wash patient's scalp using soap and water.
9. Shave hair on frontal scalp.
10. Mark Kocher's point, approximately 10 cm posterior to the nasion and 3 cm lateral to the midline, roughly on the midpupillary line.

11. Mark a linear, 3 cm incision.
12. Secure the patient's head to the bed with silk tape.
13. Attach Head Device to head of patient.
14. Attach Reference Marker to Head Device.
 - Note: first securely attach the Head Device to the patient, attach the Reference Marker to the Head Device thereafter.
15. Confirm tracking accuracy of Reference Marker.
 - Gently move your head around (make a small circle with your head) to stabilize tracking.
 - Note: confirm stability of tracking, see Tracking Stability Troubleshooting in the section above.
16. (Optional) calibrate the tracking of the Reference Marker if needed.
17. Indicate anatomical landmarks on patient using the Pointer Tool.
18. Perform image-to-patient registration.
19. (Optional) amend EVD trajectory to improve burr hole intersection.
20. Flip up AR-HMD visor.
21. Remove unsterile Reference Marker.
22. Scrub and put on sterile gown.
23. Drape the surgical table with a sterile sheet and open cranial access kit and EVD kit.
24. Clean area around the marked incision using antiseptic solution.
25. Place fenestrated drape around surgical site.
26. Place sterile Reference Device optical marker on top of drapes.
27. Make incision down to bone.
28. Scrape pericranium using handle of the scalpel.
29. Retract wound.
30. Make burr hole using twist drill or automatic trephine.
31. Pierce dura using spinal needle.
32. Circulating nurse flips down HoloLens 2 visor.
33. (Optional) amend EVD trajectory to improve burr hole intersection.
34. (Optional) calibrate the tracking of the Reference Marker if needed.
35. Assisted by the information supplied by Lumi Referenced, pass the EVD into the frontal horn of the lateral ventricle.
 - Note: Do not hand over the HoloLens 2 during an ongoing EVD workflow to prevent potential application instability of crashes. Each EVD workflow should be completed by a single user using a properly calibrated HoloLens 2.
36. Withdraw stylet to check for Cerebrospinal Fluid (CSF).
37. Circulating nurse flips up HoloLens 2 visor.
38. Connect distal end of the EVD to the serrated end of the trocar.
39. Tunnel the trocar, aiming to emerge from the skin approximately 3 to 5 cm lateral and posterior to the incision.
40. Measure and record the depth at which the catheter exits the skin.
41. Secure the catheter to the skin with a purse-string suture.
42. Cut the distal end of the catheter close to the trocar.
43. Attach the adapter and cap to the distal end of the catheter.
44. Remove the retractor and close the incision with a continuous suture.
45. Secure the distal end of the EVD to the skin using two more sutures.

46. Connect the EVD to the sterile tubing from the connecting system.
47. Adjust the height of the collecting system so that the pressure transducer is level with the external auditory canal.
48. Wait a few seconds for the triphasic intracranial pressure waveform to stabilize, and then record the first consistent reading.
49. Dress the wound with an antibiotic-impregnated disk and a sterile transparent film dressing.
50. Further post-operative management of the EVD should be conducted in accordance with the manufacturer's guidelines.

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 Referenced uses Azure's built-in security features, including Microsoft Defender for Cloud, to protect against malware and other threats.
- **Audit logfiles:** Lumi Referenced collects logfiles on both user and system level to capture activities and events that occur within Lumi Referenced. 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 Lumi 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 information security group 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 Referenced:

| 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 | Number of patient and 3D Patient landmarks are displayed in red | The number of landmarks on the real patient does not match the number of landmarks on the 3D Patient | Remove or add patient or 3D Patient landmarks |
| 3 | Warning | Lumi HL2 Application | Outline of tracking tool is displayed in red | The tracking tools is tracked at a suboptimal rotation or distance | Move your head closer and more straight to the tracking tool to ensure tracking from an optimal position |
| 4 | Warning | Lumi HL2 Application | Track the reference marker / pointer tool first | One of the trackers is not tracked completely | Move your head to track both tracking tools properly |
| 5 | Warning | Lumi HL2 Application | Your battery level is xx% | The battery level of the XR glasses is below xx% | Charge the XR glasses until a higher battery level is reached. When working with the EVD Workflow, charge your battery until >80% before you proceed. |

| No. | Type | Platform | Message/Display | Cause | Actions |
|-----|---------|------------------------------------|--|---|--|
| 6 | Error | Lumi Web Application | Scan upload failed | The upload of the DICOM scan to Lumi.cloud failed | <ul style="list-style-type: none"> - 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 |
| 7 | Error | Lumi Web Application | 3D Model upload failed | The upload of the 3D Model to Lumi.cloud failed | <ul style="list-style-type: none"> - 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 |
| 8 | Error | Lumi HL2 Application | EVD workflow cannot be started because of missing elements | The 3D Patient misses a CT scan, the skin, skull, or ventricles and therefore the EVD workflow cannot be started | Ensure your 3D Patient contains at least a CT scan, the skin, skull, and ventricles |
| 9 | 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: <ul style="list-style-type: none"> - Save changes - Discard changes - Cancel |
| 10 | 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: <ul style="list-style-type: none"> - Cancel - Save and close - Close |
| 11 | 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' |
| 12 | Warning | Lumi HL2 Application, EVD Workflow | Environment tracking lost, please wait... | HoloLens 2 has lost tracking of environment, marker tracking not possible | Gently look around the room and wait till the warning "Environment tracking is stable" appears |
| 13 | Warning | Lumi HL2 Application, EVD Workflow | Environment tracking is stable | Environment tracking of HoloLens 2 is restored, marker tracking is possible | Check if marker tracking is accurately restored, continue EVD workflow |
| 14 | Warning | Lumi HL2 Application, EVD Workflow | User not detected, please wait... | User has flipped up HoloLens 2 visor or has not calibrated eye tracking. Marker tracking is not allowed | Flip down HoloLens 2 visor or calibrate your eyes (<i>Settings > System > Calibration</i>) |

| No. | Type | Platform | Message/Display | Cause | Actions |
|-----|---------|------------------------------------|--|--|---|
| 15 | Warning | Lumi HL2 Application, EVD Workflow | User detected again | User detected after being absent | Check if marker tracking is accurately restored, continue EVD workflow |
| 16 | Warning | Lumi HL2 Application, EVD Workflow | Performance (FPS) too low | Performance of HoloLens 2 is too low for reliable marker tracking. The hologram might be too complex (heavy) or the user is doing too much too complex tasks simultaneously | Simplify your hologram or stop running complex tasks (for example drawing) |
| 17 | Warning | Lumi HL2 Application, EVD Workflow | FPS became acceptable again | Performance of HoloLens 2 returned to acceptable level after having dipped below acceptable level | Check if marker tracking is accurately restored, continue EVD Workflow |
| 18 | Error | Lumi HL2 Application, EVD Workflow | The system temporarily lost its tracking reference. If recovery is not possible, the application will close and must be restarted. Please note that unsaved changes may be lost. | Environment tracking was lost during marker tracking. This is a known condition in which the app can become unstable. If the user chooses to continue, the app might crash and unsaved changes might be lost | Gently look around the room and see if environment tracking restores, otherwise close the hologram and EVD Workflow |

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 Referenced has been designed to comply with the following standards:

Regulations

EU Medical Device Regulation
EU 2021/2226

Regulation EU 2017/745 of 25 May 2017

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 and the User Guide are supplied in electronic form. The user is able to request a paper form of the Instructions for Use and/or User Guide 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.

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 calendar 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 Instructions For Use | - |
|  | Date of manufacture | Indicates the date when the medical device was manufactured | Date on which the software version was released Example: Date of manufacture: YYYY-MM-DD (ISO 8601-1) |

| Symbol | Title | Description | Meaning |
|--|--------------------------|--|--|
|  | 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 |