

e-ASPECTS®

User Manual

Version 14.1

e-ASPECTS-MAN-14.1 - 2025-10-29

e-ASPECTS is part of Brainomix 360

U.S. Patent No. 10902596

EU Patent No. 3701495

Historic revisions (<https://www.brainomix.com/docs/>)

- 1 Introduction
 - 1.1 Overview
 - 1.2 ASPECTS
- 2 Intended Use
 - 2.1 Indications
 - 2.2 Contraindications
 - 2.3 Warnings
 - 2.4 Precautions
 - 2.5 Clinical Benefits
 - 2.6 Use Environment
- 3 Installation and Training
 - 3.1 Installation
 - 3.2 Training
- 4 System Specifications
 - 4.1 Server
 - 4.2 Clients
 - 4.3 Languages
 - 4.4 Performance and Lifetime
- 5 Scanner and Image Compatibility
- 6 Cybersecurity
- 7 Access Control and Notifications
 - 7.1 Logging In
 - 7.2 Logging Out
 - 7.3 Changing Your Password
 - 7.4 Two-factor authentication
 - 7.5 On-Call Status
 - 7.6 App Notifications
- 8 Desktop Interface
 - 8.1 Patient List

- 8.2 Finding Patients
- 8.3 Patient Viewer
- 8.4 e-ASPECTS Display
- 8.5 Manual Results
- 9 Mobile Display
 - 9.1 Patient List
 - 9.2 Patient Viewer
 - 9.3 Messaging
 - 9.4 Flag a patient for intervention
- 10 Result Outputs
 - 10.1 DICOM
 - 10.2 Cloud Sync
 - 10.3 Mobile App Notifications
- 11 Uploading and Processing
 - 11.1 Processing Scans
 - 11.2 The DICOM log
- 12 Administration
- 13 Troubleshooting
- 14 Service Maintenance and Upgrades
- 15 Incident Reporting
- 16 Decommissioning
- 17 Symbols
- 18 Request a Paper Copy

Regulatory Information

	Brainomix Limited First Floor Seacourt Tower West Way Oxford OX2 0JJ United Kingdom	 0197					
		EU/EEA/Türkiye <table><tr><td> EC REP </td><td> Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem Netherlands </td></tr><tr><td></td><td> Brainomix Europe Limited Suite 10380 26/27 Upper Pembroke Street D02 X361, Dublin 2 Ireland </td></tr></table>		EC REP	Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem Netherlands		Brainomix Europe Limited Suite 10380 26/27 Upper Pembroke Street D02 X361, Dublin 2 Ireland
EC REP	Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem Netherlands						
	Brainomix Europe Limited Suite 10380 26/27 Upper Pembroke Street D02 X361, Dublin 2 Ireland						
		Switzerland <table><tr><td> CH REP </td><td> Freyr Life Sciences GmbH Bahnhofplatz CH-6300 Zug Switzerland </td></tr><tr><td></td><td> Stryker Osteonics AG Burgunderstrasse 13 4562 Biberist Switzerland </td></tr></table>		CH REP	Freyr Life Sciences GmbH Bahnhofplatz CH-6300 Zug Switzerland		Stryker Osteonics AG Burgunderstrasse 13 4562 Biberist Switzerland
CH REP	Freyr Life Sciences GmbH Bahnhofplatz CH-6300 Zug Switzerland						
	Stryker Osteonics AG Burgunderstrasse 13 4562 Biberist Switzerland						
	+44 (0) 1865 582740 (tel:+441865582740)						

1 Introduction

1.1 Overview

Brainomix 360 e-ASPECTS (referred to throughout as both "Brainomix 360 e-ASPECTS" and "e-ASPECTS") is a software medical device for processing brain Computed Tomography (CT) scans for stroke patients. It is supplied as a web service, with users accessing the system through a web browser on any machine with a connection to the Brainomix 360 software (e.g. a LAN or Internet connection) and may connect with other DICOM-compliant devices over a local network connection, including CT scanners and PACS systems.

Typically, non-contrast brain CT scans of stroke patients should be sent via a DICOM C-STORE operation from a CT scanner to the Brainomix 360 software. Brainomix 360 can be configured to automatically transfer the generated result series to a PACS via a DICOM C-STORE operation. Brainomix 360 may additionally be configured to send results and patient reports to additional destinations, whenever a scan is processed by the software. These destinations may include Brainomix 360 Cloud or other Brainomix 360 instances, and Brainomix 360 Mobile app notifications.

1.2 ASPECTS

ASPECTS (Alberta Stroke Program Early CT Score) is a topographic scoring system that divides the brain territory that is affected by the stroke into 10 areas of interest. There are six cortical regions (M1-M6), and four basal ganglia regions (caudate, lentiform, insula, and internal capsule). For each of the defined points, a single point is subtracted for an area of early ischemic change, such as parenchymal hypoattenuation. A score of zero indicates diffuse ischemic damage throughout the affected hemisphere, while a normal brain CT scan is assigned an ASPECTS of 10 points.

Note that non-acute ischemic changes are not included when computing an ASPECTS score.

pc-ASPECTS

An additional scoring system for use in posterior circulation stroke is pc-ASPECTS (posterior-circulation ASPECTS) as defined in Puetz et al., Stroke, 2008 (<https://doi.org/10.1161/STROKEAHA.107.511162>). It divides into 8 areas of interest: thalami (1 point each), occipital lobes (1 point each), midbrain (2 points), pons (2 points), cerebellar hemisphere (1 point each). A normal brain CT scan is assigned a pc-ASPECTS of 10 points.

Note that the pc-ASPECTS score, acute and non-acute ischemic changes in the pc-ASPECTS regions are not computed by e-ASPECTS.

2 Intended Use

This section contains important safety information regarding the usage of Brainomix 360 e-ASPECTS

Brainomix 360 e-ASPECTS is an image processing software package to be used by trained professionals, including stroke physicians and radiologists. The software runs on standard "off-the-shelf" hardware (physical or virtualized). Data and images are acquired through DICOM compliant imaging devices. This includes DICOM files uploaded through a web interface.

Brainomix 360 e-ASPECTS provides both analysis and viewing capabilities for brain CT datasets of stroke patients. The analysis capabilities are for detection of changes in the image related to stroke, calculation of the extent of these changes (such as ASPECTS, the Alberta Stroke Program Early CT Score), and visualization of these changes.

2.1 Indications

1. Brainomix 360 e-ASPECTS is indicated as an aid to diagnosis and treatment of acute ischemic stroke patients with an MCA (middle cerebral artery) occlusion or ICA (internal carotid artery) occlusion.
2. Brainomix 360 e-ASPECTS is indicated for use on non-contrast brain CT scans for these patients as a decision support tool, providing automated image analysis and ASPECTS scoring.
3. Brainomix 360 e-ASPECTS is indicated for use on non-contrast brain CT scans for highlighting suspected abnormal hyperdensities through automated image analysis.

2.2 Contraindications

1. Brainomix 360 e-ASPECTS is not suitable for use on brain scans displaying neurological pathologies other than acute stroke, such as tumours or abscesses.
2. Brainomix 360 e-ASPECTS must not be used by anyone with a physical or other impairment that would hinder their ability in perceiving and interpreting the output of the software or render them unable to interpret imaging without e-ASPECTS assistance to confirm any outputs.

2.3 Warnings

	Brainomix 360 e-ASPECTS should not be used as sole basis for diagnosis. The output should not be considered as a definitive diagnosis. Brainomix 360 e-ASPECTS should only be used by a trained professional with an understanding of CT image interpretation, as an aid to interpret images.
	Brainomix 360 e-ASPECTS should only be used by professionals who have received adequate training on the use of the software by qualified trainers of Brainomix or authorized third parties.
	Brainomix 360 e-ASPECTS may not detect all chronic (old) infarcts or may incorrectly classify them as fresh ischemic damage.

	Brainomix 360 e-ASPECTS will not correctly identify early ischemic changes in every scan and may generate false positives or false negatives in any region. The user should use their own expertise in CT image analysis to verify that the software's output is correct.
	Brainomix 360 e-ASPECTS may not detect all abnormal hyperdensities or may incorrectly highlight areas of the image that are not abnormal hyperdensities.
	Brainomix 360 e-ASPECTS is not intended for primary interpretation of CT images. It is used to assist physician evaluation.
	Brainomix 360 e-ASPECTS should not be used in cases of ischemic stroke outside of the ICA/MCA territory.
	Cases with structural abnormalities such as tumours or other imaging artifacts may mimic the symptoms of an ischemic stroke and may affect the performance of Brainomix 360 e-ASPECTS. Brainomix 360 e-ASPECTS should not be used in these cases. Other cases with non-ischemic stroke conditions and structurally normal scans may also mimic the symptoms of an ischemic stroke and should not be processed using Brainomix 360 e-ASPECTS.
	Brainomix 360 e-ASPECTS should only be installed within a secure network which is subject to appropriate protective measures including antivirus, antimalware and firewall protection.
	To minimise the risk of unauthorised use of Brainomix 360 e-ASPECTS, users should not share access credentials and should log-off when not using the system.
	Users accessing the Brainomix 360 e-ASPECTS web user interface must ensure that they perform any analysis or diagnostic image review using an approved radiology viewing display.
	Brainomix 360 e-ASPECTS is not intended for diagnostic image review when accessed from mobile devices.
	Before evaluating the processing results, the accuracy of the automatically segmented ASPECTS regions should be reviewed. If there is any disagreement or concern with the quality of the ASPECTS region segmentation, users should either manually edit or disregard the results.
	In the event Brainomix 360 e-ASPECTS becomes partially or entirely unavailable, or if processed scans cannot be retrieved, users should rely on standard methods of image interpretation according to the standard of care.
	Users should ensure that notifications are enabled on their Android or iOS mobile devices in order to receive a push notification.

	A notification may not be generated or may be delayed for several reasons, including but not limited to: ▪ Algorithmic data problems or processing errors during the analysis of scans (see Precautions for more information) ▪ Artifacts, motion or other factors reducing registration quality Lack of disk space to process new scans ▪ Underlying server platform failure ▪ Slow network connectivity ▪ Slow connectivity from scanner/PACS to the Brainomix 360 server ▪ Slow connectivity to the Brainomix 360 Cloud service over the internet ▪ Delays in the Apple or Google mobile notification services ▪ Poor signal on the receiving mobile device ▪ Power saving modes of some mobile devices may delay notifications
---	---

2.4 Precautions

	The performance of Brainomix 360 e-ASPECTS is limited by the quality of the input CT image. If Brainomix 360 e-ASPECTS receives poor quality, invalid or corrupted data, it may affect the system's ability to process results effectively. The user should therefore manually inspect the image for scanner artifacts and poor-quality images to avoid incorrect results.
	Brainomix 360 e-ASPECTS is dependent on the correct functioning of the underlying server platform on which it is installed and is not intended to be used as a data store. Results and original data should be stored in a PACS system and backed up appropriately.
	Brainomix 360 e-ASPECTS has only been validated and is intended to be used in adult patient populations. Safety and effectiveness in paediatric cases has not been established.

2.5 Clinical Benefits

The primary benefit of Brainomix 360 e-ASPECTS is to provide the intended user a reference ASPECTS score with the sensitivity and specificity at the level of an expert.

2.6 Use Environment

Brainomix 360 e-ASPECTS is intended to be used on desktop or mobile devices approved by the healthcare organisation for clinical use. Both desktop and mobile view deliver benefits of the device; however, mobile preview images should not be used as an aid to diagnostic readings.

3 Installation and Training

Prior to first use of Brainomix 360 e-ASPECTS, installation of the software and training for its user(s) are required.

3.1 Installation

Brainomix 360 e-ASPECTS can be installed for your organisation either via a cloud-based server deployment or a local physical server installation. Prior to the installation, Brainomix (or an authorised distributor) collects all necessary installation information, including location, power and networking requirements and any third-party systems that may interact with the Brainomix 360 e-ASPECTS software. Liaise with Brainomix or authorised distributor with regards to the method and requirements for installation.

In order to use the software on mobile devices (smart phone and tablet), download the Brainomix 360 Mobile app on your device:

- App Store (for iOS devices) (<https://apps.apple.com/us/app/e-stroke-mobile/id1443749413>)
- Google Play (for Android devices) (<https://play.google.com/store/apps/details?id=com.brainomix.ess.android&gl=US>)

Follow the instructions of your mobile device to complete the installation process.

3.2 Training

The use of Brainomix 360 e-ASPECTS requires competency in the interpretation of non-contrast CT scans for the management of patients with acute ischaemic stroke. Training is required prior to first use of the software. The training is organised in advance and delivered by qualified trainers of Brainomix (or third-party trainers appointed by Brainomix) at the time of the initial installation to the clinical and/or IT representative(s) of your organisation. Subsequently, new users may be trained in the use of the software by the designated lead trainer(s) of your organisation. Brainomix will communicate if any new training is required following the initial deployment. For any questions related to training, please contact the lead trainer(s) of your or organisation or contact Brainomix at support@brainomix.com (<mailto:support@brainomix.com>)

4 System Specifications

4.1 Server

The following should be considered minimum specifications for reliable use of the application.

Processor	x86-64 compatible processor with 4 cores at 3.5+ GHz supporting AVX instructions (e.g. Intel Xeon, AMD EPYC)
Memory	16GB RAM
Disk	500GB SSD
Network	1Gb Ethernet
Operating System	Ubuntu Linux 24.04

4.2 Clients

The following web browsers and platforms should be considered minimum requirements for reliable operation of the web user interface.

Web Browser	Supported Version
Google Chrome	Latest version
Mozilla Firefox	Latest version
Microsoft Edge	Latest version
Mobile Safari (iOS)	Latest version
Platform	Minimum Specifications
PC (desktop or laptop)	Memory: 4GB RAM Screen size: 13.3 inches and above Screen resolution: 1024 x 768 Processor: Intel or AMD CPU
Tablet	Memory: 2GB RAM Screen size: 9.4 inches and above Screen resolution: 2048 x 1536
Mobile phone (iPhone or Android)	Memory: 2GB RAM Screen size: 4.7 inches and above Screen resolution: 1334 x 750

4.3 Languages

The following languages are supported in the current version of the software.

- Bulgarian (bg)
- Czech (cs)
- Welsh (cy)
- German (de)
- Greek (el)
- English (en)
- Spanish (es)
- Finnish (fi)
- French (fr)
- Croatian (hr)
- Hungarian (hu)
- Italian (it)
- Latvian (lv)
- Lithuanian (lt)
- Dutch (nl)
- Polish (pl)
- Portuguese (pt)
- Portuguese (Brazil) (pt-br)
- Romanian (ro)
- Serbian (sr)
- Slovak (sk)
- Slovenian (sl)
- Swedish (sv)
- Turkish (tr)

4.4 Performance and Lifetime

The following performance specifications apply to the current version of the software.

Process time (per CT scan)	≤ 1 minute (after retrieval from the PCS or from upload completion)
Sensitivity	avg. min. 50%
Specificity	avg. min. 94%

A separate technical data sheet for the Brainomix 360 platform with information relevant for your organization's IT department is provided at the time of first installation and is available upon request.

The product lifetime of Brainomix 360 e-ASPECTS is indefinite for the current software version and for the duration of the contracted service provision when deployed on a virtual machine that receives regular software updates from Brainomix.

5 Scanner and Image Compatibility

The Brainomix 360 e-ASPECTS software is designed to work with non-contrast CT scans sent via the DICOM protocol. These scans should have the following characteristics:

Slice thickness	2mm maximum slice thickness
Acquisition volume	Single cerebrum sequence from circle of Willis level or below, up to the vertex
Reconstruction method	Soft tissue kernel (no excessive smoothing). Iterative, deep learning or FBP reconstruction may be used as long as kernel size is not too large.
Window	Brain window (not bone window)

Use of thicker slices or excessively low dose can lead to the introduction of image artifacts, and consequently reduced scoring performance. Using the wrong window will typically lead to Brainomix 360 e-ASPECTS failing to process the scan.

6 Cybersecurity

Brainomix 360 e-ASPECTS is installed on a server (either physical or virtual) within the hospital network and as such is potentially vulnerable any malware or viruses penetrating the hospital network in which Brainomix 360 e-ASPECTS is embedded, or to any other form of unauthorized access.

Brainomix 360 e-ASPECTS does not present a specific vulnerability to the hospital network in which it is embedded and is unlikely to be intentionally exploited. However, should such risks occur, they could potentially result in corruption or loss of processing data being received, stored or sent, corruption, loss or damage to stored configuration data or interruption or prevention of normal operation.

Brainomix 360 e-ASPECTS has been designed and developed with features and requirements to mitigate these cybersecurity risks. In particular the system has been designed such that:

- User access can be restricted and controlled
- Data storage components are not accessible over a network other than through Brainomix web-service components
- Only the minimum number of ports required for all functionality are left open
- Data transmission across untrusted connections is secured and encrypted
- Brainomix can remotely monitor the system and securely install security updates as needed

Brainomix 360 e-ASPECTS has been designed to employ a layered authorization model based on user roles. This includes standard users who access and use the system and Administrators who have additional privileges to enable them to:

- Access patient data or system configuration
- Set and manage security options
- Delete patient data/scans
- Modify or remove users

The installation package for Brainomix 360 e-ASPECTS includes local firewall, antivirus and antimalware protection for the server. These can be changed or amended to suit local security policies; however, it is important that Administrators contact Brainomix support before removing or re-configuring these default protections to avoid compromising the security of the system.

To prevent unauthorized access, Brainomix 360 e-ASPECTS includes inbuilt username/password and two-factor authentication mechanisms which are described in the Access Control section of this user manual.

If users or administrators suspect that a user's log-on credentials have been compromised, the password should be changed immediately, or the account disabled.

Passwords can be set and re-set by users and/or administrators but must meet minimum password complexity requirements. Minimum password complexity requirements are set to a default but can be configured by Administrators to facilitate options for more complexity where this is required or mandated by local security policies.

These options include setting the mandatory use of special characters, creating blacklists of passwords which may not be used and setting the maximum age for re-setting passwords. Two-factor authentication is optional by default but may also be enforced by Administrators.

Brainomix 360 e-ASPECTS can be set to automatically disable user accounts that have had no activity for a defined period and, for active users, also includes an automatic time-out feature which will log out users after a period of inactivity.

To minimize the risk of unauthorized use of Brainomix 360 e-ASPECTS, users should not share access credentials and should log-off immediately when not using the system.

Administrators can also opt to use Active Directory user accounts (via LDAP) in place of the default Brainomix authentication system.

Although various cybersecurity measures have been designed and implemented, the successful mitigation against security vulnerabilities for Brainomix 360 e-ASPECTS depends on the security infrastructure of the hospital network environment, best practice by users and management by Administrators.

Brainomix 360 e-ASPECTS should only be installed within a secure hospital network which is protected by a network level firewall, antivirus and antimalware software and, ideally, Intrusion Detection Software (IDS).

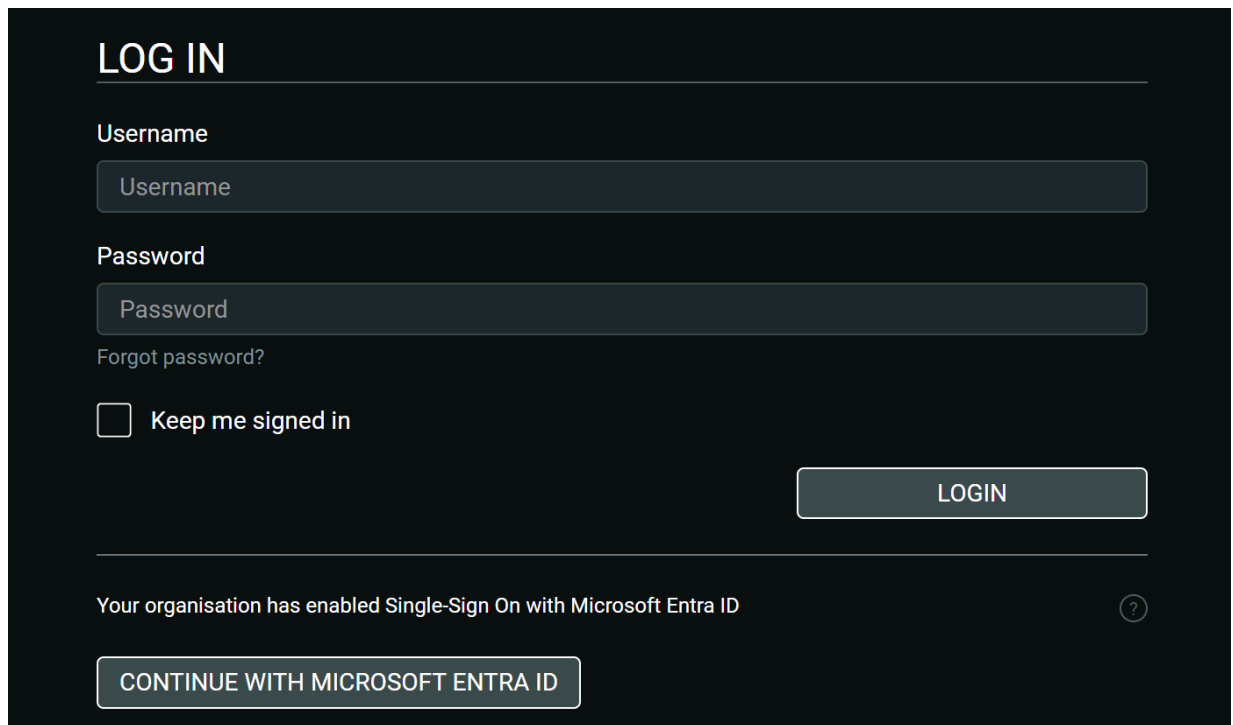
Client machines used to access the server hosting Brainomix 360 e-ASPECTS should also be protected by antivirus/antimalware software and IDS and should be kept up to date with security patches and updates.

7 Access Control and Notifications

7.1 Logging In

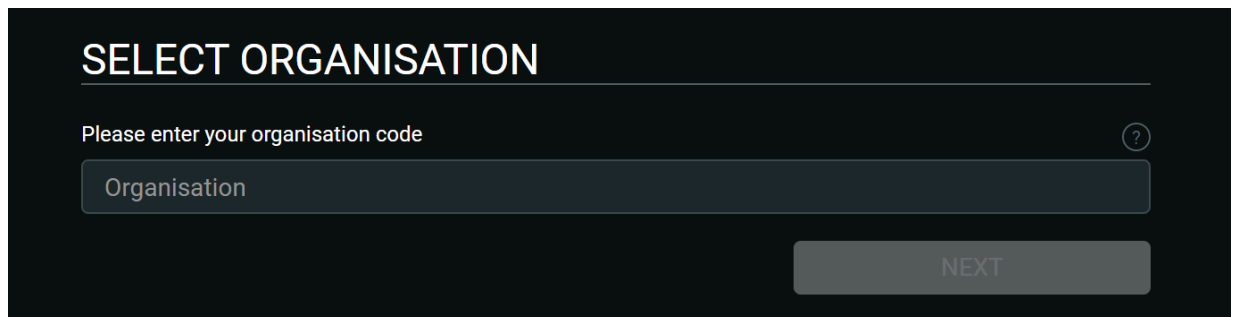
1. Go to the Brainomix 360 or Brainomix 360 Cloud server address in your web browser.
2. You will be prompted to log in if you have not used the application recently from your current web browser. Your system administrator can provide login credentials.

Brainomix 360:



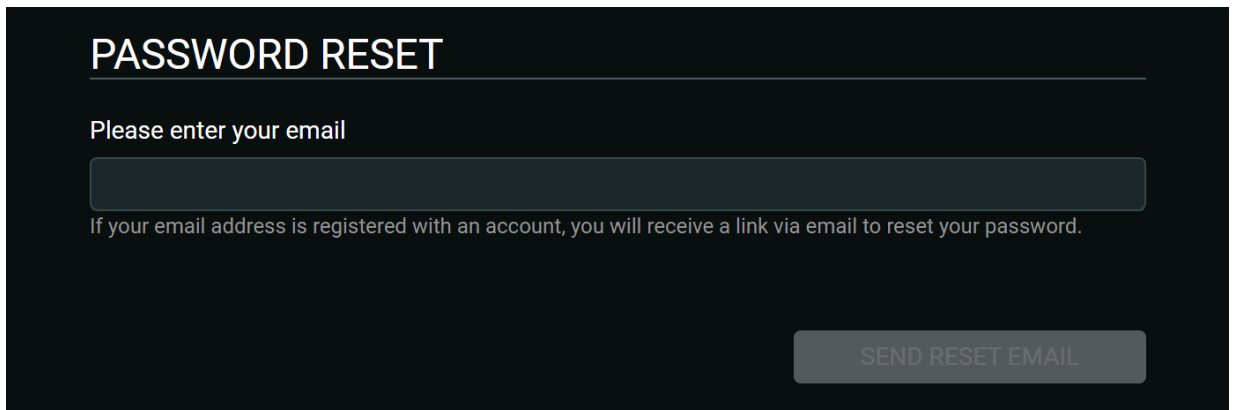
The image shows the login interface for Brainomix 360. It has a dark background with white text. At the top, it says 'LOG IN' in large, bold, white letters. Below this, there are two input fields: 'Username' and 'Password'. The 'Username' field has a placeholder text 'Username' and the 'Password' field has a placeholder text 'Password'. Below the 'Password' field, there is a link 'Forgot password?'. Below that, there is a checkbox labeled 'Keep me signed in'. To the right of these fields, there is a 'LOGIN' button. At the bottom, there is a message 'Your organisation has enabled Single-Sign On with Microsoft Entra ID' with a question mark icon. Below this message, there is a button labeled 'CONTINUE WITH MICROSOFT ENTRA ID'.

Brainomix 360 Cloud:



The image shows the 'SELECT ORGANISATION' screen for Brainomix 360 Cloud. It has a dark background with white text. At the top, it says 'SELECT ORGANISATION' in large, bold, white letters. Below this, there is a text prompt 'Please enter your organisation code' with a question mark icon. Below this prompt, there is an input field with a placeholder text 'Organisation'. To the right of this field, there is a 'NEXT' button.

1. If logging into Brainomix 360 Cloud, enter your organisation ID
 2. If your organisation has enabled Single Sign On, press "Continue with Microsoft Entra ID" and follow the standard login process. Otherwise:
 3. Enter your username and password.
 4. Leave the box unchecked if you want to be automatically logged out after 1 hour, or when you quit the browser. Check the box if you want to remain signed in on this computer until you sign out.
 5. Click the Login button
3. If you have forgotten your password, you can request a password reset email by clicking the "Forgot password?" text.



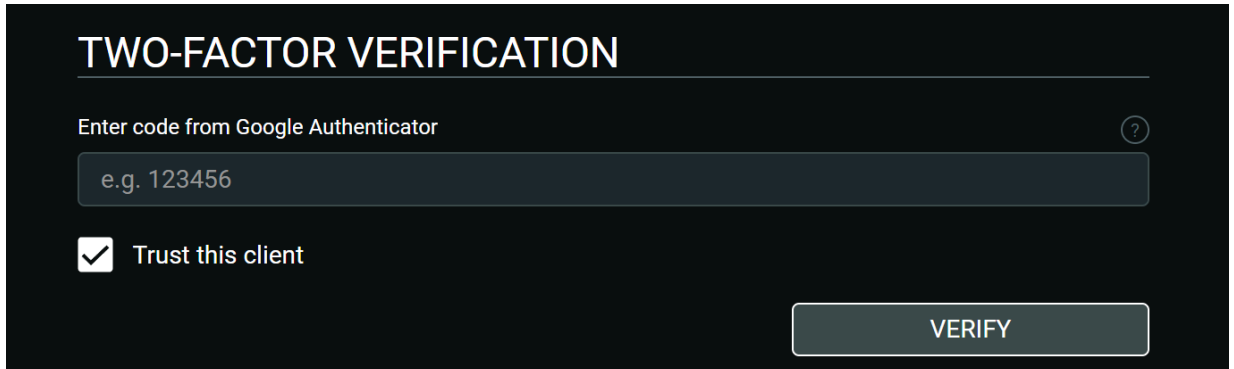
PASSWORD RESET

Please enter your email

If your email address is registered with an account, you will receive a link via email to reset your password.

SEND RESET EMAIL

4. If you have enrolled in two-factor authentication, you may be prompted to enter a token code from your authenticator app.



TWO-FACTOR VERIFICATION

Enter code from Google Authenticator

e.g. 123456

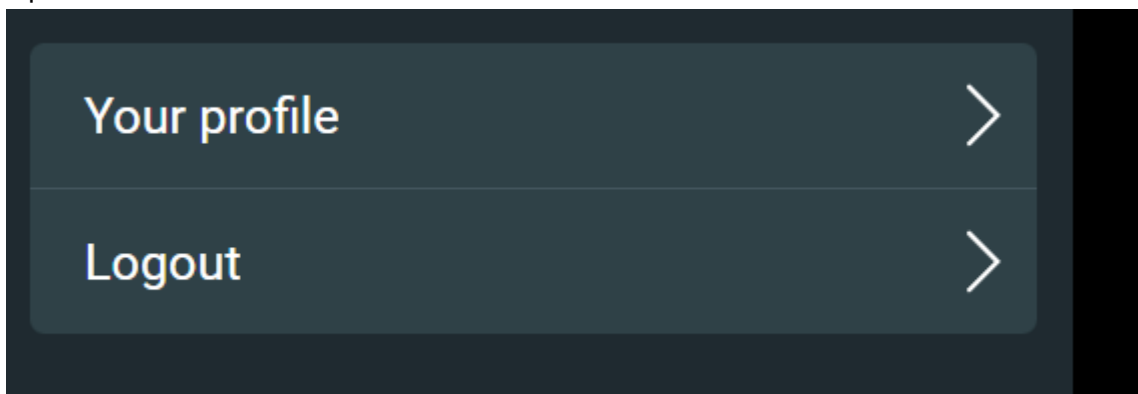
☒ Trust this client

VERIFY

- Select "Trust this client" to avoid being asked for a token code again on this device or browser. Do not use this option on shared devices.
- If you cannot get a token code from your authenticator app, you can enter an unused recovery code from the list given when enrolling in two-factor authentication.

7.2 Logging Out

1. Open the Menu and scroll to the bottom.



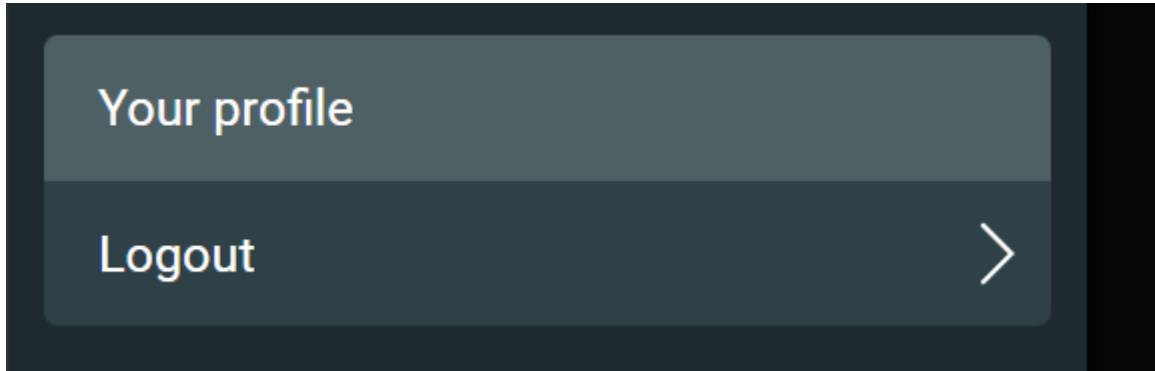
Your profile

Logout

2. Click **Logout**

7.3 Changing Your Password

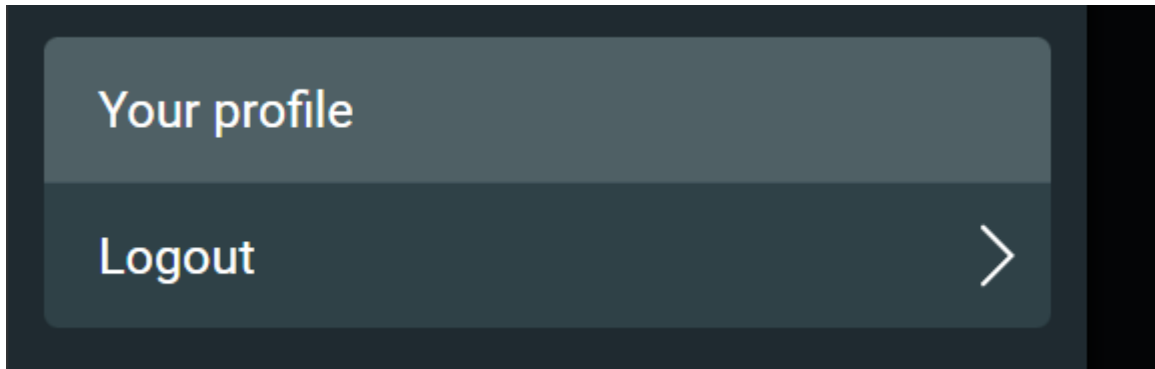
1. Open the Menu and scroll to the bottom.



2. Click **Your profile**
3. Click on the tab labelled **Change password**
4. Enter your old and new passwords (Passwords must meet minimum complexity requirements: 8 characters with at least one number and letter.)
5. Click **Save** or press enter

7.4 Two-factor authentication

1. Open the Menu and scroll to the bottom.

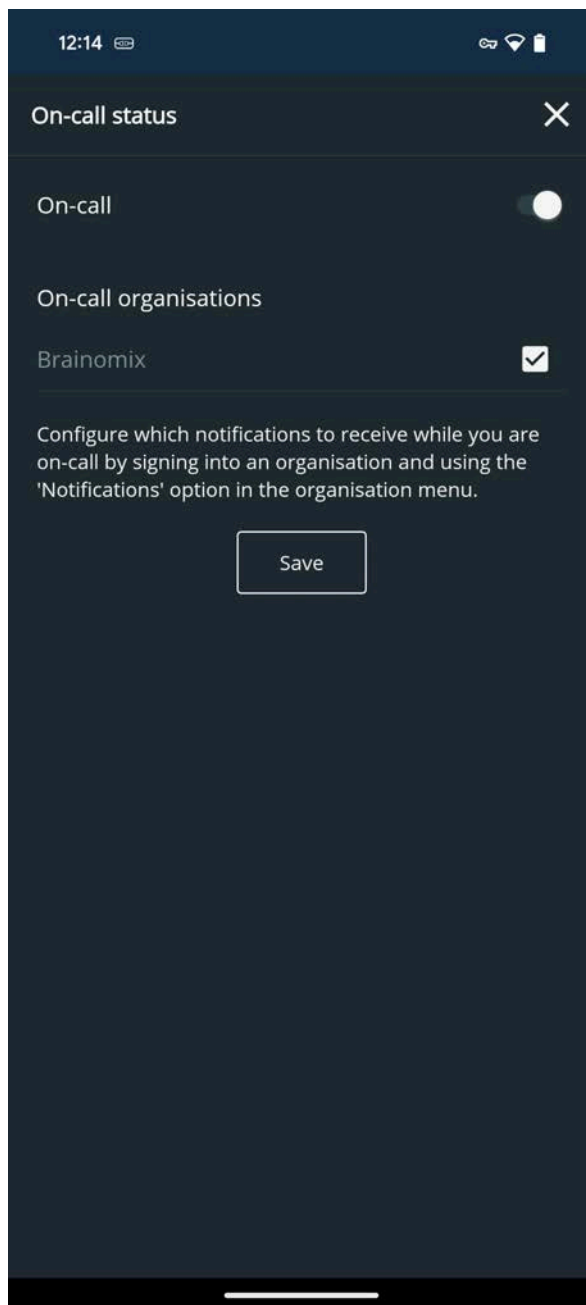


2. Click **Your profile**
3. Click on the tab labelled **Two-factor authentication**
4. Click the **enroll** button.
5. Follow the on-screen enrollment instructions.

7.5 On-Call Status

Configuration

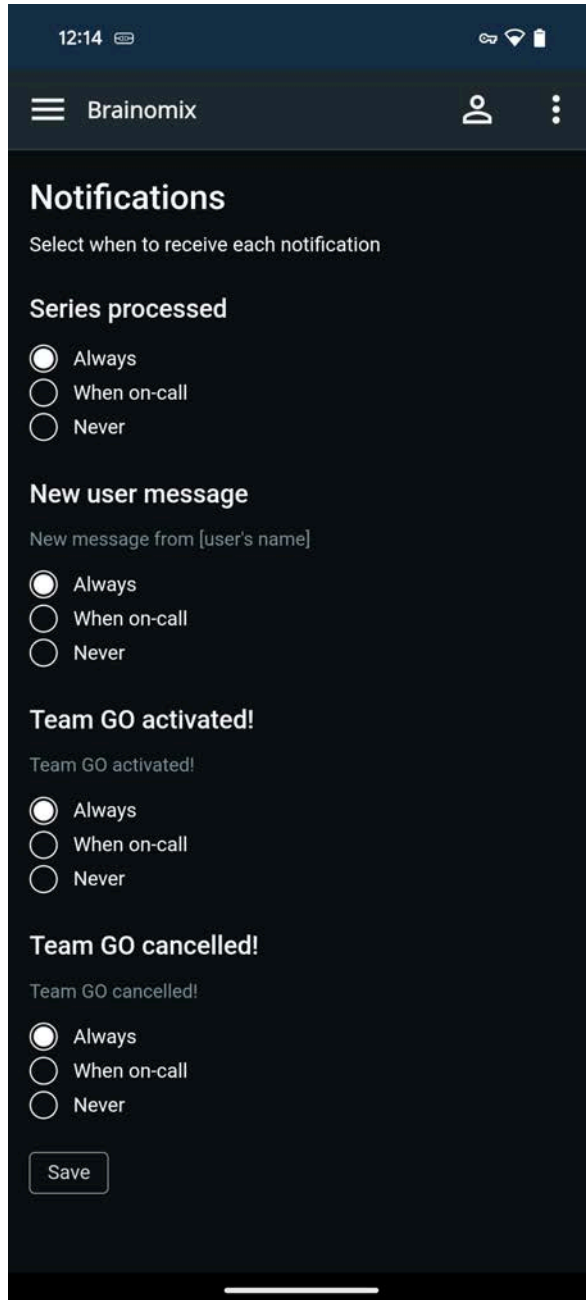
1. Your on-call status can be configured through the app. You can choose to be on-call or not, and which organisations you are going to be on-call for.



7.6 App Notifications

1. You can choose to always receive notifications, only receive them when you are on-call for an organisation, or never receive them.

2. These settings can be configured by tapping 'Notifications' in the app menu for an organisation.



In order to receive notifications from the Brainomix 360 Mobile app, you must ensure that notifications are enabled on your mobile device. This can be done at the time of the installation of the Brainomix 360 Mobile app on your mobile device or can be set later following the below steps.

iOS

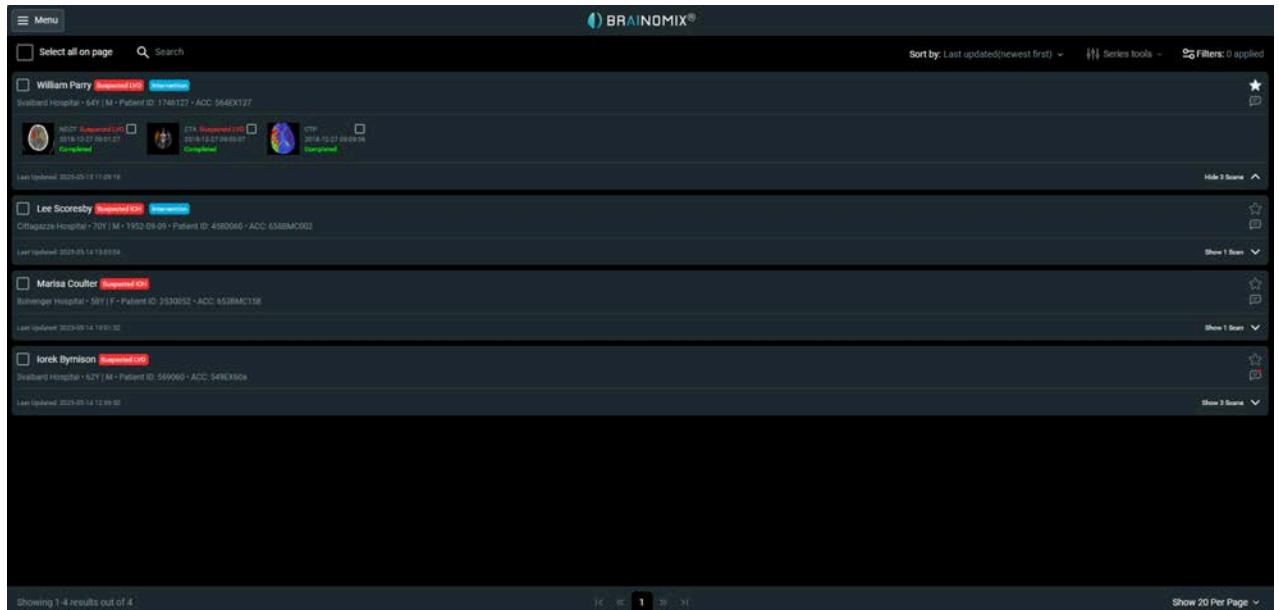
- Launch the Settings app.
- Tap Notifications.
- Scroll to Brainomix 360 Mobile > Tap.
- Toggle the **Allow Notifications** switch to **On** to enable notifications.
- Toggle the **Time-Sensitive Notifications** switch **On** (notifications are always delivered immediately and remain on the Lock Screen for an hour).
- Choose your alert preferences - it is recommended to select all (Lock Screen, Notification Centre and Banners) and set the **Banner Style** to **Persistent**.
- Toggle the **Sounds and Badges** switches to **On** (recommended).

Android

- Launch the Settings app.
- Tap Apps.
- Scroll to Brainomix 360 Mobile > Tap.
- Tap Notifications.
- Toggle the **Allow notification** switch to **On** to enable notifications, including messages, sounds and vibration.
- Toggle the **Show silently** switch **Off** (recommended).
- Toggle the **Set as priority** switch **On** to turn on the screen while "Do not disturb" is turned on (recommended).

8 Desktop Interface

8.1 Patient List



- The patient list page shows all patients available to you. By default, they are listed in order of the last patient updated.
- Move through the pages of patients by clicking on the page numbers below the list.
- Click on a patient to open it in the Patient Viewer (see the Patient Viewer section).
- Click on the  icon to expand the patient details to see scan details and a preview thumbnail of each scan.

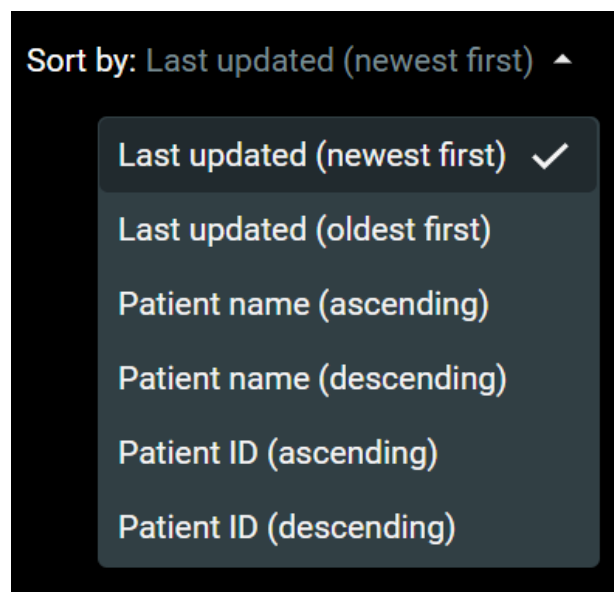
8.2 Finding Patients

Sorting

Sort the patient list by clicking the Sort by button.

Sort by: Last updated(newest first) ▾

Select a sort preference from the drop-down list.



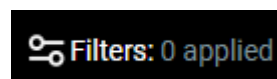
Search

Search for a patient by name, accession number or ID by entering text into the search box above the patient list.



Filtering

Filter the patients by pressing the Filters button.



Select the options that you want to filter by. Only those patients with series or results matching the selected filters will be shown in the patient list.

The screenshot shows a 'FILTERS' panel with a close button (X) in the top right corner. The panel contains several filter sections: 'FAVORITES' with a 'Show Favorites' checkbox; 'TRIAGE NOTIFICATION(S)' with 'Suspected ICH Detected' (unchecked) and 'Suspected LVO Detected' (checked), each with a corresponding red status label; 'DELETED SERIES' with a dropdown arrow; 'LAST UPDATED' with radio button options for 'All', 'Last hour', 'Last 6 hours', 'Last 24 hours' (selected), 'Last 48 hours', and 'Select date range...', along with an 'Edit dates' link; and four dropdown menus for 'INSTITUTION NAME', 'STATE', 'WORKFLOW', and 'SCANNER'. A 'Clear Filters' button is at the bottom.

8.3 Patient Viewer

Overview

When opening a patient from the patient list, you will arrive within the Patient Viewer.

There is patient-specific information in the left side bar:

- View: view all scan details available for selected patient
- Series: view the full metadata for this scan, along with any processing warnings
- Messaging: view and send messages for this patient

Above the Patient Viewer and side bar is the patient information card. This shows patient details and provides the "star" option to mark a patient as favourite. Note that this information may have been removed if the patient has been pseudonymized, e.g. if it has been received by peer-to-peer sync or you are viewing the patient on Brainomix 360 Cloud.



Viewing scans

Below the patient information card, and above the image view, is a row of image view controls. These are, from left to right:

- The view selector ("Source" is shown). This allows for quick view changes.
- The Slab Thickness control. If available, this allows for adjusting the slab thickness by combining adjacent slices with mean, MIP or MinIP filters.
- The windowing control. This provides window width/level adjustment and several presets. Windowing can also be adjusted by right-clicking and dragging the mouse.
- The overlay toggle. Pressing this button will toggle overlays off or on.
- The MPR control. If available, pressing this button will give options for changing to axial, sagittal or coronal views.
- The Maximize button. Pressing this will expand the image view to take up as much space as possible.

The main component of the patient viewer is the image view. This displays the current slice of the selected view, with the appropriate window, slab and MPR filters applied. Overlays for information, and from algorithm results, may be displayed over the base image.

At the top right corner of the image view, indicators are displayed from algorithm results, along with any user edits or intervention flags.

Below the image view is the slice control. You can scroll through all slices by dragging the slider.

Windowing

Pixels in a CT scan are measured in Hounsfield Units (HU), which must be converted to grey levels for display. The windowing level and width controls in the **Windowing** menu allow you to adjust the range of HU values which are displayed.

These preset windows are provided to help you manually assess the scan:

- **Tissue:** Provides a good overall view of brain tissue.
- **Vessels:** Provides a better contrast to make enhanced vessels more easily visible.
- **Bone:** Good for viewing bone structures.
- **High-contrast:** Provides a high contrast view to make early hypodense changes more easily visible.

Window width and level can also be adjusted by right-clicking and dragging the mouse over the viewer, moving up/down (to change level) or left/right (to change width).

Series Details

The series date/time is presented in an overlay at the top left corner of the image view, along with viewing parameters such as slice thickness and slice number. Additional details are located in the Series tab. Some details are taken from the source DICOM series tags (e.g. study description) while others are derived from the software itself (e.g. algorithm version).

8.4 e-ASPECTS Display



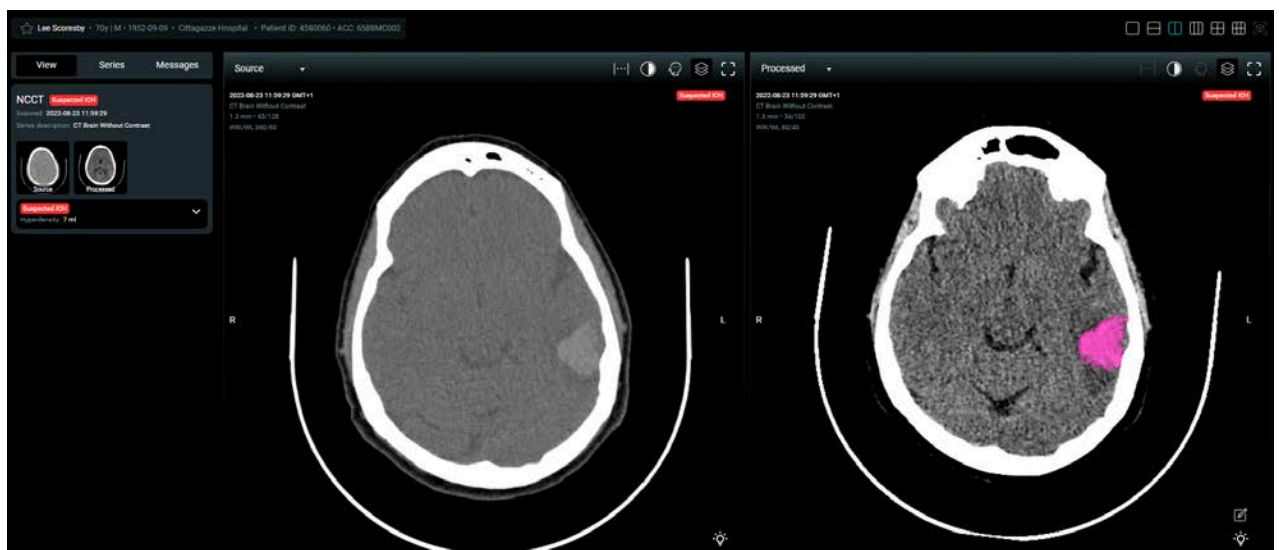
Results Summary

The ASPECTS score and related information are displayed on the Result Summary view. This contains the following information.

ASPECTS

This section shows the ASPECTS score calculated by e-ASPECTS and a list of regions which have been scored as containing acute hypodensity and have therefore reduced the ASPECTS score.

Volumes - Hyperdensity



Brainomix 360 e-ASPECTS will attempt to detect abnormal hyperdensities within a non-contrast CT scan. Abnormal hyperdensities refer to regions of elevated HU values within the brain, compared to what would normally be expected for a healthy brain CT scan. Common causes of such

hyperdensities in stroke suspect patients are acute bleeds, as fresh blood is typically more hyperdense than grey or white matter, or contrast leakage, although this should not be seen in a non-contrast CT scan if contrast agent was not recently administered.

If a hyperdense region is detected within the CT scan, the region will be segmented and displayed as an overlay, and the volume of the segmented region will be reported (in millilitres). Although this volume measurement should correctly correspond to the segmented region, the user must visually verify that the segmented region is correct with respect to the underlying hyperdensities in the image.

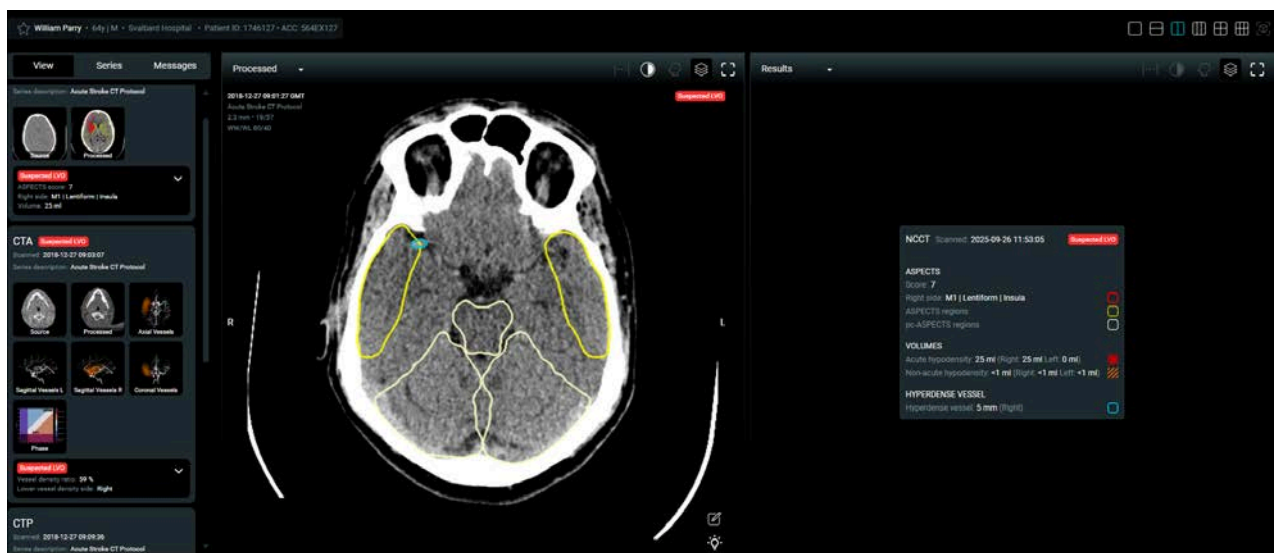
Note that this feature is separate from the vessel hyperdensity feature, which will attempt to identify occlusions or calcifications in vessels.

When a large hyperdense volume is detected, the hypodense volume, ASPECTS score, and hyperdense vessel results will be suppressed. If an administrator has enabled manual editing, this feature can be used to reinstate the suppressed results.

Volumes - Acute / non-acute hypodensity

The volume of hypodense signs in ml, as calculated by Brainomix 360 e-ASPECTS. This is a measure of the "heat map". The accuracy of the volume calculation will depend on the quality of the "heat map", which should be manually verified.

Hyperdense Vessels



e-ASPECTS attempts to identify localized vessel hyperdensities on non-contrast CT scans, typically indicative of occlusions (clots) or calcifications. Image properties such as the shape of hyperdensity and HU values within a hyperdense vessel are taken into consideration when classifying these features, with calcifications typically having higher and more sharply defined HU values compared to clots. The hyperdense area will be segmented and highlighted in results image output.

If one or more occlusions are detected, the length of the occlusion will be indicated based on a measurement of the longest axis of the segmented region associated with the occlusion. In the case where occlusions are detected on both hemispheres of a brain CT scan, the length measurements will be given per hemisphere.

Note that some hyperdensities may not be detected by the software, and false positives may also be flagged. It is also possible that these features are highlighted outside of vessels, in which case the hyperdensity would not be due to an occlusion, even if incorrectly detected as such.

Processed

The Processed view shows the CT image after processing and analysis with e-ASPECTS. The slices are annotated to show the segmentation of ASPECTS regions and identified hypodense or hyperdense signs.

Overlays

Individual overlays shown on the Processed view are as follows:

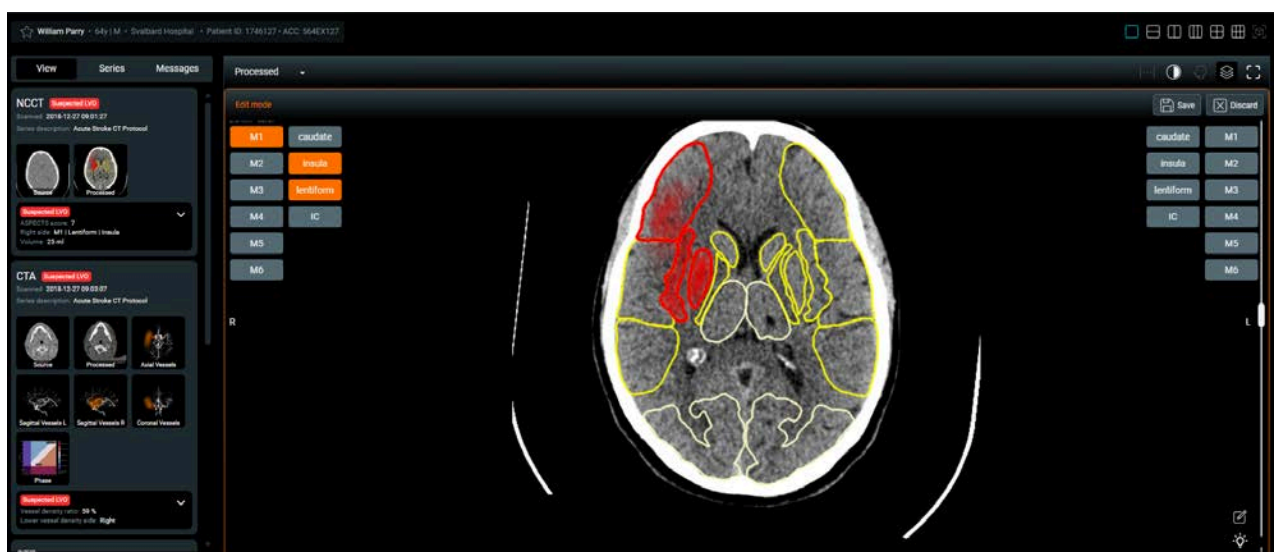
- **ASPECTS regions:** Shows the segmentation of ASPECTS regions.
- **Affected regions:** Highlights the ASPECTS regions scored as containing acute hypodense changes.
- **Acute hypodensity:** Highlights areas with acute hypodense changes.
- **Non-acute hypodensity:** Highlights areas with older hypodense changes which have been excluded by the e-ASPECTS algorithm.
- **Hyperdensity:** Highlights areas with abnormal hyperdense signs.
- **Hyperdense vessel:** Highlights hyperdense vessels detected as occlusions.
- **Calcification:** Highlights hyperdense vessels detected as calcifications.
- **pc-ASPECTS regions:** Shows the segmentation of pc-ASPECTS regions.
- **Mid-sagittal plane:** Shows the mid-sagittal plane indicator line.
- **Text annotations:** Shows the side indicators and other informational text overlays.

Warnings

If there is an exclamation mark icon in the Info or Series button, there are warnings from e-ASPECTS which may affect the accuracy of the score.

8.5 Manual results

If enabled by your administrator, you can edit the automatic result and save your own manual result on Brainomix 360.



You can edit the automatic result by saving your own score. Click the 'Edit' pencil icon in the bottom right of the image view to open the editing window.

Click the region names which should contribute to the ASPECTS score to calculate your manual ASPECTS score.

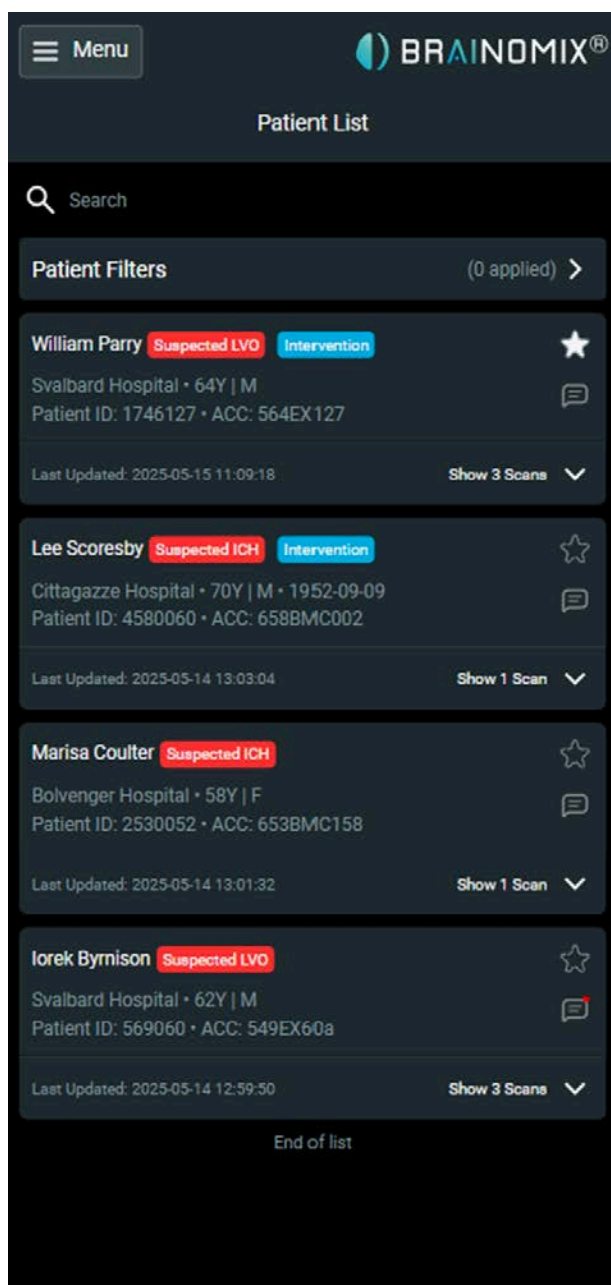
You can then choose to save or discard your result.

9 Mobile Display

9.1 Patient List

If you access Brainomix 360 or Brainomix 360 Cloud using your phone, you can view a list of all the patients. Tap a patient to open the Patient Viewer. Swiping down will refresh the patient list.

Press on the ☆ icon to mark a patient as a favourite, or on the ★ icon to unmark a favourite.



9.2 Patient Viewer

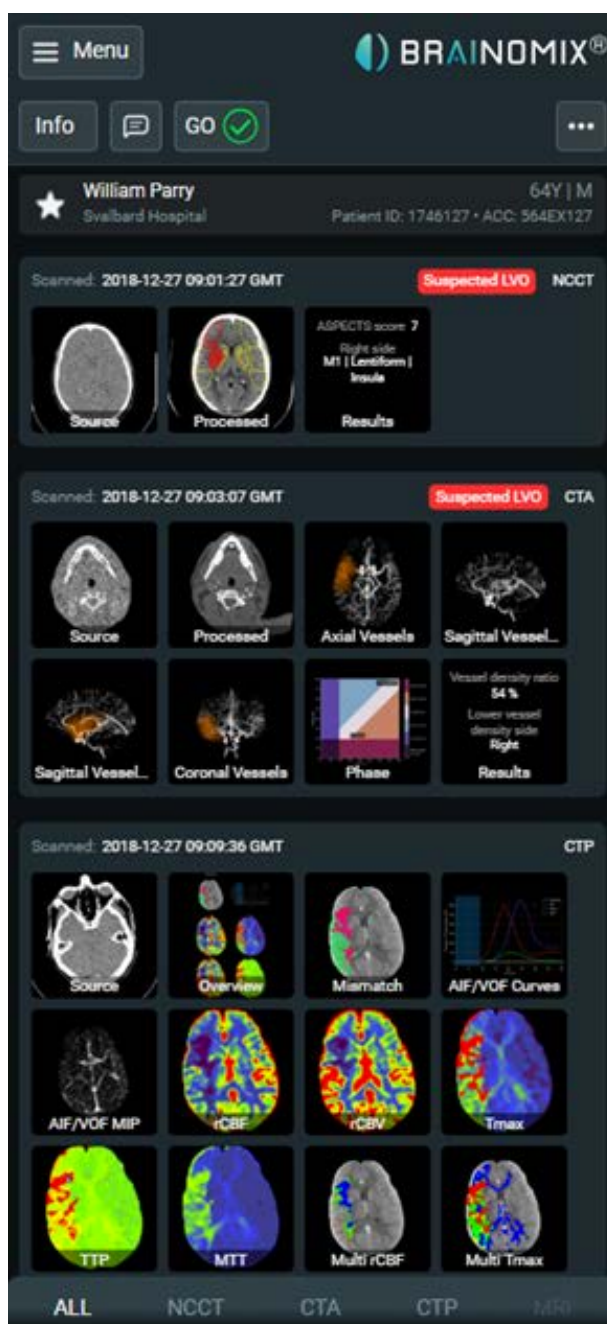
All series

When opening a patient from the patient list, you will arrive at the All Series view. Alternatively, if you are already in the viewer, tap the ALL button in the bottom left corner. You can see all the series and results for this patient, and navigate to any available view by tapping the thumbnail.

You can also use the modality-specific buttons at the bottom to go directly to the results view of a scan:

- NCCT: if available, view the non-contrast CT scan for this patient and any associated results
- CTA: if available, view the CT Angiogram for this patient and any associated results
- CTP: if available, view the CT Perfusion scan for this patient and any associated results
- MRI: if available, view MRI scans for this patient and any associated results

Note that the Brainomix 360 platform will show results from all licensed products. This screenshot shows results from other products in addition to e-ASPECTS.



Viewing scans

The viewer layout shows some patient-specific controls at the top, with access to:

- Info: view the full metadata for this scan, along with any processing warnings
- Messaging: view and send messages for this patient
- GO: flag this patient for intervention

Using pinch-to-zoom, you can zoom the scan to see it in more detail and you can move it around by dragging it with two fingers.



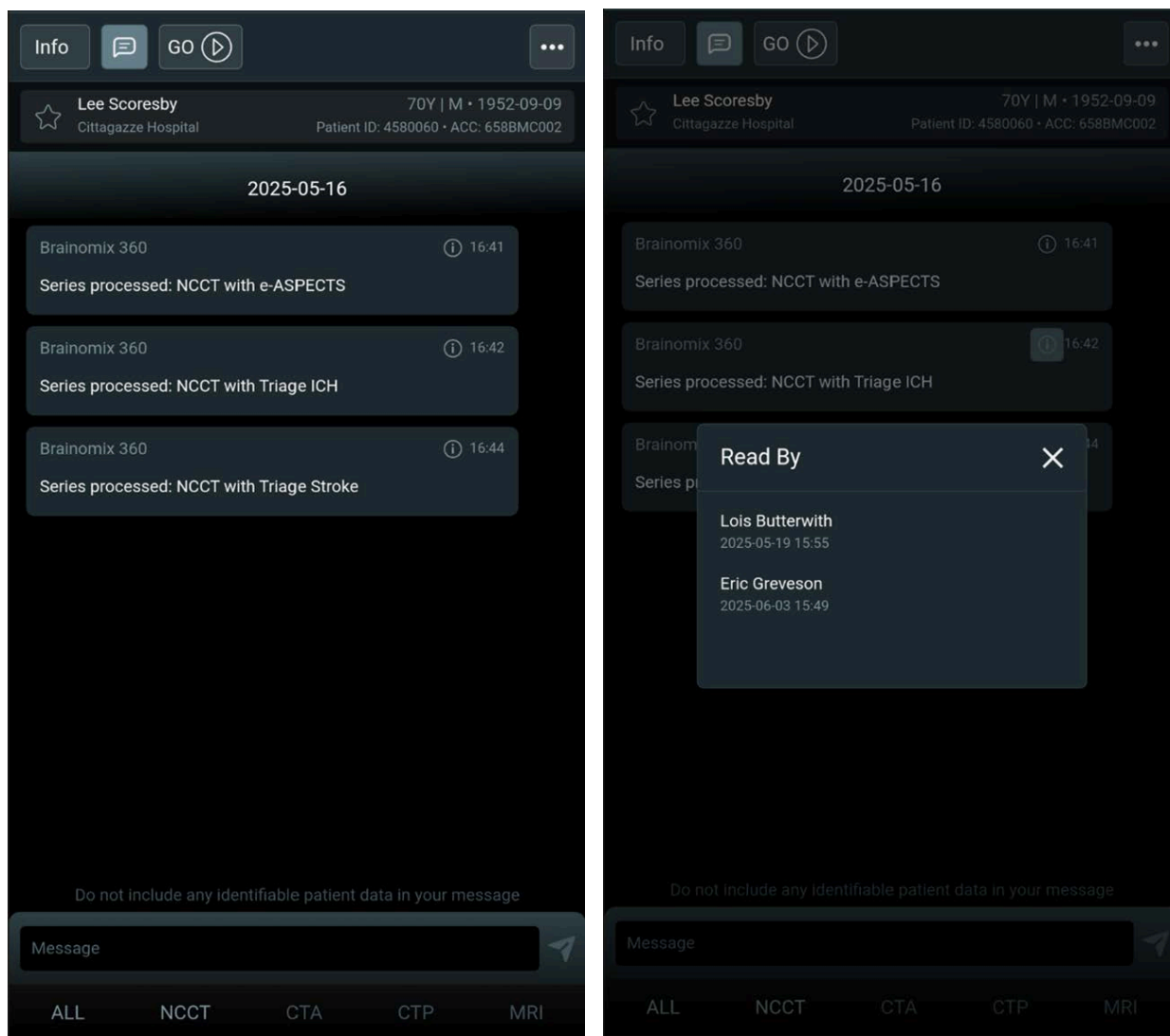
9.3 Messaging

If enabled by your system administrator, messages can be viewed and sent for a patient. As new messages arrive they can be viewed in the chat area and if configured, a mobile app notification will be sent to all registered users.

New messages will appear at the bottom of the chat area as they are received.

To send a message, type in the box at the bottom, and click the send button to the right.

To see who has read a message, click the info icon. To close the "Read By" list, click the close icon.



9.4 Flag a patient for intervention

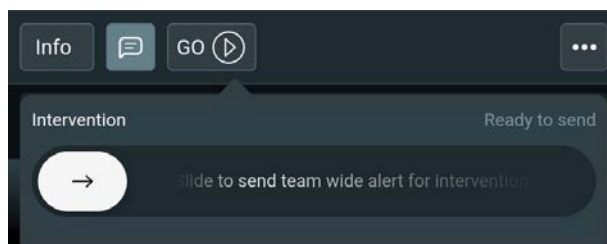
If this functionality is enabled by your system administrator, you can manually flag a patient for intervention from the patient viewer.

Press the "GO" button and slide to confirm. Any users with intervention notifications enabled will be notified that the patient has been flagged.

The flag can be cancelled if required, and users with intervention notifications enabled will be notified that it has been cancelled.

It is also possible to mark an intervention as Complete for an already-flagged patient.

Note that this is a purely manual communication tool, and this feature cannot be triggered using automated results.



10 Result Outputs

10.1 DICOM

If configured at your site, result DICOM series will be transferred to PACS over a DICOM network connection once processing has finished.

10.2 Cloud Sync

If configured at your site, full results will be synchronised to the Brainomix 360 Cloud service with optional pseudonymization. Results can be viewed on Brainomix 360 Cloud as if the scan had been processed there.

10.3 Mobile App Notifications

If sync with Brainomix 360 Cloud is enabled, push notifications can be configured to notify users of the Brainomix 360 Mobile app that a result is available.

11 Uploading and Processing

This section applies only to Brainomix 360. It is not possible to upload or process scans directly on Brainomix 360 Cloud.

11.1 Processing Scans

Workflows

Brainomix 360 can be configured to provide different workflows for use in the acute clinical pathway or for clinical studies. Each workflow can be configured to send results to different target DICOM devices.

Two default sets of workflows are supplied, "Acute" and "Study". The acute workflows are intended to process a small number of scans with high priority, while the study workflows are suited to processing large numbers of lower priority scans. If a scan is being processed by a study workflow when an acute scan is received, Brainomix 360 will pause it and process the acute scan before continuing.

For assistance in configuring your workflows and integration with external systems (PACS, CT scanners, email etc.), contact your local distributor or Brainomix support.

Manual DICOM Transfer

1. Ensure the source DICOM device (e.g. PACS or CT scanner) and the controlling application (e.g. PACS viewer) are configured with the Brainomix 360 server address and Application Entity Title for the appropriate Brainomix 360 incoming scan queue linked to the desired workflows (see above). Your system administrator should be able to help you configure these.
2. Use the controlling DICOM application to transfer a scan series to the Brainomix 360 server. Refer to the application's instructions for more information.
3. The Brainomix 360 server will automatically begin processing the series.
4. To monitor processing in your web browser:
 1. Go to the Brainomix 360 server address in your internet browser
 2. You will be prompted to log in if you have not used the application recently from your current web browser. Log in as described in the previous section.
 3. Select **Patient List** from the menu bar at the top of the page.
 4. The new scan should appear in the Patient List. If it does not, consult the DICOM log to check for errors.
5. If configured, DICOM results will be sent to PACS automatically when processing is completed. Use your PACS viewer to see these results.
6. Alternatively, click on the patient in the Patient List to view the results in your web browser.

Automatic DICOM Transfer

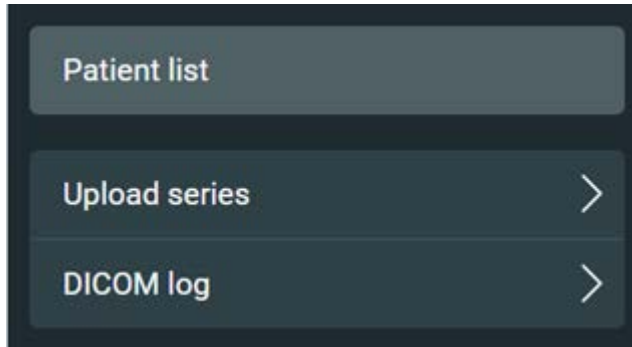
An external application may be configured to automatically transfer scan series to the Brainomix 360 server.

If configured, DICOM results will be sent to PACS automatically when processing is completed. Use your PACS viewer to see these results. In this configuration you do not need to use the Brainomix 360 web interface at all.

Alternatively, log in and the scans will appear in the Patient List as soon as they are queued for processing. Results can be viewed by clicking on a patient. The DICOM network activity can be monitored by viewing the DICOM log.

Manual Upload via Web Interface

1. Log in to Brainomix 360
2. Open the menu using the menu icon at the top of the page.
3. Select **Upload series** from the menu.



4. Select the appropriate incoming scan queue from the drop-down menu below the upload area. This setting will be set to use the study incoming scan queue by default.
5. Click **Select files** to select DICOM image files or compressed zip files containing DICOM images.
Tip: You can drag and drop files directly onto the upload area if the browser supports drag and drop.
Note: If you select too many files the browser will reject them. If this occurs, you should compress the DICOM images into a single zip file and upload that instead.
6. Your files will be uploaded and indexed. If there are a very large number of files this may take several minutes.
7. Scans will be routed to a workflow automatically. When uploading completes, click **OK**.
8. When processing completes, results emails and DICOM results will be sent automatically as configured for the workflow.
9. Click on the patient in the Patient List to view the results in your web browser.

11.2 The DICOM log

Click on the "DICOM log" link to view a log of DICOM series requested, received and sent by the Brainomix 360 server.

DICOM Log

Search for a Patient ID, Patient Name, Accession number, Series instance UID or Internal patient UID:

Search

Filter by event type

☒ Select all

☒ Series requested

☒ Series received

☒ At least one workflow can process the series

☒ No workflows can process the series

☒ Upload failed

☒ Transfer failed

☒ Series sent to external system

☒ New series was found by querying the external system

Filter by dates

2025-07-31

-

2025-08-20

Time	Patient ID	Name	Accession number	
2025-08-08 09:52:28 BST	ID1A	Name 1A	2010357	View
Series instance UID	1.3.12.2.1107.5.1.4.24320.4.0.5219886421837613			
Description	Transfer failed			
Details	Exception while processing command 'store': Association Request Failed: 0006:031c TCP Initialization Error: No route to host			
Internal patient UID	bdb17958-83f8-4a35-abc0-e50eae5d335b			

12 Administration

Administrator users have extra features available to them for managing users, deleting scans and configuring the integration of the Brainomix 360 system into the clinical workflow. In general, these settings will not need to be changed and incorrect settings may result in data loss, incorrect operation or compromised security. If you require assistance with the integration of your Brainomix 360 system into your clinical workflow, please contact your local distributor or Brainomix support.

13 Troubleshooting

In case of any issues encountered during use or if presented with any error messages, contact your local administrator or Brainomix support at one of the contact options indicated in the Regulatory Information section.

14 Service Maintenance and Upgrades

In the event of a planned maintenance, Brainomix will inform impacted users in advance that maintenance work is being carried out and what level of interruption to service is expected. User access may be denied during the maintenance window. If the Brainomix 360 Mobile app is installed on a mobile device, ensure to update to the latest version when prompted or made available on the Google Play or the Apple App Store.

15 Incident Reporting

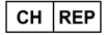
Please contact us via support@brainomix.com (<mailto:support@brainomix.com>) if you have discovered a potential issue with any of our Brainomix 360 suite services. Note that any information you submit will be governed by our Privacy Policy (https://www.brainomix.com/privacy-eu/#:~:text=For%20users%20of%20Brainomix%20products,in%20order%20to%20provide%20support.)). If a serious incident has occurred in relation to any of our products, please also report it to the local competent authority of your country:

- Member States of the European Union (<https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human>)
- United Kingdom of Great Britain and Northern Ireland (<https://www.gov.uk/report-problem-medicine-medical-device>)
- Switzerland (<https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas/users---operators.html>)
- Türkiye (<https://www.titck.gov.tr/>)

16 Decommissioning

In the event of discontinuation and removal of service, Brainomix will coordinate the process with the relevant stakeholders at your organization to ensure smooth and complete removal of the Brainomix 360 system, including any assets and data. The impact of removal will be assessed to determine whether it will result in changes to your clinical workflow and/or the configuration of other systems. Any assets owned by Brainomix will be reclaimed and integrations will be removed from the system to ensure there is no more data transfer taking place to or from the to be decommissioned asset(s). For more information on the process of decommissioning of your Brainomix 360 system, please contact your local distributor or Brainomix support.

17 Symbols

Symbol	Description of symbol
	Indicates the medical device manufacturer's name and address.
	Indicates the date when the medical device was manufactured.
	Indicates the carrier that contains unique device identifier information.
	Indicates the authorized representative in the European Community.
	Indicates the authorized representative in Switzerland.
	Indicates the entity importing the medical device into the locale.
	Indicates the need for the user to consult the instructions for use.
	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.
	Indicates the item is a medical device.
	CE marking indicates that a product complies with the applicable European Union regulations.

18 Request a Paper Copy

Should you require a printed hard copy of this revision of the user manual of Brainomix 360 e-ASPECTS, please consider printing out this webpage (right click + Print or download the latest revision from our website (<https://www.brainomix.com/docs/>)). If this option is not available for you, please contact us via support@brainomix.com (<mailto:support@brainomix.com>) with your request and a printed copy will be sent to you within 7 calendar days of the receipt of request. This service is provided free of charge.