

# e-CTA<sup>®</sup>

## User Manual

### Version 14.1

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e-CTA is part of Brainomix 360

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

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# Regulatory Information

|                                                                                     |                                                                                                              |                                                                                             |                                                                                                                |
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# 1 Introduction

## 1.1 Overview

Brainomix 360 e-CTA (referred to throughout as both "Brainomix 360 e-CTA" and "e-CTA") is a software medical device for processing 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, brain CTA 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 CTA-CS

The CTA-CS score (Tan et al., AJNR, 2009) (<http://www.ajnr.org/content/30/3/525>) is a scale from 0 to 3, where 0 represents no collaterals in the area affected by the stroke, and 3 indicates excellent collaterals.

| CTA-CS | Description                                                                                                                       |
|--------|-----------------------------------------------------------------------------------------------------------------------------------|
| 0      | No collaterals (collateral supply filling less than 10% of affected MCA territory compared to contralateral hemisphere)           |
| 1      | Poor collaterals (collateral supply filling between 10% and 50% of affected MCA territory compared to contralateral hemisphere)   |
| 2      | Good collaterals (collateral supply filling between 50% and 90% of affected MCA territory compared to contralateral hemisphere)   |
| 3      | Excellent collaterals (collateral supply filling greater than 90% of affected MCA territory compared to contralateral hemisphere) |

Note that some of these thresholds, in particular the 10% and 90% thresholds, are different from those originally described in the Tan et al. paper, where corresponding thresholds of 0% and 100% were used instead. However, the modified thresholds are more practical to enable use of the CTA-CS 0 and 3 scores on real CTA scans.

The phase of CTA image acquisition on single-phase baseline CTA is assessed in accordance with the methodology used by Rodriguez-Luna et al. (<http://stroke.ahajournals.org/content/45/3/734.long>), described in the table below. The phase (early arterial, peak arterial, equilibrium, peak venous, late venous) is determined by evaluating Hounsfield units (HU) on the contralateral (unaffected)

vasculature at the MCA M1 branch and straight sigmoid sinus vein. The contralateral vasculature was chosen to measure the HU to minimize the potential impact from any proximal occlusion on the ipsilateral side.

| CTA acquisition phase | Arterial HU                                                | Venous HU                        |
|-----------------------|------------------------------------------------------------|----------------------------------|
| Early arterial        | Higher than venous vasculature                             | Less than or equal to 190        |
| Peak arterial         | At least 100 higher than venous vasculature                | Greater than 190                 |
| Equilibrium           | Less than 100 higher than, or equal to, venous vasculature | Greater than 190                 |
| Peak venous           | Greater than 190                                           | Higher than arterial vasculature |
| Late venous           | Less than or equal to 190                                  | Higher than arterial vasculature |

## 1.3 Large vessel occlusion (LVO) detection

Brainomix 360 e-CTA will attempt to detect large vessel occlusions in brain CTA images. The software will attempt to find occlusions in the ICA-T, MCA M1 and proximal MCA M2 arteries. Note that the software will not attempt to detect occlusions in other vessels, such as the ACA or posterior arteries. Positive detections will be highlighted on the image viewer (see e-CTA display for details).

It is important to note that the software may generate false positives (highlighting an occlusion where there is none) and false negatives (failing to highlight an occlusion that is present in the image), and results must be manually verified.

## 2 Intended Use

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

Brainomix 360 e-CTA is an image processing software package to be used by trained professionals, including stroke physicians, neurologists, and radiologists, for decision support. 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 browser interface.

Brainomix 360 e-CTA provides both analysis and viewing capabilities for brain CT Angiography datasets of stroke patients. The analysis capabilities are for detection of changes in the image related to acute stroke, including assessment of collateral status, and visualization of these changes.

### 2.1 Indications

1. Brainomix 360 e-CTA is indicated as an aid to assess the presence or absence of intracranial arterial occlusion.
2. Brainomix 360 e-CTA is indicated for use on contrast enhanced CT Angiography scans for these patients as a decision support tool, providing automated image analysis, scoring the extent of collaterals and identifying large vessel occlusion.

### 2.2 Contraindications

- Brainomix 360 e-CTA is not suitable for use on brain scans containing evidence of haemorrhage (intracranial, sub-arachnoid, etc).
- Brainomix 360 e-CTA is not suitable for use on patients with posterior circulation stroke.
- Brainomix 360 e-CTA is not suitable for use on images that contain coils, shunts, embolization or movement artifacts.
- Brainomix 360 e-CTA is not suitable for use on brain scans displaying neurological pathologies other than acute ischaemic stroke, such as tumours or abscesses.
- Brainomix 360 e-CTA is not intended to be used for analysing CTA images in intracranial vascular pathologies such as arterial aneurysms, arteriovenous malformations or venous thrombosis.

### 2.3 Warnings

|                                                                                     |                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Brainomix 360 e-CTA should not be used as sole basis for diagnosis. The output should not be considered as a definitive diagnosis. Brainomix 360 e-CTA should only be used by a trained professional with an understanding of CT image interpretation, as an aid to interpret images for estimation of collateral status. |
|  | Brainomix 360 e-CTA 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.                                                                                                                                   |

|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Before evaluating the processing results, the accuracy of the collateral status should be reviewed. If there is any disagreement or concern with the quality of the collateral score, users should disregard the results.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|    | Brainomix 360 e-CTA may not correctly identify collaterals in every scan, and may generate false positives or false negatives. The users should use their own expertise in CTA image analysis to verify that the software's output is correct.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|    | Brainomix 360 e-CTA is not intended for primary interpretation of CT images. It is used to assist physician evaluation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|    | Brainomix 360 e-CTA 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-CTA, users should not share access credentials and should log-out when not using the system.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|    | Users accessing the Brainomix 360 e-CTA web user interface must ensure that they perform any analysis or diagnostic image review using an approved radiology viewing display.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|   | Brainomix 360 e-CTA is not intended for diagnostic image review when accessed from mobile devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|  | In the event Brainomix 360 e-CTA 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|  | <p>A notification may not be generated or may be delayed for several reasons, including but not limited to:</p> <ul style="list-style-type: none"> <li>▪ Algorithmic data problems or processing errors during the analysis of scans (see Precautions for more information)</li> <li>▪ Artifacts, motion or other factors reducing registration quality</li> <li>▪ Lack of disk space to process new scans</li> <li>▪ Underlying server platform failure</li> <li>▪ Slow network connectivity <ul style="list-style-type: none"> <li>▪ Slow connectivity from scanner/PACS to the Brainomix 360 server</li> <li>▪ Slow connectivity to the Brainomix 360 Cloud service over the internet</li> </ul> </li> <li>▪ Delays in the Apple or Google mobile notification services</li> <li>▪ Poor signal on the receiving mobile device</li> <li>▪ Power saving modes of some mobile devices may delay notifications</li> </ul> |

## 2.4 Precautions

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | The performance of Brainomix 360 e-CTA is limited by the quality of the input CT image. If Brainomix 360 e-CTA 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. The user of e-CTA should also monitor the image quality used for automated analysis in general, e.g. concerning motion artifacts. |
|  | Brainomix 360 e-CTA 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.                                                                                                                                                                                                                                      |
|  | The user should monitor the circumstances of contrast injection, which is also mandatory for medical reasons.                                                                                                                                                                                                                                                                                                                                                                                        |
|  | Brainomix 360 e-CTA 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 clinical benefits of e-CTA are, as follows:

- To provide a reference CTA collateral score with the sensitivity and specificity at the level of an expert.
- To support informed clinical decisions by providing fast and accurate identification and localisation of large vessel occlusions.

## 2.6 Use Environment

Brainomix 360 e-CTA 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-CTA, installation of the software and training for its user(s) are required.

### 3.1 Installation

Brainomix 360 e-CTA 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-CTA 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-CTA requires competency in the analysis and interpretation of brain CTA scans of patients with acute ischaemic stroke. Training in the use of the software 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) (<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<br>Screen size: 13.3 inches and above<br>Screen resolution: 1024 x 768<br>Processor: Intel or AMD CPU |
| Tablet                           | Memory: 2GB RAM<br>Screen size: 9.4 inches and above<br>Screen resolution: 2048 x 1536                                |
| Mobile phone (iPhone or Android) | Memory: 2GB RAM<br>Screen size: 4.7 inches and above<br>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)                                       | ≤ 2 minute (after retrieval from the PCS or from upload completion) |
| LVO Detection Sensitivity                                        | Proximal occlusions (ICA-T/M1) > 85%                                |
| LVO Detection Specificity                                        | Proximal occlusions (ICA-T/M1) > 90%                                |
| Collateral Score agreement with experts                          | Intraclass correlation coefficient > 70%                            |
| Sensitivity for detection of favourable collateral flow (CS 2-3) | > 65%                                                               |
| Specificity for detection of favourable collateral flow (CS 2-3) | > 90%                                                               |

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-CTA 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-CTA software is designed to work with contrast-enhanced CT scans sent via the DICOM protocol. These scans should have the following characteristics:

|                              |                                                                                                                                                  |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Slice thickness</b>       | 1mm maximum slice thickness                                                                                                                      |
| <b>Acquisition volume</b>    | Full brain acquisition (e.g. arch-to-vertex in a single sequence, or cerebrum sequence)                                                          |
| <b>Reconstruction method</b> | Soft tissue kernel (no excessive smoothing). Iterative, deep learning or FBP reconstruction may be used as long as kernel size is not too large. |
| <b>Bolus timing</b>          | Peak arterial or equilibrium phase (good acquisition timing) preferred                                                                           |

Use of thicker slices or other reconstruction methods (e.g. iterative reconstruction) can lead to the introduction of image artifacts, and consequently reduced scoring performance.

Cropped acquisition (e.g. missing top part of the skull) can reduce scoring performance.

If the acquisition phase is too early, the contrast will not have had time to reach all areas of the brain tissue and results may be computed incorrectly. Likewise, if the acquisition phase is too late, the contrast in arteries may be too low for the software to compute results accurately.

## 6 Cybersecurity

Brainomix 360 e-CTA 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-CTA is embedded, or to any other form of unauthorized access.

Brainomix 360 e-CTA 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-CTA 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-CTA 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-CTA 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-CTA 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-CTA 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-CTA, 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-CTA depends on the security infrastructure of the hospital network environment, best practice by users and management by Administrators.

Brainomix 360 e-CTA 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).

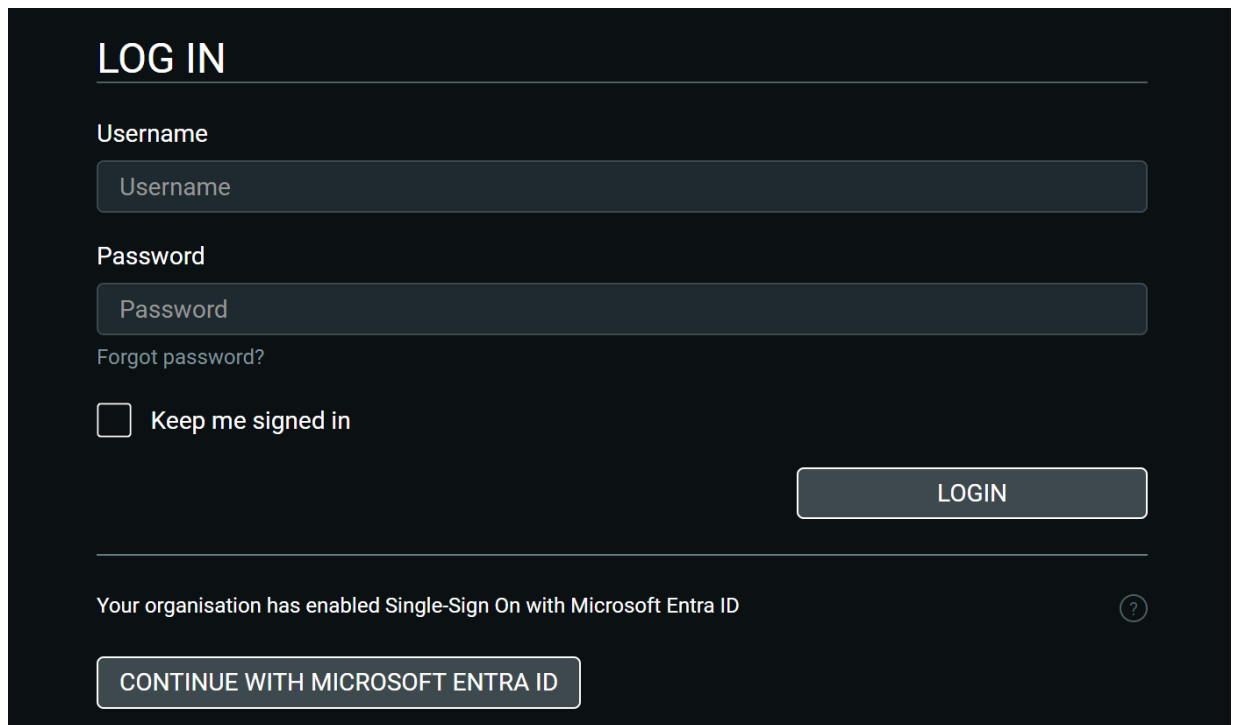
Client machines used to access the server hosting Brainomix 360 e-CTA should also be protected by antivirus/antimalware software and IDS and should be kept up to date with security patches and updates.

# 7 Access Control and Notifications

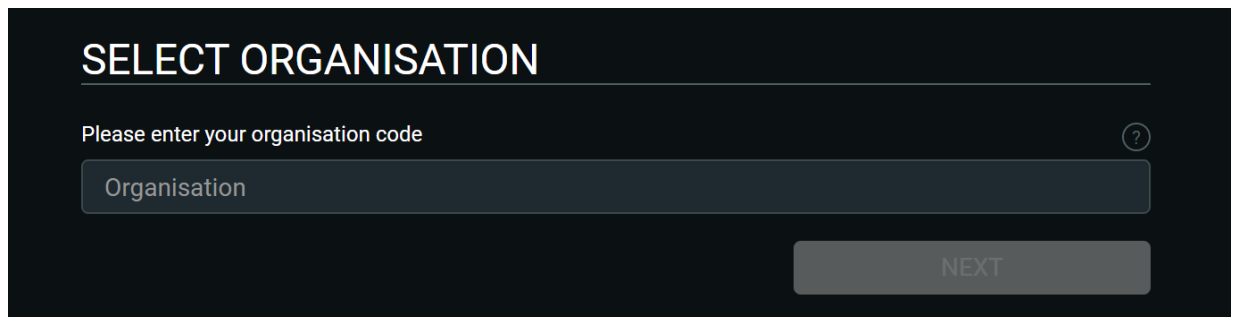
## 7.1 Logging In

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.

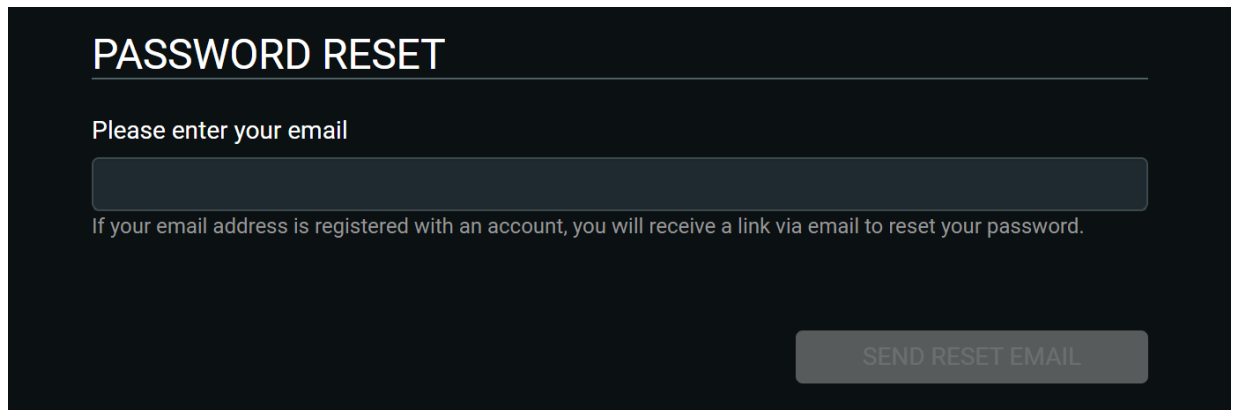
Brainomix 360:

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

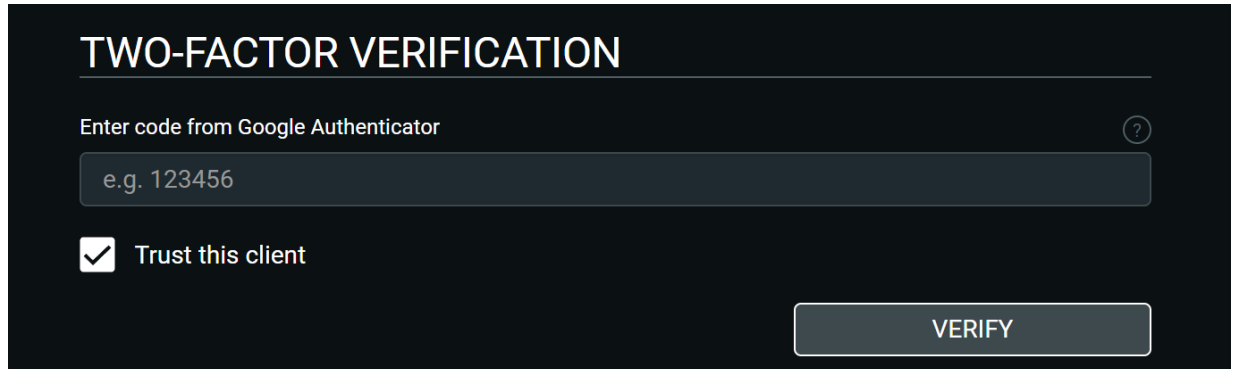
Brainomix 360 Cloud:

The image shows the 'SELECT ORGANISATION' screen for Brainomix 360 Cloud. It has a dark background with white text. The title 'SELECT ORGANISATION' is underlined. Below it is a prompt 'Please enter your organisation code' followed by a question mark icon. There is a single input field labeled 'Organisation'. At the bottom right, 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.



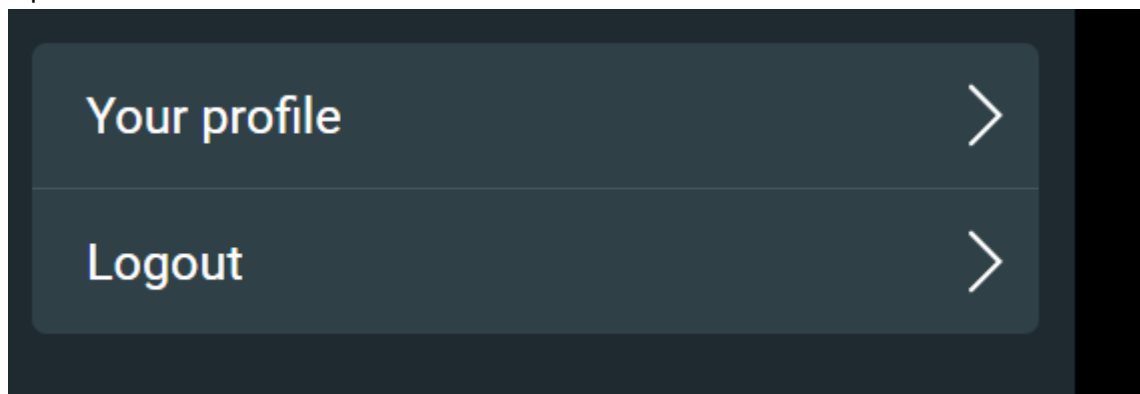
4. If you have enrolled in two-factor authentication, you may be prompted to enter a token code from your authenticator app.



- 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

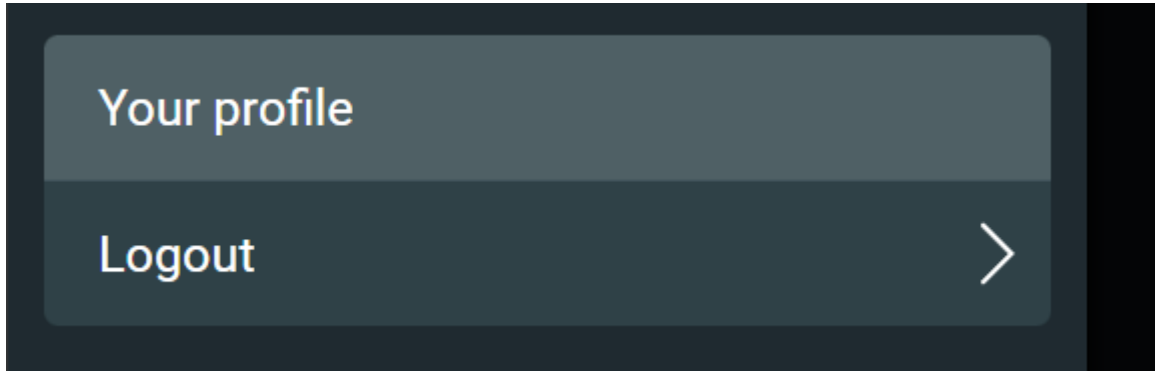
1. Open the Menu and scroll to the bottom.



2. Click **Logout**

## 7.3 Changing Your Password

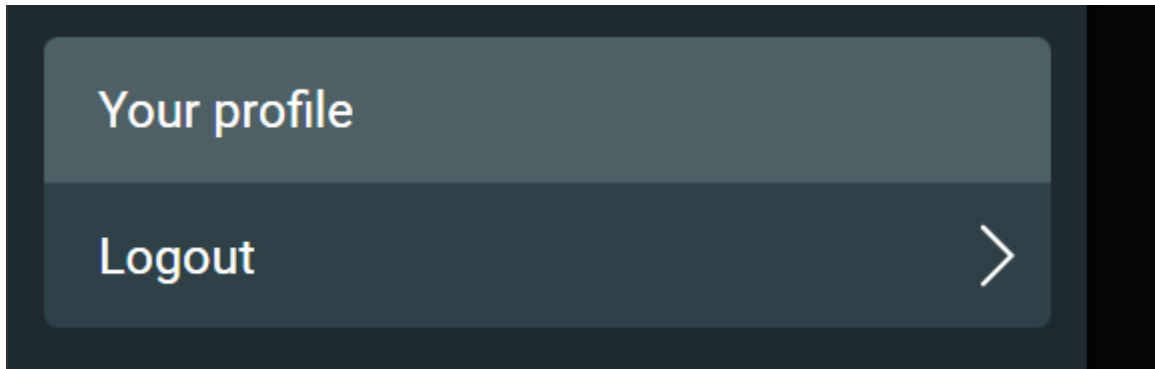
1. Open the Menu and scroll to the bottom.



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.

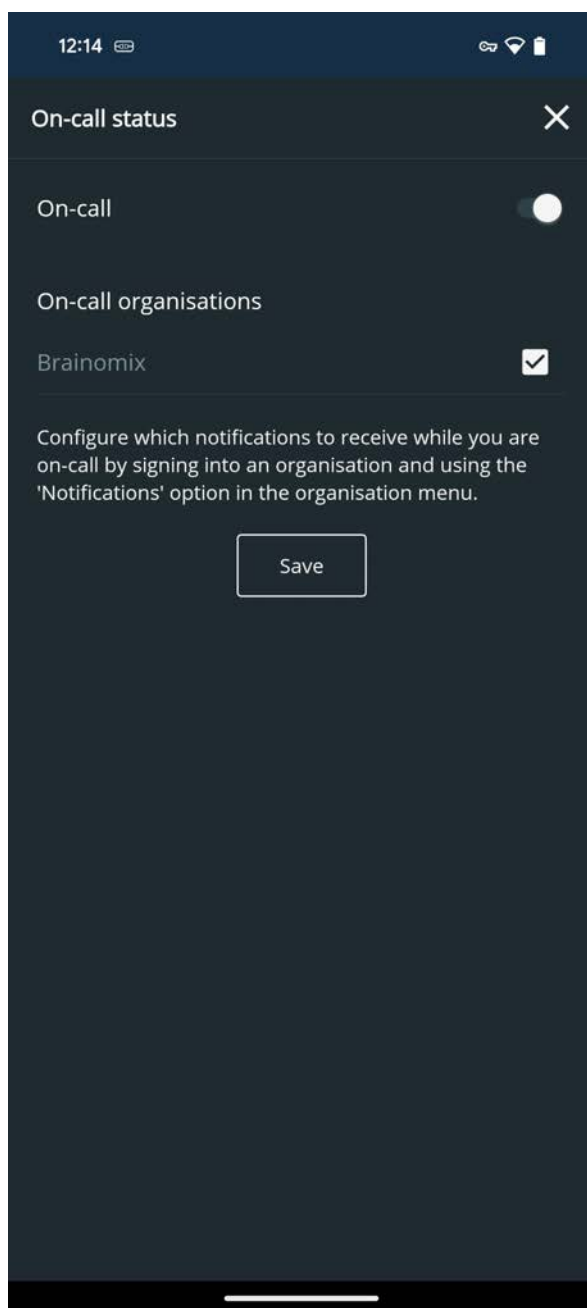


2. Click **Your profile**
3. Click on the tab labelled **Two-factor authentication**
4. Click the **enroll** button.
5. Follow the on-screen enrollment instructions.

## 7.5 On-Call Status

### Configuration

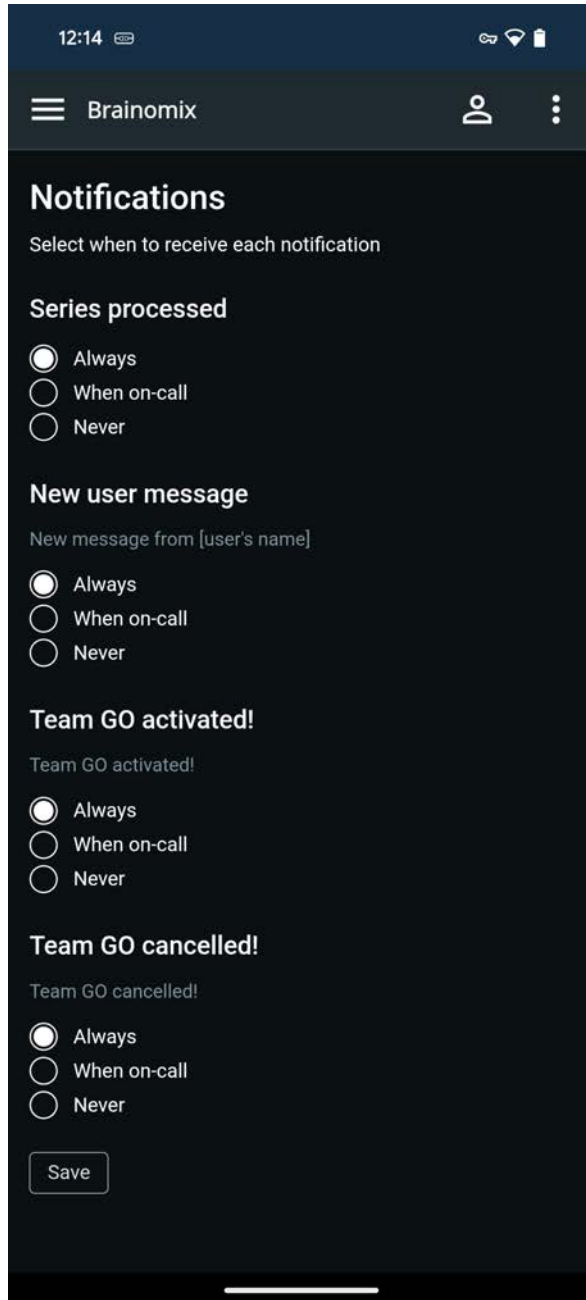
1. Your on-call status can be configured through the app. You can choose to be on-call or not, and which organisations you are going to be on-call for.



## 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

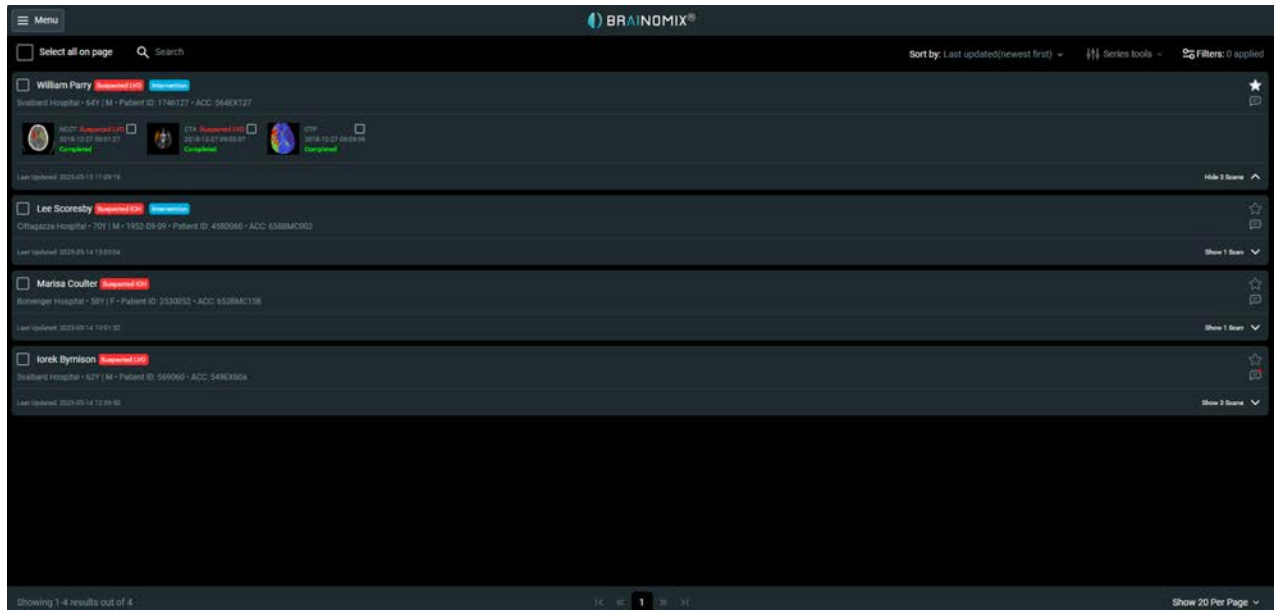
- Launch the Settings app.
- Tap Notifications.
- Scroll to Brainomix 360 Mobile > Tap.
- Toggle the **Allow Notifications** switch to **On** to enable notifications.
- Toggle the **Time-Sensitive Notifications** switch **On** (notifications are always delivered immediately and remain on the Lock Screen 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.

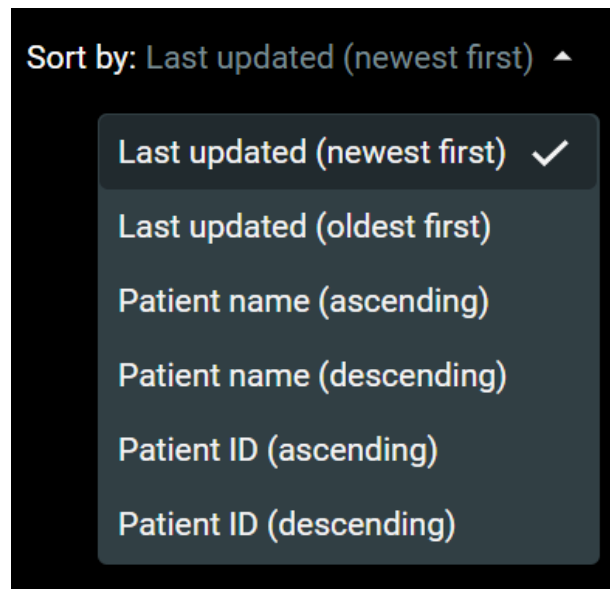
## 8.2 Finding Patients

### Sorting

Sort the patient list by clicking the Sort by button.

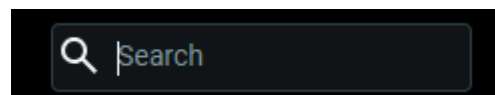
Sort by: Last updated(newest first) ▾

Select a sort preference from the drop-down list.



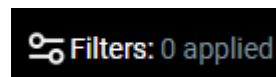
### Search

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.

**FILTERS** ✕

**FAVORITES** ^

☐ Show Favorites

**TRIAGE NOTIFICATION(S)** ^

☐ Suspected ICH Detected Suspected ICH

☒ Suspected LVO Detected Suspected LVO

**DELETED SERIES** v

**LAST UPDATED** ^

☐ All

☐ Last hour

☐ Last 6 hours

☒ Last 24 hours

☐ Last 48 hours

☐ Select date range... [Edit dates](#)

**INSTITUTION NAME** v

**STATE** v

**WORKFLOW** v

**SCANNER** v

Clear Filters

## 8.3 Patient Viewer

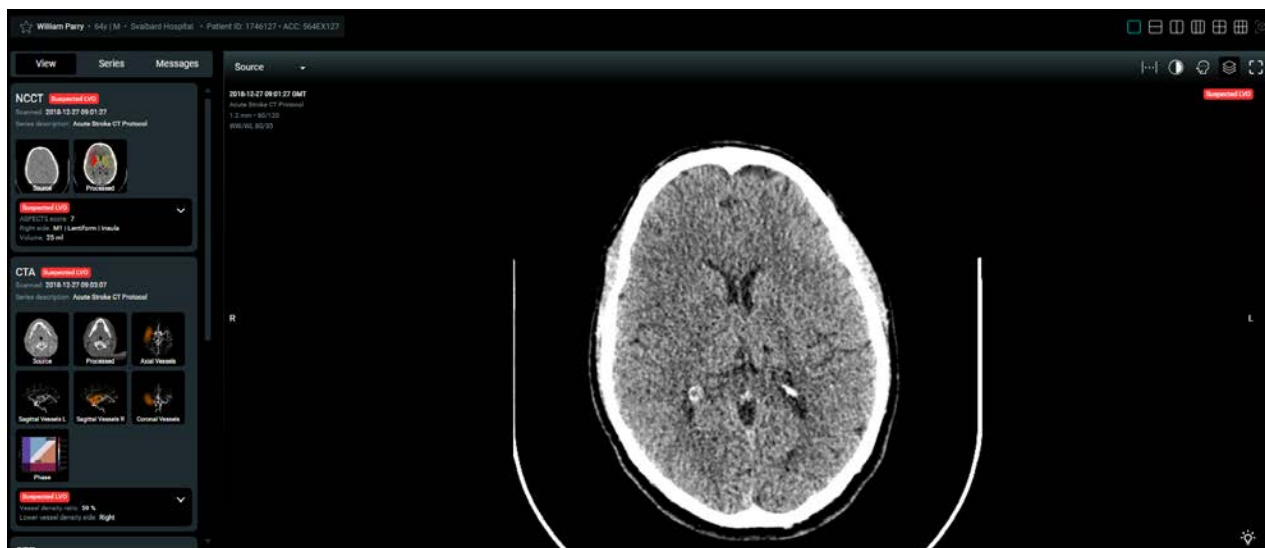
### Overview

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:

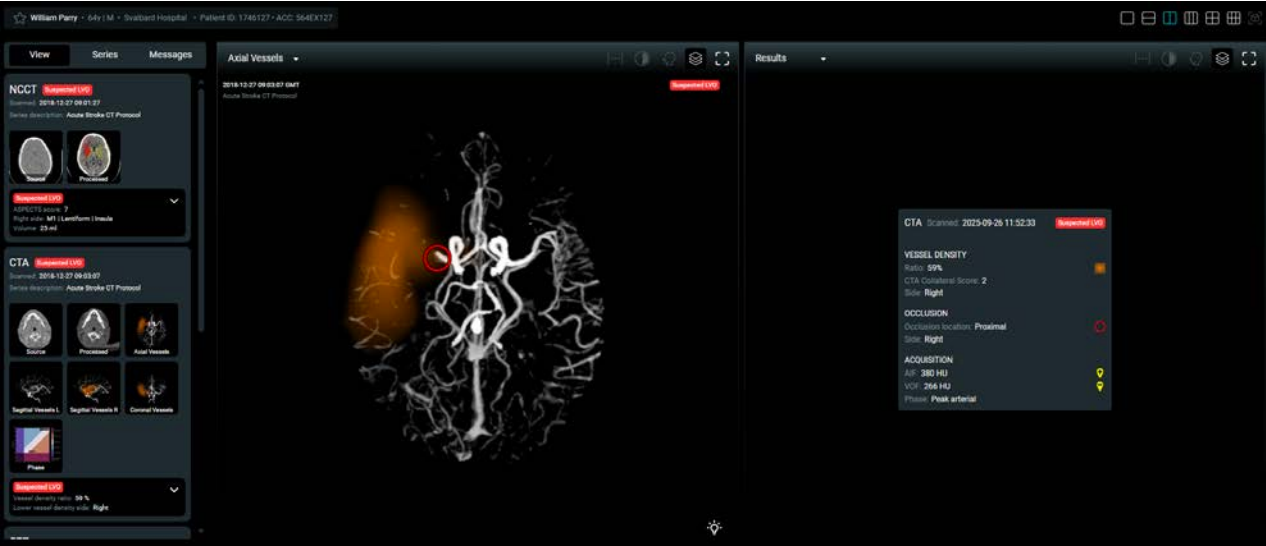
- **Tissue:** Provides a good overall view of brain tissue.
- **Vessels:** Provides a better contrast to make enhanced vessels more easily visible.
- **Bone:** Good for viewing bone structures.
- **High-contrast:** Provides a high contrast view to make early hypodense changes more easily visible.

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-CTA Display



# Result Summary

The results of the e-CTA analysis are displayed on the Result Summary view. This contains the following information.

## Vessel Density

The vessel density ratio on the affected side is used to calculate the CTA Collateral Score, as follows:

| CTA Collateral Score | Description                                                                                                                       |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| 0                    | No collaterals (collateral supply filling less than 10% of affected MCA territory compared to contralateral hemisphere)           |
| 1                    | Poor collaterals (collateral supply filling between 10% and 50% of affected MCA territory compared to contralateral hemisphere)   |
| 2                    | Good collaterals (collateral supply filling between 50% and 90% of affected MCA territory compared to contralateral hemisphere)   |
| 3                    | Excellent collaterals (collateral supply filling greater than 90% of affected MCA territory compared to contralateral hemisphere) |

## Occlusion

This section shows the detected side of the brain where the CTA Collateral Score indicates a lack of collaterals. If an LVO has been detected, the details of the vessel and the location will be displayed here.

## Acquisition

This section shows the computed CTA acquisition phase for single-phase CTA scans. Possible phases (earliest to latest) include: early arterial, peak arterial, equilibrium, peak venous, and late venous. For a full definition, see section CTA acquisition phase. Scans acquired in early or late phases may lead to inaccurate collateral assessment. The AIF and VOF measurement values are also displayed.

## Vessel MIP Images

Maximum intensity projections of the detected vascular system in axial, coronal and left and right hemisphere sagittal views are available to view. Switch between them using the title menu on the MIP image. You can access all the MIP images, the results scan and the unannotated scan from this menu.

An orange shaded vessel density map will be displayed as an overlay on the MIP image where the vessel density ratio is lower than the contralateral side. Stronger orange shading corresponds to a greater local decrease in vessel density.

If an LVO has been detected, its location will be displayed on these images as a red circle.

## Phase Assessment Graph

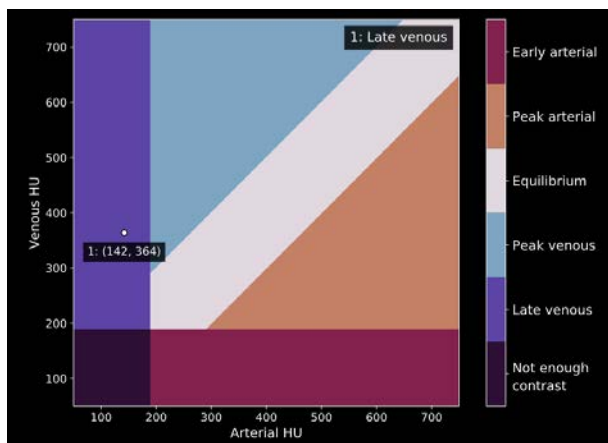
Visualisation of the CTA acquisition phases based on the AIF and VOF measurements. The acquisition phase thresholds are defined in the CTA acquisition phase section.

For best algorithm performance, AIF and VOF measurements between 400-700 HU are preferred, with higher values generally being better. Contrast levels outside this range may adversely affect algorithm performance.

### Single Phase

In a single-phase acquisition the best phases for occlusion detection are early and peak arterial. Vessel density can be assessed best from peak arterial and equilibrium phases. If the scan is in a venous phase or no contrast is detected, then the analysis will not be accurate.

Below is an example of a late single-phase acquisition which is likely to give inaccurate results:



## Processed

The Processed view shows the CT image after processing and analysis with e-CTA. The slices are annotated to show the vessel density, major vessels, arterial input location and venous output location, and any LVO that has been detected.

# Overlays

Individual overlays shown on the Processed view are as follows:

- **Vessel density:** Highlights areas where a lack of contrast has been detected.
- **Major vessels:** Colour-codes the large vessels supplying the brain.
- **Occlusion location:** Shows the point where an occluded vessel has been detected.
- **Arterial input function location:** Shows the voxels used to compute the arterial input contrast.
- **Venous output function location:** Shows the voxels used to compute the venous output contrast.
- **ASPECTS regions:** Shows the segmentation of ASPECTS regions.
- **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.

## 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 the ASPECTS score, acute and non-acute ischemic changes in the ASPECTS regions are not computed by e-CTA.

## 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-CTA.

## Warnings

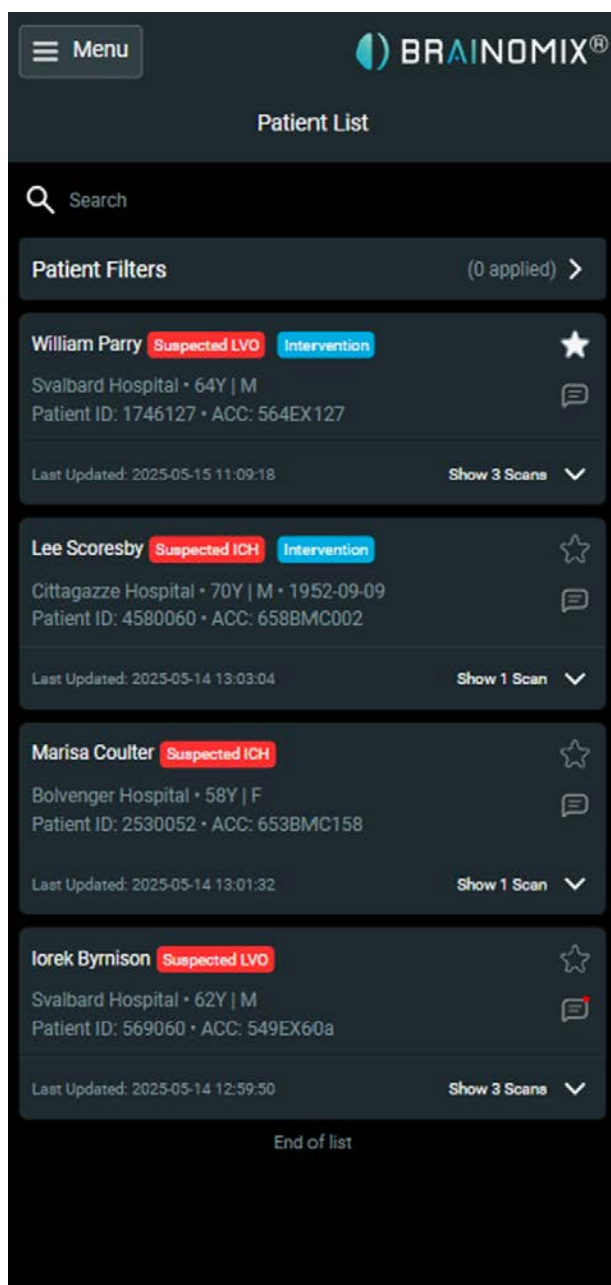
If there is an exclamation mark icon in the Info or Series button, there are warnings from e-CTA which may affect the accuracy of the score.

# 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

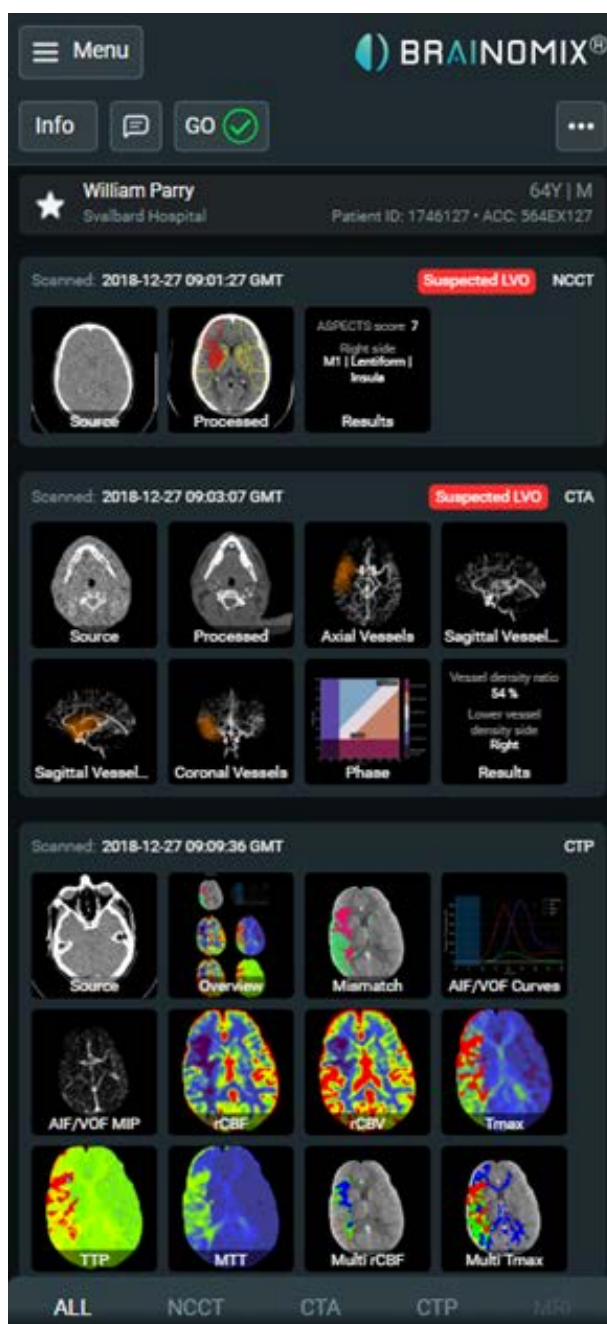
## All series

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-CTA.

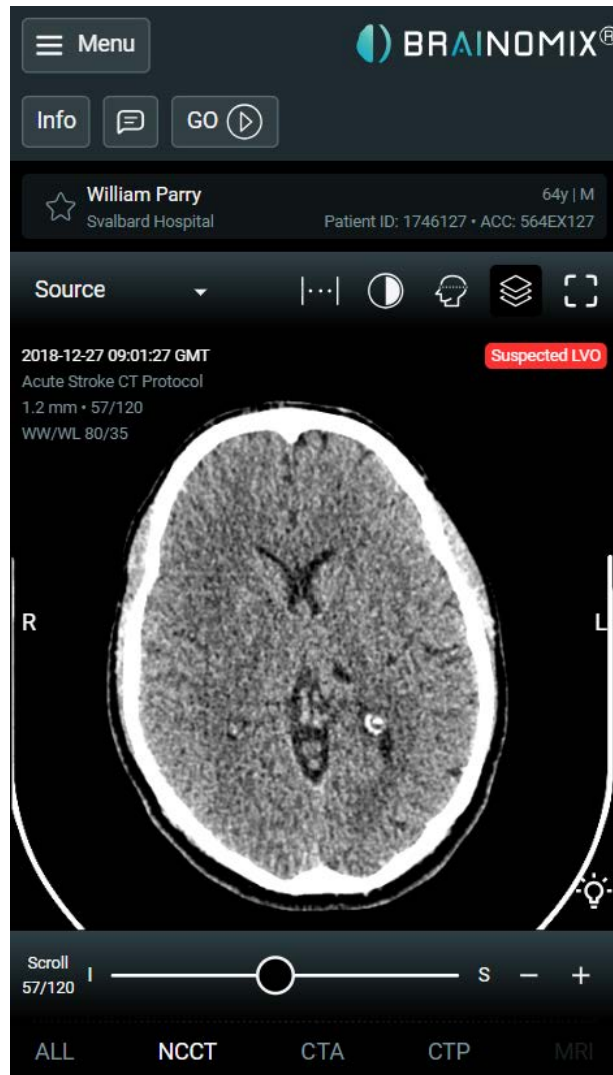


## Viewing scans

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.



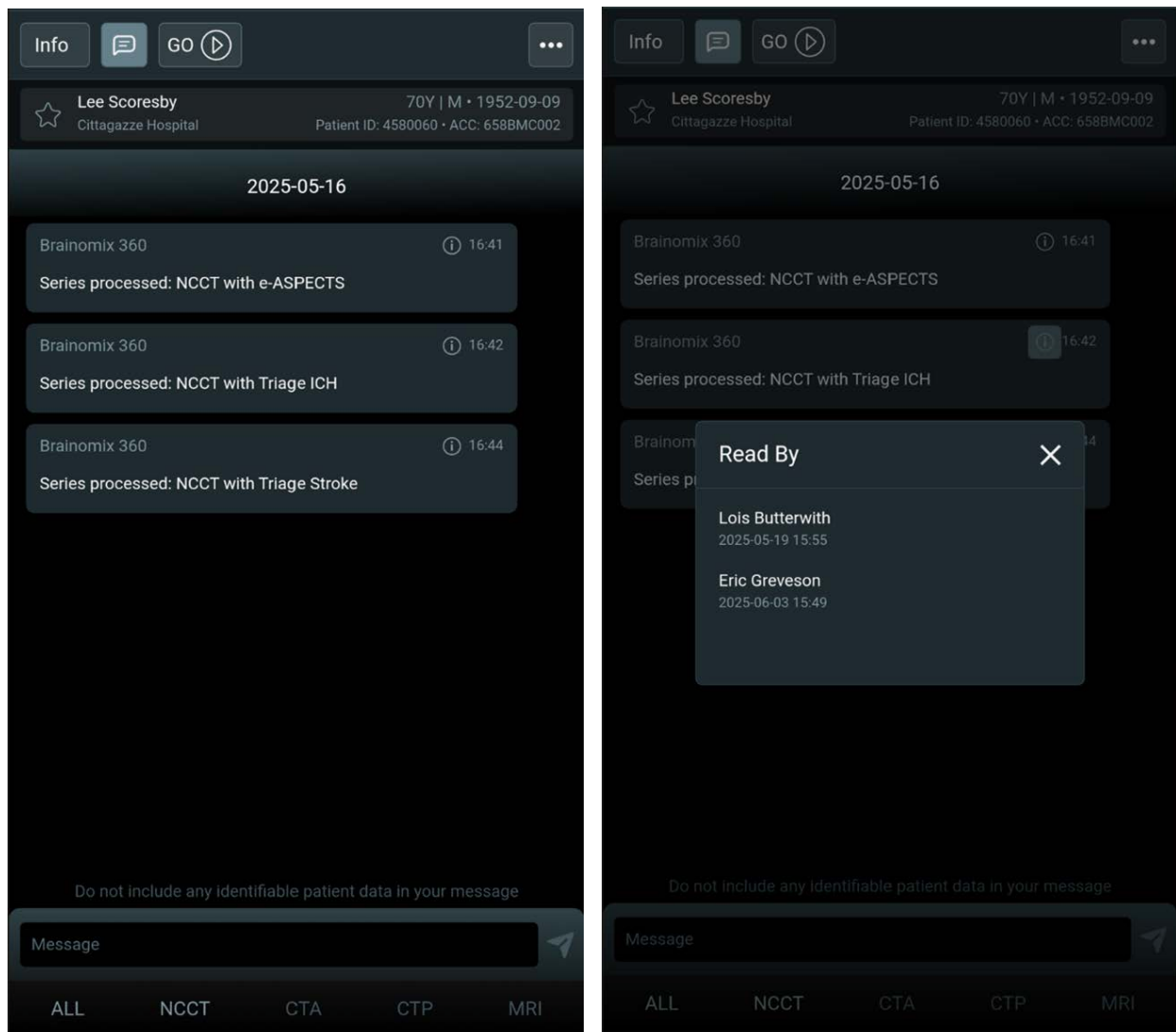
## 9.3 Messaging

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

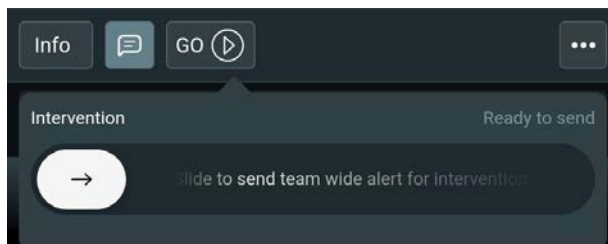
If this functionality is enabled by your system administrator, you can manually flag a patient for intervention from the patient viewer.

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

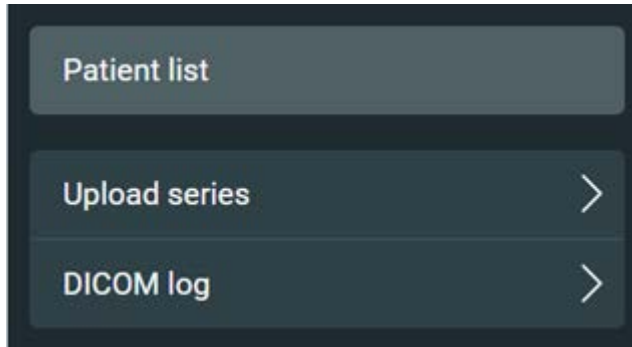
An external application may be configured to automatically transfer scan series to the Brainomix 360 server.

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          | <div>View</div> |
| Series instance UID     | 1.3.12.2.1107.5.1.4.24320.4.0.5219886421837613                                                                                  |         |                  |                 |
| Description             | Transfer failed                                                                                                                 |         |                  |                 |
| Details                 | Exception while processing command 'store':<br>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

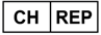
Please contact us via [support@brainomix.com](mailto:support@brainomix.com) (<mailto:support@brainomix.com>) if you have discovered a potential issue with any of our Brainomix 360 suite services. Note that any information you submit will be governed by our Privacy Policy ([https://www.brainomix.com/privacy-eu/#:~:text=For%20users%20of%20Brainomix%20products,in%20order%20to%20provide%20support](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-CTA, 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) (<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.