# e-CTP/e-MRI®

# User Manual

## Version 14.1

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e-CTP/e-MRI is part of Brainomix 360

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

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# 1 Introduction

## 1.1 Overview

Brainomix 360 e-CTP/e-MRI (referred to throughout as both "Brainomix 360 e-CTP/e-MRI" and "e-CTP/ e-MRI") software allows for visualization of DICOM compliant CT (Computed Tomography) and MRI (Magnetic Resonance Imaging) scans. The software has been designed to run with off-the-shelf physical or virtual servers and provides for viewing, quantification, analysis, and reporting, as an aid to physician diagnosis. The software does not provide computer aided detection or diagnosis. The software system consists of platform functionality and two processing modules:

i. e-CTP - provides both analysis and viewing capabilities for brain CT Perfusion datasets. The analysis capabilities are for the characterization of perfusion parameters in the image following the injection of a contrast bolus, and visualization of these parameters.
ii. e-MRI - provides both analysis and viewing capabilities for functional and dynamic imaging datasets acquired with MR including Diffusion Weighted Imaging (DWI) and Dynamic Susceptibility Contrast (DSC). The DWI capabilities are for visualization of local water diffusion properties from the analysis of diffusion-weighted MR data and optional comparison with Fluid Attenuated Inversion Recovery (FLAIR) data. The DSC capabilities are for the characterization of perfusion parameters in the image following the injection of a contrast bolus, and visualization of these parameters

## 1.2 e-CTP

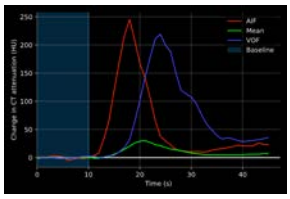
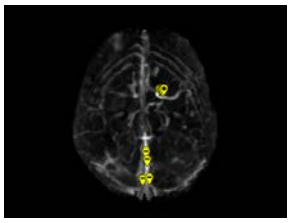
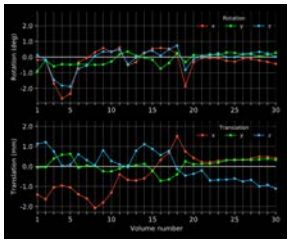
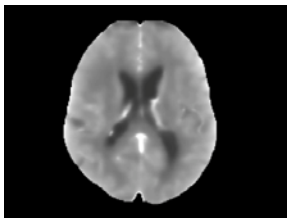
e-CTP is the module responsible for processing brain CT Perfusion (CTP) scans. It is supplied as a web service, with users accessing the system through a web browser on any machine with a connection to the Brainomix 360 software (e.g. a LAN or Internet connection) and may connect with other DICOM-compliant devices over a local network connection, including CT scanners and PACS systems.

Typically, brain CTP scans 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.

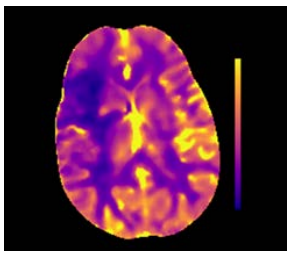
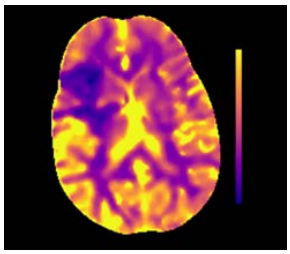
### 1.2.1 CTP analysis

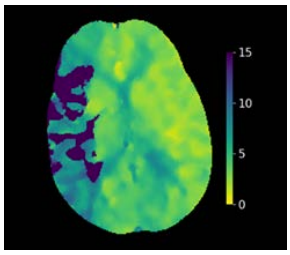
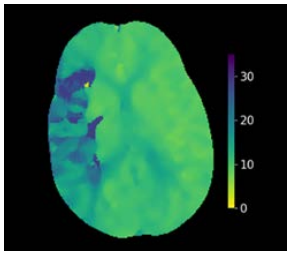
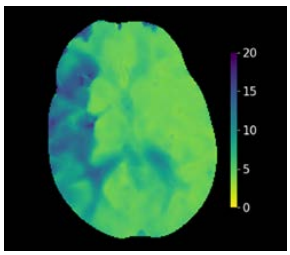
e-CTP will process an input time series of CT volumes to compute standard perfusion parameters, using a deconvolution algorithm based on block-circulant singular value decomposition (bSVD). An arterial input function (AIF) is automatically detected to allow fully automated computation of perfusion parameter maps. The software then performs automated analysis on these results, including thresholding of perfusion parameter maps, to compute quantifications of volume and mismatch.

AIF / VOF curves and motion correction charts are generated by the software to allow for review of the CTP acquisition and quality control. These outputs are shown in the table below.

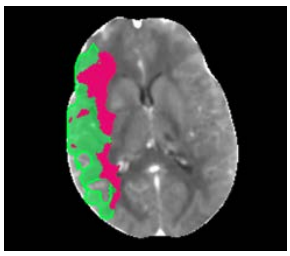
| Output | Description | Example |
|---|---|---|
| AIF/VOF curves | Arterial input function (AIF) and venous output function (VOF) chart, showing the HU values in these vessels over time. The baseline shows the part of the acquisition prior to contrast inflow, and the mean HU change across the image is also shown. |  |
| AIF/VOF MIP | Axial maximum intensity projection (MIP) image within the brain, showing the locations of voxels sampled for AIF and VOF values with + and - markers, respectively. |  |
| Motion correction chart | Frame-to-frame motion correction of the time series, showing rotations and translations applied to align each image over the acquisition time period. |  |
| Unannotated image | The unannotated image shows a mean image over acquisition time, with frame-to-frame motion correction applied. |  |

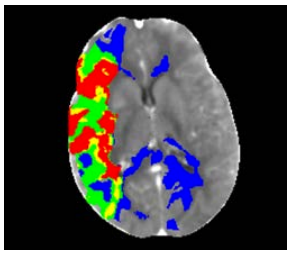
The detected AIF is used as an input to the deconvolution algorithm, which then computes standard perfusion parameters for all voxels. These parameters are displayed as colour-mapped images as follows:

| Parameter | Description | Example |
|---|---|---|
| rCBF | The rCBF (relative cerebral blood flow) map indicates the amount of blood flow through each voxel. This is a dimensionless quantity, as a percentage relative to the median CBF for tissue with Tmax < 4 seconds. |  |
| rCBV | The rCBV (relative cerebral blood volume) map indicates the amount of blood volume (based on contrast accumulation) in each voxel during the acquisition. This is a dimensionless quantity, as a percentage relative to the median CBV for tissue with Tmax < 4 seconds. |  |

| Parameter | Description | Example |
|---|---|---|
| Tmax | Tmax is the time to maximum of the deconvolved residue function computed from the bSVD algorithm. This is measured in seconds. |   |
| TTP | TTP (time to peak) is the time to maximum contrast in the voxel relative to the bolus arrival time (as displayed on the AIF/VOF chart as the end of the baseline period). This is measured in seconds. |   |
| MTT | MTT (mean transit time) corresponds to the average time, in seconds, that the contrast takes to transit a voxel. It is measured by MTT = CBV / CBF. |   |

Once the perfusion parameters have been computed, additional post-processing steps are applied to the parameter maps to compute standardized quantities. These steps typically consist of applying thresholds to particular maps and reporting the total volume of voxels meeting the threshold, together with values derived from these volumes. Default thresholded outputs are shown in the table below, although administrators may configure custom threshold outputs.

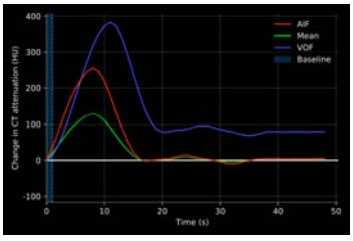
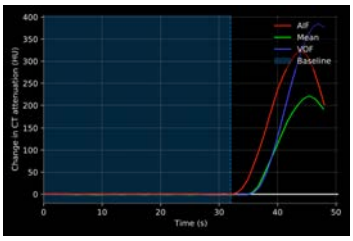
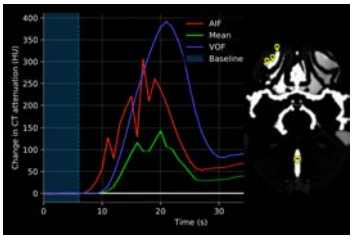
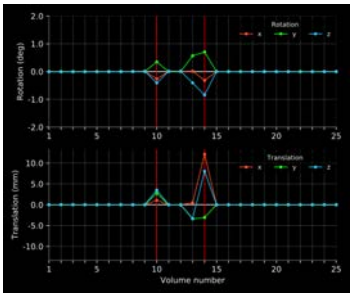
| Output | Description | Example |
|---|---|---|
| Mismatch | The mismatch summary output is based on applying thresholds to two parameters. By default, the applied thresholds are rCBF < 30% (core, shown in red by default) and Tmax > 6s (hypoperfusion, shown in green by default when outside the core map), with volumes given in ml for each. The core map is always masked by the hypoperfusion map rule. |  |
| Mismatch results | Several mismatch parameters are derived from the above maps: mismatch volume (hypoperfusion volume - core volume), mismatch ratio (hypoperfusion volume / core volume), and relative mismatch (mismatch volume / hypoperfusion volume). Additionally, the HIR (Hypoperfusion Intensity Ratio) is computed based on the volumetric ratio of (Tmax > 10) / (Tmax > 6). |   |

| Output | Description | Example |
|---|---|---|
| Multi-threshold maps | Multiple thresholds can be applied to perfusion parameters to compute volumes at different applied threshold levels. By default, multi-threshold maps for rCBF and Tmax are defined. |  |

## 1.2.2 Quality control

Before using results from e-CTP, the acquisition quality should be checked by manual inspection of the AIF/VOF curves, AIF/VOF MIP and motion correction charts (see Precautions). Poor quality will typically lead to inaccurate perfusion parameter maps and subsequent inaccurate thresholded volume and mismatch values.

Examples of particular issues to check for are given below.

| Problem | Description | Example |
|---|---|---|
| Insufficient baseline | The scan acquisition has started too late relative to the contrast bolus delivery time. As a result, e-CTP/e-MRI does not have sufficient pre-contrast data to establish an accurate baseline image. |  |
| Truncated acquisition | The scan acquisition has finished too early, before the contrast bolus has completed its first transit of the cerebral circulation. As a result, e-CTP/e-MRI does not have sufficient data to provide accurate deconvolution results. |  |
| Failed AIF detection | e-CTP/e-MRI has failed to correctly identify the major arterial vessels to sample, or contrast in these vessels is too low, leading to incorrect AIF detection. This means that deconvolution results and subsequent threshold volumes will be invalid. |  |
| Excessive motion | The patient has moved significantly during the scan acquisition. This can lead to failed motion correction, motion artifacts in the image, and inaccurate HU values in the scan. |  |

# 1.3 e-MRI

e-MRI is the module responsible for processing brain Magnetic Resonance (MR) scans. 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 MR scanners and PACS systems.

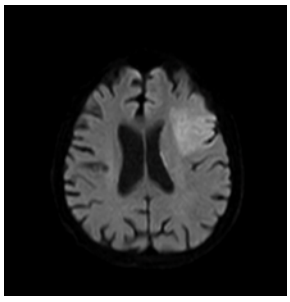
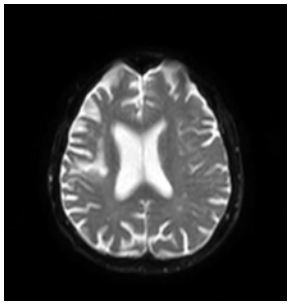
Typically, brain MR scans should be sent via a DICOM C-STORE operation from an MR scanner to the Brainomix 360 software. Brainomix 360 can be configured to automatically transfer the generated result series to a PACS via a DICOM C-STORE operation. Brainomix 360 may additionally be configured to send 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.

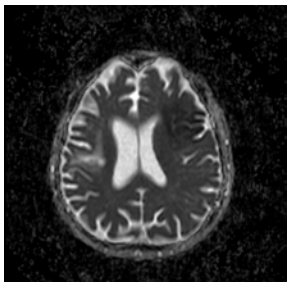
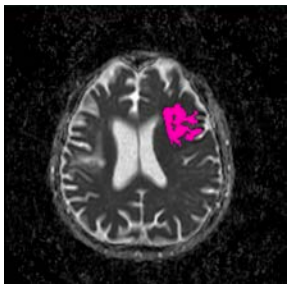
## 1.3.1 DWI (Diffusion Weighted Imaging) Analysis

e-MRI will process an input DWI MR series to compute standard diffusion parameters, including an ADC (Apparent Diffusion Coefficient) map.

An automated algorithm will further process the DWI and ADC images to compute a result map where low ADC values with corresponding high DWI signal are flagged. This result map shows areas likely to contain abnormally restricted diffusion.

In addition to these outputs, images are generated using the input DWI data for different diffusion weightings (b values). The outputs are shown in the table below.

| Output | Description | Example |
|---|---|---|
| DWI (b=max) | The DWI b=max image shows the isotropic DWI image with maximum diffusion weighting applied. |  |
| DWI (b=0) | The DWI b=0 image shows the T2* weighted image with no diffusion attenuation. |  |

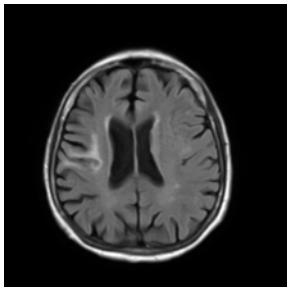
| Output | Description | Example |
|---|---|---|
| ADC | The ADC (Apparent Diffusion Coefficient) image is a measure of the magnitude of diffusion within tissue, and is computed from the DWI acquisition. |  |
| Results | The results image shows the ADC image with areas of likely abnormally restricted diffusion (low ADC and high DWI signal) highlighted. |  |

## FLAIR (Fluid Attenuated Inversion Recovery) Analysis

When provided in addition to a DWI series, e-MRI will process an input FLAIR series to compute DWI-FLAIR mismatch.

The DWI and FLAIR images are co-registered, and the voxels within the FLAIR image within the ROI (region of interest) defined by the DWI ADC results map are compared (as a ratio) with a contralateral ROI.

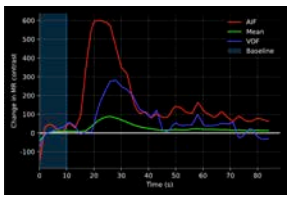
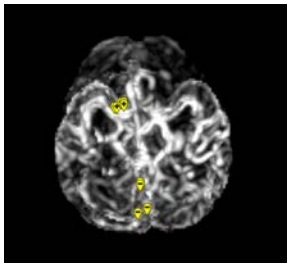
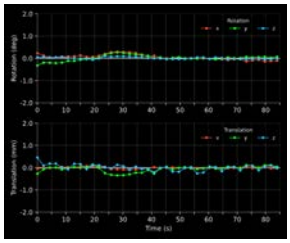
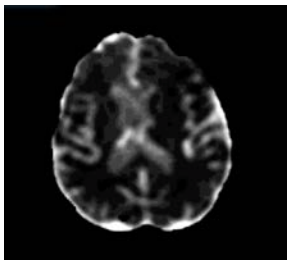
The results of this comparison are then reported in terms of median ratio and IQR (interquartile range), and an overall indication of whether this ratio suggests that the FLAIR signal is positive or not based on comparison to a threshold.

| Output | Description | Example |
|---|---|---|
| FLAIR | The input FLAIR image is displayed, co-registered to the other DWI, ADC and results images displayed. |  |

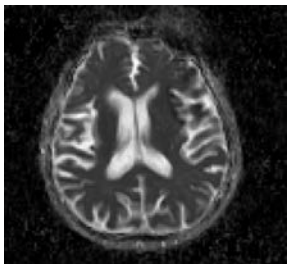
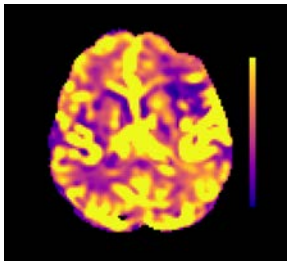
# 1.3.2 DSC (Dynamic Susceptibility Contrast) Analysis

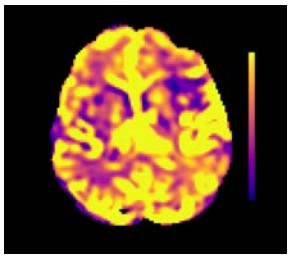
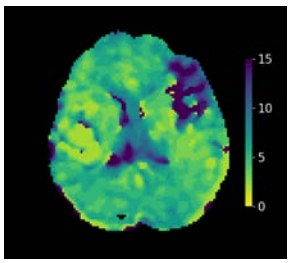
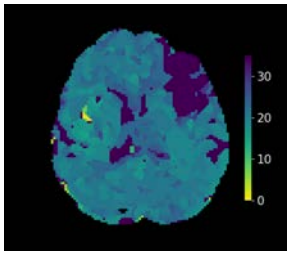
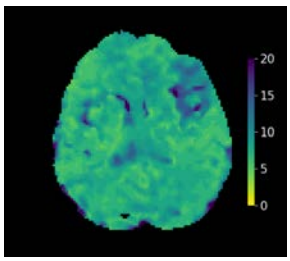
e-MRI will process an input time series of DSC MR volumes to compute standard perfusion parameters, using a deconvolution algorithm based on block-circulant singular value decomposition (bSVD). An arterial input function (AIF) is automatically detected to allow fully automated computation of perfusion parameter maps. The software then performs automated analysis on these results, including thresholding of perfusion parameter maps, to compute quantifications of volume and mismatch.

AIF / VOF curves and motion correction charts are generated by the software to allow for review of the DSC MR acquisition and quality control. These outputs are shown in the table below.

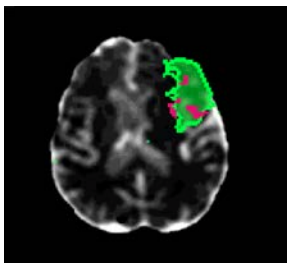
| Output | Description | Example |
|---|---|---|
| AIF/VOF curves | Arterial input function (AIF) and venous output function (VOF) chart, showing the voxel values in these vessels over time. The baseline shows the part of the acquisition prior to contrast inflow, and the mean voxel value change across the image is also shown. |  |
| AIF/VOF MIP | Axial maximum intensity projection (MIP) image within the brain, showing the locations of voxels sampled for AIF and VOF values with + and - markers, respectively. |  |
| Motion correction chart | Frame-to-frame motion correction of the time series, showing rotations and translations applied to align each image over the acquisition time period. |  |
| Unannotated image | The unannotated image shows a mean image over acquisition time, with frame-to-frame motion correction applied. |  |

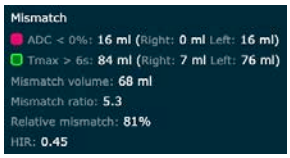
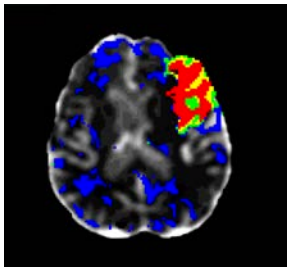
The detected AIF is used as an input to the deconvolution algorithm, which then computes standard perfusion parameters for all voxels. These parameters are displayed as colour-mapped images as follows:

| Parameter | Description | Example |
|---|---|---|
| ADC | The ADC (apparent diffusion coefficient) map (where available, computed from DWI imaging), is a measure of the magnitude of diffusion of water molecules within tissue. This is measured in units of $mm^2/s$. |  |
| rCBF | The rCBF (relative cerebral blood flow) map indicates the amount of blood flow through each voxel. This is a dimensionless quantity, as a percentage relative to the median CBF for tissue with Tmax < 4 seconds. |  |

| Parameter | Description | Example |
|---|---|---|
| rCBV | The rCBV (relative cerebral blood volume) map indicates the amount of blood volume (based on contrast accumulation) in each voxel during the acquisition. This is a dimensionless quantity, as a percentage relative to the median CBV for tissue with Tmax < 4 seconds. |  |
| Tmax | Tmax is the time to maximum of the deconvolved residue function computed from the bSVD algorithm. This is measured in seconds. |   |
| TTP | TTP (time to peak) is the time to maximum contrast in the voxel relative to the bolus arrival time (as displayed on the AIF/VOF chart as the end of the baseline period). This is measured in seconds. |   |
| MTT | MTT (mean transit time) corresponds to the average time, in seconds, that the contrast takes to transit a voxel. It is measured by MTT = CBV / CBF. |   |

Once the perfusion parameters have been computed, additional post-processing steps are applied to the parameter maps to compute standardized quantities. These steps typically consist of applying thresholds to particular maps and reporting the total volume of voxels meeting the threshold, together with values derived from these volumes. Default thresholded outputs are shown in the table below, although administrators may configure custom threshold outputs.

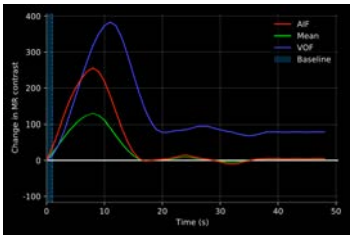
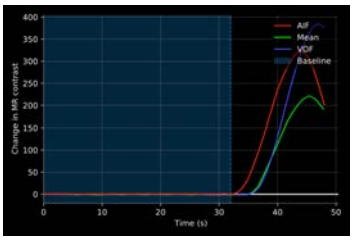
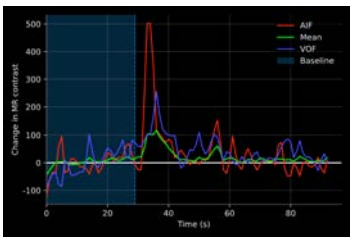
| Output | Description | Example |
|---|---|---|
| Mismatch | The mismatch summary output is based on applying thresholds to two parameters. By default, the applied thresholds are low ADC (core, shown in red by default, with a backup of rCBF < 30% if DWI imaging is not available) and Tmax > 6s (hypoperfusion, shown in green by default when outside the core map), with volumes given in ml for each. The core map is always masked by the hypoperfusion map rule. |  |

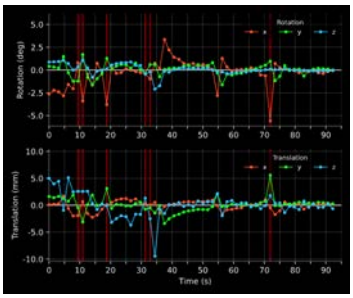
| Output | Description | Example |
|---|---|---|
| Mismatch results | Several mismatch parameters are derived from the above maps: mismatch volume (hypoperfusion volume - core volume), mismatch ratio (hypoperfusion volume / core volume), and relative mismatch (mismatch volume / hypoperfusion volume). Additionally, the HIR (Hypoperfusion Intensity Ratio) is computed based on the volumetric ratio of (Tmax > 10) / (Tmax > 6). |  |
| Multi-threshold maps | Multiple thresholds can be applied to perfusion parameters to compute volumes at different applied threshold levels. By default, multi-threshold maps for rCBF and Tmax are defined. |  |

## 1.3.3 DSC Quality Control

Before using DSC results from e-MRI, the acquisition quality should be checked by manual inspection of the AIF/VOF curves, AIF/VOF MIP and motion correction charts (see Precautions). Poor quality will typically lead to inaccurate perfusion parameter maps and subsequent inaccurate thresholded volume and mismatch values.

Examples of particular issues to check for are given below.

| Problem | Description | Example |
|---|---|---|
| Insufficient baseline | The scan acquisition has started too late relative to the contrast bolus delivery time. As a result, e-CTP/e-MRI does not have sufficient pre-contrast data to establish an accurate baseline image. |  |
| Truncated acquisition | The scan acquisition has finished too early, before the contrast bolus has completed its first transit of the cerebral circulation. As a result, e-CTP/e-MRI does not have sufficient data to provide accurate deconvolution results. |  |
| Failed AIF detection | e-MRI has failed to correctly identify the major arterial vessels to sample, or contrast in these vessels is too low, leading to incorrect AIF detection. This means that deconvolution results and subsequent threshold volumes will be invalid. |  |

| Problem | Description | Example |
| --- | --- | --- |
| Excessive motion | The patient has moved significantly during the scan acquisition. This can lead to failed motion correction, motion artifacts in the image, and inaccurate voxel values in the scan. |  |

# 2 Intended Use

This section contains important safety information regarding the usage of Brainomix 360 e-CTP/e-MRI

Brainomix 360 e-CTP/e-MRI is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard off-the-shelf computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM compliant imaging devices. This includes DICOM files uploaded through a web browser interface.

Brainomix 360 e-CTP/e-MRI provides both viewing and analysis capabilities for imaging datasets acquired with CT Perfusion and MRI including Dynamic Susceptibility Contrast (DSC) and Diffusion Weighted Imaging (DWI). The DWI MRI analysis capabilities are used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data and optional comparison with Fluid Attenuated Inversion Recovery (FLAIR) data. The CT Perfusion and MRI DSC analysis capabilities are for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue blood flow (perfusion) and tissue blood volume.

## 2.1 Indications

Brainomix 360 e-CTP/e-MRI is indicated for use on contrast enhanced CT Perfusion brain and DWI/DSC MRI scans as a decision support tool, providing automated image analysis, parametric maps and thresholded versions of these maps.

## 2.2 Contraindications

- Brainomix 360 e-CTP/e-MRI is not suitable for use with scan data containing image features associated with coils, shunts, embolization or movement artifacts
- Brainomix 360 e-CTP/e-MRI 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-CTP/e-MRI assistance to confirm any outputs.

## 2.3 Warnings

| | |
|---|---|
| ⚠ | Brainomix 360 e-CTP/e-MRI should not be used as a standalone aid to diagnosis. Brainomix 360 e-CTP/e-MRI should only be used by a competent healthcare professional with an understanding of brain CT/MR Perfusion image acquisition and interpretation, as an aid to image interpretation of cerebral perfusion abnormalities. |
| ⚠ | Brainomix 360 e-CTP/e-MRI 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-CTP/e-MRI may not correctly identify perfusion parameters on brain scans containing major anatomical abnormalities (e.g. hydrocephalus, large tumours, intracerebral hemorrhage, craniectomy) and additional care should be taken when reviewing such results. |
| ⚠ | Brainomix 360 e-CTP/e-MRI may not correctly identify perfusion abnormalities in every cerebral CT/MR Perfusion dataset. Users should use their own expertise in cerebral CT/MR Perfusion image interpretation to verify that the software's output is correct. |
| ⚠ | Brainomix 360 e-CTP/e-MRI is intended for analysis and quantification of CT/MR Perfusion images. The interpretation of perfusion results is the responsibility of the user. |
| ⚠ | Brainomix 360 e-CTP/e-MRI 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-CTP/e-MRI, users should not share access credentials and should log-out when not using the system. |
| ⚠ | Users accessing the Brainomix 360 e-CTP/e-MRI web user interface must ensure that they perform any analysis or diagnostic image review using an approved radiology viewing display. |
| ⚠ | Brainomix 360 e-CTP/e-MRI is not intended for diagnostic image review when accessed from mobile devices. |
| ⚠ | In the event Brainomix 360 e-CTP/e-MRI becomes partially or entirely unavailable, or if processed scans cannot be retrieved, users should rely on standard methods of image/parameter 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:<br>▪ Algorithmic data problems or processing errors during the analysis of scans (see Precautions for more information)<br>▪ Artifacts, motion or other factors reducing registration quality<br>▪ Lack of disk space to process new scans<br>▪ Underlying server platform failure<br>▪ Slow network connectivity<br>  ▪ Slow connectivity from scanner/PACS to the Brainomix 360 server<br>  ▪ Slow connectivity to the Brainomix 360 Cloud service over the internet<br>▪ Delays in the Apple or Google mobile notification services<br>▪ Poor signal on the receiving mobile device<br>▪ Power saving modes of some mobile devices may delay notifications |

## 2.4 Precautions

| | |
|---|---|
| ⚠ | The user of Brainomix 360 e-CTP/e-MRI should monitor the image quality of input data used for automated analysis, e.g. concerning motion artifacts. |
| ⚠ | Brainomix 360 e-CTP/e-MRI 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. |
| ⚠ | The user should verify that the arterial input function (AIF) is correctly located and detected by Brainomix 360 e-CTP/e-MRI, by reviewing the AIF / VOF localization and time curve from the software. |
| ⚠ | Brainomix 360 e-CTP/e-MRI has only been validated in adult populations. Safety and effectiveness in pediatric cases has not been established. |

## 2.5 Clinical Benefits

The clinical benefits of e-CTP/e-MRI is to aid diagnosis and treatment decision making by identifying patterns of abnormal perfusion or restricted diffusion of the brain from CTP or MRI images in patients with neurological illness.

## 2.6 Use Environment

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

## 3.1 Installation

Brainomix 360 e-CTP/e-MRI 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-CTP/e-MRI 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-CTP/e-MRI requires competency in the interpretation of CT Perfusion or MRI scans. 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<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.

| | |
|---|---|
| **LVO Perfusion Abnormality Detection Sensitivity** | ≥ 90% |
| **LVO Hypoperfusion Accuracy** | ≥ 95% |
| **Mean Lateralisation Index** | ≥ 85% |
| **FLAIR positivity accuracy** | ≥ 75% |
| **FLAIR AUC** | ≥ 85% |
| **MR-DWI Regional Deficit Jaccard Index** | ≥ 60% |
| **Average MR-DWI Lateralisation Lesion Map** | ≥ 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-CTP/e-MRI 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

## 5.1 e-CTP

The e-CTP module is designed to work with contrast-enhanced CT Perfusion scans sent via the DICOM protocol. Both the image acquisition parameters, and the bolus delivery, are critical for best quality results. A standardized protocol should be configured on the CT scanner, and all series in the study to be processed should be sent in one group of images, with minimum time delays between successive images. These scans should have the following characteristics.

| | |
|---|---|
| **Slice thickness** | Maximum 5mm slice thickness recommended. Thin slice acquisitions (e.g. 1mm) are supported. |
| **Acquisition volume** | As large a coverage as possible when performing CT Perfusion acquisitions on the CT scanner, ideally up to full brain coverage. |
| **Acquisition mode** | Shuttle mode and jog mode acquisitions are supported. Typically this would mean a sequence time of at least 45 seconds. |
| **Temporal resolution** | One time point (volume) acquired every 1-4 seconds. |
| **Acquisition timing** | At least 5 seconds baseline captured prior to bolus arrival, and full AIF peak and wash-out from first circulation of the bolus captured. Typically this would mean a sequence time of at least 45 seconds. |
| **Matrix size** | 512x512 recommended |
| **Field of view** | Approx 24cm recommended (typical head CT FOV) |
| **Image acquisition parameters** | 70-80kV<br>170-400 mAs |

Use of thicker slices or lower temporal resolution may lead to poor sampling of the AIF and correspondingly lower quality results.

Excessively small coverage will mean that brain parenchyma is not imaged, and volumes will be unreliable as lesions may be missed due to being outside the scan volume.

If the acquisition is too early or too late compared to the bolus timing, the AIF may not be fully captured and deconvolution results may be inaccurate.

## 5.2 e-MRI

The e-MRI module is designed to work with MR images including DWI (Diffusion Weighted Imaging), FLAIR (Fluid Attenuated Inversion Recovery), and DSC (Dynamic Susceptibility Contrast) scans sent via the DICOM protocol. Both the image acquisition parameters, and the bolus delivery for DSC, are

critical for best quality results. A standardized protocol should be configured on the MR scanner, and all series in the study to be processed should be sent in one group of images, with minimum time delays between successive images. These scans should have the following characteristics.

## 5.2.1 DWI (Diffusion Weighted Imaging)

| | |
|---|---|
| **Sequence** | Single-shot diffusion-weighted spin-echo echoplanar imaging. |
| **Acquisition parameters** | ▪ TR ≥ 4000ms but can be as high as needed to fit all slices<br>▪ TE minimum (partial Fourier)<br>▪ b=0 and 1000 sec/mm$^2$ (other max b values also supported)<br>▪ At least 3 orthogonal directions<br>▪ Eddy current correction (dual-spin echo or postprocessing) |
| **Slice thickness** | 5mm slice thickness recommended |
| **Slice gap** | 0 to 1mm |
| **Acquisition volume** | Full brain coverage (typically using ≥ 12 slices), field of view ≈ 24cm |
| **Matrix size** | 128x128 recommended |
| **Phase encoding** | Along A/P direction |
| **FLAIR image** | Optional (if supplied, DWI-FLAIR mismatch will be computed) |

## 5.2.2 DSC (Dynamic Susceptibility Contrast)

| | |
|---|---|
| **Sequence** | Single-shot gradient-echo echoplanar imaging. |
| **Acquisition parameters** | ▪ TR ±1500ms<br>▪ TE=35 to 45ms at 1.5T, TE=25 to 30ms at 3T<br>▪ Flip angle=60° to 90° at 1.5T, flip angle = 60° at 3T |
| **Slice thickness** | 5mm slice thickness recommended. |
| **Slice gap** | 0 to 1mm |
| **Acquisition volume** | Full brain coverage (typically using ≥ 12 slices), field of view ≈ 24cm |
| **Temporal resolution** | One time point (volume) acquired every 1-4 seconds. |
| **Acquisition timing** | At least 5 seconds baseline captured prior to bolus arrival, and full AIF peak and wash-out from first circulation of the bolus captured. Typically this would mean a sequence time of at least 45 seconds. |

| | |
|---|---|
| **Matrix size** | 128x128 recommended |
| **Phase encoding** | Along A/P direction |

Use of lower temporal resolution may lead to poor sampling of the AIF and correspondingly lower quality results.

If the acquisition is too early or too late compared to the bolus timing, the AIF may not be fully captured and deconvolution results may be inaccurate.

# 6 Cybersecurity

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

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

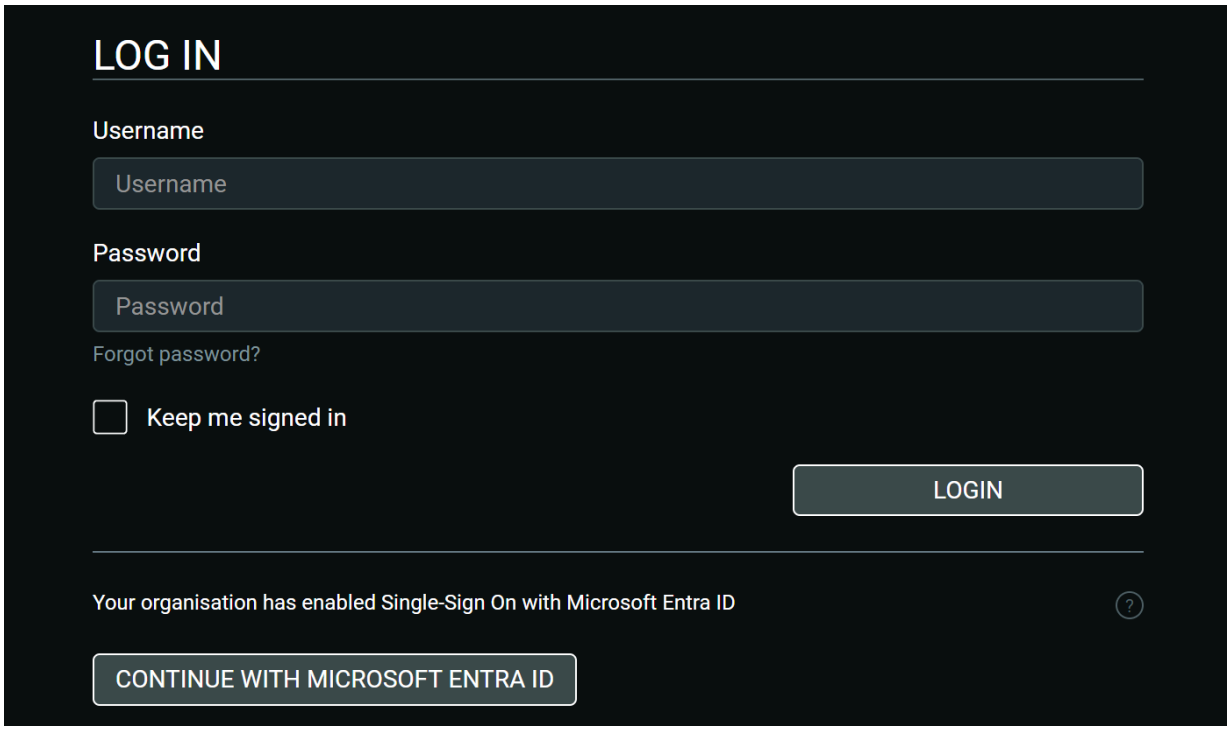
Brainomix 360 e-CTP/e-MRI should only be installed within a secure hospital network which is protected by a network level firewall, antivirus and antimalware software and, ideally, Intrusion Detection Software (IDS).

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

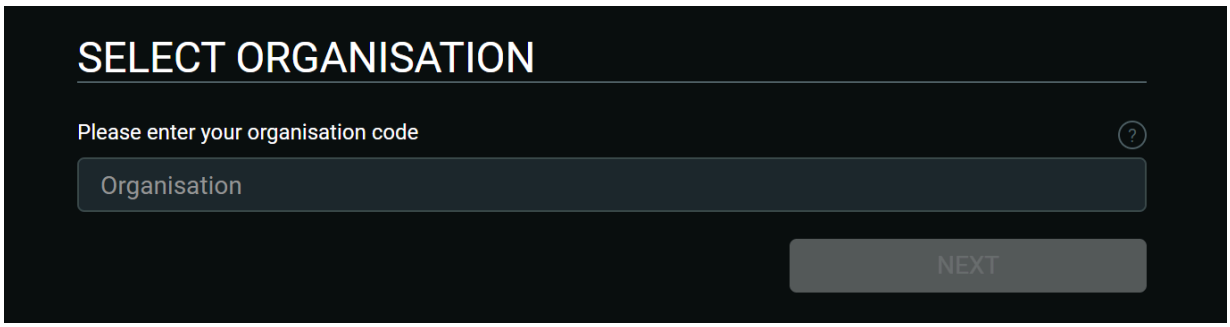
# 7 Access Control and Notifications

## 7.1 Logging In

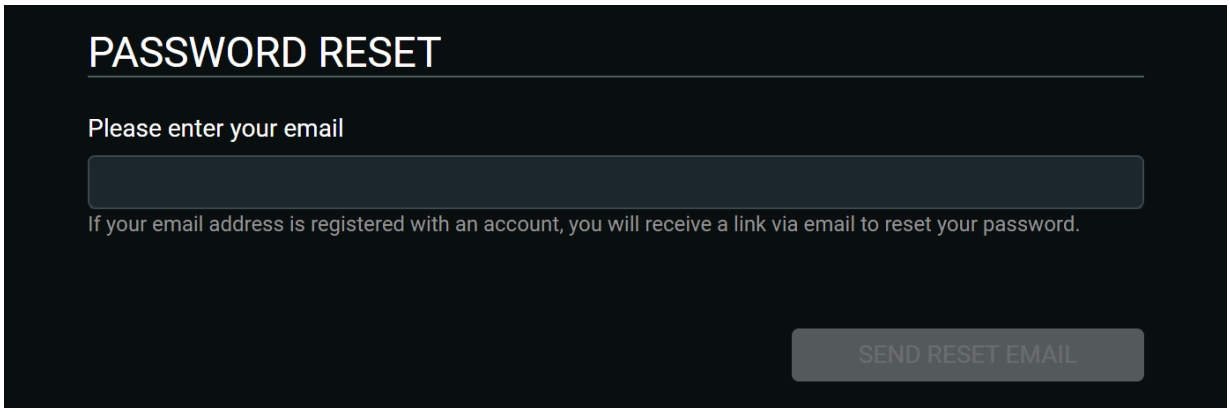
1. Go to the Brainomix 360 or Brainomix 360 Cloud server address in your web browser.
2. You will be prompted to log in if you have not used the application recently from your current web browser. Your system administrator can provide login credentials.
   Brainomix 360:



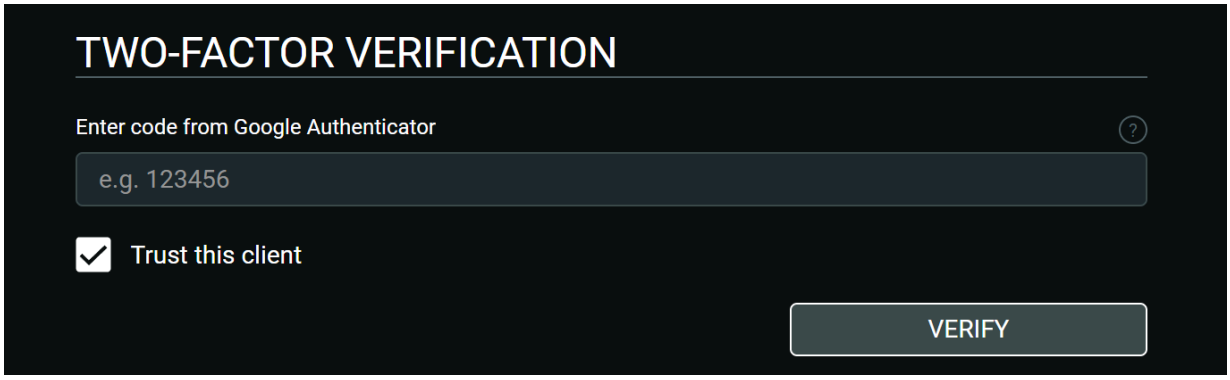

   Brainomix 360 Cloud:




   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.



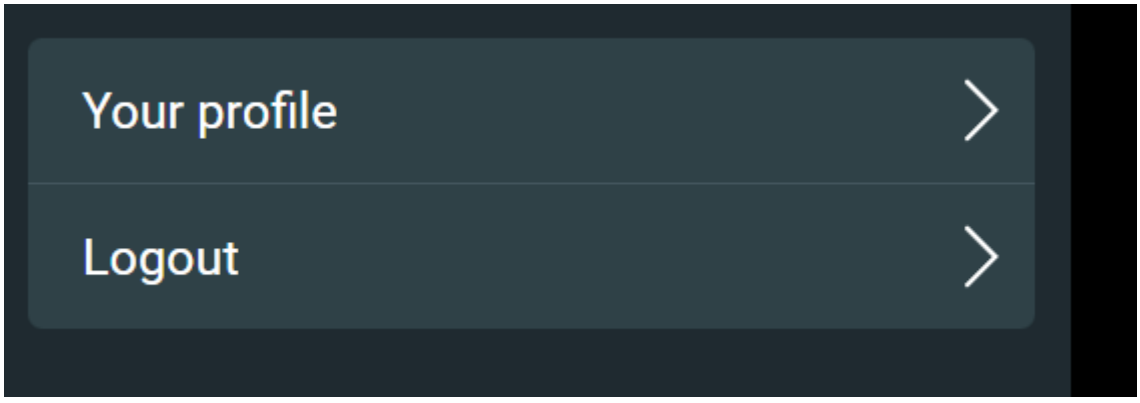

4. If you have enrolled in two-factor authentication, you may be prompted to enter a token code from your authenticator app.




   - 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

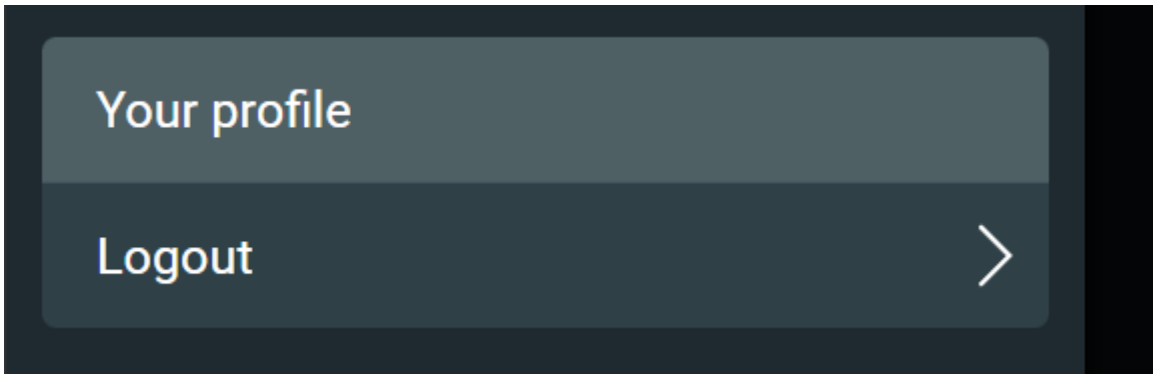
1. Open the Menu and scroll to the bottom.




2. Click **Logout**

# 7.3 Changing Your Password

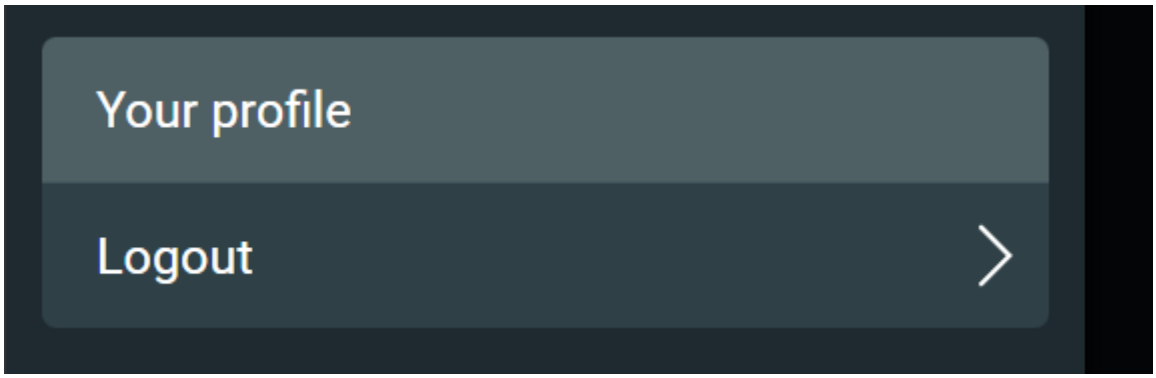
1. Open the Menu and scroll to the bottom.




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.

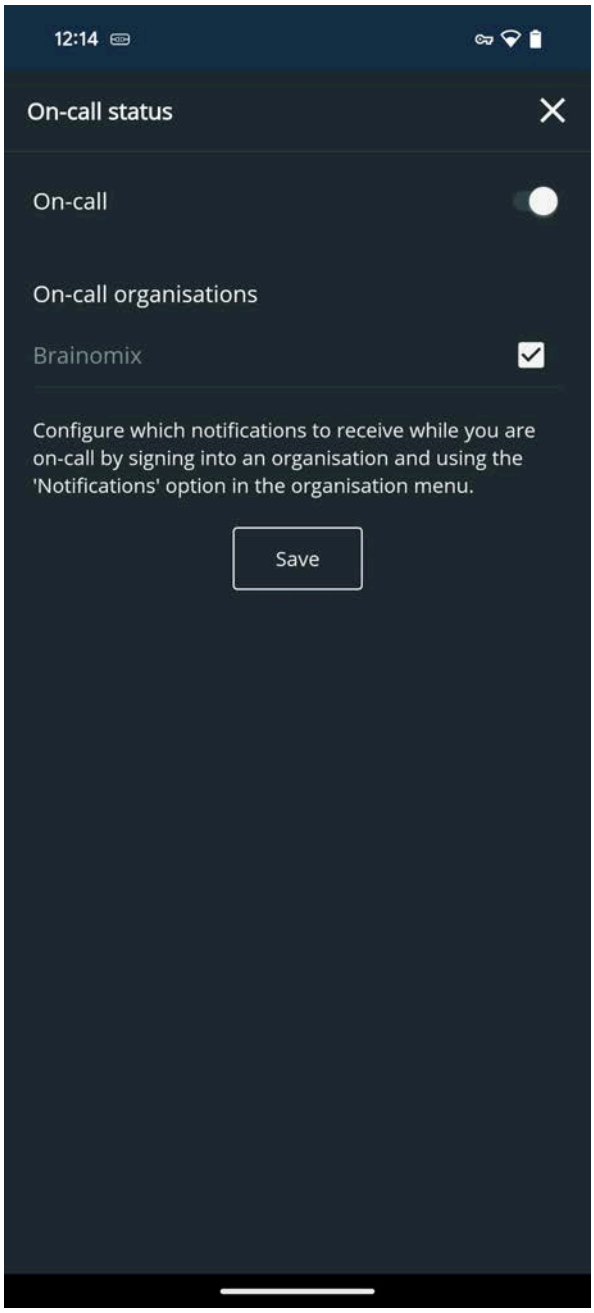



2. Click **Your profile**
3. Click on the tab labelled **Two-factor authentication**
4. Click the **enroll** button.
5. Follow the on-screen enrollment instructions.

# 7.5 On-Call Status

## Configuration

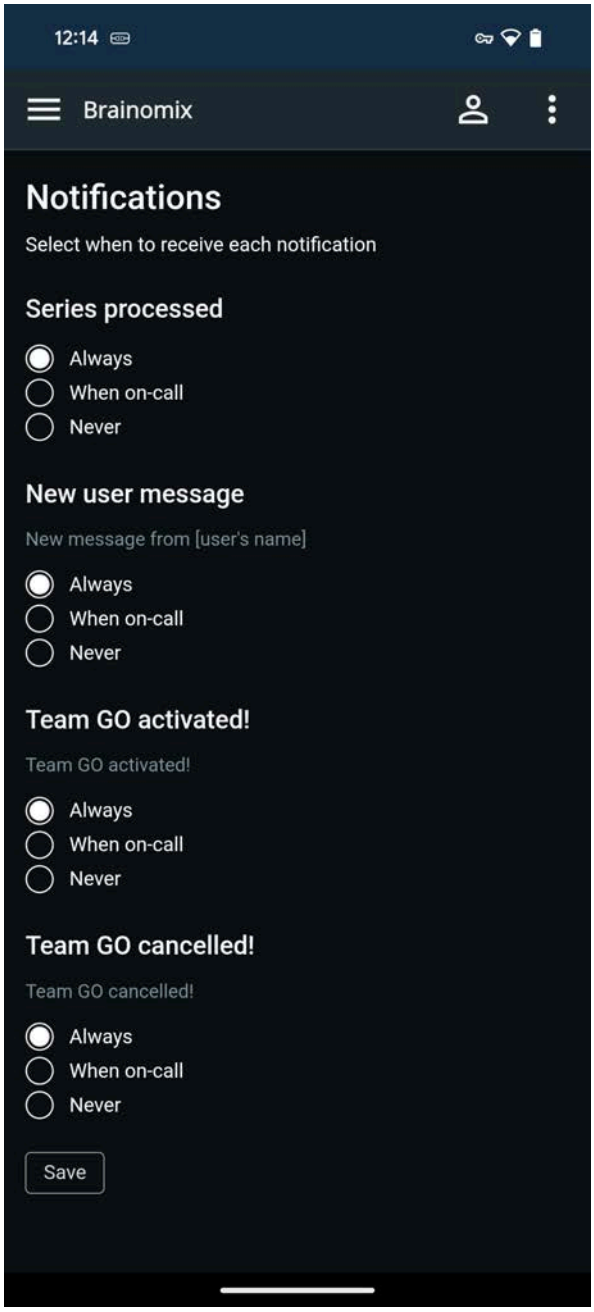
1. Your on-call status can be configured through the app. You can choose to be on-call or not, and which organisations you are going to be on-call for.




## 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

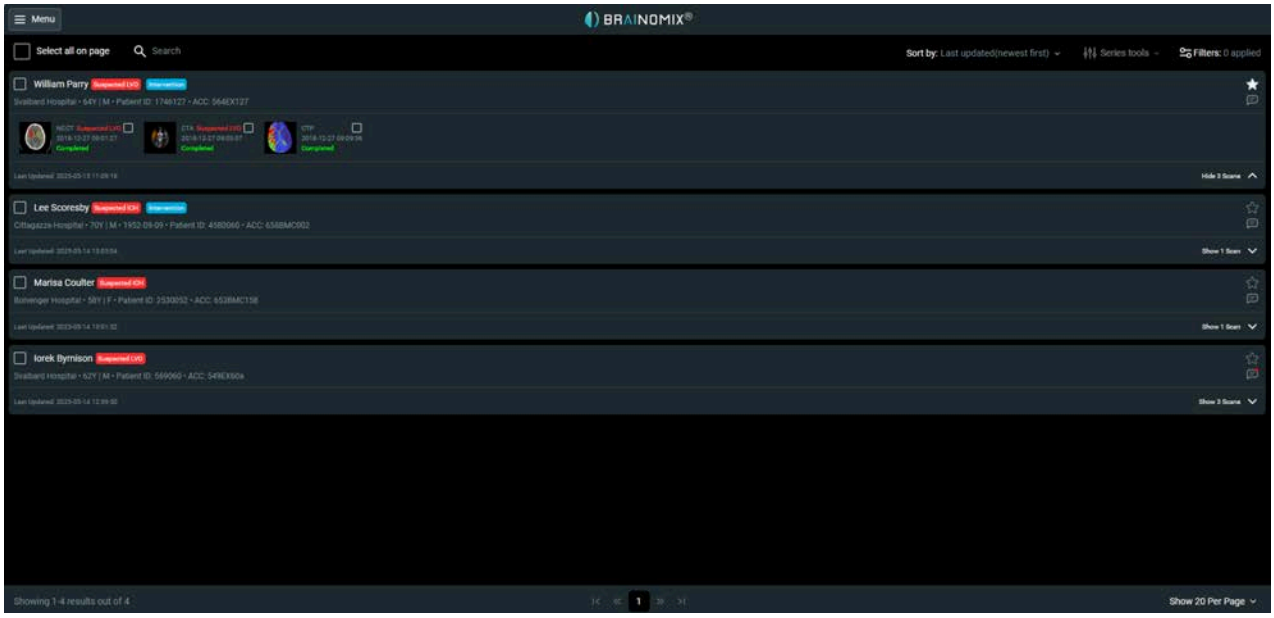
- Launch the Settings app.
- Tap Notifications.
- Scroll to Brainomix 360 Mobile > Tap.
- Toggle the **Allow Notifications** switch to **On** to enable notifications.
- Toggle the **Time-Sensitive Notifications** switch **On** (notifications are always delivered immediately and remain on the Lock Screen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

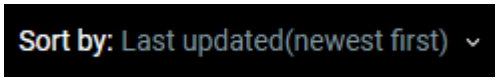



- The patient list page shows all patients available to you. By default, they are listed in order of the last patient updated.
- Move through the pages of patients by clicking on the page numbers below the list.
- Click on a patient to open it in the Patient Viewer (see the Patient Viewer section).
-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

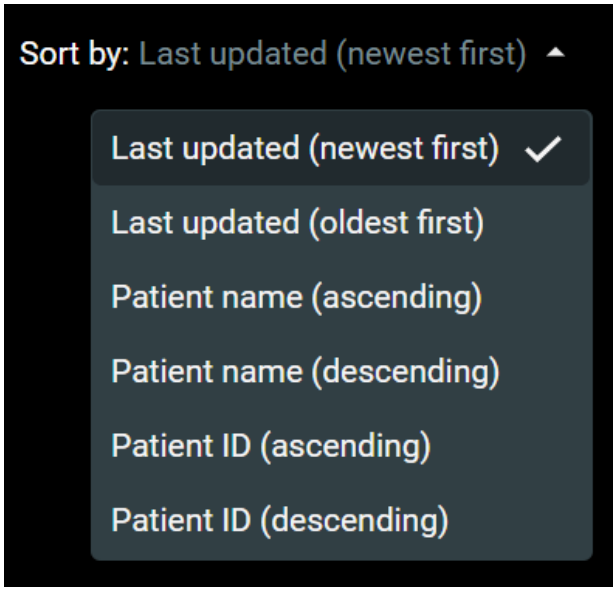
# 8.2 Finding Patients

## Sorting

Sort the patient list by clicking the Sort by button.




Select a sort preference from the drop-down list.



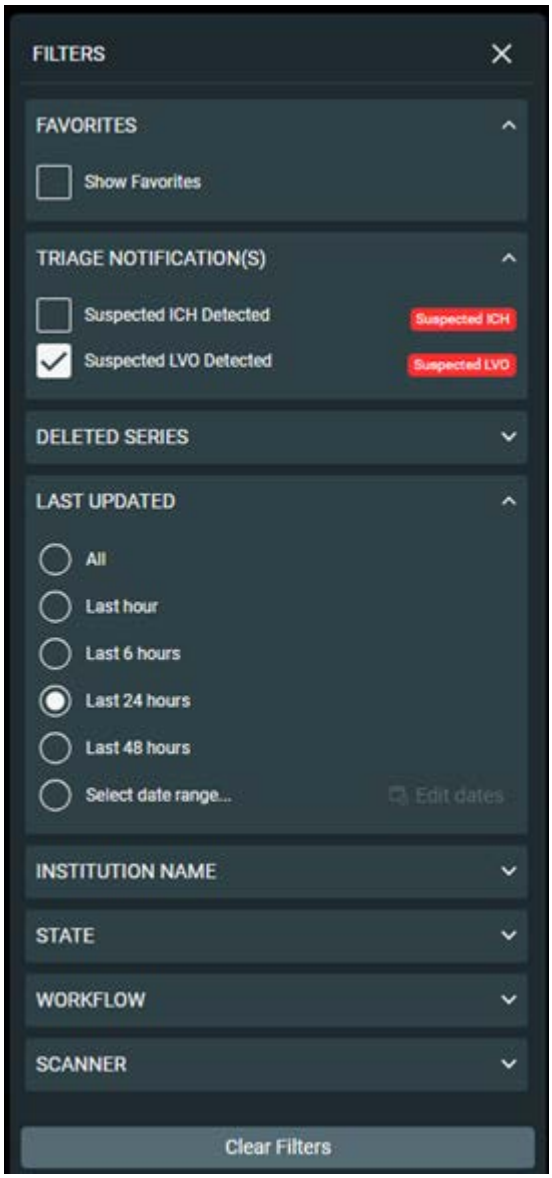

## Search

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.




# 8.3 Patient Viewer

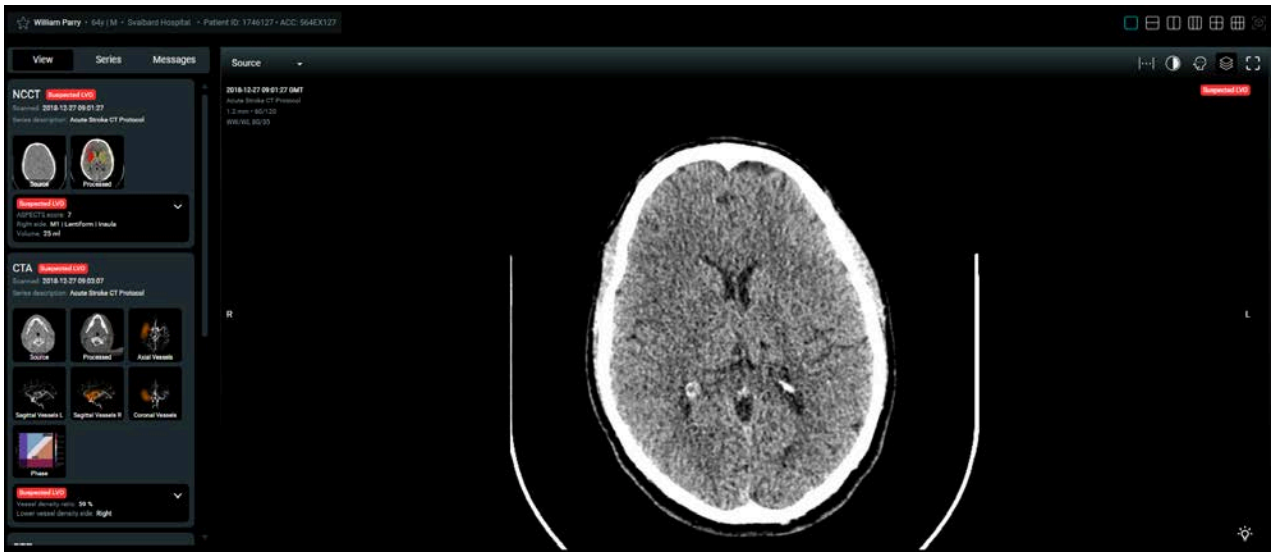
## Overview

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.

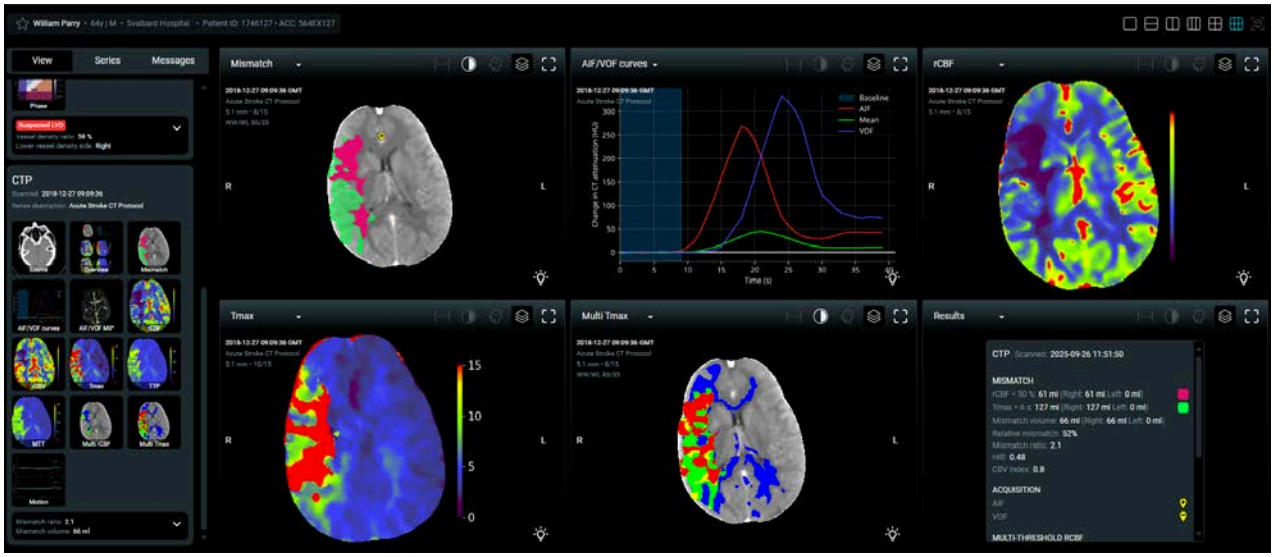
Window width and level can also be adjusted by right-clicking and dragging the mouse over the viewer, moving up/down (to change level) or left/right (to change width).

## 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-CTP/e-MRI Display

# 8.4.1 e-CTP Display




## Results Summary

The perfusion volumes, mismatch, and related information are displayed on the Result Summary view. This contains the following information.

### Detected Volumes

Thresholded volume results in ml, as calculated by e-CTP. These are computed by applying pre-defined thresholding rules to the parameter maps computed by e-CTP (the default rules are based on CBF and Tmax thresholds). The accuracy of the volume calculation will depend on the quality of the parameter maps. This in turn depends on the quality of input data, motion correction, and correct detection of the arterial input function (AIF), which should be manually verified by looking at the AIF curve and motion charts.

## Processed

### Summary mismatch map

The summary mismatch map shows the thresholded volume extent on the pre-bolus arrival mean image.

### AIF/VOF chart

The AIF/VOF chart shows the arterial input function (in red) and venous output function (in blue) over time. This image should be reviewed to ensure the bolus timing is good and that the AIF is correctly detected.

### AIF/VOF vessel MIP image

The AIF/VOF MIP image shows a maximum intensity projection of the vessels within the perfusion volume, together with the points that were selected for the AIF (in red) and the VOF (in blue).

### Motion correction chart

The motion correction chart shows the rotation and translation frame-to-frame corrections applied by the software. This image should be reviewed to check for excessive motion during the CT Perfusion acquisition.

### Individual parameter maps

The individual parameter maps show colour-mapped values for perfusion parameters: CBV (relative cerebral blood volume), CBF (relative cerebral blood flow), Tmax (time at which maximum value of residue function occurs, relative to AIF peak), TTP (time to peak contrast) and MTT (mean transit time).

### Multi-threshold parameter maps

If configured, multi-threshold parameter maps show volume extents for multiple thresholds applied to the parameter, one colour per threshold.

## Overlays

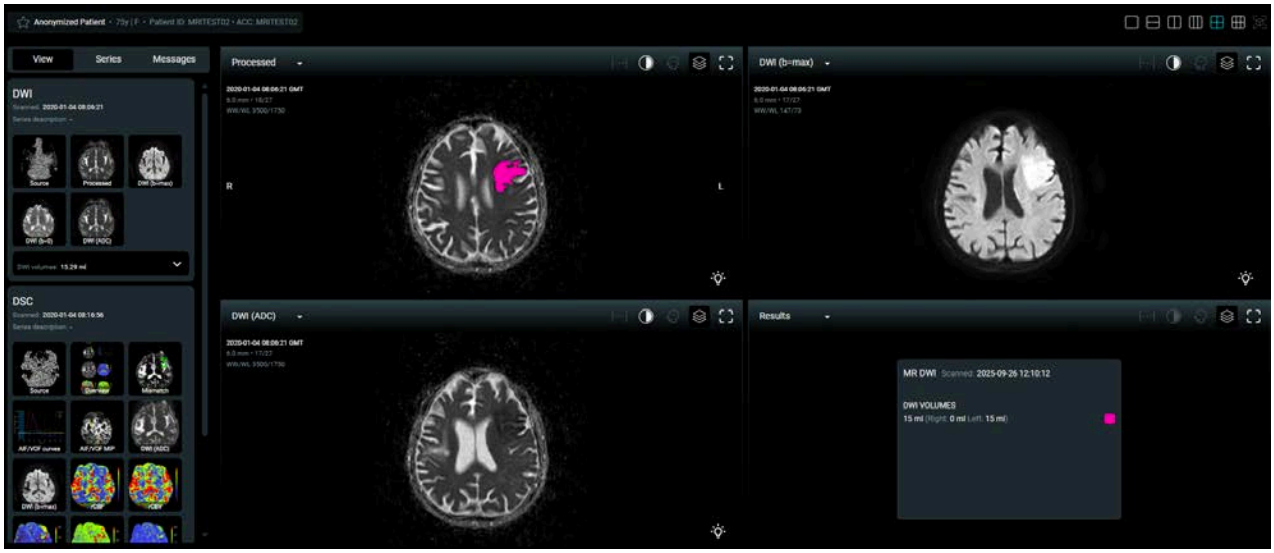
Individual overlays shown on the Processed view are as follows:

- **Core map:** Highlights the area thresholded according to the first mismatch rule. Used as 'core' in mismatch calculations.
- **Hypoperfusion map:** Highlights the area thresholded according to the second mismatch rule. Used as 'hypoperfused region' in mismatch calculations.
- **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.
- **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-CTP which may affect the accuracy of the score.

# 8.4.2 e-MRI DWI Display



# Results Summary

The DWI volumes, FLAIR mismatch, and related information are displayed on the Result Summary View. This contains the following information.

## DWI Volumes

DWI volume results in ml, as calculated by e-MRI. These are computed by an algorithm which looks for low ADC values with corresponding high DWI signal.

## FLAIR Mismatch

FLAIR mismatch results, as calculated by e-MRI. The FLAIR intensity ratio is computed as the ratio of the FLAIR values within the co-registered low ADC ROI to its contralateral ROI. The ratio is reported as a median followed by an IQR (interquartile range). If the median ratio is above a configured threshold, the mismatch will be reported as "FLAIR positive".

# Images

## DWI (b=max)

The DWI b=max image shows the isotropic DWI image with maximum diffusion weighting applied.

## DWI (b=0)

The DWI b=0 image shows the T2* weighted image with no diffusion attenuation.

## ADC

The ADC (Apparent Diffusion Coefficient) image is a measure of the magnitude of diffusion within tissue, and is computed from the DWI acquisition.

## Processed

The Processed view shows the ADC image with areas of likely abnormally restricted diffusion (low ADC and high DWI signal) highlighted.

## FLAIR

If available, the input FLAIR image will be displayed, co-registered to the DWI images.

# Overlays

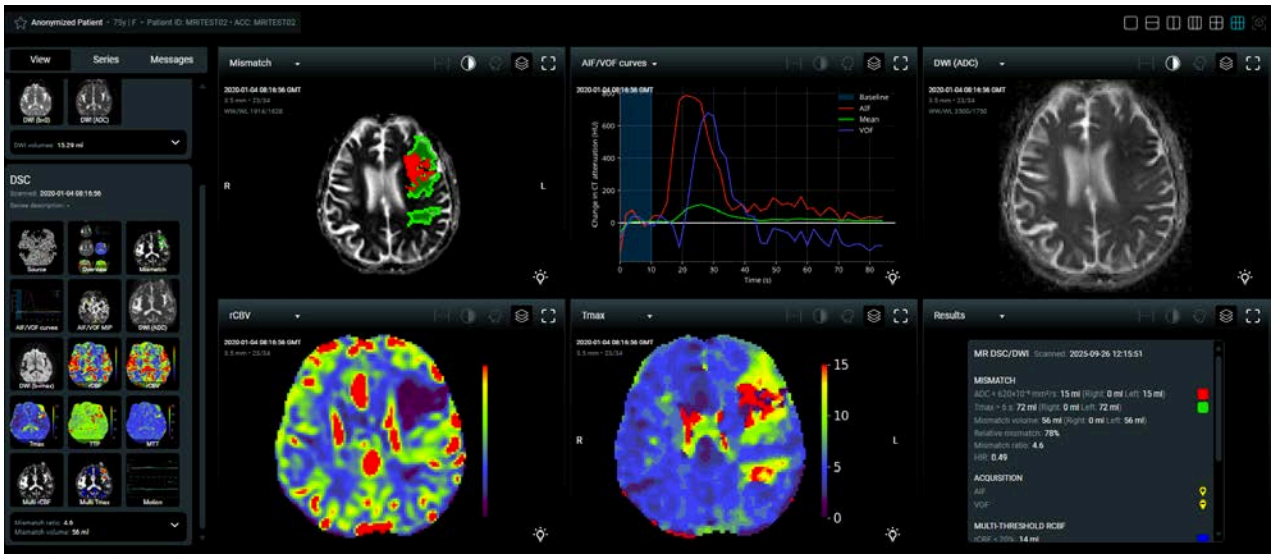
Individual overlays shown on the Processed view are as follows:

- **ADC core:** Highlights the area of likely abnormal diffusion restriction, corresponding to low ADC values and high DWI signal.
- **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-MRI which may affect the accuracy of the results.

# 8.4.3 e-MRI DSC Display




## Results Summary

The perfusion volumes, mismatch, and related information are displayed on the Result Summary view. This contains the following information.

### Detected Volumes

Thresholded volume results in ml, as calculated by e-MRI. These are computed by applying pre-defined thresholding rules to the parameter maps computed by e-MRI (the default rules are based on ADC and Tmax thresholds, with a fallback to CBF if ADC is not available). The accuracy of the volume calculation will depend on the quality of the parameter maps. This in turn depends on the quality of input data, motion correction, and correct detection of the arterial input function (AIF), which should be manually verified by looking at the AIF curve and motion charts.

## Processed

### Summary mismatch map

The summary mismatch map shows the thresholded volume extent on the pre-bolus arrival mean image.

### AIF/VOF chart

The AIF/VOF chart shows the arterial input function (in red) and venous output function (in blue) over time. This image should be reviewed to ensure the bolus timing is good and that the AIF is correctly detected.

### AIF/VOF vessel MIP image

The AIF/VOF MIP image shows a maximum intensity projection of the vessels within the perfusion volume, together with the points that were selected for the AIF (in red) and the VOF (in blue).

### Motion correction chart

The motion correction chart shows the rotation and translation frame-to-frame corrections applied by the software. This image should be reviewed to check for excessive motion during the DSC acquisition.

### Individual parameter maps

The individual parameter maps show colour-mapped values for diffusion and perfusion parameters: ADC (apparent diffusion coefficient), CBV (relative cerebral blood volume), CBF (relative cerebral blood flow), Tmax (time at which maximum value of residue function occurs, relative to AIF peak), TTP (time to peak contrast) and MTT (mean transit time).

### Multi-threshold parameter maps

If configured, multi-threshold parameter maps show volume extents for multiple thresholds applied to the parameter, one colour per threshold.

## Overlays

Individual overlays shown on the Results view can be toggled on and off here.

- **Core map:** Highlights the area thresholded according to the first mismatch rule. Used as 'core' in mismatch calculations.
- **Hypoperfusion map:** Highlights the area thresholded according to the second mismatch rule. Used as 'hypoperfused region' in mismatch calculations.
- **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.
- **Text annotations:** Shows the side indicators and other informational text overlays.

### Warnings

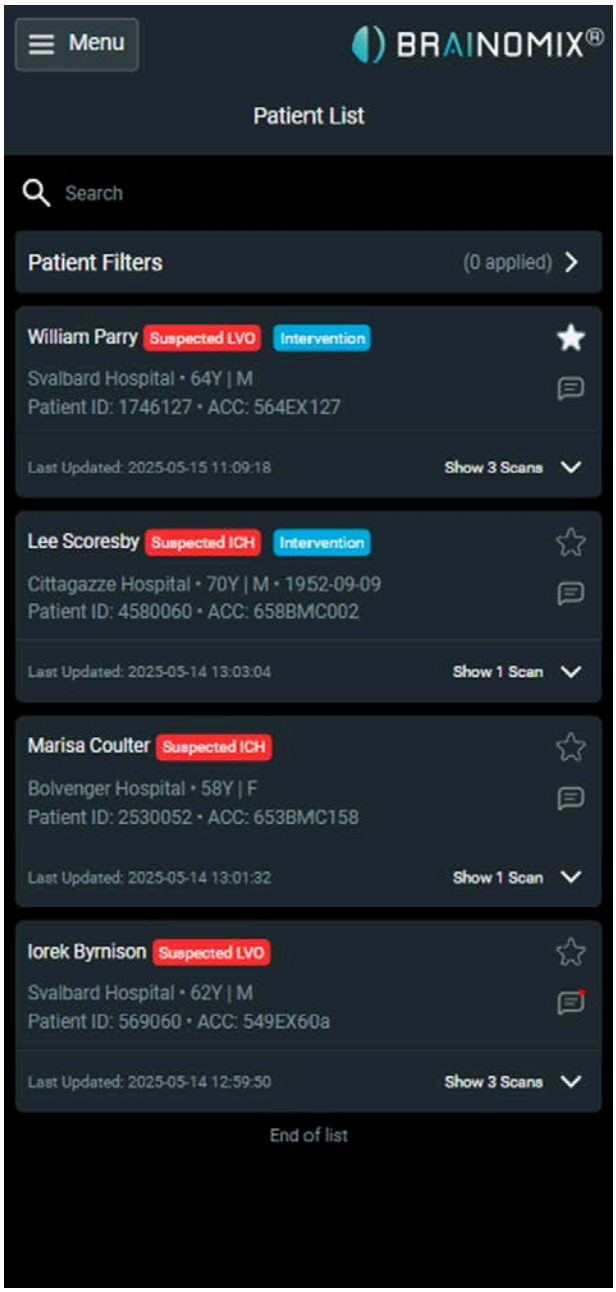
If there is an exclamation mark icon in the Info or Series button, there are warnings from e-MRI which may affect the accuracy of the results.

# 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**

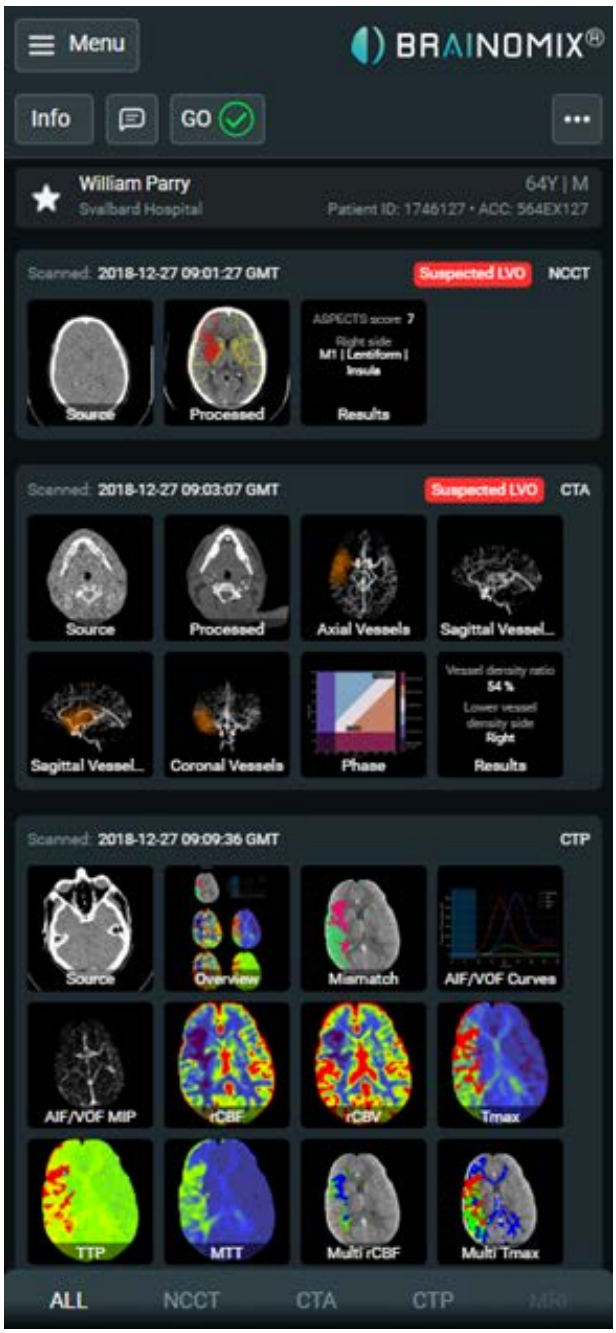
# All series

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-CTP/e-MRI.

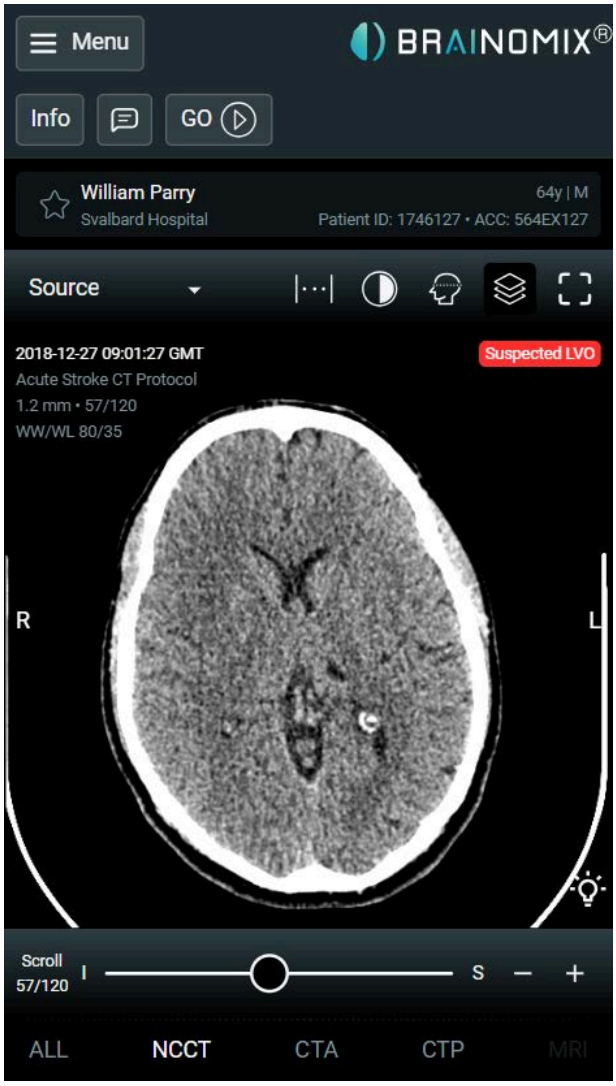


# Viewing scans

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.



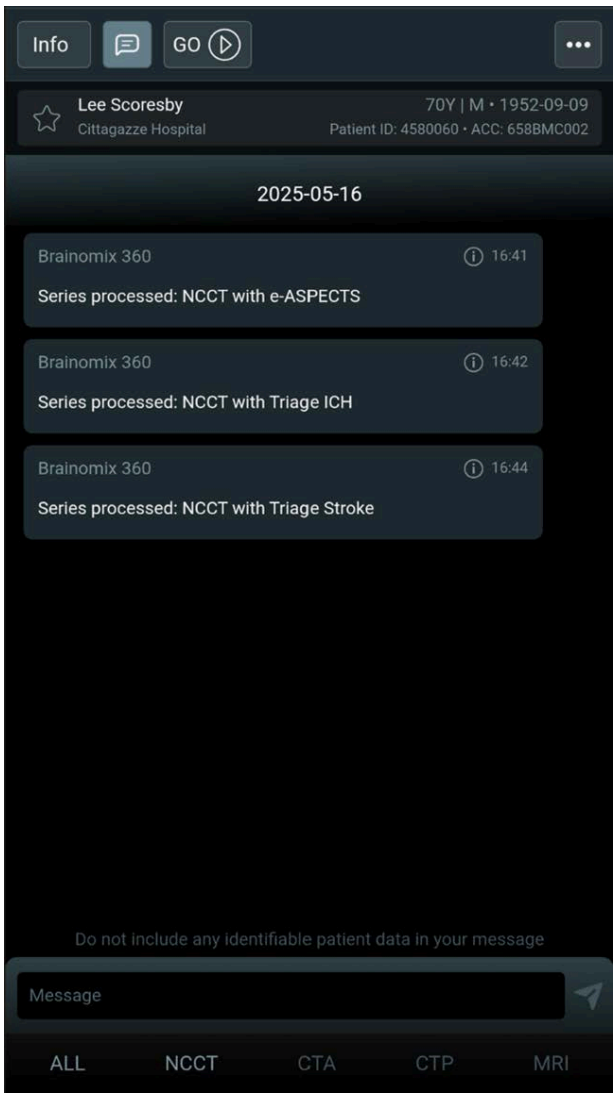
# 9.3 **Messaging**

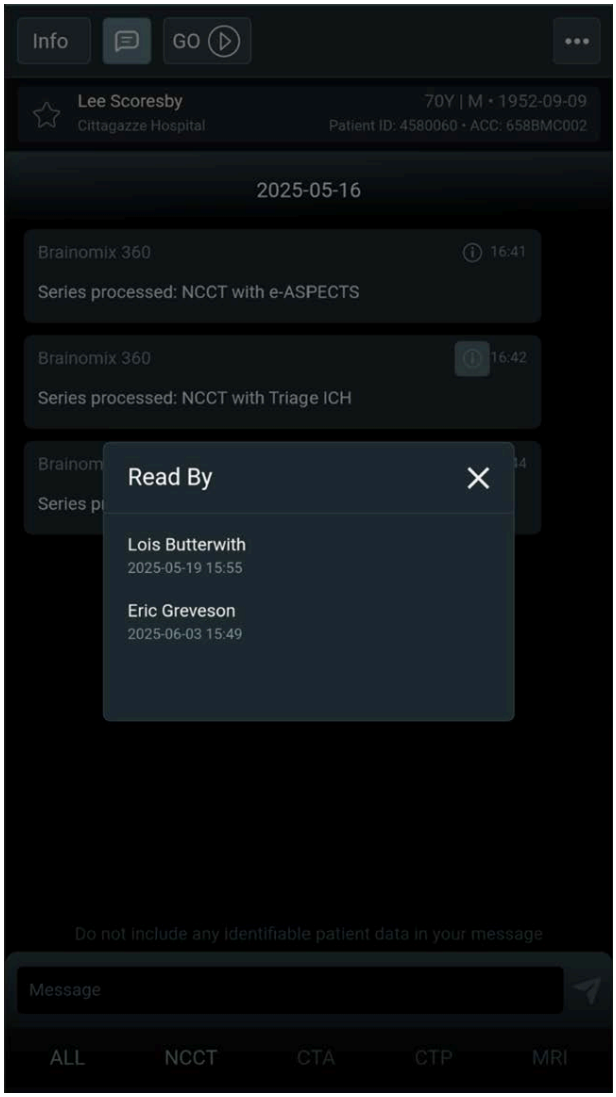
If enabled by your system administrator, messages can be viewed and sent for a patient. As new messages arrive they can be viewed in the chat area and if configured, a mobile app notification will be sent to all registered users.

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

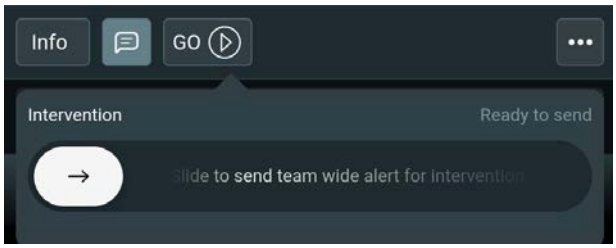
If this functionality is enabled by your system administrator, you can manually flag a patient for intervention from the patient viewer.

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

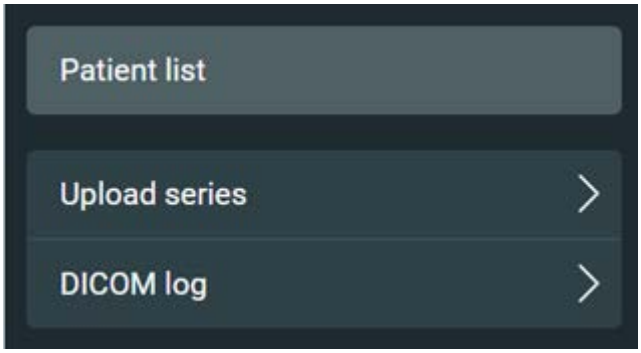
An external application may be configured to automatically transfer scan series to the Brainomix 360 server.

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

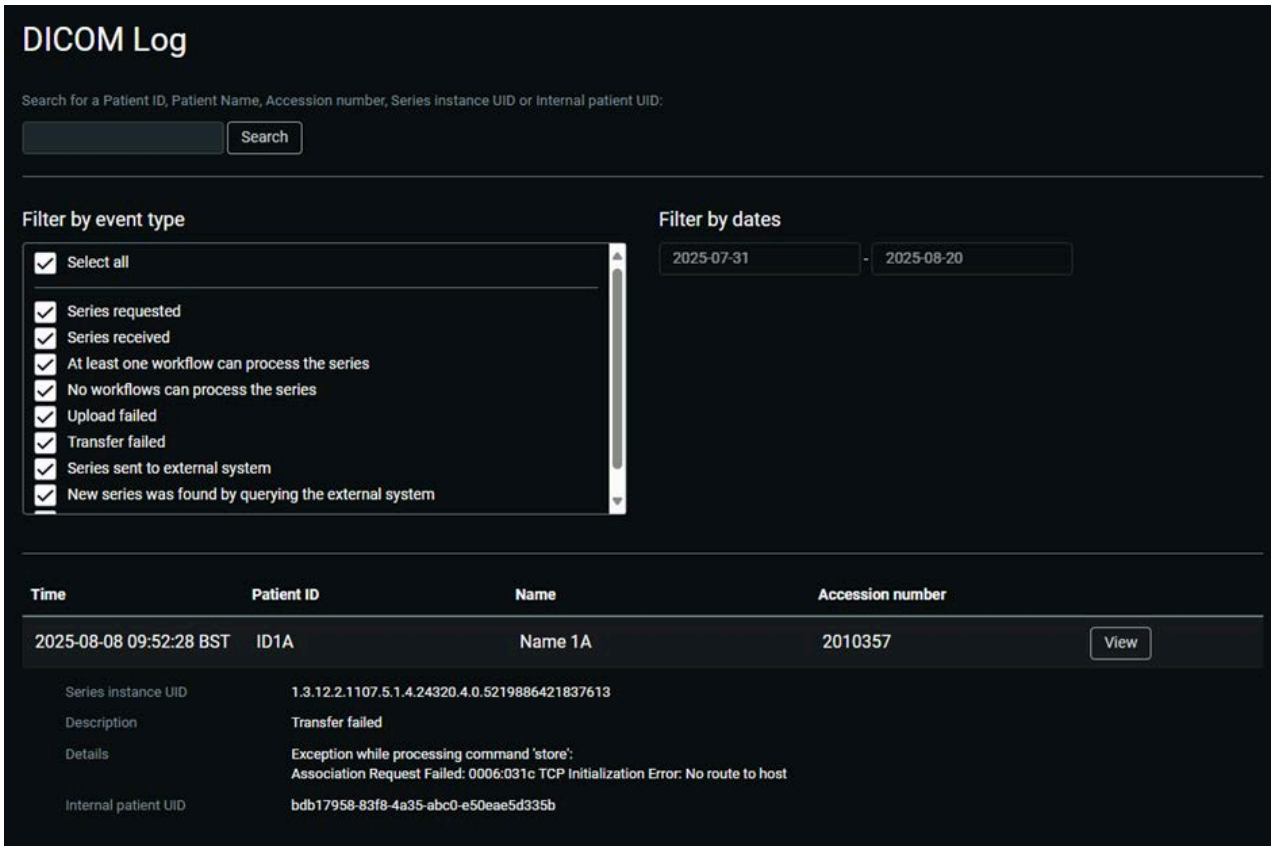
1. Log in to Brainomix 360
2. Open the menu using the menu icon at the top of the page.
3. Select **Upload series** from the menu.




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

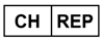
Please contact us via support@brainomix.com (mailto:support@brainomix.com) if you have discovered a potential issue with any of our Brainomix 360 suite services. Note that any information you submit will be governed by our Privacy Policy (https://www.brainomix.com/privacy-eu/#:~:text=For%20users%20of%20Brainomix%20products,in%20order%20to%20provide%20support).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

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