



DIADEM Instructions for Use

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1 Intended Use

DIADEM is intended to be used for the automatic labelling, visualisation, and volumetric quantification of segmentable brain structures from a set of Magnetic Resonance (MR) images. The software automates the current manual process of identifying, labelling, and quantifying the volumes of segmentable brain structures identified on MR images.

DIADEM does not directly generate any diagnostic output and is indicative only.

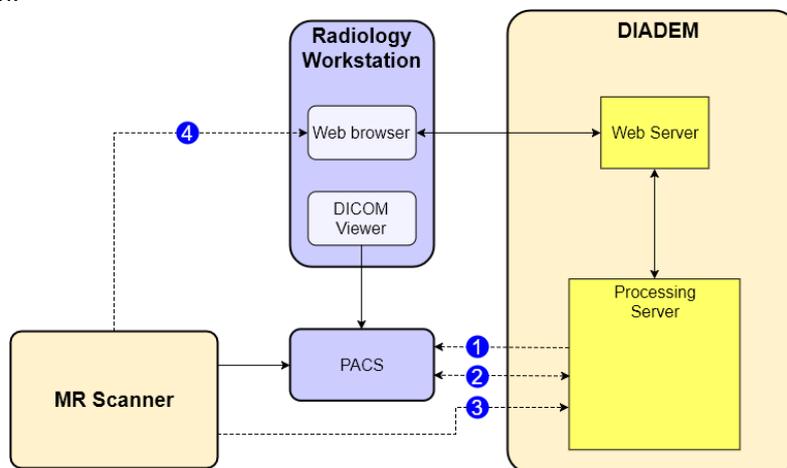
It is intended to be used by healthcare professionals such as radiologists and neuroradiologists in a clinical setting to better inform their clinical judgement on assessment of whole brain or brain region volumes for the purpose of informing their report to Neurologists/Psychiatrists who make patient management decisions.

DIADEM is indicated to be used for patients with suspected neurological conditions, referred for structural imaging as part of their diagnostic assessment.

2 Scanning

2.1 Automatic Operation

DIADEM connects directly to the PACS, and also provides a web-based user interface, as shown in the following diagram.



DIADEM can be configured in a number of ways as indicated by the numbered circles above:

- (1) The system can be configured to push resulting reports into the PACS automatically.
- (2) The system can be configured to detect new scans that have been uploaded to the PACS and to process them automatically.
- (3) The system can be configured to process scans that are pushed to it from a scanner, the PACS, or other DICOM source.
- (4) The system can be configured to allow scans to be manually loaded for processing via the web interface.

2.2 Suitable Scans



2.2.1 Protocols

DIADEM will only attempt to process scans that meet the following criteria. Other scans will be rejected as “unsuitable”.

- The receive coil must be a head coil / brain coil.
- The magnetic field strength must be at least 1.5 T.
- The slice thickness must be no more than 1.5 mm.
- The protocol name or series description must be “MP-RAGE”, “mprage” or similar.

Suitable MR pulse sequence parameter ranges, verified on a data set acquired with a range of scanners from all major scanner manufacturers (GE Medical, Siemens, Philips) with magnetic field strengths 1.5T and 3T are as follows:

- TR: 6.6 - 15ms
- TE: 2.84 - 5.4ms
- flip angle: 8 - 15deg

2.2.2 Brain Coverage

DIADEM processing will fail if the patient’s skull is not entirely contained within the scan. More precisely, the patient’s brain must be contained within the scan with a margin of at least 2.5 cm on all sides.

3 Web Client

3.1 Interface Overview

1. Study Filter Controls

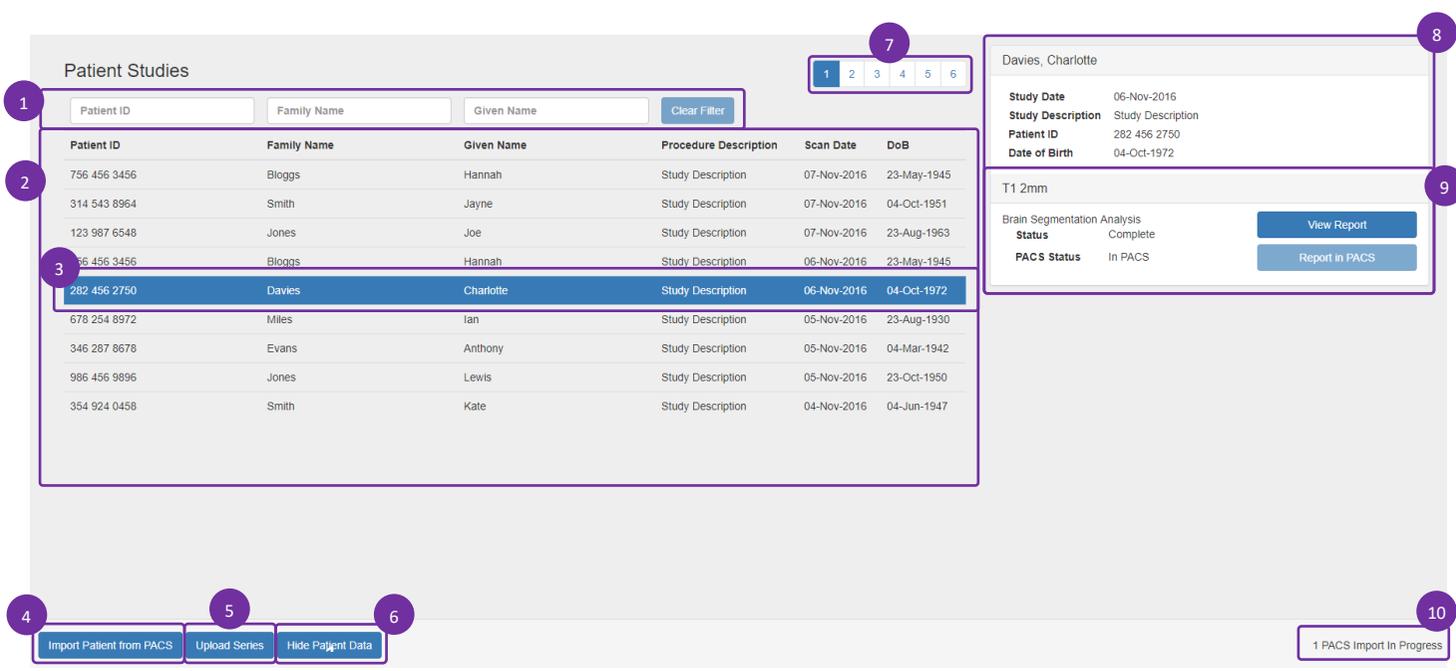
2. Study List

3. Study Selection Indicator

4. Patient Import from PACS Button

5. Series Upload Button

6. Patient Data Visibility Controls



The screenshot shows the 'Patient Studies' interface. At the top, there are filter controls for Patient ID, Family Name, and Given Name, along with a 'Clear Filter' button. Below this is a table of patient studies. The table has columns for Patient ID, Family Name, Given Name, Procedure Description, Scan Date, and DoB. The study for Charlotte Davies (Patient ID: 282 456 2750) is highlighted in blue. To the right of the table is a detailed view for the selected study, showing the patient's name, study date, description, patient ID, and date of birth. It also displays analysis results for 'T1 2mm' Brain Segmentation Analysis, which is 'Complete', and the 'PACS Status' as 'In PACS'. There are buttons for 'View Report' and 'Report In PACS'. At the bottom of the interface, there are buttons for 'Import Patient from PACS', 'Upload Series', and 'Hide Patient Data'. A status display at the bottom right indicates '1 PACS Import In Progress'. A pagination control at the top right shows page numbers 1 through 6, with page 1 selected.

7. Study page navigation controls

8. Study details panel

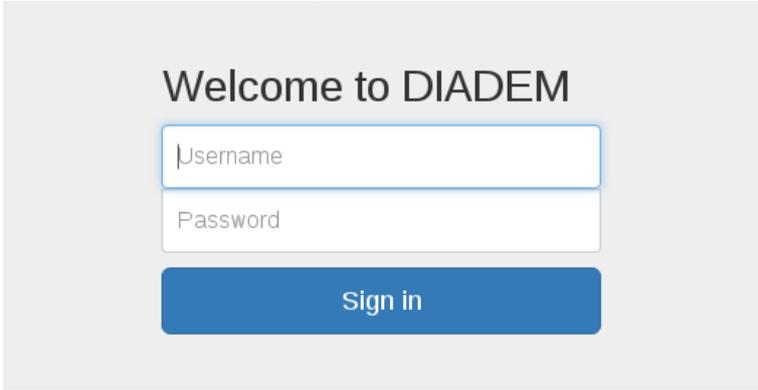
9. Analysis Detail Section

10. PACS Import Status Display

3.2 Accessing the DIADEM System

3.2.1 Logging In

Before accessing any of the functions within the DIADEM system, it is necessary for users to log in. Users will be provided with credentials for accessing DIADEM by their local DIADEM administrator. Users must enter their credentials into the login form, shown below.



The screenshot shows a login interface with the following elements:

- A heading: "Welcome to DIADEM"
- A text input field labeled "Username"
- A text input field labeled "Password"
- A blue button labeled "Sign in"

If the username or password provided are incorrect, a warning message will appear. Please double check the details entered and try again.

3.2.2 Logging Out

Users must logout when they are finished using the DIADEM system. This can be achieved using the link shown below the current user's information in the top right of the screen.

3.2.3 Automatic Log Out

To protect the DIADEM system (and ensure data security) users will be automatically logged out after a locally configured duration of inactivity. If logged out due to inactivity, the system will display a message and provide instructions on how to log back in.

3.3 Working with Patient Studies and Analyses

3.3.1 Locating and Selecting a Patient Study

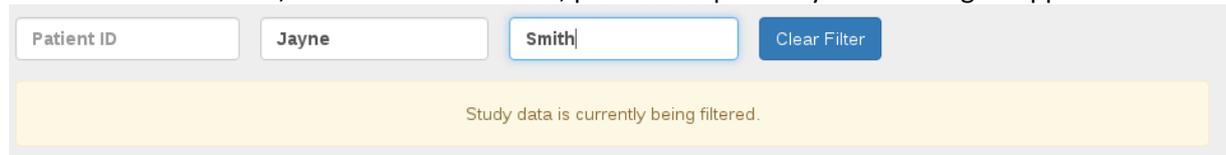
All studies within the DIADEM system are listed in the Study List (Item 2).

They are shown in date order, with the most recent studies appearing first.

The list may be filtered using the Filter Controls (Item 1) to select studies based on Patient ID, Patient Given Name, and Patient Family Name.

When studies are being filtered, the message shown below appears. This acts as a reminder that only a subset of studies is being displayed.

The Clear Filter button, next to the filter fields, provides a quick way of removing all applied filters.



The Study List may span several pages, as indicated by the Page Navigation Controls (Item 7) These controls may be used to move between pages.

When a study has been selected, it is highlighted as shown in Item 3 and the details of the study are displayed in the Details Panel (Item 8). The Details Panel provides more information about the selected study and lists any analyses that are associated with the study.

3.3.2 View Analysis Status

The status of each analysis is displayed, which may be one of the following:

- **Queued**
The analysis is currently queued for processing. Processing will begin automatically once system resources are available.
- **Processing Possible**
The analysis is not configured for automatic processing. It can be queued by the user.
- **Processing**
The analysis is currently in progress.
- **Complete**
The analysis is complete, and results may be viewed.
- **Cancelling**
The analysis is in the process of being cancelled.
- **Cancelled**
The analysis was manually cancelled.
- **Rejected**
The series submitted for analysis was unsuitable.
- **Failed**
The analysis failed.

3.3.3 View Analysis Results

Once the desired analysis has been found, the final report may be viewed by using the *View Report* button

MPRAGE 1mm

Brain Segmentation Analysis		
Status	Complete	View Report
PACS Status	In PACS	Report in PACS

3.3.4 Manually Start or Restart an Analysis

Depending on the configuration of the system it may be necessary to start selected analyses manually. Additionally, there may be occasions where a previously cancelled analysis must be restarted.

Once the desired analysis has been found, it may be started manually by using the *Start Processing* button.

MPRAGE 1mm

Brain Segmentation Analysis		
Status	Processing Possible	Start Processing

3.3.5 Manually Cancel an Analysis

If an analysis was erroneously started it may be cancelled manually.

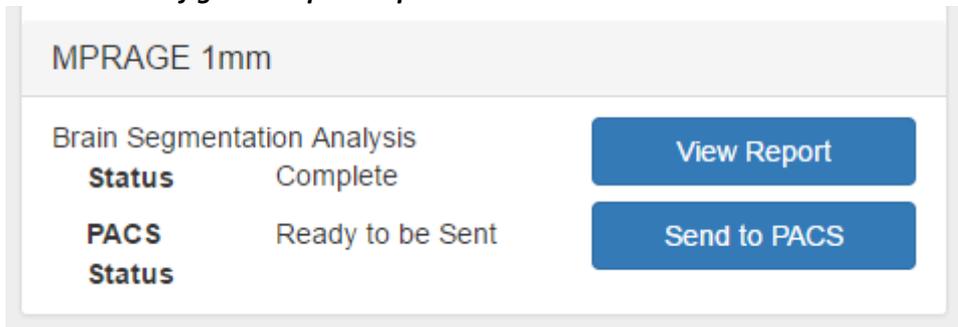
Once the desired analysis has been found, it may be cancelled manually by using the *Cancel Processing* button.

MPRAGE 1mm

Brain Segmentation Analysis		
Progress	Running: 02:00:01	
Status	Processing	Cancel Processing

3.3.6 Export Analysis Results to PACS

The report from a completed analysis may be configured such that it is not automatically sent to the Institution’s PACS system. It may however be sent manually, by finding the desired analysis then using the *Send to PACS* button to begin the export process. **If this button is not visible, then your system has not been configured to push reports to the PACS.**



The state of the results of each analysis is displayed next to the *Send to PACS* button

- **Ready to be Sent**
The report is available to be sent to PACS.
- **Sending**
The report is currently being sent to PACS.
- **In PACS**
The report is already stored in the PACS.
- **Sending Failed**
Sending the report to the PACS failed. Additional information may be found by speaking to the system administrator.

3.3.7 Temporarily Hide Patient Data

Patient data may be hidden by using the *Hide Patient Data* button (Item 6) (which will then become the *Show Patient Data* button).

This redacts any identifiable patient data that is currently on screen, as shown below

Patient ID	Given Name	Family Name	Procedure Description	Scan Date	DoB
756 456 3456	██████	██████	Study Description	07-Nov-2016	██████
314 543 8964	██████	██████	Study Description	07-Nov-2016	██████

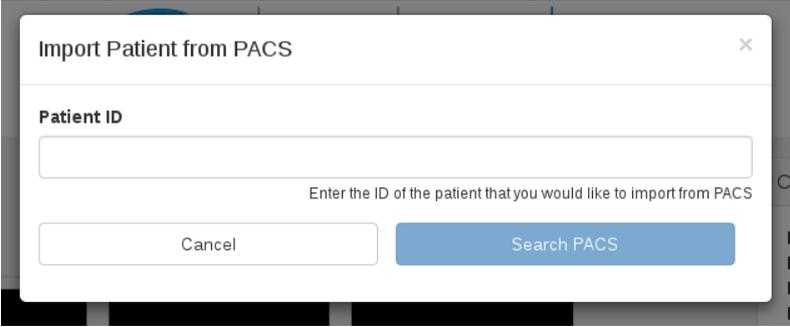
Visibility of patient data may be restored by using the *Show Patient Data* button (Item 6).

3.4 Importing Patient Data from PACS

It may be necessary to import historical patient data from PACS to allow retrospective processing using the DIADEM system.

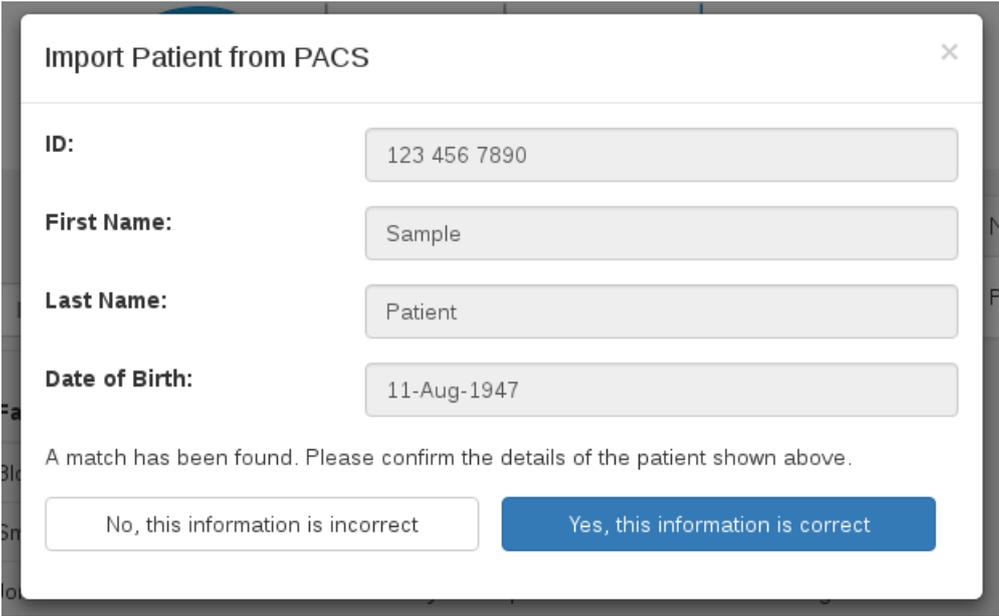
The Import function requires that the Patient ID is known. This can be taken from PACS or RIS. To begin the import process, use the *Import Patient from PACS* button (Item 4). **If this button is not visible, then your system has not been configured for direct connection to the PACS.**

The system will then prompt for the ID of the Patient to be imported.



Once entered, click *Search PACS* to retrieve the details of the selected patient from the Institutions PACS system. The results of this search are displayed, to give an opportunity to cancel the import if an incorrect Patient ID was used.

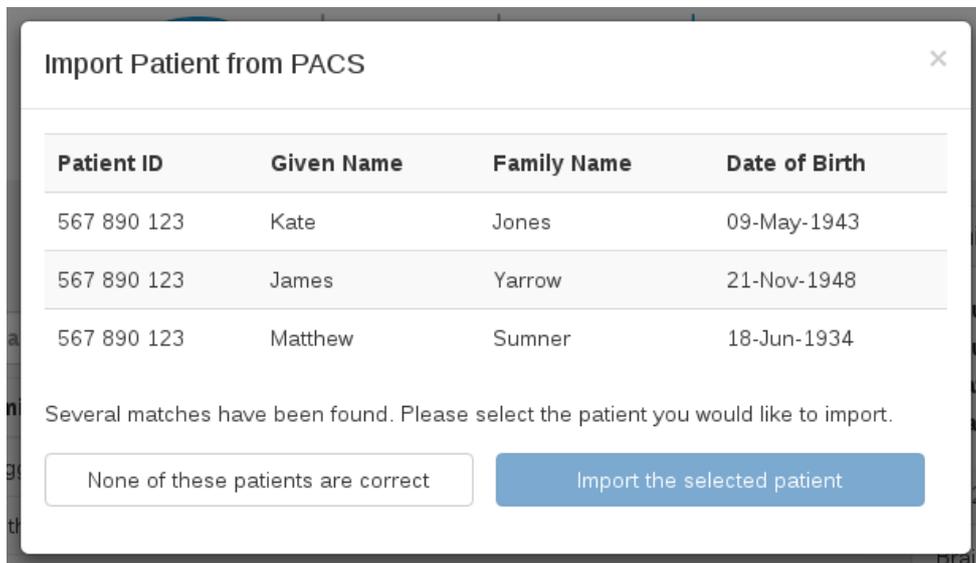
Single Search Result:



If the details are correct, press the *Yes, the information is correct* button to begin the import process. If the patient details displayed are incorrect, click the *No, this information is incorrect* button to go back to the previous step and re-enter the patient ID.

Multiple Search Results:

If multiple patients are found with the given ID, they will be listed, along with additional information such as Name and Date of Birth as shown below



If the patient to import is shown, click their name, and then click *Import the selected patient*. If the patient to import is not shown, click *None of these patients are correct* and double check the search criteria.

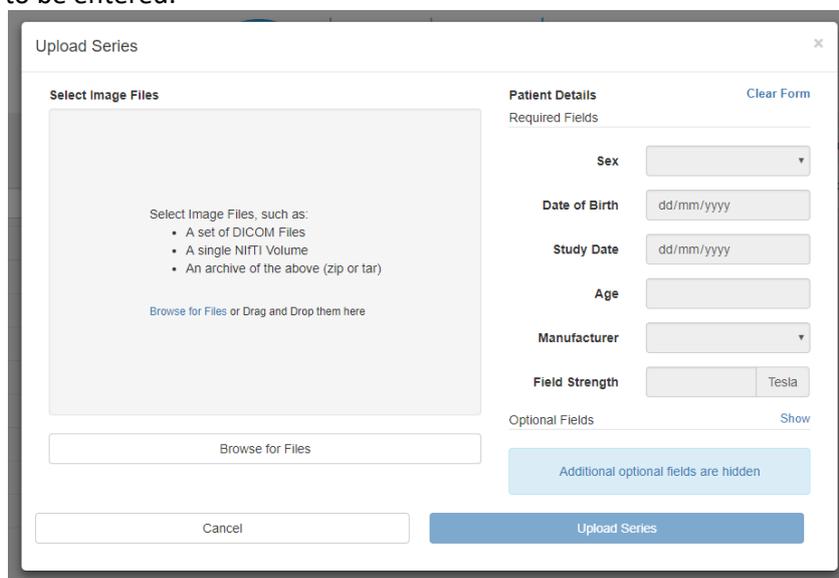
Once the import has successfully completed, the system will show a notification which, when clicked, filters the study list to show only those studies related to the newly imported patient.

3.5 Upload Series

It may be necessary to process a Patient series that is stored somewhere other than in the PACS, for example a departmental network share or a local computer.

The Upload Series workflow facilitates this processing and is started by clicking the *Upload Series* button (Item 5). ***If this button is not visible, then your system has not been configured for scans to be uploaded via the web interface.***

The system will display the window shown below, which allows Image Files to be selected and Patient Details to be entered.



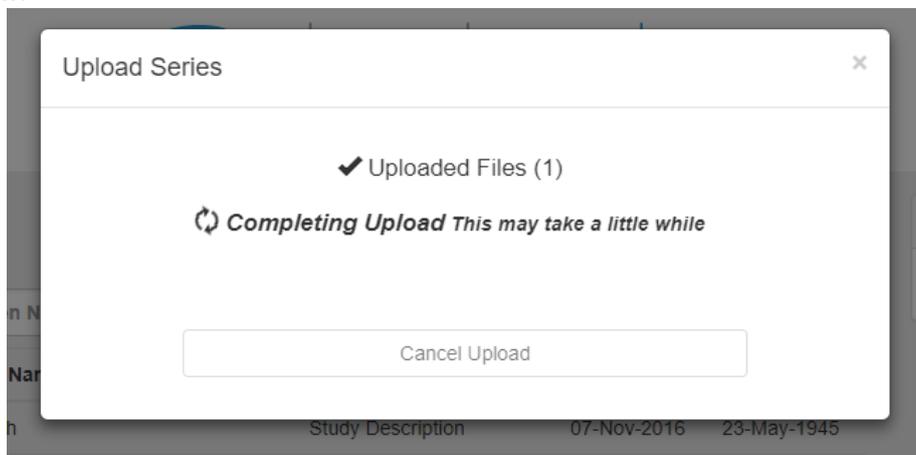
Acceptable Image Files include:

- A set of DICOM Files
- A single NiftI Volume
- An archive (ZIP or tar) containing either of the above

Warnings will be shown below the file list if there are issues with the files selected, such as files being of the wrong type or metadata being unreadable.

Once a set of images have been selected, the system will attempt to read their metadata and prefill as much of the Patient Details form as possible. It is important that this information is carefully reviewed before submission.

Once all Image Files have been selected and the Patient Details have been entered and verified, press *Upload Series* to begin the upload process. The progress of the upload is reported by the window shown below.



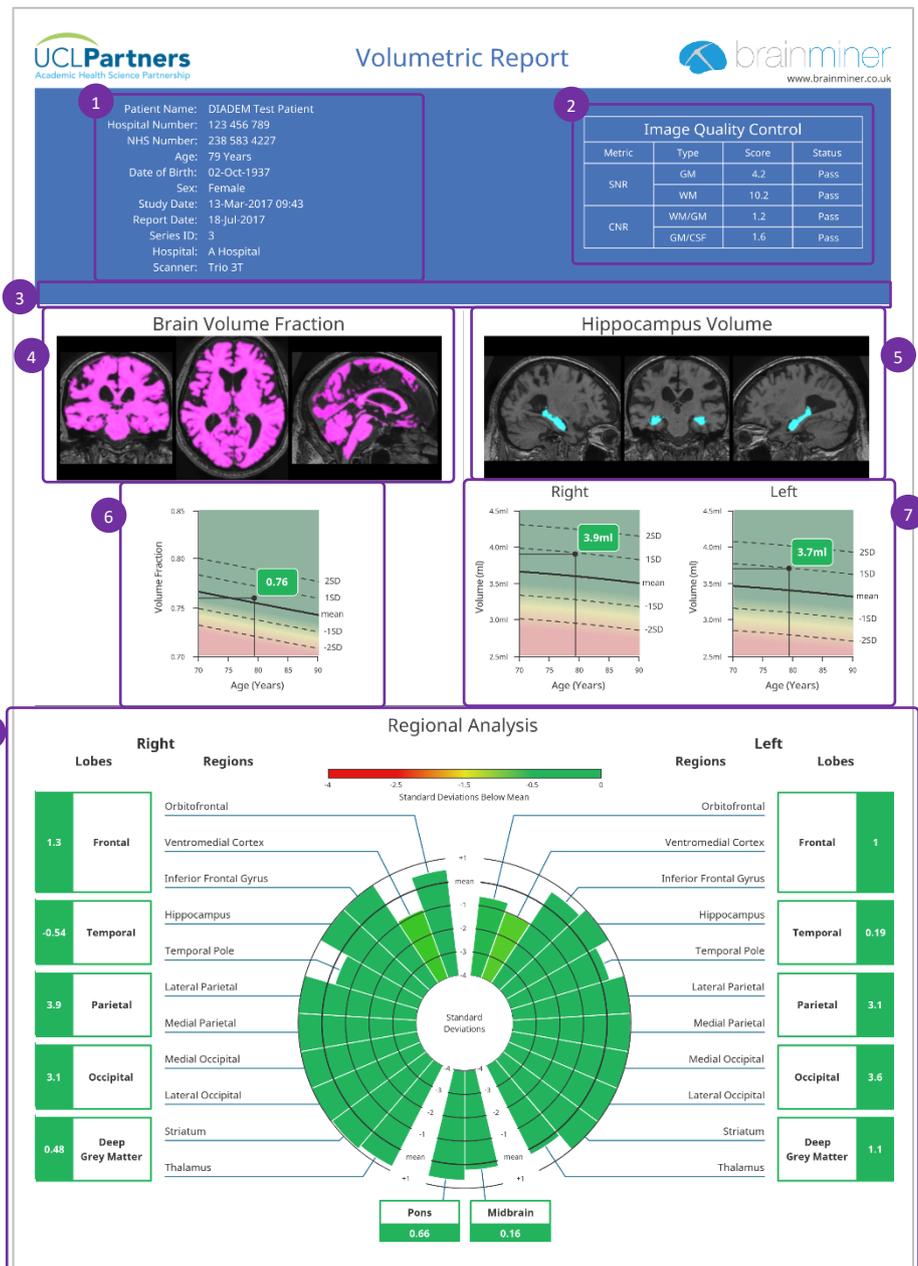
After upload, the files will be validated to ensure that they are compatible with the DIADEM system. If not, an error message will be returned.

Once the upload is complete, the patient’s details will be displayed, and the pipeline progress will be available from the Study List view.

4 Report

4.1 Overview

1. Patient and Study Information
2. Image Quality Control Table
3. Report Warning Display
4. Brain Volume Fraction QC Image
5. Hippocampus Volume QC Image
6. Brain Volume Fraction Plot
7. Hippocampus Volume Plot
8. Regional Analysis Plot



4.2 Report Heading

4.2.1 Verifying Patient Identity

The report heading contains Patient and Study information (Item 1) to allow clinicians to reliably identify the patient to whom the report relates.

This data should be verified each time a report is interpreted to ensure the correct patient is being assessed.

4.2.2 Interpreting Image Quality Control

The DIADEM system calculates the Signal-to-Noise Ratio (SNR) and Contrast-to-Noise Ratio (CNR) for the provided image, which are reported (Item 2) to allow the clinician to gauge the quality of the image and report provided.

The following metrics are calculated:

- SNR:WM – White Matter Signal-to-Noise Ratio
- SNR:GM – Grey Matter Signal-to-Noise Ratio
- CNR:WM/GM – White Matter / Grey Matter Contrast-to-Noise Ratio
- CNR:GM/CSF – Grey Matter / Cerebral Spinal Fluid Contrast-to-Noise Ratio

Each metric has a score which must be interpreted by the clinician using their experience of the installed scanners at the site and the protocols they use.

Additionally, when a supported scanner is used, the report also displays a status. This is calculated based on the expected performance of a given scanner and is compared against configurable limits.

4.2.3 Warnings

Unexpected data may result in a warning being displayed on the report (Item 3). The possible warnings are shown below:

- **Report heading may contain errors**
An unknown error occurred when loading the patient information. Please review the patient information and interpret the report accordingly.
- **NHS Number is Invalid**
The NHS Number retrieved from the scan's DICOM data appears to be invalid. Please review the patient information carefully to ensure the correct patient data is present.
- **Patient information may contain errors**
An unknown error occurred when loading the patient information. Please review the patient information and interpret the report accordingly.
- **Patient Age is below 50**
The DIADEM system is designed to work with patients above the age of 50. The results still may be used, but extra care should be taken when interpreting the report.
- **Patient Sex unknown**
It was not possible to determine the patient's sex from the given scan. As the population data is normalised against age and sex, this may result in non-ideal expected values. Extra care should be taken when interpreting the report.
- **Image Quality Control contains Cautions**
The SNR or CNR of the scan fall outside of expected limits. Extra care should be taken when interpreting the report.
- **Image Quality Control contains Warnings**
The SNR or CNR of the scan fall outside of allowable limits. Extra care should be taken when interpreting the report.
- **Unsupported scanner used, Image Quality Control status not provided**
An unsupported scanner was used to collect the image. As such it is not possible to determine the

image quality control status as no comparative data exists. Extra care should be taken when interpreting the report.

- **Image Quality Control contains Errors**

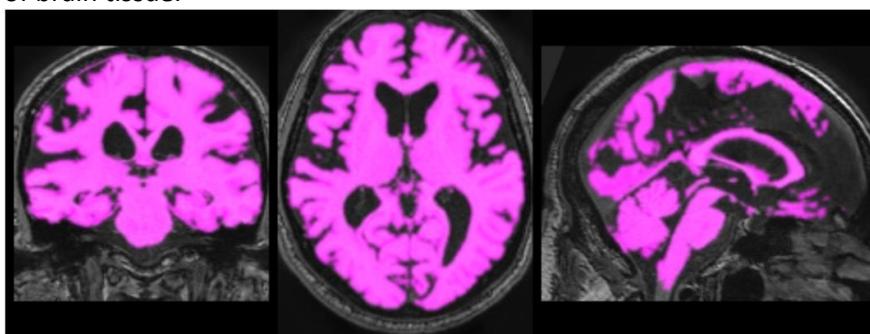
An unknown error occurred when calculating the Image Quality Control table, please review the table and interpret the report accordingly.

If a warning is present it is important for the clinician to review the raw images that were used to generate the report and to use their clinical experience when interpreting the report.

4.3 Brain Volume Fraction

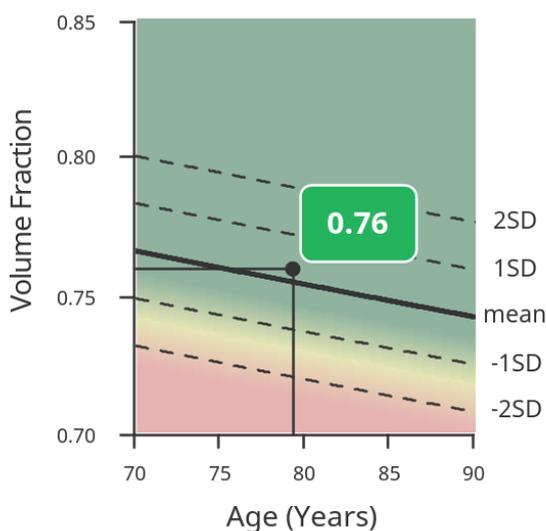
4.3.1 Quality Control Image

The quality control images (Item 4) provide a visual display of where the system believes brain tissue is present within the cranium. This provides the clinician with an opportunity to spot any misallocation of brain tissue.



4.3.2 Volume Fraction Plot

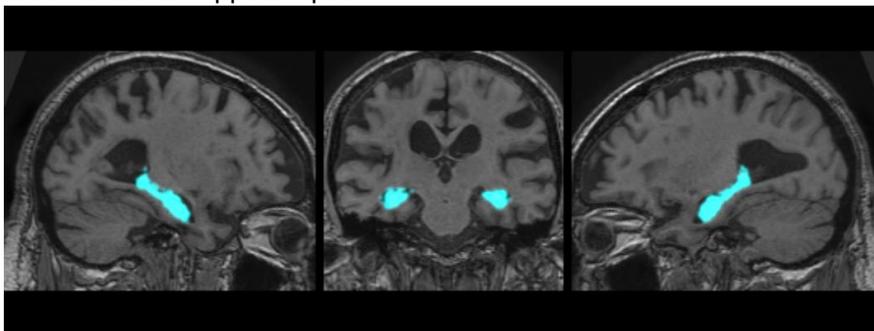
The Brain Volume is plotted (Item 6) against the expected volume fraction for a given age and gender. Additionally, standard deviation lines of ± 1 and ± 2 standard deviations are displayed. Please see Section 5 for a description of the statistical model used and explanation of the curve transparency.



4.4 Hippocampus Volume

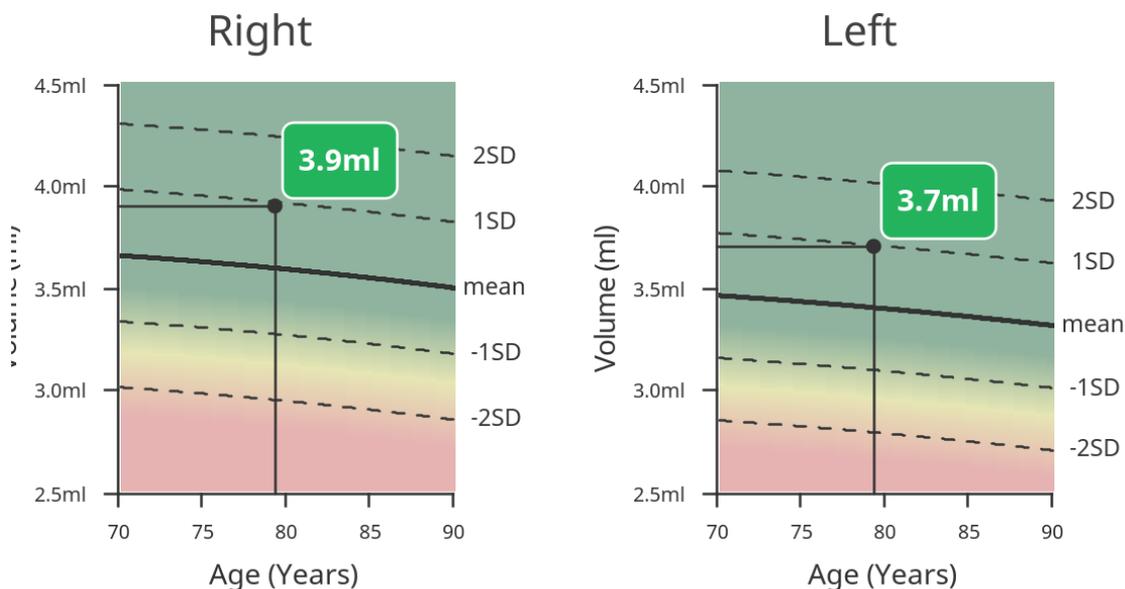
4.4.1 Quality Control Image

The quality control image (Item 5) provides a visual display of where the system believes the hippocampi are located within the brain. This provides the clinician with an opportunity to spot any obvious mislocation of either hippocampus.



4.4.2 Volume Plot

The hippocampus volume for both the left and right hippocampi are plotted (item 7) against the expected volume for a given age and sex. Additionally, standard deviation lines of ± 1 and ± 2 standard deviations are displayed. Please see Section 5 for a description of the statistical model used and explanation of the curve transparency.



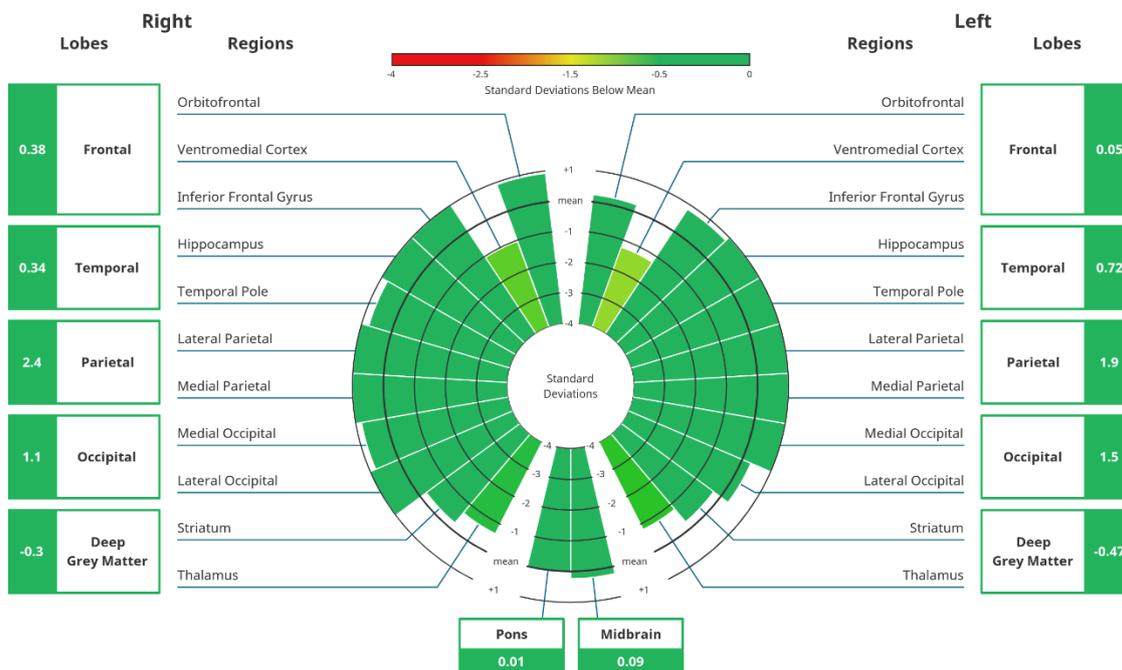
4.5 Regional Analysis

The results of the analysis are displayed within the Regional Analysis plot (Item 8). This displays brain regions as compared to an age and sex normalised population.

4.5.1 Regions

Specific regions of interest have been selected to be displayed prominently as bars on the regional analysis plot. Each bar displays how many standard deviations the measured volume was away from the expected volume for the given region. Positive numbers indicate a larger than expected brain region volume whilst negative numbers indicate a smaller than expected volume.

The image below shows regions with both larger and smaller than expected volumes. The expected volume, or mean, is shown by the darker line.



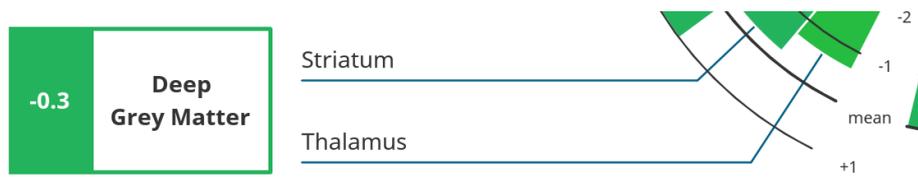
4.5.2 Lobes

Lobes summarise the volumes of several regions.



Lobes include some regions that have not been selected to be displayed individually. **As such, the number of standard deviations shown in a lobe heading may differ from that indicated by the regions displayed.**

For example, the image below shows the Deep Grey Matter at -0.3 standard deviations away from the mean, whilst the Striatum is at approximately -0.3 and Thalamus is at approximately -0.8. This is because the Deep Grey Matter lobe consists of more regions than just the Striatum and Thalamus.

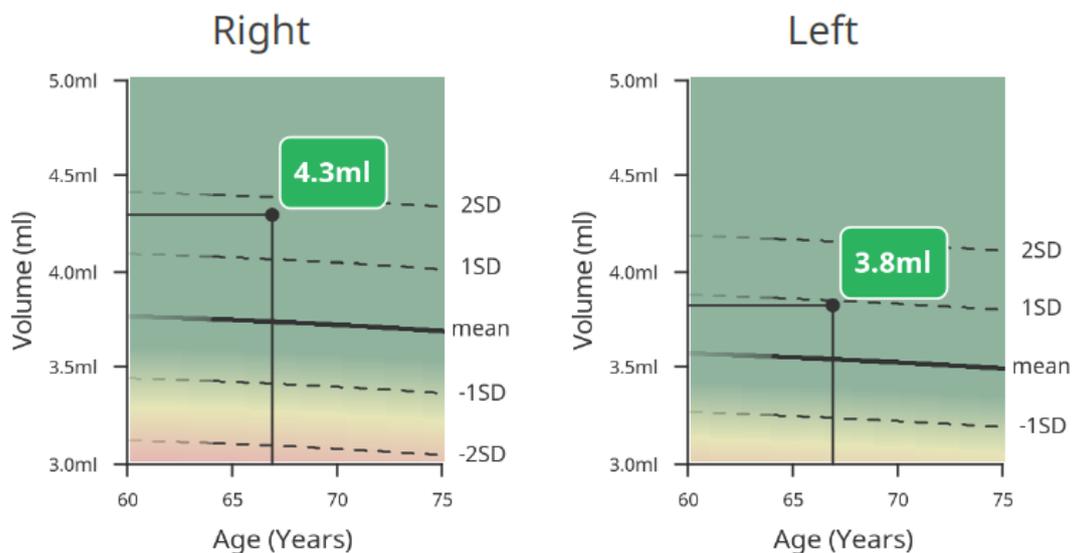


5 Statistical Model



The statistical model used to compare a patient against the normal population results in two distinct curves – one valid for younger patients (aged up to 64) and one valid for older patients (those aged 64 or over). The appropriate curve is selected when comparing a given patient against the normal database and this curve is then depicted in the plots within the report.

For patients who are aged close to 64 the curve becomes fainter towards one edge of the plot. This is to indicate that the model settings used for the patient is moving away from the range in which it can be considered valid, and so should not be relied upon to interpret trends or comparisons.



6 Brain Region Hierarchy

The regional analysis is calculated by combining various brain structures into the displayed regions and lobes. The exact structure used is shown below:

6.1 Left / Right

6.1.1 Frontal

- Anterior Cingulate Gyrus
- Anterior Orbital Gyrus
- Central Operculum
- Frontal Operculum
- Frontal Pole
- Gyrus Rectus
- Lateral Orbital Gyrus
- Medial Frontal Cortex
- Medial Orbital Gyrus
- Middle Frontal Gyrus
- Opercular Part of The Inferior Frontal Gyrus
- Orbital Part of The Inferior Frontal Gyrus
- Posterior Orbital Gyrus
- Precentral Gyrus Medial Segment
- Precentral Gyrus
- Subcallosal Area
- Superior Frontal Gyrus Medial Segment
- Superior Frontal Gyrus
- Supplementary Motor Cortex
- Triangular Part of The Inferior Frontal Gyrus

6.1.1.1 Orbitofrontal

- Anterior Orbital Gyrus
- Lateral Orbital Gyrus
- Medial Orbital Gyrus
- Posterior Orbital Gyrus

6.1.1.2 Ventromedial Cortex

- Anterior Cingulate Gyrus
- Gyrus Rectus
- Medial Frontal Cortex
- Subcallosal Area
- Superior Frontal Gyrus Medial Segment

6.1.1.3 Inferior Frontal Gyrus

- Opercular Part of The Inferior Frontal Gyrus
- Orbital Part of The Inferior Frontal Gyrus

- Triangular Part of The Inferior Frontal Gyrus

6.1.2 Temporal

- Amygdala
- Entorhinal Area
- Fusiform Gyrus
- Hippocampus
- Inferior Temporal Gyrus
- Middle Temporal Gyrus
- Parahippocampal Gyrus
- Planum Polare
- Planum Temporale
- Superior Temporal Gyrus
- Temporal Pole
- Transverse Temporal Gyrus

6.1.2.1 Hippocampus

- Hippocampus

6.1.2.2 Temporal Pole

- Temporal Pole

6.1.3 Parietal

- Angular Gyrus
- Parietal Operculum
- Superior Parietal Lobule
- Supramarginal Gyrus
- Postcentral Gyrus
- Postcentral Gyrus Medial Segment
- Posterior Cingulate Gyrus
- Precuneus

6.1.3.1 Lateral Parietal

- Angular Gyrus
- Parietal Operculum
- Superior Parietal Lobule
- Supramarginal Gyrus

6.1.3.2 Medial Parietal

- Posterior Cingulate Gyrus
- Precuneus

6.1.4 Occipital

- Calcarine Cortex
- Cuneus
- Inferior Occipital Gyrus
- Lingual Gyrus
- Middle Occipital Gyrus
- Occipital Fusiform Gyrus
- Occipital Pole
- Superior Occipital Gyrus

6.1.4.1 Medial Occipital

- Calcarine Cortex
- Cuneus
- Lingual Gyrus
- Occipital Fusiform Gyrus

6.1.4.2 Lateral Occipital

- Inferior Occipital Gyrus
- Middle Occipital Gyrus
- Occipital Pole
- Superior Occipital Gyrus

6.1.5 Deep Grey Matter

- Accumbens Area
- Caudate
- Pallidum
- Putamen
- Thalamus Proper

6.1.5.1 Striatum

- Caudate
- Putamen

6.1.5.2 Thalamus

- Thalamus Proper

6.2 Medial

6.2.1 Pons

- Pons

6.2.2 Midbrain

- Midbrain

7 Troubleshooting

Symptom	Probable Cause	Solution
Unable to view the user interface	System is not running	Check that DIADEM is running
	No network connectivity	Check physical network connections
	Invalid SSL certificate	Disable SSL or ensure clients have appropriate certificate installed
Unable to log in	Invalid credentials	Check the username and password provided are valid
	LDAP server offline	Ensure the LDAP server is running
	LDAP configuration incorrect	Check the settings for DIADEM’s LDAP connection and search strings
Series are not appearing in the pipelines queue	The PACS is offline	Check PACS is online and connected to the network
	The PACS cannot be contacted due to a networking issue	Check physical network connections
	The PACS is not configured to send series data to DIADEM	Check the settings for DIADEM’s connection to the PACS
Pipelines are created as “failed” or “rejected”	Series do not meet the criteria for processing – see section 2.2.1	Ensure desired images loaded to PACS comply with processing criteria
Pipelines start to process but processing fails after a few minutes	Insufficient clearance around the brain in the scan – see section 2.2.2	Ensure desired images loaded to PACS comply with brain coverage criteria
	The patient’s brain morphology is very unusual, and the algorithm cannot match it to its database	Ensure that the patient does not present any of the contraindicators outlined in Section 8.2

8 Warnings, Cautions & Symbols

8.1 Warnings

- DIADEM can only be used with MR images and only in accordance with the instructions for use.
- DIADEM is designed to work with MRI scans with a slice thickness up to a maximum of 1.5mm. Scans with slice thickness greater than 1.5mm will be rejected by the system as unsuitable.
- The report from DIADEM is for use by trained physicians only.
- The report from DIADEM must be interpreted with consideration of the method determining lobe volume described in Section 4.5.2 and the statistical model described in Section 5.
- DIADEM uses patient demographic information; incorrect recording of patient date of birth will result in incorrect reporting of values. Clinicians using the reports should ensure that the data is correct.
- DIADEM is only compatible with MRI scanners and protocols as described in Section 2.2.1.
- The accuracy of the DIADEM report can be degraded by imaging artefacts which can affect the technical quality of the MR images and quality of the report.
- Unexpected data may result in a warning being displayed on the report. If a warning is present it is important for the clinician to review the raw images that were used to generate the report and to use their clinical experience when interpreting the report.
- DIADEM generates absolute measures of Hippocampus Volume – these measures must not be compared between different software solutions, as the algorithms used to generate these measures are not compatible.
- DIADEM software should only be used for analysis of data from patients aged forty-five years or older.
- DIADEM software is intended for installation in environments suitable for normal computer operation such as data closets or other low radiation areas. Use of DIADEM software in high EMC environments has not been fully evaluated.
- DIADEM is intended to be installed by trained personnel of BrainMiner or of its contracted resellers

8.2 Cautions & Contraindications

- The reports from DIADEM are not directly comparable with reports from other software.
- DIADEM is not suitable for detecting other non-atrophy related pathologies in the white and grey brain matter and therefore they would be contra-indicated for use of the system. Any congenital or acquired structural abnormalities (incl. normal variants) and space-occupying lesions may hamper the diagnostic accuracy of the software and the results should be cautiously interpreted.
- If there is a clinical requirement to characterize a mass lesion or other abnormal pathological feature which differs significantly from the normal brain, the user should not rely upon the values generated by the DIADEM software without carefully reviewing the quantified values and graphical quality control output and determining if they meet the accuracy required by the clinician. DIADEM's output is intended only to supply adjunctive information that may be used along with other relevant information to help the clinician develop an overall opinion concerning the patient's status
- The normative data that each subject is compared against is derived from a typically right-handed population, which may result in a left-handed patient displaying greater deviations from normal. This should be considered when interpreting the report for a left-handed patient.

8.3 Specific Target Populations (requiring special attention)

- Specialist advice should be taken when interpreting scans in people with learning disabilities (NICE, 2006)

8.4 Explanation of Symbols & Statements



Caution

WARNING

This is a statement that alerts the user to the possibility of serious injury or other adverse reactions with the use or misuse of the device



Manufacturer

CAUTION

This is a statement that alerts the user to the possibility of a problem with the system associated with its use or misuse



Consult Operating Instructions



Serial number
(includes year of manufacture)



Medical Device Directive
93/42/EEC



Caution: Federal (USA) law restricts this device to sale on or by the order of a licensed healthcare professional



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