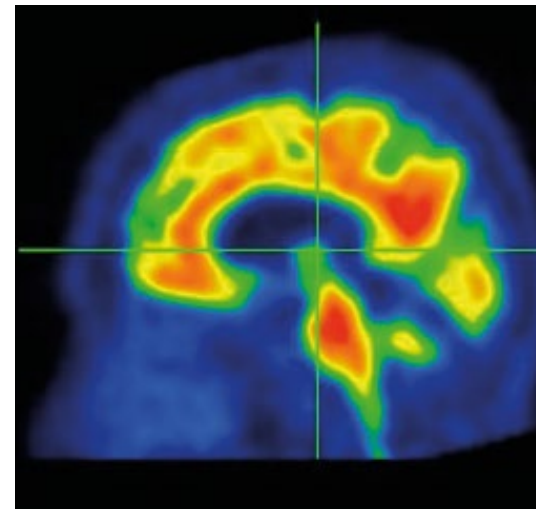
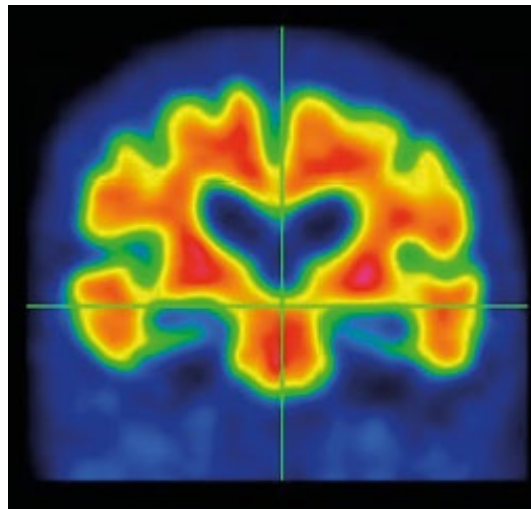
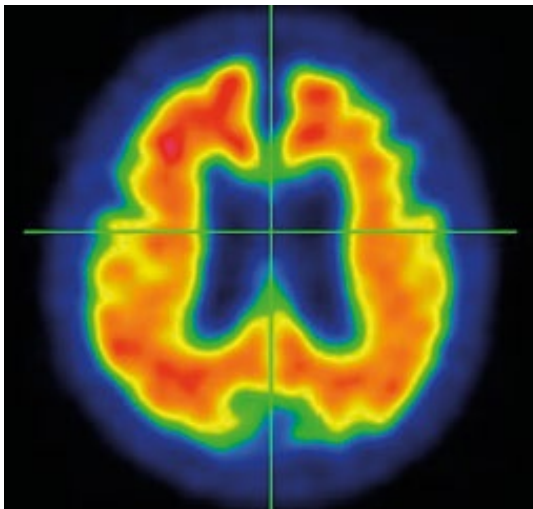




GE HealthCare

Vizamyl™ (Flutemetamol F 18 Injection)

A guided summary to Vizamyl image interpretation



Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.



VIZAMYL™
Flutemetamol F18
Injection

Product Indications and Important Safety Information – VIZAMYL

PRODUCT INDICATIONS AND USE

VIZAMYL™ (flutemetamol F 18 injection) is indicated for positron-emission tomography (PET) of the brain to estimate amyloid beta neuritic plaque density in adults with cognitive impairment for:

- Evaluation of Alzheimer's disease (AD) and other causes of cognitive decline
- Selection of patients who are indicated for amyloid beta-directed therapy as described in the prescribing information of the therapeutic products.

CONTRAINDICATIONS

VIZAMYL is contraindicated in patients with a history of hypersensitivity reaction to VIZAMYL or polysorbate 80.

WARNINGS AND PRECAUTIONS

- **Anaphylaxis and Other Serious Hypersensitivity Reactions:** Serious hypersensitivity reactions including anaphylaxis, presenting with flushing, dyspnea, and hypotension have been observed within minutes following administration and may occur in patients with no history of exposure to VIZAMYL. Obtain a history of allergy or hypersensitivity reactions. Always have resuscitation equipment and trained personnel immediately available at the time of VIZAMYL administration. If a hypersensitivity reaction is suspected, immediately discontinue the injection and initiate appropriate therapy. VIZAMYL is contraindicated in patients with a history of hypersensitivity to VIZAMYL or polysorbate 80.
- **Risk of Image Misinterpretation and Other Errors:** Errors may occur in the estimation of amyloid beta neuritic plaque density during VIZAMYL image interpretation. The use of clinical information in the interpretation of VIZAMYL images has not been evaluated and may lead to an inaccurate assessment. Extensive brain atrophy and motion artifacts that distort the image may limit the ability to distinguish gray and white matter on a VIZAMYL scan. Perform image interpretation independently of the patient's clinical information. For cases where there is uncertainty as to the location of cortical signal, use co-registered anatomical imaging to improve localization of signal or examine the striatum for VIZAMYL signal as it is less affected by atrophy.
- **Radiation Risk:** VIZAMYL contributes to a patient's long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe drug handling to protect patients and health care providers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

ADVERSE REACTIONS

The most commonly reported adverse reactions in clinical trials were flushing (2 %), increased blood pressure (2 %), headache (1 %), nausea and dizziness (1 %). Postmarketing experience included anaphylactic reactions. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There are no available data on VIZAMYL in pregnant woman to evaluate drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. All radiopharmaceuticals, including VIZAMYL, have the potential to cause fetal harm depending on the stage of fetal development and the magnitude of the radiation dose. If considering VIZAMYL administration to a pregnant woman, inform the patient about the potential for adverse pregnancy outcomes based on the radiation dose from the drug and the gestational timing of exposure.
- **Lactation:** There are no data on the presence of flutemetamol F 18 or metabolites in human milk or its effects on the breastfed infant or milk production. Exposure of VIZAMYL to a breastfed infant can be minimized by temporary discontinuation of breastfeeding. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VIZAMYL and any potential adverse effects on the breastfed child from VIZAMYL or from the underlying maternal condition.
- **Pediatric Use:** The safety and effectiveness of VIZAMYL have not been established in pediatric patients.
- **Geriatric Use:** No overall differences in safety or effectiveness were observed between subjects 65 years of age and older and younger adult subjects.

OVERDOSAGE

The major risks of overdosage relate predominantly to increased radiation exposure, with long-term risk for neoplasia. In the event of administration of a radiation overdose with VIZAMYL, hydration and frequent urination should be encouraged to minimize radiation exposure to the subject. It is unknown whether or not the flutemetamol is dialyzable.

Prior to VIZAMYL administration, please read the full Prescribing Information for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800 FDA 1088 or www.fda.gov/medwatch

RESOURCES

Customer Service: 800 292 8514

Vizamyl Support Center: 844 225 1595

Clinical applications for applications and training support:

Support.MIApps@gehealthcare.com

Medical Affairs for Clinical and Scientific Support:

800 654 0118. (option 2, then option 3) or medical.affairs@gehealthcare.com

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Introduction

Vizamyl™ (flutemetamol F 18 injection) is indicated for Positron Emission Tomography (PET) of the brain to estimate amyloid beta neuritic plaque density in adults with cognitive impairment for:

- Evaluation of Alzheimer's disease (AD) and other causes of cognitive decline
- Selection of patients who are indicated for amyloid beta-directed therapy as described in the prescribing information of the therapeutic products

Vizamyl should be used in conjunction with a clinical evaluation.

Imaging with Vizamyl enables image interpretation with precise color scaling

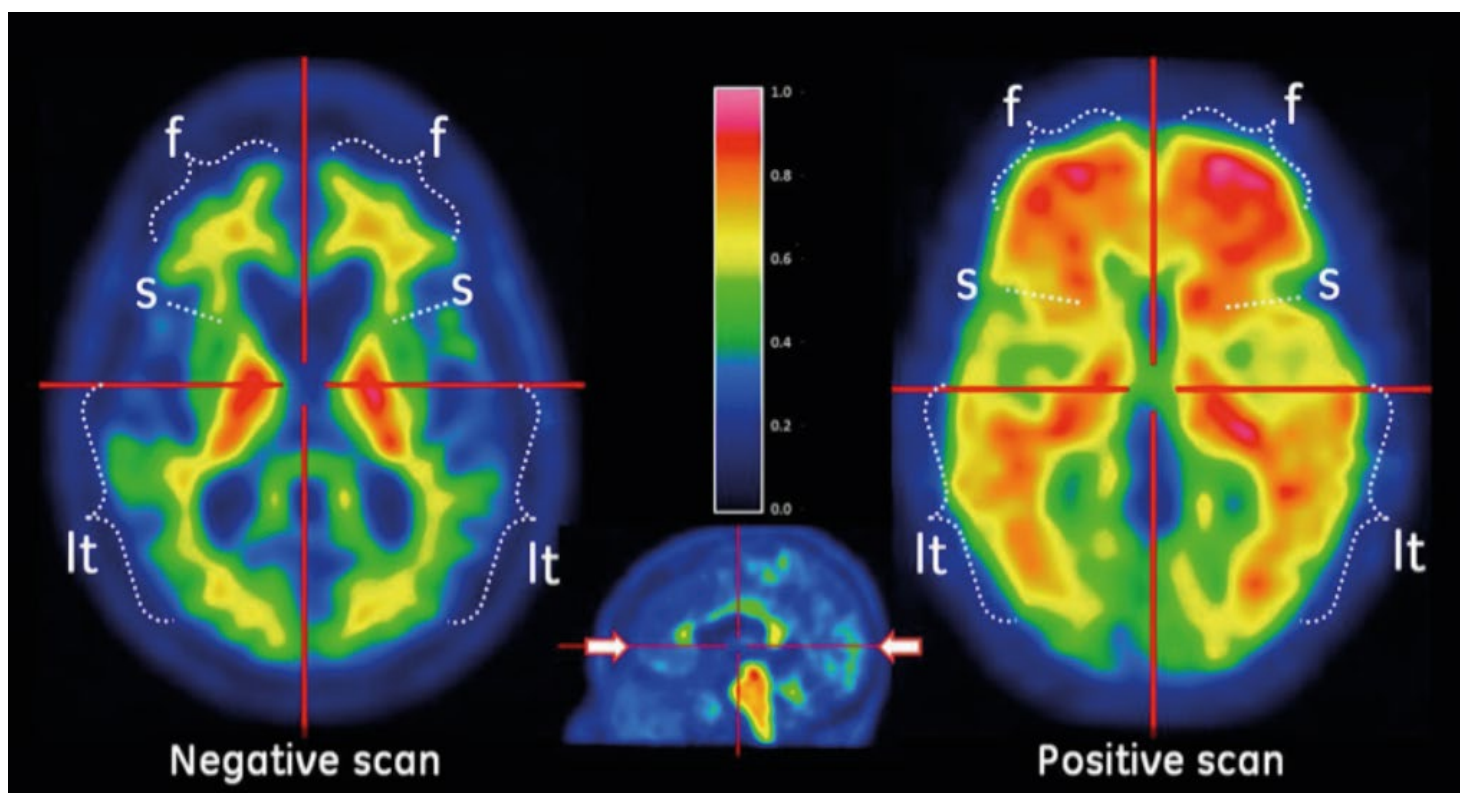
- A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD
- A positive scan indicates moderate to frequent plaque density

Vizamyl is administered intravenously, followed by a 10 to 20 minute scan at approximately 60 to 120 minutes post injection.

AD, Alzheimer's disease; PET: Positron Emission Tomography.

Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

Introduction



PET cases showing examples of Vizamyl™ (Flutemetamol F18 Injection).
Negative scan (left) and positive scan (right) displayed in axial review.
Images on file, GE HealthCare.

Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

General reading principles

Interpretation of Vizamyl™ (Flutemetamol F18 Injection) images provides a visual estimate of brain β -amyloid plaque density.

Imaging with Vizamyl should be used in conjunction with a clinical evaluation.

Some scans may be difficult to interpret due to image noise, atrophy with a thinned cortical ribbon or image blur, which could lead to interpretation errors.

It is also recommended to review MRI or CT images when available to aid interpretation of the Vizamyl image, especially when atrophy is suspected.

The following pages will demonstrate a summary of the general principles of Vizamyl image interpretation.

The contents of this booklet do not replace the reader training program available at readvizamyl.com.

General reading principles

1

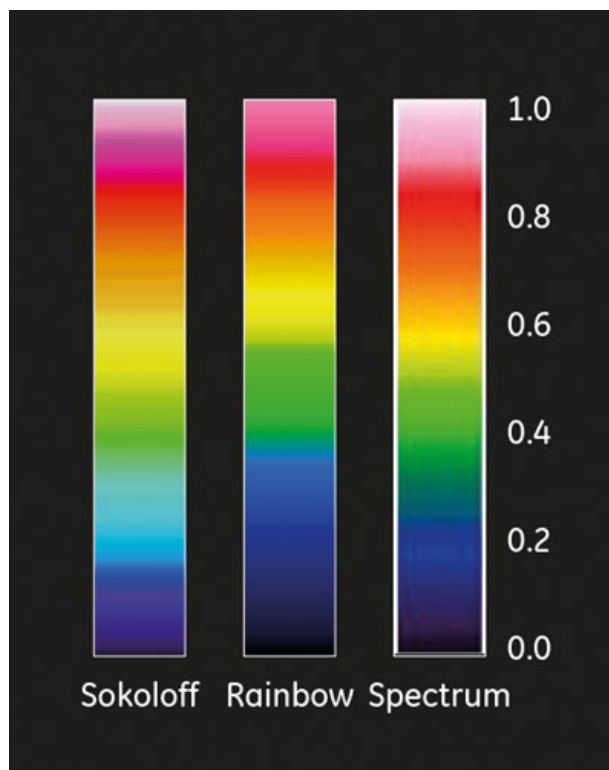
Basic set-up



Color scale

Recommended color scales:

- Sokoloff
- Rainbow
- Spectrum



General reading principles

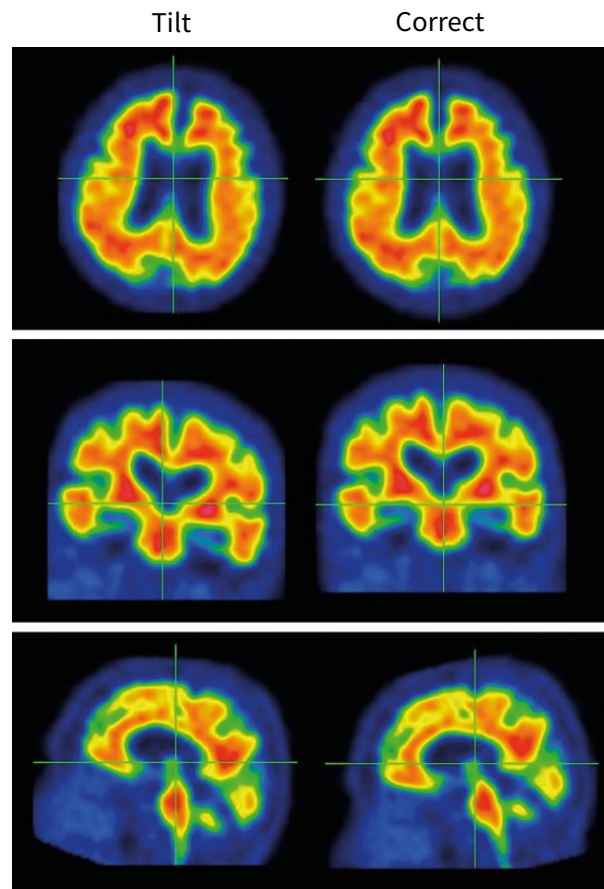


Orientation

Carefully review the image set to ensure that the full cerebrum is in the field of view.

Check that the images are free of motion artifacts and the scan is of acceptable quality.

Check images for any rotation or tilt and realign as necessary in all three planes.



Images on file, GE HealthCare.

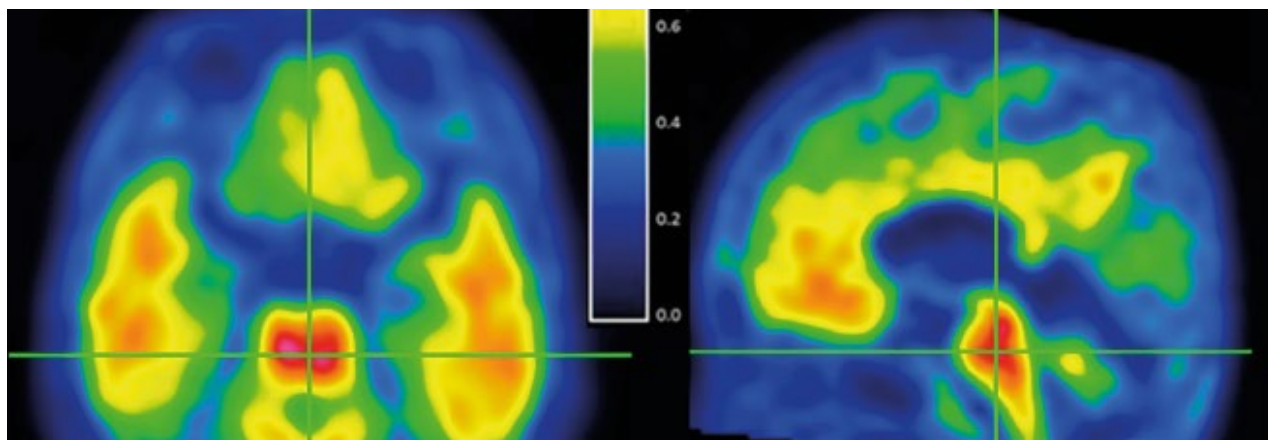
General reading principles

2

Set the pons to 90% of color scale's maximum intensity



Vizamyl™ (Flutemetamol F18 Injection) images should be scaled with the pons (see cross hair) set to 90% of the color scale's maximum image intensity.



Images on file, GE HealthCare.

Pons uptake of Vizamyl in negative and positive cases is comparable.

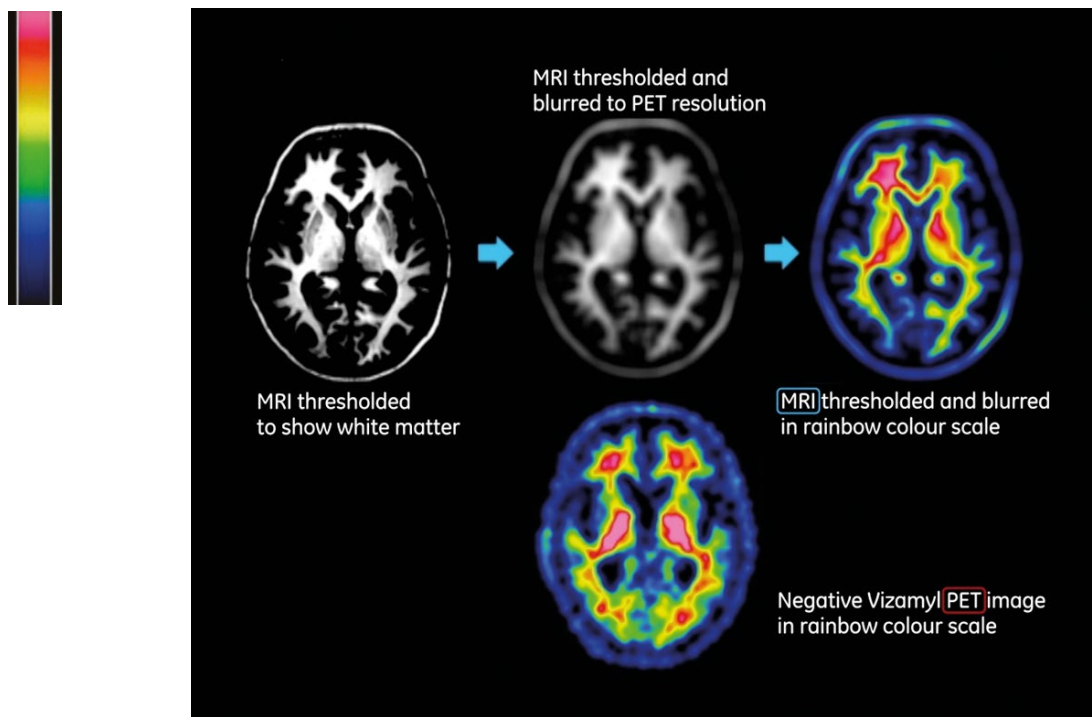
When all images are scaled to 90% of the color scale's maximum image intensity, it allows accurate interpretation of white and grey matter uptake within and between cases.

Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

General reading principles

3

Recognize the white matter pattern in a negative PET scan



Images on file, GE HealthCare.

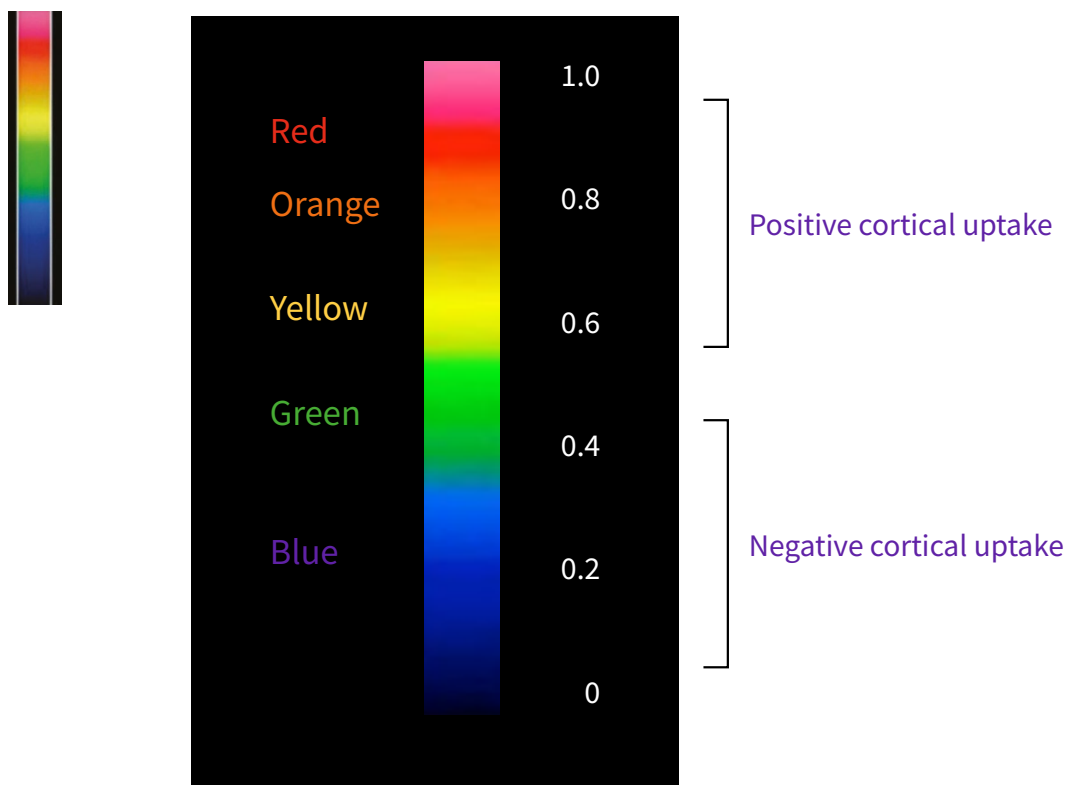
MRI, Magnetic Resonance Imaging; PET, Positron Emission Tomography.

Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

General reading principles

4

Cortical uptake is associated with a shift from blues and greens to oranges and reds



Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

General reading principles

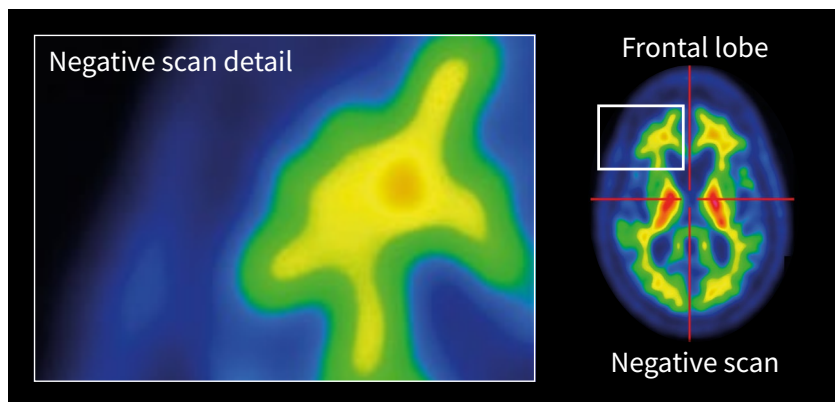
4

Examples of Vizamyl™ (Flutemetamol F18 Injection) uptake



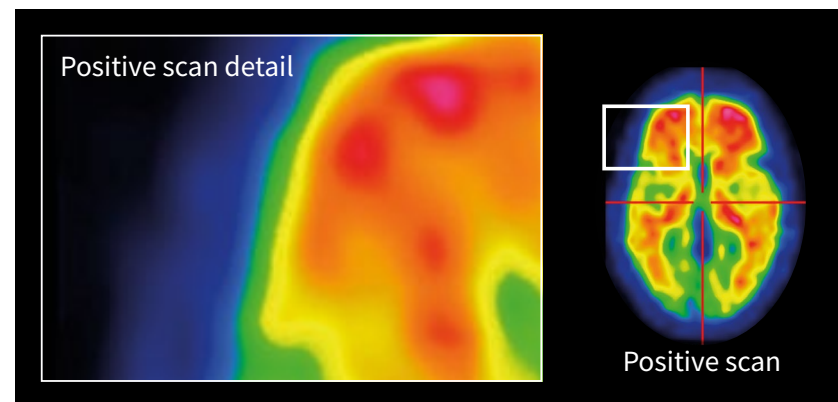
Mostly blues and greens in the grey matter

- Little to no amyloid plaque density
- Tracer uptake consistent with white matter pattern
- Gradual change in color gradient towards the edge of the brain
- Inconsistent with diagnosis of AD



Mostly oranges and reds in the grey matter

- Moderate to high amyloid plaque density
- Tracer uptake demonstrated in the grey matter
- Abrupt change in color gradient at the edge of the brain
- Does not independently establish a diagnosis of AD or other cognitive disorder



Images on file, GE HealthCare.
AD, Alzheimer's disease.

General reading principles

5

Regional review methodology



Frontal and lateral temporal lobes read in AXIAL REVIEW

A scan is deemed positive if any one of the 5 review regions is positive: Frontal, lateral temporal, posterior cingulate/precuneus, inferolateral parietal, and striatum.

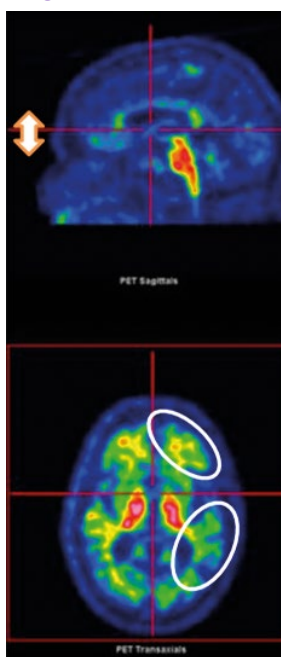
Images on file, GE HealthCare.

Frontal: Sagittal can be used as an optional secondary review plane.

Lateral temporal: coronal can be used as an optional secondary review plane.

AC-PC, anterior commissure - posterior commissure.

Negative scan

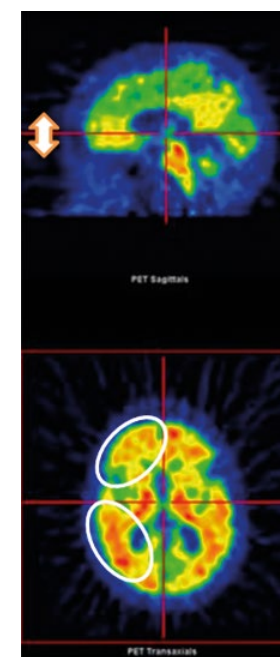


Position of axial review seen in sagittal plane

Scroll the AC-PC plane

Axial review

Positive scan



Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

General reading principles

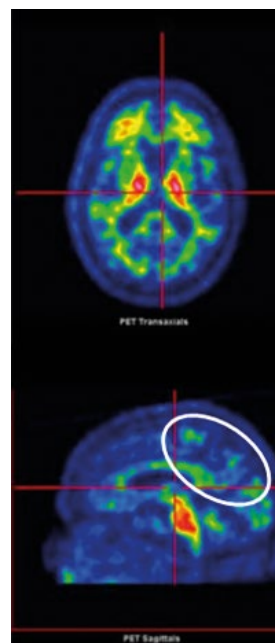
5

Regional review methodology

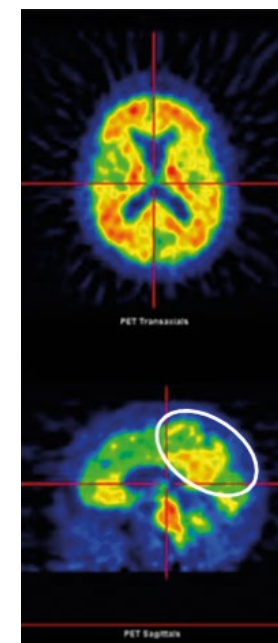


Posterior cingulate/precuneus
read in SAGITTAL REVIEW

Negative scan



Positive scan



Position of sagittal review
seen in axial plane

Move vertical crosshair just
off the midline to assess
medial surface

Sagittal review

Images on file, GE HealthCare.

Posterior cingulate and precuneus:
Coronal can be used as an optional secondary review plane.

Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

General reading principles

5

Regional review methodology



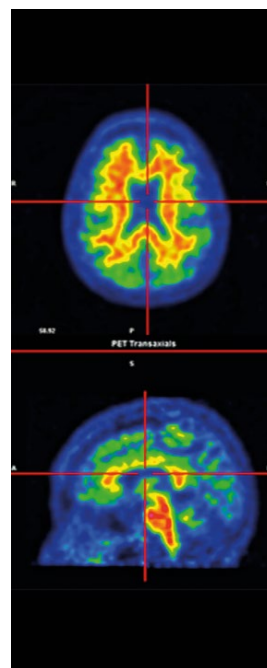
Sagittal review of posterior cingulate/precuneus: Finding the correct review plane

If the discrete shape of pons is lost the review plane is too far from the midline.

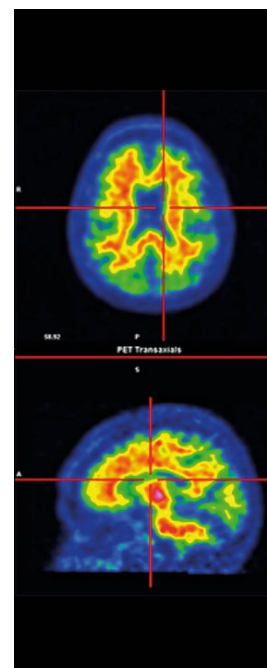
Finding the correct review plane is particularly important in negative images to avoid a false positive read.

Negative scan

Correct review plane



Too far from midline



Images on file, GE HealthCare.

General reading principles

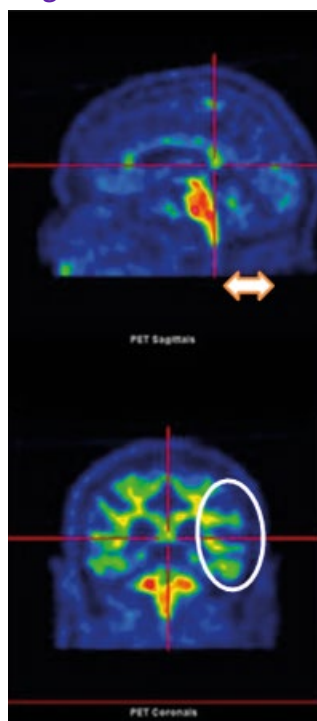
5

Regional review methodology

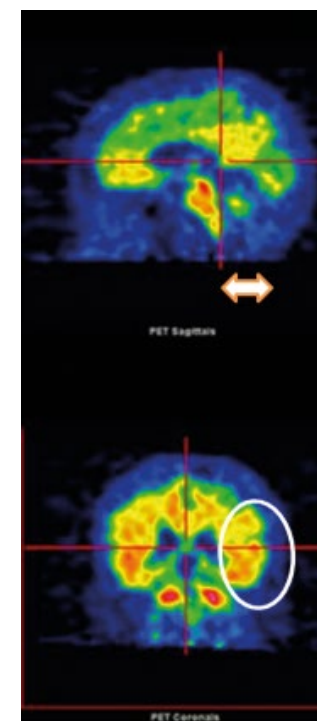


Inferolateral parietal
lobe read in CORONAL
REVIEW

Negative scan



Positive scan



Scroll between end of base of
pons and posterior to white
matter in cerebellum
(see arrows)

Coronal review

Images on file, GE HealthCare.

Inferolateral-parietal: Axial can be used as an optional
secondary review plane.

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General reading principles

5

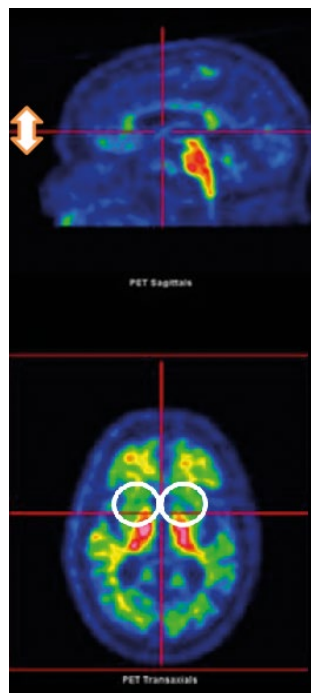
Regional review methodology



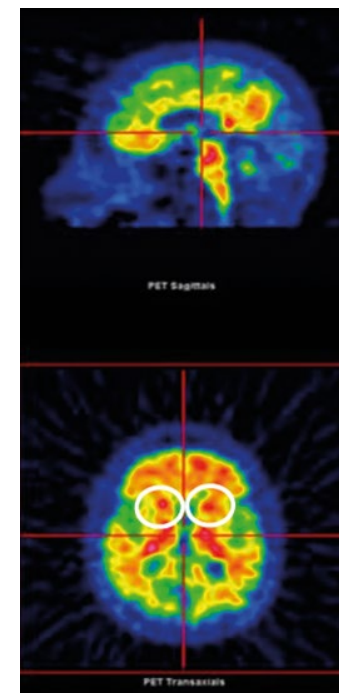
Striatum: AXIAL REVIEW

Striatum: Intensity gap in negative case between thalamus and frontal white matter. Positive case appears as 'dot'-like structure.

Negative scan



Positive scan



Position of axial plane seen in sagittal view

Scroll AC-PC plane

Axial review

Images on file, GE HealthCare.

Striatum: Sagittal can be used as an optional secondary review plane.

AC-PC, anterior commissure - posterior commissure.

Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

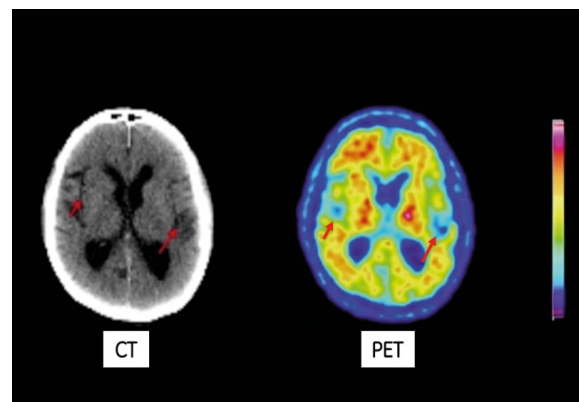
Suspicion of atrophy



Atrophy can cause false negative read results.

Assess all regions carefully when atrophy is suspected.

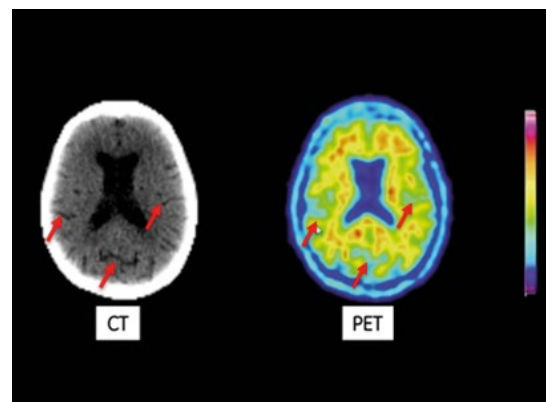
Positive scan



Red arrows show location of atrophy in CT and PET

Review MRI or CT images to locate areas of atrophy.

Negative scan



Red arrows show location of atrophy in CT and PET

Images on file, GE HealthCare.

CT, Computed Tomography;

MRI, Magnetic Resonance Imaging;

PET, Positron Emission Tomography.

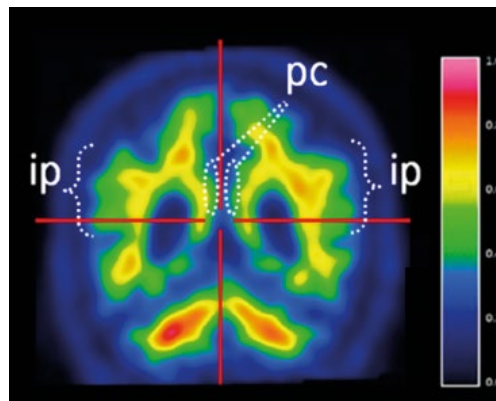
Please see Important Safety Information on page 2 and click [here](#) for full Prescribing Information.

Suspicion of atrophy

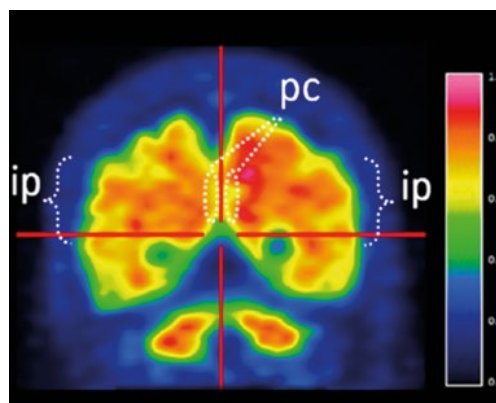


Inferior parietal region is less susceptible to atrophy than other regions (frontal/temporal/superior parietal).

Negative scan



Positive scan



Reference: Internal experience from examination of structural and PET images from development program. Methodology now included in full image reader training.

ip: inferior parietal
pc: posterior cingulate and precuneus
PET: Positron Emission Tomography

Images on file, GE HealthCare.

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Summary

5 steps to follow:

- 1 Basic set-up: Choice of color scale (rainbow or similar scale) and correct orientation
- 2 Set pons to red (90%) establishing the color scale's maximum intensity as an anchor point for scaling in all images
- 3 Recognize typical white matter pattern and additional cortical uptake
- 4 Understand cortical (grey matter) uptake associated with a shift from blues and greens to orange and reds
- 5 Assess the 5 key regions (see Full Prescribing Information)*

*frontal lobes/posterior cingulate and precuneus/lateral temporal lobes/inferolateral parietal lobes/striatum

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October 2025 JB12580US