

AiMIFY™ Software

Indications for Use

AiMIFY is an image processing software that can be used for image enhancement in MRI images. It can be used to increase contrast-to-noise ratio (CNR), contrast enhancement (CEP), and lesion-to-brain ratio (LBR) of enhancing tissue in brain MRI images acquired with a gadolinium-based contrast agent. It is intended to enhance MRI images acquired using standard approved dosage per the contrast agent's instructions for use.

Cautions

AiMIFY-enhanced images should not be used alone to assist patient diagnosis. The standard post-contrast image must always be reviewed first before using AiMIFY-enhanced images for patient diagnosis.

Please be aware that AiMIFY is not intended for artifact reduction, such as metal artifact and motion artifact. Enhanced images may have similar artifacts as input images.

AiMIFY may enhance intensity differences between pre-and post-contrast images that are caused by 1) registration errors between the sequences or 2) image artifacts in either sequence.

AiMIFY may enhance vessel conspicuity more than standard acquired post-contrast images. In cases where vessel conspicuity interferes with or delays diagnosis, the standard post-contrast image should be used for adjudication.

AiMIFY-enhanced images may contain false lesions due to enhancement of image quality issues in either input sequences, due to being introduced by the AiMIFY algorithm, or both. The standard post-contrast image should be used to rule out false lesions.

Please be aware that AiMIFY has only been trained and tested on head MRI for contrast enhancement. Using the AiMIFY software in other anatomies or use cases not defined in this user manual could result in unknown image enhancement performance.

The internal morphology of tissue in input sequences have been tested to be moderately preserved by AiMIFY processing both for lesion tissue and parenchyma tissue. Internal morphology may appear to be missing due to window leveling of the image, and can be obtained by adjusting the window levels.

Please be aware that AiMIFY is intended for use only with standard of care quality images. Standard approved dose contrast images should be acquired per the contrast agent's instructions for use. The standard of care should not be adjusted in preparation for using AiMIFY.

Please be aware that AiMIFY should not be used for acquiring stat scans or emergent scans, as image processing time may delay diagnosis.

Standard approved dose contrast images should be acquired per the contrast agent's instructions for use. AiMIFY-enhanced images are not fully equivalent to post-contrast images acquired with a higher than recommended actual dosage of contrast. However, the high-dose-

like appearance of AiMIFY-enhanced images offers a potentially safer alternative to actually acquiring post-contrast images beyond standard dosing.

Contraindications

AiMIFY is an image processing software that inherently doesn't cause harm to patients of any subpopulation. However, gadolinium-based contrast agents are associated with contraindications, precautions, and warnings for certain subpopulations. Strictly follow the gadolinium-based contrast agent's instructions for use, including but not limited to contraindicated patient populations, prior to processing with AiMIFY.

Limitations

AiMIFY has been trained and tested using a diverse DICOM image dataset collected from different MR imaging applications at 0.3T, 1.5T, and 3.0T, including:

- T1 weighted imaging for pre and post-contrast brain scans obtained with gadolinium-based contrast agents in 2D sequences, such as fluid-attenuated inversion recovery (FLAIR) and fast spin echo (FSE).
- T1 weighted imaging for pre and post-contrast brain scans obtained with gadolinium-based contrast agents in 3D sequences, such as BRAin VOlume (BRAVO) inversion-recovery-prep fast split echo (SPGR) and Magnetization Prepared Rapid Gradient Echo (MPRAGE).
- Acquisition in axial, coronal, and sagittal orientations.
- Images acquired with GE Medical Systems, Philips Medical Systems, Siemens Healthineers, and Hitachi scanners (see separate Scanner List for models).
- Images (for performance testing) spanning a variety of pathologies including patients with Cerebritis, Glioma, Inflammation, Lymphoma, Meningioma, Metastatic lesions, Multiple sclerosis, Neuritis, other tumor-related lesions (e.g., resection/radiation necrosis / suspected cyst / etc.), and other abnormalities.
- Patients aged 7 to 86 years old with an even distribution of females and males in the test dataset.
- Lesions in the dataset were small (<1 cc) and large (>1 cc).

Any imaging sequences/applications outside the above list may result in prolonged processing time and/or unreasonable results.

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