Notification of a Voluntary Product Recall for Software Used in a Prior Published Article

J.M. Mettenburg

AJNR Am J Neuroradiol 2021, 42 (6) E34
doi: https://doi.org/10.3174/ajnr.A7063
http://www.ajnr.org/content/42/6/E34

Notification of a Voluntary Product Recall for Software Used in a Prior Published Article

On December 14, 2020, a voluntary product recall was issued for the Neuroreader Medical Image Processing Software that we utilized in our article "Improved Detection of Subtle Mesial Temporal Sclerosis: Validation of a Commercially Available Software for Automated Segmentation of Hippocampal Volume,"[1] published in the March 2019 issue of *AJNR*. The recall was issued because the normative data base used for demographic correction of the postprocessed volumes was produced from MRIs performed on 218 healthy patients, instead of the 231 MRIs expected by the FDA. This normative data base was used to calculate the proprietary Neuroreader Index that we reported as a secondary outcome in our research. The normative data did not affect our main outcome variable of segmented hippocampal volume as a percentage of intracranial volume.

We believe that the results of our research are still valid, as only small changes in normative values would be expected when adding 13 additional healthy brains to the 218 already in the data base. Furthermore, only the results of our secondary outcome could be affected. Nevertheless, we felt obligated to immediately inform the editorial staff of the *AJNR* and your readers of this unfortunate event. The latest version of the Neuroreader software has corrected this flaw.

http://dx.doi.org/10.3174/ajnr.A7063

REFERENCE

1. Mettenburg JM, Branstetter BF, Wiley C, et al. **Improved detection of subtle mesial temporal sclerosis: validation of a commercially available software for automated segmentation of hippocampal volume.** *AJNR Am J Neuroradiol* 2019;40:440–45 CrossRef Medline

J.M. Mettenburg
Department of Radiology
University of Pittsburgh School of Medicine
Pittsburgh, Pennsylvania