

Comprehensive All-In-One Reporting

HepaFat-AI performs fully automated and comprehensive all-in-one liver fat analysis and reporting:

- NASH-CRN Steatosis Grade
- Proton Density Fat Fraction (PDFF)
- Volumetric Liver Fat Fraction (VLFF)
- Liver Fat Distribution Map

Steatosis Grading

- Provides a validated NASH-CRN histopathological steatosis grading;
- The only regulatory cleared MRImethod capable of reporting a steatosis grading.

Proton Density Fat Fraction (PDFF)

- Provides the commonly reported liver MR fat metric from imaging and spectroscopy;
- PDFF has been widely shown to correlate with the degree of hepatic steatosis, with a cut-off of 5% being indicative of NALFD.

Volumetric Liver Fat Fraction (VLFF)

- Provides an MR liver fat metric that correlates with hepatocyte macrovesicular fat volume;
- Enhanced signal to noise acquisition for improved performance.



Patient ID: Anon Name: Anon Birth Date: 0000 Kirest Pate 26 Apr 2017 Referrer: Anon MRI Center: Anon

	Result	95% Cl (confidence interval)	Normal Range
VLFF (Volumetric Liver Fat Fraction)	41.5%	32.8 - 52.7	$0 - 4.1^{1}$
PDFF (Proton Density Fat Fraction)	45.6%	36.0 - 57.9	0 - 4.8 ²
Steatosis Grade	3		0 ³
1) The normal VLFE range is derived from direct comparison betw	ween VLEE measurements and	NASH-C'RN grading of biopsy (St. P	ierre et al. PLoS One. 2016-11

(8)). 2) The normal PDFF range is derived from the calibration between VLFF and PDFF measurements. 3) Refer to the NASH-CRN steatosis grading guide below for interpreting Steatosis Grade (Kleiner DE et al. Hepatology. 2005 Jun;41(6):1313-21):





HepaFat-AI automatically analyses MRI datasets to assess liver fat in patients, providing doctors with a comprehensive, multi-metric solution for use in the assessment of individuals with confirmed or suspected fatty liver disease. From one quick, non-invasive MRI scan, doctors have access to a suite of metrics relating to a patient's liver health.

HepaFat-AI produces these patient results for clinician interpretation within seconds, providing accurate, reliable and reproducible results across MRI centres and scanner models.

HepaFat-AI is ideally suited for single and multi-center clinical trials in nonalcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD).

HepaFat-AI has received 510(k) clearance from the US Food and Drug Administration (FDA), European CE marking, and approval from the Australian Therapeutic Goods Administration (TGA).

www.hepafat.com www.resonancehealth.com

Key HepaFat-Al Features

- Comprehensive, all-in-one, rapid results reporting from MRI images:
 - Steatosis grading no biopsy required;
 - Proton density fat fraction (PDFF);
 - Volumetric liver fat fraction (VLFF);
 - Includes a liver fat map for illustrative purposes.
- Notifies in cases of suspected high liver iron content;
- Highly repeatable and reproducible;
- Fully standardised work flow processing from image acquisition to analysis and report generation;
- Ideally suited for single and multi-center NASH clinical trials;
- Fits easily into existing workflows;
- Quantitative results available in real-time;
- Uses non-invasive, contrast free MRI scan images acquired during single-breath-hold;
- No new MRI scanner hardware or software required;
- Suitable for use with 1.5 Tesla and 3 Tesla MRI scanners;
- Standardised metrics across multiple MRI vendors.
- Clear report layout for easy interpretation, including fat map for quick overview of fat distribution.
- HepaFat-AI has regulatory clearances from the US FDA, Australian TGA, and European CE marking.