HepaFat-AI
for automated measurement of liver fat

HepaFat-AI assesses liver fat in patients from one quick, non-invasive MRI scan.

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

Will I need an MRI?

- Yes. **HepaFat-AI** assesses MRI images of your liver. You will need to have a short MRI - the acquisition of the images takes approximately one breath-hold (approximately 20 seconds).

- The MRI scan is non-invasive and there will not be any contrast agent used during your scan;

- MRI is painless and does not use ionising radiation.

- Your MRI center will be able to answer any of your questions about the MRI procedure.

What happens after my MRI?

After your MRI, the MRI centre will contact your doctor when your results are ready for release. An example of a **HepaFat-AI** Liver Fat Assessment Report is included overleaf.

## What will HepaFat-AI report?

HepaFat-AI reports the following:

- NASH-CRN Steatosis Grade

- Proton Density Fat Fraction (PDFF)

- Volumetric Liver Fat Fraction (VLFF)

- Liver Fat Distribution Map

When interpreted by a trained physician, HepaFat-AI results can be used to: monitor patients undergoing weight loss management; to screen the livers of live donors for transplant suitability; monitor patients with or suspected to have non-alcoholic fatty liver disease (NAFLD) or the more serious subtype, non-alcoholic steatohepatitis (NASH).

www.hepafat.com   www.resonancehealth.com

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
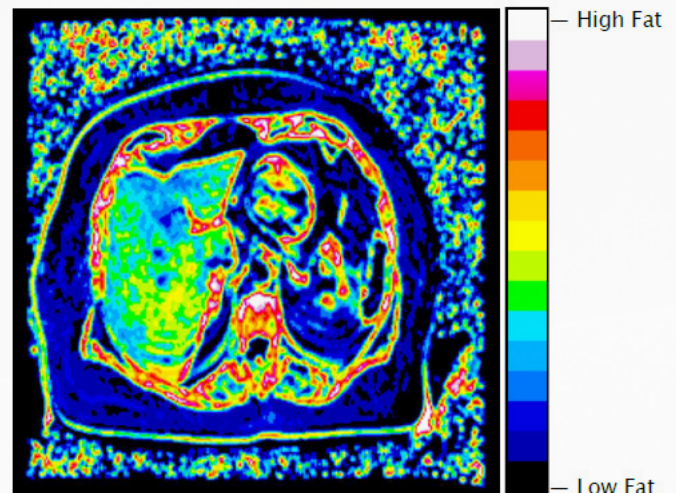
Steatosis Grading

- Provides a validated NASH-CRN histopathological steatosis grading;
- The only regulatory cleared MRI-method 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 macro-vesicular fat volume;
- Enhanced signal to noise acquisition for improved performance.

### HepaFat-AI — Liver Fat Assessment Report

Patient ID: Anon
Name: Anon
Birth Date: 0000

Scan Date: 26 Apr 2017
Analysis Date: 12 Jan 2021
Referrer: Anon
MRI Center: Anon

	Result	95% CI (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 VLFF range is derived from direct comparison between VLFF measurements and NASH–CRN grading of biopsy (St. Pierre 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):

	NASH–CRN Steatosis Grading Guide
0	Involvement by steatosis in < 5% of hepatocytes
1	Involvement by steatosis in 5 to 33% of hepatocytes
2	Involvement by steatosis in 33 to 66% of hepatocytes
3	Involvement by steatosis in > 66% of hepatocytes

1st Out-of-Phase   In-Phase   2nd Out-of-Phase
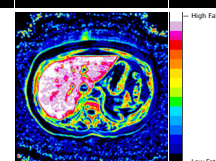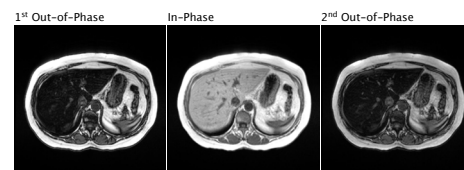
Liver Fat Distribution Map[4]

4) The Liver Fat Distribution Map is a guide to illustrate the distribution of fat in the liver. The colour display is relevant to the liver region only and colours outside the liver are not related to fat content. The colour lookup table is specific to each individual case. It should not be used for diagnostic purposes.

If you have questions on the current analysis result and/or slice selected, please contact Resonance Health at support@resonancehealth.com.

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