

## HepaFat-Scan<sup>®</sup> - MRI Measurement of Liver Fat Fraction

HepaFat-Scan is an FDA cleared MRI-based solution for measuring hepatic steatosis in patients at risk from fatty liver disease. It provides a reliable non-invasive measure of the volume fraction of fat in liver tissue for screening, diagnosis, treatment planning and monitoring of patients in a variety of clinical settings.

### Potential Clinical Applications

#### Gastroenterology and Hepatology Applications

- Workup for NAFLD diagnosis, patient education and counselling
- Liver fat analysis on patients being screened or monitored for fibrosis or cirrhosis

#### Surgical Applications

- Fatty liver assessment prior to liver surgery, due to increased complications with the presence of liver fat
- Screening for suitability of living donors for liver transplants by assisting in determining the viability of the liver
- Pre and post-operative analysis of bariatric patients to track clinical outcomes

#### Applications by Primary Care Physician

- Screening of patients prior to prescribing hepatotoxic medications
- Monitoring of patients undergoing an intervention (e.g. limiting alcohol consumption or weight loss)
- Monitoring of patients' prescribed medications known to induce steatosis

### HepaFat-Scan Key Features

- ✓ FDA, CE mark and TGA cleared
- ✓ Clinically validated against biopsy measurements of liver fat (59 cases)
- ✓ Clinically insignificant bias compared with stereological measurements on biopsies (1.4%)
- ✓ Suitable for 1.5T MRI scanners
- ✓ No new software or hardware required, charged per scan only
- ✓ No contrast agent required
- ✓ 2 minute scan time
- ✓ Results are reliable and reproducible between MRI models making it suitable for clinical trials
- ✓ Large liver region >300 times larger than biopsy, reducing sampling error
- ✓ ISO 13485 quality certified
- ✓ High sensitivity and specificity

### Sensitivity and Specificity of HepaFat-Scan<sup>®</sup>

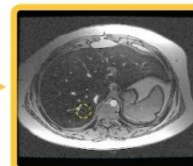
Steatosis Grades	Grade 0 vs 1 – 3 (≥5%)	Grades 0-1 vs 2-3 (≥33%)	Grades 0-2 vs 3 (≥66%)
Sensitivity (%) (95% conf interval)	96.8 (83-100)	100.0 (83-100)	100.0 (78-100)
Specificity (%) (95% conf interval)	96.0 (80-100)	94.4 (81-99)	87.8 (74-96)
AUROC (standard error)	0.963 (0.032)	0.996 (0.005)	0.971 (0.019)

### HepaFat-Scan<sup>®</sup> Service Model



Patient referred for 2 min MRI scan at an approved Radiology Centre

MRI data is securely transmitted to the Resonance Health Service Centre



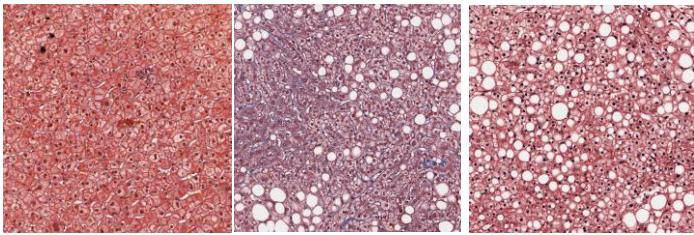
HepaFat-Scan analysis and quality checks performed

Liver Fat Fraction Report available for secure download by Radiology Centre within target time of 2 business days

## Fatty Liver Disease Epidemic

Risk factors for NAFLD include age, male gender, obesity, hypothyroidism, hypopituitarism, hypogonadism, sleep apnoea, type 2 diabetes and polycystic ovary syndrome.

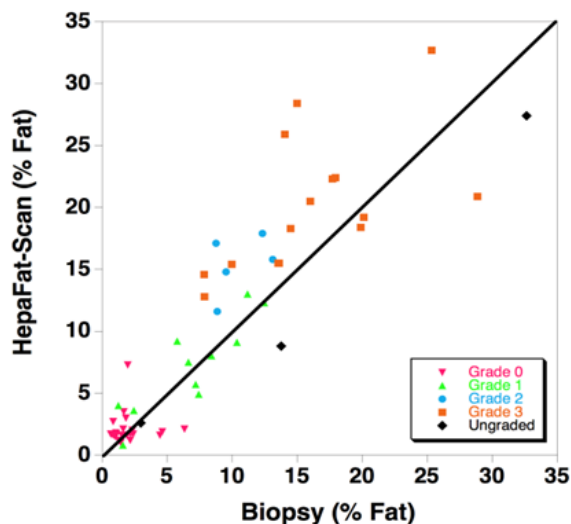
- NAFLD is considered the most common liver disease in the western world affecting 20-30% of the population<sup>1,2</sup> rising to 70-90% of the obese population<sup>3</sup> and approximately 50% of the diabetic population.
- In 2012 ~70% of US adults were overweight with 35% of adults in the obese category<sup>4</sup>.
- In the UK, according to the 2012 Health Survey for England, approximately one quarter of adults are obese.
- Over the last ten years, the rate of obesity has doubled in adults and tripled in children in the US<sup>5</sup>.
- NASH is the third most common indication for liver transplantation in the US and is on a trajectory to become the most common<sup>6</sup>.
- NAFLD without cirrhosis is an independent risk factor of hepatocellular carcinoma<sup>7</sup>.
- Steatosis has been associated with increased postoperative morbidity and mortality after liver resection<sup>8</sup>.
- NAFLD is the number one risk factor for cardiovascular disease<sup>9</sup>.



L-R, Histological sections of liver tissue with 1.0%, 15% and 30% volumetric liver fat fractions

## Diagnostic Advantage of HepaFat-Scan

HepaFat-Scan reports the volumetric fraction of the liver that comprises fatty lipids. The fractional area of a liver biopsy histological section that appears as fat is equivalent to the volumetric liver fat fraction and thus can be compared directly with HepaFat-Scan results. HepaFat-Scan has been validated against liver biopsy in a cohort of 59 subjects with volumetric liver fat fractions ranging from 0.8 to 32.7%. Other MRI methods for assessing liver steatosis are either semi-quantitative or report the ratio of protons in fat and water molecules. Proton ratios are not equivalent to volumetric liver fat fractions and do not have linear relationships with the fractional area of fat vesicles seen in liver biopsy sections.



## Clinical Validation

The figure (left) shows a comparison of HepaFat-Scan measurements of liver fat fraction with those measured from biopsy sections (n=59) using stereology. The solid line is the line of equivalence. Symbols are colour/shape-coded to indicate the NAS CRN steatosis grade assessed by a histopathologist.

All grades of steatosis were represented in the study [Grade 0 (47%); Grade 1 (13%); Grade 2 (9%); Grade 3 (30%)]. The patients in the study had a range of aetiologies including autoimmune hepatitis (n=3), alcoholic liver disease (n=2), chronic viral hepatitis B/C (n=16), non-alcoholic fatty liver disease (n=10), nonalcoholic steatohepatitis (n=17), primary sclerosing cholangitis (n=4).

## References

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