

US FDA Clearance for LiverSmart®

Highlights

- The United States Food & Drug Administration grants 510(k) clearance for LiverSmart®
- LiverSmart® can now be commercially marketed and sold in the United States of America
- LiverSmart® is a fully automated software medical device using Artificial Intelligence (“AI”)
- Provides a more comprehensive assessment of the liver reporting liver-iron and liver-fat
- Enables screening of escalating populations with ferritin values exceeding cut-off values
- Appears to fulfill requirements for two new US CPT Codes that become effective in Jan 2022



FDA Clearance for LiverSmart®

Resonance Health Ltd (ASX: RHT) (“Resonance Health” or “Company”) advises that its newest medical device, LiverSmart®, has today obtained 510(k) regulatory clearance from the United States Food & Drug Administration (“FDA”). The FDA clearance allows LiverSmart® to be commercially marketed and sold in the United States of America, which is the Company’s largest customer base.

LiverSmart® combines two existing FDA regulatory-cleared Resonance Health products, FerriSmart® and HepaFat-AI®, into a single multi-parametric MRI session, avoiding the need for multiple MRI appointments, and delivering a more complete and comprehensive assessment of a person’s liver. An example of the LiverSmart® report is enclosed with this announcement at Annex A.

Instead of obtaining individual FerriSmart® and HepaFat-AI® reports via separate scanner sessions, which adds to cost and inconvenience, patients and clinicians will soon be able to obtain both analyses at the same time with one referral, and in one consolidated report. Clinicians seeking both analyses will simply refer for a LiverSmart® assessment, by Resonance Health.

New CPT Codes & Reimbursement

Importantly, the Company believes that LiverSmart® may be eligible for two new US (Cat III) Current Procedural Technology (“CPT”) codes published by the American Medical Association (“AMA”) which become active in January 2022. The Company is awaiting definitive determination of LiverSmart’s eligibility for these codes from a US certified CPT coder and believes that the FDA clearance may expedite this. Resonance Health will advise the market upon receipt of confirmation of code applicability.

CPT codes are a national procedural coding set maintained by the AMA, and recognised by US government agencies, used to describe medical services for reimbursement by both government payers such as Medicare, Medicaid, and private payers including private health insurers. The codes are used by physicians and health care professionals for reporting and tracking medical services performed by healthcare providers.

CPT codes start as temporary Cat III codes and, when there is sufficient reporting of the codes, they are upgraded to Cat I, at which point they become permanent and reimbursable. If LiverSmart® is eligible for the new codes, it will be another milestone in the pathway to widespread payer and insurer reimbursement in the US and will better facilitate LiverSmart® being reimbursed by private payers such as private health insurers, as well as Medicare and Medicaid.

Chief Scientific Officer of Resonance Health, Dr. Wenjie Pang commented:

“We are delighted that the FDA has moved so quickly in clearing LiverSmart®, with this being the fastest FDA clearance we have achieved for any of our FDA cleared medical devices, which speaks to the quality and depth of experience we have in navigating the FDA regulatory framework.

LiverSmart® is a natural evolution of our existing product offering and responds to the growing trend in software as medical devices (SaMD), for more holistic assessment of organs. We’ve used AI in this device to further evolve our products and to achieve rapid turnaround and enhanced scalability”.

Chief Medical Officer of Resonance Health, Prof. John Olynyk commented:

“Liver diseases are unfortunately on the rise, and we are seeing an explosion of liver related health complications globally, including in developed nations where obesity and unhealthy diets are causing a range of long-term liver-related health complications.

With the alarming and currently unchecked growth in liver-diseases and the advent of credible scientific research pointing to linkages between non-alcoholic fatty liver disease and global endemic problems such as the metabolic syndrome comprising diabetes mellitus, hypertension, elevated blood triglycerides and obesity, LiverSmart® is well positioned to respond to these health challenges.

It is pleasing that the Company is evolving with LiverSmart® which uses AI and this should enable the rollout of the device to a broader global audience, including to parts of the world where the manual analysis services provided by Resonance Health are unaffordable. Fatty-liver related diseases are a significant problem in many large emerging markets including in India and Middle Eastern nations.”

Managing Director of Resonance Health, Mitchell Wells, said the following:

“LiverSmart® leverages our core expertise in the liver and our global standing in liver-iron-and-fat assessment through our existing regulatory-cleared liver products. LiverSmart® provides a more complete assessment of the liver by combining multiple MRI appointments and assessments into a singular multi-parametric scanning session, enhancing patient convenience, and reducing cost.

Importantly, we believe that LiverSmart may be eligible for two new United States (Category III) CPT Codes, and we are now awaiting a definitive determination from a US code certifier. If the codes are determined to be applicable to LiverSmart® this will represent a major milestone on our pathway to more widespread reimbursement in the USA.”

This announcement has been authorised for release in accordance with the delegated authority of the Board of Directors of Resonance Health Ltd.

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About Resonance Health

Resonance Health is an Australian healthcare technology and services company, specialising in the development and delivery of noninvasive medical imaging software and services.

The Company's products are used globally by clinicians in the diagnosis and management of human diseases and by pharmaceutical and therapeutic companies in their clinical trials. Resonance Health has gained endorsement by leading physicians worldwide for consistently providing high quality quantitative measurements essential in the diagnosis and management of diseases.

Resonance Health's dedication to scientific rigour and quality management has enabled it to achieve regulatory clearances for a range of Software as a Medical Device (**SaMD**) products in the USA, Europe, and Australia and to proudly carry ISO 13485 certification for the design and manufacture of medical devices. Some of the SaMD products incorporate the use of Artificial Intelligence (**AI**):

- **FerriScan®** - provides an accurate measurement of liver iron concentration (**LIC**) through a non-invasive MRI-based technology, for use in the assessment of individuals with iron overload conditions. FerriScan® is internationally recognised as the gold standard in LIC assessment.
- **FerriSmart®** - an AI-driven system for the automated real-time measurement of LIC in patients using non-invasive MRI-based technology.
- **HepaFat-AI®** - an AI-driven system for the automated real-time multi-metric measurement of liver fat in patients using non-invasive MRI-based technology, for use in the assessment of individuals with confirmed or suspected fatty liver disease.
- **CardiacT2*** – the most widely accepted MRI based method for assessing heart iron loading. Resonance Health also offers a dual analysis of FerriScan® and CardiacT2*. CardiacT2* has regulatory clearance from the FDA, TGA and CE Mark.

The Company has an active development pipeline of additional medical imaging analysis products and services, including, **LiverSmart®** and **Alert-PE™**, an AI tool for the automated review of chest CT scans of patients with suspected pulmonary embolism.

Stakeholders including clinicians and patients are encouraged to follow Resonance Health on FaceBook, LinkedIn and Twitter.

Annex A



A Multiparametric Analysis of
Liver Tissue Composition
Combining FerriSmart and HepaFat-AI

Report No: EzNWa4XxhhrABGnuNMZBXQ	Scan Date: 12 Aug 2021
Patient ID: 10054136-000017	Analysis Date: 28 Oct 2021
Name: 10054136-000017	Referrer:
Birth Date:	MRI Center:

SUMMARY OF RESULTS

Average Liver Iron Concentration

2.0 mg/g dry tissue	37 mmol/kg dry tissue
[95% CI: 1.5 – 2.8]	[95% CI: 26.6 – 50.2]
(NR: 0.17 – 1.8)	(NR: 3 – 33)

For further details, see the Liver Iron Concentration Report

Liver Fat Assessment

	Result	95% CI (Confidence interval)	Normal Range
VLFF (Volumetric Liver Fat Fraction)	2.8%	2.2 – 3.6	0 – 4.1
PDFF (Proton Density Fat Fraction)	3.3%	2.6 – 4.2	0 – 4.8
Steatosis Grade	0		0

For further details, see the Liver Fat Assessment Report

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



FerriSmart™
Powered by **FerriScan**

Liver Iron Concentration Report

Patient ID: 10054136-000017
Name: 10054136-000017
Birth Date:

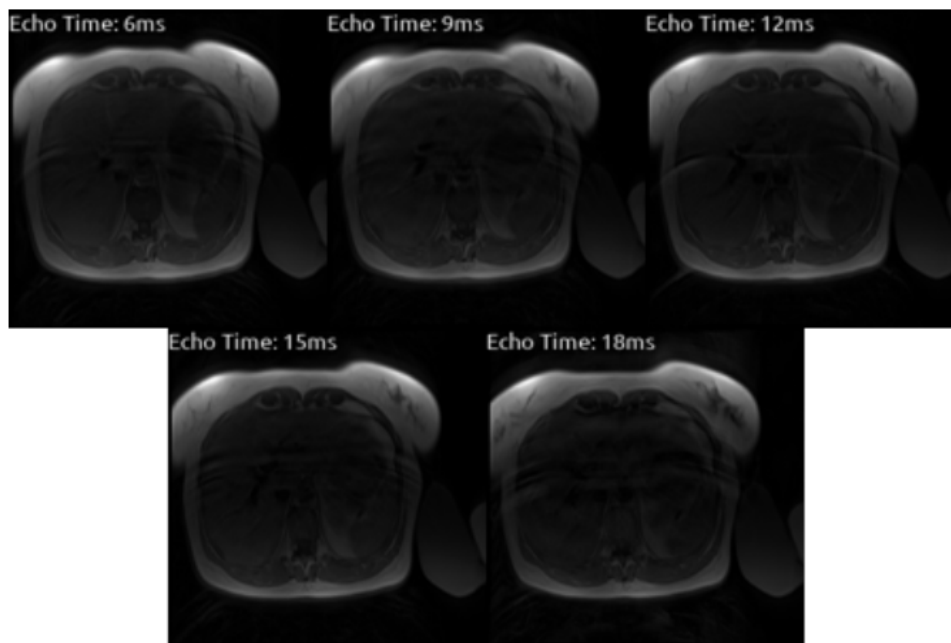
Scan Date: 12 Aug 2021
Analysis Date: 28 Oct 2021
Referrer:
MRI Center:

Average Liver Iron Concentration:

2.0 mg/g dry tissue
[95% CI: 1.5 – 2.8]
(NR: 0.17 – 1.8)

37 mmol/kg dry tissue
[95% CI: 26.6 – 50.2]
(NR: 3–33)

The 95% confidence intervals [95% CI] are derived from a study of repeat measurements by St Pierre et al., HemaSphere 2018;2: 188
Normal range (NR) is taken from Bassett et al., Hepatology 1986;6: 24-29



Liver Iron Concentration thresholds in Transfusional Iron Overload

Extract from Olivieri et al, Blood 1997;89, 739-61

LIC Range	Clinical Relevance
0.17–1.8 mg Fe/g dw	Normal range in non-disease patients in healthy population
3.2–7.0 mg Fe/g dw	Suggested optimal range of LIC for chelation therapy in transfusional iron loading
7.0–15.0 mg Fe/g dw	Increased risk of complications
> 15 mg Fe/g dw	Greatly increased risk of cardiac disease and early death in patients with transfusional iron overload

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



Liver Fat Assessment Report

Patient ID: 10054136-000017
 Name: 10054136-000017
 Birth Date:

Scan Date: 12 Aug 2021
 Analysis Date: 28 Oct 2021
 Referrer:
 MRI Center:

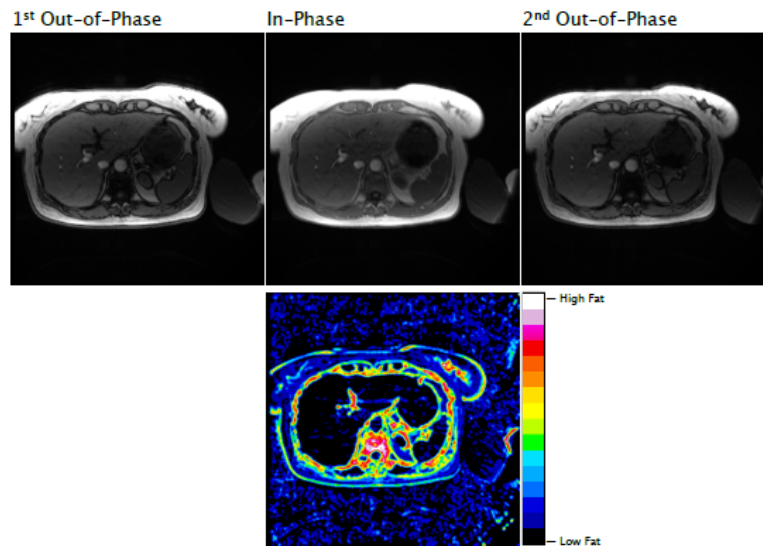
	Result	95% CI (confidence interval)	Normal Range
VLFF (Volumetric Liver Fat Fraction)	2.8%	2.2 – 3.6	0 – 4.1 ¹
PDFF (Proton Density Fat Fraction)	3.3%	2.6 – 4.2	0 – 4.8 ²
Steatosis Grade	0		0 ³

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, 2015;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



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.

Resonance Health Analysis Services Pty Ltd

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