
UPDATED HepaFatSmart® CLEARED BY US FDA

Highlights

- HepaFatSmart® has received US FDA clearance, and will now replace HepaFat-AI®
 - Provides significantly improved diagnostic performance compared with HepaFat-AI®
 - Suitable for monitoring fatty liver diseases including globally endemic NAFLD and NASH
 - HepaFatSmart® will replace HepaFat-AI®, which received US FDA clearance in Dec 2020
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Resonance Health Ltd (ASX: RHT) (**Resonance Health** or **Company**) is pleased to advise that it has received regulatory clearance from the United States Food and Drug Administration (**US FDA**) to market its improved artificial intelligence (**AI**) trained liver-fat assessment software-as-a-medical device in the USA, HepaFatSmart®. HepaFatSmart® will replace HepaFat-AI® in the US which received US FDA regulatory clearance in Dec 2020.

About HepaFatSmart®

HepaFatSmart® is a Software-as-a-Medical Device (**SaMD**) that automatically analyses magnetic resonance imaging (**MRI**) images for the quantitative assessment of a patient's liver fat. Specifically, it provides clinicians with three liver fat biomarkers; volumetric liver fat fraction (**VLFF**), proton density fat fraction (**PDFF**), and a steatosis grade.

HepaFatSmart® has been trained utilising AI against HepaFat-Scan®, Resonance Health's established manual analysis service for assessing liver fat, as the reference standard. HepaFat-Scan® is regulatory cleared for marketing and use in the USA, Australia, and the European Union.

HepaFatSmart® offers significantly improved diagnostic performance compared with Resonance Health's existing AI trained automated liver fat assessment device, HepaFat-AI®, which it will replace in all markets once the required regulatory clearances for the new device are obtained.

Unlike HepaFat-AI®, which also used a neural network to predict the VLFF, PDFF and steatosis grade, HepaFatSmart® more closely simulates the manual analysis approach performed by the Company's highly trained analysts by defining a liver region of interest (**ROI**) on acquired MRI images for HepaFat-Scan®.

The sensitivities and specificities of HepaFatSmart® for predicting HepaFat-Scan® VLFF values in the validation dataset are provided in Table 1 below and range from 98% to 100%. HepaFatSmart® can be accessed through the Company's cloud-based user portal, or via onsite platforms which include third parties' (channel partner) platforms.

Resonance Health Managing Director, Mitchell Wells commented:

"HepaFatSmart® is our first software-as-a-medical device to receive US FDA regulatory clearance, developed entirely in-house by Resonance Health's AI Development Project Team. The team worked closely with the Company's experienced technical analysts to develop a new and materially improved approach to training HepaFatSmart® that more closely emulates the HepaFat-Scan® manual analysis methodology, achieving a sensitivity and specificity of 98-100%, versus HepaFat-Scan®. This is one of several initiatives completed in recent months that collectively serve to significantly de-risk and improve the business into the future while ensuring we have control of our corporate destiny".

VLFF threshold	Clinical relevance	Sensitivity (95% CI) (%)	Specificity (95% CI) (%)
4.1 %	<ul style="list-style-type: none"> Boundary between grade 0 (<5%) and grade 1 (5 - 33%) steatosis by histological inspection. Used to define the absence (0) or presence (1) of NAFLD. 	100.0 (97.3 – 100.0)	98.6 (94.9 – 99.6)
12.1 %	<ul style="list-style-type: none"> Boundary between grade 1 (5-33%) and grade 2 (33-66%) steatosis by histological inspection. 	98.8 (93.6 – 99.8)	98.0 (94.9 – 99.2)
16.2 %	<ul style="list-style-type: none"> Boundary between grade 2 (33-66%) and grade 3 (> 66%) steatosis by histological inspection. 	100.0 (93.8 – 100.0)	99.6 (97.5 – 99.9)

Table 1. Sensitivities and specificities of HepaFatSmart® for predicting HepaFat-Scan® VLFF values greater than three clinically relevant thresholds.

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

Resonance Health's dedication to scientific rigour and quality has enabled it to achieve regulatory clearances for a range of Software-as-Medical Devices (**SaMDs**) in the USA, Europe, UK, and Australia, and to proudly carry ISO 13485 certification for the design and manufacture of medical devices. Regulatory cleared SaMD products, some of which incorporate Artificial Intelligence (**AI**), include:

- **FerriScan®**, a core-lab product that provides an accurate assessment of liver iron concentration (**LIC**) through non-invasive MRI-based technology, for use in the assessment of individuals with iron overload conditions. Internationally recognised as the gold standard in LIC assessment.
- **FerriSmart®**, an AI-trained, non-invasive MRI-based device for the automated real-time assessment of LIC in patients, calibrated against the global gold standard, FerriScan®.
- **HepaFat-Scan®**, an MRI-based solution which provides a reliable non-invasive assessment of liver-fat in liver tissue for use in the assessment of individuals with confirmed or suspected fatty-liver-disease.
- **HepaFatSmart®**, an AI-trained, non-invasive device for the automated real-time multi-metric assessment of liver-fat in patients, for the assessment of individuals with confirmed or suspected fatty liver disease.

- **LiverSmart®**, an AI-trained, non-invasive MRI-based multi-parametric device combining FerriSmart® and HepaFat-AI® into a consolidated report providing accurate assessment of LIC and liver fat.
- **CardiacT2***, the most widely accepted MRI method for assessing heart iron loading. Resonance Health offers a dual analysis of FerriScan® and CardiacT2*. CardiacT2* is TGA and CE Marking regulatory cleared.

The Company has a development pipeline of additional medical imaging analysis products and services, including the **MRI Liver Fibrosis Project**, aimed at accurately assessing the presence and progression of liver fibrosis utilising non-invasive MRI analysis.

Stakeholders, including clinicians, patients, and shareholders, are encouraged to register their interest at www.resonancehealth.com and to follow Resonance Health on Facebook, LinkedIn, and Twitter.

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