

11 July 2018

Resonance Health Ltd announces TGA, CE Mark clearance for A.I. Solution FerriSmart®

Resonance Health Limited (ASX: RHT) (“Resonance Health”) is pleased to announce that FerriSmart®, its groundbreaking AI solution for the quantification of liver iron concentration (LIC), has now achieved TGA and CE Mark clearance, making it the only regulatory approved artificial intelligence tool for use in liver iron quantification.

Clinicians and radiologists worldwide will now be able to access the pay per use service via Resonance Health’s own cloud-based portal (screenshots below), or via channel partner Blackford Analysis (5th July 2018, ‘Resonance Health announces Alliance Partner Agreement with Blackford Analysis’). Any hospital site will now be able to onboard and manage their patient reports and accounts in relative autonomy, requiring less input from Resonance Health personnel. Quantification of liver iron concentration via FerriSmart® takes a matter of seconds and will be provided at a lower cost than a FerriScan® analysis. This combined with the high accessibility of the tool means significantly improved access pathways for previously unreachable customers and markets for Resonance Health products. FerriSmart®’s application for FDA clearance is expected to be submitted by the end of July.

Resonance Health’s current flagship product, FerriScan®, is used globally for several reasons: It is TGA, CE Mark, and FDA cleared, and results are generated in a strictly controlled, ISO certified core laboratory. The high sensitivity and specificity of FerriScan®, the standardisation of the protocol and analysis techniques, the verification of all scanners globally, and the independent validation of results calibrated to biopsy, have all resulted in FerriScan® becoming the gold standard of non-invasive measurement of liver iron concentration.

This extremely high benchmark set by FerriScan® has now been applied to the FerriSmart® technology. FerriSmart® performs numerous input quality control checks, runs analyses, and returns patient results to clinicians and radiologists in almost real-time. Additionally, security against counterfeiting has been added with the generation of a QR code for each report, which allows patients and doctors to verify the authenticity of their reports. The pay per use model used by Resonance Health is ideal for customers that don’t want to incur high, upfront licence fees or costs when trialing or using software in their radiology centres.

With the Company’s ongoing work in developing FerriSmart®, Resonance Health has now built significant capability in machine learning, adding to the Company’s extensive knowledge and experience in obtaining and maintaining regulatory clearance for software products and for commercialising medical solutions.

Additional work in machine learning continues with the Company’s focus on developing and deploying

cutting-edge assistance tools for clinicians and radiologists for various disease states. Resonance Health is also currently assessing various opportunities for collaboration with others. Further updates will be provided as work progresses.

Alison Laws

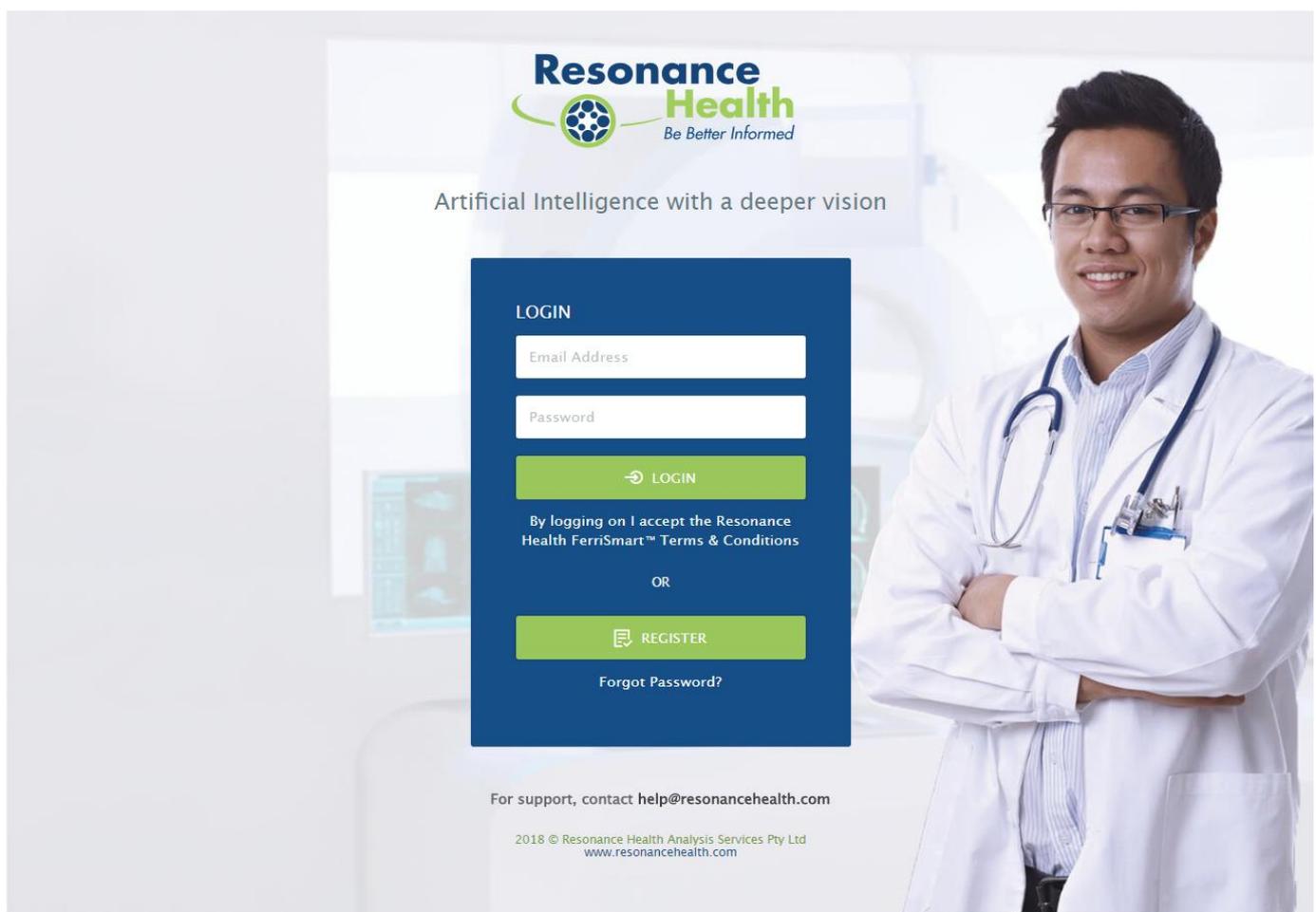
Chief Executive Officer

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- **Web Portal Landing Page**



FerriSmart™
Powered by **FerriScan**

Liver Iron Concentration Report

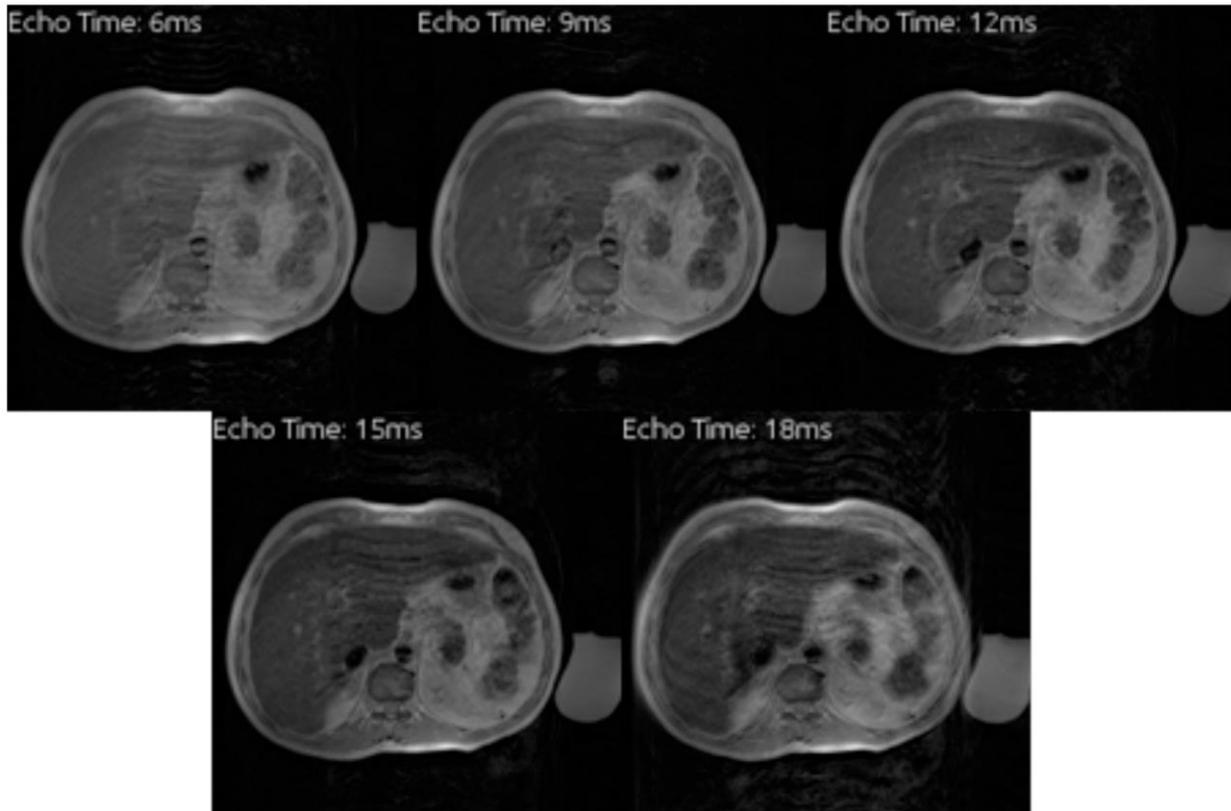


Validate Report

Report No: ac2cb7d3abd47628
Patient ID: ABC-12345678
Name: PATIENT, Patient
Birth Date: 10 Aug 2003
Scan Date: 30 Aug 2017
Analysis Date: 02 Jul 2018
Referrer: Dr Doctor
MRI Center: MRI Centre Name

Average Liver Iron Concentration:
3.5 mg/g dry tissue (NR: 0.17 - 1.8)
63 mmol/kg dry tissue (NR: 3-33)

Normal range (NR) is taken from Bassett et.al,
Hepatology 1986;6: 24-29



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- FerriSmart Sample Report (PDF)