

Welcome to our second newsletter of 2017, bringing you a summary of our global promotional activities, new bone marrow iron assessment product launch, a FerriScan update, plus other exciting developments

Customer in Focus: FerriScan Centres Lead Best Practice As Concerns Grow Over Unsafe T2* Techniques for Assessing Iron



Thalassaemia
International
Federation

TIF Media Release and Clinical Alert

The Thalassaemia International Federation (TIF), a leading patient organisation in the field of iron overload, has issued a **Media Release and Clinical Alert** to warn of the potential dangers of an unvalidated magnetic resonance imaging T2* technique (www.ironcalculator.com) that is used widely for iron overload assessment. TIF emphasise the critical need to use validated techniques, specifically referencing Resonance Health, whose regulatory cleared FerriScan® R2-MRI is the globally recognised gold standard for the assessment of iron overload.

Resonance Health's Chief Scientific Officer, Prof. Tim St Pierre, presented the results from a recent study to a packed crowd at the European Haematology Association (EHA) congress. The abstract, *Assessment of the performance of a widely available T2*/R2* liver iron concentration method used in clinical practice in a population of Thalassaemia patients* is available [here](#) and will be published later in the year. The study concluded that the unvalidated but widely available T2* technique was 'unsafe for clinical use'. This has raised considerable concerns by TIF for patient safety, as thousands may have been exposed to unreliable results at centres using this unvalidated T2* method for assessing iron overload.

The **Media Release and Clinical Alert** warns "The Thalassaemia International Federation (TIF) is now urging all hospitals and centres using non-regulated or non-

calibrated MRI methods to measure LIC, to review their techniques and re-call patients, at least those whose clinical status mandates the need for accurate measurement of liver iron content, to proceed to the measurement by a validated method."

Panos Englezos, President of the TIF Board of Directors, George Constantinou, Key Member of TIF Advocate Board, and Dr Eletheriou, Executive Director of TIF commented:

"TIF feels strongly that the issue of iron monitoring by MRI should be given immediate and serious attention and priority by all involved in the care of these patients so that patients' rights for access to quality healthcare services cease to be violated..."

"We urge all centres and health care professionals to ensure that they are using only validated techniques. TIF is seeking collaboration with all Governments, other involved stakeholders, the industry, and in particular Resonance Health, who at the moment are providing the only validated tool to date, so as to identify ways to expand to the maximum access of its patients for LIC measurements globally."

To read the full media release please [click here...](#) If you are concerned that your patients may have been affected by the inferior technique and need guidance or for more information please email emmas@resonancehealth.com.

R&D Update: FerriScan not Confounded by Fat



There is new evidence demonstrating that FerriScan is not confounded by the presence of liver steatosis. This information comes from new study results that were presented in Amsterdam at the International Liver Congress run by the European Association for the Study of the Liver (EASL) in April this year.

The study results highlight a significant advantage of using FerriScan, given an accurate LIC result is provided even in the presence of liver fat, unlike liver T2*, whose results (due to the nature of the technique) are impacted by the presence of fat. Within the rise of the global obesity epidemic and as fatty liver becomes more and more prevalent, the requirement for an assessment tool to accurately report iron levels, even in the presence of liver fat, becomes increasingly important in making correct patient management decisions. Additionally, fatty liver (like iron overload) is also commonly found in cancer survivors who received transfusions as part of their treatment, and as such FerriScan is particularly suited to assessing transfusional iron overload in this cohort.

Previous studies have also demonstrated the FerriScan is not affected by the presence of liver inflammation, fibrosis, or cirrhosis. These factors, together with its regulatory clearances, strengthen the position of FerriScan as the gold standard in liver iron measurement.

Resonance Health customers are able to access both liver iron and liver fat measurements in combination. In the same MRI visit both a FerriScan for liver iron concentration and HepaFat-Scan® for volumetric liver fat fraction (VLFF) measurements can be performed to give a more complete indication of liver health status.

To read more about FerriScan's unique advantages in the presence of liver fat, please [click here...](#)

Cancer Abstract Highlights Concerns of Serum Ferritin as a Screening Tool in Cancer Survivors

At last week's European Hematology Association (EHA) Congress, Resonance Health's Chief Scientific Officer, Prof. Tim St Pierre, presented an abstract on *The Relationship Between Serum Ferritin and Liver Iron Concentration in Pediatric Cancer Survivors*, a study conducted in collaboration with the University of Minnesota. The abstract is available [here...](#)



This study took patients with elevated serum ferritin levels and iron overload to assess the accuracy of serum ferritin in comparison to the reference standard, FerriScan, which measures liver iron concentration (LIC). LIC is recognised as the most effective measure of total body iron stores.

This study and associated abstract arose from the knowledge that paediatric cancer survivors are at risk of transfusion-related iron overload, caused by their intensive treatment regimes. The study results concluded that serum ferritin levels are influenced by factors including patient cohort and age groups, which highlights the difficulty in relying on serum ferritin to screen for and manage iron overload. With such complications in the current screening method for cancer survivors (serum ferritin), FerriScan remains ideally positioned as a reliable, non-invasive alternative.

To read further information on this study please [click here...](#)

Bone Marrow Iron Assessment Launch

Resonance Health is excited to announce that our new technology, Bone Marrow R2-MRI, for the assessment of iron levels in bone marrow, is now available for clinical application in Europe, Australia, and New Zealand, following its launch at the European Haematology Association (EHA) Congress. This allows clinicians to refer patients for Bone Marrow R2-MRI in the clinical community, rather than being limited to use in a research setting.

Elevated bone marrow iron is of particular significance in the bone marrow transplant setting, where iron levels can be elevated due to multiple blood transfusions. The knowledge and quantitative assessment of iron levels in bone marrow prior to a patient's bone marrow transplant is believed to assist with predicting potential complications and patient prognosis post-transplant. Elevated bone marrow iron levels are associated with a range of poorer health outcomes post-transplant, including:

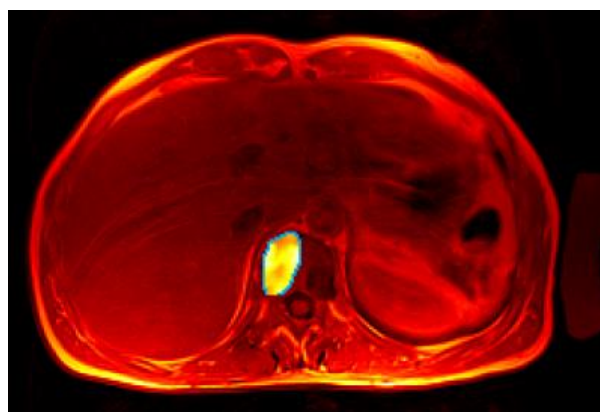
- Lower overall survival and disease-free survival
- Independent risk factor for invasive aspergillosis (a major cause of death following hematopoietic stem cell transplant)
- Increased risk of severe infection or bacterial infection

Knowledge of bone marrow iron levels may also inform the use of precautionary interventions (anti-bacterial, anti-fungal, iron chelation, or phlebotomy) to improve patient outcomes.

The current 'gold standard' (best practice) for assessing bone marrow iron is histopathological grading from biopsy, which is semi-quantitative, non-standardised, and subject to large inter-observer error. Conversely, Bone Marrow R2-MRI is non-invasive, quantitative, and correlates significantly with iron in bone marrow, making it an affordable, safe, and pain-free alternative. Bone Marrow R2-MRI is also standardised, meaning the subjectivity between pathologists is eliminated.

FerriScan is currently used at leading institutions to assess body iron stores prior to bone marrow transplant. The new bone marrow specific test expands on this capability and is targeted to further assist clinical decisions for patients being considered for bone marrow transplantation. Bone Marrow R2-MRI data is acquired with the same MRI scanning protocol as FerriScan and as such Bone Marrow R2-MRI can be combined with FerriScan to provide a more complete picture of a patient's iron status, or performed as a standalone assessment. A further advantage of using the FerriScan protocol for Bone Marrow R2 analysis is that the bone marrow assessment can be performed retrospectively if a patient has had a FerriScan previously. Resonance Health's regulatory authority cleared Cardiac T2* measurement for heart iron assessment is also available in combination as a 'triple test'.

Resonance Health remain dedicated to improving patient outcomes wherever possible and with over 50,000 bone marrow transplants performed globally each year, we feel this new test will make a real difference. If you have any questions about bone marrow iron, or wish to find out more about the Bone Marrow R2-MRI, please view the fact sheet located [here](#), or email emmas@resonancehealth.com for any further information.



We are launching a naming competition for our new Bone Marrow R2-MRI technology and would be delighted to receive your suggestions. We welcome you to submit any suggestions to chadt@resonancehealth.com by 15th July 2017. If your name is chosen you will receive \$500 AUD either towards a travel grant for any educational event of choice or donation to a Bone Marrow Transplant Patient Organisation.

A New Home for HQ

Resonance Health is pleased to announce that due to expansion, we are relocating our main headquarters and core lab, in Claremont to new, more spacious offices in Burswood, Western Australia. Our move into the new office will take place in mid-July, with no downtime anticipated during the transition. We welcome the move into our more central office with beautiful park views.

New Address: **141 Burswood Rd, Burswood, Western Australia, 6100**

New Postal Address: **PO Box 71, Burswood, Western Australia, 6100**

Phone (unchanged): **+61 (0)8 9286 5300**

Please be sure to update your records with the new details.

Conference Round Up



The Resonance Health team has had a busy conference schedule in the last quarter with attendance across the UK, USA, Germany, Spain, and the Netherlands. We have welcomed the opportunity to meet with a variety of new and existing customers during these key conferences as we've continued to develop our global partnerships in the clinical community and expand patient access to our services.

The first conference this quarter was the Genetic Haemochromatosis Scientific Conference in the UK, which saw Chief Scientific Officer, Prof. St Pierre present as a key speaker to discuss FerriScan and highlight the challenges of using serum ferritin as a substitute for liver iron concentration.

Amsterdam was next on the itinerary for Prof St Pierre and Dr Sherif Boulos our Clinical Research Manager who joined over 10,000 delegates to attend the European Association for the Study of the Liver (EASL) where Prof. St Pierre presented new data showing that FerriScan is not confounded by the presence of liver fat.

The local US team joined the 11th Annual Sickle Cell Disease Research and Educational Symposium in the US. Delegates were keenly interested in the use of FerriScan to monitor iron in transfused sickle cell patients and the symposium provided numerous networking opportunities.

In Germany we reinforced our dedication to the sickle cell community, with our German representative attending a two-day Pan-European Consensus Conference on Newborn Screening for Haemoglobinopathies. The importance of early screening in children was highlighted during the two

day event and FerriScan was favourably positioned in the long-term management of iron loading in sickle cell patients.

The 44th UK Forum on Haemoglobin Disorders in London was our 5th conference of the quarter with our UK team in attendance. The London conference allowed for successful distribution of our recent clinical survey report on current practice in iron monitoring in cancer survivors, and served as an excellent opportunity to further develop relationships with key opinion leaders and to meet new customers.

Resonance Health ended the quarter with a trip to the 22nd European Hematology Association (EHA) Congress in Spain last week. This was a hectic finale to the conference program for the team with the presentation of two key abstracts, the launch of our new Bone Marrow R2-MRI technology, and participation in multiple key meetings with leading clinicians, patient advocacy groups, and pharmaceutical companies.

We look forward to a more peaceful travel schedule next quarter to catch up on all of our exciting developments.

Team Member in Focus: QA & Reg. Affairs Manager: Celine Royet



Celine joined us here at Resonance Health back in June 2015, taking on the position of Quality Assurance and Regulatory Affairs Manager. In this position, Celine is responsible for assuring all products and processes are of the highest quality, and remain in line with Australian and global regulations through continual communication with the TGA, FDA, and other regulatory bodies. Celine has also been integral to our most recent validation efforts during the launch of the Bone Marrow R2-MRI technology.

Before joining Resonance Health, Celine worked in Regulatory Affairs, Quality Assurance, and Operations for numerous international pharmaceutical companies, including Bayer and Mylan. She also worked at biotech company, Genzyme, in the field of cell therapy and regenerative medicine.

In her spare time, Celine likes to indulge in cooking traditional French cuisine and getting her hands dirty with the odd home renovation project.