

FerriScan[®] R2-MRI Fact Sheet – Sickle Cell Disease and Iron Overload

Sickle cell disease patients who receive regular or intermittent blood transfusions are at risk of iron overload. Excess iron is stored in the liver and an accumulation can lead to organ damage such as liver fibrosis or cirrhosis.

7% of sickle cell patients' deaths are directly attributable to iron overload³. The accurate assessment and monitoring of body iron is therefore crucial.

FerriScan has been established in Sickle Cell Centres of Excellence throughout the world as the most accurate MRI-based method for measurement of liver iron, eliminating the need for liver biopsy.

FerriScan is recommended in treatment guidelines for the annual measurement of liver iron concentration.

The 2008 Nursing Practice Guidelines: Care of the Patient with Sickle Cell Disease and Iron Overload recommends an accurate quantification of LIC at the beginning of chelation therapy and regularly thereafter. FerriScan is endorsed as a suitable test.

The 2008 Standards for the Clinical Care of Adults with Sickle Cell Disease in the UK recommends all transfused patients have regular monitoring of LIC using MRI.

The UK Sickle Cell Society recommends FerriScan for measuring LIC in sickle cell disease patients receiving blood transfusions.

The liver is the body's primary site of iron storage and is closely correlated to total body iron stores⁴. An accurate estimate of these iron levels is therefore vital to both the diagnosis and management of patients with iron overload.

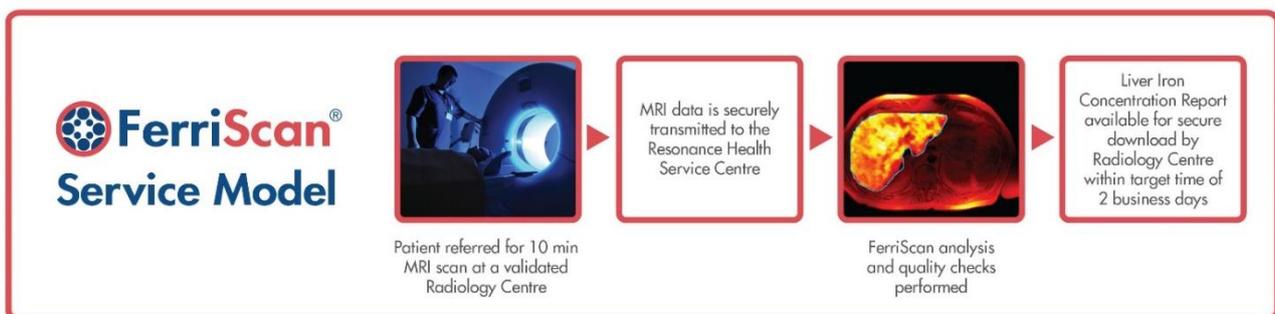
FerriScan applies its unique patented software and analysis process to R2-MRI images, providing a highly accurate measurement of Liver Iron Concentration¹.

FerriScan provides the clinician with accurate, reliable information on which to base patient management decisions on commencement of chelation therapy, adjustments to dosage and changing the mode of chelator delivery.

Testing of serum ferritin levels can provide a useful adjunct to FerriScan analysis as it indicates how iron levels are trending over time. However, the correlation between serum ferritin and LIC is not close enough for it to be used as a basis for the accurate determination of treatment options².

Key FerriScan Features:

- ✓ FerriScan provides an accurate, validated MRI-based measurement of liver iron concentration
- ✓ FerriScan is non-invasive, requires no contrast agents and has a scan time of approximately 10 minutes
- ✓ FerriScan has high sensitivity and specificity for measuring LIC
- ✓ Image analysis and LIC reporting is performed at a central ISO 13485 certified Service Centre
- ✓ FerriScan has international regulatory clearance (USA, Europe, Australia)
- ✓ Results are available within a target time of two business days
- ✓ FerriScan can measure LIC over the entire range encountered in clinical practice³
- ✓ FerriScan results are clinically validated to be unaffected by inflammation, fibrosis or cirrhosis
- ✓ FerriScan requires no breath-hold and may therefore be used for paediatric patients
- ✓ Results are accurate, reliable and reproducible over time and between MRI centres and models of scanner
- ✓ There is no requirement for customers to purchase new software or hardware
- ✓ FerriScan is suitable for 1.5 Tesla MRI scanners
- ✓ FerriScan is charged per scan only



References

1. St.Pierre TG *et al* Noninvasive measurement and imaging of liver iron concentrations using proton magnetic resonance. *Blood* 2005; 105: 855-861
2. Karam LB *et al*. Liver biopsy results in patients with sickle cell disease on chronic transfusions: poor correlation with ferritin levels *Paediatric Blood Cancer* 2008; 50: 62-65
3. Darbari *et al*. Circumstances of death in adult sickle cell disease patients. *American Journal of Hematology* 2006; 81: 858-863
4. Angelucci, E *et al* Hepatic iron concentration and total body iron stores in thalassemia major. *New England Journal of Medicine* 2000; 343:327-331