HepaFat-AI

for automated measurement of liver fat

Instruction Manual

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INTRODUCTION

HepaFat-AI is a software platform designed to automatically analyse magnetic resonance imaging (MRI) datasets to generate an assessment of the patient's liver fat by providing:

- The patient's volumetric liver fat fraction (VLFF);
- The patient's proton density fat fraction (PDFF); and
- The patient's steatosis grade.

To carry out an analysis, the user simply uploads a zip file containing the raw DICOM images required for HepaFat-AI analysis. No user input is required for the analysis thus minimising the impact of human error on obtained results. HepaFat-AI requires that the image input data has been acquired according to a specific data acquisition protocol found in the following user manual.

The MR images are to be acquired on a 1.5T or 3T scanner using a multi-echo spoiled gradient echo breath-hold sequence with image acquisition parameters as described in Table 1 below.

INDICATIONS FOR USE

HepaFat-AI is indicated to:

- Assess the volumetric liver fat fraction, proton density fat fraction and steatosis grade in individuals with confirmed or suspected fatty liver disease;

When interpreted by a trained physician, the results can be used to

- Monitor liver fat content in patients undergoing weight loss management and can be used to
- Aid in the assessment and screening of living donors for liver transplant

IMAGING PROTOCOL

- HepaFat-AI requires MR image data in DICOM 3 format as input for the measurement.
- HepaFat-AI requires images to be acquired on a 1.5T or 3T scanner using a multi-echo spoiled gradient echo breath-hold sequence.
- To ensure the highest degree of accuracy in the fat measurements it is essential to provide Resonance Health with image data that is acquired using the specified parameters shown in the table below. Of particular importance are: the scanning sequence, echo-times, repetition time, flip angle, FOV size, imaging position and level of artefacts.

Parameter	Value	
Field Strength	**1.5 Tesla**	**3 Tesla**
Scanning Sequence	Spoiled Gradient Recalled Echo	
Echo-times (TE)	**2.38, 4.76 and 7.14 (± 0.15) ms**	**1.19, 2.38 and 3.57 (± 0.10) ms.**
	OP1, IP1 and OP2 respectively, where OP is Opposed-Phase and IP is In-Phase. Refer to the Dixon method. Please ensure to match these echo-times as closely as possible	
Repetition time (TR)	88 ms	
Flip angle (FA)	70 degrees	
Matrix size**	256 x 256 (or smaller if needed)	
Field of view (FOV) size and position*#	Just fit in the subject torso from left to right by minimising background noise region as per patient size (see Fig 2). **Avoid lung crest (liver position may change after the localiser/scout)**	
Voxel size	1.56 x 1.56 or bigger or smaller when FOV > 400 mm or < 400 mm	
Phase Encoding Direction	COL (Anterior-Posterior) **NOT** in L-R	
Partial fourier	6/8 or 4/8 depending on scan time	
Bandwidth (Water Fat Shift –WFS)	500 Hz/pixel or close (± 62.5 kHz for GE scanners, WFS 0.4 for Philips scanners)	1000 Hz/pixel or close (± 62.5 kHz or higher for GE scanners, WFS ~0.3 for Philips scanners)
Number of excitations	1	
Number of slices#	**3** (the middle slice through the largest axial cross section of the liver) **Reposition the slices and REPEAT the scan if lung crest is visible in the acquired images**	
Slice thickness	4 mm	
Slice distance	6 mm centre to centre distance (or distance factor 50% of slice thickness)	
Percent Sampling	100%	
Filters/ Fat suppression	None	
Scan Time	< 13 seconds, increase acceleration factor when needed to shorten scan time	
Philips MR scanners		
RF coil sensitivity normalization	CLEAR (recommended for Philips MR scanners)	

** ***Acquisition Matrix Size*** *may be reduced for GE scanner in order to allow 3 required TEs to be acquired with a single breath hold multi-slice multi-echo GRE sequence.*

* **FOV size selection is dependant in patient size**. FOV is recommended to include patient complete torso with background space minimised at left and right sides of the torso . For very small subject (e.g. New born), reduce the FOV size as per above to make the liver visible in the same way as normal size subject (Left-Right FOV size just fits the left-right torso size).

 # Review images for visible lung crest*. Review the acquired images to ensure the middle slice roughly is set at the largest cross-section area of liver without lung crest visible. Otherwise, repeat the scan with the recommended imaging position.*

Table 1 - Recommended image acquisition parameters

WARNING

Elevated liver iron concentrations, incorrect slice positioning resulting in visible lung crest, extremely high liver fat content, very small liver visible due to incorrect slice positioning or unnecessary large FOV used relatively to patient size and strong breathing artefacts may result in anomalous readings or an inability to report a VLFF or a PDFF value or a steatosis grading.

Failure to adequately implement the required scanning protocol or review the quality of the acquired images prior to processing could result in situations which may yield anomalous readings, some of these are:

- incorrect slice positioning resulting in visible lung crest in the MR image,
- very small liver visible due to incorrect slice positioning or unnecessary large FOV used relatively to patient size, and
- strong breathing artifact

SCANNING THE TEST SCAN

A test scan using saline bags as a proxy for a patient is recommended after implementing the HepaFat protocol in order to validate your scanner and ensure correct acquisition settings prior to patient scanning.

Note: When using a Philips MR scanner to acquire the images please use Constant LEvel AppeaRance (CLEAR) during the acquisition.

Note: Most scanners require a single breath-hold. However, GE scanners may require the reduction of Acquisition Matrix Size to achieve the required parameters (TEs) with a single breath hold GRE sequence. Contact support@resonancehealth.com for assistance if encountering issues

1. Place the two saline bags (1 litre) as shown in Figure 1

2. Place the abdomen/torso/chest coil on the top of the saline bags and use additional padding and/or straps as necessary to ensure the anterior array element is secure and approximately 15 – 30 cm from the posterior elements.

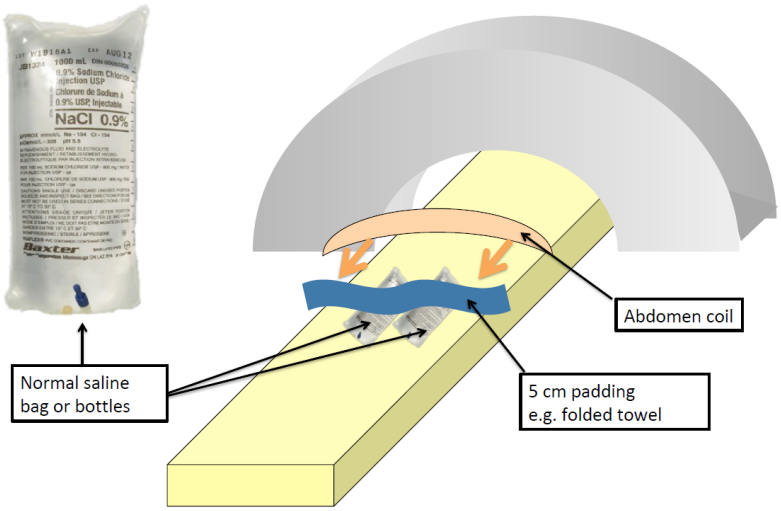


Figure 1. Arrangement of saline bags on scanner bed [*Note: Please make sure that the height distance between the coil and the bed is between 15 and 30cm.*]

3. Register the study in accordance with your standard procedure, using Test Scan in the **Patient Name** and **Patient ID** fields.

4. Enter the **Patient's Weight** as **80 kg** (to ensure sufficient signal is acquired).

5. Run the scout/localizer sequence.

6. Open the previously established HepaFat Imaging Protocol sequence (table above).

7. Using the coronal scout/localizer image, position the 3 slices to cover the saline bags. It is fine if some of the slices are outside the saline bags region.

8. Position (and adjust if necessary) the FOV to include the entire saline bags with some empty margins around the saline bags.

9. When all images have been acquired, export the DICOM images in classic DICOM-3 format to a location that can be retrieved for uploading so that the images can be verified.

SCANNING PATIENTS

Note: When using a Philips MR scanner to acquire the images please use Constant LEvel AppeaRance (CLEAR) during the acquisition.

1. In accordance with your MRI Centre's standard procedure, run the patient through your checklist for any contraindications to MRI, and inform them of the scanning process.
2. Please DO not be tempted to change the protocol in order to improve image quality.

NOTE: Most scanners require a single breath-hold. However, GE scanners may require the reduction of Acquisition Matrix Size to achieve the required parameters (TEs) with a single breath hold GRE sequence. Contact support@resonancehealth.com for assistance if encountering issues.

3. Register the study as per your standard procedure including the patient name, the patient ID, and the patient date of birth.
4. Run the scout protocol while the patient is breathing gently.
5. Check the scout image to ensure that the whole liver is well within the sensitive area of the abdomen/torso coil (refer to Figure 1 below).
6. Refer to the coronal scout image and position the middle slice at the largest axial cross-sectional area of the liver. The slice gap must be 2 mm and slice thickness MUST be 4 mm (i.e. slice gap 50% of slice thickness).

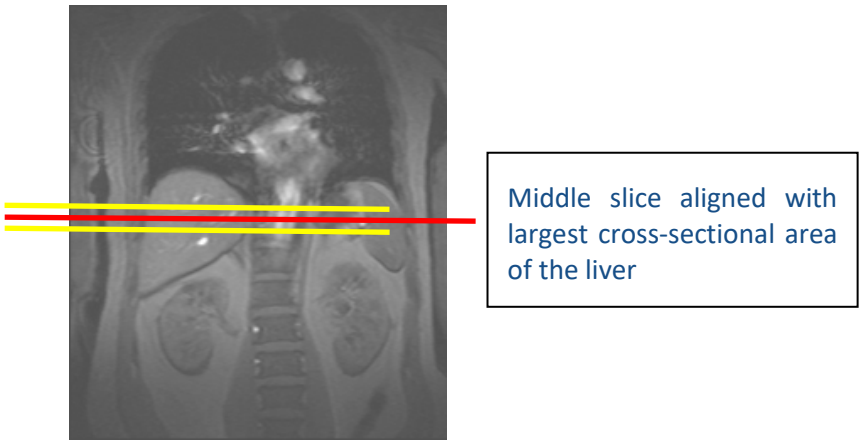


Figure 1 Example of slice positioning. Note liver position may change after the localiser/scout. **Avoid lung crest in images. Otherwise, repeat the scan**.

NOTE: Breath-hold imaging quality can be improved by decreasing scan time to a comfortable level for a better likelihood of successful breath-hold; ideally scan time is below 13 seconds. Parallel Imaging method may be used to decrease scan time. Please contact Resonance Health if you are unable to achieve a suitable scan time.

7. Set the FOV so that the entire cross section of the liver is visible in the axial image slice, as shown in Figure 2. If possible, place the FOV to allow some empty space (clearance) on at

least one side or at the top of patient's body. The region of empty space around the patient's torso is used to estimate the background noise signal level.

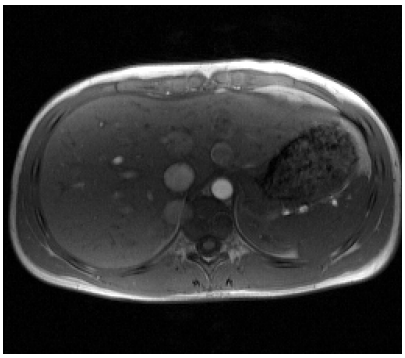


Figure 2 Example of HepaFat-AI image acquisition FOV size and position (**minimise background noise region from left to right sides of the torso**). Target at large liver cross-section area without lung crest visible. Note, liver position may move after the localiser/scout. **Rescan the data if lung crest or severe artefact is present in the acquired images.**

8. Confirm correct sequence parameters according to Table 1 and run the acquisition.

NOTE: Please review the images during and/or directly after the scan, while the patient is still in the scanner. If severe artefact or lung crest is detected, a rescan is required to acquire images without artefact (refer to next section) and lung crest.

9. When all of the images have been acquired, review them for artefact as per the instruction on the next page and if suitable save them in DICOM 3 format. Ensure that the image data is not compressed.

MOTION ARTEFACT

Ensure the images are reviewed during and directly after the scan, while the patient is still in the scanner, to identify unacceptable motion artefact. Motion artefact may be caused by either unsuitable breath holding or patient movement.

- An example of unsuitable breathing artefact is shown in Figure 3. Please re-acquire the whole set without artefact.

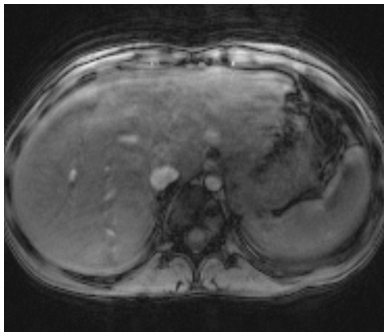


Figure 3 Examples of unacceptable artefact

Reviewing for movement can be performed by sequentially comparing the 3 TEs for a given slice in the same window (i.e. rather than a side by side comparison). Please re-acquire the whole set without movement.

NAVIGATING YOUR REPORT

A HepaFat-AI analysis report is automatically generated once images are uploaded successful

At the top of the report, the Job information is displayed including the Patient ID, scan date and Referring Physician.

NOTE: This information is obtained from the DICOM header and cannot be corrected once the report is generated. Ensure that correct details are entered when registering patient on the scanner.

The results are displayed in the rectangle box as seen below.

Pictures of the 3 TEs of the analysed slice are also seen below. **Check the 3 TE images against the following warning:**

Warning

Elevated liver iron concentrations, incorrect slice positioning resulting in visible lung crest, extremely high liver fat content, very small liver visible due to incorrect slice positioning or unnecessary large FOV used relatively to patient size and strong breathing artefacts may result in anomalous readings or an inability to report a VLFF or a PDFF value or a steatosis grading.
It is the radiologist's responsibility to check that the image analysed is a liver image, and the result provided is consistent with other relevant clinical results.

The following situations which may yield anomalous readings:

- elevated liver iron concentrations,
- incorrect slice positioning resulting in visible lung crest in the MR image,
- very small liver visible due to incorrect slice positioning or unnecessary large FOV used relatively to patient size, and
- extremely high liver fat content, and
- strong breathing artifact

HepaFat-AI

Liver Fat Assessment Report

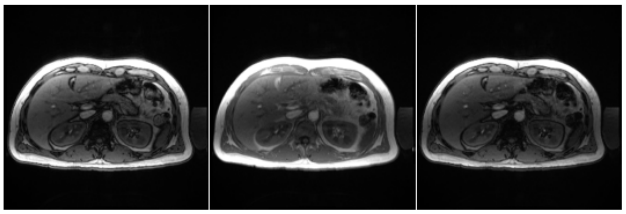
Patient ID:	LS-Anon-000010	Scan Date:	16 May 2019
Name:	LS-Anon-000010	Analysis Date:	14 Feb 2022
Birth Date:		Referrer:	
		MRI Center:	

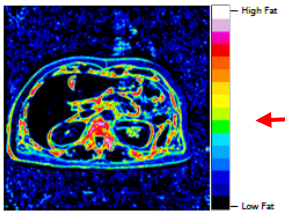
	Result	95% CI (confidence interval)	Normal Range
VLFF (Volumetric Liver Fat Fraction)	2.9%	2.3 — 3.7	0 — 4.1[1]
PDFF (Proton Density Fat Fraction)	3.4%	2.7 — 4.3	0 — 4.8[2]
Steatosis Grade	0		0[3]

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. 2016;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

1st Out-of-Phase | In-Phase | 2nd Out-of-Phase





Liver Fat Distribution Map[4]

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.

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CE ARTG:223853 510(k):K201039

Job information

Results

Steatosis Grade and the associated grading

Images of the slice analysed (3 TEs)

Illustrative liver fat distribution map

The HepaFat-AI system has been validated/tested to detect fatty liver in the range of: 0 to 41.7% VLFF

In the event that high liver fat content is detected (i.e. above 41.7% VLFF), the HepaFat-AI analysis process will generate a different report with a warning message that indicates the value is outside the validated calibration range and that the associated uncertainty makes a precise estimate too unreliable for reporting. This report means the VLFF is 41.7% or higher, indicating severe steatosis, but a specific VLFF value is not provided.

This can be seen in the table below:

	Result	Normal Range
VLFF (Volumetric Liver Fat Fraction)	≥ 41.7% *	0 – 4.1[1]
PDFF (Proton Density Fat Fraction)	≥ 45.8% *	0 – 4.8[2]
* Extremely high liver fat content detected. The value is outside the validated calibration range and the associated uncertainty makes a precise estimate too unreliable for reporting.		
Steatosis Grade	**3**	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. 2016;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):

In the event that high liver iron concentration is suspected, or that there is possible lung crest present due to incorrect slice position*, no result will be shown on the generated HepaFat-AI report. Instead the report will show the following message:

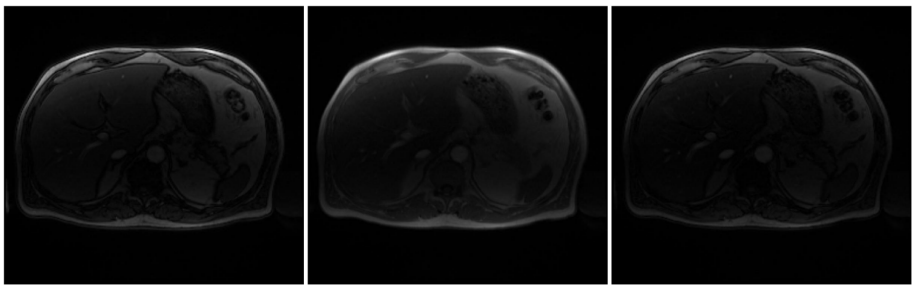
No result can be generated as one of the following potential anomalies have been detected:

1) **High liver iron concentration is suspected.** Elevated liver iron concentration prevents an accurate liver fat assessment. It is recommended to undertake a regulatory-cleared MRI-based Liver Iron Concentration measurement.

OR

2) **Incorrect slice position suspected with possible lung crest present.** The cross-section of the liver is not large enough to provide an accurate liver fat assessment. Please review the slice positioning and if necessary re-scan the patient ensuring the largest cross-section of the liver is present in the images.

1st Out-of-Phase | In-Phase | 2nd Out-of-Phase



*The HepaFat-AI system was trained to detect/identify anomalies associated with high liver iron concentration only.
The situations which might yield anomalous readings are:

- elevated liver iron concentrations,
- incorrect slice positioning resulting in visible lung crest in the MR image,
- very small liver visible due to incorrect slice positioning or unnecessary large FOV used relatively to patient size, and
- extremely high liver fat content, and
- strong breathing artifact

GETTING ACCESS TO HEPA FAT-AI

There are two ways to access HepaFat-AI, via the Resonance Health Web portal and via partner software platforms.

PARTNER SOFTWARE PLATFORMS

HepaFat-AI is deployed bundled together with partner software platforms. End users will not need to install or configure HepaFat AI directly. Resonance Health and your platform provider will enable and configure HepaFat-AI for you. Typically HepaFat-AI will be deployed as a SAS (Software as a Service) within your software providers' platform. Specific instructions on how to request access to HepaFat-AI will depend on your provider and in some cases your software provider may require a commercial agreement to be signed with Resonance Health before setting up access to HepaFat-AI.

Once your software provider has configured your access to HepaFat-AI you will need to acquire HepaFat-AI data per the specification in this document and have the DICOM data stored in your PACS. Your software provider is responsible for running HepaFat-AI on each relevant HepaFat-AI data. This can be done on demand via an end user request or automatically, depending on your provider's software.

Resonance Health provides second line support via your software provider for please contact your software provider with any issues or questions.

RESONANCE HEALTH WEB PORTAL

If you are accessing HepaFat-AI via the Resonance Health Web Portal then your software provider is Resonance Health and access to HepaFat-AI is via a web browser rather than via PACS integration. Your institution will require site, super user and user configuration to be performed. This is done by contacting Resonance Health directly. Once you have been issued login credentials you will have the ability to login, manage your site's users, upload dicom data, run HepaFat-AI and download or view the resulting reports in the browser. The Resonance Health Web Portal has a FAQ and a support ticketing system for requesting support or asking questions.

HEPAFAT-AI CYBERSECURITY CONTROLS FOR INTENDED USE ENVIRONMENTS

HepaFat-AI is not a computer system; hence the Hosting Software and associated Computer Environment must mitigate the majority of the cybersecurity risks. To support deployment through other platforms, RHAS has prescribed the below mandatory requirements for ensuring secure and correct interfacing of any Hosting Software with HepaFat-AI, which must be followed by anyone implementing HepaFat-AI. Additionally, further guidelines for Hosting Software and Computer Environments managed by other organisations are recommended below.

Mandatory Guidelines

- HepaFat-AI must be given access to the local file system to facilitate file exchange between the Hosting Software and HepaFat-AI. Specifically, HepaFat-AI requires access to two temporary folders – input and output.

- The Hosting Software must ensure that:
  - HepaFat-AI is only called on-demand (only when an end-user requests an analysis);
  - the input folder contains only one DICOM study when HepaFat-AI is initialised;
  - there are at least one CPU core and 2 Gigabytes of free memory available when HepaFat-AI is called; and
  - both the input and output folders are re-initialised or deleted once HepaFat-AI has finished its run.

- The Hosting Software must retain logs / StdOut files generated from running HepaFat-AI.

Recommended Guidelines

Hosting Software and Computer Environments are recommended to include the following or similar controls as well:

- **Network Security**: To protect local network from intrusion, only allow inbound connections if they have an internet-facing firewall and supporting security settings.

- **User Management:** Implement
  - Two-factor authentication for account setup
  - IP whitelisting for privileged accounts
  - Centralised addition, modification and removal of users
  - Login and logout events recording
  - Auto (timed) logout

- **Scaling:** To maintain service availability, ensure that additional computing resources are available and set up to automatically kick in when HepaFat-AI is in large demand

- **Data Security:**
  - To ensure communication confidentiality and integrity, configure HTTPS / TLS 1.3 such that data transferred between end-users and the Hosting Software is encrypted
  - Ensure that all persisted data is encrypted using AES-256 or equivalent

- **Antivirus:** Regularly run antivirus software on servers in compute environments.

PRODUCT INFORMATION

HepaFat-AI Software Version		
Version	Release	Comments
V0.1.4	28-Feb-2020	First version released
V0.1.12	12-May-2021	Data management process improvements, output reporting format to 1 decimal place, improvements to IQC processes.
V0.2.2	05 Nov 2021	Updated version
V0.2.3	28 Jan 2022	Minor updated for cloud deployment.

Instruction Manual Revision History			
Revision	Qualio Version	Date	Description of Change
0		17 Feb 2021	New Document
1		14 May 2021	Updated Document process improvements and report formating
2		18 Feb 2022	Reviewed and updated for minor changes required in the development of LiverSmart. Sample report image updated, clarification of the test scan process using saline bag. Updated the protocol table to better clarify the FOV choice and imaging position. Re-phrashed some situations of possible anomalous readings and warning information.
NA	1.0	04 Jul 2022	Further instruction added to protocol table regarding position of FOV in relation to patient size and lung crest, reposition/ format result interpretation warning message in Navigation of report section to emphasie the importance of this information. Updated requirements for GE scanner sequence settings. Highlight warning message
NA	2.0	11 Jul 2022	Correct date in revision table, add PDF copy of document to Qualio

Manufacturer	EU Representative
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CE

ARTG: 223853
510(k): K201039

APPENDIX A – FREQUENTLY ASKED QUESTIONS

HepaFat-AI

What is HepaFat-AI?

HepaFat-AI is a non-invasive MRI-based technique designed to automatically analyse MRI datasets to generate an estimate of the patient's volumetric liver fat fraction (VLFF).

HepaFat-AI images can be acquired on a 1.5T or 3T scanner using a multi-echo gradient echo breath-hold sequence with specific image acquisition parameters.

HepaFat-AI is a prescription only medical device (Rx Only) and is indicated to:

- Assess the volumetric liver fat fraction, proton density fat fraction and steatosis grade in individuals with confirmed or suspected fatty liver disease;
- Monitor liver fat content in patients undergoing weight loss management;
- Aid in the assessment and screening of living donors for liver transplant.

HepaFat-AI is a fully automated analysis service that uses AI (Artificial Intelligence) for image analysis.

It comprises:

- A specific MRI data acquisition protocol designed for 1.5T and 3T MRI scanners. No invasive procedures are required, and no contrast agent is administered.
- An AI analysis tool which analyses the images and returns a VLFF, PDFF, and steatosis result.

Who is Resonance Health?

Resonance Health is an Australian-based medical device company (www.resonancehealth.com) specialised in the development and commercialisation of MRI-based non-invasive analysis tools.

Resonance Health has been established since 2003 and is certified to the international quality standard ISO 13485 to ensure the company consistently meets customer and regulatory requirements applicable specifically to medical devices.

How does HepaFat-AI work?

HepaFat-AI is based on the Dixon principle of measuring the in-phase and out-of-phase MRI signal in liver tissue. Measurements are achieved through the acquisition of a series of spoiled gradient recalled echo images at three specific echo times.

The series of images is then automatically analysed by the AI tool which produces a VLFF value within the liver. This VLFF value is then used to yield a PDFF value using a calibration curve that has been determined through the measurement of liver VLFF and PDFF in 50 human subjects. The VLFF value is also used to generate a Steatosis Grade based on the direct comparison of VLFF measurements and NASH-CRN grading of liver steatosis by needle biopsy in 59 human subjects.[1]

Finally, a result report is produced to be viewed on-screen or downloaded as a pdf report.

The process from data upload to report generation takes under 60 seconds for completion.

HepaFat-AI has been through extensive validation to ensure results are accurate and reproducible. The HepaFat-AI tool is considered a medical software (see section *Is HepaFat-AI approved by any regulatory authorities?*).

HepaFat-AI Diagnostic Results

VLFF threshold	Clinical relevance	Positive percent agreement (95% CI) (%)	Negative percent agreement (95% CI) (%)
4.1 %	• 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.	95 (90 – 98)	95 (90 – 98)
12.1 %	• Boundary between grade 1 (5-33%) and grade 2 (33-66%) steatosis by histological inspection.	94 (87 – 98)	96 (93 – 99)
16.2 %	• Boundary between grade 2 (33-66%) and grade 3 (> 66%) steatosis by histological inspection.	90 (79 – 96)	97 (94 – 99)

Positive and negative percent agreement of HepaFat-AI for predicting HepaFat-Scan VLFF values above selected clinically relevant thresholds.

Do we need any new software or hardware?

No. HepaFat-AI can be set up on most 1.5 Tesla and 3 Tesla MRI scanners (Philips, Siemens or GE). There is no requirement for you to purchase any additional hardware or software.

My patient files are taking too long to upload, what can I do?

Unfortunately, poor upload speeds are typically related to your local internet conditions and therefore outside of Resonance Health's control.

To reduce the strain on your upload speeds, it is recommended that you reduce the size of your image files by zipping the images into a compressed ZIP folder and/or by removing unnecessary image and data files.

Can I upload several patient jobs at the same time?

HepaFat-AI only allows zipped files to contain information from one patient. Please make sure that each patient's images are separated into their own ZIP folder prior to HepaFat-AI analysis. There should be only 9 (nine) HepaFat-AI images in the zip file. Please remove any extra files or folders not required for HepaFat-AI analysis (e.g. localiser images) before creating the zip file.

What are the format of images supported?

HepaFat-AI image files need to be in the DICOM 3 format and acquired using the HepaFat-AI protocol.

Supported archive file types accepted include; .tar, .gz, .7z (7 Zip) and .zip.

Is HepaFat-AI approved by any Regulatory Authorities?

Yes – HepaFat-AI was cleared by the FDA in December 2020 with TGA clearance and CE marking coming in February 2021.

Our MRI scanner has gone through major software upgrades, is this an issue for HepaFat-AI?

We recommend that you notify Resonance Health if any of your MRI scanners have recently gone through significant software or hardware upgrades, significant changes include operating system upgrades and/or gradient system changes.

The Resonance Health Service Centre team will then be able to monitor your HepaFat-AI data for several subsequent patient scans for any anomalies and assist you in any corrections required. This may result in a test subject needing to be scanned again to confirm verification.

Please contact support at help@resonancehealth.com if you have any concerns or wish to notify Resonance Health of any significant upgrades that have taken place at your site.

We already have one scanner approved for HepaFat-AI, how I can add a new scanner?

Any patient or test job lodged through your account will automatically alert Resonance Health if the scanner isn't on the approved scanner list.

If you want to add a new scanner then just scan a test subject with the new scanner like the one approved already and submit the test image data as you would any patient for your new scanner to be verified. If the verification is successful, you will be informed the new scanner has been added and is ready for patient scan.

The patient name on the report is not correct and/or appears with a ^ in its formatting, can I edit this on the report?

All information generated on the HepaFat-AI patient report is obtained via the DICOM header information and cannot be edited. This is to maintain integrity in the data content.

Please ensure that all spelling and information provided during patient registration on the scanner is accurate before processing as this may not be editable after analysis occurs.

APPENDIX B - UNDERSTANDING ERROR CODE MESSAGES

Error #	Display Message	Meaning	Troubleshooting
001	*Expected echo time (TE) Missing: X. This batch has: Y* **or** *An incorrect number of TE has been uploaded: 3 required, Y supplied. This batch has TE values [Y]*	HepaFat-AI requires 3 echoes with TE values of 2.38, 4.76, and 7.14 ms at 1.5T and 1.19, 2.38, and 3.57 ms at 3T.	• Check that you have acquired images with the correct echo times. • Check that you have submitted all 3 echo series. • Check that none of the images have been corrupted (this can be done by checking that the images can be viewed with a DICOM viewer) • Re-acquire and resubmit the data if necessary
002	*Repetition time (TR) is not 88 ms. This batch has: X*	HepaFat-AI has detected a repetition time TR that is not 88 ms for all images. HepaFat-AI requires that all data are acquired with a repetition time of 88 ms .	• Check the TR that has been used to acquire the data • Re-acquire the data with a TR of 88 ms • Submit the newly acquired data
003	*Repetition time is not the same for all images. This batch has: X*	HepaFat-AI has detected a repetition time TR that is not 88 ms for some images. HepaFat-AI requires that all data are acquired with a repetition time of 88 ms .	• Check that TR is 88 ms for all 3 echo series • If necessary, re-acquire the data with a TR of 88 ms • Resubmit the newly acquired data
004	*Flip angle is not 70 degrees. This batch has: X*	HepaFat-AI has detected that the flip angle is not 70 degrees in some or all of the images. HepaFat-AI requires the flip angle to be 70 degrees for all images.	• Check the flip angle in each echo time series • Re-acquire the data with a flip angle of 70 if necessary • Submit the newly acquired data
005	*Flip angle is not the same for all images. This batch has: X*	HepaFat-AI has detected that the flip angle is not 70 in some or all of the images. HepaFat-AI requires the flip angle to be 70 for all images.	• Check the flip angle in each echo time series • Re-acquire the data with a flip angle of 70 if necessary • Submit the newly acquired data
006	*Magnetic field strength must be 1.5 / 15000 or 3.0 / 30000.*	HepaFat-AI has detected that your scanner is not 1.5 or 3T. HepaFat-AI	• Re-acquire data on a 1.5 T or 3T scanner

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	This batch has: X	requires a 1.5 or 3T magnetic field strength scanner. Data acquired from scanners with magnetic field strengths different from 1.5 or 3T will generate erroneous results.	
007	*More than one value of magnetic field strength. This batch has: X*	HepaFat-AI has detected data acquired with different magnetic field strengths. The most likely cause for this error message is that data from different scanners have been mixed together. HepaFat-AI requires data from 1.5 or 3T scanners.	• Ensure data from a single scanner are submitted
008	*Slice thickness must be at least 3mm (Target 4 mm). This batch has: X*	HepaFat-AI has detected that some images have a slice thickness that is less than 3 mm. HepaFat-AI requires that all slices from all echo time series have slice thickness at least 3 mm.	• Check to see which images have an incorrect slice thickness • Re-acquire the data making sure that all images have a slice thickness at least 3 mm. • Submit the newly acquired data
009	*The slice thickness in each TE is not the same. This batch has: X*	HepaFat-AI has detected that not all images in the dataset have the same slice thickness. HepaFat-AI requires that all images have the same slice thickness.	• Check that all echo series are acquired with the same slice thickness • Check that the slice thickness is least 3 mm • Re-acquire the data ensuring all series are acquired with the same slice thickness • Submit the newly acquired data
010	*Spacing between slice centres is less than 150% of the slice thickness (Target 6mm). This batch has: X*	HepaFat-AI has detected that some images have a spacing between slice centres less than 6 mm or 150% of the slice thickness.	• Check that the center to center slice spacing is at least 6 mm or 150% of the slice thickness. • Re-acquire the data ensuring all series are acquired with the correct slice gap • Submit the newly acquired data
011	*Spacing between slice centres is not the same. This batch has:*	HepaFat-AI has detected that not all images in the dataset have the same slice	• Check that all echo series are acquired with the same slice spacing • Re-acquire the data ensuring all series are acquired with the same

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	X	spacing. HepaFat-AI requires that all images have the same slice spacing.	slice thickness • Submit the newly acquired data
012	*The slice location for each TE is not the same. This batch has: X*	HepaFat-AI has detected that the slice location across the TE's is not consistent. E.g. TE1 (55.93, 49.93, 43.93) has different slice locations compared to TE2 (48.12, 42.12, 36.12) and TE3 (48.12, 42.12, 36.12).	• Check that the location of each slice is the same for each TE series. • Re-acquire the data ensuring all series are acquired with the same slice locations. Do not move table between TE series. • Submit the newly acquired data
013	*Incorrect data acquisition method. Please contact Resonance Health for further information.*	HepaFat-AI has detected that the image data have been acquired using an incorrect method (E.g. SE instead of GR). HepaFat-AI requires that images are acquired with spoiled gradient pulse recalled echoes.	• Please contact for further advice
014	*More than one data acquisition method used. This batch has Scanning Sequence values:*	HepaFat-AI has detected that some images have been acquired with different scanning sequences between TEs. Scanning sequences should be consistent between TEs.	• Please contact for further advice
015	*More than one data acquisition method used. This batch has Scan Options values:*	HepaFat-AI has detected that some images have been acquired with different scan options between TEs. Scan options should be consistent between TEs.	• Please contact for further advice
016	*Pixel spacing is not consistent across all images acquired. This batch has: X*	HepaFat-AI has detected that the pixel spacing is not the same for all images. HepaFat-AI requires that the pixel spacing is the same for all images.	• Check that the field of view is the same for all echo series • Check that the image matrix size is the same for all echo series • Check that the pixel size is the same for all echo series • Re-acquire the data ensuring that field of view, matrix size, pixel size are the same for all echo series

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			• Submit the newly acquired data
017	*The number of rows of pixels is not uniform across all images. This batch has: X*	HepaFat-AI has detected that the number of rows of pixels is not the same for all images acquired. HepaFat-AI requires that all images submitted have the same number of rows of pixels.	• Check that the matrix size and phase field of view are the same for all echo series • Re-acquire the data making sure that all echo series have the same matrix size and phase field of view • Submit the newly acquired data
018	*The number of columns of pixels is not uniform across all images. This batch has: X*	HepaFat-AI has detected that the number of columns of pixels is not the same for all images submitted. HepaFat-AI requires that every image submitted has the same number of columns of pixels.	• Check that the image matrix size is the same for all echo series. • Re-acquire the data making sure that all echo series have the same matrix size • Submit the newly acquired data
019	*More than one patient ID has been detected in this image set. This batch has: X*	HepaFat-AI has detected that the images submitted contain data from more than one patient or subject. HepaFat-AI will only accept data from one patient at a time.	• Check that you have not inadvertently submitted datasets from two or more patients simultaneously • Remove any excess image data to ensure that data from only a single patient is submitted • Resubmit the data
020	*An insufficient number of images has been uploaded: 9 required, x supplied.*	HepaFat-AI has detected that an insufficient number of images has been submitted. HepaFat-AI requires 3 gradient echo series with each series having 3 slices. As such, HepaFat-AI expects 9 images.	• Check that you have included all of the data that you acquired • Check that 3 slices were acquired for each echo series • Check that 3 echo times were acquired
021	*More than one patient dataset has been uploaded.*	HepaFat-AI has detected that the images submitted contain data from more than one patient or subject. HepaFat-AI will only accept data from one patient at a time.	• Check that you have not inadvertently submitted datasets from two or more patients simultaneously • Remove any excess image data to ensure that data from only a single patient are submitted • Resubmit the data

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022	*No valid DICOM files have been uploaded*	HepaFat-AI has detected that images submitted are not in the DICOM 3 format. Supported format are DICOM3, and could be zipped with the following file type .tar .gz .7z and .zip	• Check that the images submitted are in DICOM format • Check you have not inadvertently submitted other type of images.
023	*Bandwidth must be approximately 500 Hz/pixel at 1.5T or 1000 Hz/pixel at 3T. This batch has bandwidth: X and magnetic field strength: Y.*	HepaFat-AI will only accept a bandwidth close to 500 *Hz/pixel at 1.5T or 1000 Hz/pixel at 3T.*	• Check that bandwidth has been set correctly
024	*Bandwidth is not the same for all echo times. This batch has: X*	HepaFat-AI will only accept a consistent bandwidth value of 500 *Hz/pixel at 1.5T or 1000 Hz/pixel at 3T.*	• Check that bandwidth values are consistent across all echo times.
025	*The number of slices for each TE is not the same: Each TE requires exactly 3 slices. This batch has number of slices: X*	HepaFat-AI has detected that although 3 gradient echo time series have been submitted as required, the number of images in each gradient echo time series is not 3. HepaFat-AI requires 3 gradient echo time series with each series having exactly 3 slices.	• Check that only three slices were acquired for each TE.
026	*We found data from more than one MRI Scanner. This batch has: X*	HepaFat-AI has detected that not all images in the dataset have the same MRI Scanner (i.e. Manufacturer). HepaFat-AI requires that all images are acquired with the same MRI Scanner.	• Check that you have not inadvertently submitted datasets from two different scanners simultaneously
027	*Assessment of Liver Fat failed due to unknown error. Please contact support.*	The assessment algorithm for liver fat has failed to produce results for unknown reasons.	• Please contact for further advice