Hepatica Medical Device Patient Acquisition Manual for GE

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August, 2021

Use and Limitation

This Manual is intended to be used as a reference guide for the acquisition of images using either a GE 1.5T or 3T MRI system with CardioMaps. Perspectum shall not be held liable for improper installation, operation, or maintenance of the system in circumstances where procedures and specifications set out in this Manual have not been followed correctly. It is essential therefore, that you follow the specifications, procedures, and recommendations outlined in this Manual.

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1. Glossary

Term	Description
A-P	Anterior-Posterior
ARRT	The American Registry of Radiologic Technologists
B0	Main magnetic field
CE	Continuing Education
DICOM	Digital Imaging and Communications in Medicine
DOB	Date Of Birth
ECG	ElectroCardioGram
F-H	Feet-Head
FFE	Fast Field Echo
GRE	Gradient Recalled Echo
IDEAL	Iterative Decomposition of water and fat with Echo Asymmetry and Least-squares estimation
ID	Identifier
LAVA	Liver Acquisition with Volume Acceleration
LMS	LiverMultiScan
MOLLI	Modified Look Locker Inversion Recovery
MOST	Magnitude Only thin-Slice T2*
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
PACS	Picture Archiving and Communication System
PG	Peripheral Gating
PII	Personally identifiable Information
PPU	Peripheral Pulse Unit
R-L	Right-Left
RF	Radio Frequency
RIS	Radiology Information System
S-I	Superior-Inferior
SAR	Specific Absorption Rate
SCIC	Surface Coil Intensity Correction
SNR	Signal-to-Noise Ratio
SSFP	Steady State Free Precession
dB/dt	Time varying gradient

2. Introduction

2.1. Scope

This manual is intended to describe the correct procedure to perform the Perspectum set up protocol to an *MR* operator on GE scanners. Please use this document as a reference guide when performing the protocol acquisitions. The manual is divided in three main sections: Preparation, Acquisition and Data Export.

2.2. Continuing Education

In some territories, such as the USA, this training is eligible for continuing education (*CE*) credit. The *CE* is sponsored by Perspectum and will be presented by a member of the Imaging Applications team. The presenter's name, date, and attendees will be written on the Imaging Staff Training Checklist at the time of training; this form will be kept in Perspectum's records of site training activities and an electronic copy will also be sent to the site. In order to qualify for *CE*, the document, Multiparametric Liver MRI Applications Training – MRA1157, should also be provided along with the training. This document includes post-activity evaluations that must be completed to award credit.

2.3. Compatibility and Requirements

All sequences described in this manual require scanner hardware and software to be compliant with all manufacturer's specifications, especially gradient performance, eddy current compensation, and magnetic field (*B0*) homogeneity and stability. The protocols cannot be utilized on scanners outside of the manufacturer's service specifications and calibration schedules. Do not use phased-array coils with failed elements or without *SNR* checks passed.

2.3.1. Volume requirement

The system should have *3D* T1 LAVA sequences available. This will allow a three-dimensional spoiled gradient echo pulse sequence. A multi-echo variant of this sequence with a water-fat separation *3D* T1 Flex LAVA is preferred. The latter allows acquiring in-phase and out-of-phase images in one single acquisition, to calculate water-only and fat-only images.

2.3.2. T1 Mapping Requirement

T1 mapping protocols require the manufacturer's clinically approved software product CardioMaps.

2.3.3. T_2^* and Proton Density Fat Fraction Mapping Requirement

The system should also have the Multi-Echo Fast Gradient-Echo package available. This package is offered as a product on most GE scanners without the need of additional license.

2.4. References

Hepatica Supported MR Systems – PDM0384

Image Acquisition Protocols - MRA0671

3. Preparation

3.1. Patient Registration

> ⚠ **CAUTION**
> Ensure the subject is registered to a new *MR* study.

The minimum required information for registering the patient is as follows:

- Patient *ID*: <Use agreed Subject ID Naming Scheme>
- Patient Name: <Use Agreed Subject Naming Scheme>
- Date of birth (*DOB*): <Use agreed DOB Scheme>
- Operator: Enter Your Initials
- The patient's height (when available), weight and sex

Date of Birth (*DOB*) Scheme: If *PII* is allowed, the patient's date of birth *DOB* may be used. Otherwise, **please use 01-Jan, and the correct YEAR of birth.**

Please note that the MRI technician/radiographer who performs patient acquisition must have undergone training by either:

- (a) Authorised Perspectum Imaging Applications specialists
- (b) Previously trained site personnel authorised to perform internal training

A record of such internal training must be provided to Perspectum with the appropriate Imaging Staff Training Checklist.

3.2. Breath-hold Instructions

Breath-holding should be explained and practised when required because variations in the depth of a subject's breathing can markedly alter the image quality and the consistency of the abdomen position between acquisitions. End-expiration breath-hold is chosen because breathing out is a more repeatable process. This should be explained to the patient: 'The scans are better if you hold your breath after breathing out comfortably.' The following instructions should be given to the patient ahead of each scan:

- Breathe in.
- Breathe out.
- Stop and hold your breath there.
- Breathe away or Resume breathing (after data has been acquired).

3.3. Patient preparation

LMS requires end-expiration breath-hold and requires phased-array receiver coils.

LMS requires cardiac gating, end-expiration breath-hold and phased-array receiver coils.

Please prepare the patient following these steps:

1. Explain and demonstrate the breath-hold instructions as above.
2. Position the patient in the supine position.
3. Set up cardiac trace input (gating or simulator) and check the signal has clear R-wave triggering.
4. Select the correct trigger source in the Gating Window.
5. Patient arms can be positioned at the sides, though above the head is acceptable if subject does not easily fit into bore.
6. Use the spine array and the torso/body phased-array coil.
7. Scanner laser should be landmarked on the xiphisternum of the patient.

3.4. Cardiac Trace Input

Some pulse sequences require cardiac triggering/gating. This input can be from either the patient or a cardiac trace simulator. Both methods are outlined below.

3.4.1. Cardiac Trace Simulator

Note that the *ECG* simulator only runs if the system has SimulatePac.

If a 60bpm trace cannot be set as shown at the following instructions, please use the standard cardiac gating (ECG or PG leads) to obtain cardiac trace input.

Method 1:

1. Go to "Service Desktop Manager" and click on "C-shell".
2. In the "xterm" box type **`mgd_termc`** and **Enter**.
   If nothing happens, please go to the **Method 3, point 2**.
3. Two new windows/terminals will appear. In the SCP windows/terminal, press **Enter** (a sign **"->"** will appear).
   If it pops up just 1 window called ICE terminal, please go to the **Method 2**, **point 3**.
4. In the SCP window/terminal type **`EmulatePac`** and press **Enter**.
5. In the AGP window/terminal, type **`sendPPGBPMUpdate 60`**. (in the case of selecting the "VCG gating")
   If you select the "PG gating", the command will be **`sendPPGBPMUpdate 60`**. If it gives an error, unluckily it's not possible to select 60bpm.

> **TIP**
> If only one window/terminal pops up, please go to **Method 2, point 4**.

Method 2:

1. Go to "Service Desktop Manager" and click on "C-shell".

2. In the "xterm" box type **`mgd_termc`** and press **Enter**.
3. A new window/terminal called "ICE Terminal" will appear. In this window/terminal, press **Enter**
4. Type **`EmulatePac`** and press **Enter**
5. Return to the xterm and type **`rlogin agp`** and press **Enter**.
6. Type **`agp`** and press **Enter**.
7. Type the password: **`agpservice`** and press **Enter** (the password may not be visualized while typing).
8. Type **`updateECGBPM 60`** and press **Enter**.

Method 3:

1. Go to "Service Desktop Manager" and click on "C-shell".
2. In the "xterm" box type **`rlogin scp`** and press **Enter**.
3. As login, type **`scp`**and press **Enter**.
4. As password, type **`scpservice`** and press **Enter** (letters may not be visualised while typing).
5. Type **`EmulatePac`** and press **Enter**.
6. Type **`exit`** and return to the xterm and type **`rlogin agp`** and press **Enter**.
7. As login, type **`agp`** and press **Enter**.As password, type **`agpservice`** and press **Enter** (letters may not be visualised while typing).
8. Type **`updateECGBPM 60`** and press **Enter** (in the case of selecting the "*VCG* gating")
   If you select the PG gating, the command will be **`updatePPGBPM 60`**.

If 60bpm cannot be selected, please use standard cardiac gating (*PG* or ECG leads) to obtain cardiac trace input. Once the simulator required scan is completed, the ECG simulator can be turned off by "TPS Reset".

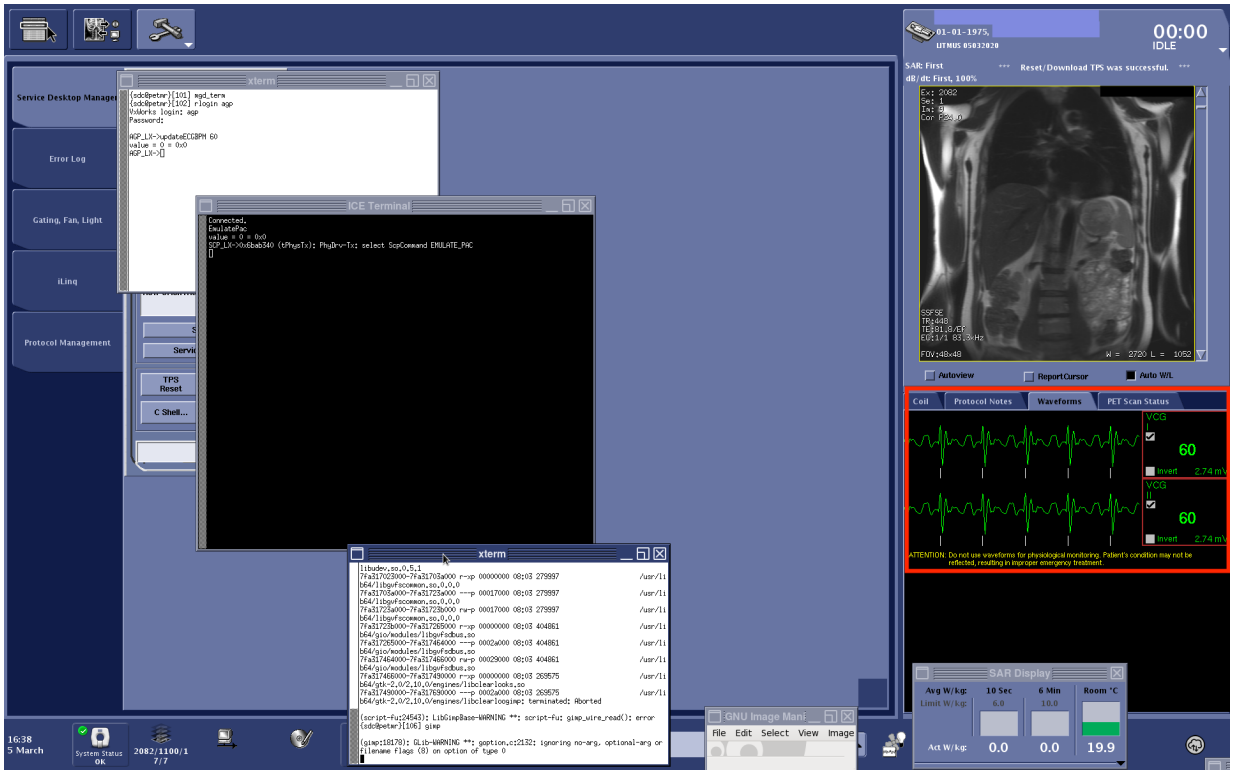

Figure 1. The simulated heartbeat is highlighted with a red box.

3.4.2. Cardiac Gating

1. Use *ECG* or pulse oximeter to set up the patient's cardiac gating.
2. select the correct trigger source in the gating window (physiology monitoring window) and confirm the signal has clear R-wave.

If a pulse oximeter is used, please ensure *PG* trigger is selected in the trigger window (see Figure 2 (page 6)) for LMS sequences.

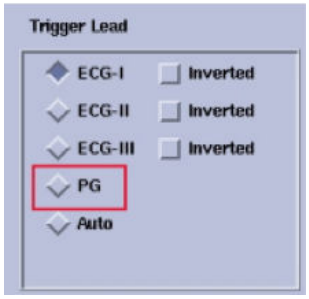

Figure 2. Trigger window, “PG” is preferable to ECG leads for LMS studies if not using cardiac trace simulator.

4. Acquisition

Please note that:

1. All protocols must be acquired before any contrast agent injection. Note that contrast agents are not necessary for any of the acquisitions.
2. All scans are performed during end-expiration breath-hold, including the Localizer scan.

CAUTION

All protocols must be run in first level *SAR* and *dB/dt* mode. Running *LMS MOLLI* in normal mode will change the timing parameters and will result in unusable data.

CAUTION

Protocol parameters should not be changed. Any changes not specifically covered in these instructions risk corrupting the resultant parameters and cause data rejection by Perspectum Ltd.

IMPORTANT

On GE scanners, the *TE*/*TR* autoset values (Min or Min Full) may get changed unintentionally due to coil selection changes. Please take note of the default autoset values before changing coil selection and make sure to change it back to the default autoset values as necessary.

CAUTION

Please do NOT inject any contrast agent prior to the acquisition of *LMS* protocol. This might result in erroneous parameter quantification.

4.1. Localization Protocols

4.1.1. Three-plane Localizer

A three-plane Localizer should be run at end-expiration breath-hold to produce at least one sagittal, one coronal and one transversal view of the abdomen.

> ⚠ **CAUTION**
> Check that the phased-array coil is positioned to give good *SNR* over the entire liver. Reposition the coil on the patient if necessary. Low image *SNR* adversely impacts the quality of the resulting parameter estimates.

4.1.2. Additional Localizers (optional)

Additional localizers may be run to acquire axial/transversal slices to find the right view for subsequent *LMS* slice positioning.

4.2. Volume Acquisition

LMS Volume:

This acquisition is a LAVA sequence with full coverage of the entire liver volume. This volumetric scan requires a breath-hold of approximately 15 seconds and is not cardiac-gated.

Alter the centre of the image volume so that the entire craniocaudal extent of the liver and spleen is captured. If the Flex option is available on the scanner, please make sure it is selected for this scan.

> ⚠ **WARNING**
> Position the centre of the image volume so that the entire craniocaudal (S-I) extent of the liver and spleen is captured. The number of slices can be increased to cover the entire craniocaudal extent of the liver but the slice thickness should remain the same.

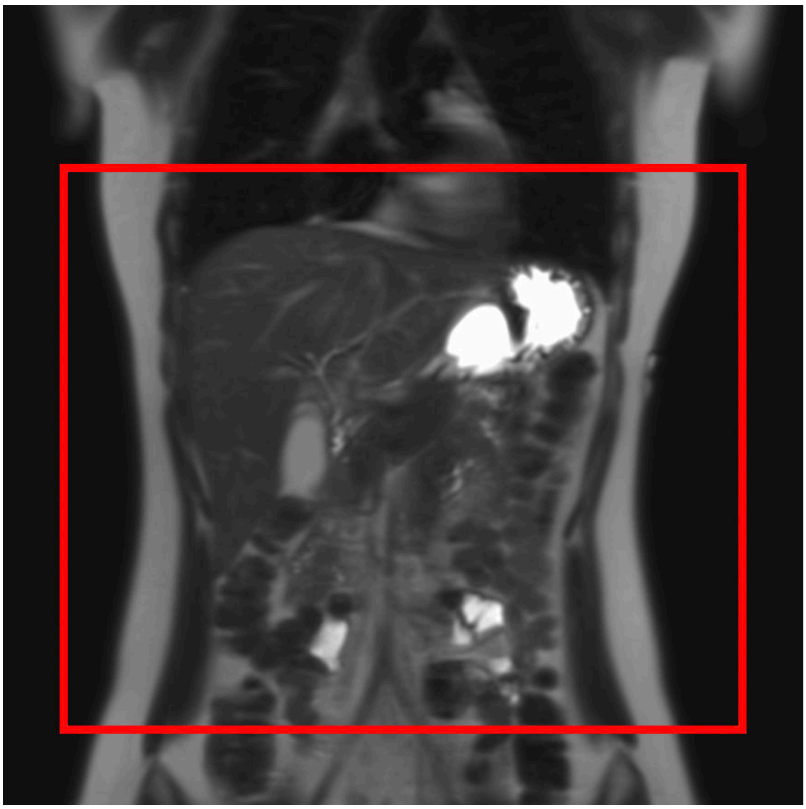

Figure 3. Example of the region which should be scanned with the LMS Volume acquisition

Motion and breathing : The LMS Volume image will need to be re-acquired if there is a motion artefact due to breathing as shown in Figure 4 (page 9).

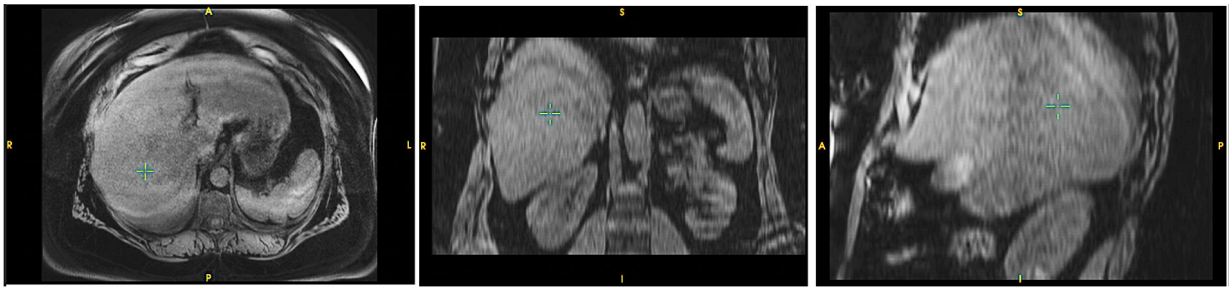

Figure 4. If the LMS Volume image shows motion artefacts due to breathing, re-acquire the image.

FOV coverage: If the acquired image doesn't cover the whole liver, as an example shown in Figure 5 (page 10), increase the number of slices and ensure the entire craniocaudal extent of the liver is covered. The slice thickness should not be changed.

Figure 5. The Dome of the liver has been excluded in the acquisition, re-acquire the image with correct FOV positioning and increase the number of slices if necessary. Do not change the slice thickness.

4.3. Liver LMS Imaging Location

4.3.1. Base Slice Positioning

This slice location will be used as the centre for the majority of the sequences. Hence it is imperative to position correctly. The base slice should be positioned such that it intersects the porta hepatis, and it should display the liver, spleen, and may also contain the stomach.

If the lungs are visible in the transverse slice, please shift the image lower on the patient's abdomen as the lungs will cause susceptibility artefacts. Please refer to the localizer images in Figure 6 (page 10) for positioning of the transverse slice.

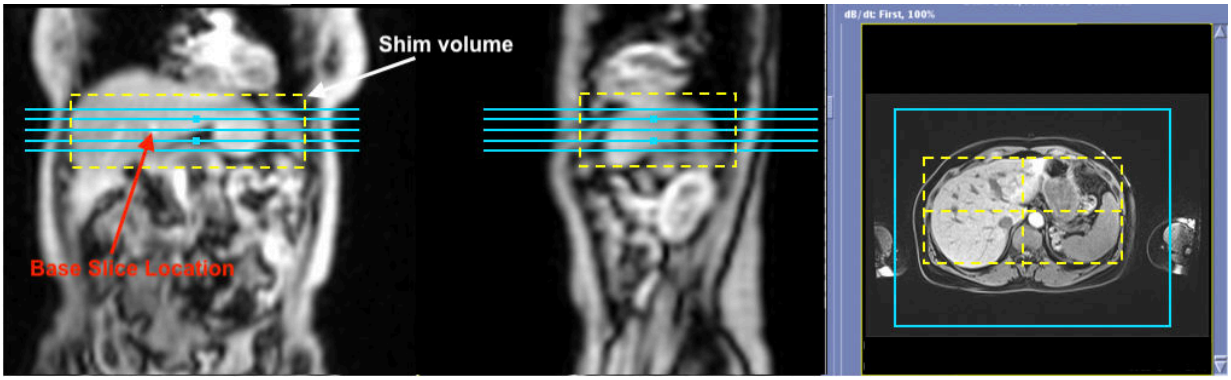

Figure 6. Three-plane Localizer view of the abdomen in coronal, sagittal, and transversal (axial) plane. The base slice location for LMS protocol is indicated in blue and the shim volume in yellow.

4.3.2. Shimming

The shim volume should be centred as shown in Figure 6 (page 10) . The *F-H* direction should cover the entire stack of slices and should be remained as in the protocol. In the *R-L* and *A-P* directions, the shim volume can be adapted until the liver is fully covered, excluding as much air as possible. Please also exclude the subcutaneous fat in obese patients.

⚠ **CAUTION**

Shim adjustments other than those described in this manual may corrupt the parameter mapping.

⚠ **CAUTION**

Susceptibility Artefacts

Magnetic susceptibility artefacts appear due to: poor shim, proximity to the lungs, bowel gas or metallic implants. Susceptibility artefacts in the liver will preclude accurate parameter estimation in the areas affected as shown in Figure 7 (page 11).

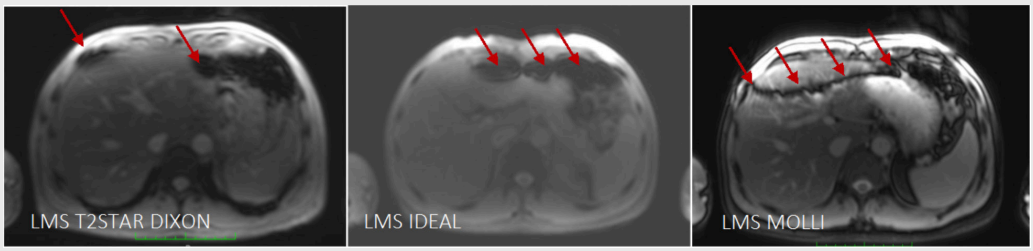

Figure 7. Susceptibility artefacts will appear as dark, distorted areas, in LMS MOLLI it also can appear as a banding artefact.

To mitigate susceptibility artefacts:

1. Ensure the centre of the multi-slice is at isocentre and make sure the shim volume is positioned as shown in Figure 6 (page 10).

2. Force a re-shim by :

Details tab > Shim > change to “On” from “Auto” > Run the sequence

3. Re-acquire the data.

4.4. Liver LMS IDEAL

This is a 5-slice multi-echo sequence performed at end-expiration breath-hold. The breath-hold lasts approximately 9 seconds. This sequence will be used to generate a PDFF map of the liver.

1. Prescribe the slice stack so that the 3rd slice (middle slice) intersects the porta hepatis.

2. The shim volume should be centered as the slice stack and the R-L and A-P directions can be adapted to ensure the entire abdomen is included in the transverse view and the liver and the spleen are completely covered as shown in Figure 6 (page 10) .

3. The (F>>H) shim volume thickness should be manually adjusted to '90mm'.

4.5. Liver LMS MOST

This is a multi-slice multi-echo gradient-echo sequence performed at end-expiration breath-hold. The breath-hold lasts approximately 11 seconds. This sequence will be used to generate a T2* map of the liver.

1. Link the centre of the slice and the shim volume to the LMS *IDEAL* series selecting only "scan coverage" (unticking all other boxes below it) and "shim volume" marked as ticked.
2. Change the shim box's *F-H* direction to 6cm. If the number of slices change please go back to 7 slices (1.5 T) or 12 slices (3 T). The *F-H* direction should cover the entire stack of slices and should be left as set in the protocol.
3. In the *R-L* and *A-P* directions, the shim volume can be adapted until the liver is fully covered. Please exclude the subcutaneous fat in obese patients.

4.6. Liver LMS T2STAR DIXON

This is a single-slice multi-echo gradient-echo sequence performed at end-expiration breath-hold. The breath-hold lasts approximately 10 seconds. This sequence will be used to generate a T2* map of the liver.

1. Link the centre of the slice and the shim volume to the *LMS MOST* series selecting only "scan coverage" (unticking all other boxes below it) and "shim volume" marked as ticked.
2. If the number of slices change please go back to 1 slice.
3. The shim in the *F-H* direction should cover the entire slice thickness and should be left as set in the protocol. In the *R-L* and *A-P* directions, the shim volume can be adapted until the liver is fully covered. Please exclude the subcutaneous fat in obese patients.

4.7. Liver LMS MOLLI

This is a multi-slice, multi-breath-hold, cardiac-gated acquisition performed at end-expiration breath-hold. This scan acquires 5 transverse slices, one slice per breath-hold. Each breath-hold lasts approximately 9-12 seconds. This sequence will be used to generate a T1 map of the liver.

After each slice has been acquired the operator will be prompted to give breathing instruction for the next slice. During the scan, it is imperative to monitor the physiological recording trace to check **no heartbeats are missed** by the system’s triggering algorithm.

1. Link the centre of the slice and the shim volume to the *IDEAL* series selecting only "scan coverage" and "shim volume" (unticking all other boxes), ensure the number of slices is 5.

2. The slice stack and shim volume should be positioned as shown in Figure 6 (page 10) .

5. Data Export

UPLOAD SINGLE COMPRESSED FILE

Please compress all sets of data for the **same** patient into **one** file and proceed with the upload.

IMPORTANT

Please follow the arrangement for personally identifiable information (*PII*) as agreed for your site, as the removal of *PII* may not be necessary for your site.

Private *DICOM* tags are special tags added by the manufacturer to describe the MRI sequence. They do NOT refer to private information, nor *PII*. Many *DICOM* anonymization tools have an option to remove all Private Tags. Do not remove Private Tags when exporting data.

CAUTION

Private *DICOM* tags must be preserved in any data export. Private *DICOM* tags are not PII tags.

These instructions cover exporting data from the GE scanner for transfer. If your site is unable to export from the scanner directly and transfers data via a *PACS* system please use the *PACS* export to save the *DICOM* images.

5.1. Saving *DICOM* Images for Transfer

To export data from the GE MRI Scanner directly, save the data from the Image browser to a location where it can be uploaded to Perspectum portal.

Exporting data to a CD, DVD, USB or external hard drive:

Please export the data with the following steps:

1. Select CD/DVD/USB from the Data Apps.
2. Select the media to be used from the drop down.
3. Click on the export button.

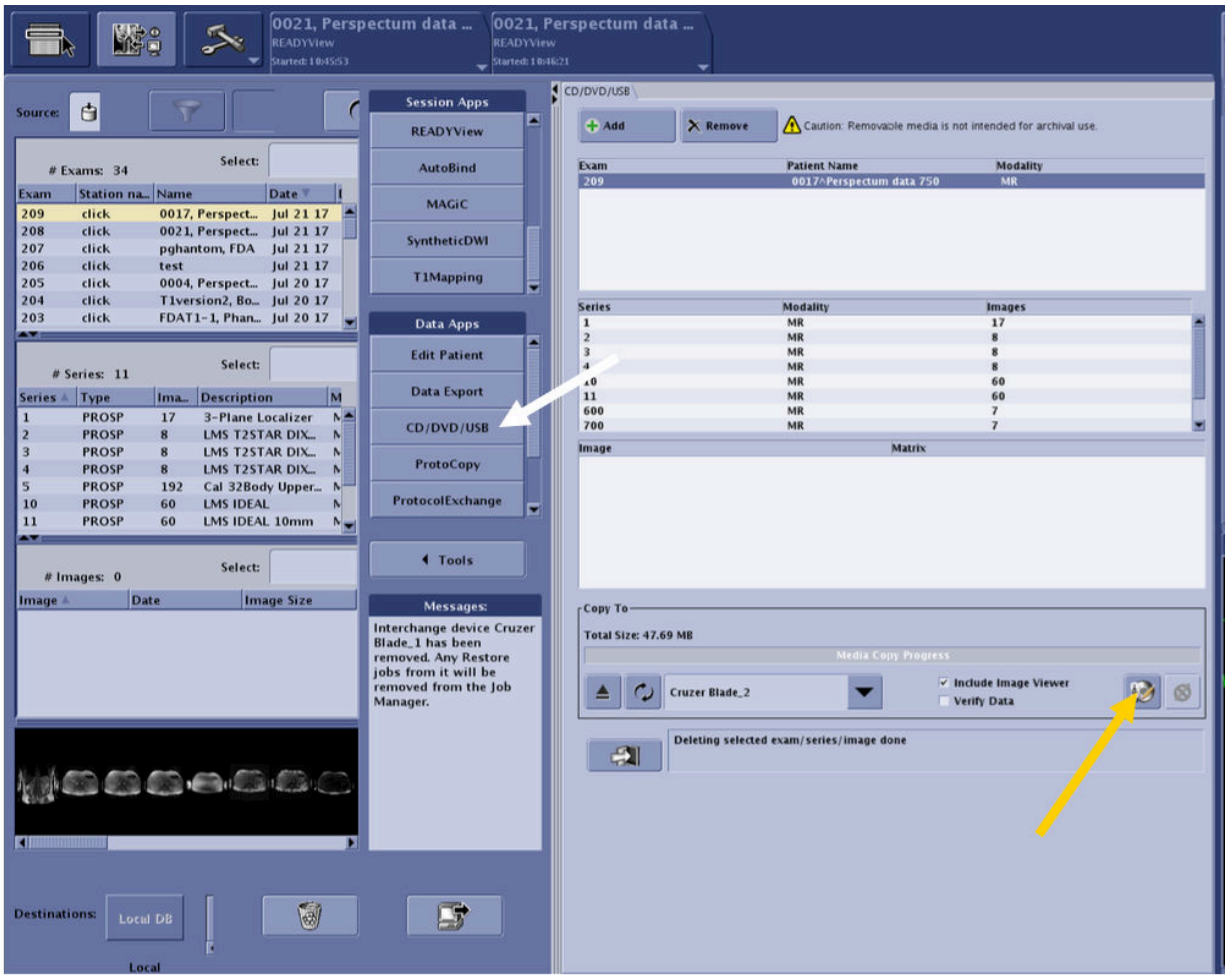

Figure 8. Exporting data. Select the data to be sent to Perspectum in the browser, then press the CD/DVD/USB button (white arrow). Press the copy button (yellow arrow) to start copying to the selected media. Please do not include the image viewer.

It is preferable to compress the folder of exported DICOMs and submit the single compressed file to the Portal.

- **On a Windows**: right click on the folder in Windows Explorer and select <Send To> and <Compress (zipped) folder>. If the folder resides on a CD or DVD, you will need to copy the folder to a location that can be saved to.
- **On a Mac**: hold Ctrl and click on the folder, then select <Compress>.

Upload the compressed file to the Perspectum Portal.

For additional instruction on using the Portal, please see the Portal Customer User Guide - PDM0077 on the Portal website.

6. Acquisition Checklist

Step	Task
Patient information	☐ Patient name: Use agreed patient naming scheme ☐ Registration ID: Use agreed patient ID naming scheme ☐ Date of birth: Use agreed scheme ☐ Correct sex, height, weight and exam date ☐ Operator: Input the initials of the operator performing the examination. ☐ Patient Position: Select the appropriate position. ☐ Leave the rest of the fields empty.
Localiser (one breath-hold)	☐ Run localiser on expiration
LMS Volume (one breath-hold)	☐ Place the FOV to cover the entire craniocaudal extent of the liver ☐ Scan the sequence at end of expiration ☐ Check image quality, if there is motion artefacts or the liver isn't fully covered, re-acquire the sequence.
LMS IDEAL (one breath-hold)	☐ Place the slice stack (5 slices) so that the middle slice (third slice) will intersect the porta hepatis. ☐ Position the shim volume centred on the slice stack. ☐ Adjust the shim volume only in R-L and A-P directions to the patient's dimensions so all of the abdomen is included in the transverse view. ☐ Scan the sequence at end of expiration. ☐ Check image quality, if there is motion artefacts please re-acquire the sequence.
LMS MOST (one breath-hold)	☐ Position the multi with the same centre of LMS IDEAL, intersecting the porta hepatis. ☐ Position the shim volume centred on the slice stack; shim volume is thicker than the slice stack. ☐ Adjust the shim volume only in R-L and A-P direction to the patient's dimensions so all of the abdomen is included in the transverse view. ☐ Scan the sequence at end of expiration. ☐ Check image quality, if there is motion artefacts please re-acquire the sequence.

Step	Task
LMS T2STAR DIXON (one breath-hold)	☐ Position the slice with with the same centre of LMS MOST, intersecting the porta hepatis. ☐ Position the shim volume centred on the slice. shim volume is thicker than the slice thickness. ☐ Adjust the shim volume only in R-L and A-P direction on the patient's dimensions so all of the abdomen is included in the transverse view. ☐ Scan the sequence at end of expiration. ☐ Check image quality, if there is motion artefacts please re-acquire the sequence.
LMS MOLLI (5 breath-holds)	☐ Position the slice stack with the same centre of LMS IDEAL. ☐ Make sure the shim volume is centred on the slice stack and adjust the shim volume only in R-L and A-P direction so all of the abdomen is included in the transverse view. Exclude subcutaneous fat as much as possible. ☐ Check image quality for each slice; are there artefacts? If so, please re-acquire the sequence.

7. Issue control

Issue	Details	Date	Initial
1.0	New document	Oct 26, 2020	FSN
2.0	Correct MOLLI slice number	Aug 19, 2021	FSN

8. Approvals

Job title	Name	Signature
Chief Operating Officer	Dr. Rexford Newbould	
Chief Technical Officer	Prof. Matthew Robson	
Chief Quality and Regulatory Compliance Officer	Dr. Jaco Jacobs	
Product Manager	Dr. Sean Pollock	