



Hepatogram *plus*⁺ **User Manual**

For Software Version 3

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Section 1 – Introduction

It is recommended that you read this instruction manual carefully before use.

Hepatogram plus⁺ is a software tool designed by Resoundant to help draw reproducible regions-of-interest (ROIs) for the stiffness measurement from Magnetic Resonance Elastography (MRE) and multi-point Dixon fat/water (F/W) images by providing preliminary automated ROIs in the liver of these images. The preliminary ROIs should be verified and, if necessary, modified by an experienced MRE reader before being used as an element for clinical care.

Please carefully read the precautions with  symbols, to ensure that the device is used in best conditions and in complete safety.

1-1 Contents

Hepatogram plus⁺ software. Configuration and available options may vary based on the service or method of installation. Options include:

- **Hepatogram plus⁺** server, which generates MRE inversion results, automated ROIs, and Summaries with images and statistics.
- **Hepatogram plus⁺** viewer, which allows review and manual editing of exams processed by **Hepatogram plus⁺** server, as well as generation of Summaries.

1-2 System Description

Hepatogram plus⁺ software is a tool for assisted MRE and multi-point F/W image analysis which calculates preliminary automated ROIs. The **Hepatogram plus⁺** viewer may be available to facilitate the review, approval, and modification of the ROIs by trained readers. All ROIs, regardless of their source –automated or manual—must be reviewed and approved by a trained reader before the stiffness reported in the summaries can be used clinically.

The inputs for **Hepatogram plus⁺** are the MRE and F/W images. In the case of MRE, this includes magnitude images (showing anatomy) and phase images. Inputs for F/W images include fat, water, fat fraction, and, optionally, R2*.

From these images, **Hepatogram plus⁺** calculates automated ROIs which must be reviewed by an authorized trained reader. For MRE data, **Hepatogram plus⁺** outputs wave images (showing wave propagation with multiple time points across the wave cycle), elasticity images and confidence images calculated by an inversion algorithm packaged with **Hepatogram plus⁺**. No secondary images are created from F/W inputs. **Hepatogram plus⁺** additionally outputs ROIs and a summary image containing calculated stiffness and/or PDFF/R2* values, all in a DICOM archive compatible format.

1-2-1 Non-diagnostic

Hepatogram plus⁺ is an automated ROI assistance and analysis tool, it is not a diagnostic tool. All outputs are intended for review by a trained reader or physician and used as an element of clinical care.

1-2-2 Users of the software

Users of the software must understand the images being analyzed to effectively determine if the automated output is acceptable or requires manual modification.

1-2-3 Input data sources

Only certain data sources—pulse sequences from specific MRI manufacturers—are supported.

Hepatogram plus⁺ only supports display and calculation from a maximum of four slices. More slices may be available in the input data, but only four will be displayed in reports and used in composite calculations of quantitative output.

1-2-4 Patient population and anatomy

The software is intended for use in patients with approximately normal liver anatomy. If tumors are present, these may need to be removed from the ROI during manual review. The MRE or PDFF exam should be of a quality that would be considered acceptable by a trained reader. The intended use does not cover images with significant artifact such as respiratory ghosting, signal dropout due to implant, or a lack of signal (no MRE waves, severe iron overload).

1-2-5 Use cases and effectiveness

In MRE analysis, 95% of cases processed by **Hepatogram plus⁺** produced results that were equivalent to expert human readers without modification.

In 2.5% of MRE cases studied, **Hepatogram plus⁺** produced automated ROIs that expert readers deemed inaccurate. These often contained non-liver tissue that, when removed from ROIs, produced stiffness measurements different by 20% or more from the automated result. For this reason, it is necessary that all ROIs are reviewed by trained readers to confirm the validity of quantitative results and, when necessary, manually modify the ROI.

In another 2.5% of MRE cases, **Hepatogram plus⁺** failed to produce sufficient ROI area to yield a result, whereas an expert reader was able to manually produce sufficient-size ROIs in the same data. When the automated system produces no ROIs or small ROIs, such that the composite ROI data is deemed too small, **Hepatogram plus⁺** will not automatically report composite stiffness value (or report the stiffness as 0). If these cases are manually approved in **Hepatogram plus⁺**, a summary will be generated with stiffness values reported for any ROI area that is greater than zero.

Though only a total of 5% of cases require manual modification, expert users have been observed to electively modify ROIs in one or more slice in 20% of all cases. These elective

modifications have a non-significant impact (less than 20% change in stiffness) on the calculated stiffness and are not necessary. Examples include when a small portion of an ROI is in non-liver tissue, or when the ROI includes non-liver tissue of similar stiffness to the liver.

In F/W analysis, **Hepatogram plus⁺** has produced optimal ROIs in >99% of cases studied. The two possible modes of failure are having an ROI include non-liver tissue which has the same fat-fraction as the liver, and having an ROI include tissue of different fat fraction. The first mode can occur in patients with low fat-fraction (<5%) if the acquired slices are prescribed too high or too low in the body to include the heart, lung, or kidneys. The inclusion of these tissues would not affect the liver PDFF in such a patient. The issue can be identified by reviewing anatomy in the water image in the **Hepatogram plus⁺** viewer, or another DICOM viewer. The second failure mode is including blood vessels, abdominal fat, or the noise in the visceral space. These structures may have a very different PDFF value than the liver, however, for that reason this failure mode would typically include only a small amount of these structures, thus only a small amount of the composite liver PDFF may be affected.

1-3 Operator Manual Information

Operator manual is available:

- Under the Help menu of **Hepatogram plus⁺**
- On the Resoundant website, www.resoundant.com
- Via email request to software-support@resoundant.com
- Via written request to:

Resoundant, Inc.
421 First Avenue SW STE 204W
Rochester, Minnesota 55902 USA

1-4 Use of Symbols

Installation and information technology professionals should understand the following symbols used for caution and warning explanations:

	Manufacturer
	Authorized Representative in the European Community
	General Warning
	eIFU Indicator

	Refer to instruction manual/booklet
MD	Medical Device
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician

Note: Other symbols used in device labeling that are NOT accompanied by adjacent text are defined in FDA recognized standard ISO 15223, latest version.

1-5 Safety

U.S. federal law restricts use of this device by or on the order of a physician.

1-5-1 System Operating Safety

There are no operator safety concerns associated with the operation of this software.

1-5-2 Patient Safety

There are no patient safety concerns associated with the operation of this software.

1-5-3 Modifications

Other than configuration settings, changes or modifications to the **Hepatogram plus⁺** software application are not permitted.

1-5-4 Reporting of Incidents

Users should contact Resoundant immediately to report an incident and/or injury to an individual, operator or maintenance employee that occurred as a result of system operation.

For reporting of incident and/or injury, contact:

Resoundant, Inc.
 421 First Avenue SW STE 204W
 Rochester, Minnesota 55902 USA
 Phone: 507.322.0011
 Email: quality@resoundant.com

If an accident occurs as a result of system operation, do not operate the application until an authorized investigation is conducted.

1-5-5 Residual Risks

Appropriate control measures have been applied to all known risks associated with **Hepatogram plus⁺**. The benefit/risk comparison is overwhelmingly favorable and

residual risks are defined to be low. Residual risks are further communicated and addressed within general warnings and cautionary statements.

1-6 Environmental Requirements

There are no environmental requirements associated with this software.

1-7 Installation and Troubleshooting

Technical support for the **Hepatogram plus⁺** application may be obtained through the following sources:

Email: software-support@resoundant.com

Please have the following information ready when contacting Resoundant:

- **Hepatogram plus⁺** version information
- Source(s) of the images (MR scanner make and model, software level)
- Detailed description of the problem experienced
- Your contact information

1-8 External Standards

ISO 13485:2016: The development and manufacturing processes associated with this product conform to the requirements of ISO 13485:2016.

1-9 Quality Assurance

Prior to using **Hepatogram plus⁺**, follow all installation instructions, and confirm that datasets are complete and have undergone appropriate processing prior to use.

Section 2 – Indications for Use and Setup

2-1 Indications for Use

Hepatogram plus⁺ is an assisted ROI drawing tool for liver MRE and Fat/Water images and is used for receiving, displaying, ROI selection, and summary generation. It displays to a trained reader MRE and Fat/Water images, preliminary ROIs that it calculates from these images, and statistical analysis calculated from the ROIs and images. ROIs and images are presented for review and, optionally, modification by the trained reader.

2-1-1 Contraindications

Hepatogram plus⁺ is contraindicated to situs inversus, where major visceral organs are mirrored from their normal positions and may produce automated ROI in the right side of the body in a non-liver organ. This does not preclude use of the tool to manually correct the ROI.

Hepatogram plus⁺ is contraindicated to conditions that lead to heterogenous liver stiffness. In this case, the automated ROI may only include tissue with homogenous stiffness. An example of this is Primary Sclerosing Cholangitis (PSC) where, typically, heterogenous fibrosis results in exterior liver being stiffer than the interior. The automated ROI may only be in the soft tissue, excluding the stiffer exterior. This does not preclude use of the tool to manually correct the ROI.

2-1-2 Intended users

Hepatogram plus⁺ must only be used by medical image readers trained with MRE and F/W. Users with suitable training may be image analysis techs, radiologists, radiology residents, researchers, or other qualified individuals who have received training from experienced MRE and F/W readers, and have experience calculating stiffness from liver MRE and parameters from F/W, or are under the supervision of trained readers.

Any use by non-trained, inexperienced unsupervised readers, or use for purposes other than calculation of stiffness from liver MRE images and PDFF/R2* from liver F/W images is contraindicated.

The User must:



Be specially trained and qualified to analyze MRE and F/W images.



Carefully review each automatically generated ROI provided by **Hepatogram plus⁺** for accuracy and modify when necessary. This includes ensuring that the ROIs include only liver tissue and avoid areas with artifact.



Check that the input images displayed by **Hepatogram plus⁺** look reasonable for contrast and SNR, appear in appropriate order, and that the final ROIs are acceptable to an experienced reader's best standard.



Consider patient history and patient-specific factors when appropriate to ROI selection or interpretation of the stiffness value.



Only use **Hepatogram plus⁺** for measurements in liver data from acquisitions for which it has been validated.

2-2 Installation and Setup

See "Hepatogram Plus – Server Integration" for details

2-3 Conditions for Normal Use

When starting **Hepatogram plus⁺** the user will be presented by a splash screen that includes version information. Following that, the blank main screen is displayed, indicating it is ready to load a case.

Section 3 – Maintenance

3-1 Software Updates

See “Hepatogram Plus – Server Integration” for details

3-2 Cybersecurity updates

See “Hepatogram Plus – Server Integration” for details

3-3 Use and Operation

3-3-1 Runtime parameters

See “Hepatogram Plus – Server Integration” for details

3-3-2 Supported acquisitions

Hepatogram plus⁺ processes MRE and multi-point Dixon F/W images.

Hepatogram plus⁺ is designed to receive an entire liver MR exam dataset, and will review the dicom header information of all data provided to discover which series contain MRE or F/W datasets that can be processed. Any pulse sequences that it does not recognize will be ignored.

If **Hepatogram plus⁺** discovers multiple datasets of any type that can be processed, determination of how these are processed are determined by server-side configuration. Each MRE and F/W exam can be processed separately or as combinations/permutations of MRE and F/W.

3-3-3 MRE: Images required

A complete set of Magnitude and Phase images. For most of the supported datatypes, the number of phase offsets acquired must be the same for each slice.

Hepatogram plus⁺ will derive stiffness, wave, and confidence images for MRE exams from the MRE magnitude and phase images. Many MRI manufacturer sequences do not save one or more of these in the MRE dataset; offline re-processing avoids problems resulting from missing data causes. This can yield results that look different from those processed on the scanner, particularly in the cases of colorized images, but are quantitatively equivalent.

Supported acquisition types:

	MRE	F/W
GE	MR-Touch	IDEAL/IQ
Philips	gremre	mDixon-quant
Siemens	gremre, seepimre	qDixon

NOTE: Supported sequences are identified by DICOM metadata. Unrecognized DICOM headers cannot be processed by **Hepatogram plus⁺**. See Revision History for a list of vendors and software versions supported.

If you believe your pulse sequence should be recognized but **Hepatogram plus⁺** is not processing it, contact Resoundant for support.

3-3-4 F/W: Images required

Fat Fraction (PDF) and Water contrasts are required. R2* contrast is optional, and will be used to calculate R2* measurements if this image set is present. In-phase and opposed-phase images, if present, will be available for viewing in the graphical interface (GUI).

3-3-5 Automated ROI generation

Automated ROI generation algorithms within **Hepatogram plus⁺** will attempt to find and segment the liver then produce an ROI within that boundary avoiding artifact, tumors, and blood vessels. Automated ROIs are shown to be as effective as human drawn ROIs for finding quantitative values of liver stiffness and fat fraction in >95% of cases. In the remaining 5% of cases, modification of ROIs or manual re-draw is required. In all cases, for the quantitative results to be valid, a trained reader must verify that ROIs are acceptable.

Hepatogram plus⁺ processing takes 3-5 minutes per dataset. For example, a study containing one MRE series and one F/W series will take 6-10 minutes. After this time, the corresponding processed file should appear in the list when using the Load Finished Case button in the GUI (described below).

3-3-6 Verifying, Modifying, and Accepting ROIs

Open case to review: Run the **Hepatogram plus⁺** executable to launch the viewer.

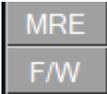
Press the Load Finished Case button. Finished cases are referenced by their data digest file, with file extension “.alc2”. If no such file exists, the case may not have been processed or processing may have failed and generated an error log.

The **Hepatogram plus⁺** main display (Figure 1) shows MRE and F/W images, with ROI overlays and calculated values. This is for at-a-glance confirmation that the ROIs properly include valid areas of the image, including entirely or primarily liver tissues and excluding image artifacts. If any ROIs need modification, the process is discussed below. Once all ROIs are acceptable, the exam can be approved, and the report will be generated.



Main screen features:

“Main menu” buttons

	Load new Hepatogram plus⁺ dataset	Open a case processed by server or previously edited for review
	Create Hepatogram plus⁺ summary	Generate Hepatogram plus⁺ report. Will copy archivable outputs to <outputDir>
	Help	Display help, version information, device label, and contact information.
	Take snapshot	Blank patient information and create snapshot image. Hover over icon: will show the snapshot format. Click: Takes snapshot with option to save to file.
	Toggle View of MRE and F/W	Use to display or hide the view of MRE and F/W data, as available.

“Patient information” Displays Patient Name, Hospital ID, and Exam information.

“Messages” Dialog box that indicates status of case in review.

Calculated values

Hepatogram plus⁺ calculates mean, range, and area or volume from ROIs, both per-slice and composite values. Composite values are displayed in a frame above the images, while per-slice values are immediately below the images.

Composite mean, range, and ROI volume are calculated for MRE and F/W data, separately, from all ROIs and data presented on the screen.

Elastography Series 5	Composite 4 slices	Mean: 3.25 kPa	10%, 90%: 2.57 - 3.96 Area: 14,912 (pix)
Fat Fraction Series 10	Composite 4 slices	Mean: 9.47 % Median: 10.00 %	10%, 90%: 7.00 - 11.00 Area: 7221 (pix)

- **Composite mean:** Composite mean is a weighted average of each per-slice mean value weighted by the area of that slice's ROI. If a slice does not contain an ROI, it is excluded from the composite results.
Median values can be displayed, consult Server Integration for changing the mreplus.cfg file.D
- **Composite range:** Composite range is 10-90%, or the smallest and largest values from the middle 80% of the data, where the data is all pixels included in the ROIs.
- **Composite area:** Composite area is calculated as the sum of all per-slice ROI areas.

Per-slice values:

Per slice mean and ROI volume are displayed below each slice image.

User controls:

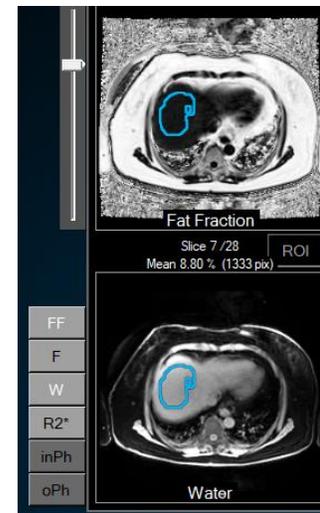
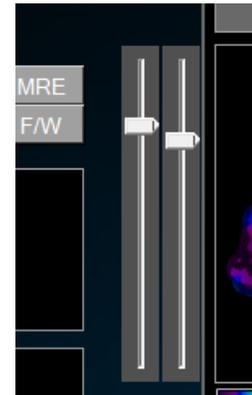
Window and Level can be adjusted by right-click-and-hold on an image, then dragging left/right or up/down.

Brightness of ROI and confidence overlay (for MRE data) can be adjusted by the level sliders located to the left of the images.

MRE images displayed: MRE stiffness images are always displayed in the top row. The "Mag" and "Wav" buttons to the left of the second row can be used to switch between magnitude and wave images in the second row of displayed images. If "Wav" is selected, a Play button appears to scroll through phase offsets and show wave propagation.

Fat/Water display: The buttons to the left of the F/W images can be used to change display between FF (Proton density fat fraction), F (Fat), W (Water), R2* (R2*) images. If an image set is not available, the corresponding button will be unavailable.

Fat/Water contrast selection: Left-clicking a contrast button will select the data displayed in the top row, while right-clicking a contrast button will change the data displayed in the second row.



D

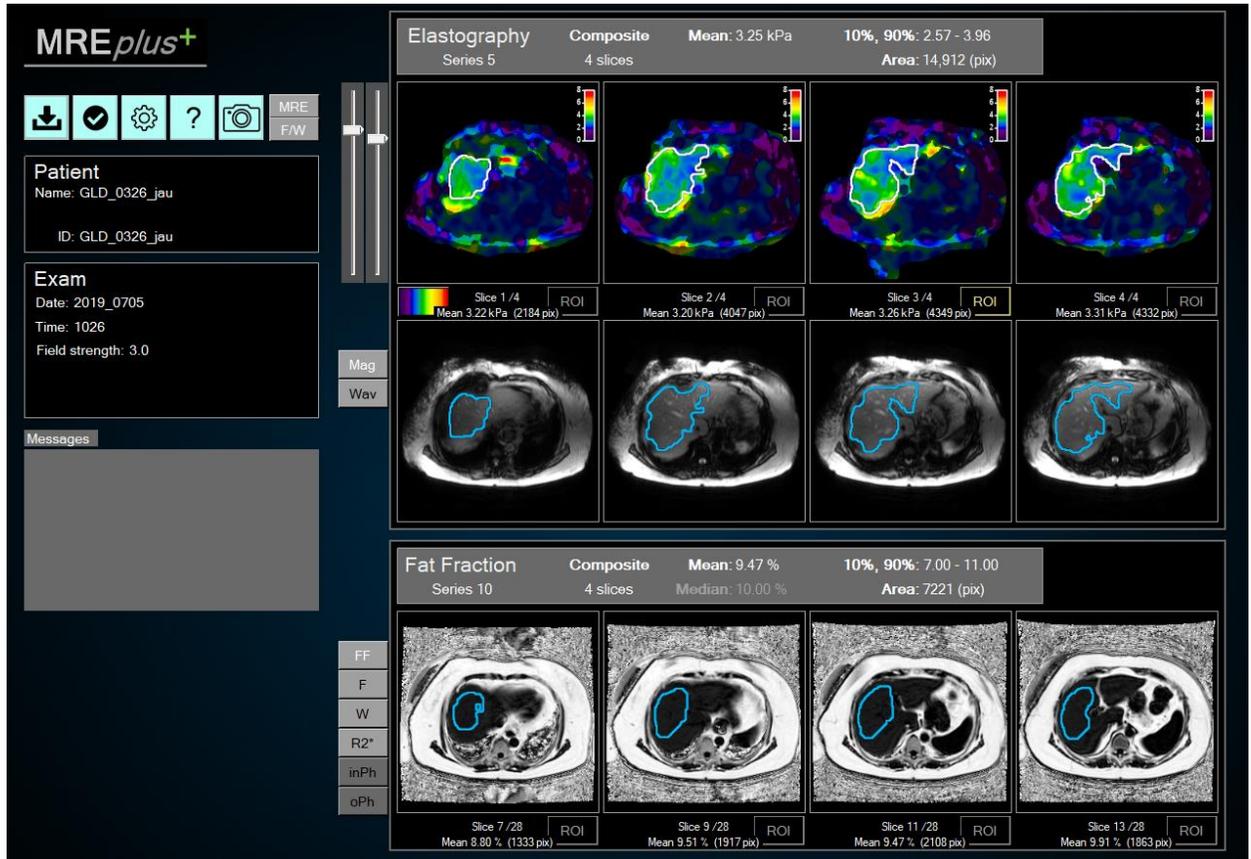


Figure 1: The main review screen

To Modify an ROI, press the “ROI” button located near the slice to launch the Modify ROI interface.

Overview of the ROI modification interface:

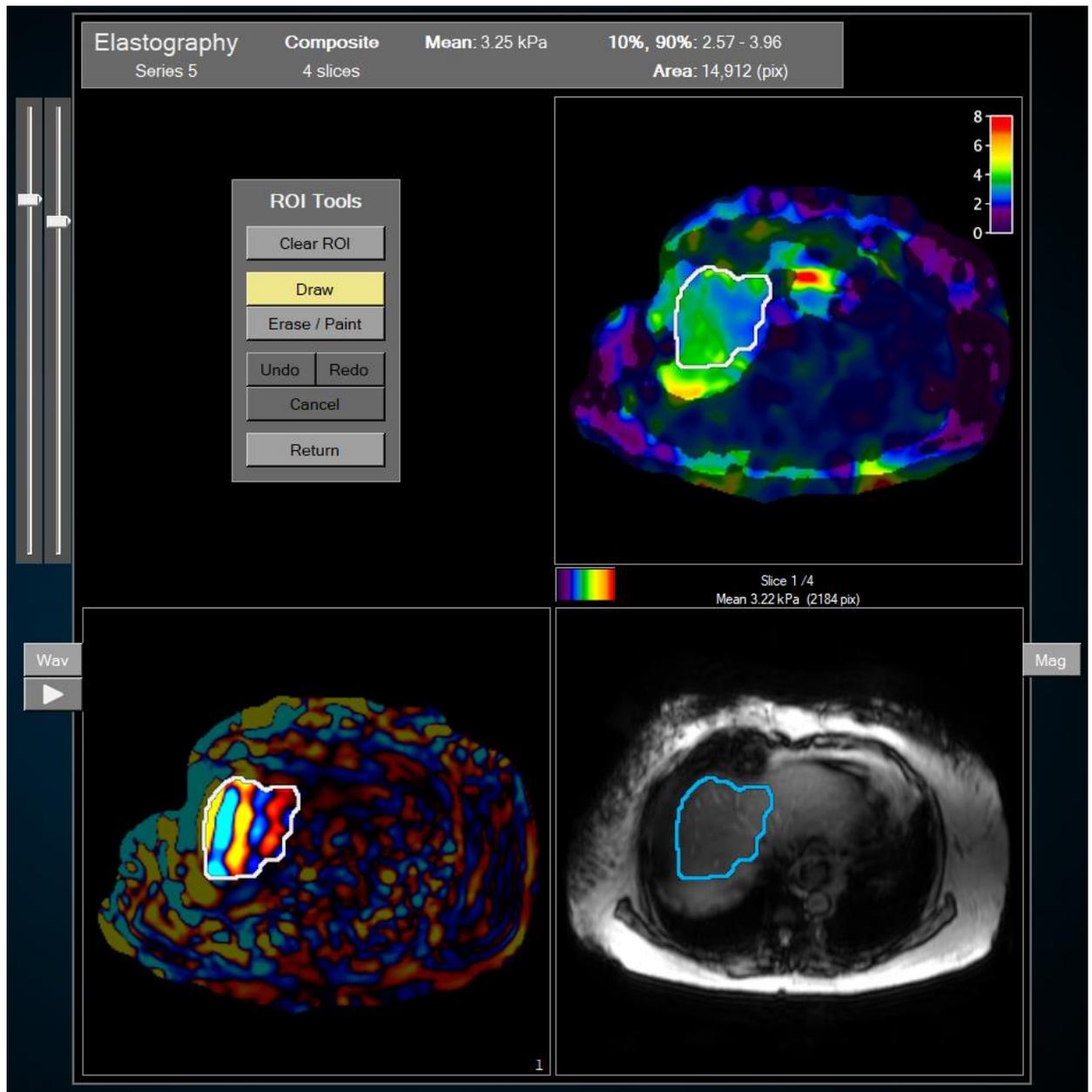


Figure 2: MRE modify ROI screen

Modify ROIs

- ROIs can be drawn onto any displayed, static image, and it will be shown on all other images.
- ROIs will appear in a higher-weight line while being drawn; any existing ROIs will appear in lighter weight.
- (Applicable to MRE Only) If a manual ROI is drawn over a low-confidence region, the program will automatically “snap back” to the edge of the low-confidence zone, as low-confidence areas cannot be included in the calculation of stiffness.

- Calculated per-slice and composite values are updated after each change. These results are not applied to the composite results until the user clicks Return.
- The user must click the “Create an **Hepatogram plus⁺** Summary” button to save the changes.
- If a newly drawn ROI is completely outside of the existing ROI, **Hepatogram plus⁺** will automatically apply the Add area function.
- If a newly drawn ROI is completely inside of an existing ROI, **Hepatogram plus⁺** will automatically apply the Subtract area function. Brightness and Contrast (Window and Level) can be adjusted by right-click (and hold), and dragging the mouse up/down and left/right.

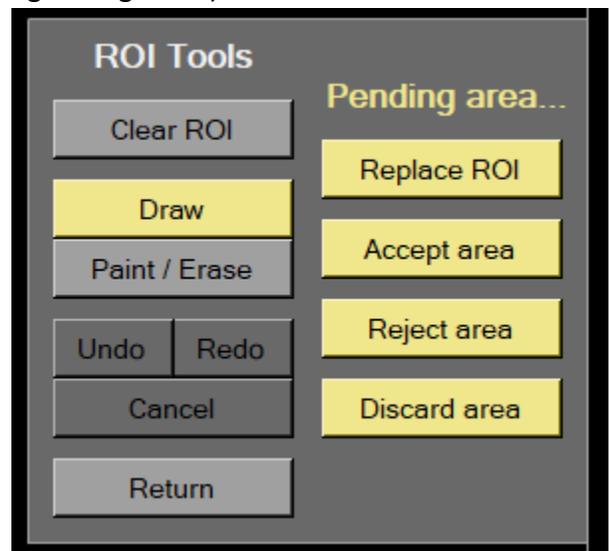
ROI Tool buttons:

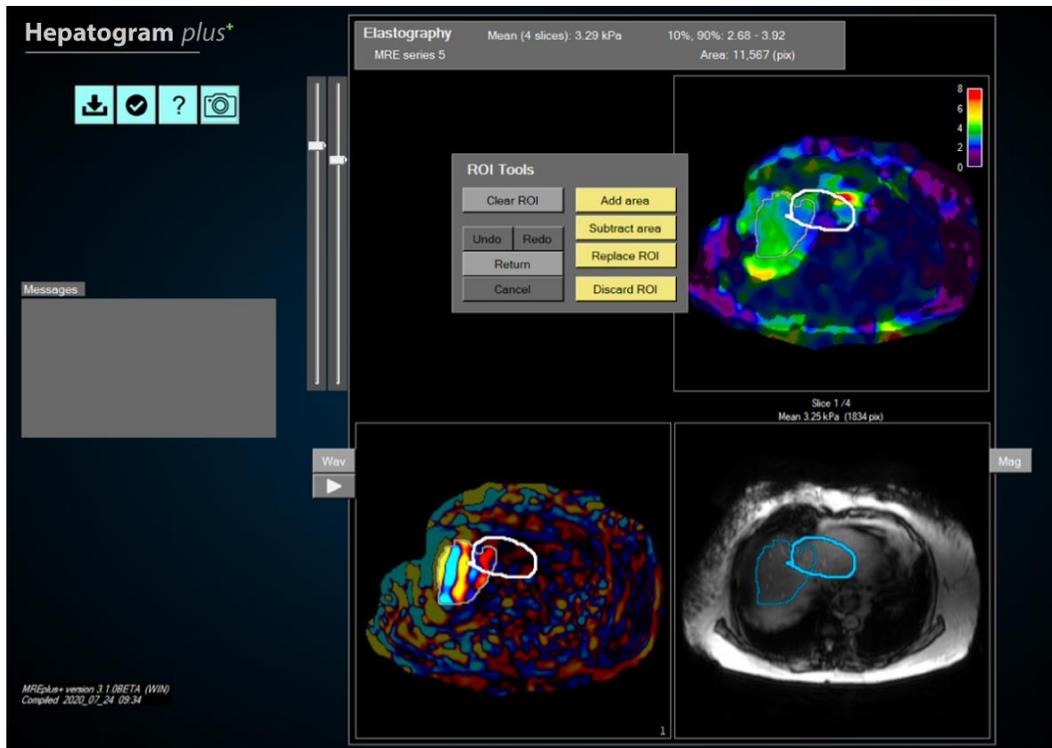
- **Clear** – Removes all ROI in image
- **Draw** – Use the pencil tool interact with image (see below)
- **Paint/Eraser** – add (paint) or remove (erase) from the ROI. Use [and] to change brush size
- **Undo/Redo** – Previous change is removed or re-applied.
- **Cancel** – all changes are discarded, and the ROIs revert to their state at the start of the modification.
- **Return** – all changes to ROIs are displayed on the main screen, and per-slice and composite values are updated

Draw ROI tool Buttons (appear after making a change using Draw):

- **Replace ROI** – will remove previous ROI and replace with newly drawn ROI
- **Accept area** – will add the newly drawn ROI area to existing ROI
- **Reject area** – will remove the newly drawn ROI area from existing ROI
- **Discard area** – will cancel the pending change

In some cases, one of these actions will happen automatically, for example, drawing an ROI completely inside an existing ROI will automatically “reject” and remove what was drawn.





3-3-7 Suspend for later

All changes are immediately updated once they are made, so there is no need to save progress. **Hepatogram plus+** can be closed at any time. A previous session can be resumed by loading the processed case (.alc2 file)

3-3-8 Approving an Exam

When all ROIs are acceptable, press the “Create an **Hepatogram plus+** Summary” button. This will generate a clinically archivable image.



Depending on your institution’s installation configuration, the summary may be immediately sent to the clinical archive. Any sessions or modifications that occur after Approval will generate new summaries.

3-3-9 ROI Size

A composite ROI area of 2000px is the minimum recommended size for MRE data, and 500 pixels for F/W data. If **Hepatogram plus+** yields a smaller preliminary ROI, it will have a reported stiffness of 0 in any automatically generated summary. In the GUI, the current values are displayed, and the composite results field will have a red background, indicating the small ROI area.

Fat Fraction	Composite	Mean: 9.23 %	10%, 90%: 7.00 - 11.00
	1 slice	Median: 9.00 %	Area: 465 (pix)

If there is no automated ROI present, but the image quality and slice placement are acceptable, it is likely that the preliminary ROI failed in this exam and you should draw a new ROI using the Modify ROI button according to the standard procedure. **Hepatogram plus⁺** viewer will display the stiffness regardless of ROI size, and the displayed values will be applied to the summary if the user approves the review. It is the discretion of the user to determine if the ROI area is sufficient, or if the exam should be reported as a failed acquisition.

Indicators of poor MRE data quality include:

- 1) Low signal-to-noise (SNR) or low magnitude signal (dark liver).
- 2) Absence of waves (flat wave image that shows no wave propagation when played as a movie).
- 3) Noisy wave images (patchy, aberrantly changing wave images).
- 4) Motion artifact (ghosting in the magnitude image, patchy confidence map, unclear wave pattern)
- 5) Low confidence (most of the elastogram is masked out with the confidence mask checkerboard).

3-3-10 Measurements

Measurements that are made and reported for the calculated ROI include:

- Area
- Mean
- Median
- Range

The Mean, Median, and Range measurements apply to the contrasts on which the ROI is applied, such as stiffness, fat fraction, and R2*.

3-3-11 Degree of Accuracy

Precision of measurements is +/- 1 of the least significant digit.

Accuracy of mean, median, range, and area measurements are equal to the specified precision. **Hepatogram plus⁺** acts upon the quantitative values that were input, and makes no claim to the accuracy of these inputs.

Section 4 - Troubleshooting and Support

4-1 Troubleshooting

Exam failed to process: Consult the error log for additional information. Exam may not be recognized due to insufficient detail in the DICOM header, the DICOM header may have been changed, or the data may have been transferred incompletely.

Exam processed successfully, but there are no ROIs or data: **Hepatogram plus⁺** may not have found any areas that meet its selection criteria for automated ROIs. Review case manually to determine if viable data is present.

4-2 Support

4-2-1 User Manual

A current copy of this User Manual can be found under the Help icon of **Hepatogram plus⁺** or online:

World Wide Web: <http://www.resoundant.com>

4-2-2 Contact Resoundant Technical Support

Questions regarding the installation and use of **Hepatogram plus⁺** software may be obtained by utilizing any of the following sources:

World Wide Web: <http://www.resoundant.com>

Email: software-support@resoundant.com

When contacting Resoundant Technical Support, please have the following information ready:

- License Key (or product number – however it is defined in the software)
- Version of software being used
- Scanner model and software version
- Your Contact information (email, telephone)

4-2-3 Contact Manufacturer

For other questions, contact:



Resoundant, Inc.
421 First Avenue SW STE204W
Rochester, Minnesota 55902 USA
Phone: 507.322.0011
Email: mreinfo@resoundant.com

4-2-4 European Authorized Representative



VISAMED GmbH
Kastellstrasse 8
D-76227 Karlsruhe-Germany
Phone: +49(0)721-4764847
Email: www.visamed.com

Appendix 1

Hepatogram *plus*⁺ report summary examples:

