

Name	Priority (L, M, H)	Line #	Section #	Issue	Proposal	Resolution
Hans Peeters	M		Page 29	GRE MRE	Rename to FFE MRE	Done
Hans Peeters	M		Page 29	SE-EPI MRE	SE-EPI MRE (WIP)	Done
Hans Peeters	H		Page 30	The notes section does not contain Philips terminology	Integrated body coil; ASSET = SENSE; GREMRE = FFE MRE; note 3 can be removed; note 5 can be removed	Done
Hans Peeters	L		Page 29	The scan time for SE-EPI MRE is shorter than 19 seconds	Scan time = 13 seconds	Done
Hans Peeters	M		Page 29	Default FOV is incorrect	FOV/RFOV = 450 mm/90%	Done
Hans Peeters	H		Page 31/32	Same issues as indicated for Page 29 and 30 (1-5)	Same proposals	Done
Hans Peeters	M		Page 44 (Philips 1.5T)	SE-EPI MRE is WIP	2D SE-EPI MRE (WIP)	Done
Hans Peeters	M		Page 45	No. of slices should be 4	No. of slices: 4	Done
Hans Peeters	M		Page 45	FOV should be 300/100%	FOV 300/100%	Done
Hans Peeters	M		Page 45	Flip angle should be 30	FA 30 deg	Done
Hans Peeters	L		Page 45	Matrix should be 200x64	200x64	Done
Hans Peeters	L		Page 45	BW/pixel is 218 iso 288	218	Done
Hans Peeters	L		Page 45	SENSE is not used for acceleration. As it concerns phantom experiments, no parallel imaging is used.	Acceleration: No	Done
Hans Peeters	L		Page 45	No breath holds are involved	Breath holds: No	Done
Hans Peeters	L		Page 46	GREMRE = FFE MRE	FFE MRE	Done
Hans Peeters	L		Page 46	SE-EPI MRE is WIP	SE-EPI MRE (WIP)	Done
Hans Peeters	L		Page 46	Scan time: 1:44	Scan time 1:44	Done
Hans Peeters	L		Page 46	Drive power = 10%	Drive power: 10%	Done
Hans Peeters	L		Page 46	Axis of MEG: AP	Axis of MEGL AP	Done
Hans Peeters	L		Page 46: NOTE:	The Philips phantom protocol is performed with the head coil, not the torso coil. It is being talked about ASSET. Philips terminology is SENSE, but SENSE is not used in the phantom setup. The recommended FOV is 300 mm. The provided protocol by Philips is delivered with the scanner and is recommended to be used.	Update Notes section with Philips terminology, numbers and recommendation to use the provided protocol in the Philips database provided with the scanner.	Done

Hans Peeters	L		Page 45: Slice positioning	Philips can provide photos in which the Philips setup is shown.	Use photos of the Philips setup in the Philips table	Done
Hans Peeters	L		Page 46-48: Philips 3T phantom protocol	All issues as provided for the Philips 1.5T protocol with respect to photo's, sequence parameters and notes section.	Update as indicated for the issues with the 1.5T table.	Done
Jacob Fluckiger	M	215	3.6	See proposal	Consider adding: "Lack of signal in the Liver from T2* effects confound MRE processing"	Done
Jacob Fluckiger	L	254	3.1	GE systems report the stiffness in pascals (Pa)	Please add "or Pascals (Pa)"	
Jacob Fluckiger	M	254	3.1	Clarification needed to image processing	Consider adding, or something similar: "Magnitude, Phase/Wave, and color Elastograms should be used for guiding the placement of the ROI's. The final ROI output values need to come from the Grey scale Elastogram, they contain valid quantitative values"	Done
Jacob Fluckiger	H	348	Appendix D	The protocols for GE systems are for older SW versions. Please contact me for up to date protocol information	Please contact me for up to date protocol information. jacob.fluckiger@ge.com	Contacted
Timothy Hall	H	55	Closed Issues	The linearity of MRE versus ultrasound SWS stiffness assessments should be consistent among profiles, assuming the analogous claims are being made.	Liaison communication among biomarker committees needs to be robust.	Not addressed, outside scope of profile
Timothy Hall	H	150	Profile Activities	To perform periodic QA it is suggested that the user scan a phantom with known stiffness, but this concept is counter to the statement that it is currently not possible to determine the stiffness of phantoms.	Some resolution of this discrepancy is needed.	Not addressed, outside scope of profile
Timothy Hall	M	190	Technical Success	The criteria for "technical success" of inducing a wave field in the torso are, at best, vague. Some objective metric to describe the target displacement peak amplitude would be desirable.	Provide an objective metric of particle displacement amplitude (compared to the desired amplitude).	Not addressed, outside scope of profile
Timothy Hall	M	195	figure 3	There is clear evidence for a wave field only near the perimeter of the liver. As stated in the comment above, some metric describing the desired wavefield magnitude would be useful.	see above.	Not addressed, outside scope of profile
Timothy Hall	M			The heterogeneity of wave fields and elastic modulus images is not addressed.	Some statement regarding the validity (consistent bias) of modulus estimates near the liver boundary (v. center of any lobe) is needed.  Heterogeneity of modulus estimates needs some discussion. How is estimate variance distinguished from low quality data?	This was addressed in the text/figures
Timothy Hall	M		figure 8		the confidence map shown in this figure seems to indicate the region over which elastic property estimates can be trusted. If this is proposed as the metric by which data are included or excluded, the 'failed' acquisition demonstrated in the previous figures should be presented as tutorial examples (maybe they were and I missed it).	This was addressed in the text/figures
Timothy Hall	M	250	3.10 Image Analysis	manual segmentation is suggested, but if there is a trusted region defined by a "confidence map", why not estimate the elastic properties everywhere within that region? Isn't the subjective selection of an ROI inserting a user bias and variance?		Not addressed, outside scope of profile

Timothy Hall	M	260	figure 9 caption	the term "incoherent waves" is used without definition		Addressed in text
Kevin O'Donnell	L	84	2	Only the claim and headings need bolding	You can change the body paragraphs in Clinical Context and Discussion back to unbolded.	Done
Kevin O'Donnell	L	85	2	Very nice clinical context	But the second sentence could use a few more commas. :-)	Done
Kevin O'Donnell	L	97	2	Is "in this patient" needed?	Drop	Done
Kevin O'Donnell	M	99	2	Per template guidance, "Holds when" is used to identify clinical limitations or subpopulations, not to reiterate profile requirements.	If it is a requirement that acquisition be done on the same scanner, or with the same parameters, that should be a requirement in Image Acquisition, (and/or a requirement in Image QA for the radiologist to bump the measurement out of the profile if that did not happen). Remove from here though.	Put in open issues
Kevin O'Donnell	M	104	2	The wCV value is really your fundamental technical performance claim. Essentially, if actors follow the profile they will achieve measurements with a wCV of 7%.	Move this into an additional claim.	Put in comments for discussion
Kevin O'Donnell	M	112	2	Doesn't make it clear that it's a decrease in kPa	Change to "-1.0 ± 0.49 kPa". In fact I might be tempted to represent the confidence interval as (-1.49, -0.51) which lets you see that it doesn't straddle zero.	Decided to keep current reporting standard
Kevin O'Donnell	L	114	2	This seems to be a discussion about why a certain QA activity doesn't make a lot of sense.	I'd be half tempted to move it to the Discussion in 3.3.1	Not moved
Kevin O'Donnell	M	139	3.2	QIBA convention is to put requirements into Shall Tables.	Reformat this as a QIBA Shall Table (see template). Doing so will also require you to assign this requirement to a particular actor. The current passive voice text says it has to happen but no one is actually responsible for making it happen. Conversely if your experience has been that manufacturer-defined procedures and specifications are <u>always</u> performed, then it's not a real problem and you could drop the requirement.	Done
Kevin O'Donnell	L	137	3.1	Per the template, pre-delivery is "prior to delivery of equipment to a site", so "onsite pre-delivery" is contradictory.	You could just remove this section since there are no normative requirements. If you think it's important to highlight the lack of normative requirements you can leave it in and drop the word "onsite".	Done
Kevin O'Donnell	M	142	3.3	There is no "Specification" section and no Shall language so on the surface this appears to be informative material. Should means we'd like you to do this but you don't have to.	If this is intended to be a requirement, it should go into a Shall table, with shall language and assign responsibility to one of the actors. E.g. "Physicist shall validate the field of view and image linearity using the method and frequency specified by the manufacturer". The other paragraphs can stay in the discussion sub-section.	Done
Kevin O'Donnell	L	158	3.4	Since there aren't any requirements or much substantive discussion...	Consider dropping the section.	Done
Kevin O'Donnell	M	160	3.5	None of these appear to be requirements.	If any are, make a shall table and make an actor responsible for them.	Done
Kevin O'Donnell	M	205	3.6	If this is a problem, do you want to control for it?	Consider adding an acquisition requirement on the tech to avoid colonic interposition between paddle and liver, or an image QA requirement on the radiologist to disqualify images where it happens	Done

Kevin O'Donnell	M	210	3.6	If this is a problem, do you want to control for it?	Consider adding a requirement (like line 205 comment)	Done
Kevin O'Donnell	M	215	3.6	If this is a problem, do you want to control for it?	(like line 205 comment)	Done
Kevin O'Donnell	M	177	3.6	None of these appear to be requirements.	If any are, make a shall table and make an actor responsible for them.	Done
Kevin O'Donnell	M	218	3.7	None of these appear to be requirements.	If any are, make a shall table and make an actor responsible for them.	done
Kevin O'Donnell	M	238	3.8	None of these appear to be requirements.	If any are, make a shall table and make an actor responsible for them.	Done
Kevin O'Donnell	L	245	3.9	No real content.	Suggest dropping the section.	Done
Kevin O'Donnell	L	137-271	3	Don't need to bold all paragraphs.	Shift body paragraphs to normal text.	Done
Kevin O'Donnell	M	248	3.1	No normative requirements specified	Put requirements into a shall table and assign a responsible actor. Informative material can remain in the Discussion subsection.	No shall table required, left as original
Kevin O'Donnell	L	256	3.1	Informative text may be overlooked in figure titles.	Consider breaking out into paragraphs and reference the figure.	Done
Kevin O'Donnell	M	266	3.11	No normative requirements specified.	Put requirements into a shall table and assign a responsible actor. Informative material can remain in the Discussion subsection.	Done
Kevin O'Donnell	M	296-309	4.1	Assessment Procedures are procedures to assess particular requirements from Section 3 that need to be assessed in a specific way. Performing the Shear Measurement should be described in Section 3.10. (You can rename the Section 3.10 activity to be Measure Shear if you like).	Lines 296-300 go into Section 3.3 (some of it is already there). Don't want to state the same requirement in two places using different words. Then it's not clear which is "right". Lines 302-304 could go into a Staff Qualifications section (See template). Lines 307-309 go into 3.10.	Reorganized and addressed
Kevin O'Donnell	M	311	4.2	This one is an assessment procedure.	Consider renaming to 4.1 Assessment Procedure: Analysis Software wCV	Addressed in text
Kevin O'Donnell	M	317	4.2	The requirement on the Analysis Software wCV is a good one. Should add it to the requirements.	Add a requirement to 3.1 (which you might want to rename "Product Validation") that the Analysis Software shall demonstrate a within-subject coefficient of variation of < 0.07. See 4.1 Assessment Procedure: Analysis Software wCV.	Added to comments to address
Kevin O'Donnell	M	320	4.2	If it's necessary that the same scanner be used at both timepoints, that should be made a requirement.	Add to 3.6 Image Data Acquisition shall table to do it or to the Image QA requirements to disqualify if it hasn't been done.	Done
Kevin O'Donnell	M	339	4.2	It's not clear from the text above and here whether the requirement is on the wCV or RC%.	Admittedly they're "equivalent" but it's simpler to pick one.	Added to comments to address