Rev 1: September 2018

FSN Ref: FSN-2026-001-DRAFT FSCA Ref: FSCA-2026-001-DRAFT

Date: 26:FEB:2026

Urgent Field Safety Notice
Resoundant Acoustic Driver System

For Attention of*:MRI Scanner Manufacture - Philips

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Resoundant, Inc.

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Urgent Field Safety Notice (FSN)
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Incorrect MRE measurements resulting from small pixel size

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	GMDN 65288 - Magnetic resonance elastography acoustic driver
1.	2. Commercial name(s)
	Resoundant MR Elastography System
1.	3. Unique Device Identifier(s) (UDI-DI)
	00850011790021, 00850011790151
1.	4. Primary clinical purpose of device(s)*
	The Resoundant MR Elastography System is intended for use with magnetic resonance diagnostic devices (MRDD) that include legally marketed MR elastography capabilities. It is indicated for generating acoustic vibrations in the body during an MRI exam in order to assess tissue elasticity for diagnostic purposes as part of magnetic resonance elastography (MRE). When interpreted by a trained physician, this information can be useful in determining a diagnosis.
1.	5. Device Model/Catalogue/part number(s)*
	RESYS3001-RESYSAB, RESYS4001-RESYSAB
1.	6. Software version
	Philips scanners with r5.x, r11, and r12 software (all of which have MMDI 3.0.4 as part of MRE View) and that scan the default Philips protocol for MRE.
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	This issue affects all Philips users of r5.x, r11, and r12 software (all of which have MMDI 3.0.4 as part of MRE View) and that scan the default Philips protocol for MRE.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Default MRE acquisition parameters installed on current Philips scanners result in incorrect measurements of liver stiffness. This can affect clinical staging of liver disease and is therefore a patient safety risk.
2.	2. Hazard giving rise to the FSCA*
	Patients in the late F3 to early F4 range have severe disease but do not typically have symptoms. Incorrectly assigning fibrosis stage based on an erroneous stiffness value would change the way these patients are managed.
2.	3. Probability of problem arising
	This issue affects all Philips users of r5.x, r11, and r12 software (all of which have MMDI 3.0.4 as part of MRE View) and that scan the default Philips protocol for MRE.
2.	4. Predicted risk to patient/users
	Medium Risk to patient (indirect)
2.	5. Further information to help characterise the problem
	- No death or serious injury has been reported. - Clinical assessment has determined that the issue could potentially delay treatment or follow up care.
	6. Background on Issue

2.	MMDI v3.0.4 algorithm, part of MRE View, uses a kernel with fixed number of pixels to estimate stiffness, regardless of pixel size. If pixel sizes are too small, a convolution effect results in artificially soft stiffness estimates. For this reason, Resoundant recommends 1.65mm pixels, based on history of use with 420mm FOV and 256x256 image resolution. MMDI 3.2 introduced a new feature to keep kernel size constant in image space and therefore adjusts to pixel size. Philips has validated the MRE application using 450mm FOV and 300x300 resolution, or 1.5mm pixel size. This was recently measured in conjunction with the NMPA submission of the MR 7700 platform, which verified accurate values in calibrated phantoms. Unfortunately, default pixels sizes are for MRE protocols 1.17mm for GRE and 1.25 for SE-EPI MRE: significantly smaller than both recommended and validated. Analysis of in vivo data shows significantly softer estimates using the default MRE settings from the recommended/validated settings. The following figure of 390 exams, acquired on a Philips Ingenia 3T, r5.4.1.2, shows a percentage change as a function of stiffness. There are a significant number of cases that are sufficiently low estimates that they would likely have been diagnosed as a full fibrosis stage lower than actual, which would negatively affect their treatment plan.
2.	7. Other information relevant to FSCA
	- No death or serious injury has been reported. - Clinical assessment has determined that the issue could potentially delay treatment or follow up care.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None **Requested actions:** **• Correction:** **- Resoundant will request Philips to change the default MRE parameters to an image pixel size of 1.5mm via updates to releases R5, R11, and R12.** **• Corrective action:** **- Adoption of MMDI v3.2 into MRE View. This version automatically adjusts for pixel size to produce accurate results. This version has been provided to Philips in an SICR in January of 2025 and is scheduled for inclusion in R14.**	
3.	2. By when should the action be completed?	TBD
3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? Yes	

	All exams done with these parameters should be reprocessed to identify any cases that were significantly different. Those cases should be contacted.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☒ Other ☐ None - Resoundant IFU update - Resoundant Additional training media to be released	
3	6. By when should the action be completed?	30 days (Resoundant actions only)
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Resoundant, Inc.**
	b. Address	**421 First Ave SW, STE 204W, Rochester, MN, USA**
	c. Website address	**www.resoundant.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * - Yes (MDR# 3013695852-2026-00001)	
4.	9. List of attachments/appendices:	**www.resoundant.com**
4.	10. Name/Signature	**John Hartigan, VP QA/RA**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.