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[CFR Title 21](#)¹⁶ [Radiation-Emitting Products](#)¹⁷ [X-Ray Assembler](#)¹⁸ [Medsun Reports](#)¹⁹ [CLIA](#)²⁰ [TPLC](#)²¹[New Search](#)[Back to Search Results](#)**Class 2 Device Recall MR 5300**

Date Initiated by Firm	August 21, 2026
Date Posted	September 18, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-3241-2026
Recall Event ID	99769 ²³
510(K)Number	K193215 ²⁴ K223442 ²⁵ K251808 ²⁶
Product Classification	System, nuclear magnetic resonance imaging ²⁷ - Product Code LNH ²⁸
Product	MR 5300 Model Number (REF): 1. 782110, 2. 782152;
Code Information	1. Model Number (REF): 782110; UDI-DI: 884838099364; Serial Numbers: 63383, 63384, 63385, 63386, 63422, 63435, 63643, 63346, 63021, 63054, 63091, 63092, 63113, 63313, 63314, 63315, 63322, 63521, 63524, 63565, 63572, 63593, 63604, 63639, 63694, 63697, 63705, 63706, 63707, 63716, 63721, 63727, 63736, 63737, 63739, 63743, 63750, 63753, 63754, 63755, 63769, 63773, 63617, 63560, 63038, 63484, 63023, 63064, 63066, 63075, 63086, 63149, 63161, 63183, 63194, 63195, 63198, 63199, 63308, 63319, 63331, 63334, 63336, 63364, 63371, 63412, 63425, 63429, 63430, 63452, 63515, 63525, 63609, 63615, 63633, 63636, 63638, 63666, 63668, 63675, 63687, 63689, 63690, 63695, 63696, 63729, 63730, 63742, 63763, 63765, 63774, 63787, 63806, 63829, 63686, 63193, 63257, 63431, 63583, 63592, 63123, 63155, 63474, 63576, 63416, 63748, 63337, 63456, 63046, 63157, 63357, 63569, 63000, 63325, 63504, 63506, 63104, 63110, 63115, 63186, 63248, 63250, 63252, 63343, 63344, 63586, 63785, 63820, 63821, 63328, 63664, 63771, 63457, 63070, 63356, 63011, 63013, 63022, 63028, 63083, 63095, 63107, 63202, 63292, 63365, 63432, 63490, 63499, 63500, 63594, 63031, 63217, 63219, 63220, 63221, 63271, 63309, 63025, 63125, 63211, 63451, 63508, 63541, 63559, 63623, 63745, 63019, 63034, 63058, 63084, 63168, 63218, 63374, 63443, 63510, 63057, 63063, 63493, 63513, 63564, 63612, 63684, 63719, 63812, 63366, 63372, 63026, 63074, 63093, 63099, 63109, 63111, 63112, 63130, 63169, 63175, 63176, 63177, 63178, 63188, 63210, 63223, 63224, 63228, 63229, 63240, 63312, 63333, 63341, 63342, 63389, 63408, 63413, 63428, 63466, 63483, 63487, 63523, 63531, 63532, 63533, 63557, 63566, 63567, 63571, 63596, 63598, 63602, 63614, 63618, 63619, 63632, 63650, 63665, 63672, 63673, 63677, 63732, 63749, 63035, 63041, 63043, 63047, 63062, 63090, 63100, 63128, 63136, 63140, 63141, 63150, 63152, 63160, 63162, 63172, 63173, 63182, 63222, 63238, 63244, 63253, 63258, 63363, 63367, 63370, 63393, 63394, 63126, 63323, 63558, 63080, 63699, 63514, 63388, 63410, 63411, 63723, 63311, 63375, 63507, 63159, 63396, 63122, 63068, 63433, 63001, 63784, 63679, 63409, 63756, 63762, 63434, 63259, 63379, 63277, 63301, 63187, 63464, 63758, 63759, 63098, 63134, 63326, 63355, 63418, 63561, 63562, 63624, 63032, 63036, 63069, 63139, 63437, 63438, 63439, 63610, 63700, 63708, 63709, 63710, 63733, 63738, 63746, 63786, 63103, 63164, 63534, 63563, 63589, 63631, 63127, 63603, 63720, 63482, 63489, 63494, 63498, 63547, 63555, 63106, 63108, 63402, 63475, 63698, 63775, 63776, 63822, 63825, 63273, 63424, 63626, 63397, 63398, 63445, 63006, 63008, 63009, 63015, 63016, 63024, 63030, 63042, 63044, 63049, 63053, 63105, 63135, 63138, 63151, 63153, 63154, 63492, 63352, 63059, 63497, 63681, 63488, 63503, 63722, 63071, 63072, 63294, 63295, 63296, 63297, 63299, 63340, 63361, 63455, 63519, 63724, 63770, 63067, 63174, 63191, 63197, 63449, 63674, 63800, 63798, 63039, 63165, 63318, 63330, 63380, 63440, 63012, 63014, 63018, 63029, 63033, 63087, 63196, 63203, 63204, 63316, 63520, 63587, 63477, 63530, 63740, 63201, 63400, 63401, 63446, 63453, 63478, 63502, 63550, 63597, 63605, 63616, 63704, 63747, 63757, 63780, 63823, 63824, 63833, 63119, 63442, 63461, 63570, 63766, 63767, 63810;

	2. Model Number (REF): 782152; UDI-DI: N/A; Serial Numbers: 69304, 69349, 69098, 69101, 69250, 69318, 69321, 69338, 69238, 69239, 69024, 69026, 69034, 69039, 69046, 69081, 69083, 69105, 69151, 69235, 69023, 69037, 69041, 69066, 69112, 69152, 69233, 69302, 69299, 69193, 69194, 69241, 69287, 69320, 69070, 69071, 69106, 69110, 69127, 69161, 69360, 69366, 69044, 69045, 69048, 69116, 69286, 69300, 69351, 69055, 69073, 69075, 69086, 69191, 69207, 69243, 69252, 69258, 69260, 69261, 69262, 69264, 69268, 69270, 69288, 69290, 69295, 69296, 69297, 69000, 69003, 69008, 69010, 69011, 69014, 69015, 69017, 69030, 69147, 69312, 69325, 69326, 69327, 69328, 69329, 69330, 69331, 69332, 69333, 69334, 69289, 69340, 69115, 69200, 69201, 69263, 69154, 69342, 69348, 69170, 69135, 69139, 69197, 69271, 69277, 69133, 69185, 69215, 69234, 69038, 69189, 69053, 69058, 69065, 69078, 69085, 69092, 69103, 69122, 69123, 69169, 69177, 69179, 69216, 69220, 69221, 69224, 69225, 69228, 69229, 69267, 69301, 69305, 69306, 69307, 69313, 69314, 69323, 69343, 69365, 69316, 69027, 69096, 69097, 69186, 69212, 69240, 69254, 69255, 69063, 69064, 69069, 69080, 69095, 69126, 69176, 69315, 69005, 69067, 69175, 69198, 69247, 69294, 69298, 69336;
FEI Number	3016618143
Recalling Firm/ Manufacturer	Philips North America Llc 222 Jacobs St Cambridge MA 02141-2289
For Additional Information Contact	Customer Care Solution Center 800-722-9377
Manufacturer Reason for Recall	A software issue will terminate an examination during the image reconstruction process if the scan parameters are manually adjusted such that reconstruction requirements exceed the available system memory.
FDA Determined Cause ²	Software design
Action	On August 24, 2026 URGENT Medical Device Correction letters were sent to customers. Actions to be taken: " To prevent this issue from occurring, - o Use the standard 3D Vane scan protocol from the Philips Examcard Database, or - o For custom 3D Vane scan protocols, use a maximum of 480 for the reconstruction matrix and use a maximum of 167 for the number of slices. " You may continue to use affected systems in accordance with their intended use. " Circulate this notice to all users or new owners of this device so that they are aware of the issues and associated hazard/harm. " Please retain this Urgent Medical Device letter with your system(s) until the software upgrade is installed; ensure the notice is in a place likely to be seen/viewed. Actions planned by Philips to correct the problem A Philips representative will contact you to schedule time for a Field Service Engineer (FSE) to install a software upgrade to resolve the issue (reference 2026-PD-MR-006).
Quantity in Commerce	611
Distribution	Worldwide distribution - US Nationwide and the countries of Albania, Algeria, Andorra, Angola, Argentina, Australia, Austria, Bahamas, Bahrain, Bangladesh, Belarus, Belgium, Belize, Bolivia, Bosnia and Herzegovina, Brazil, Bulgaria, Canada, Cayman Islands, Chile, China, Colombia, Costa Rica, Côte D'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Estonia, Fiji, Finland, France, French Polynesia, Georgia, Germany, Ghana, Greece, Guadeloupe, Guernsey, Honduras, Hong Kong, Hungary, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Japan, Jersey, Jordan, Kazakhstan, Kenya, Korea, Republic of, Kuwait, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Lebanon, Libya, Lithuania, Luxembourg, Macao, Macedonia, Madagascar, Malaysia, Maldives, Malta, Martinique, Mauritius, Mayotte, Mexico, Moldova, Monaco, Mongolia, Montenegro, Morocco, Myanmar, Nepal, Netherlands, New Zealand, Nicaragua, Nigeria, Norway, Oman, Pakistan, Palestine, State of, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Réunion, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Syrian Arab Republic, Taiwan, Tanzania, Thailand, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Ukraine, United Arab Emirates, United Kingdom, Uzbekistan, Venezuela, Viet Nam, Yemen, Zambia;
Total Product Life Cycle	TPLC Device Report ²⁹

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)³⁰.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

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