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Class 2 Device Recall Ingenia



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Class 2 Device Recall Ingenia



Date Initiated by Firm	August 28, 2026
Date Posted	September 25, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-3310-2026
Recall Event ID	99834 ²³
510(K)Number	K183063 ²⁴ K193215 ²⁵ K213583 ²⁶ K223458 ²⁷ K251397 ²⁸ K251808 ²⁹
Product Classification	System, nuclear magnetic resonance imaging ³⁰ - Product Code LNH ³¹
Product	Ingenia Ambition S and Ingenia Ambition X.; Model number (REF): 1. 781359 (S), 2. 782108 (S), 3. 782139 (S), 4. 782159 (S), 5. 782194 (S), 6. 781356 (X), 7. 782109 (X), 8. 782138 (X), 9. 782160 (X), 10. 782195 (X); Software Versions: R11, R12 and R13;
Code Information	1. Model number (REF): 781359 (S); UDI-DI: 00884838090057; Serial Numbers: 48010, 48023, 48028, 48047, 48122, 48160, 48173, 48180, 48196, 48286; 2. Model Number (REF): 782108 (S); UDI-DI: 00884838098343; Serial Numbers: 48507, 48510, 48530, 48548, 48554, 48576, 48577, 48580, 48586, 48607, 48616, 48620, 48653, 48686, 48688, 48726, 48746, 48778, 48818, 48831, 48847, 48872, 48878, 48888, 48893, 48896, 48897, 48917, 48922, 48931; 3. Model Number (REF): 782139 (S); UDI-DI: 00884838108639; Serial Numbers: 29016, 29017, 29018, 29020, 29026, 29029, 29031, 29041, 29054, 29063, 29069, 29071, 29076, 29078, 29079, 29086, 29104, 29115, 29118, 29144, 29145, 29150, 29160, 29164, 29169; 4. Model Number (REF): 782159 (S); UDI-DI: 00884838115705; Serial Numbers: 91007, 91027, 91031, 91038, 91043, 91051; 5. Model Number (REF): 782194 (S); UDI-DI: 00884838128477; Serial Numbers: 22401, 22410; 6. Model Number (REF): 781356 (X); UDI-DI: 00884838090040; Serial Numbers: 47004, 47006, 47011, 47012, 47013, 47014, 47018, 47020, 47026, 47027, 47028, 47029, 47037, 47038, 47039, 47043, 47048, 47051, 47057, 47059, 47063, 47067, 47068, 47070, 47092, 47094, 47098, 47099, 47177, 47187, 47188, 47189, 47195, 47197, 47199, 47203, 47206, 47211, 47215, 47221, 47222, 47233, 47237, 47242, 47248, 47253, 47260, 47268, 47270, 47271, 47274, 47276, 47278, 47279, 47281, 47282, 47289, 47290, 47292, 47294, 47297, 47303, 47305, 47313, 47314, 47322, 47344, 47347, 47348, 47351, 47353, 47356, 47371; 7. Model Number (REF): 782109 (X); UDI-DI: 00884838098350; Serial Numbers: 47502, 47503, 47505, 47507, 47508, 47512, 47517, 47518, 47519, 47520, 47534, 47535, 47541, 47542, 47543, 47549, 47552, 47555, 47558, 47562, 47567, 47568, 47569, 47570, 47572, 47580, 47588, 47589, 47590, 47594, 47595, 47596, 47598, 47599, 47608, 47610, 47612, 47614, 47615, 47622, 47623, 47634,

47642, 47646, 47648, 47651, 47653, 47654, 47661, 47662, 47663, 47668, 47669, 47671, 47674, 47681, 47682, 47687, 47692, 47693, 47694, 47699, 47700, 47702, 47703, 47706, 47709, 47710, 47711, 47714, 47717, 47718, 47719, 47721, 47722, 47723, 47724, 47726, 47727, 47728, 47729, 47730, 47731, 47732, 47733, 47752, 47760, 47761, 47762, 47766, 47767, 47771, 47778, 47779, 47780, 47781, 47788, 47789, 47795, 47796, 47797, 47800, 47807, 47808, 47809, 47812, 47815, 47816, 47817, 47818, 47820, 47823, 47824, 47826, 47834, 47839, 47843, 47848, 47849, 47851, 47862, 47863, 47864, 47874, 47876, 47881, 47882, 47884, 47885, 47886, 47887, 47891, 47892, 47893, 47894, 47895, 47899, 47932, 47944, 47962;

8. Model Number (REF): 782138 (X);

UDI-DI: 00884838108622;

Serial Numbers: 49000, 49001, 49004, 49014, 49015, 49019, 49020, 49022, 49025, 49027, 49028, 49033, 49037, 49038, 49041, 49043, 49045, 49047, 49048, 49049, 49053, 49056, 49057, 49058, 49062, 49063, 49071, 49072, 49075, 49097, 49099, 49100, 49102, 49106, 49109, 49111, 49113, 49124, 49128, 49129, 49136, 49145, 49153, 49154, 49155, 49156, 49158, 49161, 49162, 49163, 49164, 49165, 49168, 49170, 49171, 49172, 49174, 49177, 49178, 49180, 49183, 49189, 49190, 49194, 49196, 49197, 49203, 49206, 49207, 49210, 49212, 49215, 49216, 49217, 49219, 49220, 49221, 49222, 49223, 49228, 49229, 49230, 49231, 49233, 49237, 49238, 49243, 49246, 49247, 49250, 49251, 49253, 49257, 49261, 49265, 49268, 49269, 49270, 49272, 49282, 49287, 49288, 49290, 49291;

9. Model Number (REF): 782160 (X);

UDI-DI: 00884838115712;

Serial Numbers: 92000, 92003, 92006, 92016, 92022, 92024, 92028, 92029, 92031, 92035, 92036, 92039, 92042, 92046, 92053, 92056, 92067, 92068, 92069, 92070, 92072, 92084, 92097;

10. Model Number (REF): 782195 (X);

UDI-DI: 00884838128484;

Serial Numbers: 55004, 55005, 55011, 55012, 55018, 55019, 55021, 55024, 55032;

FEI Number 3006648320

**Recalling Firm/
Manufacturer** Philips North America

222 Jacobs St

Cambridge
MA
02141-2296

**For Additional
Information Contact** 800-722-9377

**Manufacturer Reason
for Recall** When exporting diffusion tensor imaging (DTI) scans from a MR system using the Enhanced MR DICOM format, the exports contain incorrect data (diffusion directions). If the Enhanced MR DICOM export is used in conjunction with third-party software for tractography (e.g. for mapping nerve fiber pathways in the brain), the software will not be able to correctly process the DTI data for reconstruction.

**FDA Determined
Cause ²** Software design

Action On August 28, 2026, URGENT Medical Device Correction letters were sent to customers.
Actions to be taken:
1. To prevent the issue from occurring while Philips is developing the software solution, use the Classic DICOM transfer option for exporting DTI scans.
2. You may continue to use your system(s) in accordance with the intended use.
3. Circulate this notice to all users of this device so that they are aware of the issue and associated hazard/harm.
4. Please retain this Urgent Medical Device Correction letter with your system(s) until the software upgrade is installed; ensure the notice is in a place likely to be seen/viewed.

Quantity in Commerce 422

Distribution Worldwide distribution - Nationwide and the countries of Algeria, Argentina, Australia, Austria, Bangladesh, Belgium, Brazil, Canada, Chile, China, Colombia, Cyprus, Czech Republic, Denmark, Dominican Rep, Ecuador, Egypt, Equator. Guinea, Finland, France, French Guiana, Georgia, Germany, Ghana, Greece, Honduras, Hong Kong, Hungary, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kyrgyzstan, Latvia, Lebanon, Luxembourg, Malaysia, Malta, Martinique, Mauritius, Mexico, Moldova, Monaco, Morocco, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Norway, Pakistan,

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Total Product Life Cycle [TPLC Device Report](#)³²

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](#)³³.

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

[510\(K\)s with Product Code = LNH](#)³⁴

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