



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

## Class 2 Device Recall MR 5000 Series



[510\(k\)](#)<sup>7</sup> [DeNovo](#)<sup>8</sup> [Registration & Listing](#)<sup>9</sup> [Adverse Events](#)<sup>10</sup> [Recalls](#)<sup>11</sup> [PMA](#)<sup>12</sup> [HDE](#)<sup>13</sup> [Classification](#)<sup>14</sup> [Standards](#)<sup>15</sup>  
[CFR Title 21](#)<sup>16</sup> [Radiation-Emitting Products](#)<sup>17</sup> [X-Ray Assembler](#)<sup>18</sup> [Medsun Reports](#)<sup>19</sup> [CLIA](#)<sup>20</sup> [TPLC](#)<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

### Class 2 Device Recall MR 5000 Series



|                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Date Initiated by Firm</b>             | August 28, 2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Date Posted</b>                        | September 25, 2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Recall Status</b> <sup>1</sup>         | Open <sup>3</sup> , Classified                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Recall Number</b>                      | Z-3312-2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Recall Event ID</b>                    | <a href="#">99834</a> <sup>23</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>510(K)Number</b>                       | <a href="#">K223442</a> <sup>24</sup> <a href="#">K223458</a> <sup>25</sup> <a href="#">K251397</a> <sup>26</sup> <a href="#">K251808</a> <sup>27</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Product Classification</b>             | <a href="#">System, nuclear magnetic resonance imaging</a> <sup>28</sup> - <b>Product Code</b> <a href="#">LNH</a> <sup>29</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Product</b>                            | MR 5300;<br>Model number (REF): 1. 782110, 2. 782152, 3. 782156, 4. 782196;<br>Software Versions: R11, R12 and R13;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Code Information</b>                   | <p>1. Model number (REF): 782110;<br/>UDI-DI: 00884838099364;<br/>Serial Numbers: 63007, 63027, 63064, 63076, 63097, 63123, 63132, 63137, 63148, 63150, 63160, 63236, 63237, 63238, 63258, 63300, 63302, 63360, 63370, 63394, 63397, 63398, 63445, 63523, 63576, 63599, 63636, 63696, 63735, 63766, 63767, 63774, 63806;</p> <p>2. Model Number (REF): 782152;<br/>UDI-DI: 00884838112841;<br/>Serial Numbers: 69000, 69007, 69008, 69012, 69015, 69016, 69017, 69030, 69048, 69067, 69068, 69070, 69071, 69076, 69078, 69089, 69094, 69096, 69097, 69101, 69102, 69110, 69121, 69124, 69126, 69128, 69134, 69135, 69137, 69143, 69150, 69154, 69160, 69161, 69171, 69175, 69180, 69193, 69194, 69198, 69209, 69212, 69238, 69239, 69240, 69241, 69247, 69249, 69250, 69263, 69264, 69265, 69266, 69287, 69289, 69290, 69299, 69300, 69304, 69307, 69309, 69310, 69312, 69316, 69318, 69319, 69320, 69321, 69338, 69342, 69344, 69345, 69366, 69367;</p> <p>3. Model Number (REF): 782156;<br/>UDI-DI: 00884838115675;<br/>Serial Numbers: 93000, 93007, 93008, 93018, 93023, 93026, 93028, 93037, 93054, 93073, 93084, 93100, 93101, 93102, 93103, 93104, 93105, 93106;</p> <p>4. Model Number (REF): 782196;<br/>UDI-DI: 00884838128446;<br/>Serial Numbers: 54016, 54024, 54036, 54040, 54050, 54054;</p> |
| <b>FEI Number</b>                         | 3006648320                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Recalling Firm/Manufacturer</b>        | Philips North America<br><br>222 Jacobs St<br><br>Cambridge<br>MA<br>02141-2296                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>For Additional Information Contact</b> | 800-722-9377                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturer Reason for Recall</b>    | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>FDA Determined Cause <sup>2</sup></b> | Software design                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Action</b>                            | On August 28, 2026, URGENT Medical Device Correction letters were sent to customers.<br>Actions to be taken:<br>1. To prevent the issue from occurring while Philips is developing the software solution, use the Classic DICOM transfer option for exporting DTI scans.<br>2. You may continue to use your system(s) in accordance with the intended use.<br>3. Circulate this notice to all users of this device so that they are aware of the issue and associated hazard/harm.<br>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.                                                                                                                                                                                                                                                        |
| <b>Quantity in Commerce</b>              | 131                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Distribution</b>                      | 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, Palestine, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Fed., Saudi Arabia, Serbia, Singapore, Slovakia, South Africa, South Korea, Spain, Sweden, Switzerland, Syria, Taiwan, Thailand, Tunisia, Türkiye, United Kingdom, Uruguay, Utd.Arab.Emir., Uzbekistan, Vietnam. |
| <b>Total Product Life Cycle</b>          | <a href="#">TPLC Device Report</a> <sup>30</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

<sup>1</sup> 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](#)<sup>31</sup>.

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

<sup>3</sup> 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](#)<sup>32</sup>  
[510\(K\)s with Product Code = LNH](#)<sup>33</sup>

#### Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>

15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD\_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tpic.cfm
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start\_search=1&event\_id=99834
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K223442
25. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K223458
26. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K251397
27. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K251808
28. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LNH
29. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LNH
30. /scripts/cdrh/cfdocs/cfTPLC/tpic.cfm?id=LNH
31. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>
32. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start\_search=1&productcode=LNH&knumber=&applicant=Philips%20Medical%20Systems%20Nederland%20B%2EV%2E
33. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start\_search=1&productcode=LNH&knumber=&applicant=Philips%20Medical%20Systems%20Nederlands%20B%2EV%2E

Page Last Updated: 09/28/2026

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No FEAR Act](#) [Nondiscrimination](#) [Website Policies / Privacy](#)



U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)  
[Contact FDA](#)



[For Government For Press](#)

[Combination Products Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#) [Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry Health Professionals](#) [FDA Archive](#) [Vulnerability Disclosure Policy](#)



U.S. Department of **Health & Human Services**

#### Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm

16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD\_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start\_search=1&event\_id=99834
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K223442
25. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K223458
26. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K251397
27. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K251808
28. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LNH
29. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LNH
30. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=LNH
31. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>
32. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?  
start\_search=1&productcode=LNH&knumber=&applicant=Philips%20Medical%20Systems%20Nederland%20B%2EV%2E
33. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?  
start\_search=1&productcode=LNH&knumber=&applicant=Philips%20Medical%20Systems%20Nederlands%20B%2EV%2E