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Class 2 Device Recall Philips EPIQ Elite Diagnostic Ultrasound System



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Class 2 Device Recall Philips EPIQ Elite Diagnostic Ultrasound System



Date Initiated by Firm	August 07, 2026
Date Posted	September 18, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-3249-2026
Recall Event ID	99706 ²³
510(K)Number	K260123 ²⁴ K260680 ²⁵
Product Classification	System, imaging, pulsed doppler, ultrasonic ²⁶ - Product Code LYN ²⁷
Product	Philips EPIQ Elite Diagnostic Ultrasound System Model # 795234
Code Information	All Philips EPIQ Elite Ultrasound Systems running software version 14.0, UDI(s): (01)00884838102514 (01)00884838107540 (01)00884838114159 (01)00884838124912 (01)00884838128125
FEI Number	3019216
Recalling Firm/ Manufacturer	Philips Ultrasound, LLC 22100 Bothell Everett Hwy Bothell WA 98021-8431
For Additional Information Contact	Philips Image Guided Therapy Devices Customer Service 1800-228-4728
Manufacturer Reason for Recall	Due to software issue with ultrasound system, doppler sample is displayed shallower than its actual measurement location, potentially causing inaccurate blood flow velocity measurements and misdiagnosis.
FDA Determined Cause ²	Software Design Change
Action	On August 7, 2026, Philips issued a Urgent Medical Device Correction Notification to affected consignees. Philips requested consignees take the following actions: 1. Due to possibility of a weak PW Doppler Signal on EPIQ Elite running 14.0 SW, customers are advised not to use C5-1 Abd Vasc Tissue Specific Preset (TSP). Please use a different TSP (e.g., Abd Gen, Abd Renal) within C5-1. Please note that this issue (i.e., Weak PW Doppler signal) is restricted to the Abd Vasc TSP with C5-1 on EPIQ Elite running SW 14.0 only. 2. Otherwise, you may continue to use your device in accordance with the IFU. 3. Circulate this notice to all users of the device so that they are aware of the product issue and associated hazard / harm. 4. Post this notice near the affected unit(s) for ease of reference 5. Please return the completed response form at the end of this notice, indicating that information on this issue has been read and understood. Philips asks that you return the completed response form no later than 30 days from receipt of this letter.

Quantity in Commerce	219 units
Distribution	Worldwide - US Nationwide distribution in the states of AL, CA, CT, FL, GA, KS, MD, MN, NJ, NY, OH, PA, SC, TN, TX, VA, WA, WI and the countries of Austria, Denmark, Finland, France, Germany, Greece, Italy, Japan, Lithuania, Netherlands, Norway, Philippines, Poland, Romania, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, United Kingdom, Vietnam.
Total Product Life Cycle	TPLC Device Report ²⁸

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](#)²⁹.

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 = IYN](#)³⁰

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