



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

MAUDE Adverse Event Report: GE COROMETRICS FETAL MONITOR



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

GE COROMETRICS FETAL MONITOR

[Back to Search Results](#)

Model Number 250CX SERIES MATERNAL/FETAL MONI

Event Date 11/11/2015

Event Type Death

Event Description

Ge corometrics 250cx series maternal/fetal monitor produced inconsistent coincidence monitoring during high risk labor. The equipment failure may have been a contributory factor in the subsequent fetal demise. Used during labor until emergent c-section.

[Search Alerts/Recalls](#)²²

[New Search](#) | [Submit an Adverse Event Report](#)²³

Brand NameCOROMETRICS
Type of DeviceFETAL MONITOR
Manufacturer (Section D)GE
MDR Report Key5413568
Report NumberMW5060030
Device Sequence Number1
Product Code[HGM](#)²⁴
Report SourceVoluntary
Reporter OccupationRISK MANAGER
Type of ReportInitial
Report Date02/03/2016
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received02/03/2016
Is This A Product Problem Report?Yes
Device OperatorHealth Professional
Device MODEL Number250CX SERIES MATERNAL/FETAL MONI
Was Device Available For Evaluation?No Answer Provided
Is The Reporter A Health Professional?Yes
Was the Report Sent to FDA?
Event LocationNo Information

Was Device Evaluated By Manufacturer?No Answer Provided

Is The Device Single Use?No Answer Provided

Is this a Reprocessed and Reused Single-Use Device?Yes

Type of Device Usage

Patient TREATMENT DATA

Date Received: 02/03/2016 Patient Sequence Number: 1

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. <http://www.fda.gov/default.htm>
4. <https://www.fda.gov/MedicalDevices/default.htm>
5. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
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/MedicalDevices/Safety/ListofRecalls/default.htm>
23. <https://www.accessdata.fda.gov/scripts/medwatch/>

24. ../cfPCD/classification.cfm?start_search=&ProductCode=HGM

Page Last Updated: 01/31/2019

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](#) [Site Map](#) [Nondiscrimination](#) [Website Policies](#)



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](#)



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

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <https://www.fda.gov/MedicalDevices/default.htm>
5. <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmnm.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/MedicalDevices/Safety/ListofRecalls/default.htm>
23. <https://www.accessdata.fda.gov/scripts/medwatch/>
24. ../cfPCD/classification.cfm?start_search=&ProductCode=HGM