

# GE Healthcare Product Hold Notice

Product Hold Number	Local Hold Number	Revision	Status	Effective Date
DOC1623343	DOC1623343	7	Open	Monday, November 03, 2014

Site QA Leader or designee	Hold Owner	Hold Originator
Breitkreuz, Felix	Steffan, Uwe	Breitkreuz, Felix

Hold Type	Reason Category for Hold	Detailed Reason for Hold
Planned	Regulatory Clearance	Regulatory clearance hold for CardioSoft V6.7 Win8.

Reference Number(s) (if applicable)
DOC1403180 Regulatory Compliance Plan, DOC1616817 Marketing Readiness Plan

Product(s) / Assembly(s) on Hold
DVD CARDIOSOFT V6.73 SP2 DVD CS V6.73 SP2 PHTM INSTALLATION GUIDELINE CS ON CITRIX PHTM CARDIOSOFT LANGUAGE PACK US PHTM CARDIOSOFT LANGUAGE PACK ENG NON-US PHTM CARDIOSOFT LANGUAGE PACK GER PHTM CARDIOSOFT LANGUAGE PACK FRE PHTM CARDIOSOFT LANGUAGE PACK SPA PHTM CARDIOSOFT LANGUAGE PACK ITA PHTM CARDIOSOFT LANGUAGE PACK DAN PHTM CARDIOSOFT LANGUAGE PACK SWE PHTM CARDIOSOFT LANGUAGE PACK NOR PHTM CARDIOSOFT LANGUAGE PACK DUT PHTM CARDIOSOFT LANGUAGE PACK CHS PHTM CARDIOSOFT LANGUAGE PACK JPN PHTM CARDIOSOFT LANGUAGE PACK RUS PHTM CARDIOSOFT LANGUAGE PACK CZE PHTM CARDIOSOFT LANGUAGE PACK POL PHTM CARDIOSOFT LANGUAGE PACK HUN PHTM CARDIOSOFT LANGUAGE PACK POR PHTM CARDIOSOFT LANGUAGE PACK TUR PHTM CARDIOSOFT LANGUAGE PACK KOR PHTM CARDIOSOFT LANGUAGE PACK FIN PHTM CARDIOSOFT LANGUAGE PACK SLK PHTM CARDIOSOFT LANGUAGE PACK GRE PHTM CARDIOSOFT LANGUAGE PACK RUM PHTM CARDIOSOFT LANGUAGE PACK EST PHTM CARDIOSOFT LANGUAGE PACK HRV PHTM CARDIOSOFT LANGUAGE PACK SRP PHTM CARDIOSOFT LANGUAGE PACK LIT PHTM CARDIOSOFT LANGUAGE PACK SPA VENEZ PHTM CARDIOSOFT LANGUAGE PACK INDONESIAN PHTM CARDIOSOFT LANGUAGE PACK BRA POR PHTM CARDIOSOFT LANGUAGE PACK MEX SPA

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Part / Lot Serial Number(s) on Hold
2006301-037 2045295-013 2060450-012 2060450-401 2060450-402 2060450-403 2060450-404 2060450-405 2060450-406 2060450-407 2060450-408 2060450-409 2060450-410 2060450-411 2060450-414 2060450-415 2060450-416 2060450-417 2060450-418 2060450-419 2060450-420 2060450-421 2060450-422 2060450-423 2060450-424 2060450-425 2060450-426 2060450-427 2060450-428 2060450-429 2060450-430 2060450-431 2060450-432 2060450-433

Business(es) Affected	Applicable to	Input Source
DCAR	Distribution/Logistics/Demo Pool  <b>Other:</b> N/A	Regulatory Clearance

Hold Action(s)
The items affected by this hold can be shipped to those countries listed as Complete in the country list that is attached to DOC1623343 in MyWorkshop.

Hold Closure Criteria
The End of Life of the product CardioSoft V6.7 Win8 is reached.

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Hold Closure Objective Evidence
EOL documentation.

Expected Closure Date
Saturday, May 31, 2025

Site Affected	Site Hold Contact
HCS Freiburg	Breitkreuz, Felix
HCS Helsinki	Lehtinen, Jonna-Mari
HCS Juarez	Gonzalez, Armando

## Hold Change / Closure History

Revision	Change Description	Reason for Change
1	Initial Hold. Sales Orders 49016396 and 2160868 are released from hold.	See Reason for Hold. Released sales orders are destined for M3 sites.
2	Completed list of affected items. Following Sales Orders are released from hold: SO 2160245 SO 2160431 SO 2160868 SO 2160869	Language phantoms are affected items. Sales Orders for M3 sites.
3	Updated list of countries released from hold.	M4 has been signed off, Marketing Readiness Plan was revised.
4	Updated list of countries released from hold.	Marketing Readiness Plan was revised.
5	Updated status of French Oversea Territories. Replaced hold owner.	RCP and Marketing Readiness Plan were updated to include French Oversea Territories into France. Usual hold owner currently absent.
6	Released United States from hold.	Marketing readiness confirmed.
7	Updated country list.	Updates of Regulatory and Marketing Readiness.

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