



Technical Service Bulletin

Cardio Products

Welch Allyn, Inc.®
4341 State Street Road
Skaneateles Falls, New York 13153-0220 USA

Bulletin Type: As Needed

Tel: 1-315-685-4100 Fax: 1-315-685-4653
www.WelchAllyn.com

Date: 2012-09-26

SAP DIR #: 20013269

Subject: TSB-HRX00, SW, FW, SD-CARD MATRIX

CAR Number: N/A

Distribution Scope: WA Internal
WA Technical Support, Product Service, & International Service Centers

Product(s) Referenced: WA Holter HR100 & HR300, WA Holter Software PCHXXX CD

SW Version: WA Holter SW versions 1.4.0.2, 1.6.3.1, 1.6.4.0, 1.7.1.0

Serial No. / Lot Code: N/A

Summary: This TSB communicates a compatibility matrix for the WA Holter Recorder Firmware Versions, SD-Card sizes and Software Versions.
This bulletin (20013269) is based on Service Bulletin "SB-0038" issued by Global Instrumentation LLC to Welch Allyn.

Issue: The following tables communicate which individual WA Holter components, detailed above, are compatible with each other.

Action: No action required. The following tables are supplied for informational use only.

HR100 Firmware Compatibility Table:

HR100 Recorder Serial Number	HR100 Recorder Recommended Firmware Version
HR100-1000 through HR100-02749	Version 21
HR100-02750 through HR100-03699	Version 101
HR100-03700 or greater	Version 200

HR300 Firmware Compatibility Table:

HR300 Recorder Serial Number	HR300 Recorder Recommended Firmware Version
HR300-1000 through HR300-1582 HR300-1633 through HR300-1761 HR300-1772 through HR300-1796 HR300-1823 through HR300-1847	Version 25
HR300-1583 through HR300-1630 HR300-1764 through HR300-1769 HR300-1799 through HR300-1820 HR300-1849 or greater	Version 15

HR100 Firmware SD Card Size Compatibility Table:

HR100 Recorder Firmware Version	SD Card supported
Version 17	SanDisk 256MB
Version 18	SanDisk 256MB
Version 19	SanDisk 256MB or SanDisk 1GB
Version 20	SanDisk 256MB or SanDisk 1GB
Version 21 or later	SanDisk 256MB through SanDisk 16GB

HR100 Firmware SD Card Size Compatibility Table:

HR100 Recorder (EBT) Firmware Version	SD Card supported
Version 100 or later	SanDisk 256MB through SanDisk 16GB

HR100 Firmware SD Card Size Compatibility Table:

HR100 Recorder (LCD) Firmware Version	SD Card supported
Version 200 or later	SanDisk 256MB through SanDisk 16GB

HR300 Firmware SD Card Size Compatibility Table:

HR300 Recorder Firmware Version	SD Card supported
Version 18	SanDisk 256MB
Version 19	SanDisk 256MB or SanDisk 1GB
Version 20	SanDisk 256MB or SanDisk 1GB
Version 21	SanDisk 256MB or SanDisk 1GB
Version 22	SanDisk 256MB or SanDisk 1GB
Version 23	SanDisk 256MB or SanDisk 1GB
Version 24 or later	SanDisk 256MB through SanDisk 16GB

HR300 Firmware SD Card Size Compatibility Table:

HR300 Recorder Firmware Version	SD Card supported
Version 11 or later	SanDisk 256MB through SanDisk 16GB

PCHXXX CD Firmware Support list:

WA Software PCHXXX CD version 1.4.0.2 has firmware:

- HR100 Firmware Version 20
- HR300 Firmware Version 22

WA Software PCHXXX CD version 1.6.3.1 has firmware:

- HR100 Firmware Version 21
- HR100 (EBT) Firmware Version 100
- HR300 Firmware Version 25

WA Software PCHXXX CD version 1.6.4.0 has firmware:

- HR100 Firmware Version 21
- HR100 (EBT) Firmware Version 101
- HR300 Firmware Version 25

WA Software PCHXXX CD version 1.7.1.0 has firmware:

- HR100 Firmware Version 21
- HR100 (EBT) Firmware Version 101
- HR100 (LCD) Firmware Version 200
- HR300 Firmware Version 25
- HR300 (EBT) Firmware Version 15

Reference to Standards:

- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Updates:

N/A

Service Strategy:

Standard TSB Distribution

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Required Training: N/A

Required Tools: N/A

Required Materials: N/A

Quality Process for failed units or components: N/A

Procedure: N/A

Quality Documents: **All service centers using SAP to record service transactions:** For each product serviced, record the service activity in SAP.

All other service centers and Field Service: For each product serviced, complete and file a service report and attach to the service DHR.

Notes:

1. Contact the Welch Allyn Complaints Department to initiate or process a medical device complaint resulting from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

End of Bulletin

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	Initial Release	D*	SMB	D*	D*
D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL					