Technical Service Bulletin
Monitoring Products

Bulletin Type: As Needed

Subject: TSB-WA1500PM Main Software v1.1.3

Distribution Scope: WA ASP's and Distributors
WA Technical Support, Product Service Centers, Field Service and Authorized Service Providers

Product(s) Referenced: Welch Allyn 1500 Patient Monitor (WA1500PM)

Summary: WA1500PM main software version 1.1.3 has been released. This software version implements Italian, Dutch and Norwegian languages within the monitor software.

Additionally, version 1.1.3 corrects a problem that may cause the device to reset after 49 days of continuous operation. Note: this may have also generated a technical alarm after 49 days of continuous operation.

Reference to Standards:
- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Main SW v1.1.3 Release Notes:
- Add support for Italian, Dutch, and Norwegian
- Fix problem where unit was resetting after 49 days of continuous running (this fix was done by releasing a new version of the VBPDLLce.dll).

Service Strategy:
- Main software v1.1.3 is not to be installed by customers.
- Main software v1.1.3 is the new WA Product Service Center service and repair minimum and is to be installed by default on all monitors returned for service with Main software v1.1.2 or below. Monitors with Main software v1.3.0 or above do not require a software update.
Service Strategy (continued):

- Reference the device Service Manual for instructions on performing the main software update. See the Procedure section below for the manufacturer’s update verification.

- Record all changes to the monitor software versions or enabled license options on the Software Update Service Record provided in Appendix A of this TSB. The completed record shall be forwarded to the regional Product Service Center or Field Service Coordinator that supports the installation. The Product Service Center or Field Service Coordinator is responsible for ensuring this record is forwarded to SCHILLER and attached to a service notification or service report for each monitor.

Required Training:

Ensure training records for the following documents are updated, as applicable, for personnel engaged in service of the WA1500PM:

- 20012960 ver A, TSB-WA1500PM Main Software v1.1.3
- 30037422 ver J WA1500 Software Matrix

Procedure:

After successful update of the WA1500PM, proceed as follows:

1. Turn off the device
2. Remove the USB stick
3. Turn on the device
4. Check software version in setup configuration menu (Main 1.1.3)

Quality Documents:

All service centers using SAP to record service transactions: For each monitor serviced, record the service activity in SAP.

All other service centers and Field Service: For each monitor 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

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<th>Version</th>
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D* - Refer to SAP DIR digital signature log for approval details.
APPENDIX A:

软件更新服务记录
WA1500PM SW v1.1.3 更新

S/N: ________________________ (791.xxxxx)

记录更新前的配置

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确认更新后的变化:

- [ ] NA

MAIN:

- [ ] 1.1.3

许可证更改:

- [ ] NA

- [ ] Acuity 连接启用
- [ ] 12 导联静息 ECG 与测量启用
- [ ] 全心律选项启用
- [ ] 全心律和 ST 选项启用

评论:

- [ ] NA

名称

- 打印: __________________________
- 标题: __________________________
- 签名: __________________________
- 组织: __________________________
- 日期: __________________________ (yyyy-mm-dd)

转发此记录至 serkan.sezer@schiller.ch

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