**Technical Service Bulletin**

**Monitoring Products**

**Bulletin Type: As Needed**

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**Subject:**
TSB - WA1500PM Version 1.4 Release

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

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

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**Summary:**
WA1500PM version 1.4 has released. Version 1.4 is a global release that integrates the additional monitoring features introduced in version 1.3 with Acuity connectivity.

The WA1500PM features include: Cardiac Output, Hemodynamic and Drug Calculations, etCO₂ with Integrated Pulmonary Index (IPI), additional IBP and temperature channels, and support for Masimo SpO₂.

The WA1500PM version 1.4 is compatible with Acuity 8.20.x, but is not backwards compatible with Acuity 8.10.01 or below.

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

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**Main SW v1.4.0 Release Notes:**

*Changed Functions:*
- Support for interface to Welch Allyn's Acuity Central Station (release 8.20.x)
- Additional language support: Russian
**Fixes incorporated in release 1.4.0:**

- Enhancement to recorder (printer) performance
- Device response to corrupted settings file
- Feedback displayed to user for IBP zeroing status

**Updates:**

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**Service Strategy:**

- To support the installed base of Acuity, Welch Allyn Service will support two versions of the WA1500PM, versions 1.1 and 1.4. Version 1.1 maintains compatibility with both Acuity 8.10 and Acuity 8.20. Version 1.4 is compatible with Acuity 8.20 and above only.

- Main software 1.1.x will remain the service minimum software level. See the most recent 1.1.x TSB for details on this software release.

- Repair BOM **1500PM_RBOM** includes all materials, documents, and upgrades that are compatible with version 1.1 monitors.

- Main software 1.4.0 will supersede main software 1.3.0. Update all monitors that are returned for service with main software 1.3.0 to 1.4.0.

- Monitors with main software 1.1.x or below should only be updated to 1.4.0 at the customer’s request, as part of an upgrade, or as part of an Acuity 8.20 installation.

- Repair BOM **1500PM_1.3_RBOM** includes all materials, documents, and upgrades that are compatible with version 1.4 monitors.

- Service activities for the WA1500PM are to be documented in SCHILLER’s electronic DHR tracking tool. See the **SCHILLER Tracking Tool** section below for details.

- As part of an Acuity 8.20 installation, the Acuity option on the WA1500PM monitor may be enabled free of charge for all monitors being upgraded from main software 1.3.0 to 1.4.0.

- Distributors performing on-site software updates from 1.1.x to 1.4.0 may request a 2-IBP license key and an IPI license key (if CO\(_2\) is enabled on the monitor) from regional Welch Allyn Service to complete the update. Distributors performing Acuity-connection license keys for each stand-alone 1.3.0 monitor being upgraded to 1.4.0. The monitor specific Service ID is required to generate these license keys, which should be provided free of charge in the above scenarios.
Enabling Acuity License in 1.4.0:

For monitors with main software 1.4.0 installed, the following steps must be performed to enable the Acuity License. If performing an update to main software 1.4.0 where Acuity is to be enabled, follow these steps to execute the software update and licensing.

1. Navigate to the Setup > Administrator > Service menu and take note of all enabled license features on the device.
2. Install main software 1.1.3 in the unit.
3. Power up the unit running 1.1.3 and navigate to the Setup > Administrator > Service menu.
4. Select the option “Enable Acuity connection,” and enter the appropriate license key to enable the option.
5. Verify that the “Feature enabled” message appears after entering the key.
6. Install main software 1.4.0 in the unit.
7. Power up the unit running 1.4.0 and navigate to the Setup > Administrator > Service menu.
8. Enter the appropriate license keys to unlock the option(s) that were previously enabled on the unit. Options 6 through 10 will need to be re-enabled if they were enabled prior to installing main software 1.1.3.

   These options consist of: “Enable 2 IBP channels,” “Enable 4 IBP channels,” “Enable CO and 4 IBP channels,” “Enable second temperature,” and “Enable IPI.”
9. Verify that the “Feature enabled” message appears after entering each license key.
10. Document the final software and licensing configuration per the SCHILLER Tracking Tool section below.

SCHILLER Tracking Tool:

SCHILLER has released a web-based DHR tracking tool to capture changes to the monitor hardware and software configuration. Reference Work Instruction 20012982 version A for details.

For version 1.4 monitors, all changes to hardware and software configurations will be tracked in the SCHILLER Tracking Tool.

For version 1.1 monitors, only changes to hardware will be maintained via the Tracking Tool. Changes to software configuration will continue to be managed per the Software Update Service Record appended to the most recent version 1.1 TSB.

Welch Allyn Field Service and distributors performing software or license updates will download the monitor configuration file and forward it to the regional Field Service Coordinator for upload to the Tracking Tool.
v1.4 Upgrades:

When updating main software from 1.1.x or below to 1.4.x:

- Update the balance of monitor software per the latest version of the WA1500 Software Matrix, DIR 30037422.
- Enable the 2 IBP channels option in the Service Menu.
- Enable the IPI option in the Service Menu on all monitors equipped with CO₂.

The following upgrades are now supported for the WA1500PM. These upgrades will be performed at regional Product Service Centers, and can be applied to previous versions of the monitor or monitors already at version 1.4. The upgrade job-rate material and a brief description are listed here:

- UPG1500-CO-4IBP, Enable Cardiac Output and 4 IBP channels
- UPG1500-2TEMP, Enable the second temperature channel
- UPG1500NELL-MAS, Convert Nellcor SpO₂ to Masimo SpO₂
- UPG1500MAS-NELL, Convert Masimo SpO₂ to Nellcor SpO₂

When adding new version 1.4 features:

- If the monitor has a side panel that only supports one temperature and two IBP channels, replace the side panel with the appropriate 2TMP 4IBP side panel from the 1500PM_1.3_RBOM.
- If performing a SpO₂ conversion, reference the Converting the SpO₂ module chapter of the Service Manual for instruction.
- Update the main software to 1.4.x.
- Enable the appropriate software options per the 1500PM Option Configuration W/I, DIR 20012186.
- Cover any inactive parameter connectors with blanking covers.
- Unless otherwise indicated by the Service Manual, the material number label on the device does not need to be updated. If the REF / patent label (material 4.120541) is replaced as part of an upgrade or repair, no additional material number label replacement is required.
Masimo Module Replacement: Upon replacement of a Masimo MX-3 module, the new module must be enabled with the Masimo Factory Enabler. To enable the Masimo module, follow these steps:

1. Power the monitor on.
2. Insert the Masimo Factory Enabler into the monitor's Masimo SpO₂ port.
3. The LED indicator on the Masimo Factory Enabler will be solid orange during the programming process.
4. If successful, the Masimo Factory Enabler generates one audible beep and the LED is solid green. If the update fails, the LED will flash red.
5. Remove the Masimo Factory Enabler from the monitor, and power the monitor off.

If enabling the module was not successful, repeat the above process. Reference the Masimo Factory Enabler Directions for Use for additional troubleshooting.

Main Board Replacement: Replacement of the ZM2-1 main board, material 3.2810, in Masimo-equipped monitors requires a new main board with index G or later. This revision included additional connectors for compatibility with the Masimo MX-3 module.

Required Training: Ensure training records for the following documents are updated for all personnel engaged in the service and repair of the WA1500PM:

- 20013007 ver B, TSB-WA1500PM Version 1.4 Release
- 30037422 ver K, WA1500 Software Matrix
- 20012982 ver A, W/I, Service, SCHILLER Tracking Tool

New Service Materials: The following new service parts have been released for the WA1500PM:

- 2.100793, SVC,1500PM,NELLCOR MODULE INSTALL KIT
- 2.100794, SVC,1500PM,MASIMO MODULE INSTALL KIT
- 4.240034, SVC,1500PM,RUBBER HEAT SINK PAD (5MM)
- 4.240035, SVC,1500PM,RUBBER HEAT SINK PAD (3MM)
- 2.523078, SVC,1500PM, SERIAL NUMBER LABEL

Note: material 2.523078 is a made-to-order replacement label. Welch Allyn will need to provide the monitor serial number to SCHILLER at the time of ordering.
The following two loaner materials may be used for tracking and managing a version 1.4 loaner pool. Existing version 1.3 loaners should be updated to version 1.4.

- 1500V1_3M-L, LOANER,1500PM,VERSION 1.3,MASIMO
- 1500V1_3N-L, LOANER,1500PM,VERSION 1.3,NELLCOR

See the Service Manual and applicable Repair BOMs for a comprehensive list of service parts and version compatibility.

**Procedure:**

Upon 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 SW-Version in setup configuration menu:
   - Main - 1.4.0

**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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| A       | Initial Release  
- Per MPD SOP-20155 Rev. 5, D* statement below has been modified to meet compliance requirements until this template is updated | D* | CB | D* | D* |
| B       | Added Section: Enabling Acuity License in 1.4.0 | D* | CB | D* | D* |

**D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL**