



**Technical Service Bulletin**

**Blood Pressure Products**

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**Bulletin Type: As Needed**

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**Subject:** TSB – ProBP 3400 Regulatory Marking Update

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

**Product(s) Referenced:** ProBP 3400

**Summary:** Regulatory markings on the ProBP rear housing and battery door have been updated for product registrations in South Korea and China.

**Action:** The rear housing artwork has been updated to include “Made in USA.” The updated rear housing will be structured to all production BOMs and the 104128 Rear Housing Service Kit upon consumption of the remaining stock of the previous version.

**Updated Rear Housing:**



New artwork has been added to the battery door for product registration in China. The updated battery door has been structured to all production BOMs and the 3400-100 Battery Door replacement kit.

#### Updated Battery Door:



- All devices shipping into China must have an updated battery door with the Chinese characters shown above. As necessary, replace the battery door with the updated version prior to shipping a service device into China.
- For all devices shipping into South Korea, install an updated rear housing with the “Made in USA” text, upon distribution of the updated housing. Distribution of the updated housing is currently expected to begin in May 2012.

**Note:** For the Service Center managing South Korea, it is recommended to update all ProBP exchange devices with the “Made in USA” rear housing.

#### Reference to Standards:

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

#### Required Training:

All personnel engaged in the service and repair of the products referenced should complete a read and sign of this service bulletin.

#### 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**

<b>Revision History</b>					
<b>Version</b>	<b>Description</b>	<b>Change #</b>	<b>Init</b>	<b>Release Date</b>	<b>Appr</b>
A	TSB-ProBP 3400 Regulatory Marking Update	D*	CB	D*	D*
D* - Refer to SAP DIR digital signature log for approval details.					