



Technical Service Bulletin

Blood Pressure Products

Welch Allyn, Inc.®
8500 SW Creekside Place
Beaverton, Oregon 97008-7107 USA

Bulletin Type: As Needed

Tel: 1-800-289-2501 Fax: 1-503-526-4910
www.WelchAllyn.com

Date: 2011-09-06

SAP DIR #: 20012699

THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

It can be distributed or made available to only those individuals, companies, and organizations which have current Welch Allyn Confidentiality Agreements, and have a need to know.

- Subject:** TSB - ProBP 3400 Serial Number Label Replacement
- Distribution Scope:** WA Internal
WA Product Service & International Service Centers
- Product(s) Referenced:** ProBP 3400
- Summary:** This Service Bulletin defines the service requirements for replacement of the serial number labels on the ProBP 3400.
- Action:** Reference the **Service Strategy** section below when replacement of the serial number labels is required.
- Reference to Standards:**
- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Service Strategy:

The ProBP 3400 has two serial number labels adhered to the rear housing, as shown below. The exterior serial number label is located in a recess on the bottom of the device. The interior serial number label is located in a recess inside of the battery well and is normally covered by the battery door. Each of these labels contains the device reference number and serial number.

Exterior label:



Interior label:



During the course of repair, replacement of the serial number labels may be required, due to replacement of the rear housing or damage to the label itself.

Exterior label replacement:

Material 408594 has been released as a service-only exterior label replacement. This exterior serial number label can be printed using the ZLABEL transaction in SAP and a Zebra GX430t thermal printer. See the **Required Materials** section below for the label stock and ribbon requirements. The replacement exterior label should be applied to the device in the location and orientation shown above.

Interior label replacement:

Replacement of the interior label is not required. The information contained on this label is a duplicate of the exterior label, and the exterior label meets all requirements for device labeling for the ProBP 3400.

Required Training:

Welch Allyn employees and contractors engaged in the service and repair of the ProBP 3400 shall be trained to the contents of this bulletin.

Required Tools:

- 20017152, Zebra GX430t thermal printer

Required Materials:

- 716452, LABEL 1.5 X 1 (38.1 X 25.4mm), 2 PART
- 714171, RIBBON PERFORMANCE RESIN BLACK ROL

Note: Ribbon materials 714171 and 713100 are equivalent per their specification documents. Material 714171 was created to change the SAP unit of measure to ROLL, instead of CASE.

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

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	Initial Release	D*	CB	D*	D*
D* - Refer to SAP DIR digital signature log for approval details.					