



Technical Service Bulletin

Blood Pressure Products

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Bulletin Type: Information Only

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Subject: TSB-ProBP 3400 Software Version 1.02.00

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

Product(s) Referenced: ProBP 3400

SW Version: 1.02.00

Summary: Software version 1.02.00 has been released for the ProBP 3400 device. This software version was implemented in production of ProBP devices on 2011-02-25.

Issue: Multiple opportunities to enhance the ProBP 3400 functionality and interface were identified for this release. These enhancements include changes to Bluetooth implementation and minor user interface improvements.

Action: To enhance the Bluetooth functionality, the 1.02.00 software implements the Simple Secure Pairing (SSP) protocol for Bluetooth. This protocol improves the security of data transmitted over Bluetooth, and may reduce pairing issues in the field. Differences between pairing via the SSP protocol and the legacy Bluetooth protocol are described in the Procedure section below.

Software version 1.02.00 also includes minor improvements to the user interface. Clinical operation of the device and the menu structure are unchanged. Changes to the device UI include:

- Time format and date format have been moved so the format is selected prior to setting the time or date.

- Close button has been removed from the Cycle Count screen.
- Minor changes to on-screen text and coloration for clarity.

Reference to Standards:

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

Updates:

Technical Manual	<input type="checkbox"/>	Repair Tool	<input type="checkbox"/>
Service Plan	<input type="checkbox"/>	Internet/Intranet	<input type="checkbox"/>
Procedures	<input type="checkbox"/>	Price List	<input type="checkbox"/>
Training Material	<input type="checkbox"/>	Other	

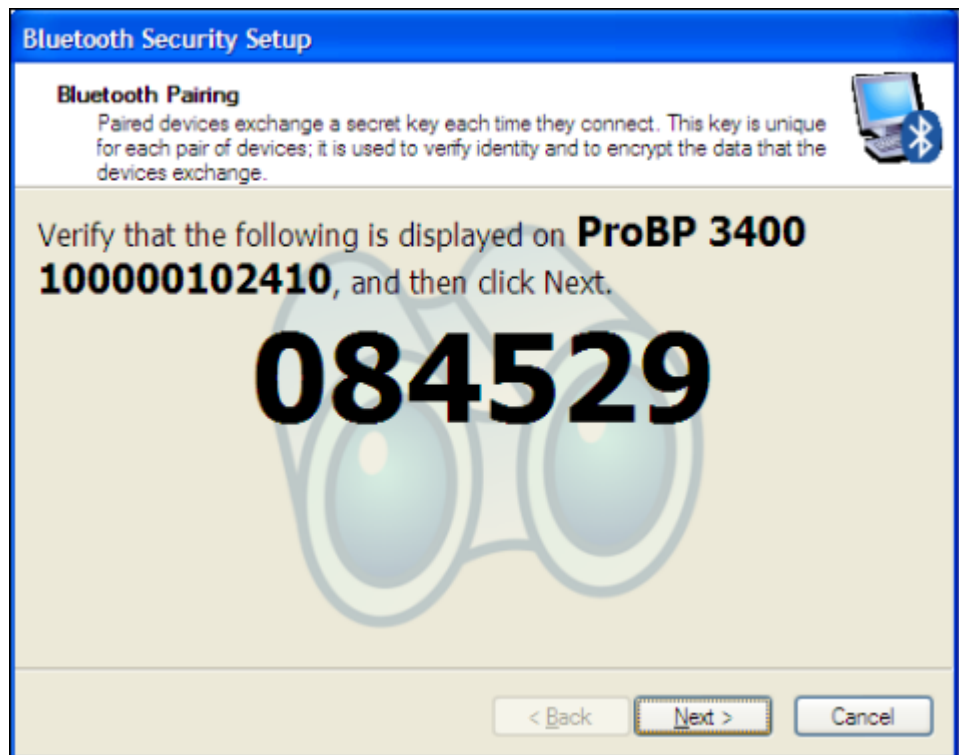
Service Strategy:

Software updates may be pushed out to customers via PartnerConnect and the Welch Allyn Service Tool. Use the service tool to verify the current host firmware version on the device.

Procedure:

Pairing with Simple Secure Pairing (SSP):

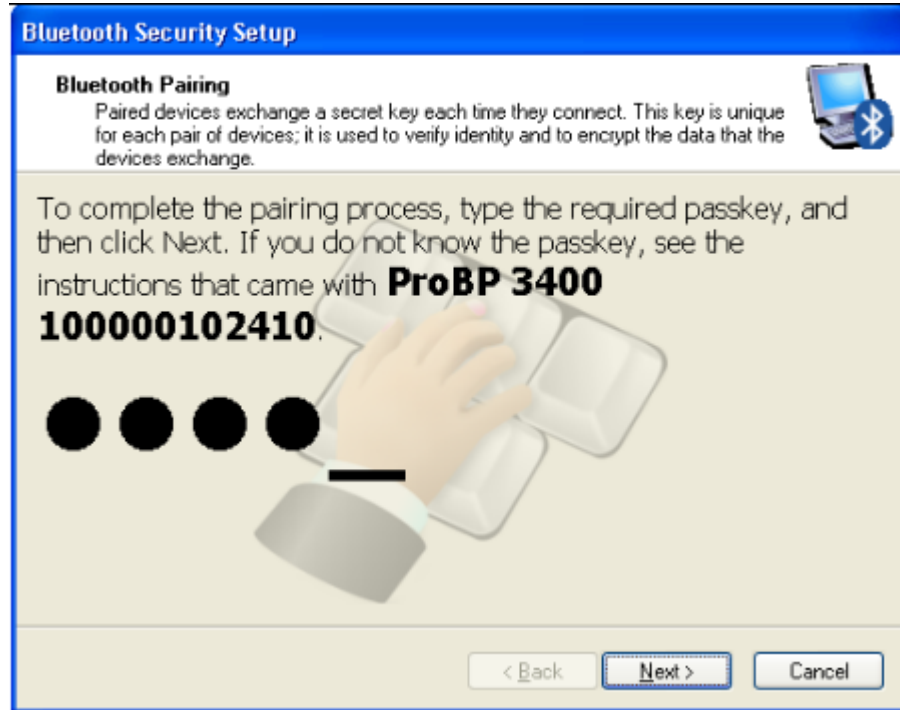
When pairing a ProBP 3400 device with software version 1.02.00 to a PC utilizing Bluetooth version 2.1 or above, the devices will pair per the SSP protocol. While pairing, the PC will display a number, and prompt the user to verify the same number is displayed on the ProBP device.



If the device displays the same code as the PC, the user should continue the pairing process.

Pairing with Bluetooth legacy pairing:

When pairing a ProBP 3400 device with software version 1.02.00 to a PC utilizing Bluetooth version 2.0 or below, the devices will pair per the legacy Bluetooth pairing protocol. Additionally, pairing of a ProBP device with software version 1.00.00 to any PC will utilize this pairing protocol. While pairing, the PC will prompt for a passkey (PIN).



At this point, the user should enter “1234” and continue the pairing process.

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	TSB-ProBP 3400 Software Version 1.02.00	D*	CB	D*	D*
D* - Refer to SAP DIR digital signature log for approval details.					