


Title: OEM ProBP 3400 SW LICENSE		Document Number: 70022245	
		Version: A	
Department: Low End Vitals(LEVI)			Area: Skaneateles
Document Type: MFG-OEM		Standard Element: N/A 21 CFR Part 820.70 Production & Process Controls ISO 13485:2003, 7.5.1, Control of Production and Service Provision 93/42/EEC, Medical Device Directive – European SOR/98-282, Canadian Medical Device Regulation - CMDR	
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Parent Document: MPD SOP-20070, Production and Process Control			

1.0 Purpose

This document defines ProBP 3400 Digital Blood Pressure Device Software Licensing (SW) for variant configuration modeling.

2.0 Scope

This document covers Software Licensing (SW) ProBP 3400 Digital Blood Pressure Device products and options sold by Welch Allyn. This document is subject to MPD WI-6407, Create Engineering Change Request, and any changes must be Change Order approved.

3.0 Responsibilities

The engineering representative, in coordination with marketing, customer service, and technical service is responsible for maintaining this document.

4.0 Definitions

ERP: Enterprise Resource Planning

BOM: Bill of materials

5.0 Safety & Environment

N/A

6.0 Associated Documents

6.1 Parent Document: MPD SOP-20070, Production and Process Control

6.2 MPD WI-6407, Create Engineering Change Request

Reason for Change:

Version	Sec/Para Changed	Change Made	Date
A	D*	Release to Production	2010-08-31

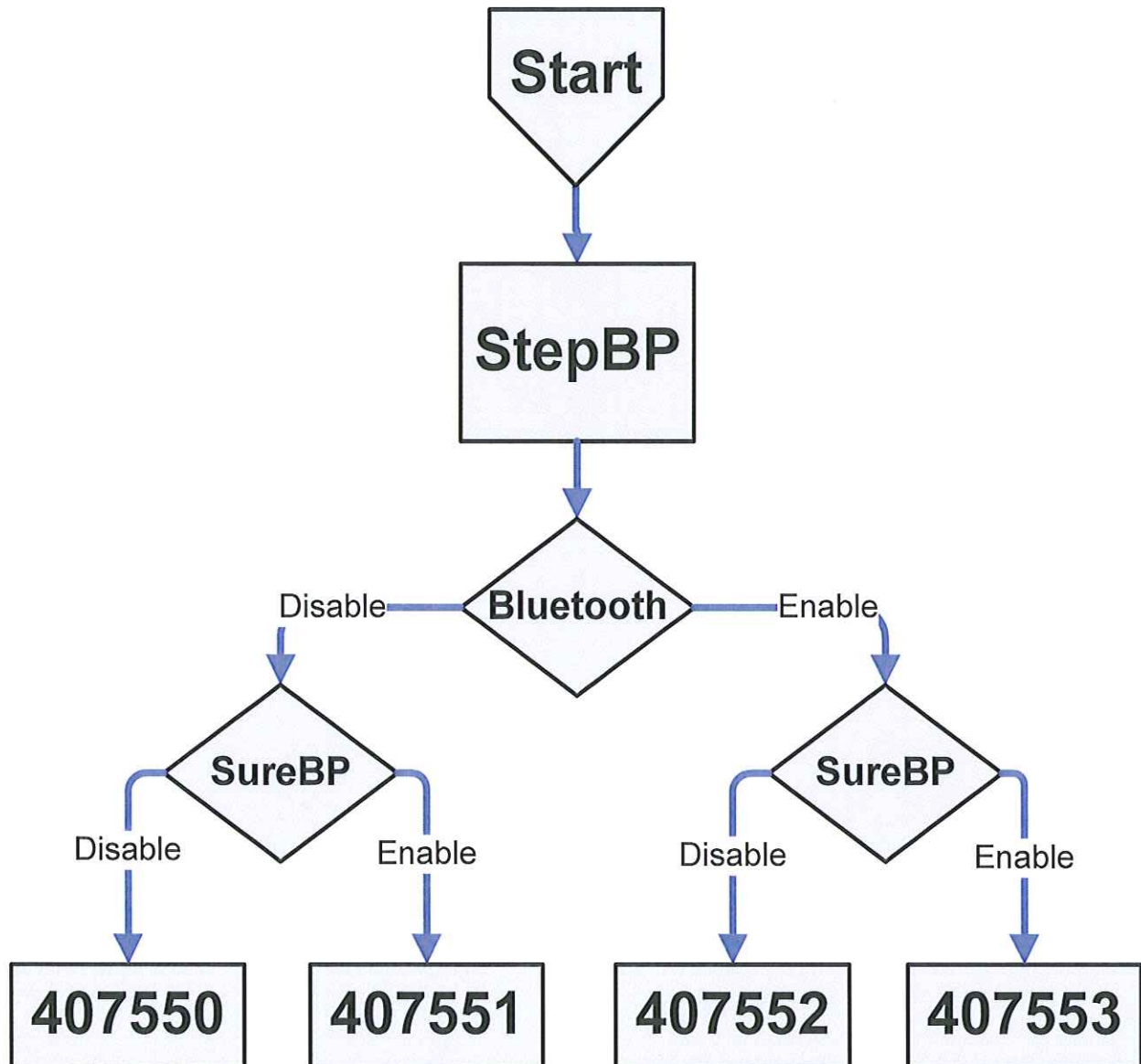
Department/ Function	Required Approvers (or authorized delegate, D*)	Date
R &D Engineering		
Marketing		
Customer Service		
Service Engineering		
Operations		
Quality Representative	D*	D*
Regulatory Affairs		
Variant Configuration Coordinator	<i>Linda Gerrard Linda Gerrard</i>	<i>2010-09-13</i>

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

ProBP 3400 Material and License Options Definition:

Model	Description	StepBP	SureBP	Bluetooth
407550	PROBP 3400 STANDARD	X		
407551	PROBP 3400 SUREBP	X	X	
407552	PROBP 3400 BLUETOOTH	X		X
407553	PROBP 3400 SUREBP & BLUETOOTH	X	X	X

- All ProBP 3400 models manufactured will be defined with a corresponding equipment masters. Update SAP table ZEQUIMATNR with models.



SAP Classification for Software License:

Classification

Classification	PROBP3400
Characteristics	PROBP3400_OPTIONS
	LICENSE_OPTIONS
	LICENSE_OPTIONS_GRP

Characteristics

PROBP3400_OPTIONS	
Char Value	Description
B	Bluetooth
0	No Bluetooth & No SureBP
S	SureBP
BS	Bluetooth & SureBP

LICENSE_OPTIONS_GRP	
Char Value	Description
ProBP 3400	ProBP 3400

LICENSE_OPTIONS		
License	Char Value	Description
Enable StepBP	PROBP_STEPBP	PROBP_1_0xFFFFFFFF
Enable SureBP	PROBP_SUREBP	PROBP_2_0xFFFFFFFF
Enable Bluetooth	PROBP_BLUETOOTH	PROBP_3_0xFFFFFFFF
Disable SureBP	PROBP_SUREBP_DISABLE	PROBP_2_0X00000000
Disable Bluetooth	PROBP_BLUETOOTH_DISABLE	PROBP_3_0X00000000

- All characteristic values are case specific.