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Author: Michael Banks

Version	Sec, Pg, Para Changed	Change Made	Date Version Created	Version Created By (initials)
A	All	Initial release	2015-02-11	MEB
B	TOC Sect 3 Sect. 4 4.2.2 and 4.2.3 Sect 4.3.1 Sect 4.5.1 Sect 4.6.1 Sect 4.9	<ol style="list-style-type: none"> 1. Updated TOC 2. Replaced 80019843 with 80020120. 3. Update Tools and equipment reference to “Data sheet” in section 4.9 not 5.8. 4. Added Record Firmware version and Release date in the Data sheet comment 5. Connect to 500 ml (CC) port. Added set up drawing that was omitted. 6. Connect to 500ml (CC) port. 7. Connect to 500ml (CC) port. 8. Updated Data sheet by: <ul style="list-style-type: none"> - Adding Firmware version and release dates into the data sheet - adding formulas for Leakage and Deflation rates test - Add initials, Date and S/N field to data sheet. 	2015-04-15	MEB

See SAP for Change Number, Approver(s) Name, and Date(s) of Approval.

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1. PURPOSE

This Work Instruction details how to perform an evaluation and calibration of the PROBP-2400 device.

2. SCOPE

The steps and procedures in this work instruction apply to PROBP-2400.

3. REFERENCE DOCUMENTS

80020120	DFU PROBP 2400
PROBP2400_RBOM	PROBP 2400 REPAIR BOM

4. VERIFICATION and CALIBRATION

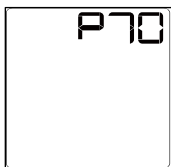
4.1 Tools and equipment:

Manometer	SETRA DATUM 2270 or equivalent
Tubing	As needed
350-500 ml vessel	401028, 407672 or equivalent
Squeeze bulb or pressure system	OTS parts
Hemostats (non-serrated)	OTS hand tools=
“T” connectors	OTS parts
Timer or Stopwatch	OTS
Data sheet	Section 4.9
DFU	80020120

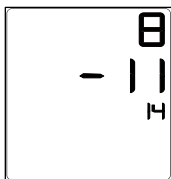
4.2 How to place the PROBP-2400 into Calibration Mode

4.2.1 Push and hold “Start/Stop” button while powering on the UUT. After the UUT powers up, continue to hold the “Start/Stop” button.

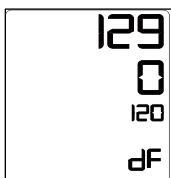
4.2.2 The firmware version displays. Record the version in the data sheet:



4.2.3 Then the firmware release date. Record the Release date in the data sheet:

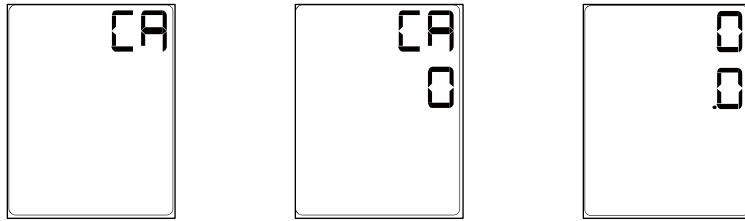


4.2.4 EEPROM setting and parameter of deflation rate next display:




EXAMPLE: “129 0” for EEPROM setting and “120 dF” for parameter setting of deflation rate.

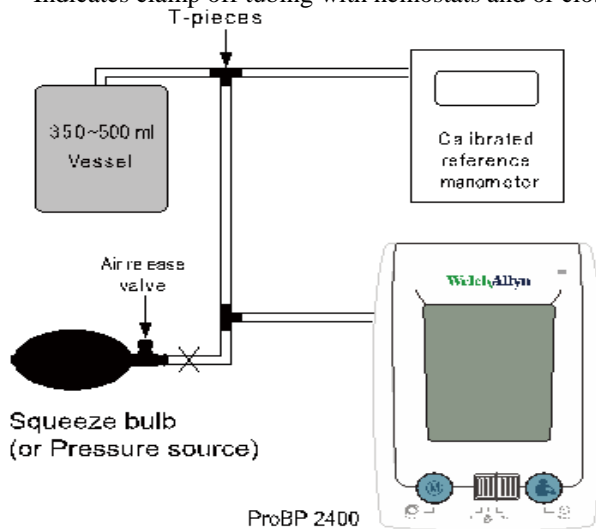
4.2.5 Lastly, the “CA”, then “CA 0” and finally “0 .0” display:



4.3 Static Accuracy test

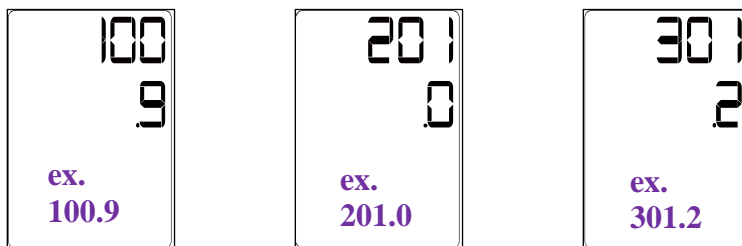
4.3.1 Connect the equipment as shown below: Connect to 500ml (CC) port.


NOTE:  Indicates clamp off tubing with hemostats and or close air release valve when increasing pressure.



NOTE: If difference between device and reference manometer at each calibration point exceeds +/- 3mmHg adjust the pressure parameter to calibrate device following process in step 4.4. If the measurements are all in tolerance, go to Step 4.5.

- 4.3.2 Increase pressure to 300 mmHg (+/- 5mmHg) as read on the reference manometer.
- 4.3.3 Record the UUT pressure on the sheet in section 4.9
- 4.3.4 Adjust the pressure for 200 mmHg (+/- 5mmHg) as read on the reference manometer.
- 4.3.5 Record the UUT pressure in on the sheet in section 4.9
- 4.3.6 Adjust the pressure for 100 mmHg (+/- 5mmHg) as read on the reference manometer.
- 4.3.7 Record the UUT pressure in on the sheet in section 4.9.



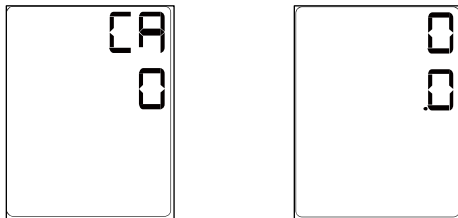
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4.4 Pressure Calibration Adjustment process

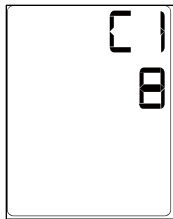
NOTE: Range calibration adjustment - When adjusting each range you can only increase the number. Once you reach the top of the range (20) when you increase again it will start over @ zero, then 1, 2, etc....

4.4.1 Power down the unit.

4.4.2 Push and hold “Start/Stop” button to power on device until “CA 0” then “0 .0” displays for adjusting pressure parameters.



4.4.3 Push “M” button. “C1 8” displays and 8 flashes. An “8” is an example for pressure parameter at 100mmHg.

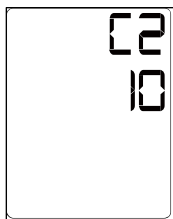


4.4.4 A “C1” indicates first calibration point which is at 100mmHg.

4.4.5 Push “M” button to incrementally increase the number. The range is from 0 to 20 (refer to **Note: Range calibration adjustment above**).

4.4.6 Push “Start/Stop” button to confirm number.

4.4.7 Push “M” button again. “C2 10” displays and 10 flashes. A “10” is an example for pressure parameter at 200mmHg.

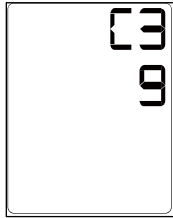


4.4.8 “C2” indicates second calibration point which is at 200mmHg.

4.4.9 Push “M” button to incrementally increase the number The range is from 0 to 20 (refer to **Note: Range calibration adjustment above**).

4.4.10 Push “Start/Stop” button to confirm number.


4.4.11 Push “M” button again. A “C3 9” displays and 9 flashes. This “9” is an example for pressure parameter at 300mmHg.

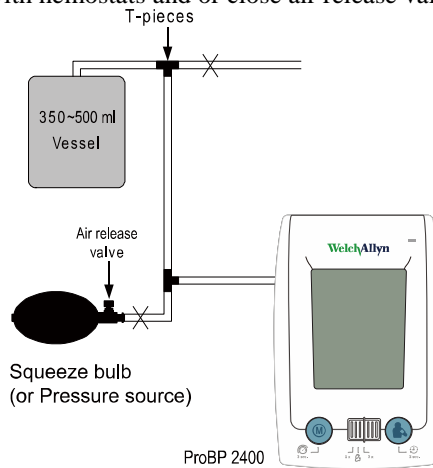


- 4.4.12 The “C3” indicates third calibration point which is at 300mmHg.
- 4.4.13 Push “M” button to incrementally increase the number. The range is from 0 to 20 (refer to **Note: Range calibration adjustment above**).
- 4.4.14 Push “Start/Stop” button to confirm number.
- 4.4.15 Perform Step 4.3 to make sure all ranges are in calibration.

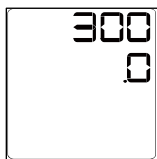
4.5 Leakage test

- 4.5.1 Connect the equipment as shown below. Use the hemostats to clamp off the tubing where the manometer was. Connect to 500ml (CC) port.


NOTE:  Indicates clamp off tubing with hemostats and or close air release valve when increasing pressure.

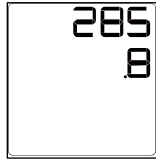


- 4.5.2 Push and hold “Start/Stop” button while powering on the UUT. After the UUT powers up, continue to hold the “Start/Stop” button until “0 .0 CCC” displays. This should take approximately 15 seconds
- 4.5.3 Push “Start/Stop” button to start the pump. The pump will stop @ 300mmHg.



- 4.5.4 Wait 1 minute for pressure stabilization.
- 4.5.5 Record the UUT reading as “Start pressure” ((S);Example, “285.8”) on the sheet in Section 4.9.

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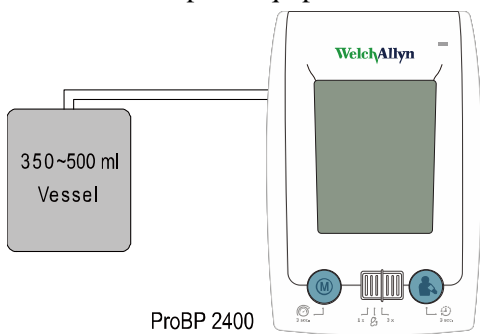
- 4.5.6 Start the stop watch and at the end of 5 minutes, stop the stop watch.
- 4.5.7 Record the UUT reading as “End pressure” ((E);Example, “280.2”) on the sheet in Section 4.9.



- 4.5.8 Calculate Leakage (Start pressure – End pressure) / 5 = Leakage of air (mmHg/min.).
Example = (285.8mmHg-280.2mmHg)/5min. = 1.12 mmHg/min.
- 4.5.9 The result must be ≤ than 6 mmHg/min to pass.

4.6 Deflation rate test


- 4.6.1 Set up the equipment as shown below. Connect to 500ml (CC) port.:



- 4.6.2 Power on UUT.
- 4.6.3 **Set UUT to 《1x》 mode.**
- 4.6.4 Set maximum inflation pressure at 240mmHg by:
 - 4.6.4.1 Holding the M Button for 3 seconds until the column with pressure values flashes.
 - 4.6.4.2 Press the Start/Stop Button to select the preferred pressure 240 mmHg.
- 5.2.1.1 Press the M Button to confirm the selected value.
- 4.6.5 Push “Start/Stop” button to obtain a measurement. Pressure increases to 240mmHg.
- 4.6.6 When the pressure drops to 180 mmHg start the stop watch.
- 4.6.7 When the pressure reaches 60 mmHg, stop the stop watch.
- 4.6.8 Record the time (T) in seconds
- 4.6.9 Calculate the Deflation rate (DR) using the formula:”

$$DR = (180 \text{ mmHg} - 60 \text{ mmHg})/T$$
 Example: If T is 22.9 seconds.

$$DR = 120/22.9 \text{ or a DR of } 5.24\text{mmHg/sec.}$$
- 4.6.10 Record the DR and Pass/Fail in the sheet in Section 4.9
Calculated results should be between 2 to 6 mmHg to pass.

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NOTE: If the “Err 1” message appears, this indicates “the pulse signals on the cuff are too weak”. It displays because the unit is not connected to a patient.

4.6.11 Set UUT to 《manual》 Mode”.

4.6.12 Push “Start/Stop” button to obtain a measurement.

4.6.13 Pressure increases to 240mmHg deflates.

4.6.14 When the pressure drops to 180 mmHg start the stop watch.

4.6.15 When the pressure reaches 60 mmHg, stop the stop watch.

4.6.16 Record the time (T) in seconds

4.6.17 Calculate the Deflation rate (DR) using the formula:”

$$DR = (180 \text{ mmHg} - 60 \text{ mmHg})/T$$

Example: If T is 38.5 seconds.

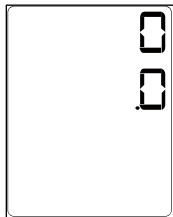
$$DR = 120/38.5 \text{ or a DR of } 3.12\text{mmHg/sec.}$$

4.6.18 In 《manual》 mode, the deflation rate must be between 2 to 4 mmHg to pass the test.

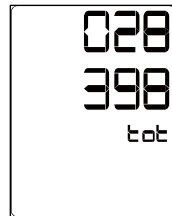
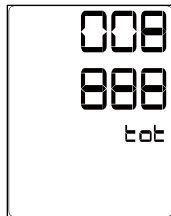
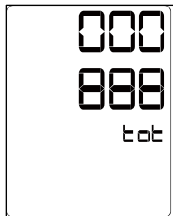
4.6.19 The unit deflates automatically then goes to stand-by when the cuff pressure less than 20 mmHg.

4.7 Cycle counter

4.7.1 Push and hold “Start/Stop” button while powering on the UUT. After the UUT powers up, continue to hold the “Start/Stop” button until “0 .0” displays. This should take approximately 10 seconds.



4.7.2 Push and hold “Start/Stop” button again for approximately 7 seconds until total number of measurements performed displays.



EXAMPLE: “000 088 tot” displays.


“tot” = Total.

“000 888” = Indicates the measurements performed is 888”.

“008 888” = Indicates 8,888 measurements.

“028 398” = Indicates 28,398 measurements.

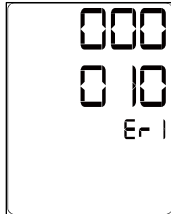
The counter records up to 999,999 measurements and **can’t** be deleted.

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4.7.3 Record the **Cycle Counts** in the data sheet

4.7.4 Push “M” button for numbers of Error 1s to display.

“000 010 Er 1” indicates Error 1 was recorded 10 times as shown below.



4.7.5 Record this Er 1 information in the data sheet

4.7.6 Push “M” button again to reveal number of Error 2s to display.

“000 004 Er 2” indicates Error 2 was recorded 4 times as shown below.



4.7.7 Record Er 2 information in the data sheet

4.7.8 Push “M” button again to reveal number of Error 3s to display.

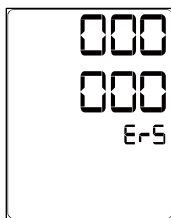
“000 009 Er 3” indicates Error 3 was recorded 9 times as shown below.



4.7.9 Record Er 3 information in the data sheet


4.7.10 Push “M” button again to reveal number of Error 5s to display.

“000 005 Er 5” indicates Error 5 was recorded 0 times as shown below.



4.7.11 Record Er 5 information in the data sheet

4.7.12 Push “Start/Stop” button to stand by.

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4.8 Troubleshooting and Error Messages

- 4.8.1 Troubleshooting table is located in the DFU on page 29.
- 4.8.2 Error Messages table is located in the DFU on page 29 and 30.

4.9 ProBP2400 data sheet

Manometer: Asset #: _____		Calibration Due Date: _____	
Firmware version: _____		Firmware Release Date: _____	
Device S/N: _____			
PRE Technical Check		Post Technical Check	
_____	_____	_____	_____
Date	Technician Initials	Date	Technician Initials
Static Pressure test Pass <input type="checkbox"/> Fail <input type="checkbox"/>		Static Pressure test Pass <input type="checkbox"/> Fail <input type="checkbox"/>	
(maximum difference +/- 3mmHg)		(maximum difference +/- 3mmHg)	
Reference unit (in mmHg)	UUT (in mmHg)	Difference (in mmHg)	
_____ - _____	= _____	mmHg	
Reference 300(+/-5) -	Displayed	= Difference	
_____ - _____	= _____	mmHg	
Reference 200(+/-5) -	Displayed	= Difference	
_____ - _____	= _____	mmHg	
Reference 100(+/-5) -	Displayed	= Difference	
Leakage test Pass <input type="checkbox"/> Fail <input type="checkbox"/>		Leakage test Pass <input type="checkbox"/> Fail <input type="checkbox"/>	
(max. 6mmHg/min)		(max. 6mmHg/min)	
_____ - _____ /5	= _____	mmHg/min	
Start - End	/Time = Leakage of Air		
Pressure Pressure			
Deflation Rate Pass <input type="checkbox"/> Fail <input type="checkbox"/>		Deflation Rate Pass <input type="checkbox"/> Fail <input type="checkbox"/>	
(<1x> mode)		(<1x> mode)	
(within 2 – 6 mmHg/sec)		(within 2 – 6 mmHg/sec)	
120 mmHg / _____	= _____	mmHg/sec	
Pressure drop / Time	= Deflation Rate		
Deflation Rate Pass <input type="checkbox"/> Fail <input type="checkbox"/>		Deflation Rate Pass <input type="checkbox"/> Fail <input type="checkbox"/>	
(<Manual> mode)		(<Manual> mode)	
(within 2 – 4 mmHg/sec)		(within 2 – 4 mmHg/sec)	
120 mmHg / _____	= _____	mmHg/sec	
Pressure drop / Time	= Deflation Rate		
Cycle Counts			
Er 1 (Error 1)		Er 3 (Error 3)	
Er 2 (Error 2)		Er 5 (Error 5)	