

SUBJECT: <b>A&amp;D MEDICAL DIGITAL BLOOD PRESSURE MONITOR ASSEMBLY</b>	DOCUMENT NUMBER: <b>910-00059-01</b>	REVISION: <b>08</b>	PAGE: <b>1 of 18</b>
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# UMW02 ASSEMBLY & TEST SPECIFICATION

**910-00059-01**

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Proprietary Information

**Revision History**

<b>DATE</b>	<b>VERSION</b>	<b>DESCRIPTION</b>	<b>AUTHOR</b>
05/21/08	01	Initial release of document	David W Smith
05/22/08	02	Added details to Functional Verification process	David W Smith
06/09/08	03	Added FCC labeling details	David W Smith
06/24/08	04	Updated rework instructions to reflect UWM in location of best performance	David W Smith
7/16/08	05	Added details of test application, setup and test process.	David W Smith
7/17/08	06	Define all distances in meters	David W Smith
7/18/08	07	Clarify the use of System test on starting of test application.	David W Smith
7/25/08	08	Added FCC statement on section 1.1	David W Smith

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## **1 INTRODUCTION**

### **1.1 Purpose of this document**

The purpose of this document is to specify the assembly and functional test requirements for the A & D Medical Digital Blood Pressure Monitor with the Universal Wireless Module (UWM).

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

In adherence to FCC regulations any changes or modifications not expressly approved by FitSense/FitLinxx could void the user's authority to operate the device.

### **1.2 Document Overview**

This document is divided into the following sections for organizational purposes.

**Incoming Inspection;** Describes UWM PCB packaging to be received by A&D Medical.

**Incoming Test;** Describes the equipment, setup, and process for incoming test of the UWM PCB.

**Rework Instructions;** Describes the wiring and mounting of the UWM PCB in the Digital Blood Pressure Monitor.

**Functional Test;** Describes the equipment, setup, and process to Functionally Test the wireless Blood Pressure Monitor containing the UWM PCB.

## **2 INCOMING INSPECTION**

The UWM (P/N 710-00041-01) will be received in an ESD bubble bag with two bar coded serial number labels and an FCC label as shown below .

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A ID Number label along with the FCC label is to be adhered to the blood pressure monitor as described in the BP Monitor Rework Instructions. The second ID Number label can be used on the product carton, packaging or as the manufacturer deems appropriate.

The bar coded serial number label contains alpha and numerical characters. The alpha characters represent the Device ID type as a BP monitor. The numerical characters represents the Device ID Number plus a checksum. The bar code format is UPC128.

The UWM PCB can be functionally verified and the corresponding labeling checked utilizing the Incoming Test process described below. The UWM can be sample tested per the MIL 105E Level II Acceptance Plan.

### **3 INCOMING TEST**

#### **3.1 Test Equipment**

The following test equipment is required for Incoming Test of the UWM PCB.

- USB based Personal Computer or laptop with Windows XP/2000 O.S. (provided by A & D Medical)
- Custom Incoming Test Fixture (provided by FitSense)
- 3.30vdc power source for the UWM PCB Test Fixture (provided by A & D Medical)
- Digital Multimeter
- Known good ActiLink (provided by FitSense)
- ActiBPMfgTest test application (provided by FitSense)

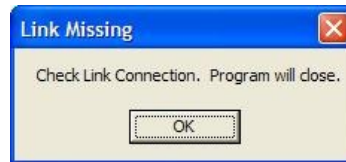
#### **3.2 UWM Test application**

The **System Test** portion of the **ActiBPMfgTest** Manufacturing Test application should be used for Incoming Test of the UWM PCB. When the application is started, Select the tab for System Test.

The application (**ActiBPMfgTest.exe**) is installed in the **C:\Program Files\ActiBP Manufacturing Test**. The application can be setup as a shortcut on the desktop.

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A known good ActiLink must be installed in the USB port of the test PC prior to starting the application. If no ActiLink is present, or the ActiLink is not functioning properly, an error message “**Check Link Connection, Program will close**” will be displayed and the program will exit when the operator clicks on the “**OK**” tab as shown below.



The application has a Test Configuration screen which allows manufacturing engineers to enable/disable tests and set specific test parameters. Test configuration limits that can be modified include firmware **Version** and **ID Number**. To access the Test Configuration screen, the engineer would select “**Edit**”, then “**Limits**”, then enter the **password**.

No password is set when the application is first installed. Select “**OK**” to access the Test Configuration limits screen for the first time. To setup a password, select “**Edit**”, then “**Limits**”. Select “**Advanced**”, then select “**Password**”. Enter the new password and select “**OK**”. The new password is now required each time to access the Test Configuration screen.

Once in the Test Configuration screen, the test “limits” should be set as follows for Incoming Test of the UWM PCB;

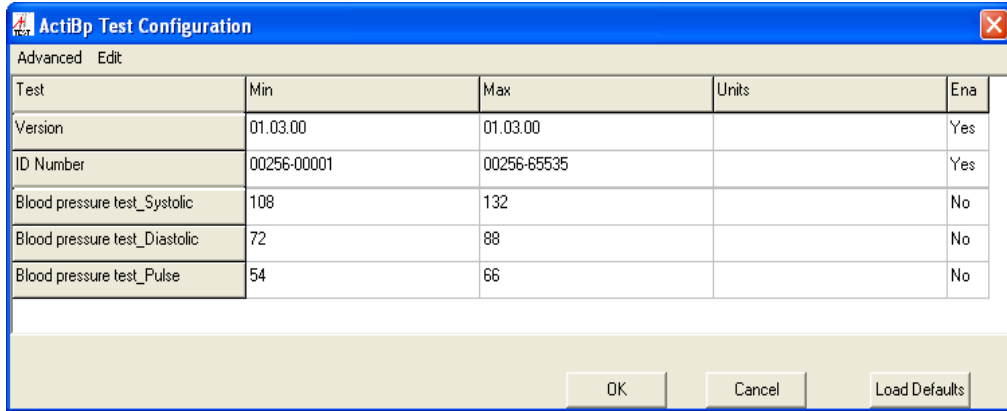
- **Version - Min and Max** values should be set to reflect the latest revision of UWM PCB firmware. The current firmware Version is 1.3.0
- **ID Number - Min and Max** values should be set to reflect the range of UWM PCB ID Numbers for the BP monitor. The current ID Number range is from 00256-00001 through 00256-65535.

In the Test Configuration screen, each sub-test can be enabled or disabled as required by entering **Yes** or **No** in the “**Ena**” column. For Incoming Test of the UWM PCB, the tests should be enabled/disabled as follows and as shown in the screen capture below.

- **Version** - Enabled with a **Yes** in the **Ena** column.
- **ID Number** - Enabled with a **Yes** in the **Ena** column.
- **Blood pressure test\_Systolic** - Disabled with a **No** in the **Ena** column.
- **Blood pressure test\_Diastolic** - Disabled with a **No** in the **Ena** column.

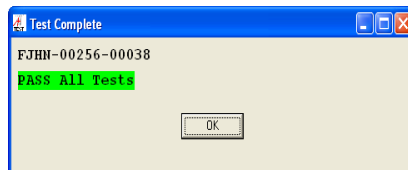
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- **Blood pressure test\_Pulse** - Disabled with a **No** in the **Ena** column.



Once the test limits have been correctly set as described above for Incoming Test of the UWM PCB, select the “**OK**” tab. This will save the Test Configuration limit settings, which will now be utilized each time the test application is started.

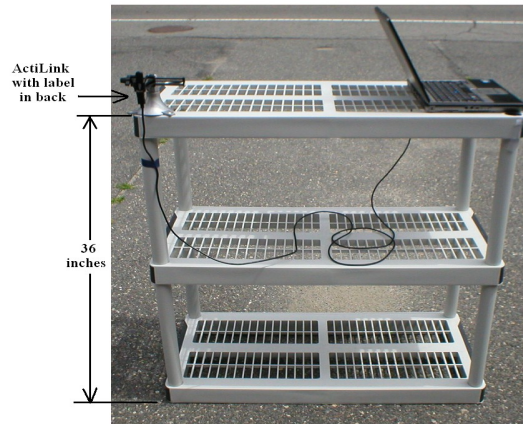
When the application has completed testing of a UWM PCB, a message with a **PASS ALL Tests** or a **FAIL** status and the ID Number of the tested PCB will be displayed across the top of the test screen, as shown below.



All results, pass or fail, are captured in a log file located in C:\Program Files\ActiBP Manufacturing Test folder. The log file will also contain information regarding the Mfg. **Plant** and test **Station Number**. To set the Plant and test Station Number, select “**Edit**”, then “**Location**”, and enter the specific information. Select the “**Ok**” tab when complete.

### 3.3 UWM Incoming Test Setup

A PC or laptop is required for Incoming Test of the UWM PCB. The PC or laptop should be placed at one end of a non-metallic table top at a height of 36 inches (0.914 meters) from the floor. The ActiLink should be placed on the opposite side of the laptop or PC at a height of 36 inches (0.914 meters) from the floor using a USB extension cable. Refer to photograph below.

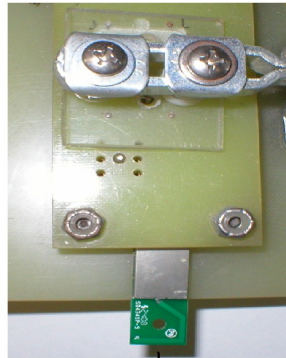


The ActiLink label should be facing opposite the direction of the UWM PCB under test, as shown in the photograph below.



The Incoming Test fixture containing the UWM PCB under test should be placed at a distance of 100 feet (30.5 meters) at one end of a non-metallic table top, at a height of 36 inches (0.914 meters) off the floor, with the tip of the antenna facing the ActiLink. Refer to the photograph below.

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Pointed  
towards  
ActiLink

All wireless devices should be removed from the test area, and the PC or laptop wireless capability should be turned off or disabled.

No obstacles should be between the ActiLink and the UWM PCB under test.

### 3.4 UWM Incoming Test Process

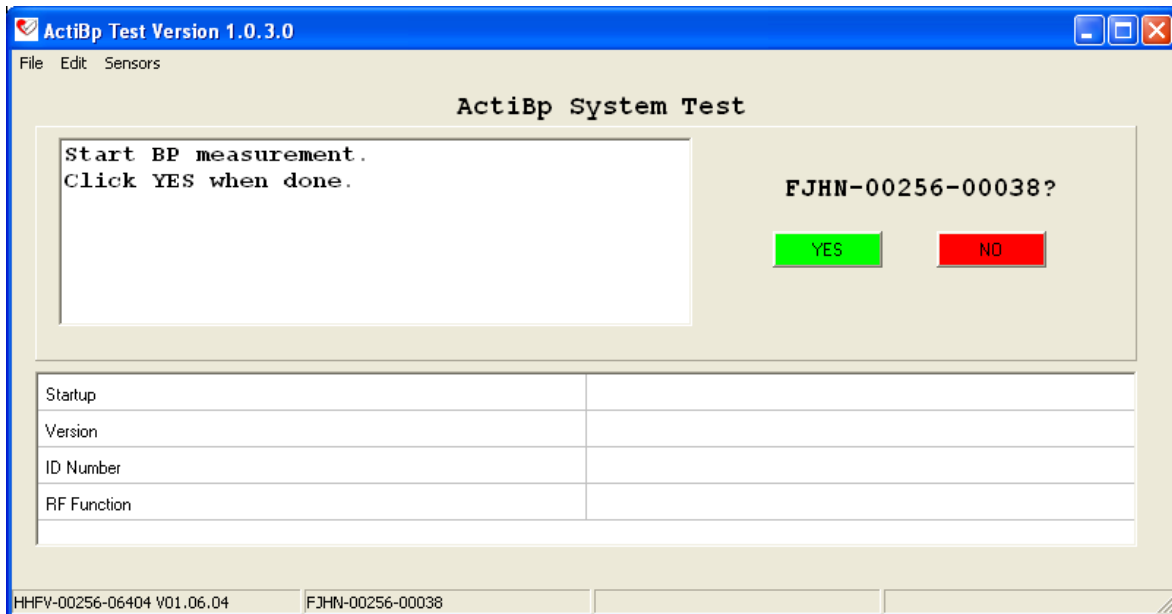
The following test process can be used to verify the UWM PCB functionality prior to being reworked into Digital Blood Pressure Monitor.

With an ActiLink installed in the PC's USB port, start the **ActiBPMfgTest.exe** test application from the shortcut on the desktop and select **System Test**. The Test Configuration limits must be set correctly as detailed in Section 3.2

- 3.4.1 Install the UWM PCB to be tested into the test fixture at the 100 foot (30.5 meters) distance with the UWM antenna tip facing the ActiLink. Power up the test fixture.
- 3.4.2 In the upper right corner of the **System Test** screen above the **YES** **NO** tab, the ID Number of the UWM PCB to be tested will boldly appear approximately 5 seconds after power is applied, as shown below for ID Number FJHN-00256-00038.



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If the ID Number of a UWM PCB other than that to be tested appears in the upper right of the test screen, selecting the **[NO]** tab will enable a **filter** preventing the application from detecting the **unwanted sensor**. This allows the operator to filter out all other UWM PCBs other than the specific UWM to be tested. To enable the application to detect all UWMs again, select the “**Sensors**” tab, then “**Clear Reject List**”.

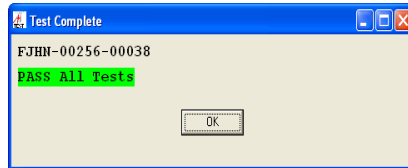
**3.4.3** With the ID Number of the UWM PCB under test boldly displayed on the screen, the operator would select the **[YES]** tab to start the test.

The application will now perform the following 4 sub-tests;

- **Startup**  
This test verifies that the application has RF communication with the UWM PCB prior to starting the test.
- **Version**  
This test verifies the UWM PCB has the correct firmware Version as defined in the **Min** and **Max** test “**Limits**”.
- **ID Number**  
This test verifies the Serial Number or ID Number of the UWM PCB is within the specified range as defined in the **Min** and **Max** test “**Limits**”. The operator should verify that the ID Number label on the UWM PCB matches the device being tested by the application.
- **RF Function**  
This test verifies the RF transmit and receive function of the UWM PCB.

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- 3.4.4 Once all 4 sub-test have completed, a status message of **PASS ALL Tests** or **FAIL**, and the **ID Number** of the UWM PCB that was tested will be displayed across the top of the test screen as shown below for ID Number FJHN-00256-00038.



- 3.4.5 The operator should **verify** that the **Device ID displayed by the test application**, and the **labels** on the UWM PCB and contained in the ESD bubble bag, **all match**.
- 3.4.6 Using a digital multimeter, verify the CR1225 lithium battery on side 2 of the UWM PCB measures between 3.00 to 3.30vdc. **Do not remove the battery to perform this test.**

## 4 BP MONITOR REWORK INSTRUCTIONS

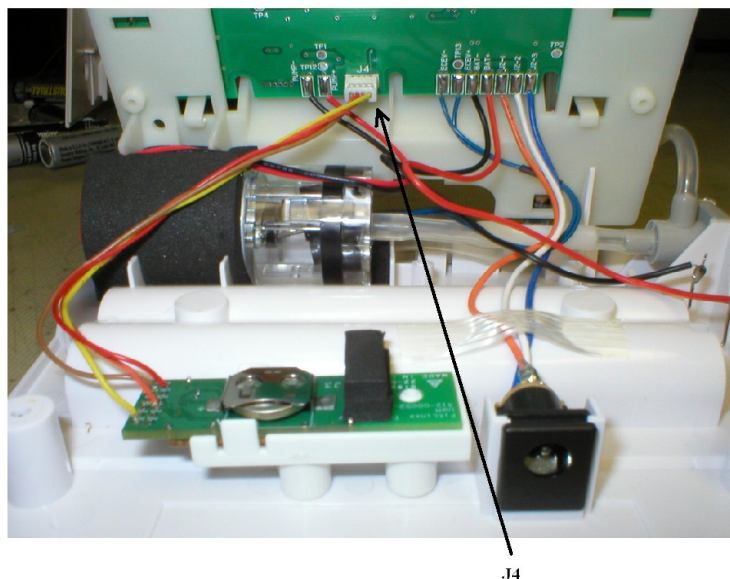
The UWM PCB is integrated into the BP monitor using four (4) 30AWG (7/38) stranded wires at specific lengths to accommodate the proposed mounting of the UWM PCB with the connection to the BP monitor PCB at connector J4 as shown in the photograph below.

Four (4) test points on the UWM PCB connector J1 are wired to the four pins of J4 on the BP monitor PCB as follows;

<u>UWM PCB</u>	<u>Signal Name</u>	<u>Wire Color</u>	<u>BP Monitor PCB</u>
J1 - 1 (V)	3.30vdc	Brown	J4 - 1
J1 - 2 (G)	Ground	Red	J4 - 2
J1 - 8 (RX)	UART RX Data	Orange	J4 - 3
J1 - 11 (P00)	Wakeup	Yellow	J4 - 4

- 4.1 Install the UWM PCB into the clip and install in base with compression foam as shown in photograph below.
- 4.2 Plug J4 connector from the UWM PCB into the BP monitor PCB as shown in photograph below.

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- 4.3 Assemble BP monitor per manufacturing assembly process.
- 4.4 **Clean** the location for the ID Number and FCC label with **90% Isopropyl Alcohol** and allow to dry. Place labels per the manufacturing assembly process.
- 4.5 Test the functionality of the BP monitor per Section 5 of this document.

## 5 FUNCTIONAL TEST

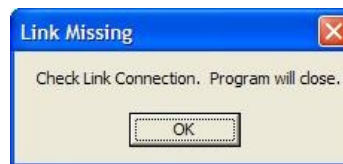
- 5.1 **Test Equipment**  
The following test equipment is required to test the wireless blood pressure monitor.
  - A USB based Personal Computer with Windows XP/2000 O.S. (provided by A & D Medical).
  - A known Blood Pressure Systolic, Diastolic, and pulse
  - A know good ActiLink (provided by FitSense)
  - ActiBP Manufacturing Test application (provided by FitSense)
  - Faraday cage (if required by manufacturing)
- 5.2 **ActiBP Manufacturing Test application**

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The **System Test** portion of the **ActiBPMfgTest** Manufacturing Test application should be used for Incoming Test of the wireless BP monitor. When the application is started, Select the tab for System Test.

The application (**ActiBPMfgTest.exe**) is installed in the **C:\Program Files\ActiBP Manufacturing Test**. The application can be setup as a shortcut on the desktop.

A known good ActiLink must be installed in the USB port of the test PC prior to starting the application. If no ActiLink is present, or the ActiLink is not functioning properly, an error message "**Check Link Connection, Program will close**" will be displayed and the program will exit when the operator clicks on the "**OK**" tab as shown below.



The application has a Test Configuration screen which allows manufacturing engineers to enable/disable tests and set specific test parameters. Test Configuration limits that can be modified include **Blood pressure test\_Systolic**, **Blood pressure test\_Diastolic**, **Blood pressure test\_Pulse**, **Version**, and **ID Number**. To access the Test Configuration screen, the engineer would select "**Edit**", then "**Limits**", then enter the **password**.

No password is set when the application is first installed. Select "**OK**" to access the Test Configuration limits screen for the first time. To setup a password, select "**Edit**", then "**Limits**". Select "**Advanced**", then select "**Password**". Enter the new password and select "**OK**". The new password is now required each time to access the Test Configuration screen.

Once in the Test Configuration screen, the limits should be set as follows for Functional Test of the wireless Digital Blood Pressure Monitor;

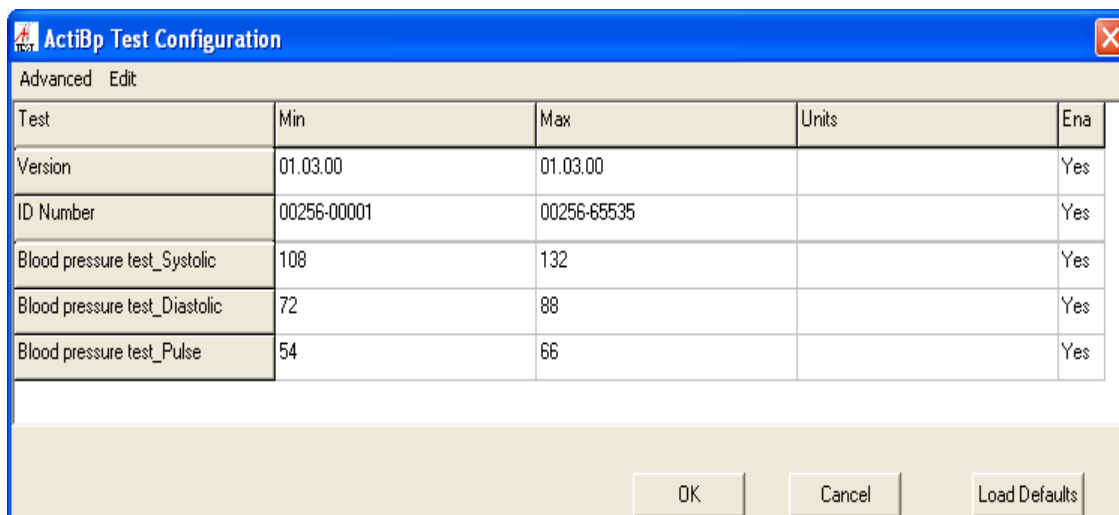
- **Version - Min and Max** values should be set to reflect the latest revision of UWM PCB firmware. The current firmware Version is 1.3.0
- **ID Number - Min and Max** values should be set to reflect the range of UWM PCB ID Numbers for the BP monitor. The current ID Number range is from 00256-00001 through 00256-65535.
- **Blood pressure test\_Systolic – Min and Max** values should be set to plus/minus 10 percent of the Systolic value being used by manufacturing to test the BP Monitor. At the time this document was created, the value of 120 was used.

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- **Blood pressure test\_Diastolic** - **Min** and **Max** values should be set to plus/minus 10 percent of the Dastolic value being used by manufacturing to test the BP Monitor. At the time this document was created, the value of 80 was used.
- **Blood pressure test\_Pulse** - **Min** and **Max** values should be set to plus/minus 10 percent of the Pulse value being used by manufacturing to test the BP Monitor. At the time this document was created, the value of 60 was used.

In the Test Configuration screen, each sub-test can be enabled or disabled as required by entering **Yes** or **No** in the “**Ena**” column. For Functional Testing of the BP monitor, the tests should be enabled/disabled as follows and as shown in the screen capture below.

- **Version** - Enabled with a **Yes** in the **Ena** column.
- **ID Number** - Enabled with a **Yes** in the **Ena** column.
- **Blood pressure test\_Systolic** - Enabled with a **Yes** in the **Ena** column.
- **Blood pressure test\_Diastolic** - Enabled with a **Yes** in the **Ena** column.
- **Blood pressure test\_Pulse** - Enabled with a **Yes** in the **Ena** column.

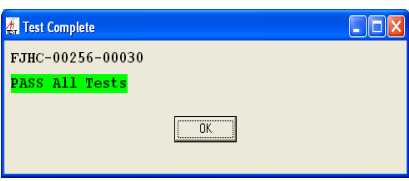


Once the test limits have been correctly set as described above for Functional Testing of the BP monitor, select the “**OK**” tab. This will save the Test Configuration limit settings, which will now be utilized each time the test application is started.

When the application has completed testing the BP monitor, a message with a **PASS ALL Tests** or a **FAIL** status and the ID Number of the BP monitor under test will be

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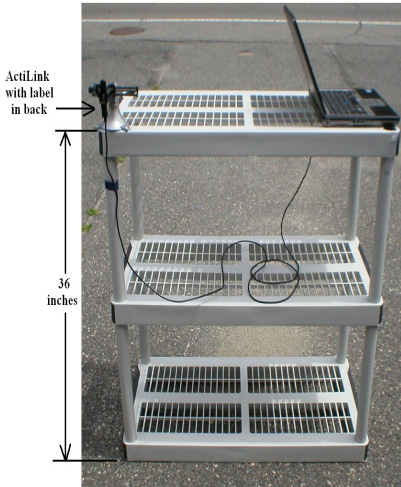
displayed across the top of the test screen, as shown below for ID Number FJHC-00256-00030.



All results, pass or fail, are captured in a log file located in C:\Program Files\ActiBP Manufacturing Test folder. The log file will also contain information regarding the Mfg. **Plant** and test **Station Number**. To set the Plant and test Station Number, select **“Edit”**, then **“Location”**, and enter the specific information. Select the **“OK”** tab when complete.

**5.3 Test Setup**

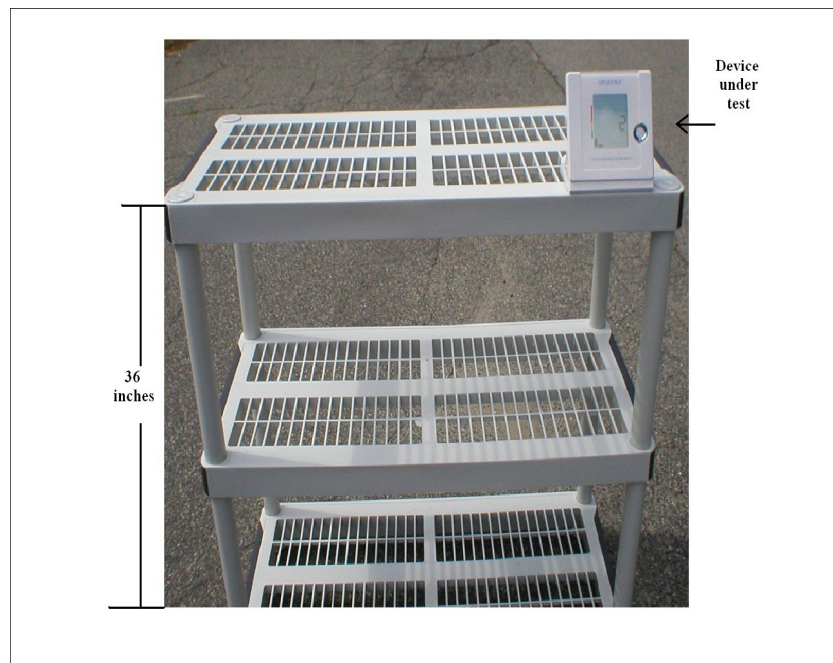
A PC or laptop is required for Functional Testing of the wireless Digital Blood Pressure Monitor. The PC or laptop should be placed at one end of a non-metallic table top at a height of 36 inches (0.914 meters) from the floor. The ActiLink should be placed on the opposite side of the the laptop or PC at a height of 36 inches (0.914 meters) from the floor using a USB extension cable. Refer to photograph below.



The ActiLink should be orientated such that, the Serial Number label is facing the opposite direction of the BP monitor under test, as shown in the photograph below.



The BP monitor under test should be placed at a distance of 100 feet (30.5 meters) at one end of a non-metallic table top, at a height of 36 (0.914 meters) inches off the floor, and with the front of the BP monitor facing the ActiLink. Refer to the photograph below.



All wireless devices should be removed from the test area, and the PC or laptop wireless capability should be turned off or disabled.

No obstacles should be between the ActiLink and the BP monitor under test.

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#### 5.4 Functional Test Process

Two (2) operators are required to Functionally Test the BP monitor at a distance of 100 ft (30.50 meters). The first operator will control the test application on the laptop or PC. The second operator will operate the BP monitor.

With an ActiLink installed in the PCs USB port, start the **ActiBPMfgTest.exe** test application from the shortcut on the desktop and select **System Test**. The Test Configuration limits must be set correctly as described in **Section 5.2**

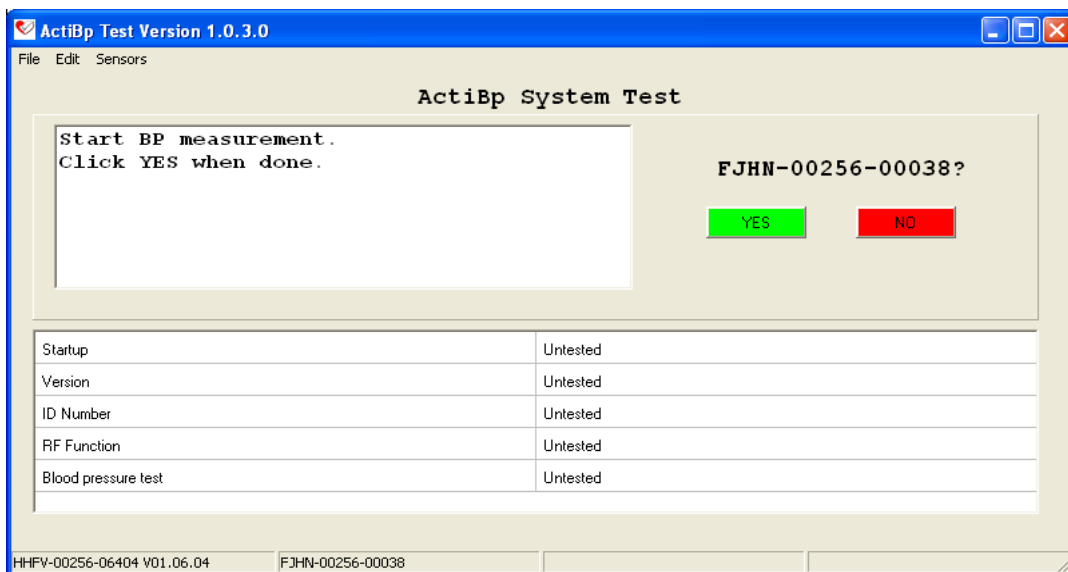
The following test process should be used to verify functionality of the BP monitor.

- 5.4.1** The operator will activate the BP monitor and allow it to complete the measurement as indicated on the LCD display. With the results on the LCD display of the BP monitor, the operator should walk to a distance of at least 10 feet to the side or rear of the monitor to prevent interfering with the RF test.

#### NOTE

**Once the BP Monitor is powered up and activated, the operators have approximately 60 seconds to complete the test before the monitor enters a low power sleep mode.**

- 5.4.2** The PC operator will then watch the upper right of the **System Test** screen, just above the **YES** **NO** tab, for the ID Number of the BP monitor under test to boldly appear as shown in the screen capture below for ID Number FJHN-00256-00038. This will take approximately 5 seconds after the BP monitor has been activated.





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If the ID Number of any BP monitor other than that to be tested is displayed by the application, the operator selects the **[NO]** tab for each device detected until the UUT is detected. The **[NO]** tab will place the ID Number in a reject list, and the rejected device will not be displayed again by the application until the operator selects “**Sensors**”, then selects “**Clear Rejected List**”.

- 5.4.3** With the blood pressure results displayed on the LCD display of the BP monitor, the PC operator then starts the test as instructed on the test screen by selecting the **[YES]** tab.

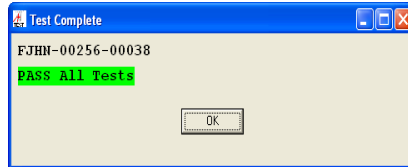
**Start BP measurement.**  
**Click YES when done.**

The application will now perform the following 7 sub-tests;

- **Startup**  
This test verifies that the application has RF communication with the under test prior to starting the test.
- **Version**  
This test verifies the UWM PCB in the has the correct firmware Version as defined in the Test Configuration Version limits.
- **ID Number**  
This test verifies the ID Number of the UWM PCB in the is within the specified range as defined in the Test Configuration **Min** and **Max** ID Number limits. The operator should verify that the ID Number label on the matches the device being tested by the application.
- **RF Function**  
This test verifies the RF transmit and receive function of the UWM PCB.
- **Blood pressure test\_Systolic**  
This test verify the UWM PCB was wired to the proper test point on the BP monitor, and that the UWM can RF transmit the value display on the BP monitor, to the test application.
- **Blood pressure test\_Diastolic**  
This test verify the UWM PCB was wired to the proper test point on the BP monitor, and that the UWM can RF transmit the value display on the BP monitor, to the test application.
- **Blood pressure test\_Pulse**  
This test verify the UWM PCB was wired to the proper test point on the BP monitor, and that the UWM can RF transmit the value display on the BP monitor, to the test application.

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- 5.4.4 Once all 7 sub-test have completed, a status message of **PASS ALL Tests** or **FAIL**, and the **ID Number** of the BP monitor tested will be displayed across the top of the test screen as shown below.



## 6 PACKAGING

Packaging of the A&D Medical Wireless Digital Blood Pressure Monitor is TBD.