Welch Allyn®
Ambulo® 2400

AMULATORY BLOOD PRESSURE MONITOR

SERVICE MANUAL

Manufactured by Welch Allyn, Inc., Skaneateles Falls, NY U.S.A.

CE 0459

CAUTION: *Federal law restricts this device to sale by or on the order of a physician.*

© 2019 Welch Allyn This document contains confidential information that belongs to Welch Allyn, Inc. No part of this document may be transmitted, reproduced, used, or disclosed outside of the receiving organization without the express written consent of Welch Allyn, Inc. Welch Allyn is a registered trademark of Welch Allyn, Inc. E-Scribe, ELI, and VERITAS are trademarks of Welch Allyn, Inc. Cisco® is the registered trademark of Cisco Systems, Inc. DICOM® is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

For patent information, please visit www.welchallyn.com/patents

For information about any Welch Allyn product, visit: https://www.welchallyn.com/en/about-us/locations.html

Customer Service and Technical Support: https://www.welchallyn.com/en/other/contact-us.html

1.888.667.8272, mor_tech.support@hillrom.com

REF **9516-182-50-ENG Rev F**
Revision Date: 2019-10

901050 AMBULATORY BLOOD PRESSURE MONITOR

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153 USA

www.welchallyn.com

EC REP EU IMPORTER

Welch Allyn Limited
Navan Business Park, Dublin Road,
Navan, Co. Meath C15 AW22
Ireland

TABLE OF CONTENTS

NOTICES **3**

Manufacturer's Responsibility 3
Responsibility of the Customer 3
Equipment Identification 3
Copyright and Trademark Notices 3
Other Important Information 3
Notice to EU Users and/or Patients: 3
Disposal: 3

WARRANTY INFORMATION **4**

Your Welch Allyn Warranty 4

USER SAFETY INFORMATION **6**

WARNING(S) 6
Caution(s) 7
Note(s) 8

EQUIPMENT SYMBOLS AND MARKINGS **9**

Symbol Delineation 9

ELECTROMAGNETIC COMPATIBILITY (EMC) **10**

Guidance and Manufacturer's Declaration: Electromagnetic Emissions 10
Guidance and Manufacturer's Declaration: Electromagnetic Immunity 11
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Equipment .. 13

DEVICE CONFIGURATION **14**

Configuration Commands 14
Summary of Configuration 14
Device Configuration 14
Configuration Settings 14
Software Version 14

MAINTENANCE & CALIBRATION **15**

Device Cleaning & Disinfecting 15
Maintenance and Calibration Procedure 17
Perform a Visual Inspection of the Following Items: 17
Communication Testing 18
Main Processor Calibration - (Using CCT commands) 19
Safety Processor Calibration 21
Ambulo 2400 Calibration Record 24

CONFORMANCE TESTING **25**

Required Equipment: 25
Initial Device Configuration 26
Leak Testing and Pressure Sensor Test 29
Overpressure Safety Control Test 30
Configuration Setup for BP Measurement Test 30
Pressure Accuracy Test 35
CCT/Python Command method: 35
Hypertension Diagnostic Suite method: 35

Data Download 36
Diagnostic Testing 37
Safety Testing 37
Ambulo 2400 Conformance Test Record 38

UNIT DISASSEMBLY 39

Ambulo 2400 Unit Disassembly 39
Removing Bottom Cover 39
Removing the Electro-mechanical Assembly and Manifold 40
Removing the PCB 41

DEVICE SPECIFICATIONS 45

Ambulo 2400 Specifications 45

TROUBLESHOOTING 46

System Troubleshooting Chart 46

DEVICE PROGRAMMING 47

Programming the Main Processor 47
Safety Processor Programming 49

NOTICES

Manufacturer's Responsibility

Welch Allyn, Inc. is responsible for the effects on safety and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out only by persons authorized by Welch Allyn, Inc.
- The device is used in accordance with the instructions for use.

Responsibility of the Customer

The user of this device is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification

Welch Allyn, Inc. equipment is identified by a serial and reference number on the back of the device. Care should be taken so that these numbers are not defaced.

Copyright and Trademark Notices

This document contains information that is protected by copyright. All rights are reserved. No part of this document may be photocopied, reproduced, or translated to another language without prior written consent of Welch Allyn, Inc.

Other Important Information

The information in this document is subject to change without notice.

Welch Allyn, Inc. makes no warranty of any kind with regard to this material including, but not limited to, implied warranties of merchantability and fitness for a particular purpose. Welch Allyn, Inc. assumes no responsibility for any errors or omissions that may appear in this document. Welch Allyn, Inc. makes no commitment to update or to keep current the information contained in this document.

Notice to EU Users and/or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Disposal:

This product and its accessories must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste. For more specific disposal information see www.welchallyn.com/weee.

WARRANTY INFORMATION

Your Welch Allyn Warranty

WELCH ALLYN, INC. (hereafter referred to as "Welch Allyn") warrants that components within Welch Allyn products (hereafter referred to as "Product/s") will be free from defects in workmanship and materials for the number of years specified on documentation accompanying the product, or previously agreed to by the purchaser and Welch Allyn, or if not otherwise noted, for a period of twenty-four (24) months from the date of shipment.

Consumable, disposable or single use products such as, but not limited to, PAPER or ELECTRODES are warranted to be free from defects in workmanship and materials for a period of 90 days from the date of shipment or the date of first use, whichever is sooner.

Reusable product such as, but not limited to, BATTERIES, BLOOD PRESSURE CUFFS, BLOOD PRESSURE HOSES, TRANSDUCER CABLES, Y-CABLES, PATIENT CABLES, LEAD WIRES, MAGNETIC STORAGE MEDIUMS, CARRY CASES or MOUNTS, are warranted to be free from defects in workmanship and materials for a period of 90 days. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

a) Freight damage;

b) Parts and/or accessories of the Product/s not obtained from or approved by Welch Allyn;

c) Misapplication, misuse, abuse, and/or failure to follow the Product/s instruction sheets and/or information guides;

d) Accident; a disaster affecting the Product/s;

e) Alterations and/or modifications to the Product/s not authorized by Welch Allyn;

f) Other events outside of Welch Allyn's reasonable control or not arising under normal operating conditions.

THE REMEDY UNDER THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT WITHOUT CHARGE FOR LABOR OR MATERIALS, OR ANY PRODUCT/S FOUND UPON EXAMINATION BY WELCH ALLYN TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Welch Allyn of any alleged defects promptly after discovery thereof within the warranty period. Welch Allyn's obligations under the foregoing warranty will further be conditioned upon the assumption by the purchaser of the Product/s (i) of all carrier charges with respect to any Product/s returned to Welch Allyn's principal place or any other place as specifically designated by Welch Allyn or an authorized distributor or representative of Welch Allyn, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Welch Allyn is limited and that Welch Allyn does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Welch Allyn is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence there from relating to the Product/s. If Welch Allyn should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Welch Allyn shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

EXCEPT AS SET FORTH HEREIN WITH RESPECT TO REIMBURSEMENT OF LABOR CHARGES, A PURCHASER'S SOLE EXCLUSIVE REMEDY AGAINST WELCH ALLYN FOR CLAIMS RELATING TO THE PRODUCT/S FOR ANY AND ALL LOSSES AND DAMAGES RESULTING FROM ANY CAUSE SHALL BE THE REPAIR OR REPLACEMENT OF DEFECTIVE PRODUCT/S TO THE EXTENT THAT THE DEFECT IS NOTICED AND WELCH ALLYN IS NOTIFIED WITHIN THE WARRANTY PERIOD. IN NO EVENT, INCLUDING THE CLAIM FOR NEGLIGENCE, SHALL WELCH ALLYN BE LIABLE FOR INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR FOR ANY OTHER LOSS, DAMAGE, OR EXPENSE OF ANY KIND, INCLUDING LOSS OF PROFITS, WHETHER UNDER TORT, NEGLIGENCE OR STRICT LIABILITY THEORIES OF LAW, OR OTHERWISE. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

USER SAFETY INFORMATION

WARNING: Means there is the possibility of personal injury to you or others.

Caution: Means there is the possibility of damage to the device.

Note: Provides information to further assist in the use of the device.

WARNING(S)

- This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.
- Device captures and presents data reflecting a patient's physiological condition that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis.
- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Welch Allyn Technical Service for additional training options.
- To avoid the potential for spread of disease or infection, blood pressure cuffs should be cleaned after each patient use.
- This device is intended for use with ambulatory patients. This device is not intended for use with unconscious or sedated patients.
- Warning: During device configuration using the HDS (Hypertension Diagnostic Suite) Software if a "Top Inflation Pressure" above 300mmHg is entered the system will automatically enter the value of 300mmHg. Further, if a "Top Inflation Pressure" above 285mmHg is entered and sent to an AMBULO 2400 device the HDS software returned an error message. If the AMBULO 2400 device is then disconnected from the system running the HDS software, the device displays an error "SE 18" indicating "Data memory area is unexpectedly erased" and the "Top Inflation Pressure" defaults to 180mmHg automatically.
- Use only approved blood pressure (BP) cuffs specifically intended for use with the Ambulo 2400.
- Do not fold, clamp, cut, or alter the pressure hose of the cuff or the monitor.
- Instruct the patients to check the limb connected to the cuff for adequate perfusion, circulation, and function. Repeated NIBP measurements can lead to hematomas, limb ischemia, and other limb injuries. Kinked or blocked hoses can lead to prolonged impairment of blood circulation and lead to injury.
- Educate the patient to relax, rest, and lie still during inflation and pressure measurements. Patient movement can lead to artifacts or errors.

- The pressure measurement might be influenced by patient position, physical conditions, and other factors.
- Avoid placing the blood pressure cuff on the arm next to where a patient has had a mastectomy.
- Avoid applying the cuff to a wounded limb as this can cause further injury. Use with caution in patients with dermatological disease, subcutaneous laceration, or other integumentary compromise as there may exist a skin damage hazard during electronic NIBP measurements. Follow prudent evidence-based clinical practice to determine if an electronic blood pressure is safe for these patients.
- There may be an increased risk of hematomas in patients with serious coagulation problems.
- Avoid applying the cuff to a limb with a catheter, arterio-venous shunt or infusion pump applied. The cuff pressure could produce damage to the tissues surrounding the catheter, shunt or the infusion needle, or compromise the infusion flow.
- NIBP measurements may be inaccurate or be adversely affected in the presence of arrhythmias, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, motion artifacts, shivering, or trembling patients.
- NIBP cuffs and hoses supplied with the Ambulo 2400 do NOT contain any Latex. If the patient develops an allergic reaction or rashes, immediately remove the cuff.
- Inflation of the NIBP cuff can cause a temporary degradation of monitoring of other parameters derived from the same limb, including invasive pressure and SpO2 measurements. If applicable, place the SpO2 sensor and the NIBP cuff on different limbs.
- The Ambulo 2400 should not be used for measurement of blood pressure in neonate patients.

Caution(s)

- Do not attempt to clean the device, patient cuffs or tubing by submersing into a liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. Wipe the exterior surfaces with a warm water and mild detergent solution and then dry with a clean cloth. Use of unspecified cleaning/disinfecting agents, failure to follow recommended procedures, or contact with unspecified materials could result in increased risk of harm to users, patients and bystanders, or damage to the device.
- No user-serviceable parts inside. Screw removal by qualified service personnel only. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.
- No calibration or special equipment are needed for the proper operation or maintenance of the device.
- When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
- Do not connect the device to any unauthorized devices or use any third-party accessories. This may cause inaccurate measurements or harm the patient.

- Do not operate the device in conjunction with or in close proximity to other devices such as high frequency surgical instruments, defibrillators, imaging systems, or other diagnostic or therapeutic devices. Simultaneous operation may damage the device or lead to erroneous results.

- It is recommended to keep proper functioning backup items such as a spare patient cuff, extension hose, interface cable, batteries and other equipment on hand to prevent delayed treatment due to an inoperable device.

- While the Hypertension Diagnostics Suite software can operate in a multi-user networked-environment and support hundreds of patient records, its performance may degrade with increasing database file size. In such situations or perhaps on a regular basis, it is recommended that patient records be archived and a new patient database be created. Refer to the Software Operation section of this User Manual for further information on how to archive existing and create new databases.

Note(s)

- There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.

- As defined by IEC 60601-1, the device is classified as follows:
  - Class I equipment or internally powered.
  - Type BF and defibrillation-proof applied part.
  - Ordinary equipment.
  - Equipment not suitable for use in the presence of flammable or explosive environments including anesthetic mixtures.
  - Continuous operation.

- This device is intended to be used in an ambulatory setting as prescribed by a licensed physician, and should be used and stored according to the environmental conditions specified below:

Operating temperature:	+5° to +40°C (+41° to +104°F)
Operating humidity:	30% to 95% RH, non-condensing
Atmospheric pressure:	1033 hPa to 550 hPa
Storage temperature:	-20° to +55°C (-4° to +131°F)
Storage humidity:	15% to 95% RH, non-condensing
Atmospheric pressure:	1059 hPa to 550 hPa

CAUTION: *The device may not provide accurate results or may be damaged if operated or stored beyond the specifications.*

- The device is CSA classified:

C US 240805

WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, CAN/CSA C22.2 No. 601.1, IEC 60601-1-1, CAN/CSA C22.2 No. 60601-1-1-02, IEC60601-2-30 AND CAN/CSA C22.2 No. 601.2.30-99

EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation

	CAUTION The cautions statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.
	WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. In addition, when used on a patient applied part, this symbol indicates defibrillation protection is in the cables. Warning symbols will appear with a grey background in a black and white document.
IPX1	Indicates device has been tested for safety from vertically dripping water; specifically, it indicates DRIP PROOF, a higher than ordinary level of protection from drips, leaks, and spills.
	Defibrillator-proof type BF applied part.
C US	Tested for safety by the Canadian Standards Association according to applicable U.S. and Canadian standards and requirements.
	Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements.
0459	Indicates compliance to applicable European Union directives.
7d welchallyn.com	Follow instructions/directions for use (DFU) – mandatory action. A copy of the DFU is available on this website. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.
MD	Medical Device
#	Model Identifier
REF	Reorder Number

ELECTROMAGNETIC COMPATIBILITY (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the device.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the device according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The device should not be used adjacent to, or stacked on top of other equipment. If the device must be used adjacent to or stacked on top of other equipment, verify that the device operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See the appropriate table for recommended separation distances between the radio equipment and the device.

Operation of the equipment beyond its specified ranges, or beyond normal physiological conditions of human subjects, may cause inaccurate results.

The use of accessories, transducers, and cables other than those specified by Welch Allyn may result in increased emissions or decreased immunity of the equipment.

The essential performances of the Ambulo 2400 are:

Measurement Ranges
Systolic: 60 to 280 mmHg
Diastolic: 40 to 160 mmHg
Pulse Rate: 30 to 180 bpm

Measurement Accuracy
Blood pressure: ±3 mmHg mean difference ±8 mmHg standard deviation
Pulse rate: ±3 bpm

According to ANSI/AAMI SP-10 & BHS (Grade A/A) and ANSI/AAMI/ISO 81060-2

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	Compliance	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *UT is the AC Mains voltage prior to application of the test level.*

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.34 \sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Equipment

The equipment is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended in the table below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter (m)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.34\sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.33 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.33 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.*

NOTE 3: *If the equipment exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.*

DEVICE CONFIGURATION

Configuration Commands

The configuration pages define all operational conditions that do not change on a daily or patient-to-patient basis.

The device configuration settings are entered by Welch Allyn at the time of device manufacture and are not intended to be changed by the user. Configuration settings should only be changed by authorized Welch Allyn service personnel if a new main circuit board is being installed during service operations.

Summary of Configuration

Communication port will need to be verified through device manager, as this is needed for all CCT commands. COM5 is used below as an example. For CCT installation and setup information, see the "Maintenance, Calibration and Testing" section of this manual.
cct.py –s com5 –d

Device Configuration

Enter the following as prompted:

- Manufacturing Lot – Enter current manufacturing lot, Enter '6'
- Hardware Version – Enter current hardware version, Enter '1'
- S/N of the device – 5 digit number as read from the back label of the device
  (may also be scanned off the barcode and must not be larger than 65565)
- Manufacturer Code (Location) – Enter "3" for Milwaukee

- Device ID – Enter '1' for 010-2400-01 model number ; enter '2' for 010-2400-02.

Configuration Settings

Software Version

Software Version	Identifies the version of the Hypertension Diagnostics Suite software. In the Hypertension Diagnostics Suite software, click the "Help" menu at the top, then "About Hypertension Diagnostics Suite Software". Version will be displayed, for example "Version 2.50"
Device Firmware Version	Identifies the firmware version of an Ambulo 2400 device. Install batteries in the Ambulo 2400 device, as device powers up, it will display the 3 digit firmware version. For example, "1 49". Is also displayed in the Hypertension Diagnostics Suite software during device diagnostics, or at the table view under "Device Information"
Calibration Date / Time	Identifies the last calibration date and time of an Ambulo 2400 device. Is displayed in the Hypertension Diagnostics Suite software during device diagnostics, or at the table view under "Device Information"

MAINTENANCE & CALIBRATION

Device Cleaning & Disinfecting

WARNING

- Remove the batteries from the device before inspecting or cleaning.
- Do not get the device wet or immerse in water.
- Do not drop the device or subject it to shock and/or vibration.
- Do not use organic solvents, ammonia-based solutions, or abrasive cleaning agents which may damage equipment surfaces.

Recommended Supplies

- Clean lint free cloth
- Mild detergent
- Luke warm water
- 10% Household bleach and water solution (Sodium Hypochlorite solution consisting of a minimum 1:500 dilution and maximum of 1:10 dilution for disinfecting use only)

Device Cleaning

Clean the exterior surface of the device with a damp, soft, lint-free cloth using a solution of mild detergent diluted in water. After cleaning thoroughly dry off the device with a clean, soft cloth or paper towel.

Device Disinfecting

Clean the device per the instructions defined above, then wipe the exterior of the device with a damp (not wet), soft, lint-free cloth using a solution of 10% bleach and water. Allow the device to air dry after disinfecting before returning to use.

Cleaning the Cuffs

1. Prior to washing, remove any internal cuff bladders and engage the Velcro hook and loop fasteners to prevent lint from collecting in the hooks.
2. For general cleaning of cuffs, use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Be careful not to get liquid inside of the tubes. Allow to air dry.
3. For excessive perspiration marks or odor, the exterior of the cuff can be hand-washed under running water with a mild detergent. Do not allow water to enter the bladder including with single-piece cuffs without an internal bladder. Allow to air dry.
4. If required, use of non-chlorine bleach is recommended. Chlorine bleach solutions will shorten the service life of the cuff.
5. Sterilize the cuff and bladder using commercially available disinfectants. Note that some disinfectants may cause skin irritation and dark colored disinfectants may stain the cuff. Test a single cuff to ensure that no damage or staining will occur. Follow the manufacturer's instructions and thoroughly rinse each component to remove any residual disinfectants. Allow the components to air dry and then insert the bladder.
6. Cuffs can be sterilized with Ethylene Oxide. Do not autoclave or iron the cuff as the hook and loop fasteners will melt at temperatures above 325°F (162°C).

7. Use caution with excess liquid.
8. Do not use excessive drying techniques such as forced heat.

WARNING: *Prevent liquid from penetrating the device and do not attempt to clean/disinfect the device or cuff by submerging into a liquid, autoclaving, or steam cleaning.*

WARNING: Certain maintenance and calibration operations of the Ambulo 2400 system, such as safety processor calibration and deflation rate calibration, should only be performed by Welch Allyn authorized service personnel.

Confidence Test

- Place 2 AA batteries in the device, and verify that it successfully powers on, making note if the software version displayed on the screen is not current (example "1 49"). If the device display eventually alternates between the time and "PAUSE", proceed to the next step. If the device displays "HE##", "SE##" or something other than PAUSE/time, refer to the "System Troubleshooting Chart".

- If firmware is version 1.49 or older, it is recommended that the main processor receive software upgrade (to the current version) and calibration. But first, verify that the device passes communication testing below.

Maintenance and Calibration Procedure

Preventive maintenance and Calibration of the Ambulo 2400 is recommended to be performed at least once per year.

In order to configure, calibrate and test the Ambulo 2400 ABPM system, a set of custom-developed utilities – henceforth referred to as CCT (Command & Control Terminal) - must be installed and used on a computer. Developed using the Python programming language, these utilities can run under Microsoft Windows using the MS-DOS Command Prompt or in a Linux-based environment.

> ***NOTE:*** *Before proceeding with any CCT commands, you must first install and setup the Hypertension Diagnostics Suite software, as well as Python and CCT with the following instructions.*

1. Install current Welch Allyn Hypertension Diagnostics Suite software. This will install the Ambulo 2400 USB driver, which is necessary for the device to be recognized by the PC.

2. Download and install Python 2.6.1 (**location to be determined**). Make note of install folder for next steps. For example, C:\Python26.

3. Download Pyserial 2.5 (Python Serial Extension) (**location to be determined**) to Python install folder (from previous step) and install.

4. Download Pywin32-210 (**location to be determined**) to Python install folder and install.

5. Download and install CCT application software (**file location to be determined**) to local directory (for example, C:\CCT).

Perform a Visual Inspection of the Following Items:

- Device outer casing, coupler and LCD faceplate. Make note of any heavy wear, damage or signs of drop. If faceplate is cracked, this is likely an early version of this part (which was prone to cracking) and it is recommended that the entire top cover be replaced (the revised LCD faceplate is more durable). Some early Tiba devices also have a plastic air socket, which has since been replaced with a more durable metal design. In the event that a Tiba branded Ambulo 2400 needs service of the outer case, it is recommended that the complete case be replaced with Welch Allyn branded plastics.

- If a customer has included accessories with their Ambulo 2400 system, inspect hoses and cuffs for excessive wear or leaks. If accessories are noted as being in questionable condition, or if the device is suspected of having leaks, these accessories will be identified during the “leak test” portion of this procedure. If a puncture is discovered in the hose, it may be possible to trim the damaged piece and salvage the accessory. Otherwise it is recommended that the customer replace the accessory.

Communication Testing

- Verify that the device can successfully communicate with a PC by connecting it via USB cable, and opening the Hypertension Diagnostics Suite software.

- Verify that after 3-5 seconds, the device displays “USB”. If it does not, proceed to the next step. Otherwise open the Hypertension Diagnostics Suite, click “configure device”, select a Demo patient, and then “One Click Device Programming”. When the software asks if you would like to continue, click “Yes”. If software freezes or fails during configuration, force quit program, disconnect device, open the program, connect the device, wait until it is recognized by the PC, and retry. Once successfully configured, put the device in AUTOMATIC mode by holding the START button for 3-5 seconds. Ensure that the Ambulo 2400 shows the correct time of day (per the PC clock) and a countdown to the next scheduled measurement. Proceed to Calibration/Calibration Verification.

    - If the device continues to alternate between PAUSE and the time, reconnect the USB cable to an alternate port on the PC. If the device does not display USB, then the port has likely failed and the PCB should be replaced.

Main Processor Calibration - (Using CCT commands)

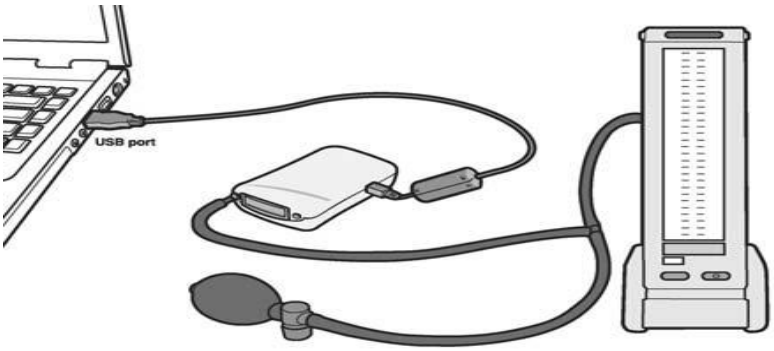
(Note: It is recommended that the device be checked and calibrated once every year, in accordance with ANSI/AAMI/ISO 80601-2-30:2009 & A1:2013 standards.)

***CAUTION**: Incorrectly calibrating the device will result in erroneous measurements. Only attempt to calibrate the device when absolutely certain the process can be completed successfully.*

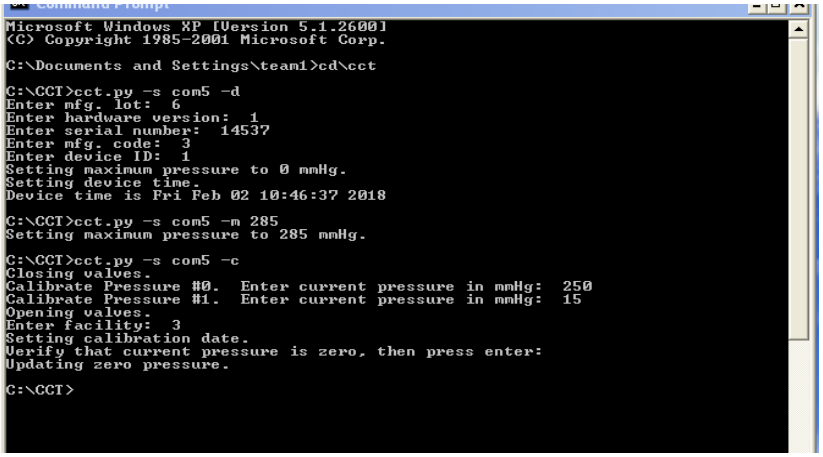
UUT correct calibration setup requires the following components:

- Ambulo 2400 device
- Manometer/NIBP Simulator
- T-connector air hose
- Sphygmomanometer Manual Hand pump
- USB cable

Once the components are setup correctly (refer to diagram shown), proceed with the calibration process.



1. At the computer's command prompt will display as below:



```
Microsoft Windows XP [Version 5.1.2600]
(C) Copyright 1985-2001 Microsoft Corp.

C:\Documents and Settings\team1>cd\cct

C:\CCT>cct.py -s com5 -d
Enter mfg. lot:  6
Enter hardware version:  1
Enter serial number:  14537
Enter mfg. code:  3
Enter device ID:  1
Setting maximum pressure to 0 mmHg.
Setting device time.
Device time is Fri Feb 02 10:46:37 2018

C:\CCT>cct.py -s com5 -m 285
Setting maximum pressure to 285 mmHg.

C:\CCT>cct.py -s com5 -c
Closing valves.
Calibrate Pressure #0.  Enter current pressure in mmHg:  250
Calibrate Pressure #1.  Enter current pressure in mmHg:  15
Opening valves.
Enter facility:  3
Setting calibration date.
Verify that current pressure is zero, then press enter:
Updating zero pressure.

C:\CCT>
```

2. At the computer's command prompt at location **C:\CCT**, set max pressure to 285 mmHg by entering the following command.

*(**NOTE**: This procedure must be completed within 3 minutes or the board may reset.)*

3. Command **cct.py –s com5 –m 285 (Enter)**

4. Command **cct.py –s com5 –c (Enter)**

5. Once the calibration setup asks for pressures, enter the first as "**250**" mmHg.

6. Manually raise the pressure by pumping the bulb on the simulator to just above the **250 mmHg** level. Watch the deflation on gage, and once it is **exactly 250 mmHg**, press **ENTER** to confirm this to the software. Be as accurate as possible.

7. Once the calibration setup asks for pressures, enter the second as "**15"** mmHg.

8. **UUT** turning the knob on the bulb counterclockwise to release the pressure exactly **15 mmHg**, then press **ENTER**.

9. **UUT** you will then be asked to enter a calibration location (facility code); enter **'3'**.

10. Finally, you will be asked to provide a zero-pressure reading. Open the valve of the Hand Pump by turning the knob counterclockwise and drain the system of all pressure. When you are certain it is empty, confirm by pressing ENTER.

Safety Processor Calibration

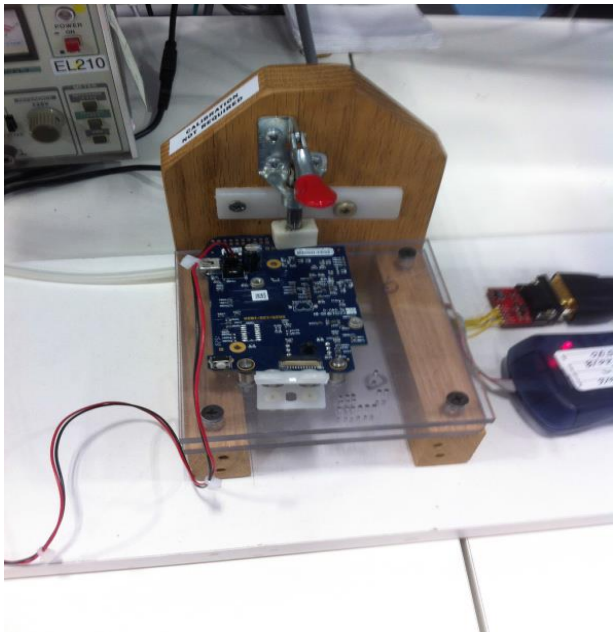
Safety Processor calibration is only required if the unit fails the 'overpressure safety control test' defined in the conformance testing section of this manual.

Conformance testing should be performed after the calibration process has been completed.

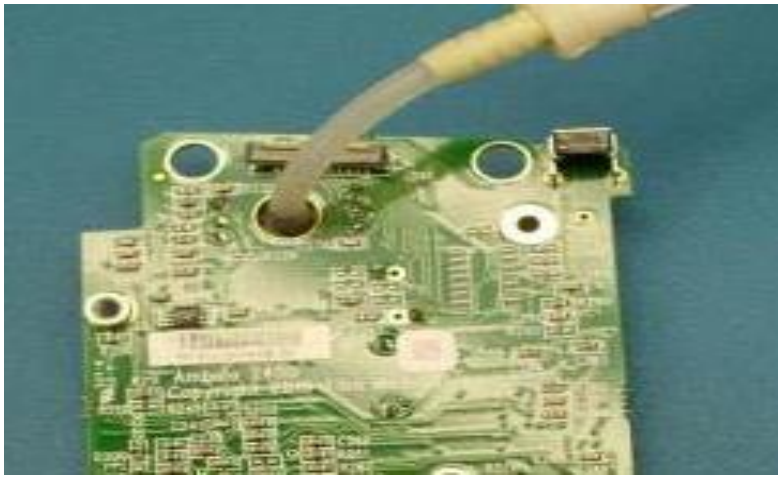
Required Equipment

QTY	Part number	Description / Specification
1	TF-0539	Computer workstation loaded with AMBULO2400 programming software
1	TF-0542	Fixed volume of air
1	EL109 or equivalent	DC Power Supply. Set at 3VDC connected at UUT location P379.
1	EL319 or equivalent	Clinical Dynamics AccuPulse NIBP simulator
1	008-0008-01	AMBULO 2400 USB cable
1	11070-001-50	AMBULO 2400 Hypertension Diagnostics Suite software

1. The following picture indicates the recommended setup for the components of safety processor calibration, with the fixture handle ½ way up.



2. The input of the pressure transducer should be connected to a calibrated pressure source (attach the tubing to the pressure port as below).



3. Once the simulator is turned on, press the “Leak Test” button to get to the correct screen. Press the F4 button again to change the inflation from “Auto” to “Manual”. This enables the hand-pump to be used.
4. Once the simulator is correct setting. Turn on the External DC power supply.

5. Plug the USB cable into both the AMBULO 2400 and the computer. The PC must recognize the AMBULO 2400, and should install an appropriate USB-to-Serial driver. This process can be confirmed by viewing the Device Manager application under Windows Control Panel – System – Hardware section. Verify the serial port number that is assigned to the AMBULO 2400. In the following examples (in this document), COM5 is used.

6. Open the DOS command prompt window by typing “**cmd**” in the Run prompt (under the Windows Start menu). Navigate to the **C:\CCT** directory.

7. Enable the pressure sensor by entering the following command.

   Command **cct.py –s com5 --dump 1**

8. Set pressure source to the maximum pressure of **315 mmHg** by manually pumping the pressure bulb.
9. Tell the processor to save this reading. This is done by entering the following command and pressing “ENTER” **exactly** when the pressure is **315 mmHg**.

   Command **cct.py –s com5 --pump 1**

10. Slightly drop the pressure to **285 mmHg** by opening and then closing the release valve on the bulb.

    Save the reading by entering the following command and then pressing “ENTER” **exactly** when the pressure is **285 mmHg**.

    Command **cct.py –s com5 --pump 0**

11. Drop the pressure to **10 mmHg**, then save the reading by entering the following command and then pressing “ENTER” **exactly** when the pressure is **10 mmHg**.

    Command **cct.py –s com5 --pump 1**

12. Turn of the External DC power supply and disconnect the USB cable from the board. Next turn on the External power supply again. The board should beep once. If it beeps more than once, the safety processor calibration was not done properly. Repeat steps 6 through 8 until the UUT passes. If UUT board beeps once return to step 1 and repeat the testing procedure.

    (Note: If the safety processor needs to be re-calibrated, then the EEPROM must first be initialized by connecting it to the AVR programming utility and re-programming the safety processor).

Ambulo 2400 Calibration Record

Unit Serial #:_____Incoming Firmware Version: _____

□ **Clean Device**

□ **Device Inspection**

Communication Testing □ Pass □ Fail

Device Calibration

Firmware Update □ Yes – to version _____ □ No

Main Processor Calibration (Method used= □ HDS □ CCT) □ Pass □ Fail

Safety Processor Calibration (if applicable) □ Pass □ Fail □ N/A

Performed by: _____ Date:_____/_____/_____

CONFORMANCE TESTING

Required Equipment:

- SWITCH PANEL TF0814
- HAND PUMP BULB
- SIMULATOR EL374
- 2 AA BATTERY RECHARGEABLE NiMH
- Computer workstation loaded with AMBULO programming software (TF-0827 CNR)
- AMBULO 2400 Hypertension Diagnostics Suite software; P/N: 11070-001-50
- AMBULO2400 USB cable; P/N: 008-0008-01

Make sure the far left manifold switch is placed in the “Test” position.

Check that all the other switches are in the down position on the manifold.

Initial Device Configuration

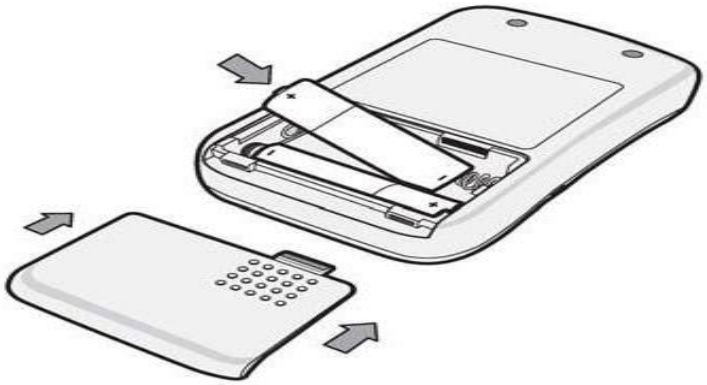
Install the batteries.
(See picture below)

A. Always use fully-charged rechargeable NiMH AA batteries for each ABPM procedure.

B. Ensure the batteries are in the correct polarity.

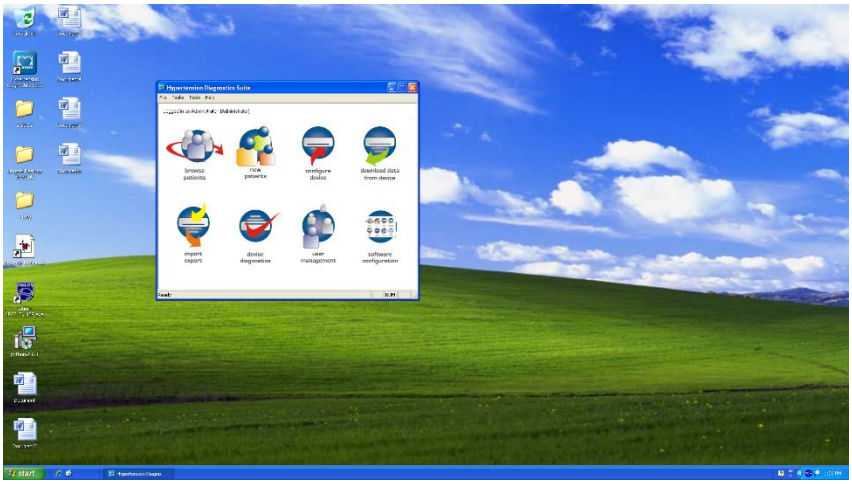
C. The device will beep and it should power-on when the batteries are inserted correctly. Close the battery cover.

D. Device now should flashing "PAUSE and TIME"

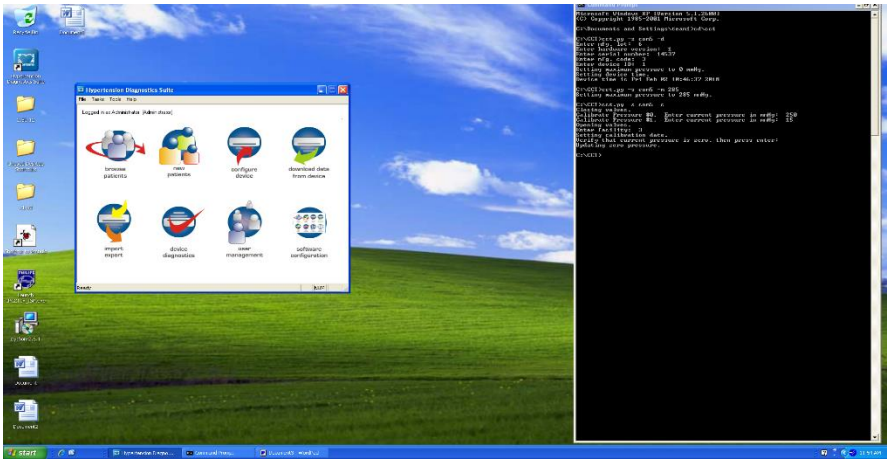


1. Turn on the PC TF0827 CNR System.

2. Open the Hypertension Diagnostics Suite as below.



3. Open the computers device manager screen and open Command prompt.



4. Turn on the **EL374 RIGEL** by **press & hold** until it beeps, then release.

5. Press **F3** “NIBP”, verify the **EL374 RIGEL** displays the correct setting as shown below:

Heart Rate: 80 bpm/ Systolic: 140 mmHg/ Diastolic: 100 mmHg

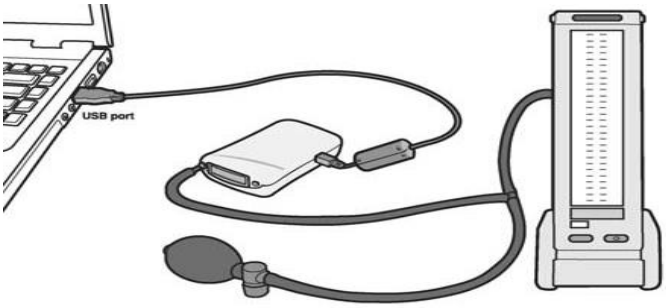
- If incorrect setting is displayed, press **F3** “NIBP” one more time to bring up the NIBP setting screen.

- Press “**F4**”. Press the blue down “**Arrow**” button to the Systolic/Diastolic slot, press the blue **Right or Left** “**Arrow**” and select the correct setting. Press **F4** twice (The EL374 will beep). Press on the “**Green**” button on the EL374 to activate the setting and the waveform will now be flashing in the lower right of the EL374 simulator screen.

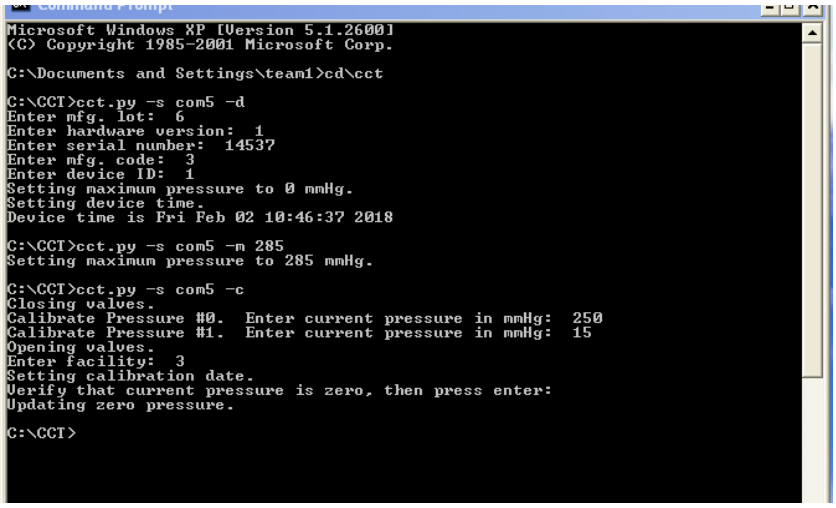
6. Connect the USB cable from the PC to the UUT USB port.

7. Check to make sure the UUT is flashing USB and TIME.

8. Connect the tube into the UUT as shown below.



9. At the computer, the command prompt will display as below:



```
Microsoft Windows XP [Version 5.1.2600]
(C) Copyright 1985-2001 Microsoft Corp.

C:\Documents and Settings\team1>cd\cct

C:\CCT>cct.py -s com5 -d
Enter mfg. lot:  6
Enter hardware version:  1
Enter serial number:  14537
Enter mfg. code:  3
Enter device ID:  1
Setting maximum pressure to 0 mmHg.
Setting device time.
Device time is Fri Feb 02 10:46:37 2018

C:\CCT>cct.py -s com5 -m 285
Setting maximum pressure to 285 mmHg.

C:\CCT>cct.py -s com5 -c
Closing valves.
Calibrate Pressure #0.  Enter current pressure in mmHg:  250
Calibrate Pressure #1.  Enter current pressure in mmHg:  15
Opening valves.
Enter facility:  3
Setting calibration date.
Verify that current pressure is zero, then press enter:
Updating zero pressure.

C:\CCT>
```

- Go to C:\Documents and Settings\team1>

  Then type cd\cct as below

  C:\Documents and Settings\team1>cd\cct (Enter)

- Go to C:\CCT>

  Then Type this command follow cct.py -s com5 -d as below

  C:\CCT>cct.py -s com5 -d (Enter)

11. Enter the current Manufacturing Lot. When prompted type in **"6"**

12. Enter the Hardware Version.

- When using motherboard assembly **010-0004-03** enter **"1"**
- When using motherboard assembly **26025-125-150** enter **"2"**

13. Enter the Serial Number. When prompted type in the 5 digit # or 12 digit # as read from the back label of the device.

14. Enter the Manufacturing Code (Location).

    When prompt type in **"3"** for Milwaukee

15. The **"Device ID**" enter below is tied to the part number of the device being built.
    - For model number **010-2400-01** and **010-2400-03** enter **"1"** for units with Actigraphy.
    - For model number **010-2400-02** and **010-2400-04** enter **"2"** for units without Actigraphy.

Leak Testing and Pressure Sensor Test

1. UUT raise the maximum allowed pressure by issuing the following command:
   Command **cct.py –s com5 –m 285**

2. Close the dump valve by issuing the following command:
   Command **cct.py –s com5 -- --dump 1**

3. Close the proportional valve by issuing the following command:
   Command **cct.py –s com5 -- --prop 1**

4. Verify the pressure sensor test by issuing the follow command:
   Command **cct.py –s com5 -- --gp**

   (Verify that the pressures provided by the ABPM device are within ±3 mmHg of the pressures indicated by the simulator).

5. Using the manual inflation bulb, pump up the simulator above **250** mmHg, and then turning the knob counterclockwise to release the pressure exactly **250 mmHg**. Observe the deflation rate on the simulator – ensure that this is within the acceptable range (less than 4 mmHg drop over 10 second period). Confirm by pressing ENTER.
   (***Record the measurement values on the test Sheet***).

6. Then release valve on the bulb, lower the pressure to **150 mmHg**. Observe the deflation – ensure that this is within the acceptable range (less than 4 mmHg drop over 10 second period). Confirm by pressing ENTER. Verify the pressure by issuing the follow command. Then press ENTER.

   Command **cct.py –s com5 -- --gp**

   (***Record the measurement values on the test Sheet)***

7. Then release valve on the bulb, lower the pressure to **50 mmHg**. Observe the deflation – ensure that this is within the acceptable range (less than 4 mmHg drop over 10 second period). Confirm by pressing ENTER. Verify the pressure by issuing the follow command. Then press ENTER.

   Command **cct.py –s com5 -- --gp**

   (***Record the measurement values on the test Sheet)***

Overpressure Safety Control Test

Verify the overpressure safety controls by observing that pressure releases once pressure exceeds the maximum allowable pressure.

*(Note: The maximum allowable pressure should already be set at **285 mmHg** per the previous step.)*

1. Close the dump valve by issuing the following command:
   Command **cct.py –s com5 --dump 1**

2. Close the proportional valve by issuing the following command:
   Command **cct.py –s com5 --prop 1**

3. Using the inflation bulb, manually increase the pressure to just beyond the set maximum pressure of 285 mmHg, and observe that the pressure drops to zero within 3 seconds.

   (NOTE: The device has a safety feature so that the maximum pressure cannot exceed 285 mmHg. Raising the pressure beyond this value will cause the device to release all pressure from the system and reset.)

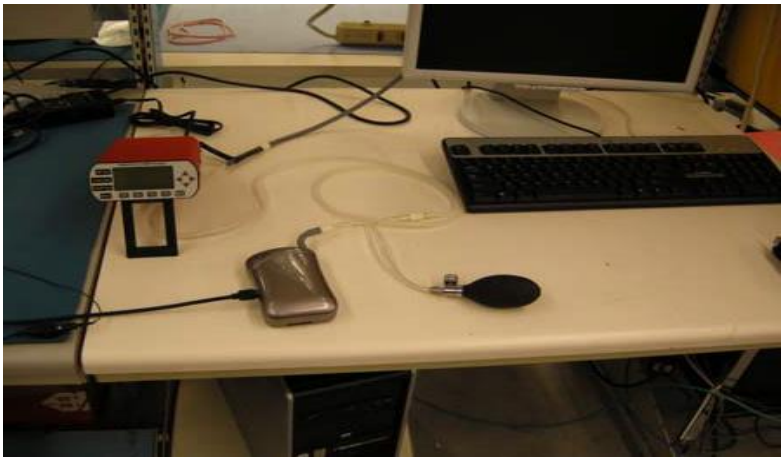
   (NOTE: The device has a safety feature so that the pressure in the system cannot be above 15 mmHg for more than 3 minutes. If pressure above 15 mmHg is maintained for more than 3 minutes, the device will release all pressure from the system and reset. This will cause the calibration process to fail and the process must be repeated.

Configuration Setup for BP Measurement Test

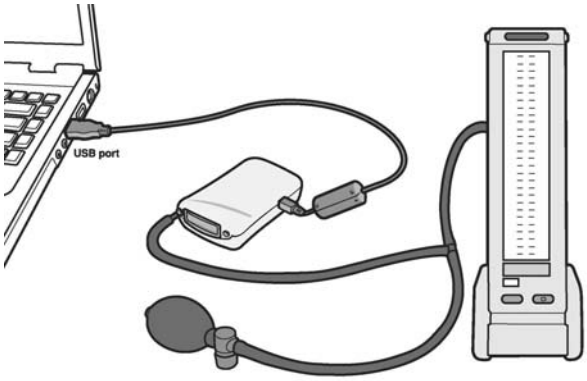
(See connections below)

Correct calibration setup requires the following components:

- Ambulo 2400 device
- Manometer/NIBP Simulator
- T-connector air hose
- Sphygmomanometer Manual Hand pump
- USB cable

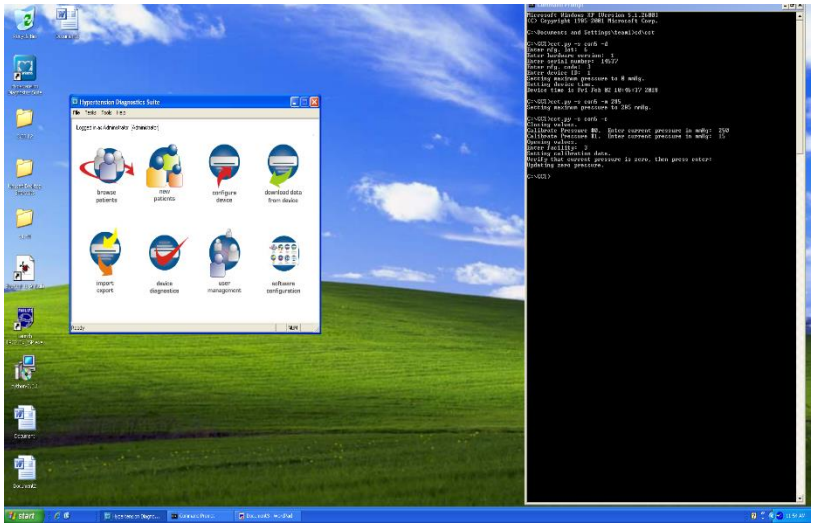


Once the components are setup correctly (refer to diagram(S) shown), proceed with the calibration process.

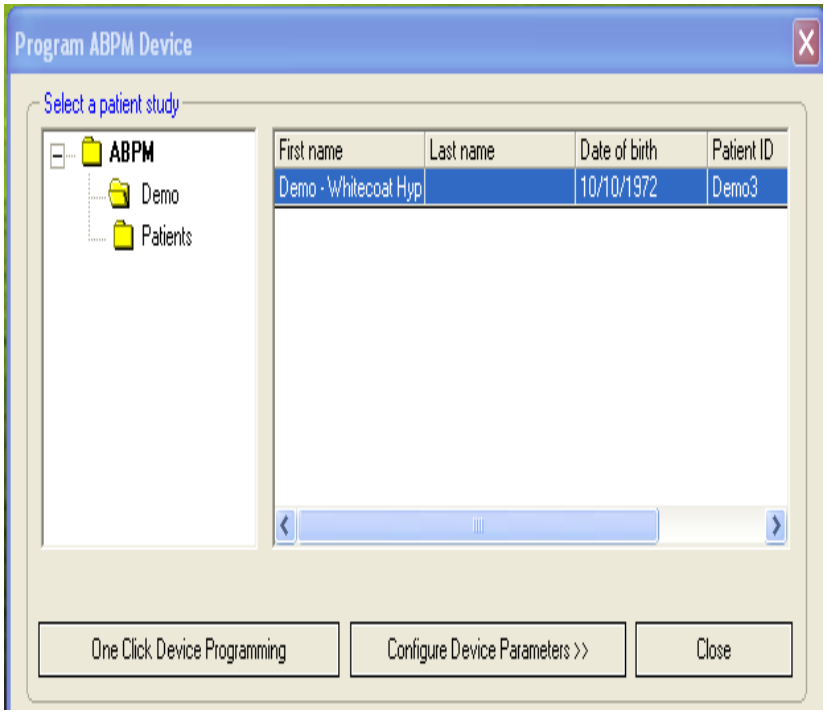


1. On the PC go to the Hypertension Diagnostics Suite screen as below:

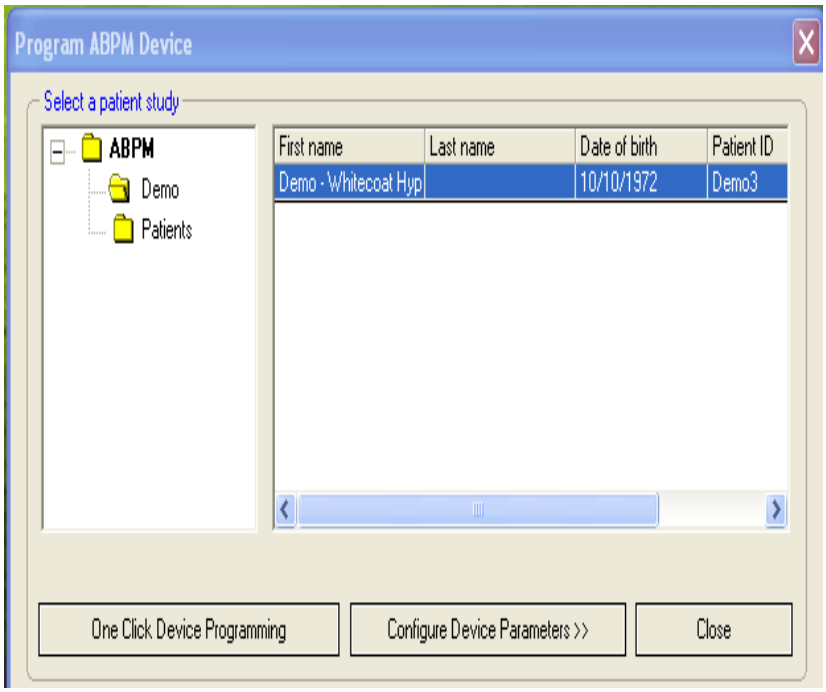
   Select "**Configure Device**" icon.

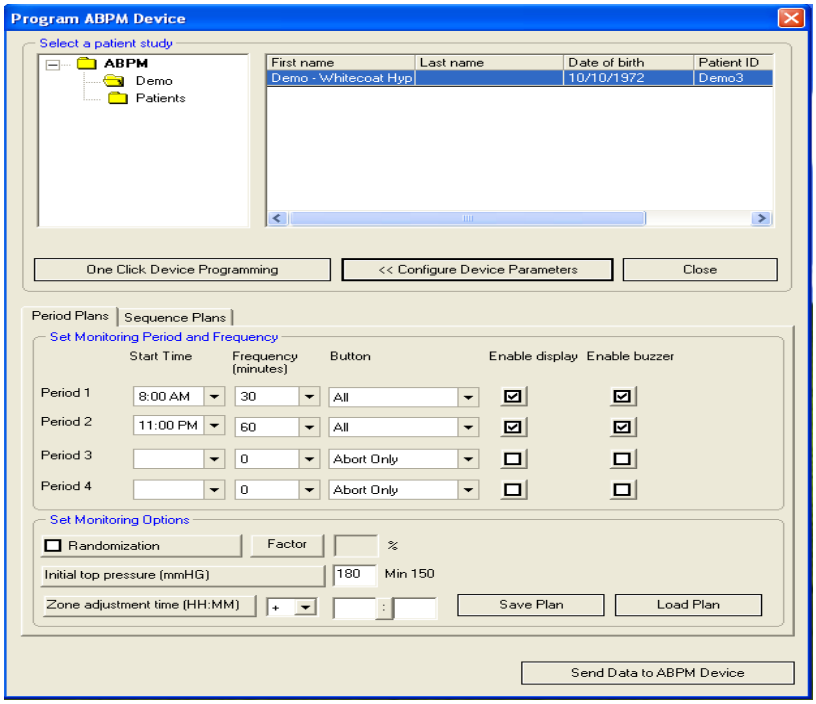


2. Select "**Demo**" Folder



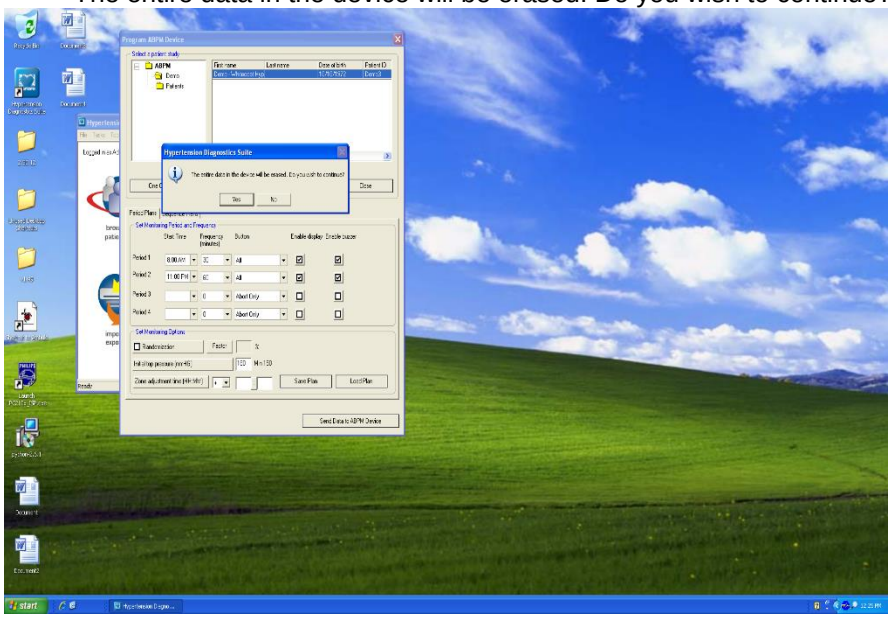
3. **UUT** select "**Configure Device Parameters**".





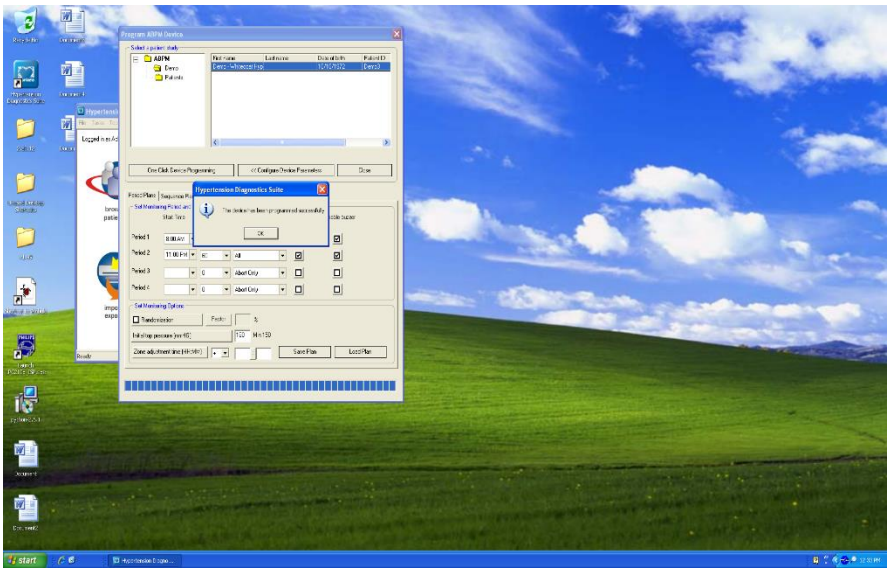
4. **UUT** select "**Send Data to ABPM Device".**
5. Select "**Yes**" when the window appears stating:

   "The entire data in the device will be erased. Do you wish to continue?"



6. Select "**OK**" when the screen displays:

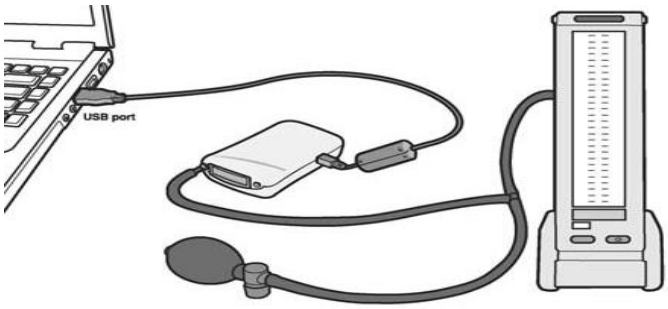
“The device has been programmed successfully.”



Pressure Accuracy Test

The pressure accuracy testing can be performed by using either the 'Hypertension Diagnostic Suite' software or via Command & Control Terminal CCT/Python commands as defined below.

Test configuration shown below, calibrated measurement device may vary.



CCT/Python Command method:

1. **Navigate to the CCT command prompt (typically C:\CCT)**
2. **Enter the following commands to perform the defined functions (including spaces and double dashes where shown).**

cct.py –s com5 --dump 1 (close the dump valve)
cct.py –s com5 --prop 1 (close the proportional valve)

3. **Use the pressure bulb to set the pressure to the following values, as measured by the calibrated measuring device, read the pressure as seen by the UUT for each value per the command in step 6.**

Target Pressure values – 250, 150, 50, 0 (+/- 5%)
cct.py –s com5 –-gp (get pressure from UUT)

4. **All measurements must be within +/-3mmHg to pass the test.**

Hypertension Diagnostic Suite method:

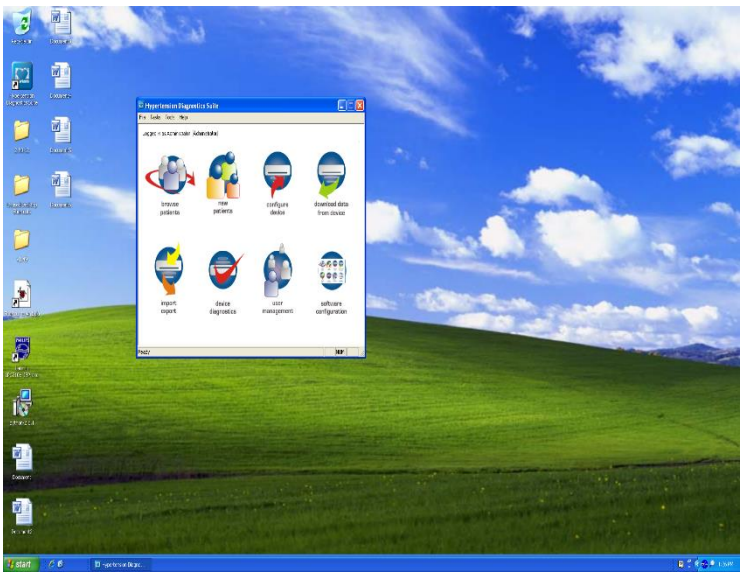
1. **Within the Hypertension Diagnostics Suite software's main screen, select the Check Calibration item from the Tools menu.**
2. **Once the check calibration wizard begins, you will be able to read the pressure as seen by the UUT at various values set between 0 and 250mmHg.**
3. **Use the pressure bulb to set the pressure to the following values, as measured by the calibrated measuring device, read the value as seen by the UUT for each value per the HDS software.**

Target Pressure values – 250, 150, 50, 0 (+/- 5%)

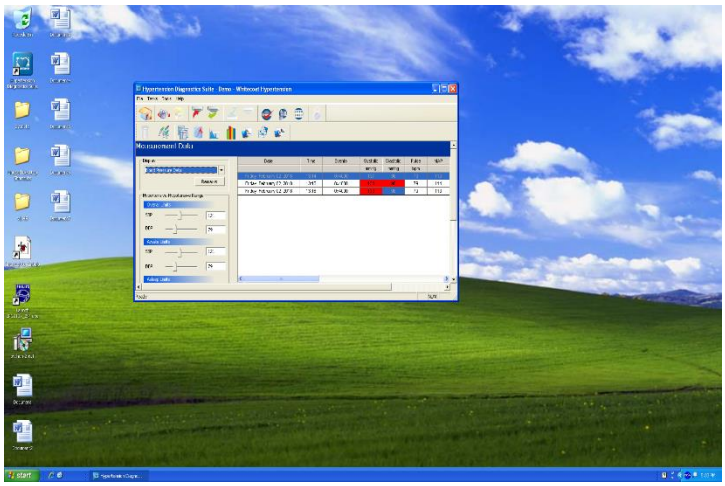
4. **All measurements must be within +/-3mmHg to pass the test.**

Data Download

1. Connect the device via USB cable to a PC, and open the Hypertension Diagnostics Suite software. Wait 3-5 seconds for the PC to recognize the device, and click “download data from device” on the main menu. If software freezes or crashes during download, force quit the software, disconnect device, open the software, reconnect the device, and retry download. Verify that measurements are successfully downloaded and displayed in the table view.



2. Click the “**House**” icon upper left corner to Exit.

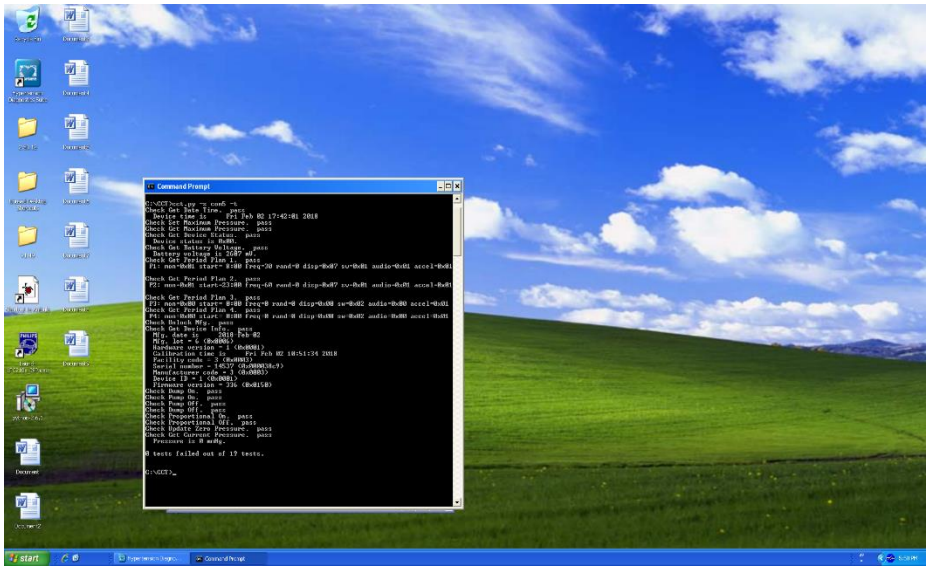


Diagnostic Testing

1. Run a quick diagnostic test by issuing the following command.

   Command **cct.py –s com5 –t**

2. Verify the dump valve closes and the pump is active briefly during this test. These two checks should be verified by listening to the UUT. There should be no failures listed once the command is issued.



(NOTE: This command can also be performed using the Hypertension Diagnostics Suite software by technicians or end users. From the main menu, click "device diagnostics", and select "Perform Diagnostics". Verify the dump valve closes and the pump is active briefly during this test. These two checks should be verified by listening to the UUT.)

3. Select "Configure Device" on the Hypertension Diagnostic Suite.
4. Select "Configure Device Parameter".
5. Select "Send Data to ABPM Device", then click "Yes" and then click "OK"
6. Indicate the testing results on the test data record.
7. Disconnect the USB cable and the tubing from the device.

Safety Testing

Safety testing is not required for the Ambulo 2400, unless the device is being distributed in countries accredited by INMETRO (Brazil).

If INMETRO safety testing is required, refer to MIS-03-182-01 to perform the necessary testing.

Ambulo 2400 Conformance Test Record

Unit Serial #:_____Incoming Firmware Version: _____

□ **Clean Device**

□ **Device Inspection**

Leak Test (<4 mmHg drop over 10 seconds) / Pressure Sensor Test (+/- 3 mmHg)

Deflation Rate @ 250 mmHg **/** Actual Input_____mmHg Reported_____mmHg □ Pass □ Fail

Deflation Rate @ 150 mmHg **/** Actual Input_____mmHg Reported_____mmHg □ Pass □ Fail

Deflation Rate @ 50 mmHg **/** Actual Input_____mmHg Reported_____mmHg □ Pass □ Fail

Overpressure Safety Control Test

Overpressure control □ Pass □ Fail

Pressure Accuracy Test (record both Target & UUT reading, tolerance of +/-3mmHg)

250 Target _____ mmHg UUT _____ mmHg

150 Target _____mmHg UUT _____ mmHg

50 Target _____ mmHg UUT _____ mmHg

0 Target _____ mmHg UUT _____ mmHg □ Pass □ Fail

Diagnostic Testing

Data Download □ Pass □ Fail
Diagnostic Testing □ Pass □ Fail
Functional Testing □ Pass □ Fail

Safety Testing □ **Not Required** □ **Required for Brazil** (refer to attached test report)

Performed by: _____ Date:_____

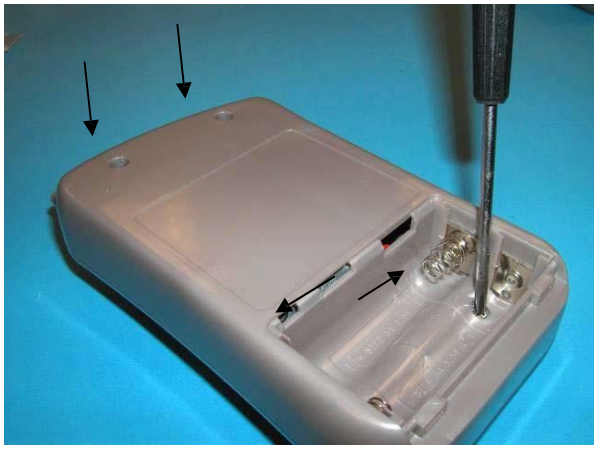
Unit Disassembly

Ambulo 2400 Unit Disassembly

NOTE: Unit assembly is the reverse of the disassembly procedure.

Removing Bottom Cover

1. Remove the battery door and 4 T6 Torx screws from bottom cover (2 in the battery compartment). The bottom cover is now secured only by the battery connector.

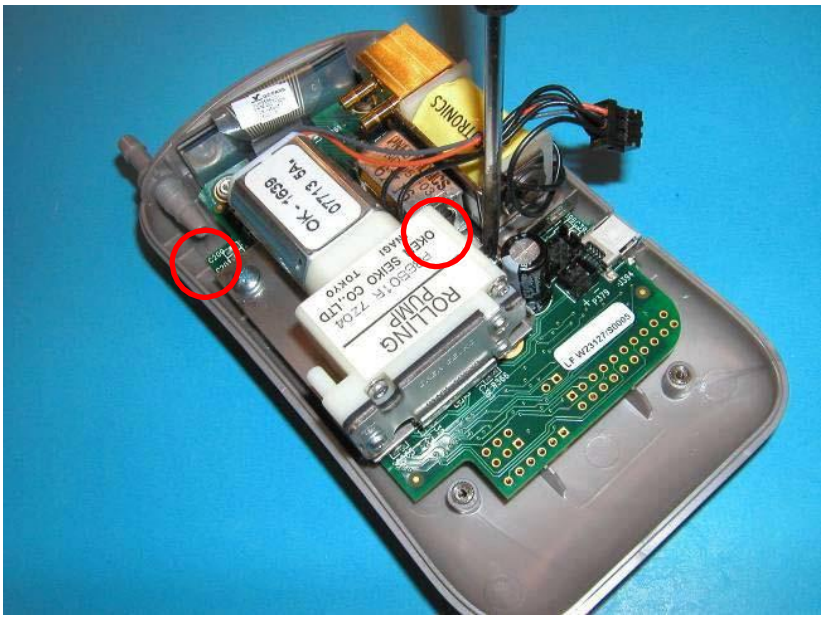


2. Carefully lift the bottom cover and disconnect the Hirosi-terminated battery connector from the PCB. You can now remove the bottom cover from the device.

Removing the Electro-mechanical Assembly and Manifold

3. Disconnect the electro-mechanical lead from the 6-pin mating connector on the PCB, and disconnect the manifold where it connects to the lower nozzle of the pump.

4. Remove the 2 screws that secure the electro-mechanical assembly to the PCB, one will be hidden under the left side of the manifold.



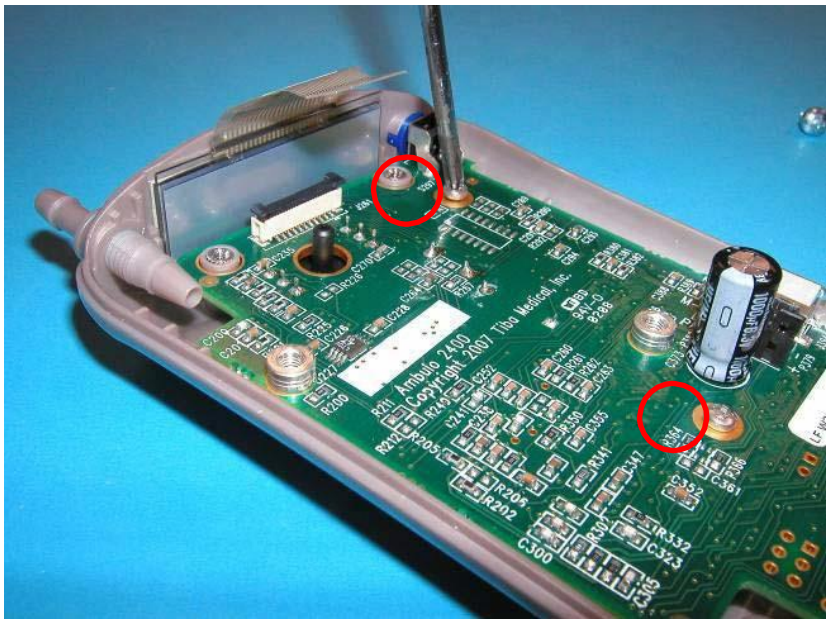
5. Gently lift the right side of the electromechanical assembly (the side opposite the air socket) until you feel the manifold disconnect from the pressure sensor port on the PCB. The assembly will now be secured only by its connection to the air socket.

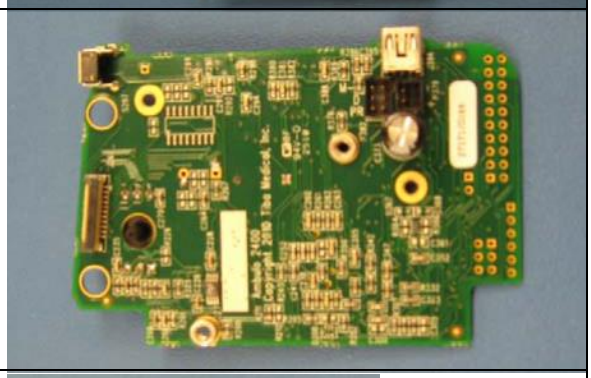
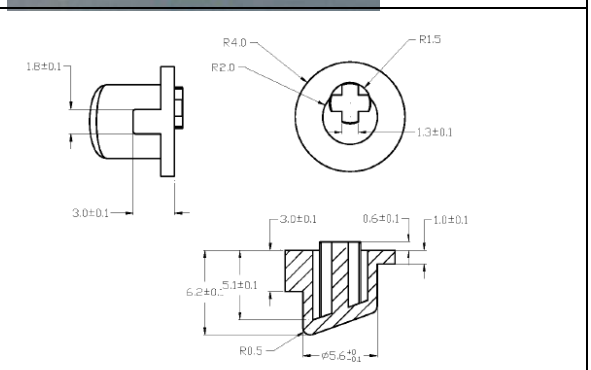
   Gently pull the left side of the manifold straight away from the air socket until it slides free with the electro-mechanical assembly attached. You can now remove the electro-mechanical assembly and manifold from the device.

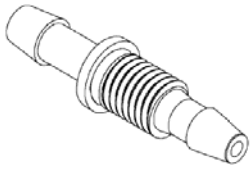
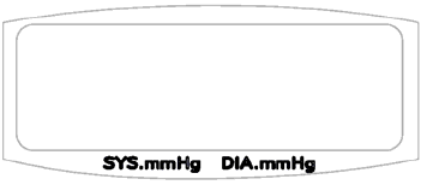
Removing the PCB

6. Gently lift both sides of the ZIF connector socket, to unlock. Disconnect the LCD ZIF connector from the socket on the PCB.

7. Remove the 2 screws that connect the PCB to the top cover. You can now remove the PCB from the device.



Ambulo 2400 Item Identification Table		
Part #	**Description**	**Picture**
010-0003-01	SUBASSY ELECTRO MECH AMBULO 2400	
010-0004-03	SUBASSY MOTHERBOARD AMBULO 2400	
500-0001-01	DISPLAY LCD 40x15MM	
8362-005-50	TOP BUTTON AMBULO 2400	

Ambulo 2400 Item Identification Table		
Part #	**Description**	**Picture**
8362-007-50	COUPLER THREADED BARB AMBULO 2400	
010-0001-01 010-0001-02	SUBASSY BACK COVER AMBULO 2400 (refer to item BOM below for listing of subcomponents) (Same item – Cool Grey Color)	
010-0002-01 010-0002-02	SUBASSY TOP COVER AMBULO 2400 (refer to item BOM below for listing of subcomponents) (Same item – Cool Grey Color) *Note: Cool Grey item does not have cutout to fit the tall piezo buzzer used with older white plastic units.*	
8362-003-50 8362-003-60	BATTERY DOOR AMBULO 2400 (Same item – Cool Grey Color)	
8362-004-50	LCD BEZEL AMBULO 2400	
8362-005-50 8362-005-60	TOP BUTTON AMBULO 2400 (Same item – Cool Grey Color)	Picture Not Available

SUB-ASSEMBLY BOM LISTING	
SUB-ASSEMBLY	**SUB-COMPONENTS**
010-0001-01	8362-002-50 BOTTOM COVER AMBULO 2400 504-0003-01 WIRE STRANDED 24AWG UL1061 BLACK 504-0004-01 WIRE STRANDED 24AWG UL1061 RED 610-0004-01 CONNECTOR,RECEPTACLE,2P,2MM CTR,ST 3400-025 CONTACT FEMALE 24-28AWG CRIMP TIN DF3
010-0002-01	500-0001-01 DISPLAY LCD 40x15MM 650-0001-01 TAPE DOUBLE COATED 0.8MM AMBULO 2400 7401-010 TAPE DBL COATED URETHANE FOAM 0.045x0.75 8362-001-50 TOP COVER AMBULO 2400 8362-004-50 LCD BEZEL AMBULO 2400 8362-005-50 TOP BUTTON AMBULO 2400 8362-007-50 COUPLER THREADED BARB AMBULO 2400 9326-009 ADHESIVE CYNOACRYLATE PERMABOND 910

SCREW IDENTIFICATION TABLE	
Part Number	**Where Used**
6020-0006-01	Used to fasten rear housing to device.
6020-630	Used to fasten Electro-Mechanical assembly to the front housing.
6020-033-01	Used to fasten the Motherboard assembly to the front housing.

DEVICE SPECIFICATIONS

Ambulo 2400 Specifications

FEATURE	SPECIFICATION
Dimensions	4.7 x 2.7 x 1.2" (119 x 68 x 32 mm)
Weight	9.0 oz (253 g) (with batteries)
Measurement Principle	Patented oscillometric technique with linear deflation.
Measurement Ranges	Systolic: 60 to 280 mmHg Diastolic: 40 to 160 mmHg Pulse Rate: 30 to 180 bpm
Measurement Accuracy	Blood pressure: ±3 mmHg mean difference ±8 mmHg standard deviation Pulse rate: ±3 bpm According to ANSI/AAMI SP-10:2002 & BHS (Grade A/A) and ISO 81060-1:2007
Measurement Intervals	Four adjustable intervals during 24-hour period, each configurable to 0, 5, 10, 15, 20, 25, 30, 45, 60, 75, 90, 105, or 120-minute measurements. Optional randomization factor up to 75% within intervals. Supports measurement over extended periods of time, typically 24 hours, and up to 7 days. Optional configuration support for Phase I clinical trials involving PK/PD dosing using discrete measurement time points based on protocol requirements. Measurements taken based on a sequence of time points until completed.
Available Cuffs	Regular, large and small adult cuffs included. EasyWear™ cuff optional.
Actigraphy Option	Recording of 3-axis of motion via accelerometer for display and categorization of awake/asleep cycles via application software.
Memory	Solid-state Flash technology. Sufficient for 2,700 blood pressure measurements and 7 days of continuous actigraphy.
PC Interface	USB
Battery Power Requirements	2 x 1.2V NiMH rechargeable batteries; 2.4V DC; Maximum current: 610mA. Sufficient for approximately 300 measurements using regular adult cuff.
Software	Hypertension Diagnostics Suite requires PC running Microsoft Windows XP SP2, Windows Vista, or Windows 7 with a minimum graphics resolution of 1024 x 768.

TROUBLESHOOTING

System Troubleshooting Chart

"SE XX" is related to an internal software error encountered by the device after power-up. Often pressing the button will continue past such errors.

"HE XX" is related to an internal hardware error. These errors typically require service.

LCD Message	Problem	Correction
HE 1	Main processor needs programming	Program and calibrate main processor
HE 37 or HE 18	Device has not been calibrated, or calibration has been corrupted	Either the customer must calibrate the device using the HDS instructions (requires a manometer - preferably digital, tubing, and a hand pump), or have serviced by Welch Allyn.
SE 1	No main processor calibration detected	Calibrate main processor
SE 18	Bad configuration	Configure device. If problem persists, recalibrate.
SE 25	Bad configuration	Configure device.
SP Err	Improper safety processor calibration.	Recalibrate safety processor. If problem persists, reload safety processor firmware and then recalibrate main processor again
Does not display "usb" when connected via USB.	Bad PCB likely	Replace PCB, calibrate main processor
Device does not respond to power, display remains blank	Safety processor reset, or bad PCB	Load safety processor firmware, calibrate safety processor, load main processor firmware, verify that PCB beeps when connected to power
Err 41	Pressure timeout to high pressure limit. Device leaks	Correct air leak by testing accessories and device using NIBP simulator, replace leaking accessories or complete electro-mechanical assembly if device cannot pass leak test
Err 40 and/or Err 162	Rare, and have often been reported together. Device would not inflate	PCB and prop valve had to be replaced. Or cuff may have leak.
Err 163 and/or Err 23	Err 23 has been reported alongside Err 163. Associated with complaints of Slow deflation, sometimes	Typically solved by upgrading to firmware with dynamic deflation adjustment (V1.47 or newer) and calibrating main processor
Err 166	Overpressure error, meaning that the pressure has reached higher levels than the max set. Device miscalibrated, typically in the field	Device needs main processor calibration
Err 164	Associated with complaints of slow deflation and older firmware	Main processor needs firmware upgrade and calibration

Device Programming

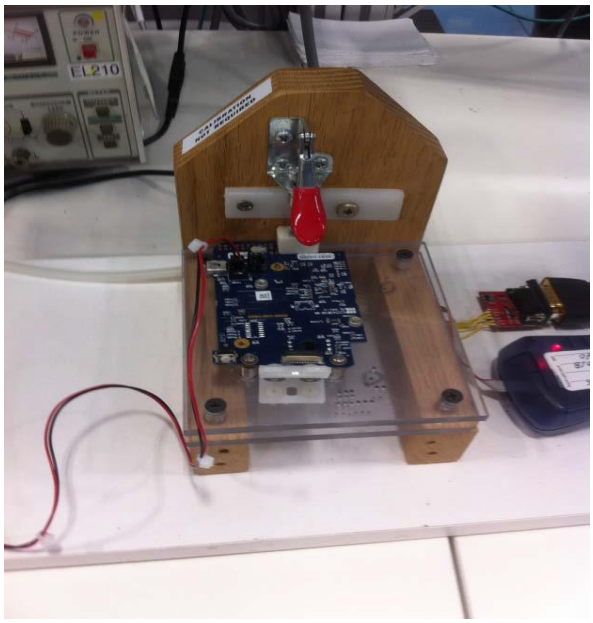
Programming the Main Processor

Required Equipment

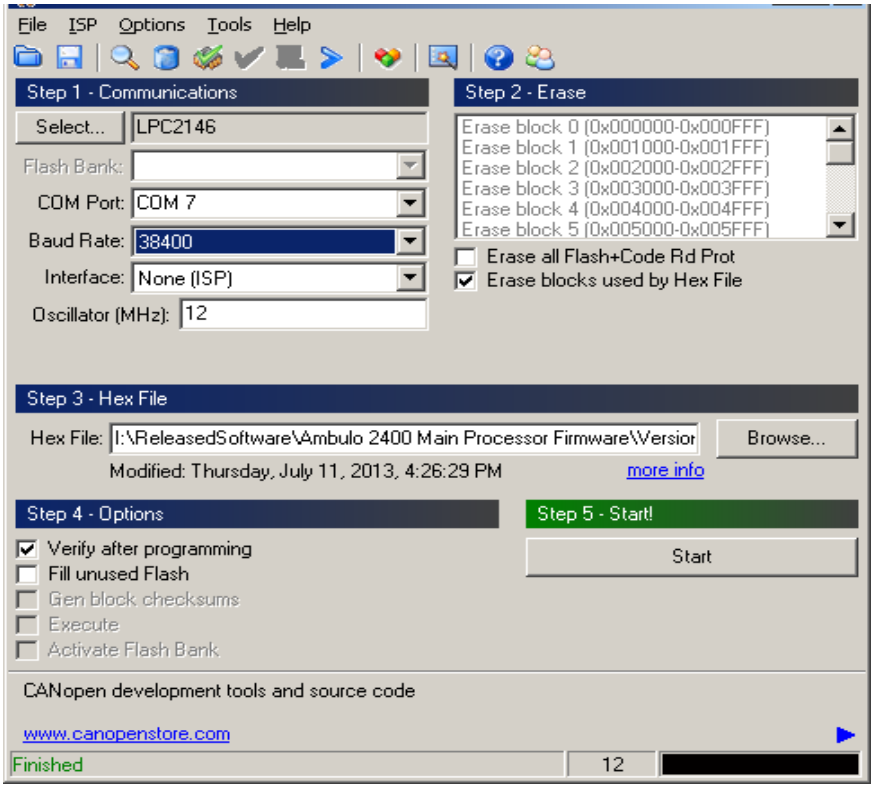
QTY	Part number	Description / Specification
1	TF-0539	Computer workstation loaded with AMBULO2400 programming software
1	TF-0541	Serial Cable with Spark fun LPC programmer
1	EL109 or equivalent	DC Power Supply

1. Place TF-0541 in the corresponding programming leads on the board at location P163 (see picture below).

With fixture handle all the way down



2. Run the Flash Magic utility, by opening the Flash Magic icon from the TF-0539 desktop. Select the appropriate COM port and a speed of 38400.
   Select LPC2146 for the Device, none for Interface, and 12 MHz for Oscillator.



3. Click “Start”. This will program the main processor.

   (The Programming will display **“Finished**”).

4. After the Programming is finished, Power down the Power Source, and then release the handle of the Fixture. ***The board now should be upward position and the Fixture handle should be ½ way up.***

   If the programming fails, you will know from a resulting error. Most likely this would be due to the programming leads failing to maintain contact for the duration of programming.

   (Note: If the programming fails, the process can be repeated until successful)

   This version is the .hex file displayed in the Hex File window of the LPC programming Utility.

Safety Processor Programming

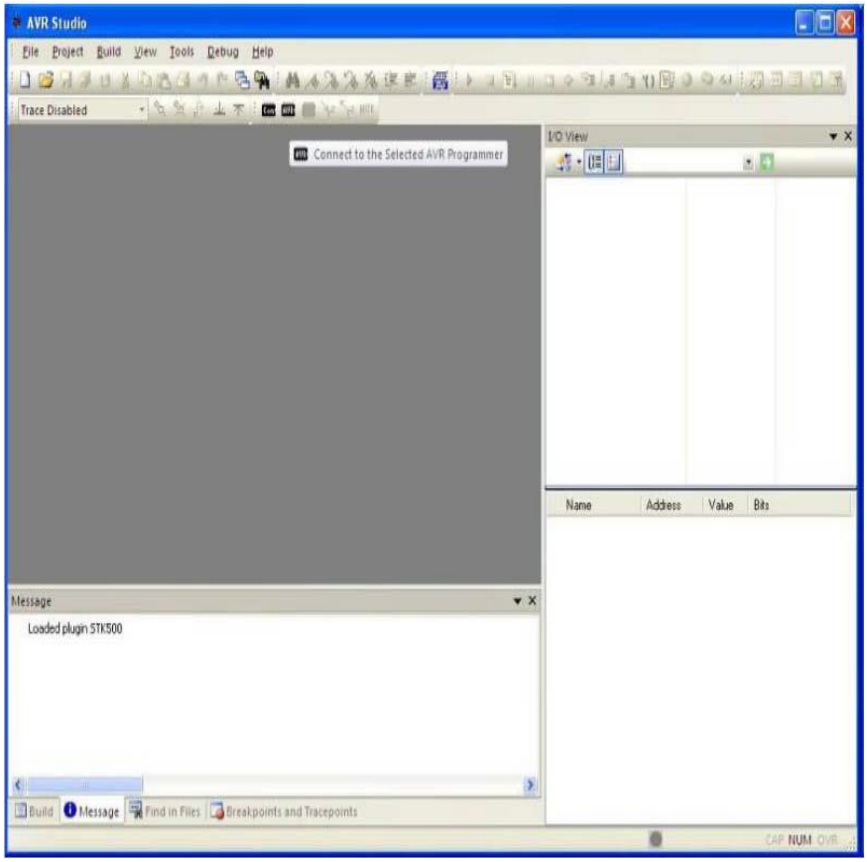
*(NOTE: If the UUT continually fails the BP Measurements Test, then perform the "**Programming the Safety Processor**" for the main board.)*

*(NOTE: Programing the safety Processor can be performed at the production facility due to the availability of the "**Required Equipment".**)*

Required Equipment

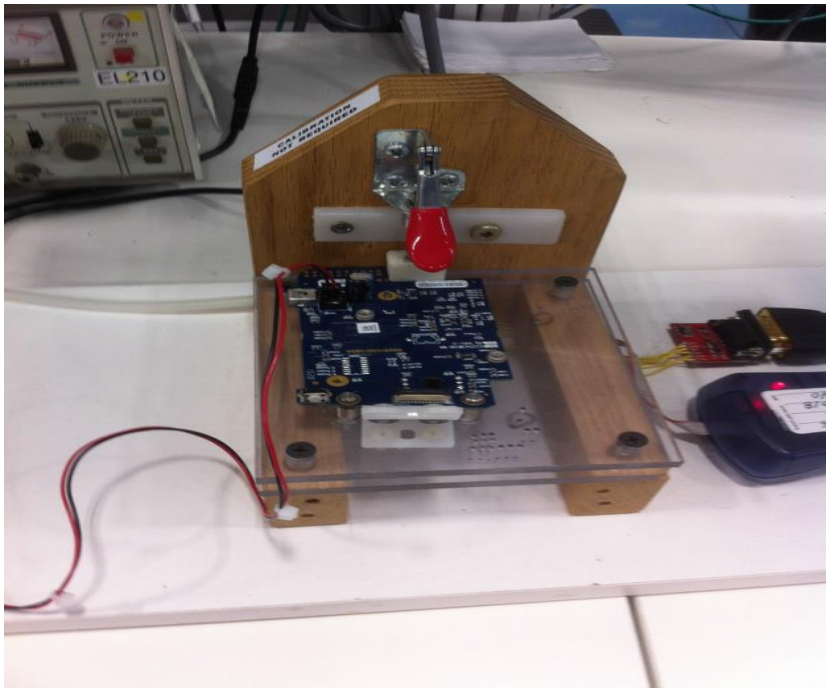
QTY	Part number	Description / Specification
1	TF-0539	Computer workstation loaded with AMBULO2400 programming software
1	TF-0540	AVR mkII Atmel Programming Fixture
1	TF-0541	Serial Cable with Spark fun LPC programmer
1	EL109 or equivalent	DC Power Supply

1. Connect TF-0540 to TF-0539 via the USB cable connection. Open the 'AVR Studio' shortcut Icon from TF-0539 desktop. Click the AVR button, shown below:



2. Ensuring the correct polarity (with the board positioned as shown below, the colored cable on the programming cable should be on the right side; see below picture), insert the AVRISP mkII header into the board at location P174. Ensure power is connected to UUT at location P379 using back cover assembly. At this point, the light on top of the AVRISP should turn green, to indicate connectivity.

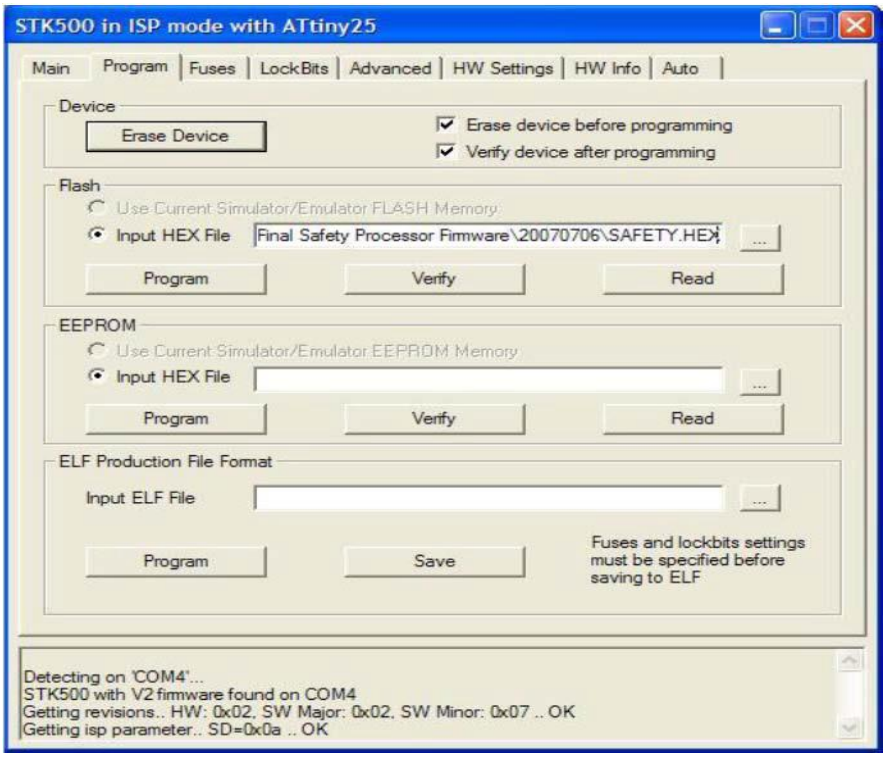
With fixture handle all the way down:



3. In the computer device manager screen, verify which com port number the AMBULO device is assigned. Select device ‘ATtiny25’ and verified COM port number in AVR Studio, and use the factory defaults for fuses: Efuse FF Hfuse DF Lfuse 62

4. In the Programming process, turn on the External DC power supply, and set at **“3VDC”**

5. In the Program tab indicated in the picture below, select the ‘Program’ button. Confirm that the software reported the programming has been completed successfully.



6. After programming is completed, note the firmware version provided at the bottom of the programming software window.