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Ambulo 2400
AMBULATORY BLOOD PRESSURE MONITOR
USER MANUAL

Manufactured by Mortara Instrument, Inc., Milwaukee, Wisconsin U.S.A.



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



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NOTICES

Manufacturer's Responsibility

Mortara Instrument, 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 Mortara Instrument, 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

Mortara Instrument, 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.

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MORTARA INSTRUMENT, INC. (hereafter referred to as “Mortara”) warrants that components within Mortara 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 Mortara, 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 Mortara;
- 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 Mortara;
- f) Other events outside of Mortara’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 MORTARA TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Mortara of any alleged defects promptly after discovery thereof within the warranty period. Mortara’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 Mortara’s principal place or any other place as specifically designated by Mortara or an authorized distributor or representative of Mortara, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Mortara is limited and that Mortara does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Mortara 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 Mortara should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Mortara shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

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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 Mortara 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/repared 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:



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



Attention, consult accompanying documents.

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.



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. Per European Union Directive 2002/96, requires separate handling for waste disposal according to national requirements.



Indicates compliance to applicable European Union directives.



Consult accompanying documents

GENERAL CARE

Precautions

- 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.

Inspection

Inspect your equipment prior to operation.

- Check the device for any visible damage.
- Inspect cuffs, bladders, and tubes for any visible damage.

If you notice anything that requires repair, do not use the equipment. Contact Mortara Technical Service for any necessary repairs.

Cleaning the Cuffs

Orbit Cuffs

1. Orbit cuffs may be cleaned with a mild disinfectant spray. The outer shell of the Orbit cuffs can be machine washed using warm water and soft detergent. Line dry. Refer to additional Instructions for Use provided with the cuffs. After removal for washing, the bladders can be rolled and carefully placed back in place. Ensure that the bladder is properly put back in place and is flat without kinks.

Other Cuffs including EasyWear™ 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. Suntech Orbit cuffs may be machine washed by removing the bladder and washing the shell using warm cycle (50-140° F or 10-60° C). 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.
9. Refer to additional Instructions for Use provided with the cuffs. After removal for washing, the bladders can be rolled and carefully placed back in place. Ensure that the bladder is properly put back in place and is flat without kinks.



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.*

Cleaning the Device

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.

Cautions

Improper cleaning products and processes can damage the device and void the warranty. Use care and proper procedure whenever cleaning or maintaining the device.

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 Mortara Instrument 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	
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	<p>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.</p> <p>Recommended separation distance</p> $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.17\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.34\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

- 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.

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Manual Purpose

This manual is intended to provide the user with information about:

- Using and understanding the Ambulo™ 2400, its LCD panel, and program icons.
- Preparing the Ambulo 2400 for use. (Section 2)
- Installing the software. (Section 3)
- Starting the program. (Section 4)
- Viewing data measurements. (Section 5)
- Performing an ABPM procedure. (Section 6)
- Troubleshooting and maintenance. (Appendix A)
- Error and diagnostic codes. (Appendix B)

***NOTE:** This manual may contain screen shots. Any screen shots are provided for reference only and are not intended to convey actual operating techniques. Consult the actual screen in the host language for specific wording.*

Audience

This manual is written for clinical professionals. They are expected to have working knowledge of medical procedures and terminology as required for monitoring patients.

Intended Use

The Ambulo 2400 is intended to be a compact, non-invasive Ambulatory Blood Pressure Monitoring (ABPM) system. ABPM technology involves the use of an automatic, non-invasive device to measure blood pressure over an extended period of time – typically 24 hours. The ABPM procedure is an essential tool for physicians, clinical researchers, and other healthcare professionals to analyze a patient's blood pressure as it relates to his/her circadian rhythm. This process offers insight into diagnostic factors as they relate to the spectrum of activity within everyday life.

Indications for Use

The Ambulo 2400 Ambulatory Blood Pressure Monitor is indicated for use in adult & pediatric patient populations; it is not indicated for use with neonates.

The Ambulo 2400 Ambulatory Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure and pulse rate of adults and pediatric patients, using the oscillometric method on a cuffed arm.

Contraindications

The Ambulo 2400 device is not intended for measurement of blood pressure in neonate patients.

Clinical Validation

The Ambulo 2400 has been independently validated to ensure that it meets various clinical accuracy requirements. The independent validation was performed by Dr. Bruce Alpert, MD at the University of Tennessee, USA and published in the Blood Pressure Monitoring journal as “Validation of the Tiba Medical Ambulo 2400 ambulatory blood pressure monitor to the ISO Standard and BHS protocol”, PubMed ID #20559140. A copy of this publication may be requested through your Mortara Representative.

This study involved comparison of a set of measurements taken by trained observers on 85 adult, adolescent and pediatric subjects, and comparing the results to those taken by the Ambulo 2400. To determine the diastolic measurements during auscultation, the trained observers used the K5 Korotkoff sounds on 55 subjects and the K4 Korotkoff sound on 30 subjects. The results of the study indicate that the Ambulo 2400 meets the highest standards of both the global ISO 81060-2 as well as the stringent requirements of the British Hypertension Society’s protocols ensuring that the system performs equally well in all blood pressure ranges.

Pediatric Features

The Hypertension Diagnostics Suite software has specific features particularly suited to use in pediatrics, including automatic adjustment of blood pressure range limits using, at the user’s option, either data from the U.S. Centers for Disease Control (CDC) or data from the German Working Group on Pediatric Hypertension, Wühl et al, as reported in “Ambulatory Blood Pressure Monitoring in Children and Adolescents: Recommendations for Standard Assessment,” by Urbina et al, Hypertension Journal; 2008;52;433-451.

System Description

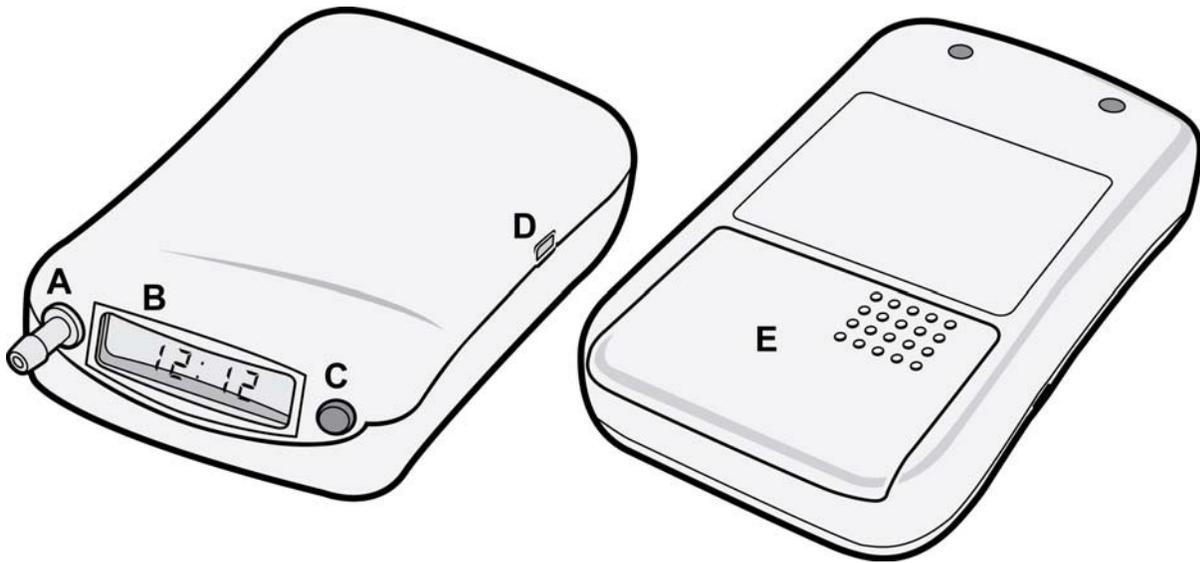
The Ambulo 2400 is a lightweight, quiet, and comfortable ABPM system that does not interfere with daily activities. The device is easily configured and individually-fitted for each patient by a physician or nurse. The 24-hour measurements for systolic and diastolic blood pressure, the mean arterial pressure, and the pulse rate are automatically obtained without medical supervision, and later downloaded to a computer for analysis and interpretation.

The Ambulo 2400 system includes a number of components that are essential to carrying out successful ABPM procedures on a wide variety of patients. While exact configurations will vary depending upon what options are chosen and where the system is purchased from, it will generally include the following:

- Carry pouch with belt clip and shoulder strap
- Adult cuffs: large, regular, with optional small adult and child cuffs
- Extension hose
- USB cable
- (2) rechargeable NiMH batteries
- CD-ROM Software

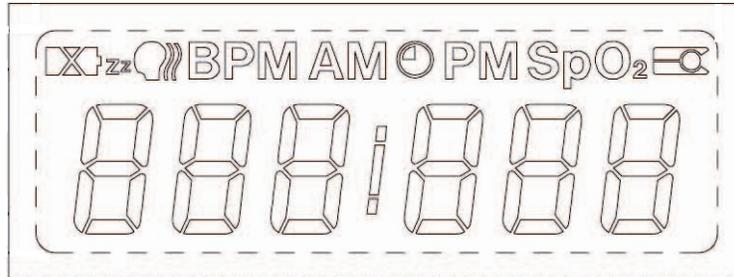
Device Overview

Figure 1-1



- A. Air socket
- B. LCD panel
- C. Start/Stop button
- D. USB interface
- E. Battery door

LCD Panel



During initial power-up, all available segments of the LCD will be turned on to verify correct functionality of the display. Not all available segments on the LCD are relevant to this device at any given time, and they may be activated during different operations.

Depending upon the mode of operation, the LCD panel will show any of the following items:

LCD Display	Description
PAUSE	Device is paused
BPM	Indicates Beats per Minute (Pulse)
AM	AM (12:00 AM – 11:59 AM)
PM	PM (12:00 PM – 11:59 PM)
	Low battery

- Current time.
- If the device is paused and not taking any measurements, the LCD will display PAUSE.
- If the device is in a measurement cycle, the LCD will display current time and, depending upon device configuration, time remaining until the next measurement.
- If the device is in the process of taking a pressure measurement, the LCD may display the current pressure level (in mmHg) during the inflation/deflation cycle.
- If the device has completed the measurement, the LCD may display the results of the current measurement—including systolic and diastolic pressure alternating with the pulse rate, as indicated via the BPM segment—for a few seconds.
- Any error messages.

Indicates that the device's batteries are low and need to be replaced/recharged. This symbol may appear during cuff inflation, and immediately disappear afterwards. If so, it indicates the device has sufficient standby power, but not enough power to inflate/deflate the cuff. Once battery condition becomes extremely low, the LCD display will indicate "Lo Bat" and the device will be inoperative until the batteries have been replaced.

Start/Stop Button

Press this button once to manually trigger a measurement. This function may be disabled via the software.

During a measurement, whether triggered manually or automatically, press this button to immediately stop the measurement in progress and deflate the cuff.

Press and hold the button for **five seconds** to put it in PAUSE mode. In this mode, the LCD will alternate between displaying the current time and PAUSE. This function is necessary if the patient does not want measurements taken automatically. This could be the case if the 24-hour measurement period is complete, or if there is a need for a rest (e.g., bathing or changing clothes).

If the device is in PAUSE mode, press and hold the button for five seconds to return to automatic mode. Depending upon how the device is configured, the screen will alternate between showing the current time and the time remaining until the next measurement.

In order to reset the Ambulo 2400 to go through its full-scale baseline measurement mode—from initial top pressure set all the way down to 45 mmHg (50 mmHg in firmware versions 1.48 and beyond)—**press and release the button three consecutive times**. The LCD display should then display “Hi <top pressure>,” where <top pressure> is the initial top pressure set on the device. This would be used in cases where wide fluctuations from the previously obtained values for systolic or diastolic are anticipated, such as after heavy exercise.

***NOTE:** Depending upon user configuration via the software, the Start/Stop button may be disabled. If so, the user will not have control over manually triggering a measurement and/or moving the device into PAUSE mode. The user can still stop a measurement in progress by pressing the button.*

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 81060-2:2013
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 cuffs included. Small adult, child and EasyWear™ cuffs 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; or 2 x 1.5V Lithium batteries. Maximum current: 610mA. Sufficient for approximately 300 measurements using regular adult cuff.
Software	Hypertension Diagnostics Suite requires PC running Microsoft Windows 7 or Windows 8.1 64-bit with a minimum graphics resolution of 1024 x 768. <i>Note: Requirement for signed USB drivers must be turned off in Windows</i>
Maximum Noise Level	46 dBA during inflation; not measurable above ambient level during deflation.

Accessories

Part Number	Description
008-0004-01	AA NiMH Batteries – Quantity 2ea
008-0005-01	EasyWear™ cuff
008-0006-01	Extension Hose
008-0007-01	Carrying Pouch, Belt Clip, and Shoulder Strap
6400-012	USB Cable
9515-182-50-CD	Ambulo 2400 User Manual CD

All purpose cuffs:

Part Number	Description
008-0001-01	CUFF BP AMBULO SMALL ADULT 17-25 CM
008-0002-01	CUFF BP AMBULO ADULT 23-33 CM
008-0002-02	CUFF BP AMBULO ADULT LONG 23-33 CM
008-0003-01	CUFF BP AMBULO LARGE ADULT 31-40 CM
008-0003-02	CUFF BP AMBULO LARGE ADULT LONG 31-40 CM
008-0004-01	CUFF BP AMBULO CHILD 12-19 CM

Orbit cuffs:

Part Number	Description
6901-023-01	CUFF BP AMBULO SMALL ADULT 18–27 CM
6901-023-02	CUFF BP AMBULO ADULT 25–35 CM
6901-023-03	CUFF AMBULO ADULT PLUS 33–40 CM
6901-023-04	CUFF AMBULO LARGE ADULT 39–46 CM

Contact your dealer or go to www.mortara.com for more information.

Air Socket

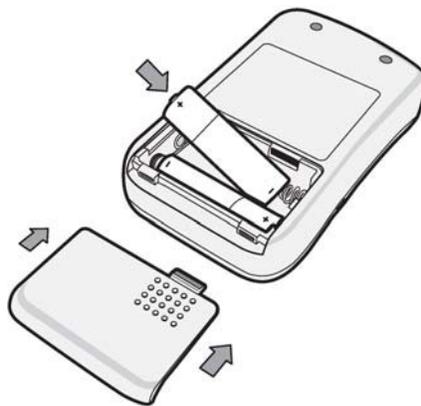
The air socket is used for inflation of the blood pressure cuff. When using the device directly on the EasyWear™ cuff, connect the air socket to the mating hose of the cuff. If the device is not placed directly on the EasyWear cuff, use the extension hose to connect the air socket and the blood pressure cuff. To attach, simply connect the hose to the air socket. To detach, pull away the hose from the air socket.

Inserting/Replacing Batteries

Slide open the battery door on the back of the device. This is accomplished by pressing down firmly on the studded section of the door and firmly pushing away from the device. The correct battery polarity is indicated inside of the battery housing. To replace the cover once the batteries are inserted, slide it along the side-rails until the tab on the top of the door clicks shut inside its housing.

Once powered, the device will beep and the LCD will briefly indicate the current firmware version of the device followed by the current time of day. The device will then continue operating in its last known configuration.

Figure 2-1



When replacing the batteries, please remember the following important directions:

- For best results, use fully-charged NiMH (Nickel-Metal Hydride) batteries or Lithium batteries with the device.
- The rechargeable NiMH batteries shipped with the device must be fully charged before use.

 **CAUTION:** Install the batteries exactly as instructed in the diagram. Incorrect installation of the batteries with the wrong polarity may damage the ABPM device and may void the warranty.

 **CAUTION:** It is recommended you use the provided NiMH rechargeable batteries or Lithium AA batteries for best results.

 **CAUTION:** Do not mix different types of batteries such as Alkaline disposables, NiMH, NiCD and Lithium rechargeable batteries.

 **CAUTION:** It is recommended that new batteries be used with each new 24-hour ABPM procedure. Low battery power may prevent measurements from being taken over the full 24-hour period, and may cause errors in communication with the device.

 **CAUTION:** When replacing the batteries, an internal battery preserves the internal real-time clock for 10 minutes. After this time, the date and time information will be cleared and must be resent.

 **CAUTION:** Rechargeable batteries should always be fully charged before use. This will ensure maximum performance of the device.

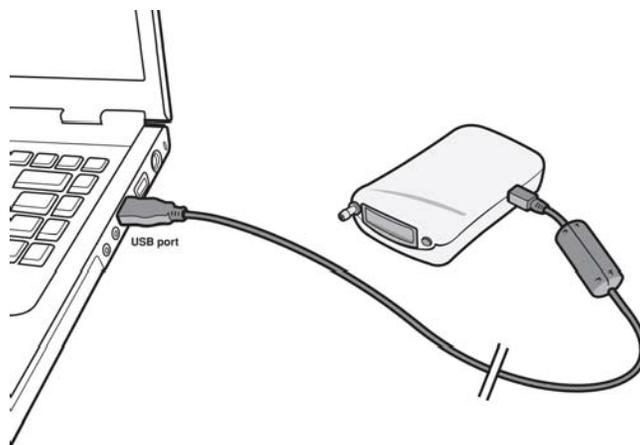
USB Interface

To use the ABPM device, it must be properly configured via the accompanying software on a Microsoft® Windows®-based personal computer. To do this, connect the ABPM to the PC using the provided USB cable. The Ambulo 2400 system has been successfully tested with both USB 2.0 and USB 1.1-based systems.

 **CAUTION:** Do not attach the ABPM device to a patient when it is connected to a PC via the USB cable.

NOTE: Do not connect the ABPM device to USB without batteries installed. While the ABPM device may turn on solely on USB-supplied power, it will not operate reliably in this manner and needs batteries to properly function including during device configuration, data download or testing.

Figure 2-2



Once connected, the LCD will alternate between displaying “USB” and the current time – indicating that the ABPM device is connected to the PC. While in this mode, the ABPM device will not take measurements.

Software Requirements

The computer must meet the minimum hardware requirements to successfully install the ABPM software:

Operating System	Windows 7 (any version) Windows 8.1 64-bit <i>NOTE: Requirement for signed USB drivers must be turned off for Windows 8.1</i>
Memory (RAM)	256 MB
Disk Space	50 MB (for the application software)
Drives	CD or DVD drive (for software installation)
USB	USB 2.0 or 1.1
Display	1024 x 768 resolution at minimum

The ABPM system software can be installed on multiple computers at separate locations such as multiple computers in one office, computers in two different office locations, or computers at both a clinic and a home office.

Installing the Software

- Insert the Hypertension Diagnostics Suite software CD into the computer’s CD drive. The installation routine should start automatically. If this does not occur, use one of the following methods to manually start the software installation process:
 1. Locate the CD drive on the computer via the My Computer feature. Double click on the **SETUP.EXE** application to start the installation process. Or,
 2. From the Windows Start menu, select **Run** and type “**X:SETUP**” to start the installation process (replace ‘X:’ with the appropriate CD drive, typically D or E).

***NOTE:** Entry is not case sensitive.*

***NOTE:** Software installation may require administrative privileges. Contact your computer administrator or IT help desk.*

- Follow the program directions and click **Next** when directed.
- You may be prompted to approve installation of drivers. If prompted, click “Install this driver software anyway”.
- Upon the successful completion of the installation, click **Finish**.
- When the installation is complete, remove the software CD from the computer’s CD drive. An icon designated as Hypertension Diagnostics Suite should be available on the computer’s Desktop. Use either the icon or the Start  Programs menu to launch the program.

Removing the Software

To remove the ABPM system software, use the Add/Remove Programs feature within the Windows Control Panel. From the Windows Start menu, select **Control Panel**  **Add/Remove Programs**  **Hypertension Diagnostics Suite**.

Upgrading the Software

Before upgrading the ABPM system software, make sure to backup any patient and measurement database file and uninstall any previous version of the software. Use the instructions provided in this section (see Installing the Software). Once installed, open the previously backed up patient and measurement database file.



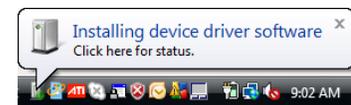
CAUTION: Do not delete, remove, or modify any of the program files or data files used by the ABPM system software. Doing so can damage the program and data files.

Installing USB Drivers

USB drivers are pre-installed with the software installation. The first time the ABPM is connected to the computer, Windows will automatically complete USB driver installation. No manual steps are necessary, but the installation process may take a few moments to complete.

The first time the ABPM is connected to the computer, Windows will display a “Found New Hardware” dialog box. It is not necessary to locate installation media; the driver has already been installed in a location where Windows can find it. Simply click Next. Windows may prompt you to approve driver installation.

Image shown is an example of what will appear in the system tray (typically lower right-hand side of the PC screen) when the device is connected to the PC for the first time.

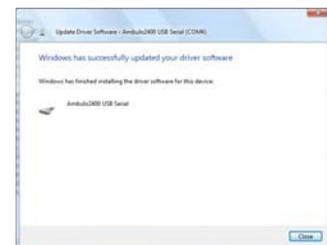


On some systems, a warning may appear regarding the driver software. This warning may be disregarded. If this warning appears, select “Install this driver software anyway”.



NOTE: The Ambulo 2400 USB driver is unsigned. To successfully install the Ambulo 2400 USB driver on certain Windows operating systems such as Windows 8.1, it is necessary to temporarily disable the driver signature enforcement of Windows prior to successful installation. Please refer to the Microsoft Windows technical documentation and instructions or relevant articles available on the Internet as to how to perform this task.

After installation is complete, Windows will acknowledge a successful driver installation.



Starting the Program

To run the ABPM system software application:

- Double-click the **Hypertension Diagnostics Suite** program icon on the computer desktop. Or,
- From the Windows Start menu, select **Programs 7 Mortara Instrument Inc 7 Hypertension Diagnostics Suite**.

The application software window should open and after the splash screen displays, the Main menu will appear.

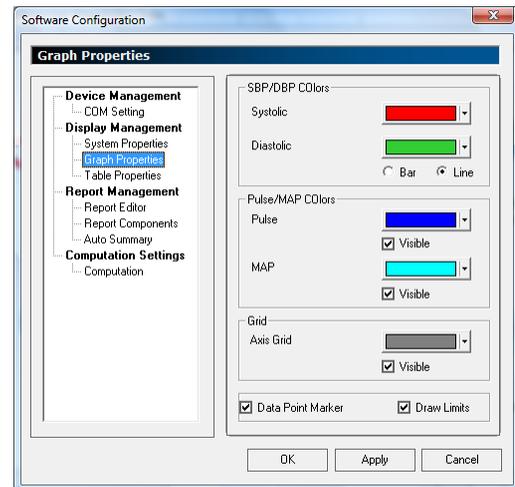
Use the Main menu icons to access the various aspects of the program, including data retrieval and analysis.

	Use the Browse Patients icon to select a patient and study data to analyze by way of tables and graphs, as well as print reports.
	Use the New Patients icon to add new patients.
	Use the Configure Device icon to configure the device for a patient and customize the details of their monitoring plan.
	Use the Download Data from Device icon to automatically extract measurements from the Ambulo 2400 (device must be connected to the PC via the USB cable), and add the information to a patient's records.
	Use the Import/Export icon to export/import patients and studies to/from external files.
	Use the Device Diagnostics icon to check the device for errors.
	Use the User Management icon to add or remove user accounts from the Hypertension Diagnostics Suite, as well as change passwords and account types.
	Use the Software Configuration icon to control display options within the software.

Software Configuration Menu

With Software Configuration, users can control display options within the software. To access the Software Configuration menu, click the **Software Configuration** icon, or select the option from the Tools menu at any time.

- Device Management
 - COM Port Setting
- Display Management
 - System Properties
 - Graph Properties
 - Table Properties
- Report Management
 - Report Editor
 - Report Components
 - Auto Summary
- Computation Settings
 - Computation



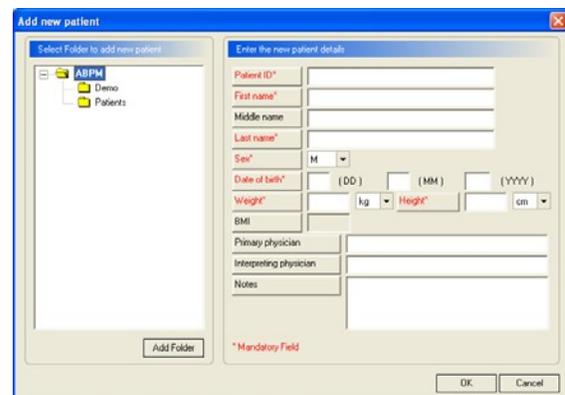
Each of these options pertains to a particular software screen or feature, and will be explained in this manual when relevant.

New Patients

When using the software for the first time, or to establish a new patient record, click the **New Patients** icon.

To create a new patient, the following fields are required (marked in **red** in the program):

- Patient ID – This can be any ID that is compliant with the physician’s labeling system. Common IDs are last names, account numbers, or social security numbers. This ID can be up to sixteen characters long.
- First Name
- Last Name
- Sex (M or F)
- Date of Birth
- Weight (lbs. or kg.)
- Height (in. or cm.)



Optional fields can be printed on the report if data is entered:

- Middle Name
- Primary Physician
- Interpreting Physician
- Notes – Any relevant notes on the patient or the procedure, including the physician’s interpretation of the results, may be entered here before, during, or after the procedure. This information will be included in the report. Note that medication information can be entered in a separate area once a study has been successfully completed.

Click **OK** to save the data.

In Clinical Research mode (defined in Software Configuration – System Properties), this screen looks different as shown below:

NOTE: New patients can be saved in the existing “Demo” folder; however, it is recommended you create a new subfolder in the ABPM directory to store patient information. Click **Add Folder** to create a new folder.

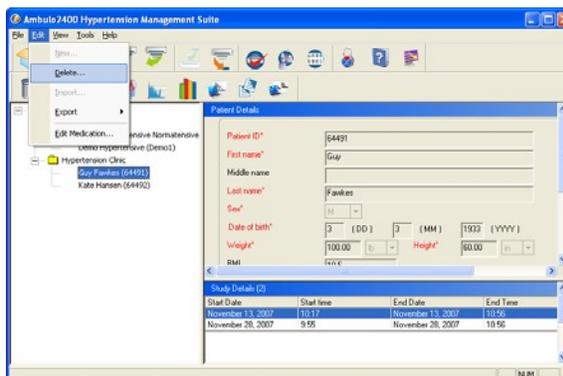
Browse Patients

To review, edit, or delete existing patient information, click the **Browse Patients** icon. The Add New Patient screen will appear, but the folder view on the left side will be expanded to list all the patients.

To review patient information, select a patient in the folder view or select a study for that particular patient. Use the toolbar at the top of the screen to go through the various views. To create a specific folder, right click the top-level folder in Patient View or Browse Patients and select **New Folder**. Enter a folder name at the prompt.

To edit information on an existing patient, select the desired patient and click **Edit**.

To delete a patient and all corresponding measurements, select the desired patient and then select **Delete** from the Edit drop-down menu. To delete an entire folder, right click the desired folder and select **Delete Folder**; to delete all the patients within a folder but not the folder itself, select **Delete All Patients**.



NOTE: Users must be logged into the program as an administrator or standard user to edit patients or delete patients who lack studies. To delete patients with studies or exclude patient data, users must be logged into the program as an administrator.

Configuring Device



CAUTION: Prior to configuration, ensure that any data measurements on the ABPM device have been previously uploaded and saved. Avoid mixing patient data measurements.

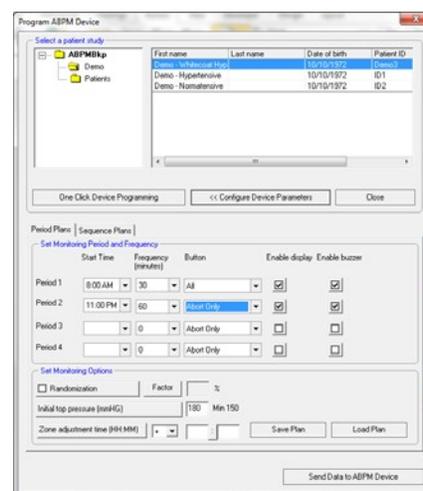
Prior to use with each patient, the device needs to be configured. Select **Configure Device** from the main program screen, or from the Patient View screen toolbar.

Once a patient has been created and/or selected, use the **Configure Device Parameters** button to schedule the intervals, frequencies, and other aspects of the ambulatory measurements. The window will expand into monitoring period options.

Period Plans

The default *Period Plans* tab configures the device to perform measurements at specific times of day. This configuration mode is generally well suited to clinical patient monitoring as it is designed for easy adjustment to awake/sleep periods as per the patient's sleep habits. The *Sequence Plans* tab configures the device to perform measurements at specified intervals, initiated by pressing and holding the Start/Stop button to start the sequence. This mode is preferred in specialty situations, such as drug trials, when measurements are needed at specific intervals following some external event whose timing may not be known in advance.

Within the *Period Plans* tab there are options to control various aspects of measurement within the prescribed monitoring period. Monitoring typically lasts 24 hours, but may be shorter or longer. The options are as follows:



NOTE: This screen is where the physician can select how much control or information the patient has access to, by way of option checkboxes per measurement period.

- **Start Time** – Dictates when the measurement period will begin, and is limited by the start time of the following period. Note that the start times for the four periods must be consecutive.
- **Frequency** – Pertains to how often a measurement is taken within the set period times.
- **Button** – Depending on the setting for each period, defines the functions available via the button. The options include 1) “abort only” to stop a measurement in progress; 2) “abort and pause” to allow automatic measurements to be placed in PAUSE mode (for instance upon completion of a 24-hour study or when the patient wishes to take a shower or change) in addition to aborting a measurement; 3) “abort and ad-hoc” which allows manual measurements to be taken as well as aborting measurements in progress; and finally 4) all, implying all available button functionality. Note that baseline reset via three consecutive button presses is always available.
- **Enable Display** – If the display is enabled, the patient will see it report the pressure (in mmHg) as the cuff is inflated/deflated during the measurement cycle. The patient will also see the values for systolic and diastolic blood pressure, as well as pulse rate, directly on the LCD after the measurement. If the display is disabled, the LCD will alternate between showing the current time and the time remaining until the next measurement. The pressure during inflation/deflation and the results of the measurement will not display.
- **Enable Buzzer** – If the buzzer is enabled, the device will beep one minute prior to a scheduled measurement to remind the user that a measurement is about to begin. The device will also beep during the measurement cycle (i.e., deflation) and when a measurement has been completed. The repeated beeping is helpful to remind patients that the measurement is in progress and they should not move their arm during the deflation cycle.
- **Randomization** – Causes the actual measurement times to fluctuate around the defined frequency interval. This can be useful if predictable measurement times are not desired. The frequency of the measurements will remain within the bounds defined, but will be randomized accordingly with the percentage selected.
- **Initial Top Pressure** – To encompass the patient’s blood pressure measurement range and still be as efficient as possible, the device will take an initial measurement to establish a baseline blood pressure profile for each patient. It will pump up to this value on the first reading, but should not overstep this top pressure at any time. The device will also pump up to this value if any measurement fails to produce a valid result. The default value should typically be set to 180mmHg. Increase this value for hypertensive patients. Decrease this value for hypotensive patients, to decrease the time required for the baseline measurement and increase patient comfort. The minimum acceptable value is 150mmHg.



CAUTION: *Unless specified, the initial top pressure applied to each patient is dependent on their particular systolic blood pressure range and determined by the healthcare professional. Setting the initial top pressure too low can lead to an erroneous study where the device will not have sufficient inflation to measure the patient’s systolic blood pressure.*

NOTE: *The maximum value allowed for the initial top pressure is 285 mmHg. The minimum value allowed for the initial top pressure is 150 mmHg.*

- **Zone Adjustment Time** – Makes correctional adjustments for when the patient travels outside of the current time zone (as determined by the PC’s time) while measurements are being taken.
- **Save Plan** – Uses the previous settings from the Set Monitoring Period and Frequency, and saves them to a disk file for use at a later time.
- **Load Plan** – Prompts the end user for a disk file and then the HDS reads the setting from the disk file, automatically updating the screen to the previously programmed settings. These setting include Start Time, Frequency (minutes), Enable Button, Enable Display, and Enable Buzzer.

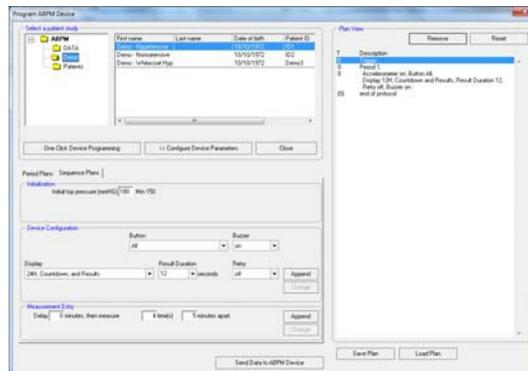
Click **Send Data to ABPM Device** to send the period plan to the attached Ambulo2400 device. As part of configuration, the non-volatile memory of the device will be automatically cleared.

Sequential Plans

The *Sequential Plans* tab further expands the dialog to include a listing of measurements and periods.

This screen provides options for configuring measurements to occur at specified intervals following an initiating trigger rather than occurring at predetermined times of day.

Initial top pressure is a single study-wide setting which applies to all measurements. Due to the anticipated uses of sequential planning, randomization and time zone adjustment are not provided. Initial top pressure in Sequential plans operates the same as initial top pressure in Period plans.



 **CAUTION:** Unless specified, the initial top pressure applied to each patient is dependent on their particular systolic blood pressure range and determined by the healthcare professional. Setting the initial top pressure too low can lead to an erroneous study where the device will not have sufficient inflation to measure the patient's systolic blood pressure.

Like Period mode, Sequential mode uses up to four periods. In each period, different display, accelerometer, buzzer, button, and retry settings may be specified. Unlike Period mode, Sequential periods do not have clock times at which they start and stop. The first Sequential period begins when a Start/Stop button press (the trigger event) transitions the device from PAUSE mode to Automatic mode, and the device automatically starts running its measurement sequence. When the delays and measurements in the first period have been completed, the device immediately starts the second period. The configured sequence continues in this fashion until all configured measurements and delays have been completed. Current configuration periods, measurements, and delays in the order in which they will occur will display on the right-hand side of the dialog box in the sequence list.

NOTE: This screen is used to configure how much information is available to the patient or subject, by way of the option settings per configuration period.

Configuration options for Sequential Plans include:

- **Button** – The patient always has the capability to abort a measurement in progress by pressing the Start/Stop button (Abort function). Other Start/Stop button settings include starting a measurement if none is active (Ad-Hoc function) and returning the device to PAUSE mode from Automatic mode (Pause function).
- **Buzzer** – If the buzzer is enabled, the device will beep one minute prior to a scheduled measurement to remind the user that a measurement is about to begin. The unit will also beep during the measurement cycle (i.e., deflation) and also when a measurement has been completed. The repeated beeping is helpful to remind patients that the measurement is in progress and they should not move their arm during the deflation cycle. Available settings are On or Off.
- **Display** – Current time is always displayed in either 12-hour or 24-hour format (12H or 24H). Other display elements which may be enabled or disabled are: number of minutes until the next measurement (Countdown), the inflation pressure in mmHg during a measurement (Pressure), and the results of the most recent measurement (Results).

- **Result Duration** – Controls the number of seconds for which the results are displayed. Choose a value from the drop-down menu or type the desired value in the space available. If Result is not part of the Display setting, results are not displayed and the value for Result Duration has no effect.



CAUTION: *Measurements are not taken while a result from a prior measurement is displayed. Choosing a large value for Result Duration may cause some measurements to be skipped.*

- **Retry** – Determines whether the device will retry the measurement due to error, or not retry and proceed in the sequence with an error in place of the sequenced measurement. Available settings are On or Off.

The Append button will append a new configuration with the selected settings. To add a new period configuration, click the measurement group from the sequence list which the new configuration is to follow. Set up the desired configuration in the configuration frame, and then click **Append**. The new configuration will immediately follow the selected item in the sequence list.

If the selected item in the sequence list is a configuration, the Change button will be enabled. Change the settings in the selected configuration, and then click **Change**. The selected configuration will be updated with the modified settings.

Measurements may be added to the sequence at any point after the configuration of the first period. Measurements are entered in groups, with each group having an optional initial delay, a number of measurements in the group, and the delay following each measurement in the group. A measurement group may have only one measurement or none at all if an adjusting delay is required to set the proper timing of measurements. Click **Append** in the measurement entry frame to append a measurement group following the selected item in the sequence list. If a measurement group is selected in the sequence list, its settings may be modified by making changes in the measurement frame and clicking **Change**. As an aid in setting the proper sequence of measurements, the leftmost column of the sequence list shows the time, in minutes, since trigger time.

A measurement group or configuration period may be removed by first selecting it in the sequence list, and then clicking **Remove**. Click **Reset** to clear and reset the entire sequence plan.

Save a sequence plan to XML format by clicking **Save Plan**. Previously saved sequence plans may be loaded by clicking **Load Plan**.

Up to 20 measurement groups are allowed in each configuration period. Up to four configuration periods may be used in the sequence plan. Within each measurement group, as few as zero or as many as 9,999 measurements may be entered. It should be noted that entry of the maximum possible number of measurements, measurement groups, and configuration periods will result in a sequence plan that considerably exceeds the device's available battery power and storage memory.

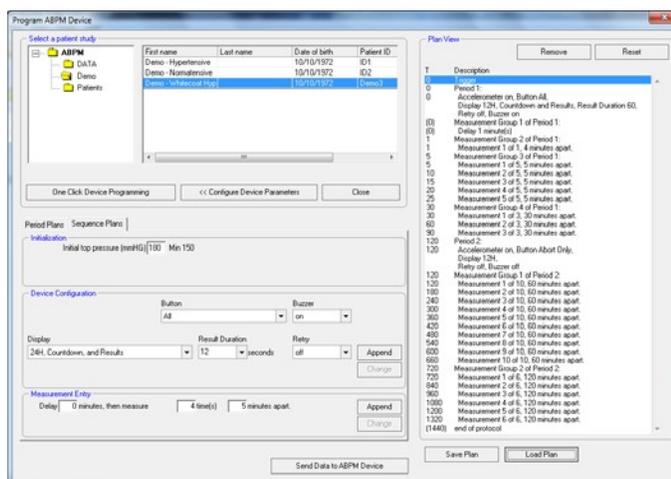
Click **Send Data to ABPM Device** to send the sequence plan to the attached Ambulo2400 device. As part of configuration, the non-volatile memory of the device will be automatically cleared.

Sequence Plan Example

A sample sequence plan is installed with the software. It is located in the application's installation directory and is named SequenceSample.xml. This sequence plan may be loaded into the Device Configuration window by using **Load Plan**.

The right hand side of the screen displays a sample sequence plan where the initial period is configured to enable the buzzer and all button operations, disable retries, display 12-hour time, display the countdown to the next measurement, and display measurements results for 60 seconds following the measurement.

In this plan, immediately following the press and hold of the Start/Stop button which initiates the sequence, the device would observe a 1 minute delay. Following the delay, the device would perform one measurement and then delay until 4 minutes have passed since beginning the measurement.



Since the time required to perform a measurement varies based on cuff size, activity level, and other factors, the delays and 'minutes apart' are always counted from the beginning of a measurement to the beginning of the following measurement. It is not necessary to adjust the delays or the minutes apart times for the length of time required to take and display a measurement—the device takes care of this automatically.

In the sample plan, after the four-minute delay, the device would alternate measurements and five-minute delays, then alternate measurements and 30-minute delays. In the long sequence list on the right side of the window, the leftmost column displays the time in minutes, following the initial trigger, at which each measurement takes place. This elapsed time column may be used to help order a plan as required.

At 120 minutes after the initial trigger, the device would enter a second configuration period. In this period, the accelerometer is still enabled, but button and display options are disabled. Such changes may be advisable in a particular protocol as it prevents the wearer of the device from knowing the results of blood pressure measurements. Following this configuration change, the device would take measurements hourly until the 12-hour mark, then every two hours until the 24-hour mark. The device would return itself to PAUSE mode on completion of its sequence.

Defining the Default Measurement Plan & One-Click Programming

Users can access a default Period plan that can be quickly programmed for any study. Under the Tools menu option, select **Define Default Monitoring Plan**. While the software comes with a pre-programmed default plan, users can define their own study plan if the typical measurement period varies in any way. Once defined, the default plan will be stored until changed.

To utilize the default period plan, select **One Click Device Programming** in the configuration window. The device will automatically adopt the default plan for the patient's study, eliminating the need to define a new monitoring plan for each patient.

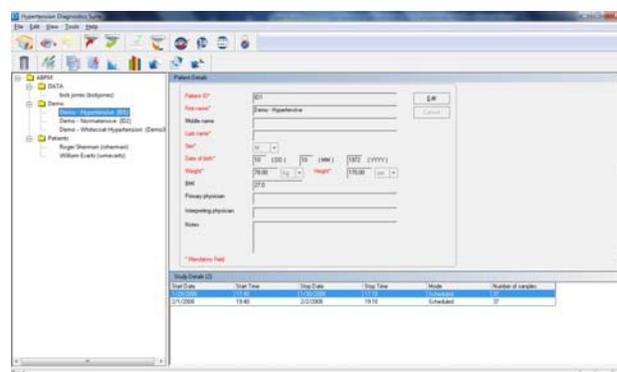
Getting Data Measurements

To download measurement data from the device, it must be connected to a PC (via USB cable) hosting the ABPM software and the software must be running. Click the **Download Data from the Device** icon on the Main menu or use **Download Data** from the Patient View toolbar. A status bar will appear to show the progress of the download. The data will automatically be associated with its corresponding patient file based on the pre-programmed patient ID in the device. If the data on the device does not have a patient associated with it on the PC, you will be prompted to create a new one (refer to New Patients in this section).

If data measurements with the same time range have previously been obtained and exist for the patient, you will be prompted as to whether or not to replace the saved data with the current download. If the device includes the actigraphy option, this information will be downloaded subsequently.

Selecting a Study

For many patients, there may be multiple ABPM studies over the course of their care. To select a specific study, select the patient in Patient View and find the measurement ranges in the bottom right-hand section of the screen. To view the details of a particular study in Table View, double-click the line that contains the desired details, or select the patient, and then click **Table View** on the toolbar.



Deleting a Study

To delete a time range, right click the desired study and select **Delete Study**.

TIP: Use the Start Date as an indicator of which study to select.

Adding Medication Information

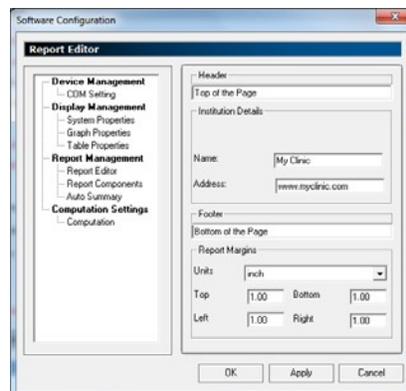
To add or edit the current medications that a patient is taking, select the patient and then the study that requires medication information. Click **Edit Medication**.

Each study is separate and may be assigned distinct medications based on prescribed therapy in effect at the time for each patient and study. Categories include medication type, dosage, frequency, and additional notes. Medication information can be printed on the final reports. Click **OK** to save or **Cancel** to exit.

Additional Operations

Setting Institutional Information

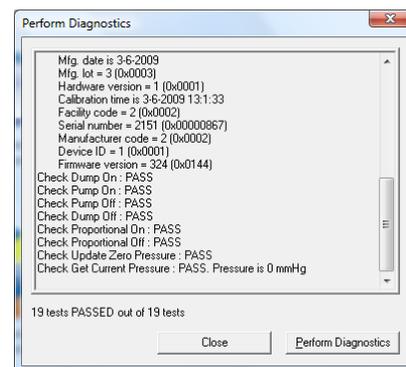
To add your institution/clinic name and address onto generated reports, click on the **Report Editor** tab in the Software Configuration menu. You may include the clinic name and up to three lines of contact information.



Performing Diagnostics

To run diagnostic tests on your ABPM device, click the **Device Diagnostics** icon on the Main menu or the toolbar. Ensure that the device is properly connected to the PC via the USB cable, and that the program COM port settings are correct. Once the test begins, a screen similar to the one shown will display:

At the conclusion of the diagnostics, a total error report line will display at the bottom of the window. If tests have failed, troubleshoot the device using this manual or contact Mortara Technical Support for assistance.



WARNING: *Ensure AMBULO 2400 has fresh AA batteries before running the diagnostics program.*

NOTE: *Do not connect the ABPM device to USB without batteries installed. While the ABPM device may turn on solely on USB-supplied power, it will not operate reliably in this manner and needs batteries to properly function including during device configuration, data download or testing.*

Import/Export of Patient Data

To import patient information, including measurement data from another source, click the **Import/Export** icon on the Main menu. The import function can also be accessed from the menu toolbar, or by right clicking on a folder in the Browse Patients View. To import, confirm the action and select the file to import into the database. Files can only be imported in the Extensible Markup Language (XML) format as defined by the software. As such, this function is mostly useful for exporting and importing patient information from one instance of the application (running on one PC) to another instance (running on a different PC).

To export a patient and their data, click the **Import/Export** icon on the Main menu. The export function can also be accessed from the menu toolbar, or through right-click menu items when a database, folder, or individual patient is selected. A default file name for the patient record containing patient information and session number is supplied automatically. As such, information for all patients in the database, a particular folder, or an individual patient can be exported in XML format. When reviewing specific study information on a patient, basic patient information and blood pressure measurements may be exported in delimited format for import into other applications, such as Microsoft Excel, from the menu toolbar.

NOTE: The file name used for patient export is also used for saving or printing a report.

Import Preview

At any point from the Browse Patient View, it is possible to right click on a patient's folder and select the "Import Preview". This will cause the HDS software to scan the configured Search Directory on the computer, looking for patient data waiting to be imported, along with displaying a listing of available patient data for import and review.

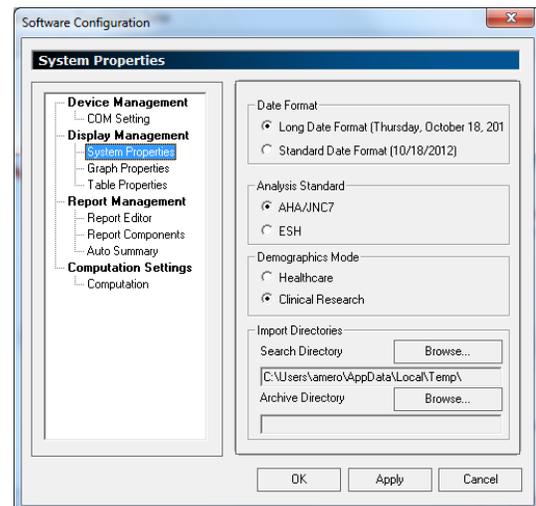
The location searched on the computer can be configured in system properties located in the software configuration window.

NOTE: This function is mainly used in combination with the Mortara Web Upload 3.0 product. See Web Upload 3.0 User Manual for more details.

System Properties

A selection may be made to display a long date format or a short date format. The analysis criteria may be selected between American Heart Association /Joint National Committee (AHA/JNC7) or European Society of Hypertension (ESH) rules. The demographic information fields made available by the software can be selected between Healthcare or Clinical Research demographic mode. Healthcare mode provides demographic fields appropriate for normal clinical use, while Clinical Research mode provides fields necessary for clinical research trials, like study name and protocol.

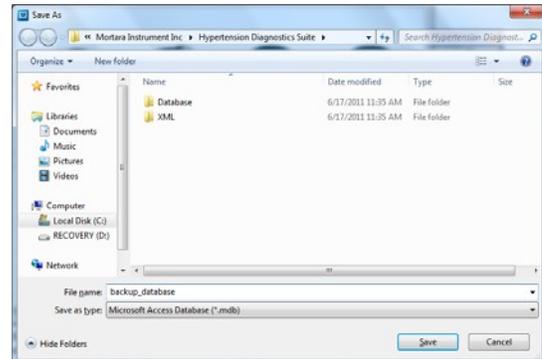
Locations may be specified for import preview root Search Directory, as well an optional Archive Directory where a copy of the imported data will be stored for archival purposes whenever a recording is imported.



New/Open Database

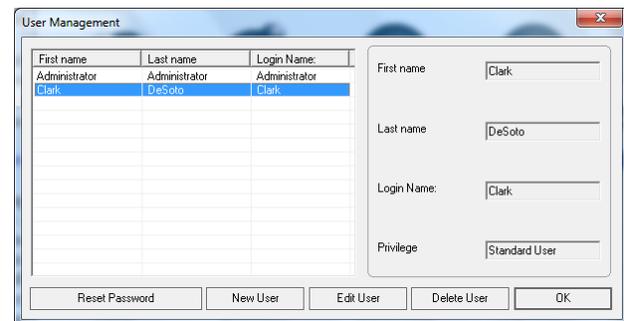
At any point, it is possible to create an entirely new database or open a previously created database for storing patient information. This may be done for several reasons, including:

- Keeping information for different physicians or clinics, or information from one year to another, separate from each other.
- Creating a database file on a network file server for simultaneous access by multiple users.



User Management

To add or change users, click on the **User Management** icon on the Main menu. The User Management function is only available to those logged in with Administrator privileges; the management screen will be disabled for all standard users. Click the **New User** to create a new login for the software. (Passwords must consist of at least eight characters.) Depending upon whether or not a password was ever created for the default user, it may not be required for initial login. To edit or delete a user, use the corresponding buttons at the bottom of the window. Be certain to safeguard passwords.



Changing a Password

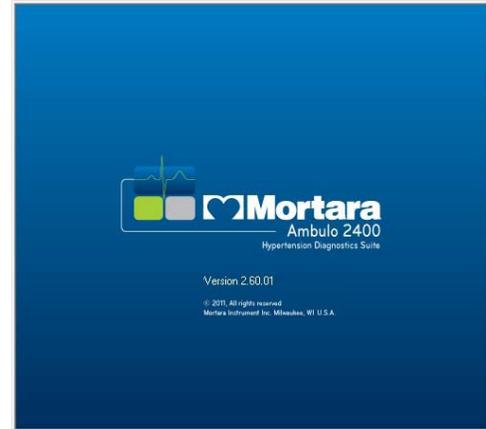
User passwords can only be changed with administrative privileges. Click on **Edit User** to alter passwords. To reset a password for a user who has lost their password, click **Reset Password**—the password will revert to the login name (note that this is case sensitive).

Database Backup

To backup the current database of patients and associated measurement studies, select **Backup Database** from the File menu. You will be prompted to create a name for the Microsoft Access database file, and to determine where it should be saved to.

Help Menu

Under the Help drop-down menu, click **About** to see the details of the current software package. The version number of the software will be displayed along with copyright information. This information might be necessary if you ever need to obtain technical support from your Mortara Technical Support representative. Use the available link to access an electronic version of the End User License Agreement.



Closing the Program

To close the ABPM software application select the **Exit** option under the File menu. Select **Yes** at the prompt. You can also exit the application by using any of the standard Windows application controls.

Table View

Table View is used to expand a study into a comprehensible spreadsheet format. The data is represented without any visual aids (i.e. pictures, charts, or graphs), and the raw numbers can be compared side-by-side. To isolate blood pressure measurements exceeding specific prescribed limits, the limit sliders on the left-hand side of the window may be adjusted (or entered manually in the corresponding text boxes) to reflect the desired ranges of focus for overall, awake, and asleep cycles, independently. Information about the individual device being used for the study appears at the bottom left of the Table View screen. This may be referenced for troubleshooting purposes, and can also be helpful as an audit trail.

Excluding a Measurement Row

If a single measurement appears to be invalid or erroneous, it can be excluded so that it does not skew the overall results. While the Ambulo 2400 has built-in capabilities to detect and reject certain motion artifacts, it is possible to get outlier measurements – typically due to excessive motion of the arm during the deflation cycle of the measurement. Not all error codes are measurement related, and not all error codes necessarily imply that the measurement should be excluded. To exclude a measurement, right click on the row for the measurement to exclude and choose **Exclude Measurement**. An excluded measurement is displayed in the data table in a strikeout font, and is not included in statistical or graphical analyses.

The software has built-in capabilities to automatically exclude measurements called outliers which appear to be well outside expected norms. This capability is turned on by default, and the exclusion is performed when data are downloaded from the device. The norms used for adults are: SBP between 70 and 240 mmHg; DBP between 40 and 140 mmHg; DBP less than SBP; heart rate between 30 and 125 bpm; and pulse pressure between 25 and 150 mmHg (defined in configuration settings). Norms used for pediatric patients (i.e., age based on date of birth and date of ABPM procedure is less than 18 years) are: SBP between 60 and 220 mmHg; DBP between 35 and 120 mmHg; DBP less than SBP; heart rate between 40 and 180 bpm; and pulse pressure between 25 and 150 mmHg (defined in configuration settings). The automatic exclusion of values falling outside adult or pediatric norms may be disabled in the Computation area of Software Configuration

Including an Excluded Measurement Row

If you wish to return an excluded measurement to the overall results, right click on the row for the excluded measurement, and choose **Include Measurement**.

Setting Awake/Asleep Time (Optional Actigraphy software required)

The Awake/Asleep times (delineated by shading of the rows) can be found under the Actigraphy View button on the menu toolbar. Changing these ranges will reflect back upon the Table View. To have the software automatically calculate these ranges, use the **Calculate Awake/Asleep** button on the bottom of the Actigraphy View. Check to ensure that the ranges have been calculated properly.

In addition to hourly increments, the Awake/Asleep times can be changed to more specific figures. To edit the minutes, highlight them with the cursor and manually enter the values. Switching to another view (i.e., Table View) will automatically save and apply these values to the measurement data.

Range Limits

Range limits are numbers that can target specific sets of data by changing the color of the numbers presented on the table. Typically the color changes come into effect for numbers that are either above, below, or within the target ranges (they will be different colors). Define the color scheme within the Software Configuration menu.

Editing the Range Limits

To edit the range limits and highlight specific data, use the sliders on the left side of the Table View or enter specific ranges into the adjacent numeric boxes. Awake/Asleep limits will change the color of the numbers themselves, and only within the time period allotted to those cycles in Actigraphy View; Overall limits will affect the entire table, and the distinctions will be highlighted by a color change within the affected measurement cells. To accept the ranges and reflect the limit changes, click **Refresh View** beneath the limit sliders.

Range Limits for Pediatric Patients

For pediatric patients, the software adjusts the blood pressure range limits based on clinical guidelines. When the patient is pediatric, as determined from the patient's birth date and the start date of the study, the default range limits are modified to limits appropriate to the patient. By default, data from the Wühl studies are used to determine pediatric limits, indexed by the patient's age. A setting in the Computation area may be used to specify a preference for data from the U.S. Centers for Disease Control, Wühl data indexed by height, or Wühl data indexed by age.

Adding Comments to Individual Measurements

To add a comment to a measurement, click on **Remarks** within the appropriate row or simply enter them on the remarks column for a given measurement row. Pre-defined comments may be assigned using the Remarks button, and selected via the drop-down selection on each cell in the Remarks row.

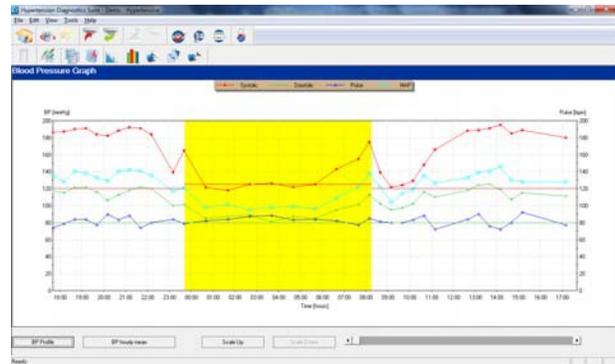
Other Table View Options

By default, only "Blood Pressure Data" is shown in the Table View. To view the hourly mean blood pressure for a patient, or to review a list of events and error codes as they occurred, use the drop-down menu on the top left of the Table View. Not all event and error codes are measurement related, and not all necessarily imply that a measurement was invalid. Error codes may be logged for other technical issues, such as a USB connect/disconnect or power-on reset. Changing the viewing options from the drop-down menu will change the focus of the table and the time range frequency.

Graphical View

Graphical View is used to view selected data measurement ranges as plotted within an X & Y-axis diagram. Prior to selecting **Graphical View** on the menu toolbar, a patient name must be selected in the Patient View. If there are multiple studies for a patient, ensure that the appropriate study is selected.

The diagram displays systolic and diastolic blood pressure measurements on the Y (vertical) axis, and the time of day on the X (vertical) axis. Settings under the Software Configuration menu will determine whether or not the points are connected by time or type of measurement (i.e. systolic, diastolic).



Graphing the BP Hourly Mean

To view a graph of the BP Hourly Mean, click **BP Hourly Mean** below the graph; to return to the standard profile graph, click **BP Profile**.

Bar Display Option

The default display setting is where the points are connected by the type of measurement. In the Software Configuration menu select **Bar Display** to change the graph to a time-based format.

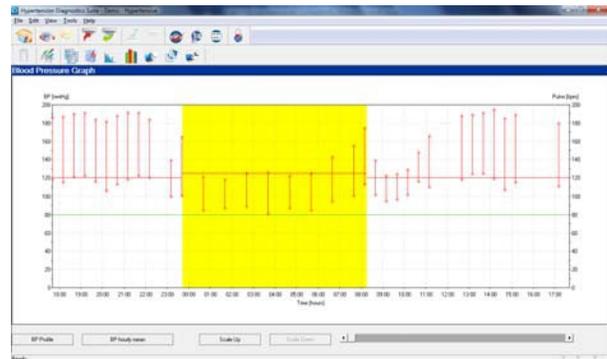


Diagram or Hide Pulse and MAP Measurements

Select whether to display the Pulse and MAP data within the Software Configuration menu, under Chart View.

Scaling Up/Scaling Down/Scrolling

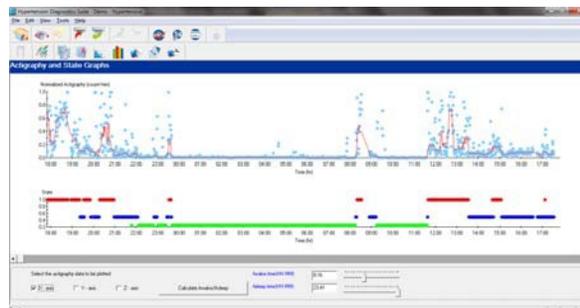
If the data set that is being plotted contains many measurements, the graph will automatically scale itself down to accommodate all the information on one screen. If you wish to see the details more closely, use the **Scale Up** button below the graph. Scaling up is only possible if the graph initially had to be collapsed to fit the screen. Scroll across the zoomed data by using the scroll bar below the graph. To return to a comprehensive view, click **Scale Down**.

Actigraphy View

Actigraphy View is used to track the degree or severity of motion that the patient exerts throughout the 24-hour measurement period. This information can be extremely relevant to the diagnosis of blood pressure-related conditions, so it is advisable to use this feature whenever possible. The device will collect actigraphy data along with blood pressure readings.

NOTE: *Not all models of the Ambulo 2400 include the actigraphy option.*

If actigraphy data exists along with the patient's measurements, it can be viewed by clicking **Actigraphy View** in the menu toolbar. If there are multiple studies for the patient, ensure that the appropriate study is selected.



Data for the X, Y and/or Z axis may be viewed. The actigraphy algorithm categorizes the level of activity for the patient during each study, according to the approach shown:

Activity Level	Display Color
Daily awake activities, such as walking, working, etc.	Red
Restful activities, including sitting or relaxing	Blue
Idle activities, including sleep	Green
Unit in PAUSE mode (no measurements collected)	Black

NOTE: *If the device is in PAUSE mode or if the accelerometer data has not been collected during a particular period, the time range will be displayed as idle.*



CAUTION: *Actigraphy information is provided as an aid for determining awake/asleep cycles. Use of patient diaries and interviews are also recommended for correct analysis and interpretation of the ABPM study.*

Changing the Awake/Asleep Cycle

To change the Awake/Asleep periods, drag the slider bars to the relevant hours or enter values. The bars display in military time (e.g. 15 = 3 P.M). To edit the minutes, highlight them with the cursor and manually enter the minute values. Changing this data will also affect the Awake/Asleep limits for all the other data views. To have the software automatically calculate the Awake/Asleep time periods, use the **Calculate Awake/Asleep** button at the bottom of the screen. Ensure that the time designation is accurate.



CAUTION: *Awake/Asleep cycle time periods are only applicable to a 24-hour period. For studies that extend beyond 24 hours, the same cycle information is extended regardless of a different awake/asleep pattern beyond the first 24 hours.*

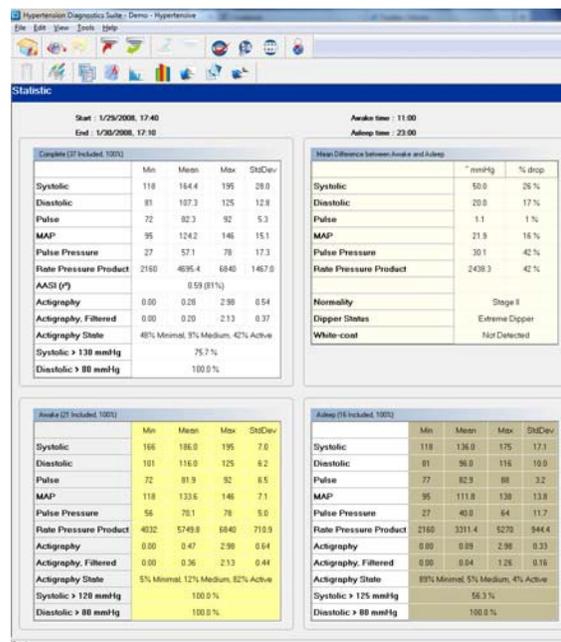
Histogram View

Use the Histogram tab to view the selected data range in a bar graph. This graph represents the distribution of the systolic, diastolic and pulse measurements as a percentage of the total measurements, and is divided into four distinct data sets: Systolic (Awake), Systolic (Asleep), Diastolic (Awake), and Diastolic (Asleep). In each graph, the Y (vertical) axis is the percentage of total measurements for that time period; the X (horizontal) axis is the pressure value in mmHg. This view helps to track trends in total numbers that may not be obvious when looking at the Graphical View.



Statistics View

Statistics view provides one of the quickest and most effective snapshots of the patient's systolic, diastolic, pulse, MAP, pulse pressure (difference between systolic and diastolic), rate pressure product (heart rate times pulse pressure), ambulatory arterial stiffness index (AASI, an index determined by regression of diastolic pressure against systolic; higher values correspond to a stiffer arterial tree), and actigraphy measurements. Specifically, it provides the number of included measurements (i.e., those that were not zeroed by some error condition or marked as excluded in Table View), and the percentage of included measurement attempts which resulted in valid measurements. Of particular note are the minimum, hourly mean, maximum, and standard deviation that are displayed for systolic and diastolic blood pressure, pulse, MAP, pulse pressure, rate pressure product, and actigraphy. This data is provided for the full range of data measurements, and is also broken down into Awake and Asleep readings. A smaller standard deviation represents a more clustered distribution of data measurements around the mean (average) value. Conversely, a larger standard deviation indicates more substantial swings of data between the minimum and maximum values recorded.

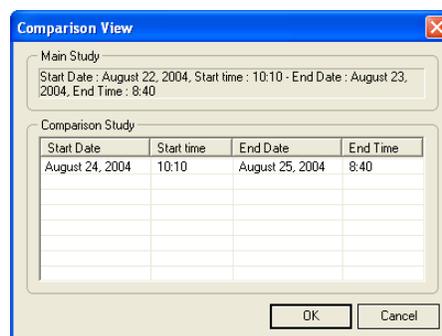


The percentages of measurements exceeding certain limits—referred to as “blood pressure load” in clinical terminology—are provided for Overall, Awake, and Asleep measurements (these limits may be changed in the Table View, on the left-hand-side of the window). Statistics View also includes a measure of the mean difference in blood pressure and pulse rate between Awake and Asleep measurements—the average drop in pressure that the body exhibits between these two states—as expressed in mmHg and in percentages. Note that negative values for dipping percentages indicate a rise in the values. Additionally, Statistics View analyses the day, night, and overall measurements to categorize normality, dipper behavior (based on systolic blood pressure only), and white-coat behavior. Statistics View is most useful for quickly obtaining an assessment of the patient’s blood pressure measurements throughout the 24-hour period. No changes or selections can be made in this view.

Comparison View

Comparison View is used to generate comparison charts for two separate ABPM studies. This function is useful for monitoring changes on a patient from one study to another study (perhaps as part of assessing the effects of changes in therapy and medication in a before-and-after manner). Comparison View provides the ability to analyze trends between two measurement periods for compatibilities and changes in Systolic, Diastolic, Pulse, and MAP measurements.

Access Comparison View by selecting the patient and then clicking **Comparison View** on the menu toolbar. You will be prompted to select another study for comparison.



Once you have selected the appropriate study, the full Comparison View should load. Note that the start times for each study are normalized to the start of the awake cycle, based upon that study’s awake and asleep settings. Ex: in the main study the patient may have been awake starting at 7:00 a.m., and in the comparison study starting at 8:00 a.m.. These time periods are normalized to period “0” accordingly, and the 24-hour plots are generated from that point for each study. As such, subtle differences on the Awake/Asleep cycles for each study are accounted for when displaying the comparison.



A comparison report can be exported from this screen with measurement details for each study, along with a list of the medications in effect for each study. The exported report can be saved into an appropriate location, or printed.

Report View

The Report View is used to generate a presentable summation of all the collected measurements and data on a particular patient. You may choose to create a report in Rich Text Format (RTF) or HTML, either of which you may print from its corresponding application, save on a disk, or transmit via e-mail.

NOTE: In order to print in Adobe® Acrobat PDF format, install a third-party PDF printer driver. PDF drivers can be obtained for free from many locations on the Internet.

Concise vs. Detailed Reports

When printing a report, select either a concise or detailed report. The concise report consists of the patient data, the statistical overview, and the diagnostic summary with any notes written by the interpreting physician. The format of this report cannot be altered. The detailed report consists of more information, all of which can be included or excluded based upon preference. To change the form of a detailed report, use on **Report Components** under the Software Configuration menu. The following information can be included or excluded:

- Blood Pressure Graph
- Tabulated Data
- Histograms
- Medication Information on the Study
- Actigraphy Graph (Accelerometer Data)
- Notes
- Detailed Statistics

Report Editor

The Report Editor option in the Software Configuration menu will allow you to change the header and footers for your patient report. Institution data and the report margins can also be set through this option.

Auto Summary

Control what elements appear in the final Summary on the report form using the Auto Summary tab.

Blood pressure naturally fluctuates throughout a full day according to various factors, including sleep patterns, medication, diet, exercise/activity, and stress as well as body position (e.g., standing, supine, seated). The science of ambulatory blood pressure monitoring has evolved from the problems associated with the inherent variability of a person's blood pressure over time. Traditionally, the belief was that one average blood pressure reading was adequate for obtaining the information necessary for sound diagnosis and treatment. More recently-published literature, however, indicates that multiple blood pressure readings over an extended period of time often reveal unaccounted-for discrepancies that are simply unavailable and unacknowledged within a single measurement.

Blood pressure measurements determined with the device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard for Electronics or Automated Sphygmomanometer (ANSI/AAMI SP10), the British Hypertension Society's validation protocol as well as the International ANSI/AAMI/ISO 81060-2 standard.

- **Precision:** Utilizes a fast and highly-accurate Oscillometric algorithm based on patented digital signal-processing techniques.
- **Actigraphy:** Automatic categorization of asleep/awake cycles based on patented technology reduces cumbersome reliance on diaries.
- **Ease of Use:** Sophisticated and intuitive software interface for easy programming, data download, and report generation.
- **Form Factor:** Sleek and modern design is compact, durable, and easy to use.
- **EasyWear™ Options:** Device can be integrated onto the blood pressure cuff, clipped onto a belt, or strapped around the shoulder.
- **Validation:** Validated according to the ANSI/AAMI/ISO 81060-2 and AAMI SP-10 protocols as well in accordance with the British Hypertension Society's protocol.



CAUTION: Results of the ABPM procedure must be evaluated and interpreted by a trained and licensed healthcare practitioner.



CAUTION: The Ambulo 2400 should NOT be used for measurement of blood pressure in neonates.



CAUTION: The Ambulo 2400 may not provide accurate results in patients who have arrhythmias such as atrial or ventricular premature beats or atrial fibrillation.

Start/Stop Button

Press the Start/Stop button once to manually trigger a measurement. This function may be disabled via the software.

During a measurement, whether triggered manually or automatically, press the Start/Stop button to immediately stop the measurement in progress and deflate the cuff.

Press and hold the Start/Stop button for five seconds to put it in PAUSE mode. In this mode, the LCD will alternate between displaying the current time and PAUSE. This function is necessary if the patient does not want measurements taken automatically. This could be the case if the 24-hour measurement period is complete, or if there is a need for a rest (e.g., bathing or changing clothes).

If the device is in PAUSE mode, press and hold the Start/Stop button for five seconds to return to Automatic mode. Depending upon how the device is configured, the screen will alternate between showing the current time and the time remaining until the next measurement.

In order to reset the device to go through its full-scale baseline measurement mode—from initial top pressure set all the way down to 50 mmHg—press and release the Start/Stop button three consecutive times, quickly. The LCD display should then display “Hi <top pressure>,” where <top pressure> is the initial top pressure set on the device. Use this in cases where wide fluctuations from the previously obtained values for systolic or diastolic are anticipated, such as after heavy exercise.

***NOTE:** Depending upon device configuration, the Start/Stop button may be disabled. If the Start/Stop button is disabled, the user will not have control over manually triggering a measurement; however, the user will still be able to stop a measurement in progress.*

Performing an ABPM Procedure

The device must be programmed for each patient using the Hypertension Diagnostics Suite.

- Connect the device to the PC using the included USB cable.
- Open the Hypertension Diagnostics Suite software.
- Select an existing record, or create a new patient.
- Click on **Configure Device**.
- Select **One Click Programming** if a Default Monitoring Plan has been defined. Select **Configure Device Parameters** to allow entry of all measurement parameters, including monitoring periods and frequencies.
- Send the data to the device by clicking on **Send Data to ABPM Device**. Configuration is now complete.
- Disconnect the USB cable and begin patient set-up. The device will restart into PAUSE mode and should display the correct time.
- Press and hold the Start/Stop button for five seconds to change the device mode from PAUSE to Automatic. Once in Automatic mode, the device may display a countdown in addition to the time.

Patient Hook-up

1. Ideally, the patient should wear a loose-fitting, short-sleeved shirt or blouse for this procedure. Thick sweaters and dresses may complicate the hook-up of the device.
2. Review the ABPM procedure with the patient, including the various parts and functions of the device which they will be wearing.
3. Select an appropriate-sized cuff, depending upon the size of the patient's non-dominant arm. Follow the cuff's markings including range indicators to ensure that the arm circumference falls within the cuff's range.



CAUTION: *To obtain optimal results, it is important to select an appropriately-sized blood pressure cuff. Selecting the wrong cuff may be the source of measurement-related problems—a cuff that is too small or too large may result in erroneous readings and cause patient discomfort.*



CAUTION: *Do not connect the ABPM device to any other devices or use any third-party accessories. This may cause inaccurate measurements or harm the patient.*



CAUTION: *Avoid restricting, compressing, or crimping the blood pressure tubing.*

4. Place the cuff on the patient's non-dominant arm such that the artery indicator rests on the brachial artery, and the air tube is pointing up towards the patient's shoulders. If using the Orbit cuff, simply slide the sleeve up the patient's arm, ensuring the artery arrow points down the arm. The cuff should be midway between the elbow and shoulder. Be certain that the artery marker is over the patient's brachial artery. Wrap the cuff snugly around the upper arm (bicep). Do not tighten the cuff too firmly; allow a finger's worth of slack between the cuff and the arm.



CAUTION: *Immediately remove the blood pressure cuff if extreme discomfort, bruising, or a rash develops. Some discomfort may be normal while the cuff applies pressure to the arm.*



CAUTION: *Allow sufficient time between measurements so as to avoid reduced blood circulation and minimize patient discomfort.*



CAUTION: *A typical ABPM procedure lasts 24 hours though longer-term assessments are performed in research settings. Long-term use of the system may cause discomfort, bruising, or other adverse symptoms.*

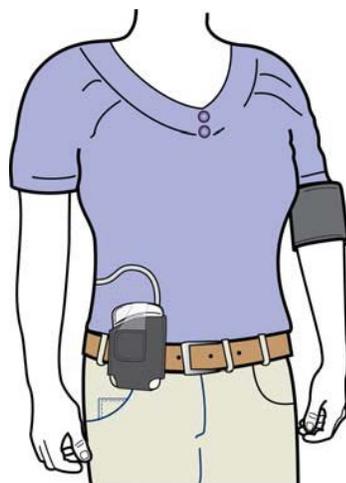
The Ambulo 2400 can be worn in four distinct configurations, depending upon patient comfort and anticipated activity:



EasyWear™ Cuff



Shoulder Strap



Belt Clip



Asleep (Standard Cuff)

5. If using the EasyWear cuff, the cuff can be further secured on the patient's arm using the snap and an ECG electrode. Simply connect the ECG electrode to the cuff snap, place the cuff on the patient's bare arm and remove the adhesive on the back of the ECG electrode and gently attach it to the patient's skin. This will ensure that the cuff and device will not roll down the patient's arm during daily activity. The ECG electrode does not have any electrical connection to the device and is not used for any measurements.
6. Depending upon the size of the patient, connect the extension hose to the cuff's air tube. The two ends couple by being inserted into one another. Run the hose behind the patient's shoulders or back and eliminate any excess slack (without crimping or kinking the hose, or exposing it to the threat of crimping or kinking).

7. Plug the device in to the air hose. The device can be clipped onto a belt or worn via the shoulder strap, depending upon which is more comfortable for the patient. With the shoulder strap, the device can be worn on the opposite side as the cuffed arm or the same side as the cuffed arm (depending on patient preference and comfort). Make sure to provide enough slack so that the patient can comfortably move around and carry out daily activities.
8. If necessary, take away any slack close to the cuff (or in the way of the patient). The hose can be coiled together and secured close to the device. Make sure that the hose is not crimped or kinked. Any slack should be concentrated near the device, rather than the cuff.



CAUTION: *Ensure that the hose does not have any crimps or kinks as this would likely cause the device to misread or malfunction and potentially harm the patient.*

9. Instruct the patient that when a blood pressure measurement is in progress, they should relax their cuffed arm and try to rest it on a flat surface. Any movement for the duration of the measurement should be minimized; ideally, movement should cease altogether. The arm should not be swinging or shaking. Any tapping, external pressure, or shock to the cuff will affect the measurement accuracy and should be avoided. If possible, the patient should be comfortably seated or lying down, and the patient's arm or leg should be relaxed, extended, uncrossed and resting on a stationary support.
10. To verify correct operation, press and release the Start/Stop button to initiate a manual measurement. Note the systolic, diastolic and pulse measurements displayed on the LCD panel (depending upon display settings), and make any adjustments to the position of the cuff as necessary. The first measurement for any patient will be a baseline measurement. Baseline measurements pump all the way up to the initial top pressure, and then down to 50 mmHg to baseline the patient's normal blood pressure. If this baseline measurement fails to find the patient's diastolic pressure, the subsequent measurement will also be a baseline measurement, this time with pressure declining to 27 mmHg. Once systolic and diastolic pressures are found, the device will go slightly above and slightly below the last known systolic and diastolic pressures respectively. If measurement fails, or if the patient anticipates a large shift and presses the button three times successively, the device will go through this baseline procedure again.



CAUTION: *It is important that the patient remain still and allow the cuff to complete the full measurement cycle. In baseline measurements, this means that the device will deflate to 50 mmHg which may take some time—particularly when using larger cuff sizes. Any movement before the measurement cycle is complete – including hand movement and muscle flexing – may result in erroneous measurements and/or repeat measurements.*

NOTE: *In certain cases with patients who have very large arm sizes and very high blood pressure, the device may take more than a minute to pump up to the target pressure and may not be able to obtain a valid measurement in the prescribed 3-minute period.*

NOTE: *If a measurement cannot be obtained during a normal measurement cycle, the device will revert to a baseline measurement cycle for the subsequent measurement.*

11. Before the patient leaves, carefully review all the information on the Patient Instruction Sheet. Specifically point out to the patient the position of the Start/Stop button, and ask them to PAUSE measurements when not wearing the device, or at the completion of the 24-hour procedure. Pausing is accomplished by holding down the Start/Stop button for five seconds. This will help preserve battery life, and avoid erroneous measurements when the device is not worn.
12. Complete the top of the Patient Diary form and ask that the patient to make any necessary notations in the form throughout the 24-hour period. The form contains relevant diagnostic information, and it should be brought back with them at the end of the procedure.

Downloading and Reviewing Data Measurements

When the patient returns upon completion of the prescribed ABPM procedure, collect the ABPM device and all applicable accessories. If necessary, assist the patient with disconnecting the system. Review all the parts and accessories to ensure that everything has been brought back and is in good working condition.

1. Review the Patient Diary form and clarify any information that is not legible, clear, or missing.
2. Connect the USB cable to both the device and the PC. Run the Hypertension Diagnostics Suite application software on the PC.
3. From the Main menu, click the **Download Data from Device** icon to obtain the data measurements from the device. Refer to the Troubleshooting section for any problems.
4. Review the measurements and make any necessary notations on the specific measurements based upon the Patient Diary form.
5. If necessary, open the Actigraphy View and adjust the Awake/Asleep times.
6. Review the Table, Graphical, Actigraphy, Histogram, Statistical, Comparison, and Report views as needed.
7. Enter any appropriate observations and analyses which should be included as part of the patient chart notes. This can be done from the Browse Patients icon, after selecting the patient and clicking the **Edit** button.
8. Print an ABPM data report by selecting **Report View**.
9. As appropriate, review the results and findings with the patient, as well as the referring physician.

Troubleshooting

Power-On Issues

Ensure the device is using fully-charged batteries. If the LCD does not illuminate or display any characters, check the charge level and polarity of the batteries. Polarity indicators can be found in the bottom of the battery compartment. Check that the batteries have been placed correctly. If the batteries are in the correct configuration and the issue persists, contact Mortara Technical Service.

***NOTE:** Do not connect the ABPM device to USB without batteries installed. While the ABPM device may turn on solely on USB-supplied power, it will not operate reliably in this manner and needs batteries to properly function including during device configuration, data download or testing.*

Communication Errors

To correct communication problems and/or errors between the PC and the device, follow this simple checklist.

1. Ensure the device is using fully-charged batteries, and that the LCD screen is displaying the time of day.

***NOTE:** Once the batteries are removed, the device loses its date and time information after some time.*

2. Check the cable connections to the USB port on the PC and also the device. Ensure that both sides are secure and tight. When plugged in, the LCD of the device will alternate between the current time and “USB”.
3. Unplug and then reconnect the USB cable. If this fails, reboot the computer and attempt communications again.

***NOTE:** If the device downloads erroneously or has trouble communicating with the software, unplug the USB cable from the computer and plug it in again. Wait for the computer to recognize the device before proceeding.*

4. If communication problems persist, contact Mortara Technical Service.

ABPM Device not Functioning

If the device is not taking measurements properly, follow this checklist to troubleshoot the problem.

1. Try connecting the device to the PC using the USB cable. Run the diagnostic test in the software application to see if errors are detected. Note any errors that are detected.



WARNING: Ensure AMBULO 2400 has fresh batteries before running diagnostics.

2. If no errors are detected by the diagnostic scan, attempt to configure the device for use by a patient. Once configuration is complete, disconnect the device from the USB cable and press the Start/Stop button to initiate a manual measurement.
3. If the device still fails to take measurements, note any errors displayed on the LCD and refer to the Error and Diagnostic Codes section in this manual. Contact Mortara Technical Service for further assistance.

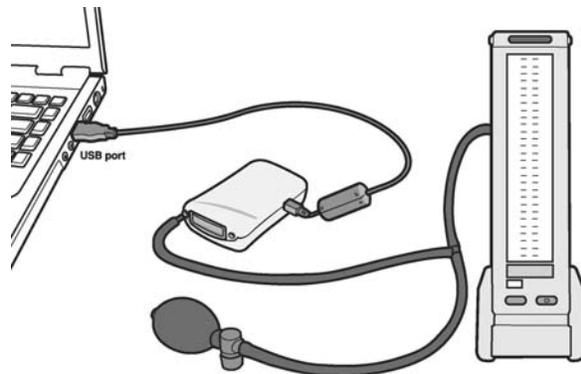
Maintenance

- Except for calibration check or data-management purposes, do not attach the ABPM device to any other devices or instruments. Doing so can cause the device to malfunction, and can affect its accuracy.
- When not in use, store the device in a clean environment. Avoid direct exposure to sunlight, dust, and high humidity.
- Remove the batteries if the device will not be used for an extended period of time (this will clear the date and time on the device after some time).
- Do not disassemble or open your device. Doing so may damage the device and will void the warranty.
- Do not use third-party accessories and/or parts (i.e., unsanctioned blood pressure cuffs) with your device. Doing so can affect the accuracy of any measurements and is not recommended.

Check Calibration of the ABPM Device

It is recommended that you check the calibration of you device every years, in accordance with the manometer test requirements of the ANSI/AAMI/ISO 80601-2-30:2009 & A1:2013 standard and according to the following procedure:

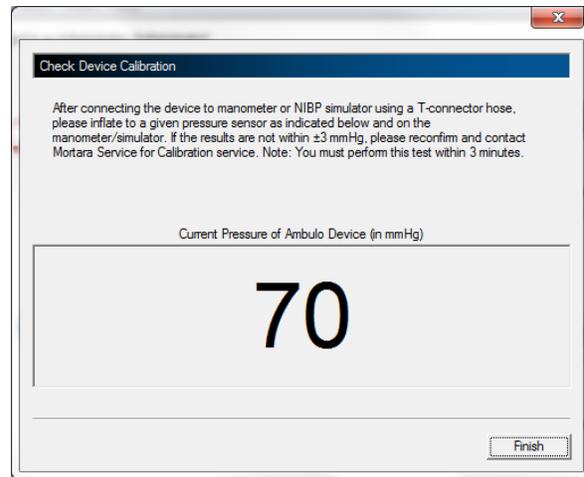
1. Consult *Software Configuration* in this manual for diagnostic instructions and other helpful tips.
2. Install the batteries.
 - Always use fully-charged rechargeable NiMH and/or Lithium AA batteries.
 - Ensure the batteries are in the correct polarity.
 - The device should power-on when the batteries are inserted correctly. Close the battery cover.
3. The calibration check requires the following components:
 - Ambulo 2400 device
 - Sphygmomanometer or NIBP simulator
 - Y-connector air hose
 - Hand pump bulb or built-in pump in NIBP simulator
 - USB cable



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

4. Check Calibration

- Within the Hypertension Diagnostics Suite software's main screen, select the Check Calibration item from the Tools menu. Once the check calibration wizard begins, you will be able to confirm the pressure sensor settings at various values (e.g., between 0 and 250mmHg). If the values shown by the manometer/NIBP simulator and those shown for the Ambulo 2400 via this screen differ for more than ± 3 mmHg, then your device will require factory calibration. Otherwise, your device is properly calibrated. You can close this screen and continue using the Ambulo 2400.



NOTE: If you determine and confirm that the Ambulo 2400's pressure sensor requires calibration, please contact Mortara Technical Support or your Mortara representative to arrange for calibration service. This will require that you send the device to an authorized Service Center for calibration.

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.

Consider using a NIBP simulator for testing of the device. Contact Mortara Technical Service for recommendations.

NOTE: Baseline measurements will go through a cuff deflation calibration procedure. This procedure pumps up to 120mmHg, followed by the cuff deflating for approximately 5 seconds and then re-inflating. This is generally a one-time per patient process. From this point on, the device will track the deflation and continue as normal. If necessary, this deflation calibration can be re-initiated by putting the device into baseline mode by pressing the START/STOP button three times consecutively (LCD shows something like "Hi 180" assuming the initial top pressure was set to 180).

ERROR AND DIAGNOSTIC CODES

The device can display a variety of error and diagnostic codes during or after measurements. Use this table to identify the source of error and the recommended solution.

Code	Description	Cause & Suggested Solutions
Err AP	Could not determine the Mean Arterial Pressure	Set initial top pressure to a higher value and/or instruct patient to remain still during measurement.
Er SYS	Could not determine the systolic pressure	Set initial top pressure to a higher value.
Er DIA	Could not determine the diastolic pressure	Press the Start/Stop button three times to reset the baseline mode.
Er Hr	Could not determine pulse rate	Retry measurement.
Lo bat	Low battery	Replace the battery.
Er Abr	User abort	User stopped the measurement.
USB	USB Connected	Device connected to PC via USB.
On	Device is in automatic mode	Device will not display the number of minutes remaining until the next automatic measurement
-----	Dashes across the display	The device configuration prohibits displaying the cuff pressure during inflation and deflation
## : ##	Time of day	Time of day is displayed in hh:mm
## ##	BP reading	BP reading presented as systolic diastolic
PAUSE	Devices in Pause Mode	Press the Start/Stop button for 5 seconds to reenter acquisition mode
Battery	Battery is low	Replace AA batteries
SP Err	Device error	Safety processor fault; contact technical support
Er ABR	Aborted Measurement	Measurement aborted due to user action, press Start/Stop button to resume acquisition
USB	USB connected	Messages presented when USB cable is connected to device
Er 40	Pressure timeout to 15mmHg	Attach cuff or correct air leak.
Er 41	Pressure timeout to high pressure limit	Correct air leak.
Er 42	Pressure timeout to minimum pressure	Timeout has occurred before reaching minimum pressure on deflation. Attempt reacquisition
Er 43	Excessive movement	Remain still and do not move arm or body during measurement cycle.
Er 47	Non-zero pressure detected at start of measurement	Ensure the cuff is fully deflated at start of measurement cycle or re-calibrate the system.
Er 48	Timeout	Timeout during adjustment of proportional valve contact technical support
Er 50	Timeout	Timeout during adjustment of proportional valve contact technical support
Er 161	Power Supply Fault	Power supply failure, contact technical support
Er 162	Pressure sensor fault	Pressure sensor fault contact technical support

Code	Description	Cause & Suggested Solutions
Er 163	Pressure >15mmHg for more than 175 seconds	Wait and retry the measurement.
Er 164	Overpressure error	Pressure exceeds threshold 2 (initial top pressure +70 mmHg) for more than 5 seconds
Er 165	Overpressure error	Pressure exceeded threshold 1 (285 mmHg) for more than 10 seconds
Er 166	Overpressure	Pressure exceeded threshold 0 (295 mmHg) for any duration
Er 167	Calibration error	Device has been incorrectly calibrated. Please recalibrate or contact Mortara Technical Service.
Er 168	Calibration error	Pressure sensor not calibrated, contact technical support
Er 171	Device error	Safety processor fault; contact technical support
Er 172	Battery critically low	Replace batteries
Er 175	Device error	Real-time clock date/time invalid. Replace batteries and reprogram unit
Er 195	Device error	Proportional valve duty value out of range, contact technical support
Er 196	Device error	Proportional valve duty valve invalid, contact technical support
Er 212	Device error	BP reading above maximum Max pressure
Er 213	Device error	BP data sample readings invalid, reacquire data
Er 214	Device error	BP memory full, download data
Er 216	Configuration error	Patient ID mismatch
Er 217	Zero Pressure Unstable	Ensure that the cuff is fully deflated and stable prior to starting a new measurement.
Er 218	Calibration error	Invalid pressure sensor offset, contact technical support
Er 225	User error	Keypress aborted establishment of zero pressure valve
Er 228	Configuration error	Measurement plan has invalid time until measurement
Er 236	Device error	Data memory area is unexpectedly not erased, reconfigure system and assure data is downloaded
Er 237	Device error	Data memory area fails verification, contact technical support
Er 238	Device error	Data memory area is unexpectedly erased, contact technical support
Er 239	Device error	Data memory area has bad CRC, contact technical support
Er 240	Device error	Data memory area reports incorrect length, contact technical support

Code	Description	Cause & Suggested Solutions
HE 1	Device error	Device error in retrieving device information, contact technical support
HE 2	Device error	Device error in saving data to device, contact technical support
HE 16	Device error	Data memory area reports incorrect length, contact technical support
HE 17	Device error	Data memory area has bad CRC, contact technical support
HE 18	Device error	Data memory area fails verification, contact technical support
HE 19	Device error	Data memory area fails verification, contact technical support
HE 34	Calibration error	Invalid pressure, reattempt acquiring blood pressure, if problem persists contact technical support
HE 37	Calibration error	Error calculating sensor slope, contact technical support
HE 60	Device error	Proportional valve duty value invalid, contact technical support
HE 81	Device error	Real-time clock date/time invalid, reinitiate configuration
SE 10	Device error	Unable to read requested data sample from flash; requested offset is out of range. Contact technical support
SE 16	Device error	Data memory area reports incorrect length
SE 17	Device error	Data memory area has bad CRC
SE 18	Device error	Device not properly configured
SE 19	Device error	Data memory area fails verification, contact technical support
SE 20	Device error	Data memory area is unexpectedly not erased, contact technical support
SE 24	Configuration error	Measurement plan index error, contact technical support
SE 25	Configuration error	Measurement plan invalid, contact technical support
SE 26	Configuration error	Error matching measurement plan, contact technical support
SE 27	Configuration error	No active measurement plan, reconfigure Ambulo device
SE 28	Configuration error	Measurement plan has invalid time until measurement, contact technical support
SE 29	Configuration error	Measurement plan has invalid type, contact technical support

Code	Description	Cause & Suggested Solutions
SE 31	User error	Key press aborted establishment of zero pressure value, reinitiate acquisition
SE 32	Configuration error	Max pressure too high
SE 38	Calibration error	Invalid pressure sensor offset, contact technical support
SE 39	Device error	Zero pressure value unstable, contact technical support
SE 40	Configuration error	Patient ID mismatch, re-download patient demographics
SE 42	Device error	BP memory full, download information to HDS
SE 43	Device error	BP data sample readings invalid, contact technical support
SE 44	Device error	BP reading above maximum max pressure
SE 48	Communication error	Actigraphy block index not found, contact technical support
SE 49	Device error	Actigraphy memory full, download data to HDS
SE 50	Device error	Actigraphy Vector count out of range, contact technical support
SE 51	Device error	No Actigraphy vectors, contact technical support
SE 81	Date/time invalid	The time of day clock for date/time is invalid due to extended battery removal. Reconfigure the device.
SE 84	Battery critically low	Replace AA batteries
SE 85	Device error	Safety processor fault; contact technical support
SE 88	Calibration error	Pressure sensor not calibrated, contact technical support
SE 89	Calibration error	Pressure sensor zero point not set, contact technical support
SE 90	Overpressure error	Pressure exceeded threshold 0 (295 mmHg) for any duration
SE 91	Overpressure error	Pressure exceeded threshold 1 (285 mmHg) for more than 10 seconds
SE 93	Overpressure error	Pressure exceeded threshold 3 (10 mmHg) for more than 175 seconds
SE 94	Device error	Pressure sensor fault, contact technical support
SE 95	Device error	Power supply fault, contact technical support
SE 97 - 128	An i2c communications error occurred (accelerometer error)	Contact technical support

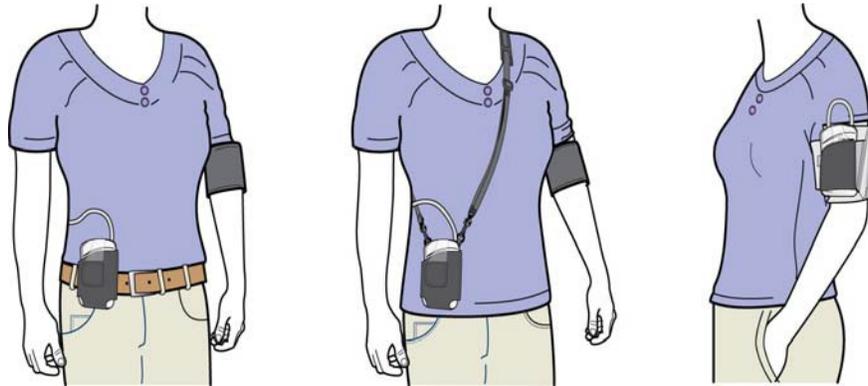
If at any time after power-on-reset the LCD displays “SE XX”, this is an internal soft error encountered by the device after power-up. The most common such occurrence is “SE 81” which means the date/time have been lost after the batteries have been removed for longer than 10 minutes. Pressing the Start/Stop button generally allows the user to continue past such soft errors. If an error condition persists, contact Mortara Technical Service.

Patient Instruction

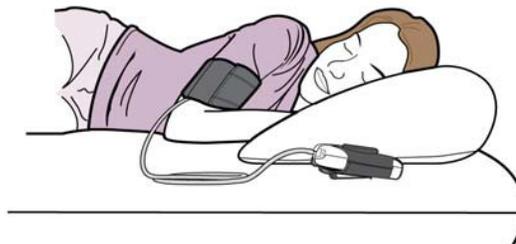
Your physician has recommended a 24-hour Ambulatory Blood Pressure Monitoring (ABPM) procedure for you. This is a relatively straight-forward procedure that measures your blood pressure over specific intervals during the day and night. ABPM may be done to get a more accurate measurement of your average blood pressure, or because you have different readings in the doctor's office than at home, or for other reasons. To ensure a successful result, carefully follow these instructions, as well as any additional information provided to you by your clinical team.

- This is a safe and painless procedure.
- You will wear a portable blood pressure monitor on your arm for approximately 24 hours.
- For your visit, please wear a shirt or blouse with loose fitting sleeves

The blood pressure cuff will be placed on your upper arm under your clothing, directly against the skin. The cuff connects with a rubber tube to the ABPM monitor. This is a small device that can be worn over your shoulder with a strap, attached to your belt, or carried in a large pocket in your clothes (see the picture below).



At night the cuff is kept on, and the monitor is placed next to you in your bed or under your pillow. You will not be able to take a bath or shower while wearing the cuff and you should not plan to do heavy exercise (that is, exercise to the point where you sweat a lot). Otherwise, you should go about your usual daily activities, including work, household tasks, and so on.



Typically, the monitor will take a reading every 15 minutes during the day, and every 30 minutes at night. While a reading is being taken, the cuff will inflate and squeeze your arm firmly, just as the blood pressure cuffs used in the office or in stores do. While the cuff is inflating and deflating, it is best to try to avoid moving your arm, as this may interfere with the reading. If the monitor has trouble getting a reading, it may re-inflate in a minute or so to try a second time.

We strongly urge you to leave the cuff on for as close to 24 hours as possible. If the cuff is simply too uncomfortable (which is rarely the case), you can remove it by peeling cuff off of your arm. Do not press any of the buttons on the monitor itself. When you return the next day to have the cuff removed, the nurse or medical assistant will take off the cuff and you are free to leave.

- When a blood pressure measurement is in progress, rest your arm on a flat surface and relax it. Minimize any movement for the duration of the measurement. DO NOT swing or shake your arm. AVOID any tapping, pressure or shock to the cuff as it will affect the measurement accuracy.
- Avoid any kinks, crimping, compression or restriction of the tubes. **DO NOT** puncture or cut the tubes.
- **DO NOT** get the ABPM unit wet or submerge it in liquids. **DO NOT** drop, shake or pound on the ABPM unit. The ABPM system includes expensive and sensitive electronic equipment. You are responsible for the safekeeping of the equipment.
- **DO NOT** remove the batteries from the ABPM unit unless necessary. If the batteries have a low charge, replace them with fully recharged NiMH and/or Lithium batteries.
- **DO NOT** attempt to open, disassemble, tamper or repair the ABPM unit.
- If you notice rashes or bruises on your arm, discontinue measurements, remove the cuff and contact your physician.
- Pressing the START/STOP button during a measurement will cancel the measurement in progress and deflate the cuff.
- Activate a manual reading by pressing the START/STOP button.
- If you take the cuff off to disrobe, to bathe, or upon the completion of the 24-hour procedure, hold the START/STOP button for five seconds to PAUSE the measurements. Once you put the cuff back on your arm and it is connected to the ABPM unit, hold the button for five more seconds to disengage the PAUSE function.

Use the patient diary to record the time of measurements, your physical position and activity during measurements, as well as any symptoms or conditions that may exist. Also take note of meals, snacks, and medications taken. Return the diary to your physician's office along with the ABPM system.

Contact your healthcare provider should you have any questions or require further assistance.

