Ambulo™ 2400

User’s Guide

For use with
Hypertension Diagnostic Suite software in Clinical Trial Mode
1 Start Here

Open and inspect the contents of your system, including all accessories and documentation as noted on the packing slip.

This guide will show you how to configure and conduct a successful ABPM procedure on a research subject using the Ambulo 2400 device, its accessories and software. Please consult the attached User’s Guide for detailed instructions, as well as other important information and helpful tips.

NOTE

See ABPM study reference materials for protocol specific information and Central Lab contact details.

2 Install the Batteries

- Always use fully-charged rechargeable NiMH or approved alkaline AA batteries for each ABPM procedure.
- Make sure that the batteries are in the correct polarity.
- Once powered, the LCD will come on and the device will beep. Close the battery cover.
3 Configure the Ambulo 2400 for Each Subject

- The Ambulo 2400 must be programmed for each subject using the software. This should only take a few minutes.
- Connect the Ambulo 2400 to the supplied PC using the included USB cable.
- Open the Hypertension Diagnostics Suite – CLINICAL TRIAL MODE software.

- For your convenience, the HDS-CTM software has been preinstalled on the supplied PC and the study ABPM requirements have been preconfigured.
- Select an existing or create a new subject - including all relevant information.
- Click on the ‘Configure Device’ icon.

- Choose the appropriate Visit ID from the drop-down list. Select the ‘One Click Programming’ button and then ‘Yes’ to confirm action.

**CAUTION**
Programming ABPM device will erase any previously recorded data on the device. Always ensure procedures are downloaded from ABPM device onto laptop at time of completion.
- Device will be initialized and configured with the preconfigured study ABPM inflation and display requirements.
- Message to be displayed upon successful completion.
- You may disconnect the USB cable and begin subject set-up. The Ambulo 2400 will restart into PAUSE mode and should display the correct time.
- Press and hold the button for 5 seconds to change the device mode from PAUSE to AUTOMATIC. Once in AUTOMATIC mode, the device may display a countdown in addition to the clock time.
4 Subject Set-up

- Measure the subject’s study-designated arm and select an appropriate-sized cuff. Each cuff is labeled with range markers to indicate the min and max circumference that can be accommodated by that cuff.
- Place the cuff on the subject’s study-designated arm such that the artery indicator rests on the brachial artery. Do not tighten the cuff too firmly; allow a finger’s worth of slack between the cuff and the arm.
- The Ambulo 2400 can be worn in four distinct configurations, depending upon the protocol requirement:

EasyWear™ Cuff  Shoulder Strap
Belt Clip  Asleep (Standard Cuff)
5 Collecting Measurements and Transmission to Central Lab

- At the completion of the ABPM procedure, connect the Ambulo 2400 to your PC using the USB cable. Run the software.
- From the Main Menu, click the ‘Download Data from Device’ icon to collect the data measurements from the ABPM unit.
- Viewing of the measurement results will depend on the study and protocol requirements.

**NOTE**

ABPM procedures need to be transferred to the Central Lab on the day of collection to allow for analysis and report generation.

- To transfer the ABPM procedures, exit the HDS-CTM software and connect the laptop to your network either via Ethernet cable or Wi-Fi to enable internet access.
- Double-click on the ‘IDrive’ program icon that is on your Desktop.

**NOTE**

IDrive application has been preconfigured and will not require adjustment.

- Select ‘Backup Now’ and allow program to prepare files for transmission.
- Backup progress bar will display and View Log option will appear upon complete.
- Select ‘Yes’ to view log and confirm file transfer. Reinitiate process as necessary.
- Once file transfer is confirmed, IDrive application can be closed and laptop shutdown and placed in secure location.

If you have any problems or need further information, please refer to the detailed instructions in the Full User’s Guide and the ABPM study reference materials. You can obtain service and support by contacting your Central Lab Customer Service Representative as indicated in the ABPM study reference materials.
Copyright Notice

© 2008-2010 - Tiba Medical, Inc.
All Rights Reserved

NO-WARRANTY – This technical information is being furnished to you AS-IS, and Tiba Medical makes no warranty as to its accuracy or use. Any use of the technical documentation or the information contained therein is at the risk of the user. Documentation may include technical or other inaccuracies or typographical errors. Tiba Medical reserves the right to make changes without prior notice.

No part of this publication may be copied without the express written permission of Tiba Medical.

Trademarks

Tiba Medical, Ambulo, Ambulo 2400, and EasyWear are trademarks of Tiba Medical, Inc.

Windows®, Windows XP®, and Windows Vista® are registered trademarks of Microsoft Corporation. Adobe and Acrobat are trademarks of Adobe Systems Incorporated. Other product names mentioned in this manual may be trademarks of their respective companies and are hereby acknowledged.

Printed in the United States of America

Part Number: 810-0004-01
Product License

This product and its accompanying software are subject to Tiba Medical’s End User License Agreement. By using this product and its accompanying software, you agree to the terms and conditions specified therein.

Additional Notices

Portions of this product include software and components that are copyrighted by their respective owners including:

AVR Libc Package
Copyright © 1999-2007
The Regents of the University of California. All rights reserved.

KISS FFT Package
Copyright © 2003-2004
Mark Borgerding. All rights reserved.

LPCUSB USB Device Driver for LPC Microcontrollers
Copyright © 2006
Bertrik Sikken (bertrik@sikken.nl) All rights reserved.

SOFTWARE IS PROVIDED BY THE COPYRIGHT HOLDERS AND CONTRIBUTORS "AS IS" AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING (BUT NOT LIMITED TO) THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE DISCLAIMED. IN NO EVENT SHALL THE COPYRIGHT OWNER OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION), HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY; WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE); ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.
Cautions, Notes and Other Symbols

The following symbols are used throughout this User’s Guide to provide cautions, notes and warnings.

---

**CAUTION**

A CAUTION indicates a potential for inaccurate measurements, property damage or injury.

---

**NOTE**

A NOTE indicates important information that helps you make better use of your system.

---

The following explains the symbols indicated on the Ambulo 2400 device label:

---

**Attention, consult accompanying documentation including this User’s Guide.**

---

**IPX1**

Indicates the 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.

---

**Safety classification of Type BF Applied Part Defibrillation Proof.** The device or its applied parts have conductive contact with the patient/subject for medium or long-term.

---

**Tested for safety by the Canadian Standards Association according to applicable US and Canadian standards and requirements.**

---

**The CE Mark indicates conformance to the European Medical Device Directive.**
Declaration of Conformity

We, Tiba Medical, Inc.
2701 NW Vaughn Street, Suite 470
Portland, Oregon 97210
USA

Declare and certify that the product described below is in conformity with the applicable provisions of Council Directive 93/42/EEC concerning medical devices.

Ambulo 2400 Ambulatory Blood Pressure Monitoring System

The product has been verified as conforming via the procedure relating to the Declaration of Conformity as set out in Annex II, excluding Section 4, of the European Directive.

____________________________
October 1, 2010

President

Date

Certification Registration No.: 409736 MR2

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

0297
# Contents

INTRODUCTION.......................................................................................................................... 1

  OVERVIEW .............................................................................................................................. 1
  INDICATIONS FOR USE......................................................................................................... 1
  THE ABPM PROCEDURE ....................................................................................................... 1
  THE AMBULO 2400 SYSTEM ................................................................................................. 1
  FEATURES ............................................................................................................................. 2
  PEDIATRICS .......................................................................................................................... 2

AMBULO 2400 SYSTEM OVERVIEW ......................................................................................... 4

  SYSTEM COMPONENTS ......................................................................................................... 4
  ABPM DEVICE AT A GLANCE ............................................................................................... 5
  LCD PANEL ............................................................................................................................ 5
  AIR SOCKET .......................................................................................................................... 6
  START/STOP BUTTON ........................................................................................................... 7
  INSERTING & REPLACING BATTERIES IN THE DEVICE .................................................... 7
  USB INTERFACE ................................................................................................................. 10

SOFTWARE OPERATION ......................................................................................................... 11

  STARTING THE PROGRAM ..................................................................................................... 11
  ENTERING SUBJECT INFORMATION .................................................................................... 12
    Creating a New Subject ........................................................................................................ 12
    Selecting a Subject ............................................................................................................. 13
    Configuring Device ........................................................................................................... 13
  GETTING & VIEWING MEASUREMENT DATA ...................................................................... 15
    Selecting a Completed Procedure ....................................................................................... 16
  TABLE VIEW ........................................................................................................................ 17
    ADDITIONAL OPERATIONS ............................................................................................... 17
      Performing Diagnostics .................................................................................................... 17
      Getting Help .................................................................................................................... 18
      About the Software .......................................................................................................... 18
      Closing the Program ...................................................................................................... 19

PERFORMING AN ABPM PROCEDURE .................................................................................... 20

  CONFIGURING THE ABPM DEVICE ................................................................................... 20
  SUBJECT HOOK-UP .............................................................................................................. 21
  DOWNLOADING AND REVIEWING MEASUREMENT DATA .............................................. 25
  TRANSFERRING ABPM PROCEDURES TO CENTRAL LAB .............................................. 26

CARE & MAINTENANCE .......................................................................................................... 29

  GENERAL CARE & MAINTENANCE .................................................................................... 29
  ELECTROMAGNETIC COMPATIBILITY (EMC) ..................................................................... 30

TROUBLESHOOTING .............................................................................................................. 31
POWER-ON ISSUES................................................................. 31
COMMUNICATION ERRORS ..................................................... 31
ABPM DEVICE NOT FUNCTIONING ............................................. 32

ERROR & DIAGNOSTIC CODES................................................. 33
SPECIFICATIONS.................................................................... 35
Introduction

Overview

The Ambulo 2400 is 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/subject’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 designed to measure systolic and diastolic blood pressure and pulse rate of adults who are eighteen (18) years and older using the oscillometric method on a cuffed arm.

The ABPM Procedure

Blood pressure naturally fluctuates throughout a full day according to various factors, including: sleep patterns, medication, diet, exercise, and stress. 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.

The Ambulo 2400 System

The Ambulo 2400 ABPM system is lightweight, quiet, comfortable, and does not interfere with daily activities. It is easily configured and individually-fitted for each patient/subject 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.

Blood pressure measurements determined with this 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 SP10-2002).
Features

- **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, modern design that is compact, durable, and easy to use.
- **EasyWear™ Options**: Unit can be integrated onto the blood pressure cuff, clipped onto a belt, or strapped around the shoulder.
- **Validation**: Validated according to the AAMI SP-10 protocol and in accordance with the British Hypertension Society’s protocol.

Pediatrics

Like many other ambulatory blood pressure monitors, the Ambulo 2400 is approved only for use in adults, not pediatrics. Unlike other monitors, the Ambulo 2400 has been validated with children and adolescents as well as with adults. The independent validation of the Ambulo 2400 was performed by Dr. Bruce Alpert, MD at the University of Tennessee, USA and published in 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. This indicates that the Ambulo 2400 meets the highest standards of both the global ISO81060-2 as well as the stringent requirements of the British Hypertension Society’s protocols ensuring that the system performs equally well in all BP ranges.

---

**CAUTION**

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

**CAUTION**

The Ambulo 2400 system may not provide accurate results in subjects who have arrhythmias such as atrial or ventricular premature beats or atrial fibrillation.
Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers.

The efficacy and accuracy of the Ambulo 2400 system has been validated according to a number of standards, including AAMI SP-10:2002, ISO81060-2 and the British Hypertension Society’s protocol. Please contact your Customer Service Representative to obtain a copy and for details regarding the findings of such testing, as well as the accuracy claims of the system vs. that of trained observers.
Ambulo 2400 System Overview

System Components

You system will include a number of components that are essential to carrying out successful ABPM procedures on a wide variety of subjects. While exact configurations will vary depending upon the requirements of the study, it will generally include the following:

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>010-2400-01</td>
<td>Ambulo 2400 ABPM Device</td>
</tr>
<tr>
<td>B</td>
<td>1</td>
<td>008-0007-01</td>
<td>Carrying Pouch with Belt Clip</td>
</tr>
<tr>
<td>C</td>
<td>1</td>
<td>810-0004-01</td>
<td>User’s Guide</td>
</tr>
<tr>
<td>D</td>
<td>1</td>
<td>008-0006-01</td>
<td>Extension Hose</td>
</tr>
<tr>
<td>E</td>
<td>1</td>
<td>008-0005-01</td>
<td>EasyWear™ Cuff</td>
</tr>
<tr>
<td>F</td>
<td>1</td>
<td>008-0008-01</td>
<td>USB Cable</td>
</tr>
<tr>
<td>G</td>
<td>1</td>
<td>008-0009-01</td>
<td>CD-ROM Software</td>
</tr>
<tr>
<td>H</td>
<td>1</td>
<td>008-0007-01</td>
<td>Shoulder Strap</td>
</tr>
<tr>
<td>I</td>
<td>2</td>
<td>501-0002-01</td>
<td>Rechargeable NiMH Batteries</td>
</tr>
<tr>
<td>J</td>
<td>1</td>
<td>008-0039-01</td>
<td>Large Adult Cuff</td>
</tr>
<tr>
<td>K</td>
<td>1</td>
<td>008-0038-01</td>
<td>Regular Adult Cuff</td>
</tr>
<tr>
<td>L</td>
<td>1</td>
<td>008-0037-01</td>
<td>Small Adult Cuff</td>
</tr>
</tbody>
</table>
In addition, you may have received a carrying case, disposable cuffs and/or Subject Information Sheets/Subj ect Diary Forms with your ABPM system.

Please review the contents of your system with the packing slip to ensure that you have received all materials.

**ABPM Device at a Glance**

![ABPM Device Diagram](image)

**LCD Panel**

During initial power-up, all available segments of the LCD will be turned on to verify correct functionality of the display. Please note that not all available segments on the LCD are relevant to this device at any given time, and that they may be activated during different operations.
Depending upon the mode of operation, the LCD panel will show any of the following items:

- Current time.
- If the system is paused and not taking any measurements, the LCD will display PAUSE.
- If the system is in a measurement cycle, the LCD will display the current time and, depending upon how the device has been configured, the time remaining until the next measurement.
- If the system 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 system 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.
- Error messages, if any.

**NOTE**

Depending upon the study configuration via the software, the LCD may NOT display any or all of the following: a) time remaining to next measurement, b) current pressure level, and/or c) results of a recent blood pressure measurement.

<table>
<thead>
<tr>
<th>LCD Display</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAUSE</td>
<td>Device is paused</td>
</tr>
<tr>
<td>BPM</td>
<td>Indicates Beats per Minute (Pulse)</td>
</tr>
<tr>
<td>AM</td>
<td>AM (12:00 AM – 11:59 AM)</td>
</tr>
<tr>
<td>PM</td>
<td>PM (12:00 PM – 11:59 PM)</td>
</tr>
<tr>
<td>Low battery</td>
<td></td>
</tr>
</tbody>
</table>

-low battery indicates that the Ambulo 2400’s batteries are low and need to be replaced/recharged. This indicator may only come on during cuff inflation, and immediately disappear afterwards. This action indicates that the Ambulo 2400 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.

**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.

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 three 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 subject 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 three 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 50mmHg – 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.

---

Depend upon the study configuration via the software, the button may be disabled. If this is the case, the user will not have control over manually-triggering a measurement. The user will still be able to stop a measurement in progress by pressing the button.

---

Inserting & Replacing Batteries in the Device

To insert 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 casing. 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.

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

---

![CAUTION]

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

---

![CAUTION]

**Always use fully-charged rechargeable NiMH or approved alkaline AA batteries for each ABPM procedure.**
CAUTION

Do not mix different types of batteries – such as Alkaline disposables, NiMH and NiCD rechargeable batteries.

CAUTION

It is recommended that new batteries be used with each new ABPM procedure. Low battery power may prevent measurements from being taken over the full recording 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 reset.
**USB Interface**

To use the ABPM device, it must be properly configured via the accompanying software on a Windows-based Personal Computer. To do this, connect the ABPM to the supplied 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 subject when it is connected to a PC via the USB cable.*

---

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 Operation

Starting the Program

For your convenience, the Hypertension Diagnostic Suite - Clinical Trial Mode software has been preinstalled on the supplied PC and the study requirements have been preconfigured.

To run the ABPM system software application:

   Double-click on the “Hypertension Diagnostics Suite” program icon that is on your Desktop

   OR

   From the Windows START menu, select:
   
   Programs → Tiba Medical → Hypertension Diagnostics Suite

At this point, the application software window should open and be available for use. After the splash screen displays, the Main Menu will appear.

The Main Menu icons will take you to the various aspects of the program, including data retrieval and analysis.

**Browse Subjects** – This icon will take you to the Subject View screen, in which you may select a subject and study data to analyze by way of tables and graphs. You may also view measurement data depending on the study requirements.
**New Subjects** – This icon will take you to the Add New Subject screen.

**Configure Device** – This icon will take you to device configuration, allowing you to configure the device for a subject and visit with the preset monitoring plan.

**Download Data from Device** – This icon will automatically extract measurements from the Ambulo 2400 (device must be connected to the PC via the USB cable), and add the information to the subject’s records.

---

**Entering Subject Information**

**Creating a New Subject**

To establish a new subject record, click on the ‘New Subjects’ icon to advance to the ‘Add New Subject’ window.

![Add New Subject Window](image)

**NOTE**

New subjects will be saved in the existing ‘Subjects’ folder.
To create a new subject, press ‘OK’ after filling in the following fields (mandatory fields are marked in red * in the form):

- **Subject ID** – Primary identification number for subject. Enter per study requirements.
- **Subject Initials** – Enter per study requirements.
- **Randomization Code** – Enter per study requirements and as information becomes available.
- **Clinician Initials** – To document individual responsible for subject record creation.
- **Sex** – Select M or F from drop-down list.
- **Date of Birth** – All numeric as DD MM YYYY.
- **Other demographic information as required by study.**
- **Notes** – Any relevant notes on the subject may be entered here before the procedure.

---

**NOTE**

Once a subject record is created, it cannot be edited via the HDS-CTM software. Data discrepancies will be address via the Central Lab data clarification & correction process and updated ABPM reports will be issued as necessary.

---

**Selecting a Subject**

To view completed procedures for an existing subject, click the ‘Browse Subjects’ icon on the Main Menu and select a subject in the folder view, select a completed procedure for that particular subject, and use the toolbar at the top of the screen to go through the various views.

---

**NOTE**

View options will be per study requirements.

---

**Configuring Device**

Prior to use with each subject, the device needs to be configured. The ‘Program ABPM Device’ window can be launched from the icon on the main screen or from the toolbar icon on the Subject View (within Browse Subjects). In the ‘Program ABPM Device’ window, select the ‘Subjects’ folder to list the entered subjects. Subject details must be previously entered to appear on the list.
Choose a subject by highlighting the corresponding row and select a Visit ID from the drop-down list. Once a subject and Visit ID are selected, press the ‘One Click Device Programming’ button to program with device with the study-specific configuration.

![Program ABPM Device](image)

A confirmation prompt will be presented.

![Hypertension Diagnostics Suite](image)

**Programming ABPM device will erase any previously recorded data on the device. Always ensure procedures are downloaded from ABPM device onto laptop at time of completion.**

Select ‘Yes’ if you are certain that the data on device has been previously downloaded or is nonexistent. If uncertain, select ‘No’ and proceed to ‘Download Data from Device’ before programming ABPM.
Upon selecting ‘Yes’, the device contents will be cleared, and the monitoring plan and date & time set. A message will appear upon successful completion.

![Successful Programming Message]

**Getting & Viewing Measurement Data**

To download the measurement data from the Device, you must have it connected to the supplied laptop via the USB cable, and the HDS-CTM software must be running.

Click on either the ‘Download Data from the Device’ icon on the Main Menu or the ‘Download Data’ toolbar button in the Subject View. A status bar (shown below) will appear to show the progress of the download. The data will automatically be associated with its corresponding subject record based on the Subject ID and Visit ID assigned during device configuration.

![Download Status Bar]

The actigraphy information will be downloaded subsequently.

In the case that the data on the device does not already have a subject associated with it on the laptop (based on a match of the Subject ID), you will be prompted to create a new one.

![Create New Subject Prompt]
Click ‘Yes’ to continue; refer back to the Creating a New Subject section for instruction in record creation.

In the case that data measurements with the same time range have previously been downloaded and exist for this subject, you will be prompted as to whether or not to repeat the download.

Selecting a Completed Procedure

For many subjects, there may be multiple ABPM procedures over the course of a study. To select a specific procedure, select the subject in Subject View and find the recording ranges in the bottom right-hand section of the screen. Double-clicking a completed session will expand it into the table view.
NOTE

Viewing of measurement data will be per study requirements.

Table View

The Table View is used to expand a completed procedure into a comprehensible spreadsheet format. Availability of this information on your laptop will be dependent on the study requirements.

Additional Operations

Performing Diagnostics

To run diagnostic tests on your ABPM device, select ‘Device Diagnostics’ from ‘Tools’ on the menu bar or click the icon in the Subject View toolbar. Please ensure that the device is properly connected to the supplied PC via the USB cable, and that the program COM port settings are correct. Once the test begins, you should see a screen similar to the following:
At the conclusion of the diagnostics, you will see a total error report line at the bottom of the window. If tests have failed, please troubleshoot your device using this guide or contact your Customer Support Representative for assistance.

**Getting Help**

At any point, you can select the Help menu, which is located in a drop-down menu at the top of the window. The ‘Online Help’ menu item opens an electronic version of this manual. This provides detailed information on the use and navigation of the ABPM software.

**About the Software**

Under the ‘Help’ drop-down menu, click ‘About’ to see the details of your current software package. The version number of the software will be displayed here along with Copyright information. This information might be necessary if you ever need to obtain technical support from your Customer Service Representative.
Closing the Program

You can close the ABPM software application by selecting the exit option under the ‘File’ menu. This will prompt you as to whether you want to exit the program or not, and selecting **YES** will exit the application. You can also exit the application by using any of the standard Microsoft Windows application controls.
Performing an ABPM Procedure

This section explains how to configure the ABPM system on a subject, including the hardware configuration, hook-up, and collection of 24-hour measurements. It provides an easy-to-follow checklist to ensure that the ABPM procedure can be done quickly, seamlessly, and with the maximum level of accuracy and subject comfort. Please refer to the previous sections of this User’s Guide for the exact details on how to carry out each step in this process.

NOTE

The instructions are general guidelines for performing an ABPM procedure. See your ABPM study reference materials for protocol specific requirements for performing ABPM procedures.

Configuring the ABPM Device

The Ambulo 2400 must be programmed for each subject using the software. This should only take a few minutes.

CAUTION

Programming ABPM device will erase any previously recorded data on the device. Always ensure procedures are downloaded from ABPM device onto laptop at time of completion.

1. Connect the Ambulo 2400 to the supplied laptop using the included USB cable.
2. Open the Hypertension Diagnostics Suite – CLINICAL TRIAL MODE software.

![Hypertension Diagnostics Suite -- CLINICAL TRIAL MODE --](image)
3. Select an existing or create a new subject - including all relevant information.
4. Click on the ‘Configure Device’ icon to advance to the ‘Program ABPM Device’ window.
5. Open the ‘Subjects’ folder to list the entered subjects.
6. Choose the appropriate Visit ID from the drop-down list.
7. Select the ‘One Click Programming’ button and then ‘Yes’ to confirm action.

8. Message will display upon successful completion of device configuration.
9. Disconnect the USB cable and begin subject set-up. The Ambulo 2400 will restart into PAUSE mode and should display the correct time. Press and hold the button for 5 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.

**Subject Hook-up**

1. Ideally, you have advised the subject to wear a loose-fitting short-sleeved shirt or blouse for this procedure. Thick sweaters and dresses may complicate the hook-up of the system.

2. Review the ABPM procedure with the subject, including the various parts and functions of the system which they will be wearing.

3. Measure the subject’s study-designated arm and select an appropriate-sized cuff. A regular adult, large adult, and small adult cuff are generally provided with the ABPM study supplies. You may also have received an EasyWear cuff, depending upon configuration options selected. Each is labeled with range markers to indicate the minimum and maximum circumference that can be accommodated by that cuff.
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; selecting a cuff that is too small or too large may result in erroneous readings and cause subject discomfort. To ensure correct cuff application, please review the following recommendations for arm circumference.

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

Avoid restricting, compressing, or crimping the blood pressure tubing.

4. Place the cuff on the subject’s study-designated arm such that the artery indicator rests on the brachial artery, and the air tube is pointing up towards the subject’s shoulders. Wrap the cuff 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.

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.

The Ambulo 2400 can be worn in four distinct configurations, depending upon subject comfort and anticipated activity:
5. If using the EasyWear cuff, the cuff can be further secured on the subject’s arm using the snap and an ECG electrode (not supplied with the Ambulo 2400 system). Simply connect the ECG electrode to the cuff snap, place the cuff on the subject’s bare arm and remove the adhesive on the back of the ECG electrode and gently attach it to the subject’s skin. This will ensure that the cuff and device will not roll down the subject’s arm during daily activity. The ECG electrode does not have any electrical connection to the Ambulo 2400 and is not used for any measurements.

6. Depending upon the size of the subject, connect the extension hose to the cuff’s air tube. The two ends couple by being inserted into one another. As
shown in the diagrams above, run the hose behind the subject’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 air hose in to the ABPM unit. The device can be clipped onto a belt or worn via the shoulder strap, depending upon which is more comfortable for the subject. Using the shoulder straps, the device can be worn on the opposite side as the cuffed arm or the same side as the cuffed arm (depending on subject preference and comfort). Make sure to provide enough slack so that the subject 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 subject). The hose can be coiled together and secured close to the ABPM device. Make sure that the hose is not crimped or kinked. Any slack should be concentrated near the ABPM device, rather than the cuff.

---

**CAUTION**

Ensure that the hose does not have any crimps or kinks, as they would likely cause the device to misread or malfunction and potentially harm the subject.

---

9. Instruct the subject 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.

10. To verify correct operation, press 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 upon any subject 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 subject’s “normal” blood pressure. If this baseline measurement fails to find the subject’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 subject anticipates a large shift and presses the button three times successively, the device will go through this baseline procedure again.
It is important that the subject 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 on subjects with larger cuff sizes. Movement before the measurement cycle is complete will result in erroneous measurements and/or repeat measurements.

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

In certain cases, with subjects 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.

11. Before the subject leaves, carefully review all the information on the Subject Instruction Sheet. Specifically point out to the subject the location 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 button for three seconds. This will help preserve battery life, and avoid erroneous measurements when the system is not worn.

12. Complete the top of the Subject Diary form and ask that the subject 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 Measurement Data**

When the subject returns upon completion of the prescribed ABPM procedure, collect the ABPM system and all applicable accessories. You may need to assist the subject 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 Subject Diary form and clarify any information that is not legible, clear, or missing.
2. Connect the USB cable to both the ABPM device and the supplied laptop. Run the ‘Hypertension Diagnostics Suite - Clinical Trial Mode’ application software.

3. From the Main Menu, click the ‘Download Data from Device’ icon to obtain the data measurements from the ABPM unit. Refer to the Troubleshooting chapter in this User’s Guide if you have any problems.

**Transferring ABPM Procedures to Central Lab**

Transfer the collected subject ABPM procedures to the Central Lab for analysis and ABPM report generation as required per protocol.

1. To transfer the ABPM procedures, exit the HDS-CTM software and connect the laptop to your network either via Ethernet cable or Wi-Fi to enable internet access.
2. Double-click on the ‘IDrive’ program icon that is on your Desktop or right-click on the IDrive icon in the system tray.

---

**NOTE**

*IDrive application has been preconfigured and will not require adjustment.*

---

3. Select ‘Backup Now’ and allow program to prepare files for transmission.
4. Backup progress bar will display and View Log option will appear upon complete.

![Backup Progress](image1.png)

5. Select ‘Yes’ to view log and confirm file transfer. Reinitiate process as necessary.

![View Log](image2.png)

```
---------- BackupSet Number: 9 ----------
User name jimnie
Backup Operation: Interactive
Version No: 3.3.31
Total backup set size: 4.11 MB
[11-05-2010 13:34:38] [Full Backup] Backed up file: C:\HDS-CTM\ABPM database\Protocol ABC-123_db.mdb, 4.11 MB
BACKUP START TIME: 11-05-2010 13:34:33
BACKUP END TIME: 11-05-2010 13:34:38
Total Time: 00:00:05
Backup Completed: [Backed up Files: 1 of 1]
```
6. Once file transfer is confirmed, IDrive application can be closed and laptop shutdown and placed in secure location.

NOTE

ABPM procedures need to be transferred to the Central Lab on the day of collection to allow for analysis and report generation.
Care & Maintenance

General Care & Maintenance

Please follow these simple guidelines to ensure the safekeeping and longevity of your ABPM system:

- Avoid dropping the device, or subjecting it to shock and/or vibration.

- The device can be cleaned with a soft or damp cloth. Do not use any abrasive cleaning solutions or solvents.

- As with any other electronic equipment, avoid getting the device wet or submerging it in liquids. Doing so will likely damage the device and/or affect its accuracy, and will also void your warranty. Please contact your Customer Service Representative if the device ever gets wet or is submerged in liquids.

- Cuffs can be wiped clean using a mild detergent on a slightly damp cloth. Be careful not to get liquid inside of the tubes. In the event of 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. Prior to washing, remove any internal cuff bladders and engage the Velcro hook and loop fasteners to prevent lint from collecting in the hooks. If required, use of nonchlorine bleach is recommended. Chlorine bleach solutions will shorten the service life of the cuff. Always allow the cuff to air dry after cleaning. The user is responsible for validating any deviations from the recommended cleaning method.

- The cuff and bladder may be sterilized with commercially available disinfectants however, 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 them to air dry and then insert the bladder. 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 325º degrees F, 162º degrees C.

- Except for calibration or data-management purposes, do not attach the ABPM system 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 system 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. Note that this will clear the date and time on the device.

• Do not disassemble or open your device. Doing so may damage your system and will void your warranty.

• Do not use third-party accessories and parts (such as unsanctioned blood pressure cuffs) with your ABPM system. Doing so can affect the accuracy of your measurements and is not recommended.

**Electromagnetic Compatibility (EMC)**

Electromechanical medical equipment requires special precautions regarding EMC, and needs to be installed and put into service according to the information provided in this document. Portable and mobile equipment that transmit radio frequency signals can affect the Ambulo 2400.

The Ambulo 2400 should not be used adjacent to or stacked with other electronic equipment. If it becomes necessary to breach the above conditions, the unit should be carefully observed to ensure that it maintains proper operational capabilities. Please refer to the specifications and regulatory notices provided in this User’s Guide to help identify any such conditions.

The Ambulo 2400 should only be used with the USB cable and other accessories provided by Tiba Medical.

Operation of the Ambulo 2400 beyond its specified ranges, or beyond normal physiological conditions of human subjects, may cause inaccurate results.
Troubleshooting

Power-On Issues
If you have placed fully-charged or new alkaline batteries inside of your ABPM device and the LCD does not illuminate or display any characters, please check the charge level and polarity of the batteries – ensure that they have been placed correctly. Polarity indicators can be found in the bottom of the battery compartment.

If your batteries are in the correct configuration and the issue persists, please contact your Customer Service Representative for further assistance.

Communication Errors
If you encounter communication problems and/or errors between your PC and the ABPM device, please follow this simple checklist to correct the problem.

1. Make sure that you have fully recharged or new alkaline batteries in the ABPM device, and that the LCD screen is displaying the time of day.

   Once you remove the batteries, the device loses its date and time information.

   NOTE

2. Check the cable connections to both USB port of your PC and the side of the ABPM 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 your computer and attempt communications again.

   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 it before proceeding.

   NOTE

4. If communications problems persist, please contact your Customer Service Representative for further assistance.
ABPM Device not Functioning

If your ABPM device is not taking measurements properly, please follow this checklist to troubleshoot your problem.

1. Try connecting the device to your PC via the USB cable. Run the diagnostic test on the software application to see if errors are detected. In the event that they are, please note them.

2. If no errors were detected by the diagnostic scan, attempt to configure the device for use by a subject (refer back to the Configuring Device section of this guide). Once configuration is completed, 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, please note any errors displayed on the LCD and refer to the error table in this guide. If you cannot resolve the problem, contact your Customer Service Representative for further assistance.
# Error & Diagnostic Codes

The ABPM system 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 to the problem.

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
<th>Cause &amp; Suggested Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Err AP</td>
<td>Could not determine the Mean Arterial Pressure</td>
<td>Set initial top pressure to a higher value and/or instruct subject to remain still during measurement</td>
</tr>
<tr>
<td>Err SYS</td>
<td>Could not determine the systolic pressure</td>
<td>Set initial top pressure to a higher value</td>
</tr>
<tr>
<td>Err DIA</td>
<td>Could not determine the diastolic pressure</td>
<td>Press the START-STOP button three times to reset the baseline mode</td>
</tr>
<tr>
<td>Err Hr</td>
<td>Could not determine pulse rate</td>
<td>Retry measurement</td>
</tr>
<tr>
<td>Lo bat</td>
<td>Low battery</td>
<td>Replace the battery</td>
</tr>
<tr>
<td>Err Abr</td>
<td>User abort</td>
<td>User stopped the measurement</td>
</tr>
<tr>
<td>USB</td>
<td>USB Connected</td>
<td>Device connected to PC via USB</td>
</tr>
<tr>
<td>Err 33</td>
<td>Low battery</td>
<td>Replace the battery</td>
</tr>
<tr>
<td>Err 40</td>
<td>Pressure timeout to 15mmHg</td>
<td>Attach cuff or correct air leak</td>
</tr>
<tr>
<td>Err 41</td>
<td>Pressure timeout to high pressure limit</td>
<td>Correct air leak</td>
</tr>
<tr>
<td>Err 43</td>
<td>Excessive movement</td>
<td>Remain still and do not move arm or body during measurement cycle</td>
</tr>
<tr>
<td>Err 47</td>
<td>Non-zero pressure detected at start of measurement</td>
<td>Ensure the cuff is fully deflated at start of measurement cycle or recalibrate the system</td>
</tr>
<tr>
<td>Err 163</td>
<td>Pressure &gt;15mmHg for more than 175 seconds</td>
<td>Wait and retry the measurement</td>
</tr>
<tr>
<td>Err 217</td>
<td>Zero Pressure Unstable</td>
<td>Ensure that the cuff is fully deflated and stable prior to starting a new measurement</td>
</tr>
</tbody>
</table>

If at any time after power-on-reset, the LCD display shows “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. You can generally press the START/STOP button to continue past such soft errors.
If an error condition persists and you are not able to solve the problem, please contact your Customer Service Representative.
# Specifications

## Physical

<table>
<thead>
<tr>
<th>Device Size</th>
<th>119mm × 68mm × 32mm (4.7” x 2.7” x 1.2”)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Weight</td>
<td>253 grams (9 oz.)</td>
</tr>
</tbody>
</table>

## Blood Pressure Measurement

<table>
<thead>
<tr>
<th>Measurement Principle</th>
<th>Patented oscillometric algorithm with micropump and proportional valve deflation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement Ranges</td>
<td>Systolic 60 to 280 mmHg  Diastolic 30 to 160 mmHg  Pulse Rate 30 to 180 bpm</td>
</tr>
</tbody>
</table>

### Accuracy

<table>
<thead>
<tr>
<th>Blood Pressure:</th>
<th>±3 mmHg mean difference  ±8 mmHg standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Rate:</td>
<td>±3 bpm</td>
</tr>
</tbody>
</table>

### Top Pressure

According to ANSI/AAMI SP-10:2002
British Hypertension Society; Grade: A/A
ISO81060-2
Default of 180 mmHg
User configurable to 285 mmHg

## Sample Measurement Intervals

Four adjustable intervals during 24 hour periods each configurable to 0, 5, 10, 15, 20, 30, 45, 60, 90, or 120 minute measurements. Optional randomization factor up to ±75% within above intervals.
Sequential mode for phase I cardiovascular safety trials.

## Miscellaneous

### Actigraphy

Recording of 3-axis of motion via accelerometer for display and categorization of sleep/awake cycles via application software

### Memory

Solid-state Flash technology. Sufficient for 3000 blood pressure measurements and 7 days of continuous actigraphy

### PC Interface

USB 2.0 with mini-B connector
Maximum cable length: 1 meter

### PC Display

minimum 1024x768 (XGA, or extended VGA)

## Electrical

### Battery Type

2 x 1.2V AA batteries – use either rechargeable NiMH or approved alkaline batteries only
<table>
<thead>
<tr>
<th><strong>Battery Capacity</strong></th>
<th>300 measurements using two fully charged 2000mAh NiMH batteries</th>
</tr>
</thead>
</table>
| **Voltage & Current** | Voltage: 2.4V DC  
Maximum Current: 610mA  
Idle Current: 1.3 mA |
| **Environmental** |  |
| **Operation** | Temperature: +5°C to +40°C  
Humidity: 30% RH to 95% RH; non-condensing  
Altitude: -171m (1034hPa) to +5000m (540hPa) |
| **Storage** | Temperature: -20°C to +55°C  
Humidity: 15% RH to 95% RH, non-condensing  
Altitude: -382 m (700hPa) to +5000m (540hPa) |
| **Protection** | Type BF Input Protection Defib-Proof  
IPX-1 |
| **Regulatory Standards** |  |
| **Safety** | EN/IEC 60601-1  
EN/IEC 60601-2-30:2000  
EN/IEC60601-1-4:1996  
AAMI/ANSI SP10:2002  
Relevant US Food & Drug Administration guidance & consensus standards as well as 21 CFR 820 |
| **EMC** | EN/IEC60601-1-2:2001 |
| **Environmental** | IEC 68-2-29  
MIL – STD 810E, 1989  
ISTA Series 2 AB |

**CAUTION**

The Ambulo 2400 may not provide accurate results or may be damaged if operated or stored beyond the above specifications. This may also void your warranty coverage.
For study-specific support, contact your Central Lab Customer Service Representative. See your ABPM study reference materials for Central Lab contact details.

Address: 2701 NW Vaughn Street, Suite 470
Portland, OR 97210
U.S.A.

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands