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1 What is Pulsewave™?

Pulsewave™ is a personal health monitoring system that allows you a more active role in managing your health.

The Pulsewave™ system includes:

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
<th>Current Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device</td>
<td>Pulse Acquisition Device, Wrist Cuff, and USB Cable</td>
<td>Pulsewave™ PAD</td>
</tr>
<tr>
<td>Software</td>
<td>Pulse Acquisition Software - a client application installed on your computer</td>
<td>Pulsewave™ PAS</td>
</tr>
<tr>
<td>Website</td>
<td>A website where you can download the Software, access on-line help and view all readings and results to monitor your health</td>
<td><a href="http://www.myufit.com">www.myufit.com</a></td>
</tr>
<tr>
<td>Web Services</td>
<td>A storage of all measurement readings in database records and the medical measurement engine on the Biosign Technologies Inc. secure servers</td>
<td>VIMIS</td>
</tr>
<tr>
<td>Measurement Services</td>
<td>Medical Measurement Services (MMS)</td>
<td>UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services</td>
</tr>
</tbody>
</table>

Disclaimer

This device is intended for use only by adults (18 years or older).

This device is not intended to replace regular medical examinations.

Do not use this device to adjust your medication, diet, or lifestyle without first consulting a physician.
Advisory

Blood pressure measurement may not be accurate according to specifications in the presence of arrhythmias. Results may not be displayed in the presence of severe arrhythmias.

Pulsewave™ measurement of blood pressure complies with all hardware and software requirements defined by ANSI/AAMI SP10:2002/A1:2003/A2:2006/(R)2008 pertaining to an automated sphygmomanometer that uses the auscultatory method as the reference standard.


Pulsewave™ requires an Internet connection to provide results. Please see Section 6.1 Windows system requirements, for detailed information on computer configuration.
2 How does Pulsewave™ work?

2.1. Pulsewave™ Device and Pulsewave™ Software collect your pulse signal and display it on the computer screen.

2.2. The signal is encrypted and sent over the Internet to our secure servers where it is saved in a database.

2.3. The signal is analyzed and medical measurement functions are performed.

2.4. Measurement results are returned to your computer over the Internet and displayed. *

2.5. Go to www.myufit.com to download software, get support and monitor your progress.

* Note: Measurements results are displayed only if you are subscribed to MMS (UFIT® TEN-10, for example).
3 Package contents

- Inflatable Wrist Cuff
- USB Cable
- Pulsewave™ PAD
- Setup Guide
- Carrying Pouch
4 Setting up the Pulsewave™ Device

This section describes setting up the Pulsewave™ PAD.

- Connect the USB cable to the Pulsewave™ PAD, and to your computer, as illustrated below
- The LED light on the Pulsewave™ PAD will turn amber — indicating that the connection was successful

![USB connection diagram]

Note: When connecting for the first time, Microsoft® Windows will install a driver and may prompt you to restart your computer.

![Warning symbol]

Please use only the USB cable and cuff provided with the device. This ensures the best performance of your device.
5  A closer look at Pulsewave™ PAD

Top view

Multi-colour LED
This indicates the device status.

Reset button
Pressing this will stop operation and, if already inflated, will deflate the cuff.

Bottom view

The label on the bottom of the device contains a unique serial number and other manufacturing and regulatory information.

Manufacturer & Distributor

Attention: consult accompanying documents (IEC 348)

Type BF equipment (IEC 878-02-03)
Body Floating (BF) type Applied Part as defined in international standard EN60601-1, clause 2.2.25

DC Current 5V

Canadian Standards Association

European Union Market Clearance
6 Installing Pulsewave™ Software

This section describes installing the Pulsewave™ PAS. Since the Pulsewave™ PAD is operated and controlled by software, it cannot function on its own and thus requires the installation of Pulsewave™ PAS on your computer.

6.1 Windows system requirements

In order for this application to function properly, your computer must meet the following minimum conditions:

- Supported Operating Systems: Windows XP SP2; Windows Vista 32-bit; Windows Vista 64-bit; Windows 7 32-bit; Windows 7 64-bit
- Processor: 1 GHz Pentium III processor or equivalent (minimum)
- Memory: 256 MB (minimum); 1 GB (recommended)
- Hard Disk: 100 MB (Up to 500 MB of available space may be required for installation)
- USB: One available USB 1.1 compatible port
- Display: 800 x 600, 24-bit (minimum); 1024 x 768, 32-bit (recommended)
- Mouse/ touchpad and keyboard
- Internet Connection: 28.8 Kbps (minimum); Broadband (recommended)

6.2 Locating, downloading, and installing Pulsewave™ PAS

To install the Pulsewave™ PAS, follow the steps below:

6.2.1: Open your web browser.

6.2.2: Type www.myufit.com into the URL or address bar.
6.2.3: Click on the **Register here** link.

6.2.4: Follow the instructions in the information panel to fill in the registration form and click **Register**.

Passwords are case-sensitive. In the future, you must always use the exact upper and/or lower case sequence of letters that you entered here.
6.2.5: After successful registration, you are presented with the End User License Agreement. If you accept it, click I accept and you may proceed to download the software.

6.2.6: The website will guide you through the necessary steps to download/install the Pulsewave™ PAS.
6.2.7: After installation has completed, the Pulsewave™ PAS icon will appear on your desktop.

The Pulsewave™ PAS will then start and ask you to enter the User name and Password you created at registration. Click Log in.

You are now ready to use Pulsewave™.
When measuring blood pressure, regardless of the method and device used, an accurate reading requires that the person be relaxed and sitting comfortably.

It is essential that the blood pressure cuff be placed against bare skin, as readings taken over a shirtsleeve are less accurate. In addition, it is advisable to remove any jewellery, e.g. bracelets or watches or any other items worn on the arm that may restrict blood flow.

In order to achieve the best possible reading, you must sit upright in a chair with your feet flat on the floor and your limbs uncrossed.

During the reading, your left arm should rest on the table and be kept at heart level. The cuff is to be worn on the wrist, preferably the left wrist if possible.

**Only use the cuff on a wrist that has intact skin, and not on skin with cuts, scrapes, open wounds, etc.**
Pulsewave™ Reading

The cuff on the left wrist, and at heart level

The Pulsewave™ PAS Getting Started screen provides a reminder of the necessary steps to operate the software and to take a proper reading.
When the Pulsewave™ PAD is connected to the computer, the Device Control Button shows the start icon.

When the Pulsewave™ PAD is not connected to your computer, the Device Control button shows the device-not-found icon. In that case, plug in the USB cable (see section 4 Setting up the Pulsewave™ Device). The multi-colour LED light should now flash amber, and then turn green.
### 7.1 Taking a reading

#### 7.1.1: Put on the cuff

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove any jewelry and roll up shirt sleeves. If possible, always place the cuff on your left wrist. The cuff will accommodate a wrist circumference ranging from 13.5 to 23 cm (5.3 to 9.1 in).</td>
<td></td>
</tr>
<tr>
<td>Open the cuff’s Velcro® tab.</td>
<td></td>
</tr>
<tr>
<td>Pull the flap through the metal clip to loosen the cuff. Do not pull the cuff through the clip beyond the stopper installed in the cuff.</td>
<td></td>
</tr>
<tr>
<td>Insert your hand through the cuff.</td>
<td></td>
</tr>
<tr>
<td>Bend the flap.</td>
<td></td>
</tr>
<tr>
<td>Pull the flap through the metal clip to tighten the cuff. Make sure that the cuff is attached comfortably to your wrist. It should be neither too tight nor too loose.</td>
<td></td>
</tr>
<tr>
<td>Note: The positioning of the cuff pictured at left depicts the optimal position for comfort. However, the inflatable cuff can be inverted or rotated otherwise than is presented here.</td>
<td></td>
</tr>
</tbody>
</table>
Pulsewave™ PAD will record — in real time — your pulse signal. It is imperative that you

- do not move
- do not talk
- stay as still as possible for the duration of the reading
- close any application or screensavers that may distract you while taking your reading

7.1.2: Click the start icon.

A timer appears and you are reminded to relax and remain still and silent during the reading.
7.1.3: Initialization

A hardware test is performed to initialize the device.

7.1.4: Inflation

The cuff on your wrist inflates to the predetermined maximum target pressure. Progress is displayed in the Pressure Gauge pane.

If required, click the Stop button to halt the operation and deflate the cuff.
7.1.5: Deflation

The cuff begins to deflate and pulse signal data are captured in real time.

7.1.6: Reading submission

The deflation process is completed (i.e. the predetermined minimum target pressure is reached), and the Send Reading screen appears.

You may now remove the cuff.

Enter your password and type in some notes (e.g. how are you feeling, medication taken, changes in diet/exercise, etc.).

When you click Send, your reading is sent to our servers, where analysis and measurement functions are performed.

Note the date and time displayed in the Send Reading window. These are read from your computer system and should accurately reflect your time zone. If they do not, please adjust your computer’s date and time settings accordingly.
7.1.7: Results are displayed

Clicking on the Blood pressure results (SYS, DIA) in the Results Pane will display the corresponding point in the Pulse Signal Pane.

Moving the gray bar in the Full Reading Pane will display a magnified version in the Pulse Signal Pane.

Note: Measurement results are displayed only if you are subscribed to MMS.

7.1.8: Printing a report

You have the option of generating and printing a report of the reading that you just took.

Click on the Report button to view a report of the reading.

Click on the Print button to print the report or the Save button to save it on your hard drive.
7.2 Profile management

By registering additional Personal Pulsewave™ Accounts, more than one person can use Pulsewave™ to monitor their health.

7.2.1: Click the User profiles icon

7.2.2: Click on the Add icon

7.2.3: Enter a User name and Password and click Log in.

This will add the account to the list of users in the Pulsewave™ PAS and allow them to take a reading.

Note: Only registered users may be added.

7.2.4: You have now configured Pulsewave™ PAS for more than one user. To switch between user accounts, choose your name from the list under the User profiles icon, or select your name from the list of when you first launch the software.

Click Select.
7.3 Offline readings

There may be times that an Internet connection is not available at the time of taking a reading. In this case, the Pulsewave™ PAS can save your reading as an Offline Reading.

Click on the Save button to save the reading on your hard drive. Since no data are sent to our servers in the Offline Reading state, calculations cannot be performed on our servers, therefore results are not displayed.
The reading is stored in queue for you to send to our servers once an Internet connection is available.

Click on the Offline tab.

The list of your Offline readings is displayed.
Enter your Password and click on the **Send all** button.

Once the saved readings are sent to our servers, you will be able to see the results on [www.myufit.com](http://www.myufit.com).

Click the **Open myUfit.com** button to open the myufit.com website in your browser.
8 Software preferences

Click on the Preferences button.

Reading Mode
By default, Pulsewave™ PAS is set to perform one reading at the time.

Checking the Multi-reading mode, you can take multiple readings at set intervals.
See section 8.1 Multi-reading mode.

Target pressure high displays the maximum (inflation) target pressure.
Target pressure low displays the minimum (deflation) target pressure.
These pressure values can be set by the Target pressure preference:
Auto – Self-adjusts target pressures based on results
Fixed – Default between 220 mmHg and 45 mmHg
Manual – you can set the values

My Account
You can read about the details of the MMS to which you have subscribed.

This information constitutes the claim based on which the medical measurement function obtained market clearance.
See section 15 Product approvals.
Language and Region
You can change the language you prefer the Pulsewave™ PAS to display. Region is configured within your account at www.myufit.com.

Voice Recognition
When active, this allows for hands-free use of the Device Control Button. You can customize the phrases for starting and stopping a reading. A microphone may need to be installed on your computer for this feature.

Integration
These settings are necessary for the Pulsewave™ system to integrate with other healthcare management platforms. When active, the results are copied to the Clipboard for use. The Custom string dictates how these results are formatted.
**Connection**

The server information is displayed. Your readings are sent to this location.

**Log**

This tracks system messages that may appear in Pulsewave™ PAS. You may be asked to reference this information by Customer Support when troubleshooting.

**About**

This panel displays the software and hardware version information.

Please have this handy when you contact Customer Support.
8.1 Multi-reading mode

Multi-reading mode is useful in conditions where periodic readings need to be taken automatically.

Check **Multi-reading mode** in the **Preferences** window on the **Reading Mode** tab and click **OK**.

Enter your log in information and click **Log in** to activate the changes.
Next time you take a reading, you will be presented with the Multi-Reading screen where you can set the parameters of the reading session:

![Multi-Reading Screen]

**Target high:** The maximum inflation pressure of the cuff.

**Target low:** The deflation pressure to be reached to end the reading.

**Readings:** The number of readings that will be taken in this session under Multi-reading mode.

**Interval:** The duration between readings.

**Retries:** The number of re-tries available to the session in the event of an error.

**Notes:** Any relevant notes about this session.

Put on the cuff and click the **Multi** button to start taking readings.

Use the **Single** button to bypass the Multi-reading mode at any time. Please note that any target pressure settings are over-ridden by Multi-reading mode.
The usual reading process will commence with the countdown timer and then the reading begins. You can track the progress of the Multi-reading session under the **Reading Series** heading. When the reading is complete, it is automatically sent to our servers.
Results are returned and the interval countdown to the next reading begins.

This process repeats for as many readings were set in the Multi-Reading screen. Please note that the last reading will not be automatically sent to the server and will require you to click the Send button to complete the series.
9 Monitoring your progress

If you are a subscriber to a Pulsewave™ Service, the measurement results provided by that service are displayed after a Pulsewave™ reading is stored in our database. You can view all of your readings and results online.

Click the Open myUfit.com button to open the myufit.com website in your browser.

Enter your User name and password and click Log in to enter your account. This is the same User name and password used to submit a Pulsewave™ reading.
You will be able to explore all your readings in detail, see trends and charts, and be notified of the next suggested time to take your next reading. The website will guide you by means of information bars and “tool tips” on most of the buttons.

For further assistance, please visit the Biosign Support site, by clicking Support.
10 Device care and maintenance

10.1 Precautions

- The device may be cleaned with a water-dampened cloth
- Never immerse the device in water or any other liquid
- Do not spill water or any other liquid on the device
- Avoid exposure to strong shocks, such as dropping it on the floor
- Never attempt to disassemble the device
- Store the device according to the conditions listed in the Technical specifications section under Storage Temperature and Humidity
- Do not under any circumstance attempt to separate the air tube attached to the wrist cuff from the device

10.2 Disinfecting the cuff

The cuff may be disinfected if required:

- Disconnect Pulsewave™ Device from the USB cable prior to disinfection
- Use Isopropyl Alcohol 70% USP (minimum)
- Use a spray applicator adjusted to 1ml/spray or use an alcohol wipe
- Spray or wipe the surfaces of the cuff (it is not required to soak the cuff)
- Allow ample drying time before use; minimum 3 minutes

10.3 Calibration

Pulsewave™ pressure transducer accuracy is pre-calibrated, and does not need further maintenance or validation by the user.

11 Things to know about your Pulsewave™

Conditions that adversely affect use

- Temperature and relative humidity outside the specified operating range (refer to Technical specifications)
- Mechanical vibrations
- Incorrect positioning of the cuff (e.g. placed too far up from the wrist, too loose or too tight)
- Wrist not aligned at heart level
- Any movement, including talking, during the reading
- Your physiological condition (such as arrhythmias, and pregnancy)
12 Troubleshooting

12.1 Codes in Pulsewave™ PAS

If the analysis of your reading on our server detects conditions that affect the quality of the reading in any way, a message may be sent to the Messages Pane in the software. These messages are designed to inform you about what may be causing a reduction in reading quality (or the inability to analyze the reading at all). They are also designed to suggest ways to correct the issue. These messages have codes noted at the end of them. You may use these codes to look up detailed troubleshooting articles on the Support website at support.biosign.com.

Reading messages are messages that deal with the reading itself.

Device messages are messages that deal with the Pulsewave™ Device.

If a message appears with results, it means that the issue should be corrected for your next reading. If a message appears without results, it means that the issue must be corrected right away for any results to be returned.
### 12.2 Pulsewave™ PAS Troubleshooting - Basics

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Reason</th>
<th>Troubleshooting Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Device Button shows the following icon:</td>
<td>The Pulsewave™ PAD is not recognized by the Pulsewave™ PAS</td>
<td>• Unplug the USB cable from your computer and plug it back in</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Unplug the USB cable from your Pulsewave™ PAD and plug it back in</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Press the red Reset button on the Pulsewave™ PAD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Quit and re-launch the Pulsewave™ PAS (with the Pulsewave™ PAD connected)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Restart your computer</td>
</tr>
<tr>
<td>Internet Connection or Server is not available messages</td>
<td>Your computer is not connected to the Internet</td>
<td>• Type a note about your reading if you wish to do so and click the <strong>Save</strong> button.</td>
</tr>
<tr>
<td>Unable to submit readings and they are being stored as Offline</td>
<td>The Server at Biosign Technologies Inc. may be offline</td>
<td>Your reading can be sent when you are on the Internet, or the server is back online.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Confirm that your computer is connected to the Internet (i.e. can you browse the web?)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Troubleshoot your Internet connection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Go to <strong>Biosign Support</strong>, where notices about an interruption of service will be posted</td>
</tr>
</tbody>
</table>

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12.3 Pulsewave™ PAD Troubleshooting - LED

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Reason</th>
<th>Troubleshooting Steps</th>
</tr>
</thead>
</table>
| Pulsewave™ PAD is connected via USB and LED status of PAD shows RED | Pulsewave™ PAD is powered, but the computer does not recognize the device | • Unplug the USB cable from your computer and plug it back in  
  • Unplug the USB cable from your Pulsewave™ PAD and plug it back in  
  • Press the red Reset button on the Pulsewave™ PAD  
  • Restart your computer  
  • Run Windows Update  
  • Your computer’s USB ports may be disabled. Contact your Systems Administrator for assistance |

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Reason</th>
<th>Troubleshooting Steps</th>
</tr>
</thead>
</table>
| Pulsewave™ PAD is connected via USB and LED status of PAD shows AMBER | Pulsewave™ PAD is powered and recognized by the computer, but not communicating with the Pulsewave™ PAS. | • Launch the Pulsewave™ PAS if it is not already running  
  • Unplug the USB cable from your computer and plug it back in  
  • Unplug the USB cable from your Pulsewave™ PAD and plug it back in  
  • Press the red Reset button on the Pulsewave™ PAD  
  • Quit and re-launch the Pulsewave™ PAS (with the Pulsewave™ PAD connected)  
  • Restart your computer |

Still require help? | Customer Support at 1-877-712-7446 support.biosign.com |

For further assistance, please visit Biosign Support
# Technical specifications

<table>
<thead>
<tr>
<th>Physical Dimensions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit size (L/H/W)</td>
<td>9.5/3.0/6.0 cm</td>
</tr>
<tr>
<td></td>
<td>3.74/1.18/2.36 in</td>
</tr>
<tr>
<td>Tube length (L)</td>
<td>60 cm</td>
</tr>
<tr>
<td></td>
<td>23.62 in</td>
</tr>
<tr>
<td>Tube outside diameter (OD)</td>
<td>0.6 cm</td>
</tr>
<tr>
<td></td>
<td>0.24 in</td>
</tr>
<tr>
<td>Tube inside diameter (ID)</td>
<td>0.3 cm</td>
</tr>
<tr>
<td></td>
<td>0.12 in</td>
</tr>
<tr>
<td>Cuff size (L/W)</td>
<td>36/8 cm</td>
</tr>
<tr>
<td></td>
<td>14.2/3.1 in</td>
</tr>
<tr>
<td>Unit weight</td>
<td>216 grams</td>
</tr>
<tr>
<td></td>
<td>7.62 oz</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Features</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer interface</td>
<td>USB</td>
</tr>
<tr>
<td>Power source</td>
<td>USB</td>
</tr>
<tr>
<td>Computer compatibility</td>
<td>USB 1.1 (Low Speed)</td>
</tr>
<tr>
<td>Cuff inflation</td>
<td>Automatic pump</td>
</tr>
<tr>
<td>Rapid pressure release</td>
<td>Automatic release</td>
</tr>
<tr>
<td>Cuff Deflation</td>
<td>Passive release valve</td>
</tr>
<tr>
<td>Pulse wave detection</td>
<td>Piezo resistive sensor</td>
</tr>
<tr>
<td>Over pressure protection</td>
<td>320 to 330 mmHg</td>
</tr>
<tr>
<td>Protection fuse</td>
<td>1 A</td>
</tr>
<tr>
<td>Transient and over voltage protection</td>
<td>25A,8/25μs</td>
</tr>
<tr>
<td>Wrist Cuff size</td>
<td>13.5 to 23 cm</td>
</tr>
<tr>
<td></td>
<td>5.3 to 9.1 in</td>
</tr>
</tbody>
</table>
## Limitations and Specifications

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuff Velcro® endurance supported up to</td>
<td>3000</td>
</tr>
<tr>
<td>Cuff operating range (Velcro® fastened)</td>
<td>0 to 299 mmHg</td>
</tr>
<tr>
<td>Cuff operating range (fastened to wrist)</td>
<td>0 to 299 mmHg</td>
</tr>
<tr>
<td>Unit operating range</td>
<td>0 to 299 mmHg</td>
</tr>
<tr>
<td>Unit pressure accuracy at calibration</td>
<td>±3 mmHg</td>
</tr>
<tr>
<td>Operating voltage range</td>
<td>4.5 to 5.5 V</td>
</tr>
<tr>
<td>Maximum operating current</td>
<td>500 mA</td>
</tr>
<tr>
<td>Unit endurance supported up to</td>
<td>10000 cycles</td>
</tr>
<tr>
<td>Pulse rate measurement range</td>
<td>30 to 200 /min</td>
</tr>
<tr>
<td>Pulse bandwidth</td>
<td>0 to 10 Hz</td>
</tr>
<tr>
<td>Pulse quantization</td>
<td>10 bits</td>
</tr>
<tr>
<td>Simultaneous pulse and pressure sample rate</td>
<td>10 to 100 Hz</td>
</tr>
<tr>
<td>Humidity</td>
<td>15 to 95 %RH</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>-20 to +50 °C</td>
</tr>
<tr>
<td></td>
<td>-4 to +122 °F</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>+10 to +40 °C</td>
</tr>
<tr>
<td></td>
<td>+50 to +104 °F</td>
</tr>
<tr>
<td>Water/Liquid resistance</td>
<td>None -</td>
</tr>
<tr>
<td>Receive interference</td>
<td>Vibrations -</td>
</tr>
<tr>
<td>Drop to rigid surface onto rest base</td>
<td>&lt;15.5 cm</td>
</tr>
<tr>
<td></td>
<td>&lt;6.10 in</td>
</tr>
<tr>
<td>Drop to rigid surface onto five sides</td>
<td>&lt;7.6 cm</td>
</tr>
<tr>
<td></td>
<td>&lt;2.99 in</td>
</tr>
<tr>
<td>Drop to rigid surface onto eight corners</td>
<td>&lt;7.6 cm</td>
</tr>
<tr>
<td></td>
<td>&lt;2.99 in</td>
</tr>
</tbody>
</table>
14 Limited One-Year warranty

Biosign Technologies Inc. grants a Limited One Year Replacement Warranty on Pulsewave™ PAD starting on the date of purchase. Within the warranty period, we will repair or replace the device, free of charge, for defects resulting from faults in materials or workmanship. This warranty covers the Pulsewave™ PAD, specifically the hardware, when used in accordance with the instructions provided with the device.

This warranty extends to every country where the Pulsewave™ PAD is sold by Biosign Technologies Inc. or its distributors. This warranty extends to registered users of our services.

This warranty does not cover: any damage (whether intentional, accidental or elemental), alteration, modification or tampering of any kind, failure to maintain, scratches or defects in product finishes, theft, vandalism, any use outside of device specifications. This warranty does not cover interaction with non-Biosign Technologies Inc. products, including the use of interface cables not supplied with the product.

BIOSIGN TECHNOLOGIES INC. SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER INCIDENTAL, CONSEQUENTIAL OR INDIRECT COSTS, EXPENSE OR DAMAGES.

Validation of warranty and qualification of coverage are assessed by Customer Support. If you need assistance, please contact them at:

Biosign Customer Support

Hours: Monday – Friday, 09:00 – 17:00 Eastern Time

Online: support.biosign.com

Telephone: North America
Toll Free: 1-877-712-7446
Local: 416-218-9800
International: (+1) 416-218-9800
15 Product approvals

- Health Canada License # 70264 for UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Controls
- FDA Pre-market Clearance K122443, under Section 510(k) for UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services
- ISO 9001:2008 Quality Management System
- ISO 13485:2003 Medical Devices Quality Management System
- CAN/CSA C22.2 No. 601.1-M90 “Medical Electrical Equipment Part 1: General Requirements for safety” (Complies with UL 2601-1)
- IEC 60601-1-2-2001 for EMC/EMI compliance

Manufactured by:
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European Representative:
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