

# HealthGuard®-15 Owner's Manual

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CE 0459



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## SECTION 1

# **REGULATORY INFORMATION**

### **Indications for Use**

The HealthGuard-15 is a non-invasive screening device intended for use in corporate wellness facilities and in health/fitness clubs. It is not for use in medical facilities such as hospitals or doctor's offices. This device measures systolic and diastolic blood pressure, heart rate, percent body fat, and weight. It is operated by the client supplied PC computer. The device is intended for users eighteen years and older.

<u>U.S. Food and Drug Administration</u>	<u>European Union</u>			
<b>Medical Device</b>	<b>Medical Device</b>			
Trade Name: HealthGuard-15 Portable Health Kiosk	<table><tr><td>LNE/G-MED</td><td>CE</td><td>0459</td></tr></table>	LNE/G-MED	CE	0459
LNE/G-MED	CE	0459		
Common Name: Non-invasive Blood Pressure Measurement System				
Classification Number: 21 CFR 870.1130				
Classification: Class II	Automatic electronic sphygmomanometer, Body composition analyzer, Pulse analyzer			
Panel: Circulatory System Device Panel	Classification: Class IIa			
Product Code: DXN				



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## SECTION 2

# **SAFETY INFORMATION**

*To assure correct use of this product, basic safety measures should always be taken including the warning and cautions listed in this section.*

SAFETY SYMBOLS USED IN THIS OWNER'S MANUAL	
 <b>WARNING</b>	Indicates a potentially dangerous situation which, if not avoided, could result in severe injury or death.
 <b>CAUTION</b>	Indicates a potentially dangerous situation which, if not avoided, could result in minor injury to the user or patient or damage to the equipment or other property.

### **DEVICE OPERATING CAUTIONS & WARNINGS**



Contact your physician for detailed information and advice about your blood pressure. Self-diagnosis and treatment using measurement results may be dangerous. Follow the instructions of a licensed healthcare provider.



The HealthGuard-15 is not intended to be a diagnostic device and is for screening purposes only.



Read all of the information in the Owner's Manual before operating the device.



This device is intended to measure blood pressure, weight, heart rate, and percent body fat for adults. Do not use this device on children or people who cannot express their intentions.



This device may cause discomfort or bruising on the upper arm. If this develops press the **STOP** button on the side of the measurement device or on the computer screen.



Operate the HealthGuard-15 only in the manner intended. Do not use this device for any other purpose.



Dispose of the device and accessories according to applicable local regulation.



Do not use a mobile device near the instrument. It could result in an operational failure



Use only Futrex and HealthGuard authorized parts and accessories. Parts and accessories not approved for use with the device may damage the unit and void the warranty.



The HealthGuard-15 is limited for measurement of individuals with arm circumference from 9 to 13 inches.

## **CARE AND MAINTENANCE**



Do not subject the monitor to strong shocks, such as dropping the device on the floor.



Do not expose the device or any of the components to water or submerge in water.



Store the device and components in a cool, clean, dry, and safe location.



Changes or modifications to the device not approved by the manufacturer will void the warranty. Do not attempt to repair the unit or components or disassemble the unit without expressed permission from Futrex.

## **SECTION 3**

# **BEFORE TAKING A MEASUREMENT**

To obtain the most reliable readings, follow these instructions:

1. Avoid eating, drinking alcohol, smoking, exercising and bathing for 30 minutes before taking a measurement. Rest for three to five minutes before taking a measurement.
2. Stress raises blood pressure. Avoid taking measurements during times of stress.
3. Remove tight-fitting clothing from your left arm.
4. Remain still and do not talk during the testing.
5. Wait 2 to 3 minutes between measurements. The wait time allows arteries to return to the condition prior to taking the blood pressure measurement. You may need to increase the wait time depending on your individual physiological characteristics.
6. Ensure that your left palm is down and your arm is comfortably resting on the arm rest.
7. Keep a record of your blood pressure and heart rate readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a period of time.

## SECTION 4

# WARRANTY INFORMATION

The following warranty card is included with your HealthGuard-15. Please read the card and return it to Futrex. HealthGuard support is available by calling 301-733-9368 or e-mailing [service@Futrex.com](mailto:service@Futrex.com).

### Warranty Registration

(Please complete and return within 10 days) — Please Print—

MODEL NO. and/or DESCRIPTION \_\_\_\_\_ SERIAL NO. \_\_\_\_\_  
DATE PURCHASED \_\_\_\_\_  
NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_  
  
DEALER'S NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_  
  
☐ Check box if you desire to receive reprints of scientific papers on the performance of the Futrex Inc. product.  
(There is no charge for this.)  
OWNER: \_\_\_\_\_  
SIGNATURE \_\_\_\_\_

### 1 YEAR LIMITED WARRANTY

Your Futrex Inc. equipment is warranted to be free from defects in material or workmanship for 1 year from date of delivery. Repair (or at our option, replacement) will therefore be made of any unit which proves to be defective during this period, provided the unit is returned properly packed, with all transportation charges prepaid, to Futrex Inc. at the address given below. Any repair approved hereunder will be made without charge to the owner for parts or labor. This limited warranty extends only to the original purchaser, is not transferable, and is limited to the purchase price of equipment. In no event will Futrex Inc. be liable for any incidental damages resulting from the equipment or any defect.

Claims under this limited warranty must be accompanied by the original sales ticket or shipping documents to establish date of purchase.

This limited warranty does not extend to units which have been subjected to misuse, abuse, neglect, accident or to units that have been used in violation of operating instructions. Equipment which, in our judgement, shows evidence of having been altered, modified or serviced without our authorization, or which has had its serial number altered or removed, will be ineligible for service under this limited warranty.

This warranty gives you specific legal rights, and you also may have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion or limitation may not apply to you. Return of the enclosed warranty registration is not a condition precedent to warranty coverage and performance.

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## SECTION 5

### **CLEANING AND MAINTAINING THE** **HealthGuard-15**

The HealthGuard-15 can be cleaned using soapy warm water. Alcohol swabs should be used to disinfect the cloth cuff and other surfaces that the arm may come into contact.

**In the event that harmful materials are used for cleaning, damaged equipment will not be serviced without charges regardless of the warranty period.**



## SECTION 6

### **SERVICE REQUIREMENTS**

For service within the warranty period or following; please contact Futrex Support and Service at 301-733-9368 or via e-mail [Service@Futrex.com](mailto:Service@Futrex.com). Futrex is the only authorized service representative for HealthGuard products.

**DO NOT** attempt to repair equipment without Futrex's expressed approval. This will result in a void of warranty.

Failure to follow the cleaning and maintaining requirements outlined in SECTION 5 may result in failure of the equipment and possible health hazards. If there are any problems with the equipment, please take the following steps.

1. Gather the instrument model, serial number, date of purchase, and a description of the problem.
2. Call Futrex Service at 301-733-9368 or e-mail the information to [Service@Futrex.com](mailto:Service@Futrex.com).
3. If necessary, Futrex will issue a Return Materials Authorization (RMA) number which you will need to include with your instrument if it requires to be sent back for service. More information will be provided to you about this process during your call to Futrex Service.

## SECTION 7

# ELECTRICAL SAFETY

Prior to the operation of the HealthGuard-15, make sure to check the following items:

- Is the battery that will be powering the HealthGuard-15 the same battery that is described in the Client-Supplied parts on Page D-20.
- Are the power connections properly made to the equipment?
- Is the battery properly charged?

The answer to all of these questions should be **YES**. Once you have checked for electrical safety, you may power on the instrument as instructed in the “Getting Started” section below.



Electrical Safety is important to maintaining the instrument and preventing fires. Use caution at all times you are using AC power, like when connecting a personal computer or a battery charger to AC power. **DO NOT** overload power strips, as this is a common cause of electrical fires.

## **SECTION 8**


### **ELECTROMAGNETIC TESTING AND SAFETY**

The HealthGuard-15 has been manufactured in compliance with current EMI/EMC requirements; however the use of this system in the presence of an electromagnetic field can cause temporary degradation of the HealthGuard-15. If this occurs, Futrex suggests a review of the environment in which the system is being used to identify possible sources of radiated emissions. These emissions can be from other electrical devices used within the same room or an adjacent room. Communication devices such as cellular phones can cause these emissions. The existence of TV, radio, or microwave transmission equipment located nearby can cause these emissions. If EMI/EMC causes disturbances, it may be necessary to relocate your system.

As is required by formal standards, Futrex has supplied four tables applicable to the HealthGuard-15 EMC Testing and Safety. These tables are available in the following 4 pages.

<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>		
The HealthGuard-15 is intended for use in the electromagnetic environment specified below. The customer or user of the HealthGuard-15 should assure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF Emissions CISPR 11	Group 1	The HealthGuard-15 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The HealthGuard-15 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Not Applicable	

<b>Guidance and Manufacturer's Declaration – Electromagnetic Immunity</b>			
The HealthGuard-15 is intended for use in the electromagnetic environment specified below. The customer or the user of the HealthGuard-15 should assure that it is used in such an environment.			
<b>Immunity Test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment – Guidance</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	$\pm 6$ kV Contact $\pm 8$ kV Air	$\pm 6$ kV Contact $\pm 8$ kV Air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	Not Applicable	The HealthGuard-15 does not use AC Power / Power Supply Lines during operation
Surge IEC 61000-4-5	$\pm 1$ kV line(s) to line(s) $\pm 2$ kV line(s) to earth	Not Applicable	The HealthGuard-15 does not use AC Power / Power Supply Lines during operation.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0,5 cycle $40\% U_T$ ( $60\%$ dip in $U_T$ ) for 5 cycles $70\% U_T$ ( $30\%$ dip in $U_T$ ) for 25 cycles $<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 s	Not Applicable	The HealthGuard-15 does not use AC Power / Power Supply Lines during operation.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3A/m	3A/m	The HealthGuard-15 was tested and performs normally within the specification limits.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The HealthGuard-15 is intended for use in the electromagnetic environment specified below. The customer or the user of the HealthGuard-15 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the HealthGuard-15, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended Separation Distance:</b></p> $d = 1.2\sqrt{P}$ <p><math>d = 1.2\sqrt{P}</math> 80 MHz to 800 MHz  <math>d = 2.3\sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters.</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1 At 80 MHz to 800 MHz, the higher frequency range applies			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, 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 HealthGuard-15 is used exceeds the applicable RF compliance level above, the HealthGuard-15 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HealthGuard-15.</p> <p><sup>b</sup> Over the frequency range of 150kHz to 80MHz, field strengths should be less than 3 V/m.</p>			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the HealthGuard-15			
The HealthGuard-15 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HealthGuard-15 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HealthGuard-15 as recommended 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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 absorption and reflection from structures, objects and people.			

## SECTION 9

# **ELECTROSTATIC DISCHARGE**

Electrostatic Discharge (ESD), commonly referred to as static shock, is a common naturally occurring phenomenon. ESD is most common in conditions with low humidity, which can be caused by heating or air conditioning. In low humidity conditions, electrical charges naturally build up on individuals and can create static shocks. An ESD condition occurs when a person with an electrical energy build-up comes in contact with objects such as metal doorknobs, file cabinets, other people, or electronic equipment. The static shock is a discharge of the electrical energy build-up from a charged person to a lesser or non-charged individual or object.

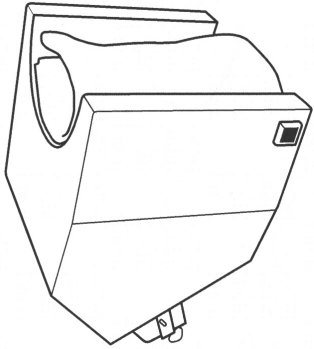
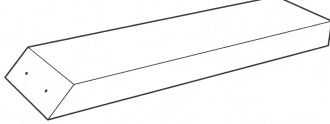
ESD can also build up from actions such as wearing socks on carpet. The HealthGuard-15 takes weight measurements and some clients may prefer to remove their shoes. It is important to note that the level of electrical energy discharged from a user of the HealthGuard-15 to the instrument can be significant enough to cause damage to the equipment. The following precautions can help to reduce ESD:


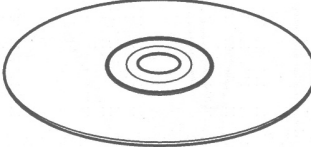

- Anti-Static Spray on Carpets & Linoleum
- Anti-Static Mats
- Grounding between the HealthGuard system and the table

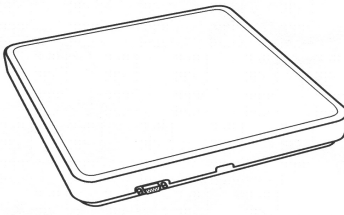
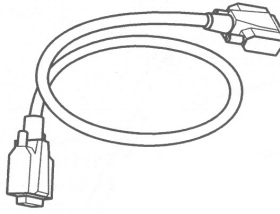


## SECTION 10

### APPEARANCE AND PART NAMES

	
Cuff Housing	Arm Rest

		
Optical Standard	Software CD	Communications Cable

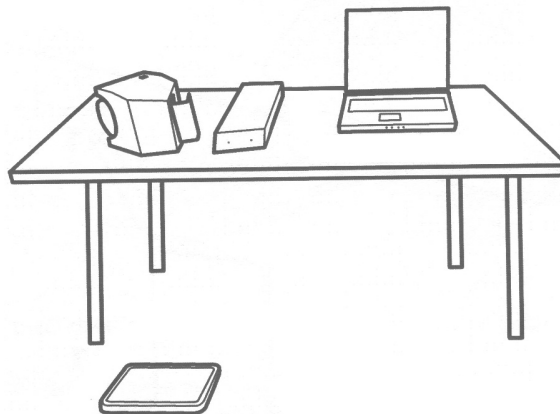
	
Health-o-Meter Medical Scale	Scale Cable

The HealthGuard-15 should include all of the components identified above.

## SECTION 11

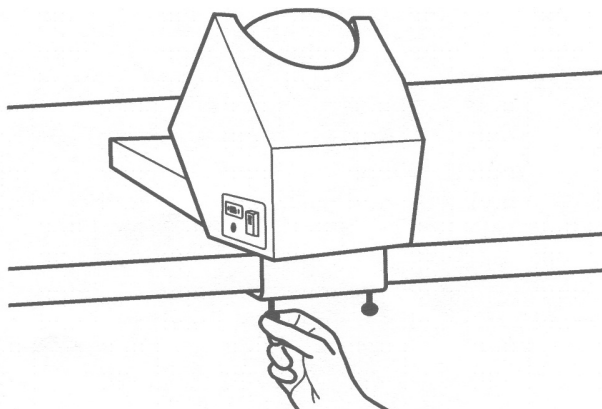
# ASSEMBLING AND SETTING UP YOUR HealthGuard-15

**Step 1** – Provide enough room to place the Scale, Cuff Housing, Arm Rest, and your computer as shown in the illustration below.



**Figure 1**

**Step 2** - Attach the Cuff Housing to the table top using the supplied thumbscrews as shown below. Then attach the Arm Rest. The arm rest will be held in place by the Velcro strips that are attached to the Arm Rest and to the Cuff Housing



**Figure 2**

### **Client Supplied Parts – Minimum Requirements**

#### **Personal Computer**

- PC Running Windows XP or higher version
- Pentium Class Processor
- One Available Communications Port
- 1 GB RAM
- 500MB Available Hardware Space
- 1024 x 768 Resolution

#### **Battery**

- Talentcell 6000 mAh Li-Ion Battery Pack (Battery Charger supplied with Battery)

### **PRECAUTION**

The HealthGuard-15 is designed to be powered and operated only using the Talentcell battery pack described above. Do not attempt to use an alternative power supply. Using a power supply other than the battery pack above will void your warranty.

### **Step 3: Installing the HealthGuard-15 Software**

Insert the Software CD into your CD drive. The CD will start automatically, and you will see the following screen:

Note: If the CD does not start automatically, view the contents of the CD and double click the setup.exe file.



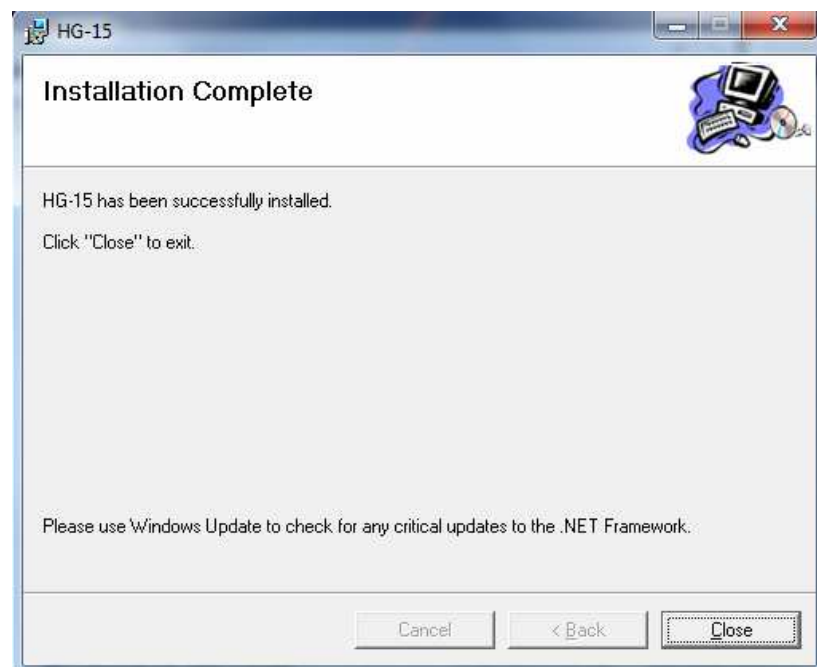
**Figure 3**

After selecting the 'Next' button displayed in the lower right hand corner of the installer the installation will begin. You will shortly see the dialog box below:



**Figure 4**

Select 'OK' to continue. When instructed, press enter and the driver installation will be completed. After this set you will see the following message:

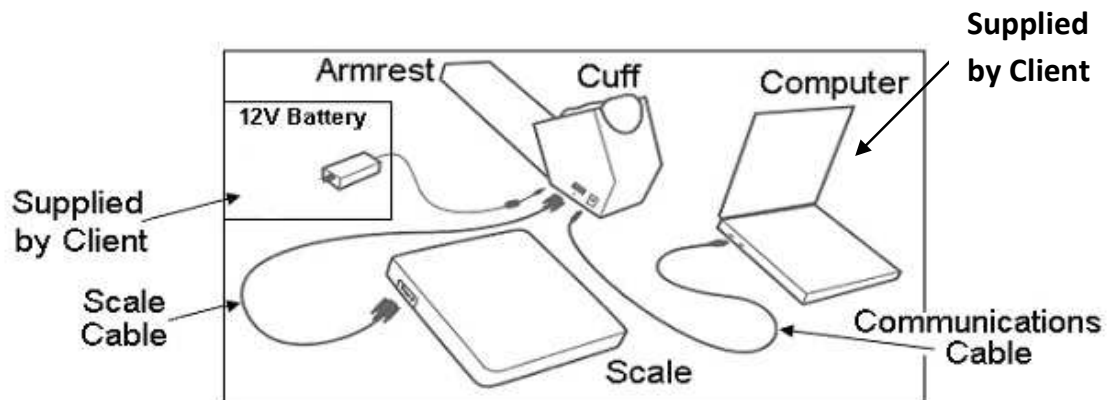


**Figure 5**

After the screen in **Figure 5** has appeared there will be a HG-15 icon on the desktop. Select this icon to open the installed software.

**The cable connections must be done in the order explained below:**

**STEP 4** - The HG-15 can now be connected to your PC.



**Figure 6**

1. Scale Cable - Connect the scale cable to the Scale and then to the Cuff Housing.
2. PC Connection – Plug the communications cable into an available input on the computer. Then plug the connector on the opposite end of the communications cable into the Cuff Housing.
3. Power Connection - Connect a charged battery pack (as specified on Page D-19) to the connector located on Cuff Housing.

Note: The HG-15 may take 2 to 5 minutes to warm up before it is recognized by your PC.

## SECTION 12

# USING THE HEALTHGUARD-15

### Software Setup Options

The HealthGuard software is equipped with a number of settings the owner can personalize to their preferences. These are set in the “Kiosk Administration Screen”. To enter the Kiosk Administration Screen, you must first touch or click on the “Click to Begin” opening screen. It will then ask for a language, select your language. Next, set Age to “999”. This is the “Username” code to access the Administrator Settings. It will then ask for the Kiosk Password. By default this password is “123ADMIN”. Enter this password in and you will now be taken to the Kiosk Administration Screen. Here you can adjust Kiosk Administration Settings such as Online Access, Weight Scale use, Measurement Units, and the Default Language used by the Kiosk. The included screenshots show the program flow:

Enter Age

Please enter your Age

Enter “Age” as 999 and select Ok in the bottom right hand corner. This will take you to the password screen shown in the next figure.

999|

7 8 9

4 5 6

1 2 3

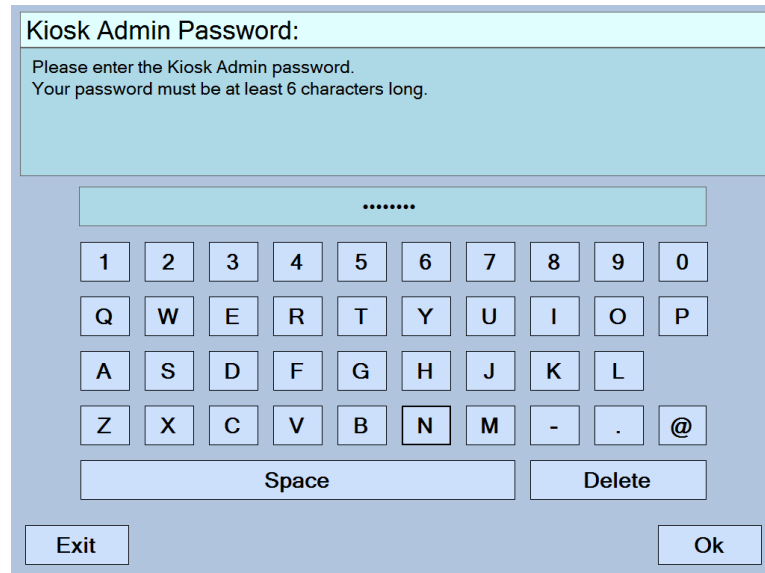
0

Delete

Exit Ok

**Figure 7**

The next screen that will appear after entering 999 for age is the Kiosk Admin Password screen. The password to access the kiosk administrator screen is **123ADMIN**. Enter this password using the on-screen keyboard and select “Ok” in the bottom right corner.



**Kiosk Admin Password:**

Please enter the Kiosk Admin password.  
Your password must be at least 6 characters long.

.....

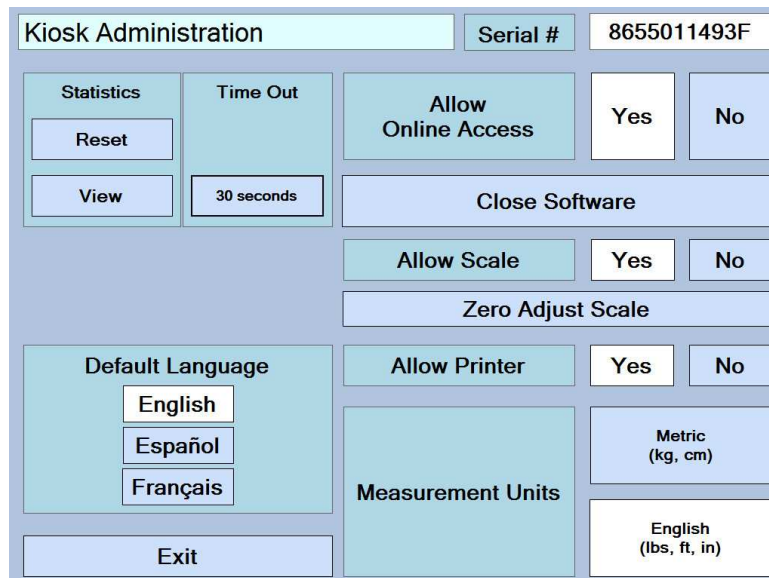
1	2	3	4	5	6	7	8	9	0
Q	W	E	R	T	Y	U	I	O	P
A	S	D	F	G	H	J	K	L	
Z	X	C	V	B	N	M	-	.	@

Space Delete

Exit Ok

**Figure 8**

You will now see the Kiosk Administration Screen, as shown in the figure below. There are a number of settings that can be adjusted at this screen. These settings adjustments are explained over the next few pages of this document.



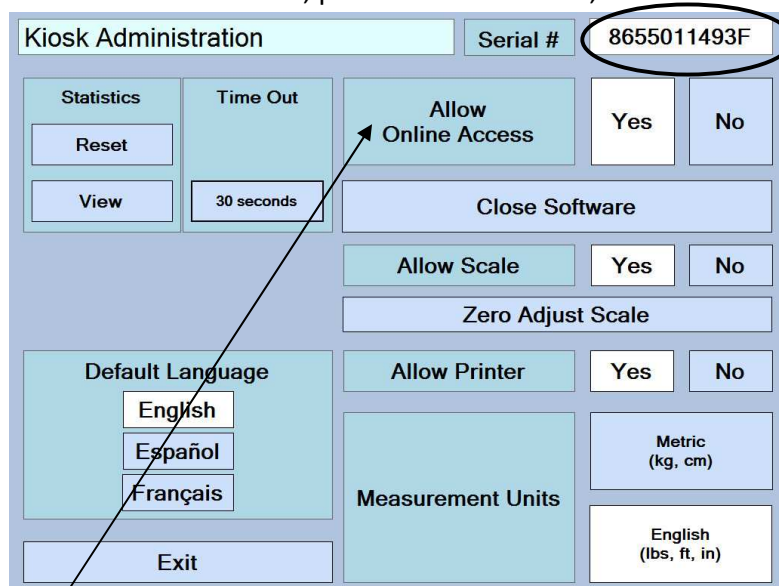
**Kiosk Administration** Serial # 8655011493F

<b>Statistics</b> Reset View	<b>Time Out</b> 30 seconds	<b>Allow Online Access</b> Yes No
<b>Close Software</b>		<b>Allow Scale</b> Yes No
<b>Default Language</b> English Español Français		<b>Zero Adjust Scale</b>
<b>Exit</b>		<b>Allow Printer</b> Yes No
<b>Measurement Units</b>		Metric (kg, cm) English (lbs, ft, in)

**Figure 9**

### **Ensure Serial Number Is Correct**

After entering the Kiosk Administration Password it will ask for the Kiosk's Serial Number. If this hasn't already been entered by the manufacturer, you may enter this by looking for the 11-digit serial number sticker on any one of the parts of the Kiosk. If this serial number has already been entered, you must at least look for it in the Kiosk Administration Screen. It will be located at the top right of the screen. If for some reason this serial number is incorrect, please contact Futrex, Inc.



The screenshot shows the 'Kiosk Administration' screen. At the top right, the 'Serial #' field contains the value '8655011493F', which is circled. Below this, there are several configuration options: 'Allow Online Access' with 'Yes' and 'No' buttons, 'Close Software', 'Allow Scale' with 'Yes' and 'No' buttons, 'Zero Adjust Scale', 'Allow Printer' with 'Yes' and 'No' buttons, 'Measurement Units' with 'Metric (kg, cm)' and 'English (lbs, ft, in)' buttons, and a 'Default Language' section with 'English', 'Español', and 'Français' buttons. There are also 'Statistics' (Reset, View), 'Time Out' (30 seconds), and an 'Exit' button.

**Figure 10**

### **Online Access**

By default, the HG-15 Kiosk will have Online Access turned off. If you wish to use Online Access, you must:

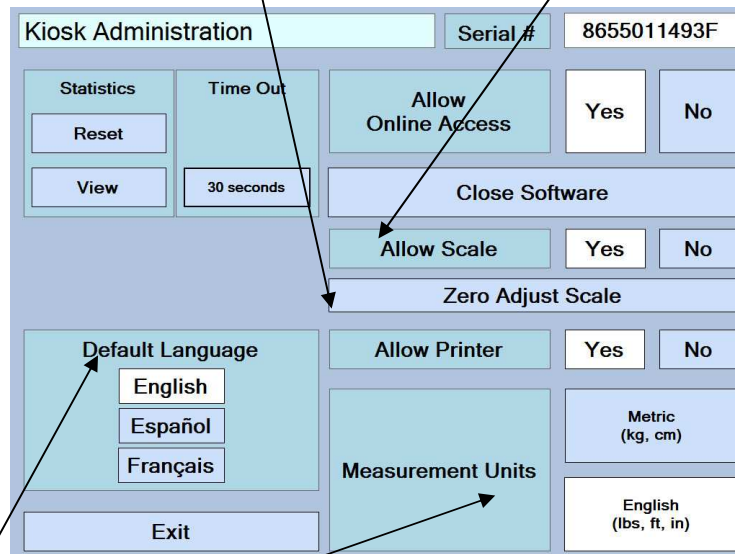
1. Connect the computer that is running the software to the internet.
2. Access the Kiosk Administration Screen.
3. Allow Online Access via Kiosk Options by selecting "Yes"

Make sure to test the Online Access by taking a measurement and selecting to email the results. This function has been added to allow the person being test to email the test results to their home or doctor.



### **Weight Scale**

The Weight Scale can be turned off if desired by changing the “Allow Scale” option. Before operation of the weight scale, it is recommended that the Kiosk Administrator press the “Zero Adjust Scale” button so that it will measure a correct weight after installation. Please ensure there is nothing on the scale before pressing the “Zero Adjust Scale” button.



**Figure 11**

### **Measurement Units**

The Kiosk supports English and Metric units, only the Kiosk administrator can select this. This setting is used for all measurements by the Kiosk.

### **Default Language**

The HealthGuard software allows you to select the default language with which the “Touch Here to Begin” screen will appear. The customer will then select the language they desire on the following page. After the measurement the software will revert back to the default language. The software currently supports English, Spanish, and French.

## Time Out

The HealthGuard software has a “Time Out” feature that reverts the software back to the home screen if a client has not changed from another screen within the software for a set period of time. This prevents clients from inadvertently leaving their results pages on the computer’s screen so others could see them. In addition it readies the software for the next person’s reading. The kiosk administrator can set this length of time by clicking the “Time Out” setting.

The screenshot shows the 'Kiosk Administration' interface. At the top, there is a header bar with 'Kiosk Administration' on the left and 'Serial # 8655011493F' on the right. Below this, the interface is divided into several sections. On the left, there is a 'Statistics' section with 'Reset' and 'View' buttons. In the center, there is a 'Time Out' section with a dropdown menu currently set to '30 seconds'. On the right, there are several toggle switches: 'Allow Online Access' (Yes/No), 'Allow Scale' (Yes/No), 'Zero Adjust Scale' (a button), 'Allow Printer' (Yes/No), and 'Measurement Units' (Metric (kg, cm) and English (lbs, ft, in)). At the bottom left, there is a 'Default Language' section with buttons for 'English', 'Español', and 'Français', and an 'Exit' button at the very bottom. Three arrows originate from the text above: one points to the 'Time Out' section, another points to the 'Statistics' section, and a third points to the 'Close Software' button (which is located below the 'Allow Online Access' toggle).

**Figure 12**

## Statistics

The HG-865 Kiosk records every measurement anonymously and safely with 128-bit standard government encryption to be used by the Kiosk Administrator. These records are shown statistically within the Kiosk Statistics screen. These statistics can also be reset when needed. An example of the Statistics page is shown in the first figure on the next page of this manual.

## Close Software

The final option in the Kiosk Administrator page is to close the HealthGuard software. This is done by clicking the “Close Software” button. You will need to click on the HealthGuard icon on the desktop to open the software again.

## Kiosk Statistics

Type	Value	Type	Male	Female	Type	Male	Female	Type	Male	Female
▶ Complete Scans	8	Weight (lbs)			Heart Rate (bpm)			Body Fat (%)		
Weight Scans	7	Range	158 - 487	---	Range	41 - 106	---	Range	4 - 40	---
Blood Pressure Scans	5	Median	416	---	Median	82	---	Median	20	---
Total Scans	20	Ratings			Ratings			Age (years)		
Male %	100.0	EXCELLENT	1	0	Ok	4	0	Range	25	---
Female %	0.0	GOOD	1	0	Caution	5	0	Median	---	---
Male Users	9	FAIR	2	0	HIGH	4	0			
Female Users	0	NEEDS IMPROVEMENT	11	0	VERY HIGH	0	0			
Total Users	9	RISKY	0	0	Blood Pressure (mmHg)					
Initialized On:	9/19/2012	Body Mass Index			Systolic					
Reset On:	9/19/2012	Range	23 - 72	---	Range	90 - 129	---			
		Median	61	---	Median	107	---			
		Ratings			Diastolic					
		UNDERWEIGHT	0	0	Range	62 - 95	---			
		NORMAL	2	0	Median	83	---			
		OVERWEIGHT	2	0	Ratings					
		OBESE	11	0	Normal	4	0			
		Basal Metabolic Rate (cals)			Pre-Hypertension	5	0			
		Range	1558 - 2517	---	Hypertension I	4	0			
		Median	2354	---	Hypertension II	0	0			

Exit

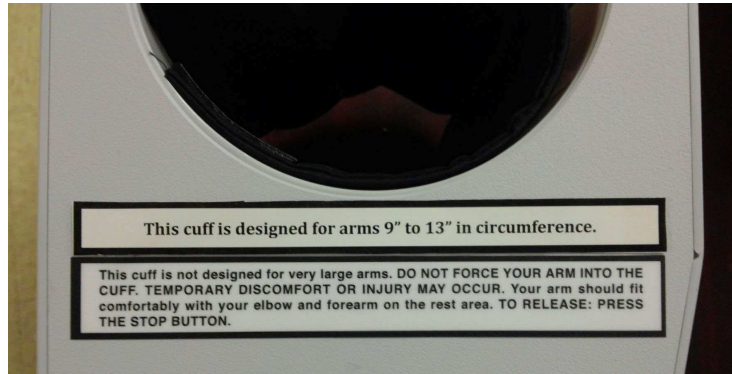
**Figure 13**

## SECTION 13

### PERFORMING A MEASUREMENT

#### PRECAUTION

The HealthGuard-15 is only to be used for screening purposes, and is not intended for diagnosis.



**NOTE: As seen in the labeled cuff above, the cuff is designed for arms 9" to 13" in circumference.**

The display on the computer's monitor allows you, without any other assistance, to perform a self measurement.

To start a measurement click or touch anywhere on the first computer screen:



**Figure 14**

You will then be prompted to enter the following data:

Select Your Language

Hello!

English

¡Hola!

Español

Bonjour!

Français

First, you will select a language (English, Spanish, & French available) and hit the “Next” button in the bottom right to continue.

Exit

Next

**Figure 15**

Enter Age

Please enter your Age

|

7 8 9

4 5 6

1 2 3

0


Delete

Exit


Next, you will be prompted “Please enter your Age”. When an age is entered, the “Next” button will appear in the same position in the bottom right-hand corner.

**Figure 16**

Select Your Gender



Male



Female

The software will next prompt you to select your gender. This can be done by clicking the Male / Female text or clicking on either image. When a selection is made the “Next” button will appear in the bottom right hand corner.

Exit

**Figure 17**

Figure 18 (below) allows you to select from three measurement types. All three are explained at length as seen below. Examples of all three measurement types are shown throughout the following pages. When a measurement type is selected, the “Next” button will appear in the bottom right hand corner.

Select Measurement Type:

Please select the type of measurements you wish to take.

Complete Analysis	<ul style="list-style-type: none"> <li>Measure your Weight and calculate your Body Mass Index and Basal Metabolic Rate.</li> <li>Measure your Body Fat Percentage.</li> <li>Measure your Blood Pressure and Heart Rate.</li> <li>Show Ratings for your Weight and Blood Pressure.</li> </ul>
Blood Pressure Analysis	<ul style="list-style-type: none"> <li>Measure just your Blood Pressure and Heart Rate, and show your Blood Pressure Ratings.</li> </ul>
Weight Analysis	<ul style="list-style-type: none"> <li>Measure just your Weight and calculate your Body Mass Index, Basal Metabolic Rate, and show Weight Ratings.</li> </ul>

Exit

**Figure 18**

## **MEASUREMENT TYPE 1 – COMPLETE ANALYSIS**

The “Complete Analysis” measurement type performs the weight, percent body fat, blood pressure, and heart rate measurements in a single test. After selecting “Complete Analysis” on the previous page, follow the steps below:

Enter Height:

Please enter your height in feet and inches

You will be prompted to enter their height in feet and inches. When a height has been entered, the “Next” button will appear in the bottom right hand corner.

7 8 9

4 5 6

1 2 3

0

Delete


Exit

**Figure 19**

Figure 20 (below) is the screen that appears prior to the weight measurement. When you are ready, simply press the “Begin” button and the scale will take a weight measurement.).

Weight Analysis

- Please step onto the scale.
- Breathe normally, avoid talking, and remain still.
- Press BEGIN Button to begin taking measurements.

 If you are unable to stand on the scale, please press here to enter your weight.

ABORT

BEGIN

**Figure 20**

Weight Analysis

- Measuring your weight now.
- Breathe normally, avoid talking, and remain still.

Did You Know?

Chronic alcohol consumption can lead to high blood pressure.

This screen is shown when the weight measurement is being taken.  
The software will automatically go to the next screen (Figure 9, below) when the weight has been obtained.

**Figure 21**

Figure 22 (below) is the screen shown prior to the blood pressure and body fat measurements being taken. These measurements are taken simultaneously. Place the left arm into the cuff so that the bottom edge of the cuff is about one inch above the elbow. press the “Begin” button in the bottom right hand corner. This will begin the blood pressure and body fat measurements.

Blood Pressure Analysis

- Make sure your bare left arm is inserted into the cuff.
- Keep your left palm down and relaxed.
- Breathe normally, avoid talking, and remain still.
- Press BEGIN Button to begin taking measurements.

Weight295 lbs

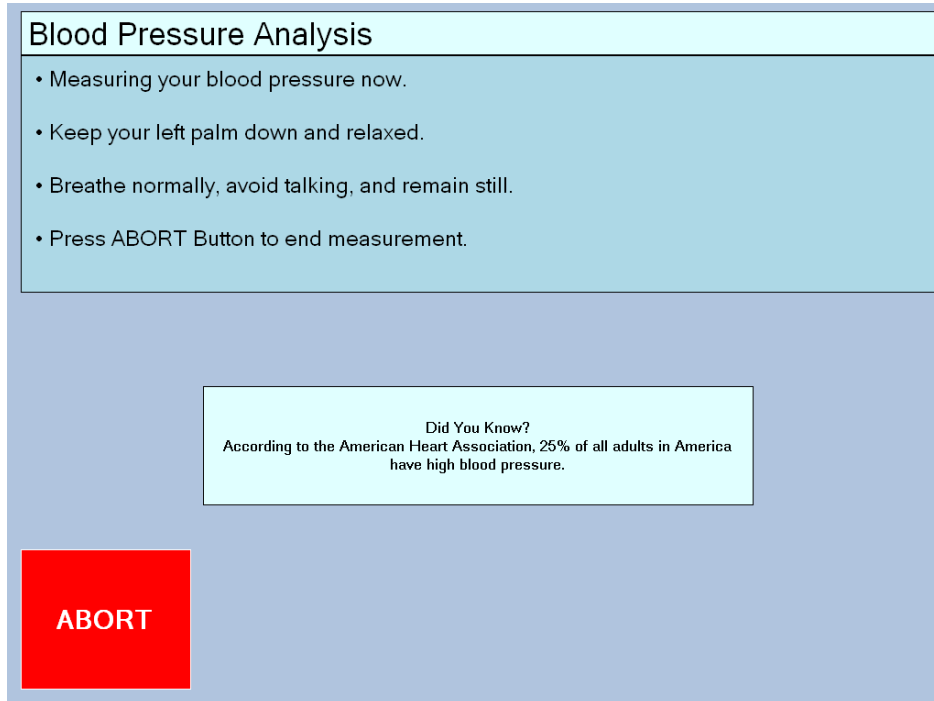
ABORT

BEGIN

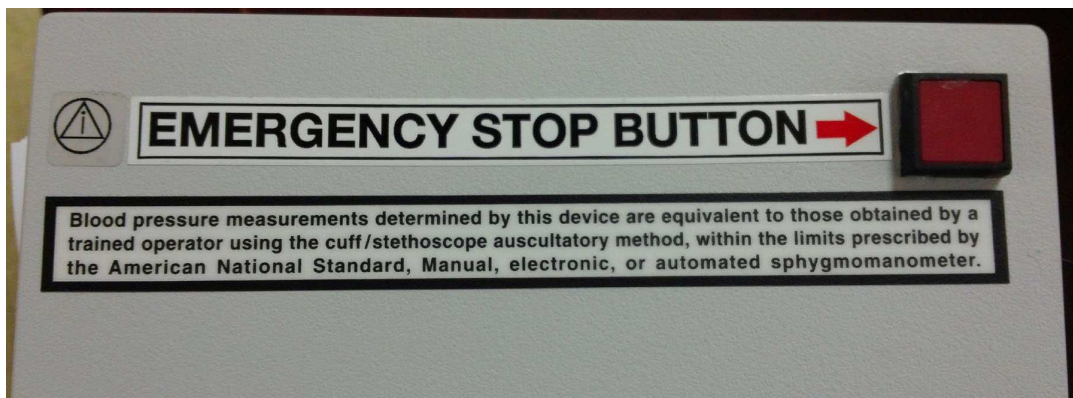
**Figure 22**



Figure 23 (below) is shown while the measurements are being taken. Scrolling facts (see middle screen, Figure 23) are provided for you during the measurement. The measurement can be aborted at any time by pressing the ABORT button in the bottom left hand corner OR by pressing the EMERGENCY STOP button on the side of the blood pressure cuff (see Figure 24, below).



**Figure 23**



**Figure 24**

As soon as the measurements are completed a results screen will appear that provides an evaluation of the information that was gathered from the measurements. There are three results pages, as seen below.

Weight Analysis Results		
Gender	Male	Ratings
Age	38	
Height	5' 6"	
Weight	218 lbs	NEEDS IMPROVEMENT
Body Mass Index	35.2	OBESE
Basal Metabolic Rate	1,838.4 calories	
Clear Results		<p>Weight Analysis Results Page shows first. You can advance to the next results page by clicking "Next Page" in the bottom right hand corner.</p>

**Figure 25**

Figure 26 (below) shows the results of the blood pressure measurement as seen here.

Blood Pressure Analysis Results		
Blood Pressure		Ratings
<p>Systolic 129</p> <p>Diastolic 81</p>	<p>Systolic</p> <p>129 mmHg</p>	
	<p>Diastolic</p> <p>81 mmHg</p>	<p>American Heart Association Rating</p> <p>Caution</p>
	<p>Heart Rate</p> <p>71 bpm</p>	<p>National Institutes of Health Rating</p> <p>Pre-Hypertension</p>
<p><b>RECOMMENDATION:</b> Change to a healthier lifestyle to help lower your blood pressure. This recommendation is the result of a Systolic value between 120 AND 139 mmHg OR a Diastolic value between 80-89 mmHg.</p>		
Clear Results	Previous Page	Next Page

**Figure 26**

The third and final results page is the Body Composition Results. An example of this page can be seen in Figure 27 (below). The results pages will stay visible unless it remains on the same page for sixty seconds. If this happens the software will automatically return to the “Click Here to Begin” screen seen in Figure 14.

Body Composition Results		
Body Fat	32.9%	Body fat provides a reservoir of energy for the body. High percent of body fat significantly increases the risk of diabetes, heart attacks, strokes, and certain forms of cancer.
Fat Mass	71.9 lbs	The total weight of all the fat in your body is called the Fat Mass. In an equation: Fat Mass = (total body weight X percent body fat) / 100
Lean Mass	146.7 lbs	The total weight of everything in your body except fat, including your bones, organs, and muscles. In an equation: Lean Mass = total body weight - fat mass
<p>Always consult your physician before changing your diet, or beginning a new exercise program.</p>		
<input type="button" value="Clear Results"/>		<input type="button" value="Previous Page"/>

**Figure 27**

If you select the “Clear Results” button seen in the bottom left corner of the results pages in Figures 25, 26, & 27 you will be prompted if you would like to email or save your results. These screens can be seen in Figures 28 & 29. If you select to email or save their results an on-screen keyboard will be provided to enter your email address as well as prompt for a unique username and password if the results are to be saved. Once these have either been completed or declined (by pressing “No”) the software will return to the “Click Here to Begin” screen seen in Figure 14.

Email Your Results
Would you like to email your results?
<div>Yes</div> <div>No</div>

**Figure 28**

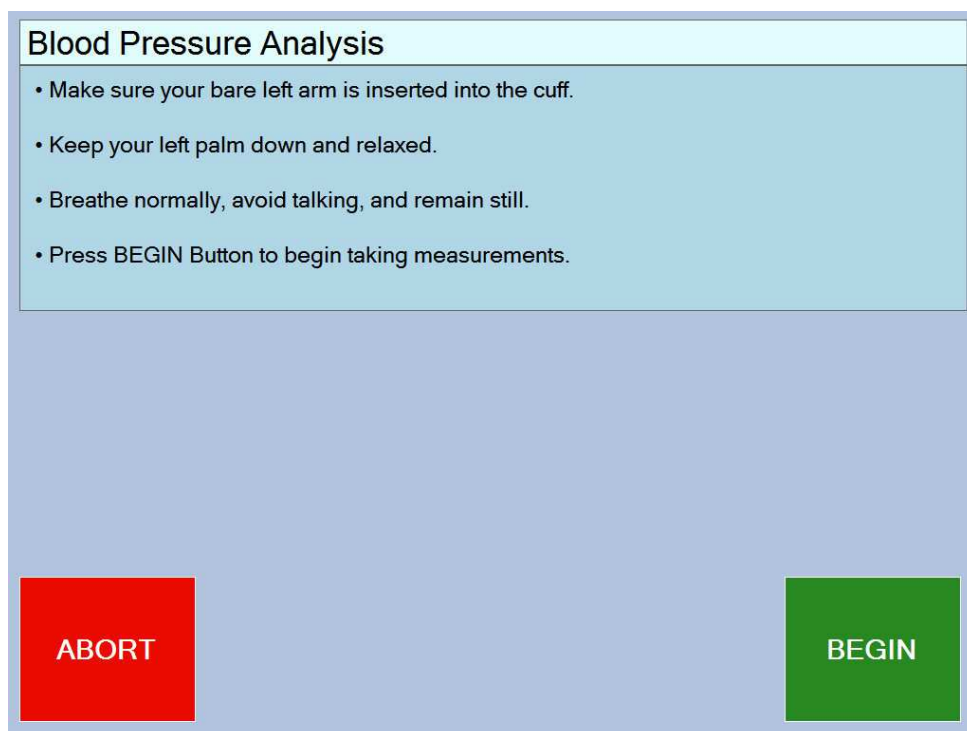
Save Results
Would you like to save these results and view your measurement history?
<div>Yes</div> <div>No</div>

**Figure 29**

## **MEASUREMENT TYPE 2 – BLOOD PRESSURE ANALYSIS ONLY**

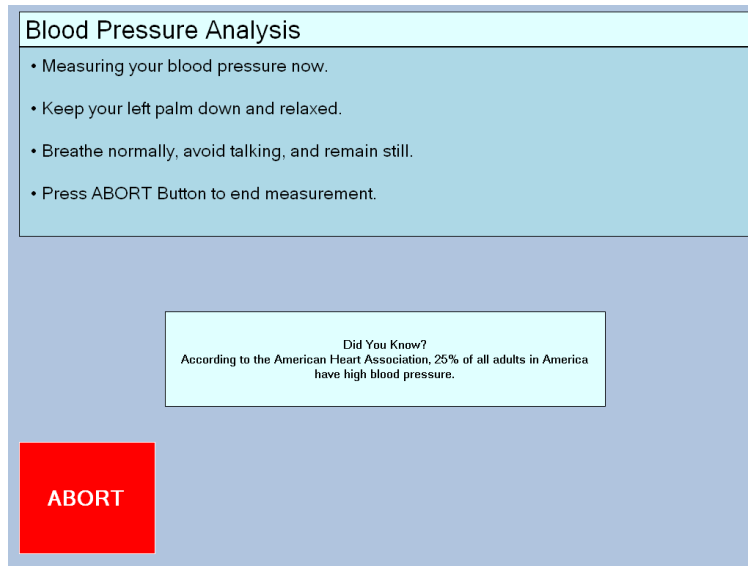
If the second Measurement Type, Blood Pressure Analysis, is selected the weight measurement will not be performed and you will not be asked to enter your height. The following outlines the steps after selecting blood pressure analysis as the measurement type.

Figure 30 (below) is the screen shown prior to the blood pressure measurement being taken, after selecting the Blood Pressure Analysis Measurement type. Place the left arm into the cuff so that the bottom edge of the cuff is about one inch above the elbow. Press the “Begin” button in the bottom right hand corner. This will begin the blood pressure measurement.

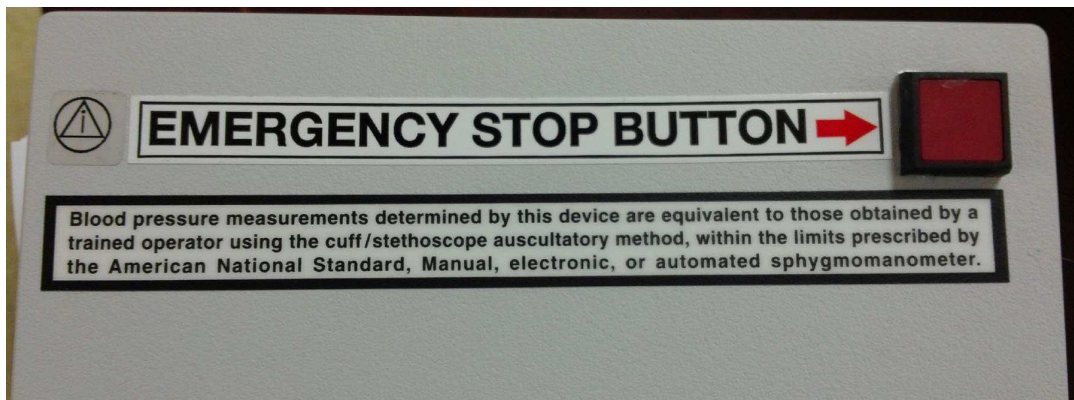


**Figure 30**

Figure 31 (below) is shown while the measurements are being taken. Scrolling facts (see middle screen, Figure 31) are provided for you during the measurement. The measurement can be aborted at any time by pressing the ABORT button in the bottom left hand corner OR by pressing the EMERGENCY STOP button on the side of the blood pressure cuff (see Figure 32, below).

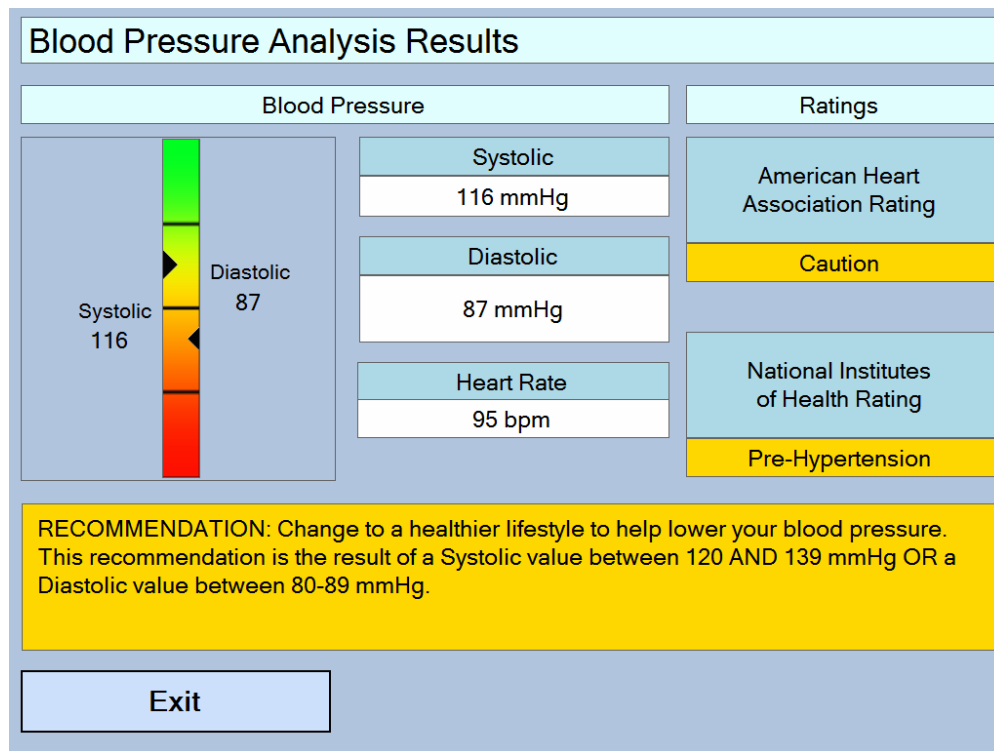


**Figure 31**



**Figure 32**

As soon as the measurement is completed a results screen will appear that provides an evaluation of the information that was gathered from the blood pressure measurement. Only the Blood Pressure Analysis Results page, seen below in Figure 33, will be shown for the Blood Pressure only measurement type.



**Figure 33**

If you select the "Exit" button seen in the bottom left corner of the blood pressure result page in Figures 33 (above) you will be prompted if you would like to email or save your results. These screens can be seen in Figures 34 & 35. If you select to email or save their results an on-screen keyboard will be provided to enter your email address as well as prompt for a unique username and password if the results are to be saved. Once these have either been completed or declined (by pressing "No") the software will return to the "Click Here to Begin" screen seen in Figure 14.

Email Your Results

Would you like to email your results?

Yes

No

**Figure 34**

Save Results

Would you like to save these results and view your measurement history?

Yes

No

**Figure 35**



### **MEASUREMENT TYPE 3 – WEIGHT ANALYSIS ONLY**

If the third measurement type, Weight Analysis, is selected the software will only perform a weight measurement and there is no need for the user to insert their arm into the blood pressure cuff. The following outlines the steps after selecting the “Weight Analysis” measurement type.

**Enter Height:**

Please enter your height in feet and inches

You will be prompted to enter their height in feet and inches. When a height has been entered, the “Next” button will appear in the bottom right hand corner.

ft

7 8 9

4 5 6

1 2 3

0

Delete


Exit

**Figure 36**

Figure 37 (below) is the screen that appears prior to the weight measurement. When you are ready, simply press the “Begin” button and the scale will take a weight measurement.

**Weight Analysis**

- Please step onto the scale.
- Breathe normally, avoid talking, and remain still.
- Press BEGIN Button to begin taking measurements.

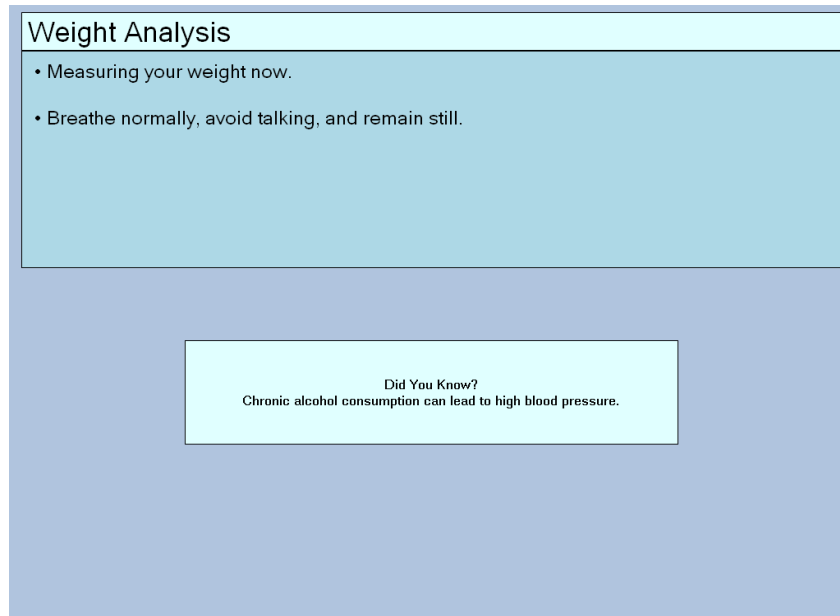
 If you are unable to stand on the scale, please press here to enter your weight.

ABORT

BEGIN

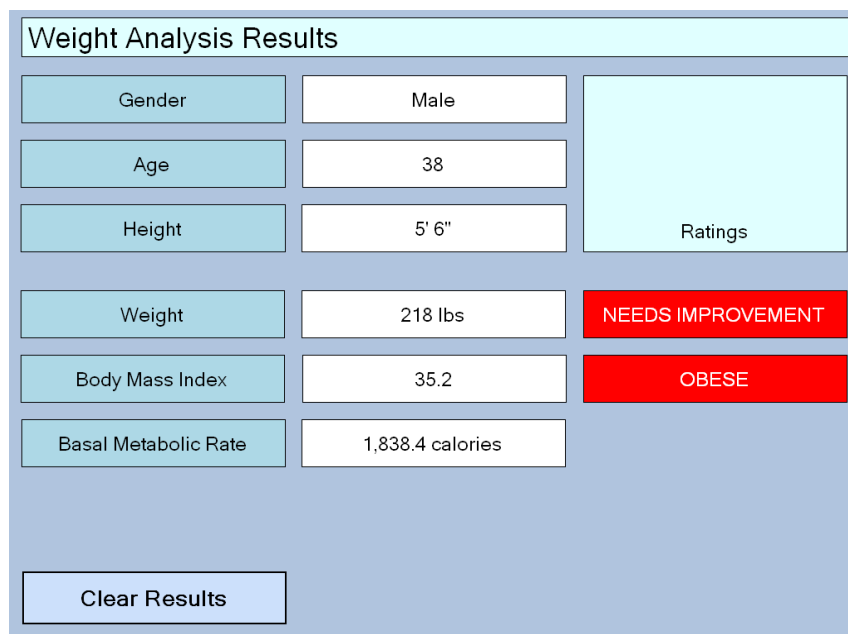
**Figure 37**

After pressing begin, remain still on the scale. The screen shown below will appear during the weight measurement. Once the scale obtains a weight, the results page (below, Figure 39) will show.



The screen displays a title bar 'Weight Analysis' in a light blue box. Below it, a larger light blue box contains two bullet points: '• Measuring your weight now.' and '• Breathe normally, avoid talking, and remain still.' In the center of the screen, there is a white box with a black border containing the text 'Did You Know? Chronic alcohol consumption can lead to high blood pressure.'

**Figure 38**



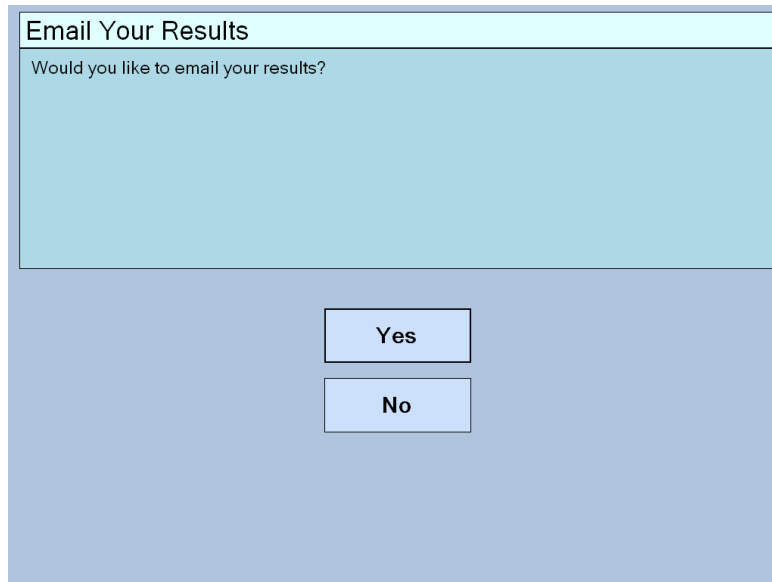
The screen displays a title bar 'Weight Analysis Results' in a light blue box. Below it, there is a table of personal data and a ratings section.

Gender	Male	Ratings
Age	38	
Height	5' 6"	
Weight	218 lbs	NEEDS IMPROVEMENT
Body Mass Index	35.2	OBESE
Basal Metabolic Rate	1,838.4 calories	

At the bottom left, there is a button labeled 'Clear Results'.

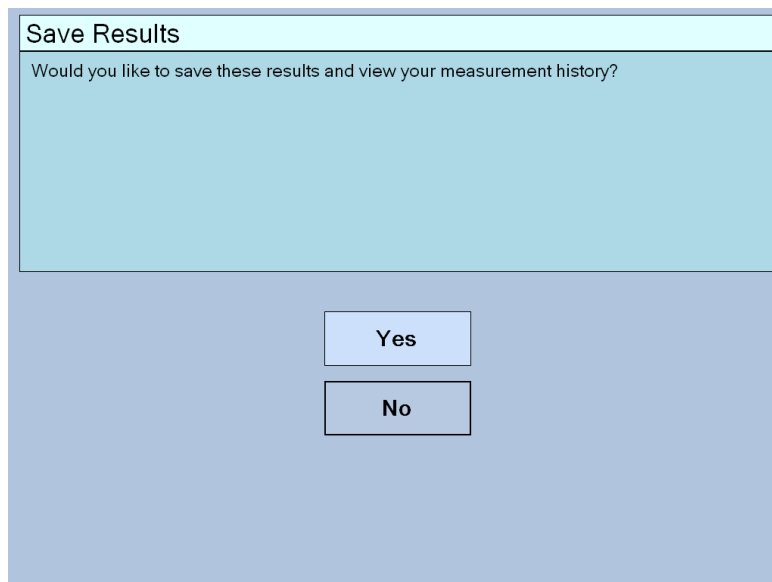
**Figure 39**

If you select the “Clear Results” button seen in the bottom left corner of the results page in Figure 39 you will be prompted if you would like to email or save your results. These screens can be seen in Figures 40 & 41. If you select to email or save their results an on-screen keyboard will be provided to enter your email address as well as prompt for a unique username and password if the results are to saved. Once these have either been completed or declined (by pressing “No”) the software will return to the “Click Here to Begin” screen seen in Figure 14.



The screenshot shows a dialog box titled "Email Your Results" with a light blue header. Below the header, the text "Would you like to email your results?" is displayed. At the bottom of the dialog, there are two buttons: "Yes" and "No".

**Figure 40**



The screenshot shows a dialog box titled "Save Results" with a light blue header. Below the header, the text "Would you like to save these results and view your measurement history?" is displayed. At the bottom of the dialog, there are two buttons: "Yes" and "No".

**Figure 41**

## **SAVE RESULTS & EMAIL FUNCTIONS – EXPANDED**

The “Save Results” and “Email Results” functions have been mentioned throughout Section 12 (Performing a Measurement) section of this manual. This section will expand on the explanation of their functionality.

If Online Access is enabled (see Figure 10, Page D-20 for more information) the software will ask the client if they would like to email their results (See Figure 40). If the client selects “Yes” the following screen will appear:

Email Address:

Please enter your email address.

[REDACTED]@MYACTV.NET|

1 2 3 4 5 6 7 8 9 0

Q W E R T Y U I O P

A S D F G H J K L

Z X C V B N M - . @

Delete

Exit Ok

**Figure 42**

Once the client has entered their email address, if they click “Ok” in the bottom right-hand corner a copy of their results will be sent to their email. The client will next be asked if they would like to save their results (see Figure 41). If the client elects to save their results they will be asked to enter a User Password of a minimum of six characters. They will use this password to access their results on all future readings. This allows the user to view readings over time. Figure 43 below shows the password entry screen. Figure 44 is an example of saved results that can be viewed over time. The software will save and track results for Blood Pressure, Body Fat Percentage, Weight, Basal Metabolic Rate, Body Mass Index, and Heart Rate. Once the client is done viewing their saved results they will select “Exit” and the software will return to the main screen.

User Password:

Please enter your user password.  
It must contain at least 6 characters.

.....|

1	2	3	4	5	6	7	8	9	0
Q	W	E	R	T	Y	U	I	O	P
A	S	D	F	G	H	J	K	L	
Z	X	C	V	B	N	M	-	.	

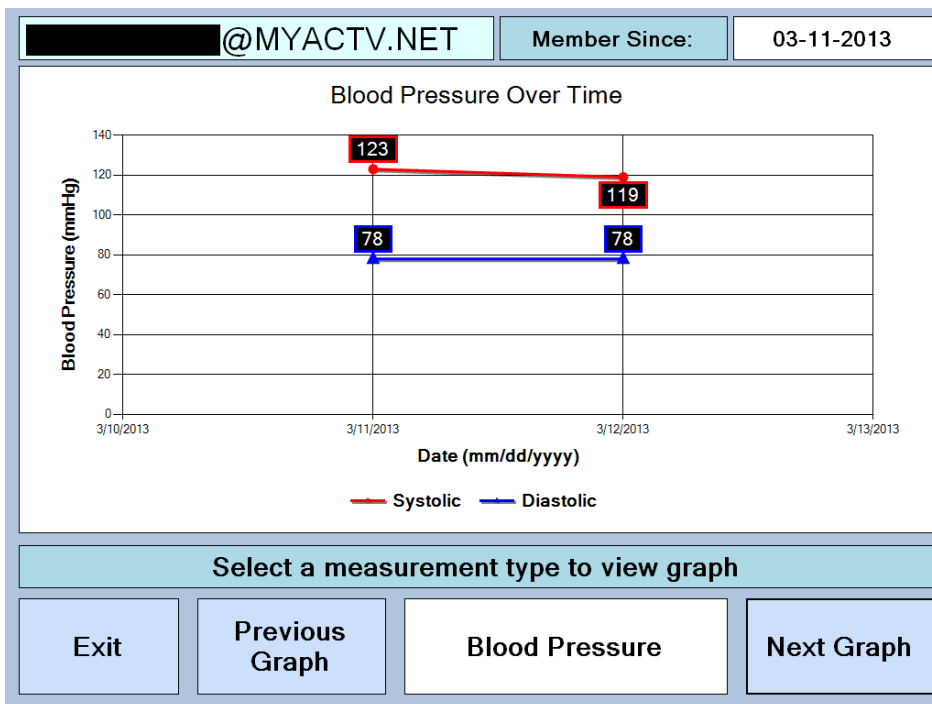
Space

Delete

Exit

Ok

**Figure 43**



**Figure 44**

## SECTION 14

# TROUBLESHOOTING

Problem	Probable Cause(s)	Corrective Measures
Display Shows HG-15 NOT CONNECTED	a) Bad Connection between the HG-15 and the communications port  b) No Power to the HG-15    c) HG-15 is not warmed up	a) Ensure that the Communications Cable is connected to both the PC and the HG-15  b) Ensure that the battery pack is charged and that is fully plugged into the power connector on the HealthGuard-15.  c) The HG-15 takes 1-2 minutes to warm up (sometimes a bit longer). Wait for a minute or two, and then try again.
Poor Repeatability on Blood Pressure Measurements	Subject moved during the evaluation.	Repeat the evaluation, and be sure to remain still and quiet during the evaluation.
Unusually high blood pressure readings	Subject has not relaxed enough to be at normal resting blood pressure.	Have the subject sit quietly for 2-3 minutes, and then repeat the test.
Error measuring Body Fat. Display is ---	Sleeve was in the way of the body fat sensor.	Ensure that the subject has his or her sleeve rolled up. The skin must be bare for reading.
Poor Repeatability on Body Fat Measurements	a) Subject moved during the evaluation  b) Sleeve was in the way of the body fat sensor.	a) Repeat the evaluation, and be sure to remain still and quiet during the evaluation.  b) Ensure that the subject has his or her sleeve rolled up. The skin must be bare for a body fat reading.
Error taking Weight Measurement when stepping on scale	Bad connection between the scale and the HG-15  Moving your body when standing on scale	Ensure that the Serial Cable is connected to both the scale and the HG-15  Stand still, no talking
HG-15 becomes unresponsive after using emergency stop button	HG-15 lost communication with PC	Wait 1 – 5 minutes to allow the instrument to regain communications with the PC as the system resets.

## SECTION 15

# **FCC STATEMENT**

Note:

POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for U.S.A. only)

This product has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. The product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the product and the receiver.
- Connect the product into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for Canada only)

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the interference-causing equipment standard entitled "Digital Apparatus", ICES-003 of the Canadian Department of Communications.

## SECTION 16

# HEALTHGUARD-15 SPECIFICATIONS

<b>Blood Pressure and Pulse Accuracy</b>	Pressure: $\pm 3$ mmHg or 2% of readings above 200 mmHg Pulse: $\pm 5\%$ of reading
<b>Body Composition Accuracy</b>	Comparable to Hydrostatic Weighing, universally considered the “Gold Standard” in Body Composition Analysis.
<b>Measurement Ranges</b>	Blood Pressure: 0 to 280 mmHg Heart Rate: 40 to 180 beats/min Percent Body Fat: 2.5% to 45% Weight: 40 to 440 lbs (200 kg)
<b>Arm Size Range</b>	9” to 13” in circumference
<b>Age Ranges</b>	18 and up for Blood Pressure 18 and up for Percent Body Fat
<b>Blood Pressure Measurement Method</b>	Oscillometric
<b>Overpressure Limit</b>	300 mmHg
<b>Body Composition Measurement Method</b>	Near Infrared Interactance
<b>Evaluation Time</b>	Typically less than one minute
<b>Storage Temperature / Humidity Range:</b>	Temperature: -4° F to 131° F (-20° C to 55° C) Humidity: 15% to 90% RH (non condensing)
<b>Operating Temperature / Humidity / Barometric Pressure Range</b>	Temperature: 50° F to 104° F (10° C to 40° C) Humidity: 15% - 90% RH (non condensing) Barometric Pressure: 105kPa to 80 kPa (790 – 600 mmHg)
<b>Table-top Unit Dimensions</b>	Height: 7 inches Width: 7 inches Depth: 10 inches Weight: approx. 11 lbs.
<b>Weight Scale Dimensions</b>	Height: 2 ½ inches Width: 12 inches Depth: 12 inches Weight: approx. 10 lbs.
<b>Power Source</b>	User-Supplied Talentcell Rechargeable 6000 mAh Li-Ion Battery Pack



## **Appendix 1**

### **Defining the “Ratings” that are Provided with Each HG-15 Measurement**

The HealthGuard-15 (the “HG-15”) provides measurement of blood pressure percent body fat, and weight. The results of the measurements are provided on the computer’s display and also on the optional printout capability. The following describes the various ratings that accompany each measurement:

#### **Blood Pressure Ratings**

The HG-15 displays the recommended blood pressure ratings published by the National Institutes of Health (the “NIH”). These NIH ratings are:

- **“Normal”** – This rating is if the person’s systolic measurement is less than 120 mmHg and with the diastolic being less than 80 mmHg.
- **“Pre-hypertension”** – This rating is if either the systolic or diastolic blood pressure is higher than the “Normal” values, when the systolic measurement is less than 140 mmHg or the diastolic result is less than 90 mmHg.
- **“Stage 1 Hypertension”** – If rating is if either the systolic or diastolic blood pressure is higher than the “Pre-Hypertension” values, when the systolic measurement is less than 160 mmHg or the diastolic result is less than 100 mmHg.
- **“Stage 2 Hypertension”** – If the systolic or diastolic measurement is higher than that given for “Stage 1 Hypertension”, then the result is shown as “Stage 2 Hypertension.”

#### **Percent Body Fat**

Currently no official national ratings have been established for percent body fat. For that reason, no body fat ratings are provided with the measurement results.

#### **Weight**

The weight rating that is shown when a measurement is made is based upon the combination of two major mortality studies performed by:

- Metropolitan Life Insurance Company, and
- The National Institutes of Health

These large scale studies provide meaningful recommended ratings to compare a person’s weight. The following summarize the weight ratings:

**MALE (Adults)**  
**Weight (lbs)**

<b>Height</b>	<b>Risky Less than</b>	<b>Good</b>	<b>Excellent</b>	<b>Fair</b>	<b>Needs Improvement</b>
<b>5' 2"</b>	89	89-130	131-141	142-169	170+
<b>5' 3"</b>	91	91-132	133-143	144-171	172+
<b>5' 4"</b>	92	92-134	135-145	146-174	175+
<b>5' 5"</b>	94	94-136	137-148	149-177	178+
<b>5' 6"</b>	95	95-138	139-151	152-180	181+
<b>5' 7"</b>	97	97-141	142-154	155-184	185+
<b>5' 8"</b>	99	99-144	145-157	158-187	188+
<b>5' 9"</b>	101	101-147	148-160	159-191	192+
<b>5' 10"</b>	103	103-150	151-163	164-195	196+
<b>5' 11"</b>	105	105-153	154-166	167-198	199+
<b>6' 0"</b>	107	107-156	157-170	171-203	204+
<b>6' 1"</b>	110	110-159	160-174	175-207	208+
<b>6' 2"</b>	112	112-163	164-178	179-212	213+
<b>6' 3"</b>	114	114-166	167-182	183-216	217+
<b>6' 4"</b>	117	117-170	171-187	188-222	223+

**FEMALES (Adults)**  
**Weight (lbs)**

<b>Height</b>	<b>Risky Less Than</b>	<b>Good</b>	<b>Excellent</b>	<b>Fair</b>	<b>Needs Improvement</b>
<b>4' 10"</b>	75	76-108	109-121	122-143	144+
<b>4' 11"</b>	76	77-110	111-123	124-145	146+
<b>5' 0"</b>	78	79-115	113-126	127-148	149+
<b>5' 1"</b>	79	80-114	115-129	130-151	152+
<b>5' 2"</b>	81	82-117	118-132	133-155	156+
<b>5' 3"</b>	83	84-120	121-135	136-159	160+
<b>5' 4"</b>	85	86-123	124-138	139-162	163+
<b>5' 5"</b>	87	88-136	137-141	142-166	166+
<b>5' 6"</b>	89	90-129	130-144	145-170	171+
<b>5' 7"</b>	91	92-132	133-147	148-174	175+
<b>5' 8"</b>	93	94-135	136-150	151-177	177+
<b>5' 9"</b>	95	96-138	139-153	154-181	182+
<b>5' 10"</b>	97	98-141	142-156	157-185	186+
<b>5' 11"</b>	99	100-144	145-159	160-188	189+
<b>6'</b>	101	102-147	148-162	163-192	193+

## **Appendix 2**

### **Essential Performance Report**

The HealthGuard-15 Essential Performance includes listing all functions that the device performs. The following functional listing is in chronological order. Next to each function is whether it is performed by the device's hardware or device's software.

- Power Up (hardware)
- Warm Up (hardware)
- Acquire Subject Height, Sex, and Age; Prevent Invalid Entries (software)
- Acquire Subject Weight; Prevent Invalid Entry (hardware/software)
- Initiate Reading (software)
- Measure Percent Body Fat (hardware)
- Measure Blood Pressure; Prevent Cuff Over-inflation (hardware)
- Transmit Results (hardware)
- Save Results (software)
- Display Results (software)
- Print Results (software)
- E-Mail Results (software)

#### **Functions of Essential Performance**

Referring to the Risk Management File given in Section 17-2 and Appendix B, the only function that contains unacceptable risk is:

#### ***Measure Blood Pressure; Prevent Cuff Over-inflation***

In terms of essential performance, the term "over-inflation" is defined as any cuff pressure that could cause bruising or other harm to the user's arm. The risk is mitigated in three ways:

- 1) There is an on-screen "ABORT" button. When pressed, the Abort command is sent to the firmware running within the HG-15. This sends a signal to the Blood Pressure module forcing it to instantly end the reading and immediately open the pressure relief valve to allow the cuff to rapidly deflate.
- 2) In addition to the above, there is an "EMERGENCY STOP" pushbutton built on the HealthGuard-15's Cuff Housing. This pushbutton is easily accessible by the user's right hand. When this button is pressed, it grounds the lines connected to the Non Maskable Interrupt pin on the HealthGuard-15's microprocessor. This immediately forces a system reset, which forces the blood pressure module to reset, thereby, opening the pressure relief valve which rapidly deflates the cuff.

- 3) In the unlikely event that neither of the above approaches succeed in initiating the rapid cuff deflation, the power cord can be disconnected from the system. As soon as the blood pressure module loses power, the cuff rapidly deflates.

Pass/Fail Criteria for EMC Testing and All Operations

<b>PASS</b>	HealthGuard-15 Blood Pressure Cuff does not cause bruising on the user's arm and never exceeds 299 mmHg under any condition.
<b>FAIL</b>	HealthGuard-15 Blood Pressure Cuff causes bruising, or if the cuff pressure exceeds 299 mmHg.



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