HeartTest LABORATORIES



MyoVista DG-200 12-Lead ECG with MyoVista® Color Waveform Technology

User Manual

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PREFACE

The MyoVista DG-200 12-Lead Electrocardiograph (ECG) with MyoVista Color Waveform Technology is a medical device that performs electrocardiograms, generates reports, and archives the test results.

This User Manual describes how to set up, operate, maintain, clean, and troubleshoot the MyoVista DG-200. It includes technical specifications and error messages. An authorized representative should provide initial installation and training.

Audience

The MyoVista DG-200 is intended for trained medical professionals who use, maintain, clean, and troubleshoot the system. They are expected to have a working knowledge of medical procedures and terminology required for evaluating cardiac patients.

The MyoVista Informatics and Glasgow Interpretive Analysis are intended to be used with other relevant patient information and interpreted by a physician.

Document Conventions

In this User Manual, the MyoVista DG-200 is also referred to as the device. The following additional conventions are used in this User Manual.

Convention	Meaning	Description
	Note	Notes emphasize or supplement important points of the main text.
	Tip	Tips provide helpful information, guidelines, or suggestions for performing tasks more effectively.

Typographic Conventions

Convention	Description
Bold	Indicates software screen elements including button names, tabs, field names, dialog box titles, etc. Also used for emphasis.
Italics	Indicates document titles.
Bullets	Indicate a list.

IMPORTANT

Users should read this User Manual carefully before using the medical device. Contact Heart Test Laboratories immediately for any safety concerns.

Contacting Heart Test Laboratories

Contact Heart Test Laboratories (HTL) product support directly with inquiries and comments by emailing: info@heartestlabs.com.

Electronic Manual

This document consists of original instructions from the manufacturer.

To print pages, from a personal computer open the File menu and select Print. Specify the appropriate page numbers as shown in the status field at the bottom of the window.

We suggest you print a single page first. You might need to set the printer to Print TrueType Fonts as Bitmaps (or Graphics) if the character spacing is incorrect.

Revision History

Revision	Date	Comment
Rev. A	13 July 2016	Initial release

1. INTRODUCTION

Topics:

- *Intended Use (page 10)*
- *Indications for Use (page 10)*
- *Contraindications (page 10)*
- *Prescription Device Statement (page 10)*

This chapter introduces the MyoVista DG-200 Electrocardiograph.

Intended Use

The MyoVista DG-200 Electrocardiograph is a 12-lead resting electrocardiograph with interpretive analysis and MyoVista Informatics. After the data is acquired, it can be stored and/or printed with resting ECG interpretation analysis provided for physician review. This device is intended primarily for use in hospitals, medical clinics, and offices of any size.

Indications for Use

The MyoVista DG-200 Electrocardiograph is a non-invasive prescription device. The device is indicated for use:

- To acquire, analyze, display, and print electrocardiographic information.
- To provide standard established 12-Lead interpretive analysis and calculations of the QRS, P, and T wave portions of the electrocardiograms, as well as signal processing-based information for consideration by a physician.
- In a clinical setting by a physician or by trained personnel who act on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- On adult and pediatric populations.

The interpretations of EGG offered by the device are significant only when used with a physician review along with consideration of all other relevant patient data.

Contraindications

The MyoVista DG-200 is not intended for use in the following ways:

- As a vital signs physiological monitor
- To provide alarms for arrhythmia detection
- For people whose skin is irritated by electrodes with silver and silver chloride or the adhesive
- For infants
- For diagnosis of specific heart conditions

Prescription Device Statement

U.S. Federal Law restricts the sale of this device by or on the order of a licensed healthcare practitioner.

2. SAFETY SUMMARY

Topics:

- *Safety Conventions (page 12)*
- *General Warnings and Cautions (page 12)*
- *Electrical Safety (page 15)*
- *Patient Safety (page 16)*
- *Symbols (page 16)*
- *Labeling (page 19)*
- *Device Identification (page 20)*
- *Training (page 21)*
- *Medical Device Classification (page 21)*

This chapter provides information about the safe use and regulatory compliance of the MyoVista DG-200. You should be familiar with this information and understand all instructions before using this device.

Note: Ignoring the provided safety information and intended use is considered misuse of the MyoVista DG-200 and could result in harm to the patient, operator, medical facility, or device.

Safety Conventions

Convention	Meaning	Description
	Caution	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in minor injury, harm to the patient or operator, or damage to property or the device.
	Warning	Warnings indicate a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.

General Warnings and Cautions

Warnings

General Warnings in this User Manual are listed below and displayed with the following Warning symbol.



Warning: Operators must read and understand the following safety-related information before operating the MyoVista device.



Warning: This is a Class A product. In a domestic environment, this product may cause radio interference, in which case the user may be required to take adequate measures.



Warning: Operators must read and understand the INTENDED USE STATEMENT.



Warning: This device may ONLY be used by trained operators under the direct supervision of a licensed healthcare practitioner.



Warning: DANGER OF ELECTRIC SHOCK. Do not open the device case. Only personnel authorized by the manufacturer may service the device, open the enclosure, or open the battery compartment.



Warning: DANGER OF ELECTRIC SHOCK. THERE ARE NO USER-SERVICEABLE PARTS IN THIS DEVICE. The battery is not user-serviceable.



Warning: DANGER OF ELECTRIC SHOCK. Do not operate the device if the power adapter is damaged or suspected of being damaged.



Warning: DANGER OF ELECTRIC SHOCK. Do not attempt to repair or alter the device. It can result in unpredictable operation and risk to the patient.



Warning: The device, accessories, and packaging have safety labels. Operators must be able to recognize them and understand their meaning (see “Symbols” on page 16).



Warning: Only cables and electrodes provided by Heart Test Laboratories are to be used with the MyoVista DG-200. Do not use electrodes or cables that have not been approved.



Warning: Do not use electrodes if the backing has been removed or damaged.



Warning: Do not reuse electrodes. The electrodes approved for this device are for single use only.



Warning: Never put any cable other than the power adapter into a wall receptacle.



Warning: Never use the device in the presence of flammable vapors or gases.



Warning: Do not use the device beyond the safe limits of environmental conditions of temperature and humidity (see “Environmental Specifications” on page 95).



Warning: Do not allow liquids to enter the device. Do not have liquids or drinks near the device. An accidental spill of liquid on the device can create a hazard of electric shock or damage to the device. If liquid does get into the device, contact an authorized technician before use.

Warning: The MyoVista Informatics and Glasgow Interpretative Analysis must be interpreted by a licensed healthcare practitioner.

Cautions

General cautions in this User Manual are listed below and displayed with the following Caution symbol.

Caution: Always confirm the patient's identification and the information displayed before starting a test.

Caution: When using the VESA mount interface on the back panel, be careful to check the adequacy of the surface (for example, the cart, wall, or shelf) to which the device will be attached. The VESA mount and surface should be able to support 8 kg (17.6 lbs).

Caution: When setting up, be careful to place the device in a stable location, away from the edge of tables or carts. Avoid entangling the cables with the patient or the operator.

Caution: Do not attempt to reposition the device by pulling the cables. Be careful not to cause the device to fall by attempting to pull the device by the cables. Always ensure all cables are positioned properly to avoid damage.

Caution: Patient cable must be inserted properly into the device, with the screws secured tightly to ensure signal capture.

Caution: The device should be plugged into a grounded outlet with surge protection.

Caution: The device and cables should be cleaned regularly according to instructions.

Caution: Periodically check the battery performance, and have the battery replaced or serviced by an authorized technician if necessary. For instructions about monitoring the battery, see "Built-In Battery" on page 35.

Caution: Do not use the device beyond its intended lifetime, which is 7 years from the manufacturing date.

Caution: Improper placement of electrodes, patient cable and leads can provide improper results. Ensure that correct electrode placement protocol is followed.

Caution: Do not store or use the device in the presence of strong magnetic fields or ionizing radiation.

Caution: Do not store or use the device next to other instruments that generate strong vibration.

Caution: The patient must be at rest and not moving (other than normal breathing) during the test.

Caution: Always check the quality of the ECG waveforms to ensure the patient connections and device have been set up properly before starting the test.

Caution: If poor electrical grounding exists in the clinic, or if a noisy power source is being used, the device should operate ONLY on battery power when running a test, and use the AC power ONLY to maintain battery charging.

Caution: At the end of its service life, the device and its accessories must be disposed of in compliance with the local governmental guidelines regulating the disposal of medical devices.

Caution: Discard test results if power is lost or interrupted during testing.

Electrical Safety

Leakage Current: The patient connection interface complies with safety standards for medical device leakage current levels.

Ensure that the AC power voltage complies with the device requirement.

Patient Safety

The MyoVista DG-200 is designed for use on any patient for whom a resting 12-lead ECG test is indicated, with the exceptions noted in “Contraindications” on page 10. The device meets the essential requirements of the European Medical Device Directive for General Product Safety and complies with the applicable U.S. and Canadian medical safety standards. The primary data source for test reports is a Portable Document File (PDF) file or printed report.

The design of the equipment, accompanying documentation, and labeling on the equipment take into consideration that the purchase and use of the MyoVista DG-200 are restricted to trained operators.

This User Manual excludes warnings of various hazards that are obvious to a medical professional and operator of this equipment, consequences of product misuse, and potentially adverse effects in patients with abnormal conditions.

- Do not use the device beyond the safe limits of environmental conditions of temperature and humidity (see “Environmental Specifications” on page 95).
- Magnetic field: If this device is used in the presence of magnetic resonance imaging (MRI), the picture resolution of the MRI may be affected. This environment might also interfere with the operation of the device.
- RF Interference: The device conforms to ANSI/AAMI/IEC 60601-2-25:2011; however, avoid environments with high levels of RF noise.
- Electromagnetic Interference: This device conforms to ANSI/AAMI/IEC 60601-2-25:2011.
- Other interference: The presence of electrocautery device, infrared energy, or defibrillator may impact the operation of this device.
- Biocompatibility: All materials that are subject to user or patient contact are of the type commonly used in a clinical environment.

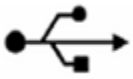
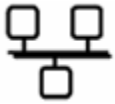
Symbols

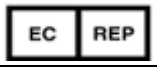
Symbols are used to convey warnings, cautions, prohibitions, mandatory actions, or information. Familiarity with these symbols assists in the safe and proper use and disposal of the equipment.

Table 2-1 describes the symbols or icons that might appear on the device or its packaging. Not all of the symbols in the table apply to a particular device or its packaging.

- Colored symbols indicate there might be a danger, warning, or mandatory action.
- Black symbols provide additional information or might indicate a caution.

Table 2-1. Symbols and Icons on the Device and Its Packaging

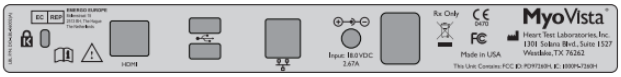
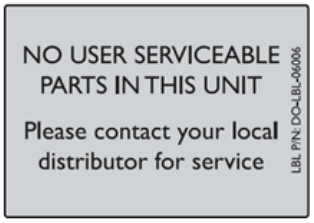
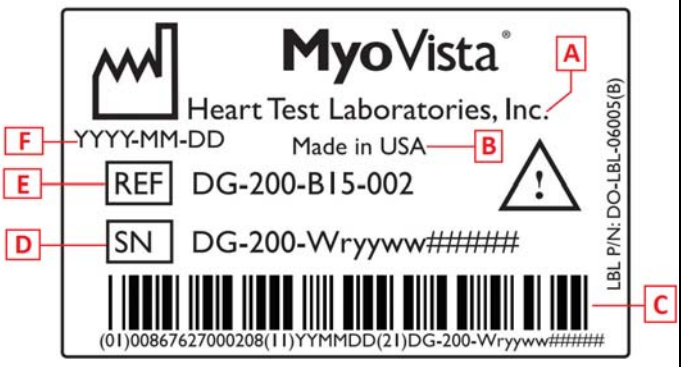
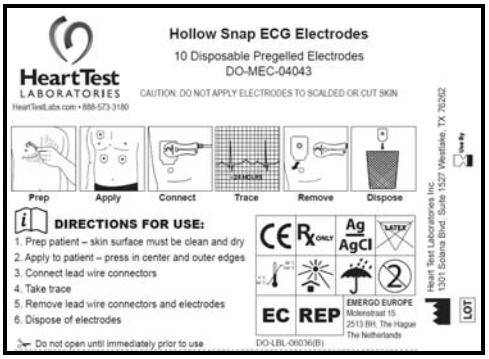
Symbol	Description
	Manufacturer (might be accompanied by manufacturer name and address)
	Date of manufacture
	Caution, consult accompanying documents
	Consult user manual
	Alternating current
	Direct current
	Kensington security slot
	Universal Serial Bus (USB) interface
	Network interface
	Use by date
	Temperature limitation; indicates both upper and lower limits by upper and lower horizontal lines
	Keep dry
	Device is running on AC power and/or charging

Symbol	Description
	Device is running on DC power; charge level is indicated by battery icon filling
	Standby icon; LED is illuminated when device is in standby mode. LED also indicates power source and charge level.
	Center negative symbol. Indicates output plug (tip) center is Negative (-) and output plug barrel (ring) is Positive (+).
	Symbol for electrical and electronics devices marking for Directive 2012/19/EU. Device, accessories, and packaging waste must be disposed of properly at end of usage. Local disposal ordinances and regulations must be followed.
	Defibrillation-proof Type CF Applied Part
	Keep away from sunlight
	Do not reuse/single use only
	European Community authorized representative
	Serial number
	Catalog number
	Meets FCC requirements
	USA only: for use by or on the order of a physician
	Conforms with applicable EU directives

Labeling

Table 2-2 shows the labels that might be on the device or its packaging. Not all of the labels in the table apply to your particular device or its packaging.

Table 2-2. Symbols and Icons on the Device and Its Packaging

Symbol	Location	Description
	Rear of device	Identifies symbols, ports, and connectors. See “Symbols” on page 16.
	Battery compartment	Identifies that the unit is not serviceable by user. The battery is not a user-serviceable part. For all servicing needs contact Heart Test Laboratories or an authorized representative.
	Bottom of device	Uniquely identifies this unit. See “Device Identification” on page 20.
	Electrode pouch	Identifies directions for use of electrodes.

Device Identification

Every MyoVista DG-200 device has a product label that identifies the manufacturer information, device name, part number, and unique serial number. This information is required when contacting an authorized representative.

This label is in conformance with all 78 FR 58785 standards.

Device Label Format

The device label legend in Figure 2-1 and Table 2-3 describe the label component.

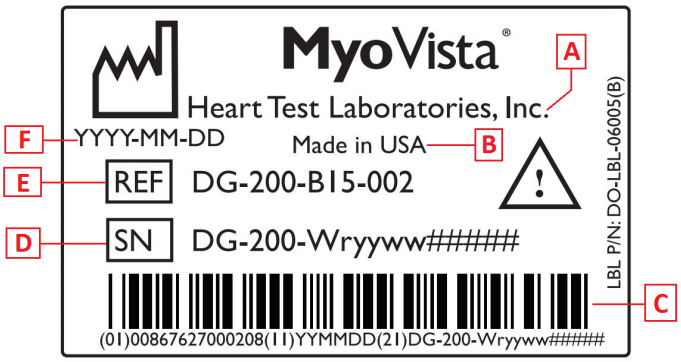


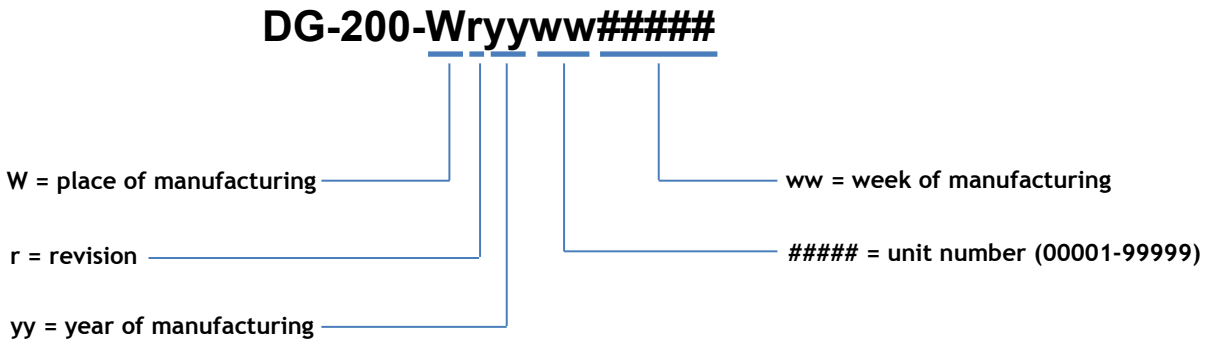
Figure 2-1. Device Label

Table 2-3. Device Label

Symbol	Description
A	Manufacturer
B	Country of origin
C	Bar code
D	Device serial number
E	Device part number and revision
F	Date of manufacture in YYYY-MM-DD format

Serial Number Format

Each device has a serial number that uniquely identifies the device and provides important information about the device. The serial number format is shown in the following figure.



Training

This User Manual provides information about patient setup, performing a test, interpreting the results, and using the software. It is intended as a supplement to, not a substitute for, thorough product training.

Medical Device Classification

The device is classified as follows per ANSI/AAMI/IEC 60601-1:2005/(R)2012.

Category	Classification
Protection against electric shock	Class I externally powered ME equipment. Internally powered ME equipment.
Degree of protection against electrical shock	Defibrillation-Proof Type CF Applied Part.
Protection against harmful ingress of water or particulate matter	The device is classified IP00 (non-protected) for harmful ingress of particulate matter and water.
Methods of sterilization	N/A
Suitability for use in an oxygen-rich environment	The device is not suitable for use in the presence of flammable vapors or gases.
Mode of operation	Continuous operation

3. GENERAL OVERVIEW

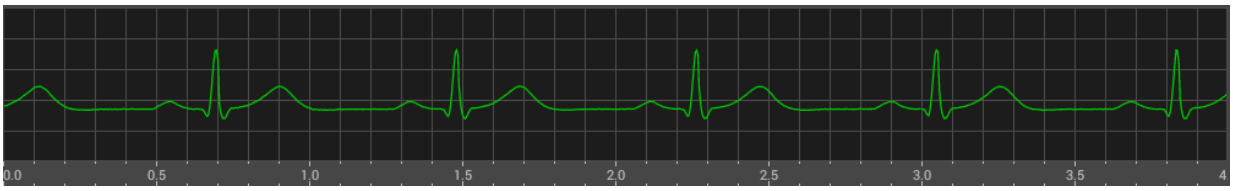
Topics:

- *Traditional 12-Lead ECG Waveform (page 23)*
- *Glasgow Interpretative Analysis (page 23)*
- *MyoVista Informatics (page 23)*
- *System Overview (page 27)*

This chapter describes the features and capabilities of the MyoVista DG-200 device. It also provides an overview of system elements including the MyoVista Informatics.

Traditional 12-Lead ECG Waveform

The MyoVista DG-200 provides traditional 12-lead waveforms. These waveforms represent the overall direction and magnitude of the heart's electrical potential during the cardiac cycle by measuring depolarization and repolarization over time from 12 different directions. The waveform is a graph representing voltage versus time. The sampling rate is 500 samples per second.



Glasgow Interpretative Analysis

The Glasgow Interpretive Analysis software provides an interpretation of the traditional resting 12-lead ECG. It can recognize and report ECG abnormalities such as myocardial infarction, acute myocardial infarction, ventricular hypertrophy, ST-T abnormalities, and other common abnormalities of rhythm. Defects in electrical conduction and other anomalies are also reported.

MyoVista Informatics

The MyoVista Informatics represent a unique technology that provides non-invasive assessment by analyzing energy values related to the myocardium. The MyoVista DG-200 uses Continuous Wavelet Transform (CWT) mathematics, which enable the device to display the energy during the cardiac cycle using a scalogram methodology that shows energy values. The accumulated data is processed to provide information related to the energy levels of the myocardium during repolarization.

The visual output is displayed as a colorized waveform representing cardiac cycles within the test period.

The numerical output consists of indices representing energy values of the left and right ventricles. This provides a comparison of ventricular energy values.

The MyoVista Energy Category provides an assessment of the level of energy on a relative basis during the test period.

MyoVista Color Waveform

Figure 3-1 shows an example of the MyoVista Color Waveform after signal processing, using the Continuous Wavelet Transform and its relationship to the QRST (Q, R, S, and T waves) complex.

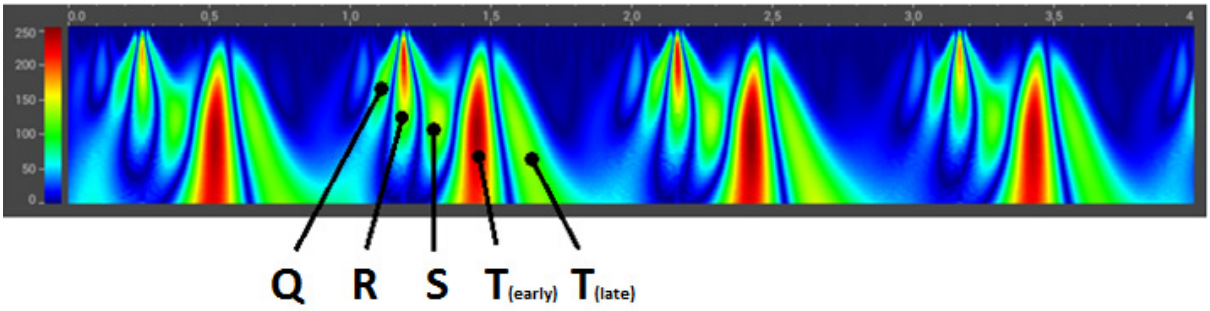


Figure 3-1. MyoVista Color Waveform Generated After Signal Processing Using CWT

The color scaling provides a non-linear mapping of energy. The color scale from 0 to 255 represents a level of energy detected from the heart at each point in time and frequency. Blue represents low energy, red represents high energy, and intermediate energy levels are shown according to the color bar above (see the bar key to the left in Figure 3-1). The colors represent a distribution of energy detected during the cardiac cycle rather than providing absolute values.

The horizontal axis (x-axis) is time and the vertical axis (y-axis) is frequency. The frequencies range from 3 Hz at the bottom of the display to 200 Hz at the top using a non-linear scale.

MyoVista Ventricular Index

The MyoVista Ventricular Indices range from 0 to 255. The indices are a relative measure of the energy detected from the heart during repolarization. The peak value of energy for each lead during the early and late phase of repolarization is calculated by considering factors such as sex and age. The values displayed for the right ventricle early and late measures are the average of the peak energy values for leads V1 and V2. The values displayed for the left ventricle early and late measures are the average of the peak energy values for leads V4, V5, and V6. The average measures for each of the right and left ventricle are the summation of the respective (right or left) early and late measures divided by the heart rate in beats per minute.

Figure 3-2 shows an example of a MyoVista Ventricular Index.

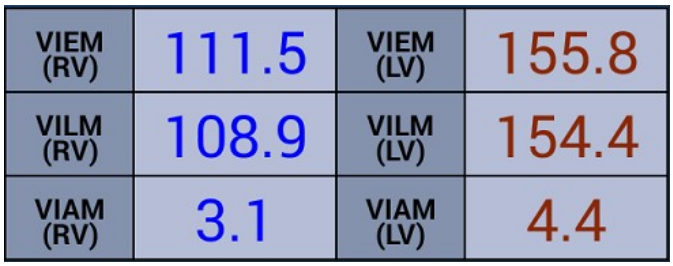


Figure 3-2. Example of a MyoVista Ventricular Index

Table 3-1. Legend

Index	Description
VIEM (RV)	Ventricular Indices Early Measure (Right Ventricle)
VILM (RV)	Ventricular Indices Late Measure (Right Ventricle)
VIAM (RV)	Ventricular Indices Average Measure (Right Ventricle)
VIEM (LV)	Ventricular Indices Early Measure (Left Ventricle)
VILM (LV)	Ventricular Indices Late Measure (Left Ventricle)
VIAM (LV)	Ventricular Indices Average Measure (Left Ventricle)

MyoVista Energy Category

The MyoVista DG-200 classifies patients into three categories, depending on the energy level detected during repolarization of the heart. The device considers factors such as gender and age.

- If the full energy scale is displayed, the energy detected is categorized as high (see Figure 3-3).
- If only two of the three segments are displayed, the energy detected is categorized as moderate (see Figure 3-4).
- If only one segment is displayed, the energy detected is categorized as low (see Figure 3-5).

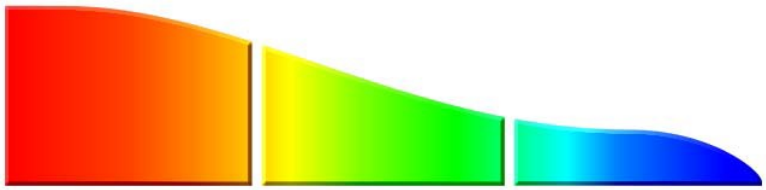


Figure 3-3. High Energy Level

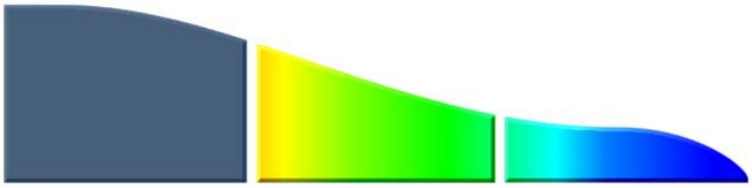


Figure 3-4. Moderate Energy Level



Figure 3-5. Low Energy Level

System Overview

This section provides an overview of the MyoVista DG-200 panels, controls, and connectors.

Front Panel

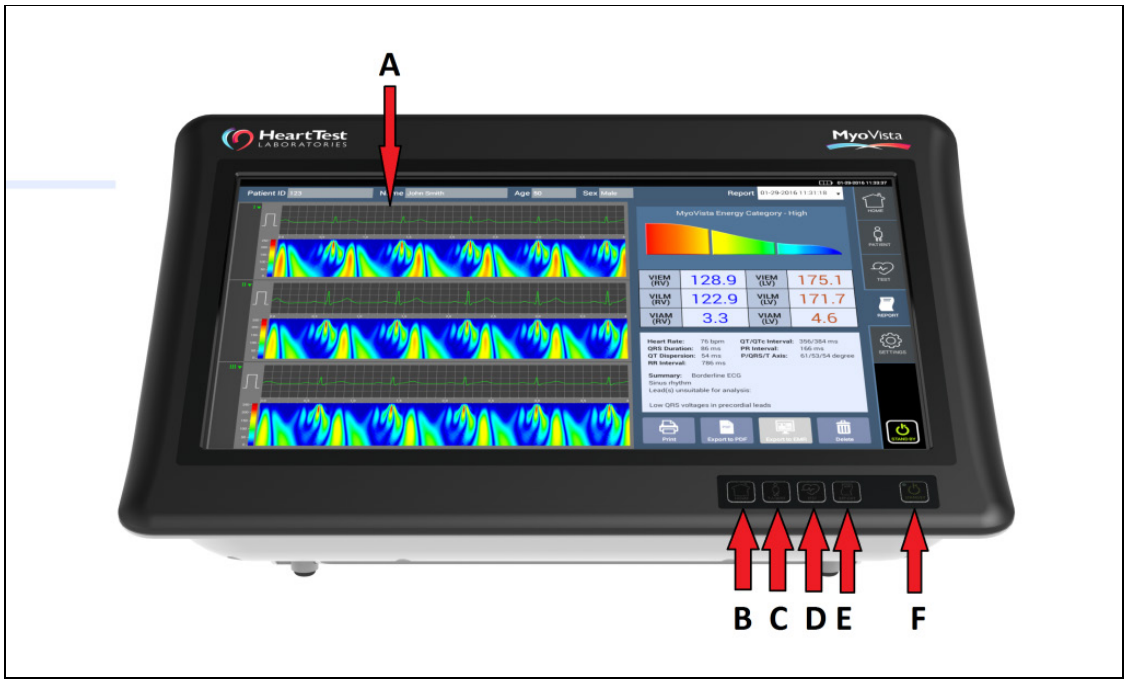


Figure 3-6. MyoVista DG-200 Front Panel

Table 3-2. Front Panel Legend

Callout	Description
A	Touchscreen LCD display
B	Home button
C	Patient button
D	Test button
E	Report button
F	Standby button and LED

Rear Panel

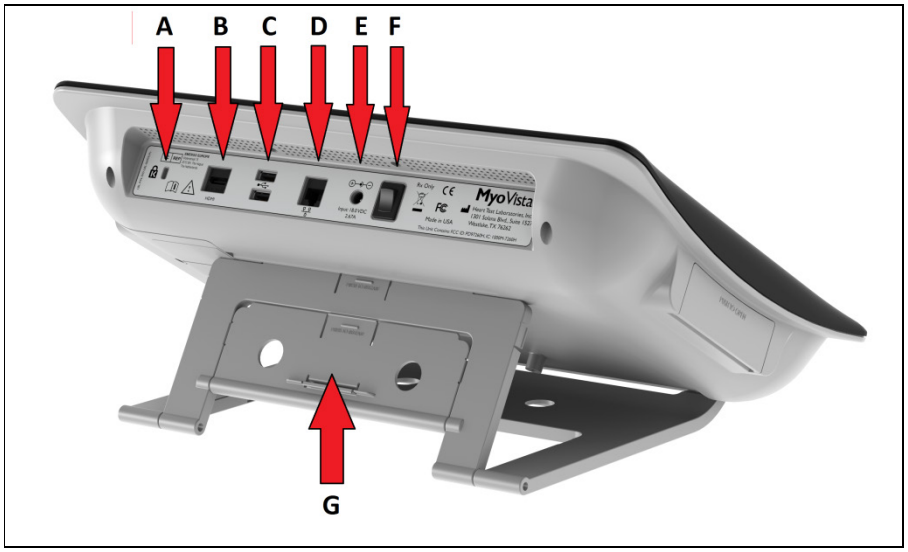


Figure 3-7. MyoVista DG-200 Rear Panel

Table 3-3. Rear Panel Legend

Callout	Description
A	Kensington security slot
B	HDMI port
C	Two USB ports
D	Ethernet port
E	Power adapter connector
F	Power switch
G	Adjustable stand

Note: A USB storage media inserted into the bottom port in Figure 3-7 is identified as **udisk** and a USB storage media inserted into the top port is identified as **udisk1**. Only FAT32 and NTFS file formats are supported on USB storage devices.

Right Side with Patient Cable Port

Figure 3-8 shows the right side of the device. Callout **A** identifies the 15-pin patient cable port.

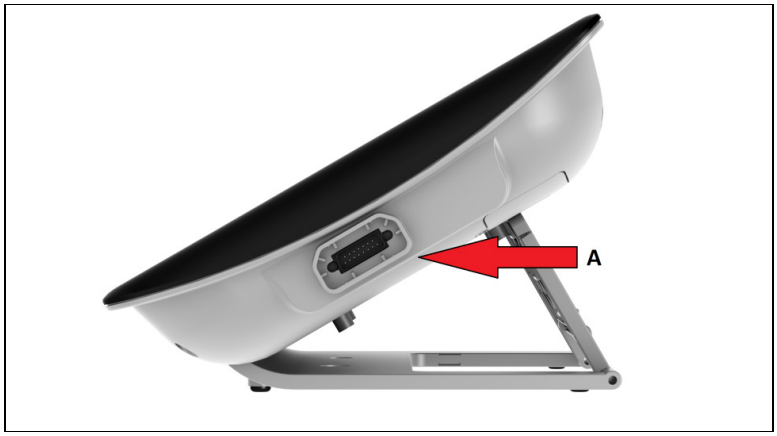


Figure 3-8. Right Side of the MyoVista DG-200

Left Side with USB Ports

Figure 3-9 shows the left side of the device. Callouts **A and B** identify the two USB ports for connecting a USB storage media or peripheral device.

Note: A USB storage media inserted into one of the side ports in Figure 3-9 will be shown as follows: port A **udisk2** and port B **udisk3**.

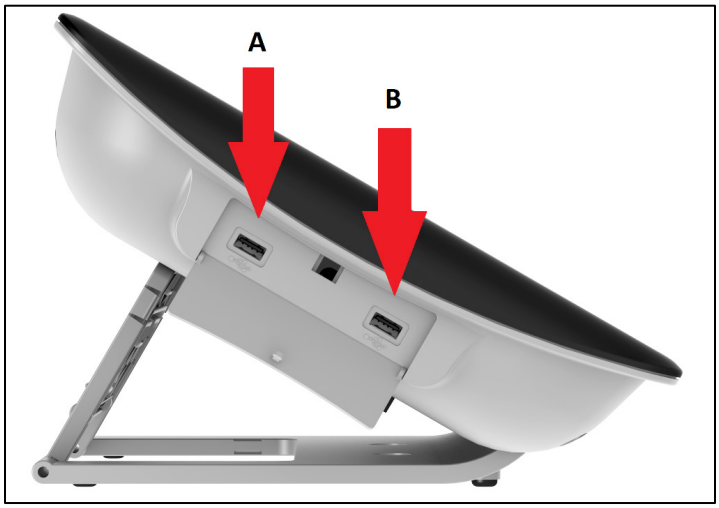


Figure 3-9. Left Side of the MyoVista DG-200

4. MYOVISTA OPERATIONS

Topics:

- *Getting Started (page 31)*
- *System Setup and Operation (page 32)*
- *Recommended Operating Environment (page 36)*

This chapter describes the operations you can perform using the MyoVista DG-200.

Getting Started

Unpacking the Device

Carefully unpack the device and make sure that all items listed in “Package Contents” below are included in the package.

All package contents should be visually inspected for damage prior to installation and use.

Package Contents

- MyoVista DG-200 device
- Patient cable
- External AC/DC power adapter and cord
- 1 box of 25 pouches containing 10 electrodes per pouch
- User Manual on USB storage media

Installing the MyoVista DG-200

Installation by authorized representative is preferred. Installation instructions for the MyoVista DG-200 are provided in “Setting Up the MyoVista DG-200” on page 32.

System Setup and Operation

Setting Up the MyoVista DG-200

Warning: DANGER OF ELECTRIC SHOCK. Do not operate the device if the power adapter is damaged or suspected of being damaged.

Note: If using the optional VESA mount interface, see Appendix C for VESA mounting instructions.

To set up the MyoVista DG-200:

1. Attach the supplied power adapter to the supplied power cord.
2. Connect the power adapter to the receptacle on the device, as shown in Figure 4-1.
3. Plug the power cord into an AC outlet.

Note: To avoid personal injury, store the power cable properly when not in use. The power cord might pose a tripping hazard or result in the device falling and breaking if pulled.

Warning: AVOID ELECTRICAL SHOCK. This device must be connected only to an AC outlet with protective grounding.

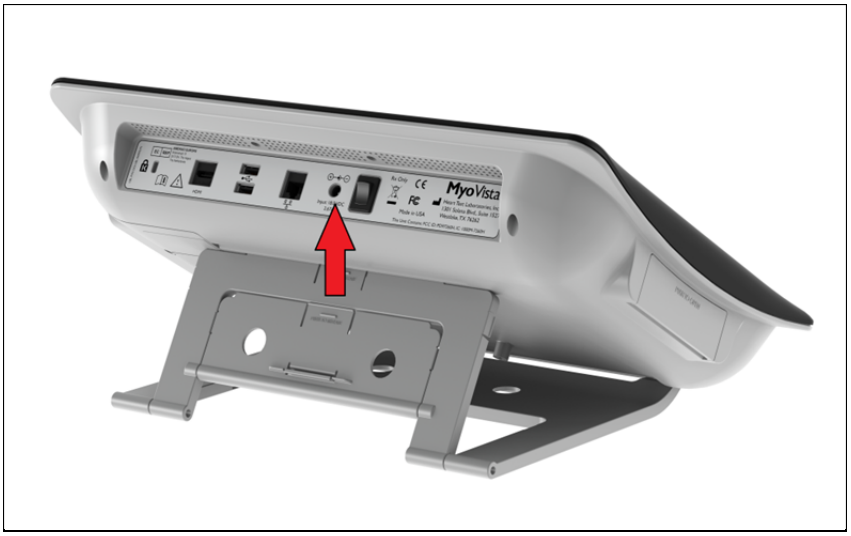


Figure 4-1. Connecting the Power Adapter

4. Connect the 15-pin patient cable into the patient cable port, as shown in Figure 4-2 and the following figures.

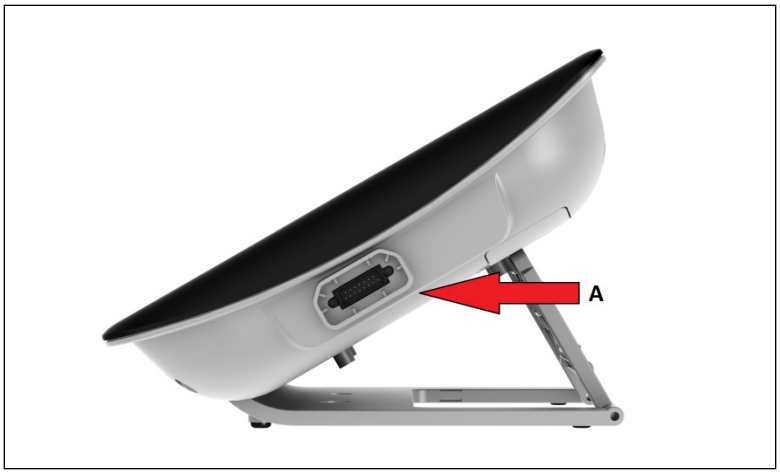
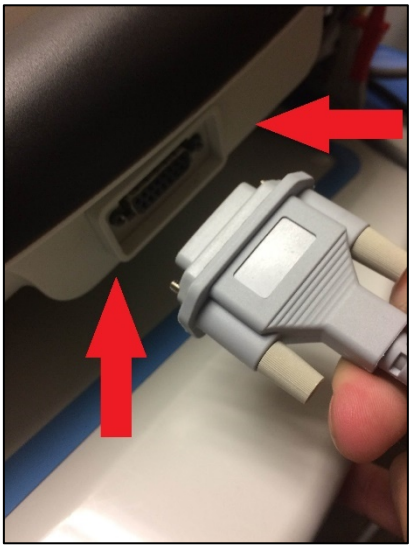


Figure 4-2. Connecting the Patient Cable

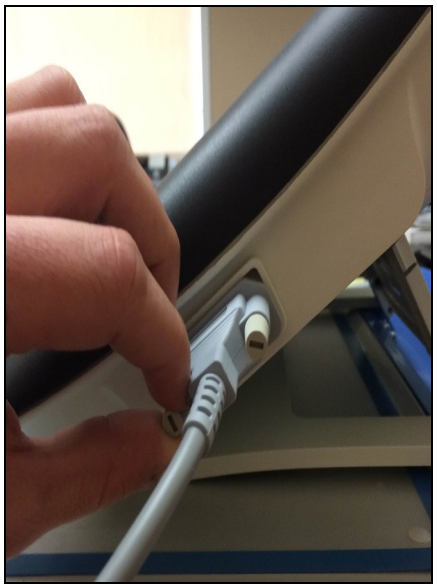
4A. Align the MyoVista patient cable with the 15-pin port on the side of the MyoVista DG-200.

Ensure the orientation of the cable snout, pins, and shroud matches the orientation of the receiving port on the MyoVista DG-200.

Insert the MyoVista patient cable into the 15-pin port on the side of the MyoVista DG-200. If it does not plug in easily, check the orientation of the connector on the cable and the MyoVista device. Forcing the connector may damage the cable or device. DO NOT BEND CONNECTOR PINS.



4B. Tighten the MyoVista patient cable thumb screws securely into the device. Do not over tighten.



5. Push the **Power** switch to the **ON** position (see Figure 3-7 on page 28). A MyoVista boot/splash screen appears followed by the Home screen (see "Home Screen" on page 46).

Initial Software Setup

Initial installation and software setup by an authorized representative are highly recommended. The initial installation of the device **must** include the following steps, which are performed from the Settings screen:

1. Configure the language to the applicable setting for the user's geographic location (page 84).
2. Configure the time and date to the applicable settings for the user's geographic location (page 68).
3. Configure the ECG **s**ettings for the appropriate AC power frequency for the user's geography (page 81).

Note: Before running a test, configure the Test Length and Filter settings. It is recommended that you find the utility/mains frequency of your country/region and set filters appropriately. For example, North America users should set the Frequency Interface to 60 Hz, while users in Europe should set the Frequency Interface to 50 Hz.

The Myoelectricity Interface filter might impact the results of the icon and index calculations by reducing the amount of biologics data that the algorithms have available. We recommend not using a filter for this setting unless necessary because biologic information available to process will be reduced.

Built-In Battery

The MyoVista DG-200 contains a built-in rechargeable battery. The device can be operated either from the AC power adapter or from the battery. However, if you use battery power, note that the battery will provide power for one hour.

If the device screen is active, an icon in the status bar shows the power source. If the device is in standby mode, an illuminated LED on the **Standby** button shows the power source and/or battery charge level (see Figure 4-3).

Note: The LED on the **Standby** button is not illuminated when the screen is on.

Table 4-1 On-Screen Power Source Indicator

Icon	Description
	Device is operating on AC power and/or is charging.
 and	Device is operating on battery power and has sufficient charge to perform a test.
	Device is operating on battery power; battery is close to depletion and must be charged and/or switched to AC power.
	Device is operating on battery power; battery is almost fully depleted. The device should be immediately charged and/or switched to AC power before running a test.



Figure 4-3. Power Source Indicator on Standby Button

Table 4-2. Battery LED Colors

Color	Description
Solid green	Device is operating on AC power and/or is charging.
Blinking green	Device is operating on battery power and has sufficient charge to perform a test.
Blinking yellow	Device is operating on battery power; battery is close to depletion and must be charged and/or switched to AC power.
Blinking red	Device is operating on battery power; battery is almost fully depleted. The device should be immediately charged and/or switched to AC power before running a test.

The built-in battery operates in the following modes:

- Charging or Fully Charged
- Discharging

These modes are indicated by a battery symbol in the status bar or the LED on the **Standby** button.

Using the Built-in Battery

Due to storage and transportation time, the initial battery charge might not be sufficient to power up the device or support a complete patient cycle. Therefore, when using the device for the first time, operate the MyoVista DG-200 on AC power only. **Before running a test, always confirm that the battery has sufficient power to complete the test.**



Note: The total runtime of all rechargeable batteries reduces over time. The device can remain connected to AC power source and will charge the battery as well as maintain the full battery charge if fully charged.

Monitoring the Battery

Monitor the battery gauge on the status bar of the device. If the battery begins to deplete at a faster rate than usual, it may be time to replace the battery. Contact an authorized representative for service.

Recommended Operating Environment

The MyoVista DG-200 is a sensitive device. Its ability to detect and process signals embedded within the QRST complex depends on preventing noise from interfering with the device's operation. Pay particular attention to the placement of the device and the surrounding environment.

For accuracy and consistency of test results, observe the following recommendations:

- The clinical setting should be away from elevators and high-voltage power supplies.
- Lighting should be sufficient to perform the test processes accurately before beginning.
- The power adapter should not share an AC outlet with another device.
- Do not locate the MyoVista DG-200 next to another powered device.
- For optimal performance, do not operate the MyoVista close to wireless transmission devices.
- The power socket must be grounded.

Note: For hazards related to environmental conditions, see warnings and cautions in Chapter 2.

Caution: If the clinic has poor electrical grounding, or if a noisy power source is being used, run tests using battery power only and use AC power only to maintain battery charging.

5. PATIENT TESTING

Topics:

- *Patient Recommendations (page 39)*
- *Electrode Placement (page 39)*
- *Connecting Electrodes to Leads (page 45)*
- *Home Screen (page 46)*
- *Patient Screen (page 49)*
- *Test Screen (page 55)*
- *Report Screen (page 60)*
- *Settings Screen (page 65)*

This chapter describes how to perform patient testing procedures using the MyoVista DG-200.

Patient Recommendations

- Patients should not have caffeine less than 2 hours prior to the test.
- Significant alcohol consumption on the previous day may affect test results.
- If blood has been drawn, allow 20 minutes before testing.
- Patients should lie in a horizontal position with a resting heart rate.
- Patients should remain calm during the test.
- The test can be performed multiple times.

Patient Condition and History

Certain medications can affect test results. Examples include medications taken for heart disease, hypertension, diabetes, including beta-blockers, digitalis, dobutamine, amildarone, and narcotics. Review the patient's history of health issues and medications. Test subjects should not drink water less than 15 minutes before the test.

Electrode Placement

The MyoVista electrode placement protocol is aligned with the standard AHA or IEC 12-lead ECG electrode placement protocol.

Attaching Electrodes to the Patient

To obtain strong signals, connect electrode connectors and electrodes firmly. For instructions about proper placement of electrodes on the patient, see "Electrode Configurations" starting on page 40.

Caution: To avoid placing tension on the electrodes, allow sufficient slack in the patient cable.

1. Prepare the skin appropriately for good electrode adhesion and conduction.
2. Peel the electrodes from the protective sheet.
3. Place the electrodes on the skin surface (see "Electrode Configurations" starting on page 40).

Electrode Configurations

The following figures show the various ECG electrode configurations.

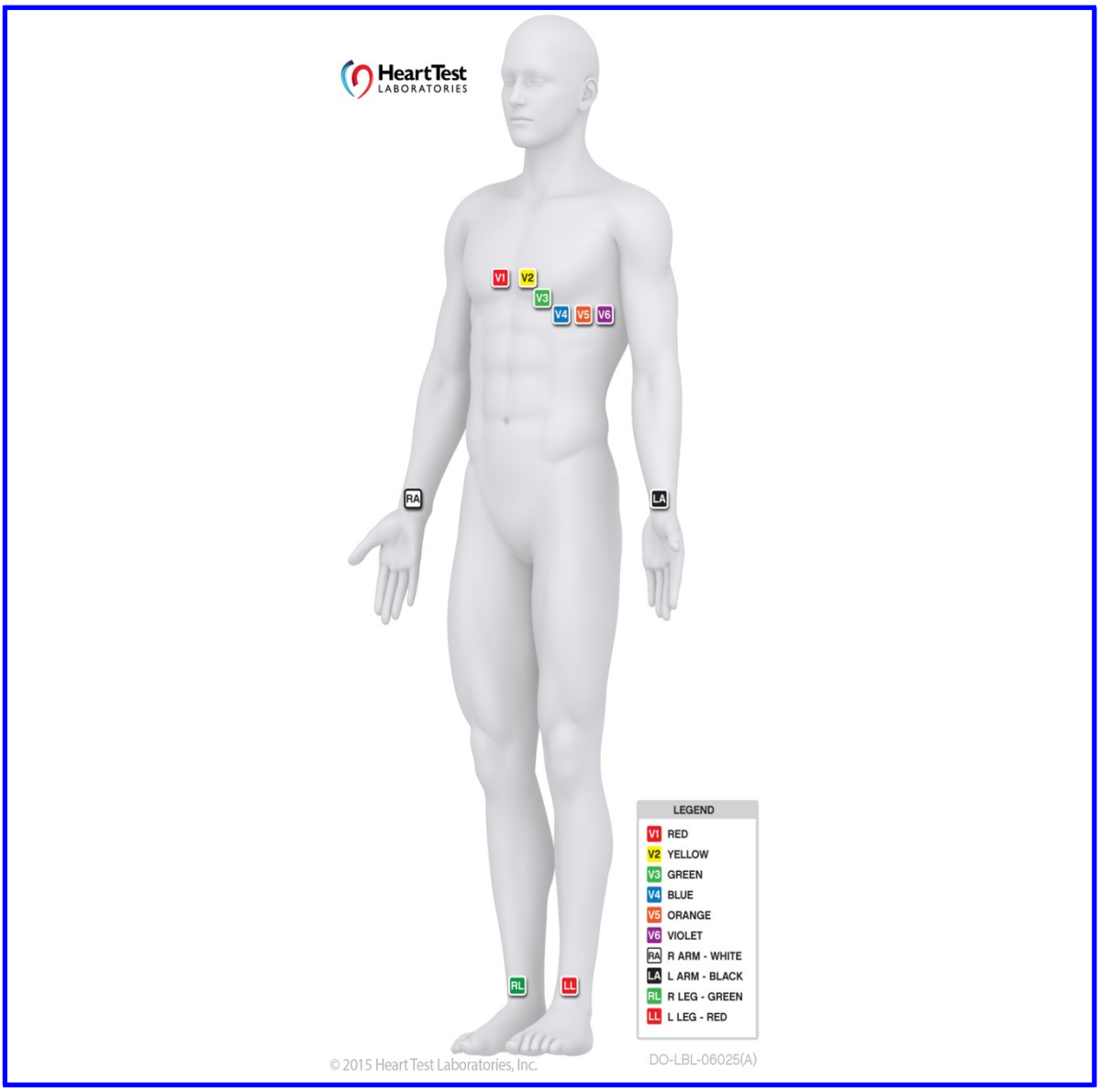


Figure 5-1. AHA Diagnostics ECG Electrode Chest and Appendages Placement

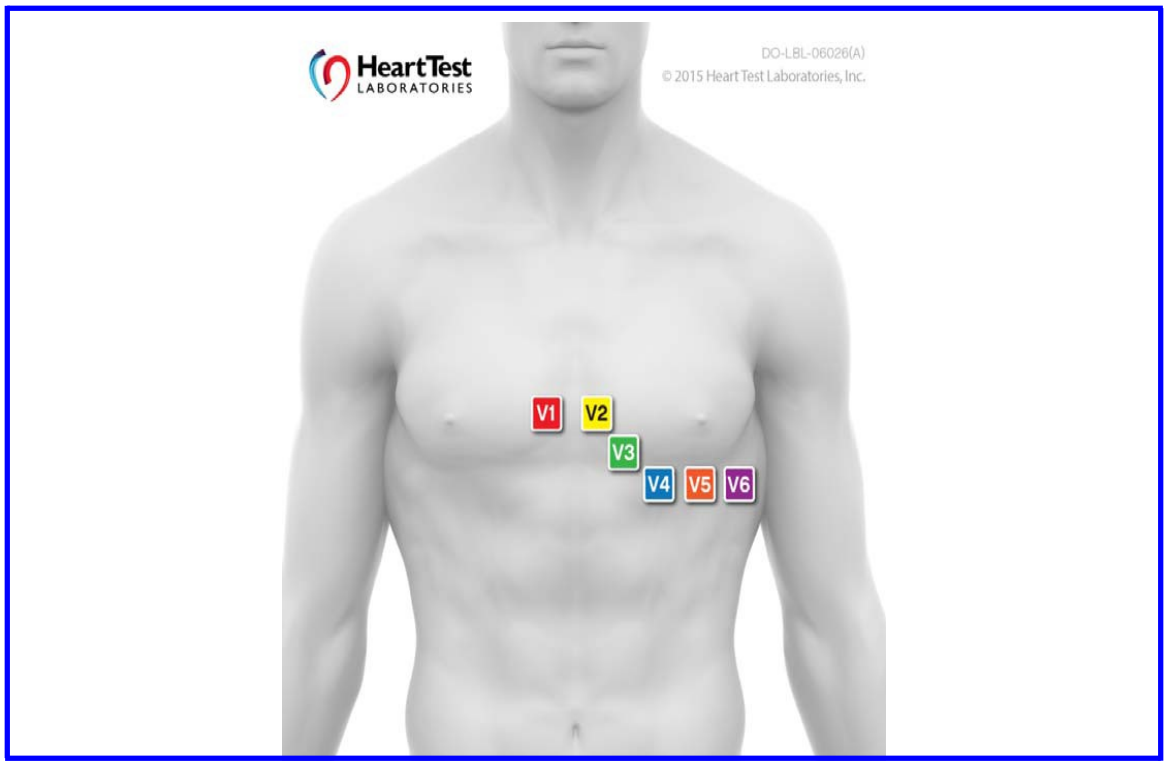


Figure 5-2. AHA Diagnostics ECG Electrode Chest Placement

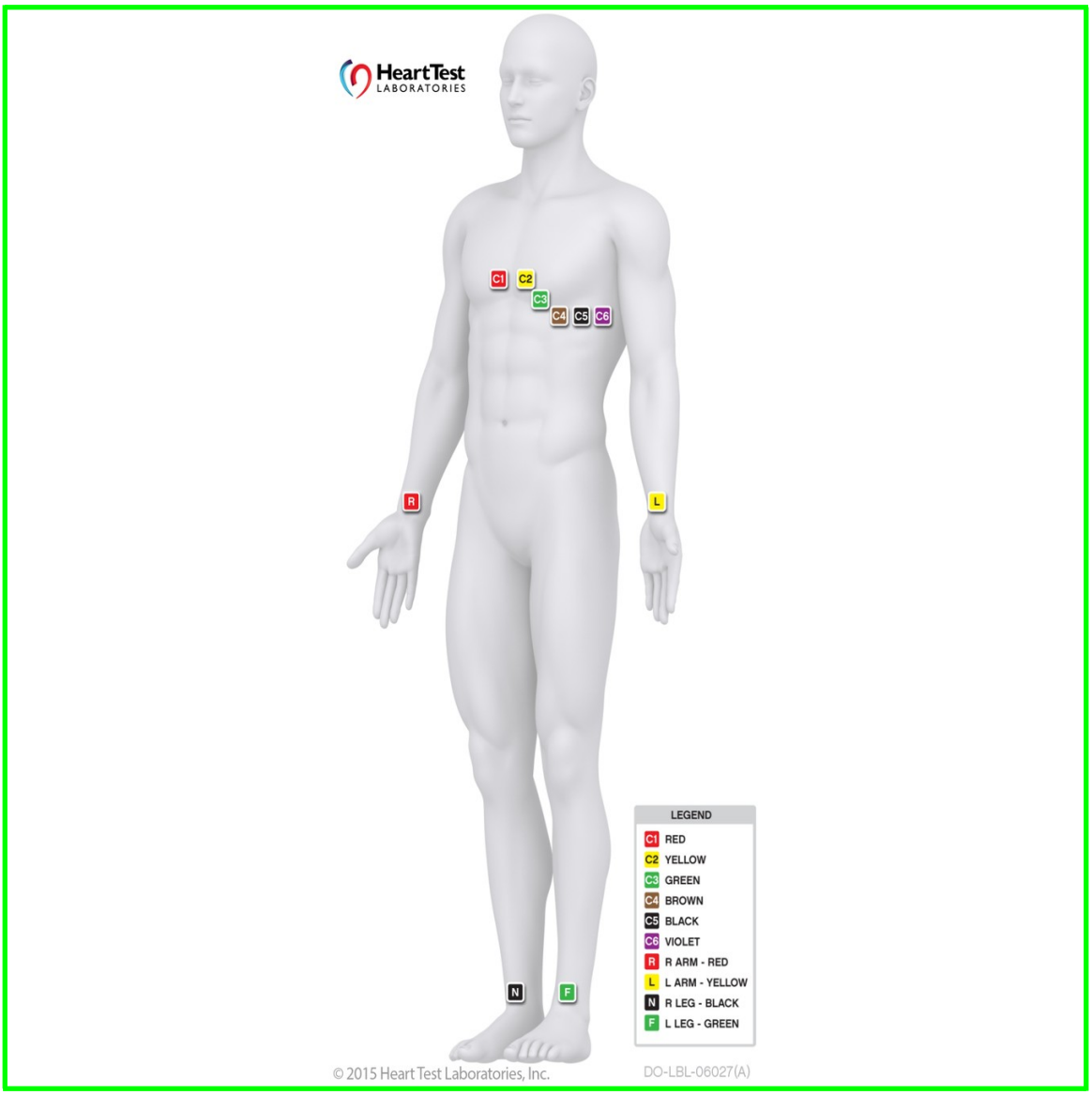


Figure 5-3. IEC Diagnostics ECG Electrode Chest and Appendages Placement

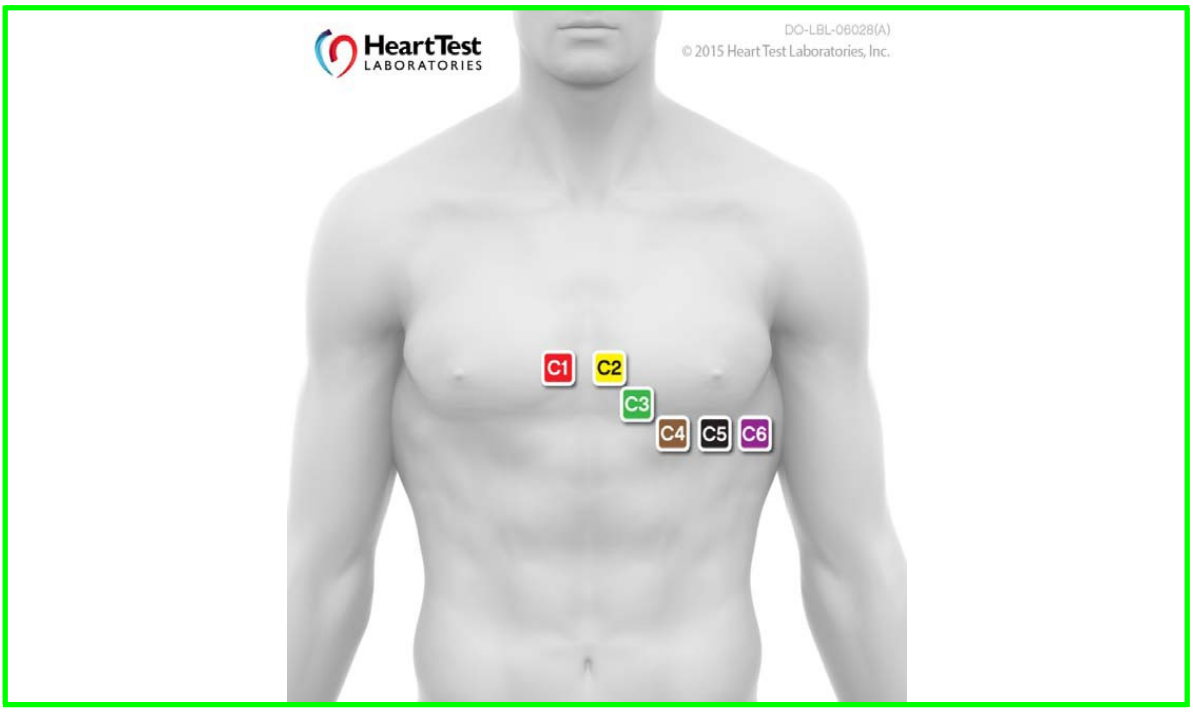


Figure 5-4. IEC Diagnostics ECG Electrode Chest Placement

Electrode Colors

Table 5-1. AHA Electrode Identification

System	Electrode ID	Color Code
Limb Leads	RA	White
	LA	Black
	RL	Green
	LL	Red
Wilson Precordial	V1	Red
	V2	Yellow
	V3	Green
	V4	Blue
	V5	Orange
	V6	Purple

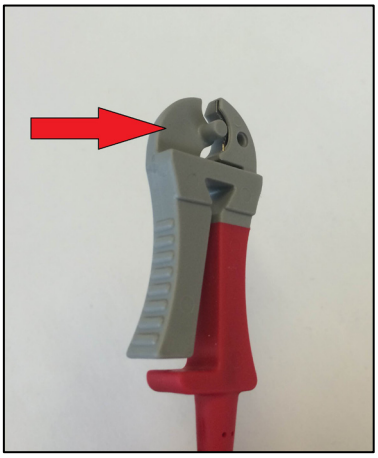
Table 5-2. IEC Electrode Identification

System	Electrode ID	Color Code
Limb Leads	R	Red
	L	Yellow
	F	Green
	N	Black
Wilson Precordial	C1	Red
	C2	Yellow
	C3	Green
	C4	Brown
	C5	Black
	C6	Purple

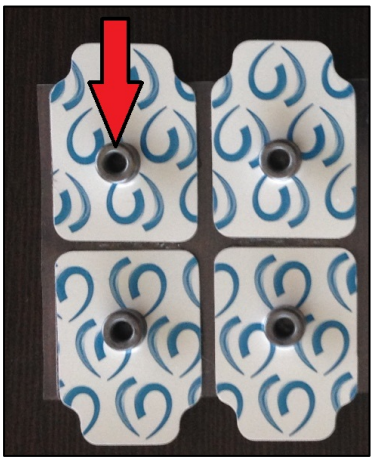
Connecting Electrodes to Leads

Use the following procedure to connect the electrodes to the leads.

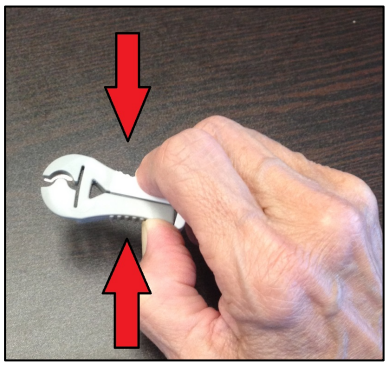
1. To attach the MyoVista patient cable to the Heart Test Laboratories Hollow Snap Electrodes, find the peg on the end of the grabber.



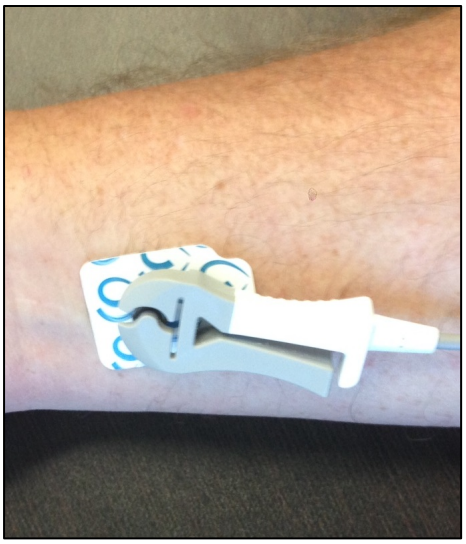
2. Align the grabber peg with the center hole of the Hollow Snap Electrodes.



3. Squeeze to open the claws of the grabber.



4. Place the peg in the Center Ridge Hollow Snap, and then release the grabber.



Home Screen

This section describes the MyoVista DG-200 graphical user interface (GUI) software.

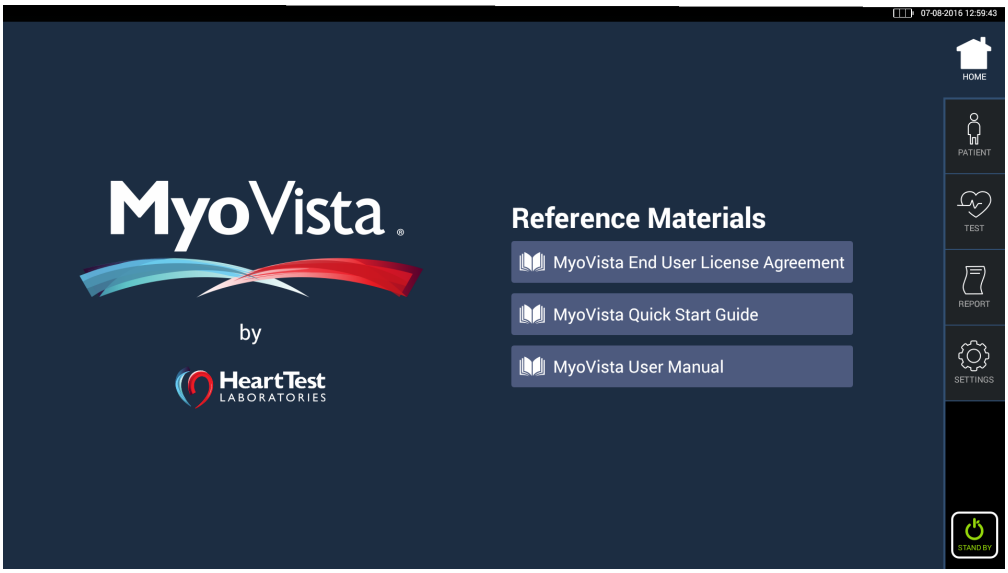


Figure 5-5. Home Screen

Table 5-3 describes the buttons in the right toolbar and the **Reference Materials** buttons with their active links.

Table 5-3. Home Screen Legend

Button	Button Name	Description
	Home	Returns you to the Home screen from any other screen.
	Patient	Opens the patient screen.
	Test	Opens the Test screen.
	Report	Opens the Report screen.
	Settings	Opens the Settings screen.
	Standby	Places device in Standby mode and turns the screen black.
	Quick Start Guide	Opens the Quick Start Guide on the Home screen.
	MyoVista User Manual	Opens the MyoVista DG-200 User Manual on the Home screen.

Common Buttons

Table 5-4 describes frequently used buttons.

Table 5-4. Common Buttons

Button	Description
	Saves the current screen information.
	Cancels the operation and closes the screen without savingnew information.
	Closes the screen.
	Continues the current operation.

Keyboard

Figure 5-6 shows the touchscreen keyboard primary function keys and Table 5-5 describes them.

Note: If you prefer using an external keyboard, connect one to a MyoVista DG-200 USB port.

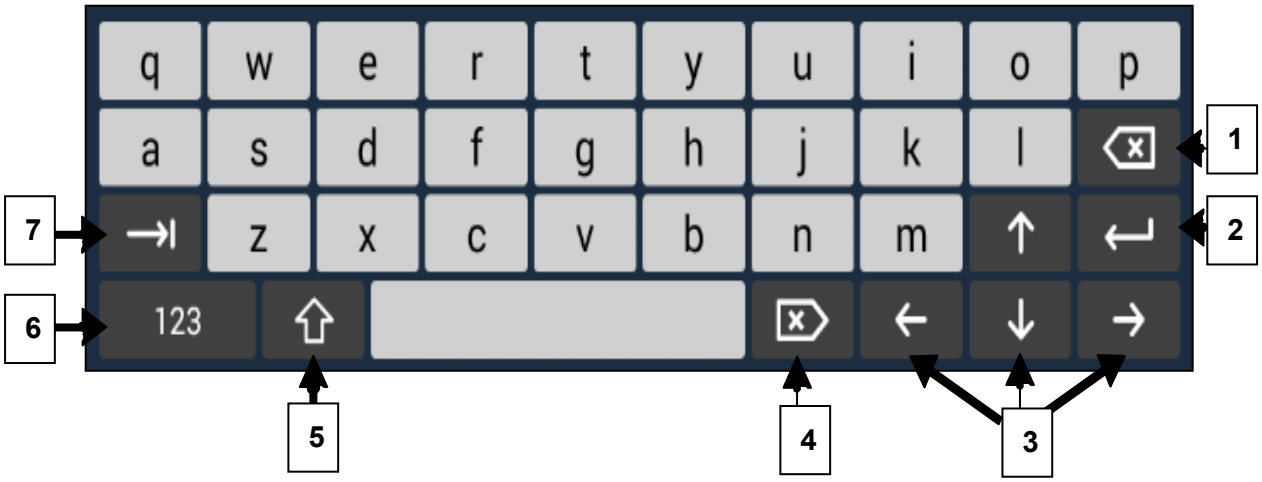


Figure 5-6. Touchscreen Keyboard

Table 5-5. Touchscreen Keyboard Legend

Callout	Description
1	Backspace Deletion key
2	Enter key
3	Up, Down, Right, Left arrow keys
4	Forward Deletion key
5	Shift/Caps Lock key: Select this key one time to activate Shift (only one capital character) or two times to activate Caps Lock. All typed characters are capitalized until turned off by selecting the button twice.
6	Number key: Displays numeric keypad and other non-alpha characters.
7	Tab key

Patient Screen

Using the Patient screen, you can:

- Add a new patient record. See “Adding a New Patient” on page 50.
- Select a patient. See “Selecting a Patient” on page 52.
- Search patients. See “Searching for a Patient” on page 52.
- Edit a patient record. See “Editing Patient” on page 53.
- Delete a patient record. See “Deleting a Patient” on page 54.

Displaying the Patient Screen

To display the Patient screen:

- From the toolbar on the right, select the **Patient** soft button.

  OR

- Below the screen, select the **Patient** hard button.

Note: There may be more patient records than shown on the display. To view additional patient records, swipe vertically to scroll through the patient records list.

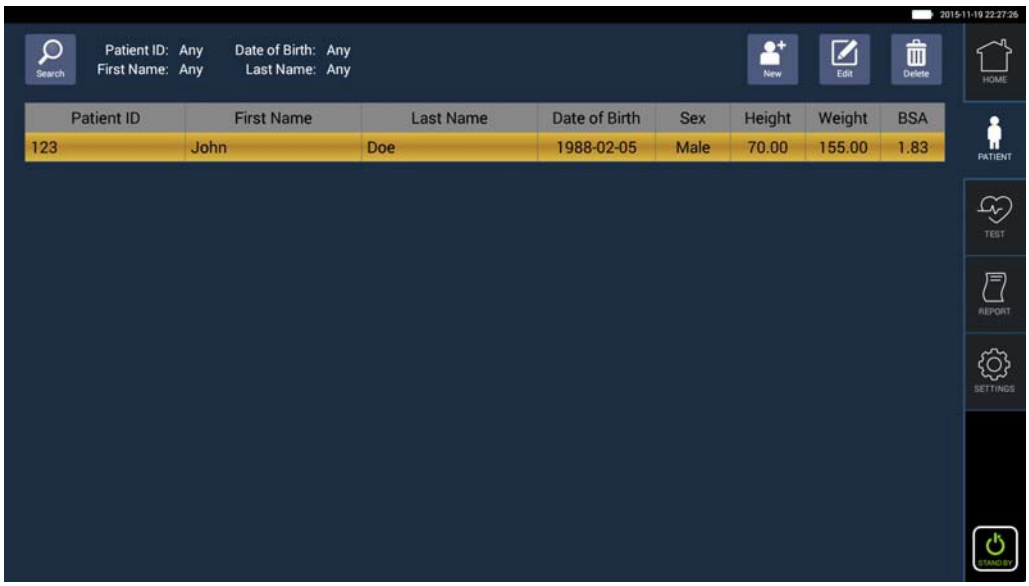


Figure 5-7. Patient Screen

Table 5-6 describes the buttons on the Patient screen.

Table 5-6. Buttons on the Patient Screen

Button	Button Name	Description
	New Patient	Adds a new patient record. See the procedure below.
	Edit Patient	Edits a patient record. See page 53.
	Delete Patient	Deletes a patient record. See page 54.
	Patient Search	Searches for a patient record based on selected criteria. See page 52.

Adding a New Patient

To add a new patient:

1. Select the **New Patient** button. The New Patient screen appears.

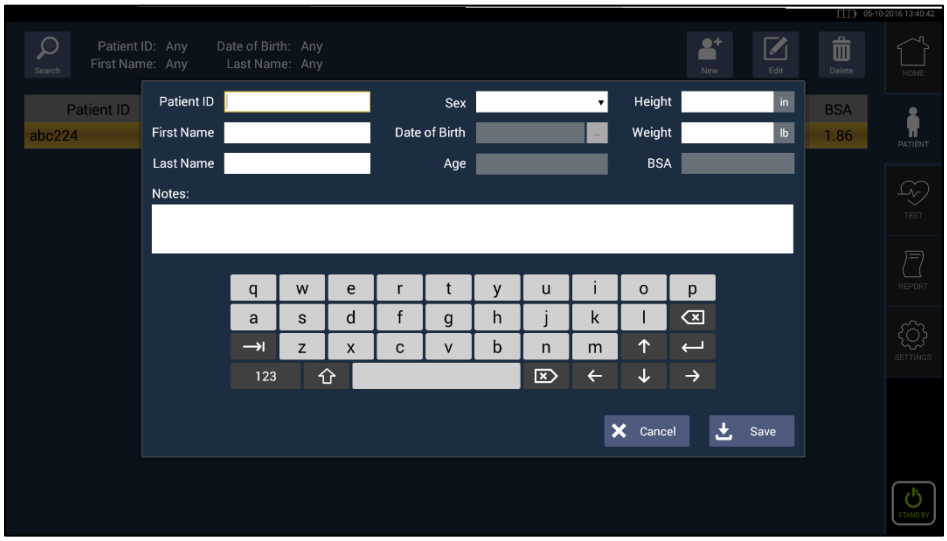


Figure 5-8. New Patient Screen

2. Enter the following patient information:

Field	Description
Patient ID	Enter a unique identification number for the patient: numeric, alpha, or alphanumeric. We recommend you use the patient medical record number MRN. This field is required. The system prevents you from creating duplicate patient IDs. If you receive a warning dialog, confirm that the data you entered is correct. You can search for the existing record using the Search function (see "Searching for a Patient" on page 52).
First Name	Enter the first name of the patient.
Last Name	Enter the last name of the patient.
Sex	Select the patient's gender. This field is required. Choices are: • Female • Male
Date of Birth	Enter the patient's date of birth. This field is required.
Age	Age of the patient. The software calculates this value automatically.
Height	Enter the height of the patient. This field is required. To change between English and metric units, press the unit at the right side of the field.
Weight	Enter the weight of the patient. This field is required. To change between English and metric units, press the unit at the right side of the field.
BSA	The software calculates this value automatically. • BSA (based on the Mosteller formula) • Mosteller formula (U.S. customary units): BSA = $\sqrt{\frac{\mathbf{Height(in)x\ Weight(lbs)}}{\mathbf{3131}}}$ • Mosteller formula (metric): BSA = $\sqrt{\frac{\mathbf{Height(cm)x\ Weight(kg)}}{\mathbf{3600}}}$
Notes	Enter any medical notes.

3. Select the **Save** button or select **Cancel** to not save the record.



Figure 5-9. Example of Patient Screen with New Record

Selecting a Patient

From the Patient screen, you can select a patient record or scroll through the patient database to find a patient record. To select a record, press or select anywhere on the patient entry.

Searching for a Patient

To search for a patient:

1. On the Patient screen, select the **Patient Search** button. The Search Conditions screen appears.



Figure 5-10. Search Conditions Screen

2. Enter the appropriate search criteria.
3. Select the **Search** button to start searching (or select **Cancel** to cancel the search). A patient search results screen shows only the records that meet your search criteria.
4. To select a patient, select anywhere on the patient entry. The selected patient appears in the Patient Selected screen (see Figure 5-11). If no matching patient records are found, the following message appears:

   No records found!

5. Select the **OK** button to return to the patient screen.



Figure 5-11. Patient Selected Screen

Editing Patient Information

To edit patient information:

1. On the Patient screen, select the record of the patient you want to edit.
2. Select the **Edit Patient** button. The Edit Patient screen appears.

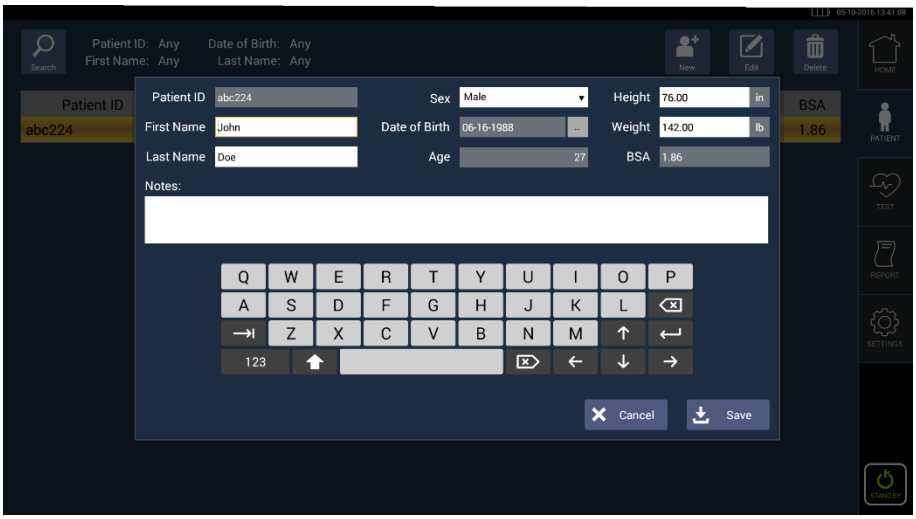


Figure 5-12. Edit Patient Screen

3. Edit the following: **First Name**, **Last Name**, **Sex**, **Date of Birth**, **Height**, **Weight**, and **Notes**.
4. Select the **Save** button to save the changes or select **Cancel** to discard them.

Deleting a Patient

The following procedure describes how to delete a patient.

Note: When you delete a patient, all the records associated with the patient are removed from the device.

1. On the Patient screen, select the record of the patient you want to delete.
2. Select the **Delete Patient** button. The following message appears:

   Permanently Delete Patient from Database?

3. Select the **Yes** button to delete the record or select **No** to retain it.

Test Screen

Using the Test screen, you can:

- Set test parameters. See “Setting Test Parameters” on page 56.
- Run a test. See “Running a Test” on page 57.
- Re-synchronize the waveforms. See “Resyncing the Waveforms” on page 59.

Note: To access the Test screen, you must first select a patient record. The device prompts you to select a patient before performing a test.

Displaying the Test Screen

To display the Test screen:

- From the screen menu on the right side, select the **TEST** tab.

  OR

- Below the screen, press the **Test** button.



Figure 5-13. Test Screen

Note: We recommend enabling an A/C line-frequency filter in the Settings screen. Enabling this option may require 10 seconds for traces to stabilize.

Test Screen Buttons

Table 5-7 describes the buttons on the Test screen.

Table 5-7. Buttons on the Test Screen

Button	Button Name	Description
	Settings	Sets the test parameters. See page 56.
	Start Test	Starts a test. See page 57.
	Stop Test	Stops a test; this button appears after a test starts. See page 57.
	Test Countdown	Displays a countdown timer for test completion.
	Re-Sync	Re-syncs waveforms. See page 59.
	Re-Sync Countdown Time	Shows a countdown timer until waveforms are re-synced.

Setting Test Parameters

To set test parameters:

1. On the Test screen, select the **Settings** button. The Test Time Setup screen appears, with the test parameter displayed.

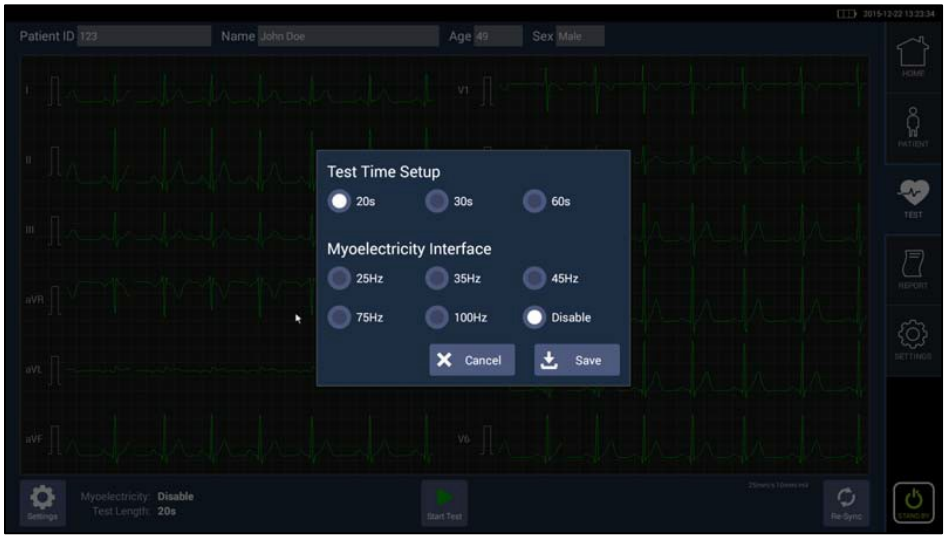


Figure 5-14. Test Time Setup Screen

2. On the screen, under **Test Time Setup**, select a test duration: **20s**, **30s**, or **60s**.
3. If necessary, under the **Myoelectricity Interface**, select an option: **25Hz**, **35Hz**, **45Hz**, **75Hz**, **100Hz**, or **Disable**.

Caution: The Myoelectricity Interface filter might impact the results of the Icon and Index calculations by reducing the amount of biologics data that the algorithms have available. We do not recommend using a filter for this setting unless absolutely necessary.

4. Select the **Save** button to save the settings or select **Cancel** to discard them.

Note: When a new patient is selected, these settings return to their default values.

Running a Test

Before running any test:

- Be sure waveforms have been given at least 10 seconds to stabilize from the point when the patient was connected properly to the device.
- Confirm the patient's name, date of birth, and gender.

Caution: Having the correct date of birth and gender are critical to the MyoVista algorithms and must be confirmed as accurate before running the test.

- Be sure there is sufficient battery power to complete test.
- Check the adequacy of ECG waveforms prior to running a test. Perform any necessary corrections to resolve any noise or other problems with the input signal.

At any point during testing, the MyoVista DG-200 warns if the cables or electrodes are not connected adequately by displaying lead-off indicators and causing the lead label to blink red to indicate that the respective lead needs attention (see Figure 5-15).

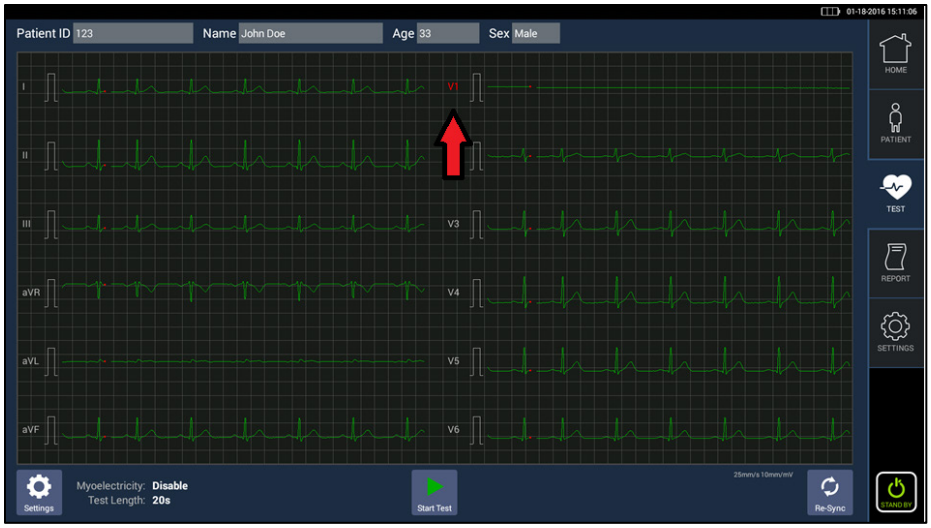




Figure 5-15. Lead Off



Figure 5-16. Test Screen

1. On the Test screen, select the **Start Test** button. The test begins, a countdown timer appears, and the **Start Test** button changes to **Stop Test**. When the test completes, the Report screen appears.



Caution: If power is lost or interrupted during testing, discard test results. Do not change power source (i.e., switch from AC to battery), disconnect the power, or power down the device during a test.

2. To stop a test:

   a. Press the **Stop Test** button. The following message appears:

   The test results were not saved. Select the OK button to continue.

   b. Select the **OK** button to cancel the test and discard the collected data.

Resyncing the Waveforms

If you observe a problem or misrepresentation of the data on the screen, resync the waveform. Re-syncing the waveforms dissipates DC-bias between the patient and the device, and re-centers the traces in the trace areas.

1. On the Test screen, select the **Re-Sync** button. The **Re-Sync** button changes to a countdown timer. When the countdown timer reaches 0, the waveforms are re-synced.

Report Screen

Using the Report screen, you can:

- Print a patient test report. See “Printing a Patient Test Report” on page 61.
- Export a test report. See “Exporting a Test Report in PDF Format” on page 64.
- Delete a test report. See “Deleting a Test Report” on page 65.

Caution: To ensure accuracy, verify all data on the report, including patient height, weight, and units of measurement.

Displaying the Report Screen

The Report screen appears after a test completes successfully.

To manually navigate to the Report screen:

- From the screen menu on the right side, press the **Report** soft button.

  OR

- Below the screen, press the **Report** hard button.

Note: To access the Report screen, you must first select a patient record. The device prompts you to select a patient before viewing a report.

ECG and MyoVista color waveforms in reports are interactive. To view:

- Other time segments, scroll through the report by swiping horizontally across the device surface on the appropriate lead's data.
- Waveform data from other leads, swipe vertically across the device surface. To change viewable lead, select the drop-down lead icon on the left side of the waveform.

The drop-down box in the top-right corner allows you to view previous reports from the selected patient. Reports are labeled by date and time.

Use the scale to the left of the MyoVista Color waveform to interpret the scale intensity. The Energy Category appears at the top-right side of the active window. The ventricular indices appear below the energy category. For more information about interpreting the MyoVista Informatics, see “MyoVista Informatics” on page 23. If the Glasgow Analysis report area has off-screen text, use swiping motions in that area to scroll and view the text.

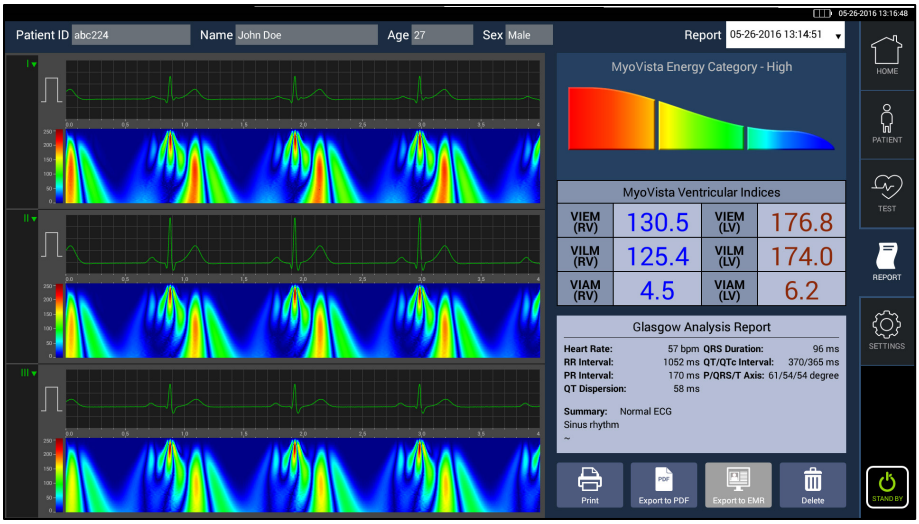


Figure 5-17. Report Screen

Report Screen Buttons

Table 5-8 describes the buttons on the Report screen.

Table 5-8. Buttons on the Report Screen

Button	Button Name	Description
	Print	Prints a patient test report. See page 61.
	Export to PDF	Exports a patient test report to PDF format. See page 64.
	Delete	Deletes a patient test report. See page 65.

Printing a Patient Test Report

When printing a patient test report, observe the following guidelines:

- Before printing a report, select a direct USB printer or a network-based printer. See “Configuring Printing Setting” on page 73.
- To protect patient privacy, do not print to a shared, unmonitored, or remote printer.
- Do not change power source (i.e., switch from AC to battery), disconnect power, or power down the device while printing.
- Print quality varies and should be considered when viewing a report. If print quality is poor, use the MyoVista on-screen report or an external high-definition monitor.

To print a test report:

1. Select the **Print** button. The Print Preview Settings screen appears.

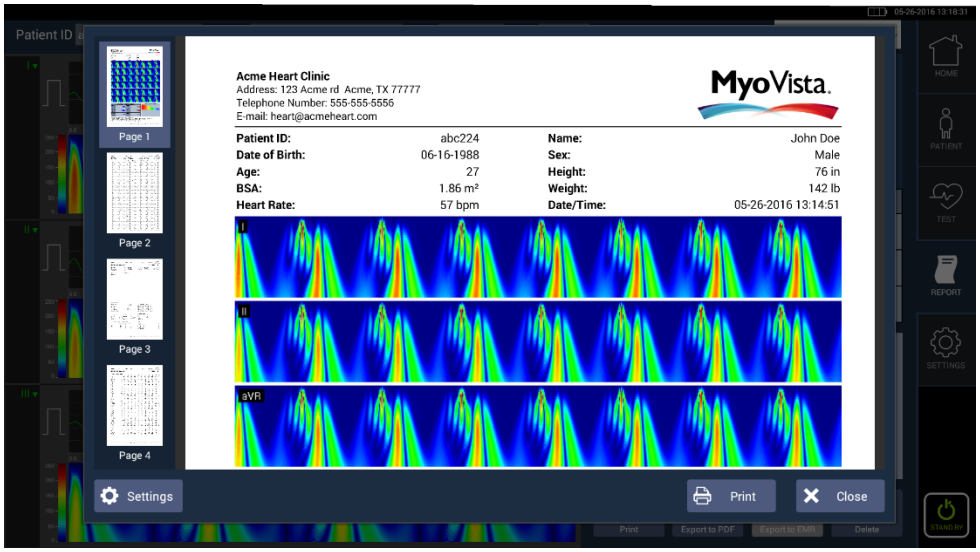


Figure 5-18. Print Preview Settings Screen

2. Select **Settings**. The Report Settings screen appears.

Note: If you change print settings, the changes apply to the current report only and are not saved. If you print a new report, reconfigure the print settings for the new report.

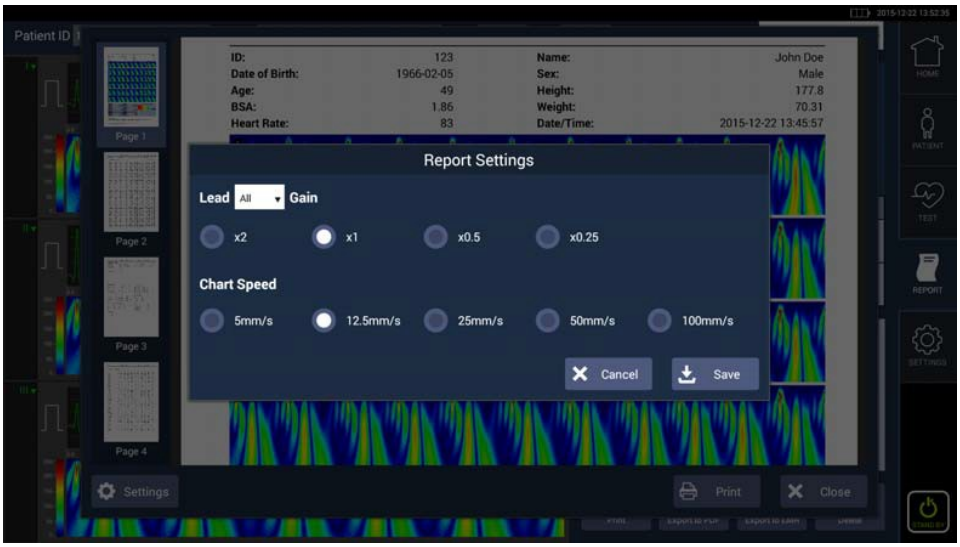


Figure 5-19. Report Settings Screen

The gain option affects the vertical scale of the ECG traces. This scale represents the amplitude in millivolts (MV) per division on the grid. For each lead, the gain setting is displayed to the left of the waveform.

Selecting **All** from the **Lead Gain** drop-down menu activates the **All Gain** option button, as shown in Figure 5-19. The default option for the Lead Gain setting is **x1**.

3. Select a **Gain** setting: **x2, x1, x0.5,** or **x0.25**.
4. Under **Chart Speed**, select a setting: **5mm/s**, **12.5mm/s**, **25mm/s**, **50mm/s**, or **100mm/s**.
5. Select the **Save** button to save the print report settings or select **Cancel** to discard them.
6. Select **Print**. When a list of configured printers appears, select the appropriate printer, and then select **Print**.

   The Printing Screen and progress bar appear, as shown in Figure 5-20. If no problems are encountered, the Print Settings screen appears after the device sends the report to the printer. The following message confirms that the data was sent to the printer:

Print successful

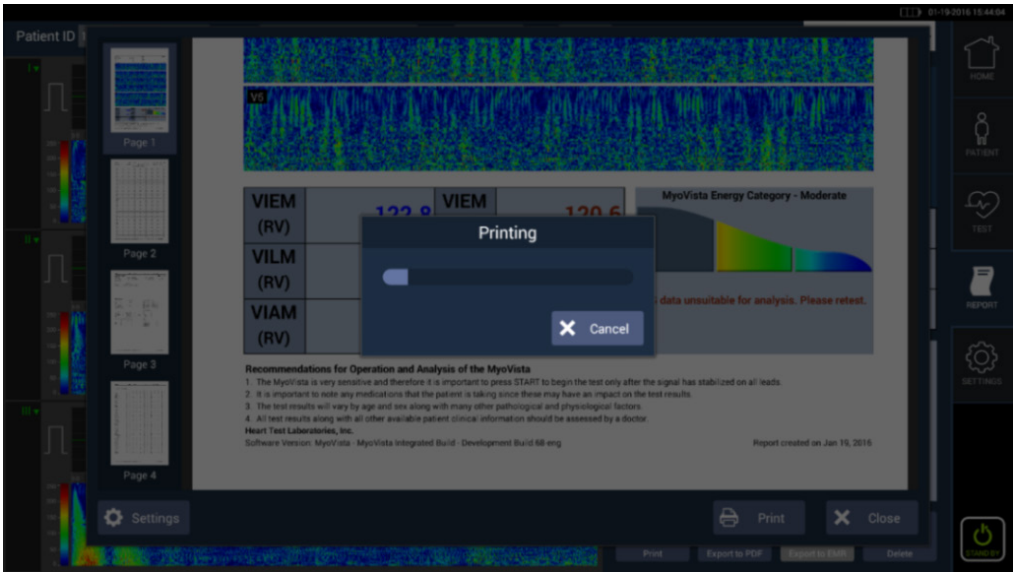


Figure 5-20. Printing Screen with Progress Bar

Exporting a Test Report in PDF Format

The following procedure describes how to export a test report to PDF format. This procedure requires a USB storage device.

Observe the following guidelines when attaching a USB storage media:

- The USB storage media must be connected directly to one of the device's USB ports. The MyoVista-DG-200 might not recognize USB devices connected through a USB hub.
- The MyoVista-DG-200 accesses only the first supported partition of a USB storage media's main (root) directory. We recommend you use blank media for all USB functions and avoid using storage media with formatted partitions.
- If multiple USB storage media are connected, select one from the drop-down menu. For information about USB mapping, see "System Overview" on page 27.

To export a test report in PDF format:

1. Insert a USB storage media into a USB port on the MyoVista DG-200.
2. Select the **Export to PDF** button. The Export PDF screen appears, as shown in Figure 5-21.

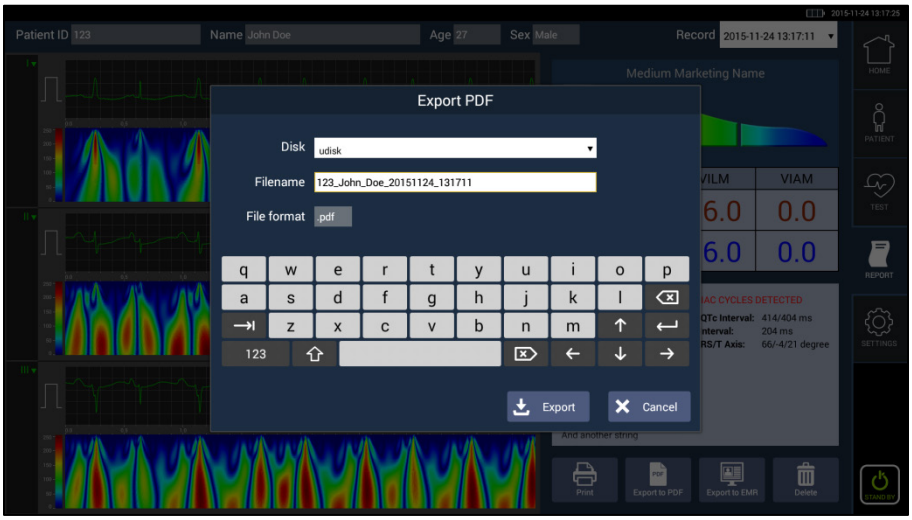


Figure 5-21. Export PDF Screen

3. The **Filename** field is populated automatically. However, you can change this value if desired.
4. Select **Export**. If the PDF exports successfully, the following message appears:

The report export succeeded.

Deleting a Test Report

To delete a test report:

1. On the Report screen, select the record of the patient to delete.
2. Select the **Delete** button. The following message appears:

   Delete the current report?

3. Select the **Yes** button to delete the report or select **No** to cancel.

Settings Screen

Using the Settings screen, you can change:

- System settings. See “Configuring System Settings” on page 67.
- ECG settings. See “Configuring ECG Settings” on page 81.
- User settings. See “Configuring User Settings” on page 83.

Displaying the Settings Screen

To display the Settings screen, from the screen menu on the right side, select the **SETTINGS** tab.



Figure 5-22. Settings Screen

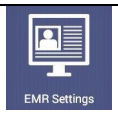
Identifying the Current Software and Firmware Versions

The software version appears at the lower left side of the Settings screen. The ECG board firmware version appears at the lower right side of the Settings screen. As shown by the arrows on figure 5-22.

Settings Screen Buttons

Table 5-9 describes the buttons on the Settings screen.

Table 5-9. Buttons on the Settings Screen

Button	Button Name	Description
System Settings (page 67)		
	Update/Factory Reset	Updates software to a newer version, updates the Home page documentation, restores device settings to factory defaults, and displays the current software version. See page 69.
	Network	Displays the current network connection and allows you to configure wireless network settings. See page 71.
	Printing	Configures printer settings. See page 73.
	Database	Displays database information, backs up the current database on external storage media, and deletes and restores the database. See page 75.
	Date/Time	Sets the system date and time. See page 68.
	Auto-Standby	Sets the timer that places the device in standby mode automatically. See page 79.
	EMR	This feature is disabled.
	Display Brightness	Configures screen brightness. See page 80.
ECG Settings (page 81)		
	Filters	Sets Line and Myoelectricity Interface filter default settings. See page 81.
	ECG Trace Color	Sets ECG lead trace color and grid brightness. See page 82.
	Test Length	Sets the test length default.

Button	Button Name	Description
User Settings (page 83)		
	Language	Sets the device language. See page 84.
	Clinic Information	Used to input clinic information. See page 83.
	Patient Units	Sets the default displayed measurement units for patient height and weight. See page 85.

Configuring System Settings

The following sections describe how to:

- Change the system's date and time settings. See "Changing the Date/Time Settings" on page 68.
- Update the system software. See "Updating System Software" on page 69.
- Restore factory default settings. See "Restoring the Device to the Factory Default Settings" on page 70.
- Configure network settings See "Configuring Network Settings" on page 71.
- Configure printer settings. See "Configuring Printing Setting" on page 73.
- Configure database settings. See "Configuring Database Settings" on page 75.
- Configure auto-standby settings. See "Configuring Auto-Standby Setting" on page 79.
- Configure display brightness. See "Configuring LCD Brightness Setting" on page 80.

Changing the Date/Time Settings

To change the system's date and time settings:

1. Under **System Settings**, select the **Date/Time** button. The Date/Time screen appears, as shown in Figure 5-23.



Figure 5-23. Date/Time Screen

2. Select the appropriate date or time settings field: **MONTH**, **DAY**, **YEAR**, **HOUR**, and **MINUTE**.
3. Modify the information using the touchscreen keypad.
4. Repeat steps 2 and 3 to modify each field.

Note: After you change the value in a field, the device moves to the next field automatically.

5. Select **AM** or **PM**. The keypad displays only the **AM** and **PM** keys.
6. Select one of the following date formats to change the date order:
   - **MM-DD-YYYY** (Month Day Year)
   - **DD-MM-YYYY** (Day Month Year)
   - **YYYY-MM-DD** (Year Month Day)
7. Select the **Save** button to save the modified settings or select **Cancel** to discard them.

Updating System Software

The following procedure describes how to update the system software. When you update the software, all patient data and relevant user settings are preserved.

Before you update system software, observe the following guidelines:

- Do not remove power from the device until the update process completes.

⚠ **Caution:** Do not turn off the device during a system update; otherwise, it can render the MyoVista DG-200 inoperable. System updates should be performed by authorized service representatives.

1. Under **System Settings**, select the **Update/Factory Reset** button. The Update/Factory Reset screen appears, as shown in Figure 5-24.



Figure 5-24. Update/Factory Reset Screen

2. Select **Update Software**. The following message appears:

A system update will upgrade your device with a new version of the software. All patient data and relevant user settings will be preserved.

3. Select the **Continue** button to proceed or select **Cancel** to stop the update. If you select **Cancel**, the following message appears:

The system update has been aborted.

4. Select **OK**. The Update/Factory Reset screen appears.

Restoring the Device to the Factory Default Settings

The factory reset function resets device and user settings to the factory default and removes all patient data. It does not change the MyoVista DG-200 software version. During this procedure, you have the option to back up the database.

Warning: Do not remove power from the device until the update/factory reset process completes.

To restore the MyoVista DG-200 to factory default settings:

1. Under **System Settings**, select the **Update/Factory Reset** button. The Update/Factory Reset screen appears (see Figure 5-24 on page 69).
2. Select the **Factory Reset** button. The following message appears:

   A factory reset will erase the database. Do you want to back it up?

3. To back up the database before restoring factory defaults, select the **Backup** button. Otherwise, select the **Skip** button to go directly to the factory restore operation. Selecting **Cancel** closes the screen without restoring the factory default settings.
   - If you select **Backup**, you are prompted to complete a database backup. After this function is performed, you are prompted to proceed and erase data or cancel the operation. See “Backing Up a Database” on page 76.
   - If you select **Skip**, you are prompted to proceed and either erase data or cancel the operation.
     - If you select **Cancel**, the factory reset operation ends, the following message appears, and you should select **OK** to return to the Update/Factory Reset screen:

       The Factory Reset operation has been aborted

     - If you select **Proceed and Erase Data**, the device reverts to factory default settings.

Configuring Network Settings

Note: We recommend you connect to secured wireless networks only.

Network Status

Under **System Settings**, select the **Network** button. The Network screen shows the current network status:

- If a wired Ethernet connection is in use, the wired network information is shown.



Figure 5-25. Wired Network Screen

- If wireless networks are available, they are shown.

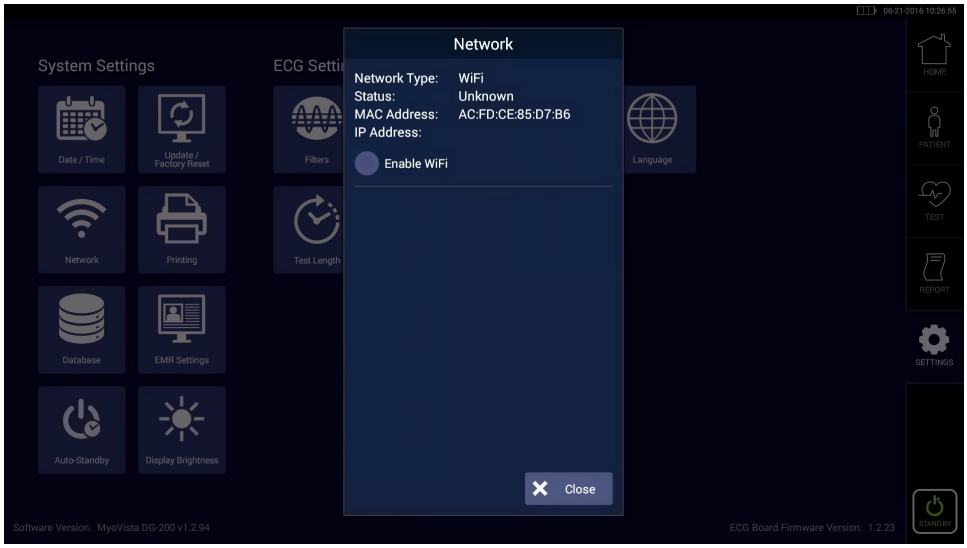


Figure 5-26. Wireless Network Screen

Selecting a Wireless Network

To select a wireless network:

1. Under **System Settings**, select the **Network** button. The Network screen appears, as shown in Figure 5-26.

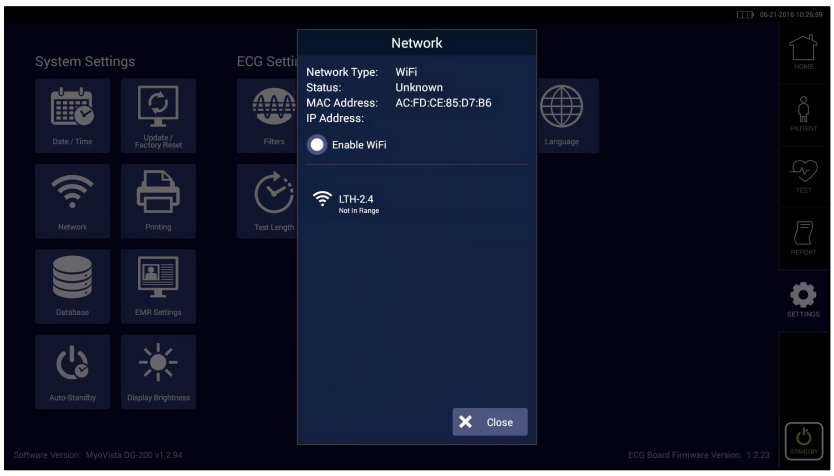


Figure 5-26. Network Screen

2. Select **Enable WiFi**. A list of available wireless networks appears.
3. Select a wireless network. If the selected network is protected, enter the Wi-Fi password in the password screen, and then select the **Connect** button. The Network screen appears.



Figure 5-27. Entering a Password

4. Select the **Save** button to the save the Wi-Fi connection settings.
5. Select close to return to the settings screen.

Configuring Printing Settings

Note: Before a network-based printer can be connected, a network must be configured properly. See “Configuring Network Setting” on page 71.

Selecting a Printer

1. Under **System Settings**, select the **Printing** button. The Printing screen appears, as shown in Figure 5-28.

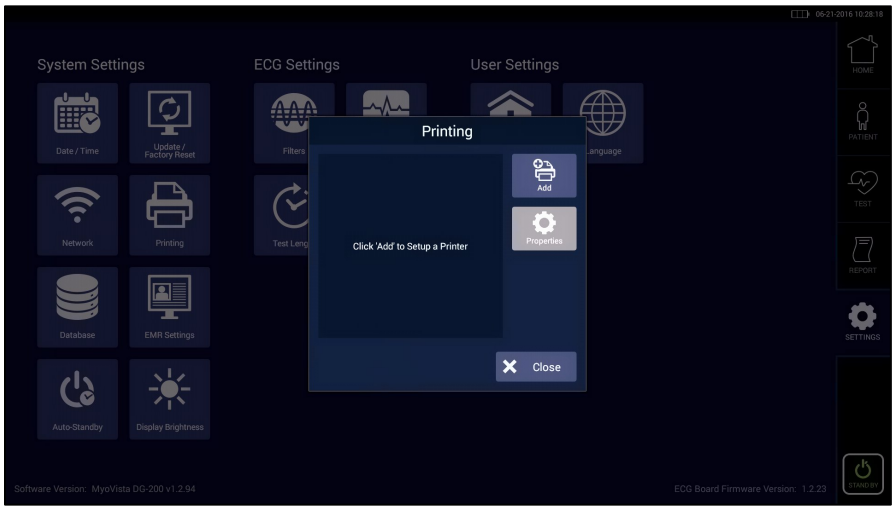


Figure 5-28. Printing Screen

2. Select a printer or select the **Add** button to add a new printer. If you select **Add**, the Add Printer screen in Figure 5-29 appears.

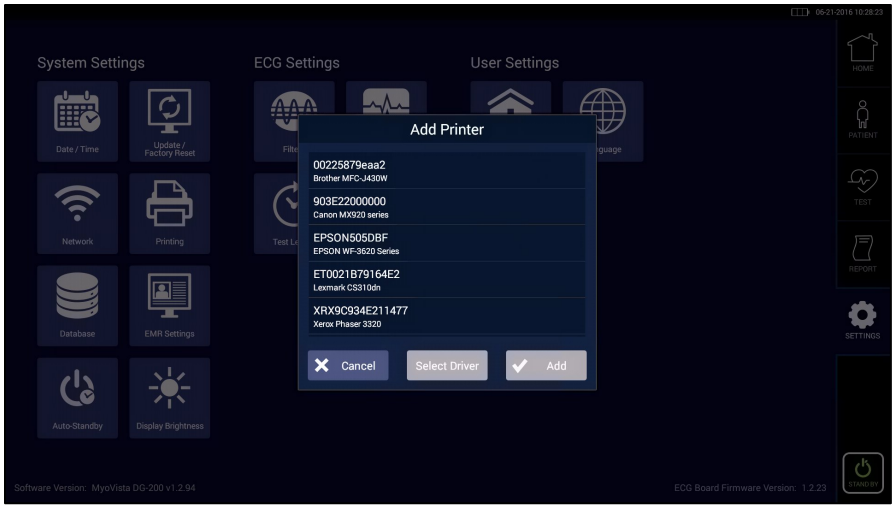


Figure 5-29. Add Printer Screen

3. From the Add Printer screen, select the printer you want to use, and then press the **Add** button. A dialog box confirms that the printer was set up successfully.

Note: If the printer selection fails, select a driver manually using the Select Driver function (see Figure 5-30). Select the first driver listed, and then press the **Add** button. If printer setup fails again, select other drivers until the printer setup succeeds.



Figure 5-30. Select Driver Screen

Configuring Database Settings

Use the procedures in this section to:

- View the current database. See “Viewing the Current Database Information” below.
- Delete the database. See “Deleting a Database” on page 76.
- Back up the database. See “Backing Up a Database” on page 76.
- Restore the database. See “Restoring a Database” on page 78.

Viewing the Current Database Information

To view information from the current database:

1. Under **System Settings**, select the **Database** button. The Database Information screen appears, as shown in Figure 5-31.



Figure 5-31. Database Information Screen

The following information appears in the screen:

- **Database space** = size of the database.
- **System disk free space** = amount of available storage space.
- **Total Patient Count** = total number of patient records.
- **Total Test Report Count** = total number of patient test reports.

2. Use the buttons in the screen as required (see Table 5-10).

Table 5-10. Buttons on the Database Information Screen

Button	Button Name	Description
	Delete Database	Removes the current patient database. See page 76.
	Backup Database	Creates a database backup to external media. See page 76.
	Restore Database	Restores a previously backed up database from external media. See page 78.

3. When you finish using the Database Information screen, select **Close** to close it.

Deleting a Database

To delete a database:

1. Under **System Settings**, select the **Database** button. The Database Information screen appears, as shown in Figure 5-31 on page 75.
2. In the **Database Information** screen, select the **Delete** button. The following message appears:

   The existing database will be erased. Proceed?

3. Select **Yes** to delete the database or select **No** to retain it.

Backing Up a Database

1. Under **System Settings**, select the **Database** button. The Database Information screen appears, as shown in Figure 5-31 on page 75.
2. Connect a USB storage media to a USB port on the MyoVista DG-200.

Observe the following guidelines when attaching a USB storage media:

- The USB storage media must be connected directly to the USB port. The MyoVista DG-200 might not recognize USB storage media connected through a USB hub.
- The MyoVista DG-200 accesses only the main (root) directory of a USB storage media. We recommend you use blank media for all USB functions.

- Do not move a backed-up database file into a separate directory on the USB storage media. Database files can only be restored if saved in the main (root) USB storage media directory.
- The MyoVista DG-200 recognizes only the first supported partition on a USB storage media. Do not use storage media with multiple formatted partitions.
- Store backed up databases in compliance with HIPAA controls and policies for handling sensitive patient information.
- Deleting a database deletes all patient information and reports permanently, but does not affect system and device settings.

3. Select **Backup**. The Backup Database screen appears, as shown in Figure 5-32.

Note: If multiple USB storage devices are connected, select one from the drop-down menu. For information about USB mapping, see “System Overview” on page 27.

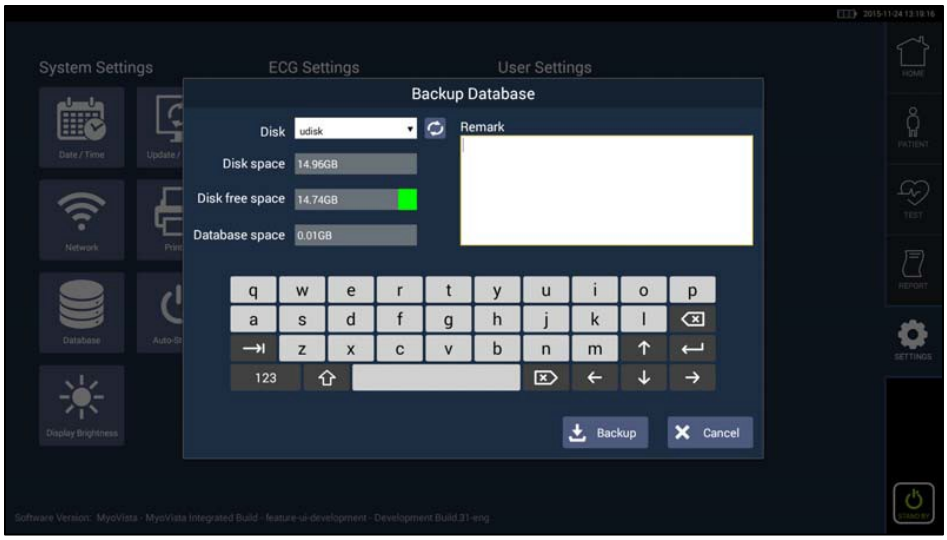


Figure 5-32. Backup Database Screen

4. Under **Remark,** add an optional note.

Tip: We recommend you add a note in the remark box to help identify the database backup correctly.

5. Select the **Backup** button to back up the existing database or select **Cancel** to not back up the database. If you select **Backup**, the following message appears:

Backup Successful

6. Select the **OK** button to display the Database Information screen or select **Cancel** to return to the Database Information screen.

Restoring a Database

Restoring a database deletes the existing database and replaces it with data from the restored database.

To restore a database:

1. Under **System Settings**, select the **Database** button. The Database Information screen appears, as shown in Figure 5-31 on page 75.
2. Connect USB storage media to a USB port on the MyoVista DG-200.

Note: If multiple USB devices are connected, select one from the drop-down menu.

3. Select **Restore**. The Restore Database screen appears, as shown in Figure 5-33.

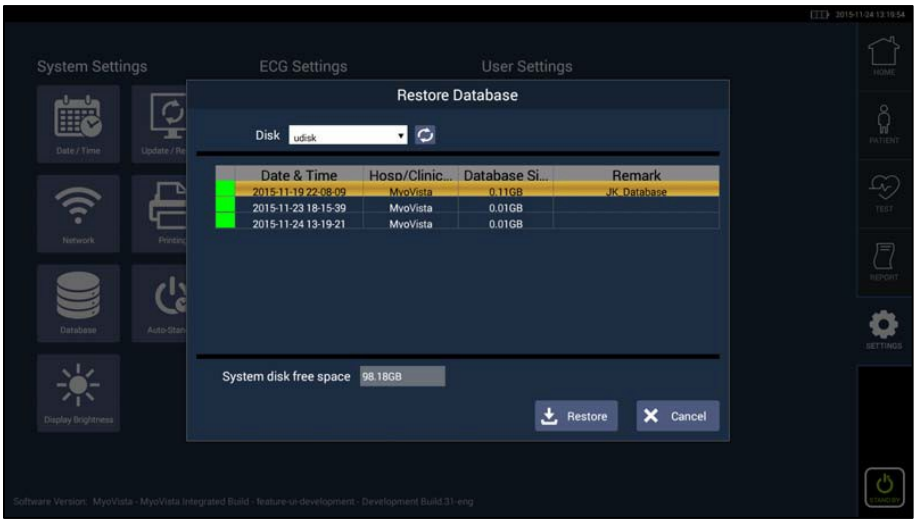


Figure 5-33. Restore Database Screen

4. In the table, select the database file to restore. Review the information in the **Remark** column to confirm that the correct database is selected.

5. Select the **Restore** button to restore the database or select **Cancel** to not restore. If you select **Restore**, the following message appears:

Restore Successful

6. Select the **OK** button. The Restore Database screen appears.

Configuring Auto-Standby Settings

To configure auto-standby settings:

1. Under **System Settings**, select the **Auto-Standby** button. The Auto-Standby screen appears, as shown in Figure 5-34.

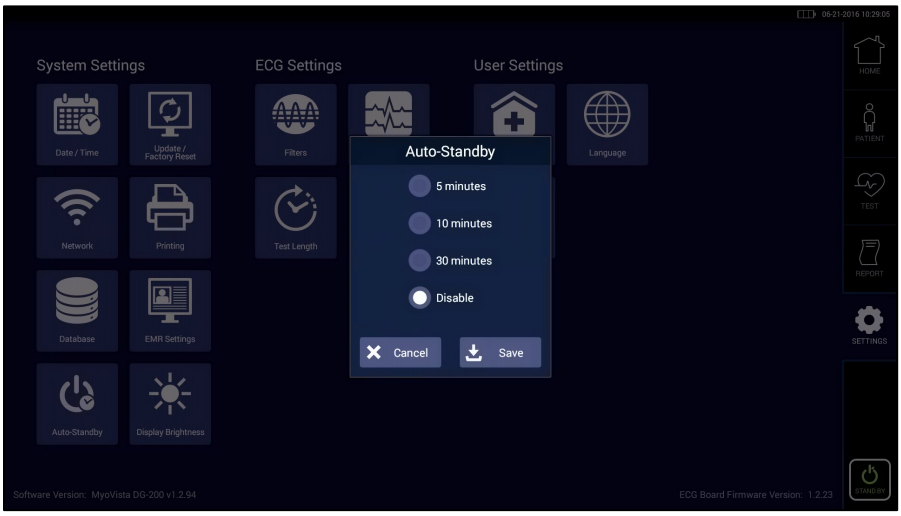


Figure 5-34. Auto-Standby Screen

2. Select the number of minutes of inactivity that is acceptable before the device enters standby mode: **5 minutes**, **10 minutes**, **30 minutes**, or **Disable**.
3. Select the **Save** button to save the setting or select **Cancel** to discard it.

Note: To exit Standby mode, press the **Standby** button or press anywhere on the touchscreen.

Configuring LCD Brightness Settings

To configure LCD brightness settings:

1. Under **System Settings**, select the **Display Brightness** button. The Display Brightness screen appears, as shown in Figure 5-35.



Figure 5-35. Display Brightness Screen

2. Move the slider left or right to select the appropriate brightness.
3. Select the **Save** button to save the setting or select **Cancel** to discard it.

Configuring ECG Settings

This section covers the Myoelectricity Interface filters settings (described below) and ECG trace color settings (described on page 82).

Configuring Filters

The **Frequency Interface** setting determines the A/C line filter setting.

To configure default settings for filters:

1. Under **ECG Settings**, select the **Filters** button. The Filters screen appears, as shown in Figure 5-36.

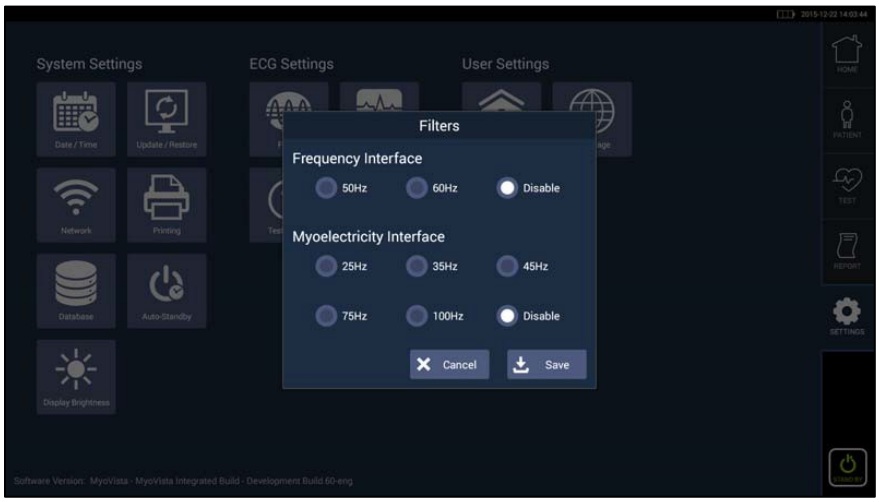


Figure 5-36. Filters Screen

2. Set the default **A/C Line Frequency Interface Filter** setting: **50Hz**, **60Hz**, or **Disable**.

Note: You can also configure these settings on the Test Screen for each individual test (see page 55). Settings return to their default values each time a new patient is selected.

3. Set the default **Myoelectricity Interface** filter setting: **25Hz, 35Hz, 45Hz, 75Hz, 100Hz**, or **Disable**.

Caution: Myoelectricity Interface filters reduce the amount of biologic data available. Heart Test Laboratories does not recommend using a filter for this setting unless absolutely necessary.

4. Select the **Save** button to the save the settings or select **Cancel** to discard them.

Configuring ECG Trace Colors

To configure ECG trace colors:

1. Under **ECG Settings**, select the **ECG Trace Color** button. The ECG Trace Color screen appears, as shown in Figure 5-37.

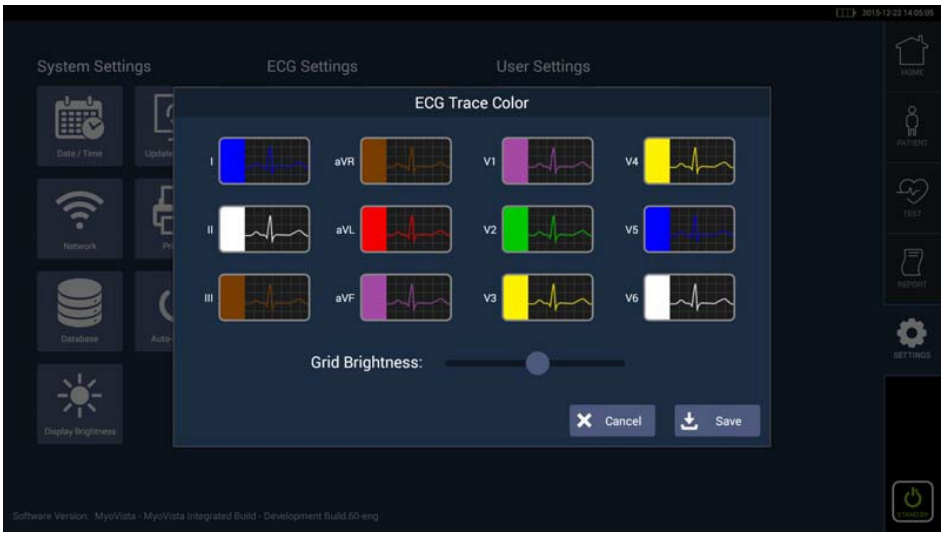


Figure 5-37. ECG Trace Color Screen

2. Select a lead to change the color, and then keep pressing over the desired lead to toggle through all the colors until you select the desired color. The available colors are: green, blue, brown, purple, yellow, white, and red.
3. Repeat step 2 for each desired lead.
4. Move the **Grid Brightness** slider to the right or left to select the desired grid brightness.

Note: Grid Brightness determines the transparency of the grid lines behind the ECG waveform traces. It does not change the brightness of the screen where the grid is displayed. To change screen brightness, see “Configuring LCD Brightness Settings” on page 80.

5. Select the **Save** button to the save the settings or select **Cancel** to discard them.

Configuring User Settings

This section describes the following topics:

- Clinic information setting. See “Entering or Modifying the Clinic Information” below.
- Language setting. See “Configuring a Language” on page 84.
- Patient unit of measurement. See “Configuring the Patient Unit of Measurement” on page 85.

Entering or Modifying the Clinic Information

To enter or modify clinic information:

1. Under **User Settings**, select the **Clinic Information** button. The Clinic Information screen appears, as shown in Figure 5-38.

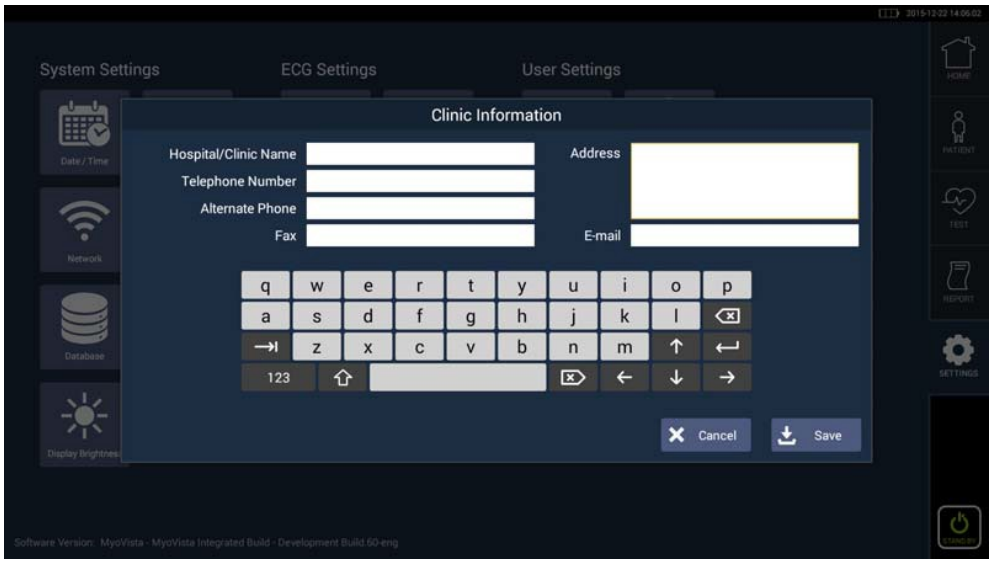


Figure 5-38. Clinic Information Screen

2. Enter or modify the following clinic information in the appropriate fields: **Hospital/Clinic Name** (appears in printed and exported PDF reports), **Telephone Number**, **Alternate Phone**, **Fax**, **Address**, and **E-mail**.
3. Select the **Save** button to save the clinic information or select **Cancel** to discard it.

Configuring a Language

The following procedure describes how to configure a language. If you change the language, the MyoVista DG-200 reboots.

1. Under **User Settings**, select the **Language** button. The Language screen appears, as shown in Figure 5-39.

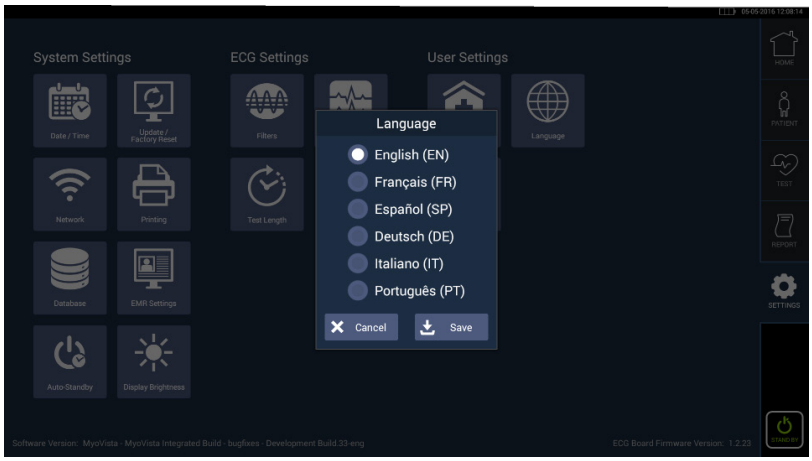


Figure 5-39. Language Screen

2. Select the appropriate language.
3. Select the **Save** button to the save the setting or select **Cancel** to discard it. If you select **Save**, the following message appears:

MyoVista will restart to change the language.

4. Select **OK** to continue with the reboot or select **Cancel** to cancel the operation.

Configuring the Patient Unit of Measurement

To configure the patient unit of measurement:

1. Under **User Settings**, select the **Patient Units** button. The Patient Units screen appears, as shown in Figure 5-40.



Figure 5-40. Patient Units Screen

2. For **Height**, select **cm** or **in**.
3. For **Weight**, select **kg** or **lb**.
4. Select the **Save** button to save the settings or select **Cancel** to discard them.

6. TROUBLESHOOTING

Topics:

- *Troubleshooting Table (page 87)*

In the unlikely event you encounter a problem using the MyoVista DG- 200, use the information in this chapter to identify and resolve the problem.

Troubleshooting Table

Table 6-1 lists common device errors, with their causes and solutions.

Table 6-1. Troubleshooting Table

Problem	Cause	Solution
USB device is not recognized	The MyoVista DG-200 does not recognize the USB device connected to its USB port	Be sure the USB device is connected directly to the USB port Try a different USB port or USB device Ensure the USB storage media is properly formatted (see Pg. 29)
A backed up database cannot be accessed while attempting to restore the database	User changed the database file location on the USB disk. Database file is found in a directory other than the main directory	Move the database file to the main directory on the USB device
One or more waveforms is not stable	Patient cable or electrode lead wires are loose, or the electrode has improper skin contact	Be sure the patient cable is fully seated into device's patient cable port Check all electrode lead wire connections to electrodes Be sure electrodes have proper skin contact
MyoVista DG-200 does not power up	Battery is fully discharged and the power adapter is not connected Power cord and supply are not attached	Connect the power adapter to the MyoVista DG-200 Connect the power cord and supply to the MyoVista DG-200
MyoVista DG-200 powers down	Battery is discharged Power adapter is not connected	Connect the power adapter to device
Incorrect language displays	Incorrect language system setting is selected	Select the appropriate device language
Report does not print.	Printer or network is not configured properly	Select and configure the printer. If using a network printer, be sure the network is configured properly
No network connection	Network connection is not configured properly	Configure network settings
Noise or decaying signal artifact present after each pacing pulse	Pacemaker spikes may be interfering with ECG signal quality	Disable the Line **Frequency Interface** setting before running test (see "Configuring Filters" on page 81)
No real-time traces present	Patient cable is damaged or connected improperly	Confirm that the patient cable is not damaged and is connected properly. If the patient cable is damaged, replace it
Incorrect report data	The device is configured for the wrong date or time, the date is not set, or the patient information is incorrect	Change or enter the correct data

Problem	Cause	Solution
Degraded test results.	The environment in which the device is operating is subject to electromagnetic interference (EMI), MRI, or other imaging activity, such as interference from microwaves, cell phones, and similar devices.	Move the device to an area that has less interference.

7. MAINTENANCE AND CLEANING

Topics:

- *Warnings (page 90)*
- *Maintenance (page 90)*
- *Periodic Inspection (page 92)*
- *Battery Maintenance (page 93)*
- *Supplies and Accessories (page 93)*

This chapter covers maintenance and cleaning procedures for the MyoVista DG-200.

Warnings

Warning: DANGER OF ELECTRIC SHOCK. THERE ARE NO USER-SERVICEABLE PARTS IN THIS DEVICE. The battery is not user-serviceable. Do not open the device case. Only personnel authorized by the manufacturer may service the device, open the enclosure, or open the battery compartment.

Maintenance

Regular maintenance, regardless of how often the MyoVista DG-200 is used, is essential to ensure that the equipment will be functional when used. Regular maintenance includes cleaning and inspection.

Maintenance Items To Remember

Before performing maintenance on the device, be sure that an authorized representative has provided proper training of device functions and safety precautions.

If there is any uncertainty about maintenance or cleaning instructions or procedures, refer to the supplied maintenance and cleaning instructions.

The following maintenance instructions do not override any statutory or local regulations or procedures for the prevention of accidents and environmental protection.

When inspecting and cleaning the device:

- Turn off the system and unplug the device.
- Do not immerse any part of the equipment in liquid.
- Do not use organic solvents, ammonia based solutions, or abrasive cleaning agents. These may damage the equipment surfaces.

Warning: Before cleaning, ensure power is turned off and that the power adapter is unplugged.

Caution: DO NOT use corrosive cleaning agents. DO NOT use cleaning agents that contain phenols.

Caution: DO NOT use detergent solutions for cleaning equipment or cable accessories. DO NOT immerse equipment and cables in liquid.

Cleaning and Disinfecting

Clean and disinfect the exterior surfaces of the MyoVista DG-200 device before you use it for the first time. After the initial cleaning, clean the device every month, or more frequently if required by healthcare facility protocol.

Housing Cleaning

To clean the housing of the MyoVista DG-200:

1. Wipe with a clean cloth dampened in a mild soap and water solution.
2. To disinfect, wipe with a cloth dampened with alcohol.
3. Use the following solutions, as recommended in the APIC Guidelines for Selection and Use of Disinfectants (1996):
   - Sodium hypochlorite (5.2% household bleach) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution
   - Any sodium hypochlorite wipe product that meets the above guidelines can be used.
4. Dry with a clean cloth or paper towel. Drying times depend on environmental conditions.

Patient Cable Cleaning

1. Before cleaning, remove the patient cable and the electrode lead wires from the device.
2. To clean the cable, wipe with a lightly moistened cloth dampened in a mild soap and water solution.
3. To disinfect, wipe a cloth dampened with isopropyl alcohol.

   Use the following solutions, as recommended in the APIC Guidelines for Selection and Use of Disinfectants (1996):
   - Sodium hypochlorite (5.2% household bleach) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution
   - Any sodium hypochlorite wipe product that meets the previous guidelines can be used.
4. Dry with a clean soft cloth or paper towel. Drying times depend on environmental conditions.

LCD Screen Cleaning

The MyoVista DG-200 system incorporates a touch panel. Fingerprints and other stains are likely to appear on the touch panel.

Note: Never use a strong or acidic cleaning solution. Do not wipe the surface with any coarse-textured cloth or gauze, as it may damage the specially coated screen. Use a non-abrasive soft cleaning cloth only.

Use a commercially available cleaning solution designed for LCD screens. A soft cleaning cloth or eyeglass cleaning cloth may also be used. Do not get the device wet or introduce liquids. Dry with a clean soft cloth.

Periodic Inspection

Visually inspect the MyoVista DG-200 every 6 months or as required by facility protocol.

Warning: If service is required, it should be performed only by qualified service personnel.

Seasonal Safety Check

Clean the power adapter plug at least once a year. An excessive amount of dust on the plug might cause a fire.

Note: For proper performance and safety, have the device inspected and tested annually by authorized service personnel. Only authorized service personnel trained for the MyoVista DG-200 maintenance should inspect and test it.

Annual Inspection

Perform the following safety checks at least every 12 months and record the data per your facilities protocol. If the device is not working properly or fails any of the following conditions, it must be repaired:

- Inspect the equipment and accessories for mechanical and functional damage.
- Inspect the relevant safety labels for legibility.
- Verify that the device functions properly, as described in this User Manual.
- Test the protective ground resistance according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit:0.1Ω
- Test the ground leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995:
  Limit NC: 500μA, SFC: 1000μA.

- Test the enclosure leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995:
  Limit NC: 100μA, SFC: 500μA.
- Test the patient leakage current according to IEC 60601-1:1988 + A1:1991:
  Limit AC: 10μA, DC: 10μA
- Test the patient leakage current under single fault condition according to IEC 60601-1:1988 + A1:1991 + A2:1995:
  Limit AC: 50μA, DC: 50μA.
- Test the patient leakage current Mains voltage on applied part according to IEC 60601-1:1988 + A1:1991 + A2:1995:
  Limit AC: 50μA

Battery Maintenance

- Avoid water, high temperature, and high humidity. The storage environment should be free of dust, salt, sulphide gas, and kept dry. See “Environmental Specifications” on page 95.
- Never open the battery enclosure or remove the battery from the enclosure.
- Monitor the battery performance, and have it serviced or replaced by an authorized service technician when necessary. See Monitoring the Battery on page 35.
- Discontinue battery use if battery power appears weak.
- Follow local ordinances or regulations for disposal.

Supplies and Accessories

Use only genuine Heart Test Laboratories disposable electrodes.

APPENDIX A. TECHNICAL DATA

Device Specifications

Specification	Description
Dimensions (height x width x depth):	11.75 in. x 16.75 in. x 3.0 in. excluding stand or accessories
Weight:	8.4 lbs. including battery
Patient cable connection:	DB-15 ECG with proprietary pin-outs
Ports:	USB (4), DC Power Input, HDMI, LAN
Materials:	Bayblend FR3010 - Polymer blend based on bisphenol A - polycarbonate/acrylonitrile-butadiene-styrene copolymer (PC/ABS), flame-retarded (low halogen content, free from chlorine and bromine)
Disposal:	According to WEEE: Directive 2012/19/EU - Device, accessories, and packaging waste must be disposed of properly at end of each usage. Follow Local Ordinances and Regulations for disposal.
Built-In Monitor	
Size:	Effective display area 15.6 in.
Resolution:	1920 x 1080 dots per inch (DPI)
Controls:	Touchscreen and membrane key panel
Memory	
Storage:	Patient Test Records: > 50,000

Electrical Specifications

Specification	Description
Power Supply	
Voltage:	100~240 VAC, 50/60 Hz
Power consumption:	48 Watts max
Battery:	Operation with built-in rechargeable battery
Battery (new battery with full charge)	
Capacity:	1 hour normal use
Battery life:	~ 2 hours standby
Recharging time:	Normal operating conditions: 1 yr. 90% Capacity: approximately 4.5 hrs. 100% Capacity: approximately 10 hrs.
Line frequency filter:	Distortion-free suppression of superimposed 50 or 60 Hz sinusoidal interferences by adaptive digital filtering

Environmental Specifications

Specification	Description
Temperature	
Operating:	+5˚C to +40˚C (41˚F to 104˚F)
Storage:	-20˚C to +50˚C (-4˚F to 122˚F)
Humidity (non-condensing)	
Operating:	≤80% RH non-condensing
Storage:	≤80% RH non-condensing

ECG Specifications

Specification	Description
ECG	
Leads:	Standard 12 simultaneous leads
Touchscreen Display	
Leads:	12-channel display of the selected leads, selectable amplitude 5, 10, 20 mm/mV
Status:	Filter status (on/off) Insufficient electrode contact Date and time Patient demographics
Printout	
Chart print-out speed:	5/25/50/100 mm/s (manual print)
Sensitivities:	5/10/20 mm/mV, either automatically adjusted or manually selected
Recording track:	12-channel presentation, automatic baseline adjustment
Data Record	
Fields:	Patient data (name, age, sex, height, weight, BSA), user ID and logo with optional interpretation program ECG measurements results
Filter	
Muscle noise filter:	Myogram filter: 25 Hz, 35 Hz, 45 Hz, 75 Hz, 100 Hz, and 150 Hz can be switched on/off.

EGG Specifications

Specification	Description
ECG Amplifier	
Simultaneous recording:	All 10 active electrode signals (= 12 leads)
Sampling frequency:	1000 Hz
Resolution:	5 µV/14 bit
Pacemaker detection:	≥± 2 mV/pulse widths ≥0.1 ms
Frequency range:	0.05 - 150 Hz (IEC/AHA)
Measurement range:	Dynamic ± 10 mV, DC ± 300 mV
CMRR:	>60 dB
Input impedance:	≥2.5MΩ (actually arrived ≥50MΩ)
Defibrillation protection:	5,000 VDC

Networking with MyoVista

The MyoVista DG-200 uses the network interface to connect to network-attached printers to print ECG test reports. This interface is provided as a convenience and is not required to operate the MyoVista DG-200 system successfully for ECG testing or result analysis. The MyoVista direct USB and printing report export capabilities are available for users who cannot use the network interface.

Configuration

Specification	Description
Ethernet:	Microtel Gigabit Ethernet: 10/100/1000Mbps IEEE 802.3 compliant
WLAN:	Intel Dual Band 2.4 GHz, 5 GHz, IEEE 802.11 ac/a/b/g/n
Wi-Fi connection:	WEP- or WPA-enabled access point with password only (no LADP- or Active Directory-enabled authentication requiring username and password).

Data Use

The MyoVista DG-200 transmits the following data over network connections: ECG Test results, containing patient information (patient ID, name, date of birth, sex, height, and weight) and ECG tests results (multiple lead traces accompanied by multiple post-test analyses).

Potential Issues with Network-Based Printers

Delayed test results can occur due to network availability or load/congestion. If you are unable to print over the network, use another method to view the ECG results (on screen, USB printer, or export to PDF on USB).

Though unlikely, a report may contain inaccurate data under certain circumstances, such as due to electromagnetic interference. The TCP/IP protocol and Ethernet/WLAN transport typically resolve these issues automatically without software or end-user action. Review and verify all data on printed and exported reports.

Printing to an unattended or remote group printer can result in an unauthorized individual viewing patient and clinical data. We caution against using unattended or remote printers.

APPENDIX B. ERROR MESSAGES

Message	Occurs when...	Action
The password is not valid for network security mode	The device connects to a wireless network and the wrong password is entered	Select the Close button, and then enter correct password
Failed to configure network		
No storage disk selected	The database is being restored, but the device did not find a USB device connected to its USB ports	Select the OK button Connect a USB device into either of the device's USB ports

APPENDIX C. VESA MOUNTING

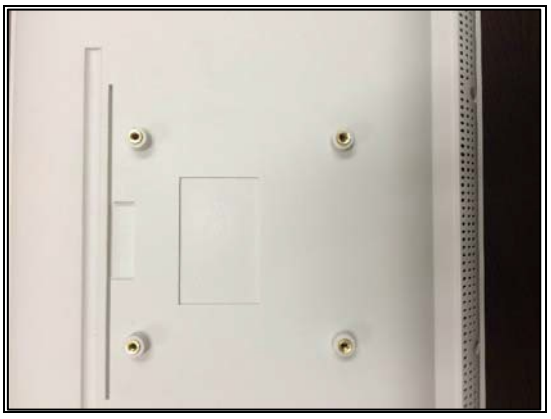
This appendix describes how to attach a VESA mount.

Caution: If mounting the device using the VESA mounting interface on the back panel, check the adequacy of the surface attachment. The VESA mount and surface should be able to support at least 8 kg (17.6 lbs).

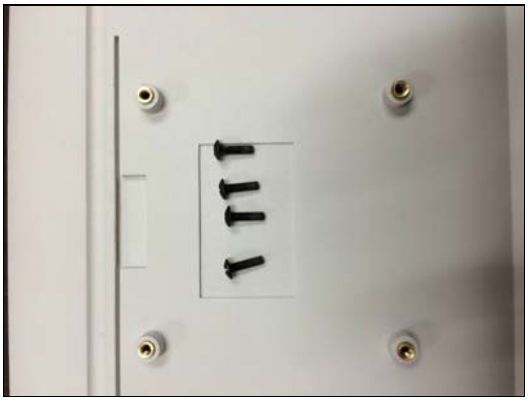
Note: The MyoVista DG-200 accommodates a 100 mm by 100 mm standard VESA mount. The adjustable stand does not have to be removed when using the VESA mount.

To attach a VESA mount:

1. Locate the four VESA mount holes on the back of the MyoVista DG-200.



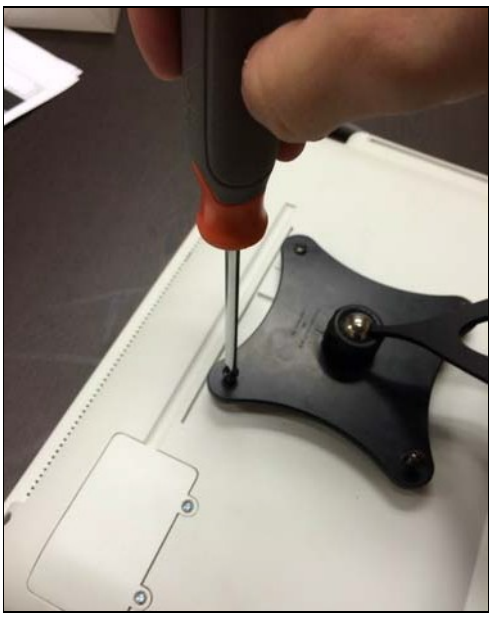
2. Locate the four screws from the VESA mount kit (100 mm/ 100 mm VESA mount standard screws).



3. Align the VESA mount kit with the VESA mount holes, and then insert the screws.



4. Tighten the VESA mount screws. Do not overtighten the screws.



5. Confirm that the mount is secure.



APPENDIX D. GLOSSARY

Acronym	Description
CWT	Continuous Wavelet Transform
ECG	Electrocardiograph
EMR	Electronic Medical Record
HDMI	High-Definition Multimedia Interface
IFU	Instructions for Use
MCW	MyoVista Color Waveform
VIEM	Ventricular Index – Early Measure (for both Left Ventricle and Right Ventricle)
VILM	Ventricular Index – Late Measure (for both Left Ventricle and Right Ventricle)
VIAM	Ventricular Index – Average Measure (for both Left Ventricle and Right Ventricle)

APPENDIX E. END USER LICENSE AGREEMENT

END USER LICENSE AGREEMENT

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3.2. Limited Software Warranty. Except as indicated otherwise below, HTI warrants that (i) for Ninety (90) days from the date of purchase of such Product, that the Licensed Software will perform substantially in accordance with the applicable Documentation, (ii) it has not inserted any Disabling Code (as defined herein) into the Licensed Software and (iii) it will use reasonable commercial efforts consistent with industry standards to scan the Licensed Software for and remove any software viruses before installation into the Product. Except as indicated otherwise below, HTI

warrants that it has the right to license or sublicense the Licensed Software to Customer as set forth in Section 2.1 (License Grant). As used in this warranty statement, (i) "Disabling Code" means computer code that is designed to delete, interfere with, or disable the normal operation of the Product; provided, however, that code included in the Licensed Software for monitoring compliance with this Agreement will not be deemed to be Disabling Code.

3.2.1. Exclusions. This Limited Software Warranty does not apply to any product that was not purchased or leased from HTL or any of its authorized distributors. If the HTL serial number on the Product has been altered, damaged, rendered defective, or removed from the Product, this Limited Software Warranty is void. This Limited Software Warranty does not cover normal wear and tear or any loss, damage, or defects caused by: (1) attempted disassembly or repair by anyone not authorized by HTL; (2) failure to follow instructions for use, maintenance, and cleaning; (3) drops, impacts, fire, water damage, misuse, abuse, neglect, accident, or external forces, (4) the Product having been altered or tampered with in any way, (5) the Product having been used or maintained in any manner that is inconsistent with HTL instructions or warnings included with the Product, as applicable, (6) the Product having been used in any manner that is inconsistent with the intended purpose or design of the Product, as applicable, as described in HTL published documentation for the Product, (7) transportation to the Licensee's facility, (8) Licensee's or any third party's supplied software, interfaces, parts, supplies, or accessories, (9) operation outside of environmental specifications for the Product, or (10) improper site preparation or maintenance. HTL is not responsible for any costs, expenses, or charges incurred by Licensee for any attempted disassembly or repair by anyone not authorized by HTL. This Limited Software Warranty does not apply to any accessories that are designed to be disposable or for single use and which have been reused, or attempted to be reused. With respect to Products, if Licensee has not provided HTL with completed warranty registration information within thirty (30) days after purchase or lease of a Product, then the benefits of this Limited Software Warranty do not apply. Notwithstanding any other statement in this Agreement, this Limited Software Warranty does not apply to any third party code within the Licensed Software, which third party code is warranted under the warranty provided by the such third party, if any, to the extent that HTI is authorized to pass such third party warranty through to Licensee.

3.3. DISCLAIMER OF WARRANTY. OTHER THAN THE EXPRESS WARRANTY MADE IN SECTIONS 3.1 AND 3.2, LICENSOR MAKES NO WARRANTY, WHETHER EXPRESS, IMPLIED OR STATUTORY. FURTHER, THE LICENSED SOFTWARE IS PROVIDED "AS IS" AND WITHOUT ADDITIONAL WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, AND EXCEPT FOR THE EXPRESS WARRANTEES SET FORTH IN SECTIONS 3.1 AND 3.2, LICENSOR DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, IMPLIED WARRANTIES OF, ACCURACY, MERCHANTABILITY, NON-INFRINGEMENT, TITLE, AND FITNESS FOR A PARTICULAR PURPOSE, AND ANY WARRANTIES THAT MAY ARISE FROM COURSE OF DEALING, COURSE OF PERFORMANCE, OR USAGE. LICENSOR DOES NOT WARRANT THAT LICENSEE'S EXERCISE OF RIGHTS GRANTED HEREIN WILL BE UNINTERRUPTED, ERROR-FREE OR SECURE, OR THAT DEFECTS IN THE LICENSED SOFTWARE WILL BE CORRECTED. NO OPINION, ADVICE OR STATEMENT BY OR ON BEHALF OF LICENSOR SHALL CREATE ANY WARRANTY OTHER THAN THAT SET FORTH IN SECTIONS 3.1 AND 3.2. LICENSEE'S EXERCISE OF ANY RIGHTS GRANTED HEREIN IS ENTIRELY AT LICENSEE'S RISK. THIS AGREEMENT PROVIDES NO INDEMNITY TO LICENSEE.

3.4. Licensee represents and warrants that Licensee has read and understands the description of the Licensed Software as may be included in the Licensed Software or indicated at the address specified by any URL provided for such description.

4. Consulting Services

4.1. No consulting or professional services are provided as part of this Agreement.

5. Confidential Information.

5.1. Use and Disclosure Restrictions. The Licensee hereby acknowledges and agrees that Confidential Information constitutes and contains valuable proprietary information and trade secrets of the Licensor, and embodies substantial creative efforts and Confidential Information, ideas, methods, and expressions. Accordingly, Licensee agrees: (i) to protect Confidential Information of the Licensor from unauthorized dissemination and use; (ii) to use such Confidential Information only for the exercise of its license rights as set forth in Section 2.1 (Grant of License); (iii) to limit the use of and access to such Confidential Information to such employees and contractors set forth in Section 2.1 (Grant of License); (iv) not to disclose, license, transfer, sell, publish, disclose, display or otherwise provide to any third party any of the Licensed Software, and/or any of Licensor's Confidential Information, or any part or parts of such Licensed Software and Confidential Information; (v) to undertake whatever action is necessary to prevent or remedy (or authorize the Licensor to do so in the Licensee's name) any breach of the confidentiality obligations set forth herein; (vi) not to remove or destroy any proprietary, confidential, or copyright legends or markings placed upon or contained within the Licensed Software, or on any other Confidential Information disclosed or provided by or for the Licensor to the Licensee; and (vii) promptly to notify the Licensor in writing of any unauthorized disclosure, theft and/or unauthorized use of any Confidential Information of the Licensor.

5.2. Exceptions. For purposes of this Agreement, Confidential Information shall not include, and the confidentiality and non-use obligations provided hereunder shall not apply to, information that: (i) is now or subsequently becomes generally available to the public through no fault of the Licensee; (ii) the Licensee can demonstrate by dated documents was rightfully in its possession prior to disclosure or provision by the Licensor; (iii) the Licensee rightfully obtained or obtains from a third party who has the right, without obligation to the Licensor, to transfer or disclose; or (iv) is released by the Licensor without restriction and in writing.

5.3. Disclosure by Order from Authority. If a Licensee becomes legally compelled to disclose any Confidential Information of the Licensor, the Licensee shall immediately notify the Licensor in writing so that the Licensor may, at its option, seek a protective order or other appropriate remedy, or waive compliance with one or more provisions of this Agreement. If the Licensor elects to seek a protective order or other appropriate remedy, the Licensee shall cooperate with, and not object to, any such actions. If a protective order or other remedy is not obtained or the Licensor waives compliance with any of the provisions of this Agreement, the Licensee shall furnish only that portion of the Confidential Information which it reasonably believes on advice of counsel is legally required to be disclosed.

5.4. Equitable Relief. Licensee acknowledges that Confidential Information has unusual and extraordinary value, and that the breach or prospective breach of any confidentiality provision of this Agreement, by the Licensee will cause Licensor great and irreparable harm, for which remedies available at law are inadequate. Therefore, Licensor shall be entitled, without posting bond, to seek injunctive and other equitable relief, including, but not limited to, specific performance, to prevent a breach, continued breach or threatened breach of any confidentiality obligation of this Agreement, in addition to any damages that may be awarded to Licensor.

6. Limitation of Liability.

6.1. LICENSOR SHALL NOT BE RESPONSIBLE OR LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR OTHER DAMAGES TO LICENSEE OR ANY OF ITS PERMITTED EMPLOYEES AND CONTRACTORS (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF BUSINESS, LOSS OF DATA OR LOST PROFITS) ARISING OUT OF OR RELATING IN ANY WAY TO THIS AGREEMENT OR TO THE USE OF THE LICENSED SOFTWARE, WHETHER ARISING IN AN ACTION OR CLAIM BASED ON CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF LICENSOR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL LICENSOR'S LIABILITY, WHETHER BASED ON AN ACTION OR CLAIM IN CONTRACT OR TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED THE AMOUNT PAID BY LICENSEE FOR THE PRODUCT.

7. **Option of Licensor**

As a result of any claim of infringement against the Licensed Software, or if Licensor believes that the Licensed Software is likely to become the subject of a claim of infringement, Licensor at its option and expense may discontinue the licenses granted herein on one (1) month's written notice.

8. **Termination**

8.1. Licensor shall have the right to terminate this Agreement or the licenses granted herein:

8.1.1. Upon ten (10) days' written notice in the event that Licensee or its employee or contractor violates any provision of this Agreement including, but not limited to, confidentiality provisions, or acts beyond the scope of the licenses granted in Section 2.1 (License Grant).

8.1.2. In the event Licensee:

8.1.2.1. Terminates or suspends its business; or

8.1.2.2. Becomes insolvent or becomes subject to direct control by a trustee, receiver or similar authority.

8.2. If Licensee initiates any proceeding or action, or participates in or otherwise prosecutes any proceeding or action (or assists any third party to initiate, participate in, or otherwise prosecute any proceeding or action) challenging the validity, enforceability or scope of any Intellectual Property Right licensed under this Agreement (including challenging that any of the Licensed Software is not a trade secret), then Licensor may immediately terminate this Agreement effective upon written notice to Licensee.

8.3. Obligations on Termination. Upon termination of this Agreement for any reason, all of Licensee's rights to the Licensed Software and the Documentation including, but not limited to, use and access, shall automatically terminate. In addition, Licensor shall have the right, at any time after termination of the license, to take immediate possession of the Licensed Software and all copies wherever located, without demand or notice.

8.4. Survival of Obligations. Licensee agrees that its obligations and duties which by their nature extend beyond the expiration or termination of this Agreement shall survive any expiration or termination and of this Agreement. Termination of the license shall not relieve Licensee of its obligations with respect to the Licensed Software.

8.5. Termination of any of the licenses granted herein, or of the entire Agreement, shall be in addition to and not in lieu of any equitable or other remedies available to Licensor. Further, no termination of this Agreement shall relieve Licensee of any obligation of Licensee hereunder.

9. **Miscellaneous**

9.1. No Implied Licenses. Nothing contained in this Agreement shall be construed as conferring any license or right by implication, estoppel or otherwise, under any Intellectual Property Rights, other than the licenses expressly granted in this Agreement. Licensor is not required hereunder to furnish or disclose to the Licensee any technical information.

9.2. Entire Agreement; Amendment; Waiver. This Agreement, together with all exhibits and schedules hereto, if any, constitute the entire agreement between the parties pertaining to the Licensed Software and supersede all prior agreements, understandings, negotiations and discussions, whether oral or written, of the parties. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the parties hereto. Waiver of any of the provisions of this Agreement must be in writing. No waiver shall be deemed or shall constitute a waiver of any other provision hereof (whether or not similar), nor shall any waiver constitute a continuing waiver unless otherwise expressly provided in writing.

9.3. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Texas, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Texas or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Texas. Each party irrevocably agrees to the jurisdiction of the state and federal courts located in Dallas County, Texas. Notwithstanding the foregoing, any action based on Section 5.4 (Equitable Relief) may be brought in any court of competent jurisdiction.

9.4. Section Headings. The section headings contained in this Agreement are inserted for reference purposes only and are not intended to be a part, nor should they affect the meaning or interpretation, of this Agreement.

9.5. Notices. All notices, requests, demands and other communications which are required or may be given under this Agreement shall be in writing and shall be deemed to have been duly given when transmitted for download to Licensee’s unit(s) of the Product, or otherwise provided to Licensee.

9.6. Nonassignability. Licensee may not, directly or indirectly, in whole or in part, assign, delegate or transfer this Agreement and any attempted assignment, delegation or transfer shall be null and void. Licensor may assign this Agreement at any time.

9.7. Enforcement of Agreement. Licensor shall have the right to collect from Licensee its reasonable expenses, including attorney's fees, incurred in enforcing this Agreement.

9.8. Severability. In the event that any one or more of the provisions contained in this Agreement or in any other instrument referred to herein, shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, then to the maximum extent permitted by law, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement or any other such instrument.

9.9. Independent Contractors. There is no relationship of agency, partnership, joint venture, employment, or franchise between the parties. Neither party has the authority to bind the other or to incur any obligation on its behalf.

9.10. Remedies Cumulative. All rights and remedies with respect to breach of any obligation herein are cumulative of each other and of every other right or remedy such party may otherwise have at law or in equity, and the exercise of one or more rights or remedies shall not prejudice or impair the concurrent or subsequent exercise of other rights or remedies.

APPENDIX F. LIMITED WARRANTY

NOTICE: Heart Test Laboratories, Inc. regards any use you make of the Product (defined below), accompanying or embedded software, or any Accessories (defined below) as agreement to the terms of this Limited Warranty set forth below.

General

This Heart Test Laboratories Limited Warranty ("Limited Warranty") and Software Licensing Agreement is made by one of the following: Heart Test Laboratories, Inc. or its subsidiary or affiliate operating in the country where the Purchaser (defined below) is located at the time of initial purchase (collectively, "Heart Test Labs") and applies only to the Purchaser of a genuine Heart Test Labs-branded MyoVista product ("Product") and any Heart Test Labs-branded genuine parts, supplies, peripherals, or accessories such as lead wires, lead wire connectors, batteries, or similar products ("Accessories").

NOTICE The use of unauthorized, non-Heart Test Labs patient cables or electrodes voids this Limited Warranty in its entirety. This Limited Warranty does not apply to any non-Heart Test Labs products or non-Heart Test Labs branded accessories or peripherals external to the Product such as external storage subsystems, displays, keyboards, mice, printers, and other peripherals, which are provided "AS IS" without Heart Test Labs warranty of any kind. However, non-Heart Test Labs manufacturers and suppliers or publishers may provide their own warranties directly to you. Heart Test Labs is not responsible for any interoperability or compatibility issues that may arise when (1) products, software, options, parts, supplies, peripherals, or accessories not supported by Heart Test Labs are used; (2) configurations not supported by Heart Test Labs are used; or (3) Accessories intended for one Product are installed in another of different make or model. A "Purchaser" is defined as the initial end user purchaser of the Product or Accessory who purchased or leased the Product or Accessory directly from Heart Test Labs or a Heart Test Labs authorized representative, and any reference herein to "you" or "your" means the Purchaser. This Limited Warranty gives the Purchaser express limited warranty rights from Heart Test Labs. In addition, you may also have other legal rights under applicable local law. This Limited Warranty is applicable in all countries and may be enforced in any country or region where Heart Test Labs or its authorized service providers offer warranty service for the same Product or Accessory model number subject to the terms and conditions set forth in this Limited Warranty. Unless otherwise stated, and to the extent permitted by local law, new Products and Accessories may be manufactured using new materials or new and used materials equivalent to new in performance and reliability.

Limited Hardware Warranty

Heart Test Labs warrants to the Purchaser that it will repair or replace the Product or Accessory free of charge (except for those not warranted under "Exclusions" below) if it is defective in materials or workmanship under normal use and service. Heart Test Labs' obligation under this Limited Warranty is limited to the repair or replacement, at Heart Test Labs' option, of applicable Products and Accessories. This Limited Warranty will only apply to defects that are reported to Heart Test Labs within the Applicable Warranty Period and which, upon examination by Heart Test Labs, prove to be defective. The "Applicable Warranty Period" is defined as: (i) for Products, (excluding Cables,) the one (1) year period commencing on the date of purchase; and (ii) for Cables and Accessories, the ninety (90) day period commencing on the date of purchase. The date on your sales receipt or purchase contract is the date of purchase unless Heart Test Labs or your authorized representative informs you otherwise in writing. This Limited Warranty extends only to the Purchaser of a Product or Accessories, and is not transferable or assignable. Heart Test Labs may discharge its Limited

Warranty as to any Product or Accessory by refunding the purchase price of the Product or Accessory and taking back the Product or Accessory.

Exclusions

This Limited Warranty does not apply to any Product or Accessory that was not purchased or leased from Heart Test Labs or any of its authorized representatives or resellers. If the serial number on the Product or Accessory has been altered, damaged, rendered defective, or removed from the Product or Accessory, this Limited Warranty is void. This Limited Warranty does not cover normal wear and tear or any loss, damage, or defects caused by: (1) attempted disassembly or repair by anyone not authorized by Heart Test Labs; (2) failure to follow instructions for use, maintenance, and cleaning; (3) drops, impacts, fire, water damage, misuse, abuse, neglect, accident, or external forces, (4) the Product or Accessory having been altered or tampered with in any way, (5) the Product or Accessory having been used or maintained in any manner that is inconsistent with Heart Test Labs instructions or warnings included with the Product or Accessory, as applicable, (6) the Product or Accessory having been used in any manner that is inconsistent with the intended purpose or design of the Product or Accessory, as applicable, as described in Heart Test Labs published documentation for the Product or Accessory, (7) transportation to the Purchaser's facility, (8) Purchaser or third party supplied software, interfaces, parts, supplies, or accessories, (9) operation outside of environmental specifications for the Product or Accessory, or (10) improper site preparation or maintenance. Heart Test Labs is not responsible for any costs, expenses, or charges incurred by Purchaser for any attempted disassembly or repair by anyone not authorized by Heart Test Labs. This Limited Warranty does not apply to any Accessories that are designed to be disposable or for single use and which have been reused, or attempted to be reused.

Disclaimers

EXCEPT FOR THE LIMITED WARRANTY SET FORTH IN THE IMMEDIATELY PRECEDING PARAGRAPH, HEART TEST LABS MAKES NO WARRANTY WHATSOEVER WITH RESPECT TO THE PRODUCTS OR ACCESSORIES, INCLUDING ANY (A) WARRANTY OF MERCHANTABILITY, (B) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE (EVEN IF HEART TEST LABS HAS BEEN INFORMED OF SUCH PURPOSE), (C) WARRANTY OF DESIGN, (D) WARRANTY OF SATISFACTORY QUALITY, OR (E) WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD PARTY WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE. IF ANY IMPLIED WARRANTY CANNOT BE DISCLAIMED UNDER APPLICABLE LAW, THEN SUCH IMPLIED WARRANTY SHALL BE LIMITED IN DURATION TO THE APPLICABLE WARRANTY PERIOD. HEART TEST LABS DOES NOT WARRANT THAT THE OPERATION OF THIS PRODUCT OR ACCESSORY WILL BE UNINTERRUPTED OR ERROR-FREE. HEART TEST LABS IS NOT RESPONSIBLE FOR DAMAGE THAT OCCURS AS A RESULT OF YOUR FAILURE TO FOLLOW THE INSTRUCTIONS INTENDED FOR THE HEART TEST LABS PRODUCT OR ACCESSORY. FURTHER, HEART TEST LABS DOES NOT WARRANT THAT THE PRODUCT OR ACCESSORY IS NOT VULNERABLE TO INTRUSION OR ATTACK.

Limitation of Liability

HEART TEST LABS IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING OR ARISING FROM THE SALE, INSTALLATION, USE OF THE PRODUCT OR ACCESSORY OR A DEFECT OF THE PRODUCT OR ACCESSORY COVERED OR NOT COVERED BY THE LIMITED WARRANTY, INCLUDING BUT NOT LIMITED TO ANY LOSS OF, DAMAGE TO, OR CORRUPTION OF DATA, LOSS OF PROFIT, LOSS OF USE OF PRODUCT OR ACCESSORY OR EITHER'S FUNCTIONALITY, LOSS OF BUSINESS, LOSS OF CONTRACTS, LOSS OF REVENUES, OR LOSS OF ANTICIPATED SAVINGS, INCREASED COSTS OR EXPENSES OR FOR ANY INDIRECT LOSS OR DAMAGE, CONSEQUENTIAL LOSS OR DAMAGE OR SPECIAL LOSS OR DAMAGE. TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEART TEST LABS' LIABILITY SHALL BE LIMITED TO THE PURCHASE VALUE OF THE PRODUCT OR ACCESSORY GIVING RISE TO THE LIABILITY. THE LIMITATIONS SET FORTH IN THIS LIMITED WARRANTY ARE

INTENDED TO LIMIT THE LIABILITY OF HEART TEST LABS AND SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OR ANY LIMITED REMEDY.

Limitation of Remedies

THE REMEDIES IN THIS LIMITED WARRANTY ARE YOUR SOLE AND EXCLUSIVE REMEDIES.

Defects Occurring After Applicable Warranty Period for the Product

Charges for repairs to the Product after the Applicable Warranty Period, but within the Product's service life, will be based upon actual hours spent on the repair at the prevailing rate, plus the price of parts required and transportation charges. You may also elect to purchase an extended warranty. Continued support beyond the Applicable Warranty Period may require an annual support and update fee. For information about purchasing an extended warranty on your Product, contact your authorized representative.

Warranty Service

You must obtain a return authorization from your authorized representative to arrange for the return of your Product or Accessory before you send it to the designated Heart Test Labs service center for repair or replacement. Contact your authorized representative to obtain information on returning the Product or Accessory and obtaining warranty service.

Under this Limited Warranty, Products purchased in one country/region may be transferred to the same Purchaser in another country/region, where Heart Test Labs or its authorized service providers offer warranty service for the same Product or Accessory model number, without voiding the warranty. Warranty terms, service availability, and service response times may vary from country/region to country/region. Standard warranty service response time is subject to change due to local parts availability. Your Heart Test Labs authorized service provider can provide you with details. Heart Test Labs is not responsible for any tariffs or duties that may be incurred in transferring the Products or Accessories. Transfer of the Products or Accessories may be covered by export controls issued by the United States or other governments.

Heart Test Labs may repair or replace Products or Accessories (a) with new or previously used Products or Accessories or parts equivalent to new in performance and reliability, or (b) with products or accessories that are equivalent to an original Product or Accessory that has been discontinued. Replacement parts are warranted to be free from defects in material or workmanship for the remainder of the Applicable Warranty Period of the Product or Accessory they are replacing or in which they are installed. All component parts or hardware products replaced or removed under this Limited Warranty become the property of Heart Test Labs.

Customer Responsibilities

To enable Heart Test Labs to provide the best possible support and service during the Applicable Warranty Period, you will be required to:

- Maintain a proper and adequate environment, and use the Product or Accessory in accordance with the instructions furnished.
- Verify configurations, load most recent firmware or software, install software patches, run Heart Test Labs diagnostics and utilities, and implement temporary procedures or workarounds provided by Heart Test Labs while Heart Test Labs works on permanent solutions if needed.
- Where available and applicable, allow Heart Test Labs or its authorized representative to keep resident on your systems or sites certain system and network diagnosis and maintenance tools to facilitate the

performance of warranty support (collectively referred to as “Proprietary Service Tools”). Proprietary Service Tools are and remain the sole and exclusive property of Heart Test Labs.

- Additionally, you will:
  - Use the Proprietary Service Tools only during the applicable warranty period and only as allowed by Heart Test Labs.
  - Install, maintain, and support Proprietary Service Tools, including any required updates and patches.
  - Provide remote connectivity through a Heart Test Labs-approved communications line, if required.
  - Assist Heart Test Labs or its authorized representative in running the Proprietary Service Tools.
  - Use the electronic data transfer capability to inform Heart Test Labs or its authorized representative of events identified by the Proprietary Service Tools.
  - Return the Proprietary Service Tools or allow Heart Test Labs to remove these Proprietary Service Tools upon termination of warranty support.
  - Not sell, transfer, assign, pledge, or in any way encumber or convey the Proprietary Service Tools.
  - In some cases, Heart Test Labs may require additional software such as drivers and agents to be loaded on your system in order to take advantage of `these solutions and capabilities.
  - Use Heart Test Labs remote solutions where applicable. Heart Test Labs strongly encourages you to use available technologies provided by Heart Test Labs. If you choose not to deploy available remote capabilities, you may incur additional costs due to increased resource requirements.
  - Cooperate with Heart Test Labs in attempting to resolve the problem over the telephone. This may involve performing routine diagnostic procedures, installing additional software updates or patches, removing third-party options, and/or substituting options.
  - Make periodic backup copies of your configuration data, files, data, or programs stored on your hard drive or other storage media or devices as a precaution against possible failures, alteration, or loss. Before returning any Product or Accessory for warranty support, back up your configuration data, files, data, and programs, and remove any confidential, proprietary, or personal information.
  - Maintain a procedure to reconstruct your lost or altered configuration data, files, data, or programs that is not dependent on the Product or Accessory under warranty support.
  - Notify Heart Test Labs if you use Product or Accessories in an environment that poses a potential health or safety hazard to Heart Test Labs employees or subcontractors. Heart Test Labs may require you to maintain such Products or Accessories under Heart Test Labs supervision and may postpone warranty service until you remedy such hazards.
  - Perform additional tasks as that Heart Test Labs may reasonably request in order to best perform the warranty support.

Advance Unit Replacement Warranty Service

Your Heart Test Labs Limited Warranty may include an advance unit replacement warranty service for Products or Accessories. Under the terms of the advance unit replacement warranty service, Heart Test Labs or its authorized representative will ship or deliver a replacement unit directly to you if the Product you purchased is diagnosed as defective. On receiving the replacement unit, you will be required to return the defective unit back to Heart Test Labs, in the packaging that arrives with the replacement unit, within a defined period of time, normally five (5) days. Heart Test Labs or its authorized representative will incur all shipping and insurance costs to return the defective unit to Heart Test Labs, if shipped in accordance with Heart Test Labs instructions. Failure to return the defective unit may result in Heart Test Labs or its authorized representative billing you for the replacement unit. In countries or regions where this Limited Warranty may be enforced but where advance unit replacement warranty service is not available, Heart Test Labs will, in its sole discretion, substitute another type of warranty service.

Transfer to a Third Party

To the extent allowed by law, this Limited Warranty applies only to bona fide end users of the Product or Accessory and may be enforced only by those end users or their authorized agents. The initial bona fide end user of the Product or Accessory must have purchased the Product or Accessory directly from Heart Test Labs or a Heart Test Labs-authorized reseller.

Freeware Operating Systems and Applications

Heart Test Labs does not provide support for software provided under public license by third parties, including operating systems or applications ("Freeware"). Support for Freeware provided with Products or Accessories is provided by the Freeware vendor. Please refer to the Freeware operating system or other Freeware application support statement included with the Product or Accessory.

Contacting Heart Test Labs

- If a Product or Accessory fails during the Applicable Warranty Period and the information in the documentation for the Product or Accessory, most recent software release notes, and other technical information on the Heart Test Labs Web site do not help you solve the problem, contact your local Heart Test Labs authorized representative. To find out how to contact your local authorized representative, see www.hearttestlabs.comand select “Support”. Be sure to have the following information available before you call:
- Serial number, name, and model number for the Product or Accessory.
- Detailed description of the symptoms, including when the symptoms first occurred, how frequently they are occurring, and applicable error messages.
- Detailed description of any changes made to your Product or Accessory’s configuration or network environment prior to the start of the symptoms occurring.
- Detailed description of the troubleshooting steps you have performed and the results of those steps.
- Software revision currently on the Product, operating system, and third-party hardware or software on or connected to the Product.

Governing Law

This Limited Warranty is governed by and will be construed in accordance with the laws of the State of Texas, exclusive of its conflict of law principles. The United Nations' Convention on Contracts for International Sale of Goods shall not apply.

Modifications to the Limited Warranty

Statements made by any person, including representatives of Heart Test Labs, a distributor, reseller or seller of the Product or Accessory, which are inconsistent with or conflict with the terms of this Limited Warranty, shall not be binding upon Heart Test Labs, unless reduced to writing and signed by an authorized representative of Heart Test Labs.

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MyoVista DG-200 12-Lead ECG with MyoVista® Color Waveform Technology
July 13, 2016
Document version: Version 1