PREMIER

HEART

MCG Technical Manual

MCG Technical Manual

Contents

1. Before you Begin

On behalf of the entire Premier Heart team, thank you for purchasing our product. The MCG system is a revolutionary and advanced diagnostic tool designed to help you achieve the most accurate diagnosis of coronary ischemia possible using non-invasive methods. Please take a moment to familiarize yourself with this manual and the associated Quick Guide prior to first using the MCG device — In order to provide the best possible diagnostic accuracy the attending physician and technicians must adhere to the guidelines provided in these documents.

This manual details the setup and configuration of the MCG device. It is not a clinical practices guide, but rather a technical document designed to help you set up the MCG system in a way that will maximize your efficiency testing patients and provide the best quality diagnostic results possible.
For information on clinical practices and patient testing, please see the Quick Guide included with your MCG unit.

1.1. Important Notices and Warnings

While the MCG device you have received is very robust, it is a sensitive piece of electronic equipment. The following precautions should be taken to ensure that your MCG unit is kept in peak operating condition:

- Do not modify the MCG unit without authorization from Premier Heart Staff.

- Do not operate the MCG unit outside of the operating limits described in Appendix B of this manual.
  Failure to observe the operating limits of the MCG unit can result in damage, and may void your warranty coverage.

- The MCG unit should be shut down at the end of each testing day and plugged in to charge its internal battery.
  In "24x7" environments the MCG unit should be allowed to fully charge at least once every 24 hours.

- The ECG cables should be connected or disconnected only when the MCG unit is powered off and unplugged.
  Connecting or disconnecting ECG cables with the unit on may damage the capture card.

- If the MCG unit is dropped or subjected to sever impact or vibration, especially while in use, contact Premier Heart for service.
  Severe impacts or vibration may affect the unit's calibration.

- If the MCG unit is drenched or immersed in water or other liquids discontinue use immediately and contact Premier Heart for service.
  If the MCG unit becomes wet during use power the unit off immediately and disconnect the patient.

- If the MCG unit is exposed to significant voltage anomalies (e.g. through a lightning strike) discontinue use immediately and contact Premier Heart for service. Significant voltage anomalies may affect the unit's calibration.

It is preferable for the MCG unit to be plugged into a UPS, power conditioner or TVSS (surge suppressor) for charging to minimize risk of damage due to voltage anomalies.

1.2. About Batteries

Portable MCG Units are powered by rechargeable Lithium-Ion batteries. These batteries are high-performance devices with long lifespans – a typical battery will last several hundred charge cycles before degrading to a point where battery life is no longer acceptable for normal use – however like all rechargeable batteries they will eventually diminish in capacity and may require replacement.

In order to ensure maximum battery life your battery must be routinely used (or "exercised"). When used regularly in accordance with the operating instructions in this manual and the Quick Guide the internal battery pack will provide several hours of routine testing operation and be maintained in optimal condition. If you have a low volume of tests or do not routinely use the MCG unit you should fully discharge and recharge the battery at least once per month.

If you will be storing your MCG unit for more than 30 days the battery should be drained to 50% capacity prior to storage. Prolonged storage with the battery fully charged or fully discharged may result in diminished capacity.

Battery Life and Temperature

If you use the MCG system at temperatures above the operational limits you may permanently damage your battery and result in diminished capacity. Charging the battery outside the operating limits presents an increased risk of damage due to additional heat generated by the charging process. Storing the battery at temperatures outside the storage limits may also cause permanent damage.

If you use your MCG field unit at low temperatures you may find that the battery capacity is lower than normal. Unlike the damage caused by high temperatures, this condition is temporary and your battery will operate normally once it has warmed up.
Note that using, charging or storing the battery at temperatures below the operational limits may

still result in permanent damage to the battery. For optimum battery life do not operate or store the MCG unit outside of the specifications provided in this manual.

To ensure the best battery life your MCG unit should be operated and charged at temperatures between 68- 72°F (20-22°C).

Battery Disposal

The battery pack in portable MCG units uses Lithium-Ion technology. The battery pack should not be disposed of with ordinary trash or medical waste – doing so may be hazardous. Please contact Premier Heart for information on safe disposal of your battery pack.

Premier Heart provides two MCG system models designed to meet the requirements of different sites.

The MCG units are designed for maximum versatility. All systems are capable of being carried as a portable testing kit (with optional accessory bag).

All MCG Field Unit and Base Station systems include a built-in battery to enable use in remote locations or where AC power is not readily available. The MCG batteries also provide protection in the event of a power failure during testing – The system will continue running on battery power, allowing you to complete any running tests with no loss of data.

Part I.

3DMP Field Units

1. Overview

The 3DMP are ruggedized systems designed for use in the most demanding environments such as EMS and military use. The 3DMP is based around GETAC's fully rugged military grade laptop and meets the MIL-STD-810F requirements for dust, water, vibration and shock protection. The battery modules supplied with the 3DMP are capable of up to 5 hours of sustained use and testing.

The 3DMP has been superseded by the CF19.

Figure 1.1.: 3DMP

1 - MCG Unit		4 - Battery *
2 - Power Adapter		5 - Capture Card *
3 - AC Line Cord		6 - ECG Cable
	* - Internal Component	

1.1. Input/Output Connections

The 3DMP comes with an array of Input/Output connections on the device. Aside from the supported connections listed below, Authorization from Premier Heart is required to use any of the Input/Output connections located on the device. For any questions on the supported and unsupported Input/Output connections located on your device please contact Premier Heart.

Supported Ports
Usb Port
VGA Port
Ethernet Port
Modem Port
ECG Connection
Power Supply Connection

2. Parts

For questions on repairing, replacing or ordering parts for your 3DMP device please contact the Premier Heart Staff

2.1. User Serviceable Parts

Serviceable Parts are components that can be replaced by an approved service personnel.

2.1.1. Power Supply

The power supply is actually broken up in to two separate parts, the Power Adapter and the AC line cord. If you believe that your Power Supply is no longer working, please contact the Premier Heart staff and they can walk you through the steps of determining which of these parts needs to be replaced.

2.1.1.1. Power Adapter

To replace the Power Adapter, first make sure that the power supply is not connected to the 3DMP or to a power source. Once you have verified this, you simply remove the AC line Cord from the broken Power Adapter and insert it into your new Power Adapter.

2.1.1.2. AC line Cord

To replace the AC line Cord, first make sure that the power supply is not connected to the 3DMP or to a power source. Once you have verified this, you simply remove the broken AC line Cord from the Power Adapter and insert your new AC line Cord into the Power Adapter.

2.1.2. Battery

To replace the battery from your 3DMP first make sure that the unit is turned off and is not connected to the Power Supply. Placing the device with the handle facing you check the left side of the 3DMP device and you will see a small rectangle door with a handle and 2 thumb screws. You can remove the old battery being replaced by loosening these screws and pulling on the handle to pull the battery out. Once you have fully removed the old battery, you will insert the new battery and proceed to tighten the thumb screws to hold it securely into place.

3. Electromagnetic Compatibility Information

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                    ELECTROMAGNETIC EMISSIONS
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3DMP Field Units are suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes, provided the following warning is heeded:

```
  3DMP Field Units and related accessories are intended for use by trained
operators only.  This equipment may cause radio interference or may disrupt
the operation of nearby equipment.  It may be necessary to take mitigation
measures such as re-orienting or relocating the 3DMP Field Unit or the affected
equipment, or shielding the location.
```

3DMP Field Units may emit electromagnetic energy in order to perform their intended function. Nearby electronic equipment may be affected by these emissions. Potential sources of electromagnetic emissions include:

- Wireless Network Connectivity
  (IEEE 802.11 ; 2.4GHz, 3.6GHz, and 5GHz bands)

- Bluetooth connectivity
  (2.4GHz band)

3DMP Field Units are not suitable for interconnection with other equipment, other than approved accessories as described in this manual. Unapproved connections or modifications may cause unacceptable electromagnetic interference.

3DMP Field Units are intended for use in environments as described below.

- Floors should be hard surfaced (e.g. linoleum, vinyl tile, ceramic tile, concrete, or wood). If floors are covered with carpeting or other synthetic materials the relative humidity should be at least 35%, and precautions should be taken when connecting ECG cables to avoid exposing the unit to electrostatic discharge.

- Mains power used for charging 3DMP Field Units with internal batteries should be of typical Hospital or Commercial grade.
  If the quality of the local power supply is in doubt the 3DMP Field Units should be connected to an appropriately rated power conditioner or uninterruptible power supply.

- Electromagnetic emissions from other equipment may affect the accuracy of MCG results. Refer to Table 3.1 on page 18 on the following page for more information.

Premier Heart recommends the following minimum separation distances from portable and mobile RF communications equipment (transmitters)

Transmitter Power (Watts)	Recommended Separation	
	80MHz - 1GHz <1KHz AM	Other
0.01W	3 Meters	2 Meters
0.1W	5 Meters	2 Meters
1W	10 Meters	3 Meters
10W	20 Meters	10 Meters
> 10W	NR	

Table 3.1.: Transmitter Separation Minimums

Note: Premier Heart does not recommend the use of 3DMP Field Units to capture patient data in the vicinity of RF transmitters exceeding 10W of output power.

For best accuracy 3DMP Field Units should not be used in the vicinity of equipment that radiates RF energy. This includes, but is not limited to, radiotherapy and radiosurgery equipment, X-Ray systems, MRI systems, CT Scanners, large electric motors, and cellular telephones/pagers.

3.1. Troubleshooting

3.1.1. The MCG Unit fails to turn on

1. Unit functions correctly with AC Line cord connected

    a) Battery Exhausted

       i. Plug the MCG unit in and allow it to charge overnight

    b) Battery Removed or incorrectly installed.

        i. Remove and re-install the battery

    c) Battery at end of life

        i. Contact Premier Heart for replacement battery

2. Unit does not function with AC Line cord connected

    a) Contact Premier Heart for service.

3.1.2. The MCG Unit fails to power off

1. Software Locked Up

    a) Hold the power button for 30 seconds or until unit powers off

2. Hardware fault (system does not shut down when holding power button)

    a) Unplug AC line cord and remove battery

    b) Contact Premier Heart for service if this condition occurs frequently.

3.1.3. The MCG Unit does not recognize the ECG Capture Device

- Note any error messages and contact Premier Heart technical support for service.

3.1.4. The MCG Unit recognizes the ECG Capture Device but does not capture data

1. Poor ECG lead connection

    a) Carefully follow patient preparation and testing instructions in the Quick User Guide

2. Damaged ECG cable

    a) Contact Premier Heart for replacement ECG cable

3. Hardware or Software fault

    a) Contact Premier Heart technical support for service.

See the testing guide for causes of poor-quality ECG tracings and their solutions

Part II.

CF19 Field Units

1. Overview

The CF19 is the second-generation replacement for the 3DMP. CF19 systems are semi-rugged, and are designed for use in typical clinical environments with the capability to handle limited duty in more demanding situations such as all-weather EMS use. The CF19 is substantially lighter than its predecessor while improving portability and utility: an improved keyboard, longer battery life (approximately 6 hours of continuous testing), and a resistive touchscreen suitable for clinical use (pressure-operated, usable with a stylus or a gloved finger) contribute to a vastly improved user experience.

The CF19 systems also feature improved electromagnetic compatibility through a hardware "RF kill switch", allowing users to enable or disable wireless capabilities (Bluetooth, 802.11) or check the radio status before powering the system on in potentially sensitive environments.

The CF19 has been engineered for use in hospitals and larger practices, adding the ability to mount the system on any medical cart supporting standard VESA mounting attachments or on a specialized pedestal stand designed for the MCG system.

Figure 1.1.: CF19

1 - MCG Unit	4 - Battery *
2 - Power Adapter	5 - Capture Card *
3 - AC Line Cord	6 - ECG Cable
	* - Internal Component

1.1. Input/Output Connections

The CF19 comes with an array of Input/Output connections on the device. Aside from the supported connections listed below, Authorization from Premier Heart is required to use any of the Input/Output connections located on the device. For any questions on the supported and unsupported Input/Output connections located on your device please contact Premier Heart.

Supported Ports
Usb Port
VGA Port
Ethernet Port
Modem Port
ECG Connection
Power Supply Connection

2. Parts

For questions on repairing, replacing or ordering parts for your CF19 device please contact the Premier Heart Staff

2.1. User Serviceable Parts

Serviceable Parts are components that can be replaced by an approved service personnel.

2.1.1. Power Supply

The power supply is actually broken up in to two separate parts, the Power Adapter and the AC line cord. If you believe that your Power Supply is no longer working, please contact the Premier Heart staff and they can walk you through the steps of determining which of these parts needs to be replaced.

2.1.1.1. Power Adapter

To replace the Power Adapter, first make sure that the power supply is not connected to the CF19 or to a power source. Once you have verified this, you simply remove the AC line Cord from the broken Power Adapter and insert it into your new Power Adapter.

2.1.1.2. AC line Cord

To replace the AC line Cord, first make sure that the power supply is not connected to the CF19 or to a power source. Once you have verified this, you simply remove the broken AC line Cord from the Power Adapter and insert your new AC line Cord into the Power Adapter.

2.1.2. Battery

To replace the battery from your CF19 first make sure that the unit is turned off and is not connected to the Power Supply. Placing the device so the handle is facing you, check the right side of the device and you will find a small rectangle door with a picture of a battery on it. To remove the old battery you must slide the lock on the door away from the arrow and then slide it down to open the door. Remove the old battery and replace it with the new one. Close the door, and this time slide the lock towards the arrow to secure the battery in your CF19 device.

3. Electromagnetic Compatibility Information

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                      ELECTROMAGNETIC EMISSIONS
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CF19 Field Units are suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes, provided the following warning is heeded:

```
  CF19 Field Units and related accessories are intended for use by trained
operators only.  This equipment may cause radio interference or may disrupt
the operation of nearby equipment.  It may be necessary to take mitigation
measures such as re-orienting or relocating the MCG Field Unit or the affected
equipment, or shielding the location.
```
CF19 Field Units may emit electromagnetic energy in order to perform their intended function. Nearby electronic equipment may be affected by these emissions. Potential sources of electromagnetic emissions include:

- Wireless Network Connectivity
  (IEEE 802.11 ; 2.4GHz, 3.6GHz, and 5GHz bands)

- Bluetooth connectivity
  (2.4GHz band)

CF19 Field Units are not suitable for interconnection with other equipment, other than approved accessories as described in this manual. Unapproved connections or modifications may cause unacceptable electromagnetic interference.

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ELECTROMAGNETIC IMMUNITY

CF19 Field Units are intended for use in environments as described below.

- Floors should be hard surfaced (e.g. linoleum, vinyl tile, ceramic tile, concrete, or wood). If floors are covered with carpeting or other synthetic materials the relative humidity should be at least 35%, and precautions should be taken when connecting ECG cables to avoid exposing the unit to electrostatic discharge.

- Mains power used for charging CF19 Field Units with internal batteries should be of typical Hospital or Commercial grade.
  If the quality of the local power supply is in doubt the CF19 Field Units should be connected to an appropriately rated power conditioner or uninterruptible power supply.

- Electromagnetic emissions from other equipment may affect the accuracy of MCG results. Refer to Table 3.1 on page 32 on the next page for more information.

Premier Heart recommends the following minimum separation distances from portable and mobile RF communications equipment (transmitters)

Transmitter Power (Watts)	Recommended Separation	
	80MHz - 1GHz <1KHz AM	Other
0.01W	3 Meters	2 Meters
0.1W	5 Meters	2 Meters
1W	10 Meters	3 Meters
10W	20 Meters	10 Meters
> 10W	NR	

Table 3.1.: Transmitter Separation Minimums

Note: Premier Heart does not recommend the use of CF19 Field Units to capture patient data in the vicinity of RF transmitters exceeding 10W of output power.

For best accuracy CF19 Field Units should not be used in the vicinity of equipment that radiates RF energy. This includes, but is not limited to, radiotherapy and radiosurgery equipment, X-Ray systems, MRI systems, CT Scanners, large electric motors, and cellular telephones/pagers.

3.1. Troubleshooting

3.1.1. The MCG Unit fails to turn on

1. Unit functions correctly with AC Line cord connected

    a) Battery Exhausted

        i. Plug the MCG unit in and allow it to charge overnight

    b) Battery Removed or incorrectly installed.

      i. Remove and re-install the battery

    c) Battery at end of life

      i. Contact Premier Heart for replacement battery

2. Unit does not function with AC Line cord connected

    a) Contact Premier Heart for service.

3.1.2. The MCG Unit fails to power off

1. Software Locked Up

    a) Hold the power button for 30 seconds or until unit powers off

2. Hardware fault (system does not shut down when holding power button)

    a) Unplug AC line cord and remove battery

    b) Contact Premier Heart for service if this condition occurs frequently.

3.1.3. The MCG Unit does not recognize the ECG Capture Device

- Note any error messages and contact Premier Heart technical support for service.

3.1.4. The MCG Unit recognizes the ECG Capture Device but does not capture data

1. Poor ECG lead connection

    a) Carefully follow patient preparation and testing instructions in the Quick User Guide

2. Damaged ECG cable

   a) Contact Premier Heart for replacement ECG cable

3. Hardware or Software fault

   a) Contact Premier Heart technical support for service.

See the testing guide for causes of poor-quality ECG tracings and their solutions

Part III.

CFBS Base Stations

1. Overview

The CFBS is a base station, designed to be used in conjunction with Capture Units. CFBS systems are semi-rugged, and are designed for use in typical clinical environments with the capability to handle limited duty in more demanding situations such as all-weather EMS use. The CFBS is substantially lighter than its predecessor while improving portability and utility: an improved keyboard, longer battery life (approximately 6 hours of continuous testing), and a resistive touchscreen suitable for clinical use (pressure-operated, usable with a stylus or a gloved finger) contribute to a vastly improved user experience.

The CFBS systems also feature improved electromagnetic compatibility through a hardware "RF kill switch", allowing users to enable or disable wireless capabilities (Bluetooth, 802.11) or check the radio status before powering the system on in potentially sensitive environments.

1.1. Input/Output Connections

The CFBSs comes with an array of Input/Output connections on the device. Aside from the supported connections listed below, Authorization from Premier Heart is required to use any of the Input/Output connections located on the device. For any questions on the supported and unsupported Input/Output connections located on your device please contact Premier Heart.

Supported Ports
Usb Port
VGA Port
Ethernet Port
Modem Port
ECG Connection
Power Supply Connection

2. Parts

For questions on repairing, replacing or ordering parts for your CFBS device please contact the Premier Heart Staff

2.1. User Serviceable Parts

Serviceable Parts are components that can be replaced by an approved service personnel.

2.1.1. Power Supply

The power supply is actually broken up in to two separate parts, the Power Adapter and the AC line cord. If you believe that your Power Supply is no longer working, please contact the Premier Heart staff and they can walk you through the steps of determining which of these parts needs to be replaced.

2.1.1.1. Power Adapter

To replace the Power Adapter, first make sure that the power supply is not connected to theCFBS or to a power source. Once you have verified this, you simply remove the AC line Cord from the broken Power Adapter and insert it into your new Power Adapter.

2.1.1.2. AC line Cord

To replace the AC line Cord, first make sure that the power supply is not connected to the CFBS or to a power source. Once you have verified this, you simply remove the broken AC line Cord from the Power Adapter and insert your new AC line Cord into the Power Adapter.

2.1.2. Battery

To replace the battery from your CFBS first make sure that the unit is turned off and is not connected to the Power Supply. Placing the device so the handle is facing you, check the right side of the device and you will find a small rectangle door with a picture of a battery on it. To remove the old battery you must slide the lock on the door away from the arrow and then slide it down to open the door. Remove the old battery and replace it with the new one. Close the door, and this time slide the lock towards the arrow to secure the battery in your CFBS device.

3. Electromagnetic Compatibility Information

ELECTROMAGNETIC EMISSIONS

CFBS base stations are suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes, provided the following warning is heeded:

```
  CFBS base stations and related accessories are intended for use by trained
operators only.  This equipment may cause radio interference or may disrupt
the operation of nearby equipment.  It may be necessary to take mitigation
measures such as re-orienting or relocating the MCG Field Unit or the affected
equipment, or shielding the location.
```
CFBS base stations may emit electromagnetic energy in order to perform their intended function. Nearby electronic equipment may be affected by these emissions. Potential sources of electromagnetic emissions include:

- Wireless Network Connectivity
  (IEEE 802.11 ; 2.4GHz, 3.6GHz, and 5GHz bands)

- Bluetooth connectivity
  (2.4GHz band)

CFBS base stations are not suitable for interconnection with other equipment, other than approved accessories as described in this manual. Unapproved connections or modifications may cause unacceptable electromagnetic interference.

ELECTROMAGNETIC IMMUNITY

CFBS base stations are intended for use in environments as described below.

- Floors should be hard surfaced (e.g. linoleum, vinyl tile, ceramic tile, concrete, or wood). If floors are covered with carpeting or other synthetic materials the relative humidity should be at least 35%.

- Mains power used for charging CFBS base stations with internal batteries should be of typical Hospital or Commercial grade.
  If the quality of the local power supply is in doubt the CFBS base stations should be connected to an appropriately rated power conditioner or uninterruptible power supply.

3.1. Troubleshooting

3.1.1. The CFBS Unit fails to turn on

1. Unit functions correctly with AC Line cord connected

    a) Battery Exhausted

        i. Plug the MCG unit in and allow it to charge overnight

    b) Battery Removed or incorrectly installed.

        i. Remove and re-install the battery

    c) Battery at end of life

        i. Contact Premier Heart for replacement battery

2. Unit does not function with AC Line cord connected

    a) Contact Premier Heart for service.

3.1.2. The MCG Unit fails to power off

1. Software Locked Up

    a) Hold the power button for 30 seconds or until unit powers off

2. Hardware fault (system does not shut down when holding power button)

    a) Unplug AC line cord and remove battery

    b) Contact Premier Heart for service if this condition occurs frequently.

3.1.3. The MCG Unit does not recognize the ECG Capture Device

- Power off the CFBS unit and disconnect the ECG capture device.
- Reconnect the ECG capture device and power on the CFBS unit.
- If the ECG capture device is still not recognized note any error messages and contact Premier Heart technical support for assistance.

3.1.4. The MCG Unit recognizes the ECG Capture Device but does not capture data

1. Poor ECG lead connection

    a) Carefully follow patient preparation and testing instructions in the Quick User Guide

2. Damaged ECG cable

    a) Contact Premier Heart for replacement ECG cable

3. Hardware or Software fault

a) Contact Premier Heart technical support for service.

See the testing guide for causes of poor-quality ECG tracings and their solutions

Part IV.

JH2L Capture Units

1. Overview

Figure 1.1.: JH2L Capture Device

1 - JH2L Device	3 - Limb Clips (not shown)
2 - Patient Lead Cable	6 - USB Cable(not shown)

* - Internal Component

The JH2L is a portable ECG capture device that is designed for use in conjunction with MCG Base Stations as listed in the chart below.

Base Station
CFBS

1.1. Input/Output Connections

The JH2L device has connections are for the ECG (patient) cable and the USB cable connecting to the PC.

There is also a battery compartment, which is unused at this time.

1.2. Controls and Status Indicators

The JH2L device operates in two modes: MCG (USB Direct Capture), and Holter (Independent Recording). At this time Holter functionality is not enabled for the JH2L devices, therefore the two Holter controls (the "Mode" button on the front of the unit and the Holter power switch on the bottom of the unit) should not be used. The Holter power switch should be left in the "Off" position when operating in MCG/USB mode.

1.2.1. MCG (USB) Mode Operation

When operating in standard MCG mode the JH2L device is entirely controlled by the MCG Clinical Client software. The three status lights for MCG mode and their meaning are:

POWER The JH2L Device is connected to the PC and receiving power over the USB cable.

RUN The JH2L Device is currently operating and recording ECG data.

ERROR The JH2L Device has encountered an internal error that requires operator attention. The specific error will be displayed on the Base Station - If necessary the MCG Clinical Client will notify the operator to discard the current test and restart sampling.

NOTE: If any light on the Holter status bar illuminates during testing in USB mode stop testing and power-cycle the JH2L device by disconnecting it from the USB cable and reconnecting it.
If lights continue to illuminate on the Holter status bar contact Premier Heart support.

1.2.2. Holter (Independent Recording) Mode Operation

JH2L Devices do not currently operate in Holter mode. A future device firmware and Base Station software upgrade may enable this functionality.

2. Parts

For questions on repairing, replacing or ordering parts for your JH2L device please contact Premier Heart Support.

2.1. User Serviceable Parts

Serviceable Parts are components that can be replaced by an approved service personnel.

2.1.1. USB Cable

To replace the USB interface cable for your JH2L device, verify that the PC you are connecting to is powered off, then disconnect the old USB cable from the JH2L device and from the PC and install your replacement cable.
If excessive force is required to remove the USB cable from either the PC or the JH2L field unit, **stop** and contact Premier Heart support for assistance.

Note: Premier Heart supplies approved USB cables for use with the JH2L Device, and replacement cables may be ordered through Premier Heart.
Users may at their option substitute a commodity USB cable of their choice, however this cable is not to exceed 2 meters (6 feet 6 inches) in length (See Table 3.2 on page 59).

2.1.2. Patient Cable

To replace the patient cable, ensure that your JH2L device is powered off. It is recommended that you disconnect the USB cable from the JH2L device.

Removal	**Installation**

Grasp the locking collar of the ECG cable next to the arrow.
Pull straight out from the socket to remove the old cable.

Align the arrow on the locking collar with the mark on the socket and push together. The connector will lock in position with an audible click.

3. Electromagnetic Compatibility Information

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                    ELECTROMAGNETIC EMISSIONS GUIDANCE
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JH2L Field Units are suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes, provided the following warning is heeded:

```
  JH2L Field Units and related accessories are intended for use by trained
operators only.  This equipment may cause radio interference or may disrupt
the operation of nearby equipment.  It may be necessary to take mitigation
measures such as re-orienting or relocating the MCG Field Unit or the affected
equipment, or shielding the location.
```
JH2L Field Units may emit electromagnetic energy in order to perform their intended function. Nearby electronic equipment may be affected by these emissions. Potential sources of electromagnetic emissions include:

- Wireless Network Connectivity
  (IEEE 802.11 ; 2.4GHz, 3.6GHz, and 5GHz bands)

- Bluetooth connectivity
  (2.4GHz band)

JH2L Field Units are not suitable for interconnection with other equipment, other than approved accessories as described in this manual. Unapproved connections or modifications may cause unacceptable electromagnetic interference.

Emissions Test	Compliance	Notes/Guidance
RF Emissions CISPR 11	Group 1	The JH2L Field Unit must emit electromagnetic energy in order to perform its intended function. Nearby equipment may be affected.
RF Emissions CISPR 11	Class B	See Electromagnetic Emissions Guidance
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuation / Flicker Emissions IEC 61000-3-3	Not Applicable	

Table 3.1.: Electromagnetic Emissions Information (IEC 60601-1-2 Table 1)

ELECTROMAGNETIC IMMUNITY Guidance

JH2L Field Units are intended for use in environments as described below.

- Floors should be hard surfaced (e.g. linoleum, vinyl tile, ceramic tile, concrete, or wood). If floors are covered with carpeting or other synthetic materials the relative humidity should be at least 35%, and precautions should be taken when connecting ECG cables to avoid exposing the unit to electrostatic discharge.

- Mains power used for charging JH2L Field Units with internal batteries should be of typical Hospital or Commercial grade.
  If the quality of the local power supply is in doubt the JH2L Field Units should be connected to an appropriately rated power conditioner or uninterruptible power supply.

- JH2L Field Units are not intended to be used adjacent to or stacked with other equipment. If use in close proximity to other equipment is necessary the JH2L device should be evaluated for proper function by a trained operator or Premier Heart service personnel.

- Electromagnetic emissions from other equipment, including mobile communications equipment (cellular phones, pagers, etc.) may affect the accuracy of MCG results.
  Refer to Table 3.3 on page 61 for more information.

- **Reduced Electromagnetic Immunity Compliance Levels and Additional Operating Restrictions**
  Due to the nature of MCG analysis it is not possible to filter all possible sources of environmental interference. During laboratory testing it was determined that the JH2L field units meet IEC 60601-1-2 requirements at a lower Compliance Level than specified in the standard. Reduced compliance levels and operating guidance are provided in Table 3.2 on page 59.

Immunity Test	IEC 60601 Test Level	Compliance Level	Notes

Table 3.2.: JH2L Immunity Compliance Levels (60601-1-2 table 2, table 4)

Immunity Test	IEC 60601 Test Level	Compliance Level	Notes
Electrostatic Discharge 61000-4-2	Contact: 2-6kV Air: 2-8kV	2kV	Operation of JH2L devices in environments with active electrostatic discharges is not recommended. Particular attention should be paid to tracing quality in these environments.
Radiated RF 61000-4-3	3V/m 80Mhz – 2.5GHz	Compliant at 60601-1-2 test level	Minimum separation distance $d = \frac{7}{3}\sqrt{P}$
Electrical Transients 61000-4-4	Multiple	Not Applicable ($<= 250$V)	No AC or DC power lines exceeding 3 meters are used. Operation of JH2L devices in environments with substantial electrical transients (250V or greater) is not recommended.
Surge IEC 61000-4-5	1kV Line-to-Line 2kV Line-to-Earth	Not Applicable	Device is not AC powered
Conducted RF IEC 61000-4-6	3Vrms 150KHz - 80MHz	1V	Reduced compliance level required as MCG analysis requires unfiltered input. Minimum separation distance $d = 3.5\sqrt{P}$

Immunity Test	IEC 60601 Test Level	Compliance Level	Notes
AC Voltage Variations IEC 61000-4-11	Multiple	Not Applicable	Device is not AC Powered
Power Frequency Magnetic Fields IEC 61000-4-8	3A/m	Compliant at 60601-1-2 test level	-
Separation distance formulas – d is distance in meters (m), P is transmitter power in watts (W)			

Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones, pager systems, amateur radio, AM/FM Radio, and Television broadcast equipment can- not be predicted theoretically with accuracy. To assess the electromagnetic environment due to these fixed transmitters an RF site survey may be conducted. If the measured field strength in the location in which the JH2L Field Unit is to be used exceeds the compliance level noted above the JH2L Field Unit should be observed to ensure normal operation. If abnormal performance is observed additional steps (such as relocating the JH2L Field Unit or the source of interference, adding shielding, etc.) may be necessary.

For best results observe the transmitter separation recommendations in Table 3.3 on page 61.

The JH2L Field Unit is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or user of the JH2L Field Unit can help prevent electromagnetic interference by maintaining a minimum distance between both portable and fixed RF communications equipment (transmitters) as outlined in the table below.

Transmitter Power	Recommended Separation Distance	
	80MHz – 1GHz <1KHz AM $d = \left(3 + \frac{\sqrt{P}}{2}\right) + \left(6\sqrt{P}\right)$	Other Frequencies $d = \left(2 + \frac{\sqrt{P}}{2}\right) + \left(\frac{7}{3}\sqrt{P}\right)$
0.01W	3 Meters	2 Meters
0.1W	5 Meters	3 Meters
1W	10 Meters	5 Meters
10W	24 Meters	11 Meters
> 10W	NR	
Separation distance formulas – d is distance in meters (m), P is transmitter power in watts (W)		

Table 3.3.: Transmitter Separation Minimums (IEC 60601-1-2 Table 6)

Note: Premier Heart does not recommend the use of JH2L Field Units to capture patient data in the vicinity of RF transmitters exceeding 10W of output power. If the JH2L Field Unit must be used near a fixed transmitter exceeding 10W output power an electromagnetic site survey is recommended to ensure that the transmitter will not cause interference with the JH2L Field Unit.

For best accuracy JH2L Field Units should not be used in the vicinity of equipment that radiates RF energy. This includes, but is not limited to, radiotherapy and radiosurgery equipment, X-Ray systems, MRI systems, CT Scanners, large electric motors, and cellular telephones/pagers.

Part V.

MCG Software

1. The MCG Operating System

MCG Field Units and Base Stations are shipped with Premier Heart's proprietary MCG Operating System and Clinical Client software. This software is designed to make setting up and using your MCG system as fast and easy as possible, as well as to ensure the security and integrity of patient data recorded for MCG analysis.

Figure 1.1.: MCG Field Unit Desktop

1 - Activities Menu	8 - MCG Clinical Client
2 - Time/Date Settings	9 - MCG Reports (web browser)
3 - Sound/Volume	10 - Network Test Tool
4 - Bluetooth Devices	11 - Remote Assistance Tool
5 - Network Settings	12 - Show Applications
6 - Power/Battery	13 - All/Frequent Applications
7 - Logout / Shutdown	14 - Applications List

The MCG Unit is a special-purpose appliance computer. As such it allows a restricted subset of general-purpose computing tasks designed to help effectively test and diagnose patients. Figure 1.1 on page 66 shows the default MCG Desktop with the Activities menu open and indicates the immediately available utilities. Each one is described briefly below - for more detailed information refer to the appropriate section in either this manual or the Quick User Guide.

1.1. Activities Menu

The Activities Menu contains programs which are frequently used on MCG systems.
When opened the activities menu dims the screen and provides Quick Launch icons for the MCG Clinical Client, MCG Report Viewer, Network Test Tool, and Remote Assistance tool. It also contains the Applications menu.

These items are described in greater detail below.

1.2. Date/Time Settings

A network-synchronized clock and calendar is displayed on the desktop. Clicking on the date/time display will allow you to access the Date and Time settings to reset the MCG system's clock and/or time zone if necessary.

1.3. Sound/Volume

This icon allows control of the MCG Unit's internal sound card volume for delivering operating system audio alerts.
Note that the MCG Clinical Client software does not use audible alerts.

1.4. Bluetooth Devices

This icon allows you to set up Bluetooth devices for use with the MCG Field Unit, including Bluetooth ECG Capture devices.

MCG Field Units may also use Bluetooth keyboards and mice, however their use while testing patients is not recommended.

1.5. Network Settings

The Network Settings icon allows you to connect to wired or wireless networks, as well as to access and modify the MCG System's network settings. For additional information on configuring the network on your MCG system seeSection 4.2 on page 76.

1.6. Power/Battery Utility

This icon indicates the current state of the MCG Unit's power supply, as well as the battery charge level when operating on battery power.
An estimate of battery charge and time remaining may be displayed by clicking on the icon. Note that the battery icon and time/percentage remaining is an estimate. For best performance, ensure that the MCG unit's battery is fully charged prior to testing patients.

1.7. Logout / Shutdown

To shut down your MCG system, click on this menu item and select "Power Off".

Other options on this menu should be used only when directed by Premier Heart support staff.

1.8. MCG Clinical Client

The MCG Clinical Client Quick Launch, displayed when the Activities menu is open, allows you to start the MCG Clinical Client if you have exited it.

1.9. MCG Reporting System (web browser)

MCG Systems are provided with a limited-use web browser which is designed solely for viewing MCG results. This icon will launch the web browser and connect to the Premier Heart Reporting Application.

1.10. Network Test Tool

In order to facilitate support all MCG systems are shipped with a Network Test Tool which attempts to verify that the network being used meets the minimum requirements for sending MCG test data to Premier Heart and viewing the resulting reports. This icon will launch the Network Test Tool.

Information from the Network Test Tool is intended to help Premier Heart support staff and your IT department in troubleshooting issues with the MCG system.

1.11. Remote Assistance Tool

In order to better support systems in the field Premier Heart includes a Remote Assistance tool on all MCG field units. This icon will launch the Remote Assistance tool to allow Premier Heart technicians to connect to your MCG system. For more information see 3.3 on page 73.

1.12. Applications and Settings

The Applications menu can be displayed when the Activities menu is open, and allows you to run less common tools, such as the Touchscreen Calibration utility and manual software updates. The applications menu also gives you access to accessibility features (such as the on-screen keyboard) and language localization settings for the MCG Operating System.

2. The MCG Clinical Client

The MCG Clinical Client is the primary program used for testing patients. See MCG Quick Guide for specific instructions on patient testing and use of our MCG Clinical Client.

3. Premier Heart Support Applications

Premier Heart provides a number of support applications in addition to the Clinical Client software. These applications are designed to assist Premier Heart in diagnosing problems with your field unit without requiring a site visit or the return of your unit to a Premier Heart service center.

3.1. The MCG Bug Report Tool

The MCG Bug Report tool is used to report issues with the MCG System's hardware or software. It is automatically invoked under certain circumstances, but may also be run manually to report issues.

3.2. Network Test Tool

The Network Test Tool attempts to contact Premier Heart's servers and reports any problems encountered. It can be used as a troubleshooting tool, or to confirm network setup.

3.3. Remote Assistance

The Remote Assistance application enables Premier Heart technicians to connect to your MCG unit to perform diagnostics - It should be used when instructed by Premier Heart.

3.4. Update Manager

The Update Manager will contact Premier Heart's servers and check for available software updates. Under normal circumstances the MCG system will notify you of available updates, however if your system is not connected to the internet or if you have missed an update that resolves an issue you have reported you may be asked to run the update manager manually.

4. MCG Unit Setup

4.1. Initial Setup

Before initially using any MCG system please connect the power cord and allow the unit to charge for 24 hours. This ensures that the battery is fully charged and will function correctly during setup and testing.

4.2. Network Setup
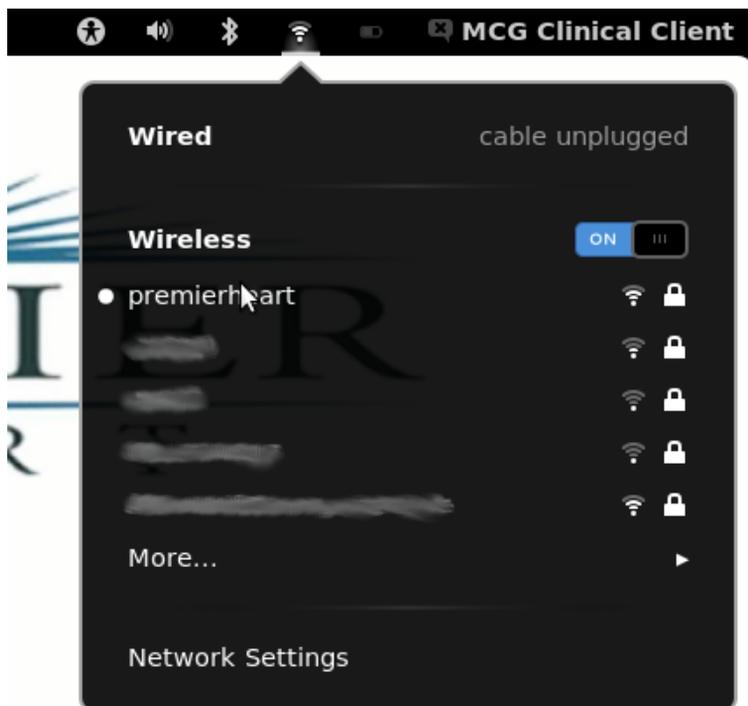
In order to submit your tests to Premier Heart's central servers and retrieve diagnostic reports your MCG unit must be connected to the Internet.

All network configuration is accomplished via the Network Settings icon on the task bar. The MCG unit is designed to be very flexible in the types of network connections you can use, and

has minimal bandwidth requirements.

4.2.1. Wired Network Setup

The MCG Field Unit is configured to operate in "roaming" (DHCP) mode at the factory – under normal circumstances you simply need to connect an Ethernet cable to the system and your network connection will be automatically detected and enabled. If the network is not automatically detected, click on the network utility icon and select "Wired Network" to attempt to acquire an IP address

4.2.2. Wireless Network Setup

Premier Heart has designed the MCG field unit to handle a wide variety of WiFi 802.11 networks. If your MCG unit is equipped with wireless capability wireless networks will be listed when you click on the network utility icon. Select your network from the list.

If your wireless network does not broadcast its SSID you may manually enter the SSID and other required information by selecting "Network Settings", selecting the wireless interface, and choosing "Other..." from the list of network names.

IMPORTANT

Wireless Networking should be deactivated while testing patients to prevent possible interference from the WiFi transmitter in the MCG system. You may deactivate wireless networking by using the virtual switch which is displayed when you click on the Network Settings icon, or by activating the RF kill switch if that feature is installed on your device.

4.2.3. Other Network Connections

In addition to the standard wired/wireless networking options above the MCG field unit is capable of connecting to networks via dial up modem(PPP dial up) and GPRS/UMTS("Cellular Modem") connectivity.

Please Note

Premier Heart does not officially support these connection methods.
They are documented here for informational purposes only.

4.2.4. Manual Network Configuration

Please Note

Contact your local network administrator before modifying these settings.
Incorrect network configuration settings may render your MCG system non-functional.

Under normal circumstances MCG systems will work with most networks without requiring any modification to the default network settings, however some sites may require static or customized network configuration. For these situations you may select the "Network Settings" menu item, choose the interface you wish to modify, and click "Options..." to bring up the manual network configuration screen.

Your network administrator will be able to supply the required information for manual configuration.
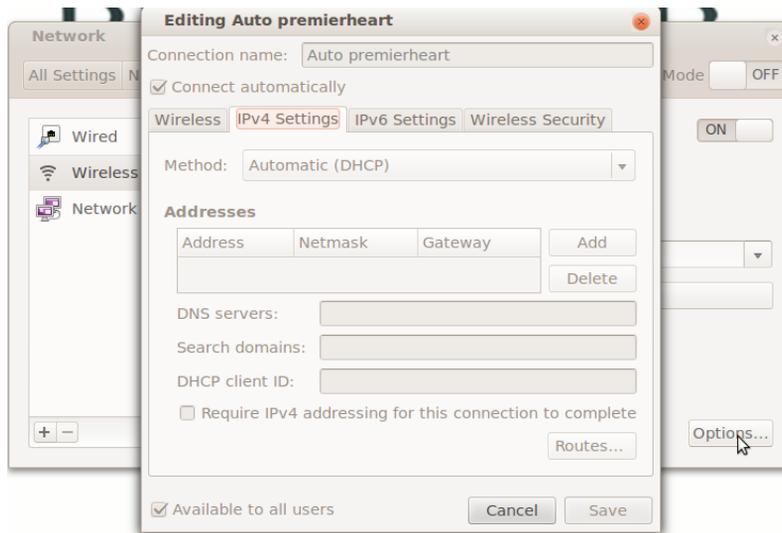
Figure 4.1.: Manual Network Configuration screen

4.2.5. Network Test

Once you have completed network configuration you may run the *Network Test Tool* included on the MCG unit to verify your settings. This tool will attempt to connect to Premier Heart's servers and provide a report indicating any errors it encounters. This tool can be found on the Activities Menu Quick Launch bar.
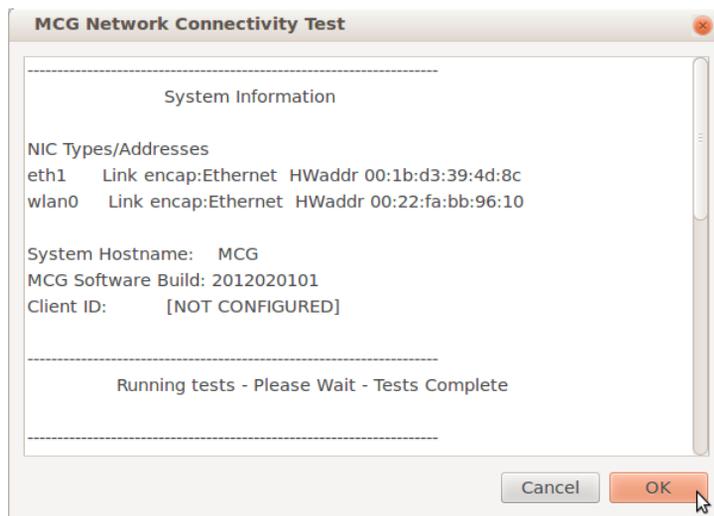
Figure 4.2.: Successful Network Test

4.3. International Support

Premier Heart has begun translating the MCG system into various languages. If you have requested a specific language and localization scheme your system will be shipped with that config-

uration from the factory.

If you would like to change the language or keyboard layout you may do so using the Region & Language application.

4.3.1. Changing Language Settings

The MCG Clinical Client language is determined by the operating system language.
To change the system language select the *Language* tab in the Region & Language application.
To change or add keyboard layouts select the *Input Sources* tab.
To set date/time/currency/measurement formats select the *Formats* tab. (Note that Format settings are currently not used by the MCG Clinical Client application and must be set as described in 4.3.2).

You will need to reboot the MCG system for your changes to take effect.
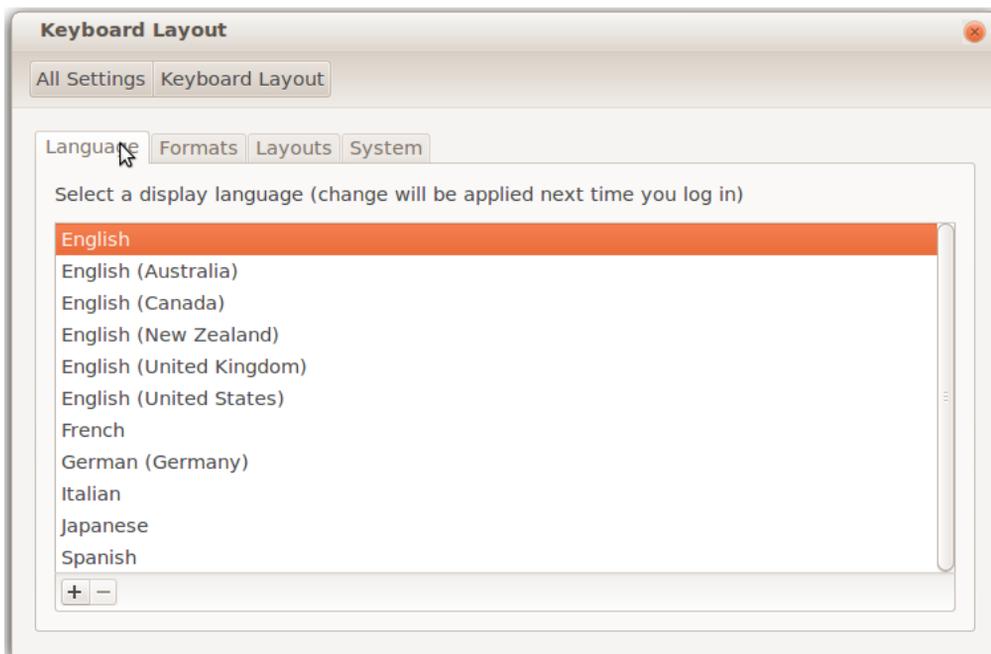
Figure 4.3.: Language Selection

Note that MCG systems will typically auto-detect keyboard layouts for Bluetooth and USB keyboards attached to the system.

4.3.2. Changing Height and Weight Units

The MCG Clinical Client allows users to select whether they prefer to enter patient height and weight in metric units (cm & Kg) or imperial units (inches & pounds). To change this setting

select *User Preferences* from the MCG client's Options menu and click on the *Localization* tab.
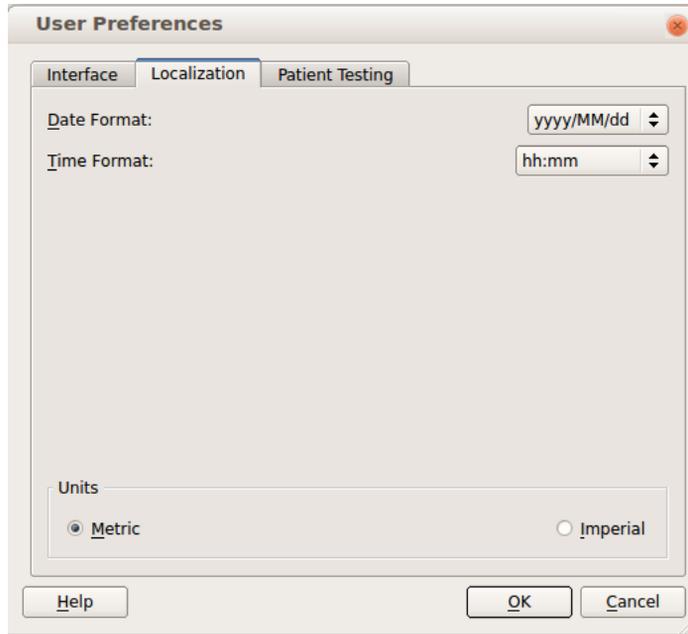
Figure 4.4.: Height & Weight Units

The MCG system stores all height and weight measurements in metric units internally. As a result there may be a slight rounding error when entering or viewing data in imperial units. This rounding error does not affect the diagnostic accuracy of the MCG system.

4.4. Mouse and Keyboard Customization

Options such as key repeat rate, mouse movement speed, and double-click speed may be set from the System Settings application. The default settings are suitable for most users, however feel free to adjust them as necessary to suit your requirements.

4.4.1. Date and Time

Premier Heart will configure your MCG system with an appropriate time zone based on the information you provided when you purchased the system. If you wish to change the time zone you may do so by clicking on the date/time on the desktop and selecting "Date and Time Settings" As shipped all MCG systems are configured to use Network Time Protocol (NTP) to synchronize their clocks automatically when connected to the internet. You may also update the system time manually if your system is unable to reach the default NTP servers.

4.4.2. Touch Screen Support

Figure 4.5.: Touchscreen Calibration Utility

Some MCG field units and base stations are supplied with a touch screen interface in in addition to a traditional mouse or trackpad. The touch screens on these units are calibrated at the factory, however over time the touch sensors may drift or become less accurate. If your touch screen is out of calibration you may recalibrate it by selecting *TouchScreen Calibration* from the Applications section of the Activities menu.
This utility will do nothing on units without a touchscreen interface.

4.5. Clinical Client User Preferences

The MCG Clinical Client can be customized to suit your users typical workflows.
These preferences are per-user, and can be set from the Options menu in the Clinical Client.

4.5.1. Interface Settings
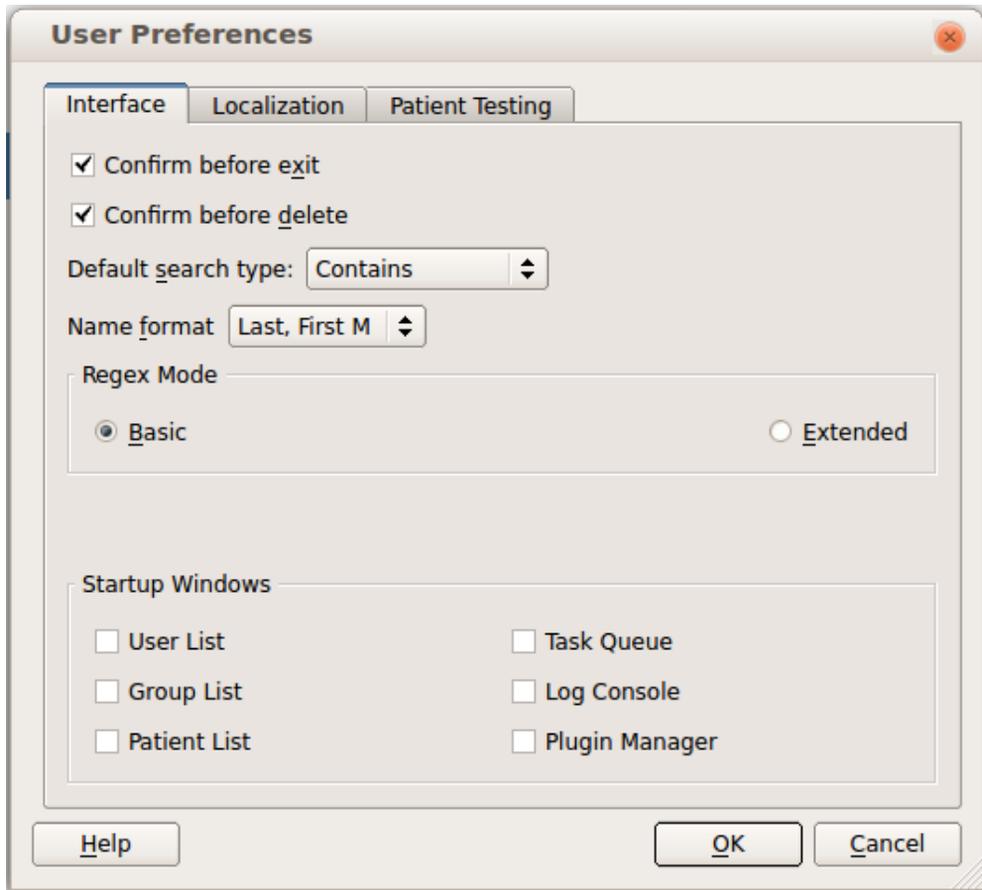
Figure 4.6.: Clinical Client Interface Settings

The MCG Clinical Client's default Interface settings are shown in the image above.
From this preference panel you can disable some confirmation dialog boxes, alter the default Search type (used when searching for patients) and Patient Name format, and select which windows you would like the system to open when starting the clinical client.

If the Default search type is set to Regular Expressions (Regex) you may also choose between standard and extended regular expressions.

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4.5.2. Patient Testing Preferences
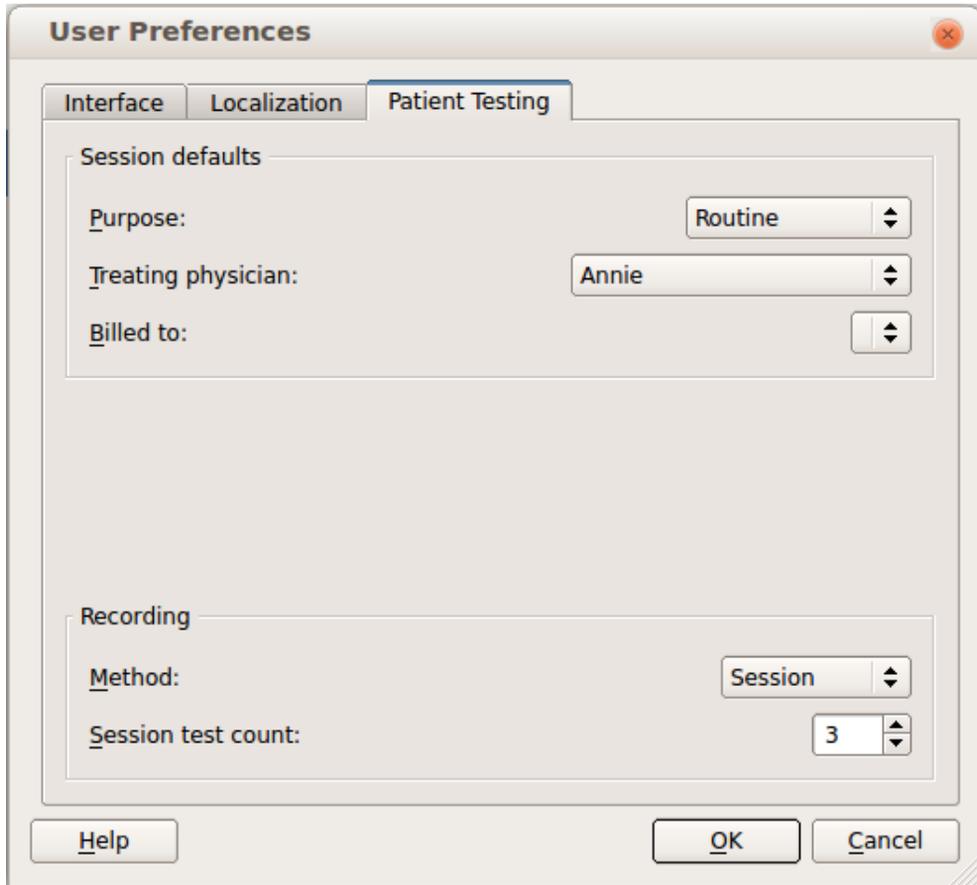
Figure 4.7.: Clinical Client Patient Testing Settings

The MCG Clinical Client defaults to Premier Heart's standard testing profile (Testing purpose is "Routine", default recording type is Session, and a Session consists of 3 Tests).

On this preference pane you may modify the default testing purpose, treating physician, and recording type (Session, Single-Test, or Continuous). You may also set the number of tests in a Session to a higher value if you desire (the minimum number of tests in a session is 3).

4.6. Clinical Client System Preferences

The MCG Clinical Client has a number of internal functions which can be configured by MCG users with the `Manage System` privilege (typically this is the first user on your system set up by Premier Heart). These settings can be modified by selecting `System Config` from the `Admin` menu in the Clinical Client.

> **NOTE:** These settings should only be changed when instructed by Premier Heart. Improperly modifying these settings may result in your MCG system becoming unusable.
>
> If settings have been inadvertently changed you may restore the system defaults by selecting `Reset System Config` from the `Admin` menu.

5. MCG Software Maintenance

5.1. Software Updates

From time to time Premier Heart will issue software updates which introduce new features, improve the functionality of the MCG system, or correct issues noted by our users. The MCG field unit includes an automatic update system which can download and install these updates as they become available.
Updates can also be downloaded manually using the "Download Updates" application.

Update Release Notes will be displayed prior to downloading any update package from the server. These release notes should be reviewed to ensure you are aware of any functionality changes which may occur as a result of the software update.
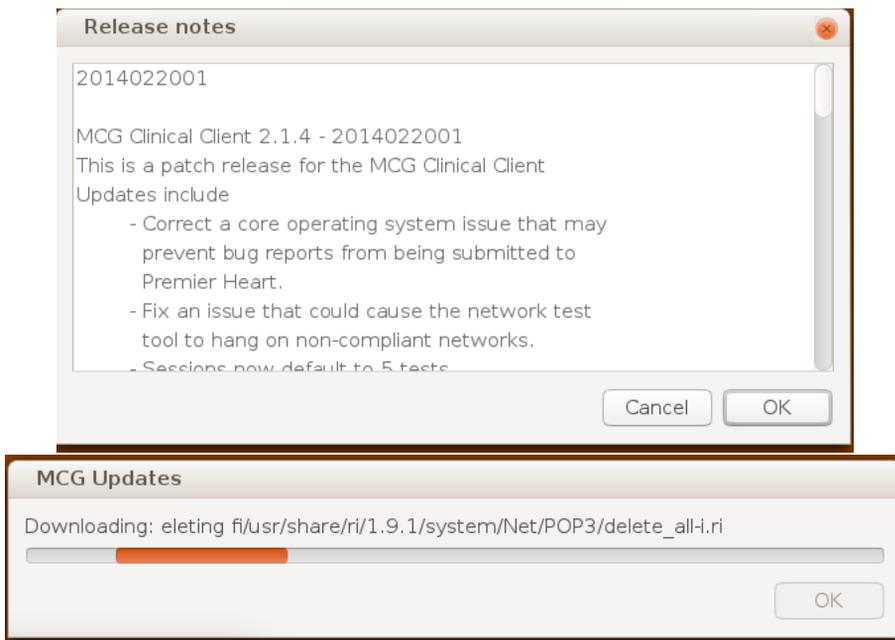
Figure 5.1.: Update Utility - Release Notes and Download Progress screens

To ensure uninterrupted availability of the MCG diagnostic services updates should be installed as soon as possible. In cases where an update is necessary to insure clinical integrity or the security of patient data Premier Heart will make every effort to notify all users as quickly as possible, and may disable the ability to upload data from systems running older versions of the MCG operating system and Clinical Client in order to ensure the integrity of the diagnostic data.

6. Hardware Maintenance

6.1. Hardware Support Table

Premier Heart occasionally releases new versions of the MCG hardware which add new features or resolve issues encountered in earlier revisions.

Premier Heart recognizes the substantial capital investment in diagnostic equipment, and we are committed to maintaining diagnostic support for older hardware models for a minimum of three years after they are discontinued. Beyond this three-year commitment Premier Heart will continue to maintain diagnostic support for end-of-life models for as long as technically practical, however new features may not be made available for older revisions of the hardware after they are discontinued, and discontinued models may cease to function after their End of Support Life date.

For more information please see the table of field units and their support life on the following page

MCG Unit Type	Introduction	Discontinued	End of Support Life
MCG 3DMP (770)	2005	12/2008	12/2011
MCG 3DMP (790)	2005	06/2009	12/2012
MCG CF19	2009	–	–
MCG CFBS	2009	–	–
MCG JH2L	2010	–	–

Table 6.2.: MCG Field Units — Support Life

6.2. Hardware Cleaning

Periodic surface cleaning will help keep your MCG unit looking its best and operating properly.

NOTE

All cleaning should be carried out with the MCG unit unplugged and powered off

- Dust may be removed from the monitor using a dry, non-abrasive lint-free cloth

  - For fingerprints or harder to remove marks on the monitor, the cloth may be moistened with water or a commercially available monitor cleaning solution.
    Note: DO NOT use cleaning products containing alcohol or ammonia to clean your monitor - permanent damage may result. Premier Heart recommends Klear Screen by Merridew Enterprises for monitor cleaning.

  - *Apply cleaning solution to the cloth only. DO NOT apply directly to the monitor or damage may occur.*

- Dust and finger oils may be removed from the keyboard and trackpad using a non-abrasive lint-free cloth moistened with alcohol

- The outer case of the MCG field unit may be wiped clean with a dry, non-abrasive lint-free cloth.

  - For harder to remove marks on the outer case, the cloth may be moistened with water or alcohol, however take care to avoid getting water or alcohol into any ports or connectors on the MCG unit.

- The Four limb leads should be cleaned before each patient with alcohol to disinfect as well as to ensure good tracing quality.

  - For more information on this please see the Quick Guide provided with our MCG field unit.

6.3. Periodic Calibration

To ensure diagnostic accuracy Premier Heart recommends that all MCG Data Sources undergo a periodic calibration check. The calibration period varies by data source, and is listed in MCG Data Sources — Calibration Interval.

Note: Because the MCG analysis process is sensitive to variations in the ECG signal Premier Heart is unable to guarantee the accuracy of results if data was recorded on a field unit which is beyond its calibration expiration date.

MCG Data Source Type	Calibration Interval
MCG 3DMP (770) Field Unit	3 years
MCG 3DMP (790) Field Unit	3 years
MCG CF19 Field Unit	3 years
MCG JH2L Field Unit	3 years
TZ Medical AeraCT	3 years

Table 6.4.: MCG Data Sources — Calibration Interval

7. Troubleshooting

7.1. Important Troubleshooting Information

In addition to the specific steps outlined below, the following points should be checked when troubleshooting any problems:

- *Are all necessary cables connected securely?*
  Many problems can be traced to poor cable connections. Ensure that all cables are securely connected to the MCG unit, and ensure that ECG electrodes are making good contact with the patient's skin.

- *Were any changes made to the unit recently?*
  This may include hardware or software upgrades issued by Premier Heart, new cables or electrodes, etc. Try reversing any changes if possible – If you are able to isolate the fault our support team will be better able to assist you.

- *Were any changes made to your environment recently?*
  This may include moving the MCG unit from one room to another, making network configuration changes, changing ISPs, etc. Try reversing any changes if possible – If you are able to isolate the fault our support team will be better able to assist you

- *Has the MCG unit been subjected to rough handling?*
  The MCG hardware is designed to stand up to a wide range of physical conditions and stress, however rough handling (drops, falls, etc.) or exposure to adverse conditions (liquid spills, extreme temperatures) may cause damage and require repair or recalibration.

7.2. Software Troubleshooting

7.2.1. The MCG System hangs on start up

- The MCG system periodically performs self tests on start up. These tests happen every 180 days, or when the MCG system detects a possible hardware fault.
  If the hard disk activity light () is lit, the system is likely performing these tests – do not interrupt this process.

  – To see the current status of the startup process, press escape (ESC) to drop to the console. The system startup messages will be displayed.
  Note: If you see a message on this console asking you to reboot hold the power button until the system shuts down, then restart normally.

- If the MCG unit has not updated progress or displayed an error message after 5 minutes and the hard disk activity light is no longer lit you may power the machine off by holding down the power button, wait 30 seconds and power the machine back on (See the appropriate instructions in the troubleshooting section for your field unit or base station if the unit does not power off).

- If the unit hangs repeatedly on start up contact Premier Heart for assistance.
  IMPORTANT: Do not repeatedly power-cycle the MCG system when attempting to resolve start up hangs. Doing so may render your system non-operational.

7.2.2. The MCG System displays an error message on Start up or Shutdown

- Note the error message and contact Premier Heart technical support.
  Please include as much information as possible when contacting support, including:

– What you were doing when you encountered the error

– Steps to reproduce the error (if possible)

• Please refer to the Premier Heart troubleshooting form on page ?? and have as much information available as possible when contacting technical support to enable us to better assist you.

7.2.3. The MCG System displays a login screen

1. Under certain circumstances the MCG field unit may briefly display a graphical login screen.
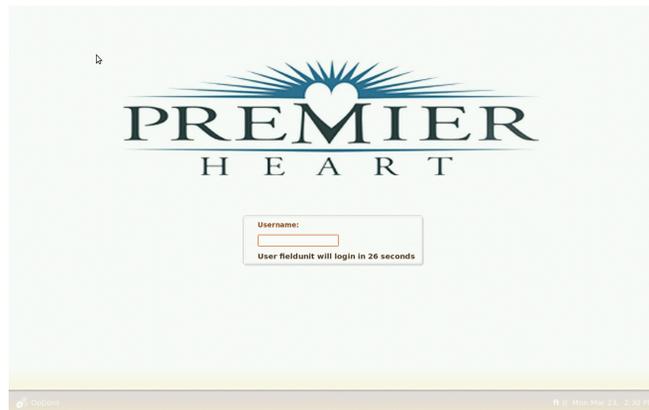
Figure 7.1.: Graphical Login Screen

No action is required — The unit will automatically log in and display the MCG testing desktop if no action is taken.

    a) If the system displays the login screen for longer than 60 seconds, or if the login screen does not include the "User field unit will login in _ _ seconds" message, you may press the power button to shut the system down.
If the system does not shut down or the login screen returns after rebooting contact Premier Heart for assistance.

2. If the MCG field unit displays a text login screen, power the unit off, wait 30 seconds and power the unit back on.

    a) If the unit fails to restart or displays a text-based login screen again contact Premier Heart for assistance.

7.2.4. The MCG System shows an incorrect date/time

———*Please*

Note
The MCG Operating System uses the Network Time Protocol (NTP) to set the system clock, which provides a high degree of accuracy for the system time.
Slight clock variations are normal - If the MCG field unit's time is within 10 minutes of your office time the MCG unit's clock is likely correct.
The following steps are intended for troubleshooting large (>10 minute) variations in time.

For all of these troubleshooting steps, click on the date/time display on the field unit desktop and select "Date and Time Settings".

1. Verify the time zone setting is correct. If the region and city are not correct, update them as needed.

2. Verify that "Network Time" is ON.
   The Date and Time controls below this option should be inactive.

3. Connect the MCG unit to the Internet if it is not already connected (if you are already connected to the internet, disconnect, wait 30 seconds and reconnect).

4. Run the Network Test Tool. In the "Additional Informational Tests" section the tool will report the status of its NTP test.

   a) If the NTP test passed your MCG field unit will automatically adjust its clock. Note that it may take approximately 5-10 minutes to initially set the clock, and up to 30 minutes to fully synchronize.

   b) If the NTP test failed, check your internet connection and firewall settings to verify that NTP traffic is allowed, or manually adjust your clock as described below.

Manual Clock Adjustment

In the event that you are unable to use NTP to set the MCG Field Unit's clock (or the date/time set by using NTP is substantially inaccurate) you may manually set the clock as follows:

1. Click on the date/time display on the field unit desktop and select "Date and Time Settings"

2. Verify that the time zone setting is correct. If the region and city are not correct, update them as needed.

3. Set "Network Time" to OFF.
   The date and time controls should now be activated

4. Set the date and time on your system. This change takes effect immediately.

Note: If Network Time is disabled you may periodically need to verify and adjust the date and time periodically.
Premier Heart recommends using Network Time (NTP) whenever possible.

7.3. Network Troubleshooting

———*Please*

Note

All MCG units are verified functional and able to connect to both wired and wireless test networks at the factory prior to shipping. Any additional troubleshooting beyond the steps outlined in this section should be referred to your site's network administrator.

Premier Heart recommends running the Network Test Tool provided with the MCG Operating System to diagnose network problems prior to proceeding with the steps below. The Network Test Tool will isolate the majority of problems quickly and greatly simplifies the troubleshooting process.

7.3.1. General Network Troubleshooting

7.3.1.1. The MCG Unit connects to the network but does not get an IP address

1. No DHCP server on network, DHCP server not reachable, MCG unit not authorized on DHCP server, or no available addresses in DHCP pool

   a) Contact your network administrator for assistance

7.3.1.2. The MCG Unit is unable to send test data

1. The MCG unit is not connected to a network

    a) Verify network connection via the network utility icon

2. The MCG unit can not connect to Premier Heart

    a) Run the Network Test Tool and correct any issues reported

3. Your account has been administratively deactivated

    a) Contact Premier Heart

7.3.1.3. The MCG Unit is unable to retrieve reports

1. The MCG unit is not connected to a network

    a) Verify network connection via the network utility icon

2. The MCG unit can not connect to Premier Heart

    a) Run the Network Test Tool and correct any issues reported

7.3.2. Wireless Networks (802.11)

7.3.2.1. The MCG Unit is not able to connect to the wireless network

1. No WiFi signal

    a) Ensure that the wireless network is configured and all base stations are operating

    b) See steps for troubleshooting low WiFi signal strength in the section for your particular hardware.

2. Wireless Network Configuration not supported

a) See page 77 for information on supported WiFi configurations.

3. RF Kill Switch engaged

a) MCG Field Unit models 3DMP and CF19, as well as Base Station model CFBS include a hardware RF Kill Switch.
When activated Bluetooth and WiFi hardware are physically disabled, and the Wireless networks list will show "Hardware Disabled".
See the instructions for your specific system model for information on the RF Kill Switch.

7.3.2.2. The MCG Unit shows poor WiFi signal strength

1. Unit too far from WiFi base station

a) Move the MCG Unit closer to a wireless base station

b) Install additional WiFi base stations to improve coverage

2. Radio Interference

a) Ensure the MCG unit is not being used near heavy diagnostic equipment (e.g. CT Scanners, X-Ray, radiation therapy or MRI equipment)

3. RF-Insulated walls
Walls made of concrete or walls designed to screen out radiation (e.g. those around X-Ray suites) will block the WiFi signal.

a) Ensure the MCG unit is not used in a room with RF-Insulated walls.

7.3.3. Wired Networks (Ethernet)

7.3.3.1. The MCG Unit is not able to connect to the wired (Ethernet) network

1. Contact your network administrator to verify network settings

2. Verify that the network cable is functional

    a) Replace cable if necessary

3. Verify that the network cable is correctly routed

    a) Reroute cable as needed to avoid sources of interference, e.g.

        i. Fluorescent lighting

        ii. Diagnostic equipment (CT Scanners, radiation therapy, X-Ray & MRI equipment)

8. Technical Support

Premier Heart Help You

Prior to calling technical support, please try the appropriate troubleshooting steps from Chapter 7, as well as any hardware-specific troubleshooting steps in the section for your MCG hardware model.

If these steps have not resolved your problem please refer to the form on page ?? for the information you need to have ready when calling, or using email / web request to report an issue.

The Premier Heart Technical Support office is open between 9 AM to 5 PM (US-Eastern), Monday through Friday excluding federal holidays. You may reach the support department using any of the following methods:

- **By Email**
  support@premierheart.com

- **By Telephone**
  USA/International: +1-516-883-3383
  USA Toll-Free: +1-888-380-8338

- **On the web**
  See the *Help and Support* section of the Premier Heart webapp.

Please have your MCG Product's Serial Number available when you call. It is also helpful if you have your MCG product and accessories available and connected to the internet to speed up our troubleshooting process.

A. Safety Notices

- Follow the normal safety procedures for any electronic equipment when using the MCG Unit

- Ensure that all cords and cables are routed so as to avoid a tripping hazard

- Use only the AC line cord and power adapter supplied with the MCG unit
  Use of unauthorized adapters will void your warranty.

- Use only the battery supplied with the MCG unit or a Premier Heart supplied replacement
  Use of unauthorized batteries will void your warranty.

- Do not connect the MCG unit to outlets controlled by a dimmer switch. Doing so may subject the MCG unit to voltages/currents outside its operational limits and damage the power supply.

- Avoid connecting the MCG unit to outlets controlled by wall switches or shared with other equipment

- Do not attempt to open the MCG unit case. Doing so will void your warranty.
  There are no user serviceable components inside the MCG unit. Refer all servicing to qualified personnel.

B. Technical Specifications

B.1. MCG Unit Operating Limits

Temperature: Operating 50–95°F (10–35°C) at stable temperature.
Storage: 0–120°F (-17–48°C)

Humidity: 20-80% Relative Humidity, non-condensing

Power: 105-245 VAC 50-60Hz (*For charging only*)

B.2. ECG Equipment

Leads: V5 and II

Input Impedance: Transdermal electrode, signal amplifier, A/D converter

Frequency Domain / Resolution: 0.2Hz

Input Offset Tolerance: Protected; 2kV ± 25V

B.3. Internet Connectivity

The MCG unit must be able to send data to Premier Heart in order for you to receive diagnostic reports. A functional connection to the public Internet is required. In addition, services such as

the Premier Heart Remote Assistance tool require an Internet connection to function.

All required traffic from the MCG system travels over TCP ports 80 (HTTP) and 443 (HTTPS). It is recommended that the MCG system have a direct connection to the Internet with these ports open. The use of proxy servers may adversely affect some MCG tools, such as the Remote Assistance service.

If your site has a proxy server it MUST NOT cache, filter or otherwise modify traffic to or from the premierheart.com domain. Modification of traffic to or from this domain may cause inaccurate diagnostic results.

For optimal performance you should allow NTP traffic (UDP/123) to one or more NTP servers specified in the MCG Unit's Date/Time settings, or specify an internal NTP server to keep your MCG unit's clock synchronized to the correct time.