MCG Quick Testing Guide

Model CF19 with Premier Heart Clinical Client

Premier Heart, LLC
New York, 2022

Premier Heart, LLC
Port Washington, New York, USA

Revision 2.4.0

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	Operating Temperature Range Minimum: 10°C (50°F) Maximum: 35°C (90°F) Stable temperature required for correct operation.
	Consult operating instructions prior to use
	Keep Dry - Do not use in wet environments.
	Caution: Federal law restricts this device to sale by or on the order of a physician.

For technical or medical support contact Premier Heart
US: (888) 380-8338 – support@premierheart.com – Int'l: (516) 883-3383

Contents

1 Important Information

Notices

Premier Heart's diagnostic technology applies a revolutionary new method of analysis to ECG data. As such, it is extremely sensitive to induced noise in the ECG signal.

To ensure the best results, please ensure that:

- The testing suite is located away from potential sources of interference.
  (X-Ray, CT or MRI suites, emergency generators, etc.)
- All potential sources of radio-frequency interference (cell phones, pagers, etc.) have been removed from both the patient and technician.
  (A minimum distance of 3 feet (1 meter) from the field unit and cables is recommended.)
- All High-Frequency Surgical Equipment is powered off and disconnected from the patient.
- The patient is lying comfortably without moving or straining during the test.
- The limb and chest electrodes have adequate electrical contact with the patient's skin.
- Only Premier Heart approved accessories, cables and power supplies are used.

For more information on the safe operation, transport, storage and measures or conditions necessary for the installation and preparation of your MCG field unit please see our Technical Manual.

1.1 Indications for Use and Contraindications

MCG is intended to be used as an aid to diagnosis by means of analysis of the EKG waveform in the frequency domain.

Contraindications

The MCG system has no specific contraindications, however precautions should be taken for patients who cannot tolerate pressure from the limb clips for the duration of testing (e.g. diabetic patients), or or patients susceptible to contact dermatitis from ECG electrodes (use hypo-allergenic electrodes).

Additionally MCG results have not been extensively validated in patients younger than age 14.

Patients should, otherwise, be tested normally.

1.2 Other Operating Guidance

1. **It is the user's responsibility to check the dated calibration sticker on the back of the field unit and contact Premier Heart to set up a calibration service check.**
2. MCG is intended for use in typical clinical settings, such as doctor's offices and hospitals. MCG systems may be used in other locations at the discretion of the treating physician, provided all system requirements are met.
3. Prior to use, the MCG system and cables should be inspected for signs of wear/damage. Any components exhibiting wear or damage should be replaced. If in doubt about a component's condition, contact Premier Heart.
4. Electrodes should not be permitted to come in contact with conductive surfaces (including ground/earth connectors).

5. Defibrillator application should be avoided while the MCG system is connected to the patient. If the MCG system is connected while defibrillator power is applied, it is recommended that the unit and accessories be returned to Premier Heart for recalibration and service.

    a) For proper defibrillator protection use only Premier Heart Approved accessories listed in the Technical Manual.

6. The MCG system should not be used in environments with high-frequency surgical equipment.
   MCG Systems do not include protection features for high-frequency/radiosurgery environments.

7. **Patients with Pacemakers:**
   MCG systems have been tested on patients with pacemakers. No impact on MCG diagnostic accuracy or pacemaker function was noted during these tests.

1.3 Powering Unit On and Off

1.3.1 Powering Unit On

Locate the power switch on your MCG field unit and switch the MCG field unit on. For help locating the power switch for your particular model refer to the Technical Manual.

1.3.2 Powering Unit Off

To properly shut off your MCG field unit click on MCG Clinical Client at the top right of your screen. This will open a menu at which point you will select Power Off. A pop up window will appear stating the system will now power off in 60 seconds. You can either let the device count down the 60 seconds and power off on its own or select the Power off button to power off the device

immediately. For any model related questions pertaining to powering off your unit or turning off specialized components that may come with your model refer to the Technical Manual.

2 Performing Tests

⚠ TEST PATIENTS ON BATTERY POWER ONLY ⚠
⚠ DISABLE WIRELESS PRIOR TO TESTING ⚠
⚠ REMOVE POWER CORD PRIOR TO TESTING ⚠
⚠CONNECT AND DISCONNECT ECG CABLE WHILE UNIT IS OFF ⚠

MCG Testing can be completed in as little as 30 minutes.
To ensure accurate test results the procedures outlined below must be carefully followed.

2.1 Equipment Preparation

- Connect the ECG cable
- Turn the MCG system on
  - Allow at least 10 minutes for the system to warm up if it has been off for a significant length of time ($>$ 1 hour)
  - Allow the MCG unit to reach a stable operating temperature before testing patients
- Clean the limb clamp electrodes with alcohol and/or antiseptic wipes thoroughly prior to testing
- Ensure that the limb clamp screws are securely tightened

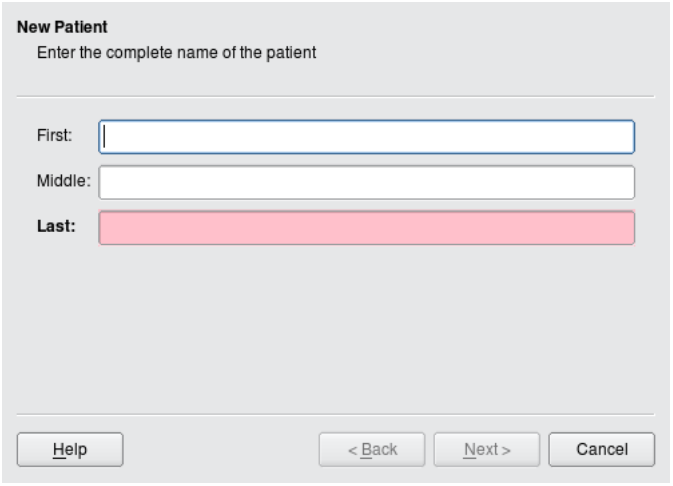
2.2 Patient Preparation

- Remove all electronics and metallic objects from the patient
  (Cell phones, watches, bracelets/anklets, etc.)
- Clean the patient's skin with alcohol or saline solution to ensure a good electrical connection
  - Shave the attachment points for the limb and chest leads (if necessary)
  - Conductive gel may be used with the limb clamps to improve tracing quality
  - Single use gel electrodes may also be used, however slight pressure has to be applied to the electrode to ensure good contact with the patient's skin.
- Have the patient relax on their back for 5-10 minutes prior to testing
  - Ensure that the patient is comfortable and not straining to hold their arms/legs in position
  - Allow the patient to reach a normal resting heart rate
    (MCG testing achieves its best results between 60 and 70 BPM)
- Lay the yoke of the ECG cable between the patient's legs and fan the five lead wires out to their destinations
  - Limb leads should be placed 1.5 inches (3cm) depth in from the crease of the wrist, and the same distance from the ankle bone
  - The chest lead should be placed at V5 – the intersection of the 5th intercostal space and the anterior axillary line
  - Ensure that the lead wires do not cross each other, any metal objects (chairs, the exam table) or any other wires (power/network cables)

2.3 Patient Information Entry

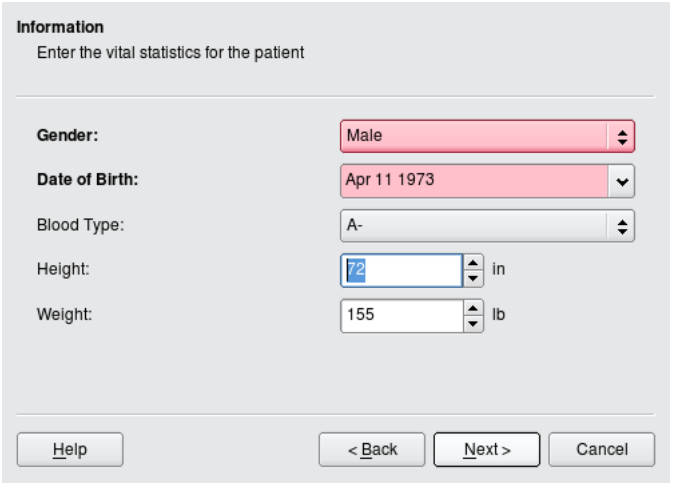
If this is the first time you are testing this patient you will need to enter their information into the MCG system. To do this, click on *Create a new patient* in the tool bar or on the main screen and follow the prompts. You must fill out all highlighted fields.

- The patient's name (First, Middle and Last) *Used for identification and searches.*

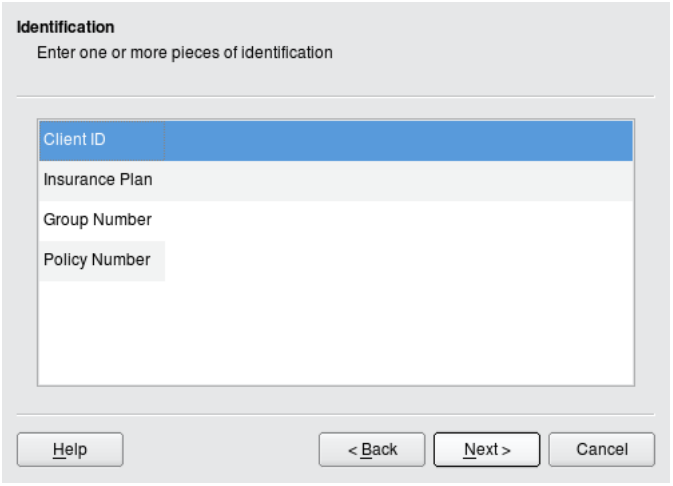


- The patient's vital statistics including
  - sex
  - date of birth
  - blood type
  - height
  - weight

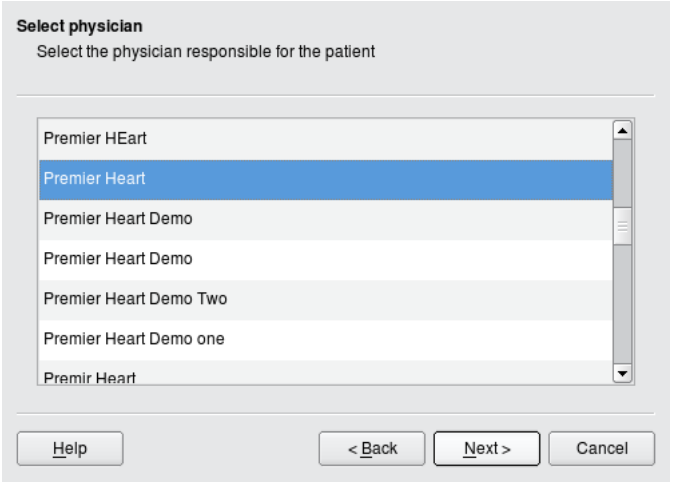
  This information is used by the MCG diagnostic process, and also for statistical purposes.



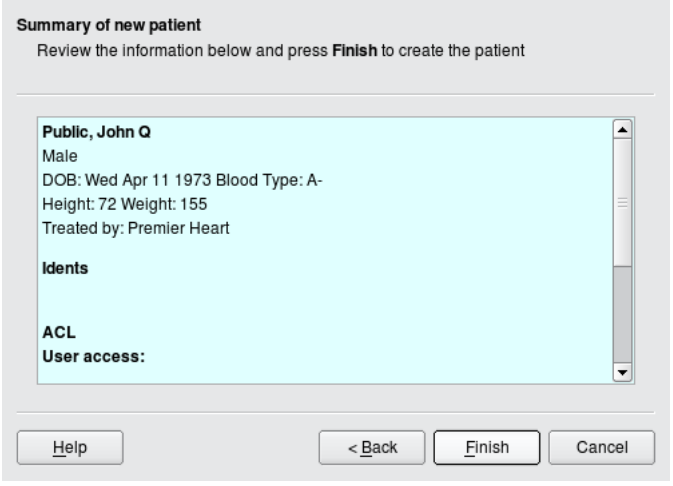
- Patient Identifying Information (Optional)
  This information is used to cross-reference MCG data with your existing record systems.



- A treating physician from your practice.
  This information is used for reference, as well as when contacting Premier Heart for medical support.



When you have entered all the required information the system will display a summary page to allow you to review it before creating the patient.
If the information is correct press *Finish* to create the patient.



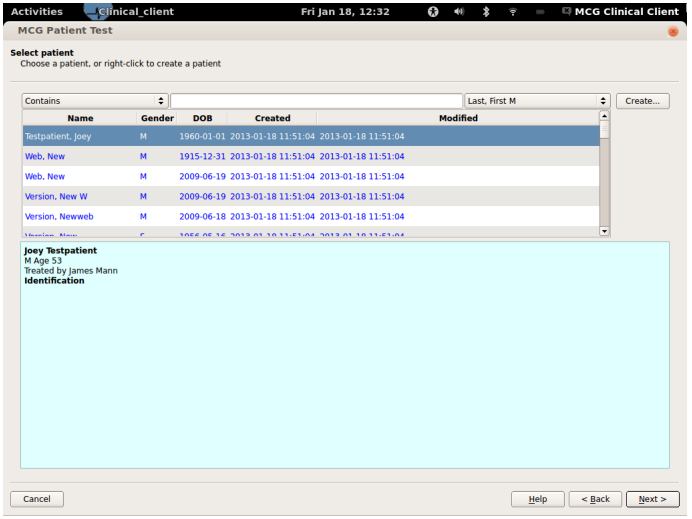
2.4 Patient Testing

To begin testing a patient select *Test a patient* from the main screen and follow the prompts.

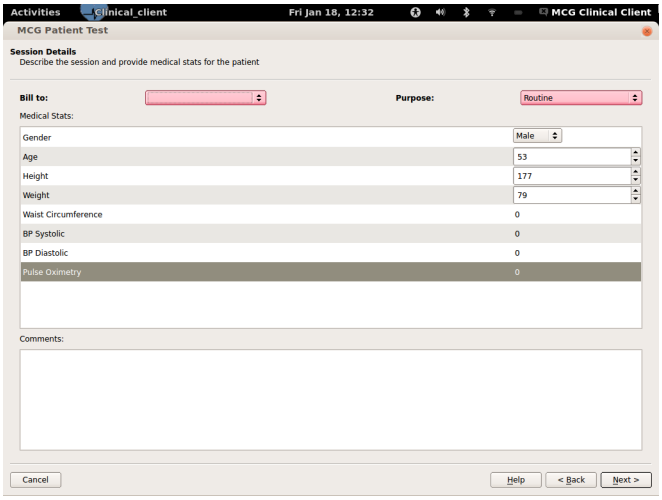
MCG testing is wizard-driven – The system will lead you through the steps required to test a patient and submit the tests to Premier Heart for analysis.

- You will be given a list of patients you have access to for testing –
  Select the patient you wish to test and click *Next*.

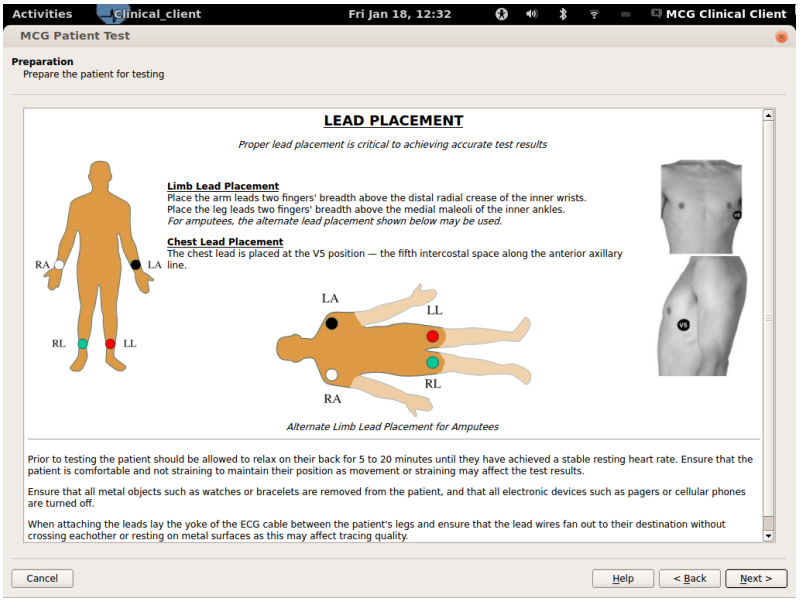
If the patient you wish to test is not listed click the `Create...` button to open the New Patient Wizard. From here you can follow the Patient Information Entry steps in Section 2.3 to create a new patient.



- Verify the session clinical information for your patient and make updates as necessary.
  You may also enter free-form clinical notes regarding the test at this time.
  Click *Next* when you are done.



- Verify the lead placement based on 2.2 Patient Preparation or the on-screen instructions. Click Next when ready to begin recording data.



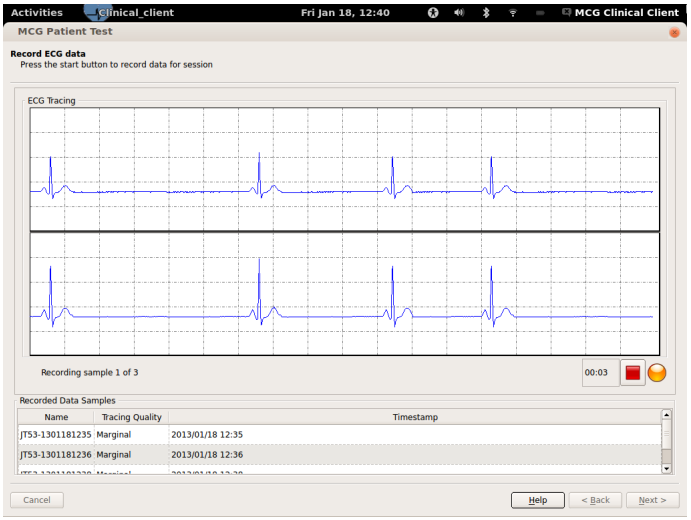
- The MCG system will now show the testing screen, displaying live tracing data. Adjust the leads as necessary to achieve a good quality tracing.

The Tracing Quality Indicator may be used for guidance:

Green indicates a tracing that *may* be acceptable

Yellow indicates a tracing which *may not* be acceptable

Red indicates a tracing which is *most likely not* acceptable



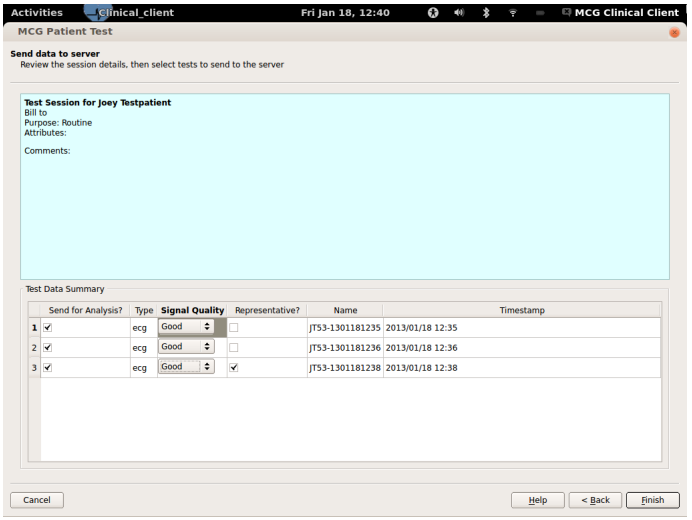
When you are satisfied with the tracing quality press the *Record* button. The system will automatically acquire 5 samples (82 seconds per sample, this process takes approximately 7 minutes).

If your patient coughs, moves or detaches a lead during testing you may press the *Stop* button to cancel the current sample and resume recording when the issue has been corrected.
When recording is finished click *Next* to proceed to the final review page.

Important Note Regarding Tracing Quality

Accurate MCG results are dependent upon tracing quality – A poor quality tracing may result in false-positive or false-negative diagnoses. The MCG system's assessment of tracing quality is meant to assist you in classifying tracings, however it *is not* a definitive tool. Testing personnel must monitor tracing quality and classify tracings appropriately.

- The final review page allows you to examine the individual recordings for quality issues (double-click on a test sample to review it).
  Review each recorded tracing and select the ones you wish to send for analysis. The MCG system will automatically mark the test it considers "best" as the *Representative Test*, however you may override this if you believe a different test is of better quality.



When you have selected the tests you wish to have analyzed click *Finish* – The tests will be queued and submitted to Premier Heart.

For best accuracy Premier Heart recommends sending at least 3 samples of good quality for analysis. Poor and Marginal tests may be submitted for analysis, however the diagnostic accuracy of the results will be affected.
Premier Heart bills on a per-report basis – You may submit as many tests as you wish without being charged until a diagnostic report is generated. We encourage you to record as many tests as necessary to achieve the best tracing quality possible.

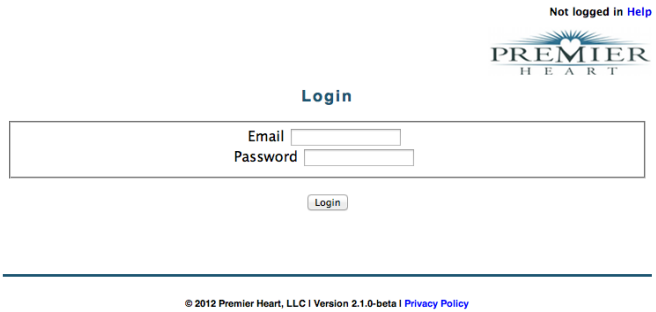
3 Viewing MCG Results

If your MCG system is connected to the internet you may request reports by opening the web browser included with the system, or by using any device capable of connecting to the internet. This browser will take you directly to the MCG Reporting System login page. You may also access reports from any computer with an internet connection by visiting http://www.premierheart.com and clicking on the Login link in the upper-right corner of the page. This webapp exists for retrieving patient test results, and also user management/creation if you are a webapp user with administration rights.

MCG reports are typically available within 30 minutes of submitting your tests to our servers.

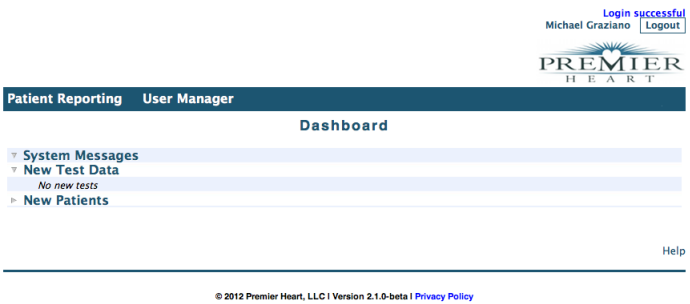
3.1 Logging In to the Premier Heart Webapp

- Log in to the MCG Reporting Application.
  Your username and password should be provided by your site's MCG administrator.



If you are connecting to the MCG Reporting system from a PC you may get to the login screen by going to *http://www.premierheart.com/* and clicking the "Sign On" link at the top right of the screen.

- Select "Patient Reporting" from the Dashboard menu.

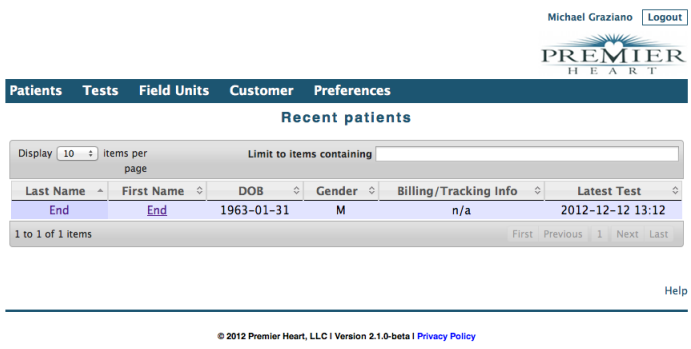


The MCG Dashboard is displayed on login, and will show test sessions and patients created since your last visit.
Note: The MCG Dashboard displayed on login may include important system messages.

3.2 Viewing Results by Patient

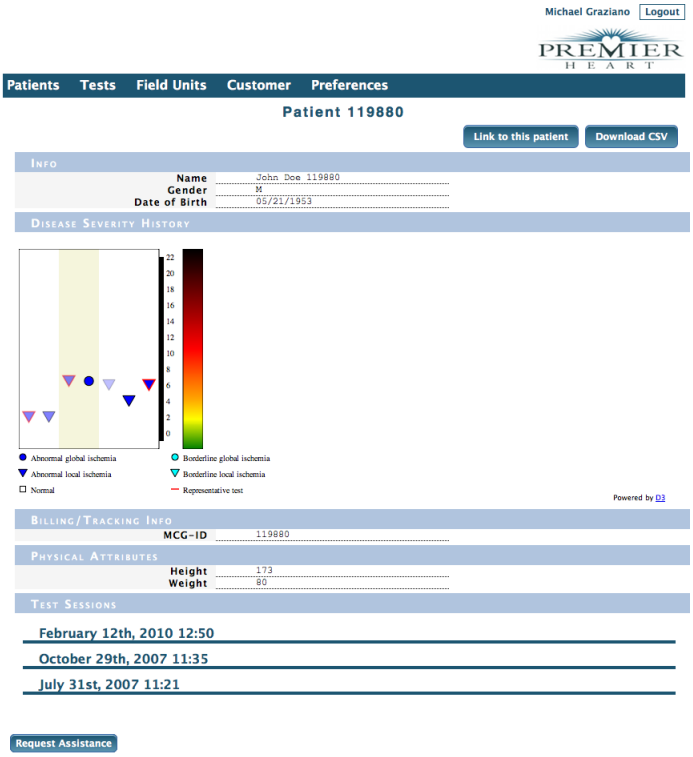
During normal use you will typically be generating reports for patients who were created or tested recently. As such when you select Patient Reporting from the dashboard the Recent Patients page is displayed by default, showing patients created or tested within the last 30 days.
If the patient you wish to view results for is not shown in the list of Recent Patients hover over the "Patients" link in the reporting menu. You will have the option to view Recent patients, Browse all patients, or Search for a patient by specific criteria.

- Select the patient whose records you wish to view.



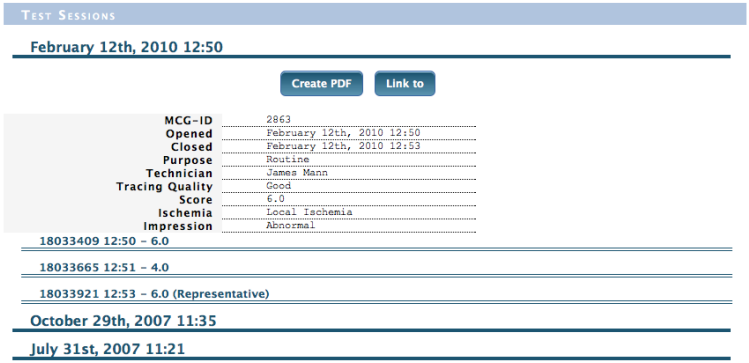
If a large number of patients are displayed you may limit the display in real-time by entering a portion of the patient's name, date of birth, or other identifying information in the "Limit to items containing" field.

- The patient history screen will be displayed.



The Patient History screen is designed to provide you with an at-a-glance summary of a patient's MCG history over time. Individual test session results are available in the Test Sessions block at the bottom of the page.

- To view details of a particular test's results, click on the session date.
  A summary of the test results will be displayed, along with the option to view details of specific tests



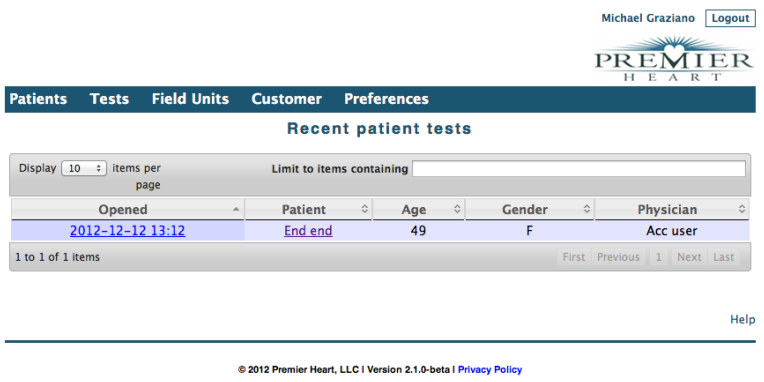
Additional detail, including secondary and tertiary conditions, ECG tracings, and DSP plots, may be viewed by expanding the individual tests within a session.

3.3 Viewing Results by Test Session

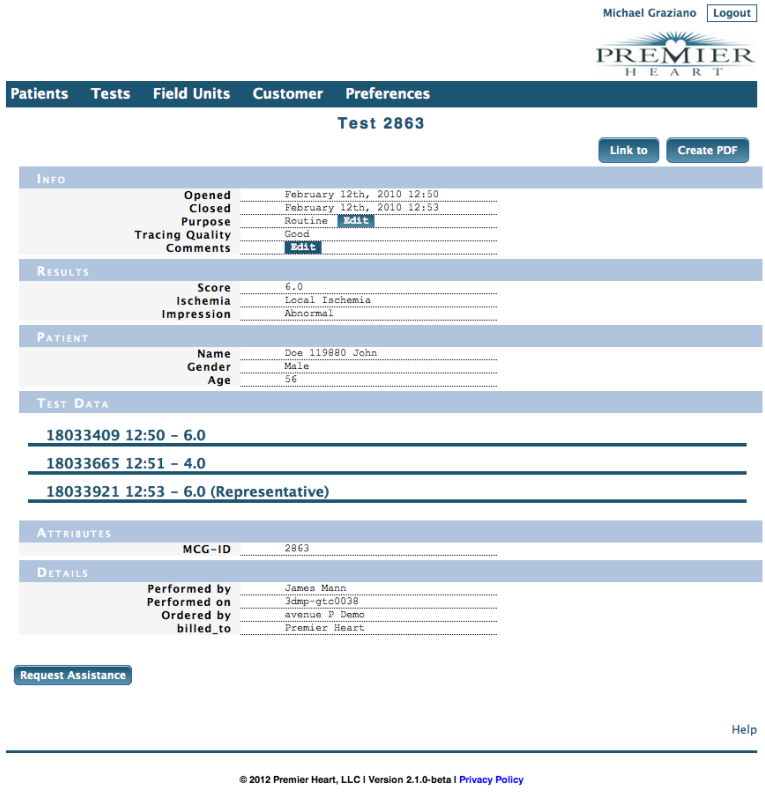
If you are looking for information on an existing patient who was tested recently, or wish to look up details of a specific test session, click the Tests link in the reporting menu.
This will display the Recent Patient Tests screen, showing test sessions conducted within the last 30 days. If the session you are looking for is older than 30 days simply hover over the "Tests" link in the reporting menu, and you will have the option to search or browse for sessions.

View the session information by selecting either the session open date or the patient's name.

- If you select the `Opened` date you will be taken directly to the Session page.
- If you select the patients's name you will be taken to the Patient History page.



- The Session page is equivalent to the expanded Test Session from the Patient History page.



3.4 Other Features

3.4.1 Downloading Results

Results for a Test Session or an individual Test may be downloaded in PDF format for printing and inclusion in patient medical records. The Create PDF button in various locations will allow you to create a PDF version of the results for a specific Test or Session.

3.4.2 Requesting Assistance from Premier Heart

In addition to our normal support channels, you may request assistance with a specific Patient, Session, or Test by clicking the "Request Assistance" button.
These requests are handled by our medical support team, and are intended for clinical issues and interpretation questions. For general support, please use the regular Premier Heart support channels.

4 Tracing Quality Guidelines

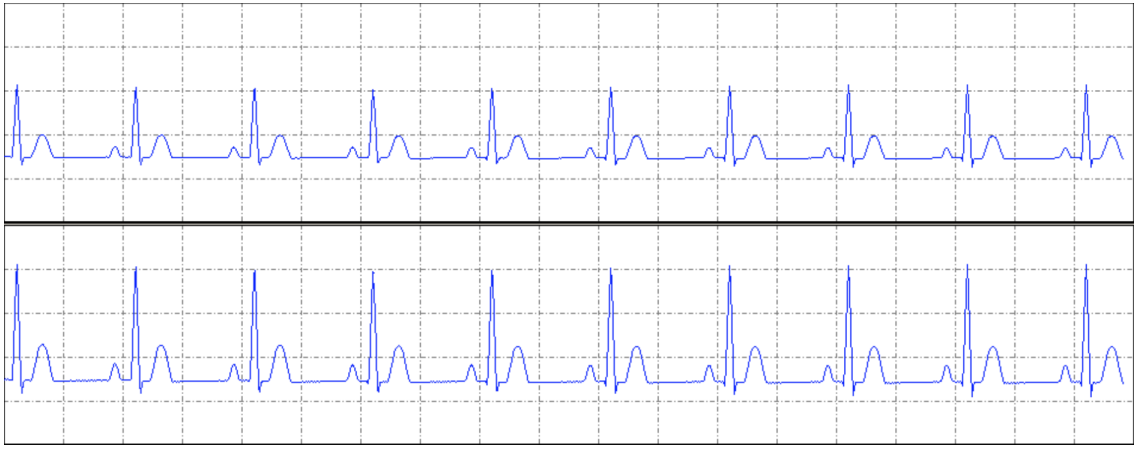
The MCG system's approach to ECG analysis involves examining the ECG data in the frequency domain. This technique is extremely sensitive and extracts a great deal of latent data from the ECG signal. As a result of this analysis process MCG is sensitive to noise in the ECG signal, and excessive noise will significantly impair the diagnostic accuracy of the test.

The MCG system has a limited self-characterization ability which will detect gross anomalies in the ECG signal, however its assessment is predicated on a normal ECG rhythm and can be confused by anomalies introduced by arrhythmias or conduction disorders.

Because a human eye is vastly superior in determining tracing quality, we ask that technicians review the tracings and characterize them as "Good", "Marginal" or "Poor" prior to submitting them for analysis.

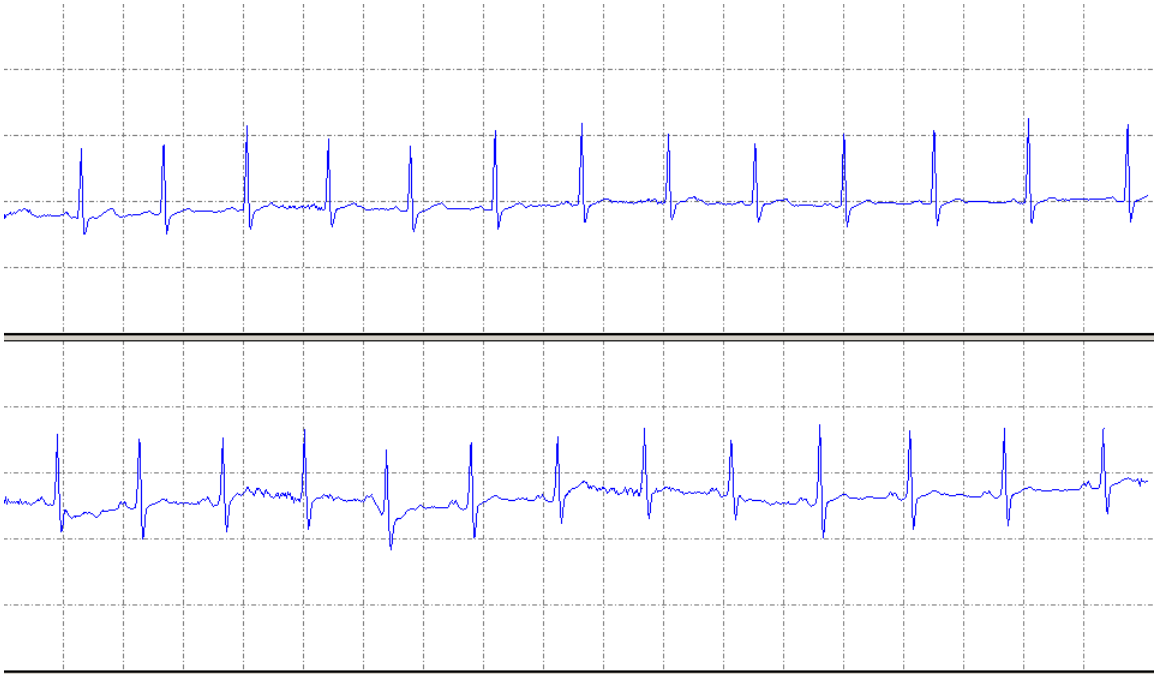
The following pages contain descriptions of what qualifies tracings as "Good", "Marginal" or "Poor", as well as examples in each category to assist you in characterizing your tracings. If you are in doubt as to the quality of a particular tracing it is always advisable to repeat the test and attempt to obtain a good quality tracing.

Good Quality Tracings



A Good tracing shows a flat baseline with sharp, well-defined peaks and little to no noise. Good tracings will provide the best diagnostic results.

Marginal Quality Tracings



Marginal tracings show minor variations in the baseline or noticeable levels of background noise, however the standard ECG waveform (P – QRS – T) is still clearly visible.
Marginal tracings can result from patients straining to hold their arms/legs in place, heavy breathing, lotion, or dry skin. Adjusting the patient's position or using conductive gel on the electrodes may improve tracing quality.

Poor Quality Tracings

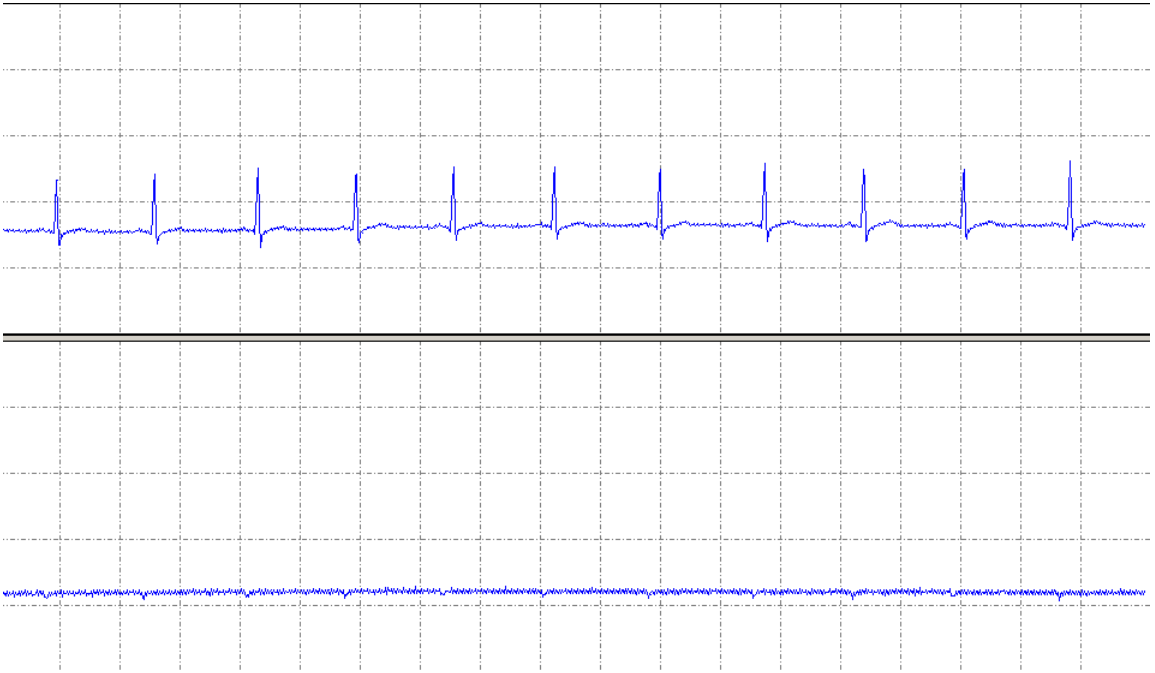
Poor quality tracings show significant fluctuations in the baseline and/or large amounts of noise, with indistinct or completely obscured peaks.
Poor tracings can be caused by ECG cables crossing or touching metal objects, interference from cell phones, dry skin, lotion, the patient moving and talking, or power line noise. Damaged ECG cables may also produce certain poor-quality tracing patterns
Poor quality tracings will not produce accurate diagnostic results. The cause of the poor tracing should be corrected and the test repeated.
If you are unable to isolate the cause of a poor tracing contact Premier Heart for assistance.

5 Troubleshooting

5.1 Common Tracing Problems

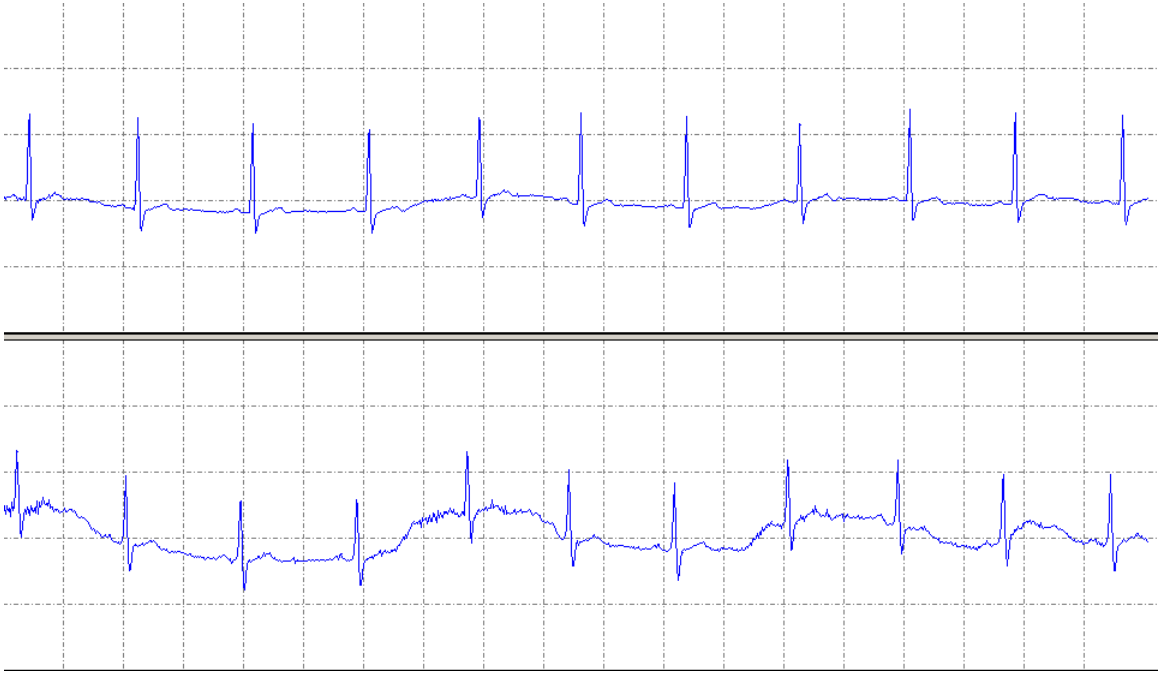
Certain poor-quality tracing patterns indicate specific issues, typically with the ECG cable or patient connection. The tracing strips below show the most common failure modes.
If you observe these patterns follow the suggested courses of action below, or contact Premier Heart for assistance.

Disconnected ECG Cable



This tracing pattern indicates that an ECG cable has come loose.
If observed on lead V5 check the V5 electrode connection.
If observed on Lead II or on both leads check all electrode connections, as well as the ECG cable connection to your MCG system.
In rare cases a damaged ECG cable may produce this tracing pattern as well. If you believe your cable may be damaged contact Premier Heart for a replacement.

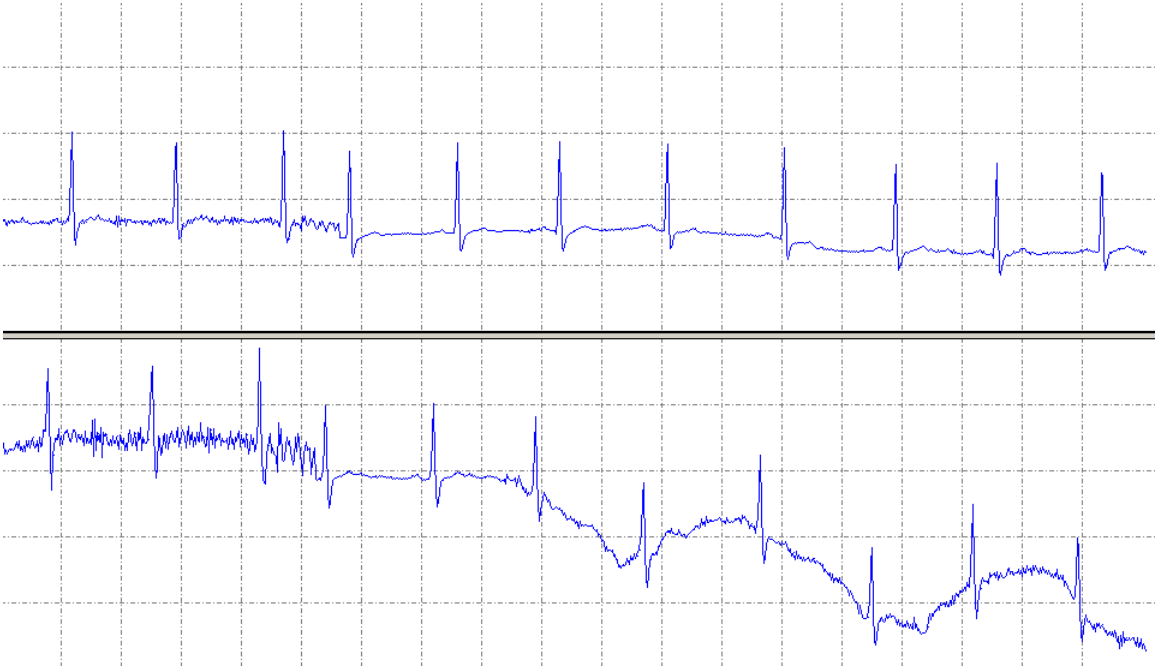
"Ocean Waves" (patient respiration or movement)



The "Ocean Waves" tracing pattern is characterized by a wandering baseline – this is typically caused by heavy breathing or movement during the testing process. Ensuring that your patient is resting comfortably during the test and allowing additional time for them to relax can reduce the baseline movement.

Ocean Waves may also be caused by the ECG cable shifting during testing. Ensure that the ECG cable is routed correctly with all 5 lead wires fanning to their destinations without crossing each other, and verify that the cable is not crossing any metal objects or moving/swaying during the test.

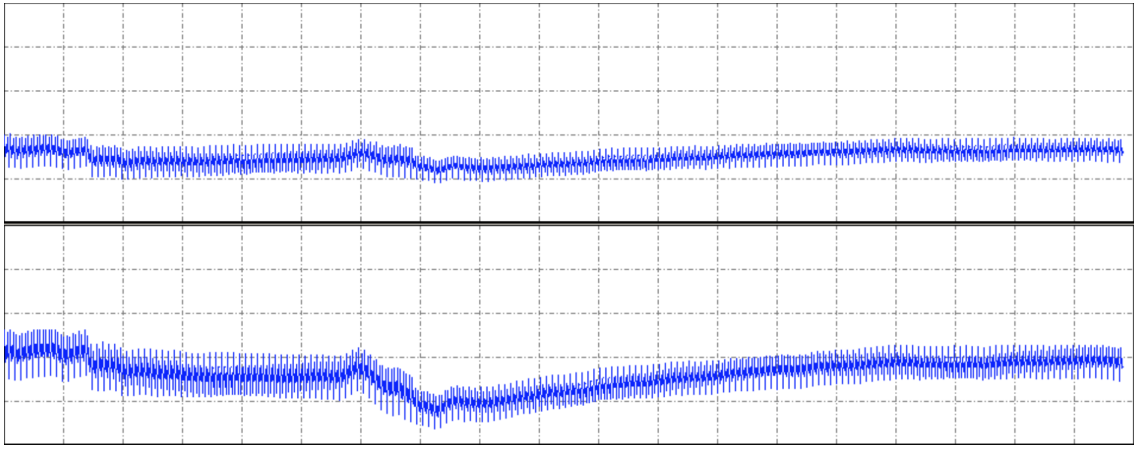
Converging/Diverging Tracings (patient respiration or movement)



Converging or Diverging tracings are characterized by Lead II / Lead V5 baselines moving in opposite directions, giving the tracing strip the appearance of the tracings moving toward or away from each other. This pattern is typically caused by the same conditions that result in the "Ocean Waves" tracing described earlier, or by a patient who has not had sufficient rest prior to testing.

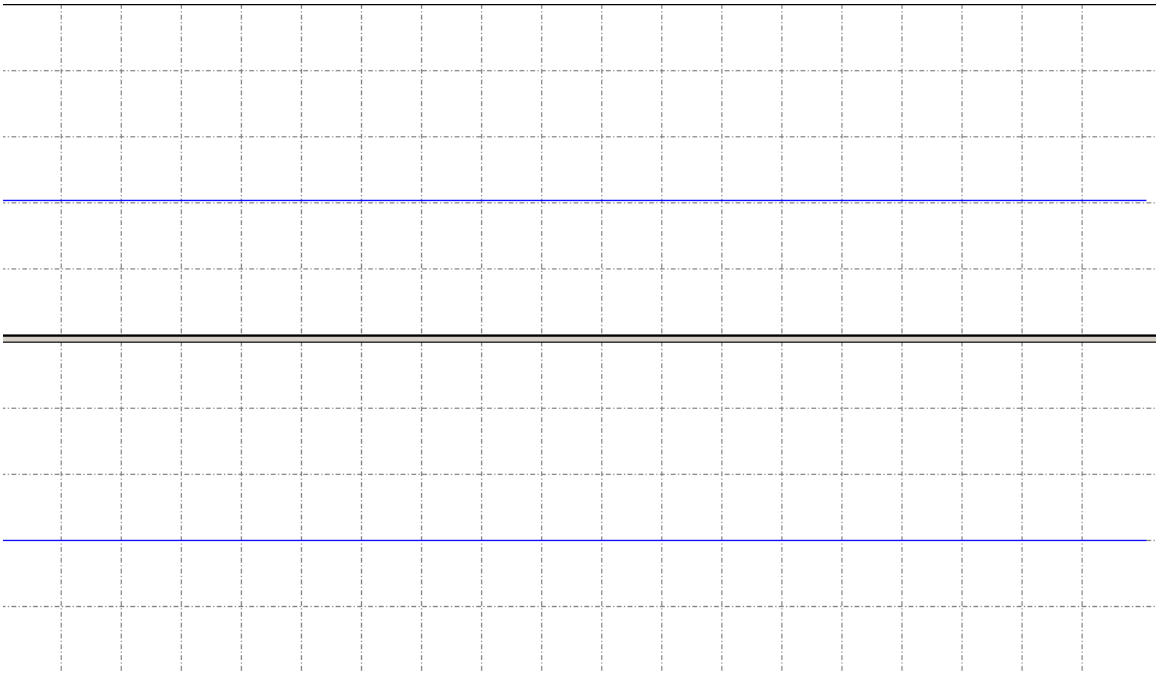
This tracing pattern can have a significant impact on the MCG analysis results, therefore tests which exhibit this pattern should be repeated.

Damaged ECG Cable or Poor Connection



This tracing pattern indicates an extremely poor connection or a damaged ECG cable (due to strain, pinching or pulling). A disconnected ground (Right Leg) lead may also produce this pattern.
If you observe this pattern and normal tracing quality troubleshooting does not resolve it contact Premier Heart for a replacement ECG cable.

Loop Connector Installed or Damaged Amplifier Board



A nearly flat tracing pattern with minimal noise/interference indicates that the amplifier board in your MCG unit has been damaged or internally disconnected – Contact Premier Heart for service. *The affected MCG system should be removed from use until serviced by Premier Heart.*
If your MCG system is operated with the calibration loop connector installed you will also see this tracing. Power the MCG unit off, remove the loop plug and connect the supplied ECG cable. *The calibration loop plug should only be used when instructed by Premier Heart.*

5.2 Frequently Asked Questions

- **I am having difficulty recording good-quality tracings – How can I improve tracing quality?**
  Tracing quality can be influenced by many factors. As general mitigation steps, ensure that the ECG cable is not tangled and is not crossing any power cords or metal surfaces. In addition ensure that the limb clip electrodes are clean and making good contact with the patient's skin. For patients where it is difficult to obtain good electrical contact a cotton ball soaked in a saturated saline solution may be placed between the limb clip and the patient's skin to improve the signal, or disposable (adhesive) electrodes may be used.
  Ensure that any adhesive electrodes used are in good condition – If there is any doubt as to the quality of the electrodes Premier Heart recommends opening a fresh package.
  Do not use expired electrodes, electrodes where the conductive gel or adhesive has dried out, or electrodes with any evidence of damage. Do not reuse adhesive electrodes.

- **I finished testing a patient, but was not able to find their data on the web site. How can I fix this?**
  With your MCG system connected to the internet click Admin at the top. Select Task Manager from the drop down menu, by clicking on it. This will show you the pending and failed tasks. If your patient/test data has not been sent to Premier Heart's servers they will appear in the Pending Tasks list – To force the system to attempt to send the tasks click select *Pause Queue* from the Admin menu, wait a moment then select *Resume Queue* from the same menu.
  If your tasks have been marked as failed you may re-submit them by right-clicking on the failed task and selecting *Retry Task*. If the task fails a second time contact Premier Heart Support for assistance.
  If the tasks in your queue will not submit you may have a network issue. To test your network connection, minimize the clinical client window and click on the *Network Test Tool* icon on the sidebar on the left side of the screen. Premier Heart or your network administrator will be able to assist you further based on the results of this tool.

- **I accidentally created two of the same patient and I can't delete them. How do I delete the unneeded patient?**
  A patient can not be deleted if they have any pending tasks waiting. First go to Task Manager to make sure there are no pending tasks for the patient you want to delete. You can open Task Manager by clicking Admin at the top. Than select Task Manager from drop down menu by clicking on it. If there are any tasks you can either send them across or delete them.
  Once you have made sure there are no pending tasks you can click on View existing patients to open Patient Manager. Alternate click on the patient you want to delete. Click on Delete in the menu. Then click Yes to confirm the deletion (Remember, this can not be undone).
  If you have recorded or submitted tests for the erroneous patient and would like the data merged into a single patient in the reporting system please contact Premier Heart for assistance.

- **I created a new patient and their height or weight does not match what I entered – why?**
  The MCG system stores height and weight data in Kilograms and Centimeters internally.
  If you enter information in alternative units (for example, Inches and Pounds) the data will be converted and any fractional results discarded.

- **Patient information displayed on the website (date of birth, gender, etc.) is incorrect. How can I correct this?**
  To correct information in the MCG reporting system you must fix it on your MCG Field Unit. Ensure that your MCG system is online, then click on *View Existing Patients* in the toolbar to open the patient manager. Right click on the patient you wish to update and select *Edit*, then update the patient's information as needed. The report on the Premier Heart web site will update with the correct information once your MCG system sends the update task to our servers.

- **How do I connect my MCG system to a wireless network?**
  To connect your MCG system to any network, wired or wireless, use the Network Manager icon in the upper-right corner of the screen (the appearance of this icon will vary depending

on the state of your network connection). Left-click on the icon, click select network, and select the network you wish to join.
Consult your network administrator for more information on connecting to your local network.

- ***I have a question that was not addressed here***

  If you have a question that was not addressed by this QuickGuide or the MCG software's online help and documentation please contact Premier Heart at +1-516-883-3383, or via email to *support@premierheart.com*. Our technical and medical support team is available to assist you Monday through Friday from 9am to 5pm Eastern time. Emergency off-hours support is also available.

  It is helpful if your MCG unit is powered on and connected to the internet when you call as we may ask for remote access to the system in order to troubleshoot your issue.