MCG Quick Testing Guide

Model VH12 with Premier Heart Clinical Client

Premier Heart, LLC

Premier Heart, LLC
Port Washington, New York, USA

Revision 2.4.0

	**Premier Heart LLC** 110 Main Street, Suite 201 Port Washington NY 11050-2861
	**Operating Temperature Range (VH12)** Minimum: 15°C (59°F) Maximum: 35°C (95°F) *Stable temperature required for correct operation.*

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

Contents

1. Important Information

⚠ SAFETY NOTICES ⚠

Premier Heart's MCG analysis 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) between the testing area and any RF transmitters 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.

1.1. Indications for Use

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

1.2. Contraindications

There are no absolute contraindications for MCG testing, other than patient refusal.

Some patients may have allergies or sensitivities to the adhesives used to affix lead electrodes, or metal sensitivities to the electrode plating on limb clip / suction ball style electrodes. Use of hypoallergenic electrodes (available from various manufacturers) is recommended if allergy or sensitivity is suspected.

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

1.3. Other Operating Guidance

- **It is the user's responsibility to check the dated calibration sticker on the VH12 Device and contact Premier Heart to set up a calibration service check.**
- 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.
- Prior to use, the MCG system and cables have to be inspected for signs of wear/damage. Any components exhibiting wear or damage need be replaced. If in doubt about a component's condition, contact Premier Heart.
- Electrodes cannot be permitted to come in contact with conductive surfaces (including ground/earth connectors).

- Defibrillator application must 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.
  - *For proper defibrillator protection use only Premier Heart approved cables and accessories.*
- 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.
- **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.

2. MCG System Preparation

Preparing your MCG system for use each day before testing patients will ensure that MCG tests can be completed quickly and efficiently.

2.1. Hardware Setup

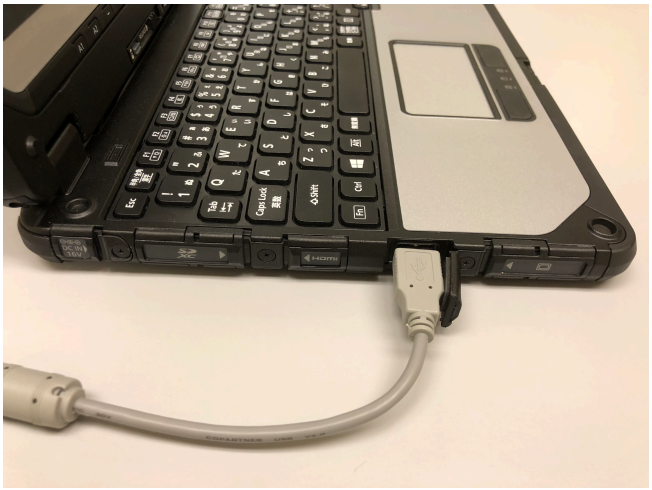
To minimize electrical interference Premier Heart recommends the use of a laptop PC with testing conducted on battery power. Suitable laptops with medical-grade power supplies and preinstalled MCG software are available from Premier Heart.

2.1.1. Connecting the VH12 ECG Capture Device

Prior to using the VH12 ECG capture device, inspect the device and all cables for damage. If any damage is observed contact Premier Heart to obtain replacement components.

The ECG capture device must be connected with the PC powered off.

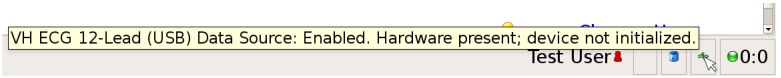
- Connect the USB cable to an available USB port on the computer running the MCG Clinical Client software.



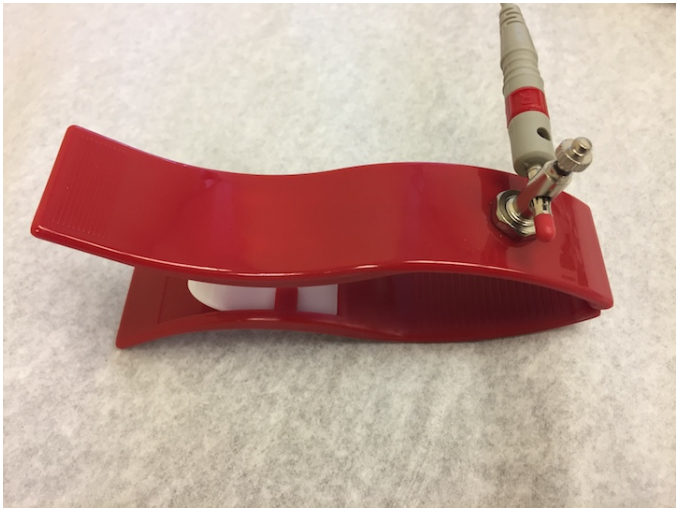
The example shown here is a Panasonic CF-20 tablet-convertible system.

- Connect the USB cable and ECG cable to the Capture Device as shown in the aside image.

- Power on the PC, the MCG Clinical Client software will start automatically.
  - Ensure that the VH12 ECG capture hardware is recognized (note the USB symbol in the status area, lower-right corner of the Clinical Client screen)



- Clean the limb clip electrodes with alcohol or antiseptic wipes prior to testing.
- Ensure the limb clip screws are tightly secured. If adhesive electrodes are to be used for the limb leads ensure the snap-adapters fit snugly over the banana plugs.

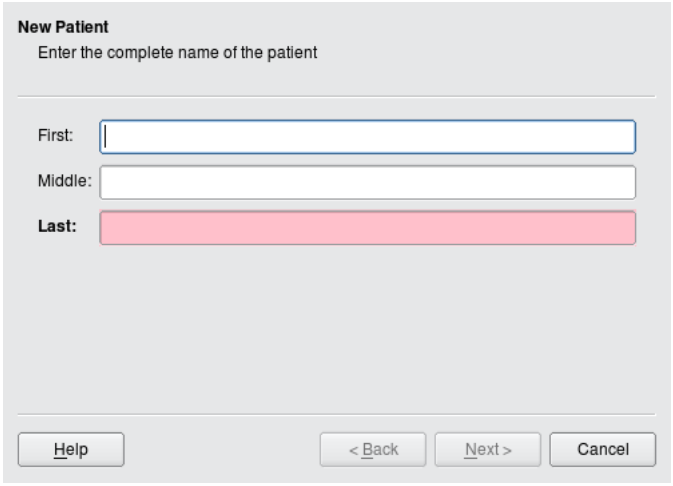


- In the case of ECG Cabling that uses snap connections, either use sticky electrodes that snap into the plugs, or snap the electrodes onto the snap connection on the limb clips as shown.

2.2. Patient Information Entry

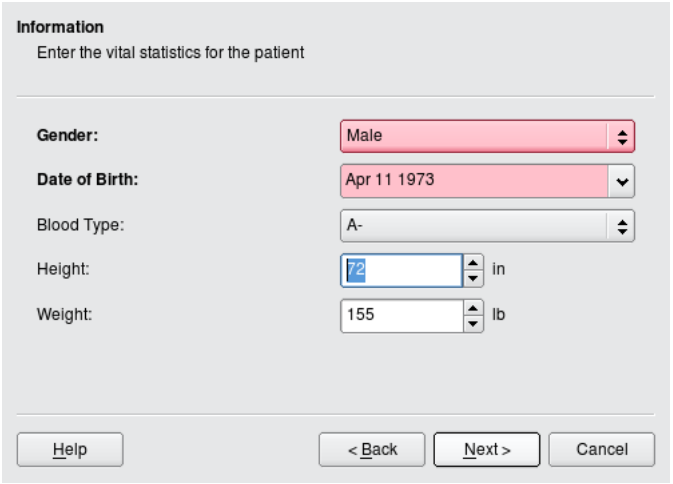
If you are testing patients for the first time you will need to enter their information into the MCG system. If the patient's clinical information is available you may do this prior to their arrival to save time.
Click on *Create a new patient* in the tool bar or on the main screen and follow the prompts. You must fill out all highlighted fields.

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

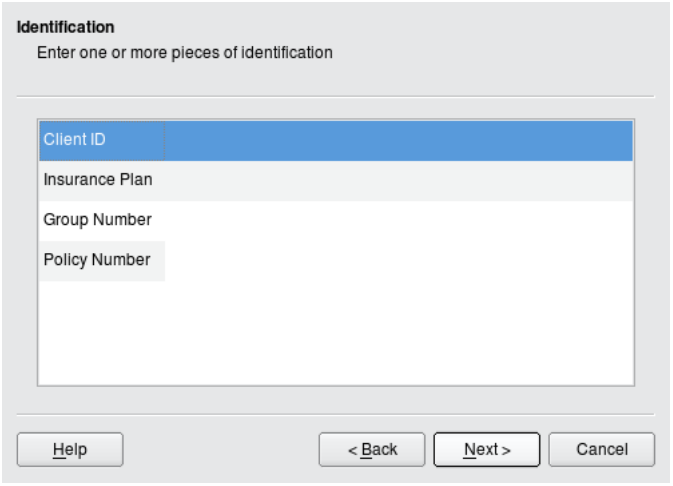


- The patient's vital statistics including
  - sex
  - date of birth
  - blood type
  - height
  - weight

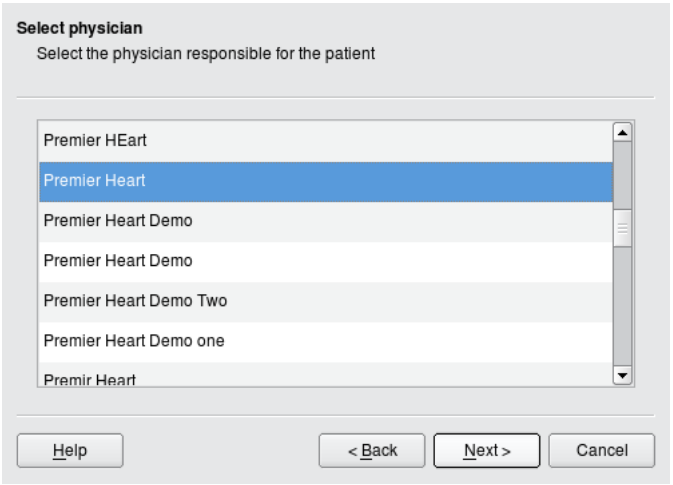
  This information is used by the MCG diagnostic process, and also for statistical purposes.



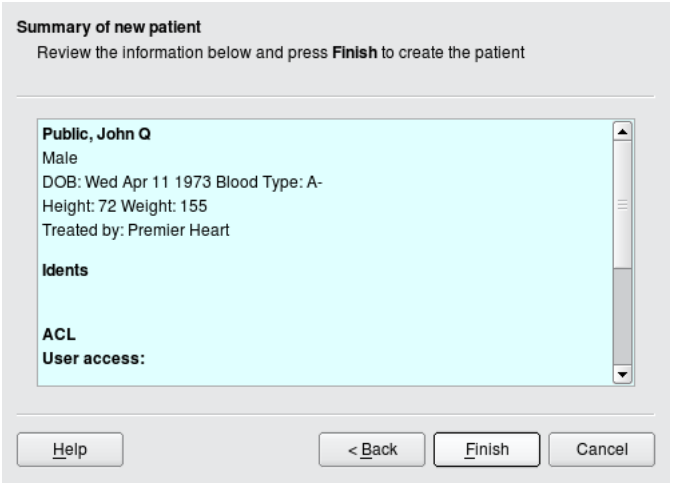
- Patient Identifying Information (Optional)
  This information is used to cross-reference MCG data with your existing record systems.



- 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.



3. Patient Testing

A typical MCG testing session requires between 10 and 15 minutes. The process is similar to a traditional ECG recording, however tracing quality and proper lead placement are critical to achieving accurate results.

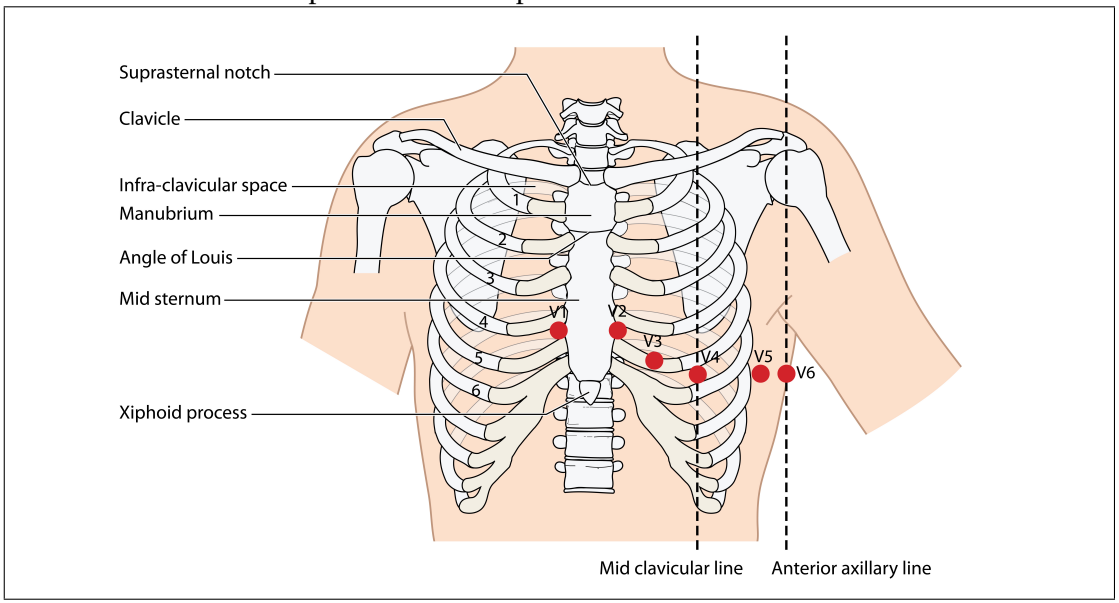
3.1. Patient Preparation

Proper patient preparation is required in order to achieve accurate MCG results.

- Remove all electronics and metallic objects from the patient
  (Cell phones, watches, bracelets/anklets, etc.)
- 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)
- Prepare the patient's skin at the sides of electrode placement for good electrical contact
  - Shave the contact area for the limb and chest leads if necessary
  - Remove makeup or lotion products using soap and water, or an alcohol swab

  - Remove dead skin using skin prep paper (3M 2236 or equivalent)
  - Conductive gel may be used with the limb clips to improve tracing quality

- Lay the yoke of the ECG cable between the patient's legs and fan the lead wires out to their destinations.
  - The limb leads must be placed 1.5 inches (3cm) in from the crease of the wrist, and the same distance from the ankle bone.
  - The chest lead should be placed on the V5 position



- For best tracing quality ensure that the lead wires are not tangled, do not lay across any metal objects (chairs, the exam table), and are not near any other wires (power/network cables).

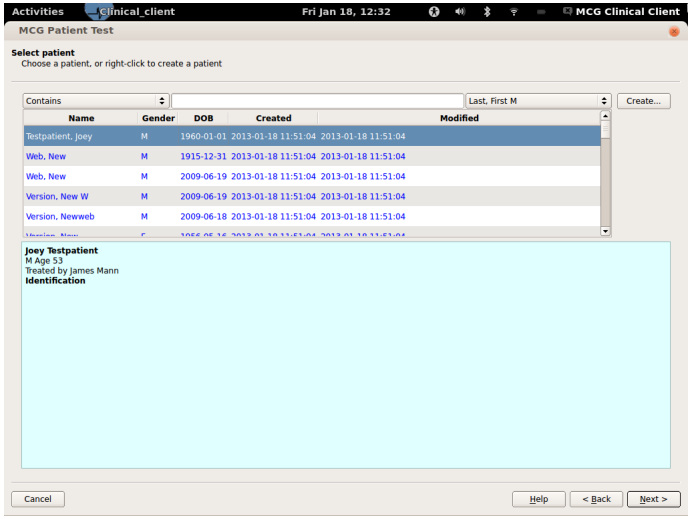
3.2. Recording Tests

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

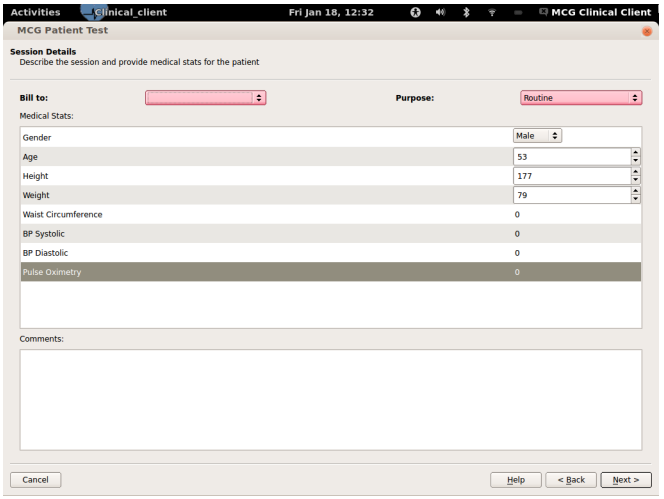
MCG testing is wizard-driven – The system will lead you through the steps required to test a patient and submit the tests to Premier Heart for analysis.

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

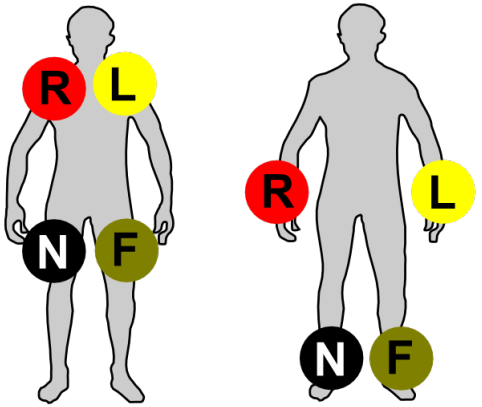
If the patient you wish to test is not listed click the `Create...` button to open the New Patient Wizard. From here you can follow the Patient Information Entry steps in Section 2.2 to create a new patient.



- 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 lead placement as described in Section 3.1or using the provided graphic here for limb lead placement. 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 good tracing quality on the live tracing preview.

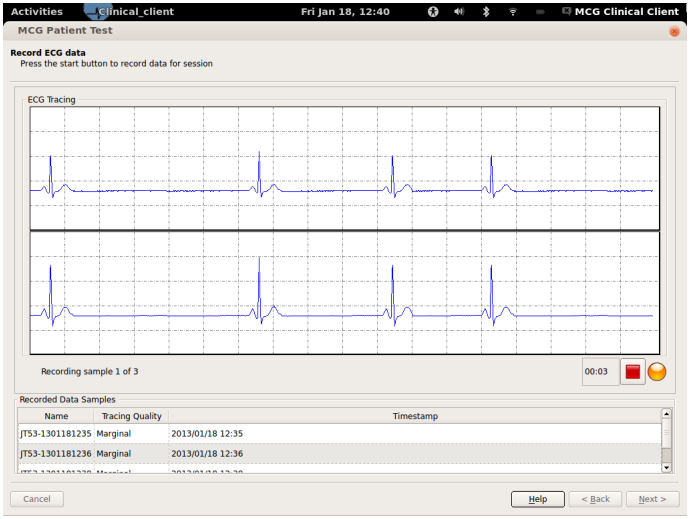
The Tracing Quality Indicator may be used for guidance:

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).

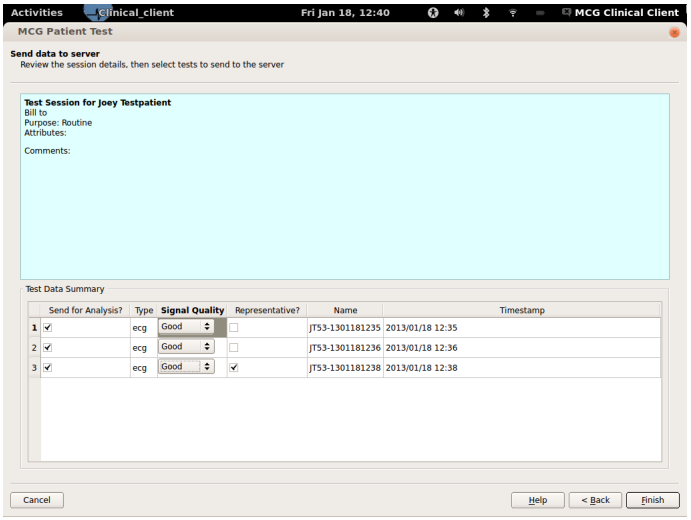


If your patient coughs, moves or detaches a lead during testing you may press the *Stop* button to cancel the current sample and resume recording when the issue has been corrected.
When recording is finished click *Next* to proceed to the final review page.

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.

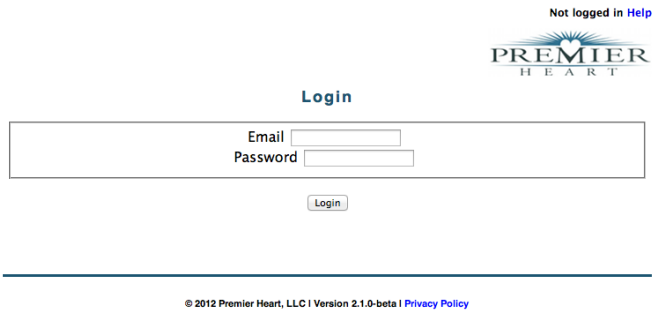
4. Viewing MCG Results

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 https://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.

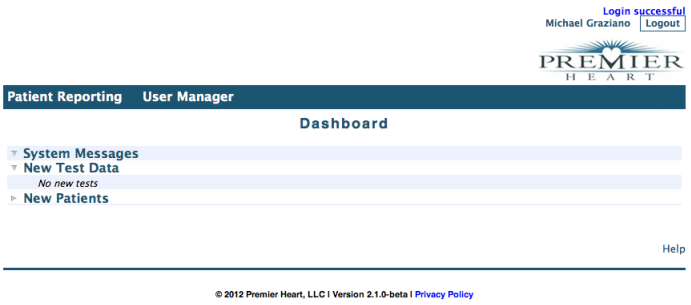
4.1. Logging In to the Premier Heart Webapp

- Log in to the MCG Reporting Application.
  Your username and password will 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 "Login" link at the top right of the screen.

- Select "Patient Reporting" from the Dashboard menu.

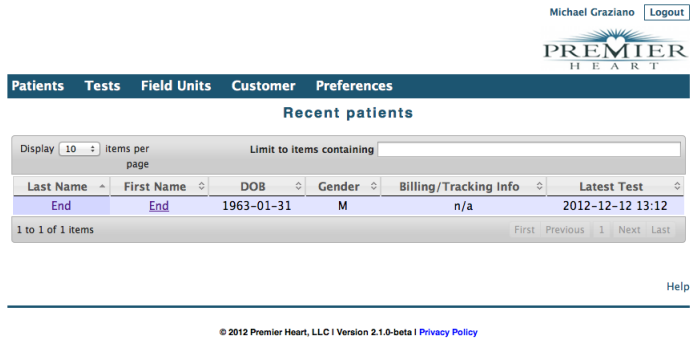


The MCG Dashboard is displayed on login, and will show test sessions and patients created since your last visit.
Note: The MCG Dashboard displayed on login may include important system messages.

4.2. Viewing Results by Patient

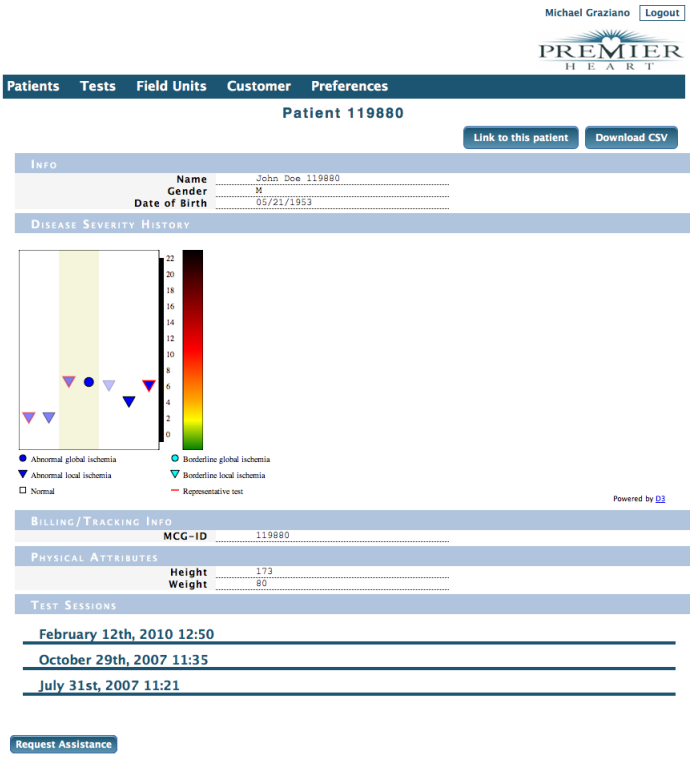
During normal use you will typically be generating reports for patients who were created or tested recently. As such when you select Patient Reporting from the dashboard the Recent Patients page is displayed by default, showing patients created or tested within the last 30 days.
If the patient you wish 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.



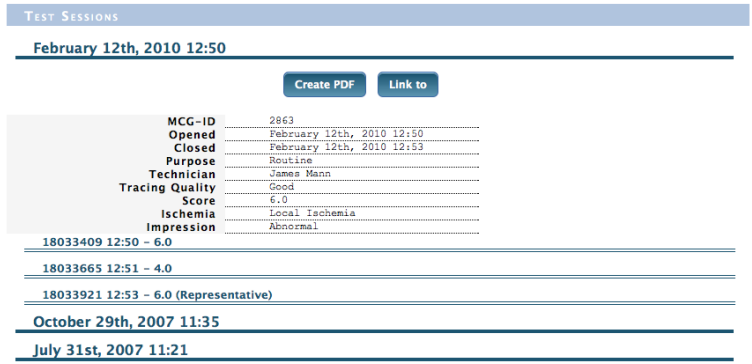
If a large number of patients are displayed you may limit the display in real-time by entering a portion of the patient's name, date of birth, or other identifying information in the "Limit to items containing" field.

- 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



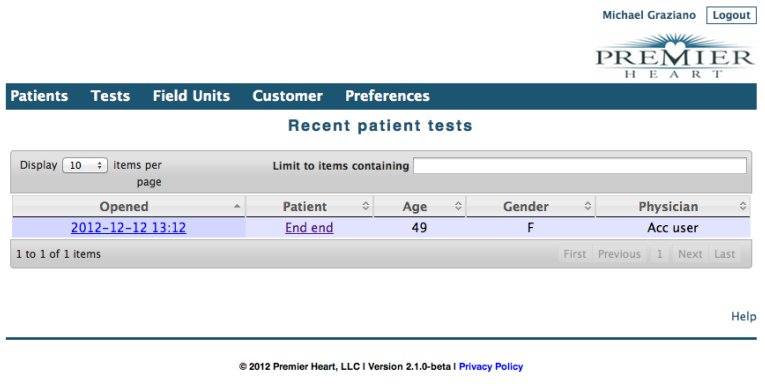
Additional detail, including secondary and tertiary conditions, ECG tracings, and DSP plots, may be viewed by expanding the individual tests within a session.

4.3. Viewing Results by Test Session

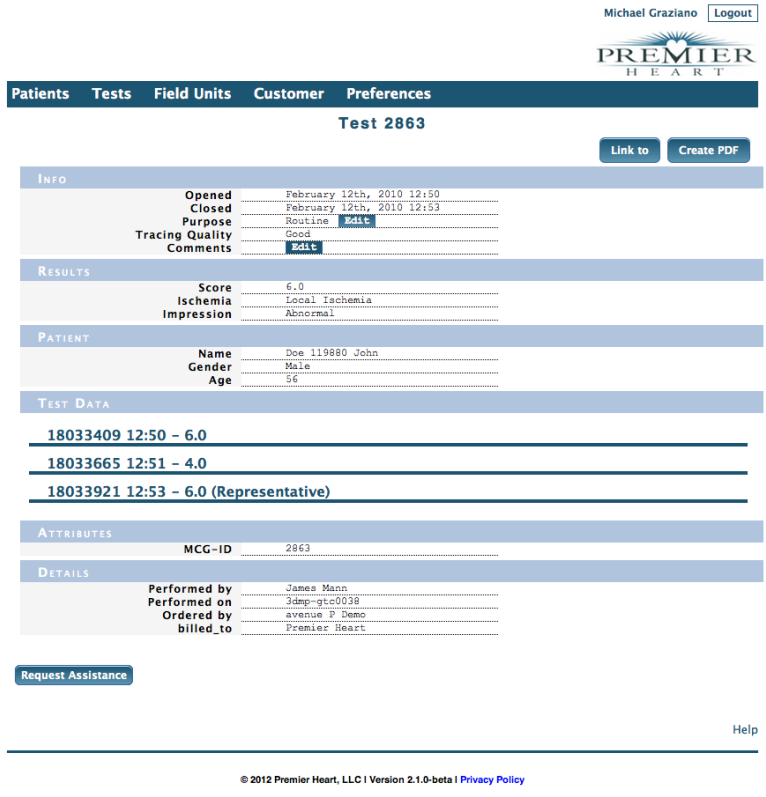
If you are looking for information on an existing patient who was tested recently, or wish to look up details of a specific test session, click the Tests link in the reporting menu.
This will display the Recent Patient Tests screen, showing test sessions conducted within the last 30 days. If the session 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 patient's name you will be taken to the Patient History page as described in Section 4.2.



- The Session page is equivalent to the expanded Test Session from the Patient History page, and functions as described in Section 4.2.



4.4. Other Features

4.4.1. 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.

4.4.2. Sharing Results for Consultation

In order to facilitate collaboration between physicians, Premier Heart offers the ability to share an anonymized version of MCG results with others. The various "Link to" buttons will send you to the anonymous data application, and the URL generated may be shared with other physicians without disclosing patient identification information.

4.4.3. Requesting Interpretive Assistance from Premier Heart

In addition to email and telephone support, you may request interpretative assistance on a specific Patient, Session, or Test by clicking the "Request Assistance" button in the Premier Heart web application. These requests are handled by our medical support team, and are intended for clinical issues and interpretation questions. For technical support or general questions please contact us via email at support@premierheart.com, or via telephone at (516) 883-3383.

A. Tracing Quality Guidelines

MCG analysis extracts a great deal of latent information from the ECG signal. As a result it is sensitive to tracing quality, and poor-quality tracings will produce less accurate results.

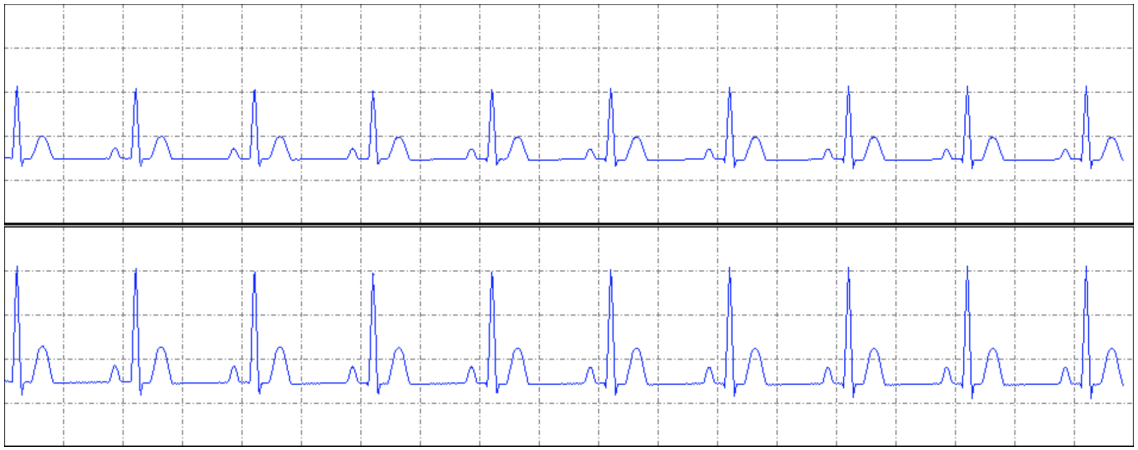
The MCG Clinical Client software has a tracing quality assessment feature, however human judgment is still superior to these automated assessments, therefore the testing technician must review the tracings and characterize them as “Good”, “Marginal” or “Poor” prior to submitting them for analysis.

The following pages contain examples of “Good”, “Marginal”, and “Poor” quality tracings to assist technicians in making this determination.

If there is a question as to the quality of a particular tracing it is always advisable to record additional samples and attempt to obtain a better quality tracing.

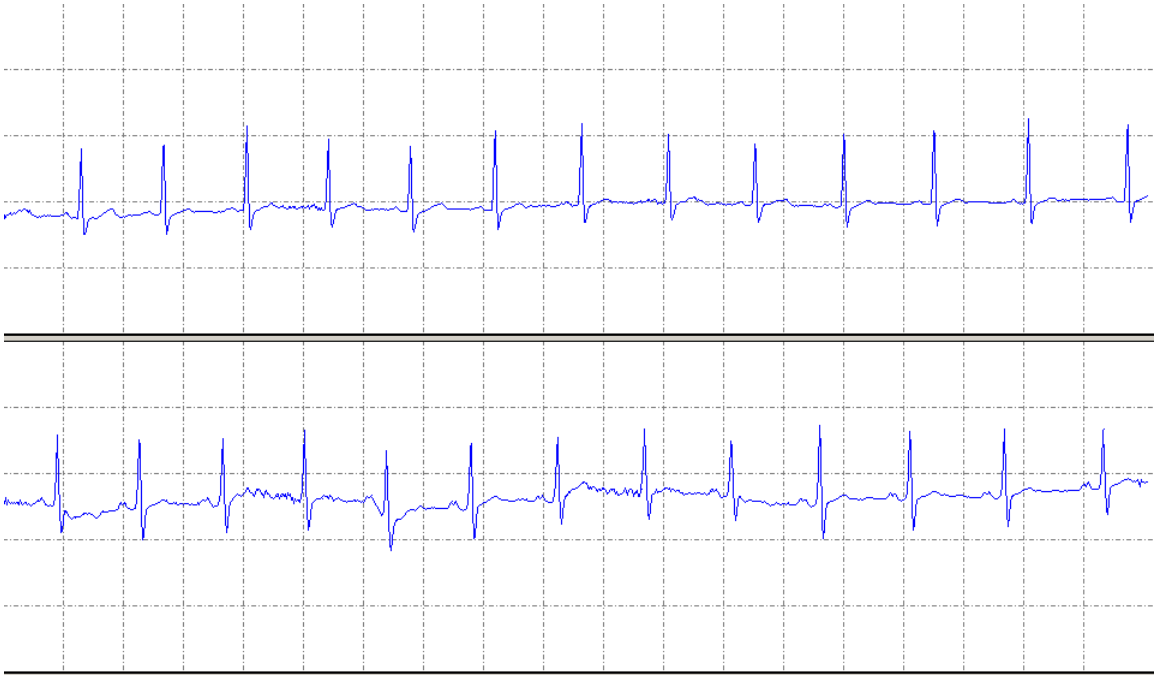
,

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

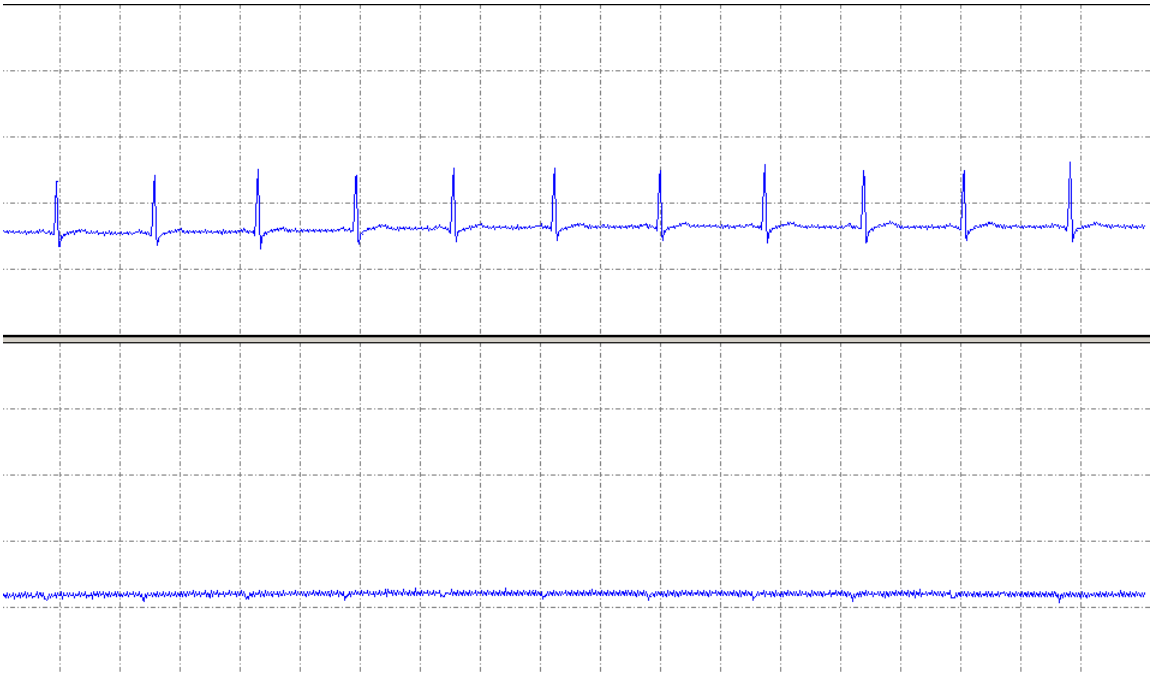
Poor quality tracings show significant fluctuations in the baseline and/or large amounts of noise, with indistinct or completely obscured peaks.
Poor tracings can be caused by ECG cables crossing or touching metal objects, interference from cell phones, dry skin, lotion, the patient moving and talking, 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 has to be corrected and the test repeated.
If you are unable to isolate the cause of a poor tracing contact Premier Heart for assistance.

B. Troubleshooting

B.1. Tracing Quality Problems

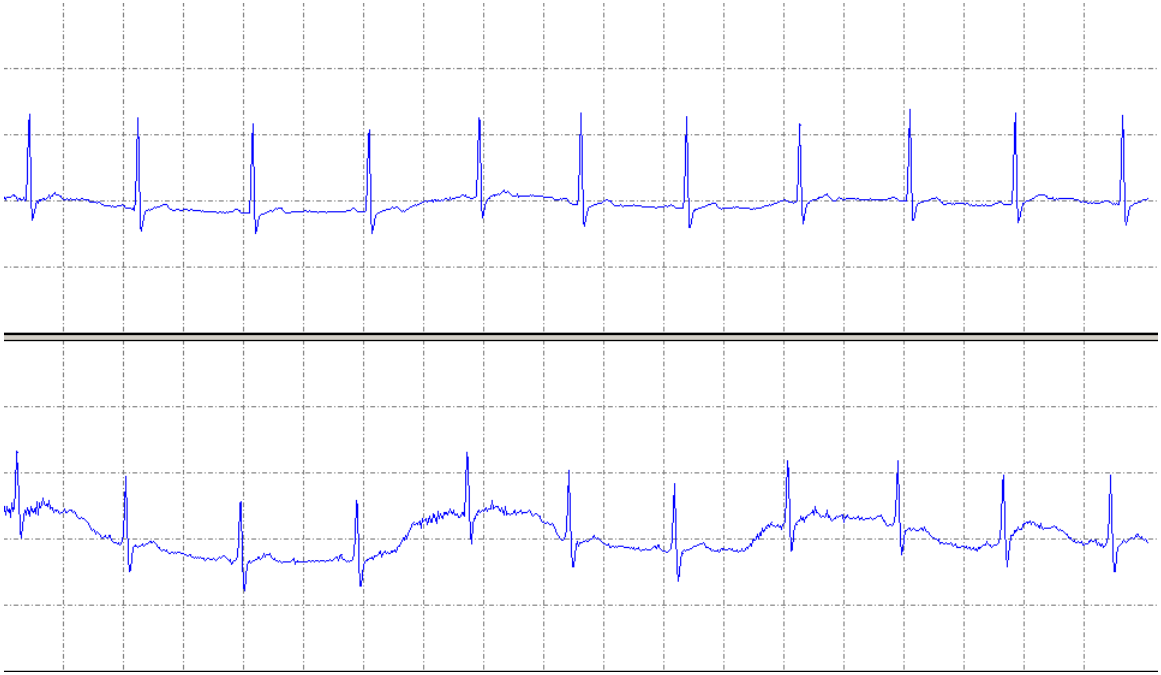
The examples below show some common tracing quality issues you may encounter during MCG testing. If you observe these issues follow the suggested courses of action below, or contact Premier Heart for assistance.

Disconnected or Damaged ECG Cable



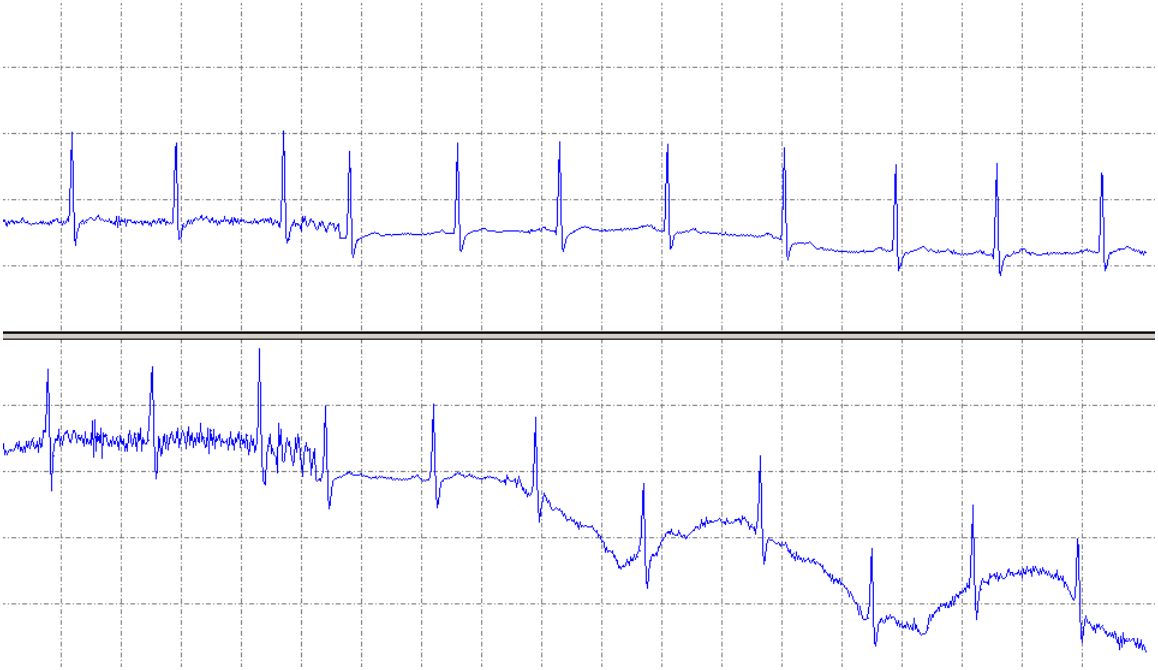
This tracing pattern indicates that an ECG cable has become detached from the device, or has been damaged due to mishandling.
If observed on lead V5 check the V5 electrode connection.
If observed on Lead II or on both leads check all electrode connections, as well as the ECG cable connection to your MCG system.
If you believe your cable may be damaged contact Premier Heart for a replacement.

Baseline Drift ("Ocean Waves")



The "Ocean Waves" tracing pattern is characterized by a wandering baseline – this may be caused by patient movement during the test, heavy breathing, or unusually high skin impedance.
Following the patient preparation steps outlined in Section 3.1 of this guide will minimize baseline drift during testing. In addition ensure that the patient is resting comfortably for the duration of the test to minimize movement or heavy breathing, and that the ECG lead wires are not pulling on the electrodes.

Converging/Diverging Baseline Drift

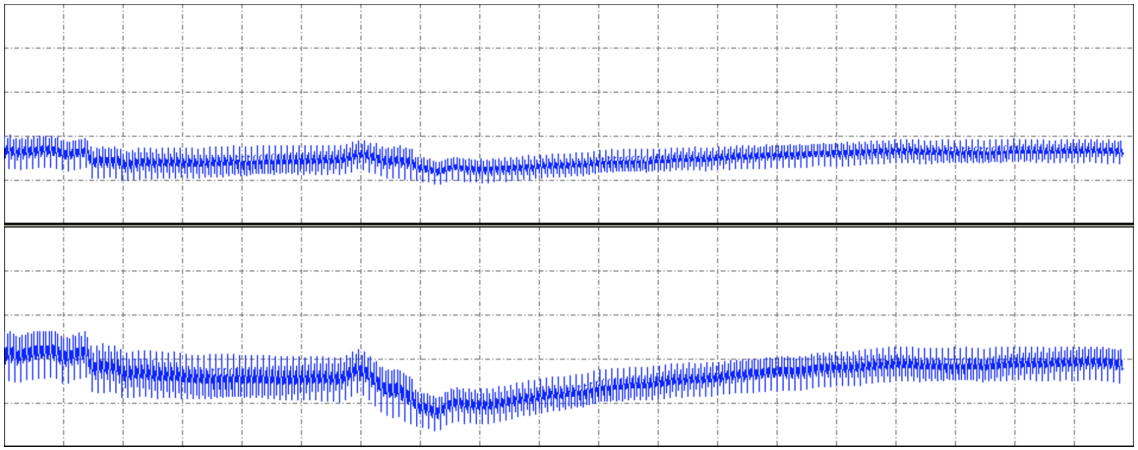


Converging or Diverging tracings are characterized by Lead II / Lead V5 baselines moving in opposite directions, giving the tracing strip the appearance of the tracings moving toward or away from each other.

This pattern is typically caused by the same conditions that result in the “Ocean Waves” tracing described earlier, and may be resolved in the same way.

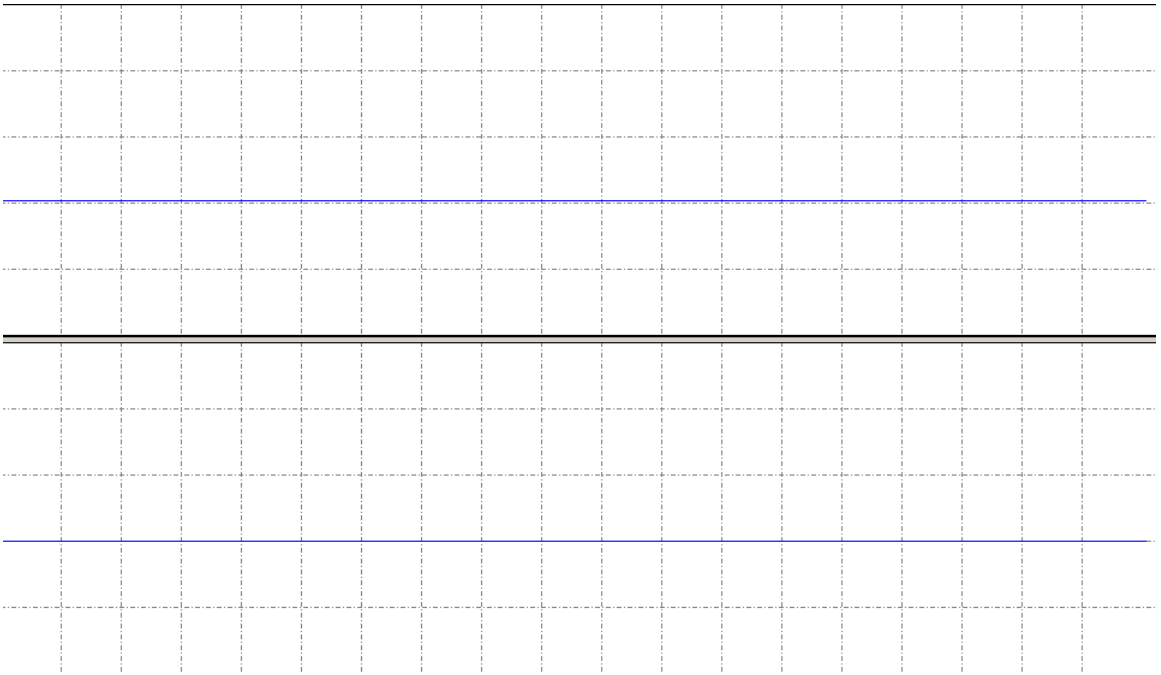
This tracing pattern can have a significant impact on the MCG analysis results, therefore tests which exhibit this pattern have to be repeated.

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 reference (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 must 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 can only be used when instructed by Premier Heart.*

B.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 click Activities on the top left corner, then select Applications. In the Applications menu select *Network Test Tool*. 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 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 on-line

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.